Vaccinations Are Safe: Explaining Why

SCIENCE IS KEY

Vaccines are remarkable scientific achievements that have greatly reduced rates of death and disease around the world. This document begins to explain the science underpinning public confidence in today's vaccines. Each segment provides part of the total picture. Together, the accumulated scientific evidence explains the prudence of routine vaccination policies.

Vaccines are the safest of all medications.

- Before FDA licensing, vaccines are studied in larger populations than are other drugs.
- Once licensed and put to use, multiple layers of safety surveillance continue as long as the vaccines are distributed.

Every scientific authority recommends routine vaccination. This includes the Centers for Disease Control and Prevention, Food and Drug Administration, American Academy of Pediatrics, American Academy of Family Practitioners, American College of Obstetricians and Gynecologists, American Medical Association, American Nurses Association, American Pharmacists Association, National Academy of Medicine, and World Health Organization, plus every state health department, every city health department, and every children's hospital.

DISCUSSION POINTS

Vaccines do not cause autism.

BACKGROUND

A 1998 British journal article making a claim of a connection between the measles vaccine and the development of autism was retracted by the journal's editors, who said they had been deceived. The author was found guilty by the United Kingdom General Medical Council of dishonesty and flouting ethics protocols. As a result, they revoked his license to practice medicine.[1,2] In spite of these rebukes, the erroneous belief that vaccination causes autism took hold with a small group.

SCIENCE

- Vaccinated children develop autism at the same rate as unvaccinated children.[3,4]
- A litany of well-controlled studies show that vaccines do not cause autism.[3-8]
- Properly designed studies involving over 1.2 million children established no links between vaccines and autism or autism spectrum disorder.[4,8]
- Scientists agree: Vaccines do not cause autism.

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1 Dyer C. *Lancet* retracts Wakefield's MMR paper. *BMJ* 2010, 340: c696. www.bmj.com/content/340/bmj.c696
2 Boseley S. *Lancet* retracts 'utterly false' MMR paper. *The Guardian*. 2010 Feb 02, London.
3 Hviid A, Stellfeld M, Wohlfahrt J, Melbye M. Association between thimerosal-containing vaccine and autism. *JAMA*. 2003;290:1763–6.
4 Taylor L, Swerdfeger AL, Eslick GD. Vaccines are not associated with autism: An evidence-based meta-analysis of case-control and cohort studies. Vaccine 2014;32(29):3623–29.
5 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;163:561-7.
6 CDC. Science Summary: CDC Studies on Thimerosal in Vaccines. www.cdc.gov/vaccinesafety/pdf/cdcstudiesonvaccinesandautism.pdf
7 Committee to Review Adverse Effects of Vaccines. Adverse Effects of Vaccines: Evidence and Causality. Washington, DC: Institute of Medicine, 2011. www.nap.edu/catalog/13164/adverse-effects-of-vaccines-evidence-and-causality
8 Madsen KM, Hviid A, Vestergaard M, et al. A population-based study of measles, mumps, and rubella vaccination and autism. *N Engl J Med*. 2002;347:1477–82.

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Because we continue to vaccinate, rates of diseases that vaccines prevent are low.

SCIENCE

- Infection rates for certain serious diseases in the U.S. fell because of widespread vaccination programs against diseases such as polio, diphtheria, tetanus, pertussis (whooping cough), measles, mumps, and rubella. But the viruses and bacteria that cause these diseases are still around. Disease rates will remain low only if we maintain high levels of vaccination.
- High vaccination rates protect the community. This is known known as "community immunity" or "herd protection."
    - Community immunity occurs when enough people are vaccinated that it slows down spread of contagious microbes. Then those who are not directly protected by vaccination (because they are too young or have an underlying disease) are indirectly protected, simply because they are less likely to be exposed.
    - Herd protection occurs when vaccination rates exceed a certain level, which varies by disease. With polio, for example, 50% to 95% of people must be vaccinated to slow transmission of the disease. Because the measles virus is easier to transmit, 95% of people must be immune to achieve the same effect.[1,2]
- While infection rates are low for many preventable diseases in the U.S., they are much higher in some parts of the world. If vaccination rates in the U.S. become too low, measles and other vaccine-preventable diseases can easily return.
- The 2019 measles outbreak involved nearly 1,300 cases across 31 U.S. states. The 2019 outbreak started when international travelers brought measles into the U.S., allowing the disease to spread through unvaccinated communities.[3,4] There were so many measles cases, the U.S. almost lost its status as having eliminated measles transmission in the country.

Each component in each vaccine serves a purpose.

SCIENCE

- Vaccines do not contain toxins.
- Some vaccines may contain trace amounts of chemicals from their production process.
- If any of these trace chemicals is in a vaccine, it is at a lower level than found naturally in the body or the environment.

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1 Truelove S, Graham M, Moss WJ, et al. Characterizing the impact of spatial clustering of susceptibility for measles elimination. *Vaccine* 2019; 37(5):732-741. www.sciencedirect.com/science/article/pii/S0264410X18316724
2 Guerra F, Bolotin S, Lim G. et al. The basic reproduction number (R0) of measles: A systematic review. *The Lancet* 2017;17(12): e420-e428. www.sciencedirect.com/science/article/pii/S1473309917303079?via%3Dihub
3 CDC. Measles cases and outbreaks. Accessed December 5, 2019. www.cdc.gov/measles/cases-outbreaks.html
4 McDonald R, Ruppert PS, Souto M, et al. Measles outbreaks from imported cases in orthodox Jewish communities – New York and New Jersey, 2018–2019. MMWR 2019;68:444–445.

- Each of these components is added intentionally to perform an important function.[1]
- The following ingredients are used to boost immune responses, maintain purity of multi-dose containers, or prepare the vaccine's active ingredients:[1]
    - Thimerosal is a preservative that helps maintain sterility of multi-dose vaccine vials. Thimerosal helps prevent bacterial contamination as multiple doses are withdrawn from the vials. All vaccines are available in single-dose formulations that do not contain thimerosal.[2] Thimerosal is a chemical that contains ethylmercury, not methylmercury. This distinction is important because ethylmercury is quickly cleared from the body and bloodstream, whereas methylmercury (the type found in canned tuna) can accumulate in the body.[3]
    - Aluminum is added to some vaccines to help induce a stronger immune response. Aluminum is the third most common element on our planet, after oxygen and silicon. During the first 6 months of life, a breastfed infant will swallow more aluminum through their diet than they will acquire via recommended vaccination.[4]
    - Formaldehyde in trace quantities is used to prepare diphtheria toxoid and tetanus toxoid. The average newborn has 50–70 times more naturally-produced formaldehyde in their body than is found in a single vaccine dose.[5]

1 CDC. "What's in Vaccines" fact sheet. August 7, 2019. www.cdc.gov/vaccines/vac-gen/additives.htm.
2 FDA. Thimerosal and vaccines. February 1, 2018. www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/thimerosal-and-vaccines
3 CDC. Thimerosal in vaccines. 2015 www.cdc.gov/vaccinesafety/concerns/thimerosal/index.html
4 Keith L, Jones DE, Chou CH. Aluminum toxicokinetics regarding infant diet and vaccinations. Vaccine 2002;20(3): S13-S17. www.sciencedirect.com/science/article/pii/S0264410X02001652
5 FDA. Common ingredients in US licensed vaccines. www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/common-ingredients-us-licensed-vaccines

Some viral vaccines have a remote link to fetal cells from four abortions that occurred decades ago.

SCIENCE

- Vaccines do not contain aborted fetuses.
- In the 1960s, scientists used fetal cells to develop culture methods ("cell lines") to grow certain viruses used in vaccines. These cell lines are still used today.
- No further sources of cells are needed to produce the vaccines involved.[1]
- Ethicists, such as those at the National Catholic Bioethics Center, have considered this situation and concluded that routine vaccination is appropriate because it prevents serious infections.[2]
- Fetal cells are used in other medical fields as well. Researchers are using these cells to study and find treatments and cures for birth defects, eye diseases, Parkinson's disease, amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease), and spinal-cord injuries.[3]

1 Grabenstein JD. What the world's religions teach, applied to vaccines and immune globulins. *Vaccine*. 2013;31(Apr 12):2011-23.
2 IAC. Religious Concerns. www.immunize.org/talking-about-vaccines/religious-concerns.asp
3 Congressional Research Service. Human Fetal Tissue Research: Frequently Asked Questions. August 8, 2019. https://crsreports.congress.gov/product/pdf/R/R44129/9
4 U.S. Conference of Catholic Bishops. Answers to Ethical Questions About COVID-19 Vaccines, Jan 2021. www.usccb.org/resources/Answers%20to%20Key%20Ethical%20Questions%20About%20COVID-19%20Vaccines.pdf

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Live vaccines contain weakened (i.e., "attenuated") viruses or bacteria that protect us by inducing immunity.

SCIENCE

- Some vaccines contain weakened (i.e., attenuated) viruses or bacteria.
- The viruses or bacteria in these vaccines have been attenuated in a laboratory so that they do not cause the diseases they are intended to prevent.[1]
- In their attenuated state, they help train the immune system to protect from future infections. The body recognizes them as foreign and creates antibodies, resulting in immunity against the actual virus or bacteria when encountered in the future.
- Mild symptoms may occur following live virus vaccinations, but they are rarely harmful, unless the recipient has a weakened immune system. Healthcare providers screen patients to determine if they should receive live virus vaccines.
- While shedding of virus after vaccination with live virus 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 virus vaccines, to better protect the person with weak immunity.[2]

1 CDC. Understanding how vaccines work. 2018. www.cdc.gov/vaccines/hcp/conversations/understanding-vacc-work.html
2 Rubin L, Levin MJ, Ljungman P, et al. IDSA clinical practice guideline for vaccination of the immunocompromised host. *Clinical Infectious Diseases* 2014;58(3): e44–e100 https://academic.oup.com/cid/article/58/3/e44/336537

The Vaccine Injury Compensation Program (VICP) has sustained the U.S. vaccine supply for more than 30 years, even while providing a no-fault program for petitioners claiming injury.

BACKGROUND

The VICP was created in the 1980s to protect public health and avoid vaccine shortages by enabling manufacturers to develop and distribute vaccines. Between 2006 and 2019, over 4 billion doses of vaccines covered by VICP were distributed in the U.S. For petitions filed in this time period, 5,820 received compensation under the no-fault VICP.[1]

1 Health Resources & Services Administration (HRSA). Vaccine Injury Compensation Data. www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/data-statistics-report.pdf

SCIENCE

- For each 1 million doses of vaccine distributed in the U.S., approximately 1 recipient was compensated.[1]

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- Being awarded compensation through the VICP does not mean that the vaccine caused the alleged injury. Approximately 70% of all compensations awarded went through an expedited process that used a no-fault system for award, a payment of a negotiated settlement between the parties.[1]
- Petitioners can have their legal fees covered through the VICP, regardless of the outcome.[3]
- Over 50% of claims during 2017–18 were from Shoulder Injury Resulting from Vaccine Administration (SIRVA), which is caused by the act of injecting a fluid through a needle in the wrong location, not the vaccine itself. SIRVA can be addressed through proper injection technique and training of vaccinators.[4]
- 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.[3]
- See also "The Vaccine Injury Compensation Program of 1986: An Effective Balance of Public Health and Personal Remedy" at www.immunize.org/catg.d/p2075.pdf

3 HRSA. National Vaccine Injury Compensation Program. Accessed October 10, 2019. www.hrsa.gov/vaccine-compensation/index.html
4 Fleischer J. Half of all new federal vaccine cases allege injury from shots given incorrectly. May 2, 2018. www.nbcwashington.com/news/local/12-of-new-vaccine-cases-allege-injury-by-shots-given-wrong_washington-dc/53622/

U.S. Courts look favorably on vaccination requirements that protect the public.

SCIENCE AND POLICY

- Various courts, including the U.S. Supreme Court, have found that a community's need to be protected from infectious diseases justifies requirements to be vaccinated. The U.S. Supreme Court recognizes the government's authority to establish policies that protect the health and well-being of children and of communities.[1]
- Vaccination protects recipients directly. When many people are vaccinated, vaccination protects communities as a whole ("community immunity"). Vaccination laws protect the entire community, as well as individuals who are in close contact with one another, such as students, neighbors, and vulnerable family members.
- States have processes so that people can be exempted from vaccination for valid medical reasons. Some states allow for other forms of exemptions.[2]
- State laws recognize that, if too many people go without vaccination, the ability of viruses or bacteria to spread increases dramatically, threatening the public health with disease outbreaks.[3]

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1 Weithorn LA, Reiss DR. Legal approaches to promoting parental compliance with childhood immunization recommendations. *Human Vaccines & Immunotherapeutics* 2018;14(7): 1610-1617. www.tandfonline.com/doi/full/10.1080/21645515.2018.1423929
2 National Conference of State Legislatures (NCSL). States with religious and philosophical exemptions from school immunization requirements. April 30, 2021. www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx
3 Olive JK, Hotez PJ, Damania A, Nolan MS. The state of the antivaccine movement in the United States: A focused examination of nonmedical exemptions in states and counties (Policy Forum). *PLoS Medicine* 2018;15(6): e1002578. Erratum 2018;15(7):e1002616. https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002578

Most vaccines must be given at very young ages to provide the greatest protection.

SCIENCE

- Today's U.S. vaccination schedule is the best approach to protecting children from serious infections as early in life as possible.
- The U.S. schedule is based on a careful review of the scientific evidence by a committee of distinguished civilian physicians and researchers, known as the Advisory Committee on Immunization Practices (ACIP).
- The ACIP schedule ensures that infants, children, adolescents, and adults get vaccines at time points when they are vulnerable to infection and when there is solid evidence that the vaccines will protect and is safe for the people who will get them.[1,2]
- The American Academy of Pediatrics, American Medical Association, American Academy of Family Physicians, American College of Obstetricians and Gynecologists, and American College of Nurse-Midwives, public health officials, and multiple other medical organizations have all been consulted on and approve the Centers for Disease Control and Prevention's childhood immunization schedule.
- These groups warn against delays, as there are no benefits to delaying vaccination. In fact, delays can cause harm by increasing the time a child remains vulnerable to vaccine-preventable diseases.[3]
- The human immune system, including in newborns, can fight off many different viruses and bacteria at the same time.
- No reputable study has found increased risk of disease based on the number of vaccines or vaccine components ("antigens") given during childhood or at any other age.[4]
- The current childhood vaccination schedule contains fewer vaccine components ("antigens" or "proteins") than in previous decades (3,000 proteins in eight vaccines in the 1980s and 1990s vs. 305 proteins in today's 14 vaccines).[5]
- Vaccines harness the natural power of the human immune system to build up a body's ability to specifically avoid infection.

Vaccines are extensively studied before widespread use.

SCIENCE

- Vaccines have used and continue to use double-blind placebo-controlled studies to prove that they are effective and safe in the people who receive them.

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1 CDC. Who sets the immunization schedule? 2012. www.cdc.gov/vaccines/parents/schedules/sets-schedule.html
2 CDC. Reasons to follow CDC's recommended immunization schedule. www.cdc.gov/vaccines/parents/schedules/reasons-follow-schedule.html
3 Children's Hospital of Philadelphia. 2019. Vaccine schedule: Altering the schedule. www.chop.edu/centers-programs/vaccine-education-center/vaccine-schedule/altering-the-schedule
4 Roush S, Murphy TV; Vaccine-Preventable Disease Table Working Group. Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States (National Vaccine Recommendations). *JAMA*, 2007;298:2155–63. https://jamanetwork.com/journals/jama/fullarticle/209448
5 CDC. How vaccines strengthen your baby's immune system. www.cdc.gov/vaccines/parents/why-vaccinate/strengthen-baby-immune.html

- When investigating new vaccines, it is not ethically appropriate to deprive people in a control group (i.e., a group of people for whom vaccines are intentionally withheld) of existing vaccines already shown to be safe and effective.[1]

1 Rid A, Saxena A, Baqui AH, et al. Placebo use in vaccine trials: Recommendations of a WHO Expert Panel. 2014;32(37): 4708–4712. www.sciencedirect.com/science/article/pii/S0264410X14005374?via%3Dihub

Although vaccine-preventable infections usually are mild, they can also cause serious disease.

SCIENCE

- All diseases targeted by vaccination carry substantial risks for serious illness or even death.
- Before vaccine approval and widespread use, these diseases caused an unacceptable burden of disease.[1]
    - Chickenpox (varicella) is not just a childhood disease. Serious complications can include pneumonia, encephalitis, and bloodstream infections.[2]
    - Measles infections can lead to serious complications, including death. In addition, measles infection can also impair the body's ability to battle other non-measles infections by erasing the immune system's memory. This leaves people vulnerable to other illnesses for months or even years after the measles virus has left the body.[3]
    - Before vaccine licensing, measles, mumps, diphtheria, and pertussis (whooping cough) caused hundreds of thousands of cases and thousands of deaths each year in the U.S. A 92% decline in cases and a 99% decline in deaths has been seen for diphtheria, mumps, pertussis, and tetanus since these vaccines became widely used.[1]

1 Roush S, Murphy TV; Vaccine-Preventable Disease Table Working Group. Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States (National Vaccine Recommendations). *JAMA*, 2007;298:2155–63. https://jamanetwork.com/journals/jama/fullarticle/209448

2 CDC. 2018. Chickenpox (Varicella). Complications. www.cdc.gov/chickenpox/about/complications.html

3 Mina M, Kula T, Leng Y, et al. Measles virus infection diminishes preexisting antibodies that offer protection from other pathogens. *Science*. 2019; 366(6465): 599-606. https://science.sciencemag.org/content/366/6465/599

Vaccine Adverse Event Reporting System (VAERS): One piece of a multi-level U.S. vaccine safety program

SCIENCE

- VAERS is one of several overlapping systems used by FDA and CDC to monitor vaccine safety.
- VAERS exists to detect possible vaccine safety signals as early as possible. It emphasizes speed of detection over scientific validity.
- A VAERS report does not prove cause and effect between a vaccine and a reported event.

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- VAERS reports may be coincidental and due to some other cause.[1]
- VAERS report forms are publicly available at https://vaers.hhs.gov. No medical expertise is needed to submit a report. CDC and FDA encourage medically untrained people to seek the help of a healthcare professional in reporting to VAERS.[2]
- CDC and FDA manage several programs using several different methods, to provide the U.S. with rapid, consistent, and thorough assessment of vaccines. Considered together, these provide a robust post-licensing monitoring infrastructure across the U.S.[3,4]
- VAERS is just one part of post-licensing monitoring. VAERS reports can be submitted by anyone in the country. VAERS reports have the advantage of having a low threshold for reporting. On the other hand, VAERS reports have the disadvantage of not having a control group to help assess cause and effect.
- CDC also operates the Vaccine Safety Datalink (VSD) that encompasses over 12 million Americans, enabling comparisons of large numbers of vaccine recipients and non-recipients in routine clinical settings.[5]
- CDC's Clinical Immunization Safety Assessment (CISA) Project gives CDC's public-health experts the ability to consult with practicing clinical safety experts at leading academic medical centers. The CISA Project provides U.S. clinicians who have vaccine safety questions about a specific patient residing in the U.S. with consultation services.[6]
- FDA's PRISM (Post-licensure Rapid Immunization Safety Monitoring) system uses a large database of health insurance claims data to monitor for potential vaccine safety signals.[7]

SUMMARY

The United States has a strong and transparent vaccine infrastructure to protect public health, based soundly in objective science.

Vaccines are studied extensively before, during, and after licensing by the FDA and other scientists.

Extensive scientific evidence overwhelmingly demonstrates the safety and effectiveness of vaccines.

1 HHS. Guide to Interpreting VAERS Data. https://vaers.hhs.gov/data/dataguide.html
2 FDA. Vaccine Adverse Events Reporting System (VAERS) Questions and Answers. www.fda.gov/vaccines-blood-biologics/vaccine-adverse-events/vaccine-adverse-event-reporting-system-vaers-questions-and-answers
3 CDC. About the Immunization Safety Office. 2015. www.cdc.gov/vaccinesafety/iso.html
4 CDC. Vaccine Safety Monitoring. www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/index.html
5 CDC. Vaccine Safety Datalink (VSD). www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html
6 CDC. Clinical Immunization Safety Assessment (CISA) Project. www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html
7 CDC. Public Workshop: The Sentinel Post-Licensure Rapid Immunization Safety Monitoring (PRISM) System. 2016. www.fda.gov/vaccines-blood-biologics/workshops-meetings-conferences-biologics/public-workshop-sentinel-post-licensure-rapid-immunization-safety-monitoring-prism-system