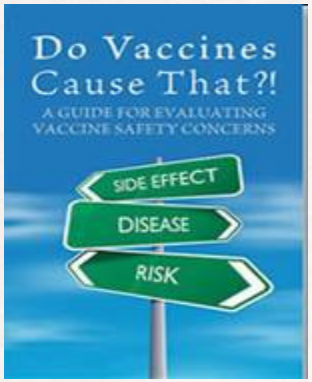
How Vaccines Cause Adverse Events

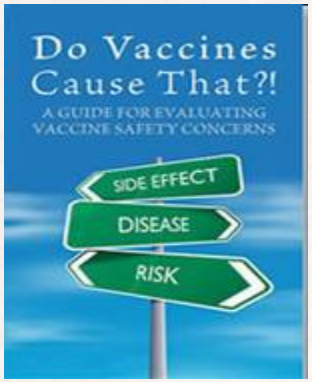
Salvacion R. Gatchalian, MD,
FPDS, FPIDSP, FPSMID
Director Clinical R & D and Medical Affairs Biologicals GSK

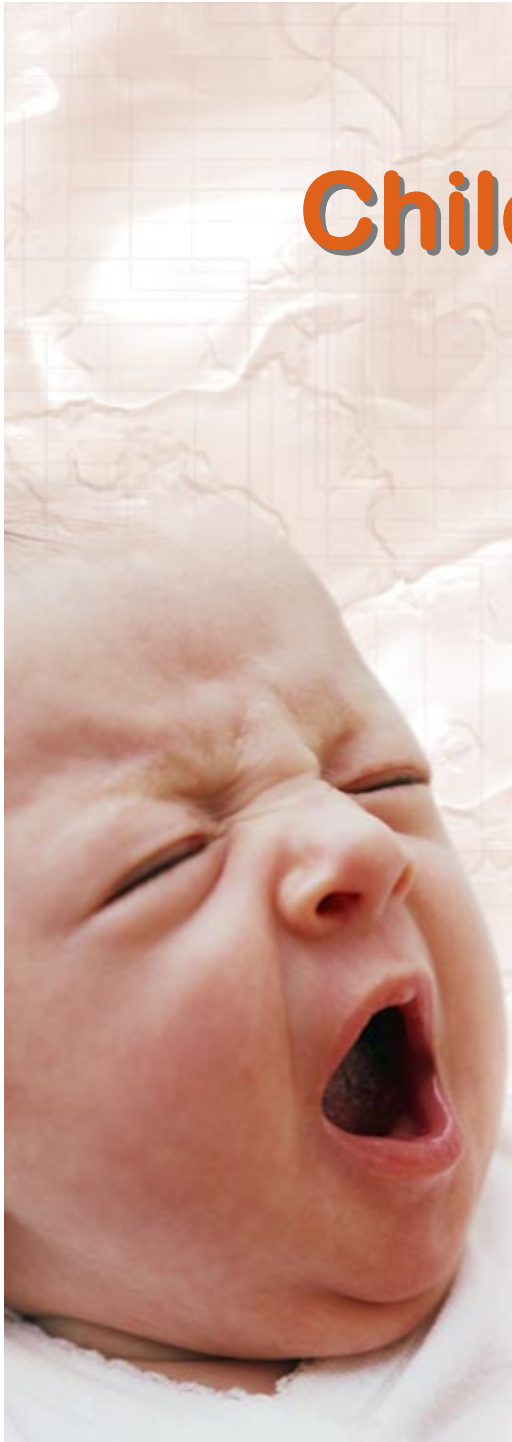
DISCLAIMER



- **Director, Clinical R and D and medical affairs, biologicals, GSK Philippines**

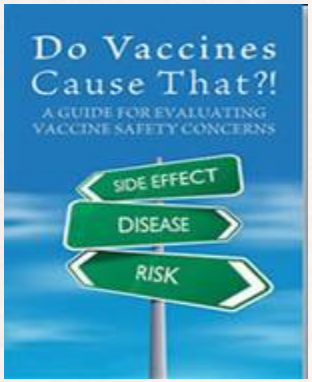
Childhood Immunization





- **Most successful preventive health measure**
- **“An ounce of prevention is worth more than a pound of cure”**

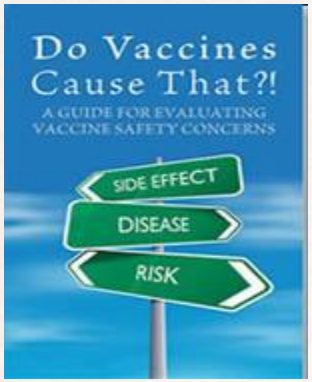
Immunization

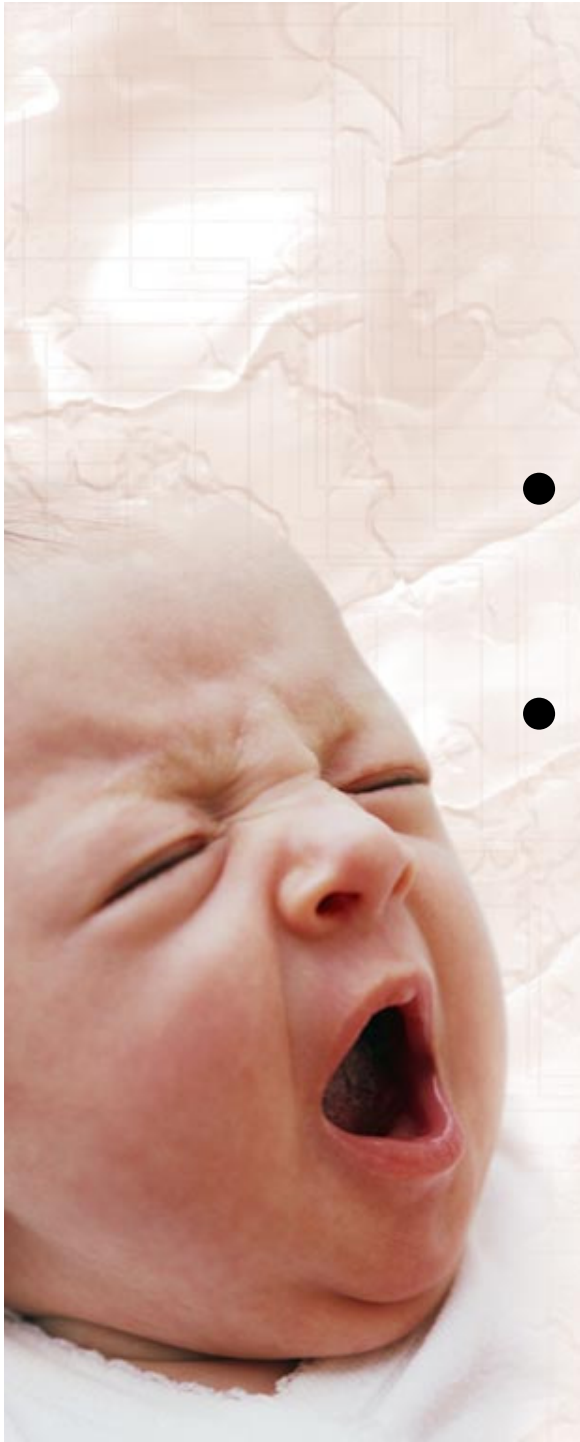


Recommendations for Vaccination

- Characteristics of immunobiologics
- Scientific knowledge on active & passive immunization
- Epidemiology of diseases
- Judgements of public health officials and specialist

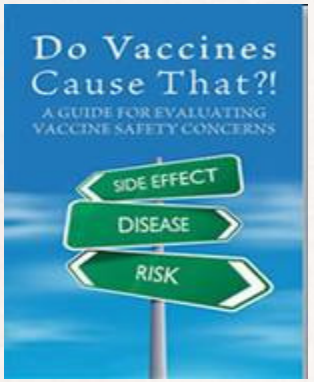
Immunization

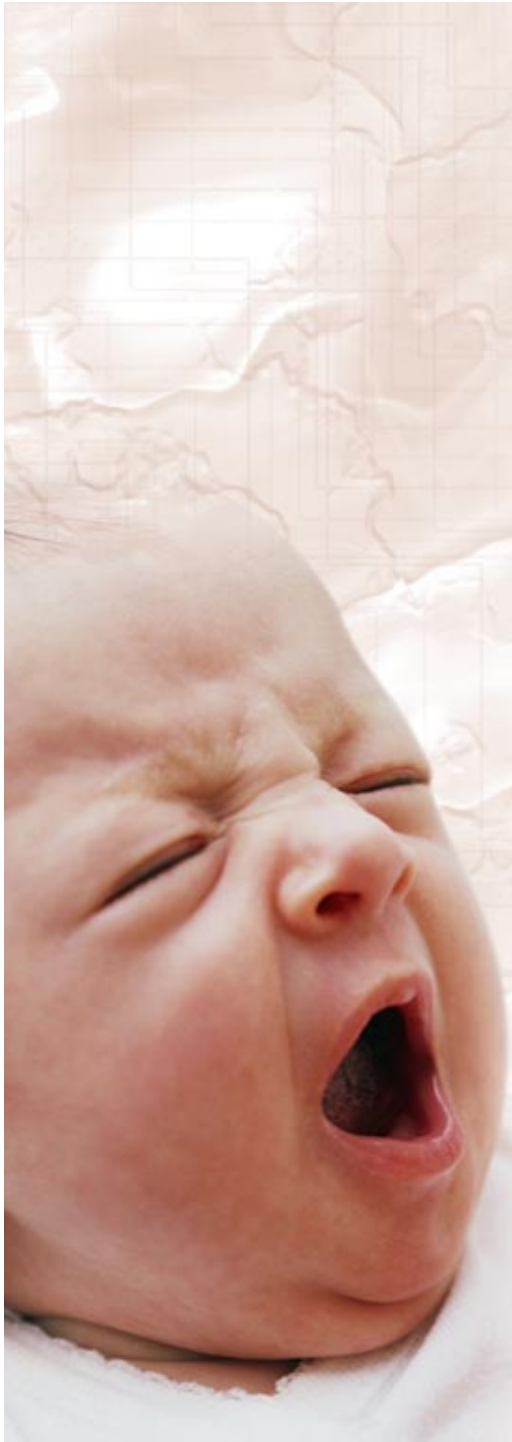




- No vaccine is completely safe nor completely effective
- Benefits
  - Partial to complete protection
  - Asymptomatic or mild infection
  - Severe consequences

Risk of Vaccination

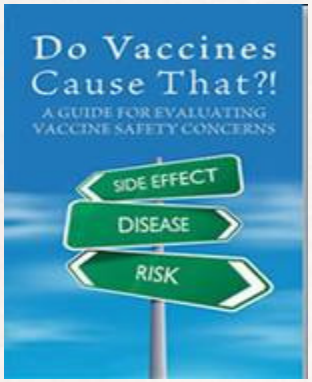




- **Common, minor, and inconvenient side effects**
- **Rare, severe, and life-threatening conditions**

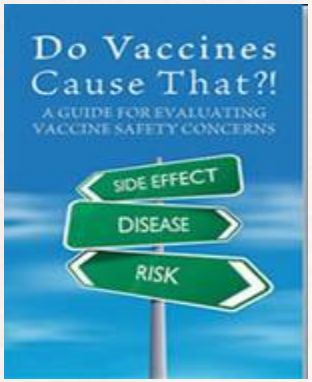
Recommendations balance scientific evidence of benefits, cost, and risk to achieve optimal levels of protection

Vaccine Safety



- Encounter patients with reservation
- Many reasons for fear or repulsion to vaccination
  - Religious or philosophic objections
  - Meddling by the Government
  - Concerned about safety and/or efficacy of vaccines
  - Vaccine-preventable diseases do not pose a health hazard

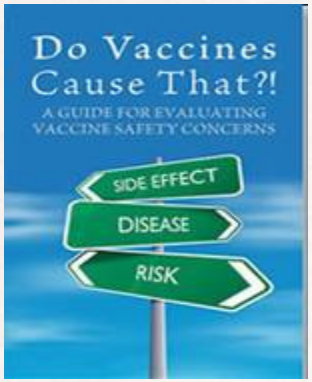
Quality and safety of vaccines from development to delivery



- High standard of safety
- Stringent measures to ensure quality and safety
  - Research and Development
  - Manufacturing
  - Licensing
  - Transport
  - Storage
  - Use of vaccines
  - Disposal of needles & other equipment

Ref: www.who.int/entity/mediacentre/factsheets/fs295/en/

Research and Development of Vaccines



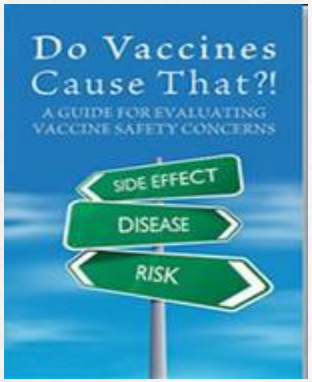
- Vaccines carefully evaluated:
  - Effectiveness
  - Potential harmful effects
- Good safety results → phased trials with humans

Safety Monitoring of Licensed Vaccines

- Vaccines licensed for general use and administered to large populations → monitoring continues
  - Identify less common adverse events
  - Events that occur after a long time
  - Events that occur in specific subgroups of target population

Ref: www.who.int/entity/mediacentre/factsheets/fs295/en/

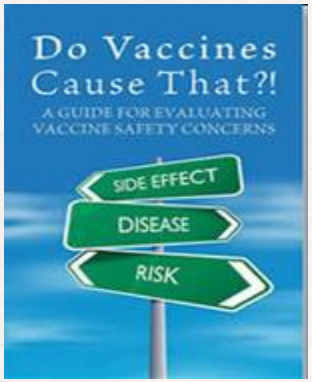
Safety Monitoring of Licensed Vaccines



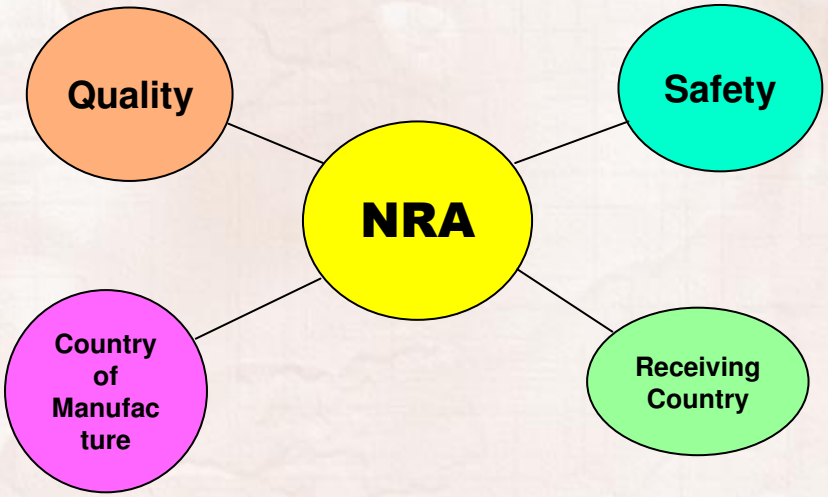
- **Spontaneous reporting system**
  - **AEFI reported to health authorities**
  - **Post-licensure monitoring in Phase IV trials**
- **Detection of AEFI does not necessarily mean event was caused by vaccine**
  - **Cause and effect relationship requires investigation**

Ref : www.who.int/entity/mediacentre/factsheets/fs295/en/

Manufacturing of Vaccines



- **Regulations ensure safety and quality of vaccines**
  - **Identification (characterization) of starting material**
  - **Compliance with GMP**
  - **Control procedures**
  - **Release of vaccines on a lot-by-lot basis by National Regulatory Authorities**



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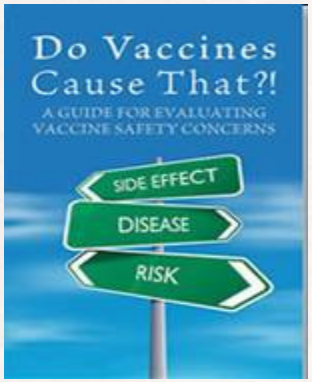
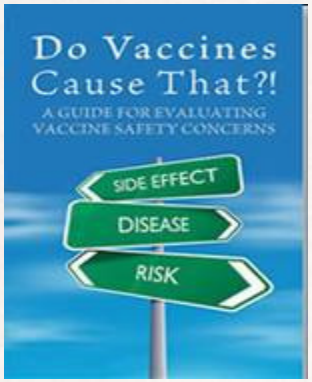
Vaccine Transportation and Storage

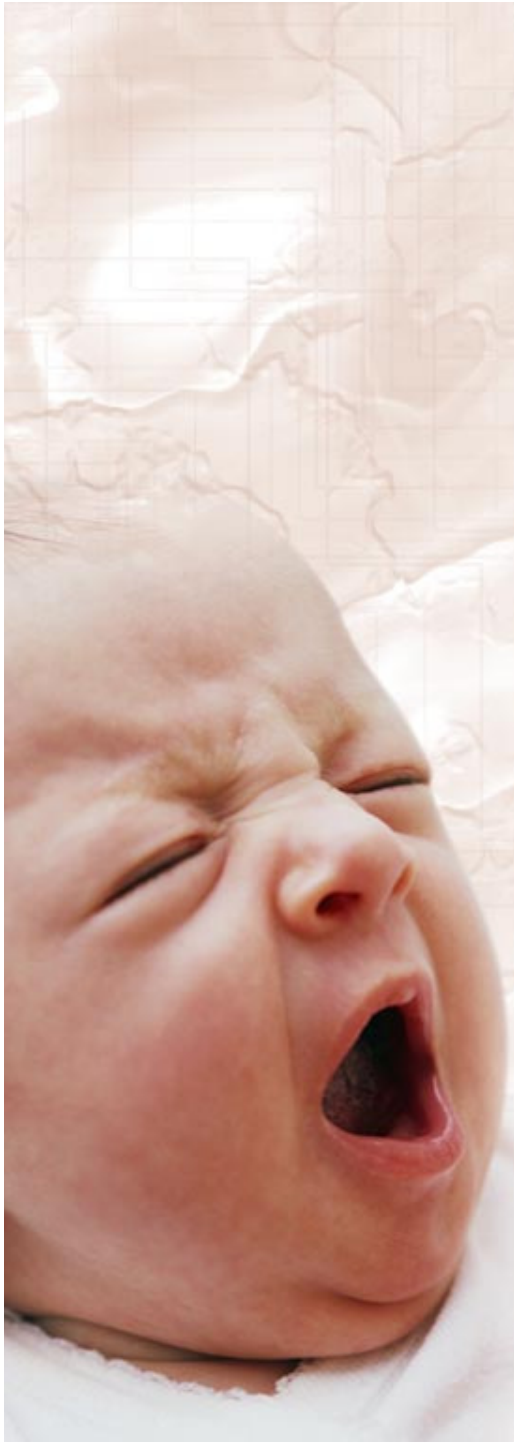


- Kept at optimal T° (2°C – 8°C) from manufacturer to point of use
  - Logistical challenge in developing countries
- Cold chain must be maintained
  - Ensure required T° maintained

Ref : www.who.int/entity/mediacentre/factsheets/fs295/en/

Safe Injections

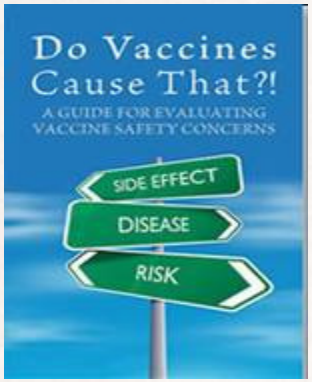




- Many vaccines delivered by injections
- Safe injection practices promoted by WHO as priority
- Vaccine-related injections safe for recipient
  - Health worker uses sterile syringe, sterile needle, sterile technique

Ref : www.who.int/entity/mediacentre/factsheets/fs295/en/

How vaccine cause Adverse Events

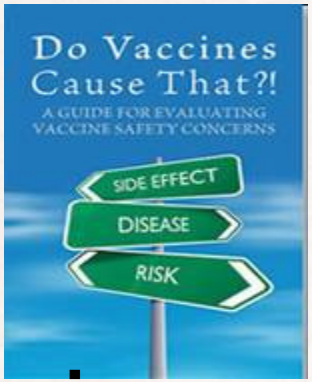


- Inception of vaccination → AEFI will occur
- Frequency of AEFIs is directly related to number of vaccine doses administered
  - Inherent properties of vaccine
  - Linked to errors in administration
  - Quality, storage, transport of vaccine
- Large population vaccinated → serious events that occur rarely with or without vaccination will be observed coincidentally

➢ Investigate causality of AEFIs
  - Challenging

Ref : WER 23 Mar 2001: www.who.int/entity/vaccine_safety/causality/en/

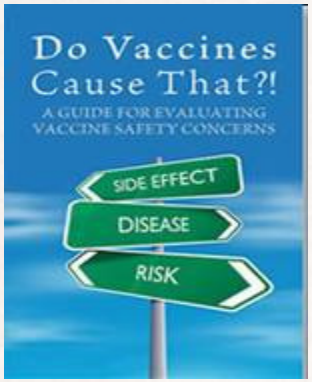
Causality of AEFIs



- **Risk and side effects with vaccines**
  - **SAE mostly rare**
- **Side effects are symptoms & signs**
  - **Local – pain or redness at injection site**
  - **Systemic – headache or fever**
- **Adverse event – something that occurred at about the same time a vaccine was given**
  - **Caused by vaccine**
  - **Coincidence**

Ref : WER 23 Mar 2001: www.who.int/entity/vaccine_safety/causality/en/
www.immunizationinfo.org/vaccine_safety_detail.cfv?id=67

Causality of AEFI

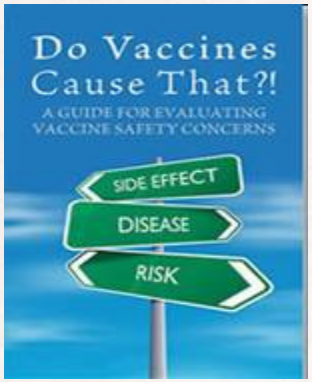


- **Adverse event occurs → determine whether AE by vaccine or coincidental**
  - **It is going to happen anyway**

Ex. Vaccines given to children at age when developmental & other problems are recognized. Something happened at same time vaccine was given – does not mean vaccine caused the problem

Ref : www.immunizationinfo.org/vaccine_safety_detail.cfv?id=67

Causality of AEFI



- Saved millions of lives
- Cause conditions not completely understood despite no scientific evidence
  - Asthma
  - Autism
  - Diabetes type 1
  - Multiple Sclerosis
  - SIDS

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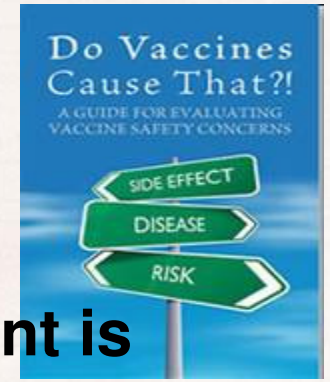
Causality of AEFI



- Way to determine an adverse event is causally related to vaccine → compare rates of event in vaccinated vs non-vaccinated via randomized trial
  - Never large enough to assess very rare events
  - PMS – identify events potentially-related to vaccination
- Assessments vary from causal observation to carefully controlled study
- Majority not trained in interpreting studies

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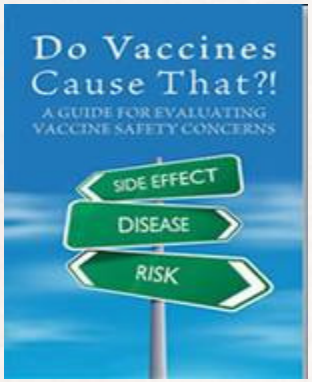
Causality of AEFI



- **Public forms decision about vaccine safety**
  - **Based on information available**
  - **Report based on nonscientific observations or analyses that fail to stand scrutiny of scientific investigation**
- **AEFI reports in medical literature resulted in controversy**
  - **Studies did not fulfill criteria needed to draw conclusions**
  - **Had major influence on public debate and opinion-making**

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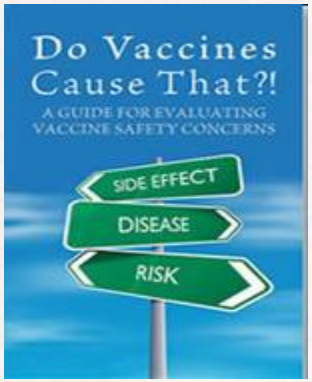
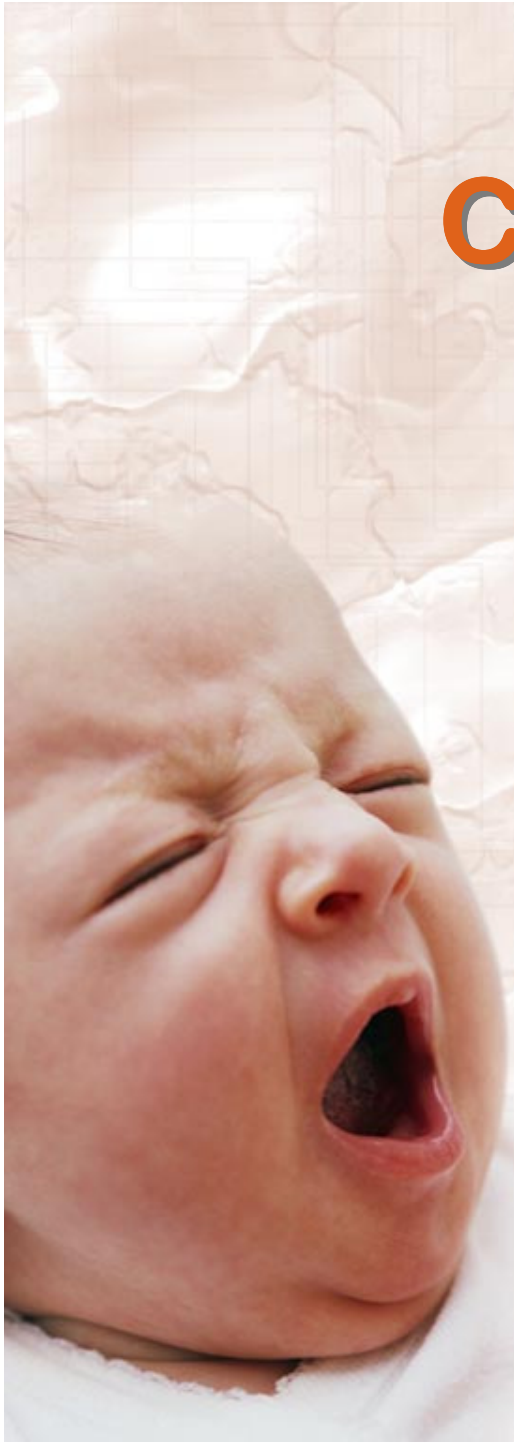
Causality of AEFI

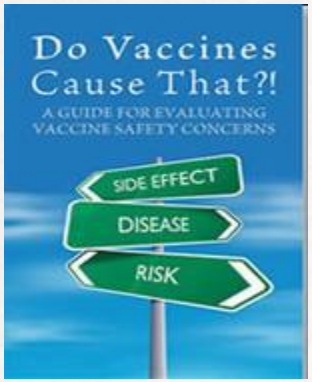




- **Debate spills to political arena and policy-making and determine acceptance of vaccine**
  - **Balance known benefits vs possible but unverified risks**
- **Correct assessment of causality is vital**

Ref : WER 23 Mar 2001: www.who.int/entity/vaccine_safety/causality/en/

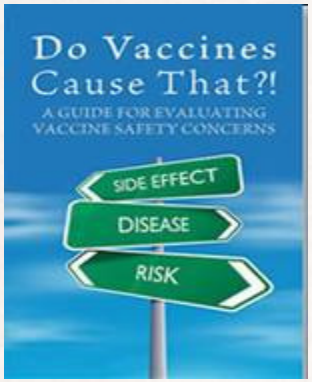
How to determine if vaccine causes AE or not

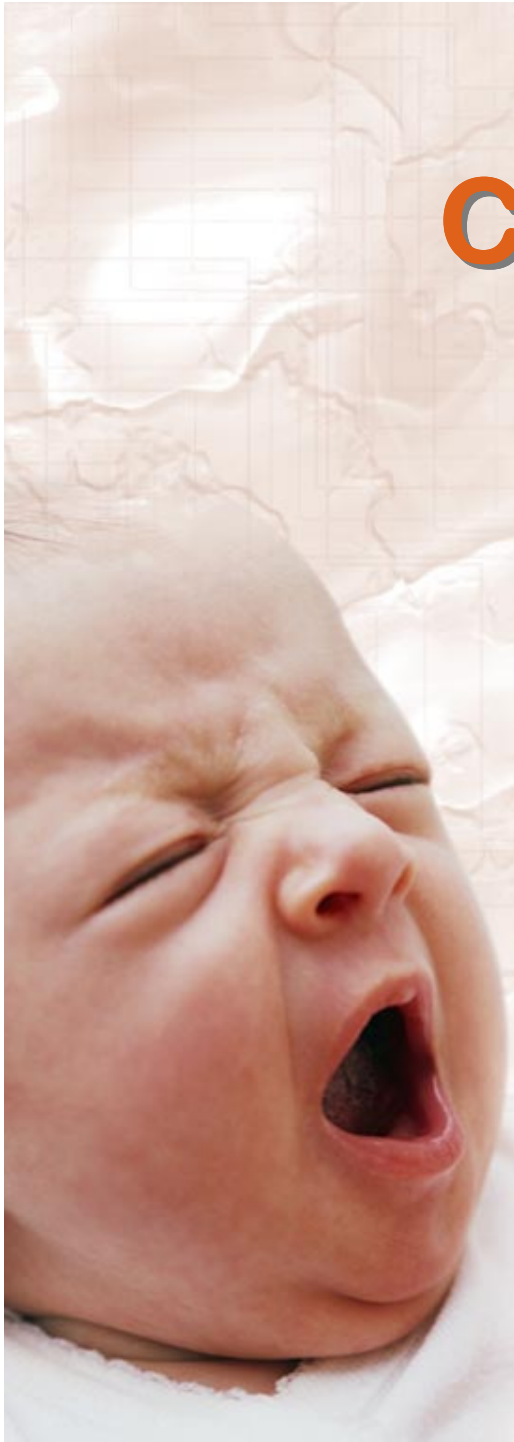


- **Time of onset** – Onset of disease follow vaccination. If symptoms occur before vaccination → vaccine not cause
- **Virus isolation** – Live virus vaccine, cause if virus recovered from sterile body site
- **Uniqueness of clinical syndrome** – Inferred if disease only occurs after vaccination or occurs a second time with repeat exposure

Ref : www.immunizationinfo.org/vaccine_safety_detail.cfv?id=67

Causality of AEFI

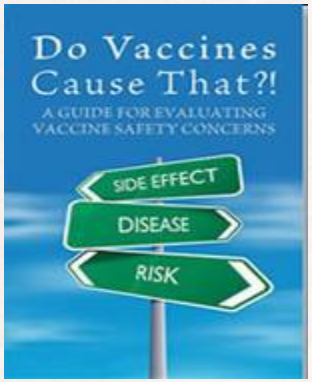




- **Biological Mechanism – not sufficient to prove vaccine is cause**
  - **Evidence of association present in epi studies, may explain association scientifically**
- **Epidemiologic studies – Provide evidence**
  - **Determine whether risk higher in manfold**
  - **Higher rate of disease in vaccination**
  - **Epi helps determine cause and risk factors**

Ref : www.immunizationinfo.org/vaccine_safety_detail.cfv?id=67

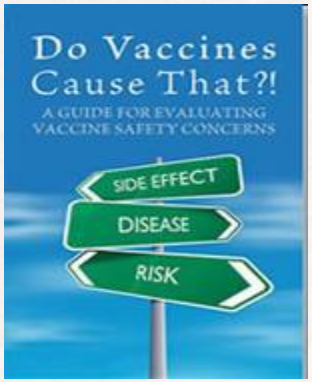
Causality of AEFI



- Derived from Epi studies
- Criteria for causality
  - Strength of association - > difference in rates → more likely with causal relationship
- Consistency of association – more studies that show similar results → more likely as cause
- Dose response – increasing risk with increasing dose, more likely causal relationship

Ref : www.immunizationinfo.org/vaccine_safety_detail.cfv?id=67

Causality of AEFI



- Epi studies useful to identify cause in general population
- Hard for Epi to find cause of rare diseases in small population
- Epi unable to prove negative – cannot prove that a vaccine does not cause a disease

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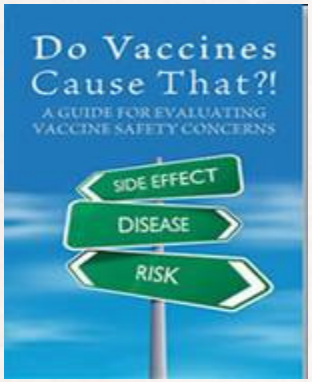
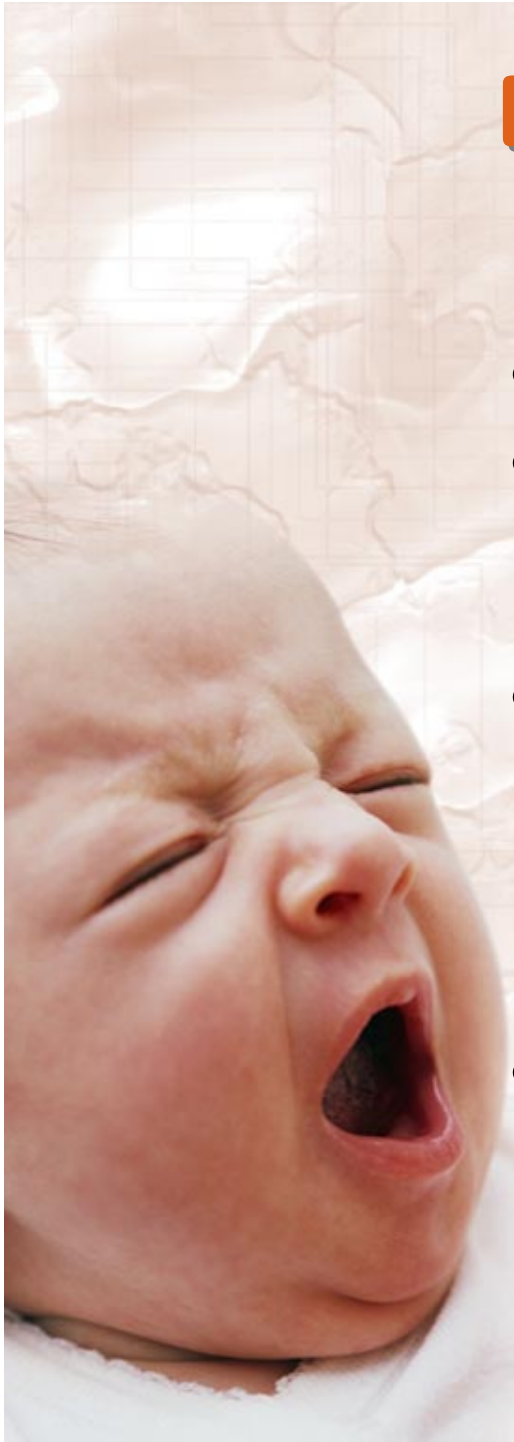
Reasons how vaccines cause AE

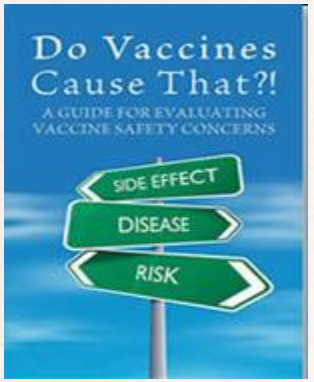




- Inherent properties of vaccine
- Errors in administration (wrong route, use of improper gauge of needle, aseptic technique
- Quality, storage & transport – Cold Chain maintenance
  - If T^{o} not followed, may render vaccine impotent or ↑ risk of local reaction, ↓ efficacy
- Wrong diluent – only diluent supplied by manufacturer specific for vaccine should be used

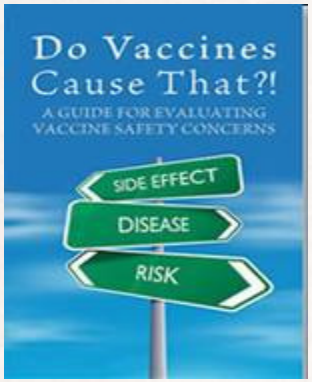
Ref : WER 23 Mar 2001: www.who.int/entity/vaccine_safety/causality/en/
www.immunizationinfo.org/vaccine_safety_detail.cfv?id=67
Global Advisory Committee on Vaccine Safety, WHO (2008)

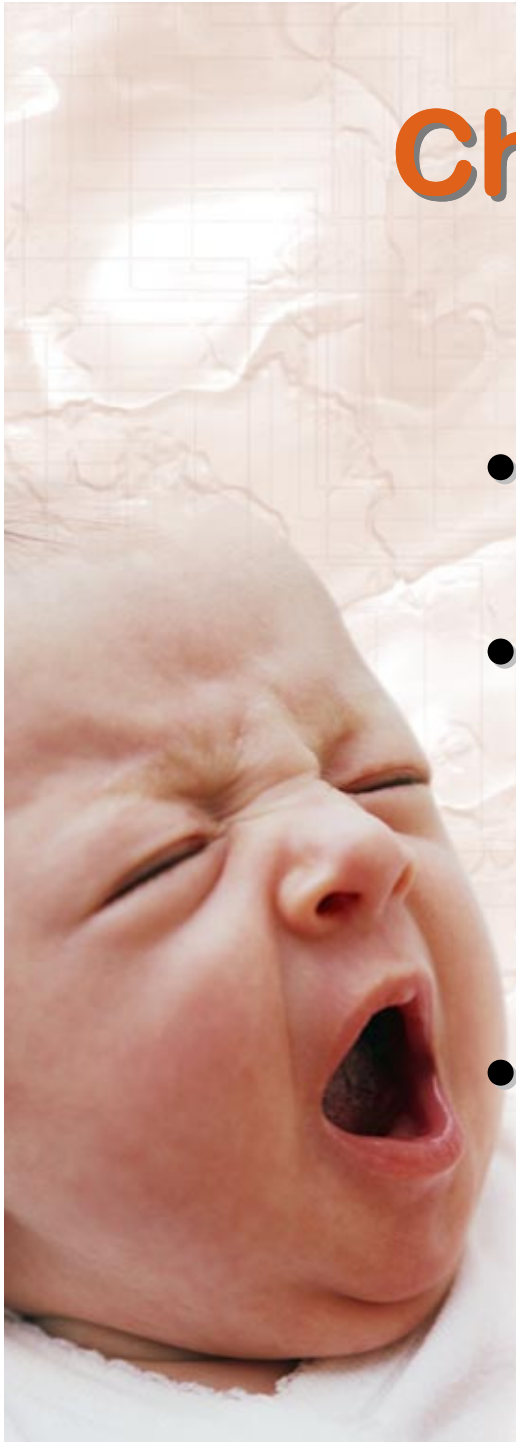
Chemical Additives in Vaccines



- Prevent growth of bacteria
- Help to preserve vaccine
- Prevent vaccine from losing its potency

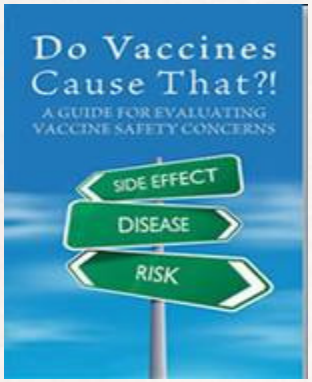
Chemical Additives in Vaccines





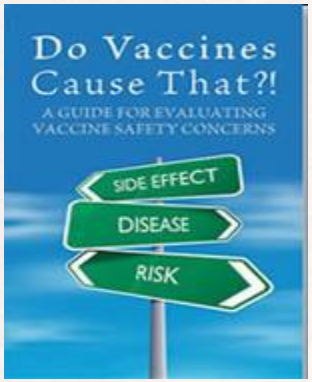
- **Antibiotics** – prevent growth of germs
  - Neomycin most common
- **Aluminum gels** – adjuvants to help vaccine stimulate production of antibodies
  - Promote earlier, more potent or more persistent response
- **Formaldehyde** – kill unwanted viruses and bacteria

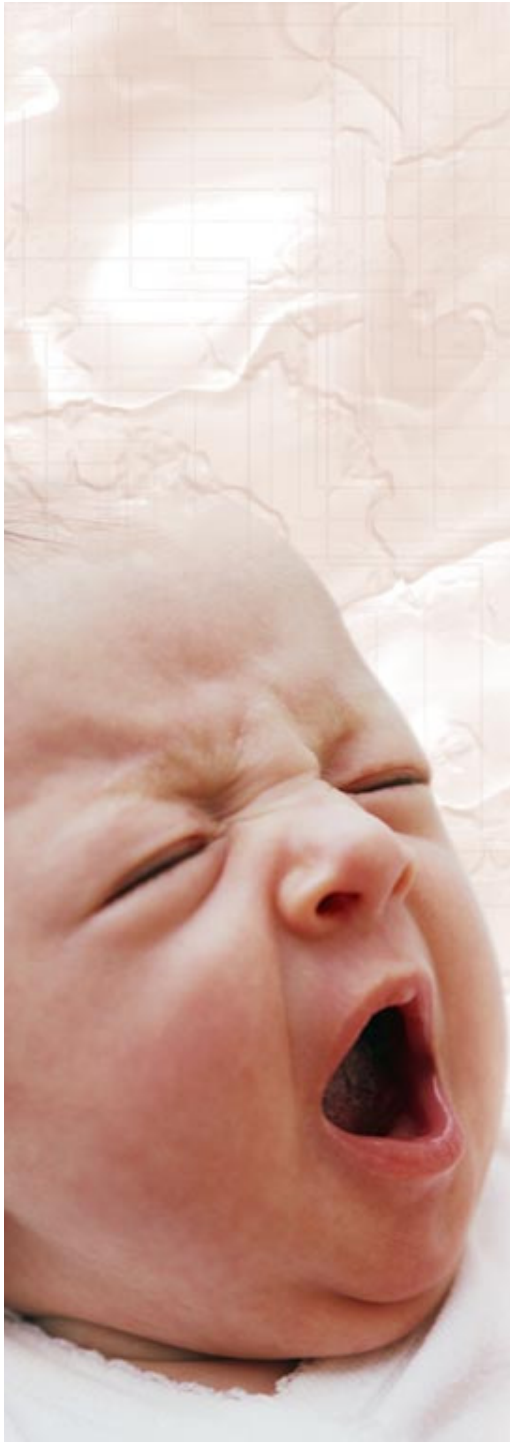
Chemical Additives in Vaccines



- **Monosodium Glutamate (MSG)** – used as a stabilizer
  - Help vaccine remain unchanged
- **Sulfites** – act as stabilizer
  - Help stabilize and preserve the vaccine if exposed to adverse conditions

Chemical Additives in Vaccines

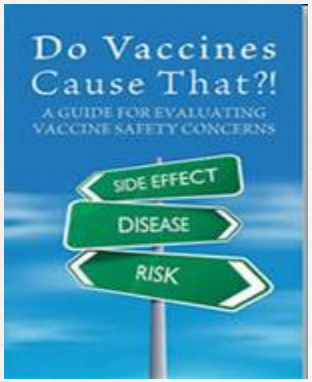




- **Thimerosal**
  - Mercury-containing preservative
  - Effective in preventing bacteria and fungal contamination
  - Mercury is a neurotoxicant
  - Little known about ethyl mercury
  - Remove thimerosal from vaccines to reduce mercury exposure
  - Exposure to thimerosal could be associated with neurodevelopmental disorders not established
    - Indirect and incomplete information from analogs
    - Levels of maximum mercury exposure from vaccine

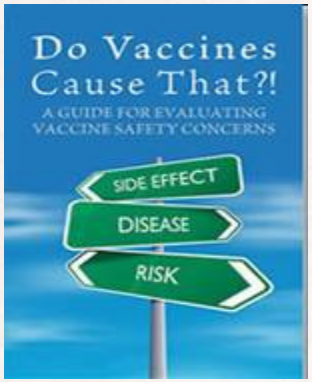
➡ **Biologically possible**

Chemical Additives in Vaccines



- **Thimerosal**
  - Evidence inadequate to accept or reject causal relationship
  - Limited and unpublished epidemiological data
  - Weak and inconclusive
  - Remains in some vaccines
  - Public health attention paid to this issue
    - Policy review and analysis
    - Public health and biomedical research
    - Improved communication strategies

Vaccine Safety Misconceptions

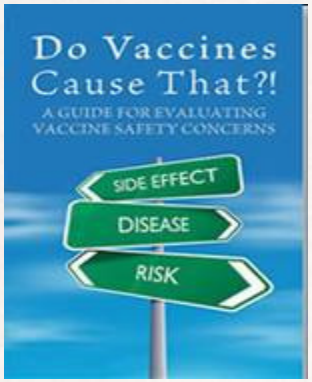


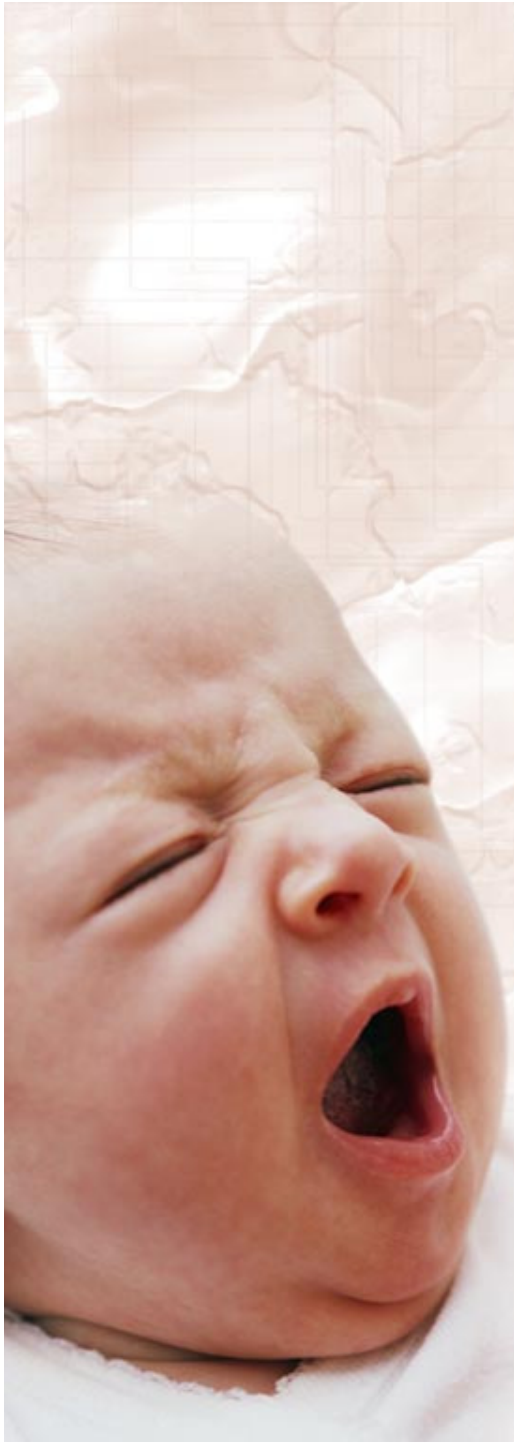
"Vaccines cause many harmful side effects, illnesses and even death - not to mentions possible long term effects"

- **Vaccines very safe**
- **Vaccines AE are minor & temporary**
- **Serious AE occur rarely**
- **Vaccine causing death very few**
  - **Difficult to assess risk statistically**
  - **Little or no evidence exist to suggest vaccines contributed to reported deaths**
- **Institute of Medicine, 1994 – risk of death from vaccine "extraordinarily low"**

Ref : http://www.who.int/immunization_safety/aefi/immunization_misconceptions/en/

Vaccine Safety Misconceptions



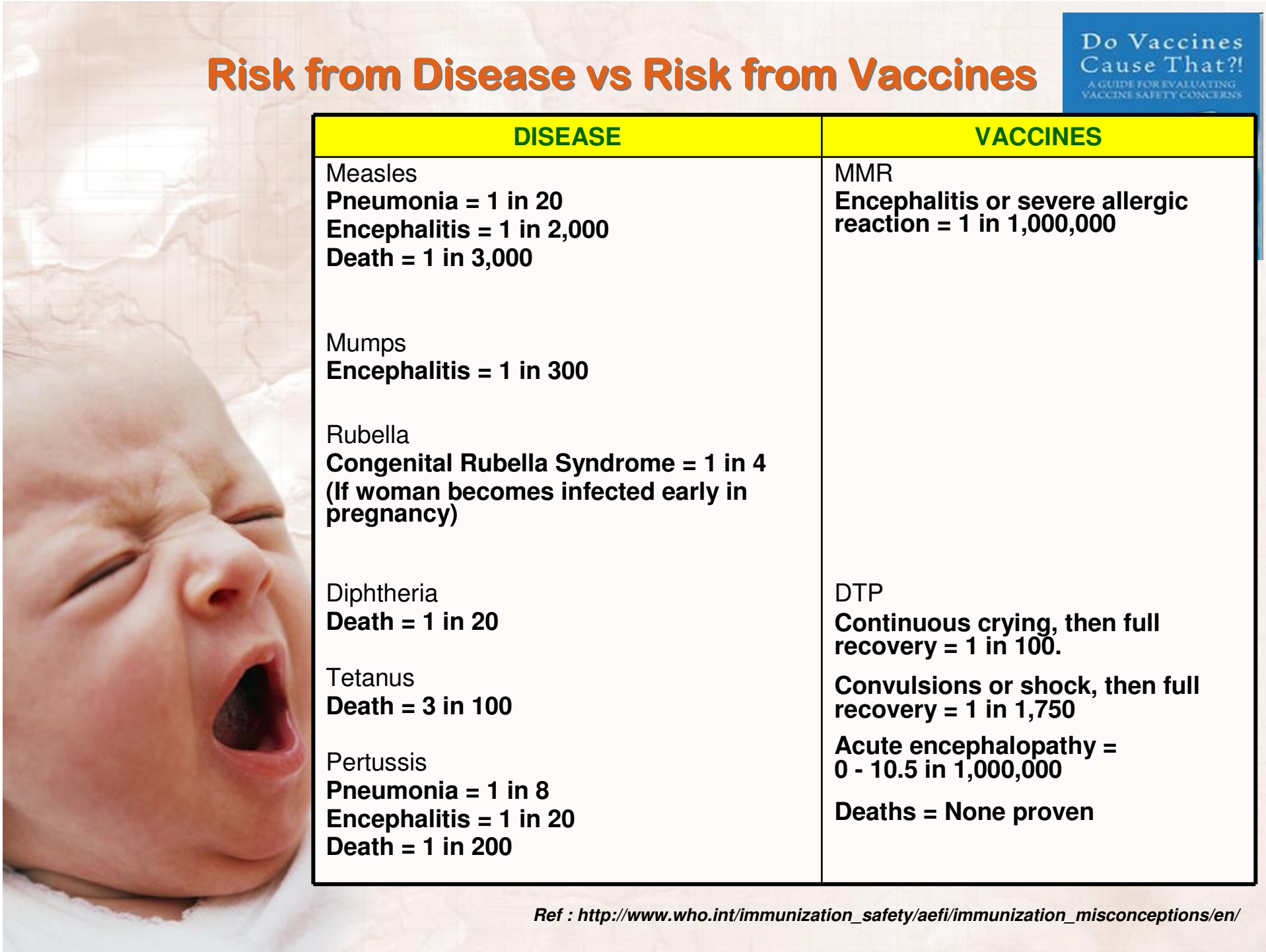


"Vaccines cause many harmful side effects, illnesses and even death – not to mentions possible long term effects"

- **Look at risk and benefit**
- **Serious adverse effect in a million doses cannot be justified if no benefit from vaccination**
- **No vaccine – many more cases of disease, more serious SE, death**

Ref : http://www.who.int/immunization_safety/aefi/immunization_misconceptions/en/

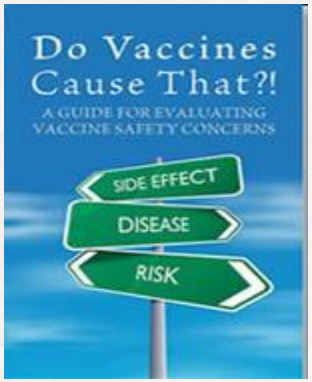
Risk from Disease vs Risk from Vaccines



DISEASE	VACCINES
Measles **Pneumonia = 1 in 20** **Encephalitis = 1 in 2,000** **Death = 1 in 3,000**	MMR **Encephalitis or severe allergic reaction = 1 in 1,000,000**
Mumps **Encephalitis = 1 in 300**	
Rubella **Congenital Rubella Syndrome = 1 in 4 (If woman becomes infected early in pregnancy)**	
Diphtheria **Death = 1 in 20**	DTP **Continuous crying, then full recovery = 1 in 100.**
Tetanus **Death = 3 in 100**	**Convulsions or shock, then full recovery = 1 in 1,750**
Pertussis **Pneumonia = 1 in 8** **Encephalitis = 1 in 20** **Death = 1 in 200**	**Acute encephalopathy = 0 - 10.5 in 1,000,000** **Deaths = None proven**

Ref : http://www.who.int/immunization_safety/aefi/immunization_misconceptions/en/

Vaccine Safety Misconceptions

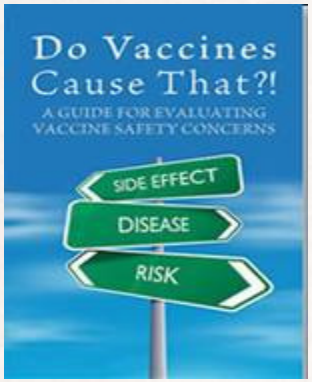


"Vaccines cause many harmful side effects, illnesses and even death – not to mentions possible long term effects"

- **A child more likely to be seriously injured by one of the diseases than by vaccine**
- **Benefits of vaccination outweigh, slight risk and injuries, deaths occur without vaccines**
- **Not to use vaccines is unethical, unforgivable and inhuman**

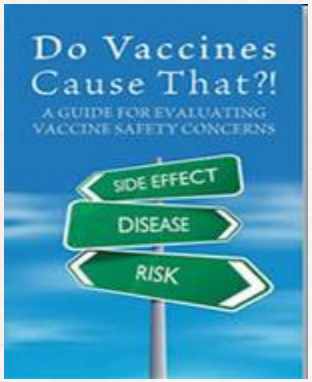
Ref : http://www.who.int/immunization_safety/aefi/immunization_misconceptions/en/

VACCINE AND CHRONIC DISEASE



- No conclusive evidence proving vaccines cause chronic illness
- Vaccines associated with chronic illness
  - Autism and MMR
  - Diabetes and Hib
  - Multiple Sclerosis and Hepatitis B
  - DTP and SIDS
- Role of vaccine in adverse event
  - Assess whether vaccine actually causes a certain AE
- Association between AE and vaccine not evidence that vaccine causes AE

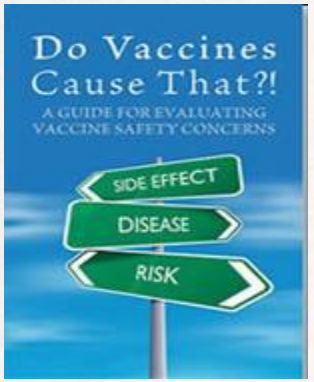
Vaccines and Allergic Diseases

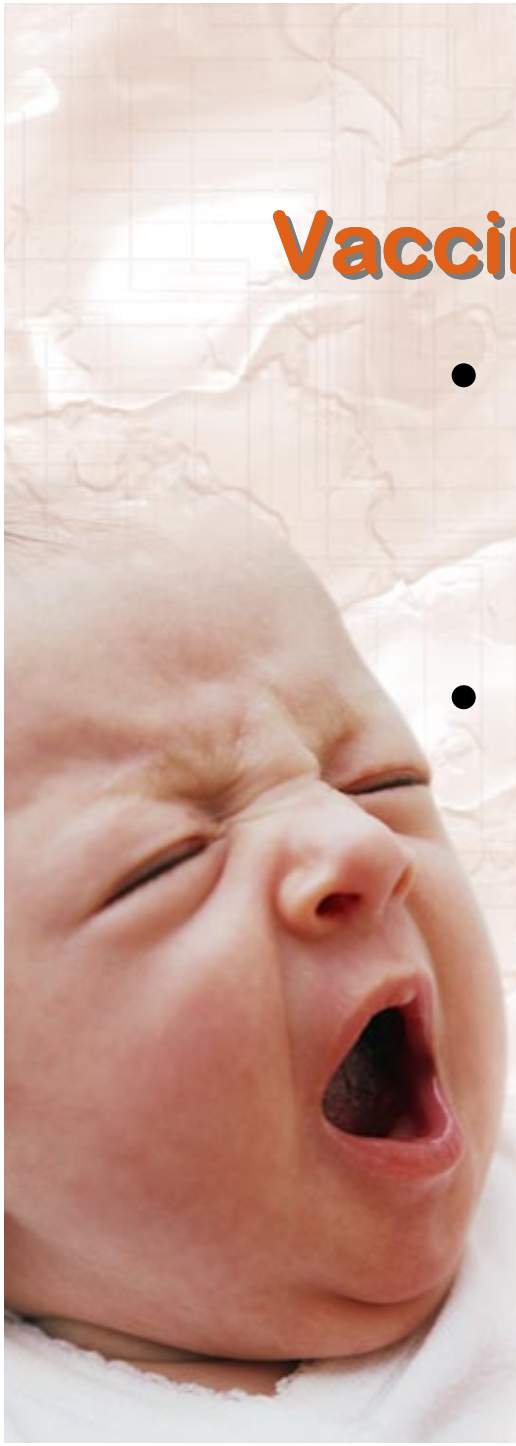


- **Exaggerated immune response**
  - **↑ production of allergen – specific IgE**
  - **Binding of IgE to mast cells**
  - **Release by mast cells of specific mediator of inflammation (eg. Hestamine)**
- **Inflammatory mediators induce series of events → contraction of stomach muscles, ↑ vascular permeability, hyper-secretion of mucus → wheezing, urticaria, sneezing, rhinorrhea or conjunctivitis**

Ref : Offit et al, Pediatrics Mar 2003; III(3): 653 – 659
Kay AB N Eng J Med 2001; 344: 30 - 37

Vaccines and Allergic Diseases

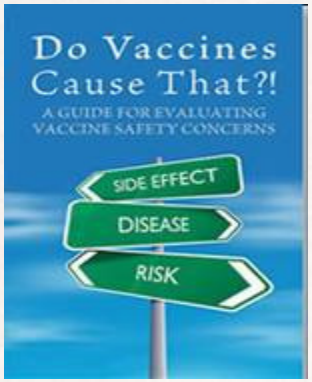




- **Mechanism prepared – Focus on factors that prolongs or enhance Th2-type responses and decrease Th1-type responses**
- **Hygiene hypothesis – Delay in early childhood infections prevents development of Th1-type responses and allows persistence of Th2 type responses initiated before birth**
  - **Th2-type responses promote secretion of IgE, risk of allergic diseases ↑**
  - **Vaccines prevent childhood infections, some say that they might prolong Th2-type responses and ↑ risk of allergens**

Ref : Offit et al. Pediatrics Mar 2003; 111(3): 653 – 659

Vaccines and Allergic Diseases

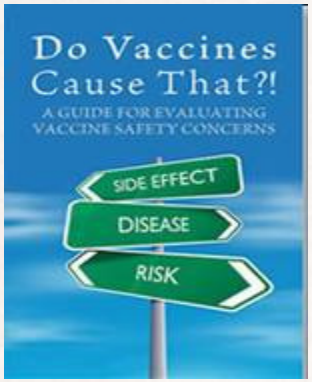


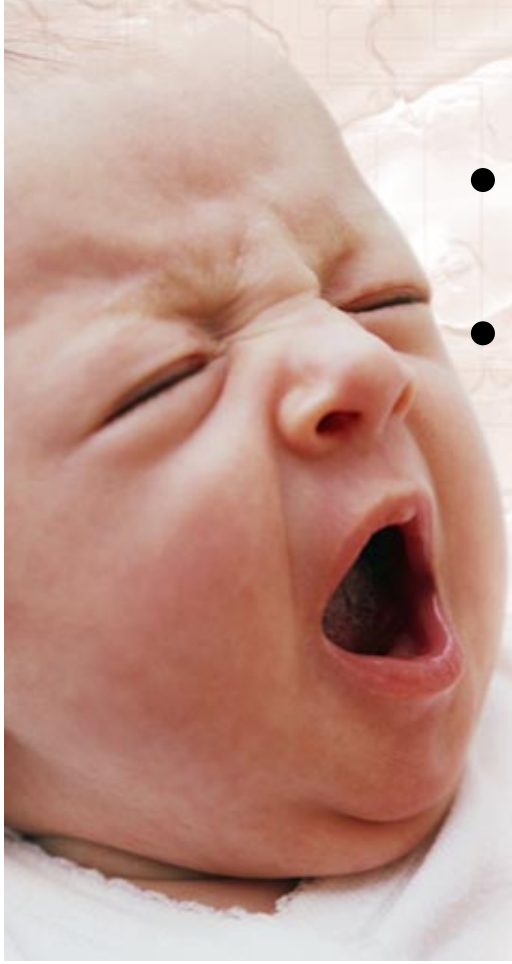
- **Hypothesis that vaccines cause allergies by preventing childhood infection and that allergies are caused by Th1-Th2 inbalance are flawed**
  - **Vaccines do not prevent most childhood infections**

    Ex. Study in Cleveland, 2500 illnesses, children experienced 6 – 8 infections in first 6 yr of life, viral
  - **Diseases prevented by vaccines, DPT, MMR, Varicela are highly contagious & easily transmitted**
  - **Children infected with worms & helminthes have lesser incidence of allergies than to other children**
  - **Diseases with strong Th1-type immune response occur in same regions as those with ↑ frequency of allergies.**

Ref : Offit et al. Pediatrics Mar 2003; 111(3): 653 – 659
Dingle et al. The Press of Western Research Univ; 1964
Van den Biggeluar et al. Lancet 2000; 356: 1723 – 1727
DuBois et al. N Eng J Med 1999; 341: 1302 - 1304

Vaccines and Allergic Diseases

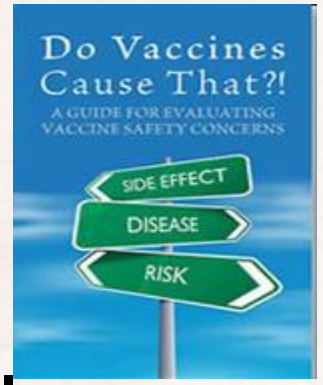




- **Well-controlled study using computerized records of children born between 1991 – 1997**
- **This cohort was used to identify 18,407 children with asthma**
- **Relative risk of asthma**
  - **Vaccinated children** — **0.92 (DTPw)**, **1.09 (OPV)**, **0.97 (MMR)**
  - **Unvaccinated children** — **1.07 (Hib)**, **1.09 (Hep B)**

Ref : De Stefano et al, Pediatr Infect Dis J 2002; 21: 498 - 504

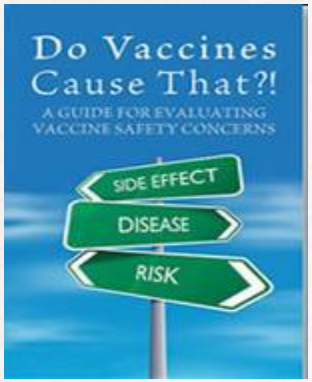
Vaccines and Allergies



- **Well-controlled study prospectively evaluated risk of allergies after receipt of pertussis vaccine in 669 children beginning at 2mos**
  - **One group – 2-component DPTa**
  - **2nd group – 5-component DPTa/DTPw**
  - **Control group – DT**
- **Follow-up 2.5yrs & risk of allergy was determined by parent questionnaires & medical records**
- **Asthma, atopic dermatitis, allergic rhinoconjunctivitis, urticaria & food allergens**

Ref : Nilsson et al Arch Pediatr Adolesc Med, 1998; 152: 734 - 738

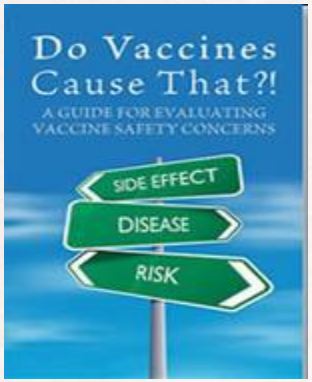
Vaccines and Allergies



- **No differences in incidence of allergic diseases were observed in children who or did not receive pertussis vaccine**
- **Children with normal pertussis infection were more likely to develop allergic diseases than children not infected with pertussis**

Ref : Nilsson et al Arch Pediatr Adolesc Med, 1998; 152: 734 - 738

Vaccines and Allergies

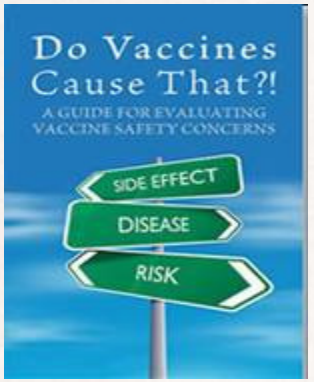


Conclusion

- Other controlled studies found no evidence that vaccines increased the risk for allergic diseases
- Studies fail to support the hypothesis that vaccines cause allergic diseases

Ref : Offit et al, Pediatrics Mar 2003; III(3): 653 – 659

Vaccines and Autoimmune Diseases

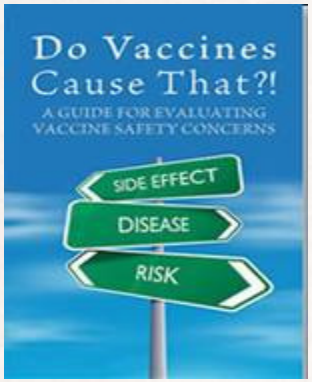


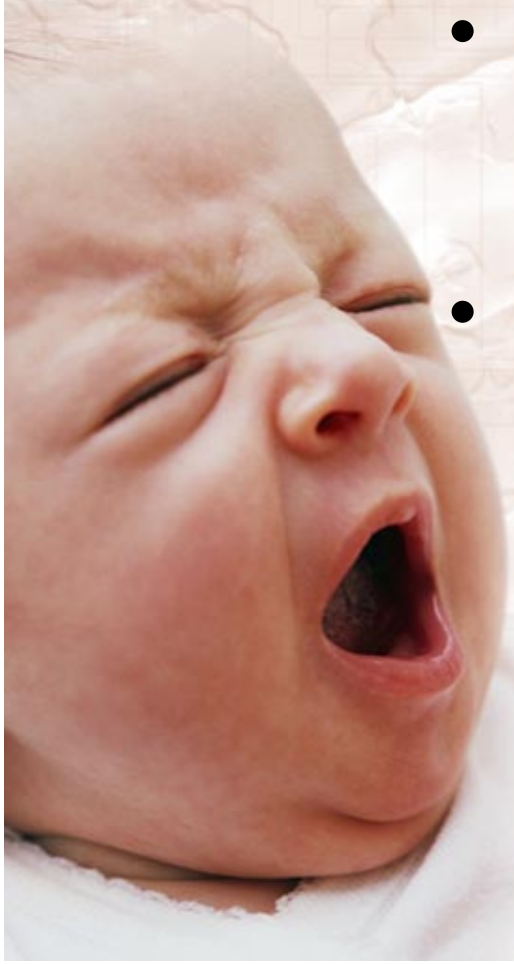
- Pathogenesis dependent on recognition of self-antigens by activated T and B cells
- Several infections cause autoimmune diseases

  Ex. Grp A β-hemolytic strep → RF (RHD)
- Molecular mimicry – mechanism by w/c natural infections are likely to cause autoimmune disease
  - Biological organisms share parts of many genes, some microbial pathogens are similar to human proteins
  - In responding to proteins on invading microbes, immune system might also respond to self-proteins ("molecular mimicry") & cause damage

Ref : Zafriskie et al. J Exp Med, 1966; 124: 661 – 678
Steinman L. Nat Immunol. 2001; 2: 762 – 764
Rogner et al. Nat Immunol. 2001; 2: 185 – 188
Albert et al. N Engl J Med 1999; 341: 2068 – 2074
Offit et al. Pediatr 2003; III: 653 - 659

Vaccines and Multiple Sclerosis

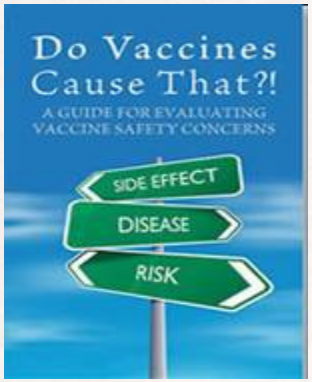




- Hallmark of MS is loss of myelin in CNS
- Activated self-reactive T cells are believed to infiltrate CNS, attach to self antigens (eg. Myelin basic protein [MBP]) & cause demyelination
- Hep B & Influenza vaccines proposed to cause or exacerbate MS by molecular mimicry
  - French government suspended school-based program of Hep B vaccination due to animal studies, anecdotal reports & 2-case control studies that are statistically significant

Ref : Offit et al. Pediatr 2003; III: 653 – 659
Fujinami et al. Science 1985; 230: 1043 - 1045
Herroelen et al. Lancet 1991; 338: 1174 - 1175
Noaler et al. Clin Infect Dis 1993; 17: 928 - 929
Fourrier et al. Pharmacoepidemiol Drug Saf 1999; 8 (Suppl): S140 – S141
Sturkenboom et al. Pharmacoepidemiol Drug Saf 1999; 8 (Suppl): S170 – S171
Touze et al. Rev Neurol 2010; 156: 242 - 246

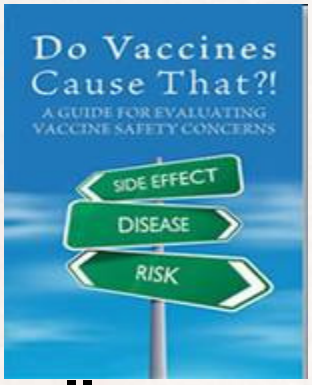
Vaccines and Multiple Sclerosis



- **Hypothesis that Hep B vaccine causes MS is flawed**
  - **Protein in Hep B vaccine is HBsAg & not similar to MBP**
    - **Studies of Hep B virus polymerase protein in rabbits is irrelevant**
    - **Natural infection w/ HBV is associated with production of large quantities of HBsAg but is not associated with ↑ risk of MS**
      - » **Natural infection – 100 μg/ml – 500 μg/ml HBsAg**
      - » **Hep B vaccine – 10 – 40 μg/ml HBsAg**

Ref : Offit et al. Pediatr 2003; III: 653 – 659
Weecherfenning et al. Cell 1995; 80: 695 - 705
Robinson, WS. Principles & Practices of Infectious Diseases, 5th ed Philadelphia, PA: Churchchill Livingstone; 2000: 1656

Vaccines and Multiple Sclerosis

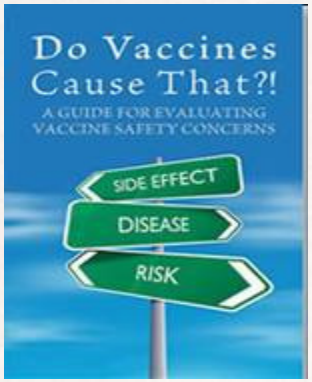


- Capacity of vaccines to cause or exacerbate MS has been evaluated in well-controlled epidemiologic studies
- Two large case-control studies evaluated whether Hep B vaccine causes MS or whether Hep B, Tetanus or Influenza exacerbate symptoms of MS
- 121,700 nurses followed from 1976
  116,671 nurses followed from 1989
  - 645 matched controls

  Identify 192 women w/ MS
- Vaccination status determined
  - Mailed questionnaire
  - Vaccination certificates

Ref : Ascherio et al. N Engl J Med 2001; 344: 327 – 332
Offit et al. Pediatr 2003; III: 653 - 659

Vaccines and Multiple Sclerosis

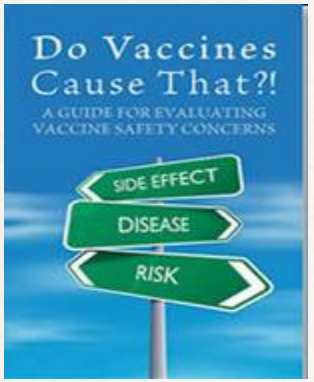


- **Results**
  - Multivariate RR of MS to Hep B = 0.9

    RR w/in 2yrs before onset of disease = 0.7
  - No association with number of doses of Hep B vaccine and risk of MS
  - Second study w/ 643 patients w/ relapse of MS between 1993 & 1997 from European Database for MS
    - Vaccination status determined
      - » Telephone interviews
      - » Medical records
    - Exposure to vaccination in 2-month period before relapse compared with 4 previous 2-month control periods to determine RR
      - » RR w/ any vaccine = 0.71
      - » RR w/ Hep B = 0.67
      - » RR w/ Tetanus = 0.75
      - » RR w/ Influenza = 1.08
    - Therefore, vaccines do not appear to cause or exacerbate symptoms of MS

Ref : Ascherio et al. N Engl J Med 2001; 344: 327 – 332
Confavreux et al N Engl J Med 2001; 344: 319 - 326

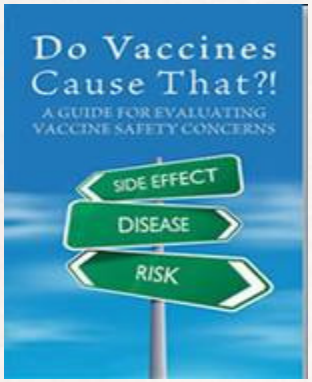
Vaccines and Multiple Sclerosis



- Additional well-controlled studies found that influenza vaccine did not exacerbate symptoms
- Retrospective study of 180 patients with relapsing MS
  - Infection with influenza virus was more likely than immunization w/ influenza vaccine to cause exacerbation of symptoms
  - MBP – specific T cells were mildly stimulated after natural infection but not after influenza immunization
- Findings suggest influenza vaccine is more likely to prevent than cause exacerbation of MS

Ref : De Keyser et al J Neurol Sci 1998; 159: 51 - 53
Moriabadi et al Neurology 2001; 56: 938 – 943
Miller et al Neurology 1997; 48: 312 - 314

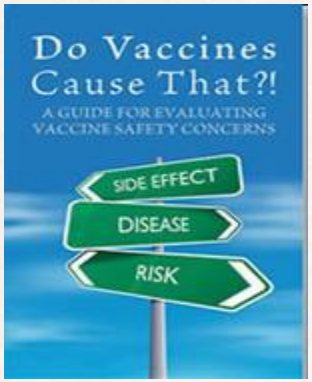
Vaccines and Type 1 Diabetes



- Type 1 diabetes attributable to a deficiency of insulin caused by destruction of pancreatic islet cells
- Antibodies vs pancreatic islet cells proteins present
- Natural infections cause type 1 diabetes in genetically susceptible
- Hypothesis: Timing of vaccines either causes or prevents type 1 diabetes
- First tested on uncontrolled observational studies
  - Lower incidence of Type 1 diabetes in subjects w/ BCG at birth
  - In Finland, Higher incidence of Type 1 diabetes in those with 4-doses of Hib compared to 1 dose at 14 months

Ref : Classen et al. Infect Dis Clin Pract. 1997; 6: 449 - 454
Dahlquist et al. Diabetologia. 1995; 38: 873 - 874
Allen et al. Diabetes Care. 1999; 22: 1703 - 1707

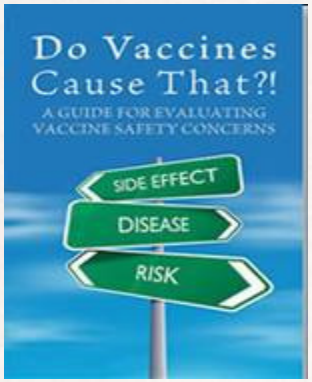
Vaccines and Type 1 Diabetes



- **Subsequent studies**
  - **BCG did not prevent Type 1 diabetes**
  - **Finnish study – Hib vaccine incorrect, no significant differences in incidence of Type 1 diabetes in Hib vaccinated infant**
  - **21,421 children received Hib conjugate vaccine between 1988 – 1990 in US and followed up x 10 years**
    - **Risk of Type 1 diabetes when compared with children who did not received vaccine = 0.78**

Ref : Dahlquist et al. Diabetologia. 1995; 38: 873 - 874
Allen et al. Diabetes Care. 1999; 22: 1703 – 1707
Institute for Vaccine Safety Diabetes Workshop Panel. Pediatr Infect Dis J. 1999; 18: 217 – 222
Black et al. Pediatr Infect Dis J. 2002; 21: 568 - 569

Vaccines and Type 1 Diabetes

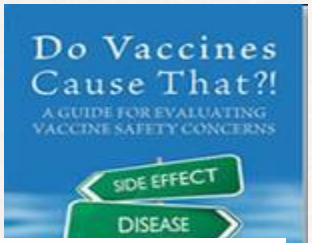


- **Well-controlled study evaluating relationship between vaccines and Type 1 diabetes**
  - **Used data from Vaccine Safety Datalink**
  - **252 cases of Type 1 diabetes compared with 768 matched control**
- **Other well-controlled retrospective study found immunization not associated with increase risk of developing Type 1 diabetes**

The best available evidence does not support the hypothesis that vaccines cause Type 1 diabetes

Ref : DeStefano et al. Pediatr. 2001; 108 (6)
Heijbel et al. Diabetes Care. 1997; 20: 173 – 175
Graves et al. Diabetes Care. 1999; 22: 1694 – 1697
Hummel et al. Diabetes Care. 2000; 23: 969 - 974

Vaccines and Autism



http://www.npr.org/blogs/thetwo-way/2010/02/autism_mmr_vaccine_link_lancet.html?ft=1&f=103943429/r:t

Congrats Mom!

Autism And MMR Vaccine-Link Lancet Article Retracted

By Frank James

The prestigious British medical journal, The Lancet, is washing its hands completely of a study it published in 1998 that helped fuel global concerns of ties between the combined vaccine for measles, mumps and rubella, or MMR, and autism.

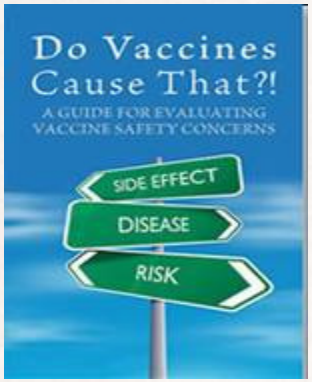
Such a retraction is a big deal in the world of peer-reviewed journals. One reason for experts in the same fields of research as the submitted papers to review these studies in the first place is to prevent exactly this kind of embarrassing backtracking.

A layperson would have a hard time understanding the significance of all this based on the headline on The Lancet retraction: "Retraction--Ileal-lymphoid-nodular hyperplasia,
non-specific colitis, and pervasive developmental disorder in children."

Reuters breaks it down in English:

> LONDON, Feb 2 (Reuters) - The Lancet medical journal formally retracted a paper on Tuesday that caused a 12-year international battle over links between the three-in-one childhood vaccine MMR and autism.
>
> The paper, published in 1998 and written by British doctor Andrew Wakefield, suggested the combined measles, mumps and rubella (MMR) shot might be linked to autism and bowel disease.
>
> His assertion caused one of the biggest medical rows in a generation and led to a big fall in the number of vaccinations, prompting a worrying rise in cases of measles.
>
> "It has become clear that several elements of the 1998 paper by Wakefield ... are incorrect," the internationally renowned scientific journal said in a statement.
>
> A disciplinary panel of Britain's General Medical Council ruled last week that Wakefield had shown a "callous disregard" for the suffering of children and had brought the medical profession "into disrepute".

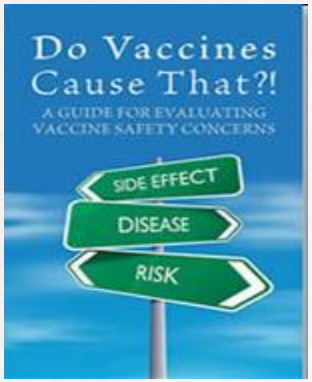
Vaccine and Allergic and Autoimmune Diseases



- Several mechanism proposed
  - Flaws consistent with large well-controlled epidemiologic studies that do not support hypothesis
  - Infections with wild-type bacteria more likely to expose self-antigens and induce levels of cytokines > that found after immunization
    - Some vaccines are likely to prevent or modify than cause or exacerbate autoimmune diseases

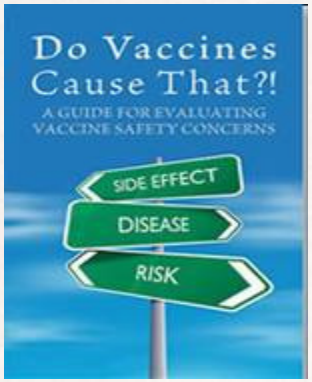
Ref : Offit et al. Pediatr. 2003; 111: 653 - 659

VACCINE AND CHRONIC ILLNESS



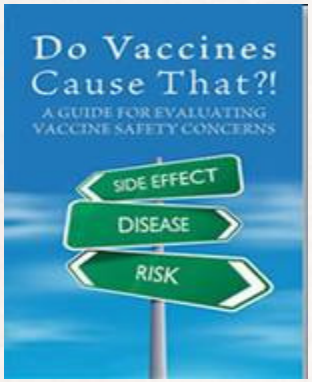
- Based on best available evidence, published articles do not support causal relationship between vaccines and allergies, chronic diseases and autism
- Medical conclusions about safety of vaccines or cause of a disease must be judged on quality of scientific research and weight of evidence
- Association of vaccine with chronic illness faulty, deceiving, and misrepresented

Immunization



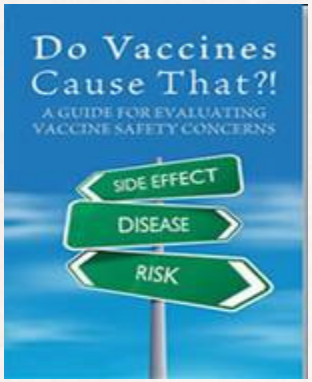
- Highly immune population
- Universal immunization important in good health care, accomplished by routine and intensive programs in public health and physicians clinic
- Adhere to standards of immunization practices
  - Define appropriate immunization practices
  - Provide guidance on how to make immunization service more conducive
  - Eliminate barriers to vaccination

Immunization

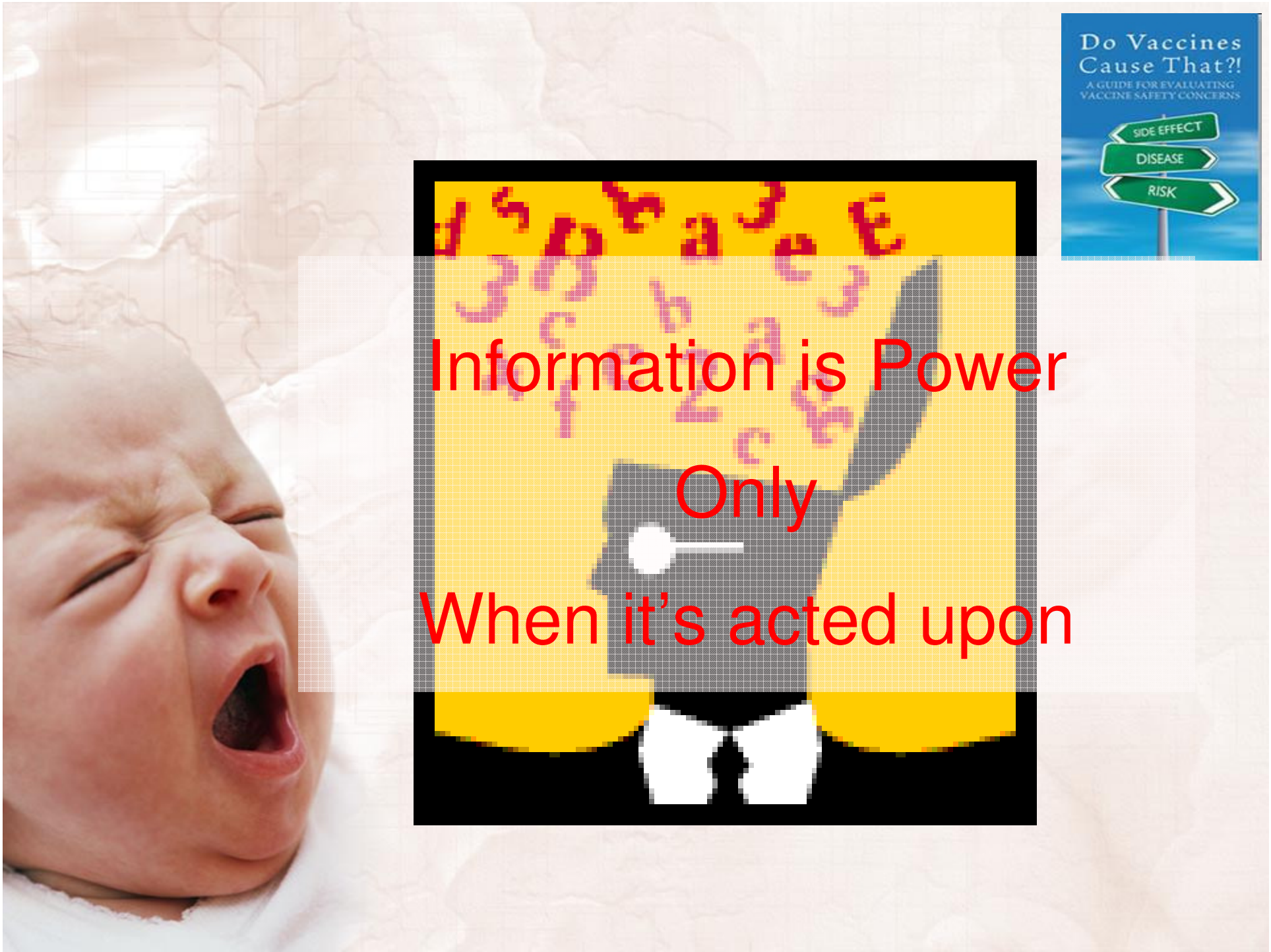


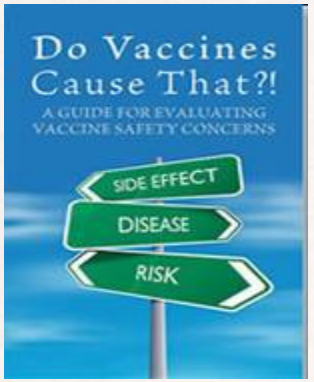
- No vaccine is without risk
- Balance scientific evidence of benefits, costs, and risks when recommending vaccines
- Protect against infectious disease

Vaccine Safety



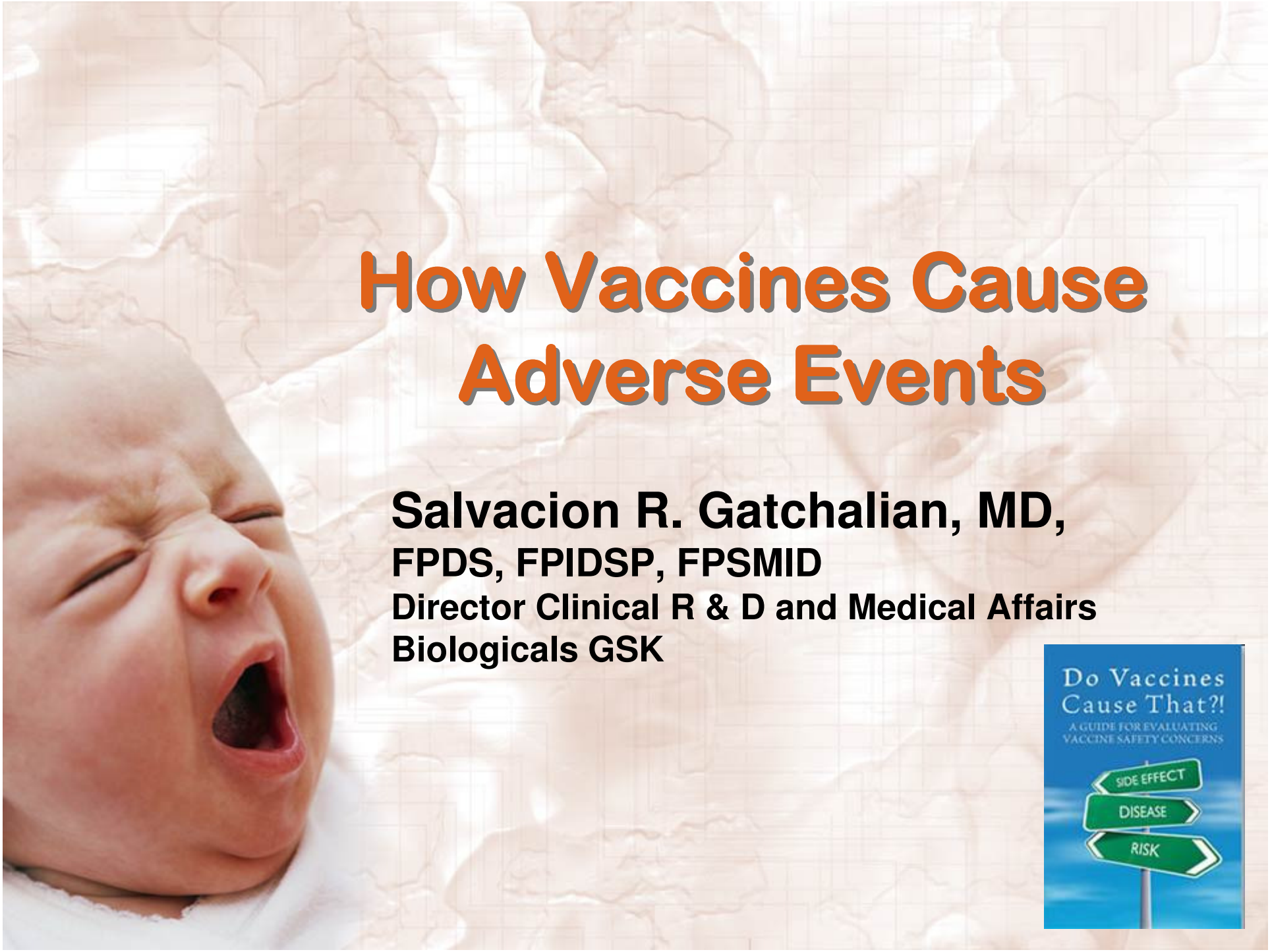
- Practitioner has responsibility to listen, understand patient concerns, fears, beliefs
- Strengthen bond of trust between patient and provider
- Decide arguments effective in persuading patients to accept vaccination


Do Vaccines Cause That?!
A GUIDE FOR EVALUATING VACCINE SAFETY CONCERNS
SIDE EFFECT
DISEASE
RISK
Information is Power
Only
When it's acted upon



The pessimist complains
about the wind;
The optimist expects
it to change;
The realist adjusts the sails


Thank you....
Hi hi hi.....



How Vaccines Cause Adverse Events

Salvacion R. Gatchalian, MD,
FPDS, FPIDSP, FPSMID
Director Clinical R & D and Medical Affairs
Biologicals GSK