What I did to competently comply with SB 277

Part I In My Defense

Part II The CDC and the Science

Part III Addendum

I never wanted to do anything untoward, but there was a lot of confusion and ambiguity on how to write medical exemptions under the law based on SB 277, I created a detailed Policy & Procedure manual after careful examination of the medical literature.

I wanted to do the right thing for the children who came to me under the circumstances. I had a responsibility to protect the vulnerable under the parameters of the new law.

But no one in officialdom came forward to assist with understanding what the new law meant or how to implement it in the context of writing medical exemptions for a couple of years.

Policy and Procedure

In the Evaluation of
Patients for Adverse Risk Following Immunizations

By KP Stoller, MD

Version 7

Lack of Standard

Despite Dr. Pan's reassurance that there would be no limitations in writing Medical Exemptions, practically speaking no one has complete discretion to do whatever they want.

I reached out to the Medical Board to review and clarify what I had the discretion to do and was rebuffed.

"We don't do that, we just respond to complaints," I was told.

Policy and Procedure

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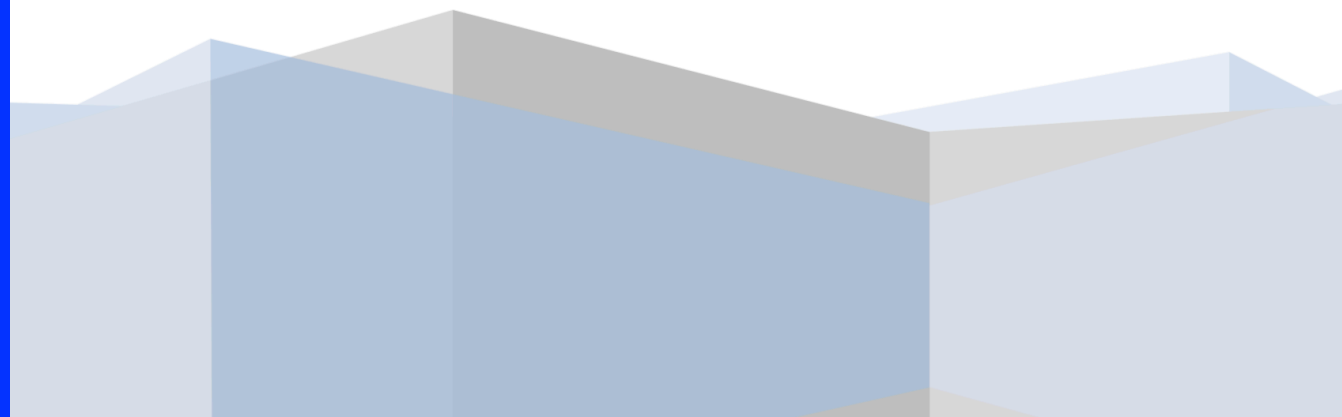


Many physicians and **even knowledgeable lawyers** believed the law based on SB 277 changed the criteria for Medical Exemptions by making a physician's determination of "safety" the benchmark.

“including, but not limited to, family medical history, for which the physician does not recommend immunization,”

…….but…….

"is not considered safe" is a very broad phrase given there is nothing to compare "safe" to, nor does the law define safe. Safe is not just a word.

Dr. Pan seemed to clear that up when he said: “There are no limitations to writing a medical exemption other than the physician’s medical judgment.”

“There is no specific list of things that they can or cannot exempt for.”

Pan was either defining a new Standard for writing exemptions or he was creating great confusion and ambiguity about writing Medical Exemptions.

Before SB 277 – Medical Exemptions were limited to CDC contraindications, which do not take into account family history or genetics. And the word contraindication was even edited out of the law.

Based on the explicit statements of Dr. Pan many physicians thought SB 277 did in fact change change the law and the standard of care.

He encouraged physicians to think they had the discretion to write medical exemptions beyond CDC suggested guidelines, but then called them fraudsters for doing what he encouraged them to do.

But let’s say SB 277 didn’t create a new Standard, still I and many others thought it did and acted in good faith.

A medical exemption is not a treatment – it is “advice” (see Cal. Business & Professions Code section 2234.1(a) protecting alternative treatments and advice). So a medical exemption inquiry begs the question whether the doctor proactively gave any advice to protect the patient and community from infectious disease.

Each one of my patients were informed that *“the medical exemption letter is ‘a recommendation’ that does not prohibit your child from obtaining a second opinion or obtaining vaccination from another physician. The medical exemption is written from my integrative/functional medicine perspective. It is my medical opinion about the risk your child may experience based on their genetics. Having said that, integrative physicians who practice* ***alternative or complementary*** *medicine routinely function in different medical communities than conventional physicians you are encouraged to get the opinion of a conventional physician as well if you so choose to do so.”*

"different doctors may disagree in good faith upon what would encompass the proper treatment or diagnosis of a medical problem in a given situation. Medicine is not a field of absolutes. There is not ordinarily only one correct route to be followed at any given time. There is always the need for professional judgment as to what course of conduct would be most appropriate with regard to the patient's condition."

Barton v. Owen, 71 Cal. App.3d 484, 501-502 (Cal.App.2.Dist. 1977).

The MBC's current position is SB 277 didn't change anything, the Standard of Care didn't change.

I submit that SB 277 was rejected and replaced with 276 for the express reason that it did give physicians the authority to write medical exemptions beyond CDC contraindications and that was not really what its proponents intended. It was SB 276 that was the desired law and the SB 277 was just a temporizing measure, because 276 would never have passed in 2015.

“Where there is more than one recognized method of diagnosis or treatment, and no one of them is used exclusively and uniformly by all practitioners of good standing, a physician and surgeon is not negligent if, in exercising his best judgment, he selects one of the approved methods, which later turns out to be a wrong selection, or one not favored by certain other practitioners.”

California Civil Jury Instruction (BAJI) 6.03. Se also, BAJI Instruction 214-A, California Jury Instructions, Civil, 4th Revised Edition.

There was a systemic problem with the ambiguous law created by SB 277.

Real Standard of Care is making a reasonable effort to provide the best care under the circumstances.

Real Standard of Care would include informed consent - something that was eliminated by SB 277.

With Informed Consent functionally eliminated understanding what “safe” meant became even more important especially since “safe” in the context of SB 277 was what the physician determined was safe.

So, if safety is the determining factor how does a competent physician deal with the cognitive dissonance that just came from the World Health Organization meeting where they admitted that vaccine hesitancy is backed by science not misinformation and that the mantra vaccines are safe or adequately tested is not the compete truth.

Vaccine Injury is real and while those vulnerable may be a minority that is the point – they are a minority and have rights to be protected not eroded. They deserve to be safe, and those few physicians who actually screened them for risk should not be disciplined for conscientiously doing what they thought the law called for.

In the zeal to protect the Vaccine Program and Vaccine Policy the primary objective of protecting every child to the greatest extent possible from harm has been lost. Every child susceptible to a vaccine injury or injured by a vaccine deserves better. They deserve to be screened for risk, and if required protected.

Part II What CDC documents, the WHO and Government Science Reveals

When it comes to vaccines the CDC and the IOM (Institute of Medicine) are considered the highest law in the land.

So what did they know and when did they know it?

In 1999, the CDC looked at the Hep B vaccine (Results not released to the Public or the Medical Community)

The results of this study were never released by the CDC, and an abstract of the study was only recently obtained under a FOIA request. Children vaccinated with Hepatitis B vaccine in the first month of life, compared to children receiving no vaccines in the first month of life, had an increased risk of 829% for ADHD, 762% for autism, 638% for ADD, 565% for tics, 498% for sleep disorders, and 206% for speech delays.

Verstraeten, Thomas M., MD, NIP, Division of Epidemiology and Surveillance, Vaccine Safety and Development Branch, Mailstop E-61, 770-639-8327.
EIS Class Year of Entry: 1999
No previous EIS Conference presentations
Mackel Award consideration: No
Number of abstracts submitted: 2, priority this abstract: 1
Strong preference for poster presentation: No

Thomas M. Verstraeten, R. Davies, D. Gu, F DeStefano

Increased risk of developmental neurologic impairment after high exposure to thimerosal-containing vaccine in first month of life.

Background: Concern has risen on the presence of the ethylmercury containing preservative thimerosal in vaccines. We assessed the risk for neurologic and renal impairment associated with past exposure to thimerosal-containing vaccine using automated data from the Vaccine Safety Datalink (VSD). VSD is a large linked database from four health maintenance organizations in Washington, Oregon and California, containing immunization, medical visit and demographic data on over 400,000 infants born between '91 and '97.

Methods: We categorized the cumulative ethylmercury exposure from thimerosal containing vaccines after one month of life and assessed the subsequent risk of degenerative and developmental neurologic disorders and renal disorders before the age of six. We applied proportional hazard models adjusting for HMO, year of birth, and gender, excluding premature babies.

Results: We identified 286 children with degenerative and 3702 with developmental neurologic disorders, and 310 with renal disorders. The relative risk (RR) of developing a neurologic development disorder was 1.8 (95% confidence intervals [CI] = 1.1-2.8) when comparing the highest exposure group at 1 month of age (cumulative dose > 25 ug) to the unexposed group. Within this group we also found an elevated risk for the following disorders: autism (RR 7.6, 95% CI = 1.8-31.5), nonorganic sleep disorders (RR 5.0, 95% CI = 1.6-15.9), and speech disorders (RR 2.1, 95% CI=1.1-4.0) . For the neurologic degenerative and renal disorders group we found no significantly increased risk or a decreased risk.

Conclusion: This analysis suggests that high exposure to ethylmercury from thimerosal-containing vaccines in the first month of life increases the risk of subsequent development of neurologic development impairment, but not of neurologic degenerative or renal impairment. Further confirmatory studies are needed.

Not released to the Public

In June of 2000 the CDC held a secret meeting to discuss more disturbing results. Fifty-one vaccine and vaccine safety researchers and experts meet in Georgia to review data regarding Thimerosal in vaccines and nervous system disorders. A report summarizing the meeting was presented to ACIP.

What was disclosed at Simpsonwood?

That the relative rates of increased risk to children exposed to greater than 25 mcg of Thimerosal according to the original study:

ADHD: 11.35 times more likely
autism: 7.62 times more likely
ADD: 6.38 times more likely
Tics: 5.65 times more likely
Speech and language delay: 2.08 times more likely

Any relative risk higher than 2 is considered positive.

What was disclosed at Simpsonwood?

The experts at Simpsonwood could not decide if it was Thimerosal (mercury) or something else in the vaccine that was causing the problems they were finding. At that time almost all the vaccines had Thimerosal in them and not at the reduced levels now seen today. They knew they had a problem but were uncertain which vaccine component(s) to blame. They just decided to hide the information not research what the problem was.

Simpsonwood 2000 vs WHO meeting on Global Vaccine Safety 2019?

While a CDC meeting that took place in the year 2000 might seem like it is only of historical interest, because the CDC and other experts decided not to research their alarming findings and cover them up, the same issues were brought up 20 years later by the WHO.

Simpsonwood vs WHO meeting on Global Vaccine Safety 2019?

page 19-20, Walt Ornstein says, “Aluminum and mercury are often simultaneously administered to infants …However, we also learned that there is absolutely no data, including animal data, about the potential for synergy, additivity, or antagonism, all of which can occur in binary metal mixtures that relate and allow us to draw any conclusions from the simultaneous exposure to these two salts in vaccines.”

Twenty years later… from the WHO

There’s a lot of vaccine safety science that’s needed, and without the good science we can’t have good communication. So, although I’m talking about all these other contextual issues and communication issues, it absolutely needs the science as the backbone. You can’t repurpose the same old science that’s relevant to new problems. So we need much more investment in safety science.

Heidi Larson, Director of the WHO’s Vaccine Confidence Project.

From Simpsonwood…

"There are just a host of neurodevelopmental data that would suggest we've got a serious problem." (p. 24)

"The second point I could make is that in relationship to aluminum, being a nephrologist for a long time, the potential for aluminum and central nervous system toxicity was well established by dialysis data. To think there isn't some possible problem here is unreal." (p. 24-25)

Dr. Weil (Pediatrician representing the Committee on Environmental Health of the Academy)

From the WHO…

"As we add adjuvants…the primary concern, though, is systemic adverse events rather than local adverse events. And we tend to get in the Phase II and Phase III studies quite good data on the local reactogenicity…But this is not the major health concern. The major health concerns which we are seeing are accusations of long-term effects. So to come back to this, I'm going to once again point to the regulators. It comes down to ensuring that we conduct the Phase II and the Phase III studies with adequate size and with the appropriate measurement."

Martin Howell Friede, Coordinator, Initiative for Vaccine Research, WHO

From Simpsonwood…

"…The number of dose related relationships are linear and statistically significant. You can play with this all you want. They are linear. They are statistically significant." (p. 207)

"…The increased incidence of neurobehavioral problems in children in the past few decades is probably real…I work in the school system where my effort is entirely in special education and I have to say that the number of kids getting help in special education is growing nationally and state by state at a rate we have not seen before. So there is some kind of an increase. We can argue about what it is due to…But there are certainly more kids with ADD and there are more kids with speech and language disorders than there have been in the past." (p. 207)

Dr. Weil

From the WHO…

We have a very wobbly health professional frontline that is starting to question vaccines and the safety of vaccines. When the frontline professionals are starting to question or they don't feel like they have enough confidence about the safety.

Heidi Larson

The only post-market safety surveillance system that the CDC has is the passive VAERS reporting system even though it admits the VAERS system leaves out over 99% of actual adverse events. This CDC publication reveals that between 1997-2013 **79.4%** of SIDS deaths had a vaccine in the last 24 hours.

Paradoxically, they concluded there were no concerning patterns of the deaths reported.

Published in final edited form as:
Clin Infect Dis. 2015 September 15; 61(6): 980–987. doi:10.1093/cid/civ423.

Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997–2013

Pedro L. Moro, **Jorge Arana**, **Maria Cano**, **Paige Lewis**, **Tom T. Shimabukuro**
Immunization Safety Office, Centers for Disease Control and Prevention, Atlanta, Georgia

Abstract

Background.—Vaccines are among the safest medical products in use today. Hundreds of millions of vaccinations are administered in the United States each year. Serious adverse reactio are uncommon. However, temporally associated deaths can occur following vaccination. Our ai was to characterize main causes of death among reports submitted to the US Vaccine Adverse Event Reporting System (VAERS), a spontaneous vaccine safety surveillance system.

Methods.—We searched VAERS for US reports of death after any vaccination from 1 July 19 through 31 December 2013. Available medical records, autopsy reports, and death certificates were reviewed to identify cause of death.

Results.—VAERS received 2149 death reports, most (n = 1469 [68.4%]) in children. Median was 0.5 years (range, 0–100 years); males accounted for 1226 (57%) reports. The total annual number of death reports generally decreased during the latter part of the study period. Most common causes of death among 1244 child reports with available death certificates/autopsy reports included sudden infant death syndrome (n = 544 [44%]), asphyxia (n = 74 [6.0%]), septicemia (n = 61 [4.9%]), and pneumonia (n = 57 [4.6%]). Among 526 adult reports, most common causes of death included diseases of the circulatory (n = 247 [46.9%]) and respiratory systems (n = 77 [14.6%]), certain infections and parasitic diseases (n = 62 [11.8%]), and malign neoplasms (n = 20 [3.8%]). For child death reports, 79.4% received >1 vaccine on the same day Inactivated influenza vaccine given alone was most commonly associated with death reports in adults (51.4%).

Conclusions.—No concerning pattern was noted among death reports submitted to VAERS during 1997–2013. The main causes of death were consistent with the most common causes of death in the US population.

Obviously, if you believe that no children are harmed from a vaccine or that the most dangerous ingredient in a vaccine is water, as per Dr. Pan, or that vaccines are the only means to deal with infectious disease then any physician who provides an exemption is grossly negligent.

The CDC commissioned a study to see if the VAERS system could be improved upon – *the Harvard-Pilgrim* Support for *Public Health–Vaccine Adverse Event Reporting System.*

The data was collected between 2007 and 2010.

What the CDC found out was the actual Adverse Event rate from vaccines was 1 in 39 (not the 1 in a million the public is told).

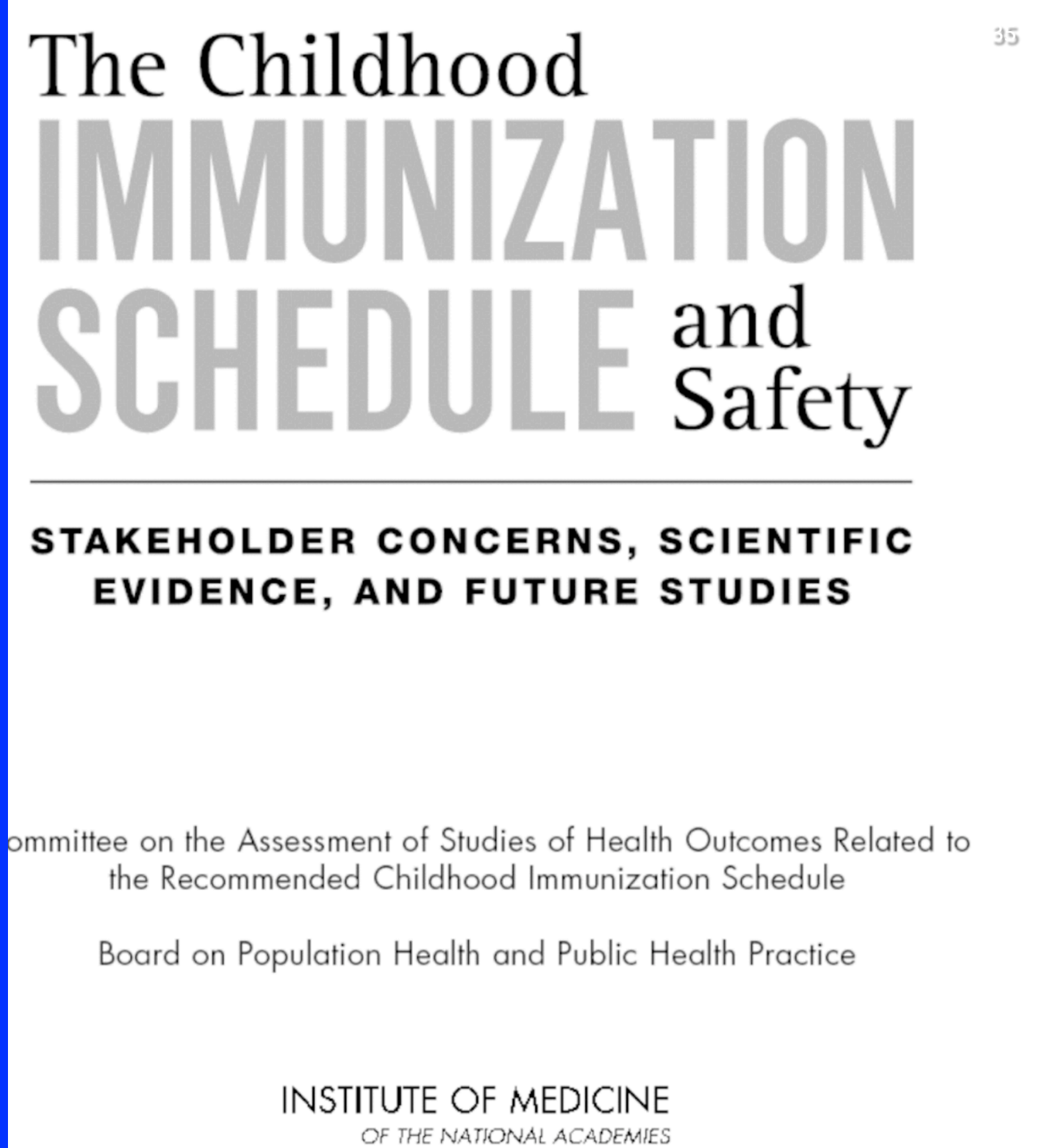
The CDC ignored the study and ghosted the scientists involved.

In 2013 the IOM stated:

"Because [vaccine] trials are primarily ... for determination of efficacy, conclusions about vaccine safety derived from these trials are limited."

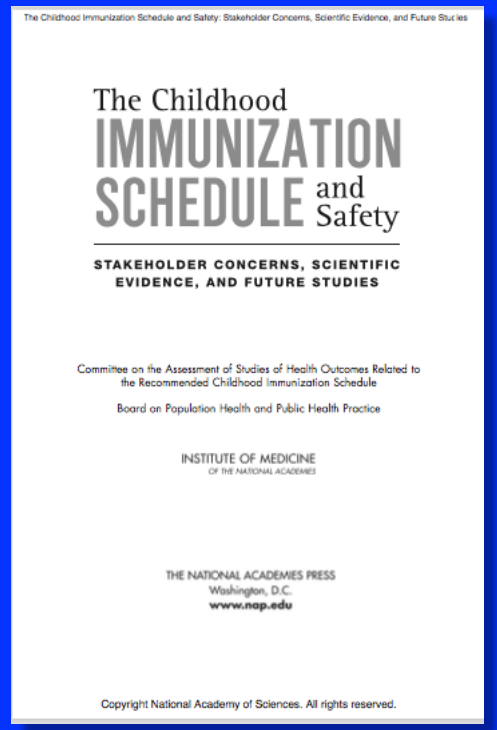
And that efficacy is research efficacy not clinical efficacy.

So, at least one respected faction of the Government/HHS is saying you can say vaccines are safe all you want but make no mistake - the studies that are being done are not safety studies.



Lack of Vaccine Safety Science

2013 IOM Report on Safety of Entire Immunization Schedule



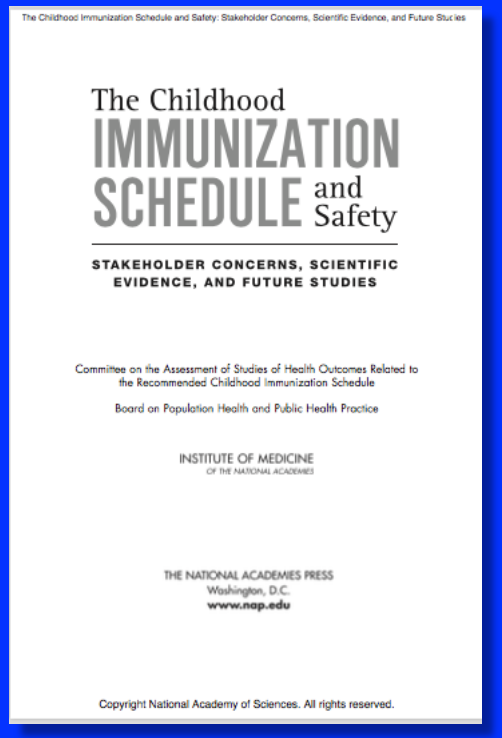
"committee's literature searches and review were intended to identify health outcomes associated with some aspect of the childhood immunization schedule. Allergy and asthma, autoimmunity, autism, other neurodevelopmental disorders (e.g., learning disabilities, tics, behavioral disorders, and intellectual disability), seizures, and epilepsy were included as search terms."

"No studies have compared the differences in health outcomes … between entirely unimmunized populations of children and fully immunized children. Experts who addressed the committee pointed … to the fact that existing research has not been designed to test the entire immunization schedule. … [Furthermore,] studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted."

https://www.nap.edu/download/13563

Lack of Vaccine Safety Science

2013 IOM Report on Safety of Entire Immunization Schedule

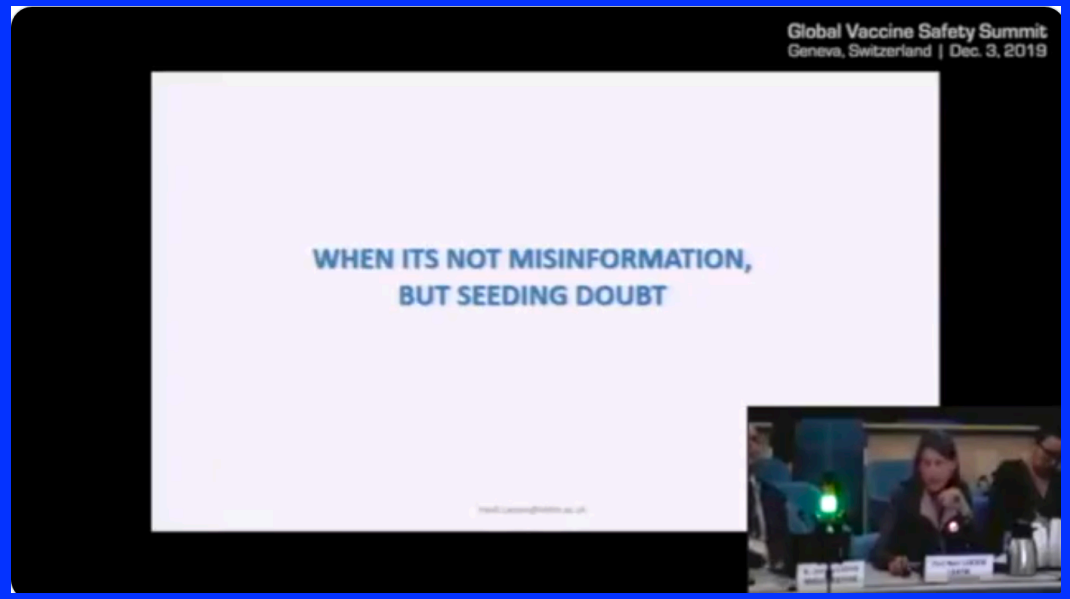


The IOM report essentially said there is no Vaccine Safety Science being conducted, which is legally untenable given The 1986 Vaccine Injury Act required HHS to report to Congress every two years about safety issues.

But there are no reports….. Decades of no reports.

Lack of Vaccine Safety Science

Now… why would there be no reports to Congress as required by law?

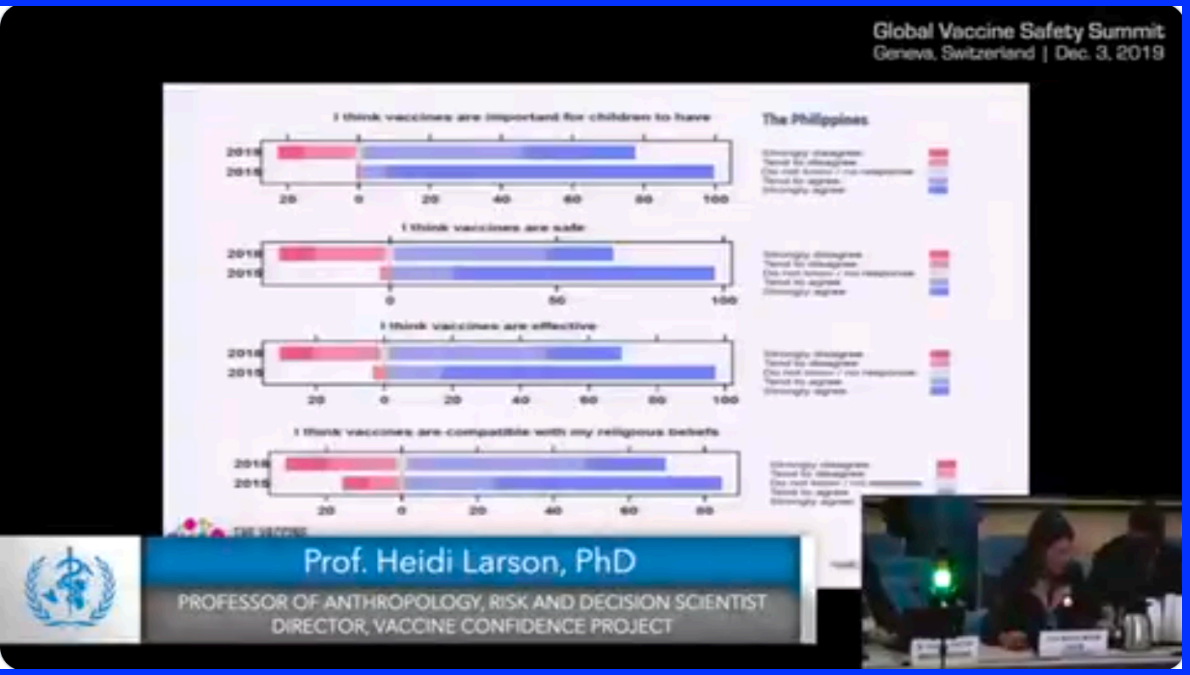


If you don’t do safety evaluations some feel you can say there is safety when there is none.

On Dec 2-3, 2019, the WHO held an important meeting called the Global Vaccine Safety Summit where they admitted there is no vaccine safety science but their concern was the Public Perception of this information. They said it is not misinformation that there is almost no safety science and that vaccine safety needs to BEGIN to be monitored or the Public will lose confidence.

Lack of Vaccine Safety Science

Even though there is no vaccine safety science the public must think there is.



Here Dr. Larson explains that Global Health Policy inadvertently created a vaccine dependent population and if the (false) confidence in vaccine safety is lost there could be major outbreaks, because natural immunity has been lost (because of the use of vaccines).

Lack of Vaccine Safety Science

How did vaccine safety research get left out of the program when saying vaccine are safe has become an axiom?

Dr. Friede's answer was that they NEED TO CONDUCT THE STUDIES! With adequate size and appropriate measurement!

He said that because the studies are NOT being done.

Lack of Vaccine Safety Science

Dr. Soumya Swaminathan, the Chief Scientist of the World Health Organization, admitted that some vaccines are killing people during the WHO Global Vaccine Safety Summit

"One should be able to give a very factual account of what exactly is happening, what the cause of deaths are, but in most cases there's some obfuscation at that level and therefore there's less and less trust in the system,"

The system she is talking about is the vaccine program that is losing trust because safety has not been studied.

In 2014 the CDC published this study….

Not only did they find the Pertussis vaccine didn't work, because 90% of the bacteria had evolved beyond the vaccine's reach but that getting the vaccine increased the chances of coming down with Pertussis four fold.

Obviously, the ability to produce antibodies does not make a vaccine efficacious if those antibodies do less than nothing. But that is clinical efficacy and is not used by the CDC/FDA as a criteria of efficacy.

CVI
Journals.ASM.org

Prevalence and Molecular Characterization of Pertactin-Deficient *Bordetella pertussis* in the United States

L. C. Pawloski,[a] A. M. Queenan,[b] P. K. Cassiday,[a] A. S. Lynch,[b] M. J. Harrison,[a] W. Shang,[b] M. M. Williams,[a] K. E. Bowden,[a] B. Burgos-Rivera,[a] X. Qin,[c] N. Messonnier,[a] M. L. Tondella[a]

Meningitis and Vaccine Preventable Diseases Branch, Centers for Disease Control and Prevention, Atlanta, Georgia, USA[a]; Janssen Research & Development LLC, Raritan, New Jersey, USA[b]; Seattle Children's Hospital, Seattle, Washington, USA[c]

Pertussis has shown a striking resurgence in the United States, with a return to record numbers of reported cases as last observed in the 1950s. *Bordetella pertussis* isolates lacking pertactin, a key antigen component of the acellular pertussis vaccine, have been observed, suggesting that *B. pertussis* is losing pertactin in response to vaccine immunity. Screening of 1,300 isolates from outbreak and surveillance studies (historical isolates collected from 1935 up to 2009, isolates from the 2010 California pertussis outbreak, U.S. isolates from routine surveillance between 2010-2012, and isolates from the 2012 Washington pertussis outbreak) by conventional PCR and later by Western blotting and *prn* sequencing analyses ultimately identified 306 pertactin-deficient isolates. Of these pertactin-deficient strains, 276 were identified as having an IS*481* in the *prn* gene (*prn*IS*481* positive). The first *prn*IS*481*-positive isolate was found in 1994, and the next *prn*IS*481*-positive isolates were not detected until 2010. The prevalence of pertactin-deficient isolates increased substantially to more than 50% of collected isolates in 2012. Sequence analysis of pertactin-deficient isolates revealed various types of mutations in the *prn* gene, including two deletions, single nucleotide substitutions resulting in a stop codon, an inversion in the promoter, and a single nucleotide insertion resulting in a frameshift mutation. All but one mutation type were found in *prn*2 alleles. CDC 013 was a predominant pulsed-field gel electrophoresis (PFGE) profile in the pertactin-positive isolates (203/994) but was found in only 5% (16/306) of the pertactin-deficient isolates. Interestingly, PFGE profiles CDC 002 and CDC 237 represented 55% (167/306) of the identified pertactin-deficient isolates. These results indicate that there has been a recent dramatic increase in pertactin-deficient *B. pertussis* isolates throughout the United States.

PEDIATRICS®
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Article

Age at First Measles-Mumps-Rubella Vaccination in Children With Autism and School-Matched Control Subjects: A Population-Based Study in Metropolitan Atlanta

Frank DeStefano, Tanya Karapurkar Bhasin, William W. Thompson, Marshalyn Yeargin-Allsopp and Coleen Boyle

Pediatrics February 2004, 113 (2) 259-266; DOI: https://doi.org/10.1542/peds.113.2.259

The CDC's senior scientist for its seminal MMR-autism study has recently revealed that the CDC concealed an association between MMR and autism and shredded the study's data so no one would know.

"Oh my God, I can't believe we did what we did. But we did. It's all there. It's all there."

"I have great shame now when I meet families with kids with autism because I have been part of the problem ... the CDC is so paralyzed right now by anything related to autism. They're not doing what they should be doing because they're afraid to look for things that might be associated. So anyway there's still a lot of shame with that. ... I am completely ashamed of what I did."

Knowing there are safety problems and not disclosing them is exactly what would make a vaccine manufacturer legally liable… the only thing that would make them liable, and yet this is exactly what the CDC does….

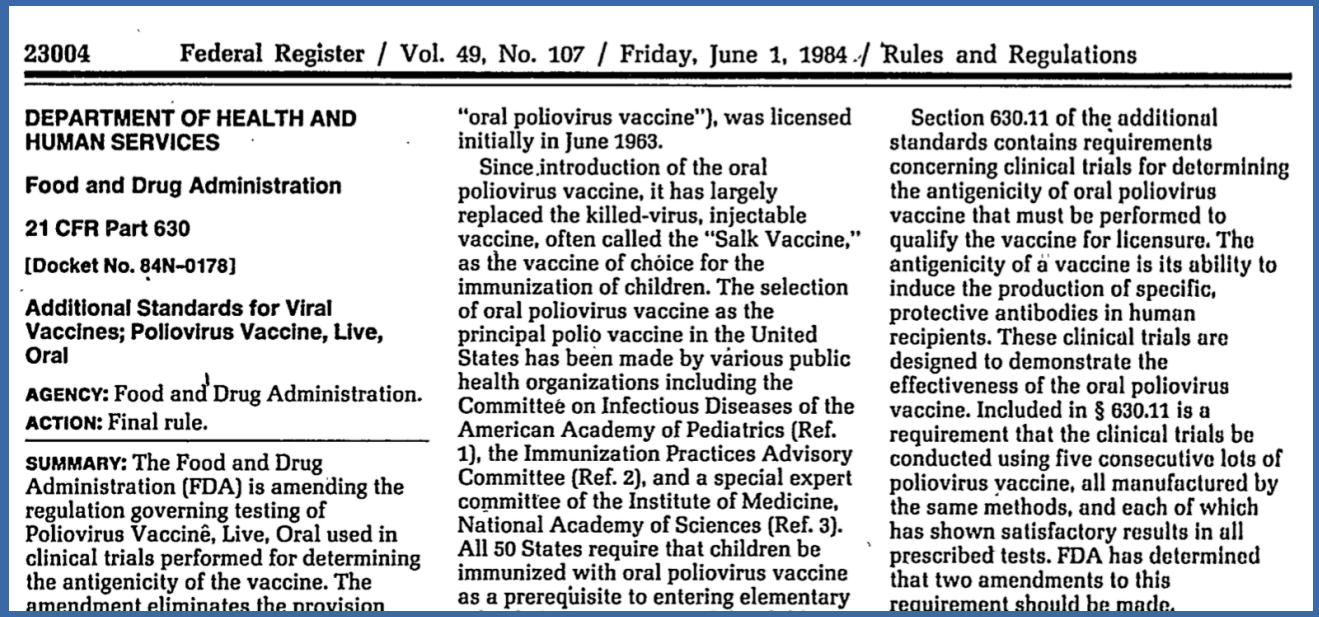
The CDC… the organization most physicians just revere, the purveyor of truth and science, and the last word on anything vaccine is not what we think it is. It is the largest buyer and seller of vaccines in the country. They own 54 patents on vaccines, and via their foundation except millions of dollars from the vaccine stake holders. The organization is riddled with conflicts of interest and their intention is not to promote public health but public health policies.

The FDA is no better….

"any possible doubts, whether or not well founded, about the safety of the vaccine cannot be allowed to exist in view of the need to assure that the vaccine will continue to be used to the maximum extent consistent with the nation's public health objectives."

This is the policy of the FDA as it was stated in 1984.

Doubts about Safety cannot be allowed



23004 Federal Register / Vol. 49, No. 107 / Friday, June 1, 1984 / Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 630

[Docket No. 84N-0178]

Additional Standards for Viral Vaccines; Poliovirus Vaccine, Live, Oral

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation governing testing of Poliovirus Vaccine, Live, Oral used in clinical trials performed for determining the antigenicity of the vaccine. The amendment eliminates the provision

"oral poliovirus vaccine"), was licensed initially in June 1963.

Since introduction of the oral poliovirus vaccine, it has largely replaced the killed-virus, injectable vaccine, often called the "Salk Vaccine," as the vaccine of choice for the immunization of children. The selection of oral poliovirus vaccine as the principal polio vaccine in the United States has been made by various public health organizations including the Committee on Infectious Diseases of the American Academy of Pediatrics (Ref. 1), the Immunization Practices Advisory Committee (Ref. 2), and a special expert committee of the Institute of Medicine, National Academy of Sciences (Ref. 3). All 50 States require that children be immunized with oral poliovirus vaccine as a prerequisite to entering elementary

Section 630.11 of the additional standards contains requirements concerning clinical trials for determining the antigenicity of oral poliovirus vaccine that must be performed to qualify the vaccine for licensure. The antigenicity of a vaccine is its ability to induce the production of specific, protective antibodies in human recipients. These clinical trials are designed to demonstrate the effectiveness of the oral poliovirus vaccine. Included in § 630.11 is a requirement that the clinical trials be conducted using five consecutive lots of poliovirus vaccine, all manufactured by the same methods, and each of which has shown satisfactory results in all prescribed tests. FDA has determined that two amendments to this requirement should be made.

Something to Ponder

Given the HHS/CDC has not done adequate safety testing, how did they develop their guidelines?

Regulators say they rely on a passive post marketing surveillance program to determine safety called

Vaccine Adverse Events Reporting System (VAERS)

5,911,700

In 2016, VAERS received ~~59,117~~ reports including:

43,200 ~~432~~ deaths,
109,100 ~~1,091~~ permanent disabilities,
413,200 ~~4,132~~ hospitalizations, and
1,028,400 ~~10,284~~ emergency room visits.

"fewer than 1% of adverse events are reported"
(Source: Report Funded by HHS)

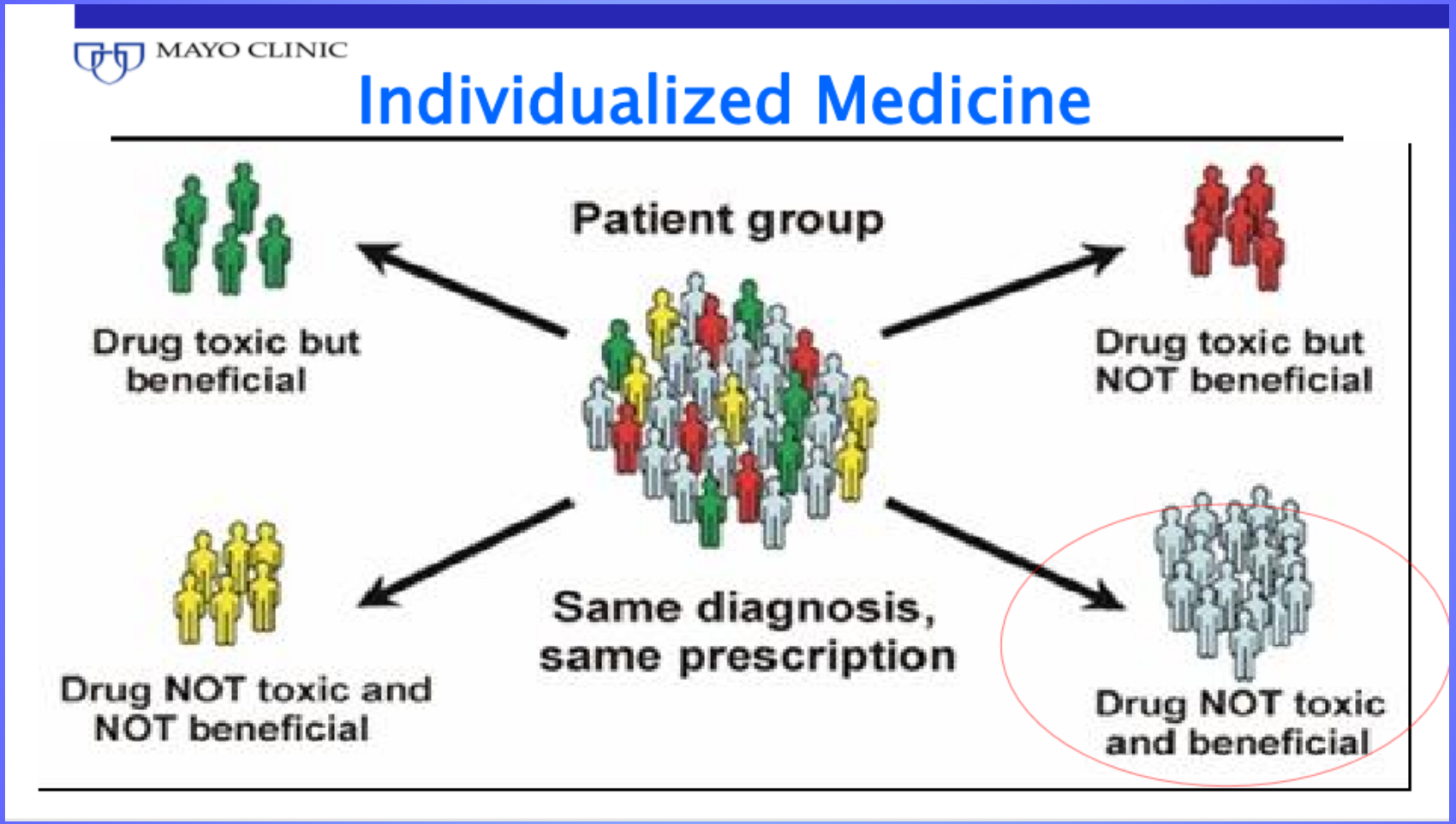
"Former FDA Commissioner David A. Kessler has estimated that VAERS reports currently represent only a fraction of the serious adverse events."
(Source: U.S. Congressional Report)

Part III – the Addendum

According to Dr. Poland at the Mayo Clinic, extremely high levels of safety are required for using vaccines, because…

"The one-size-fits-all approach to vaccination ignores the complexity and diversity of the human immune system and host genome."

One-size-fits-all is the opposite of an Individualized Medicine approach



Slide from Gregory Poland's presentation: "The case for personalized Vaccinology in the 21st Century"
Poland is Editor-in-Chief of the journal Vaccine and head of the Vaccine Research Group at the Mayo Clinic

The emerging field of Vaccinomics will usher in predictive Vaccinology

MAYO CLINIC

Vaccinomics

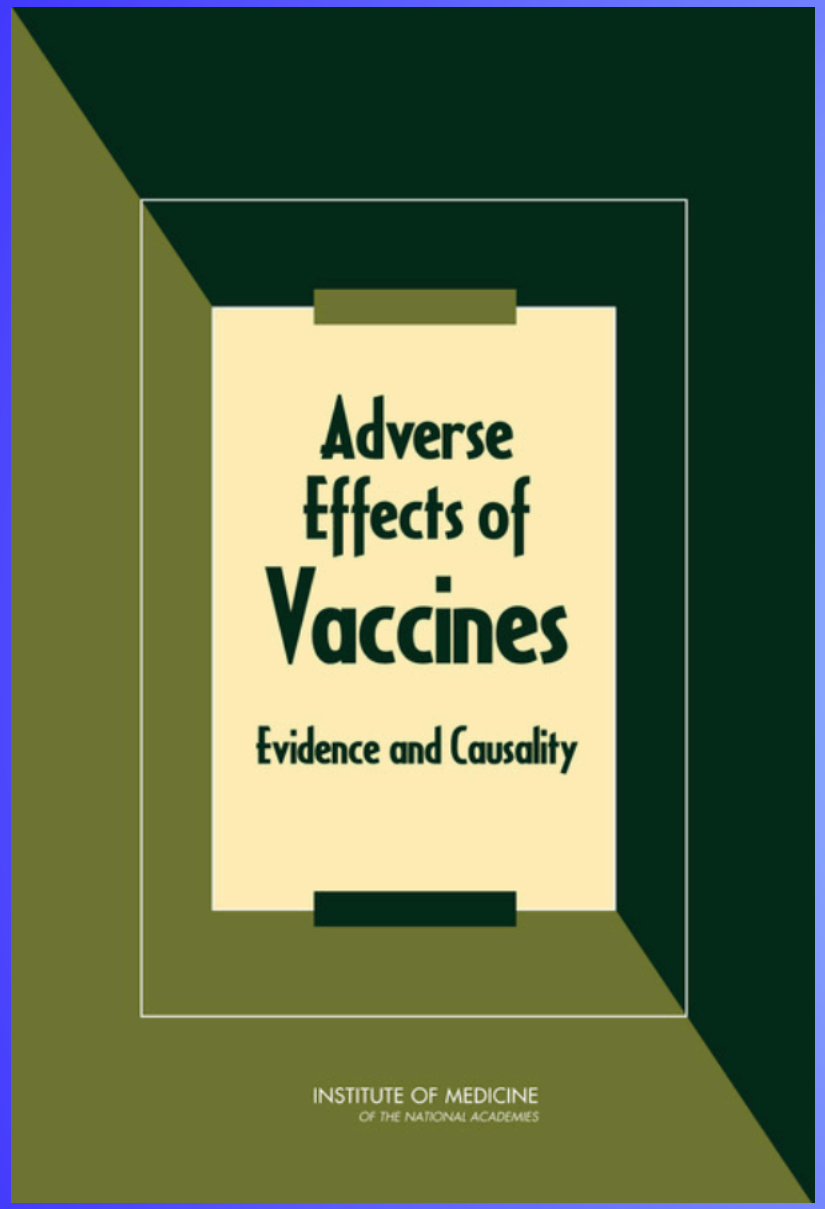
Vaccinomics is the integration of a systems biology approach with the immune response network theory, immunogenomics, *immune profiling and functional studies* in order to understand and predict vaccine-induced immune responses; and uses this information to engineer vaccine candidates and to drive *individualized vaccinology.*

1. Poland et. al. Vaccinomics and a new paradigm for the development of preventive vaccines against viral infections. OMICS: A Journal of Integrative Biology, 2011;15(9):625-36.
2. Poland et. al. Systems biology approaches to new vaccine development. Current Opinion in Immunology 2011;23(3):436-443.
3. Poland et al. Vaccinomics and personalized vaccinology: Is science leading us toward a new path of directed vaccine development and discovery? PLoS Pathogens. 2011, 7(12):e1002344.
4. Poland GA, et al. Seminars in Immunology 2013.

MAYO CLINIC

Vaccinomics: The Future

- **We predict a new era of personalized "*Predictive Vaccinology*" whereby we:**
  - Abandon a "one size and dose fits all vaccine approach"
  - Predict whether to give a vaccine based on likelihood of response (and perhaps need)
  - Predict the likelihood of a significant adverse event to a vaccine
  - Predict the number of doses likely to be needed to induce a protective response to a vaccine (HBV , HPV, measles examples)
  - Design/develop new vaccines

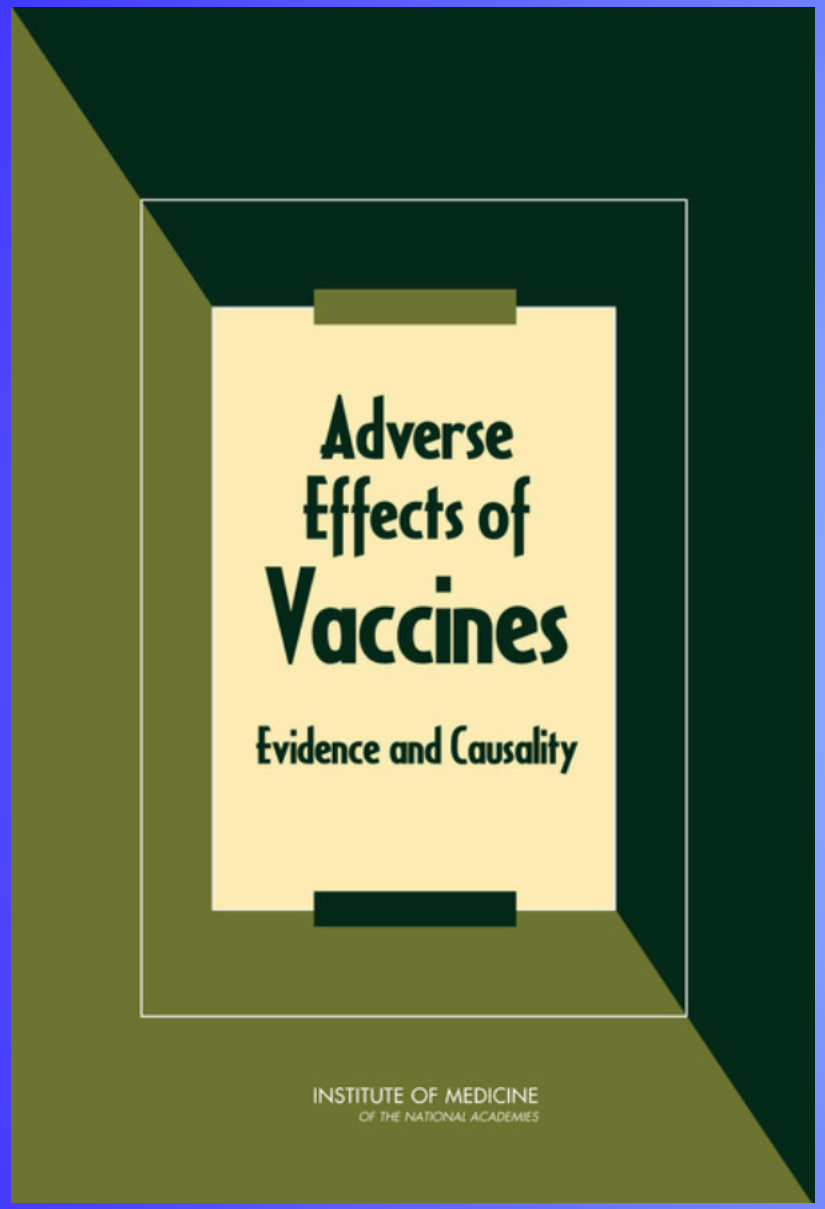


In the book,[1] Adverse Effects of Vaccines: Evidence and Causality (2012) , the IOM acknowledges there is individual susceptibility to serious vaccine injuries and a child's genome, behaviors, microbiome, intercurrent illness, and environmental exposure should be used to determine that susceptibility.

But HHS has not followed thru on determining any of this even though there is a law requiring HHS to do this type of research.

The IOM admonished HHS to *"develop a framework that clarifies and standardizes definitions of … populations that are potentially susceptible to adverse events."2*

1.https://www.nap.edu/read/13164/chapter/5#82
2. https://www.nap.edu/read/13563/chapter/9#130



The IOM correctly points out in 2011 that given the *"widespread use of vaccines" and "state mandates requiring vaccination of children ... it is essential that safety concerns receive assiduous attention."***

In other words, vaccine safety is a public health imperative.

(They did not say it was a mere public relations issue)

*https://www.nap.edu/read/13164/chapter/3#28

Ironically Vaccinomics is being misused today. In Europe where the vaccine injured can still sue vaccine manufacturers for Adverse Events, against vaccine injured children.

If a child has a mutation on the SCN1A* gene their case against the manufacturer of the DPT vaccine will be dismissed, because of the documented association between that gene mutation and brain inflammation caused by the DPT vaccine.

*While there are several genes associated with adverse events for certain vaccines, no comprehensive evaluation of their potential for causing adverse events have been examined for other vaccines. It would be precautionary to assume they do.

Where I would have given a medical exemption to a child with an SCN1A mutation, in Europe a child with this same mutation will not get their day in court because it was their fault they had this mutation and they should have known better before getting the DPT vaccine.

Not only was “safety” (or the lack thereof) the only criteria in SB 277 for granting an exemption, but CDC contraindications were edited out of the law which thus, “*makes it clear that doctors can use their own sound professional judgement when determining an exemption.*” (Bonilla letter)

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SUSAN A. BONILLA
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ASSEMBLYWOMAN, FOURTEENTH DISTRICT

COMMITTEES
HEALTH
UTILITIES AND COMM

57

July 7, 2015

Lawyers Opposed to California SB 277
1808 Sixth Street
Berkeley, CA 94710

Dear Friends,

As you know, Senate Bill 277, which changes the immunization requirements for children in California, was approved by both houses of the Legislature and signed by the Governor. First and foremost, I would like to thank you for your feedback and advocacy. I value and take into account all of your concerns. Since the introduction of SB 277, my Capitol and District offices have received an immense number of phone calls, e-mails, letters, faxes, voicemails, and meeting requests. As your state representative, I would like to provide you with my personal response and a recap of my efforts to ensure that the bill would strike the right balance between increasing public health and protecting parental rights.

After SB 277 was approved by the Senate, it was referred to the Assembly Committee on Heath. As a sitting member of this committee, I advocated for multiple amendments that addressed the significant concerns I had with the bill. The amendments are as follows:

- Clarify that if a child has a personal belief exemption in place, he/she would not be required to be up-to-date on vaccines until their next checkpoint in pre-school, kindergarten, or 7th grade.
- Ensure that special needs students in an individualized education program (IEP) would be guaranteed access to essential services regardless of their vaccination status.
- Protect a physician’s freedom to use their sound, professional judgment when providing a medical exemption.
- Remove the word “contraindicate” from the bill to specify that a physician is not required to adhere to the Center for Disease Control (CDC) recommendations for what conditions are “contraindicated” for vaccines. Removing this term further reinforces and makes it clear that doctors can use their own sound, professional judgment when determining an exemption.
- Allow doctors to consider family medical history as a condition for providing a medical exemption, to help prevent a sibling of a child who suffered adverse effects from being required to comply with the vaccination schedule.

… the authors of SB 277 did not elaborate on what they meant by “safety” but they did say there was no limitation on a physicians ability to interpret the term:

"If a physician feels there is a genetic association in a sibling, a cousin or some other relative that is not safe for a vaccine then they can provide a medical exemption for that vaccine - there is no limitation."

Senator Richard Pan 2015 testimony in front of the legislature

"One of the things we talked about is how important it is that there be a strong, robust medical exemption so that anybody who has a legitimate medical concern - genetic predisposition, immunological problem - they can go to a doctor anywhere in the state and get a medical exemption from that doctor. That is very important to me."

Senator Ben Allen 2015 testimony in front of the legislature

The legislative intent of SB277 is evidenced by the following Assembly Committee hearing transcript (June 9, 2015) and Governor's signing statement (June 30, 2015):

> "Rob Bonta: Thank you, Dr. Pan. And then finally, we have an amendment regarding the medical exemption and a physician's judgement. And I've heard from a number of constituents and Californians regarding concerns that a medical exemption is difficult to obtain or was difficult to obtain. **I believe that current law states that a physician has complete, professional discretion over the writing of a medical exemption. However, I have asked the author to take an amendment to clarify that a medical exemption is entirely within the professional judgement of a physician and we have agreement on that amendment.**
>
> "Richard Pan: **Yes."**
>
> **…**
>
> Governor Jerry Brown's Signing Statement, dated June 30, 2015 ("Thus, SB 277, while requiring that school children be vaccinated, **explicitly provides an exception when a physician believes that circumstances – in the judgement and sound discretion of the physician** – so warrant.")

Since vaccines are safe, having a law that makes safety the benchmark for a medical exemption wasn't a concern because vaccines are safe and everyone knows they are safe, so there should be no medical exemptions.

But in the real world.....

"litigation costs associated with claims of damage from vaccine had forced several companies to end their vaccine R&D programs as well as to stop producing already licensed vaccines."[1]

Instead of letting market forces compel vaccine makers to create safer vaccines, Congress granted companies financial immunity from CDC recommended vaccines.[2]

1. https://www.nap.edu/read/2138/chapter/2
2. 2 U.S.C. § 300aa-1 et seq.

National Childhood Vaccine Injury Act

Not only removed liability from vaccine manufacturers but relieved them from determining safety as well.

Immunity from Liability Not responsible for Safety

The only way one can hold a vaccine maker liable is if you can show they knew there was a safety problem and they didn't disclose it, so they were incentivized to do no safety testing.

National Childhood Vaccine Injury Act (1986)

Made HHS responsible for Vaccine Safety

HHS

FDA CDC HRSA NIH

Using SIDS as an example:

The manufacturer comes right out and says, *"cases of SIDS can be expected to follow receipt of the DPT/DTaP vaccines"* – even though they imply that is just happenstance. They are now legally off the hook and have immunity.

HHS/FDA/CDC are responsible for safety so they looked at those happenstance numbers….

AHFS Category: 80:08

3105097

268

Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Tripedia®

DTaP

℞ only

DESCRIPTION

Tripedia®, Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP), for intramuscular use, is a sterile preparation of diphtheria and tetanus toxoids adsorbed, with acellular pertussis vaccine in an isotonic sodium chloride solution containing sodium phosphate to control pH. After shaking, the vaccine is a homogeneous white suspension. Tripedia vaccine is distributed by Sanofi Pasteur Inc.

In the German case-control study and US open-label safety study in which 14,971 infants received Tripedia vaccine, 13 deaths in Tripedia vaccine recipients were reported. Causes of deaths included seven SIDS, and one of each of the following: enteritis, Leigh Syndrome, adrenogenital syndrome, cardiac arrest, motor vehicle accident, and accidental drowning. All of these events occurred more than two weeks post immunization.[2] The rate of SIDS observed in the German case-control study was 0.4/1,000 vaccinated infants. The rate of SIDS observed in the US open-label safety study was 0.8/1,000 vaccinated infants and the reported rate of SIDS in the US from 1985-1991 was 1.5/1,000 live births.[34] By chance alone, some cases of SIDS can be expected to follow receipt of whole-cell pertussis DTP[35] or DTaP vaccines.

Additional Adverse Reactions:

- As with other aluminum-containing vaccines, a nodule may be palpable at the injection sites for several weeks. Sterile abscess formation at the site of injection has been reported.[3,36]
- Rarely, an anaphylactic reaction (ie, hives, swelling of the mouth, difficulty breathing, hypotension, or shock) has been reported after receiving preparations containing diphtheria, tetanus, and/or pertussis antigens.[3]
- Arthus-type hypersensitivity reactions, characterized by severe local reactions (generally starting 2-8 hours after an injection), may follow receipt of tetanus toxoid.
- A few cases of peripheral mononeuropathy and of cranial mononeuropathy have been reported following tetanus toxoid administration, although available evidence is inadequate to accept or reject a causal relation.[37]
- A review by the Institute of Medicine (IOM) found evidence for a causal relationship between tetanus toxoid and both brachial neuritis and Guillain-Barré syndrome.[37]
- A few cases of demyelinating diseases of the CNS have been reported following some tetanus toxoid-containing vaccines or tetanus and diphtheria toxoid-containing vaccines, although the IOM concluded that the evidence was inadequate to accept or reject a causal relationship.[37]

Adverse events reported during post-approval use of Tripedia vaccine include idiopathic thrombocytopenic purpura, SIDS, anaphylactic reaction, cellulitis, autism, convulsion/grand mal convulsion, encephalopathy, hypotonia, neuropathy, somnolence and apnea. Events were included in this list because of the seriousness or frequency of reporting. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequencies or to establish a causal relationship to components of Tripedia vaccine.[2]

Reporting of Adverse Events

The National Vaccine Injury Compensation Program, established by the National Childhood Vaccine Injury Act of 1986, requires

Even though the CDC crunched the numbers (2015) and found that 79% of the reported SIDS cases received a vaccine in the 24 hours prior to their SIDS event, they somehow concluded there were no concerning patterns among the death reports.

In fact the CDC comes right out and says there is no link between vaccines and SIDS. 1 However independent researchers have found a significant correlation between Infant Mortality Rates and the number of vaccines administered.2

79.4% of infants died on the same day vaccinated isn't a concerning pattern?

1 https://www.cdc.gov/vaccinesafety/concerns/sids.html
2 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3170075/pdf/10.1177_0960327111407644.pdf

Published in final edited form as:
Clin Infect Dis. 2015 September 15; 61(6): 980–987. doi:10.1093/cid/civ423.

Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997–2013

Pedro L. Moro, **Jorge Arana**, **Maria Cano**, **Paige Lewis**, **Tom T. Shimabukuro**
Immunization Safety Office, Centers for Disease Control and Prevention, Atlanta, Georgia

Abstract

Background.—Vaccines are among the safest medical products in use today. Hundreds of millions of vaccinations are administered in the United States each year. Serious adverse reactic are uncommon. However, temporally associated deaths can occur following vaccination. Our ai was to characterize main causes of death among reports submitted to the US Vaccine Adverse Event Reporting System (VAERS), a spontaneous vaccine safety surveillance system.

Methods.—We searched VAERS for US reports of death after any vaccination from 1 July 19 through 31 December 2013. Available medical records, autopsy reports, and death certificates were reviewed to identify cause of death.

Results.—VAERS received 2149 death reports, most (n = 1469 [68.4%]) in children. Median was 0.5 years (range, 0–100 years); males accounted for 1226 (57%) reports. The total annual number of death reports generally decreased during the latter part of the study period. Most common causes of death among 1244 child reports with available death certificates/autopsy reports included sudden infant death syndrome (n = 544 [44%]), asphyxia (n = 74 [6.0%]), septicemia (n = 61 [4.9%]), and pneumonia (n = 57 [4.6%]). Among 526 adult reports, most common causes of death included diseases of the circulatory (n = 247 [46.9%]) and respiratory systems (n = 77 [14.6%]), certain infections and parasitic diseases (n = 62 [11.8%]), and malign neoplasms (n = 20 [3.8%]). For child death reports, 79.4% received >1 vaccine on the same day Inactivated influenza vaccine given alone was most commonly associated with death reports in adults (51.4%).

Conclusions.—No concerning pattern was noted among death reports submitted to VAERS during 1997–2013. The main causes of death were consistent with the most common causes of death in the US population.

When 79.4% of infants died on the same day vaccinated maybe this shouldn't be called SIDS but called VIDS.

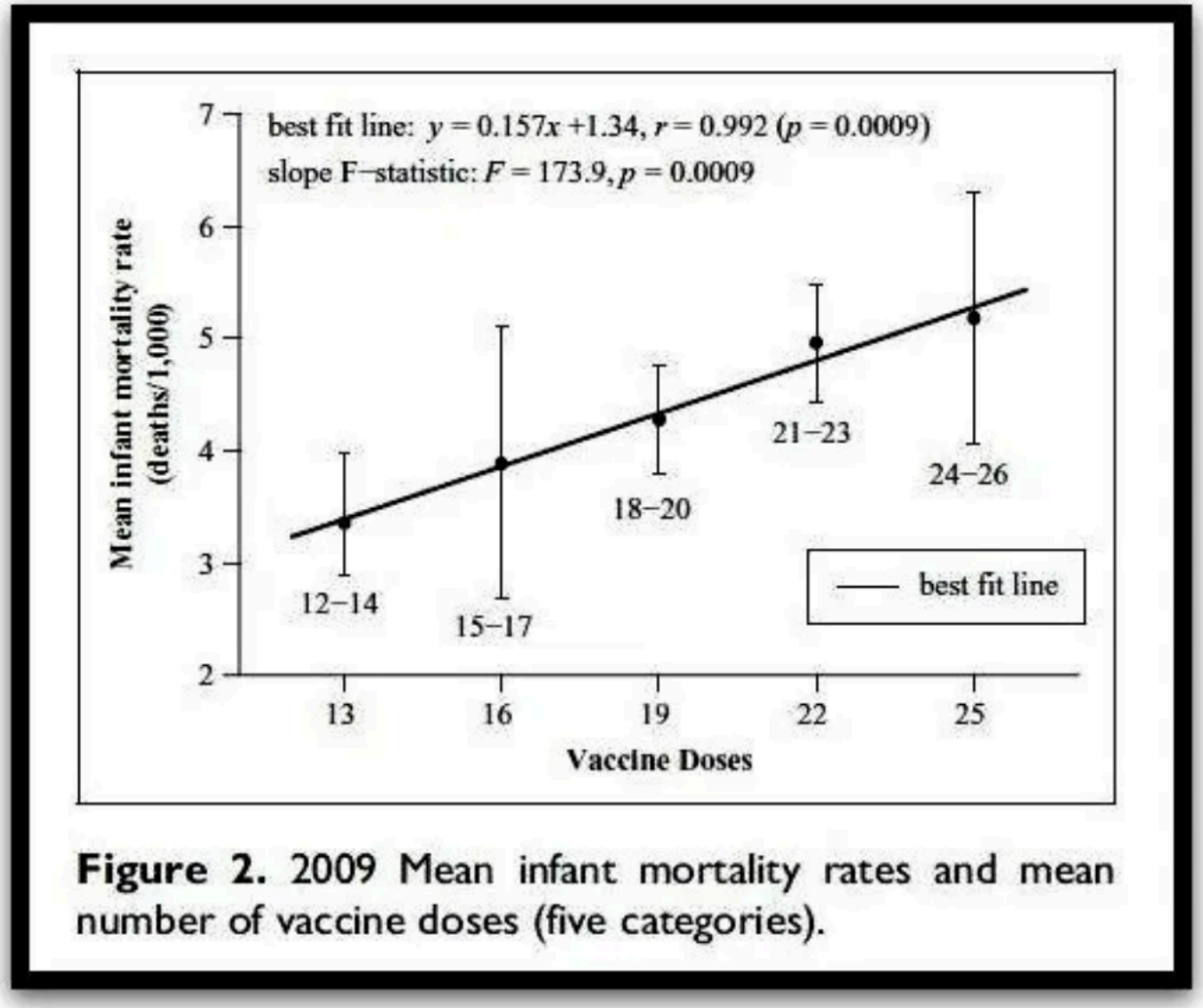


Figure 2. 2009 Mean infant mortality rates and mean number of vaccine doses (five categories).

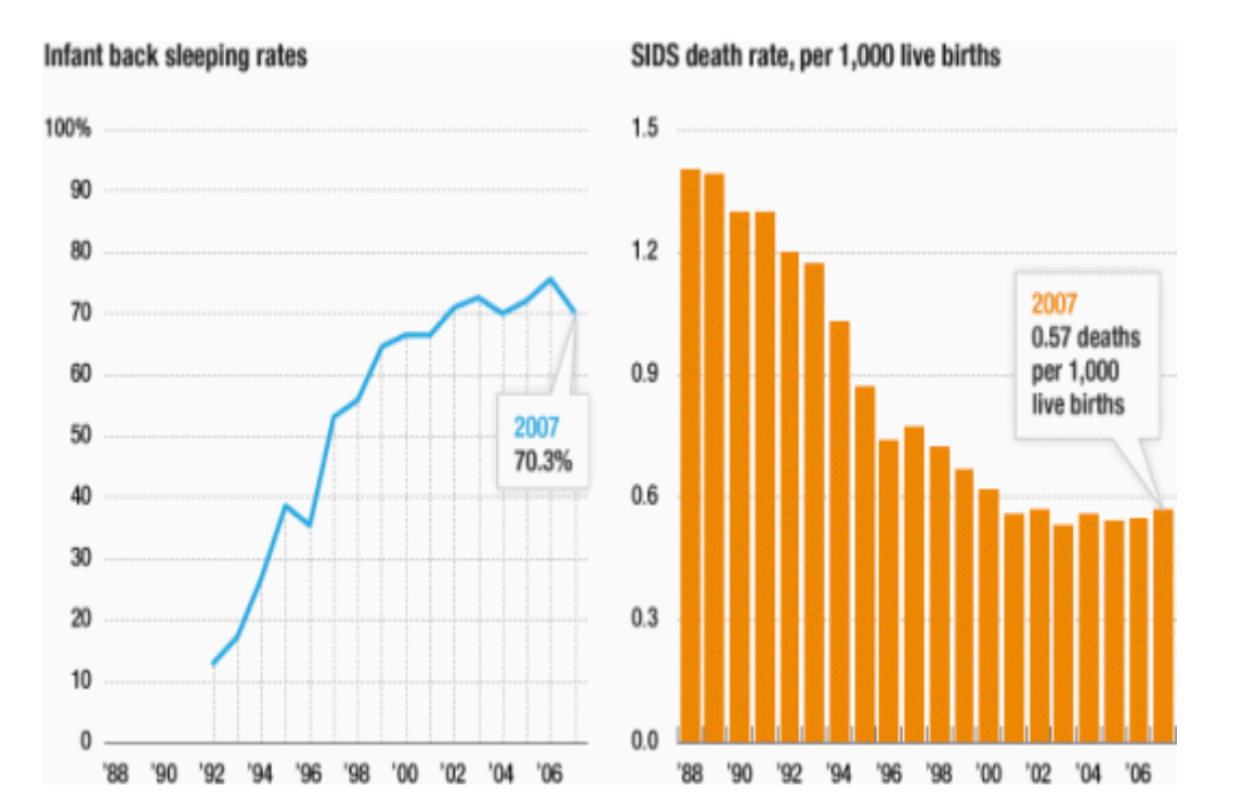
ttps://www.ncbi.nlm.nih.gov/pmc/articles/PMC3170075/pdf/10.1177_096032711407644.pdf

How did the government/pediatric medical community respond to exploding SIDS rates?

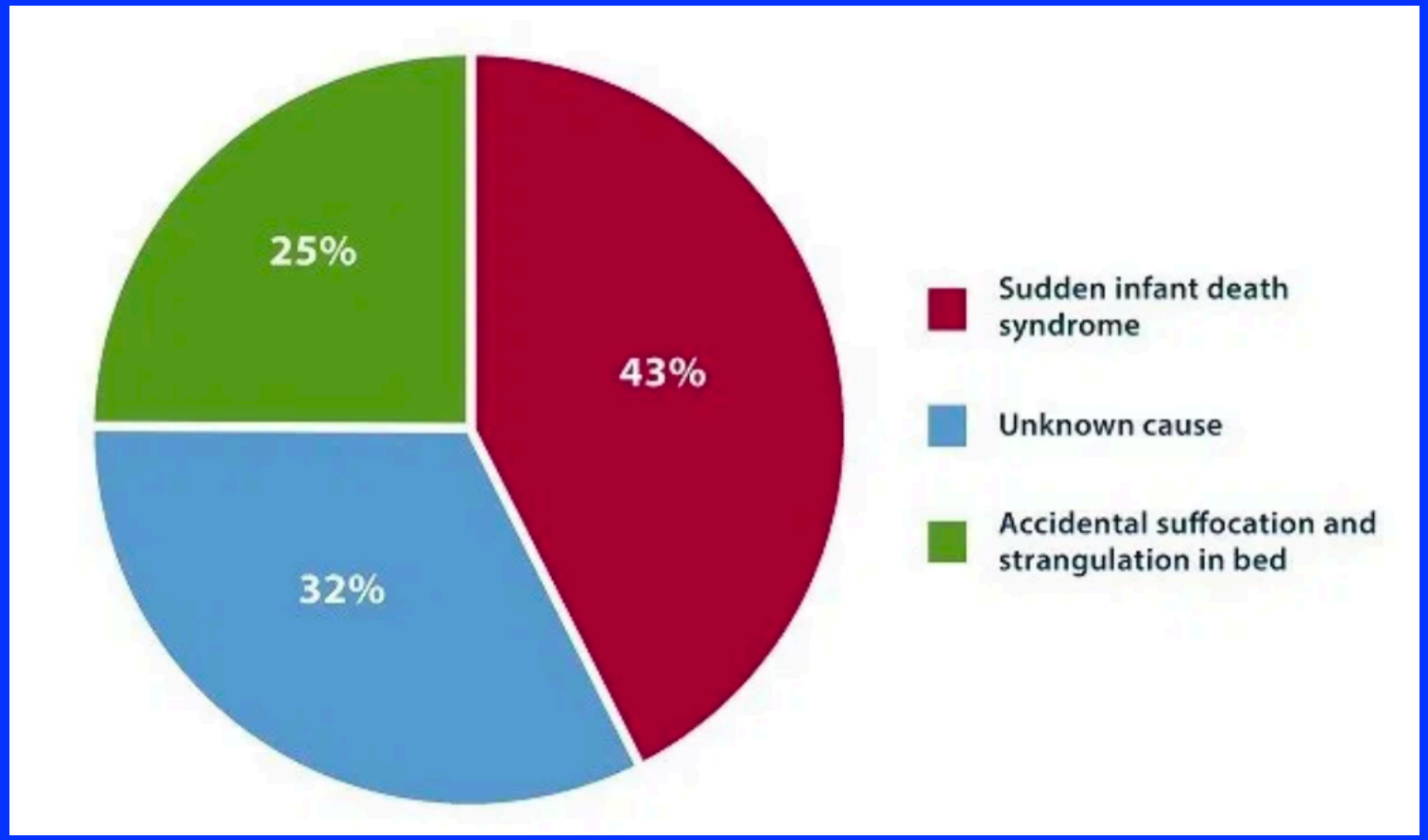
Miller/Goldman explain that, "*In 1992, to address the unacceptable SIDS rate, the American Academy of Pediatrics initiated a 'Back to Sleep' campaign, convincing parents to place their infants supine, rather than prone, during sleep.*"

The CDC tells us that it has decreased the SIDS rate dramatically. Here is the CDC graph touting the success of the "Back to Sleep" campaign. Making the campaign appear effective.

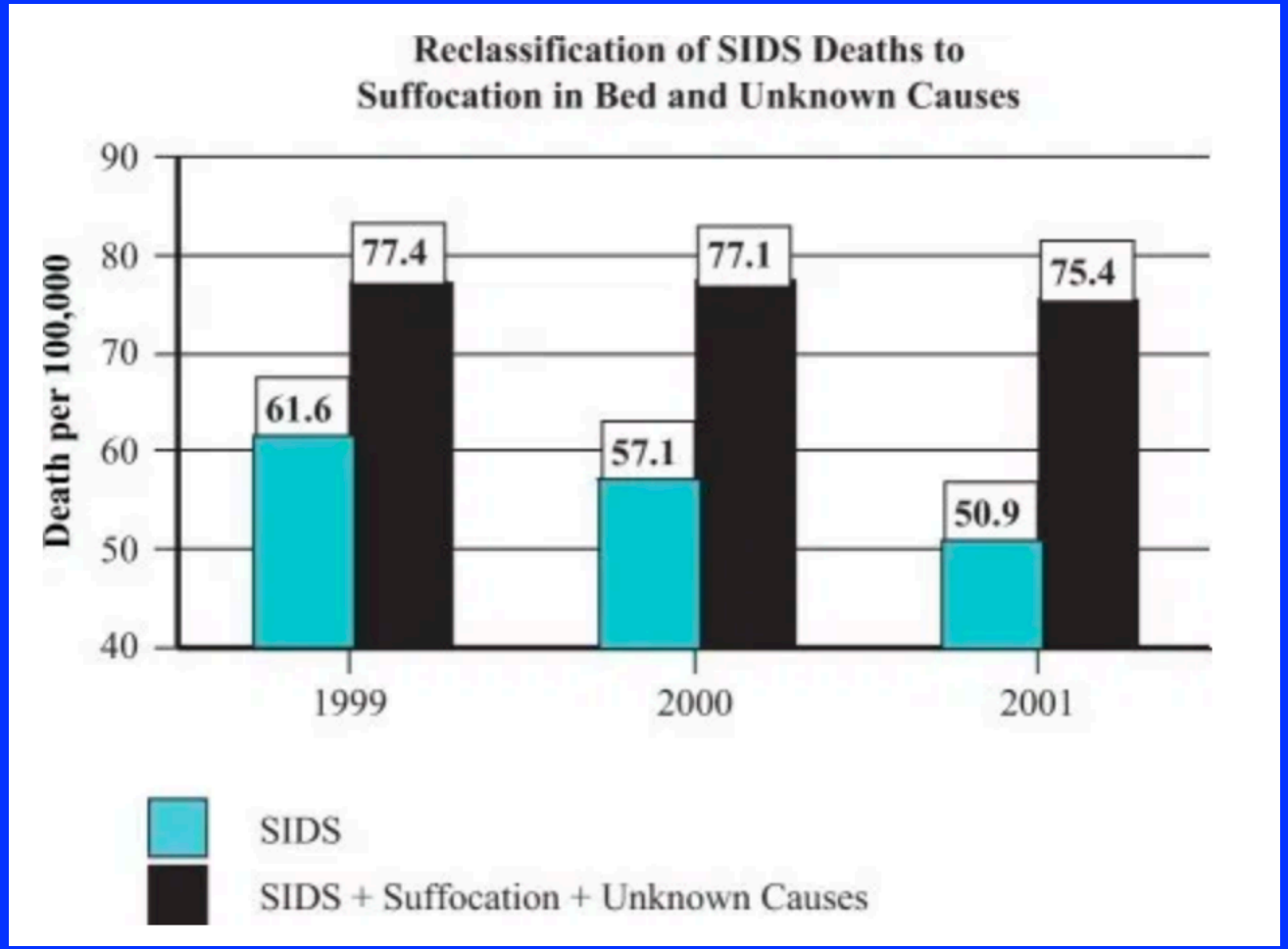
Did SIDS rates really fall or are these statistics smoke and mirrors?



The public was mislead through reclassification of deaths. Infant deaths that would have been categorized as SIDS prior to the Back to Sleep campaign began being classified in new categories, leading to the false public perception that unexplained infant mortality was actually decreasing. Here is a CDC pie graph illustrating infant death in 2015. Notice there are now 3 “top” categories for SIDS (in actuality there are multiple new sudden unexplained death categories, but most deaths fall into these top 3).

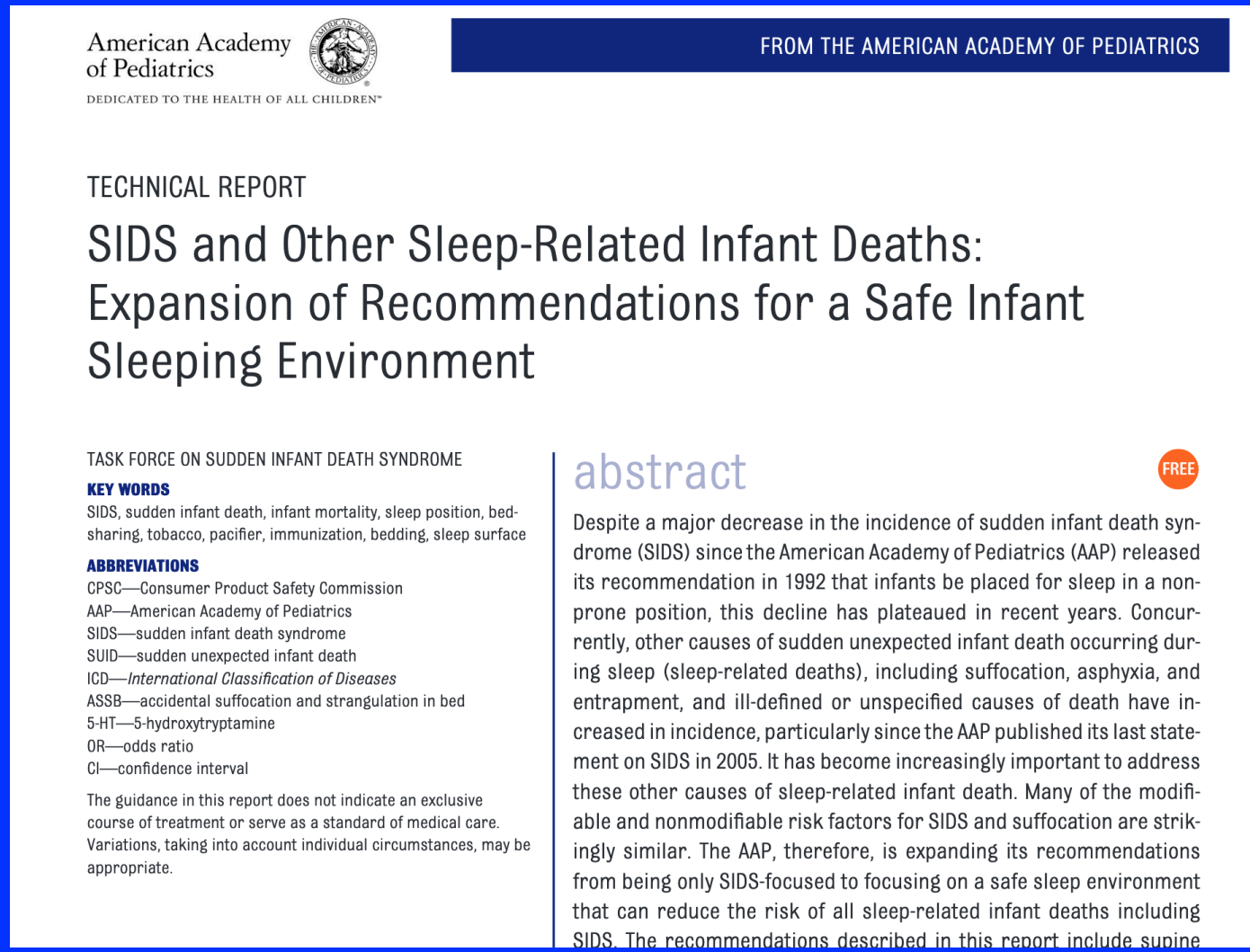


The Miller/Goldman study includes this graph depicting the data. Notice that the overall infant mortality rate from 99-01 is relatively constant. Only the reported SIDS deaths decline, because they are being re-categorized.



This report published in Pediatrics in 2011 states, "*Between 1984 and 2004, ASSB (accidental suffocation and strangulation in bedding) infant mortality rates more than quadrupled, from 2.8 to 12.5 deaths per 100,000 live births, which represents 513 infant deaths attributed to ASSB in 2004 compared with 103 in 1984.*"

So, the Back to Sleep campaign did not have an effect on SIDS death.



American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

FROM THE AMERICAN ACADEMY OF PEDIATRICS

TECHNICAL REPORT

SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment

TASK FORCE ON SUDDEN INFANT DEATH SYNDROME

KEY WORDS

SIDS, sudden infant death, infant mortality, sleep position, bed-sharing, tobacco, pacifier, immunization, bedding, sleep surface

ABBREVIATIONS

CPSC—Consumer Product Safety Commission
AAP—American Academy of Pediatrics
SIDS—sudden infant death syndrome
SUID—sudden unexpected infant death
ICD—*International Classification of Diseases*
ASSB—accidental suffocation and strangulation in bed
5-HT—5-hydroxytryptamine
OR—odds ratio
CI—confidence interval

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

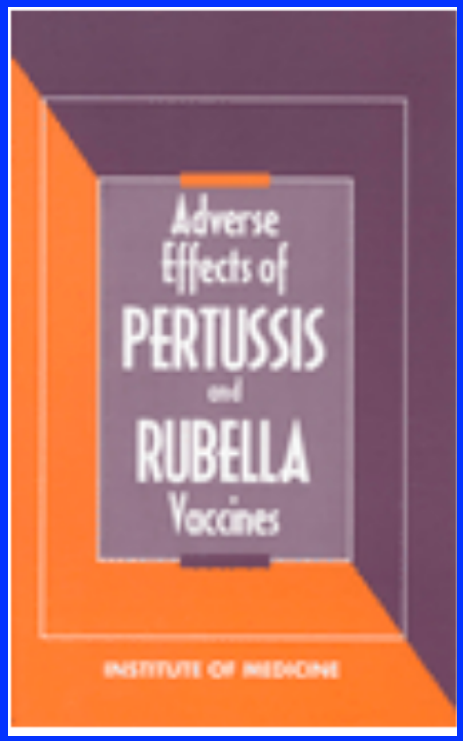
abstract

FREE

Despite a major decrease in the incidence of sudden infant death syndrome (SIDS) since the American Academy of Pediatrics (AAP) released its recommendation in 1992 that infants be placed for sleep in a nonprone position, this decline has plateaued in recent years. Concurrently, other causes of sudden unexpected infant death occurring during sleep (sleep-related deaths), including suffocation, asphyxia, and entrapment, and ill-defined or unspecified causes of death have increased in incidence, particularly since the AAP published its last statement on SIDS in 2005. It has become increasingly important to address these other causes of sleep-related infant death. Many of the modifiable and nonmodifiable risk factors for SIDS and suffocation are strikingly similar. The AAP, therefore, is expanding its recommendations from being only SIDS-focused to focusing on a safe sleep environment that can reduce the risk of all sleep-related infant deaths including SIDS. The recommendations described in this report include supine

https://pediatrics.aappublications.org/content/128/5/e1341.full#xref-ref-13-1

In *Evidence Concerning Pertussis Vaccines and Deaths Classified as Sudden Infant Death Syndrome*, the IOM concluded that the DPT vaccine, *"may be a generally unrecognized major cause of sudden infant and early childhood death, and that the risks of immunization may outweigh its potential benefits. A need for re-evaluation and possible modification of current vaccination procedures is indicated by this study."*

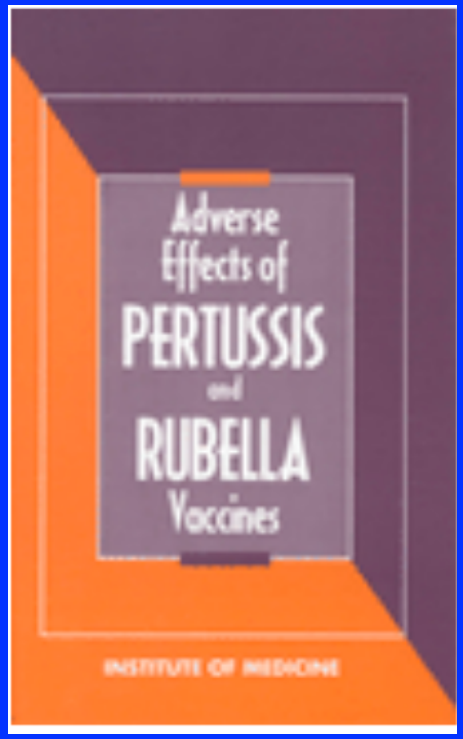


https://www.ncbi.nlm.nih.gov/books/NBK234363/pdf/Bookshelf_NBK234363.pdf

"…and that the risks of immunization may outweigh its potential benefits."

One part of the government is stating the risks of the DPT outweigh the benefits, and another part of the government saying there is nothing to see here – vaccines are safe.

Not only does this create confusion, but it points to a systemic problem that is not in the best interest of children.



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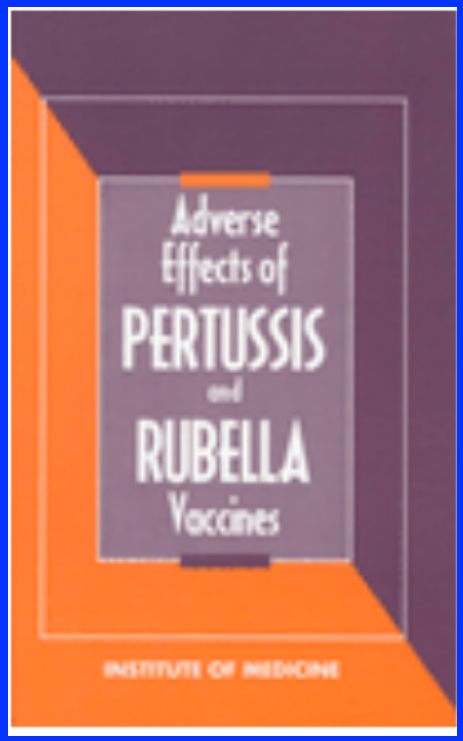
This study found that two-thirds of babies who had died from SIDS had been vaccinated against DPT (diphtheria-pertussis-tetanus toxoid) prior to death. Of these, 6.5% died within 12 hours of vaccination; 13% within 24 hours; 26% within 3 days; and 37%, 61%, and 70% within 1, 2, and 3 weeks, respectively. It also found that vaccinated babies died most often at 2 and 4 months- the same ages when initial doses of DPT were given to infants.



https://www.ncbi.nlm.nih.gov/books/NBK234363/pdf/Bookshelf_NBK234363.pdf

The 2011 study, *"A modified self-controlled case series method to examine association between multidose vaccinations and death"* concluded that based on a review of 300 sudden unexplained deaths occurring after a pentavalent or hexavalent vaccination, *"a 16-fold increase after the 4th dose could be detected with a power of at least 90 percent. A general 2-fold risk increase after vaccination could be detected with a power of 80 percent."*

Stat Med. 2011 Mar 15;30(6):666-77. doi: 10.1002/sim.4120. Epub 2010 Nov 30.

A modified self-controlled case series method to examine association between multidose vaccinations and death.

Kuhnert R[1], Hecker H, Poethko-Müller C, Schlaud M, Vennemann M, Whitaker HJ, Farrington CP.

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Abstract

The self-controlled case series method (SCCS) was developed to analyze the association between a time-varying exposure and an outcome event. We consider penta- or hexavalent vaccination as the exposure and unexplained sudden unexpected death (uSUD) as the event. The special situation of multiple exposures and a terminal event requires adaptation of the standard SCCS method. This paper proposes a new adaptation, in which observation periods are truncated according to the vaccination schedule. The new method exploits known minimum spacings between successive vaccine doses. Its advantage is that it is very much simpler to apply than the method for censored, perturbed or curtailed post-event exposures recently introduced. This paper presents a comparison of these two SCCS methods by simulation studies and an application to a real data set. In the simulation studies, the age distribution and the assumed vaccination schedule were based on real data. Only small differences between the two SCCS methods were observed, although 50 per cent of cases could not be included in the analysis with the SCCS method with truncated observation periods. By means of a study including 300 uSUD, a 16-fold risk increase after the 4th dose could be detected with a power of at least 90 per cent. A general 2-fold risk increase after vaccination could be detected with a power of 80 per cent. Reanalysis of data from cases of the German case-control study on sudden infant death (GeSID) resulted in slightly higher point estimates using the SCCS methods than the odds ratio obtained by the case-control analysis.

https://www.ncbi.nlm.nih.gov/pubmed/21337361

As recently explained in a SCOTUS opinion, *"[N]o one—neither the FDA nor any other federal agency, nor state and federal juries—ensures that vaccine manufacturers adequately take account of scientific and technological advancements. This concern is especially acute with respect to vaccines that have already been released and marketed to the public. Manufacturers ... will often have little or no incentive to improve the designs of vaccines that are already generating significant profit margins."**

In other words if a vaccine is profitable it almost always gets left on the schedule even if it is contributing to significantly increasing morbidity and mortality.

*Bruesewitz v. Wyeth LLC, 562 U.S. 223 (2011)

The HHS covers up serious safety information about vaccines and runs interference for the vaccine program. Why they would do this is clear. They are responsible for approving the vaccines, recommending them, promoting them, defending them in vaccine court, and distributing them.

You don’t have the person in charge of safety also be responsible for making sure the ship sails on time, selling tickets and promoting the cruise.

Aside from the obvious cover-up of vaccine injury, and the censoring of critics, such a situation can lead to FRAUD.

On the subject of Ships

Two senior Merck scientists, Stephen Krahling and Joan Wlochowski, filed their Federal whistleblower lawsuit* in 2010 claiming Merck fraudulently added extra antibodies to human blood samples. The antibody titers are what is used to determine efficacy, and thereby Merck won the MMR monopoly. When the scientists threatened to expose the fraud, Merck officials offered bribes, threatened them with prison and then destroyed the laboratory evidence in garbage bags.

This is no longer just about safety this is about National Security

A naval ship, the USS Fort McHenry, has been unable to come ashore since early January because of a mumps contagion that has devastated its crew—even though the military vaccinates all personnel against the virus and despite the Navy having immediately subjected the crew in question to another MMR booster.

The USS Fort McHenry was quarantined at sea for months in 2019 due to a Mumps outbreak in its fully vaccinated crew.

*http://probeinternational.org/library/wp-content/uploads/2014/09/chatom-v-merck.pdf

Merck’s defective MMRII is currently causing dangerous Mumps epidemics in fully vaccinated adults across the globe. A National Security risk if it takes a whole Navy ship out of commission for months.

At FDA’s behest (GSK) recently published the results of US clinical trials for the hasty licensing of Glaxo’s (MMR) vaccine Priorix®

Knowing that no MMR can survive safety testing against an inert placebo, FDA allowed GSK to test Priorix against Merck’s MMR II. The results were so horrifying for both vaccine formulations that Glaxo and FDA decided against publishing them in the main paper burying them instead in a supplemental table within an addendum.

https://academic.oup.com/jpids/advance-article/doi/10.1093/jpids/piz010/5372494#131942742

Clinical Trial of GlaxoSmithKline MMR-RIT Vaccine Versus Merck's MMR II Vaccine with No Placebo

Immunogenicity and Safety of a Measles-Mumps-Rubella Vaccine Administered as a First Dose to Children Aged 12 to 15 Months: A Phase III, Randomized, Noninferiority, Lot-to-Lot Consistency Study.

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13 Department of Pediatrics, University of North Texas Health Science Centre, Fort Worth.
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15 Puerto Rico Clinical and Translational Research Consortium, San Juan.
16 Department of Pediatrics, Children's Hospital at Montefiore, Bronx, New York.
17 Department of Pediatrics, University of Cincinnati College of Medicine and Pediatric Associates of Mt. Carmel, Inc, Ohio.
18 GlaxoSmithKline, Rockville, Maryland.

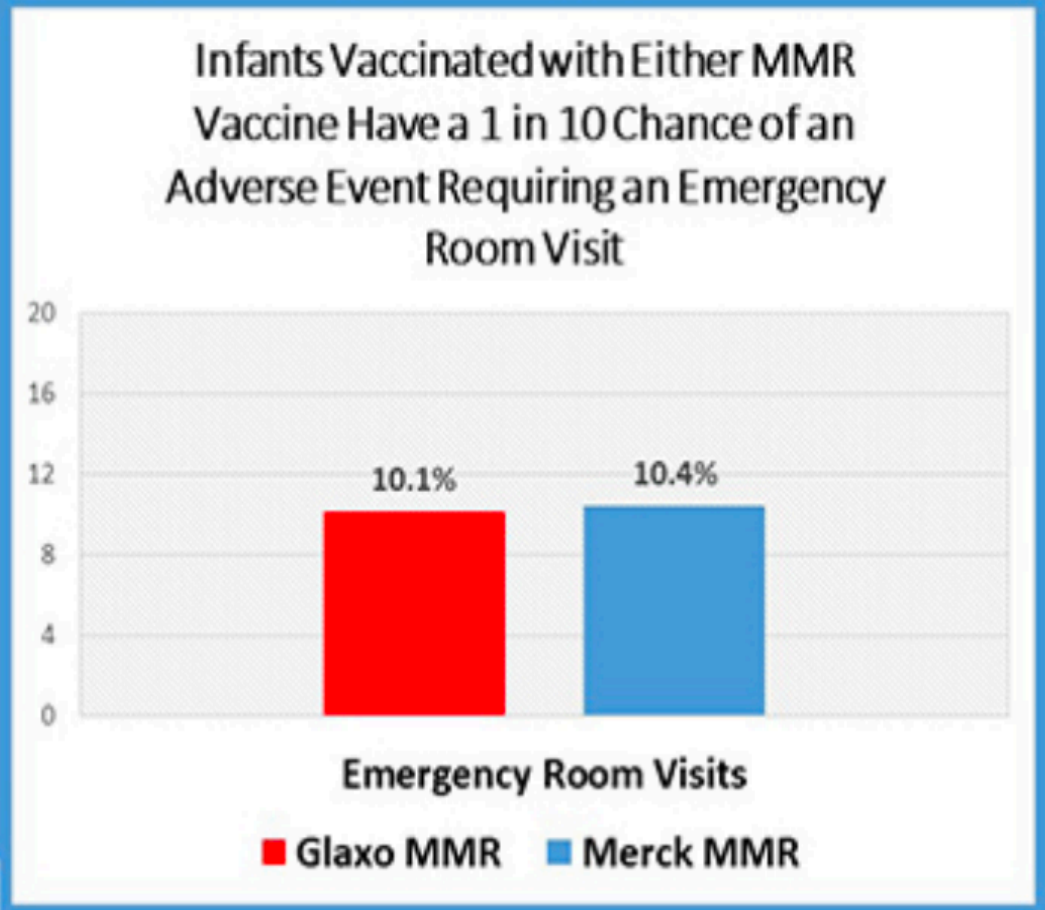
Abstract

BACKGROUND: MMR II (M-M-R II[Merck & Co, Inc.]) is currently the only measles, mumps, and rubella (MMR) vaccine licensed in the United States. A second MMR vaccine would mitigate the potential risk of vaccine supply shortage or delay. In this study, we assessed the immunogenicity and safety of another MMR vaccine (MMR-RIT [Priorix, GlaxoSmithKline]) compared with those of the MMR II in 12- to 15-month-old children who received it as a first dose.

METHODS: In this phase II, observer-blinded, noninferiority, lot-to-lot consistency clinical trial (ClinicalTrials.gov identifier NCT01702428), 1003 healthy children were randomly assigned to receive 1 dose of MMR-RIT (1 of 3 production lots) or MMR II along with other age-recommended routine vaccines. We evaluated the immunogenicity of all vaccines in terms of antibody concentrations (by using an enzyme-linked immunosorbent assay or electrochemiluminescence assay) and/or seroresponse rates 43 days after vaccination. We also assessed the reactogenicity and safety of the vaccines.

RESULTS: Immunoresponses after vaccination with MMR-RIT were ro

Published March, 2019



A 1 in 10 chance of having to go to the Emergency Room

The MMR vaccine will cause a New Chronic Disease in 1 in 28 children

Clinical Trial of GlaxoSmithKline MMR-RIT Vaccine Versus Merck's MMR II Vaccine with No Placebo

J Pediatric Infect Dis Soc. 2019 Mar 8. pii: piz010. doi: 10.1093/jpids/piz010. [Epub ahead of print]

Immunogenicity and Safety of a Measles-Mumps-Rubella Vaccine Administered as a First Dose to Children Aged 12 to 15 Months: A Phase III, Randomized, Noninferiority, Lot-to-Lot Consistency Study.

Klein NP[1], Abu-Elyazeed R[2], Povey M[3], Macias Parra M[4], Diez-Domingo J[5], Ahonen A[6], Korhonen T[6], Tinoco JC[7], Weiner L[8], Marshall GS[9], Silas PE[10], Sarpong KO[11], Ramsey KP[12], Fling JA[13], Spelcher D[14], Campos M[15], Munjal I[16], Peltier C[17], Vesikari T[6], Baccarini C[2], Caplanusi A[3], Gillard P[3], Carryn S[3], Henry O[18].

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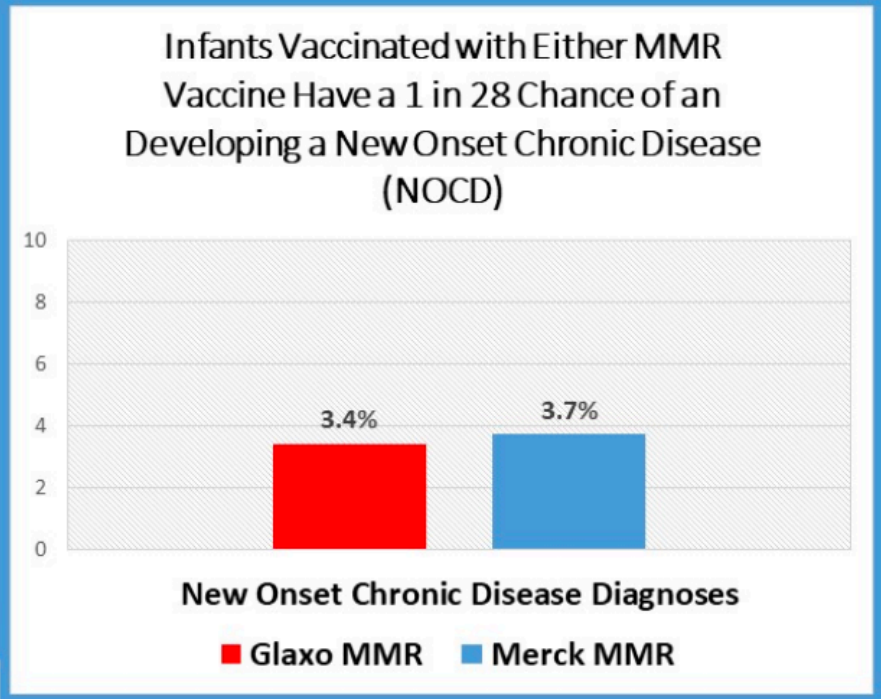
Abstract

BACKGROUND: MMR II (M-M-R II [Merck & Co, Inc.]) is currently the only measles, mumps, and rubella (MMR) vaccine licensed in the United States. A second MMR vaccine would mitigate the potential risk of vaccine supply shortage or delay. In this study, we assessed the immunogenicity and safety of another MMR vaccine (MMR-RIT [Priorix, GlaxoSmithKline]) compared with those of the MMR II in 12- to 15-month-old children who received it as a first dose.

METHODS: In this phase III, observer-blinded, noninferiority, lot-to-lot consistency clinical trial (ClinicalTrials.gov identifier NCT01702428), 5003 healthy children were randomly assigned to receive 1 dose of MMR-RIT (1 of 3 production lots) or MMR II along with other age-recommended routine vaccines. We evaluated the immunogenicity of all vaccines in terms of antibody concentrations (by using an enzyme-linked immunosorbent assay or electrochemiluminescence assay) and/or seroresponse rates 43 days after vaccination. We also assessed the reactogenicity and safety of the vaccines.

RESULTS: Immunoresponses after vaccination with MMR-RIT were roi
Immunogenicity of the 3 production lots of MMR-RIT was consistent; n

Published March, 2019



"NOCDs were documented in 3.4% of MMR-RIT recipients and in 3.7% of MMR II recipients; the most common NOCDs were atopic dermatitis (0.7% in the MMR-RIT group, 0.5% in the MMR II group) and eczema (0.4% in the MMR-RIT group, 0.8% in the MMR II group)."

The MMR vaccine will cause a New Chronic Disease in 1 in 28 children

Nearly 50% of vaccine recipients experienced adverse events within 42 days of vaccination and over 10% of these required emergency room visits.

Roughly 2% of these adverse events were “serious” and 3.5% of vaccine recipients were diagnosed with a “new onset chronic disease” within 6 months of vaccination.

These documented adverse event results are astronomically higher than those in the vaccine industry talking points which claim vaccine adverse events are “one-in-a-million”.

The 1 in 28 number is more in line with the results of the DHHS’s Lazarus study* (Harvard-Pilgram) where 1 in 39 vaccine recipients showed an adverse reaction.

*https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

What kind of safety testing does get done on vaccines?

All non-vaccine drugs licensed by the FDA undergo long-term multi-year double- blind safety studies during which the rate of adverse reactions in the group receiving the drug under review is compared to the rate of adverse reactions in a group receiving an inert placebo, such as a sugar pill or saline injection. For example, Lipitor's pre-licensure trials lasted a median of 4.8 years and controls received a sugar pill. *

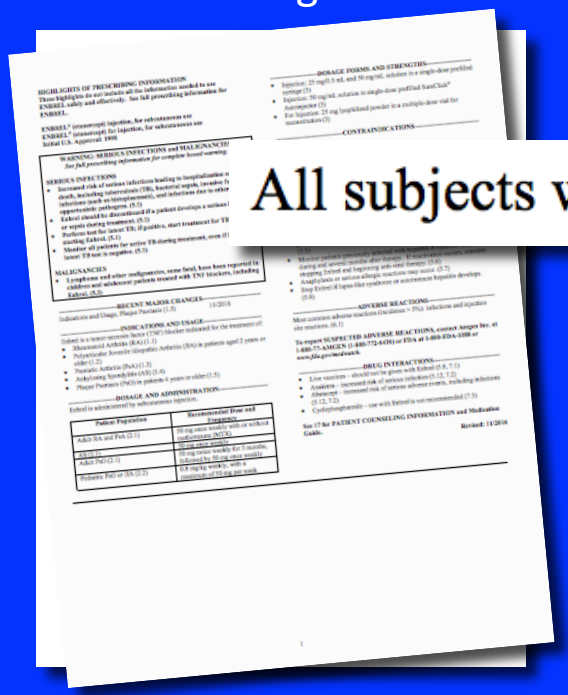
Given vaccine makers have no liability for injuries caused by their vaccines, one would expect that pre-licensure safety testing for vaccines would be more RIGOROUS than that required for drugs, but the rub is if they do safety testing and find something unsafe but fail to disclose it, they become liable for injuries caused by their vaccines.

*https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/ 020702s056lbl.pdf

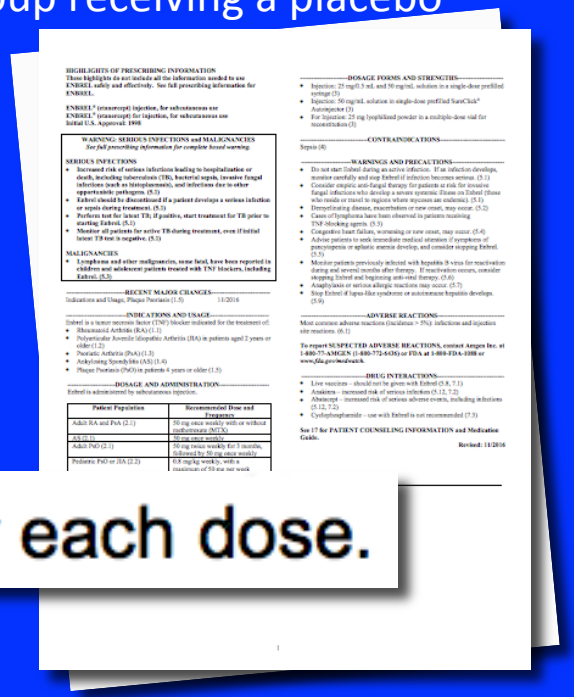
But the FDA states Vaccines do undergo rigorous safety testing,
But how rigorous are clinical trials be that last less than a week and are not placebo-controlled?

Recommended Age (First Dose)	Vaccine/ Manufacturer	Safety Review Period Prior to Licensure	Subject Group	Placebo Group*
1 Day Old	Hep-B (Engerix)/ GlaxoSmithKline	4 Days[1]	Hep-B	No Placebo
1 Day Old	Hep-B (Recombivax)/ Merck	5 Days[2]	Hep-B	No Placebo

* Not a single clinical trial for vaccines given to babies and toddlers has had a control group receiving a placebo



All subjects were monitored for 4 days post-administration.

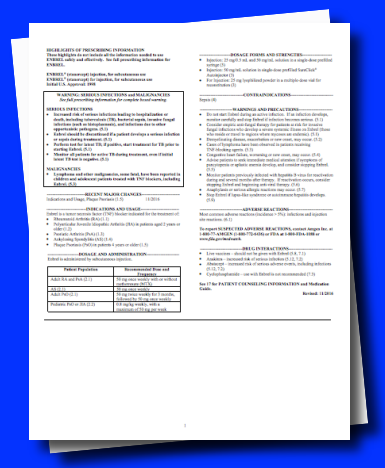


monitored for 5 days after each dose.

1. https://www.fda.gov/downloads/BiologicsBloodVaccines/ Vaccines/ApprovedProducts/UCM224503.pdf
2. https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/ 020702s056lbl.pdf

Is it normal to have Safety Review Periods that only last for a couple of days?

Recommended Age (First Dose)	Vaccine/ Manufacturer	Safety Review Period Prior to Licensure	Subject Group	Placebo Group
1 Day Old	Hep-B (Engerix)/ GlaxoSmithKline	**4 Days**	Hep-B	**No Placebo**
1 Day Old	Hep-B (Recombivax)/ Merck	**5 Days**	Hep-B	**No Placebo**
2 Month Old	Polio (PVI- Monkey Kidney)/ Sanofi Pasteur	**48 hours***	Polio + DTP	**DTP**



48 hours post-vaccination.

Because IPV was given in a different site but concurrently with Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed (DTP), these systemic reactions could not be attributed to a specific vaccine.

*https://www.fda.gov/downloads/BiologicsBloodVaccines/ Vaccines/ApprovedProducts/UCM133479.pdf

Instead of being compared to an inert placebo each new vaccine need only be roughly as safe as one or several previously licensed vaccines, which themselves were not compared to a placebo. Not only is this unscientific but it cannot establish the actual safety profile of any vaccine.

The IOM explains: "*Because [vaccine] trials are primarily ... for determination of efficacy, conclusions about vaccine safety derived from these trials are limited.*" *

* https://www.nap.edu/read/13563/chapter/4

IS THERE SOMETHING WRONG WITH THE IOM (now called the National Academy of Medicine)?

Vaccine safety can't be determined
From current clinical trials

Didn't they get the MEMO*?

Here is a fellow who got the Memo

*This is not a joke, I was invited to testify in front of the Gov Reform & Oversight committee regarding getting affected children into treatment, but was told off the record, "Everyone in Government who wants to know whether vaccines were causing kids autism already knows and are never going to do anything about it"

It is scientifically impossible to ascertain if babies will develop immunological, developmental or neurological disorders beyond these short safety review periods. There is no justifiable reason why HHS refuses to examine whether giving 29 vaccine doses by one year of age can lead to health issues at 5 years of age.

Target Disease	Product Name (Manufacturer)	Duration of Safety Review After Injection	
		Solicited Reactions	Unsolicited Reactions
Hepatitis B	Recombivax HB (Merck)[118]	5 days	5 days
	Engerix-B (GSK)[119]	4 days	4 days
Hib	ActHIB (Sanofi)[120]	3 days	30 days
	PedvaxHIB (Merck)[121]	3 days	3 days
	Hiberix (GSK)[122]	4 days	31 days
DTaP	Infanrix (GSK)[123]	8 days	28 days
	Daptacel (Sanofi)[124]	14 days	6 months
Poliovirus	Ipol (Sanofi)[125]	3 days	3 days
Pneumococcal	Prevnar 13 (Wyeth)[126]	7 days	6 months
Combination Vaccines	Pediarix (GSK)[127]	8 days	30 days + phone call at 6 months
	Pentacel (Sanofi)[128]	7 days	60 days + phone call at 6 months

While the formulation of each vaccine is not identical, they do share many of the same ingredients and adjuvants and it is not known yet which of these shared components are potentially responsible for adverse events.

We do know that all the vaccines on the mandated schedule share the fact that they are all untested for safety.

Since there is no functional safety testing being done, we know nothing about which vaccine components are problematic. With so many shared ingredients, if a child is at risk, it is currently impossible to know which of these ingredients are putting them at risk, and one can argue the precautionary principle should be applied to high risk children and it would be prudent to avoid the whole lot.

Tertiary vaccine failure has to also be taken into account when evaluating safety, because even if a vaccine is mostly safe* if the disease has mutated or evolved beyond the vaccine there is no efficacy. This has happened for the Pertussis vaccine, the mumps vaccine and even the measles vaccine.

*Vaccines are not tested for carcinogenicity, teratogenicity or impairment of fertility, so one can't actually say they are mostly safe.

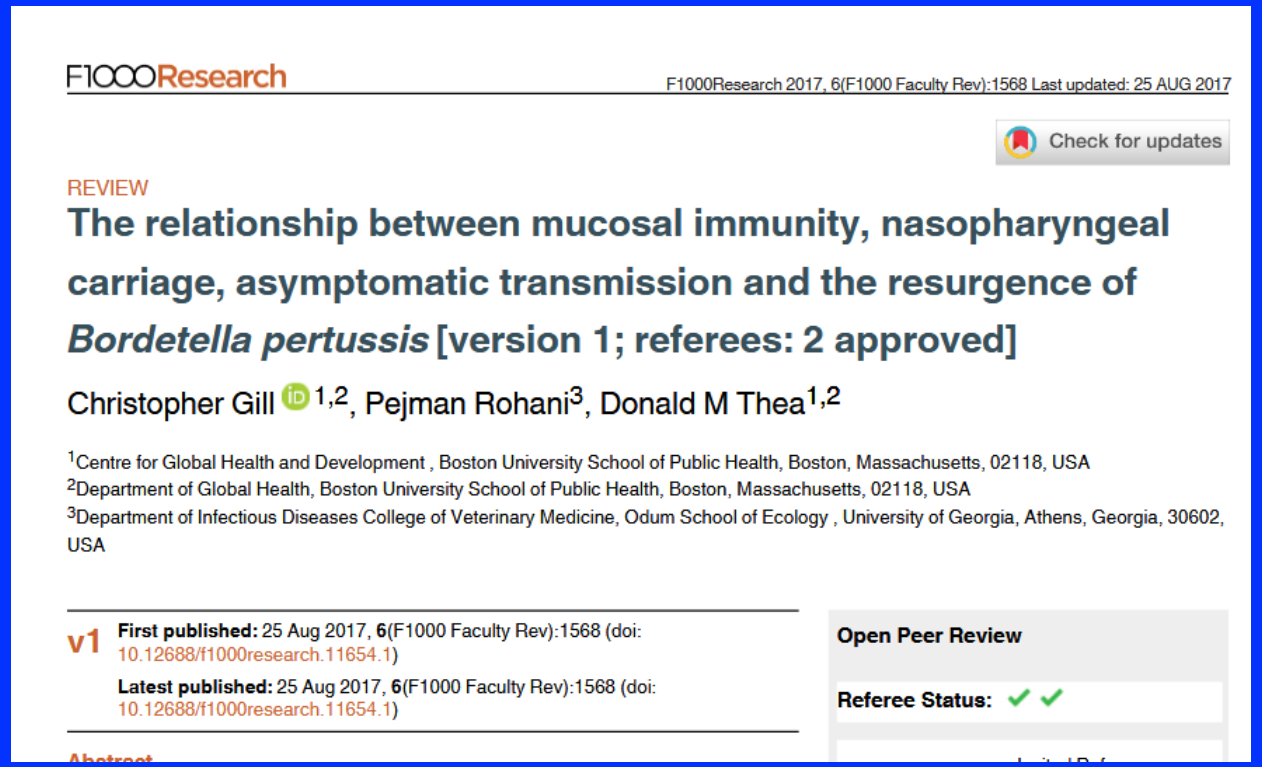
Despite 100% vaccine requirement, pertussis outbreak forces closure of Houston school

1. Even after 5 doses, the DTaP vaccine does not prevent pertussis. (Lapidot &Gill 2016) (Warfel 2013)

2. DTaP permanently damages children's immune systems "priming" inoculated kids for an increased lifetime risk of catching pertussis: ie; THE VACCINE PROMOTES PERTUSSIS! (Cherry 2019) (Lono et al 2010)

3. Pertussis vaccines target symptoms rather than the bacterium transforming many kids into asymptomatic carriers. These children unknowingly spread the disease to their classmates, endangering immuno-compromised people and making a mockery of Pharma's theory of vaccine induced "herd immunity". (Warfel et al 2014)

Gill et al. state *"This disease is back because we didn't really understand how our immune defenses against whooping cough worked, and did not understand how the vaccines needed to work to prevent it....Instead we layered assumptions upon assumptions, and now find ourselves in the uncomfortable position of admitting that we made some crucial errors. This is definitely not where we thought we'd be in 2017"*



F1000Research F1000Research 2017, 6(F1000 Faculty Rev):1568 Last updated: 25 AUG 2017

Check for updates

REVIEW

The relationship between mucosal immunity, nasopharyngeal carriage, asymptomatic transmission and the resurgence of *Bordetella pertussis* [version 1; referees: 2 approved]

Christopher Gill [1,2], Pejman Rohani[3], Donald M Thea[1,2]

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v1 **First published:** 25 Aug 2017, **6**(F1000 Faculty Rev):1568 (doi: 10.12688/f1000research.11654.1)
Latest published: 25 Aug 2017, **6**(F1000 Faculty Rev):1568 (doi: 10.12688/f1000research.11654.1)

Open Peer Review

Referee Status: ✓ ✓

Dr. Pan has said vaccines "work the way they work", but if they don't work is that still the way they work? … they work by not working? This is Orwellian Doublespeak.

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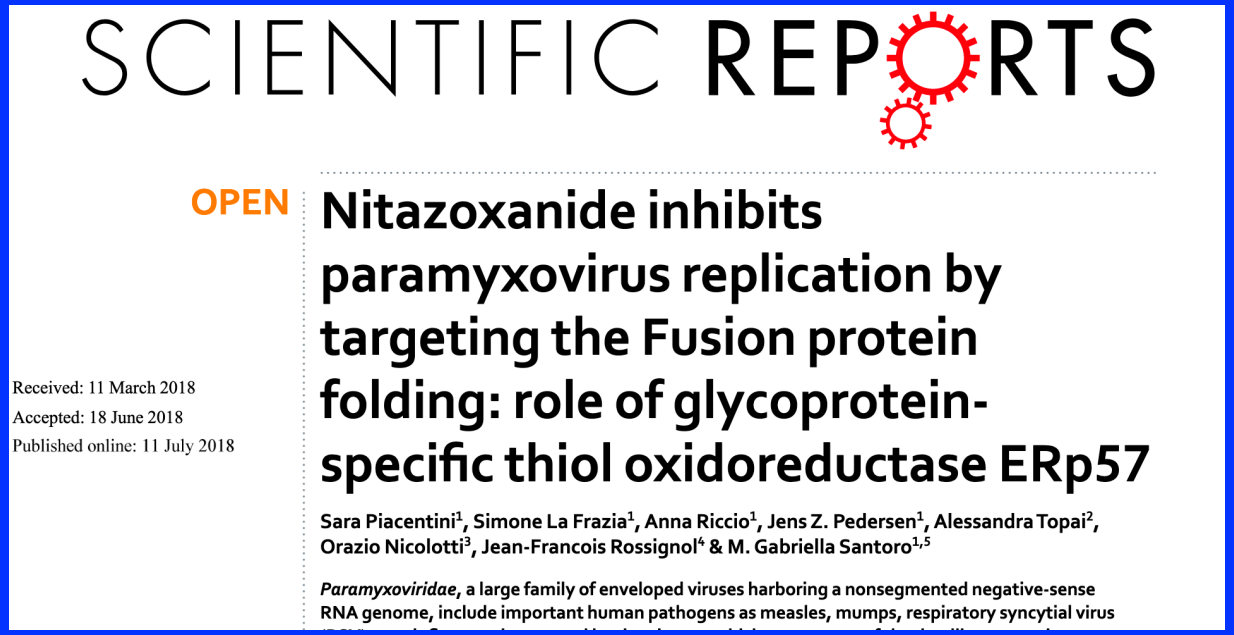
Antigenic Drift Defines a New D4 Subgenotype of Measles Virus

Miguel Ángel Muñoz-Alía,[a] Claude P. Muller,[c] Stephen J. Russell[a,b]

Department of Molecular Medicine,[a] and Division of Hematology,[b] Mayo Clinic, Rochester, Minnesota, USA; Department of Infection and Immunity, Luxembourg Institute of Health, Esch-Sur-Alzette, Luxembourg[c]

Does it matter how many times one is vaccinated for genotype “A” when what is circulating in the real world is a different virus.

Do we really have no other options to control certain infections than to vaccinate for a mismatched virus over and over again? That is good for vaccine sales but is it good medicine? Is it good for the public?



SCIENTIFIC REPORTS

OPEN

Nitazoxanide inhibits paramyxovirus replication by targeting the Fusion protein folding: role of glycoprotein-specific thiol oxidoreductase ERp57

Received: 11 March 2018
Accepted: 18 June 2018
Published online: 11 July 2018

Sara Piacentini[1], Simone La Frazia[1], Anna Riccio[1], Jens Z. Pedersen[1], Alessandra Topai[2], Orazio Nicolotti[3], Jean-Francois Rossignol[4] & M. Gabriella Santoro[1,5]

Paramyxoviridae, a large family of enveloped viruses harboring a nonsegmented negative-sense RNA genome, include important human pathogens as measles, mumps, respiratory syncytial virus

Nitazoxanide is an antiviral drug that has activity against the Measles virus family. But one would never know there are other options out there because they compete with the infectious disease consensus paradigm, which is controlled by vaccine stakeholders.

U.S. FOOD & DRUG ADMINISTRATION

Investigating Viruses in Cells Used to Make Vaccines; and Evaluating the Potential Threat Posed by Transmission of Viruses to Humans

"Some of these tumor-forming cell lines may contain cancer-causing viruses that are not actively reproducing. Such viruses are hard to detect using standard methods. These latent, or 'quiet,' viruses pose a potential threat, since they might become active under vaccine manufacturing conditions."

While an obvious concern to the FDA, vaccines are not evaluated for their potential ability to cause cancer or whether the stealth viruses they are known to harbor are a safety problem.

Safety is not something assumed.

Both Salk and Sabin polio vaccines were inadvertently contaminated with the SV 40 virus and given to 100 million people.

"SV40 is significantly associated with and may be functionally important in the development of some human malignancies."

Not so silent cancer virus. But regulators are silent because testing for vaccine carcinogenicity is not required nor done. THEY DON"T CARE TO KNOW.

This is not an "Oh well" situation because vaccines are still contaminated with various oncogenic viruses. But if you don't evaluate for carcinogenicity you don't get cancer safety questions answered.

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Clin Microbiol Rev. 2004 Jul; 17(3): 495–508.
doi: 10.1128/CMR.17.3.495-508.2004
PMCID: PMC452549
PMID: 15258090

Emergent Human Pathogen Simian Virus 40 and Its Role in Cancer

Regis A. Vilchez[1,2] and Janet S. Butel[2,*]

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ABSTRACT

Go to:

The polyomavirus simian virus 40 (SV40) is a known oncogenic DNA virus which induces primary brain and bone cancers, malignant mesothelioma, and lymphomas in laboratory animals. Persuasive evidence now indicates that SV40 is causing infections in humans today and represents an emerging pathogen. A meta-analysis of molecular, pathological, and clinical data from 1,793 cancer patients indicates that there is a significant excess risk of SV40 associated with human primary brain cancers, primary bone cancers, malignant mesothelioma, and non-Hodgkin's lymphoma. Experimental data strongly suggest that SV40 may be functionally important in the development of some of those human malignancies. Therefore, the major types of tumors induced by SV40 in laboratory animals are the same as those human malignancies found to contain SV40 markers. The Institute of Medicine recently concluded that "the biological evidence is of moderate strength that SV40 exposure could lead to cancer in humans under natural conditions." This review analyzes the accumulating data that indicate that SV40 is a pathogen which has a possible etiologic role in human malignancies. Future research directions are considered.

Lack of Vaccine Safety Science

Vaccinated vs. Unvaccinated studies are few and oft unpublished perhaps because they suggest the vaccines don't work.

Contents lists available at ScienceDirect

EBioMedicine

journal homepage: www.ebiomedicine.com

The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment

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ARTICLE INFO

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DTP
Measles vaccine
Non-specific effects of vaccines
Oral polio vaccine

Accepted 29 January 2017

ABSTRACT

Background: We examined the introduction of diphtheria-tetanus-pertussis (DTP) and oral polio vaccine (OPV) in an urban community in Guinea-Bissau in the early 1980s.

ulation had been followed with 3-monthly nutritional weighing sessions since 1978. From
were offered from 3 months of age at these sessions. Due to the 3-monthly intervals be-
ren were allocated by birthday in a 'natural experiment' to receive vaccinations early or
nths of age. We included children who were <6 months of age when vaccinations started
the end of December 1983. We compared mortality between 3 and 5 months of age of
DTP-vaccinated and not-yet-DTP-vaccinated children in Cox proportional hazard models.

Results: Among 3–5-month-old children, having received DTP (±OPV) was associated with a mortality hazard ratio (HR) of 5.00 (95% CI 1.53–16.3) compared with not-yet-DTP-vaccinated children. Differences in background factors did not explain the effect. The negative effect was particularly strong for children who had received DTP-only and no OPV (HR = 10.0 (2.61–38.6)). All-cause infant mortality after 3 months of age increased after the introduction of these vaccines (HR = 2.12 (1.07–4.19)).

Conclusion: DTP was associated with increased mortality; OPV may modify the effect of DTP.

1. Introduction

Individually randomized studies to measure impact on child survival of different vaccines were not conducted when the Expanded Program on Immunization (EPI) was introduced in low-income countries in the 1970s. The disease-protective effects were well documented, so the main issue was at which age to introduce the vaccine most effectively (The Expanded Programme on Immunization, 1982). Except for measles vaccine (MV), surprisingly few studies examined the introduction of vaccines and their impact on child survival (Aaby et al., 1983, 2003a; Holt et al., 1990; The Kasongo Project Team, 1981). One trial of measles-vaccinated and measles-unvaccinated communities in Congo showed a larger than expected reduction in child mortality (Aaby et al., 1981); this observation was subsequently corroborated by community "trials" and before-after studies in several countries (Aaby et al., 1984, 1993, 2003a; Holt et al., 1990; Kapoor and Reddaiah, 1991). Hence, a vaccine may have non-specific effects (NSEs) on susceptibility to other infections (Aaby et al., 1995). WHO's Strategic Advisory Group of Experts on Immunization (SAGE) recently reviewed the potential NSEs of BCG, diphtheria-tetanus-pertussis (DTP) and MV and recommended further research (Higgins et al., 2014; Strategic Advisory Group of experts on Immunization, 2014).

Though protective against the target diseases, DTP may increase susceptibility to unrelated infections (Aaby et al., 2003b, 2004a, 2012) (Appendix A). The SAGE review noticed that the majority of studies found a detrimental effect of DTP (Higgins et al., 2014). However, SAGE considered the evidence inconsistent because two studies reported beneficial effects (Higgins et al., 2014) and that most studies underestimated the benefit of DTP because studies were conducted in situations with herd immunity. Furthermore, all studies gave DTP and OPV together, making it impossible to separate effects of DTP and OPV (SAGE non-specific effects of vaccines Working Group, 2014).

On the other hand, the "unvaccinated" children in these studies have usually been frail children too sick or malnourish to get vaccinated, and the studies may therefore have underestimated the negative effect of DTP. We therefore examined what happened when DTP and OPV were first introduced, but not always given together, in 1981–1983 in the capital of Guinea-Bissau. In this situation the children were allocated by birthday to receive vaccines early or late and the "unvaccinated" were therefore not frail children.

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http://dx.doi.org/10.1016/j.ebiom.2017.01.041
2352-3064/

5. Conclusions

DTP was associated with 5-fold higher mortality than being unvaccinated. No prospective study has shown beneficial survival effects of DTP. Unfortunately, DTP is the most widely used vaccine, and the proportion who receives DTP3 is used globally as an indicator of the perfor-

DTP was associated with 5-fold higher mortality than being unvaccinated.

able evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis. Though a vaccine protects children against the target disease it may simultaneously increase susceptibility to unrelated infections.

The recently published SAGE review called for randomized trials of DTP (Higgins et al., 2014). However, at the same time the IVIR-AC committee to which SAGE delegated the follow-up studies of the NSEs of vaccines has indicated that it will not be possible to examine the effect of DTP in an unbiased way. If that decision by IVIR-AC remains unchallenged, the present study may remain the closest we will ever come to a RCT of the NSEs of DTP.

10x

Table 3
Mortality rate and hazard rate (HR) for children from 3 months of age until first examination without vaccination or 6 months of age. Natural experiment.

Age group 3–5 months	Mortality rate (deaths/person-years)			HR (95% CI) DTP vs unvaccinated
All				
Unvaccinated (N = 651)	4.5 (5/111.4)	DTP (±OPV) (N = 462)	17.4 (11/63.1)	5.00 (1.53–16.3)
		DTP only (N = 101)	35.2 (5/14.2)	10.0 (2.61–38.6)

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/pdf/main.pdf

Bear in mind that there are no clinically validated studies showing the DPT vaccine actually works. The tetanus component has never been clinically validated and there are *“no prospective study has shown beneficial survival effects of DTP.”*

“It should be of concern that the effect of routine vaccinations on all-cause mortality was not tested in randomized trials. All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis.”

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/pdf/main.pdf

“All currently available evidence suggests that DPT vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis”

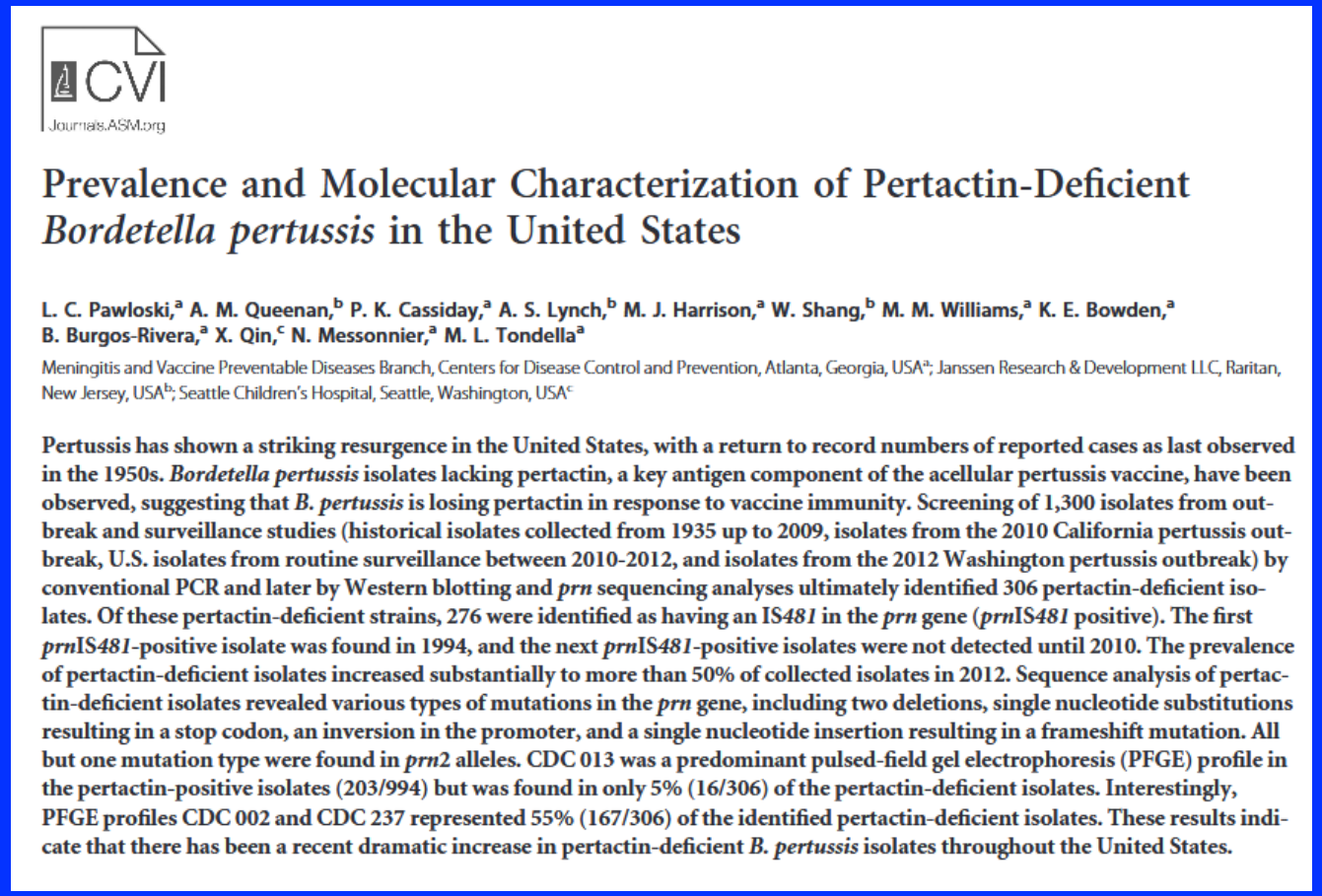
Dr. Aaby’s study was more reliable than other vaccine safety studies because the subjects were accurately matched. An increasingly recognized problem in vaccine safety studies is that subjects are typically not well-matched. People with pre- existing health problems are reluctant to receive a vaccine, and are therefore unwittingly used as controls. When this happens, the control group is sicker than the vaccine-exposed group at the outset of the study. Studies with this problem give wrong results, and make the vaccine look much safer than it really is. Dr. Aaby’s study was one of the few specifically designed to avoid this error.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/pdf/main.pdf

If the CDC did a Vaxxed vs unVaxxed study on the DPT what would it look like?
It would look like this study because they did do one.

The CDC found not only doesn't the Pertussis vaccine work but it increase the chances the child will be infected FOUR FOLD.

It doesn't work because 90% of the circulating Pertussis bacteria have mutated to such an extent the vaccine can't work. And getting the vaccine sets the child up for infection.



CVI
Journals.ASM.org

Prevalence and Molecular Characterization of Pertactin-Deficient *Bordetella pertussis* in the United States

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Pertussis has shown a striking resurgence in the United States, with a return to record numbers of reported cases as last observed in the 1950s. *Bordetella pertussis* isolates lacking pertactin, a key antigen component of the acellular pertussis vaccine, have been observed, suggesting that *B. pertussis* is losing pertactin in response to vaccine immunity. Screening of 1,300 isolates from outbreak and surveillance studies (historical isolates collected from 1935 up to 2009, isolates from the 2010 California pertussis outbreak, U.S. isolates from routine surveillance between 2010-2012, and isolates from the 2012 Washington pertussis outbreak) by conventional PCR and later by Western blotting and *prn* sequencing analyses ultimately identified 306 pertactin-deficient isolates. Of these pertactin-deficient strains, 276 were identified as having an IS*481* in the *prn* gene (*prn*IS*481* positive). The first *prn*IS*481*-positive isolate was found in 1994, and the next *prn*IS*481*-positive isolates were not detected until 2010. The prevalence of pertactin-deficient isolates increased substantially to more than 50% of collected isolates in 2012. Sequence analysis of pertactin-deficient isolates revealed various types of mutations in the *prn* gene, including two deletions, single nucleotide substitutions resulting in a stop codon, an inversion in the promoter, and a single nucleotide insertion resulting in a frameshift mutation. All but one mutation type were found in *prn*2 alleles. CDC 013 was a predominant pulsed-field gel electrophoresis (PFGE) profile in the pertactin-positive isolates (203/994) but was found in only 5% (16/306) of the pertactin-deficient isolates. Interestingly, PFGE profiles CDC 002 and CDC 237 represented 55% (167/306) of the identified pertactin-deficient isolates. These results indicate that there has been a recent dramatic increase in pertactin-deficient *B. pertussis* isolates throughout the United States.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3910938/pdf/zcd119.pdf

While it may be legal to administer, for example, the DPT vaccine, once one finds out the vaccine is flawed, increases the chances of getting the disease, increases overall mortality, is giving this vaccine ethical? Is it in the best interest of the public's health?, is it professional?

The answer is it is not ethical, is not in the public's interest and it is unprofessional, which are the very externalized accusations being made against physicians trying to screen children at high risk for having untoward reactions to vaccines.

If the CDC did a Vaxxed vs unVaxxed study on the Hep B vaccine what would it look like?
It would look like this study because they did do one.

The results of this study were never released by the CDC, and an abstract of the study was only recently obtained under a FOIA request. Children vaccinated with Hepatitis B vaccine in the first month of life, compared to children receiving no vaccines in the first month of life, had an increased risk of 829% for ADHD, 762% for autism, 638% for ADD, 565% for tics, 498% for sleep disorders, and 206% for speech delays.

Verstraeten, Thomas M., MD, NIP, Division of Epidemiology and Surveillance, Vaccine Safety and Development Branch, Mailstop E-61, 770-639-8327.
EIS Class Year of Entry: 1999
No previous EIS Conference presentations
Mackel Award consideration: No
Number of abstracts submitted: 2, priority this abstract: 1
Strong preference for poster presentation: No

Thomas M. Verstraeten, R. Davies, D. Gu, F DeStefano

Increased risk of developmental neurologic impairment after high exposure to thimerosal-containing vaccine in first month of life.

Background: Concern has risen on the presence of the ethylmercury containing preservative thimerosal in vaccines. We assessed the risk for neurologic and renal impairment associated with past exposure to thimerosal-containing vaccine using automated data from the Vaccine Safety Datalink (VSD). VSD is a large linked database from four health maintenance organizations in Washington, Oregon and California, containing immunization, medical visit and demographic data on over 400,000 infants born between '91 and '97.

Methods: We categorized the cumulative ethylmercury exposure from thimerosal containing vaccines after one month of life and assessed the subsequent risk of degenerative and developmental neurologic disorders and renal disorders before the age of six. We applied proportional hazard models adjusting for HMO, year of birth, and gender, excluding premature babies.

Results: We identified 286 children with degenerative and 3702 with developmental neurologic disorders, and 310 with renal disorders. The relative risk (RR) of developing a neurologic development disorder was 1.8 (95% confidence intervals [CI] = 1.1-2.8) when comparing the highest exposure group at 1 month of age (cumulative dose > 25 ug) to the unexposed group. Within this group we also found an elevated risk for the following disorders: autism (RR 7.6, 95% CI = 1.8-31.5), nonorganic sleep disorders (RR 5.0, 95% CI = 1.6-15.9), and speech disorders (RR 2.1, 95% CI=1.1-4.0) . For the neurologic degenerative and renal disorders group we found no significantly increased risk or a decreased risk.

Conclusion: This analysis suggests that high exposure to ethylmercury from thimerosal-containing vaccines in the first month of life increases the risk of subsequent development of neurologic development impairment, but not of neurologic degenerative or renal impairment. Further confirmatory studies are needed.

What happens when you administer a vaccine to the public that is not tested for safety?

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PMCID: PMC4266455
PMID: 25395338

Evolution of multiple sclerosis in France since the beginning of hepatitis B vaccination

Dominique Le Houézec

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Abstract

Go to:

Since the implementation of the mass vaccination campaign against hepatitis B in France, the appearance of multiple sclerosis, sometimes occurring in the aftermath of vaccinations, led to the publication of epidemiological international studies. This was also justified by the sharp increase in the annual incidence of multiple sclerosis reported to the French health insurance in the mid-1990s. Almost 20 years later, a retrospective reflection can be sketched from these official data and also from the national pharmacovigilance agency. Statistical data from these latter sources seem to show a significant correlation between the number of hepatitis B vaccinations performed and the declaration to the pharmacovigilance of multiple sclerosis occurring between 1 and 2 years later. The application of the Hill's criteria to these data indicates that the correlation between hepatitis B vaccine and multiple sclerosis may be causal.

Keywords: Hepatitis B vaccine, Multiple sclerosis, Demyelinating disease, Pharmacovigilance, Vaccine adverse events

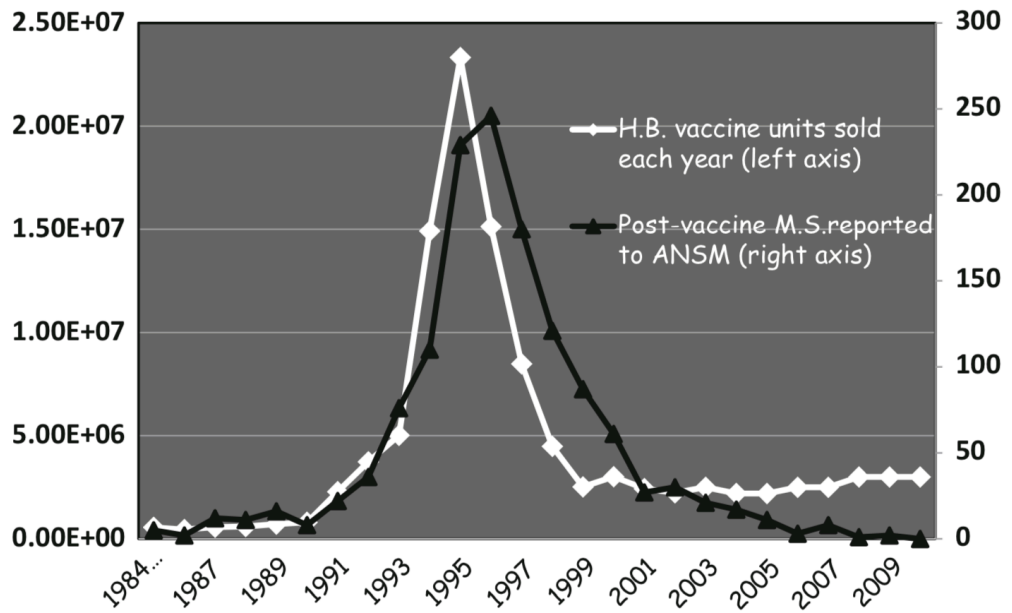

Fig. 2 Sales of Hepatitis B (HB) vaccine every year in France, comparison with report of post-vaccine MS to the national pharmacovigilance agency (ANSM) (1984–2010)

In France they found it caused Multiple sclerosis, but what in the vaccine did this? Contamination with other viruses, the Aluminum adjuvant? Since no one bothers to find out we don't know. But the FDA approved the vaccine to be given to babies even though it only had 4 days of testing.

These untested adjuvants are dangerous

ELSEVIER

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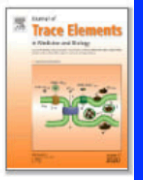
Volume 58, March 2020, 126444



Toxicology

Acute exposure and chronic retention of aluminum in three vaccine schedules and effects of genetic and environmental variation

Grant McFarland [a], Elaine La Joie [a], Paul Thomas [b], James Lyons-Weiler [a]

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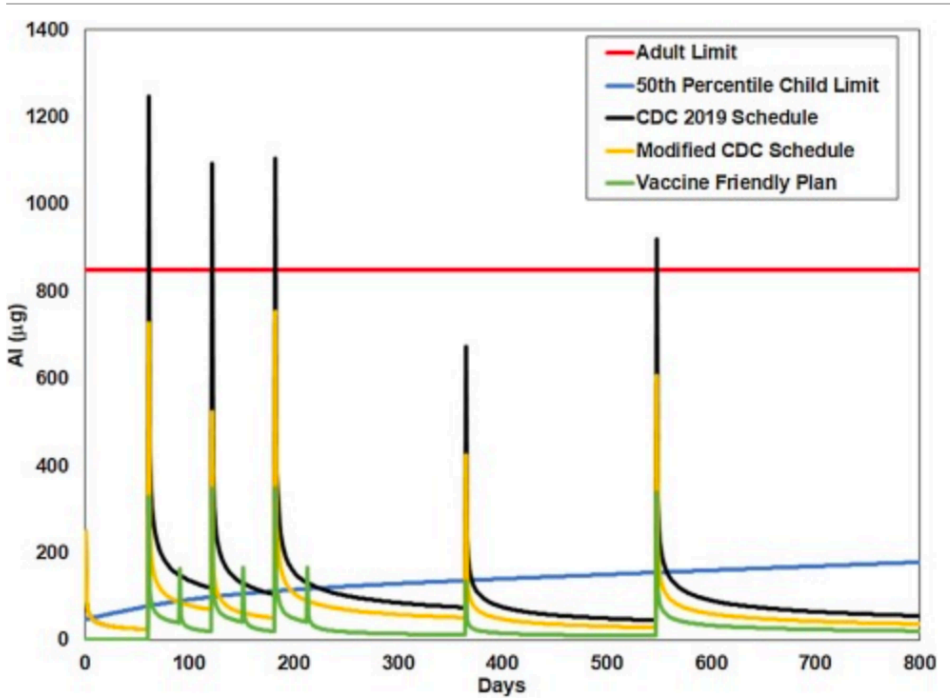

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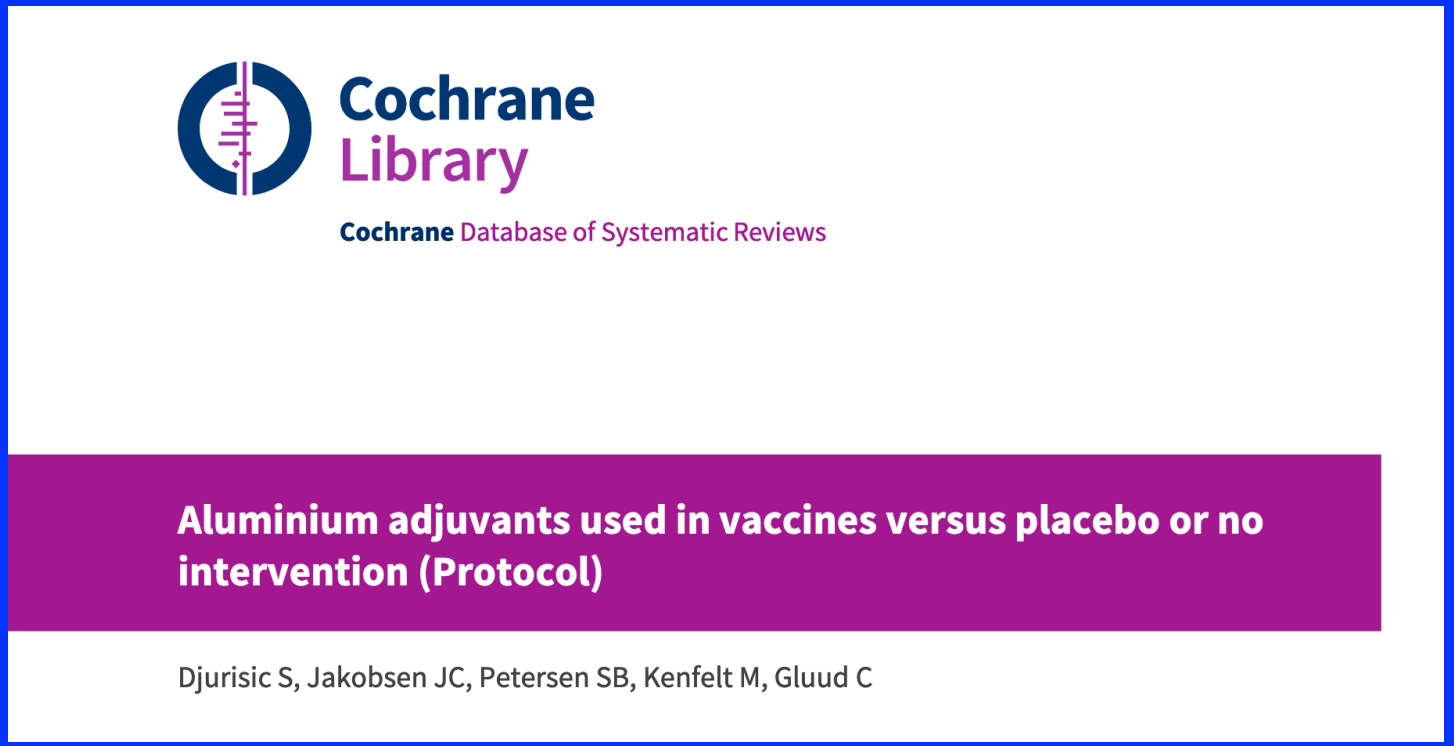
Fig. 2. Aluminum Content in Body over First Two Years for Three Vaccine Schedules.

This study found that infants in the USA spend 70% of their first year with levels of Aluminum in their bodies considered to be neurotoxic because of the vaccines they were given.

Cochrane is concerned enough to have propose a review of the literature on this subject



The problem is they aren't going to find any clinical trials to review. Certainly no Randomized Control Trials.

One could ask the question: Are we dealing with gross incompetence when it comes to vaccine safety or is this actually criminal negligence?

SB 277 was the only remaining Firewall in California that could potentially protect medical fragile or high risk children from Adverse Events Following Immunization

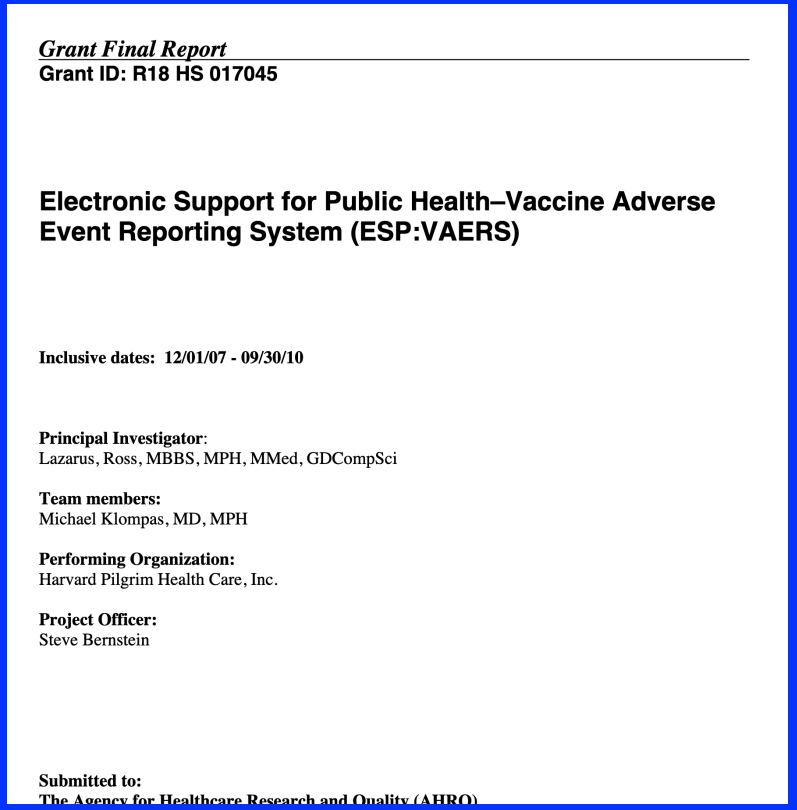
With over 100 physicians under investigation for doing what they thought the new law gave them the authority to do this is about an institutional failure to provide guidance and parameters. If physicians were lead astray by SB 277, the appropriate thing to do was issue an alert, a bulletin, and provide guidance.

If 1 Out Of Every 39 Passengers Was Going To Get injured, Maimed Or Killed Every Time A Plane Took Off, Would you Fly?

In 2007 HHS granted Harvard Pilgrim Health Care $1 million to Automate VAERS reporting (Active Surveillance not Passive). 1.4 million doses of 45 different vaccines were tracked in 376,452 patients – 35,570 reactions were identified over 3 years.

After finding out the adverse event rate was 2.6% or 1 in 39 the CDC ghosted the study and its investigators.

1 in 39 is not the 1 in a 1,000,000 the CDC claims is the rate of adverse events.



Grant Final Report

Grant ID: R18 HS 017045

Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS)

Inclusive dates: 12/01/07 - 09/30/10

Principal Investigator:
Lazarus, Ross, MBBS, MPH, MMed, GDCompSci

Team members:
Michael Klompas, MD, MPH

Performing Organization:
Harvard Pilgrim Health Care, Inc.

Project Officer:
Steve Bernstein

Submitted to:
The Agency for Healthcare Research and Quality (AHRQ)

https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

Most people would not fly if there were a 1 in 39 chance of having their luggage lost.

That is why the study was Ghosted by the CDC

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HHS/FDA/CDC can and does ignore the massive body of Science Supporting Vaccine Injury

But there will be consequences for ignoring, and censoring and faking the science. This tragedy has not been concluded.

The CDC's vaccine schedule has increased from 11 injections of 4 vaccines in 1986 to 56 injections of 30 vaccines in 2017 along with a precipitous increase in childhood chronic illness and developmental disabilities – from 12.8% to 54%.*

The 2011 IOM Report makes it clear that little has been ruled out with regard to what injuries are caused by vaccines and no studies have been conducted to assess the safety of any part of the vaccine schedule.

So what is safe in a sea of fraud and disinformation? Maybe it just what a physician judges to be safe or unsafe as codified by SB 277.

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Perspective

The Denial of Adverse Event Risk Following Immunization and the Loss of Informed Consent - A Perspective

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Abbreviations

HHS: Department of Health and Human Services; CDC: Centers for Disease Control; FDA: Food and Drug Administration; WHO: The World Health Organization; AEFI: Adverse Event Following Immunization; AAP: American Academy of Pediatrics; DTP: Diphtheria-Tetanus-Pertussis; OPV: Oral Polio Vaccine; PIC: Physicians for Informed Consent; VAERS: Vaccine Adverse Event Reporting System; EMA: European Medicines Agency; AAHS: Amorphous Aluminum Hydroxyphosphate Sulfate; NACCHO: National Association of County and Public Health Officials; GSK: GlaxoSmithKline; SV40: Simian Virus 40; MMR: Measles, Mumps and Rubella; I3C?: Indole-3-Carbinol.

safety, while at the same time actual evidence of vaccine harm is systematically ignored by vaccine manufacturers and authorities who work together under multiple unethical conflicts of interest. Consequently, vaccines are a grave threat to public health and medical ethics. Furthermore, informed consent in vaccination is deeply endangered today both in medical practice and as an ethical principle in society. Natural immunity is similarly endangered today due to modern vaccination policy. Promoting categorically unsafe vaccines and discouraging the responsible development of natural immunity has become state sponsored policy where the policy itself is what gets protected – not the public.

In the U.S., the Food and Drug Administration (FDA) has stated their policy on this issue clearly, "any possible doubts, whether or

*https://www.ncbi.nlm.nih.gov/pubmed/20159870

When uncontested medical research demonstrates a vaccine has no apparent clinical efficacy, or worse actually increases the susceptibility to the very disease it is supposed to offer protection from what happens next?

Since nothing happens next, isn't it unreasonable to blame physicians doing their conscientious best to protect those who could be at increased risk for an adverse event (as codified by SB 277)?

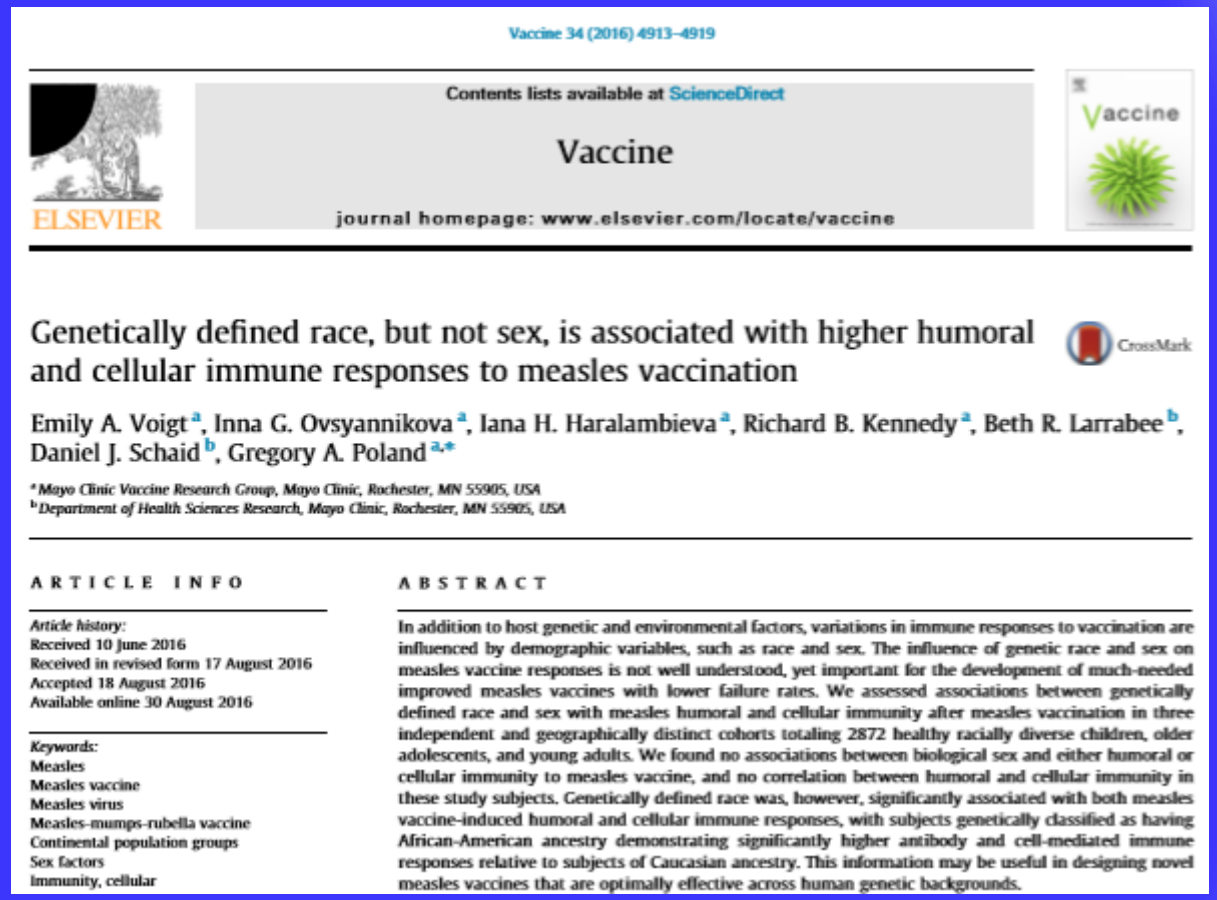
There are also genetic and racial disparities that make a vaccine safer for some than for others

So, the lack of vaccine safety and denial of vaccine injury is actually a racist policy.

African-American ancestry leads to a much more intense immune response from the MMR

"Genetically defined race was, however, significantly associated with both measles vaccine-induced humoral and cellular immune responses, with subjects genetically classified as having African-American ancestry demonstrating significantly higher antibody and cell-mediated immune responses relative to subjects of Caucasian ancestry." (Poland, et al 2016) https://www.sciencedirect.com/science/article/pii/S0264410X16307563

This scientific finding is consistent then with the CDC* data showing African-American males have a 340% increase in autism post MMR vaccine



Vaccine 34 (2016) 4913–4919

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Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Genetically defined race, but not sex, is associated with higher humoral and cellular immune responses to measles vaccination

Emily A. Voigt[a], Inna G. Ovsyannikova[a], Iana H. Haralambieva[a], Richard B. Kennedy[a], Beth R. Larrabee[b], Daniel J. Schaid[b], Gregory A. Poland[a,*]

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ABSTRACT

In addition to host genetic and environmental factors, variations in immune responses to vaccination are influenced by demographic variables, such as race and sex. The influence of genetic race and sex on measles vaccine responses is not well understood, yet important for the development of much-needed improved measles vaccines with lower failure rates. We assessed associations between genetically defined race and sex with measles humoral and cellular immunity after measles vaccination in three independent and geographically distinct cohorts totaling 2872 healthy racially diverse children, older adolescents, and young adults. We found no associations between biological sex and either humoral or cellular immunity to measles vaccine, and no correlation between humoral and cellular immunity in these study subjects. Genetically defined race was, however, significantly associated with both measles vaccine-induced humoral and cellular immune responses, with subjects genetically classified as having African-American ancestry demonstrating significantly higher antibody and cell-mediated immune responses relative to subjects of Caucasian ancestry. This information may be useful in designing novel measles vaccines that are optimally effective across human genetic backgrounds.

*Confession of CDC whistle blower Dr. William Thompson

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Article

Age at First Measles-Mumps-Rubella Vaccination in Children With Autism and School-Matched Control Subjects: A Population-Based Study in Metropolitan Atlanta

Frank DeStefano, Tanya Karapurkar Bhasin, William W. Thompson, Marshalyn Yeargin-Allsopp and Coleen Boyle

Pediatrics February 2004, 113 (2) 259-266; DOI: https://doi.org/10.1542/peds.113.2.259

The CDC's senior scientist for its seminal MMR-autism study has recently revealed that the CDC concealed an association between MMR and autism and shredded the study's data so no one would know.

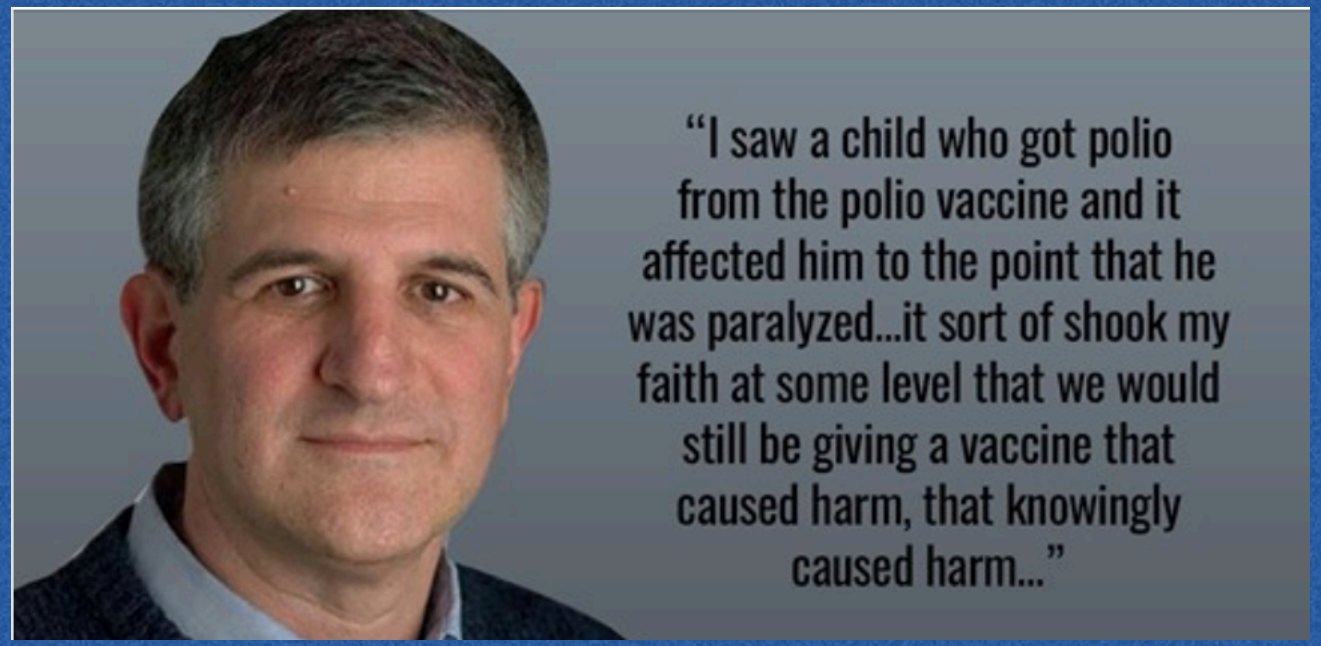
"Oh my God, I can't believe we did what we did. But we did. It's all there. It's all there."

"I have great shame now when I meet families with kids with autism because I have been part of the problem ... the CDC is so paralyzed right now by anything related to autism. They're not doing what they should be doing because they're afraid to look for things that might be associated. So anyway there's still a lot of shame with that. ... I am completely ashamed of what I did."

Genetic susceptibility, also called genetic predisposition, is an increased likelihood or chance of developing a particular untoward disease or response such as a vaccine adverse event due to the presence of one or more gene mutations with or without a family history of an increased risk

For example, compared to white children, the native American Apache children have significant impairment of their antibody response to *H. influenzae* type b polysaccharide , thus they may be prone to develop adverse events if administered a *H. influenzae* vaccine with *H. influenzae* type b polysaccharide as its component.

Siber GR, Santosham M, Reid GR, Thompson C, Almeido-Hill J, Morell A, de Lange G, Ketcham JK, Callahan EH: Impaired antibody response to Haemophilus influenzae type b polysaccharide and low IgG2 and IgG4 concentrations in Apache children. N Engl J Med. 1990, 323 (20): 1387-1392. 10.1056/ NEJM199011153232005.



Dr. Offit is very pro-vaccine; although, very selective about which vaccines he thinks cause harm, but the point is why "we would still be giving a vaccine that causes harm…"

What is a conscientious physician to do about knowing harm is being done in the name of policy? In the name of standard of practice?