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Understanding vaccine safety information from the Vaccine Adverse Event Reporting System

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Abstract

The Vaccine Adverse Event Reporting System (VAERS) is administered by the Food and Drug Administration and CDC and is a key component of postlicensure vaccine safety surveillance. Its primary function is to detect early warning signals and generate hypotheses about possible new vaccine adverse events or changes in frequency of known ones. VAERS is a passive surveillance system that relies on physicians and others to voluntarily submit reports of illness after vaccination. Manufacturers are required to report all adverse events of which they become aware. There are a number of well-described limitations of such reporting systems. These include, for example, variability in report quality, biased reporting, underreporting and the inability to determine whether a vaccine caused the adverse event in any individual report. Strengths of VAERS are that it is national in scope and timely. The information in VAERS reports is not necessarily complete nor is it verified systematically. Reports are classified as serious or nonserious based on regulatory criteria. Reports are coded by VAERS in a uniform way with a limited number of terms using a terminology called COSTART. Coding is useful for search purposes but is necessarily imprecise. VAERS is useful in detecting adverse events related to vaccines and most recently was used for enhanced

reporting of adverse events in the national smallpox immunization campaign. VAERS data have always been publicly available. However, it is essential for users of VAERS data to be fully aware of the strengths and weaknesses of the system. VAERS data contain strong biases. Incidence rates and relative risks of specific adverse events cannot be calculated. Statistical significance tests and confidence intervals should be used with great caution and not routinely. Signals detected in VAERS should be subjected to further clinical and descriptive epidemiologic analysis. Confirmation in a controlled study is usually required. An understanding of the system's defined objectives and inherent drawbacks is vital to the effective use of VAERS data in vaccine safety investigations.