

Vaccine Safety Issues

Lessons from Hepatitis B and other Immunization Programs

Mark A. Kane MD, MPH

A lie can travel half way around the world while
the truth is putting on its shoes.

Mark Twain

Blood

- Hepatitis B immunization born into safety concerns in 1982
- Plasma derived hepatitis B vaccine was a blood product
- AIDS discovered but cause not identified: bloodborne virus suspected
- Prominent doctors warned causative agent of AIDS may be in vaccine
- When HIV virus discovered it was quickly proven not to be in vaccine but damage was done until advent of DNA recombinant vaccine 1986
- When DNA recombinant vaccine came onto market manufacturer used fear of contamination as marketing strategy vs competitors

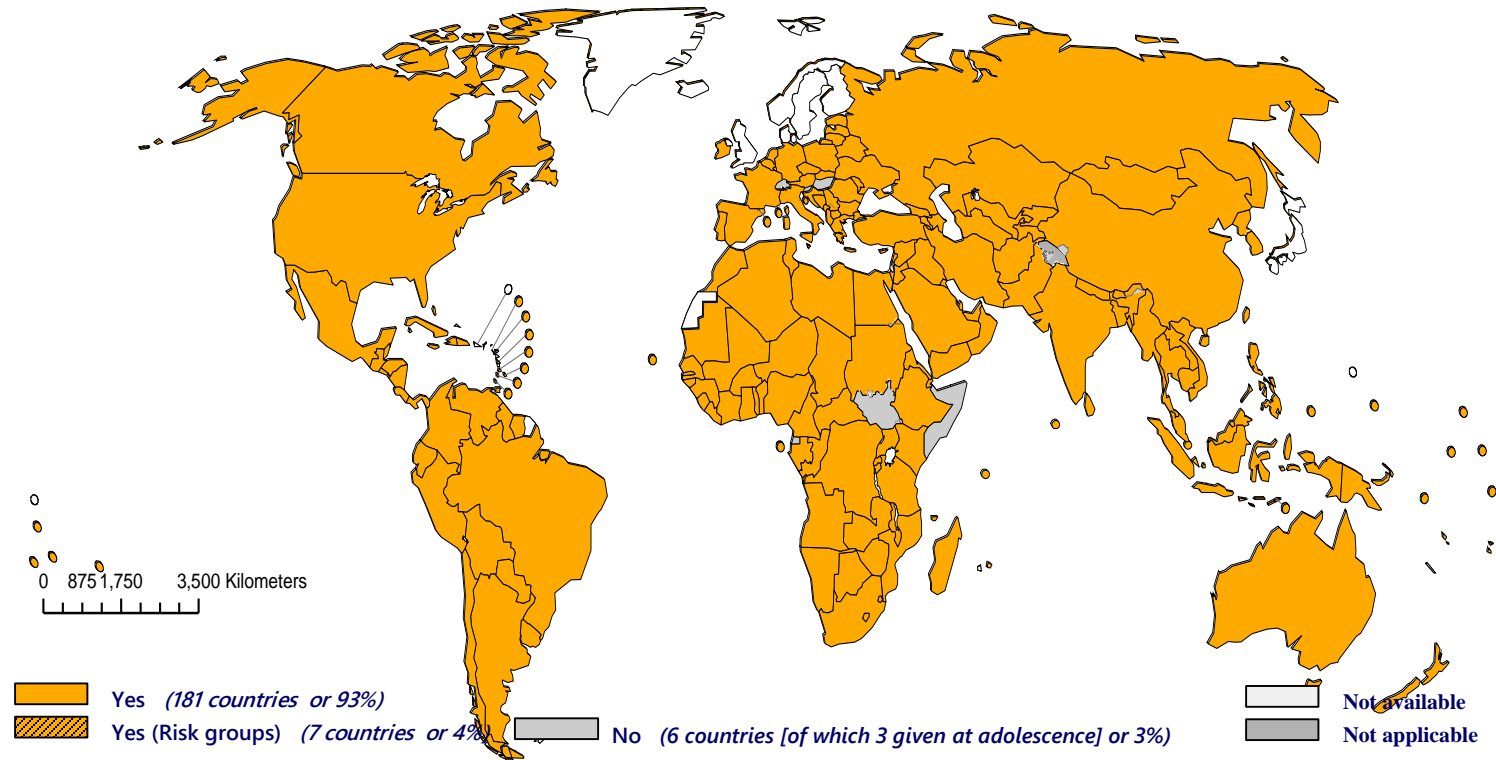
Sex, drugs, and a failed immunization strategy

- Hepatitis B is a sexually transmitted virus and most acute cases in industrial countries were transmitted by sex or needle sharing
- Initial recommendations for use of HBV “high risk” group strategy recommended immunization of sex workers, gay men, STI patients, and people with “multiple partners” (more than you) plus IVDU and other groups
- This strategy protected some individuals but failed to impact rates of disease and led to globally recommended strategy of universal infant immunization
- Many aspects of delivering vaccine to sexually active and drug using populations failed
- “high risk” strategy still primary strategy in Scandinavia and UK

Immunizing older children and adolescents

- All countries National Immunization Programs good at reaching infants but reaching older children, adolescents, and adults is difficult
- Many countries tried to reach adolescents with HBV either as a primary target or parallel to infant immunization to speed immunity
- Adolescent programs saw similar issues to HPV issues we face now from the anti-vaccine community
- Giving adolescents “permission to have sex”
- Adolescents fainted especially in group immunization settings
- France stopped school based adolescent HBV immunization after a “very bad morning” of multiple psychogenic fainting episodes

Countries using Hepatitis B vaccine in national immunization schedule, 2012



World Health
Organization

Safety concerns damage National Program

- In 1996 French Neurologist reported to the press that he had noticed what appeared to be an increase in cases of multiple sclerosis among his patients who had received hepatitis B vaccine. Picked up by anti-vaccine groups
- Political pressure led to Government suspension of the Adolescent Vaccination program and severe damage to infant program
- WHO and VHPB quickly convened an “expert meeting” to examine the evidence and issue it’s findings in the WHO WER
- Multiple studies done subsequently showed no association between MS and Hep B vaccine
- The damage to the French program persists to this day with very low rates of both infant and adolescent coverage. Infant coverage up with Hexavalent vaccine
- To this day French courts are awarding damages for MS caused by Hep B vaccine

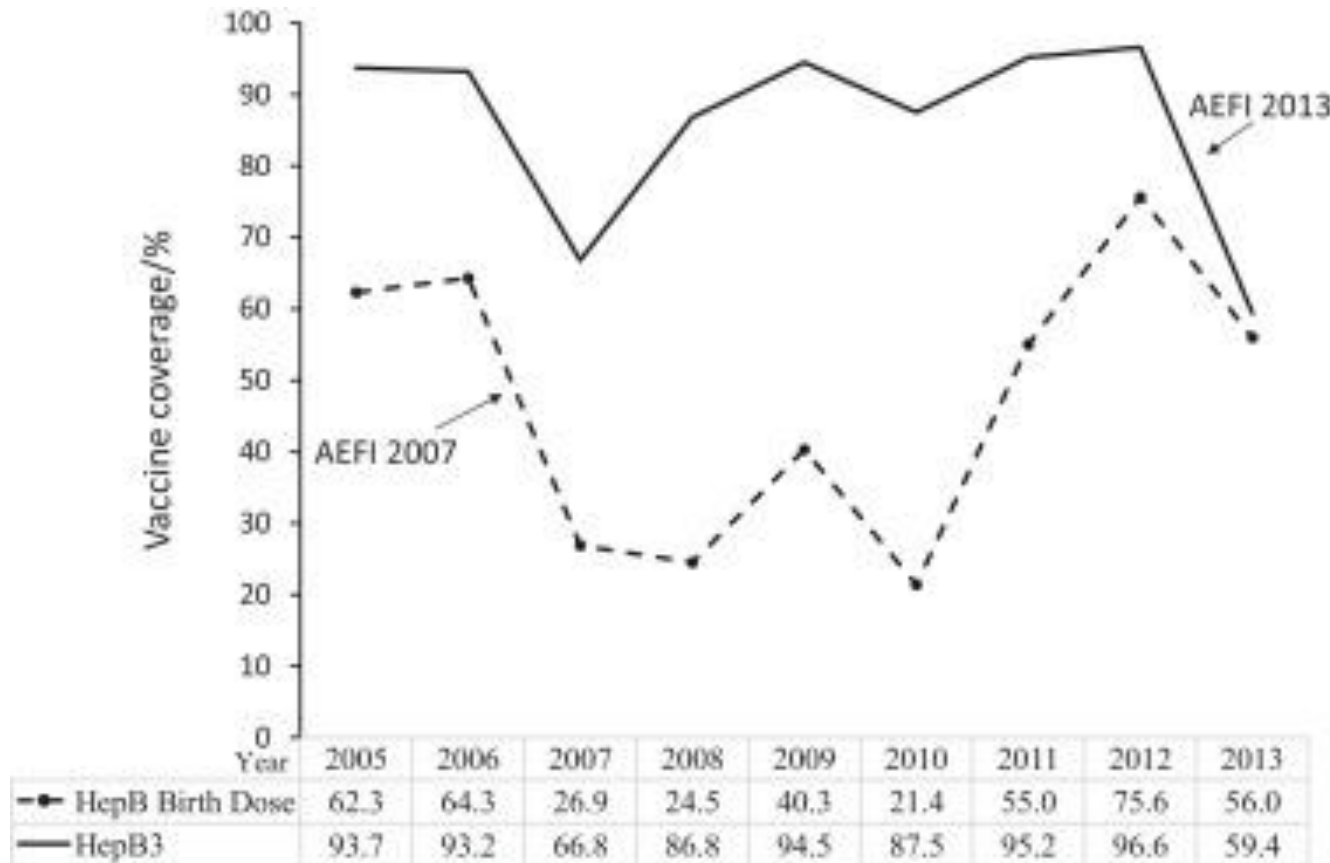
World Health Organization. Expanded programme on immunization. Lack of evidence that hepatitis B vaccine causes multiple sclerosis. Weekly Epidemiological Record 72:149-152, 1997.

Mark A. Kane, Francoise Roudot-Thoraval, Nicole Guerin, Vassiliki Papaevangelou, Pierre Van Damme & on behalf of the Viral Hepatitis Prevention Board (2016) Editorial on “What is a potentially damaging vaccination delay in children younger than 2 years?”, Human Vaccines & Immunotherapeutics, 12:8, 2053-2056.

Safety concerns damage National Programs

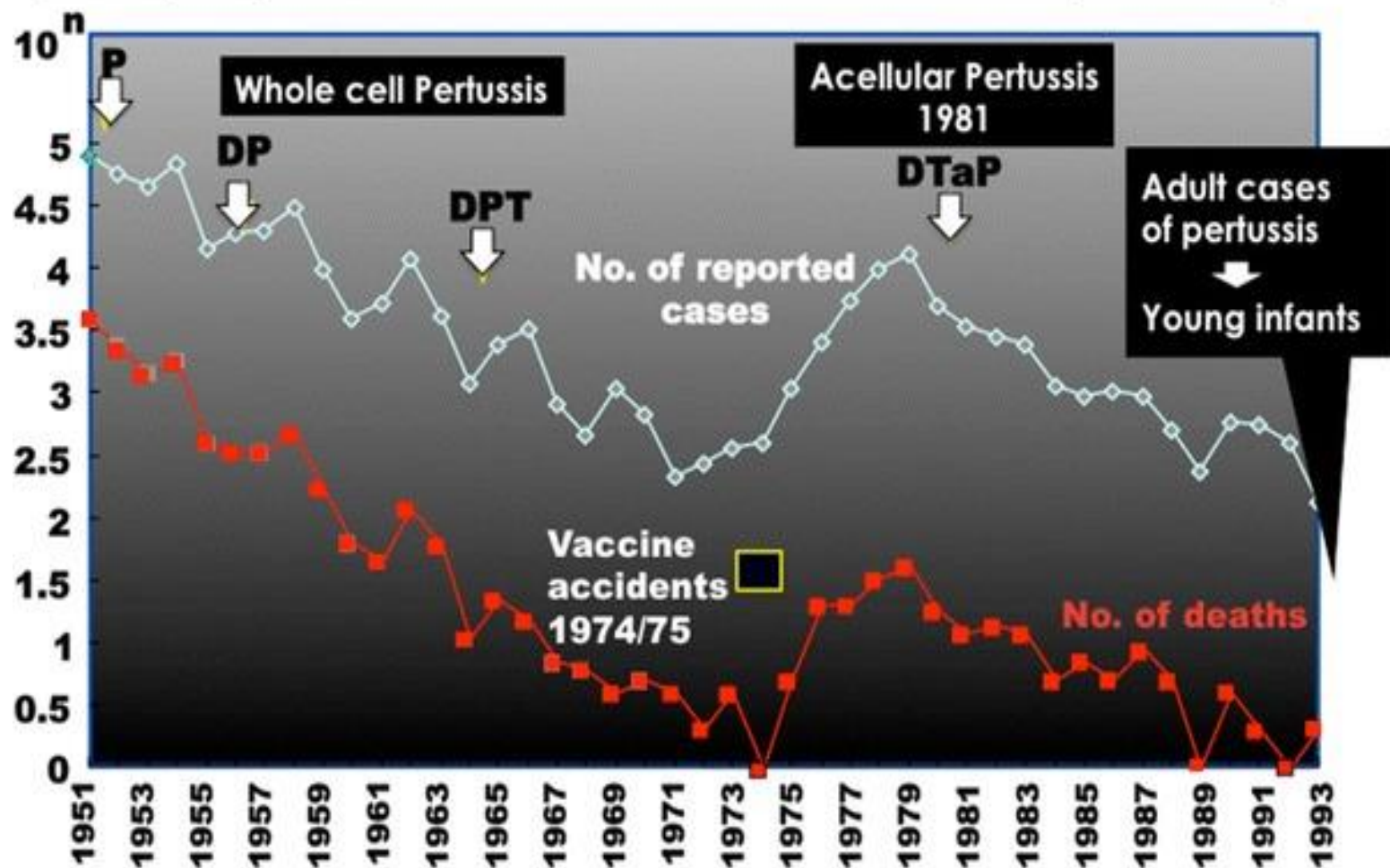
- Viet Nam 2007 and 2013
- Similar reports in China 2015
- 3 deaths due to program error in 2013
- Media rapidly reports rumors of deaths due to vaccine
- Drop in birth dose coverage from 76% to 56%
- Estimated impact: 90,000 chronic infections and 17,000 excess deaths
- Government slow to investigate reports and report issued months or years after the events, long past when the damage done
- Investigation showed deaths not related to Hep B vaccine
- It can take years for immunization coverage to recover
- AEFI reporting needs to be accompanied by training on how to deal with adverse events with the media and public

Hepatitis B vaccine coverage Vietnam 2005-2013



[Xi Li](#), [Eric Wiesen](#), [Sergey Diorditsa](#), et al. Impact of Adverse Events Following Immunization in Viet Nam in 2013 on chronic hepatitis B infection. *Vaccine*. [Volume 34, Issue 6](#), 3 February 2016, Pages 869–873.

History of pertussis vaccine and surveillance of pertussis

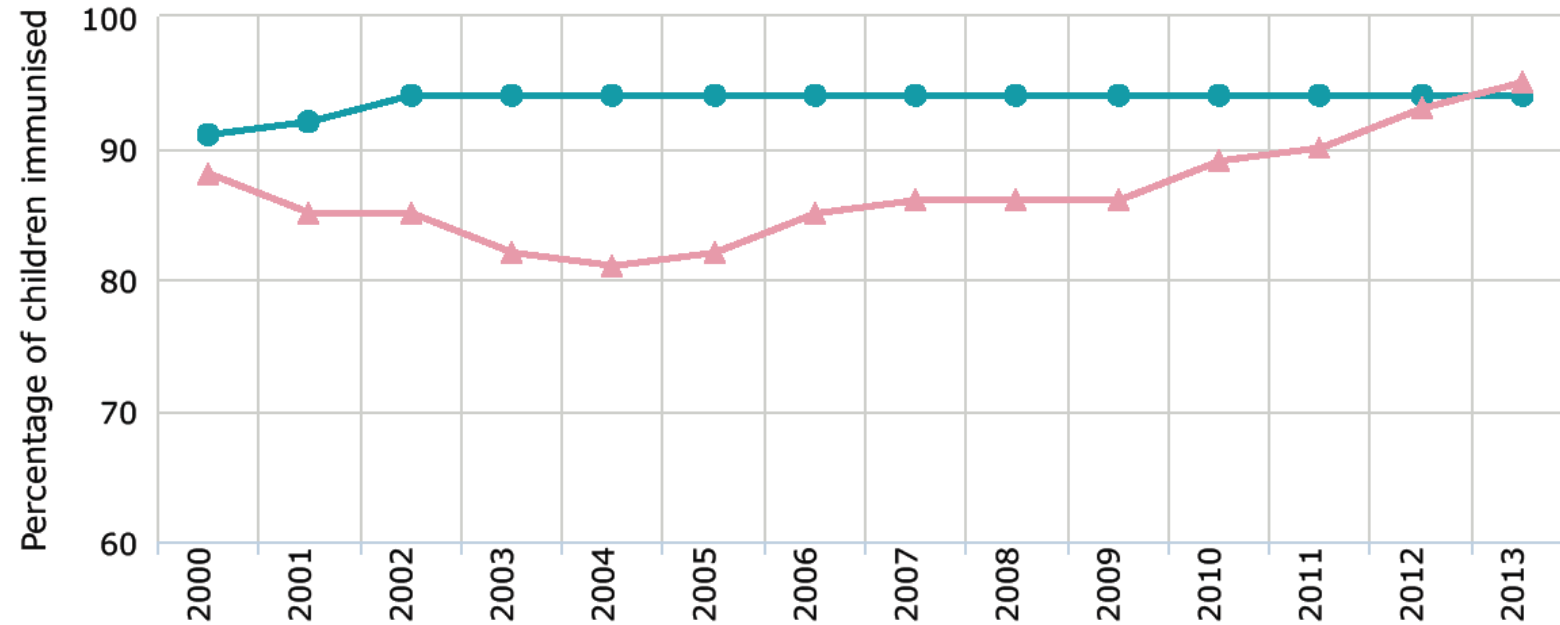


[Vaccine chronicle in Japan](#)

Tetsuo Nakayama

J Infect Chemother. 2013; 19(5): 787–798. Published online 2013 Jul 9. doi: 10.1007/s10156-013-0641-6

How does UK's measles immunisation coverage compare internationally?



Click on series name to show or hide

Australia Belgium Canada France Germany OECD Best (Greece)
Ireland Italy Netherlands New Zealand Portugal Spain Sweden
United Kingdom United States

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Spectrum of “vaccine hesitancy”

- Honestly concerned parents
- People frightened by media coverage of vaccine dangers
- Parents who believe they or their families were damaged by vaccines
- “Alternative medicine” patients and health providers
- People who distrust governments and/or Big Pharma motives for pushing immunization “sterilize girls” “profits for unnecessary dangerous vaccines”
- Political groups using vaccination to attack political opponents
- Some religious groups
- Lawyers who make money suing doctors and companies
- Media looking for a good conflict story

Alternative Medicine and vaccine hesitancy

What I learned

- Gave a series of lectures at major Naturopathic College in US
- Worked with a group of young Naturopaths to write guidelines on immunization for their professional society
- They were polite and very knowledgeable about anti-vaccine literature (autism, mercury, aluminum, too many injections, auto-immune disease, distrust of government and Big Pharma, etc)
- Shifting hypotheses with underlying assumption that vaccine is cause of problem (the antigen, then the mercury, then the aluminum, then too many vaccines)
- Believed that “one size fits all” immunization is not good medicine. Each child should be uniquely assessed for individual vaccine needs.
- Some children need delayed immunization or viral but not bacterial vaccines, or no vaccines at all, etc.
- Could not clearly explain criteria for making above decisions

Alternative Medicine and vaccine hesitancy

What I learned (cont.)

- Diseases were going away anyway before immunization
- Good nutrition protects children against severe childhood infections
- Wild type infection is best vaccine
- Government and corporations (Big Pharma) lie to the public daily. Why believe them about vaccine safety, efficacy, and need?
- Giving parents permission to not vaccinate children is an important component of their business model and there is demand for this service
- Some young Naturopaths are concerned that their anti-vaccine position is hurting chances at being licensed in many states
- Seem most vulnerable to argument that they are not good citizens and taking advantage of parents who get their children immunized to protect children who are not
- One Naturopathic professional society has issued pro-vaccine recommendations

Baxter's Eight Factors in opposition to immunization (paraphrased)

- “primum non nocera” AEFI in healthy people especially children without consent less tolerated
- Rapid dissemination of information and misinformation in media, exacerbated in modern social media
- Willingness of respected doctors to give credence to AEFI hypotheses. Even if few, publicity is disproportionate
- Public perception of damaged children and emotional, media savvy, and often highly organized parents vs “cold” health officials spouting data
- Politicians joining forces with anti-vaccination groups
- Unavailability of scientific data to refute AEFI claims and theories at the time of the controversy. It may take months or years to conduct definitive research
- Complexity of arguments surrounding immunization cannot be explained in a three minute news slot (balance of risk and benefit, direct vs herd immunity, etc)
- Balance of media reporting does not reflect actual weight of data or opinion of professional community

Homo economicus

- Homo economicus is a mythical consumer who makes absolutely rational decisions about his or her economic and medical care decisions
- Economists have realized that models based on this mythical creature are incorrect and that humans often do not make rational choices
- The recent US election is a good case in point
- Health education models such as KAP that assume that consumers are rational actors that just need proper information to change health behaviors are equally naïve
- “vaccine hesitancy” behavior in many/most cases will not change when the individual is given what we believe to be “correct information”
- How do we navigate in a “post-factual” world?

The Media

- Vaccine issues often covered by inexperienced reporters or reporters with an agenda
- Anti-vaccine groups very media savvy, often more so than health officials
- The sin of false equivalence. If someone claims the earth is flat the media gives both sides equal coverage. We have a new US president thanks partly to that.

What we need to do

- Governments need to train immunization workers in how to respond to vaccine safety concerns to the public and the media
- Know the data. Explain AEFI data to media and public. Most AEFI concerns are not new and have been thoroughly disproved.
- Rapid response to alleged side effects
- Bold government defense of immunization programs. Be able to show benefits of immunization and costs of damaging program
- Workshops with key media before events occur. They need to understand the cost of damaging the immunization program with potentially inaccurate information
- Talk about cancer not sex

Comparison of maximum and current reported morbidity, and vaccine-preventable diseases, United States

DISEASE	PRE- VACCINE	YEAR	1999**	% CHANGE
Diphtheria	206,939	1921	1	-99.99
Measles	894,134	1941	86	-99.99
Mumps	152,209	1968	352	-99.76
Pertussis	265,269	1934	6,031	-97.63
Polio (wild)	21,269	1952	0	-100.00
Rubella	57,686	1969	238	-99.58
Cong.Rub S	20,000+	(1964-5)	3	-99.98
Tetanus+	1,560	1923	33	-97.88
Invasive Hib Disease (>5y)	20,000+	1984	33	-99.83
TOTAL	1,639,066		6,777	-99.58

source : MMWR

HPV situation in Denmark

Rare “condition” and common exposure (Mc Donalds problem)

“condition” is ill defined. Most allegations of AEFI are diseases of unknown or complex causes (MS, Guillian Barre, autism, chronic fatigue, pain syndromes, weakness) often neurologic, auto immune, or some combination.

AEFI claims may severely damage programs before there is time to do research to disprove the claims

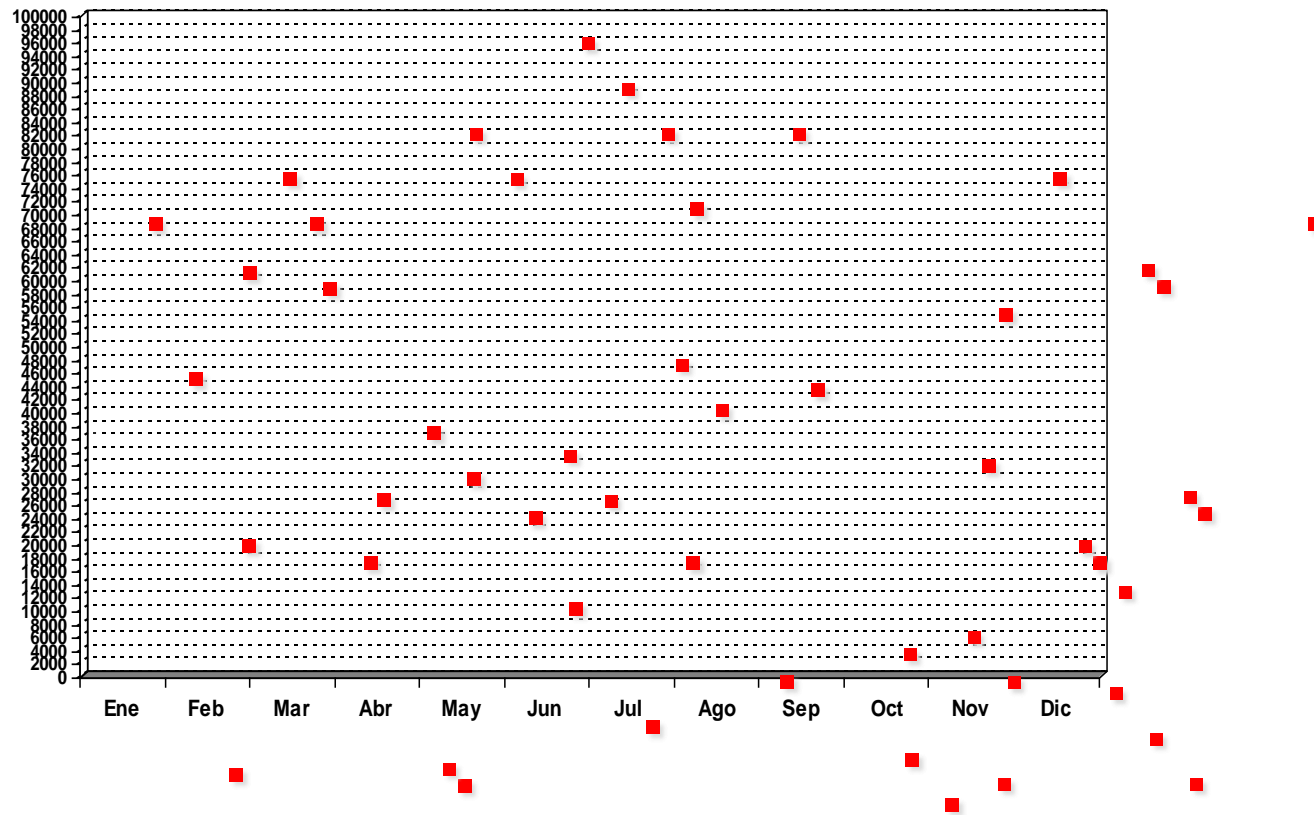
Respected scientists making claims get disproportionate coverage from media and are used by anti-vaccine groups

- Thomas theorem: "*If men define situations as real, they are real in their consequences*"
- "*Life can only be understood backwards; but it must be lived forwards.*" - Soren Kierkegaard
- Public health is the art of making good decisions with incomplete information

Human Papilloma Virus Immunization in Adolescent and Young Adults

A Cohort Study to Illustrate What Events Might be Mistaken for Adverse Reactions

Pediatr Infect Dis J 2007;26: 979–984

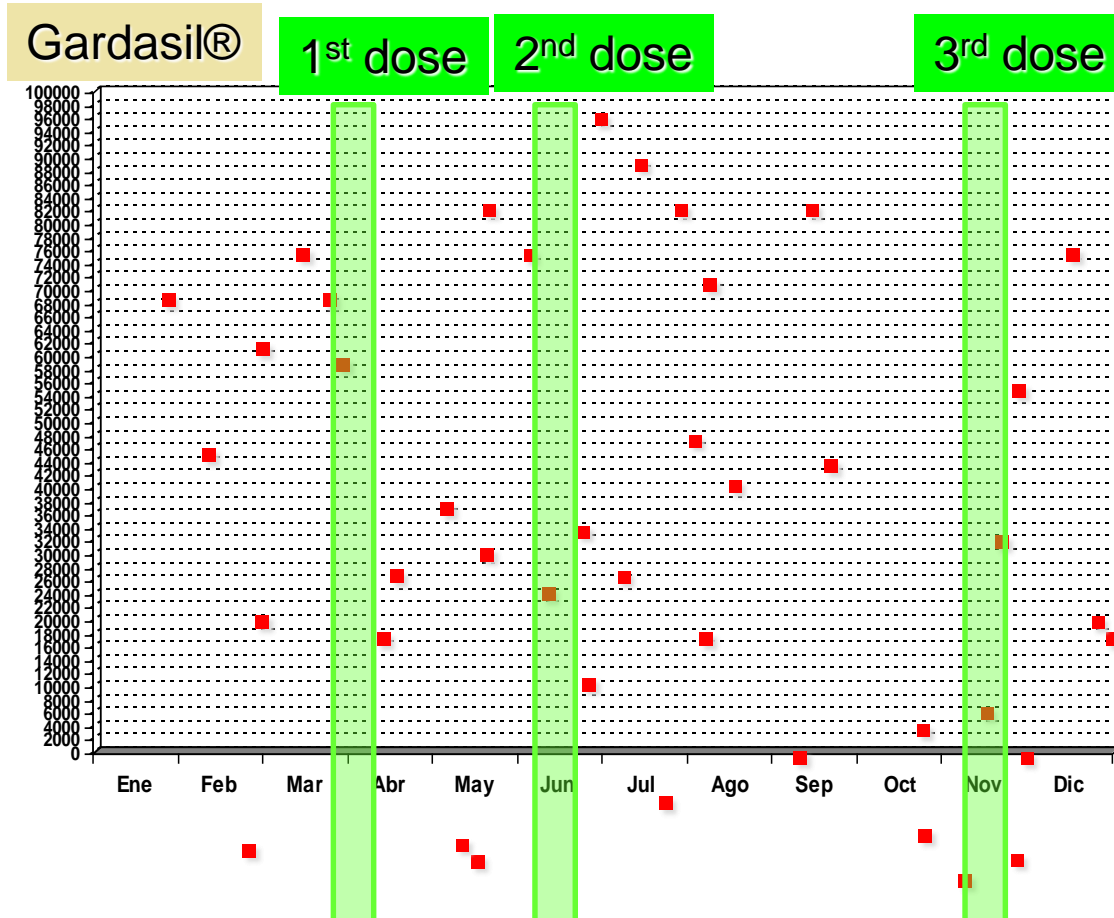


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Thank You