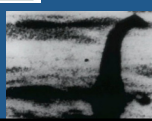


Dispelling the Common Anti-Vaccine Myths

Paul J Carson, MD, FACP

NDSU CENTER FOR IMMUNIZATION RESEARCH AND EDUCATION



Overview

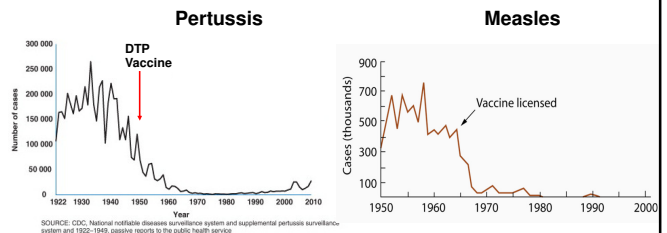
- The tremendous success of vaccination
- Success of vaccination, especially for the most vulnerable, is dependent on high communal uptake - being threatened by increasing skepticism and hesitance
- Review the current main concerns for vaccine hesitancy and evidence basis for their safety

The Tremendous Impact of Immunization on Our Health

| Disease | 20 th Century Annual Morbidity* | 2013 Reported Cases† | Percent Decreased |
|-------------------------------|--|----------------------|-------------------|
| Smallpox | 29,005 | 0 | 100% |
| Diphtheria | 21,053 | 0 | 100% |
| Pertussis | 200,752 | 28,639 | 86% |
| Tetanus | 580 | 26 | 96% |
| Polio (paralytic) | 16,316 | 1 | >99% |
| Measles | 530,217 | 187 | >99% |
| Mumps | 162,344 | 584 | >99% |
| Rubella | 47,745 | 9 | >99% |
| Congenital Rubella Syndrome | 152 | 1 | 99% |
| <i>Haemophilus influenzae</i> | 20,000 (est.) | 31‡ | >99% |

Sources:
 * JAMA. 2007;298(18):2155-2163
 † CDC. MMWR August 15, 2014;63(32):702-715. (MMWR 2013 final data)
 ‡ *Haemophilus influenzae* type b (Hib) <5 years of age. An additional 10 cases of Hib are estimated to have occurred among the 385 reports of HI (<5 years of age) with unknown serotype

The Tremendous Impact of Immunization on Our Health



Impact of Routine Childhood Immunization

U.S. Birth Cohort, 2009


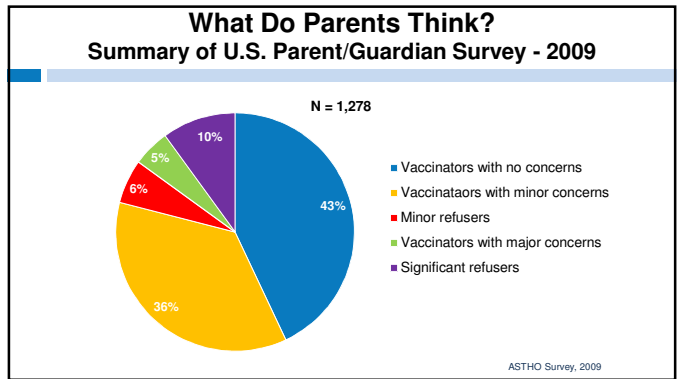
| | |
|---------------------------------|----------------|
| Cases prevented | 20,000,000 |
| Deaths prevented | 42,000 |
| Direct costs saved | \$13.5 billion |
| Direct and indirect costs saved | \$68.8 billion |

Zhou. Pediatrics. 2014

Vaccines have become victims of their own success



Increasingly, parents are skeptical of the safety and necessity of vaccines and are opting out of immunizing their children

Stop Forced Vaccinations
ExperimentalVaccines.org

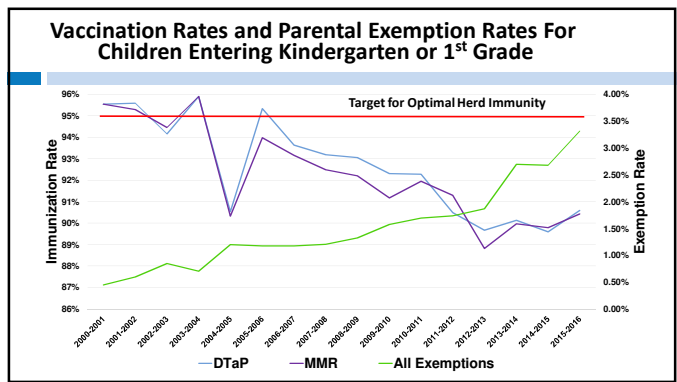
Prevent autism?
Don't vaccinate!




Without a Doubt, It's Time to Stop the Push for More Vaccines 2013

Sudden Infant Death Syndrome
Up to 60% of Immune System Destroyed

| | |
|---|----------------------------|
| Neurological Disease | Attention Deficit Disorder |
| Organ Disease | Learning Disabilities |
| Autism | Brain Cell Loss |
| Cancer | Allergies |
| Asthma | Phobias |
| Leukemia | Total Paralysis |
| Spermatogenic Toxicity | Multiple Sclerosis |
| Developmental Damage | Auto-Immune Diseases |
| Seizures - Epilepsy - Dizziness - Blindness | |
| Central Nervous System Damage | |
| Death | |



Herd Protection



Herd Immunity Threshold (1 - 1/R0)

USA TODAY

Measles cases in U.S. rise; most unvaccinated, CDC says

By Donald G. McNeil, Jr. MAY 29, 2014

Pertussis

By Dee Riggs
World staff writer
Tuesday, December 28, 2010

facoma

By DAN MITCHINSON
KIRO Radio


Specific Parental Concerns

- Risk of autism from the MMR vaccine
- Believe child receives too many shots too soon
- Risks from "toxins" in the vaccines, (mercury-thimerosal, aluminum, formaldehyde)
- Dangers from the disease are minimal, vaccine not necessary (influenza, chickenpox, neonatal hepatitis B)
- Long-term effects of vaccine and possible links to chronic auto-immune disease
- Ethical and safety concerns about vaccines grown in cell lines derived from an aborted fetus

Specific Parental Concerns

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What is the Science of Causality?



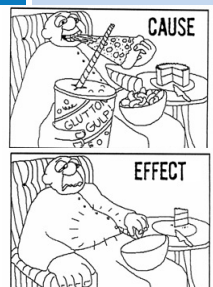
"He was vaccinated and something changed. My son is my science"

IT'S A FAIR QUESTION TO ASK.

Our Brains are Hardwired to Make Associations




Some Associations Help Us and Some Don't



Observation: People who sleep in their shoes frequently wake up with headaches

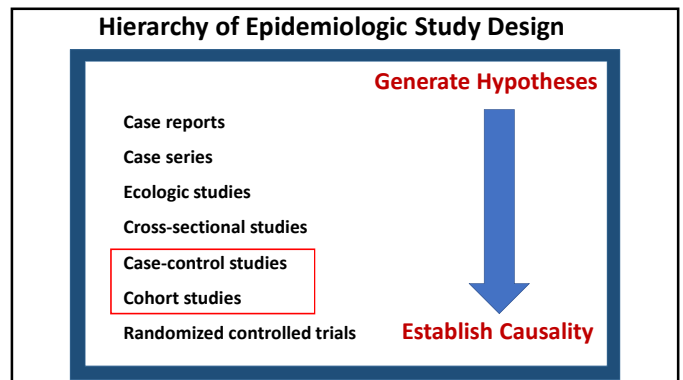
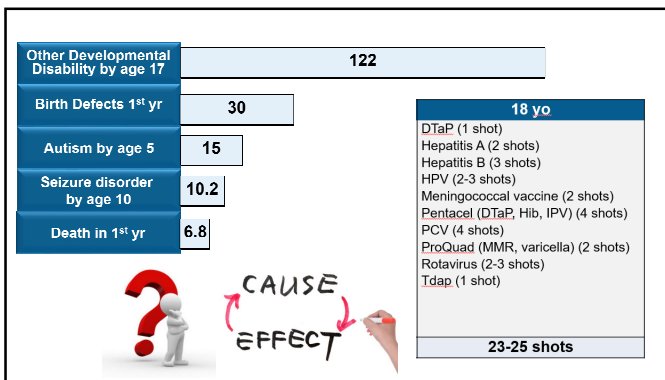
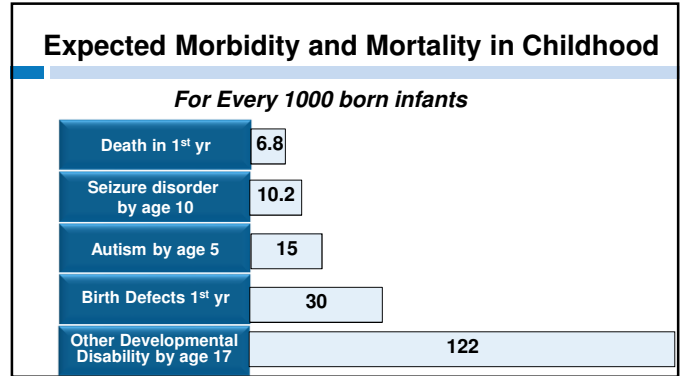
Conclusion: Going to bed with shoes on causes headaches



DEADLY CHOICES


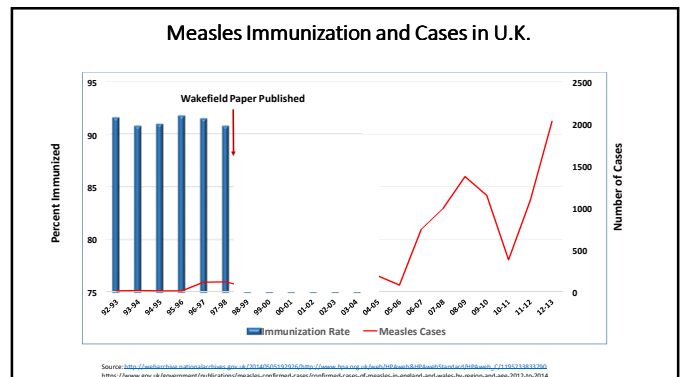
— HOW THE ANTI-VACCINE MOVEMENT THREATENS US ALL —

PAUL A. OFFIT, M.D.

Modern Anti-Vaccine Origins

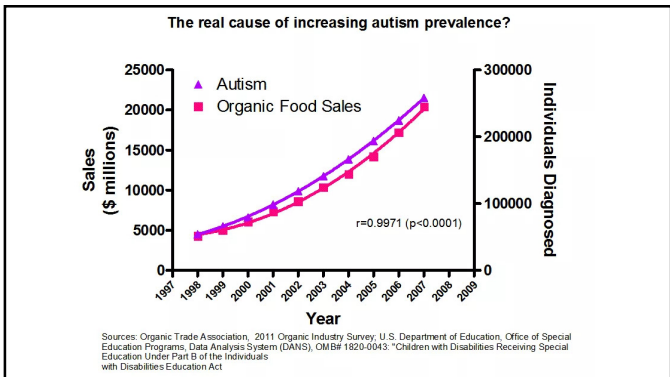
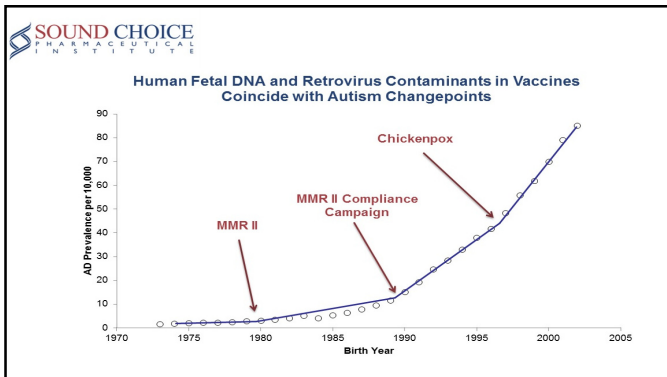
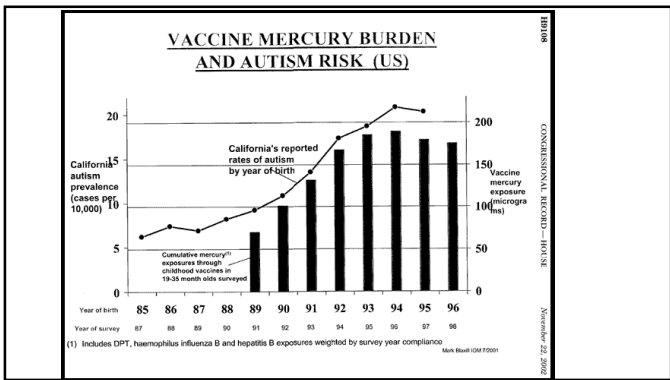
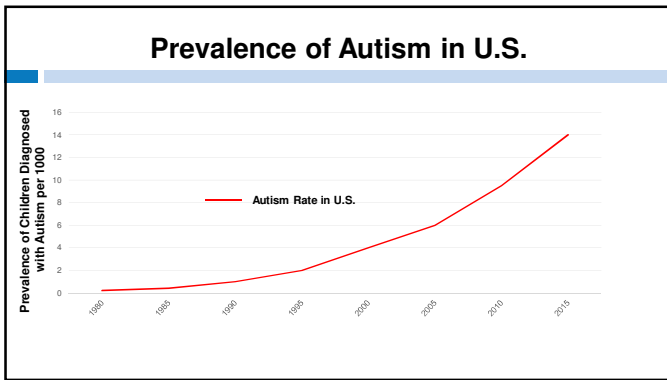
- British physician and researcher, gastroenterologist
- Study published in Lancet 1998
- Study of 12 children with a history of autism or developmental disorder "referred" to gastroenterology clinic.
- Findings:
 - Onset of behavioral symptoms, per parents, started after MMR immunization in 8 of the children
 - Bowel abnormalities in all of the children on endoscopy
- Conclusions: speculated a connection between bowel pathology after MMR immunization that allowed "toxins" to circulate to brain causing brain damage and autism

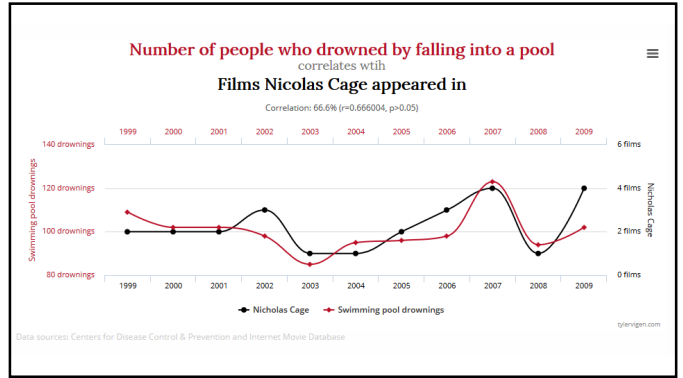
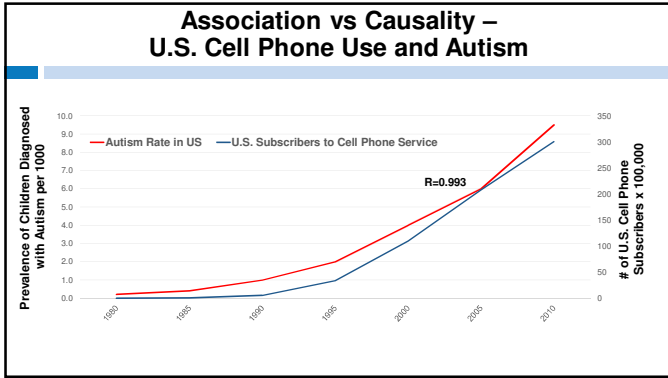





Americans Beliefs About Autism and Vaccines

- Online Harris poll of 1756 adults for the National Consumer League in 2013
- Only 39% of parents described themselves as being extremely or very knowledgeable about how vaccines work..... Yet.....
- 33% of parents of children under 18, and 29% of adults agree with the statement, "vaccinations can cause autism".

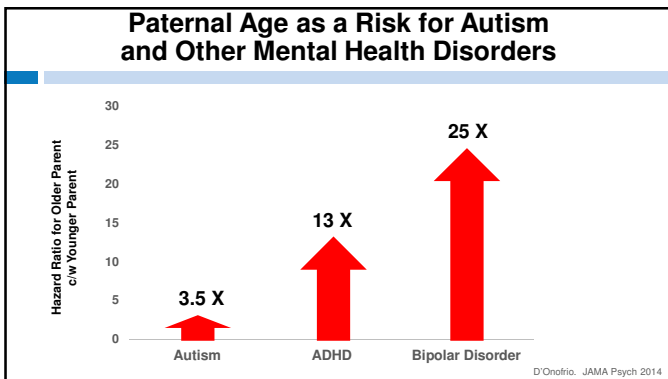
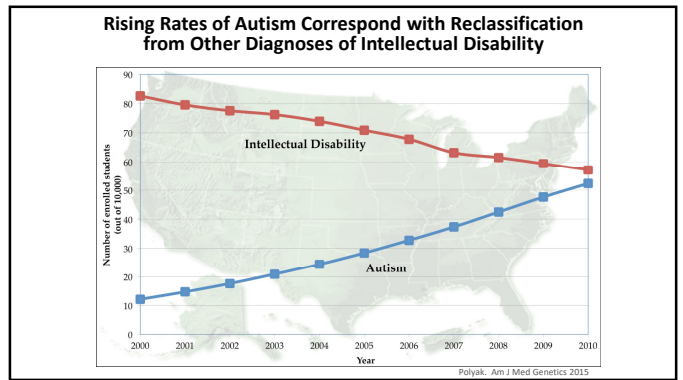




Autism Signs Present Before Vaccination

- Focal patches of abnormal brain development in prefrontal and temporal brains of ASD children suggesting abnormal prenatal development¹
- Fetal US shows abnormal head and abdominal circumference around 20 wks gestation²
- Experts reviewing 1 y.o. birthday videos could correctly identify autistic vs non-autistic children 10/11 times in 2 separate groups³

1. Stoner R. N Engl J Med 2014; 370:1209-1219
 2. Sattler L. International Congress of the Royal College of Psychiatrists, 2014
 3. Osterling J. et al. J of Autism and Developmental Disorders, 1994



Cohort Studies Comparing Risk of Autism/ASD with Exposure to MMR, Mercury, or Thimerosal



| Study name | Statistics for each study | Odds ratio and 95% CI |
|--|---------------------------|-----------------------|
| <p>Total number of children studied in these 5 Cohort Studies N = 1,256,407</p> <p>Avg length of follow up – 8.6 yrs</p> <p>Conclusions – No association</p> | | |

Taylor LE. Vaccine 2014.

Cochrane Review of Autism/MMR Link

- Respected independent collaboration that undertakes exhaustive reviews of the medical literature
- Feb 2012 released their review of **27 cohort studies, 17 case-control studies, 5 time-series trials, 1 case cross-over trial, 2 ecological studies, 6 self-controlled case series**
- All told – involved **14,700,000** children assessing safety and efficacy of MMR vaccine
- Conclusions: Vaccine was **not associated with autism, asthma, leukemia, hay fever, diabetes, gait disturbance, Crohns disease, or demyelinating disease**

Brian Deer - Investigative Reporter



Early signs

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

Summary

Background

Results

Conclusions

RETRACTED

Do Too Many Vaccines “Overwhelm” the Immune System?

1940

DTP
SMALLPOX

*some children got 4 shots before the age of 2. NEVER with more than 1 shot per visit

1980

DTP (2 months)
DTP (4 months)
Polio (4 months)
Polio (6months)
MMR (12 months)
DTP (18 months)
DTP (5 years old)

*children got 8 shots before age 2 and NEVER with more than 2 shots per visit

2012

Flu/H1N1 (Pneumonia)
HepB (Bilirubin)
Dtap (2 months)
Polio (2 months)
Hib (2 months)
Dtap (2 months)
Rotavirus (2months)
HepB (2 months)
Dtap (4 months)
Polio (4 months)
Hib (4 months)
Rotavirus (4 months)
Dtap (6 months)
Polio (6 months)
Hib (6 months)
Rotavirus (6 months)
Dtap (8 months)
Polio (8 months)
Hib (8 months)
Rotavirus (8 months)
Dtap (10 months)
Polio (10 months)
Hib (10 months)
Rotavirus (10 months)
Dtap (12 months)
Polio (12 months)
Hib (12 months)
Rotavirus (12 months)
Dtap (15 months)
Polio (15 months)
Hib (15 months)
Rotavirus (15 months)
Dtap (18 months)
Polio (18 months)
Hib (18 months)
Rotavirus (18 months)
Dtap (24 months)
Polio (24 months)
Hib (24 months)
Rotavirus (24 months)

*49 DOSES of 14 vaccines by the age of 6 (in 2012)

Educate Before You Vaccinate

groud parents of unvaccinated children find us on facebook

Antigens are what activate the immune system, not numbers of vaccines or shots.

Need to count antigens!

More Childhood Vaccines— But Fewer Antigens

Thanks to advances in technology, vaccines today contain fewer antigens. Even with more vaccines, the total immunologic load is much less.^{1,2}

| Number of Immunogenic Proteins and Polysaccharides Contained in Vaccines Over the Past 100 Years | | | | | | | |
|--|-------------|--------------|--------------|--------------|----------|---------------------|---------------------------|
| 1900 | | 1960 | | 1980 | | 2000 | |
| Vaccine | Proteins | Vaccine | Proteins | Vaccine | Proteins | Vaccine | Proteins/ Polysaccharides |
| Smallpox | ~200 | Smallpox | ~200 | Diphtheria | 1 | Diphtheria | 1 |
| TOTAL | ~200 | Diphtheria | 1 | Tetanus | 1 | Tetanus | 1 |
| | | Tetanus | 1 | WC pertussis | ~3000 | Acellular pertussis | 2-5 |
| | | WC pertussis | ~3000 | Polio | 15 | Polio | 15 |
| | | Polio | 15 | Measles | 10 | Measles | 10 |
| | | TOTAL | ~3217 | Mumps | 9 | Mumps | 9 |
| | | Rubella | 5 | Rubella | 5 | Rubella | 5 |
| | | TOTAL | ~3041 | Hib | | Hib | 2 |
| | | Varicella | | Varicella | | Varicella | 69 |
| | | Pneumococcus | | Pneumococcus | | Pneumococcus | 8 |
| | | Hepatitis B | | Hepatitis B | | Hepatitis B | 1 |
| | | TOTAL | | TOTAL | | TOTAL | 123-126 |

WC = Whole-cell

References: 1. Offit PA, et al. Pediatrics. 2002;109(1):124-129. 2. CDC. Vaccines and How They Work. 4th ed. CDC. National Immunization Program, Immunization Services Division; 2004.

Do Too Many Vaccines “Overwhelm” the Immune System?

- Infants have tremendous capacity to generate immune responses except to antigens that are T-cell independent (like polysaccharides). Excellent responses to T-cell dependent antigens
- Estimated cellular capacity: Could easily handle up the immune load of up to 10,000 vaccines at any one time
- Can predict that 11 vaccines given to an infant at one time “makes use of” only ~ 0.1% of their immune capacity
- Can easily demonstrate the robust immune response children display after given multiple vaccines (not a “weakened” or “overwhelmed” response)

Dangerous Chemicals - Would You Put This in Your Body?

- 3-methyl-butylaldehyde
- Ethyl ethanoate
- Tocopherol
- Alpha-terpanine
- Terpinyl-acetate
- Proline
- Octene
- Hexanal
- Benzaldehyde



Components of Vaccines

| Type of Ingredient | Purpose | Examples |
|-----------------------------------|--|-------------------|
| Adjuvants | Improve the body's immune response to antigens | Aluminum salts |
| Preservatives | Prevent contamination | Thimerosal |
| Stabilizers | Maintain vaccine potency during transportation and storage | Sorbitol, gelatin |
| Residual antibiotics | Prevent contamination by bacteria during manufacturing process | Neomycin |
| Residual inactivating ingredients | Kill virus or inactivate toxins during the manufacturing process | Formaldehyde |
| Residual cell material | To grow enough of the virus or bacteria to make the vaccine | Egg protein |

Source: Centers for Disease Control and Prevention

Which Vaccines Have Adjuvants?

| Vaccine | Adjuvant |
|--------------------|----------------------------------|
| MMR | None |
| Varicella | None |
| Rotavirus | None |
| Polio | None |
| Seasonal Influenza | None |
| Hepatitis A and B | Aluminum |
| DTaP, Tdap | Aluminum |
| Hib, Pneumococcus | Aluminum |
| HPV | Aluminum, (Lipid A for Cervarix) |

Source: Centers for Disease Control and Prevention

Paracelsus, "Father of Toxicology" 1493-1541



"Alle Dinge sind Gift und nichts ist ohne Gift, allein die Dosis macht es, dass ein Ding kein Gift ist."

"The dose makes the poison!"

Thimerosal in Vaccines

Ethyl Mercury:
half-life of 7 days



1 vaccine dose - 50 mcg ethyl-mercury

Methyl Mercury:
half-life of 50 days



1 can tuna - 85 mcg methyl-mercury

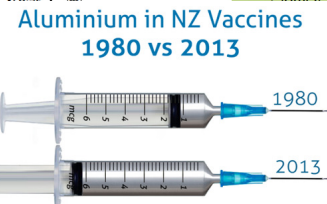
- Very effective preservative that prevents bacterial and fungal contamination of vaccines
- Multiple studies have shown it to be safe with no long-term effects
- **Removed from all childhood vaccines in 2001.** MMR, varicella, and IPV never contained thimerosal
- Still present in multi-dose vials of influenza vaccine (not in individual dose vaccine)

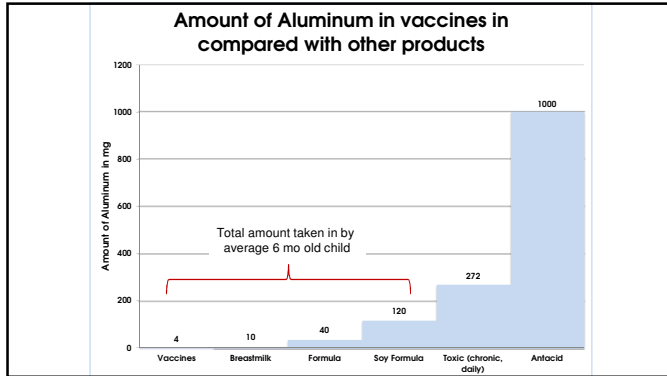
"Aluminum is Toxic to All Forms of Life!"



Dr. Suzanne Humphries, MD

"My current opinion about vaccinations is that they have never been safe. Never has there been a safe vaccine. Never will there be a safe vaccine and it is not possible to have a safe vaccine."





“But you are *injecting* the toxin, not ingesting!”

- Healthy subjects will absorb only about 0.3% of ingested aluminum where much more will be absorbed after injection, so there is a difference
- However, we *ingest* logarithmically more aluminum than is taken in from vaccines
- Doesn't matter as far as elimination goes. Must enter bloodstream to be “toxic”, and once in bloodstream, eliminated the same as if ingested. Kinetics: ~ 50% eliminated in 24h, 85% at 13d
- Al levels in normal mature human tissue: 20 mg/kg in lung, 5-10 mg/kg in bone (a 10 kg child will ultimately have 25-50x more Al in these tissues than what they will receive from all vaccines over their lifetime)

Formaldehyde in Vaccines

- Used to kill the viruses that are used in producing inactivated viral virus vaccines
- Naturally occurs in many foods and is made by the human body
- Can be toxic when inhaled in large quantities over prolonged periods of time
- The EPA oral reference dose considered safe for long-term exposure is ingesting less than 200 mcg / kg body-weight per day (70 kg man could ingest **14,000 mcg daily** for prolonged periods)

Formaldehyde in Vaccines

Concerned about formaldehyde in vaccines? Consider the pear...

A pear contains ~60,000 µg of formaldehyde, naturally.

Vaccines contain ~100 µg, or 0.16% of the formaldehyde in a typical pear.

Circulating normally in The bloodstream:

1100 mcg/mL

The amount of formaldehyde in a vaccine is so tiny that it doesn't even affect the naturally occurring levels of formaldehyde in a child's blood.
Refutations to Anti-Vaccine Memes

Vaccine Safety

Why the Provider Can be Very Confident

FDA Process for Vaccine Licensure

- Rigorous process to assure safety and efficacy before vaccine is licensed
- Multiple stages
 - File IND – outlines method of manufacture, quality control tests, animal safety and efficacy data, and proposed human clinical trials
 - Pre-licensure trials
 - **Phase I** – safety and immunogenicity in small number of subjects
 - **Phase II** – dose ranging studies in hundreds of subjects
 - **Phase III** – efficacy and safety data collected on thousands of subjects
- Process can take up to 10 yrs before vaccine is licensed

Additional Measures Beyond Usual FDA Process

- Government passed the [National Childhood Vaccine Injury Act](#) in 1986
 - Requires health providers to provide a Vaccine Information Statement ([VIS](#))
 - Providers are required to report certain adverse events to the Vaccine Adverse Events Reporting System ([VAERS](#))
 - Formed the National Vaccine Injury Compensation Program ([NVICP](#))
 - Tasked the Institute of Medicine to review all science on vaccine safety
- Established the Vaccine Safety Datalink ([VSD](#)) collaboration in 1990
- Clinical Immunization Safety Assessment ([CISA](#)) Network

Institute of Medicine - Immunization Review Committee

- Immunization Safety Review Committee
- Tasked with addressing current and emerging vaccine-safety concerns and reviewing all the literature and evidence - exhaustive
- Go to great lengths to provide independent, non-biased advice to the public, practitioners, and vaccine-policy makers
 - Painstaking effort to avoid any COIs
- Usually includes chance for public commentary and input

Institute of Medicine Reports

- Immunization Safety Review: [MMR Vaccine and Autism - 2001](#)
- Immunization Safety Review: [Thimerosal-containing Vaccines and N-D disorders - 2001](#)
- Immunization Safety Review: [Multiple-immunization and immune dysfunction - 2002](#)
- Immunization Safety Review: [Hepatitis B Vaccine and demyelinating disorders - 2002](#)
- Immunization Safety Review: [SV-40 Contamination of Polio Vaccine and Cancer - 2002](#)
- Immunization Safety Review: [Vaccinations and SIDS - 2003](#)
- Immunization Safety Review: [Influenza vaccine and neurological complications - 2004](#)
- Immunization Safety Review: [Vaccines and Autism - 2004](#)

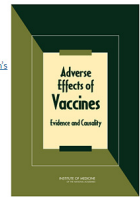
IOM Report on Adverse Effects of Vaccines - 2011

HHS charged the IOM with providing a thorough review of the current medical and scientific evidence on vaccines and vaccine adverse events.

The IOM Committee on Vaccines and Adverse Events released its report, "[Adverse Effects of Vaccines: Evidence and Causality](#)" on August 25, 2011. This analysis was used to update the [National Vaccine Injury Compensation Program's \(VICP\)](#) [Vaccine Injury Table \(VIT\)](#) and provide scientific basis for future review and decisions on VICP claims.

The IOM Committee used peer-reviewed literature to review eight vaccines given to children or adults:

- Measles, mumps, and rubella (MMR)
- Varicella
- Influenza
- Hepatitis A
- Hepatitis B
- Human papillomavirus (HPV)
- Meningococcal
- Diphtheria-tetanus, and acellular pertussis-containing vaccines



The findings indicate that these vaccines are very safe and that serious adverse events are quite rare. The IOM has conducted two similar extensive

Adverse Events Associated with Vaccination

| Vaccine | Event | Risk |
|-------------|------------------|---------------|
| Any | Anaphylaxis | 1 : 1,000,000 |
| MMR | ITP | 1 : 40,000 |
| MMR | Febrile Seizures | 1 : 2,500 |
| MMRV | 12-47 mos old | 1 : 1,250 |
| RRV-TV | Intussusception | 1 : 11,000 |
| RV1 and RV5 | Intussusception | 1: 20-100,000 |

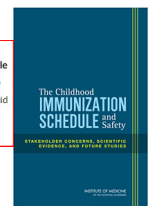
Bohike. *Pediatrics* 2003;112:815; Mantadakis. *J Pediatr* 2010;156:623; Peter. *Pediatrics* 2002;110:e67; Klein. *Pediatrics* 2010;126:e140; Meeting. June 2013

IOM Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule - 2013

IOM convened the Committee on Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule to conduct an independent evaluation of the safety of the childhood immunization schedule.

The IOM report, "[The Childhood Immunization Schedule and Safety](#)" was issued on January 16, 2013. In it, the Committee expressed support for the [childhood immunization schedule](#) as a tool to protect against vaccine-preventable diseases. The Committee recommended using healthcare records data to continue to study the safety of vaccines. The Committee also reaffirmed a [finding](#) (PDF - 631 KB) of the National Vaccine Advisory Committee (NVAC) that said conducting a study requiring some children to receive fewer vaccines than recommended, as would be needed for a randomized controlled trial, would be unethical.

[Read the full report](#)



No drug, device, process, or procedure in healthcare is as heavily scrutinized and monitored for safety and efficacy as are vaccines!



Resources

- CDC - <http://www.cdc.gov/vaccinesafety/index.html>
- AAP - <http://www2.aap.org/immunization/families/safety.html>
- Shot of Prevention - <http://shotofprevention.com/>
- Voices for Vaccines - <http://www.voicesforvaccines.org/>
- Children's Hospital of Philadelphia Vaccine Education Center – <http://vec.chop.edu/service/vaccine-education-center/home.html>
- Pertussis videos: <http://www.youtube.com/watch?v=Fm1q2to0qs> <https://www.youtube.com/watch?v=S3oZtMGDMW>

**Vaccinate
With
Confidence!**

