

IMMUNIZATIONS

Immunizations are one of the great public health success stories of the 20th century, having made once-common diseases such as diphtheria, measles, mumps, and pertussis diseases of the past. Vaccines are now available to protect children and adults against 15 life-threatening or debilitating diseases. This has reduced cases of all vaccine-preventable diseases by more than 97% from peak levels before vaccines were available, saving lives and saving treatment and hospitalization costs.

Polio has been eradicated from this hemisphere, even though many Americans can still remember iron lungs, leg braces, and worried parents forbidding their children to swim in lakes and rivers during the summer. CDC and its partners believe that polio will soon be eradicated from the rest of the world as well, leading to savings of at least \$350 million in the United States alone, since polio vaccines will no longer be necessary.

Despite these success stories, several challenges remain. Even though coverage has improved, pockets of under-immunized children remain, leaving the potential for outbreaks of disease. Many adolescents and adults are under-immunized as well, missing opportunities to protect themselves against vaccine-preventable diseases such as hepatitis B, influenza, and pneumococcal disease. The safety of vaccines requires continued monitoring by systems like the Vaccine Adverse Event Reporting System, so that adverse effects—like those associated with the recent recall of the rotavirus vaccine—can be detected quickly. CDC works closely with public health agencies and private partners to improve and sustain immunization coverage and to monitor the safety of vaccines so that this public health success story can be maintained and expanded in the century to come.

ADULT AND ADOLESCENT IMMUNIZATION

WHAT IS THE PUBLIC HEALTH ISSUE?

Each year, 46,000 to 48,000 adults die from vaccine-preventable diseases. Influenza vaccination levels remain low for adults. As of 2002, only 67% of adults aged 65 years or older and 29% of high-risk adults aged 18 to 64 years reported receiving influenza vaccination. Influenza vaccination coverage levels among persons aged 65 years or older were lower among African Americans (48%) and Hispanics (54%) compared to non-Hispanic whites (68%). The gap is even wider for pneumococcal vaccination. In 2000, hepatitis B coverage, recommended for all adolescents, was only 44% among 13 to 15 years old, based on parent-held vaccination records.

WHAT HAS CDC ACCOMPLISHED?

In 2001, the Department of Health and Human Services made eliminating racial and ethnic disparities in influenza and pneumococcal vaccination for people 65 years of age and older a priority. To address this priority, CDC established the Racial and Ethnic Adult Disparities in Immunization Initiative (READII) demonstration project in 5 sites (Chicago, Rochester [NY], San Antonio, Milwaukee, and 19 counties in the Mississippi Delta region). These sites are developing and implementing community-based plans by partnering with public health professionals, healthcare providers, and community organizations. CDC and the Centers for Medicare and Medicaid Services (CMS) also continue to collaborate to improve influenza and pneumococcal vaccination rates in nursing homes and hospitals.

CDC also makes available a number of tools for immunization programs:

- Published by CDC in 2002, the Adult Immunization Schedule is the first schedule ever approved by the Advisory Committee on Immunization Practices; it has also been accepted by the American College of Obstetricians and Gynecologists and the American Academy of Family Physicians.
- In 2003, the *Standards for Adult Immunization Practices* (Standards) were revised based on previous efforts to improve adult immunization coverage and in response to changes in the healthcare delivery system. These revised standards focus on vaccine accessibility, effective communication of vaccination information, improving vaccination rates, and community partnership development.
- The Adult Clinic Assessment Software Application, created in 2002, is a tool that practitioners or clinic managers can use to estimate the vaccine coverage levels of the patients they serve and to help determine an appropriate course of action to improve coverage.
- A collaboration between CDC and the Association of Teachers of Preventive Medicine produced a “What Works” CD-ROM which individual practice and clinic staff can use to test their adult vaccination knowledge; reference a substantial amount of background material; review frequently asked questions and model practices; select strategies to increase vaccination rates; and create an action plan.

WHAT ARE THE NEXT STEPS?

- Continue working with other federal agencies; state and local health departments; and private and community partners to
- Support state health departments to develop comprehensive plans for vaccination of adolescents and adults.
- Address and eliminate persistent racial and ethnic disparities in adult immunization coverage levels.
- Develop, evaluate, and promote standing orders and patient/provider reminder systems.
- Help improve physician and institutional practices that lead to increased vaccination coverage among adolescents and adults.

For additional information on this or other CDC programs, visit www.cdc.gov/program

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ANTHRAX VACCINE

WHAT IS THE PUBLIC HEALTH ISSUE?

The purpose of the Anthrax Vaccine Research Program (AVRP) is to conduct studies to determine factors associated with side effects from the vaccine. The goal is to discover whether the vaccine route can be changed and the number of doses reduced, while still providing protection against anthrax disease. The studies are also expected to provide more information on when a person becomes protected and how long the protection lasts. The current anthrax vaccine is injected in a series of 6 doses over 18 months, followed by a booster dose given each year. One of the most common side effects of the vaccine is redness and swelling in the arm because the shot is given just under the skin instead of into the muscle. Some recent studies have shown that if the shot is given in the muscle, there may be less pain and swelling. It may also be possible to protect people with fewer than 6 shots. By doing this research, CDC hopes to reduce the number of side effects seen with the vaccine, while maintaining its effectiveness and increasing its acceptability.

WHAT HAS CDC ACCOMPLISHED?

CDC designed and initiated a human clinical trial to assess route change and dose reduction. To date, the five study sites have enrolled 1470/1560 (94%) of volunteers; full accrual is expected by March 2004. The interim analysis will be presented to the Food and Drug Administration in September of 2004. The goals are to reduce the number of doses administered by dropping the 2 week dose in the priming series (currently recommended 0, 2, and 4 weeks in the primary series) while not diminishing the peak anti-protective antibody levels following the 4 week dose and to change injection site to the intramuscular way of administration. The final analysis will be presented to FDA in 2007.

CDC also designed and implemented non-human primate (NHP) studies to determine correlates of protection against inhalation anthrax and to support research on dose reduction in the human clinical trial. Animals are vaccinated by similar regimens as in human study and are challenged at 12, 30 and 42 months post-vaccination with lethal doses of *B. anthracis* spores. The NHP experiments began in 2002 and final data are expected by 2005. Data from these studies will determine whether a person is protected by anthrax vaccine, when protection is achieved, and what the duration of protection is. CDC has developed laboratory assays to measure the human and animal vaccine study primary endpoints. These assays will be used to assess human immune response to second generation anthrax vaccines now in development. The anthrax vaccine studies were endorsed by the Institute of Medicine Committee for CDC Anthrax Vaccine Safety and Efficacy Plan.

WHAT ARE THE NEXT STEPS?

For bioterrorism preparedness, CDC has undertaken studies to test efficacy of an anthrax immune globulin product as treatment for persons who are ill with anthrax, but failing traditional antibiotic therapy. The benefits of this research extend to both the military and civilian communities. The AVRP studies will help optimize the use of the current vaccine, increase its acceptability, and provide greater understanding about correlates of protection that will extend to next generation anthrax vaccines.

DEVELOPMENT OF IMMUNIZATION REGISTRIES

WHAT IS THE PUBLIC HEALTH ISSUE?

In 2002, 25% of the nation's 2-year-olds were not fully up-to-date on immunizations, placing them and others at risk of vaccine-preventable diseases. Public health officials cannot easily predict which communities are at risk for outbreaks of vaccine-preventable diseases. Because about 23% of U.S. children change healthcare providers by age 2 and/or receive immunizations from more than one provider; incomplete records are scattered among different doctors, resulting in both redundant and insufficient vaccination. The public's concerns about potential adverse health effects associated with vaccination have increased in recent years. Immunization information systems are needed that can easily and accurately track immunization coverage and data related to vaccine safety.

WHAT HAS CDC ACCOMPLISHED?

- CDC worked with the American Immunization Registry Association and the Association of Immunization Managers to form the Programmatic Registry Operations Workgroup (PROW) to develop the PROW *Standards of Excellence*. The National Vaccine Advisory Committee in 2003, endorsed this document which supports vaccine management, provider quality assurance, service delivery, consumer information, vaccine-preventable disease surveillance, and vaccination coverage assessment.
- 12 minimum registry functional standards and Standards for Certification were established. Certification is a voluntary process that will be performed at the request of the registry. In 2002, three statewide registries self-reported that they met all of the standards.
- Immunization registries demonstrated the value of immunization registry data by providing reliable information on the impact of the DTaP and pneumococcal conjugate vaccine shortage on vaccination coverage levels.
- A cost study to characterize the costs of immunization registries in the United States was conducted at 24 sites and the results of this study will be published in Spring 2004. In addition, CDC staff is working with the Utah Department of Health to collect data that measure the administrative impact of its immunization registry on the Vaccine for Children Program's related reporting activities.
- CDC, the Vaccine Adverse Event Reporting System, and Kaiser Permanente staff have demonstrated that vaccine adverse events can be reported in standard health level 7 (HL7) immunization electronic messages by providers and state/local health departments. Final message structure and processes will be completed and published in 2004.
- Updates to the HL7 Implementation Guide for Immunization Data Transactions and the de-duplication tool kit are now available online at www.cdc.gov/nip/registry/hl7guide.pdf and www.cdc.gov/nip/registry/dedup/dedup.htm.

WHAT ARE THE NEXT STEPS?

Healthy People 2010 objectives include increasing the proportion of children less than 6 years of age participating in fully operational immunization registries to 95%. To reach this goal, future immunization registry activities, supported by Section 317 Immunization Grant Program funds, will focus on

- Increasing the proportion of children and healthcare providers that participate in registries.
- Ensuring the privacy, confidentiality, and security of registry data.
- Promoting the use of accurate and efficient immunization registries and data.

IMMUNIZATION GRANT PROGRAM (SECTION 317)

WHAT IS THE PUBLIC HEALTH ISSUE?

Almost 50,000 adults and 300 children in the United States die annually from vaccine-preventable diseases or their complications. Despite high immunization coverage levels for preschool-aged children, pockets of need remain. A January 2003 survey revealed that 19 states reported insufficient 317 funds to implement Pneumococcal Conjugate Vaccine recommendations. Additional doses of vaccines are needed for children who are not eligible for the Vaccines for Children program, but go to state and local public health departments for vaccinations. Children served through 317 are under-insured and therefore under-immunized. A stable immunization program, at the state level, is necessary to fully vaccinate all children.

Immunization infrastructure is crucial, especially when public health priorities can shift rapidly in the event of an outbreak of a vaccine-preventable disease, or a bioterrorism event. Managing immunization resources to deal with urgent events poses a challenge to state programs. During the 2003–2004 influenza seasons, the use of 317 funds to respond to influenza season challenges reduced the grant funds available for essential routine vaccination programs.

WHAT HAS CDC ACCOMPLISHED?

Federal funding for the Immunization Grant Program (also called the “317 grant program”) was launched in 1963. Forty years later, CDC awarded \$408 million in federal grants to state, local, and territorial public health agencies for program operations and vaccine purchases. The majority of 317 program funds are dedicated to routine childhood programs, with a smaller portion remaining for adult immunization programs. Despite high immunization coverage rates of preschool-aged children, adult vaccination rates remain considerably lower.

The 317 grant program works to ensure that children, adolescents, and adults receive appropriate immunizations by partnering with health providers in the public and private sectors. The program helps assure the implementation of effective immunization practices and proper use of vaccines to achieve high immunization coverage, and supports infrastructure for essential activities such as immunization registries, outreach, disease surveillance, outbreak control, education, and service delivery. A strong immunization infrastructure ensures optimal coverage with routinely recommended vaccines.

- During the 2003–2004 influenza seasons, grantees assisted with the redistribution of influenza vaccine to individuals at high risk for complications. This vaccine management role is similar to the vital role grantees play during pediatric vaccine shortages.
- Flexibility of 317 grant funds allowed states to deliver additional doses of influenza vaccine to alleviate some of the shortages reported during the early severe influenza outbreaks of the 2003–2004 seasons.
- CDC has partnered with the Department of Agriculture to assess the immunization status of the children participating in the Women, Infants and Children program; children missing recommended immunizations may be referred to a healthcare provider.

WHAT ARE THE NEXT STEPS?

CDC will continue to work with federal, state, and local partners to

- Build support for adult immunizations, increase immunization coverage, and educate parents and providers.
- Address pockets of need where there are substantial numbers of under-immunized groups.

For additional information on this or other CDC programs, visit www.cdc.gov/program

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IMMUNIZATION SAFETY

WHAT IS THE PUBLIC HEALTH ISSUE?

No vaccine is 100% safe. As more and more people receive vaccinations and the risk of disease decreases, both real and perceived vaccine side effects increase. The end result is heightened public concern about the safety of vaccines and loss of public confidence in vaccines, which could result in decreased vaccination levels, followed by epidemics of disease. A credible immunization safety monitoring system to determine which illnesses are caused by vaccines, and which are not, must exist to maintain public confidence in immunizations and prevent the return of disease epidemics.

WHAT HAS CDC ACCOMPLISHED?

CDC has implemented a multi-faceted strategy to address immunization safety issues, which includes various programs and partnerships. The Vaccine Adverse Event Reporting System (VAERS) is operating in collaboration with the Food and Drug Administration and serves as an early-warning system to detect problems that may be related to vaccines. CDC is adding Web-based reporting to improve the timeliness, accuracy, and efficiency of VAERS. Work is also under way to ensure vaccine safety through continued research and enhancements to the Vaccine Safety Datalink (VSD) project. VSD is a linked database containing comprehensive medical and immunization histories of over 7.5 million people. VSD enables researchers to compare the incidence of health problems between vaccinated and unvaccinated people. CDC has established a vaccine safety data sharing process so that external researchers can access final datasets created through VSD.

Other programs aimed at improving immunization safety include the Clinical Immunization Safety Assessment (CISA) Network, which provides in-depth, standardized clinical evaluations for individuals with unusual or severe vaccine adverse events, and the Safe Injection Global Network, a global consortium working to solve the problem of unsafe injections as a major means of transmitting diseases like hepatitis B, C, and HIV/AIDS.

CDC is also working with the Institute of Medicine to increase outside participation in evaluating safety concerns and guiding research efforts. CDC is continuing its efforts to determine how best to disseminate information on the benefits and risks of vaccinations; develop safer vaccines and delivery methods (especially needle-free jet injectors for mass immunization campaigns); and establish a global collaboration to standardize case definitions for study of vaccine reactions, thereby creating a common “vocabulary” for vaccine safety research.

Example of Program in Action

VSD provided valuable information regarding the safety of influenza vaccine in children to the Advisory Committee on Immunization Practices,⁷ which led to the formulation of the committee’s policy recommendation for routine influenza vaccination of children to 23 months of age in the United States.

WHAT ARE THE NEXT STEPS?

To enhance the current immunization safety program, CDC plans to

- Increase the knowledge of genetic risk factors for vaccine reactions.
- Enhance analysis of VAERS data and increase research of immunization safety concerns through VSD and CISA.
- Conduct research regarding how the public perceives and accepts the risks and benefits of vaccines.
- Improve vaccine benefit-risk communication to parents and healthcare professionals through partnerships.

INFLUENZA IMMUNIZATION

WHAT IS THE PUBLIC HEALTH ISSUE?

About 36,000 deaths and 114,000 hospitalizations per year in the United States are the result of influenza infections. These infections occur in all age groups, but deaths occur most frequently among persons aged 65 years or older. In 2003, an unusually early onset of severe influenza outbreaks resulted in strong consumer demand for influenza vaccine. This demand exceeded that seen in previous flu seasons. In prior years, the supply of influenza vaccine was generally sufficient to meet demands. However, demand in 2003 remained high well into December, when flu vaccination clinics are typically winding down.

Production of influenza vaccines is a complex process that requires many steps, including selection of suitable vaccine viruses, reproduction of these viruses in eggs, and testing to ensure the safety and purity of the vaccine. Recommendations for strains to be included in U.S. vaccines are based on year-round surveillance. Typically, these recommendations are released in February for vaccines that will be used in the following season.

WHAT HAS CDC ACCOMPLISHED?

During the 2003 influenza season, contracts were developed to deliver additional vaccine to state and local health departments to alleviate spot shortages reported. Work with the vaccine manufacturers, distributors, healthcare providers, and state and local public health departments was performed to redistribute vaccine wherever possible. Communication was extensively initiated throughout the year to advise partners and others about developments related to the production, distribution, and administration of influenza vaccine; provider and patient educational materials to encourage timely vaccination of high-risk groups were revised; and CDC participated in media events to highlight the benefits of influenza vaccination. These communications relied upon strengthened influenza disease surveillance, resulting in the systematic dissemination of information to characterize the degree and extent of influenza disease.

Ongoing influenza programs continued to work on making influenza vaccinations more broadly available. During 2003, CDC updated immunization recommendations and developed education materials for the new nasal-spray, FluMist™, Live Attenuated Influenza Vaccine, licensed in 2003. Also, CDC and the Centers for Medicare and Medicaid Services completed a 3-year program to promote and evaluate the use of standing orders of vaccines in nursing homes. Initial data showed that standing orders are both more effective and more cost-effective than other available methods for immunizing nursing home residents against influenza and pneumococcal diseases.

WHAT ARE THE NEXT STEPS?

CDC will continue to work with other federal agencies, state and local health departments, and private and community partners to facilitate communication and collaboration about influenza vaccine supply and distribution; develop strategies to improve annual immunization coverage among high-risk populations; and encourage providers to extend vaccination efforts into December and beyond where needed. Improving physician and institutional practices will lead to increased vaccination coverage among adolescents and adults. Efforts are also underway to address the unique supply issues associated with a seasonal vaccine that changes annually. CDC will continue to plan, prepare, and exercise responses to the eventual occurrence of an influenza pandemic.

PANDEMIC INFLUENZA PLANNING

WHAT IS THE PUBLIC HEALTH ISSUE?

New strains of influenza viruses can emerge unpredictably and spread rapidly and pervasively through susceptible populations. A significant shift in the virus's genetic structure could mean that the entire population would be vulnerable. Influenza pandemics, or global epidemics, occurred three times during the 20th century: in 1918, 1957, and 1968. The 1918 pandemic resulted in more than 500,000 deaths in the United States and over 20 million deaths globally. Experts agree that future pandemics of influenza are likely, if not inevitable. In the United States alone, preliminary estimates indicate that an influenza pandemic would cause between 89,000 and 207,000 deaths and that the economic impact would range from \$71 billion to \$166 billion, not including disruptions to commerce and society.

Pre-pandemic planning is essential if influenza pandemic-related morbidity, mortality, and social disruption are to be minimized. The sudden and unpredictable emergence of pandemic influenza and its potential to cause severe health and social consequences necessitate developing a national plan and implementing preparedness activities called for by that plan.

WHAT HAS CDC ACCOMPLISHED?

CDC worked with federal partners to develop the Pandemic Influenza Preparedness and Response Plan, which was submitted to the Department of Health and Human Services. The goal of this preparedness and response plan is to limit the total burden of disease (morbidity and mortality) caused by an influenza pandemic and to reduce social disruption and economic loss. Objectives include strengthening global and domestic surveillance, public health and healthcare system readiness, and conducting research to improve influenza vaccines and other preventive interventions.

In collaboration with the Council of State and Territorial Epidemiologists, CDC assists state and local public health and emergency management agencies in developing their pandemic influenza plans. A software program, FluAid, 2.0, that estimates the number of deaths, hospitalizations, and outpatient visits that may occur during the next pandemic was developed. It helps state and local public health officials and policymakers prepare for the next influenza pandemic. The software also will help planners calculate the potential burden of an influenza pandemic on healthcare resources (e.g., number of hospital beds required and doctors available to see outpatients as a percentage of existing capacity).

CDC has also supported and strengthened the World Health Organization's global system of influenza laboratories and the U.S. influenza lead physician, virologic, and mortality surveillance systems. CDC has contributed to pandemic influenza vaccine development efforts by producing reassortant pandemic vaccine candidate viruses against avian influenza A viruses subtypes H5 (Eurasian lineage) and H9. CDC has also identified key cell surface receptors that contribute to the decline in immune function in the elderly. This research will lead to the development of more effective vaccines.

WHAT ARE THE NEXT STEPS?

CDC will continue to work with partners to enhance preparedness for an influenza pandemic based on the National Preparedness and Response Plan. Areas of future attention include providing increased technical assistance to states for pandemic planning, including the development of tabletop and field exercises, assuring a supply of antiviral drugs, improving the adult immunization infrastructure, and developing a hospital surveillance system to monitor more severe cases of influenza.

PEDIATRIC VACCINE STOCKPILES

WHAT IS THE PUBLIC HEALTH ISSUE?

An unprecedented and unanticipated shortage of routinely-recommended vaccines occurred in the United States beginning in 2001; this shortage included vaccines administered against 8 of the 11 vaccine-preventable childhood infectious diseases. This situation led the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians to recommend deferral of certain immunizations and to set priorities for high-risk patients until vaccine supplies returned to normal. These deferrals posed an increased risk of otherwise preventable infectious diseases.

Vaccine stockpiles, first developed by CDC in 1983, can be used to interrupt disease outbreak situations and ameliorate short-lived production problems, which are likely to occur from time to time. The pediatric vaccine stockpiles use dynamic inventory systems in which vaccine stock is rotated, as older vaccines are rotated into the market for use, fresh doses of vaccines enter the stockpiles. Stockpiles do not currently exist for all recommended childhood vaccines. CDC needs to ensure that a 6-month national supply of all recommended childhood vaccines is available for use in case of supply disruptions or outbreaks of vaccine-preventable diseases. In light of recent vaccine shortages and increased concerns about an influenza pandemic or bioterrorism event, expansion of CDC's stockpiles has become a pressing public health need. Due to supply constraints, as of December 2003, there has been no stockpile purchase of diphtheria, tetanus, and acellular pertussis (DTaP) vaccine.

WHAT HAS CDC ACCOMPLISHED?

The Department of Health and Human Services' Office of General Counsel has reviewed the legal authority of the *Omnibus Reconciliation Act* (OBRA) of 1993 legislation and confirmed the Secretary's authority under current law to build Vaccines for Children (VFC) program stockpiles equal to the amount needed for the U.S. pediatric population for 6 months of routinely recommended vaccines. In 2003, CDC began purchasing vaccine for expanded national pediatric stockpiles with the \$172 million of VFC funds apportioned for the stockpile. CDC has purchased 6-month stockpiles of measles, mumps, rubella (MMR), varicella, and inactivated polio (IPV) vaccines. Completion of delivery of all varicella and IPV doses is expected in 2004. CDC has also purchased partial stockpiles of hepatitis B, hepatitis A, pneumococcal conjugate (PCV) and *Haemophilus influenzae* type b (Hib) vaccines. CDC plans to continue purchasing those vaccines and others, like DTaP, for the stockpiles in 2004.

With input from key stakeholders, CDC has completed its strategic plan for the management of the pediatric vaccine stockpiles. This plan addresses the Government Accounting Office's (GAO) recommendations about the number of doses needed nationally, vaccine form (e.g., bulk, filled, labeled, packaged), storage location, and maintenance.

WHAT ARE THE NEXT STEPS?

Legislation improving the VFC program has been proposed and includes a provision to simplify the administration of the stockpiles with respect to stockpile sales. The new legislation will allow stockpile funds to be used to purchase 6-month national stockpiles of DTaP, Hib, hepatitis A, hepatitis B, influenza, IPV, MMR, PCV, and varicella vaccines. The combination vaccine *Pediarix*, containing DTaP, IPV, and hepatitis B, will also be eligible with these funds.

RACIAL AND ETHNIC ADULT DISPARITIES IN IMMUNIZATION INITIATIVE

WHAT IS THE PUBLIC HEALTH ISSUE?

About 46,000 to 48,000 adults in the United States die each year from vaccine-preventable diseases and about 114,000 people are hospitalized because of influenza. An average of 36,000 people, mostly aged 65 years and older, die annually due to influenza and its complications. Annually, about 60,000 cases of invasive pneumococcal disease occur in the United States, with one-third of these cases and half of the resulting deaths occurring in people 65 years of age and older. African Americans and Hispanics have significantly lower influenza and pneumococcal immunization coverage levels compared to the rest of the population. Influenza vaccination coverage among adults 65 years of age and older is 68% for whites, 48% for African Americans, and 54% for Hispanics. The gap for pneumococcal vaccination coverage among ethnic groups is even wider, with 60% for whites, 38% for African Americans, and 36% for Hispanics. Little is known about the best intervention strategies for these populations.

WHAT HAS CDC ACCOMPLISHED?

The Department of Health and Human Services (HHS) has made the elimination of racial and ethnic disparities in influenza and pneumococcal vaccination coverage for people 65 years of age and older a priority. To address these disparities and to assist in reaching the 2010 national health goal of 90% influenza and pneumococcal vaccination rates among persons 65 years of age and older, HHS, in collaboration with CDC and other federal partners, launched the Racial and Ethnic Adult Disparities Immunization Initiative (READII) in July 2002.

CDC is implementing the READII project with the support of the Centers for Medicare and Medicaid Services, the Health Resources and Services Administration, the Administration on Aging, the Agency for Healthcare Research and Quality, and other federal agencies. A READII demonstration project is being conducted in five sites (Chicago; Rochester [NY], San Antonio, Milwaukee, and 19 counties in the Mississippi Delta region) to improve influenza and pneumococcal vaccination rates for African Americans and Hispanics 65 years of age and older. READII sites have developed partnerships with public health professionals, medical providers and community organizations (e.g., large health plans, insurers, minority health professional organizations, churches, local community groups, and civic leaders). They are collaborating with these stakeholders to develop and implement community-based plans focusing on evidence-based interventions and innovative approaches to increasing immunization levels.

READII interventions include provider-based interventions (assessment and feedback to providers, multi-component provider education, standing orders, and provider reminder/recall); increasing community demand for vaccinations (client reminder/recall and multi-component interventions including community-wide and clinic-based education); enhancing access to vaccination services (expanding access in healthcare settings and reducing out of pocket costs); and vaccination interventions in nonmedical settings. Interventions vary by site and are based on state and local choice. Each site has developed multifaceted evaluation plans containing outcome, intervention specific, and process measures.

WHAT ARE THE NEXT STEPS?

At the conclusion of the READII demonstration project, CDC plans to share lessons learned and, should additional resources become available, replicate “what works” in other sites across the country.

For additional information on this or other CDC programs, visit www.cdc.gov/program

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TRACKING VACCINE-PREVENTABLE DISEASES

WHAT IS THE PUBLIC HEALTH ISSUE?

Dramatic declines in the incidence of vaccine-preventable diseases have created a need for surveillance systems that are sensitive enough to detect rare cases and isolated outbreaks of vaccine-preventable diseases. As new vaccines are licensed and recommended, new strategies for monitoring the incidence of additional diseases are also needed. Some of the diseases that have been newly identified as vaccine-preventable are not easily monitored through existing public health surveillance systems. These diseases require development of new and more complex strategies for surveillance.

WHAT HAS CDC ACCOMPLISHED?

CDC provides leadership and guidance for vaccine-preventable disease surveillance, investigation, and outbreak control throughout the United States. Recent accomplishments include documenting the elimination of naturally-acquired polio and indigenous measles in the United States. Scientific assistance provided to state and local health departments enables disease trends to be monitored and has demonstrated the effectiveness and impact of vaccines in controlling rubella, mumps, tetanus, diphtheria, *Haemophilus influenzae* type b, and chickenpox.

Example of Program in Action

Illness from nine infectious diseases (i.e., smallpox, diphtheria, pertussis, tetanus, paralytic polio, measles, mumps, rubella, and *H. influenzae* type b) has decreased by 95% to 100% since the beginning of the 20th century. Surveillance challenges presented by newly licensed vaccines against diseases such as chickenpox, which is not nationally notifiable, have led CDC to develop enhanced surveillance methods that include documentation of vaccine usage and the impact of vaccine recommendations. Results from three sites indicate a decrease in cases of chickenpox in all age groups, with the greatest decline occurring among children 1 to 4 years of age, the primary target group for vaccination. Results also show that the varicella vaccine is more than 90% effective in preventing moderate to severe cases of chickenpox when given routinely. Accomplishments have also been made through the New Vaccine Surveillance Network. This network has documented the burden of disease due to influenza among children 6 to 23 months of age.

WHAT ARE THE NEXT STEPS?

The need for enhanced surveillance to define disease burden and monitor vaccine impact continues. New approaches to surveillance include increased use of data from managed-care organizations, proprietary hospital discharge databases, state-based immunization registries, and laboratories.

VACCINES FOR CHILDREN PROGRAM

WHAT IS THE PUBLIC HEALTH ISSUE?

In the past, private providers referred children to public health department clinics for immunizations when the children lacked health insurance or their health insurance did not cover vaccinations. Since 1994, the Vaccines for Children (VFC) program, established by Section 1928 of the *Social Security Act*, has allowed children to receive vaccinations as part of routine care, supporting the reintegration of vaccination and primary care.

While VFC covers underinsured children, their access to vaccines has been limited, permitting them to receive vaccines only at federally-qualified health centers or rural health centers. Because the VFC authorizing legislation still imposes a price cap on all vaccines for which a federal contract existed prior to May, 1993, manufacturers of Tetanus Diphtheria (Td, DT) vaccines have refused to bid on CDC contracts since 1998. Consequently, these vaccines are unavailable for purchase through the VFC program. An unprecedented shortage of many routinely recommended vaccines included in the VFC program occurred in the United States, beginning in 2001. These shortages posed an increased risk to children of preventable infectious diseases. To ensure that providers enrolled in the VFC program adhere to the many VFC program requirements, increased automated accountability processes are needed.

WHAT HAS CDC ACCOMPLISHED?

The VFC program is CDC's largest public-private partnership. Based on the total doses of routinely recommended pediatric vaccines distributed in the United States, the VFC program served about 41% of the childhood population in 2002. The VFC program provides publicly purchased vaccines for use by all participating providers. These vaccines are given to eligible children without cost to the provider or the parent. In 2003, CDC awarded \$975 million in VFC funds to state, local, and territorial public health agencies for program operations and the purchase of vaccines.

The VFC program provides immunizations for children who are uninsured, Medicaid recipients, Native Americans, and Alaska Natives at their doctors' offices. VFC also provides immunizations for children whose insurance does not cover immunizations at participating federally-qualified health centers and rural health clinics. By decreasing referrals to public health departments, the VFC program has improved the continuity of care and promoted the "medical home" concept. The program has contributed to high immunization rates and reduced delays in immunizations and, subsequently, the risk of serious illness or death from vaccine-preventable diseases.

The VFC program ensures that all eligible children receive the benefits of newly recommended vaccines, thus strengthening immunity levels in their communities. The program also ensures that access to newly recommended vaccines for children in low-income and uninsured families does not lag behind that for children in middle- and upper-income families.

WHAT ARE THE NEXT STEPS?

Legislation improving the VFC program has been proposed and includes expanding access to underinsured children seeking immunization services in state and local public health clinics; removing the price caps on vaccines and allowing Td and DT to be purchased with VFC funds again; and amending authorities to simplify the administration of the pediatric vaccine stockpile with respect to stockpile sales. Pediatric vaccine stockpiles are being expanded in 2004–2006 to create a 6-month supply of all recommended pediatric vaccines.

For additional information on this or other CDC programs, visit www.cdc.gov/program

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VACCINE-PREVENTABLE DISEASES

WHAT IS THE PUBLIC HEALTH ISSUE?

Each day 11,000 babies are born in the United States who will need up to 20 vaccinations before they are 2 years old, to be protected against 11 vaccine-preventable diseases. For most of the vaccine-preventable diseases, there has been a 99% or greater reduction in morbidity. However, we cannot take high immunization coverage levels for granted. To continue to protect America's children and adults from vaccine-preventable diseases, we must attain maximum immunization coverage in all populations, establish effective partnerships, conduct reliable scientific research, implement immunization systems, and ensure vaccine safety.

WHAT HAS CDC ACCOMPLISHED?

CDC provides national leadership to reduce disability and death from diseases that can be prevented through vaccination. Through the continued work of CDC vaccination programs, especially the Section 317 Grant Program and Vaccines for Children Program, outstanding progress has been made in coverage rates for children up to 2 years of age. Immunization levels for most individual vaccines such as measles, polio, Hib, hepatitis B, and three doses of diphtheria-tetanus-acellular pertussis (DTaP) are at 90% or higher.

Disparities in childhood immunization coverage rates among racial and ethnic groups have been eliminated or greatly reduced for most vaccines. For example, in 1970, the measles immunization rate for racial and ethnic minority children was 18% lower than the rate for white children. According to the 2002 National Immunization Survey, over 93% of children 19 to 35 months of age in all races had received three or more doses of any diphtheria and tetanus toxoids and pertussis vaccines. Vaccination rates for Hispanic, white, and Asian, Pacific Islander, Alaska Native, Native Hawaiian or other Pacific Islander children, 19 to 35 months of age were reported to be at or above 90%, and African American vaccination coverage rates were 85%.

Licensed in 1995, the varicella vaccine for chickenpox is one of the most recently added vaccines on the recommended childhood schedule. The development of new vaccines creates opportunities for better health but also presents difficult challenges for immunization programs because they increase the complexity and cost of the immunization schedule. In spite of these challenges, great progress has been made in educating healthcare provider and the public about the benefits of the varicella vaccine. Coverage jumped from 57.5% in 1999 to over 80% in 2002; an increase of about 28% in just 3 years.

WHAT ARE THE NEXT STEPS?

CDC is committed to improving the health of all Americans and individuals internationally through vaccination. Next steps include

- Extending the success of domestic childhood immunizations program to the adult population.
- Increasing and sustaining vaccine coverage levels in all populations for all recommended vaccines.
- Assisting partners in implementing proven strategies for immunization by assuring adequate vaccine supplies, supporting community- and state-based immunization registries, and focusing efforts to increase immunization in areas with low coverage levels.
- Continuously improving vaccine safety efforts by working with other agencies and partners to improve CDC's Vaccine Adverse Event Reporting System; expand the Vaccine Safety Datalink; and increase opportunities for communications, epidemiological, and genetic vaccine safety research.

For additional information on this or other CDC programs, visit www.cdc.gov/program

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