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

References: 1. Heller G, Roberts M. Turning the tide: addressing vaccine hesitancy and timely immunizations through a social marketing campaign. Presented at: 44th National Immunization Conference, Atlanta, Georgia, April 21, 2010. Abstract 22697. **2.** Opel DJ, et al. *Hum Vaccines.* 2011;7(4):419-425. **3.** Dempsey AF, et al. *Pediatrics.* 2011;128(5):848-856. **4.** Gust DA, et al. *Pediatrics.* 2008;122(4):718-725.

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

3

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

References: 1. Omer SB, et al. *N Engl J Med.* 2009;360(19):1981-1988. **2.** Dr. John Talarico, California Department of Public Health, personal communication, October 5, 2011. **3.** National Conference of State Legislatures. States with religious and philosophical exemptions from school immunization requirements. http://bit.ly/14m1gjt. Accessed April 28, 2014.

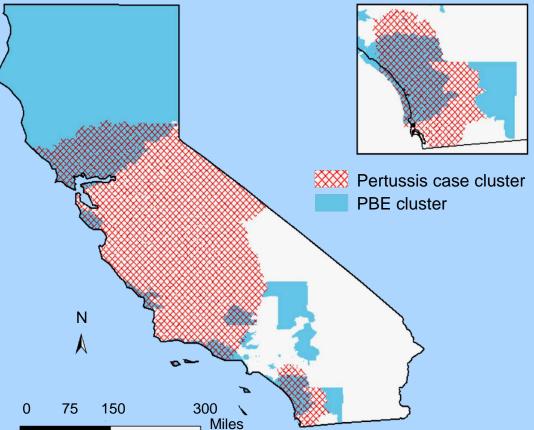
Impact of Non-Medical Exemptions on Vaccination Rates

- 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

References: 1. Omer SB, et al. N Engl J Med. 2012;367(12):1170-1171. 2. Omer SB, et al. N Engl J Med. 2009;360(19):1981-1988. 3. Omer SB, et al. JAMA. 2006;296(14):1757-1763. 4. Buttenheim A, et al. Am J Public Health. 2012;102(8):e59-e67. 5. Centers for Disease Control and Prevention (CDC). MMWR. 2014;63(22):496-499.
6. Omer SB, et al. Am J Epidemiol. 2008;168(12):1389-1396. 7. Imdad A, et al. Pediatrics. 2013;132(1):37-43.
8. Atwell JE, et al. Pediatrics. 2013;132(4):624-630.

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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Reference: 1. Atwell JE, et al. *Pediatrics*. 2013;132(4):624-630.

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

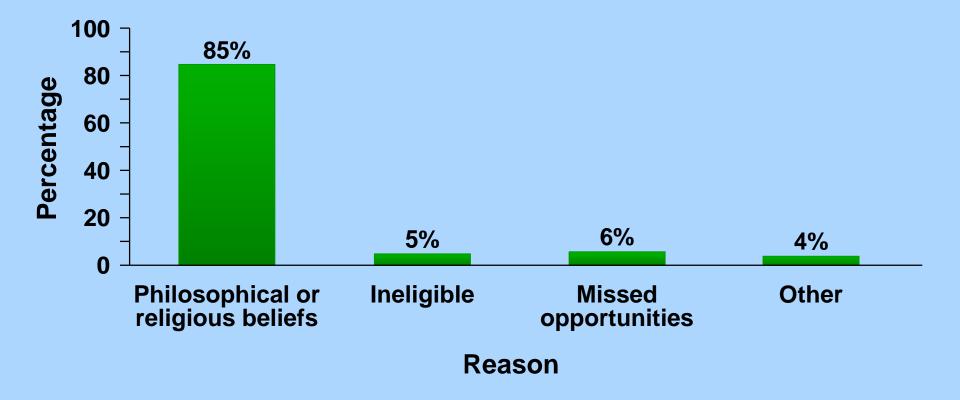


^a Import-associated describes cases brought into the US from other countries; cases linked epidemiologically to importations of measles into the US; cases with virologic evidence suggesting recent importation; and cases linked to patients with virologic evidence of recent importation. Map reproduced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

References: 1. CDC. *MMWR.* 2012;61(15):253-257. **2.** National Conference of State Legislatures. States with religious and philosophical exemptions from school immunization requirements. http://bit.ly/14m1gjt. Accessed April 28, 2014.

High Prevalence of PBEs Among US Residents With Measles: January 1–May 23, 2014¹

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



^a Figure reproduced from CDC.¹

Reference: 1. CDC. MMWR. 2014;63(22):496-499.

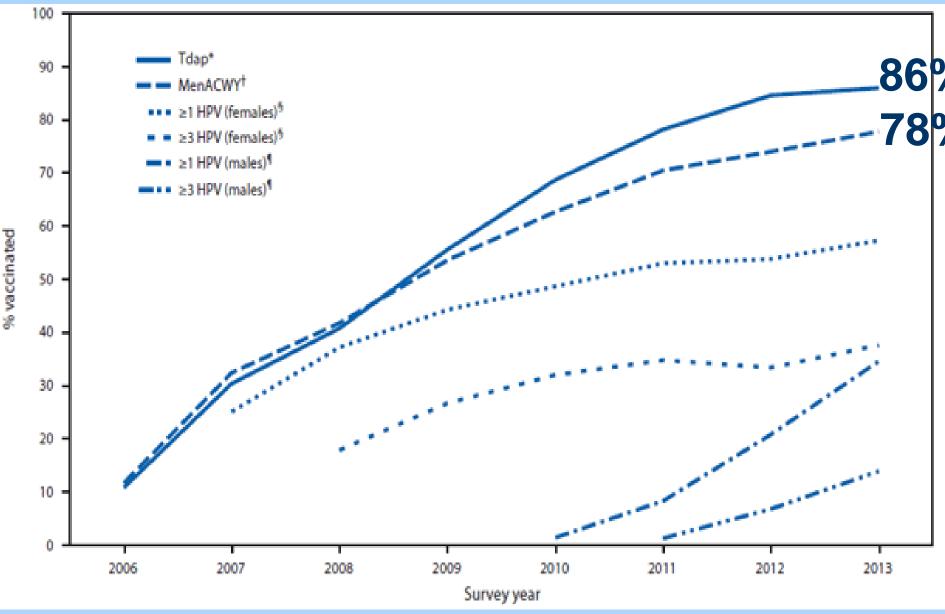
It's a small world after all

- 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?

NIS-Teen Vaccine Rates 2006-2013



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

| | MCV4 mandated | 2013 NIS coverage | Tdap mandated | 2013 NIS coverage | |
|----------------|------------------|----------------------|------------------|----------------------|--|
| Mississippi | No | 50 | Yes | 60 | |
| Missouri | No | 61 | Yes | 82 | |
| Montana | No | 52 | Yes | 84 | |
| Nebraska | No | 78 | Yes | 86 | |
| Nevada | No | 64 | Yes | 88 | |
| New Hampshire | No | 86 | Yes | 95 | |
| New Jersey | Yes | 92 | Yes | 86 | |
| New Mexico | No | 71 | Yes | 86 | |
| New York | No | 83 | Yes | 90 | |
| North Carolina | Yes | 87 | Yes | 89 | |
| North Dakota | Yes | 94 | Yes | 95 | |
| Ohio | No | 69 | Yes | 84 | |
| Oklahoma | No | 66 | Yes | 78 | |
| Oregon | No | 65 | Yes | 87 | |
| Pennsylvania | Yes | 90 | Yes | 90 | |

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

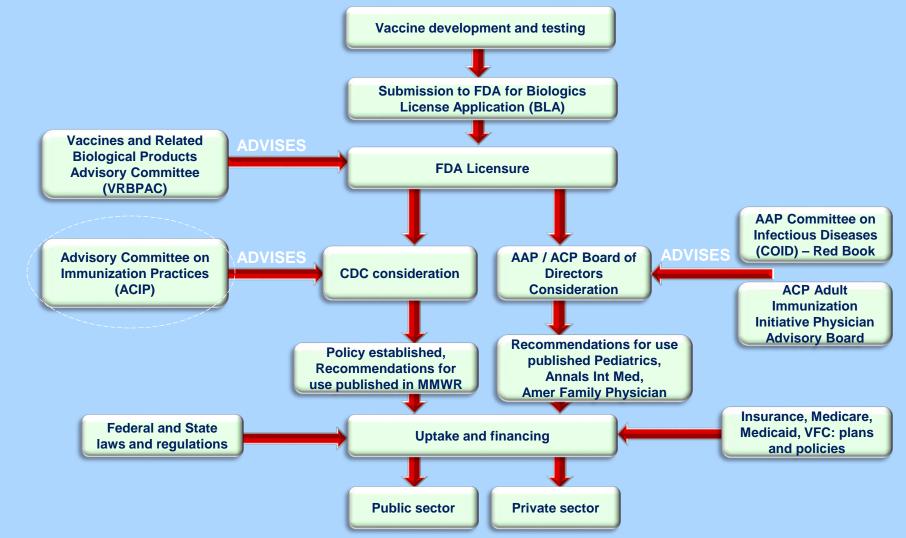
• What is the federal government's role here?

What is the Role of the

Federal Government?

Developing Vaccine Recommendations and Policy

Development of Vaccine Recommendations & Policies



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

Establishes National IZ Policy, Develops National recommendations



 Advisory Committee on Immunization Practices THE KEY DECISON BODY

 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

Advocacy for members, Provide recommendation s for members

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 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

| Vaccine | Birth | 1 mo | 2 mos | 4 mos | 6 mos | 9 mos | 12 mos | 15 mos | 18 mos | 19–23 mos | 2-3 yrs | 4-6 yrs | 7-10 yrs | 11-12 yrs | 13–15 yrs | 16–18 yrs |
|---|----------------------|--------------------------|----------------------|----------------------|----------------------|----------|--------------------------|------------------------------------|--------------|------------------------------|----------------------|-------------------------------|----------|---------------------|----------------------------|-----------|
| Hepatitis B [†] (HepB) | 1 st dose | ≪ 2 nd | dose> | | < | | 3 rd dose | | > | | | | | I | | |
| Rotavirus ² (RV) RV1 (2-dose series) ; RV5 (3-dose series) | | | 1 st dose | 2 nd dose | See footnote 2 | | | | | | | | | | | |
| Diphtheria, tetanus, & acellular pertussis³ (DTaP: <7 yrs) | | | 1 st dose | 2 nd dose | 3 rd dose | | | 4 th | dose> | | | 5 th dose | | | | |
| Tetanus, diphtheria, & acellular pertussis⁴ (Tdap: ≥7 yrs) | | | | | | | | | | | | | | (Tdap) | | |
| Haemophilus influenzae type b⁵ (Hib) | | | 1 st dose | 2 nd dose | See footnote 5 | | 3rd or 4 See for | I th dose,> otnote 5 | | | | | | | | |
| Pneumococcal conjugate [∉] (PCV13) | | | 1 st dose | 2 nd dose | 3 rd dose | | ≺ 4 th | dose> | | | | | | | | |
| Pneumococcal polysaccharide ⁶ (PPSV23) | | | | | | | | | | | | | | | | |
| Inactivated poliovirus ⁷ (IPV: <18 yrs) | | | 1 st dose | 2 nd dose | < | | 3 rd dose | | > | | | 4 th dose | | | | |
| Influenza [®] (IIV; LAIV) 2 doses for some: See footnote 8 | | | | | | Annual | vaccination (| IIV only) 1 or | 2 doses | | Annual vao IIV) 1 | ccination (LA I or 2 doses | IV or | Annual vacci 1 c | ination (LAIV dose only | or IIV) |
| Measles, mumps, rubella ⁹ (MMR) | | | | | See foo | otnote 9 | < 1 st (| dose> | | | | 2 nd dose | | | | |
| Varicella ¹⁰ (VAR) | | | | | | | < 1 st (| lose> | | | | 2 nd dose | | | | |
| Hepatitis A ¹¹ (HepA) | | | | | | | 2 | dose series, S | See footnote | 11> | | | | | | |
| Human papillomavirus ¹² (HPV2: females only; HPV4: males and females) | | | | | | | | | | | | | | (3-dose series) | | |
| Meningococcal ¹³ (Hib-MenCY ≥ 6 weeks; MenACWY-D≥9 mos; MenACWY-CRM ≥ 2 mos) | | | See footnote 13 | | | | | | | 1 st dose Booster | | | | | | |
| Range of recommended ages for aggs for ages for | | | | | | | | | | | | | | | | |

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. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (http://www.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/vaccines/recs/vac-admin/contraindications.htm) or by telephone (800-CDC-INFO [800-232-4636]).

DISCUSSION