



**DEPARTMENT
of HEALTH
and HUMAN
SERVICES**

**Fiscal Year
2008**

**Centers for Disease Control
and Prevention**

*Justification of
Estimates for
Appropriation Committees*

IMMUNIZATION AND RESPIRATORY DISEASES

AUTHORIZING LEGISLATION

PHSA §§ 301, 307, 310, 311, 317, 317(a), 317(j), 317(j)(1)³, 317(k)(1), 319, 319E, 327, 340C, 352, 2102 (6), 2102(7) 2125, 2126, 2127, Title XXI, 1928 of Social Security Act (42 U.S.C 1396s)

Immunization and Respiratory Diseases (Dollars in Thousands)	FY 2006 Actual	FY 2007 CR	FY 2008 Budget	FY 2008 +/- FY 2007
Discretionary Immunization and Respiratory Diseases Program	\$507,064	\$477,733	\$532,183	\$54,450
<i>Section 241, PHS Evaluation Transfer</i>	\$12,794	\$12,794	\$12,794	\$0
Subtotal, Discretionary Immunization Program	\$519,858	\$490,527	\$544,977	\$54,450
Vaccines for Children (VFC)	\$1,974,295	\$2,905,330	\$2,761,957	(\$143,373)
Total Immunization and Respiratory Diseases	\$2,494,153	\$3,395,857	\$3,306,934	(\$88,923)

STATEMENT OF THE BUDGET

The FY 2008 total Budget of \$3,306,934,000 for Immunization and Respiratory Diseases reflects a decrease of \$88,923,000 below the FY 2007 Continuing Resolution of \$3,395,857,000. The FY 2008 Budget of \$544,977,000 for the discretionary Immunization and Respiratory Diseases program reflects an increase of \$54,450,000 above the FY 2007 Continuing Resolution of \$490,527,000. The FY 2008 estimate of \$2,761,957,000 for the VFC program reflects a decrease of \$143,373,000 below the FY 2007 estimate of \$2,905,330,000.

PROGRAM DESCRIPTION

CDC strives to prevent disease, disability, and death through immunization and by control of respiratory and related diseases. Strategic priorities of Immunization and Respiratory Diseases program include:

- Improve infant, child, adolescent and adult immunization programs by:
 - Increasing coverage of recommended vaccines while eliminating disparities (e.g., racial/ethnic or financial),
 - Strengthening systems to assure adolescent and adult immunization, and
 - Improving effectiveness and efficiencies of state immunization programs.
- Establish and/or strengthen systems to evaluate effectiveness of national policies for immunization and respiratory disease prevention and control.
- Accelerate and sustain reduction of vaccine-preventable diseases domestically and globally through improved use of available vaccines, research and development of new vaccines, and program monitoring (including, as appropriate, surveillance).
- Reduce burden of complications associated with pneumonia and influenza.
- Improve preparedness for pandemic influenza with a strategy that will improve response to seasonal influenza.
- Improve national, state, local and global public health capacity to respond to outbreaks of respiratory and related diseases (e.g., reduce time to detect, investigate, respond, control, and recover).
- Identify and promote evidence-based strategies for reducing respiratory and related infections, vaccine-preventable diseases, and for controlling antimicrobial resistance in communities.

- Improve CDC's ability to identify and characterize the cause of respiratory and related infectious disease syndromes.

The related diseases for which this new organization will have primary responsibility for CDC include gastroenteritis (e.g., norovirus), non-vaccine preventable disease herpes viruses (e.g., Cytomegalovirus), non-respiratory Streptococci (e.g., group B, C, and G streptococcus), and community-acquired neonatal sepsis.

CDC's ongoing commitment to immunization and control of respiratory and related diseases is an essential component of its public health mission. Many life-threatening and/or debilitating infectious diseases, including polio, diphtheria, measles, *Haemophilus influenzae* type b (Hib), and pertussis, were once common in this country. Now, widespread use of vaccines, particularly among children, has resulted in elimination or low levels of these diseases. Appropriate administration of safe and effective vaccines is one of the most successful and cost-effective public health tools for preventing disease, disability, and death and for reducing economic costs resulting from vaccine-preventable diseases. To maintain the success of the immunization program, CDC provides national leadership in the ongoing effort to protect children, adolescents and adults from vaccine-preventable diseases and to ensure the safety of vaccines. These responsibilities focus on the goal of ensuring that every person, of every age, in every part of the country is protected from vaccine-preventable diseases.

CDC strives to ensure control of vaccine-preventable diseases by working with partners to: develop national immunization policy; ensure high quality immunization infrastructure and services; increase community participation, education and partnerships; improve systems to detect and monitor disease; improve vaccination coverage, vaccine effectiveness, and immunization safety; improve vaccines and vaccine use; and, provide vaccine to millions of children, adolescents, and adults annually who otherwise could not afford them.

Both seasonal and pandemic influenza represent substantial threats to the U.S. and global populations. Preparation to prevent, detect and conduct surveillance of seasonal influenza translates into enhanced preparedness for pandemic influenza. Every year in the United States, on average, more than 200,000 people are hospitalized from influenza complications and about 36,000 people die from influenza. Although seasonal influenza most adversely affects young children, elderly, and those with chronic illness, it impacts Americans at every stage of life. The health consequences of an influenza pandemic would be even more severe. CDC's ongoing activities include conducting and supporting research on influenza to understand who is at greatest risk of complications and how best to prevent those complications; monitoring the onset and spread of seasonal and pandemic influenza; conducting surveillance that monitors changes in the influenza viruses and advises development of seasonal influenza vaccines and candidate vaccines for pandemic preparedness; conducting research to improve effectiveness of influenza vaccines and other means to prevent and treat influenza; and developing strategies for the early detection and control of pandemic influenza globally.

CDC is working throughout the world, in support of the President's National Strategy on Pandemic Influenza, the Health and Human Services Pandemic Influenza Plan, and other initiatives to ensure that the U.S. is prepared for an influenza pandemic. Internationally, the focus is on the development of capacity for surveillance and rapid response to increase the chances for identification of early case and clusters that may lead to a pandemic, thus increasing the possibility of slowing or stopping the spread of a new pandemic influenza virus.

For many cases of serious infectious diseases, the cause remains unknown. CDC is at the forefront of pathogen discovery and detection, using the latest technology to identify and characterize both known and previously unrecognized infectious agents. CDC's laboratories played a key role in rapidly identifying a new coronavirus linked with the 2003 global outbreak of severe acute respiratory syndrome (SARS), a new nipah virus, and multiple new picornaviruses, many of which caused serious disease. These laboratories also focus on developing state-of-the-art technologies to enhance detection of known pathogens to improve outbreak detection and appropriately focus response efforts. As the effects of international travel, global commerce, and changing ecosystems continue to provide new opportunities for the emergence and rapid spread of new pathogens, new methods and capabilities of detecting these threats are urgently needed.

In carrying out its mission CDC:

- Awards grants through the Section 317 of the Public Health Service Act and the Vaccines for Children (VFC) program to assist state and local health departments in purchasing safe and effective vaccines and in planning, developing, and conducting immunization programs.
 - The VFC program serves children and adolescents without insurance, those eligible for Medicaid, American Indian/Alaska Native children, and children who are underinsured and receive care through Federally Qualified Health Clinics, and Rural Health Centers. Through the VFC program, federally purchased vaccines are distributed to public health clinics and enrolled private providers, enabling vaccination of all eligible children.
 - The Section 317 program provides vaccines for children, adolescents and adults who primarily present at local health departments for immunization services but are not eligible for the VFC program. These populations are predominately underinsured (i.e., their insurance does not cover immunization) or insured but cannot afford high deductibles (i.e. the working poor). Vaccines are provided to adolescents and adults, as funding allows, but to a much lesser extent than children.
- Provides technical, epidemiological, laboratory, statistical, scientific and educational assistance to state and local health departments.
- Supports national and sentinel surveillance as well as laboratory confirmation of diseases for which effective immunization agents are available.
- Implements strategies during the seasonal influenza season that will ultimately improve capacity in the event of an influenza pandemic. Strategies include: reducing disease burden, improving provider and patient expectations regarding influenza supply, improving predictability of vaccine supply, demand, and distribution; improving laboratory and epidemiologic capacity at local and state levels; strengthening linkages between health care sector and public health.
- Works to ensure the safety of recommended vaccines by monitoring harmful effects, conducting scientific research to evaluate the safety of vaccines, and communicating the benefits and risks of vaccines to the public.
- Encourages external participation in its immunization safety research agenda: collaborates with the National Vaccine Program Office and its National Vaccine Advisory Committee to solicit external scientific comments in the development of its Vaccine Safety Datalink (VSD) research agenda.
- Establishing an extramural immunization safety research activity to support investigator-initiated, peer-reviewed external research into genetic susceptibility to adverse events following routine immunizations.

Vaccines are one of the most successful and cost-effective public health tools for preventing disease and death.

COST-EFFECTIVENESS OF CHILDHOOD VACCINES	
For every \$1 spent on an individual vaccine:	
Diphtheria-Tetanus-acellular Pertussis (DTaP) saves \$27	
Measles, Mumps, and Rubella (MMR) saves \$26	
Perinatal Hepatitis B saves \$14.70	
Varicella saves \$5.40	
Inactivated Polio (IPV) saves \$5.45	
For every \$1 spent:	
Childhood Series (7 vaccines) saves \$16.50 ¹	

¹ (Series includes DTaP, Td, Hib, IPV, MMR, Hep B and Varicella)
Source: various peer reviewed publications. Direct and indirect savings included.

Despite great success and achievements in immunization and the control of respiratory diseases, there are challenges:

- Every day in the U.S. approximately 11,000 babies are born who will need as many as 28 vaccinations before they are two years of age to be protected against 14 vaccine-preventable diseases. Nearly one million two-year-olds in the U.S. have not received one or more of the recommended vaccines. Even though coverage levels for preschool immunization are high in many states, pockets of need, or areas within each state and major city where substantial numbers of under immunized children reside, continue to exist.
- In 1983, vaccines for seven diseases were available and recommended for routine use in children in the U.S. By January 2007, vaccines for 16 diseases were available and routinely recommended for children and adolescents. With these new recommendations for immunizations, it is now estimated to cost \$1,181.60 to fully immunize a female through age eighteen and \$894 to fully immunize a male through age eighteen with the complete set of Advisory Committee on Immunization Practices (ACIP) recommended vaccines (the difference between males and females is related to the human papillomavirus vaccine (HPV), which is currently recommended for females only).
- The ACIP recommended the newly licensed HPV vaccine for the routine vaccination of 11-12 year old girls in 2006. This vaccine targets HPV types that cause up to 70 percent of all cervical cancers. HPV is a cause of cervical cancer, which kills approximately 3,700 women annually in the United States.
- While the pneumococcal conjugate vaccine (PCV) has dramatically reduced the number of pneumococcal infectious caused by resistant strains, strains not covered by the vaccine are emerging and some are highly resistant to multiple antibiotics.
- In contrast to children, the burden of vaccine-preventable diseases in adults in the United States remains high. Approximately 46,700 U.S. adults die annually of vaccine-preventable diseases. Pneumonia and influenza were the fifth leading cause of death in all persons aged 65 and older based on 2000 national mortality data. A major challenge related to immunizations is extending the success in childhood immunization to the adult population. The ACIP also recently recommended a newly licensed vaccine against herpes zoster (shingles) in individuals 60 years of age and older.
- With the recent widespread outbreaks of avian influenza in poultry and wild migratory birds in Asia, Eastern Europe, and Africa and ongoing reported human deaths due to infections with avian A (H5N1) influenza, CDC must be vigilant in the surveillance for avian viruses and other novel influenza viruses that may adapt and become easily transmissible in humans. The health consequences of an influenza pandemic would be severe. Modeling studies suggest that, in the absence of any control measures, a "medium-level" pandemic in the U.S. could result in an estimated 89,000 – 207,000 deaths, 314,000 – 734,000 hospitalizations, 18 – 42 million outpatient visits, and another 20 – 47 million people being sick if 15 – 35 percent of the U.S. population develops influenza. The associated economic impact on the U.S. could range from \$71 – \$167 billion. A severe pandemic could result in up to 1.9 million deaths.
- Although more than 200 million individuals are recommended to receive annual influenza vaccine, supply and demand have not caught up with these recommendations and uptake remains below optimal. In the 2005-2006 influenza season, more than 81 million doses were distributed; however, approximately 88 million were produced. For the 2006-2007 influenza season, vaccine manufacturers produced more than 100 million doses of influenza vaccine, a record production level. It is unknown how much vaccine has been administered to date. In order to keep high levels of supply and demand for influenza vaccine, CDC works closely with partners in the public and private sectors to increase demand in the offices of healthcare providers and among individuals for whom the vaccine is recommended and to address provider and public expectations regarding the timing of vaccine availability given the uncertainties involved in phased influenza vaccine distribution. Although vaccine distribution is mostly a private sector enterprise, CDC works to influence influenza vaccine distribution and use through recommendations, guidelines, and extensive collaborations.
- Immunizations are subject to a higher standard of safety than other medical interventions because they are given to healthy people. Actively monitoring and assuring the safety of vaccines is essential for maintaining public confidence in immunizations, thereby preserving high coverage levels and preventing a resurgence of vaccine-preventable diseases.

CDC is committed to:

- Ensuring that childhood immunizations remain at high levels so the incidence of vaccine-preventable diseases continues to decline significantly.
- Achieving high vaccination coverage rates for adolescents especially for newly recommended vaccines. CDC is strengthening the delivery of vaccines to adolescents by identifying adolescent health care providers and integrating these new vaccines into the delivery of other clinical preventive services recommended for them.
- Providing effective, proactive leadership on vaccines and immunization by fostering sound vaccine recommendations and policies, conducting quality research, developing and distributing educational material, and enlisting and engaging the contributions of a wide range of professional groups and other organizations. This includes the development of a childhood and adolescent routine immunization schedule with the ACIP, the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). CDC also works to develop a single routine Adult Immunization Schedule endorsed by ACIP, AAFP, and the American College of Obstetricians and Gynecologists. Both schedules are continually evaluated to ensure the highest level of effectiveness, efficiency and safety.
- Supporting national and global influenza pandemic preparedness through technical assistance offered on influenza surveillance, laboratory detection and confirmation, and guidance on incorporating effective immunization practices into pandemic preparedness and emergency response plans.
- Providing assistance to state and local health departments to investigate outbreaks of disease and identifying and implementing prevention measures.
- Conducting ongoing surveillance to monitor trends in disease incidence and the impact of the vaccination program.
- Strengthening immunization science and communicating the results, such as:
 - Undertaking and promoting a wide range of scientific activities, including tracking and monitoring diseases, characterizing disease-causing pathogens, conducting disease outbreak investigations; evaluating vaccine effectiveness, impact of prevention programs, health care delivery methods and systems; and conducting social and behavioral science research.
 - Working to translate research findings into actions and recommendations and to communicate these to the appropriate audiences.
 - Providing technical, epidemiological, educational, statistical, laboratory support and scientific assistance to state and local health departments.
- Monitoring adverse events following immunization and studying the occurrence and scientific basis for adverse events following immunization.
- Fostering and establishing partnerships and collaboration: CDC works with local, state, and national partner organizations to increase awareness of immunization recommendations, foster the development and implementation of effective immunization programs, and achieve high immunization coverage levels. CDC also develops partnerships with community organizations and private health care providers to increase awareness of immunization recommendations and the use of best practices.
- Providing effective, responsive immunization education and information. CDC helps health departments, physicians, nurses, pharmacists, and other health care providers attain the knowledge and skills needed to effectively implement immunization recommendations. Patient education materials are also provided to assist health care providers in educating parents, adolescents and adults about the importance, benefits, and risks of immunization recommendations.
- Protecting against disease outbreaks and vaccine supply disruptions through a national pediatric stockpile of recommended vaccines available for U.S. children.

NARRATIVE BY ACTIVITY
INFECTIOUS DISEASES
IMMUNIZATION AND RESPIRATORY DISEASES

- Developing and improving laboratory diagnosis of respiratory and vaccine preventable diseases. Accurate and timely detection is imperative for detection and control of respiratory and vaccine preventable disease. CDC works to improve existing tests, develop new diagnostic tests, and ensure best practices are used to diagnose respiratory and vaccine preventable diseases in partnership with state and local health departments as well as international partners.
- Using state-of-the-art laboratory methods to monitor respiratory and vaccine preventable diseases. CDC's laboratories use molecular techniques to detect critical changes in influenza viruses that might signal a pandemic or a need for a new vaccine strain. Molecular techniques are also critical components of vaccine preventable disease monitoring systems to trace patterns of spread and direct control efforts such as with polio viruses, and to monitor emergence of antibiotic resistant strains of bacteria.
- Continuing to include immunization among its most vital programs, recognizing it as a core public health activity and an excellent example of effective primary prevention as it has done since 1962, when the first national effort to improve the immunization status of children was proposed by Congress. Immunization has been cited as one of the top ten public health achievements of the 20th century. In the U.S., vaccine-preventable diseases are at or near record low levels.

Vaccines have reduced cases of many vaccine-preventable diseases by more than 97 percent from peak levels before vaccines were available, indicated by the 20th century annual morbidity baseline, saving lives as well as treatment and hospitalization costs (see table below).

INDIGENOUS CASES OF VACCINE PREVENTABLE DISEASES IN THE U.S. FINAL REPORTS FOR 2003, 2004 AND 2005					
	20 th Century Baseline Annual Morbidity ¹	2003 ²	2004 ²	2005 ⁸	2010 Goal
Diphtheria ³	175,885	0	0	0	0
Measles ⁴	503,282	32	10	42	0
Mumps ⁴	152,209	231	258	314	0
Pertussis ⁵	147,271	3,719	6,850	7,347	2,000
Polio ⁴ (paralytic, wild-type)	16,316	0	0	0 ⁹	0
Rubella ⁴	47,745	7	7	8	0
<i>Haemophilus influenzae</i> (type b + unknown) ⁶	20,000	259	196	226	0
Congenital Rubella Syndrome (CRS) ⁷	823	1	0	0	0
Tetanus ³	1,314	6	6	5	0

¹ This table compares the 20th century annual morbidity for vaccine preventable diseases with the current incidence of vaccine preventable diseases and indicates disease was much more prevalent in the pre-vaccine era. Baseline data for 20th century annual morbidity is referenced in [MMWR](#) 1999 Apr 2;48(12):243-8.

² 2003-2005 cases correspond to Healthy People 2010 and GPRA reports on progress toward targets

³ Persons under 35 years of age reported 2002-2005

⁴ All ages reported

⁵ Children under seven years of age

⁶ Children under five years of age

⁷ Children under one year of age reported 2003-2005 Estimated

⁸ 2005 final NNDSS data. [MMWR](#) 2006 Aug 18; 55(32): 880-881

⁹ A panel of polio experts convened by CDC confirmed a case of paralytic polio on the basis of standard clinical evidence, and the case was classified as imported vaccine-associated paralytic poliomyelitis (VAPP) with onset of illness within 30 days before entry into the United States, in accordance with CDC protocol" [MMWR](#) 2006 Feb3; 55(04):97-99.

RATIONALE FOR THE BUDGET

The FY 2008 total Budget of \$3,306,934,000 for Immunization and Respiratory Diseases reflects a decrease of \$88,923,000 below the FY 2007 Continuing Resolution of \$3,395,857,000. The FY 2008 Budget of \$544,977,000 for the discretionary Immunization and Respiratory Diseases program reflects an increase of \$54,450,000 above the FY 2007 Continuing Resolution of \$490,527,000. The FY 2008 estimate of \$2,761,957,000 for the VFC program reflects a decrease of \$143,373,000 below the FY 2007 estimate of \$2,905,330,000.

Discretionary Immunization Program (+\$54.5 million)

Pandemic Influenza (+\$54.5 million)

Fund States to Increase Demand for Influenza Vaccine (+\$19.8 million)

CDC will increase demand for influenza vaccine by providing funds to States and through communication activities. CDC will increase the demand for and uptake of annual influenza vaccine, particularly to accommodate high-risk populations. Increasing vaccine demand will stimulate vaccine manufacturers to produce additional vaccine, thereby increasing vaccine production capacity and helping the nation's preparedness for a pandemic.

Develop an Ongoing Repository of Pandemic Virus Reference Strains for Manufacturing (+\$19.8 million)

The U.S. laboratory system lacks sufficient capacity to analyze large quantities of viral samples of circulating strains to identify suitable vaccine candidates. There is also a lack of dedicated facilities for development and evaluation of vaccine reference strains. Increased funding in the FY 2008 President's Budget will allow CDC to increase laboratory and analytical capabilities for genetic and antigenic analysis of influenza viruses.

Increase Stock of Diagnostic Reagents for Influenza (+\$14.9 million)

CDC and state reference laboratories have the capacity for molecular detection of H5N1 avian influenza virus and other strains with pandemic potential, but detection is not distributed widely or at levels sufficient to respond to pandemic and pre-pandemic situations. It is vital to develop, validate, and continuously update new rapid bedside detection assays with subtype specificity for use during a pandemic. The United States also requires investments in rapid test capacity for novel influenza viruses. With increased resources in the FY 2008 President's Budget, CDC will provide for the acquisition, storage, shipping, and support of a newly acquired inventory either internally or through a commercial vendor. CDC will also work with the manufacturer to work toward more stringent quality assurance and control by instituting control protocols to ensure reagents are used properly. Finally, CDC will provide incentives for the manufacturer to make reagents available when needed.

Vaccines for Children (\$-143.3 million)

The FY 2008 estimate reflects a decrease of \$143.3 million for the VFC program. CDC received \$40 million per year through VFC from FY 2004 through FY 2007 to create a pediatric influenza vaccine strategic reserve. CDC is evaluating whether to continue including this funding in FY 2008 and beyond. At this time, \$20 million is being funded in FY 2008 for influenza stockpile activities, a decrease of \$20 million. Additionally, funds associated with contractual support for VMBIP terminate in FY 2007, making funding for these activities unnecessary in FY 2008. For the pediatric vaccine stockpile, fewer funds are required in FY 2008 to continue stockpiling a six month national supply of all recommended vaccines. Finally, vaccine purchase funding reflects a decrease due to a decline in one-time catch-up funding for some vaccines. Funding for VFC has increased by more than \$780 million from FY 2006 to FY 2008.

PERFORMANCE ANALYSIS

PART Results

Following its PART review, the Section 317 program initiated a business improvement project to revamp the entire vaccine distribution process and enhance the efficiency and accountability of vaccine management systems. Once fully implemented, the new systems will automate and integrate vaccine ordering and management by centralizing distribution of all public purchased vaccines.

Several ongoing actions to improve performance continue within the Immunization program including program evaluation and vaccine distribution improvements. CDC has been engaged in a comprehensive evaluation and has been working with grantees to better measure outcomes and improve understanding of the criteria for allocating resources. The next phase of the evaluation will assess differences in performance, controlling for external factors that may affect performance. Efforts have ensued since PART through the evaluation and the establishment of efficiency measures and improvements to the grant process that better integrate program budget and performance.

The program is also participating in budget and performance integration efforts in accordance with CDC's agency-wide program planning, tracking and performance measurement system.

Current Activities:

Influenza

CDC builds capacity domestically and internationally to improve systems for early detection of unusual increase in influenza activity and novel influenza viruses by:

- Providing leadership to the National Pandemic Influenza Preparedness and Response Task Force.
- Enhancing current national influenza surveillance systems to enable early detection of pandemic influenza and initiation of rapid response.
- Working with Association of Public Health Laboratories and World Health Organization (WHO) on training workshops for state laboratories on the use of molecular laboratory techniques to identify H5 viruses.
- Working with the Council of State and Territorial Epidemiologists (CSTE) to train state and local epidemiologists in response to a pandemic and strengthen public health surveillance during a pandemic.
- Working closely with WHO and National Institutes of Health (NIH) on developing and safety testing of vaccine candidates and development of additional vaccine virus seed candidates for H5N1 and other subtypes of influenza A viruses.
- Conducting worldwide monitoring of influenza viruses to collect data that contribute to annual vaccine decisions domestically and globally.
- Working with WHO to investigate influenza H5N1 among humans and provide assistance in the development of epidemiological and laboratory diagnostics capacity and training to international health authorities.
- Planning, developing and implementing laboratory and epidemiologic training in collaboration with the Global AIDS Program to enhance countries' ability to detect H5N1, especially in Africa.
- Providing funding and training to support development of pandemic planning, influenza diagnosis and surveillance capacities, and rapid response teams in developing countries.

Immunization

CDC supports the immunization efforts of states by providing funding for vaccine purchase and operations/infrastructure activities.

- Vaccine grants support the purchase of ACIP recommended vaccines through CDC's consolidated vaccine purchase contracts available to state and local health departments.
- According to the Institute of Medicine's "Calling the Shots" Report, operations funding is vital to the integration of new vaccines into routine medical care for everyone, increasing vaccination coverage rates, and decreasing racial and ethnic disparities.
- Operations funds support front-line public health professionals, including nurses who administer vaccines; professionals who work with immunization providers to improve their immunization practices and their handling of vaccines; and managers who coordinate and direct the complex activities needed to assure vaccination of a population.
- Operations funds pay for syringes and other equipment needed to vaccinate as well as immunization information systems that track the vaccination status of individuals.

NARRATIVE BY ACTIVITY
INFECTIOUS DISEASES
IMMUNIZATION AND RESPIRATORY DISEASES

- Operations funds support surveillance systems that monitor the occurrence of vaccine preventable diseases at the state and local level. Surveillance of vaccine-preventable diseases also helps detection and facilitates a more rapid response to outbreaks and other changes in disease incidence.
- Operations funds also support education and outreach activities, such as educational campaigns, public and private provider education and quality assurance reviews.

In 2005 and 2006, CDC implemented an unprecedented number of expanded recommendations for children, adolescents and adults. Listed in the order in which they were recommended, new vaccines and/or expanded recommendations include:

- Use of meningococcal vaccine (MCV4) for adolescents and college freshmen to protect against meningococcal disease in adolescence and young adulthood.
- Replacement of the Td booster with the more comprehensive tetanus, diphtheria, and pertussis (Tdap) vaccine to reduce the number of cases of pertussis (whooping cough) in infants, adolescents and adults.
- Universal use of hepatitis A vaccine and lowering the age indication for vaccine to 12 months of age. Previously, the hepatitis A vaccine was recommended for use in only certain high risk groups and children living in states, communities or counties with high annual incidence of hepatitis A during 1987-1997.
- Use of the combination measles, mumps, rubella, and varicella (MMRV) vaccine to protect children aged 1 to 12 years against these four preventable diseases.
- Use of a single dose of Tdap (instead of Td) in adults 19 to 64 years of age to reduce pertussis among adults and reduce transmission of pertussis to infants.
- Use of vaccine to protect against rotavirus, a viral infection that can cause severe diarrhea, vomiting, fever and dehydration (gastroenteritis) in infants and young children.
- Expansion of routine recommendation of influenza vaccination to include all children 6 to 59 months of age.
- Recommendation of Tdap for health care workers, with an encouragement to receive the Tdap dose at an interval as short as two years from the last dose of Td.
- Routine recommendation of vaccination of girls 11 to 12 years of age against HPV, the most common sexually transmitted infection in the U.S. and the cause of most cervical cancers. Catch-up recommendation is recommended for all females up to 26 years of age.
- A second dose of varicella (chickenpox) vaccine to offer more protection to children, adolescents, and adults.
- A single dose of zoster vaccine to protect adults 60 years of age and older from the risk of herpes zoster (shingles), which symptoms can include prolonged debilitating pain.
- A second dose of MMR or mumps vaccine for health care workers

CDC promotes and facilitates the use of evidence-based immunization strategies that have been scientifically proven to sustain and raise vaccination coverage levels such as:

- Developing and using state-based immunization information systems to help identify high-risk and under-immunized populations.
- Using reminder and recall systems to improve immunization levels in children, adolescents, and adults.
- Developing software tools to assess immunization coverage in health care settings and increase immunization coverage rates.

CDC conducts prevention activities through cooperative agreements, contracts, in-house research, technical assistance and consultation, as well as planning and evaluation in cooperation with states and local agencies. Prevention activities include:

- Evaluating program performance by measuring vaccination coverage at the national, state, and urban grantee levels.

NARRATIVE BY ACTIVITY
INFECTIOUS DISEASES
IMMUNIZATION AND RESPIRATORY DISEASES

- Conducting operational research to develop new and improved immunization delivery strategies to raise or sustain coverage levels.
- Conducting surveillance of vaccine-preventable and respiratory infectious diseases to detect and respond more rapidly to outbreaks and other changes in disease incidence.
- Providing laboratory support, training, and technical assistance to state health departments.
- Assessing vaccination coverage levels in adults and conducting research to determine strategies for raising coverage levels.
- Increasing community participation, education, and partnerships through public information campaigns.
- Increasing education and training for providers and partnerships with community-based and professional organizations, national minority organizations, and other federal agencies.
- Conducting ongoing immunization safety surveillance activities and studying the occurrence and scientific basis for infrequent adverse events following vaccination.

Best Practices

CDC is improving the vaccine purchase and distribution process by leveraging commercial best practices to address all aspects of vaccine procurement, ordering, distribution and management and achieve cost savings and efficiencies.

- The Vaccine Management Business Improvement Project (VMBIP) is a comprehensive review and update of the public pediatric vaccine supply chain from the distribution of vaccine by the manufacturer to the point of administration (either public clinic or private provider's office).
 - CDC awarded a national centralized vaccine distribution contract in fall 2006 and will begin pilot testing the model in February 2007. Centralized distribution will result in streamlined inventories and increased efficiencies in the distribution of federally purchased vaccines. Centralized distribution will also increase the visibility of the vaccine supply, enhancing CDC's ability to address public health emergencies such as vaccine shortages.
 - CDC is maintaining a contractual mechanism for the consolidated purchase of vaccine for states and local agencies with their own funds as well as federal funds provided through grants.
- CDC maintains a stockpiled supply of recommended childhood vaccines for use in case of supply disruptions or outbreaks of vaccine-preventable diseases. Since its inception in 1983, the pediatric vaccine stockpile has been accessed more than twelve times.

Vaccine Safety

Continuous monitoring of vaccines and ongoing assessment of immunization benefits and risks are vital components of sound immunization policies and recommendations affecting the health of the nation. As a national leader in immunization safety, CDC conducts several immunization safety activities including:

- Managing the Vaccine Adverse Event Reporting System (VAERS), in collaboration with the FDA. VAERS serves as an early warning system to detect problems that may be related to vaccines.
- Supporting the Vaccine Safety Datalink (VSD) Project, a collaborative effort involving CDC and several large managed care organizations (MCOs). The VSD was established primarily to assess immunization safety issues in the U.S. through a large-linked database (LLD) that utilizes administrative data sources at each MCO. Each participating site gathers information regarding the vaccination and medical records of millions of children and adults. Collectively, the data from VSD studies are derived from participating MCOs that contain more than nine million members, of which the VSD Project collects comprehensive medical information for more than 5.5 million people annually. The VSD enables population-based immunization safety research studies to compare the incidence of health problems between vaccinated and unvaccinated people.
- Providing in depth, standardized clinical evaluations for individuals with unusual or severe vaccine adverse events through the Clinical Immunization Safety Assessment (CISA) Network.
- Developing case definitions for adverse events following immunization through the support of the Brighton Collaboration, an international voluntary collaborative effort.

NARRATIVE BY ACTIVITY
INFECTIOUS DISEASES
IMMUNIZATION AND RESPIRATORY DISEASES

- Promoting safer, simpler, and swifter vaccine delivery technologies to overcome potential dangers and drawbacks of using needle-syringe to administer vaccine through the Vaccine Technology Development (VAXDEV) activity.
- Establishing an extramural research activity for immunization safety. This program will support investigator-initiated, peer-reviewed research conducted by external researchers to better understand risk factors for serious adverse events following immunization. Potential areas of study include genetics involved in serious adverse events following routine immunizations, and/or the genetics involved with the failure to mount a normal immune response.
- The CISA Network collaborates with six academic centers to investigate pathophysiologic mechanisms and biologic risks of adverse events following immunization. CISA began enrolling subjects in the newly established centralized registry of clinical data and repository of biological specimens, which will be important in increasing our understanding of virologic, immunologic and genetic markers for post-vaccination adverse events.

Significant Accomplishments:

- The nation's childhood immunization coverage rates are at record high levels for most vaccines and for all the vaccination series measures. As childhood immunization coverage rates increase, cases of vaccine preventable diseases decline significantly.

VACCINATION COVERAGE LEVELS AMONG CHILDREN AGED 19 - 35 MONTHS, NATIONAL IMMUNIZATION SURVEY, U.S.								
Vaccine/ Dose	1999 (%)	2000 (%)	2001 (%)	2002 (%)	2003 (%)	2004 (%)	2005 (%)	2010 Goal
DTP 4 ¹⁺	83	82	82	82/95	85/96	86	86	90
Polio 3+	90	90	89	90	92	92	92	90
Hib 3+	94	93	93	93	94	94	94	90
MMR 1+	92	91	91	92	93	93	92	90
Hepatitis B 3+	88	90	89	90	92	92	93	90
Varicella	58	68	76	81	85	88	88	90

¹ In 2002 and 2003, CDC temporarily modified reporting on DTaP from four doses to three doses because vaccine shortages limited the availability of the fourth dose.

Other significant accomplishments include the following:

- Addressed the expanded influenza epidemiology, laboratory and extramural responsibilities through the establishment of a new Influenza Division.
- Advanced development of a rapid influenza diagnostic test, exercised organizational preparedness, and convened experts to improve influenza surveillance strategies.
- Placed staff in strategic overseas positions to coordinate avian influenza activities and provide ongoing technical assistance to improve international pandemic preparedness.
- Developed the first H5N1 Clade 2 pandemic influenza vaccine candidate for distribution to vaccine manufacturers.
- Collaborated with other partners within and outside of CDC to identify and promote health behaviors (e.g., hand hygiene, cough etiquette, and respiratory hygiene) that can prevent the spread of influenza and other respiratory infections.
- Provided onsite outbreak assistance, technical assistance and/or training to China, Vietnam, Thailand, Indonesia, Nigeria, Turkey, Brazil, Laos, Cambodia, Ukraine, Kenya, Uganda, Kazakhstan, Egypt, Djibouti, and Romania for the avian influenza outbreaks.
- Offered technical assistance through training held at CDC and regionally for many countries affiliated with the Western Pacific Regional Office and the South East Asia Regional Office of WHO
- Developed training materials for deployment of international and national rapid response teams early in a pandemic. These materials have been used in courses worldwide to train more than 500 epidemiologists, with additional courses planned in 2007.

NARRATIVE BY ACTIVITY
INFECTIOUS DISEASES
IMMUNIZATION AND RESPIRATORY DISEASES

- Announced the first annual National Influenza Vaccination Week during the week of November 27th to December 3rd, 2006 – in conjunction with the Department of Health and Human Services, the National Influenza Vaccine Summit, partners, and stakeholders – to help raise awareness of influenza vaccination recommendations and the importance of continuing vaccination efforts throughout November and beyond.
- Documented an ongoing, dramatic effect of PCV vaccination on disease in children less than 5 years of age and on unvaccinated adults by decreasing spread from children through CDC's Emerging Infections Program's Active Bacterial Core Surveillance for invasive pneumococcal disease.
 - CDC demonstrated that PCV vaccine is reducing the disparity in disease burden between whites and blacks in the U.S.
 - CDC data from the first five years of vaccine use in the United States shows that the cost effectiveness of the childhood vaccine is more favorable than anticipated before the vaccine was licensed, because the effects on protection among the adult nonvaccinated population has been substantial.
 - Original estimates indicated only 38,000 cases would be averted at the cost of \$112,000 per life year saved. Now we know that an estimated 109,000 cases of invasive pneumococcal disease were averted through vaccination in the first five years at a cost of only \$7,500 per life year saved. The cases averted occurred not only among those vaccinated but also among the nonvaccinated.
- Documented, according to 2005 National Immunization Survey data, that there is no statistically significant difference in vaccination coverage rates between black and white children nationwide, although pockets of low coverage and disparities for individual vaccines continue to exist. Continued vigilance is needed in monitoring for disparities, identifying causes of disparities where they exist, and developing and evaluating strategies to eliminate disparities.
- Investigated the largest outbreak of mumps in the U.S. in more than a decade in conjunction with state and local health departments, with over 6,000 reported cases in 2006. CDC/HHS coordinated surveillance activities and field investigations, served as the national reference laboratory for mumps laboratory diagnosis, and provided expert technical assistance to develop and implement prevention and control activities, including revising policy recommendations for prevention and control of mumps in the United States. Because of high vaccination coverage rates in the affected states, the attack rate from this outbreak remained low. As part of the public health response, over 25,000 doses of MMR vaccine were released for outbreak control from the pediatric vaccine stockpile.
- Evaluated the economic impact of seven vaccines (DTaP, Td, Hib, polio, MMR, hepatitis B, and varicella) routinely given as part of the childhood immunization schedule and found that vaccines are tremendously cost effective. Routine childhood vaccination with these seven vaccines, which prevent nearly 14 million cases of disease and over 33,000 deaths over the lifetime of children born in any given year, resulted in annual cost saving of \$9.9 billion in direct medical cost and an additional \$33.4 billion in indirect cost savings. This study in the Archive of Pediatrics and Adolescent Medicine is the first time the seven vaccine series has been examined together with a common methodology.
- Documented elimination of the rubella virus in the U.S. Once a common disease in this country, rubella is now a rare threat. This remarkable achievement is a tribute to having a safe and effective vaccine and a successful immunization program. In spite of the remarkable achievement, the U.S. should continue its current efforts and vigilance against rubella and Congenital Rubella Syndrome to ensure that elimination of rubella is maintained.
- Assisted in the investigation of more than 100 outbreaks of gastroenteritis in 31 states, the District of Columbia, and on cruise ships in 2006; the majority of these outbreaks were linked to noroviruses.
 - Viral gastroenteritis associated with contaminated food and water affects millions of Americans each year and can have serious consequences for children, the elderly and immunocompromised persons. Despite the large public health impact, these infections remain largely undiagnosed because of a lack of routine clinical testing.

NARRATIVE BY ACTIVITY
INFECTIOUS DISEASES
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- Noroviruses (previously called Norwalk-like viruses) are the most common cause of infectious gastroenteritis in the United States; data indicate that approximately 50% of all foodborne outbreaks are caused by noroviruses. Although traditionally these viruses have been difficult to identify, new technologies (pioneered by CDC) have been developed and made available to almost all state health departments, enabling rapid diagnosis and use of molecular tools to help identify transmission patterns during large outbreaks.
- In response to the influenza vaccine shortfall and resulting prioritization of influenza vaccine in 2004-2005, the VSD conducted a rapid assessment of influenza vaccination coverage among MCO members in Northern California.
- In 2005, findings from the Vaccine Adverse Events Reporting System (VAERS) resulted in educational efforts targeted to health care providers and changes to the newly licensed MCV4 (Menactra®) vaccine's recommendations and instructions for use. CDC published three MMWR articles to inform public health professionals of this information in FY 2006 and FY 2007.
- The Brighton Collaboration is working with 71 countries to develop standardized case definitions and guidelines for vaccine adverse events. The Brighton Collaboration finalized 11 journal articles and 6 case definitions.

OUTPUT TABLE

OUTPUT TABLE	FY 2006 ENACTED	FY 2007 CR	FY 2008 BUDGET	FY 2008 +/- FY 2007
# of children able to be fully vaccinated with 317 funds ¹	223,526	218,296	213,500	(4,795)
Section 317 State Operations				
Number of grantees with full time adult/influenza coordinators	16	24	30	6
Number of grantees achieving 80% on the 4:3:1:3:3:1 series	33	41	45	4
Number of grantees with 95% of the children participating in fully operational, population-based registries	18	23	24	1
Prevention Activities				
Support clinical evaluations to study newly hypothesized or alleged vaccine related syndromes	80	80	80	0
Immunization Registries participating in safety monitoring with VAERS	17	17	17	0
CISA centers in operation	6	6	6	0
Vaccines for Children Program				
Number of doses of Tdap purchased	2,438,820	3,137,135	3,293,992	156,857
Number of doses of Rotavirus purchased ²	1,112,310	3,327,316	3,493,682	166,366

NARRATIVE BY ACTIVITY
INFECTIOUS DISEASES
IMMUNIZATION AND RESPIRATORY DISEASES

OUTPUT TABLE	FY 2006 ENACTED	FY 2007 CR	FY 2008 BUDGET	FY 2008 +/- FY 2007
Influenza				
Number of reporting domestic sentinel physician sites to improve influenza surveillance	1,300	1,300	1,300	0
Number of state/local health departments supported to build epidemiological and lab capacity for influenza	47	47	47	0

¹ The reduction in this output reflects an increase in the vaccine recommendations to include a second dose of varicella, rotavirus, and expanded recommendations for influenza as well as anticipated price increases.

² Rotavirus was licensed, recommended, and funded for part of FY 2006.

FUNCTIONAL TABLE

Immunization and Respiratory Disease Budget by Functional Activity (Dollars in Thousands)	FY 2006 Actual	FY 2007 CR	FY 2008 Budget	FY 2008 +/- FY2007
317 Immunization Program	\$454,489	\$425,123	\$425,123	\$0
Vaccine Purchase Grants	\$261,656	\$232,158	\$232,158	\$0
State Operations/Infrastructure Grants	\$192,833	\$192,965	\$192,965	\$0
Program Operations	\$62,710	\$62,743	\$82,543	\$19,800
Pandemic Influenza	\$2,659	\$2,661	\$37,311	\$34,650
Total	\$519,858	\$490,527	\$544,977	\$54,450

INFECTIOUS DISEASES

IMMUNIZATION AND RESPIRATORY DISEASES

Efficiency Measure	FY	Target	Result
1. Make vaccine distribution more efficient and improve availability of vaccine inventory by reducing the number of vaccine inventory depots in the U.S. [E]	2008	Reduce inventory depots by 50%	1/2009
	2007	Reduce inventory depots by approximately 17%	1/2008
	2006	Award contract to centralize distribution, validate existing baseline	Yes (Met)
	2005	Establish estimated baseline of inventory points in the contiguous states	>400 (Met)
Data Source: Grantee annual report (VFC Management Survey), grantee interviews, and site visits were used to gather the baseline information. A VMBIP semi-annual survey instrument is being developed and will be administered to grantees to track vaccine storage locations.			
Data Validation: Data submitted from grantees will be analyzed by the CDC program staff and validated through a regularly scheduled review process.			
Cross Reference: HHS-8			

Efficiency Measure 1:

The Vaccine Management Business Improvement Project (VMBIP) is a CDC initiative aimed at increasing the efficiency, visibility, and management of publicly purchased vaccines by centralizing and consolidating vaccine inventory and distribution. Currently, publicly purchased vaccine, including vaccine purchased by the Section 317 program, is held at various third party distribution depots or in state run depots. It is estimated that 400 storage locations exist. Even though the current system works, it is inefficient. The large number of depots results in redundancy of distribution resources, reduces the efficiency of distribution, and impedes the program's ability to track vaccine.

CDC, through VMBIP, contracted with McKesson Specialty Distribution in September 2006 to consolidate national inventory in significantly fewer inventory depots than currently exist and distribute vaccine through a streamlined central system. The expected efficiencies gained from consolidation of vaccine depots include improved management of vaccine inventory through use of distribution best practices and increased visibility of the location of vaccines throughout the public vaccine supply chain. As phased implementation progresses, the number of locations holding vaccines will decrease until full implementation is complete by FY 2009 and vaccine inventory depots are reduced by 98 percent. The first pilot sites which are Washington State, California, the City of Chicago, and Maryland will begin distributing through the centralized distribution system in February 2007.

GOAL 1: REDUCE THE NUMBER OF INDIGENOUS CASES OF VACCINE-PREVENTABLE DISEASES.				
Measure	FY	Target	Result	
1. The number of indigenous cases of paralytic polio ¹ , rubella ¹ , measles ¹ , <i>Haemophilus influenzae</i> invasive disease (type b and unknown types) ² , diphtheria ³ , congenital rubella syndrome ^{4,5} , and tetanus ³ will remain at or be reduced to 0 by 2010. [O]		<i>Paralytic Polio</i>	<i>Paralytic Polio</i>	
	2008	0	9/2009	
	2007	0	9/2008	
	2006	0	9/2007	
	2005	0	0 (Met)	
	2004	0	0 (Met)	
	2003	0	0 (Met)	
			<i>Rubella</i>	<i>Rubella</i>
	2008	15	9/2009	
	2007	15	9/2008	

PERFORMANCE DETAIL
INFECTIOUS DISEASES
IMMUNIZATION AND RESPIRATORY DISEASES

GOAL 1: REDUCE THE NUMBER OF INDIGENOUS CASES OF VACCINE-PREVENTABLE DISEASES.			
Measure	FY	Target	Result
	2006	15	9/2007
	2005	15	8 (Exceeded)
	2004	15	7(Exceeded)
	2003	15	7 (Exceeded)
		<i>Measles</i>	<i>Measles</i>
	2008	50	9/2009
	2007	50	9/2008
	2006	50	9/2007
	2005	50	42 (Exceeded)
	2004	50	10 (Exceeded)
	2003	50	32 (Exceeded)
		<i>Haemophilus influenzae</i>	<i>Haemophilus influenzae</i>
	2008	150	9/2009
	2007	150	9/2008
	2006	150	9/2007
	2005	150	226 b = unknown (Unmet)
	2004	150	196 b + unknown (Unmet)
	2003	175	259 b+unknown (Unmet)
		<i>Diphtheria</i>	<i>Diphtheria</i>
	2008	5	9/2009
	2007	5	9/2008
	2006	5	9/2007
	2005	5	0 (Exceeded)
	2004	5	0 (Exceeded)
	2003	5	0 (Exceeded)
		<i>Congenital rubella Syndrome</i>	<i>Congenital rubella Syndrome</i>
	2008	5	9/2009
	2007	5	9/2008
	2006	5	9/2007
	2005	5	0 (Exceeded)
	2004	5	0 (Exceeded)
	2003	5	1 (Exceeded)
		<i>Tetanus</i>	<i>Tetanus</i>
	2008	25	9/2009
	2007	25	9/2008
	2006	25	9/2007
	2005	25	5 (Exceeded)
	2004	25	6 (Exceeded)
	2003	25	6 (Exceeded)

GOAL 1: REDUCE THE NUMBER OF INDIGENOUS CASES OF VACCINE-PREVENTABLE DISEASES.			
Measure	FY	Target	Result
2. Reduce the number of indigenous cases of mumps in persons of all ages from 666 (1998 baseline) to 0 by 2010. [O] ⁵		<i>Mumps</i>	<i>Mumps</i>
	2008	200	9/2009
	2007	200	9/2008
	2006	200	9/2007
	2005	200	314 (Unmet)
	2004	200	258 (Unmet)
	2003	250	231 (Exceeded)
3. Reduce the number of indigenous cases of pertussis among children under 7 years of age. [O]		<i>Pertussis</i>	<i>Pertussis</i>
	2008	2,300	9/2009
	2007	2,300	9/2008
	2006	2,300	9/2007
	2005	2,300	7,347 (Unmet)
	2004	2,300	6,850 (Unmet)
	2003	2,500	3,719 (Unmet)
Data Source: National Notifiable Disease Surveillance System (NNDSS), National Congenital Rubella Syndrome Registry (NCRSR), Active Bacterial Core Surveillance (ABCs), Emerging Infections Programs.			
<p>Data Validation: NNDSS - CDC receives reports of notifiable diseases from the 50 state health departments, New York City, the District of Columbia, and five U.S. Territories. These reports are initiated when health care providers suspect or diagnose a case of a notifiable disease. Clinical laboratories also report results consistent with reportable diseases. Reporting of nationally notifiable diseases to CDC by the states is voluntary and only mandated (i.e., by state legislation or regulation) at the state level. All case reports, especially for low incidence and internationally quarantinable diseases, must be verified by the appropriate state officials. NNDSS case counts are likely incomplete, and therefore, these data are considered to represent a minimum number of cases. State reporting practices and some administrative procedures used in processing the NNDSS data may impact surveillance data reports and analyses. CDC staffs provide technical assistance relevant for data verification to ensure data accuracy, completeness, and timeliness. Specifically, assistance includes: computer specifications and software for reporting from state and territorial health departments, development and implementation of procedures to validate surveillance data, and identification of incomplete records, transmission errors, and deviations from expected numbers. NCRSR - CDC maintains the NCRSR with supplemental information to NNDSS. The registry includes data only on cases classified as confirmed or compatible. Cases are also classified as indigenous (exposure within the United States) and imported (exposure outside the United States) and are tabulated by year of birth. In contrast, cases reported to the NNDSS are tabulated by year of report. ABCs is an active laboratory and population-based surveillance system for invasive bacterial pathogens of public health importance, and currently operates in 10 sites in the U.S. For each case of invasive disease in the surveillance population, a case report with basic demographic information is completed and bacterial isolates are sent to CDC and other reference laboratories for additional laboratory evaluation. The ABCs program provides routine laboratory audits to ensure the completeness of data collection. Each month, CDC staff review data and communicate potential errors to state personnel for evaluation. Performance standards for active surveillance have been established in each site to permit aggregation of data collected via somewhat different approaches. Detailed instructions for completion of case report forms ensure consistency across sites. Timeliness and completeness of reporting in ABCs is evaluated using threshold percentages of isolate collection and enrollment into special studies. Surveillance "fatigue" or operational problems are assessed using isolate shipping schedules, audit sensitivities, and the timeliness of the audit data being completed by set deadlines.</p>			
Cross Reference: Measure 1 - HHS-1, HP-14.1a, 14.1b, 14.1c, 14.1e, 14.1h, 14.1i, 14.1j, PART, 500-1; Measure 2 - HHS-1, HP-14.1f, 500-1; Measure 3 - HHS-1, HP-14.1g, 500-1			

¹ All ages.

² Children under five years of age.

³ Persons under 35 years of age.

⁴ Children under one year of age. Result column indicates all cases – indigenous and imported. Imported cases will be differentiated in 2007, but those data are not yet available.

⁵ Results column indicates all cases – indigenous and imported. Imported cases will be differentiated in 2007, but those data are not yet available.

Goal 1, Performance Measure 1:

Haemophilus influenzae type B (Hib) – Conjugate vaccines for the prevention of Hib are highly effective. Hib is no longer the leading cause of meningitis among children younger than five years old in the U.S. The number of possible cases reported increased from 196 cases in 2004 to 226 cases in 2005, and the FY 2005 target of 150 cases remains unmet. In accordance with the Healthy People 2010 goal, this measure includes both type b cases (for which vaccine would be effective) and those with unknown serotypes. The number of cases with unknown serotypes that are actually type b cannot be confirmed. Neither Healthy People 2010 targets nor GPRA targets have been adjusted to account for cases with unknown serotype. Therefore, while this goal remains unmet, the actual number of type b cases (both serotyped and not) for which the vaccine would have been effective may have remained the same or even decreased; the increase in cases from 2004 to 2005 may be explained by these disease reporting challenges. To address this issue of incomplete serotyping, CDC is working with state partners to provide technical assistance for enhanced Hib surveillance and laboratory support.

Goal 1, Performance Measure 2:

Provisional data indicate that the mumps disease targets will not be met in 2005 or 2006 due to a large national mumps outbreak that began in December 2005 and continued through 2006. Although the highest number of cases was reported from states in the Midwest, most states reported increases in number of mumps cases. The majority of cases occurred among persons 18-25 years of age, many of these persons were vaccinated with two doses, reflecting the 90%-95% effectiveness of this vaccination schedule. As a result of this outbreak, vaccination recommendations were modified to better define evidence of immunity, ensure routine vaccination for health care workers, and address additional vaccination needs for persons in outbreak settings. Prior to 2004, there had been some progress in mumps disease reduction – reflected by a two-thirds reduction in cases from 1998 (666 cases) to 2003 (231 cases). However, the number of mumps cases in 2004 increased to 258 and CDC did not meet the 2004 goal of 200 cases.

Goal 1, Performance Measure 3:

Pertussis (whooping cough) is a highly contagious, vaccine-preventable bacterial illness characterized by prolonged and severe cough and sometimes pneumonia. Although pertussis affects all age groups, complications and death are most frequently recognized among unvaccinated infants. The 2005 target was to reduce the number of pertussis cases among children under seven years of age to 2,300. The actual number of cases in this age group was 7,347. Most of these cases occurred among children who are not fully protected from disease. Children are not fully protected until they receive four doses of the vaccine by 15-18 months. Many cases occur among infants who are exposed to disease before they receive their first vaccination at two months of age. Introduction in 2005 of adolescent and adult versions of improved acellular pertussis vaccines with tetanus and diphtheria booster (DTaP vaccine) provides new opportunities for reducing severe pertussis and its complications in all age groups in the U.S.

GOAL 2: ENSURE THAT 2-YEAR-OLDS ARE APPROPRIATELY VACCINATED.			
Measure	FY	Target	Result
1. Achieve or sustain immunization coverage of at least 90% in children 19- to 35-months of age for: -4 doses DTaP vaccine ¹ -3 doses Hib vaccine -1 dose MMR vaccine ² -3 doses hepatitis B vaccine -3 doses polio vaccine -1 dose varicella vaccine -4 doses pneumococcal conjugate vaccine (PCV7) ³	2008	90% coverage	8/2009
	2007	90% coverage	8/2008
	2006	90% coverage	8/2007
	2005	90% coverage	DTaP 86%; Hib 94%; MMR 92%; Hepatitis B 93%; Polio 92%; Varicella 88% (Exceeded, with the exception of DTaP and Varicella)
	2004	90% coverage	DTaP 86%; Hib 94%; MMR 93%; Hepatitis B 92%; Polio 92%; Varicella 88% (Exceeded, with the exception of DTaP and Varicella)

GOAL 2: ENSURE THAT 2-YEAR-OLDS ARE APPROPRIATELY VACCINATED.			
Measure	FY	Target	Result
	2003	90% coverage	DTaP 96%; Hib 94%; MMR 93%; Hepatitis B 92%; Polio 92%; Varicella 85% (Exceeded, with the exception of Varicella)
Data Source: Data are collected through the National Immunization Survey (NIS) and reflect calendar years.			
Data Validation: The NIS uses a nationally representative sample and provides estimates of vaccination coverage rates that are weighted to represent the entire population, nationally, and by region, state, and selected large metropolitan areas. The NIS, a telephone-based survey, is administered by random-digit-dialing to find households with children aged 19 to 35 months. Parents or guardians are asked about the vaccines—with dates—that appear on the child's "shot card" kept in the home; demographic and socioeconomic information is also collected. At the end of the interview with parents or guardians, survey administrators request permission to contact the child's vaccination providers. Providers are then contacted by mail to provide a record of all immunizations given to the child. Examples of quality control procedures include 100% verification of all entered data with a sub-sample of records independently entered. The quarterly data files are reviewed for consistency and completeness by CDC's National Immunization Program, Immunization Services Division - Assessment Branch and CDC's National Center for Health Statistics' (NCHS) Office of Research and Methodology. NCHS also conducts a separate qualitative assessment of 10% of the records. Random monitoring by supervisors of interviewers' questionnaire administration styles and data entry accuracy occurs daily. Annual methodology reports are available to the public for review.			
Cross Reference: HHS-1, HP-14.24a, PART, PAR, 500-1			

¹ Due to a shortage in vaccine and temporary change in recommendations, 3 doses were reported from 2002 – 2003.

² Includes any measles-containing vaccine.

³ Performance targets for any newly recommended vaccines, such as pneumococcal conjugate and influenza vaccines, are reported in GPRA five years after an ACIP recommendation is made and once NIS data become available. The timing of data availability may also be impacted by the age group for which that particular vaccine is recommended.

Goal 2, Performance Measure 1:

The ACIP Recommended Childhood and Adolescent Immunization Schedule recommends routine vaccination of children for the above diseases. The target of 90 percent coverage was met in 2005 for most vaccines with the exception of varicella and the fourth dose of DTaP.

In 2005, the coverage rate for four doses of DTaP containing vaccine did not yet achieve the 90 percent goal. However, the coverage rate for the fourth dose has steadily increased since the change to a four dose schedule, as recommended by the ACIP in 1991. The ACIP also recommends that a fifth dose be given to children between four and six years of age for full vaccination. This goal continues to be difficult to achieve because it requires that the fourth dose be given to the child between 15 and 18 months of age. The administration of DTaP tends to coincide with regular well-baby visits through the third dose; however, the fourth dose does not, requiring a visit specifically for this purpose. Coverage rates are 96 percent for the first three DTaP doses. Although the first three doses are considered to be most critical, CDC and the ACIP feel strongly that the fourth dose and also the fifth dose are important for full vaccination. Varying state requirements for the four-dose vaccine schedule may have also led to a slower increase in coverage. In 2002 and 2003, CDC modified reporting on DTaP from four doses to three doses because vaccine shortages limited the availability of the fourth dose. This change was made because the ACIP recommends that if this vaccine is in short supply, or not available, the fourth dose of DTaP may be dropped. The performance reporting change was temporary and reporting for the fourth dose has now been implemented.

Varicella is the most recently introduced vaccine that has a measurable target. Varicella vaccination rates are rising with coverage at only 43 percent in 1998 and reaching 88 percent in 2005. CDC is close to meeting the 90 percent varicella vaccines coverage goal, and is continuing to increase coverage. CDC/HHS and the ACIP recently made policy changes for the use of varicella (chickenpox) vaccine to include a recommendation for routine two-dose varicella vaccination of children. This new recommendation is expected to further reduce the number of cases and outbreaks of varicella in the United States.

The prevention of pneumococcal infections with PCV is becoming more important because of problems with treatment due to antibiotic resistance. The ACIP added PCV to the 2001 Recommended Childhood Immunization Schedule. Accountability for performance targets will begin with CY 2006 data which will not be available until the next budget cycle. The vaccination coverage level for PCV in 2005 is 83 percent for three doses.

GOAL 3: INCREASE THE PROPORTION OF ADULTS WHO ARE VACCINATED ANNUALLY AGAINST INFLUENZA AND EVER VACCINATED AGAINST PNEUMOCOCCAL DISEASE.			
Measure	FY	Target	Result
1. Increase the rate of influenza and pneumococcal vaccination in persons 65 years of age and older to 90% by 2010.	2008	Influenza 85% Pneumococcal 80%	1/2010
	2007	Influenza 74%; pneumococcal 69%	1/2009
	2006	Influenza 74%; pneumococcal 69%	1/2008
	2005	Influenza 74%; pneumococcal 69%	Influenza 59.6% (Unmet) pneumococcal 56.2% (Unmet)
	2004	Influenza 74%; pneumococcal 69%	Influenza 65% (Unmet); pneumococcal 57% (Unmet)
	2003	Influenza 74%; pneumococcal 69%	Influenza 66% (Unmet); pneumococcal 56% (Unmet)
2. Increase the rate of influenza and pneumococcal vaccination among non-institutionalized high-risk adults aged 18 to 64 years to 60% by 2010.	2008	Influenza 40%; pneumococcal 35%	1/2010
	2007	Influenza 32%; pneumococcal 22%	1/2009
	2006	Influenza 32%; pneumococcal 22%	1/2008
	2005	Influenza 32%; pneumococcal 22%	Influenza 25.3% (Unmet) pneumococcal 22.6% (Met)
	2004	Influenza 32%; pneumococcal 22%	Influenza 35% (Met); pneumococcal 21% (Unmet)
	2003	Influenza 32%; pneumococcal 22%	Influenza 34% (Met); pneumococcal 21% (Unmet)
Data Source: National Health Interview Survey (NHIS).			
Data Validation: NHIS is a cross-sectional household interview survey. Households chosen for interviews are a probability sample representative of the target population. The annual response rate is more than 90 percent of eligible households in the sample. NHIS has three modules: 1) The basic module remains largely unchanged from year to year and allows for trend analysis. Data from more than one year can also be pooled to increase the sample size for analytic purposes. The basic module contains a family core, a sample adult core, and a child core through which data are collected on the family unit and from one randomly selected adult and child. 2) Periodic modules collect more detailed information on some of the topics included in the basic module. 3) Topical modules respond to new data needs as they arise. Data are collected through a personal household interview conducted by staff employed and trained by the U.S. Bureau of the Census according to procedures delineated by CDC. Data are reviewed and analyzed extensively to ensure their validity and reliability. The survey sample is designed to yield estimates that are representative and that have acceptably small variations. Before the actual survey, cognitive testing is performed by CDC's Questionnaire Design Research laboratory, and pretests are conducted in the field. Once collected, data are carefully edited, checked, and compared to data from earlier surveys and/or independent sources. Staff members calculate descriptive statistics and perform in-depth analyses, which result in feedback on the analytic usefulness of the data.			
Cross Reference: <u>Measure 1</u> - HHS-1, HP-14.29a, 14.29b, 500-1; <u>Measure 2</u> - HHS-1, HP-14.29c, 14.29d, 500-1			

Goal 3, Performance Measure 1:

During the past decade, vaccination coverage levels among older adults increased steadily as CDC implemented national strategies and promoted adult and adolescent immunization among healthcare providers and state and local governments. Influenza vaccination coverage levels among the elderly have increased from 30 percent in 1989 to 65 percent in 2004. However, data suggest that influenza vaccination levels may have reached a plateau, and in 2005 a decrease to coverage of 60 percent was observed. This is most likely related to unprecedented shortages of influenza vaccination in the 2004-2005 season and delays of influenza vaccinations in the 2005-2006 seasons.

Despite recent vaccine availability issues, the increase in vaccination coverage began to slow before 2000. The plateau is not fully understood. Because large gaps remain between existing coverage levels and some of the targets for subsequent years, CDC has decided to maintain an influenza vaccination target of 74 percent for 2005, 2006 and 2007. There was an increase in vaccine supply to over 100 million doses in the 2006-2007 influenza season, and it is anticipated that supply will continue to increase in upcoming years. CDC and partners such as the National Influenza Vaccine Summit will continue to aggressively promote vaccination. Additionally, the FY 2007 and FY 2008 President's Budgets request funds to increase demand for influenza vaccine. Therefore, CDC has increased the target in 2008 to 85 percent coverage for influenza vaccination.

An increasing proportion of older adults also reported receipt of pneumococcal vaccination, from 15 percent in 1989 to 57 percent in 2004. Although the proportion of older adults receiving pneumococcal vaccine in 2005 (56.2%) remained consistent with the 2004 result, in neither year was the goal of 69% met. Adult vaccination rates are slowly increasing, and CDC has worked with the Centers for Medicaid and Medicare Services to raise the reimbursement rate for influenza and pneumococcal vaccines. Similar challenges apply to pneumococcal vaccination in adults as influenza vaccination. Because large gaps remain between existing coverage levels and some of the targets for subsequent years, CDC has decided to maintain the same targets for 2005, 2006 and 2007 for pneumococcal vaccination in this age group. However, due to an anticipated increase in aggressive vaccine promotion efforts, especially focused on influenza vaccination, but also including messages about pneumococcal vaccination, CDC has raised the 2008 goal to 80 percent.

Goal 3, Performance Measure 2:

The ACIP Recommended Adult Immunization Schedule recommends vaccination for influenza for adults at high risk of complications each year and pneumococcal vaccination for those persons at high risk. Current levels of coverage among adults vary widely among different age, risk, and racial and ethnic groups. High-risk adults aged 18 to 64 years may not have insurance coverage for influenza and pneumococcal vaccines, may make fewer visits for preventive care, and may not recognize they are recommended to receive influenza and pneumococcal vaccinations. Persons with high-risk conditions, such as heart disease and diabetes, remain at increased risk from these diseases. For this population of high risk adults 18 to 64 years of age, the pneumococcal vaccination goal of 22% has been met. However, as was noted for adults 65 years of age and older, a decrease in influenza vaccine coverage was seen in 2005 for the 18 to 64 year old population. It is likely that issues with vaccine availability, distribution, and recognition of priority group recommendation affected coverage status.

GOAL 4: PROTECT AMERICANS FROM INFECTIOUS DISEASES – INFLUENZA			
Measure	FY	Target	Result
1. By 2010, enhance preparedness for pandemic influenza by establishing influenza networks globally through bilateral cooperative agreements that are actively producing usable samples for testing as measured by geographic and population coverage.	<i>2008</i>	20 networks	12/2008
	<i>2007</i>	20 networks	12/2007
	<i>2006</i>	9 networks	13 (Exceeded)
	<i>2005</i>	9 networks	12 (Exceeded)
	<i>2004</i>	N/A	9 networks; 1 with 100% geographic coverage and 70% population coverage; 8 with 10-40% geographic coverage and 10-40% population coverage per country network.
	<i>2003</i>	Baseline	1 network; 60% geographic coverage; and, 60% population coverage per country network
Data Source: International bi-lateral cooperative agreement data and specimens received through the WHO Global Influenza Surveillance Network.			
Data Validation: CDC provides on-site technical assistance and review and analyzes the data for submittal of influenza samples and isolates for seasonal and pandemic influenza. Given that global coverage is necessary for both routine influenza virus monitoring and development of capacity to identify avian influenza for containment and response, ability to test of avian and other influenza and submit timely specimens is critical. Increasing geographic participation and enhancing capacity in more countries greatly increases the probability of detecting a case or cluster of H5N1.			
Cross Reference: HHS-4, 5, PART, 500-4			

Goal 4, Performance Measure 1:

This measure tracks CDC's efforts to increase the number of influenza networks globally to enhance early detection of viruses with pandemic potential and improve vaccine decision-making. Early detection of pandemic viruses will benefit the international community by allowing the maximum lead time possible to develop pandemic vaccines, thus reducing morbidity and mortality globally. The accomplishment of this measure will also establish the influenza surveillance foundation necessary to conduct influenza burden studies, formulate vaccine policy, and reduce illness due to influenza through vaccination. Ideally, a network will be a nationwide system developed to collect virologic and epidemiologic data for influenza by establishing five or more sites with good distribution throughout the country. Each site will consist of a local laboratory and one or more clinics or hospitals for data collection. However, some flexibility of this definition may be needed based on geographic and resource considerations.

Currently, CDC supports 13 influenza surveillance networks globally through cooperative agreements. Support is provided through on-site training, the provision of technical assistance, and funding for equipment and supplies. As part of the overall plan to develop networks in Asia, key staff have been located in Asia with CDC assignments to Vietnam, Laos, Cambodia and the Western Pacific Office of WHO. CDC provides technical assistance and support for enhancing or developing influenza surveillance networks. In addition, CDC provides support and assistance to foreign governments for the establishment of surveillance networks in Cambodia, Korea, Indonesia, Pakistan, India, Philippines, Thailand, Mongolia, Malaysia, China Vietnam, Kazakhstan and Pacific Public Health Surveillance Network (a consortium of seven countries and territories including Cook Islands, Fiji, Guam, Wallis and Futuna, Palau and Tonga). Finally, CDC provided critical support to partners in Department of Defense (DOD) at both Naval Medical Research Unit (NAMRU)-2 in Jakarta and NAMRU3 in Cairo. The collaborations enhance technical assistance regionally and improve sharing of international specimens. Expansion of the bilateral cooperative agreements in FY 2007 is planned with a focus on countries outside of Asia affected by avian influenza.

GOAL 5: PROTECT AMERICANS FROM INFECTIOUS DISEASES - PNEUMOCOCCAL DISEASE.				
Measure	FY	Target	Result	
1. By 2010, reduce the rates of invasive pneumococcal disease in children under 5 years of age to 46 per 100,000 and in adults aged 65 years and older to 42 per 100,000. [O]		<i>Children under 5 years of age</i>	<i>Children under 5 years of age</i>	
	2008	46	6/2009	
	2007	47	6/2008	
	2006	48	6/2007	
	2005	50	21.3 (Exceeded)	
			<i>Adults 65 years and older</i>	<i>Adults 65 years and older</i>
	2008	42	6/2009	
	2007	45	6/2008	
	2006	47	6/2007	
	2005	55	38.8 (Met)	
Data Source: The Active Bacterial Core surveillance (ABCs)/ Emerging Infections Program Network.				
Data Validation: The data are collected by 10 states through active contact with all clinical laboratories in population catchment areas; the data are sent to CDC monthly for review, editing and cleaning. States conduct audits for missed cases either monthly or in some cases bi-yearly. Pneumococcal isolates are collected and validated at three quality-controlled reference laboratories.				
Cross Reference: HHS-1, HP-14.5, PART				

Goal 5, Performance Measure 1:

Incidence of pneumococcal disease fell between 2001 and 2005. These data indicate that CDC is on track to reach disease reduction targets. Progress is aided by the introduction of the pneumococcal conjugate vaccine that was licensed for use in children in the U.S. in 2000. Vaccinating children has reduced disease in adults through reduced transmission. However, some challenges remain. Supplies of the conjugate vaccine were inadequate between 2001 and 2004. CDC has worked with the vaccine manufacturer, ACIP, and professional organizations to promote optimal and equitable use of vaccine during times of shortage. Vaccine supply is now adequate. However, a small increase in disease caused by strains not covered by the pneumococcal conjugate vaccine has been detected, and CDC is monitoring trends in these strains.

GOAL 6: IMPROVE VACCINE SAFETY SURVEILLANCE.			
Measure	FY	Target	Result
1. Improve capacity to conduct immunization safety studies by increasing the total population of managed care organization members from which the Vaccine Safety Datalink (VSD) data are derived annually to 13 million by 2010.	<i>2008</i>	11 million	6/2009
	<i>2007</i>	10 million	6/2008
	<i>2006</i>	10 million	6/2007
	<i>2005</i>	10 million	9.0 million (Unmet)
	<i>2004</i>	10 million	7.5 million (Unmet)
	<i>2003</i>	10 million	7.5 million (Unmet)
	<i>2002</i>	Baseline	7.5 million
Data Source: VSD			
Data Validation: Annual reports and other published information from the VSD-participating managed care organizations.			
Cross Reference: HHS-1, 2, 4, HP-14.31, 500-3			

Goal 6, Performance Measure 1:

The VSD is a collaborative effort involving CDC and several large managed care organizations (MCOs). The VSD was established primarily to assess immunization safety issues in the U.S. by conducting scientific studies utilizing a large-linked database (LLD) that incorporates administrative data sources at each MCO and also utilizing additional site resources such as medical charts. Each participating site gathers information regarding the vaccination and medical records of millions of children and adults. Collectively, the data from VSD studies are derived from participating MCOs that contain more than nine million members, of which the VSD project collects comprehensive medical information for more than 5.5 million people annually. The VSD enables population-based immunization and safety research studies to compare the incidence of health problems between vaccinated and unvaccinated people. The performance target for this goal was not met in FY 2005 because increasing populations in LLDs is contingent on cooperating entities, resources, and technologies. This performance measure reflects only one aspect of CDC's immunization safety surveillance; CDC's immunization safety activities are not limited to this one project.