AAP Webinar Series

Vaccine Hesitancy:

Advocating for Children
April 3, 2015:

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What Is Vaccine Hesitancy?

• Intent to skip or delay at least 1 of the vaccines recommended by the Advisory Committee on Immunization Practices (ACIP)

• Uncertainty as to whether a vaccine should be administered in accordance with the ACIP recommended immunization schedule

Vaccine Hesitancy: Not a New Problem

• Turn of the 19th century: Vaccination is introduced in the US

• 1809: Massachusetts is the first state to make smallpox vaccination compulsory

• 1850s: US anti-vaccination movement arises in response to the proliferation of smallpox vaccination mandates
  – Activists object to regulations requiring submission to a procedure that involves discomfort and that might not be safe

• 1870s: Smallpox re-emerges in the US, as a result of a decline in vaccination rates
  – Opposition to vaccination increases as new laws are passed and old ones to control smallpox are reinforced

Evolution of Public Health Laws Concerning Vaccination

• 1905: *Jacobson v Massachusetts* establishes rights of states to pass and enforce vaccination laws
  – Not a federal jurisdiction

• 1910: First philosophical exemption law is passed

• 1922: Supreme Court finds school immunization laws constitutional

• 1970s: Immunization laws are strengthened and strongly enforced

• 2015: School immunization laws vary among states
  – 50 states permit medical exemptions
  – 48 states permit religious exemptions
  – 19 states permit personal belief exemptions

Impact of Non-Medical Exemptions on Vaccination Rates

• Overall mean state-level rates of non-medical exemptions have increased; pace of that increase has accelerated

• Vaccination coverage rates are lower in states with personal belief exemptions than in states permitting only religious exemptions

• Children with non-medical exemptions tend to aggregate within schools and communities

• Vaccine-preventable diseases tend to cluster in areas where exemption rates are highest

Role of PBEs in the Resurgence of Pertussis: California, 2010¹

- In 2010, the incidence of pertussis was higher in PBE clusters than in areas outside those clusters.
- From 2005–2010, the mean census-tract–level rate of PBEs had increased among the state’s incoming kindergartners.

As illustrated in the larger map, clusters of pertussis cases in California with onset in 2010 overlapped with PBE clusters. The inset shows the relative locations of case clusters and PBE clusters in San Diego County.

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High Incidence of Measles in States That Allow PBEs: US, 2011

Red check marks indicate states that allow PBEs and had a high incidence of measles during 2011

- Import-associated describes cases brought into the US from other countries; cases linked epidemiologically to importations of measles into the US; cases with virologic evidence suggesting recent importation; and cases linked to patients with virologic evidence of recent importation. Map reproduced from CDC.¹

High Prevalence of PBEs Among US Residents With Measles: January 1–May 23, 2014

Of the 195 US residents with measles who were unvaccinated against the disease, 85% had philosophical or religious objections.

- Philosophical or religious beliefs: 85%
- Ineligible: 5%
- Missed opportunities: 6%
- Other: 4%

a Figure reproduced from CDC.1
It’s a small world after all

• Disneyland is the epicenter of the 2015 outbreak

• Nearly 200 cases over 17 states

• Almost all cases where details are known have been in unimmunized or under-immunized

• This outbreak has reinvigorated discussions in several states about the public health impact of PBEs
  – Will anything change?
What about Adolescents

- Vaccine hesitancy is not restricted to parents of young children
- Substantial hesitancy remains among parents of teens, particularly around influenza and HPV vaccines
- What does the national coverage look like for vaccines routinely recommended by ACIP for our teens?
State by State

- Healthy People 2020 goal is for 80% or more of 13-15 yr olds to have received Tdap, MCV4, and 3 doses of HPV (females only for now)

- 42 states exceed 80% for Tdap
- 18 states exceed 80% for MCV4
- 0 states exceed 80% for HPV
  - Rhode Island leads at 57%, most states around 40%
State laws requiring vaccines for middle school

- Tdap: 46 states and DC
- MCV4: 21 states and DC
- HPV: only DC
- Influenza: none
  - Although preschool requirement now for 2 states and NYC
<table>
<thead>
<tr>
<th>State</th>
<th>MCV4 mandated</th>
<th>2013 NIS coverage</th>
<th>Tdap mandated</th>
<th>2013 NIS coverage</th>
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<td>50</td>
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<td>Yes</td>
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<td>No</td>
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<td>Yes</td>
<td>86</td>
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<td>New York</td>
<td>No</td>
<td>83</td>
<td>Yes</td>
<td>90</td>
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<td>North Carolina</td>
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<td>87</td>
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<td>North Dakota</td>
<td>Yes</td>
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<td>Yes</td>
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<td>No</td>
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<td>Oklahoma</td>
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<td>Yes</td>
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<td>Oregon</td>
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<td>65</td>
<td>Yes</td>
<td>87</td>
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<tr>
<td>Pennsylvania</td>
<td>Yes</td>
<td>90</td>
<td>Yes</td>
<td>90</td>
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</tbody>
</table>
Strategies to improve vaccine rates

- State mandates make a clear difference
- New mandates are now met with suspicion and reluctance
- Making a vaccine ‘required’ for school entry (or for work, as in HCP) may have negative consequences as well

- What is the federal government’s role here?
What is the Role of the Federal Government?

Developing Vaccine Recommendations and Policy
Development of Vaccine Recommendations & Policies

Vaccine development and testing

Submission to FDA for Biologics License Application (BLA)

FDA Licensure

CDC consideration

AAP / ACP Board of Directors Consideration

Policy established, Recommendations for use published in MMWR

Recommendations for use published Pediatrics, Annals Int Med, Amer Family Physician

Uptake and financing

Federal and State laws and regulations

Public sector

Private sector

Vaccines and Related Biological Products Advisory Committee (VRBPAC)

Advisory Committee on Immunization Practices (ACIP)

AAP Committee on Infectious Diseases (COID) – Red Book

ACP Adult Immunization Initiative Physician Advisory Board

Insurance, Medicare, Medicaid, VFC: plans and policies
US Immunization Policy Timeline: Key Milestones

- 1955: Poliomyelitis Vaccination Assistance Act – start of Federal funding for immunization
- 1962: Creation of the immunization grant program (Section 317)
- 1963: Creation of National Immunization Program at CDC
- 1964: Establishment of Advisory Committee on Immunization Practices (ACIP)
- 1972: Federal Advisory Committee Act (FACA) – ACIP designated as a Federal Advisory Committee
- 1986: Creation National Injury Compensation Program
- 1993: Childhood Immunization Initiative – Vaccines for Children (VFC) Program adopted
Immunization Recommending Bodies

- Advisory Committee on Immunization Practices
- American Academy of Pediatrics Committee on Infectious Diseases – Red Book
- American Academy of Family Physicians
- American College of Physicians
- American College of Obstetricians and Gynecologists

Establishes National IZ Policy, Develops National recommendations

Advocacy for members, Provide recommendations for members

THE KEY DECISION BODY
ACIP – Background

- ACIP established 1964 by US Public Health Service
- Role: provide advice and guidance to CDC Director and HHS Secretary on most effective means to prevent vaccine-preventable diseases in the civilian population
  - FDA-licensed vaccines (and unlicensed vaccines if warranted)
  - Vaccines related agents (e.g., antisera, immune globulins, antivirals)
- 3 meetings annually – February, June, October; each meeting is 2 days
ACIP – Background

- Agenda items
  - Topics solicited from ACIP members, liaisons, CDC staff and others
  - Finalized by ACIP Steering Committee
- Emergency meeting can be called if warranted
- Follow FACA rules and procedures including meetings that are open to the public with time for public comment
- Meeting slides, live webcast archive, minutes posted on ACIP website
- Recommendations become final once approved by CDC Director and published in MMWR
The Advisory Committee on Immunization Practices (ACIP) is a group of medical and public health experts that develop recommendations on how to use vaccines to control diseases in the United States...more

Register for the upcoming ACIP meeting
June 25-26, 2014
(Wednesday - Thursday)
Deadline for registration:
Non-US Citizens: June 2, 2014
US Citizens: June 9, 2014
Registration is NOT required to watch the meeting via webcast
The ACIP Process: Considerations in Development of Recommendations

- FDA licensed indications and schedule
- Disease burden, morbidity and mortality overall and in high risk groups
- Data on safety and efficacy/effectiveness in general and in specific groups
- Acceptability/Feasibility in the context of existing recommendations
- Equity in access to vaccine and good use of public funds (cost effectiveness)
- Recommendations of other groups (e.g., AAP, AAFP, ACP, ACOG)
Evidence Based Recommendations (EBR)

- EBR approach approved by ACIP in October 2010
- System to be used: Grading of Recommendations, Assessment, Development and Evaluation (GRADE) framework*

- Implemented to date:
  - HPV vaccine in males
  - Hepatitis B vaccine in people with diabetes mellitus
  - Pneumococcal vaccines
  - Meningococcal vaccines
  - Influenza vaccines

* Ahmed F et al. Methods for developing evidence-based recommendations by the ACIP Vaccine 2011;29(49):9171-9176
FDA vs ACIP

- FDA licenses the vaccine
  - Safe and effective

- ACIP sets policy and recommended use

- ACIP policy not same as FDA approval/indication
  - Tdap over age 65
  - MCV4 two doses for all teens
  - Zoster ages 50-59
Immunization Policy Product: Two Immunization Schedules

ACIP establishes National immunization policy

1. ACIP, AAP, and AAFP produce a “harmonized” childhood and adolescent immunization schedule with each vaccine in the context of the other vaccines

2. ACIP, AAFP, ACP and ACOG produce a harmonized adult immunization schedule with each vaccine in the context of the other vaccines

Both schedules:
- updated annually
- published in January: MMWR, Pediatrics, Annals Internal Medicine, American Family Physician
<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Birth</th>
<th>1 mo</th>
<th>2 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>16-18 yrs</th>
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<tbody>
<tr>
<td>Hepatitis B (HepB)</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>Rotavirus (RV): RV1 (2-dose series); RV5 (3-dose series)</td>
<td>1st dose</td>
<td>2nd dose</td>
<td>See footnote 2</td>
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<td>Diphtheria, tetanus, &amp; acellular pertussis (DTaP: &lt;7 yrs)</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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<td>Tetanus, diphtheria, &amp; acellular pertussis (Tdap: ≥7 yrs)</td>
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<tr>
<td>Haemophilus influenzae type b (Hib)</td>
<td>1st dose</td>
<td>2nd dose</td>
<td>See footnote 3</td>
<td>3rd or 4th dose</td>
<td>See footnote 5</td>
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<tr>
<td>Pneumococcal conjugate (PCV13)</td>
<td>1st dose</td>
<td>2nd dose</td>
<td>3rd dose</td>
<td>4th dose</td>
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<td>Pneumococcal polysaccharide (PPSV23)</td>
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<td>Inactivated poliovirus (IPV; &lt;18 yrs)</td>
<td>1st dose</td>
<td>2nd dose</td>
<td>3rd dose</td>
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<tr>
<td>Influenza (IIV; LAIV): 2 doses for some; See footnote 8</td>
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<td>Annual vaccination (IIV only) 1 or 2 doses</td>
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<td>Measles, mumps, rubella (MMR)</td>
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<td>Annual vaccination (LAIV or IIV) 1 or 2 doses</td>
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<td>Varicella (VAR)</td>
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<td>Annual vaccination (LAIV or IIV) 1 dose only</td>
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<td>Hepatitis A (HepA)</td>
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<tr>
<td>Human papillomavirus (HPV2: females only; HPV4: males and females)</td>
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<tr>
<td>Meningococcal (Hb-MenCY ≥ 6 weeks; MenACWY-D ≥ 9 mos; MenACWY-CRM ≥ 2 mos)</td>
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<td>See footnote 13</td>
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</table>

This schedule includes recommendations in effect as of January 1, 2015. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at [http://www.cdc.gov/vaccines/hcp/acip-recs/index.html](http://www.cdc.gov/vaccines/hcp/acip-recs/index.html). Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online ([http://vaers.hhs.gov](http://vaers.hhs.gov)) or by telephone (800-822-7967). Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online ([http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm](http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm)) or by telephone (800-CDC-INFO [800-232-4636]).
DISCUSSION