Vaccine Safety Communication in a Pandemic

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With Crisis (can) Come Opportunity

- COVID-19 has caused global morbidity, mortality, and social & economic disruptions
- Seemingly very effective and very safe vaccines
- Demonstrate the value of science and vaccines

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COVID Vaccine Challenges

- New vaccine technology
- If we build it, they may not come
  - Variable perceptions of disease burden
  - Politics impacting science and response
  - Distrust of pharma-industrial complex
  - Perception vaccines rushed
- Real or coincidental adverse events derailing the program

Vaccine Safety Science: Rigor

- Approval process ensures benefits > risks for populations & outcomes studied
- Observational studies after approval to examine uncommon events, excluded populations, subpopulations, and delayed onset adverse events
- Infrastructure (large healthcare databases) very helpful for rigor and timeliness

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Clinical Trial Limitations: Sample Sizes Needed to Detect Rare Adverse Events and Impact

Rates (%)	Sample Size *	Number Potentially Affected**
0.1 vs. 0.2	50,000	328,000
0.1 vs. 0.3	17,500	656,000
0.05 vs. 0.1	100,000	164,000
0.01 vs. 0.02	500,000	32,800
0.01 vs. 0.03	175,000	65,600

*Two-arm trial, power 80%, alpha (2 sided) = 5%

** 100% vaccine coverage for the US

Source: Adapted from Ellenberg 2001

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Post Hoc, Ergo Propter Hoc

"After this, therefore because of this" is a logical fallacy … since that event *followed* this one, that event must have been *caused* by this one

dictionary.sensagent.com/post+hoc+ergo+propter+hoc/en-en/

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Estimates of Coincident, Temporally-Associated Events

Coincident events	Number of coincident events since a vaccine dose: *Within 1 day*	*Within 7 days*	*Within 6 weeks*	Baseline incidence rate used for estimate
Guillain-Barré Syndrome (per 10 million vaccinated people)	0.51	3.58	21.50	1.87 per 100,000 person-years (all ages; UK Health Protection Agency data)
Optic Neuritis (per 10 million female vaccinees)	2.05	14.40	86.30	7.5 per 100,000 person-years in US females
Spontaneous abortions (per 10 million vaccinated pregnant women)	3,970	27,800	166,840	Based on data from the USA (12% of pregnancies)
Sudden death within 1 hour of onset of any symptoms (per 10 million vaccinated people)	0.14	0.98	5.75	Based upon UK background rate of 0.5 per 100,000 person-years

Black *et* al. Importance of background rates of disease in assessment of vaccine safety during mass immunisation with pandemic H1N1 influenza vaccines; Table 6. *Lancet* 2009; 374; Oct. 30 [Epub.]

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Monitoring COVID Vaccine Safety
What is Needed?

- Identify adverse events following immunization and evaluate if caused by vaccine
  - GBS in 1976
- Address spurious associations
  - Bad things happen every day & will happen after vaccination
- Ability to distinguish between the two with rigor, speed and credibility

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Examples of What Works #1
The Cutter Incident

- Launch of the polio vaccine program was accompanied with reports of paralysis following vaccination
- Langmuir had recently formed the Epidemic Intelligence Service (EIS) at CDC to rapidly investigate outbreaks
- Investigation identified some vaccine (primarily manufactured by Cutter Laboratories) was not fully inactivated and had caused wild disease
- Vaccine program was halted for a very short time
- Because of this rapid investigation, robust and rigorous science, objectivity of risk assessment and transparency the program quickly resumed

Example of What Works #2
2009-10 H1N1 Safety Monitoring and Communication

- Mass vaccination program
  - In midst of vaccine crisis in confidence
  - 1976 Swine Flu Fiasco
- Most comprehensive vaccine safety and communication program ever, anywhere
- Vaccine safety crisis around H1N1 never occurred in US

What Hasn't Worked?

- **Autism**
- Simultaneous Vaccines
- Vaccine Ingredients

16 methodologically sound, controlled epidemiological studies exploring an association between Autism Spectrum Disorder (ASD) and receipt of MMR vaccine, thimerosal in vaccines, and simultaneous vaccination with multiple vaccines **by 2019**

First author	Journal	Pub Year - month	Country	Exposure
Taylor B	Lancet	1999-06	UK	MMR
Farrington CP	Vaccine	2001-06	UK	MMR
Taylor B	BMJ	2002-02	UK	MMR
Madsen KM	NEJM	2002-12	Denmark	MMR
Makela A	Pediatrics	2002-11	Finland	MMR
Hviid A	JAMA	2003-10	Denmark	Thimerosal
Verstraeten T	Pediatrics	2003-11	US	Thimerosal
Smeeth L	Lancet	2004-09	UK	MMR
Andrews N	Pediatrics	2004-09	US	Thimerosal
Croen LA	Am J Obstet Gynecol	2008-09	US	Thimerosal
Price CS	Pediatrics	2010-10	US	Thimerosal
Uno Y	Vaccine	2012-06	Japan	MMR/Multi-vaccines
DeStefano F	J Pediatr	2013-08	US	Multi-vaccines
Jain A	JAMA	2015-04	US	MMR
Uno Y	Vaccine	2015-05	Japan	MMR/Thimerosal
Hviid A	Ann Intern Med	2019-03	Denmark	MMR

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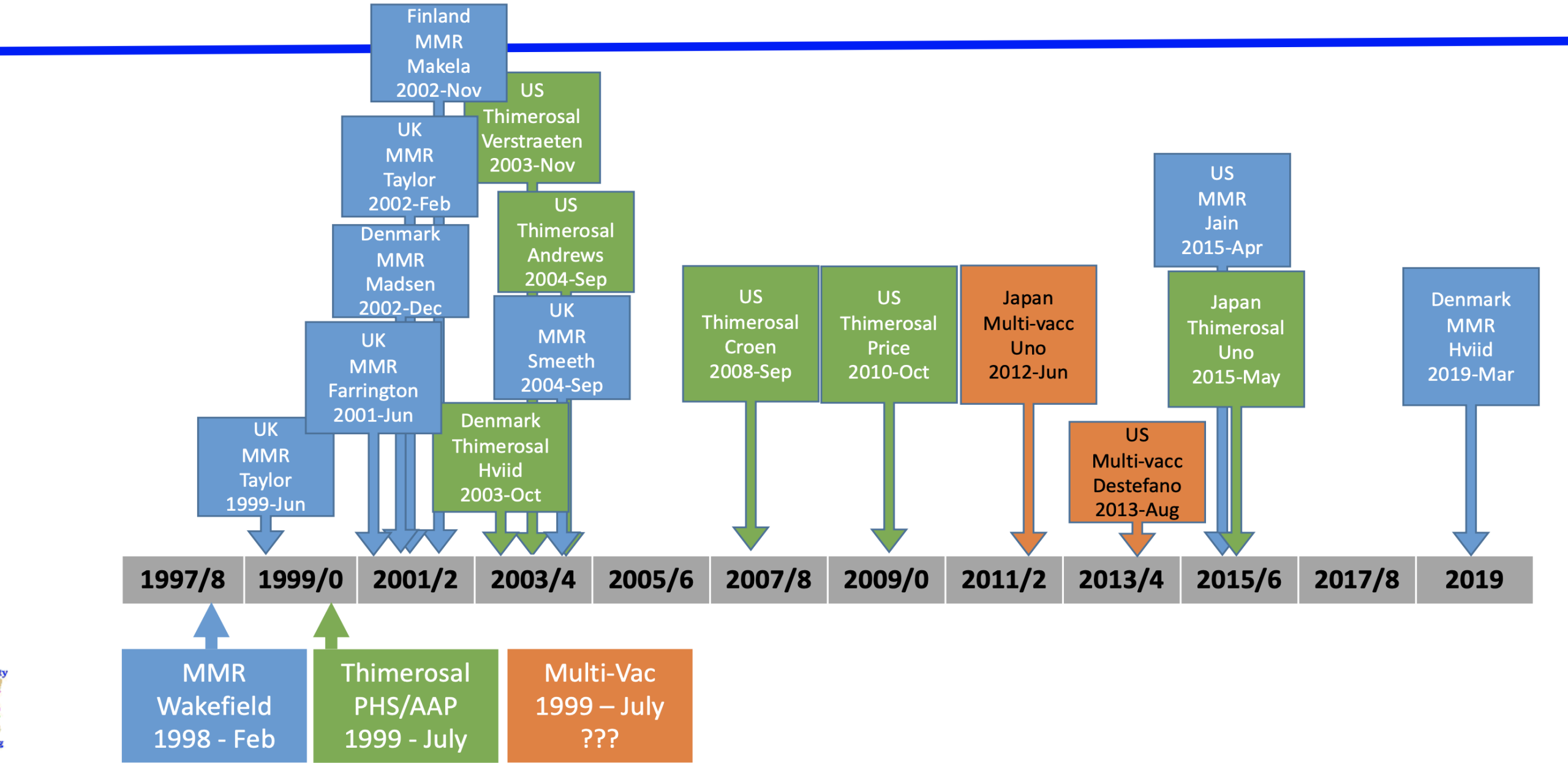
Vaccine Autism Controversies and Studies Over Time



Vaccine Safety Science & Communication

- Good science takes time whereas anecdote, sensationalism and bad science travels quickly
- Very difficult to changes someone's mind (cognitive dissonance and affirmation bias)
- Need to inform views as being formed

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