



Vaccine Safety

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.msnbc.com

WHY NOT TO INDUCE • GENDER-FREE KIDS' CLOTHES

The Natural
Family Living
Magazine

Mothering

NO. 105 MAR/APRIL 2001

MERCURY in your vaccines

EXCLUSIVE REPORT
on the Second
International
Vaccine Conference

NO. 105 MAR/APRIL 2001
\$5.95 US \$7.95 CANADA
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04

Strategies for Talking With Parents Who Question Vaccines¹



- Take time to listen
- Solicit and welcome questions
- Use science
- Acknowledge benefits and risks
- Respect parent's authority
- Follow up

1. Centers for Disease Control and Prevention (CDC). Talking with Parents about Vaccines for Infants Strategies for Health Care Professionals (Reviewed March 2012).

Ask Questions-Does the Patient Have a Valid Contraindication?¹



- Severe allergic reaction (eg, anaphylaxis) after a previous vaccine dose
- Severe allergic reaction to a vaccine component
 - Egg, gelatin, neomycin
- Serious reaction after vaccination
 - Encephalopathy, Guillain-Barre syndrome
- Immunosuppression
- Pregnancy*

*Live attenuated vaccines, MMR, nasal flu, varicella.

1. Centers for Disease Control and Prevention (CDC). *MMWR Morb Mortal Wkly Rep.* 2011;60(2).

Conditions Commonly Misperceived as Contraindications¹



- Mild to moderate local reaction (ie, swelling, redness, soreness); low-grade or moderate fever after previous dose
- Lack of previous physical examination in well-appearing person
- Current antimicrobial therapy
- Convalescent phase of illness
- Premature birth
- Recent exposure to an infectious disease
- History of penicillin allergy, other non-vaccine allergies, relative with allergies, receiving allergen extract immunotherapy

**There may be considerations for some of these individuals;
however, they are not considered contraindications**

1. Centers for Disease Control and Prevention (CDC). *MMWR Morb Mortal Wkly Rep.* 2011;60(2).

Religious and Personal Belief Exemptions¹



- 48 states allow religious vaccination exemptions
 - Court has generally upheld the right of states to mandate vaccination in spite of parents' religious beliefs
- 20 states allow philosophical or personal belief objections
 - Parents usually must file a one-time or annual form attesting to personal objection
 - These increased from 0.99% to 2.45% between 1991 and 2004

1. The History of Vaccines. *Vaccination Exemptions*. 24 January 2014. Available at <http://www.historyofvaccines.org/content/articles/vaccination-exemptions>, Accessed Mar 18, 2014.

Respect and Address Concerns



The following slides address many of the myths that lead to hesitation and rejection of vaccination

**MYTH:
VACCINES DON'T WORK**



Reduction in Morbidity and Mortality From Vaccine-Preventable Diseases: *Historical review of vaccines licensed or recommended before 1980, US¹*



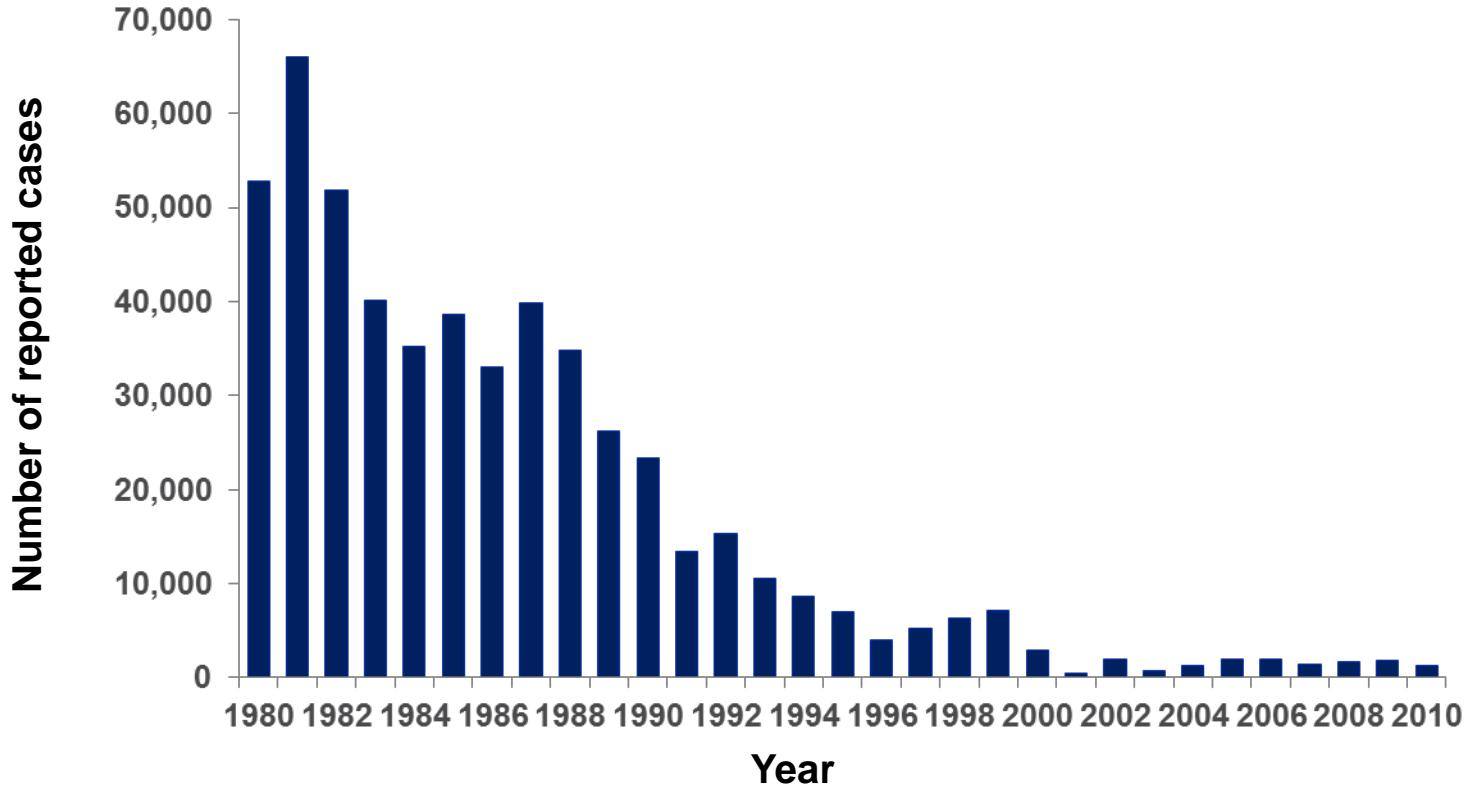
	Cases Prevaccine*	Cases Postvaccine (2006)	Deaths Prevaccine†	Deaths Postvaccine (2004)
Diphtheria	21,053	0	1,822	0
Mumps	162,344	6,584	39	0
Pertussis	200,752	15,632	4,034	27
Rubella	47,745	11	17	0
Tetanus	580	41	472	4

*Estimated annual average (diphtheria: 1936-1945, mumps: 1963-1968, pertussis: 1934-1943, rubella: 1966-1968, tetanus: 1947-1949).

†Most recent postvaccine reported number.

Vaccines have eliminated or substantially reduced the number of cases of multiple major infectious diseases

Global Impact of Vaccines: Number of Cases of Poliomyelitis Globally, 1980–2010¹



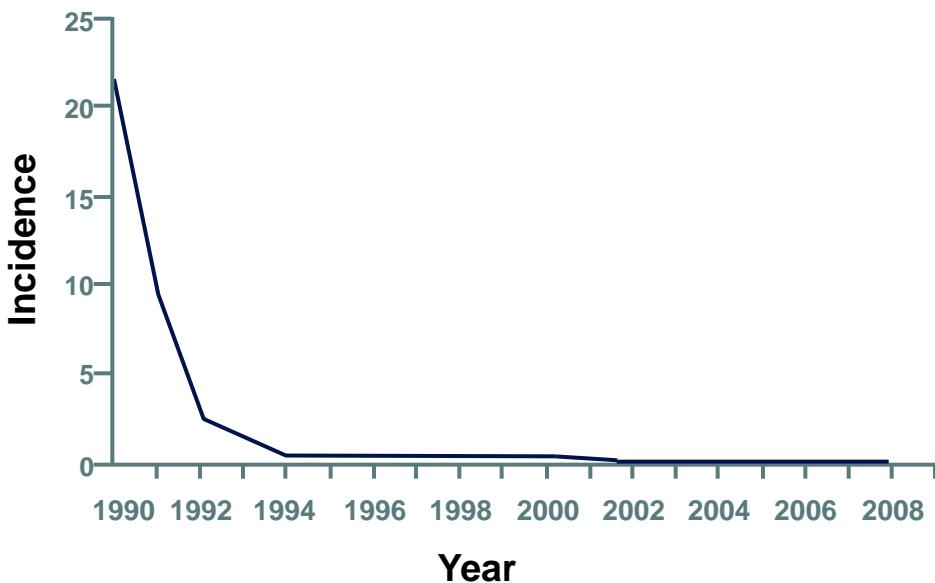
Polio cases globally have decreased by 98% since 1981

Hib Decline Following Routine Vaccination

United States and England & Wales

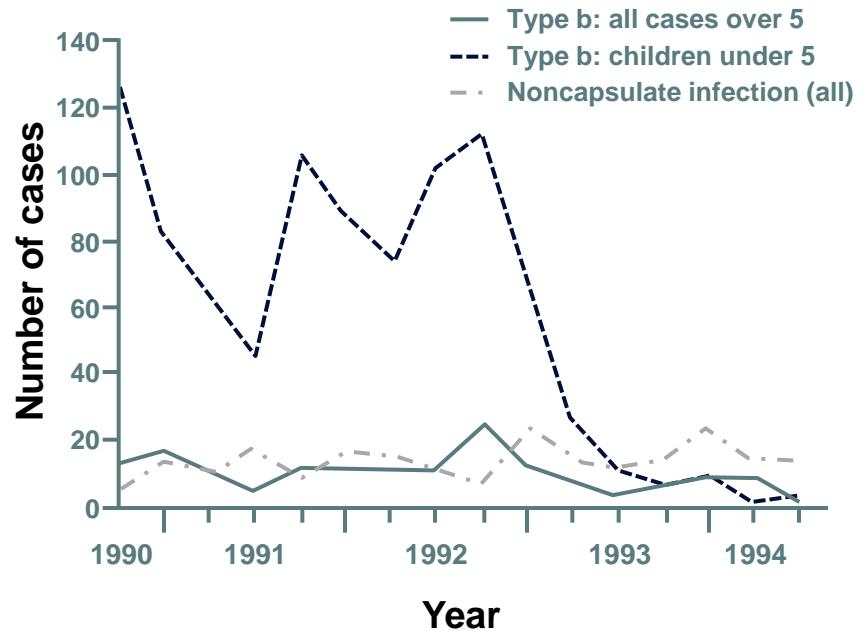


Incidence* of Invasive Hib Disease 1990–2009, US¹



*Rate per 100,000 children <5 years of age

Cases of Invasive Hib Disease 1990–1994, England & Wales²



Since the introduction of Hib conjugate vaccines in the United States (1988) and United Kingdom (1992), the incidence of Hib disease has declined by 99% and 98%, respectively³

Hib=*Haemophilus influenza* type b.

1. Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Atkinson W et al, eds. 11th ed. Washington DC: Public Health Foundation, 2011. 2. Hargreaves RM et al. *BMJ*. 1996;312(7024):160-161. 3. Heath PT et al. *JAMA*. 2000;284(18):2334-2340.

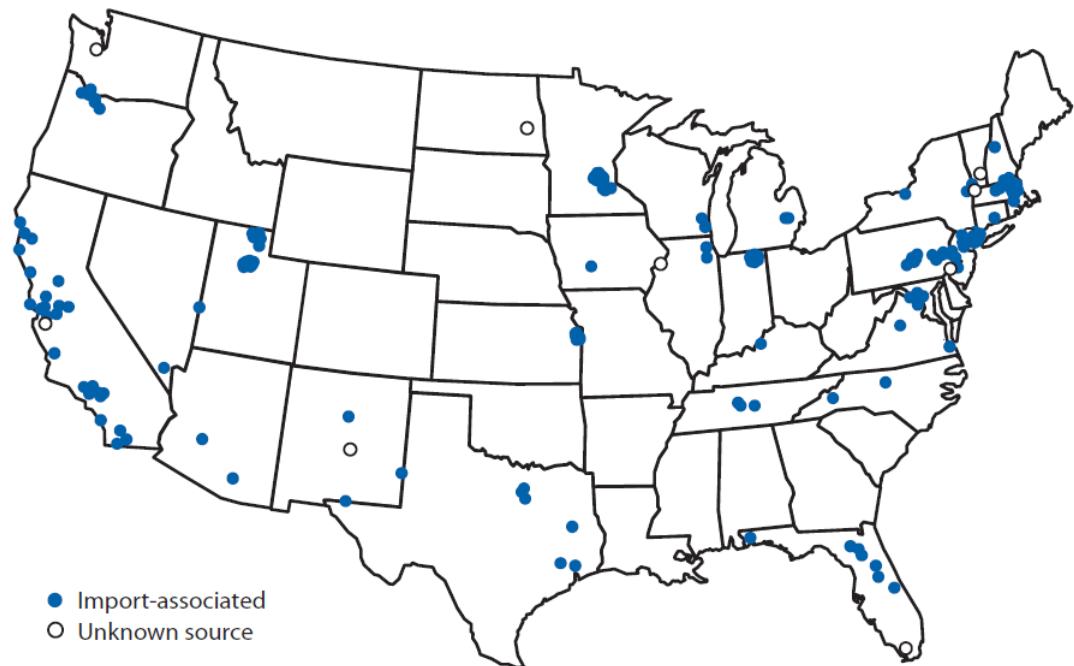


Vaccines

Measles Outbreaks – United States 2011



Origin of Reported Measles Cases (N=222)¹



- **90%** of the outbreaks were associated with importations from other countries
- **86%** of patients were unvaccinated or had unknown vaccination status
 - **85%** were eligible for MMR vaccination
 - **11%** were too young for vaccination
- **32%** were hospitalized

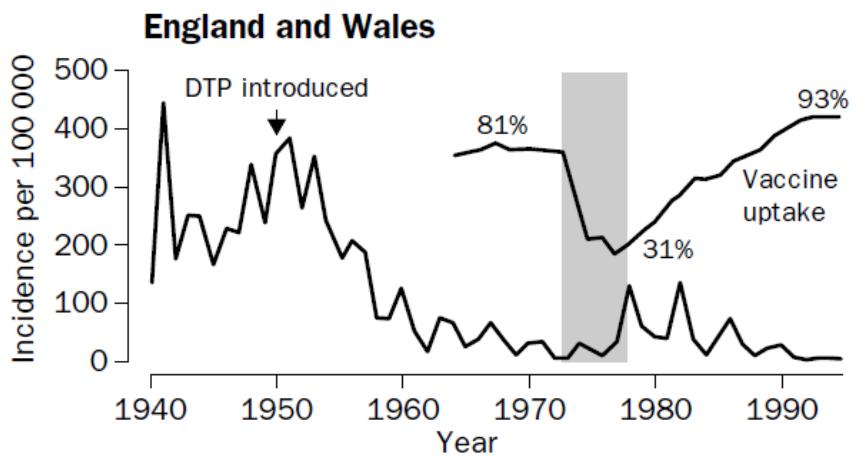
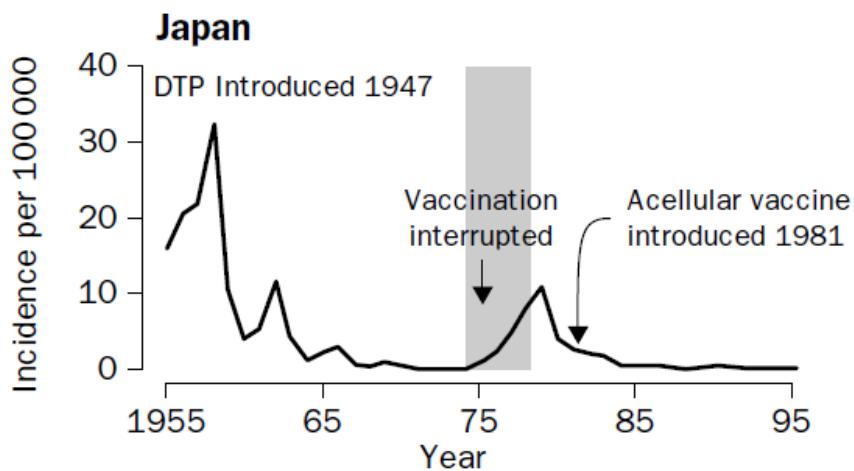
The cost of containing one case of measles in Iowa in 2004: ~\$140,000²



Interruption of Vaccination Led to Rebound of Pertussis¹



Rise in Pertussis Following Vaccine Interruption



Gray areas indicate movements against whole cell pertussis vaccines.

Note: Scales vary.

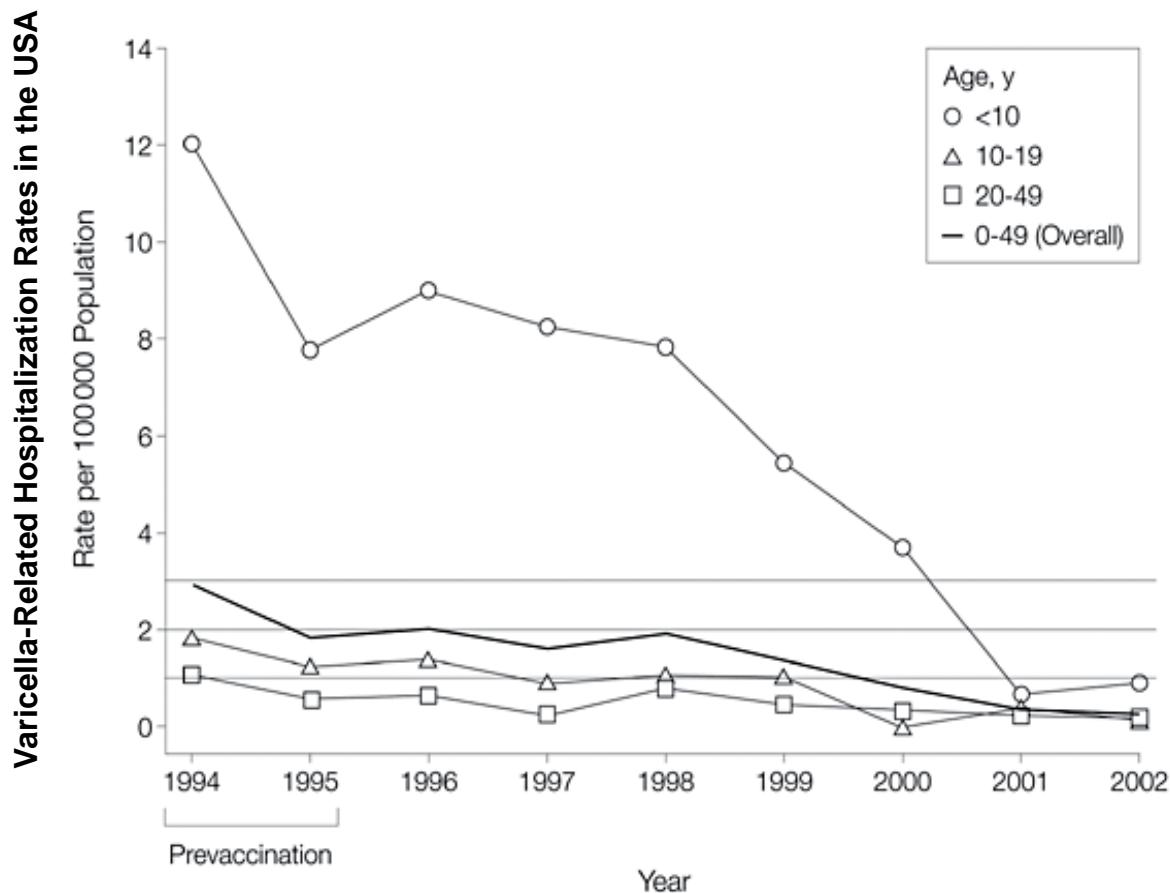
**MYTH:
IMPROVED HYGIENE LED TO
DECREASE IN DISEASE**



Vaccines Introduced During Times of Modern Hygiene Are Effective¹



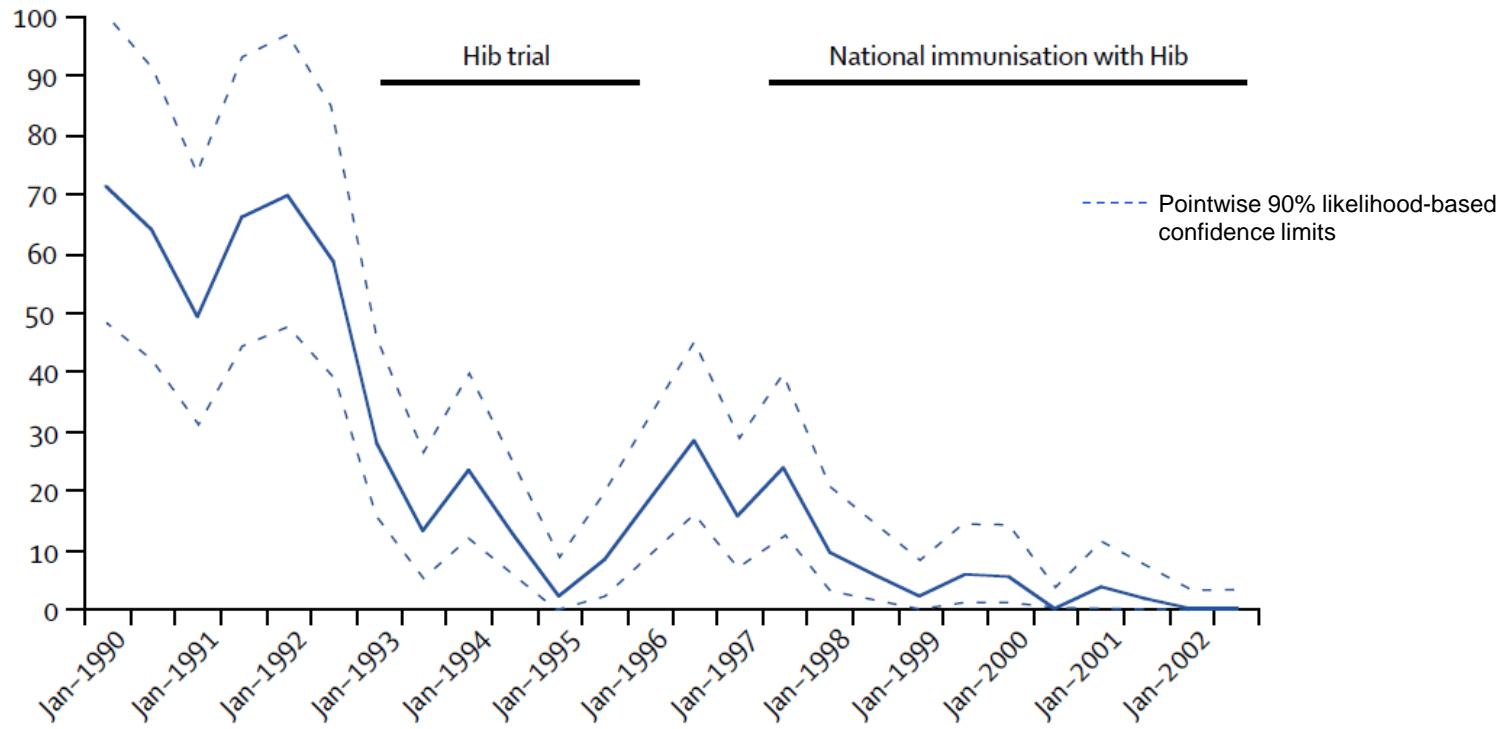
Decline in Varicella Hospitalizations After Routine Vaccination



Vaccines Work in Countries With Poor Hygiene



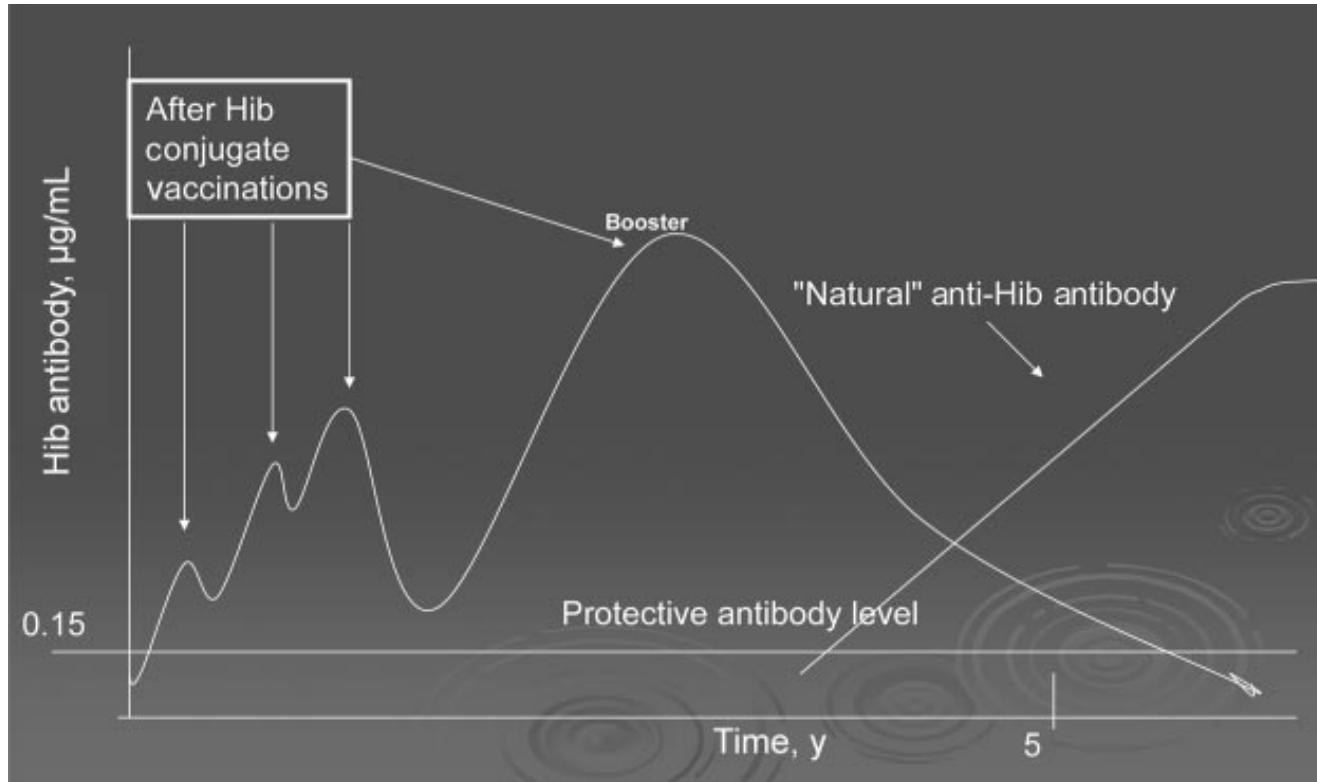
Hib Incidence in the Western Region of The Gambia, Children <5 Years of Age¹



In 2004, 65% of population had access to safe water and 23% to sanitary facilities²

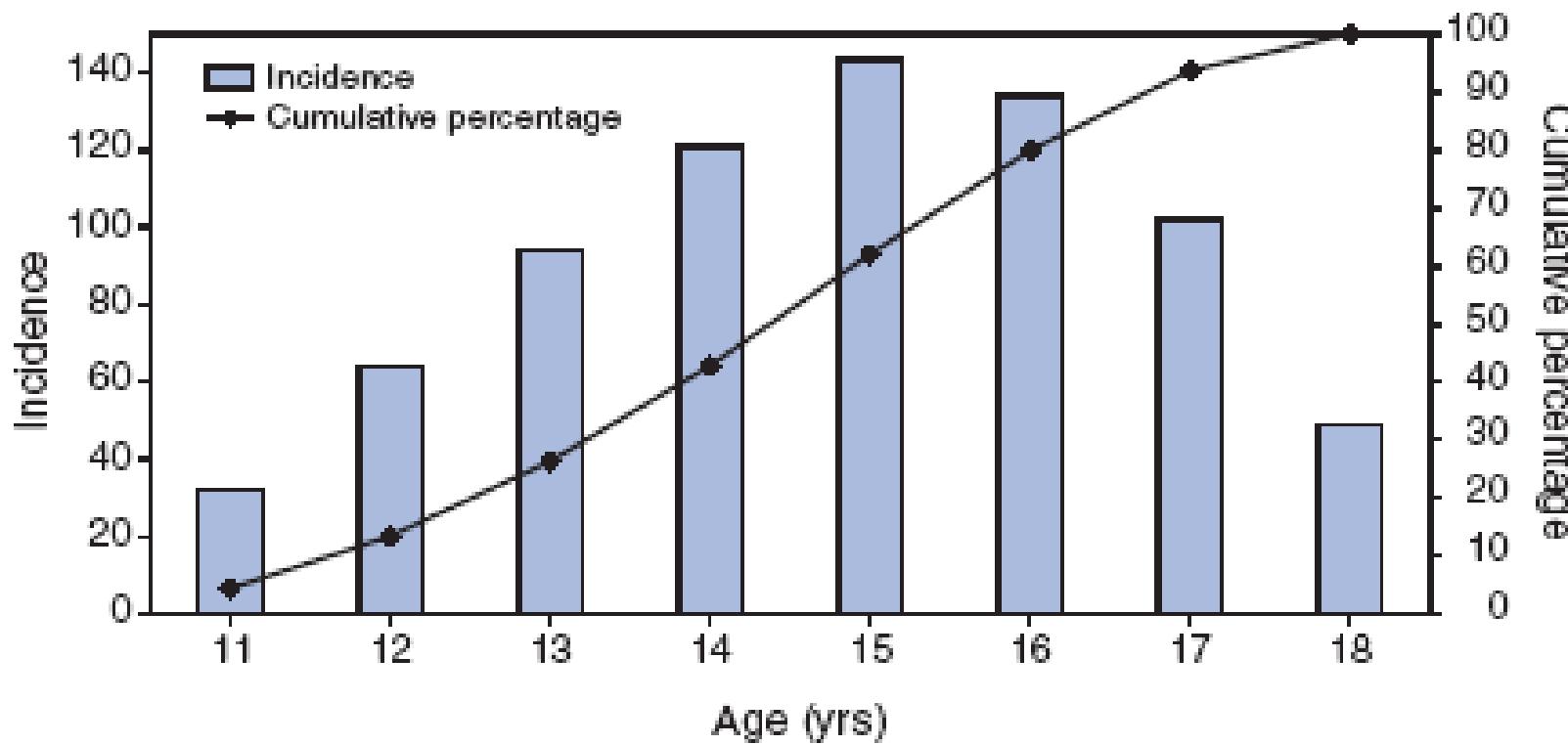
VACCINE EFFECTIVENESS

Some Vaccines Require Multiple Doses



- Some vaccines provide a low level of protection after a single dose, but additional doses provide a greater response¹
- Agents that change often and older versions would not offer protection (eg, Influenza)²

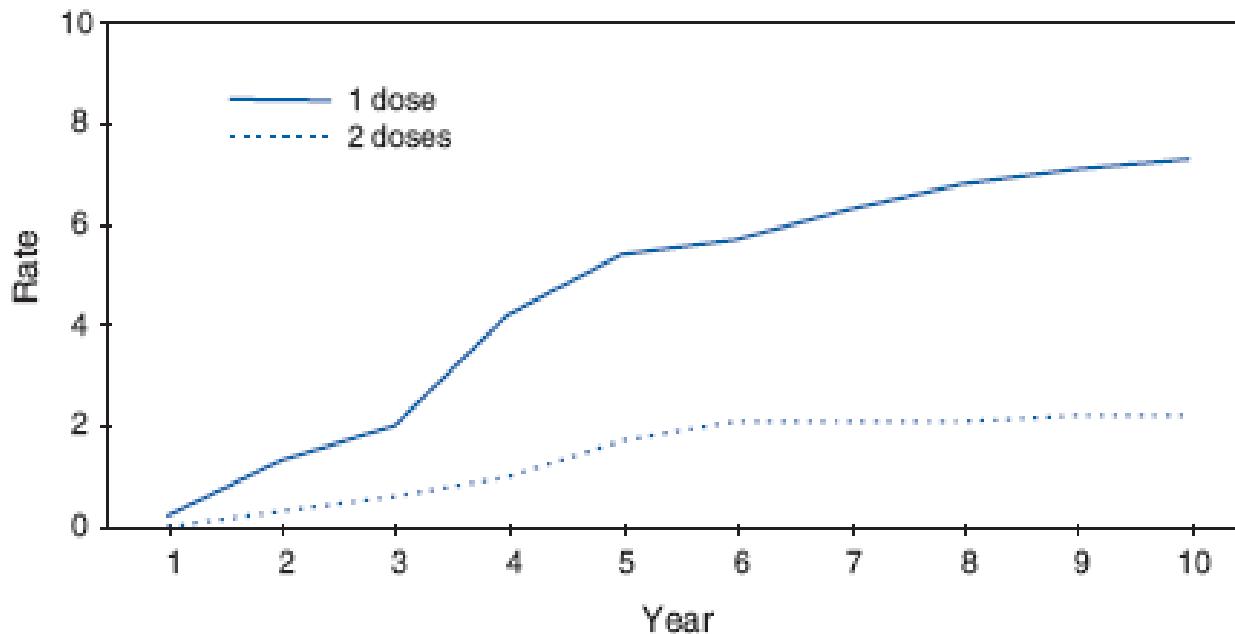
Waning Vaccine-Induced Immunity Led to Pertussis Outbreaks¹



Average annual incidence* of reported pertussis in adolescents by age-MA, 1996-2004 (CDC 2005, *per 100,000 population)



Varicella Booster Reduces Breakthrough Rate Among Children¹



Cumulative Breakthrough Rates per 100 person-years at risk for 1 and 2 doses of single antigen varicella vaccine among children aged 12 mo-12yr by number of years after vaccination-USA,1993-2003

First dose 12–15 mo of age and second dose 4–6 yrs of age

**MYTH:
VACCINES ARE NOT SAFE**

**THERE ARE HOT LOTS OF
VACCINES**

Regulatory Phases of Vaccine Development¹



Clinical Trial Phase



Phase 1

Safety
Immunogenicity

Phase 2

Safety
Immunogenicity
Dose ranging

Phase 3

Safety
Immunogenicity
Efficacy

Post-Clinical Trial Phase

Continued safety
and efficacy
monitoring

Vaccine development involves many years and multiple well regulated phases for efficacy and safety

Continuous testing for safety after approval

VAERS

FDA Does Rigorous Testing to Ensure Vaccine Product Safety¹



- Each batch is tested for safety, potency, and purity
- Each lot of product must be tested

¹. Food and Drug Administration (FDA). *Ensuring the Safety of Vaccines in the United States*. 2011. <http://www.fda.gov/downloads/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM298181.pdf>. Accessed March 24, 2014

Clinical Trials Assess Vaccine Safety in Tens of Thousands of Subjects¹



Case Study:

Rotavirus Efficacy and Safety Trial (REST)²

- Nearly 70,000 infants enrolled from 356 sites in 11 countries worldwide



**Dodger stadium seat capacity
56,000³**

1. Food and Drug Administration (FDA). Inside Clinical Trials: Testing Medical Products in People. <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143531.htm>. Accessed March 24, 2014.
2. Clinicaltrials.gov NCT00090233. <http://clinicaltrials.gov/ct2/show/results/NCT00090233?term=Rotavirus+Efficacy+and+Safety+Trial&rank=1>. Accessed March 24, 2014.
3. Dodger Stadium History. <http://losangeles.dodgers.mlb.com/la/ballpark/information/index.jsp?content=history>. Accessed March 24, 2014.

Thimerosal Safety



- Thimerosal is a mercury-based preservative used for decades in the United States in multi-dose vials of medicines and vaccines¹
- Thimerosal contains **ethylmercury**, not **methylmercury**, which can be toxic to people¹
- According to CDC, thimerosal does not stay in the body long, so it does not build up and reach harmful levels¹
- Since 2001, thimerosal is not used as a preservative in routinely recommended childhood vaccines (except some flu vaccines)³

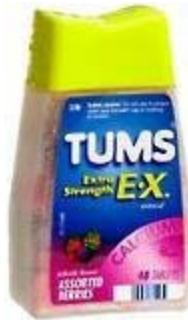
1. Centers for Disease Control and Prevention (CDC). Frequently Asked Questions About Thimerosal. http://www.cdc.gov/vaccinesafety/concerns/thimerosal/thimerosal_faqs.html.
2. Centers for Disease Control and Prevention (CDC). Timeline: Thimerosal in Vaccines (1999-2010). http://www.cdc.gov/vaccinesafety/concerns/thimerosal/thimerosal_timeline.html.
3. Centers for Disease Control and Prevention (CDC). Vaccine Safety. <http://www.cdc.gov/vaccinesafety/Concerns/Thimerosal/Index.html>.

Aluminum is everywhere



USDA United States Department Of Agriculture
Agricultural Research Service

Breeding Aluminum Tolerance Into Wheat



**50 mg of aluminum/slice
in wrapped processed cheese**



Typical adults ingest 7 to 9 milligrams of aluminum per day.

Aluminum in Vaccines¹



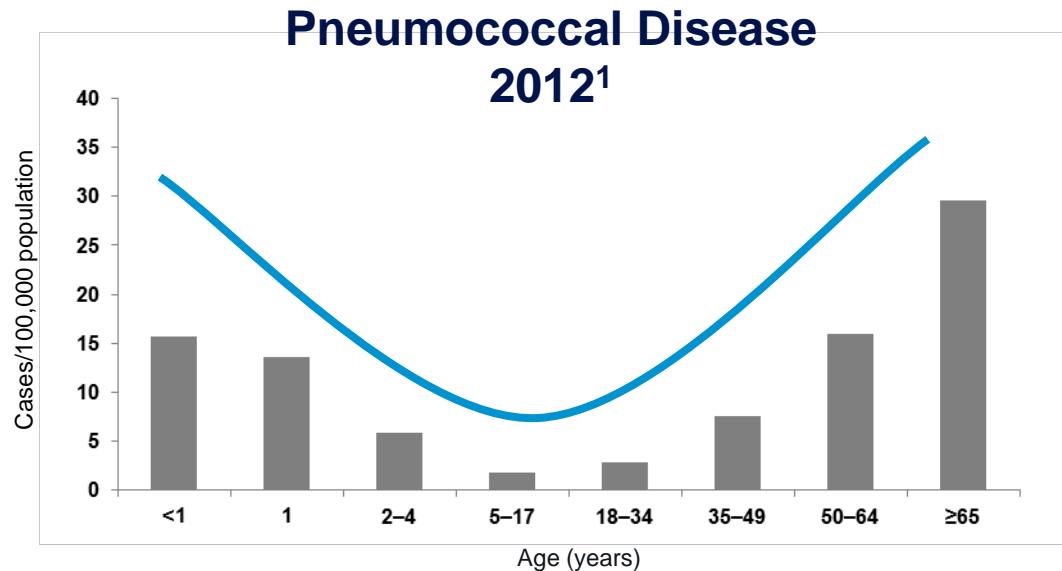
- Aluminum is present in several vaccines to improve immune response, allowing for fewer shots
- The body rapidly eliminates aluminum
- Those harmed by aluminum have kidney dysfunction and must receive large quantities of aluminum for months/years
- During the first 6 months of life
 - 4 mg of aluminum in vaccines
 - 10 mg in breast milk
 - 40 mg in infant formula
 - 120 mg in soy-based formula

MYTH: THE VACCINE SCHEDULE IS UNSAFE

Vaccination of Infants and Older Individuals Is Important



- Diseases that vaccines prevent often occur in very young infants and older individuals¹
- Infants and older adults are capable of making a protective immune response^{2,3}



Combination Vaccines¹



- Combination vaccines have more than one vaccine in a single shot
- Combinations carry no greater risk for adverse side effects
- Combinations vaccines have been used in the United States since the mid-1940s
- Combination vaccines help to immunize children as quickly as possible, allow fewer office visits and less discomfort for the child

Multiple Vaccines Do Not Overwhelm the Immune System¹



- In theory a child could respond to 10,000 vaccines
 - Using this estimate, 11 vaccines would “use up” 0.1% of an infant’s immune system
- Today’s vaccines contain fewer antigens

Number of Antigens Contained in Vaccines Over the Past 100 yrs

1900		1960		1980		2000	
Vaccine	Proteins	Vaccine	Proteins	Vaccine	Proteins	Vaccine	Proteins/ Polysaccharides
<u>Smallpox*</u>	~200	Smallpox	~200	Diphtheria	1	Diphtheria	1
<u>Total</u>	~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
		<u>Total</u>	~3217	Mumps#	9	Mumps	9
				Rubella**	5	Rubella	5
				<u>Total</u>	~3041	Hib††	2
						Varicella††	69
						Pneumococcus§§	8
						<u>Hepatitis B </u>	1
						<u>Total</u>	123-126

**MYTH:
THE MMR VACCINE
CAUSES AUTISM**



No Causal Link Between the MMR Vaccine and Autism



- Many large, well-designed studies have found no link between vaccination with MMR and autism¹
- Autism usually presents around the age when MMR is given¹
- Autism likely has multiple components, including genetics²
- MMR prevents wild measles-induced subacute sclerosing panencephalitis (SSPE)³

1. Centers for Disease Control and Prevention (CDC). Vaccine Safety. *MMR Safety*.

<http://www.cdc.gov/vaccinesafety/vaccines/mmr/mmr.html>, Accessed March 18, 2014. 2. CDC Facts About ASDs

<http://www.cdc.gov/nccddd/autism/facts.html>, Accessed March 18, 2014. 3. CDC. Measles (Rubeola). *Complications of Measles*.

<http://www.cdc.gov/measles/about/complications.html>, Accessed March 18, 2014.

Retraction of the Wakefield Paper



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

Following the judgment of the UK General Medical Council's Fitness to Practise Panel on Jan 28, 2010, it has become clear that several elements of the 1998 paper by Wakefield et al¹ are incorrect, contrary to the findings of an earlier investigation.² In particular, the claims in the original paper that children were "consecutively referred" and that investigations were "approved" by the local ethics committee have been

proven to be false. Therefore we fully retract this paper from the published record.

The Editors of The Lancet
The Lancet, London NW1 7BY, UK

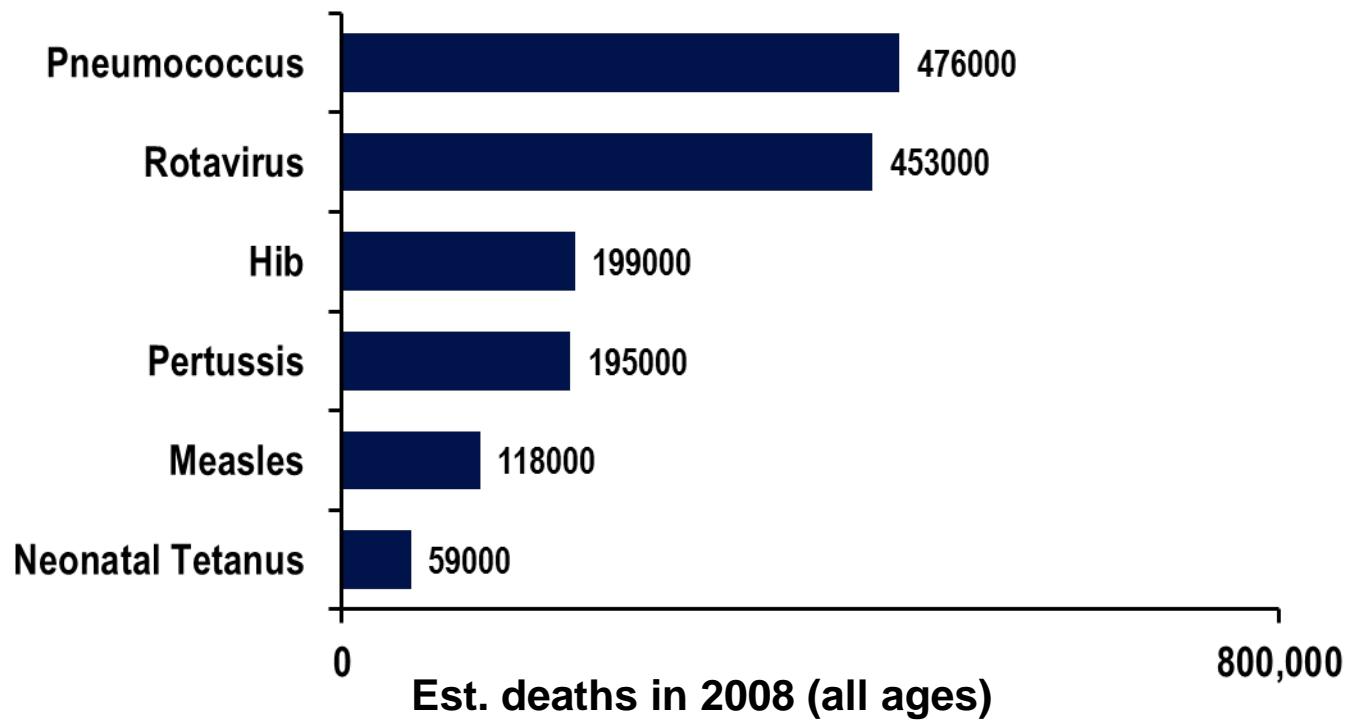
- 1 Wakefield AJ, Murch SH, Anthony A, et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet* 1998; 351: 637-41.
- 2 Hodgson H. A statement by The Royal Free and University College Medical School and The Royal Free Hampstead NHS Trust. *Lancet* 2004; 363: 824.

10 of the 13 authors of the study have withdrawn their support of the article and the lead author was found guilty of medical misconduct and has lost his medical license in the UK.²

**MYTH:
NATURAL INFECTION IS
BETTER THAN IMMUNIZATION**

Infection Comes With a High Price

- Of the estimated 8.8 million deaths in children less than 5 years old in 2008, 17% were vaccine preventable.¹



1. World Health Organization (WHO). Global Immunization Data. 2014 .
http://www.who.int/immunization/monitoring_surveillance/Global_Immunization_Data.pdf

Infection Comes With a High Price



Courtesy of CDC/NIP/
Barbara Rice



Courtesy of CDC



Courtesy of CDC/Dr. Andre J. Lebrum



Courtesy of CDC

Reasons to Continue to Vaccinate



- Disease occurs in the United States at very low levels; when immunization rates drop, outbreaks occur¹
- Disease occurs frequently in other parts of the world and can be imported by travel²
- Certain infectious agents like tetanus, which is part of soil flora, cannot be eliminated³



**DON'T WORRY ABOUT EVERY
POSSIBLE QUESTION**

Reliable Sources for Immunization Information



American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™



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

- Disease information
- Questions/concerns
- Immunization schedules
- Possible side effects

<http://www2.aap.org/immunization/>

- Disease information
- Immunization schedules
- Vaccine safety

<http://vaers.hhs.gov/index>

- Vaccine adverse event reporting

