ASIAN VACCINATION INITIATIVE

Sri Lanka National Immunization Program

FINANCING ASSESSMENT

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Abbreviations

AD	auto-disable
Atd	adult tetanus and diphtheria vaccine
AEFI	adverse effects following immunization
BCG	anti-TB vaccine
DDHS/MOH	Divisional Director of Health Services/Medical Officer of Health
DPT or DTP	diphtheria and tetanus toxoids and pertussis vaccine
DT	diphtheria and tetanus vaccine
EPI	Expanded Program on Immunization
EPI Unit	Epidemiological Unit
FHB	Family Health Bureau
GAVI	Global Alliance on Vaccines and Immunization
HepB	Hepatitis B vaccine
HIB	Haemophilus influenzae type B
JICA	Japan International Cooperation Agency
MCH	Maternal and Child Health Unit
MOH	Ministry of Health
MR	measles rubella vaccine
MRI	Medical Research Institute
MSF	Médecins sans Frontières
NID	National Immunization Day
NGO	nongovernment organization
OPV	oral polio vaccine
SNID	Subnational Immunization Day
TB	tuberculosis
Td	diphtheria (reduced component) and tetanus vaccine
TT	tetanus toxoid
TRUST	Plantation Housing and Social Welfare Trust
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
WHO	World Health Organization

Executive Summary

This financing assessment of the national immunization program of Sri Lanka was carried out under the Asian Vaccination Initiative and in collaboration with the Government of Sri Lanka.

Since independence, the Government of Sri Lanka has made it a priority to develop an equitable health-care system with a focus on primary health care. As a result, health indicators are excellent, particularly relative to comparable low- or lower-middle-income countries. Immunization has been an integrated component of the primary health care program for 20 years.

The national immunization program of Sri Lanka has an excellent record, with low incidence of EPI disease and high coverage for all EPI vaccines

The national immunization program of Sri Lanka has an excellent record, with low incidence of Expanded Program on Immunization (EPI) disease and high coverage (more than 95 percent) for all EPI vaccines. However, unless the country pays attention to key issues of program quality it could lose the advantages it has gained in disease control over the last 20 years. Consolidation of gains and successful expansion of the program will depend primarily on ensuring that improvements are made in the cold chain and service quality and that hard-to-reach populations have access to quality safe vaccinations.

Rather than being a comprehensive review of the program, this assessment was made to:

- Estimate current and future costs of the program, including the added costs of strengthening and expanding it
- Identify future funding sources, and determine any financing gaps
- Recommend ways of strengthening the program and enhancing its financial sustainability

The assessment was also intended to provide a useful tool for immunization financial planning, policy dialogue, and funding negotiation with donors and international agencies.

It is clear the Government is committed to the immunization program, and since 1998 Sri Lanka has been self-sufficient in vaccine procurement. UNICEF, which has provided funds for supplies and capital equipment, has been the major donor so far although the level of its future support is unclear.

Over a period of five years, the projected minimum cost of implementing the routine immunization program is estimated at $8 million, or between $1.5 million and $1.8 million per year, assuming that the use of sterilizable equipment for injections is maintained. Introducing hepatitis B vaccine, strengthening laboratory capacity and adverse effects following immunization (AEFI) reporting, continuing polio eradication, improving the cold chain and supervision, and completing the upgrade of sterilization equipment would cost an additional $7 million. Of this amount, $3.4 million would go to capital investment and $1.1 million each to the introduction of hepatitis B vaccine and a measles campaign. As yet, there are no confirmed donors for these expenditures, and if the Government funds all core EPI activity and the vaccine for polio eradication there will be a funding gap of about $6.4 million.

Administrative decentralization has made it difficult to form a coherent picture of the total cost of delivering routine immunization services in Sri Lanka. The central Government aggregates historical data only to a limited extent and accounting at all levels is not reported on functional lines.

The projected minimum cost of implementing the routine immunization program over a period of five years is about $8 million, or between $1.5 and $1.8 million a year

The recommendations in this paper concern financing policies and requirements. They take into account the fiscal constraints on the Government and the need to maintain high coverage of quality safe vaccinations. It is recommended that the Government:

- Improve financial sustainability by ensuring full internal funding of all basic operational costs of the routine program
- Minimize cost by considering multi-year planning and procurement contracts, reducing wastage, establishing a national inventory and monitoring system, and undertaking preventive maintenance on equipment
- Mobilize external resources to strengthen the cold chain, upgrade injection equipment, and undertake a measles campaign
- Make the program more accessible to hard-to-reach populations in the north and east and in the estate sector by ensuring that any investment strategy meets their resource needs

Finally, the findings and recommendations of this paper should be viewed in the context of the strategic plan and five-year budget that will follow after the full program review in March 2001. The review was planned to prepare for the Government's application for funding to the Global Alliance on Vaccines and Immunization (GAVI) for the introduction of Hepatitis B vaccine.

Introduction

Purpose

This assessment was made under the Asian Vaccination Initiative (AVI) of the Asian Development Bank.

A coherent analysis of financial requirements, available resources, and financing gaps is an important aspect of medium-term planning

Through this assessment of financing issues in the national immunization program (NIP) of Sri Lanka and a review of existing documentation, this paper seeks to identify the following:

- The financial status of the program, including financing gaps
- Future funding requirements for a routine (or expanded) program
- Sustainable financial options for strengthening the program
- Anticipated and potential funding sources

A coherent analysis of financial requirements, available resources, and financing gaps is an important aspect of medium-term planning.

Methodology

The data used in this report were collected over a period of six weeks, including a two-week field visit to Sri Lanka by the international consultant. Most of the data are national level, obtained through documents and a series of interviews with key government and donor informants at central and provincial level. The appropriate UNICEF officials were unfortunately not in Sri Lanka during the visit.

The cost and financing analyses used data from the central Ministry of Health, particularly its Epidemiological Unit and Family Health Bureau, management reports including the Country Report on the immunization program, the findings of a previous consultant, and country and global logistic reports of UNICEF.

Information used to estimate target populations came from the Epidemiological Unit and the Population Information Center.

Background

The possibility of increased revenue to the public sector in the medium term is limited by the continuing internal conflict and by the high cost of rehabilitating and reinvesting in economic infrastructure once the conflict is resolved

Socioeconomic Situation

Sri Lanka has had an open economy since economic liberalization in 1977. In the mid-1980s and early 1990s economic growth was rapid, and Sri Lanka now ranks as a lower-middle-income country.[1] Despite 17 years of internal conflict the economy has been resilient, recording an average growth rate of 5.2 percent a year during the last decade (see Table 1). In 1999, gross development product (GDP) per capita was $829 (compared with $473 in 1990) and inflation (in Colombo) was 4.7 percent (versus 21.5 percent in 1990).

Increased civil unrest in the late 1980s caused military spending to equal 20 percent of GDP and, exacerbated by high debt service, led to significant increases in the budget deficit. In response, the Government since 1995 has targeted reductions in capital investment and begun extensive privatization. In 1999, all Government programs underwent a 10 percent cut in capital investment. The possibility of increased revenue to the public sector in the medium term is limited by the continuing internal conflict and by the high cost of rehabilitating and reinvesting in economic infrastructure once the conflict is resolved.

Table 1: **Macroeconomic Indicators, 1990 to 1999**

Indicator	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
GDP per capita (US$)	473.0	522.0	557.0	588.0	656.0	719.0	759.0	814.0	839.0	829.0
GDP per capita (PPP$)										3,056.0
GDP growth rate (% change)	6.4	4.6	4.3	6.9	5.6	5.5	3.8	6.3	4.7	4.3
GNP per capita (US$)	469.0	518.0	556.0	588.0	652.0	710.0	748.0	804.0	823.0	807.0
Annual inflation rate (%)										
GNP deflator	20.0	11.1	10.0	9.5	9.4	8.4	12.2	8.7	8.4	4.4
Colombo CPI	21.5	12.2	11.4	11.7	8.4	7.7	15.9	9.6	9.4	4.7
Government expenditure as % of GDP	30.6	31.3	28.0	28.7	28.9	31.0	28.8	26.5	26.3	25.1
Total government health expenditure as % of GDP	1.5	1.4	1.5	1.4	1.6	1.6	1.6	1.4	1.4	1.4
Government health expenditure as % of total government expenditure	5.0	4.7	5.5	4.9	5.5	5.3	5.3	5.1	5.4	5.6

Source: Central Bank of Sri Lanka, annual reports

In 1987, a political solution to the conflict was attempted through the 13th amendment to the constitution, which decentralized the political and administrative system. The Provincial Councils Act in 1989 gave limited power to the provinces, placing each one under an elected Provincial Council. There are now 8 provinces, 25 districts, and 302 divisional sections. The central Government retains control over financial revenue and

[1] World Bank (2000)

The success of the strategy of public/private funding for the health sector has kept Government spending modest but efficient and effective

allocates up to 90 percent of the requirements of the provinces; local taxes must cover the remaining 10 percent. Provinces are not required to report back to the center on their expenditures, reducing accountability and transparency.

Health resource allocation

Consecutive governments since independence have prioritized health and social welfare spending. Policy objectives have addressed income redistribution and poverty alleviation, reflecting the country's long-term commitment to equity. The success of the strategy of public/private funding for the health sector has kept Government spending modest but efficient and effective. Despite recent fiscal pressures, public expenditure on health has averaged 5.5 percent of Government expenditure and 1.5 percent of GDP over the past decade. Community health services received about 15.4 percent of the total budget in 1998. But while health is likely to retain its privileged position in the budget, current economic constraints make any increase unlikely. Funding for capital expenditure in particular will have to come from external sources.

With liberalization, a rapidly growing private health sector has emerged. The sector attracts about half of national health expenditure, largely for outpatient services or the purchase of drugs. This has resulted in national health spending equal to 3.4 percent of GDP (1996).

Demographic and Health Indicators

Sri Lanka has a population of about 19 million, half of this in the southern, central, and western provinces (see Table 2). Seventy-five percent live in the rural areas. The last national census took place in 1981; all demographic figures should therefore be treated as estimates. The next census will be in 2001.

Table 2: **Demographic Indicators, 1990 to 1999**

Indicator	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
Estimated midyear population (millions)	17.0	17.3	17.4	17.6	17.9	18.1	18.3	18.6	18.8	19.0
Crude birth rate	19.9	20.7	20.5	19.9	19.9	18.9	18.6	17.9	17.3	17.3
Crude death rate	5.7	5.5	5.6	5.5	5.6	5.8	6.5	6.1	5.9	6.0
Population growth (annual %)	1.4	1.5	1.0	1.2	1.4	1.1	1.1	1.2	1.2	1.4
Registered live births[a] (thousands)	294	304	357	351	356	343	331	325	324	329
Female population 15–49 years (millions)	4.49	4.58	4.68	4.77	4.86	4.96	5.05	5.13	5.20	5.28
Population under 5 years (millions)	1.65	1.64	1.62	1.61	1.60	1.59	1.57	1.57	1.57	1.57
Fertility rate (total fertility rate)	2.3	2.2	2.2	2.2	2.2	2.1	2.1	2.0	1.9	1.8

Source: Department of Census and Statistics (1999), Abeykoon (1998), and De Silva (1997)
[a] Excludes northern and eastern provinces in 1997, and Kilinochchi and Mullaitive districts of the northern province in 1998; figures for 1997–1999 are provisional

The past decade has witnessed a steady decline in population growth. While the crude death rate has remained stable, the crude birth rate slowed down from 19.9 percent in 1990 to 17.3 percent in 1999 and the fertility rate over the same period from 2.3 to 1.8

Table 3: **Health Indicators, 1990 to 1999**

Indicator	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
Infant mortality rate (per 1,000 live births)	19.5	17.7	17.9	16.3	16.9	16.5	17.3	15.9	—	—
Neonatal mortality rate (per 1,000 live births)	—	12.9	13.0	12.0	12.8	12.5	12.9	—	—	—
Maternal mortality rate (per 10,000 live births)	—	4.2	2.7	2.5	2.1	2.4	2.3	—	—	—
Life expectancy at birth, male	—	69.5	69.5	69.5	69.5	70.7	70.7	70.7	70.7	70.7
Life expectancy at birth, female	—	74.2	74.2	74.2	74.2	75.4	75.4	75.4	75.4	75.4

Source: Department of Census and Statistics (1999) and Abeykoon (1998)

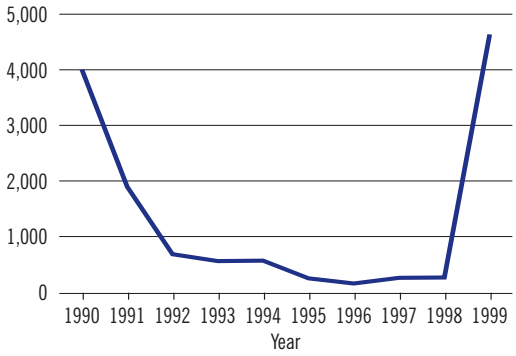
(see Table 3). The demographic shifts that will occur as a result will pose new challenges for the social sector in general, and the health sector in particular.

Sri Lanka's equitable health system has achieved excellent health indicators, particularly relative to comparable low- and lower-middle-income countries. Infant and maternal mortality rates were 17.3 and 2.3, respectively,[2] in 1996, and the proportion of live births in hospitals was 88.8 percent in 1998. Life expectancy reached 70.7 years for males and 75.4 years for females in 1999. However, the nutritional status of children is a persistent problem: 23.3 percent of the children in Sri Lanka are considered chronically malnourished.

Reflecting an epidemiological transition, noncommunicable diseases are on the increase. The primary causes of hospitalization are neoplasm and diseases of the circulatory, genito-urinary, digestive, and nervous systems. Mental health and suicide are also significant health problems. In contrast, hospitalization due to parasitic and respiratory diseases has increased only marginally. HIV/AIDS shows no sign of posing a major public health problem.

The literacy rate in the country, excluding the north and east, is 90.1 percent, but in the plantation estate sector it is only 55 percent.

Figure 1: **Incidence of Measles, 1990 to 1999**



Source: EPI Unit

Vaccine-preventable diseases

High immunization coverage has caused a sharp drop in the incidence of vaccine-preventable EPI diseases in Sri Lanka during the past decade (see Appendix A). No diphtheria or poliomyelitis cases have been reported since 1994, and cases of pertussis continue to decline. Neonatal tetanus has an incidence rate of 0.1 per 100,000 and has effectively been eliminated. Measles fell from 27 per 100,000 in 1990 to 1.4 per 100,000 in 1998, but a widespread outbreak occurred in 1999–2000 with 4,611 clinically confirmed cases (see Figure 1). The prevalence and incidence of Hepatitis B are unknown. A sero-prevalence study in March 2001 will provide data in this regard. The incidence of tuberculosis stayed at 35–39 per 100,000 from 1990 to

[2] Maternal deaths could be underreported by as much as 50 percent.

The politicization of health service management further hampers rational health planning

1998 but then rose to 54 per 100,000 in 1999. The vaccination of high-risk populations has caused the incidence of Japanese encephalitis to drop, from 44 in 1996 to 3 in 1999.

Health System

The broad health goals of the Sri Lankan Government, according to the 1996 national policy statement, are to:

- Further increase life expectancy by reducing preventable deaths due to communicable as well as noncommunicable diseases
- Improve the quality of life by reducing preventable diseases, health problems, and disability, and by emphasizing the positive aspects of health through health promotion

The Cabinet of Ministers, headed by the President, is ultimately responsible for national health policy. The National Health Development Committee, under the Minister of Health, meets monthly to recommend policies to the Cabinet based on inputs sought by the Director General of Health Services from national, provincial, and district senior health managers.

The current policy agenda is largely based on recommendations made in 1997 by the Presidential Task Force for the Implementation of National Health Policy. These recommendations deal primarily with health sector reform, in line with current trends in international health. However, most of the proposals have not been welcomed by the line ministry and public-sector unions, and implementation has therefore been slow.

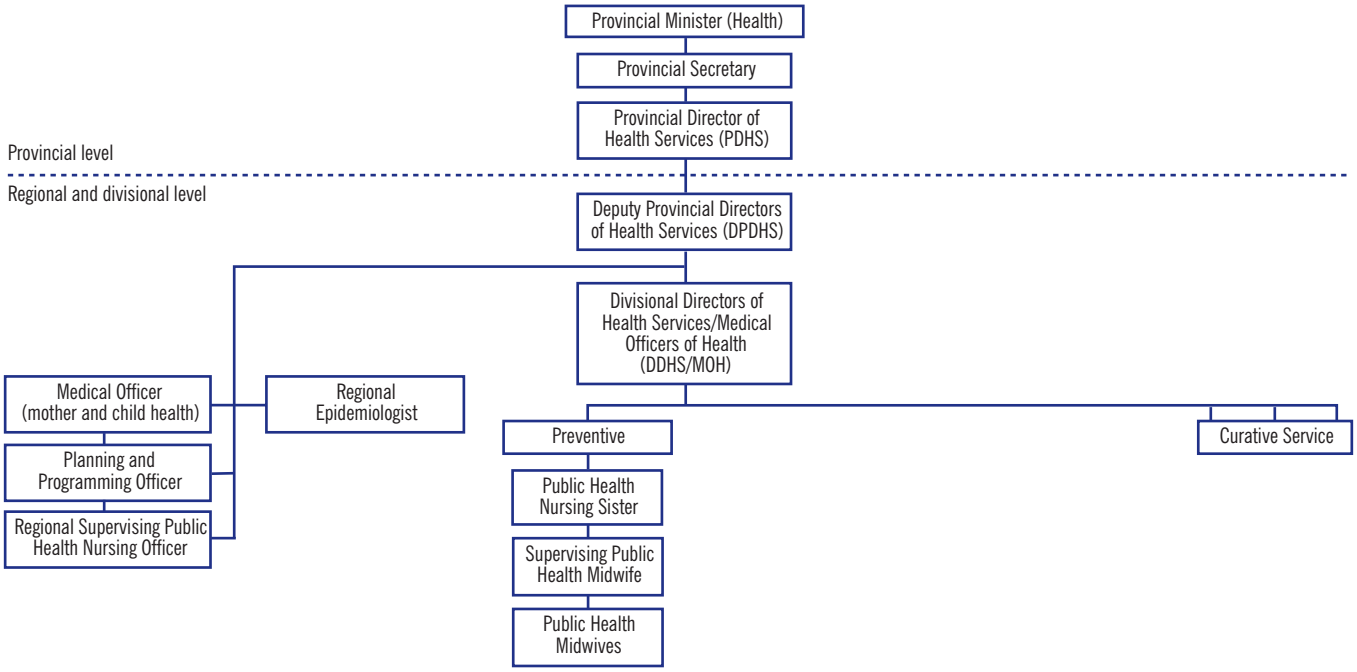
In any case, it has been argued that the health system lacks the capacity to manage organizational reform. The provinces in particular do not have the human and financial resources and the management information systems to plan, manage, and monitor health services. The politicization of health service management further hampers rational health planning.

Structure and decentralization

The devolution of health services under the Provisional Council Act resulted in a Ministry of Health (MOH) at the central level and eight separate provincial ministries of health. Vertical programs were abolished and the role of the central agencies was largely confined to direction setting, giving technical advice, procuring medical supplies in bulk, and monitoring and evaluating the performance of the provincial agencies. National programs (such as that for malaria control) are implemented and supervised by central functional units. The MOH also retained control over teaching and specialized hospitals. The management of all other medical institutions, including primary health care facilities, was transferred to provincial health authorities. Figure 2 shows the provincial health structure as it relates to the immunization program.

Health units (offices of the Divisional Directors for Health Services and the Medical Officers of Health) are responsible for implementing health services in the periphery.

Figure 2: **Organization of Provincial Health Services in Relation to Immunization Services**



Decentralization has also led to duplication and overlapping of responsibility, creating considerable administrative confusion and a complex system of information flows

Decentralization has almost doubled the number of these units, from 131 in 1990 to 245 in 1998. As a result, many units lack the required buildings, human resources, and vehicles. Wide disparities in the regional distribution of personnel (caused by a reluctance to move to the periphery) have worsened staff shortages in some areas.

Decentralization has also led to duplication and overlapping of responsibility, creating considerable administrative confusion and a complex system of information flows. Weaknesses in local management and the politicization of services have focused central-level time on the functions and responsibilities of the health units rather than on policy development, planning, direction, coordination, and monitoring and evaluation.

Finance

Treasury draws up the national health budget, using estimates submitted annually by the MOH and the Provincial Councils. Once the budget is approved by Parliament, MOH receives its allocations directly. The provincial health budget passes through the Ministry of Provincial Councils to the Provincial Council, which in turn allocates it to the Provincial Ministry of Health. Health revenue and spending patterns from 1995 to 1999 are shown in Table 4.

Provincial Councils have discretion in the use of central Government allocations and do not have to report on their expenditure. This has resulted in weak management and control of funding as well as minimal data on health expenditure. In 1999, the provinces

Table 4: **Government Expenditure on Health, 1995 to 1999**

Item	1995 Million Rupees	1995 %	1996 Million Rupees	1996 %	1997 Million Rupees	1997 %	1998 Million Rupees	1998 %	1999 Million Rupees	1999 %
Spending agency										
Ministry of Health	6,255	59	7,663	67	8,794	69	11,279	71	13,029	72
Provincial Ministries of Health	4,278	41	3,759	33	3,988	31	4,663	29	4,989	28
Total	**10,533**	**100**	**11,422**	**100**	**12,782**	**100**	**15,943**	**100**	**18,018**	**100**
Source of funds										
Sri Lanka Government	10,073	96	11,129	97	12,160	95	14,435	91	17,119	95
Foreign aid	460	4	293	3	622	5	1,508	9	899	5
Total	**10,533**	**100**	**11,422**	**100**	**12,782**	**100**	**15,943**	**100**	**18,018**	**100**

Source: Ministry of Health

accounted for 28 percent of the total health expenditure; most of this went to recurrent expenditure,[3] while 5 percent funded capital requirements.

Large capital expenditure programs of the provinces are funded through MOH and reflected as MOH capital estimates. Major capital budget items fall under the Medium-Term Investment Plan (MITP), which requires the final approval of the Ministry of Finance and Planning.

A national health accounts system has been planned under the World Bank project. The system would provide information on flow of funds, use of expenditure by function, and distribution of health expenditure by province. The development of the system, however, appears to have stalled.

Donor support

Donors provide support mostly in preventive health; their role in overall health services is not significant

Donors provide support mostly in preventive health; their role in overall health services is not significant. The current IDA/World Bank Health Services Project, with a budget of $18.8 million for 1997–2001, is the largest donor program. It concerns itself with three preventive programs: malaria control, nutrition, and sexually transmitted diseases and AIDS. The People's Republic of China provided $2.8 million in 1999 and the Republic of Korea $14 million in 1998–2000 for hospital services. The United Nations Fund for Population Activities (UNFPA) contributed $5.0 million in 1997–2000 for reproductive health services. UNICEF has a budget of $2.1 million for 1997–2001 and has so far spent $1.1 of this on immunization. The World Health Organization (WHO) contributed about $4.1 million in its 1998–1999 biennial program, largely for technical assistance and training. Nongovernment organizations (NGOs) such as Médecins sans Frontières (MSF) implement health programs in the north and east; however, data on NGO expenditure in this regard were unavailable.

[3] Provincial Councils receive three types of allocations from the Ministry of Provincial Councils: block, criteria-based, and matching grants. Block grants are based on recurrent requirements. Criteria-based grants are for economic, social, and other development needs of the province. Matching grants are intended to reimburse the province for revenue generated within the province and transferred to the Treasury the previous year. Matching grants make up a negligible proportion of allocations in many provinces except the wealthiest western province.

National Immunization Program

No comprehensive assessment of the national immunization program has been made within the past three years, although a cold-chain study was undertaken in 1997. In preparation for an application to GAVI for Hepatitis B funding, arrangements are under way for a full review of the program in 2001. WHO and UNICEF will provide technical assistance.

Strategic Plan

EPI in Sri Lanka began in 1978 and has been revised and expanded since then. The Country Report (Epidemiological Unit 2000a) identifies the four objectives of the program:

- To reduce mortality and morbidity associated with vaccine-preventable diseases such as tetanus, diphtheria, whooping cough, poliomyelitis, tuberculosis, measles, rubella, and Japanese B encephalitis
- To eradicate polio by 2000
- To achieve zero incidence of neonatal tetanus
- To prevent congenital rubella syndrome

After the assessment in March 2001, a five-year strategic plan will be developed.

Immunization has been an integrated component of the maternal and child health (MCH) program since the start of EPI

The current national immunization schedule is presented in Table 5. Changes to be introduced in March 2001, which are highlighted, reflect the addition of routine measles rubella vaccine (MR) for all children, adult tetanus and diphtheria vaccine (aTd) for children between 10 and 15 years, and rubella vaccine for all females 11 to 15 years. The schedule has also been adjusted for the potential introduction of Hepatitis B vaccine (the timing of oral polio vaccine, or OPV, and diphtheria and tetanus toxoids and pertussis vaccine, or DTP, vaccinations is now aligned with Hepatitis B), to reduce the programmatic impact the introduction may have. Vaccinations are given free of charge at Government facilities. Private service providers receive the vaccine for free from the Government but charge a fee for the service.

Organizational Structure

National immunization services are within the purview of the Deputy Director General of Health Services (Public Health), who is responsible for the Maternal and Child Health (MCH) Unit and the Epidemiological (EPI) Unit. The MCH Unit assists in program implementation by disbursing equipment, providing training, and supervising service delivery. The EPI Unit is accountable for the surveillance of EPI diseases, vaccine management and distribution, and immunization program planning, monitoring, and evaluation.

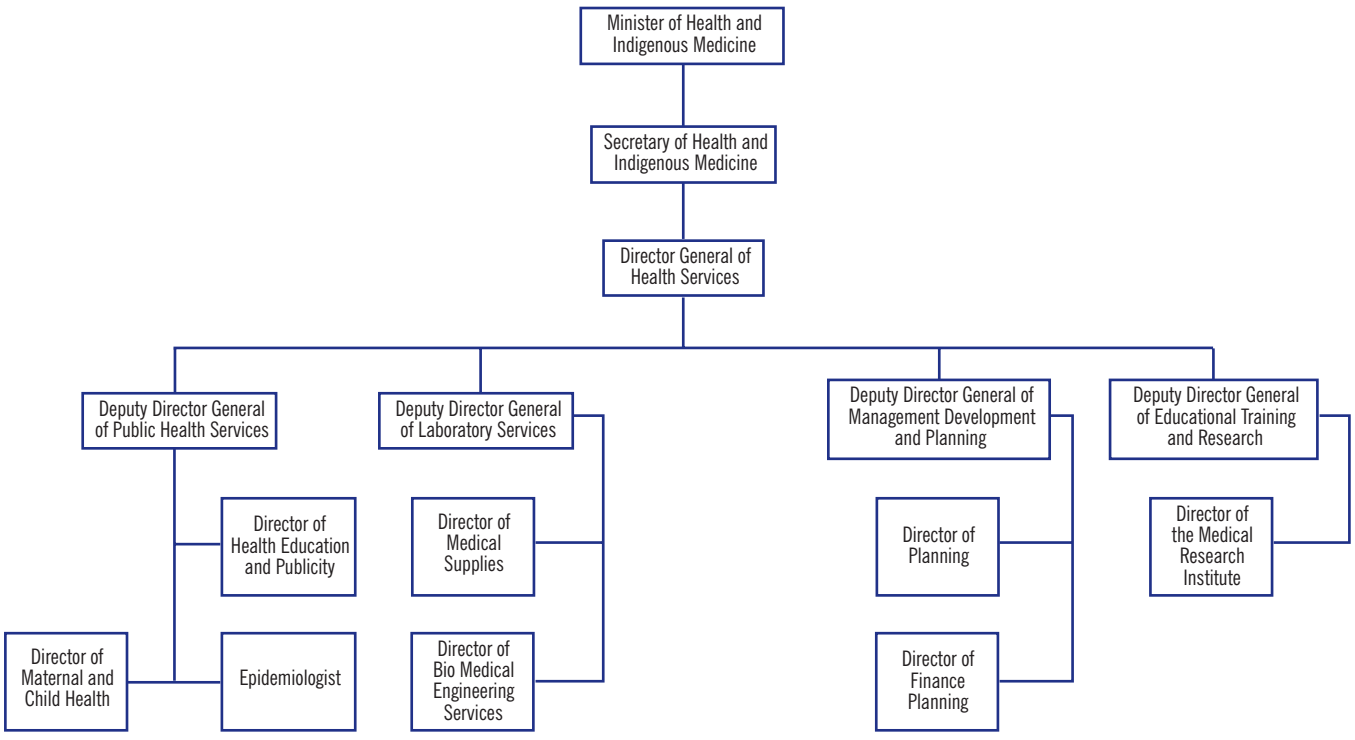
Other central MOH departments with immunization responsibilities are shown in Figure 3.

Table 5: **Immunization Schedule for Sri Lanka**

BCG	DPT	OPV	Measles	DT	TT	MR	aTd	Rubella	HBV
0–4 weeks									
Within 24	2 months	2 months							2 months
hours of birth	3 months	3 months							
at hospital	4 months	4 months							4 months
	5 months	5 months							
	6 months	6 months							6 months
	7 months	7 months							
			9 months						
	18 months	18 months							
						3 years			
		5 years		5 years					
					10–14 years (in school)		10–15 years (in school)	11–15 years (in school)	
					12 weeks after pregnancy				
					6–8 weeks after first dose				
					TT3–TT5 for subsequent pregnancies			16–44 years	
								11–44 years	

Note: Proposed changes and additions to the program are shaded

Figure 3: **Ministry of Health Departments with Immunization Responsibilities**



At the district level (see Figure 2), Medical Officers (Maternal and Child Health), Regional Epidemiologists, and Divisional Directors, Health Services (DDHS)/Medical Officers of Health work together to provide immunization services. All three positions are independent of one another but are accountable to the Deputy Provincial Director of Health Services (DPDHS), who is responsible for a health division (corresponding to the civil administrative district) comprising about 60,000 people.

Immunization has been an integrated component of the maternal and child health (MCH) program since the start of EPI. As such, it is primarily done in MCH clinics staffed by public health midwives and responsible to the DDHS. Each MCH clinic provides services for between 2,000 and 3,000 people. All in all, immunization services are provided at more than 5,000 facilities including hospitals, maternity homes, central dispensaries, and outreach clinics.

Accounting reports at all levels are prepared not along functional lines but along three general budget lines. Any attempt to disaggregate immunization data is further complicated by the program being an integrated component of the MCH program

Coverage

Administrative reports place the coverage of routine infant EPI vaccinations at more than 90 percent since the mid-1990s. However, such rates should be treated with caution because:

- Internal migration (including displaced people) and the lack of recent census data mean an unreliable denominator. In many instances coverage is reported to be more than 100 percent.
- An increasing number of vaccinations take place in the private sector, particularly in urban areas (up to 10 percent in Colombo). Private providers are not obliged to report vaccination numbers.

Nonetheless, various cluster surveys in 1998 and 1999 have confirmed these high coverage figures and in some cases have shown full coverage for some vaccines. No surveys have been made in conflict zones.

Financial Structure

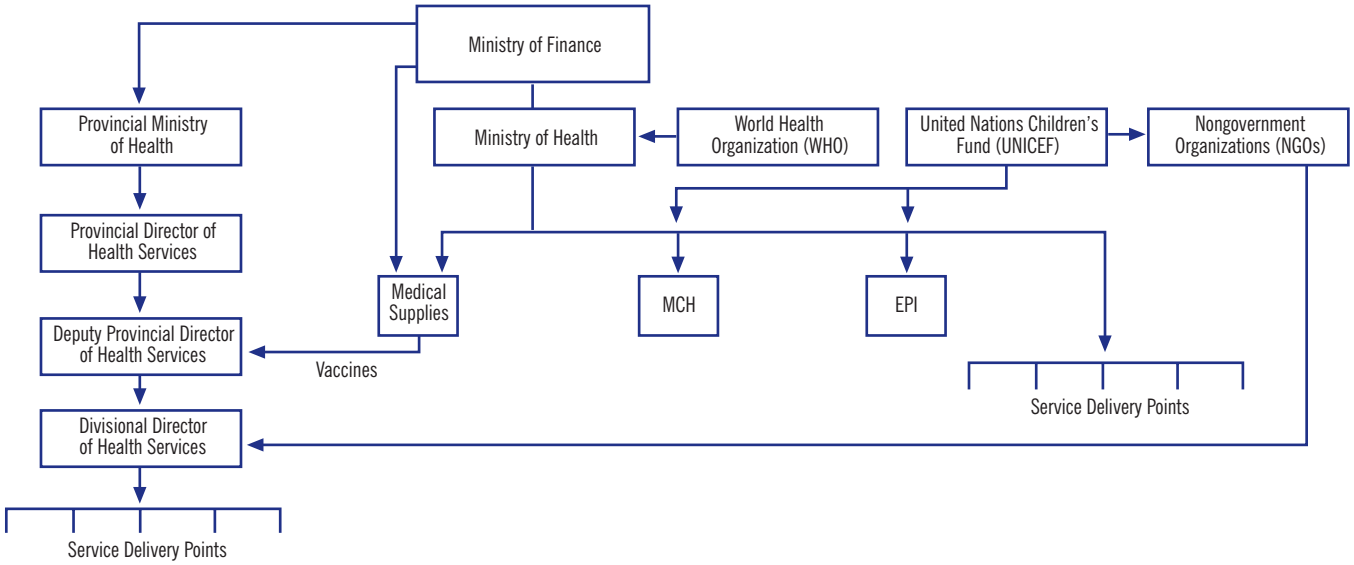
An accurate picture of the costs involved in delivering the immunization system nationwide is difficult to obtain for the following reasons:

- Service delivery expenditure is managed by provincial and district health authorities, which under the decentralized system do not have to report expenditures to the center. Hence, expenditure data are not aggregated nationally.
- Only limited aggregation of historical data takes place at the central level. Where information is available, it is not easily accessible and requires significant time to retrieve and consolidate.
- Accounting reports at all levels are prepared not along functional lines but along three general budget lines.[4] Any attempt to disaggregate immunization data is further complicated by the program being an integrated component of the MCH program.
- Many logistic and social mobilization costs are absorbed by NGOs (such as Médecins sans Frontières and Rotary) and are therefore not reflected in the national accounts.[5]

[4] General administration and staff services, patient care services, and community health services.
[5] MSF was unable to provide data for this assessment.

The immunization program is funded principally by the Government, UNICEF, and WHO. For special activities such as National Immunization Days (NIDs), NGO resources provide logistic and technical support. Figure 4 illustrates the flow of funds for the immunization program.

Figure 4: **Flow of Funds for the Immunization Program**



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Government sources: National level

There is no national budget line for immunization in general or vaccines in particular.[6] However, at the start of each financial year, Treasury allocates funds to:

- MOH for:
  - The administrative costs of the EPI and MCH Units
  - The cost of all vaccines (funds are provided directly to the Department of Medical Supplies, which manages procurement)
  - Hospitals that are directly managed by the MOH and that provide immunization services
  - The Medical Research Institute, which is the national control laboratory
  - All capital requirements for the program, although these costs are currently met (where possible) by donor agencies
- Provincial Councils and Provincial Ministries of Health, for program implementation

Government sources: Provincial level

Most provinces have very limited local revenue sources (local taxes and license fees). Nonetheless, when no central support is available, provinces will use these funds to purchase immunization equipment, such as refrigerators, that are considered priorities.

[6] Vaccines are included in a general "medical supplies" budget line.

The Government also fully funds non-EPI vaccines, including the expensive Japanese encephalitis vaccine, which costs $1.5 million per year

Past and Current Financing

Vaccine costs

From 1995, the Sri Lankan Government provided an increasing proportion of vaccine finance until it became self-sufficient for all vaccines on the national schedule in 1998. Before that, UNICEF was the primary donor. In 1999, EPI vaccines, including OPV for NIDs, cost $830,000 (see Table 6), or 46 percent of the total program cost. The Government also fully funds non-EPI vaccines, including the expensive Japanese encephalitis vaccine, which costs $1.5 million per year.

Nonvaccine costs

Nonvaccine costs shown in Table 6 are not comprehensive owing to the difficulties in data collection noted above. However, they do serve to show the approximate proportions of

Table 6: **Expenditures for the Routine Immunization Program, 1999** (US$)

Item	Central	Provincial Government	UNICEF	WHO	NGOs	Total	% of Total
Operating cost							
Vaccines							
BCG	118,286					118,286	
DPT	90,714					90,714	
DT	27,064					27,064	
OPV	266,786					266,786	
Measles	78,257					78,257	
TT	9,514					9,514	
RU	252,500					252,500	
Subtotal	**843,121**					**843,121**	**45.9**
Supplies							
Syringes/needles			81,050			81,050	4.4
Other			10,850			10,850	0.6
Subtotal			91,900			91,900	5.0
Personnel	111,003					111,003	6.0
NIDs			697		2,400	3,097	0.2
Other	94,272		44,626	21,037	7,287	167,222	9.1
General		232,022				232,022	12.6
Capital cost							
Cold chain	3,260		38,815			42,075	2.3
Sterilization equipment			253,684			253,684	13.8
Subtotal	**3,260**		**292,499**			**295,759**	**16.1**
Total	**1,051,656**	**232,022**	**429,722**	**21,037**	**9,687**	**1,744,124**	
%	**60.3**	**13.3**	**24.6**	**1.2**	**0.6**		

Sources: EPI Unit, MCH, UNICEF, WHO, and Department of Health Services, Ministry of Health
Notes:
- Total expenditure given is the minimum
- OPV cost includes NID requirements
- "Other" costs include travel, stationery, maintenance, and contractor services
- Personnel costs are calculated at 80 percent of the yearly salary budget of the EPI Unit ($74,953) and 15%–20% of MCH costs ($36,050)
- The contribution of the provincial government includes the salary component
- NGO costs primarily include UNICEF contributions to TRUST and Rotary for social mobilization for NIDs

the main expenditure areas. Capital costs make up 16 percent of the total, largely on account of the significant investment in injection equipment, which may influence future injection safety strategies (see "Safety of Injections" below). The central-level personnel budget shown in the table is an estimate; it includes the salaries of staff in the EPI and MCH units as well as provincial salaries, and composes about 14 percent of the total expenditure.

Social mobilization costs and the total cost of NIDs (personnel, transport, and social mobilization) are not shown for lack of data. Likewise (and importantly), provincial government contributions for the procurement and maintenance of cold-chain equipment could not be ascertained.

Overall

UNICEF has supported the immunization program since its start and has formed a strong and reliable relationship with MOH officials

Funds for the immunization program come mainly from the Government, which contributed 74 percent, 60 percent from the central level, in 1999. UNICEF contributed 25 percent of the overall total in 1999 and is clearly the primary donor, although there are no data on the full cost of NGO contributions. UNICEF has supported the immunization program since its start and has formed a strong and reliable relationship with MOH officials. For its 1997–2001 program UNICEF has allocated $1.2 million, of which it has so far spent about $1.1 million. It provides equipment, supplies, and technical assistance directly to MCH in response to requests from the Director. WHO contributed $74,000 in its 1998–1999 biennial program, largely for technical assistance through workshops and consulting services.

Future Financing

Key Issues

The immunization program of Sri Lanka has an excellent record, with low levels of EPI disease and high coverage. However, the advantages gained in disease control over the last 20 years could be lost unless attention is paid to key issues of program quality. Gains can be consolidated and the program successfully expanded if improvements are made in the cold chain and in service quality. The future costs and financing aspects of these areas are discussed below but should be considered only indicative. The comprehensive review in March 2001 may highlight other areas of concern and should provide more detail on issues requiring financial support. Policy and financing options are discussed in the next main section. Detailed cost estimates are provided in Appendix B.

Although there is no separate national budget line for vaccines, the Sri Lankan Government has demonstrated its strong commitment to the immunization program by providing full funding for the national immunization schedule since 1998

Vaccine supply: Sustainability, quality assurance, and price

Vaccine self-sufficiency is a key element in the sustainability of any immunization program. A country is self-sufficient in vaccines if it purchases or produces all of the routine EPI vaccines that it needs. A critical component of self-sufficiency is good-quality vaccines.

Although there is no separate national budget line for vaccines, the Sri Lankan Government has demonstrated its strong commitment to the immunization program by providing full funding for the national immunization schedule since 1998. The introduction of MR and aTd vaccines (both relatively expensive) in March 2001 has been approved by the Treasury. In addition, the Government provides funding for the costly Japanese B encephalitis (JE)[7] vaccine ($1.5 million per year). Discussions with Government officials confirmed the high priority placed on the immunization program by all the relevant departments. With no record of dispute over price, quantity, or need, the Government's commitment appears firm. Cost-effective purchasing strategies will help sustain this support.

Vaccines are procured by the State Pharmaceutical Committee directly from WHO-prequalified manufacturers through open bidding. Prices in 1999 were competitive, and in some cases lower than UNICEF contract prices.

Quality assurance

Vaccines, being biological, are fundamentally different from drugs and require specialized procurement knowledge and skills. Vaccine imports must be managed by a national regulatory authority established by appropriate laws. Such an authority, as recommended by WHO, should be independent and competent and should at least carry out the critical

[7] JE is not part of the EPI schedule but is provided to high-risk target populations.

control functions of licensing, surveillance of the safety and efficacy of vaccines in the field, and lot release.[8] The authority must also have access to adequate laboratory services for routine lot testing or for testing on demand when there are concerns about shipments, breakdowns in the cold chain, or adverse reactions following vaccination.

For sustainability reasons, it would be remiss of immunization partners to suggest providing support for the purchase of vaccines

The drug regulatory law in Sri Lanka is the Cosmetics Devices and Drugs Act (1980). The Drugs Regulatory Authority (DRA) is responsible for licensing, and the MOH undertakes surveillance in coordination with the DRA and the Medical Research Institute (MRI). MRI operates as the national control laboratory, fulfilling the laboratory access function, and from 2000 has been responsible for lot release. All these bodies are answerable to the Cosmetics, Devices, and Drugs Technical Advisory Committee, which was set up to advise the Minister of Health on drug policy.

An assessment of the vaccine regulatory system by WHO in November 2000 found weak reporting from the private sector on adverse effects following immunization (AEFI). A training workshop was recommended to address this deficiency. The assessment also disclosed the need to strengthen the lot release and laboratory access functions of MRI, primarily through the training of national staff.

Opinions vary as to the value of lot testing. Some argue that it contributes to quality control and can therefore reduce dependence on prequalified manufacturers. As prequalified manufacturers are usually more expensive, purchasing from nonprequalified sources would lower costs. The degree of savings would depend on the vaccine or antigen but is likely to be higher in cases where a program seeks to expand beyond the basic EPI vaccines to introduce newer (more expensive) vaccines. Some non-EPI vaccines have few, if any, WHO-prequalified suppliers (there are none for JE, for example); more stringent quality assurance in the importing country is therefore required. MRI has indicated that its infrastructure for routine lot testing is sufficient but that it requires investment in equipment and continuing support for supplies.

WHO argues that testing only confirms consistency and identity, and does not assure quality. Vaccines procured from prequalified suppliers do not need to be routinely retested on arrival. WHO further maintains that procurement from nonprequalified manufacturers may save on cost but is very risky, as experience has shown. For example, testing cannot predict poor presentation or AEFI. The WHO assessment recommends continued vaccine procurement through prequalified suppliers.

Costs and financing

EPI vaccine requirements will cost about $1.2 million in 2001, according to the orders already placed by the EPI Unit. The introduction of MR and aTd vaccines will add almost $550,000, or 76 percent, to the total. For 2002–2005, needs are forecast using target population and actual wastage rates instead of historical data (as used by the EPI Unit; see "Vaccine Management and the Cold Chain"), but not stock levels. For the next five years

[8] Lot release is a regulatory activity in both manufacturing and purchasing countries. It involves checking each lot of vaccine to determine or confirm its compliance with the country's regulations. In purchasing countries this is done before distribution. Vaccine quality is subject to lot-by-lot variations.

the total cost will be about $5.9 million, as shown in Table 7. It is assumed that the Government will meet all costs. For sustainability reasons, it would be remiss of immunization partners to suggest providing support for the purchase of vaccines.

Table 7: **Projected EPI Vaccine Costs, 2001–2005** (US$)

Item	2001	2002	2003	2004	2005	Total
BCG	107,692	103,729	101,655	99,622	97,629	510,327
DPT	121,795	104,533	102,443	100,394	98,386	527,551
OPV	230,769	261,333	256,107	250,985	245,965	1,245,159
Measles	96,154	100,513	98,503	96,533	94,602	486,304
Subtotal	**558,411**	**572,111**	**560,710**	**549,536**	**538,587**	**2,769,340**
DT	38,462	64,228	62,943	61,684	60,451	287,767
TT	23,077	72,584	71,133	69,710	68,316	304,820
Rubella	76,923	44,722	43,827	42,951	42,092	250,515
MR	538,462	512,615	401,890	393,853	385,976	2,079,011
aTd	15,385	16,057	15,736	15,421	15,113	77,711
Total	**1,250,719**	**1,282,317**	**1,156,239**	**1,133,155**	**1,110,533**	**5,932,964**

Note: Population data projections are based on information provided by the EPI Unit and information published in Population Information Center (1998). All vaccine prices are based on estimates provided by the EPI Unit (OPV=$0.13, DPT=$0.06, BCG=$0.08, measles=$0.13, rubella=$0.15, BCG=$0.08, TT=$0.05, Dt=$0.08, MR=$0.77, aTd=$0.08). Prices were provided in Sri Lankan rupees and converted using the current (October 2000) exchange rate of 78 rupees:US$1. Actual wastage factors of OPV=1.3, DPT=1.3, BCG=4.3, and measles=2.5 are used. Projected wastage rates of 2.0 are used for MR and aTd. MR needs are based on 70% coverage for the first two years, and 80% after that. aTd has a 30% coverage target. All other vaccines assume 100% coverage. Although actual prices for 1999 where provided by both the EPI Unit and the Department of Medical Supplies (DMS) (responsible for procurement), there were large discrepancies. In theory, DMS prices include customs and handling costs, and should therefore be 10%–15% higher than EPI Unit prices, which are the same as the purchase prices. However, the differences were not uniform either in direction or in proportion. The most notable was the price of OPV (EPI Unit=$0.16, DMS=$0.06, UNICEF contract price=$0.085).

MRI has indicated that its infrastructure for routine lot testing is sufficient but that it requires investment in equipment and continuing support for supplies

Laboratory services and surveillance

Strengthening the laboratory access function of MRI will require $3,500 and undertaking a workshop on AEFI reporting will require $20,000, according to WHO estimates. Sources for these costs have not been identified.

If Sri Lanka chooses to introduce lot testing, using cost estimates provided by MRI (Table 8), it will need $64,000 in capital expenditure to establish capacity for testing of DPT, OPV, measles, and TT. An additional $20,000 over five years will be required to cover operating costs. No source of funds has been identified. The extent of cost savings possible through the use of nonprequalified suppliers would require more investigation.

Table 8: **Laboratory Quality Assurance Service Needs over Five Years**

			Total	
Item	Year 1	Years 2–5	Rupees	US$
Capital expenditure	5,000,000		5,000,000	64,103
Operating cost	332,800	1,664,000	1,996,800	21,333
Total			**6,996,800**	**85,436**

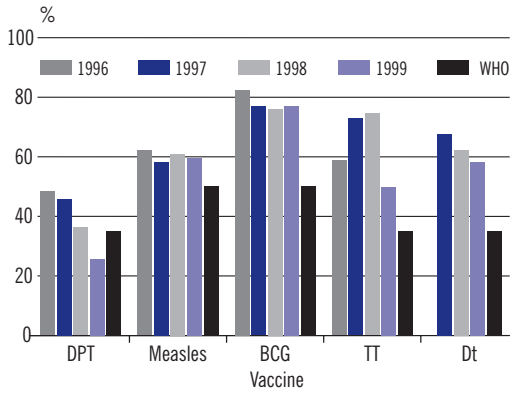
Source: MRI

Vaccine management and the cold chain

Good vaccine management decreases cost and risk, and increases the sustainability of a national program. Apart from tight stock control, it requires a well-functioning cold chain, including suitable central and regional storage facilities and a distribution system with adequate transport capacity.

Wastage rates

Figure 5: **Actual and WHO Standard Wastage Rates, 1996–1998**



National wastage rates for the past four years, shown in Figure 5 alongside standard WHO rates, indicate room for improvement. Wastage control has not been a high priority for the program so far although it now receives increasing attention. Particularly with the addition of expensive new vaccines to the national schedule, any reduction in wastage will lead to cost savings in the medium term.

Wastage may occur in the distribution system or at point of use. System wastage often contributes the most to overall rates, and can be minimized by accurate forecasting, good stock control, timely distribution of vaccines, and a reliable cold chain, including the use of vaccine vial monitors.

Wastage may be reduced at point of use by:

- Reducing the number of immunization sessions, thus improving the ratio between children and vials
- Introducing the new open-vial policy[9] of WHO for OPV, TT, DPT, DT, and Hepatitis B, which could reduce wastage rates by up to 30 percent
- Using a combination of different-dose vials

Although wastage rates are calculated at the district level and constructive feedback is provided on how to improve them (where necessary), an overall analysis of the source of wastage in the Sri Lanka program is not available. Further study is needed to ensure that the most effective waste reduction strategies are used.

Forecasting

Vaccine needs are forecast annually on the basis of stock levels, target population, and the previous year's use at the district level. Accurate wastage rates can lead to more precise forecasting, decreasing the potential for over- or understocking and therefore minimizing cost. Also, careful forecasting increases the reliability of multi-year planning and thus allows the negotiation of longer-term procurement contracts and, hence (usually), lower prices.

Storage

Inadequate storage facilities at the central and district levels compromise the efficiency and safety of vaccine handling. At the central level, the EPI program uses five Government

Good vaccine management decreases cost and risk, and increases the sustainability of a national program

[9] WHO (2000)

cold-room facilities, which are 15–30 years old and are located in three different places (EPI Unit, Family Health Bureau, and Colombo General Hospital). The facilities are not always accessible. If the storage requirements exceed cold-room capacity or one of the cold rooms breaks down, space in another storeroom is leased from a private supplier. At the regional level, vaccines are stored in individual refrigerators and freezers, usually of domestic design and mostly 10–15 years old. At both central and regional levels, frequent breakdowns, limited supply of spare parts, and constant electricity fluctuations and shortages contribute to logistic (and financial) inefficiencies, which risk compromising the quality of the cold chain.

At both central and regional levels, frequent breakdowns, limited supply of spare parts, and constant electricity fluctuations and shortages contribute to logistic (and financial) inefficiencies, which risk compromising the quality of the cold chain

Three previous EPI reviews (1981, 1986, and 1989) recommended the construction of a single cold-room complex in Colombo. Building started in 1986 but has been significantly delayed by bureaucratic complications and funding constraints. Although the World Bank provided some financial support in 1993, the complex is still only partially complete.

Transport

Poor transport conditions or delays in distribution can jeopardize the potency of vaccines. Timely access to dependable vehicles is essential, particularly in cases of outbreaks or cold-chain breakdowns. Standard delivery vans and lorries are currently being used to distribute vaccines at the central and regional levels. These vehicles are old (more than 10 years) and unreliable, and regional centers must often resort to borrowing vehicles to distribute vaccines on time.

In addition, anecdotal evidence points strongly and consistently to the need for improved transport capacity at the periphery and within the estate sector, particularly where mobile clinics operate. A comprehensive assessment is required to determine the demand for and the cost of providing appropriate vehicles at the lower levels of the distribution system.

Equipment

In 1997, a WHO consultant assessed the cold chain and determined it to be well functioning but "fragile," a situation that continues to this day. Primary concerns include:

- Aging and nonfunctioning cold-chain equipment, with no overall plan for upgrading equipment, including transfer to CFC refrigeration (about 10 percent of refrigerators are CFC-free). UNICEF supplied most of the equipment in 1985.
- No systematic monitoring of cold-chain equipment and no national inventory.
- Common, if risky, reliance on private service maintenance for refrigerators and freezers. These services can be irregular and expensive, and may not be available in all areas.

Central accountability for various aspects of the cold chain is fragmented. The EPI Unit is responsible for the proper storage of vaccines, including technical support, and for cold-chain training and monitoring. However, MCH as the implementing agency is responsible for the procurement and distribution of national program equipment. In practice, MCH

Good-quality and timely maintenance of cold-chain equipment reduces costs. However, this is largely carried out by private-sector contractors, who are often unreliable as well as expensive

does not have funds for cold-chain equipment; instead, it acts as the conduit through which provinces can gain access to the resources of UNICEF, which supplies 95 percent of equipment requests. If funds are available, provincial governments will purchase urgently needed cold-chain equipment. With no specific budget for EPI cold-chain equipment, and no single central body with overall responsibility for cold-chain quality or the status of equipment, little attention has been given to:

- Establishing a national inventory or monitoring system
- Undertaking a comprehensive assessment of needs
- Developing a national strategy for upgrading equipment

As a result, any projections of needs are broad estimates at best. The EPI Unit has begun to take on a more comprehensive management role, preparing funding proposals for upgrading the cold chain and requesting baseline information on all cold-chain equipment from MOH units. The cold-chain assessment in March 2001 is expected to provide a more accurate analysis of needs.

The extra cold-chain equipment reserved for polio Subnational Immunization Days (SNIDs) is a valuable resource. The possibility of using it should be taken into account when forecasting needs.

Maintenance

Good-quality and timely maintenance of cold-chain equipment reduces costs. However, this is largely carried out by private-sector contractors, who are often unreliable as well as expensive. A viable alternative would be to build the internal capacity of cold-chain officers at the regional level, allowing systematic preventive maintenance and timely repairs to take place. The EPI Unit coordinated a one-time training program in 2000 to initiate this, and plans to undertake a more comprehensive program in 2001. Regular training and updates should be built into the immunization program.

Costs and financing

As shown in Table 9, significant savings can be generated by reducing wastage. Considering the needs for 2002, assuming full coverage of the target population, and using vaccines where the wastage rate is now relatively high,[10] expenditure can be reduced by up to $300,000 per year. MR accounts for the largest proportion (50 percent) of this cost savings.

Vaccine inventory control is currently undertaken manually. A computerized system (costing about $5,000, according to the EPI Unit) would improve management capacity as well as forecasting, and wastage and quality control.

Capital investment, including the construction of cold stores, the purchase of vehicles, and the complete upgrading of refrigerators, will amount to about $2.4 million, as shown

[10] In practice, Hepatitis B and MR will be phased in.

Table 9: **Cost Savings Through Reduced Wastage (selected vaccines)**

	Current/Projected Wastage		Less 10%			Less 15%–20%		
Item	**Rate (%)**	**Cost (US$)**	**Rate (%)**	**Cost (US$)**	**Saving**	**Rate (%)**	**Cost (US$)**	**Saving**
Measles	60	100,513	50	80,410	20,103	40	68,349	32,164
DT	60	66,904	50	53,523	13,381	40	45,495	21,409
TT	50	72,585	40	61,697	10,888	30	50,809	21,776
MR	50	512,615	40	435,723	76,892	30	358,831	153,784
Hepatitis B	30	547,922	20	508,785	39,137	15	469,647	78,275
Total				**160,401**			**307,408**	

Note: Projected wastage rate for MR was provided by the EPI Unit. Hepatitis B rates are based on those for DPT. The ideal wastage rate for Hepatitis B is 15%, according to UNICEF.

in Table 10. Spare parts and maintenance will cost another $107,000 per year (averaged over the life of the equipment), of which 92 percent would need to be met from provincial resources. Other cold-chain equipment needs, such as cold boxes and vaccine carriers, are unknown. By no longer using private cold storage facilities, the Government can save about $4,000 per year.

Table 10: **Cold-Chain Capital Investment Costs**

Item	**Quantity**	**Price per Unit (US$)**	**Total (US$)**	**Spare Parts (US$)**	**Maintenance (US$)**	**Life of Equipment (years)**	**Repair/Maintenance per Year (US$)**
Storage facilities							
Central cold-room complex	1		192,308		38,462	15	2,564
Equipment for cold room	1		89,744	26,923	808	10	2,773
Regional cold room	23	22,179	510,128		102,026	15	6802
Standby generator, central	1		12,821	3,846	385	10	423
Standby generator, regional	23	6,410	147,436	44,231	4,423	10	4,865
Subtotal			**952,436**	**75,000**	**146,103**		**17,427**
Vehicles							
Central	2	25,000	50,000	12,500	1,500	5	2,800
Regional	23	25,000	575,000	143,750	17,250	5	32,200
Subtotal			**625,000**	**156,250**	**18,750**		**35,000**
Equipment							
Ice-lined deep freezers	46	1,700	78,200	23,460	2,346	5	5,161
Ice-lined freezer/refrigerator	308	1,300	400,400	120,120	12,012	5	26,426
Domestic refrigerator	902	385	346,923	104,077	10,408	5	22,897
Subtotal			**825,523**	**247,657**	**24,766**		**54.485**
Total Capital Cost			2,402,959				
Total Operating Cost per Year							**106,912**

Source: EPI Unit
Notes: Spare parts for refrigerator and freezer = 30 percent of unit price; vehicles = 10 percent of unit price. Equipment prices are based on UNICEF contract prices except for domestic refrigerators.

An up-front investment for all capital equipment may not be feasible. A phased approach over three years for storage and vehicles, and over five years for freezers and refrigerators, is shown in Table 11.

Table 11: **Costs of Phasing in Cold-Chain Needs over Three Years** (US$)

	Year 1		Year 2		Year 3	
Item	**Capital**	**Operating**	**Capital**	**Operating**	**Capital**	**Operating**
Storage facilities						
Central cold-room complex, construction	192,308	2,564		2,564		2,564
Equipment for cold room	89,744	2,773		2,773		2,773
Regional cold room	199,615	2,662	155,256	4,732	155,256	6,802
Standby generator, cold room	12,821	423		423		423
Standby generator, regional	57,692	1,904	44,872	3,385	44,872	4,866
Vehicles						
Central	25,000	1,400	25,000	2,800		2,800
Regional	225,000	12,600	175,000	22,400	175,000	32,200
Equipment						
Ice-lined deep freezers	15,640	1,032	15,640	2,064	15,640	4,128
Ice lined freezer/refrigerator	80,080	5,285	80,080	10,570	80,080	21,140
Domestic refrigerator	69,385	4,579	69,385	9,158	69,385	18,316
Total	**967,285**	**35,222**	**565,233**	**60,869**	**540,233**	**85,116**

Source: EPI Unit
Notes: Central facilities and storage are introduced in the first year. Regional vehicles and storage facilities are phased in at 9/7/7 per year. Equipment is phased in at 20 percent per year. Repairs and maintenance are only for new purchases.

An investment in vehicles is not risk-free and must at least be accompanied by a plan to ensure that all associated costs (running costs, driver training) are met, particularly at the periphery

An investment in vehicles is not risk-free and must at least be accompanied by a plan to ensure that all associated costs (running costs, driver training) are met, particularly at the periphery. Good fleet management systems and plans are crucial, but these presuppose a centralized system, which would be difficult in decentralized Sri Lanka. Whole-of-life contracts are one of the best approaches, and would change the cost structure significantly.

The purchase of refrigerated vehicles for countries with small populations (less than 70 million) is not considered cost-effective: transport with regular vehicles and cold boxes is more practical. Procuring such vehicles through UNICEF or directly from the factory may reduce prices by up to 25 percent.

The Japanese Government has indicated that it might provide between $200,000 and $500,000 per year over three years to support the strengthening of the cold chain. In line with Japanese policy, assistance would not be available for vehicles. For large-scale cold-chain support, no other sources of funds have been identified.

UNICEF has about $70,000 of its five-year (1997–2001) budget remaining. The use of these funds will depend largely on requests placed by MCH in January 2001. The expected size of the next program budget is not known, but it is likely to be significantly less than the current one.

Costs provided by the EPI Unit indicate that training for refrigerator and freezer maintenance at the district level, including the provision of start-up spare-part packs, will cost about $8,000. An ongoing monitoring, management, and training plan for the 1,300 cold-chain officers will require more resources at the central level. Costs will depend on an assessment of needs and the training strategies employed, but for the purposes of this report have been estimated to be $10,000 per year. WHO will provide about $1,500 in technical assistance for training in 2001.

All discussions with health officials showed them to be concerned about the deteriorating levels of knowledge and skills among immunization providers and managers

Quality and community commitment

Quantitative EPI indicators in Sri Lanka are very good. To sustain these, program credibility, particularly at the periphery, must be maintained. Any decrease in quality may:

- Lessen the efficacy of vaccines, compromising disease control
- Lead to an increase in AEFI, damaging public confidence in the program
- Cause users to seek more convenient and comfortable services in the private sector, which is unregulated and does not usually provide reporting or surveillance data to the national program

Decreasing experience of vaccine-preventable diseases in the community may also lessen service use. Service quality and social mobilization efforts must therefore be maintained.

Supervision

All discussions with health officials showed them to be concerned about the deteriorating levels of knowledge and skills among immunization providers and managers. The reasons for this deterioration may include:

- Decentralization, which has caused the number of health units to almost double, creating shortages of staff, including supervisors; at the same time, financial and human resource capacity at the central level has remained relatively stable, limiting the provision of technical support and supervision to the periphery
- A wide disparity in the regional distribution of health personnel, leaving some districts without adequate supervisory personnel and the capacity to provide on-the-job training
- The limited number of vehicles, inhibiting supervisory access to immunization clinics
- A lack of reference materials on immunization for peripheral workers
- Competing health priorities within the MCH program

The extent to which quality has deteriorated has not been determined. An assessment of quality aspects will be undertaken with WHO assistance in 2002 and the results should guide planning for improvement. It is likely that improved supervision, access to vehicles, and on-the-job competency-based training for vaccinators (public health midwives) will be recommended.

Environment

The quality of the environment for immunization has begun to influence the use of services. Many clinic buildings are in disrepair and may lack electricity, water, heating, or toilets. Because of the integrated nature of primary health care, the costs of upgrading infrastructure are not linked directly to immunization. Moreover, many clinics are held in public buildings (e.g., temples, community centers) that do not belong to the provincial government. Where clinic settings are inferior, parents may choose to reject services or seek vaccinations in the (unregulated) private sector if they can afford it.

Costs and financing

The cost of providing extra vehicles for supervision is just over $464,000, as shown in Table 12, but this figure only reflects central and regional needs. Table 13 shows the cost per year, if purchases were phased in over three years. Requirements for supervisory access at the lower levels or for outreach work are not known but need to be determined and included in future funding considerations. It is at the lower levels were access is most critical. There is no identified source of funds for this investment.

Table 12: **Cost of Supervising Vehicles for Central and District Levels**

Item	Quantity	Price per Unit (US$)	Total (US$)	Spare Parts (US$)	Maintenance (US$)	Life of Equipment (years)	Repair/Maintenance per Year (US$)
Central	2	25,000	50,000	12,500	1,500	5	300
Regional	23	18,000	414,000	103,500	12,420	5	23,284
Total			**464,000**	**115,500**	**13,920**		**23,584**

Sources: EPI Unit estimates and private market sources

Table 13: **Cost of Supervising Vehicles, Using Phased Approach** (US$)

	Year 1		Year 2		Year 3	
Item	Capital	Operating	Capital	Operating	Capital	Operating
Central	25,000	1,400	25,000	2,800	—	2,800
Regional	162,000	9,072	126,000	16,128	126,000	25,200
Total	**187,000**	**10,472**	**151,000**	**18,928**	**126,000**	**28,000**

Sources: EPI Unit estimates and private market sources

A response to increased training and supervision will require both up-front capital investment and long-term financial support for human resource development. A comprehensive and ongoing training program will demand extra human and financial resources at the central and district levels, and will require policy support. These projections assume that training will cost at least $20,000 per year.

WHO plans to provide resources for training in cold-chain maintenance, vaccine logistics, safe injections practices, and AEFI surveillance (a total of $3,500), and for a survey of immunization coverage and qualitative aspects of the program ($1,500).

Estimating the costs of upgrading infrastructure is beyond the scope of this report.

A response to increased training and supervision will require both up-front capital investment and long-term financial support for human resource development

Equitable access

People living in the north and east (conflict zones), the plantation estate sector, and urban Colombo have limited access to good-quality health services. Table 14 shows low immunization (TT) coverage rates in two of these areas. Any investment in the immunization program must ensure that these populations are equitably served.

The privatization of the estate sector in 1992 transferred the responsibility for providing basic social services to estate management. Predictably, health and social welfare components assumed a low priority in the management's budget, causing the quality of immunization services to suffer

Table 14: **TT Coverage in Vulnerable Populations, 1999–2000**

TT Dose	Underserved Populations in Colombo District, 1999	Estate Sector (Badulaa and Neliya District), 2000
TT1	41	51
TT2	41	49
Booster	100	45
Not indicated	4	1

Source: EPI Unit (2000a)

Estate sector

The estate sector constitutes one of the most disadvantaged population groups in Sri Lanka. Its social welfare levels are well below the national average. With a population of about 875,000 (4 percent of the total population) the yearly birth cohort is, on average, 12,500.

The privatization of the estate sector in 1992 transferred the responsibility for providing basic social services to estate management. Predictably, health and social welfare components assumed a low priority in the management's budget, causing the quality of immunization services to suffer. Quality issues are similar to those outside the sector.

The functions of technical support, coordination, and monitoring were transferred to an autonomous government organization, the Plantation Housing and Social Welfare Trust (TRUST). TRUST works in collaboration with MOH (e.g., in coordinating vaccine distribution) but has no administrative authority over estate management, health staff, or health programs on estates.

Regional TRUST managers identified the provision of transport for the collection of vaccines, the outreach program, and supervision as their top priority. An investment in vehicles, as with the broader immunization program, requires an in-depth assessment of needs.

Conflict zones in the north and east

There has been internal conflict for 17 years, and the quality of health services in the north and east has obviously suffered. The consequences are difficult to quantify, as statistics for these areas are of poor quality, given the security problems and the large numbers of displaced people. Personnel, equipment, and supplies are often difficult to come by. For the immunization program, the cold chain is under considerable stress; in particular, to quote a report on the Save the Children program in 1997, "fridges are few in number and old, poorly monitored and overused, spare parts are non-existent, maintenance poor and irregular."[11]

[11] The situation is not likely to have improved substantially since then.

Costs and financing

The resources required to improve and sustain quality coverage in hard-to-reach populations have not been assessed in detail. However, to ensure equitable access to safe vaccinations, the specific needs of these areas must be accommodated in any investment strategy.

The Government does not provide assistance for program support in the estate sector, although UNICEF does. In keeping with the current structure, any donor support should use TRUST as the financial distribution mechanism, rather than the central or provincial Ministries of Health.

NGOs have contributed significantly to the delivery of health services in the conflict zones, and deserve to be given adequate financial assistance as part of any investment in immunization.

Disposable syringes purchased by parents have been used in the past but health care workers actively discourage this. Reuse and repackaging of syringes in Sri Lanka is an acknowledged problem

Safety of injections

There is no official national safe injection policy or plan, although a policy of using a clean syringe and needle for each child has been practiced for the last 10 years. Sri Lanka uses reusable equipment for all vaccinations. Disposable syringes purchased by parents have been used in the past but health care workers actively discourage this. Reuse and repackaging of syringes in Sri Lanka is an acknowledged problem.

Evidence of a recent trend of abscess formation after immunization has raised concerns about the quality of injection techniques. As with other elements of the program, this relates to issues of quality (see "Quality and Community Commitment" above) and could strongly affect community use of immunization services. Again, continuing skill-based training on the job and increased supervision are required.

A joint WHO-UNICEF-UNFPA statement[12] released recently calls for all immunization programs to use only AD syringes by 2003. This would require a comprehensive strategy for implementation. Operational costs will rise significantly. Training, supervision, and sensitization activities will need to be undertaken. Equally important will be the introduction of safety boxes, a strict and supervised waste management policy, adequate waste disposal infrastructure (e.g., high-temperature incinerators), and technical assistance and training to ensure safe disposal of syringes.

Costs and financing

In choosing between the existing system and the introduction of AD syringes, the following cost implications will need to be considered:

[12] WHO (1999)

- The extensive up-front investment in sterilizable equipment (both past and future)
- The difference in operating costs; for sterilizable equipment, continuing expenditure for spare parts, replacements, and fuel will be required whereas AD syringe expenditure includes recurrent syringe supplies, distribution, destruction, and final containment; the cost for sterilizable equipment has been estimated at $5.40–$15.16 per 1,000 parenteral procedures, compared with $75.61–$99.31 for AD syringes[13]
- Training requirements; training will be required for a measles campaign in 2003 (see "Introduction of New Vaccines" below), which may use AD syringes and may be part of a more comprehensive introduction plan

Most injection equipment was originally provided 10–15 years ago. Of the 5,000 sterilizers required for the entire program, about 2,000 have been replaced over the last two years (by UNICEF), representing a significant investment. There are plans to replace the remaining 3, 000 over the next three years, at a cost of $150,000 per year. The source of funds is unclear. UNICEF has not yet announced its new program budget and may not support the procurement of sterilization equipment from 2003 onward if it decides to confine its funding to the procurement of AD syringes.[14]

Figure 6: **AD Syringe and Sterilizable Equipment Costs Compared, 2001–2005**

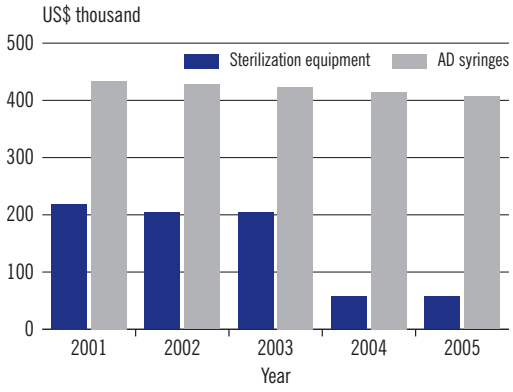


Figure 6 shows the substantial difference in costs between the two approaches. Capital and operating costs for sterilizable equipment will amount to $740,000 over five years, including repairs and maintenance, while AD syringes will require over $2 million. As long as safety is maintained, the injection strategy of using sterilizable equipment is the more cost-effective and financially sustainable.

A separate study would be required to estimate the cost of providing an adequate waste management system and infrastructure.

Introduction of new vaccines

Hepatitis B

Hepatitis B is considered to be, and treated as, an emerging public health problem in Sri Lanka, although there are few data on its disease burden. In 1992 one district survey indicated a Hepatitis B surface antigen positivity rate of 2.5 percent, representing intermediate endemicity. In 1993 a study in two districts showed a very low prevalence of Hepatitis B surface antigen (less than 1 percent) and low infectivity status.

Routine introduction of Hepatitis B vaccine will depend on the results of a sero-prevalence survey to be undertaken with WHO assistance early in 2001. If required, a detailed action plan for the introduction of the vaccine will be developed with WHO/UNICEF support. At present, the vaccine is given to select high-risk groups, mainly health professionals.

[13] Battersby et al. (1999)
[14] Policy clarification has been sought from UNICEF.

The national immunization schedule has been adjusted (beginning March 2001) to align Hepatitis B vaccinations with DPT and OPV, thereby minimizing the additional burden on immunization clinics and users. This also provides an opportunity for a combination vaccine to be used (Hepatitis B–DPT).

Costs and financing

On the basis of plans to phase in the introduction of Hepatitis B vaccine, Table 15 projects the additional vaccine cost to the program. Full introduction will cost about $470,000 per year in vaccine. This does not take into account additional cost for supplies, or other associated programmatic expenditure.

Table 15: **Cost of Introducing Hepatitis B Vaccine into the National Program**

Year	Birth Cohort	Doses (3)	Wastage (%)	Total Doses	Price per Dose (US$)	Transport (US$)	Total (US$)
2003	152,345	457,035	1.3	594,146	0.400	9,506	247,165
2004	240,785	722,355	1.3	939,062	0.400	15,025	390,650
2005	289,477	868,431	1.3	1,128,960	0.400	18,063	469,647
Total							**1,107,462**

Source: Population figures from EPI Unit (2000b)
Note: Wastage rate of 25% is assumed. Price per dose is projected cost in 2003.

Use of the combination (Hepatitis B–DPT) vaccine will cost $815,447 more per year, as shown in Table 16. If AD syringes are used instead of sterilizable syringes, there will be minor cost savings (due to reduced injections) resulting in an overall additional cost of $788,051. The global availability of this vaccine will be limited until 2003, when production should increase in response to demand generated by the Global Alliance for Vaccines and Immunisation (GAVI). No significant price drop is expected as a result.

Hepatitis B is considered to be, and treated as, an emerging public health problem in Sri Lanka, although there are few data on its disease burden

Table 16: **Cost per Year of Introducing Combination Hepatitis B–DPT Vaccine** (US$)

Item	Vaccine	Syringes	Total
Hepatitis B	469,647	27,396	—
DPT	105,785	27,396	—
Subtotal	**575,432**	**54,792**	**630,224**
Hepatitis B–DPT	1,390,879	27,396	1,418,275
Difference	**(815,447)**	**27,396**	**(788,051)**

WHO is providing technical assistance worth $20,000 for the disease burden survey and, if required, will provide additional assistance for the development of an action plan for the introduction of the vaccine, together with UNICEF.

Should the vaccine be introduced, the country will apply for GAVI assistance. As Sri Lanka will satisfy the relevant criteria, support is likely to be provided. No other donor has been identified. If necessary, the Government will probably provide funds. In any case, the additional cost per year will be long-term and Government commitment to financing must be gained.

Despite an increase in overall coverage rates for measles vaccine from 80 percent in 1990 to 95 percent in 1999, coverage in some districts remained below 80 percent and in 1999–2000 the country experienced an outbreak that resulted in 4,611 clinically confirmed cases

Introducing Hepatitis B vaccine into an already fragile cold chain presents risks. If frozen, the vaccine will lose its potency, resulting in limited population protection and financial loss. Policies and procedures to prevent freezing will need to be in place. Cold-chain storage capacity may need to be increased, depending on the vaccine formulation chosen. Other cost considerations include the need for comprehensive training, revisions in EPI forms and materials, and information, education, and social mobilization activities.

Haemophilus influenzae type B (Hib)

The Government is not considering introducing Hib vaccine at this stage.

Disease control initiatives

Polio

Even with enhanced AFP (acute flaccid paralysis) surveillance capability throughout the country, no cases of polio have been reported since 1993. To ensure the eradication of the disease, Sri Lanka has implemented NIDs since 1996, and began SNIDs and mopping-up campaigns costing $174,000 per year (for OPV) in 2000 with the full financial support of the Government.

Special strategies are being implemented for hard-to-reach populations in conflict zones, refugee camps, the estate sector, and the Colombo urban area. Ongoing support from Rotary and NGOs operating in conflict and border areas will remain crucial. Their contribution in terms of logistics, human resources, and social mobilization has been critical, although it cannot be accurately estimated in financial terms. Therefore, the costs of nonvaccine needs for SNIDs and mopping-up campaigns cannot be forecast.

Measles

The incidence of measles gradually decreased from a rate of 87 in 100,000 in 1982 to 0.5 in 100,000 in 1998. Despite an increase in overall coverage rates from 80 percent in 1990 to 95 percent in 1999, coverage in some districts remained below 80 percent and in 1999–2000 the country experienced an outbreak that resulted in 4,611 clinically confirmed cases. The objective of the MOH is to eradicate measles, and it has prepared an action plan to guide activities.

In response to the outbreak and as part of its eradication strategy the MOH plans to:

- Introduce MR vaccine in 2001 for all children 3 years of age
- Conduct a catch-up campaign in 2002 for children aged 1 to 14 years (using AD syringes)
- Conduct follow-up mass immunization campaigns every three to seven years
- Strengthen epidemiological and laboratory surveillance
- Assess vaccine efficacy under field conditions

The basic cost of implementing the EPI program is $1.7 million for 2001 and about $8 million over the five-year period from 2001 to 2005

Costs and financing

Once full coverage has been achieved for MR vaccine, immunization will cost an additional $400,000 per year (see "Vaccine Supply: Sustainability, Quality Assurance, and Price" above), which the Government will fully fund. The mass catch-up campaign will require an additional $665,000 for vaccines and $480,000 for AD syringes and safety boxes. There is no identified source of funds for the campaign.

WHO is providing technical assistance of about $5,000 in 2001 for training in the detection, investigation, reporting, and management of measles cases, and for a review of measles surveillance activities in institutions.

Neonatal tetanus

Neonatal tetanus is considered to have been eliminated when cases reach less than 1 per 1,000. Sri Lanka has achieved this: the incidence of the disease is less than 0.0092 per 1,000. However, the objective of the immunization program was to reach zero-incidence by the end of 2000. In addition to routine immunization (where vaccine costs total about $70,000 per year), those in high-risk groups have been targeted. Marginal costs associated with this strategy are absorbed within the general immunization program or broader health expenditure, and not independently reported.

Financing Needs, Sources, and Gaps

The following analysis is only at the national level, although provinces will absorb most of the maintenance costs. There are insufficient data to determine financing gaps in particular districts, which may affect the quality of services provided.

Projected costs: Basic EPI program

The minimum costs of maintaining the national immunization program over the next five years are projected in Table 17. Vaccine needs are based on forecast population growth and actual wastage rates, but do not take into account current stock levels. The basic cost of implementing the EPI program is $1.7 million for 2001 and about $8 million over the five-year period from 2001 to 2005. On average, vaccines account for 74 percent of the total cost.

Projected costs: Strengthened/expanded program

The costs of introducing Hepatitis B vaccine, eradicating polio, implementing a measles campaign, strengthening laboratory capacity and AEFI reporting, improving the cold chain, increasing routine training, and completing the upgrade of sterilization equipment are projected and summarized in Table 18. The marginal operating costs incurred for the introduction of Hepatitis B vaccine, polio eradication efforts, and the measles campaign

Table 17: **Projected Minimum Costs of the Standard Immunization Program, 2001–2005** (US$)

Item	2001	2002	2003	2004	2005	Total	%
Operating expenses, center							
Vaccines	1,250,719	1,282,317	1,156,239	1,133,155	1,110,533	5,932,964	74
Supplies	57,611	57,611	57,611	57,611	57,611	288,057	4
Personnel, EPI unit, MCH	104,038	104,038	104,038	104,038	104,038	520,191	6
Training, EPI update	5,128					5,128	
Travel	3,846	3,846	3,846	3,846	3,846	19,231	
Supplies (office)							
Stationery	897	5,962	5,962	5,962	5,962	24,744	
Fuel	2,885	2,885	2,885	2,885	2,885	14,423	
Other	1,795	1,795	1,795	1,795	1,795	8,974	
Maintenance	5,256	5,256	5,256	5,256	5,256	26,282	
Contractual services							
Communication	5,128	5,128	5,128	5,128	5,128	25,641	
Other	6,596	6,596	6,596	6,596	6,596	32,981	
Cold storage	5,000	5,000	5,000	5,000	5,000	25,000	
Subtotal	**1,448,901**	**1,480,435**	**1,354,357**	**1,331,273**	**1,308,651**	**6,923,615**	**86**
Operating expenses, provincial	232,022	232,022	232,022	232,022	232,022	1,160,110	14
Total	**1,680,923**	**1,712,457**	**1,586,379**	**1,563,295**	**1,540,673**	**8,083,725**	

Source: Provincial cost estimates calculated in Table 6, vaccine costs given in Table 7, and estimates for 2001 from the Department of Health Services
Note: Center-level salary costs = 80% for EPI Unit and 20% for MCH Unit. Maintenance costs met at district level are not known and therefore not included.

The total cost of improvements in the first year equals twice the cost of the basic program. Of this increase, the majority is due to the first phase of capital investment. In the second year, operational costs rise significantly as a result of the measles campaign

are not included, nor is the cost of intended activities in hard-to-reach populations. Annual replacement costs for the cold chain are also not included. With no national inventory, estimates would be unreliable.

The total cost of improvements in the first year equals twice the cost of the basic program. Of this increase, the majority is due to the first phase of capital investment. In the second year, operational costs rise significantly as a result of the measles campaign. Decreases in the fourth and fifth year represent the completion of the capital investment program, although this is mostly offset by the introduction of Hepatitis B vaccine in the third year. As noted above, these costs are only indicative and an assessment, based on a more accurate analysis of requirements, will need to made once the findings of the March 2001 review are known.

Projected Sources and Funding Gap

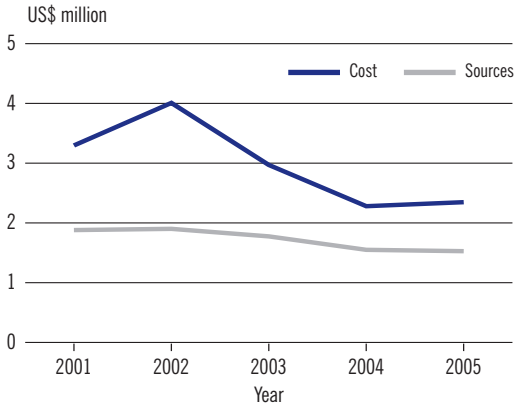
UNICEF and WHO have been the primary donors so far. For 2001, WHO will contribute $24,150 for technical assistance and UNICEF has $70,000 remaining in its 1997–2001 budget allocation, which may be used for training and for cold-chain and sterilization equipment purchases.

WHO has indicated that it is likely to continue with its current level of support (about $75,000 every two years), to be used for technical assistance and training. UNICEF has not yet made available its forecast contribution under its new five-year program beginning 2002, but it is likely to be significantly less than its contribution under its current program. The Japanese Government at this stage has indicated only preliminary interest

Table 18: **Strengthened and Expanded EPI, 2001–2005** (US$)

Item	2001	2002	2003	2004	2005	Total
Operating costs						
Basic program	1,675,923	1,707,457	1,581,379	1,558,295	1,535,673	8,058,725
Hepatitis B introduction						
Assessment	20,000					20,000
Vaccine			247,165	390,650	469,647	1,107,462
Polio eradication	153,846	174,381	174,381			502,608
Measles campaign		1,144,667				1,144,667
Laboratory costs						
Reagents, etc	4,267	5,333	5,333	5,333	5,333	25,600
Training	3,500					3,500
Surveillance, AEFI workshop	20,000					20,000
Maintenance (cold chain/vaccine management)						
Storage	10,326	13,877	17,428	17,428	17,428	76,487
Vehicles	14,000	25,200	35,000	35,000	35,000	144,200
Equipment	10,896	21,792	32,688	43,584	54,480	163,440
Maintenance (supervision), vehicles	10,472	18,928	25,200	25,200	25,200	115,472
Maintenance (injection)	15,120	20,160	25,200	25,200	25,200	110,880
Training						
Cold chain	7,692	10,000	10,000	10,000	10,000	47,692
Quality	20,000	20,000	20,000	20,000	20,000	100,000
Subtotal	**1,966,042**	**3,161,795**	**2,173,773**	**2,130,690**	**2,197,962**	**11,630,261**
% increase	**117%**	**185%**	**137%**	**137%**	**143%**	
Capital costs						
Laboratory costs	64,103					64,103
Inventory control	5,000					5,000
Cold chain/vaccine management						
Storage	552,180	200,128	200,128			952,436
Vehicles	250,000	200,000	175,000			625,000
Equipment	165,105	165,105	165,105	165,105	165,105	825,525
Supervision, vehicles	187,000	151,000	126,000			464,000
Injection equipment	146,050	146,050	146,050			438,150
Subtotal	**1,369,438**	**862,283**	**812,283**	**165,105**	**165,105**	**3,374,214**
Total	3,335,480	4,024,078	2,986,056	2,295,795	2,363,067	15,004,475
% increase	**199%**	**236%**	**189%**	**147%**	**154%**	

Figure 7: **Overall Financing Gap for Improved EPI, 2001–2005**



and has not been considered. GAVI assistance will be applied for, but cannot be guaranteed and therefore has also not been included.

Table 19 shows the gap in EPI financing for an improved program over the next five years. It assumes that the Government of Sri Lanka will meet all routine costs, but no capital costs because of fiscal constraints. The table includes the five-year forecast for WHO assistance. Future UNICEF contributions, although potentially large enough to alter this gap analysis, have not been included, as the amount and distribution of funding is still unknown.

The analysis suggests that an additional $6.4 million (43 percent) will be needed to undertake all the planned improvements over the five-year period. The largest unfunded activity is cold-chain support, if vehicle costs are included. This is followed by the cost of introducing Hepatitis B vaccine and the measles campaign in 2002. Figure 7 shows the total gap between costs and sources.

Table 19: **Total Financing Gap for an Improved EPI, 2001–2005**

Item	Total Cost (US$)	Available/Committed Funds (US$)	Gap (US$)	% of Total Financing Required
Operating costs				
Basic program		7,978,725	7,978,725	
Hepatitis B introduction				
Assessment	20,000	20,000		
Vaccine	1,107,462		(1,107,462)	17.0
Polio eradication		502,608	502,608	
Measles campaign	1,144,667		(1,144,667)	18.0
Laboratory costs				
Reagents, etc	25,600		(25,600)	0.4
Training	3,500		(3,500)	
Surveillance, AEFI workshop	20,000		(20,000)	0.3
Maintenance (cold chain/vaccine management)				
Storage	76,487		(76,487)	1.0
Vehicles	144,200		(144,200)	2.0
Equipment	163,440		(163,440)	2.0
Maintenance (supervision), vehicles	115,472		(115,472)	3.0
Maintenance (injection)	110,880		(110,880)	3.0
Training				
Cold chain	47,692		(47,692)	1.0
Quality	100,000		(100,000)	2.0
Subtotal	**11,630,261**		**(3,048,928))**	**47.0**
Capital costs				1.0
Laboratory costs	64,103		(64,103)	0.1
Inventory control	5,000		(5,000)	16.0
Cold chain/vaccine management				
Storage	952,436		(952,436)	10.0
Vehicles	625,000		(625,000)	8.0
Equipment	825,525		(825,525)	14.0
Supervision, vehicles	464,000		(464,000)	7.0
Injection equipment	438,150		(438,150)	7.0
Subtotal	**3,374,214**		**(3,374,214)**	**53.0**
Total	**15,004,475**	**8,687,908**	**(6,423,142)**	**(43.0)**

Note: Measles campaign includes the cost of AD syringes

Policy and Financing Options

Financing gaps at the national level need to be addressed before the immunization program can be strengthened and expanded. Over the next five years these gaps will primarily affect the cold chain, service quality and safety, and measles control. Failure to address these issues could erode the significant gains of the past 20 years. Closing these gaps will require increased support from external partners, and the introduction of policies that can lead to cost savings.

The underfunded health system and the shift in resources toward larger medical institutions have deprived primary health care services of the necessary staff, supplies, and infrastructure. Additional funding and human resources are needed to improve the capacity and quality of such services. Any discussion of financing for immunization must take this broader context into account, particularly since the immunization program is so well integrated into the primary health care system.

The immunization program enjoys strong Government support for vaccine procurement, largely because of its excellent reputation. Hence, there has been little pressure to cut costs

Policy Options

Implementing the following policies will improve financial sustainability through potential cost savings and increased efficiencies:

Vaccine management

The immunization program enjoys strong Government support for vaccine procurement, largely because of its excellent reputation. Hence, there has been little pressure to cut costs. But with the vaccine budget expanding by 75 percent in 2001, the potential introduction of Hepatitis B vaccine in 2003 (costing an additional 42 percent) and current fiscal constraints on the Government, automatic funding should not be taken for granted. Policies that will lower the overall cost of vaccine purchases, while maintaining coverage and quality, will help sustain Treasury support.

To date, the immunization program has viewed vaccine wastage as a price it must pay for ensuring that every child is immunized. However, less wastage could mean lower costs, making wastage rates a useful financial management tool. As high coverage has already been achieved, wastage rates must now be analyzed in depth (to identify causes) and the appropriate reduction strategies implemented.

Donor dependence

Issues of financial sustainability extend beyond a commitment to vaccine procurement. Relying on donors to meet operational costs increases the risk that essential supplies will

be unavailable, and can compromise program integrity. UNICEF has been a partner of EPI since the start, and its continued (substantial) assistance is assumed. This dependent relationship has limited planning to transfer responsibility of funding critical supplies, such as syringes, to the Government. UNICEF (or any other donor) support will not be provided indefinitely, particularly as EPI diseases decrease and other priorities arise. At the very least, the Government should take responsibility for funding recurrent costs.

Cold-chain equipment: Management and procurement

Capital investment, and therefore the supply of adequate cold-chain equipment, is the responsibility of the central Government. While the EPI Unit is accountable for monitoring the cold chain, MCH is in charge of procuring and distributing equipment. This split in management responsibility has meant that inventory control and monitoring of equipment have not been adequate.

Consequently, the country's equipment needs and the status of its equipment inventory are not known, and accurate planning, for financial and other requirements is not known. Consolidating responsibility in one unit would lead to more efficient and effective management of the cold chain. Given the EPI Unit's vaccine storage responsibilities, reporting mechanisms, and strong management capacity, the unit should also be made responsible for equipment planning, procurement, and distribution.

While the EPI Unit is accountable for monitoring the cold chain, MCH is in charge of procuring and distributing equipment. This split in management responsibility has meant that inventory control and monitoring of equipment have not been adequate

Monitoring

Significant resources are required to implement a national immunization program, and managing them well will reduce costs. Cold-chain and sterilization equipment and vehicles should be inventoried and their functional status, performance, and maintenance schedule monitored to optimize their efficiency and longevity. A national (centralized) inventory and monitoring system will facilitate needs-based planning and make resource mobilization more efficient. More importantly, it will identify where (limited) resources are most needed and can be most effectively used.

An important element of good monitoring is responsiveness. Breakdowns in the cold chain, for example, need to be addressed as quickly as possible. This will require financial resources, and a discretionary budget for emergencies, at the national level, is justifiable.

Any investment in capital equipment should support the establishment of an effective and responsive monitoring system.

Financing Options

The size of financing gaps identified in this report must be considered only indicative. More accurate information will come from comprehensive assessments. This report should be read in conjunction with the EPI review (including a cold-chain assessment) in March–April 2001 and the five-year strategic plan to be developed after that.

Given its vital role in the program and assumed continuing assistance, UNICEF must clarify its future funding plans as soon as possible.

Vaccines

The Sri Lankan Government is committed to providing sufficient funds for the purchase of all vaccines. Donor funding is neither required nor advisable.

The Government may reduce costs by procuring from nonprequalified suppliers and using lot testing to verify quality. However, the savings may not compensate for the risks involved. WHO does not recommend this strategy.

Vaccine management and the cold chain

Investment in technical assistance for analysis of wastage rates and the introduction of appropriate reduction strategies is well justified

The costs of improving vaccine distribution capacity and strengthening the cold chain are not clear. Estimates provided assume the complete replacement of all vehicles and the uniform addition of refrigerators and freezers to all health units, and are not based on a systematic assessment of needs. Further, there has been no inventory of vaccine carriers, cold boxes, and icepacks. Any cold-chain investment must be preceded by a more accurate assessment (available after April 2001). Vehicle requirements, particularly at the periphery, must be assessed in relation to both vaccine distribution and supervision needs to minimize duplication.

Current estimates indicate a capital investment funding gap of $2.4 million ($952,000 for storage, $625,000 for vehicles, $825,000 for equipment). This total does not include maintenance costs of just over $100,000 per year. If a three-year phased-in approach is used, an investment of $960,000 in the first year, followed by about $500,000 in the next two years, will be required. Projections are based on these investments only and do not include a budget for replacement costs.

The establishment of a national inventory and monitoring system for equipment and a management and maintenance system for vehicles should be either a condition of any assistance package or a part of the package. Ongoing district-level training for cold-chain officers, costing about $10,000 per year, should accompany any equipment provided.

No committed source of funds for cold-chain equipment has been identified, although the Japanese Government has indicated interest in providing medium-term support. In line with Japanese policy, assistance will not be provided for vehicles. The UNICEF budget for cold-chain equipment is unknown.

Quality and community commitment

Strengthening the quality of the immunization program is arguably the most important priority. The risk of losing the tremendous advantages gained in disease control should not be underestimated.

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The medium-term injection strategy for the immunization program will need to be decided soon. Introducing auto-disable (AD) syringes as recommended by WHO/ UNICEF, will have significant financial consequences

As with the cold chain, the exact financial resources required should be studied further. The provision of vehicles is an important component but increased human resource capacity at the central and district levels is also needed. The cost and feasibility of strengthening capacity in a sustainable manner will require a broader analysis than that contained in this report, particularly since immunization is an integral part of the primary health care system. Financing for training, estimated at $20,000 at the minimum, should be contingent on the development of a medium-term training strategy, which includes adequate follow-up and supervision. WHO has earmarked $3,500 for training in various areas.

Problem areas that will require specific training should be identified through a survey of qualitative aspects in 2001 supported by WHO.

Capital investment in vehicles for the central and district levels will cost about $464,000. Vehicle needs at the periphery must also be assessed. Access by public health midwife supervisors and MCH to all clinics is important, and may require the purchase or replacement of motorcycles, for example. Conditions of vehicle assistance are outlined in the "Future Financing" section above.

Equitable access

Some of the resource needs of the estate sector and the conflict zone were included in the foregoing cost analyses, but further study will determine the extent and type of extra funding that will help ensure or increase quality coverage of these hard-to-reach populations. Any financial assistance for the immunization program should explicitly address these needs.

Injection safety

The medium-term injection strategy for the immunization program will need to be decided soon. Introducing auto-disable (AD) syringes, as recommended by WHO/UNICEF, will have significant financial consequences. Recurrent expenditure will increase dramatically and up-front investment for training and sensitization activities as well as an adequate waste management system will be necessary.

As long as safety is maintained, sterilizable equipment is more cost-effective: the estimated yearly cost of supplying AD syringes is $430,000, the same amount required to upgrade steam sterilizers throughout the program. Should the present system be retained, resources for the replacement of old sterilizers must be identified. UNICEF funding cannot be guaranteed.

Injection safety must be maintained, and investments in equipment are well justified. However, as with cold-chain equipment, these investments must be preceded by an in-depth assessment of needs, include the establishment of a national monitoring system for equipment and supplies, and be accompanied by training in maintenance. The investment should also be contingent on Government financing of all recurrent costs.

Introduction of new vaccines

In theory, an immunization program should be expanded only when it is already robust enough. To introduce new vaccines into a fragile cold chain is to risk damaging the vaccines, leading to significant financial loss and limited improvement in disease control. If routine Hepatitis B immunization is introduced, either the Global Alliance on Vaccines and Immunization (GAVI) or the Government will likely cover the funding requirements. Indirect but crucial support can be provided through investments in general program strengthening, including the cold chain.

Some of the resource needs of the estate sector and the conflict zone were included in the foregoing cost analyses, but further study will determine the extent and type of extra funding that will help ensure or increase quality coverage of these hard-to-reach populations

Disease control strategies

There is good justification for developing medium-term financing arrangements to ensure support for the eradication of measles. The minimum investment for a catch-up campaign in 2002 is $1.3 million, including AD syringes but not the associated program costs. Follow-up mass campaigns every three to seven years will require similar funding. Any assistance must consider the policy and financial tension between focusing on a single disease and ensuring a strong program overall.

Summary

The use of wastage rates in vaccine planning and management could lead to cost savings. In-depth analysis should identify causes and recommend appropriate strategies to reduce vaccine usage without compromising quality or coverage.

To strengthen the immunization program, additional funding is required in three areas: cold chain (storage, vehicles, equipment, and training), quality (vehicles and training), and injection safety (equipment). Liaison with UNICEF and JICA will facilitate a comprehensive donor approach to supporting these areas.

To expand the program, additional funding is required for measles eradication, a priority for the Government following the outbreak in 1999–2000.

Three funding options are available to the Sri Lankan Government: increase national spending; increase donor funding; or assume (soft) loan obligations. Substantial Government increases are unlikely in the short term, given the reasons outlined above. Donor funding and loan obligations may provide opportunities to strengthen the program but should not be relied on to deliver essential components of the program, such as injection supplies.

Recommendations

These recommendations should be reviewed in light of the overall program assessment in March 2001, and the five-year strategic plan and budget to be prepared after that

To strengthen and expand the national immunization program of Sri Lanka, the Government should examine cost reduction strategies and policy issues, and mobilize resources. In view of the primary need to consolidate the substantial gains achieved in coverage and disease control, the following courses of action are recommended:

- Improve financial sustainability by ensuring full internal funding of all basic operational costs (particularly syringes and needles) for the routine program.
- Minimize cost by:
  - (i) Investigating the cost advantages of multi-year planning and procurement contracts
  - (ii) Using wastage rates when forecasting vaccine needs
  - (iii) Seeking technical assistance to:
    - (a) analyze the cause of vaccine wastage
    - (b) if appropriate, develop and implement waste reduction strategies and policies
  - (iv) Establishing a national inventory and monitoring system for equipment and supplies (see the third recommendation below)
  - (v) Undertaking preventive maintenance on equipment
- Mobilize external resources to fund the following:
  - (i) *A national inventory control system* for vaccines, equipment, and other supplies
  - (ii) *A stronger cold chain*, including storage, vehicle, and equipment needs. The following are further recommended:
    - (a) A comprehensive assessment of needs should precede any investment.
    - (b) Vehicle support should consider cost-effective management systems (such as whole-of-life contracts) and ensure that sufficient resources are available for the associated operating costs.
    - (c) Equipment support should provide assistance for the implementation of replacement and maintenance systems, including the cost of expanding and sustaining maintenance capacity at the district level.
    - (d) Full management of cold-chain equipment should be transferred to the EPI Unit.
  - (iii) *Better-quality service,* through improved capacity for supervision and training. The following are further recommended:
    - (a) A comprehensive assessment of needs (including those at the periphery) should precede the purchase of vehicles.
    - (b) Support should be contingent on (or provide assistance for) the development of a medium-term plan to improve service capacity.
    - (c) Support should be provided for the production and distribution of an immunization manual for health care workers.
  - (iv) *Replacement of injection equipment* (assuming the continued use of sterilizable equipment). The following are further recommended:
    - (a) Any investment should be subject to the same conditions as investment in cold-chain equipment (see above).

(b) Support should be contingent on Government commitment to cover all relevant operating costs (see the first recommendation above).

(v) A measles eradication campaign

- Improve equitable access for the hard-to-reach, particularly in the north and east and the plantation estate sector, by drawing up investment strategies that explicitly address the financial resource needs of these populations.
- Urge UNICEF to clarify its short and medium-term funding plans as soon as possible.

These recommendations should be reviewed in light of the overall program assessment in March 2001, and the five-year strategic plan and budget to be prepared after that.

APPENDIX A

Incidence of EPI Target Diseases, 1990–1999

Year	Diphtheria	Pertussis	Tetanus	Poliomyelitis	Measles	TB	Neonatal Tetanus
1990	1	271	184	9	4004	6666	14
1991	2	25	188	1	1896	6174	10
1992	1	6	231	2	682	6802	9
1993	0	18	196	15	558	6809	13
1994	0	59	193	0	566	6132	7
1995	0	171	163	0	248	5710	9
1996	0	34	132	0	155	5366	16
1997	0	316	95	0	257	6542	12
1998	0	153	80	0	263	6925	13
1999	0	112	64	0	4637	10395	15

Source: Medical Statistics Unit

Working Papers

1. Forecast Vaccine Costs

Prices: EPI 2001 estimates (C&F) used

OPV

Year	Cohort	Doses (5)	Wastage	Total Doses	$ per Dose	Total
2001	320,000	1,800,000		1,800,000	0.128	230,769
2002	313,600	1,568,000	1.3	2,038,400	0.128	261,333
2003	307,328	1,536,640	1.3	1,997,632	0.128	256,107
2004	301,181	1,505,907	1.3	1,957,679	0.128	250,985
2005	295,158	1,475,789	1.3	1,918,526	0.128	245,965
Total						**1,245,159**

DPT

Year	Cohort	Doses (4)	Wastage	Total Doses	$ per Dose	Total
2001	320,000	1,900,000		1,900,000	0.064	121,795
2002	313,600	1,254,400	1.3	1,630,720	0.064	104,533
2003	307,328	1,229,312	1.3	1,598,106	0.064	102,443
2004	301,181	1,204,726	1.3	1,566,143	0.064	100,394
2005	295,158	1,180,631	1.3	1,534,821	0.064	98,386
Total						**527,551**

BCG

Year	Cohort	Doses (1)	Wastage	Total Doses	$ per Dose	Total
2001	320,000	1,400,000		1,400,000	0.077	107,692
2002	313,600	313,600	4.3	1,348,480	0.077	103,729
2003	307,328	307,328	4.3	1,321,510	0.077	101,655
2004	301,181	301,181	4.3	1,295,080	0.077	99,622
2005	295,158	295,158	4.3	1,269,179	0.077	97,629
Total						**510,327**

Measles

Year	Cohort	Doses (1)	Wastage	Total Doses	$ per Dose	Total
2001	320,000	750,000		750,000	0.128	96,154
2002	313,600	313,600	2.5	784,000	0.128	100,513
2003	307,328	307,328	2.5	768,320	0.128	98,503
2004	301,181	301,181	2.5	752,954	0.128	96,533
2005	295,158	295,158	2.5	737,895	0.128	94,602
Total						**486,304**

Rubella

Year	Cohort	Doses (1)	Wastage	Total Doses	$ per Dose	Total
2001	197,750	500,000		500,000	0.154	76,923
2002	193,795	193,795	1.5	290,693	0.154	44,722
2003	189,919	189,919	1.5	284,879	0.154	43,827
2004	186,121	186,121	1.5	279,181	0.154	42,951
2005	182,398	182,398	1.5	273,597	0.154	42,092
Total						**250,515**

Note: Demographic projections from Population Information Center

MR

Year	Cohort	Doses (1)	Wastage	Total Doses	$ per Dose	Total
2001	340,000	700,000		700,000	0.769	538,462
2002	333,200	333,200	2.0	666,400	0.769	512,615
2003	326,536	261,229	2.0	522,458	0.769	401,890
2004	320,005	256,004	2.0	512,008	0.769	393,853
2005	313,605	250,884	2.0	501,768	0.769	385,976
Total						**2,232,796**

Note: 2001 cohort based on 1998 live births (see EPI 2000a). Assumes 70% coverage in years 1 and 2, 80% in years 3 to 5

Dt

Year	Cohort	Doses (1)	Wastage	Total Doses	$ per Dose	Total
2001	355,000	500,000		500,000	0.077	38,462
2002	347,900	347,900	2.4	834,960	0.077	64,228
2003	340,942	340,942	2.4	818,261	0.077	62,943
2004	334,123	334,123	2.4	801,896	0.077	61,684
2005	327,441	327,441	2.4	785,858	0.077	60,451
Total						**287,767**

Note: 2001 cohort based on 1996 live births

TT

Year	Cohort	Doses (2)	Wastage	Total Doses	$ per Dose	Total
2001	361,071	450,000		450,000	0.051	23,077
2002	353,849	707,698	2.0	1,415,396	0.051	72,584
2003	346,772	693,544	2.0	1,387,088	0.051	71,133
2004	339,837	679,673	2.0	1,359,347	0.051	69,710
2005	333,040	666,080	2.0	1,332,160	0.051	68,316
Total						**304,820**

aTd

Year	Cohort	Doses (1)	Wastage	Total Doses	$ per Dose	Total
2001	355,000	106,500		200,000	0.077	15,385
2002	347,900	104,370	2.0	208,740	0.077	16,057
2003	340,942	102,283	2.0	204,565	0.077	15,736
2004	334,123	100,237	2.0	200,474	0.077	15,421
2005	327,441	98,232	2.0	196,464	0.077	15,113
Total						**77,711**

Note: Assumes 30% coverage

Plus Polio Subnational Immunization Days

Year	Cohort	Doses (5)	Wastage	Total Doses	$ per Dose	Total
2001	618,259	1,200,000		1,200,000	0.128	153,846
2002	618,259	1,236,518	1.1	1,360,170	0.128	174,381
2003	618,259	1,236,518	1.1	1,360,170	0.128	174,381
Total						**502,608**

Note: Based on 2000 population and dose requirements

Plus Measles Campaign

Year	1–15	Doses (1)	Wastage	Total Doses	$ per Dose	Total
2003	**4,719,000**	**4,719,000**	**1.1**	**5,190,900**	**0.128**	**665,500**

AD Syringes

Year	1–15	Doses (1)	Syringes	Wastage (4%)	Total	$ per Unit	$	Transport	Total
AD syringes	4,719,000	4,719,000	4,719,000	188,760	4,907,760	0.07	343,543	103,063	446,606
Safety boxes			47,190		47,190	0.60	28,314	4,247	32,561
Total									**479,167**

Note: Transport based on 30% of cost for syringes and 15% of cost for safety boxes; UNICEF indicative prices used

2. Injection Equipment

No. of Injections Required

Year	DPT	Measles	BCG	HepB	Rubella	DT	TT	MR	aTd	Total
2001	1,280,000	320,000	320,000	960,000	395,500	355,000	361,071	238,000	71,400	4,300,971
2002	1,254,400	313,600	313,600	940,800	387,590	347,900	353,849	247,694	74,308	4,233,742
2003	1,229,312	307,328	307,328	921,984	379,838	340,942	346,772	277,418	83,225	4,194,147
2004	1,204,726	301,181	301,181	903,544	372,241	334,123	339,837	271,869	81,561	4,110,264
2005	1,180,631	295,158	295,158	885,473	364,797	327,441	333,040	266,432	79,930	4,028,059

AD Syringes

Year	No. of Years	Wastage (4%)	Total	$ per Unit	Total ($)	Transport	Subtotal	Safety Boxes	$ per Unit	Total	Transport	Subtotal	Total
2001	4,300,971	172,039	4,473,009	0.07	313,111	93,933	407,044	43,010	0.55	23,655	3,548	27,204	434,247
2002	4,233,742	169,350	4,403,091	0.07	308,216	92,465	400,681	42,337	0.55	23,286	3,493	26,778	427,460
2003	4,194,147	167,766	4,361,913	0.07	305,334	91,600	396,934	41,941	0.55	23,068	3,460	26,528	423,462
2004	4,110,264	164,411	4,274,675	0.07	299,227	89,768	388,995	41,103	0.55	22,606	3,391	25,997	414,993
2005	4,028,059	161,122	4,189,181	0.07	293,243	87,973	381,216	40,281	0.55	22,154	3,323	25,477	406,693
Total 2003–2005							**1,167,145**						**1,245,148**
Total 2001–2005							**1,974,870**						**2,106,855**

Sterilizable Equipment
Capital Costs

Item	Number	Price	Total ($)	Transport	Total	R&M	Total	R&M/Year
Steam sterilizers, double rack 750600	1,000	107	107,000	16,050	123,050	21,400	144,450	4,280
Steam sterilizers, single	200	95	19,000	2,850	21,850	3,800	25,650	760
Kerosene stoves	100	10	1,000	150	1,150			
Total					**146,050**	**25,200**	**170,100**	**5,040**

Note: R&M = repair and maintenance

Operating Costs per Year

Item	Price	Transport	Total
Syringe, 5 ml	12,006	1,801	13,807
Syringe, 0.5 ml epi	26,243	3,936	30,179
Needles	7,500	1,125	8,625
Fuel			5,000
Hard water pad			3,000
TST			5,000
Total			**57,611**

Note: Based on cohort of 350,000

Yearly Costs

Item	Year 1	Year 2	Year 3	Year 4	Year 5
Sterilization Equipment					
Capital	146,050	146,050	146,050		
Operating					
Supplies	57,611	57,611	57,611	57,611	57,611
R&M	15,120	20,160	25,200	25,200	25,200
Subtotal	72,731	57,611	57,611	57,611	57,611
Total	**218,781**	**203,661**	**203,661**	**57,611**	**57,611**
AD syringes					
Total	**434,247**	**427,460**	**423,462**	**414,993**	**406,693**

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