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AMERICAN PUBLIC HEALTH ASSOCIATION
International Health Programs

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PRIMARY HEALTH CARE ISSUES is a series of reports designed to provide a concise, accurate and authoritative overview of important developments in the field of primary health care (PHC). The series is directed primarily to concerned health professionals such as program managers and decision makers who plan and implement programs around the world. The series will constitute a system of information transfer for an audience with a special need for timely, relevant and useful information that is at once generically useful and specifically applicable. The series will:

- address PHC policy issues of national and international concern;
- analyze common problems in PHC program management including planning, implementation and evaluation;
- identify gaps in knowledge about PHC and recommend research to fill those gaps;
- provide up-to-date technical and policy information on PHC delivery.

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Reactions and comments from readers are invited and should be addressed to the Director, APHA/IHP, 1015 Fifteenth Street, N.W., Washington, DC 20005, U.S.A.

An infant receiving a DPT immunization in Malaysia illustrating the "Under-One Strategy" of immunization delivery discussed in Chapter III. photo: World Health Organization

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Health worker administering oral polio vaccine to young child in Thailand. photo: World Health Organization

introduction

"Immunization against the major infectious diseases" is defined as one of nine key basic components of primary health care according to the report of the WHO-UNICEF Conference on Primary Health Care held at Alma Ata in 1978. Even before the primary health care movement, there was universal consensus that essential and basic child health services must include childhood immunizations.

Of an estimated one hundred twenty-five million children born every year, approximately twelve million (or nearly 10 percent) die before age one—97 percent of the deaths occurring in developing countries. The major causes of deaths are gastrointestinal and respiratory diseases alone and in combination with malnutrition. A significant portion of these deaths could be prevented by effective infant immunization, yet only about 10 percent of the children in developing countries are properly immunized at present. Expansion of immunization coverage is a necessary and important step in reaching the World Health Organization goal of "Health for all by the year 2000."

Why is immunization delivery a major area of emphasis in primary health care?

1. Part of the reason is its impact on illness and its life saving potential. The United States and Europe reduced the incidence of polio, diphtheria, and pertussis by 95 percent to 100 percent during the twenty years following the introduction of these vaccines. While improved living standards also helped to reduce severity of these diseases, vaccines had far more impact. The success of the worldwide campaign against smallpox has been an impetus in seeking to reduce morbidity and mortality due to vaccine-preventable diseases among children.

2. The delivery of immunizations lends itself to systemization more than other aspects of primary health care. Although immunization delivery is clearly not simple, it does allow for the setting of clear objectives and routine procedures.

3. Unlike some other health interventions, immunization delivery requires little change in a population's habits, living patterns or social organizations. It is a feasible intervention in that the actions required of populations are minimal and, if properly planned, can readily fit into existing daily activities.

4. New techniques are available which improve the effectiveness of immunization programs. These include (a) simultaneous vaccinations through combining antigens (b) concentration on children less than one year of age and (c) improved cold chain systems.

5. Finally, international, technical and financial assistance is readily available for broad coverage immunizations. Although national governments need eventually to take responsibility for immunizations, at the present time developing countries can benefit from training courses, technical advisors, and vaccine supplies offered by the World Health Organization, UNICEF and numerous bilateral donors.

Despite the potential impact of immunizations on child health, immunization delivery constitutes only one step toward achieving "Health for all by the year 2000." Currently available vaccines have no impact on major killers and cripplers such as diarrheal diseases, malaria, schistosomiasis and other parasitic diseases. Essential steps to control these problems include adequate water and nutrition, suitable waste disposal, control of certain disease vectors, and infant, child and maternal health services other than immunizations. Many experts believe that good immunization coverage will not be possible until a broad health infrastructure has been developed and people have organized to improve their own health status. The subject of health development in this broad sense is addressed repeatedly in this paper just as it is often addressed in international meetings where immunization delivery is discussed.

SMALLPOX: FIRST TO BE CONQUERED

Variolation against smallpox was not introduced into Europe until 1721 although it apparently had been practiced in Africa, China and India for centuries before. The Reverend Cotton Mather learned of the practice from enslaved Africans who introduced variolation to Boston in the 17th century. The procedure was risky because the live smallpox virus was used. In 1796 the Englishman, Edward Jenner, discovered that vaccine derived from cowpox produced immunity with much less risk. By 1803, more than 100,000 persons had been vaccinated in England, and the King of Spain had begun efforts to promote vaccination in the Spanish colonies.

The first vaccines other than smallpox were developed in the late 19th and early 20th century, but

some of the most important vaccines for current programs did not become available until the 1950's and 1960's. Diphtheria and tuberculosis vaccines were tested in the 1920's and tetanus toxoid in the 1930's. Pertussis (whooping cough), measles and polio vaccines, all developed in the late 1950's and early 1960's, are still being refined. Though the history of immunizations is a long one, it is only in the last two to three decades that significant efforts have been made toward more universal protection.

Early immunization efforts in developing countries were either directed to epidemic control or were limited to isolated areas served by mission hospitals or health clinics so that relatively few people were effectively immunized. Because these efforts were isolated and unsystematic, logistic support and cold chain linkages were never developed and continuity and broad coverage were rarely achieved.

The World Health Assembly first resolved to eradicate smallpox in 1958, but it was not until 1967 that WHO began a coordinated worldwide campaign. The next decade saw intense efforts in three continents. Smallpox eradication was characterized by intensive mobilization of resouces. Thousands of temporary staff were hired, and the program was usually run vertically, outside of routine government health services.

The effort succeeded; smallpox was eradicated, from South America in 1971, from Asia in 1975 and from Africa in 1977. The staff and logistics structure became available for other immunization activities. These structures are being used in some countries for broad coverage immunizations but with mixed results due to differences between smallpox and other immunizable diseases.

BROAD COVERAGE IMMUNIZATIONS

Even before the eradication of smallpox, the World Health Assembly resolved in 1974 that WHO should assist member states to expand their immunization activities. The Expanded Program of Immunizations (EPI) was created and now assists member states throughout the world with vaccines, equipment, training and technical assistance. The EPI Secretariat at WHO headquarters in Geneva acts as a coordinator and information clearinghouse for global immunization activities.

Current efforts in immunization delivery differ from earlier ones in several important respects.

1. Unlike the smallpox campaign, immunizations will not completely eradicate the diseases they protect against. Some of the significant immunizable diseases have non-human reservoirs and so will remain even if everyone has been immunized. However, measles and paralytic polio do not have non-human reservoirs and so could be eradicated in theory.

2. Several of the important vaccines require multiple doses. Since they do not leave scars (like smallpox), a follow-up system is necessary to track children through their immunization series. Since a new group of vulnerable children is born each year the system to reach them must be permanent and closely coordinated with other routine health services.

3. Broad coverage immunizations depend on national level networks and logistics instead of isolated or sporadic activities such as those undertaken in the years before smallpox eradication. Governments are trying to plan and coordinate and improve immunization delivery throughout their nations. National coordination facilitates bulk procurement of vaccines and development of a single cold chain system. National coordination can help concentrate resources on priority age groups and geographic areas.

INTEGRATION OF IMMUNIZATIONS INTO PRIMARY HEALTH CARE

Despite consensus on the importance of broad coverage immunizations in essential child health services and the key role immunizations will play in progress toward the goal of health for all by the year 2000, there is continued debate on how broad coverage immunizations can be achieved.

The central issue is one which appears in discussions of the delivery of any health service—the advantages and disadvantages of vertically organized versus integrated health services. At first glance, the integration of immunizations into primary health care seems to be a false problem since immunizations of children in developing countries are often today a part of regular health services, particularly mother/child health services. But immunizations through health services typically reach only a small proportion of the vulnerable population.

To boost effective coverage, using up to six vaccines proposed by WHO, from today's 10 percent to 20 percent of the under 2 age group to 60 percent or 80 percent is an ambitious goal which may require an almost military-type campaign—the sort of effort most often identified with vertically organized health programs.

This report does not take a position regarding the question of integration beyond the observation that nearly all experts agree that integration of immunization services is a desirable but difficult goal to achieve. The purpose of this report is to show the difficulties and outline alternatives in achieving the overall goal of service integration in primary health care.

CHAPTER I

Vaccine-Preventable Diseases and Immunizations

ACTIVE VERSUS PASSIVE IMMUNITY

Animals, including human beings, have the ability to produce antibodies and antitoxins to fight pathogenic organisms and toxins which invade the body. When a child is ill with measles, his/her body produces an antibody against the measles virus and will continue to produce that antibody for the rest of the child's life, giving lifelong immunity to the disease.

When a child makes his/her own antibodies, the child has *active immunity*. This can occur in two ways: by becoming ill with the disease (natural active immunity) or by being vaccinated by a weakened measles virus to stimulate antibody production (artificial active immunity). *Passive immunity* occurs when a child receives antibodies from another person or an animal. For example, during gestation, maternal antibodies such as tetanus antitoxins pass from the mother to the fetus. Also after birth, antibodies are passed to the infant through mother's milk to protect the newborn against diseases such as tetanus, measles and malaria during the first months of life. Eventually, these maternal antibodies are destroyed by the infant's body; the protection is lost; and other protection becomes necessary.

Live and killed vaccines

Live vaccines such as BCG against tuberculosis, polio (Sabin), and measles contain live but weakened (attenuated) organisms which grow in the body and stimulate antibody production. Killed vaccines, such as those for diphtheria, tetanus and pertussis (whooping cough) contain killed organisms or toxoids of the organisms which also stimulate antibody production. Toxoids are toxins or poisons of organisms which have been rendered inactive by chemical action or heat.

In general, killed vaccines are not as effective in producing antibodies as live vaccines so that repeated doses are usually required to produce a safe level of immunity. The most commonly used polio vaccine is live, although a killed version is used in Europe, parts of Canada, and the United States. The live vaccine is administered orally (in a liquid form or on a sugar cube), while the killed version is inoculated.

Live vaccines are more sensitive (easily rendered inactive) than are dead vaccines. They can also be killed by heat, by antiseptics or by alcohol used in cleaning vaccination equipment. Live vaccines can be freeze dried to increase stability, but they must then be mixed with a diluent before administration. *After vaccines, live or killed, have been heat damaged, their potency cannot be restored. This is a difficult yet crucial point to communicate to transport agents and health workers.*

VACCINES AVAILABLE

A wide range of vaccines has been developed for use in immunization programs. Some have only limited utility in routine primary health care activities, but may be used for epidemic control or other special circumstances. The following vaccines are available:

cholera	plague
diphtheria	rabies
influenza	rubella (german measles)
measles	smallpox
mumps	tetanus
pertussis (whooping cough)	tuberculosis (BCG)
pneumococcal meningitis	typhoid fever
meningococcal meningitis	typhus
polio	yellow fever

The range of available vaccines constantly changes. Because smallpox has been eradicated, that vaccine should no longer be used in the general population. New vaccines against malaria and certain diarrheal diseases are under development. Several of the vaccines listed above can be mixed in a combined vaccine. DPT (diphtheria-pertussis-tetanus) and MMR (measles-mumps-rubella) are the most common examples. Killed type (Salk) polio vaccine can be combined with one or more of the DPT elements.

CHOICE OF VACCINES

The choice of vaccines for a particular program depends on three factors:

(1) the effectiveness of available vaccines in a given locale;
(2) the incidence and severity of vaccine-preventable diseases; and
(3) the resources and capacity of the health services network.

The first two of these factors are discussed briefly below, while the third is a complex factor discussed in much of the remainder of this monograph.

Effectiveness of vaccines:

Vaccines differ in their effectiveness; that is, the ability to produce an immune response in a susceptible population vaccinated under optimal conditions. Four

vaccines—diphtheria, measles, polio and tetanus—have effectiveness levels in the 95 percent range according to the World Health Organization (see Table I). Pertussis has an effectiveness level of 80 percent while the effectiveness of BCG vaccine is currently open to controversy [2].

Some countries choose to omit one or more of these vaccines because the disease is not a serious problem there or because the health infrastructure is too undeveloped. Countries also add other vaccines when they are able.

Cholera is a public health problem in a number of countries but the effectiveness level of the cholera vaccine falls considerably below 80 percent. This is also the case with typhoid vaccine. Yellow fever vaccine is used in a number of immunization programs in Africa and South America. Pneumococcal-meningitis vaccine is used in immunization programs in some Sahel region countries. Plague, cholera and other vaccines not used routinely may be used in mass campaigns during an epidemic. Yellow fever, typhoid fever and meningitis vaccines should be included in some routine immunization programs, but only in those countries where the epidemiological situation warrants it.

Incidence and Severity of Vaccine-Preventable Diseases:

Measles is the major cause of morbidity and mortality among vaccine-preventable diseases in the developing world, followed by pertussis. In some countries, neonatal tetanus occurs in 5 to 10 percent of the live births and usually results in death. Surveys show that polio causes lameness in 2 to 9 of every 1,000 school age children in some developing countries [3].

Using criteria such as the above regarding choice of vaccines, WHO has recommended highest priority for the following vaccines:

DPT (diphtheria-pertussis-tetanus)	Measles
Tetanus Toxoid	Polio
BCG (Bacille-Calmette-Guerin for tuberculosis)	

When high coverage has been achieved for these basic six diseases, countries may consider adding other vaccines to their public health programs, for example, the vaccination of women with rubella vaccine. Although individual countries may use different combinations of vaccines in their immunization programs, to simplify the task of this paper, discussion is limited here to the basic six diseases and vaccines addressed by the Expanded Program on Immunization.

Table I summarizes some characteristics of these vaccines, including their effectiveness level, recommended age for first dose, and temperature at which the vaccine must be stored to retain potency. Information on cost is not included here because it depends greatly on procurement arrangements. Only measles vaccine is strikingly more expensive than the other vaccines recommended by WHO. Required storage temperature, cold chain equipment needed, delivery costs and number of contacts required are as important as vaccine cost in choosing among the vaccines listed in Table I for use in an immunization program. (See also Chapter III regarding costs.)

UNDERSTANDING THE TARGET DISEASES

A lesson of the smallpox eradication campaign is the importance of *knowing* disease epidemiology in detail in order to intervene in the disease process in the most effective and precise manner possible. In a program addressing six diseases instead of one, disease epidemiology becomes more complex, and knowledge of each disease becomes more vital to the success of the program. A brief review of six vaccine-preventable diseases follows:

(1) Measles—A highly contagious disease which 90 percent of the unprotected under 5 population contract in some countries. A relatively mild disease in developed countries, measles is a major cause of childhood mortality in many developing countries particularly in Africa and Central America. Poor nutritional status seems to be the main factor leading

TABLE I: VACCINE EFFECTIVENESS, DOSAGE AND STABILITY

disease	*effectiveness*	*no. of doses*	*minimum age of first dose*	*long term storage temp.**
measles	95%	1	9 months**	−20 degrees C.
polio	95%	3	2-3 months	−20 degrees C.
tuberculosis	[see footnote 2]	1	after birth	+ 4 to +8 degrees C.
diphtheria	95%	2-3	2-3 months	+4 to +8 degrees C.
pertussis	80%	3	2-3 months	+4 to +8 degrees C.
tetanus	95%	2	2-3 months	+4 to +8 degrees C.

Source: Book I of the Field Manual of the Expanded Program of Immunization, World Health Organization, Geneva, 1977.

*For more information on storage of vaccines see Chapter III of this paper.

**Malnourished children may lose maternal antibodies somewhat earlier.

to the most severe consequences of measles. The common practice of withholding food during a child's illness exacerbates the condition. Death is caused by pneumonia, diarrhea or in a small number of cases, encephalitis, in association with the disease. Maternal antibodies transferred through the placenta protect the infant during the first months of life. If measles vaccine is given to the infant before nine months of age, these antibodies may prevent the vaccine from producing immunity in the child. But if the child is vaccinated too late, the period of greatest danger to the child will be past. The issue of immunization scheduling is discussed more fully later in Chapter III.

(2) Pertussis—Pertussis (whooping cough) is second to measles as a cause of morbidity and mortality among vaccine-preventable diseases in some developing countries. The World Health Organization estimates that up to 80 percent of unimmunized children will contract it. Pertussis, an acute bacterial infection affecting the respiratory tract, is very contagious in the first week or two of infection. The spasmodic coughing or "whooping" that characterizes the disease is readily recognized and lasts one to two months. Pertussis is most severe in children under 5 months of age and may lead to death through pneumonia or other conditions. In very young children, there is no characteristic whoop so the disease may be difficult to recognize. Immunity requires three vaccinations which may begin as early as 2 months of age.

(3) Tetanus—Caused by a toxin of a bacterium which enters the body through broken skin, neonatal tetanus is often caused by infection from the cut umbilical cord. Pregnant women who receive two tetanus toxoid immunizations within 3 years of delivery pass immunity which protects the newborn during the first months of life. Tetanus bacteria reside in soil so, unlike smallpox, there is no hope of eliminating the reservoir of harmful organisms. Instead protection comes only through immunization against the disease or through improved hygiene.

(4) Poliomyelitis—A viral disease spread by contact with objects, food or water contaminated with excreta, polio infection is universal but most persons have no symptoms. In a small minority of cases, polio leads to varying degrees of paralysis and some times, death. The older the child at age of infection, the more likely the infection will lead to severe consequences. The use of polio vaccines in the last 20 years in developed countries has markedly reduced the incidence of polio; however, its relative infrequency has led to laxity and occasional outbreaks among the unimmunized. In developing countries, the incidence of paralytic polio appears to have been seriously underestimated. Good evidence for the paralytic form of polio is lameness with no loss of the sense of touch or pain in the affected limb.

(5) Tuberculosis (TB)—TB is a bacterial disease spread by coughing and the sputum of infected persons. The disease takes many forms in children, infecting the bones, lungs or brain. Often it may not be recognized as the same disease that affects adults. TB is particularly common where many persons share the same crowded living quarters. In some cities in developing countries, one percent of the adults may be in the active infective stage of the disease. Beyond infancy, improved housing, clothing, diet, early detection and uninterrupted treatment are all necessary to effectively control TB. That these measures are difficult to achieve in many developing countries explains the importance of immunization as a means to protect those not infected by TB.

(6) Diphtheria—A major child killer of the past in temperate countries, the mortality and morbidity of diphtheria is the least well documented of the six diseases in developing countries today. Although typically manifested as an acute infection of the throat, diptheria toxin can affect the heart or brain of infants and young children. Vaccination against diphtheria over the past 50 years has eliminated the disease in many developed countries. Skin infections with *C. diphtheriae* in cuts and abrasions may protect many children in developing countries from the severe infection.

Of the six diseases reviewed here, measles and paralytic polio are the most likely to be eliminated (although not eradicated) through a continuous and comprehensive immunization program. TB and tetanus are greatly influenced by general living conditions and sanitation, and will decrease as standards of housing and hygiene improve. The overall incidence of measles and pertussis is not greatly affected by living standards, but cases are much less severe and occur later when children are well nourished. Diphtheria and polio, by contrast, may actually increase as standards of living improve. Diphtheria bacilli reside in soil while polio is transmitted through feces. Many children in developing countries gain some immunity gradually through contact with the soil and with feces. For all its benefits, improved hygiene and sanitation may lessen this mode of acquiring partial immunity thus increasing the importance of polio and diphtheria immunizations in developed as well as developing countries.

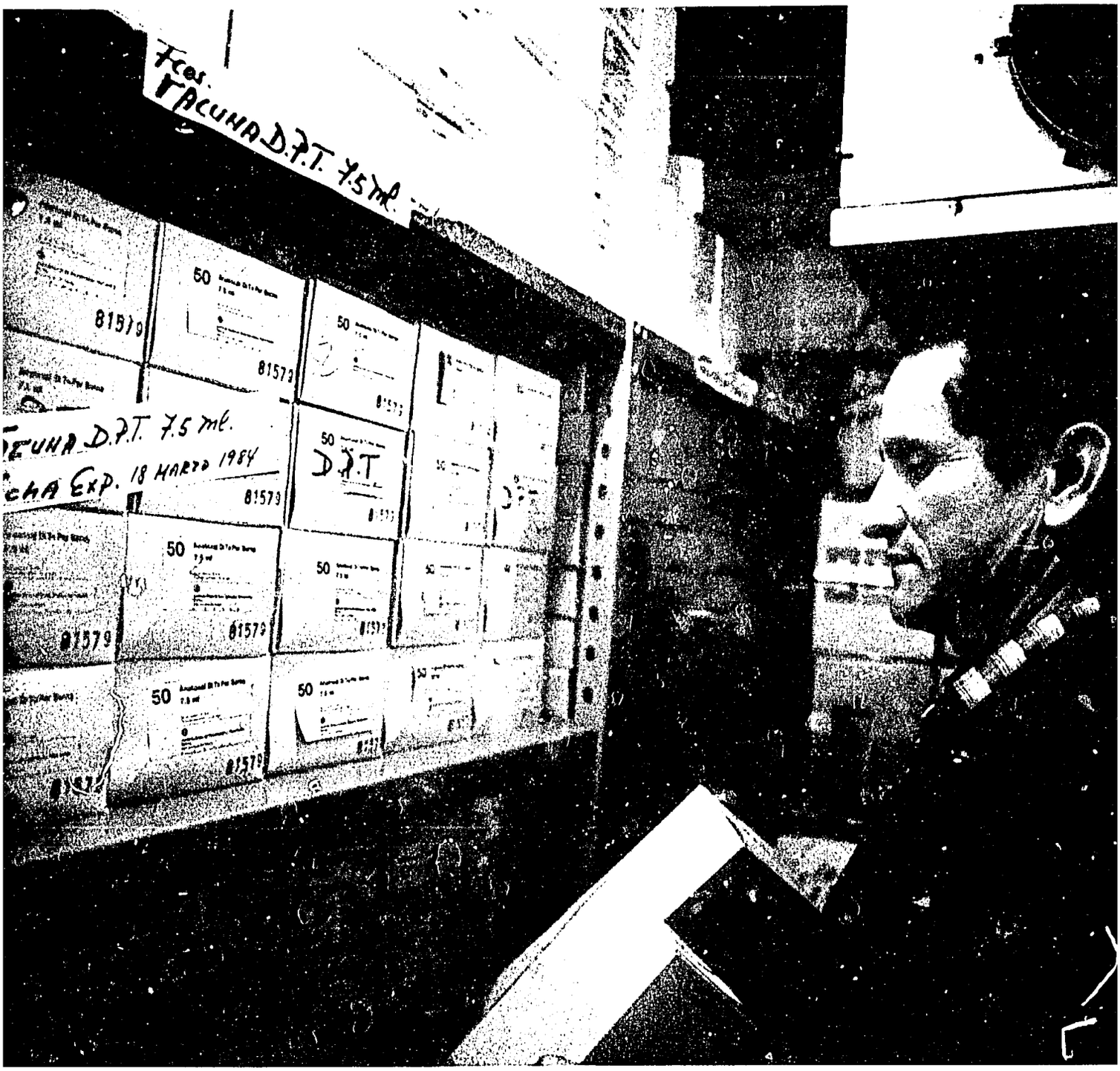
IMMUNIZATION SIDE EFFECTS

As is the case with nearly all medicine, immunization has some undesirable side effects. However, most experts believe that the benefits of vaccines far outweigh the risk of common mild side effects and rare severe side effects. Parents should be warned of the common side effects of immunizations; otherwise they may suspect that immunizations cause rather than protect against illness. In some cases,

measles vaccination produces a mild fever easily controlled by aspirin and a rash which may occur 8 to 12 days after vaccination. Reactions to oral polio vaccine, a paralysis similar to poliomyelitis, are very rare—perhaps one in every million doses. BCG vaccination will cause a small sore to develop at the vaccination site which usually disappears after one to two months. In some children this sore will not heal but will become a chronic ulcer.

In the case of DPT vaccinations, the most frequent reactions are fever and redness, swelling and pain at the site of injection. The pertussis component, in rare cases, can cause several neurologic reactions, some of which are severe.

More dangerous than side effects of vaccines is infection by contaminated needles and syringes. This problem is not only associated with immunizations given under unsanitary field conditions but also with injections of all kinds. This issue will be discussed more fully in Chapter VI.



A vital link in the cold chain is the central vaccine storage facility with an adequate supply of vaccine. Shown here is the central cold room in San Jose, Costa Rica. photo: Marcelo Montecino

Immunization Delivery: The Cold Chain

To vaccinate a child may seem simple. Bring a health worker armed with a potent vaccine and a parent with a child together at the same time and in the same place. But there are dozens of variations on when, where and how this simple meeting takes place—each variation with implications regarding cost, feasibility and coverage. Vaccines which require multiple doses spread over time further complicate this basic meeting. Sometimes viewed as a cheap or simple method of preventing communicable diseases, there is nothing simple about the organization, supervision, supply and delivery of immunization on a continuing broad coverage basis. Basic to the entire process is the cold chain.

Cold Chain Defined

A cold chain is the logistics system, composed of people and equipment, that moves and monitors vaccines at acceptable temperatures from manufacturer to persons who are vaccinated. The cold chain is vital because vaccines are sensitive to heat. It is a crucial link in any immunization program. The most organized field program reaching a high percentage of the target population is at best, ineffective, and at worst, undermines the people's confidence in the health care system, if the vaccine is not potent due to improper refrigeration or handling somewhere along the chain.

In the late 1960's an AID supported smallpox/measles mass immunization campaign in Nigeria achieved initial success and brought about a dramatic fall in the incidence of measles, especially in urban areas like Ibadan in the South [5]. In months which followed, however, an increasing number of measles cases were seen at University Hospital in Ibadan, many of the cases in children with a clear record of having been immunized. When this was noted, samples of measles vaccine were obtained and tested for potency. Of 20 samples tested, only one showed evidence of active measles virus capable of producing an immune response in a child. The balance of the samples were inactive due to cold chain failure, an all too common occurrence early in immunization programs.

There are three essential elements of the cold chain:

(1) people to organize and manage vaccine distribution;
(2) equipment to store and transport vaccines; and
(3) regular and dependable handling procedures.

Table II outlines the maximum storage times and temperatures for six vaccines at different stages in the cold chain. Vaccines differ in stability and refrigeration requirements, but all vaccines can be kept up to one month at various levels in the cold chain at temperatures ranging from +4°C to +8°C. Tetanus toxoid (TT), diphtheria-pertussis-tetanus (DPT) and tuberculosis (BCG), can be stored for relatively long periods at this temperature, a year and a half in the case of the first two vaccines and one year in the case of BCG. DPT and TT, however, must be kept from freezing. Polio vaccine is less stable than DPT and TT. Both polio and measles vaccines can be kept up to two years. The latter vaccines are best preserved fro-

TABLE II: TEMPERATURE REQUIREMENTS AND MAXIMUM STORAGE TIMES FOR FIVE VACCINES LISTED BELOW*.

	central store	*transport to region*	*regional store*	*transport*	*static unit*	*mobile team*
measles	2 years at −20°C	−20°C to +8°C	3 months at −20°C	−20°C to +8°C	1 month	1 week at 4-8°C
oral polio	2 years at −20°C	−20°C to +8°C	3 months at −20°C	−20°C to +8°C	1 month	1 week at 4-8°C
BCG	8 months at 4-8°C	+4°C to +8°C	3 months at 4-8°C	+4°C to +8°C	1 month	1 week at 4-8°C
DPT	1½ yrs at 4-8°C	+4°C to +8°C	3 months at 4-8°C	+4°C to +8°C	1 month	1 week at 4-8°C
tetanus	1½ yrs at 4-8°C	+4°C to +8°C	3 months at 4-8°C	+4°C to +8°C	1 month	1 week at 4-8°C

Source: Supply Directive #55, UNICEF Supply Division, New York, Geneva, and Copenhagen, March 1980, page 3.

*In theory, if proper storage temperature is maintained, vaccines can be maintained at the periphery just as long as they can at the central store. However, the cold chain is usually weaker at the periphery than it is at the center and so small quantities of vaccine should be stored at these levels.

zen at −20°C but can be stored for shorter periods of time at +4°C to +8°C. Because of rapid improvements in vaccine stability, recent information (as in Table II) is soon outdated. Those with cold chain responsibility should check with regional WHO offices for the most recent information on vaccine stability.

LEVELS IN THE COLD CHAIN

In many countries there are four levels in the cold chain. They are:

- central,
- regional,
- health center, and
- local health post or vaccination site.

Backup facilities where vaccines may be stored in the event of equipment failure should be identified at all levels. Coolers in non-health facilities such as food warehouses or breweries can be used. If there is a distribution system already in existence in the country for commodities which must be kept cold, for example ice cream, use of this network for vaccine maintenance should be explored. When backup facilities are not designed for vaccine storage, their use and temperature must be closely monitored.

The central store is usually located in the national capital or principal city and receives vaccine from the manufacturer, usually by way of the airport. The central store is designed for long-term storage of large amounts of vaccine. Necessary equipment includes a walk-in cold room capable of maintaining temperatures of 4°C to 8°C, or a bank of refrigerators as well as freezers adequate for −20°C temperatures. A backup power supply, thermometers, thermorecorders, and a warning alarm system are necessary.

Receipt of vaccines at the airport is a unique and problematic situation. In many national immunization programs there have been instances where serious and expensive cold chain failures occurred at the airport. The following procedures can prevent cold chain failures at the airport:

- Advance notification arrangements should be written into vaccine contracts so the manufacturers will notify a specific person, office and address in advance of shipment.
- A specific person and vehicle should be responsible to meet every expected vaccine shipment. Airport or customs officials should notify this person when a shipment arrives.
- If the airport has cold storage facilities, arrangements can be made to place vaccines in the facility until they are collected.
- Necessary documents should be prepared in advance so customs can be cleared without delay.

The *regional level store* is usually located in a department or provincial capital city. Vaccine can be transported from the central store to the regional level in refrigerated vehicles or large cold boxes (insulated containers) with sufficient ice packs to keep the vaccine between +4°C and +8°C for the duration of the trip. Facilities in the regional store include refrigerators and freezers equipped with thermometers and possibly thermorecorders and alarm systems. Vaccines can be kept here for up to three months. National airlines may be willing to transport vaccines without charge in the country when space permits. A drawback to this procedure occurs when paying cargo at the last minute displaces the vaccine shipments which can sit on the runway in the sun for a long period of time.

The *health center store* is often located in a large town with or without electricity and may supply vaccine to surrounding sub-centers or satellite units. A refrigerator capable of 4°C to 8°C storage, not always with freezing capability, is sometimes available. If outreach is a major activity, a freezer for producing ice packs or cold dogs for cold boxes may be necessary at this level. A thermometer should be kept in the refrigerator at all times. A major problem with health center refrigerators is that they are often the only ones available for the staff. This results in frequent openings which can easily strain the refrigerator's capacity and result in vaccine failure. Strict discipline may be needed; *warning messages should be attached to the refrigerator, and supervisors should check for contents other than vaccines whenever they visit.*

Smaller cold boxes or vaccine carriers with ice packs may be used for transporting vaccines to the *subcenter or local level.* Vaccines can be stored in their original carriers up to the limit of cold life (usually 48 to 120 hours). Vaccination sessions can be planned to coincide with the arrival of vaccine from the health center store. If the cold life of the cold box is not exceeded, excess vaccine can be returned to the health center store.

COLD CHAIN EQUIPMENT

The organization, skills, training and motivation of the people who make up the cold chain are probably more critical to a successful cold chain than the equipment in use. Nevertheless, adequate and efficient equipment can better protect vaccines, simplify tasks, reduce maintenance and permit more effective use of personnel.

WHO and UNICEF are cooperating to test cold chain equipment and make recommendations regarding equipment performance under field conditions. Product information sheets describing the results of equipment tests are available from UNICEF or WHO. Equipment tested includes:

- cold rooms for bulk storage of vaccines;
- refrigerators and freezers for vaccine storage;
- refrigerated vehicles and portable refrigerators;
- cold boxes, insulated carriers, and packaging for the transport of vaccines;
- ice packs (cold dogs) for cooling vaccine packaging; and
- thermometers and thermorecorders for monitoring vaccine storage.

Front-opening refrigerators, the rule in many areas, are less capable of protecting vaccines from high external temperatures than top-opening models because cold air in front-opening models empties out each time the door is opened. In a top-opening model cold air tends to remain inside even with the lid open. None of the front-opening gas or kerosene refrigerators tested were able to protect vaccines when outside temperatures reached 43°C. or 110°F. Frequent door opening and, in the case of electric refrigerators, varying voltage and erratic supply of electricity contributed to the poor performance of front-opening models. Commercial-type chest freezers converted to act as vaccine refrigerators have the following advantages over front-opening refrigerators built for home use:

- better insulation,
- less escape of cold chain air,
- better configuration of space in the storage area, and
- smaller temperature differences in the storage area.

When ice packs or plastic bottles of water are frozen and placed around the walls of a converted freezer (called an ice-lined refrigerator) vaccine storage temperatures can be maintained with low voltage electricity or with only 8 hours of current in every 24-hour period even in outside temperatures of 110°F.

Certain top-opening kerosene (paraffin) refrigerators have been identified by UNICEF and WHO as capable of storing vaccines at high external temperatures. Development is proceeding on a kerosene vapor burner to replace wick burners in refrigerators. The vapor burner appears to be more efficient than the wick burner; it requires less maintenance and can operate on contaminated fuel, a common cause of failure in kerosene refrigerators. See Appendix I for more information on cold chain equipment.

Experience in many countries indicates that the risks of damage to vaccine are greatest at the health center and local levels. Health center staff often have many duties and cannot continuously supervise vaccine storage equipment. Even under the best condition, cold chain equipment requires attention and preventive maintenance. The most important procedures of maintenance are the routine day-to-day and weekly checking and cleaning of equipment, tedious or seemingly unimportant chores, which are often left undone by overburdened staff. The problem of maintenance will be compounded in those countries where the concept of preventive maintenance for machines is not well understood.

INVENTORY AND QUALITY CONTROL

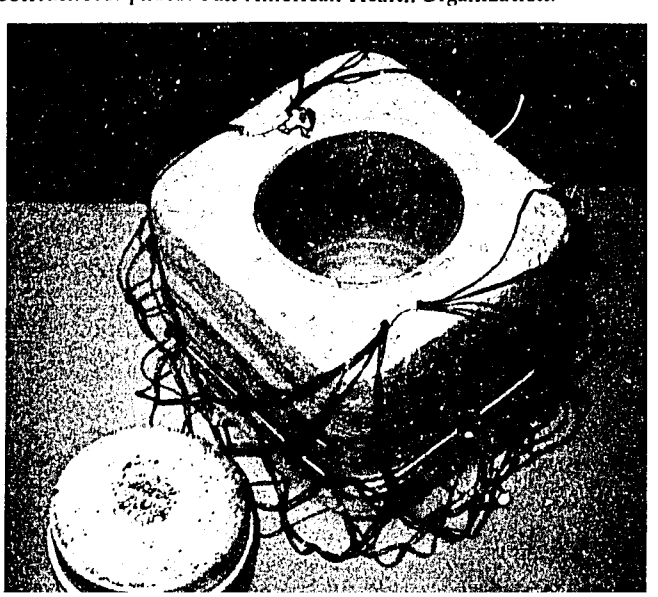
Records on vaccine movements should be kept at all levels of the system, and problems should be flagged when summary reports are sent to managers. Program managers need to know how much vaccine they are using, how much they need, where the vaccine is and where it should be. They need to be able to detect bottlenecks and project vaccine requirements long in advance. The date of manufacture and source should be recorded using tally sheets and each batch tracked as it makes its way through the "pipeline."

A vial of impotent vaccine in the hand of a vaccinator looks and feels the same as potent vaccine. Administering ineffective vaccines is a waste of resources, does nothing to reduce death and disability and may cause a loss of confidence or even hostility among previously cooperative groups.

The most efficient loci from which to draw vials for testing are peripheral delivery points. If a problem is found there, it can be traced back through the system to the cause. The more sensitive vaccines, such as polio and measles, should be tested at least once a year. Vaccine testing facilities exist in a number of countries, and the WHO representative can usually assist with the testing of vaccine through a WHO collaborating laboratory.

Managers need to know what kind of equipment they have, where it is located, and how well it is functioning. Supervisors need to know whether routine maintenance procedures are being followed. Persons in charge of a storage facility of any kind need to know whether their appliances are losing effectiveness.

The cold box pictured below is an example of appropriate technology from Ecuador. A plastic bucket is inserted into layers of insulating foam recycled from vaccine shipping containers. photo: Pan American Health Organization.



Young child receives immunization at a health center in the Republic of Yemen. photo: UNICEF

CHAPTER III

Immunization Delivery: Strategy and Costs

COVERAGE

Coverage is the percent of children to be immunized who have received the necessary doses of vaccine. High coverage is the key issue for effective immunizations since immunizations on a spotty or irregular basis already take place in all developing countries. The most basic decision regarding immunization delivery is whether people will be brought to the immunization site or immunizations taken to where the people are. The first strategy is more economical, but coverage is usually less extensive. The second strategy ensures better coverage but at a substantially greater expense. In practice, there are other options in the delivery of immunizations [6]. These are:

- fixed facilities delivery;
- outreach from fixed facilities to satellite facilities; and
- mobile teams.

1. Fixed Facilities

The *fixed facility* option is based in a clinic or health center. Staff are permanently assigned to the facility and vaccinate as part of their routine mother/child health care or other duties. The staff remain in the facility and vaccinate people there. A fixed program is usually the least expensive type because it uses resources that currently exist and minimizes transportation costs.

2. Outreach from Fixed Facilities

The second option is an *outreach or satellite strategy from a clinic or a health facility.* As in a fixed program, the staff are permanently assigned to the facility and vaccinate in addition to other duties, but staff may travel to dispensaries or satellite units in surrounding areas, or to villages where no facilities are available. Village health workers, who may not be trained to give vaccinations, can help mobilize their communities for increased participation in the program. Outreach is more expensive than a fixed program due to the cost of organizing immunization sessions, transportation of staff, and cold storage equipment for vaccines.

3. Mobile Teams

The mobile team is a special group of health workers who travel to areas where no health facilities are available. This group is not assigned to any facility but usually operates from a regional headquarters. The mobile team strategy is the most expensive one due to the cost of specialized personnel, their transportation, equipment and per diem expenses.

Most immunization programs are heavily based on fixed facilities, but satellite and mobile units are used when:

- peripheral health staff have not yet been trained or qualified in immunization techniques;
- significant population groups are outside the reach of routine health services; or
- sufficient resources are available to pay for the extra cost.

Mobile teams and outreach may initially be the easiest way to reach these areas, but immunization delivery (unlike smallpox eradication) requires continuous contacts year after year. Immunization programs will, therefore, benefit greatly as governments are able to provide immunizations on a routine basis from fixed facilities rather than from special outreach campaigns.

MODES OF DELIVERY

After deciding on the strategies listed above, a further decision must be made on whether to carry out immunizations by means of:

- collection-point immunization; or
- house-to-house immunization.

1. Collection-Point Immunization:

Health personnel inform or persuade the public to come to a centrally located place at a given time where equipment and personnel are assembled for a vaccination session. This is typical of immunizations in a fixed facility such as a health center but can also be used as part of outreach or mobile team activities. The collection-point mode enables efficient use of personnel. Equipment can be brought in a single vehicle (if not already present at the site) and set up for an organized vaccination session. However, the outcome of the collection-point mode depends greatly on the extent to which the community has been involved in the planning, scheduling and operation of the immunization activity. Without such involvement, there may be passive or active public opposition, and sessions inadvertently may be scheduled at less than ideal times or locations. With such

involvement, existing channels of communication (from opinion leaders to citizenry and among families) can be utilized. The collection-point mode, even more than house-to-house immunization, requires active knowledge and motivation among the population being served.

Distance from the immunization site is even more important in determining the success of collection-point immunizations. During an immunization campaign in Ghana, for example, coverage was 87 percent complete within a one-mile radius of the site and 68 percent complete at one to three miles. A rule of thumb is that without transportation, a collection-point strategy will lose effectiveness rapidly beyond a radius of 5 km. from the immunization site.

2. House-to-House Immunization:

In this strategy, health personnel visit individual homes to locate and vaccinate infants, small children and pregnant women. The advantage of the house-to-house mode is improved coverage in that those with the greatest risk of contracting diseases can be identified and immunized. However, this method is costly in health personnel time relative to the number of children vaccinated. There is potential for vaccine wastage and supervision of health personnel is more difficult.

Community health workers successfully administered tetanus toxoid vaccines during home visits in an integrated health services project sponsored by the International Center for Diarrheal Disease Research in rural Matlab, Bangladesh. Several factors which may not be found in other regions or projects contributed to this effort's success:

- The health workers were well trained and supervised.
- They had easy access to a central vaccine source.
- Population density was high so many mothers could be seen in a short time.
- Health workers knew the families and had established trust during previous visits.

SPECIAL MASS CAMPAIGNS

A mass immunization campaign can involve all the delivery strategies listed above or a combination of several. Usually health workers in a mass campaign discontinue other routine activities to devote themselves exclusively to vaccinations for a short time (a week or a month). With publicity and promotion, it is possible to elicit the interest and cooperation of the community. Volunteers from the community can help increase coverage by promoting participation.

Even when mass campaigns are not used for routine immunizations, an epidemic of yellow fever or cholera, for example, may call for special mass campaigns. Governments are wise to have contingency plans for a mass immunization campaign in the event of epidemics.

Mass campaigns become more complicated when immunizations require two or more contacts with the person immunized to complete the vaccination series. Unlike smallpox vaccinations which leave a characteristic scar on the arm of those vaccinated, DPT, measles and polio vaccines do not leave a readily observable scar to serve as a marker of vaccination. Record-keeping is essential. The feasibility of records or vaccination cards as markers of the completion of vaccination series is discussed in Chapter VI.

Another disadvantage of mass campaigns is that they disrupt other health program activities during the time of the campaign. Also, usually it is not possible to keep staff and community interest high over a period of time in a mass campaign. Coverage is often good the first year but diminishes during the following year. For these reasons, many countries seek to shift their efforts from periodic mass immunization campaigns to ongoing and continuous vaccination activities on a routine basis.

TARGETING IMMUNIZATION DELIVERY

Most governments would like to immunize all children as well as women of childbearing age, but very few countries have either the personnel or financial resources to do so. In order to achieve the greatest possible reduction in morbidity and mortality, many governments are choosing to concentrate their resources on those most easily reached from fixed facilities and those most susceptible to vaccine-preventable diseases.

An important lesson of the smallpox eradication campaign was to break down the overall job of eliminating smallpox into less complex sub-tasks capable of being completed. The same lesson applies to the challenge of providing immunizations to large numbers of previously unvaccinated children. Increasing immunization coverage from 10 percent of the children of a given country to perhaps 80 percent is such an ambitious task that a more limited or targeted approach may be more feasible.

1. Geographic Targeting

Central regions and more urbanized areas are usually given priority for three reasons:

- because the cold chain weakens as distance from the source of vaccines increases;
- because the volume of demand in these areas ensures fuller utilization of personnel and equipment; and
- infection rates in some cases are higher in urban areas than in sparsely settled rural areas.

Peripheral areas, especially sparsely settled areas, are

usually given lower priority until urban areas served by fixed facilities have been reached.

2. Targeting the Most Vulnerable Age Groups

Infants are the most vulnerable age group for many diseases, especially after the loss of maternal antibodies and subsequent contact with disease pathogens in the environment. Exposure to the pathogens leads to lifelong natural immunity for most children, but a significant number fail to survive. The most cost-effective immunization strategy is to stimulate production of maternal antibodies before birth (for tetanus only) and to immunize infants as soon as possible after the loss of passive immunity. Once natural immunity has developed, there is no benefit to be gained from vaccination.

A study in Cameroon showed that 75 percent of the 6 to 11 month old children were susceptible to measles, while only 25 percent of those 18 to 36 months old were susceptible [7]. Studies in Kenya and elsewhere have shown that the highest number of measles cases occur in the 6 to 12 month age group, while pertussis mortality rates are highest under the age of 6 months [8]. There is always some chance that a child being immunized is already immune. Natural immunity can only be detected through serological tests—an impractical task among large populations in developing countries. *Except for the action of maternal antibodies, the younger a child is when immunized, the more years of protection from disease are provided and the less likely are immunizations to be "wasted" due to naturally acquired immunity. Thus, immunization through schools, while very convenient, is no longer recommended because the majority of those inoculated have already achieved immunity.* The effect of maternal antibodies on immunizations is discussed in Chapter I.

Immunization of pregnant women with tetanus toxoid benefits future infants because it will protect them against the risk of neonatal tetanus. The mother is, of course, also protected. Some programs find it convenient to immunize women of childbearing age whenever they happen to be in the clinic, rather than to develop special programs to identify those who are pregnant. Other programs lack the necessary resources and choose to give higher priority to those in immediate need. A cost/benefit comparison of two tetanus immunization strategies—one directed to pregnant women and the other to the general population (including men)—showed that mortality reduction per dollar expended was much greater when aimed at the more specific target group [9].

3. The Under-One Strategy

The preceding considerations led WHO to recommend that immunization programs focus on two relatively small target groups—infants under 1 year of age and pregnant women. A recent training manual states the under-one strategy as follows [10].

> These infants (under 1 year) are a relatively small target group (compared to children 0-4 years) the vaccination of whom will prevent a large portion of the vaccine-preventable diseases and deaths in early childhood. One of the mistakes in earlier immunization efforts has been an attempt to vaccinate too large an age group. It is believed that many of the vaccinations of older children were wasted. . . .
>
> (Broad coverage immunizations) are made easier when efforts are concentrated on a relatively small, well-defined target group. Children up to age 5 account for 15 to 20 percent of the total population (in many developing countries) while infants below age 1 constitute only 3 to 4 percent of the total population.
>
> It is obvious that a new group requiring vaccination is born each year. A program that cannot vaccinate all or nearly all the children born *each year* will not be able to keep the . . . diseases under control.

IMMUNIZATION SCHEDULING

Immunization scheduling is affected by two biomedical factors: the age at which the infant can develop active antibodies, and the number of shots which must be given. It is also greatly affected by the capabilities of the health delivery system.

As noted earlier in this report, the most critical time in the life of an infant occurs after the loss of maternal antibodies and before the acquisition of natural immunity. If an immunization is given too soon, the infant will still have passive immunity and will not develop antibodies. If the shot is delayed, the infant is vulnerable and may fall victim to disease. Malnourished children may lose maternal antibodies faster than others. It is impossible to know the optimal time for immunization for a particular child except through blood testing (not a feasible proposition in any program).

Table I in Chapter I showed that BCG could be given after birth, DPT at age two to three months and measles at nine months. Four of the six vaccines reviewed in this paper require multiple doses given at least one month apart. Health staff need a method for identifying those who need further immunizations. Parents must be informed of this requirement and motivated to bring their children for additional immunizations. This problem is complicated when immunizations are provided by a mobile team rather than from a fixed facility.

1. Short Versus Long Immunization Cycle

The productivity or coverage capability of a mobile team or an outreach unit of a health center depends upon how soon the unit must return to its starting point to begin a second, third, or fourth cycle of immunizations to follow-up immunizations to children and mothers reached during the previous rounds.

In a fixed facility where immunizations are given

on a frequent and regular basis, a short immunization cycle is possible; for example, the following schedule would be ideal:

SAMPLE IMMUNIZATION SCHEDULE FOR A FIXED FACILITY

age of child	*immunization*
3 months	1st DPT, BCG, 1st polio
4 months	2nd DPT, 2nd polio
5 months	3rd DPT, 3rd polio
9 months	measles

While the preceding schedule is ideal from the point of view of the protection afforded the child, a mobile team or a satellite outreach unit may not be able to travel through its assigned territory on a monthly cycle—therefore a compromise schedule is necessary. The following is a sample immunization schedule for a unit visiting a number of satellite health posts or sites in a region surrounding a health center.

SAMPLE IMMUNIZATION SCHEDULE FOR A SATELLITE UNIT

age of child	*immunization*
3-5 months	1st DPT, BCG, 1st polio
6-8 months	2nd DPT, 2nd polio
9-14 months	3rd DPT, 3rd polio, measles

The above schedule has a cycle of approximately 3 months and requires only three rather than four contacts between the health worker and the child. In the case of mobile teams, which typically cover vast territories unserved or underserved by health facilities, further compromise of the immunization schedule is often necessary. The following schedule is based on a six-month cycle.

SAMPLE IMMUNIZATION SCHEDULE FOR A MOBILE TEAM

age of child	*immunization*
3-8 months	1st DPT, BCG, 1st polio
9-14 months	2nd DPT, 2nd polio, measles
15-21 months	3rd DPT, 3rd polio

FOLLOW-UP: THE SECOND AND THIRD DOSE

Studies of immunization coverage in some countries have noted a sharp fall-off in coverage between the first and third doses of DPT and polio vaccines. Fewer than half of those starting a series may complete it, and only those few who continue will be fully protected. Common reasons for the drop-off in completion of immunization series include:

- parents may believe one dose to be enough;
- the clinic may fail to give the parent a specific date for return, or the parent may forget it;
- previous experience with the service may be unpleasant;
- the parent may actually return, but the clinic may be overcrowded or the vaccine not available;
- the family may move, either seasonally or for a longer duration;
- the parent or the clinic may lose records and not know who needs which injections; and
- the child crying or side effects of the immunization may alarm parents.

These are universal problems, as prevalent in developed countries as they are in rural Africa, Asia or Latin America. The clinic needs to make sure that each parent understands the need for follow-up and, if possible, knows the specific date and time for return. These matters are often explained in group sessions, perhaps in a waiting hallway, but parents may not be able to interpret a group explanation to their individual circumstances.

Close scheduling of second and third doses may help; people are more likely to forget if the time for return is a long time away. The return date should be given to each parent individually, if possible. Staff in some programs write the return date on a health card kept by the parent. If this is the case, staff need to state the date verbally as well. One final device is to post a clinic worker or community volunteer at the exit to make sure that each parent knows the next date before he or she leaves. Research in one country showed that 33 to 50 percent of parents did not know when they needed to return and this is likely to be a problem in other countries as well.

Chapter IV stresses the importance of cultural factors and community participation in achieving broad coverage immunizations. This is particularly true in completing immunization series.

COST OF IMMUNIZATION

Compared with the cost of treatment of childhood communicable diseases, the cost of immunizations is small. But compared with per capita expenditures by governments of developing countries on health services (see Table III on page 21), the cost of immunizations is substantial. Even when the benefits of immunizations are clear, scarcity of resources may prevent a country from launching a broad coverage immunization program. To decide the feasibility of such an undertaking, information on the cost of immunizations is essential. However, information on cost of broad coverage immunizations in a developing country setting is sparse as is information on how, precisely, these costs have been calculated.

1. Immunization Costs in Kenya

Mobile teams immunized preschoolers in a sparsely settled area of the Machakos District in Kenya [11]. The six vaccines discussed in this paper were used in the Kenya program together with smallpox. Schools were used as collection points and school children played a key role in dissemination of information about immunizations in the Connecticut-sized project area.

In 1976, two years after the program began (four six-month cycles for the mobile teams), program costs and coverage were evaluated. Coverage was higher (82 percent of the children age 9 to 14 months) in the more densely settled section of the project area than in the sparsely settled zone (57 percent). In all study areas, coverage was higher due to mobile teams than was coverage in control areas served only by fixed facilities.

Costs per fully immunized child ranged from $1.50 to $1.67 in the more densely settled zone and $1.94 to $2.35 in the sparsely settled zone at the time of the study. The cost of the vaccines themselves was estimated to be 75¢ per child fully immunized. The balance of the cost was for transport, staff, supplies (other than vaccines), administration and supervision. The high side of the above figures resulted from the use of a 4-wheel-drive vehicle by the mobile teams. Later in the project, these vehicles were unavailable and ordinary passenger cars were used resulting in a considerable savings (the low side of the above cost figures).

2. Immunization Costs in the Danfa Project

Prior to a mass immunization program begun in 1974 at 16 sites in the Danfa District of Ghana, immunization coverage of preschoolers was less than 10 percent [12]. The goal of the immunization program was to increase coverage of preschoolers to 80 percent. The mid 1970's population of the district was about 16,000.

A one year cycle of immunizations by mobile teams combined with a follow-up visit to a fixed center was chosen as most replicable nationwide in Ghana. Children received a BCG, DPT, and an oral polio vaccination during the first year of life from the mobile team and their second dose of DPT-polio from the Danfa Health Center or satellite clinic. Booster doses of DPT and oral polio were given during the second visit of the mobile team one year later, as well as a measles and small pox vaccination.

After three annual cycles of immunizations carried out between 1974 and 1976, program evaluators found that 51 percent of the children in the Danfa District under age two were completely immunized, far short of the program's 80 percent coverage goal. One factor in the short-fall, according to evaluators, was that while area residents were willing to walk long distances for *curative* care, the 1 to 2 mile average distance to the collection point was a barrier for *preventive* care. Sustained and intensive health education was seen as necessary for increased coverage. The cost of the Danfa mass immunization program was estimated to be about $1.90 in 1976 for each child immunized.

3. Immunization Costs for the 1980's

Expanded Immunization Program planners estimate that development costs in starting up broad coverage immunization programs together with operating costs once they are underway will total at least $3 per fully immunized child in the 1980's [13]. Approximately half this amount will consist of personnel costs, facilities, and operating expenses. The rest of this amount will be needed for vaccines, cold chain equipment and transportation. Expanded Program planners believe that many developing countries can supply personnel, facilities and operating expenses, but that external resources will be needed to pay for the latter items in the poorest countries; that is, vaccines, cold chain equipment and transport will need to come from external donors.

Table III shows the estimated median annual per capita expenditures for health by governments of 69 developing countries which receive assistance from the U. S. Agency for International Development (AID). The regional categories used in Table III are the same as those used by AID. The amounts in Table III do not include private or personnel expenditures for health.

TABLE III MEDIAN ANNUAL PER CAPITA: PUBLIC EXPENDITURES FOR HEALTH BY REGION

Region	*Public Expenditure for Health*	*Number of Countries*
Africa	$3 per year	36
Asia	$2 per year	9
Latin America	$9 per year	15
Near East	$9 per year	9

Source: Ruth L. Sivard, *World Military and Social Expenditures, 1980*, World Priorities Publications, Leesburg, VA, pp. 25-29.

Table III shows that the governments of developing countries, particularly those in Asia and Africa have very limited budgets for health. The $3.00 per immunized child cost projected by the WHO Expanded Program seems high compared with current per capita governmental expenditures; however, the $3.00 figure applies mainly to children under 1 year of age, a group which makes up only three to four percent of the population in most developing countries. On the other hand, if children under age 5 and pregnant women are also treated as target groups, a larger proportion of the population would be involved.

The cost of immunization delivery in a number of

developing countries has been escalated by sharp rises in the cost of gasoline. Imports of gasoline require scarce foreign exchange. The cost of fuel is a recurrent cost in health programs which most international donors are unable to support. When donors supply vehicles, they can help reduce costs by choosing ones that are relatively cheap to operate and maintain. Four wheel drive vehicles are versatile and sturdy, but they are not cheap to operate and this may not always be the best choice for use in a broad coverage immunization program. One effect of increased transportation costs in some countries has been to limit immunization programs to populations reached at lower cost, i.e. those living in cities and towns.

The WHO Expanded Immunization Program Global Advisory Group has urged participating countries to commit themselves to paying at least two-thirds of the cost of immunization programs in their countries. Most countries in Latin America are already contributing more than this, partly because PAHO's revolving fund for vaccines has reduced costs. Movement toward two-thirds local payment will be essential if the Expanded Program is to meet its goal of making immunizations available to all children by 1990.

4. Vaccine Procurement

Vaccines used in immunization programs are already being produced in a number of developing countries. This production is likely to increase as UNICEF and other agencies assist indigenous manufacturers. Local production can reduce vaccine costs (in particular transportation costs) but quality control is a problem in some cases. Developing countries have complained that European and American drug companies have been unwilling to share key aspects of vaccine technology [14].

As countries attempt to increase coverage, demand for vaccines will increase. This is occurring now in that vaccine shortages have been reported in the Africa region. Countries which import vaccines obtain them in one of three ways:

- through donations from bilateral and international agencies,
- through purchase from international agencies or multinational revolving funds, and
- through purchase directly from the vaccine manufacturers.

Until now much of the vaccine used in immunization programs in developing countries was donated but with increasing demands for vaccine, this source of supply cannot be counted upon. Bulk procurement of vaccines is much cheaper than purchase in small lots. By pooling their orders, countries can negotiate lower prices and the best shipping arrangements.

A cooperative revolving fund established by the Pan American Health Organization (PAHO) in the Western Hemisphere has these features and permits countries to pay for vaccine in local currency to save scarce foreign exchange [15]. In 1980, 28 countries participating in the PAHO revolving fund are expected to order 44 million doses of vaccine at the total cost of $3 million (about seven cents a dose). During 1980, the fund negotiated an 18 percent decrease in the cost of measles vaccine, the most costly of the Expanded Immunization Program vaccines. Similar revolving funds are under consideration in West Africa and East Asia but such funds need (a) a large initial capitalization (about $2.7 million in the case of the PAHO fund) and (b) member countries which can afford to pay at least some of the cost of the vaccines.

5. Costs of Vaccines

The price of vaccines purchased by the Pan American Health Organization, UNICEF or other international agencies for use in national level or regional immunization programs is treated as confidential information because each year the agencies accept competitive bids from suppliers for large quantities of vaccine at low prices. Planners who need exact prices should contact their national Expanded Immunization Program manager for price lists from international agencies. The following prices of vaccines (for a recent year) available through an international agency are for illustration only. The prices listed here do not include transportation costs from the supplier nor a small service charge from the international agency. For this agency, prices charged for small orders are the same per unit of vaccine as for large orders.

SAMPLE VACCINE PRICES

Vaccine	*Vial Size*	*Price per Dose * (U.S. cents)*
Trivalent Oral Polio	10 dose	$.04
	20 dose	.03
Measles	10 dose	.11
DPT	10 dose	.04
	20 dose	.03
Tetanus Toxoid	10 dose	.03
	20 dose	.02
BCG	20 dose	.05
	50 dose	.03

* Prices rounded off to nearest cent, FOB supplier

6. Cost of Cold Chain Equipment

Appendix I of this report lists resources regarding cold chain equipment. One such important resource is the product information sheets distributed by EPI/

WHO and UNICEF which evaluate the performance of various products, list the suppliers and provide price information. The following price list is adapted from product information sheets cited in Appendix I.

SAMPLE COLD CHAIN EQUIPMENT PRICES 1979

Product	*Capacity*	*Price*
Walk-in Cooler (or Freezer)	5 to 17 cubic meters	$2,700 to $4100 FOB Finland
Modular Cold Room (or Freezer)	10 to 20 cubic meters	$9,000 to $25,000 FOB France
Portable Refrigerator (electric 220 or 12 volts)	37 liters	$933 FOB France
Portable Refrigerator (electric 220 or 12 volts)	24 liters	$360 FOB Japan
Top-Opening Refrigerator/Freezer (kerosene or LP gas)	142 liters	$731 FOB Sweden
Front-Opening Refrigerator (kerosene)	144 liters	$641 FOB Sweden
Cold Box (cold life @ 110° F = 132 hours)	21 liters	$230 FOB Sweden
Cold Box (cold life @ 110° F = 17 hours)	30 liters	$ 27 FOB USA
Cold Box (cold life @ 110° F = 130 hours)	36 liters	$153 FOB Indonesia
Disposable Syringes		$ .06 cents each in large quantities *

* Price for syringes comes from same international agency as previous table.

Vaccination of school-age children in rural Africa. Field vaccinations are made possible through the use of the cold box pictured below which protects vaccines from high outside temperatures. photo: World Health Organization

A mobile team vaccinating a young child in India. photo: Ralph Heller

CHAPTER IV

Integrated services and community participation

Broad coverage immunizations on a continuing basis require a well-developed health infrastructure and good logistic and transportation support. This chapter will discuss the advantages and disadvantages of vertical versus integrated immunization programs and the vital link between integrated health services and community participation.

One method of integrating immunizations into primary health care has been the simple addition of immunizations to the list of tasks which primary health care workers are expected to perform. Experience from the field shows that this facile and superficial approach *does not work*. Successful broad coverage immunizations on a continuing basis (as new infants enter the population) are more complex to organize than many planners realized. Besides sophisticated logistics and substantial supervisory requirements, they require disease surveillance and record-keeping to ensure successful completion of immunization series.

The tasks just mentioned are together well suited to a vertical or categorical program approach (as the smallpox eradication effort was organized in many countries); yet developing countries do not have the resources to field and indefinitely maintain cadres of single-purpose immunization workers throughout the countryside. Furthermore, the target groups for an expanded immunization program—pregnant women and children under 1 to 2 years of age—are the same target groups for nutrition improvement, MCH care and other health interventions. Recognizing these constraints and these parallels, WHO's stated policy is to integrate broad coverage immunization activities as much as possible into ongoing and future primary health care programs—"to deliver immunizations through—and not in competition with existing health services."

OBSTACLES TO INTEGRATION OF SERVICES

O'Connor et al., contractors for a primary health care program assisted by AID in Afghanistan, believe that the health programs which had the most impact on the health of rural Afghans were largely vertical in organization. These included smallpox eradication, malaria control, and the training of traditional birth attendants. Attempts at integrating immunizations into a system of Basic Health Centers were not successful. O'Connor et al note: [16].

An "integrated" program involves combining several existing separate programs. Few Afghan health programs are organized and managed well enough to be combined with other, equally ill-managed programs. The result is to weaken each of the programs so that none functions as well as it had previously.

The mass immunization program was organized vertically with a number of mobile teams providing specific vaccinations as an extension of the smallpox eradication program. Supervised and supplied by staff in Kabul and regional centers, it was reasonably effective in its mission. The Ministry, as a step towards integration, began to have Basic Health Centers (BHC) take more responsibility for immunizing the target population around the BHC with mobile teams dealing with more remote areas.

Unfortunately, since the BHCs do not have a long experience with drugs and equipment actually in place, vaccines and cold-chain facilities may not consistently reach BHCs in the future. At least in the short run, the target populations of rural areas in Afghanistan will likely receive fewer vaccinations than they have in the past due to the uncertainties of BHC performance in this expanded role.

Underutilization

Broad coverage immunizations require complex logistics, skilled personnel and relatively expensive equipment. When immunization infrastructure is integrated into primary health care services and moved too far to the periphery of the system, there is a risk of underutilization of immunization infrastructure.

In a cost analysis of an expanded immunization program in Thailand in 1980, Creese found that the fixed costs of personnel, cold chain equipment and facilities were relatively constant for nine sub-district health centers [17]. The costs per child immunized with DPT and BCG vaccines (which ranged from $5 to $10 per fully immunized child under age 1) varied according to the number of children reached. The more children immunized, the lower the cost per child.

Creese concludes "health centers are providing immunization services to populations of sub-optimal size from the viewpoint of economic efficiency and that resources would be saved . . . if immunization services were provided on a district rather than a (sub-district) basis." Creese shows that integration of immunization with other health services at village level may not be cost effective. The deployment of the skills, equipment and logistic support to village level health workers who provide immunizations along with their other duties, may not be realistic according to Creese and risks underutilization of immunization infrastructure.

ADVANTAGES OF INTEGRATED SERVICES

Motivation for participation in prevention programs is generally weaker than motivation for curative services. Combining immunization with other services has, in some countries, resulted in better coverage and completion rates. The Chilean Health Service which includes food supplements as part of its immunization program reports that 92 percent of eligible infants have received all three doses of DPT and polio vaccine [14].

An unpublished evaluation of the Zaire immunization program found fewer DPT dropouts in rural areas where immunizations were linked with malaria prophylaxis and other services than in urban areas where services were separate. In the interest of integrated services, all future Expanded Immunization Training courses will include a session on the oral treatment of diarrheal disease [14].

Implementing broad coverage immunizations through integrated health service programs at the present time and in the future, is both feasible and necessary because skilled personnel, transport, supervision and other resources are in short supply and must be shared. The stringent logistic requirements of the immunization cold chain will benefit other health services because medicine and supplies can travel along with vaccines to remote areas. The clear-cut method and the need for communication, supervision and evaluation that go with immunization programs, will improve other health services delivered in conjunction with immunizations. For its part, immunizations cannot reach broad coverage goals on a continuing basis unless it is incorporated (integrated) into existing (and future) health services. Few countries can afford the investment necessary to achieve immunization goals throughout rural areas for one service alone.

THE ROLE OF COMMUNITY PARTICIPATION IN INTEGRATED SERVICES

The most efficient immunization program delivering viable vaccines via well-trained and well-supervised personnel will fail if mothers or other child caretakers do not bring children to the vaccination site to be immunized. Unless the program has adopted the costly house-to-house strategy of immunization delivery, community involvement or participation is the *only* means by which broad coverage goals can be achieved in an immunization program.

Broad coverage immunizations are (and can be) integrated into primary health care even when village level health workers are not themselves giving immunizations. This is true because the village level worker can have a crucial role in ensuring immunization coverage. That role is in the area of community involvement or active community participation.

The remainder of this chapter will outline advantages and difficulties in organizing community participation. Community participation is central to program success because the community has many of the resources needed to make broad coverage immunizations (or any health program) successful. These are:

- time,
- energy,
- relationships,
- motivation,
- interest of people who live in the community who desire better health for their children, and
- knowledge of the target population, i.e., pregnant women and infants under 1 year.

One of the advantages of working through an established primary health care system is that village level workers may already be in close touch with the community and may be in the best position to approach community leaders. If the village level worker has nutrition or MCH responsibilities, she may already know infants in need of protection. With minimal training, the worker can educate the public about the benefits and side effects of immunizations.

MEANING OF COMMUNITY PARTICIPATION

Community participation has two different meanings in immunization programs, and it is important to differentiate them.

- In the first sense, participation means *active involvement* in program design, implementation or evaluation by people benefiting from a program.
- In the second sense, participation means acceptance of a service, that is the degree to which parents bring their children for immunizations when they are made available.

Participation in the "acceptance" sense means medical compliance or acceptance, while "active involvement" participation involves self-help and the mobilization of village level resources. The two are not alternative approaches, but rather two different program elements, either or both of which may exist in a particular setting. The first meaning of participation, called here *active community participation*, is the primary focus of this section.

1. Active Community Participation

The benefits of active community participation are many.

- Studies show that communication from respected local leaders, neighbors or family members is better understood and more influential than posters or radio messages delivered by outsiders.
- In societies where men control the movement of

women outside the home, the men's approval and even enthusiasm are essential.

- Community people are much more likely than outsiders to know the most convenient times and locations for clinic sessions.
- Community people can provide an early warning system when rumors develop that threaten the program.
- Volunteers can help to manage clinic sessions, remind parents of upcoming immunization dates, and follow up on those who miss a date. If low participation rates continue, they can help to find out why.

These contributions enable a health service to reach the maximum of its target population. In many communities there is a reservoir of interest in new ideas, and people may have high expectations regarding program benefits. Later, problems appear when expectations are disappointed or rumors develop and spread before they can be stopped. Many programs wait until this point to involve the community, but public disillusionment may make it difficult to recover lost ground.

Active community participation is not easy to achieve in practice. Health program planners usually do not allocate sufficient time, personnel or resources to enlist the cooperation of village level workers, receive input from community leaders or organize community groups.

Health personnel, frequently in short supply in rural areas, are not essential in the process of building community participation. Other village level workers can approach teachers, community leaders, and others who have important roles to play. Programs may find it useful (and educational) to have the community do its own survey of immunization coverage; school children can be taught about immunizations and then given a small number of families to contact regarding missed shots.

An example of the important supportive role of villagers in an immunization program is provided by the Danfa project in Ghana [12]. Village volunteers were recruited and given brief training. They returned to their villages to tell people of the coming program, the diseases to be prevented, the age groups to be vaccinated, the benefits to the child, and the expected side effects. The volunteers periodically reminded villagers of coming dates, aided in selecting vaccination sites and, on immunization days, helped organize lines of flow and tallied the number vaccinated.

Building active community participation is a long-term and slow process. Results cannot be expected immediately. As Rifkin states [18]:

> The process must be seen in terms of long-term goals rather than short-term achievements. It is often necessary to sacrifice what might seem a radical improvement in health status for a period of education in which people unfamiliar with medical terminology and technology may learn to put these ideas into their own context. All too often, campaigns for vaccinations, for instance, get high results when first introduced. However, if second or third injections are needed, the number of people who reappear is very much reduced. If the process moves too quickly and does not become part of the new conceptualization of village people, then it is questionable whether improvement in health status, let alone community participation, has really materialized.

2. Acceptance of Service

Whether or not active community participation is achieved, parents and child caretakers must have two types of information in order to accept services:

- *General information* regarding immunizable diseases, the benefits and possible side effects of inoculations, and the need for repeat doses; and
- *Specific dates, times and locations* and clear directions on who should come for each immunization session.

Parents and others who bring children to be immunized should know the following:

- which diseases the immunizations protect against, that immunizations will not protect against all diseases;
- which age groups are to be immunized and why other age groups are excluded;
- the need for repeat doses;
- that immunizations are safe and that side effects, such as fever, are signs that the vaccines are working to build their child's protection; and
- that vaccines do little or no good once a child has contracted the disease.

These are often complicated messages to put across. Personal communication by health workers, community leaders, and parents of previously immunized children is likely to be the most effective means for conveying them.

Local media are better suited than mass media for publicizing specific immunization sessions. Where women are the major child caretakers, messages need to reach them as well as the men. If women do not read, for example, posters should be supplemented with other forms of communication. Posting announcements in public places is a good method unless women spend the majority of time at home. It may be necessary to study communications patterns among women as these may be very different than among men. A loud speaker on a truck was useful in an urban Cameroon immunization program. Some programs have made school children responsible for bringing in a sibling to be immunized.

Cultural Beliefs

Cultural beliefs regarding health, illness and medicine can hinder acceptance of an immunization pro-

gram. For example, the disease in question may not be perceived as an important disease or it may be thought to be inevitable. But cultural beliefs can also be used to increase participation in a program—for example, the favorable attitude toward injections in many countries. In taking advantage of the latter belief, care should be taken not to exaggerate the benefits of immunizations.

Language

Immunization planners must recognize that language, especially medical language, can obscure, intimidate and confuse as readily as it can clarify or enlighten. Local words must be sought for the names of diseases addressed in the immunization program, recognizing that there may be no direct translati ı for some diseases. For example, the lameness attributed to polio may not be distinguished in the local language from lameness in general. The childhood form of tuberculosis may not be perceived as the same disease as the adult form of tuberculosis. The initials BCG are universally meaningless in translation and is more aptly named tuberculosis vaccine.

Courtesy

While information and communication are essential, the public will only accept services if they are convenient and seem effective. There is a common misconception that most non-acceptors of services are ignorant or fatalistic; in fact, many have experienced the services or clinic and found them unpleasant or degrading.

The motivation for preventive health care is often too weak to persuade most parents to wait for hours in the sun, be treated with disrespect by the clinic staff, or return another day because of misunderstanding or miscommunication. Welcoming parents to immunization sessions, allowing time for questions and explanations, and avoiding long waits in line are all stressed by program planners to avoid a "cattle chute" operation. Unannounced or last minute changes in the time and place of a scheduled immunization session will increase the population's distrust and undermine future participation.

Shown above is a simple visual projector used for community health education in Uganda. photo by UNICEF

CHAPTER V

Program Management

Chapter IV showed that it is desirable for immunization programs to be integrated with other health services as fully as possible but several prerequisites of an effective immunization program—especially maintaining the cold chain and vaccine quality control—are not easily added to other services unless additional personnel are specifically assigned to those tasks. Integration of health services cannot be addressed without specifying *at what level* in the health service structure integration occurs and with what personnel [19].

INTEGRATION AND PROGRAM MANAGEMENT

Managing national immunization programs includes a number of activities:

- planning and allocating of resources,
- managing the cold chain,
- disease surveillance,
- training and supervising personnel, and
- managing information.

Integrated horizontal programming usually means that activities are managed by different individuals or different units within the Ministry of Health. The person in charge of information management, for example, will usually have this responsibility for all of the ministry's programs and may not give immunization delivery particular attention. Horizontal organization requires great effort to coordinate ministerial units at the national level, but it greatly reduces the problem of coordination in the field.

Under *vertical programming*, all of these functions may be combined into a single unit with its own budget, personnel recruitment system and logistical services. Vertical programming allows unified national management, but it usually means that immunization field work proceeds separately from other health care delivery. There is something to be said for both approaches.

Advantages and Disadvantages of Vertical Programming

Smallpox eradication was a vertically organized program, which helped its success. O'Connor, et al., cited in Chapter IV, believe that vertical programs have more impact than integrated ones because they can be organized along a quasi-military model with distinct lines of authority and responsibility at each level. Vehicles, supplies and equipment can be deployed with fewer clearance procedures from central headquarters. Tasks can be routinized and objectives clearly stated, making it easier for both employees and supervisors to evaluate performance. Smallpox eradication demonstrated the value of good management, and the World Health Organization firmly believes that these techniques can be adapted to other aspects of primary health care delivery as well.

The Global Advisory Group of The Expanded Program on Immunization recommends that participating countries name a single individual to supervise and coordinate all aspects of immunization delivery. In integrated programs, this person acts as a coordinator since some of those involved will not be under his or her direct authority. Some countries have established intra-ministerial planning groups to facilitate cooperation. The program manager may or may not be given a separate budget. Specialists recommend such a budget for vaccines and equipment and whatever other program elements are under the manager's own control.

Where within the ministry structure should the immunization program manager be located? Location within an MCH or other health services unit generally means that immunizations will be integrated with primary health care. Placement in an epidemiology unit gives greater emphasis to evaluation and to immediate follow-up of epidemics, but it may complicate integrated service delivery. Some ministries create separate immunization units (or relabel old smallpox units), but this is less appropriate for integrated programs. The choice of someone to head the immunization program is a critical one; both the individual's personal qualities and his or her position within the bureaucratic structure should be considered.

Should the program manager be full time, or should he or she have other ministry functions? Large countries, generally, have full-time managers, while small ones do not. Many ministries of health in the developing world with fewer than two dozen central professional staff, may not be able to focus on single programs. Although full-time vertical management probably gives the program greater attention, it simply may not be feasible.

Should the immunization program have distinct personnel at the regional level? If the program is large enough, regional operations officers are usually appointed to oversee maintenance of the cold chain, vaccine distribution and program evaluation, and to supervise personnel. Each province in Pakistan, for

example, has its own program manager. Smaller and/or fully integrated programs may not be able to afford a separate immunization coordinator at the regional level but they do need to ensure that whoever handles vaccines and collects data understands the special requirements of this program.

PERSONNEL SELECTION AND TRAINING

Personnel requirements for broad coverage immunization activities include:

- *direct service providers*—people who work directly with mothers and children. [such as auxiliary nurses, community health workers, vaccinators, community organizer, medical personnel and others]
- *logistics personnel*—inventory managers, drivers and other staff who are responsible for operating the cold chain and reliably delivering potent vaccines and other supplies to the field;
- *administrators and supervisors*—people who plan and manage immunization in particular or primary health care programs in general;
- *researchers*—statisticians, survey specialists, and laboratory technicians who collect and analyze surveillance, coverage, serological and vaccine potency data; and
- *trainers of personnel.*

An inventory of personnel is a very useful tool in planning broad coverage immunizations. Key questions which program planners should ask include:

- What personnel resources are currently available in my country?
- What is their degree of training with respect to immunization?
- Where are they located?
- What is the turnover rate?
- Can the present health staff cover the vaccination needs of the community?
- What is the average number of persons to be vaccinated by each of the available health staff?
- Is the health staff motivated to do immunizations?
- What percent of the population is served by currently existing health personnel?

Training

Personnel at all levels used in broad coverage immunization activities whether they will be hired specifically for immunizations or with other duties will need specialized training. WHO places such emphasis on program management that its training courses and manuals may be considered as models for many primary health care systems. Persons with operational responsibility can obtain course modules and manuals from the World Health Organization and can attend PAHO/WHO-developed management courses. Subjects covered include:

- epidemiology of immunizable diseases,
- vaccines,
- programming,
- public participation,
- conducting vaccination sessions,
- allocating resources,
- conducting disease surveillance,
- supervision of performance,
- providing training,
- evaluation of vaccination coverage, and
- managing the cold chain.

Several countries are developing their own training programs based on the above models, while others are giving this type of training to all health care workers.

Job descriptions and objectives

One of the potential strengths of immunization delivery is that its objectives can be clearly stated and its procedures routinized. Field workers can know what is expected of them, and supervisors can judge how they are performing. Job descriptions should be developed that reflect

- what workers are actually doing,
- what they are capable of doing, and
- what they are willing to do.

What workers are actually doing is important because many have more tasks than they can handle. If new tasks are added, the job description should balance conflicting demands. Particular worker needs may have to be compromised to maximize coverage. Mutually accepted objectives may motivate behavior better than ones set by management alone. Although such a process may be difficult to carry out in practice, particularly in an integrated program, the workers themselves and technical staff from other programs (MCH, curative services, etc.) should be involved as much as possible.

Who does immunization?

Vaccinators may either be categorical workers, who do little besides immunizations, or they may be polyvalent, with broad curative, preventive and educative responsibilities. Workers who spend most of their time on a single function are likely to get very good at it, while broad purpose workers frequently have more responsibilities than they can effectively handle. There is a threshold: workers who do too few immunizations are not worth training and supporting, while those who specialize in immunizations have to work either in a city or in a mobile unit if their skills are to be fully utilized. Most programs

opt for the middle ground: train polyvalent workers to do immunizations but exclude village level staff and others at the periphery.

The functions of vaccinators usually include the following:

- determination of who should be immunized;
- recognition of contraindications;
- maintenance of appropriate sterilization and immunization technique;
- maintenance of vaccines at proper temperatures, including the return or discard of vaccine;
- record-keeping; and
- communication with the community to explain the program and possible side effects.

SUPERVISION

Supervisory contacts provide a good opportunity to evaluate how well immunizations and other activities are actually being carried out. The supervisor has an opportunity to dispel the feeling shared by many personnel working in remote health facilities that they are isolated, cut off from and not an important part of, the whole primary health care structure.

These supervisory visits also provide the opportunity to work with the health staff, to motivate them, to resolve any questions or problems they may have and make needed improvements. Training or continuing education can take place in the form of introducing new concepts or methods of application. Supervisory visits are therefore crucial in improving the quality of health care services and should be scheduled as a routine part of immunizations in particular and primary health care in general. The supervisor can also transport needed supplies and vaccine to the health care facility.

In view of fuel shortages and the scarcity of travel allowances, primary health programs have had to use every available opportunity to maintain communication between field workers and supervisors. Some adaptations include:

- schedule conversations when field workers come to health centers for their pay or for supplies;
- hold routine meetings where all field staff gather at a central location;
- have drivers or other delivery personnel check refrigerator maintenance or inventory control whenever they visit a health post;
- establish radio contact between the center and the periphery;
- ask supervisors to ride on other government vehicles going to the field; and
- have supervisors use scooters or public transport.

Primary health care programs badly need additional funds for local transportation, and program administrators need to expedite travel reimbursements. Very few supervisors are willing to pay these expenses from their own pockets, yet a number of national programs are in effect forcing them to do so.

The best trained subordinate is one who knows what he can and cannot do and queries his supervisor when there is a problem; the best type of supervisor is one who openly encourages such communication and gives all possible moral and technical support to his or her workers.

MANUALS AND STANDING ORDERS

Manuals can answer not only questions on *who* is to do *what*, *where* and *how*, but they can also encourage workers to solve individual problems using solutions relevant to local conditions. Very often, the local worker is best suited to solve a problem because he or she is most familiar with local resources and politics. However, directives, manuals and orders often come down from above in absolute form. People at the central level may feel they have studied the problem, have more expertise and training than the local health worker, hence can give ideal solutions for most conceivable problems. Solutions, however, tend to be different when viewed from the national capital, with its excellent transportation and communications, than from a remote health center.

One of the reasons for the success of the smallpox eradication program was decentralization of the decision-making process. Workers at district and regional levels were freed from central level directives and allowed to innovate. Local areas cannot be left completely on their own, however. Directives from the center must continue to be based on the best internationally accepted information on such essential technical questions as:

- dosages,
- number of doses of vaccine to administer,
- intervals between doses, and
- storage temperatures.

The challenge is how to stimulate problem-solving abilities at the local level, yet still maintain enough conformity for high quality performance and proper supervision and evaluation. Once goals are laid out, the local worker may be the most knowledgeable on how to carry them out.

1. Inappropriate Use of Manuals

Manuals cannot anticipate the rich complexity of conditions found at the local level. Local workers should be encouraged to solve problems with facilities on hand. At one health center a health supervisor visited a district vaccine storeroom and found that the vaccine was not being kept in the refrigerator as it should have been. After embarrassed explana-

tions and listening to regulations, the vaccinators took the official a few hundred meters away to a refrigerated vegetable warehouse. Here the bulk of the vaccine was found, stored at the proper temperature, packed in a corner of a room filled with potatoes. The warehouse had a 24-hour guard enabling constant access to the vaccine as well as an emergency backup system in case of power failure. In some areas the only refrigeration available may be in a bar or warehouse rather than a health center.

Another drawback of manuals is that they are often written to accompany training courses rather than be self-administered. If training is not available, a basic checklist prepared locally may be more appropriate on:

- when to give immunizations,
- when not to give them,
- sterilization techniques,
- inventory control,
- routine maintenance for cold chain equipment, and
- record-keeping.

Manuals often do not show workers how to adapt ideal standards to field conditions. Many workers must decide on a day-to-day basis whether to immunize as many children as possible or, instead, to follow standing orders regarding sterilization of his/her equipment and contraindications. This is an important decision: the risks of non-immunization may be greater than the risks of immunization under suboptimal conditions. The best people to decide are medical professionals, not field workers, but professional guidelines will not be followed if they do not take field conditions into account.

Virtually every medical textbook and immunization manual insists that needles and syringes be thoroughly sterilized for twenty minutes between each injection. This is rarely done in the field, partly because personnel may not fully understand the need, but more importantly, because they usually do not have sufficient needles to afford a sterile one for each injection. Programs should make every effort to supply this material, and in the meantime make every effort to make sterilization more accessible. For example, by using appropriate technology such as pressure cookers or simple teapots instead of autoclaves. Above all, greater efforts are needed to see that immunization programs have necessary needles and syringes.

2. Contraindications

Program managers need to consider both the risks and the benefits of vaccinating during sick visits, and they may need to revise their standing orders accordingly. Immunizations should not be given when a child is severely debilitated, but discretion is needed if conditions are less serious. While immunization during a mild fever or diarrhea may be somewhat risky, non-immunization may ultimately expose the child to greater danger or even death. If the parent is turned away, he or she may become discouraged and not return.

Malnutrition can interfere with the production of antibodies thus reducing the protection afforded by immunizations in malnourished populations [20]. On the other hand, it is precisely the malnourished who are in need of protection from diseases such as measles [21]. There is consensus that in most cases, malnutrition should not be considered a contraindication for immunizations and that the immune response is not affected by mild to moderate malnutrition.

Mothers in Zambia show their orange clinic cards which include a record of immunizations received by their children. The cards are examples of patient retained records. photo: World Health Organization

CHAPTER VI

Management information and evaluation

Program managers need to decide what kind of information they want and how much investment information gathering is worth to them. They should think initially in terms of purpose—what knowledge is essential in order to plan, manage and evaluate the program. Most programs have found that they need to know some or all of the following:

Disease Surveillance
how common immunizable diseases are in their country, before, during and after an immunization effort;

Immunization Coverage
the proportion of children that have been immunized in various parts of the country;

Vaccine Quality Control
the quantity of vaccines available and on order and whether the vaccines being used meet quality standards and are still potent;

Equipment Inventory/Cost Data
what equipment is available, and what repairs and routine maintenance are needed; and

Personnel Information
what personnel are working in the immunization program and how well they are performing.

Both quantitative and qualitative information may be useful for these purposes. Programs should adopt the systems that are most appropriate and affordable for their individual circumstances.

DISEASE SURVEILLANCE

Before the start of the program, managers need to know what diseases are a problem in their country, which age and socioeconomic groups the diseases affect, and what is the geographic distribution of the diseases in order to choose priorities. After the program has begun, surveillance can determine whether the program is having the expected impact. *In particular, it is important to know whether children contracting a vaccine-preventable disease have already been immunized, which may indicate failures in the cold chain.* Good disease surveillance data also help justify program expenditures, since budget makers often want "hard" facts to support programs.

An important lesson of the smallpox eradication campaign was the value of good surveillance. For example, in one Asian country, an expensive and cumbersome program to vaccinate women isolated by *purdah* was dropped when it was learned that smallpox cases among these women were all but unknown. Continuing surveillance in the smallpox program was extremely effective in identifying outbreaks of disease and controlling rapid spread, even in areas in which vaccination coverage had been poor [22].

The three elements of a surveillance system are:

- disease recognition;
- disease reporting, statistical aggregation and analysis; and
- feedback and utilization of results.

If one of these is missing, the other two may be ineffective.

1. Disease Recognition

Three of the six diseases discussed in this paper (measles, whooping cough, and tetanus) show distinctive symptoms, but polio and the diverse forms of infant tuberculosis are often difficult to recognize. Health workers at all levels should be trained to recognize diseases covered by the immunization program, whether or not they give immunizations. A book of vivid color photographs with space left under each for printing of text in the local language is available from WHO. Line drawings to reflect local disease patterns can be used to supplement WHO photographs.

2. Disease Reporting and Statistical Aggregations

When the disease is recognized, it needs to be reported and this should be as systematic as possible. Instituting overly complex procedures or trying to cover the whole country, while impressive in annual reports, may provide faulty data. A simpler, less ambitious system may provide better information than a more complicated one.

In spite of the difficulties, a number of developing countries, particularly in Latin America, have implemented full-scale information systems with relatively complete and detailed reporting. Country level systems should eventually collect information on:

- number of cases,
- number of deaths,
- the characteristics of persons affected (particularly age),
- location and date of outbreaks, and
- immunization status by vaccine, dose and age group.

Sentinel Stations

Some countries use "sentinels," a small number of reporting stations where good data are collected for a limited area. If sentinels are used, they should be as representative as possible. Often this is not the case because a facility good at data collection is probably good at immunization delivery as well. For epidemic detection, sentinel reports should be supplemented because otherwise only outbreaks near the facilities are likely to be discovered. "Sentinels" represent a good starting point for countries without a full disease surveillance system.

Sample Surveys

Sample surveys can supplement sentinel stations, but sample surveys have a weakness in that parents may not recall if or when their child had a particular disease, or may not be able to recognize it when it occurs. Surveys of paralytic polio are relatively easy because the resulting lameness is fairly obvious. The incidence of neonatal tetanus may also be measurable because the disease symptoms are easily recognized.

3. Feedback and Utilization of Results

Mini computers are relatively cheap and can be programmed to produce tables periodically as surveillance data are received. Some countries may wish to use such computers as the timely analysis and presentation of surveillance data are key to making use of the information. Publishing surveillance data in a monthly newsletter is a good way of keeping people informed about the extent to which program objectives are being achieved. A newsletter helps identify problem areas and provides rewarding feedback to field staff. Besides program personnel, politicians, local leaders and others who can influence the program should receive copies.

IMMUNIZATION COVERAGE

Knowing the proportion of the target population which has been effectively immunized is essential. There are two measurement systems used, one based on service statistics, the other on sample surveys. Coverage estimates based on service records require data on the number of immunizations and the size of the target population.

1. Service Statistics

The simplest way to estimate the number of immunizations given by type, during a given time period and within a specified area is to calculate the amount of vaccine used and then subtract for wastage. A more accurate way is to keep simple tally sheets for the number of shots given at each session. A grid with immunizations listed on the vertical axis and age groups (including pregnant women) on the horizontal axis will suffice. A stroke is made in the appropriate box each time an immunization is given. (See Figure I: Vaccination Reporting Form.) Results from these forms should be compared to the quantity of vaccines distributed and any unusual discrepancies investigated.

Target Population

The second datum needed using service statistics to estimate coverage is the number of children and pregnant women who should be immunized in the given area and time period. This cannot be known exactly, but an approximate birth rate and population size are usually adequate. Coverage is estimated by dividing the number of shots given by the target population.

2. Coverage Surveys

A check on service statistics is provided by coverage surveys using statistical methods to obtain cluster samples of the target population. Villages are selected at random from a list of villages in the survey area. Within villages, dwelling units are selected and all children resident there who would have been in the appropriate age group at the time when vaccinations were given are seen to determine if they were in fact immunized and if not, why not. Children of inappropriate ages who were vaccinated are also noted. Vaccination cards, if retained by the family, can be examined at this time. Detailed instructions on how to carry out a survey to evaluate coverage using cluster sampling are provided in Section 3, Book V of the *Field Manual of the Expanded Program on Immunization* [4].

RECORDS FOR IMMUNIZATION FOLLOW-UP

The kind of records which are kept and the follow-up systems linked to them will influence the proportion of children receiving all of their required shots. Some programs, particularly mass campaigns and those using mobile units may not keep any individual records at all. They may simply rely on parents' memory or the presence of a BCG scar to tell who has already received shots.

Programs which use patient records may either give them to the parent or keep them in a health center. There are advantages and disadvantages to each method. A few programs are able to maintain duplicate records, one for the parent and one for the health center.

Parent-Held Records

In Botswana as in many countries, each infant is issued a road-to-health chart which parents are known to keep for up to five years. The chart includes a weight and age graph to show whether weight is increasing appropriately with age, a schedule for recommended immunizations, and a record of actual immunizations. The parent brings the record each

FIGURE I: SAMPLE AGGREGATE VACCINATION REPORTING FORM

Signature:_____ Team Leader	Date	From: To:
	Place	
Estimated Populate under 14 months of age:_____	Man-days worked	

age group / vaccines	3-5 months	6-8 months	9-11 months	12-14 months	school children	pregnant women	vaccine used	
							doses per container	no. of containers
DPT & polio #1								
DPT & polio #2								
DPT & polio #3								
BCG								
Measles								
DT								
Tetanus #1								
Tetanus #2								

SOURCE: Book I "Programme Design" of the *Field Manual of the Expanded Program of Immunization*, World Health Organization, Geneva, Switzerland, 1977, p. 15.

time he or she visits the clinic, and clinic staff record both the immunizations given and the dates for return. The staff can confirm that the child is up to date each time he or she visits, and the parent can use the card as a reminder for return dates. The system works as long as the parent keeps the card and returns as scheduled.

Health Center Records

The alternative system is to keep records in the health center and, if possible, use them to identify children who miss immunization dates for follow-up. One program in Costa Rica, for example, maintains a tickler file with each child's record filed behind the date on which he or she is due to return. If the parent does not appear within a week or two of the date, someone is sent out to visit the child's home. In the Northwest Frontier Province of Pakistan, clinics include staff members whose sole job is to contact dropouts. In other countries, communities have provided volunteers for this purpose. These follow-up techniques require a fairly sophisticated system in which records are properly filed, follow-up workers available, and parents sufficiently informed and motivated so that only a minority of cases need follow-up. In urban areas, a lack of good addresses has, at times, been an obstacle to immunization follow-up.

QUALITY CONTROL

Even if everyone is vaccinated, immunity will not be achieved unless the vaccine causes an immunological response. This response can be verified by serological testing—measuring the antibody levels in the blood. Serological tests indicate the distribution and duration of natural immunity and whether or not there are other conditions in the population that negate or suppress the effect of the vaccine. Acute malaria is one such condition in some populations. Serological tests can help planners select the target population, the optimal ages for vaccination, and the strength and intervals of vaccine doses.

Serological research is expensive and requires good laboratory facilities. Moreover, mothers and children do not like having blood samples taken, which can have a negative effect on their subsequent cooperation with the immunization program. Therefore, serological testing should be used only when it is necessary to establish the efficacy of the vaccine within the target population. If surveillance data at any time indicate that diseases are occurring in populations that have been vaccinated with potent vaccines, serological research can be very useful.

COST DATA

Cost information needed in a program depends on the structure of the health system. Programs which are fully integrated into primary health care may still have separate budget line items for supplies and equipment, training programs and certain types of data collection. Any program element with a separate budget line needs to account for expenditures, and the accounting needs to correspond with evaluation and planning cycles.

National governments need to pay just as much attention to the cost of external assistance as they do to items in their own budget. Most foreign assistance is temporary and will eventually have to be assumed by the recipient. Donor agencies are occasionally remiss in analyzing and fully discussing the recurrent cost implications of their projects, and estimates developed before the start of the project need to be reviewed periodically to see whether they are still accurate.

Special types of cost analysis may be appropriate in certain programs. Cost efficiency analysis compares costs with the number of immunizations delivered. Cost effectiveness analysis compares cost with the number of deaths, disability and illness prevented. Cost benefit analysis compares the cost of alternative delivery techniques, say, fixed facilities versus mobile units, to see whether one is substantially more expensive relative to its benefit than the other.

Cost benefit analysis can compare whether immunization or health education is the best means to reduce neonatal tetanus. An analysis in Austria, for example, showed that measles vaccination of all children under one year of age was almost three times as cost effective as treating and caring for sick children [23]. Economists believe the ratio is even higher in most developing countries because of the greater prevalence and higher rates of mortality from vaccine-preventable diseases [24].

Cost effectiveness and cost benefit analyses require special accounting systems and refined calculations to accurately measure program costs. Such models can only be as useful as the data or information system on which they are based. These effectiveness and cost benefit studies should not precede basic improvements in information gathering.

footnotes

1. D.A. Henderson, "A Victory for All Mankind" in *World Health*. May 1980, p. 5. Smallpox is unusual in that it must be passed from one person to another in a continuing chain of infection. There is no animal reservoir of the disease and no asymptomatic carrier (a person having the disease but showing no symptoms).
2. "BCG Vaccines: Tuberculosis Experts to Discuss Lack of Protection" *WHO Chronicle*, Vol. 34, March 1980, pp. 118-119 and personal communication with Dr. George Comstock, Training Center in Public Health, Johns Hopkins University, Hagerstown, Maryland, March 18, 1981.
   The above article and Dr. Comstock reviewed the large scale trial of BCG vaccine in Southern India which was launched in 1971 and involved 260,000 individuals one year of age and older in 210 villages and towns. The strains of the vaccine used were the best available and the study design appears to be without fault, yet the trial showed that BCG offered no protection against lung tuberculosis. The study also showed that BCG vaccination does no harm. Various theories have been advanced to explain these results—among them the fact that the South Indian population may be atypical in some way and that the BCG strain may have mutated in the many generations since it was created by Dr. Calmette and Guerin in the late 1920's. Experts are divided regarding the effectiveness of continued BCG vaccination in light of the Indian and other trials which showed low effectiveness. Despite controversy regarding BCG, there is universal consensus on the need for an anti-tuberculosis vaccine even if future research proves that current strains of BCG do not qualify.
3. BELCHER, D.W., Nicholas, D.D., Ofosu-Amaah, S.O. *et al.*: "Comparison of Methods for Estimating the Frequency of Paralytic Poliomyelitis in Developing Countries." *Bulletin of the World Health Organization* 1979, Vol. 57, No. 2, pp. 301-307.
4. *Field Manual of the Expanded Program on Immunization*, World Health Organization, Geneva, Switzerland, 1977, with revised later sections, Book I.
5. Hendrickse, R.G. "Problems of Future Measles Vaccination in Developing Countries," *Transactions of the Royal Society of Tropical Medicine and Hygiene*, Vol. 69, No. 1, p. 31.
6. Sections of this chapter on delivery strategy and immunization scheduling are adapted from: A.N. Agle, S.O. Foster, R.C. Hogan, and J.S. Weisfield. "Immunization Programs" pp. 34-50, in *Communicable Disease Control Planning*, Volume I of the International Health Planning Methods Series of the Office of International Health, U.S. Department of Health and Human Services.
7. A.M. McBean *et al.* "Evaluation of a Mass Measles Immunization Campaign in Yaounde, Cameroun" *Transactions of the Royal Society of Tropical Medicine and Hygiene*, Vol. 70, No. 3, 1976, pp. 206-208.
8. "Expanded Programme on Immunizations: Measles Immunization in Kenya" *Weekly Epidemiological Report* No. 44, November 2, 1979, pp. 337-339.
9. B. Cvjetanovic *et al.* "Epidemiological Model of Tetanus and its Use in the Planning of Immunization Programmes" *International Journal of Epidemiology*. Vol. 1, 1972, pp. 125-137
10. "The EPI Minimum Vaccination Schedule" Unit 3 in Module II in *Course on Planning, Management and Evaluation of EPI*, Pan American Health Organization Washington, D.C., pp. 10-15.
11. "Study of the Feasibility, Coverage and Cost of Maintenance Immunizations for Children by District Mobile Teams in Kenya" *Weekly Epidemiological Report* November 24, 1977, pp. 197-204.
12. "The Danfa Comprehensive Rural Health and Family Planning Project, Ghana: Final Report" Joint Publication of the University of Ghana Medical School and UCLA School of Public Health, 1979, pp. 6-37 through 6-43.
13. "Medium Term Program, Expanded Program on Immunization" WHO/EPI Publication, October, 1979, p 13.
14. Personal Communication with participants at the Expanded Program on Immunization Global Advisory Group Annual Meeting, Geneva, October 20-24, 1980
15. *EPI Newsletter:* "Expanded Program on Immunization in the Americas," Vol. II, No. 4, August 1980.
16. O'Connor, Ronald (editor) *Managing Health Systems in Developing Areas: Experience from Afghanistan*, Lexington Books, Lexington, Mass. and Toronto, Canada. 1980, p. 144.
17. Creese, A.L. "Cost Analysis: Expanded Program on Immunization Thailand" World Health Organization Publication EPI/GEN/80/6, p. 3.
18. Rifkin, Susan, "Community Participation in Health A Planner's Approach" in *Readings in Health, Development and Community Participation* ed. by Rifkin, *Contact*. Special Series #3, June 1980, p.7.
19. Many references to immunization programs and recommendations which appear in Chapter VI and VI are based on personal communications (see footnote 14) and Expanded Program materials (see footnote 4)
20. Fault, W.P. and Geoffery Edsall "Vaccine and Vaccination Programs—Special Emphasis in Malnutrition" *American Journal of Clinical Nutrition*, Vol. 31, December 1978, pp. 2237-2247.
21. Ifekwunigwe, A.E., Grasset, N., Glass, R. *et al.*: "Immune Response to Measles and Smallpox Vaccinations in Malnourished Children." *The American Journal of Clinical Nutrition* March 1980, Vol. 33, pp. 621-624
22. Henderson, Donald "Smallpox Shows the Way" in *World Health*, magazine of the World Health Organization, February-March 1977, p. 26.
23. Ambrosch, F., Wiedermann, G., Harasek, G., "Costs and Benefits of Measles Vaccination," *Fortschr. Med.* Vol. 96, No. 8. February 23, 1978, pp. 409-414.
24. Creese, A.L. and R.H. Henderson, "Cost-benefit Analysis and Immunization Programmes in Developing Countries," *Bulletin of the World Health Organization*, Vol. 58, No. 3, 1980, pp. 491-497.
25. Barnum, H.N., D. Tarantola and I.F. Setiady, "Cost Effectiveness—an Immunization Programme in Indonesia," *Bulletin of the World Health Organization* Vol. 58, No. 3, 1980, pp. 499-503.

research and resources on immunization delivery

RESEARCH

Research by the World Health Organization, national governments and private drug companies is directed toward discovering new vaccines and ways to modify existing vaccines to simplify logistics and personnel requirements. Work on new vaccines for leprosy and malaria is promising. Work is proceeding on further heat stabilization of current vaccines. Preliminary tests show that improved measles vaccines can remain potent when stored at 37°C for 30 days. If enough progress is made with measles and other vaccines, it may be possible to eliminate the cold chain at the most problematic level—the peripheral or village level.

Adverse reactions to vaccines are being studied to reduce these rare phenomena even further. Interference of malnutrition and/or parasitic infection with the immune response to vaccines and possible risks associated with the administration of vaccines to malnourished children are also under investigation.

New methods of administering vaccines are being tested, which include the administration of vaccines through aerosal sprays and development of more practical low cost jet injectors for local health worker use.

Means of improving equipment and making them more relevant to developing country situations are under study. The Center for Disease Control (CDC) of the Department of Health and Human Services and the National Aeronautics and Space Administration (NASA) are presently cooperating in field testing solar powered refrigerators in several countries. Work is continuing on a kerosene aerosal burner to replace the problematic wick burners now used in kerosene refrigerators.

Other innovations being tested include using time-temperature indicators (enzyme-based chemicals that change color when exposed to temperatures greater than a predetermined level over a given time interval) in UNICEF vaccine shipments to monitor vaccine conditions during transit to a country.

Equipment already being produced, but not yet widely distributed at the field level includes liquid crystal thermometers and ice lining refrigerators which keep vaccines within acceptable temperatures with only eight hours of electricity per day.

RESOURCES FOR TRAINING

"Training the trainers in cold chain operations." *WHO Chronicle*, Vol. 34: pp. 182-185, 1980.

Describes the objectives and content of the WHO Expanded Immunization Program Logistics and Cold Chain Workshop.

Logistics and cold chain. A workshop for EPI trainers. 127 pages. Languages: English, French and Portugese.

A guide for a 5½ day workshop for middle-level managers of the cold chain. The participants are expected to prepare cold chain training materials relevant to their own programs. The course consists of a pre- and post-test, a cold chain game, case studies, films, slide shows, small group and large group discussions.

"Looking after your vaccine." A set of 20 color slides. Text 8 pages. Languages: English and French.

A slide set with an accompanying text to train field level workers in proper vaccine handling. Subjects presented are: the importance of keeping vaccine cold, proper refrigerator loading, use of cold boxes and vaccine carriers. Practical suggestions are given on procedures to conserve vaccines in an emergency.

"Looking after your cold chain equipment." A set of 20 color slides. Text: 10 pages. Languages: English and French.

The slide set illustrates the daily maintenance required to keep cold chain equipment running effectively. Practical suggestions are made on how to get the best performance out of refrigerators used for storing vaccines.

"The cold chain: or how vaccines should be handled." A 30 minute color film. Languages: English and French.

This film describes the cold chain in Ghana from the airport to a remote village. It illustrates the precautions that have to be taken and the kinds of mistakes that can occur. 16mm, optical sound track. Available on loan or can be purchased for US $250 per copy.

"Immunize and Protect Your Child" A 5 minute color film, non verbal animated cartoon.

This film was developed to motivate mothers in developing countries to bring their infants to the local health center for a series of vaccinations, without the use of words, either spoken or written, hoping that the film can be used without regard to linguistic or cultural boundaries. Available from INF/FTV, World Health Organization, Avenue Appia, 1211 Geneva 27, Switzerland, and from Spears Associates, P.O. Box 1207, Arlington, Virginia 22210, U.S.A.

RESOURCES FOR COLD CHAIN EQUIPMENT

"Improving the Cold Chain IV: Progress Report, January/December 1979," WHO Document EPI/CCIS /80.4, Geneva, 1980.

This 1980 report is the fourth in a series of annual evaluation reports by the Expanded Immunization Program unit of WHO on progress in the cold chain during the preceding year. The reports started in 1977. Progress during 1979 include: developing international guidelines for vaccine packaging and shipping procedures; cold chain equipment care and repair courses; development of other cold chain training materials; research into central, regional and local vaccine storage and transport; and development of an information system. The annex includes an annotated cold chain bibliography.

Product Information Sheets. 60 pages.
Reference: SUPDIR 55, AMT 2.
Languages: English, French and Spanish.

These sheets are an essential reference for people purchasing equipment for the cold chain. Performance analysis and purchasing descriptions are given for 6 types of cold rooms, 2 types of refrigerated vehicles, 14 types of refrigerators and freezers, 21 types of cold boxes, 4 types of cold packs, 11 types of thermometers. Also distributed by UNICEF.

Guidelines for establishing national and regional vaccines stores.
July 1980. 33 pages.
Reference: EPI/CCIS/80.15.
Languages: English. French available end 1980.
A review of problems and solutions in establishing bulk vaccine stores. Subjects covered include: how much space is needed, what equipment is required, how to purchase and install a cold room and how to improve an existing cold room.

Summary of vaccine refrigerator testing. Consumer's Association:
United Kingdom. 8 pages.
Reference: EPI/CCIS/79.5.
Languages: English and French.
Test results are given for nine domestic gas, kerosene and electric refrigerators performing in outside temperatures of 32°C and 43°C, and fluctuating temperatures of 15°C to 43°C. Recommendations are given on the best of these refrigerators if they are to be used for storing vaccines.

Summary report on jet injector testing in the laboratory and field.
May 1980. 10 pages.
Reference: EPI/CCIS/80.14.
Languages: English and French.
Four models of jet injector were subjected to 120,000 shots in a laboratory and 240,000 shots in Ghana. They were monitored for variations in dosage, jet velocity, frequency of breakdown and spare parts consumption. Two of the guns failed before 10,000 shots had been completed; the remaining two failed before 30,000 shots.

Summary of test report on three brands of reusable syringes.
2 pages.
Reference: EPI/CCIS/80.6.
Languages: English and French.
This paper describes the performance of 12 types of plastic syringes after 25, 50, 100 and 200 sterilizations. At each step a judgment is made on the capacity of the syringe, leakage, transparency and legibility of the scale. Recommendations are made for buyers.

"This refrigerator protects lives."
Reference: WHO 79188.
Languages: English, French, Spanish and Arabic.
A poster intended for the door of a vaccine refrigerator. It gives instructions on how to load the refrigerator to get the best performance. Free in small quantities, US $2.50 per 1,000 in bulk.

"A Guide to Estimating Capacity of Equipment for Storing and Transporting EPI Vaccine," WHO Document EPI/CCIS/80.10, Geneva, 1980.
This is a method for obtaining an approximate estimate of the capacity of equipment required to store and transport vaccines based on a number of assumptions. However, if a more accurate estimate is required before purchasing equipment, it is strongly recommended that the assumptions used in this calculation be checked.

How to Look after a Refrigerator.
1980, 58 pages, English
Appropriate Health Resources and Technologies Action Group (address below)
This book uses simple text and many clear illustrations to give step-by-step instructions for the care and maintenance of kerosene, gas and electric refrigerators. It also describes how to store vaccines safely in the refrigerator, cold boxes and vaccine carriers. Cost is $11 air mail or $7.40 surface mail.

ADDRESSES FOR FURTHER INFORMATION

Purpose: For manuals, training materials, technical advice on immunization delivery and information concerning research on vaccines and the cold chain
Address: Expanded Program on Immunization
World Health Organization
1211 Geneva 27
Switzerland

Purpose: Progress of The Expanded Program in Latin America. Information on Vaccine Revolving Fund
Address: Expanded Program on Immunization
DPC/DCD
Pan American Health Organization
525 23rd Street, N.W.
Washington, D.C. 20037

Purpose: Appropriate Technology in Cold Chain Equipment
Address: Appropriate Health Resources & Technologies Action Group Ltd.
85 Marylebone High St.
London W1M 3DE
United Kingdom

Purpose: Solar powered refrigerator
Address: National Aeronautics and Space Administration
Lewis Research Center
Cleveland, Ohio 44135
or
International Immunization Division, B.S.E.
Center for Disease Control
Atlanta, GA 30333

Purpose: Liquid Crystal Thermometers
Address: American Thermometer Co.
P.O. Box 1509
Dayton, Ohio 45401

Purpose:. Chemical Coolant Refrigerators
Address: The Zeopower Co.
75 Middlesex Ave.
Natick, MA 01760

Purpose: Self-contained temperature recorder
Address: The Johns Hopkins University
Applied Physics Laboratory
Johns Hopkins Road
Laurel, MD 20810

brief annotated bibliography on immunizations in developing countries

AGLE, A.N., and others: "Immunization Programs." *Communicable Disease Control Planning* in International Health Planning Methods Series, Vol. I, pp. 34-50. Office of International Health, Department of Health and Human Services, 1978.

An important review article on the implementation of broad coverage immunization programs by immunization experts at The Center for Disease Control, U.S. Department of Health and Human Services, Atlanta. Oriented to immunization activities in developing countries.

"Measles in the Tropics." *British Medical Journal* December 1976, No. 6048, pp. 1339-1340.

Measles pattems in the tropics contrasts with temperate industrialized countries as follows: statistics in morbidity and mortality are less certain; certain cultures forbid treatment; age of occurrence is lower; mortality from measles is high from hospital samples; and most deaths from measles occur in the second year of life.

"Poliomyelitis Vaccines." *British Medical Journal* September 1978, Vol. 2, pp. 845-846.

An article on the Salk vs. Sabin vaccine debate. Developing countries use oral polio vaccine for economy and simplicity. Should attempt as near as possible to reach 100 percent immunization rate. Inactivated vaccine can be used in the tropics with proper handling where live vaccine has failed to "take." LDC use of oral vaccine supported by WHO . However, use of Salk is good if LDC's can afford associated costs.

Field Manual of the Expanded Program of Immunization, World Health Organization, Geneva, Switzerland, 1977, 1 vol. various paging.

Looseleaf notebook format contains five sections on (1) program design, (2) program management, (3) vaccine handling, (4) health education for immunizations, and (5) program evaluation. Remains the basic guide for implementation of broad coverage immunizations.

"The Cold-Chain for Vaccine Conservation: Recent Improvements." *WHO Chronicle* 1979, Vol. 33, pp. 383-386.

An informative 1979 up-date on the latest developments in cold chain technology. Findings include that in areas with poor electric supplies, commercial chest freezers are better than domestic front-opening refrigerators. Tests show front-opening kerosene refrigerators can't maintain vaccine temperature when ambient temperature is above 43°C. Portable refrigeration equipment enables transport of frozen ice packs and vaccine or the conversion of cold boxes to static or mobile refrigerators. Cold boxes and carriers are manufactured by the following countries for use in their cold chains: Ghana, India, Pakistan, Indonesia, Philippines, Senegal, Thailand.

"Expanded Programme on Immunization, Study of Feasibility, Coverage, and Cost of Maintenance Immunization for Children by District Mobile Teams in Kenya." *Weekly Epidemiological Review* 1977, Vol. 52, no. 24, pp. 197-199.

A study was designed to improve the routine immunization coverage of children by a system of half-yearly rounds by mobile teams, and to test the operational feasibility of the system with respect to cost and coverage in three zones of different population density. The strategy of operation was based on 1) use of BCG and smallpox vaccination scars as markers, 2) acquisition of a knowledge of the structure of the community concerned in order to improve community participation, 3) use of schoolchildren to disseminate information. The results of this study appears in Chapter III of this paper under the heading, "The Costs of Immunizations."

"Saving Lives by Immunization." *WHO Chronicle* 1979, Vol. 33, pp. 128-130.

This is a summary article on the Expanded Immunization Program, including details on implementation, financial resources required, and program medium-term objectives. Medium term objectives include 1) formulation of regional and country level immunization plans, which should have quantifiable objectives, and 2) financial resources—cost to fully immunize a child against 6 diseases, including development costs is 3 U.S. dollars. Funds from national and external sources are needed, etc.

BANKES, D.D.: "Manufacture and use of Vaccines in Developing Countries." *Journal of Medical Sciences* February 1979, Vol. 33, No. 2, pp. 47-49.

Outlines problems associated with local production of vaccines, a long-term objective for most LDCs. India is self-sufficient in production of smallpox, cholera, rabies, typhoid-paratyphoid, and BCG vaccines, but does not produce enough DPT and poliovirus vaccine. Problems include not meeting WHO standards, loss of potency. Suggested use of intradermal jet to reduce amount of vaccine needed per child. Recommends setting up fully equipped regional control lab in each of WHO regions to examine samples to assure potency, purity and safety.

BELCHER, D.W., Nicholas, D.D., Ofosu Amaah, S. et al: "A Mass Immunization Campaign in Rural Ghana: Factors Affecting Participation." *Public Health Reports* Mar.-Apr. 1978, Vol. 93(2), pp. 170-176.

Evaluation of mother's reasons for attending or not attending vaccination sessions, as part of Danfa study. Emphasizes importance of well publicized immunization sessions. Factors affecting participation in a mass immunization program are: 1) family preference of clinics because they are seen as more effective, and 2) measles and whooping cough are easily recognized diseases thus the public is aware of the danger. Unfavorable factors to participation are: 1) distance from vaccination collection point, 2) work loss, 3) side effects of vaccination, and 4) lack of clarity as to which childhood diseases are being covered; age group to be immunized; and number of hours the immunization team would be in the village, or at the collection point.

BELCHER, D.W., and others: "Comparison of Methods for Estimating the Frequency of Paralytic Poliomyelitis in Developing Countries." *Bulletin of the World Health Organization* 1979, Vol. 57, No. 2, pp. 301-307.

Standard reporting systems have proved to be unreliable in estimating the frequency of paralytic poliomyelitis in many developing countries. The effectiveness of three survey methods for estimating the prevalence of lameness attributable to poliomyelitis were compared in the Danfa Health Project district of rural Ghana. Lameness was studied because it is easily identified by inexpensive survey techniques. The observed prevalence of lameness attributable to poliomyelitis was 7 per 1000 school-aged children, and the annual incidence is estimated to be at least 28 per 100,000 population.

BERGGREN, W.L.: Changing Incidence of Fatal Tetanus of the Newborn." *American Journal of Tropical Medicine and Hygiene* May 1971, 20(3), pp. 492-494.

There are two approaches to neonatal tetanus fatality reduction: Immunization of pregnant women and distribution of sterile delivery kits. In a population of 1,629 women between the ages of 15 and 60 years, tetanus of the newborn was determined retrospectively to have caused the death of 1,143 of their 7,248 liveborn children. Declines in frequency could be directly related to preventive programs. A program that immunized all women with tetanus toxoid, whether or not they were pregnant, provided the means of reducing tetanus of the newborn as a public health problem.

BERGGREN, W.L.: "Control del Tetanos Neonatal en el Medio Rural de Haiti Mediante la Utilizacion de Auxiliares de Medicina." *Boletin Oficina Sanitaria Pan Americana;* Julio 1974, pp. 6-12 (Spanish).

Neonatal tetanus is a disease of major public health importance in Haiti. Twelve years of hospital-based services performed by professional personnel of the Albert Schweitzer Hospital had failed to control the disease. The use of locally recruited and trained medical auxiliaries permitted the accomplishment of this goal despite the limitations of having few available health professionals and a small budget. Tetanus immunizations of women in the child-bearing years were part of this program. The dollar value of the treatment services averted was more than seven times the cost of the program.

BOFFEY, P.M.: "Polio: Salk Challenges Safety of Sabin's Live-Virus Vaccine." *Science* April 1977, Vol. 196, pp. 35-36.

Reviews history of the Salk vs. Sabin polio vaccine debate. Rationale for choice of Sabin: greater acceptability, produces longer lasting immunity, immunizes unvaccinated people because of spread of low grade infection, suppresses wild virus in intestines.

BREMAN, J. G., and others: "Evaluation of a Measles-Smallpox Vaccination Campaign by a Sero-Epidemiologic Method." *American Journal of Epidemiology* 1973, Vol. 102, pp. 564-571.

Cluster sampling method used to evaluate mass measles campaign in Ivory Coast. An assessment technique has been devised whereby children from 30 randomly chosen sampling sites are visited within three days of measles-smallpox vaccination and one month later. Vaccination coverage is measured at house visits and immunologic status is determined by collection of early and late blood samples on filter papers from substratified children in priority age-groups, and by looking at vaccination scars. The method was employed in a rural area of the Ivory Coast during the maintenance phase of a measles-smallpox vaccination program.

BUNOWES, J., Cruickshank, J.G.: "At What Age Should Measles Vaccine be Given? Report of a small trial in Bulawayo." *Central African Journal of Medicine* 1976, Vol. 22, No. 3, pp. 45-47.

This paper is a study on rural and urban African infants to find out a) the earliest age at which most can be successfully vaccinated, b) if a reduced vaccine dose can be used, c) if a higher dose will cause response in infants, and d) determine the danger period between the time when maternal antibodies are absent and child begins to produce its own.

CVJETANOVIC, B., and others: "Epidemiological Model of Tetanus and its Use in the Planning of Immunization Programmes." *International Journal of Epidemiology* 1972, Vol. 1, pp. 125-137.

A mathematical model of tetanus, based on the natural history and dynamics of the infection, was constructed. It was used to simulate the effect of various immunization programmes such as: (a) one mass immunization of the population with 50% coverage, (b) repeated mass immunizations at 10-year intervals, and (c) continuous immunization of just pregnant women with 90% coverage. In addition, the effectiveness of simultaneous mass vaccination and immunization of pregnant women was simulated. Program (c) had the best cost-benefit and cost-effectiveness ratios.

DE QUADROS, C.A. "More Effective Immunization," *Proceedings of the Royal Society of London,* Vol. 209, Number 1174, July 28, 1980, pp. 111-117.

This paper was presented at a meeting on "More Technologies for Rural Health" and outlines the success of Ecuador and Costa Rica in expanding immunization coverage of children using strategies of the Expanded Program on Immunization. Coverage was assessed through a survey using cluster sampling so only a minority of children immunized were seen. This economical type of coverage assessment could be applied to other types of child health programs.

DICK, B., Smith, T., Kipps, A.: "A Minimum Age for Measles Vaccine Administration to Coloured Children." *South African Medical Journal* November 1975, Vol. 49, pp. 1951-1954.

The antibody response to attenuated live virus measles vaccine was assessed in 67 Coloured children between the ages of 6 and 12 months. Children less than 9 months of age were found to have suboptimal seroconversion rates and the authors recommend that the routine administration of measles vaccine should be restricted to children over the age of 8 months. High-risk groups and problems of vaccine administration and storage are discussed.

FAULK, W.P., Edsall, G.: "Vaccines and Vaccination Programs, Special Emphasis in Malnutrition." *American Journal of Clinical Nutrition* December 1978, Vol. 31, pp. 2237-2247.

Immunization programmes intended for developing countries must take into account the delay and the lowering of cellular and humoral immune responses in malnourished children. The authors review this problem.

FOEGE, W.H., Foster, S.O.: "Multiple Antigen Vaccine Strategies in Developing Countries." *American Journal of Tropical Medicine and Hygiene* 1974, Vol. 23, No. 4, pp. 685-689.

A 1974 article by two smallpox eradicators which discusses the theory and possible program strategy for an Expanded Program on Immunization. Immunization programs constitute one of the most economical and efficient approaches to preventive medicine in developing countries. Costs can be reduced further by administering several antigens simultaneously. Available evidence suggests it is safe and effective to administer the usual range of antigens utilized in developing countries at one time. Likewise, operational experiences in the past five years indicate the delivery of multiple antigens is logistically feasible. Mobile vaccination teams can be expected to reach a high percentage of children and by means of objective screening systems vaccine wastage and duplication can be avoided without the need for individual immunization records using the scar marker system.

HENDERSON, R.H.: "The Expanded Program on Immunization: A World Commitment to Provide all Children with a Basic Preventive Medical Service." *Tropical Pediatrics and Environmental Child Health* 1978, Vol. 24, No. 4, pp. 201-202.

The 27th World Health Assembly (May 1974) urged members to develop and maintain immunization programs. WHO collaborates closely with governments, to make quality vaccine available and undertake educational activities. Recommends incorporation of immunization activities as component of PHC.

IFEKWUNIGWE, A.E., and others: "Immune Response to Measles and Small Pox Vaccinations in Malnourished Children." *The American Journal of Clinical Nutrition* March 1980, Vol. 33, pp. 621-624.

Children with different levels of nutritional status were studied to determine their immune response or complications from live measles vaccine and smallpox vaccine. 241 children aged 5 months

to nine years were studied and ranked relative to their weight for age. The study showed that the rate of immune response was independent of age, sex, and the nutritional status of the children. The authors concluded that since measles is a very severe disease, which in malnourished children can carry a case fatality rate as high as 50 percent, malnutrition should be a prime indication for measles immunization and certainly not a contraindiction.

IKIC, D., et al.: "Stability of Live Freeze-Dried Measles Vaccine at Various Temperatures." in *Proceedings of a Symposium on Stability and Effectiveness of Measles, Polio, Pertussis Vaccines* Publication of the Yugoslav Academy of Sciences and Arts, Zagreb, 1976, pp. 113-116.

A study of live freeze-dried measles vaccine stored at different temperatures from +4°C to +37°C. Titres of freeze-dried measles vaccine were examined after storage at refrigerated and higher temperatures. Results show that with adequate storage at +4°C, measles vaccine was relatively stable. Stability fell off rapidly with storage temperature rise.

KING, B.: "Measles Vaccination in a Rural Tanzanian Community." *East African Medical Journal* 1978, Vol. 55, No. 6, pp. 252-255.

5,430 children were vaccinated against measles using live attenuated virus vaccine. The success rate was estimated by taking 169 prevaccination and 129 post vaccination blood specimens on filter paper to measure measles antibody. A seroconversion rate of 78 percent was achieved in children over one year old and 53 percent in children under one year. Children under one year old who are vaccinated should be revaccinated later. All measles vaccination programmes should include assessment. Recommends delaying measles vaccination until 9 months of age.

KOPLAN, J.P., and others: "Pertussis Vaccine—An Analysis of Benefits, Risks, and Cost." *New England Journal of Medicine* 1979, Vol. 301, No. 17, pp. 906-911.

Using decision analysis, the authors estimated the benefits, risks and cost of routine childhood immunization against pertussis. Without an immunization program, they predict that there would be a 71-fold increase in cases and an almost 4-fold increase in deaths per cohort of one million children. Their analysis supports continuation of vaccination in routine childhood immunization programs, but suggests the need for more reliable data on complications from the vaccine, further study of the epidemiology of pertussis and development of a less toxic vaccine.

MADKOUR, M., Khalifa, A.S.: "A Critical Review of BCG Vaccination Programme in Egypt." *Journal of Tropical Medicine and Hygiene* 1977, Vol. 80, No. 7, pp. 144-146.

70 percent of those vaccinated in a 1974 BCG program in Egypt did not respond to TB testing. Recommendations include that even highly trained staff needs appropriate supervision. Independent retesting teams are needed to evaluate previous work. Health education is essential for public to seek vaccination.

MAHIEU, J.M., Muller, A.S.: "Pertussis in a Rural Area of Kenya: Epidemiology and Preliminary Report on a Vaccine Trial." *Bulletin of the World Health Organization* 1978, Vol. 56, No. 5, pp. 773-780.

Compares two versus three doses of DPT vaccine with respect to the pertussis component. In the course of 2 years surveillance of whooping cough by fortnightly home visits among a population of 24,000 in a rural area of Kenya, 918 cases were observed with a peak of 218 in December 1974–January 1975. Pertussis agglutinating antibody determinations showed an equally satisfactory response after two and after three DPT vaccine doses.

McBEAN, A.M., Foster, S.O., Herrmann, K.L. et al: "Evaluation of a Mass Measles Immunization Campaign in Yaounde, Cameroon." in *Transactions Royal Society of Tropical Medicine and Hygiene* 1976, Vol. 70, No. 3, p. 206.

A mass measles immunization campaign carried out in Yaounde, Cameroun has been evaluated. Sixty percent of the children were immune to measles at the time of the campaign. Only 51 percent of the susceptible children received vaccine. This was caused by a lack of attendance at the vaccination centers and errors in the selection of children given vaccine. The vaccine administered was relatively ineffective: 40 percent seroconversion. Difficulties which probably contributed to the low seroconversion rate included sub-optimal vaccine titre, inadequate doses of vaccine, and the relatively long time of vaccine utilization under tropical temperatures.

MILLER, D.L.: "Monitoring Communicable Disease: Vaccination Programmes." *International Journal of Epidemiology* 1976, Vol. 5, No. 1, pp. 45-50.

Discussion of components of a vaccine surveillance system, and its importance. The success of vaccination as a means of disease prevention depends on its appropriate application and its reputation with professionals and the public. Surveillance, by providing accurate information on effectiveness and the frequency and nature of hazards, is essential to this purpose. Several factors that influence the success and safety of vaccination programmes are discussed. The essential elements of a vaccine surveillance scheme are outlined with special reference to experience derived from monitoring vaccines in current use.

MORLEY, D.C.: "Measles in the Developing World." *Proceedings of the Royal Society of Medicine* Nov. 1974, Vol. 67, pp. 4-7.

The experience of the island of Fiji is used as an example of measles problems in LDCs. Measles was first introduced to Fiji in 1875 and caused one third of the population to die. The high mortality was influenced by poor living conditions, age of cases and the malnourished state of cases.

NAZARI, F., and others: "A Model for Developing Countries of Mass Serological Survey of Children Vaccinated against Diphtheria and Tetanus." *Journal of Biological Standardization* 1976, Vol. 4, pp. 329-333.

Immunizations against diphtheria, tetanus and pertussis have been conducted in Iran since 1950 but on an irregular or individual basis. Mass immunization campaigns began in 1965 but were replaced with immunizations in health centers where people were supposed to bring their children for free vaccinations. But the poor and recent migrants to the city did not come to the health centers, and new outbreaks of diphtheria were feared. Therefore the mass campaign system was reinitiated following 1970 in most regions of Iran.

PAUL, S.S., Nath, A.K., Chhabra, A.K. et al.: "Comparison of BCG Inoculation by Conventional Intradermal and jet Methods." *Indian Pediatrics* 1978, Vol. 15, No. 4, pp. 341-347.

300 Mantoux-negative babies were given BCG vaccination, half by the conventional intradermal and half by the Jet methods. All were observed for 6-12 weeks for the development of the BCG scar and postvaccinal allergy. It was concluded that both methods were equally safe and effective and that the appearance of BCG scar, irrespective of its size is a reasonable index of the development of immunity.

PEETERMANS, J., and others: "Stability of Live, Freeze-Dried Virus Vaccines." *Developing Biological Standards* 1977, Vol. 36, pp. 291-296.

Discusses the important question of the loss of potency in vaccines after removal from refrigeration. Stability of live, freeze-dried vaccines is a major factor for successful immunization. The routine use of an accelerated stability test, e.g. exposure of each lot manufactured to 37°C during 7 days, provides useful information regarding the stability of the vaccine at +4°C. In general the loss during the accelerated stability test is higher than the loss after 24 months storage in the refrigerator. Specifications requiring that each vaccine lot must possess, after the accelerated test, a titer equal to or higher than the minimum titer needed for immunization, are a guarantee of sufficient potency at the time of ad-

zation, are a guarantee of sufficient potency at the time of administration. To solve the problem of immunizations in tropical countries stable vaccines are essential.

PERIER, H., Husser, J.A.: "Is the Appearance of the 1st Tooth a Good Indicator for the Choice of When to Vaccinate for Measles?" *Medicin Tropical* 1979, Vol. 39, pp. 559-563.

The criterion of the dental evolution has been proposed when a precise birth date is lacking. Its insufficiencies are stressed, and the rapid introduction of health records recommended.

PONNIGHAUS, J.M.: "The Cost-Benefit of Measles Immunization. A study from Southern Zambia." *Medicine in Developing Countries* 1979, Vol. 3, Peter Lang Co., Frankfort.

The study shows that financial benefits can only be expected from a measles immunization programme in urban areas (provided with a 24-hour supply of electricity). If 100 percent coverage were provided in rural areas, the cost per child immunized would be 16 times higher than in urban areas. (German Language)

SHAH, P.M., Karande, S.C., Panjabi, G.T. et al.: "Use of Jet Injectors for BCG Vaccination." *Indian Pediatrics*, 1978, Vol. 15, No. 2, pp. 117-120

Detailed account of problems associated with the use of jet injectors to administer BCG vaccine. Most problems originated with frequent malfunctions of jet injectors.

SINHA, D.P., Bang, F.B.: "Protein and Calorie Malnutrition, Cell-Mediated Immunity and BCG Vaccination in Children from Rural West Bengal." *Lancet* September 11, 1976, pp. 531-534.

The post-vaccinal reaction rate was much higher among children classified as nutritionally healthy than in those severely malnourished. There was no significant difference between those who were merely underweight and those were were nutritionally healthy.

TOMASZUNAS, S.: "A Challenge to South East Asia: The Expanded Programme on Immunization." *WHO Chronicle* 1979, Vol. 33, pp. 209-213.

Discusses the establishment of Expanded Immunization activities in South East Asia. Outlines what has been done to implement the Expanded Program in one of WHO's six regions. States the reasons why immunization programs have not been as successful in South East Asia as in the industrialized countries. Discusses the epidemiology of the six diseases addressed by The Expanded Program in South East Asia.