Progress Toward Achieving the 1990 Immunization Objectives

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SYNOPSIS

Dramatic progress has been made in reducing morbidity due to infectious diseases of childhood through programs of universal immunization of children. This success has been achieved by a program that involves a remarkable integration of private and public endeavors and cooperation between official and voluntary agencies.

Similar models of cooperation and integration have not yet been developed for selective use vaccines and new vaccines. As a consequence, although it seems likely that the childhood immunization objectives will be achieved by 1990, the ability to achieve objectives for selective use and new vaccines is in doubt.

The National Institute of Allergy and Infectious Diseases has undertaken, as an initiative, the accelerated development of new vaccines. The goal is to expedite the availability of needed vaccines by selecting a few candidate vaccines for extra research and development efforts. Studies are in progress on more than 50 antigens for more than 30 different bacterial, viral, and parasitic diseases.

IMMUNIZATION IS ONE OF THE MOST EFFECTIVE ways of preventing infectious disease. Prevention objectives for immunizations were developed for vaccines that are currently recommended for universal use in children as well as for vaccines which are used in a more limited fashion (*1*). Objectives were also established for the vaccines that will be introduced in the future.

Assumptions

In preparing the objectives, certain assumptions were made. These are listed and discussed subsequently.

1. At least stable private sector support. Nationwide, approximately one-half of all childhood immunizations are delivered in the private sector, but there is substantial variation in this proportion around the country. Current indications are that this level of support in the private sector will continue.

2. At least stable public sector support. Public sector support for childhood immunization derives from local, State, and Federal levels, and there have been substantial variations in the level of this support in the past. Although retrenchment pressures have been felt at all levels of government, support for childhood immunization programs has been relatively stable, and it should continue in that fashion. Limited use vaccines are primarily a private sector service, although there are a few notable exceptions (such as Medicare reimbursements for pneumococcal vaccination and scattered State-supported programs for influenza vaccination). At present, no major changes are foreseen in the level of private sector support for these immunizations, nor is there any indication of a likely increase in public sector support.

3. Continued availability of vaccines at reasonable cost. Vaccines remain one of the great bargains of health care. At government contract prices, the total cost for vaccines necessary to complete a series of immunizations in a child—five doses of diphtheria, tetanus, pertussis (DTP) vaccine, four doses of polio vaccine, and one dose of measles, mumps, rubella (MMR) vaccine—is less than $10. However, vaccine prices have been rising in recent years and, specifically, the cost of MMR vaccine has risen more than 40 percent in 1981–82. Consequently, rising costs may influence immunization programs in the future.

4. Routine use of combined vaccines. Both the Public Health Service and the American Academy of Pediatrics recommend the routine use of combined MMR vaccine. In the public sector, at least 75 percent of all measles antigen is given in combination

with either rubella or mumps and rubella. This pattern seems likely to continue.

5. Permanent immunity in 90 percent or more of MMR recipients. Recent studies indicate that 95 percent or more of recipients of MMR vaccine have antibodies 1 to 2 years after vaccination and so are protected initially. To date there has been no evidence of loss of protection for measles after up to 16 years followup, so it appears that vaccine-induced immunity will likely be lifelong. The same seems to hold for mumps and rubella, although these vaccines have not been available quite as long.

6. Continued enforcement of school immunization requirements. All 50 States have immunization requirements for first entry to school, and in most States these extend to children at all grade levels. Continued support for, and enforcement of, these requirements seem likely.

7. No new serious adverse reactions. Identification of a previously unknown serious adverse reaction associated with vaccination could seriously impair vaccine acceptance and achievement of the objectives. No such reactions have been identified. The known adverse events associated with vaccination rarely cause permanent disability or death.

8. No worsening of liability situation. Presently, the recourse for persons damaged as a result of vaccine use is through the courts. Proposals have been made by various organizations, including the American Academy of Pediatrics, for the adoption of a "no fault" compensation system for those injured by a vaccine. It is difficult to gauge with certainty trends in litigation and settlements. Nevertheless, concerns about liability continue to be voiced by vaccine manufacturers as well as providers and recipients.

9. At least stable support for development of vaccines and improved recruitment of volunteers. Development of new vaccines depends heavily on support for research and, with the evolving technology of genetic manipulation and the ability to synthesize fragments of antigens, the potential number of new vaccines that could be developed has greatly enlarged in recent years. A small number of vaccines have been targeted for accelerated development by the National Institute of Allergy and Infectious Diseases; these are discussed subsequently. Once vaccines are developed in the laboratory, fear of possible adverse reactions has impeded recruitment of volunteers for clinical trials. Although support for development of vaccines appears relatively stable, the problems in recruiting volunteers have not been resolved.

In general, it appears that the assumptions made when the objectives were drafted in 1979 are still valid, although concerns remain about liability issues and about the increasing costs of vaccines.

Table 1. Comparison of maximum number of cases, 1990 target levels, and 1982 cases of diseases preventable by vaccination during childhood

Disease	Maximum cases		1990 target, less than—	Provisional 1982 totals
	Number	Year		
Diphtheria	206,939	1921	50	3
Measles	894,134	1941	[1] 500	[2] 1,697
Mumps	[3] 152,209	1968	1,000	5,196
Pertussis	265,269	1934	1,000	1,784
Poliomyelitis	21,269	1952	10	7
Rubella	[4] 57,686	1969	1,000	2,283
Congenital rubella syndrome	20,000+	1964–65	10	7
Tetanus	[5] 601	1948	50	81

[1] All imported or import-related cases.
[2] Approximately 37 percent were imported or import-related cases.
[3] First reportable in 1968.
[4] First reportable in 1966.
[5] First reportable in 1947.

Progress in Childhood Immunization

Improved health status. American children should receive immunization against seven diseases: diphtheria, measles, mumps, pertussis, poliomyelitis, rubella, and tetanus. Widespread use of these vaccines in childhood has brought about dramatic reductions in the occurrence of disease. Table 1 shows the maximum number of cases of those diseases ever recorded, the 1990 target levels, and the provisional morbidity figures for 1982. The targets for diphtheria, paralytic poliomyelitis, and congenital rubella syndrome have already been met. If progress continues as at present, it seems highly likely that the other morbidity targets will also be met.

Improved services and protection. Three objectives were set for improved services and protection (table 2). Two of these relate to immunization levels in children and the third to the preparation of a national plan for mass immunization programs in the face of epidemic disease. Table 2 summarizes the progress toward meeting the immunization level objectives. Data are not available for all 2-year-old children; however, of those in Head Start programs

or in day care centers, more than 90 percent are immunized. The objective for school age children has already been met. A national plan for mass immunizations in the face of pandemic influenza has been prepared and is currently undergoing review and updating to make it applicable to other diseases as well. It seems likely that all targets will be met and maintained.

Increased public and professional awareness. The major target set was that all new mothers should receive immunization information before leaving the hospital with their newborn infants. In 35 of 52 reporting areas (50 States, New York City, District of Columbia) maternal education programs are in operation in 90 percent or more of targeted hospitals. Childhood immunization will also be a part

Table 2. The 1990 objectives and current status for childhood immunizations and for selected use and new vaccines

1990 objectives	*Current status*
Childhood immunization—improved services and protection	
• At least 90 percent of children have their basic immunization series by age 2 years	• 92.6 percent of Head Start children completed the basic series at the end of the 1981–82 operating year • Immunization levels of children 19-27 months old cared for by the Indian Health Service in September 1982: Oral polio vaccine ..... 95.8 percent Measles, mumps, rubella ..... 95.3 percent Diphtheria, tetanus, pertussis ..... 4 doses, 86.0 percent Diphtheria, tetanus, pertussis ..... 3 doses, 98.5 percent
• At least 95 percent of children in day care centers and kindergarten through grade 12 are fully immunized	• Day care centers report levels of 90 percent or higher for 1981–82 • 90 percent or more of primary care and National Health Service Corps sites have 90 percent or more of 2- and 6-year-olds completely protected • All 50 States have school immunization laws • Immunization levels of children at school entry 1981–82: Measles, rubella, polio, DTP ..... > 95 percent Mumps ..... > 90 percent • Public sector recall systems in place in 42 of 52 reporting areas; private sector systems in place in 17
• National plan for mass immunization programs	• National plan for immunizations prepared
Childhood immunization—increased public and professional awareness	
• All new mothers receive immunization instruction before leaving hospital	• Hospital-based maternal education programs in 90 percent of targeted hospitals in 35 of 52 reporting areas • Healthy Mothers, Healthy Babies campaign • "Keep Measles a Memory" Work Group
Childhood immunization—improved surveillance and evaluation	
• At least 95 percent of all children through age 18 should have up-to-date official immunization records in a uniform format	• All 50 States have official immunization records
• Surveillance systems that report at least 90 percent of those hospitalized and at least 50 percent of those not hospitalized with vaccine-preventable diseases of childhood, using uniform case definitions	• Active measles surveillance systems in 45 of 52 reporting areas • Standard definitions for measles, poliomyelitis, and congenital rubella syndrome in use
Selected use and new vaccines—improved services and protection	
• At least 60 percent of high-risk populations receive annual influenza immunization	• Influenza immunization levels of ± 20 percent • Only a few States support public programs • Medicare does not reimburse for influenza vaccinations
• At least 60 percent of high-risk populations receive pneumococcal immunization	• Lack of consensus about the vaccine's efficacy • Extent of population covered by vaccination unknown • Medicare reimburses for pneumococcal vaccination
• At least 50 percent of target populations receive new vaccines within 5 years of licensure	• Hepatitis B vaccine was licensed in 1982; series cost is $100, no public programs are in place • Many new vaccines are on the horizon

of the "Healthy Mothers, Healthy Babies" campaign. A related public-professional awareness activity has to do with the effort to eliminate measles; an Interagency Workshop to "Keep Measles a Memory" met in December 1982 and laid out a series of activities to try to assure that necessary levels of awareness are maintained.

Improved surveillance and evaluation. It may be difficult to measure accomplishments of the objective concerning immunization records; however, schools are increasingly requiring that children produce the official State immunization record as proof of immunity, and it seems likely that by 1990 the objective—that at least 95 percent of all children through age 18 have up-to-date official records in a uniform format—will have been met. Morbidity surveillance systems vary according to the disease, but reporting for measles, poliomyelitis, tetanus, and diphtheria seem to be fairly complete once the disease is diagnosed. Standard case definitions have been developed and are being used for measles, poliomyelitis, and congenital rubella syndrome. Continuing efforts are underway to improve surveillance for the other vaccine-preventable diseases.

Obstacles to Achieving the Objectives

Five major obstacles have been identified that might impede achievement of the 1990 objectives for childhood vaccination.

1. Perceived fragility of Federal support. Although the level of Federal support of childhood immunization activities has been relatively stable over the past 5 years, it had undergone substantial variation before that time, and there is a continuing perception of fragility in the level of Federal support. As support continues to be stable in the future, this perception should diminish.

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2. Continuing liability concerns. Concerns about liability continue to be voiced by vaccine manufacturers, providers, and recipients. If these concerns increase, they might have a negative effect on achievement of the objectives.

3. Substantial increases in vaccine costs. Vaccine prices have increased considerably in recent years and have been rising somewhat faster than the overall consumer price index.

4. Reduced perception of benefits and enhanced perception of risks of vaccination. Because of the success in reducing the incidence of childhood diseases, parents may perceive these diseases as less of a threat, and rare, serious reactions to vaccines may receive increased attention. For example, although the risk of paralysis associated with polio vaccine is only 1 in 3.2 million doses distributed, approximately one-half of all poliomyelitis cases in the United States in the period 1969–82 were related to polio vaccine. Continuing assessment of the balance of benefits and risks of vaccination is necessary, but it seems likely that the benefits from these vaccinations during childhood will far outweigh the risks of vaccination for the foreseeable future.

5. Problems in reaching adults with rubella vaccine. Although present levels of cases of congenital rubella syndrome indicate that the 1990 objective has already been met, serious consideration is being given to elimination of indigenous rubella from the United States. Accomplishing this objective will require a much improved ability to immunize adults in settings such as family planning clinics, general office visits, and postpartum obstetrical services. This objective will require increased awareness and activity among internists, family practitioners, and others providing health care to adults who have not traditionally had as strong an orientation to immunizations as have those providing health services to children.

Accelerated Development of New Vaccines

Recent scientific advances have opened the way for expanded efforts in the development of new vaccines. These advances, including recombinant DNA and hybridoma technologies as well as increased understanding of the immune system, stimulated the National Institute of Allergy and Infec-

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tious Diseases (NIAID) to recommend "Accelerated Development of New Vaccines" as a specific initiative of the Department of Health and Human Services (DHHS).

In the fall of 1980, the Secretary of DHHS accepted the recommendation of the Department's Steering Committee for the Development of a Health Research Strategy that the NIAID proposal be 1 of 4 new initiatives added to the 11 previously identified in December 1979. The 15 initiatives then constituted the Department's proposed initiatives for fiscal year 1981.

The purpose of the NIAID initiative is to develop within the Department a clearly identified, coordinated, and recognized approach to the further conquest of vaccine-preventable disease. To expedite the availability of needed vaccines, a few candidate vaccines will be selected for extra research and development efforts. Studies, most of them investigator-initiated, are in progress on more than 50 vaccine antigens for more than 30 different bacterial, viral, and parasitic diseases (table 3). The vaccines are in various stages of development: some are undergoing early testing in human beings; for others, the appropriate antigens have yet to be identified or purified.

Reaching the goals of the initiative depends on the assistance of existing advisory committees and of workshop participants who conduct state-of-the-art reviews; coordination with the DHHS Interagency Group to Monitor Vaccine Development, Production, and Usage; and enhanced collaboration with industry. With this cooperation, the Institute hopes to bring a few selected, high priority candidate vaccines into use several years earlier than might otherwise be the case.

Two major determinants were applied to select 10 diseases or disease categories for intensified effort: (*a*) diseases for which safe, effective vaccines do not now exist, but which result in high morbidity, mortality, or socioeconomic costs and (*b*) current technical feasibility and prospects for accelerated development of a vaccine if new and emerging technology is used.

NIAID has targeted the following diseases for prevention by immunization with new or improved vaccines within the next 10 years, some by 1990:

Meningitis in infants (*Haemophilus influenzae*, group B streptococci)
Gonorrhea
Croup and pneumonia in infants and children (respiratory syncytial virus)
Whooping cough (*Bordetella pertussis*)
Influenza
Diarrhea (cholera, typhoid, dysentery, rotaviruses)
Hepatitis (type A, type B—second generation)
Chickenpox
Genital herpes
Malaria

The proposed initiative calls for a review of diseases that are potentially preventable by vaccines from the standpoint of their socioeconomic and medical costs and for an assessment of the cost-benefit ratios of vaccines for each disease. In the fall of 1982, the Institute of Medicine began this review and evaluation in order to assist NIAID in setting priorities for development of vaccines. The Institute will also recommend to NIAID a new model system for decision making that can be applied to the setting of priorities in the future.

Achieving Objectives for New Vaccines

Objectives established for selective use and new vaccines are listed in table 2, as is progress toward meeting these objectives. It is clear that much remains to be done if these objectives are to be met. The major obstacles to achieving these objectives follow.

1. These vaccines are delivered primarily by practitioners in private practice. An important component of the success of childhood immunizations has been the provision of vaccine to children through public health departments; this avenue of delivery is currently not generally available for selective use vaccines. Medicare does not reimburse for influenza immunizations, and categorical immunization grants are limited to childhood immunization.

2. Continuing controversy about the effectiveness of influenza and pneumococcal vaccines has impeded acceptance of these vaccines.

Table 3. Status of vaccine development efforts by the National Institute of Allergy and Infectious Diseases, October 1, 1982

Agent and vaccine type	Number of preparations available	Animal model studies		Human trials	
		Antigenicity	Efficacy	Antigenicity	Efficacy
		Bacterial vaccines			
Bordetella pertussis					
OB acellular vaccine	1	in progress	in progress	DR	DR
Japanese acellular vaccine	1	completed	completed	planned	planned
Escherichia coli					
Pili, type I	1	....do....	....do....	completed	completed
Pili, colonizing factor antigen (CFA)I	1	....do....	NA	....do....	needed
Pili, colonizing factor antigen (CFA)II	1	....do....	NA	planned	planned
Whole cell, killed, oral	3	....do....	NA	completed	completed
Attenuated CFA II, Tox — (Rowe)	1	planned	planned	in progress	in progress
Attenuated CFA II, Tox B + A —	1	....do....	....do....	planned	planned
Heat labile toxoid	1	completed	completed	needed	needed
Heat labile and heat stabile toxoids	1	in progress	in progress	DR	DR
Haemophilus influenzae					
Polyribophosphate (PRP)—pertussis or DTP complex	1	completed	completed	in progress	DR
E. coli K100 polysaccharide	1	....do....	....do....	....do....	DR
PRP—CRM-197 D conjugate	1	in progress	in progress	DR	DR
PRP—D conjugate	1	completed	completed	planned	DR
Outer membrane protein	3	in progress	in progress	DR	DR
Neisseria gonorrhoeae					
Fimbria (pilus) protein	3	NA	NA	in progress	NA
Protein I (outer membrane protein)	5	NA	NA	....do....	in progress
Neisseria meningitidis					
Group C variant polysaccharide	1	NA	NA	in progress	DR
Group B protein-group B polysaccharide complex	1	in progress	NA	....do....	in progress
Pseudomonas					
Polysaccharide	7	....do....	in progress	planned	planned
Lipopolysaccharide (LPS) (heptavalent)	1	....do....	....do....	in progress	in progress
Cell wall extract	1	....do....	....do....	....do....	....do....
Rocky Mountain spotted fever					
Inactivated (whole organism)	1	....do....	....do....	completed	completed
Cell component preparation	1	....do....	....do....	DR	DR
Streptococcus group A					
M protein synthetic peptides (some preparations linked to polylysine or tetanus toxoid carriers)	9	....do....	....do....	DR	DR
Streptococcus group B					
Polysaccharide	6	completed	....do....	in progress	DR
Polysaccharide-protein complex	2	....do....	....do....	....do....	DR
Streptococcus pneumoniae					
14-valent polysaccharide licensed	1	NA	NA	....do[1]...	NA
Vibrio cholerae					
Inactivated:					
Oral (El Tor-Inaba-Ogawa, phenol-alcohol)	1	completed	completed	completed	in progress
B subunit	1	....do....	....do....	....do....	needed
Whole cell + B subunit	1	....do....	in progress	....do....	planned
Procholeragenoid	1	....do....	completed	planned	....do....
Flagella sheath	1	....do....	....do....	DR	DR
Outer membrane proteins	3	....do....	needed	DR	DR
Lectin-protease	1	....do....	....do....	DR	DR
Attenuated:					
B + A — Texas Star	1	completed	completed	completed	completed
B + A — Baltimore Bullet	1	in progress	in progress	DR	DR
B + A — Mechalonis strain	1	....do....	....do....	DR	DR

Table 3. Status of vaccine development efforts by the National Institute of Allergy and Infectious Diseases, October 1, 1982
Continued

Agent and vaccine type	Number of preparations available	Animal model studies		Human trials	
		Antigenicity	Efficacy	Antigenicity	Efficacy
			Fungal vaccines		
Coccidioides immitis					
Mycelia cell wall antigen	1	in progress	in progress	planned	planned
Spherule cell wall antigen	1	....do....	....do....	....do....	....do....
			Parasitic vaccines		
Malaria					
Gametes	1 (live organisms)	in progress	in progress	DR	DR
Asexual strategy	4 (irradiated merozoites, killed merozoites, merozoite/ schizont antigen, sporozoite antigen)	....do....	....do....	DR	DR
Schistosoma					
Irradiated larval stages	1	....do....	....do....	DR	DR
Nonspecific immune stimulation	(?)	....do....	....do....	DR	DR
Toxoplasma					
Attenuated strains	(?)	....do....	....do....	DR	DR
Trypanosoma					
Cell surface glycoprotein	Numerous variant-derived preparations	....do....	DR	DR	DR
Leishmania					
Promastigote membrane antigens	(?)	....do....	in progress	DR	DR
			Viral vaccines		
Cytomegalovirus					
Attenuated	1	completed	completed	in progress	needed
Hepatitis B					
Subunit, inactivated	6	....do..(2)	....do..(2)	completed(4)	in progress(2)
Polypeptide, chemically synthesized	1	in progress	planned	DR	DR
Hepatitis A					
Attenuated	2	....do....	in progress	NA	NA
Influenza A and B					
Subunit	2	completed(6) in progress(2)	planned(2)	completed(2)	needed
Attenuated (temperature-sensitive and cold-adapted)	6	completed(10) in progress(6) planned(5)	completed(1)	completed(7) in progress(2) planned(7)	planned(4)
Inactivated (whole virus) licensed	0	NA	NA	0	planned(1)
Parainfluenza virus 3	in progress	NA	NA	NA	NA
Rabies					
Killed, whole virus	1	completed	completed	completed	completed
Rotavirus					
Live, human strain WA	1	....do....	....do....	in progress	DR
Live, human strain D	1	planned	planned	DR	DR
Live, human strain DSI	1	....do....	....do....	DR	DR
Varicella					
Attenuated	1	completed	NA	completed	in progress

[1] Immunogenicity studies in high risk populations.
NA = not applicable.
DR = depends on results of current studies.
( ) = number of preparations being tested.

3. Many of these vaccines will be directed at specific target groups other than children, and there is no existing infrastructure to reach target populations other than children effectively.

4. Other than the perceived health benefits, incentives to become immunized (for example school requirements) do not exist for these vaccines, as they do for the childhood vaccines.

These obstacles are not so easily addressed as are the remaining obstacles to achieving the childhood immunization objectives. Overcoming them may require development of further scientific information and consensus, formulation of new policies, changes in legislation, and commitment of resources.

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Statewide Survey of Risk Factor Prevalence: the Ohio Experience

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SYNOPSIS

In 1982, a statewide survey was conducted to determine the prevalence of health risk factors among Ohio's population. The survey was mandated by a health education-risk reduction grant to the Ohio Department of Health. The background, development, and validation of the survey instrument are described. The four goals of "Health Ohio"—the collection of descriptive statistics on selected risk factors for adult Ohioans, the compilation of baseline data, the development of a standard methodology for a prevalence survey, and the reporting of these findings for potential users of the data—were achieved.

The population sample consisted of 607 Ohioans aged 18 and older who were polled by telephone. Subjects were selected through a modified random digit dialing technique. As a result of this technique and the designation of a specific household respondent, demographic characteristics of the sample matched those of the State's population in the 1980 census.

Among the implications of the survey findings were the needs to (a) *remove economic barriers that apparently impede the installation of residential smoke detectors,* (b) *initiate health education at an earlier age to counter cigarette smoking trends, and* (c) *encourage adult self-determination in reducing health risks. The February 1982 "Health Ohio" data describing the need for intervention to reduce health risk factors have become the basis for health education-risk reduction efforts of the Ohio Department of Health.*

In addition, "Health Ohio" has spawned two local prevalence surveys in the State; these resulted in more precise local data on the prevalence of health risk factors. Other multiplier effects of health education-risk reduction projects should be documented for future reference.

IN THE LATE 1970s CONGRESSIONAL commitment to health education as a means of protecting the public's health was demonstrated by the health education-risk reduction grants to the States through the Public Health Service's Centers for Disease Control (CDC). Among the activities mandated by CDC's grant to Ohio was a statewide prevalence survey of risk factors. These risk factors were defined by the