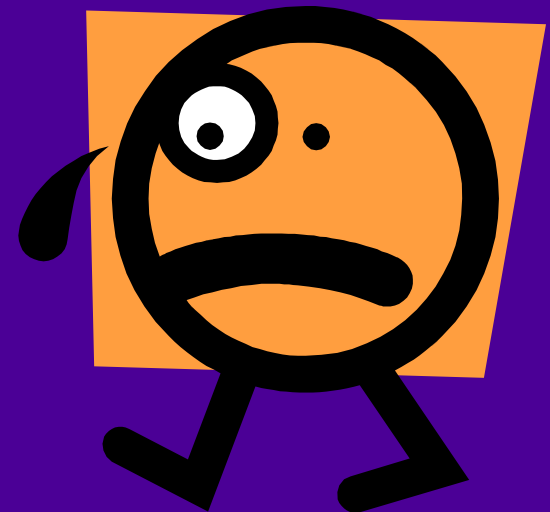


Parental Concerns on Vaccine Safety

Edna P. Sunga-Mallorca, MD

General Concerns

- Vaccines don't work
- Vaccines aren't necessary
- Vaccines are not safe



Vaccines don't Work



- Educate parents on the efficacy and our goal in vaccination e.g BCG, Rota virus
- dramatic reduction in the incidence of diseases such as measles, Hib, pertussis, etc
- Elimination of certain diseases such as smallpox and polio

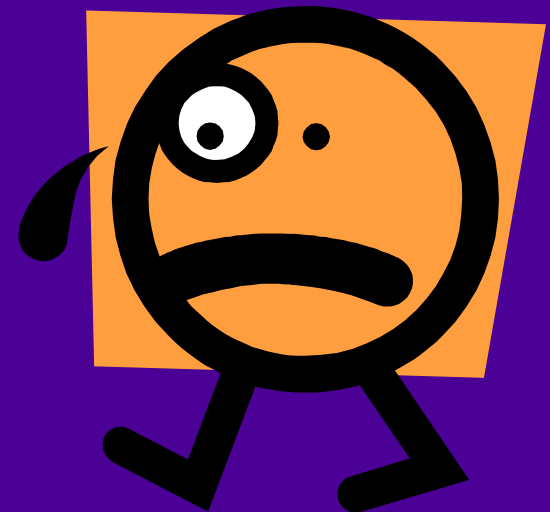
Vaccines aren't necessary



- Some diseases are so prevalent
 - decision not to give vs risk disease e.g. pertussis, Hib.
- Some diseases still occur at low levels
 - e.g. measles
 - immunization rates drop, → outbreaks
- Some diseases have been nearly eliminated globally
 - e.g. polio
 - outbreaks in some areas of the world.
 - high rate of international travel, these diseases could be easily imported by travelers or immigrants.

General Concerns

- Vaccines don't work
- Vaccines aren't necessary
- **Vaccines are not safe**



Vaccines are not SAFE



- Definition

- Harmless

- Having been preserved from a real danger

- the danger (the disease) must be significantly greater than the means of protecting against the danger (the vaccine)

*Danger of
the disease*

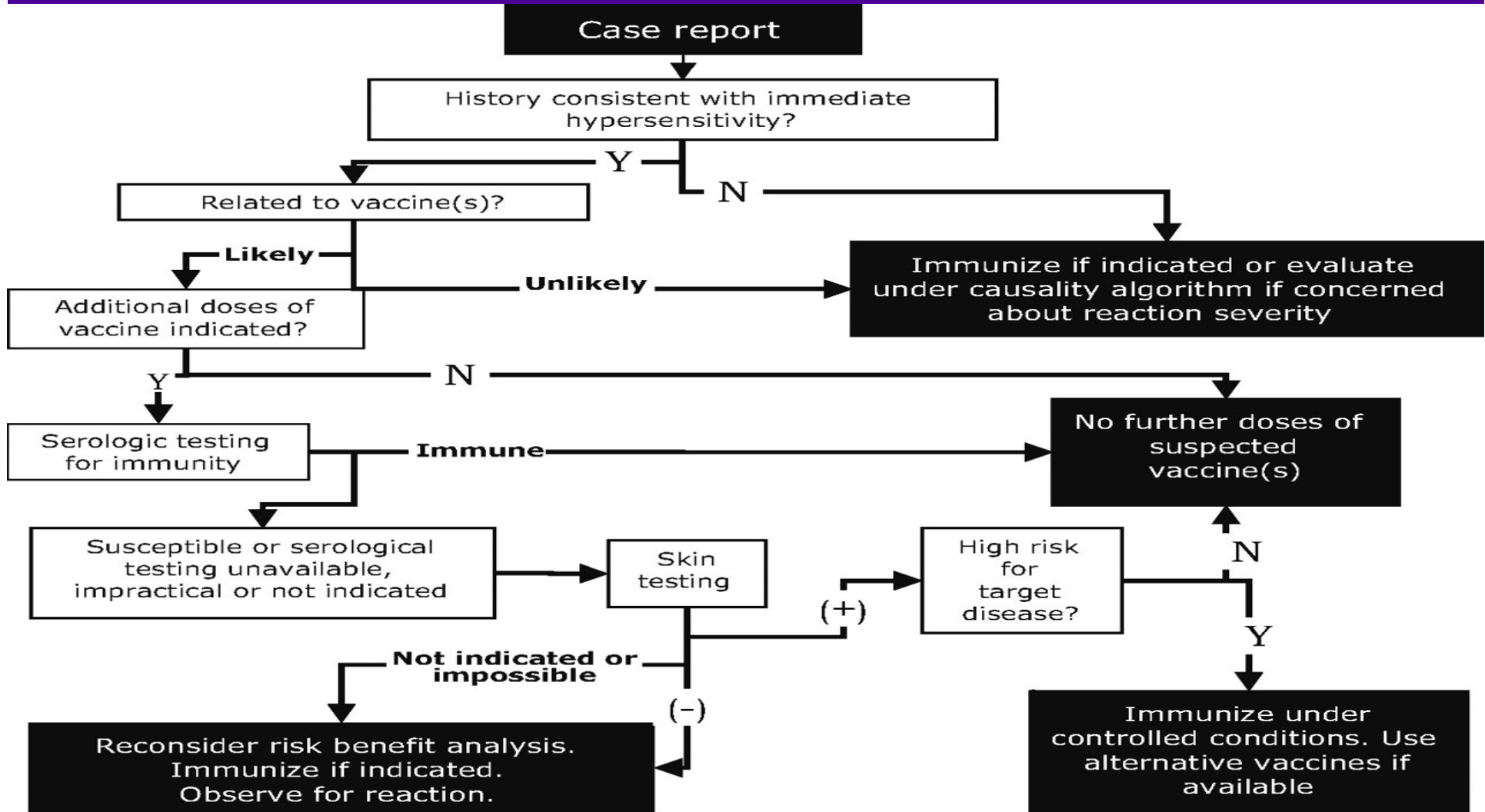


*Danger of
vaccine*

Concern: Anaphylaxis

- Estimates of immediate hypersensitivity reactions to vaccines range from 1 per 50,000 doses for DPT to 1 per .5 to 1M doses for other vaccines.
- Vaccine Safety Datalink, >7.5 million doses
 - 0.65 cases per million doses

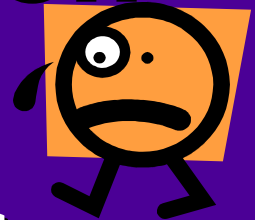
FIGURE 1 An algorithm for the management of suspected allergic reactions to vaccines

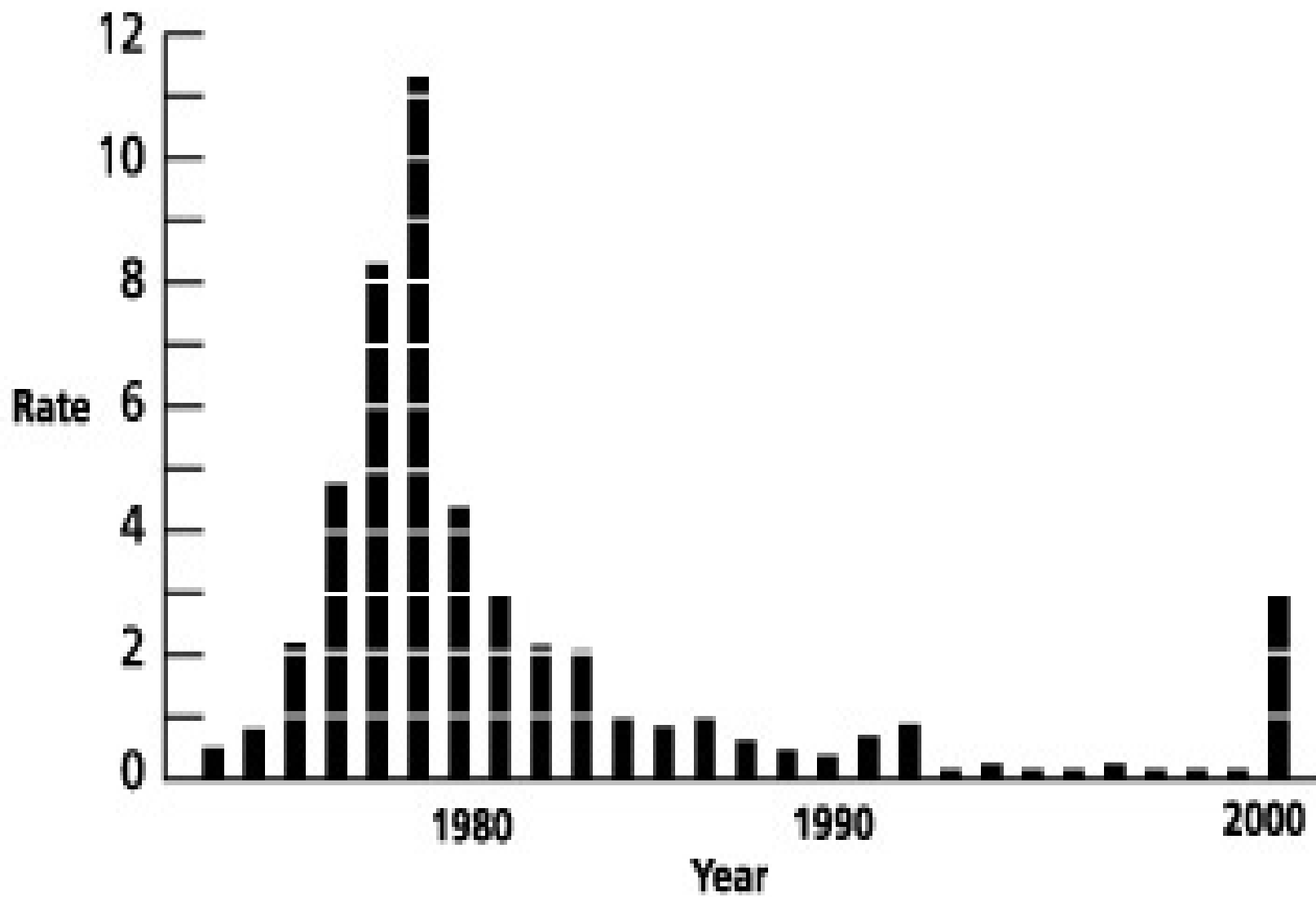


Wood, R. A. et al. Pediatrics 2008;122:e771-e777

Concern: whole cell pertussis vaccine reaction

- Persistent, inconsolable crying occurred in one of every 100 doses
- fever greater than 105°F occurred in one of every 330 doses
- seizures with fever occurred in one of every 1,750 doses





Japan's Pertussis Rate (per 100,000 population)

Concern: Rotavirus vaccine caused intussusception

- A vaccine was withdrawn for use because of a problem with safety
- associated intussusception
- given to about 1 million children in the US between 1998 and 1999.
- About one of every 10,000 children developed intussusception and one mortality

Concern: Rotavirus vaccine caused intussusception

- The Advisory Committee on Immunization Practices (ACIP) voted on October 22, 1999 to no longer recommend use of the RotaShield® vaccine for infants
- Also at that time, the manufacturer, voluntarily ceased further distribution of the vaccine.

Concern: Rotavirus vaccine caused intussusception

- 11,000 children had been tested before the vaccine was licensed, it had not been really possible to detect such a rare side effect.
- at least 60,000 children has to be tested before the next rotavirus vaccine is licensed

Concern: Rotavirus vaccine caused intussusception

- Over 70,000 children, to assess a risk of intussusception conducted before licensure of 2 rotavirus vaccines. **No association found between the vaccine and an increased risk of intussusception.**
- While these safety data from the clinical trials are reassuring, the safety is continuously being monitored closely post licensure.

Concern: Vaccines cause autism

■ Wakefield Studies

- Hypothesis: The MMR vaccine caused a series of events that include intestinal inflammation, entrance into the bloodstream of proteins harmful to the brain, and consequent development of autism.
- twelve children with developmental delay, of whom eight had autism.
- All had intestinal complaints and developed autism within one month after receiving MMR

– Lancet

Concern: Vaccines cause autism

Arguments:

- intestinal symptoms were observed **after**, not before, symptoms of autism in all eight cases.
- MMR is administered at an age when signs/symptoms of Autism are more evident to parents as well as to pediatricians
- Children diagnosed with autism recently received MMR is, therefore, expected.

Vaccines does not cause autism

- 2 studies examined the relationship between the increase in the number of cases of autism and receipt of the MMR vaccine
- The percentage of children immunized with MMR vaccine between 80's and mid 90's was compared with the incidence of autism.
- Dramatic **increase** in the incidence of children with **autism**, however, the percentage of children that received **MMR vaccine** remained the **same**.
- Therefore, the increase in the number of children reported to have autism was not associated with an increase in the use of the MMR vaccine.

Natalie Smith, JAMA
Hershel Jick, BMJ

Vaccines does not cause autism

- The largest study to examine the relationship between the MMR vaccine and autism is among 537,000 children in Denmark
- Children who received or did not receive the MMR vaccine were followed up for six years.
- **Conclusion:** The incidence of autism was the same in children among those who did or did not receive the MMR vaccine. Furthermore, there was no association between the age of vaccination and the development of autism.

Madsen and colleagues NEJM, Nov 2002

Vaccines does not cause autism

- In 2005, [The Cochrane Library](#) performed a meta-analysis and systematic review on [MMR in children](#).
Verdict: Exposure to MMR was unlikely to be associated with Crohn's disease, ulcerative colitis, autism or aseptic meningitis
- Case-control study and meta-analysis. MMR vaccination and pervasive developmental disorders
 - **No increased risk of autism or PDD with MMR**

L Smeeth et al. Lancet 2004 364: 963-969.

Concern: Thimerosal in vaccines harms children

- Thimerosal is a preservative that is used in vaccines (flu, hep B)
- thiosalicylic acid and mercury.
- an organic form, ethylmercury.
- prevent vaccines from becoming contaminated esp. multidose vials

Concern: Thimerosal in vaccines harms children

- The form of mercury that has contaminated the environment is methylmercury
- Mercury at high levels can damage the nervous system and kidneys.

Concern: Thimerosal in vaccines harms children

- On October 1, 2001, the Institute of Medicine (IOM) issued a report on the use of thimerosal in vaccines.
- The IOM recommended the use of thimerosal-free DTaP, Hib, and hepatitis B vaccines in the United States.

Concern: Thimerosal in vaccines harms children

- In 1971 Iraq imported grain that had been fumigated with methylmercury. Farmers ate bread made from this grain.
- Methylmercury in the grain caused the hospitalization of 6,500 Iraqis and killed 450.
- Pregnant women who ate bread delivered babies with epilepsy and mental retardation. but didn't increased the risk of autism.

F. Bakir, et.al

Concern: Thimerosal in vaccines harms children

- **Ethylmercury** is excreted in the urine more quickly than methylmercury and is less likely to accumulate in the body.
- Vaccines are administered to children after , not before birth
 - The development of the nervous system in early pregnancy is critical, but by the time a child gets a vaccine, the nervous system is more mature and, hopefully, much less likely to be susceptible to the harmful effects of mercury.

Concern: Thimerosal in vaccines harms children

- Methylmercury is found in low levels in water, infant formula, and breast milk.
- An infant who is exclusively breast-fed will ingest more than twice the quantity of mercury that is contained in vaccines.

Concern: Thimerosal in vaccines harms children

- Denmark Study

- Population-based cohort study of all children born in Denmark from January 1, 1990, until December 31, 1996 (N = 467 450) comparing children vaccinated with a thimerosal-containing vaccine with children vaccinated with a thimerosal-free formulation of the same vaccine.

Conclusion: There was no association between use of thiomersal and the risk of developing autism or autistic spectrum. Neither was there any dose-response with increasing exposure to ethylmercury.

CDC Statement on Autism and Thimerosal

Evidence from several studies examining trends in vaccine use and changes in autism frequency does not support an association. Furthermore, a [scientific review](#)* by the Institute of Medicine (IOM) concluded that "the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism." CDC supports the IOM conclusion.

Why are vaccine makers now making vaccines that don't use thimerosal as a preservative?

1. Single-dose vials have largely replaced multidose vials. Therefore, the risk of contamination with bacteria or fungi is much lower.
2. Other preservatives are now available and can be used in some vaccines.
3. Eliminate fear of parents on vaccine containing thimerosal

Sudden Infant Death Syndrome (SIDS) caused by Vaccines

- The ABC television program 20/20 aired a story on the hepatitis B vaccine caused SIDS.
 - one-month-old girl who had died of SIDS sixteen hours after receiving her second dose of hepatitis B vaccine.
- Every year in the United States, thousands of infants die of SIDS.

Concern: Sudden Infant Death Syndrome (SIDS) caused by Vaccines

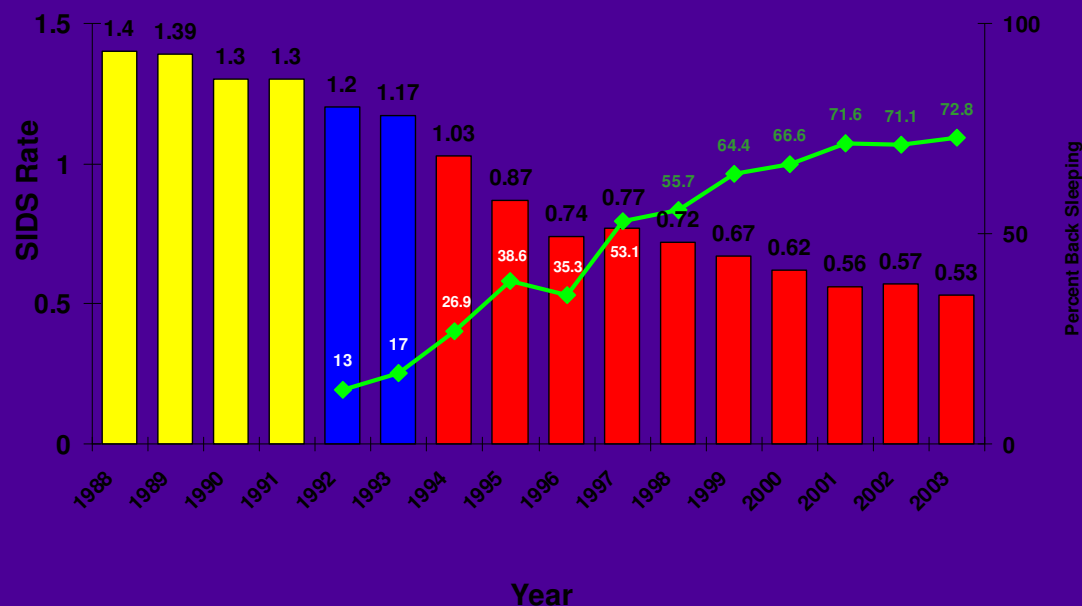
- The Institute of Medicine (IOM) in 2003 reviewed epidemiologic evidence on relationships between SIDS and the individual vaccines DTwP, DTaP, HepB, Hib, and polio; and specific combinations of vaccines or any combination of vaccines.
- The committee **did not find enough evidence to show vaccines cause SIDS.**

Concern: SIDS caused by Vaccines

- A study using [Vaccine Safety Datalink \(VSD\)](#) data, found no association between immunization and deaths in young children one month to 7 years.
- Studies that looked at the age distribution and seasonality of deaths reported to the [Vaccine Adverse Event Reporting System \(VAERS\)](#) SIDS and DTP and hepatitis B vaccination found **no association between SIDS and vaccination.**

SIDS Rate and Sleep Position

SIDS Rate and Sleep Position, 1988-2003
(Deaths per 1,000 Live Births)



SIDS rates have decreased and percent of back sleeping has increased since the campaign began.

Yellow (1985–1991): Pre-AAP recommendation
 Blue (1992–1994): Post-AAP recommendation
 Red (1995–1999): Back to Sleep campaign

Source: National Institute of Child Health and Human Development Household Survey Final Data 2003, National Center for Health Statistics, Centers for Disease Control and Prevention

Concern: Vaccines cause diabetes

- Dr. Bart Classen claimed that infants immunized with a single dose of the Hib vaccine at 14 months of age were less likely to get diabetes than if they received four doses of the Hib vaccine at 3, 4, 6, and 14 months
- Concluded: **the risk of diabetes could be reduced if children did not receive vaccines at a young age**

Concern: Vaccines cause diabetes

- **Population-based, case-control study, Two hundred fifty-two confirmed cases of diabetes and 768 matched controls**

***Conclusions.* No increased risk of type 1 diabetes associated with any of the routinely recommended childhood vaccines**

- A cohort children born in Denmark from January 1, 1990, through December 31, 2000, for whom detailed information on vaccinations and type 1 diabetes was available.
- Type 1 diabetes was diagnosed in 681 children during 4,720,517 person-years of follow-up
- **Conclusions: Do not support a causal relation between childhood vaccination and type 1 diabetes.**

Concern: Vaccines cause diabetes

CDC:

1. The incidence of diabetes was the same in vaccinated as in unvaccinated children.
2. **No evidence** exists to support the notion that **vaccines should be delayed.**

The DTP vaccine causes a shaken baby-like syndrome

- Some lawyers have chosen to defend people accused of abusing children by saying that bleeding was caused by the pertussis component of the DTP vaccine.
- However, **no evidence** exists to support this contention. Neither pertussis nor the pertussis vaccine cause bleeding around the brain or on the back of the eye

The polio vaccine is the cause of AIDS

- An article in a magazine claims that the origin of AIDS could be traced to polio virus vaccines that were administered in the Belgian Congo between 1957 and 1960.
- The explanations behind this assertion were as follows:
 - (1) All virus vaccines are made from cells,
 - (2) the polio virus vaccine was grown in monkey kidney cells,
 - (3) monkey kidney cells used at that time, contained a simian immunodeficiency virus, or SIV
 - (4) people were inadvertently inoculated with SIV, which then mutated to HIV and caused the AIDS epidemic.

The polio vaccine is the cause of AIDS

- Although monkeys can be infected by SIV, a disease similar to HIV, SIV is not found in kidney cells.
- SIV and HIV, although deadly viruses, are fairly fragile. If given by mouth, would be rapidly destroyed by the enzymes and acids in the mouth and stomach.
- Original lots of the polio vaccine were recently tested for the presence of HIV using **PCR**. **No HIV was present in any of those lots.**

Vaccines contain the agent that causes mad-cow disease

- On February 8, 2001, the New York Times Five Drug Makers Use Material with Possible Mad-Cow Link.
- July 2000, about 175,000 cows in the UK developed mad-cow disease.
- At least 73 people in the UK developed variant Creutzfeldt-Jakob disease (vCJD) that may have resulted from eating meat prepared from cows with mad-cow disease

Vaccines contain the agent that causes mad-cow disease

- vCJD is caused by a prion (proteinaceous infectious particle)
- found in the brains of cows with mad-cow disease and in the brains of humans with vCJD
- blood from infected animals or infected people has never been shown to be a source of human infection

Vaccines contain the agent that causes mad-cow disease

- Viral vaccines are grown in medium containing fetal bovine serum.
- Maternal-fetal transmission of prions has never been documented in animals.
- Therefore, **prions are unlikely to be propagated in the cells used to grow vaccine viruses.**

The hepatitis B vaccine causes arthritis, multiple sclerosis, and chronic neurologic disorders

- A segment of the ABC television show 20/20 told of children and adults who developed arthritis, multiple sclerosis, or neurologic disabilities following receipt of the hepatitis B vaccine.

- conclusion:

The incidence of multiple sclerosis was the same in those who received the hepatitis B vaccine and those who hadn't.

The hepatitis B vaccine causes arthritis, multiple sclerosis, and chronic neurologic disorders

A control study in two large cohorts of nurses

- included 192 women with multiple sclerosis and 645 matched controls
- Conclusion: No association between hepatitis B vaccination and the development of multiple sclerosis

Alberto et al NEJME,2001

The hepatitis B vaccine causes arthritis, multiple sclerosis, and chronic neurologic disorders

A Case-control study involving cases of multiple sclerosis or optic neuritis among adults

- 440 case and 950 control subjects
- Conclusion: Vaccination against hepatitis B, influenza, tetanus, measles, or rubella is **not associated with an increased risk of multiple sclerosis or optic neuritis.**

Concern: Syncope after Immunization

- Since 2005, VAERS detected a trend of increasing syncope reports. VAERS received
 - 463 syncope reports from January 1, 2005 – July 31, 2007,
 - 203 January 1, 2002 – December 31, 2004.
- Among ≥ 5 years old, 49% were adolescent females

Concern: Syncope after Immunization

- At least one of the three vaccines (HPV, MCV4, and Tdap) were received in 60% of reports involving a single vaccine
- HPV was the most frequent
- 49% - less than 5 mins
80% - less than 15 mins