

Vaccine Safety and Vaccine Safety Communication

**Otherwise known as
The Vaccine Wars**

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Objectives

- List some of the events that led to the current climate of vaccine safety concern
- Describe factors that contribute to parental concerns about vaccines
- Develop talking points to address common myths about vaccine safety
- Develop answers to the question-What is wrong with an alternative vaccine schedule?

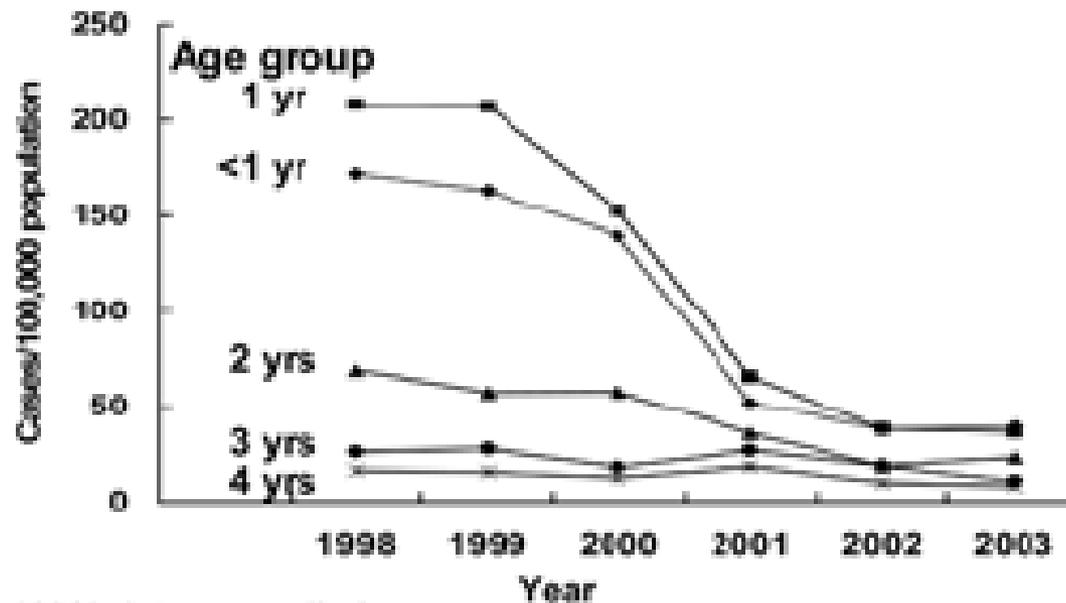
Vaccination is the top Public Health achievement of the 20th Century



E. JENNER EXPERIMENTANT LE VACCIN SUR SON FILS

MMWR 1999; 48:241

Invasive Pneumococcal Disease by Age and Year—Children <5 Years, 1998-2003*



*2003 data are preliminary.

Source: Active Bacterial Core Surveillance/EIP Network

Newsweek

July 31, 2000 : \$3.50

**MIDEAST
FALLOUT**

**TOBACCO'S
NEXT
WAR**

Understanding **Autism**

Why More
Kids & Families
Are Facing the
Challenge of
'Mindblindness'

By Geoffrey Cowley

Russell Rollens, 9

Parents Wonder: Is it Safe to **Vaccinate?**

Many families of autistic kids blame the MMR shot for the disorder. Experts say they shouldn't.

newsweek.msrbc.com

The Things You Hear...

- Are vaccines safe?
- Vaccines and autism
 - ✓ MMR
 - ✓ Thimerosal
 - ✓ Other vaccine ingredients
 - ✓ Vaccines in general
- Too many vaccines overwhelm the immune system
- Diseases no longer exist—or aren't that dangerous
- It is all a giant money-fueled conspiracy
- Individual rights vs. public health needs



**How did we get
here?**

Real Vaccine Risks

- 1950-1980's: Whole cell DTP vaccine
- 1976: Guillain-Barré from influenza vaccine
- 1980's: OPV causing paralysis despite no cases of polio
- 1990's: intussusception from rotavirus vaccine

**How have we dealt with real
vaccine risks?**

Response to real vaccine adverse events

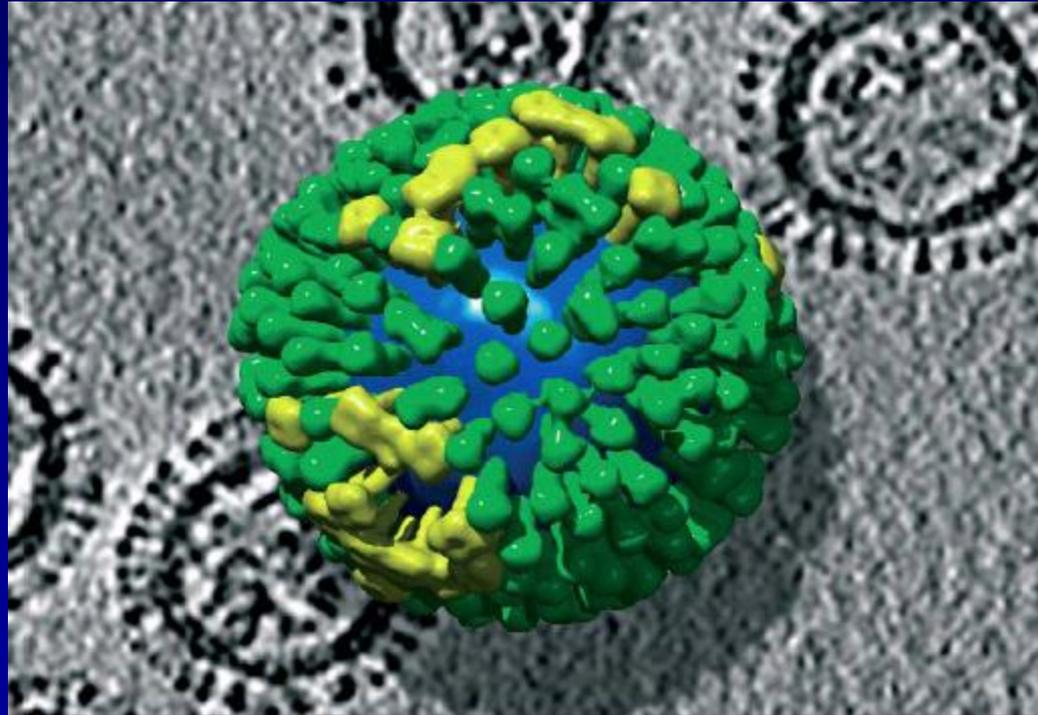
- Elimination of killed measles vaccine
- Transition from plasma derived Hep B vaccine to recombinant Hep B vaccine
- Transition from DTP to DTaP (Some countries suspended pertussis immunization)
- Transition from OPV to IPV
- Withdrawal of first rotavirus vaccine

Rotashield: Final Analysis

Doses distributed	1,800,000
Doses administered	1,500,000
Children immunized	1,000,000
Hospitalizations prevented	15,000
Deaths prevented	10
Excess intussusceptions	100
Excess deaths	1
Phone calls avoided	???

Ottit, in Marshall. The Vaccine Handbook. Lippincott Williams & Wilkins, 2003

Did H1N1 Influenza Vaccine Cause Guillain-Barre Syndrome?



H1N1 Influenza Vaccine Safety

- Closely monitored by CDC and National Vaccine Program Office
- Multiple large population databases scoured for adverse events related to H1N1 vaccine
 - ✓ Vaccine Safety Datalink
 - ✓ VA Health System and Dept. of Defense
 - ✓ PRISM Health Plan/Immunization Registry link
 - ✓ HIS
 - ✓ Emerging Infections Program
- More than 10 million post-H1N1 vaccination lives under observation

1998-99: The Vaccine Safety Concern 1-2 Punch



Wakefield History

EARLY REPORT

Early report

Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

A J Wakefield, S H Murch, A Anthony, J Linnell, D M Casson, M Malik, M Berelowitz, A P Dhillon, M A Thomson, P Harvey, A Valentine, S E Davies, J A Walker-Smith

Summary

Background We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder.

Introduction

We saw several children who, after a period of apparent normality, lost acquired skills, including communication. They all had gastrointestinal symptoms, including abdominal pain, diarrhoea, and bloating and, in some

Thimerosal-the beginning

Notice to Readers

Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service

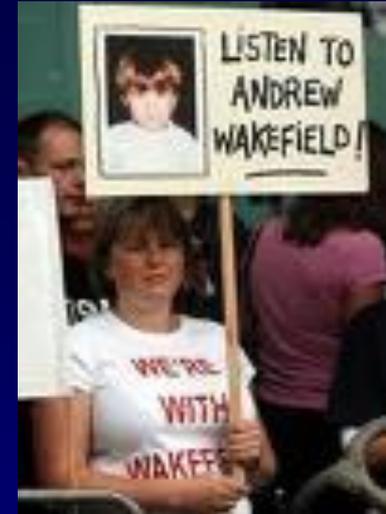
The Food and Drug Administration (FDA) Modernization Act of 1997 called for FDA to review and assess the risk of all mercury-containing food and drugs. In line with this review, U.S. vaccine manufacturers responded to a December 1998 and April 1999 FDA request to provide more detailed information about the thimerosal content of their preparations that include this compound as a preservative. Thimerosal has been used as an additive to biologics and vaccines since the 1930s because it is very effective in killing bacteria used in several vaccines and in preventing bacterial contamination, particularly in opened multidose containers. Some but not all of the vaccines recommended routinely for children in the United States contain thimerosal.

MMWR 1999; 48 (26):564-566

Wakefield

...and the rest of the story

- Findings never reproduced
- Wakefield had serious financial conflicts
- Co-authors withdraw from paper
- Paper retracted from Lancet
- Hearings held by British Health Authorities
- Wakefield sanctioned and license revoked
- The details of "an elaborate fraud" published in the British Medical Journal
- Omnibus Vaccine Court has rejected autism claims



Thimerosal history

- Mercury content of recommended vaccines reviewed
- Recommendation to reduce mercury exposure
- Delay in hepatitis B vaccination of newborns to minimize mercury exposure
- Once MMR couldn't be targeted as a cause of autism, thimerosal became an attractive target

Factors that have increased concern

- Distrust
 - ✓ Industry
 - ✓ Government
 - ✓ Doctors
- Uncertainty
- Rapid increase in the number of vaccines
- Rapid increase in the number of cases of autism
- Internet/Media/Celebrities

Know Your Source



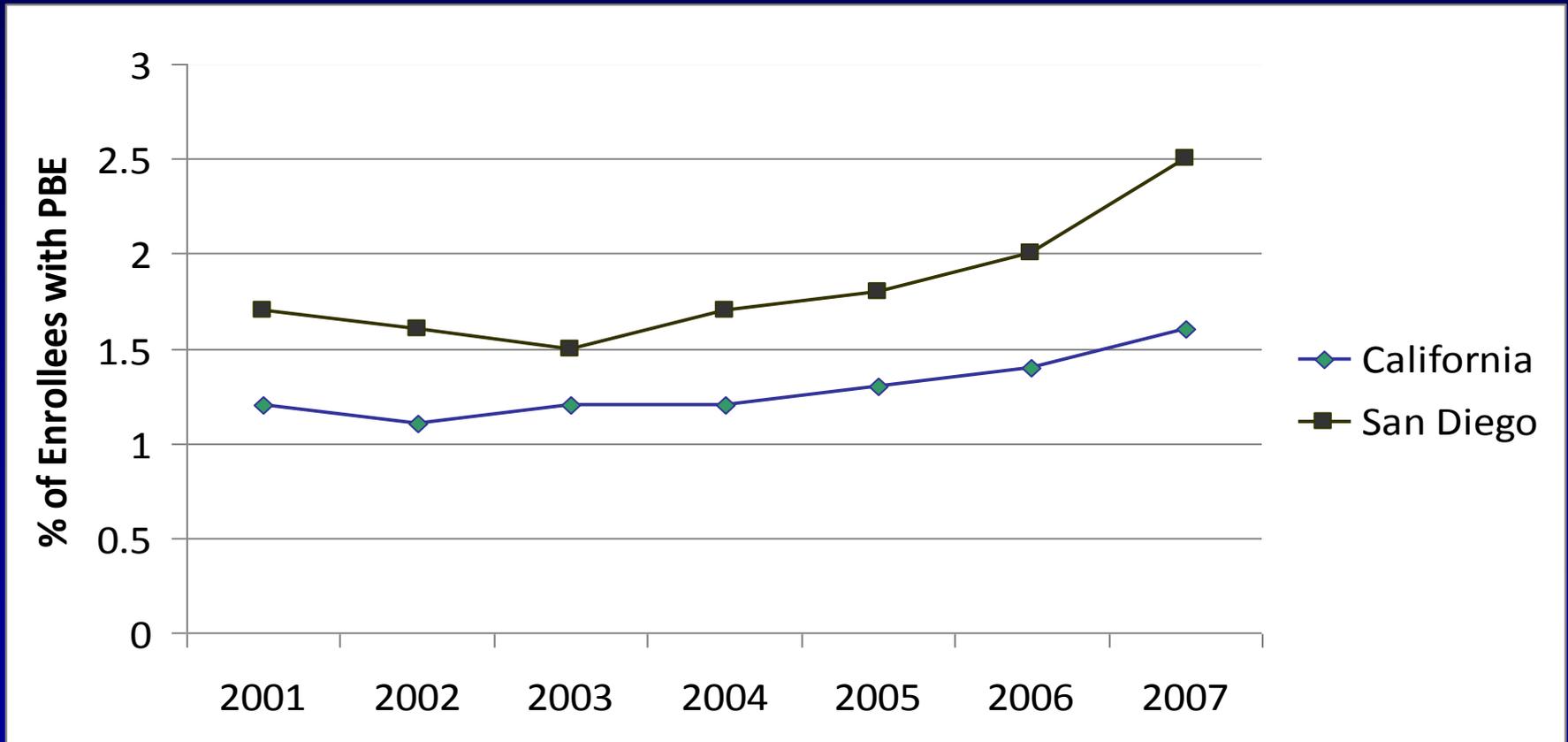
What has been the effect?

Falsehood flies and the truth comes
limping after so that when men
come to be undeceived it is too
late. The jest is over and the tale
has had its effect

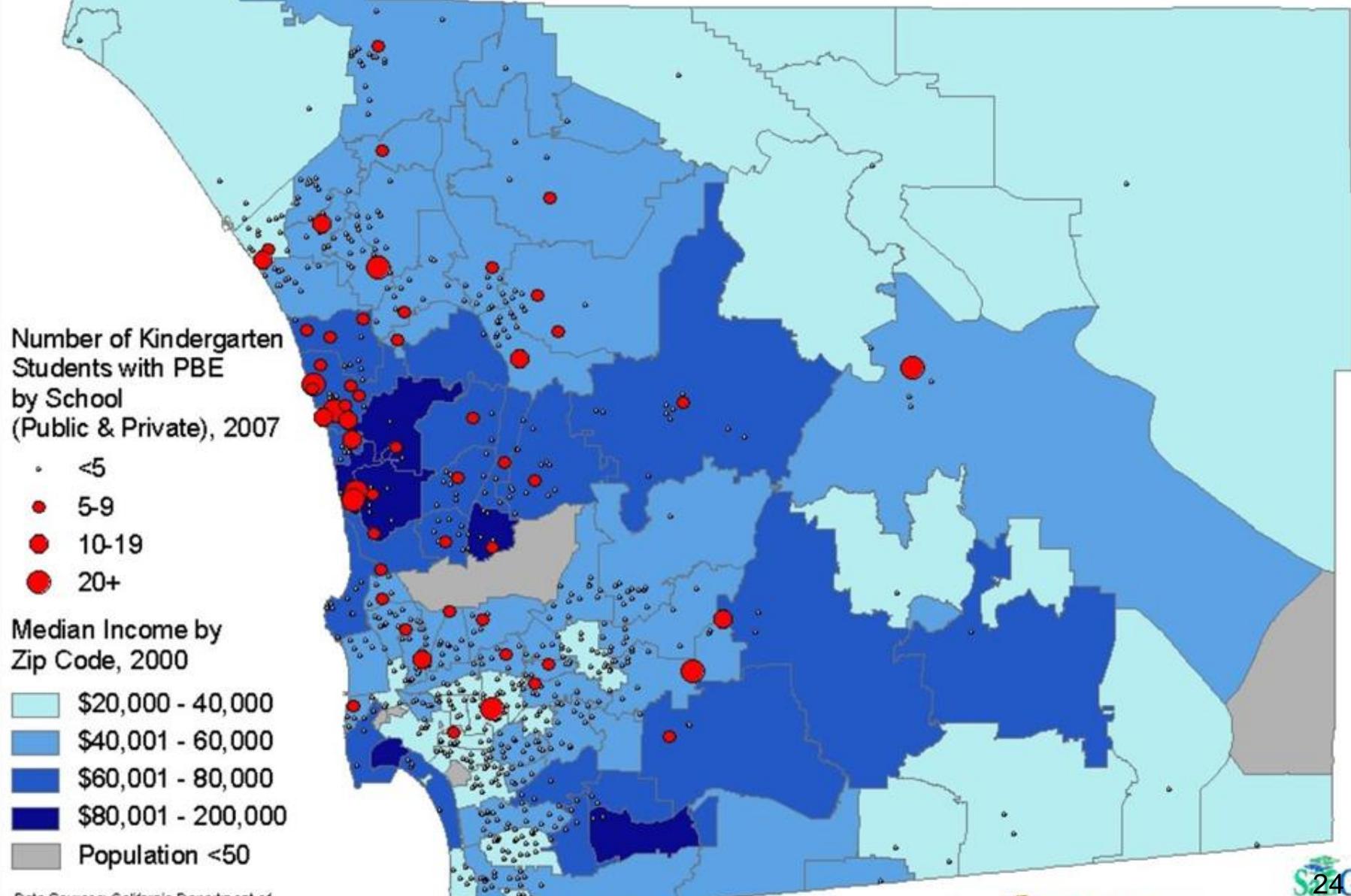
Jonathan Swift, The Examiner Nov. 9, 1710

Increasing Vaccine Refusals

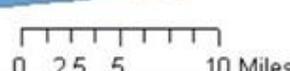
California Kindergarten PBE Rates: 2001-2007



San Diego County Personal Belief Exemptions (PBE) among Kindergarten Students by School and Median Income by Zip Code

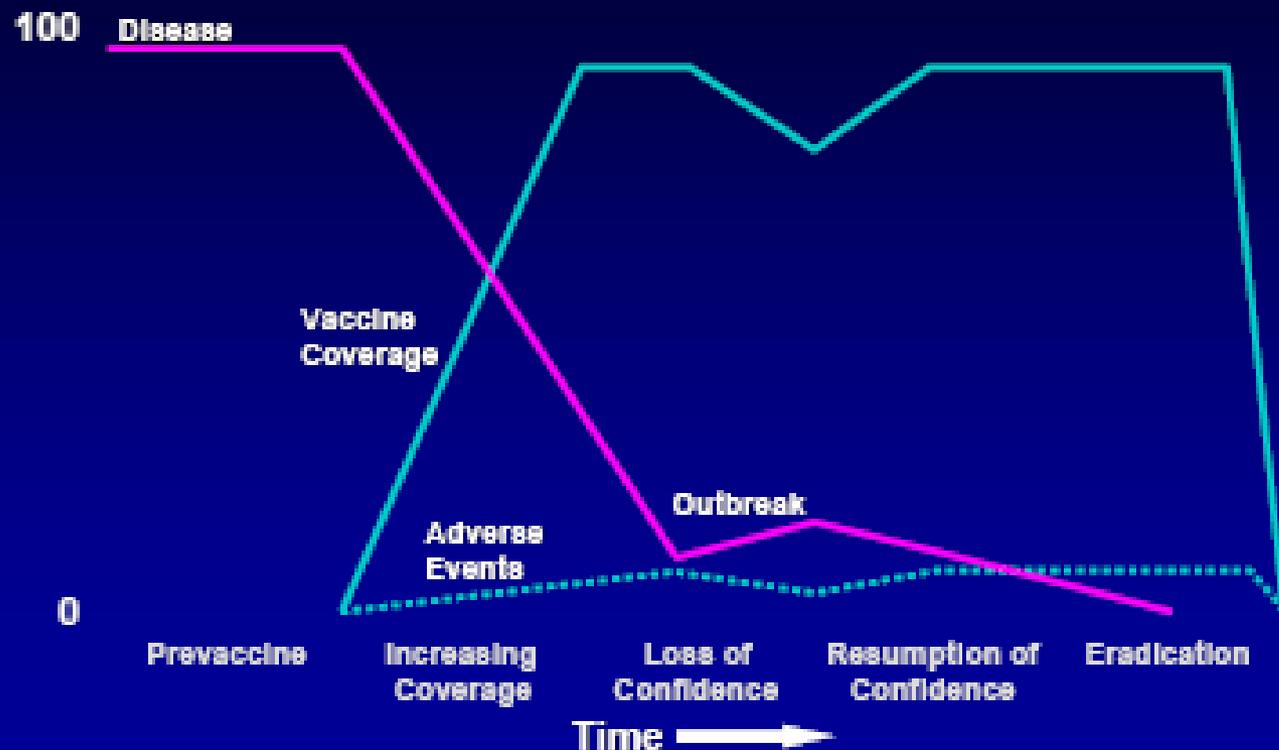


Data Sources: California Department of Public Health, 2007 Kindergarten Assessment
 SANDAG Data Warehouse, 2000 Census Data
 Map Date: June 4, 2008



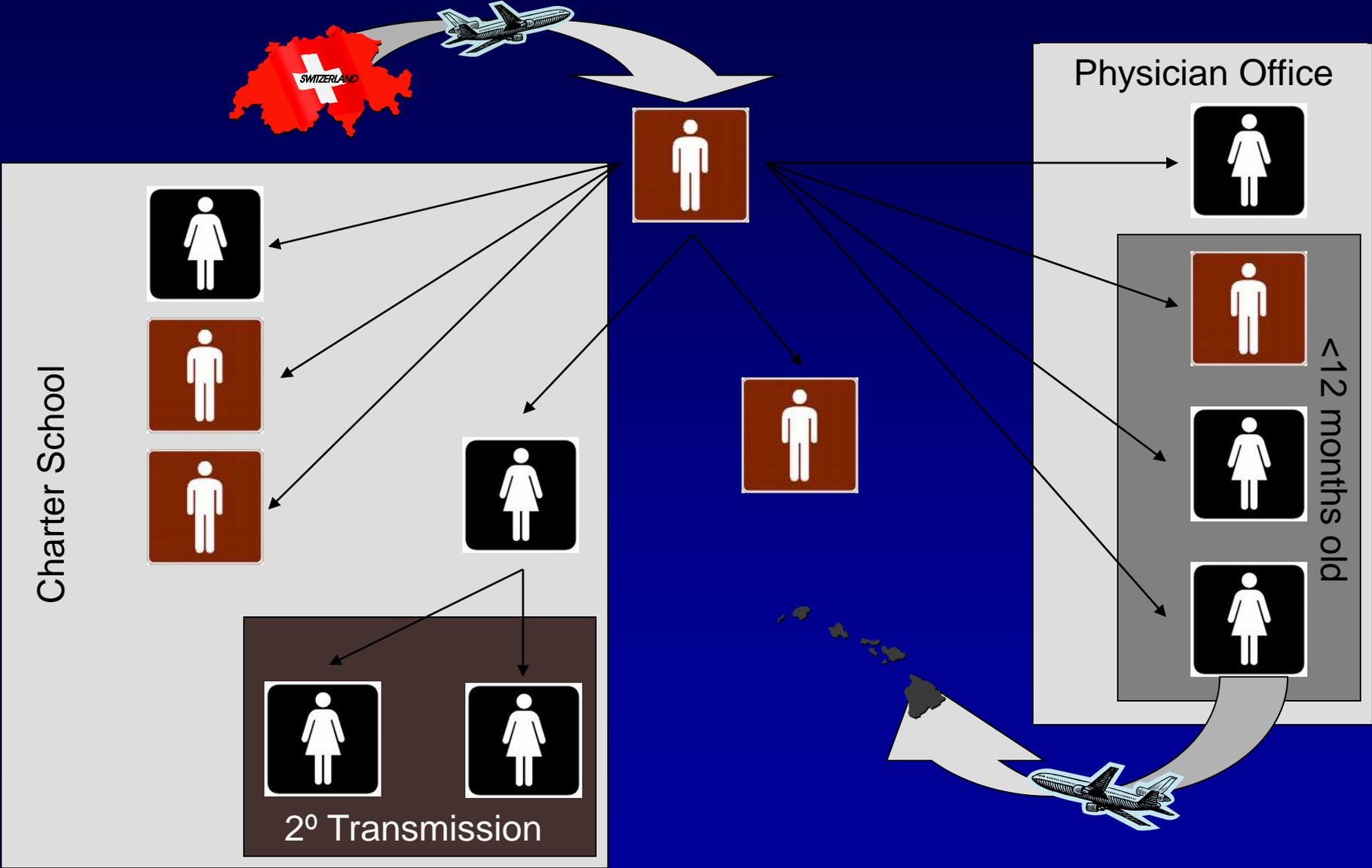
County of San Diego
 Health and Human Services Agency
 Public Health Services
 Community Epidemiology

Evolution of Immunization Programs



Chen. In Plotkin & Grenstein. Vaccines, 2004; Saunders

San Diego Measles Outbreak 2008



Other Measles Outbreaks in the U.S.-2008

- 131 cases from Jan-June 2008 (Average cases =63 annually 2000-2007)
- Washington outbreak (n=19) included 16 school-aged children-all unimmunized
- Illinois outbreak (n=30) included 25 school-aged children-all unimmunized
- Altogether 91% of cases were unimmunized
- 89% related to imported cases

Need recent outbreaks

...and

- Measles outbreak in Minnesota centered in Somali population
- Measles in Utah right now
- California pertussis outbreak-10 deaths

Individual Risk of Exemption - Pertussis

Age Group	Rate per 100,000 exemptors	Rate per 100,000 vaccinated	Relative Risk (95% CI)
3-5	191	11	17 (9 - 31)
6-10	142	9.4	15 (9 - 25)
11-14	35	19	1.9 (0.8 - 5)
15 -18	0	13	0 (0 - 2)
3 -18	80	13	5.9 (4 - 8)

Other Vaccine Components and Autism

It ain't over until the fat lady sings...

- ✓ Aluminum
- ✓ Bovine serum albumen
- ✓ Adjuvants
- ✓ Yeast proteins
- ✓ Human cell line derivatives
- ✓



Porcine Circovirus in Rotavirus Vaccine

- Porcine circovirus types 1 and 2 found in both licensed rotavirus vaccines
- Temporary suspension of GSK/Rotarix vaccine lifted May 14, 2010
- No concern for adverse events related to these adventitious viruses
- Raises questions about what else is out there...



What we know

- Wakefield retraction
- Danish study
- California study
- Recent studies
- Causes of autism
 - ✓ Heritability
 - ✓ Early recognition
 - ✓ Changes that had to occur in utero

Danish Cohort Study

The Past

MMR
1,647,504 person-yr

No MMR
482,360 person-yr

Children born between
01/01/91 and 12/31/98

Population of Denmark

The Present

Autism: 263
ASD: 345

Autism: 53
ASD: 77

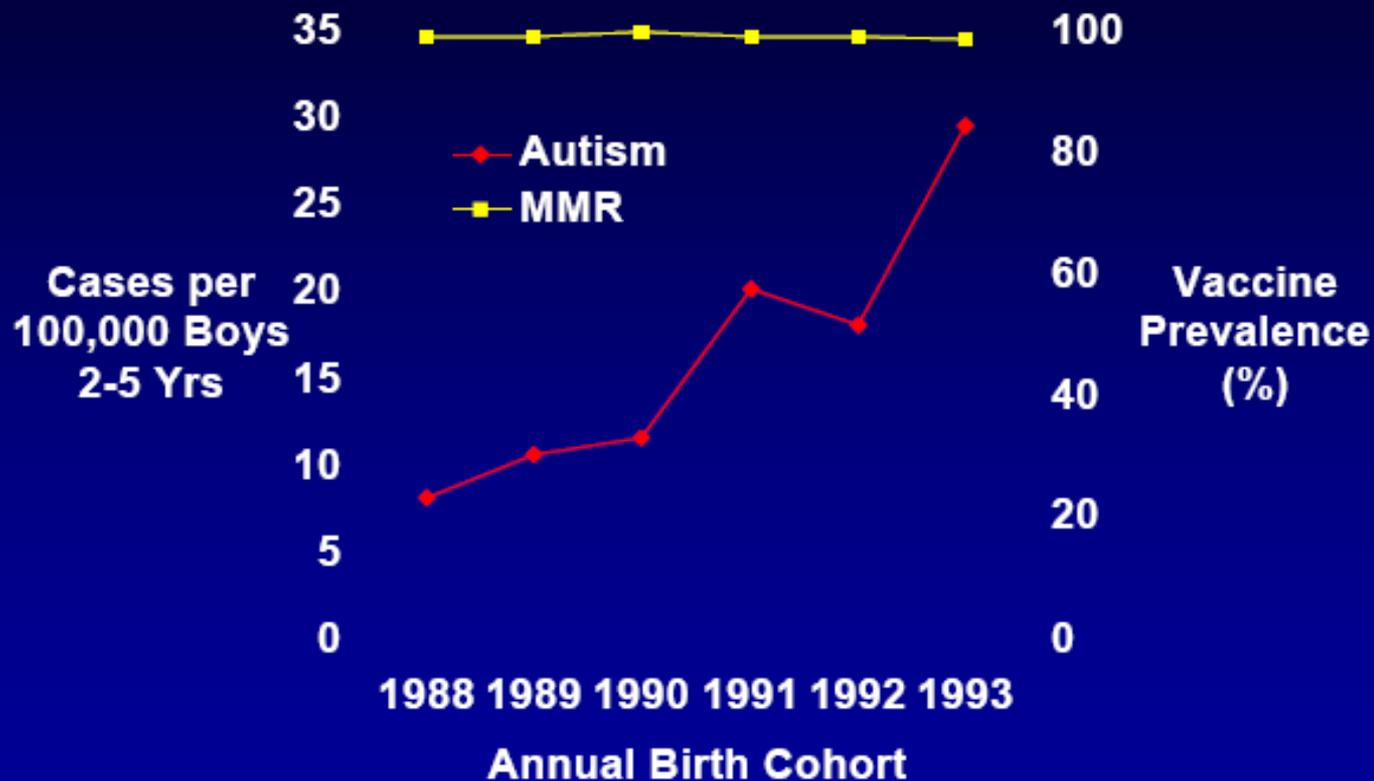
Relative risk:

Autism: 0.92 (0.68-1.24)

ASD: 0.83 (0.65-1.07)

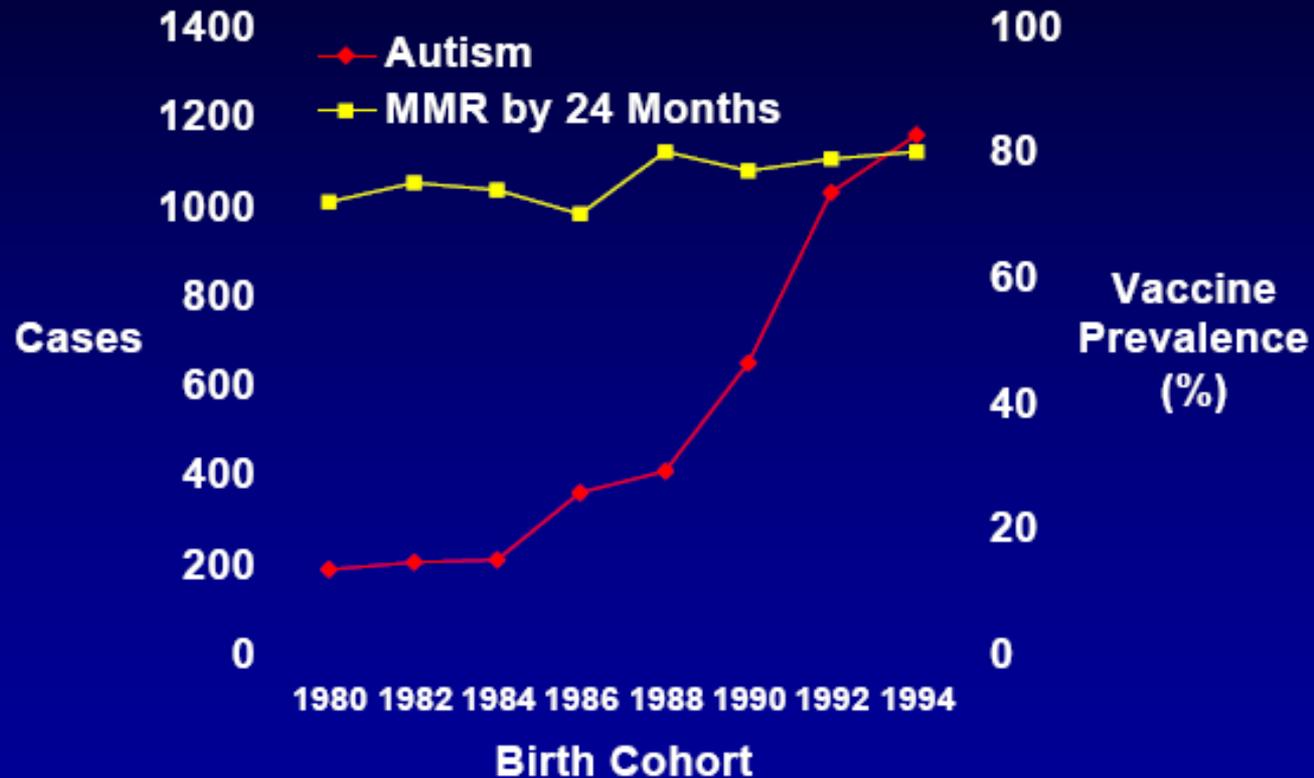
Madsen. *N Engl J Med* 2002;347:1477

Autism and MMR: United Kingdom



Kaye JA. *BMJ* 2001;322:460

Autism and MMR: California

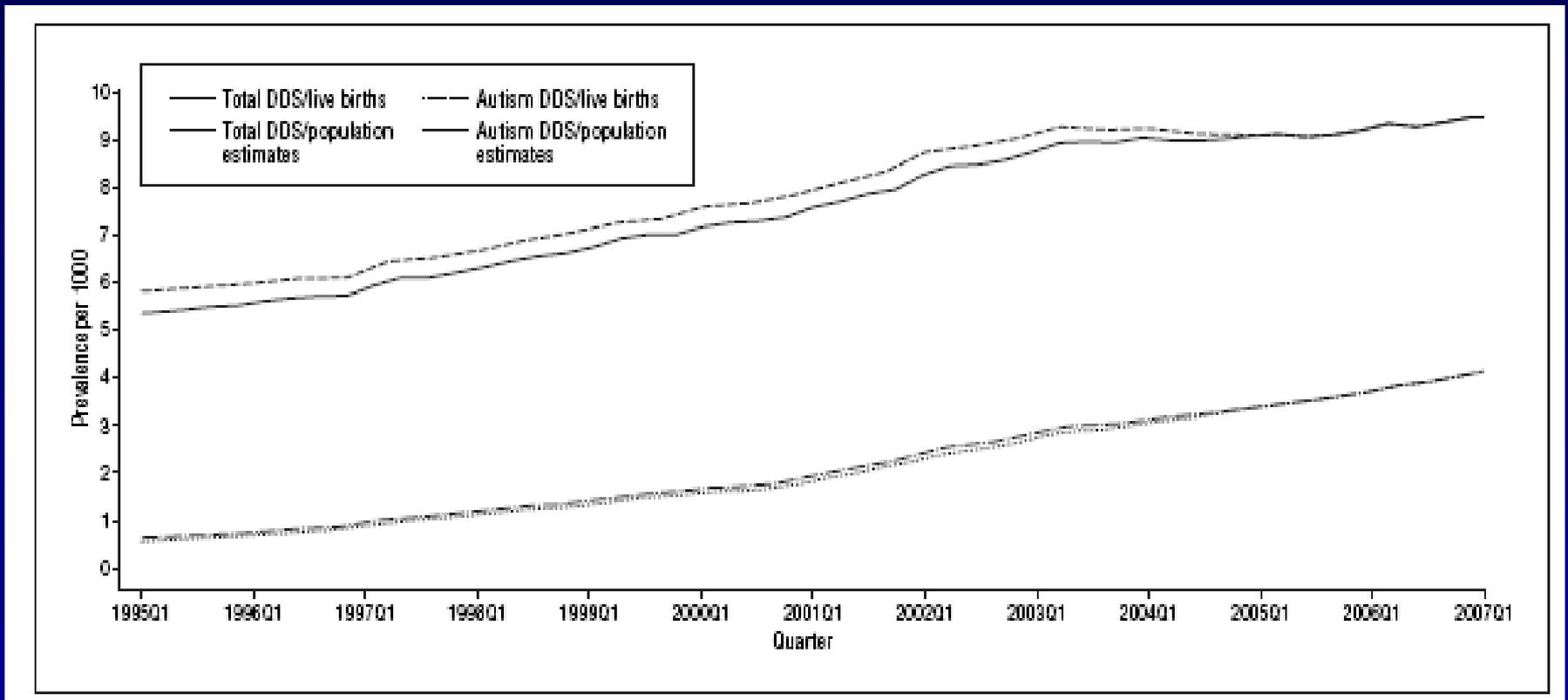


Dales L. JAMA 2001;285:1183

Thimerosal and Neuropsychological Function

- 1047 children 7-10 years of age
- Formal neuropsychological testing
- Correlated outcome with thimerosal exposure
- No evidence for a link between thimerosal exposure and neuropsychological functioning

2008 California Study



VSD Studies

What we know about autism

- Highly heritable (more than breast cancer)
- Behavioral changes of autism often present before 1 year of age
- New screening tool developed to be used at 12 months of age
- Autism associated with an increase in the number of neurons (i.e. insult occurs in utero)
- Rates of autism may not be any different now than they were 40 years ago

How can you respond?

- Are vaccines safe?
- Do vaccines cause autism?
- Aren't we overwhelming the immune system?
- Isn't natural immunity better?
- Diseases no longer exist—or aren't that dangerous
- It is all a giant money-fueled conspiracy
- It's my right to decide what's best for my child

Know Your Source

Talking Points



- Majority of sites found on an Internet search of “Vaccines” are anti-vaccine sites
- NNII site provides tips on how to evaluate the credibility of Web sites
<http://www.immunizationinfo.org>
- How to identify a credible web site
 - ✓ Scientific studies cited and are current
 - ✓ Lack of financial conflict of interest (selling a book)
 - ✓ Experience in field
 - ✓ Lack of anecdotes

Vaccines are Safe

Talking Points

- Hundreds of millions of doses of vaccine given every year in U.S. with no problem
- Billions of vaccines are given in the world every year with no problem
- Vaccine safety infrastructure is large
 - ✓ VAERS
 - ✓ VSD
 - ✓ CISA
 - ✓ FDA
 - ✓ CDC

Vaccines DO NOT Cause Autism

Talking Points

- Genetic factors related to autism-autism is more heritable than breast cancer
- Brain changes associated with autism relate to events that occur in utero (Corchesne E)
- Symptoms of autism present before many vaccines are given
- Ongoing studies specifically looking at risk of vaccines: none identified
- Autism hasn't gone away despite thimerosal being taken out of vaccines
- Vaccine court has rejected the autism claim

Do vaccines overwhelm the Immune System?



- Your immune system responds to hundreds of things every day
- No evidence that children get more infections right after they are immunized
- Clinical trials test multiple vaccines
- Increased vaccine purity

Is natural immunity better?



- For some infections natural immunity “better” because it lasts longer
- Natural immunity is not complete
 - whooping cough, rotavirus
 - Multiple types of some disease agents (Pneumococcus, influenza)
- Natural immunity is only better if you survive the illness without serious consequences
- Natural immunity comes at a price
 - ✓ deafness, brain damage, hospitalization, pneumonia, paralysis, permanent scars

Diseases Are Not That Bad

- Prior to the availability of pneumococcal vaccine there were 200 deaths/year from this disease
- Out of the 5 cases of Hib reported last year in Minnesota, one died
- San Diego measles outbreak-out of 12 cases, one hospitalized
- Quote your own experience....

Parents' Choice vs. the “Greater Good”

- **Not vaccinating puts your child at risk**
- **Not vaccinating your child also puts others at risk**
- **3 innocent bystanders infected during San Diego measles outbreak**

**Personal beliefs about
immunization are
affecting people who
do not share those
beliefs**

You can't hide in the herd

- Herd immunity is very important
 - ✓ Elimination of H. flu disease
 - ✓ Decrease in influenza and pneumococcal disease in elderly because of pediatric immunization
 - ✓ Drop in Hepatitis A disease in California
- But, you can't hide in the herd, especially if your herd thinks like you do



Vaccine Safety:

Responding to Parents' **Top 10** Concerns



California Immunization Coalition materials



1. Are Vaccines safe?

Yes. Millions of children and adults have been vaccinated safely. While any medication, even foods, can cause reactions, a child takes a much greater risk of getting a disease if he or she is not vaccinated. The most common vaccine [side effects](#) are mild and include swelling, tenderness, and fever. Set realistic expectations by acknowledging that vaccines cause mild, self-limited reactions, like injection site swelling and pain, in many children. A pain reliever may help, but parents should call the office if concerned. [Serious reactions](#) are very rare and can occur in about 1 or 2 people per million shots given.

Scientists and doctors are very careful about the way we test and use vaccines. We also vaccinate our own kids. That's because we know that thousands of people participate in clinical trials to test vaccines before they can be approved by the [Food and Drug Administration \(FDA\)](#). Even after licensing, the Vaccine Adverse Events Reporting System ([VAERS](#)) tracks any adverse reaction that could be associated with a vaccine. Newer vaccines like HPV ([Gardasil](#)[®]) are tracked closely. Continued [monitoring](#) helps ensure that vaccines have a safe track record over time.

2. Why do children today need so many immunizations?

To save lives. Advances in medical science have developed vaccines to protect us against more than 15 dangerous diseases. Only a few years ago vaccines prevented just a small handful of diseases. Babies are especially vulnerable. Children under age one (still too young to get some shots like varicella) are at high risk of hospitalization or serious complications from vaccine-preventable diseases. These include seizures, brain damage, blindness, and even death. That's why we have continued to develop new vaccines. And, that's the reason children get more immunizations today than in the past.

3. Are diseases of the "old days" really still something to worry about?

Vaccine-preventable diseases still occur—though many young parents haven't seen them. This is due to the success of our country's immunization program. But unvaccinated children (and adults) are still at-risk for common illnesses like [influenza](#), [whooping cough](#), and [chicken pox](#). Some parents may be surprised to learn that before the chicken pox vaccine, almost 11,000 Americans had to be hospitalized, and over 100 died, each year from

http://immunizeca.org/documents/IMM-917_web.pdf

What about the Sears schedule?

	DTaP	Rotavirus	Pc	Hib	Polio	Mumps	Varicella	Rubella	Hep A	Hep B	Measles
DR. BOB'S VACCINATION SCHEDULE											
2 months	•	•									
3 months			•	•							
4 months	•	•									
5 months			•	•							
6 months	•	•									
7 months			•	•							
9 months					•						
12 months					•	•					
15 months			•	•							
18 months	•						•				
2 years					•			•			
2½ years									•	•	
3 years										•	•
3½ years								•		•	

The Sears Schedule

- Based on the premise that it is better to spread out vaccines
- Based on Dr. Sears' opinion about what diseases are dangerous and what diseases a child is likely to encounter
- Based on the assumption that aluminum in vaccines causes a problem
- Based on the premise that as long as enough people don't follow the schedule, herd immunity will be maintained

What's Wrong with Alternative Vaccine Schedules?

What's Wrong With Alternative Immunization Schedules?

- There is no scientific basis for them
- They leave children at risk for disease
- They leave our community at risk for outbreaks, including among those who are immunized
- They increase healthcare costs

Being Unimmunized Leaves You at Risk

Talking Points

- The unimmunized are at increased risk to develop disease and expose others
 - ✓ All of the measles cases in San Diego in 2008 were unimmunized
 - ✓ 3 of them were too young to be immunized and were exposed in a doctor's office
- Unimmunized children are at increased risk for pertussis, mumps, chickenpox in schools

The Details of What's Wrong With Alternative Vaccine Schedules

PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

The Problem With Dr Bob's Alternative Vaccine Schedule

Paul A. Offit and Charlotte A. Moser

Pediatrics 2009;123:e164-e169

DOI: 10.1542/peds.2008-2189

Sears Message #1

Doctors don't understand vaccines

Possible Responses

- Find a doctor you trust
- Doctor's do not blindly follow anyone's recommendations
- CDC, ACIP, and the AAP Committee on Infectious Disease have experts in public health, infectious disease, pediatrics whose job it is to gather and interpret ALL of the data

Sears Message #2

You Can't Trust CDC, AAP, your doctor

Possible Responses

- What motive does your individual physician have to recommend vaccines if they didn't believe in them?
- Why do you trust your doctor when they recommend drugs or surgery?
- Show me a report that people at CDC make money from pharmaceutical companies

Sears Message #3

Diseases Are Not That Bad

Possible Responses

- Prior to the availability of pneumococcal vaccine there were 200 deaths/year from this disease
- Out of the 5 cases of Hib reported this week in Minnesota, one died
- San Diego measles outbreak-out of 12 cases, one hospitalized
- Quote your own experience

Vaccine-Preventable Disease Are Dangerous Talking Points

- 1 hospitalization out of 12 measles cases in San Diego (February 2008)
- Several deaths every year from pertussis in California
- At least 10% of people with meningococcal disease die
- Influenza kills thousands every year

Sears Message #4

Hide in the Herd



Possible Responses

- Everyone else is NOT immunized
- It depends on what herd you are in- a partially immunized herd is a dangerous herd
- 5 cases of Hib reported this week in Minnesota suggesting that herd immunity is waning
- You will be thrown out of the herd (quarantined) if an outbreak occurs

Sears Message #5

Natural Infection is Better

Possible Responses

- Natural immunity comes at a cost-death, deafness, mental retardation, paralysis, chronic hepatitis
- Natural immunity doesn't work for many diseases because there are so many types
- You are taking a chance with letting your child develop natural immunity

Why Should I Put My Child At Risk For The Greater Good? Talking Points



- Because you are actually putting your child at risk by not having them immunized.
 - ✓ Measles exemptors: 35x increased risk
 - ✓ Pertussis exemptors: 5.9x increased risk
- When you or your child are not immunized, they put others at risk: measles in San Diego
- None of us want to see a resurgence of the diseases we have largely eliminated

California Immunization Coalition materials

Alternative Vaccine Schedules:

Helping Parents Separate Fact From Fear



A Guide for Physicians

Parents want to keep their children safe and healthy. Questions about the recommended immunization schedule create an opportunity for you to listen and respond to requests for “alternative schedules,” including the Dr. Bob Sears’ schedule. Help empower parents to make an informed decision about vaccinating their kids. We offer these tips to assist practitioners to respond effectively and compassionately and to build trusting relationships with patients and parents.

► **CONCERN: CDC schedules seem generic; alternative schedules cater to individual needs**

The immunization schedule exists to protect children at the age they are most vulnerable to each disease. Children are vaccinated as soon as they are developmentally able to create an effective immune response.

Explain: Alternative schedules are not custom-made. That’s actually what doctors do. Doctors consider a patient’s medical history and give the best advice for each child. Some medically-sensitive kids are also at high risk for diseases, making shots especially important.

Ask: *Do you have specific concerns about your child’s health? Let’s talk about it.*

► **CONCERN: “Too many” vaccines, “too soon” could be harmful**

Are there more vaccines now than 20 years ago? Yes—and that’s a good thing. Newer vaccines save children from terrible diseases like Hib and Meningococcal disease. This devastating infection can cause organ failure, limb amputations, and brain damage. Postponing shots increases the time a child is defenseless. Recent outbreaks of measles and Hib tell us that postponing shots puts healthy kids at risk for diseases none of us thought would come back.

Explain: A baby’s immune system can handle multiple shots with weakened or killed virus much better than it can fight off a serious disease. Postponing shots means your child could get sick and risk serious complications. It’s obvious you want to protect your child, but alternative schedules take advantage of parents’ worries; they’re not based on science.

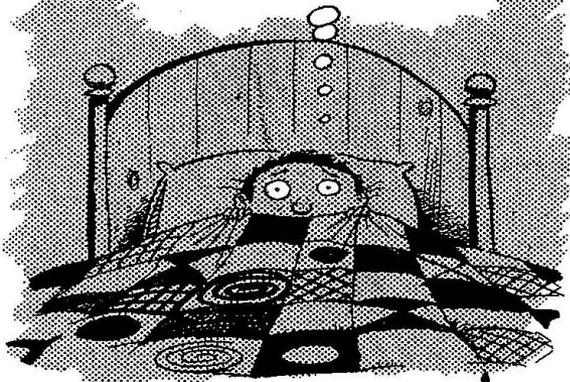
Ask: *Which vaccines are causing you worry?*

<http://immunizeca.org/documents/IMM-988.pdf>

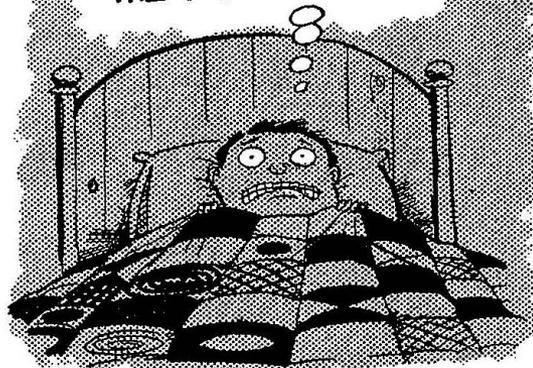
Steve Breen THE SAN DIEGO UNION-TRIBUNE

STEVE BREEN San Diego Union-Tribune
COPLEY NEWS SERVICE ©

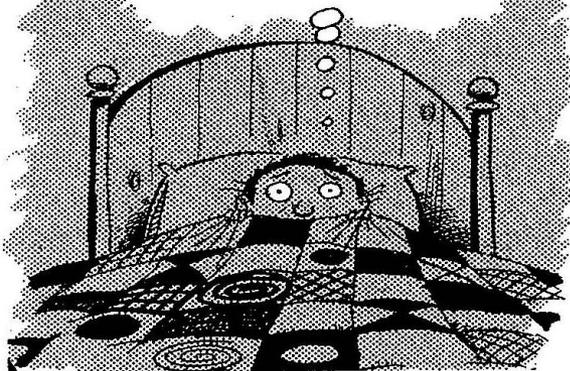
I DON'T BELIEVE
IN MONSTERS...



I DON'T BELIEVE
IN GHOSTS OR
THE BOGEYMAN...



BUT MY PARENTS
DON'T BELIEVE IN
VACCINATING...



THAT'S WHAT
KEEPS ME UP AT
NIGHT!



Information for Health-Care Professionals

NNII (www.immunizationinfo.org)

VEC (www.vaccine.chop.edu)

IAC (www.immunize.org)

CDC/NIP (www.cdc.gov/nip)

AAP (www.aap.org)

AAFP (www.aafp.org/)

IVS (www.vaccinesafety.edu)

Vaccine Page (www.vaccines.org)

Every Child by Two (www.ecbt.org)