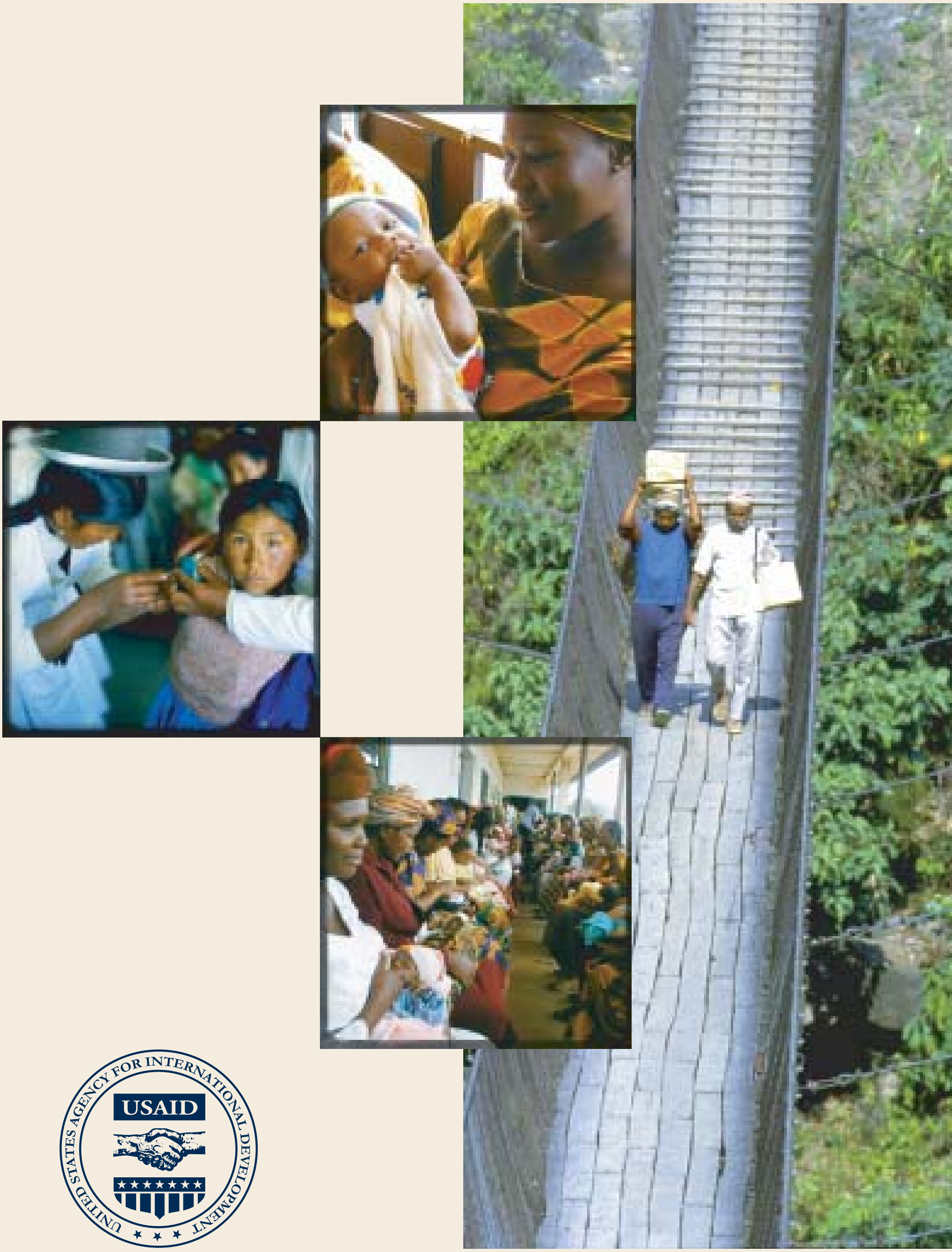
Immunization Essentials

A Practical Field Guide



USAID
UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT

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Immunization Essentials: A Practical Field Guide has been produced and funded by the Office of Health, Infectious Diseases, and Nutrition, Bureau for Global Health, U.S. Agency for International Development (USAID). Production of this document has been coordinated and facilitated by the Monitoring, Evaluation and Design Support (MEDS) Project, and the Population, Health and Nutrition Information (PHNI) Project.

The MEDS Project is funded by USAID under Contract No. HRN-I-02-99-0002-00, Task Order No. 02, and is implemented by LTG Associates, Inc. and TvT Global Health and Development Strategies™, a division of Social & Scientific Systems, Inc. The PHNI Project is funded by USAID under contract no. HRN-C-00-00-00004-00, and is managed by Jorge Scientific Corporation with Futures Group International and John Snow, Inc.

USAID would also like to thank the CHANGE Project and the BASICS II Project for contributing expert technical staff to the preparation of this Guide.

CHANGE is a cooperative agreement (No. HRN-A-00-98-00044-00) between USAID and the Academy for Educational Development with its subcontractor, The Manoff Group, Inc., to provide leadership for behavior change innovation and state-of-the-art tools and strategies.

BASICS II is a global child survival project funded by the Office of Health, Infectious Diseases, and Nutrition, Bureau for Global Health, USAID. BASICS II is conducted by The Partnership for Child Health Care, Inc., under contract no. HRN-C-00-99-00007-00. Partners are the Academy for Educational Development, John Snow, Inc., and Management Sciences for Health. Subcontractors include Emory University, The Johns Hopkins University, The Manoff Group, Inc., the Program for Appropriate Technology in Health, Save the Children Federation, Inc., and TSL.

ISBN 0-9742991-2-X

October 2003

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Preface

"The best way to escape from a problem is to solve it."

– Alan Saporta

Like its predecessor, *EPI Essentials* (1988), this manual has been written for immunization program managers at national and sub-national levels in developing countries and for people who support these managers, particularly field staff of donor agencies. Our intention is to provide information that is practical as well as technically and operationally sound. For readers who would like to explore topics in greater depth, we have provided additional references.

In revising *EPI Essentials*, we have tried to listen to readers' feedback, which was generally very positive. Users very much appreciated having such a variety of practical information in one compact volume; the user-friendly format with many photos, forms, tables, and quotations; the accessible writing style; and, at times, the authors' provocative attitude.

USAID decided to revise the earlier volume because it had long been out of print and because, over the past 15 years, immunization programs have undergone a number of significant changes. These include new objectives (e.g., accelerated disease control for polio, measles, and neonatal tetanus), new vaccines (e.g., hepatitis B and Hib), new procedures to solve old problems (e.g., injection safety), new technologies for vaccine delivery and cold chain, and health sector reforms. Such changes underscore the need for constant attention, sharing of experience, creativity, and flexibility in responding to problems.

A central theme is that there is not just one way of doing things. We provide managers and other decision-makers with scientifically based principles, policies, and standards; technical specifications for vaccines and equipment; and operational considerations that they must weigh to devise the best solutions for their circumstances. We have drawn on real life experiences to illustrate how technical and operational issues can be addressed in the field.

In addition to technical changes, immunization has been subject to boom and bust funding cycles, which are mirrored in fluctuations in coverage rates and disease transmission. We see a need to use the boom times to build strong managerial capacity, stable funding commitments, and a wide base of support for the task required to be done year after year for the foreseeable future to protect every child in every country.

We view the provision of a primary series of vaccines in the first year of life (often called "routine immunization") as the cornerstone of all immunization efforts and other primary health care efforts as well. The fact that immunization gives each child five contacts with the health system before the age of one year is a tremendous opportunity that is often underutilized. While the necessity for "routine immunization" for every birth cohort remains constant, immunization programs are anything but static. Decentralization, integration, and other changes in primary health service delivery pose a continual challenge, and public health personnel must be ever vigilant to make sure that the tremendous promise of immunization is sustained.

While the impact of immunization on childhood morbidity and mortality has been great, its full potential has yet to be reached. Millions of children still die from vaccine-preventable diseases each year. It is our fervent hope that this manual will assist those responsible for immunization programs to meet this challenge. The protection of children, a task every immunization worker takes on every day, is a high calling. If this manual can make that task a little easier, then the effort to prepare it has been worthwhile.

Acknowledgements

Technical Writing Group:	Murray Trostle (USAID) Robert Steinglass (BASICS II) Rebecca Fields (CHANGE Project) Michael Favin (CHANGE Project) Stacey Ballou (USAID)
Writing Consultant:	Kristina Engstrom
Graphic Designers:	Matthew J. Baek, Craig Manning
Editorial Consultant:	Linda Kean
MEDS Project Support:	Daniele Avila Julie Klement Karen Lombardi Muthoni Njage
PHNI Project Support:	Matthew J. Baek, Kristin Kilbane Marcia MacNeil, Sarah Melendez

Technical Reviewers:

Caroline Akim
John Barenzi
Kristine Bisgard
Lyndon Brown
James Cheyne
Pierre Claquin
Andrew Clements
Margaret Cortese
Frances Davidson
Carter Diggs
Rachel Feilden
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David Gittelman
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Nancy Pielemeier
Bryn Sakagawa
Tina Sanghvi
Fred Shaw
Lora Shimp
Diana Silimperi
Peter Strebel
Tej Tiwari
Mark Weeks

Reviewers were sought for the breadth and scope of their technical expertise and a wide range of perspectives. USAID would like to acknowledge and thank all those involved for their contributions. They included staff from BASICS II, CDC, Emory University, FBA, MSH, Ministry of Health (Tanzania), National Council for Children (Uganda), PATH/CVP, PHRplus, QAP, World Bank, WHO, UNICEF, USAID, and other independent immunization experts.

Selected Acronyms

A-D	Auto-disable (syringe)
AEFI	Adverse events following immunization
AFP	Acute flaccid paralysis
BCG	Bacillus Calmette-Guerin vaccine
CDC	U.S. Centers for Disease Control and Prevention
cVDPV	Circulating vaccine-derived polio virus
DHMT	District health management team
DT	Diphtheria-tetanus vaccine
DTP	Diphtheria-tetanus-pertussis vaccine
EPI	Expanded Program on Immunization
FIC	Fully immunized child
GAVI	Global Alliance for Vaccines and Immunization
Hep B	Hepatitis B vaccine
Hib	*Haemophilus influenzae* type b
HIPC II	Highly Indebted Poor Countries II
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
ICC	Inter-agency Coordinating Committee
IIP	Immunization in Practice
IMCI	Integrated Management of Childhood Illness
IPV	Inactivated polio vaccine
MLM	Mid-level management

MMR	Measles-mumps-rubella vaccine
MOH	Ministry of Health
MR	Measles-rubella vaccine
NGO	Non-governmental organization
NID	National immunization day
NRA	National Regulatory Authority
OPV	Oral polio vaccine
PEI	Polio Eradication Initiative
SIGN	Safe Injection Global Network
SNID	Sub-national immunization day
SWAp	Sector-wide approach
Td	Tetanus-diphtheria vaccine
TT	Tetanus toxoid vaccine
UCI	Universal Childhood Immunization
UNFPA	United Nations Fund for Population Activities
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VAD(D)	Vitamin A deficiency (disorder)
VAPP	Vaccine-associated paralytic polio
VVM	Vaccine vial monitor
WHO	World Health Organization
WinCOSAS	Coverage Survey Analysis System
YF	Yellow fever vaccine

Chapter 1: **Introduction**

> **"The health of the people is really the foundation upon which all their happiness and all their powers as a state depend."**
>
> **– Benjamin Disraeli**

Courtesy of Thomas Cooper Library, University of South Carolina

On May 14, 1796, Edward Jenner, a British physician, performed an experiment that would revolutionize public health. He made two small cuts on the arm of an eight-year-old boy, James Phipps, and inserted material taken from a sore on a woman infected with cowpox, a mild disease common to dairy workers. Six weeks later, Jenner injected the boy with fluid from a smallpox lesion, and James did not contract smallpox. With this experiment, Jenner discovered that inoculation of a person with relatively harmless disease material could protect the person from a more dangerous disease. He called this process "vaccination", derived from the Latin name for cowpox, vaccinia.

Milestones in Vaccine Development

1885	First use of live attenuated viral vaccine (rabies) in humans
1909	First live attenuated bacterial vaccine (Bacillus Calmette-Guerin, or BCG) created for use against tuberculosis
1921	Diphtheria toxoid developed
1924	Tetanus toxoid produced
1930s	Pertussis vaccine developed
1932	Yellow fever vaccine developed
1940s	Diphtheria-tetanus-pertussis (DTP) combination introduced
1955	Inactivated polio vaccine introduced
1963	Live attenuated oral polio vaccine introduced
1963	Measles vaccine introduced
1986	First recombinant vaccine (hepatitis B) introduced
1990	First polysaccharide conjugate vaccine (*Haemophilus influenzae* type b) introduced

By the time the World Health Assembly declared in 1980 that smallpox had been eradicated, scientists had developed vaccines for many other diseases. Today, there are many vaccines available to prevent illness. Indeed, vaccination has become one of the most important preventive health care interventions of all time. Every year millions of children and adults receive vaccinations that protect them from a host of infectious diseases; meanwhile, the arsenal of vaccines is growing rapidly through bio-medical research.

Immunity

Immunity is the ability of the body to tolerate material that is indigenous to it and eliminate material that is foreign. The immune system is comprised of organs and specialized cells that protect the body by identifying harmful substances, known as antigens, and by destroying them by using antibodies and other specialized substances and cells. There are two basic ways to acquire this protection – active immunity and passive immunity.

- Active immunity is provided by a person's own immune system. This type of immunity can come from exposure to a disease or from vaccination. Active immunity usually lasts for many years and often is permanent.
- Passive immunity results when antibodies are transferred from one person or animal to another. The most common form of passive immunity occurs when a fetus receives antibodies from his or her mother across the placenta during pregnancy. Other sources of passive immunity include blood and blood products, immune or hyper-immune globulin, and animal antitoxins. Passive immunity disappears over time, usually within weeks or months.

Live microorganisms or antigens bring about the most effective immune responses, but an antigen does not need to be alive for the body to respond.

Types of Vaccine

Live attenuated vaccines are derived from disease-causing viruses or bacteria that have been weakened under laboratory conditions. They will grow in a vaccinated individual, but because they are weak, they will cause either no disease or only a mild form. Usually, only one dose of this type of vaccine provides life-long immunity, with the exception of oral polio vaccine, which requires multiple doses.

Inactivated vaccines are produced by growing viruses or bacteria and then inactivating them with heat or chemicals. Because they are not alive, they cannot grow in a vaccinated individual and therefore cannot cause the disease. They are not as effective as live vaccines, and multiple doses are

Types of Vaccine

- **Live attenuated**
  - – Virus, e.g., oral polio vaccine (OPV), measles, yellow fever
  - – Bacteria, e.g., BCG
- **Inactivated**

  Whole
  - – Virus, e.g., inactivated polio vaccine (IPV)
  - – Bacteria, e.g., whole-cell pertussis

  Fractional
  - – Protein-based
    - – Subunit, e.g., acellular pertussis
    - – Toxoid, e.g., diphtheria and tetanus
  - – Polysaccharide-based
    - – Pure, e.g. meningococcal
    - – Conjugate, e.g., *Haemophilus influenzae* type b (Hib)
- **Recombinant**, e.g., hepatitis B

required for full protection. Booster doses are needed to maintain immunity because protection by these vaccines diminishes over time.

Inactivated vaccines may be whole-cell or fractional. Whole-cell vaccines are made of an entire bacterial or viral cell. Fractional vaccines, composed of only part of a cell, are either protein- or polysaccharide-based.

Credit: Aventis Pasteur

Polysaccharide-based vaccines are composed of long chains of sugar molecules taken from the surface capsule of the bacteria. Unless coupled with a protein, pure polysaccharide vaccines are generally not effective in children under the age of two years. This coupling process is known as "conjugation."

Recombinant vaccines are produced by inserting genetic material from a disease-causing organism into a harmless cell, which replicates the proteins of the disease-causing organism. The proteins are then purified and used as vaccine.

Vaccines used in national immunization programs in developing countries are described in detail in Chapter 12.

Disease Transmission and the Impact of Immunization

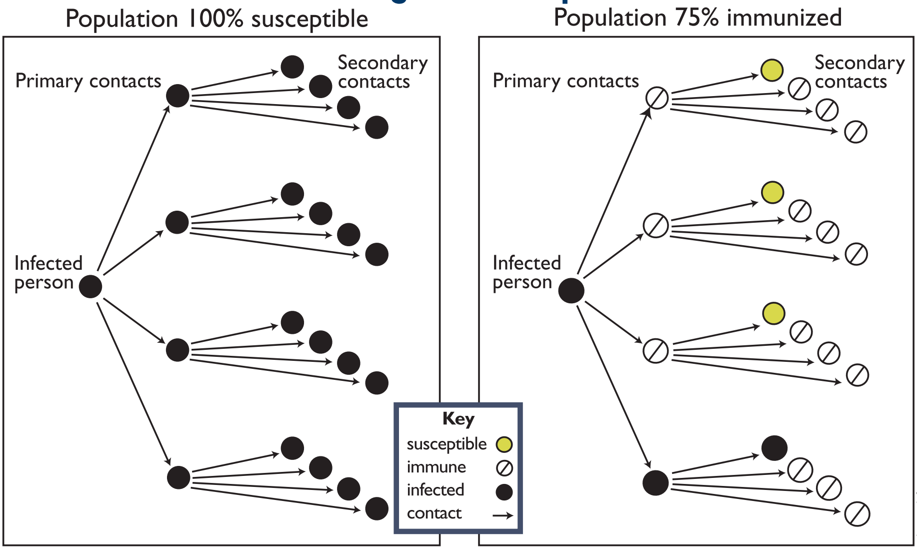
An infectious disease is an illness that occurs when an infectious agent is transmitted from an infected person, animal, or reservoir to a susceptible host. Some of the factors that influence transmission include:

- Contagiousness of the infective agent
- Duration of infectivity
- Disease fatality and attack rate
- Route of transmission
  (e.g. person-to-person, vector-borne, water or food-borne)
- Nature of the vector
- Population density and size
- Nutritional status
- Hygiene and sanitation
- Access to clean water
- Poverty
- Population immunity

A basic concept of public health is that every individual who is protected from a disease as a result of an immunization is one less individual capable of transmitting the disease to others. Individuals who have been immunized serve as a protective barrier for other individuals who have not been immunized, provided that the number immunized has reached a certain level. Reaching and maintaining that level, which varies by communicable disease, provides "herd immunity" to unimmunized individuals.

Credit: WHO

Good immunization coverage can also protect the unvaccinated



Adopted from: Fine, 1994

CONCLUSION

In this hypothetical population consisting of only susceptible individuals, the disease can spread through the population exponentially, eventually infecting everyone because everyone will come in contact with an infected individual.

CONCLUSION

In this hypothetical population where 75% of the population has been immunized, some non-immunized and susceptible individuals (as shown by the green circles) will not become infected because of the fact that they will not come in contact with an infected individual. Therefore, the growth rate of the infection is held in check with only a 75% immunization coverage rate.

The figure above illustrates the concept of herd immunity. It shows two hypothetical populations in which each individual comes in contact with four other members of the population. Both populations have been exposed to a hypothetical disease that is 100% contagious. The first group has no immunity to the disease and, therefore, the disease spreads to everyone.

The second population is partially immune due to vaccination services that have protected 75% of the population. Even though only 75% are immune because of vaccination, the disease does not spread to all of the remaining 25% of susceptible individuals. This is because some of the remaining susceptibles are protected by the fact that they do not come in contact with an infected individual. This is how herd immunity can protect more people than those who actually receive vaccinations and thus inhibit the spread of disease. Note that if the susceptible individuals are unevenly distributed, e.g., if they cluster in urban slums, the level of protection in that population will need to be higher to prevent transmission.

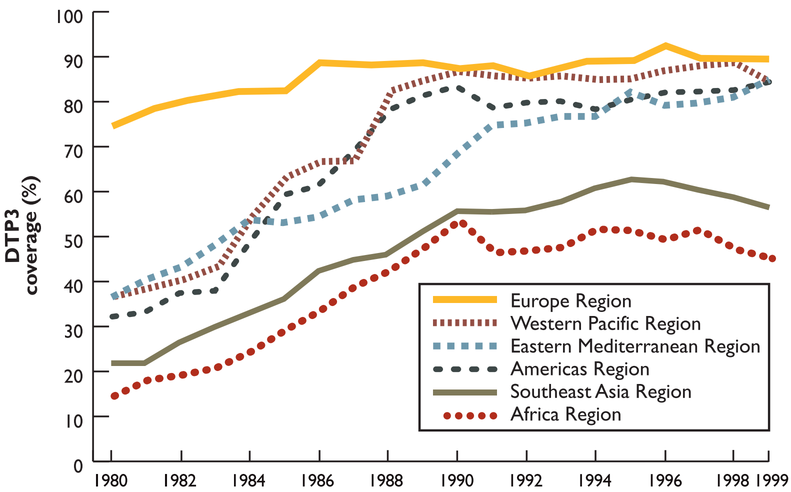
The Global Effort to Immunize All Children

In the 1970s, at the end stage of the global campaign to eradicate smallpox, the World Health Organization (WHO) launched the Expanded Programme on Immunization (EPI). Coverage for basic vaccines was an estimated 5% in developing countries at that time. The EPI goals were to ensure that every child received protection against childhood tuberculosis, polio, diphtheria, pertussis, tetanus, and measles by the time he or she was one year of age and to give tetanus toxoid vaccinations to women to protect them and their newborns against tetanus.

EPI Logo. Credit: WHO

During the 1980s, national immunization programs in developing countries made substantial progress in meeting the EPI goal, with the support of WHO, the United Nations Children's Fund (UNICEF), the U.S. Agency for International Development (USAID), the Italian government, and other partners. EPI and the program to control diarrheal diseases were the "twin engines" that powered child survival programs worldwide. As immunization coverage in developing countries soared, EPI was helping lay the foundation for other primary health care services. By 1990, average reported coverage for the six antigens was over 70%. As a result of the increase in coverage, the incidence of vaccine-preventable diseases began to fall dramatically.

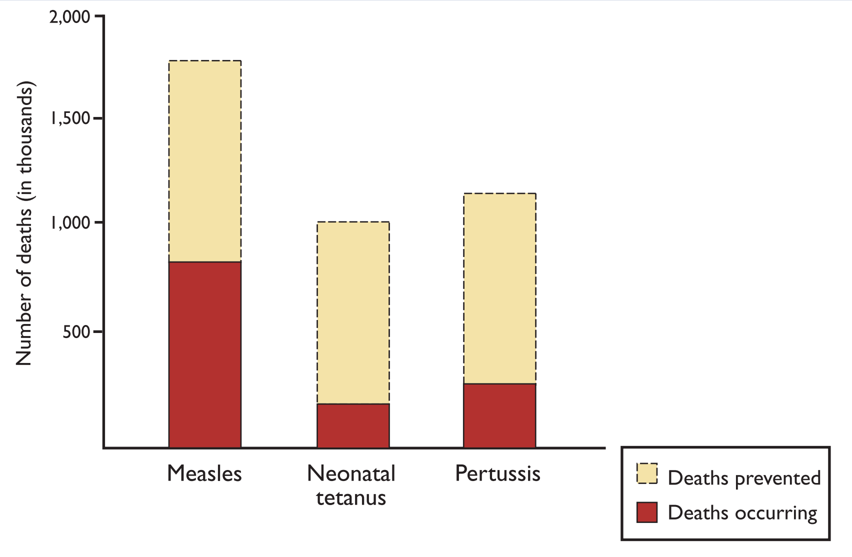
Reported DTP3 Coverage by WHO Region, 1980 - 1999



In the 1990s, coverage leveled off and even declined in some countries. There were a number of reasons why it proved difficult to maintain the momentum of the early EPI years. When coverage peaked in 1990, many believed that the job was finished and turned their attention to other immunization activities such as vertical disease eradication programs. Some donors became fatigued with immunization altogether and, noting the declining incidence of vaccine-preventable diseases, shifted their resources to other health priorities. Another factor was that the remaining unimmunized children were primarily the hard-to-reach children with whom routine health services generally had little or no contact.

Furthermore, health sector reform and structural adjustments diverted attention away from maintaining effective preventive services in many countries and, in some cases, created confusion regarding where the responsibility for immunization resided within the health sector. Whatever the reasons, the result was a declining investment in training, equipment, logistics, and communications.

Global Estimated Deaths Occurring and Prevented, 2000: Measles, Neonatal Tetanus and Pertussis



Despite the slowdown of progress in the 1990s, over two million deaths were prevented in the year 2000 as the result of measles, pertussis, and tetanus immunizations alone (see graph). Clearly, however, the job is far from complete: approximately 800,000 children die each year from measles, 400,000 from pertussis, and 200,000 from tetanus.

The deteriorating situation in the 1990s sounded alarms in the public health community, and at the turn of the century, governments and their partners began to renew their commitment to routine immunization services. New coordination and funding mechanisms were set up. Most noteworthy was the formation of the Global Alliance for Vaccines and Immunization (GAVI), which supports immunization efforts worldwide. GAVI is a coalition of governments and international, bilateral, and private-sector partners with the purpose of helping countries strengthen immunization services and introduce new and underutilized vaccines.

The lessons of the 1980s and 1990s and the new opportunities put forth at the turn of the century have set the stage for great strides in national immunization programs. Realizing the potential of immunization requires a commitment from a broad coalition of partners. That coalition involves everyone from the village health worker to the research scientist, from the national EPI manager to the global policy maker, from the donor agency health officer to the Minister of Health. If these partners can work together in coordinated strategies that give appropriate attention to all the essentials of immunization, then the world's children will face a much safer and brighter future.

Overview of Immunization Essentials

This guide describes what is necessary to administer potent vaccines to children and women in a safe and effective manner on a continual basis. Immunization services must be provided and used throughout the year, every year, to enable each new cohort of newborns and women of childbearing age to become adequately protected. Developing and managing systems to do this requires attention to many program details, which are described in the chapters that follow:

Chapter 2: Immunization Program Management

Roles of the public and private sectors, organization of immunization services, personnel required, donor coordination, global partnerships, community participation, and the impact of health sector reform

Chapter 3: Delivery of Immunization Services

Immunization schedules, organizing routine services, why people use these services, strategies for increasing use, and supplemental immunization strategies

Chapter 4: Monitoring, Evaluation, and Information Management

Using information to record, monitor, and evaluate services, to raise coverage, and to reduce drop-out rates; tools to support these objectives

Chapter 5: Vaccine Supply and Quality

Forecasting vaccine needs, vaccine wastage, procurement, and quality assurance

Chapter 6: Cold Chain and Logistics

Storing, handling, and distributing vaccines and other commodities; essential equipment and procedures; and transportation management

Chapter 7: Injection Safety

Assessing safety, developing the policies and practices to promote injection safety, managing waste, and selecting appropriate equipment

Chapter 8: Disease Surveillance

Planning and implementing surveillance activities for disease control and adverse events

Chapter 9: The Role of Behavior Change

Determining feasible actions for parents, health staff, and others to enhance immunization programs; developing comprehensive strategies to promote and facilitate those behaviors

Chapter 10: Costs and Financing

Mobilizing resources, options for financing, costing and budgeting, and using resources efficiently and effectively

Chapter 11: New Vaccines and Technologies

Introducing new vaccines and technologies into existing programs; new vaccines and technologies in the pipeline

Chapter 12: Vaccines and Vaccine-Preventable Diseases

Details on vaccines used in developing country programs, the diseases they prevent, and disease-specific strategies for their control

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Full page photo credit: Kelley Sams, BASICS II

Chapter 2: **Immunization Program Management**

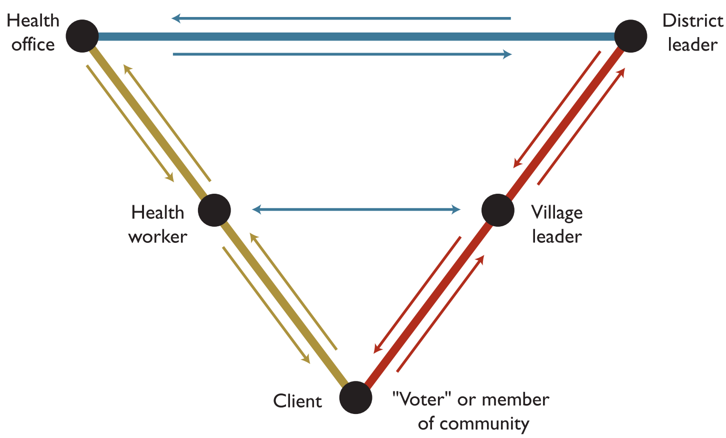
"Tis skill, not strength, that governs a ship."

– Thomas Fuller, 1732

Immunization program managers operate within the context of the overall health system. Consequently, whether they think in terms of "systems" or not, their decisions and activities can strengthen the system or weaken it. This happens because most functions in the health system are shared among programs and services — personnel, budgets, facilities, equipment, supplies, transportation, logistics, supervision, and more. Changes in one activity ripple through the whole system.

Priorities, organization, and resources differ among health systems. In recent years, many health systems have faced pressure to improve efficiency, raise quality, and increase access to services, while simultaneously reducing costs. The experience of health sector reform has underscored the extent to which the health system affects, and is affected by, the political, economic, and social environment, as shown below. Clients, health workers, and health officials interact in numerous ways among themselves and with the political structure. As voters or members of the community, clients can provide the critical link between the health system and the political environment.

Good health is good politics



The Public and Private Health Sectors

Public Sector

The public health sector includes ministries of health, public hospitals, and government health facilities at the local, district, other sub-national, and national levels. Public health officials formulate policies, standards, and guidelines for national immunization programs. They monitor immunization coverage and disease incidence. They are responsible for ensuring that all immunization service providers, including those in the private sector, comply with the national immunization schedule, maintain the vaccine cold chain, practice injection safety, and follow other policies governing equity and quality. Health personnel from the public sector provide the majority of vaccination services in most developing countries.

Private Sector

The private sector includes non-governmental and for-profit components.

Non-governmental organizations (NGOs) are nonprofit groups that provide curative and preventive health services directly and/or support government-provided services. They range in size and scope from small religious or community-based organizations to large international groups with hundreds and even thousands of employees.

A traditional strength of NGOs is their ability to reach people that lack access to public-sector services. Many NGOs have good relationships with people in the communities they serve and involve community members in planning and supporting activities. People often regard health services provided by NGOs as being of higher quality than those provided by the public sector.

In some countries, involvement of health-focused NGOs in immunization programs is limited, largely because they do not have access to vaccines and immunization equipment. On the other hand, their extensive involvement in programs like Integrated Management of Childhood Illness (IMCI), in which they manage drugs and supplies and provide services, indicates that given adequate support, NGOs can contribute to immunization.


Credit: Hari Krishna Shah, BASICS II

An outpatient center.

National immunization programs can take advantage of NGOs' experience and appeal by encouraging their participation in:

- Organizing and providing immunization services directly, although the government should always be responsible for ensuring that NGO services adhere to government policies, norms, and standards.
- Supporting public-sector services with in-kind assistance (e.g., transportation, lodging, and meals), financial support, or technical support (e.g., cold chain equipment, maintenance, and repair).
- Mobilizing the community to demand and preparing the community to receive immunization services.
- Reporting cases of vaccine-preventable diseases and tallies of vaccinations that NGOs provide.

For-profit providers consist of individuals and organizations that provide services or products for monetary gain. For-profit service providers include professionally-trained health workers, traditional practitioners, private hospitals, and clinics. This sector also includes manufacturers and sellers of pharmaceuticals, health products, and equipment, as well as companies that provide laboratory services, fleet management, equipment repair and maintenance, training, and other services.

Vaccination services offered by these private providers are available to those who pay for them. People who are unable to pay and who are often most at risk of vaccine-preventable diseases must be reached by the public sector, if they are reached at all.

The Organization of Immunization Services

In recent years, ministries of health have been increasingly faced with the challenge of balancing the potential benefits of local decision-making with the efficiencies of centralized policymaking and procurement. Setting policies and standards at the central level helps to ensure technical reliability and consistent practices throughout their countries. Central-level procurement of some commodities, particularly vaccines, makes it easier to negotiate lower prices and to control quality. Staff in local health facilities and district health offices need to continue to plan and monitor the services that they are responsible for delivering.

In 1998, Feilden and Nielsen studied the impact of health sector reform on immunization in two African countries. Based on this analysis, they developed a matrix to help decentralization planners distinguish the immunization service functions that should be retained at the national level from those that, although traditionally a national responsibility, could effectively be located at more peripheral levels.

Distribution of Immunization Service Functions Among Levels		
Function	**National level only**	**National and/or other levels**
Formulating national policies, standards, and guidelines	Yes	
Planning international coordination (e.g., for NIDs)	Yes	
Planning service delivery strategies		National coordinates with other levels and disseminates news of creative and successful local solutions.
Advocacy for allocation of funds from central government; coordinating donor support	Preferable to ensure equitable distribution	
Procurement: preparation of tender documents, monitoring quality of products bought under the tender (vaccines, equipment, and supplies)	Yes	
Purchase, customs clearances, storage, stock management, distribution		These functions may be delegated (as in South Africa).
Forecasting, quantification	Monitor the quantities forecast	With bottom-up forecasting, national level can aggregate totals from lower levels, but total quantity ordered may be others' responsibility.
Monitoring, surveillance, and reporting; design of formats for use nationwide	Aggregate data from lower levels; key role for AFP (acute flaccid paralysis) surveillance. Forward data to WHO Regional Office	Local staff, close to point of service, can act promptly, before data reach the national level.
Focal point for research pertaining to immunization	Yes: choice of topics, priority setting and coordination are needed for best use of resources	
Organizing reviews	Yes	Lower levels participate.
In-service training; updating skills	Skill requirements defined as per policies, standards and guidelines	National participates in curriculum development; training itself can be delegated and decentralized.
Supervision		Yes

Immunization Service Personnel

Typical assignments of immunization functions of government personnel at various levels of the system are shown in the table below. It is important for government planners and partners to recognize that most of these people have responsibilities in addition to immunization services, so their workloads may be heavy.

The table excludes personnel who are less directly involved in immunization services, such as health planners, human resource managers, and financial managers. The list also excludes members of the community who participate voluntarily.

Government Personnel Directly Involved in Immunization Services

National	District	Health Facility*
National Manager **Disease surveillance officers** **Information management specialist** **National vaccine store manager and storekeepers** **National cold chain and logistics manager** **Workshop managers and technicians** For repairs of cold chain equipment that cannot be made at more peripheral levels **Transport officer** **Training officer and training staff** May be a private-sector organization **Communication and social mobilization staff** Often part of a health education or social mobilization unit that assists multiple health services **Laboratory technicians** **Accounting and clerical workers**	**District Health Management Team** Day-to-day immunization operations may be the responsibility of a public health nurse or district cold chain officer on the team. **Disease surveillance officer or focal point** **Cold chain and logistics officer** **Transport officer** In some districts **Accounting and clerical workers**	**Officer-in-charge** Usually a nurse who plans, manages, and monitors immunization services, among other responsibilities. In small facilities, this may be the only person who is authorized to give injections. **Nurse assistant** Usually prohibited by law from giving injections but can give OPV, register, and advise parents. **Custodial staff** Responsible for maintenance and repair of cold chain equipment and vehicles. In some facilities, they may take on some of the nurse assistant roles. **Clerical workers** May be volunteers

* In many small dispensaries and health posts, the staff consists of one person who is a manager, medical professional, technician, administrator, and custodian, all in one.

Source: Adapted from Feilden and Nielsen, 2001

In addition to the three levels shown in the table, many countries also have sub-national levels (provincial, regional, or state), but few staff members at these levels are dedicated solely to immunization services. Even surveillance officers who were initially appointed solely to monitor acute flaccid paralysis (AFP) for the polio eradication initiative now are responsible for finding and investigating other communicable diseases.

Coordination of Immunization Activities– Inter-agency Coordinating Committees

The public- and private-sector individuals and groups involved in immunization service provision or support need to coordinate their activities at all levels. Inter-agency Coordinating Committees (ICCs) have been formed in many countries to respond to this need at the national and, sometimes, other levels.

These committees usually include:

Credit: Kelley Sams, BASICS II

"Many hands make light the work."

- Ministry of Health staff (e.g., the national immunization program manager and the director of preventive services)
- Staff from related ministries (e.g., the Ministry of Finance and Ministry of Planning)
- Multilateral donors (WHO and UNICEF)
- International development banks
- Bilateral agencies (e.g., USAID, Department for International Development [DFID], Japan International Cooperation Agency [JICA])
- Non-governmental organizations

ICCs work with national and sub-national immunization personnel to assist with multi-year and annual planning and reviews; coordinate financial and other resource needs; and analyze, design, implement, monitor, and supervise immunization services. One of their most important tasks is to ensure that adequate funding is available for immunization services (see Chapter 10). ICC sub-committees are often formed to focus on specific technical issues, such as vaccine supply, logistics, or social mobilization.

WHO has developed generic terms of reference for ICCs, which include suggestions for their roles, as shown in the box.

The Role of ICCs

Technical

- Development of a national policy framework for vaccines and immunization that gives priority to immunization activities, sets targets, and provides guidelines
- Sponsorship of periodic in-depth assessments of national immunization programs
- Advisory body for national strategic plans of action
- Support for the implementation of strategies
- Monitoring of service performance; tracking of disease surveillance data
- Monitoring quality control and adherence to international standards
- Development of proposals for program support

Financial

- Evaluation of the use of resources
- Financial planning
- Mobilization of additional resources when necessary

Political

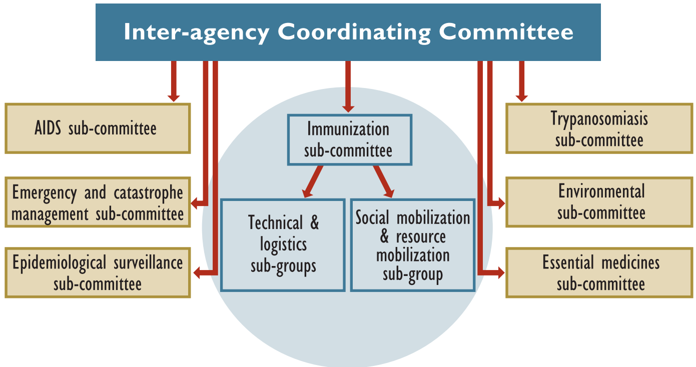
- Advocacy for increased commitment to immunization at all levels
- Social mobilization

Capacity Building

- Development of government capacity for managing and delivering immunization services

ICCs work most effectively when a national representative, such as a high-ranking Ministry of Health official, directs them, when roles and responsibilities are clearly defined, when opportunities for in-depth technical discussions are provided, and when all members agree to terms of reference that outline these roles and responsibilities. All members should have decision-making authority from their own organizations, and the structure should allow for the frank discussion of even sensitive issues.

The structure of the ICC in the Democratic Republic of Congo (DRC), described on the following page, has worked well in that country.



Credit: Nelson and Shimp,2002

Enhancing the Effectiveness of an ICC

The ICC for immunization in the DRC was formed in the late 1990s as a unit of a health sector-wide ICC, which has seven sub-committees to address interventions that have been designated by the DRC government as high priority. Members include various branches of the Ministry of Health, WHO, UNICEF, foreign government donors (e.g., USAID, Government of Japan, and the European Union), technical subcontractors of foreign governments, NGOs, and missionary groups. The immunization sub-committee is divided further between two subgroups, as shown in the diagram.

The experience of the DRC Ministry of Health has shown that a number of elements are needed in order for an ICC to be effective:

- Harmonizing different objectives, priorities, agendas, work plans, and budgeting cycles of different institutions
- Building an open, inclusive, and collegial partnership among members that resolves conflicts transparently and avoids favoritism
- Designating a single focal organization to call meetings, draft documents, monitor progress, etc.
- Fostering continuity in membership by making assignments for two years or longer
- Communicating frequently
- Conducting meetings with clear objectives, agendas, time management, meeting minutes, and follow-up
- Establishing systems of checks and balances
- Focusing on the long-term development of immunization services (including financing)

Global Partnerships — Global Alliance for Vaccines and Immunization

Created in 1999, the Global Alliance for Vaccines and Immunization (GAVI) is a public-private partnership to strengthen immunization services and introduce new and underutilized vaccines. GAVI provides a forum for partners to agree upon goals, share strategies, and coordinate activities. As of 2003, the financial arm of GAVI, the Vaccine Fund, provides financing to over 70 countries to help them reach national and GAVI objectives (see Chapter 10). The box below summarizes GAVI's organizational structure.

Organizational Structure of GAVI

GAVI Board – includes the highest-level representatives of Alliance members to set policy.

Renewable members:

WHO
UNICEF
The World Bank
Bill & Melinda Gates Foundation
The Vaccine Fund

Rotating members:

One foundation
Two developing country governments
Three industrialized country governments
One NGO
Pharmaceutical industry – industrialized country
Pharmaceutical industry – developing country
Research institute
Technical health institute

GAVI Working Group – comprises managers from GAVI partner institutions, some on a rotating basis. Supports the Board in policy development and implementation. Members make sure that GAVI priorities are reflected in their institutions' work plans.

GAVI Secretariat – facilitates coordination among partners and manages the review of country proposals to the Vaccine Fund.

GAVI Task Forces – time-limited. They address specific issues of concern to the Board, including:
Advocacy and Communication
Implementation
Financing

Regional Working Groups (RWGs) – includes partners with a technical presence in regions. These groups coordinate technical assistance activities between national and international levels.

Source: Global Alliance for Vaccines and Immunization, 2002

Community Participation

Community participation in immunization programs has been shown to result in higher coverage and, ultimately, reduce the numbers of cases of vaccine-preventable diseases. Managers at all levels should seek the participation of local politicians, religious leaders, community group leaders, and parents in scheduling the days and hours for immunization sessions, organizing outreach activities, promoting immunization, and monitoring performance. Community members also can help solve specific service delivery problems, as described below.

Village Development Councils Improve Immunization Services!


Credit: Mizan Siddiqi

The Primary Health Care Center (PHC) in Abba, Nepal, had a refrigerator but no kerosene to run it. The lack of refrigeration for vaccines meant that every day a member of the PHC staff would have to go to the district health office to collect vaccines for the catchment area. In turn, village health workers (VHWs) would come to the PHC every day to collect vaccines for use that day in their villages. When vaccines were not brought from the district to the health center or when VHWs were not able to collect vaccine from the center, fixed sessions were cancelled. Outreach sessions were difficult to schedule. The availability of frozen icepacks was also a problem.

The Ministry of Health could not provide funds for the purchase of kerosene, so Village Development Councils (VDCs) met with PHC and district officials and eventually agreed to cover that cost. The PHC now has kerosene for its refrigerator and stores adequate stocks of vaccines. Fixed sessions are held as scheduled, and more outreach sessions are offered. The VDCs participate more actively in planning and monitoring immunization activities in their areas, and there are indications that coverage is increasing and the drop-out rate is decreasing.

Community participation made the difference.

Source: Siddiqi and Weeks, 2002

The Impact of Health Sector Reform on Immunization Services

Immunization services everywhere are continually in transition, as governments try to meet political pressures, improve efficiency, reduce costs, identify reliable funding sources, and increase access to and quality of services. These never-ending changes affect all aspects of government, including the health sector. It is imperative that immunization program managers participate in any national level discussions on the organization and financing of the overall health sector.

Common Elements of Health Sector Reform

There is no single formula for health sector reform. Therefore, reforms should be adapted to address the situation in a particular country, taking into account health, economic, administrative, and political factors. Some common elements of health sector reform that are most likely to affect the management and delivery of vaccination services include:

Decentralization: moving decision-making authority and resources (financial and human) from the central level to more peripheral levels

Integration: not just of services at the peripheral level, but also of management functions (for example, logistics or information management) at central, regional, or district levels

Public-private mix and changes in financing: alternative strategies for service delivery or financing that are intended to increase the funding base for services

Source: WHO, 2002

One of the many lessons of health sector reform has been that health priorities are not the same at the national and local levels. Indeed, one result of decentralization in many countries has been a reduction in support for immunization and other preventive services. District health management teams tend to give higher priority to curative care and services, such as ambulances, that are visible to the public and to politicians.

Credit: Kelley Sams, BASICS II

Members of the community share their concerns with local health officials.

Another lesson of health reform is that when responsibility for the delivery of health services is shifted from one level of the system (e.g., national) to another (e.g., district), resources must follow. To ensure that continuous funding is available for immunization, some national governments are providing grants to districts for immunization or primary health care services.

Staff resources are as critical as financial resources. Over the coming years, as district health management team members get training and work experience in public health and preventive care, their skills and knowledge should begin to reach the level of their national counterparts. Because these team members make budget decisions, they also need to be skilled in assessing the merits of competing demands, setting priorities for allocating and disbursing limited resources, strategic planning, and dealing with the public.

A third lesson of health sector reform is that the same individuals who are given explicit responsibility and authority for managing immunization services should be involved in planning, budget development, monitoring, and evaluation, not only for immunization services but also for the overall health sector. Although the adaptation of program management and services to fit local circumstances is necessary, it must be counterbalanced with the need to adhere to technical standards set at the national level. For example, the vaccination schedule and the appropriate temperatures for vaccine storage should not vary from place to place within a country.

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Full page photo credit: WHO

Chapter 3:
Delivery of Immunization Services

"Every journey begins with a single step."

– Lao Tsu

In order to reduce mortality, morbidity, and disability, immunization programs must safely administer potent vaccines to susceptible children and women before they are exposed to vaccine-preventable diseases. This chapter describes some of the barriers that prevent people from using immunization services and then outlines delivery strategies for overcoming some of these problems.

Immunization Schedules

The schedule recommended by WHO for delivering the primary series of vaccines to children below the age of one year reflects a balance between epidemiology and practicality. Although the approximate ages and intervals

WHO's Recommended Schedule for Primary Series of Childhood Vaccinations in Developing Countries

Age	Vaccines
Birth	BCG OPV0 Hep B*
6 weeks	DTP1 OPV1 Hep B* Hib1**
10 weeks	DTP2 OPV2 Hep B* Hib2**
14 weeks	DTP3 OPV3 Hep B* Hib3**
9 months	Measles Hep B* Yellow fever***

***Only three doses of hepatitis B vaccine are needed for full protection. Hepatitis B vaccination schedules vary by country. See Chapter 12.**

**Hib stands for *Haemophilus influenzae* type b. See Chapter 12.

***In countries where indicated.

between doses in country schedules should not deviate from those that WHO recommends, there is no single schedule that is appropriate for all countries. An understanding of local epidemiology and national policy is needed to adapt the recommended schedule to a given country's needs. In so doing, local experts should keep in mind the importance of limiting the number of contacts and reaching children as soon as their immune systems are able to respond to the vaccine.

Provision of Routine Immunization Services

There are several strategies for the routine delivery of immunization services in or from health facilities.

Fixed facility: This refers to the regular delivery of vaccinations in a health facility on specified days of the week and hours of the day. Larger facilities may give vaccinations whenever eligible clients come.

Credit: Veronique Leger

Outreach: Outreach is the delivery of services to people who cannot get to health facilities or who can do so only with difficulty. Trips to outreach sites are usually completed within a day and are made by health facility staff on foot or using motorized vehicles, bicycles, or pack animals. Monthly visits provide the most timely protection for children, although less frequent visits may be necessary where distances are far, travel is difficult, or staff resources are limited. Rainy seasons or snowy winters may make it necessary to schedule a pre-season and a post-season outreach visit with a gap of several months in between.

In some countries, such as India, outreach visits for primary vaccinations that are conducted once, twice, or three times a year are called "pulse immunization."

Mobile strategy: This usually describes trips of more than one day by district or regional health workers for the purpose of delivering services to people living in remote areas. Mobile teams may spend several days traveling to reach the people. In Nepal, it can take up to ten days of walking from the district center to reach some villages.

In general, the cost per vaccination is higher when services are provided through outreach and mobile strategies than through fixed services, because health workers spend more time to reach each child and because there are transportation and per diem costs involved. However, some people cannot be reached in any other way.

Why People Use Routine Immunization Services

Studies in many developing countries show that the great majority of parents view immunization as a worthwhile and relatively easy health practice. Childhood immunization only requires parents to take action about five times in the first year of a child's life and is generally accepted by families and communities. This contrasts with other practices, such as exclusive breastfeeding, which require repeated and frequent actions on the part of mothers and which are sometimes contrary to cultural norms and beliefs.

Scheduling immunization sessions to be accessible is only half the battle – people must actually use the services. Research from many countries indicates that people will use immunization services at least once if they know what services are offered and where and when they are available. They will return if:

- They know when to come back.
- They have been treated respectfully.
- They have confidence that they will receive the vaccinations that they come for.

Credit: Kelley Sams, BASICS II

Health workers should be sure mothers know when and where to return for the next vaccination.

We also know why families do not use immunization services. Focus group discussions, interviews, and knowledge-attitude-practice surveys in a wide range of countries have consistently found that a majority of parents wish to immunize their children but that many encounter obstacles, such as those described below. These are often due to perceived and actual deficiencies within the health services.

Lack of information. Many families lack accurate information about immunizations and immunization services. In fact, this is often the primary obstacle to achieving full immunization of children and women who have good access to services. They do not know when and where immunizations are available or when their next vaccination is due. They often are unaware that if they miss a scheduled immunization date, they can still be immunized; so they should come as soon as they can.


Credit: Kelley Sams, BASICS II

Poor services. Some people receive one or more immunizations, but are unwilling to return because they are dissatisfied with the services they have received for such reasons as:

- Long waits
- Rudeness or insensitivity on the part of health workers
- Poor vaccination techniques that cause abscesses or other discomfort
- Unauthorized fees charged by health care providers
- Unscheduled facility closures
- Shortages of personnel, vaccines, drugs, or other supplies

Time constraints. Making a trip to a health facility with a healthy child may not be the first priority for people with other important things to do. For many parents, particularly women, collecting and preparing food for daily meals requires working from dawn to dusk. Others have agricultural work that takes them far from home, inflexible working hours, other family obligations, or they lack child care.

Social, cultural, or political barriers. Many people who live within geographic reach of health facilities do not use them because of social, cultural, or political barriers. Migrants, people from minority ethnic groups, urban squatters, and illegal residents often try to avoid contact with any public authority. People will not return to health facilities where they feel unwelcome.

Misinformation. False beliefs or malicious rumors also keep people from using services. Common *misconceptions* include the following:

- Children are safe from vaccine-preventable diseases because a religious or supernatural being protects them.
- Children are fully protected because they have received some immunizations.
- Sick children cannot be vaccinated.
- Immunizations commonly cause sterilization, disease, or dangerous side effects.

- Vaccinators would come to their homes or communities if the vaccinations were truly important because they have done so before during immunization campaigns.

Distance. Some people simply do not live within reach of health services. Some of these people live in permanent communities, and others are on the move (e.g., nomads and seasonal migrants).

Strategies for Increasing the Use of Routine Services

The reasons why people never use immunization services or stop using them after one or two encounters differ from place to place, but most strategies focus on one or more of the following goals:

- Reaching the unreached
- Reducing drop-outs
- Limiting missed opportunities

Reaching the Unreached

In many countries, geographical barriers are not the only — or even the primary — reason why people are not vaccinated. Access is also impeded by inconvenient scheduling, lack of information, and lack of opportunities — problems that can be solved relatively simply by improving scheduling, raising awareness, or expanding outreach.

Improvements in scheduling. Immunization sessions should be scheduled to be convenient for parents. Health facility managers should assess their facilities' immunization schedules at least once a year and change them if necessary to reflect the current needs of the community. Both epidemiological and practical considerations are important. For example, holding sessions less often than once per month may delay protection, but overly ambitious schedules may keep health workers from performing other responsibilities or result in cancelled sessions. For outreach, scheduling visits to individual villages every two months instead of every month permits health workers to reach twice as many villages.

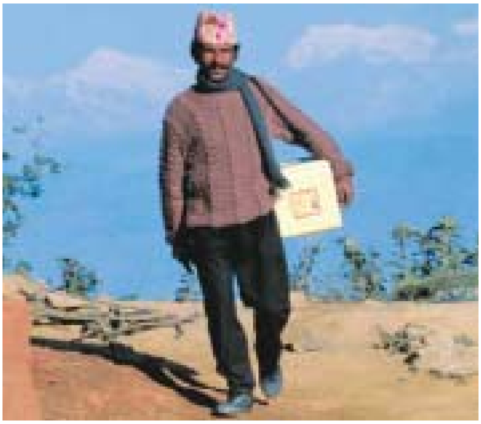
Credit: Kelley Sams, BASICS II

A clear schedule of vaccination sessions can help parents avoid wasted trips.

One indicator of good management is the number of vaccination sessions that are actually held compared to the number planned.

Raising awareness. Families need to know about immunization services before they can use them. Local health workers play a particularly important role in increasing awareness and providing information to the target population. Individual volunteers and community-based groups can assist in this effort, as described in Chapter 9.

Improving and expanding outreach. Effective outreach must be well planned, organized, and supported. Vehicles must have fuel and must be in good condition. Vaccines, sterile syringes and needles, vaccine carriers, icepacks, and other supplies must be available in the right amount, in the right place, and at the right time. In addition, outreach workers often need per diems.



Credit: WHO

Several strategies can be employed to maximize limited resources and assure continuity of outreach services. Village health days can be used to reach remote populations three times per year with vaccinations, vitamin A supplementation, and other health services. Communities can also support visiting teams by providing work sites, furniture, food, and lodging. These strategies can broaden the appeal of outreach, share costs with other programs, and help avoid overdependence on external funding sources.

Targeting services to meet urban needs. Although vaccination coverage rates often appear higher in cities than in rural areas, these figures may mask pockets of much lower coverage in high-risk areas such as urban slums. Reaching unreached populations in urban areas is particularly important epidemiologically because:

- Population density increases the intensity of disease transmission. Epidemics occur more frequently in urban than rural areas, resulting in infection of younger children, more severe illness, and higher mortality.
- Chains of transmission, particularly of measles and pertussis, often begin in cities and towns and then spread to rural areas.
- The poor sanitation and poor nutrition found in densely populated slum areas weakens residents' resistance to disease and increases their risk of severe illness and death.

Improving immunization coverage in urban areas can be complex. In some situations, the ministry of health, municipal governments, ministry of local governments, and NGOs all share responsibility for managing and providing vaccination services. Ongoing coordination is needed to ensure that policies and standards are applied uniformly, trained health workers are available, and marginalized populations that may fall outside of established jurisdictions, such as transient slum-dwellers, have access to services. Data on vaccination coverage and disease surveillance should be collected from all service providers, private as well as public.


Credit: Richard Pollard

Pockets in urban areas are likely to have low coverage and high disease transmission.

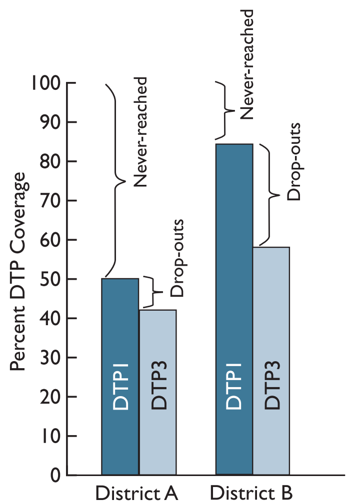
Urban health facilities, like their rural counterparts, can marshal the help of community members and local health teams to identify who is not being reached and to find out why. For example, people who live within walking distance of a health facility may not use its services because of lack of information, cultural or physical barriers, or previous negative experience. Different communication and service delivery strategies may be needed to reach populations with diverse language, cultural, and socioeconomic backgrounds. Planners should take advantage of the many events that are available in urban areas, such as public concerts, sports matches, fairs, and religious gatherings, to promote immunization.

Reducing Drop-Outs

Drop-outs are people who begin the vaccination schedule but do not complete it. They have at least periodic access and motivation to use immunization services, but they stop using them for one or more of the reasons described above. With the increased use of expensive vaccines like Hep B, Hib, and combination vaccines against multiple diseases, monitoring drop-outs and devising strategies to prevent them merit greater attention. If a child does not receive all of the doses required for full protection, the resources that have been used to partially vaccinate that child are mostly wasted.

Many health districts have problems with never-reached segments of the population and with drop-outs. Because resources are limited, planners have to

Understand the Problem — Never-Reached or Drop-Outs?



Never-reached = 100% minus DTP1 % coverage

$$\text{Drop-out} = \frac{\text{DTP1 coverage} - \text{DTP3 coverage}}{\text{DTP1 coverage}} \times 100$$

District A. 50% of children have access to immunization services using DTP1 coverage as an indicator. 42% complete the three-dose series of DTP. The drop-out rate therefore is 16% :

$$\left(\frac{50\% - 42\%}{50\%} \right) \times 100 = 16\%$$

In District A, planners should give priority to raising DTP1 coverage by reaching the 50% of children who have never been reached. Reducing drop-outs would, at best, result only in a gain in DTP3 coverage from 42 to 50% .

District B. 85% of children have received DTP1. 58% complete the three-dose DTP series. The drop-out rate is 32% :

$$\left(\frac{85\% - 58\%}{85\%} \right) \times 100 = 32\%$$

In District B, reaching the last 15% of the population that has never been reached is likely to be labor-intensive and expensive. On the other hand, following up on drop-outs and persuading them to complete the series could raise coverage of DTP3 from 58% to 85%. Unless additional information indicates otherwise, District B should give priority to reducing drop-outs.

decide where their efforts will result in the greatest benefit, as shown in the example on the previous page. Drop-out rates can be calculated using either absolute numbers or percentages.

Formulas for calculating and monitoring drop-out rates are discussed in Chapter 4. System failures that cause drop-outs, such as vaccine stock-outs or lack of other essential supplies, are discussed in Chapters 5 and 6. Techniques for increasing public knowledge and improving the communication skills of health workers are described in Chapter 9.

Limiting Missed Opportunities

A missed opportunity occurs when a client, present in a situation in which vaccinations should be available, does not receive all of the vaccines for which he or she is eligible. Missed opportunities delay protection and prolong the risk of getting the disease. The missed opportunity and 30-cluster surveys are good tools for identifying whether potential vaccination clients are being missed and for what reasons. (See pages 82-83.) Those reasons are sometimes system related, i.e. health workers do not have sufficient quantities of vaccine or the appropriate equipment. More commonly, missed opportunities can be corrected by health workers themselves, as described below.

Failure to Screen Can Be Fatal

While on a visit to a health center in her district, the supervisor talked with a woman whose baby had recently died of neonatal tetanus. She was receiving weekly treatment for tuberculosis from a health facility a few hundred meters from her home, but not once during her pregnancy had she been screened for tetanus toxoid. This was the second baby she had lost to neonatal tetanus.

Improve screening. Health workers should check children's and women's vaccination status every time a client visits a health facility or outreach site, regardless of the reason for the visit. Sick children should always be screened for vaccination, as recommended in protocols like those for Integrated Management of Childhood Illness (IMCI). Girls and women receiving antenatal and postnatal care should be screened and, if eligible, vaccinated with tetanus toxoid.

Credit: Kelley Sams, BASICS II

Vaccination cards are of primary importance in determining eligibility for vaccination and in avoiding missed opportunities. Health workers should advise the mother to bring vaccination cards every time she visits the health facility for any reason. Health facility registers also can be used to identify children who are due for a vaccination. Vaccination cards, registers, and other methods of record-keeping are described further in Chapter 4.

Give all vaccines due. Some studies have found that health workers fail to give from 30 to 40% of the vaccinations that are due at the time of clients' visits. For example, a nine-month-old child may be given DTP and OPV but not measles vaccine, despite being eligible for all three vaccines. This often reflects a belief on the part of health workers or parents that giving too many vaccines at once will harm a child, when, in fact, vaccines are as safe and effective in combination as they are individually. Some health workers mistakenly delay the measles vaccination because they believe that it must be the last vaccination given to the child.

Credit: Kelley Sams, BASICS II

Job aids can help remind health workers how to administer vaccines correctly.

Sometimes, missed opportunities reflect an organizational problem. For example, a mother arrives at a busy session, and a health worker or volunteer checks her child's card and determines that the child is eligible for DTP3, OPV3, and measles vaccine. The health worker gives the child DTP3 and returns the card to the mother, assuming that the mother will go to a nearby table for the next vaccination. Instead, the mother leaves the facility thinking that she is finished. The child's card shows that three vaccines have been

Contraindications and Precautions

While vaccines offer significant benefits for most individuals, there are rare situations where vaccination is not recommended. Contraindications and precautions identify circumstances when vaccines should not be given. Contraindications are conditions in the recipient that greatly increase the chance of a serious adverse reaction.

Precautions are conditions in the recipient that may increase the chance of an adverse reaction or may impair the ability of the vaccine to produce immunity. Most contraindications and precautions are temporary, so the vaccine may still be given once the condition passes. Since contraindications and precautions vary by vaccine, health workers are strongly advised to understand the appropriate restrictions for each vaccine and to screen recipients carefully.

given that day, but the child has received only one.

Eliminate false contraindications. There are few true contraindications to vaccination. Children with low-grade fever, a cold, diarrhea, vomiting, or other mild illness can safely and effectively be vaccinated. Prematurity, low birth weight, and breastfeeding are not reasons to withhold a vaccination. It is particularly important that malnourished children be immunized because they are much more likely to die from a vaccine-preventable disease than well-nourished ones.

Over the past several years the need for clear policies regarding vaccination of children with HIV infection has been recognized. WHO recommendations for vaccinating children with HIV infection are summarized in the box below.

Vaccinating in the Presence of HIV

Policy makers and program staff must address the difficult question of vaccinating children with compromised immune systems. Live attenuated vaccines are a particular risk because the vaccines can cause a form of the disease, and children with weakened immune systems may not be able to fight off even a mild infection. This risk, however, must be balanced against the threat of the disease that the vaccine is intended to prevent. Such diseases can be very severe in HIV-infected children.

The problem is that most infants who have been infected with the HIV virus do not show symptoms, and it is difficult to know if they should be excluded from vaccination. With respect to the vaccines that may present the greatest threat to HIV-infected children, WHO recommends the following:

BCG – BCG should be given to all infants, even if their mothers have HIV, unless the infant shows HIV/AIDS symptoms, which is highly unlikely. Since testing infants for HIV before they are vaccinated is generally not feasible, virtually all newborns should receive BCG.

This practice will protect HIV-positive and -negative children who are at high risk of exposure to tuberculosis because their mothers are HIV-infected.

OPV – In highly HIV-endemic countries, as in other countries, individuals without HIV/AIDS symptoms should be immunized with OPV according to standard schedules.

Measles – Measles can be very severe in HIV-infected children. WHO currently recommends that an early dose be given at six months followed by the scheduled dose at nine months to children who are known to be infected with HIV. For children with AIDS disease, the potential risks and benefits must be evaluated on an individual basis. The overall risk of adverse events from the vaccine is relatively low compared with the risk of measles infection in HIV-infected children.

Children should not be screened for HIV antibody status before receiving measles vaccine.

Yellow fever – Yellow fever vaccinations should not be given to patients with symptomatic HIV infection nor to pregnant women.

These are WHO policies concerning vaccination and HIV at the time of the preparation of this field guide. The reader is strongly advised to check the most current policy through WHO.

Because both health workers and parents may hesitate before vaccinating a sick child, some countries have issued policies on contraindications, such as the one shown below.

Policy on
Immunizing Sick Children

1. Recent studies in Kenya have shown that one of the biggest obstacles to achieving full immunization in children is the failure to immunize sick children.
2. Controlled, scientific studies have shown that vaccination of sick and malnourished children in Africa is both SAFE and EFFECTIVE.
3. Babies of low birth weight should be immunized according to the standard KEPI schedule as long as their weight at the time of immunization exceeds 2000 grammes.
4. MOH and KEPI policy advocates the administration of vaccines to all eligible children, including those who are ill. This policy is included in KEPI training materials.
5. There are ***no contraindications to immunization.*** All children admitted to hospital must be screened and if they are eligible for immunization, should receive it upon admission. *
6. No child should be discharged from hospital without receiving all the vaccines for which he or she is eligible, based on age and vaccination status.

Sick children should not be denied their right to protection against vaccine-preventable diseases. They are in greatest need of this protection.

7. The immunization status of ***every child*** coming for health services should be checked, regardless of the service being sought, and ***immunization should be provided to all eligible children.***
8. Many diseases may have similar presentation. Therefore, the child should be immunized regardless of whether the mother says the child has already had the disease. This is especially true for measles.
9. All children should be properly screened to ensure that they receive every vaccine for which they are eligible, based upon their age.

Parents should be encouraged to bring their children for immunization despite illness.

Health workers should not deny immunization to sick or malnourished children.

Director of Medical services

If you have any questions or concerns about the attached policies, please contact the District Medical Officer of Health.

Source: KEPI, Ministry of Health, Kenya. 1993

*This policy predates clear guidance from WHO about immunization of children with HIV/AIDS.

Clarify policy on multi-dose vials. Health workers often hesitate before opening vaccine vials for one or a few clients for fear of running out of vaccines before the next delivery. Governments need to set policies on when to open multi-dose vials and whether opened vials can be used in subsequent sessions (see page 92). Health workers, in turn, need guidance on applying the policy, taking into account such factors as:

- The size of vaccine vials available
- The frequency of immunization sessions
- The likelihood that the parent will return for the vaccination another time

Supplemental Immunization Strategies

Supplemental strategies are used to reach children who have not been vaccinated or have not developed sufficient immunity after previous vaccinations. Strategies differ according to the epidemiology of the disease. Some of the common features are: the target age group is expanded, all children are vaccinated regardless of their immunization status, immunizations do not need to be marked on vaccination cards, volunteers are used, and civil society is mobilized. Examples include polio national immunization days (NIDs) and measles campaigns. Supplemental immunization strategies should not replace routine services.

Accelerated Disease Control

Accelerated disease control strategies differ by disease. For polio, population immunity levels must be increased quickly in order to interrupt chains of poliovirus transmission. In the few remaining polio-endemic countries, NIDs are held two or more times annually to vaccinate everyone in the target population (usually children under five years of age) in a one- to- three-day period. In non-endemic countries with low population immunity, NIDs are needed approximately every three years.

Credit: Ellyn W. Ogden/USAID

Using local transport to move vaccine.

In addition to NIDs, polio eradication planners use sub-national immunization days (SNIDs) and even local immunization days (LIDs) to reach children who were missed in previous campaigns and are not reached by routine services.

With respect to tetanus, supplemental immunization activities also focus on high-risk areas; however, they cannot interrupt transmission because tetanus is not a contagious disease. (See Chapter 12.)

Catch-up campaigns for accelerated measles control are conducted during a period of several days or a week over wide geographic areas. Follow-up campaigns are held after catch-up campaigns to reach children in a narrower age range.


Credit: WHO

Children receiving vitamin A during measles campaign.

Measles catch-up and follow-up strategies provide a "second opportunity" because all children in the target population are included, regardless of immunization status. For those who were missed before, such strategies provide a second opportunity to be vaccinated. For those who were vaccinated earlier but failed to develop immunity, these strategies provide a second opportunity to be immunized. (See the measles section in Chapter 12 for more information.)

Door-to-Door Vaccinations

The door-to-door, or child-to-child, strategy is sometimes used as a supplemental immunization strategy to reach families that are not served at health facilities and other collection points.


Credit: Daniel Cima, American Red Cross

At least two visits to the same area may be necessary: the first to map residences, enumerate the target population, and publicize the approaching visit, and the second to provide vaccinations and perhaps other services. Even when going door to door, health workers must make a special effort not to miss sick children, sleeping children, very young infants, children who are visiting, and children on upper floors of apartment buildings.

The door-to-door strategy can be effective, but it is also expensive in terms of human resources, transport, and other costs.

Mop-up strategies are used occasionally when control activities have succeeded in reducing the incidence of disease and in containing the disease geographically, but some children still remain unreached. These activities often target high-risk children who live in poor urban areas, hard-to-reach rural areas, and areas with transient populations. Mopping-up requires intensive vaccination efforts, including door-to-door visits. As in other supplemental immunization activities, screening is not required.

Outbreak Response

When an outbreak of a vaccine-preventable disease occurs or is suspected, managers must decide whether an immediate vaccination campaign is warranted and, if so, which populations to target. Target populations for such campaigns are people who are at risk in terms of both age and location. Decisions about target groups, age range, geographic scope, and type and duration of response activities should be based on local epidemiological data.

Outbreak control must be timely to be effective. Although vaccination campaigns during outbreaks are almost always appropriate for yellow fever and other diseases with relatively slow transmission, many countries cannot respond in time to halt faster-moving diseases like measles. Nevertheless, governments can provide information, treatment, rehabilitative care, and in measles outbreaks, vitamin A supplementation. If the response includes vaccination campaigns, health and other public officials should explain that people might already be incubating the disease when they are vaccinated and therefore may get the disease despite being vaccinated.

To respond quickly, staff from local facilities and district, regional, and even national offices often have to participate. Local health workers may offer vaccinations at their own facilities or through outreach visits, and mobile teams may go to remote areas. To be effective, outbreak control must be timely.

Special Populations

Refugees and people in other emergency situations are often more susceptible to infection because of unsettled conditions, lack of services, population movements, and crowded living conditions. Measles poses a particular risk in emergencies because measles case fatality can be as high as 50%. Therefore, the minimum immunization target should be to rapidly reach all children up to 15 years of age with measles vaccine and vitamin A supplementation. Campaigns to vaccinate people in emergencies can prevent outbreaks and may also supplement routine immunization services, as shown in the example on the following page.

Protecting Refugees against Disease

All children in refugee camps in Macedonia who were younger than 48 months of age were targeted for immunization against eight vaccine-preventable diseases. Three mass campaigns were carried out in three consecutive months in seven camps, achieving coverage ranging from 73% to 91%. After the first campaign, weekly immunization clinics were established in every camp. These achieved an average of 93% coverage.

Although many individuals were vaccinated, planners were disappointed because:

- The campaigns did not begin until weeks after the refugees arrived, which could have resulted in outbreaks.
- The constant turnover meant that many children did not complete the schedule for vaccines requiring more than one dose.

Source: Koop, Darryl G. B.M. Jackson, and G. Nestel. October 2001

Credit: Tim Healing, Merlin

References

Koop, Darryl G., B.M. Jackson, and G. Nestel. October 2001. *Results of the Expanded Program of Immunization in the Macedonian Refugee Camps.* American Journal of Public Health, 91 (10); 1656-1659.

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WHO. 1991. *Plan to Provide Immunization Services. Training for Mid-level Managers.* Revised. Geneva: World Health Organization. WHO/EPI/MLM/91.3.

Full page photo credit: WHO


YEAR
TOTAL
1988
1989
1990

Chapter 4: **Monitoring, Evaluation, and Information Management**

"Not everything that counts can be counted, and not everthing that can be counted, counts."

– Albert Einstein

Immunization program managers and service providers need a continuous flow of information that tells them:

- Whether immunization services are accessible to the target population.
- How many individuals in the target population are being vaccinated, who is not being vaccinated, and why.
- Whether the quality of services meets program standards.
- Whether resources are used efficiently.
- Whether service strategies are meeting objectives.
- Whether mortality and morbidity from vaccine-preventable diseases are being reduced.

Policy makers, political leaders, health planners, donors, providers of technical assistance, and members of the general public also need information. This chapter describes systems, methods, and tools for the collection, analysis, and dissemination of information on coverage, drop-outs, and quality of services. (Collection and use of data for disease surveillance are discussed in Chapter 8.)

Health Information

A good information system avoids over-burdening health-care workers by limiting the information they need to collect and record to that which is most essential for program management and assessment. The following questions can help information system developers distinguish "need to know" from "nice to know" data:

Time To Tally?

A nurse in East Africa reported: "You have mothers waiting for you. You have children waiting for you. You have curative waiting for you. You have antenatal waiting for you. You have family planning waiting for you. It is very difficult to rush back and tally."

Source: GAVI, 2001

- What do we (all of the interested parties) need to know? Why?
- How will people at various levels of the system use the data, including health workers, supervisors, community members, and managers?
- Does the use of the data justify the work and expense involved in their collection, collation, and analysis?
- Which indicators are most likely to tell us that we are progressing or having problems?
- How will we collect, collate, and analyze data?
- How, when, and to whom will data be reported?
- How will we monitor the timeliness, completeness, and accuracy of reports?
- How will we provide feedback to interested parties?

Health information systems generally focus on collecting patient names, recording treatment or visit dates, and counting the number of events. These data are not sufficient, however, to allow managers to evaluate services and monitor changes over time, for example, disease incidence, patient characteristics, or the impact of health interventions. To do this, managers need information that is:

- Relevant
- Specific and quantitative
- Understandable
- Sensitive to changes and trends

Credit: Kelley Sams, BASICS II

To limit the time, effort, and cost involved in collecting, collating, and analyzing data, planners have to restrain the common impulse to add information items. At the same time, they must ensure that the items that they choose provide the information they need to make program decisions.

For immunization programs, coverage and drop-out rates are used as indicators of the availability, accessibility, and use of services, as well as of other program characteristics. As the name implies, an indicator describes one or more aspects of services and shows only that there may be a problem. A mix of indicators, as shown in the table, should be used to get a more complete picture of services and to identify problems that should be investigated.

Immunization Coverage and Drop-Out Indicators		
Indicator	**What It May Indicate**	**Limitations**
DTP1 coverage	Availability of, access to, and initial use of immunization services by children.	Measures only the first in a three-dose series. BCG, although the first vaccination in the schedule, is not an effective indicator where births take place at home and no BCG is given. When BCG is given to babies born in hospitals, it may be recorded in a different information system, if at all.
DTP3 coverage	Continuity of use by parents, client satisfaction with services, and capability of the system to deliver a series of vaccinations.	Shows only completion of DTP series and not other antigens.
Measles coverage	Protection against a disease of major public health importance.	Does not indicate the capability of the system to deliver a series of vaccines. Supplementary doses may be confused with routine doses.
DTP1 to DTP3 (Difference in the number of children who receive DTP1 and the number who receive DTP3, expressed as a rate)	Quality of service as perceived by parents and the quality of communication between parents and health workers — this is the classic drop-out indicator.	Does not stand on its own; must be interpreted in light of actual coverage levels. Does not give a complete picture of drop-outs that may be occurring between other antigens.
TT1 coverage	Availability of, access to, and use of immunization services by pregnant women.	Measures only the first dose in a multi-dose series.
TT2+ (TT2, TT3, TT4, and/or TT5 coverage)	Continuity of use, client satisfaction, and capability of the system to deliver a series of vaccinations to women.	The series of five TT doses is given at different intervals over the course of many years. Once a woman has received five doses, she should no longer be counted in the denominator as a member of the target population.
Fully immunized child (FIC)	Capability of the system to provide all vaccines in the childhood schedule at the appropriate age and the appropriate interval between doses in the first year of life; also measures public demand and perceived quality of services.	Generally not available from routine service statistics. Information can usually be derived from population-based surveys analyzed by WinCOSAS or other software. Absence of vaccination cards limits the reliability of this indicator. The definition of FIC may vary among countries.

Governments, organizations that provide technical assistance, donors, and community leaders use indicators such as those listed above to measure whether they are achieving their objectives and to make strategic decisions on resource allocation. For example, some community-based health committees use DTP3 coverage as an indicator of the performance of all public health services in their communities. GAVI uses DTP3 coverage by district as an indicator of progress toward its goals.

Managers also use indicators to assess quality, efficiency, effort, and impact. Some examples are given below.

Quality and Other Indicators

Indicator	What It May Indicate	For More Information, Refer to:
Number of immunization sessions that are actually held compared to the number planned	Quality of program management	Chapter 3
Supply of unexpired vaccines	Effectiveness of vaccine procurement, delivery, and management	Chapter 5
Vaccine usage	Effectiveness of fixed and outreach session scheduling, vaccination administration, and vaccine handling	Chapter 5
Temperature monitoring of cold chain equipment	Quality of cold chain management	Chapter 6
Updated inventory (models, location, and age) of refrigeration equipment at national, subnational, and district levels; monthly reporting at district level on status of equipment	Quality of cold chain management	Chapter 6
Use of a sterile syringe and needle for each injection	Quality of injection practices	Chapter 7
Disease incidence	Impact of immunization services	Chapter 8
Parents' knowledge of common side effects and when to return for additional vaccinations	Quality of communication between parents and health workers	Chapter 9

Basic Monitoring Tools

Many of the basic monitoring tools that could benefit health workers, their supervisors, and managers throughout the system are neglected because people don't know how to use them. This is true despite the fact that many have been available for years. The most important of these are maps, patient registers, vaccination cards, tickler files, tally sheets, and immunization monitoring charts, each of which is described below.

Maps

In addition to geographical distribution of cases (see Chapter 8), maps can show access to services, particularly in rural areas. For example, local maps can show population distribution in relation to the location of health facilities. Maps should indicate geographical features (e.g., mountains and rivers) and infrastructure (e.g., roads and bridges), because these are important considerations for improving access.

Credit: Kelley Sams, BASICS II

Hand-drawn maps posted where they are to be used can be helpful in planning.

Patient Registers

Most health facilities use a patient register to record information about every person who comes to the facility for any health-related reason – preventive or curative, outpatient or inpatient. For immunization, registers are used to identify children who are due for a vaccination, to monitor missed opportunities, to check the accuracy of reporting, and to target case investigations.

At a minimum, a patient register should include: the day, month, and year of visit; the patient's name; the patient's address; the patient's date of birth; and a summary of services provided, including vaccinations given and dose number.

Another way to organize the immunization register is to set aside one or more pages for each month of the year. When a child comes to the facility, a health worker records the child's name on the page for the month of his or her date of birth. As vaccinations are given to that child, they are recorded on the same line in the register.

Some health facilities keep special immunization registers. At the end of every month, health workers review the register to identify the children who have not received the vaccination or vaccinations for which they are eligible and then follow up with these children. For example, children should have a measles

Credit: WHO, 2003

vaccination at age nine months. At the end of each month, health workers should make a list and follow up on children born more than nine months earlier who did not yet get their measles vaccinations.

Vaccination Cards

Vaccination cards and other home-based records enable parents and health workers to monitor an individual child's progress toward full immunization. Families keep these records of childhood and tetanus toxoid vaccinations to remind them which vaccinations and doses have been given, which have not, and when vaccinations are due. These cards may be the only records health workers have of vaccination history and status if patient registers are not well maintained or for clients who have moved from another health facility.

A vaccination record may be a separate document or part of a general child health card. Regardless, it should include the child's name, date of birth, address, a parent's name, and the date of each vaccination by dose. A general health card reinforces the importance of taking advantage of all health contacts and missing no opportunities to provide preventive services; this applies whether a child has come for an immunization and needs growth monitoring or a woman has come for antenatal care and needs a tetanus toxoid vaccination.

Credit: Jereo Salama Isika, JSI/Madagascar

Home record and reminder materials from Madagascar.

There is reliable evidence that clients generally value and retain their cards and that, if reminded, they will bring the cards to the health facility at each visit. However, the cards' meaning and possible utility is not always recognized. Before any new card is introduced, health workers and representative families should be asked to assess how well they can read and understand everything on it. Managers should make sure that health workers have adequate supplies of cards; many health facilities fail to issue them because there are none available.

It can be difficult to interpret the information on vaccination cards without assistance. Oral reminders may be needed to communicate information, particularly to people with poor reading skills.

When new vaccines are added to national immunization programs, changes to the old cards may be required. To avoid the expense and effort of revising the card, programs may leave a space in which to write additional vaccines as they are introduced.

Credit: Craig Manning

Do They Understand the Card?

A recent study of 600 mothers in one country revealed that many could not understand basic information on their vaccination card.

A reading test was first given to all mothers. Those who could read (490 of 600) were asked to look at a "typical" card filled out by researchers.

- Only 49% of the literate mothers could say how many immunizations the child received during the last visit.
- Only 45% could tell when the next immunization was due.
- Only 44% could identify which vaccines the child had already received.

Source: CHANGE Project, 2002

Credit: Kelley Sams, BASICS II

Tickler Files

Tickler files are boxes in which copies of children's vaccination cards or similar records are filed according to the month when each child's next vaccination is due. For example, when a child comes to a health facility and receives a vaccination card, a health worker writes on the card the vaccine, dose, and date of each vaccination the child receives that day. The health worker makes a copy of the card and files it in the box behind the divider for the month when the child's next vaccination is due. The cards behind each month-divider are alphabetized by last name. As children come for vaccinations during the month, their cards are pulled, updated, and moved to the divider for the month when the next vaccination is due.

At the end of each month, cards remaining behind the divider for that month represent drop-outs. Health workers then plan strategies to ensure that each of these children receives the vaccinations that are now overdue.

Tally Sheets

Tally sheets are forms on which health workers make a mark every time they administer a vaccination. These are used as a basis for reporting to the district level. Supervisors use them to monitor the accuracy of reporting from health facilities to districts.

Daily Tally Sheet

For recording immunization and children protected at birth against neonatal tetanus

Health center:__________________________________ Date:___________________

	Children under one year of age	TOTAL	Children over one year of age	TOTAL
BCG				
OPV 0				
OPV 1				
OPV 2				
OPV 3				
DPT 1				
DPT 2				
DPT 3				
Measles				
Hib 1				
Hib 2				
Hib 3				
Hep 1				
Hep 2				
Hep 3				
Women of childbearing age				
	Pregnant	Total	Non-pregnant	Total
TT1				
TT2				
TT3				
TT4				
TT5				
Children protected at birth against neonatal tetanus All children who receive DPT 1 should be assessed for protection at birth against neonatal tetanus.				
	Child IS protected against neonatal tetanus at birth	Total	Child is NOT protected against neonatal tetanus at birth	Total

Source: WHO, Immunization in Practice (2002 draft)

The tally sheet shown has a space to record every vaccine and every dose of vaccine offered by the national immunization program. Children under one year and over one year of age are recorded separately in order to accurately calculate coverage in children under one. This tally sheet also enables health workers to specify which dose of tetanus toxoid was given and whether the woman to whom it was given was pregnant at the time. (In most developing countries, pregnant women are the target population for tetanus toxoid.) A space is provided to record whether children receiving DTP1 were protected at birth from neonatal tetanus.

Determining Tetanus Protection at Birth		
If the number of valid doses already received is:	**And the last dose received was:**	**Last born child must be considered as:**
0		Not protected
1	At any time	Not protected
2	Less than three years before last birth	Protected
3	Less than five years before last birth	Protected
4	Less than ten years before last birth	Protected
5 or more	At any time	Protected

Immunization Monitoring Charts

Every health facility that offers immunization services needs to monitor progress toward coverage objectives. Providing tools such as monitoring charts and ensuring that health workers have the skills to use them can motivate health workers, enhance performance, and improve the quality of data.

The information on the following page explains how to complete and interpret a monitoring chart.

Immunization monitoring charts should be posted in every health facility for inspection by health facility staff, clients, and supervisors. The charts can be shared with political and community leaders.

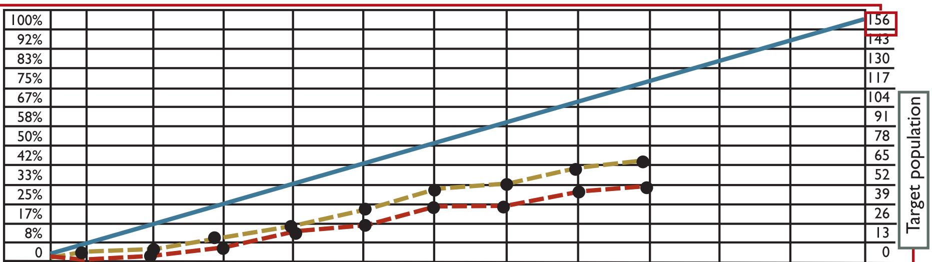
Credit: Kelley Sams, BASICS II

Example of Completing and Interpreting a Monitoring Chart

Cumulative Coverage and Drop-Out Monitoring Chart

Health Facility or level: Sitapur______________ Annual target population: 156____

Year: ______



	Jan	Feb	Total	Mar	Total	Apr	Total	May	Total	Jun	Total	Jul	Total	Aug	Total	Sep	Total	Oct	Total	Nov	Total	Dec	Total
DTP 1	6	5	11	4	15	9	24	10	34	7	41	3	44	12	56	9	65						
DTP 3	4	5	9	3	12	6	18	7	25	6	31	0	31	10	41	4	45						
DO #	2		2		3		6		9		10		13		15		20						
DO %					20 %						24%						31%						

DO = drop-out = $\frac{\text{DTP1 - DTP3}}{\text{DTP1}} \times 100$

DTP1 – – – –
DTP3 – – – –

STEP 1: Estimate size of target population

The target population for childhood immunizations is all children under one year of age. The target population for tetanus toxoid is pregnant women. If the actual number of pregnant women is not available, the number is assumed to be the same as, or slightly higher than, the number of children under one year.

In some places, health workers can ask community leaders for help in counting children under one year of age and pregnant women in their catchment area.

STEP 2: Enter yearly and monthly coverage objectives

In the monitoring chart, a printed diagonal line goes straight from the lower left corner to the upper right corner. This represents regular progress over a 12-month period toward a coverage objective of 100%. In this example, the objective has been divided evenly across 12 months, and each monthly objective is shown as a percent on the left side of the table and as a number on the right.

STEP 3: Record vaccine doses per month

Two vaccines given at different ages are selected, such as DTP1 and DTP3. The number of vaccinations recorded on the tally sheet is written in the box for that month under the graph.

STEP 4: Calculate the cumulative and annual totals and drop-out rates

Every month, the total for that month is added to the previous month's cumulative total and recorded in the monitoring chart, in the box labeled Total. At the same time, the monitoring chart is marked with a dot that represents the cumulative total, and the dots are connected.

STEP 5: Interpret and use the information

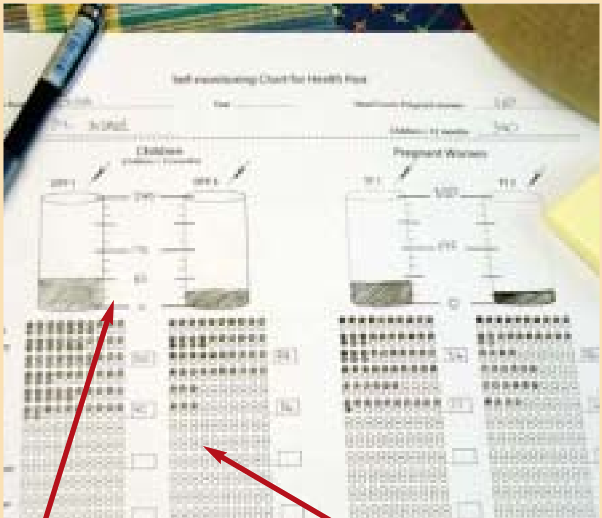
When the drawn line is on or above the printed line, the facility is on track to meeting the coverage objective. When the drawn line is below the printed line, the facility is not on track.

After several months, the monitoring chart will begin to show whether progress is being made toward the objective, and any slippage below the target can be corrected in the following months by exceeding the target. The difference between the printed and drawn line for DTP1 in the example above may be used as an indicator of the unreached population.

The space between the two drawn lines for DTP1 and DTP3 is the visual equivalent of drop-out. As of September in the example above, the facility is experiencing approximately 30% drop-out. It is not on track to reach the coverage target, but it can still take action in the next three months to catch up.

Sample Self-Monitoring Chart for a Health Post

It has been shown that if service providers understand such information, they can use it to guide action to improve immunization coverage. In order to accomplish this, data should be presented in a way that is useful to health workers and understandable by community members. This is an example of a combined tally sheet and monitoring chart that might be used by peripheral health workers with limited arithmetic skills. In this example, the health worker did an annual head count in the community and identified 340 children less than 12 months of age. Dots are filled in to represent doses of vaccine given. They are counted and compared against quarterly targets as shown in the glasses of water (cylinders).



The level of water is hand-drawn each quarter. Based upon the tally sheet below the glass, the health worker and the community can clearly see that only 90 children have been vaccinated with DTP1. Despite 6 months of activity, the glass is only one-quarter full. Children are being missed.

Each darkened circle represents one person vaccinated with DTP1. In this example, 90 children have been vaccinated during the first six months of the year.

Such charts provide a visual reminder of both the overall immunization objective and a gauge of the facility's progress in achieving it. If all goes well, the chart could also foster a sense of accomplishment.

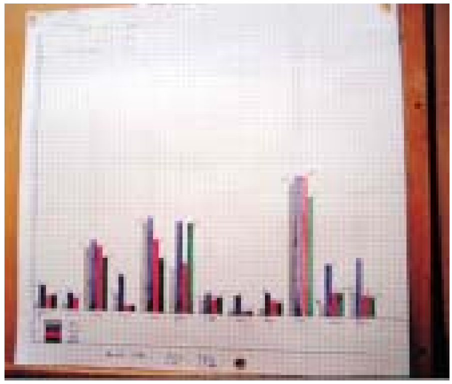
Analysis and Use of Routine Data

The data that health workers collect should be used by the health workers themselves and by their supervisors, managers at all levels, and community leaders to monitor performance in general and, specifically, to monitor immunization coverage and the drop-out rate.

Immunization Coverage

Immunization coverage is the proportion of the target population that has been vaccinated. The difficulty of calculating and interpreting immunization coverage rates often stems from problems related to estimating the size of the target population. These, in turn, are the result of inaccurate or outdated census counts, population migrations, and unforeseen changes in birth rates or infant mortality.

At the end of the month, health staff add the daily tallies of vaccinations and convert them into a percentage called coverage. The box below shows three examples of the annual coverage rate by vaccine. The second box shows how to estimate the number of surviving infants for use in calculating coverage rates.



Credit: Lauren Goodsmith

Immunization chart in Morocco.

Calculating Annual Coverage for DTP1, DTP3, and Measles Vaccines for 2003

DTP1 coverage:

$$\frac{\text{number immunized by 12 months with DTP1 in 2003}}{\text{number of surviving infants <12 mos. of age in 2003}} \times 100$$

DTP3 coverage:

$$\frac{\text{number immunized by 12 months with DTP3 in 2003}}{\text{number of surviving infants <12 mos. of age in 2003}} \times 100$$

Measles coverage:

$$\frac{\text{number immunized by 12 months with measles vaccine in 2003}}{\text{number of surviving infants <12 mos. of age in 2003}} \times 100$$

Example of Estimating the Number of Surviving Infants

Total population: 5,500,000

Crude birth rate (CBR): 30/1000

Infant mortality rate (IMR): 80/1000

Number of surviving infants = Total population x CBR x (1–IMR)

= 5,500,000 x 30/1000 x (1–0.080)

= 5,500,000 x 0.030 x 0.920

= 151,800

If coverage rates indicate that people are not using immunization services, health workers and their supervisors need to find the causes and take appropriate action. Comparing coverage rates for different vaccines sometimes points toward the likely problem as well as possible solutions, as shown below.

Examples of Using Coverage Data to Improve Vaccination Services			
Coverage Data	**Issue**	**Possible Reasons**	**Suggested Remedy**
Example 1: BCG 80% DTP1 60% DTP3 55% Measles 55%	Why the decrease between BCG and DTP1 vaccinations?	Missed opportunities to give vaccination card and information at place of birth	When mothers give birth in maternity centers, give their babies BCG vaccine and: -A vaccination card for the baby -Information on where and when to bring the baby for other vaccinations -Encouragement to get the baby immunized again as soon as he or she reaches 6 weeks of age
Example 2: BCG 80% DTP1 75% DTP3 70% Measles 45%	Why the decrease between DTP3 and measles?	The long interval between vaccination with DTP3 at 14 weeks and measles at nine months	Inform parents about preventing measles by means of vaccination. Remind parents when and where to bring the child in for measles vaccine.
Example 3: BCG 70% DTP1 70% DTP3 40% Measles 60%	Why is measles coverage higher than DTP3?	Difficult and/or infrequent access to vaccinations Health workers may be (incorrectly) re-starting DTP series after long intervals between doses.	Remind health workers that if a child has reached nine months of age without completing DTP vaccinations, a DTP vaccination can be given at the same time as measles vaccine. After DTP1 vaccination, remind parents that three doses are needed and when to bring child for DTP2 and DTP3.

Drop-Out Rates

High drop-out rates may reflect problems in demand for vaccinations, client satisfaction with services, and the ability of the immunization program to provide those services. To calculate drop-out rates, the number of doses of any two antigens administered at different ages are needed, for example, BCG and measles, DTP1 and DTP3, DTP1 and measles, or TT1 and TT2+. Under most circumstances, a drop-out rate of 10% or less is considered acceptable, although full immunization is always the goal.

Health workers should investigate the reasons, determine the solutions, and take action when drop-out data indicate a problem. Supervisors, community leaders or other interested community members should also be involved.

To facilitate monitoring and use of drop-out information, health facility staff can use and post a chart to monitor drop-outs.

Drop-Out Rate Monitoring Chart, 2004														
Health Facility:		Sub Health District:						District:						
			Month											
			J	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**
DTP1	A. Month													
	B. Cumulative													
DTP3	C. Month													
	D. Cumulative													
E. Cumulative Drop-Out DTP1–DTP3 (B–D)														
F. Cumulative Drop-Out Rate %														
		60%												
G. Bar Chart		55%												
		50%												
		45%												
		40%												
		35%												
		30%												
		25%												
		20%												
		15%												
	Good Performance	10%												
	Drop-Out Rate	5%												
	10% or less	0%												
		-5%												
		-10%												
		-15%												
		-20%												
		-30%												

INSTRUCTIONS:

A. Enter the monthly total of DTP1 immunizations given to children below the age of one year.

B. Enter the cumulative total of DTP1 immunizations given. Cumulative includes the current monthly total plus the monthly totals for all of the previous months during the year.

C. Enter the monthly total of DTP3 immunizations given to children below the age of one year.

D. Enter the cumulative total of DTP3 immunizations given.

E. Subtract the cumulative total for DTP1 from the cumulative total for DTP3. This is the cumulative total number of drop-outs for DTP1 to DTP3 for the year.

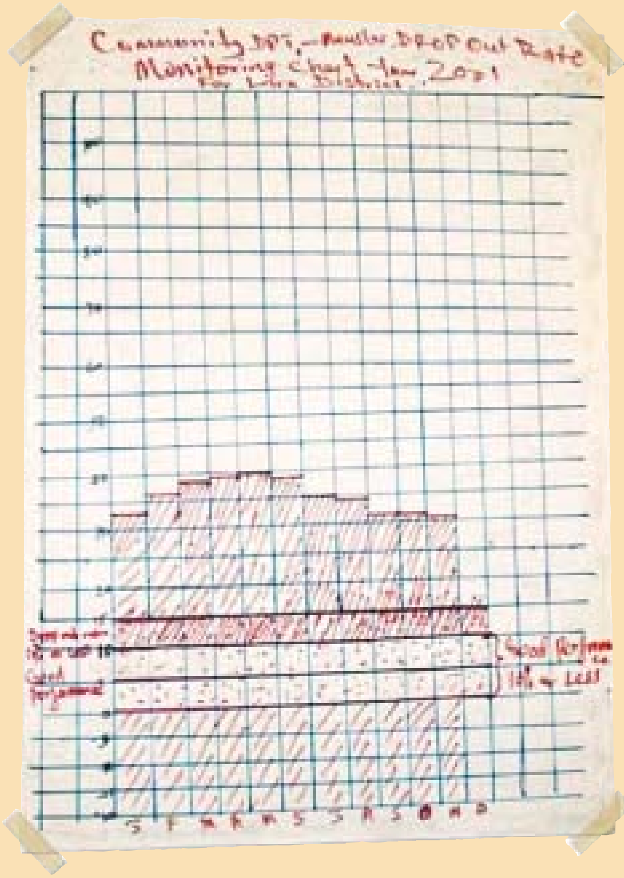
F. Calculate the Cumulative Drop-Out Rate as follows:

$$\frac{\text{DTP1 Cumulative Total - DTP3 Cumulative Total}}{\text{DTP1 Cumulative Total}} \times 100$$

G. Chart the Cumulative Drop-Out Rate by shading in the area up to the drop-out rate on the chart.

PLACE THIS CHART WHERE IT CAN BE SEEN BY YOUR STAFF, EVERY DAY !

Example of Monitoring Drop–Out Rates



Credit: Mark Weeks, BASICS II

A drop-out chart used in a health facility in Uganda helps health workers track their progress in reducing drop-outs. In this example, drop-out rates between DTP1 and measles were monitored.

Because their drop-out rate is higher than the 10% national target, health workers should try to determine the causes for the drop-out so that they can correct the problem in the months remaining in the year.

Other Uses of Data

In addition to their use in monitoring performance and progress toward objectives, routine immunization data may be used to track the implementation of policies and to justify budget requests.

Monitoring the implementation of policies. In Kyrgyzstan, managers used data on contraindications to identify a problem and then used the same data to track the impact of a new policy. Monitoring and feedback provided evidence of improvements in the application of the policy and a resulting increase in coverage.

Monitoring the Use of Contraindications

Health workers throughout Kyrgyzstan keep immunization records on every child. Included in these records is the number of times that children were denied vaccinations because of contraindications. For years, these data were ignored, but when they were finally examined, managers realized that health workers were applying unnecessary contraindications that left many children unprotected.

The Ministry of Health issued a policy to clarify the use of contraindications, but health workers continued to use invalid contraindications.

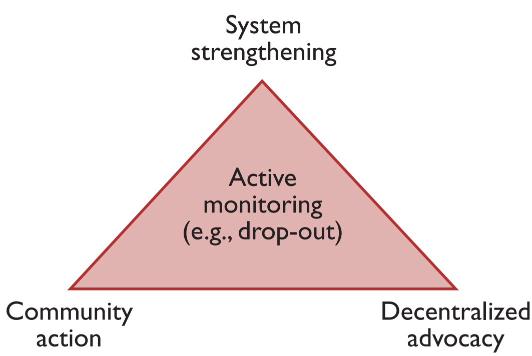
Then supervisors in one district were specifically asked to monitor the percentage of eligible children who were denied a DTP vaccination because of contraindications. As the study began, a very high proportion (28%) of children was being denied vaccinations because of contraindications. When staff at all levels became aware of the magnitude of the problem, they took action. Twelve months later, failure to immunize because of contraindications had declined to less than 5%.

Expanded throughout Kyrgyzstan, the monitoring approach succeeded in reducing contraindications nationwide to less than 5% annually.

Source: Weeks et al., 2000

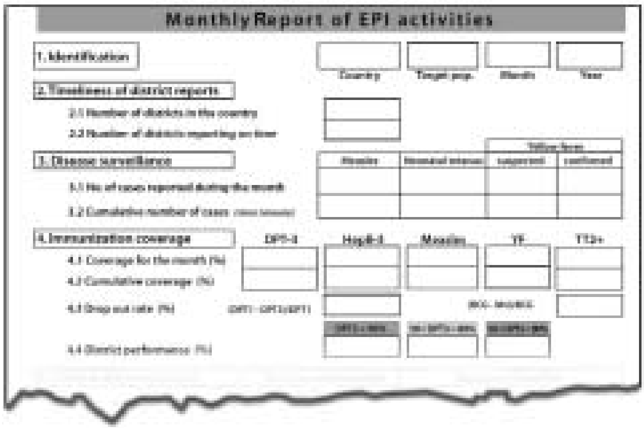
Justifying budget requests. Health reform and decentralization have increased the need to advocate for immunization services at the district level, where budgetary decisions are increasingly being made. Active monitoring and sharing of a few indicators on coverage, drop-outs, and other data can be used to mobilize communities, determine strengths and weaknesses in health services, attract political support, and justify funding requests.

Constellation of Activities



Routine Reporting

By a specified date at the end of every month, designated staff members at each health facility should report to the district level. These reports should provide a summary and analysis, not simply a collation of all of the data that facilities collected during the month.


Monthly Report of EPI activities

1. Identification — Country / Target pop. / Month / Year

2. Timeliness of district reports
2.1 Number of districts in the country
2.2 Number of districts reporting on time

3. Disease surveillance — Measles / Neonatal tetanus / Yellow fever: suspected / confirmed
3.1 No of cases reported during the month
3.2 Cumulative number of cases

4. Immunization coverage — DPT-3 / HepB-3 / Measles / YF / TT2+
4.1 Coverage for the month (%)
4.2 Cumulative coverage (%)
4.3 Drop out rate (%) (DPT1 - DPT3)/DPT1 — BCG - Measles
4.4 District performance (%)

District health management teams usually need coverage data for all vaccines by dose. They may also ask for data on other aspects of immunization services, such as amount of vaccine used and disease incidence.

A team at WHO's Africa Regional Office developed the monthly reporting form shown here, initially for use in West Africa. The form is designed for the national level, but managers have found that it can be adapted easily for district use.

District health management teams aggregate the data from all health facilities in their district, then send the aggregated figures to the next administrative level, and so on, until the data reach the national level, where they are collated into a national coverage report. The Joint Reporting Form is submitted by 15 April of each year to WHO Regional Offices and to WHO and UNICEF headquarters, which publish the information in a joint annual report.

Monitoring the Information System

Supervisors and managers can monitor a health facility's information system by:

- Checking the patient register: Is it complete and up to date?
- Checking vaccination cards: Are there enough in stock? Are they completed properly and up to date? Do the holders of the cards understand their purpose?
- Reviewing the immunization monitoring chart: Is it on the wall of the health facility? Is it up to date? Can health workers in the facility explain what it means?

Completeness and timeliness of reporting can be tracked on a chart that lists the units from which monthly reports are expected and the dates when the reports are actually received.

Accuracy of reporting, as well as completeness and timeliness, should be monitored. Inflating or deflating performance levels in reports can be tempting when benefits seem to be associated with certain outcomes. Innocent mistakes can also occur. To make sure that data are accurate, users should rely on their knowledge of the area, their experience, and even their intuitions about "funny numbers," i.e., numbers that are unexpected, that stand out in some way, or that otherwise don't make sense. Some true examples of funny numbers from the field are described in the box.

"Funny Numbers" for Immunization Coverage

Coverage over 100%?

Example 1: For six months in a row, one health center recorded immunization coverage that exceeded expectations. Upon investigation, health workers realized that clients were coming to their center from another catchment area where vaccine shortages were common. These individuals had not been included in the denominator used to calculate coverage.

Example 2: Health workers included children over 12 months of age in calculating coverage for their routine reports. This inflated the numerator for the coverage equation, and since the denominator included only children under 12 months of age, the health facility's coverage often appeared to be above 100%.

Higher DTP3 than DTP1?

Last year 51 of the 110 districts in the country reported higher figures for DTP3 than DTP1. National staff found that, during a catch-up campaign, health workers classified all DTP vaccinations as DTP3 without checking whether individuals had received DTP1 or DTP2.

Variations among Health Facilities

As of May, most health facilities in the country were reporting 30% to 40% cumulative measles coverage, which is approximately what one would expect. One center, however, reported 100% coverage. This center had conducted a measles vaccination campaign in their catchment area to prevent a predicted outbreak and had inappropriately included the vaccinations given during the campaign in its routine reports. (Vaccinations given during campaigns should be reported separately and not included in routine reporting.)

Giving health workers the tools and skills to use data to assess their own performance can improve staff motivation, strengthen performance, and improve data quality. Self-assessment through a process of active, continuous monitoring at each level should always be encouraged.

The final step in monitoring information systems is to provide feedback to the data collectors. Such feedback can include assessments of data quality, data from other facilities, and reports of actions taken at district and higher levels, as well as guidance for local action.

Credit: Anne B. Keiser

Evaluation

An evaluation can be a comprehensive study of the whole health system, a service or program within the system, or a single function, such as the cold chain, disease surveillance, or training. Like monitoring, evaluation should lead to action. Unlike monitoring, which is carried out continually, evaluation is periodic.

Evaluations should answer the following kinds of questions:

- What do clients, health workers, managers, and/or other stakeholders think about the service or specific aspects of it? What do they like? What do they dislike?
- Were stated objectives achieved? How?
- Which inputs led to improvements and which did not?
- Were there any unintended, positive outcomes? What were they? How can they be replicated?
- How efficiently were activities implemented?
- Were the outcomes worth the cost?
- Which strategies should be continued? How can they be improved?
- What was the impact of the service on organizational or national goals?

Health service evaluations usually focus on outcomes (e.g., changes in immunization coverage), processes (e.g., vaccine delivery), and/or client satisfaction. Impact evaluations, which examine the effect of activities on goals such as reduction of morbidity and mortality, are less common because of the difficulty in sorting out variables and determining cause and effect relationships. Measuring impact is time-consuming and requires significant resources and epidemiological expertise. Nevertheless, impact evaluations

Credit: Kelley Sams, BASICS II

are needed periodically to show whether activities have made a difference in the health status of the population.

Unfortunately, the results of evaluations are often not used to the extent they could be to improve programs. One solution is participatory evaluation, which enables key stakeholders to participate in designing, planning, and executing the evaluation.

Participatory Evaluation

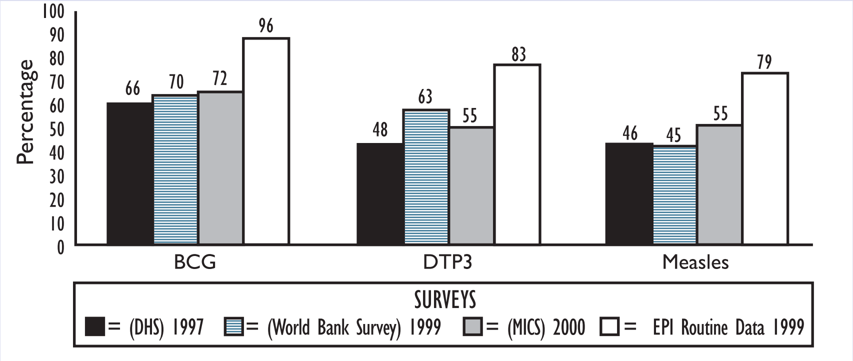
A participatory evaluation is a collaborative process that involves the people who will be affected by decisions based on the evaluation findings. These stakeholders should participate in planning when and how to evaluate and what methods to use, collecting and analyzing information, and making recommendations. Their participation means that the issues that are important to them will be examined, they will learn more about the issues, and they will feel more committed to use the results.

Source: Feuerstein, 1986

Interpreting Coverage from Different Sources

Immunization coverage rates are usually estimated based on routine (administrative) figures that are derived from tally sheets filled in at the health facility. In addition, population-based surveys conducted periodically for special purposes also serve as a source of data for estimating coverage. Survey data may tell a different story from routine data, so managers and other users need

Comparing Immunization Coverage Rates from Different Sources



In this instance, the two sources of data that cover approximately the same time period are the routine EPI data and the Multi-Indicator Cluster Survey (MICS). Dramatic differences can be seen between these two sets of figures. A careful analysis revealed that at least one reason for the high coverage rates from routine EPI data is that children over 12 months of age were included in the numerator but not the denominator of these coverage estimates. The population-based MICS included estimated coverage by 12 months of age, and excluded doses given to children over 12 months.

to be able to figure out which data are most suitable to use in a given situation. The data in the box on the previous page from one African country highlight the complexities of coming up with clear figures for estimating coverage.

As seen from the example, coverage estimates can vary greatly by the source of data. To make sense of any data, users need to be aware that:

- The age group and geographic scope can differ among studies or data sources.
- Some surveys report coverage based only on what is documented by vaccination cards, while others include data from caretakers' recall. Parents' recall of what vaccines were given to which of their children on what dates is not always reliable.
- Some surveys of children 12-23 months of age include the vaccinations that these children received only up to 12 months of age. This is the recommended survey methodology for immunization coverage. However, other surveys include the vaccinations that children received up to the time of the survey, which means that vaccinations given to children when they were older than 12 months of age will be included and thereby inflate coverage estimates.
- Different data can be used for different purposes. For example, valid, population-based data should be used for estimating the proportion of the population protected against vaccine-preventable diseases. But cruder estimates, including those based on routine data, can be used to detect trends from year to year or to estimate drop-out rates.
- Not all coverage data can be compared in a constructive way. In the example, it would be meaningless to compare the Demographic and Health Survey (DHS) data from 1997 with 1999 routine EPI data because both the sources of data and the time periods covered are different.
- Population-based surveys will detect vaccinations provided by the private sector that may be missed by the facility-based tallies used to estimate routine coverage.
- Indicators are only markers of possible problems. Further investigation is needed to confirm that there is a problem and to clarify its causes so that good planning can be done.

The Inter-agency Coordinating Committee (ICC), or a technical sub-committee, is an appropriate forum for discussions of such issues. In the example above, the analysis of coverage data was done to prepare the ICC for a multi-year planning exercise.

Tools for Assessment and Evaluation

Many tools are now available for identifying immunization service delivery problems and determining how best to fix them. National-level health managers, academicians, donors, and international development organizations use these for assessments, evaluations, reviews, coverage surveys, and other purposes.

Immunization Services Assessment Guide

This guide (sometimes called "the common assessment tool") is used to analyze current services in order to plan program improvements and calculate resource needs. It was prepared by WHO/EPI for adaptation by partners of GAVI, national immunization programs, and other users. It can be used at the beginning of a planning cycle or when a change, such as introduction of a new vaccine, is under consideration. The guide enables users to conduct a comprehensive assessment of all levels of immunization services and to examine their relationship to the health system as a whole.

Immunization Coverage Surveys

A standard WHO methodology for determining immunization coverage is based on a survey of small numbers of individuals (210 in 30 clusters of 7 individuals each). Homes are visited and immunization records examined to calculate immunization coverage in children 12 to 23 months of age and tetanus toxoid immunization coverage for mothers of infants. Respondents are asked to describe their perceptions of immunization services and any problems they have had.

The surveys use a cluster sampling technique to ensure that data from a small sample of homes can be generalized to a larger population, but these data can be used only in the aggregate. They say nothing about individual clusters or specific health facilities.

A Coverage Survey Analysis System (WinCOSAS) is available for the compilation and analysis of data from cluster sampling surveys. The software can be used to identify:

- Coverage by 12 months of age and coverage from 12 to 23 months of age for each vaccine dose

Coverage Surveys Can Make a Difference!

A country in South America refrained from making additional investments in its immunization program because government officials had accepted reports from national staff that immunization coverage was approximately 80%. The government renewed its support when coverage survey data revealed that coverage was closer to 40%.

Source: GAO, 1999

- Percentage of children who are fully vaccinated
- Average age when each vaccine and dose is received
- Percentage of newborns protected against neonatal tetanus
- Number of vaccination sessions in which attending children and women did not receive all of the vaccinations for which they were eligible
- Percentage of vaccines and doses given by type of facility — hospitals, health centers, maternal and child health centers, or outreach posts
- Whether DTP, OPV, Hib, and Hep B doses have been given at appropriate ages and intervals
- Number of measles vaccine doses given before the recommended age of nine months

For more information, refer to *Training for Mid-level Managers: The EPI Coverage Survey* (WHO). WinCOSAS software is available on the WHO/EPI website.

Credit: Richard Pollard

Seventy-Five-Household Survey

This method focuses on households that have easy access to health facilities. The theory is that if people in the 75 to 100 households that are closest to health facilities are not receiving services, then use of services in the wider catchment area must be poor indeed. This type of survey is valuable because it encourages interaction between community members and the health workers who collect the data from people at home. It is most useful in areas where the population is stable and coverage unknown. For more information refer to *Training for Mid-level Managers: Increase Immunization Coverage*, Annex C (WHO).

Missed Opportunity Survey

A missed opportunity survey assesses whether all clients who were present in a facility offering vaccinations for which they were eligible that day received them. Available from WHO/EPI, the survey includes reviews of coverage data and patient registers and interviews with clients as they leave health facilities.

Lot Quality Assurance Sampling

This technique is used to assess the quality of service, coverage, or both for the purpose of directing attention and support to the facilities or areas that need it most. It is often used in areas that do not correspond to official reporting sites, such as urban slums. This type of survey addresses a limitation in the immunization coverage survey technique that does not allow analysis of data from individual clusters. For more information, refer to *Monitoring Immunization Services Using the Lot Quality Technique* (WHO).

Large-Scale Population-Based Surveys

DHS and UNICEF's Multi-Indicator Cluster Surveys (MICS) are periodic, large-scale, population-based surveys that are good sources of data on national health sectors and target populations. More information on these methodologies is available from USAID and UNICEF.

Computerized Information Systems

Computers are used increasingly to track the number of vaccinations administered and to compute coverage, vaccine in stock, vaccine wastage, disease incidence, age of vehicles in use, and other data. Although computerization can solve arithmetic errors and perform additional analyses, it does not guarantee the production of high-quality data or its use. Skilled health workers are needed in the first instance to collect data and report them accurately, completely, and on time.

When considering using computers for immunization data, managers and donors should keep in mind the:

- Reliability of power supply
- Adequacy of telephone, Internet, and computer networks
- Availability and applicability of software
- Ability to attract and retain competent information system staff
- Availability of budget for training, maintenance, support, and paper, ink, and other consumables
- Direct access that trained staff have to computers

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Full page photo credit: CCP

Chapter 5:
Vaccine Supply and Quality

"He who would do good to another must do it in Minute Particulars."

– William Blake

The potential of vaccination to protect millions of mothers and children each year cannot be fulfilled unless potent vaccine is available when and where it is needed. To ensure an adequate vaccine supply, managers must competently estimate supply needs. Also, regulatory mechanisms are needed to monitor vaccine quality.

Forecasting Vaccine Needs

Whether the source of vaccine is local or international, managers need to forecast vaccine needs accurately. This involves assessing the impact of policies and plans on vaccine needs, determining the size of the target population, knowing the amount of stock on hand, setting supply intervals, and calculating reserve requirements. Vaccine use and wastage are also critical factors.

Vaccine Vial Size and Session Frequency

Policies, coverage objectives, and service delivery strategies all have an impact on vaccine needs. For example, increased promotion of routine immunization services should increase demand, and an adequate supply of vaccines must then be available to meet that demand.

Credit: Harvey Nelson

Vaccines come in a variety of presentations, depending on the particular vaccine, including vials containing one, two, five, six, 10, or 20 doses. Managers and suppliers need to work together to ensure that the best vial size is procured, given availability, demand, storage space, transportation capabilities, and cost.

Another factor is session size. If only a few children typically attend sessions in a health facility, use of single-dose vials might mean that less vaccine would be discarded at the end of a day. However, single-dose presentations (which are available for measles, Hib, and Hep B vaccines) are considerably more expensive per dose than multi-dose presentations.

Size of the Target Population

The accuracy with which the target population is measured or estimated is as critical in vaccine forecasting as it is in calculating coverage (see Chapter 4). To increase accuracy, target population figures should be adjusted annually, especially in urban areas where populations constantly change and in rural areas subject to high migration.

Overestimating the Target Population for Campaigns May Result in Oversupply

In preparing for high-visibility campaigns, planners forecast vaccine requirements based on the desire to have an adequate supply of vaccines. At every level, they tend to calculate target population size, coverage objectives, and vaccine wastage on the high side to avoid shortages. Sometimes existing stock balance is not considered, so vaccines are ordered as if none were already in the system. The result is that after campaigns, there can be a sizable stock of vaccines at the district and health facility levels.

After campaigns, managers should collect excess vaccine, move it to higher and safer levels of the cold chain for storage, and make adjustments in future vaccine orders to account for the presence of these stocks. In addition, campaign planners should use the number of children immunized in previous campaign rounds to estimate the target for the next.

Inaccurate or outdated census counts, population migrations, and unforeseen changes in birth rates contribute to difficulties in determining the size of a target population. Local health managers may try to overcome such problems by working with community leaders to count people in their catchment areas ("head counts"), but this is not easy, as any demographer can attest.

In addition to problems in counting people, some managers inflate the size of the target population to make sure that they receive an adequate supply of vaccines. In other cases, as discussed in Chapter 4, they may deflate the size to make coverage rates look high!

Estimates should begin to improve as supply systems become more reliable and staff are better supported in solving problems, rather than punished for low coverage rates. As health workers begin to collect and use vaccine data in which they have confidence, usage, rather than population size, is likely to become the preferred basis for calculating vaccine needs.

Stock on Hand

The amount of stock on hand should always be counted at each vaccine storage point before new stock is ordered. Stock should be kept within designated minimum and maximum levels to ensure that:

- Adequate amounts are available
- Space is available to store the stock
- Vaccine is used before the expiry date
- The duration of storage is consistent with recommendations (see Chapter 6)

It is good stock management practice to organize vaccines by type and expiry date.

Supply Intervals

Another variable in calculating vaccine needs is frequency of supply. Typical supply intervals, which should be adapted by each level to account for transport availability, cold chain storage capacity and quality, and continuity of energy supply, are listed below.

Typical Supply Intervals for Vaccines at Different Levels	
Level	**Interval**
National store	Six months
Regional stores	Three months
District stores	One month
Health centers	One month
Health posts	One week

Storage Capacity

An additional consideration in forecasting vaccine needs is the amount of cold chain storage space available at each level for vaccines. A vaccine volume calculator has been developed by WHO to help national immunization programs determine their space requirements when introducing new vaccines. With this tool, managers can use the national

A vaccine volume calculator spreadsheet is available from WHO.

immunization schedule and the vaccine vial sizes to estimate net storage requirements per fully immunized child and woman of childbearing age.

Reserve Stock

Reserve, or buffer, stock is a quantity of vaccine that can be used if new supplies are delayed or if there is a sudden increase in demand. Facilities should always maintain a reserve stock, which is typically calculated at 25% of the amount expected to be used during a given supply period. Experience may justify a higher or lower amount. To avoid overstocking, the figure should be reviewed and adjusted every time an order is placed.

Note that reserve stock is not the same as a wastage allowance. Both are needed in forecasting vaccine needs.

Vaccine Use and Wastage

Vaccine use and wastage, two sides of the same coin, are also factors in forecasting vaccine needs. Vaccine use is defined as the proportion of the vaccine supply that is actually administered to a child or mother. Vaccine wastage is the proportion of vaccine that is supplied but never administered, calculated as shown below.

Calculating Vaccine Wastage

Formula:

$$\frac{\text{doses supplied* - doses administered}}{\text{doses supplied}} \times 100 = \text{wastage rate}$$

Example:

Doses supplied: 200

Doses administered: 150

$$\frac{200 - 150}{200} \times 100 = 25\% \text{ wastage}$$

* "Doses supplied" is calculated from stock records by adding the starting balance of usable vaccine doses at the beginning of a designated period to the new doses received during that period and subtracting the balance remaining at the end of the period: *Starting balance + doses received - balance remaining = doses supplied*

Some so-called "wastage" is not wastage at all but rather a predictable and acceptable cost of providing immunization services. Common causes of unavoidable loss of vaccine include the following:

- It is impossible to get all vaccine out of a multi-dose vial. A 20-dose vial does not yield 20 doses, only 17 or 18.

- Any immunization session may attract fewer eligible people than anticipated. For example, based on experience, a health worker expects seven or eight children to show up for measles vaccinations in the weekly immunization session. The first child arrives and the health worker appropriately reconstitutes the vaccine in a 10-dose vial. By the end of the day, she has administered measles vaccine to only four other children. The remaining vaccine must be discarded.

Credit: WHO

Unlike the messy refrigerator on the left, the tidy refrigerator on the right permits better management of vaccine stocks.

On the other hand, wastage rates higher than 20% can be an indicator of problems that might be avoided, such as:

- Repeated instances of lower-than-planned attendance at sessions.
- Poor stock management
- Cold chain failure that exposes vaccines to unacceptably high or low extremes of temperature
- Incorrect mixing of freeze-dried vaccine
- Incorrect dosage, e.g., the administration of three drops of OPV instead of two, or the injection of 0.6 ml of vaccine instead of 0.5 ml
- Inappropriately large vial sizes. BCG, however, is only available in 20 dose vials.
- Failure to comply with a multi-dose vial policy

WHO's policy on multi-dose vials is intended to reduce wastage.

WHO Multi-Dose Vial Policy Recommendation

1.2.1 The revised policy applies only to OPV, DTP, TT, DT, hepatitis B, and liquid formulations of Hib vaccines that:

- Meet WHO requirements for potency and temperature stability
- Are packaged according to ISO [International Organisation for Standardisation] standards
- Contain an appropriate concentration of preservative

1.2.2 For these vaccines, the revised policy states:

Multi-dose vials of OPV, DTP, TT, DT, hepatitis B, and liquid formulations of Hib vaccines from which one or more doses have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 4 weeks, provided that all of the following conditions are met:

- The expiry date has not passed.
- The vaccines are stored under appropriate cold chain conditions.
- The vaccine vial septum has not been submerged in water.
- Aseptic technique has been used to withdraw all doses.
- The vaccine vial monitor (VVM), if attached, has not reached the discard point.

1.2.3 The revised policy does not change recommended procedures for handling vaccines that must be reconstituted, that is, BCG, measles, yellow fever, and some formulations of Hib vaccines. Once they are reconstituted, vials of the vaccines must be discarded at the end of each immunization session or at the end of six hours, whichever comes first.

Source: WHO, 2000

Credit: Anne B. Keiser

Managers should carefully interpret data that indicate wastage and avoid taking actions to reduce it that could result in a decrease in the number of immunizations administered.

Three Ways to Reduce Vaccine Wastage

In the early 1990s, approximately half of all vaccines supplied to immunization programs worldwide were never used and eventually had to be discarded. In addition to better stock management and improvements in service delivery, three steps have proven successful in reducing vaccine wastage:

1) The strategic use of smaller-dose vials, when funds and storage space are available.
2) Implementation of opened multi-dose vial policies, when training and monitoring are included to ensure compliance.
3) The use of vaccine vial monitors (VVMs), when training and monitoring are provided (see Chapter 6).

Calculating How Much Vaccine to Order

As discussed above, to calculate the amount of vaccine to order, managers need to know the size of the target population, number of doses in the primary series, expected coverage given the strategies to be used, supply interval, and wastage rate. The basic formula for calculating the order size for any vaccine is:

target population x expected coverage x number of doses of the particular vaccine required x wastage factor

The calculation is then adjusted based on the amount of stock on hand and the reserve stock needed, as shown below.

An Example of Calculating Order Size for DTP

Number of doses required

Target population = 1000

Expected coverage = 70%

Number of doses per child required = 3

1000 x 0.70 x 3 = 2100 doses

Wastage rate

Wastage rate in this district is 25%.

Wastage factor or multiplier: 100/(100–25) = 1.33

2100 doses x 1.33 = 2800 doses

Number of doses required per supply period

Supply period in district is every 3 months (0.25 of a year).

2800 x 0.25 = 700 doses

Vaccine in stock

The amount of DTP that is needed in the district for this three-month supply period is 700 doses. If the district already has 400 doses in stock, the amount of vaccine to be ordered is 300 doses, **not** 700 doses. It is a common and costly mistake to order vaccine without adjusting for the amount in stock.

Reserve stock required

A percentage should be added for reserve stock. If 25% reserve stock is used, then an additional 175 doses are needed (25% of 700).

Amount to order: 300 + 175 = 475 doses

Forecasting the requirements for tetanus toxoid (TT) is more difficult than for childhood vaccines because the target population for TT is girls and women, who have approximately 30 years of eligibility, usually between ages 15 to 44 years. Furthermore, the intervals between each of the five doses vary. The previous year's TT usage will usually provide the best estimate of the current year's need, but that figure should be adjusted to the situation. For example, a TT campaign in high-risk areas may increase the demand for TT, while the demand will begin to decrease when several years of good TT coverage results in a build-up of protected women.

Vaccine Procurement and Quality Assurance

Some countries procure vaccines themselves, while others rely on international organizations, particularly UNICEF, that specialize in vaccine procurement and supply. If a country program is directly procuring vaccines, the activity should be managed at the national level to ensure that standards are maintained. Procurement is not a simple task, as suggested in the box. Specialized procurement units should perform these tasks, as described in detail in the WHO manual *Procurement of Vaccines for Public-Sector Programs*.

Steps for Procuring Vaccines at the National Level

- Pre-qualify vaccines and suppliers
- Prepare for procurement
- Prepare bid documents
- Prepare for bid evaluation
- Solicit and receive bids
- Evaluate and compare bids
- Select a supplier
- Make an award
- Write a contract
- Make financial arrangements
- Set up a contract monitoring system
- Arrange for and monitor shipment
- Accept delivery and clear customs

WHO's *Ensuring Quality of Vaccines at Country Level–Guidelines for Health Staff* describes international requirements that national immunization programs need to follow for shipping, verifying vaccine quality, assessing production, and monitoring the National Regulatory Authority (NRA). These guidelines also provide instructions on how to protect vaccines against dangers like those listed on the following page.

A vaccine arrival procedure has been developed to monitor and record the condition of vaccines upon arrival. This is described in Chapter 6.

All countries need National Regulatory Authorities, or control authorities, to monitor the quality of vaccines. NRAs in countries that purchase their vaccines directly from manufacturers are also responsible for:

- Licensing all vaccines used in the country
- Establishing procedures for releasing each lot of vaccines used in the country
- Monitoring adverse events following immunization (AEFI) (see Chapter 8).

Access to a laboratory is needed to monitor vaccine quality, whether countries are procuring vaccines from external sources or producing the vaccine themselves.

A Short List of Threats to Vaccine Quality

- **During shipment:** Inadequate notice of arrival, scheduling arrival during long holidays, route deviations, en route delays, cold chain breaks
- **Upon receipt:** Vaccine quality not checked
- **Central storage:** Cold chain breaks, inadequate recording, inadequate stock control system, power failure
- **Release for use:** Release certificates from the NRA in the producing country not checked, no formal release system
- **Distribution:** Freeze-dried vaccines not distributed with diluents in matching quantities, cold chain breaks, freezing of DTP, TT, DT, Td, Hep B, liquid Hib
- **Point of use:** Inadequate storage, reconstitution, administration, and disposal

International organizations, particularly WHO and UNICEF, also provide vaccine quality assurance and financing services. Once WHO is satisfied that a producer meets its standards, UNICEF and other United Nations purchasing agencies are advised that they may purchase from this producer. Many countries also benefit from UNICEF donor funds and procurement service agreements.

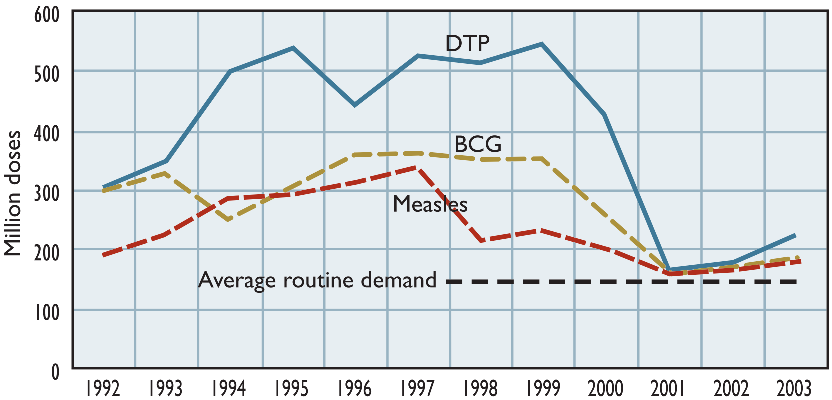
UNICEF also finances the purchase of vaccines – directly or with funds contributed by donors. Payment usually is required in advance and must be made in a convertible currency, unless the government has made other arrangements. The PAHO Revolving Fund and the Vaccine Independence Initiative (VII) both function as payment guarantees in lieu of prepayment for vaccines (see Chapter 10).

Global Vaccine Shortages

The supply of the six traditional vaccines was more than adequate to meet demand until the late 1990s. Some manufacturers then stopped producing these vaccines, and as their availability decreased, prices began to rise significantly.

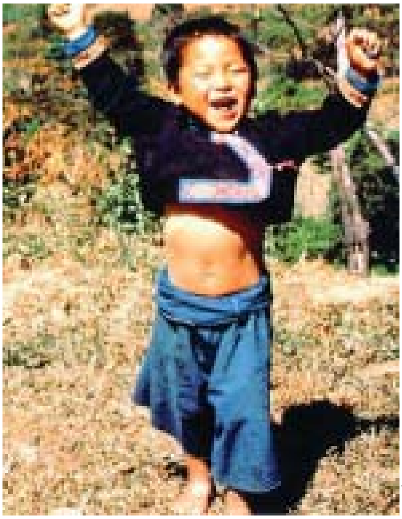
By 2002, most vaccines given to children and women in developing countries, including the newer vaccines, were in short supply. Reduction in the availability of some of the traditional vaccines is shown in the graph below.

Availability Versus Demand for Traditional Vaccines Procured Through UNICEF



Source: UNICEF, 2002

Supplies can be jeopardized if there are significant variations in vaccine production, sizable batch failures during manufacturing, or changes in vaccine formulations that require approvals and increased manufacturing capacity. Poor forecasting, inefficient use, and sudden increases in demand can add to shortages. Global responses to shortages include:



Credit: BASICS

- Providing manufacturers with sufficient guarantees that the vaccines that they produce will be purchased
- Making long-term funding available to cover vaccine costs
- Improving the accuracy of forecasting, especially long-term

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Schnur, Alan. 2001. *Vaccine Wastage and Monitoring the EPI.* Technet Meeting, New Delhi.

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WHO. 2000. *WHO Policy Statement: The Use of Opened Multi-Dose Vials of Vaccine in Subsequent Immunization Sessions.* Geneva: World Health Organization. WHO/V&B/00.09.

WHO. 1999. *Procurement of Vaccines for Public-Sector Programmes: A Reference Manual.* Geneva: World Health Organization. WHO/V&B/99.12.

WHO. 1991. *Training for Mid-level Managers: Manage the Cold Chain.* Geneva: World Health Organization. WHO/EPI/MLM/91.5.

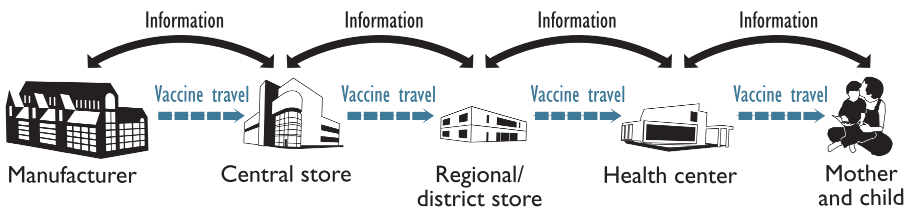
Credit full page photo: WHO

Chapter 6:
Cold Chain and Logistics

"A desk is a dangerous place from which to view the world."

– John LeCarré

An immunization program's ability to provide vaccination services to all members of the target population depends on attention to detail, and nowhere is this more necessary than in cold chain and logistics. Ensuring that vaccines, supplies, and staff arrive on time and where they are needed requires an integrated system of equipment, people, policies, and procedures. This integrated system is called the cold chain, and information links its parts.



National and sub-national program managers, district health management teams, cold chain technicians, logisticians, drivers, and health facility staff all play a role in getting vaccines from the manufacturer to the point of use. These individuals deal with vaccine stock management, temperature monitoring, equipment selection and maintenance, vaccine handling, and transporting people and vaccines.

Vaccine Stock Management

Having too much vaccine for too long in one part of the cold chain increases the risk of some vaccine reaching its expiration date and having to be destroyed. In contrast, when too little vaccine is available, not all the children and women in the target population can be vaccinated. Too much vaccine in one part of the cold chain may mean too little in another.

To be sure that the appropriate amount of vaccine is available, vaccine stocks must be checked continuously, and records kept of all movements of stock in and out of storage areas.


Credit: REACH Project/JSI

Staff should be ready to collect the vaccines upon arrival.

Vaccine Arrival

The successful arrival of vaccines from international sources requires that programs avoid such problems as:

- Shipment of vaccines by way of airports that lack cold rooms
- Consignments to the wrong party
- Shipment of the wrong vial sizes
- Shipment of the wrong quantity of vaccines and diluents
- Shipment of vaccines that are due to expire soon
- Arrival of vaccines on weekends or holidays
- Shipment of vaccines without:
  - Advance notification
  - Sufficient icepacks
  - Cold chain monitors
  - Documentation needed for customs clearance

Every international shipment of vaccines from a manufacturer should include a blank vaccine arrival report (VAR) form, as shown on the following page. When the shipment arrives, the individual responsible for monitoring vaccine arrivals and storage fills in the VAR and gives a copy to the local office of the procuring agency. The report documents the condition of the shipment and the quantities received, and it confirms that all other necessary documentation is included. If problems occur, the VAR can be the basis for initiating corrective action or making claims.

Vaccine Arrival Report

Country			
report No		Date of report	

Place of inspection	Date and time	Name of cold store, date and time vaccines entered into cold store

PART I - ADVANCE NOTICE

Date received by consignee	Copy of airwaybill (AWB)	Copy of packing list	Copy of invoice	Copy of release certificate
	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

Other documents (if requested)

PART II - FLIGHT ARRIVAL DETAILS

AWB number	Airport of destination	Flight No.	ETA as per notification		Actual time of arrival	
			Day	Time	Day	Time

Name of clearing agent: ______________________ On behalf of: ______________________

PART III - DETAILS OF VACCINE SHIPMENT

Procurement agency	Purchase order No.	Consignee	Vaccine description (Type and doses/vial)	Manufacturer	Country

Vaccine				Diluent/droppers			
Lot number	Number of boxes	Number of vials	Expiry date	Lot number	Number of boxes	Number of units	Expiry date

(Please continue overleaf if necessary)

	Yes	No	Comments
Was quantity received as per shipping notification?			
If not, were details of short-shipment provided prior to vaccine arrival?			

PART IV - DOCUMENTS ACCOMPANYING THE SHIPMENT

Copy of invoice with packing list	Copy of release certificate	Vaccine arrival report	Other
Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	

PART V - STATUS OF SHIPPING INDICATORS (List only no. of boxes inspected, coolant and any problems noted)

Total number of boxes inspected:		Coolant type:	Dry ice ☐	Ice packs ☐	None ☐
Box No. (boxes with problems only)	Lot No.	VVM (1,2,3,4)	Cold chain monitor card index (A,B,C,D)	Freeze watch indicator (DTP, DT,TT,HEP B,HIB liq)	Date/time of inspection

(please continue overleaf if necessary)

Temperature recorder (if available, attach copy of record)	Box No.	Model	Serial No.

PART VI - GENERAL CONDITIONS OF SHIPMENT

What was the condition of boxes on arrival?	
Were necessary labels attached to shipping boxes?	
Other comments: (continue overleaf if necessary)	

PART VII - NAME AND SIGNATURE

______________________	__________	______________________	__________
Authorized inspection supervisor	Date	Central store or immunization services manager	Date

Source: WHO, 2001

Use of this WHO-recommended VAR form helps logisticians to identify and document problems at the highest link of the cold chain through which all imported vaccines pass. Problems identified at this level are usually more easily and inexpensively solved. For more information, see WHO's *Guidelines on the International Packaging and Shipping of Vaccines* (WHO, 2001).

Vaccine Stock Records

Accurate vaccine forecasting and ordering depends on knowing the quantity of vaccines in stock at all times. Whenever vaccines and diluents enter or leave a storage area, they should be counted. Ordering should be based on a physical count of vaccine stocks rather than on stock records alone.

VACCINE STOCK RECORD

Store Name: ____________ Vaccine: ____________ Vial Size: ____________

Region: ____________ Province: ____________ District: ____________

Date	From: Manufacturer /Supplier	To: Store/ Health Unit	Batch Number	Expiry Date	VVM Status	Vaccine Quantities Received (doses)	Issued (doses)	Balance (doses)	Remarks
-	-	-	Carried forward from previous sheet:-						
					Totals:				
							Physical Stock Check:		
							Carried Forward:		

Source: WHO, 2003

Vaccine stock records, like the one shown above, are used to record the name of the manufacturer of each lot of vaccine, the vial size, the lot number, expiry date, vaccine vial monitor status (see pages 106-109), doses of vaccine received, doses issued, and the balance remaining in stock. This type of card can be used in a stock book or ledger or as a stock card at any level of the system.

Credit: WHO

To ensure that no vaccine remains too long in storage, stocks should be arranged in order of "earliest expiration date — first out" (EEFO) at every level. This helps ensure that old vaccine stocks are distributed before newer ones and limits wastage caused by expiration.

Temperature Monitoring

Keeping vaccines at the right temperature is not an easy task, but the consequences of not doing so can be disastrous. Once vaccine potency is lost, it cannot be regained. Damaged vaccines must be destroyed, which can leave a country without adequate vaccine stocks and can cause serious budget problems when the losses involve large lots and/or expensive vaccines. Children and women who receive a vaccine that is not potent are not protected.

> **Beer and Vaccines**
>
> Whenever there is a discussion on immunization service logistics, someone asks why cold beer is available in remote areas but vaccines at the required temperature are not. Of course, beer is a profitable commodity, but more to the point, it does not require continuous cold. In contrast, vaccines can lose their potency if they are exposed to heat, or, in the case of some vaccines, freezing temperatures.

Vaccines have different cold storage requirements, which change at different levels of the cold chain, as shown below.

WHO-Recommended Vaccine Storage Conditions

<table>
<tr><th rowspan="3"></th><th rowspan="2">Primary</th><th colspan="2">Intermediate</th><th rowspan="2">Health center</th><th rowspan="2">Health post</th></tr>
<tr><th>Region</th><th>District</th></tr>
<tr><th>6 months</th><th>3 months</th><th>1 month</th><th>1 month</th><th>Daily use</th></tr>
<tr><td>OPV</td><td colspan="2">-15°C to -25°C</td><td colspan="3" rowspan="13">+2°C to +8°C</td></tr>
<tr><td>BCG</td><td colspan="2" rowspan="6">WHO no longer recommends that freeze-dried vaccines be stored at -20°C. Storing them at -20° C is not harmful, but it is unnecessary. Instead, these vaccines should be kept in refrigeration and transported at +2° to +8° C.</td></tr>
<tr><td>Measles</td></tr>
<tr><td>MMR</td></tr>
<tr><td>MR</td></tr>
<tr><td>Yellow fever</td></tr>
<tr><td>Hib freeze-dried</td></tr>
<tr><td>Hep B</td><td colspan="2" rowspan="6"></td></tr>
<tr><td>DTP-Hep B</td></tr>
<tr><td>Hib liquid</td></tr>
<tr><td>DTP</td></tr>
<tr><td>DT
TT</td></tr>
<tr><td>Td</td></tr>
<tr><td colspan="6">Diluent vials must NEVER be frozen. When the manufacturer supplies a freeze-dried vaccine packed together with its diluent, ALWAYS store the products at between +2° and +8° C. Where space permits, diluents supplied separately from the vaccine may safely be stored in the cold chain at between +2°C and +8°C.</td></tr>
</table>

Source: WHO, 2003

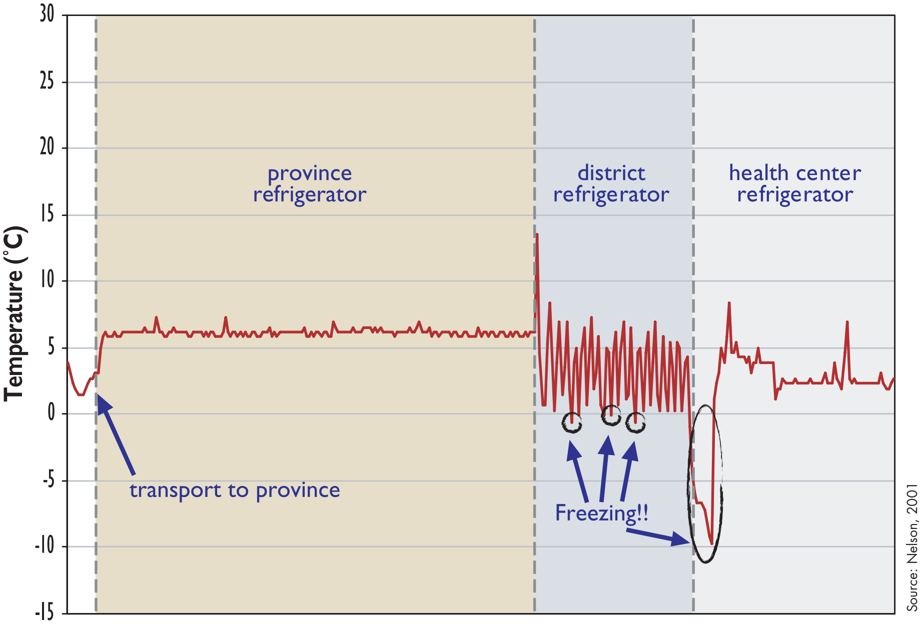
Freezing Vaccines

Some vaccines spoil if they are frozen, including DTP, TT, DT, Td, Hep B, and liquid formulations of Hib. The risk is real and the costs may be high.

In Indonesia, logisticians used continuous temperature monitoring devices to track 16 shipments of vaccine from the national manufacturer to the point of use. Vaccine in 12 of the 16 shipments froze at various points in the cold chain. The biggest risk for freezing occurred during transport from province to district with vaccine in 10 shipments affected. Freezing episodes at such a high level of the cold chain affect several month's worth of vaccine supplied to many districts and health centers. In the Indonesian study, vaccine was also frozen at district levels within ice-lined refrigerators and in some health center refrigerators. The temperature is shown below for one vaccine shipment from a province to a district to a health center. Freezing occurred during storage at both district and health center levels.

New methods to keep vaccines cold without freezing them are being developed and some old practices challenged. For example, using cardboard or paper partitions in a cold box or carrier to keep freeze-sensitive vaccines from

Freezing Study Results, Indonesia



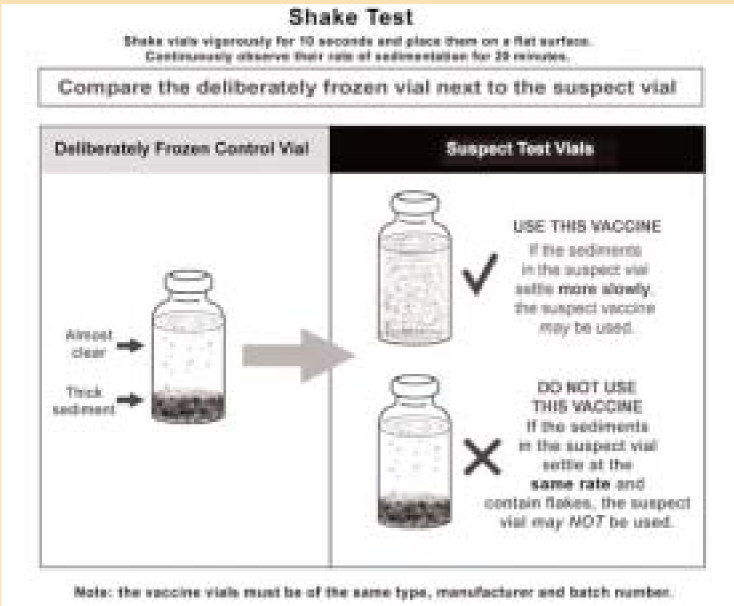
Temperature Readings over Time

Extra care and precautions to prevent freezing should be emphasized in training, supervision, and monitoring.

touching icepacks has proven to be ineffective against freezing. During immunization sessions, vaccines can be kept cool but should be protected from freezing by standing opened vials in a foam pad above the ice packs in the vaccine carrier.

"Shake Test"

The shake test is designed to determine whether adsorbed vaccines such as DTP, DT, Td, TT or hepatitis B have been frozen. Adsorbed vaccines are manufactured in such a way that one substance attaches to the surface of another



To perform the shake test, take a vaccine vial of the same type, manufacturer and batch number as the vaccine vial you want to test. Freeze the vial for at least 10 hours at -10°C until the contents are solid, and then let it thaw. This vial is the "control" sample and should be labeled as "frozen" to avoid its use for vaccination.

Then take a vaccine vial from the batch that you suspect has been frozen. This is the "test" sample. Vigorously shake the control and test samples for 10 seconds, place both vials on a flat surface to rest, and continuously observe them over the following 20 minutes.

View both vials against the light to compare the rate of sedimentation. If the test sample shows a much slower sedimentation rate than the control sample, the test sample has probably not been frozen and may be used.

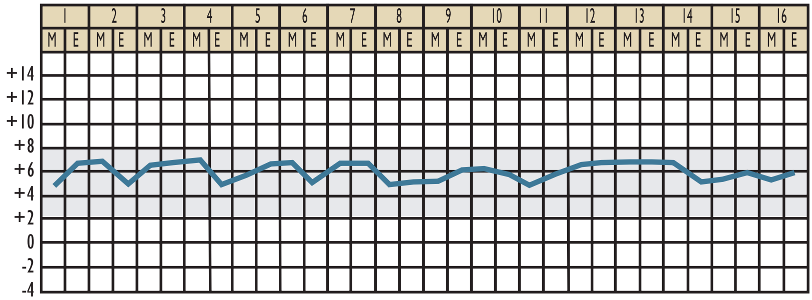
However, if the sedimentation rate is similar and the test sample contains flakes, the test sample has probably been damaged by freezing and should be withdrawn from use. The health worker must notify the supervisor immediately to ensure that any other damaged vials are also identified and withdrawn from use.

material. After freezing, the vaccine is no longer a uniform cloudy liquid, but tends to form flakes that gradually settle to the bottom after the vial has been shaken. Sedimentation occurs faster in a vaccine vial that has been frozen than in a vaccine vial from the same manufacturer that has never been frozen.

Temperature Monitoring Devices

Keeping a record of temperature changes is critically important. Health workers should record the temperature of their vaccine refrigerator twice a day on

Daily Temperature Chart (°C)



a chart like the one above. The shaded area on the chart represents the temperature range that is acceptable, from +2° to +8°C. When they visit health facilities, district- and higher-level managers and supervisors should review these charts to emphasize the importance of maintaining appropriate vaccine temperatures. Recording thermometers that automatically make such recordings also are available.

The numbers in the top row are calendar days. The columns in the second row are divided into morning (M) and evening (E) for recording temperatures twice a day.

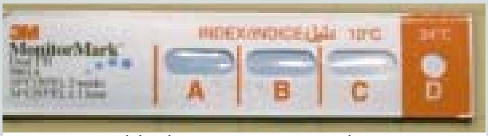
Different types of thermometers, thermo-recorders, and chemical indicators are used to monitor vaccine temperatures, as described on the following page.

Vaccine Vial Monitors

A vaccine vial monitor (VVM) is a small colored disk printed on a vial label or, for freeze-dried vaccines, placed on the vial cap. A square inside the disk darkens irreversibly when exposed to heat over time. By comparing the color of the inner square to that of the outer ring, users can determine the extent to which the vaccine inside has been exposed to heat.

Some Tools Used for Monitoring Temperature

Credit: WHO



Vaccine Cold Chain Monitor Card (CCM)

This is used to monitor temperature during transport and in storage. It irreversibly records cumulative heat exposures above +10°C and any exposure over +34°C.

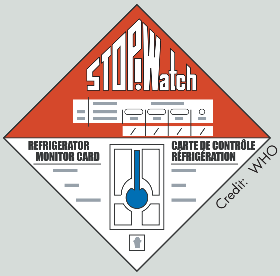
Manufacturers should pack a CCM card or manufacturer-validated monitor in each carton of vaccine shipped. When these cartons are opened and vials put into smaller boxes for distribution to lower levels of the cold chain, the value of the monitor is diminished. The CCM card shown above indicates that substantial exposure to heat has occurred.

Credit: WHO

Freeze indicator (FreezeWatch™)

This is an irreversible temperature indicator that bursts when a shipment is exposed to freezing temperatures. The most recent model (Product Information Sheet code E6/45) releases blue liquid and stains the white backing card when the indicator is exposed to temperatures below 0°C for more than an hour.

Manufacturers pack these devices with DTP, TT, DT, Td, liquid Hib, and hepatitis B vaccines. They can also serve as "silent supervisors" in refrigerators. However, they do **not** indicate whether vaccine in individual vials has been frozen.

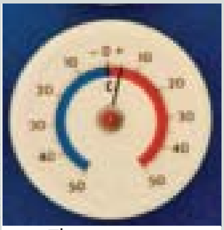


Credit: WHO

Cold Chain Monitor and Freeze Watch (STOP!Watch™)

A combination of a Cold Chain Monitor and Freeze Watch™ indicator is used to continuously monitor temperature range in vaccine refrigerators. The heat indicator irreversibly records cumulative heat exposures of +10°C or any exposure over +34°C. The freeze component bursts at temperatures below freezing.

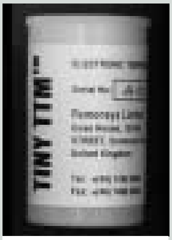
Credit: WHO



Thermometer

Different types of thermometers are used for transport and for storage at different levels of the cold chain.

This functions as a "reusable cold chain monitor" for use in vaccine refrigerators, shipments, and cold chain studies. It stores data that can be downloaded by special cable to the serial port of a computer with MS Windows-supported software.



Credit: WHO

Temperature data logger (Tiny TTM™)

Different VVM models correspond to the heat stability of different vaccines and, therefore, react at different rates. For example, a VVM on a vial of OPV, which is the most heat-sensitive of all vaccines used in national immunization programs, will reach its end point within two days of exposure to +37°C. At the other extreme, a VVM on a vial containing TT, which is very stable, will reach its end point only after 30 days of +37°C exposure.

Credit: WHO

Always check the VVM before using the vial. The vaccines in these vials can be used because the inner square is still lighter than the outer ring.

VVMs have been available on all vials of OPV procured through UNICEF since 1996 and are becoming available for all other UNICEF-procured vaccines, as well as vaccines from other sources. Countries that purchase their own vaccines directly from manufacturers should include VVMs in their procurement specifications.

Reading the Vaccine Vial Monitor

IF: • the inner square is lighter than the outer ring and the expiry date has not been passed		✓ OK to use
IF, at a later time: • the inner square is still lighter than the outer ring and the expiry date has not been passed		✓ OK to use
IF: • the inner square matches the color of the outer ring. The vaccine has reached the Discard Point.		✗ Do NOT use!
IF: • the inner square is darker than the outer ring. The vaccine is beyond the Discard Point.		✗ Do NOT use!

When health workers use VVMs correctly, they can:

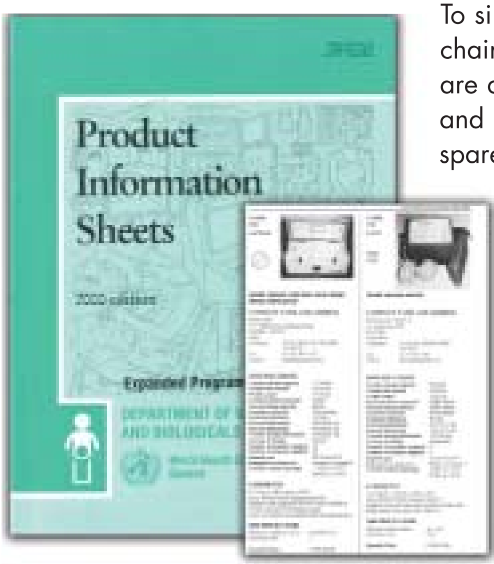
- Identify heat-damaged vaccine and discard it
- Avoid unnecessarily discarding vaccine because of suspected heat exposure
- Extend accessibility to vaccinations in remote areas beyond the reach of the cold chain

- Monitor the amount of vaccine discarded due to excessive heat exposure
- Identify cold chain problems

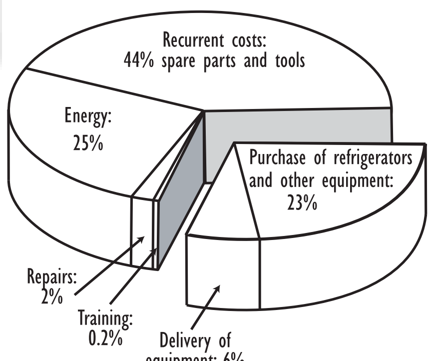
For these benefits to be realized, national immunization programs have found that they must issue policies authorizing staff to use VVMs; disseminate clear instructions to public and private health facilities; provide hands-on training in reading and interpreting the monitors; and monitor and provide feedback on VVM use.

Selection of Storage Equipment

People who are responsible for procuring cold chain storage equipment generally use Product Information Sheets to find out about different types of equipment, costs, ordering details, and how to select products. Items in the Product Information Sheets are independently tested and must meet product specifications defined by WHO.



To simplify maintenance and repair, cold chain equipment managers and donors are advised to procure the same types and models of equipment. The costs of spare parts, tools, repairs, and fuel to run the equipment must not be overlooked during budget preparation. As the pie chart shows, these costs are much more significant over a 10-year period than the initial cost to purchase cold chain equipment.



Cost of Cold Chain Equipment over a 10-year Period

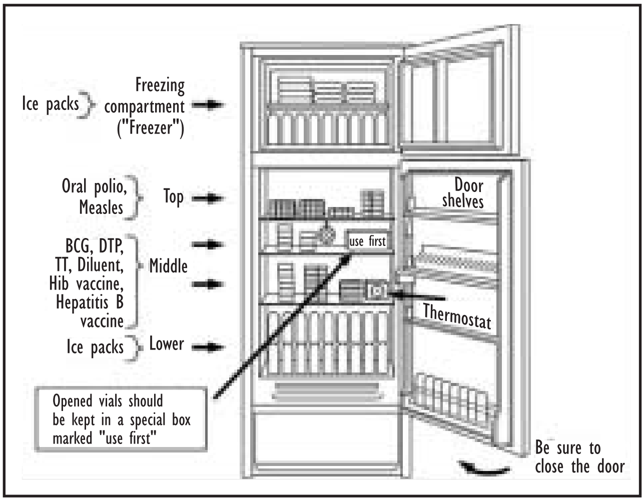
Cold Rooms

Cold rooms are large, specially constructed rooms or self-contained buildings located at the national, and in some cases regional, level for storage of large quantities of vaccines. They have a 24-hour temperature monitoring system with an alarm, a recorder, and a back-up generator that will turn on automatically when the regular power is interrupted.

Freezers and Refrigerators

Freezers and refrigerators are used in district, regional, and central stores. Freezers are used for freezing icepacks and storing certain vaccines, particularly OPV, that need to be kept at

Storage of Vaccines and Ice packs in the Refrigerator



Credit: WHO

CFC-Free Equipment

The Montreal Protocol banned the manufacturing and use of chlorofluorocarbons (CFCs) in industrialized countries on January 1, 1996 and in developing countries beginning on January 1, 2010. These chemicals have been widely used as refrigerants in compression refrigeration circuits and as foaming agents for insulating cold storage equipment. UNICEF, WHO, and equipment manufacturers are working to make a gradual transition to CFC-free equipment for all vaccine storage and transport purposes in all countries by 2010.

How to dispose of equipment in the course of this transition is a question that has yet to be completely resolved.

temperatures below 0°C. Other vaccines are stored in refrigerators, which are also used for chilling diluent before it is mixed with freeze-dried vaccine. Ice-lined refrigerators, which are used at the central and sub-national levels, are capable of maintaining temperatures below +8°C even when electricity fails for as many as 16 of every 24 hours, day after day.

Factors in addition to price should be considered when selecting cold chain refrigerators and freezers, including:

Service delivery strategies. The freezing compartment of refrigerators in health facilities should be large enough to freeze and store icepacks needed for outreach and fixed sessions.

Source of power. Electric appliances are the least expensive to buy and the easiest to maintain, but reliable electric power is not available in many rural areas. Voltage stabilizers are usually needed to avoid damage to compressors caused by fluctuations in power. Where electricity is unreliable, gas or kerosene appliances may be the best choice, despite their high costs, maintenance demands, and ongoing need for fuel.

Where gas or kerosene delivery is unreliable, solar power may be used, despite the high cost of installation and need for maintenance.

Storage capacity. Space needs vary at different levels of the system, depending on the amount and type of vaccine expected to be stored. In a typical health center, a refrigerator should be expected to hold a one-month supply of vaccines and diluent, and one to two weeks of reserve stock. Half the total space in a refrigerator should be left empty so that air can circulate, and there should be room in the bottom for frozen icepacks or sealed bottles of cold water to keep the interior cool if the power fails.

Supply interval. The supply interval also must be considered in calculating the amount of space needed to store vaccines. For example, where roads are impassable during parts of the year, health facilities may need to have a three-month supply of vaccines and other supplies delivered just before roads close and sufficient refrigerator space to store all of this vaccine.

Cold Boxes and Vaccine Carriers

Cold boxes and vaccine carriers are insulated containers that are lined with icepacks to keep vaccines and diluent cold.

Credit: Kelley Sams, BASICS II

At this health facility, a cold box is used to store vaccines on a temporary basis.

Managers should consider a number of technical questions in selecting a cold box or vaccine carrier, including:

- How much vaccine, ice, and diluent must be carried
- How much the equipment weighs – especially if it is to be carried on a bicycle or by a person on foot
- How long the equipment is supposed to last
- How much “cold life” they need

Cold life is the interval between the time that the coldest point in the load stored in a piece of equipment passes -3°C until the temperature reaches

+10°C at a given ambient temperature, usually +32°C and +43°C. Cold life is measured "without openings." At +43°C (a temperature easily reached in a closed vehicle in the tropics), cold life can range from eight hours for NID carriers to 120 hours for large long-range cold boxes.

Cold boxes are normally used to transport vaccine from the central level to the provinces, from provinces to districts, and sometimes from districts to the service delivery level. (Refrigerated vehicles are rarely used for vaccines in developing countries because they are costly and subject to frequent breakdowns: a good cold box works as well or better.) Cold boxes also are used for temporary storage when a refrigerator is out of order or being defrosted.

Vaccine carriers, which are more portable, are commonly used to transport vaccine from district stores to smaller health facilities and to outreach sessions. Special "NID carriers" are bags or boxes that have the benefit of being lightweight; however, they have a short cold life and are not durable.


Credit: WHO

Icepacks inside vaccine carrier.

Icepacks

An icepack is a flat rectangular plastic container designed to be filled with water, frozen, and then used to keep vaccines cold. Icepacks must be placed in a cold box or vaccine carrier in a precise way, so their size is important. When buying a cold box or vaccine carrier, purchasers are advised to order at least one extra set of icepacks so that while one set is being used, the other is being frozen, a process that usually takes at least 24 hours.


Credit: WHO

Placing icepacks inside a cold box.

Management of Storage Equipment

Obtaining the best available and most appropriate equipment at the lowest cost is only one aspect of keeping the cold chain in operation. A second, and perhaps even more important, task is to manage the equipment, which requires:

- Keeping an equipment inventory
- Planning and budgeting for maintenance and repair
- Planning and budgeting for replacements
- Preparation for emergencies

These tasks are described in detail in the documents cited in the reference section at the end of the chapter.

Equipment Inventory

Equipment management includes setting up and updating records about the equipment, tools, and spare parts that are being used or in stock. A good equipment inventory will provide the information that is needed to track the location of larger pieces of equipment, schedule maintenance and replacement, and evaluate the adequacy of stock. Records for each piece of equipment should include:

- Technical information (brand, model, serial number, year of manufacture, date of entry into service, projected replacement date, and date of final removal from service)
- Specific location
- Current condition (working, in repair, out of commission)

Equipment Maintenance and Repair

Maintenance is performed to reduce the likelihood of equipment failure, and repair is performed to fix equipment when it fails. Planning for maintenance includes identifying what needs to be done on a regular basis to clean the equipment and keep it running, ensuring that appropriate tools and spare parts are available, and scheduling these activities. Some types of equipment, e.g., vaccine refrigerators, need daily, weekly, and monthly attention; others need maintenance after use, e.g., cold boxes and vaccine carriers.

Credit: WHO

Equipment manufacturers usually describe maintenance requirements in the manuals and other documents that accompany their products. Health workers and others who use or are responsible for maintaining cold chain equipment need training.

Since any equipment can break down, repair workshops are needed with appropriate tools, spare parts, and skilled technicians.

The availability of tools, spare parts, fuel, training, and labor for maintenance and repair can be major problems. Planners and donors tend to fund the purchase of new equipment and vehicles without also planning and budgeting for fuel, spare parts, maintenance, and repair.


Credit: TRANSAID

Regular maintenance and repair can extend the life of vehicles.

Replacement Planning

Even with the best of care, equipment will eventually wear out or become obsolete. To avoid interruptions of immunization services, long-term and annual plans are needed for replacing equipment. Most manufacturers provide estimates of the life expectancy of their equipment, and the Product Information Sheets, a reference published every few years by WHO and UNICEF, include life-expectancy norms.

> "It is sometimes easier to get a donor to provide a new vehicle than a set of new tires for a vehicle that we already have."
>
> – An African health worker

Some governments have established policies, based on WHO recommendations, that call for the replacement of all refrigerators and freezers after ten years of use. WHO also recommends that refrigerators for storing vaccines be installed in all new health centers.

As equipment is inventoried and installed, a replacement date should be determined and recorded in the inventory. Schedules can be set for selecting and ordering equipment, which may take a number of months to be delivered; and plans made for financing the purchase.

Technicians at national, provincial, and district levels need training in equipment installation, especially when new types, such as CFC-free and solar equipment, are introduced.

Planning for Emergencies


Credit: Anne B. Keiser

Continuous monitoring of vaccine stocks is needed, as shown in this national cold room.

Many things can interrupt immunization services, including equipment breakdown, loss of electric power, and shortage of spare parts or fuel. Planning for these emergencies can minimize damage to vaccines and disruptions in immunization services. In every place that has vaccine storage equipment, staff should set up warning systems for identifying an equipment failure and make arrangements in advance for moving vaccines to the nearest location that has appropriate substitute equipment. In provincial and district stores, standby equipment and power generators should be available on the premises. In health facilities at the peripheral level, equipment for emergency use may be found in businesses or private homes.

Equipment outages caused by shortages of spare parts and fuel should not occur. They should be avoided if there is regular monitoring of stocks and ordering of new supplies.

Vaccine Handling

Proper handling of vaccines requires correct packing and storing of vaccines and diluents, and correct reconstitution of freeze-dried vaccines.

Packing Vaccines in Cold Boxes and Vaccine Carriers

Freeze-sensitive vaccines may be damaged if they are placed in close contact with icepacks. This can be an expensive loss, especially when new vaccines are involved. Health workers are therefore advised to remove icepacks from the freezer and keep them at room temperature before putting them in cold boxes or carriers. This "conditioning" process


Credit: Anne B. Keiser

takes several hours at an ambient temperature of +20°C and less time at higher temperatures. The ice is conditioned when it begins to move around inside the icepack and makes a rattling sound when shaken next to the ear.

Storing Diluent

Diluent is a liquid that is used to reconstitute BCG, yellow fever, measles, and freeze-dried formulations of monovalent Hib vaccines. Combination vaccines that include freeze-dried Hib are reconstituted with DTP or with a DTP-Hep B combination. The manufacturers of freeze-dried vaccines also manufacture the diluents needed for reconstituting their vaccines. The vaccine should always be reconstituted with the diluent provided by the manufacturer for that same vaccine.

Diluent can be stored at +2°C to +8°C or at room temperature but should not be frozen, as diluent ampoules are fragile and may crack in freezing temperatures. If stored at room temperature, they should be cooled to below +8°C before use to avoid thermal shock to the vaccine.

Reconstitution

A sterile needle and sterile syringe are needed to remove diluent from its ampoule and add it to freeze-dried vaccine in its vial. Again, only the diluent supplied by the vaccine's manufacturer should be used, and care should be taken to use the whole amount of diluent for reconstitution. Once reconstituted, the vaccine vial should be wrapped in the foam pad from a vaccine carrier, in paper, or in foil to protect it from direct sunlight. The wrapped vial should be kept on ice.

After six hours or at the end of a session, whichever comes first, reconstituted vaccines must be discarded.

Transportation Management

For immunization services to function properly, vaccine, fuel, spare parts, and health workers have to be at the right place at the right time. Transportation management has a critical role to play. It consists of five components, as described by TRANSAID in its *Transport Management Manual.*

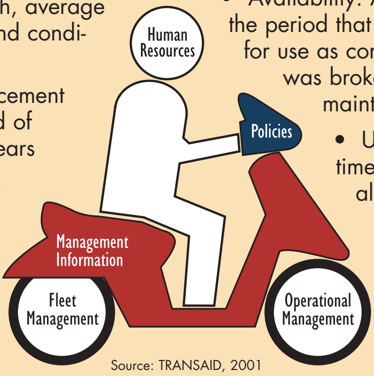
> Cable from country to headquarters: "The trucks don't keep vaccine cool."
> Headquarters' response: "Park in the shade."
> Return cable from country: "Send trees."

The Five Components of Transportation Management

Fleet management

This consists of the selection, purchase, record keeping, maintenance, and repair of the vehicles operated under a single authority, such as a program or district health management team. It includes:

- Setting up and maintaining a vehicle inventory that records for each vehicle: year, make and model, physical location, major use, total kilometers, average kilometers per month, average days used per month, and condition
- Identifying vehicle replacement needs for a given period of time, for example five years
- Defining technical specifications for the purchase of vehicles; selecting and procuring vehicles
- Providing preventive maintenance that includes driver training, daily vehicle defect reporting, vehicle inspection, vehicle servicing at regular intervals, and correction of defects; maintenance may be performed by an organization's own staff or an outside contractor
- Arranging for disposal of vehicles at the end of their useful lives



Source: TRANSAID, 2001

Operational management

This involves planning, scheduling, and controlling the use of vehicles and defining roles and responsibilities of managers, transport officers, drivers, and users. When done correctly, it can increase the number of kilometers traveled per vehicle by 20% per month and increase the total length of time that vehicles can be used for service delivery. Such savings can mean that fewer vehicles are needed or that available vehicles can be used to extend services to unreached populations or meet other service objectives.

Management Information

Transportation management relies on information. Transportation experts recommend that information on the following performance indicators be compiled and analyzed on every vehicle every month:

- Kilometers traveled
- Fuel utilization: Number of kilometers traveled for each liter of fuel used
- Running cost per kilometer, including fuel, maintenance, and tire costs
- Availability: Amount of time during the period that the vehicle was ready for use as compared to the time it was broken down or undergoing maintenance
- Utilization: Amount of time that a vehicle was actually used
- Needs satisfaction: Percentage of authorized requests for vehicle use that were met
- Safety record

Human Resources

All staff members contribute to the effectiveness of the transport system, but specialists are needed to manage and operate it. The specialists for whom training and supervision are required include transport officers, service managers, vehicle operators, mechanics, vehicle inspectors, and vehicle operator trainers.

Policies

Policies are needed to guide or give direction to transport systems, which is why they are shown as handlebars on the motorcycle above. Policies should address:

- Authorized vehicle operators and passengers
- Roles and responsibilities of managers, transport specialists, operators, and passengers
- Selection, procurement, replacement, and disposal of vehicles
- Vehicle planning at national, subnational, district, and local levels.

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Full page photo credit: WHO

Chapter 7:
Injection Safety

"First do no harm."

– from the Hippocratic Oath

Vaccination is one of the most effective and safe health interventions—when vaccines are good quality, appropriately stored and handled, and when injections are given safely. Chapters 5 and 6 address the vaccine quality, storage, and handling aspects of immunization safety. This chapter discusses safe injection practices, selection of injection and other equipment, and waste disposal.

A safe injection is defined by the World Health Organization as an injection that:

- Does not harm the **recipient**
- Does not expose the **health care worker** to any avoidable risks
- Does not result in waste that is dangerous to **the community**

Over 16 billion injections are given every year in developing countries for immunizations, therapeutic purposes, transfusion of blood and blood products, and as injectable contraceptives. Any of these injections, if unsafe, can transmit hepatitis B, hepatitis C, HIV, hemorrhagic fevers, malaria, tetanus, and other diseases. Poor injection techniques can cause abscesses and infected lymph nodes as well.

Global Estimates of Infections Attributable to Unsafe Injections from Any Type of Injection	
Hepatitis B cases	20 million (39% of all new hepatitis B infections per year)
Hepatitis C cases	2 million (40% of all hepatitis C cases per year)
HIV infections	250,000 (5.4% of all HIV infections per year)

Source: Hauri, 2003

Only 5% of the 16 billion injections given annually are for immunizations, and studies have shown that immunization injections are among the safest. However, most vaccines currently available are given by injection, and global concern about unsafe injections has compelled immunization managers and providers to address safety issues more seriously than ever. Improved equipment, such as auto-disable (A-D) syringes and safety boxes, has helped, but changes are required in human behavior and in the health system, too. The first step is to identify the primary causes of unsafe injections. Programs can then plan and implement training, supervision, provision of injection equipment, waste disposal, information campaigns and other activities as appropriate.

Safe Injection Global Network (SIGN)

SIGN is an association of stakeholders sharing a common interest in the safe and appropriate use of injections. SIGN associates include international organizations such as WHO and UNICEF, NGOs, developing country governments, donor organizations, universities, health care worker organizations, industries, and others. SIGN exchanges information, ideas, and experience from diverse groups and fosters the development and use of innovative, cost-effective approaches to promote safe and appropriate use of injections for all health care applications.

Assessing Injection Safety

Unsafe injection practices may not always be obvious nor the causes and magnitude of problems clear. To help national immunization programs and others evaluate injection safety, WHO has made a number of assessment tools available through SIGN and the Expanded Programme on Immunization. These tools enable managers to assess policies, plans, and standards; health worker practices and reasons for them; and issues related to equipment. They include the Rapid Assessment and Response Guide, the EPI tool to assess the safety of injection practices, and a WHO tool to assess health care waste management.

As with any generic assessment instrument, these tools should be adapted to reflect local needs and conditions. Most importantly, an effort should be made to ensure that the information generated by any assessment is actually used to improve injection safety. This requires engaging stakeholders at the outset in the decision to conduct an assessment, and later in design, planning, data collection, analysis, and formulation of recommendations.

Safe Injection Policies

Governments have the primary responsibility for ensuring that injections are safe. At a minimum, policies are needed to address the following key issues:

- Reduction of the total number of unnecessary injections
- Promotion of safe injection practices
- Provision of sufficient quantities of appropriate injection equipment and infection control supplies
- Management of sharps waste

A policy that addresses only immunization injections is insufficient. Safe injection policies should apply to all public and private health care services, including maternal and child health, dentistry, family planning, curative care (including HIV/AIDS), blood collection, and laboratory services. The policies should be introduced to all stakeholders, including donors, clients, and their families. Health care budgets should include adequate resources to cover the costs of:

Credit: Daniel Cima, American Red Cross

- Needles and syringes
- Safety boxes
- Training
- Incinerator equipment and spare parts
- Fuel for incinerators
- Sterilizing equipment, spare parts, and fuel in places where sterilizable injection equipment continues to be used

An Integrated Approach to Policy Making and Planning

Integrated policies should take into account the following programs and concerns:

- HIV/AIDS prevention programs should raise awareness about the risks of unsafe injections.
- National drug policies should address injection overuse.
- Essential drugs programs should budget for sterile syringes and needles, safety boxes, and other equipment.
- Governments and partners should provide matching quantities of sterile syringes and needles and safety boxes.
- Health systems should include sharps waste management as a required "duty of care."

To assist countries with planning for injection safety, SIGN has published an aide-memoire on developing a national strategy for the safe and appropriate use of injections. This document provides both a checklist and more detailed guidance on steps that countries can take in developing and implementing injection safety policies.

Setting, communicating, and adhering to clear national policies is especially important in mass vaccination campaigns, when a large number of immunization injections are given in a short time, often by personnel who do not routinely give injections. Such campaigns also involve temporary distribution systems for vaccine, supplies, and equipment and arrangements for waste management. To help governments conduct safe campaigns, in 2002, WHO/EPI issued another aide-memoire that outlines the actions needed to reduce the risk of unsafe injections.


Injection Safety
AIDE-MEMOIRE
Checklist
Words of advice
Department of Vaccines and Biologicals
Safety of mass immunization campaigns
Checklist

Credit: WHO

Injection Practices

Changing the behavior of health workers and clients may be the most important step required to make injections safe. SIGN and WHO have identified critical issues and made recommendations for addressing them, as outlined on the next page. Training and supervision are discussed further in Chapter 9.

Injection Practice Problems and Recommendations	
Problems	**Recommendations**
1. Use of unsterile injection equipment. Auto-disable syringes and needles, which are recommended by WHO for immunizations, may be unavailable. Sterilization equipment or fuel may not be available for sterilizable syringes and needles, which are still commonly used for therapeutic purposes.	To assure that health workers use a sterile syringe and needle for each injection, managers should forecast, order, and assure reliable delivery of adequate quantities. Health workers should alert supervisors of shortages. Managers should ensure that equipment, fuel and spare parts are included in the budget and provided as planned.
2. Unsafe collection of sharps. Health workers are unaware of the danger to themselves and others caused by their not placing disposable syringes and needles in safety boxes. Health workers are unaware of the dangers of recapping needles. Health workers do not have or do not use safety boxes.	The health system should promote safe handling of injection equipment through policies, training, supervision, and informational campaigns. Trainers should require that health workers demonstrate mastery of safe injection techniques. Supervisors should monitor handling of injection equipment, use of safety boxes, and management of supplies.
3. Unsafe management of waste. Health workers do not know how to handle waste or lack the appropriate equipment to destroy it. Used equipment is dumped into public areas where children and others scavenge it.	Trainers and supervisors should require that health workers demonstrate the ability to handle and destroy waste. Supervisors should monitor waste management. The health system should provide information to the public about the risks of handling medical waste.
4. Overuse of therapeutic injections. Because it is the norm to use injections, injections are over-prescribed. Some health workers believe that injections work faster and better than oral medications. Patients may prefer injections to oral medication.	Health workers should prescribe oral medication whenever possible. The health system should educate the public on the effectiveness of oral medication.

Another response to injection safety problems is public information, but this can be a double-edged sword. While information campaigns can increase the demand for injection safety, they can also discourage people from getting those injections that are needed, such as vaccinations. To inform people about injection safety without frightening them, health officials should communicate what is being done to solve the problem whenever a situation involving unsafe injections occurs. People also should be told what they can do themselves to reduce the risks.

Local circumstances and awareness of the problem should be used to gauge how best to share information with the public. For example, in a country with high rates of HIV/AIDS and awareness that dirty needles and syringes can transmit HIV, publicizing the introduction of A-D syringes for immunization could reassure people that something is being done to address a problem they recognize. In other settings, publicity about A-D syringes may create needless anxiety and do more harm than good.

Of course, the most important factor in maintaining public confidence in immunization services is to ensure the safety of injections.

Credit: SIGN

Improper disposal of syringes and other medical waste behind a clinic.

Injection Equipment

Injection equipment that can be used to administer injectable vaccines includes:

- Auto-disable syringes
- Standard disposable syringes
- Pre-filled, single dose, non-reusable devices (e.g., Uniject™)
- Sterilizable syringes and needles

Auto-Disable Syringes

Credit: Becton-Dickinson

Auto-disable (A-D) syringe.

A-D syringes are disposable injection devices that are specially made to prevent reuse and are therefore less likely than standard disposable syringes or sterilizables to cause person-to-person transmission of blood-borne pathogens. Many health workers prefer A-D syringes because they save the time that they would otherwise spend on sterilization. Although these syringes are more costly than other types, the cost is decreasing as demand increases.

The use of A-D syringes, however, generates a large volume of potentially dangerous waste. As with any equipment, there is no guarantee against improper use; therefore policies, training, supervision, and other measures are needed to support correct use and disposal of A-D syringes. The use of A-D syringes greatly increased in 2001, when GAVI advised the Vaccine Fund to provide them in sufficient quantity to cover both newly-introduced and "traditional" vaccines for at least three years, based on acceptable country proposals for immunization injection safety.

WHO-UNICEF-UNFPA Statement on the Use of Auto-Disable Syringes in Immunization Services

In a joint statement issued in December 1999, WHO, UNICEF, and the United Nations Fund for Population Activities (UNFPA) said:

The auto-disable syringe, which is now widely available at low cost, presents the lowest risk of person-to-person transmission of blood-borne pathogens (such as hepatitis B or HIV) because it cannot be reused. The auto-disable syringe is the equipment of choice for administering vaccines, both in routine immunization and mass campaigns.

- WHO, UNICEF and United Nations Fund for Population Activities (UNFPA) urge that, by the end of 2001, all countries should use auto-disable or sterilizable syringes only. Standard disposable syringes should no longer be used for immunization.
- WHO, UNICEF and UNFPA urge that, by the end of 2003, all countries should use only auto-disable syringes for immunization.

Source: WHO, 1999

Conventional Disposable Syringes

Conventional disposable syringes are plastic syringes with steel needles that are provided by the manufacturer in a sterile package. The needle may either be fixed to the syringe when it is produced or attached by the health worker just before use. These syringes are intended to be used only once, but they are, in fact, quite easy to use multiple times. Since they cannot be properly sterilized, their re-use places the public at high risk of disease and death, and WHO and UNICEF recommend that they not be used for immunization purposes.

Pre-Filled, Single-Dose, Non-Reusable Devices

Some injection devices (e.g. Uniject™) package vaccine, needle, and syringe together in a sealed foil pouch. They are designed to ensure that clients get the correct amount of vaccine and that the injection is safe. In some settings, they have been used to take more heat-stable vaccines like tetanus toxoid and hepatitis B vaccine to hard-to-reach areas beyond the cold chain. Their relatively higher cost, greater storage requirements, and more limited availability suggest that they are appropriate for use in selected circumstances.

Credit: San Francisco Chronicle

Pre-filled, single-dose, non-reusable devices.

Sterilizables

Sterilizable injection equipment consists of plastic syringes and steel needles that are designed for re-use after cleaning and sterilization in a steam sterilizer or autoclave.

Sterilizables are the least expensive per injection and have the lowest volume for re-supply and waste disposal. However, they require more handling by health workers for cleaning and sterilizing the equipment, which may increase the risk of needle-stick injury. Health personnel must also order supplies such as fuel and spare parts for the sterilizers. Supervisors need to monitor the use of this equipment constantly.

Sterilizable syringes and needles are being phased out for immunization injections but continue to be used for reconstituting freeze-dried vaccines. They are still used extensively for injections other than immunization.

Reconstituting Freeze-Dried Vaccines with Syringes and Needles

Even if A-D syringes are adopted for use with all vaccines, there will still be a need to order and distribute mixing syringes to reconstitute lyophilized vaccines such as measles, BCG, and some Hib vaccines. To ensure safety, one sterile mixing syringe and needle should be used for **each new vial** of vaccine that is reconstituted. If small vial sizes are introduced, for example, two-dose vials of pentavalent vaccine, the quantity of mixing syringes required will increase substantially compared to needs for 10-dose or 20-dose vials.

Where A-D syringes are used for all vaccine administration and steam sterilizers are no longer required for immunization equipment, managers will have to decide whether to dispose of mixing syringes after each vial is reconstituted or to sterilize them along with other non-immunization equipment.

Sterilization of Injection Equipment

Credit: Veronique Leger

Wherever health workers use sterilizable needles and syringes, they must sterilize them after each use. They should use appropriate sterilization equipment and carefully adhere to manufacturers' directions.

Sterilizers made for vaccination equipment have one, two, or three racks, each of which holds approximately 40 syringes and 50 needles. In addition to the sterilizer itself, the following items are needed for the cleaning and sterilizing procedure: a basin for washing used syringes and needles, forceps, a timer, stove, and fuel. Time, steam, and temperature indicators (TST) are required for every sterilization cycle. These strips or spots change color irreversibly when the contents of a sterilizer have been sterilized. Health workers must keep records of their use to document that sterilization has been done.

These Practices Are Unsafe!

- Recapping needles (can result in needle sticks for health workers)
- Changing the needle after an injection but using the same syringe
- Reusing the needle and syringe for multiple patients
- Boiling needles and syringes
- Flaming the needle
- Reusing mixing syringes

In compliance with a joint statement issued by WHO, UNICEF, UNFPA, and the International Federation of Red Cross and Red Crescent Societies, steam sterilizers made for vaccination equipment will not be available from UNICEF Supply Division after 2003. Spare parts and sterilizable syringes will continue to be available for a limited time until national immunization programs make the full transition to A-D syringes.

Management of Sharps Waste

Credit: San Francisco Chronicle

As the use of A-D syringes has increased, so has the urgency of ensuring that all injection supplies are disposed of properly. Careless disposal places health workers and the public at high risk of needle-stick injuries.

Used syringes and needles should **never** be dumped in open areas where people might pick them up, step on them, or come in contact with them in any other way.

The need to better manage contaminated sharps has prompted the development of tools to assist countries with planning and policy development. Available from WHO and SIGN, these tools include an assessment tool for health care waste management that examines current practices, level of awareness of risks, and the country's regulatory framework in order to provide essential information for designing an action plan. Also available is an aide-memoire for developing a national strategy for safe health care waste management.

Safety Boxes

Safety boxes, or sharps containers, are puncture-resistant containers into which A-D syringes and needles are placed immediately after use and temporarily stored until they can be destroyed. They should be supplied in sufficient quantity such that a safety box is always within reach of a vaccinator, even during outreach sessions.

The volume of used syringes and needles that safety boxes must accommodate can be significant, as described in the box.

Credit: WHO

A safety box should be available within reach of every health worker who gives an injection.

Wastage Volume of Used Needles and Syringes

Approximately 100 2ml syringes and needles (used for most childhood vaccinations) fill a five-liter safety box. Five and 10ml syringes take up more space.

For a health facility with a catchment population of 30,000, a birth rate of 30 per 1000, and 100% childhood immunization coverage, eight five-liter safety boxes will be filled every month with used syringes and needles.

Credit: SIGN

In addition to the eight boxes per month for children's immunizations, the health facility will need additional boxes for TT and curative care injection equipment. The volume of waste produced in immunization campaigns, which may cover children up to five or more years of age, is also significant.

Waste Disposal and Destruction

Once nearly full, safety boxes should be incinerated. If an incinerator is not available, a much less desirable and effective alternative is to douse them with kerosene and burn them. In planning waste disposal, managers should consult medical waste disposal policies and environmental regulations for the national and local levels. They should make plans for the:

Credit: D. Marchand/IDRC

Improper disposal poses risks to the community.

- **Location of disposal facilities:** Ideally, every health facility would have an incinerator. Because cost and demand limit the practicality of this solution, districts may install incinerators at strategic locations, such as hospitals.
- **Disposal of filled safety boxes:** Properly functioning incinerators, operated by trained personnel, ensure the most complete destruction of syringes and needles. They also produce less air pollution than burning by other means at lower temperatures. Burning in a metal drum is considered the next best option after incineration but may not destroy the waste completely and may result in heavy smoke. Open burning and burying are much less effective and not recommended.
- **Schedule and budget for destruction of safety boxes:** A regular schedule should be developed and maintained, and funds should be provided for sufficient quantities of fuel.
- **Logistics:** What arrangements are needed to ensure transport of waste from health facilities to incineration sites, a reliable supply of fuel for incinerators, provision of spare parts, and tools for maintenance and repair?
- **Training:** Training is needed for health workers, incinerator operators, and others, for example, those who transport waste. Such considerations should be included in training curricula.

Incineration Equipment

Auto-combustion incinerators that reach temperatures of over 800°C destroy contaminated sharps and syringes most effectively. Work is now under way in many countries to equip district hospitals and large health centers with this kind of incinerator. However, means of disposing of waste from small facilities, like dispensaries and health posts, and at the end of outreach visits are still under study.

While improvements in waste management continue, work is under way to develop new disposal technologies. Some of the technologies that soon may be available are described in Chapter 11.

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Full page photo credit: Don Douglas/PATH

Chapter 8: **Disease Surveillance**

"All interest in disease and death is only another expression of interest in life."

– Thomas Mann

During the 1970s and 1980s, the national and global focus of the Expanded Programme on Immunization was primarily on reaching the Universal Childhood Immunization goal of 80% coverage by 1990. In the 1990s, national program managers and donors started to look more closely at the effect of immunization services on the incidence of disease, and disease surveillance became a more prominent activity.

Credit: Ann Jimerson

Health worker at a rural clinic displays the surveillance and coverage charts he created.

Disease surveillance is the collection, analysis, and interpretation of data to determine disease trends and patterns. Disease surveillance provides information such as:

- Disease incidence, morbidity, and mortality, and progress in achieving disease control goals
- Changes in patterns of morbidity and mortality among different age groups in different geographical areas and among different economic, social, or cultural groups
- Impact of immunization strategies on disease incidence
- Disease trends

The overriding value of disease surveillance, however, is its use as a tool to identify the presence of infectious diseases and guide actions to prevent them from becoming threats to public health. This chapter describes the activities required to carry out that function.

Types of Disease Surveillance

Different methods are used to obtain different types of surveillance information, as described below.

Credit: Veronique Leger

Facility-Based Routine Surveillance

In many countries, health workers are required to report on the number of individuals that come to their facility and are diagnosed with reportable diseases. These reportable diseases are usually diseases that have outbreak potential, such as cholera, polio, and measles, or diseases that are targets of national control programs, such as malaria and tetanus. Data on individual patients, which are recorded in patient registers (Chapter 4), are used to calculate the number of cases of reportable diseases diagnosed by health facility staff over a certain period of time. These data are periodically reported to district authorities who compile and send them to higher administrative levels. This process of detecting and reporting information on diseases that bring patients to the health facility is known as passive surveillance.

Passive surveillance yields only limited data because many sick people do not visit a health facility and because those cases that do show up may not be correctly classified, recorded, or reported. If managers fail to fully understand and account for these limitations, they may incorrectly interpret trends and patterns of infectious diseases.

Credit: Kristina Engstrom

Active surveillance.

One way to overcome the limitations of passive surveillance and get a better picture of disease burden in the community is for health workers to visit health facilities and communities to seek out cases. This is known as active surveillance.

Since passive surveillance has limitations due to its lack of access to some groups within the population, active surveillance is often used to enhance the completeness of a passive surveillance system. Active surveillance is also more expensive than a passive system and requires considerable additional effort to organize. This means that active surveillance is usually conducted on a limited segment of the population and for only a brief period. Active surveillance is, therefore, used to gain targeted insight into a situation and not collect routine data over a long period of time.

Routine surveillance by health facilities, whether passive or active, is often hampered by the difficulty of making accurate diagnoses. Health workers may lack the proper equipment or training for diagnosis in the health facility, and laboratory services are often not available to confirm clinical diagnoses.

In certain instances, health workers conduct case-based investigations to learn more about a specific illness pattern, for example, when there is a suspected case of a disease targeted for eradication, such as polio, or during suspected outbreaks of epidemic-prone diseases such as yellow fever. In case-based investigations, health workers record information such as the patient's name, age, vaccination status, location, date of disease onset, suspected diagnosis, and laboratory results (when available).

Credit: Kelley Sams, BASICS II

Community-Based Surveillance

With training, members of the community can expand facility-based surveillance by detecting and reporting cases that may go undetected by the health facility. A good example of this is the use of community members to detect cases of guinea worm (*dracunculiasis*). In villages where the disease is endemic, volunteers are trained to detect and report cases using a standard diagnostic criterion, e.g., painful legs that have skin ulcers with worms protruding. They then may undertake treatment, referral, and containment measures such as bandaging the ulcer, instructing infected persons not to bathe in water from ponds and streams, and promoting the use of filtered drinking water.

Community-based surveillance needs the support of trained health care workers who in turn provide training to the community on how to recognize the disease and how to respond when people are ill. While the focus of community surveillance may be on a specific disease, community members may also be trained to detect an array of health problems. Community members and health workers can work together to organize transport, childcare, and other assistance and, sometimes, provide medical supplies, treatment, and vaccinations. Reports by community members should be incorporated into the overall surveillance data managed by health personnel. Health systems should also provide feedback to the community about disease patterns in their own and surrounding areas.

Community-based surveillance can be very useful in detecting and treating some illnesses. However, it generally has a high error rate and should be used carefully. Case definitions need to be very simple and specific for community identification and this means that diagnoses need to be confirmed by someone with more advanced training. While it is always wise to involve the community as much as possible in health initiatives, community-based surveillance is not appropriate for all conditions and situations. Health workers should carefully test the community-based approach before initiating it and should be prepared to regularly monitor activities to ensure that definitions are being applied correctly and that the health of the community members is being served well by this approach to surveillance.

Sentinel Surveillance

Sentinel surveillance is the collection and analysis of data by designated institutions selected for their geographic location, medical specialty, and ability to accurately diagnose and report high quality data. For example, district hospitals may be required to report specific conditions such as bacterial meningitis in order to quantify the burden of disease due to *Haemophilus influenzae* type b. Generally, sentinel surveillance is useful for answering specific epidemiologic questions, but, because sentinel sites may not represent the general population or the general incidence of disease, they may have limited usefulness in analyzing national disease patterns and trends.

Surveillance Activities

Surveillance for communicable diseases involves:

- Detection
- Reporting
- Analysis and interpretation
- Presentation
- Response

Detection

Surveillance begins with case detection. To accurately detect disease, health workers need case definitions that are appropriate for the local context, and they need practice in applying them, especially when they do not see a specific illness very often. For example, health workers in one country had difficulty identifying yellow fever cases according to the clinical symptoms of yellow eyes or dark urine, but case detection became easier after they learned the local term for the disease: "horse-urine eye disease."

Even with appropriate case definitions, clinical diagnoses can be a problem. Many illnesses have similar symptoms, such as fever and rash, and can be differentiated only by laboratory tests that may not be accessible.

Reporting

Most ministries of health require that facilities routinely report the total count of cases of each reportable disease that has occurred within a specified time period (weekly or monthly). When no cases have occurred during the period, the report should indicate this fact. WHO has developed forms for reporting each disease that can be adapted to meet national needs.

Zero Reporting: Does No News Necessarily Mean Good News?

A hypothetical health post's disease report showed the following:

Disease	Number of cases
Measles	25
Cholera	
Diphtheria	0

In this example, it is clear that there were no cases of diphtheria during the reporting period, but it is not clear whether there were any cases of cholera. The practice of putting a "0" when there are no cases is called "zero reporting." Knowing that there were no cases of a specific disease may be just as important as knowing the number of cases that were detected.

In most countries, policies require that routine reports include the aggregate number of cases of each disease over a specified time period, for example one month. But for some diseases or conditions, such as acute flaccid paralysis (AFP), cases must be notified immediately upon detection. Individual case reports usually include case information, exposures prior to illness, contacts after illness, and laboratory results, but the details differ depending on the disease.

Reporting procedures should be designed to operate effectively under the wide variety of local conditions in a given country. Health officials at the national level should not assume that the electric power, telephone lines, and computers available to health facilities in the capital city are available to health workers throughout the country. They should recognize that some facilities might depend on truck drivers or other travelers to carry news of an outbreak to the appropriate authorities. For example, only half the health facilities in the study reported below would be able to report an outbreak by telephone.

Telecommunications Capacity to Report Disease in One African Country

Means of communication	**Percent of Facilities with Access**		
	Regional Health Bureaus (n = 11)	Zonal Health Departments (n = 12)	Health Facilities (n = 33)
Telephone services	100%	67%	48%
Radio communications	100%	33%	3%*
Computers	64%	25%	12%
Computers with modem	27%	8%	3%*

Source: WHO, January 2001
**one facility only*

The ability to report and act immediately becomes critical when dealing with diseases that have outbreak potential, such as measles and cholera. When communication capabilities do not allow for immediate notification of outbreaks, local health workers should have the authority and resources to take quick action to stem the spread of the disease while help is being summoned from district or national authorities.

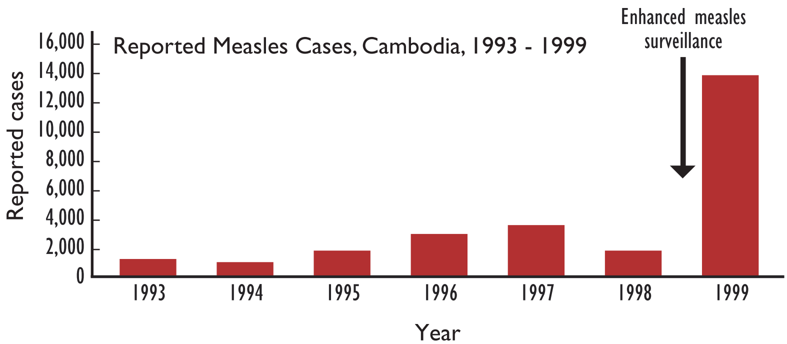
Analysis and Interpretation

Surveillance data are of little use for local decision-making and planning unless health workers know how to analyze the data and understand their implications. Health workers need to be able to interpret trends and patterns of disease in order to inact prompt control measures and avoid actions that are not appropriate.

In order to analyze and interpret surveillance data, health workers need to be aware of the limitations and peculiarities of the data set. They need to conduct basic analyses first and then proceed to more complex forms of analysis. They need to recognize when the data will no longer support the type of analysis they are proposing, and finally, their analyses should be directed at answering critical questions that are needed for planning, implementation and evaluation of public health actions.

Health workers also need to be aware of phenomena such as "the surveillance effect" that occurs when improvements are made in disease surveillance — that is, the number of reported cases almost invariably increases because of better reporting rather than because of an increase in disease incidence, as shown in the example.

Measles Outbreak or Improved Surveillance?



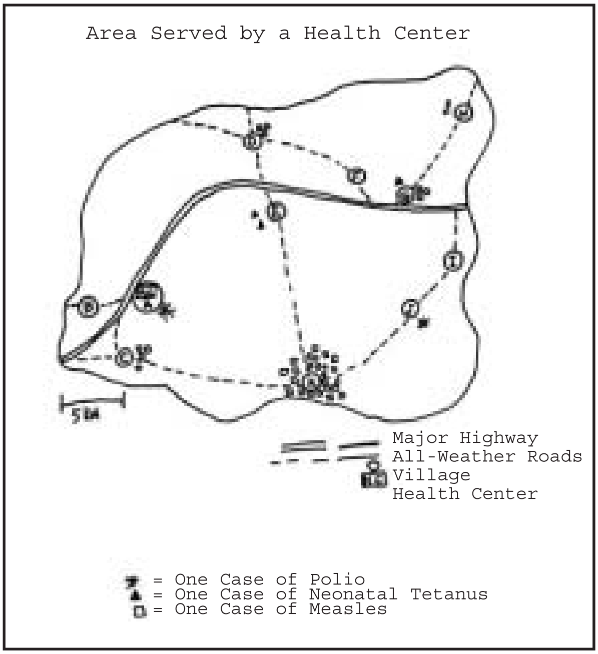
Source: WHO, 2000

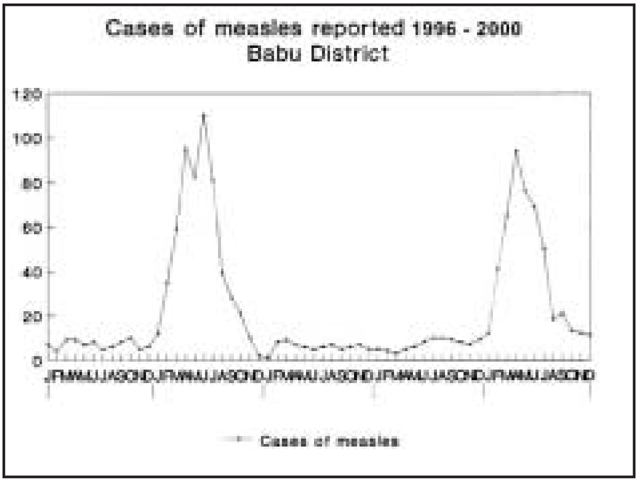
In this example, even though an increase like the one that occurred in 1999 may simply reflect the surveillance effect rather than a genuine rise in disease incidence, because such data can also indicate real problems, they should not be ignored. Trend data only indicate possible problems, so health workers need to investigate further to be able to correctly interpret their meaning and determine what actions to take.

Other cautions should be taken in interpreting surveillance data. For example, some diseases are still underreported, notably neonatal tetanus and measles. Planners must realize that these diseases are major contributors to child mortality even if the data are incomplete. Similarly, immunization services also can be the victims of their own success when planners use disease surveillance data as the basis for budget allocations. Because there are fewer deaths and disabilities caused by vaccine-preventable diseases when people are vaccinated, fewer resources may be allocated for the prevention, identification, and treatment of vaccine-preventable diseases. In some cases, a decrease in the number of reported cases causes districts to shift priorities from immunization services to other interventions, thus weakening immunization programs and risking a return of vaccine-preventable diseases.

Presentation

When data are analyzed and the results interpreted, the information must be presented in a way that meets the needs of the target audience. For example, highly technical presentations of data may be appropriate for senior ministry officials but not for local government staff. A presentation to the Minister of Health about the impact of a health event should be designed differently than one made to the Minister of Finance.





A variety of presentation methods are available. For example, maps that show the location of cases are useful for presenting surveillance information, as well as for analyzing incidence. They can illustrate relationships among cases and geographical and demographic features as well as show how cases are clustered. Maps of district and facility catchment areas can be sketched by hand, or government maps may be available in hard copy or electronically.

Besides maps, information can be made more understandable by use of rates, tables, graphs, trend lines, data transformations, and projections. All of these methods help make raw data more easily understood and should be tailored to the appropriate audience.

Response

Disease surveillance enables managers to respond to existing problems and take steps to prevent anticipated problems. Responses may include verification of reported cases, treatment, search for new cases, or supplemental vaccination activities, but all must be tailored to the disease and the situation. For example, it may be difficult to quickly contain an outbreak of a highly contagious disease, such as measles, with only a mass vaccination response. For other less contagious diseases, such as yellow fever, mass vaccination can have a more dramatic short-term impact.

The ability to report and act immediately becomes critical when dealing with diseases that have outbreak potential, such as measles and cholera. When communication capabilities do not allow for immediate notification of

Outbreak Preparedness Committees

Outbreak preparedness committees are used at subnational, national, regional, and global levels to prepare for and coordinate responses to outbreaks. Committee membership varies but usually includes epidemiologists, logistics experts, government planners, NGOs, donors, and multilateral agencies.

Before outbreaks occur, committees may:

- Establish guidelines for when and how to respond to outbreaks of different diseases
- Assess the capacity of the health system to respond
- Advocate for training in field epidemiology
- Ensure that vaccine stocks and other supplies will be available in case of an outbreak
- Establish communication channels among partners
- Set up response coordination mechanisms

During an outbreak, the committee coordinates the response, making sure that technical advice is available where needed, that supplies and manpower are distributed and used appropriately, and that communication links are maintained with the public, the media, neighboring countries, and regional and global networks.

outbreaks, local health workers should have the authority and resources to take quick action to stem the spread of the disease while help is being summoned from district or national authorities.

Responding to routine reports is as important as responding to emergencies. Routine surveillance data, together with coverage and other information, can lead to improvements in immunization services such as the implementation of strategies to provide unreached children with services. Managers who receive surveillance reports should also provide feedback on their timeliness and accuracy, send summaries of the analysis back to health facilities, and describe how they used the data.

Laboratories


Credit: WHO

Not all diseases can be diagnosed accurately using clinical definitions alone. Laboratories are needed to identify the exact cause of the illness, but well-functioning public health laboratories are still unavailable in many developing countries. Even when available, they often lack the equipment, reagents, and trained staff to properly carry out their functions.

The process of collecting and transporting specimens from the patient to the laboratory can also be problematic. There are also problems getting laboratory results back to health workers. Results often come too late to inform treatment or control activities, or they never come, leaving health workers to respond as best as they can with inadequate information.

To overcome some of these problems, research is being done on the development of rapid diagnostics that can be used to supplement the public health laboratory. These diagnostics are simple tests that can be performed by a trained health worker in the field to confirm a suspected diagnosis. Decentralized laboratory facilities are also being considered as a way to move diagnostic confirmation closer to the health facility.

As with other aspects of surveillance, communication is important. Health workers need to advise laboratories about the samples they are sending, laboratories need to inform health workers and managers of their test findings, and health workers need to notify patients about laboratory results.

Adverse Events Following Immunization (AEFI)

Adverse events following immunization occur even in the safest programs. Only rarely is there a causal relationship between a vaccination and an adverse event, but health officials need to be vigilant to the possibility of a connection and take appropriate action.

Causes of adverse events are classified under four categories:

1. Program error. An error in vaccine preparation, handling, or administration, such as:

- Giving too much vaccine in one dose
- Injecting vaccine in the wrong place, such as the buttocks
- Not using sterilized syringes and needles for each injection
- Using the wrong diluent or the wrong amount of diluent
- Giving the wrong vaccine or other biological substance

2. Vaccine reaction. The reaction of a particular individual to the inherent properties of a particular vaccine even when the vaccine has been prepared, handled, and administered correctly. A reaction is usually one of three types:

Local: The most common type of reaction usually shows as pain, swelling, or redness at the site of injection. These reactions occur within a few hours of injection, go away in a short period of time, and pose little danger. Parents should still report any local reaction that persists to a health worker. This type of reaction is most commonly caused by inactivated vaccines.

Systemic: Generalized reactions may include fever, malaise, muscle pain, headache, or loss of appetite. They are similar to a very mild form of the disease but pose no serious health risk. These reactions occur more commonly after injections with live attenuated vaccines than with inactivated vaccines.

Allergic: These are the most serious and most rare reactions. They are caused by the body's reaction to a particular component in a vaccine. Severe allergic reactions can be life threatening, which is why good screening prior to vaccination is important. Health workers who give vaccinations should know the signs of allergic reactions and be prepared to take immediate action.

Local and systemic reactions, or side effects, are described for each vaccine in Chapter 12.

3. Coincidental. The adverse event occurs after a vaccination has been given but is not caused by the vaccine or its administration. A coincidental event is one that would have occurred even if the person had not been vaccinated.

4. Unknown. The adverse event cannot be directly related to the vaccine, its administration, or any other identifiable cause.

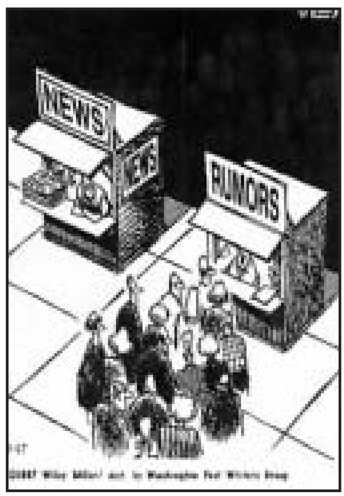
While every effort needs to be taken to eliminate avoidable adverse events, concern over the possibility of an adverse reaction needs to be balanced against the threat that the disease poses. With respect to vaccine-preventable diseases in developing countries, the danger from the disease is much greater than from the vaccine. For example, measles poses a far more serious threat than the possibility of an adverse reaction to a measles-containing vaccine, as shown below.

One of the responsibilities of National Regulatory Authorities (NRAs) described in Chapter 5 is to monitor and investigate adverse events. Most adverse events are caused by errors in the handling and administration of vaccines long after they have left the manufacturer. However, NRAs must also investigate the possibility that a particular vaccine was mislabeled or not manufactured correctly even though such problems are extremely rare.

Complications Caused by Measles Compared to Adverse Events following Measles Vaccination

Complication	Measles Complications per 100,000 Cases	Measles Vaccine Adverse Events per 100,000 Vaccinations
Encephalopathy/ encephalitis	50 - 400	0.1
Convulsions	500 - 1,000	0.02 - 190
Death	10 - 10,000	0.02 - 0.3

Dealing with Rumors



Credit: Washington Post

Health officials often have to deal with rumors, especially when adverse events occur. Out of genuine fear, concern, or less respectable motives, people start and spread rumors about vaccination. These exaggerations of risk can seriously disrupt immunization programs.

There are four things that health officials should do to combat rumors:

- **Predict:** The same rumors circulate regularly, for example, the unfounded accusation that tetanus toxoid causes sterilization or the false association of measles-mumps-rubella vaccine (MMR) with autism.
- **Prepare:** Knowing what rumors are likely to arise, health officials can prepare materials to counteract them in advance. Information should always be available for parents and the media on common side effects of vaccines.
- **Fast, positive response:** When an adverse event occurs, action should be taken immediately to discover the cause and then to correct the problem and minimize its impact by giving out information. Messages

should be honest and in language that the public understands.

- **Professional and political support:** Endorsement of immunizations and assurance of their safety should be sought from academic institutions, professional associations, politicians, and respected community leaders.

The Expanded Programme on Immunization unit in WHO has created informational and training materials on how to deal with the public and the press when an adverse event occurs.

> **Rumors Have Legs!**
>
> A two-year old boy in an Asian country died five days after he was given vitamin A during a national immunization day for polio. The child's doctor said that the boy had died of childhood pneumonia, a common cause of death for malnourished children in the area.
>
> In spite of the fact that there was no indication that vitamin A was associated with the child's death, other doctors began to say that vitamin A had caused the death. The rumor spread throughout the country, and health officials were forced to cancel the rest of the campaign. As a result, millions of children received neither polio vaccination nor vitamin A supplementation.
>
> Rumors have legs and travel quickly. In essence, it is the rumor itself that puts children's lives at risk.

Integrated Disease Surveillance

Many national health care systems have separate disease surveillance systems that serve different purposes or users. For example, vertical disease programs, such as polio eradication and tuberculosis and malaria control, often have their own surveillance systems in order to facilitate rapid response.

A fragmented approach to disease surveillance results in costly and inefficient duplications of effort, and many countries are trying to respond by developing Integrated Disease Surveillance (IDS) systems. The collection of disease surveillance data has always been integrated at the service delivery level, but as that information flows upward, it branches out to numerous users in other departments and ministries. If integration can make this process more efficient and still meet the information needs of various users, it will make a valuable contribution to the increase of knowledge about diseases and to the improvement of public health services.

> **WHO Surveillance Software**
>
> - **EpiInfo.** Organizes data for disease surveillance systems, as well as other epidemiological information.
> - **EpiMap.** Produces and displays maps from geographic boundary files and data values entered from the keyboard or EpiInfo.
> - **Information for Action (IFA).** Developed for the computerization of surveillance data for EPI.

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Chapter 9:
The Role of Behavior Change

**"Knowing is not enough, we must apply,
Willing is not enough, we must do."**

– Goethe

As described in Chapter 3, immunization services are less likely to be used by people who are:

- Uninformed
- Dissatisfied
- Too busy
- Poor and powerless
- Misinformed
- Distant

Other chapters discuss health system actions that can address these problems, such as shifting session schedules and ensuring that vaccines are available when clients seek them. This chapter describes how to take a comprehensive approach to behavior change in order to improve the delivery of immunization services and encourage their appropriate use.

In country after country, studies have shown that most people will use immunization services as long as they to know when and where to bring their children, and those services are available, accessible, reliable, and friendly. Thus, the role of communication activities in achieving these conditions is important but not sufficient. Dissemination of information, training, supervision, and other ways of improving services need to be employed in a mutually supportive way to promote complete and timely immunization of women and children.

Achievement of immunization goals is affected by the behavior of many groups, including: politicians, community leaders, health care providers, managers and supervisors, women of reproductive age, parents, children, and their families. The focus of this chapter is on health care providers and caretakers.

Some of the desired behaviors for different groups that affect immunization services are listed on the following page. These behaviors are generally applicable but should be modified as needed to fit specific situations.

Desired Immunization-Related Behaviors

Mothers and Other Primary Caretakers

- Bring children to immunization service delivery points at the ages recommended in the national schedule.
- Bring each child's health or vaccination card to each health visit.
- Treat side effects as recommended.
- Seek tetanus toxoid immunizations for yourself. (This is applicable to mothers and other women of childbearing age.)
- For campaigns, bring children of the recommended ages to immunization sites on the day(s) recommended. For a house-to-house strategy, keep those children around the home and have them immunized when the team arrives.

Fathers

- Bring children to immunization service delivery points yourself, or encourage their mother to do so.
- Provide mothers with money for transport or other expenses related to immunizing children.

Health Workers

- Perform immunization tasks correctly, including those that ensure safe injections.
- Give mothers and other caretakers essential information.
- Schedule and organize services to make them convenient for parents.
- Praise families whose children are fully immunized by one year of age.

Political and Public Health Leaders

- Allocate sufficient financial and human resources for immunization services.
- Show personal support for immunization services.

Community Leaders

- Describe the benefits and safety of vaccinations to others in the community.
- Remind families when children need to receive the next dose(s) of vaccine.
- Encourage families to complete each child's basic immunizations in his or her first year of life.
- Inform families about outreach services, supplemental immunization activities, and new vaccines and improvements in the immunization program.
- Assist health facility staff in planning and monitoring services.
- Provide logistical support, e.g., by transporting vaccines, supplies, and staff.

Source: WHO, UNICEF, and USAID, 2002

Identifying Barriers to Desired Behaviors

Indications that various groups are not carrying out the desired behaviors can be found in low immunization coverage data, high drop-out rates, and increased disease incidence. In light of such indications, program staff should undertake additional information gathering to understand the causes of these problems and, in behavioral terms, the gaps between desired and actual performance.

Qualitative methods, such as focus group discussions and in-depth interviews, can be used to discover reasons why people act as they do. The methods selected depend on the nature of the questions to be answered and the type of respondents. For example, parents and community leaders may reveal information and beliefs in focus group discussions that they would not share in one-on-one interviews. In-depth individual interviews, on the other hand, work better with health workers, whose worry about giving "wrong answers" regarding knowledge and practices may keep them silent in front of their peers.

Focus group discussions are in-depth discussions, usually lasting one to two hours, in which six to ten representatives of a target audience talk about their experiences, attitudes, perceptions and feelings regarding a focused topic under the guidance of a facilitator. Participants are purposefully selected, for example, because they are mothers of fully immunized children or fathers of drop-outs.

Credit: Ann Jimerson

Focus group participants exchange views on health-related topics.

In-depth interviews are one-on-one conversations between an interviewer and a respondent, held in a private, confidential setting. In effective interviews, respondents will offer insights into their practices, thoughts, feelings, and beliefs.

Quantitative methods, such as knowledge, attitude, and practice (KAP) surveys, are helpful in prioritizing causes and calculating the scope of problems identified through qualitative methods. Quantitative data may be useful for convincing decision-makers of the need to take action. They also provide a baseline for evaluating results.

What Mothers Say about Vaccination

In focus group discussions, mothers in an African country expressed their perceptions and experiences:

1. Mothers' knowledge of immunization is poor. More than half could not name one vaccine-preventable disease. However, regardless of their level of knowledge or the vaccination status of their children, mothers universally embrace the importance of vaccination for children's health.
2. Side effects concern some mothers, but many accept the fevers and swelling as normal results of vaccinating. Some even suggest that these side effects are desired as proof that the vaccination is working.
3. The major reason children are not vaccinated is the distance to the place of vaccination. Another barrier is competing demands on mothers' time from other children and fieldwork.
4. Mothers are frustrated by inconsistencies in service provision. "We lose our motivation to go to the hospital because when we arrive there are often no medicines."
5. In some districts, scheduled vaccination by outreach is unreliable and of poor quality.
6. Mothers value and protect their child's health card like an identity card, and report that a health worker won't treat a child without it.
7. Mothers have varying views on how they are treated by health workers, ranging from "They're marvelous" to "There are some that vaccinate as though they are vaccinating a dog."
8. Health education talks are the only form of education on immunization.
9. Focus group mothers considered mothers who don't have their children vaccinated as "stupid," "criminals," or "witches."
10. Mothers generally have confidence in the technical ability of health workers–although the mothers do not feel informed enough to judge.
11. Illicit charging for services is not reported to be a big problem.

Such findings, once combined with results from other interviews and observations, will provide the basis for program actions.

While some of these findings are typical for many countries, others are not. For example, distance to health facilities is a major barrier to coverage in this particular country because the government is still rebuilding health infrastructure after years of war. Because of the variety of program circumstances in different countries, in-depth, but not necessarily large-scale, research is recommended in countries or districts that are trying to improve their coverage or reduce drop-outs.

Using a combination of methods and exploring the same topic with different groups may provide the most complete insights. For example, in one setting, health workers conducted exit interviews to measure client satisfaction after an immunization session, and the mothers interviewed reported no problems. Later, focus group discussions conducted by independent consultants showed that these same mothers had serious problems with the way they were treated by health workers. In separate interviews, the health workers themselves explained that they treated parents firmly and sometimes even harshly because they wanted parents to understand how important immunizations were. It took the presentation of findings from focus group discussions with mothers to make health workers realize that such harsh behavior, though well-intentioned, was driving the mothers away.


Credit: Kelley Sams, BASICS II

Exit interviews help health workers to understand parents' concerns.

To avoid compromising the candor of responses, it is recommended that health workers not serve as interviewers or group facilitators. If a program does decide to use health workers in these roles, they should not do research in the geographical area where they normally work.

Behavioral Analysis

To identify the barriers that seem to discourage a desired behavior and the factors that support and motivate it, a strength-weakness-opportunity-threat (SWOT) type of analysis can be carried out. In the hypothetical example in the three boxes on the next page, planners are investigating the reasons for a high immunization drop-out rate in a particular district. To help in the analysis, they record current and desired behaviors and the barriers and motivating factors they have found in their research. They look at three different groups of people who may be involved in the problem and who definitely should be involved in the solution: health workers, parents, and community leaders. Other groups might be included in another situation.

Examples of Behavioral Analyses				
	Current Behavior	**Desired Behavior**	**Barriers**	**Motivating Factors**
Health Workers	Few health workers (HWs) give information to parents about the need to return with their children for the next dose(s) and when. Few listen to parents' concerns or check for understanding.	All HWs always provide parents with this information and check for understanding	HWs don't perceive the importance of informing parents when to return for the next immunization. HWs believe that someone else in the health facility is giving the information or that the information on vaccination cards is adequate. They feel they don't have time.	HWs get positive feedback from clients when they communicate well. When communication improves, HWs see an impact in reduced drop-out rates.
Parents	One-third of parents do not bring their children back on time for subsequent doses.	All parents get their children immunized at appropriate ages and intervals, so that they are fully immunized before their one-year birthday.	Parents do not understand the importance of their children completing the primary series of vaccinations on time. They do not know when to return for the next immunization. They feel intimidated by HWs. They don't expect to receive information, to understand it, or to get a response to their questions, and so they don't ask. Many families have other priorities, so delay returning. Many families live far away from the health facility, or outreach services have been discontinued. Facility operations are poorly managed, e.g., sometimes children who come to a scheduled session cannot get vaccinated because there is no vaccine.	Parents realize that vaccines prevent some dangerous diseases. They want to protect their young children from disease. They want to do the right thing, i.e., make their children safe from vaccine-preventable diseases.
Community Leaders	Community leaders are not engaged in ensuring that children receive vaccinations on time and that they are fully immunized before the age of one year.	Leaders participate actively in getting resources for outreach. Leaders work with HWs to schedule sessions at convenient times.	Leaders believe that the health system alone is responsible for making sure that children are immunized. They do not realize that they can actually do something to help. They are contending with other social, economic, and health problems.	Child health is a priority for communities. Community leaders like to solve problems that affect members of their community. Community leaders have some control over local fund allocations. Once they are actively involved, community leaders may well see an impact on reduced drop-out rates.

Behavior Change Strategies

The research and analysis described above should give planners a good picture of feasible behaviors, barriers that must be overcome, and positive knowlege, perceptions, and circumstances. They can then devise appropriate program actions to promote and facilitate those behaviors. Such actions often include communication, training, service improvement, policy, and other activities.


Credit: Kelley Sams, BASICS II

Community members plan how to mobilize mothers and children for immunization.

Communication Strategies

Communication specialists differentiate among various types of communication depending on the purpose of the communication and the target audience they are trying to reach. Although different researchers and organizations do not always share the same terms to describe the same concepts, some widely accepted definitions are found in the box.

Types of Communication

Communication can raise awareness, increase knowledge and motivation, and facilitate people's actions. Communication activities include behavior change communication, social mobilization, and advocacy.

Behavior change (or program) communication encourages actions among target populations that directly support more effective immunization coverage and disease control; for example, providing information, motivation, and job aids so that health workers will treat parents with respect, give information clearly, and encourage parents to bring children for vaccinations as soon as they are due.

Social mobilization aims at gaining and maintaining the involvement of a broad range of groups and sectors; for example, by holding a series of meetings with representatives of private companies, other government agencies, and NGOs to discuss how they can support polio eradication as well as routine immunization. Social mobilization also includes mobilizing the public to participate in immunization activities.

Advocacy focuses on gaining and maintaining the support of political leaders, opinion leaders, and other decision-makers; for example, by making presentations and producing an information packet that describes the burden of hepatitis B disease and how this audience can support efforts to reduce it.

Adapted from UNICEF and WHO, 2000

Communication Channels

Immunization programs use numerous communication channels to reach parents and other target audiences, from radio and television, to folk media, to community events, to counseling at health facilities. Too often, decisions about what channels to use are based on the beliefs and personal preferences of people who think they know the target audience well but in fact do not. If the decision is not based on good evidence on how to reach the audience (obtained from evaluations and/or formative research), the choice of communication channels may well be inappropriate.


Credit: Kelley Sams, BASICS II

Communication experts have found that the best channels for reaching rural people are health workers, local leaders and groups, and, in some cases, radio. It is generally not very effective to use print materials with low-literacy populations or mass media for those with little access to television and other mass media. Generally, parents perceive health workers as a credible source of information about health. Growth promotion and IMCI (Integrated Management of Childhood Illness) contacts provide excellent opportunities for health workers to assess a child's immunization status and then to give needed vaccinations or advise caretakers how to get the vaccinations as soon as possible.

Disscussions between health workers and small groups of parents can be held as part of immunization sessions and on other occasions in and outside of a health facility to:

- Address people's doubts about immunizations
- Identify and fill information gaps and correct misinformation
- Respond to questions
- Reinforce positive attitudes and behaviors

One-on-one counseling is the best way to give parents information on when and where to bring their child for the next vaccination. However, simply giving people information is not enough; the message must be understood and remembered, as shown in the box.

It Was Said, but Was it Understood?

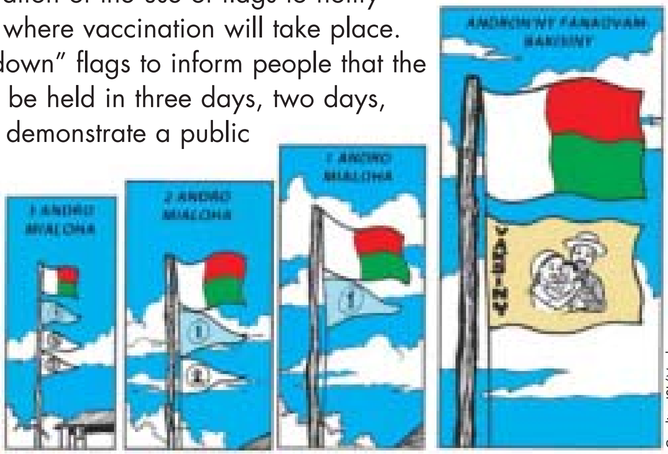
In a study conducted in the Northwest Frontier Province, Pakistan, health workers were observed telling 85% of the mothers when to bring their children for the next vaccination. Exit interviews held later the same morning with these mothers indicated that only 8% remembered when they were supposed to return!

Source: PRICOR, 1990

Mass communication media can complement the basic channel of interpersonal communication, but it is not a substitute for it and is inadequate by itself. In Mozambique, the national immunization program staff developed the following materials to support both interpersonal communication and mass media when they introduced Hep B vaccine into their routine program.

Materials for Introducing Hep B Vaccine		
Materials	**Intended Use**	**Main Messages**
Booklet for health workers	A reference for health workers to describe their responsibilities and help them respond to parents' questions	What health workers have to do to introduce Hep B vaccine Basic facts about hepatitis B disease and vaccine
Booklet for community leaders	A reference for community, religious, and social leaders to help them plan support activities and respond to the public's questions	What leaders can do to provide support Basic facts about hepatitis B disease and vaccine
Posters	To raise public awareness and provide information about the immunization schedule	Childhood vaccines offered by the national immunization program, including the new vaccine Ages at which children should get vaccines The importance of immunization for child health
Radio and television spots	To raise awareness among the public, local and national leaders, and health staff	Increased protection to the public through new vaccine and auto-disable syringes No additional visits and injections needed to benefit from the new vaccine Reinforce that caretakers should bring their children to receive all basic childhood immunizations

On the right is an illustration of the use of flags to notify communities when and where vaccination will take place. Note the use of "countdown" flags to inform people that the vaccination session will be held in three days, two days, and one day. The flags demonstrate a public commitment by health workers that the session will take place, that they will provide community members with advance notice, and that they will announce the session's start.


Credit: JSI/Madagascar

Flags indicating countdown to vaccination session.

Content. The content of the communication is as important as the channel. There is ample evidence that shows that because most parents already know that immunizations prevent some dangerous diseases, they do not need further convincing nor hear clinical details. The most essential information they need is when and where they should bring their child for his or her next immunization, what common side effects they might expect, and what they should do if these do occur. In addition, if any rumors or common misconceptions regarding immunization are detected, they should be corrected (see Chapter 8).

Advocacy and social mobilization. Advocacy and social mobilization techniques can be used to inform political leaders, community members, and partners about upcoming events and activities and increase their participation in them. Health workers at all levels should talk with leaders and other influential people individually, hold joint planning meetings and provide informational materials. The communication techniques discussed above can also be used to mobilize the community. Historically, social mobilization has been used more frequently to build support for campaigns than for routine immunization, but it is needed for both.

Training to Improve Knowledge and Skills

How can health workers and managers learn and improve communication skills, including promoting behavior change on the part of parents? Training, reinforced by supervision and reporting requirements, can increase health workers' knowledge and improve technical and communication skills. Where there are educational, cultural, and economic differences that prevent effective communication between health workers and community members, health workers may require special training to recognize and overcome these barriers. Although training can help, changes may also be needed in the organization and patient flow during vaccination sessions, as indicated in the sample behavioral analyses on page 156.

Credit: Kelley Sams, BASICS II

Knowledge. Like members of the public, health workers themselves sometimes have misconceptions about immunization. For example, some believe that giving a child antibiotics on the same day as a vaccination will destroy the vaccine's effectiveness. Some start the vaccination series all over again if a child comes late for a dose. Some fail to provide vaccinations because of false contraindications. These health workers need technical information, which is best acquired in a setting similar to their work environment.

Health workers also need information on key immunization messages, which they can find in manuals from their country program or from international sources. Reading is not enough, however; people need to use knowledge in order to retain it. Health workers also need to be confident that the health system in which they work (e.g., supervisors, vaccine supply) will support their putting correct knowledge into practice.

Technical Skills. With growing awareness of the fact that HIV/AIDS, hepatitis B, and hepatitis C can be acquired through unsafe injections, clients and parents are beginning to watch how health workers handle needles and syringes, and what they see can inspire confidence or fear. Health workers can build confidence among clients and parents by mastering skills in reconstituting and administering vaccines. They also need skills in such areas as forecasting vaccine and other supply needs, organizing fixed and outreach sessions, and handling waste. These skills are best learned from people who do them well and should be reinforced through practice.

Communication Skills. Effective communication begins when a health worker starts thinking about what keeps people from coming to a health facility and/or what prevents them from returning. As noted above, people may not get the information they need or may have unpleasant experiences with health workers. To overcome such communication problems, health workers need skills in listening, questioning, giving instructions, and confirming that they are understood. These skills are best learned by observing good models of communication and practicing using role plays and simulations.

Credit: Kelley Sams, BASICS II

As part of training, health workers use role play to practice their counseling skills.

Supervision and Other Strategies to Support Positive Behavior

For people to continue acting in positive ways, they need to feel that what they are doing is having a desired outcome and few, if any, negative consequences. For example, if health workers discard vaccine vials because the

Dissemination – A Critical Step

Dissemination is important! Unfortunately, after devoting substantial time and money to develop guidelines, tools, and other print or electronic documents, too many people and organizations then disseminate them in ways and formats that either do not reach or are not convenient for the intended audience to use. The materials often end up warehoused at some intermediate point. A few general guidelines for more effective dissemination are the following:

Design a dissemination plan that specifies:

- who is supposed to use and therefore receive the materials
- in what quantity end users need them
- by what means they will be sent to the intended users
- who is responsible for sending them
- the budget needed to do so.

Additionally,

- Use those channels that are most convenient for the audience, not those most easily used by the sender.
- Ask audience members what channels and formats are easiest for them to use.
- When feasible, make resources available in more than one format (e.g., print and electronic) and via multiple distribution channels.
- Do not rely on electronic formats alone for dissemination.
- Do not depend on colleagues to take on the dissemination burden; no matter how well intentioned, they are likely to be too busy to make this a priority.
- Monitor dissemination – that the material is reaching the intended people and that they feel it is appropriate and useful for them.

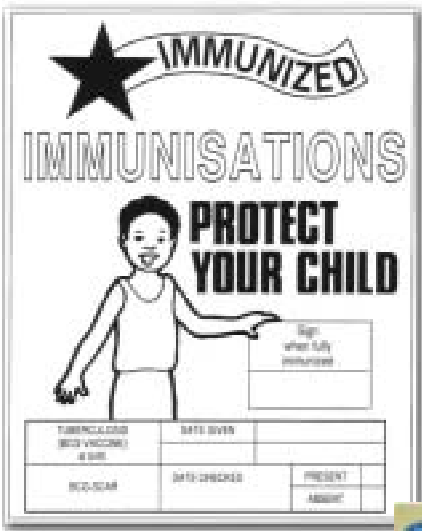
VVMs have changed color, they should be confident that they will not be punished for it, but rather recognized for taking the correct action. If they immunize a slightly ill child according to national policy, they should know that national immunization policies and their own supervisors will support them.

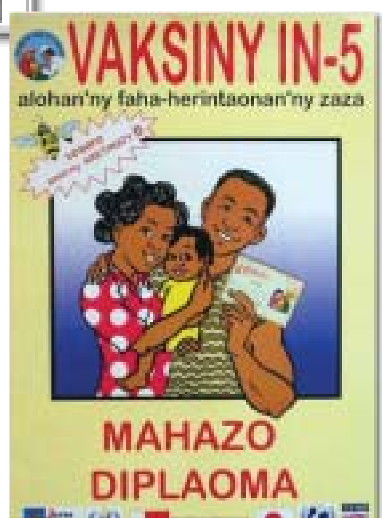
Supervision. Supervision plays a major role in supporting positive health worker performance. Supervisors can monitor performance and identify both successes and problems and then help plan corrections. They can help health workers monitor the impact of their activities.

Credit: Kelley Sams, BASICS II

Supervisors also can make sure that system supports are in place. They should provide feedback to health workers, coach them, model positive behavior, and include interpersonal communication skills in performance evaluations.

Recognition. Parents and health workers alike feel motivated when others notice and praise good performance. Some countries formally recognize a fully immunized child by using a rubber stamp to mark a seal of completion on the child's vaccination card or giving a diploma, as shown in the examples from Kenya and Madagascar.





System Support. Changes in individual behavior do not result in improved services and higher coverage without complementary actions in other parts of the health system. For example, managers must make sure that vaccines, injection equipment, and other supplies are available to meet increased demand created by social mobilization and health promotion activities. The table shows how communication activities and other interventions might interact to solve the drop-out problem discussed in earlier examples.

Comprehensive Approach to Reduce Drop-Outs

Communication	Advocacy	Social Mobilization	Training	System Support
HWs learn how to give clear information to parents on when to bring their children back for the next dose(s). Supervisors provide job aids to remind HWs of the key messages. Parents learn how to use vaccination cards as reminders about next dose(s). District Health Management Team (DHMT) and HWs explain at every opportunity the importance of completing the immunization schedule. HWs and communities publicly recognize families whose children are fully immunized by their first birthday.	DHMT persuades local politicians to publicly state the importance of completing the immunization schedule by the first birthday. DHMT persuades local politicians to provide financial support for outreach visits.	HWs organize women's groups to visit families that have dropped out of the immunization program. HWs routinely review progress toward targets with community leaders.	DHMT arranges for training to improve HW communication skills, knowledge, and behavior toward families. If language is a barrier, HWs find and train community volunteers to help HWs communicate with families.	HWs organize facility operations to enable them to spend more time with each client. DHMT and management at higher levels plan and implement timely deliveries of vaccines and supplies. Budget planners include transport and per diems for outreach in budget. Supervisors monitor and reward good HW communication. HWs and their own supervisors use data to guide appropriate actions.

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Full page photo credit: David Cantor, ORC Macro

Chapter 10:
Costs and Financing

"We know in our hearts that we are in the world for keeps, yet we are still tackling 20-year problems with five-year plans staffed by two-year personnel working with one-year appropriations. It's simply not good enough."

– Harlan Cleveland

As an investment in health, immunization is widely regarded as a "best buy." Immunization not only protects individuals and populations at low cost, but also provides a platform for delivering other health interventions, such as vitamin A. As described in the World Bank's World Development Report 1993, "In most developing countries…an 'EPI Plus' cluster of interventions in the first year of life would have the highest cost-effectiveness of any health measure available in the world today."

As one of the most effective and affordable ways to control infectious diseases, immunization should be a financial priority for national governments and donor agencies. If the financial commitment to immunization services was reduced, the subsequent increase in morbidity and mortality would have serious social and economic consequences. Therefore, immunization clearly requires a sustained commitment even though the incidence of vaccine-preventable diseases has been significantly reduced.

Ultimately, the primary responsibility for ensuring sufficient financing for immunization services rests with governments of developing countries. Since national governments alone may not be able to provide all of the required funding, it is a shared responsibility of the central government, district governments, and communities to identify and mobilize the necessary resources to sustain safe and effective immunization services.

Since infectious diseases do not honor national borders, and the full protection of any child depends on the protection of all children, donor organizations should share the burden of making services available and introducing new vaccines. This shared obligation to immunize all the world's children is embodied in the GAVI definition for sustainable financing (GAVI, 2001):

> "Although self-sufficiency is the ultimate goal, in the nearer term sustainable financing is the ability of a country to mobilize and efficiently use domestic and supplementary external resources on a reliable basis to achieve current and future target levels of immunization performance in terms of access, utilization, quality, safety and equity."

The challenge of sustaining the resources for immunization is a task that falls on many groups. National policy makers need to prioritize immunization services so that they compete successfully with other health services, donors need to provide support in ways that eliminate funding uncertainties and avoid dependencies, and program managers need to take advantage of service delivery efficiencies to minimize costs. All of these partners should assess needs, calculate costs, monitor expenditures, arrange financing, and make efficient use of resources without losing sight of the immunization program goal to minimize the impact of vaccine-preventable diseases.

What Does It Cost to Provide Vaccination Services?

Given frequent changes in the cost of new vaccines, new technologies, service delivery strategies, labor, and the variation among countries, it is difficult to state the actual cost of vaccination in absolute terms. However, it is useful to examine some of the elements that go into the cost of immunizing a child. Cost estimates, or budgets, usually include two categories: capital costs, which last one year or more, and recurrent costs, which cover items that are consumed in a year or less or services that are provided and paid for regularly. Some examples of the types of costs included in these two categories are:

CAPITAL COSTS	RECURRENT COSTS
• Building space • Vehicles • Equipment: refrigerators, cold boxes, vaccine carriers, steam sterilizers, incinerators • Long-term training (pre-service)	• Vaccines • Building operation and maintenance • Transportation: vehicle operation and maintenance, fuel, freight charges, fares for public transport, per diems • Supplies: needles and syringes, ice packs, safety boxes, fuel for refrigerators, reporting forms • Personnel • In-service training • Materials for training, health promotion, social mobilization • Contracts with commercial or nonprofit organizations for training, social mobilization, fleet management

The table on the next page shows routine immunization expenditures in Morocco, Bangladesh, and Côte d'Ivoire. This cost analysis indicates several common trends across the three countries:

- Personnel costs are over one-half of the budget.
- Vaccine costs account for the next highest share of the budget. Note that these costs are for the six traditional antigens only.
- Injection safety and social mobilization costs may be under-represented.

Estimated Costs of Immunization Services in Three Countries			
	Morocco (1997 - 1998)	Bangladesh (1997 - 1998)	Côte d'Ivoire (1998)
Number of surviving infants (1998)	735,000	3,852,000	513,000
Annual Costs of Immunization Services (percent of total budget)			
Recurrent costs			
Personnel	62	56	65
Vaccines	17	27	16
Supplies	1	3	4
Transportation	<1	1	2
Short-term training	<1	<1	<1
Social mobilization	<1	<1	<1
Maintenance/overhead	2	1	2
Subtotal	83	89	90
Capital costs			
Building	12%	6%	7%
Vehicles	<1	<1	<1
Equipment	4	4	2
Long-term training	<1	<1	NA
Subtotal	17	11	10
Total Annual Costs	**US$7,648,166**	**US$28,948,889**	**US$7,876,941**
Percent of children fully immunized (FIC)	83%	54%	65%
Cost per FIC	US$20.89	US$21.47	US$24.29

NA = not available *Adapted from Kaddar, Levin, Dougherty, and Maceira*

These data provide historical information on the actual, but not necessarily optimal, levels of expenditures. The ideal level of funding needed for each line item should be determined by monitoring program performance and allocating sufficient funding to ensure that immunization targets are being met.

What Costs Need to Be Included in an Immunization Budget?

To develop a comprehensive immunization budget, managers need to calculate the full cost of all program elements that make up a specific immunization service activity, even those that may not be obvious. Some common program elements that should be budgeted include the following:

- Vaccine
- Cold chain
- Needles, syringes, safety boxes, waste management
- Disease surveillance
- Supervision
- Training
- Management information systems
- Social mobilization, communications, and advocacy

Each of these elements has several cost components that should be included when preparing a budget. For example, a budget for vaccine procurement should include not only the cost of vaccines, but also freight, insurance, and customs clearance. Program areas such as cold chain, disease surveillance, and training require expenditures for transportation, supplies, materials, and per diems. In addition to such recurrent costs, managers should remember to include costs for conducting special studies (such as EPI reviews or injection safety studies) and developing, producing, and disseminating materials (such as training materials or cold chain manuals).

The following table illustrates the types of expenses that need to be considered in just one program function.

Credit: WHO

Posters for national polio immunization days on a boat for reaching distant populations.

Itemized List of Cost Components for Social Mobilization/Communication/Advocacy

Program Function	Possible Costs to Budget
Audience research	Staff time Consultants and/or subcontracts Per diem, lodging, and travel expenses Fuel Supplies (e.g., paper, renting or purchasing computers and other equipment)
Strategy formulation	Staff time Consultants Per diem, lodging, and travel expenses Meeting room rent Supplies (e.g., paper, renting or purchasing computers and other equipment)
Development of print materials (for all audiences)	Staff time and consultant time (e.g., for writing, drawing, photography, design, word processing) Dissemination costs (postage, fuel, staff time)
Development and airing of broadcast materials	Staff time and consultant time (managerial, creative, and technical input) Cost of subcontract to advertising firm Air time
Development of local communication channels (e.g., drama groups, mosque announcements, miking, etc.)	Staff time and consultant time (managerial, creative, and technical input) Cost of subcontract and/or of ongoing expenses (per diem, travel, etc.) Equipment purchase or rental
Pre-testing of materials	Staff and consultant time and expenses (per diem, lodging, travel) and/or subcontract Supplies (e.g., paper, video equipment, tape recorders)
Production of materials	Printing Audio and video recording and production
Training in communication, social mobilization, or advocacy	Staff and consultant time and/or subcontract for planning, implementing, and evaluation Training of health staff, local leaders, journalists, etc. Per diem and expenses of participants Training room rent
Monitoring and evaluation (routine monitoring and special studies) of communication or social mobilization efforts	Staff and consultant time (e.g., for planning, implementing, data processing) Per diem, lodging, and travel expenses Fuel

Commonly Overlooked Costs

It is important to make sure that all necessary costs have been included, because when a cost is overlooked, additional resources must be found to avoid compromising safety, quality, or the services themselves.

For example, one country's immunization program, which planned to utilize volunteers for social mobilization activities, budgeted for the bulk purchase of bicycles so as to provide one bicycle per volunteer. However, the manufacturer delivered the bicycles unassembled. Local bicycle "repairmen" had to be hired to properly assemble the bicycles, which added significant, unforeseen expenses. This required diverting funds away from other program areas.

Credit: WHO

Budgets should include the cost of vehicle repair and replacement.

The box below notes costs that are commonly overlooked in the development of immunization budgets. To avoid overlooking necessary costs, partners supporting immunization in a given country should jointly develop common immunization plans that cover all aspects of the program, including equipment and supplies. This approach helps to ensure the compatibility of spare parts, identify long-term repair and maintenance needs, and simplify training plans for personnel who use the equipment and supplies.

Commonly Overlooked and Under-Budgeted Items

The following items tend to be overlooked in budgeting for immunization services.

- Spare parts, tools, fuel for equipment, and labor costs for repair and maintenance
- Waste disposal
- Per diem and travel expenses for outreach, surveillance, and supervision
- Public announcements and other communications for routine immunization
- Replacing capital equipment, such as vehicles and refrigerators

It has been estimated that recurrent costs account for approximately 70% of the lifetime cost of a piece of equipment! A simple donation of a piece of equipment can generate an expensive legacy for the recipient.

Costs in Transition: Vaccine and Waste Management

Vaccines. One budget line item that needs special attention is vaccine. Dramatic changes are taking place in the vaccine industry:

- Fewer manufacturers are producing new vaccines.
- Manufacturers are developing new vaccines and new combinations of vaccines.
- Periodic shortages, even of traditional vaccines, may emerge.

Each of these changes will be felt in the price and availability of vaccine. While the dynamic vaccine market presents a significant opportunity to improve the public health impact of immunization, it also underscores the need for careful financial planning to ensure a steady supply of the necessary vaccines. Country program managers need to be aware of these changes in the global market and work closely with national financial planners to ensure that the resources are available to meet all vaccine requirements.

Example of the Impact of New Vaccines on Vaccine Costs

One African country decided to introduce pentavalent DTP-Hep B+Hib vaccine into its routine schedule. This decision raised the total annual cost of vaccines for the country from just under $1 million to about $8 million. The line item for vaccines jumped from 26% to 60% of the total immunization budget.

An important challenge is to ensure that this sudden increase in the vaccine line item does not displace other budget line items. If vaccines are paid for at the cost of cold chain replacement or fuel for outreach services, the impact of the new vaccines can be devastating to the overall program. New vaccine costs must be met with new resources.

Waste Management. As the field of immunization evolves, some programmatic areas increase in importance, resulting in funding needs that had not previously been fully recognized. One such area is that of waste management for contaminated needles and syringes. Increased efforts to reduce the spread of HIV/AIDS, hepatitis B, and other blood-borne pathogens have led to more attention to the area of injection safety, including waste management. Because there is no standard approach for waste management and practical solutions to the problem are still being sought, there is no standard unit cost to include in budgets. Nevertheless, managers should prepare plans and budgets that address waste management to the extent possible, basing budget estimates on local circumstances and the best information available.

How Can Different Service Delivery Strategies Affect Cost?

A variety of service delivery strategies are needed to reach different segments of the population. Some strategies that are less costly may be more appropriate and effective for reaching some groups, while other, more costly strategies are required to provide services to dispersed, or otherwise hard-to-reach groups. At first glance, the less costly strategies may seem to represent more efficient use of resources; however, efficiency includes the dimensions of both cost and effectiveness. If providing services at a low cost does not achieve the desired programmatic goal, then it is neither efficient nor cost-effective. Thus, it may be necessary to spend more money in order to achieve the desired target for the hard-to-reach segments of the population. The following example from one African country demonstrates this concept.

Location and Tactics Affect the Cost and Effectiveness of Immunization

Catchment Area 1: High Cost	Catchment Area 2: Low Cost
Key characteristics of the area Scattered population Cost of transport high	**Key characteristics of the area** Densely settled population Cost of transport low
Team organization and tactics The team was large. It provided services at many posts that were far apart. It returned to headquarters several times every month for re-supply. It identified eligible clients, traced clients who did not use the services, and followed up on drop-outs.	**Team organization and tactics** The team was small. It provided services at a few posts that were short distances apart. It returned to headquarters once a month for re-supply. Community members enumerated eligible clients for the team, traced clients who did not use the services, and followed up on drop-outs.

Adapted from Foster et al.,1998

Maximizing the use of immunization resources requires more than accurately assessing the comparative costs of line items, service delivery strategies, or activities. Planners also need to weigh the effectiveness of each strategy. What proportion of the target population will be reached? What is the likely impact of delivery strategies on other aspects of the health system and on various public health objectives?

Costs of Supplemental Immunization Activities

Budgets for special disease control initiatives and outbreak campaigns contain the same line items as budgets for routine vaccination, but the proportions and the overall size of the budgets are different. Costs for expanded outreach and door-to-door vaccination strategies are generally higher than for routine vaccination because of the need for more vaccines, personnel, transport, and per diem. Additionally, costs for social mobilization, communications, and media are usually higher so as to create broad awareness about the campaign.

Credit: WHO

How Can Resources Be Used Efficiently and Effectively?

A critical consideration in any planning and budgeting exercise is the effective and efficient use of funds. Efficiency implies a minimum of expense and waste for reaching the desired results. However, as described earlier, to reach their public health objectives of controlling disease, some immunization programs must spend more money per mother or child than other programs. Thus there should be a careful balance between efficiency and effectiveness, because systems that minimize expense to the detriment of effectiveness are not efficient. For example, if there is only one opportunity to immunize a child for a disease such as measles, but this means opening a multi-dose vial for only one child, the public health importance of immunizing the child should outweigh the cost inefficiency of opening a vial for only that child.

Efficiency in immunization programming can be achieved in many ways. Reducing waste is one important way, as is organizing services so that they achieve the desired impact with the minimum of cost. Efficiency can also be addressed through decentralizing decision making so as to allow for more timely and appropriate local response to problems. However, this may require investments to build the technical and managerial capacity of local and regional personnel. Many health care systems are organized inefficiently in that they depend heavily on centralized authority to initiate local action. Better organization of services can lead to significant savings in costs; for example, well-publicized and appropriately scheduled outreach sessions can reach large numbers of clients.

The flow of funds to where they are needed is an important aspect of efficiency. In order to ensure their effective use, resources need to move in a timely manner to the level in the health system where they are required. Bottlenecks in this flow seriously impair the efficiency of the program and can significantly reduce impact. ICCs may be able to play a useful role in identifying and taking steps to remove such bottlenecks.

Some other ways to increase the efficiency of available resources that are addressed in this book include:

- Reducing drop-outs (see Chapters 3, 4, and 9)
- Reducing missed opportunities (see Chapter 3)
- Including other interventions during outreach, for example, vitamin A supplementation (see Chapters 3 and 12)
- Scheduling sessions according to the needs of the target population (Chapter 3)
- Limiting vaccine wastage by protecting vaccines from freezing, using vaccine vial monitors, and implementing the policy on opened multi-dose vials (see Chapter 6)
- Designing activities such as disease surveillance and social mobilization so that they serve objectives in addition to the immediate intention, for example, social mobilization for polio campaigns should also inform mothers about other routine immunization services (see Chapters 8 and 9).

What Does It Cost to Reach New Targets?

Most ministries of health and immunization managers seek to improve vaccination services by increasing coverage, adding new vaccines, improving injection safety, reducing drop-outs, or strengthening disease surveillance. Each of these improvements carries with it costs that need to be reflected in immunization budgets, as detailed in the example on the next page.

Cost Implications of Increasing Vaccination Coverage by Expanding Outreach Services

Reaching new targets requires careful and detailed budgeting. Regardless of the new target or the strategy used to achieve that target, there are common steps to follow in order to budget for all components of the strategy. These steps are described below and illustrated by an example using hypothetical data for strengthening outreach services to increase coverage.

Step 1 What objective are you trying to achieve?

- Increase coverage

Step 2 How will the objective be achieved?

- Strengthen outreach

Step 3 What will be the strategy for strengthening outreach?

- Vaccinators will be provided with bicycles, equipment, and per diem to conduct outreach in under-served areas.

Step 4 What are the costs associated with this strategy?

- Transportation – bicycles, repair kits
- Transportation – maintenance, spare parts
- Per diem
- Vaccine carriers and ice packs
- Training
- Supervision

Step 5 What assumptions need to be considered in developing a budget for the strategy?

- Number of health facilities and outreach teams (500)
- New material needed for each health facility
    - 1 bicycle ($100)
    - 1 vaccine carrier and ice packs ($15)
    - 1 bicycle repair kit ($10)
- One day of training for health workers at the district office (50 districts x $200)
- Number of villages to be covered with outreach services (5,000)
- One outreach session per village per month
- Per diem ($1)
- On average 10 villages per health center
- Fuel for district supervision of health facilities (2 visits per year)
- Replacement of 10% of bicycles per year
- Maintenance of bicycles per year ($10 per bicycle)

Step 6 What factors need to be taken into account in order to develop a multi-year budget?

- Target population
- Population growth
- Coverage rate
- Inflation rate
- Vaccine costs
- Vaccine wastage rate
- Life expectancy of equipment (replacement)

Step 7 Calculate specific costs associated with outreach.

Calculation of fuel for supervision

	Year 1	Year 2	Year 3	Year 4	Year 5
Number of HC visits, each HC visited 2 times per year	1,000	1,000	1,000	1,000	1,000
Avg. distance from district HC	20	20	20	20	20
Avg. km/liter petrol	15	15	15	15	15
Cost of petrol/liter	1.10	1.21	1.33	1.46	1.61
Total cost of fuel for supervision	**1,467**	**1,613**	**1,775**	**1,952**	**2,147**

Calculation of total cost of per diem

	Year 1	Year 2	Year 3	Year 4	Year 5
Number of outreach sessions	60,000	60,000	60,000	60,000	60,000
Per diem	1.00	1.10	1.21	1.33	1.46
Total outreach per diem	**60,000**	**66,000**	**72,600**	**79,860**	**87,846**
Number of supervisory visits with per diem (20% of total)	200	200	200	200	200
Per diem	1.00	1.10	1.21	1.33	1.46
Total supervisors per diem	**200**	**220**	**242**	**266**	**292**
Total cost of per diem	**60,200**	**66,220**	**72,842**	**80,126**	**88,138**

Step 8 Prepare a multi-year budget based on the assumptions in steps 5 and 6, and the calculations in step 7.

Sample Five-Year Budget for Strengthening Outreach Services						
	Unit cost	Year 1	Year 2	Year 3	Year 4	Year 5
Capital costs						
Bicycles	100	50,000	0	0	0	0
Vaccine carriers and ice packs	15	7,500	0	0	0	0
Bicycle repair kits	10	5,000	0	0	0	0
Bicycle replacement	100	0	5,500	6,050	6,655	7,321
Recurrent costs						
Maintenance of bicycles	10	5,000	5,500	6,050	6,655	7,321
Training		10,000	0	0	0	0
Fuel for supervision		1,467	1,613	1,775	1,952	2,147
Total cost of per diem		60,200	66,220	72,842	80,126	88,138
Total		**139,167**	**78,833**	**86,717**	**95,388**	**104,927**

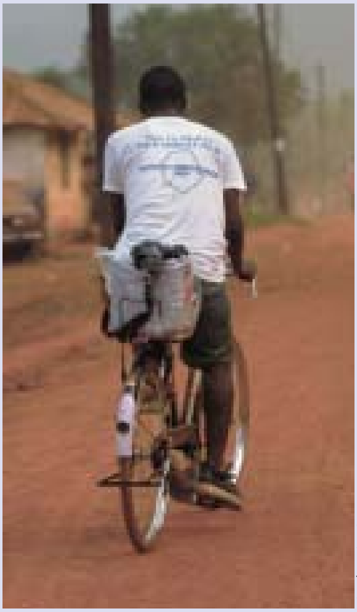
Kress, 2002

Cost Implications of Introducing a New Vaccine

With the introduction of new vaccines and new formulations, the most obvious line item to consider is that for vaccines: vaccine costs will increase dramatically in national immunization budgets.

Important, but less obvious, costs associated with new vaccine introduction include additional cold chain capacity, training of health workers in correct vaccine administration, and public education to inform parents about the added benefits of the new vaccine.

Immunization managers who plan for the expansion of the program need to work closely with financial planners who budget for the overall health sector costs. Poorly conceived and planned expansion will most likely fall short of goals and undermine confidence in the immunization program. The actual and full cost of any change to the immunization program must be carefully calculated and presented to decision-makers.



Credit: WHO

How Can Vaccination Services Be Financed?

It is important to identify adequate and sustainable sources of financing in order for immunization programs to be effective. Financing needs to be sufficient, provide for all appropriate vaccines, ensure that immunizations are delivered safely, and reach all the children in the country. Today's funding environment allows health sector officials to choose from a wide variety of options in selecting appropriate financing mechanisms for immunization.

In addition to these financing sources, there are mechanisms such as revolving funds, which do not necessarily provide funding but which allow countries to overcome obstacles such as the need for hard currency or advance payment for vaccines.

Some financing mechanisms, while appearing to be effective solutions to funding problems, may have unintended consequences that actually work to the detriment of the immunization program. One example is user fees.

User Fees

Many countries have experimented with charging user fees for immunization in a variety of circumstances with mixed results. Reviews of such experience have found that funds raised through user fees are not necessarily used for intended purposes, and in some settings, user fees were found to act as a disincentive to seeking immunization services. These findings have led the Board of GAVI to issue the following statement:

"The GAVI Board recommends that in the absence of compelling country or regional data unequivocally documenting their value, user fees should not be levied in publicly financed national immunization services."

Each type of financing has advantages and constraints that need to be carefully assessed with respect to the structure of the immunization program and its intended goals. Along with planning and management, financing is a critical determinant of whether programs reach their goals. Careful examination of each financing mechanism's characteristics is needed before selecting an appropriate strategy. It is recommended that a financing strategy be evaluated based on the following criteria:

Does the mechanism:

- Promote equity
- Achieve efficiency (cost effectiveness)
- Provide resources in an adequate, timely, and reliable manner

- Engender accountability
- Encourage maximum self-sufficiency

While each country is different in areas such as public health policy, regulatory structure, governance, macroeconomic context, and its relationship with external donors, this table provides some insight into how each mechanism would perform in light of these criteria.

Characteristics of Financing Options: A Summary					
Financing option or mechanism	Promotes equity	Achieves efficiency	Provides adequate, timely and reliable resources	Engenders accountability	Encourages self-sufficiency
Domestic public					
General revenues (central level)	+/– depends on tax structure	+ requires no additional resources to manage	– /+ allocation is often lower than program requirements; delays in accessing funds; potential exists for high levels of funding	+/– depends on quality of public administration	+
General revenues (sub-national)	– depends on tax structure; poorer sub-national units are disadvantaged	+ requires no additional resources to manage	– allocation is often lower than program requirements; delays in accessing funds	+/– depends on quality of public administration	+
Social health insurance (compulsory)	+/– depends on solidarity of system	– may have high administrative costs	+	+	+

+ generally positive effect

– generally negative effect

o no clear positive or negative effect; depends on country conditions

+/– both positive and negative effects

Characteristics of Financing Options: A Summary (cont'd.)					
Financing option or mechanism	Promotes equity	Achieves efficiency	Provides adequate, timely and reliable resources	Engenders accountability	Encourages self-sufficiency
External public					
Project grants	o	– requires additional resources to manage	+/– year-to-year allocations can vary greatly	+	–
Debt relief proceeds	+	+ requires no additional resources to manage	+	+/– depends on how procedures are established for tracking	+
Sector-wide approach (SWAps)	+	+	+	+	–
Budget support	o	+ requires few additional resources to manage	+	+	– /+ can contribute to better sectoral planning
GAVI/Vaccine Fund	o	+ requires few additional resources to manage	+	+ accountability based on program results	– /+
Mixed external and domestic public					
Development loans (no interest)	+/– depends on future tax structure	– requires additional resources to manage	+	+	+

Characteristics of Financing Options: A Summary (cont'd.)					
Financing option or mechanism	Promotes equity	Achieves efficiency	Provides adequate, timely and reliable resources	Engenders accountability	Encourages self-sufficiency
Domestic private					
User fees	–	– requires additional resources to manage	+ positive, though small contribution to volume of resources	–	–
Cross-subsidies	+/– depends on who pays the subsidies	– requires additional resources to manage	+ positive, though small contribution to volume of resources	–	+
Health insurance	–	– may have high administrative costs	+	o	+
Financial Instruments					
National trust funds e.g., endowments	o	– may have high administrative costs	+ steady availability of funding	+	+
Revolving funds	o	+ typically reduces management burden	+ access to foreign exchange on a reliable basis	+	+

Source: GAVI Financing Task Force, 2002

A recent addition to external public financing is the Vaccine Fund. Established in 1999 with a grant from the Bill and Melinda Gates Foundation and bolstered by subsequent contributions from many donor governments, the Vaccine Fund is the funding arm of the Global Alliance for Vaccines and Immunization (GAVI). GAVI encourages the strengthening of national immunization programs and increased coverage through many approaches, for example by advocating for financial commitment to immunization and providing support in the form of grants.

The Vaccine Fund

The Vaccine Fund, the financial arm of GAVI, was set up to strengthen basic immunization services and support the introduction of new and underused vaccines. The Vaccine Fund purchases vaccines (i.e., Hep B, Hib, and yellow fever) along with auto-disable syringes and safety boxes and provides financial support for immunization service strengthening. It does not pay for traditional vaccines for the routine immunization system, although it does pay for combination vaccines that contain DTP.

All countries with populations under 150 million and per capita GNP less than $1000 – over 70 countries – are eligible for support from the Vaccine Fund. Separate procedures have been negotiated to provide assistance to China, India, and Indonesia, whose populations exceed this guideline. Countries must meet four conditions to receive initial support:

1. The country must have a functioning Inter-agency Coordinating Committee (or an equivalent collaborative mechanism) that focuses on immunization to ensure local coordination and accountability.
2. The country must submit a recent assessment of immunization services.
3. The country must submit a coherent, multi-year plan for immunization.
4. The country must have an injection safety plan.

Other requirements for renewed funding include the provision of financial sustainability plans and evidence of responsible and effective use of funds.

Source: GAVI

Several other external financing mechanisms are getting increased attention. HIPC II (Highly Indebted Poor Countries II) is a debt relief program administered by the World Bank that was introduced in 1999 by the Group of Seven industrialized countries to support poverty reduction activities. In some HIPC II countries, resources no longer targeted for debt relief have been set aside for immunization services.

SWAps (Sector-Wide Approaches) are arrangements in which external donors pool their funds and direct them to the overall health budget rather than to specific programs. The recipient government works with the donors to set priorities and decide how the funds will be distributed. Many developing countries prefer this approach because it gives them decision-making authority for the use of the funds.

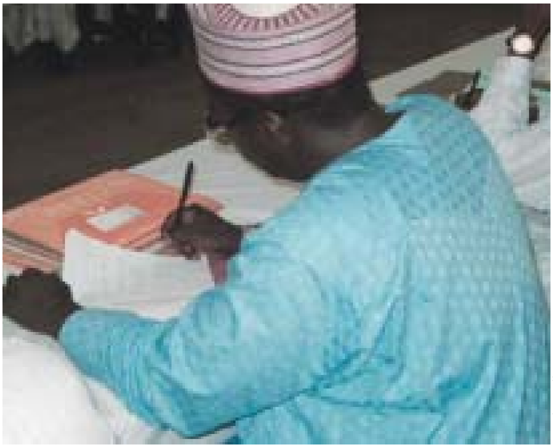
What Needs to Be Done to Obtain Funding?

The primary responsibility for identifying and mobilizing funding for vaccination services rests with the governments of developing countries. These governments need to take the leading role to secure a sustainable level of funding, from both domestic and external sources, to ensure the achievement of the country's immunization goals. Governments can consider several actions to promote sustainable financing.

These include:

- Develop a targeted program to reduce barriers to access through new delivery strategies, including involvement of the private sector, as appropriate.
- Promote allocation of resources on the basis of cost-effectiveness and public finance principles.
- Develop and implement a targeted program to reduce waste, with quantitative endpoints.
- Establish legal mandates for baseline funding of national immunization programs.
- Engage development partners in informed discussion of resource requirements, and seek structured commitments to fill in key funding gaps.
- Earmark funds and establish performance targets for sub-national entities.

A critical step that every country can take to mobilize resources for immunization is to develop a multi-year plan. This plan should be based on input from all partners. It should address operational deficiencies, define programmatic priorities (such as increasing coverage, introduction of new vaccines and reduction in drop-out rates), establish realistic targets, identify necessary inputs (such as technical assistance, training, and managerial tools), and present a clear budget that takes into account all capital and recurrent costs, including those overlooked costs mentioned earlier in this chapter. The plan needs to include a budget that takes into account all the costs associated with achieving new targets.



Credit: Kelley Sams, BASICS II

In conjunction with the multi-year plan, countries should develop a financial sustainability plan. This is a plan that assesses the financial issues that the country faces and defines a process for mobilizing the necessary resources needed to achieve the country's immunization objectives. As with the multi-year plan, the financial sustainability plan should be prepared in close coordination with partner organizations through the ICC.

GAVI notes that a good financial sustainability plan should:

- Serve as an advocacy tool
- Generate a clear picture of the financing situation and challenges
- Develop relevant, realistic, and specific strategies and actions supporting financial sustainability
- Identify process and outcome indicators to measure progress toward achieving financial sustainability

Financial planning should always take into account the financial needs at all levels of the health system. A plan that is fully funded for national-level activities is not necessarily fully funded at the operational level of the district. A financial plan should be built from the ground up, accounting for all costs required to meet program goals. All levels should provide technical review and feedback prior to finalization.

The role of the ICC is very important to this process (see pages 33-35). Ministry of health officials and donors need to be able to communicate openly and effectively with each other to ensure sustained support for the health sector and immunization specifically. Donors need to be active participants in this process and, when needed, draw on technical expertise to review plans and suggest possible approaches. MOH officials need to understand the funding cycles of donors and what constraints they are under in providing assistance. Many donors are on one-year funding cycles that make it difficult for them to give long-term commitments of support. An open dialogue between donors and MOH officials needs to be a priority for both sides in order to mobilize the resources needed to achieve the immunization goals.

Sustainability of Immunization Financing

A successful immunization program should reach every child in the first year of life, year after year. A sustained financial commitment is needed for immunization programs to succeed in preventing disease. Time-specific, short-term targets may help programs focus attention and funding. However, achievements also need to be sustained beyond the target dates. To do so, funding levels must be maintained. The level of required financial commitment increases as higher goals are set and new, more expensive vaccines are introduced into the schedule.

In the past, sustainability was equated with self-sufficiency. However, GAVI has moved the immunization community past that point toward a new concept of sustainability that embodies the following principles:

- It is a shared commitment and a shared responsibility of both governments and their development partners.

- It requires matching financing for expanding program objectives.
- It includes the concept of adequate and reliable financial resources, focusing not only on the quantity of funds but also on how well they reach the places where they are needed.
- It is related to both mobilization and efficient use of financial resources.

It is desirable, but difficult, to measure sustainability in a way that captures all the important determinants and outcomes. GAVI has worked with countries and international partners to develop and test a limited number of sustainability indicators that should allow both the detection of progress within a country and comparisons among countries.

Sustainability also has political, technical, and organizational dimensions. Immunization programs need to maintain a high level of political commitment to ensure that appropriate policies are adopted and that the allocation of resources is adequate to provide a complete range of services to all children. In addition, programs need to use the appropriate technologies and practices for the setting, they need proper training and supervision programs, and they need to be organizationally stable enough to provide services on a continual basis.

Achievable objectives and sound planning and management are essential if sustainability is to be achieved. Public demand can also contribute. Public demand for safe and effective services will help generate the political support needed to sustain immunization programs and provide the necessary level of funding. Every aspect of good program management is critical to the sustainability of immunization and the development of secure and stable funding.

Sustainability is a shared commitment among all those who support immunization as an effective and important tool in the control of childhood morbidity and mortality. Immunization has moved from being a local responsibility to a global responsibility: it therefore requires a sustained global commitment that will ensure that all children receive its benefits.

The Director of WHO, the Executive Director of UNICEF and the President of the World Bank noted that commitment when they stated:

> "Together we truly can deliver a 'global public good', a benefit for all, regardless of national borders, by making a concerted effort to use the tools that medically promise so much. Immunization remains one of the best investments in health that is within our grasp. We have a responsibility that we cannot ignore."
>
> *Source: WHO, 2002*

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Photo credit: WHO

Chapter 11:
New Vaccines and Technologies

"If you always do what you have done, you will always get what you have gotten."

– Anonymous proverb

New vaccines and technologies present both opportunities and challenges. Changing one aspect of a system has broad consequences, so anticipating the effects and preparing the system to accommodate them can mean the difference between a positive outcome and chaos. Before deciding to incorporate new vaccines into their immunization program, managers should assess the disease burden and competing public health priorities. They should estimate the cost of introducing and sustaining the new vaccine, identify funding sources, and analyze the impact on the health system as a whole. Once a change has been implemented, monitoring and evaluation are required to assess progress and identify any problems or unintended effects.

The introduction of new technologies should be treated with the same care. Before making a decision and subsequent plans, program managers should carefully consider the need for the technology, its likely benefits, its costs, the system changes needed to introduce and accommodate it, and how its use will be monitored.

If carefully managed, the introduction process provides an opportunity to affirm the importance of immunization, motivate health workers and members of the community, improve services, and ultimately serve broader health objectives.

Introducing New Vaccines

The process of introducing vaccines into a national immunization program is complex, as discussed in the following summary of key decisions to be made and factors that should be considered. Each of these factors is discussed in more detail in other parts of this guide.

Policies

A new vaccine or technology may require changes in national policies as well as guidelines to support the implementation of those policies. For example, the immunization schedule usually has to be amended and guidelines introduced on vaccine storage, injection techniques, reconstitution, and the use of open vials, among other matters. The revised policies should take into account both the epidemiology of the target disease and the feasibility of putting these policies into practice. For hepatitis B vaccination, for example, the local epidemiology should determine whether a birth dose is needed, but consideration is also needed as to how the birth dose will be delivered to newborns. A new or changed delivery strategy may itself require revisions in policies or guidelines if health personnel are to take on different responsibilities; for example, if traditional birth attendants are to administer the birth dose of Hep B vaccine.


Credit: WHO

A nurse in Malawi practices drawing up pentavalent vaccine into a syringe.

Service Delivery Strategies

In introducing new vaccines, every effort should be made to maintain the existing vaccination schedule in order to avoid creating additional visits that are not absolutely necessary. This approach helps minimize confusion and inconvenience for both caretakers and health workers. The creation of an optimal service delivery schedule for vaccination sessions is best determined at the district or sub-district level, taking into account the typical vaccination session size and the times and places that caretakers find most convenient. These factors can help reduce drop-out rates, contributing to full immunization and the efficient and effective use of all vaccines. For "traditional" as well as newer, more expensive vaccines, a balance must be struck between achieving low wastage rates and offering vaccination sessions frequently enough to avoid prolonged exposure to the disease-causing organisms.

Target Population

When a new vaccine or vaccine combination is added to the routine schedule, managers and epidemiologists must identify the age group to receive the vaccine (see Chapters 4 and 5). In the start-up year of a new children's vaccine, there are two cohorts to be considered:

- Children between 0 and 11 months of age at the beginning of the year.
- Children born during the start-up year (the birth cohort).

In principle, the decision about whether to include the two cohorts or only the birth cohort should be based on the age distribution of the disease, public expectations, availability of the new vaccine, practicality, and cost. In reality, however, funding restrictions are critical. For example, the Vaccine Fund supports the purchase of vaccines for the birth cohort only.

If the vaccine being introduced is a combination vaccine (e.g., DTP-Hep B), which includes a new vaccine (Hep B) and an old one (DTP), managers must decide what to do with children who have already been vaccinated with one or two doses of the old vaccine.

Using DTP-Hep B as an example, there are at least three options for phasing in the new vaccine:

- One alternative is to give the new combination vaccine and then stop as soon as a child has received a total of three doses of DTP. This means that some children will be only partially protected with Hep B vaccine.
- A second option is to continue giving the new combination vaccine until a child has received the full series of Hep B. This means that some children receive extra doses of DTP.
- A third option is to use monovalent Hep B for children who have already begun DTP and use the new combination vaccine for those who have not begun the DTP series. However, ordering, storing, and handling more than one formulation of vaccine introduces substantial logistical and other programmatic complexities.

Credit: WHO

Launch of pentavalent vaccine in Malawi, 2002.

Vaccine Supply

The availability of a vaccine may be limited during the first years after its introduction, as has been the case with new combination vaccines (see Chapter 5). The phasing out of an old vaccine and introduction of a new combination vaccine has to be timed carefully to avoid over- or under-stocking of

> **Are Stocks of Traditional Vaccines at Risk?**
>
> Historically, the availability of traditional EPI vaccines has been more than adequate to meet demand. In the last few years, however, ensuring the continuous supply of these vaccines has become a serious problem in developing and industrialized countries alike. Fewer manufacturers are producing vaccines, the supply has been reduced, and prices are increasing.
>
> With the introduction of new formulations and combinations of vaccines, the dynamics of vaccine supply are changing. Program managers and donors need to take this into account as they plan for and provide long-term support to immunization services. Although the benefit of these new vaccines is widely recognized, there are also concerns about maintaining consistent and dependable services to the public.

either vaccine. Immunization program managers and ICC members should develop contingency plans in the event that the anticipated vaccine formulations do not arrive in the required quantities at the specified time.

Cold Chain and Logistics

Immunization program managers must decide what vial sizes to order (see Chapters 5 and 6). For example, monovalent Hep B vaccine comes in one-, two-, six-, and 10-dose vial sizes. The most appropriate vial size should be based on the number of children at a typical immunization session, the cost of various presentations, storage requirements, and other operational factors.

Staff at all levels of the system (including the drivers who deliver the vaccines) may need new instructions about vaccine storage. These instructions should include the protection of both freeze-sensitive and heat-sensitive vaccines.

The addition of a vaccine to the immunization schedule may require increased quantities of syringes and needles. The need for such equipment must be estimated and delivery schedules planned to ensure continuous supplies. More space may be needed to store auto-disable syringes and needles and safety boxes. Vaccine arrival reports, stock control records, and requisition forms may have to be revised.

Disease Surveillance

Program managers and epidemiologists need to decide what should be reported about the "new" disease, who should report such information, and how often (see Chapter 8). Special training should be provided to enable health workers to recognize and discuss the symptoms of diseases that are not often seen or diseases that cannot be diagnosed on the basis of symptoms alone. For example, health workers need to know that jaundice is a symptom not only of hepatitis B but also of other forms of hepatitis and of yellow fever. Therefore, they should be aware that the only reliable way to detect hepatitis B infection is through serologic testing.

Communication

When a new vaccine is introduced, immunization programs should provide needed information to two main target audiences via appropriate channels. First, health workers need technical information on the disease and vaccine so that they can administer it correctly and can provide essential information to caretakers. On the other hand, parents or other caretakers need more concise information, including the name of the vaccine, its benefits (in brief), the vaccination schedule, and possible side effects. For the most part, health workers themselves are a primary source of information for parents, so it is especially important that health workers are adequately prepared to advise parents and address their concerns.

Hepatitis B: Inform but Don't Confuse

In introducing a new vaccine, immunization programs should provide essential information that the public needs to be able to make informed decisions. However, providing excessive technical information is not necessary and may even confuse people.

In the case of hepatitis B, the technical story is quite complicated. Often acquired early in life, the infection is usually asymptomatic in children, who may however, become carriers. In the 25% or so of carriers that do contract hepatitis B-related disease, this usually happens only decades later. Moreover, if publicity surrounding the introduction of Hep B vaccine discusses jaundice, cancers, and other symptoms associated with hepatitis, the public might expect the vaccine to prevent all such conditions.

Because of the difficulty of clearly explaining such complicated and subtle information, it is recommended that immunization programs provide only general information on the disease in public communication, while thoroughly preparing health workers to answer people's detailed questions.

Training

All of these changes mean that health workers, supervisors, and others need new information and, sometimes, new skills (see Chapter 9). Managers will need to identify who needs training, in what, for how long, and by whom. Job aids and supervisory skills should be developed or upgraded to reinforce the training.

Financing

Introduction of new vaccines requires additional funding. To help bridge the initial resource gap, in early 2002 the GAVI Board approved the allocation of a fixed amount of $100,000 to each country approved to receive support for introducing new and underused vaccines. These funds help pay for changes associated with their introduction. The national government, with the assistance of ICC partners, is expected to make additional resources available for ensuring the continuous use of the new vaccines.

Planning

A plan is needed to manage the introduction process. Planning should begin six to 12 months before the vaccine is to be introduced. The schedule shown on the following page, which was developed for the introduction of pentavalent vaccine (DTP-Hep B + Hib), illustrates the many steps and time needed. In this example, note that planning began more than six months before the vaccine was introduced.

Planning for the Introduction of Pentavalent Vaccine

Activity Area	2001		2002	
	Q3	Q4	Q1	Q2
Training				
Development of training materials	■			
Conduct TOT for central and district level	■			
Training of District Health Management Teams	■	■		
Training of health workers, vaccinators and community resource persons		■		
Training of clinicians		■		
Social mobilization	■			
Development, translation and production of IEC materials	■	■		
Distribution of IEC materials			■	
Advocacy and social mobilization meetings	■	■	■	
– central level	■	■	■	
– district level	■	■	■	
– sub-district and lower levels	■	■	■	
Sensitization of health professionals, MOH officials, journalists and media operators	■	■	■	
Intensified district-based mass media campaigns		■	■	■
Launching of vaccine			■	
Vaccines & injection equipment				
Place orders for vaccines & A-D syringes	■			
Procure vehicle (trailer) for vaccine distribution		■		
Arrival of vaccine into the country		■		■
Distribution to regions/districts			■	■
Distribution to health units			■	■
Introduction of vaccine			■	
Planning				
Development of micro-plans				
– central level		■		
– district level		■		
Meetings of the National Task Force	■	■	■	■
Production of guidelines for district micro-planning	■			

Planning for the Introduction of Pentavalent Vaccine *(Cont'd)*

Activity Area	2001		2002	
	Q3	Q4	Q1	Q2
Cold Chain				
Assessment of cold chain capacity	Done			
Procurement of cold chain equipment	On-going			
Distribution of equipment	On-going			
Cold chain maintenance	On-going			
Refill and distribute gas for fridges	On-going			
Monitoring				
Incorporate Hep B and Hib into existing HMIS forms				
Introduce Hep B and Hib in the existing immunization schedule				
Print reviewed cards				
Monitoring district preparation activities				
Monitoring implementation of new vaccine introduction				
Develop monitoring tool for adverse events				
Monitor adverse events				
Surveillance				
Hib rapid assessment	Done			
Setting up Hib sentinel site				
Carry out Hep B baseline survey	Done			
Establish Hep B laboratory at national laboratory				
Develop and disseminate case definitions and guidelines for Hib and Hep B				
Orient/train surveillance focal points, records assistants, & HMIS persons in Hib/Hep B surveillance				
Procure computers, e-mail for Hib and Hep B sentinel laboratories				

Adapted from UNEPI, Uganda, 2000

Monitoring and the Information System

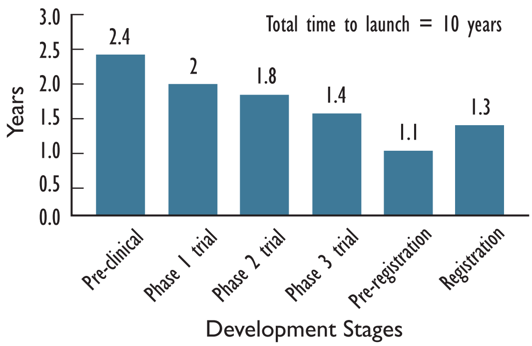
When a new vaccine is added to the schedule, new or revised forms (including tally sheets and monthly coverage reports) are required for reporting disease incidence and coverage, and vaccination cards usually have to be revised (see Chapter 4). This may be an opportunity to improve the overall information system. For example, managers may decide to monitor specific information that has not been routinely collected, such as the use and disposal of auto-disable syringes.

In the first year after introducing a new vaccine, it is particularly difficult to accurately monitor coverage for that vaccine because of changes resulting from the introduction process. For example, the vaccine may be introduced at different times in different parts of the country. Revised vaccination cards, record-keeping forms, and recording procedures may be put in place over the course of several months; this can lead to a lack of uniformity in reporting during the transitional period.

Vaccines in Development

The expanding universe of vaccine development offers the potential to prevent additional diseases and improve the ease and safety of vaccine administration. However, it may require decades before some of the most exciting developments are proven safe and effective, and are available at affordable prices.

Approximate vaccine development time



The following vaccines for children in developing countries are at various stages of development:

- Meningococcal meningitis
- Pneumococcal pneumonia
- Rotavirus (a major cause of diarrhea)
- Japanese encephalitis
- Malaria

Available Vaccines Not Widely Used in Developing Countries				
Disease and Agent	**Identification**	**Transmission**	**Occurrence and Incidence**	**Effectiveness and Limitations of Available Vaccines**
Meningococcal meningitis Bacterium *Neisseria meningitidis*	High fever, headache, and stiff neck This form of meningitis can lead to brain damage, hearing loss, or learning disability.	Close respiratory contact with infected individual	Worldwide, especially in the "meningitis belt" in sub-Saharan Africa, causing about 50,000 deaths per year	Polysaccharide vaccine is not very effective in children under two years of age. A conjugate vaccine, which protects children under two for strain A, which causes most epidemics in Africa, is under development.
Pneumococcal pneumonia Bacterium *Streptococcus pneumoniae*	Sudden onset with severe shaking, chills, high fever, chest pain, shortness of breath, rapid breathing, and coughing *S. pneumoniae* causes acute respiratory disease, meningitis, and septicemia.	Droplets, direct oral contact, or through articles soiled with respiratory discharges	*S. pneumoniae* is a leading cause of severe pneumonia in children under age five years worldwide. This bacterium causes more than one million deaths in children every year.	A 9-valent pneumococcal conjugate vaccine that protects infants is on trial in Africa. If trials go well, a license could be granted by 2006.
Rotavirus diarrhea Virus	Vomiting, fever, and watery diarrhea	Fecal-oral route possibly spread by respiratory or other contact; may be present in contaminated water	Worldwide, accounts for over 500,000 deaths and approximately one third of hospitalized cases of severe diarrhea in infants and children.	Work is in progress to improve the effectiveness of recently developed vaccines, limit unwanted side effects, and lower costs. Newer kinds of vaccines also are under development.
Adapted from Chin, 2000. *Control of Communicable Diseases Manual*. See also fact sheets issued by CDC and NIAID.				

Available Vaccines Not Widely Used in Developing Countries, Cont'd				
Disease and Agent	**Identification**	**Transmission**	**Occurrence and Incidence**	**Effectiveness and Limitations of Available Vaccines**
Japanese encephalitis Virus	Inflammation involving parts of the brain, spinal cord, and meninges.	Bite of the *Culex* mosquito.	2.4 billion people at risk in Asia/Pacific region; 500,000 cases reported annually; severe neurological damage in one third of survivors.	An inactivated vaccine has been used in several countries. Efforts are ongoing to develop alternatives with improved safety, efficacy and affordability.
Malaria *Plasmodium falciparum; P. vivax; P. ovale; and P. malariae* Parasite	Bouts of fever accompanied by other symptoms, alternating with periods of feelings of freedom from any illness The most severe forms of malaria result in organ failure, delirium, impaired consciousness, and generalized convulsions followed by persistent coma and death.	Person to person through the bite of an infected female Anopheles mosquito	Worldwide, with an estimated 300 million acute cases every year and one million deaths Heaviest toll is in Africa, where 90% of the total deaths occur. Malaria is the leading cause of death in young children.	There is no vaccine available at this time. Research is focusing on two recombinant vaccines. One addresses the pre-blood stage of the parasite and would prevent all infections. The other addresses the parasite's blood-stage and would support the acquisition of natural immunity by allowing a mild form of the disease to develop without the risk of severe disease or death. Another vaccine in development would prevent transmission of the disease from humans to mosquitoes. A combination of these types of vaccine is probable.

Adapted from Chin, 2000. *Control of Communicable Diseases Manual*. See also fact sheets issued by CDC and NIAID.

For any of these vaccines, disease burden, price, competing health priorities, and health system infrastructure should be considered. The major features of these diseases and the status of vaccine development are summarized in the preceding table.

Research is under way to develop vaccines against malaria, HIV, and tuberculosis, all of which are major causes of mortality. It is impossible to predict when these vaccines will be available for use on a large scale.

New Technologies

Immunization services rely on technologies for storing, monitoring, and administering vaccines, and for disposing of waste. As the introduction of the vaccine vial monitor (VVM) has demonstrated, even relatively simple devices can create major changes in how services are delivered. Some of the technologies under development are described below.

Needle-Free (or Jet) Injectors

These operate by ejecting a high-pressure stream of vaccine that penetrates the skin when the injector is held against it. Use of these injectors eliminates sharps waste. Work is under way to reduce any risk of cross-contamination that may be caused by successive use.

Credit: PATH

Needle Removal and Storage

The type of auto-disable (A-D) syringes that are used in immunization programs have a needle that is permanently fixed to the syringe. This creates more sharps waste than sterilizable needles and syringes. Because the needle poses a much greater danger in the waste stream than the syringe, removing the needle and storing it safely eliminates the most hazardous component. Needle removal and storage technologies, such as point-of-use needle removal, are under development. There is some

Credit: PATH

controversy as to whether the benefits of such devices in greatly reducing the volume of sharps waste and securely storing contaminated needles is offset by the disadvantage of adding extra handling steps for health workers in removing the needles. As described in Chapter 7, there is still the need for destruction of both the syringes and needles.

Vaccine Preservation

New technologies are being applied to improve the thermostability of vaccines. These promise to reduce the reliance on the cold chain, and thereby increase the accessibility of vaccines to people living in remote areas.

Auto-Reconstitution

A process is being developed to link freeze-dried vaccine and diluent so that the mixing and injection steps are combined. This technology could reduce the risks of contamination and loss of efficacy in reconstituted vaccines, but is likely to increase the need for storage space.

Improved Rapid Field Diagnostic Tests

Researchers are working on simple tests for rapidly diagnosing diseases such as measles and identifying high-risk areas and populations for tetanus. Such tools will help planners decide what prevention strategies to use and where to concentrate scarce resources.

A New Use for a Household Technology

Multi-dose vials from which at least one dose of vaccine has been removed are at risk of contamination from immersion in water. This contamination occurs when the perforated rubber stopper (septum) comes in contact with melted ice.

Health workers have found that when they put opened vials in resealable plastic bags (e.g., Ziploc® bags) and close them securely before putting the vials back in a cold box, the vial septum stays dry and uncontaminated. An added benefit is that the vaccine label does not come loose and become separated from the vial as it does when vials are soaked in water.

Clearly, technology does not have to be "high-tech," high-cost, or new. But even simple technologies should be thoroughly field-tested before they are recommended for widespread use.

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Full page photo credit: Aventis Pasteur

Chapter 12: Vaccines and Vaccine-Preventable Diseases

"An ounce of prevention is worth a pound of cure."

– Anonymous proverb

The Expanded Programme on Immunization (EPI) began with six vaccine-preventable diseases: diphtheria, measles, pertussis, polio, tetanus, and tuberculosis. In 1989, WHO recommended that yellow fever vaccine be used in endemic countries. In the 1990s, hepatitis B and *Haemophilus influenzae* type b vaccines were recommended where the disease burden was known or suspected to be high and control of the diseases was a public health priority.

This chapter describes the following vaccine-preventable diseases and the vaccines in use to prevent them:

- Diphtheria
- Hib Disease
- Hepatitis B
- Measles
- Pertussis (whooping cough)
- Polio
- Tetanus
- Tuberculosis
- Yellow fever

Vitamin A deficiency (VAD), which is being addressed as part of national immunization programs in many developing countries, is then discussed. The chapter concludes with descriptions of vaccines that are not widely used in developing countries.

Vaccine-Preventable Diseases					
Disease	**Agent**	**Reservoir**	**Spread**	**Duration of immunity induced by infection**	**Risk factors for infection in developing countries***
Diphtheria	Toxin-producing bacterium (*Corynebacterium diphtheriae*)	Humans	Close respiratory contact or contact with infectious material	Usually lifelong	Crowding
Meningitis and pneumonia caused by *Haemophilus influenzae* type b	*Haemophilus influenzae* type b, bacterium	Humans	Close respiratory contact	Usually lifelong	Not being breastfed Crowding
Hepatitis B (infection increases risk of death from liver cancer and cirrhosis)	Virus	Humans	Mother to newborn, child to child, blood, sexual. In developing countries, transmission at birth or early childhood is dominant.	If infection resolves, lifelong immunity; otherwise, lifelong carrier status	Infected mother Unsafe injections Unsafe blood transfusions In low endemicity situations: multiple sexual partners
Measles	Virus	Humans	Close respiratory contact and aerosolized droplets	Lifelong	Crowding
Pertussis	Bacterium (*Bordetella pertussis*)	Humans	Close respiratory contact	Usually lifelong	Crowding
Polio	Poliomyelitis virus – serotypes 1, 2, 3	Humans	Fecal-oral Close respiratory contact	Lifelong type-specific immunity	Poor environmental hygiene

Vaccine-Preventable Diseases, Cont'd					
Disease	**Agent**	**Reservoir**	**Spread**	**Duration of immunity induced by infection**	**Risk factors for infection in developing countries***
Tetanus	Toxin-producing bacterium *(Clostridium tetani)*	Soil Animal intestines	Spores enter body through wounds or through the umbilical cord of newborns	None	Inadequately trained birth attendants Lack of supplies for clean and safe deliveries Exposure to animal feces Untreated wounds
Tuberculosis	Bacterium *(Mycobacterium tuberculosis)*	Humans	Airborne droplets	Not known. Reactivation of old infection commonly causes disease	Crowding Immunodeficiency Malnutrition In adults, alcoholism, diabetes, and HIV
Yellow fever	Virus	Urban: humans and mosquitoes (*Aedes aegypti)* Forest: other vertebrates and mosquitoes	Bite of infected mosquito	Lifelong	Working in forest areas or living in urban areas infested by mosquitoes (*Aedes aegypti)*

* Risk factors in addition to the failure to be fully immunized

Vaccines Used in National Immunization Programs in Developing Countries							
Disease	**Nature of vaccine**	**Formulation**	**Usual number of doses in primary series and route of administration**	**Comm-on vial sizes***	**Stability at 37°C**	**Damaged by freezing?**	**Duration of immunity after primary series**
Diphtheria	Inactivated: toxoid	Liquid DTP, DT, Td	3 doses of DTP — intramuscular	10 dose 20 dose	High (for approximately 6 weeks)	Yes	Variable; 5 to 10 years
Haemophilus influenzae type b (Hib) diseases	Inactivated: conjugate poly-saccharide vaccine	Both freeze-dried and liq-uid Monovalent, DTP–Hep B+Hib,** and DTP+Hib**	3 doses — intramuscular	1 dose 2 dose 10 dose	High in freeze-dried form When reconstituted, discard after six hours.	Yes, in liquid form Diluent for reconstitution should not be frozen.	Through 5 years of age, the age group most at risk for Hib
Hepatitis B (Hep B)	Recombinant	Liquid Monovalent, DTP–Hep B,** and DTP–Hep B+Hib**	3 doses — intramuscular	1 dose 2 dose 6 dose 10 dose 20 dose	High	Yes	More than 15 years
Measles	Live attenuated	Freeze-dried Monovalent, measles-rubel-la (MR), and measles-mumps-rubella (MMR)	1 dose — subcutaneous	1 dose 10 dose	Medium in dried form. When reconstituted, discard after six hours.	Diluent should not be frozen	Lifelong if boosted by exposure to wild virus; shorter when no wild virus circu-lating
Pertussis	Inactivated whole-cell or protein-based, acellular	Liquid Available as DTP	3 doses of DTP — intramuscular	10 dose 20 dose	50% loss in potency after 1 week	Yes	At least through early childhood
Polio (Oral Polio Vaccine)	Live attenuated OPV contains 3 types of polio virus	Liquid	4 doses — oral	10 dose 20 dose	Loss of 20% potency after 1 day, 50% after 2 days	No	Lifelong if boosted by exposure to wild virus; shorter when no wild virus circu-lating

Vaccines Used in National Immunization Programs in Developing Countries, Cont'd							
Disease	**Nature of vaccine**	**Form-ulation**	**Usual number of doses in primary series and route of administration**	**Common vial sizes***	**Stability at 37°C**	**Damaged by freez-ing?**	**Duration of immunity after primary series**
Polio (Inactivated Polio Vaccine)	Inactivated, whole-cell IPV contains 3 types of polio virus.	Liquid	3 doses — subcutaneous	1 dose 10 dose	Less than 5% loss of potency per day	Yes	Unknown but suspected to be many years
Tetanus	Inactivated: toxoid	Liquid Monovalent form–TT Multivalent forms–DTP, DT, Td	DTP — 3 doses — intramuscular for children DT — intramuscular for children with contraindications for pertussis; booster for children through six years of age. TT or Td — 5 doses — intramuscular for schoolgirls and women of childbearing age	DTP:10 dose 20 dose DT: 10 dose 20 dose TT and Td: 10 dose 20 dose	High = Stable for approximately 6 weeks High High	Yes Yes Yes	5 years More than 5 years More than 30 years after five doses
Tuberculosis	*Bacillus Calmette–Guérin (BCG),* which is live attenuated *Mycobacterium bovis*	Freeze-dried	1 dose — intradermal	20 dose	Medium in dried form When reconstituted, discard after six hours.	No, but diluent should not be frozen	Unknown
Yellow fever	Live attenuated	Freeze-dried	1 dose — subcutaneous	10 dose	Medium in dried form When reconstituted, discard after six hours.	No, but diluent should not be frozen	10 — 30 years

*Availability of vial sizes varies by vaccine formulation and is subject to change.

** When designating combinations of antigens, — is used when combined antigens are presented in the same vial; + is used when they are presented in separate vials and reconstituted before use.

Diphtheria

A grayish membrane on the pharanx is a well-known sign of diphtheria.

Diphtheria is a bacterial infection caused by *Corynebacterium diphtheriae*. The infection can involve almost any mucous membrane, but the most common sites of infection are the tonsils and pharynx. This type of diphtheria can lead to obstructed breathing and death. In tropical countries, the disease usually affects the skin (cutaneous diphtheria) and may result in high levels of natural immunity against respiratory diphtheria.

Identification – In its tonsillar and pharyngeal form, diphtheria infection results in the formation of a bluish-white membrane that can cover the back of the throat, as seen in the photograph above. The membrane causes gagging and difficulty in swallowing and breathing.

WHO-Recommended Case Definition: Diphtheria

Clinical description: An illness characterized by laryngitis or pharyngitis or tonsillitis and the presence of an adherent membrane of the tonsils, pharynx, and/or nose.

Laboratory criteria for diagnosis: Isolation of *Corynebacterium diphtheriae* from a clinical specimen, or fourfold or greater rise in serum antibody (but only if both serum samples were obtained before the administration of diphtheria toxoid or antitoxin).

Source: WHO, 1998

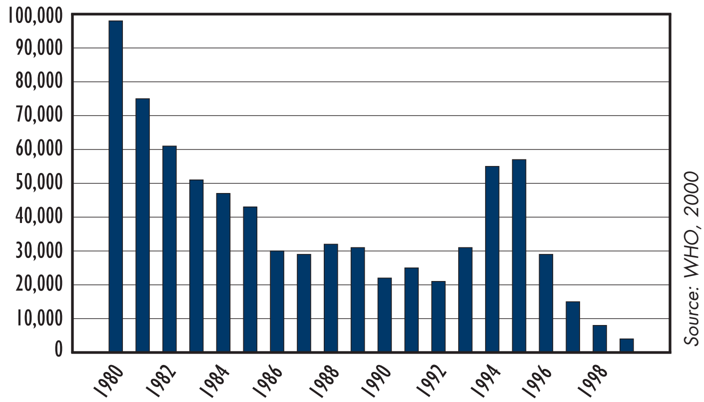
Transmission – The type of diphtheria that affects the throat and respiratory tract is spread in droplets and secretions from the nose, throat, and eyes of an infected person. Skin diphtheria is spread through direct contact with diphtheria ulcers or through clothing and other articles that have been contaminated with fluid from the ulcers. Diphtheria can also be transmitted through unpasteurized milk products.

Population at Risk – The epidemiology of diphtheria has changed considerably over recent decades due to improvements in sanitary conditions and immunization coverage. In developing countries, the disease is occurring less frequently in very young children, and more outbreaks are being seen among schoolchildren, adolescents, and adults.

Estimated Morbidity and Mortality – In 1999, according to WHO, approximately 5,000 cases of diphtheria were reported worldwide. Between 5% and 10% of patients die, even with treatment.

Occurrence – Diphtheria occurs worldwide among unimmunized populations and, in industrialized countries, among populations whose immunity has waned, largely because of the lack of routine booster immunizations for adults. As shown in the chart, diphtheria can be reduced to a very low level but then may reemerge in serious outbreaks in both temperate and tropical climates.

Reported global incidence of Diphtheria, 1980 - 1999



The largest epidemic since diphtheria vaccine was introduced in national immunization programs occurred from 1990 to 1998 in countries of the former Soviet Union, with over 50,000 cases and 1,500 deaths reported in the peak year of 1995. Among the epidemic's causes were the build-up of susceptible children and adults due to low coverage with diphtheria toxoid and large migrations of unprotected people. The response – which included vaccination of all children, diphtheria boosters for older children and adults, and treatment of cases and contacts – was initially slow because of vaccine and drug shortages, inadequate cold chains, and other operational problems. Coverage eventually improved significantly and incidence has dropped.

Treatment – Diphtheria antitoxin and antibiotics (erythromycin or penicillin) are prescribed for suspected diphtheria. Cases are isolated and contacts are vaccinated with diphtheria toxoid to prevent additional cases. People in close contact with diphtheria patients should also be given antibiotics.

Diphtheria Toxoid

The most effective way to control diphtheria is to prevent it through immunization of children in their first year of life with three doses of diphtheria toxoid, in the trivalent presentation of diphtheria, tetanus, and pertussis (DTP). Diphtheria toxoid can also be used to immunize adults during outbreaks.

Form and Presentation – Diphtheria toxoid is a liquid vaccine that does not need reconstitution. It is available in a variety of forms, including the three listed below.

Presentations of Diphtheria Toxoid		
Presentation	**Ingredients**	**Primary age group**
DTP	Diphtheria toxoid, tetanus toxoid, pertussis vaccine	Children through six years of age
DT	Diphtheria toxoid and tetanus toxoid	Children through six years of age
Td	Tetanus toxoid with reduced diphtheria content	Children seven years of age and older; adults

Diphtheria toxoid is also available with tetanus toxoid and pertussis vaccine in combinations with hepatitis B and Hib vaccines.

Efficacy – Three doses of diphtheria-containing vaccine provide over 95% protection against diphtheria for at least 10 years.

Side Effects – Mild fever and crying are common reactions to DTP. Many infants also have a mild local reaction with redness and swelling.

Severe systemic reactions (e.g., seizures, neurologic complications, and anaphylaxis) may follow DTP vaccinations, but these occur only rarely.

Contraindications – There are no contraindications to DTP except that it should not be given to children who have suffered a severe reaction to a previous dose.

Schedule and Target Age Group – For the primary series, WHO recommends that infants be given three doses of DTP, one dose each at six, 10, and 14 weeks of age.

If children do not get a second or third dose of DTP on time, they should not be given another first dose: they should continue with the remaining doses only.

Administration of DTP Vaccine – A 0.5 ml DTP dose is injected intramuscularly, usually into the outer part of the thigh. If more than one injection is given at the same time, different injection sites should be used for each.

Booster Doses after a Child's First Year – For longer-lasting protection, countries that have reached high coverage with the primary series of three DTP doses may give one or two booster doses after children reach one year

DTP Immunization Schedule for Children under One Year of Age		
Age	**Minimum Interval between Doses**	**Dose**
6 weeks		DTP1
10 weeks	4 weeks	DTP2
14 weeks	4 weeks	DTP3

of age. When one booster is given, it is administered in the second year of life. When two are given, one injection is given in the second year, and the second is given at four or five years of age.

Due to the increased risk of adverse reactions to the pertussis component in older children, DTP should not be given to children after they reach the age of seven years. These children should be given DT or Td.

Outbreak Control Strategies – During diphtheria epidemics, the largest possible proportion of the population group involved should be vaccinated, with priority given to infants and preschool children. Those who have been previously immunized should receive booster doses; unimmunized infants and children should receive the primary series of three doses. Patients and close contacts should be given antibiotics.

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Hib Disease

Haemophilus influenzae type b, or Hib, is the most common cause of bacterial meningitis in children under five years of age in most countries where it has been studied, and the second most common cause (after *Streptococcus pneumoniae*) of serious bacterial pneumonia in children. In addition to bacterial meningitis and pneumonia, manifestations of Hib disease include septic arthritis, osteomyelitis, septicaemia, and epiglottitis.

Identification – Diagnosis of Hib pneumonia is difficult, so efforts to identify Hib cases focus on bacterial meningitis, as defined in the box below.

WHO-Recommended Case Definition: Bacterial Meningitis

Clinical description: Bacterial meningitis is characterized by acute onset of fever, headache, and stiff neck. Meningitis is not specific for Hib disease, and Hib disease cannot be diagnosed on clinical grounds.

Laboratory criteria for diagnosis:

Culture method: Isolation of Hib from a normally sterile clinical specimen, such as cerebrospinal fluid (CSF) or blood. Culture of Hib from a non-sterile site, such as the throat, does not define Hib disease since the bacteria can grow in these other areas and not cause disease.

Antigen detection methods: Identification of Hib antigen in normally sterile fluids (i.e., CSF or blood) by antigen detection methods such as latex agglutination of counter immunoelectrophoresis.

Source: WHO, 1998b

Transmission – Hib bacteria are passed to other children in droplets of saliva expelled when an infected child coughs or sneezes. Hib also spreads when children share toys and other things that they put in their mouths. The risk of transmission increases when children spend long periods of time in crowded households, day care settings, or crèches.

Population at Risk – Children under one year of age are at the highest risk for Hib disease. The disease is rare in children older than five years.

Estimated Morbidity and Mortality – Population-based data on Hib incidence are limited, but WHO estimates that Hib causes approximately three million cases of serious disease and approximately 450,000 deaths each year. Approximately 20% of meningitis survivors have long-term neurological problems.

Special Aspects of Hib Surveillance

Since Hib diagnosis requires a lumbar puncture to obtain cerebrospinal fluid for laboratory confirmation, nationwide surveillance may not be practical in many countries. In such countries, disease burden and the impact of Hib immunization programs can be measured by combining Hib coverage data from all facilities that provide Hib vaccinations with disease data from sentinel surveillance sites that have the necessary clinical and laboratory capacity.

Source: WHO, 1998b

The WHO has recently devised a methodology for rapidly estimating the incidence of Hib disease. This rapid assessment tool, which requires about ten days of field work, uses detailed local data on bacterial meningitis to generate estimates of overall Hib burden. See *Estimating the Local Burden of Hib Diseases Preventable by Vaccination* (WHO, 2001).

Occurrence – There appears to be geographic variation in the occurrence of disease caused by Hib. While data from Africa and Latin America have clearly indicated its importance as a cause of pneumonia, meningitis, and other childhood diseases, studies in Asia have yielded lower-than-expected estimates of the burden of Hib disease. Ongoing research will help establish the magnitude and patterns of disease from Hib in Asian countries.

Treatment – Antibiotics are used for treatment. Bacterial resistance is now being seen with some antibiotics.

Hib Vaccine

Hib vaccination of children in the first six months of life is the most effective means of controlling invasive Hib disease, but this will only protect them from diseases caused by type b *Haemophilus influenzae*. Hib vaccine will not prevent meningitis and pneumonia caused by other types of *Haemophilus influenzae* or other agents.

As of early 2001, 71 countries had included Hib vaccine in their routine immunization schedule. Countries with Hib vaccine coverage rates above 80% for young children have documented a 99% decline in the incidence of invasive Hib disease, including Hib meningitis.

Form and Presentation – Hib vaccines are available in monovalent and multivalent forms. Its formulations include liquid and freeze-dried (or lyophilized) vaccines, as described in the box on the following page. Changing from one formulation of Hib vaccine to another before a child has completed the primary Hib series causes no harm.

Choices among Hib Vaccines

Choices among Hib vaccines are likely to change; it is always advisable to check availability with UNICEF or other vaccine suppliers.

Liquid monovalent Hib: No reconstitution is required. Monovalent Hib vaccine adds another injection to the number a child receives.

Lyophilized monovalent: This vaccine needs to be reconstituted, which increases operational complexity and the risk of contamination. As a monovalent vaccine, it requires an additional injection. Storage space is needed for the vaccine and its diluent (although diluent does not need refrigeration until shortly before reconstitution and administration).

Lyophilized combinations:

- DTP-Hep B+Hib – Freeze-dried Hib is reconstituted with DTP-Hep B. The combination reduces the number of injections needed from nine to three.
- DTP+Hib – Freeze-dried Hib vaccine is reconstituted with DTP.

Efficacy – Three doses of Hib vaccine are more than 95% effective in preventing invasive Hib disease.

Side Effects – Hib vaccine has not been associated with any serious side effects, although there may be redness, swelling, and soreness at the injection site.

Contraindications – There are no contraindications to Hib vaccine.

Schedule and Target Age Group – Hib immunization schedules for children under one year of age differ from country to country, depending on the form of Hib vaccine and the schedule for other vaccines. In general, it is given at the same time as DTP, as shown in the commonly used schedule below.

Administration – A 0.5 ml of a dose of Hib vaccine is injected intramuscularly, usually into the outer part of the thigh. If more than one injection is given at the same time, different injection sites should be used for each.

Booster Doses after a Child's First Year – Booster doses of Hib vaccine are not recommended in developing countries.

Hib Vaccination Schedule for Children under One Year of Age

Age	Minimum Interval between Doses	Dose
6 weeks		Hib1
10 weeks	4 weeks	Hib2
14 weeks	4 weeks	Hib3

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Hepatitis B

Hepatitis B is a viral infection of the liver. If not fatal, acute infection either resolves or progresses to chronic infection, which may lead to cirrhosis or liver cancer several decades later. When it resolves, patients develop lifelong immunity.

In developing countries, hepatitis B infection usually occurs in childhood — at the time of birth, during infancy, or in early childhood. Symptoms are not usually apparent in infected young people, but the likelihood that an infected child will develop lifelong chronic infection is higher than if the infection occurs in older children or adults.

Identification

Acute infection – The clinical description of acute hepatitis B is indistinguishable from that of other types of acute viral hepatitis (A through E). Note that the clinical description below is the same for all acute viral hepatitis infections, and that laboratory testing is necessary for diagnosis.

Chronic infection – People with chronic infection are often asymptomatic for decades after infection, but during this time they can transmit the virus to others and are at high risk of eventually developing liver disease themselves. The risk of death from cirrhosis and primary liver cancer is approximately 25% for persons who become chronically infected during early childhood and 15% for persons who become chronically infected at an older age.

WHO-Recommended Case Definition: Acute Viral Hepatitis Diseases

Clinical description of acute viral hepatitis disease: An acute illness typically including acute jaundice, dark urine, anorexia, malaise, extreme fatigue, and right upper quadrant tenderness. (None of these symptoms is common in infants and young children.) Biologic signs include increased urine urobilonogen and >2.5 times the upper limit of serum alanine aminotransferase.

Laboratory criteria for diagnosis:

- Hepatitis A: positive for IgM anti-HAV
- Hepatitis B: positive for IgM anti-HBc-positive or, less preferably, hepatitis B surface antigen (HBsAg)
- Non-A, non-B: negative for IgM anti-HAV and IgM anti-HBc or HBsAg
- Hepatitis C: positive for anti-HCV
- Hepatitis D (occurs only as co-infection or super-infection of hepatitis B): positive for IgM anti-HBc or, less preferably, HBsAg plus anti-HDV positive
- Hepatitis E: positive for IgM anti-HEV

Source: WHO, 1998

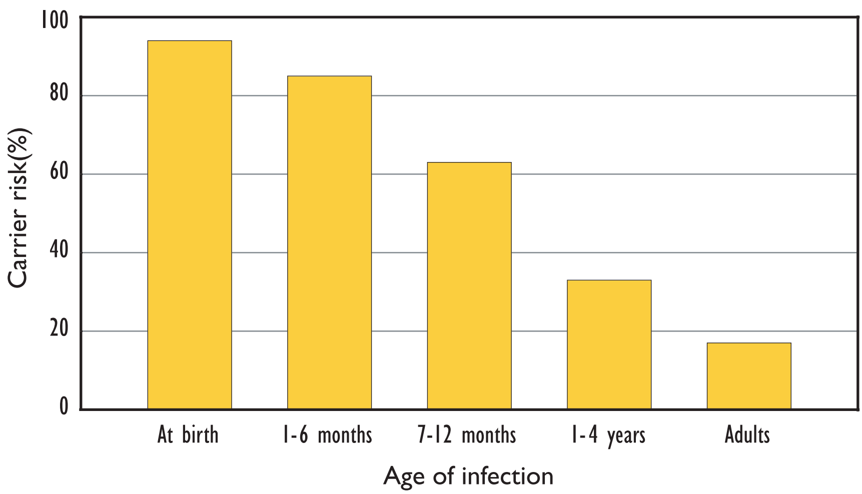
Transmission – In developing countries, the hepatitis B virus is most commonly transmitted to children by:

- Child-to-child transmission through open wounds or shared implements that contain blood or body fluids. This accounts for the majority of hepatitis B infections worldwide.
- Exposure of babies to maternal blood or other fluids during delivery, if the mother is a chronic carrier.
- Use of contaminated needles and syringes for vaccinations, injections, and transfusions.

In countries where infection occurs later in life, the disease is transmitted through sexual activity, contaminated needles and syringes, and contaminated blood products.

Population at Risk – Hepatitis B virus infection can occur at any age. In Asia and Africa, infection often occurs in infancy and childhood, when infected individuals are more likely to become chronically infected.

Age-dependent risk of becoming a carrier



Source: International Conference on the Control of Hepatitis B in the Developing World, 1991

Estimated Morbidity and Mortality – More than two billion individuals alive today have been infected at some time in their lives with the hepatitis B virus. Approximately 350 million of these are chronic carriers. Over 500,000 people die every year from cirrhosis and primary liver cancer.

Occurrence – Hepatitis B is endemic worldwide.

Treatment – The drugs interferon or lamivudine are used to treat chronic hepatitis B, but they are only moderately effective, cost thousands of dollars per patient, and are not realistic options for most people in developing countries.

Hepatitis B Vaccine

WHO recommends that hepatitis B vaccine be offered to all children under one year of age in all countries. More than 130 developing countries now routinely provide the vaccine, and more are preparing to do so with the support of GAVI and the Vaccine Fund.

Form and Presentation – Hepatitis B vaccine is available in liquid form, in monovalent and combination formulations, as shown below.

Hepatitis B vaccines are available in single-dose and multi-dose glass vials. Multi-dose vials contain two, six, 10, or 20 doses.

Formulations of Hep B Vaccines

Monovalent: This is the only Hep B vaccine that can be used at birth. May be used for later doses.

Combination vaccines: ***Must not*** be used until a child is at least six weeks of age. Combination vaccines now available include:

- DTP-Hep B (liquid)
- DTP-Hep B+Hib (Comes in two vials: liquid DTP and Hep B in one vial and freeze-dried Hib in the other. Mixing is required.)

Efficacy – Hep B is one of the safest and most effective of vaccines. Studies have shown that it is 95% effective in preventing chronic infection. For infants exposed by the mother at birth, monovalent Hep B vaccine is 90% effective in preventing transmission if the first dose is administered within 24 hours and the series completed at the recommended intervals.

Side Effects – Mild, temporary local reactions are common after an injection of Hep B vaccine. It is highly unusual to see an anaphylactic reaction.

Contraindications – There are no contraindications to this vaccine, except if a very rare anaphylactic reaction to a previous dose has occurred, then Hep B should not be given again.

Do Not Freeze Hep B Vaccine!

Freezing Hep B vaccine reduces its efficacy, and the vaccine freezes at –0.5°C, several degrees warmer than the freezing point of DTP. Since accidental freezing of DTP is common, freezing of hepatitis B vaccine is likely to be a problem as well.

Schedule and Target Age Group – Hep B is usually given as a three-dose series, with each dose at least four weeks apart. Scheduling options include a longer interval between the second and third dose and a four-dose schedule when a birth dose is given.

In countries where perinatal transmission is a significant problem, the first dose should be given at birth. Only monovalent Hep B vaccine can be given safely at this time, but later doses may be given in combination with other vaccines. Scheduling options recommended by WHO are shown below.

Options for Scheduling Hep B for Children under One Year of Age

Age	**I** **Countries with low perinatal transmission**	**II** **Countries with high perinatal transmission** **Monovalent Hep B for birth dose; thereafter, combination of Hep B and DTP**	**III** **Countries with high perinatal transmission** **Monovalent Hep B for all three doses** **Provides longer interval between Hep B2 and Hep B3**
Birth		Hep B1	Hep B1
6 weeks	Hep B1	Hep B2	Hep B2
10 weeks	Hep B2	Hep B3	
14 weeks	Hep B3	Hep B4	Hep B3

When countries introduce Hep B into their routine immunization schedules, managers must decide whether to use a gradual strategy, in which only children born after the date of introduction are immunized, or a catch-up strategy, in which children born before the date of introduction are also immunized (see Chapter 11).

Administration – A 0.5 ml dose of Hep B vaccine injected intramuscularly, usually into the outer part of the thigh. If more than one vaccine is injected at the same time, different injection sites should be used for each injection.

Booster Doses – Booster doses are not recommended.

Hepatitis B Vaccination of Health Workers

Hepatitis B vaccination is usually not recommended for health workers in developing countries because it is likely that they have been exposed to the virus during childhood. Also, they are less likely to become carriers if they become infected as adults.

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Measles

Measles is responsible for more deaths than any other vaccine-preventable disease, killing an estimated 750,000 children each year. Over one-half of these deaths occur in sub-Saharan Africa.

Credit: Daniel Cima, American Red Cross

Credit: Daniel Cima, American Red Cross

Identification – Measles is an acute viral infection characterized by a variety of symptoms, including fever, rash, cough, conjunctivitis, diarrhea, ear infections, pneumonia, and brain inflammation.

WHO-Recommended Case Definition: Measles

Clinical case definition: Any person in whom a clinician suspects measles infection or any person with fever and maculopapular rash (i.e., non-vesicular or without fluid) and cough, coryza (i.e., runny nose), or conjunctivitis (i.e., red eyes).

Laboratory criteria for diagnosis: At least a fourfold increase in antibody titer, or isolation of measles virus, or presence of measles-specific IgM antibodies.

Source: WHO, 1998

Transmission – Measles is extremely infectious. The virus is transmitted through the air by respiratory droplets expelled by infected individuals.

Ease of Measles Transmission

One study found that two-thirds of the children coming to a clinic in West Africa with measles probably caught the measles at the clinic on earlier visits one to three weeks before.

Source: Klein-Zabban et al., 1987

Susceptible individuals in close contact with infected people are most likely to become infected, so transmission is more easily maintained in crowded homes, urban slum areas, and congested places than in isolated or rural situations.

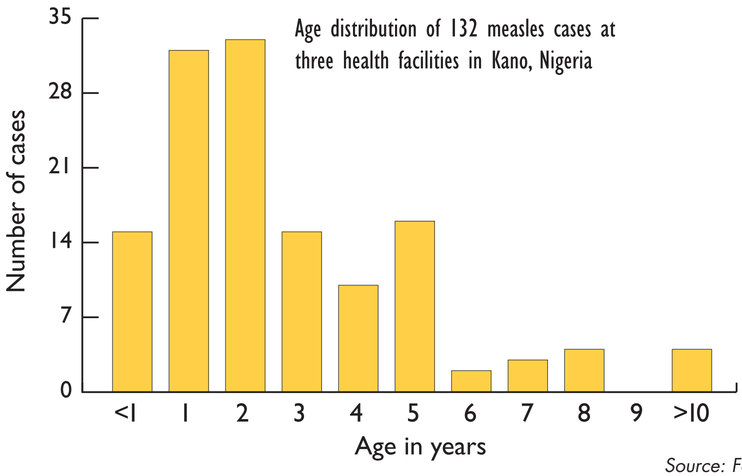
Population at Risk – A person is susceptible to measles when he or she has lost maternal antibodies, has never been infected, or has not been effectively vaccinated.

Maternal antibodies provide immunity to infants against measles infection until they are at least six months of age. After that, immunity begins to wane.

Infection provides lifelong immunity.

Vaccination provides immunity if vaccine is given at an age when the child's maternal antibodies have been lost and the child can seroconvert for protection. In developing countries, the best age for most children is nine months.

In both urban and rural areas in developing countries, the majority of measles cases occur in children less than five years of age, as illustrated by data from Nigeria.



Source: Foster, 2001

In this study, case fatality rates were estimated at 8% for children under one year of age, 4% for children ages two to four, and 2% for children five and older. Widespread malnutrition in the outbreak area was believed to have contributed to the mortality rate, which eventually exceeded 15,000.

Population density affects the age of infection. Among rural populations, the age of infection is usually older than in densely settled urban populations. In countries with low measles vaccination coverage, most measles deaths occur among unvaccinated children who are younger than five years old. However, as high measles coverage is achieved and sustained over a period of five years or longer, measles outbreaks affect older children and young adults, as has occurred in the Western Hemisphere.

Estimated Morbidity and Mortality – Measles deaths occur as a result of complications, including pneumonia, acute diarrhea and dehydration, chronic diarrhea with malnutrition, and rarely, encephalitis. The disease can also cause serious disability, including permanent blindness, deafness, and brain damage.

Infection with measles depresses the immune system, depletes the body's stores of vitamin A, leads to weight loss, and leaves children susceptible to diseases like pneumonia and diarrhea. Because the health system receives reports of complications rather than measles disease itself, measles cases and deaths are often underestimated.

Occurrence – Measles is generally a seasonal disease. In temperate climates, transmission peaks in late winter and early spring. In the tropics, it increases in the dry season. In large, crowded cities with low measles vaccine coverage, transmission can be continuous throughout the year. In these areas, measles is a particularly important problem because infection can occur before children are old enough to be effectively vaccinated.

The frequency of measles outbreaks depends on the density of people susceptible to the disease and the probability of exposure to infectious cases. In countries with low coverage, epidemics occur every two to three years. In countries with high coverage, epidemics occur at five- to seven-year intervals.

Treatment – Supportive care includes frequent food and fluid intake and treatment of complications. Vitamin A supplementation reduces the number of deaths from measles.

Vitamin A in Measles Case Management

Measles seriously depletes vitamin A in children, making them more susceptible to complications. For example, until recently, half of the blindness in children in one East African country resulted from corneal scarring following measles infection. Vitamin A supplementation for these children would have prevented this outcome.

Measles Vaccine

Measles vaccination is one of the most effective preventive measures available. Maintaining coverage above 90% can have a major impact on public health.

Form and Presentation – Most national programs, except in the Americas, use monovalent measles vaccine, which is in freeze-dried form and must be reconstituted with measles diluent from the same manufacturer.

Reconstituted measles vaccine is highly sensitive to heat and should be discarded at the end of a session or six hours after reconstitution, whichever comes first.

Measles vaccine is also available in combination with rubella vaccine as MR and in combination with mumps and rubella vaccines as MMR.

Efficacy – Up to 15% of children who are vaccinated before their first birthday do not seroconvert (develop sufficient antibodies) and so are not protected against measles. In areas where vaccination coverage with one dose of measles is high, this failure to seroconvert accounts for a large proportion of the remaining susceptible children. In these high coverage areas, a second opportunity may be advisable to protect children who did not seroconvert the first time. In areas with low measles vaccination coverage, however, failure to vaccinate with the first dose rather than failure to seroconvert is by far the more significant problem (see pages 228-229).

Side Effects – Approximately 10% of children develop a low fever after a measles vaccination, and 5% develop a generalized, non-infectious rash.

Contraindications – There are no contraindications to measles vaccination. Measles vaccine should be given to eligible children at the first opportunity, even if the child is sick or malnourished. In fact, because malnourished children are at great risk of dying from measles, their vaccination should be given priority.

In the absence of documented proof of measles vaccination, such as a vaccination card, measles vaccine should be given even if parents believe that their child has already been infected.

Because children with HIV are at higher risk of severe measles disease and measles vaccine can safely be given to HIV-infected children, measles vaccination is recommended for all children regardless of their HIV status.

Measles Vaccination in the Presence of HIV

Measles can be very severe in HIV-infected children.

WHO currently recommends that an early dose be given at six months, followed by the scheduled dose at nine months to children who are known to be infected with HIV. For children who are symptomatic for AIDS, the potential risks and benefits must be evaluated on an individual basis. The overall risk of adverse events from the vaccine is relatively low compared with the risk of measles infection in HIV-infected children.

Children should not be screened for HIV antibody status before receiving measles vaccine.

First Opportunity for Measles Vaccination

The relative importance of the first and second opportunities to vaccinate is illustrated below using two hypothetical districts with the same population size. District A is low performing with only 50% measles coverage. District B is high performing with 90%. After the first opportunity, District A has many more unprotected children (5750) than District B (2350).

	District A (low-performing)	**District B (high-performing)**
Total number of children	10,000	10,000
Vaccinated with 1 dose	5000 (cov=50%)	9000 (cov=90%)
– of whom protected (85% efficacy)	4250	7650
– of whom unprotected	750 (=5000-4250)	1350 (=9000-7650)
Unvaccinated with 1 dose	5000 (=10,000-5000)	1000 (=10,000-9000)
Total unprotected *	5750 (=5000 +750)	2350 (=1000 + 1350)
– of which due to FAILURE TO VACCINATE	87% (=5000/5750)	43% (=1000/2350)
– of which due to FAILURE TO SERO-CONVERT	13% (=750/5750)	57% (=1350/2350)
* Assuming all unprotected children eventually contract measles.		

In District A, 87% of the unprotected children are unprotected because of failure to vaccinate, and 13% remain unprotected because of a failure to seroconvert. In District B, the majority of the unprotected children (57%) are due to a failure to seroconvert.

In the same two hypothetical districts, health officials decide to offer a second opportunity for measles vaccination through mass campaigns. Coverage of 90% is achieved in both districts. The vaccine efficacy is 95% because older children are targeted. As seen in the next table, the number of unprotected children in District A drops from 5750 to 834 and in District B from 2350 to 341.

Second Opportunity for Measles Vaccination

District A		District B
10,000	Total number of children	10,000
4250	Protected after first opportunity	7650
5750	Unprotected after first opportunity	2350

5000 (no previous dose)	750 (one dose, unprotected)	Reasons for lack of protection after first opportunity	1000 (no previous dose)	1350 (one dose, unprotected)
4500 (1st dose)	675 (2nd dose)	Vaccinated after second opportunity (90%)	900 (1st dose)	1215 (2nd dose)
-4275	-641	Protected by vaccination (95% efficacy)	-855	-1154
225	34	Unprotected due to failure to seroconvert (5%)	45	61
500	75	Unprotected due to failure to vaccinate	100	135
725 + 109 = 834		Total unprotected*	145 + 196 = 341	

* Assuming all unprotected children eventually contract measles.

The success of the hypothetical campaign shown above depended on reaching a high percentage (90%) of children who were missed by routine services. The great majority of these children are now protected from measles infection, as shown below.

Protection against Measles Due to First and Second Doses

	1st opportunity	2nd opportunity	Total
District A (low-performing)			
1st dose	4250	4275	8525 (93%)
2nd dose		641	641 (7%)
			9166 (100%)
District B (high-performing)			
1st dose	7650	855	8505 (88%)
2nd dose		1154	1154 (12%)
			9659 (100%)

This example shows that, as in the real world, most children are protected by the first dose of measles vaccine that they receive, whether they receive it as a part of routine immunization services or during a campaign. It also shows that protection due to a second dose is relatively small (7% in District A and 12% in District B). Therefore, failure to deliver that first dose to all infants remains the primary reason for high measles morbidity.

Schedule and Target Age Group – Vaccination with measles vaccine is not usually effective before a child reaches nine months of age. In developing countries, measles vaccine should be given at nine months of age or as soon as possible thereafter.

The age of vaccination may be altered in response to epidemiological and other data. For example, in refugee situations, measles vaccine is often recommended at six months and again at 12 months.

Administration – The 0.5 ml dose of measles vaccine is injected subcutaneously into the upper left arm.

> **The Measles Challenge**
>
> In developing countries, vaccinations against measles are usually given at nine months of age, which is nearly six months after the other vaccines in the schedule have been given. The time gap means that even when coverage for OPV and DTP is high, coverage with measles may be low.

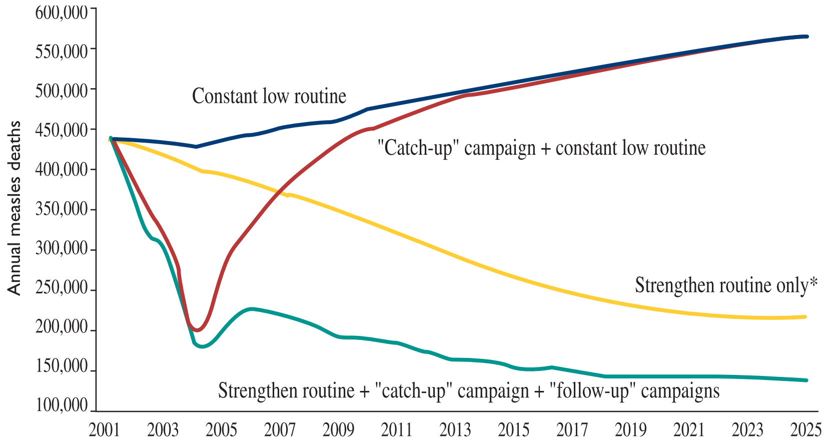
Booster Doses – Booster doses are not given.

Control Strategies – In 2001, WHO and UNICEF proposed a global strategy for measles mortality reduction that combines routine and supplemental immunization. As shown in the graph on page 231, a combination of approaches is needed to achieve and sustain reduction in measles deaths. The rapid reduction in mortality through supplemental immunization targeting a wide age range will last for only a few years unless routine immunization is also strengthened. Strengthened routine immunization, resulting in a modest increase in coverage of 5% each year, will lead to long-term sustained mortality reduction; because this will take many years to achieve in some countries, it is essential that a start be made now. Comprehensive plans for measles mortality reduction should include clear objectives and activities for strengthening routine immunization with provision of budgetary and technical support. Sustained and optimal reduction in measles mortality will only occur when both supplemental immunization and strengthened routine immunization are implemented in combination, followed by less frequent follow-up campaigns targeting a narrower age range.

The essential elements of a comprehensive control strategy include:

- Provide a first dose of measles vaccine to all infants.
- Guarantee a "second opportunity" for measles vaccination.
- Establish an effective system to monitor coverage and conduct measles surveillance.
- Improve the management of complicated measles cases, including vitamin A supplementation.

Projected impact of different measles vaccination strategies on measles deaths in Africa 2001-2025



*Note: routine strengthening assumes 5% annual improvement in routine immunization coverage until 95%

Source: WHO, 2003

Measles mortality reduction – Countries with less than 80% measles coverage should focus on improving and expanding routine immunization services. These countries may sometimes use campaigns to reach children who do not have access to routine immunization services. All children in the target age group for these campaigns, usually from nine months of age to less than five years, should be eligible for vaccination, irrespective of past measles illness or vaccination history. For some children, such campaigns provide a "second opportunity" to become immunized. Note that the upper age range may be expanded depending on the local epidemiology.

The primary objective of mortality reduction campaigns should be to reach previously unimmunized children.

Measles elimination – Some countries that have achieved and maintained measles vaccination coverage above 80% across all districts for at least three years conduct periodic campaigns to supplement routine services in order to eliminate the disease.

Routine coverage (%)	Duration of Impact in Years at Different Levels of Routine and Campaign Coverage			
	Campaign Coverage			
	20%	**40%**	**60%**	**80%**
20	0.25	0.5	0.75	1
50	0.4	0.8	1	1.6
80	1	2	3	4
90	2	4	6	9

Source: Foster, S., 2001, adapted from N. Gay

First, a "catch-up" campaign is carried out to interrupt chains of transmission in all children from the age of nine months through an upper age that is consistent with local epidemiology. Thereafter, "follow-up" campaigns are used periodically to reach those who have not been reached at all and to ensure that children who have been vaccinated but are still unprotected will seroconvert.

To maintain elimination, high coverage must continue with a combination of routine services and with periodic campaigns to prevent the build-up of susceptibles.

Outbreak response – Measles importation should be expected even in areas that have eliminated the disease, and when outbreaks occur, control can be difficult because many susceptible people can be infected before a vaccination campaign can be organized. Health services can still respond effectively, however, by treating complications, administering vitamin A supplementation, and investigating cases to determine how to prevent recurrences.

Routine measles vaccination coverage, supplemented by campaigns, should be the focus of management efforts to prevent outbreaks from occurring at all.

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Pertussis


Credit: WHO

Pertussis, also called whooping cough, is a highly contagious, acute bacterial disease affecting the respiratory tract. Worldwide, it causes an estimated 300,000 deaths per year.

Identification – Patients with pertussis have long-lasting coughs. Infants are more likely to choke than whoop, and those less than three months old may stop breathing altogether. Together, pertussis and measles account for up to one-quarter of deaths due to acute respiratory infections.

WHO-Recommended Case Definition: Pertussis

Clinical description: A person with a cough lasting at least two weeks with at least one of the following:

- Fits of coughing
- Intake of breath accompanied by a whooping sound
- Vomiting immediately after coughing and without any other apparent cause

Laboratory criteria for diagnosis: Isolation of *Bordetella pertussis* or detection of genomic sequences by polymerase chain reaction.

Source: WHO, 1998

Transmission – Pertussis is spread in droplets from the nose and throat that are expelled when an infected person coughs or sneezes. The disease spreads easily among susceptible people who live in crowded conditions.

Population at Risk – Newborns receive minimal antibody protection from their mothers, and it quickly wanes. Approximately one-third of all cases occur in infants under six months old, and half of all deaths are in children under one year.

Estimated Morbidity and Mortality – 80% or more of unprotected children get pertussis, and 1% of those who get the disease die. Pertussis can lead to frailty and wasting.

Occurrence – Pertussis occurs in both urban and rural areas. In urban areas, infants are more commonly affected; in rural areas, most cases occur in older children and are milder. The majority of pertussis cases occur in developing countries; in industrialized countries incidence is high among unimmunized infants, and outbreaks occur among adolescents and young adults.

Treatment – Antibiotics may be given to shorten the period of communicability (approximately three weeks), but they do not cure the disease or even reduce symptoms unless they are given during the incubation period or soon after symptoms appear.

Pertussis Vaccine

The most effective strategy for preventing pertussis requires the timely delivery of three doses of vaccine at the proper intervals during a child's first year of life. Pertussis vaccine also helps to reduce mortality from pneumonia, other acute respiratory infections, and malnutrition.

Form and Presentation – Two types of pertussis vaccine are available: whole-cell and acellular.

Whole-cell vaccine, which has been in use in national immunization programs in developing countries for several decades, has had a significant impact on pertussis incidence.

Concern about very rare adverse events following whole-cell pertussis vaccination led to the development of acellular pertussis vaccine. Acellular vaccines compare favorably with whole-cell vaccines in terms of efficacy and side effects, but they are more expensive. DTP with whole-cell pertussis costs approximately US$0.07 per dose compared to approximately US$10.00 per dose of DTP with acellular pertussis.

Acellular pertussis vaccine is now licensed in many industrialized countries, but in developing countries only whole-cell pertussis vaccine is used in national immunization programs.

Efficacy – Efficacy is estimated to be approximately 80% after three doses.

Side Effects – Mild fever and crying are common reactions to DTP. Many infants also have a mild local reaction with redness and swelling.

Rarely, severe systemic reactions, such as seizures, neurological complications, and anaphylaxis, follow DTP vaccination. Severe crying for three or more hours or high fever over 105°F may occur with pertussis vaccine.

Contraindications – There are no contraindications to DTP except that it should not be given to children who have suffered a severe reaction to a previous dose.

Schedule and Target Age Group – WHO recommends that three doses of pertussis vaccine in the DTP formulation be given to infants at six, 10, and 14 weeks of age.

If a child does not get the second dose of DTP at the scheduled time, he or she does not need to restart the series. The second dose should be given at the earliest opportunity, and the third dose should be given after a four-week interval.

DTP Immunization Schedule for Children under One Year of Age

Age	Minimum Interval Between Doses	Dose
6 weeks		DTP1
10 weeks	4 weeks	DTP2
14 weeks	4 weeks	DTP3

Administration of DTP Vaccine – The 0.5 ml dose of DTP is injected intramuscularly, usually into the outer part of the thigh.

Booster Doses after a Child's First Year – For longer-lasting protection, countries that have reached high coverage with the primary series of three DTP doses may give one or two booster doses after children reach one year of age up to the age of seven. Thereafter, children should not be given pertussis vaccine, even in combination, due to the increased risk of adverse reactions.

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Polio

In 1988, the World Health Assembly set a goal to eradicate poliomyelitis (polio), worldwide. Since then, national governments, WHO, UNICEF, Rotary International, CDC, USAID, and other bilateral agencies have been working to achieve the goal of polio eradication.

Identification – Polio is a disease of the central nervous system caused by three closely related polioviruses: types 1, 2, and 3. Approximately 5% of people exposed to any of these viruses have influenza-like symptoms such as fever, loose stools, sore throat, headache, or upset stomach. Some may have pain or stiffness in the neck, back, and legs, and 1% become paralyzed.

Credit: WHO

WHO-Recommended Case Definition: Poliomyelitis

Clinical case definition: Any child under fifteen years of age with acute flaccid paralysis (AFP) or any person with paralytic illness at any age when polio is suspected.

Source: WHO, 1998

In paralytic polio, severe muscle pains follow the milder symptoms, and then paralysis develops, usually in the first week of illness. The use of one or both legs or arms may be lost, and breathing without a respirator may become impossible. People with these severe symptoms can, but do not always, recover. Prior to the eradication initiative, polio was the leading cause of lameness worldwide.

Transmission – Poliovirus is highly communicable. It is spread from person to person by contact with infected feces or secretions from the nose and mouth. People who do not have symptoms may spread the disease.

Population at Risk – Every person who is not vaccinated against polio will acquire the infection if the virus is in the environment, with the following outcomes:

- 95% will show no effect.
- 4% will have a mild flu-like illness.
- 1% will become paralyzed or lame.
- 0.5% will be lame for life.
- 0.1% will die during the acute phase.

Circulating Vaccine-Derived Polio Virus (cVDPV): A Newly Emerging Threat

Under very rare circumstances that are not fully understood, the virus strains in oral polio vaccine (OPV) can regain two important properties of wild polio virus: the abilities to cause paralytic disease in humans and to spread from person to person. This phenomenon, known as circulating vaccine-derived polio virus, has been documented in Egypt, Haiti, the Dominican Republic, the Philippines, and Madagascar. In each case, vaccination coverage was very low in the affected areas. As with wild polio virus, the critical factor in controlling cVDPV is achieving and maintaining high vaccination coverage rates through a combination of strengthening the routine immunization system and supplemental vaccination.

Estimated Morbidity and Mortality – As a result of the Polio Eradication Initiative (PEI), there has been a 99% decrease in the number of confirmed polio cases compared with the 350,000 cases reported in 1988.

Occurrence – Polio can occur anywhere in the world. In regions where it has been eliminated, such as the Americas, Europe, and the Western Pacific, control measures and certification-quality surveillance must be sustained until the disease is eradicated worldwide.

Treatment – There is no specific treatment for polio. However, physical therapy can limit deformity and increase the likelihood that a patient can use and benefit from braces.

Polio Vaccine

Immunization is the only protection against polio infection.

Form and Presentation – Most immunization programs in developing countries use oral polio vaccine (OPV). OPV, unlike other vaccines, is given orally and therefore, can be given by people with limited training.

Inactivated polio vaccine (IPV) is an injectable vaccine and is relatively expensive. IPV appears to produce less immunity in the intestines than OPV, so persons who receive IPV are more readily infected with wild polio virus than OPV recipients. Such infected persons are protected from paralytic polio, but the wild virus being shed in their stool could result in transmission to other persons. Children vaccinated with IPV, as opposed to OPV, cannot spread their vaccine-derived immunity to contacts through fecal-oral contamination.

Efficacy – In more than 95% of recipients, three doses of OPV produce immunity for all three of the poliovirus types in the vaccine.

Side Effects – Reactions to OPV are rare. Vaccine-associated paralytic polio (VAPP) is a rare adverse event that occurs following the administration of OPV. It is estimated that there is one case of VAPP per 2.4 million doses given to both healthy and immunodeficient individuals.

Contraindications – There are no contraindications to polio vaccination. However, if a child has diarrhea when OPV is given, an extra dose should be administered four weeks later.

Routine Schedule and Target Age Group – WHO recommends that children receive four doses of OPV before one year of age as part of the routine immunization program. These doses should be given at least four weeks apart, usually at the same time as DTP, as shown in the table below. If the OPV0 dose is not given within 14 days of birth, it should not be given at all, and the primary series should begin with OPV1 at six weeks of age.

Administration of OPV – OPV is dropped into the mouth. Usually two drops are given, but this may differ by vaccine manufacturer.

Eradication Strategies – A combination of strategies is being used for polio eradication. These strategies must ensure that immunity remains high and susceptibility low everywhere until there is global agreement to stop vaccinating against polio.

OPV Immunization Schedule for Children under One Year of Age

Age	Minimum Interval Between Doses	Dose
Within 14 days of birth		OPV0
6 weeks	4 weeks	OPV1
10 weeks	4 weeks	OPV2
14 weeks	4 weeks	OPV3

Routine immunization. National immunization programs in all countries should immunize at least 90% of infants by one year of age with four doses of OPV through routine immunization services.

Supplemental immunization through national immunization days. To interrupt wild poliovirus circulation in endemic countries, routine polio vaccinations should be supplemented by national immunization days (NIDs). During NIDs, all children less than five years of age should receive OPV, regardless of their immunization status.

In most countries that have been able to interrupt transmission, two rounds of NIDs each year, spaced four weeks apart, were repeated for three consecutive years. In countries with continuing transmission, low routine OPV immunization, and high population density, as many as five rounds of NIDs have been required. Sometimes, door-to-door vaccination has been used to try to reach all children.

What Is Polio Eradication?

Polio eradication has been defined as the absence of cases and the absence of wild poliovirus everywhere in the world.

Sub-national immunization days (SNIDs) and local immunization days (LIDs) should be used to reach children in high-risk areas. The frequency and geographic scope of SNIDs and LIDs should reflect the epidemiology of polio in the country or neighboring countries.

Acute flaccid paralysis surveillance and laboratory investigation. AFP surveillance should be established in all polio-endemic or recently polio-endemic countries to ensure that all cases of polio are detected. According to WHO guidelines, the goal of AFP surveillance is to report and investigate "any case of acute flaccid (floppy) paralysis, including Guillian-Barre Syndrome, in a child less than 15 years and any case of suspected polio in persons of any age."

All AFP cases within the above definition should be reported immediately and investigated within 48 hours. Two stool samples should be collected 24 to 48 hours apart and within 14 days of paralysis onset for laboratory analysis. A follow-up visit to the patient should be made after 60 days.

Mop-up campaigns. Mop-up campaigns are intended for the most difficult-to-reach children in areas where wild poliovirus transmission is occurring. Immunization teams go from door to door over a large geographic area to administer two doses of OPV (at a four-week interval) to all children less than five years of age, regardless of their immunization status. Mop-up activities may also include an active search for new AFP cases.

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Tetanus


Credit: WHO

Tetanus is a common cause of neonatal and maternal mortality wherever maternal protection with tetanus toxoid is low and clean umbilical cord care practices are not followed.

Tetanus, also known as lockjaw, is caused by a bacillus (*Clostridium tetani*) that is present in the soil and in animal and human feces. After entering the body through a wound, the bacterium produces a toxin that makes muscles rigid, causes spasms, and makes breathing difficult or impossible, resulting in death. It is the only vaccine-preventable disease that is not spread from person to person.

A typical feature of the spasms associated with tetanus is the facial expression known as "risus sardonicus," or sardonic smile, as shown in the photograph.

Identification

Neonatal tetanus affects newborn babies and results from contamination with tetanus spores that occurs when babies are delivered in unclean conditions.

WHO-Recommended Case Definition: Neonatal Tetanus

Suspected case: Any neonatal death between three and 28 days of age in which the cause of death is unknown; or any neonate reported as having suffered from neonatal tetanus between three and 28 days of age and not investigated.

Confirmed case: Any neonate with a normal ability to suck and cry during the first two days of life, AND who, between three and 28 days of age, cannot suck normally AND becomes stiff or has spasms (i.e., jerking of the muscles), or both.

Note: The basis for case classification is entirely clinical and does not depend upon laboratory confirmation. Neonatal tetanus cases reported by physicians are considered confirmed. However, investigators should review neonatal tetanus case records during annual hospital record reviews.

Source: WHO

Maternal tetanus strikes women during pregnancy or within six weeks of the termination of pregnancy. Women are exposed to tetanus when non-sterile instruments or objects are used during and after delivery, including during non-sterile abortions.

Childhood and adult tetanus can result from contaminated wounds. Tetanus toxoid in a variety of formulations protects against tetanus.

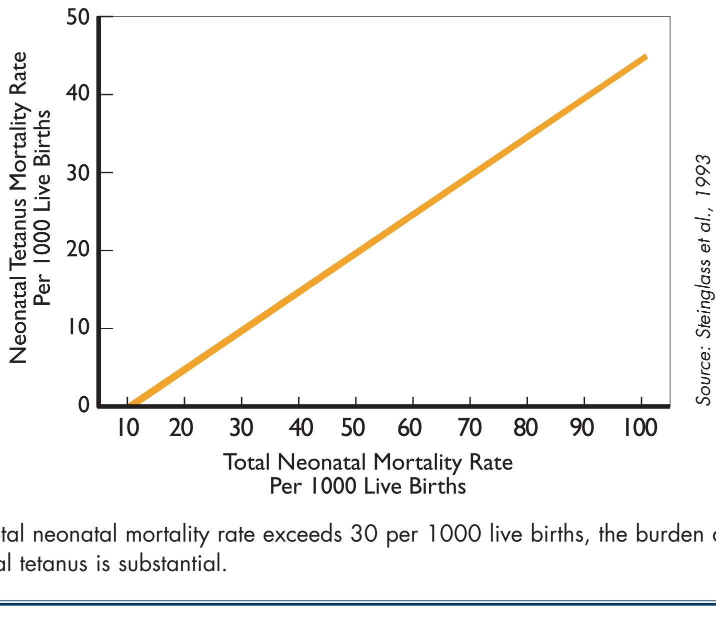
Transmission – Tetanus is not contagious. The disease can occur in any incompletely immunized person when tetanus spores in dirt, dung, or ashes enter a person's body through a break in the skin. Clusters of cases are sometimes seen among unimmunized populations sharing the same risk factors, e.g., delivery care from a practitioner who uses unsafe practices.

Population at Risk – Everyone who is unprotected through immunization is at risk.

Estimated Morbidity and Mortality – Every year, an estimated 200,000 infants die from tetanus in their first month of life. Only 5% of cases are reported because health workers seldom see infants who die at home soon after birth. Neither the birth nor the early death will be registered in vital events systems. The case fatality rate of tetanus is approximately 80%. In addition, maternal tetanus causes an estimated 30,000 deaths per year.

As shown in the graph, the proportion of neonatal tetanus deaths to total neonatal mortality does not stay constant. In high-mortality environments, neonatal tetanus is invariably a big killler of children. This is not the case in low-mortality environments such as Europe and the Americas. There are many

Tetanus as a Cause of Neonatal Mortality



If the total neonatal mortality rate exceeds 30 per 1000 live births, the burden due to neonatal tetanus is substantial.

reasons for this. Neonatal tetanus declines as socioeconomic conditions, including sanitation and personal hygiene, improve; the proportion of the population engaged in agriculture diminishes; agriculture becomes mechanized and chemical fertilizers replace use of animal manure; fertility declines; childbirth becomes more hygienic; and the use of preparations containing tetanus toxoid increases. However, without waiting for these general improvements in socioeconomic conditions, one of the most rapid and efficient ways to reduce neonatal mortality in high mortality environments is to tackle the problem of neonatal tetanus through better immunization coverage.

Occurrence – Tetanus occurs worldwide. Maternal and neonatal tetanus are considered public health problems in 57 countries.

The following characteristics may indicate that tetanus is a problem in a particular location:

- Low tetanus toxoid vaccination coverage among women
- Poor access to or use of any health service
- Poor access to or use of antenatal care services
- Home deliveries not assisted by skilled attendants
- Population engaged in agriculture
- Proximity of farm animals
- Low literacy levels and low income

These areas are often "silent areas" where disease surveillance is weak and people do not notify health workers of tetanus cases or deaths.

Treatment – Excellent 24-hour-a-day nursing care and careful use of drugs can reduce the case fatality rate in neonatal tetanus from 80% to 50% or lower.

Recovery from tetanus does not provide immunity.

Tetanus Toxoid

Tetanus can be prevented if the client receives sufficient doses of vaccine, appropriately spaced.

Form and Presentation – Tetanus toxoid is available in different formulations for different age groups, as shown below.

Tetanus Toxoid Presentations		
Presentation	**Antigens**	**Primary Age Group**
DTP	Diphtheria toxoid, tetanus toxoid, pertussis vaccine	Children under one year of age
DT	Diphtheria toxoid and tetanus toxoid	Children through six years of age
Td	Tetanus toxoid with reduced diphtheria content	Children seven years of age and older, and adults
TT	Tetanus toxoid	Adults

Tetanus toxoid is also available as DTP in combination with hepatitis B and/or Hib vaccines.

Efficacy – After a primary series of three tetanus toxoid doses, clinical efficacy is virtually 100%. Protection falls over time and routine boosters are recommended every 10 years.

Side Effects

DTP vaccine: Mild fever and pain are common reactions; many infants also have a mild local reaction with redness and swelling. Rarely, severe systemic reactions, such as seizures, neurological complications, and anaphylaxis, follow DTP vaccination.

Tetanus toxoid: The most common reported event following tetanus toxoid vaccination is a local reaction and pain, which increases in frequency and severity with the number of doses a person receives. Serious reactions to tetanus toxoid are rare.

Tetanus Toxoid Does Not Cause Abortion or Sterilization

Because tetanus toxoid is given to women of childbearing age, some people incorrectly perceive it to be a method of birth control or sterilization. Health workers need to find out whether this is believed in their areas and to correct any misinformation. Respected local leaders may be especially useful in getting the right information to the community.

Contraindications – There are no contraindications to DTP. However, DTP, DT, and Td should not be given to individuals who have suffered a severe reaction to a previous dose. DTP should not be given to children seven years of age or older.

There are no contraindications to tetanus toxoid; it is safe to give it at any time, even in the first trimester of pregnancy.

Schedules and Target Ages – For the prevention of tetanus in infants and children, three doses of DTP should be given at six, 10, and 14 weeks of age.

If a child does not get the second dose of DTP at the scheduled time, it should be given at the earliest opportunity, and the third dose should be given after a four-week interval. Children do not have to begin a series of vaccinations again if a dose is delayed.

DTP Immunization Schedule for Children under One Year of Age		
Age	**Minimum Interval Between Doses**	**Dose**
6 weeks		DTP1
10 weeks	4 weeks	DTP2
14 weeks	4 weeks	DTP3

For the prevention of tetanus in women through their childbearing years and in their newborns, women should receive five doses of tetanus toxoid. The table below shows the schedule by dose and the length of protection provided.

Td can be used instead of TT to protect against both tetanus and diphtheria.

Women who have received three doses of DTP during childhood or additional doses of tetanus toxoid-containing vaccine during their school years do not need all five doses of TT in adulthood for protection. They must retain their vaccination cards for health workers to determine the number of additional doses they do need.

Tetanus Toxoid Immunization Schedule		
Dose	**When To Give**	**Expected Duration of Protection for Woman**
TT1	As early as possible in pregnancy, or at first contact when a girl reaches childbearing age	None
TT2	At least four weeks after TT1	One to three years
TT3	At least six months after TT2 or in next pregnancy	Five years
TT4	At least one year after TT3 or in next pregnancy	10 years
TT5	At least one year after TT4 or in next pregnancy	All childbearing years

Administration of Tetanus Toxoid-Containing Vaccines

DTP: The 0.5 ml dose of DTP is injected intramuscularly, usually into the outer part of the thigh.

TT: Each 0.5 ml dose is injected intramuscularly into the upper arm.

Booster Doses of DTP after a Child's First Year – For longer-lasting protection, countries that have reached high coverage with the primary DTP series may give one or two booster doses after children reach one year of age. The booster dose can be in the form of DTP or DT. When one booster is given, it is administered in the second year of life. When two are given, the first injection is given in the second year, and the second between four and six years of age.

DTP should not be given to children after they reach the age of seven years due to the increased risk of adverse reactions to the pertussis component for older children. These children should be given DT or Td.

Maternal and Neonatal Tetanus Elimination Strategies – Because tetanus spores are found in the environment, tetanus cannot be eradicated. However, it can be eliminated as a public health problem.

Maternal and Neonatal Tetanus Elimination – Definitions

Neonatal tetanus elimination is defined as the reduction of neonatal tetanus cases to fewer than one case per 1000 live births in every district of every country.

Because maternal tetanus elimination has not been defined, the achievement of neonatal tetanus elimination is used as a proxy for maternal tetanus elimination.

UNICEF, WHO, and the United Nations Population Fund (UNFPA) have joined together to support the achievement of maternal and neonatal tetanus elimination by 2005. To achieve this goal, the organizations recommend two strategies:

- The administration of three doses of tetanus toxoid to at least 80% of all women of childbearing age in districts at highest risk. The interval between the first and second dose is a minimum of four weeks. Between the second and third dose, the minimum interval is six months. Three doses at appropriate intervals will provide immunity lasting at least five years.
- Health education and promotion of clean delivery practices focusing on the "three cleans": clean hands (washing hands with soap and water), clean delivery surface, and the use of clean instruments to tie and cut the umbilical cord.

Identification of High-Risk Areas

High-risk areas are districts with a reliable reported or estimated rate of neonatal tetanus cases greater than one case per 1000 live births.

If neonatal tetanus surveillance is not sensitive enough to rely on a count of cases, planners find out whether 70% or more deliveries are made by a physician, nurse, or trained midwife. This is defined as a "clean delivery."

If clean delivery coverage is lower than 70%, planners look at TT2+ coverage, which, if below 80%, makes the district high-risk.

Because tetanus cannot be eradicated, health officials must take steps to maintain the status of elimination year after year. To do this, UNICEF, WHO and UNFPA recommend:

- Routine vaccination of pregnant women with tetanus toxoid.
- Routine vaccination of infants with DTP.
- Access to and use of clean delivery services.
- Surveillance to identify high-risk areas, assess service quality, and monitor the maintenance of elimination status.
- School-based vaccination programs with Td or TT.

School-Based Immunization

Immunization of schoolgirls and schoolboys with one dose of TT or Td annually during the first three years of primary school protects them from tetanus during their childhood and young adulthood. Immunization of the schoolgirl population helps to prevent maternal and neonatal tetanus for first-time mothers and young women at risk.

The school-based strategy is effective only where a high proportion of girls attends primary school.

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Tuberculosis

Credit: WHO

Tuberculosis (TB) is a chronic disease that affects people of all ages and is one of the most important public health problems worldwide. National routine immunization programs use the Bacillus Calmette-Guérin (BCG) vaccine to prevent miliary and meningeal TB in the first years of life. BCG offers limited protection against tuberculosis in older children and adults.

Identification – TB is caused by *Myobacterium tuberculosis*. It usually attacks the lungs, but other parts of the body can also be affected, including the bones, joints, and brain. While nearly half of a developing country's population may be infected, only one-half to 1% of these individuals will show radiological evidence of the disease.

WHO-Recommended Case Definition: Tuberculosis

Tuberculosis suspect: any person who presents with symptoms or signs suggestive of tuberculosis, in particular cough of long duration.

Case detection: the activity of identifying infectious cases, mainly among adults attending an out-patient health facility for any reason with cough for two or three weeks or more, through sputum smear examination.

Case Definitions

A case of tuberculosis: a patient in whom tuberculosis has been bacteriologically confirmed, or has been diagnoses by a clinician.

Note: Any person given treatment for tuberculosis should be recorded.

A definite tuberculosis case: a patient with culture positive for the *Mycobacterium tuberculosis* complex (in countries where culture is not routinely available, a patient with two sputum smears positive for acid-fast bacilli [AFB] is also considered a "definite" case).

Transmission – TB is spread through the air when a person with the disease coughs, spits, or sneezes. Because it is highly contagious, it spreads rapidly where people are living in crowded situations, are poorly nourished, and cannot obtain treatment.

Children can contract tuberculosis any time after birth. Infection is almost always transmitted from another family member and frequently takes place before the source case knows that he or she has the disease.

Population at Risk – The disease is most commonly seen in adults but affects infants, children, and adolescents as well and is often more serious for younger people. Infants are more likely than adults to contract miliary and meningeal TB, which attack vital organs and are usually fatal.

Estimated Morbidity and Mortality – Nearly two million people die from tuberculosis each year. It is estimated that nearly 1% of the world's population is newly infected with tuberculosis each year.

Occurrence – TB occurs all over the world. Industrialized countries showed downward trends in incidence for many years until the 1980s, when morbidity remained stable or increased in areas with an elevated prevalence of HIV infection. Developing countries also are experiencing increases in incidence of TB associated with high rates of HIV infection.

Treatment – Patients with TB formerly required expensive and long-term care, but many people did not stay with their treatment course long enough to be cured. At the same time, they became resistant to anti-tuberculosis drugs. In response, the "DOTS" strategy was developed for both treatment and control. DOTS (Directly Observed Treatment – Short-course) is a standardized short course of chemotherapy.

BCG Vaccine

BCG vaccine protects infants infected with TB from progressing to more dangerous forms of the disease and gives them some protection against recurrence at a later age. BCG does not prevent TB itself and provides little protection against the pulmonary forms. It is not recommended for adults.

The First Step toward a Fully Immunized Child

BCG coverage rates are the highest of all vaccines because it is a single-dose vaccine given at or soon after birth, when children are more likely to be in contact with the health care system than later in life. When this encounter with the health system is a satisfactory one for the parents, they are likely to return for other vaccinations and other health services.

Form and Presentation – BCG vaccine is freeze-dried, so it must be reconstituted with BCG diluent made by the same manufacturer as the vaccine. Like other reconstituted vaccines, BCG has a short life span and, once reconstituted, must be used or disposed of within six hours.

Efficacy – Vaccination of uninfected children with BCG vaccine can provide protection for more than 90%, but the protective effect varies.

Side Effects – An injection of BCG vaccine normally results in a small sore approximately the diameter of a pencil. The sore usually heals by itself and leaves a small round scar, which health workers look for to determine whether a child has been effectively immunized. However, the absence of a scar does not mean that the BCG vaccination did not work.

When given properly, BCG vaccine has no side effects other than the ulceration described above. However, local reactions, such as abscesses and inflammation of the lymph glands, may occur if too much vaccine is given or the vaccine is injected under the skin instead of in its top layer.

Contraindications – BCG should be given to all infants, even if their mothers have HIV, unless an infant shows HIV/AIDS symptoms, which is highly unlikely. Since testing infants for HIV before they are vaccinated is generally not feasible, virtually all newborns should receive BCG.

This practice will protect HIV-positive and -negative children who are at high risk of exposure to tuberculosis because their mothers are HIV-infected.

Schedule and Target Age Group – All countries with a high incidence of TB infection should routinely immunize infants with a single dose of BCG at birth. If not given at birth, BCG may be given at the infant's first contact with the health system.

BCG Injections

Health workers say that BCG is the most difficult vaccine to administer because newborns' arms are so tiny and the vaccine must be injected intradermally, that is, in the topmost layer of the skin. Health workers need extensive and continuing practice to master this skill.

A short narrow needle (15 mm, 26 gauge) is needed for this injection. All other vaccines are given with a longer, wider needle (commonly 25 mm, 23 gauge), either subcutaneously or intramuscularly.

Administration – The 0.05 ml dose of BCG is injected intradermally into the upper arm, just below the deltoid insertion site. Some vaccine manufacturers recommend a 0.1 ml dose for children older than 12 months presenting for their first dose. Health workers administer BCG in the same place on every child so that their colleagues know where to look for the BCG scar. The presence of such a scar has been used as evidence for prior BCG vaccination.

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Yellow Fever

Yellow fever is a viral hemorrhagic fever transmitted by infected *Aedes aegypti* mosquitoes in tropical and subtropical areas. Outbreaks with major public health impact may occur suddenly, with case fatality rates ranging from 20% up to 60%.

Identification – Yellow fever begins with a sudden onset of fever and chills, head, back and muscle pain, nausea, and vomiting. These may progress to jaundice and hemorrhaging.

> **WHO-Recommended Case Definition: Yellow Fever**
>
> **Clinical description:** An illness characterized by acute onset of fever followed by jaundice within two weeks of onset of first symptoms and one of the following: 1) bleeding from nose, gums, skin, or gastrointestinal tract; or 2) death within three weeks of illness onset.
>
> **Laboratory criteria for diagnosis:**
>
> - Isolation of yellow fever virus, or
> - Presence of yellow fever-specific IgM or a fourfold or greater rise in serum IgG levels, or
> - Positive post-mortem liver histopathology, or
> - Detection of yellow fever antigen in tissues by immunohistochemistry, or
> - Detection of yellow fever virus genomic sequences in blood or organs by PCR.
>
> *Source: WHO, 1998*

Transmission – The agent that causes yellow fever is a mosquito-born virus that has three transmission cycles, sylvatic, intermediate and urban. All three types exist in Africa; only sylvatic and urban exist in South America. The transmission of yellow fever within these cycles ranges from causing sporadic cases to severe urban epidemics.

Sylvatic or jungle yellow fever occurs when monkeys living in tropical rain forests are infected with yellow fever by wild mosquitoes; yellow fever is then transmitted from monkeys to other mosquitoes. The infected mosquitoes can then bite humans who enter the forest for hunting, logging, or other activities, resulting in sporadic cases of yellow fever.

Intermediate yellow fever transmission occurs in humid or semi-humid savannahs of Africa and can produce small-scale epidemics in rural villages. Semi-domestic mosquitoes can infect both monkey and human hosts, and increased contact between humans and infected mosquitoes leads to an increase in disease. This is the most common type of outbreak seen in Africa in recent decades.

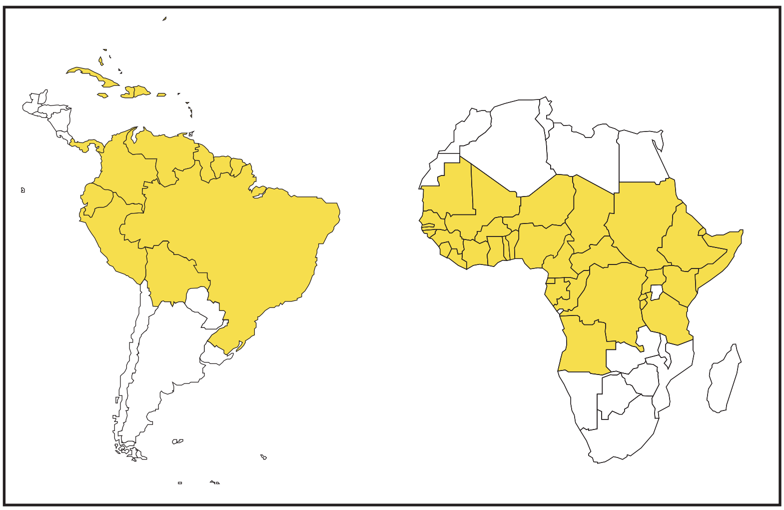
Urban yellow fever results in large explosive epidemics when travelers from rural areas introduce the virus into urban areas with high human population densities. Domestic mosquitoes, the *Aedes aegypti*, carry the virus from person to person. These outbreaks tend to spread outward from one source to cover a wide area.

Population at Risk – In the Americas, yellow fever occurs predominantly in adult males, 20 to 40 years old, who are exposed to the disease in the jungle. In Africa, the disease attacks all ages and both sexes.

Estimated Morbidity and Mortality – Yellow fever surveillance is poor, and the disease is seriously under-reported. Although fewer than 5000 yellow fever cases were actually reported in 2000, WHO estimates that, in sub-Saharan Africa alone, 200,000 cases and 30,000 deaths are attributable to yellow fever every year.

Occurrence – In 2001, more than 30 countries were considered at risk for yellow fever in Africa. These countries are located in a band 15°N to 10°S of the equator. In the same year, nine South American countries and several Caribbean islands were at risk of the disease.

Areas at Risk for Yellow Fever



Treatment – Although there is no approved and accepted antiviral medication for the treatment of yellow fever, supportive care to increase hydration and prevent hypoglycemia can improve the outcome.

Yellow Fever Vaccine

Immunization of children who are nine months of age or older with 17D yellow fever vaccine is the best protection. Inclusion of older age groups may be appropriate among populations and within areas at high risk of epidemics. A single dose provides protection against the disease for at least 10 years and often for 30 years or more.

Form and Presentation – Yellow fever vaccine is freeze-dried, so it must be reconstituted with yellow fever diluent made by the same manufacturer. Once the vaccine is reconstituted, it must be used or disposed of within six hours.

Efficacy – An injection of yellow fever vaccine is effective in almost 99% of recipients.

Side Effects – Children may get fever, headache, or mild muscle and joint pain after an injection of yellow fever vaccine.

Encephalitis has been reported following yellow fever vaccination of a few infants younger than six months, leading to the recommendation that the vaccine not be given before that age, even in an outbreak.

In those rare cases when yellow fever vaccine causes severe systemic disease, it is only in adults.

Contraindications – There are no contraindications for giving yellow fever vaccine to children older than six months of age, except for HIV. WHO recommends that yellow fever vaccinations should not be given to patients with symptomatic HIV infection or to pregnant women.

Schedule and Target Age Group – One dose should be given to children at nine months of age, at the same time as measles vaccine.

Administration – The 0.5 ml dose is given subcutaneously in the upper right arm.

Control Strategies – At-risk countries should offer immunization against yellow fever on a routine basis to infants. With support available from GAVI, more programs are setting up routine systems for yellow fever vaccinations.

In addition to immunization, the destruction of mosquito breeding sites and the use of insecticide-treated bednets reduces the mosquito population thereby reducing transmission of mosquito-born diseases such as yellow fever, dengue fever, and malaria.

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Vitamin A Deficiency


Credit: Mizan Siddiqi

Vitamin A deficiency (VAD) occurs when an individual's diet does not contain enough vitamin A for growth, development, and physiological functions. It may be exacerbated by infections such as malaria and measles and by parasites such as hookworm. Related vitamin A deficiency disorders (VADD) include subclinical and clinical problems. Mortality and morbidity caused by these disorders increase with the severity of deficiency.

Identification – In 2001, the International Vitamin A Consultative Group (IVACG) issued the criteria shown in the table below for assessing the extent and severity of vitamin A deficiency in populations.

Prevalence Criteria Indicating Significant Vitamin A Deficiency		
Clinical Criteria		
Population Group	**Indicator**	**Prevalence (%)**
Children 2 to 5 years of age	Night blindness	>1.0
	Bitot's spots	>0.5
	Corneal xerosis and corneal scars	>0.01
	Corneal scars	>0.05
Women of childbearing age	Night blindness during recent pregnancy	>5.0
Biochemical Criteria		
All age groups	Serum retinol <0.7 umol/L (20ug/dL)	>15

Source: International Vitamin A Consultative Group (IVACG), 2001

Transmission – Vitamin A deficiency is not contagious.

Population at Risk – Young children and women of childbearing age in low-income countries where intake of vitamin A is inadequate are most at risk.

Estimated Morbidity and Mortality – In the mid-1990s, xerophthalmia (which includes eye problems ranging from night blindness through corneal scars) was estimated to affect more than three million children annually. Subclinical vitamin A deficiency, which has no signs or symptoms, affected 150 to 200 million. At least one million deaths of young children are attributed to VAD every year.

Occurrence – Vitamin A deficiency occurs widely where diets are deficient in nutritious foods. Recent evidence indicates that the predominantly plant-based diets in many developing countries are unlikely to provide adequate amounts of vitamin A to meet the needs of young children.

The problem of VAD is particularly acute for infants because they are born with virtually no stores of vitamin A. Breastmilk as an infant's first and only food can provide this nutrient, but where maternal vitamin A status is poor, breastfed infants are likely to be subclinically deficient in vitamin A by six months of age.

Vitamin A Treatment for Xerophthalmia in Infants and Children

Target Group	Vitamin A dosage (IU)	Schedule
Young infants (0-5 months)	50,000	Three doses administered on days 1, 2 and 14 following diagnosis
Older infants (6-11 months)	100,000	
Children (males — 12 months or more; females — 12 months to 12 years)	200,000	

Treatment – Children with measles should be treated with two doses of vitamin A on consecutive days; the size of the doses depends on the age, as shown in the table above. A third dose should be given two to four weeks later, if there are signs of xerophthalmia. Children with severe malnutrition should be given age-appropriate doses on two consecutive days.

Women of childbearing age with night blindness or Bitot's spots should receive daily doses of not more than 10,000 IU or weekly doses of not more than 25,000 IU for at least three months duration. If a woman shows acute corneal lesions, she should receive a dose of not more than 200,000 IU on days one, two, and 14 after diagnosis.

Vitamin A Supplementation

Vitamin A supplementation for infants, children, and postpartum women is used as a preventive strategy until all members of the population are certain to get an adequate intake of vitamin A through breastfeeding, improved diet with dark green or yellow vegetables, and food fortification.

Two 200,000 IU doses of vitamin A should be given to women within six weeks after delivery at least 24 hours apart. This will benefit the woman, replacing the losses from her vitamin A stores caused by pregnancy and lactation. It will also benefit the infant by increasing breast milk and infant serum retinol concentrations.

Form and Presentation – Vitamin A is usually given in an oil-based solution in soft gelatin capsules that contain 50,000, 100,000, or 200,000 IU. The capsules should be kept dry and out of direct sunlight, but it is not necessary to keep them in the cold chain. They should not be frozen.

Side Effects – High-dose vitamin A supplements cause nausea, vomiting, and headache in 3 to 9% of children aged one to four years, but these side effects resolve spontaneously within 48 hours. In neonates and young infants under the age of 6 months, about the same percentage may develop a transient bulging fontanelle; this also subsides within 24 to 72 hours.

Contraindications – Women who are pregnant, or who may become pregnant, should not consume more than 10,000 IU per day or 25,000 IU per week.

Schedule and Target Age Group

Schedule for Routine Vitamin A Supplementation in Vitamin A-Deficient Populations

Target Group	Size of Dose	Time of Administration
Infants 6-11 months old	100,000 IU in a single dose	At any opportunity (e.g., measles immunization)
Children 12 months and older	200,000 IU in a single dose every four to six months	At any opportunity
Postpartum women	Two doses of 200,000 IU at least one day apart and/or 10,000 IU daily or 25,000 IU weekly	As soon after delivery as possible and not more than six weeks later and/or during the first six months following delivery

Source: International Vitamin A Consultative Group (IVACG), 2001

Supplementation Strategies – In more than 60 developing countries, vitamin A supplementation has been incorporated into NIDs for polio. Integration of vitamin A with NIDs has been widely accepted by families and, in most cases, has resulted in high coverage for vitamin A supplementation.

As NIDs are phasing out with progress toward polio eradication goals, health officials are trying to integrate vitamin A supplementation into the routine immunization schedule and distribute supplements through periodic outreach (e.g., health weeks or days).

A Model for Delivery of Vitamin A Supplementation

The National Vitamin A Supplementation Program in Nepal has achieved high coverage throughout the country, and it appears that this coverage can be sustained. The success of the program has been attributed to: phased-in implementation, technical support by a national NGO (Nepali Technical Assistance Group), and participation of volunteers that have been serving children and families since 1988.

Recognizing the importance of training the Female Community Health Volunteers (FCHVs) to provide quality services, the government of Nepal began vitamin A distribution in 32 high-priority districts instead of trying to launch the program countrywide immediately. The national program supported training, logistics, and community mobilization in the selected districts prior to the first distribution and later assisted with refresher training managed by district staff. After the first two distribution rounds, districts manage subsequent rounds with minimal additional input from the program, which goes on to support new districts.

Community involvement also plays a role. The national program first collected data from focus groups and key informants and developed an overall strategy based on the findings. The program encouraged districts to review the findings and decide what methods might work best in their districts. Parades, involvement of schools, magic shows, and involvement of local political leaders were used. Today, the program is so well known that once distribution dates are known, parents and other caregivers need little prompting to participate.

Now, more than 40,000 FCHVs administer a round of vitamin A supplements to children six to 60 months of age every six months throughout Nepal, and they are reaching 94% of the target population. This distribution is independent of polio NIDs.

Source: R. Houston, 2002

To date, coverage has been far higher using periodic outreach than through integration, as illustrated by the example below.

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Available Vaccines Not Widely Used in Developing Countries

Some vaccines now available are not widely used in developing countries for a variety of reasons:

- The magnitude of the disease does not justify routine vaccination.
- Routine immunization services may not be strong enough to support the introduction of more vaccines.
- The vaccine may not be effective enough.
- The limited resources available go to other priorities.

The following table provides information concerning these vaccines and the diseases they prevent.

Available Vaccines Not Widely Used in Developing Countries				
Disease and Agent	**Identification**	**Trans-mission**	**Occurrence and Incidence**	**Effectiveness and Limitations of Available Vaccines**
Chickenpox Virus	An acute, generalized viral disease with sudden onset of slight fever, rash, and malaise Can result in secondary bacterial and other complications, including skin lesions, dehydration, pneumonia, and central nervous system involvement Virus can stay in body after primary infection and lead to herpes zoster (shingles)	Most commonly, person to person via infected respiratory tract secretions	Worldwide Among children 1-14 years of age, case fatality rate is one per 100,000 cases. In adults 30-49 years of age, the case fatality rate is over 25 per 100,000 cases.	Live attenuated viral vaccine Effectiveness estimates range from 80% to 90% against infection; 95% against severe disease. Routine vaccination of children from age 12 to 18 months is now carried out in some industrialized countries.
Cholera Bacterium *Vibrio cholerae*	An acute bacterial enteric disease characterized by sudden onset, profuse painless watery stools, nausea, and vomiting in the early course of illness. If untreated, cholera leads to rapid dehydration, acidosis, circulatory collapse, hypoglycemia, and renal failure.	Ingestion of contaminated food or water	Worldwide In severe untreated cases, death may occur within a few hours and the case fatality rate may exceed 50%. In the 1990s, outbreaks occurred in South America, Zaire, and India.	The killed cholera vaccine that was formerly used is no longer recommended because it provides only partial protection of short duration. Oral vaccines that provide significant protection against certain cholera strains have recently become available in several countries. However, these vaccines do not protect against all new cholera serogroups.
Hepatitis A Virus	Abrupt onset with fever, malaise, anorexia, nausea, and abdominal discomfort followed by jaundice. Often asymptomatic or mild in children in developing countries, but can be severely disabling, and relapses can occur for one year. No chronic infection.	Person to person by the fecal-oral route.	Worldwide In developing countries, adults are usually immune and epidemics are uncommon, but adults become more susceptible as hepatitis A incidence decreases.	Several inactivated vaccines are available that are safe and almost 100% effective, but these are not licensed for children under two years of age.

Disease and Agent	Identification	Transmission	Occurrence	Vaccines Available Effectiveness and Limitations of Vaccines
Mumps – Infectious parotitis Virus	Fever, swelling, and tenderness of one or more salivary glands. Common complications include central nervous system involvement and testicular inflammation in post-pubescent males.	Airborne transmission, droplet spread, and by direct contact with saliva of an infected person	Worldwide Deaths due to mumps are rare.	Live attenuated vaccine is available as a monovalent vaccine or in combination with measles and rubella (MMR). Mumps vaccine is highly effective, but including it in national childhood immunization programs often has low priority.
Rabies Virus	Begins with sense of apprehension, headache, fever, malaise, and indefinite sensory changes; progresses to paresis or paralysis, spasm of swallowing muscles, fear of water; delirium, and convulsions	Virus-laden saliva of a rabid animal introduced by a scratch or bite	Worldwide If left untreated, rabies is almost always fatal. Causes an estimated 35,000 to 40,000 deaths a year, mostly in developing countries	Vaccines are available for pre-exposure vaccination and post-exposure treatment. WHO recommends vaccination of : • Individuals at high risk because of their occupations (e.g., veterinarians, wildlife conservation personnel, and park rangers). • Children five to 15 years of age in developing countries where canine rabies is endemic and not well controlled and where rabies immune globulin for post-exposure treatment is not available. • Dogs, cats, and other animal hosts.

Disease and Agent	Identification	Transmission	Occurrence	Vaccines Available Effectiveness and Limitations of Vaccines
Rubella (German measles) Virus	Mild rash disease in children. If rubella is contracted in the first three months of pregnancy, the consequence is fetal death or congenital rubella syndrome (CRS). CRS is characterized by blindness, deafness, brain damage, and heart defects.	By droplets or direct contact with patients Where childhood transmission is widespread, few women of childbearing age are susceptible. Where transmission is moderate, more women will be susceptible.	In developing countries, 250,000 babies are born per year with CRS. In epidemic years, incidence may increase ten times.	Live attenuated vaccine • Monovalent vaccine • Combination with mumps (MR) • Combination with mumps and measles (MMR) Rubella vaccine should be introduced only where routine immunization coverage can be sustained at 80% or higher. Lower coverage with rubella vaccine increases rather than decreases the susceptibility of women of childbearing age, by shifting infection to older ages.
Typhoid fever, paratyphoid fever Bacterial organisms	Insidious onset of sustained fever, severe headache, malaise, anorexia, a slow heart rate, enlargement of the spleen, and other symptoms	Contaminated food and water	Worldwide Annual incidence approximately 17 million cases, with 600,000 deaths	Available vaccines are safe and effective in individuals above five years of age, but further studies are needed to test the value of these vaccines for children under five years in national immunization programs.

Adapted from Chin, James. 2002. Control of Communicable Diseases Manual. Washington DC: American Public Health Association and Epidemiology and Prevention of Vaccine-Preventable Diseases. 7th edition. Atlanta, GA: Centers for Disease Control and Prevention.

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