Epidemiology of Vaccine Refusal and Evidence Base for Addressing Vaccine Hesitancy

Saad B. Omer, MBBS MPH PhD
Departments of Global Health, Epidemiology, and Pediatrics
Emory University, Schools of Public Health & Medicine
&
Emory Vaccine Center
Disclosure Statement

I was awarded the Maurice R. Hilleman Early-stage Career Investigator Award by the National Foundation for Infectious Diseases. The award was funded by an unrestricted educational grant to the National Foundation for Infectious Diseases from Merck and Co, Inc. However, I had no direct interaction with Merck.
Vaccine Coverage Levels – United States, 1962-2011

Data Source: CDC Pink Book; 2012
NIS Data & MMWRs multiple years
Evolution of Immunization Program and Prominence of Vaccine Safety

1. Prevaccine
2. Increasing Coverage
3. Loss of Confidence
4. Resumption of Confidence
5. Eradication

Incidence

Vaccine Coverage
Adverse Events
Outbreak
Eradication
Vaccinations Stopped

Chen & Hibbs, Pediatr Ann., 1998
School Immunization Requirements

- State laws (not federal)
- Major role in low rates of vaccine preventable diseases
- Exemptions
  - Medical
  - Religious
  - Personal belief (philosophical) exemptions
Exemptions to School Immunization Laws

TYPE OF EXEMPTION(S) ALLOWED

- Blue: Philosophic, Religious & Medical (20)
- Green: Religious & Medical (28)
- Orange: Medical only (2)
Relative Risk of Measles and Pertussis in Exemptors from School Laws

<table>
<thead>
<tr>
<th></th>
<th>Measles</th>
<th>Pertussis</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO (1987-98)</td>
<td>22</td>
<td>5.9</td>
</tr>
</tbody>
</table>

Feikin et al. JAMA. 2000;
Complexity of Administrative Procedures to Obtain Exemptions & Proportion of Children with Exemptions

Source: Rota et al., AJPH, 2001
State Policies

- Easy process = High exemption rates
- Exemption rates associated with individual risk of pertussis & measles
- State policies ➔ Disease incidence?
## ASSOCIATIONS BETWEEN STATE EXEMPTION POLICIES AND PERTUSSIS INCIDENCE, 1986-2004

<table>
<thead>
<tr>
<th>Type of exemption</th>
<th>Unadjusted IRR (95% CI)</th>
<th>Adjusted IRR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only Religious Exemption</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>Personal Belief Exemption</td>
<td>2.06 (1.77-2.40)</td>
<td>1.48 (1.03-2.13)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exemption ease</th>
<th>Unadjusted IRR (95% CI)</th>
<th>Adjusted IRR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficult</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>Medium</td>
<td>1.27 (1.06-1.51)</td>
<td>1.35 (0.96-1.91)</td>
</tr>
<tr>
<td>Easy</td>
<td>1.90 (1.60-2.28)</td>
<td>1.53 (1.10-2.14)</td>
</tr>
</tbody>
</table>

Adjusting for allowing parental signature for school immunization forms, proportion inside urbanized area, income (11 categories), and education (7 categories)

*Omer et al., JAMA, 2006*
Financial Impact of a State Adopting a Personal Belief Exemption

- Modeled cost of pertussis in infants, children and adolescents in Iowa
- Annual projected impact of pertussis
  - Without PBE: $273,365
  - With PBE: $410,047 (range $281,566-$582,267)
    - 50% projected increase in cost

Wells & Omer, Vaccine 2012
Non-Medical Exemptions by year
1991 - 2003
Nonmedical Exemptions for States With Religious Exemptions and With Personal Belief Exemptions -1991 - 2004

Only Religious Exemptions Permitted

Personal Belief Exemptions Permitted

Omer et al., JAMA, 2006
Data updated
Nonmedical Exemptions by Ease of Exemption
1991 - 2007

Easy Exemption Policy

Medium Exemption Policy

Difficult Exemption Policy

Omer et al., JAMA, 2006
Data updated
WA State Counties’ School Entry Exemption Rates 2006-2007

Exemption Rate

- <2.0%
- 2.0–2.9%
- 3.0–3.9%
- 4.0–4.9%
- 5.0–7.9%
- ≥8.0%

Wahkiakum (no report)

Omer et al., New Eng Journal of Medicine, 2009
Relative Locations of Pertussis Space-time Clusters & Exemptions Spatial Clusters

Overlap of Exemptions Clusters with Pertussis Clusters

Unadjusted OR
3.0 (2.5 – 3.6)

Adjusted OR
2.7 (2.2 – 3.3)

Omer, Enger, Moulton et al., Am. J. Epi., 2008
Locations of Schools Included in Exemption Clusters in California and Massachusetts
<table>
<thead>
<tr>
<th></th>
<th>Odds Ratios</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unadjusted</td>
<td>2.47</td>
<td>(2.21, 2.75)</td>
</tr>
<tr>
<td>Adjusted</td>
<td>1.73</td>
<td>(1.53, 1.96)</td>
</tr>
</tbody>
</table>

Overlap Between Personal Beliefs Exemption Clusters 2006-2010 & 2010 Pertussis clusters
Pertussis Incidence in 2010 Inside PBE vs. Outside PBE Clusters in California

Incidence Rate Ratio
(95% Confidence Interval)

Unadjusted  1.19 (1.10, 1.30)
Adjusted    1.12 (1.02, 1.23)
Consistent shot-limiting rates according to birth month
Consistent and episodic shot-limiters as a percentage of yearly birth cohort

Parents’ Perceptions by Child's Vaccination Status

Salmon, Moulton, Omer et al., AJPH, 2005
Characteristics of Unvaccinated ("Zero Dose") vs. Under-vaccinated Children

- Unvaccinated children more likely to be:
  - Male
  - White
  - Belong to households with higher income
  - Married mother with a college education
  - Live with ≥ 4 children

*Smith, Chu, & Baker, Pediatrics, 2004*
# PROVIDER PERCEPTIONS OF EXEMPT VS. VACCINATED CHILDREN

<table>
<thead>
<tr>
<th>Health Care Provides in High Category</th>
<th>Exempt</th>
<th>Vaccinated</th>
<th>Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease Susceptibility</td>
<td>11.3</td>
<td>5.7</td>
<td>1.34</td>
</tr>
<tr>
<td>Disease Severity</td>
<td>30.2</td>
<td>29.4</td>
<td>1.36</td>
</tr>
<tr>
<td>Vaccine Efficacy</td>
<td>87.0</td>
<td>88.8</td>
<td>1.21</td>
</tr>
<tr>
<td>Vaccine Safety</td>
<td>88.9</td>
<td>93.9</td>
<td>3.28*</td>
</tr>
</tbody>
</table>

* P Value <0.05

Salmon, Pan, Omer et al., Human Vacc. 2009
Sources of Vaccine Information

Salmon, Moulton, Omer et al. Arch Ped Adol Med, 2005
A Nuanced View of Vaccine Acceptance

- Immunization Advocates: 33%
- Go Along to Get Along: 26%
- Health Advocates: 25%
- Fencesitters: 13%
- Worrieds: 3%

Gust et al. Am J Health Behav., 2004
2010 HealthStyles Survey

Intentions to Vaccinate
- Already vaccinated: 82%
- Planned to vaccinate: 11%
- Intend to partially vaccinate: 5%
- Would not give any vaccine: 2%

Specific Vaccine Concerns
- Yes: 77%
- No: 23%

Kennedy et al., Health Affairs, 2011
Percentage of parents who reported hearing unfavorable information about vaccines

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Parents who intentionally delayed vaccines</th>
<th>Parents who did not intentionally delay vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unweighted sample size</td>
<td>546</td>
<td>2,365</td>
</tr>
<tr>
<td>Parents who reported hearing or reading any unfavorable information about vaccines</td>
<td>87.6 (83.6, 91.6)(^a)</td>
<td>71.9 (68.6, 75.2)</td>
</tr>
<tr>
<td>Examples of unfavorable information about vaccines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sometimes not preventing disease</td>
<td>51.6 (44.3, 58.9)(^a)</td>
<td>39.4 (35.7, 43.1)</td>
</tr>
<tr>
<td>Are not safe or have serious side effects</td>
<td>78.2 (72.6, 83.8)(^a)</td>
<td>60.9 (57.3, 64.5)</td>
</tr>
<tr>
<td>Are opposed by groups for political or religious reasons</td>
<td>44.8 (37.5, 52.1)(^a)</td>
<td>32.6 (29.2, 36.0)</td>
</tr>
<tr>
<td>Are opposed by groups that oppose vaccines for health reasons</td>
<td>39.7 (32.6, 46.8)(^a)</td>
<td>30.1 (26.7, 33.5)</td>
</tr>
</tbody>
</table>

\(^a\)Estimated percentage among parents who intentionally delayed vaccines who heard or read the unfavorable information about vaccines is significantly different from the estimated percentage among parents who did not delay vaccines.

Smith, Humiston, Parnell et al., Public Health Reports. 2010
Informed Declination

- Signed informed declination form for non-medical exemptions
- Provides information on risks to child, family, & community associated with personal belief exemption
Refusal of Vaccination for My Child

I am the parent/guardian of the child named at the bottom of this form. My healthcare provider has recommended that my child be vaccinated against the diseases indicated below. I have been given a copy of the Vaccine Information Statement (VIS) that explains the benefits and risks of receiving each of the vaccines recommended for my child. I have carefully reviewed and considered all of the information given to me. However, I have decided not to have my child vaccinated at this time. I have read and acknowledge the following:

- I understand that some vaccine-preventable diseases (e.g., measles, mumps, pertussis (whooping cough)) are infecting unvaccinated U.S. children, resulting in many hospitalizations and even deaths.
- I understand that though vaccination has led to a dramatic decline in the number of U.S. cases of the diseases listed below, some of these diseases are quite common in other countries and can be brought to the U.S. by international travelers. My child, if unvaccinated, could easily get one of these diseases while traveling or from a traveler.
- I understand that my unvaccinated child could spread disease to another child who is too young to be vaccinated or whose medical condition (e.g., leukemia, other forms of cancer, immune system problems) prevents them from being vaccinated. This could result in long-term complications and even death for the other child.
- I understand that if every parent exempted their child from vaccination, these diseases would return to our community in full force.
- I understand that my child may not be protected by "herd" or "community" immunity (i.e., the degree of protection that is the result of having most people in a population vaccinated against a disease).
- I understand that some vaccine-preventable diseases such as measles and pertussis are extremely infectious and have been known to infect even the very few unvaccinated people living in highly vaccinated populations.
- I understand that if my child is not vaccinated and consequently becomes infected, he or she could experience serious consequences, such as amputation, pneumonia, hospitalization, brain damage, paralysis, meningitis, seizures, deafness, and death. Many children left intentionally unvaccinated have suffered severe health consequences from their parents' decision not to vaccinate their child.
- I understand that my child may be excluded from his or her child care facility, school, sports events, or other organized activities during disease outbreaks. This means that I could miss many days of work to stay home with my child.
- I understand that the American Academy of Pediatrics, the American Academy of Family Physicians, and the Centers for Disease Control and Prevention all clearly support preventing diseases through vaccination.

<table>
<thead>
<tr>
<th>Vaccine / Disease</th>
<th>VIS (Y/N)</th>
<th>Vaccine recommended by doctor or nurse (yes/no)</th>
<th>I decline this vaccine (reason or parent permission)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria-tetanus-pertussis (DTP)</td>
<td>(Y)</td>
<td>doctor or nurse</td>
<td></td>
</tr>
<tr>
<td>Haemophilus influenzae type b (Hib)</td>
<td>(Y)</td>
<td>doctor or nurse</td>
<td></td>
</tr>
<tr>
<td>Hepatitis A (HepA)</td>
<td>(Y)</td>
<td>doctor or nurse</td>
<td></td>
</tr>
<tr>
<td>Hepatitis B (HepB)</td>
<td>(Y)</td>
<td>doctor or nurse</td>
<td></td>
</tr>
<tr>
<td>Human papillomavirus (HPV)</td>
<td>(Y)</td>
<td>doctor or nurse</td>
<td></td>
</tr>
<tr>
<td>Influenza</td>
<td>(Y)</td>
<td>doctor or nurse</td>
<td></td>
</tr>
<tr>
<td>Measles-mumps-rubella (MMR)</td>
<td>(Y)</td>
<td>doctor or nurse</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vaccine / Disease</th>
<th>VIS (Y/N)</th>
<th>Vaccine recommended by doctor or nurse (yes/no)</th>
<th>I decline this vaccine (reason or parent permission)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meningococcal (MCV)</td>
<td>(Y)</td>
<td>doctor or nurse</td>
<td></td>
</tr>
<tr>
<td>Varicella (Var)</td>
<td>(Y)</td>
<td>doctor or nurse</td>
<td></td>
</tr>
<tr>
<td>Pneumococcal conjugate (PCV)</td>
<td>(Y)</td>
<td>doctor or nurse</td>
<td></td>
</tr>
<tr>
<td>Polio, inactivated (IPV)</td>
<td>(Y)</td>
<td>doctor or nurse</td>
<td></td>
</tr>
<tr>
<td>Rotavirus (RV)</td>
<td>(Y)</td>
<td>doctor or nurse</td>
<td></td>
</tr>
<tr>
<td>Tetanus-diphtheria (TD)</td>
<td>(Y)</td>
<td>doctor or nurse</td>
<td></td>
</tr>
<tr>
<td>Tetanus-diphtheria-pertussis (Tdap)</td>
<td>(Y)</td>
<td>doctor or nurse</td>
<td></td>
</tr>
</tbody>
</table>

In signing this form, I acknowledge I am refusing to have my child vaccinated against one or more diseases listed above. I have placed my initials in the column titled "I decline this vaccine" to indicate the vaccine(s) I am declining. I understand that at any time in the future, I can change my mind and vaccinate my child.

Child's name: ___________________________ Date of birth: ________________________
Parent/guardian signature: ___________________________ Date: ________________________
Doctor/nurse signature: ___________________________ Date: ________________________
Selected Focus Group Findings About Vaccine Hesitancy

- Parents trusted vaccine information given **orally** by physicians.
- Parents with concerns responded to providers giving **personalized** risk/benefit information or
  - reporting they immunized **their own children**
- Parents did not want the provider to lecture or argue with them.

*Fredrickson et al. Clinical Res Meth, 2004*
Interacting with Vaccine Hesitant Parents

• Share honestly what is and is not known about the risks and benefits of the vaccine in question
• Listen respectfully to parental concerns
• Explain the risk of being unimmunized
• Discuss specific vaccines that parents are most concerned about

Diekema & AAP Committee on Bioethics, 2004
Examples of Innovative Intervention Studies

• Interactive & moderated social media website for parents concerned about vaccines
• Gain frame vs. loss frame messaging
• Practice + Provider + Patient intervention trial in OBGYN offices
• Social marketing campaign in Washington state
Approaches to Reduce Exemption Rates & Vaccine Hesitancy

- Rational administrative requirements for granting exemptions
- Informed declination
- Effective provider-parent communication tools
- Development of a robust evidence base of effective interventions
Thank You!