Delayed, Selective and “Alternative” Immunization Schedules

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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.
Overview

- What are “Alternative” Immunization Schedules?
- How common are they?
- Where did they come from?
- What are parents’ concerns with the CDC/AAP/AAFP schedule?
- Strategies for talking to parents
What percentage of parents choose to vaccinate their children according to schedule?

A. ~98%
B. ~90%
C. ~74%
D. ~62%
Research on Parental Choices Around Childhood Immunization
Glanz et al., JAMA Pediatrics 2013

- 2004-2010 study of 300,000+ children in 8 Managed Care Organizations
- Estimated prevalence of under-vaccination because of parental choice was 13.0%
• 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%)
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
What “alternatives” are parents choosing?

- ~10% of parents choose:
  - Delayed vaccination
    - Intentional, use of delayed schedule
  - Selective vaccination
    - Intentional, use of selective schedule
    - Intentional, focus on one or few vaccines:
      - Flu vaccine, HPV, Varicella

- 1-2% refuse all vaccines
## National Immunization Survey, 19-35 month olds

<table>
<thead>
<tr>
<th></th>
<th>3+DTaP</th>
<th>4+DTaP</th>
<th>3+Polio</th>
<th>1+MMR(^I)</th>
<th>Hib-FS</th>
<th>3+HepB</th>
<th>1+Var</th>
<th>4+PCV</th>
<th>4:3:1:3:1:4 Series</th>
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</thead>
<tbody>
<tr>
<td><strong>US</strong></td>
<td>95.5±0.5</td>
<td>84.6±1.0</td>
<td>93.9±0.6</td>
<td>91.6±0.8</td>
<td>80.4±1.1</td>
<td>91.1±0.7</td>
<td>90.8±0.7</td>
<td>84.4±1.0</td>
<td>73.3±1.2</td>
</tr>
<tr>
<td><strong>Colorado</strong></td>
<td>91.2±5.1</td>
<td>81.0±7.7</td>
<td>89.8±5.2</td>
<td>88.4±5.4</td>
<td>76.5±8.3</td>
<td>88.0±5.2</td>
<td>88.6±5.3</td>
<td>78.7±7.7</td>
<td>70.3±8.5</td>
</tr>
<tr>
<td><strong>HP2020 Goal</strong></td>
<td>N/A</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>80</td>
</tr>
</tbody>
</table>
What else is decreasing the coverage rates?

- **Delayed vaccination**
  - Intentional, use of delayed schedule
  - Illness at time of appointment
  - Unintentional - missed appointment, vaccine out of stock

- **Selective vaccination**
  - Intentional, use of selective schedule
  - Intentional, focus on one or few vaccines:
    - Flu vaccine, HPV, Varicella
  - Unintentional - vaccine out of stock, shortage, unable to pay for all
Worrisome signs regarding parental choices

- **Glanz et al., 2013**
  - Increased prevalence of under-vaccination from 2004 to 2008
    - Observed as cumulative days of under-vaccination
  - Increasing trend of delayed vaccination pattern from 2004 to 2008

- **Dempsey et al., 2011**
  - 30% 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.
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, 21 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
  - Pro/Con lists elevate feelings/beliefs/hunches to the level of 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
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%

Kennedy et al., Health Affairs June 2011
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
### 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

![Image: CIP Colorado Immunization Program]

## Table: Vaccines and Antigens

<table>
<thead>
<tr>
<th>Year</th>
<th>Vaccine</th>
<th>Proteins</th>
<th>Vaccine</th>
<th>Proteins</th>
<th>Vaccine</th>
<th>Proteins</th>
<th>Vaccine</th>
<th>Proteins/Polsacc</th>
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</thead>
<tbody>
<tr>
<td>1900</td>
<td>Smallpox</td>
<td>~200</td>
<td>Smallpox</td>
<td>~200</td>
<td>Diphtheria</td>
<td>1</td>
<td>Diphtheria</td>
<td>1</td>
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<tr>
<td></td>
<td>Total</td>
<td>~200</td>
<td>Diphtheria</td>
<td>1</td>
<td>Tetanus</td>
<td>1</td>
<td>Tetanus</td>
<td>1</td>
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<td></td>
<td>Tetanus</td>
<td>1</td>
<td>WC-Pertussis</td>
<td>~3000</td>
<td>AC-Pertussis</td>
<td>2–5</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>WC-Pertussis</td>
<td>~3000</td>
<td>Polio</td>
<td>15</td>
<td>Polio</td>
<td>15</td>
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<tr>
<td></td>
<td>Polio</td>
<td>15</td>
<td>Measles</td>
<td>10</td>
<td>Measles</td>
<td>10</td>
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<tr>
<td></td>
<td>Total</td>
<td>~3217</td>
<td>Mumps</td>
<td>9</td>
<td>Mumps</td>
<td>9</td>
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<tr>
<td></td>
<td>Rubella</td>
<td>5</td>
<td>Rubella</td>
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<td></td>
<td>Total</td>
<td>~3041</td>
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<td></td>
<td>Hib</td>
<td>2</td>
<td>Varicella</td>
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<td>Pneumococcus</td>
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<tr>
<td>2000</td>
<td>Varicella</td>
<td>69</td>
<td></td>
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<td>1</td>
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<td>Total</td>
<td>123–126</td>
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</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 150 immunological components or proteins. That’s literally just a drop in the ocean.

Dr. Paul A. Offit, Children’s Hospital of Philadelphia, Division Chief, Infectious Disease Section
Safety Concerns

- **Thimerosol**
  - Has been removed from nearly all childhood vaccines (2001)
  - Ethyl-mercury ≠ methyl-mercury
  - MMR never contained thimerosol
  - Thompson et al., NEJM 2007
    - Cohort study of 1,047 children
    - Follow-up with neuropsych testing at 7-10 years
    - No causal association
  - Johns Hopkins Institute for Vaccine Safety: [http://www.vaccinesafety.edu/cc-thim.htm](http://www.vaccinesafety.edu/cc-thim.htm)

- **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

1. 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
- Health care providers remain the most credible source for immunization information – and they value stories and personal recommendations from providers
## 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>• See probabilities as having personal meaning</td>
<td>• Concept of risk compression</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>
<tr>
<td>• “Locus of control” beliefs often matter</td>
<td>• “Locus of control” beliefs often matter</td>
</tr>
<tr>
<td></td>
<td>• Stories, examples, and anecdotes that resonate often most impactful</td>
</tr>
</tbody>
</table>

Adapted from 2012 NFID Clinical Vaccinology Course, Dr. Glen Nowak, NCIRD, CDC
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.

Adapted from 2012 NFID Clinical Vaccinology Course, Dr. Glen Nowak, NCIRD, CDC
## Understanding Parent’s Beliefs/Intentions

<table>
<thead>
<tr>
<th>Delayers/Hesitant (10%)</th>
<th>Refusers (1-2%)</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>

Adapted from 2012 NFID Clinical Vaccinology Course, Dr. Glen Nowak, NCIRD, CDC
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](http://www.cdc.gov/vaccines/conversation)
CIP Colorado Immunization Program

If You Choose Not to Vaccinate Your Child, Understand the Risks and Responsibilities.

Before an outbreak of a vaccine-preventable disease occurs in your community:

- Talk to your child’s doctor or nurse to learn your child’s medical record up to date regarding vaccination status. Ask for a copy of the updated record.
- Inform your child’s school, daycare facility, and other caregivers about your child’s vaccination status.
- Be aware of your child can catch diseases from people who don’t have any symptoms.
- Influenza can be spread from people who have the disease in their noses but are not ill. You can’t tell who is contagious.

Talking with Parents about Vaccines for Infants

Strategies for Healthcare Professionals

Immunization professionals and parents agree that times have changed.

Because of questions and concerns about vaccines, well-child visits can be stressful for parents. As their infant’s health care provider, you remain parents’ trusted source of information about vaccines. This is true even for parents with the most questions and concerns. Your personal relationship uniquely qualifies you to help support parents in understanding and choosing vaccination.

However, the time for infant health evaluation at each well visit is a critical opportunity to discuss these important topics and to make your best effort to ensure that parents are aware of the choices you make and the rationale for those choices. You can follow up with ongoing communication that meets their needs.

When it comes to communication, you may find that similar information—be it science or narrative—can make the difference for some parents.

CIP Colorado Immunization Program

CDC Materials
Parent Resources

FACT OR FICTION

Natural Immunity

FACT: Vaccines let your child build immunity in a safe, controlled environment.

In the past decade, we’ve seen a shift toward green, eco-friendly, and natural living. Many of us have worked to reduce our personal waste, preserve Mother Nature’s gifts, and to keep toxins and anything labeled “artificial” out of our homes and our bodies.

Some parents want to “green our vaccines” by calling out chemicals and seemingly scary-sounding ingredients.

The truth is, all vaccine ingredients are tested together to be safe, and each ingredient is there to produce a stronger response in your baby’s body to ensure immunity toward a specific disease.

http://www.immunizeforgood.com/
More Resources

http://www.immunize.org/
Thanks!

Rachel.Herlihy@state.co.us