Understanding Vaccine Safety Monitoring Systems

Why Vaccine Safety Systems Matter: ***Vaccines are among the most thoroughly tested medical products***, backed by robust safety systems to ensure they are safe, effective, and trusted. These systems protect public health and provide lifelong defense against serious diseases. Here's how vaccine safety is maintained:

1. Pre-Licensure Testing Before approval, vaccines undergo rigorous clinical trials in three phases:

- **Phase 1**: Evaluates safety and dosage in a small group of volunteers.
- **Phase 2**: Expands testing to hundreds of people, focusing on safety, immune response, and potential side effects.
- **Phase 3**: Involves thousands of people to confirm safety and effectiveness and detect rare side effects.

2. Regulatory Review and Approval

- **FDA Evaluation**: The U.S. Food and Drug Administration (FDA) reviews all trial data to ensure the vaccine meets high safety standards before approving it for public use. An advisory committee of experts (Vaccines and Related Biological Products Advisory Committee) may be convened for additional evaluation. The FDA also assesses information regarding the manufacturing of the vaccine and the facility to ensure the vaccine can be produced reliably and consistently.
- **Approval**: If the FDA is satisfied, the vaccine receives approval for public use.

3. Post-Licensure Monitoring Once vaccines are approved and distributed, multiple systems monitor their safety so that possible rare risks can be identified:

- Vaccine Adverse Events Reporting System **(VAERS)** – VAERS is a passive, early warning system that is managed by CDC and FDA and designed to alert both entities to safety issues. Anyone can report an injury, including healthcare professionals, patients, patient representatives, vaccine companies, and others. Since anyone can report their own vaccine side effects, VAERS reports cannot be used to determine a link between a side effect and vaccine, however, the information is (and has been) used to detect unexpected or unusual patterns that emerge that may indicate a safety issue that should be explored further.
- Vaccine Safety Datalink **(VSD)** – VSD is a collaborative project between CDC's Immunization Safety Office and healthcare networks and organizations across the United States. This system uses databases of medical records to track the safety of vaccines. Since it uses real-time medical records instead of self-reports like VAERS uses, this system can better help determine if a side effect is linked to a vaccine, especially rare and serious adverse events following vaccination.
- Clinical Immunization Safety Assessment (CISA) Project – CISA is a national network of vaccine safety experts from the CDC's Immunization Safety Office and several medical research centers and partners. This project addresses safety issues, conducts high quality clinical research, and assesses complex clinical adverse events following vaccination. CISA also helps to connect clinicians with experts who can help consult on vaccine safety questions related to individual patients.
- **Post-Licensure Rapid Immunization Safety Monitoring System (PRISM)** – PRISM is a partnership between the FDA's Center for Biologics Evaluation and Research and health insurance companies. It actively monitors and

analyzes data from a representative subset of the general population. PRISM links data from health plans with data from state and city immunization information systems (IIS). PRISM has access to information for over 190 million people allowing it to identify and analyze rare health outcomes that would otherwise be difficult to assess.

- **Biologics Effectiveness and Safety (BEST) System** – BEST system looks at multiple data sources to detect or evaluate adverse events or study specific safety questions.
- **V-safe** – This safety monitoring system was developed for COVID-19 vaccine monitoring but currently monitors how an individual's health after having an RSV vaccine. Individuals who have had an RSV vaccine are able to register for V-safe to receive personalized, confidential health check-ins via text or email to ask how they feel after vaccination. This information helps CDC to monitor vaccine safety and let others know what to expect after getting an RSV vaccine. COVID-19 vaccines, like all vaccines, are carefully monitored for safety. According to the CDC, COVID-19 vaccines have gone through the most intensive safety monitoring in U.S. history and will continue to be monitored as long as the vaccines are in use.

4. Ongoing Quality Control

- **Manufacturing Oversight**: Vaccine production facilities are regularly inspected, and every batch is tested for quality.
- **Lot Testing**: The FDA reviews safety and potency for vaccine lots before they are released.

5. Transparent Communication

- **Public Reporting**: Findings from safety monitoring systems are shared openly to ensure transparency and trust. The Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD) publicly share data and findings through reports, publications, and presentations, including during meetings of the Advisory Committee on Immunization Practices (ACIP). VAERS data can also be downloaded or searched online. Researchers can access VSD data and data from VSD publications through public use datasets and the VSD data sharing program.
- **Independent Reviews**: Independent advisory groups like the ACIP regularly review vaccine data and provide recommendations. ACIP review meetings are open to the public and members of the public are encouraged to submit written and oral comments.

Reliable Resources for More Information

- American Academy of Pediatrics: healthychildren.org/English/safety-prevention/immunizations/Pages/vaccine-studies-examine-the-evidence.aspx
- National Foundation for Infectious Diseases: nfid.org/immunization/vaccine-science-safety/
- Centers for Disease Control and Prevention (CDC): cdc.gov/vaccinesafety
- U.S. Food and Drug Administration (FDA): fda.gov/vaccines-blood-biologics/safety-availability-biologics/vaccine-safety-questions-and-answers
- World Health Organization (WHO): who.int/vaccine-safety

For more details, visit **Vaccinate Your Family** at vaccinateyourfamily.org.