Delayed, Selective and “Alternative” Immunization Schedules

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Overview

• What are “Alternative” Immunization Schedules?
• How common are they?
• Where did they come from?
• What are parents’ concerns with the CDC/AAP/AAPF schedule?
• Strategies for talking to parents

The Cow-Pock—or—the Wonderful Effects of the New Inoculation—vide. the Publications of ye Anti-Vaccine Society Print (color engraving) published June 12, 1802 by H. Humphrey, St. James's Street.
What percentage of parents vaccinate their children according to schedule?

A. 98%
B. 90%
C. 74%
D. 62%

2011 National Immunization Survey, Children 19-35 months

The Data

~90% vaccinate according to schedule, the other 10%:
- Delayed vaccination
  - Intentional, use of delayed schedule
  - Illness at time of appointment
  - Unintentional
- Selective vaccination
  - Intentional, use of selective schedule
  - Intentional, focus on one or few vaccines:
    - Flu vaccine, HPV, Varicella
  - Unintentional
- ~1% refuse all vaccines
Kennedy et al., Health Affairs June 2011
- 2010 HealthStyles survey data, N=376, mailed cross-sectional survey
- Majority of parents reported they had already (83%) or planned to (11%) fully vaccinate their children
- 5% intended to selectively vaccinate
- 2% reported children would receive no vaccines (NIS reports <1%)

Dempsey et al., Pediatrics, October 3, 2011
- Online cross-sectional survey, N=748
- 13% of parents of children 6 months to 6 years of age reported following an alternative schedule
- 2% reported refusing all vaccines
- 20% of alternative vaccinators had initially followed recommended schedule
- 28% of on-schedule vaccinators thought delaying doses was "safer" approach
- 22% of on-schedule vaccinators disagreed that best schedule was the one recommended by experts

There are a lot of fence sitters on this issue!
What are “alternative” immunization schedules and where did they come from?

Meet Doctor Bob

- "Dr. Bob", as he likes to be called by his little patients, earned his medical degree at Georgetown University School of Medicine in 1995. He did his pediatric internship and residency at Children's Hospital Los Angeles, finishing in 1998.
- Dr. Bob enjoys surfing the California waves, mountain biking, playing bass guitar with his teenage son guitarist, and trying to keep up with his three children.

More Doctor Bob

In 2007 Dr. Bob wrote a book

http://www.askdrsears.com/topics/vaccines
Dr. Bob’s Schedules

- Selective - decline focus
  - Includes: DTaP, Rota, PCV, Hib, HPV, Hep B (teen)
    - To cover “severe, common diseases”
  - Excludes: Polio, MMR, Flu, Varicella, Hep A, MCV

- Alternative - delay focus
  - No more than 2 at a time
  - Extra visits at 3, 5, 7, 12 month, 2.5 years, 3.5 years, 12 years and 2 months
  - MMR at 4 years?, Hep B at 2.5 years
  - To “minimize the theoretical risks of vaccines”
    - The “best of both worlds of disease prevention and safe vaccination”

The Problems with Dr. Bob’s Schedule

- He made it up, all by himself
- 2010 study in Pediatrics found no benefit of delayed schedule
- Parental fear trumps science
- Fails to acknowledge good science
  - Thimerosal
  - Aluminum
- Fails to distinguish good science from bad science or non-science
- States his intention is to give options to concerned parents, to convert non-vaccinators to at least partial vaccinators
- Unfortunately his book sounds many anti-vaccine messages and misinforms his audience on a number of issues
- Converts probable vaccinators to partial vaccinators or non-vaccinators?

What are parents most concerned about?

A. Too many vaccines too soon, overwhelmed immune system
B. Vaccines cause developmental disabilities like autism
C. Vaccines aren’t necessary, disease don’t occur in U.S.
D. Vaccines cause my child pain
Kennedy et al., Health Affairs June 2011

- Children Age 6 or younger
- Concerns reported by parents:
  - Pain - 38%
  - Too many in one visit - 36%
  - Too many during first 2 years of life - 34%
  - Fever - 32%
  - Learning disabilities, autism - 30%
  - Unsafe ingredients - 26%

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Freed et al. Pediatrics, March 2009

- Online cross-sectional survey, N=2,521
- 11.5% of surveyed parents had refused at least one vaccine:
  - HPV 56.4%, Varicella 32.3%, MCV 31.8%, MMR 17.7%
    - HPV: too new, low risk, moral concern
    - Varicella: prefer child to get disease
    - MCV: too new
    - MMR: adverse events

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Too many too soon?

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Vaccines</th>
<th>Possible Number of Shots by Age 2</th>
<th>Possible Number of Shots at a Single Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1900</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1960</td>
<td>5</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>1980</td>
<td>7</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>2000</td>
<td>11</td>
<td>20</td>
<td>5</td>
</tr>
</tbody>
</table>

Offit et al., Pediatrics, January 2002
### Shots vs. Antigens

<table>
<thead>
<tr>
<th>Year</th>
<th>Vaccine Proteins</th>
<th>Vaccine Proteins</th>
<th>Vaccine Proteins</th>
<th>Vaccine Proteins</th>
<th>Vaccine Proteins</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>15</td>
<td>15</td>
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<td>15</td>
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</tr>
<tr>
<td>Total</td>
<td>70</td>
<td>70</td>
<td>70</td>
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<tr>
<td>Smallpox</td>
<td>200</td>
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<tr>
<td>Diphtheria</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Tetanus</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>WC-Pertussis</td>
<td>3000</td>
<td>3000</td>
<td>3000</td>
<td>3000</td>
<td>3000</td>
</tr>
<tr>
<td>AC-Pertussis</td>
<td>2–5</td>
<td>2–5</td>
<td>2–5</td>
<td>2–5</td>
<td>2–5</td>
</tr>
<tr>
<td>Polio</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Measles</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
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<tr>
<td>Rubella</td>
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<td>5</td>
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<td>Mumps</td>
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<td>Varicella</td>
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<td>Pneumococcus</td>
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<tr>
<td>Hepatitis A</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>2217</td>
<td>2217</td>
<td>2217</td>
<td>2217</td>
<td>2217</td>
</tr>
</tbody>
</table>

Offit et al., Pediatrics, January 2002

### Immune System Capacity

- $10^9$ to $10^{11}$ different antibody specificities
- 10,000 antigens at one time (limited by blood volume)
- The bottom line:
  - There is no physiologic reason to design an alternative immunization schedule because of immune system capability
  - There is no biological rationale for splitting doses

### The Ocean Analogy

When an infant is in the mother's womb, they're in a sterile environment. When they enter the birth canal and are born, they're no longer in a sterile environment. Bacteria quickly begin to live on the baby's skin, their nose, their throat. The average person has trillions of bacteria living on the surface of their body. We are able to make an immune response to these bacteria. If we didn't, they would invade the bloodstream and cause death. Each bacterium has 2,000 to 6,000 proteins that our immune system is able to handle. If you consider all 14 vaccines given to children, it's probably 450 immunological components or proteins. That's literally just a drop in the ocean.
Safety Concerns

- Thimerosal
  - Has been removed from nearly all childhood vaccines (2001)
  - Ethyl-mercury ≠ methyl-mercury
  - MMR never contained thimerosal
  - Thompson et al., NEJM 2007
    - Cohort study of 1,047 children
    - Follow-up with neuropsych testing at 7-10 years
    - No causal association

- Aluminum
  - 70 year history of use
  - Known adverse events: local reactions at injection site
  - Animal studies have been used to establish conservative vaccine threshold with 30x uncertainty factor = 2 mg/kg/day
  - By 6 months, cumulative:
    - Vaccine dose = 4 mg
    - Breast milk = 10 mg
    - Formula = 40 mg
    - Soy formula = 120 mg

Offit et al. Pediatrics, December 2003

Talking to Parents

Parents – Some Things We Know

- Overall confidence in safety of recommended vaccines is high
- Mothers are usual decision-makers when it comes to their children’s health
- Mothers consistently list doctor visits and immunizations as among the most important things you can do to keep your children healthy
- Physicians remain the most credible source for immunization information – and they value stories and personal recommendations from doctors
Parents Have a Different Perspective

<table>
<thead>
<tr>
<th>Scientists and Health Experts</th>
<th>Public, Patients, Parents</th>
</tr>
</thead>
<tbody>
<tr>
<td>• See probabilities as providing helpful context</td>
<td>• See probabilities as having personal meaning</td>
</tr>
<tr>
<td>• (Temporal) Association doesn’t mean causation</td>
<td>• (Temporal) Association strongly suggests causation – especially if it fits with personal beliefs</td>
</tr>
<tr>
<td>• Comfortable with data, empirical evidence, and guidance from expert committees and reviews</td>
<td>• Data, research, and recommendations must align with personal beliefs or experiences</td>
</tr>
</tbody>
</table>

Regret Avoidance

• Trying to avoid or minimize “regret” is often a key decision making factor.
• Inaction may feel safer than action, perception that inaction leaves risk up to chance, God, etc

Understanding Parent’s Beliefs/Intentions

<table>
<thead>
<tr>
<th>Delayers/Hesitant (10%)</th>
<th>Refusers (1%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concerned about number of shots</td>
<td>Concerned about any shots</td>
</tr>
<tr>
<td>Values vaccines (just need to wait a bit)</td>
<td>Do not value vaccines</td>
</tr>
<tr>
<td>Believe in “partnership” with provider, working together for what is best for my child</td>
<td>Believe role is to challenge mainstream practice/beliefs</td>
</tr>
</tbody>
</table>
Messages to Parents

Honesty: Vaccines are not perfect, Science is not perfect

- No vaccine is 100% safe
- No vaccine is 100% effective
- All vaccines have possible side effects, most mild, rarely severe (See VIS for each)
- However, the risk of disease far outweighs the risk of vaccine
- Science is always evolving and sometimes new risks are identified
- However, science is the most reliable guide we have for making informed medical decisions. Feelings, hunches, and beliefs are never as reliable as the scientific method

Risk to others

- Your child is healthy
- If your child contracts chickenpox there is a very good chance that your child will recover uneventfully
- However, if your contagious child comes in contact with a child with leukemia or with a newborn, that child would be at very high risk for severe infection and even death
- Keep in mind that many infections, including chickenpox, can be transmitted before symptoms occur
Strategies

- Take time to listen
- Solicit and welcome questions
- Keep the conversation going
- Science vs. anecdote—depends on the parent
  - “I believe in immunizations. I am fully immunized and I immunize my children.”
- Acknowledge benefits and risks
  - “I believe vaccinating is a safer option than not vaccinating.”
- Respect parent’s authority—partnership
- Acknowledge the stress and pain associated with shots
  - Crying is normal
  - Calm parent will help calm child
  - Use favorite blanket or toy
  - Touch child, soothe, talk softly, smile, make eye contact
  - Cuddle or breastfeed, pacifiers
- Explain risks and responsibilities if they choose to not vaccinate
- Summer 2012 Olympics and measles
- Follow up after the vaccinations

What behavioral interventions may help reduce the pain from vaccinations?

A. Breastfeeding/sweet-tasting solutions
B. Sucking on a pacifier
C. Distraction
D. Topical local anesthetics,
E. Firm pressure with the alcohol wipe
F. All of the above

Resources

- New CDC Resource for Providers: Talking With Parents About Vaccines For Infants
  - Based on research with parents and developed in collaboration with AAP and AAFP
  - Provides materials for physicians and parents, including talking to parents about vaccines, vaccine-preventable diseases, and vaccine safety
  - Resources for “high information seeking parents”
  - Can be found at: www.cdc.gov/vaccines/conversation
Thanks!

Rachel.Herlihy@state.co.us
Preliminary Conclusions

- The routine childhood immunization program in one birth cohort prevents about
  20 million cases
  42,000 deaths
- It is cost saving
  saves about $13.6 billion in direct costs
  saves about $68.9 billion from societal perspective

From: Zhou F, Presented at CIP National Immunization Conference

Table 11-8: Approximate Basal Repopulation Numbers in Developed Countries and Some Countries with Fewer Cases. (Reproduced by Lawther, 2005, Unpublished Manuscript.)

<table>
<thead>
<tr>
<th>Infection</th>
<th>Basal Repopulation Number (%)</th>
<th>Grade/Need Immunity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S pneumonia</td>
<td>1.4</td>
<td>10.75</td>
</tr>
<tr>
<td>Meningitis</td>
<td>0.15</td>
<td>3.13</td>
</tr>
<tr>
<td>Meningitis</td>
<td>1.7</td>
<td>7.44</td>
</tr>
<tr>
<td>Pertussis</td>
<td>0.3-1</td>
<td>0.64</td>
</tr>
<tr>
<td>Tetanus</td>
<td>2.15</td>
<td>0.85</td>
</tr>
<tr>
<td>Rubella</td>
<td>6.7</td>
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<tr>
<td>Measles</td>
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<td>0.85</td>
</tr>
<tr>
<td>Varicella</td>
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<tr>
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</tr>
<tr>
<td>Measles</td>
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<td>3.3</td>
</tr>
</tbody>
</table>


Vaccine Adverse Events

- http://www.cdc.gov/vaccines/vac-gen/side-effects.htm