



# Vaccine Safety Resources for Nurses

The CDC supports nurses in promoting vaccination.

Vaccines are one of the greatest public health achievements in history. Immunization has dramatically reduced the burden of vaccine-preventable diseases—improvements that have continued into the 21st century.<sup>1</sup> A recent analysis of the 20 years since the U.S. Vaccines for Children program was created to pay for vaccines for children whose families could not afford them shows an estimated cost savings in preventing illnesses, hospitalizations, and premature deaths of \$1.38 trillion.<sup>2</sup>

Yet even as rates of illness and death from many vaccine-preventable diseases have decreased substantially—and even though the U.S. government maintains a comprehensive safety system governing vaccine development, licensure, and marketing<sup>3</sup>—concerns over vaccine safety persist, and such concerns are often unsupported by scientific evidence.<sup>4</sup> For example, in spite of an exhaustive review of the scientific evidence by the Institute of Medicine (now the National Academy of Medicine) and its conclusion that the measles, mumps, and rubella vaccine does not cause autism,<sup>5</sup> this belief still persists among some people.

What scientists have come to call “vaccine hesitancy” is resulting in a growing number of parents and others refusing or delaying recommended vaccinations for their children or themselves.<sup>6</sup> (To see the Centers for Disease Control and Prevention [CDC] recommended vaccine schedules for infants and children, teens, and adults, go to [www.cdc.gov/vaccines/schedules](http://www.cdc.gov/vaccines/schedules).) Undervaccination has been implicated in local and regional outbreaks of vaccine-preventable diseases, such as measles.<sup>7,8</sup> For example, between January 4 and April 2 of this year, 166 measles cases were reported in the United States, and over 80% of those were in people who were unvaccinated or had unknown vaccination status; the main reason for being unvaccinated was philosophical or religious beliefs.<sup>9</sup>

Nurses are often the ones administering vaccines and therefore play a central role in teaching parents and patients about vaccine safety and the lifesaving function of vaccines. According to a 2005 study, parents’ main source of information about vaccines is health care professionals,<sup>10</sup> and so it is critical that nurses understand and communicate to parents the importance of vaccines. Nurses might also treat

patients when vaccine adverse events require medical attention. The CDC has many resources available to nurses and other health care professionals on vaccine safety, including an established inquiry-and-response program.<sup>11</sup>

In this article we describe the CDC’s vaccine safety monitoring systems, explain how nurses and others can access the CDC’s inquiry channels and other resources, and give examples of recent inquiries and their resolution.

## THE CDC’S VACCINE SAFETY MONITORING SYSTEMS

The CDC’s Immunization Safety Office (CDC-ISO) uses several systems to monitor vaccine safety and communicate this information to health care professionals and others.

**The Vaccine Adverse Event Reporting System (VAERS)** is the national frontline spontaneous reporting surveillance system and provides early warning for identifying potential vaccine safety concerns.<sup>12</sup> As a spontaneous surveillance system, however, it is not designed to assess whether a vaccine caused an adverse event.<sup>13</sup> An example of an adverse event reported to VAERS that signaled concern was intussusception after RotaShield, the first licensed rotavirus vaccine. RotaShield was withdrawn from use in 1999 after a greater than expected number of reports of intussusception were made to VAERS and an increased risk was confirmed in other studies.<sup>14</sup>

**The Vaccine Safety Datalink (VSD)** uses electronic health record data from nine integrated health care organizations to conduct surveillance and epidemiologic studies. VSD data can be used to detect safety problems and to assess and quantify the risk of adverse events.<sup>15</sup> A VSD study was able to quantify the risk of anaphylaxis following vaccination in general in children and adolescents at one to two cases per million doses of vaccine administered.<sup>16</sup>

**The Clinical Immunization Safety Assessment (CISA) Project**, a network of vaccine safety experts at research medical centers, conducts clinical research, reviews complex vaccine safety cases and issues, and provides health care professionals with guidance on individual patients.<sup>17</sup> Clinicians with a question on vaccine safety for a patient residing in the United States that isn’t answered by Advisory Committee



on Immunization Practices (ACIP) guidelines can contact CISA via e-mail at [CISAeval@cdc.gov](mailto:CISAeval@cdc.gov). The ACIP guidelines are recommendations for use of vaccines in the United States and are available at [www.cdc.gov/vaccines/hcp/acip-recs/index.html](http://www.cdc.gov/vaccines/hcp/acip-recs/index.html).

In addition to using data from VAERS and the VSD and leveraging CISA to respond to clinical inquiries, the CDC-ISO relies on findings from clinical trials, ACIP recommendations and guidelines, Institute of Medicine reports, published studies, and input from CDC subject matter experts.

### HOW TO GET CDC ASSISTANCE ON VACCINE SAFETY

Nurses can contact the CDC for vaccine safety inquiries through various channels (see Table 1).

**CDC-INFO, the CDC's national contact center**, is staffed by both nonmedical and medical personnel who answer general and technical questions. Each day they field, on average, 1,000 calls, 250 e-mails, and six letters. They refer challenging questions and those requesting specific data to CDC scientific experts. Nurses with questions about any health topic can call (800) CDC-INFO (232-4636) or send a request online at [wwwn.cdc.gov/dcs/RequestForm.aspx](http://wwwn.cdc.gov/dcs/RequestForm.aspx).

**NIPINFO (National Immunization Program information)**. The CDC's immunization and vaccine-preventable-disease e-mail inquiry system, NIPINFO, is staffed by physicians, nurses, and health educators from the CDC's National Center for Immunization and Respiratory Diseases to answer immunization-related questions. Complex vaccine safety inquiries that cannot be adequately addressed by NIPINFO are

referred to CDC-ISO. Nurses can e-mail questions to NIPINFO directly at [NIPINFO@cdc.gov](mailto:NIPINFO@cdc.gov).

**The CDC Emergency Operations Center (EOC)**, the command center for monitoring and coordinating emergency response activities, is staffed around the clock and has procedures in place for triaging emergency vaccine safety inquiries to CDC-ISO. The phone number is (770) 488-7100.

**The VAERS program information line and e-mail box**. This resource provides answers on questions specifically related to VAERS reporting. Inquiries of a scientific or clinical nature are forwarded to CDC-ISO for a response. For VAERS reporting questions, nurses can call (800) 822-7967 or send an e-mail to [info@vaers.org](mailto:info@vaers.org).

**The CISA Project**—through the [CISAeval@cdc.gov](mailto:CISAeval@cdc.gov) e-mail address—consults with and advises health care professionals about patients who experienced an adverse event after a vaccination and makes recommendations regarding future vaccinations for that patient. When it is determined that a submitted request does not require a CISA clinical consultation, it is referred to CDC-ISO for a response.

### EXAMPLES OF VACCINE SAFETY INQUIRIES AND CDC-ISO RESPONSES

Here are examples of actual questions or concerns sent in to the CDC through various routes, and synopses of the responses given.

#### Neurologic adverse event after influenza vaccine.

In 2013, a member of the general public e-mailed CDC-INFO, which routed the question to NIPINFO, which sent it to CDC-ISO.

*Question:* "Can flu vaccine cause Guillain-Barré Syndrome, or GBS?"

*Response:* In 1976, an increased risk of GBS associated with swine influenza vaccine was reported—one to two additional cases per 100,000 people vaccinated.<sup>18</sup> The exact reason for this association remains unknown. Studies assessing the risk of GBS after seasonal influenza vaccine since 1976 have shown either no risk or a small increased risk on the order of one case per million doses administered.<sup>19</sup> Studies assessing an association of GBS with the 2009 H1N1 pandemic vaccine have shown a risk on the order of one to two GBS cases per million doses administered.<sup>20</sup>

A history of GBS within six weeks of receiving an influenza vaccine is a precaution for future doses of influenza vaccine in the patient.<sup>21</sup> A precaution indicates a possible increased risk of an adverse event in the vaccine recipient. In the case of a precaution, the health care provider must decide if the benefits of vaccination outweigh the risks. A contraindication indicates that the vaccine should not be given.<sup>22</sup>

### Additional Resources for Nurses

In addition to the CDC inquiry resources, there are several publicly available sources of vaccine safety information.

- Food and Drug Administration vaccine package inserts: [www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM093833](http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM093833)
- CDC Immunization information for health care professionals: [www.cdc.gov/vaccines/hcp.htm](http://www.cdc.gov/vaccines/hcp.htm)
- CDC vaccine safety information: [www.cdc.gov/vaccinesafety/index.htm](http://www.cdc.gov/vaccinesafety/index.htm)
- CDC immunization education and training for health professionals: [www.cdc.gov/vaccines/ed/default.htm](http://www.cdc.gov/vaccines/ed/default.htm)
- CDC immunization training and information on Twitter: <https://twitter.com/cdcizlearn>
- CDC vaccine information statements: [www.cdc.gov/vaccines/hcp/vis/index.html](http://www.cdc.gov/vaccines/hcp/vis/index.html)
- ACIP vaccine recommendations and guidelines: [www.cdc.gov/vaccines/hcp/acip-recs/index.html](http://www.cdc.gov/vaccines/hcp/acip-recs/index.html)

**Table 1. CDC Inquiry Channels**

Resource	Description	Contact Information	Purpose
CDC-INFO	National contact center	<a href="http://www.cdc.gov/dcs/RequestForm.aspx">www.cdc.gov/dcs/RequestForm.aspx</a> (800) CDC-INFO	Answers health and public health questions
NIPINFO	National Immunization Program information, an e-mail inquiry system	<a href="mailto:NIPINFO@cdc.gov">NIPINFO@cdc.gov</a>	Answers questions on vaccination
CDC EOC	Emergency Operations Center	(770) 488-7100	Responds to public health emergencies
VAERS <sup>1</sup>	Vaccine Adverse Event Reporting System program information line and e-mail box	<a href="mailto:info@vaers.org">info@vaers.org</a> (800) 822-7967	Answers questions on how to report to VAERS
CISA <sup>2</sup>	Clinical Immunization Safety Assessment Project	<a href="mailto:CISAeval@cdc.gov">CISAeval@cdc.gov</a>	Consults with health care professionals on patients with complex vaccine safety issues

<sup>1</sup>The CDC administers and manages the VAERS program through a contractor that provides help-desk services.

<sup>2</sup>CISA requests that do not meet the requirements for a clinical review are referred to the CDC-ISO inquiry response program.

**Vaccine administration errors or suspected errors involving seasonal influenza vaccine.** Here are two examples.

The first was sent in 2013 by a U.S. military health care professional to the state health department, which sent it on to the CDC EOC, then to the CDC Influenza Division, and finally to CDC-ISO.

*Concern:* Twenty personnel “were given inactivated influenza vaccine intranasally. This was not live influenza vaccine. Please provide guidance.” (Inactivated influenza vaccine is administered by intramuscular injection; live attenuated influenza vaccine is administered by intranasal spray.)

*Response:* The 20 people who received inactivated influenza vaccine intranasally should be considered unvaccinated, advised of this, and be revaccinated with either inactivated vaccine given intramuscularly or live attenuated influenza vaccine given intranasally. A search of the VAERS database for similar events revealed 72 people who had received inactivated influenza vaccine administered intranasally in error. None of these vaccine recipients reported adverse health events.

The second example was sent in 2012 by a community NP to NIPINFO and then on to CDC-ISO.

*Concern:* “I recently received a flu shot that was improperly given. It was given 1 to 2 millimeters (not centimeters) below my acromion. At the time it felt like it went into a tendon or joint and it hurt. It was extremely painful that day and night and has since improved greatly. Are you familiar with this happening?”

*Response:* In its 2012 report, the Institute of Medicine concluded that the evidence convincingly supports a causal relationship between the injection of a vaccine and deltoid bursitis.<sup>5</sup> A search of the VAERS database for similar reports for the 2011–2012 influenza season found 50 reports of the influenza vaccine being administered at an inappropriate site. Most reports stated that the injection was given “too high” in the arm, close to or at the shoulder area; a few stated the vaccine was given “too low” in the arm. Forty-nine of the 50 reports described an adverse health event such as pain, decreased arm mobility, or bursitis.

As a result of this and similar inquiries, the CDC reached out to the American Nurses Association, the American College of Physicians, and the American Pharmacists Association to remind them of the importance of education and training in proper vaccine administration techniques (for additional information on this topic, see [www.cdc.gov/flu/professionals/vaccination](http://www.cdc.gov/flu/professionals/vaccination)). The outreach included this statement: “Giving the injection too low or too high can result in injection too close to the bone or joint.”

**Sudden infant death syndrome (SIDS) following vaccination.** In 2014, a health educator sent a question to CDC-INFO, which was sent on to NIPINFO and CDC-ISO.

*Question:* “Can vaccines cause SIDS?”

*Response:* The body of scientific evidence overwhelmingly supports the safety of childhood vaccination, and there is no credible evidence to suggest that vaccination increases the risk of SIDS or other unexpected infant death.<sup>23,24</sup>



In addition to the information and references provided on the CDC Web site (at [www.cdc.gov/vaccinesafety/Concerns/sids.html](http://www.cdc.gov/vaccinesafety/Concerns/sids.html)), this response is supported by the results of a 2013 study by McCarthy and colleagues, which used VSD data on more than 13 million vaccinated people in 10 U.S. health care organizations.<sup>25</sup> Causes of death among those who died within 60 days of vaccination were compared with causes of death in the general U.S. population. The mortality rate in the vaccinated population was lower than that in the general population, and the causes of death were similar. Among children under 18 years of age, fewer deaths were due to SIDS in the vaccinated than in the general population (13% versus 16%, respectively).<sup>25</sup>

**In conclusion,** vaccines are recommended by the CDC, the American Academy of Pediatrics, the American Academy of Family Physicians, and many other organizations because they save lives and the health benefits far outweigh any risks. When vaccination coverage rates decrease, the potential for the return of life-threatening vaccine-preventable diseases increases. Nurses have a key role in helping to maintain high vaccination coverage by communicating with parents and patients about the benefits of vaccination and vaccine safety. Providing accurate and timely information on vaccine safety can help address nurses' and other health care professionals' concerns and might help to allay the fears of vaccine-hesitant parents and patients. ▼

Elaine R. Miller is an epidemiologist in the Immunization Safety Office at the Centers for Disease Control and Prevention (CDC), Atlanta, where Tom T. Shimabukuro is deputy director, Beth F. Hibbs is a nurse consultant, Pedro L. Moro is an epidemiologist, and Karen R. Broder is team lead of the Clinical Immunization Safety Assessment Project. Claudia Vellozzi is chief of the prevention branch in the CDC's Division of Viral Hepatitis. Contact author: Elaine R. Miller, [emiller@cdc.gov](mailto:emiller@cdc.gov). The authors have disclosed no potential conflicts of interest, financial or otherwise.

## REFERENCES

- Centers for Disease Control and Prevention. Ten great public health achievements—United States, 2001-2010. *MMWR Morb Mortal Wkly Rep* 2011;60(19):619-23.
- Whitney CG, et al. Benefits from immunization during the vaccines for children program era—United States, 1994-2013. *MMWR Morb Mortal Wkly Rep* 2014;63(16):352-5.
- Salmon DA, et al. Editors' introduction: vaccine safety throughout the product life cycle. *Pediatrics* 2011;127 Suppl 1:S1-S4.
- Larson HJ, et al. Addressing the vaccine confidence gap. *Lancet* 2011;378(9790):526-35.
- Stratton K, et al., eds. *Adverse effects of vaccines: evidence and causality*. Washington, DC: National Academies Press; 2012. <http://www.nap.edu/catalog/13164/adverse-effects-of-vaccines-evidence-and-causality>.
- Siddiqui M, et al. Epidemiology of vaccine hesitancy in the United States. *Hum Vaccin Immunother* 2013;9(12):2643-8.
- European Centre for Disease Prevention and Control (ECDC). *Annual epidemiological report. Reporting on 2011 surveillance data and 2012 epidemic intelligence data*. Stockholm, Sweden; 2013. Surveillance report; <http://www.ecdc.europa.eu/en/publications/Publications/Annual-Epidemiological-Report-2013.pdf>.
- Gastañaduy PA, et al. Measles—United States, January 1-May 23, 2014. *MMWR Morb Mortal Wkly Rep* 2014;63(22):496-9.
- Clemmons NS, et al. Measles—United States, January 4-April 2, 2015. *MMWR Morb Mortal Wkly Rep* 2015;64(14):373-6.
- Salmon DA, et al. Factors associated with refusal of childhood vaccines among parents of school-aged children: a case-control study. *Arch Pediatr Adolesc Med* 2005;159(5):470-6.
- Miller E, et al. Tracking vaccine-safety inquiries to detect signals and monitor public concerns. *Pediatrics* 2011;127 Suppl 1:S87-S91.
- Iskander JK, et al. The role of the Vaccine Adverse Event Reporting system (VAERS) in monitoring vaccine safety. *Pediatr Ann* 2004;33(9):599-606.
- Varricchio F, et al. Understanding vaccine safety information from the Vaccine Adverse Event Reporting System. *Pediatr Infect Dis J* 2004;23(4):287-94.
- Centers for Disease Control and Prevention. Withdrawal of rotavirus vaccine recommendation. *MMWR Morb Mortal Wkly Rep* 1999;48(43):1007.
- Baggs J, et al. The Vaccine Safety Datalink: a model for monitoring immunization safety. *Pediatrics* 2011;127 Suppl 1:S45-S53.
- Bohlke K, et al. Risk of anaphylaxis after vaccination of children and adolescents. *Pediatrics* 2003;112(4):815-20.
- Williams SE, et al. Comprehensive assessment of serious adverse events following immunization by health care providers. *J Pediatr* 2013;162(6):1276-81.
- Stratton K, et al., eds. *Immunization safety review: influenza vaccines and neurological complications*. Washington, DC: National Academies Press; 2004. Immunization safety review series. <http://www.nap.edu/catalog/10822/immunization-safety-review-influenza-vaccines-and-neurological-complications>.
- Vellozzi C, et al. Guillain-Barre syndrome, influenza, and influenza vaccination: the epidemiologic evidence. *Clin Infect Dis* 2014;58(8):1149-55.
- Salmon DA, et al. Association between Guillain-Barre syndrome and influenza A (H1N1) 2009 monovalent inactivated vaccines in the USA: a meta-analysis. *Lancet* 2013;381(9876):1461-8.
- Grohskopf LA, et al. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP)—United States, 2014-15 influenza season. *MMWR Morb Mortal Wkly Rep* 2014;63(32):691-7.
- National Center for Immunization Respiratory and Diseases. General recommendations on immunization—recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* 2011;60(2):1-64.
- Stratton K, et al., eds. *Immunization safety review: vaccinations and sudden unexpected death in infancy*. Washington, DC: National Academies Press; 2003. Immunization safety review series. <http://www.nap.edu/catalog/10649/immunization-safety-review-vaccinations-and-sudden-unexpected-death-in-infancy>.
- Vennemann MM, et al. Sudden infant death syndrome: no increased risk after immunisation. *Vaccine* 2007;25(2):336-40.
- McCarthy NL, et al. Mortality rates and cause-of-death patterns in a vaccinated population. *Am J Prev Med* 2013;45(1):91-7.