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# Vaccination errors reported to the Vaccine Adverse Event Reporting System, (VAERS) United States, 2000–2013

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ABSTRACT

*Importance:* Vaccination errors are preventable events. Errors can have impacts including inadequate immunological protection, possible injury, cost, inconvenience, and reduced confidence in the healthcare delivery system.
*Objectives:* To describe vaccination error reports submitted to the Vaccine Adverse Event Reporting System (VAERS) and identify opportunities for prevention.
*Methods:* We conducted descriptive analyses using data from VAERS, the U.S. spontaneous surveillance system for adverse events following immunization. The VAERS database was searched from 2000 through 2013 for U.S. reports describing vaccination errors and reports were categorized into 11 error groups. We analyzed numbers and types of vaccination error reports, vaccines involved, reporting trends over time, and descriptions of errors for selected reports.
*Results:* We identified 20,585 vaccination error reports documenting 21,843 errors. Annual reports increased from 10 in 2000 to 4324 in 2013. The most common error group was "Inappropriate Schedule" (5947; 27%); human papillomavirus (quadrivalent) (1516) and rotavirus (880) vaccines were most frequently involved. "Storage and Dispensing" errors (4983; 23%) included mostly expired vaccine administered (2746) and incorrect storage of vaccine (2202). "Wrong Vaccine Administered" errors (3372; 15%) included mix-ups between vaccines with similar antigens such as varicella/herpes zoster (shingles), DTaP/Tdap, and pneumococcal conjugate/polysaccharide. For error reports with an adverse health event (5204; 25% of total), 92% were classified as non-serious. We also identified 936 vaccination error clusters (i.e., same error, multiple patients, in a common setting) involving over 6141 patients. The most common error in clusters was incorrect storage of vaccine (582 clusters and more than 1715 patients).
*Conclusions:* Vaccination error reports to VAERS have increased substantially. Contributing factors might include changes in reporting practices, increasing complexity of the immunization schedule, availability of products with similar sounding names or acronyms, and increased attention to storage and temperature lapses. Prevention strategies should be considered.

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Medication errors are an important preventable public health problem. The Institute of Medicine (IOM) report *To Err Is Human: Building a Safer Health System* (IOM, 2000) identified medication errors as the most common type of error in health care [1]. In 2007, the IOM Committee on Identifying and Preventing Medication Errors issued a report on medication errors [2]. Relatively few studies in the U.S. have focused specifically on vaccination errors. Those studies have found: that commonly reported errors involved wrong vaccine or improper dosing; adverse health outcomes were uncommon [3]; that about10–35% of young children had at least 1 invalid dose administered [4,5]; and that a voluntary, team approach was effective in improving error reporting [6]. Several other studies have reported on specific vaccination errors including: extra immunization [7,8]; improper spacing of vaccine doses [9]; improper route [10,11]; expired vaccine [12]; improper storage [13] wrong drug administered [14]; and contraindication errors [15]. Other publications have highlighted possible contributors to errors, such as names and abbreviations which can soundalike and packaging that can look alike [16,17].

A review in the US Vaccine Adverse Event Reporting System (VAERS) for the period 1994–2001 identified 49 vaccination error reports, of which 42 (86%) also reported an adverse health event (AHE) [18]. In 2001–2002, 26 additional vaccination errors were identified; information on health outcomes was not included [19].

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The most frequently reported error in both reviews was wrong vaccine administered. Another VAERS review focusing on influenza vaccination in children from 1990 to 2006 found 201 reports of vaccination errors; 94% did not report any AHE [20].

Since 2000, the US immunization schedule has grown larger and more complex as new vaccines became available and recommendations expanded [21–23]. Vaccination errors, like other medical errors are preventable events. In this review we describe vaccination errors reported to VAERS from 2000 to 2013.

## 1. Methods

VAERS is the US national spontaneous surveillance system for adverse events following US licensed vaccines, jointly administered by the Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA) [24]. The primary purpose of VAERS is to detect possible vaccine safety problems that might require further evaluation [25,26]. VAERS accepts all reports, including reports of vaccination errors, regardless of whether an AHE is documented. Guidance for reporting is available on the VAERS website [27]. Signs and symptoms of adverse events are coded using Medical Dictionary for Regulatory Affairs (MedDRA) terms; MedDRA terms are not medically confirmed diagnoses [28]. VAERS is a routine surveillance program conducted as a public health function and does not meet the definition of research; thus, it is not subject to Institutional Review Board review and informed consent requirements.

We defined a vaccination error as a preventable event that might reflect incorrect use and/or potentially result in patient harm. We searched the VAERS database for US reports received from January 1, 2000 through December 31, 2013, with MedDRA terms describing vaccination errors (Appendix A). An individual VAERS report may contain more than 1 MedDRA term depending on symptoms reported; each error reported was counted in the error group totals. We used statistical package software SAS version 9.2 (SAS Institute Inc., Cary, NC) for analyses.

### 1.1. Vaccination error reports by type and reporting trends over time

We categorized reports into 11 vaccination error groups, based on MedDRA error terms and groups created by the authors. Groups were created by grouping similar MedDRA terms describing the error and a sample of reports were reviewed to assure MedDRA term consistency with a specified group. Each report in an error group contained at least 1 of the corresponding MedDRA vaccination error terms associated with that group (Appendix A). A single report may be associated with 1 or more error groups, depending on assigned MedDRA terms. Single reports documenting multiple patients were counted as 1 report. We analyzed error groups by patient age and vaccines administered, and by year to identify trends in overall error reporting and in specific error groups over time. A 5% simple random sample of the top 3 error groups was performed using SAS. Each report sample was reviewed to characterize specific errors.

### 1.2. Vaccination error reports where an adverse health event (AHE) was reported

We analyzed vaccination error reports with an AHE by error group, patient age and vaccines administered. A physician reviewed all serious reports and medical records when available and classified the AHE into body system categories as previously described [29].

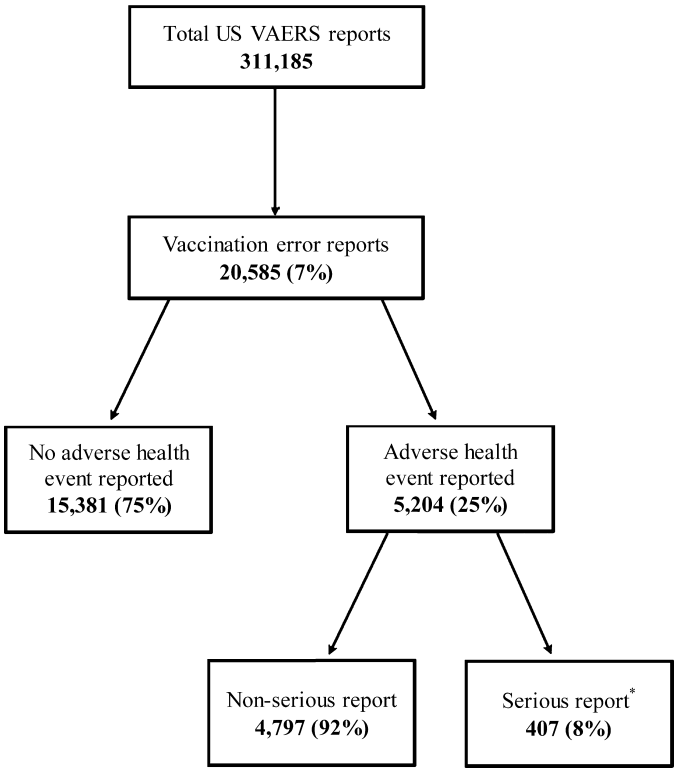


**Fig. 1.** *Vaccination error reports to VAERS, 2000–2013.* * Based on the Code of Federal Regulations a report is classified as serious if 1 of the following is reported: death, life-threatening illness, hospitalization or prolongation of hospitalization or permanent disability. Clinical review of the 407 serious reports indicated that injection site reactions and systemic symptoms (e.g., fever) were most common (103; 25%), followed by musculoskeletal (e.g., pain in extremity) (52; 13%) and neurological (e.g., headache) (50; 12%) AHEs.

### 1.3. Reports involving vaccine contraindications

We conducted clinical reviews of all vaccine "Contraindication" reports and examined all reports with MedDRA terms for maternal exposure or drug exposure during pregnancy to determine factors associated with this error.

### 1.4. Vaccination error clusters

We defined a vaccination error cluster as an incident involving more than 1 patient affected by the same error, in a distinct setting and/or involving the same vaccine provider(s). Using key word search techniques in SAS, we identified a subset of reports suggestive of vaccination error clusters. Cluster reports included multiple individual VAERS reports for the cluster incident or a single cluster report documenting multiple patients affected. We reviewed reports to confirm the existence of a cluster, documented the number of patients involved, and described the cluster incidents by vaccines administered and error group. Clusters were counted as a single incident regardless of number of persons involved or reports submitted.

## 2. Results

From January 1, 2000 through December 31, 2013, VAERS received a total of 311,185 U.S. reports, with 20,585 (7%) containing MedDRA term(s) for vaccination errors (Fig. 1). Seventy-five percent of VAERS error reports did not include any description of an AHE. Vaccination error reports increased during the study period, from 10 reports (<1% of all VAERS reports) in 2000, to 4324 (15% of VAERS reports) in 2013 (Fig. 2). Manufacturers submitted 64%