

Appendix 2: 1994 National Vaccine Plan Objectives and Progress

Updated April 2010

Reviewed January 2011

The 1994 National Vaccine Plan, which preceded the 2010 National Vaccine Plan, included measurable predicted outcomes to be achieved by the year 2000. The predicted outcomes and progress on achieving each as of April 2010 are listed below. More information on the predicted outcomes of the 1994 National Vaccine Plan is available at http://archive.hhs.gov/nvpo/vacc_plan/vacc_planp65.htm.

Anticipated Outcome: Age-appropriate immunization with all recommended vaccines will be extended to at least 90% of infants and children, and access to affordable vaccination services will be made available for every person in the United States.

Status as of April 2010:

- $\geq 90\%$ coverage for all routinely recommended childhood vaccines that have been licensed for >5 years except for diphtheria, tetanus, and acellular pertussis vaccine (DTaP) (4 doses – 84.6%) and pneumococcal conjugate vaccine (80.1%).¹
- The Vaccines for Children (VFC) program has enhanced coverage levels in children. 43% of U.S. children are receiving vaccines through the VFC program that was first implemented in 1994. Coverage levels for 19-35-month old children in the VFC program and outside of it are similar. Financial barriers to access still exist among children who are underinsured and not eligible for the VFC program.
- Financial barriers to access exist among adults <65 years who are uninsured, underinsured, or whose health insurance coverage does not include vaccinations or includes a high co-pay. Medicare part D to date has a complex payment mechanism for vaccination.

Anticipated Outcome: Diphtheria, tetanus, poliomyelitis, measles, rubella mumps, some forms of hepatitis, pertussis (whooping cough), and bacterial meningitis (from *Haemophilus influenzae* type b) will be essentially eliminated as significant causes of death, disease and disability in the United States.

Status as of April 2010:

- Diphtheria, tetanus, poliomyelitis, rubella, and invasive Hib disease, including meningitis have been virtually eliminated in the U.S.
Compared to pre-vaccine era estimates:
- Hepatitis A and B have declined 89% and 81%, respectively.^{2,3}

¹ Centers for Disease Control and Prevention. National Immunization Survey 2008. Available at: http://www2a.cdc.gov/nip/coverage/nis/nis_iap2.asp?fmt=v&rpt=tab02_antigen_iap&qtr=Q1/2008-Q4/2008.

²Rousch SW, Murphy TV; Vaccine-Preventable Disease Table Working Group. Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. JAMA 14 Nov 2007;298(18):2155-63.

³ Centers for Disease Control and Prevention. Notifiable Diseases/Deaths in Selected Cities Weekly Information. MMWR 8 Jan 2010;58(51&52):1458-1469.

- Despite greater than an estimated 93% reduction in cases, pertussis continues to occur endemically and in outbreaks.^{2,3}
- Despite an estimated 99% reduction in cases for both measles and mumps, sporadic outbreaks continue to occur.^{2,3}
- Vaccine-type invasive pneumococcal disease has been reduced by 30% in all ages.^{2,4}
- Estimated varicella illnesses have been reduced by 89%.^{2,3}

Anticipated Outcome: Educational communication networks will be in place that will inform all healthcare providers, communities, and families of the benefits and risks of vaccination.

Status as of April 2010:

- Vaccine Information Statements, by law, are to be provided to all vaccine recipients receiving vaccines covered under National Childhood Vaccine Injury Act, informing them about benefits and risks of vaccination.
- Information on vaccine benefits and risks is available on a variety of relevant federal websites.
- While no single educational communication network exists that actively reaches out to and informs all healthcare providers, families, and communities about vaccine benefits and risks, internet-based information is significantly more available than it was in 1994. For example, for providers, the American Academy of Pediatrics and the American Academy of Family Physicians newsletters and email blasts constitute a network, as does the Infectious Diseases Society of America's similar capacity with members. The Centers for Disease Control's Immunization Works is a regular effort to update programs and partners, and the Department of Defense's Milvax internet site has abundant information about their vaccination programs.

Anticipated Outcome: Globally, polio will be drastically reduced with a target to eliminate the disease, and neonatal tetanus and measles will be better controlled.

Status as of April 2010:

- Polio cases have been reduced to 1,606 in 2009⁵ from an estimated 9,000 in 1994⁶ and an estimated 350,000 in 1988.⁷

² Rousch SW, Murphy TV; Vaccine-Preventable Disease Table Working Group. Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. *JAMA* 14 Nov 2007;298(18):2155-63.

³ Centers for Disease Control and Prevention. Notifiable Diseases/Deaths in Selected Cities Weekly Information. *MMWR* 8 Jan 2010;58(51&52):1458-1469.

⁴ Centers for Disease Control and Prevention. Active Bacterial Core surveillance Report: *S. pneumoniae*, 2008. Available at: <http://www.cdc.gov/abcs/reports-findings/survreports/spneu08.pdf>.

⁵ Global Polio Eradication Initiative. Wild Poliovirus Weekly Update 9 Mar 2010. Available at: <http://www.polioeradication.org/casecount.asp>.

⁶ World Health Organization. Poliomyelitis global annual reported cases and Pol3 coverage, 1980-2008. WHO/IVB database, 2009. Available at: http://www.who.int/immunization_monitoring/diseases/Polio_coverage.gif.

⁷ Centers for Disease Control and Prevention. Notice to Readers: 50th Anniversary of the First effective Polio Vaccine-April 12, 2005. *MMWR* 8 Apr 2005;54(13):335-336.

- Measles cases have been reduced 78% worldwide between 2000-2008. In 2008, there were 164,000 global measles deaths.⁸
- Maternal and neonatal tetanus has been eliminated in 16 African countries by the end of 2008, with 8 more countries expected for 2009 (to be validated).⁹

Anticipated Outcome: Pneumococcal pneumonia and influenza in American adults over the age of 65 will be significantly reduced.

Status as of April 2010:

- Since 1999, pneumonia and influenza rates among older adults have dropped slightly in those 65-84 years, and to a greater extent in those 85 years and older.¹⁰ The disease burden and vaccine effectiveness for influenza can vary substantially from one year to the next, and annual vaccination is required to provide protection. Impact of the influenza vaccination program must be measured within individual influenza seasons, as opposed to being considered over a several year period as with other vaccine-preventable diseases where the vaccine provides long-term protection and/or prevents carriage of the pathogen.
- Annual influenza vaccination coverage among adults ≥ 65 years old has increased to more than 65%.¹¹ The Centers for Medicare and Medicaid Services has likely assisted in raising coverage in older adults by quadrupling its vaccine administration payment since 1994.¹²
- Studies of pneumococcal vaccination in adults have shown some effectiveness in preventing invasive pneumococcal disease, but no impact on the occurrence of pneumococcal pneumonia in older adults; however, childhood pneumococcal vaccination is assumed largely responsible for the drop in older adult invasive pneumococcal disease, from 61.7/100,000 in 1997¹³ to 40.4/100,000 in 2008.⁴

Anticipated Outcome: A nationwide surveillance system will report and investigate cases of vaccine-preventable diseases.

Status as of April 2010:

- Most vaccine preventable diseases are notifiable diseases; however, the completeness of reporting in this “passive” surveillance system varies.
- Case-investigations occur for some, less common vaccine preventable diseases.

⁸ World Health Organization. Measles: Key Facts, revised December 2009. Fact sheet no. 286. Available at: <http://www.who.int/mediacentre/factsheets/fs286/en/index.html>.

⁹ World Health Organization African Region. Maternal and Neonatal Tetanus elimination Programme. Available at: <http://www.afro.who.int/en/divisions-a-programmes/ddc/immunization-and-vaccines-development/programme-components/maternal-and-neonatal-tetanus-elimination.html>. Accessed 18 Mar 2010.

¹⁰ Centers for Disease Control and Prevention. National Vital Statistics Reports 24 April 2008;56(10). Table 9: Death rates by age and age-adjusted death rates for the 15 leading causes of death in 2005: United States, 1999-2005.

¹¹ Centers for Disease Control and Prevention. Vaccination coverage estimates from the National Health Interview Survey: United States, 2008. Available at: http://www.cdc.gov/nchs/data/hestat/vaccine_coverage.htm.

¹² Centers for Medicare and Medicaid Services, unpublished data.

¹³ Centers for Disease Control and Prevention. Active Bacterial Core surveillance Report: *S. pneumoniae*, 1997. Available at: <http://www.cdc.gov/abcs/reports-findings/survreports/spneu97.pdf>.

- Complete reporting (“active” surveillance) and investigation occur for some vaccine preventable diseases in certain geographical areas.

Anticipated Outcome: Vaccine safety and efficacy will be continuously monitored, and adverse events following immunization will be reported and carefully analyzed.

Status as of April 2010:

- The Vaccine Adverse Events Reporting System is a national system that continuously monitors adverse events reported by healthcare providers, manufacturers or the public.
- Other systems exist to do active surveillance, clinical assessment of persons with suspected adverse events following vaccination, and study design and implementation.

Anticipated Outcome: Improved vaccines will replace some of the vaccines in current use.

Status as of April 2010:

- Diphtheria, tetanus, and acellular pertussis vaccine (DTaP) has replaced diphtheria, tetanus, and pertussis (DTP) vaccines to reduce adverse events.
- Tetanus, diphtheria, and acellular pertussis (Tdap) vaccine has replaced tetanus and diphtheria toxoids (Td) to address pertussis in older ages.
- Inactivated poliovirus vaccine (IPV) has replaced oral poliovirus vaccine (OPV) to eliminate the risk of vaccine-associated paralytic poliomyelitis.
- *Haemophilus influenzae* (Hib) and pneumococcal conjugate vaccines have replaced polysaccharide vaccines in infants and children to increase effectiveness.
- Meningococcal conjugate vaccine has replaced the polysaccharide vaccine in children to increase effectiveness.

Anticipated Outcome: Some vaccines requiring multiple doses and multiple contacts with the health care system will be replaced by more cost-effective ones that will improve people's access to immunization.

Status as of April 2010:

- Combination vaccines have been licensed that reduce the number of injections needed to completely vaccinate infants and children, such as DTaP/Hib/Hepatitis B.
- Use of combination vaccines has not clearly increased cost-effectiveness because of higher pricing for some these products, compared to the separate vaccines, and has not affected access to immunization.

Anticipated Outcome: Many new vaccines will be developed or be much closer to licensure, for diseases for which effective vaccines do not now exist.

Status as of April 2010: Since 1994, new vaccines have been licensed and recommended for routine use against varicella, hepatitis A, pneumococcal conjugate, rotavirus, influenza, herpes zoster, and human papillomavirus.

Anticipated Outcome: New mechanisms for the more rapid assessment of vaccines proposed for licensure will be in place.

Status as of April 2010:

- Mechanism to use immune endpoint surrogates is reasonably likely to predict clinical benefit created by regulation, and has been utilized to increase influenza vaccine supply.
- Mandated under the Modernization Act in 1997, guidance for fast track designation and priority review policies were written, and have been used for vaccines. More than a dozen guidances have been issued to industry since 1994.¹⁴ The former allows for more frequent interactions with the Food and Drug Administration (FDA) during development; the latter allows 6-month review of an application versus 10-month review for a product for serious or life-threatening disease. Initial fast track draft guidance was published in 1998; final guidance was issued July, 2004.¹⁵

Anticipated Outcome: A reliable supply of all recommended vaccines and a capability to respond to emergencies and emergent threats to public health will be achieved and sustained.

Status as of April 2010:

- Supply shortages for a number of routinely recommended vaccines have occurred since 2000 (e.g., pneumococcal conjugate, influenza, meningococcal conjugate, Hib, varicella, Td).
- As a result of FDA initiatives (including provision of accelerated approval based on a likely surrogate) and intense interaction with manufacturers, supplies of influenza vaccine and number of U.S. manufacturers have doubled from 2004 to 2008. During this time, the number of U.S. licensed influenza vaccine manufacturers increased from two to six.¹⁵
- Stockpiles of routinely recommended vaccines for children have been established to mitigate the risk of shortages.
- Emergency response capacity for vaccination is being established by state and local health departments.
- Stockpiles of, and/or production plans for, pre-pandemic influenza vaccines, and smallpox and anthrax vaccines are in place.

Anticipated Outcome: Information on the costs and benefits of the national vaccine program will be made available on an ongoing basis to the American people.

Status as of April 2010:

- Cost-effectiveness analyses of the childhood schedule through vaccines routinely recommended in 1999 have been disseminated. Routine childhood immunization with the seven vaccines then recommended saved an estimated 9.9 billion dollars in direct costs and 43.3 billion dollars in societal costs.¹⁶ Several studies have demonstrated the

¹⁴ Food and Drug Administration, unpublished data.

¹⁵ Congressional Research Service Report for Congress. FDA Fast Track and Priority Review Programs. 21 Feb 2008. Available at: <http://www.nationalaglawcenter.org/assets/crs/RS22814.pdf>.

¹⁶ Zhou F, Santoli J, Messonnier ML, *et al*. Economic evaluation of the 7-vaccine routine childhood immunization schedule in the United States, 2001. *Arch Pediatr Adolesc Med* 2005 Dec;159(12):1136-44.

cost-effectiveness of several vaccines in adults, such as influenza,¹⁷ pneumococcal polysaccharide,¹⁸ and pertussis.¹⁹

¹⁷ Maciosek MV, Solberg LI, Coffield AB, *et al.* Influenza Vaccination: Health Impact and Cost Effectiveness Among Adults Aged 50 to 64 and 65 and Older. *Am J Prev med* 2006;31(1):72-79.

¹⁸ Ogilvie I, Khoury AE, Cui Y, *et al.* Cost-effectiveness of pneumococcal polysaccharide vaccination in adults: a systematic review of conclusions and assumptions. *Vaccine* 6 Aug 2009;27(36):4891-904.

¹⁹ Lee GM, Murphy TV, Lett S, *et al.* Cost effectiveness of pertussis vaccination in adults. *Am J Prev Med* Mar 2007;32(3):186-193.