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. 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.

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—concerns over vaccine safety persist, and such concerns are often unsupported by scientific evidence. 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, 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. (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.) Undervaccination has been implicated in local and regional outbreaks of vaccine-preventable diseases, such as measles. 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.

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, 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.

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)**

The national frontline spontaneous reporting surveillance system and provides early warning for identifying potential vaccine safety concerns. As a spontaneous surveillance system, however, it is not designed to assess whether a vaccine caused an adverse event. 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.

**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. 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.

**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. 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. 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.

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 www.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.

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.

The CISA Project—through the 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. 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. 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.

A history of GBS within six weeks of receiving an influenza vaccine is a precaution for future doses of influenza vaccine in the patient. 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.
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 is administered by intranasal spray.

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. 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.\(^23,24\)

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**Table 1. CDC Inquiry Channels**

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

\(^1\)The CDC administers and manages the VAERS program through a contractor that provides help-desk services.
\(^2\)CISA requests that do not meet the requirements for a clinical review are referred to the CDC-ISO inquiry response program.
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.

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REFERENCES