

TO: Members of the Wisconsin State Legislature

FROM: BioForward, Children's Wisconsin, UW Health, Marshfield Children's Hospital,
Wisconsin Medical Society and the Wisconsin Chapter of the American Academy of Pediatrics

DATE: October 15, 2020

RE: **Vaccines 101 – Vaccine Terminology, Development and FAQs**

As researchers, healthcare workers and governments continue to work to address the spread of COVID-19, there is much discussion and concern about forthcoming coronavirus vaccines. As such, we provide the following information about **vaccine terminology and the process for vaccine development**.

Definition of Terms:

- **Immunity:** Protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected.
- **Herd Immunity:** Herd immunity is established when a sufficient proportion of a population is immune to an infectious disease (either through vaccination and/or prior illness) to make its spread from person-to-person unlikely. When herd immunity exists, even individuals who are not vaccinated (such as newborns and those with chronic illnesses) are offered some protection because the disease has little opportunity to spread within the community.
- **Vaccine:** A product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease. Vaccines are usually administered through needle injections but can also be administered by mouth or sprayed into the nose.
- **Vaccination:** The act of introducing a vaccine into the body to produce immunity to a specific disease.
- **Immunization:** A process by which a person becomes protected against a disease through vaccination. This term is often used interchangeably with vaccination or inoculation.

How do Vaccines Work? Vaccines help develop immunity by *imitating* an infection from certain bacteria or viruses and stimulating the body's production of specific antibodies. This helps prepare the body to fight off an actual infection. The vaccination process, however, almost never causes illness. Sometimes, after getting a vaccine, the imitation infection can cause minor symptoms, such as fever. Such minor symptoms are normal and should be expected as the body builds immunity. Click [here](#)¹ for more detailed information about how vaccines work.

What is the Process for Developing a Vaccine? Extensive clinical trials are used to develop and test vaccines before they are available for patients. Clinical trials are conducted in "phases," primarily to ensure subject safety. Importantly, the development of COVID-19 vaccine is using all of these same clinical trial steps but utilizing a faster timeline. Rather than proceeding through each development step sequentially, some steps are being undertaken *simultaneously*, which does not impact the safety of the process but does increase the cost of production and the timing of the investment in logistics (*e.g.*, manufacturing of glass vials), which would normally be made only after

¹ <https://www.cdc.gov/vaccines/hcp/conversations/downloads/vacsafe-understand-color-office.pdf>

all testing is complete. Importantly, speeding up the vaccine development process for purposes of producing a safe and effective COVID-19 vaccine is possible due to significant financial investment from both public and private funding. No steps are being “skipped” or altered. Each phase will be completed, but on a faster timeline. Click [here](#)² for an explanation of each phase of a vaccine clinical trial.

Are vaccines safe? Vaccines are arguably the safest of all approved medications. Before FDA approves a vaccine, vaccines are studied in larger populations than other prescription drug trials. In addition, once a vaccine is approved for use, there are multiple layers of safety surveillance that continue for as long as the vaccine is distributed and allow for continuous reporting of potential adverse effects.³

- In the U.S., the **Vaccine Adverse Event Reporting System (VAERS)**⁴ exists to detect possible vaccine safety concerns as early as possible. VAERS is only one part of post-licensure monitoring.
- The CDC also operates the **Vaccine Safety Datalink (VSD)**⁵ that conducts vaccine safety studies based on VAERS data and monitors the safety of newly recommended vaccines.
- The **Clinical Immunization Safety Assessment (CISA)**⁶ **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.
- The **FDA’s PRISM (Post-licensure Rapid Immunization Safety Monitoring system)**⁷ uses a large database of primarily health insurance data to monitor for potential vaccine safety signals.

Are there large amounts of other toxins in vaccines? No. Vaccines do contain other ingredients⁸ used as preservatives, adjuvants, stabilizers and residual materials from cell cultures. However, all of these ingredients, including mercury and aluminum, are found in lower quantities in vaccines than what can be found in environmental sources and/or naturally in the body. These substances are used in vaccines to boost immunity, maintain purity, increase immune response, and inactivate viruses.

Thank you for your consideration. If you have questions, please contact Jordan Lamb, BioForward (608) 252-9358, Jodi Bloch, Children’s Wisconsin (608) 217-9508, Connie Schulze, UW Health (608) 422-8063, Tony Langenohl, Marshfield Children’s Hospital (608) 444-5076, HJ Waukau, Wisconsin Medical Society (608) 442-3807 or Kia Kjensrud, Wisconsin Chapter of the American Academy of Pediatrics (262) 751-7003.

² <https://www.cdc.gov/vaccines/parents/infographics/journey-of-child-vaccine-h.pdf>

³ <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/index.html>

⁴ <https://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-vaers-color-office.pdf>

⁵ <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html>

⁶ <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>

⁷ <https://www.fda.gov/vaccines-blood-biologics/workshops-meetings-conferences-biologics/public-workshop-sentinel-post-licensure-rapid-immunization-safety-monitoring-prism-system>

⁸ <https://www.cdc.gov/vaccines/vac-gen/additives.htm>