Nebraska Immunization Program

Let's be clear about the Vaccine Adverse Events Reporting System

The Vaccine Adverse Events Reporting System (VAERS) was established in 1990 as a national early warning system to detect vaccine safety problems. It's a reporting system co-sponsored by the CDC and the FDA. VAERS data is analyzed from reports of adverse events following receipt of US-licensed vaccines. This monitoring can help identify important new safety concerns, vaccine trends, or can be a rapid signal detection for rare adverse events.

Limitations of VAFDS

A report to VAERS generally does not prove that the identified vaccine(s) caused the adverse event described. <u>It only confirms that the reported event occurred sometime after the vaccine was given</u>. No proof that the event was caused by the vaccine is required in order for VAERS to accept the report.

Submitting a report to VAERS can be done in two ways:

- 1. Online (preferred)
- 2. A writeable PDF

VAERS reports are available to view after 6 weeks of submission, and there are no personal identifiers. VAERS data can be accessed by using the CDC Wonder online search tool. Anyone can use the search tool to query a range of information.

Let's look at CDC Wonder

https://wonder.cdc.gov/vaers.html

Following are the query results for MMR. The criteria used for this query include: Vaccine, Vaccine Manufacturer, Age, VAERS ID, and Onset Interval of 10-14 days since vaccinated over a duration of the last 5 years (Jan. 2012 – Dec. 2017) in the state of Nebraska.

VAERS ID	Age	Vaccine	Vaccine Manufacturer	Adverse Event Description ↑↓
<u>458683-1</u>	1-2 years	MEASLES + MUMPS + RUBELLA (MMR II) (26)	MERCK & CO. INC.	Presented with petechiae. Platelet count 39,000. Admitted for ITP, received IVIG.
<u>657196-1</u>	1-2 years	MEASLES + MUMPS + RUBELLA (MMR II) (26)	MERCK & CO. INC.	Parents noted two dime sized firm nodules on right thigh at the sites of vaccine administration approx. 10d previously. Also there was a quarter sized area of erythema overtop the nodules. She had Hep A and VZV given in this thigh right thigh. This was non tender and resolved gradually over about 3-4 days. She did have fever the two days prior to the 'lumps' being felt but on the day that parents noted the lumps the fever had self resolved.

The query results show that from Jan. 2012 – Dec. 2017 there were two adverse events reported in Nebraska pertaining to MMR. Keeping the criteria exactly the same but extending the time frame back to Jan. 2000 produced 22 reports. After analyzing the results the following can be concluded:

- 1. Underreporting is an issue.
- 2. MMR is a safe vaccine.

Healthcare providers are encouraged to report all clinically significant adverse events after vaccination to VAERS even if it is uncertain whether the vaccine caused the event. They are also required to report to VAERS adverse events found in the Reportable Events Table (RET) at:

https://vaers.hhs.gov/resources/infoproviders.html

For more information please contact VAERS:

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