The Evidence Base for Vaccine Safety and Efficacy

Jake Scott, MD

Clinical Associate Professor, Division of Infectious Diseases and Geographic Medicine

Stanford University School of Medicine

Testimony presented to the U.S. Senate Permanent Subcommittee on Investigations,

September 9, 2025

Executive Summary

The scientific evidence supporting vaccine safety and efficacy represents one of the most extensive and transparent bodies of medical research ever assembled. Vaccines have saved an estimated 154 million lives globally over 50 years, eliminated smallpox from the planet, and reduced diseases like polio and measles by over 99% in the United States. Since April 2025, I have co-led the development of a comprehensive public database cataloging 1,704 randomized controlled trials of vaccines spanning from 1941 to 2025, involving more than 10.5 million participants. This includes 661 trials using inert placebo controls – all with direct links to published papers through PubMed. Multiple independent U.S. surveillance systems continuously monitor vaccine safety in real-time, detecting adverse events as rare as 1 per million doses. Recent large-scale studies, including a Danish cohort following 1.2 million children, consistently demonstrate vaccine safety across diverse populations. The CDC estimates that vaccines given to children born between 1994 and 2018 will prevent approximately 419 million illnesses and 936,000 deaths over their lifetimes, averting nearly $1.9 trillion in societal costs. This vast evidence base is publicly accessible, peer-reviewed, and continuously updated. If vaccines caused a wave of chronic disease, our safety systems – which can detect 1-in-a-million events – would have seen it. They haven't.

Statement

Chairman Johnson, Ranking Member Blumenthal, and Members of the Subcommittee, thank you for the opportunity to speak with you.

I have had the privilege of co-leading an international collaborative project that has built the most comprehensive database of its kind documenting randomized controlled trials of vaccines from around the world. This database, developed with colleagues across multiple institutions and countries, has catalogued 1,704 trials spanning from 1941 to 2025, from adenovirus to Zika virus, involving more than 10.5 million participants. This living archive will serve as a resource for countless future analyses. We are currently completing data analysis for our first publication from this project.

I am also part of the Center for Infectious Disease Research and Policy's Vaccine Integrity Project, where our team is conducting a systematic review and meta-analysis of respiratory virus immunizations from approximately the last two years. This ongoing analysis has examined 590 studies from over 17,000 identified references to date. We pre-registered our study protocol on PROSPERO and discussed our methods and preliminary findings at a public webinar that was recorded and remains available on YouTube.[1]

As an infectious diseases physician at Stanford University School of Medicine, I have treated many adults with vaccine-preventable diseases throughout my career. These clinical experiences, combined with my research analyzing the extensive evidence base for vaccine safety and efficacy, inform my testimony today. I should note that I am here in my personal

[1] https://www.youtube.com/watch?v=lSuvGlxqrpg

capacity and the views I share reflect my own professional experience and analysis of the scientific evidence.

Disclosures

I have received minimal payments totaling $45.62 over multiple years for food and beverage at work-related events, as documented in the federal Open Payments database. I have received no research funding, consulting fees, or other payments from vaccine manufacturers for this testimony or related research. My research time is either self-funded or supported by Stanford University. I testify in my personal capacity as a physician-scientist committed to rigorous evidence and transparent science.

The Public Nature of Vaccine Evidence

The safety and efficacy data for vaccines are published in peer-reviewed journals, accessible through PubMed, analyzed by independent researchers worldwide, and scrutinized by regulatory agencies whose deliberations are public record. Anyone with internet access can read the same studies I read, examine the same data I examine, and verify the same conclusions.

Our international team has built a public database of randomized controlled trials of vaccines.[2] This database currently contains:

- 1,704 randomized controlled trials involving more than 10.5 million participants
- 661 trials using inert placebo controls (saline, sterile water, or other biologically inactive substances)

---

[2] https://docs.google.com/spreadsheets/d/1bX4SAJwMUufNAkBplhKHOIe4gdI0BeRhpAXM5hpfV_Y/edit?usp=sharing

- 398 inert placebo-controlled efficacy trials for antigens that childhood vaccines are based on (511 if including safety trials)
- Direct links to every published paper through PubMed

Every entry links directly to its peer-reviewed source publication, allowing anyone to examine the methods, data, and results independently. This is how science should work – open, transparent, and reproducible.

The transparency of vaccine science extends throughout history. When Edward Jenner published his vaccination findings in 1798, he self-published *Variolae Vaccinae* for public scrutiny. The 1954 Salk polio vaccine trial involved 1.8 million children in a publicly monitored study, with results announced to the world and data published for examination. This tradition continues today with large-scale epidemiologic studies published in peer-reviewed journals for all to examine.

Comprehensive Safety Monitoring Systems

The United States maintains multiple independent vaccine safety monitoring systems, each operating transparently:

The Vaccine Adverse Event Reporting System (VAERS) makes every report publicly accessible at vaers.hhs.gov, where anyone can search, download, and analyze raw data. The Vaccine Safety Datalink (VSD) covers over 10 million Americans across nine healthcare organizations, with findings regularly published in peer-reviewed journals and presented at public Advisory Committee meetings. The Post-licensure Rapid Immunization Safety Monitoring (PRISM) system monitors over 190 million people, publishing results openly.

These systems have successfully detected rare adverse events including intussusception with RotaShield (1 in 10,000 doses), leading to withdrawal; rare blood clots with Johnson & Johnson COVID vaccine (3 per million doses), detected within weeks; and myocarditis signals with mRNA vaccines, promptly investigated and quantified. When real risks exist, they are detected, quantified, disclosed, and incorporated into guidance. That is how a functioning safety system works.

Historical Context and Bipartisan Support

Vaccination has historically united Americans across political lines. George Washington ordered Continental Army variolation against smallpox in 1777, declaring "I have determined that the troops shall be inoculated." His orders, preserved in the Library of Congress, reflect understanding that disease threatened his army more than British forces.

Throughout American history, presidents from both parties have championed vaccination as essential public health policy. President Eisenhower signed the Poliomyelitis Vaccination Assistance Act in 1955, stating "We all hope that the dread disease of poliomyelitis can be eradicated from our society." President Reagan proclaimed National Adult Immunization Awareness Week, noting that "vaccination against infectious diseases saves lives and lowers health care costs." President George H.W. Bush mobilized CDC teams to cities in 1991, urging parents: "The vaccines are available. Please, make sure your child is immunized." Even recently, President Trump acknowledged: "Look, you have vaccines that work – they just pure and simple work. They're not controversial at all."

Documented Impact on Disease Prevention

The evidence of vaccine effectiveness is documented in every health department report and mortality database. These data are not hidden – they are published by the CDC and available to anyone:

Before vaccines, measles infected 3-4 million Americans annually, killing approximately 500 children each year. After widespread vaccination led to elimination in 2000, deaths typically numbered 0-2 per year. We are currently experiencing our worst outbreak in decades – 1,431 cases through September 2025, with 3 deaths, overwhelmingly in under vaccinated communities.[3]

Polio paralyzed 16,000 Americans annually in the pre-vaccine era. In 1952 alone, polio caused 57,879 cases, 3,145 deaths, and paralyzed 21,269 Americans. Since 1979, there have been zero cases of wild poliovirus in the United States – a 100% reduction.[4]

Haemophilus influenzae type b (Hib) caused 20,000 cases of severe disease in children under 5 each year, killing approximately 1,000 annually. After vaccine introduction in 1987, cases dropped by over 99%. From 2009-2018, only 36 total Hib cases occurred in American children under 5 – across that entire decade.[5]

The transformation is striking: diphtheria killed 13,000-15,000 Americans annually in the early 20th century; in 2024, we had 1 case. Pertussis killed hundreds of infants yearly; today, typically fewer than 10. Vaccines have saved an estimated 154 million lives globally over 50 years, including 146 million children under 5 years and 101 million infants. For every death averted, 66 years of full health were gained on average, translating to 10.2 billion years of full

[3] https://www.cdc.gov/measles/data-research/?CDC_AAref_Val=https://www.cdc.gov/measles/cases-outbreaks.html
[4] https://www.cdc.gov/polio/hcp/clinical-overview/index.html
[5] https://www.cdc.gov/hi-disease/php/surveillance/?CDC_AAref_Val=https://www.cdc.gov/hi-disease/surveillance.html

health gained. Vaccination has accounted for 40% of the observed decline in global infant mortality – 52% in Africa. In 2024, a child under 10 years is 40% more likely to survive to their next birthday because of historical vaccination programs.[6]

During the 2023-24 influenza season, over 200 children died from flu; among vaccine-eligible children with known vaccination status, more than 80% were not fully vaccinated.[7] In a multicenter study of 38 children with influenza-associated acute necrotizing encephalopathy, only 6 had received that season's flu vaccine.[8]

COVID-19 vaccines, developed with unprecedented transparency through publicly broadcast FDA and CDC meetings, prevented catastrophic loss of life. A rigorous analysis estimated vaccines prevented 2.5 million deaths globally from 2020-2024 (with sensitivity estimates ranging from 1.4-4.0 million).[9] The Commonwealth Fund documented 3.2 million deaths prevented in the United States.[10] Before vaccines, ICUs were overwhelmed. By mid-2021, nearly every fatal case was among the unvaccinated. In Los Angeles, 89% of nursing home resident deaths occurred before widespread vaccination.[11] During the Delta surge, unvaccinated adults were 53 times more likely to die than those vaccinated and boosted.[12]

---

[6] Shattock AJ, et al. Contribution of vaccination to improved survival and health: modelling 50 years of the Expanded Programme on Immunization. Lancet. 2024;403(10441):2307-2316. doi:10.1016/S0140-6736(24)00850-X

[7] https://www.cdc.gov/flu/whats-new/flu-summary-2023-2024.html

[8] Influenza-Associated Acute Necrotizing Encephalopathy (IA-ANE) Working Group, Silverman A, et al. Influenza-Associated Acute Necrotizing Encephalopathy in US Children. JAMA. 2025 08 26;334(8):692-701. doi: 10.1001/jama.2025.11534.

[9] Ioannidis JPA, et al. Global Estimates of Lives and Life-Years Saved by COVID-19 Vaccination During 2020-2024. JAMA Health Forum. 2025 Jul 03;6(7):e252223. doiI: 10.1001/jamahealthforum.2025.2223

[10] https://www.commonwealthfund.org/blog/2022/two-years-covid-vaccines-prevented-millions-deaths-hospitalizations

[11] van Rest, et al. COVID-19 outbreaks in nursing homes in Los Angeles County, March 2020-April 2022. Infect Control Hosp Epidemiol. 2025 Jan 7:1-7. doi: 10.1017/ice.2024.218.

[12] https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e2.htm

I cared for hundreds of COVID patients and watched far too many die. I lost many unvaccinated patients across the age spectrum – from their 30s to their 90s – who I am certain would have survived had they been vaccinated. One mother in her 40s without underlying conditions declined vaccination and died, leaving her child behind. These statistics represent preventable human tragedies.

Methodological Standards and Transparency

When vaccine safety is studied with robust designs – large, linked databases, matched cohorts, self-controlled methods comparing people to themselves over time – the findings are consistent: no broad increase in chronic diseases among vaccinated people.

A recent Danish study by Andersson and colleagues leveraged Denmark's comprehensive health registries to evaluate the association between cumulative aluminum exposure from childhood vaccines and chronic diseases.[13] Following 1.2 million children born between 1997 and 2018, researchers exploited natural variations in aluminum content of vaccines over time, creating a quasi-experimental framework. They found no association between cumulative aluminum exposure and any of 50 conditions across autoimmune, atopic/allergic, and neurodevelopmental categories.

The Henry Ford analysis highlighted by some is an example of why vaccinated versus unvaccinated studies are especially prone to bias. These designs often compare groups that differ in many fundamental ways unrelated to vaccines, including how often they seek care and how long they remain under observation. In this case, neurodevelopmental diagnoses were only

[13] Andersson NW, et al. Aluminum-Adsorbed Vaccines and Chronic Diseases in Childhood: A Nationwide Cohort Study. Ann Intern Med. 2025 Jul 15. doi: 10.7326/ANNALS-25-00997.

counted after age 2, but never-vaccinated children had about half the follow-up time of vaccinated peers, leaving many ineligible for diagnosis. The study also notes substantially lower healthcare use among never-vaccinated children, ensuring fewer opportunities to record diagnoses. Despite these biases, no association with autism was observed. These findings reflect differences in follow-up and healthcare contact, not vaccine harm.

Understanding Medical Effectiveness

Every medical intervention exists on a spectrum of effectiveness. Statins reduce heart attack risk by approximately 30%, not 100%. Cancer chemotherapy may help roughly 40% of patients, not all. We use these treatments because benefits outweigh limitations. Influenza vaccines, used since the 1940s, prevent an estimated 40-60% of influenza illness in good years, perhaps 20% in poor matches – yet still prevent thousands of deaths annually.

For respiratory virus vaccines, the primary goal and realistic expectation is to prevent severe disease and death, not infection. While vaccines cannot prevent viruses from initially entering the respiratory tract, they help our immune system recognize the pathogen and mount a rapid response that can prevent infection, transmission, or severe disease, depending on the variant and vaccine match. But vaccines excel at keeping people out of the hospital, and for that critical goal, they perform remarkably well.

A Surveillance System That Works

Our surveillance systems' transparency was demonstrated during COVID-19 vaccine monitoring. When early myocarditis signals emerged, CDC issued a Health Alert Network notice on May 27, 2021, urging clinicians to report cases to verify whether a true safety signal existed. Once confirmed through enhanced surveillance, ACIP reviewed data publicly on June 23. FDA

added warnings on June 25. The data showed rates peaked at approximately 106 per million second doses in teenage boys in 2021, mostly mild and short-lived. By 2024-25, rates with updated formulations returned to near background levels, as documented in public ACIP presentations.[14]

Our surveillance systems can detect extremely rare adverse events – as rare as 1 per million doses or even fewer. These systems identified thrombosis with thrombocytopenia syndrome following J&J COVID vaccine at less than 1 case per million doses. The sensitivity of these systems would make any widespread vaccine-related chronic disease impossible to miss.

We take vaccine safety extremely seriously. Vaccines are unique medicines given to large numbers of healthy people. Ensuring their safety through rigorous testing and continuous monitoring is critical.

Current Research and Ongoing Transparency

My current work exemplifies commitment to openness. Our public database is openly accessible on Google Drive, with search strategies available in the spreadsheets for anyone to examine and verify. The Vaccine Integrity Project team discussed our methods at a public webinar, demonstrating our commitment to transparency even before publication. Every step of our research process is designed to be reproducible and verifiable.

Beyond clinical trials, thousands of additional studies examine vaccine safety through peer-reviewed research. When concerns arise, they are investigated and results are published, whether confirming or refuting initial hypotheses.

---

[14] https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04-Meyer-COVID-508.pdf

Conclusion

The evidence for vaccine safety and efficacy exists in overwhelming abundance, accessible to anyone willing to examine it. From Washington's orders to inoculate the Continental Army to today's real-time safety monitoring systems, American vaccination policy has been built on transparency and evidence.

The data supporting vaccines are not hidden – they are reviewed by FDA, published in peer-reviewed journals, analyzed worldwide, and tracked through public surveillance systems. If vaccines caused widespread chronic disease, our safety monitoring systems would have detected it. They haven't.

The question before this Subcommittee is whether public health policy will continue to be guided by transparent, peer-reviewed evidence. As we face both emerging infectious disease threats and the return of old threats due to declining vaccination coverage – like our current measles outbreak – maintaining public confidence through evidence-based communication remains essential.

The data are public. The evidence is clear. I welcome your questions.