Vaccine Safety and Effectiveness

Required by:

20-A §6358 (3); PL 2019, c. 154

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Maine Department of Health and Human Services
Maine Center for Disease Control and Prevention

Background

Public Law 2019, Chapter 154, introduced as LD 798, *An Act To Protect Maine Children and Students from Preventable Diseases by Repealing Certain Exemptions from the Laws Governing Immunization Requirements*, requires Maine Center for Disease Control and Prevention (Maine CDC) to report each odd numbered year concerning any new developments in the evaluation of vaccine safety and effectiveness. This report outlines routine vaccine safety and effectiveness, describes the federal Vaccine Adverse Event Reporting System (VAERS), and provides a list of vaccines currently supplied through Maine CDC Maine Immunization Program.

Of note on January 5, 2026, the Acting Director of the U.S. Centers for Disease Control and Prevention (U.S. CDC) signed a decision memorandum that reduced the number of immunizations routinely recommended for all children on the U.S. CDC Child and Adolescent Immunization Schedule. Maine CDC continues to recommend clinicians follow the pediatric immunization guidance provided by the American Academy of Pediatrics (AAP) as the evidence-based recommendations for childhood vaccinations. Maine CDC is not aware of any changes in disease trends, vaccine safety concerns, or changes in product availability that informed the U.S. CDC's 2026 changes.

In Maine, vaccines remain available at no cost to eligible children 18 years of age and younger through the Maine Immunization Program (MIP). Maine's minimum immunization requirements for schools, childcare, and camp attendance remain unchanged by federal actions.

Introduction

Vaccines were first introduced in the late 18th century and, over time, have proven to be one of the most effective public health strategies to control and prevent disease. There are many safety measures required by law to ensure the safety of the vaccines we receive. Vaccines are administered to millions of healthy people across the lifespan to prevent serious diseases and these vaccines are held to the highest safety standards.

Vaccine effectiveness

Estimates of the Decline in the Morbidity of Diseases due to Vaccination[1]

Disease	Reduction
Diphtheria	100%
Measles	99.9%
Paralytic poliomyelitis	100%
Rubella	99.9%
Congenital rubella syndrome	99.3%
Smallpox	100%
Mumps	95.9%
Tetanus	92.9%
Pertussis	92.2%

[1] National Library of Medicine. Immunization in the United States: Recommendations, Barriers, and Measures to Improve Compliance. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4927017/#b6-ptj4107426.

Vaccine Development

Currently, the United States has the safest vaccine supply in its history. The United States' long-standing vaccine safety system ensures that vaccines are as safe as possible. As new information and science become available, this system is, and will continue to be, updated and improved.

The U.S. Food and Drug Administration (FDA) ensure the safety, effectiveness, and availability of vaccines for the United States. Before the FDA licenses (approves) a vaccine, the vaccine is tested extensively by its manufacturer. FDA scientists and medical professionals carefully evaluate all the available information about the vaccine to determine its safety and effectiveness.

Most common side effects of a vaccine are identified in studies before the vaccine is licensed. Some adverse events are so rare, however, that they may not be detected in these studies.
Therefore, the U.S. vaccine safety monitoring system continuously monitors for adverse events (possible side effects) after a vaccine is licensed. When millions of people receive a vaccine, less common side effects that were not identified earlier may present in populations.

How are vaccines tested for safety?

Prior to a new vaccine being introduced to people, extensive lab testing is done for several years. Once testing in people begins, it can take several more years before clinical studies are complete and the vaccine is licensed. There are three phases of clinical trials to ensure the safety of those who volunteer. Clinical trials are first done with adults.[2]

Phase 1 – 20-100 healthy volunteers

- Is the vaccine safe?
- Does the vaccine seem to work?
- Are there any serious side effects?
- How is the size of the dose related to side effects?

Phase 2 – several hundred volunteers

- What are some of the most common short-term side effects?
- How are the volunteers' immune systems responding to the vaccine?

Phase 3 – hundreds or thousands of volunteers

- How do people who get the vaccine and people who do not get the vaccine compare?
- Is the vaccine safe?
- Is the vaccine effective?
- What are the common side effects?

The FDA licenses the vaccine only if:

- It's safe and effective
- Benefits outweigh risks

[2] Centers for Disease Control and Prevention. Ensuring the Safety of Vaccines in the United States. Available at: https://www.cdc.gov/vaccines/hcp/conversations/ensuring-safe-vaccines.html.

Post licensure: Vaccine Safety Monitoring

After vaccines are licensed, they are monitored closely as people begin using them. The purpose of monitoring is to watch for adverse events (possible side effects). Monitoring a vaccine after it is licensed helps ensure that the benefits continue to outweigh the risks for people who receive the vaccine.

Continuous safety monitoring

Vaccine Adverse Event Reporting System (VAERS)[3]

Post licensure monitoring begins with the Vaccine Adverse Event Reporting System (VAERS), a national system used by scientists at FDA and the Centers for Disease Control and Prevention (CDC) to collect reports of adverse events (possible side effects) that happen after vaccination.
Health care professionals, vaccine manufacturers, vaccine recipients, and parents or family members of people who have received a vaccine are encouraged to submit reports to VAERS if they experience any adverse events after getting any vaccine.

Scientists monitor VAERS reports to identify adverse events that need to be studied further. All serious reports are reviewed by medical professionals on a daily basis.

VAERS data provide medical professionals at CDC and FDA with a signal of a potential adverse event. Experience has shown that VAERS is an excellent tool for detecting potential adverse events. Reports of adverse events that are unexpected appear to happen more often than expected, or have unusual patterns are followed up with specific studies.

VAERS data alone usually cannot be used to answer the question, "Does a certain vaccine cause a certain side effect?" This is mainly because adverse events reported to VAERS may or may not be caused by vaccines. There are reports in VAERS of common conditions that may occur by chance alone that are found shortly after vaccination. Investigation may find no medical link between vaccination and these conditions.

National Vaccine Injury Compensation Program[4]

The National Vaccine Injury Compensation Program is a no-fault alternative to the traditional legal system for resolving vaccine injury petitions.

It was created in the 1980s after lawsuits against vaccine companies and health care providers threatened to cause vaccine shortages and reduce U.S. vaccination rates, which could have caused a resurgence of vaccine preventable diseases.

Any individual, of any age, who received a covered vaccine and believes he or she was injured as a result, can file a petition. Parents, legal guardians and legal representatives can file on behalf of children, disabled adults, and individuals who are deceased.

[3] Vaccine Adverse Event Reporting System. Available at: https://vaers.hhs.gov/.
[4] Health Resources Services Administration. National Vaccine Injury Compensation Program. Available at: https://www.hrsa.gov/vaccine-compensation.

Vaccine Safety Datalink (VSD)[5]

Scientists use CDC's Vaccine Safety Datalink (VSD) to do studies that help determine if possible side effects identified using VAERS are related to vaccination. VSD is a network of eight managed care organizations across the United States. The combined population of these organizations is more than 24 million people.

Clinical Immunization Safety Assessment Link (CISA)[6]

The Clinical Immunization Safety Assessment (CISA) Project is a collaboration between CDC and seven medical research centers. Vaccine safety experts conduct individual case reviews and clinical research studies about vaccine safety.

February 2026 Maine Immunization Program Vaccine Availability[7]

The following are routinely recommended vaccines, approved by the FDA and ACIP and are available to order through the Maine Immunization Program for children 0-18 years of age.

1. DTaP Vaccines (Diphtheria, Tetanus, acellular Pertussis)
    a. Daptacel® (Sanofi Pasteur)
    b. b. Infanrix® (GSK)
2. Hepatitis A Vaccines
    a. Vaqta® (Merck)
    b. Havrix® (GSK)
3. Hepatitis B Vaccines
    a. Engerix B® (GSK)
    b. Recombivax® (Merck)
4. Polio Vaccine
    a. IPOL® (Sanofi Pasteur)
5. Hib Vaccines (Haemophilus influenzae type b)
    a. ActHIB® (Sanofi Pasteur)
    b. Pedvax HIB® (Merck)
    c. Hiberix® (GSK)
6. HPV Vaccines (Human Papillomavirus)
    a. Gardasil-9® (Merck)
7. Pneumococcal Vaccines
    a. Pneumovax 23® (Merck)
    b. Prevnar 20™ (Pfizer)
    c. Vaxneuvance® (Merck), 15-valent Conjugate Vaccine

[5] Centers for Disease Control and Prevention. Vaccine Safety Datalink. Available at: https://www.cdc.gov/vaccine-safety-systems/vsd/index.html
[6] Centers for Disease Control and Prevention. Clinical Immunization Safety Link (CISA). Available at: https://www.cdc.gov/vaccine-safety-systems/hcp/cisa/index.html
[7] Maine Vaccine Board. Approved Vaccine List. Available at: https://www.mevaccine.org/data/get_doc/097d7cbdbcd9d0fb56ae74a046e7ed65

8. Meningococcal Conjugate Vaccines
    a. Menveo® (GSK)
    b. MenQuadfi™ (Sanofi Pasteur)
9. Meningococcal Group B
    a. Bexsero® (GlaxoSmithKline)
    b. Trumenba® (Pfizer)
10. Measles, Mumps and Rubella Vaccine
    a. MMRII® (Merck)
    b. Priorix® (GSK)
11. Rotavirus Vaccines
    a. Rotarix® (GSK)
    b. RotaTeq® (Merck)
12. Tdap Vaccines (Tetanus Toxoid, Reduced Diphtheria Toxoid and acellular Pertussis – adolescent formulation)
    a. Boostrix® (GSK)
    b. Adacel® (Sanofi Pasteur)
13. Td Vaccine (Tetanus and Diphtheria Toxoid)
    a. Tenivac® (Sanofi Pasteur), single dose syringe presentation
    b. Tenivac® (Sanofi Pasteur), single dose vial presentation
14. Varicella Vaccine
    a. Varivax® (Merck)
15. Combination Vaccines
    a. Kinrix® (GSK)
    b. Pediarix® (GSK)
    c. Pentacel® (Sanofi Pasteur)
    d. ProQuad® (Merck)
    e. Quadracel® (Sanofi Pasteur)
    f. Vaxelis® (Merck)
    g. Penbraya™ (Pfizer)
16. Influenza Vaccines
    a. At least one preservative free, single dose injectable presentation
    b. FluMist® (AstraZeneca), nasal presentation
17. COVID-19 Vaccines
    a. At least one preservative free, single dose injectable presentation
18. RSV Vaccines (Respiratory Syncytial Virus)
    a. Beyfortus™ (Sanofi Pasteur)
    b. Abrysvo™ (Pfizer)
    c. Enflonsia™ (Merck)