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 y^e^ 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%

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

What “alternatives” are parents choosing?

- ~10% of parents choose:
  - Delayed vaccination
    - Intentional, use of delayed schedule
  - Selective vaccination
    - Intentional, use of selective schedule
    - Intententional, focus on one or few vaccines:
      - Flu vaccine, HPV, Varicella
- 1-2% refuse all vaccines

National Immunization Survey, 19-35 month olds

Delay

	3+DTaP	4+DTaP	3+Polio	1+MMR[I]	Hib-FS	3+HepB	1+Var	4+PCV	4:3:1:3:3:1:4 Series
US	95.5±0.5	84.6±1.0	93.9±0.6	91.6±0.8	80.4±1.1	91.1±0.7	90.8±0.7	84.4±1.0	73.3±1.2
Colorado	91.2±5.1	81.0±7.7	89.8±5.2	88.4±5.4	76.5±8.3	88.0±5.2	88.6±5.3	78.7±7.7	70.3±8.5
HP2020 Goal	N/A	90	90	90	90	90	90	90	80

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
  - Intententional, 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.

More Doctor Bob

Meet *the* Sears Family


Dr. Bill


Dr. Jim

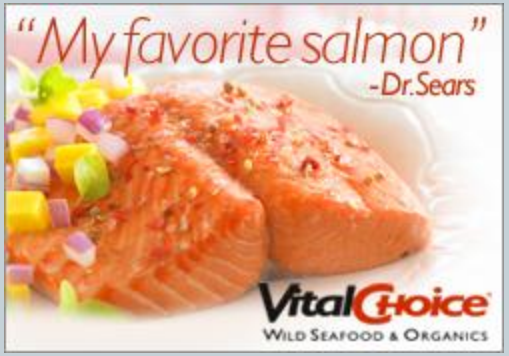

Dr. Bob

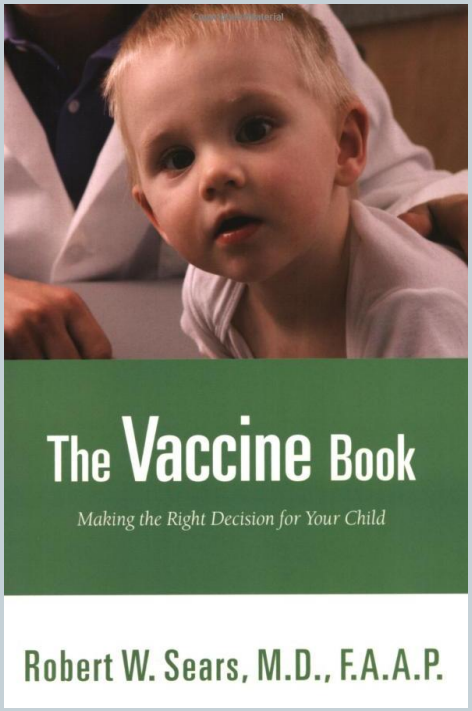

Dr. Peter


Martha

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
  - Thimerosol
  - 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

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%

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

Too many too soon?

Year	Number of Vaccines	Possible Number of Shots by Age 2	Possible Number of Shots at a Single Visit
1900	1	1	1
1960	5	8	2
1980	7	5	2
2000	11	20	5

Offit et al., Pediatrics, January 2002

Shots vs. Antigens

1900		1960		1980		2000	
Vaccine	Proteins	Vaccine	Proteins	Vaccine	Proteins	Vaccine	Proteins/ Polysacc
Smallpox	~200	Smallpox	~200	Diphtheria	1	Diphtheria	1
Total	~200	Diphtheria	1	Tetanus	1	Tetanus	1
		Tetanus	1	WC-Pertussis	~3000	AC-Pertussis	2–5
		WC-Pertussis	~3000	Polio	15	Polio	15
		Polio	15	Measles	10	Measles	10
		Total	~3217	Mumps	9	Mumps	9
				Rubella	5	Rubella	5
				Total	~3041	Hib	2
						Varicella	69
						Pneumococcus	8
						Hepatitis B	1
						Total	123–126

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
- 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 uncertainly 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,
2. Aluminum in Vaccines, What you should know: http://www.chop.edu/export/download/pdfs/articles/vaccine-education-center/aluminum.pdf

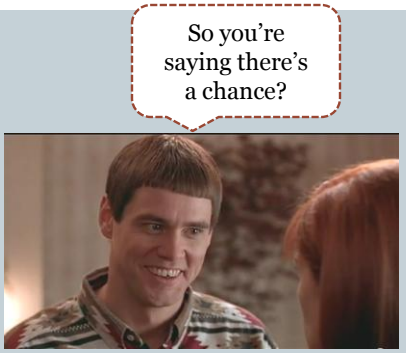
Talking to parents

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

Scientists and Health Experts	Public, Patients, Parents
• See probabilities as providing helpful context	• See probabilities as having personal meaning • Concept of risk compression
• (Temporal) Association doesn't mean causation	• (Temporal) Association strongly suggests causation – especially if it fits with personal beliefs
• Comfortable with data, empirical evidence, and guidance from expert committees and reviews	• Data, research, and recommendations must align with personal beliefs or experiences • "Locus of control" beliefs often matter • Stories, examples, and anecdotes that resonate often most impactful



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

Delayers/Hesitant (10%)	Refusers (1-2%)
Concerned about number of shots	Concerned about any shots
Values vaccines (just need to wait a bit)	Do not value vaccines
Believe in "partnership" with provider, working together for what is best for my child	Believe role is to challenge mainstream practice/beliefs

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 chicken pox, 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

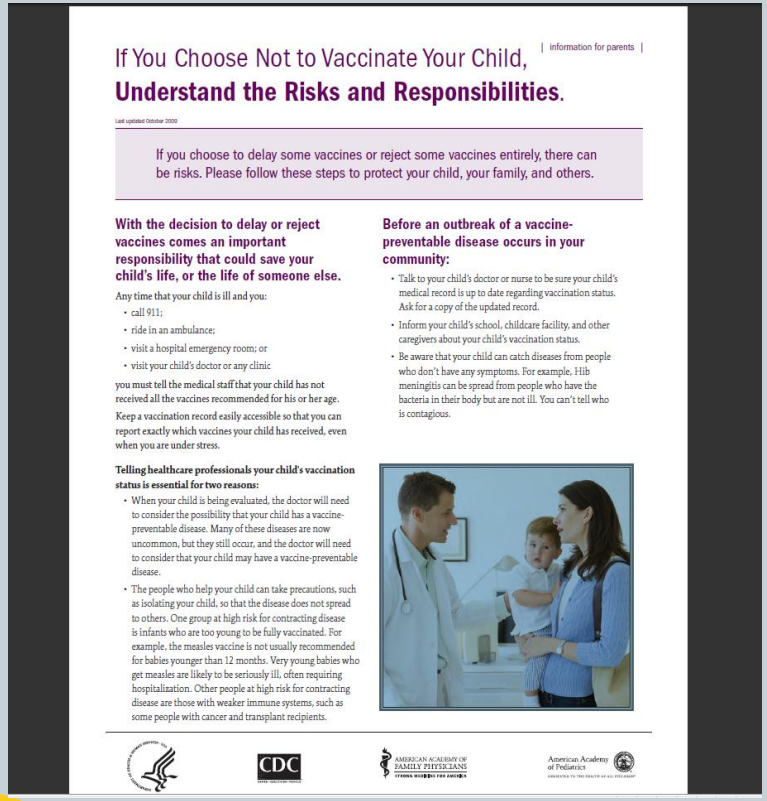
What behavioral interventions may help reduce the pain from vaccinations?

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

CDC Materials



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

| information for parents |

Last updated October 2009

If you choose to delay some vaccines or reject some vaccines entirely, there can be risks. Please follow these steps to protect your child, your family, and others.

With the decision to delay or reject vaccines comes an important responsibility that could save your child's life, or the life of someone else.

Any time that your child is ill and you:

- call 911;
- ride in an ambulance;
- visit a hospital emergency room; or
- visit your child's doctor or any clinic

you must tell the medical staff that your child has not received all the vaccines recommended for his or her age.

Keep a vaccination record easily accessible so that you can report exactly which vaccines your child has received, even when you are under stress.

Telling healthcare professionals your child's vaccination status is essential for two reasons:

- When your child is being evaluated, the doctor will need to consider the possibility that your child has a vaccine-preventable disease. Many of these diseases are now uncommon, but they still occur, and the doctor will need to consider that your child may have a vaccine-preventable disease.
- The people who help your child can take precautions, such as isolating your child, so that the disease does not spread to others. One group at high risk for contracting disease is infants who are too young to be fully vaccinated. For example, the measles vaccine is not usually recommended for babies younger than 12 months. Very young babies who get measles are likely to be seriously ill, often requiring hospitalization. Other people at high risk for contracting disease are those with weaker immune systems, such as some people with cancer and transplant recipients.

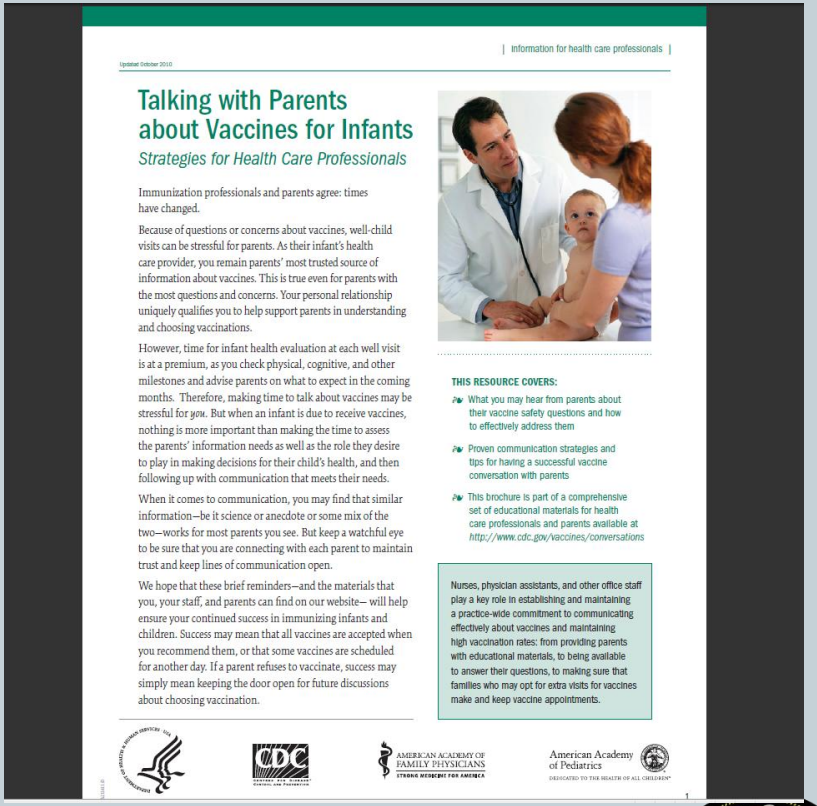
Before an outbreak of a vaccine-preventable disease occurs in your community:

- Talk to your child's doctor or nurse to be sure your child's medical record is up to date regarding vaccination status. Ask for a copy of the updated record.
- Inform your child's school, childcare facility, and other caregivers about your child's vaccination status.
- Be aware that your child can catch diseases from people who don't have any symptoms. For example, Hib meningitis can be spread from people who have the bacteria in their body but are not ill. You can't tell who is contagious.

CDC

AMERICAN ACADEMY OF FAMILY PHYSICIANS

American Academy of Pediatrics



| information for health care professionals |

Updated October 2010

Talking with Parents about Vaccines for Infants

Strategies for Health Care Professionals

Immunization professionals and parents agree: times have changed.

Because of questions or concerns about vaccines, well-child visits can be stressful for parents. As their infant's health care provider, you remain parents' most 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 vaccinations.

However, time for infant health evaluation at each well visit is at a premium, as you check physical, cognitive, and other milestones and advise parents on what to expect in the coming months. Therefore, making time to talk about vaccines may be stressful for *you*. But when an infant is due to receive vaccines, nothing is more important than making the time to assess the parents' information needs as well as the role they desire to play in making decisions for their child's health, and then following up with communication that meets their needs.

When it comes to communication, you may find that similar information—be it science or anecdote or some mix of the two—works for most parents you see. But keep a watchful eye to be sure that you are connecting with each parent to maintain trust and keep lines of communication open.

We hope that these brief reminders—and the materials that you, your staff, and parents can find on our website—will help ensure your continued success in immunizing infants and children. Success may mean that all vaccines are accepted when you recommend them, or that some vaccines are scheduled for another day. If a parent refuses to vaccinate, success may simply mean keeping the door open for future discussions about choosing vaccination.

THIS RESOURCE COVERS:

- What you may hear from parents about their vaccine safety questions and how to effectively address them
- Proven communication strategies and tips for having a successful vaccine conversation with parents
- This brochure is part of a comprehensive set of educational materials for health care professionals and parents available at *http://www.cdc.gov/vaccines/conversations*

Nurses, physician assistants, and other office staff play a key role in establishing and maintaining a practice-wide commitment to communicating effectively about vaccines and maintaining high vaccination rates: from providing parents with educational materials, to being available to answer their questions, to making sure that families who may opt for extra visits for vaccines make and keep vaccine appointments.

CDC

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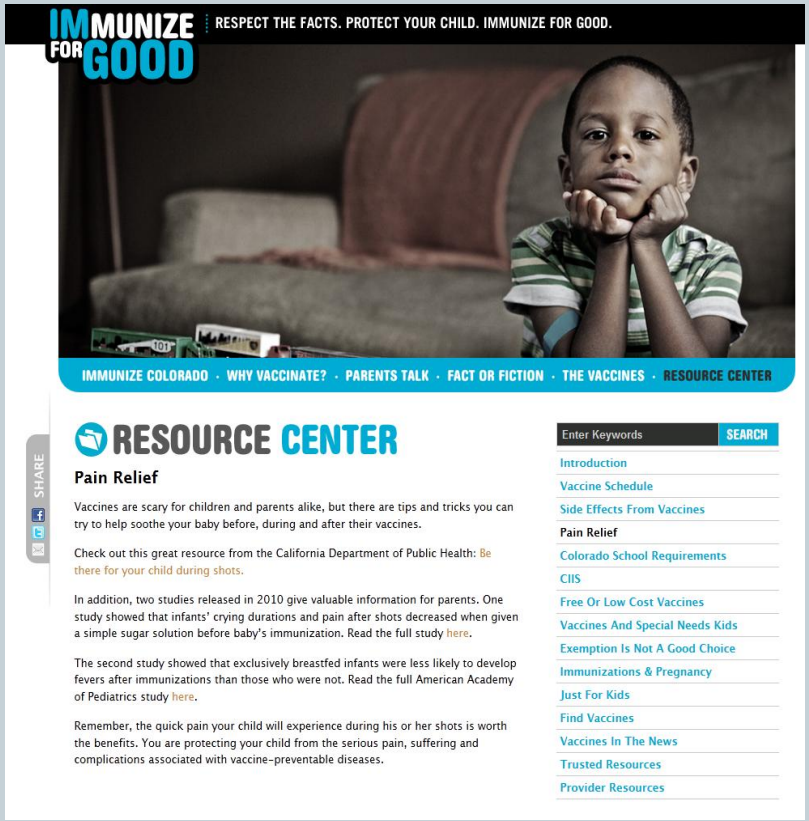
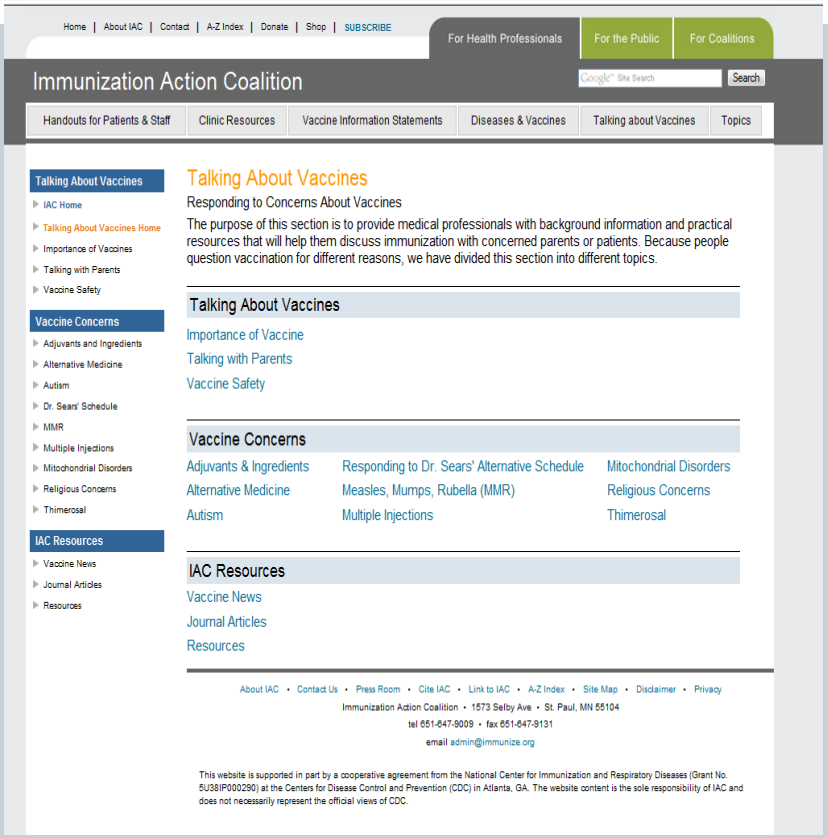
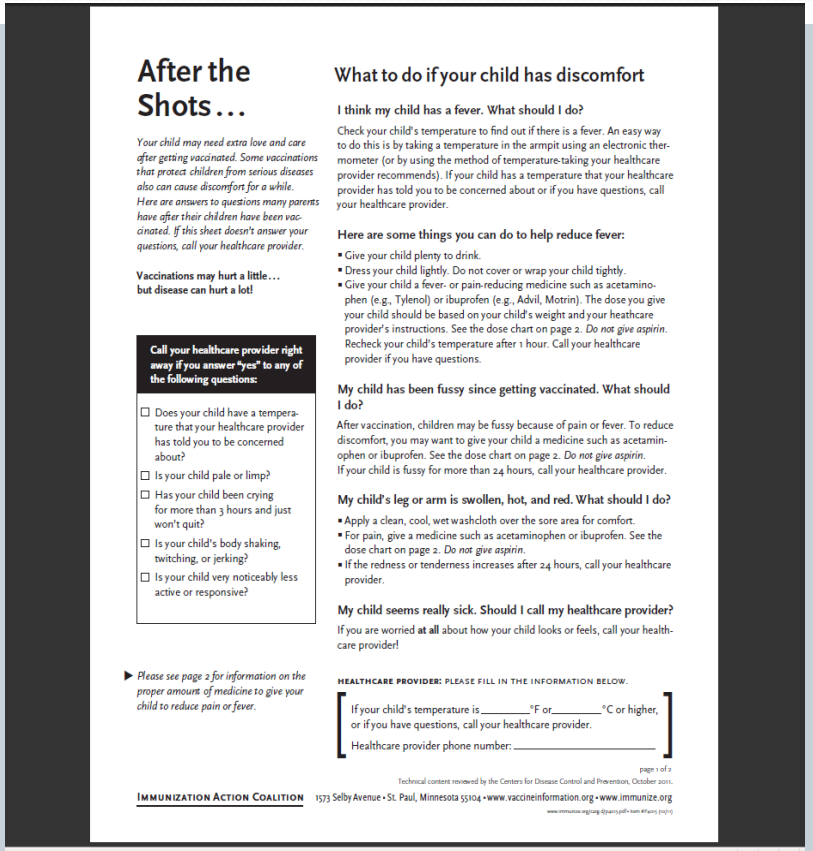
Parent Resources



http://www.immunizeforgood.com/

More Resources





After the Shots…

Your child may need extra love and care after getting vaccinated. Some vaccinations that protect children from serious diseases also can cause discomfort for a while. Here are answers to questions many parents have after their children have been vaccinated. If this sheet doesn't answer your questions, call your healthcare provider.

Vaccinations may hurt a little… but disease can hurt a lot!

Call your healthcare provider right away if you answer "yes" to any of the following questions:

- ☐ Does your child have a temperature that your healthcare provider has told you to be concerned about?
- ☐ Is your child pale or limp?
- ☐ Has your child been crying for more than 3 hours and just won't quit?
- ☐ Is your child's body shaking, twitching, or jerking?
- ☐ Is your child very noticeably less active or responsive?

▶ *Please see page 2 for information on the proper amount of medicine to give your child to reduce pain or fever.*

What to do if your child has discomfort

I think my child has a fever. What should I do?

Check your child's temperature to find out if there is a fever. An easy way to do this is by taking a temperature in the armpit using an electronic thermometer (or by using the method of temperature-taking your healthcare provider recommends). If your child has a temperature that your healthcare provider has told you to be concerned about or if you have questions, call your healthcare provider.

Here are some things you can do to help reduce fever:

- Give your child plenty to drink.
- Dress your child lightly. Do not cover or wrap your child tightly.
- Give your child a fever- or pain-reducing medicine such as acetaminophen (e.g., Tylenol) or ibuprofen (e.g., Advil, Motrin). The dose you give your child should be based on your child's weight and your heathcare provider's instructions. See the dose chart on page 2. *Do not give aspirin.* Recheck your child's temperature after 1 hour. Call your healthcare provider if you have questions.

My child has been fussy since getting vaccinated. What should I do?

After vaccination, children may be fussy because of pain or fever. To reduce discomfort, you may want to give your child a medicine such as acetaminophen or ibuprofen. See the dose chart on page 2. *Do not give aspirin.*
If your child is fussy for more than 24 hours, call your healthcare provider.

My child's leg or arm is swollen, hot, and red. What should I do?

- Apply a clean, cool, wet washcloth over the sore area for comfort.
- For pain, give a medicine such as acetaminophen or ibuprofen. See the dose chart on page 2. *Do not give aspirin.*
- If the redness or tenderness increases after 24 hours, call your healthcare provider.

My child seems really sick. Should I call my healthcare provider?

If you are worried **at all** about how your child looks or feels, call your healthcare provider!

HEALTHCARE PROVIDER: PLEASE FILL IN THE INFORMATION BELOW.

If your child's temperature is _____°F or _____°C or higher, or if you have questions, call your healthcare provider.

Healthcare provider phone number: _____

Technical content reviewed by the Centers for Disease Control and Prevention, October 2011.

IMMUNIZATION ACTION COALITION 1573 Selby Avenue • St. Paul, Minnesota 55104 • www.vaccineinformation.org • www.immunize.org

www.immunize.org/catg-d/p4015.pdf • Item #P4015 [10/11]

http://www.immunize.org/

Thanks!

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