**Ministry of Health** 

Government of the Democratic Socialist Republic of Sri Lanka

# COMPREHENSIVE MULTI-YEAR PLAN FOR IMMUNIZATION 2012 - 2016

Expanded Programme on Immunization Directorate General of Health Services

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# **Executive Summary**

The Expanded Programme of Immunization (EPI) in Sri Lanka is an integral component of the public health system. The main objective of the country's EPI is to reduce morbidity and mortality associated with vaccine preventable diseases. The unique feature of the immunization services in Sri Lanka is that for over three decades, it is integrated with the other primary health care services at all levels. Therefore service providers and other logistics are shared with other public health activities as a routine.

Sri Lanka's national immunization programme is frequently quoted as one of the strongest performers, not only in the region, but also in the world. The National EPI programme has an excellent record, with extremely low incidence of EPI diseases and high coverage of all EPI vaccines. However, unless the country pays attention to key issues of programme quality and timely introduction of newer vaccines according to the needs it could lose the advantages it has gained in disease control over the last 30 years.

The EPI is one of the priority public health activities to which the government of Sri Lanka has given due attention even during any economic and political crisis.

The main source of the government's health expenditure is the consolidated fund and the balance comes as foreign aid. Compared to the total external funding into the health sector, the amount of donor funding for immunization is proportionately very low. It is of utmost importance to highlight that the immunization programme in Sri Lanka is self funded, as nearly 98% of the cost is borne by the Government of Sri Lanka. This demonstrates good evidence of financial sustainability in the past. WHO, GAVI and UNICEF are the leading international donors supporting and covering the balance two percent. Though, the sharing of government has declined 98% in 2002, to 92% in 2004, the actual amount spent has increased by US\$ 1.4 million. GAVI funding during this review period has caused slight decline in the government proportion.

Comprehensive Multi year plan (CMYP) for immunization is a key management tool for the national immunization programmes, and in recent years managers have been asked to develop different plans to reach different immunization objectives. Developing a CMYP presents an opportunity to consolidate existing plans into a single document that addresses global, national and sub-national immunization objectives and strategies efficiently, and that also evaluates the cost and financing of the plan. CMYP articulates the future vision for the immunization programme in Sri Lanka.

The expansion of immunization activities, including polio eradication, measles elimination, elimination of neonatal tetanus, introduction of new vaccines and safer vaccination technologies have increased the need for coordination and a comprehensive response to planning and budgeting for the sustainability of the programme. High cost of all new vaccines will be a real challenge to ensure the balance between the sustainability and the expansion of the programme according to the current need.

By putting the various pieces together into one process and document, the CMYP makes it easier for the immunization programmes to set priorities, plan for implementation, and identify interactions across programmes. At the same time by assessing changes in the health sector and the political and economic situation, immunization managers can anticipate changes in funding flows or methods of service delivery in order to plan sustainable improvements.

This CMYP document sets out the medium term goals, related objectives, strategies, indicators and associated costs for the period of five years starting from January 2012 to December 2016.

The key areas identified to be improved during this period are: maintaining the high coverage of vaccines administered during the first year of life; Coverage of vaccines administered during school going age; Laboratory confirmation of reported EPI target diseases; Availability of adequate cold chain at all levels; routine detailed investigation of serious AEFI at divisional level; reduce EPI vaccine wastage; prevailing disparity in the quality of immunization services within and between districts; inadequate and maldistribution of health personel; Vaccine transport facilities at all levels; EPI related disease surveillance activities; training and research activities related to immunization; introduction of new antigen into the EPI programme; private sector contribution towards immunization; and financial sustainability of the immunization programme.

Sri Lanka is planning to introduce Pneumococcal and HPV vaccines into the national EPI programme from 2013 and 2014 respectively. For this purpose Sri Lanka will necessarily be looking for donor support. It will require an additional US\$14 million annually and this will be around 92% of the cost of the total immunization programme.

AD       Auto-disable syringe         AEFI       Adverse event following immunization         AFP       Acute flaccid paralysis         a TD       Adult tetanus and diphtheria vaccine         DT       Diphtheria and tetanus vaccine         BCG       Bacilli Calmette-Guerin (tuberculosis vaccine)         CMYP       Comprehensive multi-year plan         RDHS       Deputy provincial director of health services         DTP       Diphtheria-tetanus-pertussis vaccine         DP11       First dose of diphtheria-tetanus-pertussis vaccine         DP12       Second dose of diphtheria-tetanus-pertussis vaccine         DP13       Third dose of diphtheria-tetanus-pertussis vaccine         DP14       Effective vaccine system management         FHB       Family health bureau         GAVI       Global alliance for vaccines and immunization         GDP       Gross national product         GTN       Global training network         Hep B       Hepatitis B vaccine         Hib       Hemophilus influenzae type b vaccine         HPV       Human papilloma virus         ICC       Interagency coordinating committee         JE       Japanese encephalitis vaccine         MCH       Maternal and child health         MOH<		Acronyms
<ul> <li>AD Auto-disable syringe</li> <li>AEFI Adverse event following immunization</li> <li>AFP Acute flaccid paralysis</li> <li>a TD Adult tetanus and diphtheria vaccine</li> <li>DT Diphtheria and tetanus vaccine</li> <li>BCG Bacilli Calmette-Guerin (tuberculosis vaccine)</li> <li>CMYP Comprehensive multi-year plan</li> <li>RDHS Deputy provincial director of health services</li> <li>DTP Diphtheria-tetanus-pertussis vaccine</li> <li>DPT1 First dose of diphtheria-tetanus-pertussis vaccine</li> <li>DPT2 Second dose of diphtheria-tetanus-pertussis vaccine</li> <li>DPT3 Third dose of diphtheria-tetanus-pertussis vaccine</li> <li>DPT3 Effective vaccine system management</li> <li>FHB Family health bureau</li> <li>GAVI Global alliance for vaccines and immunization</li> <li>GDP Gross domestic product</li> <li>GTN Global training network</li> <li>Hep B Hepatitis B vaccine</li> <li>Hib Hemophilus influenzae type b vaccine</li> <li>HPV Human papilloma virus</li> <li>ICC Interagency coordinating committee</li> <li>Japanese encephalitis vaccine</li> <li>MCH Medical officer of health</li> <li>MOH Medical officer of health</li> <li>MOH Medical officer of health</li> <li>MR Measles and rubella vaccine \</li> <li>INGO International nongovernmental organization</li> <li>OPV Oral polio vaccine</li> <li>PHM Public health midwife</li> <li>TT Tetanus toxoid</li> <li>RMSD Regional medical supplies division</li> <li>UNICEF United Nations Children's Fund</li> <li>VMAT Vaccine management tool</li> <li>WHO World Health Organization</li> </ul>	The followi	ng acronyms are used in this document.
	AD AEFI AFP a TD DT BCG CMYP RDHS DTP DPT1 DPT2 DPT3 EVSM FHB GAVI GDP GNP GTN Hep B Hib HPV ICC JE MCH MR INGO OPV PHM TT RMSD UNICEF VMAT WHO	Auto-disable syringe Adverse event following immunization Acute flaccid paralysis Adult tetanus and diphtheria vaccine Diphtheria and tetanus vaccine Bacilli Calmette-Guerin (tuberculosis vaccine) Comprehensive multi-year plan Deputy provincial director of health services Diphtheria-tetanus-pertussis vaccine First dose of diphtheria-tetanus-pertussis vaccine Second dose of diphtheria-tetanus-pertussis vaccine Third dose of diphtheria-tetanus-pertussis vaccine Expanded programme on immunization Effective vaccine system management Family health bureau Global alliance for vaccines and immunization Gross domestic product Global training network Hepatitis B vaccine Hemophilus influenzae type b vaccine Human papilloma virus Interagency coordinating committee Japanese encephalitis vaccine Maternal and child health Medical officer of health Measles and rubella vaccine\ International nongovernmental organization Oral polio vaccine Public health midwife Tetanus toxoid Regional medical supplies division United Nations Children's Fund Vaccine management assessment tool World Health Organization

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# **1.INTRODUCTION**

#### 1.1 Country profile

#### 1.1.1 Basic facts

Sri Lanka is a small island in the Indian Ocean with a land area of approximately 62,705 square kilometers and a population of 20 million. Topographically, the island consists of a south central mountainous region which rises to an elevation of 2,502 meters and is surrounded by broad lowland plains at an elevation of 0-75 meters above sea level. The mean temperature ranges from 26°C to 28°C in the low country, and from 14°C to 24°C in the hill country.

Sri Lanka has a parliamentary democratic system of government in which, sovereignty of the people and legislative powers are vested in Parliament. The executive authority is exercised by a Cabinet of Ministers, presided by an Executive President. The President and Members of the Parliament are elected directly by the people.

For purposes of administration, Sri Lanka is divided into 9 provinces, 25 Districts, and 329 Divisional Secretary areas. The Provincial administration is vested in the Provincial Councils, composed of elected representatives of the people.

#### 1.1.2 Demography

The population of Sri Lanka for the year 2009 is estimated to be 20.4 million. The average annual growth rate is recorded as 1.1 for the island. Little over half of the population is concentrated in the Western, Central and Southern provinces. These three provinces together make 23.2% of the total land area of the country.

During 2009, Sri Lanka had approximately 326 persons per square kilometer (population density). The district of Colombo has the highest density of 3,410 persons per square kilometer. The districts of Mannar, Vavuniya, Mullaitivu and Monaragala that are remote from the major urban centers have a density of less than 100.

One of the most clearly visible features in Sri Lanka's population age composition is the increasing trend in the proportion of the older age groups. The median age which remained around 21.3 years until 1981, has increased to 30.9 by 2007 [DHS 2007]. It could also be observed that the proportion of the population under 15 years of age decreased from 35.2% in 1981 to 25.9% in 2007. Elderly population (65 years and above) increased from 4.3% in 1981 to 7.5% in 2007. On the other hand, the proportion of the adult population has increased over the time.

Sri Lanka has passed through the classical phases of demographic transition to reach the third phase of a declining birth rate (28.4 in 1980 to 18.8 in 2009 per 1000 population) and a relatively stable low death rate (6.2 per 1000 population 2010).

#### 1.1.3 Conflict-affected areas

The two decades of Twenty six year (1983 to 2009) civil conflict in the Northern and Eastern parts of the country have resulted in at least 60,000 deaths, many more have been disabled, and at least 800,000 people have been internally displaced. The whole population of Sri Lanka has suffered from the consequences of the conflict, but the North and East Provinces, which make up about 24% of the Sri Lanka's land area, and containing about 10% of its population and the adjacent areas, have borne the brunt of the conflict. Livelihoods, particularly for the poor in the conflict-affected areas, have been destroyed. Much of the physical infrastructure and the means of production have been damaged, destroyed, or have deteriorated over time. The conflict has been a constraint to growth, health promotion and poverty reduction. It has not only caused extensive suffering and dislocation but has also sharply reduced the economic contribution of the region to national development, required defence expenditures that became unsustainable, restrained growth in social expenditure, discouraged investment, and stifled tourism.

Since end of the civil conflict in the Northern and Eastern parts of the country in 2009, the Government is now in the process of establishing normalcy in these parts of the country by resettling the bulk of the displaced persons, rebuilding their houses, rehabilitating their villages and restoring their livelihood. Many infrastructure projects including health in these districts have been completed and many projects are underway. These efforts would bring speedy growth and development to these areas.

#### 1.1.4 Economic status

Sri Lanka's economy grew by an impressive 8.0 per cent in 2010, reflecting a fast recovery since the end of civil conflict in 2009 and moved to a high and sustainable growth path. All key sectors of the economy demonstrated a commendable performance in 2010, underpinned by the peaceful domestic environment, and improved investor confidence, favourable macroeconomic conditions and gradual recovery of the global economy from one of the deepest recessions in history.

Sri Lanka was graduated to middle-income status from the list of Poverty Reduction and Growth Trust (PRGT) eligible countries, in January 2010 by the International Monetary Fund (IMF). The strong economic performance in recent years has lifted Sri Lanka's per capita

income substantially, reaching US dollars 2,014 by 2008, well above the prevailing International Development Association (IDA) threshold and has been on a steady upward trend for, at least, the last 5 years [Central Bank Report 2010].

Sri Lanka's social indicators are among the best in the South Asian region. The country has achieved near universal literacy and, perhaps more remarkably, girls are on par with boys. Sri Lanka's poverty level is comparatively low at 15.2%.

#### 1.2 Current situation of the health sector

#### **1.2.1 National Health Policy**

The broad mission of the health policy of Sri Lanka is to achieve the highest attainable health status by responding to people's needs, working in partnership, to ensure access to comprehensive, high quality, equitable, cost-effective and sustainable health services. This is to be achieved by controlling preventable diseases and by health promotional activities.

National health policy is aimed to consolidate what has already been achieved, as well as address new health challenges, such as the increasing prevalence of emerging and reemerging communicable and non-communicable diseases, sexually transmitted infections etc. Though a countrywide network of health facilities has been already developed with health care provided free at the point of delivery by the government, relatively underserved geographical areas and population groups still exist. These groups such as the urban and rural extremely poor, estate workers and displaced populations have specific health needs. National strategies including the poverty alleviation programme and targeted specific health interventions are designed in such a way to meet the specific health needs of these disadvantaged groups.

#### 1.2.2 Organization of health services

Health care delivery in Sri Lanka is organized through both public and private sectors and include the services of those practicing within the allopathic (Western) system of health care which covers more than 85% of the total health requirement, and traditional systems of medicine namely Ayurvedic, Unani, Siddha and Homoeopathy. Consumers are free to choose services from both public and private sectors.

The public sector provides the entire range of preventive, curative and rehabilitative health care, free at the point of delivery throughout the country. The public sector curative services are provided through a wide network of health care institutions, ranging from central dispensaries to teaching hospitals. It meets more than 95% of the demand for inpatient care and one half of the demand for outpatient services. The private sector provides mainly

curative care, which is estimated to be nearly 50% of the outpatient care and is largely concentrated in the urban and suburban areas.

The preventive health care services are provided by the provincial councils according to the policy guidelines of the central government agencies such as the Epidemiology Unit, Family Health Bureau and special disease control programs / campaigns. The Medical Officers of Health (MOH) are responsible for defined geographic areas and they with the help of field health staff focus mainly on health promotion and preventive aspects of health care (i.e. public health).

#### 1.2.3 An overview of the current health status

The country's health indicators show a steady improvement over recent decades, particularly in maternal and infant mortality, and life expectancy. The maternal mortality rate of 39 per 100,000 live births and the infant mortality rate of 11.2 per 1,000 live births in 2009 are exceptional achievements for a developing country with a per capita income of around US\$ 2000. The improvement in these indicators is predominantly attributed to the maternal and child care programmes including expanded programme of immunization (EPI) implemented nationally as integral components of the state health care system. However, whilst postneonatal mortality has declined significantly, efforts to reduce prenatal and neonatal mortality have been less successful. A neonatal mortality rate of 9 per 1,000 live births (2009) suggests continuing problems requiring improvement in the quality of natal care and maternal nutrition. Life expectancy has risen steadily to around 77.9 for females and 70.3 for males (2007), and the fertility rate has declined to around 2.3 just around the population replacement level. With the rapid ageing of the population and success in combating the major communicable diseases, the disease burden has started shifting rapidly towards non-communicable diseases like diabetes, cardiovascular diseases, cerebrovascular diseases, mental illnesses, cancer, accidents and injuries. The leading causes of death by percentage of total mortality for year 2007 are ischaemic heart disease (13.1%), neoplasms (10.1%), pulmonary heart disease and diseases of the pulmonary circulation (10.1%), cerebrovascular disease (9.2%) and diseases of the intestinal tract (7.2%). However, infectious diseases such as dengue, leptospirosis, diarrhoea, and tuberculosis are still prevalent and Sri Lanka has to bear a double burden of communicable and non-communicable diseases. Nutritional status has improved but remains a serious problem among the poorer and vulnerable communities and, even on average, is not up to the expected level.

The above mentioned trends are based on information related to the whole country and does not reflect the disparities that exist between provinces. When the provincial or district level figures on infant and maternal mortality rates are compared there seems to be significant disparities, part of which may be due to differential underreporting or to the transfer of cases to adjacent districts with better health care facilities.

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#### 1.2.4 The future health challenges

The Sri Lanka health sector has been a successful model of "good outcome at low costs" in the 20<sup>th</sup> century. The success so far achieved is commendable; however, a failure would loom unless action is taken to face the rapidly changing scenario due to the epidemiological and demographic transition. Health transition is a historical phenomenon that many developed and developing countries are now experiencing, and Sri Lanka is no exception. Most of the countries share common underlying factors, i.e. transition in epidemiological patterns, change in patients' expectations, and societal demand for efficiency of healthcare system management.

The 'health transition' in Sri Lanka could be briefly explained as below:

- Group 1: Continuing problems In the developing world, prominent diseases have been infectious and, maternal and child health related conditions. They continue to remain an important problem, though the morbidity and mortality due to these conditions have fallen significantly over the years. Yet, pockets of areas where the morbidity and mortality from these conditions remain relatively high still exist. Infectious diseases, such as dengue leptospirosis and viral hepatitis continue to affect the population, while nearly a third of preschool children remain malnourished.
- Group 2: Emerging problems The social changes resulted from rapid urbanisation, industrialisation and/or the breakdown of traditional society has led to many emerging problems in recent years. They include accidents, injuries, violence and the surge of homicides in the younger age groups. Sri Lanka also faces an emerging problem of HIV/AIDS.
- Group 3: Evolving problems Some problems are evolving as a result of changing lifestyles, people's behaviour and stress in daily life. These problems are represented by an increasing propensity of non-communicable diseases such as diabetes, heart diseases, mental disorders and cancer.

In Sri Lanka, where communicable diseases and MCH-related diseases have

been drastically curtailed, these chronic ailments have evolved as a major problem

and becoming more visible due to overall ageing of the population.

The challenges posed by this health transition have to be faced by a new service delivery system by making changes in the present system. The new health care delivery system should employ an integrated approach with three functional arms, namely: preventive, curative and promotive.

Curative services alone cannot establish an efficient and cost-effective health system that is capable of challenging the health transition. Policy for integration of preventive services has to

be based on tackling the risk factors from foetal stage to old age. The policy focus on establishment of a comprehensive health care system should also highlight the importance of welfare elements. This is particularly vital to maintain a healthy society for the aged and disabled people.

#### 1.2.5 Health related financial implications\*

Sri Lanka has an impressive record of health care provision, with model accomplishments in health outcomes compared to similar developing countries. Over the decades, since independence, the Government of Sri Lanka (GoSL) has played a remarkable role in the health system; provision, financing, and regulation of health care across the country. Successes of these initiatives have been reflected in the impressive health outcomes associated with good maternal and child health, low levels of communicable diseases and long life-expectancy. Nevertheless, the growing and shifting health needs of the country, consequent to the transformation of the economy to a lower middle income level, and changes in social-demography and epidemiology, require more resources.

In order to design a better health system to fit the changing demands, it is important to examine a new financial strategy in line with cost-effectiveness under limited resources. A formula, which is applicable to countries with GDP per capita less than US\$ 1,000, indicates that these countries require US\$ 31 per capita per year for health expenditure. Currently Sri Lanka with GDP per capita US\$ 2149, is spending US\$ 68.3 per capita per year for health expenditure. According to a regression formula used for countries with GDP per capita of more than US\$ 10,000, Sri Lanka would require US\$ 530 per capita. It shows that there is a big gap in the health expenditure between the two groups of countries categorised by economic development level. Sri Lanka is presently moving towards a disease pattern seen in high GDP countries. This implies that if Sri Lanka wants to provide sufficient health care services in future, it will potentially have to shoulder a remarkably greater financial burden. A similar estimation was carried out using the old age fraction (i.e. > 60 years). Countries with a shorter life expectancy at birth of less than 68 years require 4.87% of GDP on average for health expenditure, while for countries where life expectancy is over 68 years, 5.84% of GDP is needed. Both figures are much more than the current real figure of 4% (2009) of the GDP used for health expenditure in Sri Lanka.

A more detailed projection of health expenditure demands in the future revealed that the total health expenditure in 2015 will be Rupees 267-326 billion in a moderate economic growth scenario, compared to Rupees 117.9 billion in 2006. The projected amount will be 4.5-5.0% of the GDP, compared to 4.1% in 2009.

\*Source –Sri Lanka National Health Accounts 2000 - 2002

A large gap in available funding and expenditure is expected in the health sector and now it seems time for Sri Lanka to consider an alternative financing mechanism in order to fill this

gap or to increase financing through existing mechanisms to stop reversals of the good health indicators achieved.

#### 1.2.6 Health financing and resource allocation

Health care in Sri Lanka is financed mainly by the government, with some private sector participation as well as limited donor financing. Public sector financing comes from the General Treasury, generated through taxation. Public sector services are totally free at the point of delivery for all citizens through the public health institutions scattered island-wide, while private sector services are mainly through 'out-of-pocket expenditure', private insurance and non- profit contribution.

Sri Lanka spends a relatively low percentage of GDP on health care under a public and private mixed financing. However, Sri Lanka has been witnessing a rising trend in health expenditure in recent years. Total health expenditure in Sri Lanka was Rupees 117.9 billion in 2006, which was a 98% increase from that of year 2002. As a percentage of GDP, it was 3.7% in 2000, and 4.1% in 2009. In per capita terms, expenditure on health was Rupees 2,499 (US\$ 31) in year 2000. This was increased to Rupees 7513 (US\$ 68) in 2007.

Financial resources for health care mainly come from the government through general tax revenue and donor assisted external sources, which provide the health care needs of the vast majority of the population. In 2009, government financial resources covered 45.5% of the total health expenditure. The remaining 54.2% was financed privately through out-of-pocket payment, employer-sponsored benefits, and insurance. The out-of-pocket payments contributed almost 90% of the private health expenditure. In 2002, foreign aid component of the health expenditure was Rupees 1218.2 million. This accounted for 4.5% of the health expenditure. This figure was 10% in 1998. This proportion has decreased over the years.

The government health expenditure as a percentage of total government expenditure was 4.9% in 2007, which is a decrease of over half from the 7.2% recorded in 2006. It is increasingly evident that private sector financing has become more prominent over time.

In 2002, 61.9% of the total expenditure on health in the public sector was on curative care, and the proportions spent on the public (preventive) health services and general administration were 12.0% and 24.7% respectively. In 2007, the recurrent government health expenditure as a proportion of the total government health expenditure was nearly 86%. Information on private sector investment and expenditure is inadequate, as it is not well regulated. It poses some limitation in the assessment of total expenditure on health.

#### 1.3 Multi year plan for immunization

A comprehensive multi year plan (cMYP) for immunization is the key management tool for national immunization programmes, and in recent years the EPI programme managers have

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attempted to develop plans to achieve various immunization objectives. Developing a cMYP presents an opportunity to consolidate existing plans into a single document that address global, national and sub-national immunization objectives and strategies efficiently, and that also evaluates the cost and financing of the plan.

The proliferation of immunization activities, including polio eradication, measles elimination, elimination of neonatal tetanus, introduction of new vaccines and safer vaccination technologies have increased the need for coordination and a comprehensive response to planning and budgeting to ensure sustainability of the programme. High cost of new vaccines will be a real challenge to ensure the balance between the sustainability and the expansion of the programme according to the current need. Unlike the basic EPI vaccines, new vaccines are generally more expensive. This implies that a good planning and careful decision making is essential. CMYP is a tool to fulfil this need.

By putting various pieces together into one process and document, the CMYP makes it easier for immunization programmes to set priorities, plan for implementation, and identify interactions across programmes. Meanwhile, by assessing changes in the health sector and in the political and economic scenario, immunization mangers can anticipate changes in funding flows or methods of service delivery and plan for sustainable improvements.

#### 1.3.1 The Expanded Programme on Immunization (EPI)

Immunization is a surrogate of primary health care and its functions. Often it is an entry point activity to reach disadvantageous populations and MCH related services which evolve around it. It is well recognized that immunization is one of the most cost effective interventions for disease prevention. It is also considered an important vehicle for health promotion.

The EPI is a national priority programme of the Government of the Democratic Socialist Republic of Sri Lanka. In Sri Lanka, immunization is recognized as not just an item of national expenditure but truly as a national investment. The EPI has been in operation in the country since 1978. However, immunization activities had been conducted for more than two decades earlier.

#### 1.3.2 Objectives of preparing a cMYP

The main objectives of preparing this cMYP are to;

a. Strengthen the routine immunization programme to ensure optimum coverage, quality and reliability of the immunization services.

- Effectively introduce newer vaccines and technologies into the routine immunization programme according to the real need to counter the public health consequences of diseases. (Underutilized and new vaccines in pipeline include JE, HiB, Rubella, Mumps, Pneumococal, and HPV)
- c. Facilitate effective and equitable resource planning, mobilization and allocation to sustain and further improve immunization services.
- d. Facilitate Integration of the immunization programme with other health interventions and surveillance in the health system.
- e. Strengthen the monitoring, evaluation and surveillance systems for the immunization programme

The document sets out the medium term goals, related objectives, strategies, indicators and associated costs for the period of five years starting from January 2012 to December 2016.

# 2. Situational analysis of the immunization programme in Sri Lanka

#### 2.1 Historical perspective

The history of immunization in Sri Lanka goes back to the 19<sup>th</sup> century. The law relating to compulsory vaccination (against small pox) is referred to in the Vaccination Ordinance of 1886. The Expanded Programme on immunization (EPI) established in 1978, has continued to make excellent progress over the past 30 years, most notably in terms of achieving high immunization coverage and disease control. According to the current EPI programme, all the children during their first year of life should be immunized with BCG, OPV, DPT, Hep B, Hib, JE and MMR to complete the primary series of vaccination before reaching the age of one year. Other than that, older children should be immunized with MMR, DT aTd, and pregnant women with tetanus toxoid (TT).

During the last few years, based on the data on disease burden, new vaccines for selected emerging diseases such as Rubella (1996) Hepatitis B (2003), MR, aTd (2001), Haemophilus influenza (2008), JE (2009) and MMR (2011) have been gradually introduced into the National Immunization Schedule in a phased manner. Vitamin A supplementation was added to the programme in year 2000.

From 1995 to 1999, five National Immunization Days were conducted with very high coverage in Sri Lanka with a view to eradicating polio.

Age	Vaccine	Remarks			
During first year	r of life (infancy)				
0-4 weeks	BCG	Before leaving hospital, even within 24 hours of birth. (If a scar is not present re-vaccinate after 6 months up to 5 years).			
Soon after the completion of					
2 <sup>nd</sup> Month	OPV, DTP, Hep-B, Hib- Pentavalent (1 <sup>st</sup> dose)				
4 <sup>th</sup> Month	OPV, DTP, Hep-B, Hib- Pentavalent (2 <sup>nd</sup> dose)	- Preferably 6-8 weeks after 1 <sup>st</sup> dose			
6 <sup>th</sup> Month	OPV, DTP, Hep-B, Hib- Pentavalent (3 <sup>rd</sup> dose)	Preferably 6-8 weeks after 2 <sup>nd</sup> dose			
9 <sup>th</sup> Month	JE				
Completion of one year	Mumps, Measles and Rubella (MMR)-1 <sup>st</sup> dose	MMR vaccine should be administered to <u>all</u> infants as soon as they complete one year			
In second year o	of life				
At 18 months	DTP (Booster) & OPV (Booster) – 4 <sup>th</sup> dose				
Preschool-going	g age				
On completion of 3 years of age	Mumps, Measles and Rubella (MMR)- (Booster) – 2 <sup>nd</sup> dose	One dose for those who have received the 1 <sup>st</sup> dose of MMR			
School-going ag	<u>je</u>				
At school entry (5 years)	OPV (Booster) – 5 <sup>th</sup> dose DT	One dose for those who have received the primary course of DTP/DT.			
In school (10-15 years)	aTd (Adult Tetanus and diphtheria)	One dose for those who have received the primary course of DTP/DT.			

### Table 1: National Immunization Schedule for EPI vaccines- Sri Lanka

Pregnant wome	Pregnant women					
First pregnancy	Tetanus Toxoid – $1^{st}$ dose (TT1) after the $12^{th}$					
	Tetanus Toxoid – $2^{nd}$ dose (TT2) 6-8 weeks after the first dose	Two doses of Tetanus Toxoid should be given during the first pregnancy to prevent Neonatal Tetanus				
Subsequent pregnancies	Tetanus Toxoid for the subsequent 3 pregnancies (TT3, TT4, TT5)	One dose of Tetanus Toxoid should be administered during every subsequent pregnancy, up to a maximum of five doses in all (i.e. TT1-TT5)				
Females in the o	<u>child-bearing age group</u>					
15-44 years	Rubella [or any rubella containing vaccne]	One dose of rubella vaccine to all females between 15 and 44 years of age, who have not been immunized earlier.				

#### 2.2 Programme objectives

#### The objectives of the country's EPI are as follows,

- I. Eradication of Poliomyelitis
- II. Elimination of measles, Neonatal Tetanus and Diphtheria
- III. Reduction of morbidity and mortality due to Whooping cough, Hepatitis B, Haemophilus influenza, Mumps, Tetanus, tuberculosis and Japans encephalitis.
- IV. Reduction of Morbidity and Mortality due to, CRS and Rubella and prevention of outbreaks
- V. Prevention and control of burden of selected diseases through introduction of new vaccines.

By addressing the above objectives, Sri Lanka is expected to eradicate or reduce morbidity and mortality associated with vaccine-preventable diseases to levels that are no longer public health concerns.

#### 2.3 Organization and management of the EPI

The Epidemiology Unit and the Family Health Bureau (FHB) are responsible for the implementation of the EPI. The Epidemiology Unit is responsible for the surveillance of EPI diseases, vaccine logistics (procurement, storage and distribution of vaccines), recording and processing of relevant data and planning, monitoring, and evaluation of the EPI programme and training of health staff. The FHB is responsible for the procurement and delivery of equipment and other supplies required for the EPI programme and maintenance of cold chain. The FHB also monitors the implementation of the EPI. These activities are facilitated and coordinated at the provincial and district level by the Provincial Directors of Health Services and Regional Directors of Health Services respectively.

All policy decisions on EPI are taken by the National Advisory Committee on Communicable Diseases chaired by the Director General of Health Services. The national EPI activities are regularly reviewed at the Inter-agency Coordinating Committee (ICC) chaired by the Secretary Health.

Throughout the country, immunization is being carried out along with the Maternal and Child Health (MCH) services. MCH programmes are delivered through fixed and outreach centres / clinics. Almost all MCH clinics are conducted by the Medical Officers of Health (MOOH) / Regional Directors of Health Services (RDHS). In some hospitals, maternity homes, and central dispensaries, institutional Medical Officers conduct the clinics with the assistance of field health staff. In the estate sector, immunization is being carried out at estate health centers.

In addition, private hospitals and general practitioners also provide immunization services to the community. Upon request, the EPI vaccines are provided free of charge to private hospitals and general practitioners. The recipients receive these vaccines free of charge but with a charge for the professional service.

System	Suggested indicators	National			
components	ouggested mulcators	2007	2008	2009	
	DTP3 coverage	98%	98%	97%	
	Percentage of districts with > 80% coverage by 18 months for all antigens (Total Districts-26)	100%	100%	100%	
coverage	National DTP1 – DTP3 drop-out rate	1.7%	1%	1.8%	
	Percentage of districts with drop-out rate DTP1 – DTP3 > 10	Nil	Nil	Nil	
	Percentage of districts with > 80% coverage of +TT	100%	100%	96%	
New vaccines	HepB3 coverage (based on number of Districts introduced)	98%	98%	97%	
Routine	Percentage of surveillance reports received at national level from districts compared to number of reports expected	100%	100%	100%	
Surveillance	AFP rate/100,000 children under 15 years of age	1.56	1.91	1.43	
Cold chain/ Logistics	Percentage of districts with adequate numbers of functional cold chain equipment	100%	100%	100%	
Immunization safety	Percentage of districts supplied with adequate (equal or more) number of AD syringes for all routine immunizations	100%	100%	100%	
	Was there a stock-out at national level during the last year?	No	No	No	
Vaccine supply	If yes, specify duration in months	NA	NA	NA	
	If yes, specify which antigen(s).	NA	NA	NA	
Communication	Availability of a plan	No	No	No	
Financial sustainability	What percentage of total routine vaccine spending_wasfinancedusinggovernmentfunds?(including loans and excluding external public financing)	*100%	*100%	*100%	
Linking to other health interventions	Were immunization services systematically linked with delivery of other interventions (malaria, nutrition, child health) established?	Yes, with MCH	Yes, with MCH	Yes, with MCH	
Human resources availability	No. of health workers/vaccinators per 10 000 population (Public Health Midwives).	308	NA		
Management planning	Are a series of district indicators collected regularly at national level?	Yes	Yes	Yes	

## Table 2:Situational analysis of routine EPI by system components

System	Suggested indicators	National			
components		2007	2008	2009	
NRA	Number of functions conducted	4	4	4	
ICC	Number of meetings held last year	04	04	04	
Waste disposal	Availability of a waste management plan	No	No	No	
Programme efficiency	Vaccine wastage monitoring at national level for all vaccines	Yes	Yes	Yes	
	Timeliness of disbursement of funds to districts and service delivery level				

\* GAVI co financing support for pentavelant vaccine

#### 2.4 Vaccine procurement

Currently the government of Sri Lanka purchases all vaccines used in the EPI. All vaccines are supplied by the Medical Supplies Division (MSD) of the Ministry of Health. These vaccines are procured through the government-owned State Pharmaceutical Corporation of Sri Lanka. This is carried out through a process of world-wide restricted tenders. The quality of vaccines is assured by obtaining vaccines from suppliers qualified by the WHO for bulk purchase for UN Agencies and by looking into the criteria of "good manufacturing practices" as laid down by the WHO.

Strict financial guidelines including tender procedures have to be adhered to in the procurement process. Although this ensures transparency in purchasing, it is a time consuming procedure. There is a risk of disruption of vaccine supply unless adequate supplies are stocked in advance.

#### 2.5 Vaccine supply

EPI vaccine supply is coordinated by the Epidemiology Unit. As a routine, it maintains a minimum buffer stock of EPI vaccine adequate for more than six months at central level, four months at each district level and two months at each divisional level. For the last few years, there has not been a single reported incident of lack of EPI vaccine stocks at any level.

#### 2.6 Immunization coverage

Sri Lanka is having a well established national level information system to asses the EPI vaccine coverage. This reporting system starts at the divisional level where the primary health

care services are focussed. There are 320 health divisions and all these divisions send quarterly reports of EPI to the Epidemiology Unit, which is the national focal point of the EPI. Completeness of this reporting practice is almost 100%. Based on divisional data, 26 districts (second administrative level) also report quarterly and this too is 100% complete. The national level immunization information (Table 2.2) is based on these returns sent by both divisional and district level health authorities. In addition to the government sector, private sector also provides immunization services, particularly in urban areas. Reporting from the private sector is poor. Hence the information given in Table 2.3 and 2.4 are an underestimate of the real situation.

Vaccine	Target group	Number in	Number of	Coverage %	
Vaccine	raiget group	Target group	Doses given		
BCG	Live births	364,565	353,278	96.9	
DPT1/Penta 1	Surviving Infants	361,466	340,319	94.1	
DPT3/Penta1	Surviving Infants	361,466	334,153	92.4	
OPV3	Surviving Infants	361,466	336,097	93.0	
HepB3/Penta3	Surviving Infants	361,466	332,684	92.0	
Measles 1	Surviving Infants	361,466	344,324	95.3	
MR	Surviving Infants	361,466	343,251	95.0	
TT2+	Pregnant women	364,565	312,933	85.8	

#### Table 3: National level EPI vaccine coverage for year 2010

Source: Epidemiology Unit

District	BCG %	DPT1 %	DPT 3 %	OPV3 %	MCV1 %	TT2 %
Colombo	97.7	87.2	84.6	87.2	95.6	83.9
Gampaha	94.8	90.4	92.1	91.5	95.6	90.4
Kalutara	93.0	92.8	93.2	92.7	95.6	89.0
Kandy	94.7	95.9	93.9	92.8	93.1	87.6
Matale	102.5	94.4	95.4	95.4	89.9	84.4
Nuwaraeliya	105.6	96.3	94.0	94.0	93.8	84.0
Galle	90.7	93.9	91.7	91.0	95.6	83.5
Hambantota	97.5	95.3	93.7	93.6	95.5	86.1
Matara	95.8	91.9	89.7	87.6	95.6	84.0
Jaffna	103.2	95.7	94.6	92.9	92.1	90.3
Kilinochchi	26.1	95.6	95.5	94.1	77.7	80.3
Mannar	85.2	84.0	88.2	88.7	95.6	77.2
Vavuniya	74.9	86.0	85.0	80.6	95.6	80.4
Mullaitivu	9.7	95.6	89.1	91.1	80.1	74.8
Batticaloa	105.6	89.4	87.0	83.4	95.6	77.7
Ampara	91.9	95.6	95.4	93.9	92.4	89.2
Trincomalee	95.1	95.6	94.8	94.0	93.6	85.3
Kurunegala	110.2	95.0	95.5	94.6	93.0	84.3
Puttalam	98.6	95.0	95.3	96.0	95.6	84.4
Anuradhapura	94.6	95.5	95.5	95.5	95.6	90.8
Polonnaruwa	101.0	95.6	95.4	93.9	93.6	92.5
Badulla	100.1	95.1	95.6	95.3	92.8	85.6
Monaragala	92.1	94.7	94.7	95.6	93.9	91.1
Ratnapura	100.6	94.5	94.0	92.3	95.6	83.4
Kegalle	95.5	95.4	94.8	93.7	95.6	85.2
Kalmunai	91.1	95.3	95.6	93.8	94.9	79.6
Sri Lanka	96.8	93.3	92.7	92.2	94.4	85.8

Source: Epidemiology Unit

In addition, annually, EPI coverage assessment surveys are conducted in selected RDHS divisions (i.e. district level), especially where coverage low relatively is reported. In 2008, EPI coverage surveys were conducted in the Ampara, district and in 2010, in the Colombo, Gampha and Kalutara districts.

Both routine and survey data on immunization coverage shows that the coverage for EPI vaccines during the first two years of life is above 90% and for most districts it is near 100%. However, it has been noticed that the coverage for vaccines slightly decreases with increasing of age. Relatively poor coverage when compared to the first year of life is reported for tetanus toxoid / adult diphtheria tetanus (aTd) vaccine among 10 - 15 years old, and rubella among females aged 15 - 44 years. Poor coverage of vaccines administered at school going age is partly due to improper planning of school health activities at the divisional level and inadequate support from some school authorities.

It clearly indicates that there is no marked difference in immunization coverage at district level. However, analysis of the divisional level data on coverage obtained from both routine surveillance and surveys have revealed existence of pockets of relatively low coverage areas in some districts. These low coverage pockets are mainly located in the estate sector, previously conflict zones in North and East Provinces and urban slum areas in Colombo.

#### 2.7 Current vaccine preventable disease burden

Disease	2007	2008	2009
	No. Reported	No. Reported	No. Reported
Diptheria	00	00	00
Pertussis	00	09	31
Neonatal Tetanus	00	01	00
Polio	00	00	00
Measles	44	33	21
Rubella	05	79	143
Total Tetanus	26	29	18

Table 5: Reported incidence of vaccine preventable diseases

Source: Epidemiology Unit

There are 26 notifiable diseases in Sri Lanka, including the ten EPI target diseases namely polio, tetanus, tuberculosis, whooping cough, diphtheria, measles, meningitis, Japanese encephalitis, rubella and mumps. Reporting of all EPI target diseases and AFP cases (less than 15 years of age as suspected poliomyelitis) based on clinical and/or laboratory evidence has been made mandatory in Sri Lanka. The Epidemiology Unit receives information on EPI target diseases and AFP cases from the Medical Officers of Health, as well as from the Medical Officers attached to the curative institutions where the patients seek treatment.

On receiving notifications on EPI target diseases or AFP, detailed investigation with laboratory confirmation is carried out. Currently laboratory confirmation is carried out for all suspected AFP cases, but for other EPI diseases, laboratory confirmation is somewhat limited due to lack of laboratory facilities. In the public sector, Medical Research Institute, Colombo is the only institution which carries out laboratory confirmation of EPI diseases. This is one area Sri Lanka has to improve further in future.

The main objective of any immunization programme is to bring down the morbidity and mortality in vaccine preventable diseases. With high levels of immunization coverage achived with acceptable quality, not surprisingly the incidence of the target diseases has declined to low levels and some are not being detected at all as shown by both active and passive surveillance activities. Polio cases have not been reported since 1993. Polio virus transmission has probably ceased. Laboratory confirmed cases of diphtheria have not been reported since 1995. Only 21 confirmed cases of measles were reported in 2009. No cases of neonatal tetanus were reported in 2009 and one case was reported in 2008 (Table 4). Higher levels of tetanus toxoid coverage in pregnant mothers (91.8%) and institutional deliveries (97%) have contributed to this. As a result, Sri Lanka was not included in the list of 58 priority countries identified by the WHO for elimination of neonatal tetanus. In year 2009, 143 rubella cases were reported as small isolated outbreaks.

#### 2.8 Availability and maintenance of cold chain facility

After completion of construction of the central cold room complex at the Epidemiology Unit in 2008, the country presentlyhas adequate vaccine storage facilities at national level. This new cold room complex has a capacity to store six months buffer stock of all EPI vaccines at central level. The government has already spent US\$ 1 million on this activity. The country no longer needs to depend on private cold room facilities to store vaccines at central level. This newly built cold central room complex is equipped with modern temperature monitoring equipment with alternative power supply. During this current cMYP period if the country decides to introduce Pneumococca and HPV vaccines to the EPI, the central cold room may be able to accommodate even these new vaccines without any problem.

All EPI vaccines are delivered from central vaccine stores to 26 Regional (district) Medical Supplies Divisions (RMSD) in the country once in every 2 months. With the assistance of UNICEF, cold room complexes have been already installed in 24 districts and plans are underway to install such cold rooms in the other 2 remaining districts as well. This has helped to enhance the vaccine storage capacity at district level. All these newly built cold room complexes are equipped with modern temperature monitoring equipment and alternative power supplies. During this current cMYP period if the country decides to introduce Pneumococca and HPV vaccines into the EPI, the regional cold rooms may be able to accommodate even these new vaccines without any problem

During the last five year period Sri Lanka has introduced three new antigens into the EPI, other than JE both Hib and mumps vaccines were introduced as combined vaccines (Pentavelant and MMR).Consequently the issue of expansion of divisional level vaccine storing capacity did not arise. In future introduction of new vaccines will require additional vaccine storing capacity at the divisional level.

Though Ice line refrigerators (ILR) are considered as the best option for vaccine storage at divisional level, currently domestic type refrigerators are being used to store vaccines at divisional level. Up to now the country does not have a proper divisional level cold chain equipment replacement plan. During this five year period the country hopes to develop a divisional level cold chain equipment replacement plan and replace nearly 100 domestic type refrigerators with ILR each year.

Currently the majority of vaccine storing refrigerators at divisional level has data lodgers to monitor the temperature. In the coming years it has been planned to introduce data lodgers to all vaccine storing refrigerators. Meanwhile plans are underway to introduce 250 freeze tags each year to the divisional level vaccine storing refrigerators to safeguard the freeze sensitive vaccines against freezing.

The money required for strengthening divisional level cold chain facilities will be around US\$ 750,000. Replacement of vaccine transport equipment (vaccine carriers and igloos) will also be done with this fund.

At present the EPI programme spends around 3% of total budget to maintain the cold chain facility and around 1.5% for transport. The cost for the above activities could be reduced significantly at the central level by reorganizing the present vaccine storage and transport activities, whereas at the divisional level it is unlikely to make any significant savings.

With the assistance of WHO and UNICEF, two surveys namely effective vaccine system management (EVSM) survey and vaccine management assessment (VMA) survey were carried out in 2005. The purpose of the VMA survey is to investigate knowledge and practice of vaccine management amongst health staff operating at national, sub-national and service delivery level. The EVSM survey has found that the Sri Lanka's primary vaccine store (i.e.

central vaccine store) was managed effectively in most of the key areas over a period of 12 months. Figure 2.1 shows the summary results of EVSM survey. Epidemiology unit is planning to conduct the next EVSM in 2012-2013.

# Figure 2.1: EVSM primary vaccine store assessment results, Colombo, Sri Lanka



#### 2.9 Ensuring injection safety

#### 2.9.1 Using auto-disable (AD) syringes

Reuse of injection equipment is responsible for most of the infections that result from immunization. This can be prevented by using AD syringes. In Sri Lanka AD syringes were introduced into the EPI in year 2003 with the support of GAVI in order to ensure immunization safety and improve quality. Currently for both EPI vaccines and non EPI vaccines, AD syringes are exclusively used all over the country.

#### 2.9.2 Management of sharps and safe disposal

The current practice is disposal of sharps at the immunization clinics itself. Sharps are collected into the sharps bin and are burned or buried once they are filled. Incineration is the practice in some parts of the world. There are barriers to implement this in Sri Lanka. The most important factor is the initial cost for the construction and the cost for the maintenance of incinerators. The number of incinerators needed and the distance to travel from the

immunization clinics to the incinerator sites also has to be taken into consideration. Further, donor agencies, such as World Bank disapprove construction of incinerators. It is very unlikely that in the coming years, any change will be seen in the current practice.

Another alternative option is using non-burn methods of immunization waste disposal, which is successfully practised in certain parts of India. This practice was followed in Philippines also during the large scale measles vaccination campaign two years back. In this method, needle part of the syringe is separated from the plastic part with the help of a needle remover at the point of use at the immunization site. Plastic part of the syringe is collected for re-cycling and only the needles are disposed through deep burial in safe pits. This approach minimizes the risk of needlestick injury to the vaccinator and the community, compared to situations where the waste is left in the open and not effectively contained. It is planned to conduct pilot programmes in five selected districts and then develop a national policy on safe disposal of injection waste.

#### 2.9.3 Vaccine safety- Adverse events following immunization (AEFI)

The surveillance system of AEFI is an integral part of the EPI in Sri Lanka since 1995. It provides an example for other countries in the region. Institutional medical officers and the field staff are requested to report all AEFI detected to the area Medical Officer of Health (divisional level) and the Regional Epidemiologist (district level) monthly. Additional information is collected by using a detailed investigation form in respect of all serious adverse events. This information is evaluated systematically at district level and central level and remedial measures taken whenever there is a programme failure. In 2010, notification of AEFI was nearly 100% for all districts, but detailed investigations of selected adverse events were not conducted optimally. This is partly due to limited resources at the divisional level.

The National expert committee on AEFI use to perform the causality assessment on all reported severe AEFI. The National expert committee on AEFI which consists of Epidemiologists, Clinicians, Judicial Medical Officers, Vaccinologists and Immunologists meets quarterly.

Sri Lanka is one of the early countries to share vaccine safety data with WHO Uppsala collaboration centre and maintaining vigi flow data base link.

In year 2008, the reported HHE episodes and few temporally associated infant deaths following administration of pentavalent vaccine led to temporary suspension of the pentavalent vaccine four months after introduction. However in-depth investigations carried out both by local and international expert groups revealed that none of these deaths were due to the vaccine. Based on these recommendations pentavalent vaccine was reintroduced in mid 2010.

In addition the two deaths which occurred among school children following rubella vaccination led to the suspension of rubella vaccination in 2009. In-depth investigations into these deaths revealed that use of partially purified gelatin containing rubella vaccine may be a possible trigger factor for the anaphylaxis reactions. This may raise the question of exploring the possibility of taking a policy decision in future regarding the use of either completely purified gelatin containing vaccines or gelatin free vaccines in the EPI programme

High fever and allergic reactions were the commonest AEFI reported. Injection site abscess (5%) and severe local reaction (6.4%) were also reported during the year 2010. These two AEFI are classified as programme errors and could be prevented with good immunization practices.

Type of AFEI reported	2008		2	2009	2010	
	No.	%	No.	%	No.	%
Injection site abscess	735	0.5	658	10.8	290	5.0
Lymphadenitis	13	0.2	11	0.2	09	0.2
Sever Local Reaction	608	9.2	553	9.0	371	6.4
High Fever	2343	35.5	1782	29.1	1809	31.2
Allergic Reaction	1436	21.8	1579	25.8	1503	26.0
Nodule	691	10.5	826	13.5	413	7.1
Seizures	391	5.9	382	6.2	322	5.6
Arthralgia	41	0.6	39	0.6	22	0.4
Shock	05	0.1	02	0.1	03	0.1
Scream	195	2.9	96	1.6	96	1.7
Encephalopathy	02	0.0	00	0.0	03	0.1
Meningitis	07	0.1	01	0.0	06	0.1
Injection reaction	31	0.5	76	1.2	05	0.1
HHE	44	0.7	25	0.4	48	0.8
Death	21	0.3	09	0.1	06	0.1

 Table 6 :
 Distribution of reported AEFI by type of Adverse Events 2008 - 2010

Others	27	0.4	76	1.2	790	13.6
Total	6593	100.00	6120	100.00	5790	100.00

\* Rounding off effect

#### 2.10 Vaccine wastage

Vaccine wastage for some antigens is high as it is expected especially in respect of those for which "open vial policy" cannot be practiced (e.g. for BCG, wastage is over 60%, for measles vaccine 40%). With a view to reducing vaccine wastage, Sri Lanka has introduced "open vial policy" in 2005 for EPI. Before that, opened multidose vaccine vials were discarded at the end of immunization sessions. Currently, open vial policy is operated for all liquid vaccines namely, OPV, DPT, DT, aTd, TT, JE and Hep B vaccines. At present, the average wastage for all liquid vaccines is less than 10 % and it was around 25 – 40% before the implementation of the open vial policy. This shows that the open vial policy has caused significant reduction in vaccine wastage for all liquid vaccines. It is essential to take effective steps to reduce wastage for other vaccines also in future.

The issue of vaccine wastage has acquired importance due to high cost of new vaccines. Vaccine wastage can be considered as an indicator of programme efficiency. Two critical requirements for reducing vaccine wastage are reducing the vial size, ideally for one or two doses, and careful microplanning to ensure that optimum number of children is immunized at each immunization session. However, the former has implications on cold chain capacity at all levels of storage.

#### 2.11 Quality of the immunization services

Maintenance of the quality of immunization services is a prerequisite to achieve the desired programme objectives and to ensure sustainability. However, this remarkable achievement is threatened by the recent findings of disparities in the quality of immunization services across geographic boundaries.

A loss of confidence in the programme could undermine the achievements to date and impede progress towards consolidation of these gains. The World Bank sponsored Sri Lanka Health Sector Development Project's (HSDP) Immunization Subcomponent focused on improving the quality of immunization related activities during the last five years. The expected outcome of this project was to reduce the unintended variation in immunization service quality between districts as defined in the guidelines of the Ministry of Health. A reduction in AEFI was used as the primary indicator of quality improvement. Highly motivated and skilled midwives (vaccinators) who provide services from publicly recognized clinics of excellence and whom skilled divisional and district health staff routinely support the expected outputs. The implementation of the subcomponent activities was initiated in 2006 and completed in 2009.

#### 2.11.1 Human resources

There are serious disparities in the requirement and supply of several categories of health personnel. On top of that there is also a significant imbalance existing in the distribution of human resources for health. Inadequate number of Public Health Midwives (PHM), who also function as vaccinators in field clinics, was one of the reasons for the low coverage and quality at the local level. Specially, the number and the rate of Public Health Midwives in the districts of the Northern Province (in Jaffna 1.24 and in Kilinochchi 0.53 per 10,000 populations) are extremely low while districts such as Kalutara (3.49/10,000) and Hambantota (3.96/10,000) have a significantly higher concentration. This figure for national level is 2.54/10,000 population.

The usual practice is to appoint a PHM from the adjacent PHM area to cover the duties in the vacant PHM area. However, this does not ensure complete coverage of services including household visits that ensure timely vaccination of children.

In Sri Lanka, there is no separate category of health care workers to carry out immunization activities alone. Therefore, future plans for strengthening human resources in immunization will essentially be a part of strengthening all primary health care services in the country. The Ministry of Health has identified future needs considering all public health demands in the country. The cadre requirement has been approved by the Treasury and as planned, recruitment will continue in phases for the next 10 years. The limited training capacity in the country is the main reason for the phased out recruitment.

Recruitment of new batches of PHMM during the past several years has improved the service conditions at the field level to some extent. Recently, additional payment for cover-up duties has also been introduced to encourage the covering up officers. The situation will further improve over the time once the new recruits complete the midwifery training and get absorbed into the cadre.

#### 2.11.2 Vehicles and transport

Vehicles and transport are identified as important components of the immunization programme in the country. Poor transport conditions or delay in distribution can jeopardize the

potency of vaccines. Timely access to dependable vehicles is essential. Standard delivery vans / lorries are currently being used to distribute vaccines at regional level. Some of these vehicles are old and unreliable, and regional centres very often resort to borrowing vehicles to distribute vaccines on time at divisional level

In year 2003 under GAVI phase 1 support the country got US\$ 100,000 to carry out immunization related training activities. At the same time the country managed to find funds from WHO to conduct immunization training activities in the same year. With the approval of GAVI, country utilized US\$ 100000 to purchase a lorry to transport vaccines from the centre to the regions in 2007. This new vehicle has helped to transport vaccines to the regions efficiently for the last five years. This vehicle may need to be replaced in somewhere around 2013. The money required for purchase of a new lorry will be around US\$ 100,000.

In the coming years vaccine transport within the districts needs to be strengthened. This will greatly enhance efficient vaccine distribution at district level.

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 lower levels of the distribution system. This was one of the objectives of the World Bank funded Sri Lanka HSDP Immunization Subcomponent. Other than vaccine transport, EPI programme needs additional transport facilities both at national and district levels to enhance monitoring activities. Enhancement of monitoring activities at national and district level is essential.

According to the recent estimates, the vehicle and transport cost will increase from 2% of total budget in 2005 to 4% in 2013 i.e. around US\$ 184,000 in 2005 to US\$ 669,000 in 2013. One of the future challenges is the increasing fuel price in the country. The increased fuel cost in the world market and declined purchasing power due to the depreciation of local currency will necessarily have a huge impact in future.

#### 2.12 Strengthening EPI surveillance - Epid Network

Effectiveness of the EPI programme is mainly assessed based on the reported VPD incidence. All VPDs are considered as notifiable diseases. In addition, for each reported VPD case detailed investigation is carried out by a medical officer of health using a special investigation format.

The present EPI data management system, particularly at divisional level is manual and time consuming largely due to paper work. This has also resulted in substantial delay in carrying out surveillance activities. The electronic data network will help in better planning and management, and efficient monitoring of the EPI activities. Providing computers and

communication facilities for improved data management will require additional fund of around US\$ 50,000 annually.

The Epidemiology unit of the Ministry of Health has already developed a software package for diseases and AEFI surveillance. Other than the provision of computer facilities at regional and divisional levels, which is already in progress in a phased manner, training on data management is also necessary to carry out surveillance activities efficiently.

Sri Lanka has already started the training of central level officers on data management, and is expected to expand this programme to the district and divisional levels in future.

#### 2.13 Strengthening training and research activities

Improved EPI surveillance through provision of training and research is essential. In-service training for all public health staff is a routine activity in the country to upgrade knowledge and skills. It has been estimated that special training programmes for field staff on EPI services, particularly on data management require around US\$ 10,000 annually and it is expected to obtain these funds from the country budget of the WHO. Review based training is the country's future strategy to improve knowledge and skills of the public health staff. In addition, improving the managerial skills of the officers at all levels of EPI service delivery is identified as an important activity for the next few years.

Expansion of research opportunities including both epidemiological and economic burden assessments on VPDs where index vaccines have not been introduced in Sri Lanka will help to take rational decisions regarding introduction of new vaccines into the EPI in future.

Overseas training opportunities for public health staff are important not only to upgrade their knowledge and skills, but also as an incentive to retain them in the public health sector. This is particularly important for national and district level officers, who are reluctant to stay in the public health sector due to less financial benefits compared to the curative sector.

#### 2.14 Introduction of new antigens / combined vaccines into the National EPI

Sri Lanka has planned to introduce live attenuated JE, Hib and MMR vaccines into the national EPI programme during the last cMYP period. This task was successfully completed by introducing HIB vaccine in 2008, Live JE vaccine in 2009, and MMR in 2011 respectively.

#### 2.14.1 Introduction of Pneumococcal vaccine into the EPI

Efforts are ongoing to obtain reliable surveillance data for pneumococcal disease in preparation of the introduction of potential future vaccines into the EPI against this disease. Introduction of new vaccine will need to be justified by an evidence base derived from solid epidemiological data to allow appropriate burden of disease assessments and cost-effectiveness analyses.

Though pneumonia and meningitis have been identified as public health issues, like in many developing countries, there is a scarcity of information on aetiology of these in Sri Lanka. Pneumococcal surveillance conducted among under five year old children at the Lady Ridgeway Hospital for children (LRH) under the South Asian Pneumococcal Network Alliance (SAPNA) has revealed that 4.9% of septicaemia, 2.2% of clinical meningitis and 1.2% of clinical pneumonia were of the aetiology of Streptococcus pneumonia

The most common serotypes of S.pneumoniae isolated at the LRH were 19F, 23 F, 6B, 14. Sixty two percent of these isolated serotypes at the LRH are covered by vaccine serotypes in the currently available seven valent conjugated Pneumococcal vaccine.

With a view to obtaining more valid and representative data on pneumococcal disease burden steps have been already taken to expand the pneumococcal surveillance activities to a few other major hospitals.

The country is planning to review the available disease burden data, post marketing surveillance data regarding the safety of the vaccine and vaccine affordability issues at the 2012 immunization summit. After reviving these factors the country will decide on the introductory year of pneumococcal vaccine into the EPI programme. It may be somewhere around 2013. Even if it decides to introduce pneumococcal vaccine into the EPI programme in 2013, it will be done in a phased manner. First year pneumococcal vaccine may be given to infants in the western province. That will be around 25% of the total target population and next year it will be expanded to the whole country by targeting total target population.

The cost of pneumococcal vaccine is very high at present. Sri Lanka will necessarily be looking for donor support like it was for the pentavalent vaccine. Introduction of Hib vaccine will require an additional US\$ 6.7 million annually and this will be around 44% of the cost of the total immunization programme. With more interest shown by manufacturers from developing countries and the competition, steep fall in a price of pneumococcal vaccine is expected in the coming years.

#### 2.14.2 Introduction of HPV vaccine into the EPI

Efforts are ongoing to obtain reliable surveillance data for pneumococcal disease in preparation of the introduction of potential future vaccines against these diseases in to the EPI. New vaccine introduction will need to be justified by an evidence base derived from solid

epidemiological data to allow appropriate burden of disease assessments and costeffectiveness analyses.

In Sri Lanka a community based HPV prevalence study conducted in the district of Gampaha among 2000 women of 20-59 year age group revealed the overall HPV prevalence of 3.3% and the prevalence of vaccine preventable geno type 16 and 18 as 1.2%.

Hospital based cervical cancer data reveals that cervical cancer in Sri Lanka ranks as the 2<sup>nd</sup> most frequent cancer among women.

With a view to obtaining more valid and representative data on HPV disease burden the country is planning to establish a HPV surveillance mechanism by 2012.

The country is planning to review the available disease burden data and post marketing surveillance data regarding the safety of the vaccine and vaccine affordability issues at the 2013 immunization summit. After reviving these factors, the country will decide on the introductory year of HPV vaccine into the EPI programme. It may be somewhere around 2014. Even if it decides to introduce HPV vaccine into the EPI programme in 2014, it will be done in a phased manner. In the first year HPV vaccine may be given to the females of 12 - 14 year age group who live in the Western province and next year it will be expanded to the whole country by targeting total target population.

The cost of HPV I vaccine is very high at present. Sri Lanka will necessarily be looking for donor support as for the pentavalent vaccine. Introduction of HPV vaccine will require an additional US\$ 7.5 million annually and this will be around 48% of the cost of the total immunization programme. With more interest shown by manufacturers from developing countries and the consequent competition, a steep fall in the price of HPV vaccine is expected in the coming years.

#### 2.14.3 Dengue vaccine

Currently, a vaccine is being developed for the Dengue. According to available information this vaccine may be available for use somewhere around 2014-2015. If dengue vaccine is available, the country will harness all the possible efforts to introduce it as early as possible to prevent morbidity and mortality associated with the disease.

#### 2.15 Possible outbreak control measures

#### 2.15.1 Measles and rubella (MR) Catch up campaign

During the recent past Sri Lanka has reported few isolated small scale rubella outbreaks among adolescents in different parts of the country. Same time in 2009, the country had reported a measles outbreak among internally displaced population in the Northern Province. The country had the last MR catch up campaign in 2002. By considering the above facts it is advisable to have a MR catch up campaign for the adolescents somewhere around 2015.

#### 2.15.2 Typhoid vaccination for high risk populations

The incidence rate of typhoid fever in Sri Lanka was 11.48 per 100,000 populations in 2009. But this distribution is uneven throughout the country. The highest incidence rate 390.56/ 100,000 population has been reported from the Vavuniya District, and then from the Mannar District (140.76/100,000). Medium level incidence was reported from Jaffna (98.27/100,000), Nuwara Eliya (27.21/100,000) and Puttlam Districts (10.32/100,000). Even within typhoid endemic districts, typhoid epidemiology can vary significantly from location to location. Therefore, typhoid vaccination is recommended as a risk-based strategy and targeted only for high-risk groups and population. For this purpose, the country may need nearly 200000 (1% of the total population) typhoid vaccine per year.

#### 2.15.3 Hepatitis A vaccination during outbreaks

Each year, the country experiences small scale isolated Hep A outbreaks in different parts of the country. Meanwhile Hep A outbreaks are common among IDP populations following disasters. Hep A vaccination may be a useful strategy to control the spread of the disease during outbreaks. For this purpose the country may need nearly 200000 doses (1% of the total population) of Hep A vaccine doses per year.

#### 2.15.4 Chickenpox vaccination during outbreaks

Each year the country experiences small scale isolated chickenpox outbreaks in different parts of the country. Meanwhile chickenpox outbreaks are common among IDP populations following disasters. Chickenpox vaccination may be a useful strategy to control the spread of the disease during outbreaks. For this purpose the country may need nearly 200,000 doses (1% of the total population) of chickenpox vaccine per year.

#### 2.15.5 H1N1 vaccination during outbreaks

During the last two years the country has experienced H1N1 outbreaks. Meanwhile available epidemiological data clearly shows a high mortality among pregnant mothers and patients with co-morbidities. There will be a higher chance of reappearing of H1N1 outbreaks in the coming years. Vaccination of high risk groups may be a useful strategy to reduce the mortality associated with H1N1. For this purpose, the country may need nearly 200,000 doses (1% of the total population) of H1N1 vaccine per year.

#### 2.16 Risks and challenges identified

#### 2.16.1 Expansion of vaccination

Suggested incorporation of Pneumococcal and HPV immunization into the EPI will invariably impose extra costs to the EPI. After GAVI withdraws its funding for pentavalent vaccine in 2015, the government will have to bear the cost of this vaccine too. Increasing cost of most of the vaccines will be a real challenge to ensure the balance between the sustainability and the expansion of the programme according to the current needs.

#### 2.16.2 Increased transport cost

The cost for fuel at the regional and divisional levels is financed by the provincial administration. The allocation is for the total primary health care activities and there is no separate allocation for the immunization programme. With the increasing cost of fuel, the purchasing power will be somewhat reduced. This could have an adverse effect on the supervisory activities of the immunization programme at the grassroots.

#### 2.16.3 Devalued local currency

Devaluation of the Rupee against US Dollar has been continuing in the recent past and is expected to continue further. This has an influence on the fuel prices too. Increase in the price for relevant services and supplies including vaccines make the total cost for the programme further high.

#### 2.16.4 Anti-vaccine lobby

A growing trend of anti-vaccine lobbying is seen in certain parts of the world. Although this is not a threat in Sri Lanka to date, close vigilance and timely identification of such a lobby are necessary for effective counter activities in future.

#### 2.17 Private sector collaboration

The Government of Sri Lanka firmly supports the free health services as a national policy. Therefore, introduction of user fee will never be in consideration as a strategy to reduce the EPI cost in future. Alternatively, the government will support increased private sector contribution to the EPI.

At present, the government provides selected EPI vaccines free of charge to the General Practitioners (GP) and private hospitals to carry out immunization activities. The target population receiving immunization through the private sector is around 1%-2%. There is an

increasing trend of utilization of private sector health service in the country and it can be assumed that the same trend will prevail for the immunization services also in the future. Strengthening private sector services will reduce the government burden on EPI services and thereby minimize the service cost and save the resources in future.

If the present service coverage of 1%-2% is increased to 5% in the next ten years, it will help to reduce spending by the government significantly and this saving can be diverted to other EPI activities, where adequate funding is not secured. The most challenging task is ensuring the quality of services provided by the private sector. Any diversity from the established quality of the programme will negatively affect the country's EPI. For example, if more AEFI are reported from the private sector it will no doubt damage the national EPI. Therefore continuing quality control measures in the private sector services is essential. This is one of the reasons for the government to provide vaccines free of charge to the private sector. However, if more people move to the private sector immunization service, then the government may consider charging vaccine cost (buying cost) from service providers while continuously monitoring the programme in the private sector. The involvement of the private sector is good for the national economy but if they procure costly combined vaccines from outside then this may lead to loss of foreign exchange. Therefore, some regulations, guidelines and mechanism are essential to regulate the private sector quality of immunization

# 3. Future budget requirements

In addition to vaccines that are already in use, new vaccines that are considered for scale-up / introduction in Sri Lanka during this cMYP period are Pneumococcal and HPV vaccines based on their availability and affordability and disease burden. In addition during this cMYP period it is planned to use typhoid, chickenpox and HepA vaccines for outbreak control. For this purpose 200,000 doses, each of typhoid, chickenpox and HepA vaccines will be procured annually.

Meanwhile, during this cMYP period, it is hoped to conduct a measles and rubella catch up campaign targeting the 15 -20 year age group.

Sri Lanka use to have immunization summit with the active participation of clinicians, public health experts and policy makers annually. During these summits available data on safety, affordability and disease burden related to the new vaccines are reviewed by the experts and necessary recommendations made to the Ministry of Health regarding the introduction and time of introduction.

During the last two immunization summits introduction of new vaccines were extensively discussed and decided to review the introductory plans for both Pneumococcal and HPV again in the coming immunization summit which is due in the latter part of 2011 or early 2012. Based on the future immunization summit decisions on new vaccine introduction, country's new vaccine introduction plan and cMYP will be revised and updated.

In today's context there will be a relatively higher chance of introduction of both Pneumococca and HPV vaccines in to the EPI in 2013 and 2014 respectively. Introduction of both vaccines will be done in a phased manner: first year both vaccines will be introduced to the target population in the Western province and subsequent year to the whole country with GAVI co financing support. Meanwhile, GAVI co financing support which the country gets for the pentavalent vaccine will also terminate in 2015 according to the present GAVI phase II time period.

All the budget requirements were calculated based on the above described case scenarios.

For this costing exercise, the costs of vaccines are derived from the latest available UNICEF price list. Cost projections are undertaken using the cMYP tool after taking into account the costs of salaries, allowances, campaigns and programme goals with proposed new and underused vaccine introductions. Based on these assumptions, the itemized annual costs have been calculated (Table 3.1). The consolidated costs are also shown in the table.

## Table 7:Summary Cost Projection in million US\$

Cost Category	2011	2012	2013	2014	2015	2016	Total 2012 - 2016
Routine Recurrent Costs	US\$	US\$	US\$	US\$	US\$	US\$	US\$
Vaccines (routine vaccines only)	\$5,264,025	\$7,560,725	\$8,819,693	\$15,379,493	\$20,360,021	\$19,193,621	\$71,313,555
Traditional	\$634,611	\$5,368,053	\$5,264,700	\$5,257,330	\$5,274,066	\$5,273,254	\$26,437,403
Underused	\$4,629,414	\$174,953	\$140,572	\$141,055	\$129,748	\$132,539	\$718,867
New		\$2,017,719	\$3,414,421	\$9,981,108	\$14,956,208	\$13,787,829	\$44,157,285
Injection supplies	\$640,077	\$669,950	\$707,376	\$826,642	\$917,007	\$906,488	\$4,027,463
Personnel	\$35,400	\$48,960	\$49,939	\$50,938	\$51,957	\$52,996	\$254,790
Salaries of full-time NIP health							
workers (immunization specific)	\$35,400	\$48,960	\$49,939	\$50,938	\$51,957	\$52,996	\$254,790
Transportation	\$4,140	\$4,223	\$4,307	\$4,393	\$4,481	\$4,481	\$21,886
Fix site strategy (incl. vaccine							
distribution)	\$4,140	\$4,223	\$4,307	\$4,393	\$4,481	\$4,481	\$21,886
Outreach strategy							
Mobile strategy							
Maintenance and overhead	\$283,755	\$311,373	\$340,853	\$363,695	\$388,220	\$213,005	\$1,617,145
Cold chain maintenance and	<b>*</b> ( <b>*</b> ( <b>* * * * * * * * * *</b>	<b>*</b> 4 <b>*</b> 4 <b>*</b> 4 <b>*</b>	<b>*</b> 4 <b>* * *</b>	<b>*</b> 4 <b>* * *</b>	<b>*</b> 4 <b>* *</b> 4 <b>*</b>	<b>A</b> 4 4 <b>A</b> 4	
overheads	\$181,830	\$184,612	\$188,305	\$192,071	\$196,819	\$1,104	\$762,910
Maintenance of other capital	¢101.005	¢406.764	¢150.540	¢474.604	¢101 401	¢011.001	<b>©054 005</b>
Chart tarre training	\$101,925	\$120,701	\$152,549	\$171,024	\$191,401	\$211,901	\$854,235
Snort-term training		\$38,254	\$39,631	\$40,828	\$42,296	\$43,573	\$204,581
		\$38,254	\$39,631	\$40,828	\$42,296	\$43,573	\$204,581
Disease surveillance		\$95,635	\$99,077	\$102,069	\$105,739	\$108,932	\$511,452
Programme management		\$38,254	\$39,631	\$40,828	\$42,296	\$43,573	\$204,581
Other routine recurrent costs							
Subtotal	\$6,227,397	\$8,805,628	\$10,140,138	\$16,849,713	\$21,954,312	\$20,610,242	\$78,360,034
Routine Capital Costs							
Vehicles			\$41,616				\$41,616
Cold chain equipment	\$414,324	\$101,439	\$17,855	\$30,893	\$11,869		\$162,055
Other capital equipment		\$107,100	\$109,242	\$84,897	\$86,595	\$88,326	\$476,160
Subtotal	\$414,324	\$208,539	\$168,713	\$115,789	\$98,463	\$88,326	\$679,831
Campaign Costs							
Measles -Rubella catchup (							
15-20 years cohort)					\$4,741,039		\$4,741,039
Vaccines and Injection					¢4 045 470		¢4 045 470
Supplies		1	1			1	\$1,345,173

Operational costs					\$3,395,866		\$3,395,866
HepA Vaccine -High Risk &							
Outbreak Management		\$2,235,738	\$2,239,738	\$2,243,818	\$2,247,979	\$2,252,224	\$11,219,497
Vaccines and Injection							
Supplies		\$2,035,738	\$2,035,738	\$2,035,738	\$2,035,738	\$2,035,738	\$10,178,689
Operational costs		\$200,000	\$204,000	\$208,080	\$212,242	\$216,486	\$1,040,808
Typhoid Vaccine -High Risk							
& Outbreak Management		\$617,869	\$621,869	\$625,949	\$630,110	\$634,355	\$3,130,152
Vaccines and Injection		# 4 4 7 000	<b>#</b> 447.000	<b>#</b> 447.000	<b>#</b> 4 4 <b>7</b> 000	# 4 4 7 000	<b>#0.000.044</b>
Supplies		\$417,869	\$417,869	\$417,869	\$417,869	\$417,869	\$2,089,344
Operational costs		\$200,000	\$204,000	\$208,080	\$212,242	\$216,486	\$1,040,808
Chicken Pox Vaccine -High Risk &		¢1 000 001	¢1 004 004	¢4 000 474	¢4 000 000	¢4 000 577	<b>#C 141 0C0</b>
		\$1,220,091	\$1,224,091	\$1,228,171	\$1,232,332	\$1,236,577	\$6,141,262
Vaccines and Injection Supplies		\$1,020,091	\$1,020,091	\$1,020,091	\$1,020,091	\$1,020,091	\$5,100,454
Operational costs		\$200,000	\$204,000	\$208,080	\$212,242	\$216,486	\$1,040,808
H1N1 Vaccine -High Risk & Outbreak		<b>*</b> ~~~~~~~~	<b>\$000 400</b>	<b>0040 540</b>	<b>0044740</b>	<b>0040 055</b>	<b>#0.050.004</b>
Management		\$600,000	\$606,469	\$610,549	\$614,710	\$618,955	\$3,050,684
Vaccines and Injection Supplies		\$400,000	\$402,469	\$402,469	\$402,469	\$402,469	\$2,009,876
Operational costs		\$200,000	\$204,000	\$208,080	\$212,242	\$216,486	\$1,040,808
Vaccines and Injection Supplies							
Operational costs							
Subtotal		\$4,673,698	\$4,692,166	\$4,708,486	\$9,466,172	\$4,742,112	\$28,282,634
Shared personnel costs	\$69,126	\$74,487	\$75,976	\$77,496	\$79,046	\$80,627	\$387,631
Shared transportation costs	\$106,537,283	\$108,668,029	\$110,841,390	\$113,058,217	\$115,319,382	\$117,625,769	\$565,512,787
Construction of new buildings							
Subtotal	\$106,606,409	\$108,742,516	\$110,917,366	\$113,135,713	\$115,398,427	\$117,706,396	\$565,900,418
Grand Total	\$113,248,130	\$122,430,381	\$125,918,383	\$134,809,702	\$146,917,374	\$143,147,077	\$673,222,917
Routine Immunization	\$113,248,130	\$117,756,683	\$121,226,217	\$130,101,216	\$137,451,203	\$138,404,965	\$644,940,283
Supplemental Immunization Activities		\$4,673,698	\$4,692,166	\$4,708,486	\$9,466,172	\$4,742,112	\$28,282,634

 Table 8: Total cost scenario over six years from 2011-2016

2011 (US\$)	2012 (US\$)	2013(US\$)	2014 (US\$)	2015 (US\$)	2016(US\$)	Total 2012 - 2016
\$113,248,130	\$122,430,381	\$125,918,383	\$134,809,702	\$146,917,374	\$143,147,077	\$673,222,917

#### 3.2 Sources of secure / probable funding

In this section, various sources of funding are discussed. The Government of Sri Lanka is committed to strengthen the immunization programme in Sri Lanka. Other than the GAVI co financing support for pentavalent vaccine which will extend till 2015, currently all other vaccines are funded by the government.

The cost (even with GAVI support) for newer vaccines such as Pneumococcal and HPV is proposed to be covered through domestic resources.

The estimated secure and probable funding sources are described in Tables 3.2 and 3.3. It can be seen from Table 3.2 that the major source of secure funding continues to be the Government of Sri Lanka. The GAVI funding contributes significantly for the period of 2004 -2011, but thereafter this funding is not secure. Under probable sources of funding, World Bank, WHO, GAVI, JAICA and UNICEF are considered.

Building successful and sustainable National Immunization Programme requires decision makers to have an in-depth understanding of the health and socioeconomic benefits of the immunization programme. To achieve this objective the Epidemiology unit in collaboration with the Sabin Vaccine Institute's Sustainable Immunization financing Programme, has been working for the last few years.

Secure funding	2012 (US\$)	2013(US\$)	2014(US\$)	2015(US\$)	2016(US\$)
Government	\$10,869,047	\$11,230,617	\$11,358,943	\$13,120,232	\$24,265,527
World Bank					
Sub National gov	\$ 157,375	\$172,150	\$181,847	\$194,110	\$106,502
Gov. Co-finance of	\$1 552 063	<b>*</b> 0 <b>5</b> 11 000	<b>*</b> 0.077.047	<b>*</b> 40 <b>7</b> 50 00 4	
GAVI vaccines	ψ1,002,000	\$2,511,230	\$9,077,917	\$13,750,284	
UNICEF					
WHO	\$38,254				
GAVI HSS	\$43,036				
Total secure fund	\$12,659,776	\$13,913997	\$20,618,707	\$27,064,625	\$24,372,030
Total resource	\$13 687 865	\$15,001,017	\$21 673 989	\$31 518 947	\$25 440 681
requirement	<i><i>w</i>10,001,000</i>	φ.0,001,017	φ <u>2</u> 1,070,000	<i>\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\</i>	φ <u>2</u> 0, 1 τ0,00 τ
Funding gap	\$1,028,089	\$1,087,021	\$1,055,282	\$4,454,321	1,068,651
	[8%]	[7%]	[5%]	[14%]	[4%]

Table 9:Estimated secure funding sources and gaps

# 4. National level problems and objectives related to the immunization programme

Description of problem / Areas to improve	NIP Objectives
1. Coverage of BCG, 3 doses of OPV, DPT, hepatitis B, Hib and measles vaccines, and Vitamin A of infants by the first birthday is around 95%.	To achieve near 100% coverage for BCG, 3 doses of OPV, DPT, hepatitis B, Hib and measles vaccines, and Vitamin A of infants by the first birthday by 2015.
2. Vaccines administered at school going age (DT, aTd, vaccines) show relatively poor coverage compared to infant immunization coverage.	To achieve 95% coverage for vaccine administered at school going age by 2015.
3. Availability of limited facilities to carry out laboratory confirmation of EPI target diseases.	To provide laboratory confirmation for all reported cases of EPI target diseases by 2016.
4. Availability of limited cold chain maintenance facilities at provincial and divisional levels.	To provide adequate cold chain facilities at all three levels by 2015.
5. Non availability of proper sharps management and safe disposal policy and system.	To introduce proper sharp management and safe disposal policy and system in five selected urban districts by 2015.
6. Lack of compliance of detailed investigation of AEFI at	To achieve over 95% coverage for detailed investigation of

divisional level.	AEFI at divisional level by 2015.
7. Relatively high vaccine wastage reported for all EPI vaccines.	To reduce vaccine wastage to a maximum of 10% for all liquid EPI vaccines by 2013. To reduce vaccine wastage to 20 - 25% for all other EPI vaccines by 2013.
8. Prevailing disparity in the quality of immunization services within and between districts.	To significantly reduce unintended variation of quality of immunization services within and between districts by 2015.
9. Inadequate and maldistribution of health personnel who are involved in immunization activities at divisional level.	To provide minimum number of required health personnel to carry out immunization activities at divisional level by 2016.
10. Inadequate transport facility at all levels to carry out immunization activities.	To provide adequate transport facilities to all levels by 2015.
11. EPI related disease surveillance activities at all levels need further strengthening.	To strengthen further the EPI related disease surveillance activities at all levels by 2013.
12. Training and research activities related to immunization need further strengthening.	To strengthen further the training and research activities related to immunization by 2014.

13. Introduction of new antigens into the National EPI.	To introduce Pneumococcal vaccine into the National EPI by 2013 To strengthen and expand the surveillance activities for Pneumococcal and rota virus disease by 2012. To establish the surveillance activities for HPV diseases for which vaccine is currently available by 2013. To introduce the HPV vaccine into the National EPI by 2014.
14. The target population receiving immunization through the private sector being 1% of the total.	To increase the percentage of target population (who can afford) receiving quality immunization through the private sector to 3% by 2015.
15. Inconsistent financial sustainability of the immunization programme.	To ensure uninterrupted financial support to the EPI.

# 5. Objectives, strategies and key activities of the multi year plan

Objective	Strategy	Key activities
To achieve near 100% coverage for BCG,	Using a combination of approaches to	1. Sustain high vaccination coverage,
3 doses of OPV, DPT, hepatitis B, Hib and	reach everyone under one year of age to	where it has been achieved.
measles vaccines, and Vitamin A of infants	get age appropriate immunization.	2. Identify both district and divisional level
by the first birthday by 2015.		low coverage areas (causality
		assessment).
		3. Develop and implement strategies both
		at district and divisional level to immunize
		all children less than one year of age.
		4. Supervisory follow-up in priority districts
		and divisions.
		5. Conduct quarterly EPI reviews at
		district level and provide feedback.
2. To achieve 95% coverage for vaccines	Using a combination of approaches to	1. Sustain high vaccination coverage,
administered at school going age by 2015	reach everyone at school going age to get	where it has been achieved.
	age appropriate immunization	2. Identify both district and divisional level
		low coverage areas (causality
		assessment).

		3. Develop and implement strategies both at district and divisional level to immunize all school going children.
		4. Supervisory follow-up in priority districts and divisions.
		5. Joint planning with the Education department.
		6. Conduct quarterly EPI reviews at district level and provide feedback.
3. To provide laboratory confirmation for all	Strengthening laboratory capacity through	1. Expand the existing laboratory network
reported cases of EPI target diseases by	the expansion of prevailing laboratory	up to provincial level.
2016.	network	2. Assure training and availability of
		equipment, reagents and quality control
		procedures at provincial level.
		3. Provide regular national, district and
		divisional level feedback
		4. Establish computer base laboratory
		surveillance system for VPDs.
4. To provide adequate cold chain facilities	Reorganizing the cold chain facilities at all	1. Conduct annual assessment of the
at all three levels by 2015.	three levels to cater to the need.	available cold chain maintenance facilities
		at each level.

	2. Establish 26 RMSDs with adequate
	cold room facilities.
	3. Establish 8 provincial cold room
	complexes with adequate cold room
	facilities
	4. Develop cold chain replacement plan
	for all 3 levels.
	5. Replace 10% of old cold chain
	equipment at divisional level every year.
	6 Replace 20% domestic type
	refrigerators at divisional level with II R
	every vear
	7 Introduce electronic data lodgers to all
	the district and divisional level vaccine
	storage equipment.
	9 Establish a machanism to manitar the
	temperature records of data lodgers at all

		9. Introduce 250 freeze tags each year to
		all district and divisional level vaccine
		storage equipment.
5. To introduce proper sharps	Establishing a network of incinerators and	1. Finalize national sharps waste
management and safe disposal	waste management system in five selected	management policy.
policy/system in five selected urban	districts.	2. Conduct needs assessment
		3. Select five needy districts.
		4. Provide adequate number of
		incinerators and other logistics to the
		selected districts.
6. To achieve over 95% coverage for detail	Strengthening of current divisional level	1. Provide comprehensive refresher
investigation of AEFI at divisional level by	AEFI investigation process.	training for all staffs on surveillance of
2015.		AEFI.
		2. Review the AEFI situation during the
		quarterly district reviews.
		3. Provide regular national, district and
		divisional level feedback
7a. To reduce vaccine wastage to 10% for	Developing and implementing targeted	1. Carry out a causality assessment to
all liquid EPI vaccines by 2013.	programme to reduce vaccine wastage.	find out reasons for vaccine wastage
		2. Ensure implementation of open vial

7b. To reduce vaccine wastage to 20 -		policy.
25% for all the other EPI vaccines by		3. Reschedule clinic sessions at divisional
2013.		level.
		4. Procure combined form of vaccine
		vials.
		5. Carry out annual EPI reviews in each
		district with special emphasis on vaccine
		wastage.
		6. Improve supervision at all levels.
8. To reduce significantly unintended	Using a combination of approaches to	1. Conduct 1-2 district level EPI surveys
variation in quality of immunization	identify and correct unintended variation in	annually using WHO 30 cluster method.
services within and between districts by	immunization service quality within and	2. Conduct district level EPI reviews quarterly
2015.	between districts.	with divisional level managers.
		3. Conduct national level EPI reviews
		quarterly with district level managers.
		4. Conduct annual audit to identify available
		logistics to carry out immunization activities at
		divisional level (need assessment).
		5. Determine priority districts and divisions for
		logistic distribution.
		6. Carry out supervisory follow-up in priority

		districts and divisions.
		7. Prepare a micro-plan for all districts.
		8. Identify in-service training need.
		9. Prepare comprehensive in-service training
		plan.
		10. Conduct on the job skill building training
		for PHC staff.
		11. Develop EPI data management software.
		12. Strengthen coordinating and management
		capacity at central level.
		13. Strengthen coordinating and management
		capacity at district level.
9. To provide adequate number of skilled	Improving human resource management in	1. Make an audit of available human
health personnel to carry out immunization	immunization programme.	resources at central, district and divisional
activities at divisional level by 2016.		level.
		2. Estimate cadre requirement of all
		categories of health workers for EPI
		programme for the next 5 years.
		3. Develop recruitment plan in accordance
		with the budget.
		4. Determine priority districts and divisions

		for filling vacancies.
		5. Develop a rational vehicle replacement
		plan
10. To provide adequate transport facilities	Ensuring timely distribution of vaccines	1. Hire or purchase vehicles for vaccine
to all levels by 2015.	and adequate supervisory visits at all three	transport
	levels.	2. Hire or purchase vehicles for
		supervisory visits.
		3. Determine priority districts and divisions
		for provision of vehicles.
		4. Develop a feasible replacement plan for
		the vehicles.
11. To strengthen further the vaccine	Ensuring optimally functioning VPD	1. Expand and strengthen the existing
preventable disease Surveillance activities	surveillance system.	VPD surveillance system.
at all levels by 2013.		2. Improve supervision at all levels
		3. Establish sentinel sites at each district
		for VPD surveillance.
12. To strengthen further training and	Promoting research and training activities	1. Produce local scientific evidence to
research activities related to immunization	related to immunization.	influence and prioritize public investments
by 2014.		for the development of new vaccines and
		technologies.
		2. Produce local scientific evidence to

		improve the quality of immunization.
		3. Provide training for regional /
		international health staff on AEFI by local
		experts with WHO collaboration.
16. To strengthen or establish surveillance	Justifying the introduction of new vaccines	1. Strengthen and expand the rota virus
activities for diseases for which vaccines	in future.	and Pneumococcal sentinel site
are currently available (Rota,		surveillance activities.
Pneumococcal meningitis, HPV) by 2012.		2. Establish surveillance activities for HPV
		diseases
		3. Conduct burden studies with sound
		methodologies for diseases for which
		vaccines are currently available.
13. To Introduce Pneumococcal vaccine	Ensuring effective and sustainable	1. Review the disease burden data,
into the national EPI programme by 2013.	introduction of Pneumococcal vaccine to	financial sustainability and safety issues
	the EPI schedule.	of the Pneumococcal vaccine at the
		immunization summit and take a decision
		on introduction.
		2. Obtain approval from the National
		Advisory Committee.
		3. Prepare estimates.

		4. Obtain Treasury approval for the estimates.
		<ul> <li>6. Educate / train district and divisional level programme managers and other stakeholders regarding Pneumococcal vaccine.</li> <li>7. Develop key messages to the public.</li> <li>8. Incorporate Pneumococcal vaccination</li> </ul>
14 To later dues UDV ( vession into the		into the routine EPI information system
14. To introduce HPV vaccine into the national EPI programme by 2014.	Ensuring effective and sustainable introduction of HPV vaccine into the EPI schedule.	<ol> <li>Review the disease burden data, financial sustainability and safety issues of HPV vaccine at the immunization summit and take a decision on introduction.</li> <li>Obtain approval from the National Advisory Committee.</li> <li>Prepare estimates</li> </ol>
		<ul> <li>4. Obtain Treasury approval for the estimates.</li> <li>5. Procure HPV vaccine.</li> </ul>

					<ul> <li>6. Educate / train district and divisional level programme managers and other stakeholders regarding Pneumococcal vaccine.</li> <li>7. Develop key messages to the public.</li> </ul>
					into the routine EPI information system
17. To increase the percentage of target population (who can afford) receiving	Strengthening partnership.	the	private	sector	1. Introduce necessary legal provisions to ensure quality and safety of the
quality immunization through the private					immunization activities carry out in private
sector to 3% by 2015.					sector.
					2. Establish a mechanism to monitor the
					quality and safety of the immunization
					activities carried out in the private sector.
					3. Establish a reporting mechanism to get
					the immunization details from the private
					sector to the national data base.

18. To ensure adequate and sustainable	To ensure adequate and sustainable	1. Ensure the sustainability of separate
financial support for EPI by 2012.	financial support for EPI	budget line given for the immunization
		programme.
		2. Improving government funding flows.
		3. Increasing access to the external donor
		funds.