Anaphylaxis is a rare complication of vaccination. All facilities providing immunizations should have an emergency kit containing aqueous epinephrine for administration in the event of a systemic anaphylactic reaction.

MAINTENANCE OF VACCINE RECORDS

All vaccines administered should be fully documented in the patient's permanent medical record. Documentation should include the date of administration, the name or common abbreviation of the vaccine, the vaccine lot number and manufacturer, the administration site, the VIS edition, the date the VIS was provided, and the name, address, and title of the person who administered the vaccine. Increasing use of two-dimensional bar codes on vaccine vials and syringes that can be scanned for data entry into compatible electronic medical records and immunization information systems may facilitate more complete and accurate recording of required information.

VACCINE SAFETY MONITORING AND ADVERSE EVENT REPORTING

Prelicensure Evaluations of Vaccine Safety Before vaccines are licensed by the FDA, they are evaluated in clinical trials with volunteers. These trials are conducted in three progressive phases. Phase 1 trials are small, usually involving fewer than 100 volunteers. Their purposes are to provide a basic evaluation of safety and to identify common adverse events. Phase 2 trials, which are larger and may involve several hundred participants, collect additional information on safety and are usually designed to evaluate immunogenicity as well. Data gained from phase 2 trials can be used to determine the composition of the vaccine, the number of doses required, and a profile of common adverse events. Vaccines that appear promising are evaluated in phase 3 trials, which typically involve several hundred to several thousand volunteers and are generally designed to demonstrate vaccine efficacy and provide additional information on vaccine safety.

Postlicensure Monitoring of Vaccine Safety After licensure, a vaccine's safety is assessed by several mechanisms. The NCVIA of 1986 requires health care providers to report certain adverse events that follow vaccination. As a mechanism for that reporting, the Vaccine Adverse Event Reporting System (VAERS) was established in 1990 and is jointly managed by the CDC and the FDA. This safety surveillance system collects reports of adverse events associated with vaccines currently licensed in the United States. *Adverse events* are defined as untoward events that occur after immunization and that might be caused by the vaccine product or vaccination process. While the VAERS was established in response to the NCVIA, any adverse event following vaccination—whether in a child or an adult, and whether or not it is believed to have actually been caused by vaccination—may be reported through the VAERS. The adverse events that health care providers are required to report are listed in the reportable-events table on the VAERS website at *vaers.hhs.gov/reportable.htm*. Approximately 30,000 VAERS reports are filed annually, with ~13% reporting serious events resulting in hospitalization, life-threatening illness, disability, or death.

Anyone can file a VAERS report, including health care providers, manufacturers, and vaccine recipients or their parents or guardians. VAERS reports may be submitted online (*vaers.hhs.gov/esub/step1*) or by completing a paper form requested by email (info@vaers.org), phone (800-822-7967), or fax (877-721-0366). The VAERS form asks for the following information: the type of vaccine received; the timing of vaccination; the time of onset of the adverse event; and the recipient's current illnesses or medications, history of adverse events following vaccination, and demographic characteristics (e.g., age and sex). This information is entered into a database. The individual who reported the adverse event then receives a confirmation letter by mail with a VAERS identification number that can be used if additional information is submitted later. In selected cases of serious adverse reaction, the patient's recovery status may be followed up at 60 days and 1 year after vaccination. The FDA and the CDC have access to VAERS data and use this information to monitor vaccine safety and conduct research studies. VAERS data (minus personal information) are also available to the public.

While the VAERS provides useful information on vaccine safety, this passive reporting system has important limitations. One is that events following vaccination are merely reported; the system cannot assess whether a given type of event occurs more often than expected after vaccination. A second is that event reporting is incomplete and is biased toward events that are believed to be more likely to be due to vaccination and that occur relatively soon after vaccination. To obtain more systematic information on adverse events occurring in both vaccinated and unvaccinated persons, the Vaccine Safety Datalink project was initiated in 1991. Directed by the CDC, this project includes nine managed-care organizations in the United States; member databases include information on immunizations, medical conditions, demographics, laboratory results, and medication prescriptions. The Department of Defense oversees a similar system monitoring the safety of immunizations among active-duty military personnel. In addition, postlicensure evaluations of vaccine safety may be conducted by the vaccine manufacturer. In fact, such evaluations are often required by the FDA as a condition of vaccine licensure.

CONSUMER ACCESS TO AND DEMAND FOR IMMUNIZATION

By removing barriers to the consumer or patient, providers and health care institutions can improve vaccine use. Financial barriers have traditionally been important constraints, particularly among uninsured adults. Even for insured adults, out-of-pocket costs associated with newer, more expensive adult vaccines (e.g., zoster vaccine) are an obstacle to be overcome. After influenza vaccine was included by Medicare for all beneficiaries in 1993, coverage among persons ≥65 years of age doubled (from ~30% in 1989 to >60% in 1997). Other strategies that enhance patients' access to vaccination include extended office hours (e.g., evening and weekend hours) and scheduled vaccination-only clinics where waiting times are reduced. Provision of vaccines outside the "medical home" (e.g., through occupational clinics, universities, pharmacies, and retail settings) can expand access for adults who do not make medical visits frequently. Increasing proportions of adults are being vaccinated in these settings.

Health promotion efforts aimed at increasing the demand for immunization are common. Direct-to-consumer advertising by pharmaceutical companies has been used for some newer adolescent and adult vaccines. Efforts to raise consumer demand for vaccines have not increased immunization rates unless implemented in conjunction with other strategies that target strengthening of provider practices or reduction of consumer barriers. Attitudes and beliefs related to vaccination can be considerable impediments to consumer demand. Many adults view vaccines as important for children but are less familiar with vaccinations targeting disease prevention in adults. Several vaccines are recommended for adults with certain medical risk factors, but self-identification as a high-risk individual is relatively rare. Communication research suggests that many adults with chronic diseases may be more motivated to receive a vaccine by a desire to protect their family members rather than to reduce their own risk. Some vaccines are explicitly recommended for persons at relatively low risk of serious complications, with the goal of reducing the risk of transmission to higher-risk contacts. For example, for protection of newborns, vaccinations against influenza and pertussis are recommended for pregnant women and for others who will be around the infant.

STRATEGIES FOR PROVIDERS AND HEALTH CARE FACILITIES

Recommendation from the Provider Health care providers can have great influence on patients with regard to immunization. A recommendation from a doctor or nurse carries more weight than do recommendations from professional societies or endorsements by celebrities. Providers should be well informed about vaccine risks and benefits so that they can address patients' common concerns. The CDC, the American College of Physicians, and the American Academy of Family Physicians review and update the schedule for adult immunization on an annual basis and also have developed educational materials to facilitate provider–patient discussions about vaccination (*www.cdc.gov/vaccines/hcp.htm*).

System Supports Medical offices can incorporate a variety of methods to ensure that providers consistently offer specific immunizations to patients with indications for specific vaccines. Decision-support tools