

The Louisiana Vaccine Alliance (LAVA) is working to reduce vaccine-preventable disease across the lifespan through education, advocacy and strategic partnerships.

LAVA's goals are to 1) Raise the public's awareness of vaccine-preventable disease, 2) Increase use of the Louisiana Immunization Network System (LINKS), 3) Educate healthcare providers, public and policy makers, 4) Provide evidence-based resources families need to make informed choices, and 5) Advocate for immunization policy in Louisiana that is evidence-based, ensures equitable access to immunizations, and protects communities from vaccine-preventable disease.

To that end, below are some of the most frequent questions on vaccines and the evidence-based information to address those questions and concerns.

Concern: Vaccines cause autism

Fact: The original study that made this claim was retracted and the author lost his medical license.¹

- Subsequent studies with a cumulative sample of over 1.2 million children have shown no links between vaccines and autism or autism spectrum disorder.²

Concern: Vaccination is unnecessary because infection rates are low

Fact: Infection rates for certain diseases in the US can only remain low if we maintain community protection (also called "herd immunity") and high vaccination rates to protect vulnerable people such as the elderly and infants too young for vaccination.

- Herd immunity occurs when a subsection of the population is adequately vaccinated to protect those who are not immune. Herd immunity is achieved when immunization rates reach a certain threshold, for polio this is 80-85%, but for measles herd immunity is only reached when 95% of the population is immunized.^{3,4} Additionally, while infection rates are low for some diseases in the US, this is not the case in other parts of the world.
- The 2019 measles outbreak, which saw nearly 1,300 individual cases across 31 states and almost caused the US to lose its elimination status, was started by travelers bringing measles into the US where the disease spread through unvaccinated communities.⁵

Concern: The Vaccine Injury Compensation Program (VICP) has paid out \$4 billion for vaccine injuries

Fact: The VICP was created in the 1980s to protect public health and avoid vaccine shortages by ensuring that manufacturers continued to develop and distribute vaccines. From 2006 to 2017, over 3.4 billion doses of covered vaccines were distributed in the US. For petitions filed in this time period, only 4,493 received compensation.⁶ This means for every 1 million doses of vaccine that were distributed, approximately 1 individual was compensated. A child is 100 times more likely to be struck by lightning than have a severe allergic reaction to a vaccine.⁷

¹ Dyer, C. Lancet Retracts Wakefield's MMR Paper. *BMJ (Clinical research ed.)* 2010, 340: c696. <https://www.bmj.com/content/340/bmj.c696>

² Taylor, L et al. Vaccines Are Not Associated with Autism: An Evidence-Based Meta-Analysis of Case-Control and Cohort Studies. *Vaccine* 32, no. 29 (June 2014): 3623–29. <https://doi.org/10.1016/j.vaccine.2014.04.085>

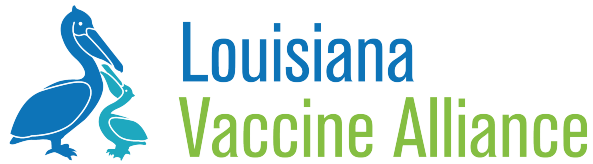
³ Truelove S, et al. Characterizing the impact of spatial clustering of susceptibility for measles elimination. *Vaccine* 37, no.5(January 2019): 732-741. <https://www.sciencedirect.com/science/article/pii/S0264410X18316724>

⁴ Guerra F, et al. The basic reproduction number (R_0) of measles: a systematic review. *Vaccine* 17, no.12 (December 2017): e420-e428. <https://www.sciencedirect.com/science/article/pii/S1473309917303079?via%3Dihub>

⁵ CDC. Measles Cases and Outbreaks. Accessed December 5, 2019. <https://www.cdc.gov/measles/cases-outbreaks.html>

⁶ HRSA VICP Monthly Report <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/data-statistics-november-2019.pdf>

⁷ Vaccinate Your Family "What Goes into a Vaccine?" 2019. <https://www.vaccinateyourfamily.org/vaccine-safety/>



- Being awarded compensation through the VICP does not mean that the vaccine caused the alleged injury. Approximately 70% of all compensations awarded were the result of a settlement that did not conclude that a vaccine caused the alleged injury.⁸ Petitioners can have their legal fees covered through the VICP regardless of the outcome.⁹
- Over 50% of new claims are from Shoulder Injury Resulting from Vaccine Administration (SIRVA), which is caused by the administration of a vaccine, not the vaccine itself, and can be addressed through proper injury tracking, notification, and training of vaccine administrators.¹⁰
- For petitioners who reject the decision of the VICP, or for vaccines not included in the VICP, a claim can be filed in civil court against the vaccine manufacturer and/or the provider who administered the vaccine.⁸

Concern: Vaccines contain aborted fetuses

Fact: Vaccines do not contain aborted fetuses—over 50 years ago, scientists used fetal cells to develop vaccines and therapeutics.

- These cell lines are still used today, and no further sources of cells are needed to produce the vaccines.¹¹
- Fetal cells are used in the medical field beyond vaccines; researchers have used these cells to study birth defects, eye diseases, Parkinson's, ALS, and spinal cord injuries.¹²

Concern: Vaccines contain toxins such as mercury, aluminum, and formaldehyde

Fact: All of these ingredients are found in lower quantities in vaccines than what can be found in environmental sources and/or naturally in the body. They are used in vaccines to boost immunity, maintain purity, increase immune response, and inactivate viruses.¹³

- Thimerosal is found in a select few multi-dose flu vaccines in order to maintain sterility. All vaccines, including those routinely recommended for children under 6, are available in formulations that do not contain thimerosal.¹⁴ Additionally, thimerosal contains ethylmercury, rather than methylmercury. Ethylmercury, as found in thimerosal, is cleared from the body and bloodstream quickly, while methylmercury is the type of mercury found in a can of tuna that is more likely to accumulate in the body and cause mercury poisoning.¹⁵
- Aluminum is the third most common naturally occurring element, after oxygen and silicon. A breast-fed infant will ingest more aluminum through their diet than through vaccination in the first six months of life.¹⁶
- The average newborn has 50-70 times more naturally produced formaldehyde in their body than a single vaccine dose.¹⁷

⁸ Health Resources and Services Administration. 2019. Data and Statistics. <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/data-statistics-november-2019.pdf>

⁹ Health Resources and Services Administration. National Vaccine Injury Compensation Program. Accessed October 10, 2019. <https://www.hrsa.gov/vaccine-compensation/index.html>

¹⁰ Fleischer J, et al. Half of all New Federal Vaccine Cases Allege Injury from Shots Given Incorrectly. May 2, 2018. <https://www.nbcwashington.com/investigations/Half-of-All-New-Federal-Vaccine-Injury-Cases-Allege-Shots-Given-Incorrectly-481441201.html>

¹¹ Immunization Action Coalition. Vaccine Safety 2018. <https://www.immunize.org/askexperts/vaccine-safety.asp>

¹² Congressional Research Service. "Human Fetal Tissue Research: Frequently Asked Questions" August 8, 2019. <https://crsreports.congress.gov/product/pdf/R/R44129/9>

¹³ CDC. Additives in Vaccines Fact Sheet. August 7, 2019. <https://www.cdc.gov/vaccines/vac-gen/additives.htm>

¹⁴ FDA. Thimerosal and Vaccines. February 1, 2018. <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/thimerosal-and-vaccines>

¹⁵ CDC..Thimerosal in Vaccines. 2015 <https://www.cdc.gov/vaccinesafety/concerns/thimerosal/index.html>

¹⁶ Keith L, et al. Aluminum toxicokinetics regarding infant diet and vaccinations. *Vaccine* 20. No 3 (May 2002): S13-S17. <https://www.sciencedirect.com/science/article/pii/S0264410X02001652>

¹⁷ Common Ingredients in US Licensed Vaccines. US Food and Drug Administration. <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/common-ingredients-us-licensed-vaccines>

Concern: Mandatory vaccinations violate civil rights

Fact: Various courts, including the US Supreme Court, have upheld mandatory vaccination policies. The Supreme Court recognizes the government’s authority to organize activities and design policies that address and advocate for the health and wellbeing of children and of communities.¹⁸

- Vaccination is not just for individual benefit. Immunization laws exist to protect the community and people that you are in contact with, such as other students, neighbors, and vulnerable family members.
- People are not physically forced to vaccinate. States have formal exemption processes for those with valid medical contraindications, and many also allow for religious and or/personal exemptions.¹⁹ However, the widespread use of non-medical exemptions exposes the community to disease and undermines state immunization infrastructure.²⁰

Concern: Live Vaccines cause the disease that they are meant to prevent and can shed the virus

Fact: Live vaccines do not cause disease— mild symptoms may occur following injection, but they are rarely harmful.

- Live vaccines contain weakened forms of viruses that cannot cause serious disease; instead, they prompt the immune system to recognize the virus and develop immunity.²¹
- While shedding of virus after vaccination with live vaccines may occur, the risk of infecting another individual is very rare. In fact, the Infectious Disease Society of America recommends that people living in the same household as a person with a weakened immune system should receive most recommended live vaccines in order to better protect the person with weak immunity²².

Concern: There are approved alternative childhood immunization schedules to avoid overloading immune systems

Fact: The American Academy of Pediatrics, public health officials, and other medical organizations have all approved the CDC’s childhood immunization schedule and warn against delays. There is no evidence of benefits to delaying immunization, and this practice leaves children’s health at risk.^{23,24}

- The schedule is based on a careful review of the evidence by the Advisory Committee on Immunization Practices (ACIP) within the CDC to ensure that infants are getting the vaccine when there is a balance of safety and susceptibility.^{22,25}
- No peer-reviewed epidemiologic study has found an increased risk of disease based on the number of vaccines or vaccine antigens administered during childhood.²⁶

¹⁸ Weithorn LA, et al. Legal Approaches to Promoting Parental Compliance with Childhood Immunization Recommendations. *Human Vaccines & Immunotherapeutics* 14, No. 7 (July 3, 2018): 1610-1617. <https://www.tandfonline.com/doi/full/10.1080/21645515.2018.1423929>

¹⁹ NCSL. States with Religious and Philosophical Exemptions from School Immunization Requirements. June 14, 2019. <http://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx>

²⁰ Olive JK, et al. The State of the Antivaccine Movement in the United States: A Focused Examination of Nonmedical Exemptions in States and counties (Policy Forum). *PLoS Medicine* 15, no. 6 (June 12, 2018): e1002578. <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002578>

²¹ CDC. Understanding How Vaccines Work. 2018. <https://www.cdc.gov/vaccines/hcp/conversations/understanding-vacc-work.html>

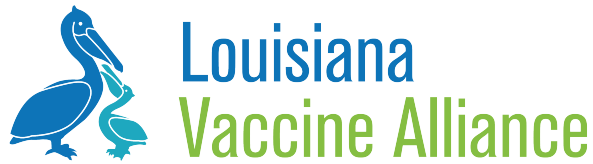
²² Rubin L. Clinical Practice Guideline for Vaccination of the Immunocompromised Host”. *Clinical Infectious Diseases* 58, no. 3 (February 2014): e44–e100 <https://academic.oup.com/cid/article/58/3/e44/336537>

²³ CDC. Who Sets the Immunization Schedule. 2012. <https://www.cdc.gov/vaccines/parents/schedules/sets-schedule.html>

²⁴ CDC. Reasons to Follow the Schedule. 2019. <https://www.cdc.gov/vaccines/parents/schedules/reasons-follow-schedule.html>

²⁵ The Children’s Hospital of Philadelphia. 2019. Vaccine Schedule: Altering the Schedule. <https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-schedule/altering-the-schedule>

²⁶ Roush S, et al. Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States (National Vaccine Recommendations). *JAMA*, 298, no. 18 (November 14, 2007): 2155–2163. <https://jamanetwork.com/journals/jama/fullarticle/209448>



- The current childhood vaccine schedule contains fewer antigens than previous decades (3,000 proteins in 8 vaccines in the 1980s and 1990s vs. 305 in the 14 vaccines today).²⁷

Concern: There are no double-blind placebo-controlled studies conducted for vaccines

Fact: Many vaccines have used and continue to use double-blind placebo-controlled studies when it is ethically appropriate to do so- examples of vaccines tested in double-blind placebo-controlled trials include those for HPV and shingles.^{28,29}

- When investigating new vaccines, it is not ethically appropriate to deprive individuals in a control group of an existing safe and effective vaccine, meaning in some cases a placebo-controlled study is not possible.³⁰

Concern: Not all vaccine-preventable diseases are serious so there is no need to vaccinate. Besides, natural exposure is better than getting a vaccine

Fact: All vaccine-preventable diseases carry serious risks for morbidity and/or mortality. Prior to vaccine approval and widespread use, these diseases caused substantial annual disease burden.³¹

- Chickenpox (Varicella) is not just a childhood disease: serious complications can include pneumonia, encephalitis, and bloodstream infections.³²
- In addition to the fact that acute measles infections can lead to serious complications, recent studies have shown that measles infection can also seriously impact the immune system's ability to battle other non-measles infections by erasing the immune system's memory, leaving people vulnerable to other illnesses for months or even years after the measles virus has left the body.³³
- Prior to vaccine licensure, measles, mumps, diphtheria, and pertussis caused hundreds of thousands of cases and thousands of deaths annually. A 92% decline in cases and a 99% decline in deaths has been seen for diphtheria, mumps, pertussis, and tetanus since the introduction of vaccines for these diseases.²⁶

Concern: Vaccine Adverse Event Reporting System (VAERS) data proves that vaccines are unsafe

Fact: VAERS exists to detect possible vaccine safety problems as early as possible. A VAERS report does not prove cause and effect between the vaccine and the reported adverse event. Reports may be coincidental and related to non-vaccine causes.³⁴

²⁷ CDC. How to Strengthen Your Baby's Immune System. 2019. <https://www.cdc.gov/vaccines/parents/why-vaccinate/strengthen-baby-immune.html>

²⁸ Garland S et al. Quadrivalent vaccine against human papillomavirus to prevent anogenital diseases. *N Eng J Med*, 356 (May 10, 2007): 1928-43.

https://www.nejm.org/doi/10.1056/NEJMoa061760?url_ver=Z39.882003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov

²⁹ Lal H et al. Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. *N Eng J Med* 372 (May 28, 2015): 2087-96.

<https://www.nejm.org/doi/full/10.1056/NEJMoa1501184>

³⁰ Rid, A et al. "Placebo Use in Vaccine Trials: Recommendations of a WHO Expert Panel" 32, no. 37 (2014): 4708-4712.

<https://www.sciencedirect.com/science/article/pii/S0264410X14005374?via%3Dihub>

³¹ CDC. Shingles. <https://www.cdc.gov/shingles/about/index.html>

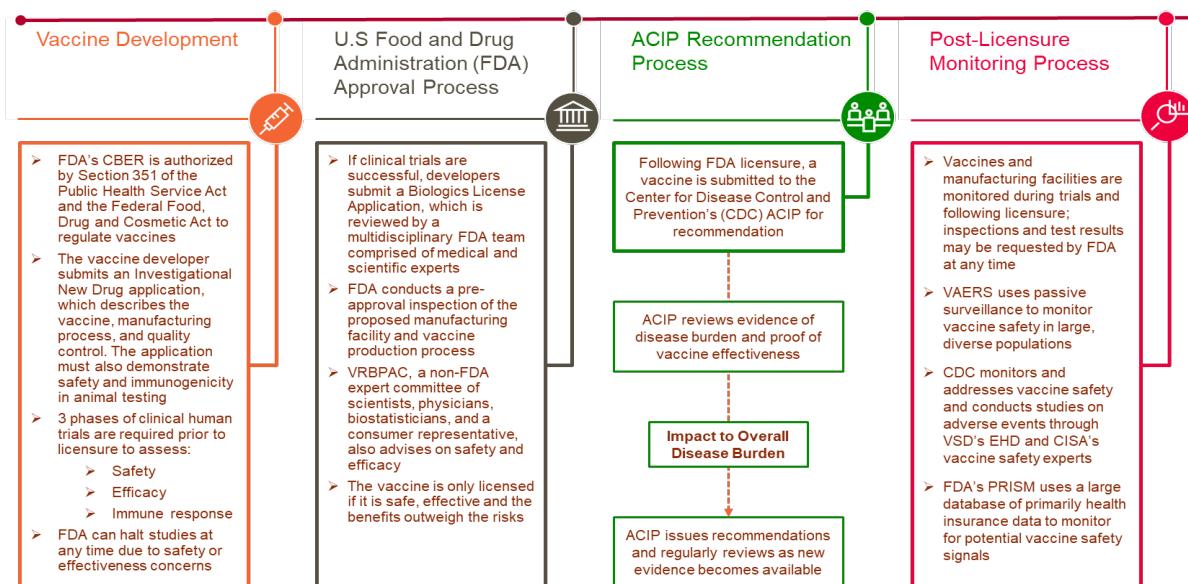
³² CDC. 2018. Chickenpox (Varicella). Complications. <https://www.cdc.gov/chickenpox/about/complications.html>

³³ Mina M, et al. Measles Virus Diminishes preexisting antibodies that offer protection from other pathogens. *Science*. 366, No. 6465 (Nov 2019): 599-606. <https://science.sciencemag.org/content/366/6465/599>

³⁴ HHS. Guide to Interpreting VAERS Data. <https://vaers.hhs.gov/data/dataguide.html>

- The CDC and FDA manage a robust post-licensure monitoring infrastructure in the US that is designed to conduct surveillance and evaluate vaccine safety on an ongoing, consistent basis.^{35,36}
- VAERS is only one part of post-licensure monitoring. The CDC also operates the Vaccine Safety Datalink (VSD) that conducts vaccine safety studies based on VAERS data and monitors the safety of newly recommended vaccines. The Clinical Immunization Safety Assessment (CISA) Project conducts clinical case reviews and research to advance vaccine safety knowledge, provides expert evaluation of vaccine safety issues, and is prepared for public health response during emergencies.^{37,38} The FDA's PRISM (Post-licensure Rapid Immunization Safety Monitoring system) uses a large database of primarily health insurance data to monitor for potential vaccine safety signals.³⁹

The United States has a strong and transparent public health infrastructure. Vaccines are studied extensively before, during and following licensure, and extensive scientific evidence overwhelmingly demonstrates their safety and effectiveness.



FDA: U.S. Food and Drug Administration; CBER: Center for Biologics Evaluation and Research; ACIP: Advisory Committee on Immunization Practices; BLA: Biologics License Application; VAERS: Vaccine Adverse Event Reporting System; CDC: Centers for Disease Control and Prevention; VSD: Vaccine Safety Database; EHD: Electronic Health Data; CISA: Clinical Immunization Safety Assessment (CISA) Project; PRISM: Post-licensure Rapid Immunization Safety Monitoring system; VRBPAC: Vaccines and Related Biological Products Advisory Committee

Source: FDA. 2019. Vaccine Product Approval Process. <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-product-approval-process>

FDA. 2019. VAERS Overview. <https://www.fda.gov/vaccines-blood-biologics/vaccine-adverse-events/vaers-overview>

CDC. 2015. Clinical Immunization Safety Assessment (CISA) Project. <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>

CDC. 2019. Vaccine Safety Datalink (VSD). <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html>

CDC. 2016. Public Workshop: The Sentinel Post-Licensure Rapid Immunization Safety Monitoring (PRISM) System. <https://www.fda.gov/vaccines-blood-biologics/workshops-meetings-conferences-biologics/public-workshop-sentinel-post-licensure-rapid-immunization-safety-monitoring-prism-system>

³⁵ CDC. About the Immunization Safety Office. 2015. <https://www.cdc.gov/vaccinesafety/iso.html>

³⁶ CDC Vaccine Safety Monitoring. <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/index.html>

³⁷ CDC. Clinical Immunization Safety Assessment (CISA) Project. <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>

³⁸ CDC. Vaccine Safety Datalink (VSD). <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html>

³⁹ CDC. Public Workshop: The Sentinel Post-Licensure Rapid Immunization Safety Monitoring (PRISM) System. 2016.

<https://www.fda.gov/vaccines-blood-biologics/workshops-meetings-conferences-biologics/public-workshop-sentinel-post-licensure-rapid-immunization-safety-monitoring-prism-system>