and are therefore particularly in need of immunization. In general, these concerns are addressed in the chapters on individual vaccines (see also Chapter 5); some issues are summarized in Table 42–2. Other groups require special consideration because of concern that their response to vaccines may be abnormal or that they may have unusually severe adverse events after immunization.

THE UNITED STATES IMMUNIZATION PROGRAM

History

In the United States, immunizations are provided through both the private and the public sectors. The public sector consists primarily of health departments but also includes other clinics, such as community and migrant health centers and public hospital–based clinics supported by public funds. The federal government has provided support to state and local health departments for maternal and child health programs since the 1920s, and some of that funding has been used to support immunizations.[73] However, there was no specific federal involvement in immunization activities until 1955, when the inactivated polio vaccine was licensed. Through the Polio Vaccination Assistance Act, Congress appropriated funds in 1955 and 1956 to the Communicable Disease Center (CDC, now the Centers for Disease Control and Prevention) to help states and local communities buy and administer vaccine. There was no further federal involvement until 1960, when Congress made a one-time appropriation of $1 million for a stockpile of oral polio vaccine to be used in combating epidemics. This was quickly used.

In February 1962, President John F. Kennedy sent the Vaccination Assistance Act of 1962 to Congress. The central thrust of this legislation was to allow the CDC to support mass immunization campaigns and to initiate maintenance programs, but no provision was made for a continuing program of support for immunizations. Two other important aspects of the bill were that it provided for vaccine instead of cash to be furnished directly to state and local health departments, and it also provided that personnel instead of cash could be furnished to grantees. These personnel were public health advisors and epidemiologists, who worked primarily in program coordination and surveillance. Direct delivery of immunization services (e.g., salaries of nurses, clinic supplies, expenses for increasing clinic hours) was not supported until 1992.

The first grants, authorized under section 317 of the Public Health Service Act, were made in June 1963. During the intervening 35 years, this grant program has thrived. There are now 64 grantees under what has become known as the "317" Immunization Grant Program: all 50 states, six large cities (including the District of Columbia), and eight territories and former territories.

The level of grant funding has varied greatly over the years. When the grant program began in 1963, the only vaccines available were diphtheria, tetanus, and pertussis (DTP), polio, and smallpox. Since that time, funding has been expanded to cover all vaccines routinely recommended for children.

During the 1960s and 1970s, grant funding fluctuated substantially. In 1966, a national effort to eradicate measles began.[15] By 1968, measles incidence had decreased by more than 90% compared with prevaccine era levels. With the licensure of the rubella vaccine in 1969 and the threat of a new epidemic of rubella, all federal funding for measles was shifted to rubella. A resurgence of measles occurred, peaking in 1971. In 1972, Congress appropriated additional funds that allowed the CDC to purchase vaccines other than rubella. Measles incidence decreased, reaching a low of 22,000 cases in 1974. During the mid-1970s, the overall budget for immunization grants decreased dramatically from the $8 to 10 million annually from 1963 to 1969 and the 1970 peak of $17 million to a low of only $5 million in 1976. A second resurgence of measles followed.[17, 18]

In 1976, a national election took place that led to significant changes in the immunization program. In the early 1970s, immunization programs around the country were in varying states of effectiveness. In Arkansas, it was apparent that much remained to be done. Mrs. Betty Bumpers, wife of the Governor, became personally interested in immunizations and succeeded in getting increased support for immunizations and improved immunization levels in Arkansas. Her husband, Dale Bumpers, was then elected to the U.S. Senate and became an important leader in the Congress on immunization. In November of 1976, Jimmy Carter was elected president. Subsequently, Mrs. Bumpers contacted the new administration and explained the deficiencies in the childhood immunization program in the United States and urged that something be done to improve the situation. As a result, in 1977, a national childhood immunization initiative was announced with two goals:

1. Attainment of immunization levels of 90% in the nation's children by October 1979
2. Establishment of a permanent system to provide comprehensive immunization services to the 3 million children born in America each year[74]

At the time, it was estimated that nearly 20 million American children needed at least one dose of a vaccine in order to be fully protected. The poor and the nonwhite populations were disproportionately represented among those needing protection.

Joseph A. Califano, Jr., the Secretary of the Department of Health, Education, and Welfare (now Health and Human Services) outlined a broad-based program involving increased federal support for immunizations, increased involvement of volunteers in all aspects of immunization activities, increased public awareness/public education activities, and increased cooperation between governmental agencies.[75]

Immunization grant funds increased dramatically from $5 million in 1976 to $17 million in 1977, $23 million in 1978, and $35 million in 1979. Intensive efforts began, concentrating on school-aged children, who experienced outbreaks of measles. A major effort was placed on reviewing immunization records of school children—in a 2-year period, more than 28 million records were

reviewed, and children in need were immunized. Efforts were also expended to enact school immunization requirements in states that did not have them and to enforce those already in existence. As a result of these efforts, all 50 states soon had, and were enforcing, school entry immunization laws. Since 1981, 95% or more of children entering school have had documented immunization. Given these levels, even with lower levels in preschoolers, the overall immunization level in children of all ages in this country was 90% or greater. Thus, the first target of the initiative was met. Unfortunately, the second target of the 1977 initiative was not met.

Although the overall level of support for immunization grants rose rapidly in the late 1970s and throughout the 1980s (reaching $126.8 million in 1989), almost all of the increase was to meet the increasing cost of vaccines or the addition of new vaccines or additional doses of existing vaccines. In the 1980s, the level of federal support to grantees to carry out maintenance elements did not increase significantly, averaging $15.9 million but fluctuating between a low of $5 million in 1988 and a high of $26.1 million in 1989. Over the years, the federal government provided more of the same vaccines, as well as new ones, to a delivery system that was remaining static (at best) in the face of demands that were increasing. Investigations of the measles epidemics of 1989 to 1991, which especially affected unvaccinated preschool children, made it clear that the public sector delivery system was unequal to the challenge and that it required substantial assistance.

A part of the problem was that policies permitted immunization grant funds to be used to purchase vaccines and to carry out surveillance, investigation, education, and coordination but did not permit these funds to be used to support the delivery of vaccines (e.g., salaries of nurses, clinic supplies, expenses with increasing clinic hours). In 1991, President George Bush announced the federal government's support to accomplish a major health goal—namely, to raise immunization levels by the year 2000 so that 90% or more of the nation's children routinely completed their basic series of vaccinations by their second birthday.[76] The President announced that model immunization plans would be developed in several areas of the country as a beginning for the national effort to ensure adequate and timely immunization of infants and young children. This began a process that ultimately resulted in the preparation of Immunization Action Plans by all states and 28 metropolitan areas. Although there was great variation in needs reported from around the country, one theme common to virtually all plans was the need to increase the availability of immunization services. Consequently, for the first time, federal immunization grant funds were allowed to be used for the actual provision of immunization services.

President Bill Clinton's announcement of a Childhood Immunization Initiative (CII) in 1993[32, 77, 78] and the leadership and major infusion of funds associated with that initiative have brought the country to the point that it is now, finally, achieving 90% coverage in preschool children.[79] Grant support for immunization programs, including service delivery (but excluding vaccine purchase), rose to a peak of $237.3 million in 1995. The five components of the CII include (1) improving the quality and quantity of vaccination delivery services; (2) expanding access to vaccines, particularly for poor children; (3) enhancing community involvement, education, and building partnerships; (4) improving the measurement of immunization coverage and the detection of vaccine preventable diseases; and (5) simplifying the immunization schedule and improving vaccines.[80]

United States Immunization Program—1998

As described earlier, in the United States, immunizations are delivered by private physicians in their offices and through local health departments and other public-sector providers. Although vaccines are given in both private and public sectors, other important components of immunization programs in the United States are primarily coordinated by health departments and other public sector agencies, including surveillance and investigation of disease, outbreak control, promotion of immunization, adverse-events monitoring, assessment of immunization levels, and implementation of regulations and laws regarding immunization.[81, 82]

In an immunization delivery system, it is important to ensure that the recipient (or parent or guardian) is adequately aware of the risks and the benefits of vaccination and that the recipient has a record of all immunizations received.[83] The National Childhood Vaccine Injury Act of 1986 and subsequent changes (section XXI of the Public Health Service Act) requires that *all* vaccine providers formally notify patients and parents or guardians of the risks and benefits of specified vaccines (DTP or components; measles, mumps, rubella vaccine (MMR) or components; *Haemophilus influenzae* type b vaccine, hepatitis B vaccine, varicella, and poliomyelitis vaccines).[84] The use of standardized vaccine information sheets with these vaccines is now mandatory.[85] One of these forms is reproduced in Appendix 3. A series of "important information" sheets has been developed for use with other vaccines purchased with federal funds. This act also established a no-fault compensation mechanism for those who are injured by the vaccines specified in the act. Persons desiring further information about this program should contact the National Childhood Vaccine Injury Program at (800) 338-2382 if their questions are not answered at this Internet site: http://www.hrsa.dhhs.gov/bhpr/vicp. The National Childhood Vaccine Injury Act also requires providers to note in the patient's permanent medical record the date the vaccine was administered, the vaccine manufacturer, the vaccine lot number, and the name, address, and title of the person administering the vaccines, in addition to noting the provision of vaccine information materials. Finally, the act requires that providers report selected adverse events occurring after vaccination and events that would contraindicate further doses of vaccines to the Vaccine Adverse Event Reporting System (VAERS) (see Table 50–1 in Chapter 50 and http://www.hrsa.dhhs.gov/bhpr/vicp/table.htm). Providers are encouraged to report all serious adverse events following all vaccines, regardless of whether they believe that a vaccine caused the event.