

**National Vaccine Plan  
Draft Framework-16 July 2008**

**Goal 4**

Points to note about the draft (from the National Vaccine Program Office):

- All milestones in this goal are considered short term (i.e., to be accomplished in less than 5 years)
- The relevant priority areas, presented to the Committee in March, addressed by each objective, are listed before the objective or group of objectives.
- Later versions will offer an introduction or preface, to put the Objectives, Strategies, and Milestones into more context. The CDC and FDA presentations at the meeting next week will offer much of that context.
- We were not able to address all the recommendations from the June 11 letter report from the expert committee. For example, the roles of non-federal stakeholders have yet to be defined, and not all potential federal collaborators are identified.
- Subsequent to the meeting, NVPO will convene a series of internal meetings to incorporate further revisions in this Goal, and complete the other Goals of the revised Plan, for completion by the end of September and submission to the Committee upon the Department's approval.

DRAFT

**National Vaccine Plan  
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**Goal 4: Achieve better use of existing vaccines to prevent disease, disability, and death in the United States.**

**Priorities: Vaccine Supply, Financing** (Assigned to lead: CDC; collaborators FDA, NVPO)

**Objective 4.1** –Ensure a consistent availability of vaccines for the United States to mitigate the impact of vaccine shortages

Strategy #1: Review and modify VFC and program policies to enhance vaccine accountability.

Milestone: Disseminate new program policy guidance to immunization programs and evaluate impact of the policies.

Strategy #2: Sustain stockpiles of all vaccines included in the Vaccines for Children program for the purposes of fighting outbreaks of vaccine preventable disease and for the maintenance of a vaccine supply in case of manufacturing disruption.

Milestone: Optimize the content of the pediatric vaccine stockpile;

Milestone: Establish criteria and process for use of the pediatric stockpile;

Strategy #3: Develop recommendations and policies for mitigating vaccine shortages using the best available clinical and epidemiologic data available.

Strategy #4: Develop guidance on the management of vaccine administration errors and vaccine storage and handling exceptions. Consider supporting the management guidance with a reporting system to track the types of vaccine administration errors that occur and to facilitate evaluation of the management guidance.

Milestone: Publish the guidance developed.

Strategy #5: Centralize the distribution of vaccines purchased through the CDC vaccine contracts as an efficient means of rapidly distributing vaccine to immunization providers, assuring visibility of vaccine as it is distributed, management of vaccine shortages, management of vaccine stockpiles, and the management of vaccines used under special circumstances such as an influenza pandemic.

Milestone: Distribute all CDC contract vaccine through the CDC-contracted vaccine distributor.

Strategy #6: Develop a provider-level vaccine ordering system to support public sector purchase of vaccines to all immunization providers, public and private. The ordering system should facilitate the maintenance of reasonable provider inventories of vaccine, the management of vaccines allocated because of shortage, and the linkage to Immunization Information Systems.

Milestone: Implement the new vaccine ordering/management system.

Strategy #7: Improve product quality and availability through better manufacturing and production oversight.

Milestone: FDA will hire staff by FY09 to develop methods and procedures for monitoring supply and evaluating adequacy of supply, monitoring supply and taking steps to rectify as needed.

Milestone: NVPO will establish of a vaccine supply coordinating committee by 2010 as a central point of contact for manufacturers and to coordinate necessary actions.

Milestone: NVPO, in collaboration with FDA, CDC, and other partners, will create an incentive program by 2012 to ensure retention of vaccine manufacturers.

Milestone: FDA will enhance outreach relevant to current Good Manufacturing Practice (CGMP) for vaccines by conducting and participating in meetings and workshops at least twice yearly to communicate regulatory expectations, promote the use of robust quality systems, and elicit meaningful dialogue with industry and foreign regulatory counterparts on CGMP issues.

Milestone: FDA will evaluate current regulations, guidance documents, policies and procedures within the next five years that are relevant to manufacturing and product evaluation to determine enhancements that could be made to improve product quality and availability via regulatory mechanisms.

Milestone: FDA will engage with licensed and new manufacturers to establish or expand facility capacity; including meetings and strategically timed site visits to advise on CGMP practice and design of facilities.

Strategy #8: FDA will support and assess adoption of new analytical and manufacturing control technologies and systems such as Process Analytical Technology (PAT) to enhance medical product quality.

Milestone: FDA will upgrade computer databases by the end of 2009 to track the number of meetings with industry as well as regulatory applications relevant to new manufacturing and control technologies and analytical methods for vaccine manufacturing.

Milestone: By 2015, FDA will assess the industry over the next five years to determine the impact of new analytical and manufacturing control technologies and systems.

Milestone: By 2015, FDA will evaluate regulatory mechanisms (e.g., current regulations, guidance documents, policies and procedures) relevant to manufacturing and product evaluation to determine enhancements that could facilitate adoption of new analytical and manufacturing control technologies.

**Objective 4.2-** Ensure access to vaccines for all children and adolescents without financial barriers (Assigned to lead: CDC)

Strategy #1: Improve access to vaccinations through the public sector

**Milestones (adapted from draft recommendations of the National Vaccine Advisory Committee's Financing Working Group, April, 2008)**

1. Prepare an annual report on the size and scope of 317 program appropriations needed and submit to Congress for review
2. HHS will encourage state and local governments and professional organizations to increase outreach to medical providers who currently serve VFC eligible children/adolescents to encourage these providers to participate in VFC
3. HHS will encourage all states and localities to develop mechanisms for billing insured children and adolescents served in the public sector, if feasible
4. HHS will continue to collect and publish data on the costs associated with public and private vaccine administration and the cost savings due to disease prevention
5. HHS will calculate the marginal increase to insurance premiums to insurance plans of including all routine--ACIP recommended vaccines

Strategy #2: Improve access to vaccination through the private sector

**Milestones: (adapted from draft recommendations of the National Vaccine Advisory Committee's Financing Working Group, April, 2008)**

1. HHS will encourage vaccine manufacturers and third party distributors to work on an individual basis with providers to reduce the financial burden for initial and ongoing vaccine inventories
2. HHS will encourage professional medical organizations to provide their members with technical assistance on efficient business practices associated with providing immunizations such as how to contract and bill appropriately
3. HHS will encourage medical providers (especially small practices to participate in pools of vaccine purchasers to obtain volume ordering discounts
4. HHS will encourage health insurers and all private payers of health care to adopt contract benefit language that is flexible enough to permit coverage and reimbursement for new or recently altered ACIP recommendations as well as vaccine price changes that occur in the middle of a contract period
5. HHS will support incentives for the receipt of immunizations by recommending that health insurers and purchasers of health care eliminate co--pays and deductibles for vaccination for all routinely recommended ACIP vaccines in their plans
6. HHS will encourage health insurers and purchasers of health care to reimburse for vaccinations in their plans based on methodologically sound cost studies of efficient practices
7. HHS will encourage professional medical organizations and other relevant stakeholders to develop and support additional employer health education efforts on value of prevention including vaccines
8. HHS will continue to collect and publish data on the costs associated with public and private vaccine administration and the cost savings due to disease prevention (See also objective 3.3)

**Priority: Surveillance of immunization coverage levels (Assigned to lead: CDC)**

**Objective 4.3** – Maintain and enhance the capacity to monitor immunization coverage for vaccines routinely administered to infants, children, adolescents, and adults.

Strategy #1: Monitor vaccination coverage among children of vaccines recommended for routine use by ACIP/CDC at the national level and at the level of the state and urban area Section 317 program grantees. The coverage monitoring is to provide a basis for assessing population protection, program accountability, and program planning.

Milestone: Publish coverage levels annually.

Strategy #2: Monitor vaccination coverage among adolescents of vaccines recommended for routine use by ACIP/CDC at the national and state levels to provide a basis for assessing population protection, program accountability, and program planning.

Milestone: Publish coverage levels annually.

Strategy #3: Monitor vaccination coverage among adults of vaccines recommended for routine use by ACIP/CDC at the national and state levels to provide a basis for assessing population protection, program accountability, and program planning.

Milestone: Publish coverage levels annually.

Strategy #4: Conduct research on cost effective methods for assessing vaccination coverage levels to assure continuing coverage monitoring in the face of a changing personal communication environment, such as the increased use of cell phones substituting for land-line telephones.

Milestone: Develop options for monitoring systems that are viable in the changing personal communication environment.

Strategy #5: Develop the capacity to use Immunization Information Systems for the assessment of small area variation of vaccination coverage levels and the identification of communities with underimmunized individuals and individuals immunized with alternative schedules.

Milestone: Incorporate a measure of immunization record completeness into objectives and goals for immunization information system participation.

Strategy #6: Develop the capacity to use Immunization Information Systems (IIS) to monitor the uptake of newly introduced vaccines and new immunization recommendations. Use IIS to monitor the adoption of temporary immunization recommendations necessary for the management of a vaccine shortage.

Milestone: Support sentinel registry sites to explore methods for using IIS to monitor the uptake of newly recommended vaccines.

**Priorities:** Childhood Immunization (Assigned to lead: CDC; collaborator CMS)

**Objective 4.4** – Achieve immunization coverage targets for infants and children.

Priority: Childhood vaccines

Strategy #1: Identify barriers to immunization services and utilization of routinely recommended and new childhood vaccines and develop strategies to address them.

Milestone: Assess parental concerns at the national level about the safety of childhood vaccines through the annual HealthStyles survey

Milestone: Monitor parental concerns at the national and state levels, linked with immunization coverage of children, through the vaccine acceptance module of the National Immunization Survey

Milestone: Develop and evaluate a toolkit to assist providers in addressing parental concerns

Strategy #2: Monitor the use of evidence-based interventions designed to raise and sustain high vaccination coverage among children.

Milestone: Develop measures indicating the extent of use of evidence-based interventions.

Strategy #3: Identify effective methods of raising and sustaining vaccination coverage levels and implementing new vaccines and disseminate results.

Milestone: Support research to evaluate strategies to increase vaccination coverage among children.

Milestone: Disseminate research findings through peer-reviewed journals, conferences, and grantee communication to facilitate implementation of evidenced-based strategies.

Milestone: Update the vaccine-preventable diseases chapter for the Guide to Community Preventive Services.

Strategy #4: Work with state and large urban area immunization programs to monitor the capacity of the primary care system to vaccinate children with recommended vaccines, and identify a sufficient number of providers, traditional and non-traditional, to vaccinate all U.S. children.

Milestone: Develop measures for assessing community immunization capacity.

**Priority: Adolescent Immunization** (Assigned to lead: CDC; collaborators CMS, [VA, DoD])

**Objective 4.5** – Achieve immunization coverage targets for adolescents 11-21 years of age.

Strategy #1: Identify, implement, and evaluate evidence-based strategies to increase vaccination coverage among adolescents.

Milestone: Support research to evaluate strategies to increase vaccination coverage among adolescents.

Milestone: Disseminate research findings through peer-reviewed journals, conferences, and grantee communication to facilitate implementation of evidenced-based strategies.

Strategy #2: Work with state and large urban area immunization programs to monitor the capacity of primary health care providers, in public and private settings, to vaccinate adolescents with recommended vaccines. Identify drivers and barriers that may need to be addressed to increase primary care providers' effectiveness in vaccinating this population.

Milestone: Support research to evaluate capacity of primary health care providers to implement adolescent vaccine recommendations.

Strategy #3: Identify settings complementary to primary care with capacity to vaccinate adolescents effectively and appropriately with recommended vaccines.

Milestone: Support research to identify complementary settings with the capacity to vaccinate adolescents.

Milestone: Enroll complementary settings into the Vaccines for Children Program.

Milestone: Monitor delivery of vaccine through complementary settings.

Milestone: Provide training and education on adolescent vaccination requirements, vaccine administration, proper vaccine storage and handling, proper vaccination record keeping, use of immunization information systems, and vaccine adverse event reporting.

**Priority: Adult Immunization** (Assigned to lead: CDC; collaborator CMS)

**Objective 4.6** – Improve control of vaccine-preventable diseases among adults through targeted immunization efforts.

Strategy #1: Identify and monitor barriers to immunization services and utilization of routinely recommended and new adult vaccines.

Milestone: Support research to identify barriers to immunization services and use of routinely recommended vaccines among adults.

Milestone: Support research to identify barriers to implementation of vaccination with newly recommended vaccines among adults.

Strategy #2: Implement and monitor the use of evidence-based strategies to increase immunization rates for vaccines recommended for widespread use among adults to achieve coverage targets and to decrease racial/ethnic disparities.

Milestone: Support research to evaluate strategies to increase vaccination coverage among adults.

Milestone: Support research to evaluate strategies to reduce racial/ethnic disparities in vaccination coverage among adults.

Milestone: Disseminate research findings through peer-reviewed journals, conferences, and grantee communication to facilitate implementation of evidenced-based strategies.

Strategy #3: Promote the development and implementation of comprehensive immunization programs to increase the coverage of health-care personnel with recommended vaccines.

Milestone: Develop and implement standing orders for vaccination of health-care personnel.

Milestone: Develop performance measures for vaccination of health-care personnel.

Milestone: Monitor vaccination rates of health-care personnel on an annual basis.

Milestone: Promote immunization coverage of health-care personnel as a quality indicator for health-care institutions and organizations.

Milestone: Document vaccination program best practices for vaccination of health-care personnel, including education, access, promotion, documentation, assessment of coverage, organizational support, etc.

Milestone: Assess the vaccination policies of professional health-care training programs.

Strategy #4: Enhance public and private health infrastructure to support and sustain adult immunization activities.

Milestone: Promote the development of state and local public health plans for vaccination of adults.

Milestone: Promote collaboration between public and private health sectors to enable access to and delivery of vaccines for adults, with attention to those persons with high-risk conditions and those persons who are uninsured or underinsured.

Milestone: Promote and monitor delivery of vaccines through complementary and traditional settings.

Milestone: Encourage professional organizations to inform and educate their members regarding the importance of adult vaccines.

Strategy #5: Develop vaccine financing policies and strategies that help assure robust private and public financing of routinely recommended and new adult vaccines.

Milestone: Monitor vaccine coverage benefits in private health insurance plans.

Milestone: Promote adult immunization coverage as a critical indicator of health plan performance.

Milestone: Monitor insurance reimbursement and administration rates for vaccination of adults

Milestone: Identify best practices to cover uninsured and underinsured adults and disseminate information to immunization grantees.

Milestone: Support research to comprehensively assess the cost to provide adult vaccines in various settings to inform adult vaccine financing policy.

**Priorities: Surveillance of immunization coverage levels, Communications/Education (Assigned to lead: CDC)**

**Objective 4.7** – Enhance the effectiveness of immunization programs.

Strategy #1: Integrate Immunization Information Systems (IIS) into routine clinical use through the development of effective messaging standards and IIS platform development.

Milestone: Publish messaging standards.

Strategy #2: Promote the use of program evaluation techniques into immunization program activities to improve the effectiveness and efficiency of immunization programs.

Milestone: Support evaluation of programmatic activities through CDC's Section 317 grant program.

Strategy #3: Monitor and evaluate the impact of state immunization laws including daycare, school, and college prematriculation requirements, insurance mandates, and immunization information systems requirements.

Milestone: Continuously track vaccine legislation introduced at the state level (including school requirements and ability to consent for vaccination).

Milestone: Develop a searchable database that contains current vaccination requirements for school entry.

Milestone: Conduct research to evaluate impact of middle school vaccination requirements on adolescent vaccination coverage.

Milestone: Support research to evaluate how current adolescent consent laws are interpreted and implemented at the state level.

**Priority: Surveillance for Disease** (Assigned to lead: CDC)

**Objective 4.8** - Enhance tracking of vaccine preventable diseases and monitoring of the effectiveness of licensed vaccines

By demonstrating the impact of vaccines on disease outcomes in the population, monitoring and evaluation of the effectiveness of licensed vaccines and trends in burden of vaccine preventable diseases provides the link between vaccination policy and outcomes. These activities are of particularly vital importance in light of the current context, which includes the large number of conditions targeted for prevention through routine vaccination, expansion of recommendations for existing vaccines, the complexity of tracking the conditions targeted by the newer vaccines, the importance of preparedness to detect and respond to outbreaks and other urgent problems, and the need to monitor long term protection of vaccines that may have been administered years or decades previously. The current context also is distinguished by the public's limited familiarity with most vaccine preventable diseases (because of their relative rarity) and some parents' concern about the safety of vaccines. Monitoring the impact of vaccines to demonstrate some of the benefits of vaccination and assuring early detection of disease resurgence takes on additional importance from this perspective.

4.8.1: Monitor vaccine preventable disease health outcomes after vaccine licensure

Strategy #1: Strengthen epidemiologic and laboratory methods and tools to diagnose disease and characterize the impact of vaccination programs on relevant clinical outcomes.

Milestone: Evaluate and improve the sensitivity and specificity of diagnostic tests for vaccine preventable diseases;

Milestone: Increase the capabilities and competency of state laboratories to use the most appropriate available diagnostic assays;

Milestone: In collaboration with partners, develop new diagnostic tests to address changes in pathogens that cause vaccine preventable diseases to improve timeliness, accuracy, cost-effectiveness, and ease of testing and to take advantage of technologic advances;

Milestone: Develop systems to monitor disease outcomes of vaccine impact not usually measured by current systems, such as HPV precancerous lesions;

Strategy #2: Adapt diagnostic methods for optimal performance among highly vaccinated populations

Strategy #3: Monitor circulating strains of relevant vaccine-preventable pathogens

Milestone: Strengthen capacity to ascertain and characterize a nationally-representative sample of strains for relevant vaccine preventable pathogens, including monitoring for resistance to antimicrobial agents;

Milestone: Strengthen international surveillance for monitoring of influenza viruses to improve vaccine strain selection;

Strategy #4: Characterize ongoing cases of vaccine preventable diseases

Milestone: Ensure availability of annual national disease burden information for all vaccine preventable diseases, through case reporting from states, ongoing monitoring of outcomes (e.g, hospitalizations or mortality) or estimation procedures;

Milestone: Strengthen states' capacity to obtain accurate follow-up information on all reported cases of vaccine preventable diseases, such as vaccination status and reasons for under or no immunization, when relevant;

#### 4.8.2: Evaluate vaccine performance

Strategy #1: Conduct field vaccine effectiveness studies

Milestone: Strengthen capacity to assess and monitor serotype or strain-specific effectiveness of relevant vaccines;

Milestone: Strengthen access to appropriate specimens to monitor for the appearance of vaccine escape mutants or drift variants;

Milestone: Expand capacity for yearly timely estimates of influenza vaccine effectiveness among populations recommended for influenza vaccination;

Strategy #2: Monitor long term protection from vaccines administered during infancy among adolescents and adults, as well as for vaccines recommended for adolescents and adults;

Milestone: Develop better laboratory-based correlates of immunity;

Milestone: Support research to evaluate duration of vaccine protection

Strategy #3: Conduct studies to quantify indirect (community or herd) protection

Milestone: Assess the impact of influenza vaccination of school-aged children on influenza-related outcomes among adults;

Milestone: Assess the effect of using expanded-valent pneumococcal conjugate vaccine (when licensed) among children on the rate of pneumococcal disease among adults

4.8.3: Assure rapid, capable response to urgent vaccine preventable disease-related concerns

Strategy #1: Investigate and control outbreaks

Milestone: improve technical capabilities of laboratory and epidemiologic infrastructure in local and state health departments;

Milestone: Ensure capacity at the Federal level for supporting State Health Department investigations

Strategy #2: Strengthen case management

Milestone: Insure timely guidance from Federal experts in response to requests for assistance from State Health Departments or international partners;

Milestone: Strengthen State Health Department capacity for timely and appropriate case management;

**Priorities: Communication and Education, Surveillance for Disease, Vaccine Safety** (Assigned to lead: CDC)

**Objective 4.9** - Maintain a strong, science-based, transparent process for development and evaluation of immunization policy

Strategy #1: Support and strengthen immunization advisory committees at the state and national levels

Milestone: Facilitate enhanced use of evidence-based decision-making by the Advisory Committee on Immunization Practices;

Strategy #2: Improve capacity for public engagement initiatives at the national, state and local levels;

Strategy #3: Expand evaluation of vaccination policies from a wide range of perspectives

Milestone: Promote NIH, CDC, FDA, and other federal partners' collaborations to address evolving vaccine-related issues.

Strategy #4: Monitor the impact of existing vaccine recommendations, through surveillance of cases of vaccine preventable diseases and vaccine safety (See also Objectives 4.8 and 2.X)

Strategy #5: Assess the impact of new vaccines and vaccine recommendations on the overall immunization schedule, including programmatic implementation, safety, and efficacy

Milestone: Evaluate effects of changes in immunization recommendations on program effectiveness (e.g., introduction of combination vaccines on timeliness of vaccination)

Milestone: Develop and implement a structured process for review of the immunization schedule as new vaccines are added to it

Milestone: Monitor the safety of simultaneous immunization in accordance with recommended immunization schedules (See also Objective 2.3 Strategy #1).

Strategy #6: Evaluate the benefits and impact of immunization through the use of cost effectiveness studies.

Milestone: Publish updated economic analysis on the routine child, adolescent, and adult schedules.

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