In compliance with ACCME Standards for Commercial Support of CME activities…

I have no relevant financial relationships to disclose.
Outline

• Background
  o Current status- child/adolescent vaccination delivery
  o Steps in making US national immunization policy

• Some remaining challenges in vaccine delivery
  o Preparing for new vaccines or new guidelines
  o Evaluating the impact of new vaccines or guidelines
  o Interventions to improve vaccination rates

(A focus on influenza, rotavirus, HPV vaccines)
Dramatic declines in vaccine-preventable diseases compared to the pre-vaccine era

<table>
<thead>
<tr>
<th>DISEASE</th>
<th>PRE-VACCINE ERA ESTIMATED ANNUAL MORBIDITY¹</th>
<th>MOST RECENT REPORTS OR ESTIMATES OF U.S. CASES</th>
<th>PERCENT DECREASE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria</td>
<td>21,053</td>
<td>1²</td>
<td>&gt;99%</td>
</tr>
<tr>
<td><em>H. influenzae</em> (invasive, &lt;5 years of age)</td>
<td>20,000</td>
<td>40²,³</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>117,333</td>
<td>3,473⁴</td>
<td>98%</td>
</tr>
<tr>
<td>Hepatitis B (acute)</td>
<td>66,232</td>
<td>19,764⁴</td>
<td>70%</td>
</tr>
<tr>
<td>Measles</td>
<td>530,217</td>
<td>667²</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>Meningococcal disease</td>
<td>2,886³</td>
<td>433³</td>
<td>85%</td>
</tr>
<tr>
<td>Mumps</td>
<td>162,344</td>
<td>1,223³</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>Pertussis</td>
<td>200,752</td>
<td>32,971³</td>
<td>84%</td>
</tr>
<tr>
<td>Pneumococcal disease (invasive, &lt;5 years of age)</td>
<td>16,069</td>
<td>1,900⁶</td>
<td>88%</td>
</tr>
<tr>
<td>Polio (paralytic)</td>
<td>16,316</td>
<td>0²</td>
<td>100%</td>
</tr>
<tr>
<td>Rotavirus (hospitalizations, &lt;3 years of age)</td>
<td>62,500⁷</td>
<td>12,500⁸</td>
<td>80%</td>
</tr>
<tr>
<td>Rubella</td>
<td>47,745</td>
<td>6³</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>Congenital Rubella Syndrome</td>
<td>152</td>
<td>1²</td>
<td>99%</td>
</tr>
<tr>
<td>Smallpox</td>
<td>29,005</td>
<td>0²</td>
<td>100%</td>
</tr>
<tr>
<td>Tetanus</td>
<td>580</td>
<td>25³</td>
<td>96%</td>
</tr>
<tr>
<td>Varicella</td>
<td>4,085,120</td>
<td>151,149⁹</td>
<td>96%</td>
</tr>
</tbody>
</table>
Also recent outbreaks of mumps
## Recommended Child/Adolescent Immunization Schedule: 2017

**Recommended Child/Adolescent Immunization Schedule for Children and Adolescents Aged 18 Years or Younger—United States, 2017.**

*NOTE: SEE THE CATCH-UP SCHEDULE (FIGURE 2).*

For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1.

### 17 vaccines!

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>0 mo</th>
<th>1 mo</th>
<th>2 mos</th>
<th>3 mos</th>
<th>4 mos</th>
<th>6 mos</th>
<th>9 mos</th>
<th>12 mos</th>
<th>15 mos</th>
<th>18 mos</th>
<th>19-23 mos</th>
<th>2-3 yrs</th>
<th>4-6 yrs</th>
<th>7-10 yrs</th>
<th>11-12 yrs</th>
<th>13-15 yrs</th>
<th>16 yrs</th>
<th>17-18 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B (HepB)</td>
<td></td>
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</tr>
<tr>
<td>Rotavirus* (RV)</td>
<td>1st dose</td>
<td>2nd dose</td>
<td>See footnote 2</td>
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<tr>
<td>Diphtheria, tetanus, &amp; acellular pertussis* (DTaP)</td>
<td>1st dose</td>
<td>2nd dose</td>
<td>3rd dose</td>
<td>4th dose</td>
<td>5th dose</td>
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<tr>
<td>Haemophilus influenzae type b* (Hib)</td>
<td>1st dose</td>
<td>2nd dose</td>
<td>3rd dose</td>
<td>See footnote 4</td>
<td>See footnote 4</td>
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<tr>
<td>Pneumococcal conjugate (PCV13)</td>
<td>1st dose</td>
<td>2nd dose</td>
<td>3rd dose</td>
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<tr>
<td>Inactivated poliovirus* (IPV; &lt;16 yrs)</td>
<td>1st dose</td>
<td>2nd dose</td>
<td>3rd dose</td>
<td>4th dose</td>
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<tr>
<td>Inactivated influenza* (IV)</td>
<td></td>
<td></td>
<td></td>
<td>Annual vaccination (IV) 1 or 2 doses</td>
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</tr>
<tr>
<td>Measles, mumps, rubella* (MMR)</td>
<td></td>
<td>See footnote 8</td>
<td></td>
<td>1st dose</td>
<td>2nd dose</td>
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<tr>
<td>Varicella* (VAR)</td>
<td></td>
<td></td>
<td>1st dose</td>
<td>2nd dose</td>
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<tr>
<td>Hepatitis A* (HepA)</td>
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<tr>
<td>Meningococcal* (Hib-MenCY ≥6 weeks; MenACWY-D ≥9 mos; MenACWY-CRM ≥2 mos)</td>
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<tr>
<td>Tetanus, diphtheria, &amp; acellular pertussis* (Tdap)</td>
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<tr>
<td>Human papillomavirus* (HPV)</td>
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<tr>
<td>Meningococcal B*</td>
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<tr>
<td>Pneumococcal polysaccharide (PPSV23)</td>
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</tbody>
</table>

**NOTE:** The above recommendations must be read along with the footnotes of this schedule.
### Recommended Adult Immunization Schedule: 2017

**Figure 1.** Recommended immunization schedule for adults aged 19 years or older by age group, United States, 2017

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>19–21 years</th>
<th>22–26 years</th>
<th>27–59 years</th>
<th>60–64 years</th>
<th>≥ 65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza(^1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 dose annually</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Td/Tdap(^2)</td>
<td></td>
<td></td>
<td>Substitute Tdap for Td once, then Td booster every 10 yrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMR(^3)</td>
<td></td>
<td></td>
<td>1 or 2 doses depending on indication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAR(^4)</td>
<td></td>
<td></td>
<td>2 doses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HZV(^5)</td>
<td></td>
<td></td>
<td></td>
<td>1 dose</td>
<td></td>
</tr>
<tr>
<td>HPV–Female(^6)</td>
<td></td>
<td></td>
<td>3 doses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HPV–Male(^6)</td>
<td></td>
<td></td>
<td>3 doses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCV13(^7)</td>
<td></td>
<td></td>
<td></td>
<td>1 dose</td>
<td></td>
</tr>
<tr>
<td>PPSV23(^7)</td>
<td></td>
<td></td>
<td>1 or 2 doses depending on indication</td>
<td></td>
<td>1 dose</td>
</tr>
<tr>
<td>HepA(^8)</td>
<td></td>
<td></td>
<td>2 or 3 doses depending on vaccine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HepB(^9)</td>
<td></td>
<td></td>
<td>3 doses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MenACWY or MPSV(^10)</td>
<td></td>
<td></td>
<td>1 or more doses depending on indication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MenB(^10)</td>
<td></td>
<td></td>
<td>2 or 3 doses depending on vaccine</td>
<td></td>
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</tr>
<tr>
<td>Hib(^11)</td>
<td></td>
<td></td>
<td>1 or 3 doses depending on indication</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Legend:**
- **Yellow** Recommended for adults who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection
- **Purple** Recommended for adults with additional medical conditions or other indications
- **Blank** No recommendation
# Recommended Adult Immunization Schedule: 2017

**Figure 2.** Recommended immunization schedule for adults aged 19 years or older by medical condition and other indications, United States, 2017

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Pregnancy</th>
<th>Immuno-compromised (excluding HIV infection)</th>
<th>HIV infection CD4+ count (cells/μL)</th>
<th>Asplenia, persistent complement deficiencies</th>
<th>Kidney failure, end-stage renal disease, on hemodialysis</th>
<th>Heart or lung disease, chronic alcoholism</th>
<th>Chronic liver disease</th>
<th>Diabetes</th>
<th>Healthcare personnel</th>
<th>Men who have sex with men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza¹</td>
<td>1 dose annually</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Td/Tdap²</td>
<td>1 dose Tdap each pregnancy</td>
<td></td>
<td></td>
<td>Substitute Tdap for Td once, then Td booster every 10 yrs</td>
<td></td>
<td></td>
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<tr>
<td>MMR³</td>
<td>contraindicated</td>
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</tr>
<tr>
<td>VAR⁴</td>
<td>contraindicated</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>HZV⁵</td>
<td>contraindicated</td>
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</tr>
<tr>
<td>HPV–Female⁶</td>
<td>3 doses through age 26 yrs</td>
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</tr>
<tr>
<td>HPV–Male⁷</td>
<td>3 doses through age 26 yrs</td>
<td></td>
<td>3 doses through age 21 yrs</td>
<td>3 doses through age 26 yrs</td>
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</tr>
<tr>
<td>PCV13⁸</td>
<td>1 dose</td>
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<tr>
<td>PPSV23⁹</td>
<td>1, 2, or 3 doses depending on indication</td>
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<tr>
<td>HepA⁸</td>
<td>2 or 3 doses depending on vaccine</td>
<td></td>
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<td></td>
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<td></td>
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</tr>
<tr>
<td>HepB⁹</td>
<td>3 doses</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
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<tr>
<td>MenACWY or MPSV4¹⁰</td>
<td>1 or more doses depending on indication</td>
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<tr>
<td>MenB¹⁰</td>
<td>2 or 3 doses depending on vaccine</td>
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</tr>
<tr>
<td>Hib¹¹</td>
<td>3 doses post-HSCT recipients only</td>
<td></td>
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</tr>
</tbody>
</table>

- **Recommended for adults who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection**
- **Recommended for adults with additional medical conditions or other indications**
- **Contraindicated**
- **No recommendation**
Some Current Challenges

• Before Vaccine:
  o Preparing for new vaccines or new guidelines

• After Vaccine:
  o Assessing the status of vaccine delivery
  
o Developing and implementing interventions to address problems in vaccine delivery
Steps in vaccine policy & research for new vaccines & new guidelines

CDC-funded and other studies of disease burden

Basic/Pre-clinical studies on vaccine development

Vaccine manufacturers develop potential vaccines

Phase I-III trials and Licensure

ACIP recommends & AAP, AAFP, ACOG, ACP

Cost & delivery studies

Studies of vaccine coverage

Studies of vaccine effectiveness, reduction in disease burden

Studies of barriers & interventions to improve rates
### Studies of Disease Burden

Many networks study disease burden
- Some use prospective surveillance
- Some use passive surveillance

<table>
<thead>
<tr>
<th>Viruses</th>
<th>To Guide:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Current</td>
<td>Future</td>
<td></td>
</tr>
<tr>
<td>Respiratory Viruses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Other respiratory viruses</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal Viruses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rotavirus</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Norovirus</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Human Papilloma Virus (HPV)</td>
<td>X</td>
<td></td>
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</tr>
</tbody>
</table>
New Vaccine Surveillance Network (NVSN)
Hospital, ED, outpatient Surveillance

- SEATTLE Children’s Hospital
- OAKLAND Children’s Hospital Research Center
- KANSAS CITY Children’s Mercy Hospital
- CINCINNATI Children’s Hospital Medical Center
- NASHVILLE Vanderbilt University Medical Center
- HOUSTON Texas Children’s Hospital
- U. ROCHESTER Medical Center
- University of Pittsburgh Medical Center
The Burden of RSV, Parainfluenza, Influenza and Human Metapneumovirus (HMPV) Infections

Influenza study guided universal flu vaccination

Vaccines are in the pipeline for RSV, paraflu, HMPV

For 0 to 4.9 yr olds
Pneumonia and Influenza Mortality from the National Center for Health Statistics Mortality Surveillance System

Data through the week ending February 4, 2017, as of February 23, 2017
Number of Influenza-Associated Pediatric Deaths by Week of Death: 2013-2014 season to present

- 2013-2014: Number of Deaths Reported = 111
- 2014-2015: Number of Deaths Reported = 148
- 2015-2016: Number of Deaths Reported = 89
- 2016-2017: Number of Deaths Reported = 34

Week of Death

- Deaths Reported Previous Week
- Deaths Reported Current Week
Rotavirus
Population Burden of Rotavirus

2006: ACIP recommended rotavirus vaccination

1 in 11 children visited an emergency department for rotavirus

1 in 11 children visited an outpatient clinic for rotavirus

1 in 150 children were hospitalized for rotavirus

Since rotavirus vaccines, norovirus is now the leading cause of medically attended acute gastroenteritis in U.S. children:

- ~14,000 hospitalizations
- ~280,000 ED visits
- ~627,000 outpatient visits
Norovirus Vaccine Policy

• Norovirus vaccines are being developed
  o Multivalent (contains GI and GII genotypes)
  o Several entering Phase II clinical trials

• Timeline still uncertain
Human Papilloma Virus (HPV)

- Most common sexually transmitted infection
- More than 50% of men and women will be infected with HPV at some point in their lives
  - ~79 million Americans currently infected
  - 14 million new infections/year in the US
  - 38,000 new infections per day
- HPV infection is most common in teens and early 20s

## HPV and cancer

<table>
<thead>
<tr>
<th>Cancer</th>
<th>% Associated With Certain HPV Types</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical</td>
<td>≥95%</td>
</tr>
<tr>
<td>Vaginal</td>
<td>50%</td>
</tr>
<tr>
<td>Vulvar</td>
<td>&gt;50%</td>
</tr>
<tr>
<td>Penile</td>
<td>50%</td>
</tr>
<tr>
<td>Anal</td>
<td>&gt;70%</td>
</tr>
<tr>
<td>Oropharyngeal</td>
<td>Up to 70%</td>
</tr>
</tbody>
</table>

HPV 16 and 18 are particularly oncogenic.

*If trends continue, the annual number of HPV-positive oropharyngeal cancers is expected to surpass the annual number of cervical cancers by the year 2020.*
Numbers of Cancers and Genital Warts Attributed to HPV Infections, U.S.

>26,000 cancers per year

>340,000 genital warts per year

Steps in vaccine policy & research for new vaccines & new guidelines

**CDC-funded and other studies of disease burden**

**Basic/Pre-clinical studies on vaccine development**

**Studies of barriers & interventions to improve rates**

**Vaccine manufacturers develop potential vaccines**

**Phase I-III trials and Licensure**

**ACIP recommends & AAP, AAFP, ACOG, ACP**

**Cost & delivery studies**

**Studies of vaccine coverage**

**Studies of vaccine effectiveness, reduction in disease burden**
Key elements for developing ACIP evidence based recommendations

- Vaccine safety
- Vaccine efficacy/effectiveness
- Burden of disease
- Economic analysis
- Implementation issues

Evidence

Tables

Not graded but considered for policy

ACIP Recommendation
Some Recent ACIP Recommendations

• Annually- child and adult schedules
• Rotavirus vaccination recommendation (2006)
• HPV Vaccine
  o Vaccine recommendation (Girls 2006, Boys 2011)
  o 2-dose series if over 15 years (2016)
• Herpes zoster vaccine (2008)
• Pneumococcal vaccination
  o PCV13 followed by PPSV23 in adults ≥65y (2014)
• Meningococcal vaccine (2015)
  o MenB in ages 16-23yrs if high risk
Steps in vaccine policy & research for new vaccines & new guidelines

- CDC-funded and other studies of disease burden
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- Studies of vaccine effectiveness, reduction in disease burden
- Cost & delivery studies
- Studies of barriers & interventions to improve rates
National Immunization Survey (NIS)

Methods

- Annual survey (19-35m olds)
  - NIS Teen periodically (2015)
- All states and largest cities
- Interviews + chart reviews
- Provides estimates of vaccine coverage:
  - By state and for the US
- Identifies vaccines with low coverage

Vaccination Rates

Does not include adults—BRFSS is good source for adults
Influenza vaccination rates

**Coverage in 2015-16**

<table>
<thead>
<tr>
<th>Age</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-23m</td>
<td>75%</td>
</tr>
<tr>
<td>2-4y</td>
<td>67%</td>
</tr>
<tr>
<td>5-12y</td>
<td>63%</td>
</tr>
<tr>
<td>13-17y</td>
<td>47%</td>
</tr>
<tr>
<td>18-49y</td>
<td>33%</td>
</tr>
<tr>
<td>50-64y</td>
<td>44%</td>
</tr>
<tr>
<td>≥65y</td>
<td>63%</td>
</tr>
</tbody>
</table>

Adult coverage assessed by BRFSS survey.

Centers for Disease Control and Prevention, MMWR 2015
Estimated Vaccination Coverage, Teens Ages 13-17 years, United States

HPV Vaccination Rates
Girls: Low rates, rising slowly
Boys: Extremely low rates, rising

MMWR, July 31, 2015 / 64(29);784-792
Two viruses for which vaccination rates are very low

Influenza Virus

Human Papilloma Virus (HPV)
Steps in vaccine policy & research for new vaccines & new guidelines

- CDC-funded and other studies of disease burden
- Basic/Pre-clinical studies on vaccine development
- Studies of barriers & interventions to improve rates

Vaccine manufacturers develop potential vaccines

Phase I-III trials and Licensure

ACIP recommends & AAP, AAFP, ACOG, ACP

Cost & delivery studies

Studies of vaccine coverage

Studies of vaccine effectiveness, reduction in disease burden
How do we measure vaccine efficacy or effectiveness?

• Pre-licensure- Phase II-III trials (efficacy)
  o RCTs (placebo-controlled, tightly monitored)
  o Outcomes:
    ▪ Immunologic
    ▪ Clinical- hospitalizations, ED visits, outpatient visits, illnesses

• Post licensure/recommendations (effectiveness)
  o Real-world study designs
  o Estimates
Influenza Vaccine Effectiveness (VE)

- NVSN study (2003-05)

- Case-Control study…….. hospital, ED, or outpatient
  - Cases = Flu positive ARIs (lab confirmed)
  - Controls = Flu negative ARIs
  - Vaccination status confirmed by chart reviews

- Influenza VE = (1 – adjusted OR) X 100

## Influenza Vaccine Effectiveness (VE) Among fully vaccinated children

<table>
<thead>
<tr>
<th></th>
<th>6m – 23m</th>
<th>24m – 59m</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003 – 2004 season</td>
<td>28%</td>
<td>66%</td>
</tr>
<tr>
<td>2004-2005 season</td>
<td>55%</td>
<td>63%</td>
</tr>
</tbody>
</table>

Influenza VE varied by age & seasons- higher for older kids
Moderate VE overall
Important to measure influenza VE each year

Networks now measuring Influenza VE against Laboratory-Confirmed Influenza in the U.S.

- **New Vaccine Surveillance Network (NVSN)**
  - 6-59 mo. Outpatient and Hospitalized

- **EIP -- Emerging Infections Program**
  - 6-59 mo. Hospitalized
  - Adults >18 Hospitalized
  - Adults >50 Hospitalized

- **Marshfield Clinic, WI**
  - ACIP recommended groups
  - Outpatient and Hospitalized
  - All Ages ≥ 6 mo. Outpatient & Hosp.

- **US Flu VE Network**
  - 4 sites
  - 6-59 mo.
  - Outpatient and Hospitalized

- **US Flu VE Network**
  - 5 sites
  - 6-59 mo.
  - Outpatient and Hospitalized

- **All Ages ≥ 6 mo.**
  - Outpatient

- **Influenza season**
  - 2003-04
  - 04-05
  - 05-06
  - 06-07
  - 07-08
  - 08-09
  - 09-10
  - 10-11
  - 11-12
  - 12-13
  - 13-14
  - 14-15
  - 15-16
ACIP votes down use of LAIV for 2016-2017 Flu Season

Rationale—3 successive years of very poor influenza VE in US
VE Studies of LAIV

Effectiveness Against A/H1N1pdm09/2015-2016 Influenza Season

Lower bound of CIs was truncated at -30.
* Effectiveness estimate against any A strain.

Slide from MedImmune, Feb 22 2017 ACIP Meeting
RotaTeq vaccine effectiveness 2007-2013: NSVN sites

A Boom JA, et al. *Pediatrics* 2010
Φ Payne DC, et al. Unpub data 2015
Γ Payne DC, et al. Unpub data 2015
Proportion of childhood AGE hospitalizations (<3yrs) testing rotavirus positive, 2006-2015

Vaccine recommended

Remaining disease burden from rotavirus

n = 1500 to >4,000 hospitalized subjects per season at 7 NVSN sites
How do we know HPV vaccination works?

Monitoring Impact of HPV Vaccine Programs:
HPV-associated Outcomes

**Early Outcomes (Years)**
- HPV Prevalence
- Genital warts

**Mid Outcomes (Years to Decades)**
- CIN/Precancers

**Late Outcomes (Decades)**
- HPV-associated cancers

How do we know HPV vaccination works?
HPV Vaccines Work

- Prevalence of vaccine types declined by more than half in U.S. (33% of teens fully vaccinated)

- High grade cervical lesions declined in Australia (80% of school aged girls vaccinated)

**Hot Off the Press**

- **14-19 Year olds:**
  - 64% decrease in quadrivalent HPV types (6, 11, 16, 18) prevalence among females aged 14 to 19 yrs.

- **20-24 Year olds**
  - 34% decrease

---

Markowitz Pediatrics 2016
HPV Vaccine Efficacy Lasts (from vaccine trials)

- Vaccine protection is long-lasting
- No evidence of waning protection after 3-dose schedule
  - Data available ~10 years for 2vHPV & 4vHPV
  - Longer follow-up, ~ 14 years, ongoing
- Antibody responses maintained after 3-dose HPV
  - Data available ~10 years for 2vHPV and 4vHPV
  - Longer follow-up, ~ 14 years, ongoing in some studies
  - Waning of detectable antibody to HPV 18 by cLIA in 4vHPV vaccinees not associated with loss of protection
- Long term protection data not available from 2-dose trials

Steps in vaccine policy & research for new vaccines & new guidelines

- CDC-funded and other studies of disease burden
- Basic/Pre-clinical studies on vaccine development
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- Phase I-III trials and Licensure
- ACIP recommends & AAP, AAFP, ACOG, ACP
- Cost & delivery studies
- Studies of vaccine coverage
- Studies of vaccine effectiveness, reduction in disease burden
- Studies of barriers & interventions to improve rates
Immunization Barrier Model

Patient:
- No access
- Extra visit
- Knowledge
- Fear
- Costs
- Hesitancy

Provider:
- Weak recommendation
- No reminder/recall
- Missed opportunities
- No QA-practice rates

System:
- Vaccine shortages
- No reminder/recall
- Financing (despite VFC)
- Scattering of care
- Few school laws
Modifiable barrier #1: No Reminder-Recall

- No access
- Extra visit
- Knowledge
- Fear
- Costs
- Hesitancy

System:
- Weak recommendation
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- Knowledge
- Fear
- Costs
- Hesitancy

HPV - Multiple shots
Influenza - Annual vaccination
Strategy to raise vaccination rates

- Study barriers - Provider, System, Parent
- Study individual interventions
- Study bundles of interventions
- Scale up, disseminate
Does patient reminder-recall raise vaccination rates?
Patient Reminder - Recall

- **Modality:** Letters, postcards, telephone, autodialer, text, email
- **Intensity:** Frequency can vary; Can be combined with outreach
- **Recipient:** Parents, adolescents
- **Source:** Primary care practice, health system (HMO), registry
- **Requirements:** Registry, patient contact, algorithms, resources

More complicated than you would think
## Comparison: Reminder-Recall (R/R) vs Control

<table>
<thead>
<tr>
<th>Any Vaccine, R/R by:</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone</td>
<td>2.3</td>
<td>1.50, 3.21</td>
</tr>
<tr>
<td>Letter</td>
<td>1.6</td>
<td>1.40, 1.87</td>
</tr>
<tr>
<td>Postcard</td>
<td>1.5</td>
<td>1.17, 2.00</td>
</tr>
<tr>
<td>Text</td>
<td>1.3</td>
<td>1.15, 1.50</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flu Vaccine, any R/R</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td>1.8</td>
<td>1.28, 2.60</td>
</tr>
<tr>
<td>Adults</td>
<td>1.5</td>
<td>1.40, 1.87</td>
</tr>
</tbody>
</table>

Summary of studies on Reminder-Recall for preschool & influenza vaccines

- Impact
  - Largest if baseline rates are low
  - Often 2-10 percentage points (mode~5%)
  - Lower among low-income populations
  - Higher if combined with outreach

- Costs vary greatly

- Mail works better than phone, but more expensive

- Even a small effect has public health impact if scaled

But............

Proportion of practices using reminder-recall........16%

- Reasons– costs, data problems, algorithms

Centralized Reminder-Recall is promising
Centralized R/R for HPV vaccine
Results of a study based in managed care

- Modest impact
  - Mail reminders +6%
  - Phone reminders +3%

- Some impact on improving WCC visit rates

- Cost-- $18 (mail) or $16 (phone) per teen/yr
  - About $1.30 per member per month
  - Number needed to treat (NNT) = Mail (22) Phone (30)

“Promising” to use centralized patient reminder-recall
If……can be scaled up to a large population

Szilagyi et al, Academic Pediatrics, 2013
Who can do centralized reminder-recall for HPV vaccine?

- HMOs
- Health systems and ACOs
- Statewide or regional immunization registries
  - In all states (and in LA)

Stay tuned for more studies
Will adding stepped outreach to tracking plus reminder-recall work even better?
RCT to test reminder-recall-outreach for adolescent vaccinations

- **Setting:** 9 large practices (60% of adolescents in the city)

- **Subjects:** 6,700 adolescents 11-15 years [no exclusions]

- **Design:** RCT, within each practice
  Intervention vs standard of care

- **Intervention:** Reminder/recall plus outreach
  - Control = standard of care

- **Outcomes**
  - Vaccination rates, well-child care visits, costs

Szilagyi et al, *JAMA Peds* 2011
Reminder, Recall, & Outreach Intervention

- **Tracking** (100% of children)
- **Reminders** (50-70%)
- **Recall** (20-40%)
- **Home Visits** (3%)

Outreach Workers in primary care practices, social worker model
## Impact of the reminder-recall-outreach Intervention

<table>
<thead>
<tr>
<th>Measure (end of study)</th>
<th>Intervention</th>
<th>Control</th>
<th>Odds Ratio</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up-to-Date: All Vaccines</td>
<td>44%</td>
<td>32%</td>
<td>1.8</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Had well-child care visit</td>
<td>67%</td>
<td>55%</td>
<td>1.7</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

- 12-16 percentage point improvement in all 9 practices
- Cost = $43 per adolescent per year ($3.55/month)
- Number needed to treat (NNT) = 9

The intervention is highly effective for urban adolescents!

But it is somewhat costly.

Szilagyi et al, *JAMA Peds* 2011
Summary: Reminder-recall for HPV and Influenza vaccines

- Reminder-recall has an important role
- Standard R/R raises rates 2-7 percentage points
- Adding stepped outreach doubles impact but at a higher cost
- Centralized reminders are promising

There are no home runs, only singles
Modifiable barrier #2

**Missed Opportunities**

- No access
- Extra visit
- Knowledge
- Fear
- Costs
- Hesitancy

- Weak recommendation
- No reminder/recall
- Missed opportunities
- No QA - practice rates

- Vaccine shortages
- No reminder/recall
- Financing (despite VFC)
- Scattering of care
- Few school laws

**HPV** - Multiple shots

**Influenza** - Annual vaccination
Can we develop interventions to reduce missed opportunities for vaccinations?
Missed opportunity for vaccination = A healthcare visit at which a patient was eligible for a vaccination but did not receive it.
Most pediatricians and family MDs vaccinate only during well-child-care (not sick/chronic) visits.

Missed opportunities occur at all types of visits.

Missed opportunities are not intentional.

Reducing missed opportunities is difficult:

- Several RCTs with negative findings.
Based on analyses of the National Immunization Surveys (2013 & 2014):

If all simultaneous MOs for HPV vaccination had been eliminated……

>90% of girls (not 53%) would have received ≥1 HPV vaccination.

~90 fewer teens/day acquiring genital warts
~15 fewer teens/day with eventual cancer

MOs represent low-hanging fruit
How to Eliminate MOs?

Provider Prompts
Use Acute Visits

Audit Feedback
Standing Orders
QI-based study in 7 CORNET practices (Prompts + Office Changes)

Modifiable barrier #3
Scattering of Care

- No access
- Extra visit
- Knowledge
- Fear
- Costs
- Hesitancy

- Weak recommendation
- No reminder/recall
- Missed opportunities
- No QA-practice rates
- Ordering vaccines

- Vaccine shortages
- No reminder/recall
- Financing (despite VFC)

- Scattering of care
- Few school laws

HPV - Multiple shots
Influenza - Annual vaccination
What are the solutions to scattering of care?
One Solution:
State Immunization Registries

Immunization Information Systems (IIS)

Potential Impact on Vaccination Rates

- Can help with problem of record scattering
- Mostly a passive system—few interventions
- Not mandated in all states
- Often not used by clinicians
- Few adult vaccinations
Another approach to address scattering of care

Vaccinate in the Medical Home + Vaccinate Outside the Medical Home
Possible settings outside medical home

Other Medical Sites
- Specialty clinics

Non-Medical Sites
- Pharmacies
- Schools
School-Located Influenza Vaccinations

Three RCTs in Monroe County NY

Aims:

• Measure impact on influenza vaccination rates (K-6th grade)

Study Design:

• 2010-11, 2011-12, and 2014-2015 flu vaccination seasons
• Multiple school districts, n>15,000 per trial
• Schools randomized to having a school clinic vs control
• Initial notification = backpack only, later added web-based notification + consent + backpack fliers

Findings:

• 5 to 8 percentage point improvement due to SLIV!

What about school-located HPV Vaccinations?

• Australia---vaccinates most adolescents in school

• In US-- two possible models
  o School-located clinics (like our influenza study)
    • Difficult to do for HPV vaccine

  o School-based health clinics (SBHCs)
    • 2,000 SBHCs across the US
Megha Shah (General Peds Fellow)

Preliminary Work & Setting

- Partnered with 2 LAUSD School Based Health Centers
- Intervention: impact of a “bundle “
  - Send VIS form to parents ahead of time for signature
  - Assess for HPV eligibility using CAIR
  - Give HPV vaccine at all visits (change workflow)
  - Give performance feedback to SBHC providers
Preliminary Results

Estimated Baseline MO Rate = 85%

Overall Missed Opportunity Rates

<table>
<thead>
<tr>
<th></th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>June</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hollywood</td>
<td>63.16%</td>
<td>74.19%</td>
<td>72.22%</td>
<td>62.96%</td>
<td>75.00%</td>
<td>62.50%</td>
</tr>
<tr>
<td>Roosevelt</td>
<td>43.75%</td>
<td>48.89%</td>
<td>51.28%</td>
<td>55.88%</td>
<td>42.22%</td>
<td>23.52%</td>
</tr>
</tbody>
</table>
Modifiable barrier #4

Provider Communication

- No access
- Extra visit
- Knowledge
- Fear
- Costs
- Hesitancy

- Weak recommendation
- No reminder/recall
- Missed opportunities
- No QA- practice rates
- Ordering vaccines

- Vaccine shortages
- No reminder/recall
- Financing (despite VFC)
- Scattering of care
- Few school laws

HPV - Multiple shots
Influenza- Annual vaccination
Can we train providers (ourselves) to communicate better about vaccinations?

Using HPV as a template
Top 5 reasons for not giving adolescents HPV vaccine — NIS-Teen, US, 2013

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6329a3.htm#tab2

- Not sexually active
- Not recommended
- Safety/side effects
- Not needed
- Lack of knowledge

[Bar chart showing reasons for not giving HPV vaccine]
Do Our Recommendations Really Matter?
Two Silly Examples

Our Recommendations DO MATTER

http://www.health.state.mn.us/divs/idepc/immunize/hcp/adoles/adohpvvideos.html
So How Can We Give a Strong Provider Recommendation?

Our Recommendations DO MATTER
RECOMMEND HPV VACCINE
THE “SAME WAY, SAME DAY”
YOUR RECOMMENDATION CAN MAKE ALL THE DIFFERENCE TO THE FAMILY’S ACCEPTANCE

Adapted from Vax Northwest – a Seattle-based collaborative
Recommend

Clearly state your recommendation for the immunizations that are due today.

Treat HPV just like the other routinely recommended adolescent immunizations (bundle).

Try Saying:
Today, Michelle should have 3 shots. They’re designed to protect her from the cancers caused by HPV, meningitis, whooping cough, tetanus, & diphtheria.

“Normalize” HPV vaccination
<table>
<thead>
<tr>
<th>Ask</th>
<th>Clarify &amp; restate their concerns so you understand.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acknowledge</strong></td>
<td>• Emphasize it is the parents’ decision.</td>
</tr>
<tr>
<td></td>
<td>• Acknowledge risks &amp; conflicting info sources.</td>
</tr>
<tr>
<td></td>
<td>• Applaud them for wanting the best for their child.</td>
</tr>
<tr>
<td></td>
<td>• Be clear that you are concerned for the health of</td>
</tr>
<tr>
<td></td>
<td>their child, not just public health safety.</td>
</tr>
<tr>
<td><strong>Advise</strong></td>
<td>• Clarify their concerns: make sure you understand &amp;</td>
</tr>
<tr>
<td></td>
<td>are answering the question they actually care about.</td>
</tr>
<tr>
<td></td>
<td>• Allow time to discuss the pros &amp; cons of vaccines.</td>
</tr>
<tr>
<td></td>
<td>• Be willing to discuss parents’ ideas.</td>
</tr>
<tr>
<td></td>
<td>• Offer written resources for parents.</td>
</tr>
<tr>
<td></td>
<td>• Tailor your advice using CDC’s Tips &amp; Time Savers.</td>
</tr>
</tbody>
</table>
If a parent declines...

• Declination is not final. The conversation can be revisited.

• End the conversation with at least 1 action you both agree on.

• Because waiting to vaccinate is the risky choice, many pediatricians ask the parent to sign a Declination Form
ANSWERING PARENTS’ MOST FREQUENTLY ASKED QUESTIONS
Tips and Time-savers for Talking with Parents about HPV Vaccine

Recommend the HPV vaccine series the same way you recommend the other adolescent vaccines. For example, you can say “Your child needs these shots today,” and name all of the vaccines recommended for the child’s age.

Parents may be interested in vaccinating, yet still have questions. Taking the time to listen to parents’ questions helps you save time and give an effective response. CDC research shows these straightforward messages work with parents when discussing HPV vaccine—and are easy for you or your staff to deliver.

CDC Research Shows:

TRY SAYING: The “HPV vaccine is cancer prevention” message resonates strongly with parents. In addition, studies show that a strong recommendation from you is the single best predictor of vaccination.

HPV vaccine is very important because it prevents cancer. I want your child to be protected from cancer. That’s why I’m recommending that your daughter/son receive the first dose of HPV vaccine today.

TRY SAYING: Disease prevalence is not understood, and parents are unclear about what the vaccine actually protects against.

HPV can cause cancers of the cervix, vagina, and vulva in women, cancer of the penis in men, and cancers of the anus and the mouth or throat in both women and men. There are about 12,600 of these cancers each year—and most could be prevented with HPV vaccine. There are also many more precancerous conditions requiring treatment that can have lasting effects.

TRY SAYING: Parents need a concrete reason to understand the recommendation that 11–12 year olds receive HPV vaccine.

We’re vaccinating today so your child will have the best protection possible long before the start of any kind of sexual activity. We vaccinate people well before they are exposed to an infection, as is the case with measles and the other recommended childhood vaccines. Similarly, we want to vaccinate children well before they get exposed to HPV.

TRY SAYING: Parents may be concerned that vaccinating may be perceived by the child as permission to have sex.

Research has shown that getting the HPV vaccine does not make kids more likely to be sexually active. In fact, studies have shown the opposite—getting the vaccine helps reduce the likelihood of starting sex at a younger age.

TRY SAYING: Parents might believe their child won’t be exposed to HPV because they aren’t sexually active or may not be for a long time.

HPV is so common that almost everyone will be infected at some point. It is estimated that 75 million Americans are currently infected with 14 million new HPV infections each year. Most people infected will never know. So even if your son/daughter waits until marriage to have sex, or only has one partner in the future, he/she could still be exposed if their partner has been exposed.

TRY SAYING: Emphasizing your personal belief in the importance of HPV vaccine helps parents feel secure in their decision.

I strongly believe in the importance of this cancer-preventing vaccine, and I have given HPV vaccine to my son/daughter/niece/nephew/friend’s children. Experts (like the American Academy of Pediatrics, the American Cancer Society, and the CDC) also agree that this vaccine is very important for your child.

TRY SAYING: Understanding that the side effects are minor and emphasizing the extent

HPV vaccine has been carefully studied by medical and scientific experts, and has not been associated with any long-term side effects. Since 2006, about 57 million doses of HPV vaccine have been used in the U.S., and in the years of HPV vaccine safety studies and monitoring, no serious safety concerns have been identified.

TRY SAYING: Parents want to know that HPV vaccine is effective.

In addition, studies in the U.S. and other countries have shown a significant reduction in infections caused by the HPV types targeted by the vaccine. Clinical trials of boys and girls, the vaccine was shown to be extremely effective. In addition, studies in the U.S. and other countries have shown a significant reduction in infections caused by the HPV types targeted by the vaccine.

Additional support for the series

If parents are resistant to the HPV vaccine series, parents will help them to complete the series.

CDC Research Shows:

http://www.cdc.gov/vaccines/who/teen-s/for-hcp-tipsheet-hpv.html
Top 5 reasons for not giving adolescents HPV vaccine — NIS-Teen, US, 2013

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6329a3.htm#tab2

- Not sexually active
- Not recommended
- Safety/side effects
- Not needed
- Lack of knowledge
FAQ #1: Why vaccinate at ages 11-12 years rather than waiting?

Because it works better!
FAQ #2: Why does it work better at a younger age?

• Antibody responses –
  • higher at ages 9-15 years than later in adolescence

• Risk of exposure –
  • The vaccine is inactive against previously acquired HPV types
  • Exposure (sexual activity) increases with age

• 11-12 year olds more likely to be seen for a health visit

http://pediatrics.aappublications.org/content/129/3/602.full
FAQ #3: Why vaccinate my kid? She won’t be sexually active.

Try Saying:

We're vaccinating today so Jack’s protected long before the chance of exposure.

We give HPV vaccine well before exposure just like we do with measles and the other routine vaccines.
FAQ #4: How is HPV spread?

• HPV exposure can occur with any type of intimate sexual contact, not just intercourse.

• Among a cohort of adolescent women without prior vaginal intercourse (followed longitudinally):
  - HPV detected in 46% prior to 1st vaginal sex
    - 70% reported non-coital risk behaviors

• Condoms do not completely stop HPV transmission.

FAQ #5: Is HPV vaccine safe?

- Concerns about both short- & long-term safety
- Not aware that HPV vaccine was tested
- Concerned child’s fertility could be affected by the vaccine

CDC. National and State Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2012
MMWR 2014; 63(29);625-633.
HPV Vaccine Safety

• More than 100 million doses distributed in US

• Most common adverse events = mild pain

• For serious adverse events reported, no unusual pattern or clustering related to HPV vaccine
  • IOM report (2012):
    ➢ Anaphylaxis (yeast and latex allergy)
    ➢ Syncope (805 within 15 minutes of vaccination)
  • No evidence for link with Guillain-Barre Syndrome

• These findings are similar to the safety reviews of MCV4 and Tdap vaccines
Try saying:

The vaccine has been used more than 100 million times and is extremely safe.

I have given HPV vaccine to my son/daughter (or grandchild/niece/nephew/friend's children).

I strongly believe in the importance of this cancer-preventing vaccine.

Experts, such as the American Academy of Pediatrics and cancer doctors also agree that the HPV vaccine is very important for your child.
FAQ #7: *Will my child see this as “permission” to 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:
  - Pregnancies
  - Counseling on contraceptives
  - Testing for, or diagnoses of STIs

Receipt of HPV vaccine does not increase sexual activity or decrease age of sexual debut

Bednarczyk *Pediatrics* Oct 2012
Several studies have shown that getting the HPV vaccine doesn’t make kids more likely to have sex or to start having sex at a younger age.
A STRONG PROVIDER RECOMMENDATION IS CRITICAL
Our Recommendations **DO** MATTER
Now for a GOOD EXAMPLE

http://www.health.state.mn.us/divs/idepc/immunize/hcp/ado1/hpvvideos.html
Four Strategies to Raise Rates

- Reminder-recall
- Reducing missed opportunities
- Other sites for vaccinations
- Better provider communication
New vaccines and vaccine policy changes on the horizon

Upcoming Changes

- Shingles vaccine
- RSV vaccine
- Zika vaccine
- Improved flu vaccine
- Norovirus vaccine?
Summary and Lessons

- Vaccination rates are high except for influenza and HPV.
- US vaccination policy depends on series of studies.
- ARI: Influenza is preventable, RSV, others in future.
- AGE: Rotavirus is preventable, Norovirus is next.
- HPV: Entirely preventable.

- 4 steps to raise vaccination rates (but no home runs):
  1. Reminder-recall
  2. Lower missed opportunities
  3. Use other sites
  4. Provider communication

- Multiple (bundled) interventions work best.
- You can help raise vaccination rates!
Immunization teams in Rochester and UCLA (LA)
Collaborators: Denver, CHOP, Chicago, UVM, Atlanta, NVSN sites
Primary Care Practices – Upstate NY, CORNET (APA), PROS (AAP)