WHO Strategic Plan for Strengthening Routine Immunization in India

April 2004 - March 2007

World Health Organization
Office of the WHO Representative to India
New Delhi

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Contents

Acronyms

AD	Auto disabled syringe
AEFI	Adverse Events Following Immunization
AIIMS	All India Institute of Medical Sciences
BCG	Bacille Calmette Guerin; vaccine against tuberculosis
DoFW	Department of Family Welfare
DIO	District Immunization Officer
DQS	Data Quality Self Assessment
EPI	Expanded Programme on Immunziation
GAVI	Global Alliance for Vaccine Initiative
GIS	Global Image Satellite
GLP	Good Laboratory Practices
GMP	Good Medical Practices
GoI	Government of India
HIS	Health Information System
HPV	Human Papilloma virus
INCLEN	India Clinical Epidemiology Network
IVD	Immunization and Vaccine Development Department
ICMR	Indian Council of Medical Research
IDP	Institutional Development Plan
JE	Japanese encephalitis
MMR	Measles, Mumps and rubella vaccine
MOHFW	Ministry of Health and Family Welfare
MSD	Medical supplies depot
MYP	Multi Year Plan
NIA	National Immunization Authority
NIFHW	National Institute of Health and Family Welfare
NPO	National Programme Officer
NPSP	National Polio Surveillance Project (under WHO)
NRA	National Regulatory Authority
NTAGI	National Technical Advisory Group on Immunization
RCH	Reproductive Child Health project
RI	Routine Immunization
SIO	State Immunization Officer
SOP	Standard Operating Procedure
TA	Technical Assistance
UIP	Universal Immunization Programme
UNICEF	United Nations Children's Fund
VPDs	Vaccine preventable Diseases
WHO	World Health Organization
WHO SEARO	World Health Organization Regional Office for South-East Asia

1. Introduction

This document highlights WHO's response to strengthen India's immunization system until the end of the Government of India's (GoI's) tenth health plan. The period covered, (April 2004 – March 2007), is seen as a transition period from polio eradication activities to increasing focus on routine immunization. The following aspects have been considered:

(1) Organizational and technical strengths of WHO

(2) WHO SEARO's IVD strategic plan, 2002-2005

(3) A phased increase in WHO routine immunization activities, in the event of polio eradication

(4) Inequities in current immunization services

(5) Broader health plans (10th health sector plan and RCH II planning)

(6) GoI's five-year-plan for implementing immunization services, 2004-2009

(7) Partner agency roles

(8) Current and possible future national management structures for immunization

All aspects of WHO's strategic immunization plan aim to support the GoI in the implementation of its multi-year plan (MYP): 2004-2009.

2. Issues

2.1 Areas of concern

Various assessments by many agencies over the last few years cite well identified problems within the immunization system. These include:

(1) Low capacity to devise, supervise, monitor and implement micro plans at district and health facility levels

(2) Lack of accurate monitoring and surveillance information on which to base decisions

(3) Lack of effective vaccine distribution to immunization sites

(4) Poor immunization infrastructure in urban slums and peri-urban areas

(5) Ageing and poorly maintained cold chain

(6) Lack of adequately trained human resources

(7) Low managerial and support capacity of central and state immunization units

(8) Weak management of fund flows

(9) Social issues e.g. Initiative, IEC, Social Constraints

Weak service delivery over five years: Rapid household surveys performed in 260 districts in 1998/9 and again in 2002/3 showed that full immunization rates have decreased in 176[1] (76%) of the districts.

Low coverage rates: On an average, 35%[2] of infants in each state are not fully immunized, but this is as high as 90% in Bihar and 81% in Uttar Pradesh. Nationally, there are at least 18[3] million infants who are not fully immunized

[1]Rapid Household Survey RCH project; International Institute for Population Sciences

[2]UNICEF MCIS survey 2001-2002

annually. Of these, 64% live in five states: Andhra Pradesh, Bihar, Rajasthan, Uttar Pradesh and West Bengal.

High drop out rates: On an average, 14%[4] of infants in each state who come into contact with immunization services to receive their BCG do not receive their measles vaccine. This is as high as 37% in Andhra Pradesh and 35% in West Bengal. Nationally, almost 6.5[5] million infants drop out between BCG and measles annually. Of these, 57% are in five states: Andhra Pradesh, Bihar, Rajasthan, Uttar Pradesh and West Bengal.

Injection safety: The recent AIIMS - INCLEN injection safety study showed that 73.9% of injections given in immunization clinics were unsafe. The GoI plans to introduce auto disable (AD) syringes in the Universal Immunization Programme (UIP) countrywide in 2005.

2.2 Broader healthcare links with RCH II

In its strategic plan, WHO has considered technically assisting the immunization components of the Reproductive Child Health project II logical framework which include:

(1) implementing the national five-year strategic plan

(2) improving immunization coverage and drop out rates

(3) implementing a safe injection policy

(4) strengthening central and state management capacity.

[3]UNICEF MCIS survey 2001-2002, 2001 census figures and assumes 3.5% population is under one

[4]UNICEF MCIS survey 2001- 002

[5]UNICEF MCIS survey 2001-2002, 2001 census figures and assumes 3.5% population is under one

3. WHO's Goal in Strengthening Routine Immunization

WHO's goal is to support and provide technical assistance to the GoI and key selected State Governments to enable the Universal Immunization Programme to:

(1) Deliver immunizations effectively, equitably and safely

(2) Strengthen the flow, quality and appropriate use of immunization data to empower health workers and planners at all levels to plan services more effectively and efficiently

(3) Select and implement the use of new and underutilized vaccines.

4. WHO Technical Assistance Targets

Each WHO response is closely linked with distinct objectives of the GoI's multi-year plan (MYP). WHO's responses will focus on enhancing capacity at national and state levels through support to their respective management structures.

National level: WHO will specifically offer support and technical assistance for the following components of the central management structure:

- Monitoring/surveillance unit
- Financial management unit
- Service delivery unit including increasing coverage/decreasing drop outs, immunization safety aspects and responding to adverse events following immunization (AEFIs)
- Research and service delivery units for aspects of new and underutilized vaccine introduction

State level: Support and technical assistance will also be provided to selected key states in a phased manner as under:

2004: Bihar, Jharkhand, Rajasthan and Uttar Pradesh;

2005-2006: other states considered for expansion include; Assam, Andhra Pradesh, Chattisgarh, Karnataka, Madhya Pradesh, Orissa and West Bengal.

WHO will specifically offer support and technical assistance for the following areas at State level:

- Monitoring and surveillance issues
- Although WHO will ***not*** have an implementing role in aspects of the cold chain, it will provide assistance to monitor and report on cold chain status to concerned authorities.

- State planning processes (facilitating policy and operational guideline distribution and adaptation of the MYP to state-specific contexts).
- Facilitating training and other processes for increasing coverage and decreasing drop-outs, including supervision practices and strengthening monitoring and surveillance practices.

4.1 Strengthened systems to deliver essential immunization services

Overview

Multi-partner involvement is critical for the GoI's implementation of its Universal Immunization Programme (UIP). WHO will provide technical assistance to increase coverage rates and decrease drop out rates through adaptation and dissemination of appropriate modules. WHO will also support the drafting and dissemination of immunization policies, strategic plans and operational guidelines as well as providing assistance for immunization reviews.

WHO will ***not*** be involved with implementation of the cold chain or vaccine logistics. However, WHO will provide support to UNICEF and GoI-led initiatives for these issues through other activities such as:

(1) Micro-planning and training (see 1 below) in Bihar, Jharkhand, Rajasthan and Uttar Pradesh

(2) General monitoring (see 4.2 below)

Planned assistance

(1) **Strengthening capacity to increase coverage and decrease drop-out rates:** WHO will provide technical assistance to the GoI and selected key states on increasing coverage rates and decrease drop out rates. A WHO/UNICEF globally available strategy has been adapted to the Indian context. It has been submitted for consideration by the GoI for either (a) discrete three-day training modules at block levels, (b) incorporation or adaptation of existing training modules or (c) incorporated into new RCH II training modules. The strategy

has five key components which link closely with successful elements of the polio eradication programme:

(a) *Reaching the underserved:* Nearly 80% of children live within 0.5km of a routine immunization service provider[6]. Outreach services will, therefore, increase focus on reaching the underserved in the identified states who live in slums, peri-urban areas and in mobile populations.

(b) *Supportive supervision:* Strengthening the actual monitoring and on-site training by line supervisors will include not only standard monitoring checklists, but also methods to increase access to routine immunization sites.

(c) *Community links with service delivery:* Encouraging community involvement in the planning and education about routine immunization.

(d) *Monitoring and use of data for action:* Focusing on the use of immunization registers, prioritizing districts and health facilities on the basis of coverage rates and drop-out rates and using data at district and health facility level for planning.

(e) *Planning and management of resources:* This involves micro planning at health facility and district levels to encourage mapping of populations, using data to plan immunization sessions more effectively and create work plans.

The dissemination of the strategy and training is aimed at the block and district levels. This will require close collaboration with UNICEF, NIFHW and institutes at state level.

Strengthening the delivery component of routine immunization, it is hoped, will impact on measles and neonatal tetanus morbidity and mortality. However, if requested, WHO will also provide technical assistance to measles mortality reduction or neonatal tetanus elimination initiatives.

(2) **Multi-year Plan (MYP):** Together with key development partners and National Technical Advisory Group in Immunization, WHO has assisted the GoI draft a technically robust five-year

[6]UNICEF MCIS survey data 2001

immunization plan. Implementation of this plan depends on cabinet approval and the strengthening of central management capacity. States will also benefit from the MYP as they go through their own planning processes. WHO will, therefore, also assist and facilitate in the dissemination and 'sensitization' of this MYP to State levels.

(3) **Immunization policy:** An initial draft immunization policy is available. However, its full development was postponed until the MYP process was complete. The development of the policy required separate discussions on issues such as safe immunization, quality control and immunization schedule. WHO will help facilitate this process and provide technical assistance to the GoI to produce a nationwide immunization policy.

(4) **Operational guidelines:** Many operational guidelines exist but are not of uniform quality. Guidelines and training modules devised for RCH I are due for review and standardization in 2004 – 2005. WHO will offer the GoI key technical inputs for the development of these guidelines, based on the new immunization policy and MYP.

(5) **Immunization review:** A UIP review was carried out during 25 August-8 September. The earlier formal and informal immunization reviews were in 1989 and 1998 respectively. The immunization review was crucial for two main reasons: (a) to provide recommendations to GoI on prioritizing activities within its MYP; and (b) a baseline evaluation before implementing GoI's MYP.

The UIP review had wide partner support with WHO playing a central role in facilitating and providing technical inputs.

(6) **Strengthening national financial management:** There is an urgent need for a clear financial overview to ensure that resources are being utilized efficiently and to plan activities effectively. WHO will provide technical guidance on immunization costing strategies and enhance planning for financial sustainability.

A WHO-coordinated financial team has provided technical assistance to the GoI. This team will assist the government in estimating immunization resource requirements, reviewing funding gaps and assist in planning for financial sustainability. Links with health economic institutes will be explored to encourage research into immunization financing issues.

Linked to the GoI multi year plan

Goal 1: objectives 1 and 2

Goal 2: objectives 2 and 3

Goal 3: objective 1

Milestones

2004: Assist GoI in ensuring an immunization policy is in place

MYP has been disseminated to UP, Bihar, Rajasthan and Jharkhand

WHO technical assistance is available for the central GoI service delivery, surveillance and monitoring, financing and new vaccines research units

WHO technical assistance is directly available in Bihar, UP, Rajasthan and Jharkhand

Joint WHO/UNICEF strategy for increasing coverage/ decreasing drop-out rates has been adapted to the Indian context

The cost of the MYP has been worked out and future resource availability mapped out

WHO provided technical assistance for a national EPI review.

2005: Routine immunization operational guidelines are in place for distribution

WHO will consider technical assistance for two more states

Increasing coverage/decreasing drop-out rate strategy available and implemented in two key selected states.

2006: Increasing coverage/decreasing drop-out rate strategy available and implemented in four key selected states

WHO reviews lessons learnt from the strategy for consideration by GoI for expansion to other States by the government

WHO technical assistance is available in at least six states.

4.2 Strengthened surveillance and monitoring systems

Overview

There is a need to improve the flow of immunization data from district to national levels and to improve the use and quality of data at all levels. WHO plans to respond to GoI's request for technical assistance to improve the flow of data, whilst also reviewing adaptation of available methods to improve data recording and reporting practices.

Planned assistance

(1) **Enhancing the flow of information:** Since 1998, recording and reporting of immunization data has been integrated into broader RCH formats. This has had a negative effect on the responsiveness and quality of immunization data available at the national level. The GoI has requested WHO to provide TA in designing a more responsive immunization health information system (HIS) that captures:

- VPD surveillance
- Coverage monitoring indicators
- Vaccine and cold chain logistics
- Immunization system performance indicators
- AEFI indicators

WHO has responded to this request and will review technically appropriate ways of transmitting this information from the health facility to the national level. The software development, maintenance and training issues will be outsourced to a vendor who will have responsibility for at least three years. WHO will provide back-up assistance to ensure that responsive data is available for use at the district level and that there are mechanisms in place for feedback from the central level. These may eventually involve data entry at district level on line, a responsive central

database, analytical tools and eventual geographical mapping of health facilities.

(2) **Increasing the accuracy and use of available data:** Accuracy of data is dependent on ensuring that quality recording and reporting practices are in place. WHO will provide technical assistance to the government and to key selected States on:

- Recording and reporting practices for monitoring
- National forms used for reporting immunization data
- Training for health workers on monitoring and using immunization data

One specific WHO initiative to improve accuracy of immunization data includes the data quality self assessment (DQS). The DQS is a tool for use by districts and states. It helps immunization managers identify weak parts of the monitoring system, and suggests changes and highlights bottlenecks in immunization data flow. The DQS uses two main methods:

(1) review of the ***quality*** of immunization monitoring system at different levels (by a questionnaire and observation eg. review of availability of monitoring forms, recording and reporting practices and ability to use immunization data at local levels)

(2) review of the ***accuracy*** of immunization data at different health system levels (eg. health facility immunization register data verified with reported data at district level)

WHO will assist the GoI and selected key states in adapting such a DQS tool to facilitate the strengthening of monitoring and surveillance practices at district level and below, and improve the use of data for planning and action at local levels.

Links with GoI multi year plan

Goal 6: objectives 1, 2 and 3

Milestones

2004: Terms of reference for the software is finalized and vendor is selected

The central repository system is installed and operational

Beta version of software is tested in four districts

Monitoring and surveillance coordination meetings for District and State Immunization Officers (DIOs and SIOs) have been held in Bihar, Jharkhand, Rajasthan and Uttar Pradesh.

2005: Final software version is ready for use and dissemination to states, after appropriate field testing

Final (net accessed) version of software in four states

DQS has been tested in two states

Beta version software operators are trained.

2006: Final version of software is available in all states

DQS has been considered for adaptation in four states.

4.3 Strengthened strategies to ensure immunization safety

Overview

Following the results of the AIIMS- INCLEN safe injection study, the GoI will introduce auto disable (AD) syringes countrywide in 2005. WHO will provide technical assistance in this area as well as in waste management. Apart from this initiative, WHO will also provide support and technical assistance in assuring the quality of vaccines used in UIP by strengthening the national regulatory authority (NRA) and inducting AEFI surveillance and response.

Planned assistance

(1) Provide support and technical assistance for the GoI and key selected States to implement the GoI injection safety and waste disposal policy, including introduction of AD syringes

(2) Provide support and technical assistance for the vaccine NRA and evaluating systems on standardization and control of the quality of vaccines used in the UIP

(3) Provide support and technical assistance for implementing and monitoring AEFI response

Links with the GoI MYP

Goal 1: objective 5

Milestones

2004: A safe injection and waste disposal policy is drafted and technical assistance is provided

Training materials on injection safety finalized for healthcare providers

An Institutional Development Plan (IDP) for the NRA is drafted;

Guidelines and standard operating procedures (SOPs) for AEFI surveillance finalized

GoI central units strengthened and responsive in AEFI surveillance

Good quality AEFI surveillance instituted in two states.

2005: A study on feasibility and cost effectiveness of alternative injection waste disposal options is completed and disseminated to partners

GMP inspection procedures and guidelines for vaccine producers standardized

All State EPI programme officers trained in AEFI surveillance

Good quality AEFI surveillance instituted in at least six States.

2006: Technical assistance provided to assist in monitoring the implementation of injection safety and waste disposal practices in three selected states

All NRA core functions for vaccine quality assurance strengthened

Good quality AEFI surveillance instituted in all the States.

4.4 Strengthened selection and implementation of new and underutilized vaccines

Overview

Hepatitis B has been introduced into 33 districts and 15 slum areas of cities since 2002. Original plans were to expand Hepatitis B to the whole country.

However, from 2005, current GoI plans are, to expand to non-slum infants in project cities but to freeze the number of areas where Hepatitis B has been introduced for at least three years. GoI has emphasized consolidation and performance improvement in the existing project areas. The present Hepatitis B programme will, therefore, require continued technical assistance for aspects of review and implementation.

Safe and effective vaccines are now available against other diseases of public health significance in the country (eg. Measles, Mumps and rubella vaccine and JE). Moreover, there are many other candidate vaccines (rota virus, cholera, HPV) which are under various phases of clinical trials in the country. There is, therefore, also a need for technical assistance to review the feasibility of introducing new vaccines.

Planned technical assistance

(1) Hepatitis B: monitoring programme outputs including vaccine logistics, regular needs estimates and stocks in medical supply depots (MSDs), GAVI annual progress reports and developing further proposals for continuation of Hepatitis B project[7]

(2) Reviewing appropriate new vaccine research and introduction, according to the GoI's needs

(3) Building country capacity for conducting clinical trials for newer vaccines in good laboratory/clinical practices and strengthening ethical committees

Links with GoI MYP

Goal 5: objectives 1 and 4

Milestones

2004: Technical assistance is provided to ensure that annual and quarterly GAVI reports are submitted on time

Clinical trials for new vaccines streamlined at the national level

Capacity for GMP/GLP and ethical committees standardized and strengthened

[7]all future Hepatitis B injections will be given in AD syringes

Technical assistance for Phase I of measles aerosol vaccine clinical trial completed

2005: Technical assistance is provided to ensure that annual and quarterly GAVI reports are submitted on time

Technical assistance for Phase II of measles aerosol vaccine clinical trial completed and Phase III trials initiated

2006: Technical assistance is provided to ensure that annual and quarterly GAVI reports are submitted on time

Technical assistance is provided for assessing the consideration and feasibility of introducing candidate vaccines in the country.

5. WHO Routine Immunization Team

The WHO routine immunization (RI) team will be managed by the WHO Representative, India, in coordination with the NPSP project manager. Members of the team will be an integral part of support to the central GoI immunization units.

Existing WHO support to GoI national level immunization units

The following professionals are already in place:

- An international coordinator to help coordinate WHO's response to strengthen routine immunization.
- A national programme officer (NPO) to provide technical assistance for NRA, quality assurance of vaccines, AEFI and clinical trials for introduction of new and candidate vaccines, measles and neonatal tetanus initiatives.
- A NPO to provide technical assistance for introduction and implementation of new vaccines (including hepatitis B), injection safety and waste disposal.
- A national RI coordinator for strengthening programme implementation.
- A national RI monitoring and surveillance coordinator will be available for VPD surveillance, monitoring and evaluation, together with inputs from NPSP.
- A national immunization finance coordinator to assist the GoI's finance unit.
- A national level data analyst to provide technical assistance for the GoI's immunization data software.
- An AEFI officer to support the GoI in AEFI surveillance and response.

- Administrative support in the form of programme and administrative assistants.

WHO support for GoI national-level immunization units under consideration:

- A national training officer to assist the GoI and NIFW to develop and disseminate training plans for increasing coverage and decreasing drop-out rates, other training plans, modules and standards
- A measles coordinator to assist the GoI and selected key states in reviewing measles data and strengthening response to unusual increases in measles cases
- A measles aerosol vaccine coordinator will be available to assist the GoI and ICMR in coordinating measles vaccine aerosol trials in the country
- A finance assistant will also be made available, if necessary.

WHO support for State-level immunization teams:

- RI officers for Bihar, Jharkhand, Rajasthan and Uttar Pradesh are already available and providing technical assistance for state RI cells, coordinating with different RI stakeholders, assisting in the dissemination and sensitization of the MYP. State assistance will evolve, depending on the demands and future role of NPSP. This support may be extended to an additional two states in 2005.
- Monitoring and surveillance officers will also be considered to provide technical assistance for the state governments of Bihar, Jharkhand, Rajasthan and Uttar Pradesh. This technical assistance will support state demographers, statisticians, data analysts and DIOs to:
  (a) strengthen the flow of RI data from the sub-centre to state levels and
  (b) increase the accuracy of information recorded and reported through enhancing supervision and monitoring visits of DIOs and SIOs.

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