EPI ESSENTIALS

A GUIDE FOR PROGRAM OFFICERS

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Some features of the guide have been adapted from or inspired by the work of others. The categories of the introductory section, "ALIVE", were first used by D.A. Henderson at Bellagio in 1984, and have been reorganized for purposes of the guide. Marjorie Pollack and Allan Bass developed program design checklists upon which ours is based. The monitoring and evaluation checklist in Section IV reflects original work by Stanley Foster. Categories and methods of evaluation listed in Section IV have been adapted from WHO.

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Resources for Child Health Project (REACH)
John Snow, Inc.
1100 Wilson Blvd., 9th Floor
Arlington, Virginia 22209 USA
Telephone: 703-528-7474 Telex: 272896

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August, 1989
Second Edition

Preface

EPI (Expanded Program on Immunization) is the title of organized efforts to achieve "Universal Childhood Immunization" in all nations. *EPI Essentials: A Guide for Program Officers* is written primarily for staff from international development agencies who administer, monitor, or support EPI, but who are not necessarily themselves experts in EPI. We hope the guide will also benefit those who are, as we so often have been ourselves, in need of concise answers to the perplexing *whys* and the *hows* of immunization program development.

The guide is written from the point of view of a technical assistance organization. It is not designed to give detailed explanations of survey design or refrigerator repair procedures; rather, like the owner's manual of a car, the guide will give the user an understanding of what the different components of a program are, how they operate when they are working correctly, and how to recognize when they do not, *before* a major breakdown.

EPI design, however, is more complex than automobile repair. We also try to examine the facts, the controversies, and the prevailing wisdom and orthodoxies guiding immunization programs today. The rules we make need to be flexible enough to adapt to the variations of geography, culture, primary health care development, political commitment, and past experience with EPI, between countries as well as within the same country. In short, immunization programs must be responsive to the varying *ecology* of the environments in which they operate. Questions also remain about the *biology* of the target diseases and even the vaccines themselves. The guide also examines the concept of sustainability in immunization programs: how much do they cost and who will pay for them? Are they even the best use of funds in countries operating on austerity budgets?

"Vaccination" and "Immunization" may be used interchangeably, although the World Health Organization prefers the latter. In this guide, we use *Vaccination* to mean the vaccine has been administered to a mother or child, and *Immunization* to mean that a person is now protected and no longer susceptible to the illness.

Even though many issues have yet to be resolved, some national programs have found innovative solutions to operational problems. The guide uses these creative approaches as examples, as well as providing specific suggestions about the qualities that lead to successful programs.

We dedicate this guide to the front-line workers in EPI upon whom rest the burden and our hope for Universal Childhood Immunization.

There has been remarkable progress in the global effort to stop the needless waste of the lives of infants and children. Through the work of presidents and peasants, private voluntary organizations and international organizations, developing countries and the generous assistance of Americans, Italians, and other bilateral donors, children throughout the developing world are reached by those key technologies that can mean the difference between life and death.

Alan Woods
Administrator
U.S. Agency for International Development
Child Survival: A Third Report to Congress on the USAID Program, 1988

CHAPTER I

EPI—AN ORGANIZATIONAL POINT OF VIEW 1

The Role Of Management—A.L.I.V.E. 3

Administration And Organization 4

Logistics 6

Information, Education, And Communication (IEC) 8

Vaccines And Vaccination Strategies To Vaccinate All Children On Time 9

Evaluation Of The Functions And Results Of EPI 10

VERONIQUE LEGER

CHAPTER II

IMMUNIZATION PROGRAM PREREQUISITES 11

Epidemiologic Facts About The Target Diseases 14

Measles 16
What Does Measles Look Like? 16
How Is Measles Transmitted? 16
Risk Factors 18
Protection Against Measles 19

Neonatal Tetanus 22
What Does Neonatal Tetanus Look Like? 22
How Is Neonatal Tetanus Transmitted? 23
Who Is At Highest Risk Of Dying From Neonatal Tetanus? 24
Protection Against Neonatal Tetanus 25

Pertussis 27
What Does Pertussis Look Like? 27
How Is Pertussis Transmitted? 27
Who Is At Highest Risk Of Death And Severe Disease? 27
Protection Against Pertussis 28

Polio 30
What Does Polio Look Like? 30
How Is Polio Transmitted? 30
Who Is At Risk Of Contracting Polio? 30
Protection Against Polio 31

Diphtheria 34
What Does Diphtheria Look Like? 34
How Is Diphtheria Transmitted? 34
Who Is At Highest Risk Of Diphtheria? 34
Protection Against Diphtheria 34

Tuberculosis 35
What Does Tuberculosis Look Like? 35
Transmission And Risk Factors 35
Protection Against Tuberculosis 35

Other Diseases Of Major Significance With Impending Vaccines 36
Hepatitis B 36
Rotavirus Diarrhea 37
Acute Respiratory Infections (ARI) 37

Establishment Of Program Objectives And Targets 38

Program Design Checklist 40

IMMUNIZATION PROGRAM COMPONENTS 45
Delivery Strategies For Vaccination 48
Delivery Strategies Used To Raise Vaccination Coverage 49
EPI In Urban Areas 52
Missed Opportunities For Vaccination 53
Vaccination Schedules And Vaccine Administration 55
Vaccination Schedules 55
Vaccination Session Records 58
Vaccination Cards 60
Vaccines And Their Administration 62
BCG Vaccination 64
Measles Vaccination 66
Diphtheria Vaccination 68
Tetanus Vaccination 70
Pertussis Vaccination 71
Polio Vaccination 72
The Logistics Of Vaccine Management 74
The Cold Chain 74
Vaccine Storage Temperatures And Stability 75
The Links Of The Cold Chain—Cold Rooms, Refrigerators, Cold Boxes, Thermometers, And Cold Chain Monitors 77
Product Information Sheets 85
Costs Of Cold Chain Equipment 86
Injection Equipment 90
Reusable And Disposable Syringes And Needles, Jet Injectors, And Single-use Devices 91
Costs Of Injection Equipment 95
Sterilization Of Injection Equipment 96
Training For EPI 98
Social Sciences In EPI 101
Social Science Investigation Techniques 102
Social Marketing 107
Health Education 111
Human Behavior As A Variable In EPI 112

We, The Task Force For Child Survival, conveners of the meeting "Protecting the World's Children—An Agenda for the 1990s" in Talloires, France on 10–12 March 1988:

Urge national governments, multi- and bilateral development agencies, United Nations agencies, non-governmental organizations and private and voluntary groups to commit themselves to:

Improve women's health and education, recognizing the importance for women themselves, recognizing women's contribution to national development and recognizing that mothers are by far the most important primary health care workers. . . .

Excerpt from the *Declaration of Talloires, Protecting the World's Children: An Agenda for the 1990's*, 1988

CHAPTER IV

IMMUNIZATION PROGRAM EVALUATION 115

Monitoring And Supervision 122

Assessing Vaccination Coverage 125

What Techniques Are Used For Determining Vaccination Coverage? 127

Calculation Of Coverage From Routine Vaccine Tally Data of Vaccinations 127

Cluster Sampling Survey 128

Lot Quality Assurance Sampling Survey 132

"75 House" Survey 133

Vaccine Efficacy And Serological Surveys 134

Disease Surveillance In EPI 135

Routine Disease Reporting 135

Sentinel Site Surveillance 136

Outbreak Investigation 138

Morbidity And Mortality Surveys 138

Comprehensive And Rapid Program Assessments 140

Cost Analyses 142

Why Are Costs Analyses Important? 143

Methods For Collecting Cost Data 143

Data Sources 149

Analysis Of Cost Data 150

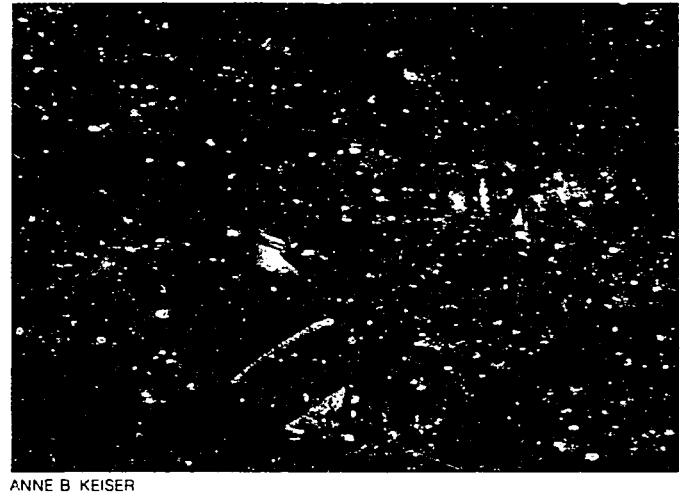
Case Study 153

Immunization is not an end but a beginning—the beginning of sustainable health care systems available to even the poor and the isolated rural families of developing countries.

M. Peter McPherson,
Child Survival: A Report to Congress
on the AID Program, 1985

EPILOGUE

SUSTAINING EPI 159



ANNE B KEISER

APPENDIX

SOURCES AND RESOURCES 165

CHAPTER I
EPI – An Organizational Point Of View

EPI—An Organizational Point of View

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The Role Of Management—A.L.I.V.E.

What is a "good" EPI? If you saw one, could you tell? Is it possible for one program with high coverage, attained swiftly, to be less vigorous than another with lower coverage, but pulling for the long haul?

This introductory section describes the attributes of a good EPI—one likely both to *achieve* and *sustain* its accomplishments. How an EPI gets to that point has a lot to do with excellent technical knowledge, political will, leadership, resources, and luck.

Before we tackle the specific, technical aspects of the operation of a program, a broad overview of EPI will help put each of the elements into place. All of the major attributes fall into five categories that we have dubbed A.L.I.V.E.—**A**dministration and organization, **L**ogistics, **I**nformation - education - communication, **V**accines, and **E**valuation.

From the global perspective, management capacity within national programmes remains the most severe constraint for the EPI.

Ralph Henderson
Director, EPI, WHO/Geneva
Bellagio II, Cartagena, October 1985

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1. ALIVE—Administration And Organization

The most potent vaccine, the best epidemiologic knowledge, and the purest of motives do not avail an EPI without orderly structure and astute management.

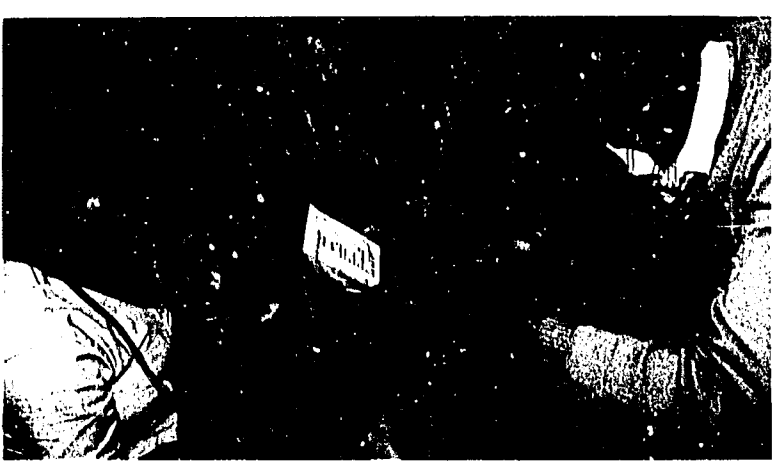
Good management is perhaps one-third technique, which can be taught. The other two-thirds comes from leadership, intelligence, motivation, morale, and creativity—qualities which cannot be taught. Everyone has at least some of these qualities to some degree, but how do you create an atmosphere that fosters them? The answer is a seeming paradox, for *success* itself is the best teacher of qualities that sustain effective programs. Just as repeated failure reinforces subsequent failure, good management is as much a result of success as a path to it.

No guide can teach the human side of good management, and the details of technique are beyond our purview. What we can do is describe aspects that sustain a successful vaccination program.

The successful EPI provides answers to three basic questions:

1. What would make parents choose vaccination as a means to protect their children from illness?
2. What would make health workers be happy to give vaccinations safely and on time?
3. How does the EPI guarantee that effective vaccines (along with sterile syringes and needles) are available when parents, child, and health workers are ready for them?

Integral to all three questions is the issue of sustainability: maintaining the interest of parents, the enthusiasm of health workers, and the various operational systems that guarantee effective programs. Sustained EPI efforts tend to have considerable local managerial authority. Targets are set locally at a manageable level. Supervision is regular, friendly, and oriented toward



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Campaign Or Continuity? The Answer Can Be Both

One considered benefit of mass EPI campaigns is the instant creation of success—a sudden catalyst to convince health workers and families that much can be achieved with a focused effort, made important by the entire society. They can energize health workers from the routine, work-a-day world of primary health care.

The more successful programs, however, are those which strengthen permanent primary care EPI services. Mass campaigns may temporarily succeed in mobilizing the nation for EPI and in taking up the "backlog" of unvaccinated children. But the regular health services are left to sustain the momentum and often are not given the resources needed to succeed.

problem-solving. Health workers participate in measuring results and, consequently, care about their achievements or failures.

Local autonomy is not equivalent to independence but relies on interdependence between various levels. Regular pay, timely supply of safe and potent vaccines, and consistent feedback of information all contribute towards maintaining morale throughout the program.

Beyond those directly involved with the program are the essential links that make an EPI a truly national effort. For example, a multisectoral advisory board makes the vaccination of children everyone's concern. At the community level, a partnership is formed between the local health unit and the citizens. These links ensure that vital information about EPI willbe disseminated through as many channels and in as many forms as possible, ranging from the use of the mass media to participatory, community activities.

In a successful EPI, the medical profession mobilizes against vaccine-preventable diseases through medical journals, pamphlets, seminars, and direct mail. The government makes sure that vaccines are available to all children at little or no cost. All means of outreach are used to get children back for the completion of their vaccination series. In more developed nations, governments pass laws requiring proof of vaccination before a child can attend school. Mass media inform parents about vaccination, and children's television shows inform children. Every outbreak of a target disease is tracked by local and national epidemiologists, whose statistics form the base of a vigilant health information system.

2. ALIVE—Logistics

For EPI, logistics entail two principal activities: timely provision of vaccines, needles, and syringes, and maintenance of a reliable cold chain to keep vaccines viable. Without a working cold chain, however, the provision of correct amounts of vaccine and other necessary equipment is useless.

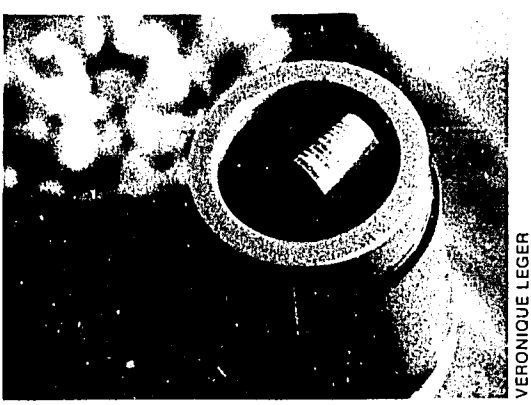
A cold chain is only as good as its weakest link. Vulnerable links center around points in the chain that rely on recurrent resources, such as gasoline, ice, and spare parts. It is these junctures that require strong management, carefully thought-out contingency plans, and resources held in reserve. Consider the bicyclist who, on planning a long tour, is likely to pack at least several tire patches, if not a spare inner tube; however, the bicyclist is not likely to carry along an extra set of reflectors or a seat, knowing that, at a minimum, the bicycle could keep going without either of these. So with the cold chain—the possibility of "flat tires" must be considered long before they occur.

Technological advances have made vaccines all the more reliable. But each time new technology is introduced, key staff must be retrained. If staff can learn to operate one robust system, the gradual introduction of new technologies coupled with ongoing training will allow for continual improvement.

The Cold Chain Monitoring Card

Cold chain monitoring cards follow the vaccines as they are distributed from manufacturers to national, regional and peripheral levels. They contain a chemical behind a visible plastic bubble that changes color gradually and irreversibly with incremental heat exposure. The cards let the EPI worker be certain about the vaccine's viability. (See also page 83.)

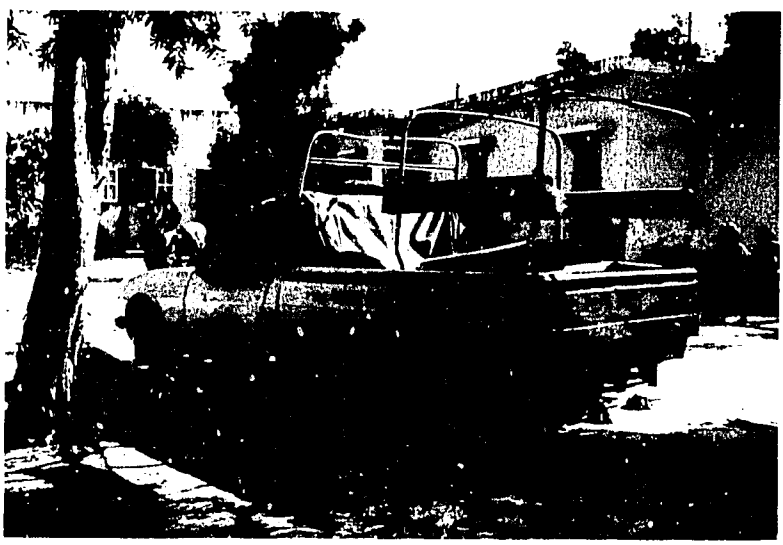
The cold chain extends from the walk-in cold room at the central stores, holding millions of doses, to the desk-top thermos at the health center holding enough for the morning's vaccinations.



VERONIQUE LEGER

Well-trained technicians are essential to a reliable cold chain. From the cold storage room of the airport or the capital city, to the vaccine-carrier box used by an outreach health worker at a peripheral unit, each technician knows how to monitor, repair and maintain the equipment that is his or her responsibility. Each technician has spare parts and tools (now available as complete kits from UNICEF). If you had to choose between a physician, an epidemiologist, or a cold chain technician—choose the technician!

In addition to technicians, a strong cold chain relies on only the minimum number of links necessary to maintain its effectiveness. In many countries, refrigerators in remote health units



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have been a total waste: the electricity or kerosene supply has been irregular, the maintenance has been poor, and parts have been absent. Several other options would be more effective. Vaccines could be delivered in two- or three-day vaccine-carriers from district stores. A seven-day, ice-lined cold box kept at each unit would be another option, if sufficient quantities of ice are available.

Transport, vaccines, injection and cold chain supplies, training materials, and record forms must be provided when and where needed. This requires a usable management information system. With data on the size of the population, the number of children needing vaccination, the number of vaccinations administered, and the results of coverage surveys and disease surveillance, an information system can effectively link targets and achievements.

3. ALIVE—Information, Education, And Communication (IEC)

IEC includes not only health promotion to families, but also training and education of health workers. EPI health workers need to know the same things parents need to know, and truly believe in the value of immunization. But, health workers must also know how to respond to families' concerns about vaccination side effects; when it is possible for parents to bring children; the correct schedules and methods of vaccination; and how to convince communities to help with vaccination sessions and outreach.

Through revised curricula, doctors, nurses and auxiliary health workers should learn to recognize and diagnose preventable childhood illnesses,basic disease biology and epidemiology, their country's EPI strategies and policies, and the latest vaccine technologies.

New types of syringes and new cold chain equipment will eventually be incorporated into EPI. With all such changes and additions, a strong EPI will have to retrain its workers and supervisors, revise manuals, educate general practitioners and the public, and revise its information and surveillance systems.

EPI has inherited the training traditions from earlier disease control programs: strong on technique, but weak on community involvement. While eradication of smallpox and control of yaws were time-limited programs, EPI is forever. The use of social marketing and mass media strategies for EPI training and education have scarcely been attempted. An effective EPI cannot for long be a military-style operation ("line them up and shoot them"), but must sustain itself as a service people expect and insist on. This means particularly that health workers—from vaccinator to the Minister—must *listen* to the people and make IEC a two way process.

Movilización social por la Salud del Niño boliviano

CLAUDE BETTS

ANNE B KEISER

4. ALIVE—Vaccines And Vaccination Strategies To Vaccinate All Children On Time

The central problem of EPI is how to sustain efforts to fully vaccinate all newly born children by one year of age. Many nations have already experimented with delivery schemes, combining such elements as fixed clinics, mobile teams, and outreach to homes. Other variables include timing, logistics, community mobilization, and cost. EPI may be delivered through the existing primary health care system or in special campaigns. A strong EPI will determine the best strategies based on the local social, geographic, epidemiologic, and political environment.

Clearly, each vaccine delivery strategy has to work within certain constraints of the biology and epidemiology of a disease. For example, nine months is an ideal age for measles vaccination, because measles vaccine has proven to be most effective in the majority of children at this age. Beyond biology, however, people's energies and time are affected by planting and harvesting seasons, community festivals, and weather. Thus it is difficult to keep to an ideal schedule of vaccines at specific ages.

A strong EPI should be ready to incorporate additional vaccines that may be added in the coming decade: improved measles, polio, and pertussis vaccines; new vaccines against hepatitis, pneumonia, and rotavirus diarrhea; and standard vaccines against meningitis and yellow fever—and all the changes in vaccine schedules and delivery strategies these will bring.

5. ALIVE—Evaluation Of The Functions And Results Of EPI

Evaluation is used to help define program goals, to determine how best to reach these goals, and to measure whether the objectives have been attained.

It is an ongoing process, and one that uses many techniques, each appropriate to the type of information needed. Health workers need to know how to evaluate their own work to do their jobs better. Program managers must evaluate to decide on program corrections, strategies, and directions. The results of evaluations have to be reported back to EPI staff and, eventually, to the public.

EPI evaluation consists of:

monitoring of vaccines, coverage, cold chain integrity, and supervision of EPI workers' performance to measure their efficiency and effectiveness;

surveillance of target diseases to determine their extent and distribution;

review of strategies and operations for improved implementation; and

analysis of data, to determine the value of EPI in terms of costs and benefits.

ANNE B KEISER

CHAPTER II
Immunization Program Prerequisites

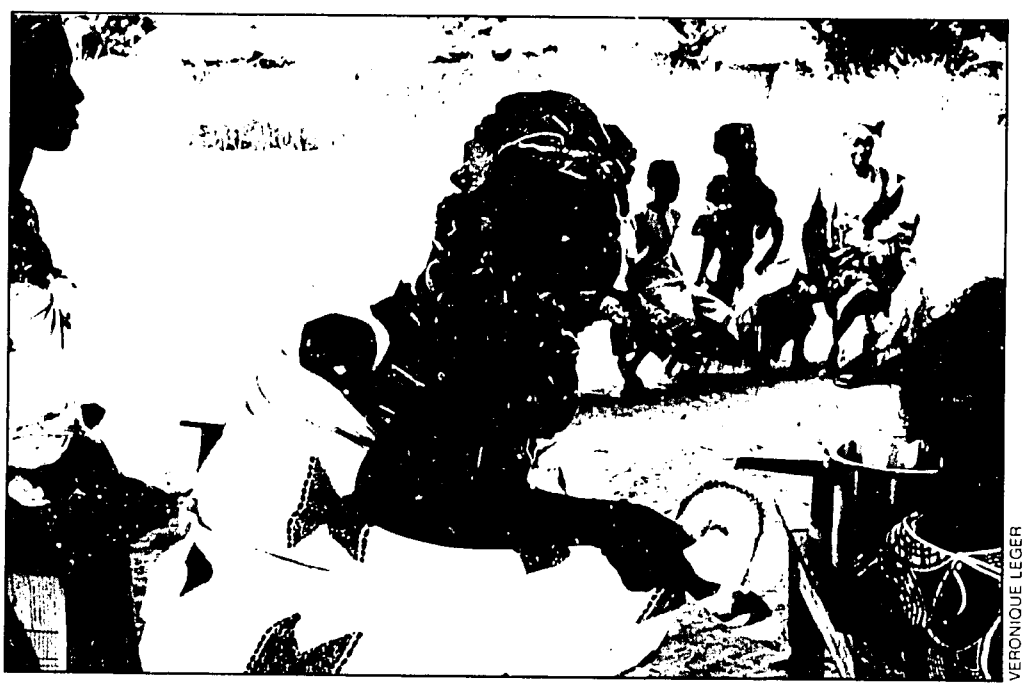
UNICEF

Immunization Program Prerequisites

Those who work with or support an immunization program should know the key clinical and epidemiologic facts about the EPI target diseases.

While this knowledge is necessary, it is insufficient for the design of an EPI. The environment in which a program will operate (political, social, geographic, resource base) must also be understood before program goals and targets are established, and the program designed.

This section on program prerequisites provides key epidemiologic facts and how they particularly affect EPI strategies. The section also discusses how goals and targets should be set based on data and realistic expectations. Finally, a Program Design Checklist is provided as a tool intended for USAID missions preparing Child Survival Strategy Papers, Project Identification Documents, and Project Papers which include EPI development; it can also serve as a generic checklist for other groups such as PVOs developing immunization projects.



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Epidemiologic Facts About The Target Diseases

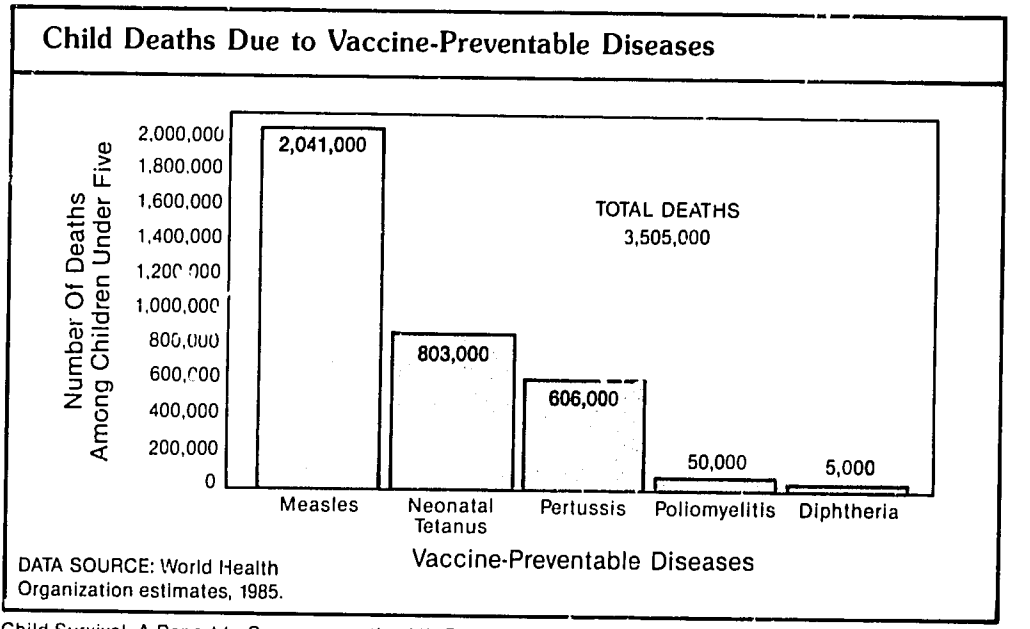
The Expanded Program on Immunization currently covers six target diseases: 1) measles 2) tetanus 3) pertussis 4) polio 5) diphtheria 6) tuberculosis. These diseases receive particular attention for two reasons:

the vaccines that exist against them are effective, relatively inexpensive, and much experience exists in their use;

the six diseases contribute to at least one-third of infant and childhood disability and mortality.

In the 1980s, just three vaccine-preventable infections—measles, whooping cough, and tetanus—have killed approximately 25 million young children—more than the entire under-five population of the United States or Western Europe. We have the low-cost means to stop that unconscionable carnage and to stop it within the next few years. If we do not use those means, then our pretentions towards civilization and our hopes of human progress will not stand up to any further examination.

James P. Grant
The State of the World's Children, UNICEF
1988



Child Survival. A Report to Congress on the AID Program, 1985.

In this section, the target diseases are ranked according to their overall impact on infant and childhood mortality and disability. Of the six target diseases, measles and neonatal tetanus kill the most children in developing countries. Priorities will differ, and the necessary degree of emphasis each disease receives in national and local programs often presents a dilemma for planners who would like to provide full protection for all children against all diseases. The EPI strategies of WHO and AID broadly stress measles and neonatal tetanus, the illnesses which result in the greatest number of deaths; neither agency, however, advocates the provision of measles and tetanus vaccines to the exclusion of others.

In the next decade, other diseases will be targeted as new vaccines are put into use, such as those against hepatitis B, or rotavirus diarrhea, and perhaps pneumonia.

Ultimately, issues of priority may be decided by finance, logistics, and the political opportunities of delivering vaccine. For example, oral poliovirus vaccine is the most sensitive to ambient temperature, requiring a well-managed cold chain; and mortality and morbidity from poliomyelitis are a fraction of that due to measles. Nonetheless, WHO has declared polio eradication a global target by the year 2000 on the expectation that this effort will energize all EPI. Currently nearly all national programs attempt to deliver all vaccines plus others needed locally, such as yellow fever.

MEASLES
A Viral Disease

What Does Measles Look Like?

WHO

A typical illness:

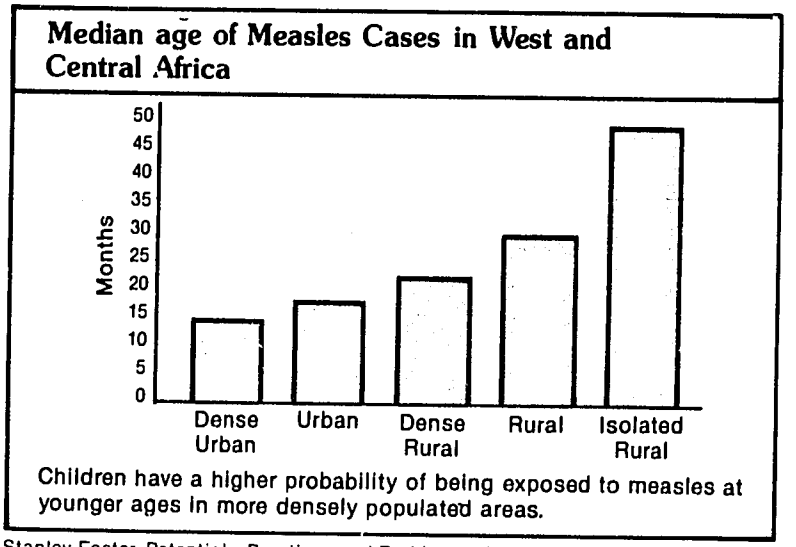
Day 1-3: The child has a cold, cough, and high fever. Eyes are pink, watery, sensitive to light.

Day 2-4: A rash spreads over the face and body, ever so slightly raised. After about a week, the rash disappears and skin may peel.

How Is Measles Transmitted?

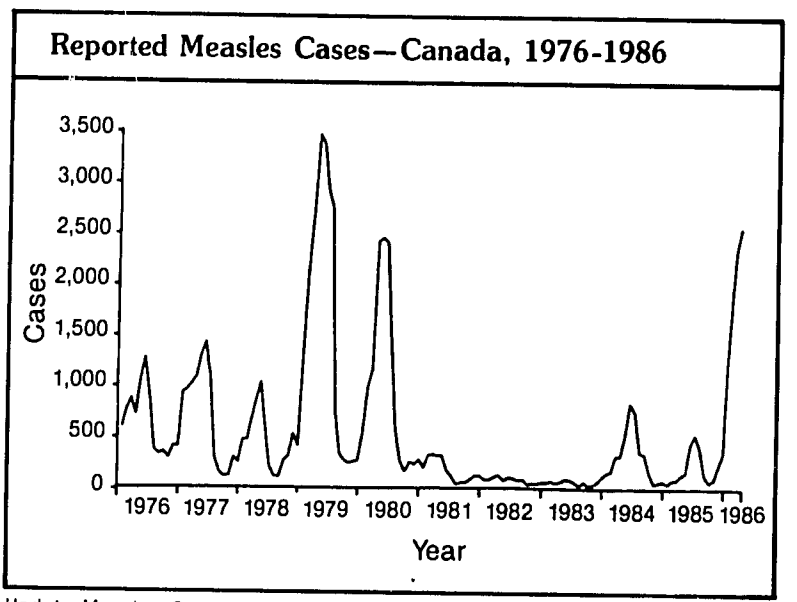
Measles virus is transmitted through the air by respiratory droplets from infected children even before a rash is seen. Transmission happens wherever infants and children gather: hospitals, houses, schools, clinics, marketplaces, refugee centers, festivals, and migrations. Measles is more rapidly transmitted in large families, crowded homes, urban areas; older children often pass it to infants, and children coming from towns and cities help spread measles to villages. Because secondary cases in homes tend to be more severe, some experts hypothesize that measles may be like smallpox: the bigger the dose of virus, the worse the illness.

Two-thirds of the children coming to one clinic in West Africa with measles probably caught the measles *at the clinic* one to three weeks before.



Stanley Foster, Potentials, Practices and Problems of Measles Immunization in West Africa. Seminar on Immunizations in Africa, Kampala, 1971.

With high population density, measles is apt to occur year-round (sometimes with seasonal peaks). In less dense areas, measles comes in epidemics occurring every two-to-three years. When a large enough "pool" of children are susceptible, a single introduction of measles leads to outbreaks.



Update-Measles-Canada 1986, *Morbidity and Mortality Weekly Report*, CDC, May 23, 1986.

Even with reasonably good vaccine coverage (80%-90%), as in Canada, some children are still susceptible and can continue to spread disease in epidemics. However, where vaccination has drastically decreased the transmission of measles, those who do get measles are older on the average; their rate of survival is greater and complications fewer.

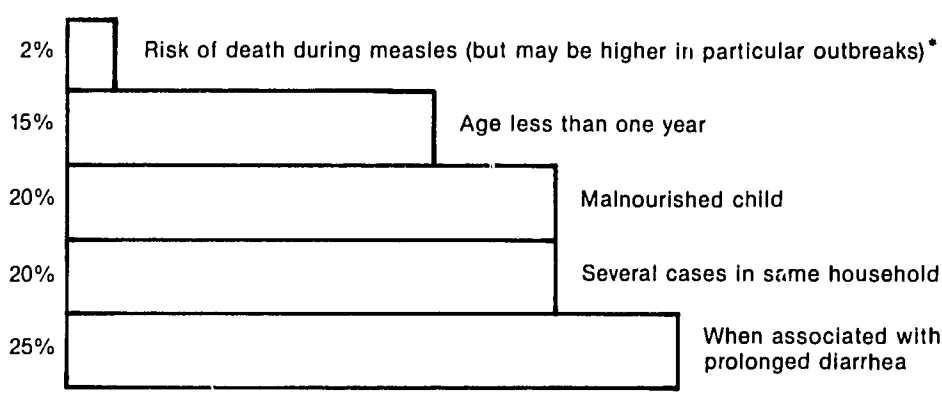
Risk Factors

Over two million children die from measles each year. It is one of the most common diseases of childhood in areas without high immunization coverage. Without vaccination, nearly everyone gets measles, and it is nearly always symptomatic.

Death from measles does not strike equally. The risk of death is increased by other factors that are influenced by both the biology of the disease and the environment in which it is found. The high risk of death following measles is related to young age, crowding, malnutrition, pneumonia, chronic diarrhea, shigella dysentery, blindness due to lack of vitamin A, and lowered resistance to other infections.

The effects of measles are not over when the rash disappears. Six months after measles, children in one Indian study had five times as much pneumonia and twice as much diarrhea. After diarrhea, measles is the most important cause of malnutrition. It takes a child, on the average, two months to return to normal weight after a bout of measles, and many never do. In one study from Africa, having measles increased the chance of death over

Risk of Death from Measles



* See, for instance, Determinants of Measles Mortality in a Rural Area of Guinea-Bissau: Crowding, Age and Malnutrition, P. Aaby et al. *Journal of Tropical Pediatrics*, Vol 30, 1984.

Measles And Blindness

In Tanzania half of blinded children have become so from corneal scarring following measles (a result of acute deficiency of vitamin A). Children should receive vitamin A (in breastmilk, food, or as a supplement) before, during, and after measles. Once blind, a child runs a high risk of dying within the year.

the next nine months by fifteen times. Those who recover, however, are immune from measles for a lifetime.

It is possible to prevent many measles-associated deaths by good medical care (oral rehydration therapy, antibiotics, vitamin A, supplemental feeding), but the cost to care properly for all children ill with measles alone is at least four times that of a complete EPI.

Protection Against Measles

Because measles has such a profound influence on childhood mortality and morbidity, measles prevention deserves to take first priority in EPI. Preventing measles by immunization will have the multiple benefit of preventing other diseases, particularly diarrhea with dehydration, dysentery, acute respiratory illness, blindness, and much malnutrition.

Infants are protected by their mothers' anti-measles antibodies, passed while in the womb, but not by breastmilk. These protein-based antibodies last up to fifteen months in developed-country children, but only to the age of eight or nine months in developing-country children. The difference may be due to higher levels of malnutrition, in which all sources of protein are cannibalized to contribute to growth and energy, leaving fewer reserves to combat infection.

In order for measles vaccine to "take," the live, attenuated (non-disease causing) vaccine virus must multiply, inducing the child to make its own antibodies. When we measure an increase in antibodies after vaccination (or after natural illness), we call the rise "seroconversion." With mothers' antibodies still present, the vaccine virus may be unable to multiply adequately and seroconversion does not take place, leaving the child still susceptible. Thus, measles vaccine given to developing-world children who are only between five and six months old will not succeed in about half of the cases. One study from Africa, however, suggests that even failures tend then to have a milder bout of measles.

On a population basis, most measles cases are prevented by immunizing children at nine months of age. This is the standard EPI recommendation. Some problems with this approach are:

knowing when the child is exactly nine months old;

nine-month old children are less likely to come to clinics for routine primary health care and thus miss being vaccinated; and

in some populations, up to a third of measles cases occur in children under nine months, and the disease is always more severe in younger children.

Measles has a deleterious effect on the nutritional status of the child more serious than any other common childhood infection. . . measles immunization is the most cost-effective public health measure now available to improve the health of children, if certain logistic problems can be solved.

David Morley
Pediatric Priorities in the Developing World
Butterworth & Company, 1973

Some EPI strategists advise a two-dose measles vaccination schedule, beginning at six to eight months and a second dose at twelve to fifteen months. This has not been accepted by the World Health Organization (WHO). The second dose would be particularly critical because one-third to one-half of all children may fail to respond to the first dose, and EPI's record in getting children to return for a second dose is not good. If measles vaccine fails, not only do the children get measles, but the credibility of EPI could be impaired. A two-dose schedule is more feasible where EPI is solidly established and coverage rates are already high (as in the USA). Otherwise, children vaccinated too early may be missed at the time of revaccination. Other experts suggest that coverage of over 90% at the right age will stop transmission to under-age children as well. This has not yet been proven. A new strain of vaccine (Edmonston-Zagreb), now undergoing extensive testing, may be capable of overwhelming mothers' antibodies even in infants as young as five to six months of age. The ability to offer an effective vaccine at an earlier age would greatly improve the odds of the health system reaching the children before the disease does.

It will be very difficult to eradicate measles. Measles vaccine is never 100% effective; nor is coverage ever 100% complete. In third-world experience, measles vaccine is 80-90% effective when correctly applied. That is, about ten to twenty of every one-hundred vaccinated children will still be susceptible to measles.

As coverage increases, then, the pool of susceptible children will tend increasingly to be made up of those already vaccinated.

Because transmission of measles, once introduced into a community, occurs so readily, one finds that the higher the coverage, the greater the proportion of cases occur in previously vaccinated children. This often makes the citizenry or even EPI staff wonder if their efforts have been effective; careful epidemiology and surveillance, however, will show that the disease load has been reduced over time. In the United States, vaccine efficacy reaches 98%; measles is not yet eradicated, although 99% of potential cases are now prevented.

With increasing coverage, the epidemiology of measles changes, and each outbreak needs individual investigation. Even if coverage is 70-90%, enough vaccinated and unvaccinated susceptibles will accumulate to create a sudden epidemic. Public health workers should not be discouraged if epidemics do occur.

Ideal vaccine strategy aside, the truth is that measles vaccine is often *not* given, even though a capable health worker, the viable vaccine, and the susceptible child are all present together.

Why is this?

The mother gives a "history" of prior measles, and so no vaccine is thought necessary. Surveys find, however, that mothers are mistaken 10-20% of the time.

Children at nine months of age visit MCH clinics less often than younger infants, because they are too heavy to carry and too young to walk.

A malnourished, small child of nine months may appear younger, and health workers may decide not to vaccinate.

Open vaccine vials should be discarded after each vaccination session, no longer than 8 hours after opening (to prevent inactivation and contamination), but then health workers accustomed to shortages are therefore reluctant to open a 10- (or 20-) dose vial to vaccinate just one or two eligible children for fear of "wasting" other doses. This practice is incorrect (as long as EPI assures a steady supply), and a vial should be opened even if for only one child.

Health workers and parents commonly believe that sick children (with fever, diarrhea, and respiratory illness) should not receive vaccines. As children may be sick 30% of the time, many fail to be vaccinated at all. Some health workers also are reluctant to give several vaccines at once. There is virtually no contraindication to full vaccination; national EPI manuals are often out-of-date on this issue.

- **Vaccinate at every opportunity!**
- **Vaccinate at every opportunity!**

To Prevent Measles

Vaccinate children wherever they gather, particularly in clinics and hospitals.

Vaccinate high-risk children as a priority: poor children, malnourished children, children in hospitals.

NEONATAL TETANUS (NT)
A Bacterial Toxin Disease

What Does Neonatal Tetanus Look Like?

WHO

This photo shows the risus sardonicus, or sardonic smile, typical of neonatal tetanus.

NT is the most underreported fatal infectious disease. Fewer than 10% of cases come to the attention of Ministry of Health statisticians, and it is seldom reported separately from tetanus at any age.

But, where NT exists, most mothers are aware of it. Because of its bizarre physical aspects, NT is viewed as a supernatural affliction in many cultures, not to be treated or prevented by modern medicine. Also, mothers are often secluded the first few weeks after giving birth, a time when the disease becomes evident in a newborn.

Medical professionals find NT frustrating to treat. It costs too much to treat in hospitals, and it is often incurable, with a 60-90% death rate.

How do we recognize neonatal tetanus in retrospect? We can be reasonably certain a child died of NT if it:

appeared healthy at birth;

sucked at the breast normally, but then refused breast feeding after a few days;

had rigidity and spasms; and

died between the 3rd and 28th day after birth (most die by the 14th day).

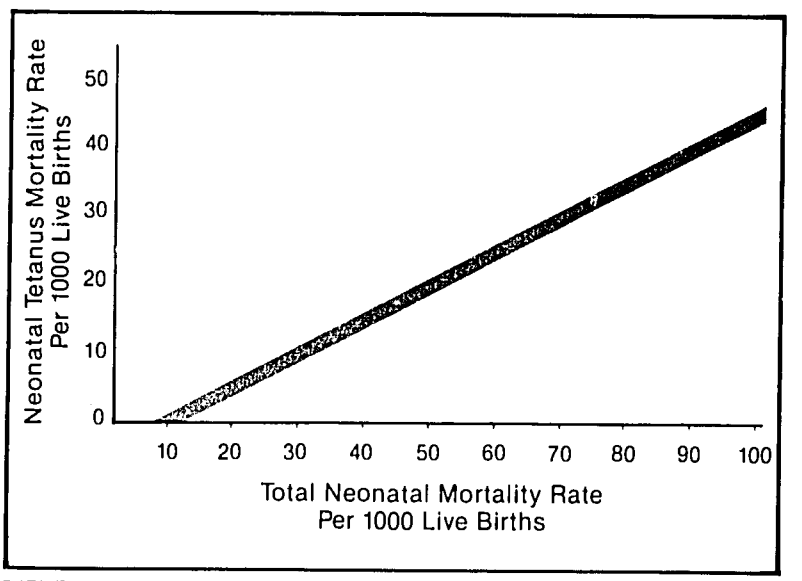
Community health workers can be trained to interview mothers about these signs of NT, so that special retrospective surveys can be used to discover the incidence of neonatal tetanus.

Where there is a high infant mortality rate, vaccination of women of childbearing age against neonatal tetanus should be a top priority for EPI along with measles vaccination. Research shows that tetanus accounts for up to half of all neonatal deaths and between 10-30% of infant mortality. The higher the overall neonatal death rate, the higher the death rate from neonatal tetanus. The incidence of neonatal tetanus mirrors poor socioeconomic conditions and insufficient maternal care.

How Is Neonatal Tetanus Transmitted?

The spores of the bacterium Clostridium tetani are prevalent especially in agricultural areas where animal dung is abundant. Most cases of neonatal tetanus result from the traditional practice of applying dung, mud, dirt, plant powders, or ashes on the umbilical cord stump. Less frequently, cutting the cord with instruments that carry the spores (bamboo, for instance) can also

- **Ministries of Health need to know that neonatal tetanus is a problem.**
- **Families need to know that it is preventable.**



If the neonatal mortality rate exceeds 30/1000, neonatal tetanus is invariably a substantial contributor.

DATA FROM: Expanded Programme on Immunization: Issues on Neonatal Tetanus control. WHO/EPI Global Advisory Group Meeting, 1987, EPI/GAG/87/WP. 11.

ANNE B KEISER

cause infection. If the spores are not exposed to air they can ge: minate to bacteria which then secrete a toxin that climbs up th nerve sheaths to fix onto the central nervous system. Most deatl occur four to ten days after birth. Even if the child recovers, im munity is not conferred.

Who Is At Highest Risk Of Dying From Neonatal Tetanus?

Infants delivered by untrained traditional birth attendants a particularly at risk of contracting NT. Some children are at high risk than others; boys usually have higher rates of NT than girl Tetanus in older children and adults is uncommon but arises fro serious injury or unsterile abortions.

In a rural area of Haiti, several thousand mothers we interviewed in a retrospective study which had a recall period 32 years. The study showed the effectiveness of trainir traditional birth attendants. In other countries, however, tl training of traditional birth attendants has had less impact on N but more impact on other causes of perinatal death.

The signs of NT are generally recognized by parents; in some cultures, the cause is thought to be a punishment from God.

"And the Lord struck the child that Uriah's wife (Bathsheba) bore unto David, and it was very sick. And it came to pass on the seventh day, that the child died."

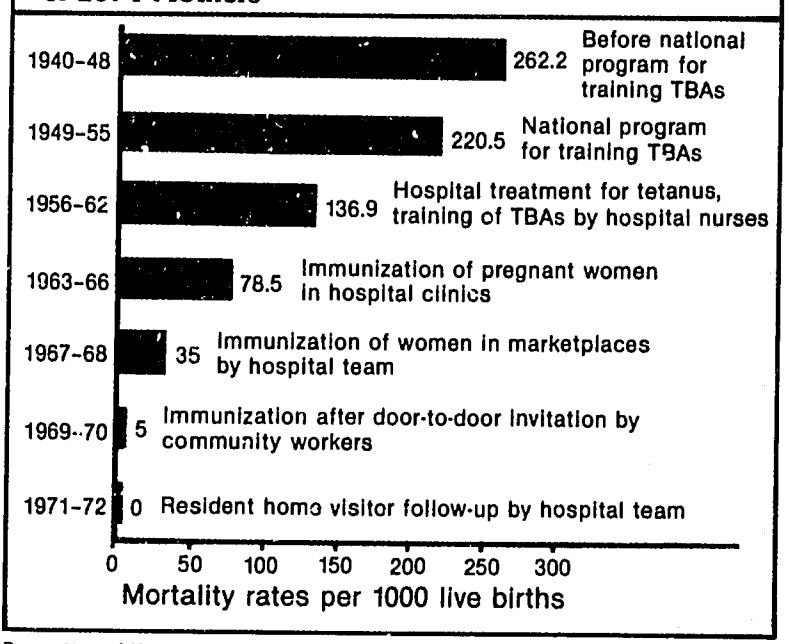
II Samuel 12:15, 18

- **Tetanus toxoid not only protects the child, but the mother as well.**
- **Emphasize tetanus control programs, particularly in high risk areas.**
- **Whenever mothers bring their children for vaccination, vaccinate the women against tetanus also, especially in high risk areas.**
- **Vaccination directed at women of childbearing age is an excellent way to kick off an EPI campaign.**

Protection Against Neonatal Tetanus

Newborns are completely protected from NT if their mothers have high levels of antibodies against tetanus toxin, which are passed on through the placenta. NT may be prevented by vaccinating women of childbearing age (including pregnant women) with at least two doses of tetanus toxoid at an interval of at least four weeks. A third dose should be given at least six months later, or anytime during the next pregnancy. A fourth and fifth dose should be given at intervals of at least one year or during subsequent pregnancies. Five doses are expected to protect all of a woman's newborns against NT. A woman who

Neonatal Tetanus Mortality per 1000 Live Births in Rural Haiti, 1940-72, from a Retrospective Study of 2574 Mothers



Prevention of Neonatal Tetanus through Immunization, WHO, 1986, from Berggren, G. Tropical Doctor, Vol 13, 1983.

To put it plainly, each child who dies of neonatal tetanus is witness, not to some inevitable act of God, but to multiple failures in the health system and in ourselves collectively, and it is a reproach to us all.

Robert Cook and Artur Galazka, WHO
"Eliminating Neonatal Tetanus—An Attainable Goal,"
Archives of Disease in Childhood, Vol. 60, 1985

received the full series of DPT in childhood and/or two doses of DT* at school age may do well with just one booster dose of tetanus toxoid before or during the first pregnancy. School age children and adults should not be vaccinated against tetanus with DPT because of potentially severe reactions to the pertussis component. They should receive the recommended series of tetanus toxoid (TT) or diphtheria-tetanus toxoid (DT or Td)* vaccine. If only one dose was given before delivery, the second should be given afterwards as soon as possible.

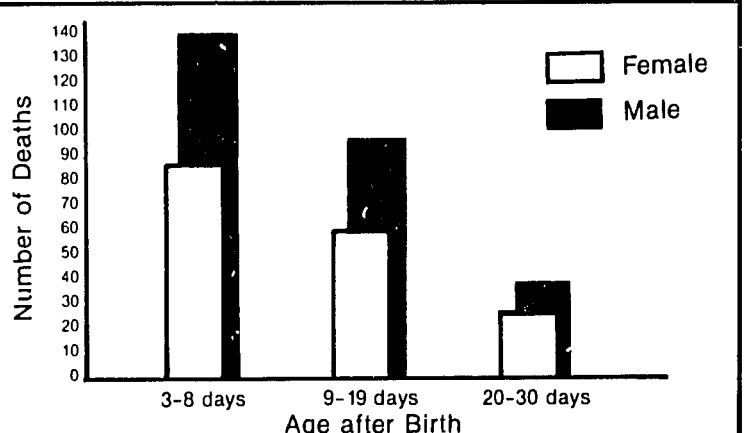
* DT (Pediatric) is a preparation for children of school age and for younger children who cannot tolerate DPT. Td (Adult) refers to a preparation for adults.

Vaccinating women to prevent NT saves mothers' lives as well. Tetanus resulting from self-induced abortion or infection during delivery accounts for a substantial portion of maternal mortality.

The vaccine can be safely given at any time during pregnancy; however, all women of childbearing age should be vaccinated, not just pregnant women. In some countries women fear the vaccine because they suspect it is linked to contraception. For this reason, as well as behaviors that result in underreporting, mass education campaigns are critical to the elimination of neonatal tetanus.

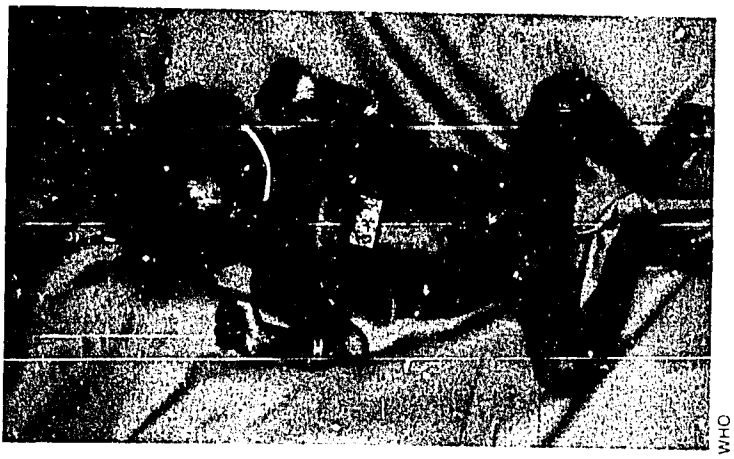
TBA training should not be done in isolation but as part of an EPI strategy to immunize women of childbearing age.

Distribution of neonatal tetanus in the Punjab, Pakistan, 1981, by age and sex



Data from: Mortality for Tetanus Neonatorum in Punjab (Pakistan), O. Suleman, Pakistan Pediatric Journal. Vol 6, 1986.

PERTUSSIS ("Whooping Cough")
A Bacterial (Toxin-Related) Disease



WHO

What Does Pertussis Look Like?

A typical illness:

First week: The child shows symptoms of a cold.

Second week: The cough gets worse, it doesn't stop (in Chinese, pertussis is called the "Hundred Day Cough"). The child struggles to breathe and "whoops" in a breath. The child may then vomit and repeat the cycle: cough-whoop-vomit.

Third week (or later): The cough slowly subsides.

How Is Pertussis Transmitted?

Pertussis is difficult to diagnose or to track epidemiologically unless there is an epidemic. The disease is very contagious, sometimes brought home by adults or school-age siblings with what seems to be a cold. It is spread through the air by respiratory droplets.

Who Is At Highest Risk Of Death And Severe Disease?

Pertussis follows measles and neonatal tetanus in frequency as a killer. Eighty percent or more of unprotected children get pertussis with up to 2% mortality, but the classical clinical picture presented above may only be seen in half of the children. Infants are more likely to choke than whoop, and those less than three months old may simply stop breathing.

The severest illness and highest fatality (3%) occur in infants. About a third of all cases are in infants under six months; half of all deaths are in children under one year, particularly in crowded urban areas. In rural areas, most cases occur in older children and are milder.

百 HUNDRED
日 DAY
咳 COUGH
The Chinese name for whooping cough

From Pediatric Priorities in the Developing World, D. Morley, 1973.

In many children the coughing spells last for weeks; relapse may occur months later with frequent vomiting. Children lose sleep and become malnourished. Pertussis and measles account for up to one quarter of deaths due to acute respiratory illness (ARI).

Protection Against Pertussis

Unlike measles and neonatal tetanus, children are not protected by mothers' antibodies. Despite its bacterial origin, antibiotics do not cure the disease. DPT (Diphtheria, Pertussis, and Tetanus) vaccination is a must for young children. Immunization against pertussis probably will reduce overall mortality from ARI and malnutrition. While the only contraindication is a neurologic reaction after a previous DPT

DPT: How Dangerous?

DPT vaccine has gotten undeserved bad press in developed countries because brain damage occurs in an estimated 1/300,000 vaccinated children due to the pertussis component. Brain damage from the disease pertussis, however, occurs one hundred to four thousand times as often. The only contraindication to DPT is a severe reaction after a previous dose. Mothers need reassurance about the normal side effects of fever and pain.

New "acellular" pertussis vaccines use only key fractions of the dead pertussis bacteria, not the whole cell. They may cause fewer side effects, but are several years away from general use.

ANNE B KEISER

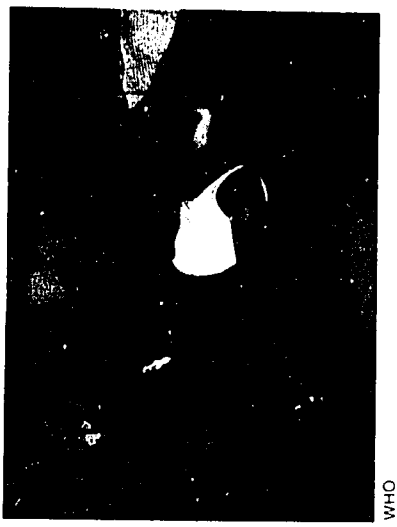
dose, parents need reassurance about the not-dangerous side effects of fever and pain. We do not know to what extent parents fail to return children for full vaccination because of those side effects.

To give optimal protection (80-90%) with the current vaccine, the standard regimen consists of three doses of DPT at one-month intervals, beginning at six weeks of age. The series should be given to all unprotected infants.

A two-dose DPT schedule in rural areas where children can be reached only every few months is still likely to be useful for reducing pertussis severity and incidence, but some children will contract the disease while waiting for the second dose. It is particularly urgent, however, to vaccinate urban children with three doses of DPT, each one month apart, before six months of age.

POLIO
A Viral Disease

What Does Polio Look Like?



WHO

A serious case of polio:

Days 1-3: The child appears unwell, may have a slight fever.

Days 3-5: Child complains of headache, stiff neck, muscle pains, increased fever.

Days 5-7: Paralysis of one or both legs; in severe cases arms, and even breathing may be paralyzed.

How Is Polio Transmitted?

Polio is transmitted by contact with fecal matter of infected persons, polluted water, and, particularly in industrialized countries, by respiratory spread.

Who Is At Risk Of Contracting Polio?

Poliovirus is everywhere, and the disease is controlled only by vaccination. Nearly every unimmunized child in the developing world is infected by poliovirus by five years of age.

95% show no effect,
4% have a mild flu-like illness,
1% become paralyzed or lame,
0.5% remain lame for life
0.1% die acutely

- **The burden of paralytic disabilities can be reduced by high vaccination coverage.**
- **Even with socioeconomic development, vaccination against polio remains important.**
- **Western travelers overseas should be vaccinated against polio.**

One can estimate the annual incidence of paralytic polio by counting those children with residual paralysis (in school, or house-to-house surveys), and applying standard epidemiologic and demographic correction factors. Lameness in five to ten per thousand school age children translates to annual incidences of polio of 1.25 to 2.5 per thousand children under five years old, or about 25 to 50 per 100,000 total population.

Although residual paralysis is a relatively uncommon event, there are nearly two million third world pre-school children with preventable lameness. As sanitation and socioeconomic status improve, polio epidemics affect older children who run a higher risk of paralysis.

Protection Against Polio

There are two types of polio vaccine. A live, attenuated oral poliovirus vaccine (OPV) is currently recommended by WHO and used most widely. An inactivated, injectable poliovirus vaccine (IPV) is also on the market and is used in some countries in both the developed and developing world.

Unlike measles, local or regional elimination of polio is possible with less than 100% coverage and less than 100% efficacy. A brief, mass campaign using oral poliovirus vaccine (OPV) results in the rapid replacement of the wild virus by the live, attenuated virus in sewage and contaminated drinking water. Children excreting vaccine virus may also infect (and immunize) others. Thus, the attenuated poliovirus can infect and immunize even those not vaccinated directly. Coverage as low as 60% to 70% may reduce the incidence of paralytic polio disproportionately. In the absence of universal coverage, however, reintroduction of the wild virus can still cause major outbreaks among susceptible children. In the Gambia, despite coverage of over 80%, wild virus still circulated and caused an epidemic in 1986.

Polio eradication: fulfilling the first EPI promise.

Ciro de Quadros
Director, EPI Unit, PAHO

Each of three strains of poliovirus may cause the disease. Standard OPV vaccine is a mixture of these three strains, attenuated. The vaccine has drawbacks. The great majority of children become immune to all three strains with the standard series of three doses,

Elimination of paralytic polio is an achievable goal.

Oral poliovirus vaccination lends itself ideally to mass campaigns taking place over a few days' time.

but a few need more doses. In developing countries diarrhea may interfere with vaccine virus uptake by the intestine. The third type of vaccine strain (Type 3) is less immunogenic than the other two. OPV is quite sensitive to heat (the cold chain is critical). These drawbacks may lead to outbreaks of polio despite high coverage levels. The three strains of inactivated virus in the injectable poliovirus vaccine (IPV) work as well as OPV vaccine, if the goal is only to prevent paralysis. However, higher coverage levels and a higher efficacy rate are needed to stop transmission of the wild virus. Some experts advocate using both IPV and OPV in national programs to increase protection. A vaccine with DPT and IPV mixed together is commercially available. EPI recommendations may change with experience, requiring the retraining of the entire work force. Therefore, one wants to be absolutely sure of recommendations given. OPV is still the official choice of WHO for EPI.

Polio Eradication

The Pan American Health Organization (PAHO) has set a target to eliminate the wild virus from the Americas by 1990; and in 1988 the World Health Assembly declared the goal of global polio eradication by the year 2000. To verify elimination, each nation must maintain efficient surveillance and virus laboratories as some other viruses can cause a polio-like illness. Strategies to eradicate polio should be carried out in ways which strengthen EPI and the development of primary health care.

Key Differences Between Oral Poliovirus Vaccine (OPV) And Inactivated (Injectable) Poliovirus Vaccine (IPV)

	OPV	IPV
1. Worldwide experience	Successful in many settings	Successful in developed nations but limited experience in developing countries
2. Current (1988) cost/dose	$0.02	$0.50
3. May be given by:	Person trained to administer drops	Vaccinator trained to give injections
4. Number of doses needed for 90-95% seroconversion against all three strains	At least 3; up to 5 in some tropical areas where diarrhea may interfere	2 (with current improved vaccine); the need for booster doses must yet be determined
5. Earliest time it may be given and interval between doses	At birth, then monthly beginning at 6 weeks of age.	Best to begin at 2 months of age, then 2 months later
6. Method of protection	Blood plus intestinal antibody	Blood antibody, possibly intestinal
7. Stability	The most heat sensitive of all EPI vaccines (the vaccine suspended in magnesium chloride is more heat resistant)	Excellent, far less heat sensitive
8. Safety	Safe (rare cause of paralysis in nearly one out of one million recipients or contacts)	Safe
9. Efficacy	80% (after 3 doses)	90% (after 2 doses)
10. In control of epidemics	Used	Not used

DIPHTHERIA
A Bacterial (Toxin-Related) Disease

What Does Diphtheria Look Like?

WHO

A greyish membrane on the pharynx is a well-known sign of diphtheria.

A typical severe illness:

Days 1-3: Child complains of mild sore throat, is unwell.

Days 4-6: Child is very ill. The neck is swollen. The diphtheria membrane on the throat is usually obvious, may obstruct breathing.

After two weeks: Diphtheria toxin may cause heart failure, paralysis of breathing.

How Is Diphtheria Transmitted?

The disease spreads easily by air droplets. Once the disease is in a household, 10 to 30% of the children may come down with diphtheria. In developing countries skin infections may harbor the diphtheria bacterium. Diphtheria is rare in developed countries.

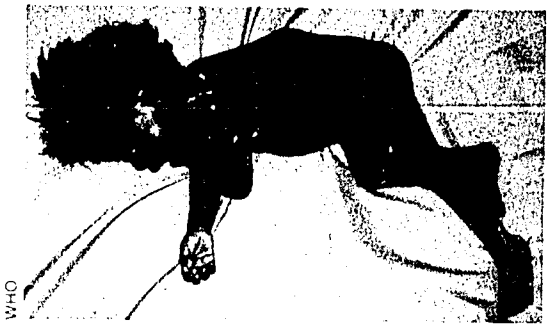
Who Is At Highest Risk Of Diphtheria?

In developed countries, diphtheria is seen among adolescents, adults and often in old, debilitated people (alcoholics, homeless persons) whose immunity has waned. Diphtheria affects predominantly children in developing countries.

Protection Against Diphtheria

Coverage for diphtheria vaccine - the "D" in DPT- is the same as DPT coverage; the global average is over 60% for three doses and few epidemics are now seen. Even two doses of DPT can be protective. Immunity is also acquired by skin and nose infections with the bacterium.

TUBERCULOSIS (TB)
A Bacterial Disease


WHO

What Does Tuberculosis Look Like?

This child has an abscess of the spinal column due to tuberculosis which, if the child survives, leads to marked deformity.

Transmission And Risk Factors

TB is a multi-system chronic disease that often plants its seeds in infancy and childhood. It emerges at particular times of stress such as adolescence, childbearing, malnutrition, and, more recently, with the suppression of immunity caused by AIDS. While nearly half of a developing country's population may be infected, only about one-half to one percent have radiologic evidence of active or latent disease. Few infants contract life-threatening TB, which is often in the virulent forms of TB meningitis or miliary (disseminated) TB.

TB is a debilitating illness that requires expensive and long-term care. Too often people do not stay with the course long enough, and their bacteria become resistant to antituberculous drugs.

Protection Against Tuberculosis

Research from many different countries has shown that BCG (Bacillus of Calmette and Guerin) given in infancy protects children from the severe forms of tuberculosis, and perhaps from TB recurring at a later age. BCG has proven effective about one-half of the time; however, it is difficult to assess the true efficacy of the vaccine because of the length of time of study before final conclusions can be drawn. Paradoxically, BCG coverage rates are the highest of all vaccines, perhaps because it is a single-dose vaccine given at or soon after birth, when many children are seen by the primary health care system. Mothers may welcome BCG because the scar is visible evidence of protection.

BCG Injections

BCG injections require special syringes and special training. Large abcesses are sometimes caused by it, which may deter some mothers from continuing to vaccinate their children against other diseases, especially as BCG is often the first vaccine given.

Other Diseases Of Major Significance With Impending Vaccines

Hepatitis B

Infection with hepatitis B is now widespread. Transmission is due to the promiscuous use of injections by practitioners who do not sterilize their needles and syringes, by contaminated blood transfusions, from child to child during rough play, or during sexual intercourse. An increasingly common route of transmission is from mother to infant during delivery. The younger children are when they contract the virus, the more likely they are to become chronic carriers of hepatitis B virus.

In some countries, up to 60% of the children have evidence of current or past infection. Hepatitis B greatly increases the risk of cirrhosis of the liver and liver cancer for those with a continuing presence of virus in their blood. Of 280 million current carriers of hepatitis B virus worldwide, some 70 million may die over the next three decades of related liver disease.

The hepatitis antigen is used in a well-tested vaccine, derived from the plasma of infected people and treated to render it incapable of reproducing. Given at birth, it is highly effective, but costly. Bio-technology has now produced an effective vaccine with the gene for the antigen incorporated into yeast DNA and mass produced by the yeast. The cost could come down quickly if the vaccine were incorporated into all immunization programs. Testing is under way.

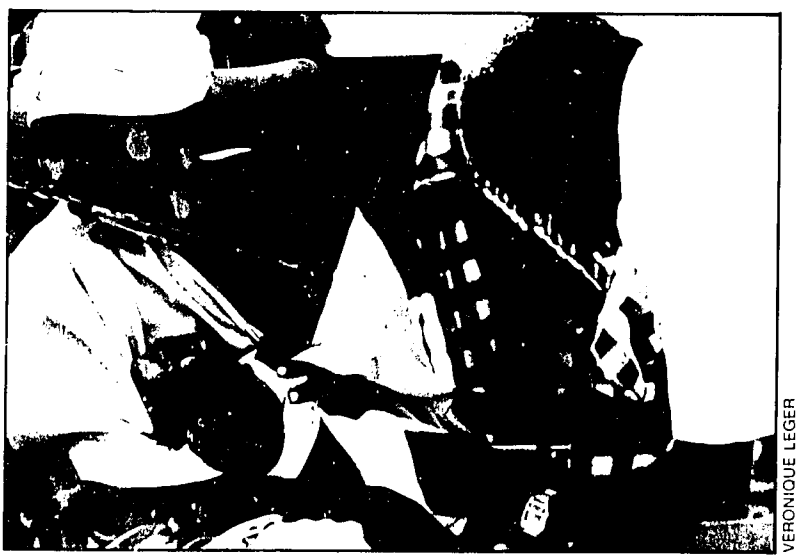
Rotavirus Diarrhea

Rotavirus causes only 5% to 10% of diarrheal cases, but is responsible for 20% to 50% of hospitalizations for dehydration and 20% of diarrheal deaths. A rotavirus vaccine that is 80% to 90% effective could eliminate a large proportion of mortality due to diarrhea. One current, live rotavirus vaccine (derived from a bovine rotavirus) has failed in some trials. The existence of several serotypes of rotavirus complicates vaccine development. Another candidate vaccine combines rhesus monkey rotavirus and serotype specific human rotavirus antigens. For logistical efficiency, oral rotavirus vaccine would ideally be given along with OPV, but research on possible interference between the two vaccines is still underway.

Acute Respiratory Illnesses (ARI)

Up to half of the cases of fatal pneumonia in third world infants are due to two species of bacteria: *Streptococcus pneumoniae* (the pneumococcus) and *Hemophilus influenzae*. Current vaccines against both bacteria are still only effective in children over two years of age. Progress is being made to increase the response in infants by manipulating chemical bonding groups in the vaccines. Thus, control of ARI for some years to come will be through antibiotic treatment in the primary health care system. As DPT and measles vaccine coverage increases, many acute respiratory illnesses will be eliminated.

Our biotechnology is far advanced; perhaps leaving behind mothers who barely understand the reasons for so many vaccinations and their detailed schedules.



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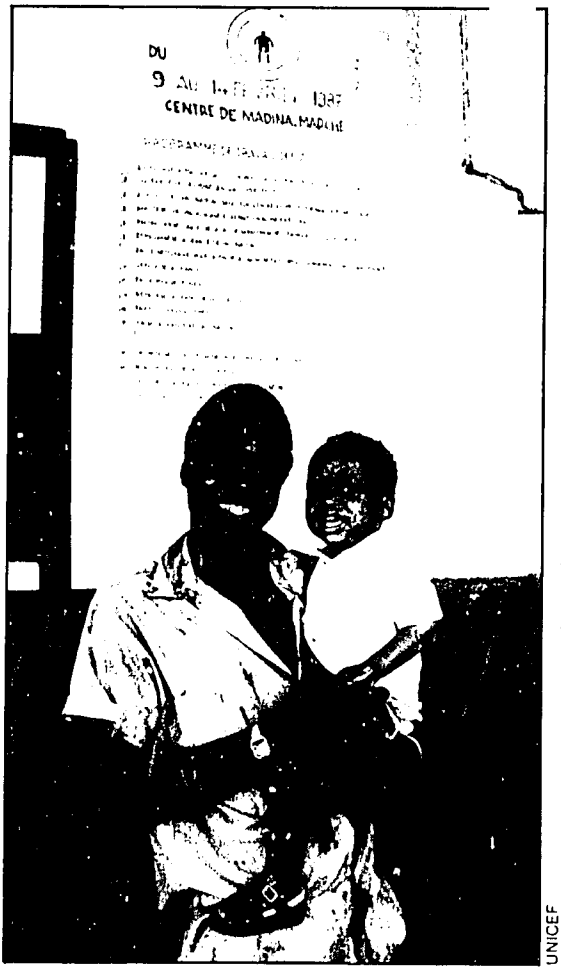

UNICEF

Fathers are often the ones who decide on medical care for their children. They as much as mothers need to know about vaccinations.

Establishment Of Program Objectives And Targets

Immunization program goals and targets are used to set priorities within a program, and, in so doing, help ration resources. If goals and targets are well chosen they also serve as a standard against which we can evaluate programs.

The overall objective of EPI is to reduce infant and child mortality and morbidity. The number of children vaccinated ("coverage") and the reduction of disease are targets set for immunization programs. Coverage targets need to be based on progress to date and the resources available to expand coverage. Disease reduction targets need to be based on reasonably good estimates of *current* morbidity and mortality rates, and what EPI managers believe can be reasonably achieved in a country.

Other Program Objectives

- **Some public health specialists call on EPI to strengthen primary care.**
- **Other disease control experts say EPI should also be used to eradicate certain diseases, as smallpox was eradicated, specifically polio.**

Concentration on coverage only will not do either; but mass health education, better primary care of illness, training of health workers, and development of regular, accessible services will lead to sustained reductions in illness and death.

A coverage target of 80% is often stated. That is, 80% of children are to be fully vaccinated. This level is based on the theory that, at 80% coverage, transmission of disease to the unprotected 20% is decreased ("herd immunity") and overall illness rates are lowered. There is some evidence that this happens, but not for all diseases and not the same way in all places.

It may be more useful to set year-by-year targets: when they are reconsidered each year, targets can more easily be adjusted to achievable levels. A subsidiary program target is to vaccinate nearly all children before their first birthday. This makes sense biologically and epidemiologically, but it may not be achievable in some areas.

If disease reduction is the ultimate goal of immunization programs, a focus on morbidity and mortality reduction would permit a wider range of disease control strategies than a single-minded pursuit of vaccination coverage. Smallpox eradication was realized, for example, by a "containment" strategy that concentrated vaccinations in areas surrounding an outbreak rather than by reaching high vaccination levels everywhere. Disease control, however, puts extra demands on EPI managers to develop good surveillance and reporting systems.

First, we need to ask whether our ultimate objective is really that of vaccinating 90% of the world's children by 1990. In my opinion it is not. Our true objective is that of preventing six diseases.

D.A. Henderson
Bellagio II, Cartagena, October 1985

Program Design Checklist

The attached Checklist is designed to serve as a guideline for program staff, consultants, and USAID Missions in their assessment of an EPI and in planning long term interventions. The list is both an outline of the background information required to develop an AID project document, as well as a comprehensive review of EPI components to measure program status and needs. Not all items apply to every program and, before embarking, one must decide what kinds of questions to ask, rather than merely collecting information for the sake of it.

The items contained in the Checklist are based upon a review of various AID project documents, and the comments of EPI specialists. A brief description of each category is given below. Examples of and suggestions for the type of information to collect are included within parentheses by the items in the Checklist.

Contents Of Program Design Checklist

Background Descriptions

This section collects information to gain an historical overview of the Ministry of Health and the EPI. When complete information is not available, best estimates should be made. The information from this section will be used for developing project documents and to gain an initial perspective on potential interventions.

Program Objectives

Define the EPI objectives, including the methods used to measure them. The review should include the most recently available data indicating the achievements to date towards the objectives, and also an assessment of the feasibility of reaching the objectives.

Current Status

Describe the current status of all EPI components including their limitations and the potential for donor assistance. Other sources of current input should be included.

Anticipated Resource Input And Major Constraints

These sections concern future input for the EPI and the perspectives of others on the status, needs, and constraints of EPI. Include any potential limitations such as inability to maintain additional equipment or dependence on limited resources.

Plan For Intervention

These items touch on the Plan of Action for a potential EPI assistance plan, including situations where EPI is part of a larger bilateral health project (primary health care, child survival). These items should refer to the implementation, management, and administration of the entire project, rather than the EPI alone.

Check List For EPI Assessment And Project Design

A. BACKGROUND DESCRIPTIONS	Data Obtained
1. Purpose of trip	☐
2. Scope of work	☐
3. General country data (area, geography)	☐
3. Economy (GNP per capita)	☐
4. Demography (children <5 yrs., <12 mos., women 15-49, data sources)	☐
5. Health Indicators:	
• Birth rate	☐
• Infant and child mortality rates	☐
• Population growth rate	☐
• Morbidity and mortality rates	☐
(disease and age specific)	☐
• Leading causes of death	☐
(include 10 year trends, age distribution)	☐
4. Health care system:	
• Organization (organogram)	☐
• Budget (% of govt. total)	☐
• Long range plans	☐
• Personnel (category, number, distribution)	☐
• Distribution of facilities by type	☐
• Cost recovery system	☐
5. Others involved in health care activities:	
• USAID	☐
• WHO, UNICEF, or other international donors	☐
• NGO/PVO	☐
• Private sector	☐
• Peace Corps	☐
6. PHC activities and projects (past, present, proposed including PHC system capacity to absorb disease control activities.)	☐
B. EPI OBJECTIVES AND STRATEGIES	**Noted**
1. Morbidity/mortality reduction	☐
2. Vaccination coverage	☐
3. Management, information and evaluation	☐
4. Training	☐
5. Vaccine and cold chain coverage	☐
6. Financing recurrent costs	☐
7. Health education	☐
8. Communication/marketing	☐
9. Operational areas (expansion)	☐

Continued

C. CURRENT STATUS OF EPI

	Data Obtained
1. Organization (internal, relationship to MOH & PHC)	☐
2. Input (TA, $, equipment, projects)	
• Other MOH Divisions (Epidemiology, Maternal and Child Health, Statistics, Transport, Maintenance)	☐
• Other government sectors (Ministries of Education, Information, Armed Forces, Social Security)	☐
• AID and other donors	☐
• WHO, UNICEF or other international donors	☐
• NGO/PVO	☐
• Private sector	☐
• Peace Corps	☐
3. Financial (% of MOH budget, accounting systems, cost recovery scheme, other funding sources)	☐
4. Planning procedures (regional and local input, frequency)	☐
5. Personnel (categories and numbers)	☐
6. Management and Supervision (central and peripheral)	☐
7. Program strategy (geographical coverage, target groups, vaccination schedules)	☐
8. Training (level {senior, mid, local}, number trained, evaluations)	☐
9. Information systems (MOH statistics, surveillance, vaccination reports)	☐
10. Evaluation (methods, reports)	☐
11. Communications/Marketing	☐
12. Cold chain network (coverage, reliability, back-up)	☐
13. Cold chain equipment (type, fuel requirements)	☐
14. Vaccines (source, inventory, adequacy)	☐
15. Logistics (vehicle distribution, fuel)	☐

D. ANTICIPATED INPUT

(Describe areas of input [e.g. technical, training, communications], number of personnel, level of funding.)

	Described
1. Ministry of Health	☐
2. Other government sectors	☐
3. AID	☐
4. WHO, UNICEF or other international donors	☐
5. NGO/PVO	☐
6. Private sector	☐
7. Peace Corps	☐

Continued

E. MAJOR CONSTRAINTS AS VIEWED BY:	Ideas Obtained
1. Government (central MOH)	☐
2. EPI staff	☐
3. Health workers	☐
4. USAID Mission	☐
5. WHO, UNICEF, or other international donors	☐
6. NGO/PVO	☐
7. Private sector	☐
8. Peace Corps	☐

F. PLAN FOR INTERVENTION (overall plan of action for EPI or larger project; should complement existing resources.)

1. Country strategy with timetable	☐
2. Project objectives	☐
3. Implementation plan and schedule	☐
4. Management/administration plan (include financial operations)	☐
5. Evaluation component with timetable	☐
6. Personnel requirements with schedule and scopes of work	☐
7. Commodity inputs and costs (e.g. $, materials, workshops)	☐
8. Peace Corps (identify skills needed, number of volunteers, and level of involvement {local, regional, national})	☐
9. Project budget (financial plan and indicate sources of funding	☐
10. Other local financing resources needed or identified	☐
11. Relationship to ongoing activities (PHC, Child Survival, other international donors,	☐
12. NGO/PVO, Peace Corps, private sector)	☐
13. Justification (including potential for long term program, bilateral project)	☐
14. Letter(s) of Agreement with government and other collaborating insitutions	☐

CHAPTER III
Immunization Program Components

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Immunization Procedures
Section 2

This section explains the guts of EPI. These essential components must be exquisitely orchestrated: it makes little sense to plan vaccination strategies but deliver spoiled vaccines; to train health workers well but fail to educate families; to have hardware working yet fail to understand the "software" of human behavior and response to EPI.

UNICEF

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Delivery Strategies For Vaccination

WHO and its member nations have long accepted that EPI should be delivered through existing primary health care systems. Experience has proven that, done correctly, EPI can strengthen primary health care. Some countries have discovered, however, that their public health infrastructures are neither developed nor flexible enough to achieve high coverage. Many programs are only able to fully vaccinate 10% to 30% of children. Even better developed programs tend to plateau at about 60%, and the figure is lower for those most susceptible, the children under one year of age.

Some donors, particularly UNICEF and Rotary International, have prompted governments to set the goal of Universal Childhood Immunization by 1990. UNICEF considers unvaccinated children a national emergency, which requires the mobilization of the entire government, mass media, voluntary organizations, the public, and the private business sectors in bold, broad campaigns. UNICEF also considers such mobilization a stroke for peace and human development. Are mass campaigns the best way to raise coverage and leave behind a strengthened EPI and strengthened primary health care? The alternative approach is to accelerate the steady development of the primary health care infrastructure that delivers all essential health services. Different countries now offer different experiences, but none has the conclusive answer.

Delivery Strategies Used To Raise Vaccination Coverage

Several approaches to delivering vaccinations vie for attention. What they are and how they relate to one another can be confusing. Strategies for delivering vaccinations can best be categorized by two dimensions: *where* vaccines are given and *when* they are given.

Vaccinations may be done at fixed facilities or from mobile or temporary locations; they may be delivered regularly or intermittently. The resulting combinations have different costs and different results. In general, the cost per vaccination is lower for fixed facilities vaccinating regularly, but often results in lower coverage; the cost per vaccination for temporary locations vaccinating intermittently is much higher, but can result in greater coverage (at least in the short term). No one has proven which combination results in the highest coverage *sustained* over the long term. It seems probable that the most robust approach is the flexible one: to combine strategies according to local needs, resources, and opportunities, yielding "the most, for the least, for the longest."

Here are a few considerations for deciding about timing and location of vaccinations:

Vaccinations may be timed to precede anticipated epidemics or to avoid planting and harvesting times when parents are too busy. Communities need to be consulted.

Each disease has its own epidemiological pattern according to locale. Measles in Africa affects many children under one because of early exposure to marketplaces and crowded houses and clinics; while in rural India, infants are kept closer to home and caste lines reduce many contacts. Measles, particularly, is spread from the city to the countryside. "Pulse campaigns" may be targeted to age or location depending on these patterns.

A primary health care system capable of frequent contacts should begin to vaccinate children at an early age to give them a better chance of becoming fully vaccinated before their first birthday.

Outreach teams need to complete their rounds with the shortest permitted intervals, to reduce the time a child is incompletely protected.

Mass campaigns need carefully planned, multi-sectoral coordination, including mass education, logistics, and mobilization. No vaccinations can take place until everything is in place.

A failed mass campaign is highly demoralizing, a success, highly energizing. EPI managers need to assess the morale of health workers after each round. A successful mass campaign may actually inhibit regular vaccinations as health workers reason that the annual campaign will do the job.

Timing of Vaccinations					
		Regular		Intermittent	
		Daily	Scheduled	"Pulsed" and Targeted	Annual "National Vaccination Days", a mass campaign, usually lasting one or a few days, three rounds, each one month apart; often many temporary vaccinators are hired; sometimes fixed facilities are by-passed
Locations of Vaccinations	FIXED FACILITY	Primary care clinics offer routine vaccinations	Primary care clinics or vaccination stations vaccinate weekly or monthly	Fixed facility stops regular curative work, staff reach out to the community	
	TEMPORARY FACILITY	—	Outreach teams on regular rounds but scheduled around seasonal events	Mobile teams; schools, churches or mosques become vaccination points, community lends resources	

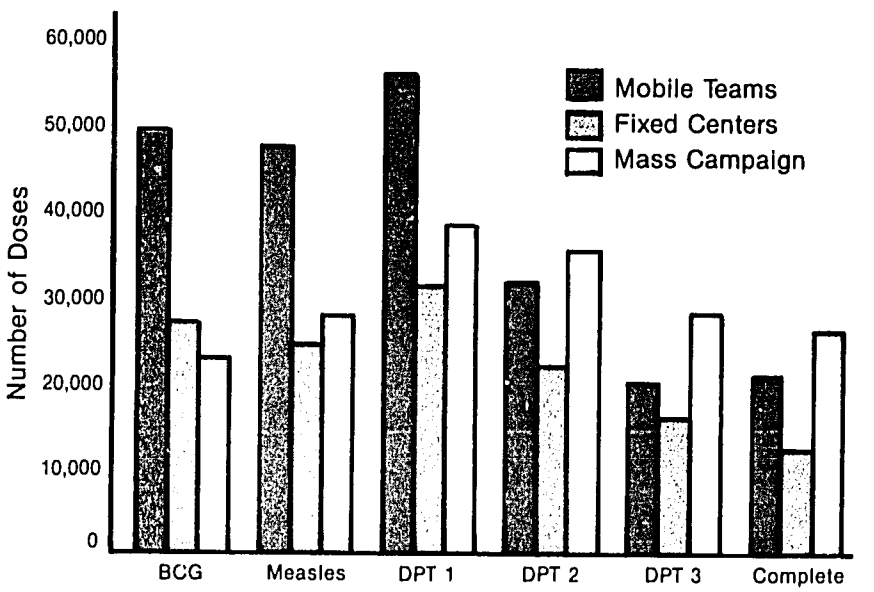
A mass campaign may focus on a single disease such as polio, or neonatal tetanus to show early, dramatic results.

If fewer fixed locations are used, then fewer vaccinators have to be trained; supervision is more centralized, there is less cold chain equipment needed, but coverage may be lower.

If more locations are used, then people have greater access; peripheral health workers are more involved, and supervision must be decentralized. EPI becomes more cost-efficient, but logistically more complex. The private sector physicians and secondary care hospitals can help increase coverage.

Mauritania is an example of a country that uses an intelligent mix of strategies based on population needs. Urban conglomerates were in the past already being served by fixed centers, which required only the strengthening of their capacity to deliver vaccines. Nomads are reached by mobile teams, even though this approach is more expensive per vaccination. Finally, several mass vaccination days have been used to catch up on the backlog of unvaccinated children and to raise public awareness of EPI, as well as strengthen the public health infrastructure's ability to deliver vaccinations.

Relative Role of Mobile Teams, Fixed Centers, and Mass Campaign for Total Numbers of Vaccinations Given in 1985 in Mauritania



The Expanded Program on Immunization (EPI) in the Islamic Republic of Mauritania, P. Claquin and L. Brenzel, 1987, John Snow, Inc.

EPI In Urban Areas

By the year 2000, half the world's population will live in cities. What does this mean for the EPI, a program now oriented to rural primary health care? Much evidence suggests that a more efficient use of resources within EPI may be in urban areas, where relatively easy logistics are coupled with strong returns in disease prevention:

The greater the population density, the more likely disease is transmitted. This means that more children will be infected, and at younger ages. The target diseases will either tend to remain endemic (as is the case with measles in cities), or come in sharp epidemics even more frequently than in rural areas.

Recent studies show that children in crowded homes have more severe cases of measles and more of them die perhaps because they are infected with higher doses of the measles virus.

"Chains of transmission" of the EPI target diseases often begin in cities and spread to rural areas. This is especially true of measles and pertussis.

In order to develop appropriate delivery strategies for cities, vaccination programs must be built on analysis and understanding of urban demographics and social structure:

What health services, public and private, are used by the population? Are the existing services so overloaded as to be ineffectual? Are there segments of the population that have no access to any reasonable services? What services do private physicians and private voluntary organizations provide? To address all these questions, utilization studies are necessary.

What is the growth rate of urban areas? The total growth rate will include the rate at which people move to cities plus the population growth rate through natural increase. The latter now

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dominates. To plan for future vaccination services one needs such measures. In most large Third World cities the actual population size is unknown and many houses—indeed, whole neighborhoods—are unregistered or illegal.

What are patterns of migration in and out of urban areas, and of transience from one part of a city to another? Transience affects the demand for vaccination services; makes registration of individuals futile.

What level of government is responsible for providing health services in urban areas? In many countries it is not the Ministry of Health, but the municipalities themselves. Do governments at any level even want to offer health services to the poorest and most transient persons if the costs are unbearable, or if thereby a "magnet" to pull more people from the rural areas is created?

EPI offers an excellent model for how primary health care services can be conducted in urban areas. EPIs in several large cities are experimenting with a mix of vaccination strategies: daily sessions at fixed sites, outreach to neighborhoods from fixed sites; sweeps of neighborhoods in "pulsed" campaigns; blanket vaccination at outpatient clinics.

. . . there are families, there are segments of villages or cities and, indeed, there are entire geographic areas that are no better off today than if 20th century science had never existed. They are no better off health-wise than were their grandparents, and they have no voice at all in the plans that we are making here this week.

William Foege
Bellagio II, Cartagena, October 1985

Missed Opportunities For Vaccination

All strategies have one purpose: to increase effective vaccination coverage; that is, giving the right dose at the right time, and giving all doses before the first birthday. Mass campaigns, social marketing, social mobilization are all solutions to perceived gaps in families' knowledge and acceptance of vaccination. The solutions assume that people are ignorant or unmotivated.

Recent research sponsored by the World Health Organization, however, also reveals that a substantial number of children do come to a clinic at the right time for vaccination, when vaccines, syringes and needles, and trained health workers are all present; yet, they leave without any vaccination! These "missed opportunities" could account for as much as 30 points on the coverage scale of 100% by one estimate (Dr. Stanley Foster, CDC).

The reasons for these misses are behaviorally subtle and have to do with how primary health care is organized:

- If the child is ill (fever, cold, diarrhea) the health worker avoids giving a vaccination for fear of being blamed by parents if the child gets worse; yet, the most common reason for visiting a clinic at all is illness. Such decisions by the health worker are reinforced by an outdated medical instruction not to vaccinate a sick child, although this is now known to be incorrect.

  Some clinics which hold special "vaccination days" have little incentive, and are unprepared, to vaccinate routinely; also, parents can seldom afford to come to clinics except for illness.

  Some health staff are unable to use calendars correctly to schedule doses of vaccines, particularly if several vaccinations are due on different dates. Some staff miscalculate the defined intervals of weeks and months and schedule appointments on national holidays and weekends.

  Crowding, long lines, and rudeness of staff, all contribute to the failure to vaccinate.

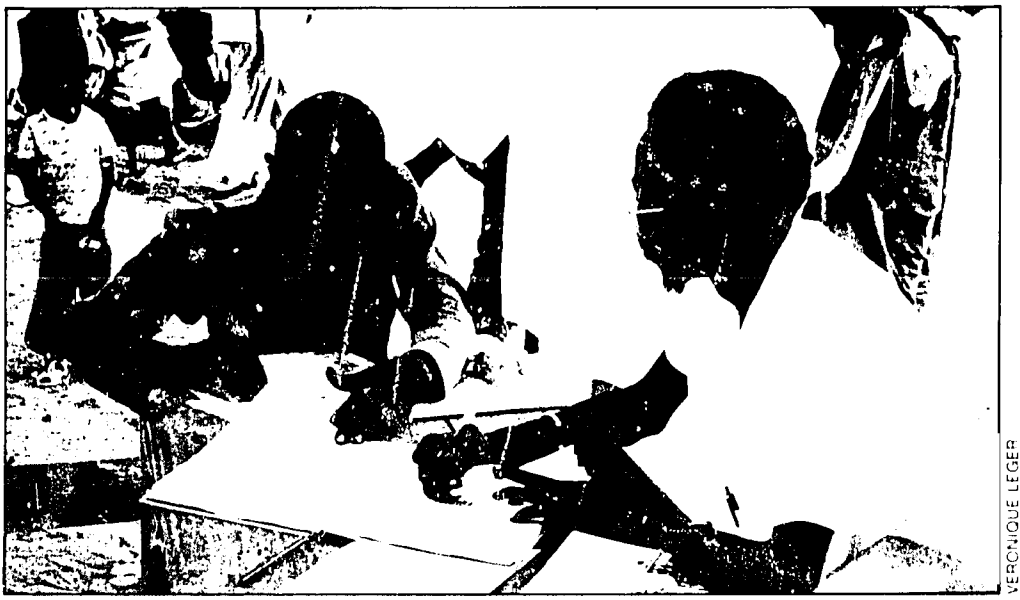
Some experts are of the opinion that mass campaigns and social mobilization are unlikely to sustain good vaccination coverage until these service delivery problems have been solved. Improving service delivery will, in itself, make visiting a clinic more appealing to parents.

Missed Opportunities For Vaccination*

Cameroon: 22% of children were sent home from health facilities without the scheduled vaccine: half for illness at the time, one-fourth because the clinic was too crowded.

Pakistan: 93% of children were sent home without the indicated vaccine: most due to minor illness, the rest due to poor organization at the clinic.

*From: *Weekly Epidemiological Record*, 1984, 59:16, 117-119, and 59:44, 341-342.



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Vaccination Schedules And Vaccine Administration

Vaccination Schedules: The Ages At Which Vaccine Should Be Given

Vaccination schedules are a compromise based on immunologic need, epidemiologic patterns, and operational reality. Children ought to be vaccinated as soon as their systems can respond; the best interval between vaccinations requiring several doses is one that is long enough for the body's immune system to process the previous dose and short enough to reduce the risk of getting the illness during the interval.

The ideal schedule consists of five contacts starting at birth and ending at nine months. This schedule is the standard to which most WHO member-nations subscribe. It is designed to provide maximal immunity to the six EPI diseases before a child's first birthday.

The five-contact schedule assumes that a well-functioning primary care system exists and that families will use the system faithfully, know when to come, and are not afraid of vaccinating even small or fragile infants. The EPI manager may, however, adopt the five-contact schedule because it has long been the standard, regardless of how the system works in a particular situation; this conformity may stifle other approaches where contacts are less frequent.

The following schedules cover a broad range of approaches, from the five-contact standard to the semi-annual mass campaign.

Vaccination Schedules

1. Schedule recommended by WHO to assure protection at an early age is as follows:

AGE	VACCINE	REASON
Birth	BCG, OPV_0^*	BCG given at the earliest possible age protects against the possibility of infection from other family members. The extent of protection against polio is increased the earlier the OPV is given.
6 weeks	DPT_1, OPV_1	An early start with DPT reduces the chances of severe pertussis.
10 weeks 14 weeks	DPT_2, OPV_2 DPT_3, OPV_3	Four week intervals between doses give effective protection, and reduce the time a child is exposed without protection, particularly to pertussis.
9 months	Measles	At least 80% of measles in children in the third world can be prevented by vaccination at this age.

*OPV: Oral Poliovirus Vaccine (dose at birth is *in addition* to the standard schedule of 3 doses)

2. WHO sample schedule for contacts at intervals from four weeks to four months:

AGE	VACCINE	REASON
Less than 6 weeks	BCG, OPV_0	This schedule is useful where populations are dispersed and accessible mostly to outreach services; protection is not optimal
Above 6 weeks	BCG (if not already given) OPV_1, OPV_2, OPV_3, DPT_1, DPT_2, DPT_3,	
Above 9 months	Measles	

Continued

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Careful screening is essential if women and children are to receive every vaccine they are eligible for when they visit a clinic.

3. WHO sample schedule for contacts every six months:

AGE	VACCINE	REASON
Less than 3 years	OPV as often as contacted; DPT up to three doses; BCG once	Semi-annual schedules inadequately protect against pertussis, polio, and measles. These schedules should only be used in the most remote areas where it is infeasible to vaccinate more often.
From 6 months to 3 years	Measles, two doses if the first is given below 9 months, otherwise one dose	

4. Semi-annual single day "pulse" campaigns (as used in Brazil):

AGE	VACCINE	REASON
All children 0-59 months old	OPV (up to 10 doses)	After mass vaccination with OPV, the vaccine virus replaces the naturally occurring disease-causing virus in the environment.
All children 9-23 months old	measles (up to 2 doses)	Giving a second dose of measles vaccine increases effective coverage.
All children 2-11 months old	DPT (2 doses)	Third DPT through regular primary health care services in clinics: 2 doses of DPT are partially effective (50-60%) against pertussis.

Continued

5. Special vaccination for women against tetanus with tetanus toxoid:

AGE	VACCINE	REASON
Puberty or as early in any pregnancy as possible.	TT_1	Begin as close to childbearing age as possible (no protection against neonatal tetanus with one dose unless DPT previously given in childhood)
At least four weeks later	TT_2	Gives 3 years protection
At least six months later, or in next pregnancy	TT_3	Gives 5 years protection
At least one year later, or in the next pregnancy	TT_4	Gives 10 years protection
At least one year later, or in the next pregnancy	TT_5	Expected to protect all infants born to that mother

Tetanus toxoid schedules for women are more flexible than childhood vaccination schedules. Women should be vaccinated at least twice with tetanus toxoid before the first birth, or anytime during pregnancy. Note that the first dose can be given as soon as early puberty when girls may still be in school. A woman who received three doses of DPT in childhood and/or two doses of DT at school age may need only one TT booster when she reaches childbearing age.

Vaccination Session Records

All vaccination sessions need a record of vaccinations performed by vaccine and age group. The easiest way to maintain records is to keep a simple tally, as shown in the form at the right. Tally records should also show the number of vials of vaccine used. In addition to recording vaccine stocks, the record allows vaccinators to compare the number of doses used to the number of children vaccinated. This gives an estimate of wastage which is used to estimate future vaccine orders.

Vaccination Session Record

Name of Health Center _____ Date of Session _____

District _____ Signature _____

District Health Officer _____ Date of Completion _____

AGE	Less Than 1 Year		1 to 2 Years		Greater Than 2 Yrs		Women 15 to 45 Yrs		TOTAL
VACCINE	Tally	Total	Tally	Total	Tally	Total	Tally	Total	
BCG									
Measles									
DPT 1									
DPT 2									
DPT 3									
TOTAL DPT									
OPV 1									
OPV 2									
OPV 3									
TOTAL OPV									
TT 1									
TT 2									
TT 3									
TT 4									
TT 5									
TOTAL TT									
NUMBER COMPLETELY VACCINATED									

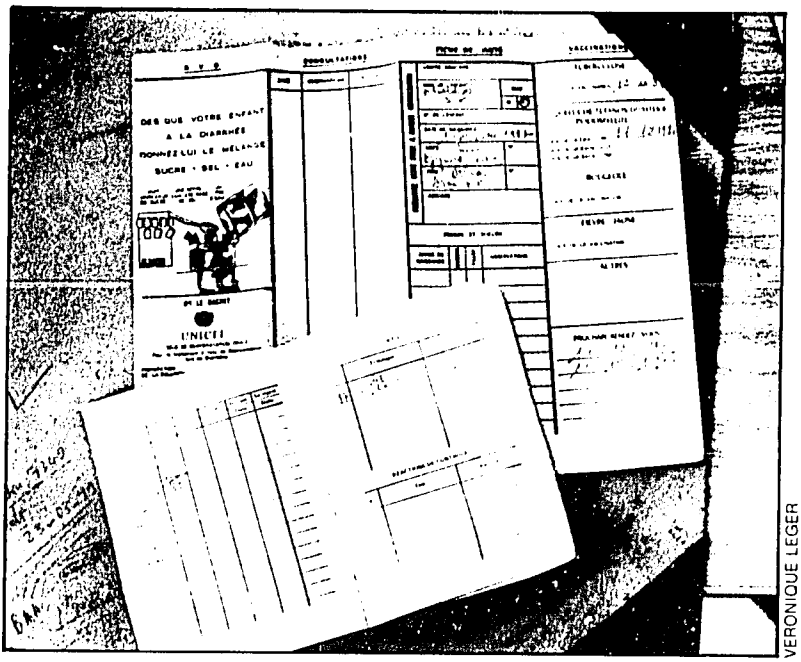
NUMBER	Vials Used	
VACCINE	Tally	Total
BCG		
MEASLES		
DPT		
OPV		
TT		
TOTAL		

Duration of Session _____ (hours)

Personnel _____ (number)

Comments: _____

WHO, EPI Mid-level Managers Course



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Vaccination Cards

Vaccination cards are kept by families. If over 90% of families can produce cards for their children, EPI has been successful in reaching the population with at least one dose, indicating high access to services. No survey of coverage or vaccine efficacy study is accurate without the use of such cards as sources of data. As families often move seasonally or permanently, family-held cards are still necessary even if the primary care program keeps good records at the health center (which few do, in fact). Separate cards should be made for women showing tetanus toxoid doses received.

Vaccination cards need to include all the information shown on the following page. They may be part of a road-to-health card, or be printed up separately according to countries' individual needs.

For example, the information shown may be printed on the different faces of a small folded card the size of the country's standard identity card. Some countries issue the card with a plastic envelope for easy keeping.

Additional information which can be included on vaccination cards includes:

- brief descriptions of the target diseases;
- the country's target age groups for EPI;
- price, if any, for vaccinations; if free, this should be stated;
- a reminder to bring vaccination cards to all health center visits.

Sample Vaccination Card

Vaccination Card

Place of Vaccination _____

Child's Name _____

Sex _____ Date of Birth _____

Name of Father _____

Name of Mother _____

Address _____

_____

_____

Vaccine	Dose (Enter date given)			
	0	1	2	3
BCG				
Polio				
DPT				
Measles				

Tetanus Toxoid Doses Mother has received:

(Enter date given)

TT1	TT2	TT3	TT4	TT5

Vaccination Schedule (Ideal)

BCG	At Birth
Polio	At Birth, then 6, 10, and 14 weeks
DPT	6, 10, and 14 weeks
Measles	9 months

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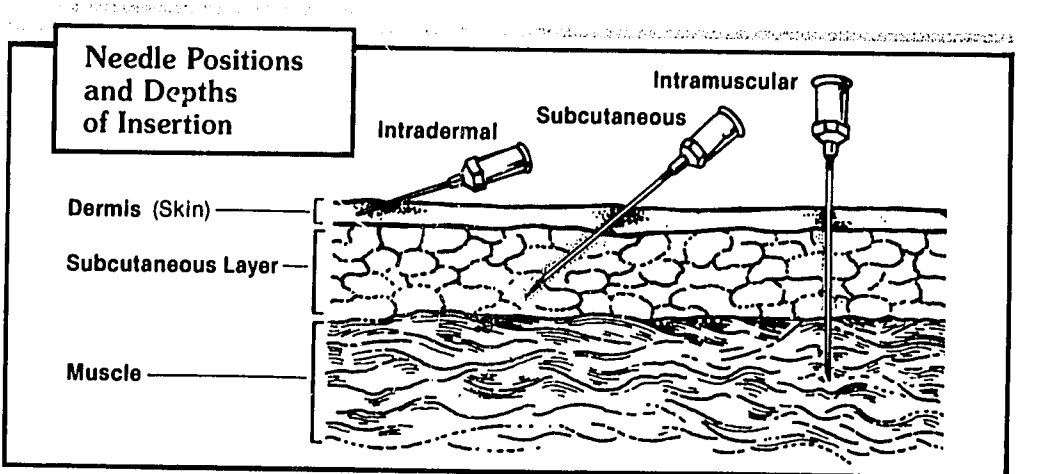
Vaccines And Their Administration

Many EPI failures are related to mismanagement of vaccines at the time they are actually given to the child. To avoid failures, health professionals must be aware of the requirements of each vaccine, which differ with regard to when and how they are given, their effectiveness, and how they are handled. Such diversity is what makes EPI so demanding. One particularly exacting requirement is that each vial of reconstituted vaccines must be discarded at the end of each vaccination session. This is to prevent loss of sterility and potency, but can lead to wastage and vaccine shortages if the EPI cannot assure a steady supply.

Other general principles which apply when screening children for vaccinations include:

> It is safe and immunologically effective to administer all EPI vaccines on the same day at different sites of the body. Measles vaccine should be given as soon as the child is 9 months old, regardless of other vaccines also scheduled to be given on that day.



Philippines National EPI Manual, 1987.

Loading the Syringe

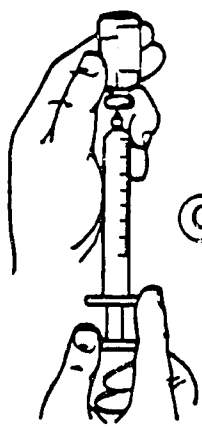
- Check the label for the correct vaccine and to be sure the vaccine has not expired. Ⓐ
- Shake the vial, so that the sediment mixes completely into the vaccine.
- Remove the center of the metal cap using an ampoule file.
- Stand the vial of vaccine in the cup of ice, or on an ice pack on the table. Ⓑ
- With forceps, take a sterile syringe (0.5, 1 ml or 2 ml)
- With forceps, fit a needle to the syringe (preferably a 0.5 ml syringe).
- 5/8" 26 G needle — BCG
  23 G needle — DPT, TT & measles
- Clean the exposed rubber cap of the vial of the reconstituted vaccine with spirit.
- Withdraw vaccine into the syringe. Ⓒ

BCG	0.1 ml *
DPT	0.5 ml
Measles	0.5 ml

- Put the vial back into the cup of ice. Ⓓ
- Expel any air bubbles from the syringe. Ⓔ
- Check that the dose drawn up is correct.
- Give the vaccine to the child immediately.

Ⓐ

Ⓑ



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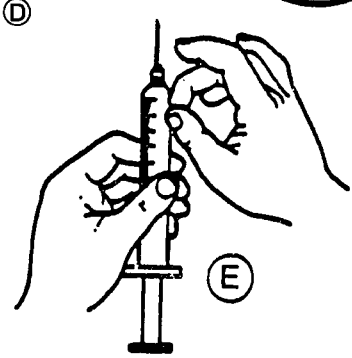
Ⓓ



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* Some Manufacturers recommend .05 ml to children less than 1 year old.

ADAPTED FROM: CCCD Job Aid, CDC.

- The vaccination schedule should not be restarted from the beginning even if the interval between doses has exceeded the recommended interval by months or years.
- Moderate fever, malnutrition, mild respiratory infection, cough, diarrhea, and vomiting are not contraindications to vaccination.

BCG Vaccination

Young children are at high risk of contracting tuberculosis: infection is almost always intrafamilial and frequently takes place before the source of infection is detected. Young children are also prone to develop serious acute forms of tuberculosis, such as meningitis and miliary disease, which are often fatal even when treated.

The control of childhood tuberculosis currently depends on BCG vaccine. Children should be vaccinated at birth or as soon as possible after birth.

Efficacy:

Most, but not all, studies of the efficacy of routine BCG vaccination programs have shown that BCG conferred protection against childhood tuberculosis. The level of protection differed substantially, however, from 0% to 80%, with a reasonable median around 50%. Higher protection may be conferred against the more severe forms of tuberculosis.

Transport And Storage:

BCG is heat and ultraviolet light sensitive. At 37°C a 50% loss of potency will occur within 20 to 60 days. The deleterious effect of heat is cumulative. Therefore, the vaccine should be kept all the time between two to eight degrees Celsius and out of direct sunlight. BCG can be frozen for extended storage.

Reconstitution:

Whether in the form of a powder or a cake in the vial, BCG must be reconstituted with a special refrigerated diluent before injection. The reconstituted vaccine should be disposed of by the end of the vaccination session.

Administration And Dosage:

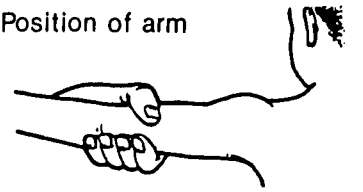
The response to BCG is dose-dependent. Usually a single 0.1 ml is administered to children over one year and 0.05 ml to infants: dosages to be injected vary and depend upon the type (and country of origin) of the product manufactured. WHO has not determined a universal dose and suggests following the manufacturer's instructions.

The dose of vaccine must be injected intradermally. The adequacy of the technique can be judged by the presence of a papule with a five to eight millimeter diameter following the injection.

Giving BCG VACCINE — Intradermal Injection

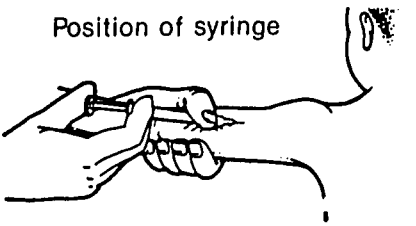
1. Hold the newborn's arm with your left hand so that:
   - Your hand is under the arm.
   - Your thumb and fingers come around the arm and stretch the skin.

Position of arm



2. Hold syringe in your right hand, *with the bevel and the scale pointing towards you.*

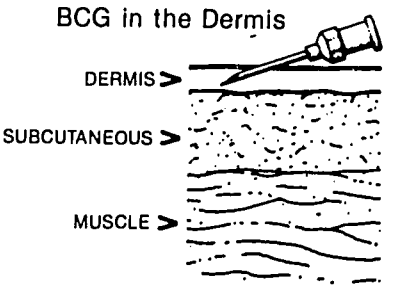
Position of syringe



3. Lay syringe and needle almost flat along the newborn's arm.

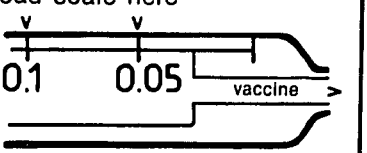
4. Inset tip of needle into the skin—just the bevel and a little bit more.
   - Keep needle flat *along the skin*, so that it only goes into the upper layer of the skin. Keep bevel facing upwards.
   - *Do not* push too far; and do not point downwards, or the needle will go under the skin. Then it will be a subcutaneous instead of an intradermal injection.

BCG in the Dermis



5. Now, put your left thumb over the needle end of the syringe to hold in position.
   - Hold plunger end of syringe between index and middle fingers of your right hand and press plunger in with your right thumb.

read scale here

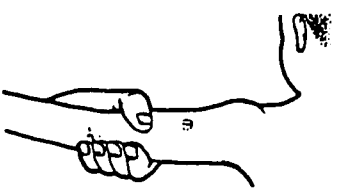


6. Inject vaccine, and then withdraw needle.
   - Make sure syringe does not leak around adaptor. If it does leak, you must fix on the needle more firmly.

Amount BCG:	*Age:*
0.05 ml	at birth -1 year
0.1 ml	for over 1 year old

If you inject BCG intradermally and correctly:

There will be a clear, flat-topped swelling in the skin. The swollen skin may look pale, with very small pits.



ADAPTED FROM: CCCD Job Aid, CDC.

Age At Vaccination:
At birth.

Reactions And Complications:
In addition to the expected ulceration (which leaves the BCG scar and requires no medical care), there is occasional severe swelling of the lymph nodes in the neck or axilla. Such complications seem related to specific brands of BCG, or inappropriate technique, but can be treated. Mothers may be distressed by these complications and not return for future vaccinations.

Contraindications:
BCG is the only vaccine which should *not* be administered to children with clinically apparent AIDS.

Measles Vaccination

Because nearly all children in unimmunized populations get measles, vaccinating children against the disease is one of the most effective public health measures available to developing countries. An eligible child should be vaccinated against measles if he or she has no written record of previous vaccination or previous measles disease.

Efficacy:
If potent vaccine is correctly administered at the right age, efficacy is usually 85-95%. Protection is lifelong.

Transport And Storage:
Freeze-dried measles vaccine should be kept below 8°C. At central stores the vaccine should be kept at -20°C when its use is not imminent.

Reconstitution:
Measles vaccine must be reconstituted with a special cold diluent. The diluent should be refrigerated well in advance of use so that warm liquid does not inactivate the vaccine. The vaccine must be used within one vaccination session.

Administration And Dosage:
Measles vaccine is given subcutaneously (45 degree angle) at the outer part of the child's upper arm in a single dose of 0.5 ml.

Age At Administration:
The currently recommended age of administration is nine months, or as soon thereafter as possible.

Reactions And Complications:
A mild fever and rash may develop in a small percentage of children. Encephalitis as a complication is very rare (one case per million doses administered).

Contraindications:
Virtually none.

Giving MEASLES VACCINE — Subcutaneous Injection

How to position the baby:

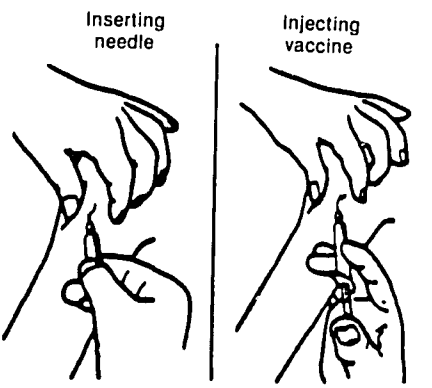
(This description is for the left arm. Some programs use the right arm.)

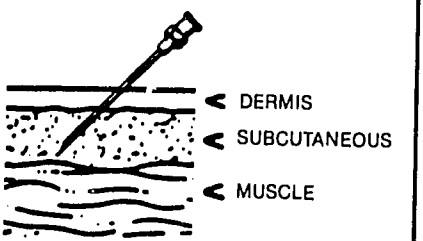
- Sit the baby on its mother's lap.
- Tuck baby's right arm away around her body.
- Mother's left arm goes around the baby, to support the head.
- Her left hand holds the baby's left shoulder.
- Her right arm hold the baby's legs out of the way.
- Her right hand holds the baby's left hand.

POSITION OF CHILD FOR MEASLES VACCINE

Giving measles vaccine:

- Pinch up the skin of the OUTER part of the child's upper arm with your fingers.
- Push the needle into the pinched-up skin—not straight in but at an angle.
  —Do not push the needle far in.
  —To control the needle, support the adaptor end of the syringe with your thumb and finger while you push the needle in.
- Withdraw the plunger to check for blood.
  —If the needle has entered a vein, blood will come into the syringe. Withdraw the needle, discard it and get another sterile syringe and needle.
- Press the plunger with your thumb to inject the vaccine.
  Withdraw the necdle.





MEASLES VACCINE IN THE SUBCUTANEOUS LAYER

REMEMBER for measles vaccine, give 0.5 ml once at 9 months of age. HEAT AND LIGHT DAMAGE RECONSTITUTED VACCINE FAST—KEEP VACCINE COVERED AND IN A CUP OF ICE.

ADAPTED FROM: CCCD Job Aid, CDC.

Diphtheria Vaccination

Diphtheria is not a serious problem in developing countries with an effective EPI. Diphtheria outbreaks in disorganized refugee camps and urban squatter settlements will occur. The diphtheria toxoid vaccine is delivered along with pertussis and tetanus toxoid vaccines (DPT).

Efficacy:

The diphtheria toxoid is highly effective. Protection lasts for decades.

Transportation And Storage:

While the diphtheria vaccine as a component of DPT is relatively stable, it should always be kept refrigerated. Warning! Freezing will destroy the vaccine.

Administration And Dosage:

DPT is given intramuscularly (90 degree angle) at the upper and outer portion of the thigh in a dose of 0.5 ml.

Age At Vaccination:

The first dose of DPT is given as soon after six weeks of age as possible. The second and third doses follow at four week intervals.

Reactions And Complications:

Fever along with redness and tenderness at the site of injection may occur.

Contraindications:

Children with previous severe reactions to the vaccine should not be given further doses of DPT but should continue with diphtheria-tetanus (DT) vaccine.

USAID/KENYA

Giving DPT VACCINE and TETANUS TOXOID (TT)

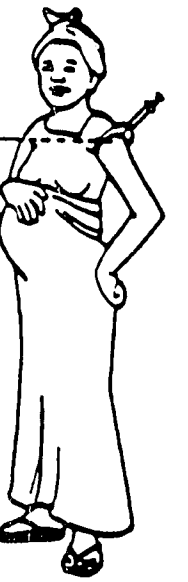
Intramuscular Injection

- The best place to inject is the OUTER part of the child's mid-thigh.

  If you inject into the buttocks, you may cause paralysis of the leg; so in many countries, health workers prefer not to use the buttocks. The arm muscles are rather small in such young people.

POSITION OF CHILD FOR DPT VACCINE

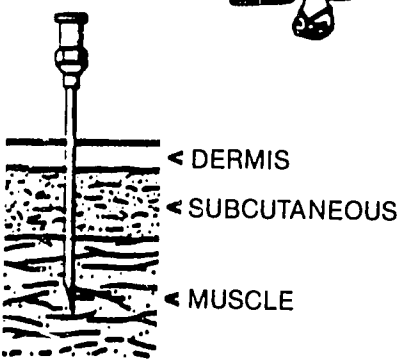
- The best place for an intramuscular injection for a woman is the outer side of the left upper arm.



PLACE FOR GIVING TETANUS TOXOID TO WOMEN OF CHILDBEARING AGE

- Put your finger and thumb on each side of the injection place.
- *Stretch the skin flat* between your finger and thumb.
- Quickly push the needle straight down through the skin between your fingers. Go deep into the muscle.
- Withdraw the plunger a little to make sure you are not in a vein.
- Press the top of the plunger with your thumb to inject the vaccine.
- Withdraw the needle.

DPT in the Muscle



- *REMEMBER,* for DPT vaccine give 0.5 ml 3 times, each 4 weeks apart—intramuscular injection into the child's thigh.
  DO NOT FREEZE THE VACCINE.

- *REMEMBER FOR TETANUS TOXOID:*
  Give 0.5 ml at least twice before the first birth or during pregnancy, at least 4 weeks apart.
  DO NOT FREEZE THE VACCINE.

ADAPTED FROM: CCCD Job Aid, CDC.

Tetanus Vaccination

Administration of tetanus toxoid to women of childbearing age is one of the most effective interventions available for reducing neonatal mortality. Tetanus toxoid is cheap and is more resistant to heat than other vaccines. In children, it is administered with diphtheria and pertussis vaccines (DPT). (Here it is used to protect against tetanus in childhood and young adulthood.) For adults, tetanus toxoid comes as a single-component vaccine (TT) or as a combined diphtheria-tetanus toxoid (Td) vaccine.

Efficacy:

Highly effective. Five doses given at the correct intervals should protect all children born to that woman.

Transportation and storage:

The vaccine should be kept refrigerated but should be discarded if ever frozen.

Administration and Dosage:

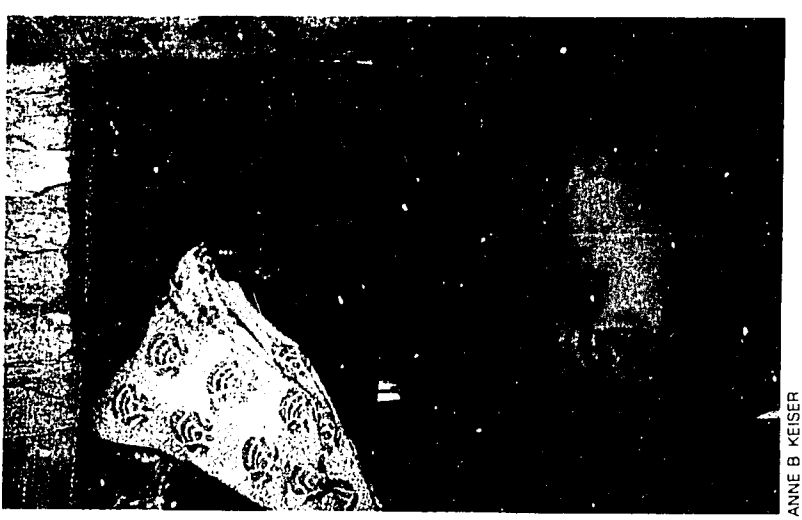
For children, see above under diphtheria. For women, tetanus toxoid is administered intramuscularly at the deltoid region of the upper arm in a dose of 0.5 ml.

Age at Administration:

All women of childbearing age should be vaccinated. Special emphasis should be placed on vaccinating women of childbearing

Of all the diseases preventable by immunization, the easiest to prevent is the least well prevented, neonatal tetanus. . . . If we are to achieve the WHO goal of reducing neonatal tetanus mortality. . . we need to stop talking and start immunizing.

Stanley O. Foster, CDC
R&D Feedback. March 21. 1985



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age with at least two doses as soon as possible. The two doses should be given with a minimum interval of four weeks. A third dose given six months to one year later protects against neonatal tetanus for five years and a fourth dose given one year after the third dose protects for ten years. It is believed that a fifth dose given at least a year after the fourth will confer immunity to all children born to that woman. TT may be given at any month in pregnancy.

Tetanus toxoid as part of DPT given to female infants will protect their children from neonatal tetanus if booster doses of TT are given at school age and in the childbearing years.

Reactions and Complications:

Fever with swelling at the site of injection may occur.

Contraindications:

Virtually none.

Pertussis Vaccination

Killed bacterial-cell pertussis vaccine is the "P" component of DPT. As mortality from pertussis is highest in young infants, the DPT series should be delivered beginning at six weeks or as soon after as possible.

Efficacy:

After three doses, pertussis vaccine is 60-90% effective. Pertussis is unusual after childhood, so protection may be considered lifetime.

Transport And Storage:

As part of DPT vaccine, pertussis vaccine should always be refrigerated and must never be frozen.

Administration And Dosage:

Refer to diphtheria, above.

Age At Vaccination:

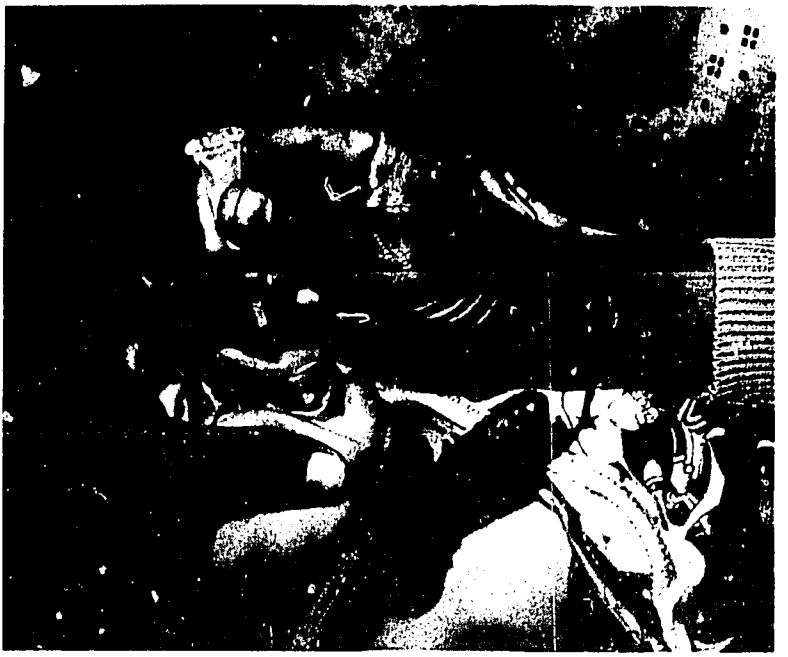
As part of DPT vaccine, the first dose should be given as early after six weeks of age as possible. Second and third doses should follow at four-week intervals.

Reaction And Complications:

Fever and swelling are common with the current vaccine. Convulsions and collapse (one per 25,000 doses administered) or permanent brain damage (one per 300,000 doses given) can occur. These complications are several hundred to thousand times more likely if the child is not immunized and contracts pertussis. New vaccines are being developed which have lower rates of complications.

Contraindications:

Children with previous severe reactions to the vaccine should not be given further doses of DPT but should continue with diphtheria-tetanus (DT) vaccine.



Polio Vaccination

In developing countries, most cases of polio occur in late infancy or early childhood, and about one out of every two hundred infections results in permanent paralysis. Since infection occurs early, the polio vaccine series should be given before the child reaches one year of age.

Efficacy:

Under ideal conditions, both OPV (given orally) and IPV (injected) provide long-lasting immunity in up to 95% of those fully vaccinated. Efficacy under actual field conditions will vary. The reasons for this are still being assessed.

Transport And Storage:

OPV is much more heat sensitive than IPV. While IPV loses 7-35% of potency per week at 37°C, OPV will lose half its potency after only two days at that temperature. Freezing destroys IPV, but the vaccine must always be kept refrigerated. OPV should be frozen at central and regional levels, and refrigerated at more peripheral levels.

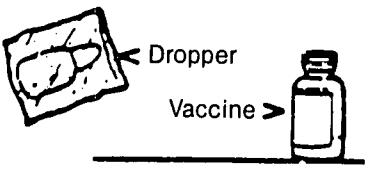
Administration And Dosage:

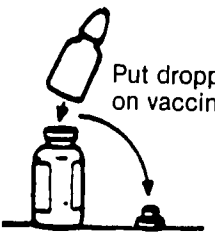
OPV is dropped in the mouth with a dropper attached to the vial, and the number of drops will depend on the manufacturer's instructions. Most EPIs use 2 drops which is about 0.1 ml. In the USA, 0.5 ml is given, The difference in volume depends on concentration. IPV is injected intramuscularly (like DPT) in a dose of 0.5 ml.

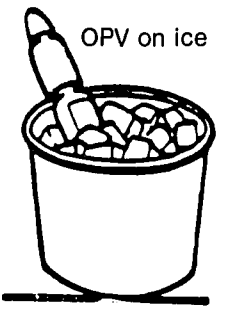
Giving ORAL POLIOVIRUS VACCINE (OPV) — By Mouth

1. Let the mother hold the child firmly.
2. Open the child's mouth:
   Then—squeeze its cheeks gently between your fingers to make the lips point forward.
3. Put 2 drops* of vaccine straight from the dropper onto the child's tongue.
4. Make sure that the child swallows it.
   If it is spit out, give another dose.

USING DROPPER DEVICE







Remember, for polio vaccine:
Dose: 2 drops, 4 times: at birth, 6 weeks, 10 weeks, 14 weeks.

*Dosage depends on specific vaccine brand used.

ADAPTED FROM: CCCD Job Aid, CDC.

Age At Vaccination:

For OPV, the first dose should be given at birth, and then three more doses should be given at four-week intervals beginning as soon after six weeks of age as possible.

For IPV, the first dose is given at two to three months of age, and the second and third doses at one- to two-month intervals (two is preferred). Two doses confer protection and may be given in the same vial as DPT in a special four-vaccine preparation.

Reactions And Complications:

OPV is associated with a very small risk of vaccine-virus induced paralysis (about one case per million doses administered to the recipient, or a contact). No side effects have been documented for modern IPV.

The Logistics Of Vaccine Management

UNICEF/MURRAY-LEE

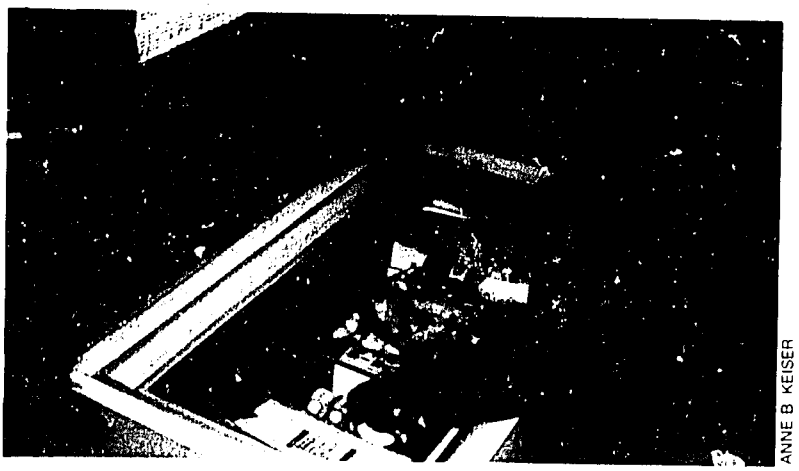
The Cold Chain

The cold chain is a system that ensures the potency of a vaccine from the time of manufacture to the time it is given to a child or woman. All vaccines are sensitive to heat, and BCG and measles vaccines are also sensitive to ultraviolet light. The frying of an egg provides an example; once the egg white is a little bit fried, it cannot return to raw. In the same way, heat and sunlight denature, or ruin, the protein structure of vaccines.

It is the cumulative effect of heat that destroys vaccines. A lot of heat at one time (e.g., in a closed vehicle in the sun) or a little amount of heat over many exposures (constant openings of a refrigerator door) can damage vaccines to the same extent. Those who are not aware of the fragility of vaccines wonder why cold beer is available in remote areas while potent vaccines are not; beer, of course, does not require a *continuous* cold chain, as do vaccines. Furthermore, some vaccines should be frozen at some points along the chain while other vaccines must never be frozen, which increases the complexity of the cold chain.

Vaccine Storage Temperatures And Stability

There is no way to tell if a vaccine is heat-spoiled by looking at the vial. Vaccine stability and potency depend on continual—and honest—checks on the temperature of each link in the chain every day. Heat-reactive chemical monitors improve our ability to monitor the integrity of the cold chain. Nothing is worse for the morale of health workers than to doubt the viability of the vaccine they are using.



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Vaccine Storage Temperatures

VACCINE LEVEL: MAXIMUM STORAGE TIME	CENTRAL STORE up to 8 months	REGIONAL up to 3 months	HEALTH CENTRE up to 1 month	TRANSPORT up to 1 week
MEASLES YELLOW FEVER ORAL POLIO	−15°C to −25°C			
DPT TETANUS TOXOID IPV DT BCG	2°C to +8°C			

NOTE:—Never freeze DPT, IPV, or TETANUS (all of which freeze at temperatures below −3°C).
—Storage times are recommended maximum figures. Remember to check expiry dates.

Adapted from *Manage the Cold Chain*, WHO, Feb. 1985.

Vaccine Stability in Tropical Temperatures		
	Vaccine	Stability at 37°C (= 98.6°F, warm tropical day)
Most sensitive to heat	Live poliovirus, (suspended in magnesium chloride)	Unstable, loss of 20% potency after one day and 50% potency after two day exposure (but varies by manufacturer)
	Freeze dried BCG	20% loss of potency after 3-14 days
	Freeze dried measles	Retains minimum potency for at least one week
	DPT	50% loss in pertussis component potency after 1 week; other components stable for about 6 weeks
	Inactivated poliovirus	0.1% - 5% loss of potency per day
Least sensitive to heat	Tetanus toxoid	Stable for about 6 weeks

Source: EPI/WHO

Vaccination sessions held outdoors need to be in the shade to protect vaccines sensitive to sunlight.

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The Links Of The Cold Chain

People and equipment make up the links in the cold chain, and each link represents a level of vaccine delivery. Every level has unique requirements. More specific information is provided in the cold chain equipment supplement.

Central and sometimes regional stores have cold rooms, refrigerators, and freezers.

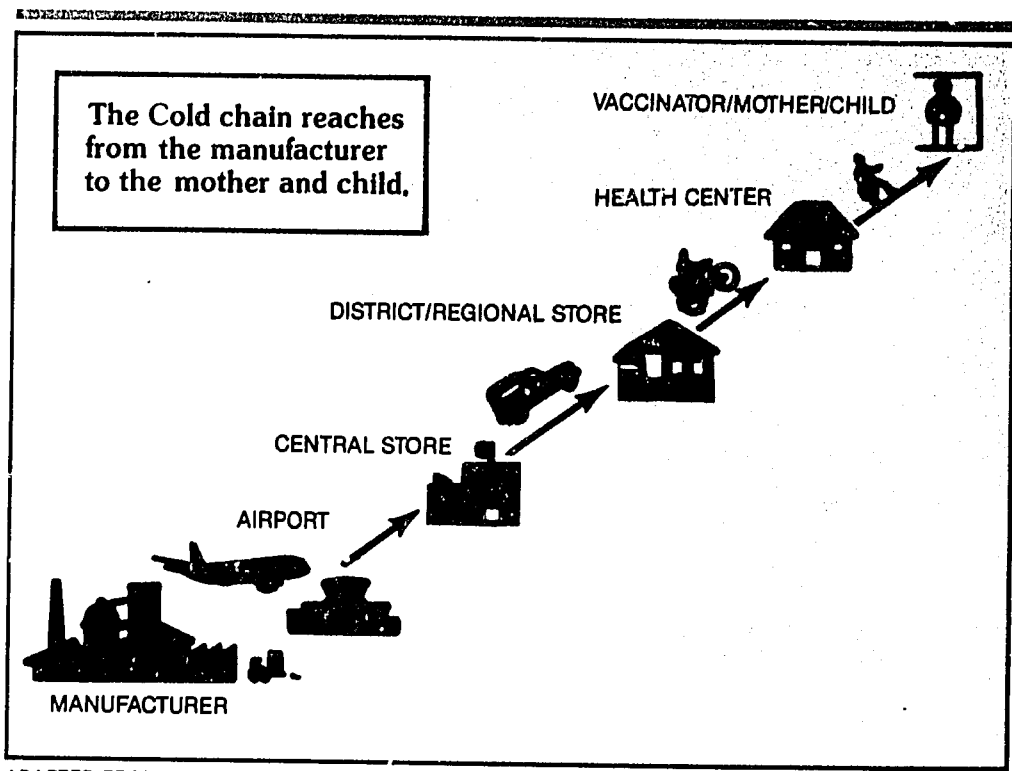
District stores and some health centers use refrigerators, cold boxes, and freezers.

Health centers and outreach units use cold boxes and insulated vaccine carriers.

A desk-top thermos or vaccine carrier holds a one-day vaccine supply at a health center or outreach post.

The cold chain equipment is also highly dependent on a continuous supply of energy: gasoline for vehicles, kerosene or electricity for refrigerators or ice-makers.

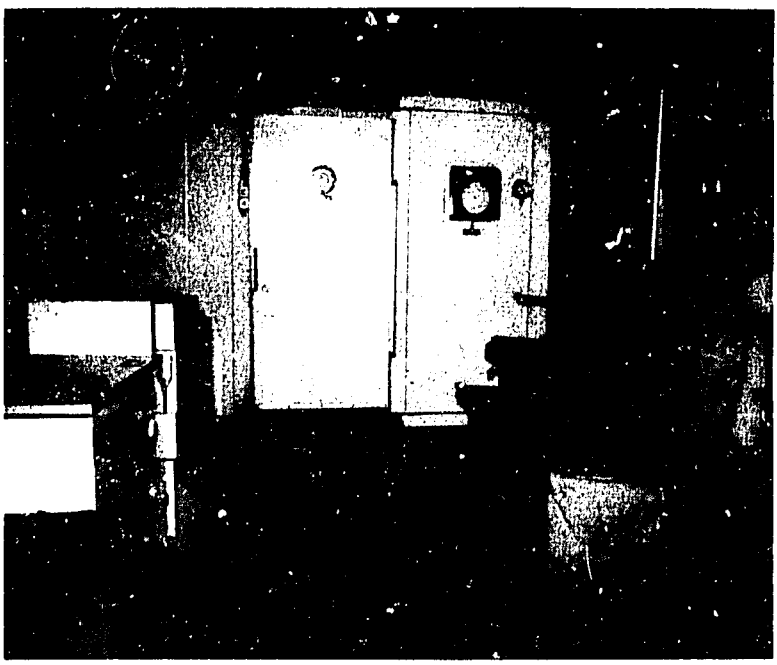
The following pages show some typical configurations and uses of cold chain equipment.



ADAPTED FROM: Manage the Cold Chain, WHO, Feb. 1985.

Vaccine Cold Rooms

Cold storage rooms are used at the national and, in some cases, regional level for refrigeration or freezing of bulk amounts of vaccines. Pre-fabricated cold rooms can be purchased by tender. More than one cold storage room may be built per cold storage building.



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A cold storage room. Continuous temperature monitoring, an alarm system to signal power outages, and back-up power sources are essential.

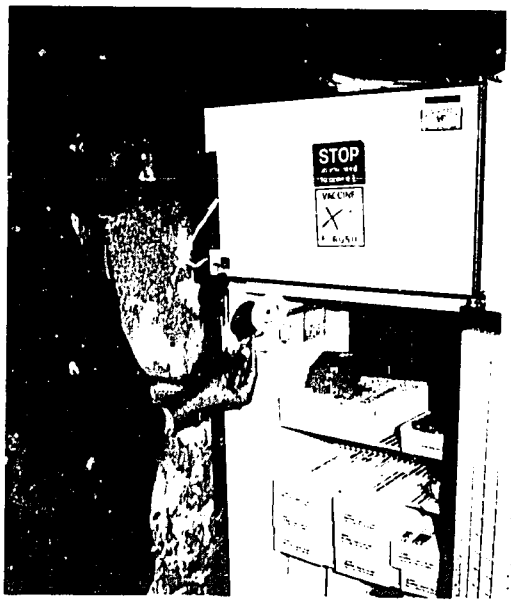
Refrigerators

The refrigerator is the basis of the cold chain at the regional and some peripheral levels. Refrigerators are powered by electricity, gas, kerosene, or solar energy. By far, the least costly and most maintenance-free method is electricity.

Because of the expense and on-going maintenance required for gas and kerosene refrigerators, they should be used only when absolutely necessary. Many health center refrigerators are inoperative; more appropriate technology is needed. High initial costs tend to discourage use of solar-powered equipment, but the technology is being continually refined.

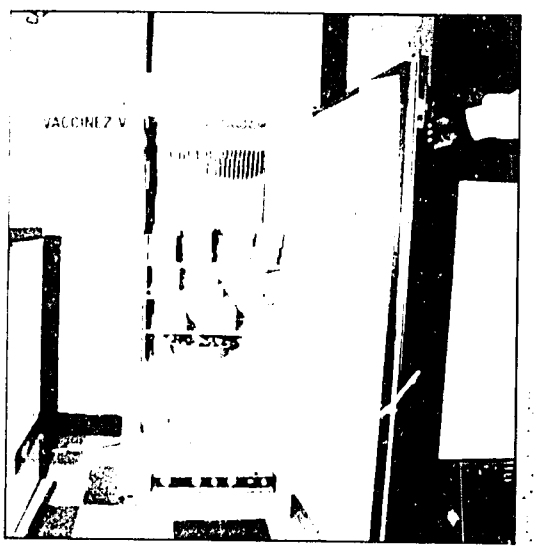
Sealed water bottles kept in the refrigerator help retain the cold.

Ice-lined refrigerators are now available which can operate on only eight hours of current per day, holding the cold for the balance.



A conventional refrigerator that can run on electricity or kerosene. Space must be left between stacks of vaccine to allow air circulation.

An ice-lined refrigerator. Tubes of water lining the inside are frozen to maintain cold temperatures when power is shut off. This model can be used as either a refrigerator or freezer. More space than shown is recommended for adequate air circulation.



Conventional refrigerators are too large for health centers that may serve populations of, say, 10,000. Smaller units have been designed specifically for vaccine storage at health centers that can run on electricity, gas, or kerosene.

Even if the refrigerator works, one can damage vaccines by:

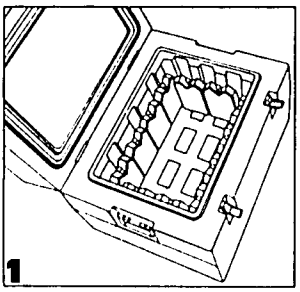
freezing DPT;

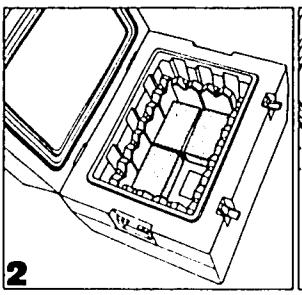
opening the door too often (cold drinks and food should not be stored with vaccines);

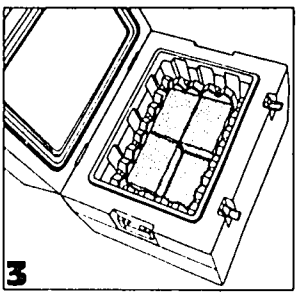
overstuffing the refrigerator impeding cold air circulation;

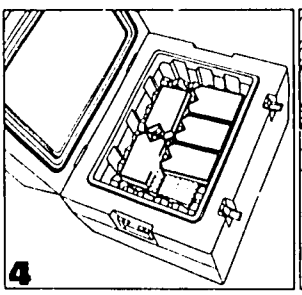
not using vaccines on a first-in, first-out basis.

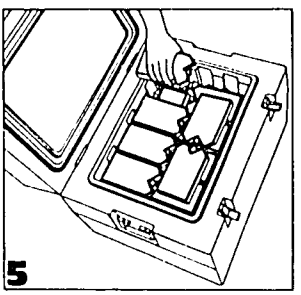
Loading A Vaccine Cold Box

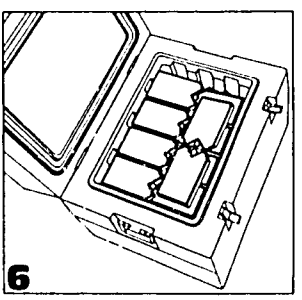












1. Place ice packs around the sides.

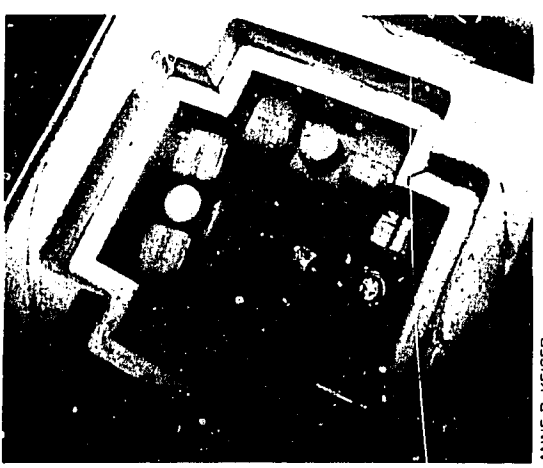
2–3. Put vaccines into box.

4–5. Place two layers of ice packs on top. DPT and TT should be wrapped to avoid touching the ice directly.

6. With this heavily insulated cold box, the vaccines can remain at the safe storage temperature of 0°C to +8°C for a period of ten days in a constant outside temperature of +32°C.

Electrolux, Insulated Transport Box RCW 25

Insulation, ice packs, a thermometer, good vaccines: all part of an unbroken cold chain. Note however that DPT and TT should not touch the ice packs directly.



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Vaccine Carriers, Cold Boxes, And Vaccine Flasks

Carriers, cold boxes, and flasks are used for keeping vaccines cold during transport. A cold box is simply an insulated box lined with ice. If kept too long in a closed car under a hot sun, it will absorb and retain heat, cooking the vaccines inside. There are wide variations in the quality and "cold life" (the length of time proper temperatures can be maintained) of cold boxes. It is important that the ice packs not be too cold, and that TT and DPT be wrapped and not placed directly on ice packs, to avoid the risk of freezing these vaccines.

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Cold boxes are insulators. They can hold in heat as well when left inside a closed, hot car.

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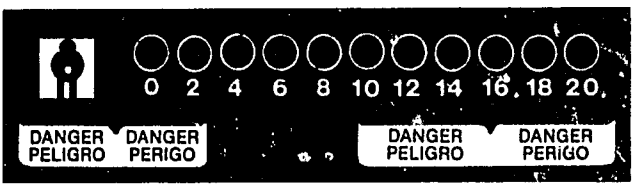
Many models of cold boxes are available; they can be adapted for backpack, as illustrated, or hand or shoulder carrying.

Thermometers

Liquid crystal thermometers are inexpensive thermometers (less than 90 cents each) used during vaccine transport and in refrigerators. They do not operate at temperatures below freezing.



Liquid crystal thermometer

Dial thermometers may be used both for transport and storage at all levels of the cold chain. Some dial thermometers can also record or give minimum/maximum readings.

Digital thermometers are now available and useful for cold chain supervision and checking equipment.

Recording thermometers should be used wherever large quantities of vaccine are stored, particularly at national and sometimes regional stores.

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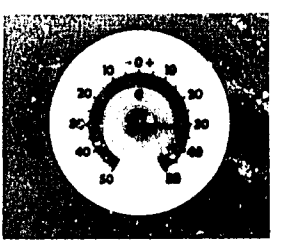
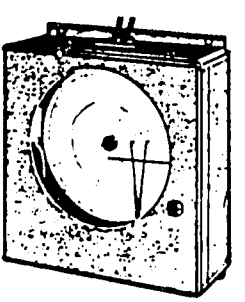


Dial thermometer



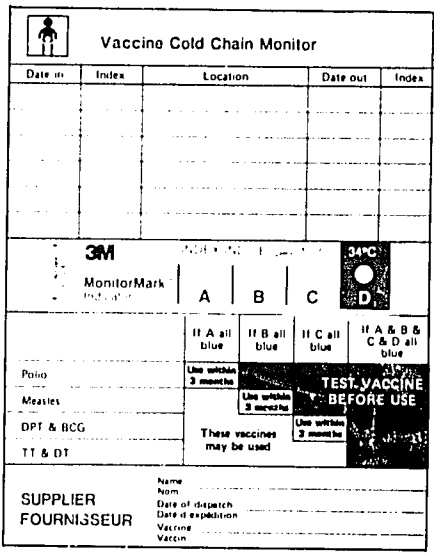
Recording thermometer

Digital thermometer

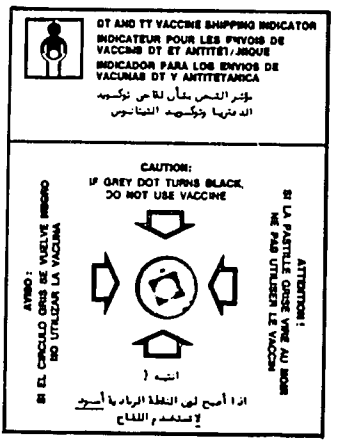
Cold Chain Monitors

3-M Monitor

One cold chain monitor is generally shipped with every 3,000 doses of vaccine. Known as the "silent supervisor," the monitor detects cumulative heat exposures above 10°C and any exposure over 34°C. Since vaccine boxes are usually broken up and the vials separated, the value of the monitor is diminished at lower levels of the cold chain. They are also used in special studies of the cold chain.

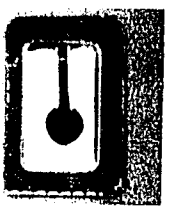


3-M cold chain monitor



DT and TT vaccine shipping indicator

Ice pack indicator



Freeze Watch™ indicator

DT and TT vaccine shipping indicator

This indicator has a temperature-sensitive dot that changes from silver-gray to black at temperatures above +48°C, temperatures which may be reached in poorly ventilated places exposed to the sun.

Ice pack indicator

This indicator is used to prevent ice packs that are too cold to be used for shipping vaccines which should not be frozen, like IPV, DPT and TT. It is stuck onto ice packs before they are frozen and will change from purple to yellow when the ice pack is frozen to below -4°C. It will turn back to purple when taken out of the freezer and allowed to warm to above -4°C, indicating that the ice pack is safe for use. The indicator is uncommonly used.

Freeze Watch™ indicator

This indicator, shaped like a small thermometer, will change from white to red (the "thermometer" will burst) if ambient storage temperatures fall below -4° C, warning the recipient of the vaccine that it may have been frozen.

The DPT, DT, TT Vaccine Shake Test

VACCINE NEVER FROZEN		VACCINE FROZEN AND THAWED
Smooth and cloudy	NOW	Contains floccules or granular particles; appears less cloudy
Still smooth and cloudy	AFTER 15 MINUTES	Has sediment sitting on the bottom of the vial
Has begun to clear, but has no sediment	AFTER 30 MINUTES	Almost completely clear with a dense sediment
Half clear, with a thick cloudy sediment which moves when the vial is tilted	AFTER 1 HOUR	Completely settled; sediment hardly moves when the vial is tilted
USE THIS VACCINE		DO NOT USE THIS VACCINE

Notes: Always compare two vials from the same manufacturer.
After some experience you should be able to recognise a frozen vial of vaccine in much less than 1 hour.

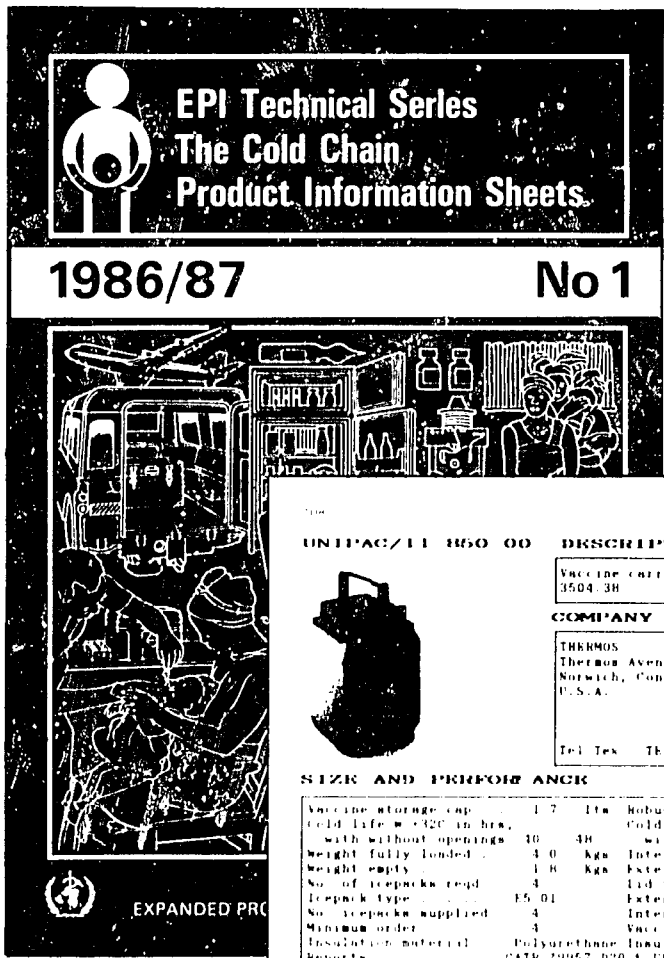
SOURCE: EPI/WHO

Keep cold, young orchard.
Goodbye and keep cold.
Dread fifty above more than fifty below.

Robert Frost
Goodbye and Keep Cold, 1953

Product Information Sheets

The standard reference for cold ch. .in equipment specifications is a book published by WHO and UNICEF called the *Product Information Sheets*. The cover and examples of product descriptions are shown below.



UNIPAC/11 860 00 DESCRIPTION P.I.S

Vaccine carrier
3504.3H

COMPANY NAME & ADDRESS

THERMOS
Thermos Avenue,
Norwich, Connecticut 06360
U.S.A.

Tel Tex TEL: 203 887 1671 TIX 628948

SIZE AND PERFORMANCE

Vaccine storage cap	17	lts	Robustness in drop test		Good
Cold life w +32C in hrs, with without openings	10	48	Cold life w +43C in hrs, with without openings		--
Weight fully loaded	40	Kgs	Internal lining material		Polye
Weight empty	18	Kgs	External surface material		Polye
No of icepacks reqd	4		Lid type & fixings		Remov
Icepack type	E5 01		External dimensions	24 x	24 x
No icepacks supplied	4		Internal dimensions	15 x	15 x
Minimum order	4		Vaccine storage dims	10 x	10 x
Insulation material	Polyurethane		Insulation thickness		40
Reports	CATR 29957 020 & UNIV I 1986				

1986 PRICES $US (FOB) Revision date 06 04 86

Qty Price 1 $21 70

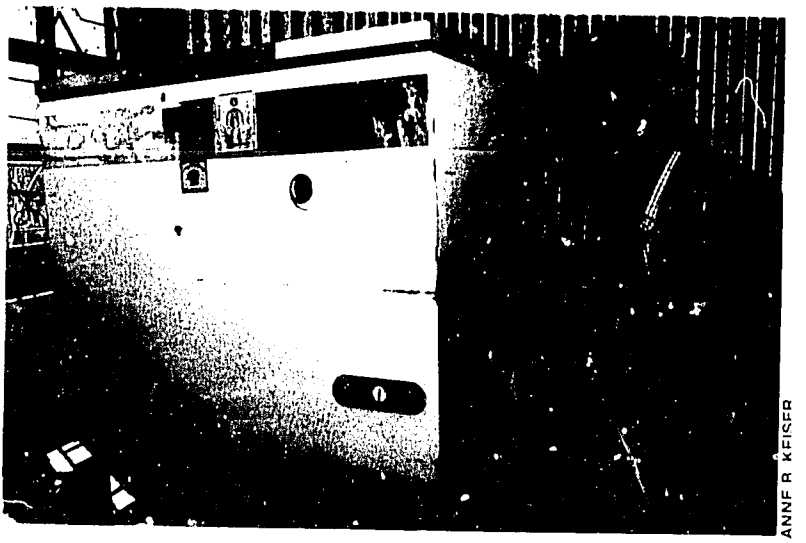
UNIPAC/11 860 75 DESCRIPTION P.I.S

Vaccine carrier
EPI PE 1.5

COMPANY NAME & ADDRESS

POLYFOAM CHEMICAL CORP
32 Miller Street
San Francisco Del Monte Ave
Quezon City
PHILIPPINES

Who will pay for spare parts and fuel to keep cold chain equipment functioning? These costs far outweigh the initial purchase price of equipment.



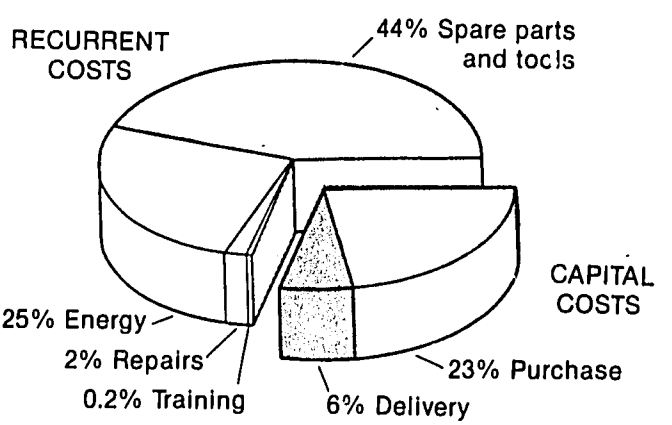
ANNE R KEISER

Costs Of Cold Chain Equipment

Start-up costs of providing cold chain equipment, vaccines, and injection equipment for a population of 10 million are estimated to be almost $2 million.

Surprisingly it is not the initial costs of purchasing equipment, but the *recurrent costs* of the cold chain which account for the largest proportion of operating costs, as shown below.

Lifetime Costs of Cold Chain Equipment



SOURCE: EPI/WHO.

Vaccine And Cold Chain Equipment Listing For National EPIs

The following is a listing of items that are likely to be needed for most national EPIs. Many programs will not include school entry vaccinations.

Vaccines	BCG (20-dose vials) DPT (20-dose vials) Measles (10-dose vials) Oral Polio (20-dose vials) DT (20-dose vials) school entry* BCG (20-dose vials) school entry* Tetanus toxoid (20-dose vials) for women of child-bearing age
Central Level Vaccine Storage	Cold Room, +4°C, 30 cu. meters −20°C Freezers Ice-pack freezers Thermorecorders Alarm systems Standby generator
Central Vaccine Distribution To Regions	Refrigerated vehicle*
Regional Vaccine Storage	Ice-lined refrigerators Ice-lined freezers Contact thermometers Alarm system Ice-pack freezers
Regional Vaccine Distribution To Districts	Cold boxes, 25 liter Ice-packs, 0.6 liter Transport, 0.5 ton van*
District Vaccine Storage	Refrigerator/freezer Thermometer Cold box, 25 liter Ice-packs, 0.6 liter Vaccine carriers Ice-packs, 0.3 liter
Health Center Vaccine Storage	Refrigerator/ice-pack freezer Thermometer Cold box, 10 liter Ice-packs, 0.3 liter
Outreach Vaccination And Vaccine Collection	Motorcycle, 80cc* Vaccine carrier Ice-packs, 0.3 liter
Vaccination Equipment At Health Center Level	0.05 ml sterilizable plastic syringes 0.5 ml sterilizable plastic syringes 5.0 ml mixing syringes forceps Heater, kerosene Steam sterilizer, 42 syringe Needles, 26g, 10mm (BCG) Needles, 23g, 25mm (DPT, Measles) (22g, 30 mm optional) Needles, 18g, 76 mm (for reconstitution) Timer clock

*Optional

Adapted from: *The Cold Chain Product Information Sheets*, WHO/UNICEF, 1986-87.

Cold Chain Equipment Supplement

Item	Model	Where Used	Power Source	Cold Life*	Comments
Cold Rooms (Walk in)	–	National/ central level	24 hour/day electricity with automatic backup generator	N.A.†	Cold Room "packages" including installation usually purchased by tender bid. See information on procedures for buying cold rooms in the *Cold Chain Product Information Sheets*
Refrigerated Vehicles	–	National/ regional level	Three main types: 1) Cooling unit fitted to engine of vehicle (cooling unit does not operate unless vehicle is running). 2) Separate cooling unit fitted to truck body with separate gas or diesel motor	N.A.	Usually only justified for very large programs (e.g., countries with populations over 75 million)
			3) Refrigerator mounted in back of a standard vehicle		Rarely justified
Refrigerators and Freezers					
Ice-Lining Refrigerator	Electrolux 1151 ice-lining (can be used as either a refrigerator or freezer)	Usually district stores, or any level of cold chain with at least 8 hours of electricity per day	Electricity 220V only	N.A.	Ideal for areas where electricity is intermittent. Water-filled tubes that line walls freeze to maintain cold temperatures. Same machine can be adjusted to be used as either a freezer or refrigerator. Relatively expensive to use uniquely as a freezer
Ice Pack Freezer	Electrolux ice pack freezer, compression type TFW 791	Any level of cold chain where large amounts of frozen cold packs frequently needed for shipping vaccines or supplying cold packs for outreach activities	Electric 220V; kerosene and gas models also available	N.A.	Has 50-liter storage space for ice packs. Freezing many cold packs in freezers where vaccines are stored may raise internal temperature

*At 43°C outside when kept closed × †N.A. = Not Applicable

Continued

Refrigerators and Freezers (Continued)

Item	Model	Where Used	Power Source	Cold Life	Comments
Refrigerator and Freezer	Sibir V240 Series (68 liter vaccine storage capacity plus 30 liter freezer)	Health centers, district stores	Depending on model chosen, can be electric (AC) and gas, or electric (AC) and kerosene	N.A.	Appropriate for programs operating in areas where kerosene or gas refrigeration needed. Accessories include external thermometer
Health Center Refrigerator and Ice Pack Freezer	Electrolux RCW42 Series (20 liter vaccine storage capacity)	Health center	Depending on model chosen can be powered by electricity (AC or DC), gas or clean kerosene	N.A.	Compact refrigerator suitable for health centers that do not have extensive outreach services
Cold Boxes					
Vaccine Package	Various Manufacturers, Example: Normco, Inc. (US, others)	Used for shipping vaccines from vaccine manufacturer; can be reused for shipments from national stores, etc.	N.A.	Models listed in PIS** vary from 69 hours to 180 hours depending on quality of box.	Sizes vary from 12 liter to 36 liter capacity. Vaccine packages are essentially insulated cardboard boxes; icepacks not included
"7 Day" Cold Box	Electrolux RCW 25	Excellent for shipping and outreach by vehicle	N.A.	156 hours	22 liter vaccine storage capacity; includes 24 ice packs
Vaccine Carrier	Thermos (US)	Transport from district stores and health centers to outreach activities	N.A.	34 hours	1.7 liter vaccine capacity. Four ice packs included
Vaccine Carrier	China National Light Industrial Products (China)	Transport from district stores and health centers, to outreach activities.	N.A.	56 hours	1.5 liter vaccine capacity. Four ice packs supplied. A good example of how locally-produced product may be cheaper & have longer cold life than US product
Icepacks	Various Manufacturers	Needed for all cold boxes. Two sets should be purchased so that one set can be frozen while the other set is being used	N.A.	N.A.	Icepacks should be of a size suitable for freezers, cold boxes & vaccine carriers used in country

**Product Information Sheets

ANNE B. KEISER

Injection Equipment

In no other area of EPI is the gap between recommendation and field application so wide as with injection practices. Despite years of EPI training programs, injection equipment is often inappropriately used due to lack of adequate supplies and insufficient sterilization.

The following pages compare and contrast injection equipment. Currently, three major options for syringes and needles are available to immunization programs:

reusable equipment that is sterilized after each use;

disposable equipment that is thrown away after a single use; and

jet injectors.

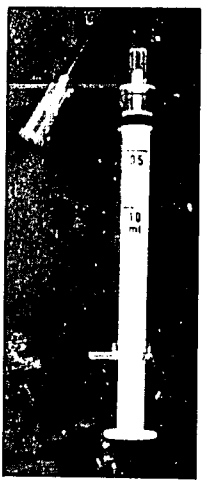
A fourth possibility is the self-destructing single-dose syringe now being tested.

Controversy continues over whether to use disposable or reusable syringes for EPI, with national programs deciding individually. Based on considerations of cost and logistics, WHO and UNICEF recommend the use of reusable plastic syringes. Sterilization equipment is necessary for primary health care generally.

Whether using disposable equipment or equipment that must be sterilized after each use, one rule applies: ONE CHILD, ONE STERILE NEEDLE, ONE STERILE SYRINGE.

Reusable Syringes and Needles

Reusable syringes and needles must be sterilized after each use. In the past, only glass syringes could be sterilized and were the only option available to immunization programs that could not afford to use disposables. However, glass syringes break easily, a liability which prompted the development of more durable plastic syringes that can withstand the heat of sterilization.



Reusable plastic syringes. Theoretically good for 200 uses, are good for fewer uses under rugged conditions.

PROS

Reusable syringes and needles are:

- good for 50 to 200 uses,
- the least expensive option,
- sterile if properly handled.

CONS

- Due to rugged use, syringes do not last as long in the field as they do under the ideal conditions of the laboratory.
- Shortages can develop because resupply is often not assured.
- Lapses in sterilization are common, particularly away from health centers, or when large groups are being vaccinated in one session.

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VERONIQUE LEGER

Reusable Needles and Syringes for the EPI

Item	Size	Use	UNIPAC No.	Price ($) (1986)
Needle (Luerlock)	10mm, 26 gauge	For BCG	07-515-02	0.45/12
Needle (Luerlock)	25mm, 23 gauge	For other vaccines	07-505	0.45/12
Needle (Luerlock)	76mm, 18 gauge	For reconstitution of vaccine	07-488-00	0.35/12
Syringe	0.05 ml	BCG, single dose	07-822-15	5.10/10
Syringe	0.5 ml	Other vaccines, single dose	07-822-20	2.00/10
Syringe	5.00 ml	For reconstitution	07-819-05	0.18 ea.

Adapted from: EPI Technical Series, Selection of Injection Equipment, WHO/UNICEF, 1986.

Disposable Syringes and Needles

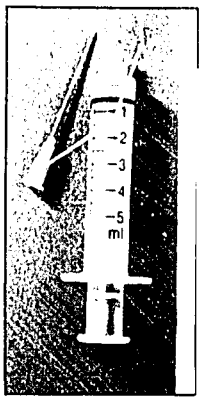
Disposable syringes are made of less durable plastic than reusables, and both the syringe and the needle are designed to be disposed of after a single use.

PROS

Single usage ensures sterility.

Disposables do not require sterilizing equipment and simplify work, particularly for outreach and mass campaigns.

Needles are always sharp.



CONS

Needles and syringes are easily diverted to unlicensed practitioners and then reuse is usually unsterile.

The logistics of shipping large numbers of syringes and needles is formidable, with shortages resulting in reuse.

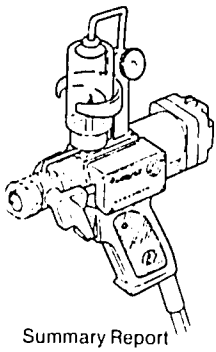
The cost is high.

Outside supply may be cut off.

Disposal must be thorough, by burning or secured burial of the plastic syringes; contaminated needles remain a hazard until burned or buried.

ANNE B. KEISER

This vaccinator is properly sterilizing plastic reusable syringes and needles; but the uncertainty of supply may prompt some EPI workers to reuse even disposable syringes and needles which withstand boiling poorly.



Summary Report on Jet Injector Testing in the Laboratory and in the Field, WHO/EPI, 1980.

Jet Injectors

Jet injectors operate by ejecting a thin stream of vaccine th penetrates the skin when the injector is held against it.

PROS

- Injectors can vaccinate large numbers of children quickly.
- Sterilization between injections is unnecessary.

CONS

- Jet injection equipment is expensive. One injector cos around $2,500, and a set of spare parts runs $700.
- The injectors require frequent repairs and adjustments, s vaccinators must be trained to use and repair equipme correctly.

Single-Use Self-Destructing and/or Pre-filled Injection Device

WHO and collaborating organizations, including AID, ar researching injection devices that auto-destruct after a single use

PROS

Auto-destructing devices do not require sterilization.

They cannot be reused.

CONS

Cost will be higher.

Field experience is limited for pre-filled devices, and no fiel trials have been conducted for self-destructing ones.

Pre-filled devices will require much more cold storage spac than an equivalent amount of vaccine in regular vials.

Staff must be extensively retrained to properly handle th devices.

The devices still require safe disposal.

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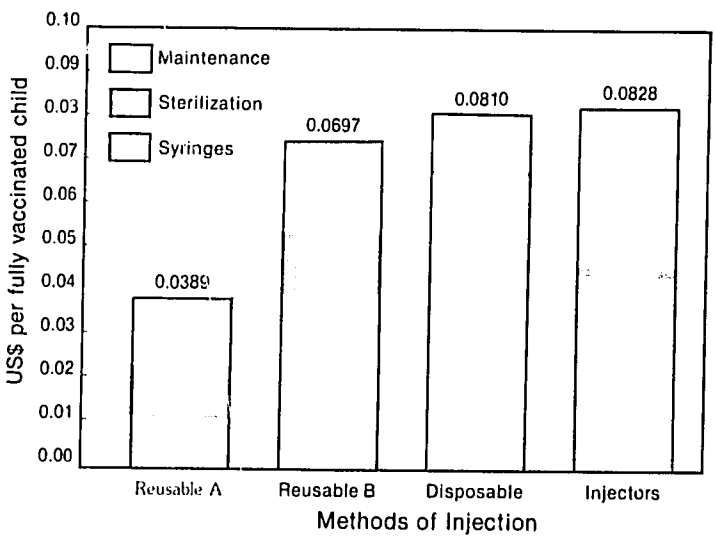
VERONIQUE LEGER

Costs of Injection Equipment

Clearly, the costs for purchasing and maintaining reusable syringes are lower than for disposables or jet injectors. Yet, opportunity costs of sterilization may make the latter cheaper for special situations, such as mass campaigns where several hundred children may be vaccinated at one site per day.

Costs of Injection Methods



Reusable A = lowest cost all-purpose syringe
Reusable B = EPI single-dose syringe

EPI Technical Series, Selection of Injection Equipment, WHO/UNICEF, 1986.

VERONIQUE LEGER

Sterilization of Injection Equipment

Sterilization is meant to kill viruses, particularly hepatitis B; pathogenic bacteria that cause abcesses, including staphylococcus and streptococcus; and spores of the tetanus bacterium. Because improper sterilization can result in serious infection, the technique must not be sloppy or casual.

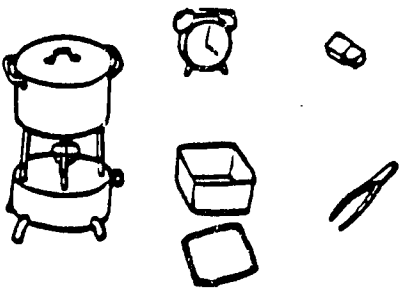
- Steam sterilization
  Steam pressure sterilization at +121°C for 20 minutes is preferred for EPI because this method guarantees that the equipment is sterile. Special steam sterilizers are available for approximately $50-$60 from UNICEF.
- Boiling
  Open boiling (100°C) for 20 minutes is still widely used because steam sterilizers have not yet become universal. Boiling is not strictly sterilization, but kills most harmful viruses and bacteria. The diagram illustrates techniques for disinfection by boiling. The same rules apply for steam sterilization. At high altitudes boiling must be carried out longer.
- Liquid disinfectants
  Liquid disinfectants are *not* recommended for sterilization of needles and syringes. Their use should be discontinued as they inactivate live vaccines, and after reuse may actually be a medium for bacterial and fungal growth.

Concern has been voiced that unsterile needles and syringes in EPI can transmit the virus that causes AIDS. Such an event has not been seen, and although it is possible, the number of potential transmissions are so few they would not be detectable epidemiologically. Transmission of hepatitis B and abscesses are more certain threats. EPI, as a leading public health program, is obliged to show an example of care and quality in its work.

Disinfecting Instruments by Boiling

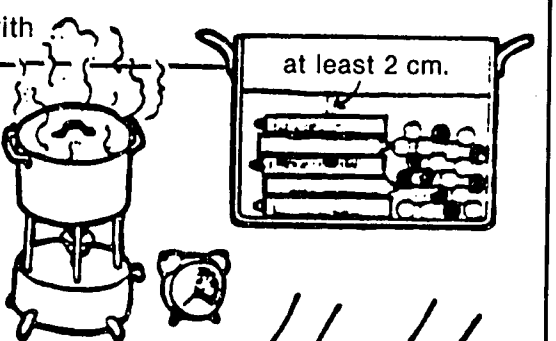
- Collect equipment needed for boiling syringes and needles.

  Kerosene stove
  Container with lid for boiling syringes and needles
  Clock
  Container with lid for cleaned needles and syringes
  Forceps
  Matches



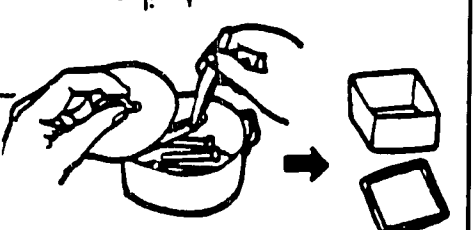
- Separate barrels and plungers of syringes.

- Cover syringes and needles with at least 2 cm. of water.
- **Boil for 20 minutes.** Use clock, watch or timer. At high altitudes boiling must be carried out longer.



- Turn off burner.
- Carefully pour out the hot water from the container holding the lid and saucepan firmly with both hands.
- Put the lid on firmly and leave it to cool.

- Lift out the syringes and needles and with a sterile forceps, place them in a sterilized tin.
- Put lid on the tin.
- DO NOT use syringes and needles until they are cool (hot needles and syringes can inactivate vaccines).



ADAPTED FROM: CCCD Job Aid, CDC.

Training For EPI

The nature of EPI operations and their quality depend greatly on the training of health workers both within the immunization program and as part of a broader effort throughout the health system. Training must be continuous and practical. Many immunization program managers and vaccinators have been trained according to the wisdom and technologies current at the time of their training. As our knowledge improves, however, and new technologies become available, countries must retrain these same workers in order to profit from the advances. Even if nothing changed about EPI, there would still be a need for ongoing training to improve skills that were not properly acquired, to correct wrong practices, to reinforce the initial training, and to train new workers. Thus training and supervision are intimately linked.

In life it is training rather than birth which counts.

Ihara Saikaku
The Japanese Family Storehouse;
or, The Millionaires' Gospel, 1600s

What Are The Types Of Training Necessary For Immunization Programs?

Standard WHO Training Courses

A series of generic EPI training programs for workers in the field and program managers has been developed by WHO. National programs can use them as they are or modify them to suit local requirements. The information may either be presented in group training sessions based solely on the material, or during in-service workshops as part of a broader curriculum. Self-instruction is possible but seldom happens. The following table gives detailed information on each level. The more a worker learns by doing, the better.

Training Materials

Is it feasible to rewrite information and training manuals as often as needed? Manual rewriting is arduous, costly, and time-consuming. Most manuals are only rewritten every five years or more. WHO training manuals from 1980 are already out-of-date. This very manual you are reading took over two years to prepare and will need revision the moment it is off the press. How the corps of EPI workers are given updated information is a critical problem for many immunization programs.

WHO EPI Training Courses

Content of Course	Typical Participants	Length of Course	Conducted by
National-level Manager Course: The course consists of a series of five modules for estimation of target diseases, program target setting, surveillance, and national and regional program priorities.	Senior-level EPI managers (country directors, other high-level staff)	10 working days	International staff and nationals who have completed course
Mid-level Managers: Training for management in all areas of mid-level implementation, including knowledge of target diseases, coverage survey methodology, cold chain management.	Regional/district EPI staff, staff of EPI in large health centers	10 working days	Same as above and mid-level staff who have completed course
Health Worker Training: *Immunization in Practice: A Guide for Health Workers Who Give Vaccines.* This course consists of seven modules that together make up a training manual for peripheral health workers who give vaccinations.	Health workers who administer vaccines	Up to 2 weeks	Mid-level staff
Logistics and Cold Chain: *Logistics and Cold Chain for Primary Health Care* is composed of 24 booklets designed to estimate the demand for vaccines and other supplies, and to store and distribute them properly.	National, regional, and district staff responsible for vaccine and logistics	Up to 4 weeks	National staff
Refrigerator Repair: *The Technician's Handbook for Compression Refrigerators* is actually a four part series covering repair techniques, troubleshooting, and keeping stock. It is a "hands-on" course.	Repair technicians at all levels	10-12 working days	International and national cold chain experts

Integrating EPI Training Into Professional School Curricula

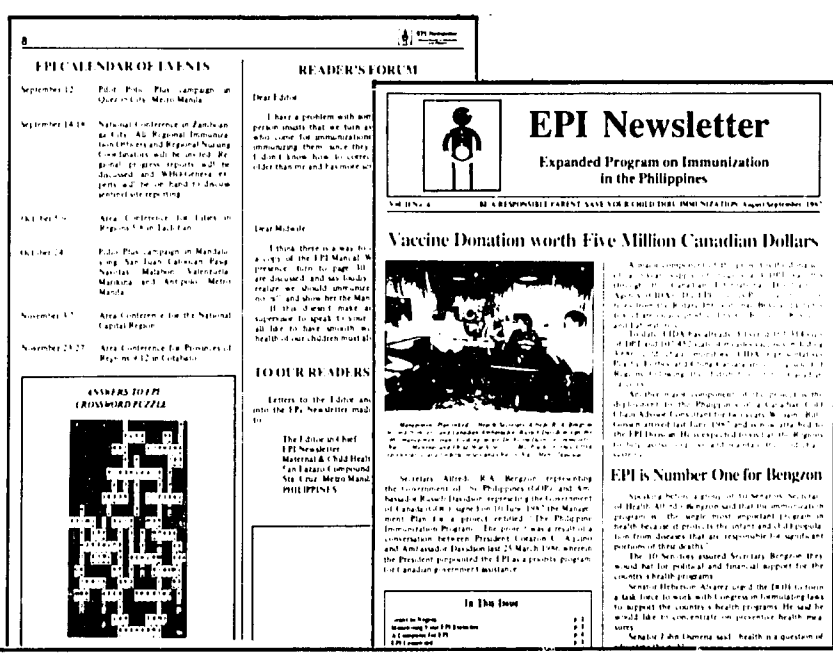
The directors, administrators, and vaccinators of the future are now studying in the medical, nursing, and public health schools of developing (and developed) countries. While standardized training materials for professional schools have yet to be developed, presentations and training materials may be prepared locally to introduce students to EPI. Internships and practicums can also be developed as time and resources permit.

Country-Specific Health Worker Training Materials

To make information more relevant to local culture and circumstances, EPI manuals, training courses, and newsletters are being increasingly developed by national programs as alternatives to standardized international manuals.

Philippines EPI Newsletter

One good example of how health workers can be kept up to date on new developments is a newsletter developed by the Philippines EPI. This newsletter is mailed directly to peripheral health workers at the delivery level in the Philippines and contains articles on the EPI calendar of events, feedback on evaluations, and a readers' forum, among others.



VERONIQUE LEGER

Social Sciences In EPI

Many EPIs can achieve coverage levels of 50-60% by hectic imposition; but to go beyond, or even to maintain the levels achieved requires a willing and informed citizenry. Therefore, planners of EPI have started to pay close attention to the social organization, cultural practices, and beliefs of the people. The following five questions outline the areas that must be taken into consideration when planning an EPI.

What social, economic, or cultural factors help determine incidence, severity, or outcome of the various vaccine-preventable illnesses?

How do parents try to protect their children from illness, and why would or would they not choose vaccination as one means?

Why do parents fail to bring children for subsequent vaccinations?

Why do health workers fail to vaccinate even when a susceptible child and viable vaccine are both at hand?

How can vaccination coverage be increased? How can vaccinations be made convenient, accessible, and safe?

Social Science Investigation Techniques

Social scientists use different approaches to investigate these questions:

Ethnography

Ethnography is an instrument of anthropology that describes human behavior and relationships in their physical and cultural contexts. Classically, the respectful, trusted investigator conducts intensive, repeated interviews with individuals and small groups in their own language; directly observes behaviors over time and under varying circumstances; and creates a framework of interpretation.

The strengths of these rigorous approaches are the richness of discovery and depth of the analyses. The discoveries, however, may be unique to the small group or area being studied. Also, interpretations can be colored by the observer's own unavoidable biases. The findings, however, can inform the design of a larger survey with statistical validity.

The knowledge-attitude-practice (KAP) survey

The KAP survey has been in use for a long time, originating with family planning programs. Structured and often lengthy questionnaires are administered to individuals to discover what people know about an issue, how they feel about it, what actions they take, and where their information comes from.

PAHO

It is probable that, on its own, the KAP survey gives only a superficial view of events and a biased one at that. For instance, many KAP surveys find parents reporting that they failed to have children vaccinated because they did not know where or when to go; deeper, more personal interviews suggest fear of the vaccine, fear of the system, and incongruence with traditional beliefs on prevention. The structure of the survey delimits what is discovered so that subjective attitudes may not emerge. Also, bias can be introduced by the interviewers themselves, who may not be well trained or motivated, or who may be perceived as outsiders.

On the other hand, the KAP survey relies on a large number of respondents, which ensures statistically valid data. From this information, correlations with observed behavior and epidemiologic data are possible. Because the survey is standardized, changes in successive surveys can be tracked over time.

KAP Surveys, Ecuador, Egypt, Honduras

Of the families of children failing to be vaccinated in Ecuador, 32% feared vaccinations or were otherwise misinformed, 18% found the medical system inaccessible or unresponsive.

Reasons children failed to begin or complete vaccination series (N=1145, Ecuador):

Family has fear of, or incorrect ideas about vaccination	32%
Child was ill that day	29%
System failure (access, communication, availability)	18%
Family unaware of EPI	13%
Child already had the disease	6%

In Egypt, only 24% of 900 mothers knew measles could be prevented by vaccination and only 9% knew DPT was given in 3 doses. However, 99% knew about polio vaccination because this had been the subject of a special television campaign.

In Honduras, although overall knowledge about the specifics of vaccination (timing, doses) was meager, a significant correlation between knowledge and acceptance of vaccination was found.

Intercept studies

These studies pose a few questions about a particular item of interest to people in public places such as a marketplace, a busy crossroad, or a place of worship. This is particularly useful in testing the design of a product or educational message (printed or graphic), or logo.

Focus groups

Focus groups bring together six to eight people from one particular stratum (working women, mothers, farmers, pediatricians) who are, preferably, strangers to one another. A skilled group leader guides (or "focuses") the discussion on a particular product (soap, medicine, cars) or idea (vaccinations, oral rehydration therapy, contraception). A productive session yields attitudes and preferences which often do not come out of KAP surveys. The information, which is usually abstracted from three to five different sessions, may then be built into a KAP questionnaire.

The weakness of the focus group is in trying to generalize the findings to the population as a whole. Also, what people *say* in a pleasant, facilitated group may not correspond to what they *do* in their regular environment.

Critical incident technique and exit interviews

These techniques are used to observe what happens in a clinic between health workers and patients to discern how health workers understand and approach their jobs; and what parents understand from the encounter.

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CLAUDE BETTS

The market place as a place to conduct a marketing study.

What have we learned from such studies?

Preliminary data from many countries suggest that there is still much to learn about people's attitudes towards vaccinations and the vaccine-preventable diseases. Most mothers want their children to be protected but may not understand how vaccination provides protection. Infecting a body with a mild illness to guard against a more severe one is not an easy concept to convey. Many families believe measles is unavoidable—is, in fact, necessary for a child's growth—so they hurry to expose their children when a case of measles is nearby. Many mothers consider infants too fragile for vaccination, particularly if they are ill at the time, which is a misconception also held by the majority of health workers. Mothers also implicitly weigh the costs (in time, effort, money) of having children vaccinated now against the potential of less disease later. They may therefore consider the marginal cost to go for a third dose of DPT, for instance, to outweigh the marginal gain.

The Exit Interview

In one African country 60% of mothers whose children received a vaccination in the clinic, thought the injection was a medicine for the illness the child had that day.

Misconceptions about the process of vaccination are numerous. Some health workers think antibiotics given for an infection on the day of vaccination destroy the vaccine in the body just as they destroy germs. Because clinics schedule special vaccine sessions, some mothers think a vaccine is effective only if given on a particular day, and if they miss the day, it is pointless to return. Some health workers start a whole vaccination series all over again if the child comes late for a subsequent dose. Also,

CLAUDE BETTS

Many mothers in developing countries put in 18-hour days to provide and care for their families. Going for vaccinations must be a calculated decision about use of precious time.

mothers may be put off by rude treatment, long waiting lines, and unsterile or painful injection techniques.

Observations at clinics will often reveal how health workers, used to shortages and undependable supply, will refuse to open a 10- or 20-dose vial of measles vaccine if only one or two children come for vaccination. Some health workers still think measles vaccine is very expensive, as it once was. Worry over wastage was standard teaching in a 1980 WHO training manual, so the health workers may have learned well what they were taught, but not been updated on current recommendations.

Social Marketing

Besides learning what health workers and families know about vaccination, "market research" can also help the EPI determine overall organization and orientation of the program. For instance, this "product" oriented research can answer the following types of questions:

- What times of the day, the month, the year are best to offer vaccinations?
- Where would parents most prefer to come for vaccinations?
- How much inconvenience would parents endure to get their children vaccinated?
- Would parents pay for effective, safe vaccinations?
- How might clinics be better organized to provide vaccinations on a routine basis?
- What side effects do parents fear and how do they manage them?
- Is there anyone to reassure them or care for serious complications?
- Is vaccination socially acceptable?

The results of market research are the basis for "social-marketing." Briefly defined, social marketing is the design, development, promotion, and "sale" of a product or an idea for the social good. Social marketing, which follows the same principles as commercial marketing, has been applied successfully to oral rehydration therapy (ORT) in several countries but less often to EPI.

টিকা ৬ টি মারাত্মক রোগের হাত থেকে
আপনার শিশুকে রক্ষা করে

"MONI" is the logo for EPI in Bangladesh.

It is within the family, where the modern (generally Western) health systems interact with the traditional social systems, that most health interventions succeed or fail.

W.H. Mosley
"Child Survival: Research and Policy" in *Child Survival: Strategies for Research*, Cambridge U. Press, 1984

The design of a social marketing effort for vaccination must therefore pay attention not only to the "consumer," but also to the "product" in the context of the community and home, such as:

- strategies of delivery;
- vaccine schedules;
- timing and support of health workers;
- supply of vaccines; and
- evaluation and correction of program flaws.

If the "product" is flawed or unavailable, no change in the consumer's behavior will last.

Unfortunately, "social marketing" has an aura of behavior manipulation by clever use of social sciences—getting people to do what we want them to do. In its best sense it is a respectful method for bringing information to a wide audience, quickly, so that people may make decisions in their own best interests. Mass media may also create an atmosphere of social acceptance for vaccination.

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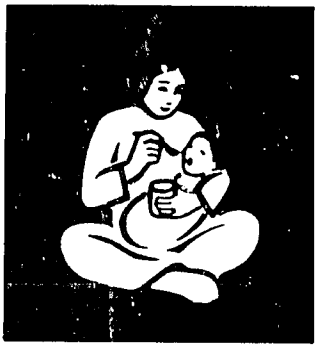
The logo for the Egyptian National Control of Diarrheal Diseases Project—the most widely recognized advertising symbol in Egypt.



Marketing Plans

MODEL	Specific to ORT Program as Actually Applied
Set Goals and Targets	Outcome goals: reduced diarrheal disease, mortality, undemutrition. Process goals: mother and provider use/understand ORT.
Establish Target Group Segmentation and Prioritization	Rural/urban mothers with children under three, physicians, nurses, pharmacists, others.
Do Market Research	What target groups know about diarrhea, where they go and what they like for treatment, what appeals in packaging, what media channels they use, etc.
Define Marketing Mix (Four P's)	
Product	Identify product(s)—Oralyte/salt-sugar.
Price	Establish price to charge and profit margin for pharmacist that will move product.
Promotion	Promote via IEC/training.
Place of Distribution	Distribution—determine best channels for product outlet (homes, private clinics, MOH, pharmacies, traditional birth attendants).
Develop Marketing Strategies, Priorities	Where to start campaign, degree of urban/rural penetration, what product to prioritize; what market share of different products to aim for.
Implement Strategies	Get product(s) out, get IEC campaign started, train people, manage program.
Evaluate Product "Sales"	Monitor activities, evaluate process, evaluate outcome, feedback for management.

Continued

MODEL	Specific to EPI as a Possibility
Set Goals and Targets	Outcome goals: reduced morbidity, mortality of neonatal tetanus, measles, polio. Process goals: increased coverage especially by completed series.
Establish Target Group Segmentation and Prioritization	Rural/urban mothers with children under two; EPI and PHC workers; "gate-keepers" (fathers, traditional healers, TBAs).
Do Market Research	What stops children and mothers from getting initial vaccinations; what stops them from getting subsequent ones; preferences on location, timing; knowledge of target diseases; risk-factor analysis of those who do not get vaccinated; conflict with current beliefs/knowledge; "missed opportunities."
Define Marketing Mix (Four P's)	
Product	Vaccine groupings (BCG, IPV vs. OPV); age at time of vaccinations; types of needles and syringes, or jet guns.
Price	Any user fees for anyone? In kind payment? Community payment? Opportunity costs to families, health workers?
Promotion	IEC/Training (T.V., radio, print, face-to-face, other).
Place of Distribution	Mobile units, static health posts, schools, outreach from health posts, pharmacies, markets, private physicians. Cold chain systems. Timing of vaccinations: season, time of day.
Develop Marketing Strategies, Priorities	Vertical program vs. integrated, urban vs. rural, universal or local, pulse campaigns, mass one-time campaign, two-dose vs. three-dose, two key vaccines vs. all vaccines. New antigen introduction.
Implement Strategies	Get products out, get IEC campaign started, train people, manage program, supervise.
Evaluate Product "Sales"	Monitor activities, evaluate process and outcome goals, feedback for management.

Children learn about vaccinations at school, and tell their parents. These children will someday be parents themselves.

Health Education

If social marketing is the "new kid on the block," health education done face-to-face is the veteran method to transfer information and concepts. Thousands of volumes of health education materials and audio-visuals have been developed world-wide, which have often been tailored to each society. The message in the materials must be tested as thoroughly as any put on television. Health workers need to be good communicators, have the time to communicate, and respect the families they are trying to reach. Not surprisingly, health education is difficult to do well at the personal level, particularly when the health worker is under pressure to achieve targets.

Written instructions are seldom sufficient. Is the mother literate and at what level? Are the materials culturally sound and relevant? Did the health worker engage the mother personally?

Human Behavior As A Variable In EPI

Human behavior is often disregarded in day-to-day management; rewards for desired performance are seldom considered in program plans and real disincentives to good work are allowed to creep in (usually without anyone realizing).

Let us present some vignettes—taken from real life—that illustrate how human behavior affects EPI, often in unintended ways.

Fining Nurses for Breakage

An old administrative rule states that if a nurse breaks a glass syringe he or she is fined.

RESULT: The nurse is reluctant to vaccinate children. (If the nurse's supervisor is strict about how many vaccinations are reported the nurse may be tempted to fabricate data.)

REASON: The nurse is too poorly paid and cannot afford a fine for dropping a syringe in use.

PCVs

Peace Corps Volunteers and their host-country colleagues ride a circuit on pick-up trucks repairing cold chain equipment and checking on supplies. The PCVs say the work is not "real" development, and, anyway, their counterparts are quite adept at the work. The PCVs are taken off the job.

RESULT: The circuit ceases, the pick-ups get assigned elsewhere, and the cold chain breaks down.

REASON: The counterparts really enjoyed the camaraderie and status of working with their "own" PCV. The job was tedious otherwise.

Cold Chain Monitor Cards

New cold chain monitor cards accompanying batches of vaccine vials have been distributed. These are cards with color indicators that gradually but irreversibly change over time, indicating the cumulative amount of exposure to excess temperature up to the point that the vaccines are no longer viable.

RESULT: The last vaccine recipient—the health clinic director—finds much of the vaccine already spoiled. The director ignores the cards.

REASON: The director knows no new vaccine will come for some time, but the pressure is on to achieve a target now. Besides, as the low person on the totem pole, the director might be blamed for the spoilage.

Fees for Health Workers

Each family pays the health worker for a vaccination card and then again after each vaccination is given. The health worker keeps half of the fee. Mass media inform parents about the vaccines and schedules.

RESULT: Increase in coverage.

REASON: Families and workers both know the system, each gets something out of it, and the recipient controls the reward.

Use of Health Centers

A poor mother who had just moved with her family from a small village to an urban slum, where her husband finally found work, heard an advertisement on the radio for *free* vaccinations at a government clinic. So, she took her youngest child on a crowded bus early the next morning to the clinic. She was embarrassed when she got there, though, because all the other mothers waiting were finely dressed and their babies were wrapped in expensive blankets.

She was even more upset when her turn came because the nurse elaborately swabbed a bit of dirt off her baby's arm which she had not done to the other babies, then demanded a fee that was all the mother had with her. She had to walk home, ashamed to be seen by so many strangers.

RESULT: The woman does not bring her child back for any further vaccinations. Instead, when the child comes down with measles she goes to a local injectionist, where most of her close neighbors go when their children get sick. The injectionist asks for only a little money, and gives injections quickly using his one syringe and needle.

REASON: At the clinic, the mother felt exposed, poor, vulnerable. She strongly preferred care from someone in a more familiar setting whom her neighbors trusted, even if—to our thinking—the care was inferior or even dangerous.

ANNE B KEISER

CHAPTER IV
Immunization Program Evaluation

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Everyone agrees evaluation of EPI is important. However, confusion greets those eager to find simple answers about what aspects of the program should be evaluated, when to conduct an evaluation, and how to go about doing it.

In strict terms, evaluation measures progress towards immunization program goals. Accordingly, a prerequisite to program evaluation is a clear statement of expected achievements. Evaluation should tell us whether the program goals themselves are appropriate and adequate. Evaluation should provide information to EPI managers they can use for program decisions.

Evaluation will never have its intended effect of assessing program goals if it is only conducted by experts or senior program managers, and then only at extended intervals. Immunization program evaluation needs to be a continuous process carried out at all program levels: where the vaccine is actually given, at administrative divisions, and, finally, at the national level.

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In general, evaluation can be used to assess one or more of the following qualities of immunization programs shown here:

QUALITY	MEASURED BY
Efficiency	Human, material, and monetary inputs related to achievements
Progress	Vaccination coverage levels
Effectiveness	Reductions in morbidity and mortality of target diseases
Adequacy	Level of resources committed to project, geographic expansion of project
Relevance	Appropriateness of EPI to the development objectives of a country, the desires of the people, and the local epidemiology of target diseases

ANNE B KEISER

Let observation with extensive view
Survey mankind, from China to Peru.

Samuel Johnson
Vanity of Human Wishes, 1749

ANNE B KEISER

The following table indicates evaluation techniques in use at different levels of immunization programs. Subsequent sections deal in greater depth with techniques that assess the most widely-used outcome indicators for immunization programs:

indicators of efficiency in EPI are tracked in the course of *monitoring and supervision*;

progress in increasing coverage is determined by *routine reporting* and by *vaccination coverage surveys;*

reductions in morbidity and mortality of target diseases are detected by *surveillance systems and surveys*; and

the adequacy and relevance of vaccination delivery are measured with *comprehensive program reviews, rapid program assessments, and cost analyses.*

Evaluation Of EPI
Where And When To Do It, How To Use The Data

Administrative Level	Evaluation Indicator	Technique	How often Done	Cost	Use of Data
Health Unit and Health Office	Number of vaccinations given by vaccine	Clinic register, stock count	Monthly	Low	Estimate vaccine requirements; compare doses delivered to children vaccinated
	Cold-chain adequacy	Thermometer, cold chain monitor, inspection	Twice daily and at each transfer of vaccine	Low	Remedy cold-chain problems, decide on vaccine viability
	Vaccination delivery management	Supervisory check-sheet and direct observation, clinic register for: —vaccine stock —vaccination technique —sterilization —adequacy of cold-chain —clinic vaccination sessions —when and why vaccination denied to child —EPI record card use by health worker, and retention by mother —community awareness	Monthly, quarterly	Low to Medium	Problem discovery and problem solution; reallocation of resources; retraining; reward scheme; detect delivery-level failures; conduit for informing program managers of field problems
Health Unit Health Office and District	Coverage	Comparison of doses delivered to eligible population	Monthly	Low	Method detects general coverage trends, and progress towards targets
		"75 House" survey of homes of children nearest health unit	During quarterly supervision	Low	Method examines vaccination status of children with excellent access

Administrative Level	Evaluation Indicator	Technique	How often Done	Cost	Use of Data
District and Region	Coverage	30-cluster sample survey	Annually or when routine reports indicate	Medium	Method detects coverage trends, and progress towards targets
	Cold-chain adequacy	Cold-chain monitors, inspection	At each transfer	Low	Restore cold-chain
(National)		(Rarely: test vaccine in laboratory)	(If large batch failure suspected)	(High)	(Decide on vaccine viability)
Region and District	Morbidity and Mortality	Cases and deaths registered by month	Monthly	Low	Detect regional and national trend in overall child-survival specific to diarrhea, measles, ARI seasons
		Surveillance by sentinel sites (hospitals, major clinics, and whole villages) for key diseases: measles, polio, neonatal tetanus, and pertussis	Monthly, quarterly	Medium	Detect trends, outbreaks, changes in epidemiologic patterns
		Measure disease incidence in adequate sample: measles, neonatal tetanus by questionnaire, polio by lameness survey	Baseline and then at major program review	High	Determine overall efficacy of EPI and formulate immunization policies
Any level*	Disease outbreak	Epidemiologic active case detection, measure vaccine efficacy by case control analysis	As needed, in EPIs with high coverage	High	Calculate vaccine efficacy
National	Program review	Full assessment of technical, logistical, managerial issues, cost-effectiveness analysis	Every 3-5 years	Very High	Redesign of program and inputs

*Special studies at any level: Operations Research into delivery methods, evaluation methods; serologic surveys for disease patterns; KAP, focus group and ethnographic research for mass media and health promotion.

Monitoring and Supervision

Monitoring and supervision is as much a program component as the cold chain and training. It shares with evaluation the characteristics of:

an orderly search for information;

computation of rates (percent of tasks done correctly, for instance); and

analytic use and feedback of data to make program changes and management decisions.

If monitoring and supervision are done well—that is, regularly, honestly, rigorously and with health workers getting feedback—one can feel quite confident that the EPI is working even before more formal program evaluations begin. The critical failure

Sample Indicators For Monitoring And Supervision

At The Health Center

Items typically checked weekly

____ Were all scheduled vaccination sessions held? If not, why not?

____ Were a sterile needle and syringe used for each injection?

____ Were there sufficient vaccines to meet all needs?

____ Was the refrigerator checked on a daily basis? Were all temperatures recorded, and in safe range (2-8°C)?

____ Was each mother informed about the need for future vaccinations and when to return?

Items typically checked monthly

____ What percentage of the monthly target population received DPT_1 or OPV_1 during the month?

____ What is the ratio of DPT_3 (OPV_3) to DPT_1 (OPV_1)?

____ What percentage of the monthly target population received measles vaccine? Were the ages correct?

____ Are cases of diseases preventable by vaccinations coming to clinics? How can they be prevented in the future?

____ Are all children coming to clinics, including the sick ones, being screened for current vaccination status and then given the necessary vaccinations?

____ Have there been any disruptions of stock or overstock (vaccines, needles, syringes, etc.)?

____ How often did supervisors come to visit? And, what were the obstacles or problems that needed to be solved? Were they solved?

Items typically checked quarterly or annually

____ Local coverage evaluation by "75 House" survey or other simple sampling method, particularly examining coverage levels and completion rates.

At The District/Regional Level

Items typically checked monthly

____ What was the total number of doses of each vaccine distributed?

____ What was the number of vaccinations by age and dose reported from centers?

____ How often were supervisory visits made?

____ What were the number of cold chain monitors showing breaks in the cold chain?

____ Were there any expired vaccines in stock or returned from health centers?

____ Were there any disruptions in stock or overstock of vaccines supplied to health centers?

____ What are the number of measles, polio, pertussis, and tetanus cases reported from sentinel sites?

Items typically checked annually

____ How many health units under jurisdiction have vaccination activities?

____ Were cluster sampling surveys of coverage done? Results?

____ Were estimates done of coverage by calculations based on vaccinations delivered?

____ How many cases of measles, polio, pertussis, and tetanus were seen?

____ What was the percentage increase in vaccinations given over the previous year?

Items typically checked bi-annually or as needed

____ Has a cold chain monitor evaluation been done?

____ Has a comprehensive regional evaluation been done?

At the National Level

Items typically checked monthly

____ Were monthly reports received from all regions?

____ How many vaccinations were performed monthly?

____ Were there any outbreaks of target diseases, and what was the response of health system?

____ What are vaccine stock levels?

Items typically checked annually

____ How many regions, districts, or zones participate in EPI?

____ What are the costs of the program?

____ Are there sufficient commodities?

____ Are all personnel slots filled?

____ Have coverage data been compiled? Results?

Items typically checked tri-annually or as needed

____ Was a comprehensive program evaluation done?

of supervision, however, is that health workers are seldom rewarded for good work and ineffectively sanctioned for poor work.

The checklist on the preceding pages for supervisors may be used by USAID and PVO project officers on field visits when they wish to assess how an EPI is doing at several levels of delivery.

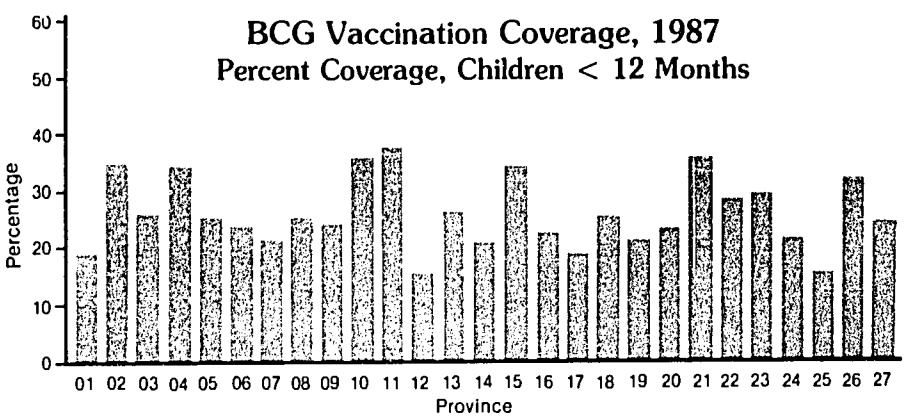
Computerized Management Information Systems

It is likely that all national EPIs will soon be using some type of computerized management information system. At its most elemental a computerized EPI information system tracks the number of vaccinations delivered by age of the child and location of delivery (by health center, district, or region). The system will then compute coverage rates automatically by comparing the number of doses delivered to the size of each target age group. Such information systems help determine program achievements, relative costs, and need for EPI supplies. Disease incidence and personnel may also be tracked. Thus, these information systems are intended for routine decision-making on a regular basis.

One example of such a system—the EPI Information System (EPIIS)—was initially developed by WHO's South-East Asia Regional Office with the Centers for Disease Control, and has been refined further by REACH. This system simplifies how data are compiled—making feedback of data to field managers more timely. Two pieces of software are linked in the program: a database program which accepts the raw data; and a spreadsheet program that produces clear tables and graphs from the data.

A hard disk with at least 20 megabytes of space is needed to run the EPIIS software. The program is simple to use; only about 2-3 days are required to train clerical staff in its use once the system is installed in an EPI, a process which can take 2-4 weeks by an expert programmer. A user's manual is now being developed.

Computed BCG coverage levels for by province in Indonesia in 1987 are shown in the EPIIS-produced graph below:



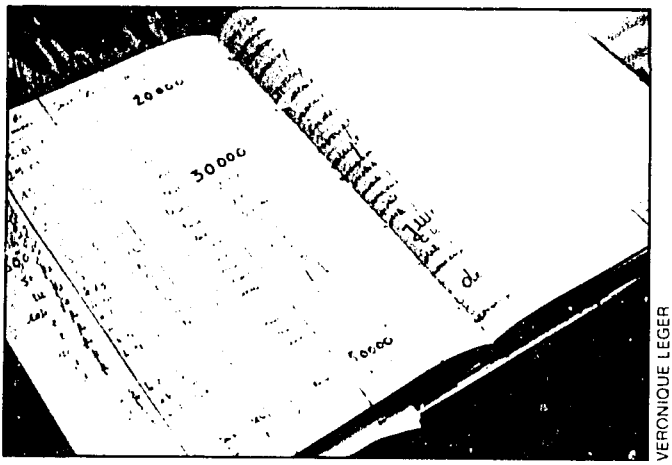
Assessing Vaccination Coverage

Vaccination coverage surveys are done to test the effectiveness of an immunization program. At a minimum they should measure four principal indicators:

- the percent of each age group of children vaccinated with each respective dose of each of the vaccines (the percentage of children who have received BCG, or DPT_1 vaccination is an indicator of access; the ratio of children receiving DPT_3 (OPV_3) to those receiving DPT_1 (OPV_1) is a measure of follow up and family acceptance; measles coverage is another indicator of EPI effectiveness as it is the last vaccine given at a specific age in life);
- the percent of each age group of children fully vaccinated (including measles at the correct age);
- the percent of women of childbearing age with each dose of tetanus toxoid; and
- the percent of families retaining vaccination cards (a sign of parent involvement and access).

The level of coverage may also be calculated from routine reporting on the number of vaccinations delivered to each age group. Coverage surveys can confirm the validity of routine reporting.

The ultimate objective of an immunization program is not simply to achieve high vaccination coverage but to reduce morbidity and mortality from the target diseases. Nevertheless, it is becoming increasingly clear that high levels of coverage have to be reached before substantial reductions in the incidence of the target diseases will be observed.



VERONIQUE LEGER

A common management target is for 80% of all children under one year to be fully vaccinated. In fact, this figure originated from the concept of "herd immunity," or the protection of an entire population if a large majority are immunized. The percentage of a population that will need to be immunized to reduce transmission, however, varies markedly by disease:

Virtually 100% coverage is needed with measles vaccine (and outbreaks still occur among the remaining susceptibles).

Live attenuated oral poliovirus vaccine may in fact require less than universal coverage to reduce transmission of disease markedly since the protective vaccine virus can spread through a population, protecting unvaccinated children (but the effective level of coverage seems to vary by locale).

The reduction in incidence of diphtheria with modest coverage by DPT suggests herd immunity.

The concept of herd immunity does not apply at all to tetanus, which has permanent reservoirs in the environment, or to pertussis which may be carried and spread by healthy persons.

Coverage evaluations provide information needed to make changes in program operations, particularly if some areas are less well covered than others. Also, they help to determine if the targeted reductions in morbidity and mortality are likely to be met.

National managers must resist the pressures to report figures of immunization coverage which are optimistic in order to demonstrate to national political leaders that their programmes are a success.

Ralph Henderson
Remarks to World Health Assembly,
May 16, 1988

What Techniques Are Used For Determining Vaccination Coverage?

Coverage can be estimated from both reported data and surveys. These methods are described briefly below.

Calculation Of Vaccination Coverage From Routine Tally Data Of Vaccinations

Rough estimates can be made of coverage by dividing the number of vaccinations given to infants, say, by the total estimated number of children in that group:

$$\frac{\text{vaccinations to under-ones}}{\text{total newborns during year}}$$

Though this method is commonly used on a national level (data are gotten quickly and cheaply), there are several potential problems that should be considered at any level:

- Target population estimates may be inaccurate and will distort the denominator of the calculation.
- The age categories given in routine reports of vaccination may be incorrect.
- The aggregated tallies may not be reliably computed at each level of reporting.

Vaccination Coverage Surveys

Because calculations of coverage from reported tally data can be unreliable, many immunization programs depend on special coverage surveys to assess program progress more accurately. Different survey alternatives are described below; decisions on the type of survey to be carried out will depend upon the resources available. Nevertheless, for all types of surveys, definitions must be made ahead of time on what documentation of vaccination is acceptable and what constitutes correct vaccination. Some examples follow.

> Is it necessary for a vaccination card to be presented for verification or will the interviewers accept the parent's verbal information? (We strongly recommend the former, though it is useful to also keep track separately of verbal histories of vaccination if cards have been lost. Though many mothers will not know the names of the vaccines their child has received, most will be able to identify the body site of administration.)
>
> What constitutes acceptable coverage in an individual child? Must a child complete all doses of the six EPI antigens by age one; or, is vaccination correct if a child has received all doses between 12 and 23 months?

By a small sample we may judge the whole piece.

Miguel de Cervantes
Don Quixote, 1605

Will a child who received all three DPT/OPV be credited with correct vaccination if given at intervals longer than one month?

Does measles vaccine given at eight months plus two weeks of age count?

In our experience, countries tend to use overly stringent definitions.

The following are vaccination coverage survey methods.

Cluster Sampling Survey*

The most commonly used method of coverage evaluation is by cluster sampling. The standard cluster sampling methodology adapted by WHO for the EPI selects 30 clusters from an area whose population is known or can be reasonably estimated (e.g., by adding annual growth rate increments to a previous census).

Cluster sampling takes place in two stages. First, clusters are chosen from towns, villages (or other recognized communities) in proportion to their population size, so that larger communities contribute more clusters. A total of 30 clusters are chosen, sometimes nationally but more often regionally. Clusters may be chosen entirely from urban, or from rural populations, or chosen by some other characteristic if program managers want to know about coverage of specific populations. The second step involves selecting one household at random per cluster as a starting point, and then visiting house-to-house until seven children of the chosen age group (usually 12-23 months old) are located. In all, 210 children then make up a 30-cluster sample (30 x 7).

*Detailed explanation of this survey methodology is found in the WHO EPI Mid-Level Managers module *Evaluate Vaccination Coverage*.

When done correctly, cluster sampling is relatively inexpensive, fast, and adequate, and is capable of revealing trends over time. The precision of the estimate is plus or minus 10%, 95% of the time. So a coverage of 70% would represent a "true" percentage of 60% to 80% in 95 out of 100 identical surveys. Percentages from individual clusters alone have no statistical validity.

The advantages and disadvantages of cluster sampling are summarized below.

Advantages

- It is simple, honored by practice.
- It gives population-based estimates of coverage.

Disadvantages

- Bias in selection of starting households in clusters tend more often to overestimate coverage.
- The small number of children surveyed over a relatively large area does not reveal performances at an individual health post level.

Statistical analysis is necessary to discover if an increase in coverage is truly significant and not simply by chance. As a short-cut, the following table indicates the changes in coverage rates that must be found, at a minimum, before one concludes improvement or deterioration from one survey to the next (assuming, of course, that the follow-up survey was comparably done).

For 210 Children In 30 Clusters

Coverage level obtained from first survey (%)	Minimum coverage finding needed on next survey to claim improvement (%)	Maximum coverage found on next survey to decide if it means deterioration (%)
10	20.6	2.8
20	33.9	8.9
30	45.5	16.5
40	55.9	25.1
50	69.1	30.9
60	75.6	43.3
70	83.2	54.9
80	90.6	66.7
90	97.3	79.2

Note: The minimums and maximums are not precisely within plus-minus 10%; this is due to statistical rules for reliably detecting differences at this sample size in clusters.

Examples Of Surveys

Let us apply the information from the table on changes in coverage rates to the results of hypothetical pairs of surveys done comparably but, say, a year apart:

Coverage Results

Survey-1	40%
Survey-2	53% — *not* a significant increase
Survey-1	60%
Survey-2	77% — a significant increase
Survey-1	50%
Survey-2	34% — *not* a significant decrease
Survey-1	80%
Survey-2	65% — a significant decrease

VERONIQUE LEGER

COSAS

Standard 30-cluster sampling surveys contain a wealth of information that usually lies buried in EPI archives: Is the program successful in vaccinating children before their first birthday? Are children being turned away for vaccinations they should get? How much does each type of health care facility contribute to total vaccinations?

Tabulating this information manually with a hand-held calculator is possible, but tedious and time-consuming—several days work for one person. To compile the data more easily, computer programs for analyzing coverage survey data are being developed.

Since the 30-cluster methodology was developed to give statistically valid information for dichotomous data only (questions that can be answered with a yes/no response), these additional analyses will not necessarily represent the whole program; yet, they can provide useful indicators on how the program is performing.

The computer program which shows the most promise was developed originally through WHO: A Coverage Survey Analysis System (COSAS). It has been field tested and is now being further refined. COSAS requires DBASE III+ software; a hard disk is not needed but will reduce computation time significantly.

Training new users of COSAS is simplified if they are already familiar with DBASE III+. About one week is needed to train a supervisor who has no previous knowledge of the program how to use DBASE III+, do data entry, interpret the data, and do trouble-shooting. A trained operator requires 9 to 10 hours to set up the program for each survey, enter the survey data, and run analyses.

Analyses generated by the program include:

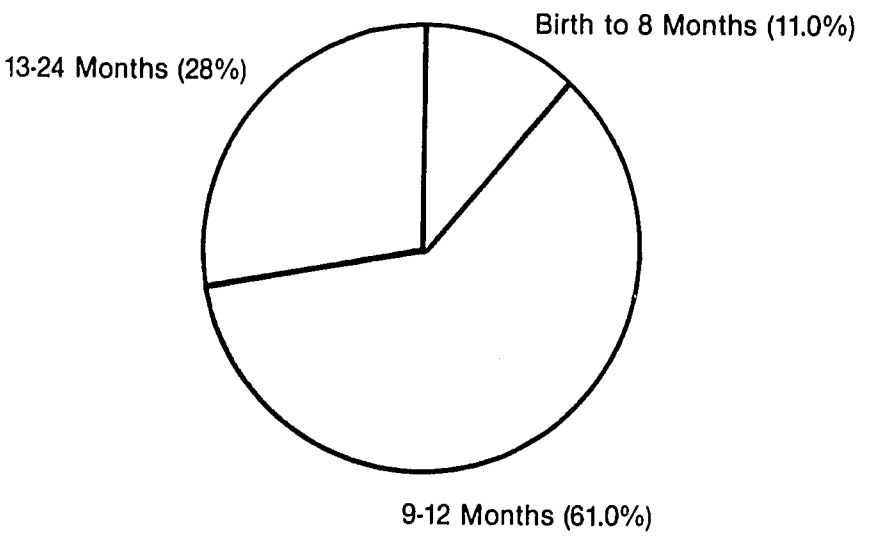
- percentage coverage levels for each vaccine dose and for children who are completely vaccinated; coverage levels can be determined for any given age (such as under-ones) and at any given date—following special campaigns or pulses, for example;
- age profiles for all antigens: how old were the children surveyed at the time that they received each antigen? (this will show how successful a program has been in reaching children at an early age);
- DPT and polio dose intervals: classifies the number of doses delivered according to the interval in weeks between the first and second, second and third, and the first and third doses;
- a measure of "missed opportunities" by classifying children surveyed according to the number of vaccination sessions they attended when they did *not* receive all of the vaccinations they were eligible for;
- classification of vaccine doses delivered by provider—were children vaccinated at hospitals, health centers, MCH centers, or outreach posts?

It is hoped that the program will be ready for general use soon.

The following graph produced from a COSAS analysis shows the breakdown by age at the time of measles vaccination for children surveyed:

Distribution of Measles Doses

By Age at Vaccination



Lot Quality Assurance Sampling (LQAS)

LQAS judges the quality of coverage within an area covered by a specific health center or other vaccination point. Operationally, this means that immunization program supervisors can identify problematic areas and take steps to remedy obstacles to higher coverage at the *local level*. This method originated from industrial quality control methods. Samples taken from groups of items are kept to the minimum number needed to identify groups that fail to meet a specified standard of quality (usually eight to fifteen items, or children as in our case).

LQAS remains largely theoretical; it has been little tested in practice. The critical problem with LQAS is getting an adequate sampling frame. For a true random sample to be selected, every household in the sampling area would need to be enumerated, a

LQAS

If, with a local random sample of 12 children of a certain age (12-23 months, say), one finds X children unvaccinated, what is the likely coverage in that locale in percent and what is the approximate confidence interval (that is, the "true" answer lies between what limits)?

One Finds # Un-vaccinated	Estimate Of Coverage (%) Then Is:	With Approximate Confidence Interval (%) Of:	Conclusion:
0	100	85 - 100	Good Coverage
1	91	70 - 95	
2	83	60 - 90	
3	75	50 - 85	
4	67	45 - 80	Uncertain if good or poor
5	58	35 - 75	
6	50	30 - 70	
7	42	25 - 65	
8	33	15 - 55	
9	25	15 - 45	Poor Coverage
10	17	10 - 35	
11	8	5 - 30	
12	0	0 - 15	

If "good" coverage is over 50% and "poor" coverage under 50%, we can only be confident of our answer if the confidence interval excludes 50%. For example:

1) All of the twelve children are vaccinated (zero are un-vaccinated). Coverage is 100%. The true answer lies between 85%-100%. Good.
2) Ten children are un-vaccinated (only two vaccinated). Coverage is 17%. The true answer lies between 10%-35%. Poor.
3) If four to eight children are un-vaccinated, the confidence intervals overlap 50%. Uncertain.

formidable and often unrealistic task. This obstacle has yet to be resolved. Random selection of children coming to a clinic may suffice, however, to describe coverage at least in that sub-population.

It is important to note that while LQAS cannot be used to calculate precise percentages of vaccination coverage at the local level, it allows a broad estimation of coverage which can then be classified as "acceptable" or "not acceptable." The results of LQAS samples from several individual areas could be combined to calculate with greater statistical validity the coverage of a larger target area.

The advantages and disadvantages of LQAS are summarized below.

Advantages

The major potential advantage that LQAS has over cluster sampling is that it can be used to identify specific vaccination delivery units responsible for successes or failures, with a much smaller sample.

Disadvantages

True random sampling of eight to fifteen children is hard to guarantee. The method has had few trials, and its real value is still unknown.

"75 House" Survey

This method was used for the first time by the Centers for Disease Control in Uganda in 1984 to assess both ORT use and EPI coverage in one of the country's districts. The idea is that if those 75-100 households closest to health facilities offering vaccination are poorly covered, then the local efforts are poor indeed; if well covered, one still must determine what happens beyond the immediate catchment.

This type of survey is most useful in areas where the population is stable, where overall coverage is unknown, and where one wishes to assess the minimum efficacy of health services.

Advantages

It is useful as shock value if one finds those areas closest to health facilities to be poorly covered. If the survey is done by health workers themselves it brings them into contact with the populations they serve, sharpens their awareness of community needs and, one hopes, motivates them to improve services in the community.

Disadvantages

If improvements in coverage are made, they may be only to the same local areas and not in the whole catchment population.

Vaccine Efficacy Surveys And Serologic Surveys

There are limitations in using reporting systems and coverage surveys to assess immunization program effectiveness, particularly if the vaccines administered were not potent enough to provide immunity. Also the surveys may be conducted incorrectly and not give a true picture. Two other methods give a more refined view.

Vaccine efficacy surveys track an outbreak of a disease and determine the vaccination status against that disease in sick children. If the overall coverage for that vaccine is known approximately, one can determine efficacy from a logarithmic graph, shown below. Efficacy below 80% generally means a cold-chain or vaccine failure needing further investigation. Vaccine efficacy studies require strong surveillance systems or epidemiologists able to do outbreak investigations. The curves show also that the higher the coverage (PPV) the more cases will be seen among vaccinated children (PCV), as no vaccine is 100% effective.

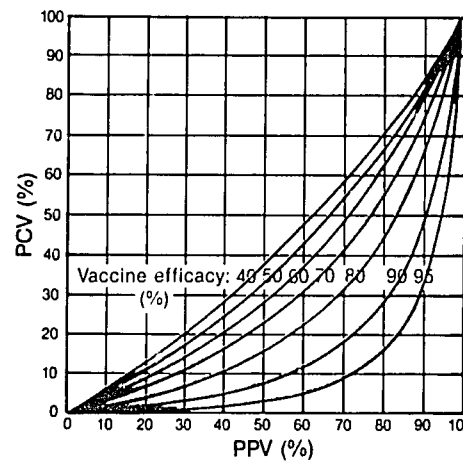
Field Vaccine Efficacy

Vaccine efficacy is measured by calculating the attack rates among vaccinated and unvaccinated persons and determining the percentage reduction in the incidence rate of disease among vaccinated persons relative to unvaccinated persons. The basic formula is:

$$VE = \frac{ARU - ARV}{ARU} \times 100$$

(VE=vaccine efficacy; ARU=attack rate in the unvaccinated population; ARV=attack rate in the vaccinated population.)

This equation can be manipulated to give the curves shown, which can be used to estimate vaccine efficacy.



Percentage of cases vaccinated (PCV) per percentage of population vaccinated (PPV), for 7 values of vaccine efficacy

WHO, Weekly Epidemiological Report, No. 18, 1985, pp. 133-134.

Serologic surveys represent a refinement on the aforementioned coverage evaluation methodologies. By measuring antibody titres in a vaccinated group as compared with a control group, much can be learned about the effectiveness of an immunization program. Seroconversion rates, the amount and duration of antibody produced, and the ages at which maternal antibodies disappear and natural infection occurs are some of the measurements.

In general, serologic surveys are too expensive to be conducted in circumstances other than special studies or vaccine research.

ANNE B KEISER

Disease Surveillance In EPI

Disease surveillance is now an integral tool for monitoring EPI. If we track outbreaks or occurrences of illness quickly, we can determine if EPI has succeeded in reducing the incidence of the disease, or if major improvements in EPI are necessary. Routine surveillance over a longer period allows EPI to determine if the program is having a sustained impact.

To conduct surveillance, we first need to be able to recognize each illness. A common case definition of each disease is essential to compare results from year to year and also from one country to the another. Many times, the diagnosis is made at the periphery of the system by poorly trained curative personnel or by primary health care workers, who are apt to report only those diseases in their surveillance scheme (such as measles, polio, and tetanus).

Several methods are commonly used to track disease, but their adequacy and utility vary greatly. Below, we examine some of the most common methods.

Routine Disease Reporting

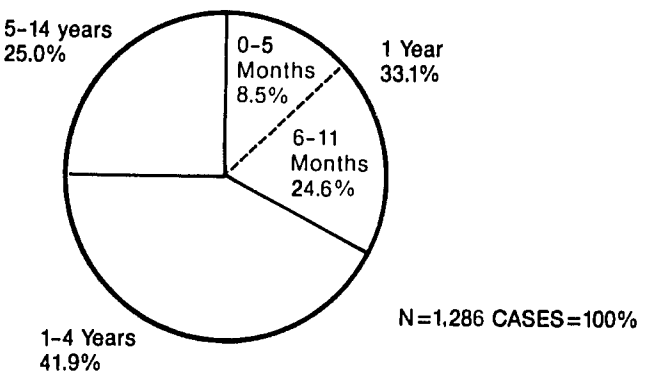
Most countries have some version of routine reporting. The numbers are often woefully underreported and the quality of diagnosis is frequently inadequate. Also, diagnoses by age are not always recorded; for instance, all tetanus deaths are lumped together.

Cause of Death in Children 0 – 4

Ideally, a routine morbidity and mortality reporting system should allow one to determine rates by age, as is shown here in data from a hospital in Panama.

Continuous surveillance will allow the determination of trends in disease incidence over time, indicating whether the program is effective in reducing cases of the disease.

Measles Cases Treated at the Hospital del Niño, by Age Group, 1985



PAHO, *EPI Newsletter*, Aug 1986, Why is there Measles in Panama?

Sentinel Site Disease Surveillance

This is fairly simple to do but is not suitable for all diseases. The selection of the sites, their number, and geographical distribution should reflect the objectives of the surveillance system; for example, if one primarily wishes to document EPI effectiveness, one would choose sites only in areas with active vaccination programs. With reliable reporting from clinics, hospitals, or several villages, tracking upsurges of illnesses like measles or polio can be relatively straightforward. Due to its high mortality, measles is the most important disease to monitor. It is also a good indicator of EPI effectiveness, as measles vaccine is normally the final antigen to be given. However, hospital data are biased because a change in people's *use* of the hospital can affect the number of admissions without a real change in the community incidence. Nonetheless, a good surveillance system will help document the reductions in morbidity and mortality that occur when high coverage levels are achieved.

Monthly EPI Surveillance Report

Health Facility _____ Month _____

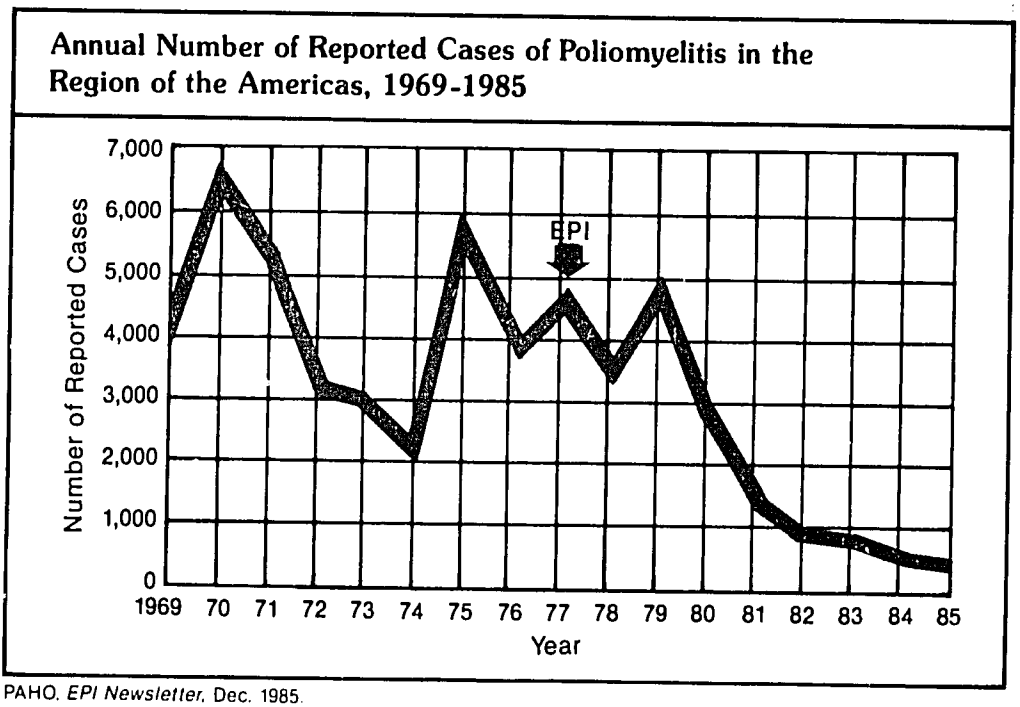
City/Village _____ Year _____

Illness	Age Group and Vaccination Status									Total Cases
	0–11 Months			1–4 Years			5+ Years			
	Vacc+	Vacc–	unknown	Vacc+	Vacc–	unknown	Vacc+	Vacc–	unknown	
Measles										
Pertussis										
Poliomyelitis										
Neonatal Tetanus*										
Diphtheria										
Tuberculosis										

*Vaccination status of mother

Source: WHO/EPI

Reported cases of target diseases over time can show the long-term impact of EPI.



PAHO. *EPI Newsletter*, Dec. 1985.

Outbreak Investigation

Outbreak investigation is used to control epidemics of vaccine-preventable diseases. The investigation should reveal who is getting the disease, when and where it is occurring, where it came from, and who among the afflicted were vaccinated (and vaccine efficacy calculated as on page 134). Outbreak investigations can also sensitize health workers to the real importance of EPI: prevention of disease.

Morbidity and Mortality Surveys

Surveys of specific EPI diseases are costly in resources but often yield reliable data. Repeated at regular intervals, they allow the evaluation of the impact of EPI. Not all EPI-preventable diseases can or should be monitored by general surveillance systems. Depending upon the disease, one or several specific methods should be used.

Listed below are the survey requirements of each of the EPI diseases.

Measles

The seasonality and cyclical pattern of measles should be kept in mind whenever one attempts to do a survey of measles incidence. Measles incidence over the past year may be estimated by history

of a measles case during any cluster sample survey of vaccine coverage, as measles is recognized by families in most cultures. However, in many, virtually any rash is identified as measles. For these reasons, sentinel surveillance and outbreak investigations are best to monitor measles. Age distribution of measles cases is an important clue to the epidemiology of measles.

Poliomyelitis

Not every country needs to do repeated poliomyelitis surveys. The best technique to discover previous polio cases is probably the polio lameness survey in communities or schools. The technique, however, only tells us about polio contracted five to nine years ago as the majority of cases occur in children under five years of age in unimmunized populations. It is thus useful mainly as a baseline survey. Active case detection, however, will be required when a country decides on polio eradication. Surveillance teams must respond promptly to reports of paralytic illness; do a clinical exam; take stool samples (and sometimes blood); and decide if this is polio, or some other condition, so that an epidemic may be contained.

Neonatal Tetanus

Surveillance is important because the disease is still underestimated and because the intervention group (women of childbearing age) differs from the target group of the other EPI preventable diseases. Household survey is the usual technique of surveillance; it is particularly relevant at the beginning of an EPI, but should be conducted at additional intervals if efforts to vaccinate women with tetanus toxoid are under way. To get reasonably valid statistics on how many newborns had the signs of tetanus, one must interview enough families in a 30-cluster sample survey to find 2,100 live births during a recall period, which may be set at the previous 4, 7, or 13 months. Even so, considerable underreporting can occur as mothers tend to suppress the details; or, some do not consider a neonate who dies as even having been born alive. Tetanus toxoid coverage should be measured at the same time.

Diphtheria

Due to low incidence and difficult diagnosis of diphtheria, it should be monitored from the annual reports of the national laboratory, despite the urban bias of this method.

Tuberculosis (TB)

Surveillance should be conducted by the national TB control program or national surveillance/epidemiology unit and not by the EPI.

Pertussis

Pertussis is often difficult to differentiate from other acute respiratory illnesses and is surveyed by special research projects only.

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Comprehensive Program Reviews

Comprehensive program reviews, usually done for an entire national program, address the larger questions of relevancy and the adequacy of immunization programs. They entail a necessarily subjective analysis of the coherency of program components, their relationship to the community, and to other health programs.

Most comprehensive program evaluations are joint efforts by the Ministry of Health, WHO, and other organizations such as UNICEF and AID. To assure a broad perspective, teams which carry them out are often composed not only of technical experts but also administrators, economists, and social scientists, both from the national and international communities.

Almost all countries participating in the EPI have conducted at least one comprehensive review at some point, and most have conducted more than one. Generally, they are done at least every five years and in many countries even more often. A standard method for conducting the surveys has been developed by WHO. This includes a series of questions to be addressed at each level (national, regional/district, health center, and home) of program implementation. While assuring comparability between evaluations, this limits flexibility to address problems and accomplishments outside the realm of the standard format. It is time consuming and often halts EPI work for one to two months as EPI managers prepare for the evaluation team.

Rapid Assessment Of Accelerated Immunization Programs

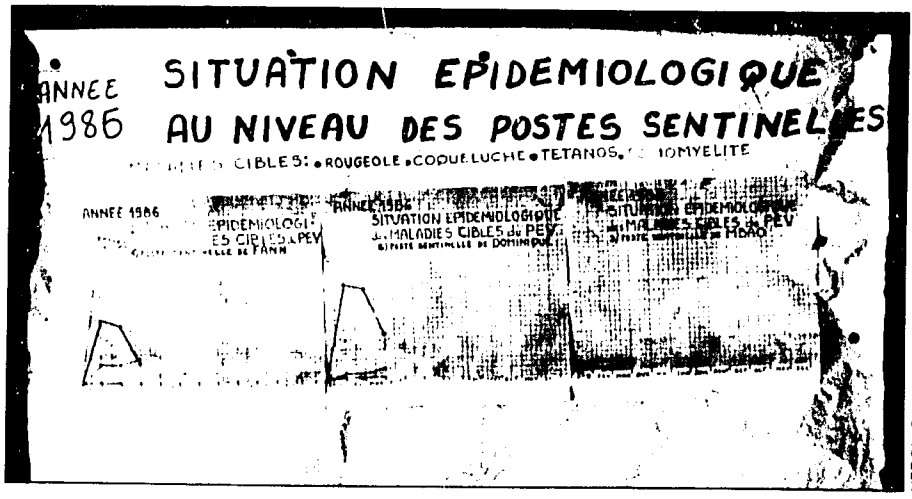
UNICEF has begun to promote the use of what are termed "rapid assessments" of EPIs that have undertaken acceleration. These differ from the comprehensive program reviews in that they take a more subjective view of specific acceleration efforts, and the lessons that may be learned from them. They are meant to supplement comprehensive program reviews—not replace them.

Rapid assessments are not evaluations in the strict sense of the word, and often do not include such measures as vaccination coverage surveys. Rather than having a fixed evaluation methodology, they focus on open-ended questions such as: What worked or did not work? Why? How did the campaign contribute to the on-going national immunization program? and so on.

With our feet well on the ground, and with no false ideas about our limitations, we also have to go beyond the emotion expressed through acts of charity or by donations in times of emergency.

And in order to do so, we must clearly establish the differences between rescue operations and development, between survival and evolution, between adjustment and growth. Otherwise, we would be condemned to live day-to-day and fall back into limitations.

Belisario Betancur Cuartas
President, Republic of Colombia
Bellagio II, Cartagena, October 1985



VERONIQUE LEGER

Cost Analyses

Primary health care has long been considered a cost-effective way to improve people's health and to extend services to the majority. Vaccination has been cited as one of the most cost-effective components of primary health care. Political declarations of "Health for All by the Year 2000" and "Universal Childhood Immunization by 1990" have led to establishment of national EPIs worldwide, and accelerations of effort.

The primary objective of accelerations is to reach the highest levels of coverage in the shortest period of time; but we are uncertain of the long-term implications. One concern is the recurrent cost of maintaining the EPI at an epidemiologically acceptable level in the future. It is unknown what it costs to sustain coverage levels, particularly in an ever-increasing population,and the long-term future financing of the EPI by countries and donors has not yet been discussed seriously.

Cost evaluations of the EPI are now being performed to address these concerns, and to develop a framework of analysis that is useful for comparisons between programs and over time within programs. This section of the manual discusses the purpose and methodologies used for determining EPI costs, and shows how cost analyses may be used for the management of national immunization programs.

Potential Uses Of Cost Information

Purpose	What Results Can Show	How Information Can Be Used
Project Design	Which delivery strategy costs less	Choose which strategy to use or where to reduce costs
Monitoring	Cost components can be identified for routine cost collection	Determine how to make operations more efficient or how fast resources are being spent
Evaluation	Total resources invested in program or strategy	Plan resources for future
	Who is investing in program	Discuss how program may be financed in the future
	Cost of different program components	Decide how to reduce or reallocate costs among categories

Why Are Cost Analyses Important?

Determining the costs of vaccination strategies has also become an important tool in the design, monitoring, and evaluation of EPI. Cost analyses can provide information on the total cost of the EPI, the cost of different delivery strategies, the balance between capital investment and recurrent costs of the program, the proportions of different types of costwhich make up total cost, and as a means to identify more and less efficient medical or geographic units.

VERONIQUE LEGER

The costs for salaries, vaccines, the cold chain and transportation account for nearly three-fourths of EPI cost.

Methods For Collecting Cost Data

Several sets of guidelines have been written which describe how to collect and analyze data on the costs of the EPI. The most widely accepted and used are the WHO EPI Costing Guidelines (Creese, 1979). The methods recommended in this guide are an elaboration which can be readily adapted to a country-specific situation.

Costs can be presented in two principal ways: by expenditure categories and by functional categories.

Expenditure categories follow a classic accounting framework, and include salaries, transportation, supplies, overhead costs, vehicles, and other equipment costs;

Functional categories are specific activities that are undertaken by the program, such as training, promotional activities, evaluation, and cold chain maintenance.

Expenditure categories

Expenditure categories are the most detailed and should form a basis for analysis of program cost by program function component. For example, $100 for transportation costs (expenditure category) may be divided into $50 for transportation related to training, $25 for transportation related to promotional activities, and $25 for evaluation.

Expenditure categories can be divided further into two major classifications of cost: investment and recurrent costs.

- *Investment costs* are those which usually occur once or infrequently during the life of an immunization program. Examples of these types of costs are vehicles and refrigerators;
- *Recurrent costs* are those which occur each day of the program, and include such items as salaries and fuel for transportation.

The following matrix provides an illustration of the classification of costs.

Expenditure Category	Investment	Recurrent
Salaries	X	X
Transportation		X
Training	X	X
Vaccines	X	X
Supplies	X	X
Media Production		X
Operation and Maintenance		X
Cold chain equipment	X	
Vehicles	X	
Other equipment	X	
Buildings	X	

These classifications are not fixed, and some expenditure categories apply to both investment and recurrent classifications. Initial stocks of vaccines and supplies, and initial training of health workers in vaccination technique may be considered investment costs of the program, especially when these initial investments are made by donors but are taken over by the host country. Expatriate salaries may be considered an investment cost, especially if expatriates are involved at the start of an EPI or acceleration of vaccination.

Expenditure categories can be further divided into their component costs. The following is a list of the cost elements that can be included in each expenditure category in order to determine the full cost of the EPI. This list is not exhaustive.

Salaries: This category includes salaries and benefits of government health workers, of government health administrators, and of non-health personnel involved in the immunization program. Incentive payments for government personnel and expatriate salaries and benefits and consultant payments are also included.

Transportation: This category encompasses fuel, oil, and maintenance costs of vehicles used for vaccination activities, as well as per diems, airfares, freight charges, and customs duties.

Vaccines: Vaccine costs represent the unit cost per vaccine type multiplied by the quantity shipped (including shipping costs) to the host country. This cost should also include a factor for wastage of vaccine. The WHO training document entitled "How to Estimate Vaccine Requirements for the First Time" and the UNICEF/UNIPAC brochures provide helpful reference for calculating vaccine costs as well.

Supplies: Supply costs can be divided into those specific to vaccination (e.g., syringes, needles, diluent, other expendable items), those specific to the cold chain (e.g., thermometers, monitoring cards, and cold packs), those related to mass media and promotion (e.g., batteries, art supplies, and overhead slides), and miscellaneous items such as office supplies. The costs of these materials should be based on their unit costs and the quantities used during the evaluation period.

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Even reusable supplies need replacing.

Training: Training costs not related to transportation or supply include honorariums for trainers, reproduction, translation, and distribution of materials.

Media production: This category includes the cost of final transmission through radio and television and the print media, and costs for printing, reproduction, and production of media materials.

Operation and maintenance: This category refers to expenses incurred for rent and utilities for the program offices including energy costs to power cold chain equipment.

Vehicles: This category includes the cost of vehicles (trucks, automobiles, motorcycles, and bicycles) which have been purchased for use in immunization programs. These costs are usually depreciated over their average functioning life, and this figure represents the average annual value of this type of equipment.

Equipment: This category can be divided into cold chain equipment, audio-visual equipment used for promotional activities, vaccination equipment, and other equipment (office furniture and medical equipment) which are used for the EPI. These costs are usually represented as their depreciated value.

Buildings: The depreciated value of buildings used for vaccination activities is included in this category.

VERONIQUE LEGER

Equipment can depreciate quickly with hard use.

Depreciation of vehicles, buildings, and equipment reflects the decline in their value over time as they are used and break down. Once a piece of equipment has been fully depreciated (the economic value is zero), that would be the time to purchase another piece of equipment for the program.

To depreciate the cost of a vehicle (according to the "straight-line" method), the purchase price of the vehicle is divided by a value that takes into account the inflation rate of money and the number of years of average use. This value has been tabulated and is located in the WHO Guidance on Costing Immunization Programs.

In order to determine how to allocate a health worker's salary to vaccination activities, a study of the activities performed by the health worker and the time required to perform these tasks is undertaken. This type of study, called a "time-motion" study, can be performed by visiting a representative sample of health facilities, determining the number and types of personnel involved in the EPI, the average weekly hours set aside for vaccination sessions, the average weekly hours of health facility operation, and the average annual salary for each type of health worker.

The proportion of salaries allocated to the EPI is therefore the ratio between the number of total health worker hours per week devoted to the EPI divided by the number of total health facility person-hours per week. For example, if there are normally five nurses who work an average of eight hours per day (they are paid to work eight hours per day, though they may not fill the entire day with health activities), then the total person-hours per week for that facility is $5 \times 8 \times 5 = 200$ hours. If two of the nurses hold vaccination sessions on each Tuesday and Thursday morning for 4 hours, and each Wednesday afternoon (4 hours), then the total person-hours per week devoted to vaccination in that facility is $2 \times 3 \times 4 = 24$. The proportion of health worker time devoted to vaccination (on average) will be 24/200 or 12%. The average annual salary of health workers can then be multiplied by 12% to result in the average salary devoted to vaccination activity.

Several financial experts have argued that salary and building costs should not be calculated specifically for the EPI, because these costs do not actually represent an additional cost to the government. They are correct in stating that the Ministry of Health usually does not incur additional salary expenses or additional expenses related to the use of already existing MOH health facilities for a new preventive program. Moreover, health workers may not work their full complement of hours, and, therefore, the EPI should not represent an additional expenditure or burden to them.

However, all inputs into the EPI have a *value* and the government is paying their health workers, regardless of their performance and regardless of which health activities the workers undertake. In order to place an "economic cost" on the EPI, it is necessary to estimate the proportion of annual salaries devoted to vaccination or the proportion of building space occupied with the EPI.

Functional categories

A collaborative effort between WHO, UNICEF, and AID has resulted in a shared definition of immunization program functional categories. These categories were determined by experts in the spring of 1987, and have since been tested in the field by consultants and program managers. The purpose of developing these categories was to have consistent categories which would capture the most important aspects of immunization programs. The following matrix illustrates these categories:

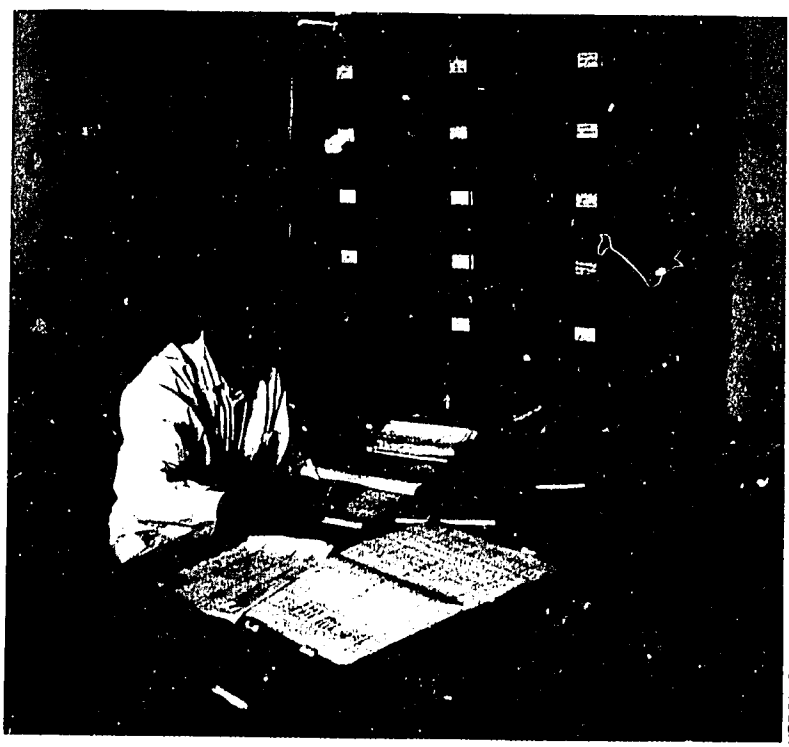
Functional Category	**Components**
Delivery of Vaccine	Salaries, Transportation, Supplies, Operation and Maintenance
Procurement of Vaccine	Vaccines, Freight, Customs
Development and Maintenance of the Cold Chain	Cold Chain Equipment, Freight, Customs
Supervision	Salaries, Transportation
Training	Supplies, Transportation, Salaries
Evaluation	Supplies, Transportation, Salaries
Social Mobilization	Media Production, Salaries
Research	Salaries, Transportation
Special Studies	Salaries, Transportation

Data Sources

Cost data can be found in a variety of sources. The most common sources of expenditure data are Ministry of Health and Ministry of Finance ledgers, and accounting records of USAID and other donors.

In order to determine the full cost of a program, the quantity of inputs into the program and their unit costs need to be assessed. For example, to determine vaccination supply costs, the total number of syringes and needles used on an annual basis and the average cost per needle and syringe are multiplied together. Information on the number of syringes and needles purchased annually and their costs can be found from UNICEF/UNiPAC orders and USAID invoices.

Cost data are rarely available in their needed form for cost analysis, and usually assumptions about either unit cost or quantity are required. For example, many ministries of health have written records of their budgets for certain health activities, not their expenditures. Often this means working backwards, from expenditures in a health facility to the national level. Estimation of salaries for the EPI are based on estimates of number of personnel and their average wage and time devoted to EPI activities.



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Analysis Of Cost Data

Although cost information is useful for determining the level of investment required for a program and for monitoring expenditures over time, comparing cost information with the effectiveness of a program can provide a good indicator of the amount of resources needed to effect a change in health status.

Immunization Program Effectiveness

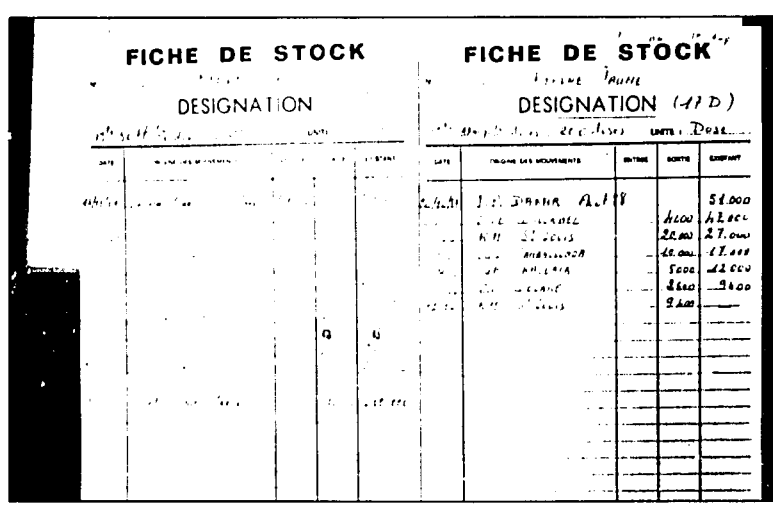
For immunization programs, there are several effectiveness measures which have been used:

a) *The number of doses administered on an annual basis.* This provides information only about the volume of services provided, not whether these services were of high quality or whether the vaccinations were administered at the proper ages.

b) *The number of children of a certain age group completely vaccinated.* This indicator is preferred, because it measures the effectiveness of the immunization program in achieving the current coverage goals of WHO. However, as the health status of a country changes and as new vaccines are

...as a result of world recession...
a very real deterioration (in) taking place in the lives of children.
what is now needed is... "adjustment with a human face."

The State of The World's Children, 1987
UNICEF, p. 90



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introduced into the EPI, it will be more and more difficult to define what is meant by "completely vaccinated," and it will be more and more difficult to compare results from one country to another.

c) *The number of children vaccinated with a specific antigen.* This indicator shows the effectiveness of partial vaccination, but poses problems for the cost analysis, which must make assumptions about how much of a total program cost is allocated to delivering specific antigens.

d) *The number of deaths averted through vaccination activities.* This indicator, though it attempts to link vaccination with change in health status, is usually measured by making several assumptions which may not be based in fact in every country.

Cost-effectiveness analysis

Cost-effectiveness analysis has been used to determine which type of activity results in a greater level of health outcomes for the least amount of financial investment. This calculation is made by dividing the total cost of a program by its outputs or outcomes, and allows one to choose one health intervention over others. Cost-effectiveness analysis for the EPI should not be done to choose between immunization and another health program (because, practically, no such choices will be made), but between different ways to organize and implement an EPI. One may then choose between alternative strategies (fixed centers versus mobile teams, for example); even so, choices may be linked more to political, cultural, and socio-economic factors than purely economic ones. A major limitation to this use of cost analysis is that the program has to have already been implemented to provide the very data to allow for a "choice." Cost effectiveness analysis is more useful to plan for optimal combination of strategies based on epidemiologic, cultural, and geographic realities.

Analysis of cost profiles as a management tool

The cost profiles of the EPI or of particular vaccination strategies can be thought of as the "snapshot" of the combination of inputs into the program at one point in time. An analysis of this snapshot can tell the program manager where most of the program resources are going and for what types of activities, such as supervision or cold chain monitoring. If a series of snapshots is monitored over time, then managers may be able to exert some financial control over how resources are spent in their program.

In addition, the cost profiles also contain information on how much donors are spending on the EPI, versus the host country government and private individuals, and for which expenditure categories.

Cost of illness prevented

Not all costs are program costs. People pay exorbitant amounts of money, relative to their income, for care of illnesses like measles; the health care system, likewise, spends most of its budget on curative care. The cost of an effective EPI, even a less efficient one, is far less than the cost of care for vaccine-preventable illness.

In Pointe Noire, Congo, the costs of measles vaccination were compared in 1985 to costs incurred in *treating* the disease. This study illustrates the magnitude of savings that can be realized through measles prevention.

The Cost Of Measles Is Many Times The Cost Of EPI*

	To Treat	To Vaccinate
Cost per Child**	$59 (hospitalized) $26 (outpatient)	$6 (per fully vaccinated child)
1985 EPI Cost Data —Pointe Noire	$198,000	$29,000 (all EPI)

It was estimated that even if operating costs were increased to ensure 100% coverage, they would at most be about 27% of current direct costs of measles treatment.

*"Measles Control in Africa," *Lancet*, F. Dabis, et al, CDC and Congo Ministry of Health, July 19, 1986.

**Mostly for medications. Cost of parents' lost wages, travel, etc., are not included.

CLAUDE BETTS

Case Study

The following section presents a case study of a cost analysis of an immunization program in a country with both urban and widely scattered populations. Cost tables and profiles are provided for edification.

What these tables show is that the cost of mobile teams was much greater than that of the fixed centers and a mass campaign held in 1985, but the mobile teams' effectiveness was midway between the two.

Total Costs And Cost Profiles For Vaccination Strategies (In 1985 Dollars)

Cost Category	Fixed Centers	Mobile Teams	Mass Campaign
A. Salaries/Benefits	$12,700	$177,350	$ 79,250
B. Vaccines	9,435	16,380	6,700
C. Transport	10,690	51,800	28,445
D. Training/Management/ Supervision	2,950	4,970	44,930
E. Media	——[a]	——[a]	10,290
F. General Costs	30	13,850	150
G. Consumable Supplies	11,690	49,960	44,140
H. Buildings/ Depreciation	18,420	——[a]	2,950
I. Vehicles/ Depreciation	4,415	33,900	——[a]
J. Cold Chain/ Equipment/Spare Parts	13,640	9,670	11,860
TOTAL	$83,970	$357,880	$228,715

[a] cost information not available or applicable

Results

The table above presents the total costs estimated for each strategy by cost category. The total cost delivering vaccines for one year was $83,970 for the fixed centers; roughly 55% of the overall cost is attributable to operating costs of the program. A high percent of total costs (44%) is attributable to the cost of buildings and to the cost of cold chain and other equipment.

By contrast, the mobile teams were the most costly vaccination strategy. Approximately 90% of the total ($314,310/ $357,880) was for operating expenditures. The mobile teams were the most expensive method of vaccination because of vehicle related expenses. In fact, about one-seventh of the total cost ($51,800/$357,880) was directly related to the purchase of fuel, and the maintenance and repair of vehicles. The mobile teams were also expensive relative to the other strategies because of the cost of maintaining a cadre of at least 50 health personnel who devoted all of their time to vaccine delivery. The cost of salaries was over 50% of the cost of operating the teams.

The overall cost of the mass campaign was $228,715, which placed the mass campaign between the routine fixed and mobile programs in terms of cost. As with the mobile teams, more than 90% of the cost of the campaigns was for recurrent costs, with salaries and supplies taking the largest proportions. The mass campaign required a high degree of mobilization of the health sector, and involved a significant amount of planning—both of which are reflected in the salary figures. The campaign also required large investments for technical equipment, including syringes, needles, and other vaccination equipment.

Media costs were specific to the mass campaign and included the cost of radio transmissions, painting of billboards, and printing and distribution of other promotional material.

One may also calculate the relative proportions of total cost for each category. Several patterns of cost allocation emerge. For the fixed centers, buildings, cold chain equipment, and salaries accounted for the greatest proportion of costs. For the mobile teams, the cost of salaries, transport, and supplies ranked the highest. Salaries, training/management/supervision, and supplies were also accountable for the greatest proportion of cost for the mass campaign. The relatively high cost of expatriate salaries contributed to the salary proportion of costs.

These proportions are similar to what has been found in other studies of cost-effectiveness (Creese, 1979). Salary costs usually account for the greatest proportion of costs, with transportation and supplies following close behind. The high costs of salaries are due to the fact that health service delivery is a highly labor-intensive activity. The dispersion of the population may be responsible for high transportation costs. Reliance on butane-operated refrigerators, although easy to use, has contributed to high supply cost.

The table on the next page illustrates the relative role of each of the strategies in completely vaccinating children less than five years of age. These figures originated from EPI monthly records. According to this

table, the mobile teams were responsible for 63 percent of children completely vaccinated by routine services, whereas the fixed centers completely vaccinated one third of the total (12,297/32,901). When the results of the campaign are joined with routine service data, the mobile teams and the fixed centers decrease in importance to 35% and 21% of children completely vaccinated, respectively. The campaign was responsible for 44% of children vaccinated in 1985.

Comparison Of The Number Of Children (0 To 5 Years) Completely Vaccinated By Different Strategies

	Fixed Centers	Mobile Teams	Total Routine	Mass Campaigns	Total
Number of Children Completely Vaccinated	12,297	20,604	32,901	25,507	58,405

However, attributing a child completely vaccinated to one strategy or another posed a methodological problem. A child could have received all of his or her vaccinations except the last doses of DPT or polio in either of the two routine services (fixed centers or mobile teams or both), but be counted as completely vaccinated by the mass campaign if he/she received the last doses during that time. The transfer problem also exists between mobile teams and fixed centers: a child could receive the first doses of DPT or polio via a mobile team, but because of migration to the cities, receive the final doses of vaccine through the fixed centers or the campaign. The probability of switching the locus of vaccination is assumed to be equivalent among strategies, and, therefore, the numbers reported to the EPI were taken as best estimates of program effectiveness. A comparison of the three strategies may underestimate the effectiveness of routine services and overestimate that of the mass campaign because of the high level of activity during that time.

Cost-effectiveness

Cost-effectiveness ratios are presented below. The cost per fully vaccinated child less than five ranges from approximately $6.80 to $17.40, with fixed centers being the most cost-effective strategy. The mobile teams are the least cost-effective, primarily because of the large operational costs of the system. The campaign cost was $8.97 per child.

Cost-Effectiveness of Vaccination Strategies

Strategies	Cost Total ($)	# Completely Vaccinated	Cost Per Fully Vaccinated Child
Fixed Centers	83,970	12,297	$ 6.83
Mobile Teams	357,880	20,604	$ 17.37
Mass Campaign	228,715	25,507	$ 8.97

Sensitivity Analysis

A sensitivity analysis was performed on both cost and effectiveness data in order to identify ways in which the efficiency of vaccination programs could be improved.

Below we present the results of several alternative scenarios. Scenario A removes building, vehicle, and equipment depreciation costs which increases the cost-effectiveness of all strategies. The cost-effectiveness of the fixed centers was roughly halved from $6.80 to $3.90 per completely vaccinated child.

One interesting result from this sensitivity analysis is depicted in Scenario B. When the effectiveness of the mobile teams and the fixed centers are improved by 50% (50% more children vaccinated), the cost-effectiveness of these strategies improves by 33%. It is known that the mobile teams are not working at full capacity, and therefore performance could be improved. This is because the number of kilometers traveled by each team is not correlated to the number of contacts that are made, and some of the teams travel equal distances but do not vaccinate children at the same rate. If the teams could spend more time in each village vaccinating children, effectiveness could be greatly improved. Similarly, a time study of fixed centers showed that more vaccinations could be handled.

Removing expatriate salary costs from the analysis, Scenario C, results in an interesting comparison and significantly reduces the cost-effectiveness ratios of both the mobile teams and the mass campaign from $17.37 to $13.29, and from $8.97 to $7.68, respectively. Therefore, without the costs of expatriate technical assistance, the mobile teams is not such a costly strategy as previously estimated, illustrating how important the issue of cost allocation is.

Sensitivity Analysis Of Cost-Effectiveness: Cost Per Fully Vaccinated Child

Scenario	Strategy: MCH Centers	Mobile Teams	Campaign National Vaccination Days
Original	$6.83	$17.37	$8.97
A	$3.86	$15.26	$8.38
B	$4.55	$11.58	$8.97
C	$6.83	$13.29	$7.68

A— Includes recurrent costs only.
B— Increases effectiveness of mobile teams by 50% (from 20,604 children completely vaccinated to 30,906) and improves fixed facility performance by 50% (from 12,297 to 18,445).
C— Excludes expatriate salary costs.

Recommendations

The routine services through fixed centers were found to be the least costly strategy and the mobile teams, the most. However, because these two strategies complement each other and are both integral to the EPI, these results were not used to choose one strategy over another. The ratios themselves provide the least amount of information about future planning, programming, and implementation of the EPI. Rather, an examination of the cost components and coverage of each strategy can tell a program manager how to improve the efficiency and effectiveness:

1. The cost-effectiveness of the fixed centers could be improved through greater coverage of the urban population, particularly through *outreach* efforts in areas of cities where fixed health facilities are poorly utilized. Specifically, the population of immigrants from rural areas and neighboring countries who typically reside in or at the periphery of cities would be an excellent target population for outreach.

2. The cost-effectiveness of the fixed centers could also be improved through continued media promotion of the benefits of vaccination in order to reduce drop-out between the first and the last doses of DPT and poliovirus vaccines.
3. The cost-effectiveness of the mobile teams could be improved by maximizing the effectiveness of the teams. Currently, mobile teams are working on average less then 50% of the time. The lack of efficiency is in part due to the breakdown of vehicles and other technical considerations. However, the mobile teams are probably not working to full capacity even when they are technically able. If the teams could reach more children by spending more time in each village, say, the cost-effectiveness of this strategy would be improved.
4. The cost-effectiveness of the mobile teams might also be improved by integrating other services into the mobile team strategy, such as basic curative care or preventive services as, say, vitamin A supplementation and ORT distribution.
5. Now that the campaign has helped to reduce the backlog of unvaccinated older children, the EPI can focus resources on younger children which may help to reduce the recurrent cost of the EPI in the long run.

Sensitivity analysis can show how to reduce selected cost components and to improve the effectiveness of the strategies. This method is one concrete way that such cost-effectiveness analyses can assist program managers to operate the EPI in the most efficient and effective manner.

LOGAN BRENZEL

Mobile vaccination teams are costly but serve a purpose. Cost analysis may help make them more efficient.

EPILOGUE
Sustaining EPI

Sustaining EPI

VERONIQUE LEGER

This guide has detailed what we know about *achieving* a successful EPI. We know little about how to *sustain* EPI—nothing more or less than to vaccinate every new child before its first birthday against six (or more) diseases, and every mother-to-be against tetanus.

We are not even certain what we mean by "sustainability." At its most elemental, sustainability is keeping things going at a level necessary to achieve the intended or desired outcome. In many countries, donor contributions to the EPI currently far outstrip contributions by the government or by individuals. UNICEF has made a particular goal of Universal Childhood Immunization by 1990, and has therefore contributed a great deal of resources to this effort. AID and WHO have also played roles in financing specific aspects of immunization programs. Donors seem willing to sustain EPI (and other child survival activities) as long as they have the moral or political imperative to think of children as members of the global village, an international world asset and responsibility (AID's long-standing assistance to family planning is an example). This clearly induces recipient nations to build donations into project support, and to use scarce internal funds for other objectives.

Yet donor support cannot be taken for granted, and is seldom secure for more than a few years; therefore we all worry how countries can sustain the health initiatives urged on them by the international agencies. EPI has particularly high recurrent costs, and its target population gets larger each year. A clean test of

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the question would be: which countries would or could sustain EPI if all external assistance stopped?

Thus, in one narrow perspective, sustainability is equated with a country's ability to pay for the program that achieves and maintains universal coverage and disease control.

As we look forward to the 1990's, in some ways we face even greater challenges. Many countries will have achieved what only a few years ago seemed like unachievable goals. Those countries need to find ways to sustain those achievements in the framework of regular budgets and everyday services, out of the limelight of international attention. It won't be easy. For other countries, the road to these goals will be longer as they strive to give every child what should be his or her birthright, a chance to thrive.

We can help them. To do so, USAID, with the support of the U.S. Congress and the American people, needs to stay the course.

Alan Woods
Administrator
U.S. Agency for International Development
Child Survival: A Third Report to Congress on the USAID Program, 1988.

Why Is Sustainability So Hard To Achieve?

Every outside-funded project is a mix of donor and country interests and priorities. Seldom will these two perspectives be identical. Rather than reflecting a country's highest priority, donor-driven projects become a country's highest *fundable* priority, which means a country will do the project if some part is paid for.

In almost every case, projects involve levels of resource commitment on the part of the country (money, staff, buildings, time), far in excess of what would have been forthcoming without the project. In every case, these resources come at the expense of other activities which *would have had a higher priority without the donor support*! This means that without the "strings" attached to donor support, most countries would be using resources in a way that would reflect different social priorities and involve different activities. This is true regardless of the efficiency, responsibility, and integrity of the countries involved.

More important is that projects often operate at a scale far in excess of what could be done without outside support. Categorical projects like EPI may become operational at the expense of other health activities such as building primary health care, AIDS control, family planning. Intensive immunization activities may divert resources away by directing limited administrative and managerial competency toward the EPI. Intensive short-run projects can create an unsustainable requirement for long-term recurrent costs (maintenance of equipment, vehicles, fuel, pensions of newly hired workers, among others).

User Fees

Most countries are reluctant to charge for health services which they have declared to be free and the right of every citizen.

Some economists also find fault with user fees for vaccinations because vaccinations are a "public good," benefiting others as well as the individual being vaccinated. If user fees were charged, some people, particularly the poorest and most in need of protection, would fail to be vaccinated, depriving others as well as themselves of the benefits. People are already paying in time, personal transport, and foregone income to be vaccinated (those costs are generally ignored in discussions of cost recovery).

Some countries, however, find they can charge for the personal vaccination card, that people accept the idea and value the cards sufficiently to pay for them. Community contributions, in cash or kind, are another form of user fee that helps recover some of the EPI costs.

It is true, however, that revenues from user-fees may just go directly to the national treasury and not be earmarked for EPI. In this instance EPI workers may not feel encouraged to collect the fees. A user-fee system also requires good financial and administrative management. This entails a cost, and much time for training.

Although people now do pay a lot for private curative health care, we are uncertain that they would do so for preventive care (most experience suggests not yet). Surely they would not pay for services that were irregular, demeaning and of poor quality.

It is unlikely that any fair user-fee system can recover all costs for EPI, particularly those requiring foreign exchange. Other methods of cost-recovery (cross-subsidization, reallocation, managerial efficiencies) also need to be tested. Someone must pay for EPI now and for a very long time.

These limits to sustainability reflect unachievable expectations rather than inadequate commitment.

Donors, therefore, work hard to modify the host country's priorities. In the case of the poorest countries, however, donors need to recognize the need for long-term outside support. If sustainability were to be the most important criterion for donor activities, many of the countries most in need of support would not even be able to get in the game.

Many donor activities, while essential, are insufficient to produce sustainable outcomes. Vehicles and kerosene refrigerators can only be effective while there is fuel for their operation. How might donors support the ability of a country to sustain outcomes or activities? Suppose donors provided hardware more slowly in exchange for longer guaranteed use, by "endowing" fuel and maintenance costs, and training of staff, say. Such an exchange within project activities would improve sustainability by reducing competition for scarce in-country resources in the future. This improvement in sustainability, however, would come at the expense of reduced outputs, a trade many donors are unwilling to make.

But sustainability is more than just financing. It describes an entire system that mobilizes political will, cultural context, mass education and motivation, and management; all toward societal goals. It is the ability and commitment to free up monetary *and* human resources for EPI that ultimately determine sustainability.

In our hard times of recession, war, and drought, it seems audacious to expect (or demand) that all nations effectively mobilize resources for women and children. But if not now, when? And if *we* are not advocates for women and children, who will be?

APPENDIX

UNICEF

Sources Of Information Or Equipment

Agency for International Development (AID), Office of Health, Bureau of Science and Technology, Agency for International Development, Washington, DC 20523, U.S.A. CONTACT: Dr Kenneth Bart

American Public Health Association (APHA), 1015 15th Street, NW, Washington, DC 20005, U.S.A. CONTACT: Dr Susi Kessler

Appropriate Health Resources and Technologies Action Group (AHRTAG), 1 London Bridge Street, London SE1 9SG, U.K. CONTACT: Ms Suzanne Fustukian

Centers for Disease Control, Public Health Service, Department of Health and Human Services, Atlanta, GA 30333, U.S.A. CONTACTS: Dr Alan Hinman, Dr Stanley Foster, Dr Michael Deming

Equipment to Charity Hospitals Overseas (ECHO), Ullswater Crescent, Coulsdon, Surrey CR3 2HR, U.K. CONTACT: Dr John Townsend

Evaluation and Planning Centre for Health Care (EPC). LSHTM, Keppel Street, London WC1E 7HT, U.K. CONTACT: Dr Patrick Vaughan

International Children's Centre. Château de Longchamp, Bois de Boulogne, F-75016, Paris, France. CONTACT: Dr N. Guerin

Institute of Child Health. Tropical Child Health Unit, 30 Guilford Street, London WC1, U.K. CONTACT: Professor David Morley

League of Red Cross and Red Crescent Societies, C.P. 372, 1211 Geneva 19, Switzerland. CONTACT: Marianne Enge

Pan American Health Organization, Expanded Programme on Immunization, 525 23rd Street, NW, Washington, DC 20037, U.S.A. CONTACT: Dr Ciro de Quadros

POLIOPLUS PROGRAM, Rotary International, 1600 Ridge Avenue, Evanston, Illinois 60201, U.S.A. CONTACT: Mr Michael McQuestion

Program for Appropriate Technology in Health (PATH), Canal Place, 4 Nickerson Street, Seattle, WA 98109, U.S.A. CONTACT: Ms Vivien Tsu

Resources for Child Health (REACH) Project, John Snow, Inc., 1100 Wilson Blvd., 9th Floor, Arlington, VA 22209, U.S.A. CONTACT: Dr Pierre Claquin, Dr Norbert Hirschhorn

Teaching Aids at Low Cost (TALC), P.O. Box 49, St Albans, Herts. AL1 4AX, U.K. CONTACT: Mrs Barbara Harvey

UNICEF, 866 United Nations Plaza, New York, NY 10017, U.S.A. CONTACT: Dr Terrel Hill

UNIPAC, UNICEF Procurement and Assembly Centre, UNICEF Plaus, Freepost—DK2100, Copenhagen, Denmark. CONTACT: Mr Fred Irmer

World Health Organization (WHO), Expanded Programme on Immunization, 1211 Geneva 27, Switzerland. CONTACT: Dr R. H. Henderson

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