SENT VIA EMAIL

Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention
acip@cdc.gov

Re: *Supplement to December 5, 2025 Presentation Titled Development of the U.S. Childhood Vaccination Schedule: With a Focus on Suggested Improvements*

To ACIP:

Please find herein additional sources for various slides for the above-referenced presentation. As disclosed in that presentation, I am the Managing Partner of Siri & Glimstad LLP which has over 100 professionals who handle civil rights, exemptions, immigration, employment, and injury claims related to vaccines.

SLIDE 11: IMPORTANCE OF CLINICAL TRIALS

The importance of the clinical trials relied upon to license each recommended childhood vaccine in ACIP's decision making is highlighted by the following chart which reflects the time period between licensure and ACIP's recommendation for each vaccine. Note that this chart reflects all routinely recommended vaccines as well as any vaccine used as a control to license a routinely recommended vaccine, and so forth, down the licensure chain.

Vaccine	Year Licensed for Children	Year ACIP Recommended for Routine Use in Children [Earlier Non-Routine Use]	Days Between Licensure & Recommendation
DTP (various)	*	1966[1]	*
M-M-R-II (Merck)	1978[2]	1978[3]	49 days
Menomune	1981[4]	[1985][5]	[1264]

[1] https://stacks.cdc.gov/view/cdc/633.

[2] https://icandecide.org/article/measles-mumps-and-rubella-vaccine-mmr/.

[3] https://stacks.cdc.gov/view/cdc/1643.

[4] https://www.drugs.com/pro/menomune.html.

[5] https://stacks.cdc.gov/view/cdc/35394.

Recombivax HB (Merck)	1986[6]	[1987][7] 1991[8]	[331] 1948 days
Engerix-B (GSK)	1989[9]	[1990][10] 1991[11]	[192] 816 days
PedvaxHIB (Merck)	1989[12]	1990[13]	133 days
Ipol (Sanofi)	1990[14]	[1994][15] 1997[16]	[1691] 2580 days
ActHIB (Sanofi)	1993[17]	1993[18]	24 days
Varivax (Merck)	1995[19]	1996[20]	294 days
Havrix (GSK)	1995[21]	[1996][22] 2006[23]	[674] 4104 days
Vaqta (Merck)	1996[24]	[1996] [25] 2006[26]	[273] 3703 days
Infanrix (GSK)	1997[27]	1997[28]	73 days
Prevnar 7	2000[29]	2000[30]	-1 days
Daptacel (Sanofi)	2002[31]	2002[32]	52 days

[6] https://purplebooksearch.fda.gov/productdetails?query=101066.

[7] https://www.cdc.gov/mmwr/preview/mmwrhtml/00019181.htm.

[8] https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm.

[9] https://purplebooksearch.fda.gov/productdetails?query=103239.

[10] https://stacks.cdc.gov/view/cdc/7460.

[11] https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm.

[12] https://www.cdc.gov/mmwr/preview/mmwrhtml/00001600.htm.

[13] https://www.cdc.gov/mmwr/preview/mmwrhtml/00001600.htm.

[14] https://usa-mama.com/wp-content/uploads/2017/02/us-vaccines.pdf.

[15] https://stacks.cdc.gov/view/cdc/26885.

[16] https://www.cdc.gov/mmwr/preview/mmwrhtml/00046568.htm.

[17] https://www.cdc.gov/mmwr/preview/mmwrhtml/00020301.htm.

[18] https://www.cdc.gov/mmwr/preview/mmwrhtml/00020301.htm.

[19] https://stacks.cdc.gov/view/cdc/76570/cdc_76570_DS1.pdf.

[20] https://stacks.cdc.gov/view/cdc/76570/cdc_76570_DS1.pdf.

[21] https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm.

[22] https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm.

[23] https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm.

[24] https://www.cdc.gov/mmwr/preview/mmwrhtml/00048084.htm.

[25] https://www.cdc.gov/mmwr/preview/mmwrhtml/00048084.htm.

[26] https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm.

[27] https://www.cdc.gov/mmwr/PDF/rr/rr4607.pdf.

[28] https://www.cdc.gov/mmwr/PDF/rr/rr4607.pdf.

[29] https://stacks.cdc.gov/view/cdc/76558.

[30] https://stacks.cdc.gov/view/cdc/76558.

[31] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5126a5.htm.

[32] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5126a5.htm.

Boostrix (GSK)	2005[33]	2005[34]	24 days
Adacel (Sanofi)	2005[35]	2005[36]	20 days
Menactra (Sanofi)	2005[37]	2005[38]	27 days
Gardasil (Merck)	2006[39]	2006[40]	21 days
Hiberix (GSK)	2009[41]	2009[42]	30 days
Prevnar 13 (Pfizer)	2010[43]	2010[44]	0 days
Menveo (GSK)	2010[45]	2010[46]	19 days
Gardisil-9	2014[47]	2015[48]	78 days
MenQuadfi (Sanofi)	2020[49]	2020[50]	62 days
Vaxneuvance (Merck)	2022[51]	2022[52]	5 days
Priorix (GSK)	2022[53]	2022[54]	17 days
Prevnar 20 (Pfizer)	2023[55]	2023[56]	56 days

[33] https://cdc.gov/mmwr/preview/mmwrhtml/rr5517a1.htm.

[34] https://cdc.gov/mmwr/preview/mmwrhtml/rr5517a1.htm.

[35] https://archive.cdc.gov/www_cdc_gov/media/pressrel/r051109.htm.

[36] https://archive.cdc.gov/www_cdc_gov/media/pressrel/r051109.htm.

[37] https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm.

[38] https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm.

[39] https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.htm.

[40] https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.htm.

[41] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5836a5.htm.

[42] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5836a5.htm.

[43] https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm.

[44] https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm.

[45] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a5.htm.

[46] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a5.htm.

[47] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a3.htm.

[48] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a3.htm.

[49] https://www.cdc.gov/acip/grade/mening-MenACWY-TT.html.

[50] https://www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

[51] https://www.cdc.gov/mmwr/volumes/71/wr/mm7137a3.htm.

[52] https://www.cdc.gov/mmwr/volumes/71/wr/mm7137a3.htm.

[53] https://www.cdc.gov/mmwr/volumes/71/wr/mm7146a1.htm.

[54] https://www.cdc.gov/mmwr/volumes/71/wr/mm7146a1.htm.

[55] https://www.cdc.gov/mmwr/volumes/72/wr/mm7239a5.htm.

[56] https://www.cdc.gov/mmwr/volumes/72/wr/mm7239a5.htm.

SLIDES 15-18: CONTROLS; SAFETY DURATIONS; STATISTICAL POWER

When our law firm seeks to establish causation between a vaccine product and a claimed injury, the primary source for proving such claims is the data from clinical trials for that product. This is because most of the studies conducted *after* licensure are retrospective epidemiological studies which are not deemed reliable for supporting causation. Hence, obtaining and reviewing the clinical trial data for each vaccine has been an important part of our legal work.

Clinical trials are also critical for assuring safety, especially for vaccines. This is because after a vaccine is licensed, many consider it unethical to conduct a placebo-controlled trial and without a proper trial, determining causation between a vaccine and a claimed adverse event is extremely difficult.

The control group in clinical trials for a new drug will often receive a placebo. As defined by the CDC and FDA, a placebo is, "[a] substance or treatment that has no effect on living beings" and an "inert substance," respectively.[57] The importance of a placebo control group is explained by the NIH as follows: "In undertaking a clinical trial, researchers … want to be as certain as possible that the results of the testing show whether or not a treatment is safe and effective. The 'gold standard' for testing interventions in people is the 'randomized, placebo-controlled' clinical trial. ... A placebo is an inactive substance that looks like the drug or treatment being tested."

How well the "pivotal trial" (the trial FDA relies upon to license a vaccine) can determine safety depends on, among other factors, (i) the duration that safety is reviewed in the trial, (ii) the number of participants in the trial, and (iii) the use of a valid control, which should be a placebo or another vaccine for the same disease that has already been licensed based on a trial that properly assessed safety. Each of these factors is essential because:

- If the control group receives a control whose safety has not been established in its own clinical trial, the control cannot be relied upon to provide a baseline of what is "safe."

- If the duration for which safety is reviewed is limited, the trial will miss safety issues that arise after the time for which safety is reviewed.

- If there are not enough participants, *i.e.* it is not sufficiently powered, it will not detect safety issues that occur at a rate not detectible at the lower level of power.

The following is a list of every stand-alone routine vaccine on the CDC's childhood vaccine schedule and a short discussion regarding the pivotal trial FDA relied upon to license each, with citation to the FDA sources:

- Hep B vaccine (CDC schedule: birth, 1 month, and 6 months)

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[57] https://www.cdc.gov/vaccines/glossary/?CDC_AAref_Val=https://www.cdc.gov/vaccines/terms/glossary.html#heading-p; https://www.fda.gov/media/130326/download.

- **Recombivax HB (Merck)**: licensed for babies based on trials with no placebo control and 5 days of safety monitoring after injection.[58]
- **Engerix B (GSK)**: licensed for babies based on trials with no placebo control and 4 days of safety monitoring after injection.[59]

- DTaP vaccine (CDC schedule: 2, 4, 6, and 15 months, and 4 years)
  - **Infanrix (GSK)**: licensed for babies based on trials with no placebo control (DTP vaccine used as a control) and up to 30 days of safety review after injection.[60] DTP, used as the control was not licensed in a placebo-controlled trial and DTP has, in most studies looking at this issue, repeatedly been found to increase mortality in infants, meaning DTP-vaccinated infants die at far higher rates than their equally situated non-vaccinated peers.[61]
  - **Daptacel (Sanofi)**: licensed for babies based on trials with no placebo control (DT or DTP vaccine used as control) and 2 months of safety review after injection, except one trial which had 6 months of safety review, no control, and 1,454 children. In that trial, "[w]ithin 30 days following any dose of DAPTACEL, 57 (3.9%) subjects reported at least one serious adverse event."[62] *See* Infanrix bullet point regarding DTP.
- PCV vaccine (CDC schedule: 2, 4, 6, and 12 months)
  - **Prevnar 13, PCV-13 (Wyeth, part of Pfizer)**: licensed for babies based on trials with no placebo control (Prevnar 7 used as a control, which was licensed based on a trial in which the control was an "Investigational meningococcal group C conjugate vaccine," meaning another experimental vaccine) and 6 months of safety review after injection which found, "[s]erious adverse events reported following vaccination in infants and toddlers occurred in 8.2% among Prevnar 13 recipients and 7.2% among Prevnar recipients."[63]
  - **Vaxneuvance PCV-15 (Merck)**: licensed for babies based on trials with no placebo control (Prevnar 13 used as the control) and up to 6 months of safety review after injection finding that, "[a]mong children who received VAXNEUVANCE (N=3,349) or Prevnar 13 (N=1,814) … serious adverse events up to 6 months following vaccination with the 4-dose series were reported by 9.6% of VAXNEUVANCE recipients and by 8.9% of Prevnar 13 recipients." Deemed "safe" because, "[t]here were no notable patterns or numerical imbalances between vaccination groups."[64]
  - **Prevnar 20, PCV-20 (Pfizer)**: licensed for babies based on trials with no placebo control (Prevnar 13 used as the control), up to 6 months of safety review after injection, and that showed high rates of serious events (this time broken up into two categories – "serious adverse events" and "newly diagnosed chronic medical

[58] *See* Section 6.1 at https://www.fda.gov/media/74274/download.

[59] *See* Section 6.1 at https://www.fda.gov/media/119403/download.

[60] *See* Section 6.1 at https://www.fda.gov/media/75157/download.

[61] https://icandecide.org/wp-content/uploads/2021/06/2021.01.28-Letter-to-Special-Rapporteur-on-Poverty.pdf.

[62] *See* Section 6.1 at https://www.fda.gov/media/74035/download; https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event.

[63] *See* Section 6.1 at https://www.fda.gov/media/107657/download; https://www.fda.gov/media/76076/download.

[64] *See* Section 6.1 at https://www.fda.gov/media/150819/download.

conditions") in both vaccine groups (experimental and control) but deemed "safe" because "no notable patterns or imbalances between vaccine groups."[65] Meaning, PCV-20 was licensed based on a clinical in which PCV-15 was the control, PCV-15 was licensed based on a clinical trial in which PCV-13 was the control, PCV-13 was licensed based on a clinical trial in which PCV-7 was the control, and PCV-7 was licensed based on a clinical trial in which another experimental, unlicensed vaccine was the control, and in each of these trials the serious adverse events in both the control and experimental groups were similar which was sufficient for a finding of "safe" for licensure by the FDA.

- Polio vaccine (CDC schedule: 2, 4, and 6 months, and 4 years)
    - **IPOL (Sanofi)**: licensed in 1990 for babies based on trials with no placebo control and 3 days of safety review after injection. Sanofi reports that, "Although no causal relationship has been established, deaths have occurred in temporal association after vaccination of infants with IPV."[66] (Note that IPOL is a different product than the polio vaccine developed by Jonas Salk in the 1950s, which was discontinued in the 1960s, including because it is "grown in vero cells, a continuous line of monkey kidney cells cultivated on microcarriers." Hence, the Salk vaccine's safety or efficacy was not relied upon to license IPOL.[67])
- Hib vaccine (CDC schedule: 2, 4, 6, and 12 months)
    - **ActHIB (Sanofi)**: licensed for babies based on trials with no placebo control (Hepatitis B vaccine used as control) and 30 days of safety review after injection during which 3.4% experienced a serious adverse event but "[n]one was assessed by the investigators [Sonafi] as related to the study of vaccines."[68]
    - **Hiberix (GSK)**: licensed for babies based on trials with no placebo control (unlicensed Hib vaccines and HibTITER used as the control) and 31 days of safety review after injection.[69]
    - **Liquid PedvaxHIB (Merck)**: licensed for babies based on trials with no placebo control (Lyophilized PedvaxHIB used a control) and 3 days of safety review after injection.[70] (Note that Lyophilized PedvaxHIB was tested in a trial in which the control group was given placebo, OPV, and DTP but there is no indication Lyophilized PedvaxHIB was ever licensed.[71])

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[65] *See* Section 6.1 at https://www.fda.gov/media/149987/download; https://www.fda.gov/media/150459/download?attachment.

[66] *See* pages 14-17 at https://www.fda.gov/media/75695/download.

[67] *See* pages 1 at https://www.fda.gov/media/75695/download; https://pubmed.ncbi.nlm.nih.gov/6740101/; https://admin.phe-culturecollections.org.uk/media/122249/vero-cell-line-profile.pdf; https://www.atcc.org/products/all/ccl-81.aspx#characteristics.

[68] *See* Section 6.1 at https://www.fda.gov/media/74395/download; *see* page 8 at http://wayback.archive-it.org/7993/20170723144656/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM244597.pdf.

[69] *See* Section 6.1 at https://www.fda.gov/media/77017/download; *see* pages 20-21 at http://wayback.archive-it.org/7993/20170722072902/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182550.pdf.

[70] *See* page 6-8 at https://www.fda.gov/media/80438/download.

[71] *See* page 6-8 at https://www.fda.gov/media/80438/download.

- Rotavirus vaccine (CDC schedule: 2, 4, and 6 months) (Note that every vaccine on the CDC childhood schedule is given via injection, except for one flu vaccine given by nasal spray and the rotavirus vaccines, which are given by oral drops in the mouth.)
    - **Rotarix (GSK)**: licensed for babies based on trials without a placebo control (the control group received an oral drop that included Dextran, Sorbitol, Amino Acids, Dulbecco's Modified Eagle Medium, and Xanthan) and 31 days of safety review after oral dose and up to a year in some trials to watch for cases of intussusception. There were more deaths in the group receiving Rotarix than the control group. "During the entire course of 8 clinical studies (Studies 1 to 8), there were 68 (0.19%) deaths following administration of ROTARIX (n = 36,755) and 50 (0.15%) deaths following placebo administration (n = 34,454). The most commonly reported cause of death following vaccination was pneumonia, which was observed in 19 (0.05%) recipients of ROTARIX and 10 (0.03%) placebo recipients (RR: 1.74, 95% CI: 0.76, 4.23)."[72]
    - **RotaTeq (Merck)**: licensed for babies based on trials without a placebo control (the control group received an oral drop that included Polysorbate-80, Tissue Culture Medium, Fetal Bovine Serum, and Sodium Phosphate) and 42 days of safety review after each oral dose and up to a year to watch for cases of intussusception.[73]
- Flu vaccine (CDC schedule: 6 and 7 months and then annually)
    - The formulation for each influenza vaccine changes annually and there is no clinical trial carried out for each new formulation. In any event, none of the clinical trials for the original formulation of any injected influenza vaccine for children had a placebo control group. In 1980, FDA licensed Fluzone (IIV3) without assessing its safety against a placebo control.[74] Nonetheless, Fluzone (IIV3) was used as the control in the trials relied upon to license Afluria (IIV3) in 2007 and Fluzone (IIV4) in 2013 for children.[75] Then, Fluzone (IIV4), Fluarix (IIV3), or Havrix were used as the controls in the clinical trials supporting the licensure of FluLaval (IIV4).[76] The safety of these products therefore rests on the safety of Fluzone (IIV3) which was licensed for pediatric use based on a trial without any control, let alone a placebo control.[77] Similarly, Fluarix (IIV4) was licensed for children in 2012 based

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[72] *See* Section 6.1 at https://www.fda.gov/media/163009/download (claims used a placebo); *see* pages 23-24 at http://wayback.archive-it.org/7993/20170722073219/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133580.pdf (explains "placebo" included all the foregoing ingredients).

[73] *See* Section 6.1 at https://www.fda.gov/media/75718/download (claims used placebo); *see* page 445 et al. at https://icandecide.org/wp-content/uploads/2023/06/rotateq_placebo.pdf.

(explains the "placebo" included all the foregoing ingredients).

[74] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619664.pdf; (Researchers did conduct one efficacy trial for Fluzone (IIV3) long *after* it was licensed which found that "the rate of hospitalization was actually higher in the vaccine group than in the placebo group" with 60% more vaccinated than unvaccinated children being hospitalized for insertion of ear draining tubes. https://www.ncbi.nlm.nih.gov/pubmed/14506120).

[75] https://www.fda.gov/media/81559/download (placebo control only used in adult trials but never in trials to license this vaccine for children); https://www.fda.gov/media/119856/download.

[76] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619548.pdf.

[77] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619664.pdf.

on a trial using Prevnar 13, Havrix and/or Varivax as controls; Fluarix (IIV4) was then used as the control to license Afluria (IIV4) in 2016.[78] This means Afluria (IIV4) was licensed because it was deemed as safe as Fluarix (IIV4), and that vaccine was licensed because it was deemed as safe as Prevnar 13, Havrix, or Varivax. However, the latter two were licensed without a placebo control; and Prevnar 13 was licensed because it was as safe as Prevnar, but that vaccine was only licensed because it was as safe as "an investigational meningococcal group C conjugate vaccine." Hence, none of those vaccines had its safety profile established based on any placebo-controlled clinical trial. The only exception is one inhaled influenza vaccine whose original trial had a placebo, but its formulation changes every year and is not safety tested in any trial.[79]

- The following chart includes each licensed trivalent (IIV3) and quadrivalent (IIV4) influenza vaccine:[80]

[78] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM220624.pdf (44% and 45% of the Fluarix (IIV4) and comparator vaccine group, respectively, reported an unsolicited adverse event within 28 days and 3.6% and 3.3%, respectively, reported a serious adverse reaction).

[79] https://www.fda.gov/media/160349/download?attachment; https://www.fda.gov/media/73706/downloads.

[80] Supporting references for each vaccine in the table: **Fluzone (IIV3)** (https://www.fda.gov/media/170019/download (As reflected in section 14.1, nineteen years after licensure a small efficacy, not safety, trial had a small group of children receiving a placebo which did not contribute to any safety finding for this product; ironically, had this trial been conducted pre-licensure, and relied upon for safety, it would have raised a serious safety issue since "the rate of hospitalization was actually higher in the vaccine group than in the placebo group" with 60% more vaccinated than unvaccinated children hospitalized for insertion of ear drainage tubes)); **Fluvirin (IIV3)** (https://www.fda.gov/media/75156/download); **Fluarix (IIV3)** (https://www.fda.gov/media/84804/download); **Flulaval (IIV3)** (https://www.fda.gov/media/74537/download); **Afluria (IIV3)** (https://www.fda.gov/media/81559/download (states placebo used in adult trials but not in trials for children); **Flucelvax (IIV3)** (https://www.fda.gov/media/85322/download); **Fluarix (IIV4)** (https://www.fda.gov/media/79278/download, states placebo used in adult trials but not in trials for children); **Flublok (IIV3)** (https://www.fda.gov/media/179778/download); **Fluzone (IIV4)** (https://www.fda.gov/media/170019/download); **FluLaval (IIV4)** (https://www.fda.gov/media/115785/download); **Afluria (IIV4)** (https://www.fda.gov/media/117022/download); **Flucelvax (IIV4)** (https://www.fda.gov/media/115862/download, states placebo used in adult trials but not in trials for children).

Initial U.S. Approval	Brand (Company)	Control	Placebo?
1980	Fluzone (IIV3) (Sanofi)	No control	**NO**
1988	Fluvirin (IIV3) (Seqirus)	No control	**NO**
2005	Fluarix (IIV3) (GSK)	Fluzone (IIV3)	**NO**
2006	Fluaval (IIV3) (GSK)	Fluzone (IIV3)	**NO**
2007	Afluria (IIV3) (Seqirus)	Fluzone (IIV3)	**NO**
2012	Flucelvax (IIV3) (Seqirus)	Fluvirin (IIV3)	**NO**
2012	Fluarix (IIV4) (GSK)	PCV13, Havrix, Varivax or unlicensed vaccine	**NO**
2013	Flublok (IIV3) (Sanofi)	No control	**NO**
2013	Fluzone (IIV4) (Sanofi)	Fluzone (IIV3) or unlicensed vaccines	**NO**
2013	FluLaval (IIV4) (GSK)	Fluzone (IIV4), Fluarix (IIV3) or Havrix	**NO**
2016	Afluria (IIV4) (Seqirus)	Fluzone (IIV4) or Fluarix (IIV4)	**NO**
2016	Flucelvax (IIV4) (Seqirus)	Afluria (IIV4), Menveo, or Menveo+Saline	**NO**

As reflected in this chart, the safety of many influenza vaccines rests on a trial that used Fluzone (IIV3) as a control or another vaccine that was licensed based on using Fluzone (IIV3) as a control. But Fluzone (IIV3) was licensed based on a small trial without any control. Researchers did conduct one efficacy (not safety) trial for Fluzone (IIV3) long *after* it was licensed which found that "the rate of hospitalization was actually higher in the vaccine group than in the placebo group" with 60% more vaccinated than unvaccinated children being hospitalized for insertion of ear drainage tubes.[81]

- MMR vaccine (CDC schedule: 12 months and 4 years)
  - **M-M-R-II (Merck)**: licensed based on a trial with a total of 834 children, no control group, and that reviewed safety for 42 days during which one-third of vaccinated participants developed gastrointestinal and a third respiratory issues.[82]

[81] https://pubmed.ncbi.nlm.nih.gov/14506120/.

[82] *See* clinical trial reports for M-M-R-II at https://www.sirillp.com/wp-content/uploads/2023/07/MMRII-FOIA.pdf. package insert; *see* package insert for M-M-R-II https://www.fda.gov/media/75191/download (The package insert for M-M-R-II does not list any pivotal trial as a basis for determining this product was safe for licensure, presumably because the trial relied upon to license this product could not establish it was safe for licensure.); *see* https://icandecide.org/wp-content/uploads/2023/08/MMR-I-clinical-trials-safety-tables.pdf (The original MMR's clinical trial was also underpowered, among other deficiencies, and showed a similarly high rate of gastrointestinal, respiratory and other issues, as compared to the small untreated control group. Also note that the original MMR was a different product that did not include millions of pieces of human DNA and cellular debris, as does M-M-R-II.). Because viruses multiply in cells, living cells are used to grow viruses for vaccine production, including the cultured cell lines of aborted fetuses. Two such cell lines are MRC-5 and WI-38, which are described by a company that sells them as follows: "The MRC-5 cell line was derived from normal lung tissue of a 14-week-old male embryo" and the "WI-38 cell line is the first human diploid cell line to be used in human vaccine preparation … [and] were isolated from the lung tissue of a 3-month-old, female, embryo." https://www.atcc.org/products/ccl-75; https://www.atcc.org/products/ccl-171. The ingredients of chickenpox, rubella, and hepatitis A vaccines each include cellular and DNA pieces from these fetal cell lines. The ingredient list for Varivax (chicken-pox) includes "MRC-5 human diploid cells including DNA & protein," for MMR-II (which includes rubella) includes "WI-38 human diploid lung fibroblasts," and for Havrix (hepatitis A) includes "MRC-5 cellular proteins." https://web.archive.org/web/20241120002123/https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/

- **Priorix (GSK)**: licensed based on trials with no placebo control (M-M-R-II used as the control) and 6 months of safety review after injection in which both vaccine groups had a high rate of serious adverse events (2.1% of Priorix group and 1.9% of M-M-R-II group), emergency room visits (10.1% of Priorix group and 10.4% of M-M-R-II group), and new onset of chronic diseases (e.g., autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, thrombocytopenia, and allergies) (3.4% of Priorix group and 3.7% of M-M-R-II group).[83]

- Varicella vaccine (CDC schedule: 12 months and 4 years)
  - **Varivax (Merck)**: licensed based on trials with no placebo control (the purported "placebo" was actually an injection of 45 mg of neomycin per milliliter) and 70 days of safety review after injection which included only one controlled trial of 956 children in which approximately half received Varivax and half received the injection of 45 mg of neomycin per milliliter, and there was one trial in which 32 children received Varivax and 29 children received nothing and then received Varivax eight weeks later; during this eight-week period, the Varivax group had double the rate of ear infection and a 50% increase in respiratory infection. As for serious adverse events, Merck did not consider any related to Varivax.[84]
- Hep A vaccine (CDC schedule: 12 and 18 months)
  - **Havrix (GSK)**: licensed based on trials with no placebo control (Engerix-B was used as a control) and 31 days of safety review after injection with a phone call follow-up at 6 months.[85] Note, as discussed above, Engerix-B was licensed for

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b/excipient-table-2.pdf. As for the quantity of human DNA in each vial, for Varivax, as the FDA explains: "human MRC-5 cells are the substrate upon which the Oka strain of varicella is grown. In the process of isolating virus from these cells, MRC-5 derived proteins and DNA are also obtained. The nearly 2 ug [2,000 nanograms] of unmodified mammalian DNA present in each dose of VARIVAX…" https://wayback.archive-it.org/7993/20170723031730/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142826.pdf. As for MMR-II, during Dr. Plotkin's deposition, I asked: "Isn't it true that MMR II contains approximately 150 nanograms cells substrate double-strand DNA and single-strand DNA per dose purposefully fragmented to approximately 215 base pairs in length?" Dr. Plotkin answered: "Yeah, that's probably correct, yes." https://icandecide.org/plotkintranscript/ at p. 328. *See* also https://soundchoice.org/wp-content/uploads/2021/01/epidemiologic-molecular-relationship-vaccine-manufacture-autism-prevalence.pdf; https://pubmed.ncbi.nlm.nih.gov/26103708/ (See Table 3, reflecting an average of 142 nanograms of single-stranded DNA and 35 nanograms of double-stranded DNA in the rubella vaccine component of each dose of MMR-II; and an average of 276 nanograms of single-stranded DNA and 35.74 nanograms of double-stranded DNA in each dose of Havrix). For DNA remaining in the final formulation, assuming pharma companies follow FDA's guidance, they would fragment "the DNA size to below approximately 200 base pairs." https://www.fda.gov/media/113760/download at pp.29-30. Doing the math, supposing only 100 nanograms of double-stranded DNA remain, and are broken down into 200 base pair fragments, this equals approximately 463 billion pieces of human DNA from an aborted fetal cell line in each vaccine dose; double that number for single-stranded DNA. https://www.technologynetworks.com/tn/tools/copynumbercalculator. In addition to the human DNA, there is also an unspecified amount of human cellular debris in each vaccine dose. *See also* https://thehighwire.com/ark-videos/aborted-fetal-tissue-in-vaccines/.

[83] *See* Section 6.1 at https://www.fda.gov/media/189623/download; *see* page 12 at https://pmc.ncbi.nlm.nih.gov/articles/instance/7192400/bin/piz010_suppl_supplementary_materials.docx.

[84] *See* Section 6.1 at https://www.fda.gov/media/76000/download; *see* page 2 at https://pubmed.ncbi.nlm.nih.gov/6325909/; *see* Varivax clinical reports at https://www.sirillp.com/wp-content/uploads/2023/07/Varivax-clinical-trials.pdf.

[85] *See* Section 6.1 at https://www.fda.gov/media/119388/download.

babies based on trials with no placebo control and 4 days of safety monitoring after injection.[86]

- **Vaqta (Merck)**: licensed based on trials with no placebo control (an injection of AAHS, an aluminum adjuvant, and thimerosal, a form of mercury, were used as a control) and up to 42 days of safety review after injection.[87] Note that no placebo control was used despite the fact the trials for Havrix and Vaqta occurred at roughly the same time when there was no licensed Hepatitis A vaccine yet licensed.

- Tdap vaccine (CDC schedule: 11 years)
  - **Adacel (Sanofi)**: licensed based on trials with no placebo control (Td, for adult use, was used as a control) and up to 6 months of safety review after injection.[88]
  - **Boostrix (GSK)**: licensed based on trials with no placebo control (DECAVAC or Adacel was used as a control) & up to 6 months of safety review after injection.[89]
- HPV vaccine (CDC schedule: 9 and 9 ½ years)
  - **Gardasil 9 (Merck)**: licensed based on trials in which safety was reviewed after injection for 1 month in five of the clinical trials, 6 months in a lot consistency trial, and 4 years in one trial of women aged 16 to 26 years. These Gardasil 9 trials were either not controlled or used Gardasil 4 as the control, except for one trial in which 306 participants received a placebo but only after receiving the full series of Gardasil 4 injections.[90] (Note that in Gardasil 4's clinical trial, controls received an aluminum adjuvant, AAHS, except 320 people labeled "Saline Placebo" who actually received all vaccine ingredients except antigens and AAHS; and across all these trials, 2-3% of participants receiving vaccine or aluminum adjuvant – a substance used to induce autoimmunity in lab animals – had a suspected autoimmune disorder.[91])
- Men4 vaccine (CDC schedule: 11 and 16 years)
  - **Menactra (Sanofi)**: licensed based on trials with no placebo control (Menomune used as the control) and up to 6 months of safety review after injection.[92] Note Menomune was licensed without a placebo-controlled trial; rather, the safety section of the package insert for Menomune lists the same trial used to license Menactra as the basis for the safety of Menomune despite the fact Menomune was used as a control in that trial.[93]

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[86] *See* Section 6.1 at https://www.fda.gov/media/119403/download.

[87] *See* Section 6.1 at https://www.fda.gov/media/74519/download (using term "placebo"); *see* clinical trial report at 454 https://www.nejm.org/doi/pdf/10.1056/NEJM199208133270702?articleTools=true (explains the purported "placebo" included the foregoing ingredients).

[88] *See* Section 6.1 at https://www.fda.gov/media/119862/download.

[89] *See* Section 6.1 at https://www.fda.gov/media/124002/download.

[90] See pages 17-19 at https://wayback.archive-it.org/7993/20190423065200/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM429166.pdf.

[91] *See* https://www.fda.gov/media/74350/download; https://pubmed.ncbi.nlm.nih.gov/27417999/.

[92] *See* Section 6.1 at https://www.fda.gov/media/75619/download.

[93] *See* https://archive.org/details/menomune-a-c-y-w-135-prescribing-information.

- **Menveo (GSK)**: licensed based on trials with no placebo control (Menactra, Boostrix, or other vaccines used as a control) and up to 6 months of safety review after injection.[94]
- **MenQuadfi (Sanofi)**: licensed based on trials with no placebo control (Menveo or other vaccines used as a control) and up to 6 months of safety review after injection.[95] Thus, Menomune was licensed without a placebo-controlled trial and was then used as the control to license Menactra; Menactra is then used as the control to license Menveo; and then Menveo is used as the control to license MenQuadfi.

For completeness, the following is a list of the stand-alone *non*-routine vaccines on the CDC's childhood vaccine schedule and a short discussion regarding the pivotal trial FDA relied upon to license each with citation to the FDA sources:

- COVID-19 vaccine (CDC schedule: 6, 7, and 10 months, and then annually.)
  - **Comirnaty (Pfizer)**: licensed only for children 12 years of age and older (not for babies) and had a placebo control (note that the placebo controls were vaccinated during the trial), 6 months of safety review after injection, and a total of 3,014 participants.[96] Note that Pfizer failed to report a serious injury in at least one child participant in its trial who received the vaccine.[97]
  - **Spikevax (Moderna)**: licensed only for children 12 years of age and older (not for babies) and had a placebo control (note that the placebo controls were vaccinated during the trial), 6 months of safety review after injection, and a total of 3,726 participants.[98]
- MenB vaccine (CDC schedule: 10 years and older if indicated)
  - **Bexsero (GSK)**: licensed based on trials in which controls were administered aluminum hydroxide and, in one trial with 120 adolescents, saline injection followed by injection of Menveo. FDA labels this an "active control," not a "placebo control" trial.[99]
  - **Trumenba (Pfizer)**: licensed based on trials with no placebo control group other than 12 people in a dose-ranging phase II study (otherwise the controls were injection of Gardasil+placebo, dTaP-IPV+placebo, HepA+placebo, or

[94] *See* Section 6.1 at https://www.fda.gov/media/78514/download.

[95] *See* Section 6.1 at https://www.fda.gov/media/137306/download.

[96] *See* Section 6.1 at https://www.fda.gov/media/151707/download?attachment.

[97] https://icandecide.org/wp-content/uploads/2023/07/3-08-2022-Ltr-to-Dr.-Paul-Richards-FDA-re-Maddie-de-Garay.pdf.

[98] https://www.fda.gov/media/155675/download.

[99] *See* pages 14-15 at https://wayback.archive-it.org/7993/20190425012223/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM434748.pdf; *see* page 40 at https://wayback.archive-it.org/7993/20190423064855/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM434714.pdf. *See* pages 14-15 at https://wayback.archive-it.org/7993/20190425012223/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM434748.pdf; *see* page 40 at https://wayback.archive-it.org/7993/20190423064855/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM434714.pdf.

Menactra+Adacel+placebo and 30 days of safety review after injection for one of the three trials and up to 11 months in the other two trials.[100]

- PPSV23 vaccine (2Y+ if indicated)
    - **Pneumovax 23 (Merck)**: licensed for children 2 years and older although there is no indication that there was any clinical trial involving anyone younger than 16 years of age that the FDA relied upon to license this vaccine.[101]
- Dengue vaccine (6Y+ if previously had dengue and live in area dengue is endemic)
    - **Dengvaxia (Sanofi)**: licensed based on a trial with 11,474 children receiving a placebo control (saline injection), over 35,000 children in the trial, and 5 years of safety review after injection. Meaning, the last listed vaccine on the CDC's childhood vaccine schedule is the only vaccine that underwent a longer-term placebo-controlled trial prior to licensure with a larger number of children.[102] Careful study of this vaccine revealed that children under 6 years old had an increased risk of severe harm and death from this vaccine and that children older than 6 who had never had dengue and received this vaccine likewise had a seriously increased risk of severe harm and death. Hence, this vaccine is only indicated for older children who have previously had dengue. "Those not previously infected are at increased risk for severe dengue disease when vaccinated and subsequently infected with dengue virus."[103] This vaccine is only recommended for children in endemic dengue areas and dengue is not endemic in the U.S.[104]

The FDA source material for each vaccine, as set forth above, reflects:

- None of the childhood vaccines recommended for routine use by the CDC were licensed based on a placebo-controlled trial nor on a trial where the vaccine used as a control was itself licensed based on a placebo-controlled trial. Rather, in each trial, there was either no control group or another vaccine or vaccine ingredient was used as a control, and none of those control vaccines were licensed based on a placebo-controlled trial.

- None of the childhood vaccines recommended for routine use by the CDC (save for one limited HPV trial) were licensed based on trials that had long-term safety follow-up after administration. Rather, safety was reviewed for a limited period, often no more than months, and often only days or weeks after administration.

- None of the childhood vaccines recommended for routine use by the CDC were licensed based on trials which were appropriate to assess whether the vaccine causes more harm

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[100] *See* page 4 at https://wayback.archive-it.org/7993/20190425012035/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM548305.pdf; *see* pages 9-10 at https://wayback.archive-it.org/7993/20190423065758/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM424626.pdf.

[101] See Sections 6.1 and 14.1 https://www.fda.gov/media/80547/download.

[102] *See* page 10 at https://www.fda.gov/media/125481/download; *see* page 4 at https://www.fda.gov/media/124379/download.

[103] https://www.fda.gov/media/124379/download.

[104] https://www.usgs.gov/faqs/what-constitutes-united-states-what-are-official-definitions.

than it prevents. This is because, as seen from the FDA source material, their pivotal trial typically had only hundreds or a few thousand children, severely limiting the power of these trials to assess safety and therefore, not sufficient to conclude, statistically, that the trialed products prevent more serious harms and deaths than they cause.

The FDA documentation reflects that, as the Secretary of Health and Human Services, Robert F. Kennedy Jr., has previously explained, none of the routine vaccines on the CDC childhood schedule (which does not include the dengue vaccine as it's not routine) underwent a long-term placebo-controlled trial, nor just a placebo-controlled trial (or even a trial where the vaccine used as a control was previously established as safe in a long-term placebo-controlled trial).

SLIDES 26-27: DTP VACCINE

DTP vaccine is the most widely used vaccine in the world. It was not licensed based on a placebo-controlled trial, and studies conducted in recent decades have found that DTP increases mortality. A landmark study on this issue was funded by the Ministry of Foreign Affairs of Denmark and the European Union and published in 2017.[105] After comparing children vaccinated with DTP to children that received no vaccines, it found that that DTP-vaccinated children were 10 times more likely to die in the first 6 months of life. The study therefore concluded:

> All currently available evidence suggests that DTP vaccine *may kill more children* from other causes than it saves from diphtheria, tetanus or pertussis.[106]

This study, and others, found that children vaccinated with DTP were dying from causes never associated with the vaccine, such as respiratory infections, diarrhea, and malaria.[107] This indicated that, while DTP reduced the incidence of diphtheria, tetanus, and pertussis, it increased susceptibility to other infections.[108]

A 2014 review of DTP and mortality by the WHO's Strategic Advisory Group of Experts (SAGE), identified 16 studies that compared death rates between children receiving DTP and children not receiving DTP, and found that a majority of the 16 studies indicated that DTP increases mortality.[109] SAGE discounted the studies showing DTP increases mortality on the basis that: (i) these studies were not "randomized" (*i.e.*, children were not randomly assigned to either receive or not receive DTP, potentially introducing bias); (ii) "OPV [Oral Polio Vaccine] was administered concomitantly with DTP in most included studies" and hence it "was not possible to separate any possible effects of DTP from OPV in the available studies"; and (iii) these studies were often

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[105] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).

[106] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).

[107] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).

[108] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).

[109] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).

conducted in communities with existing so-called "herd immunity" that could have introduced further bias.[110]

The 2017 study was designed to avoid these limitations stated by SAGE. It addressed the "randomized" issue by using data whereby vaccines were administered based on birthdates, an accepted form of randomization.[111] It addressed the "OPV with DTP" issue by comparing children receiving no vaccines with those receiving only DTP.[112] It addressed the "herd immunity" issue by looking at death rates at the time of the introduction of DTP in that region.[113] The result was the 2017 study discussed above. And because placebo-controlled trials of DTP are considered unethical, even though a placebo-controlled trial was never conducted to license this product, the 2017 study on DTP and morality is likely the best available evidence that will exist addressing whether DTP kills more children than it saves.

DTP policy has not, however, changed globally, even after another study published in 2018, which again did not have the limitations identified by SAGE in 2014, and which again found DTP increases mortality.[114] This time the study looked at children between 6 and 35 months of age. The 2018 study compared children receiving DTP, who were generally healthier and had better nutritional status, with children who did not receive DTP and who generally were unhealthier and had worse nutritional status. There, the children who did not receive DTP should have had worse health outcomes because they were generally unhealthier and had worse nutrition. The result:

> Although having better nutritional status and being protected against three infections, 6-35 months old DTP-vaccinated children tended to have higher mortality than DTP-unvaccinated children. All studies of the introduction of DTP have found increased overall mortality.[115]

A non-profit group contacted UNICEF, a primary distributor of DTP vaccine, regarding these studies, asking it to provide proof that the studies showing DTP increased mortality were incorrect. UNICEF asked CDC to help it respond to this request, but when CDC sent a proposed response to UNICEF, UNICEF asked CDC, "why we cannot prove or disprove this claim despite the fact that this issue has been followed since 2001."[116] The email exchange between CDC and UNICEF does not appear

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[110] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK). As an example of the necessity for utilizing randomization to avoid bias, unvaccinated children often do not receive vaccines because they are very frail, malnourished, or sick, and hence more likely to die irrespective of vaccination. Thus, the unvaccinated group is often sicker than the vaccinated group, making the vaccine appear safer. By randomly picking which children receive or do not receive the DTP vaccine, a researcher can avoid this type of bias.

[111] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).

[112] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).

[113] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).

[114] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5868131/pdf/fpubh-06-00079.pdf (https://perma.cc/7F7U-ZZWJ).

[115] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5868131/pdf/fpubh-06-00079.pdf (https://perma.cc/7F7U-ZZWJ).

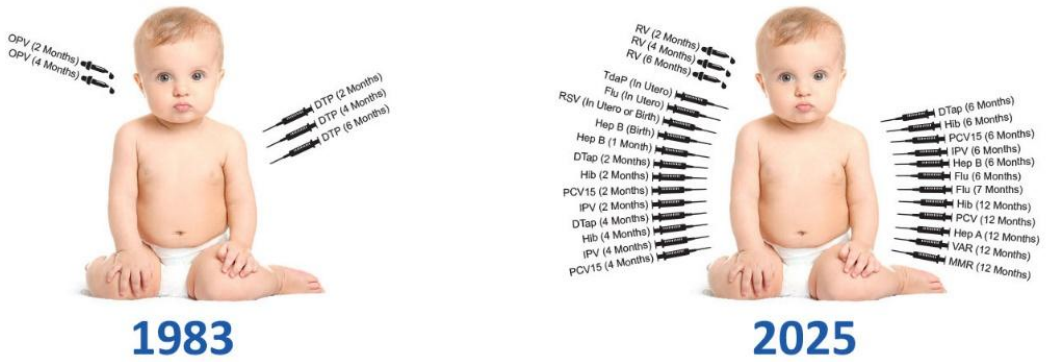
[116] https://icandecide.org/UNICEF-Emails.

to seriously consider the data or studies but, rather, appeared to view them as a public relations issue.

SLIDES 30: IMPACT OF IMMUNITY ON MARKET FORCES

Prior to 1986, when there were only 3 routine vaccines totaling 7 injections,[117] the financial liability related to injuries from these products resulted in companies exiting the market.[118] Instead of allowing economic interests to drive innovation of safer vaccine products, the National Childhood Vaccine Injury Act of 1986 (the "1986 Act") gave pharmaceutical companies immunity for vaccine injuries for those products *and* any routine childhood vaccine added to CDC's schedule thereafter.[119]

As of 2025, CDC's maternal and childhood schedules lists 19 vaccines totaling 84 injections, virtually all of which were licensed after 1986 by companies conducting clinical trials with the knowledge they would generally not be liable for any injuries caused by their vaccine products.[120] The following graphic reflects the routine vaccines, both injected and oral, an infant following the CDC's vaccine schedule would receive in utero and up to 12 months of age in 1986 versus 2025:



The following chart reflects all routine and shared clinical decision-making vaccines (COVID-19 and MenB vaccines) a child would receive in 1983 versus 2025:

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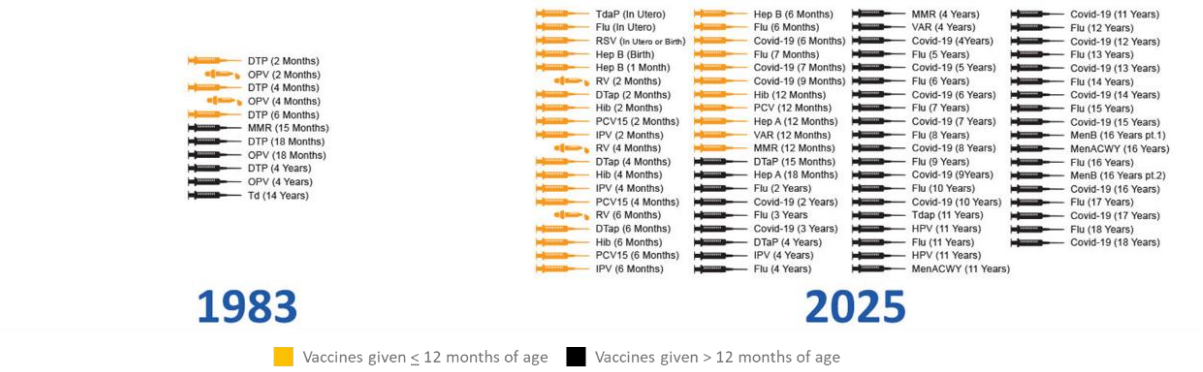
[117] https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg.

[118] *Bruesewitz v. Wyeth*, 562 U.S. 223 (2011) ("the remaining manufacturer [of DTP] estimated that its potential tort liability exceeded its annual sales by a factor of 200"); Institute of Medicine, *Adverse Events Associated with Childhood Vaccines*, at 2 (1994), https://pubmed.ncbi.nlm.nih.gov/25144097/ (By 1986, "litigation costs associated with claims of damage from vaccines had forced several companies to end their vaccine research and development programs as well as to stop producing already licensed vaccines.").

[119] 42 U.S.C. § 300aa-11 ("No person may bring a civil action for damages … against a vaccine administrator or manufacturer … for damages arising from a vaccine-related injury or death associated with the administration of a vaccine"); *Bruesewitz v. Wyeth*, 562 U.S. 223 (2011) ("[W]e hold that the National Childhood Vaccine Injury Act pre-empts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by a vaccine side effects.").

[120] https://www.cdc.gov/vaccines/parents/by-age/pregnancy.html; https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf (assumes each vaccine given individually and COVID-19 vaccine given annually).



Because companies remain liable for injuries caused by *drugs*, this provides an incentive to conduct long-term placebo-controlled trials to confirm the safety of drug products before licensure to avoid financial loss after licensure. For example, the following chart includes what are reported as the four most profitable drugs sold by Pfizer as of 2019, along with the control and safety duration in their licensure trial:

DRUG	SAFETY REVIEW	CONTROL
Eliquis	7.4 Years	Placebo
Enbrel	6.6 Years	Placebo
Lipitor	4.9 Years	Placebo
Lyrica	2 Years	Placebo

In contrast, for vaccine products, the economic incentive to assess safety prior to licensure was mostly eliminated by the 1986 Act.[121] This is because long-term placebo-controlled trials for vaccine products do not make financial sense for companies seeking to maximize profits. To the contrary, while assuring safety in drug trials is aligned with a company's economic interest, it is in conflict when it comes to vaccine trials. This provides context for the fact that, as seen in the prior section, every routine childhood vaccine recommended by the CDC was licensed without a placebo control; was monitored for safety after administration for typically six months or less, sometimes only days or weeks; and often had too few participants to detect safety signals.

Further, HHS and its agencies have a structural conflict with regard to vaccine safety. This is because HHS's responsibility to promote and defend vaccines conflicts with its safety duties.

Because duties to promote an industry inherently conflict with duties to identify and address safety issues within that industry, outside of vaccines, these duties are often separated into independent agencies. For example, DOT promotes transportation while safety functions are handled by the independent NTSB.[122] Similarly, DOE promotes nuclear power while safety functions are handled by the independent NRC.[123] But with vaccines, these conflicting duties are handled by the same entity: HHS.

[121] 42 U.S.C. §§ 300aa-1 through 300aa-34.

[122] https://www.ntsb.gov/about/history/pages/default.aspx.

[123] https://www.nrc.gov/about-nrc/history.html; https://www.energy.gov/ne/office-nuclear-energy.

Moreover, HHS is statutorily required to and does vigorously defend against vaccine injury claims. Under the 1986 Act, one can bring a claim for a vaccine injury, but it is brought against the Secretary of HHS in the Vaccine Injury Compensation Program ("VICP"). This further conflicts HHS, including because any safety issues identified can be used against HHS in the VICP.[124] Vaccines are the only consumer product I am aware of where the government defends industry interests against consumers, instead of vice-versa.

These structural conflicts in regulating vaccines can result in regulators viewing and conducting themselves as partners with pharmaceutical companies rather than as regulators. Moreover, once federal regulators have heavily promoted vaccine products, something they do not do with drug products, later admitting they cause harms could result in a loss of public confidence in HHS, the FDA, and the CDC and its vaccine schedule. It could also result in liability to HHS where it would need to pay out damages as the respondent to claims in the VICP and the Countermeasures Injury Compensation Program ("CICP"). These create intractable and concerning structural conflicts with regard to HHS addressing vaccine safety.

SLIDES 34-37: IOM REPORTS

The degree of thoroughness of the post-licensure vaccine safety literature can be seen from IOM reviews on vaccine safety paid for by HHS, CDC, and/or other federal health agencies.

In 1991, at HHS's request per the 1986 Act, the IOM issued a report that evaluated 22 reported serious injuries from pertussis and rubella vaccines.[125] The IOM located sufficient science to support that 6 serious injuries are causally related to these vaccines, including acute encephalopathy (brain damage) and chronic arthritis.[126] The IOM, however, found that studies had not been conducted in order for it to conclude whether or not these vaccines caused 12 other commonly reported serious injuries, including:

> Autism, Aseptic Meningitis, Chronic Neurological Damage, Guillain-Barre Syndrome, Juvenile Diabetes, Learning Disabilities, Attention-Deficit Disorder, Thrombocytopenia[127]

In 1994, again at HHS's request per the 1986 Act, the IOM evaluated 54 commonly reported serious injuries and vaccines for diphtheria, tetanus, measles, mumps, polio, hep B, and Hib.[128]

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[124] 42 U.S.C. § 300aa-12 ("In all proceedings brought by the filing of a petition [in VICP] the Secretary [of HHS] shall be named as the respondent."); https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf ("DOJ attorneys make full use of the apparently limitless resources available to them," "pursued aggressive defenses in compensation cases," "establish[ed] a cadre of attorneys specializing in vaccine injury" and "an expert witness program to challenge claims."); https://uscfc.uscourts.gov/vaccine-programoffice-special-masters.

[125] https://nap.nationalacademies.org/read/1815/chapter/1.

[126] https://nap.nationalacademies.org/read/1815/chapter/2#7.

[127] https://nap.nationalacademies.org/read/1815/chapter/2#7.

[128] https://www.nap.edu/read/2138/chapter/2#12.

The IOM located sufficient science to support that 12 serious injuries are causally related to these vaccines, including death, thrombocytopenia, and GBS.[129] The IOM, however, found that studies had not been conducted in order for it to conclude whether or not these vaccines caused 38 other commonly reported serious injuries, including:

> Arthritis, Aseptic Meningitis, Demyelinating diseases of the central nervous system, Insulin-Dependent Diabetes Mellitus, Myelitis, Neuropathy, Residual Seizure Disorder, Sensorineural Deafness, Sudden Infant Death Syndrome, Sterility, Transverse Optic Neuritis[130]

The IOM explained: "The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meetings indicated that many parents and physicians share this concern."[131]

Fifteen years later, in 2012, the CDC and HRSA, paid the IOM to review what they stated were the 158 most common injuries claimed to be caused by various childhood vaccines.[132] The IOM located science to support that 18 serious injuries were causally related to these vaccines, including pneumonia, meningitis, MIBE, and febrile seizures.[133] The IOM, however, found that studies had not been conducted in order for it to conclude whether or not these vaccines caused 135 other commonly reported serious injuries, including:

> Acute Disseminated Encephalomyelitis, Afebrile Seizures, Amyotrophic Lateral Sclerosis, Arthralgia, Autoimmune Hepatitis, Brachial Neuritis, Cerebellar Ataxia, Chronic Headache, Chronic Inflammatory Demyelinating Poly-neuropathy, Chronic Urticaria, Encephalitis, Encephalopathy, Erythema Nodosum, Fibromyalgia, Guillain-Barré Syndrome, Hearing Loss, Immune Thrombocytopenic Purpura, Infantile Spasms, Juvenile Idiopathic Arthritis, Multiple Sclerosis, Neuromyelitis Optica, Optic Neuritis, Polyarteritis Nodosa, Psoriatic Arthritis, Reactive Arthritis, Rheumatoid Arthritis, Seizures, Small Fiber Neuropathy, Stroke, Sudden Infant Death Syndrome, Systemic Lupus Erythematosus, Thrombocytopenia, Transverse Myelitis[134]

This means that even among the 158 serious injuries that the CDC and HRSA (an agency which defends against vaccine injury claims) identified as the most commonly claimed injuries from

[129] https://www.nap.edu/read/2138/chapter/2#12.

[130] https://www.nap.edu/read/2138/chapter/2#12.

[131] https://www.nap.edu/read/2138/chapter/12.

[132] https://www.nap.edu/read/2138/chapter/12.

[133] https://www.nap.edu/read/13164/chapter/2#3.

[134] https://www.nap.edu/read/13164/chapter/2#3.

vaccines, the CDC nor the greater scientific community have conducted the studies necessary to rule out vaccines as a cause for over 86% of these commonly claimed vaccine harms. [135]

In addition to these IOM reports, HHS has also relied upon what it has asserted is "the most comprehensive review" of the literature on vaccine safety ever conducted—a 740-page vaccine safety report from 2014 by AHRQ—to claim that routine childhood vaccines are safe.[136]

This 2014 report begins by identifying 20,478 studies as related or potentially related to vaccine safety and excludes 20,312 of them for various reasons including that they did not address vaccine safety, or had an unacceptable design.[137] After this weeding out process, AHRQ was left with only 166 studies it deemed relevant and potentially reliable for assessing vaccine safety, and only 97 of those involved children.

Hence, AHRQ, in what HHS said is "the most comprehensive review" of the literature on vaccine safety, found there were only 97 studies ever conducted that it deemed potentially reliable to assess the safety of childhood vaccines given to babies and children in the United States. This initial list did *not* mean these 97 studies supported that one or more vaccines were safe, that was just the initial universe of studies AHRQ said it identified to *potentially* answer that question.

These 97 studies were virtually all funded and/or authored (usually both) by a pharmaceutical company reviewing its own vaccine.[138] AHRQ excluded all individual case reports (usually instances of immediate and obvious vaccine injuries) despite the fact that practitioners can typically afford to publish only in this form.[139] It excluded all experimental studies which could explain the biological mechanisms of how vaccines can cause injury or death, such as studies on how vaccines or aluminum adjuvants can cause immune system dysregulation.[140] It also excluded animal studies which – because of ethical restrictions applicable to human research – often provide the scientific evidence of how vaccines can cause harm.[141]

The result is that this "comprehensive review" included only 97 studies that are applicable to children,[142] 77 of which were directly funded and/or authored (typically both) by the very pharma company whose vaccine(s) the study reviews.[143] As for the remaining 20 studies, almost all were

[135] https://www.nap.edu/read/13164/chapter/2#3.

[136] https://www.ncbi.nlm.nih.gov/books/NBK230053/; https://archive.org/details/hhs-response-1.

[137] *Id.*

[138] *Id.*

[139] *Id.*

[140] *Id.*

[141] *Id.* (AHRQ also excluded studies using VAERS, one of the few resources available to study vaccine safety without pharma type funding).

[142] Excluding two studies it double counted.

[143] https://www.ncbi.nlm.nih.gov/books/NBK230053/.

funded and/or authored by agencies and/or individuals that directly or indirectly receive funding from the pharma company whose vaccine(s) the study reviews.[144]

AHRQ then further cut down these 97 studies, explaining that comparing vaccinated (exposed) and unvaccinated (unexposed) children is critical for evaluating vaccine safety and asserts that only 59 of these studies compared "vaccinated versus unvaccinated children or adolescents."[145]

As for the 59 studies that AHRQ claims compared "vaccinated versus unvaccinated children or adolescents," the following is a breakdown of these studies by vaccine type: rotavirus (34 studies), HPV (13 studies), influenza (6 studies), Hib (3 studies), meningococcal (2 studies), and varicella (1 study). [146] Note that only 20 of these 59 studies involve an injected vaccine; the remainder involve rotavirus which is given orally and two of the influenza studies involve inhaled strains.[147]

Hence, among these 59 studies, there are no studies for the following seven vaccines: Hep B, DTaP, PCV, IPV, MMR, Hep A, or Tdap. These seven vaccines constitute a majority of the routine childhood vaccines, including four vaccines injected three times each in the first six months of life—Hep B, DTaP, PCV, and IPV.

This means that the "most comprehensive review" of the literature on vaccine safety, according to HHS, did not identify any study meeting its own criteria of reliability for a majority of the routine vaccines on CDC's childhood schedule.

As for the 59 studies AHRQ did identify for six different vaccines, AHRQ's claim that they each had an unvaccinated group is inaccurate. This is because in almost all the studies involving an injected vaccine, the control group was vaccinated or injected with one or more active vaccine ingredients.

For example, in the three Hib studies that AHRQ labeled as "vaccinated versus unvaccinated children or adolescents," the "control group" were all vaccinated. By way of example, one of these studies reviewed the Hib-PHiD vaccine made by GSK in a study funded by GSK and authored by GSK employees which, incidentally, is not a U.S. vaccine. It compared 199 infants who received Hib-PHiD, DTPa, HBV, IPV, and Hib (the experimental group) with 101 infants who received DTPa, HBV, IPV, and Hib (the control group which AHRQ labeled "unvaccinated").[148] Labeling this a "vaccinated versus unvaccinated" study is not accurate. It is noteworthy that approximately 5% of infants in each group reported a serious adverse event, yet because the rates were similar in

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[144] *Id.*

[145] *Id.*

[146] *Id.*

[147] The 34 rotavirus studies that AHRQ claims compare "vaccinated with unvaccinated children" compared children receiving oral drops of rotavirus with children receiving oral drops of the following vaccine ingredients: Polysorbate 80, Citrate, Phosphate, Dextran, Sorbitol, Amino acids, Dulbecco's Modified Eagle Medium, Calcium Carbonate, and/or Xanthan. See Chapter 10. The two studies involving LAIV, an inhaled influenza vaccine, involved a pharma company reviewing its own product: one involved 20 immunocompromised children with cancer in which 10 received LAIV and 10 received a placebo, https://pubmed.ncbi.nlm.nih.gov/21496468/ (https://perma.cc/8MP9-EHHT), and the other compared 261 children who received LAIV with 65 children who first received placebo and were then offered LAIV after 28 days, https://pubmed.ncbi.nlm.nih.gov/21060780/ (https://perma.cc/7L2Y-PW9V).

[148] https://pubmed.ncbi.nlm.nih.gov/23432812/ (https://perma.cc/7HDW-4XFY).

each group, the vaccine was deemed "safe" by the GSK employees studying a GSK vaccine in a GSK-funded study.[149]

Using one final example, in all 13 studies involving HPV vaccine that AHRQ labels "vaccinated versus unvaccinated adolescents," the "unvaccinated" group either received a vaccine *or* an injection of an adjuvant in the HPV vaccine, AAHS (save one study in which 17 girls apparently received nothing).[150] HPV vaccines were studied in adolescents and older women who, unlike children or babies, can articulate if they are experiencing a serious adverse reaction, such as neurological issues. In most of these studies, the rate of serious adverse event reports in both groups (the vaccinated group and the fake "unvaccinated" group) were, in some instances, in the double digits. The vaccine was deemed "safe" in these GSK- or Merck-funded studies using their own employees reviewing their own vaccine because the rate of harm was similar in both groups.[151]

For context, and reflecting a bias that may have driven this review, AHRQ's "comprehensive review" began by expressing concern that "vaccination rates remain well below established Healthy People 2020 targets for many vaccines" and that "[i]ncreasing vaccination rates remains critically important."[152] It laments that "public concerns about vaccine safety continue to persist" despite "the rigorous processes new vaccines must undergo before receiving approval" and that they meet "stringent criteria for safety."[153] It is unclear whether the authors of this review reviewed the clinical trials relied upon to license childhood vaccines.

It is also noteworthy that, despite only accepting a limited number of studies as reliable, it did find support for one or more childhood vaccines causing: febrile seizures, arthralgia, thrombocytopenic purpura, meningitis, and encephalitis.[154]

SLIDES 39-44: INJURY CLAIMED TO HAVE BEEN MOST THOROUGLY STUDIED

These slides discuss autism because is it is the adverse event claimed to have been the most thoroughly studied in relation to vaccines and hence provides a good indication of how well other adverse events have been studied.

While autism was relatively uncommon in the early 1980s, it was a serious enough concern that in the 1986 Act, Congress required that the federal health authorities review the scientific literature regarding whether there is a connection between pertussis-containing vaccines and autism. As provided in the 1986 Act: "the Secretary of Health and Human Services shall complete a review of all relevant medical and scientific information … on the nature, circumstances, and extent of

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[149] https://pubmed.ncbi.nlm.nih.gov/23432812/ (https://perma.cc/7HDW-4XFY); https://www.icandecide.org/wp-content/uploads/2019/09/ICAN-Reply-1.pdf at pp. 36-42 (https://perma.cc/LX4V-LDVP).

[150] https://www.icandecide.org/wp-content/uploads/2019/09/ICAN-Reply-1.pdf at pp. 36-42 (https://perma.cc/LX4V-LDVP).

[151] *Id.*

[152] *Id.*

[153] *Id.*

[154] *Id.*

the relationship, if any, between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and … Autism."[155]

HHS in turn commissioned the IOM to conduct this review. When that review was published in 1991, the IOM explained that it could not identify any study to support the claim that pertussis vaccines do not cause autism. As explained by the IOM: "No data were identified that address the question of a relation between vaccination with DPT or its pertussis component and autism."[156]

The IOM committee included the following warning in its 1991 report:

> In the course of its review, the committee found many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines. … If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped.[157]

Two decades later, in 2012, the IOM issued another report on vaccine safety, this time commissioned by the CDC and HRSA, which again assessed the evidence bearing on whether pertussis vaccines, including DTaP, cause autism. It did so because, according to HRSA, autism remained one of the most commonly claimed injuries from this vaccine.[158] This time, the request to the IOM also included reviewing whether tetanus and diphtheria vaccines can cause autism.

The IOM again convened a committee composed of individuals with expertise in pediatrics, internal medicine, neurology, immunology, immunotoxicology, neurobiology, rheumatology, epidemiology, biostatistics, and law to answer these questions.[159]

As in 1991, the IOM again was unable to locate a study supporting the claim that DTaP does not cause autism. The IOM concluded in its 2012 report: "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism."[160]

The following is the IOM's full explanation for this finding in its 2012 report:

> **AUTISM**
> **Epidemiologic Evidence**
>
> The committee reviewed one study to evaluate the risk of autism after the administration of DTaP vaccine. This one study (Geier and Geier, 2004) was not considered in the weight of epidemiologic

[155] https://nap.nationalacademies.org/read/12796/chapter/12#268.

[156] https://www.nap.edu/read/1815/chapter/1#v.

[157] https://www.nap.edu/read/1815/chapter/9.

[158] https://www.nap.edu/read/13164/chapter/2#2.

[159] https://www.nap.edu/read/13164/chapter/1#v.

[160] https://www.nap.edu/read/13164/chapter/12#545.

evidence because it provided data from a passive surveillance system and lacked an unvaccinated comparison population.

Weight of Epidemiologic Evidence

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism.

Mechanistic Evidence

The committee did not identify literature reporting clinical, diagnostic, or experimental evidence of autism after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens alone or in combination.

Weight of Mechanistic Evidence

The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism as lacking.

Causality Conclusion

Conclusion 10.6: The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism.

The single study the IOM could locate regarding whether DTaP causes autism (Geier and Geier, 2004) concluded that there was an association between DTaP and autism.[161] The IOM gave this study no weight because it was based on VAERS reports.

The 2012 report from the IOM also looked at whether MMR vaccine, recommended for routine administration after one year of age, can cause autism.[162] The IOM identified 22 studies that evaluated the connection between MMR vaccine and autism, but did not rely on 17 of them due to lack of "unvaccinated comparison population," "individual-level data," or "methodological limitations."[163] Based on the remaining five studies, none of which involved children in the United States, the IOM concluded that, "The evidence favors rejection of a causal relationship between MMR vaccine and autism."[164] This conclusion reflects that studies can be conducted which the IOM is willing to rely upon to reach a conclusion that a particular vaccine does not cause autism. That said, the IOM's conclusion regarding MMR vaccine and autism does not support the much broader claim that "vaccines do not cause autism," as it only addresses whether the MMR vaccine

[161] https://www.nap.edu/read/13164/chapter/12?term=autism#545.

[162] https://nap.nationalacademies.org/read/13164/chapter/6#145.

[163] https://nap.nationalacademies.org/read/13164/chapter/6#145.

[164] https://nap.nationalacademies.org/read/13164/chapter/6#145.

can cause autism. It does not address whether any other vaccines, especially those given to infants, can cause autism.[165]

Two years later, in 2014, the AHRQ conducted a review which again included looked at any study regarding pertussis, tetanus, and diphtheria vaccines, including DTaP, and autism.[166] HHS has explained in 2018 that this report represented "the most comprehensive review to date of published studies on the safety of routine vaccines recommended for children in the United States."[167] As with the IOM reports from 1991 and 2012, the "comprehensive review" published by AHRQ in 2014 again concluded that it could not identify a study to support the claim that DTaP, administered at 2, 4, and 6 months of age, does not cause autism.[168]

AHRQ also reviewed autism and Hep B vaccine, administered at 1 day, 1 month, and 6 months of age, and did not identify a study to support the claim that this vaccine does not cause autism.[169] Instead, the only study meeting AHRQ's criteria for reliability was from the Stony Brook University Medical Center which found a 300% increased rate of autism among newborns receiving a Hep B vaccine at birth compared to those who did not get this vaccine at birth. AHRQ's 2014 review summarizes the results of this study as follows:

> Result was significant for the risk of autism in children who received their first dose of Hepatitis B vaccine during the first month of life (OR 3.00, 95% CI 1.11, 8.13), compared with those who received the vaccination after the first month of life or not at all.[170]

AHRQ therefore identified one study that showed an association, and no studies to support that Hep B vaccine does not cause autism; its conclusion was that it does not know whether the Hep B vaccine causes autism.[171]

A subsequent October 12, 2017 letter sent to HHS and signed by Robert F. Kennedy Jr. and others explained that there are no published studies supporting that the vaccines given in the first year of life do not cause autism. The letter asked HHS to "identify the specific studies on which HHS bases its blanket claim that no vaccines cause autism."[172] The letter also cited to studies which did find an association between one or more of these vaccines and autism and provided scientific support and letters from world-leading aluminum scientists on how this particular vaccine ingredient could cause autism.[173]

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[165] https://nap.nationalacademies.org/read/13164/chapter/6#145.

[166] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf.

[167] https://archive.org/details/hhs-response-1.

[168] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf.

[169] *Id.*

[170] *Id.*

[171] *Id.*

[172] https://archive.org/details/ican-hhs-notice-1 at 13.

[173] *Id.*

On January 18, 2018, HHS sent a response which provided various links to CDC webpages but neither those links nor the content of those webpages identified a study which supports the claim that the vaccines given to infants do not cause autism.[174] This was explained in a follow-up letter to HHS which again requested any supporting studies and again reiterated the data regarding how aluminum adjuvants can cause autism.[175] It also specifically asked HHS the following:

> The following white paper provides the peer reviewed scientific support for how aluminum adjuvants injected into the body travel to the brain, can cause IL-6 production and microglial activation in the brain, and that this in turn can cause autism: http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf. Please clearly and specifically explain which steps in this chain of causation or any other aspect of this white paper HHS disputes.[176]

No response from HHS was ever provided to rebut these studies or scientific findings.[177]

On December 31, 2019, the CDC was sued in federal court for failing to provide studies in response to a Freedom of Information Act request submitted to the CDC seeking studies it relied upon to support that the vaccines the CDC recommends be given in the first year of life—DTaP, Hep B, Hib, PCV13, and IPV, individually and collectively—do not cause autism.[178]

To resolve the lawsuit, the CDC provided a list of the 16 studies and 4 reviews it claimed support the claim that the foregoing vaccines do not cause autism. This list was memorialized in a signed stipulation with the CDC on February 28, 2020, and then entered as an order of the Court on March 2, 2020.[179] The stipulation and order provided in relevant part as follows:[180]

> WHEREAS, the Institute for Autism Science and Informed Consent Action Network **("ICAN")** commenced the above-captioned lawsuit against the Centers for Disease Control and Prevention **("CDC")** regarding six Freedom of Information Act requests (the "**FOIA Requests**");
>
> WHEREAS, the FOIA Requests were as follows:
>
> - "All studies relied upon by CDC to claim that the

[174] https://archive.org/details/hhs-response-1.

[175] https://archive.org/details/ican-reply-1.

[176] *Id* at 83.

[177] https://archive.org/details/ican-follow-up-final.

[178] https://ecf.nysd.uscourts.gov/doc1/127026118709 (https://www.courtlistener.com/docket/16644712/1/institute-for-autism-science-v-centers-for-disease-control-and-prevention/); https://ecf.nysd.uscourts.gov/doc1/127126484251.

[179] https://ecf.nysd.uscourts.gov/doc1/127126484251 (https://www.courtlistener.com/docket/16644712/15/institute-for-autism-science-v-centers-for-disease-control-and-prevention/).

[180] https://ecf.nysd.uscourts.gov/doc1/127126484251 (https://www.courtlistener.com/docket/16644712/15/institute-for-autism-science-v-centers-for-disease-control-and-prevention/).

DTaP vaccine does not cause autism."

- "All studies relied upon by CDC to claim that neither Engerix-B nor Recombivax HB do not cause autism."
- "All studies relied upon by CDC to claim that Prevnar 13 does not cause autism."
- "All studies relied upon by CDC to claim that Hib vaccines do not cause autism."
- "All studies relied upon by CDC to claim that inactivated polio vaccine ('IPV') does not cause autism."
- "Copies of the studies the CDC relies upon to claim that the cumulative exposure of vaccines it recommends that babies be administered during the first six months of life do not cause autism."

WHEREAS, after conducting a search of its records, the CDC identified the following studies responsive to the FOIA Requests:

1. Madsen KM, Hviid A, Vestergaard M, Schendel D, Wohlfahrt J, et al. A population-based study of measles, mumps, and rubella vaccination and autism. N Engl J Med. 2002;347 (19):1477-1482.
2. IOM (Institute of Medicine). 2012. Adverse Effects of Vaccines: Evidence and Causality. Washington, DC: The National Academies Press.
3. IOM (Institute of Medicine). 2004. Immunization Safety Review: Vaccines and Autism. Washington, DC: The National Academies Press.
4. IOM (Institute of Medicine). 2013. The childhood immunization schedule and safety: Stakeholder concerns, scientific evidence, and future studies. Washington, DC: The National Academies Press.
5. Frombonne E, Zakarian R, Bennett A, et al. Pervasive developmental disorders in Montreal, Quebec, Canada: prevalence and links with immunizations. Pediatrics. 2006;118(1):el39-50.
6. Taylor LE, Swerdfeger AL, Eslick GD. Vaccines are not associated with autism: An evidence- based meta-analysis of case-control and coh01t studies. Vaccine. 2014;32:3623-3629.
7. Ball L, Ball R, Pratt RD. An assessment of thimerosal in childhood vaccines. Pediatrics. 2001;107:1147-1154.
8. Hviid A, Stellfeld M, Wohlfahrt J, Melbye M. Association between thimerosal-containing vaccine and autism. JAMA. 2003;290:1763-6.

9. Madsen KM, Lauritsen MB, Pedersen CB, et al. Thimerosal and the occurrence of autism: negative ecological evidence from Danish population-based data. Pediatrics. 2003;112(3 Pt 1):604-6.
10. Stehr-Green P, Tull P, Stellfeld M, et al. Autism and thimerosal-containing vaccines: lack of consistent evidence for an association. Am JPrev Med. 2003;25(2):101-6.
11. Verstraeten T, Davis RL, Destefano F, et al. Safety of thimerosal-containing vaccines: a two- phased study of computerized health maintenance organization databases. Pediatrics. 2003;112(5):1039-48.
12. Andrews N, Miller E, Grant A, et al. Thimerosal exposure in infants and developmental disorders: a retrospective cohort study in the United Kingdom does not supp01t a causal association. Pediatrics. 2004;114(3):584-91.
13. Thompson WW, Price C, Goodson B, et al. Early thimerosal exposure and neuropsychological outcomes at 7 to 10 years. N Engl JMed. 2007;357(13):1281-92.
14. McMahon AW, Iskander **Il(,** Haber P, Braun MM, Ball R. Inactivated influenza vaccine (IIV) in children <2 years of age: Examination of selected adverse events reported to the Vaccine Adverse Event Reporting System (VAERS) after thimerosal-free or thimerosal-containing vaccine. Vaccine. 2008 Jan; 26(3):427-429.
15. Schechter R, Grether Il(. Continuing increases in autism reported to California's developmental services system: Mercury in retrograde. Arch Gen Psychiatry. 2008;65:19-24.
16. DeStefano F. Thimerosal-containing vaccines: evidence versus public apprehension. Expe1t Opin Drug Saf. 2009;8(1):1-4.
17. Tozzi AE, Bisiacchi P, Tarantino V, et al. Neuropsychological performance 10 years after immunization in infancy with thimerosal-containing vaccines. Pediatrics. 2009;123(2):475-482.
18. Price CS, Thompson WW, Goodson B, et al. Prenatal and infant exposure to thimerosal from vaccines and immunoglobulins and risk of autism. Pediatrics. 2010;126(4):656-64.
19. Barile JP, Kuperminc GP, Weintraub ES, et al. Thimerosal exposure in early life and neuropsychological outcomes 7-10 years later. J Pediatr Psychol. 2012;37(1):106-18.
20. Destefano F, Price CS, Weintraub ES. Increasing exposure to antibody-stimulating proteins and polysaccharides in vaccines is not associated with risk of autism. J Pediatr. 2013;163(2):561-7.

None of these 20 studies/reviews identified by the CDC included a study to support the claim that the vaccines on the CDC's childhood vaccine schedule given to infants—DTaP, Hep B, Hib, PCV13, and IPV—do not cause autism. Instead, these 20 studies/reviews include:

- 15 studies and 3 reviews concerning MMR and/or thimerosal;
- 1 study concerning antigen (not vaccine) exposure; and
- 1 review concerning MMR, thimerosal, and DTaP.

Hence, only one of the 20 studies/reviews identified by the CDC involved a vaccine given to infants, DTaP. This was the review the IOM published in 2012, discussed above, which failed to identify a study to support that DTaP does not cause autism. Instead, it found only one study regarding DTaP vaccine and autism, and that study found an association between this vaccine and autism. Hence, the only study or review out of 20 identified by the CDC that reviewed a vaccine given during the first year of life was a study which *did find* an association between DTaP vaccine and autism.

On August 25, 2020, the head of CDC's Clinical Immunization Safety Assessment (CISA) Project, one of the four vaccine safety systems listed on the CDC's website, was questioned under oath in a case specifically about autism and vaccines. She also confirmed that there are no studies to support that infant vaccines do not cause autism:

> Q: [A]ccording to your profile, you have done most of the clinical trials relied upon to license many of the vaccines, correct, on the market?
> A: Yes, sir.
> Q: Okay. So you're highly experienced at conducting clinical trials; correct?
> A: I am highly experienced conducting clinical trials.
> Q: ... And you're familiar with many of the clinical trials that -- relied upon to license many of the vaccines currently on the market; correct?
> A: I am.
> Q: Okay. In your opinion, did the clinical trials relied upon to license the vaccines that [the child] received, many of which are still on the market today, were they designed to rule out that the vaccine causes autism?
> A: No. …
> Q: [I]n the expert disclosures for this case, it asserts that among other things you will testify that, quote, the issue of whether vaccines cause autism has been thoroughly researched and rejected, end quote. …
> Q: … It's your testimony that MMR vaccine cannot cause autism?
> A: That's correct.
> Q: It's your testimony the HepB vaccine cannot cause autism?
> A: That's correct.
> Q: It's your testimony that IPOL cannot cause autism?
> A: Yes.
> Q: It's your testimony that Hib vaccine cannot cause autism?
> A: Yes.
> Q: It's your testimony that varicella vaccine cannot cause autism?
> A: Yes.
> Q: It's your testimony that Prevnar vaccine cannot cause autism?

A: Yes.
Q: And it's your testimony that DTaP vaccine cannot cause autism?
A: Yes. …
Q: And do you have a study that supports that DTaP doesn't cause autism?
A: I have -- I do not have a study that -- that DTaP causes autism, so I don't have either.
Q: … Do you have any study one way or another of whether IPOL causes autism?
A: No, I do not, sir.
Q: Do you have any study one way or another of whether Engerix-B causes autism?
A: I do not have any evidence that it causes autism, nor that it does not.
Q: And what about HibTITERs vaccine, any evidence one way or another of whether it causes autism?
A: No. …
Q: … And what about Prevnar vaccine? Any evidence, one way or another?
A: No, sir. No, sir. …
Q: … And how about varicella vaccines … are there any studies one way or another that support whether it does or doesn't cause autism?
A: [As p]art of MMR, but not as varicella by itself, no sir. No studies that say it does or no studies that say it doesn't.
Q: … There have been studies that have found an association between hepatitis B vaccine and autism; correct?
A: Not studies that I feel are credible.
Q: Okay. Which study -- which study … are you referring to when you say that?
A: Well, why don't you show me the study and then I'll say whether I agree with it.[181]

As the foregoing reflects, and as explained by the Secretary of Health and Human Services, Robert F. Kennedy Jr., the CDC cannot claim that vaccines given in the first year of life do not cause autism. It cannot do so because the studies to disprove that the vaccines given to infants do not cause autism have not been conducted.

The need for studies regarding whether these vaccines have contributed to the autism epidemic is acute. Since the 1980s, the rise in cases of autism has occurred in lockstep across all geographic areas of the United States and across all racial, ethnic, and religious groups.[182]

Given the steep rise, the cause of autism is an environmental change that has occurred throughout the United States since the early 1980s. A study published in *Environmental Health* out of the University of Colorado reviewed the correlations between numerous environmental factors suspected of potentially causing autism and the change in the level of their exposure during childhood since the 1980.[183] The environmental exposure in the study showing the highest

[181] https://archive.org/details/kathryn-edwards-full-pdf-transcript.

[182] *See* The CDC's Autism and Developmental Disabilities Monitoring (ADDM) Network, https://www.cdc.gov/ncbddd/autism/addm.html, the U.S. Department of Education data collected pursuant to the Individuals with Disabilities Act (IDEA), https://sites.ed.gov/idea/data/, and the California Department of Developmental Services (CDDS), https://www.dds.ca.gov/transparency/autism/.

[183] https://pubmed.ncbi.nlm.nih.gov/25189402/.

statistical correlation with autism rates was the increasing doses of vaccination. The following charts are from this study. The circles represent the number of vaccine doses and the triangles represents the rate of autism:

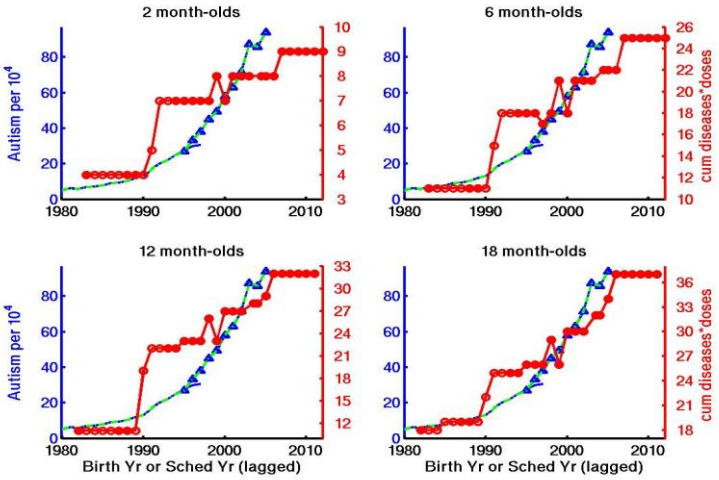

Figure S8. Temporal trend in autism compared to temporal trend in cumulative number of immunizations administered to U.S. infants and toddlers by 2, 6, 12 and 18 months via immunization according to the CDC recommended schedule.[184]

Correlation does not equal causation, but it does provide a safety signal that merits investigation, including because numerous studies support immune dysfunction as a cause of autism and vaccines are intended to and do systemically modify the immune system. Additionally, a significant proportion of parents of children with autism identify vaccines as what they believe caused their child's autism, including pointing to the vaccines given in the first six months of life.[185]

SLIDE 45: ADVERSE REACTIONS MANUFACTURERS HAVE A BASIS TO BELIEVE ARE CAUSALLY RELATED

Pharmaceutical companies have access to internal vaccine safety data that is unavailable to public health agencies and the public.

Federal law requires pharmaceutical companies to disclose, in the package insert for each vaccine, "*only* those adverse events for which there is some basis to believe there is a *causal relationship* between the drug and the occurrence of the adverse event."[186] With access to safety data that is unavailable to the public or to health authorities, the pharmaceutical companies are able to identify what injuries may be caused by vaccines that committees within HHS, CDC, IOM, and AHRQ cannot do without access to such data.

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[184] https://pubmed.ncbi.nlm.nih.gov/25189402/.

[185] https://www.ncbi.nlm.nih.gov/pubmed/16685182; https://www.ncbi.nlm.nih.gov/pubmed/25398603; https://www.ncbi.nlm.nih.gov/pubmed/16547798; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448378/.

[186] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-201.

These adverse events identified by pharmaceutical companies are typically listed in Section 6.2 of each vaccine's package insert. Only adverse events for which these companies have a basis to believe have a "causal relationship" with the vaccine are to be listed pursuant to federal law. Adverse events for which there is only a correlation with the administration of the vaccine should therefore not be listed.

Many of the chronic diseases that have risen over the prior decades are disclosed on one or more vaccine package inserts.[187]

SLIDES 46-48, 50: STUDYING UNEXPOSED GROUPS

Properly assessing the safety of a product typically requires comparing an exposed group to an unexposed group and assessing their health outcomes, i.e., comparing a group that receives the product with a group that does not receive the product. Regarding vaccines, that requires comparing the health outcomes between vaccinated (one or more vaccines) and unvaccinated (no vaccines) children. This can be accomplished by using existing databases that contain this health data.

In 2013, the IOM published a report after having been commissioned by HHS to review the overall safety of the CDC childhood schedule "to identify health outcomes associated with some aspect of the childhood immunization schedule," including "asthma, autoimmunity, autism, other neurodevelopmental disorders (e.g., learning disabilities, tics, behavioral disorders, and intellectual disability), seizures, and epilepsy."[188] This was a different IOM report than the ones previously discussed above as it did not focus on individual vaccines but rather on the safety of the CDC childhood vaccine schedule as a whole.

The IOM found that no studies had ever been conducted which compared the health outcomes of children receiving the CDC's childhood vaccine schedule with children that had not been vaccinated:

> [F]ew studies have comprehensively assessed the association between the entire immunization schedule or variations in the overall schedule and categories of health outcomes, and no study … compared the differences in health outcomes … between entirely unimmunized populations of children and fully immunized children. Experts who addressed the committee pointed not to a body of evidence that had been overlooked but rather to the fact that existing research has not been designed to test the entire immunization schedule. …

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[187] https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states.

[188] https://www.nap.edu/read/13563/chapter/2#5.

> [Also,] 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.[189]

When the IOM committee expanded its search for any evidence that could help it assess the safety of the CDC's childhood vaccine schedule, it stated that it "found a paucity of information, scientific or otherwise, that addressed the risk of adverse events in association with the complete recommended immunization schedule."[190] The IOM found: "There is no evidence that the schedule is not safe."[191]

The IOM's report from 2013 did assert that it "is possible to make this comparison [between vaccinated and unvaccinated children] through analyses of patient information contained in large databases such as VSD [the Vaccine Safety Datalink]."[192] Subsequently, the CDC commissioned a 64-page white paper, published in April 2016, that discussed how to conduct such studies using the VSD.[193] But no such study has even been published by the CDC despite the fact this white paper acknowledges that many chronic disorders children are experiencing today in epidemic numbers are biologically plausible outcomes from exposure to CDC's childhood vaccine schedule but have not yet been properly studied. [194]

While CDC and pharmaceutical-funded scientists have never published such a study, a few such studies have been published.

A pilot study, based on parental surveys of homeschool children, from the School of Public Health at Jackson State University, published in 2017, found that 33% of vaccinated preterm babies had a neurodevelopmental disorder while 0% of the unvaccinated preterm babies had a neurodevelopmental disorder;[195] and another study by the same group found that vaccinated children, compared to unvaccinated children (receiving no vaccines), had a 74% decreased risk of chicken pox and a 70% decreased risk of pertussis, *but* had an increased risk of 290% for allergies, 320% for ADHD, 320% for autism, 190% for eczema, 420% for learning disabilities, and 270% for any neuro-developmental delay.[196]

In another study aggregating data from three medical practices in the United States, the health outcomes of vaccinated and unvaccinated children born between 2005 and 2015 were compared; this study found that vaccinated children, compared to unvaccinated children, had a statistically

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[189] https://www.nap.edu/read/13563/chapter/2#5.

[190] https://www.nap.edu/read/13563/chapter/6?term=paucity#70.

[191] https://www.nap.edu/read/13563/chapter/2#12.

[192] https://www.nap.edu/read/13563/chapter/2#13.

[193] https://www.cdc.gov/vaccine-safety/media/pdfs/white-paper-safety-508.pdf?CDC_AAref_Val=https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf.

[194] *Id.*

[195] https://www.oatext.com/pdf/JTS-3-187.pdf.

[196] https://www.oatext.com/pdf/JTS-3-186.pdf.

significant increased rate of 118% for developmental delay, 349% for asthma, and 113% for ear infections.[197]

Researchers at State University of New York at Stony Brook have authored two studies concerning the hepatitis B vaccine. One of those study's findings were that male neonates vaccinated with the hepatitis B vaccine had a 3 times risk (OR=3.002, 95% CI 1.109-8.126) for parental report of autism diagnosis compared to boys not vaccinated as neonates during that same time period.[198] The second study found that the odds of receiving early intervention or special education services were 8.63 times as great (OR=8.63, 95% CI 3.24–22.98) for vaccinated boys as for unvaccinated boys after adjustment for confounders.[199]

Additional unpublished data, including from the Amish community, reflects similar findings.[200]

SLIDE 49: CDC SURVEILLANCE SYSTEMS

VAERS

The Vaccine Adverse Events Reporting System (**VAERS**) is jointly administered by the CDC and the FDA. It is a passive reporting system to which anyone can submit reports of an injury after vaccination. However, the vast majority of reports are submitted by pharmaceutical companies, health care providers, and state immunization programs.[201]

The CDC explains that VAERS cannot establish causation between a vaccine and an injury and that, at best, it can be used for signal detection. Hence, CDC explains that it should not be used to reach a causality conclusion regarding a claimed injury from one or more vaccines. But it can provide potential signals of vaccine harm based on the volume and type of reports received.

From 2013 and 2018, VAERS received 261,294 reports of adverse vaccine events, including 2,081 deaths, 5,477 permanent disabilities, and 20,778 hospitalizations.[202]

A study of VAERS reporting commissioned by the AHRQ stated that "fewer than 1% of vaccine adverse events are reported."[203] In this study, AHRQ provided a $1 million grant to create a software program at Harvard Pilgrim Health Care that would automate reporting injuries after

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[197] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7268563/.

[198] https://pubmed.ncbi.nlm.nih.gov/21058170/.

[199] https://doi.org/10.1080/02772240701806501.

[200] https://www.sirillp.com/wp-content/uploads/2025/01/Ex-D-Dr-Neuenschwander-Declaration-signed-w-exs.pdf; http://sirillp.com/Letters-to-NY-DOH.

[201] https://web.archive.org/web/20150615195821/http://vaers.hhs.gov/about/faqs.

[202] https://wonder.cdc.gov/vaers.html.

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

vaccination to VAERS.[204] The result was the successful creation of a system at Harvard Pilgrim which automatically created adverse vaccine event reports:

Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses were given to 376,452 individuals. Of these doses, 35,570 possible reactions were identified.[205]

Regrettably, the CDC did not cooperate with making this new program functional. After creating a software program that automatically created VAERS reports, the system's developers asked the CDC to take the final step of linking VAERS with the Harvard Pilgrim system so that these reports could be automatically transmitted into VAERS.[206] But as the Harvard researchers explained:

> Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.[207]

VAERS cannot be used to determine whether a vaccine causes a harm because, while VAERS can provide the number of people harmed (numerator), it cannot provide the total number of people vaccinated (denominator) from which to calculate a rate of harm. Automating VAERS reports from a fixed pool of people would have made calculating a rate and thus reaching a causality conclusion on a given harm possible. That type of automation has still not been implemented for VAERS.

It is also noted that on December 4, 2020, before the first COVID-19 vaccine was rolled out, CDC released the VAERS Standard Operating Procedures for COVID-19 ("VAERS SOP"), which stated in relevant part:

> The analyses for COVID-19 vaccine safety signals will focus on identifying deviations from preliminary safety data, and possibly from other vaccines, using disproportionality analyses and comparisons of reporting rates.
>
> Two main approaches to data mining are Proportional Reporting Ratios (PRRs) and Empirical Bayesian Geometric Means. Both have published literature suggesting criteria for detecting "signals". PRR will be used at CDC for potential signal detection; Empirical Bayesian data mining will be performed by FDA.[208]

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[204] *Id.*

[205] *Id.*

[206] *Id.*

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

[208] https://www.cdc.gov/vaccinesafety/pdf/VAERS-COVID19-SOP-4-Dec-2020-508.pdf.

This SOP thus explained that CDC planned to conduct safety signal monitoring using Proportional Reporting Ratios ("PRR") and FDA planned to conduct safety signal monitoring using Empirical Bayesian ("EB") data mining.

Our firm requested the PRR signal detection data from CDC through FOIA and was denied. In the denial letter, CDC stated that it had not conducted PRR analyses; it instead highlighted the superiority of and historical use of EB data mining, calling it the "gold standard" and the "superior method" with which to detect safety signals. However, on September 2, 2022, then-CDC Director Rochelle Walensky sent a letter to Senator Ron Johnson acknowledging that PRR had in fact been used: "CDC performed PRR analysis between March 25, 2022, through July 31, 2022, to corroborate the results of EB data mining. Notably, results from PRR analysis were generally consistent with EB data mining, revealing no additional unexpected safety signals." Our firm then sued CDC based on this admission and ultimately received 51 excel files containing PRR data. [209] These files showed that CDC's own threshold for triggering a signal for adverse events was met for numerous serious adverse events, including as seen in the following CDC tables noting that CDC had set anything above a "2" in the PRR row as a safety signal:[210]

[209] https://www.sirillp.com/wp-content/uploads/2024/06/Response-to-FDA-Stay-b390d697ad6bc29544ff90e607957c03.pdf.

[210] https://icandecide.org/cdc-proportional-reporting-ratio/ (all PRR data is available for download at this site).

N>=3 (Current Week), PRR>=2.00 (Ratio of

MedDRA Codes ALL Reports (18+)	12/14/2020-05/06/2022 COVID19 mRNA N=632725	12/14-05/06 Chi-Square	12/14-05/06 PRR
CEREBRAL THROMBOSIS	194	69.78	73.46
INTERMENSTRUAL BLEEDING	1323	481.57	62.62
CEREBRAL VENOUS SINUS THROMBOSIS	155	55.02	58.69
HEAVY MENSTRUAL BLEEDING	4246	1543.71	53.59
INTENTIONAL PRODUCT USE ISSUE	141	49.72	53.39
POSITIVE AIRWAY PRESSURE THERAPY	789	283.64	49.79
PULMONARY THROMBOSIS	610	218.11	46.20
DISEASE RECURRENCE	227	79.98	42.98
HYPERPYREXIA	111	38.38	42.03
POSTMENOPAUSAL HAEMORRHAGE	521	184.41	39.46
POLYMENORRHOEA	684	241.57	37.00
RIGHT VENTRICULAR DYSFUNCTION	96	32.71	36.35
INTENTIONAL DOSE OMISSION	94	31.96	35.59
ABNORMAL UTERINE BLEEDING	82	27.43	31.05
OLIGOMENORRHOEA	564	196.16	30.51
CEREBELLAR STROKE	80	26.68	30.29
SUSPECTED COVID-19	550	190.86	29.75
CEREBRAL MASS EFFECT	75	24.79	28.40
RIGHT VENTRICULAR DILATATION	73	24.04	27.64
DYSMENORRHOEA	1821	631.80	27.58
THROMBECTOMY	348	118.98	26.35
MYOCARDIAL STRAIN	64	20.65	24.23
HAEMOFILTRATION	62	19.90	23.48
IMPLANTABLE CARDIAC MONITOR INSERTION	61	19.52	23.10
TRANSVERSE SINUS THROMBOSIS	60	19.15	22.72
MATERNAL EXPOSURE DURING BREAST FEEDING	292	97.84	22.11
BODY HEIGHT DECREASED	57	18.02	21.58
MENSTRUAL DISORDER	2435	822.34	20.96
MENSTRUATION IRREGULAR	3240	1094.66	20.79
MESENTERIC VEIN THROMBOSIS	54	16.90	20.45
NIH STROKE SCALE ABNORMAL	54	16.90	20.45
NIH STROKE SCALE	53	16.52	20.07
CORONARY ARTERY DISSECTION	52	16.15	19.69
JUGULAR VEIN THROMBOSIS	52	16.15	19.69
LEFT VENTRICULAR DILATATION	51	15.77	19.31
ANOSMIA	3546	1186.66	19.18
NEUROLOGIC NEGLECT SYNDROME	50	15.40	18.93
CEREBRAL ARTERY OCCLUSION	98	31.29	18.55
VITAL SIGNS MEASUREMENT	146	47.19	18.43
ILLNESS	4279	1423.54	18.21
INTRACARDIAC THROMBUS	95	30.16	17.99
LYMPHOPENIA	94	29.79	17.80
THROMBOEMBOLECTOMY	47	14.28	17.80
VACCINATION SITE URTICARIA	322	104.80	17.42
COR PULMONALE ACUTE	46	13.90	17.42
HEPATIC MASS	46	13.90	17.42
WRONG PATIENT	45	13.53	17.04
PREMENSTRUAL PAIN	44	13.16	16.66
PRODUCT RECONSTITUTION QUALITY ISSUE	44	13.16	16.66
TOTAL LUNG CAPACITY DECREASED	44	13.16	16.66
PERIPHERAL ARTERY OCCLUSION	43	12.78	16.28
ANTICOAGULANT THERAPY	3684	1204.20	16.22
COLON CANCER	41	12.04	15.53
SYMPTOM RECURRENCE	163	51.45	15.43
ACUTE CARDIAC EVENT	40	11.67	15.15
PERIPHERAL ARTERY THROMBOSIS	78	23.79	14.77
CARDIOVASCULAR SYMPTOM	39	11.29	14.77

When the CDC was asked about the above data, it advised Senator Johnson that it was no longer relying upon PRR and instead would only rely upon FDA's EB data mining; as the then CDC Director wrote to Senator Johnson:

> CDC and the Food and Drug Administration (FDA) chose to rely on Empirical Bayesian (EB) data mining—a more robust technique used to analyze disproportionate reporting—rather than PRR calculations to mitigate potential false signals. . . . Given the strength of the EB data mining method, CDC and FDA plan to continue relying upon EB data mining moving forward.[211]

Given that it decided to abandon the PRR data and rely upon the EB data, our firm requested the EB data mining results from FDA through FOIA and was denied. Hence, we commenced a lawsuit against the FDA to obtain the EB data results which remains ongoing.

VSD

The next system the CDC lists as a vaccine safety surveillance tool is the Vaccine Safety Datalink (**VSD**). While this system could be helpful in assessing vaccine safety, that is not currently the case. Until around 2001, the VSD was maintained at the CDC. Thus, independent scientists were able to obtain access to the VSD at the request of members of Congress and through other legal means. The studies these independent scientists published identified various harms associated with vaccination. CDC then moved the VSD to an industry trade association starting in 2001 which took it out of the reach of the Freedom of Information Act and also limited the data to only scientists and studies it approved.[212] This resulted in selection bias with regard to studies that were allowed to access and be published using the VSD. Moreover, every study published using the VSD violates scientific standards because the underlying data is almost never available for inspection by the public and other scientists.[213] Refusal to make this data available raises serious concerns regarding reproducibility and transparency. HHS regulations provide severe penalties if researchers, using HHS funding, refuse to share data underlying their studies, but the CDC does not apply this same standard to its own VSD studies.[214]

Putting these issues aside, the VSD is not typically used to study long term health conditions. While the CDC has acknowledged that public stakeholders "have expressed more concerns about long-term than short-term health outcomes" and that "long-term health outcomes have been less well-studied in the context of vaccine safety," VSD is geared toward assessing short-term, and not long-term, health outcomes:

> The current safety surveillance systems such as the VSD … already have extensive systems in place to assess short-term outcomes … [despite the fact] the childhood immunization schedule is essentially a long-term exposure, occurring over 18 to 24 months, [and hence]

[211] https://www.documentcloud.org/documents/23940343-sen-johnson-letter-to-fda-on-eb-data-mining.

[212] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4708093/.

[213] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/accessing-data.html.

[214] https://www.federalregister.gov/documents/2016/09/21/2016-22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial-information.

> long-term adverse events may be more biologically plausible than short-term events.[215]

The deidentified data in the VSD, paid for by taxpayers, should be available to the public so that independent scientists can conduct vaccine safety studies. Until that data is released and any claimed results using this data replicated, it is an improper tool to reach any conclusion regarding vaccine safety.

V-safe

CDC's V-safe vaccine safety system is a smartphone-based program which uses "text messages and web surveys to ask how [users] feel, including if [users] experience any side effects after vaccination."[216] It was first developed and used with COVID-19 vaccines but has since been expanded for other vaccines. As explained by the CDC, the program "helps CDC gather important information and monitor any potential side effects in real time so scientists can quickly study them and determine if there is a safety concern with a particular vaccine."[217] The CDC explains that "[t]his information helps [it] communicate timely and transparent information about the safety of vaccines to public health officials, healthcare providers, and the public."[218]

On November 19, 2020, the CDC published a protocol for developing V-safe titled "V-safe active surveillance for COVID-19 vaccine safety" (**V-Safe Protocol**).[219] The V-Safe Protocol explains that "[t]he purpose of v-safe surveillance is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[220]

V-safe was launched simultaneously with the release of the first COVID-19 vaccine in December 2020. Approximately 10 million individuals signed up for V-safe, around 9 million of whom registered between December 2020 and April 2021.[221]

This period from December 2020 to April 2021 was a period when there were no Covid-19 vaccine mandates yet and there was high public interest in receiving this product. The data submitted by 10 million V-safe users is likely a good reflection of the experience of the larger population of 265 million Americans who received at least one dose of a COVID-19 vaccine.

V-safe collected data from users in two ways. The first was check-the-box options limited to (a) symptoms and (b) health impacts. The second was using free-text fields.

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[215] https://www.cdc.gov/vaccine-safety/media/pdfs/white-paper-safety-508.pdf?CDC_AAref_Val=https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf.

[216] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html (listing v-safe as one of the ways "CDC expanded and strengthened the country's ability to monitory vaccine safety").

[217] *Id.*

[218] *Id.*

[219] https://web.archive.org/web/20210102024902/https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[220] *Id*. at 1.

[221] https://data.cdc.gov/Public-Health-Surveillance/v-safe-COVID-19/dqgu-gg5d/about_data.

With regard to check-the-box symptoms, V-safe users were asked to select one or more of 10 listed symptoms that occurred within the first week after vaccination. These symptoms are those that the CDC explains are normal after vaccination and are a sign the vaccine is working by producing an immune response. As the CDC explains: "Any side effects from getting the vaccine are normal signs the body is building protection."[222] Meaning, the check-the-box symptoms data collected by V-safe had effectively no value in assessing safety of the COVID-19 vaccines. Indeed, the 10 million V-safe users reported over 70 million check-the-box symptoms, and this did not raise concerns for the CDC as seen from the studies the CDC published reflecting these high rates of check-the-box symptoms.[223]

The only other check-the-box safety information collected (other than the 10 listed symptoms) was whether users reported needing medical care, missed school or work, or could not perform normal daily activities following their vaccination ("health impact data"). If a user selected that he or she needed medical care, the user was then also asked to select whether he or she sought telehealth, urgent care, emergency care, or was hospitalized.

The health impact data was collected during the first week, then weekly for the first six weeks, and then at 3, 6, and 12 months after injection. In contrast, the check-the-box symptoms data was collected for only the first week after injection. Since the CDC dubbed V-safe a "real time" surveillance program, presumably the health impact data is the data the CDC intended to use to rapidly detect any safety issues.[224]

Since 2021, the CDC published dozens of studies to support its claim that COVID-19 vaccines are safe. Primary data used in these studies is V-safe's health impact data, with a focus on the rate of people who reported needing medical care after the vaccine. The studies form a core of the CDC's support for the safety of COVID-19 vaccines. However, the studies only report the first week of health impact data after injection despite the fact injuries from COVID-19 vaccines can occur after the first week.[225]

When the check-the-box data was released to the public, following over two years of litigation by a non-profit group to compel release of the data, it reflected that 7.7% of V-safe users reported needing medical care after a COVID-19 vaccine and an additional 25% of V-safe users reported

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[222] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html.

[223] *See e.g.*, https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e1.htm; https://www.cdc.gov/mmwr/volumes/70/wr/mm7039e4.htm; https://www.cdc.gov/mmwr/volumes/70/wr/mm7018e2.htm; https://jamanetwork.com/journals/jama/fullarticle/2778441; https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm; https://www.cdc.gov/mmwr/volumes/70/wr/mm705152a1.htm; https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e1.htm.

[224] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html ("These platforms give CDC scientists information about the safety of COVID-19 vaccines in real time.").

[225] For example, myocarditis can arise at least 42 days after vaccination. *See* https://pubmed.ncbi.nlm.nih.gov/34614329/ at Figure 1. Thrombosis with thrombocytopenia syndrome (TTS), which can also be caused by the COVID-19 vaccine, can arise up to 18 days after vaccination. *See* https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/02-COVID-See-508.pdf at slide 16.

missing school or work or being unable to perform normal activities after receiving a COVID-19 vaccine.[226]

That finding was not in accord with what the CDC had been reporting to the public, as it reflected that nearly 1 in 13 individuals in the V-safe system sought medical care after a COVID-19 vaccine, and on average, users sought medical care two to three times each. Since V-safe was supposed to assess safety, and the only metric that appears to have provided any such measure was when users reported seeking medical care, it is unclear what measure of vaccinees having to seek medical would have needed to occur in order to raise a safety concern for the CDC.

Furthermore, the CDC could have designed V-safe to be a rapid and useful safety system by including check-the-box options for harms that COVID-19 vaccines can or were suspected to cause. For example, a check-the-box option for myocarditis or for chest pain. As reflected in the first version of the V-safe Protocol, prior to the program's launch, it listed adverse events of special interest (**AESI**) in a chart titled Prespecified Medical Conditions:

Attachment 2: Adverse Events of Special Interest

Prespecified Medical Conditions
Acute myocardial infarction
Anaphylaxis
Coagulopathy
COVID-19 Disease
Death*
Guillain-Barré syndrome
Kawasaki disease
Multisystem Inflammatory Syndrome in children[1]
Multisystem Inflammatory Syndrome in adults[2]
Myocarditis/Pericarditis
Narcolepsy/Cataplexy
Pregnancy and Prespecified Conditions
Seizures/Convulsions
Stroke
Transverse Myelitis

* Capture of deaths through v-safe will be limited.

This list included acute myocardial infarction, anaphylaxis, coagulopathy, COVID-19 Disease, death, Guillain-Barre Syndrome, Kawasaki disease, Multisystem Inflammatory Syndrome in Children, Multisystem Inflammatory Syndrome in adults, myocarditis/pericarditis, narcolepsy/cataplexy, pregnancy and prespecified conditions, seizures/convulsions, stroke, and transverse myelitis.

The CDC also identified all but two (pregnancy and coagulopathy) of these AESIs in an October 22, 2020 presentation titled "CDC post-authorization/post-licensure safety monitoring of COVID-19 vaccines."[227] Many of these AESIs were also identified in a July 2020 NEJM study,[228] as well as in an October 16, 2020 JAMA article.[229]

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[226] https://icandecide.org/v-safe-data/.

[227] *See* https://cacmap.fda.gov/media/143530/download at 31.

[228] *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7377258/#ap2.

[229] *See* https://jamanetwork.com/journals/jama/fullarticle/2772137.

Nonetheless, the CDC did not include in the V-safe system any check-the-box options for these harms *or* for common symptoms from these harms. Had the agency done so, it would have enabled the CDC and the scientific community to calculate a rate for which V-safe users had myocarditis, or other adverse events that had been prespecified by the CDC as potential problems (*e.g.*, strokes, seizures, etc.). Instead, the CDC limited potential reporting of such adverse events to free-text fields to which fewer people would report issues and which would be more difficult to standardize.

V-safe was plainly designed to reach a finding that COVID-19 vaccines are safe rather than designed to assess whether COVID-19 vaccines are safe. It only included symptoms that the CDC considers normal and reflect the vaccine is creating immunity, which is also reflected by the fact it only tracked those symptoms for one week after administration. It did not include on the list of symptoms and conditions those that it listed as ones of concern/special interest. It also did not, of its own accord, reveal the health impact data to the public, which appears to be the only actual useful data for assessing safety; only after years of legal demand and litigation did it release the data, which revealed that 7.7% of V-safe users reported seeking medical care after a COVID-19 vaccine, and on average two to three times per user.

CISA

CDC regularly claims that the Clinical Immunization Safety Assessment ("**CISA**") is a critical part of the safety monitoring of vaccines. CDC describes CISA as: "a national collaborating network of vaccine safety experts from the CDC's Immunization Safety Office (ISO), eight medical research centers, and other partners" that was established "to improve the understanding of adverse events following immunization at the individual patient level."[230] CISA, like the other safety surveillance programs, is also problematic for a few reasons.

For one, as CDC states, "CISA provides consultations for U.S. healthcare providers with complex vaccine safety questions about their patients."[231] Our firm has been advised by many who suffered adverse events after their vaccination and who were not believed by their medical providers. Those individuals were unable to utilize CISA as it provides consultations only to healthcare providers and not to individual patients.

Moreover, the Principal Investigator of CISA, Dr. Kathryn Edwards,[232] has also been a paid advisor to Pfizer[233] and/or was compensated by numerous other pharmaceutical companies as a

[230] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html.

[231] *Id.*

[232] https://www.vumc.org/vvrp/person/kathryn-m-edwards-md.

[233] https://www.cbsnews.com/news/covid-19-vaccine-when-will-be-available-ready/.

consultant, including Merck,[234] GSK,[235] Sanofi,[236] Bionet,[237] Connaught, Smith-Kline Beecham, Wyeth Lederle, Moderna, Roche.[238]

SLIDE 52: RISE IN CHRONIC DISEASE

Chronic diseases are "conditions that last 1 year or more and require ongoing medical attention or limit activities of daily living or both."[239] Research confirms that the prevalence of chronic conditions is on the rise among children. In the early 1980s, data reflects that less than 10% of children had a chronic disease.[240] The current rate is above 40% of children.[241]

The chronic diseases that have risen sharply during the preceding decades are often related to some form of immune system dysregulation, including asthma, allergies, ADHD, autism spectrum disorder, atopic dermatitis, diabetes, epilepsy and mental health disorders.[242]

Asthma, allergies, and atopic dermatitis, for example, are caused by a dysregulated immune system that overreacts or reacts to harmless substances.[243] ADHD and autism spectrum disorder are highly associated with immune dysregulation.[244] Epilepsy can be caused by the immune system attacking brain tissue as well as from neuroinflammation, which can be caused by vaccination.[245] Immune

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[234] https://pubmed.ncbi.nlm.nih.gov/30938299/.

[235] https://openpaymentsdata.cms.gov/physician/651167; https://academic.oup.com/jid/article/222/8/1413/5510417.

[236] https://www.nejm.org/doi/10.1056/NEJMoa050824; https://openpaymentsdata.cms.gov/physician/651167.

[237] https://pubmed.ncbi.nlm.nih.gov/32753370/.

[238] https://pubmed.ncbi.nlm.nih.gov/32753370/; https://pedsinreview.aappublications.org/content/19/2/68; https://pubmed.ncbi.nlm.nih.gov/10617749/.

[239] https://www.cdc.gov/chronic-disease/about/index.html.

[240] https://pubmed.ncbi.nlm.nih.gov/3944229/ (https://perma.cc/NGA9-93KW) ("According to data from the National Health Interview Survey (NHIS) [1979-1981] over two million children under 17 years (3.8%) are afflicted by chronic conditions that cause some limitation of activity."); https://pmc.ncbi.nlm.nih.gov/articles/PMC1646496/ (https://perma.cc/KN4A-94TV) ("Data from the National Health Interview Survey indicate that the prevalence of activity-limiting chronic conditions among children under age 17 years doubled between 1960 and 1981, from 1.8 to 3.8 per cent."); https://pubmed.ncbi.nlm.nih.gov/9551003/ (https://perma.cc/JTZ5-JBNK) (Among "children younger than 18 years who were included in the 1992-1994 National Health Interview Survey … [a] significant proportion of children, estimated at 6.5% of all US children, experienced some degree of disability."); https://www.cdc.gov/chronic-disease/about/index.html (https://perma.cc/N4GT-38L2) ("Chronic diseases are defined broadly as conditions that last 1 year or more and require ongoing medical attention or limit activities of daily living or both.").

[241] https://pubmed.ncbi.nlm.nih.gov/21570014/.

[242] https://pmc.ncbi.nlm.nih.gov/articles/PMC5010981/; https://www.academicpedsjnl.net/article/S1876-2859(25)00035-X/fulltext.

[243] https://pubmed.ncbi.nlm.nih.gov/30741719/.

[244] https://pubmed.ncbi.nlm.nih.gov/28849096/;https://pubmed.ncbi.nlm.nih.gov/39426507/; https://pmc.ncbi.nlm.nih. gov/articles/PMC5373490/; https://pubmed.ncbi.nlm.nih.gov/39481220/.

[245] https://pmc.ncbi.nlm.nih.gov/articles/PMC10906461/.

"system dysfunction represents a key mechanism in the onset and pathophysiology of mood disorders."[246]

This widespread disregulation of children's immune systems has reached concerning rates and imposes substantial costs upon society. According to the CDC, "[n]inety percent of the nation's $4.5 trillion in annual health care expenditures are for people with chronic and mental health conditions."[247] The country's cost of chronic disease is "projected to accumulate by 2030 to more than $42 trillion, with medical outlays and productivity losses costing $8,600 per person."[248]

The sharp rise in immune dysregulation-mediated chronic diseases over the preceding decades indicates that one or more environmental factors have caused the widespread dysregulation of our children's immune systems. In considering what could be causing widespread immune system dysregulation, it is critical to rule out products administered specifically to permanently modify the immune system of our children: vaccines. This is especially true given that the rise in these immune and immune-mediated disorders has occurred in lock step with the expansion and level of uptake of CDC-recommended vaccines.

Leading up to and until the late 1980s, the CDC's immunization schedule had three routine vaccines: DTP (diphtheria tetanus pertussis), MMR (measles mumps rubella) and OPV (oral polio vaccine).[249] The first two were injected and the latter was given by oral drop.

In the 1980s, the uptake of these three products was also far below current uptake levels. According to the CDC, as of 1985, the National Health Interview Survey found that among children, only 63.6% had 3 or more doses of DTP, 61.2% had received 1 or more doses of MMR, and 53.6% had received 3 or more doses of OPV.[250] Uptake in children today is above 90% for all three of these vaccines or their current equivalent.[251]

Moreover, the administration of these three vaccines have increased from 7 injections in 1985 (1 MMR, 5 DTP, and 1 Td) to 13 injections for the equivalent vaccines in 2025 (2 MMR, 5 DTaP, 2 Tdap, including one during pregnancy, and 4 IPV).[252] In addition, over 10 additional routine vaccines have been added to the CDC's neonatal and childhood vaccine schedule since 1986, each with multiple doses, including Hep B (3 doses), Hib (3 or 4 doses), and VAR (2 doses) in the 1990s, and PCV (4 doses), IIV (between 1 and 2 doses annually), Hep A (2 doses), MenACWY, RV (2 or 3 doses), HPV (2 or 3 doses), and RSV (1 dose during pregnancy) since 2000.[253]

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[246] https://pubmed.ncbi.nlm.nih.gov/39681901/.

[247] https://www.cdc.gov/chronic-disease/data-research/facts-stats/?CDC_AAref_Val=https://www.cdc.gov/chronicdisease/about/costs/index.htm.

[248] https://doi.org/10.1146/annurev-publhealth-040218-044008.

[249] https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg.

[250] https://web.archive.org/web/20190618125412/https:/www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/coverage-levels.pdf.

[251] https://www.cdc.gov/childvaxview/about/interactive-reports.html.

[252] *Compare* https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg, *with* https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html.

[253] https://www.cdc.gov/vaccines/hcp/imz-schedules/resources.html#.

The increase in the number of vaccines since 1986 is especially pronounced during pregnancy and the first year of a baby's life. By a child's first birthdate, assuming no combination vaccines are used, a child in 1986 following the CDC's vaccine schedule would have received 3 injections with a total of 7 injections throughout childhood, whereas a child in 2025 will receive 25injections by the child's first birthdate with a total of over 50 injections throughout childhood.[254]

When studying environmental factors which could be causing the immune system of our children to dysregulate *en masse*, one factor that must be ruled out is vaccines and whether the increase in vaccine uptake and number of vaccines, especially during infancy, have been a contributing factor. While correlation does not equal causation, it does provide a safety signal that merits investigation, including because vaccines are intended to and do systemically modify the immune system and, thus, could be the cause of widespread immune system dysregulation.

See the Appendix which reviews select chronic diseases that have risen sharply in the last few decades and discuss studies related to vaccines and these diseases.

SLIDE 53: ALUMINUM ADJUVANTS

After injection, aluminum adjuvants in vaccines are picked up by a variety of immune-reactive cells and is then carried all around the body including into the brain. There are animal studies that demonstrate this and there are clinical studies of autism brain tissue that support those animal studies.[255]

SLIDE 56: TRANSMISSION

While some live-attenuated vaccines, such as Varivax for varicella, generally prevent transmission of the target pathogen in most recipients for an extended duration post-vaccination, many of the vaccines routinely recommended by CDC, including the current pertussis, tetanus, and polio vaccines, do not prevent transmission or infection of the diseases they target. See among other sources: https://www.cdc.gov/poliovirus-containment/diseaseandvirus/ ("Inactivated poliovirus vaccine (IPV) [the exclusive polio vaccine used in the United States] … does not stop transmission of the virus."); https://www.cdc.gov/mmwr/volumes/71/wr/mm7133e2.htm ("IPV does not prevent intestinal infection and therefore does not prevent poliovirus transmission."); https://www.fda.gov/media/181937/download ("aP [acellular pertussis] containing vaccines [the exclusive pertussis vaccine used in the United States] induce helper T cells (TH2) memory and neutralizing antibody responses that effectively prevent symptomatic disease but fail to prevent colonization and carriage.") https://pubmed.ncbi.nlm.nih.gov/31333640/ ("Natural infection evokes both mucosal and systemic immune responses, while aPVs [acellular pertussis vaccine] induce only a systemic immune response. … Mucosal immunity is essential to prevent

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[254] *Id.*

[255] Khan 2013 https://pubmed.ncbi.nlm.nih.gov/23557144/; Crépeaux 2015 https://pubmed.ncbi.nlm.nih.gov/26384437/; Eidi 2015 https://pubmed.ncbi.nlm.nih.gov/26082187/; Gherardi 2015 https://pubmed.ncbi.nlm.nih.gov/25699008/; Masson 2022 https://pubmed.ncbi.nlm.nih.gov/36112128/; Angrand 2022 https://pubmed.ncbi.nlm.nih.gov/36136483/; Mold 2020 https://pubmed.ncbi.nlm.nih.gov/32368656/.

colonization and transmission of B. *pertussis* organisms. Consequently, preventive measures such as aPVs that do not induce a valid mucosal response can prevent disease but cannot avoid infection and transmission. … aPV pertussis vaccines do not prevent colonization. Consequently, they do not reduce the circulation of B. pertussis and do not exert any herd immunity effect."); https://www.cdc.gov/vaccines/basics/explaining-how-vaccines-work.html (Tetanus is "not contagious" from person to person."); https://web.archive.org/web/20250112105810/www.cdc.gov/vaccines/vpd/mening/hcp/about-vaccine.html ("data suggest MenACWY vaccines have provided protection to those vaccinated, but not to the larger, unvaccinated community through population or herd immunity").

SLIDES: 66-73: MORTALITY

The CDC estimate that vaccines saved 1.1 million lives in the United States between 1994 and 2023 is routinely cited by third parties even though it is, at best, unreliable.

First, the article including this estimate is not published in a journal, but rather in the MMWR. CDC's own guidelines for the MMWR permit the publication of only articles that align with CDC policy which results in selection bias. As explained by the CDC's policies for publishing an MMWR report: "By the time a report appears in MMWR, it reflects, or is consistent with, CDC policy."[256] And the CDC's policy is that vaccines are safe and effective.

Second, this report provides no confidence intervals for its estimates. This is because they are guesswork. The true rate could be that the vaccines used in the United States from 1994 to 2023 could have saved 1.1 million lives or they could have resulted in 2 million deaths. Since the report provides no bounds for its claims, either claim could be true.

Third, the study explains that "factors other than immunization (e.g., hygiene…) might have contributed to lower disease risks in recent decades, and reductions resulting from these contributions *have not been incorporated into the model*." (Emphasis added.) Meaning, it did not account for any other advancement or factor that may have improved health outcomes. This alone renders this CDC promotion "study" wholly unreliable. It is also why it has no bounds for its estimates because it cannot calculate them with any confidence.

Finally, just a simple review of the data shows its estimate is contrary to the data. While it claims vaccines saved 1.1 million lives between 1994 and 2023, it takes only looking at the actual real-world data to see that this figure is without any merit. This can be seen by reviewing three diseases the report claims account for almost the entire 1.1 million lives purportedly saved: diphtheria, hepatitis B, and measles.

Diphtheria. Around 750,000 of the 1.1 million lives (over 68%) that CDC claims were prevented are from diphtheria. That means that it claims 25,000 lives were saved per year by this vaccine. That figure has no basis in reality.

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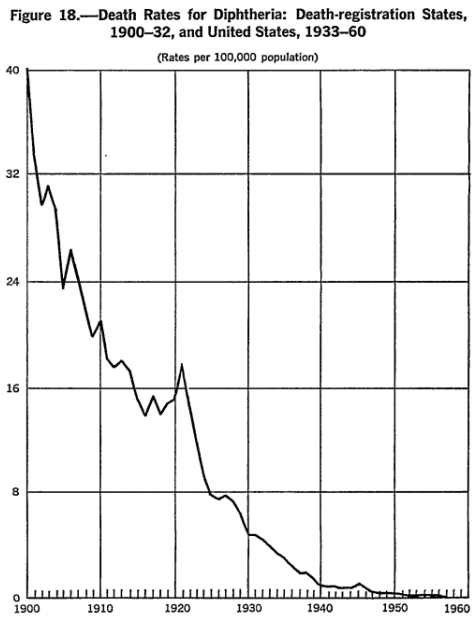
[256] https://www.cdc.gov/mmwr/author_guide_rrss.html.

The first vaccine for diphtheria was introduced in 1926. Between 1900 and 1926, as the population rose, the death rate from this disease had already declined 81%, from 40.3 to 7.8 deaths per 100,000 individuals.[257] A vaccine had nothing to do with this sharp decline since no vaccine of any kind for diphtheria existed until 1926. The further decline from 1926 until at least the mid-1940s also had little or nothing to do with the vaccine because it was rarely, if ever, used outside of certain demographics in major cities, and diphtheria mortality declined at a similar rate in areas with or without its use.[258] To the right is an official government chart reflecting same.[259] So, even as the population increased, the data clearly shows an 81% mortality decline from 1900 to 1926, a 97.3% decline from 1900 to 1940, and a 97.8% decline from 1900 to 1948; hence, using any of these time periods, it is plain vaccination had little to do with almost all of the decline in mortality from diphtheria in the last century:[260]



In 1949, DTP was first licensed, and coverage of this vaccine began to improve, and in 1948, there was a total of 634 deaths from diphtheria.[261] Yet, this MMRW report claims diphtheria vaccine is now saving 25,000 lives a year in the United States. (Also note that in 1985, the coverage for only three doses, let alone the six recommended today, was still only 63.6%.[262])

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[257] https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf.

[258] https://pmc.ncbi.nlm.nih.gov/articles/PMC1997101/pdf/pubhealthreporig01174-0001.pdf ("The simultaneous decline in diphtheria morbidity and mortality rates in all age groups of individual States located in different sections of the country, which began after a cyclic increase in incidence between 1915 and 1925, suggests the operation or influence of other factors besides, or in addition to, artificially induced immunity. Studies such as that included in the 1930 White House Conference on Child Health and Protection indicated that immunization programs were reaching a relatively large proportion of children in some areas or cities and a very low proportion in others, as late as 1930. In spite of this wide variation, both morbidity and mortality began to decline rapidly after 1925 in all States simultaneously."); https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-7-diphtheria.html ("[D]iphtheria toxoid-containing vaccines became available in the 1940s" and "universal childhood vaccination program which included diphtheria toxoid-containing vaccines beginning in the late 1940s.").

[259] https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf at 84.

[260] The death rate per 100,000 individuals in the United States in 1900, 1940, and 1948 for diphtheria was 40.3, 1.1, and 0.4, respectively, for tetanus was 2.4, 0.4., and 0.3, respectively, and for pertussis was 12.2, 2.2, and 0.8, respectively. https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf.

[261] https://www.cdc.gov/Mmwr/preview/mmwrhtml/00038200.htm.

[262] https://web.archive.org/web/20190618125412https:/www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/coverage-levels.pdf.

This claim becomes more nonsensical when considering that even after six childhood doses,[263] adults require a booster dose every ten years in adulthood,[264] and about 40% of adults skip these boosters.[265] Despite a large portion of adults not receiving boosters, the last case of respiratory diphtheria in the United States was nearly three decades ago.[266] This may reflect the literature which supports that its harmful effects may be counteracted by improvement in certain living conditions.[267]

There are diseases that had a high mortality in the United States that disappeared without a vaccine. For many of these diseases, researchers sought to develop a vaccine but failed. For example, scarlet fever was one of the deadliest infectious diseases for children in 1900, with a death rate of 9.6 deaths per 100,000 children. Researchers sought to develop a vaccine but repeatedly failed. By the 1950s, deaths from scarlet fever had significantly declined and by the late 1900s, deaths from scarlet fever were essentially non-existent.[268]

Had a vaccine for scarlet fever been developed in the 1920s, 40s, or 60s, that vaccine may still be on the childhood schedule today, and its use considered essential for controlling scarlet fever, and the MMWR article may estimate that this vaccine today also saves thousands of lives a year from scarlet fever.

Scarlet fever and diphtheria are similar in that each is caused by a bacterium that releases a potentially harmful toxin when the bacterium has been "infected" by a certain virus. Both diseases cause sore throats, and many doctors, without a lab test, will confuse diphtheria with scarlet fever, and vice versa. These two diseases also both declined at nearly the same rate beginning in 1900.

In any event, the CDC's claim that 750,000 lives have been saved from diphtheria between 1994 and 2023 is without footing given the failure to account for the actual mortality data, other factors that reduced morality from diphtheria, the lack of any bounds to its claim, the lack of population wide immunity and other factors, and the objective data regarding this disease. The reality is likely far closer to what occurred with scarlet fever absent vaccination.

Hepatitis B. As another example, the CDC article claims Hep B vaccines saved over 90,000 lives from 1994 to 2023, amounting to over 3,000 lives purportedly saved per year. This claim again defies the data because in 1980, the year before the first Hep B vaccine was introduced, there were 294 deaths in the United States from Hep B.[269]

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[263] https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf.

[264] https://www.cdc.gov/vaccines/hcp/imz-schedules/adult-age.html.

[265] https://www.cdc.gov/adultvaxview/publications-resources/vaccination-coverage-adults-2019-2020.html.

[266] https://www.cdc.gov/diphtheria/php/surveillance/index.html.

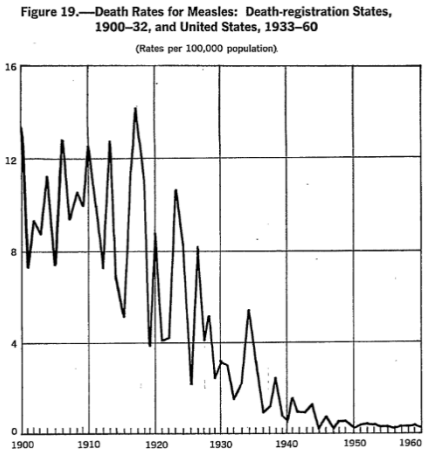
[267] https://pubmed.ncbi.nlm.nih.gov/2151460/; https://pubmed.ncbi.nlm.nih.gov/7830565/; https://pubmed.ncbi.nlm.nih.gov/4326212/; https://pubmed.ncbi.nlm.nih.gov/189004/.

[268] https://www.statnews.com/2017/11/27/scarlet-fever-cases/.

[269] https://web.archive.org/web/20190615081539/https:/www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/reported-cases.pdf.

Measles. As a final example, CDC's advertising article claims measles vaccine saved 85,000 lives from 1994 to 2023, amounting to over 2,700 lives purportedly saved per year. This claim again defies the data. The first measles vaccine came on the market in 1963.[270] In the years leading up to the first measles vaccine in 1963, the CDC data reflects around 400 deaths from measles each year.[271] There were also around 4.2 million births each year in the late 1950s and early 1960s, whereas there was around 3.8 million births each year between 1994 and 2023.[272] Yet, somehow, despite improvements in standards of living, medical care, etc., and despite smaller cohort of infants and children to infect, this model makes the data defying claim mortality went from around 400 deaths per year from measles pre-vaccine to over 2,7000 deaths per year.

Moreover, the following U.S. government chart shows the decline in the measles death rate by over 98% from 1900 to 1960, three years *before* the first measles vaccine was introduced in the United States in 1963.[273] Meaning, the measles vaccine had nothing to do with the over 98% reduction in the death rate from measles in the United States from 1900 to 1960.[274]



Taking a closer look, the CDC data reflects that in 1900, the rate of mortality from measles was 13.3 deaths per 100,000 individuals.[275] By 1960, it was 0.2 deaths per 100,000 individuals.[276] The same was true for 1961 and 1962.[277] And as noted above, a similar decline of over 99% in measles deaths occurred between 1900 and 1967 in England and Wales, and it was only after that decline that the first measles vaccine was introduced there in 1968—five years after its introduction in the United States.[278]

Hence, the same factors that caused measles mortality to decline by over 98% from 1900 to 1962 would, absent the vaccine interrupting the ecology of measles, would likely have continued to cause a further reduction in the measles mortality rate after 1962. Meaning, at least a portion of the decline in the 400 deaths per year *after* the vaccine was available is no doubt attributable to the same factors that caused a steady decline in the measles death rate for decades *prior* to the

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[270] https://www.cdc.gov/measles/about/history.html.

[271] https://web.archive.org/web/20190615081539/https:/www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/reported-cases.pdf.

[272] https://www.cdc.gov/nchs/nvss/births.htm.

[273] https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf at 85.

[274] *Id.*

[275] *Id.*

[276] https://www.cdc.gov/nchs/data/vsus/VSUS_1962_2A.pdf.

[277] *Id.*

[278] https://webarchive.nationalarchives.gov.uk/ukgwa/20160111174808/http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-215593.

introduction of the measles vaccine. Therefore, even without the measles vaccine, the death rate would have, no doubt, continued to decline after 1963.

In pockets of the country with poor nutrition, sanitation, and water, deaths from any pathogen, including measles, can occur at a higher rate. Those conditions still existed in some pockets of the United States in the early 1960s. As living conditions in those pockets of America improved with the introduction of clean water, improved sanitation, and better living conditions, deaths from measles declined, which is what typically occurs when these conditions improve. Also health care, especially the management and treatment of acute infections, has vastly improved since the 1960s.

Yet, CDC claims that measles vaccines saved a data defying over 2,800 lives a year from measles in the United States between 1994 and 2023. CDC's study also doesn't account for the increase in deaths from heart disease and cancer due to the elimination of measles, discussed below and reflected by studies that did not engage in estimates.

In sum, the CDC article must conform to CDC policy to be published, does not account for any external factors, does not account for actual mortality data related to these diseases, and lacks any confidence intervals because its claims have no statistical reliability. Thus, this study claiming 1.1 million lives were saved is unreliable at best.

SLIDE 72: MEASLES

A study which followed over 100,000 individuals in Japan for approximately 21 years found that those who had been infected with measles and mumps had a statistically significant lower risk of death from cardiovascular disease, strokes, and heart attacks.[279] For example, men who had measles and mumps (as compared to those who did not have measles and mumps), had a 17% reduction in strokes, 20% reduction in cardiovascular disease, and 29% reduction in heart attacks.[280] Critically, after 21 years, approximately 7% of the men who had measles and mumps had died of cardiovascular disease while approximately 14% of the men who never had measles or mumps died of cardiovascular disease.[281] Meaning, the men who never had measles and mumps were far more likely to die. The statistically significant findings in this study remained statistically significant even after adjusting its results for: age; body mass; family history of cardiovascular disease; alcohol intake; energy intake; smoking; walking; sports; mental stress; education; and history of hypertension, cardiovascular disease, or diabetes.[282]

Cardiovascular disease is the number one killer of Americans, taking the lives of over 900,000 Americans a year.[283] In contrast, as discussed above, according to the CDC, around 400 Americans died of measles annually in the several years before the first measles vaccine arrived in 1963 (and

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[279] https://pubmed.ncbi.nlm.nih.gov/26122188/ (https://perma.cc/6TJD-5FNZ).

[280] *Id.*

[281] *Id.*

[282] *Id.*

[283] https://www.cdc.gov/heart-disease/data-research/facts-stats/.

this number was declining without a vaccine), and around 40 Americans died annually of mumps in the several years before the first mumps vaccine was introduced in 1967.[284]

This Japanese study may reflect why measles, unlike most pathogens, may not have died out over time through natural selection.

Similar to the finding regarding heart disease, some studies, although not nearly as robust, have found that eliminating measles appears to have caused a measurable increase in certain cancer rates. For example, the International Agency for Research on Cancer found that those who never had measles had a 66% increased rate of non-Hodgkin lymphoma and a 233% increased rate of Hodgkin lymphoma.[285] These two cancers are expected to kill an estimated 20,540 Americans in 2025.[286] There are also studies documenting children with Hodgkin's disease experiencing remission when having measles.[287]

Likewise, researchers at the Department of Health Care and Epidemiology at the University of British Columbia and the Department of Biology at the University of Victoria found that those who never had measles had a 50% increased rate of ovarian cancer, which is expected to kill an estimated 12,730 Americans in 2025.[288]

Other studies have reached similar conclusions that measles, as well as mumps, rubella, pertussis, and chickenpox, reduce the rate of various forms of cancers, including a study from researchers at the University of Berne, Switzerland that specifically reviewed these fever-inducing (*i.e.*, febrile) infections and found that the "study consistently revealed a lower cancer risk for patients with a history of FICD [febrile infectious childhood diseases]."[289] And as an article in *The Quarterly Review of Biology* explained:

> [D]etailed retrospective and prospective clinical studies … supported the conclusion that frequency of the infectious fever episodes and cancer diagnoses are inversely related (Abel et al. 1986; Mastrangelo et al. 1998; Kleef et al. 2001; Kleef and Hager 2006). For example, Grossarth-Maticek et al. (1987) performed a 10-year prospective cohort study of 1353 patients, concluding that episodes of high fever as a typical reaction to an acute illness during the entire life span are inversely related to later cancer incidence. Kölmel et al. (1992), based on 271 controls versus 139 melanoma patients, demonstrated an inverse relation between the number of

[284] https://icandecide.org/wp-content/uploads/2023/10/cdc-reported-cases-and-deaths-m-vaccine-preventable-diseases-3.pdf.

[285] https://pubmed.ncbi.nlm.nih.gov/16406019/ (https://perma.cc/RHD3-986B). *See* Table 2 and in the Non-Hodgkin's Lymphoma (NHL) column divide the odds ratio 1 (never had measles) with .6 (had measles) which results in a 66% increased risk, and in the Hodgkin's Lymphoma (HL) column divide the odds ratio 1 (never had measles) with .3 (had measles) which results in a 233% increased risk.

[286] https://seer.cancer.gov/statfacts/html/hodg.html; https://seer.cancer.gov/statfacts/html/nhl.html.

[287] https://pubmed.ncbi.nlm.nih.gov/4574047/.

[288] https://pubmed.ncbi.nlm.nih.gov/16490323/; https://seer.cancer.gov/statfacts/html/ovary.html.

[289] https://pubmed.ncbi.nlm.nih.gov/9824838/.

> febrile infections and the incidence of malignant melanoma. Similarly, Wrotek et al. (2009) have reported a lower frequency of fever in a population of 355 breast tumor patients, compared to 244 healthy women volunteers.[290]

This article also explained how a survey of studies of spontaneous cancer remissions found that "approximately 70% of documented cases [of remission] were immediately preceded by an acute infection associated with high fever" and that this phenomenon has "been reported for centuries."[291]

There are also studies that have found that children who have had measles have far fewer allergies and atopic diseases, such as asthma, and adults who have had measles have a reduced risk of Parkinson's disease.[292]

SLIDE 73: MORTALITY TABLE

Disease	Year Vaccine Licensed	Number of Deaths in Year Prior to Licensure
Diphtheria	1949 (DTP)	634
Pertussis		1,146
Tetanus		506
Polio	1955	1,368
Measles	1963	408
Mumps	1967	43
Rubella	1969	24
Hepatitis B	1981	294
Hib	1990	34
Hepatitis A	1995	97
Varicella	1995	124
Pneumococcal	2000	200
Meningococcal	2005	8
Rotavirus	2006	20

[290] https://www.journals.uchicago.edu/doi/10.1086/699409.

[291] *Id.*

[292] https://pubmed.ncbi.nlm.nih.gov/19255001/; https://pubmed.ncbi.nlm.nih.gov/16854347/; https://pubmed.ncbi.nlm.nih.gov/4061437/.

Diphtheria, Tetanus, & Pertussis

Scanning down from the top of the table above, note that when a vaccine was introduced for each disease, U.S. deaths were already rare. Also, most of the deaths are attributed to diseases for which vaccines were introduced before 1950 (diphtheria, pertussis, and tetanus). The mortality rate for these three diseases had already precipitously declined before introduction or material use of a vaccine and would likely have continued to decline without a vaccine. This chart, using CDC data, reflects the decline between 1900 and 1949, the year DTP was licensed (as well as the decline between 1900 and 1940):[293]

Disease	% Mortality Decline Between 1900 and 1940	% Mortality Decline Between 1900 and 1949
Diphtheria	97.3%	97.8%
Pertussis	83.3%	92.6%
Tetanus	82.0%	87.5%

Diphtheria was discussed above in the "Slides: 66-73: Mortality" section. As for tetanus and pertussis, the mortality from these diseases declined by more than 80-90% between 1900 and the 1940s—long before vaccination played a role.[294] These vaccines were first introduced into routine use in the late 1940s with the licensure of DTP in 1949. As explained by the NIH: "The whole-cell pertussis vaccine became widely available in the United States in the 1940s, although it was first licensed in 1914. It was crudely made and had limited use until the 1940s, because of reports of serious side effects including death."[295] Similarly, as CDC explains regarding the tetanus vaccine: "In the late 1940s, tetanus toxoid-containing vaccines were introduced into routine childhood vaccination."[296]

What caused the decline in diphtheria, tetanus, pertussis, and other diseases before introduction of vaccination (and thereafter)? This decline is likely caused by many factors, including improvements in sanitation, clean water, nutrition, and medical care. For example, medical care acutely improved from the 1940s when the Nobel Prize was awarded for the development of the prefrontal lobotomy.[297] Even absent a vaccine, the death rate would have continued to decline as

[293] The death rate per 100,000 individuals in the United States in 1900, 1940, and 1948 for diphtheria was 40.3, 1.1, and 0.4, respectively, for tetanus was 2.4, 0.4., and 0.3, respectively, and for pertussis was 12.2, 2.2, and 0.8, respectively. https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf.

[294] The death rate per 100,000 individuals in the United States in 1900, 1940, and 1948 for tetanus was 2.4, 0.4., and 0.3, respectively, and for pertussis was 12.2, 2.2, and 0.8, respectively. https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf.

[295] https://web.archive.org/web/20250407045130/https://history.nih.gov/display/history/Pertussis.

[296] https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-21-tetanus.html.

[297] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4291941/.

living conditions improved, including improvements in medical care, and particularly acute medical care (as well as the decline of certain harmful medical practices).

Nonetheless, even assuming the number of deaths from a given disease remained stagnant since the year before the first vaccine for each disease was introduced, the total deaths per year, combined, would be in the low thousands. Every death is a tragedy, but this is far from the millions often claimed, and the death figures in the above chart (from a few pages back) do not account for the fact that, even absent a vaccine, the deaths caused by these diseases were almost universally on a sharp decline.

This decline would have no doubt continued absent vaccination. Meaning, had the vaccines of the 1940s instead been introduced in the 1960s or 1970s, deaths would have already declined to a mere fraction of their 1940s levels.

Polio

Next on the above chart is polio, the only disease for which a vaccine was introduced in the 1950s. In contrast to every other disease listed, where mortality was sharply declining in the decades before and after 1900, polio caused almost no deaths in 1900. Instead, it paradoxically went from being nearly innocuous up until around 1890, to then having an increasing rate of mortality, to then having a sharply increasing reported rate of mortality in the few years leading up to 1952. From that peak, its mortality rate declined sharply before introduction of the first polio vaccine in 1955. What this and the greater history about polio reflect is that one or more factors made the polio virus more lethal in the first half of the 1900s. As these outside factors declined, so did the mortality of polio.

Measles, Mumps, & Rubella

Next on the above chart is measles, which is also discussed above. The rate of mortality from measles declined by over 98% between 1900 and 1962, prior to the introduction of the first measles vaccine in 1963 and would have no doubt continued to decline without a measles vaccine.

Next on the list are mumps and rubella. The first vaccine for each was introduced in 1967 and 1969, respectively. By the time a vaccine was developed, both diseases caused few deaths annually in the several years before a vaccine was developed.[298] In addition, between 1960 and 1975, the rate of decline in mumps deaths continued at roughly the same pace before and after licensure of mumps vaccine in 1967, and the rubella deaths actually *increased* after licensure of the first rubella vaccine in 1969.[299] But either way the number of deaths were few.

Further evidencing that mumps would have disappeared without a mumps vaccine, at most 50% to 60% of children received this product in the 1970s, and they only received one dose (and we

[298] https://web.archive.org/web/20190615081539/https:/www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/reported-cases.pdf.

[299] *Id.*

now know that even two doses of the same formulation, let alone one, often fails to confer protective immunity), but mortality from mumps reached essentially zero in the 1970s.[300]

Hepatitis B

Next on the above chart is Hep B, a primarily blood-borne infection that is typically spread through sexual contact and contaminated needles. The first Hep B vaccine was introduced in 1981 and made with human blood plasma from donors who were chronically infected with the Hep B virus. In 1986, a new Hep B vaccine using recombinant DNA technology without human blood was licensed. The mortality from Hep B climbed after introduction of the 1981 vaccine, continued to climb after the introduction of the 1986 vaccine, and has never returned to pre-vaccination levels. In 1980, there were 294 deaths in the United States from Hep B.[301] Today, there are around 1,700 deaths per year.[302]

Hib

Next on the above chart is Hib vaccine. The first Hib vaccine was introduced in 1985 but was withdrawn three years later because it was entirely ineffective among children 18 months and younger and may have increased the incidence of disease in older children.[303]

In 1991, after another Hib vaccine considered effective was introduced, the CDC for the first time recommended a three-dose series of Hib vaccine in the first year of life.[304] In 1992, only 28.2% of children were vaccinated for Hib, and there were a total of 17 deaths from Hib in the United States in 1991.[305] Yet, the steady decline in mortality from Hib in the prior decades, which had dropped rapidly without the existence of any Hib vaccine, is attributed to the Hib vaccine.[306]

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[300] *Compare* https://web.archive.org/web/20190615081539/https:/www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/reported-cases.pdf *with* https://web.archive.org/web/20190618125412/https:/www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/coverage-levels.pdf; *see also* https://storage.courtlistener.com/recap/gov.uscourts.paed.381331.12.0.pdf; https://pubmed.ncbi.nlm.nih.gov/35728505/; https://pubmed.ncbi.nlm.nih.gov/8277201/.

[301] https://web.archive.org/web/20190615081539/https:/www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/reported-cases.pdf.

[302] https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b/table-2.8.htm.

[303] https://web.archive.org/web/20120506033120/http://www.cdc.gov:80/vaccines/pubs/pinkbook/hib.html ("A pure polysaccharide vaccine (HbPV) was licensed in the United States in 1985. The vaccine was not effective in children younger than 18 months of age. Estimates of efficacy in older children varied widely, from 88% to -69% (a negative efficacy implies greater disease risk for vaccinees than nonvaccinees). HbPV was used until 1988 but is no longer available in the United States.").

[304] https://www.cdc.gov/acip-recs/hcp/vaccine-specific/hib.html.

[305] *Compare* https://web.archive.org/web/20190615081539/https:/www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/reported-cases.pdf; https://www.cdc.gov/acip-recs/hcp/vaccine-specific/hib.html; *with* https://web.archive.org/web/20190618125412; /https:/www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/coverage-levels.pdf.

[306] https://www.cdc.gov/nchs/data/statab/hist001r.pdf.

Notably, mortality among infants under 1 year of age in the 1980s declined rapidly and sharply when there was no Hib vaccine for infants (not even an ineffective one like the one introduced in 1985 for children 18 months and older and then withdrawn a few years later for lack of efficacy).[307]

Hepatitis A

Next is Hep A vaccine. In the decade prior to introduction of this vaccine in 1995, there were *fewer than* 100 deaths every year in the United States from Hep A, with an average of 80 deaths per year.[308] Fast forward to the present, there have consistently been *more than* 100 deaths per year from Hep A, with an average of 166 deaths during the last five years for which death figures are available.[309]

Varicella, Pneumococcal, Meningococcal, & Rotavirus

For the final four diseases on the above chart, varicella, pneumococcal, meningococcal, and rotavirus, the annual deaths among children for each are so low that the CDC has to estimate them. This was not always the case. Long before vaccines were introduced, each of these diseases did cause deaths each year that could be counted. But by the time a vaccine was introduced, the deaths had already become so exceedingly rare, if they occurred at all, that all they could do for these four diseases was estimate. For example, the CDC admits regarding meningococcal: "Much of the decline occurred before the routine use of MenACWY vaccines. In addition, serogroup B meningococcal disease declined even though MenB vaccines were not available until the end of 2014."[310]

Even assuming the estimated deaths are accurate, these estimates reflect that an American, prior to a vaccine even existing, had around the same odds of dying from each of these four diseases as being killed by lightning.

APPENDIX

While the post-licensure vaccine safety literature is limited, this section lists findings from a relatively small pool of existing studies and reviews that either reached a positive finding of a connection between one or more vaccines and a limited number of diseases or found that the existing evidence is insufficient to reach any definitive conclusion. Either of these findings warrant further investigation as they evidence that either the studies indicate there is a basis for vaccines as a cause or the studies have not been done to rule out vaccines as a cause of a claimed harm from

[307] *Id.*

[308] https://web.archive.org/web/20190615081539/https:/www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/reported-cases.pdf.

[309] https://www.cdc.gov/hepatitis-surveillance-2022/hepatitis-a/table-1-4.html.

[310] https://www.cdc.gov/vaccines/vpd/mening/hcp/about-vaccine.html.

these products. Note that this is not intended as a full survey of the literature and there are more studies to be included below. Note also that this section does not discuss COVID-19 vaccines.

1. **Acute Disseminated Encephalomyelitis (ADEM)**

   a. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and ADEM [acute disseminated encephalomyelitis]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

   b. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and ADEM [acute disseminated encephalomyelitis]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

   c. "The evidence is inadequate to accept or reject a causal relationship between varicella vaccine and ADEM [acute disseminated encephalomyelitis]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

   d. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and ADEM [acute disseminated encephalomyelitis]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

   e. "The evidence is inadequate to accept or reject a causal relationship between HPV vaccine and ADEM [acute disseminated encephalomyelitis]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

   f. "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and ADEM [acute disseminated encephalomyelitis]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

   g. "The evidence is inadequate to accept or reject a causal relationship between meningococcal vaccine and ADEM [acute disseminated encephalomyelitis]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

   h. "The evidence is inadequate to accept or reject a causal relationship between hepatitis A vaccine and ADEM [acute disseminated encephalomyelitis]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

   i. "ADEM typically appears with the abrupt onset of neurologic symptoms 2 to 30 days after the occurrence of a preceding infection or vaccination." Noorbakhsh F., Johnson RT, Emery D., Power C. (2008). *Acute disseminated encephalomyelitis: clinical and pathogenesis features.* Neurologic Clinics 26(3):759-80. https://pmc.ncbi.nlm.nih.gov/articles/PMC7132764/

   j. "The review focused on 23 cases linking acute disseminated encephalomyelitis (ADEM) to influenza vaccination, gathered from 19 comprehensive articles." Mashkoor Y, Nadeem A, Fatima T, Aamir M, Vohra LI, Habib A, Khan A, Raufi N, Habte A. (2024). *Neurological complications of influenza vaccination:*

navigating the spectrum with a focus on acute disseminated encephalomyelitis (ADEM). Ann Med Surg (Lond). 86(2):1029-1041. https://pubmed.ncbi.nlm.nih.gov/38333316/

k. "Post-vaccination ADEM has been associated with several vaccines such as rabies, diphtheria–tetanus–polio, smallpox, measles, mumps, rubella, Japanese B encephalitis, pertussis, influenza, hepatitis B, and the Hog vaccine. We review ADEM with particular emphasis on vaccination as the precipitating factor." Huynh W, Cordato DJ, Kehdi E, Masters LT, Dedousis C. (2008) *Post-vaccination encephalomyelitis: literature review and illustrative case.* J Clin Neurosci. 15(12):1315-22. https://pmc.ncbi.nlm.nih.gov/articles/PMC7125578/

2. **Acute Renal Failure**
   a. "This is the fourth case report of acute renal failure after influenza vaccination in patients on statins therapy. The case we describe could account for a [sic] underestimated, even if very rare, phenomenon." Novati R, Nebiolo PE, Galotto C, Mastaglia M, Manes M. (2014) *Acute renal failure after influenza vaccination: a case report.* J Prev Med Hyg. 55(1):31-2. https://pubmed.ncbi.nlm.nih.gov/25916030/

3. **Allergy**
   a. "This study evaluated different dosage forms of aluminum adjuvant in generating allergic rhinitis animal models." Xi et al. (2014). *Role of aluminum adjuvant in producing an allergic rhinitis animal model.* Genetics and Molecular Research 13(3):5173-5181. https://pubmed.ncbi.nlm.nih.gov/25061742/

4. **Alopecia**
   a. "Adults receiving HBV had significantly increased odds ratios (OR) for…alopecia (OR = 7.2, $p < 0.0001$, 95% CI = 3.2 - 20)…in comparison to the TCV [control] group. Minimal confounding or systematic error was observed." Geier DA, Geier MR. (2005). *A case-control study of serious autoimmune adverse events following hepatitis B immunization*. Autoimmunity. 38(4):295-301. https://pubmed.ncbi.nlm.nih.gov/16206512/

5. **Amyotrophic lateral sclerosis (ALS)**
   a. "The evidence is inadequate to accept or reject a causal relationship between HPV vaccine and ALS." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

   b. "Another issue we should consider in this case is the possibility that the HPV vaccine accelerated the ALS pathogenesis and hastened the disease onset. The HPV vaccine contains a potent toll-like receptor 4 activator as an adjuvant, and recent animal studies have shown that toll-like receptor 4 activation is involved in the pathogenesis of ALS (9,10). Thus, at this time, it is too premature to conclude whether or not the HPV vaccine is completely safe in individuals with neurological conditions, and further investigations are needed. " Hikiami R, Yamakado H, Tatsumi S, Ayaki T, Hashi Y, Yamashita H, Sawamoto N, Tsuji T, Urushitani M, Takahashi R. (2018). *Amyotrophic Lateral Sclerosis after Receiving the Human Papilloma Virus Vaccine: A Case Report of a 15-year-old Girl.* Intern Med. 57(13):1917-1919. https://pmc.ncbi.nlm.nih.gov/articles/PMC6064690/

6. **Anaphylaxis**
   a. "The evidence convincingly supports a causal relationship between MMR vaccine and anaphylaxis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

   b. "The evidence convincingly supports a causal relationship between varicella vaccine and anaphylaxis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. “The evidence convincingly supports a causal relationship between varicella vaccine and anaphylaxis.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

d. “The evidence convincingly supports a causal relationship between hepatitis B vaccine and anaphylaxis in yeast sensitive individuals.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

e. “The evidence convincingly supports a causal relationship between tetanus toxoid vaccine and anaphylaxis.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

f. “The evidence convincingly supports a causal relationship between meningococcal vaccine and anaphylaxis.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

g. “The evidence favors acceptance of a causal relation between measles vaccine and anaphylaxis.” Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

h. “The committee concludes that the evidence favors acceptance of a causal relationship between HPV vaccine and anaphylaxis.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

i. “The evidence establishes a causal relation between DT, Td, and tetanus toxoid and anaphylaxis.” “The evidence establishes a causal relation between DT, Td, and tetanus toxoid and death from anaphylaxis.” Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

j. “The evidence establishes a causal relation between hepatitis B vaccine and fatal anaphylaxis.” Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

k. “Non-physiological AEFI [adverse event following immunization], sometimes referred to as hyper-reactions, are rare, unexpected and more severe than physiological AEFI, and they tend to occur in immunocompromised patients or patients allergic to vaccine components []. The most severe AEFI are either allergic (anaphylaxis) or neurological (encephalopathy, encephalitis, neuritis), and can lead to hospitalization or death [].” Danova J, Kocourkova A, Celko AM. (2017). *Active surveillance study of adverse events following immunisation of children in the Czech Republic*. BMC Public Health. 17(1):167. https://pmc.ncbi.nlm.nih.gov/articles/PMC5292794/

l. “Six papers pertaining to fatal anaphylaxis following vaccination were found relevant.” Palmiere C, Tettamanti C, Scarpelli MP. (2017). *Vaccination and anaphylaxis: a forensic perspective*. Croat Med J. 58(1):14-25. https://pubmed.ncbi.nlm.nih.gov/28252871/

m. “We identified 13 anaphylaxis reports following MMR; 11 (84.6%) were serious. Seven reports met Brighton level 1 case definition of anaphylaxis. The other 6 were Brighton level 2. All had symptom onset within 24 hours of vaccination; most (10) within 1 hour.” Sukumaran L, McNeil MM, Moro PL, Lewis PW, Winiecki SK, Shimabukuro TT. (2015). *Adverse Events Following Measles, Mumps, and Rubella Vaccine in*

Adults Reported to the Vaccine Adverse Event Reporting System (VAERS), 2003-2013. Clin Infect Dis. 60(10):e58-65. https://pmc.ncbi.nlm.nih.gov/articles/PMC4447805/

n. "Comparison of adverse events in different ages following acellular anti-pertussis vaccines shows no significant differences in febrile reactions, seizures and allergic reactions, which almost evenly occur in both age groups." Patterson J, Kagina BM, Gold M, Hussey GD, Muloiwa R. (2018). *Comparison of adverse events following immunisation with acellular and whole-cell pertussis vaccines: A systematic review.* Vaccine. 36(40):6007-6016. https://pubmed.ncbi.nlm.nih.gov/30143272/

7. **Antiphospholipid syndrome (APS)**

a. "Successful induction of antiphospholipid syndrome (APS) in two different non-autoimmune prone mouse strains …, was achieved by tetanus toxoid (TTd) hyperimmunization using different adjuvants … and different adjuvant pretreatments. … In this paper we have explained our model of APS based on TTd hyperimmunization which supports the concept of the mosaic of autoimmunity." L. Dimitrijevic et al. (2012). *Vaccine model of antiphospholipid syndrome induced by tetanus vaccine.* Lupus 21(2):195-202. https://pubmed.ncbi.nlm.nih.gov/22235053/

b. "There are few reports of autoimmune diseases, such as rheumatoid arthritis and anti-phospholipid syndrome after anti-tetanus vaccination. Herein, we describe four cases, of which we believe, show a clear temporal relation between anti-tetanus vaccination and the appearance of dermatomyositis, systemic lupus erythematosus, type 1 diabetes mellitus and anti-phospholipid syndrome." Ruhrman-Shahar N, Torres-Ruiz J, Rotman-Pikielny P, Levy Y. (2017). *Autoimmune reaction after anti-tetanus vaccination-description of four cases and review of the literature*. Immunol Res. 65(1):157-163. https://pubmed.ncbi.nlm.nih.gov/27435706/

c. "We included in this review animal models for rheumatoid arthritis-like disease, for systemic lupus erythematosus-like disease, autoimmune thyroid disease-like disease, antiphospholipid syndrome, myocarditis and others. All these models support the concept of ASIA, as the Autoimmune (Auto-inflammatory) Syndrome Induced by Adjuvants." Cruz-Tapias P, Agmon-Levin N, Israeli E, Anaya JM, Shoenfeld Y. (2013). *Autoimmune (auto-inflammatory) syndrome induced by adjuvants (ASIA)--animal models as a proof of concept*. Curr Med Chem. 20(32):4030-6. https://pubmed.ncbi.nlm.nih.gov/23992328/

8. **Apnea**

a. "Infants in NICU had an increased incidence of sepsis evaluations and increased respiratory support and intubation after routine immunization." DeMeo SD et al. (2015). *Adverse Events After Routine Immunization of Extremely Low-Birth-Weight Infants.* JAMA Pediatr. 169(8):740–745. https://pmc.ncbi.nlm.nih.gov/articles/PMC4523398/

b. "For infants in the NICU without apnea during the 24 hours immediately before immunization, younger age, smaller size, and more severe illness at birth are important predictors of postimmunization apnea." Klein et al. (2008). *Risk Factors for Developing Apnea After Immunization in the Neonatal Intensive Care Unit.* Pediatrics 121(3):463–469. https://pubmed.ncbi.nlm.nih.gov/18310193/

c. "The majority of preterm infants tolerated immunizations with DTP and HibC without ill effects. However, 12 (12%) infants experienced a recurrence of apnea, and 11 (11%) had at least a 50% increase in the number of apneic and bradycardic episodes in the 72 hours after immunization." Sánchez PJ, Laptook AR, Fisher L, Sumner J, Risser RC, Perlman JM. (1997). *Apnea after immunization of preterm infants.* J Pediatr. 130(5):746-51. https://pubmed.ncbi.nlm.nih.gov/9152284/

d. "In hospitalized preterm infants, the odds of apnea within 48 hours were higher after 2-month vaccinations vs after no vaccinations." Greenberg RG, et al. (2025). *Apnea After 2-Month Vaccinations in Hospitalized Preterm Infants: A Randomized Clinical Trial*. JAMA Pediatr. 179(3):246-254. https://pubmed.ncbi.nlm.nih.gov/39761016/

9. **Arthritis/Arthropathy/Arthralgia**

a. "The evidence favors acceptance of a causal relationship between MMR vaccine and transient arthralgia in women." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence favors acceptance of a causal relationship between MMR vaccine and transient arthralgia in children." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and chronic arthralgia in women." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

d. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and chronic arthropathy in children." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

e. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and arthropathy in men." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

f. "The evidence is inadequate to accept or reject a causal relationship between varicella vaccine and onset or exacerbation of arthropathy." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

g. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and onset or exacerbation of psoriatic arthritis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

h. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and onset or exacerbation of reactive arthritis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

i. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and onset or exacerbation of rheumatoid arthritis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US) https://pubmed.ncbi.nlm.nih.gov/24624471/

j. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and onset or exacerbation of juvenile idiopathic arthritis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

k. "The evidence is inadequate to accept or reject a causal relationship between HPV vaccine and transient arthralgia." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

l. "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and arthropathy." Stratton, K., Ford, A., Rusch, E., Clayton,

E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

m. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and onset or exacerbation of arthropathy." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

n. "The Advisory Committee of Immunization Practices at the Centers for Disease Control and Prevention concluded 3 years later that a causal relationship exists between arthritis and two vaccination combinations: diphtheria-tetanus-pertussis (DTP) and measles-mumps-rubella (MMR)." Agmon-Levin N, Paz Z, Israeli E, Shoenfeld Y. (2009). *Vaccines and autoimmunity*. Nat Rev Rheumatol. 5(11):648-52. https://pubmed.ncbi.nlm.nih.gov/19865091/

o. "We identified 15 reports of arthritis or arthralgia following MMR. All were in females, and onset ranged from 0 to 19 days postvaccination. One report was serious and involved a patient subsequently diagnosed with rheumatoid arthritis." Sukumaran L, McNeil MM, Moro PL, Lewis PW, Winiecki SK, Shimabukuro TT. (2015). *Adverse Events Following Measles, Mumps, and Rubella Vaccine in Adults Reported to the Vaccine Adverse Event Reporting System (VAERS), 2003-2013.* Clin Infect Dis. 60(10):e58-65. https://pmc.ncbi.nlm.nih.gov/articles/PMC4447805/

p. "Adults receiving HBV had significantly increased odds ratios (OR) for…arthritis (OR = 2.01, $p < 0.0003$, 95% CI = 1.3 - 3.1)…in comparison to the TCV [control] group." Geier DA, Geier MR. (2005). *A case-control study of serious autoimmune adverse events following hepatitis B immunization*. Autoimmunity. 38(4):295-301. https://pubmed.ncbi.nlm.nih.gov/16206512/

q. "Recombinant hepatitis B vaccine may trigger the development of Rheumatoid Arthritis in MHC class II genetically susceptible individuals." Pope, J.E., Stevens, A., Howson, W., Bell, D.A. (1998). *The development of rheumatoid arthritis after recombinant hepatitis B vaccination*. J Rheumatol. https://pubmed.ncbi.nlm.nih.gov/9733447/

r. "Adults receiving HBV [Hepatitis B Vaccine] had significantly increased odds ratios (OR) for…rheumatoid arthritis (OR = 18, $p < 0.0001$, 95% CI = 3.1 - 740)…in comparison to the [control] group. Minimal confounding or systematic error was observed." Geier, D.A., Geier, M.R. (2005). *A case-control study of serious autoimmune adverse events following hepatitis B immunization*. Autoimmunity. https://pubmed.ncbi.nlm.nih.gov/16206512/

10. **Asthma**

a. "The evidence is inadequate to accept or reject a causal relationship between LAIV [live attenuated influenza vaccine] and asthma exacerbation or reactive airway disease episodes in children younger than 5 years of age." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence is inadequate to accept or reject a causal relationship between LAIV [live attenuated influenza vaccine] and asthma exacerbation or reactive airway disease episodes in persons 5 years of age or older." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "Among children with eczema, vaccine-associated aluminum was positively associated with persistent asthma (aHR 1.26 per 1 mg increase in aluminum, 95% CI 1.07, 1.49); a positive association was also detected among children without eczema (aHR 1.19, 95% CI 1.14, 1.25)." Daley MF, Reifler LM, Glanz JM, Hambidge SJ, Getahun D, Irving SA, Nordin JD, McClure DL, Klein NP, Jackson ML, Kamidani S, Duffy J, DeStefano F. (2023). *Association Between Aluminum Exposure From Vaccines Before Age 24 Months and*

Persistent Asthma at Age 24 to 59 Months. Acad Pediatr. 23(1):37-46. https://pubmed.ncbi.nlm.nih.gov/29458196/

d. "In this study, which only allowed for the calculation of unadjusted observational associations, higher ORs were observed within the vaccinated versus unvaccinated group for developmental delays, asthma and ear infections. Further study is necessary to understand the full spectrum of health effects associated with childhood vaccination." Hooker BS, Miller NZ. (2020). *Analysis of health outcomes in vaccinated and unvaccinated children: Developmental delays, asthma, ear infections and gastrointestinal disorders*. SAGE Open Med. 8:2050312120925344. https://pubmed.ncbi.nlm.nih.gov/32537156/

11. **Ataxia**

a. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and ataxia." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence is inadequate to accept or reject a causal relationship between varicella vaccine and cerebellar ataxia." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and ataxia." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

d. "550 notification records of adverse events after MMR vaccination at 15 mo of age have been registered, and a total of 41 notifications have included "gait disturbance". This corresponds to a frequency of 8 per 100 000 doses of MMR vaccine used for 15-mo-old children. The symptoms and signs are characteristic of cerebellar ataxia." Plesner AM, Hansen FJ, Taudorf K, Nielsen LH, Larsen CB, Pedersen E. (2000). *Gait disturbance interpreted as cerebellar ataxia after MMR vaccination at 15 months of age: a follow-up study.* Acta Paediatr. 89(1):58-63. https://pubmed.ncbi.nlm.nih.gov/10677059/

e. "The report of most cases of ataxia within the first 6 weeks after vaccination (when the date of vaccination is known), reveals an unbalanced distribution of occurrence in this time period, with most cases reported in the first two weeks. This may suggest that some cases of ataxia are triggered by vaccination and warrants continuous and careful analysis of such cases after vaccination." Sheikh et al. (2012). *Ataxia after Vaccination in United States, a Report from the CDC/FDA Vaccine Adverse Event Reporting System [1990–2010] (P05.016)*. Neurology. 78(Meeting Abstracts 1). https://www.neurology.org/doi/10.1212/wnl.78.1_supplement.p05.016

f. "Although immunization with meningococcal group C conjugate vaccines has been associated with several neurological side effects, acute cerebellar ataxia has not been previously reported. The authors describe a case of a 12-year-old girl exhibiting acute cerebellar ataxia following meningococcal group C conjugate vaccination." Cutroneo PM, Italiano D, Trifirò G, Tortorella G, Russo A, Isola S, Caputi AP, Spina E. (2014). *Acute cerebellar ataxia following meningococcal group C conjugate vaccination.* J Child Neurol. 29(1):128-30. https://pubmed.ncbi.nlm.nih.gov/23275434/

12. **Autism**

a. "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. “The application of the Hill’s criteria to these data indicates that the correlation between Al in vaccines and ASD may be causal.” Tomljenovic L, Shaw CA. (2011). *Do aluminum vaccine adjuvants contribute to the rising prevalence of autism?* J Inorg Biochem. 105(11):1489-99. https://pubmed.ncbi.nlm.nih.gov/22099159/

c. “In the following article we briefly review the literature on Al neurotoxicity and the use of Al salts as vaccine adjuvants and consider not only direct toxic actions on the nervous system, but also the potential impact for triggering autoimmunity. Autoimmune and inflammatory responses affecting the CNS appear to underlie some forms of neurological disease, including developmental disorders.” Shaw, C. A., Li, D., & Tomljenovic, L. (2014). *Are there Negative CNS Impacts of Aluminum Adjuvants Used in Vaccines and Immunotherapy?* Immunotherapy, 6(10), 1055–1071. https://pubmed.ncbi.nlm.nih.gov/25428645/

d. “There was a suggestion of increased ASD risk among children whose mothers received an influenza vaccination in their first trimester, but the association was not statistically significant after adjusting for multiple comparisons, indicating that the finding could be due to chance. These findings do not call for changes in vaccine policy or practice, but do suggest the need for additional studies on maternal influenza vaccination and autism.” Zerbo O, Qian Y, Yoshida C, Fireman BH, Klein NP, Croen LA. (2017). *Association Between Influenza Infection and Vaccination During Pregnancy and Risk of Autism Spectrum Disorder*. JAMA Pediatr. 171(1):e163609. https://pubmed.ncbi.nlm.nih.gov/27893896/

e. “The aluminium content of brain tissue in autism was consistently high…. The pre-eminence of intracellular aluminium associated with non-neuronal cells was a standout observation in autism brain tissue and may offer clues as to both the origin of the brain aluminium as well as a putative role in autism spectrum disorder.” Mold M, Umar D, King A, Exley C. (2018). *Aluminium in brain tissue in autism*. J Trace Elem Med Biol. 46:76-82. https://pubmed.ncbi.nlm.nih.gov/29413113/

f. By applying Hill's criteria for establishing causality between exposure and outcome we investigated whether exposure to Al [aluminum] from vaccines could be contributing to the rise in ASD prevalence in the Western world. Our results show that: (i) children from countries with the highest ASD prevalence appear to have the highest exposure to Al from vaccines; (ii) the increase in exposure to Al adjuvants significantly correlates with the increase in ASD prevalence in the United States observed over the last two decades (Pearson $r=0.92$, $p<0.0001$); and (iii) a significant correlation exists between the amounts of Al administered to preschool children and the current prevalence of ASD in seven Western countries, particularly at 3-4 months of age (Pearson $r=0.89$-0.94, $p=0.0018$-0.0248). The application of the Hill's criteria to these data indicates that the correlation between Al in vaccines and ASD may be causal. Because children represent a fraction of the population most at risk for complications following exposure to Al, a more rigorous evaluation of Al adjuvant safety seems warranted. Tomljenovic L, Shaw CA. (2011). *Do aluminum vaccine adjuvants contribute to the rising prevalence of autism?* J Inorg Biochem. 105(11):1489-99. https://pubmed.ncbi.nlm.nih.gov/22099159/

13. **Autoimmune/inflammatory syndrome induced by adjuvants (ASIA) (Shoenfeld’s syndrome)**

a. “In recent years, four conditions: siliconosis, the Gulf war syndrome (GWS), the macrophagic myofasciitis syndrome (MMF) and post-vaccination phenomena were linked with previous exposure to an adjuvant... Relating to the current knowledge we would like to suggest to include these comparable conditions under a common syndrome entitled ASIA, ‘Autoimmune (Auto-inflammatory) Syndrome Induced by Adjuvants’”. (2011). Shoenfeld Y, Agmon-Levin N. *'ASIA' - autoimmune/inflammatory syndrome induced by adjuvants.* J Autoimmun. 36(1):4-8. https://pubmed.ncbi.nlm.nih.gov/20708902/

b. “We included in this review animal models for rheumatoid arthritis-like disease, for systemic lupus erythematosus-like disease, autoimmune thyroid disease-like disease, antiphospholipid syndrome, myocarditis and others. All these models support the concept of ASIA, as the Autoimmune (Auto-inflammatory) Syndrome Induced by Adjuvants.” Cruz-Tapias P, Agmon-Levin N, Israeli E, Anaya JM, Shoenfeld Y. (2013). *Autoimmune (auto-inflammatory) syndrome induced by adjuvants (ASIA)--animal models as a proof of concept.* Curr Med Chem. 20(32):4030-6. https://pubmed.ncbi.nlm.nih.gov/23992328/

c. “We have examined the neurotoxicity of aluminum in humans and animals under various conditions, following different routes of administration, and provide an overview of the various associated disease states.

The literature demonstrates clearly negative impacts of aluminum on the nervous system across the age span. In adults, aluminum exposure can lead to apparently age-related neurological deficits resembling Alzheimer's and has been linked to this disease and to the Guamanian variant, ALS-PDC. … In young children, a highly significant correlation exists between the number of pediatric aluminum-adjuvanted vaccines administered and the rate of autism spectrum disorders. Many of the features of aluminum-induced neurotoxicity may arise, in part, from autoimmune reactions, as part of the ASIA syndrome." Shaw CA, Tomljenovic L. (2013). *Aluminum in the central nervous system (CNS): toxicity in humans and animals, vaccine adjuvants, and autoimmunity*. Immunol Res. 56(2-3):304-16. https://pubmed.ncbi.nlm.nih.gov/23609067/

14. **Autoimmune Encephalitis**

a. " These two cases highlight the potential for AE following the administration of the Shingrix® vaccine and underscore the importance of prompt recognition and aggressive immunotherapy to prevent morbidity and mortality." Madani TA, Khoja AA, Abuzinadah AR, Abbas GM, Alotaibi AA, Alshehri ZI, Madani ST. (2025). *Post-vaccinal seronegative autoimmune encephalitis following recombinant zoster vaccination in two immunocompetent patients*. J Infect Chemother. 31(6):102713. https://pubmed.ncbi.nlm.nih.gov/40254183/

15. **Autoimmune Diseases (Generally)**

a. "Reported post-vaccination autoimmune diseases in the adult include SLE, rheumatoid arthritis (RA), inflammatory myopathies, multiple sclerosis (MS), Guillain-Barré syndrome (GBS), and vasculitis." Orbach H, Agmon-Levin N, Zandman-Goddard G. (2010). *Vaccines and autoimmune diseases of the adult.* Discov Med. 9(45):90-7. https://pubmed.ncbi.nlm.nih.gov/20193633/

b. "More than 600 cases of illnesses, many with MS-like symptoms, of people who had received the recombinant HBV vaccine, have been collected in France. A growing fraction of people who have been vaccinated against HBV claim to have experienced serious side effects. Their complaints cover a wide spectrum of diseases, among which many of an autoimmune nature and nervous system disorders. Those include rheumatoid arthritis, optic neuritis, and neurodegenerative disorders that resemble MS. The temporal association of multiple sclerosis (MS) with HBV vaccination has been reported on few occasions [22, 23]; neurological symptoms and signs, as well as magnetic resonance imaging documenting central nervous system (CNS) demyelinization have occurred days to weeks after HBV vaccination." Shoenfeld Y, Aron-Maor A. (2000). *Vaccination and autoimmunity-'vaccinosis': a dangerous liaison?* J Autoimmun. 14(1):1-10. https://pubmed.ncbi.nlm.nih.gov/10648110/

c. "The VAERS and PubMed (1966-2003) were searched for autoimmune conditions including arthritis, rheumatoid arthritis, myelitis, optic neuritis, multiple sclerosis (MS), Guillain Barré Syndrome (GBS), glomerulonephritis, pancytopenia/ thrombocytopenia, fatigue, and chronic fatigue, and Systemic Lupus Erythematous (SLE) following HBV. There were 415 arthritis, 166 rheumatoid arthritis, 130 myelitis, 4 SLE, 100 optic neuritis, 101 GBS, 29 glomerulonephritis, 283 pancytopenia/ thrombocytopenia, and 183 MS events reported following HBV. A total of 465 positive re-challenge adverse events were observed following adult HBV that occurred sooner and with more severity than initial adverse event reports. A case-report of arthritis occurring in identical twins was also identified. One would have to consider that there is causal relationship between HBV and serious autoimmune disorders among certain susceptible vaccine recipients in a defined temporal period following immunization." Geier MR, Geier DA. (2004). *A case-series of adverse events, positive re-challenge of symptoms, and events in identical twins following hepatitis B vaccination: analysis of the Vaccine Adverse Event Reporting System (VAERS) database and literature review.* Clin Exp Rheumatol. 22(6):749-55. https://pubmed.ncbi.nlm.nih.gov/15638050/

d. "Genetic leads to a predisposition in developing an autoimmune syndrome, but the presence of an external or endogenous environmental factor, recently called "exposome," is essential in triggering the immune response. Infections as well as the expositions to different other external environmental agents have been identified as potential trigger for ADs. A new syndrome, namely the autoimmune/inflammatory syndrome induced by adjuvants, has recently been defined alluding to the key role of adjuvant in inducing an immune-mediated condition." Colafrancesco S, Agmon-Levin N, Perricone C, Shoenfeld Y. (2013). *Unraveling the soul of autoimmune diseases: pathogenesis, diagnosis and treatment adding dowels to the puzzle.* Immunol Res. 56(2-3):200-5. https://pubmed.ncbi.nlm.nih.gov/23733136/

e. “Among the implicated mechanisms for these reactions is molecular mimicry. Molecular mimicry refers to a significant similarity between certain pathogenic elements contained in the vaccine and specific human proteins. This similarity may lead to immune crossreactivity, wherein the reaction of the immune system towards the pathogenic antigens may harm the similar human proteins, essentially causing autoimmune disease. In this review, we address the concept of molecular mimicry and its application in explaining post vaccination autoimmune phenomena. We further review the principal examples of the influenza, hepatitis B, and human papilloma virus vaccines, all suspected to induce autoimmunity via molecular mimicry. Finally, we refer to possible implications on the potential future development of better, safer vaccines.” Segal Y, Shoenfeld Y. (2018). *Vaccine-induced autoimmunity: the role of molecular mimicry and immune crossreaction*. Cell Mol Immunol. 15(6):586-594. https://pubmed.ncbi.nlm.nih.gov/29503439/

f. “This article reviews the case series reported from several countries describing patients with suspected severe side effects to the HPV vaccines. The described symptom clusters are remarkably similar and include disabling fatigue, headache, widespread pain, fainting, gastrointestinal dysmotility, limb weakness, memory impairment episodes of altered awareness, and abnormal movements. This constellation of symptoms and signs has been labeled with different diagnoses such as complex regional pain syndrome (CRPS), postural orthostatic tachycardia syndrome (POTS), small fiber neuropathy (SFN), myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), or fibromyalgia. It is known that autoimmunity and autoantibodies are present in a subset of patients with CRPS, POTS, SFN, ME/CFS, and fibromyalgia. This article proposes that vaccine-triggered, immune-mediated autonomic dysfunction could lead to the development of de novo post-HPV vaccination syndrome possibly in genetically susceptible individuals. Being cognizant that a temporal relationship between vaccination and symptom onset does not necessarily equate to causality, mounting evidence of case series calls for well-designed case-control studies to determine the prevalence and possible causation between these symptom clusters and HPV vaccines.” Blitshteyn S, Brinth L, Hendrickson JE, Martinez-Lavin M. (2018). *Autonomic dysfunction and HPV immunization: an overview*. Immunol Res. 66(6):744-754. https://pubmed.ncbi.nlm.nih.gov/30478703/

g. “We conclude that Hepatitis B Vaccine can induce aPL [Anti-phospholipid antibodies], although rarely. In genetically susceptible individuals or together with some other triggers such combination might confer the risk of developing a continuous autoimmune response in an individual.” Martinuc Porobic J, Avcin T, Bozic B, Kuhar M, Cucnik S, Zupancic M, Prosenc K, Kveder T, Rozman B. (2005). *Anti-phospholipid antibodies following vaccination with recombinant hepatitis B vaccine*. Clin Exp Immunol. 142(2):377-80. https://pubmed.ncbi.nlm.nih.gov/16232227/

h. “There is a clear indication that vaccination can and potentially does have autoimmune side effects and can even trigger a full-blown autoimmune disease, although it is quite rare. Secondly, the association of vaccination and autoimmunity can raise a serious medico-legal issue. The meaningful question of legal compensation to those patients who developed a life-long disease following mandatory vaccination might be tested. Thirdly, we are as yet unable to identify those who are prone to develop these complications. It is apparent that susceptibility to vaccine-induced autoimmunity is also determined by genetic predisposition, which further emphasizes the importance of ‘the mosaic of autoimmunity’ [34].” Tishler M, Shoenfeld Y. (2004). V*accination may be associated with autoimmune diseases*. Isr Med Assoc J. 6(7):430-2. https://pubmed.ncbi.nlm.nih.gov/15274537/

i. “Vaccines, in several reports were found to be temporally followed by a new onset of autoimmune diseases. The same mechanisms that act in infectious invasion of the host, apply equally to the host response to vaccination. It has been accepted for diphtheria and tetanus toxoid, polio and measles vaccines and GBS. Also this theory has been accepted for MMR vaccination and development of autoimmune thrombocytopenia, MS has been associated with HBV vaccination.” Molina V, Shoenfeld Y. (2005). *Infection, vaccines and other environmental triggers of autoimmunity*. Autoimmunity. 38(3):235-45. https://pubmed.ncbi.nlm.nih.gov/16126512/

j. “It is conceivable that attenuated viral vaccines could induce autoimmunity in a manner that is similar to the mechanisms that have been proposed to explain the viral-autoimmunity association.” Cohen, A. and Shoenfeld, Y. (1996). *Vaccine-induced Autoimmunity*. J. Autoimmunity. https://pubmed.ncbi.nlm.nih.gov/9115571/

k. "Thus, for the minority of individuals who are probably genetically susceptible, as well as for patients with active SLE disease, the influenza vaccine, among others, may trigger an overt autoimmune disease." Agmon-Levin N, Kivity S, Shoenfeld Y. (2009). *Influenza vaccine and autoimmunity*. Isr Med Assoc J. 2009 Mar;11(3):183-5. PMID: 19544711. https://pubmed.ncbi.nlm.nih.gov/19544711/

16. **Autoimmune Inflammatory Polyneuropathy (PN)**

a. "Autoimmune inflammatory polyneuropathy (PN) can be triggered by vaccination. We report 3 such cases....It is likely that in the first 2 cases, an autoimmune reaction against some axonal or neuronal components was triggered by Hepatitis B vaccine. It induced an acute sensory ataxic PN in case 1 and an acute motor and sensory axonal neuropathy (AMSAN) in case 2. The third patient had a chronic inflammatory demyelinating PN, likely triggered by yellow fever vaccination." Vital C, Vital A, Gbikpi-Benissan G, Longy-Boursier M, Climas MT, Castaing Y, Canron MH, Le Bras M, Petry K. (2002). *Postvaccinal inflammatory neuropathy: peripheral nerve biopsy in 3 cases.* J Peripher Nerv Syst. 7(3):163-7. https://pubmed.ncbi.nlm.nih.gov/12365564/

17. **Bell's palsy**

a. "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and Bell's palsy." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence is inadequate to accept or reject a causal relationship between hepatitis A vaccine and Bell's palsy." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "This study suggests a strong association between the inactivated intranasal influenza vaccine used in Switzerland and Bell's palsy." Mutsch M. *et al*. (2004). *Use of the Inactivated Intranasal Influenza Vaccine and the Risk of Bell's Palsy in Switzerland.* NEJM 350;896-903. https://pubmed.ncbi.nlm.nih.gov/14985487/

d. "Our findings revealed a signal of possible association between influenza vaccines and an increased risk of Bell's palsy." Zhou W. *et al.* (2004). *A potential signal of Bell's palsy after parenteral inactivated influenza vaccines: reports to the Vaccine Adverse Event Reporting System (VAERS) - United States, 1991-2001.* Pharmacoepidemiology and Drug Safety. 13:505-510. https://pubmed.ncbi.nlm.nih.gov/15317028/

18. **Brachial neuritis**

a. "The evidence favors acceptance of a causal relation between tetanus toxoid and brachial neuritis." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

b. "If the evidence favors acceptance of a causal relation between tetanus toxoid and brachial neuritis, then in the committee's judgment the evidence favors acceptance of a causal relation between DT and Td and brachial neuritis." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

c. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and brachial neuritis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

d. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and brachial neuritis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects

of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

e. "The evidence is inadequate to accept or reject a causal relationship between HPV vaccine and brachial neuritis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

f. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and brachial neuritis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

g. Persistent shoulder pain and dysfunction after vaccination are relatively rare but well-known complications after inoculations into the deltoid muscle. The term SIRVA (shoulder injury related to vaccine administration) is frequently used to encompass many of these occurrences; however, multiple distinct pathologies with similar presentations have been reported after vaccination...Diagnoses were divided into 3 categories: (1) local inflammatory reaction (SIRVA), (2) brachial neuritis, and (3) direct nerve injury...The included articles reported on 57 cases of SIRVA, 18 of brachial neuritis, and 4 of direct nerve injury...the brachial neuritis and direct nerve injury cases were typically confirmed with electromyography/nerve conduction studies...some (1 of 3 patients with brachial neuritis and >1 year of follow-up and 2 of 4 patients with direct injury) had residual weakness...Medical professionals should be aware of the various pathologies that can lead to prolonged shoulder pain after vaccination. Wright JO, Wiggins W, Smith MS, King JJ, Wright TW. (2023) *Shoulder Pain and Dysfunction After Vaccination: A Systematic Review*. JBJS Rev. 11(1). https://pubmed.ncbi.nlm.nih.gov/36722836/

h. Although the reporting rate of post influenza vaccination plexopathy is within the range expected in the general population, the unbalanced distribution of these cases in the first 6 weeks after vaccination suggests that the association between vaccination and some cases is not entirely coincidental. Continuous active monitoring of post-vaccination plexopathy is recommended. Shreya Shah, Nirav Sanghani, Rajanigandhi Hanumanthu, and Nizar Souayah. (2018). *Brachial plexopathy after influenza vaccination in adults in the USA. A report from the CDC/FDA Vaccine Adverse Event Reporting System (1990–2017) (P2.431)*. Neurology. 90(Supplement 15). https://www.neurology.org/doi/10.1212/WNL.90.15_supplement.P2.431

19. **Bradycardia**

a. "Infants in NICU had an increased incidence of sepsis evaluations and increased respiratory support and intubation after routine immunization." DeMeo SD et al. (2015). *Adverse Events After Routine Immunization of Extremely Low-Birth-Weight Infants*. JAMAPediatr. 169(8):740–745. https://pmc.ncbi.nlm.nih.gov/articles/PMC4523398/

20. **Bullous pemphigoid**

a. "Bullous pemphigoid (BP) is an acquired autoimmune blistering disorder of unknown etiology uncommon in childhood… We report three infants with infantile BP presenting shortly after vaccination for diphtheria, pertussis, tetanus, poliomyelitis, hepatitis B, Haemophilus influenzae B, and meningococcus C. Our cases further reinforce the causal association between childhood BP and vaccination." de la Fuente *et al*. (2013). Postvaccination bullous pemphigoid in infancy: report of three new cases and literature review. *Pediatric Dermatology* 30(6):741–744. https://pubmed.ncbi.nlm.nih.gov/24125034/

b. "Here we describe three cases of BP which were referred to our department in the last 15 years. Two of them developed an eruption of bullous lesions just a few days after vaccination for diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B and Haemophilus influenzae B." Baroero *et al*. (2017). *Three case reports of post immunization and post viral Bullous Pemphigoid: looking for the right trigger*. BMC Pediatrics 17(1):60. https://pubmed.ncbi.nlm.nih.gov/28228112/

c. "The time between the primary administration of the vaccine and the first clinical manifestations of the AIBDs approximately ranged between 1 day and 3 months, with an average of approximately 18 days. In 6 (21.4%) cases, there was an exacerbation of the disease with subsequent vaccine doses. ... Further

observational studies and registries are required to assess more comprehensively the impact of vaccines, including those against COVID-19, on the risk of AIBDs." Kasperkiewicz M, Woodley DT. (2022). *Association between vaccination and autoimmune bullous diseases: A systematic review*. J Am Acad Dermatol. 86(5):1160-1164. https://pubmed.ncbi.nlm.nih.gov/33905786/

21. **Cachexia**

a. "Here we report on a case of an 18-year-old woman who presented with extreme cachexia due to severe dysautonomia caused by the ASIA syndrome induced by the tetanus, diphtheria, and pertussis vaccine (Tdap)." Hen O, David P, Shoenfeld Y. (2021). *Dysautonomia Following Tetanus, Diphtheria, and Pertussis Vaccine (Tdap): The First Case of Extreme Cachexia Caused by Autoimmune/Inflammatory Syndrome Induced by Adjuvants (ASIA Syndrome) in a Human*. Medicina (Kaunas). 57(12):1333. https://pubmed.ncbi.nlm.nih.gov/34946278/

22. **Celiac disease**

"The observed association of a 56% increased risk of coeliac disease after qHPV [quadrivalent human papillomavirus] vaccination was strong, and the increase was strikingly similar in both risk periods after vaccination." Hviid *et al*. (2018). *Human papillomavirus vaccination of adult women and risk of autoimmune and neurological diseases*. Journal of Internal Medicine 283(2):154-65, https://pubmed.ncbi.nlm.nih.gov/29044769/

23. **Chronic fatigue syndrome**

a. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and chronic fatigue syndrome." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "Chronic Fatigue Syndrome (CFS) has emerged following vaccination in several reports, including after measles, mumps, and rubella (MMR), Pneumovax, influenza, hepatitis B virus (HBV), tetanus, typhoid, and poliovirus vaccines." Devanur, L.D. and Kerr, J.R. (2006). *Chronic fatigue syndrome.* J Clin Virol, 37(3):139–50. https://pubmed.ncbi.nlm.nih.gov/16978917/

24. **Chronic inflammatory demyelinating polyneuropathy (CIDP)**

a. "There is little doubt that the three clinical episodes of demyelinating neuropathy resulted from the administration of tetanus toxoid...This case is of particular interest in that after three episodes there can be little doubt about the antigen responsible for the clinical attacks." Pollard and Selby. (1978). *Relapsing neuropathy due to tetanus toxoid. Report of a case*. J. Neurol Sci. 37 (1-2) 113-25. https://pubmed.ncbi.nlm.nih.gov/308529/

b. "Of greatest concern is the risk of relapse following tetanus toxoid, which was 8.7% (95% CI 1.7%, 28.9%) in our patient sample. In view of these figures and previous reports of relapse of CIDP following tetanus toxoid, patients may wish to avoid routine tetanus toxoid immunization." Pritchard J. et. al. (2022). *Risk of relapse of GBS or CIDP following immunization*. J. Neurol Neurosurg Psych 73:343-350. https://pubmed.ncbi.nlm.nih.gov/12185184/

25. **Complex Regional Pain Syndrome (CRPS)**

a. "Four girls 12 to 14 years of age had 5 episodes suggestive of CRPS type I after HBVx, an estimated rate of 4 cases per million doses." Jastaniah WA, Dobson S, Lugsdin JG, Petty RE. (2003). *Complex regional pain syndrome after hepatitis B vaccine*. J Pediatr. 143(6):802-804. https://pubmed.ncbi.nlm.nih.gov/14657832/

b. "A child with CRPS-I, thought to be due to an injection trauma, after rubella vaccine is presented. We thought that, in children who developed swelling, skin changes and limited range of motion on hands or feet after a vaccination or an injection, the diagnosis of RPS-I should be kept in mind." Genc H, Karagoz A, Saracoglu M, Sert E, Erdem HR. (2005). *Complex regional pain syndrome type-I after rubella vaccine*. Eur J Pain. 9(5):517. https://pubmed.ncbi.nlm.nih.gov/16139180/

c. “Post-immunisation CRPS-1 in the paediatric population has previously been reported following rubella and hepatitis B immunisation.” Richards S, Chalkiadis G, Lakshman R, Buttery JP, Crawford NW. (2012). *Complex regional pain syndrome following immunisation*. Arch Dis Child. 97(10):913-915. https://pubmed.ncbi.nlm.nih.gov/22858647/

26. **Crohn’s disease**

a. “Subgroup analysis for Crohn’s disease (CD) and ulcerative colitis (UC) found an association between the poliomyelitis vaccine and risk for developing CD (RR, 2.28; 95% CI, 1.12–4.63) or UC (RR, 3.48; 95%CI, 1.2–9.71).” Pineton de Chambrun *et al*. (2015). Vaccination and Risk for Developing Inflammatory Bowel Disease: A Meta-Analysis of Case–Control and Cohort Studies *Clinical Gastroenterology and Hepatology* 13:1405–1415. https://pubmed.ncbi.nlm.nih.gov/25956840/

b. “Multiple factors, both clinical, immunological and physical, render Al and its compounds at risk for induction of CD.” Lerner A. (2012). *Aluminum as an adjuvant in Crohn’s disease induction.* Lupus. 21(2):231-238. https://pubmed.ncbi.nlm.nih.gov/22235058/

27. **Death (Mortality)**

a. “The evidence establishes a causal relation between vaccine-strain measles virus infection and death.” Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

b. “The evidence favors acceptance of a causal relation between measles vaccine and death from anaphylaxis.” Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

c. “The evidence establishes a causal relation between MMR and death from complications associated with severe thrombocytopenia.” Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

d. “The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and all-cause mortality.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

e. “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 performance of national vaccination programs. 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. Though a vaccine protects children against the target disease it may simultaneously increase susceptibility to unrelated infections.” Mogensen, S.W., et al. (2017), *The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment*. EBioMedicine. 17:192-198. https://pubmed.ncbi.nlm.nih.gov/28188123/

f. “Non-live vaccines (such as DTP vaccine, the pentavalent vaccine for DTP, hepatitis B virus (HBV) and Haemophilus influenzae type b, inactivated polio vaccine, single HBV vaccine, the RTS,S/AS01 malaria vaccine, and the H1N1 influenza vaccine) seem to increase susceptibility to vaccine-unrelated infections, particularly in females. Hence, non-live vaccines may have beneficial effects in preventing the target infection but negative effects by enhancing susceptibility to non-target infections. In epidemiological studies, the negative effects seem to be more pronounced than the beneficial effects, with the net effect being increased overall mortality for females.” Aaby et al. (2020). *The non-specific and sex-differential effects of vaccines*. Nature Reviews Immunology. 20(8):464-470. https://pubmed.ncbi.nlm.nih.gov/32461674/

g. “Consistent causal reactions that may result in death are very rare and maybe related to the vaccine product (e.g. anaphylaxis, viscerotrophic disease), vaccine quality defect (e.g. an incompletely attenuated live vaccine agent) or an immunization error (e.g. vaccine vial contamination).” Gold MS, Balakrishnan MR, Amarasinghe A, MacDonald NE. (2016). *An approach to death as an adverse event following immunization.* Vaccine. 34(2):212-217. https://pubmed.ncbi.nlm.nih.gov/26608326/

h. “There are statistically significant positive correlations between mortality rates of developed nations and the number of early childhood vaccine doses that are routinely given. Further investigations of the hypotheses generated by this study are recommended to confirm that current vaccination schedules are achieving their intended objectives.” Miller NZ, Goldman GS. (2023). *Neonatal, Infant, and Under Age Five Vaccine Doses Routinely Given in Developed Nations and Their Association With Mortality Rates*. Cureus. 15(7):e42194. https://pubmed.ncbi.nlm.nih.gov/37484788/

28. **Deltoid bursitis**

a. “The evidence convincingly supports a causal relationship between the injection of a vaccine and deltoid bursitis.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. In recent years, multiple case reports have documented patients developing acute subacromial bursitis shortly after receiving vaccines. Additionally, Hesse et al. (2020) used the Vaccine Safety Datalink to assess the risk of subdeltoid bursitis after influenza vaccination. They found that an attributable risk of 7.78 (95% confidence interval [CI]: 2.19–13.38) additional cases of bursitis occur per 1 million persons vaccinated. Post-vaccine subdeltoid bursitis has been observed in adults spanning an age range of 23–82 years. A common issue identified was the incorrect injection technique, particularly the placement of injections too high on the arm (see Figure 10-1), underscoring the importance of adherence to proper vaccination procedures to minimize risk of harm....Conclusion 10-1: The evidence establishes a causal relationship between vaccine administration and subacromial/subdeltoid bursitis caused by direct injection into the bursa. National Academies of Sciences, Engineering, and Medicine. (2024). *Evidence Review of the Adverse Effects of COVID-19 Vaccination and Intramuscular Vaccine Administration*. Washington, DC: The National Academies Press. https://pubmed.ncbi.nlm.nih.gov/39312602/

29. **Demyelinating event**

a. “The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and a first demyelinating event in children.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. “The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and a first demyelinating event in adults.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. “A wide variety of inflammatory diseases temporally associated with the administration of various vaccines, has been reported in the literature.” Karussis D, Petrou P. (2014). *The spectrum of post-vaccination inflammatory CNS demyelinating syndromes.* Autoimmun Rev. 13(3):215-24. https://pubmed.ncbi.nlm.nih.gov/24514081/

d. “Guillain-Barre syndrome, optic neuritis, and transverse myelitis have been reported after administration of plasma derived hepatitis B vaccines. Few such incidents have been associated with the use of recombinant vaccines, although there have been 2 reports of optic neuritis and 1 of Guillain-Barré syndrome. We describe 2 patients, 1 with known multiple sclerosis and 1 with no history of neurological disease, in whom magnetic resonance imaging showed central-nervous-system demyelination after immunisation with recombinant hepatitis B vaccine.” Herroelen L, de Keyser J, Ebinger G. (1991). *Central-nervous-system demyelination after immunisation with recombinant hepatitis B vaccine*. Lancet. 338(8776):1174-5. https://pubmed.ncbi.nlm.nih.gov/1682594/

e. “A 46-year-old man who was an extremely high titer hepatitis B surface (HBs)-antigen carrier had three attacks of acute demyelinating transverse myelitis associated with signs of meningeal irritation...The cerebrospinal fluid was characterized by elevated levels of myelin basic protein (MBP) and predominating CD4+CD29+ helper-inducer T cells during the acute stages, and also by persistently positive HBs antigen. There were neither autoantibodies nor evidence of vasculitis. However, circulating immune complexes composed of HBs antigen disappeared after treatment, indicating that immunity to hepatitis B virus played a role in the demyelinative lesion formation in the central nervous system (CNS). In light of the animal studies demonstrating autoimmunity triggered by molecular mimicry between MBP and hepatitis B virus antigens, this patient may serve as a rare example of CNS demyelination in humans with the same autoimmune etiology.” Matsui M, Kakigi R, Watanabe S, Kuroda Y. (2007). *Recurrent demyelinating transverse myelitis in a high titer HBs-antigen carrier.* J Neurol Sci. 139(2):235-7. https://pubmed.ncbi.nlm.nih.gov/8856658/

f. “Central nervous system (CNS) demyelinating episodes have been described following numerous vaccines but there is no definite conclusion about a causal relationship. Recently, in France, in the context of an Expanded Program on Immunization, several cases of CNS demyelination have been observed following injection of recombinant hepatitis B (HB) vaccine, leading to great concern. We performed a hospital-based case-control study of 121 patients with a first episode of CNS demyelination occurring between July 1993 and December 1995...These findings did not permit to exclude confidently an association between HB vaccine and the occurrence of a first CNS demyelinating episode.” Touzé E, Gout O, Verdier-Taillefer MH, Lyon-Caen O, Alpérovitch A. (2000). *Premier épisode de démyélinisation du système nerveux central et vaccination contre l'hépatite B [The first episode of central nervous system demyelinization and hepatitis B virus vaccination]*. Rev Neurol (Paris). 2156(3):242-6. https://pubmed.ncbi.nlm.nih.gov/10740095/

30. **Dermatomyositis**

a. “There are few reports of autoimmune diseases, such as rheumatoid arthritis and anti-phospholipid syndrome after anti-tetanus vaccination. Herein, we describe four cases, of which we believe, show a clear temporal relation between anti-tetanus vaccination and the appearance of dermatomyositis, systemic lupus erythematosus, type 1 diabetes mellitus and anti-phospholipid syndrome.” Ruhrman-Shahar N, Torres-Ruiz J, Rotman-Pikielny P, Levy Y. (2017). *Autoimmune reaction after anti-tetanus vaccination-description of four cases and review of the literature*. Immunol Res. 65(1):157-163. https://pubmed.ncbi.nlm.nih.gov/27435706/

31. **Developmental Delay**

a. “In this study, which only allowed for the calculation of unadjusted observational associations, higher ORs were observed within the vaccinated versus unvaccinated group for developmental delays, asthma and ear infections. Further study is necessary to understand the full spectrum of health effects associated with childhood vaccination.” Hooker BS, Miller NZ. (2020). *Analysis of health outcomes in vaccinated and unvaccinated children: Developmental delays, asthma, ear infections and gastrointestinal disorders*. SAGE Open Med. 8:2050312120925344. https://pubmed.ncbi.nlm.nih.gov/32537156/

b. “Epidemiological evidence suggests a link between mercury (Hg) exposure from Thimerosal-containing vaccines and specific delays in development. A hypothesis-testing longitudinal cohort study (n=49,835) using medical records in the Vaccine Safety Datalink (VSD) was undertaken to evaluate the relationship between exposure to Hg from Thimerosal-containing hepatitis B vaccines (T-HBVs) administered at specific intervals in the first 6months of life and specific delays in development [International Classification of Disease, 9th revision (ICD-9): 315.xx] among children born between 1991 and 1994 and continuously enrolled from birth for at least 5.81years. Infants receiving increased Hg doses from T-HBVs administered within the first month, the first 2months, and the first 6months of life were significantly more likely to be diagnosed with specific delays in development than infants receiving no Hg doses from T-HBVs. During the decade in which T-HBVs were routinely recommended and administered to US infants (1991-2001), an estimated 0.5-1million additional US children were diagnosed with specific delays in development as a consequence of 25µg or 37.5µg organic Hg from T-HBVs administered within the first 6months of life. The resulting lifetime costs to the United States may exceed $1 trillion.” Geier DA, Kern JK, Hooker BS, King PG, Sykes LK, Geier MR. (2016). *A longitudinal cohort study of the relationship between Thimerosal-containing hepatitis B vaccination and specific delays in development in the United States: Assessment of attributable risk and lifetime care costs*. J Epidemiol Glob Health. 6(2):105-18. https://pubmed.ncbi.nlm.nih.gov/26166425/

32. **Diabetes**

a. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and type 1 Diabetes." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "Exposure to HiB immunization is associated with an increased risk of IDDM." Classen JB, Classen DC. (2002). *Clustering of cases of insulin dependent diabetes (IDDM) occurring three years after Hemophilus influenza B (HiB) immunization support causal relationship between immunization and IDDM*. Autoimmunity. 35(4):247. https://pubmed.ncbi.nlm.nih.gov/12482192/

c. "There are few reports of autoimmune diseases, such as rheumatoid arthritis and anti-phospholipid syndrome after anti-tetanus vaccination. Herein, we describe four cases, of which we believe, show a clear temporal relation between anti-tetanus vaccination and the appearance of dermatomyositis, systemic lupus erythematosus, type 1 diabetes mellitus and anti-phospholipid syndrome." Ruhrman-Shahar N, Torres-Ruiz J, Rotman-Pikielny P, Levy Y. (2017). *Autoimmune reaction after anti-tetanus vaccination-description of four cases and review of the literature*. Immunol Res. 65(1):157-163. https://pubmed.ncbi.nlm.nih.gov/27435706/

33. **Encephalitis**

a. "The evidence convincingly supports a causal relationship between MMR vaccine and measles inclusion body encephalitis in individuals with demonstrated immunodeficiencies." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and encephalitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and encephalitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

d. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and encephalitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

e. "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and encephalitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

f. "The evidence is inadequate to accept or reject a causal relationship between meningococcal vaccine and encephalitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

g. "We report the occurrence of one fatal case of the encephalitis associated with measles-rubella (MR) vaccine during an immunization campaign in São Paulo, Brazil. A 31 year-old-man, previously in good health, was admitted at emergency room, with confusion, agitation, inability to stand and hold his head up. Ten days prior to admission, he was vaccinated with combined MR vaccine (Serum Institute of India) and three days

later he developed 'flu-like' illness with fever, myalgia and headache. Results of clinical and laboratory exams were consistent with a pattern of viral encephalitis. During hospitalization, his condition deteriorated rapidly with tetraplegia and progression to coma. On the 3rd day of hospitalization he died. Histopathology confirmed encephalitis and immunohistochemistry was positive for RV on brain tissue. RV was also detected by qPCR and virus isolation in cerebrospinal fluid, brain and other clinical samples. The sequence obtained from the isolated virus was identical to that of the RA 27/3 vaccine strain." Gualberto FA, de Oliveira MI, Alves VA, Kanamura CT, Rosemberg S, Sato HK, Arantes BA, Curti SP, Figueiredo CA. (2013). *Fulminant encephalitis associated with a vaccine strain of rubella virus.* J Clin Virol. 58(4):737-40. https://pubmed.ncbi.nlm.nih.gov/24216323/

h. "We identified 9 reports of encephalitis, ADEM and TM, all of which were serious and required hospitalization. Median interval from vaccination to symptom onset was 9 days (range, 1–227 days). There were 5 reports of encephalitis (2 met Brighton level 2 case definition, 2 were level 3, and 1 was level 3A). Two of these patients received MMR alone." Sukumaran L, McNeil MM, Moro PL, Lewis PW, Winiecki SK, Shimabukuro TT. (2015). *Adverse Events Following Measles, Mumps, and Rubella Vaccine in Adults Reported to the Vaccine Adverse Event Reporting System (VAERS), 2003-2013.* Clin Infect Dis. 60(10):e58-65. https://pmc.ncbi.nlm.nih.gov/articles/PMC4447805/

34. **Encephalopathy**

a. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and encephalopathy." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and encephalopathy." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and encephalopathy." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

d. "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and encephalopathy." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

e. "The evidence is inadequate to accept or reject a causal relationship between meningococcal vaccine and encephalopathy." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

f. "The evidence is inadequate to accept or reject a causal relationship between varicella vaccine and encephalopathy." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

g. "Acute encephalopathy occurred very rarely in either group. It was reported only in two cases following acellular vaccine and in 11 after whole cell preparation." Patterson J, Kagina BM, Gold M, Hussey GD, Muloiwa R. (2018). *Comparison of adverse events following immunisation with acellular and whole-cell pertussis vaccines: A systematic review.* Vaccine. 36(40):6007-6016. https://pubmed.ncbi.nlm.nih.gov/30143272/

h. "Conclusions: This clustering suggests that a causal relationship between measles vaccine and encephalopathy may exist as a rare complication of measles immunization." Weibel RE, Caserta V, Benor DE, Evans G. (1998). *Acute encephalopathy followed by permanent brain injury or death associated with further attenuated measles vaccines: a review of claims submitted to the National Vaccine Injury Compensation Program*. Pediatrics. 101(3 Pt 1):383-7. https://pubmed.ncbi.nlm.nih.gov/9481001/

35. **Erythema multiforme (EM)**

a. "The evidence is inadequate to accept or reject a causal relation between tetanus or diphtheria toxoid and EM." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

36. **Erythema nodosum**

a. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and erythema nodosum." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

37. **Fibromyalgia**

a. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and fibromyalgia." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

"The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and fibromyalgia." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and fibromyalgia." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

d. "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and fibromyalgia." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

e. "Fibromyalgia syndrome (FMS), a condition characterized by widespread pain and diffuse tenderness, is considered a multifactorial disorder. FMS is now recognized as one of the 'central' pain syndromes. Environmental and genetic factors play a role in the pathogenesis of FMS. Various triggers including trauma and stress as well as infections, may precipitate the development of FMS. Certain infections including hepatitis C virus, HIV and Lyme disease have been temporally associated with the development of FMS. There is some evidence for the possible role of vaccinations in triggering the development of FMS and related syndromes, however this association remains to be established." Buskila D, Atzeni F, Sarzi-Puttini P. (2008). *Etiology of fibromyalgia: the possible role of infection and vaccination*. Autoimmun Rev. 8(1):41-3. https://pubmed.ncbi.nlm.nih.gov/18706528/

f. "The current review summarizes the available data linking fibromyalgia to either infection or vaccination. ... Associations have been described between various vaccinations and symptom complexes including fibromyalgia and chronic fatigue syndrome. The case of Gulf War syndrome, a functional multisystem entity sharing many clinical characteristics with fibromyalgia is discussed, with emphasis on the possibility of association with administration of multiple vaccinations during deployment in the Persian Gulf and the interaction with stress and trauma. Based on this example a model is proposed, wherein vaccinations function

as co-triggers for the development of functional disorders including fibromyalgia, in conjunction with additional contributing factors." Ablin JN, Shoenfeld Y, Buskila D. (2006). *Fibromyalgia, infection and vaccination: two more parts in the etiological puzzle*. J Autoimmun. 27(3):145-52. https://pubmed.ncbi.nlm.nih.gov/17071055/

38. **Guillain-Barré Syndrome (GBS)**

a. "The evidence favors acceptance of a causal relation between DT, Td, and tetanus toxoid and GBS." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

b. "The evidence favors acceptance of a causal relation between DT, Td, and tetanus toxoid and death from GBS." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

c. "The evidence favors acceptance of a causal relation between OPV and GBS." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

d. "The evidence is inadequate to accept or reject a causal relation between IPV and GBS." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

e. "The evidence is inadequate to accept or reject a causal relation between Hib vaccines and GBS." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

f. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and GBS." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

g. "The evidence is inadequate to accept or reject a causal relationship between varicella vaccine and GBS." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

h. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and GBS." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

i. "The evidence is inadequate to accept or reject a causal relationship between hepatitis A vaccine and GBS." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

j. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and GBS." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

k. “The evidence is inadequate to accept or reject a causal relationship between HPV vaccine and GBS.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

l. “The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccines and GBS.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

m. “The evidence is inadequate to accept or reject a causal relationship between meningococcal vaccine and GBS.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

n. “In October 2005, reports indicating a possible association between Guillain-Barré Syndrome (GBS) and receipt of meningococcal conjugate vaccine (MCV4) (Menactra®, Sanofi Pasteur, Inc., Swiftwater, Pennsylvania) were made to the Vaccine Adverse Event Reporting System (VAERS) (1). GBS is a serious neurologic disorder involving Inflammatory demyelination of the peripheral nerves. During March 2005--February 2006, eight confirmed cases had occurred within 6 weeks (i.e., the time window of elevated risk noted for GBS after administration of other vaccines) after MCV4 vaccination (2,3). This report summarizes nine additional GBS cases reported to VAERS during March--September 2006. This report also provides a preliminary analysis of data from VAERS and the Vaccine Safety Datalink (VSD) since MCV4 became available in the United States in March 2005 and includes all 17 cases of GBS reported since June 2005. Although these data suggest a small increased risk for GBS after MCV4 vaccination, the inherent limitations of VAERS and the uncertainty regarding background incidence rates for GBS require that these findings be viewed with caution. Because of the risk for meningococcal disease and the associated morbidity and mortality, CDC continues to recommend routine vaccination with MCV4 for adolescents, college freshmen living in dormitories, and other populations at increased risk (4). Centers for Disease Control and Prevention (CDC).” (2006). *Update: Guillain-Barre syndrome among recipients of Menactra meningococcal conjugate vaccine*, MMWR 55, 1120-1124. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5440a6.htm

o. “We identified 18 GBS reports following MMR; 17 (94.4%) were serious. Four met Brighton level 1 case definition of GBS, 8 met level 2 case definition, 3 met level 3 case definition, and 3 had insufficient information for evaluation. Four patients received MMR alone, whereas 14 patients received concomitant vaccines. The most commonly coadministered vaccines were hepatitis B (12), influenza (11), and hepatitis A (11). Interval from vaccination to symptom onset ranged from 1 to 127 days; in 17 reports, symptom onset fell within the expected 1- to 42-day GBS risk interval.” Sukumaran L, McNeil MM, Moro PL, Lewis PW, Winiecki SK, Shimabukuro TT. (2015). A*dverse Events Following Measles, Mumps, and Rubella Vaccine in Adults Reported to the Vaccine Adverse Event Reporting System (VAERS), 2003-2013*. Clin Infect Dis. 60(10):e58-65. https://pmc.ncbi.nlm.nih.gov/articles/PMC4447805/

p. “We used data from the Vaccine Adverse Event Reporting System, supplemented by additional data provided by the Center for Biologics Evaluation and Research, to identify 189 patients with Guillain-Barré syndrome (GBS) reported after hepatitis vaccination with a mean age of 30.65 years, affecting men and women equally. Among vaccinated patients, 133 (70%) developed GBS within six weeks, 30 (15.9%) after six weeks, and for the remaining 26 (13.7%), the time between GBS occurrence and vaccination was not specified. The reporting rate of post-hepatitis vaccine GBS is approximately 3.4 cases per one million vaccinations, which is in the range expected in the general population. The unbalanced distribution of reports in the first six weeks after vaccination suggests that some cases of GBS may be triggered by vaccination. Nonetheless, the low incidence of hepatitis vaccine-associated GBS, and the dramatic incidence reduction of hepatitis and its complications after vaccination, support the current guidelines for vaccination.” Souayah *et. al*, (2012). *Analysis of data from the CDC/FDA vaccine adverse event reporting system (1990-2009) on Guillain-Barre syndrome after hepatitis vaccination in the USA*. J Clin Neurosci. 19(8):1089-92. https://pubmed.ncbi.nlm.nih.gov/22705140

q. “A 20-month-old girl was diagnosed with Guillain - Barré syndrome (GBS) based on progressive muscle weakness, areflexia, and albuminocytologic dissociation of the cerebrospinal fluid. Despite timely and systematic treatment, she eventually became paralyzed. There is a temporal correlation between the girl’s GBS and the DTaP vaccination, but the exact causal relationship between the two is still debatable. Furthermore, we summarized clinical features of other 45 published GBS cases after DTP vaccines (or vaccine substances containing tetanus) through a systematic review. The mean onset age, sex distribution, onset time after vaccination, detection of antiganglioside antibodies, and other basic clinical features of GBS after DTP vaccination (or vaccine substances containing tetanus) were analyzed. The temporal pattern of GBS after vaccination was similar to that of GBS after infection. Herein, we report this rare case of presumptive pediatric GBS after DTaP vaccination and review similar cases to draw the attention of medical personnel to similar events after vaccination. An association between DTP vaccines and GBS has been proposed, and the causal relationship between these two incidents are worthy further exploration. Moreover, surveillance and vigilance for GBS after vaccination are highly recommended.” Pan et. al. (2023). *Guillain Barré syndrome after combined diphtheria, tetanus, and acellular pertussis (DTaP) vaccine: A rare pediatric case report and review of literature*. Hum Vaccin Immunother. 19(2):2261199. https://pubmed.ncbi.nlm.nih.gov/37753771/

r. “The VAERS received 1976 reports after PCV20 administration in persons aged ≥ 19 years (6% of reports involved serious events). The most common adverse events among persons aged 19-64 years (n = 798) were injection-site reactions (231, 29%), pain (134, 17%), erythema (118, 15%), and fever (117, 15%). For persons aged ≥ 65 years (n = 1178), the most common adverse events were injection-site reactions (417, 35%), pain (180, 15%), pain in extremity (162, 14%), and erythema (158, 13%). A data mining alert (EB05 = 3.812) for the MedDRA Preferred Term "Guillain-Barre syndrome" was observed for serious reports. Clinical review verified 11 of 20 GBS reports; 7/11 vaccine recipients were aged ≥ 65 years. Among the 11 verified cases, the median time from vaccination to symptom onset was 14 days. Five persons received another vaccine on the same visit. The reporting rate of GBS after PCV20 receipt was 0.5 cases per million doses distributed.” Oliveira M, Marquez P, Ennulat C, Blanc P, Welsh K, Nair N, Taminato M, Moro PL. (2025). *Post-licensure Safety Surveillance of 20-Valent Pneumococcal Conjugate Vaccine (PCV20) Among US Adults in the Vaccine Adverse Event Reporting System (VAERS)*. Drug Saf. 48(3):279-286. https://pubmed.ncbi.nlm.nih.gov/39666166/

s. “Our study provides reassuring results regarding the risk of AID after HPV vaccination, but an apparently increased risk of GBS was detected. Further studies are warranted to confirm this finding.” Miranda S, Chaignot C, Collin C, Dray-Spira R, Weill A, Zureik M. (2017). *Human papillomavirus vaccination and risk of autoimmune diseases: A large cohort study of over 2 million young girls in France*. Vaccine. 35(36):4761-4768. https://pubmed.ncbi.nlm.nih.gov/28750853/

39. **Gulf War syndrome or Gulf War illness**

a. “All original investigations found a link between vaccination and the development of gulf war illness. Post-HPV vaccination syndrome, Macrophagic Myofasciitis, and gulf war illness display same outstanding clinical features. This resemblance supports post-HPV vaccination syndrome and Macrophagic Myofasciitis reality. Our review suggests that some vaccines or multiple vaccines given in a very short period of time may induce, in susceptible individuals, chronic pain, fatigue and dyscognition.” Martinez-Lavin M, Tejada-Ruiz M. (2020). G*ulf war illness, post-HPV vaccination syndrome, and Macrophagic Myofasciitis. Similar disabling conditions possibly linked to vaccine-induced autoimmune dysautonomia.* Autoimmun Rev. 19(9):102603. https://pubmed.ncbi.nlm.nih.gov/32659478/

40. **Headache (chronic)**

a. “The evidence is inadequate to accept or reject a causal relationship between meningococcal vaccine and chronic headache.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

41. **Hearing loss**

a. “The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and hearing loss.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines,

& Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "We found 11 published case reports of Hearing Loss (HL) following live attenuated measles and/or mumps viral strain-containing vaccines (MMCV) administration. The review of the VAERS reports identified 44 cases of likely idiopathic sensorineural HL after MMCV administration. Thus, HL following MMCV has been reported in the literature and to the VAERS." Asatryan A, Pool V, Chen RT, Kohl KS, Davis RL, Iskander JK; VAERS team. (2008). *Live attenuated measles and mumps viral strain-containing vaccines and hearing loss: Vaccine Adverse Event Reporting System (VAERS), United States, 1990–2003*. Vaccine. 26(9):1166-72. https://pubmed.ncbi.nlm.nih.gov/18255204/

42. **Hepatitis**

a. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and hepatitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence is inadequate to accept or reject a causal relationship between hepatitis A vaccine and autoimmune hepatitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

43. **Hypercoagulable states**

a. "The evidence is inadequate to accept or reject a causal relationship between HPV vaccine and hypercoagulable states." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

44. **Idiopathic Inflammatory Myopathy**

a. "Idiopathic inflammatory myopathy (IIM) causes inflammation of the muscle. Most scientific authors believe that environmental factors trigger IIM in genetically predisposed individuals." Prieto, S. and Grau, J.M. (2010). *The geoepidemiology of autoimmune muscle disease*. Autoimmun Rev, 9: A330–4. https://pubmed.ncbi.nlm.nih.gov/19906360/.

b. "IIM's three major subsets are associated with vaccines. The first report linking vaccines and IIM was published in 1964 following the smallpox vaccination in 13 cases of children." Bitum, S., Daeschner, C.W., Travis, L.B., *et al.* (1964). *Dermatomyositis*. J Pediatr, 64: 101–31. https://www.jpeds.com/article/S0022-3476(64)80325-5/abstract.

c. "Since this first published report in 1964 linking vaccines with IIM, several reports have been published associating different vaccines with developing IIM." Orbach, H. and Tanay, A. (2009). *Vaccines as a trigger for myopathies*. Lupus, 18: 1213–16. https://pubmed.ncbi.nlm.nih.gov/19880571/.

d. "A retrospective study of environmental risk factors found that those who presented as recurring IIM-patients were more likely to have previously received the MMR vaccine." Rider, G.L, Wu, L., Mamyrova, G., *et al.* (2010). *Environmental factors preceding illness onset differ in phenotypes of the juvenile idiopathic inflammatory myopathies*. Rheumatology (Oxford). 49:2381–90. https://academic.oup.com/rheumatology/article/49/12/2381/1790396.

45. **Immune thrombocytopenic purpura (ITP)**

a. "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and ITP [immune thrombocytopenic purpura]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. “An acute thrombocytopenic purpura developed shortly after measles-mumps-rubella vaccination in 23 of approximately 700,000 children immunized over a period of seven years. The mean interval from inoculation to the onset of purpura was 19 days.... Increase in platelet-associated immunoglobulin was detected in 10 of 15 patients. Circulating antiplatelet autoantibodies (AAb) against glycoprotein IIb/IIIa were detected in 5 of 15 patients. The findings are compatible with an autoimmune mechanism triggered by immune response to measles-mumps-rubella vaccination.” Nieminen U, Peltola H, Syrjälä MT, Mäkipernaa A, Kekomäki R. (1993). *Acute thrombocytopenic purpura following measles, mumps and rubella vaccination. A report on 23 patients.* Acta Paediatr. 82(3):267-70. https://pubmed.ncbi.nlm.nih.gov/8495082/

c. “An increased risk of thrombocytopenic purpura within six weeks after MMR immunisation in children aged 12 to 23 months was assessed in one case-control study (RR 6.3; 95% CI 1.3 to 30.1) and in one small self controlled case series (incidence rate ratio (IRR) 5.38; 95% CI 2.72 to 10.62). Increased risk of thrombocytopenic purpura within six weeks after MMR exposure was also assessed in one other case-control study involving 2311 children and adolescents between one month and 18 years (odds ratio (OR) 2.4; 95% CI 1.2 to 4.7).” Demicheli V, Rivetti A, Debalini MG, Di Pietrantonj C. (2012). *Vaccines for measles, mumps and rubella in children.* Cochrane Database Syst Rev. 2012 Feb 15;2012(2):CD004407. Update in: Cochrane Database Syst Rev. 2020 Apr 20;4:CD004407. https://pubmed.ncbi.nlm.nih.gov/22336803/

d. “Seventy-six percent of immune thrombocytopenia purpura cases in children aged 12 to 23 months were attributable to measles-mumps-rubella vaccination. This vaccine causes 1 case of immune thrombocytopenia purpura per every 40,000 doses. Conclusion: Measles-mumps-rubella vaccine that is given in the second year of life is associated with an increased risk of immune thrombocytopenia purpura.” France EK, Glanz J, Xu S, Hambidge S, Yamasaki K, Black SB, Marcy M, Mullooly JP, Jackson LA, Nordin J, Belongia EA, Hohman K, Chen RT, Davis R; Vaccine Safety Datalink Team. (2008). *Risk of immune thrombocytopenic purpura after measles-mumps-rubella immunization in children.* Pediatrics. 121(3):e687-92. https://pubmed.ncbi.nlm.nih.gov/18310189/

e. “MMR vaccination was associated with an increased risk of developing ITP (OR 2.4; 95% CI 1.2, 4.7).” Bertuola F, Morando C, Menniti-Ippolito F, Da Cas R, Capuano A, Perilongo G, Da Dalt L. (2010). *Association between drug and vaccine use and acute immune thrombocytopenia in childhood: a case-control study in Italy*. Drug Saf. 33(1):65-72. https://pubmed.ncbi.nlm.nih.gov/20000868/

f. “The attributable risk of developing ITP within 6 weeks after MMR vaccination was estimated to be 1 in 25,000 vaccinations (95% confidence interval 21,300, 89,400). Conclusion: This study confirms the increased risk of ITP within 6 weeks after MMR vaccination.” Black C, Kaye JA, Jick H. (2003). *MMR vaccine and idiopathic thrombocytopaenic purpura.* Br J Clin Pharmacol. 55(1):107-11. https://pubmed.ncbi.nlm.nih.gov/12534647/

g. “We identified 5 ITP reports following MMR. Onset ranged from 3 days to 2 months following vaccination. Three were serious and required hospitalization; all met Brighton level 1 case definition of ITP.” Sukumaran L, McNeil MM, Moro PL, Lewis PW, Winiecki SK, Shimabukuro TT. (2015). *Adverse Events Following Measles, Mumps, and Rubella Vaccine in Adults Reported to the Vaccine Adverse Event Reporting System (VAERS), 2003-2013.* Clin Infect Dis. 60(10):e58-65. https://pmc.ncbi.nlm.nih.gov/articles/PMC4447805/

46. **Inflammatory Joint Disorders**

a. “The hepatitis B vaccine has been implicated in a few dozen cases of extraarticular, systemic, or inflammatory joint disorders. We report two cases in which hepatitis A vaccination (Havrix, Smith Kline Beecham) was followed by a connective tissue disorder or a spondylarthropathy in two healthy males aged 50 and 24 years, respectively. Both patients were HLA B27-negative but carried the HLA DR1 and/or DR4 antigen.” Ferrazzi V, Jorgensen C, Sany J. (1997). *Inflammatory joint disease after immunizations. A report of two cases*. Rev Rhum Engl Ed. 64(4):227-32. https://pubmed.ncbi.nlm.nih.gov/9178394/

47. **Lichen Planus**

a. “Twenty-three published articles in the English language were included for the quantitative and qualitative syntheses. The demographic data, specific vaccine history, and clinical details of the lesions were recorded. The existing evidence supports that vaccines could play an important role in etiopathogenesis of pediatric LP.” Bansal D, Kamboj M, Anand R, Pandiar D, Narwal A, Sivakumar N, Devi A. (2021). *Association of*

childhood vaccination with pediatric lichen planus: A systematic review. Int J Dermatol. 62(1):22-31. https://pubmed.ncbi.nlm.nih.gov/34870853/

48. **Lupus Erythematosus**

a. "Adults receiving HBV had significantly increased odds ratios (OR) for…lupus erythematosus (OR = 9.1, p < 0.0001, 95% CI = 2.3 - 76)…in comparison to the TCV [control] group. Minimal confounding or systematic error was observed." Geier DA, Geier MR. (2005). *A case-control study of serious autoimmune adverse events following hepatitis B immunization*. Autoimmunity. 38(4):295-301. https://pubmed.ncbi.nlm.nih.gov/16206512/

49. **Macrophagic myofasciitis syndrome**

a. "Aluminium hydroxide is a well-known adjuvant used in vaccines. Although it can enhance an adaptive immune response to a co-administered antigen, it causes adverse effects, including macrophagic myofasciitis (MMF), subcutaneous pseudolymphoma, and drug hypersensitivity." Kim H, Lim KY, Kang J, Park JW, Park SH. (2020) *Macrophagic myofasciitis and subcutaneous pseudolymphoma caused by aluminium adjuvants*. Sci Rep. 10(1):11834. https://pubmed.ncbi.nlm.nih.gov/32678281/

b. "[A]djuvants can also provoke an autoimmune response....[T]he accumulated data suggest the possibility of accelerated autoimmunity/inflammation following vaccination. Perhaps the most evaluated post-vaccination condition is the macrophagic myofasciitis syndrome (MMF), in which a causal link was clearly delineated." Shoenfeld Y, Agmon-Levin N. (2011). *'ASIA' - autoimmune/inflammatory syndrome induced by adjuvants.* J Autoimmun. 36(1):4-8. https://pubmed.ncbi.nlm.nih.gov/20708902/

c. "In conclusion, long-term persistence of vaccine-derived aluminum hydroxide within the body assessed by MMF is associated with cognitive dysfunction, not solely due to chronic pain, fatigue and depression." Couette M, Boisse MF, Maison P, Brugieres P, Cesaro P, Chevalier X, Gherardi RK, Bachoud-Levi AC, Authier FJ. (2009). L*ong-term persistence of vaccine-derived aluminum hydroxide is associated with chronic cognitive dysfunction.* J Inorg Biochem. 103(11):1571-8. https://pubmed.ncbi.nlm.nih.gov/19748679/

d. There are supporting data showing a comparable transient lesion after intramuscular (IM) injection of aluminium-containing vaccines in experimental animal models. Evidence suggests that the local lesion which characterizes MMF may be caused by IM injection of aluminium containing vaccines. Vaccine Safety Advisory Committee. (1999). *Vaccine safety.* Weekly Epidemiological Record 74:337-348. https://www.who.int/publications/m/item/WER-1999-74-41

50. **Meningitis**

a. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and meningitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The highest risk of association with aseptic meningitis was observed within the third week after immunisation with Urabe-containing MMR (risk ratio (RR) 14.28; 95% confidence interval (CI) from 7.93 to 25.71) and within the third (RR 22.5; 95% CI 11.8 to 42.9) or fifth (RR 15.6; 95% CI 10.3 to 24.2) weeks after immunisation with the vaccine prepared with the Leningrad-Zagreb strain." Demicheli V, Rivetti A, Debalini MG, Di Pietrantonj C. (2012). *Vaccines for measles, mumps and rubella in children.* Cochrane Database Syst Rev. https://pubmed.ncbi.nlm.nih.gov/22336803/

c. "We present 2 adolescents with reactivated vOka meningitis, 1 immunocompetent and 1 immunocompromised, both of whom received 2 doses of varicella vaccine many years before as children. Pediatricians should be aware of the potential of vOka varicella to reactivate and cause clinically significant central nervous system disease in vaccinated children and adolescents." Harrington WE, Mató S, Burroughs L, Carpenter PA, Gershon A, Schmid DS, Englund JA. (2019). *Vaccine Oka Varicella Meningitis in Two Adolescents*. Pediatrics. https://pubmed.ncbi.nlm.nih.gov/31776194/

d. "When we carried out a literature search, we found 15 cases of immunocompetent children and adolescents with varicella vaccine meningitis; the median age was 11 years. Eight of the children had received two varicella vaccinations. Most of the children also had a concomitant herpes zoster rash, although three did not." Ramachandran P, Grose C. (2024). *Serious neurological adverse events in immunocompetent children and adolescents caused by viral reactivation in the years following varicella vaccination*. Rev Med Virol. https://pubmed.ncbi.nlm.nih.gov/38658176/

51. **Multiple Sclerosis (MS)**

a. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and onset of MS [multiple sclerosis] in adults." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and onset of MS [multiple sclerosis] in children." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and relapse of MS [multiple sclerosis] in adults." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

d. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and relapse of MS [multiple sclerosis] in children." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

e. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and onset of MS [multiple sclerosis] in children." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

f. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and the onset of MS [multiple sclerosis] in adults." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

g. "The evidence is inadequate to accept or reject a causal relationship between hepatitis A vaccine and MS [multiple sclerosis]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

h. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and onset of MS [multiple sclerosis] in adults." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

i. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and relapse of MS [multiple sclerosis] in adults." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

j. "The evidence is inadequate to accept or reject a causal relationship between HPV vaccine and MS [multiple sclerosis]." tratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

k. “The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and onset of MS [multiple sclerosis] in adults.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

l. “The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, and acellular pertussis–containing vaccine and relapse of MS [multiple sclerosis] in adults.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

“The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and relapse of MS [multiple sclerosis] in children.” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

n. “The evidence is inadequate to accept or reject a causal relationship between meningococcal vaccine and MS [multiple sclerosis].” Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

o. “Conclusions: Hepatitis B vaccination does not generally increase the risk of CNS inflammatory demyelination in childhood. However, the Engerix B vaccine appears to increase this risk, particularly for confirmed multiple sclerosis, in the longer term. Our results require confirmation in future studies.” Mikaeloff Y, Caridade G, Suissa S, Tardieu M. (2009). *Hepatitis B vaccine and the risk of CNS inflammatory demyelination in childhood.* Neurology. 72(10):873-80. https://pubmed.ncbi.nlm.nih.gov/18843097/

p. “These findings are consistent with the hypothesis that immunization with the recombinant hepatitis B vaccine is associated with an increased risk of MS, and challenge the idea that the relation between hepatitis B vaccination and risk of MS is well understood.” Hernán MA, Jick SS, Olek MJ, Jick H. (2004). *Recombinant hepatitis B vaccine and the risk of multiple sclerosis: a prospective study.* Neurology. 63(5):838-42. https://pubmed.ncbi.nlm.nih.gov/15365133/

q. “Adults receiving HBV had significantly increased odds ratios (OR) for multiple sclerosis (OR = 5.2, $p < 0.0003$, 95% Confidence Interval (CI) = 1.9 – 20)…in comparison to the [control] group. Minimal confounding or systematic error was observed.” Geier DA, Geier MR. (2005). *A case-control study of serious autoimmune adverse events following hepatitis B immunization*. Autoimmunity. 38(4):295-301. https://pubmed.ncbi.nlm.nih.gov/16206512/

r. “Physician Philippe Jacubowicz who heads an organization in Paris called REVAHB has collected data on more than 600 cases of illnesses many with MS-like symptoms in people who had received the hepatitis B vaccine. In addition, patient advocacy groups in Britain and Canada have studied more than 100 cases each, as has an out-spoken U.S. accuser of the hepatitis B vaccine Bonnie Dunbar a molecular biologist at Baylor College of Medicine in Houston.” Marshall E. (1998). *A shadow falls on hepatitis B vaccination effort.* Science. 281(5377):630-1. https://pubmed.ncbi.nlm.nih.gov/9714670/

s. “We present four incidental cases that developed partial myelitis following the administration of hepatitis B vaccine in 1998…. In all cases, there was no history of preceding infections and no clinical evidence suggestive of any other disorders that may cause myelopathy…. Similar clinical and imaging presentation of myelitis following hepatitis B vaccination within a 1-year period with no other demonstrable clinical and laboratory evidence for any other disorder raise the probability of a causal link between these two events.” Karaali-Savrun F, Altintaş A, Saip S, Siva A. (2001). *Hepatitis B vaccine related-myelitis?* Eur J Neurol. 8(6):711-5. https://pubmed.ncbi.nlm.nih.gov/11784358/

52. **Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)**
    a. "Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) is a multifactorial and poorly understood disabling disease. We present epidemiological, clinical and experimental evidence that ME/CFS constitutes a major type of adverse effect of vaccines, especially those containing poorly degradable particulate aluminum adjuvants." Gherardi *et al*. (2019). *Myalgia and chronic fatigue syndrome following immunization: macrophagic myofasciitis and animal studies support linkage to aluminum adjuvant persistency and diffusion in the immune system*. Autoimmunity Reviews 18(7):691-705. https://pubmed.ncbi.nlm.nih.gov/31059838/

53. **Myasthenia gravis**
    a. "HPV vaccination may cause MG owing to unexpected abnormal autoimmune responses." Chung *et al*. (2018). *Myasthenia gravis following human papillomavirus vaccination: a case report*. BMC Neurology 18(1):222. https://pubmed.ncbi.nlm.nih.gov/30593270/

54. **Myocardial infarction**
    a. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and myocardial infarction." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

55. **Myocarditis**
    "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and myocarditis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

    b. "We identified additional valid cases of myopericarditis following an mRNA vaccination that would be missed by the VSD's search algorithm, which depends on select hospital discharge diagnosis codes." Sharff KA, Dancoes DM, Longueil JL, Johnson ES, Lewis PF. (2022). *Risk of myopericarditis following COVID-19 mRNA vaccination in a large integrated health system: a comparison of completeness and timeliness of two methods*. Pharmacoepidemiol Drug Saf. 31(8):921-5. https://pubmed.ncbi.nlm.nih.gov/35404496/

    c. "A total of 34 patients were included in cardiac AEs following influenza vaccination, with the mean age of patients being 68.55 ± 18.23 years. Fifty-five percent of cases described were female. Myocarditis/pericarditis/myopericarditis developed in 29 patients, and Takotsubo cardiomyopathy was described in two cases. The average time of symptom onset from vaccination was 4.7 ± 4 days." Parmar K, Subramanyam S, Del Rio-Pertuz G, Sethi P, Argueta-Sosa E. (2022). *Cardiac Adverse Events after Vaccination-A Systematic Review.* Vaccines (Basel). 10(5):700. https://pubmed.ncbi.nlm.nih.gov/35632455/

    d. "We identified 4 myocarditis reports following MMR. Three were serious, including 1 report of death. Interval from time of vaccination symptom onset ranged from 7 to 13 days." Sukumaran L, McNeil MM, Moro PL, Lewis PW, Winiecki SK, Shimabukuro TT. (2015). *Adverse Events Following Measles, Mumps, and Rubella Vaccine in Adults Reported to the Vaccine Adverse Event Reporting System (VAERS), 2003-2013*. Clin Infect Dis. 60(10):e58-65. https://pmc.ncbi.nlm.nih.gov/articles/PMC4447805/

56. **Narcolepsy**
    a. "The incidence of narcolepsy was 9.0 in the vaccinated as compared to 0.7/100,000 person years in the unvaccinated individuals, the rate ratio being 12.7 (95% confidence interval 6.1-30.8). The vaccine-attributable risk of developing narcolepsy was 1:16,000 vaccinated 4 to 19-year-olds (95% confidence interval 1:13,000-1:21,000)." Nohynek *et al*. (2012). AS03 adjuvanted AH1N1 vaccine associated with an abrupt increase in the incidence of childhood narcolepsy in Finland. *PLoS One* 7(3):e33536. https://pubmed.ncbi.nlm.nih.gov/22470453/

    b. "H1N1 vaccination was associated with narcolepsy-cataplexy with an odds ratio of 6.5 (2.1-19.9) in subjects aged<18 years, and 4.7 (1.6-13.9) in those aged 18 and over."Dauvilliers *et al*. (2013). *Increased*

risk of narcolepsy in children and adults after pandemic H1N1 vaccination in France. Brain 136(Pt 8):2486-2496. https://pubmed.ncbi.nlm.nih.gov/23884811/

c. "The increased risk of narcolepsy after vaccination with ASO3 adjuvanted pandemic A/H1N1 2009 vaccine indicates a causal association." Miller *et al*. (2013). *Risk of narcolepsy in children and young people receiving AS03 adjuvanted pandemic A/H1N1 2009 influenza vaccine: retrospective analysis*. BMJ 346:f794. https://pubmed.ncbi.nlm.nih.gov/23444425/

d. "We found a significantly increased risk of narcolepsy in adults following Pandemrix vaccination in England." Stowe et al. (2016). *Risk of Narcolepsy after AS03 Adjuvanted Pandemic A/H1N1 2009 Influenza Vaccine in Adults: A Case-Coverage Study in England*. Sleep 39(5):1051-1057. https://pubmed.ncbi.nlm.nih.gov/26856903/

57. **Neurological Illness**

a. A significant association was shown between serious neurological illness and pertussis vaccine, though cases were few and most children recovered completely. Miller DL, Ross EM, Alderslade R, Bellman MH, Rawson NS. (1981). *Pertussis immunisation and serious acute neurological illness in children.* Br Med J (Clin Res Ed). 1282(6276):1595-9. https://pmc.ncbi.nlm.nih.gov/articles/PMC1505512/

b. "Non-physiological AEFI, sometimes referred to as hyper-reactions, are rare, unexpected and more severe than physiological AEFI, and they tend to occur in immunocompromised patients or patients allergic to vaccine components [10, 11]. The most severe AEFI are either allergic (anaphylaxis) or neurological (encephalopathy, encephalitis, neuritis), and can lead to hospitalization or death [12, 13]." Danova J, Kocourkova A, Celko AM. (2017). *Active surveillance study of adverse events following immunisation of children in the Czech Republic.* BMC Public Health. 17(1):167. https://pmc.ncbi.nlm.nih.gov/articles/PMC5292794/

58. **Neuromyelitis optica (NMO)**

a. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and NMO [neuromyelitis optica]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and NMO [neuromyelitis optica]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and neuromyelitis optica." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

d. "The evidence is inadequate to accept or reject a causal relationship between HPV vaccine and NMO [neuromyelitis optica]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

e. "The temporal relationship between vaccination and onset of symptoms suggests that vaccine might be a trigger of NMOSD. Genetic predisposition could be a risk factor for postvaccination NMOSD as there are evidences of family history and presence of an associated HLA allele. The prevalence of short-segment transverse myelitis seems to be higher than in typical cases of NMOSD, but the natural history is otherwise similar. All patients received acute treatment with high-dose corticosteroids, most with excellent response. Long-term immunomodulation therapy should be initiated for relapse prevention. Limitations of this study are lack of some relevant data, precision of temporal relationship, and the small number of reports." Anamnart C, et al. (2022). *Newly diagnosed neuromyelitis optica spectrum disorders following vaccination: Case*

report and systematic review. Mult Scler Relat Disord. 58:103414. https://pubmed.ncbi.nlm.nih.gov/35216789/

59. **Neuropathy**

a. "The evidence is inadequate to accept or reject a causal relation between tetanus toxoid, DT, or Td and peripheral mononeuropathy (other than those caused by direct intraneural injection)." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

b. "The evidence is inadequate to accept or reject a causal relationship between varicella vaccine and small fiber neuropathy." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and small fiber neuropathy." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

d. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and CIDP [chronic inflammatory disseminated polyneuropathy." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

e. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and CIDP [chronic inflammatory disseminated polyneuropathy]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

f. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and CIDP [chronic inflammatory disseminated polyneuropathy]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

g. "The evidence is inadequate to accept or reject a causal relation between tetanus toxoid, DT, or Td and peripheral mononeuropathy (other than those caused by direct intraneural injection)." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

h. "The evidence is inadequate to accept or reject a causal relationship between HPV vaccine and CIDP [chronic inflammatory disseminated polyneuropathy]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

i. "The evidence is inadequate to accept or reject causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and CIDP [chronic inflammatory disseminated polyneuropathy]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

"The evidence is inadequate to accept or reject a causal relationship between meningococcal vaccine and CIDP [chronic inflammatory disseminated polyneuropathy]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

k. "The evidence is inadequate to accept or reject a causal relationship between hepatitis A vaccine and CIDP [chronic inflammatory disseminated polyneuropathy]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

60. **Ocular Nerve Palsies**

a. "Independent data may help to clarify whether, when, and to what extent the rates of cranial nerve palsies following particular vaccines may exceed background levels." Woo EJ, Winiecki SK, Ou AC. (2013). *Motor palsies of cranial nerves (excluding VII) after vaccination: reports to the US Vaccine Adverse Event Reporting System*. Hum Vaccin Immunother. 10(2):301-5. https://pubmed.ncbi.nlm.nih.gov/24231288/

61. **Opsoclonus myoclonus syndrome (OMS)**

a. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and OMS." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and OMS [opsoclonus myoclonus syndrome]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

62. **Optic neuritis**

a. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and optic neuritis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and optic neuritis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and optic neuritis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

d. "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and optic neuritis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

e. "During the largest mass campaign for measles-rubella (MR) vaccination 33,000,000 people with an age range of 5-25 years were vaccinated in Iran. Some complications were encountered, including a rare case of optic neuritis. In the past 30 years of medical literature, five cases of optic neuritis have been reported but all of them were developed at least 8 days after vaccination. We are supposed to report the first case of rapid

onset optic neuritis in which the complication came out just in few hours in a 16 years old boy." Arshi S, Sadeghi-Bazargani H, Ojaghi H, Savadi-Oskouei D, Hekmat S, Jastan M, Majidpour A, Shahizareh F. (2004). *The first rapid onset optic neuritis after measles-rubella vaccination: case report.* Vaccine. 22(25-26):3240-2. https://pubmed.ncbi.nlm.nih.gov/15308345/

f. "Adults receiving HBV had significantly increased odds ratios (OR) for…optic neuritis (OR = 14, p < 0.0002, 95% CI = 2.3 - 560)…in comparison to the TCV [control] group. Minimal confounding or systematic error was observed." Geier DA, Geier MR. (2005). *A case-control study of serious autoimmune adverse events following hepatitis B immunization*. Autoimmunity. 38(4):295-301. https://pubmed.ncbi.nlm.nih.gov/16206512/

g. "Pediatric optic neuritis may occur following infection or vaccination, or in association with a systemic demyelinating process such as acute disseminated encephalomyelitis, neuromyelitis optica, or multiple sclerosis." Chang MY, Pineles SL. (2017). *Pediatric Optic Neuritis*. Semin Pediatr Neurol. 24(2):122-128. https://pubmed.ncbi.nlm.nih.gov/28941527/

63. **Orchitis**

a. "The available evidence is inadequate to accept or reject a causal relation between mumps vaccine and orchitis." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

64. **Pancreatitis**

a. "The evidence is inadequate to accept or reject a causal relationship between HPV vaccine and pancreatitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "Necrotizing pancreatitis is a severe form of pancreatitis and is associated with substantial morbidity and mortality. We report a case of necrotizing pancreatitis that developed following combined hepatitis A and B vaccination. No other causes of pancreatitis could be determined." Shlomovitz, E., Davies, W., Cairns, E., Brintnell, W.C., Goldszmidt, M., Dresser, G.K. (2007). *Severe necrotizing pancreatitis following combined hepatitis A and B vaccination.* CMAJ. https://pubmed.ncbi.nlm.nih.gov/17261831/

c. "We suggest that the pancreatitis may have been a cellular immunlogical reaction to one of the antigens of hepatitis A virus vaccine, or it might have been caused by the release of mediators of anaphylaxis such as histamine and leucotriens, induced by HAV antigens, resulting in pancreatitis without development of humoral immunization." Haviv, Y.S., Sharkia, M., Galun, E., Safadi, R. (2000). *Pancreatitis following hepatitis A vaccination*. Eur J Med Res. https://pubmed.ncbi.nlm.nih.gov/10806126/

d. "We report the occurrence of acute pancreatitis in an adult who had received measles, mumps, and rubella II vaccine." Adler, J.B., Mazzotta, S.A., Barkin, J.S. (1991). *Pancreatitis caused by measles, mumps, and rubella vaccine*. Pancreas. https://pubmed.ncbi.nlm.nih.gov/1876605/

65. **Pericarditis**

a. "A total of 34 patients were included in cardiac AEs following influenza vaccination, with the mean age of patients being 68.55 ± 18.23 years. Fifty-five percent of cases described were female. Myocarditis/pericarditis/myopericarditis developed in 29 patients, and Takotsubo cardiomyopathy was described in two cases. The average time of symptom onset from vaccination was 4.7 ± 4 days." Parmar, K., Subramanyam, S., Del Rio-Pertuz, G., Sethi, P., Argueta-Sosa, E. (2022). *Cardiac Adverse Events after Vaccination-A Systematic Review.* Vaccines (Basel). https://pubmed.ncbi.nlm.nih.gov/35632455/

66. **Poliomyelitis (Vaccine-strain, paralytic)**

a. "The evidence establishes a causal relation between OPV and death from vaccine-strain poliovirus infection, including infection that results in paralytic poliomyelitis." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events*

Associated with Childhood Vaccines: Evidence Bearing on Causality. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

67. **Postpartum Hemorrhage**

a. "Optimally-timed [prenatal TDaP] immunization was associated with small increased relative risks of: chorioamnionitis [RR=1.11, (95% CI: 1.07-1.15), overall risk=2.8%], and postpartum hemorrhage [RR=1.23 (95% DI: 1.18-1.28), overall risk=2.4%]; however, these relative increases corresponded to low absolute risk increases....Overall, prenatal Tdap immunization was not associated with newborn adverse events, but potential associations with chorioamnionitis consistent with one previous study and postpartum hemorrhage require further investigation." Layton, J.B., et al. (2017). *Prenatal Tdap immunization and risk of maternal and newborn adverse events*. Vaccine. https://pubmed.ncbi.nlm.nih.gov/28669620/

68. **Postural Orthostatic Tachycardia Syndrome (POTS)**

a. "Here we show in a cohort of 284,592 COVID-19 vaccinated individuals using a sequence-symmetry analysis, that the odds of POTS are higher 90 days after vaccine exposure than 90 days prior to exposure, and that the odds for POTS are higher than referent conventional primary care diagnoses, but lower than the odds of new POTS diagnosis after SARS-CoV-2 infection. Our results identify a possible association between COVID-19 vaccination and incidence of POTS. Notwithstanding the probable low incidence of POTS after COVID-19 vaccination, particularly when compared to SARS-Cov-2 post-infection odds which were five times higher, our results suggest that further studies, are needed to investigate the incidence and etiology of POTS occurring after COVID-19 vaccination." Kwan, A.C., Ebinger, J.E., Wei, J., Le, C.N., Oft, J.R., Zabner, R., Teodorescu, D., Botting, P.G., Navarrette, J., Ouyang, D., Driver, M., Claggett, B., Weber, B.N., Chen, P.S., Cheng, S. (2022). *Apparent Risks of Postural Orthostatic Tachycardia Syndrome Diagnoses After COVID-19 Vaccination and SARS-Cov-2 Infection.* Nat Cardiovasc Res. https://pubmed.ncbi.nlm.nih.gov/37303827/

69. **Psychiatric (mental) disorders**

a. "Subjects with newly diagnosed AN [anorexia nervosa] were more likely than controls to have had any vaccination in the previous 3 months. Influenza vaccinations during the prior 3, 6, and 12 months were also associated with incident diagnoses of AN, OCD, and an anxiety disorder. Several other associations were also significant with HRs greater than 1.40 (hepatitis A with OCD and AN; hepatitis B with AN; and meningitis with AN and chronic tic disorder)." Leslie, D.L., et al. (2017). *Temporal Association of Certain Neuropsychiatric Disorders Following Vaccination of Children and Adolescents: A Pilot Case-Control Study*. Frontiers in Psychiatry. https://pubmed.ncbi.nlm.nih.gov/28154539/

70. **Seizures**

a. "Seizure episode and seizure disorder are rare consequences of routine childhood MMR vaccination." Geier DA, Geier MR. (2021). *A longitudinal cohort study of childhood MMR vaccination and seizure disorder among American children*. Brain Dev. 2021. https://pubmed.ncbi.nlm.nih.gov/32981784/

b. "224 potential seizure events following 1,091,181 influenza vaccinations were identified for medical record review in the main safety study and were thus eligible for inclusion in the algorithm validation analysis." Thyagarajan, V., Su, S., Gee, J., Duffy, J., McCarthy, N.L., Chan, K.A., Weintraub, E.S., Lin, N.D. (2013). *Identification of seizures among adults and children following influenza vaccination using health insurance claims data*. Vaccine. https://pubmed.ncbi.nlm.nih.gov/24148576/

c. "Audio-visual recordings in 7 toddlers with unexplained sudden deaths strongly implicate that deaths were related to convulsive seizures, suggesting that many unexplained sleep-related deaths may result from seizures." Gould, L., Reid, C.A., Rodriguez, A.J., Devinsky, O.; for SUDC Video Working Group. (2024). *Video Analyses of Sudden Unexplained Deaths in Toddlers*. Neurology. https://pubmed.ncbi.nlm.nih.gov/38175965/

d. "Comparison of adverse events in different ages following acellular anti-pertussis vaccines shows no significant differences in febrile reactions, seizures and allergic reactions, which almost evenly occur in both age groups." Patterson, J., Kagina, B.M., Gold, M., Hussey, G.D., Muloiwa, R. (2018). *Comparison of*

adverse events following immunisation with acellular and whole-cell pertussis vaccines: A systematic review. Vaccine. https://pubmed.ncbi.nlm.nih.gov/30143272/

71. **Seizures - Febrile seizures**

a. "The evidence convincingly supports a causal relationship between MMR vaccine and febrile seizures." "The committee concluded that the evidence favors acceptance of a causal relationship between measles, mumps, and rubella (MMR) vaccine and febrile seizures." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "At 15 to 17 months, the risk difference of febrile seizures within 2 weeks following MMR vaccination was 1.56 per 1000 children overall." Vestergaard, M., Pedersen, C., Sidenius, P., Olsen, J., Christensen, J. (2007). *The long-term risk of epilepsy after febrile seizures in susceptible subgroups.* Am J Epidemiol. https://academic.oup.com/aje/article/165/8/911/184889

c. "First VP-SE was predominantly associated with a measles-containing vaccine at 12-months of age." Deng, L., et al. (2022). *Status epilepticus following vaccination in children aged ≤24 months: A five-year retrospective observational study.* Epilepsy & Behavior. https://pubmed.ncbi.nlm.nih.gov/35134735/

d. "Although vaccination can cause FSs, little is known on whether FSs occurring in the time soon after vaccination (vaccine-proximate febrile seizures [VP-FSs] differ clinically from non-vaccine-proximate febrile seizures [NVP-FSs])." Deng, L., Gidding, H., Macartney, K., Crawford, N., Buttery, J., Gold, M., Richmond, P., Wood, N. (2019). *Postvaccination Febrile Seizure Severity and Outcome.* Pediatrics. https://pubmed.ncbi.nlm.nih.gov/31004046/

a. "A significant risk of association with febrile seizures and MMR exposure during the two previous weeks (RR 1.10; 95% CI 1.05 to 1.15) was assessed in one large person-time cohort study involving 537,171 children aged between three months and five year of age. Increased risk of febrile seizure has also been observed in children aged between 12 to 23 months (relative incidence (RI) 4.09; 95% CI 3.1 to 5.33) and children aged 12 to 35 months (RI 5.68; 95% CI 2.31 to 13.97) within six to 11 days after exposure to MMR vaccine." Demicheli, V., Rivetti, A., Debalini, M.G., Di Pietrantonj, C. (2012). *Vaccines for measles, mumps and rubella in children*. Cochrane Database Syst Rev. https://pubmed.ncbi.nlm.nih.gov/22336803/

b. "SOE [strength of evidence] was high for the following associations in children and adolescents: measles, mumps, rubella (MMR) vaccine and febrile seizures in children under age 5…." Maglione, M.A., et al. (2014). *Safety of Vaccines Used for Routine Immunization in the United States*. https://pubmed.ncbi.nlm.nih.gov/30257278/

c. "Vaccine administration is the second leading cause of febrile seizures (FS). FS occurrence in children is a serious concern because it leads to public apprehension of vaccinations. This review discusses the clinical implications of FS, its potential link to vaccinations and its impact on official recommendations for vaccinations in children. Vaccines such as the pertussis antigen-containing vaccine, the measles-containing vaccine and the influenza vaccine have been linked to FS. However, FS events are very rare and are not usually associated with downstream complications or severe neurologic diseases. Considering their significant health benefits, vaccinations have not been restricted in the pediatric population. Nevertheless, vaccine-induced FS could be a problem, particularly in genetically predisposed children. Therefore, post-marketing surveillance studies are required to accurately assess the incidence of FS and identify individuals who are particularly susceptible to FS after vaccination." Principi, N., Esposito, S. (2013). *Vaccines and febrile seizures*. Expert Rev Vaccines. https://pubmed.ncbi.nlm.nih.gov/23984960/

d. "Sixteen subjects (11%) presented within 14 days of routine childhood vaccinations, mostly with simple febrile seizures (Table 3). Of these, 14/16 (88%) had been administered measles, mumps and rubella (MMR) containing vaccines a median of 9 days prior to their febrile seizure (3 had been administered the measles, mumps, rubella, varicella (MMR-V) vaccine); 9/16 (56%) also had at least one virus identified. One child had a febrile seizure 2 days after administration of routine 6-month immunisations (Infanrix-hexa, Prevenar-13) and another presented 9 days after Varicella zoster virus vaccination; in both cases at least one virus was

also identified. None of the children enrolled in the study had received an influenza vaccination." Francis, J.R., Richmond, P., Robins, C., Lindsay, K., Levy, A., Effler, P.V., Borland, M., Blyth, C.C. (2016). *An observational study of febrile seizures: the importance of viral infection and immunization.* BMC Pediatr. https://pmc.ncbi.nlm.nih.gov/articles/PMC5135752/

72. **Seizures - Infantile spasms**

a. "The evidence is inadequate to accept or reject a causal relation between DT and residual seizure disorder other than infantile spasms." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

b. "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and infantile spasms." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "The possible roles of pertussis immunisation and of other factors in the aetiology of infantile spasms were investigated by analysis of 269 cases reported to the National Childhood Encephalopathy Study. In 34% of the cases an antecedent factor which may have caused infantile spasms was identified; the commonest of these were perinatal hypoxia (38 cases) and tuberous sclerosis (16 cases). Case-control analyses showed no significant association between infantile spasms and pertussis immunisation in the 28 days before onset. There was, however, some clustering of cases immunised with either diphtheria-tetanus pertussis or diphtheria-tetanus vaccines in the 7 days before onset. The excess compared with controls was compensated for by a corresponding deficit over the remaining period up to 28 days. It is suggested that these vaccines do not cause infantile spasms but may trigger their onset in those children in whom the disorder is destined to develop." Bellman, M.H., Ross, E.M., Miller, D.L. (1983). *Infantile spasms and pertussis immunisation*. Lancet. https://pubmed.ncbi.nlm.nih.gov/6133070/

73. **Seizures – Residual seizure disorder**

a. "The evidence is inadequate to accept or reject a causal relation between tetanus toxoid or Td and residual seizure disorder." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

b. "The evidence is inadequate to accept or reject a causal relation between measles vaccine and residual seizure disorder." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

74. **Serum sickness**

"The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and serum sickness." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

75. **Shoulder Injuries Related to Vaccine Administration**

a. "Conclusion 10-1: The evidence establishes a causal relationship between vaccine administration and subacromial/subdeltoid bursitis caused by direct injection into the bursa. Conclusion 10-2: The evidence establishes a causal relationship between vaccine administration and acute rotator cuff or acute biceps tendinopathy caused by direct administration of vaccine into or adjacent to the tendon. … Conclusion 10-4: The evidence is inadequate to accept or reject a causal relationship between vaccine administration and adhesive capsulitis. … Conclusion 10-6: The evidence establishes a causal relationship between vaccine administration and bone injury caused by direct injection into or adjacent to the bone. Conclusion 10-7: The evidence establishes a causal relationship between vaccine administration and axillary or radial nerve injury

caused by direct injection into or adjacent to the nerve. Conclusion 10-8: The evidence is inadequate to accept or reject a causal relationship between vaccine administration and Parsonage-Turner syndrome. Conclusion 10-9: The evidence is inadequate to accept or reject a causal relationship between vaccine administration and complex regional pain syndrome." National Academies of Sciences, Engineering, and Medicine. (2024). *Evidence Review of the Adverse Effects of COVID-19 Vaccination and Intramuscular Vaccine Administration*. Washington, DC: The National Academies Press. https://pubmed.ncbi.nlm.nih.gov/39312602/

76. **Sjögren's syndrome**

a. "[T]he administration of vaccines containing Saccharomyces cerevisiae should be carefully evaluated in patients with SjS since there is the possibility that such vaccines may elicit the production of autoantibodies in these patients. Moreover, the question whether vaccines may cause an autoimmune disease in otherwise healthy subjects is still unanswered…the possible association between vaccination and autoimmune diseases, including SjS, is a matter of which physicians should be aware of." Colafrancesco et al. (2014) Sjögren's syndrome: Another facet of the autoimmune/inflammatory syndrome induced by adjuvants (ASIA). *Journal of Autoimmunity.* 51: 10-16. https://pubmed.ncbi.nlm.nih.gov/24774584/

b. "[S]everal case reports have suggested that both vaccines and silicone may trigger the development of SS." Colafrancesco *et al*. (2016). Autoimmune/Inflammatory Syndrome Induced by Adjuvants and Sjögren's Syndrome. *The Israel Medical Association Journal* 18(3-4):150–153. https://pubmed.ncbi.nlm.nih.gov/27228631/

77. **Small Fiber Neuropathy**

a. "Conclusions: This case report describes an acute onset of non-length-dependent SFN potentially related to human papillomavirus vaccine administration. Literature review includes several similar case studies, and various pathological processes have been proposed for vaccine-associated polyneuropathies. Some theories describe immune-mediated hypersensitivity to the solvents/adjuvants and/or invasion of nervous system through a prolonged, less virulent infection. However, the lack requires that evidence must be carefully reviewed." Kafaie, J., Kim, M., Krause, E. (2016). *Small Fiber Neuropathy Following Vaccination*. J. Clin. Neuromuscul. Dis. https://pubmed.ncbi.nlm.nih.gov/27552388/

b. "We report five patients who developed paresthesias within one day to two months following vaccination for rabies, varicella zoster, or Lyme disease. On examination, there was mild sensory loss in distal extremities, preserved strength, normal or minimally abnormal electrodiagnostic findings, and decreased epidermal nerve fiber densities per skin biopsy. ... We conclude that an acute or subacute, post-vaccination small fiber neuropathy may occur and follow a chronic course." Souayah, N., Ajroud-Driss, S., Sander, H.W., Brannagan, T.H., Hays, A.P., Chin, R.L. (2009). *Small fiber neuropathy following vaccination for rabies, varicella or Lyme disease*. Vaccine. https://pubmed.ncbi.nlm.nih.gov/19808027/

c. "We describe the case of a 57-y-old female who presented 1 week after receiving the second dose of the Pfizer coronavirus disease 2019 (COVID-19) vaccine with subacute onset of intense burning dysesthesias in the feet, gradually spreading to the calves and minimally into the hands, unaccompanied by other neurological or constitutional symptoms. There was no known prior COVID-19 exposure; a COVID-19 reverse-transcriptase-polymerase-chain-reaction test 9 mo before this presentation was negative. She was not on any medications and denied the use of alcohol. Besides the distal loss of pinprick and cold sensations in the feet, her examination was unremarkable." Waheed, W., Carey, M.E., Tandan, S.R., Tandan, R. (2021). *Post COVID-19 vaccine small fiber neuropathy.* Muscle Nerve. https://pubmed.ncbi.nlm.nih.gov/33851437/

78. **Sterility**

a. "The available evidence is inadequate to accept or reject a causal relation between mumps vaccine and sterility." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

79. **Stroke**

a. "The evidence is inadequate to accept or reject a causal relationship between varicella vaccine and stroke." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, &

Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and stroke." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "The study population included 14669716 beneficiaries who received influenza vaccines across the 3 influenza seasons (median age, 74 [IQR, 69-80] years; 57.75% female). We observed 29730 stroke cases in 2016 to 2017, 34518 in 2017 to 2018, and 36869 in 2018 to 2019 (Table). In 2016 to 2017, there was an association for HS during the 22- to 42-day risk window (IRR, 1.14 [95% CI, 1.02-1.28]; RD, 0.84 [95% CI, 0.14-1.54]) compared with the control interval. However, no association was identified in 2017 to 2018 or 2018 to 2019 (Figure). Temporal scans identified case clusters in control windows for several outcomes in 2017 to 2018 and 2018 to 2019." Lu, Y., Matuska, K., Ma, Y., Laniyan, L., Chillarige, Y., Anderson, S.A., Forshee, R.A. (2024). *Stroke After Influenza Vaccines in Older Adults in the US, 2016 to 2019*. JAMA Netw Open. https://pmc.ncbi.nlm.nih.gov/articles/PMC11265121/

80. **Subacute sclerosing panencephalitis (SSPE)**

a. "The evidence is inadequate to accept or reject a causal relation between measles vaccine and SSPE [subacute sclerosing panencephalitis]." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

81. **Subcutaneous pseudolymphoma**

a. "Aluminium hydroxide is a well-known adjuvant used in vaccines. Although it can enhance an adaptive immune response to a co-administered antigen, it causes adverse effects, including macrophagic myofasciitis (MMF), subcutaneous pseudolymphoma, and drug hypersensitivity." Kim, H., Lim, K.Y., Kang, J., Park, J.W., Park, S.H. (2020). *Macrophagic myofasciitis and subcutaneous pseudolymphoma caused by aluminium adjuvants*. Sci Rep. https://pubmed.ncbi.nlm.nih.gov/32678281/

82. **Sudden Infant Death Syndrome (SIDS)**

a. "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and SIDS." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence is inadequate to accept or reject a causal relation between hepatitis B vaccine and SIDS." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

c. "The evidence is inadequate to accept or reject a causal relation between polio vaccines and SIDS." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

d. "Although there is considerable evidence that a subset of infants has an increased risk of sudden death after receiving vaccines, health authorities eliminated 'prophylactic vaccination' as an official cause of death, so medical examiners are compelled to misclassify and conceal vaccine-related fatalities under alternate cause-of-death classifications. In this paper, the Vaccine Adverse Event Reporting System (VAERS) database was analyzed to ascertain the onset interval of infant deaths post-vaccination. Of 2605 infant deaths reported to VAERS from 1990 through 2019, 58 % clustered within 3 days post-vaccination and 78.3 % occurred within 7 days post-vaccination, confirming that infant deaths tend to occur in temporal proximity

to vaccine administration. The excess of deaths during these early post-vaccination periods was statistically significant ($p < 0.00001$). A review of the medical literature substantiates a link between vaccines and sudden unexplained infant deaths. Several theories regarding the pathogenic mechanism behind these fatal events have been proposed, including the role of inflammatory cytokines as neuromodulators in the infant medulla preceding an abnormal response to the accumulation of carbon dioxide; fatal disorganization of respiratory control induced by adjuvants that cross the blood-brain barrier; and biochemical or synergistic toxicity due to multiple vaccines administered concurrently. While the findings in this paper are not proof of an association between infant vaccines and infant deaths, they are highly suggestive of a causal relationship." Miller, N.Z. (2021). *Vaccines and sudden infant death: An analysis of the VAERS database 1990-2019 and review of the medical literature*. Toxicol Rep. https://pubmed.ncbi.nlm.nih.gov/34258234/

83. **Syncope**

a. "The evidence convincingly supports a causal relationship between the injection of a vaccine and syncope." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

84. **Systemic lupus erythematosus (SLE)**

a. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and onset or exacerbation of SLE." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and onset or exacerbation of SLE [systemic lupus erythematosus]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "There are few reports of autoimmune diseases, such as rheumatoid arthritis and anti-phospholipid syndrome after anti-tetanus vaccination. Herein, we describe four cases, of which we believe, show a clear temporal relation between anti-tetanus vaccination and the appearance of dermatomyositis, systemic lupus erythematosus, type 1 diabetes mellitus and anti-phospholipid syndrome." Ruhrman-Shahar, N., Torres-Ruiz, J., Rotman-Pikielny, P., Levy Y. (2017). *Autoimmune reaction after anti-tetanus vaccination-description of four cases and review of the literature*. Immunol Res. https://pubmed.ncbi.nlm.nih.gov/27435706/

85. **Thrombocytopenia**

a. "The evidence establishes a causal relation between MMR and thrombocytopenia." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

b. "The evidence is inadequate to accept or reject a causal relation between monovalent measles and mumps vaccines and thrombocytopenia." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

c. "The evidence is inadequate to accept or reject a causal relation between Hib vaccines and thrombocytopenia." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

d. "The evidence is inadequate to accept or reject a causal relationship between varicella vaccine and thrombocytopenia." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects

of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

e. An acute thrombocytopenic purpura developed shortly after measles-mumps-rubella vaccination in 23 of approximately 700,000 children immunized over a period of seven years. The mean interval from inoculation to the onset of purpura was 19 days. Bone marrow aspirates obtained from 13 patients showed increased or normal amounts of megakaryocytes. Platelet survival time was markedly shortened in the two patients studied. Fifteen patients recovered (the platelet count exceeded 100 x 10(9)/l) in one month, five in two months and two in six months. Increase in platelet-associated immunoglobulin was detected in 10 of 15 patients. Circulating antiplatelet autoantibodies (AAb) against glycoprotein IIb/IIIa were detected in 5 of 15 patients. The findings are compatible with an autoimmune mechanism triggered by immune response to measles-mumps-rubella vaccination. As evaluated by the clinical course and the presence of AAb, post-vaccination thrombocytopenic purpura appears to be indistinguishable from childhood acute idiopathic thrombocytopenic purpura. Nieminen, U., Peltola, H., Syrjälä, M.T., Mäkipernaa, A., Kekomäki, R. (1993). *Acute thrombocytopenic purpura following measles, mumps and rubella vaccination. A report on 23 patients*. Acta Paediatr. https://pubmed.ncbi.nlm.nih.gov/8495082/

f. "Adults receiving HBV had significantly increased odds ratios (OR) for… thrombocytopenia (OR = 2.3, $p < 0.04$, 95% CI = 1.02 - 6.2) in comparison to the TCV [control] group. Minimal confounding or systematic error was observed." Geier DA, Geier MR. (2005). *A case-control study of serious autoimmune adverse events following hepatitis B immunization*. Autoimmunity. https://pubmed.ncbi.nlm.nih.gov/16206512/

86. **Thromboembolic events**

a. "The evidence is inadequate to accept or reject a causal relationship between HPV vaccine and thromboembolic events." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

87. **Transverse myelitis**

"The evidence is inadequate to accept or reject a causal relation between hepatitis B vaccine and transverse myelitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. b. "The evidence is inadequate to accept or reject a causal relation between Hib vaccines and transverse myelitis." Institute of Medicine (US) Vaccine Safety Committee, Stratton, K. R., Howe, C. J., & Johnston, R. B., Jr. (Eds.). (1994). *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/25144097/

c. "The evidence is inadequate to accept or reject a causal relationship between MMR vaccine and transverse myelitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

d. "The evidence is inadequate to accept or reject a causal relationship between varicella vaccine and transverse myelitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

e. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and transverse myelitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

f. "The evidence is inadequate to accept or reject a causal relationship between hepatitis A vaccine and transverse myelitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects

of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

g. "The evidence is inadequate to accept or reject a causal relationship between HPV vaccine and transverse myelitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

h. "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and transverse myelitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

i. "The evidence is inadequate to accept or reject a causal relationship between meningococcal vaccine and transverse myelitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

j. "The pathogenesis of transverse myelitis is mostly of an autoimmune nature, triggered by various environmental factors, including vaccination." Agmon-Levin, N., Kivity, S., Szyper-Kravitz, M., Shoenfeld, Y. (2009). *Transverse myelitis and vaccines: a multi-analysis.* Lupus. https://pubmed.ncbi.nlm.nih.gov/19880568/

k. "We have disclosed 37 reported cases of transverse myelitis associated with different vaccines including those against hepatitis B virus, measles-mumps-rubella, diphtheria-tetanus-pertussis and others, given to infants, children and adults...The associations of different vaccines with a single autoimmune phenomenon allude to the idea that a common denominator of these vaccines, such as an adjuvant, might trigger this syndrome." Agmon-Levin, N., Kivity, S., Szyper-Kravitz, M., Shoenfeld, Y. (2009). *Transverse myelitis and vaccines: a multi-analysis.* Lupus. https://pubmed.ncbi.nlm.nih.gov/19880568/

88. **Urticaria (chronic)**

a. "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and chronic urticaria." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "We studied all 1197 cases of CSU to identify patients that had received vaccinations during the twelve weeks prior the first documentation of CSU symptoms and identified 14 eligible subjects who developed CSU with 12 weeks of vaccination." Magen, E.,Shalom, G., Waitman, D., Kahan, N., (2018). *Chronic Spontaneous Urticaria Following Vaccination*. Int. J. of Adv. Res. https://www.journalijar.com/article/22138/chronic-spontaneous-urticaria-following-vaccination/

89. **Varicella-zoster virus (chickenpox or shingles)**

a. "The evidence convincingly supports a causal relationship between varicella vaccine and disseminated Oka VZV without other organ involvement." "The evidence convincingly supports a causal relationship between varicella vaccine and disseminated Oka VZV with subsequent infection resulting in pneumonia, meningitis, or hepatitis in individuals with demonstrated immunodeficiencies." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence convincingly supports a causal relationship between varicella vaccine and vaccine-strain viral reactivation without other organ involvement." "The evidence convincingly supports a causal relationship between varicella vaccine and vaccine-strain viral reactivation with subsequent infection resulting in meningitis or encephalitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to

Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "Varicella vaccination of children has decreased varicella disease incidence, but introduced the occurrence of herpes zoster (HZ) from vaccine-type virus. We identified 14 vaccinated children with suspected HZ and confirmed varicella virus by polymerase chain reaction in 6 cases. Two cases were due to vaccine-type virus." Chun C, Weinmann S, Riedlinger K, Mullooly JP, Houston H, Schmid DS, Seward JF. (2011). *Laboratory characteristics of suspected herpes zoster in vaccinated children*. Pediatr Infect Dis J. https://pubmed.ncbi.nlm.nih.gov/21346684/

d. "The COVID-19 vaccine produced in response to the pandemic has been effective but can have side effects. One well-established condition is the reactivation of herpes zoster (HZ). Various risk factors increase the risk of HZ reactivation such as age, infections, and immunosuppressed states. HZ can have severe complications, including herpes zoster ophthalmicus and postherpetic neuralgia. Here, we present a unique case where a patient experienced HZ reactivation after both primary doses of the COVID-19 vaccine despite receiving early antiviral treatment." Ismaili A, Anthony S, Clark J. (2023). *Can the COVID-19 Vaccine Cause Recrudescence of Herpes Zoster Virus While Taking Antiviral Medication?* Cureus. https://pubmed.ncbi.nlm.nih.gov/37228567/

e. "Seven immunocompetent patients aged > 50 years old presented with herpes zoster (HZ) infection in a median of 9 days (range 7-20) after vaccination against SARS-CoV-2. The occurrence of HZ within the time window 1-21 days after vaccination defined for increased risk and the reported T cell-mediated immunity involvement suggest that COVID-19 vaccination is a probable cause of HZ." Psichogiou M, Samarkos M, Mikos N, Hatzakis A. (2021). *Reactivation of Varicella Zoster Virus after Vaccination for SARS-CoV-2*. Vaccines (Basel). https://pubmed.ncbi.nlm.nih.gov/34205861/

f. "We identified 13 patients with vOka varicella after transmission from 11 immunocompetent varicella vaccine recipients. In all instances, the vaccine recipient had a rash: 6 varicella-like and 5 herpes zoster. Transmission occurred mostly to household contacts. Live vaccines usually provide robust immunity but can transmit the vaccine virus." Marin M, Leung J, Gershon AA. (2019). *Transmission of Vaccine-Strain Varicella-Zoster Virus: A Systematic Review*. Pediatrics. https://pubmed.ncbi.nlm.nih.gov/31471448/

90. **Vasculitis**

a. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and vasculitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

b. "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and PAN [polyarteritis nodosa]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

c. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and onset or exacerbation of vasculitis." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

d. "The evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and onset or exacerbation of PAN [polyarteritis nodosa]." Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/24624471/

e. "Results: A total of 65 patients who developed vasculitis after influenza vaccination were identified from 45 published reports. The majority of patients were elderly, and the patients were predominantly female. The vasculitides included large vessel vasculitis (13 patients), medium vessel vasculitis (2), small vessel vasculitis (42), single organ vasculitis (5), vasculitis associated with systemic disease (1), and vasculitis associated with

probable etiology (1). Although the majority of patients achieved complete recovery or remission, there were 3 deaths in patients with ANCA-associated vasculitis and severe long-term sequelae developed in 3 patients (1 with granulomatosis with polyangiitis, 1 with IgA vasculitis and 1 with unclassified small vessel vasculitis)." Watanabe T. (2017). *Vasculitis Following Influenza Vaccination: A Review of the Literature*. Curr Rheumatol Rev. https://pubmed.ncbi.nlm.nih.gov/28521688/

f. "Adults receiving HBV had significantly increased odds ratios (OR) for…vasculitis (OR = 2.6, $p < 0.04$, 95% CI = 1.03 - 8.7)…in comparison to the TCV [control] group. Minimal confounding or systematic error was observed." Geier DA, Geier MR. (2005). *A case-control study of serious autoimmune adverse events following hepatitis B immunization*. Autoimmunity. https://pubmed.ncbi.nlm.nih.gov/16206512/