

Vaccine Safety and Risk Communication

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Number of Vaccines in the Routine Childhood and Adolescent Immunization Schedule

1985

- Measles
- Rubella
- Mumps
- Diphtheria
- Tetanus
- Pertussis
- Polio

7

1995

- Measles
- Rubella
- Mumps
- Diphtheria
- Tetanus
- Pertussis
- Polio
- Hib (infant)
- HepB
- Varicella

10

2006

- Measles
- Rubella
- Mumps
- Diphtheria
- Tetanus
- Pertussis
- Polio
- Hib (infant)
- HepB
- Varicella
- Pneumococcal disease
- Influenza
- Meningococcal disease
- HepA
- Rotavirus
- HPV

16

GREEN OUR VACCINES

*We want safe vaccines
for our children!*

Why are we giving our children so many more vaccines so early in life?

Why do we only test vaccines individually and never consider the combination risk of vaccines administered together? Given the dramatic rise of autism to epidemic levels, isn't it time for the scientific community to seriously consider the anecdotal evidence of so many parents? We urge the CDC and AAP to help us find the answers to these questions and learn why the increase in the number and composition of so many vaccinations has led to a surge in neurodevelopmental disorders. Our children deserve no less.

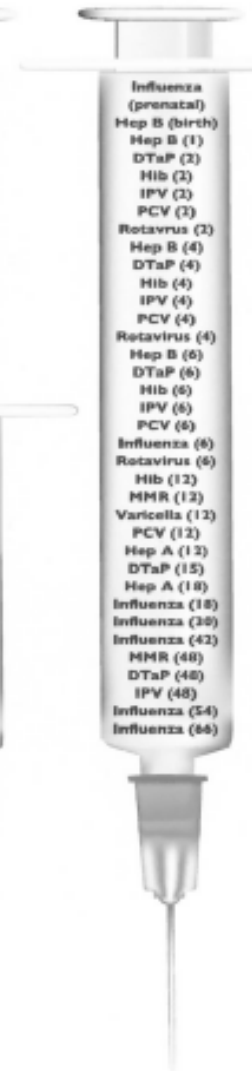
COMPARISON OF CDC MANDATORY SCHEDULE
Children birth to six years (recommended month)

USA 1983
AUTISM RATE:
1 in 10,000



10

USA 2008
AUTISM RATE:
1 in 150



36

GREEN OUR VACCINES

TOO MANY TOO SOON

Recommended Immunization Schedule for Persons Aged 0–6 Years—UNITED STATES • 2008

For those who fall behind or start late, see the catch-up schedule

Vaccine ▼	Age ►	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B ¹		HepB	HepB	^{see footnote 1}	HepB							
Rotavirus ²				Rota	Rota	Rota						
Diphtheria, Tetanus, Pertussis ²				DTaP	DTaP	DTaP	^{see footnote 3}	DTaP	DTaP			
<i>Haemophilus influenzae</i> type b ⁴				Hib	Hib	<i>Hib</i> ⁵	Hib					
Pneumococcal ²				PCV	PCV	PCV	PCV		PPV			
Inactivated Poliovirus				IPV	IPV	IPV			IPV			
Influenza ⁶						Influenza (Yearly)						
Measles, Mumps, Rubella ¹						MMR			MMR			
Varicella ⁶						Varicella			Varicella			
Hepatitis A ⁷						HepA (2 doses)			HepA Series			
Meningococcal ⁸										MCV4		

Range of recommended ages

Certain high-risk groups

This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2007, for children aged 0 through 6 years. Additional information is available at www.cdc.gov/vaccines/recs/schedules. Any dose not administered at the recommended age should be administered at any subsequent visit, when indicated and feasible. Additional vaccines may be licensed and recommended during the year. Licensed combination vaccines may be used whenever any components of the combination are indicated and other components of the vaccine are not

contraindicated and if approved by the Food and Drug Administration for that dose of the series. Providers should consult the respective Advisory Committee on Immunization Practices statement for detailed recommendations, including for high risk conditions: <http://www.cdc.gov/vaccines/paqs/ACIP-list.htm>. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete VAERS form is available at www.vaers.hhs.gov or by telephone, 800-822-7967.

MACLEAN'S

BARBARA AMIEL:
I'm home
alone P.12

AUG.
27th
2017

OUR GIRLS AREN'T GUINEA PIGS

A mass inoculation of Canadian girls against a sexually transmitted virus is under way. Experts say it's unnecessary—and potentially dangerous.



This is an official
CDC HEALTH ALERT

Distributed via Health Alert Network
Monday, March 22, 2010, 15:54 EDT (3:54 PM EDT)

Recommendation to Temporarily Suspend Usage of GlaxoSmithKline Rotarix (Rotavirus) Vaccine



Why Do We Give Vaccines at the Ages We Do?

- ❑ To provide protection from vaccine preventable diseases at the earliest age possible, or before periods of increased risk
- ❑ Given concurrently with other vaccines to coincide with established schedule of well-child visits
- ❑ Reflect ages at which vaccines are tested in clinical trials, and generally consistent with labeling

Other Issues

- Recommendations and requirements – should everything that is recommended be required?
- Public health vs. individual decisions
- Different perceptions of benefits associated with prevention of some vaccine-preventable diseases
- The expectation of “personalized medicine”
- Concern about individual susceptibility

Focus Group Methods

16 focus groups were held in March of 2009
Chicago, IL and Seattle, WA (8 in each city)

- Groups were segmented based on race (White or African American) and education (Some college or lower; Bachelor's degree or higher)
- All mothers had given their children at least one vaccine
- Mothers were screened out if they reported being "not at all confident" about vaccine safety

VPD Knowledge and Beliefs

- Mothers classified the seriousness of VPDs based on both perceived severity (including potential for death) and likelihood of catching the disease
 - Polio and hepatitis were among the VPDs considered by many to be serious
 - Influenza and varicella were consistently considered least serious
- After reading brief descriptions of VPDs, many mothers said they were surprised to find out how many could be fatal, including some they previously did not consider serious

Preliminary

Childhood Immunization Schedule

- Mothers were generally knowledgeable about the timing of vaccines
- Many reacted negatively to receiving multiple injections during one visit
- Most were vaccinating according to the recommended schedule, but several across race/education/location segments reported (generally short-term) spreading vaccinations

Preliminary

Childhood Immunization Schedule

- **Variety of reasons for spreading:**
 - concerns about children's ability to "handle" multiple vaccines;
 - concerns about ability to pinpoint source of adverse events;
 - some concerns about pain

Preliminary

Sources of Information

- Participants turned to their children's doctors most often with questions about vaccinations
- The Internet was a frequently cited source for information
 - Search engines – almost exclusively Google
 - Specific websites included WebMD and BabyCenter
- Family and friends with children also were trusted sources of information

Preliminary

2009 HealthStyles Survey

- **HealthStyles (August-September, 2009)**
 - Sent to a random sample of 7,004 households that returned earlier ConsumerStyles surveys
- **Response rate was 65% (4,556/7,004)**
- **Data are weighted to the 2008 Current Population Survey of the U.S. Census**
 - Gender, age, race/ethnicity, household income, and household size

“Which of the following best describes your plans for vaccinating your youngest child?”

My child has already received all
of the recommended vaccines.....75%

I intend to have my child receive all
of the recommended vaccines.....19%

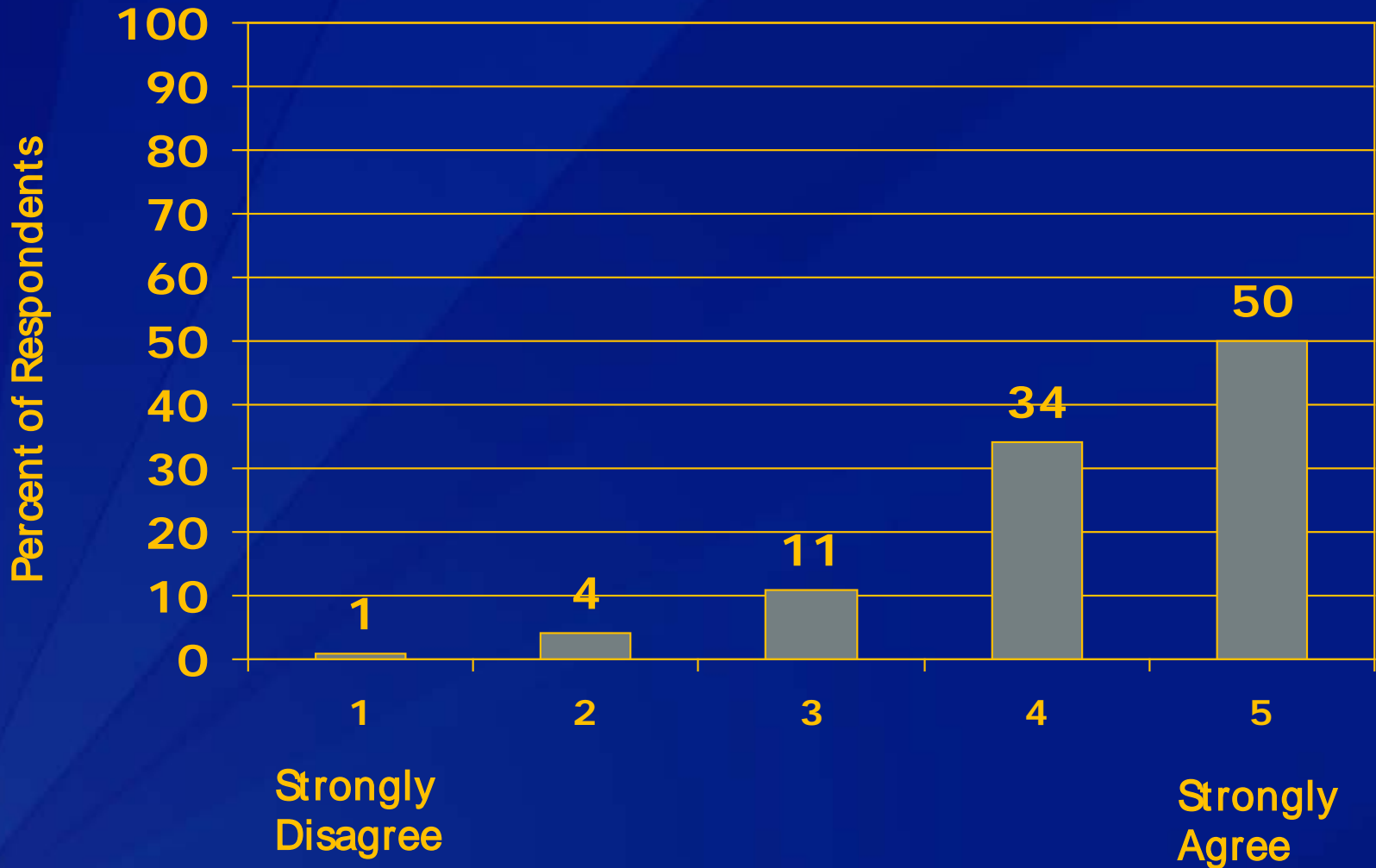
I intend to have my child receive some
but not all of the recommended vaccines.....6%

I intend to have my child receive none
of the recommended vaccines.....1%

“What are the three most important sources of information that have helped you make decisions about your youngest child’s vaccinations?”

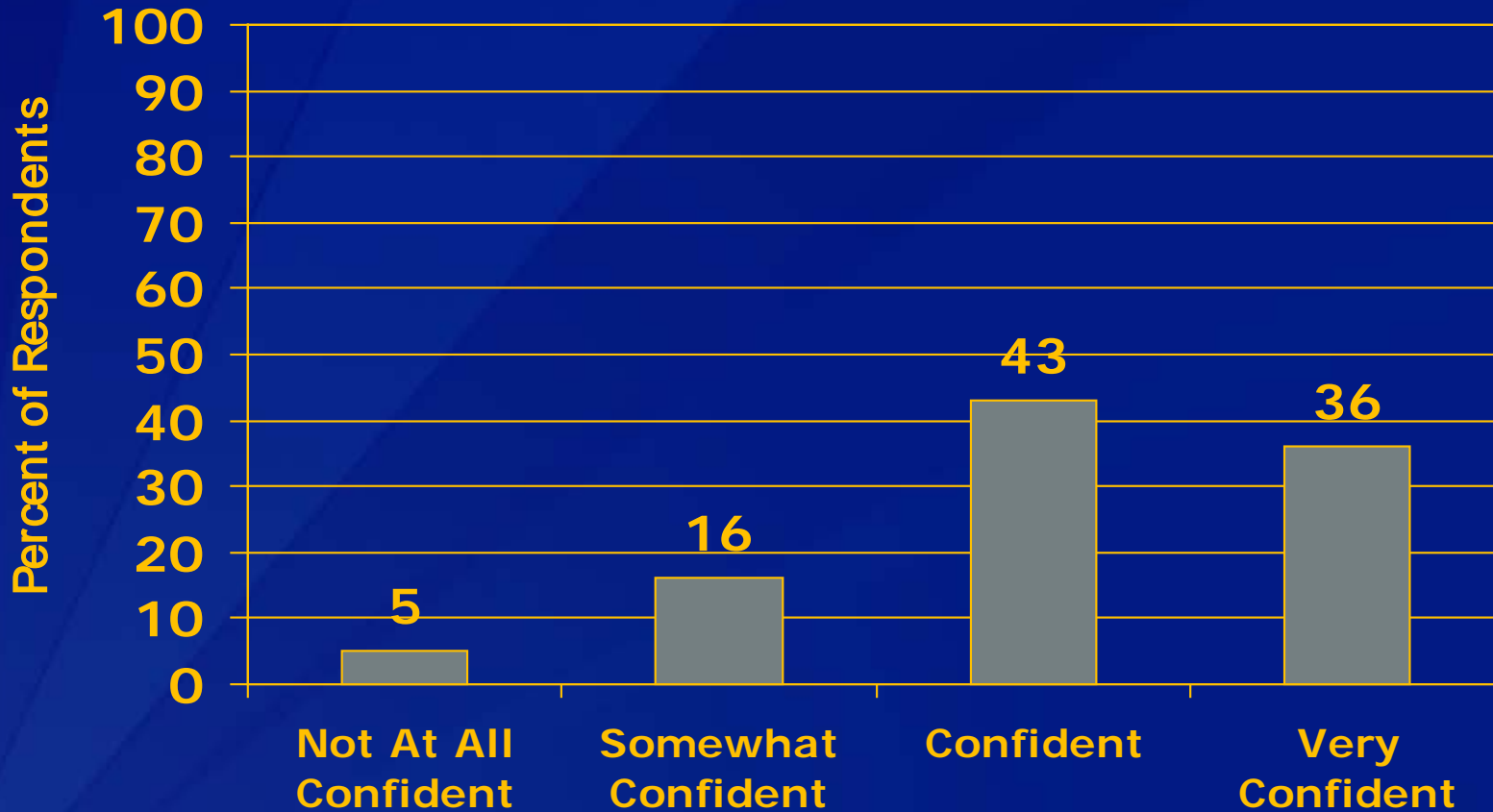
- **Child’s healthcare provider, such as a doctor or nurse (82%)**
- **Family (47%)**
- **Friends (23%)**
- **My child’s other parent (23%)**

“I trust the vaccine advice my child’s main healthcare provider gives me.”



Preliminary

“How confident are you in the safety of routine childhood immunizations?”

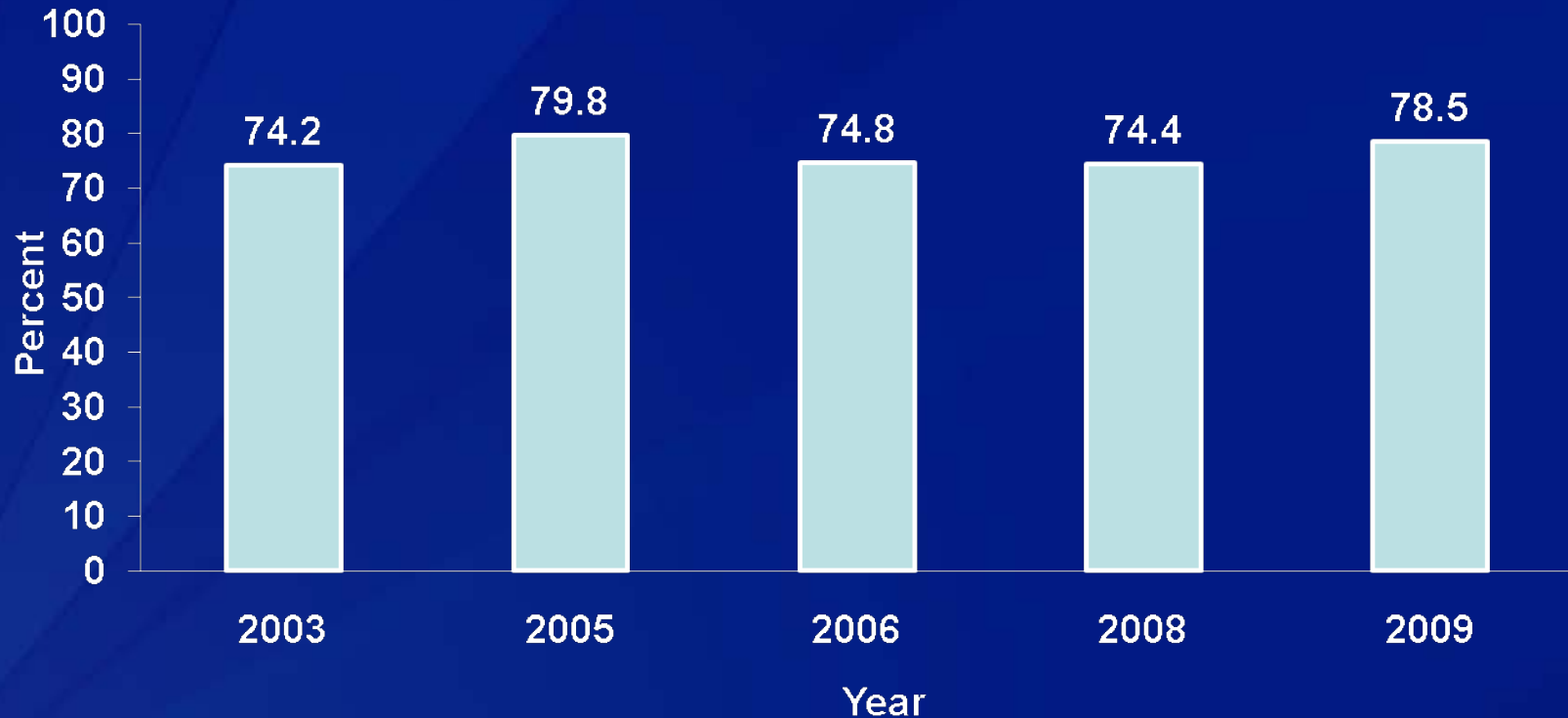


Preliminary

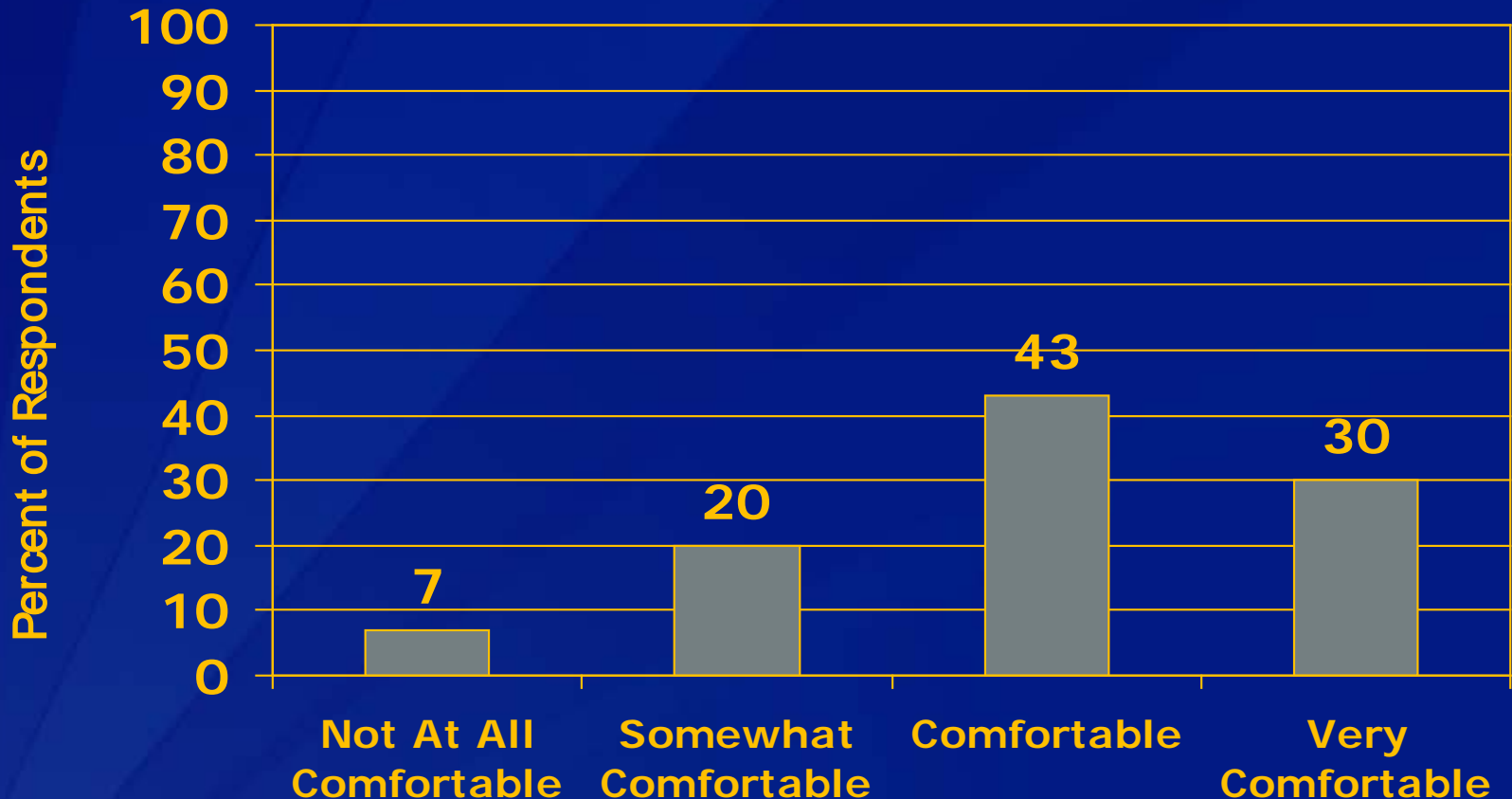
Confidence in Vaccine Safety

Percent of parents who reported that they were confident or very confident in the safety of routine childhood vaccines

(Source: PN Healthstyles)

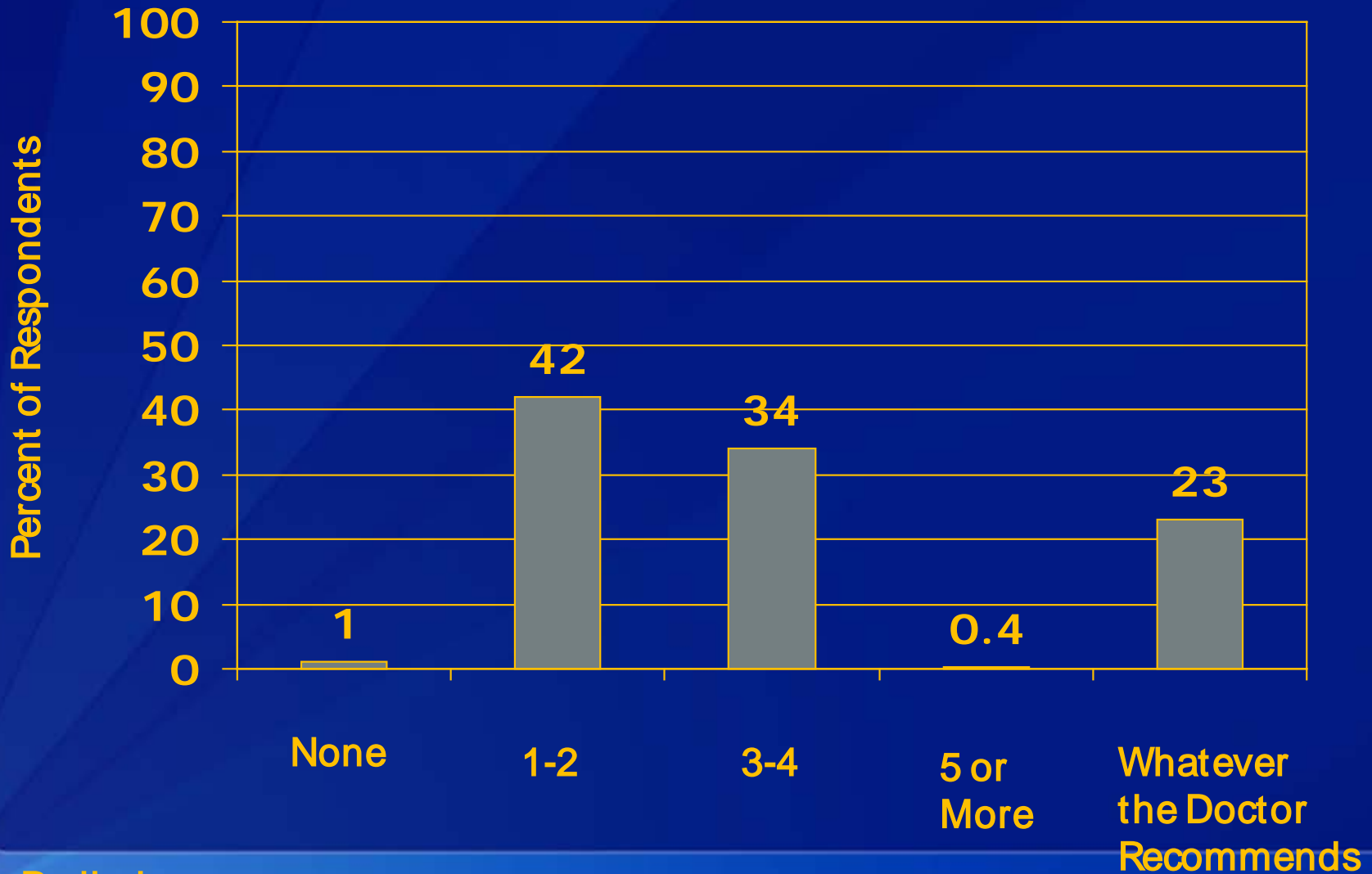


“How comfortable are you with the recommended number of childhood vaccines in the first two years of a baby’s life?”



Preliminary

“What is the most number of vaccine shots you are comfortable with your youngest child getting in one doctor’s visit?”



Preliminary

“Which concerns, if any, do you have about childhood vaccines?”

	2009 Weighted %
It is painful for children to receive so many shots during one doctor's visit.	44
My child getting too many vaccines in one doctor's visit.	34
Vaccines causing fevers in my child.	28
Children get too many vaccines in the first two years of life.	28

“Which concerns, if any, do you have about childhood vaccines?”

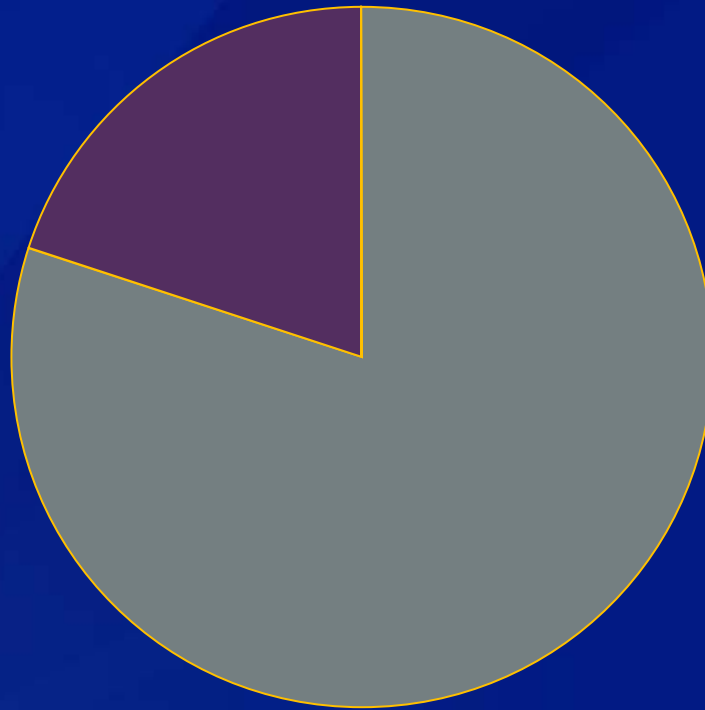
	2009 Weighted %
Vaccines may cause learning disabilities (such as autism).	26
The ingredients in vaccines are unsafe.	22
I have no concerns about childhood vaccines.	21
Vaccines may cause chronic diseases (such as diabetes, asthma, or immune system problems).	14

“Which concerns, if any, do you have about childhood vaccines?”

	2009 Weighted %
Vaccines are given to children to prevent diseases they are not likely to get.	14
Vaccines are not tested enough for safety.	13
My child will not be vaccinated on time because there are not enough of some vaccines.	10
Vaccines are given to children to prevent diseases that are not serious.	7

What Determines Credibility? Low Concern Settings

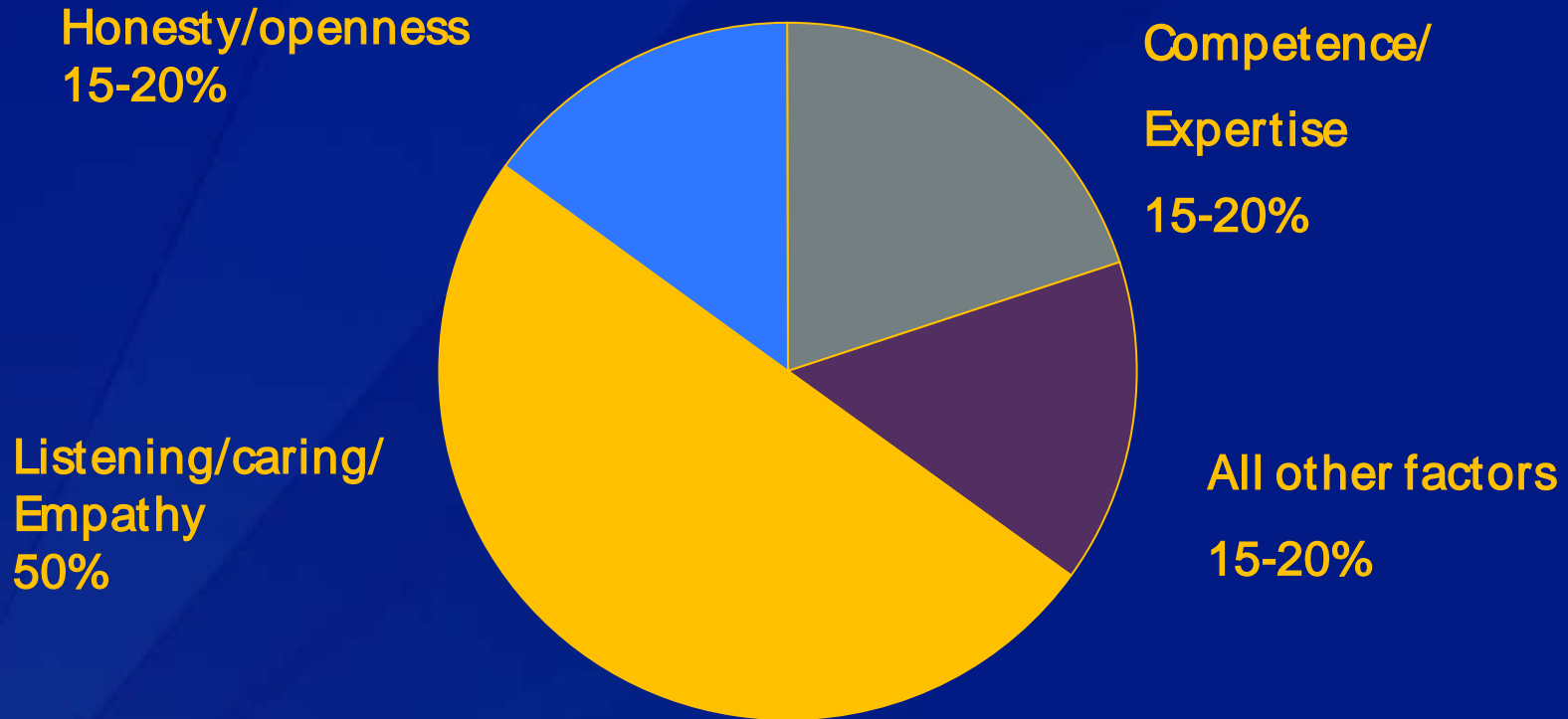
All other
factors
15-20%



Competence/
Expertise
80-85%

Randall Hyer, NIC, 2005

What Determines Credibility? High Concern Settings



Randall Hyer, NIC, 2005

Communicating with Parents

- ❑ Continued evolution of issues about which parents are concerned
- ❑ Respect – science – an individual recommendation
- ❑ “I want what is best for my child and for my patients. That’s why I recommend vaccinations.”
- ❑ New tools:
www.cdc.gov/vaccines/conversations

“Provider Resources for Vaccine Conversations with Parents” includes:

- **Talking with Parents about Vaccines for Infants**
- **Vaccine Safety Series**
 - **MMR Vaccine Safety**
- **Diseases and the Vaccines that Prevent Them**
 - **Fact Sheets on Childhood Diseases**
- **If You Choose Not to Vaccinate Your Child, Understand the Risks and Responsibilities**
- **More coming soon**

Give Feedback: www.cdc.gov/vaccines/tellus

CDC/AAP/AAFP NEW Materials “Provider Resources for Vaccine Conversations with Parents”

- Literature review
- Risk communication approach
- Development, testing, and revision of draft materials
- Input from subject matter experts
- Ongoing qualitative and quantitative research throughout the process

www.cdc.gov/vaccines/conversations

“Talking with Parents about Vaccines for Infants”

- Audience: Healthcare providers
- During the Office Visit
 - Take time to listen
 - Solicit and welcome questions
 - Keep the conversation going
 - Use a mix of science and personal anecdotes
 - Acknowledge benefits and risks
 - Respect parents’ authority
- After the Office Visit
 - Document parents’ questions/concerns
 - Follow up a few days after the visit

Information for providers |

10/1/2018 10:00 AM


Talking with Parents about Vaccines for Infants

Physicians, nurses, 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 healthcare provider, you remain parents’ most trusted source of information about vaccines, and 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 when raised
- ▶ Proven communication strategies and tips for having a successful vaccine conversation with parents

Nurses and other office staff can 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.

1

“MMR Vaccine Safety”

Understanding MMR Vaccine Safety

| vaccine safety |

➤ CDC recommends two doses of the measles, mumps, and rubella vaccine—MMR vaccine—for children because it protects them against dangerous, even deadly, diseases.

➤ The MMR vaccine has a long record of safety. Serious risks of MMR vaccine are rare. All reputable scientific studies have found no relationship between MMR vaccine and autism.

➤ The routinely recommended age for the first MMR dose is 12 through 15 months. The routinely recommended age for the second MMR dose is 4 through 6 years.

➤ If there is an outbreak of one of the diseases, health authorities might recommend the vaccine be given earlier.

If either has any concerns about a child's development. One of a pediatrician's responsibilities is to monitor a child's development for any signs of problems that can be prevented or treated. Pediatricians and parents should partner to learn the signs of normal development and to act early if they suspect there may be a problem. For more information, visit www.cdc.gov/ncbddd/nation/ActEarly/default.htm.

A second reason that some people think MMR vaccine may cause autism stems from a 1998 study in the United Kingdom. It claimed that MMR vaccine could contribute to the development of autism. This study received a great deal of media coverage. At the time of the study, MMR vaccine had been in use for only 10 years in the U.K. During that period, the diagnosis of autism increased and parents, doctors, and scientists alike wanted to know the reason why. Since 1998, 10 of the 13 authors have withdrawn their support of the study. This study was followed rapidly by many larger population studies totaling thousands of children that found that MMR vaccine is not responsible for a rise in autism. Most recently, in 2008, a study from Columbia University did not repeat the findings of the U.K. study. The 2008 study showed no connection between MMR vaccine and autism.

What's the harm in delaying the first MMR shot until my child is age two or older?

The MMR vaccine is recommended to be given during ages 12 through 15 months. If you wait to give it later, your child could get measles, mumps, and/or rubella. All of these diseases are still out there. For example, in 2008, there were 140 measles cases in the U.S., more than any year since 1996. Seventeen were children under 12 months old—too young to be vaccinated according to the routine recommendation. Another nine were in unvaccinated 12- through 15-month-olds; this is the age when the vaccine is recommended. And 72 cases were in children and teens 16 months old through 19 years old who had not received the vaccine. Seventeen people, including six children younger than 15 months old, had hospital stays for complications from measles. Following U.S. recommendations for using MMR vaccine is the best way to protect children from these diseases and avoid outbreaks.

questions and answers |

All reputable scientific studies have found no link between MMR vaccine and autism. So, why do some people think that MMR vaccine causes autism?

There are a couple of reasons for this. Some parents of children with autism say they first noticed signs of autism a few days, weeks, or months after their child received MMR vaccine. They usually explain that their child was developing normally, and then signs of autism appeared after MMR vaccination.

Sometimes, signs of autism do not appear until around the age that the first dose of MMR is given. Some toddlers who've turned one year old—or even two or three years old—regress. That is, they lose the ability to do things that they once were able to do. If regression follows a memorable event like a trip to the doctor for vaccinations, this may seem like cause and effect.

There may be signs of autism before a child is old enough to get the first dose of MMR, at age 12 through 15 months. Parents and pediatricians should work together and meet immediately



•Primary Audience: HCPs to assist in answering parent concerns about MMR vaccine

•Secondary Audience: parents who are concerned about MMR vaccine safety

•Includes scientific research references

“Diseases and the Vaccines that Prevent Them--Measles”

- Audience: Parents questioning vaccine safety and/or necessity
- Helps providers answer parent questions
- Personal story of infection with a VPD
- Quotations from authoritative sources CDC, AAP, AAFP and WHO
- Lists risks and benefits of MMR vaccine
- Provides sources for more information

MEASLES

106 Degrees

If you hear “106 degrees” you probably think “heat wave,” not a baby’s temperature. But for Megan Campbell’s 10-month-old son, a bout of measles caused two weeks of life-threatening fever.

“After picking our son up at day care because he had a fever,” says Megan, “we went straight to our pediatrician, and she said it was just a virus. But two days later his fever went up to 104 and a rash appeared on his neck.”

The rash quickly crept down to his arms and chest. San Diego-based Megan and husband Chris turned to the internet. Finding pictures of measles that looked like their son’s rash, they rushed him to the local children’s hospital.

“No one there had seen or tested for measles for about 17 years,” says Megan. “The next day, an infectious disease specialist confirmed measles.”

“We spent three days in the hospital fearing we might lose our baby boy. Even after he was released, he still had a 106-degree fever. We spent the next week making at all hours, bathing him in ice, and giving him fever reducers.”

Thankfully, the baby recovered fully.

Megan now knows that her son was exposed to measles during his 10-month check-up, when a woman brought her 10 daughter into the pediatrician’s waiting room. A CDC investigation found that the girl and her sibling had gotten measles overseas and brought it back to the U.S. They had not been vaccinated.

“People who choose not to vaccinate their children actually make a choice for all children,” Megan explains. “At 10 months, my son was too young to get MMR vaccine. But when he was 12 months old, we got him the vaccine—even though he wasn’t susceptible to measles anymore. So, he won’t suffer from mumps or rubella, or spread them to anyone else.”

Measles Symptoms

Measles begins with an increasing fever, then coughing, runny nose, or pink eye, and finally rash breaks out. Rash usually starts on the head and then spreads to the rest of the body. Fever can persist, getting as high as around 103° F, and can last for up to a week, and coughing can last about 10 days.

Measles Is Serious

According to CDC’s Dr. Kathleen Galloway, “Measles ranges from a pretty uncomfortable disease to very serious one. For example, for every 1,000 children who get measles in a developed country like the U.S., one to three of them die, despite the best treatment. Even as recently as 2000 through 2007, one out of every four persons in the U.S. who get measles had to be hospitalized.” Many of these serious cases were among children.

Exposed People Who Have Not Been Vaccinated Almost Always Get Measles

Measles is one of the most contagious diseases known. It spreads by direct contact with respiratory droplets. For example, if someone who is contagious coughs or sneezes on a surface and then someone who is susceptible comes into contact with the droplets, they are very likely to get measles as a result. You can catch measles just by being in a room where a person with measles has been—even if the person is gone!

Vaccine Has Made Measles Rare in U.S., but Not Worldwide

Thanks to vaccination, the number of cases in the U.S. reached an all-time low of 37 cases in 2004. But around the world, measles still causes more than 300,000 deaths each year. There is no drug to cure measles.

“It’s critical to remember the global picture for any vaccine-preventable disease,” says World Health Organization spokesman Dr. Peter Stierlin. “More than ever, we live in a global society where travel is common. And even if you and your family don’t travel, you can come into contact with travelers anywhere in your community from the grocery store to a sporting event.”

MMR Vaccine

The measles, mumps, and rubella (MMR) vaccine is the best way to protect against getting measles. The risk of MMR causing a serious side effect is rare.

Getting MMR is much safer than getting measles. The first dose of MMR vaccine is recommended at ages 12 through 15 months. A second dose is recommended at ages 4 through 6 years.



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

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

Information for parents

See 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

When there is vaccine-preventable disease in your community:

- It may not be too late to get protection by getting vaccinated. Ask your child's doctor.
- If there are cases (or, in some circumstances, a single case) of a vaccine-preventable disease in your community, you may be asked to take your child out of school, childcare, or organized activities (for example, playgroups or sports).
- Your school, childcare facility, or other institution will tell you when it is safe for an unvaccinated child to return. Be prepared to keep your child home for several days up to several weeks.
- Learn about the disease and how it is spread. It may not be possible to avoid exposure. For example, measles is so contagious that hours after an infected person has left the room, an unvaccinated person can get measles just by entering that room.
- Each disease is different, and the time between when your child might have been exposed to a disease and when he or she may get sick will vary. Talk with your child's doctor or the health department to get their guidelines for determining when your child is no longer at risk of coming down with the disease.

Be aware.

- Any vaccine-preventable disease can strike at any time in the U.S. because all of these diseases still circulate either in the U.S. or elsewhere in the world.
- Sometimes vaccine-preventable diseases cause outbreaks, that is, clusters of cases in a given area.
- Some of the vaccine-preventable diseases that still circulate in the U.S. include whooping cough, chickenpox, Hib (a cause of meningitis), and influenza. These diseases, as well as the other vaccine-preventable diseases, can range from mild to severe and life-threatening. In most cases, there is no way to know beforehand if a child will get a mild or serious case.
- For some diseases, one case is enough to cause concern in a community. An example is measles, which is one of the most contagious diseases known. This disease spreads quickly among people who are not immune.

If you know your child is exposed to a vaccine-preventable disease for which he or she has not been vaccinated:

- Learn the early signs and symptoms of the disease.
- Seek immediate medical help if your child or any family members develop early signs or symptoms of the disease.

IMPORTANT: Notify the doctor's office, urgent care facility, ambulance personnel, or emergency room staff that your child has not been fully vaccinated before medical staff have contact with your child or your family members. They need to know that your child may have a vaccine-preventable disease so that they can treat your child correctly as quickly as possible. Medical staff also can take simple precautions to prevent diseases from spreading to others if they know ahead of time that their patient may have a contagious disease.

- Follow recommendations to isolate your child from others, including family members, and especially infants and people with weakened immune systems. Most vaccine-preventable diseases can be very dangerous to infants who are too young to be fully vaccinated, or children who are not vaccinated due to certain medical conditions.
- Be aware that for some vaccine-preventable diseases, there are medicines to treat infected people and medicines to keep people they come in contact with from getting the disease.
- Ask your healthcare provider about other ways to protect your family members and anyone else who may come into contact with your child.
- Your family may be contacted by the state or local health department who track infectious disease outbreaks in the community.

If you travel with your child:

- Review the CDC travelers' information website (www.cdc.gov/travel) before traveling to learn about possible disease risks and vaccines that will protect your family. Diseases that vaccines prevent remain common throughout the world, including Europe.
- Don't spread disease to others. If an unimmunized person develops a vaccine-preventable disease while traveling, to prevent transmission to others, he or she should not travel by a plane, train, or bus until a doctor determines the person is no longer contagious.

For more information on vaccines, ask your child's healthcare provider, visit www.cdc.gov/vaccines/parents, or call 800-CDC-INFO (800-232-4636)

“Get the Picture” Video

- 6-minute video for parents to view in waiting rooms or on-line
- People in the video are real moms with real concerns
- Their questions mirror those expressed during focus groups
- The pediatrician who answers their questions indicates her own children are vaccinated
- The pediatrician acknowledges their concerns



Where We Are

- ❑ Immunization providers play a key role in providing parents with information to support vaccine decision-making
- ❑ Risk communication strategies can help providers effectively address parental concerns
- ❑ Immunization continues to be the best way to protect young children from 14 vaccine-preventable diseases

www.cdc.gov/vaccines

www.cdc.gov/vaccines/conversations

www.cdc.gov/vaccinesafety

[www.youtube.com/user/CDCStreaming
Health](http://www.youtube.com/user/CDCStreamingHealth)

Thank you!

www.cdc.gov/vaccines

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333

Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

E-mail: cdcinfo@cdc.gov Web: www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

National Center for Immunization & Respiratory Diseases
Office of the Director



Aggregate Summary of HPV4 AEs Reported to VAERS, June '06----Dec '09

Outcome	
Doses Distributed	30 million
Total # VAERS HPV4 Reports	15,672
# Serious VAERS HPV4 Reports (% of total reports)	1,208 (7.7%)
# (%) Most Frequently Reported	
Syncope, Syncope Vasovagal	2592 (16.5%)
Dizziness	2451 (15.6%)
Nausea	1611 (10.3%)
Headache	1501 (9.6%)
Injection site reactions	1554 (9.9%)

Select HPV4 Serious Adverse Event (SAE) Reports, confirmed by medical review

- 26 deaths
 - No clustering by cause of death, by time since vaccination, or by age
- 57 thromboembolic events*
 - 41/57 (72%) had known risk factor(s)
 - 29 had history of estrogen-containing birth control measures
 - 11/24 (46%) of cases tested for genetic coagulation mutation tested positive
 - Increased reporting rates compared to females of the same age range who received other vaccines

* pulmonary embolus, deep venous thrombosis, cerebral venous sinus thrombosis, cerebral vascular accident

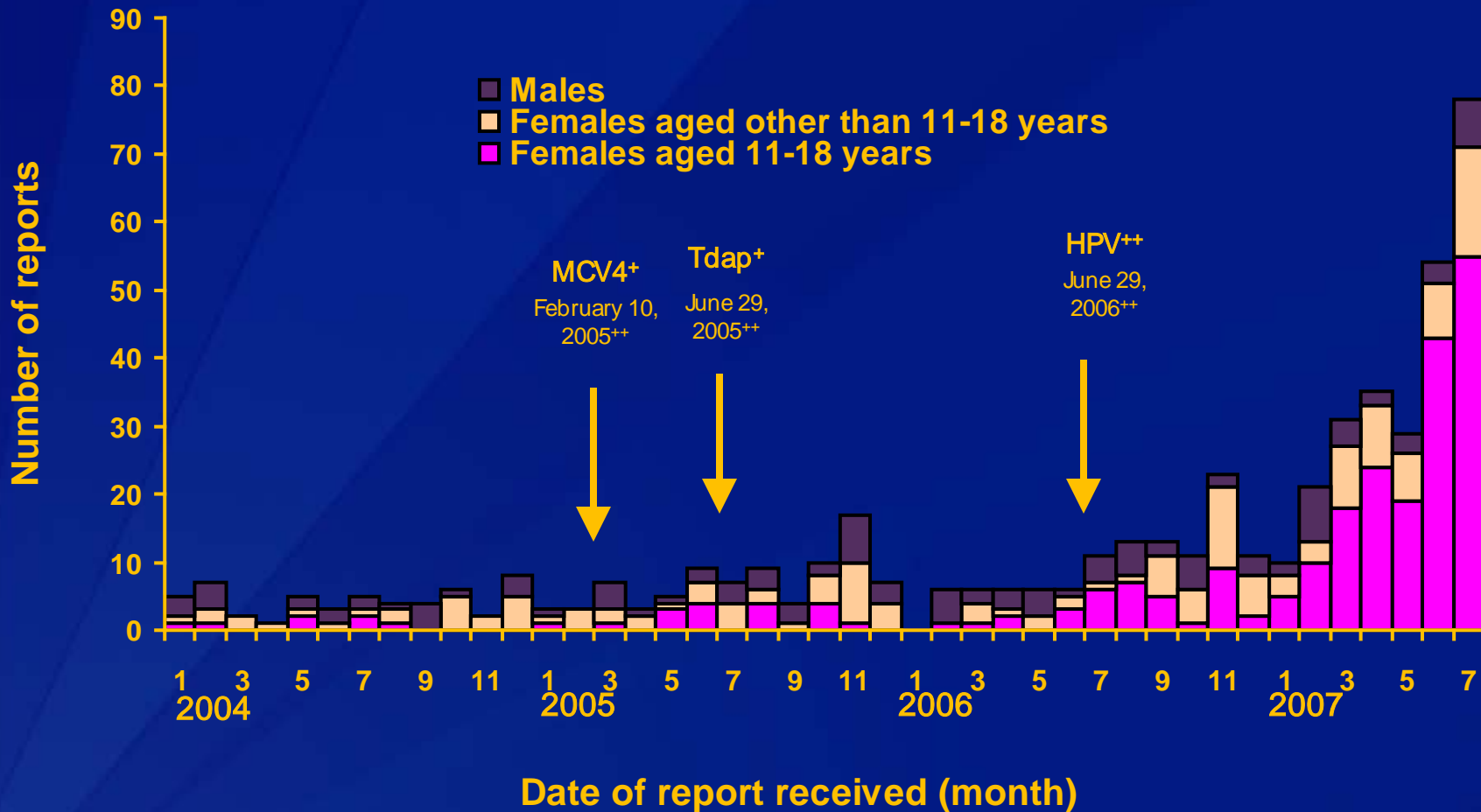
Select HPV4 Serious Adverse Event (SAE) Reports, confirmed by medical review

- 18 cases of Guillain Barre Syndrome
 - met Brighton case definition*
- 12 cases of pancreatitis
 - All confirmed cases had known risk factors**
- 2 cases of a juvenile ALS-like disorder
 - Autopsy: destruction of anterior horn cells in spinal cord
 - Rapidly progressive course

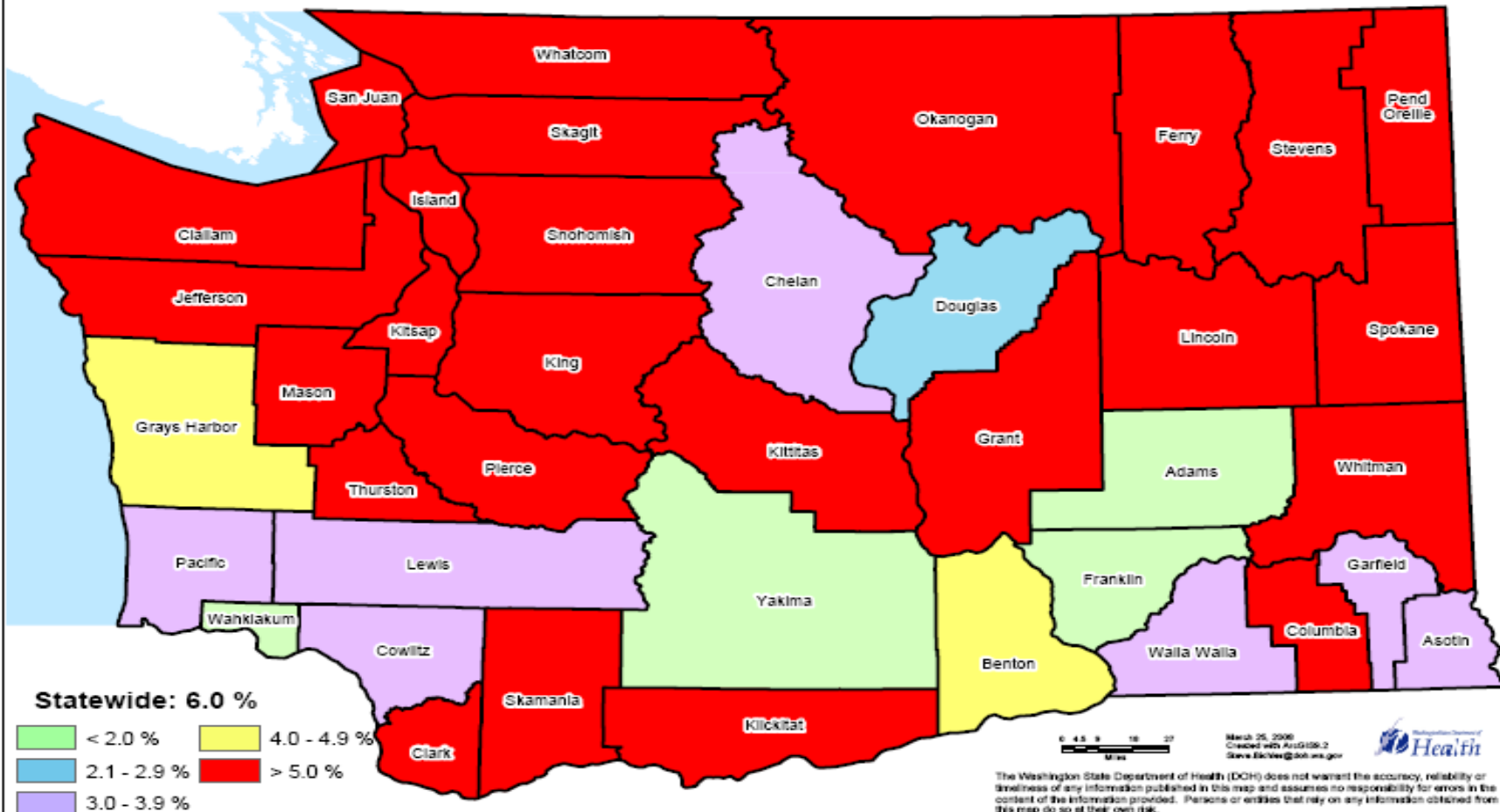
*http://www.brightoncollaboration.org/internet/en/index/definition____guidelines/document_download.html#G

**gallstones, alcohol, increased lipids, Coxsackie infection, estrogen use, obesity, ulcerative colitis, post-colectomy

Syncopal* reported to VAERS, January 1, 2004 - July 31, 2007

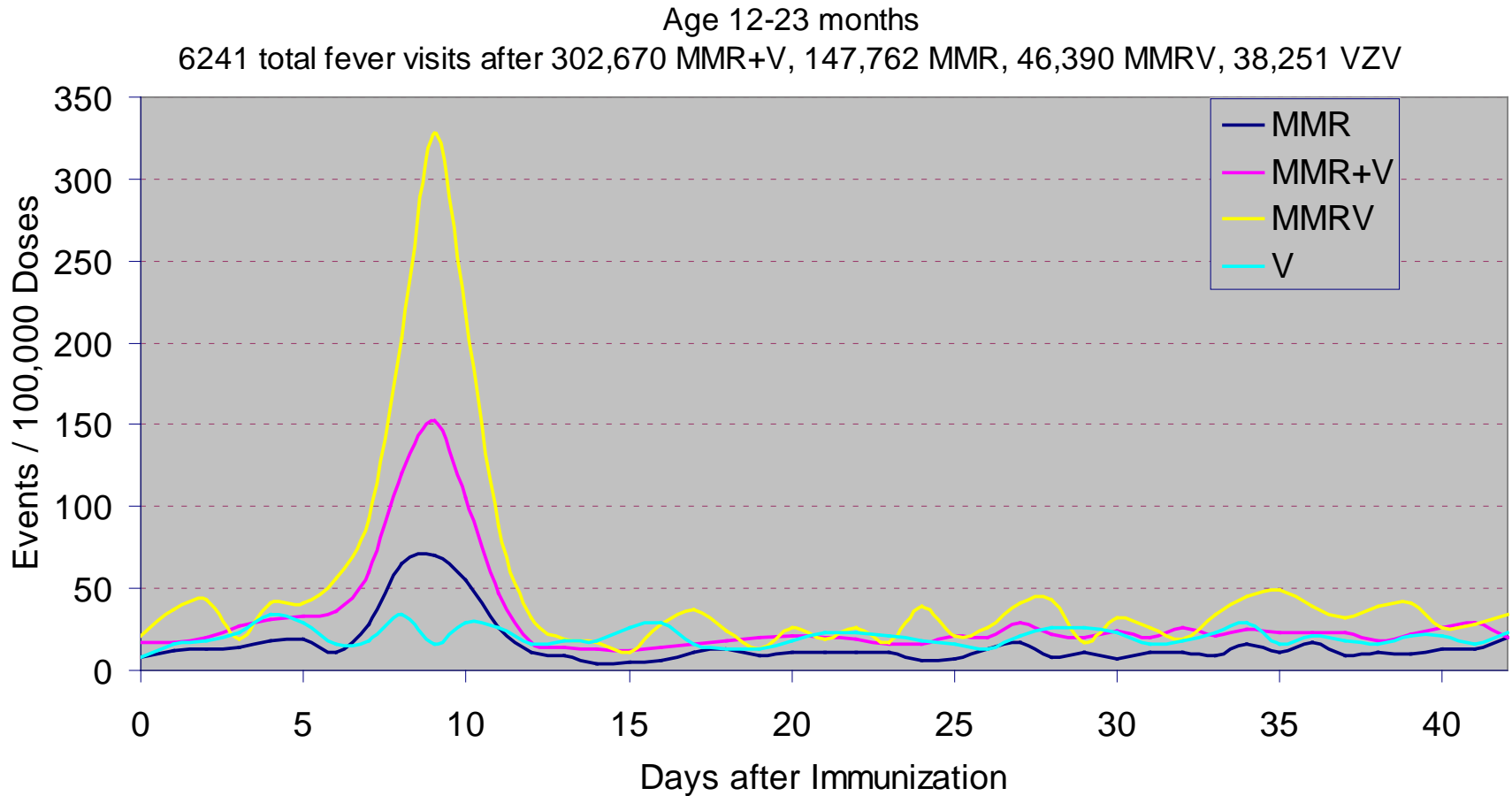


WA State Counties' School Entry Exemption Rates 2006-2007



Data source: Washington State DOH Immunization Program CHILD Profile

Outpatient Visits for Fever by Day after Vaccine at Northern California Kaiser Permanente: 1995-2008



The Science of Studying More than One Thing at a Time

- Rapid advances in multiple fields of biology have made it possible to study complex biological reactions at the cellular level
- These new “systems biology” approaches are beginning to be applied to questions about vaccines

SMEI and “Vaccine Encephalopathy”

- Epileptic encephalopathies, without other specific cause identified, with first seizure onset within 72 hours of vaccination
- Cases ascertained by child neurologists in Australia and New Zealand 2002-2003
- Diagnoses:
 - SMEI – 8 patients
 - SMEB – 4 patients
 - Lennox-Gastaut syndrome – 2 patients
- Molecular analysis:
 - Heterozygous mutations of *SCN1A* in 11 of 14 cases

Safety and Efficacy Issues Potentially Associated with the Schedule

- Data generally available on concurrent administration at licensure
- Interference between concurrently administered vaccines theoretically possible but generally not observed
 - Need for spacing of live virus vaccines
- Safety or efficacy issues associated with concurrent or antecedent exposure to vaccine components (e.g., diphtheria toxoid-containing vaccines)
- Cumulative exposure to vaccine components

Data on Simultaneous Administration for a Licensed Vaccine: ROTARIX

- 484 healthy infants randomized into two groups
- All received Pediarix, PCV7, and ActHib at 2, 4, and 6 months and either ROTARIX concurrently at 2 and 4 months or separately at 3 and 5 months
 - Co-administration: n=249
 - Separate administration: n=235
- Prespecified criteria for noninferiority of antibody response met for all antigens

Current Parent Concerns

- Focus groups with first time mothers in 3 cities: Chicago, Portland, and Richmond
- Most participants had high levels of knowledge and of concern
- Many participants know someone who is not fully vaccinating their child
- All vaccines are not seen by many parents as equally important to protect children
- Unclear what impact these concerns have had on immunization coverage

What Parents Are Concerned About (2008)

- It is painful for children to get so many shots during one doctors visit (43%)
- My child getting too many vaccines in one doctor's visit (40%)
- Vaccines causing fevers in my child (36%)
- The ingredients in vaccines are unsafe (34%)
- Children get too many vaccines in the first two years of life (33%)
- Vaccines may cause learning disabilities (such as autism) (33%)
- Vaccines are not tested enough for safety (32%)

Immunization Delivers

- ❑ The H1N1 influenza pandemic challenged all of us to do more than we have ever done before
- ❑ Planning only took us so far – after that, it was creativity, improvisation, and hard work
- ❑ Thank you for a job well done

Is Our Immunization Schedule “One Size Fits All”?

- Contraindications and precautions do provide guidance for decision-making
- Flexibility in timing within the recommended schedule
- Some children *are* vulnerable, and screening usually not possible
- Vulnerable children *can* be protected -- with safer vaccines for everyone