AVAC
ADULT VACCINE ACCESS COALITION

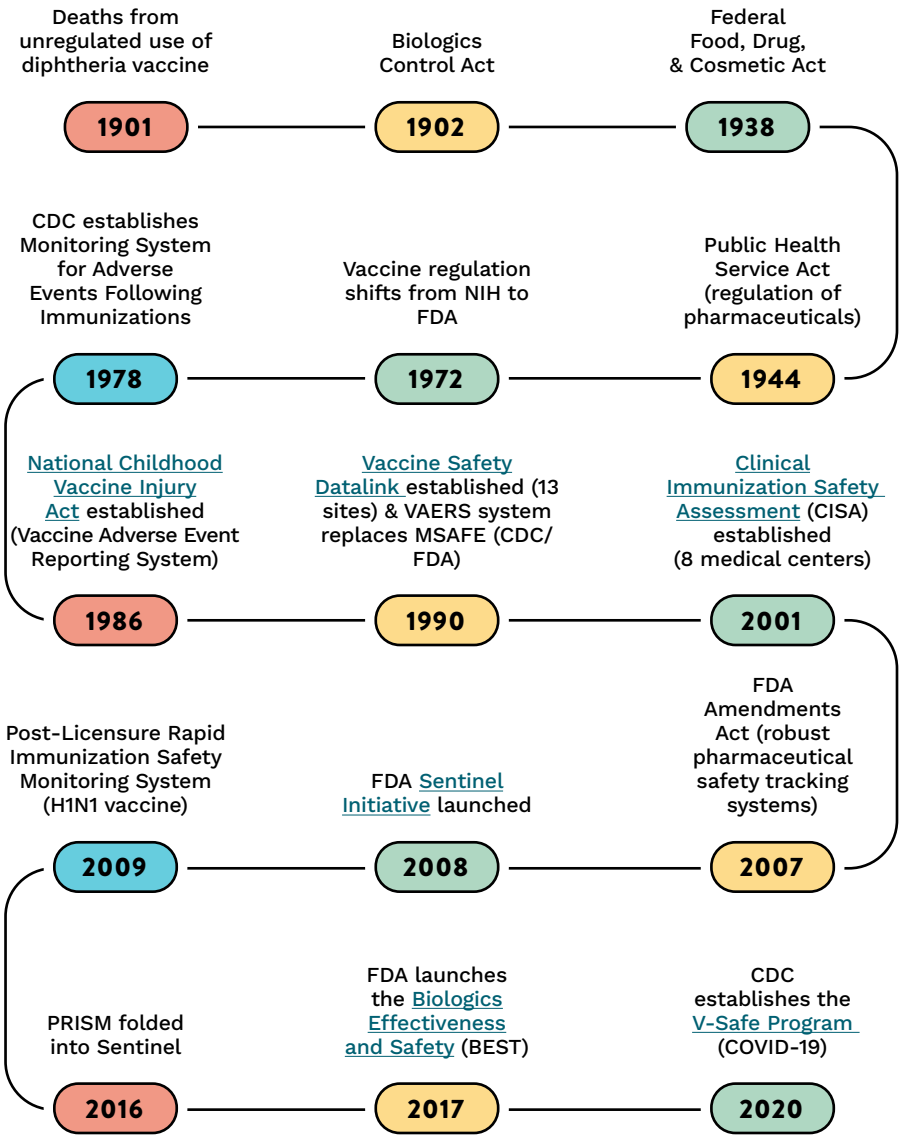
Vaccine Safety

Vaccines help reduce illness, hospitalization and death from preventable diseases and conditions. Just as important as the vaccines themselves are the systems that support vaccine safety. Vaccine safety systems were first established in 1902 and have continuously evolved and improved over the past 100+ years.

Once a vaccine has completed clinical trials, is approved by the Food and Drug Administration (FDA), and recommended for use by the Advisory Committee on Immunization Practices (ACIP), it is crucial to ensure that vaccines undergo ongoing monitoring to quickly identify any potential issues to maintain the highest levels of vaccine safety. While serious side effects from vaccines are extremely rare, federal agencies dedicated to protecting the health and safety of Americans are actively involved and engaged in vaccine safety reviews.

The United States maintains several adverse event reporting systems and clinical assessment programs that provide important data on potential adverse events following vaccination.

Timeline of Vaccine Safety Systems



Adverse Event Reporting Systems

Today, vaccine safety reporting comes in multiple forms, including Adverse Event Reporting Systems (VAERS, VSAFE, Sentinel) which work to detect early signals of potential safety issues. These reporting systems *do not determine causality* but play an essential role in collecting and analyzing reports to identify patterns that may need further investigation. There are also several vaccine safety systems (VSD, CISA) that work to ensure vaccines are safe, *help determine causality*, guide public health decisions, and inform clinical recommendations.

While the current systems provide a strong foundation for ongoing vaccine safety monitoring in the United States, there are continued opportunities to support innovation in vaccine technology.

REPORTING SYSTEM	OWNER	DATA SOURCE	TOP LINES
The Vaccines Adverse Events Reporting System (VAERS)	FDA	Mandatory reporting from vaccine manufacturers and health care providers Voluntary self reports from individuals	◆ VAERS is FDA's adverse event reporting system for vaccines. ◆ The database includes both mandatory reporting (vaccine manufacturers, providers) and voluntary reporting (individuals). Individual reporting is not fact-checked by the FDA. ◆ The agency follows up on serious adverse events (e.g., death, disability). Common adverse events include things like "pain at injection site." ◆ This is a straightforward database. It is searchable, sortable, and used to run research projects and queries.
Vaccine Safety Datalink (VSD)	CDC	EHRs at member sites VAERS	◆ VSD is a research project with 13 sites that provide data, including: Kaiser Permanente (6 sites) - Northern California, Southern California, Colorado, Northwest, Mid-Atlantic States, Washington, Harvard Pilgrim Health Care Institute, HealthPartners Institute, Marshfield Clinic Research Institute, Denver Health, Indiana University, OCHIN, Acumen. ◆ These sights have agreed to share their vaccination information with the CDC, and the VSD can also leverage VAERS for its data projects. ◆ VSD does some "active" monitoring for anomalies and any adverse events.
V-Safe	CDC	Self-report from individuals	◆ V-Safe is a self-report portal. ◆ Launched in 2020, V-safe lets you share with CDC how you or your dependent feel after getting a COVID-19 or RSV vaccine, similar to VAERS.
Clinical Immunization Safety Assessment Project (CISA)	CDC	Does not collect data	◆ Eight medical centers consult with federal partners and provide subject matter expertise on vaccine safety-related issues. ◆ Centers include: Kaiser Permanente Northern California, Oakland, Emory University & Children's Healthcare of Atlanta, Johns Hopkins University, Baltimore, Boston Medical Center, Columbia University, New York City, Duke University, Durham, Cincinnati Children's Hospital Medical Center, Vanderbilt University Medical Center, Nashville.
Sentinel	FDA	EHR data from participating system Claims data from data partners	◆ Sentinel is the FDA's real world data-based postmarked surveillance system. Sentinel pulls in claims data from insurers and some Medicare/Medicaid data, and medical record data from EHRs (from both EHR vendors and health care sites). Sentinel is NOT vaccine-specific, but it is a population-level research tool as to what regulated drug products are being used, where, by whom, and how that worked out. Sentinel uses routine monitoring AND custom programming for ad hoc analyses.
Biologics Effectiveness and Safety initiative (BEST)	FDA	EHR data from participating system Claims data from data partners	◆ BEST is the biologics-specific module of Sentinel. ◆ It is an active surveillance system that does queries/studies. ◆ Vaccines are technically biological products, but the current vaccine study projects are in Sentinel, not BEST, under PDUFA VII.

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About AVAC

AVAC consists of over 80 organizational leaders in health and public health who are committed to addressing challenges in access to adult immunization and to raising awareness of the importance of adult immunization. Our mission is informed by scientific and empirical evidence of the benefits of immunization through improving health, protecting against a variety of debilitating and deadly conditions, and saving costs to the health care system and society.

www.adultvaccinesnow.org