

“I’ve Heard Some Things That Scare Me”

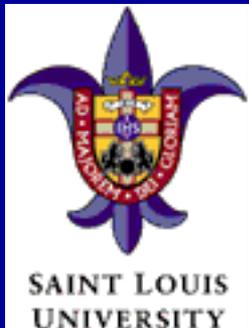
Responding With Empathy
to Parents’ Fears of Vaccinations

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The Lancet, Vol 351, February 28, 1998

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 Bereciowitz, A P Dillon, 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.

Methods 12 children (mean age 6 years [range 3–10], 11 boys) were referred to a paediatric gastroenterology unit with a history of normal development followed by loss of acquired skills, including language, together with diarrhoea and abdominal pain. Children underwent gastroenterological, neurological, and developmental

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 cases, food intolerance. We describe the clinical findings, and gastrointestinal features of these children.

Patients and methods

12 children, consecutively referred to the department of paediatric gastroenterology with a history of a pervasive developmental disorder, were investigated at the

Case presentation, part 1

A 3 month old girl was admitted onto the pediatric clinic medicine service of a university-affiliated children's hospital in the winter of 2008 with a 3-4 day history of worsening cough and fever leading to decreased oral intake. She had been brought to the emergency room by her parents and was observed to have paroxysms of cough and had a SpO₂ on room air which would drop into the 70s during these episodes. Family history was significant for a teenage brother who had had a recent persistent cough for a few weeks but had had no fever. Despite her age, the baby had not received any immunizations on the advice of the family's chiropractor. The family also said that they had "read some stuff on the internet about shots and autism," and they felt that the baby would be better off not getting immunizations than "taking a chance" that vaccines might harm her. The baby's nasopharyngeal swab was positive for pertussis, as was her follow-up culture. She required oxygen by nasal cannula for 5 days and was sent home after she was weaned to room air. The parents were counseled that the baby would likely still have a cough for many weeks to come.

This was one of three pertussis cases seen by the clinic medicine attending during one month on inpatient service, the first time in his career that he had seen more than one patient admitted for pertussis within a month.

Pertussis in Missouri

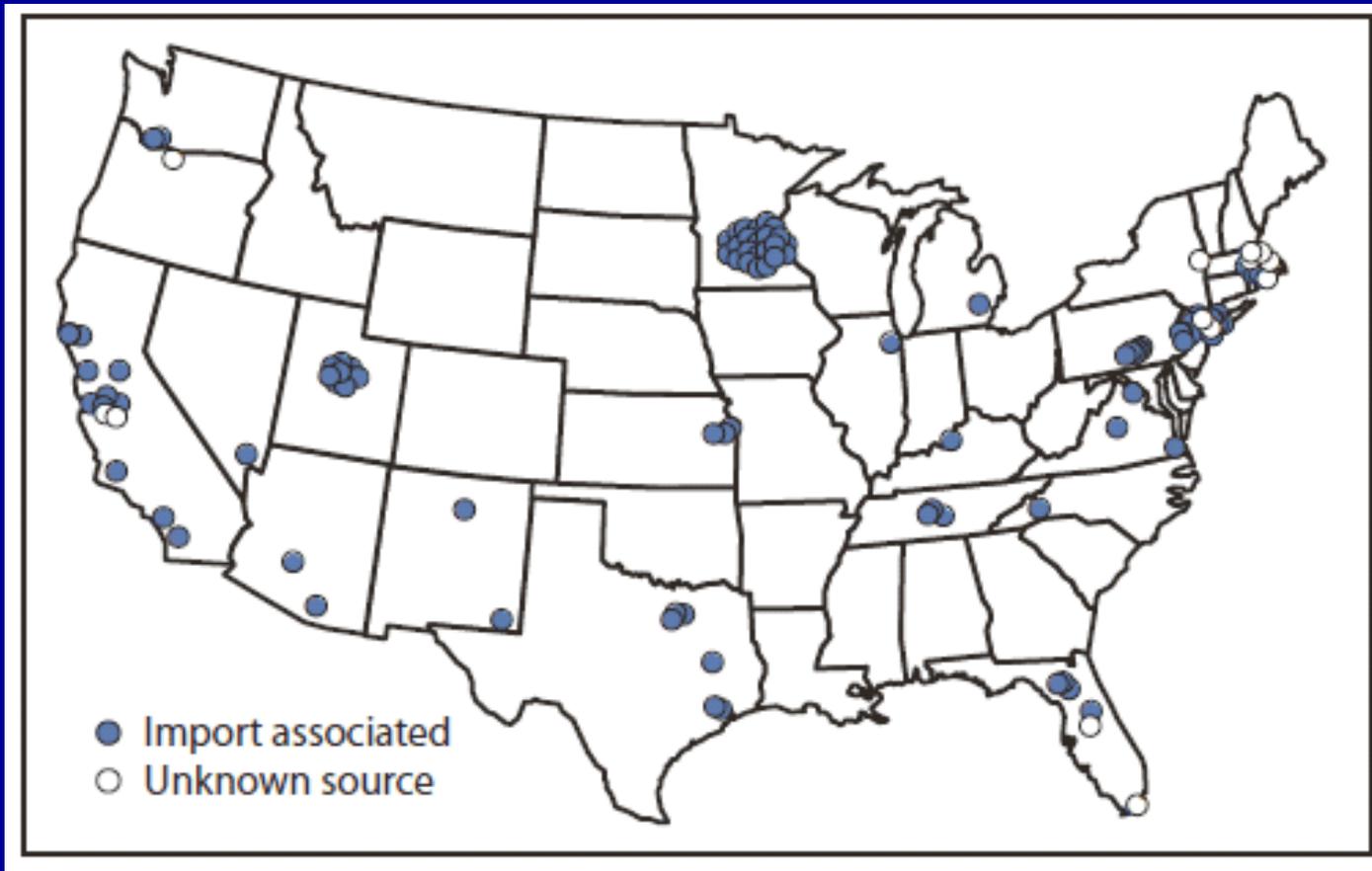
- In 2008 in the state of Missouri, there were 561 cases of pertussis reported to the Missouri Department of Health and Senior Services.
- Pertussis had been on the decline for the previous two years (308 cases in 2006 and 118 in 2007).
- The 561 Missouri pertussis cases represented an 82% increase over the five-year median of 308 cases.
- The number of reported pertussis outbreaks in Missouri also increased in 2008, from two reported in 2007 to 11 in 2008.

Pertussis in California 2010

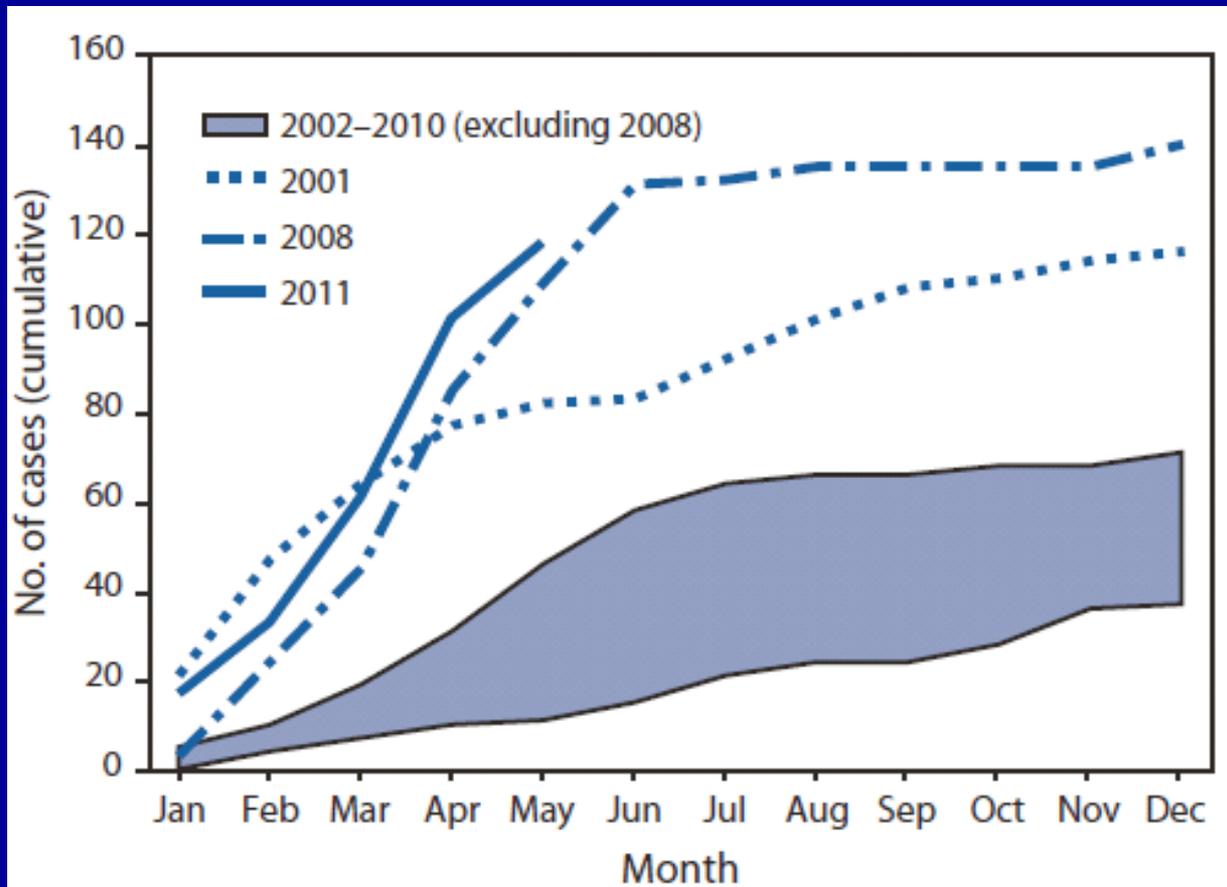
- 9,120 cases for a state rate of 23.3 cases/100,000.
- Greatest # in 63 yrs - 9,394 cases in 1947.
- Highest incidence in 52 yrs - 26.0/100,000 in 1958.
- Of the 9,120 cases, 804 (9%) were hospitalized.
 - 442 (55%) were infants <3 months of age
 - 581 (72%) were infants <6 months of age.
- Highest rates in areas with high vaccine-refusal rates.
- 10 deaths were reported.
 - 9 were infants <2 months of age at time of disease onset who had not received any doses of pertussis-containing vaccine.
 - The 10 infant was an ex-28 week preemie who was 2 months of age and had received the first dose of DTaP only 15 days prior to disease onset.

Other vaccine-preventable illnesses

- Invasive *H. influenzae* disease
 - more than doubled from 0.48 cases/100,000 to 0.99/100,000 between 1999 and 2009
 - number of reported cases (all ages, serotypes) rose from 1,174 to 1,597 cases between 1994 and 2001.
- Measles
 - 118 cases reported in the United States during the first 19 weeks of 2011
 - the highest number of reported measles cases for this period since 1996
 - 105 (89%) were associated with importation from other countries, and 105 (89%) patients were unvaccinated.



Distribution and origin of reported measles cases (N = 118) --- United States, January 1--May 20, 2011, The figure above shows the distribution and origin of reported measles cases (N = 118) in the United States during January 1-May 20, 2011.
Source: <http://www.cdc.gov/vaccines>



Cumulative number of measles cases reported, by month of rash onset --- United States, 2001--2011, The figure above shows the cumulative number of measles cases reported, by month of rash onset, in the United States during 2001-2011. During January 1-May 20, 2011, a total of 118 cases were reported, the highest number reported for the same period since 1996.

Source: <http://www.cdc.gov/vaccines>

Pediatrics: November 2011

- National survey of parents of young children regarding their attitudes toward vaccination.
- >1 in 10 parents surveyed currently use an alternative vaccination schedule
- A large proportion of parents who already use the recommended vaccination schedule have misgivings about it and are considering switching to an alternative schedule.

So what's going on?

The Panic Virus, Seth Mnookin, 2011

“It’s remarkable how static the makeup, rhetoric, and tactics of vaccine opponents have remained over the past 150 years. Then, as now, anti-vaccination forces fed on anxiety about the individual’s fate in industrialized societies; then, as now, they appealed to knee-jerk populism by conjuring up an imaginary elite with an insatiable hunger for control; then, as now, they preached the superiority of subjective beliefs over objective proofs, of knowledge acquired by personal experience rather than through scientific rigor.”

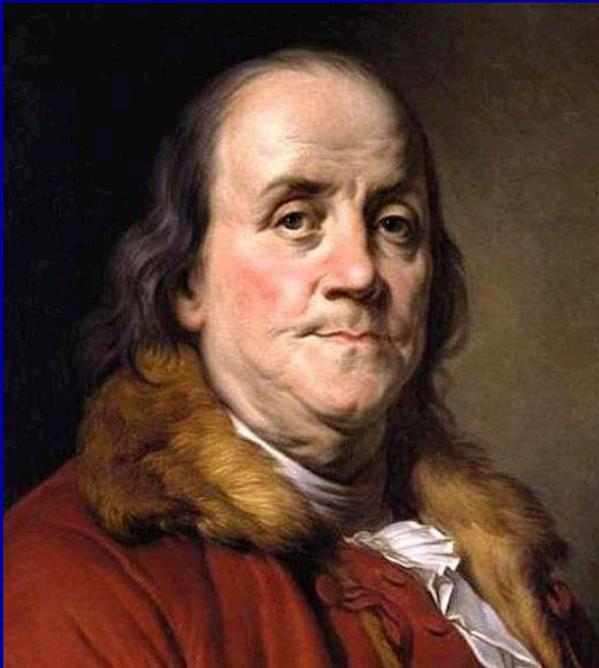
The Unnatural Act of Vaccination - a short history

- Before vaccination, inoculation
- Smallpox inoculation introduced to Europe, from China
- Implant smallpox scabs/pus into wounds in the skin of an uninfected person
- Develop milder disease & lifelong immunity
- Death after inoculation was not uncommon



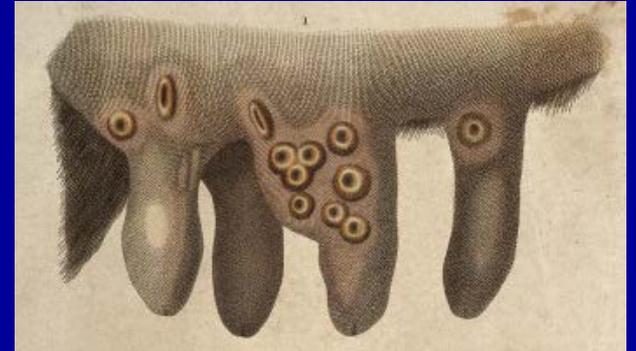
Benjamin Franklin

- Benjamin Franklin reported in his newspaper, The Pennsylvania Gazette, that, of 72 Bostonians recently inoculated with smallpox, only two died while “the rest have recovered perfect health... Of those who had [smallpox] in the common way, ’tis computed that one in four died.”
- His own son, Francis Folger Franklin, was born October 1732, and died of smallpox in 1736.



Vaccination

- Edward Jenner
- Milkmaids and Cowpox
- *Vaccinus* [Latin] of or from cows
- Ministers railed against vaccination since inoculation sometimes led to death: “Thou Shalt Not Kill.”
- Anti-vaccine political cartoons



The Cow-Pock -- or -- the Wonderful Effects of the New Inoculation! (1802), James Gillray



The Cow-Pock -- or -- the Wonderful Effects of the New Inoculation! — side. — the Publications of the Anti-Vaccinate Society.

Vaccine Problems

- 1901 St. Louis, MO: 13 schoolchildren die of tetanus after they were treated with the diphtheria antitoxin
- 1901 Camden, NJ: 9 schoolchildren die after administration of commercial vaccine allegedly tainted with tetanus
- 1902: Biologics Control Act establishes the first federal regulation of the vaccine industry

The Cutter Incident

- In 1955, Cutter Laboratories was licensed by the US government to produce Salk polio vaccine.
- A production error caused some lots of the Cutter vaccine to be tainted with live polio virus
 - 120,000 doses of polio vaccine that contained live polio virus were produced.
 - 40,000 children developed abortive poliomyelitis
 - 56 developed paralytic poliomyelitis and of these
 - 5 children died as a result of polio infection.
 - An epidemic of polio in the families and communities of the affected children, resulting in a further 113 people paralyzed and 5 deaths.

Swine Flu Vaccine

- 1976: fear of a strain of flu similar to the 1918 pandemic strain
- Ford admin spearheaded a crash vaccine program
- Became known in the press as Swine Flu
- Government rolled out its vaccine on October 1.
- By late November over 500 of 40,000,000 vaccine recipients had developed Guillan-Barre Syndrome, 7 X > expected for the population and not statistically significant
- In a hail of negative press, the program was halted on December 16

Whole cell pertussis vaccine

- Pertussis component of DPT well known as cause of high fevers in recipients
- 1980's: concerns about neurological damage from DPT vaccine.
- Vaccine manufacturers face lawsuits, threaten to leave the market
- Congress passes The National Childhood Vaccine Injury Act (NCVIA) of 1986
 - National Vaccine Injury Compensation Program (NVICP)
 - Vaccine Adverse Event Reporting System (VAERS).

Rotashield

- 1998: RotaShield (Wyeth) was licensed for use in the United States.
- Clinical trials had found it to be 80 to 100% effective at preventing severe diarrhea caused by rotavirus A
- No statistically significant serious adverse effects had detected.
- VAERS: increased risk for intussusception evident in one of every 12,000 vaccinated infants
- Wyeth withdrew it from the market in 1999.

Beyond vaccines...

- Tuskegee Syphilis Experiments
- Administered by US Public Health Service 1932-1972
- According to one mother:
“[Tuskegee] always sticks in my mind. That you really don’t know what’s happening and here these people were guinea pigs and I just don’t want my children to be part of that.”



Meanwhile...

“Autistic disturbances of affective conduct”

- 1943: Leo Kanner describes children with an inability to form normal human attachments, an extreme lack of empathy, and a tendency to get unnaturally absorbed in routine tasks
- 1949 follow-up paper “Problems of nosology and psychodynamics in early childhood autism”
- Parents of autistic kids: “Most of the parents declare outright that they are not comfortable in the company of people ... Maternal lack of genuine warmth is often conspicuous in the first visit to the clinic.”

Bruno Bettelheim

- Bettelheim biographer, Richard Pollak: “No prominent psychotherapist of this time was more antagonistic to mothers—in private and in public—as [Bettelheim] was, insisting that they caused autism by rejecting their infants and comparing them to devouring witches and the SS guards in the concentration camps... the readiness with which Bettelheim’s theories were embraced illustrates how what are thought of as indisputable, evidence-based conclusions are influenced by prevailing social and cultural norms.”

Diagnostic and Statistical Manual of Mental Disorders (DSM)

- DSM (1952): autism a separate diagnosis or syndrome, a descriptor under “Schizophrenic reaction, childhood type,” which included “Psychotic reactions in children, manifesting primarily as autism.”
- DSM-III (1980): First use of “Infantile autism” as a free-standing diagnosis.
- DSM-III-R (1987): Changed dx to “Autistic disorder.”
- DSM-IV (1994): “Pervasive developmental disorders” include autistic disorder, Rett’s disorder, Asperger’s disorder, childhood developmental disorder, and pervasive developmental disorder, not otherwise specified, (PDD-NOS), and all of which are considered autism spectrum disorders (ASD)

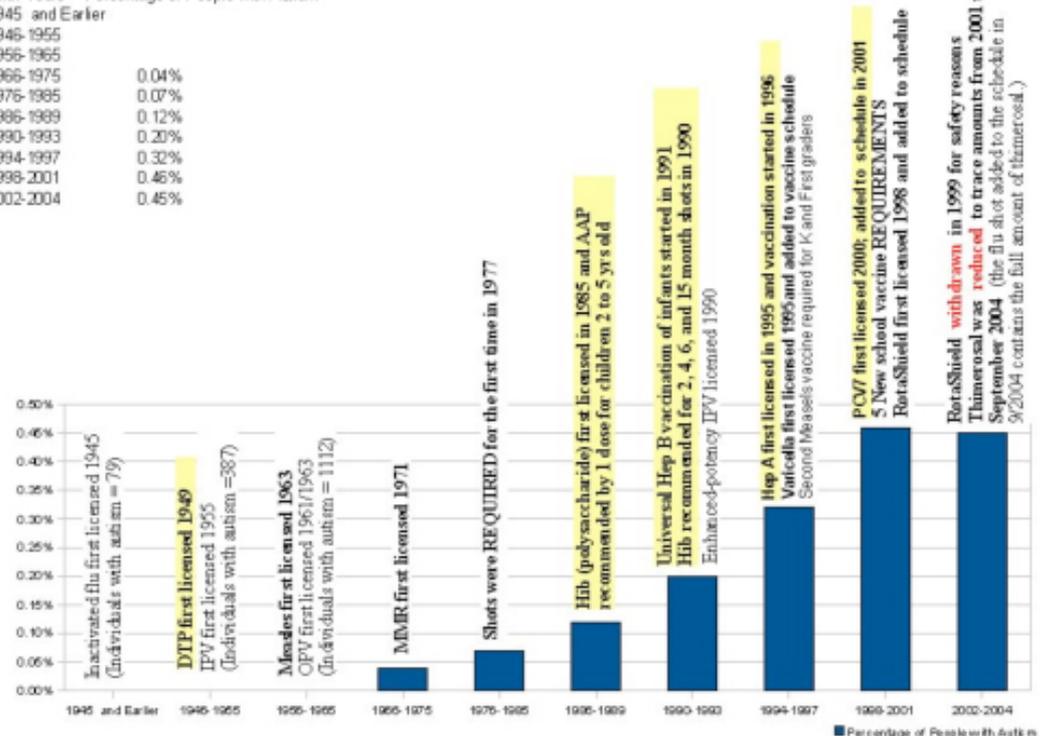
Changes in autism diagnosis and detection

- Diagnostic criteria for ASDs have been both broadened and refined
- 2007: AAP recommends observing for signs of autism at every well child visit, screening with Modified Checklist for Autism in Toddlers (M-CHAT) at the 18- and 24-month well child visits.
- More awareness of ASD's through media.

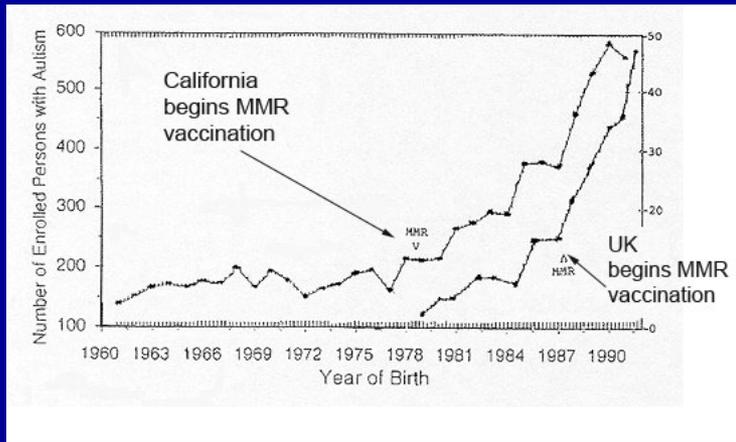
Poor risk assessment association vs. causality

Percentage of California Individuals with Autism by Birth Year compared to the Recommended Childhood Immunization Schedules

Birth Years	Percentage of People with Autism
1945 and Earlier	
1946-1955	
1956-1965	
1966-1975	0.04%
1976-1985	0.07%
1986-1989	0.12%
1990-1993	0.20%
1994-1997	0.32%
1998-2001	0.46%
2002-2004	0.45%

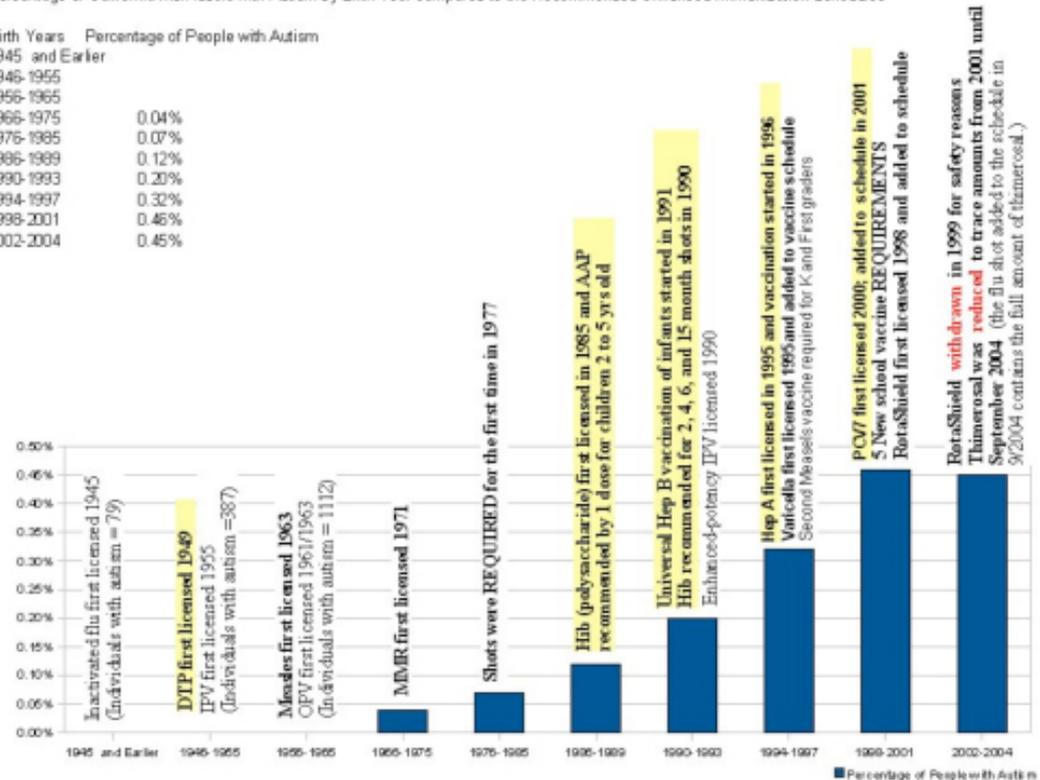


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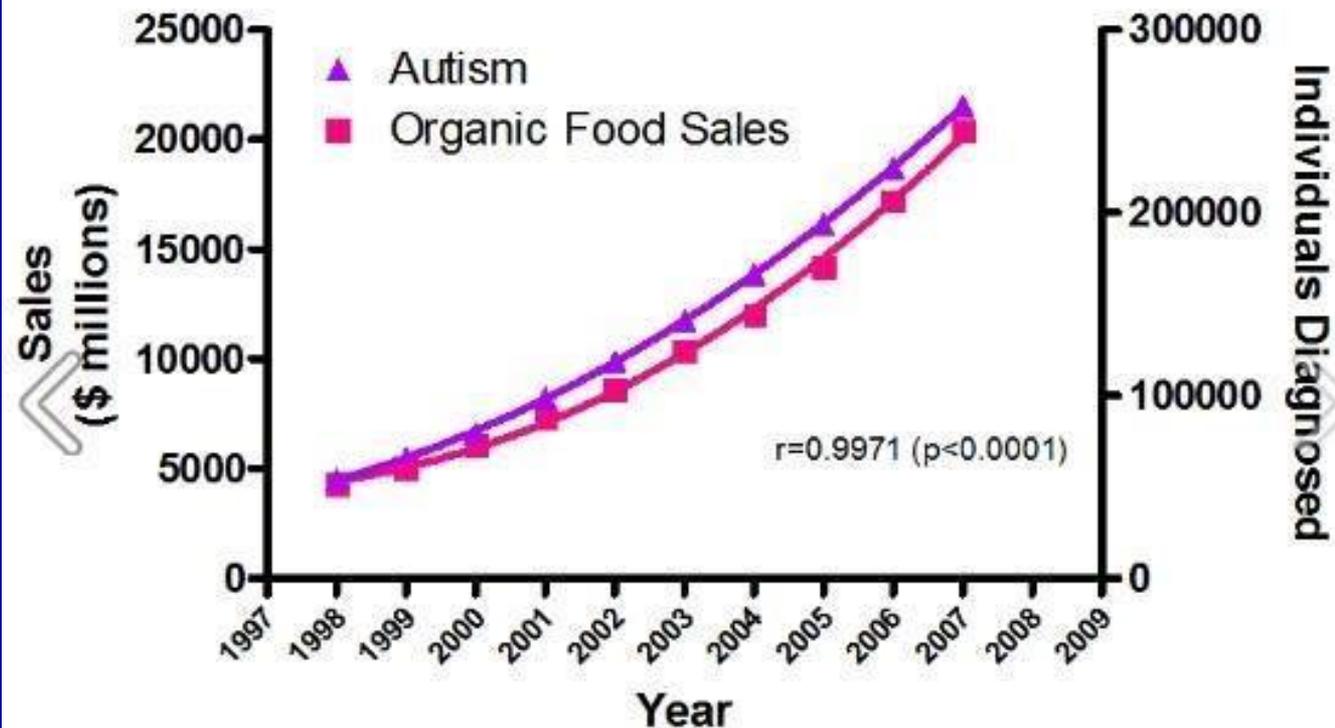


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Poor risk assessment association vs. causality



Sources: Organic Trade Association, 2011 Organic Industry Survey; U.S. Department of Education, Office of Special Education Programs, Data Analysis System (DANS), OMB# 1820-0043. *Children with Disabilities Receiving Special Education Under Part B of the Individuals with Disabilities Education Act

Andrew Wakefield



Wakefield's Paper

- Purported to show a link between behavioral changes characteristic of autism and MMR vaccine.
- Editors of *The Lancet* set up a news conference for this “preliminary report.”
- Wakefield goes off script: “With the debate that has been started, I cannot continue to support the continued use of the three vaccines together... My concerns are that one more case of this is too many and that we put children at no greater risk if we dissociated those vaccines into three...”

Aftermath

- Hysteria ensues.
- Media discussions of vaccine safety require “balance.”
- Letters to *The Lancet* almost immediately questioning/condemning the paper.
- Multiple studies show no credible link between MMR and Autism.
- Brian Deer does investigative reports on Wakefield’s paper in *The Times* of London in 2004 and in the *British Medical Journal* in 2010.
- The UK’s General Medical Council (GMC) conducts a 217-day hearing from July 2007 to May 2010 finding Wakefield unfit to practice.
- On February 2, 2010, the *Lancet* had quietly retracts Wakefield’s 1998 paper.

Brian Deer's Report on Wakefield's Paper

- Wakefield hired 1996 at £150/hour by a lawyer working to bring a lawsuit against vaccine manufacturers.
- Wakefield filed for a patent for a “safer” single measles vaccine in the UK in June 1997.
- Patients included in the study were recruited from anti-MMR groups; the study was funded for planned litigation.
- Records of the 12 children in the study showed that at least 5 had documented pre-existing developmental problems.
- Children who were portrayed as having their first behavioral concerns within days of MMR did not in fact begin having symptoms until months later.
- Wakefield obtained blood samples for controls at his child's birthday party, paying each child £5 for participating.

With science on our side, why doesn't *everyone* believe us?

- Poor risk assessment
- Creation of anti-vaccine martyrs
- Anti-vaccine advocates
 - Compassionate messages with personal narratives
- Pro-vaccine physicians
 - Science-only messages with statistics
 - Annoyance/accusation of parents

Poor risk assessment

- Proximity
- No experience of real disease risk
- Magical thinking
- Adrenaline: fight/flight/*freeze*
- Complicity with the potentially dangerous act
- Confusing association with causality
- AIDS vs. Pickup truck

Creation of anti-vaccine martyrs

- Andrew Wakefield's decredentialing established his *bona fides* as someone willing to give up everything for what he believes.
- J. B. Handley, co-founder of Generation Rescue: "To our community, Andrew Wakefield is Nelson Mandela and Jesus Christ rolled up into one... He's a symbol of how all of us feel."

Anti-vaccine advocates: Compassionate messages

- Wakefield: “What happens to me doesn’t matter. What happens to these children does matter.”
- Jenny McCarthy, actress, anti-vaccination stalwart, and president of Generation Rescue: “In profound solidarity with all the families still struggling, I decided to speak up. I wanted to give voice to options too often unspoken, and share hope for victories within reach. My family was given gifts that I wanted to share. Whether you’re in need at 3PM or 3AM, you have come to the right place. We are here for you, together resolving our heartaches and celebrating our victories.”



Generation Rescue is dedicated to recovery for children with autism spectrum disorders by providing guidance and support for medical treatment to directly improve the child's quality of life for all families in need.



<http://www.generationrescue.org/>



National Vaccine Information Center

Your Health. Your Family. Your Choice.

- “The National Vaccine Information Center (NVIC) is dedicated to the prevention of vaccine injuries and deaths through public education and to defending the informed consent ethic in medicine. As an independent clearinghouse for information on diseases and vaccines, NVIC does not advocate for or against the use of vaccines. We support the availability of all preventive health care options, including vaccines, and the right of consumers to make educated, voluntary health care choices.”
- “American Academy of Pediatrics (AAP) is a private membership organization representing 60,000 pediatricians. The AAP issues vaccination guidelines for its members and works to increase vaccine use and mandatory vaccination of all children.”
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National Vaccine Information Center

49 Doses of 14 Vaccines Before Age 6? Before you take the risk, find out what it is.

Pregnancy	Birth	2 Months	4 Months	6 Months	7 Months	12-15 Months	18 Months	3 Years	4-6 Years
Influenza	Hepatitis B	Diphtheria Tetanus Pertussis Polio HIB PCV Rotavirus Hepatitis B	Diphtheria Tetanus Pertussis Polio HIB PCV Rotavirus	Diphtheria Tetanus Pertussis Polio PCV Rotavirus Hepatitis B Influenza	Influenza	HIB PCV Measles Mumps Rubella Varicella Hepatitis A	Diphtheria Tetanus Pertussis Hepatitis A Influenza	Influenza	Diphtheria Tetanus Pertussis Polio Measles Mumps Rubella Varicella Influenza (2)



Vaccine excipients or ingredients in trace or larger amounts depending on specific vaccine (partial list):

lab altered viruses and bacteria; aluminum; mercury; formaldehyde; phenoxyethanol; gluteraldehyde; sodium borate; sodium chloride; sodium acetate; monosodium glutamate (MSG); hydrochloric acid; hydrogen peroxide; lactose; gelatin; yeast protein; egg albumin; bovine and human serum albumin; antibiotics; unidentified contaminants.



Pro-vaccine physicians

Annoyance/accusation of parents

- *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All*, Dr. Paul Offit, ID specialist at CHOP, co-developer of a rotavirus vaccine: “There’s a war going on out there... On one side are parents... On the other side are doctors... Caught in the middle are children...”
- *The Ladue News*, a local pediatrician, 2009: “I tell parents that there is absolutely no data to support [a vaccine-autism link, and failure to vaccinate children is] foolish and dangerous. Immunization is safe and effective with minimal minor side effects. There is a small but real chance of complications, including fatal complications, with both the chicken pox vaccine, which can lead to pneumonia, encephalitis and hepatitis, and the influenza vaccine, which can develop into pneumonia or other secondary bacterial infections.”

So what do we do?

Trust

- Assume parents love their kids.
- Recognize that parents have a very different knowledge base.
- Ask parents about the basis for their fears.
- Honor and value their emotions.
- Acknowledge that parental fear is real and even healthy.
- Share your stories.
- Help parents recognize the appropriate target for fear.
- Provide a fertile ground in which trust can grow.

Our Role & Our Scripts

- People respect doctors, nurses, health care providers.
Use that.
 - Be aware of tone of voice, body language, being on the same physical level
- “Yes &...”
 - **Avoid contradiction and the conjunction “but.”**
 - “That’s wrong, but what you need to know is...”
 - “I care about your kid; if *you* loved your kid...”
 - **Agree, and use the conjunction “and.”**
 - “I hear the fear in your voice. Fear for your child’s safety is normal and natural and healthy.
 - “I know you love your kid. I want the best for him too, and here’s what I’m afraid of...”

Where the Rubber Meets the Road

May I have two volunteers from the audience?

Case presentation, part 2

As they were getting ready to go home from the hospital after 5 sleepless, nerve-wracking nights, the mother of the 3 month old girl with pertussis told the clinic med attending that, if he wanted to tell people about how sick her daughter was and what she and their entire family went through to help convince other parents to vaccinate their kids on time, it might give some meaning to their ordeal.

“Dr. Haller,” she said, “I don’t ever want any other family to have to suffer what we went through.”

