

Vaccine Safety Issues

Lessons from Hepatitis B 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

- Anti-vaccination ideas have been with us since the first vaccine: all vaccines have been attacked
- I will address hepatitis B vaccine and some other issues since these seem relevant to what we are seeing with HPV vaccine
- HPV vaccine communicates with the immune system with 100% effectiveness (seroconversion) but communication between cognitive nervous systems is much less effective (anyone raised adolescents?)
- Homo economicus is a mythical consumer who makes absolutely rational economic and health care decisions. Many academic models of decision making in economics and health care communications (KAP) are based on this assumption and cannot account for the persistence of anti-vaccine and other anti-scientific ideas.
- “Cognitive sciences” and the media are now full of explanations why rational arguments and data fail to change solidly held beliefs, often described as “confirmation bias”. Unfortunately these insights help with diagnosis but not cure.
- How to communicate in a “post factual world”?

Thomas theorem: “If men define situations as real,
they are real in *their consequences*

- When an anti-vaccine parent speaks to other parents he or she speaks not primarily to their cerebral cortices but to deeper emotional (limbic) and even more primitive (reptilian) brain levels. This is much more effective, as any advertising executive will tell you, and it is one reason Mr. Trump is the US President.
- We need to do science and get our facts right, but when we communicate with the public we need to do a better job of convincing them emotionally why their children need vaccines.
- It would be nice if rational argument at least worked with medical personnel!

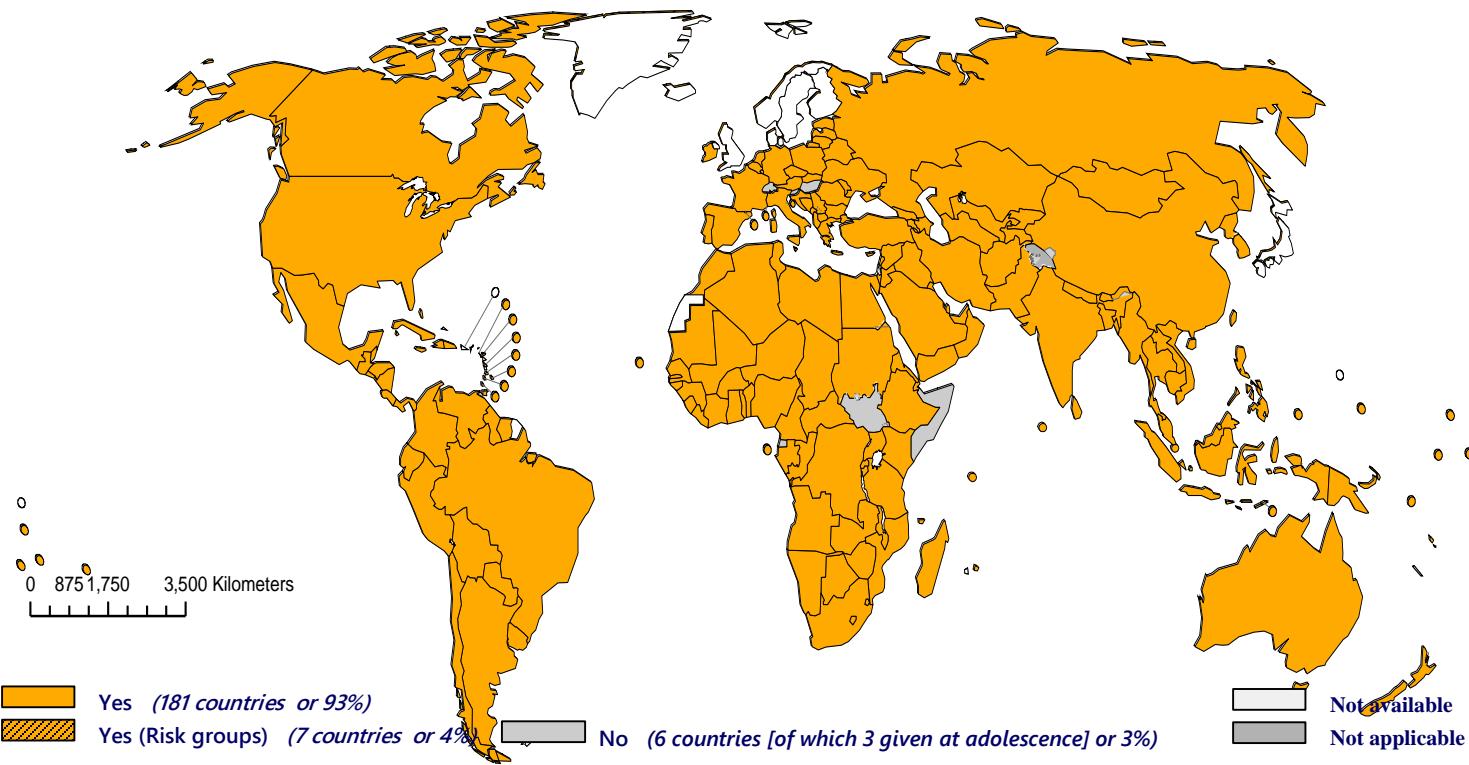
Blood

- Hepatitis B immunization born into safety concerns in 1982
- Plasma derived hepatitis B vaccine was a blood product
- AIDS emerged 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 health workers, 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 highly successful globally recommended strategy of universal infant immunization
- Many aspects of delivering vaccine to sexually active and drug using populations failed
- “high risk” strategy and maternal screening and treatment of newborns of carrier mothers is still primary strategy in Scandinavia and the UK but this may be changing in Norway and the UK with hexavalent vaccine introduction

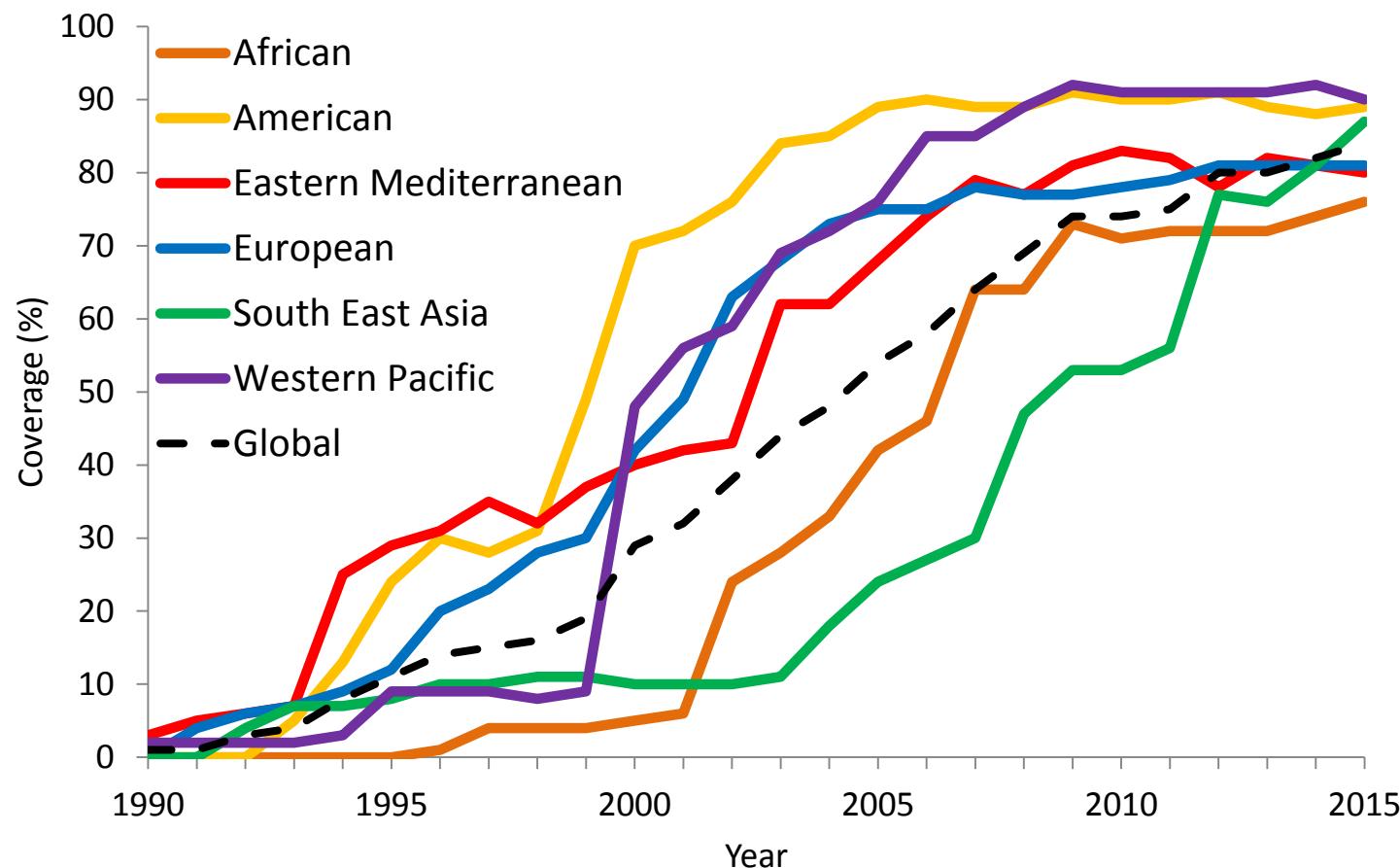
Countries using Hepatitis B vaccine in national immunization schedule, 2012



World Health Organization

3-DOSE HEPATITIS B VACCINE: 84% COVERAGE: IMPACT ON INCIDENCE

HBV



Source: WHO AND UNICEF

Immunizing older children and adolescents

- All National Immunization Programs good at reaching infants but reaching older children, adolescents, and adults is more difficult
- Some 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

Safety concerns damage National Programs

- In 1996 French Neurologist reported to the press that he had noticed 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 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
- Illustrates the damage one physician can do to a national program

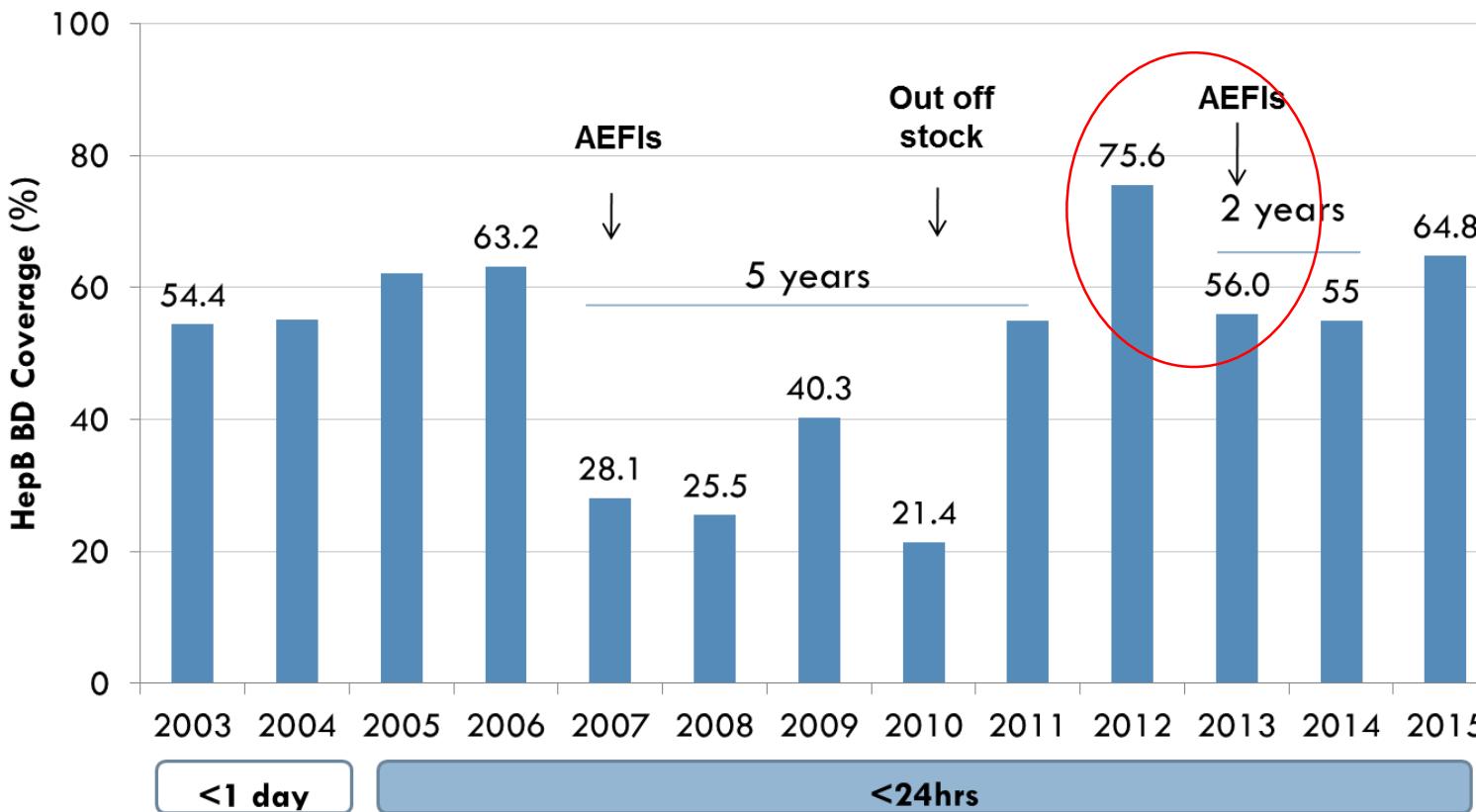
World Health Organization. Expanded programme on immunization. Lack of evidence that hepatitis B vaccine causes multiple sclerosis. Weekly Epidemiological Record 72:149-152, 1997.

Mark A. Kane, Francois 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
- 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, public, and medical community

For the hepatitis B birth dose: Public perceptions matter!



If the hepatitis B vaccination coverage had been maintained as in 2012 then:

90137 chronic infections and 17,456 future deaths could be averted

Li X, Wiesen E, Diorditsa S, et al. Impact of Adverse Events Following Immunization in Viet Nam in 2013 on chronic hepatitis B infection. *Vaccine*. 2015.

Alternative Medicine and vaccine hesitancy

What I learned

- Gave a series of lectures at major Naturopathic College in US
- 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

- 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
- 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
- Some young Naturopaths are concerned that their anti-vaccine position is hurting chances at being licensed in many states
- 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

Spectrum of “vaccine hesitancy”

- Honestly concerned parents
- People frightened by media coverage of vaccine dangers
- Parents who believe a family member was damaged by vaccines
- “Alternative medicine” patients and health providers
- People who distrust governments and/or Big Pharma motives for promoting immunization
- Political groups using vaccination to attack political opponents (sterilize girls, “guinea pigs”)
- Some religious groups
- Lawyers who make money suing doctors and companies
- Media looking for a good conflict story

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	20,000+	1984	33	-99.83
Disease (>5y)				
TOTAL	1,639,066		6,777	-99.58

source : MMWR

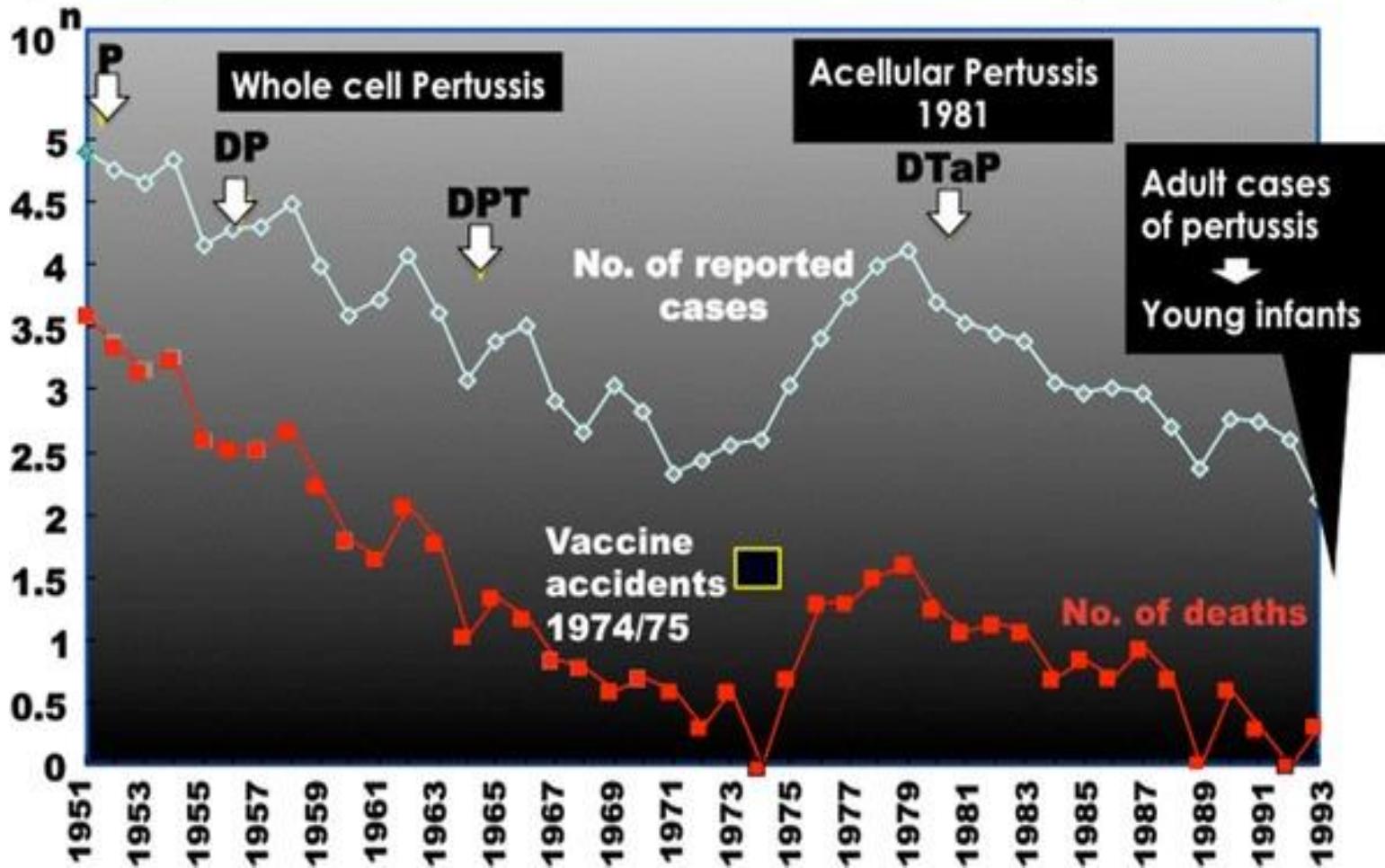
HPV situation in Denmark

Rare “condition” and common exposure (Mc Donalds problem)
“condition” is ill defined. Most allegations of AEFI are diseases of unknown or complex causes (MS, Guillain 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

History of pertussis vaccine and surveillance of pertussis

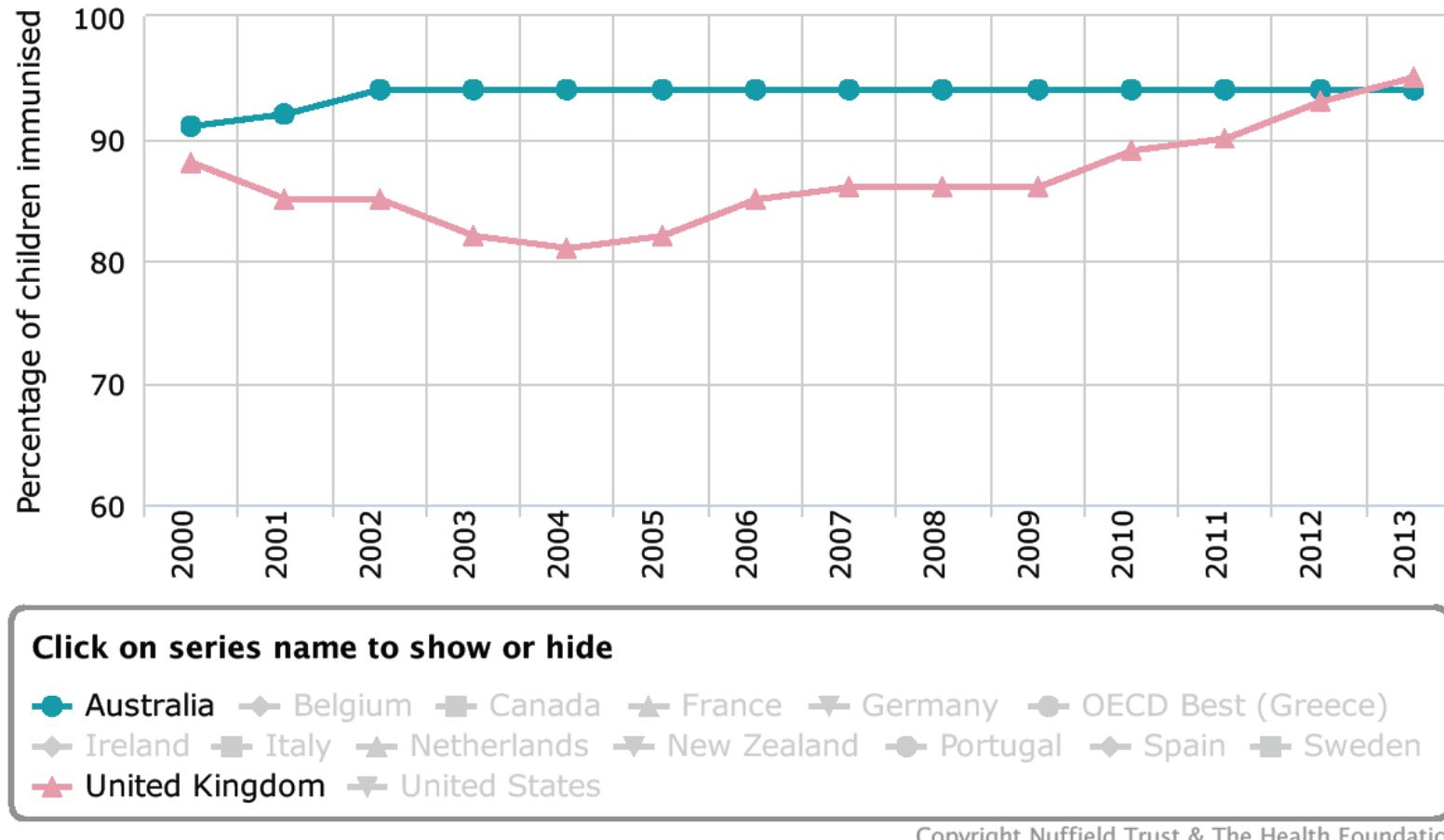


Vaccine chronicle in Japan

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?



Copyright Nuffield Trust & The Health Foundation

Thank You