THE ROLE OF THE FEDERAL MATERNAL AND CHILD HEALTH BUREAU IN PRESCHOOL IMMUNIZATIONS
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EXECUTIVE SUMMARY

PURPOSE

To examine the Public Health Service (PHS) Maternal and Child Health (MCH) Bureau’s efforts to improve preschool immunizations.

BACKGROUND

Currently, only 57 percent of two-year-olds are appropriately immunized against vaccine-preventable diseases according to 1991 preliminary data from 34 State MCH programs. During the recent measles epidemics, this age group, primarily urban, inner-city minority children, accounted for almost half of the reported cases. These low preschool immunization rates reflect fragmented efforts to deliver immunizations, the high cost of vaccines, and poor public awareness. Reaction to this situation has prompted government agencies to expand and further coordinate efforts to improve immunization rates, with the Centers for Disease Control and Prevention (CDC), Division of Immunizations, the National Vaccine Program Office (NVPO), and the MCH Bureau being among the players.

In light of continuing low preschool immunization rates, the President requested a supplemental appropriation of $300 million for FY 1993 and proposed the "Comprehensive Child Immunization Act of 1993," a multi-year initiative, to assure that all children in the United States are protected against vaccine-preventable infectious disease by their second birthday.

Both the CDC, Division of Immunizations, and the NVPO have singular missions related to the prevention and control of vaccine-preventable diseases. Toward this purpose, CDC receives approximately 99 percent of the Department of Health and Human Services’ funds designated for immunization-related activities. The NVPO, in its charge to bring coherence to a fragmented immunization system, chairs the Federal Interagency Committee on Immunizations (ICI). The ICI has developed a national immunization action plan which is intended to coordinate the immunization efforts of diverse government agencies. By contrast, the mission of the MCH Bureau is broader in scope and embraces not only the critical concern for immunizations but also the development of a comprehensive health care system for all mothers and children. However, the MCH Bureau has recently been given specific immunization responsibilities through legislation, as well as through its commitments made in the ICI Action Plan to improve preschool immunizations.

To examine the Bureau’s specific immunization role, we reviewed relevant literature and legislation, as well as conducted interviews with top MCH Bureau and other PHS officials, MCH regional program consultants, and public and private sector experts involved in immunizations. Our review was conducted prior to the announcement of the President’s new initiatives and reflects the MCH Bureau’s role since passage of the
1989 Omnibus Budget Reconciliation Act (OBRA-89) that specified national health status goals including immunization rates. Nevertheless, this report illustrates how the MCH Bureau could contribute to the President's initiatives.

FINDINGS

The MCH Bureau Has Not Fully Capitalized On Its Potential To Guide and Direct State MCH Program Efforts To Improve Preschool Immunizations.

- The MCH Bureau has not established an explicit, formal immunization initiative beyond its emphasis on comprehensive health care.

- The MCH Bureau has not met all its immunization commitments under the ICI Action Plan.

  In particular, the MCH Block Grant guidance has not been modified to direct State plans or activities to focus upon improving immunization rates.

- Technical assistance has focused on the development of comprehensive health care and has not placed an emphasis on improving immunization rates.

Requirements Related To The Collection and Reporting Of State Immunization Rates Have Been Difficult To Implement.

RECOMMENDATIONS

The MCH Bureau should play an important, if limited, role in improving preschool immunization. Toward this purpose,

PHS should:

- Ensure that the MCH Bureau strengthen its guidance and direction to State MCH programs to increase preschool immunization rates in addition to other comprehensive care services.

  - Specifically, the MCH Bureau could:

    - direct States to use MCH Block Grant funds to improve preschool immunization rates;

    - develop and implement a strategic plan with specific assignments and scheduled action steps to strengthen immunization efforts, especially for preschoolers;
- develop a system which tracks and fully documents progress under the MCH strategic immunization plan; and

- improve guidance and technical assistance to increase immunization rates.

Ensure that the MCH Bureau and the CDC closely collaborate to assure a coordinated effort to improve the immunization surveillance, reporting and delivery system.

AGENCY COMMENTS

We solicited and received comments from PHS on our draft report. PHS concurred with all our recommendations and is in the process of implementing them.

See Appendix B for the full text of the PHS comments.
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INTRODUCTION

PURPOSE

To examine the Public Health Service (PHS) Maternal and Child Health (MCH) Bureau's efforts to improve preschool immunizations.

BACKGROUND

Currently, only 57 percent of preschoolers are appropriately immunized according to 1991 preliminary data from 34 State MCH programs. This rate falls far short of the Year 2000 preschool immunization goal of 90 percent (see Appendix A). This discrepancy underscores the United States' poor ranking worldwide, placing 17th in immunizing children against vaccine-preventable diseases; 56th in immunizing minority children; 15th for polio immunizations; and 49th for polio immunizations for nonwhite populations (National Institute of Child Health and Human Development 1992). Between 1989 and 1991, the resurgence of reported measles cases was partially attributed to the failure to appropriately immunize preschoolers. This group, primarily urban, inner-city minority preschoolers, accounted for almost half of these vaccine-preventable occurrences. Also, of the 1990 measles cases among preschoolers, more than one-third of the children were not vaccinated (Center for the Future of Children 1992).

Barriers to timely immunizations, especially for preschoolers, were also brought to national attention by the 1991 publication of "The Measles Epidemic: Problems, Barriers, and Recommendations" or "The White Paper" (National Vaccine Advisory Council 1991). The National Vaccine Advisory Council (NVAC) report asserted that the measles epidemic indicated a much larger issue: the inadequacy of the nation's health care system to deliver primary and preventive health care services.

Immunizations, besides being a responsible preventive health measure, are also a cost-effective approach to reducing future health care spending. An estimated $10 - $14 are saved in later medical costs for every $1 spent on early childhood immunizations. Government agencies are beginning to coordinate efforts to improve preschool immunization rates. Recent efforts to improve the immunization system are focusing on more interactive relationships among the nation's health, income, housing, educational, and nutrition programs.

The MCH Bureau is One of Many Federal Players in Preschool Immunizations

The MCH Bureau, part of the Health Resources and Service Administration (HRSA) of the PHS, administers the Maternal and Child Health Services Programs, authorized by Title V of the Social Security Act. The mission of the Bureau is to provide
national leadership to develop, administer, coordinate, monitor and support Federal policy and programs to improve the health of the Nation's mothers and children.

Federal funds are available to the States, through the Maternal and Child Health Block Grant, for the provision or the purchase of a broad range of maternal and child health services. The law sets out a number of purposes for which the States are authorized to expend appropriated MCH Block Grant funds, including 1) reducing infant mortality; 2) increasing the availability of prenatal, delivery, and postpartum care to low-income women; 3) reducing the incidence of preventable and handicapping conditions among low-income children; 4) providing medically necessary services to children with handicaps or children with special health care needs; and 5) increasing the number of children immunized against disease and receiving health assessments.

Recent amendments through the 1989 Omnibus Budget Reconciliation Act (OBRA-89) have specified national maternal and child health status goals and objectives that should be attained by the States through reference to the Department's "Year 2000 National Health Objectives." The law also requires State reports to determine whether the States are making progress in improving the health status of mothers and children. These reports are to contain information and data that is essential for an effective evaluation of both individual State MCH Block Grant programs and the entire Title V authority. States are required to annually report by class of individuals served, on the number of individuals served under Title V; the proportion of such individuals who have health insurance; the types of services provided; and the amounts spent on each type of service; and information on the status of maternal and child health in the State, which includes reporting preschool immunization rates.

**Year 2000 Immunization Goal**

The "Year 2000" objectives identify immunization and control of infectious diseases as a high priority. The MCH Bureau has been given specific immunization responsibilities in OBRA-89 to support the "Year 2000" preschool immunization goal, as well as to report preschool immunization rates. The MCH Block Grant is one available resource for State MCH programs to support immunization-related activities. For Fiscal Year (FY) 1993, more than $557 million were disbursed to MCH Block grantees. The proportion of MCH Block Grant funds used for immunization-related activities is at State discretion.

The MCH Bureau is currently integrating the data reporting requirements into their more traditional role of providing comprehensive health services. Each State MCH program is required to annually report the proportion of appropriately immunized two-year-olds. This data is then compiled by the MCH Bureau and submitted to the Congress, as required by OBRA-89.

Additionally, the MCH Bureau has agreed to implement several action steps from an interagency plan which was developed to coordinate efforts to improve access to childhood immunizations. These actions are described on page 5.
The Centers for Disease Control and Prevention, Division of Immunization, Plays a Major Role in Preschool Immunizations

The Centers for Disease Control and Prevention, Division of Immunization (hereafter referred to as CDC), is responsible for leadership and guidance in the prevention and control of preventable childhood diseases. CDC receives 99 percent of HHS funds designated for immunization-related activities and its funding levels have significantly increased during the past five years (U.S. Department of Health and Human Services January 1992). The CDC administers the Vaccination Assistance Act of 1962, a Federal grant program, which provides financial and technical assistance to supplement State and local health department efforts to provide immunizations. FY 1993 funding was more than $349 million, approximately 3.5 times greater than the FY 1988 allocation (U.S. Department of Health and Human Services May 1992).

CDC is engaged in a myriad of immunization-related activities, including: 1) assisting States to implement "The White Paper" recommendations to improve the diagnosis, delivery, and efficacy of childhood immunizations; 2) conducting a national public information campaign on preschool immunizations; 3) expanding efforts to incorporate hepatitis B into routine infant immunization programs; 4) purchasing additional vaccines to improve age-appropriate immunization levels; 5) expanding support for State-based immunization programs; and 6) stockpiling Hib, hepatitis B, and acellur DPT. Additional CDC immunization-related activities include:

- Collecting preschool immunization data through the use of retrospective studies of school-entry immunization records. "Guidelines for Assessing Vaccination Levels of the 2-year-old Population in a Clinic Setting" was published in October 1992 and distributed to all State CDC grantees, plus members of the Association of Maternal and Child Health Programs (U.S. Department of Health and Human Services/Public Health Service October 1992).

- Conducting demonstration projects, e.g., 1) coordinating efforts with the Special Supplemental Food Program for Women, Infants, and Children (WIC) and with Aid to Families with Dependent Children (AFDC) to improve recipients' immunization levels; 2) providing free immunizations for children up to the age of two who live in communities with a high proportion of low-income individuals and 3) conducting awareness campaigns to both identify these children and inform parents (or guardians) about this service.

- Implementing an Infant Immunization Initiative (I-3) to improve immunization levels among very young children. I-3 places a special emphasis on assessment and operational research. Major issues concern the magnitude of the problem, as well as identifying attitudinal and structural barriers. In the summer of 1992, more than $45 million supplemental funds were distributed among 63 State immunization grantees, plus twenty-four selected urban areas, to develop local Immunization Action Plans (IAP). These plans focus on strengthening the
vaccine delivery infrastructure for preschool immunizations. The IAPs also focus on State assessment activities and informational/education projects for improving preschool immunizations.

Additional Key Players in HHS and Other Government Agencies

The National Vaccine Program Office

The National Vaccine Program Office (NVPO) was established in 1986 and is a part of the Office of the Assistant Secretary for Health (OASH)/PHS/HHS. Its mission is to bring coherence to a fragmented immunization system. Designated as the national vaccine policy authority, its FY 1993 budget of $3 million reflects a $5 million dollar decrease from FY 1992. However, this difference was redistributed between CDC and the National Institutes of Health (NIH) for expanded vaccine activities (U.S Department of Health and Human Services January 1992).

The NVPO coordinates and provides direction for research conducted by NIH, CDC, the Office of Biologics Research and Review of the Food and Drug Administration (FDA), the Department of Defense (DOD), and the Agency for International Development. Other responsibilities of the NVPO include 1) development of an annual National Vaccine Plan (NVP) and 2) implementation of some of the National Vaccine Injury Compensation Program's (NVICP) statutory provisions. Committees directly related to the NVPO are 1) the National Vaccine Advisory Committee and 2) the National Vaccine Program Interagency Group.

Federal Interagency Committee on Immunization (ICI)

The ICI was formed in early 1991 and is chaired by the NVPO Director. The committee has developed a comprehensive Action Plan released May 11, 1992. The plan includes 120 action steps to be implemented between 1991 and 1995. Although it does not have oversight authority to enforce the Action Plan, ICI monitors progress under the plan through regular reports to the Assistant Secretary for Health.

ICI representatives from HHS are the NVPO, CDC, HRSA (which includes the MCH Bureau), Indian Health Service (IHS), the Assistant Secretary for Planning and Evaluation, the Office of Health Planning and Evaluation, the Office of Minority Health (OMH), Office of the Surgeon General (OSG), NIH, Administration for Children and Families (ACF), and the Health Care Financing Administration (HCFA). Other government agencies represented are the Department of Agriculture (USDA), the Department of Education (DoE), and the Department of Housing and Urban Development (HUD), as well as a liaison from the NVAC. Directly responsible for implementing the Action Plan are HRSA (which includes the MCH Bureau), CDC, ACF, HCFA, IHS, NVPO, OMH, OSG, NIH, DoE, HUD, and USDA.

MCH Bureau immunization efforts under the Action Plan include: 1) providing technical assistance to support State and local health department immunization
programs; 2) coordinating with the CDC and State health officers to conduct regional workshops for State agencies involved in activities to improve preschool immunizations; 3) working with the Healthy Start program on immunization activities, including a national public education campaign; 4) modifying MCH Block Grant guidance, as well as State annual reporting requirements, to specifically focus on plans and activities to improve State immunization status; 5) working with the Association of Maternal and Child Health Programs (AMCHP) network and Department of Health and Human Service (HHS) regional office staff to determine barriers to improving immunization status; 6) disseminating "Standards for Pediatric Immunization Practices;" 7) working with designated State MCH Program directors to identify barriers to developing a partnership with health care provider organizations; 8) reviewing current approaches for increased provider participation to deliver immunizations; 9) reviewing MCH Block Grant applications to identify effective immunization program activities; 10) working with the National Conference of State Legislatures (NCSL) to increase awareness of immunization status and problems and possible legislative remedies; and 11) encouraging State and local governments to mandate appropriate immunizations prior to enrolling children in licensed day care centers (Interagency Committee on Immunizations 1992).

Barriers to Immunizing Preschoolers

Several barriers to immunizing preschoolers have been documented (Orenstein, Atkinson, Mason, and Bernier 1990; National Vaccine Advisory Committee January 1991). First, there are funding and/or logistical barriers, including limited clinic staffing and service hours, as well as inaccessible clinic locations. Second, there are policy barriers, such as appointment-only service systems which require prior physical examinations, physician referrals, or enrollment in comprehensive care well-baby clinics, and financial screening and/or charging fees to administer vaccines. Third, perceptual barriers, such as fear of adverse reactions and low parental priority to immunize may also impede immunization. Other factors mentioned are low educational attainment of either parent, large family size, low socioeconomic status, nonwhite identity, reliance on public clinics as the immunization source, young parental age, single parenthood, lack of prenatal care, and late start of the immunization series.

To address these barriers, "The White Paper" recommends: 1) making immunization services more readily available; 2) improving the management of immunization delivery; 3) creating an ongoing measurement of children's immunization status; 4) implementing a two-dose schedule for measles, mumps, and rubella (MMR); 5) establishing a revolving fund for outbreak control; 6) gathering more information about the various vaccine-preventable diseases, and 7) planning a future strategy to improve vaccine delivery.
Presidential Initiatives

In light of continuing low immunization rates, the President requested a supplemental appropriation for FY 1993 and sent the "Comprehensive Child Immunization Act of 1993" to the Congress on March 30, 1993. The goal is to assure that all children in the United States are protected against vaccine-preventable infectious diseases by their second birthday. This legislation introduced a new collaborative partnership among parents and guardians; health care providers; vaccine manufacturers; and Federal, State and local governments to immunize preschoolers.

METHODOLOGY

Several steps were involved in determining what Federal MCH Bureau and MCH regional office plans, guidance, technical assistance, monitoring mechanisms, and collaborative agreements are in place to improve preschool immunizations. Our methodology included: 1) reviewing relevant literature and legislation; 2) consulting either through either telephone or on-site interviews with public and private sector experts involved in immunizations; 3) conducting in-depth interviews with top MCH Bureau management and staff involved with immunizations, as well as with other top PHS officials; 4) conducting telephone interviews with all MCH regional program consultants; and 5) doing a content analysis of all documentation provided by the MCH Bureau and MCH regional program consultants, which included reviewers' comments on the FY 1993 MCH Block Grant applications. Our review was conducted prior to the announcement of the President's new initiative and reflects the MCH Bureau's role since passage of OBRA-89 that specified national health status goals including immunization rates. Nevertheless, this report illustrates how the MCH Bureau could contribute to the President's initiatives.
FINDINGS

THE MCH BUREAU HAS NOT FULLY CAPITALIZED ON ITS POTENTIAL TO GUIDE AND DIRECT STATE MCH PROGRAM EFFORTS TO IMPROVE PRESCHOOL IMMUNIZATIONS.

- The MCH Bureau has not established an explicit, formal immunization initiative beyond its emphasis on comprehensive health care.

The MCH Bureau has some immunization projects underway. For example, the Bureau has specifically contracted for two surveys that will be used to identify State MCH program immunization activities. These include: 1) the AMCHP’s survey of State Title V program activities, which include immunization-related activities and 2) CityMatCH’s survey of 177 urban health departments about their immunization services. Also, through the cooperative agreement with NCSL, several immunization-related publications have been produced. The NCSL also held a roundtable discussion at its 1992 annual meeting which involved immunizations.

Nevertheless, the Bureau, in its effort to emphasize development of comprehensive systems of care for children, has not established an explicit, formal immunization initiative to focus priorities and efforts for expanded immunization responsibilities. The Bureau has not developed an immunization plan or strategy beyond its activities included in the ICI Action Plan, giving the impression that improving preschool immunizations is not a program priority.

The MCH Bureau has a fragmented approach to delegating responsibilities for immunization-related activities, with these being split between MCH Bureau divisions. One division deals with program support and another focuses on data collection and analysis. We found a lack of coordination and communication among these different programmatic divisions.

There are a number of potential opportunities the MCH Bureau can use to enhance immunization efforts. For example, the Bureau has entered into a number of cooperative agreements for the purpose of sharing information and collaborating with organizations representing health policymakers at all levels of the private and public sectors. Although broad in scope, these cooperative agreements, collectively known as the Partnership for Information and Communication (PIC), in the future could incorporate specific immunization activities.

- The MCH Bureau has not met all its immunization commitments under the ICI Action Plan.

Purported efforts to implement the MCH Bureau’s portion of the Action Plan were outlined in a September 1992 progress report to the ICI. However, the MCH Bureau could not document some of these activities, particularly for the two action steps.
involving the Block Grant. First, MCH Block Grant guidance has not been modified to specifically direct State plans or activities to focus upon the improvement of immunization rates beyond immunizations as a part of the primary care system. Secondly, reviewers of the Block Grant have not been instructed to identify effective immunization program activities.

Additionally, the MCH Bureau agreed to conduct regional preschool immunization workshops for State agencies in conjunction with CDC. The MCH Bureau now reports that alternative means of informing and providing technical assistance are being used, since initial funding was not forthcoming. These alternative actions have been carried out in less than half of the MCH regions (four regions). Activities include conducting a two-day statewide conference in one of the regions; serving on a State committee to develop an immunization plan, as well as accompanying CDC regional staff during site visits to immunization grantees in two of the regions; and working with States to develop their CDC Immunization Action Plans, in addition to working on other CDC immunization plans in another region.

- **Technical assistance has focused on the development of comprehensive health care and has not placed an emphasis on improving immunization rates.**

Technical assistance regarding immunizations has been minimal. For example, the MCH Bureau reported that telephone contact is the way they most often provide technical assistance to regional offices on preschool immunizations. This contact is usually done in response to questions on immunization schedules. MCH regional offices also reported infrequent and primarily informal contact with the MCH Bureau for technical assistance on immunization-related issues. The MCH Bureau has attempted to address specific issues on an individual basis through a memo to the requesting regional office. Regionwide immunization memos are also distributed, but in the past, have primarily focused on the development of Head Start immunization policies.

The MCH regional offices also reported limited technical assistance to the States, relying primarily on telephone and written communications. Restricted travel funds are said to constrain many technical assistance activities. Regional immunization technical assistance has almost exclusively focused on Head Start. Between 1991-1992, all MCH regional offices reported either on-site or telephone Head Start immunization contacts, ranging from as few as four to as many as 69. However, it should be noted that the interagency Head Start training and technical assistance agreement supporting these activities expired on September 30, 1992.

With respect to the immunization reporting requirement, seven of ten MCH regional offices are providing technical assistance. Of these seven, three regional offices met with key State MCH persons for pre-application technical assistance; one identified consultants for State-level meetings; three held some type of conference for State agencies involved in immunizations; one used conference calls to the States; and five provided technical assistance via telephone, but only upon request. As for technical
assistance to help States focus plans or activities to improve immunization status, only two of ten MCH regional offices reported providing any technical assistance.

REQUIREMENTS RELATED TO THE COLLECTION AND REPORTING OF STATE IMMUNIZATION RATES HAVE BEEN DIFFICULT TO IMPLEMENT.

The OBRA-89 requirement for State MCH programs to report preschool immunization rates duplicates the extensive, ongoing CDC efforts to collect national preschool immunization data. All CDC immunization grantees, which includes all States, are required to conduct retrospective surveys of school-entry immunization records. CDC also encourages grantees to conduct clinical assessments of preschool immunization rates, using recently published methodological guidelines.

However, the State MCH programs are required to report preschool immunization rates. Toward this end, the MCH Bureau has contracted with the Public Health Foundation (PHF) to assess States’ capacity to collect, process, analyze, and report data for MCH programs, which includes immunization data. PHF’s Project CAN-DO (The Project for Capacity Assessment and Needs Determination for OBRA ‘89) will include a self-assessment of each State’s current data capacity, along with descriptions of current data utilization for resource allocation, evaluation and planning purposes. A workbook will be developed and used by the MCH Bureau and MCH regional offices to prioritize areas for future technical assessment.

Currently, the MCH Bureau has only included minimal reporting guidance in its Block Grant packet developed to assist States with their grant applications and annual reports. Only in the packet’s appendices are three cursory reporting references mentioned -- the probable source of data (i.e., State program data), the statutory citation (i.e., Section 506...), and the program component in which to report the information (i.e., program components A and B).

Within MCH regional offices, nine out of 10 said these guidance packets were their only source of instruction on how to assist States with the immunization reporting requirement. The remaining regional office could not recall any specific guidance being given at all. When asked about training in this area, six out of ten MCH regional offices mentioned they had attended a national data conference held in January 1992 addressing problems related to the OBRA-89 reporting requirements. Of these six, only one received any other training related to this area.

Overall, very little systematic assistance has been provided to States to help ensure the accuracy, reliability, and comparability of data on State immunization rates.
RECOMMENDATIONS

All resources in HHS which can contribute to achieving increased immunization levels in children should support the President's initiatives. The MCH Bureau's mission is to ensure a comprehensive health care system for all mothers and children, and immunization is a cornerstone of such a system. While the MCH Bureau operates under block grant restrictions with limited resources, steps can be taken to ensure the Bureau's full contribution to preschool immunization efforts and to the President's goal of immunizing all two-year-olds. The MCH Bureau should provide leadership, direction, guidance, and technical assistance for preschool immunizations to State MCH programs.

PHS should:

- Ensure that the MCH Bureau strengthen its guidance and direction to State MCH programs to increase preschool immunization rates in addition to other comprehensive care services.

  - Specifically, the MCH Bureau could:
    - direct States to use MCH Block Grant funds to improve preschool immunization rates. States should compare current rates with the "Year 2000" immunization goal of 90 percent, as specified in the MCH Annual Report guidance material. MCH Block Grant applicants should use this information to develop an action plan to reach and/or maintain preschool immunization rates of at least 90 percent. Their progress could then be monitored through the Annual Report review process. States should also include other relevant information collected from MCH/CDC support surveys.

    - develop and implement a strategic plan with specific assignments and scheduled action steps to strengthen immunization efforts, especially for preschoolers. The strategic plan should 1) incorporate all of the Bureau's ICI Action Plan commitments; 2) identify specific Bureau staff responsible for each action item; 3) specify the frequency and/or time table for each action item; and 4) identify MCH Bureau staff as liaison(s) with ICI and CDC.

    - develop a system which tracks and fully documents progress under the MCH strategic immunization plan. Equally important to developing a strategic plan is to ensure that the plan is being implemented. The tracking system would be a mechanism to achieve this goal. Complete documentation for all completed items should be maintained.
improve guidance and technical assistance to increase immunization rates. Encourage MCH regional offices to develop regional and State-level task forces to emphasize common goals, especially improving preschool immunizations. MCH officials should reciprocally participate with other agencies involved with immunization in such activities as reviewing grants, annual reports, and demonstration project applications.

- Ensure that the MCH Bureau and the CDC closely collaborate to assure a coordinated effort to improve the immunization surveillance, reporting and delivery system.

- Data collection of preschool immunization rates is already being done by CDC immunization grantees. The MCH Bureau should actively collaborate with the CDC regarding the collection, utilization, and reporting of preschool immunization data. MCH data needs should be conveyed to CDC on an ongoing basis.

- The President's initiative continues to support rebuilding the infrastructure. CDC's local immunization action plans (IAPs) provide support to communities for improving their vaccine delivery system. To ensure coordinated planning, the IAPs call for enlisting the active participation of a State's primary care association and similar groups involved in primary care. The MCH Bureau should collaborate with the CDC to assure that all State MCH programs are actively involved in the development and implementation of the IAPs.

SUMMARY OF AGENCY COMMENTS AND OIG RESPONSE

We received comments from PHS on the draft report. The complete text of the PHS comments are contained in Appendix B. PHS concurred with the two OIG recommendations shown above and is in the process of implementing them.

It should be noted we have excluded the recommendation contained in the draft report about PHS technical assistance for immunizations to ACF's Head Start program and its grantees. ACF has decided to coordinate its health technical assistance activities for Head Start through the same mechanisms they use to deliver technical assistance for education, social services, and parents. However, PHS has expressed a willingness to provide technical assistance to the Head Start program in regard to public health matters if requested in the future by ACF.
1. The first State MCH Annual Reports requiring data on preschool immunizations were reviewed in September 1992. The mean value of 57 percent excludes the territories of American Samoa, Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, Palau Islands, and the Virgin Islands. Of the territories, only one provided data, reporting a preschool immunization rate of 99 percent (see Appendix A).

2. The Maternal and Child Health Program has adopted 28 goals derived from, or consistent with, Healthy People 2000: National Health Promotion and Disease Prevention Objectives. MCH goal #10 is to increase preschool immunizations to at least 90 percent.

3. As recommended by PHS's Immunization Practices Advisory Committee (ACIP), preschool immunizations should include: 1) Diptheria/Pertussis/Tetanus [DPT]; 2) Polio -- live oral polio drops [OPV] or [Inactivated] polio vaccine shots [IPV]; 3) Measles/Mumps/Rubella [MMR]; 4) Hemophilus Conjugate Vaccine [HIB]; and 5) Hepatitis B Vaccine [HBV].

4. Some of the various estimates of the ratio of receiving immunizations to the reduction of future health care costs are $1:10 (National Institute of Child Health and Development 1992); $1:11.90 (Southwest, an Aetna Plan 1993); and $1:14 (U.S. General Accounting Office June 1992).

5. On a State-wide basis, OBRA-89 requires information about the following indicators of the status of maternal and child health in each State: 1) the rate of maternal mortality, neonatal death, perinatal death, the number of children with chronic illness/type of illness; 2) the proportion of infants born with fetal alcohol syndrome; 3) the proportion of women who do not receive prenatal care during the first trimester of pregnancy; and 4) the proportion of children, who at their second birthday, have been vaccinated against each of measles, mumps, rubella, polio, diptheria, tetanus, pertussis, Hib meningitis, and hepatitis B [Section 6504 (a)(2)(B)(ii)(I-VIII)].

6. The National Vaccine Program was authorized in 1986 through P.L. 99-66, Title XXI of the Public Health Services Act, Subtitle 1, Sections 300a1 - 300aa4.

7. The purpose of the NVPO annual National Vaccine Plan is to set priorities related to vaccine development and distribution, indicate ways to maximize resources, and describe collaborative approaches among involved agencies and departments.

8. The National Vaccine Injury Compensation Program (NVICP) is separate from the National Vaccine Program (NVP). The NVICP is responsible for compensations paid for a vaccine-related injury or death. The Office of Evaluation and Inspections, Office
of Inspector General, Department of Health and Human Services is currently studying
the NVICP ("The National Vaccine Injury Compensation Program: A Review", OEI-
02-91-01460). However, the NVPO is involved in the development of public
awareness materials concerning risks associated with immunizations; collection and
analysis of data about adverse vaccine-related events; and oversight of studies
concerning childhood vaccines and subsequent adverse reactions.

9. The National Vaccine Advisory Committee (NVAC) advises the NVPO Director
on all aspects of the program. It is comprised of 15 voting members, including the
chair, and 5 nonvoting members. The 15 voting members represent individuals from
such areas as vaccine research, manufacturers of vaccines, physicians, members of
parent organizations concerned with immunizations, representatives of State/local
health agencies or public health organizations. The five nonvoting members represent
the Director of the NIH; the Commissioner, FDA; the Director, CDC; the Agency for
International Development; and the DOD.

The National Vaccine Program Interagency Group (IAG) makes recommendations
regarding national vaccine policy and operational issues to the Assistant Secretary for
Health. The IAG is comprised of senior representatives from the Agency for
International Development, CDC, DOD (who are responsible for immunizing military
personnel), Food and Drug Administration, and the NIH.

10. As of October 1, 1992, the Healthy Start Program became a part of the MCH
Bureau. The Healthy Start Initiative is a demonstration project in which 15 urban and
rural communities with infant mortality rates of at least 1.5 times the national average
are targeted for Federal funding. In May 1992, a national public information and
education campaign was begun.

11. The Association for Maternal and Child Health Programs (AMCHP) conducted a
survey of selected preventive and primary care services for children and adolescents
supported through each state’s Title V program during FY 1991. One section of the
survey asks specific questions about immunizations services, which include current
policies, tracking, coordination with other agencies, and perceived barriers to full
immunizations.

12. CityMatCH conducted a survey of 177 urban health departments in areas with a
population greater than 100,000. They are asking about such immunization services as
administration of vaccines; purchase and distribution of vaccines; outreach and
education; barriers to age-appropriate immunizations; activities to assure age-
appropriate immunizations; and innovative approaches.

13. The Partnership for Information and Communication (PIC) cooperative
agreements include such health care policy groups as the National Governors’
Association, the National Conference of State Legislatures (NCSL), the Association of
State and Territorial Health Officers, the Association of Maternal and Child Health
Programs, the National Association of County Health Officers, the U.S. Conference of
Local Health Officials, CityMatCH, the Health Mothers/Healthy Babies Coalition, and the Washington Business Group on Health.


U.S. Department of Health and Human Services/Public Health Service/Office of the Assistant Secretary for Health. 1990. *Secretary’s Program Directions Regarding PHS Immunization Initiatives*. Washington, D.C.


APPENDICES

Appendix A  Preliminary Immunization Data

Appendix B  Full Text of Agency Comments
### APPENDIX A

**PRELIMINARY IMMUNIZATION DATA, As of September 1992**

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Source: Maternal and Child Health Bureau, Public Health Service, Department of Health and Human Services. *(All U.S. territories are excluded from the chart).
MEMORANDUM

From: Assistant Secretary for Health


To: Acting Inspector General, OS

Attached is the Public Health Service response to the subject OIG draft report. We concur with the report's recommendations and our comments describe the actions we have taken or plan to take to implement them.

Philip R. Lee, M.D.

Attachment
General Comments

Immunization is a high priority of the Maternal and Child Health Bureau (MCHB). This is underscored by MCHB's selection of an immunization objective as one of the key national maternal and child health (MCH) objectives for the year 2000. Increasing immunization rates is absolutely essential for the delivery of adequate primary care. MCHB continues to support the development of systems that assure that immunization is a critical component of comprehensive primary care.

OIG Recommendation

1. The PHS should ensure that the MCHB strengthen its guidance and direction to State MCH programs to increase preschool immunization rates in addition to other comprehensive care services.

PHS Comment

We concur with this recommendation and with the four actions which the OIG report suggests that MCHB could take to fulfill it. The proposed revision to the MCH Block Grant application and annual report guidance, currently undergoing review, requires that States focus on programming to achieve the Healthy People 2000 immunization goal. In addition, the "Annual Report Requirements for the MCH Block Grant Review Criteria" currently require that State applicants provide immunization outcome information describing the proportion of children who, at their second birthday, have been vaccinated against measles, mumps, rubella, polio, diphtheria, tetanus, pertussis, Hib, and hepatitis B by racial and ethnic group. The Health Resources and Services Administration (HRSA) believes that the changes in the Block Grant review process will fully address the concerns raised by OIG.

OIG Recommendation

2. The PHS should ensure that the MCHB and the Centers for Disease Control and Prevention (CDC) closely collaborate to assure a coordinated effort to improve the immunization surveillance, reporting and delivery system.

PHS Comment

We concur. By law, the MCHB must collect data from each State Title V program [Social Security Act, Title V] concerning the immunization status of two year old children. MCHB is working
with the States to integrate the Title V reporting requirements into a single common reporting system that will satisfy numerous reporting requirements and assure that children and families actually receive comprehensive health services. MCHB also provides technical assistance to States through grants or the MCHB's Maternal and Child Health Information Resource Center.

The Omnibus Budget Reconciliation Act of 1989 (OBRA 89) Title V State reporting requirements related to immunization data collection and reporting activities are being coordinated with CDC's efforts at both the State and local levels. The MCHB has convened and chairs a Federal Interagency work group on MCH data. This group includes representatives from CDC, the Administration for Children and Families (ACF), the Health Care Financing Administration, and the Department of Education. The first two projects of this work group are to standardize definitions and simplify reporting requirements.

In addition, MCHB and CDC work jointly to develop reporting strategies to systematically assess immunization status in a timely, recurring basis. Together they have sponsored two State MCH data meetings to strengthen coordination and problem solving, and they support data collection efforts and reporting requirements under development by the Public Health Foundation. MCHB and CDC continue to work together to coordinate efforts to meet the OBRA 89 immunization reporting requirements and the Department's Healthy People 2000 objective and goal related to immunization.

We agree with OIG that it is essential for State MCH programs to be involved in the development and implementation of CDC's local immunization action plans (IAP). We are aware of many directors of State MCH programs or programs for children with special health care needs who have been involved in the development and implementation of the IAPs under their jurisdiction. MCHB will assess whether all States have appropriately involved their Title V programs in the development and implementation of IAPs and will work with CDC to assure participation if they have not.

Finally, to improve surveillance and data collection efforts, MCHB has convened a panel of experts with representatives from State and local governments, foundations, and universities to improve MCH analysis for qualitative and quantitative problem solving. MCHB has worked with New York City, the Western Governors' Association, the Robert Wood Johnson Foundation, and the Pew Charitable Trust to develop an immunization tracking system and/or "smart card" to assist local providers in assuring that children receive proper age-appropriate immunizations.
OIG Recommendation

3. The PHS and the ACF should develop an acceptable arrangement that assures technical assistance for immunizations is provided to the Head Start program and its grantees.

PHS Comment

The ACF has responsibility for administering the Head Start program and PHS involvement is at the request of ACF. PHS is prepared to assist ACF by providing technical assistance and expertise in public health matters. We believe that the five year interagency agreement between ACF and MCHB was an excellent demonstration of how two Federal programs, working collaboratively, could provide the best services of each program to improve, promote and maintain the health of high-risk infants, preschool children and their families.

It is our understanding that the Head Start Bureau (HSB) of ACF had decided to coordinate its health technical assistance activities through the same mechanism they use to deliver technical assistance for education, social services, and parents. We respect their prerogative to discharge their responsibilities in the way they see fit. However, should HSB decide to re-negotiate the interagency agreement with MCHB (that expired on September 30, 1992) to provide the health component of the Head Start program through a Federal, State and local network for technical assistance and training, MCHB is willing to work with them to reach a mutually satisfactory agreement.