

Protecting people from Vaccine Preventable Diseases



Immunization and Vaccine Development

South-East Asia Region

Strategic Plan (2010-2013)

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INTRODUCTION

1. The IVD Mission in the Global Context

The Immunization and Vaccine Development (IVD) team supports the eleven Member States of the South-East Asia Region (SEAR) in immunization work. Guided by the Global Immunization Vision and Strategy (GIVS), IVD's goal is to protect the people of the Region against vaccine-preventable diseases.

Every year, immunization saves millions of lives and greatly reduces the burden of illness and disability caused by vaccine-preventable diseases. Recognized as one of the most cost-effective and powerful public health interventions, immunization is also one of the key driving forces behind efforts to meet the Millennium Development Goals (MDGs). Immunization programmes are particularly critical in reaching the goal to reduce deaths among children under five years of age (MDG 4). Since 2000, efforts have been scaled up to meet the MDGs and the goals set out in GIVS.

Today, more children are being immunized than ever before and an increasing number of new vaccines are being made available to protect children, adolescents and adults against life-threatening diseases. Immunization has also made a significant impact on the health of the people of South-East Asia, with services reaching and protecting even the most marginalized and vulnerable populations. Consequently, the average routine immunization coverage rate has also improved from 55% in 2005 to 72% in 2008 for DTP 3 and correspondingly, 75% for measles in 2008. Additionally, out of the eleven WHO supported member states, eight achieved the minimum level of 80% DTP3 coverage in 2008. Despite these and other significant achievements, the Region is home to 9.2 million unimmunized children, according to a 2008 assessment by WHO/UNICEF.

The strategic plan for 2010-2013 focuses on implementation strategies to increase immunization coverage, help overcome access barriers, eradicate polio, control of VPDs, strengthen vaccine-preventable disease surveillance, develop research and development capacity and ensure vaccine quality and safety. The plan outlines IVDs focus for the next four years and beyond in Member States and the priorities of national immunization programmes.

Guiding Principles for Immunizations Programs

The Regional and national immunization programmes address the specific epidemiology of the Region. The planned programme is guided by principles that ensure deliverables reach the highest possible standards. Equity, access, and partnership are at the core of all planned approaches. IVD will work to ensure that immunization services are available to all in every district, that sustainability is addressed through infrastructure, human-resource, technical and financial capacity strengthening, that there is genuine commitment to the programme from all stakeholders, that efforts are government-lead and that all the policies, plans and technical guidance provided are guided by robust data.

The South-East Asia Region's Immunization Priorities 2010-2013 are:

- Increase routine immunization coverage through integrated health system delivery.

Target: All member countries achieve the GIVS goal of 90% vaccination coverage for DTP3 and at least 80% DTP vaccination coverage in every district by 2013.

- Interrupt the transmission of wild polio-virus and sustaining polio-free status for regional certification.

Target: Attain polio free status by 2010 and regional certification of polio eradication by 2013.

- Achieve regional measles mortality reduction goal and neonatal tetanus elimination. Continue comprehensive regional efforts for rubella control.

Target: Reducing measles mortality by 90% by 2013 in comparison to 2000 estimates by providing second opportunity for measles vaccine.

Target: Eliminate Neo-natal Tetanus (NNT) in remaining countries (India, Indonesia, Timor Leste and Myanmar) and sustain maternal and neo-natal tetanus (MNT) elimination in those countries that have achieved elimination.

Target: Provide rubella vaccination to susceptible populations in the Region by 2013.

- Strengthen regional vaccine preventable disease surveillance and immunization programme monitoring.

Target: Priority vaccine preventable disease cases and outbreaks rapidly detected, reported and investigated throughout Region as per International Health Regulations, supported by WHO accredited laboratories.

- Ensure effective and sustainable introduction of new vaccines of public health importance for the Region.

Target: Introduce new vaccines as per burden of disease and national priorities. At least one new vaccine to be introduced in every country in the Region by 2013. Control of the other VPDs and other emerging diseases.

- Quality and safety of all vaccines and biologicals manufactured and used in Region assured.

Target: All National Regulatory Authorities (NRAs) meet WHO criteria to regulate safety, quality and efficacy of vaccines used in the national immunization programme.

Target: Harmonized safety and quality policies and procedures throughout Region and networks of experts to address regulatory challenges with new vaccines in place. Seasonal/pandemic vaccines, AEFI monitoring etc..

Guiding Strategies and Their Implementation in the Region

WHO Medium-Term Strategic Plan 2008–2013

WHO's Medium-Term Strategic Plan (MTSP) provides the organization with strategy direction for the time frame 2008-2013 and is linked to the 10 year General Programme of Work (GPW) as well as Country Cooperation Strategies (CCS). The plan reflects the Director-General's agenda for action. Notably, the plan addresses health development and security, systems and evidence, as well as partnerships and performance, and are described in 13 strategic objectives. IVD's plan is in line with the MSPT and supports specifically the following objectives:

Objective 1. To reduce the health, social and economic burden of communicable diseases.

Objective 10. To improve health services through better governance, financing, staffing and management informed by reliable and accessible evidence and research.

Objective 11. To ensure improved access, quality and use of medical products and technologies.

Objective 12. To provide leadership, strengthen governance and foster partnership and collaboration with countries, the United Nations system and other stakeholders in order to fulfill the mandate of WHO in advancing the global health agenda as set out in the Eleventh General Programme of Work

IVD's programme of work is especially critical to achieving the indicators and targets of objective one, which include: reducing the morbidity and mortality rate due to vaccine-preventable diseases by two thirds by 2013, increasing the coverage of interventions targeted at the control, elimination or eradication of tropical VPDs by 80% in 49 at-risk Member States by 2013, and achieving and maintaining 100% certification of poliomyelitis eradication and destruction or appropriate containment of all polioviruses.

The MTSP objectives, indicators, sub-indicators and targets have provided the basis for the development of IVD's plan of action and guide SEAR immunization activities, alongside the below presented GIVS framework.

Global Immunization Vision and Strategy

In 2005, WHO and UNICEF jointly published the GIVS framework for the period 2006–2015. With an overriding focus on the need to ensure equity in access to vaccines and immunization, the strategy sets out the steps that the immunization community needs to take in order to contribute fully to the attainment of the MDG mortality reduction targets.

Implementing the strategy calls for four main approaches: protecting more

people against more diseases; introducing new vaccines and technologies; integrating immunization with other components in the health system; and immunizing in the context of global interdependence. These global goals have added a sense of urgency to vaccine-related activities and spurred renewed efforts to complete, as far as possible, what the GIVS refers to as “the unfinished immunization agenda”.

IVD’s strategy is guided by these four, core GIVS strategies:

(1) Protecting More People in a Changing World

While several countries in the Region have attained and sustained high immunization coverage, millions of children still remain unreached by life-saving vaccines.

In 2008, six of the eleven Regional countries, namely Bangladesh, Bhutan, the Democratic People’s Republic of Korea (DPRK), Maldives, Sri Lanka and Thailand, reached the GIVS goal of higher than 90% national DTP3 coverage. In addition, DPRK, Maldives and Sri Lanka have all attained higher than 80% coverage in all districts. However, achieving GIVS goals still remains challenging for a number of countries, particularly for India and Indonesia, home to the largest cohort of unimmunized children. In India alone, WHO/UNICEF estimates that more than 8 million children do not receive DTP3.

Countries in the Region will need to overcome a number of barriers in order to strengthen service delivery and protect more people against vaccine-preventable diseases. Several countries face challenges such as underlying weaknesses of the health system, inadequate infrastructure and logistics support systems, as well as staffing issues and lack of awareness and lack of ownership by the local community. Others have a high number of unimmunized children due to the large size of the birth cohort, even with high routine coverage. Additional challenges faced by countries relate to information collection and analysis as well as financing issues.

Hence efforts to protect more people requires a number of different strategies, including systems strengthening, expanding routine services, advocacy for immunization, ensuring immunization safety, providing supplemental immunization activities and introducing specific strategies for reaching the most underserved populations. WHO will assist Member States in providing technical information, monitoring and evaluation, working together in priority national public health initiatives and coordinating with other partners.

(2) Introducing New Vaccines and Technologies

In addition to strengthening routine immunization systems, one of the key objectives of GIVS is to enhance access to new and underutilized vaccines and technologies.

Countries in the Region have, with support from the GAVI and newly available vaccines, sought to ensure children receive better protection from common disease such as hepatitis B, pneumonia and meningitis due to infections with *Haemophilus influenzae* type b (Hib). In fact, the hepatitis B vaccine has become an integral component of routine immunization in all countries in the Region, except India, where it is still being phased in. Additionally, several countries have introduced Japanese encephalitis (JE) vaccine. The Hib vaccine was introduced in Sri Lanka and Bangladesh in 2008, as well as in Nepal and Bhutan in 2009. The introduction of these vaccines have required special preparation prior to introduction, including particularly the strengthening of cold chain capacity as well as planning for long-term financial sustainability.

Accelerated efforts to develop vaccines have also produced a host of new vaccines, including ones that protect against rotavirus, pneumococcal and human papilloma virus. Within the context of their own national priorities, countries will seek to take advantage of the public health benefits that these new vaccines provide. IVD's strategy hence also focuses on providing support to countries on prioritizing and proceeding with vaccine introduction, as well as, strengthening the development of new vaccines and technologies in the Region. Countries will also be supported in carrying out disease burden studies and post-introduction assessments and capacity building of the National Regulatory Authority to oversight the quality, safety and efficacy of vaccines.

(3) Integrating Immunisation, Other Health Interventions and Surveillance in the Health Systems Context

Integrating immunization and surveillance with the delivery of other health interventions and broader vaccine-preventable disease surveillance is central to achieving the GIVS goals and also MDG 4.

Integration approaches in countries have, among others, included providing oral polio vaccine (OPV) during measles campaigns as well as adding micronutrient supplementation, such as zinc/vitamin A, distribution of insecticide treated bed nets and de-worming to supplementary immunization campaigns.

Much progress has also been made in setting up or improving broader regional and national vaccine-preventable diseases surveillance. In several countries, the high-performing polio surveillance systems have been

expanded to include reporting on other vaccine-preventable diseases such as measles, neonatal tetanus, and JE. Countries are also working to build effective surveillance systems to guide the decision-making process for the introduction of new vaccines, monitor the impact of these new vaccines on disease patterns, and conduct post-marketing surveillance to ensure the safety of all newly introduced vaccines. Country programmes are also seeking to integrate disease surveillance and monitoring systems to provide early warning of impending or ongoing disease outbreaks, providing a first-line defense against the threat of emerging or pandemic diseases, including influenza.

(4) Immunizing in the Context of Global Inter-Dependence

More than ever before, countries are vulnerable to the impact of global issues and events on vaccine supply, financing, information sharing and preparedness.

One of the main approaches in responding to this inter-dependence is the strengthening of national and regional regulatory capacity. WHO's regional focus has hence also been to harmonize and enhance vaccine regulatory capacity across the countries and promote technical collaboration among NRAs to assess vaccine dossiers for their market authorization and licensing and ensure continuous post-marketing surveillance to document safety profile of vaccines.

A core component in strengthening regulatory capacity is ensuring each country has a reliable, properly functioning national regulatory authority (NRA). NRAs carry out a number of critical functions, including licensing of vaccines. For example, in Bangladesh the NRA has been supported in developing and approving the first National Fast Track guidelines for licensing of UN pre-qualified vaccines. In addition to the above tasks, NRAs assist in adverse events following immunization (AEFI) monitoring, investigation and causality assessment. Critical activities are also carried out by the NRA's in the three vaccine-producing countries in the Region, namely India, Thailand and Indonesia. In addition to supporting the NRAs, IVD also provides technical support to country NCIPs, which provides important advice on any new immunization initiatives being introduced.

2. Regional Expected Results - WHO

IVD SEARO has five functional areas of work through which the regional objectives are supported. The regional expected results (RERs) are:

(1) Immunization Systems Strengthening

RER: Increased immunization coverage achieved through routine and supplemental immunization activities and integrated health service delivery.

(2) Polio Eradication

RER: Effective coordination and provision of support to Member States to achieve certification of poliomyelitis eradication and destruction, or appropriate containment of polioviruses, leading to simultaneous cessation of oral polio vaccination globally.

(3) Strengthening Vaccine-Preventable Disease Surveillance

RER: Cases and outbreaks of vaccine preventable diseases rapidly detected through surveillance networks supported by WHO accredited laboratories.

(4) Research and Development

RER: Regional priorities for research on prevention and control of communicable diseases, including vaccine development, strengthened through collaboration with and support to scientists and institutions in SEAR countries.

(5) Vaccine Quality and Injection Safety

RER: Availability of vaccines and biologicals of assured quality through norms and standards, strengthened national regulatory authorities, effective management of vaccines and safe injection practices.

1. Immunization Systems Strengthening

All WHO Member States in SEAR have outlined routine immunization strengthening as a priority for the period 2010-2013. GIVS will continue to provide countries with the goals for DTP 3 coverage and measles mortality reduction, as well as the programming framework to follow.

As routine or universal immunization rates vary tremendously across member states, countries will employ a combination of strategies to achieve and sustain high coverage. This will include strengthening routine services offered through health centres, outreach clinics as well as carrying out supplementary immunization campaigns when needed. A key element in improving access will be the continued use of the Reaching Every District (RED) strategy, which focuses on district-level efforts and aims to improve equity by targeting difficult-to-reach and underserved populations.

Reaching Every District (RED)

The cornerstone to achieving immunization coverage anywhere is to ensure effective service delivery at the district level. The RED strategy has been in use since 2002 and recommends the use of five operational components:

- Regular outreach services
- Supportive supervision such as in-service/location training
- Strong community links
- Data monitoring to guide programme implementation
- Planning and management of all resources

Supplementary immunization activities will also be employed to improve protection against selected diseases. Efforts to eradicate polio, reduce mortality from measles, and eliminate MNT and to control congenital rubella syndrome and Japanese Encephalitis will particularly rely on this approach, in addition to routine immunization, either nationwide or targeted at selected high-risk areas. Immunization campaigns will also be used to control disease outbreaks.

RER: *Increased immunization coverage achieved through routine and supplemental immunization activities and integrated health service delivery.*

Focus of regional activities to reach RER

- Increase capacity and coverage of routine immunization programmes.
- Develop and support national policies and strategies for accelerated disease control, specifically for measles mortality reduction and neonatal tetanus elimination.
- Introduction of new vaccines and technologies based on robust data and evidence of burden of disease.

Critical Indicators	Status	Target for end-2010	Target for end-2013
Number of countries with more than 80% DTP3 coverage in all districts and more than 90% nationally.	Five countries have reached this goal.	10/11	Eleven countries
Number of countries with more than 80% measles immunization coverage in all districts and more than 90% nationally.	Three countries have reached this goal.	8/10	Eleven countries

Plans

IVD will continue to support countries in their immunization strengthening efforts by assisting in the provision of training for health care workers to improve the quality and outreach of immunization services. This will include focusing on developing programme managers and mid-level managers (MLM) training using modules developed by HQ, monitoring and evaluation including conducting comprehensive EPI reviews, cold chain assessments and training in maintenance, logistics planning, data collection and monitoring as well as integrating immunization surveillance with other health information systems in coordination with other partners. Support will also be provided through advocacy efforts to ensure political commitment is achieved at the highest level in the Member States with the aim of securing financial sustainability for the programme.

In addition, IVD will also support countries in overcoming systems challenges and barriers to reaching more children. Special emphasis will be placed on assisting India, home to more than 8 million un-immunized children. India will be encouraged to continue employing a number of new approaches, particularly in Uttar Pradesh and Bihar, which account for most of un-immunized children and where polio continues to be endemic. Several new activities have already been launched, such as immunization days and the National Rural Health Mission (NRHM), a flagship programme. These efforts are also showing positive results in some of the most difficult areas.

Another key area of work has been to decrease the heavy burden of measles morbidity and mortality across the Region. Intense regional efforts have paid off, with measles mortality having been reduced by 42% in 2008, as compared to 2000. Moreover, all countries except India have achieved the 90% mortality reduction target. Measles routine immunization coverage in the Region has also increased from 61% in 2000, to 75% in 2008. All countries, except India and Thailand, have conducted a nation wide measles catch-up campaign to provide a second dose for susceptible age groups. In all, from 2000-2008, over 120 million children have received measles vaccination through these campaigns. Follow-up campaigns have also been conducted in 2008-2009 in Nepal, Timor-Leste and Indonesia. In addition to catch-up campaigns, Bhutan, DPRK, Maldives, Myanmar and Sri Lanka are providing a

second dose through routine immunization in all districts. Thailand has been providing a second dose through routine services since 1997. India also plans to introduce a routine second dose in 17 states with evaluated routine immunization coverage of more than 80%.

The measles campaigns have provided an opportunity to improve routine immunization services through mid-level managers and basic health worker training, establishing of AEFI monitoring systems, addressing the gaps in the cold chain and developing systems to dispose of the waste accumulated during vaccination sessions. This level of measles control has also revealed a previously unrecognized high incidence of rubella, consistent with other countries in the world with effective accelerated measles control.

Though much progress has been made in measles elimination, many challenges remain. In 2008 alone, approximately 8 million newborn children were not vaccinated against measles. Improving routine MCV1 coverage and providing children with a second dose (MCV2) has also proven challenging. Importantly, achieving the set 90% measles mortality reduction goal in the Region will require India to accelerate implementation of its measles mortality reduction strategic plan. The country's National Technical Advisory Group for Immunization (NTAGI) has hence also recommended conducting measles catch-up campaigns in 10 high priority states in 2010-2012.

IVD's strategic focus in measles mortality reduction will serve to help guide and implement planned SIAs across the Region and move India forward in their measles mortality reduction efforts. Additionally, IVD will support both Myanmar and Nepal in carrying out SIAs in order to boost immunity against measles, assist Nepal in implementing campaigns for JE and rubella immunization and support Timor-Leste in integrating vitamin A supplementation with routine immunization services.

National efforts to improve routine immunization, tackle high-priority diseases such as measles, as well as integrating surveillance are all critical for the introduction of new vaccines in the Region. The basic antigens currently included in all SEAR country national immunization programmes (NIPs) are BCG, OPV, DTP, and measles. Several countries have also expanded the list to include additional vaccines in their NIP in recent years. With support from GAVI, all countries in the Region have fully integrated hepatitis B (HepB) into their routine immunization programme, except in India where it is currently limited to 10 states and 15 cities. Bangladesh, Bhutan, India, Nepal, and Sri Lanka have also now either included or are poised to include the Hib vaccine. In addition, countries endemic to JE, that is, India, Nepal, Sri Lanka, and Thailand, have also added the JE vaccine into the routine schedule in the entire country or endemic Regions. With the rubella vaccine included by Bhutan, the Maldives, Sri Lanka and Thailand, the total Expanded Programme on Immunization (EPI) antigens being used in the Region are nine.

Countries will need guidance in establishing a focused strategic framework for choosing vaccines for inclusion in their respective programmes. Introduction of vaccines requires disease burden studies, sensitive surveillance systems including laboratory support for characterization of the prevalent pathogens, and a robust understanding of the epidemiology.

IVD will assist particularly Bangladesh, India, Maldives, Nepal, and Sri Lanka in establishing the evidence base and national capacity required to evaluate and prioritise the need for new vaccines and technologies. IVD will also provide an updated regional vaccine policy to guide effective and sustainable introduction of vaccines across Member States.

The framework of GIVS also proposes to strengthen and expand surveillance for new vaccines. Sites conducting surveillance for rotavirus diarrhea and invasive bacterial disease (IBD) that were funded by GAVI, have been proposed to be transitioned over to WHO. As a first step in 2009, from several sites in the Region that were conducting surveillance through GAVI support, seven rotavirus sites in Bangladesh, Indonesia, Myanmar, and Nepal and five IBD sites in Bangladesh, Nepal and Sri Lanka have been identified and are being supported by WHO to provide disease burden data. IVD seeks to continue collaboration with these sites to standardize the data generated as per WHO requirements.

2. Polio Eradication

SEAR continues to progress steadily towards the eradication of polio. Only India remains endemic, with localised pockets of virus transmission in western Uttar Pradesh (UP) and the Kosi river area of Bihar. All other Member States have interrupted virus transmission and successfully prevented importations and outbreaks by maintaining high population immunity.

The key challenges for the Region for 2010-2013 are to stop transmission in India, prevent importation to Nepal and to other neighboring countries, achieve high routine immunization coverage, carry out effective SIAs as well as ensuring high quality acute flaccid paralysis (AFP) surveillance in all countries.

Recognizing the importance of achieving the globally agreed polio goal, the WHO Director-General has given the Polio Eradication Initiative the highest operational priority in WHO's work.

RER: *Effective coordination and provision of support to Member States to achieve certification of poliomyelitis eradication and destruction, or appropriate containment of polioviruses, leading to simultaneous cessation of oral polio vaccination globally.*

Focus of regional activities to reach RER

- Support policy development and strategy updates on eradicating polio.
- Support the implementation of polio SIA campaigns in the Region.
- Ensure high quality and strengthened AFP/VPD surveillance systems.
- Support and maintain the accreditation of polio laboratories by WHO.

Critical Indicators	Status	Target for end- 2010	Target for end-2013
Number of polio cases in India	573 cases (as of 9 Nov 2009)	Zero cases	Zero cases
Number of countries responding to importations as per of WHO guidelines	11 countries	11 countries	11 countries
Number of countries maintaining AFP surveillance standards	10 countries	11 countries	11 countries
Number of polio laboratories providing accurate and timely results to support surveillance of AFP	Polio –17 (7 ITD labs)	Polio – 17 (11 ITD labs)	Polio – 17 (11 ITD labs)
Number of countries with completed containment certification document	6 countries	10 countries	11 countries

Plans

The intensified eradication plan continues to be implemented in India, supported by the Global Polio Eradication Initiative (GPEI) partners, with neighbouring countries assisted in carrying out preventative/responsive polio campaigns, as necessary.

The effort to end transmission in UP and Bihar is spearheaded by monthly polio immunization campaigns, supported by the network of surveillance medical officers (SMOs), primarily carrying out AFP surveillance. In 2007, the policy to sequentially eradicate subtype P1 poliovirus first by the end of 2008, and then eradicate subtype P3 in 2009 was formally adopted by the GPEI. India has not seen, particularly in Western Uttar Pradesh, polio subtype 1 for more than one year. Due to the sequential eradication strategy and the sustained use of monovalent OPV1, there was an upsurge of subtype P3 polio towards the end of 2007. However, the outbreak was rapidly contained.

Bangladesh, Myanmar and Nepal have also continued supplemental polio immunization activities in order to prevent the spread of imported wild poliovirus or vaccine-derived polio virus (VDPV). Indonesia has also included oral polio virus (OPV) into measles SIA campaigns conducted during 2006 to 2009.

IVD will, in 2010-13, focus on breaking the last chains of transmission in India and moving the Region towards certification of polio-free status. To continue to avert the risk of importations and to respond quickly and effectively should such an event occur, it is necessary for all countries to strengthen routine immunization to maintain high coverage and most importantly, for all countries to maintain the highest level of vigilance through high quality surveillance. After interruption, countries will also need to maintain certification standard

surveillance for at least three years until regional and global certification is achieved, as well as some time after the global cessation of OPV.

IVD will continue to monitor the quality of regional AFP surveillance closely, identifying and responding to gaps and challenges where they exist or emerge. IVD will also provide technical support to networks performing active AFP surveillance in Bangladesh, India, Indonesia, Nepal and Myanmar. Surveillance reviews will also be carried out in Nepal, Bangladesh, Sri Lanka, Thailand and Bhutan. Where feasible, the networks that have been largely set up for AFP surveillance will be supported in further integration with other VPD surveillance systems.

There are currently 17 WHO accredited polio laboratories in the Region, of which one is Global Specialized Laboratory (GSL) and two are Regional Reference Laboratories (RRLs). Besides the GSL and the RRLs, seven other national laboratories perform intra-typic differentiation (ITD) to differentiate wild virus and vaccine virus. There are plans to expand this to a total of 11 by the end of 2013. All polio labs in the Region have switched to the use of a new algorithm that has allowed faster detection and characterization of poliovirus (from 28 - 40 days to 14 -21 days). In 2010 – 2011, it is proposed to strengthen four more National laboratories to perform ITD. With the expansion, the Region will meet the goal of having over 75% of the stool samples from AFP cases tested by an ITD laboratory.

3. Strengthening Vaccine-Preventable Disease Surveillance

In addition to providing critical intelligence for regional disease eradication and elimination, surveillance systems also guide priority setting, planning and monitoring, as well as resource allocation for national immunization programmes.

Regionally, IVD aims to ensure VPD surveillance and immunization monitoring through an integrated epidemiological, surveillance network, as well as through laboratory support and programme monitoring that provides high quality information for measuring the impact of vaccinations. The guiding principles for Regional surveillance strengthening are integrating programme monitoring and surveillance in the health system context, building capacity at the district and health facility level, assuring quality of data, linking with other monitoring and surveillance systems and assuring financial sustainability across all programmes.

RER: Cases and outbreaks of vaccine preventable diseases rapidly detected through surveillance networks supported by WHO accredited laboratories.

Focus of regional activities to reach RER

- Strengthen and establish network of public health laboratories for VPDs
- Strengthen sub-national level surveillance activities, including migration from aggregate reporting to case-based surveillance.
- Expand the measles laboratory network and ensure they are WHO accredited.
- Establish sentinel laboratory sites detecting the burden of vaccine preventable diseases with a view to introducing new vaccines.

Critical Indicators	Status	Target for end-2010	Target for end-2013
Number of non-polio laboratories accredited to provide support to surveillance of VPDs	30	35	40
Percentage of VPD outbreaks fully investigated	75%	80%	90%
Number of countries providing timely/complete VPD Surveillance Data	7	8	9

Plans

The regional surveillance networks across the Region verify and monitor cases and outbreaks of a number of different VPD diseases in all the 11 countries. IVD supports polio, measles, rubella and JE networks based on the SMO structure and laboratories function in Bangladesh, India, Indonesia, Myanmar and Nepal.

Regionally, there is a clear need to strengthen case-based surveillance and outbreak response for diseases such as measles, as well as improving capacity for other vaccine-preventable disease surveillance. IVD's focus will be to build surveillance capacity to better monitor the performance, quality and safety of immunization programmes, and assess the impact of vaccination strategies through ongoing epidemiological surveillance supported by reliable laboratory confirmation.

More specifically, from 2010 to 2013, IVD will continue to integrate the high-performing polio networks with other disease detection networks. The team will also aim to strengthen sub-national level surveillance activities, including migration from aggregate reporting to case-based surveillance.

Moreover, IVD will assist in expanding the regional measles laboratory network (currently consists of 20 laboratories, of which 18 are accredited) and ensure they are WHO accredited. In India, the substantial network in place for polio eradication, which is run by the National Polio Surveillance Project (NPSP), will continue to separately administer measles surveillance though its

network. Additionally, IVD will continue to assist Bangladesh, Bhutan, DPR Korea, Maldives, Myanmar, Nepal, Sri Lanka and Indonesia to implement case-based measles surveillance in a phased manner. IVD will also assist select countries in their pandemic influenza surveillance. Moreover, support will be provided for sustaining the regional JE network, as well as establishing sentinel laboratory sites for detecting the burden of rota virus diarrhea, invasive bacterial disease, and HPV infection with a view to introducing new vaccines.

4. Research and Development

In the last 20 years, emerging and developing countries have taken over an increasing share of the global vaccine market. About 40% of the children worldwide are vaccinated with a vaccine coming from South-East Asia or the Western Pacific Region. The emergence of vaccine production in these countries has also stimulated research and development (R&D) efforts. However, research projects are still mostly in the pre-clinical phase and research institutes have found it challenging to move from the pre-clinical phase to mass production, due mainly to lack of government leadership in encouraging R&D and a lack of coordination between stakeholders, vaccine manufacturer, senior programme managers, research institutes and the scientific community. Consequently, the numerous new vaccines, either entering the market or at an advanced stage of clinical trials are still developed mostly in industrialized countries and will be available within the next five-to-seven years. These vaccines might, however, remain out of reach for developing countries for the next 20 years.

SEAR has a large untapped potential for vaccine R&D, with a very knowledgeable scientific community and excellent medical institutes in countries like India, Indonesia and Thailand. These countries should be encouraged to take a leadership role in developing and producing vaccines that are of public health importance for the Region (such as JE and dengue vaccines). In parallel, efforts are also being made to increase the ease and speed of vaccine delivery, decrease costs and reduce pain associated with vaccination by developing less reactogenic vaccine adjuvants or by developing needle-free injection devices, as well as transcutaneous immunization and mucosal immunization.

In light of these as well as other global and regional developments, it is of crucial importance for IVD to stimulate and support the development of a sustainable research and development agenda, which will help deliver optimal, cost-effective vaccines and technologies for priority diseases in South-East Asia.

RER: *Regional priorities for research on prevention and control of communicable diseases, including vaccine development, strengthened through collaboration with and support to scientists and institutions in SEAR countries.*

Focus of regional activities to reach RER

- Update the regional vaccine policy.
- Support countries to elaborate road map for vaccine research and development.

Critical Indicators	Status	Target for end- 2010	Target for end-2013
Regional Vaccine Policy published and disseminate	Regional vaccine policy dated 2003 available	Draft regional vaccine policy finalized and submitted to review committee	Final updated regional vaccine policy published and disseminated 2011
Vaccine producing countries have vaccine development plan that are implemented and monitored for progress.	Thailand is preparing a road-map for 5 biologicals research and development	Finalize Thailand road map for the development of 5 biologicals research project. Indonesia and India to initiate similar road maps.	The three producing countries have road maps for the development of vaccine research projects, which are implemented and monitored.

Plans

IVD supports the Region's vaccine R&D efforts by providing normative guidance, advocating for activities in support of priority vaccines and vaccination strategies, facilitating and coordinating operations research, as well as providing guidance on the establishment of a Scientific Technical Advisory Committee to review pre-clinical research work and advise stakeholders on requirements to move the products to mass production. IVD also provides technical support to ensure R&D projects are in compliance with scientific and ethical standards. Additionally, IVD also seeks to build capacity, provide training and facilitate technology transfer as well as encouraging Regional and global partnerships.

In the 2010-2013 period, IVD will review and update the regional vaccine policy and develop a roadmap for pre-clinical to mass production of vaccines. IVD will also support operational research to identify cost effective routes of vaccine administration (for example on measles aerosolized vaccine). In addition, IVD will support the regional development of pandemic influenza vaccines, particularly the clinical trials and post-marketing surveillance phases, as well as assist Thailand in developing dengue vaccine by providing support to the Thai FDA and manufacturer in establishing quality standards. All vaccine trials will need to meet Good Clinical Practices (GCP), and ethical and applicable regulatory requirements enforced by the Thai FDA. Capacity building for regional institutes in conducting such trials will therefore be a priority.

5. Vaccine Quality and Injection Safety

IVD supports countries in the Region in implementing policies and building capacity to assure the quality and sustainable supply of all vaccines delivered by national immunization services. A three-pronged approach is used to provide access to safe, assured-quality immunization services. This includes assuring vaccine quality from production to the point of use, ensuring the safety of vaccine administration in routine and mass campaigns, and safe disposal of immunization waste. To establish the causes of any adverse events following immunization and to address such causes is also closely linked to this approach.

As mentioned, SEAR is also a massive producer of vaccines and biological products. The NRAs of each of the Member States in the Region are supported by IVD in order to maintain quality control and licensing procedures of international standards. In the face of new and emerging vaccines as well as diseases, the effectiveness of the NRAs will be crucial. Any loss of confidence by the global community could result in serious interruptions in the global supply of vaccines.

Currently there are needs to review WHO global pre-qualification (PQ) procedures to address changes in the vaccine market, the growing demand from manufacturers to PQ their products and also to address the specific regulatory requirements related to introduction of new and underutilized vaccines. This is particularly important regarding the regional seasonal/pandemic flu vaccine, which poses challenges to regulatory authorities in regards to market authorization and post-marketing surveillance.

RER: Availability of vaccines and biologicals of assured quality through norms and standards, strengthened national regulatory authorities, effective management of vaccines and safe injection practices.

Focus of Regional activities to reach RER

- Consolidate National Regulatory Authorities capacity through networking of experts and linkages with Regional forum (ASEAN, APEC) initiatives to harmonize regulatory of medical supply in the Region.
- Establish Regional Working Reference Standards (RWRS) for the testing of selected vaccine.
- Establish, monitor and harmonise AEFI monitoring systems and build national capacity to conduct causality assessment.
- Establish and harmonise injection safety policies.
- Support effective vaccine management and storage practices
- Support immunization waste disposal policies and practices

Critical Indicators	Status	Target for end- 2010	Target for end-2013
All NRAs comply with WHO recommendations	4 NRAs are fully functional	5 NRAs fully functional	11 NRAs fully functional
RWRS established and available to the manufacturer for the production and testing of vaccines	0 RWRS are available	2 RWRS available	4 RWRS available with extended network of countries (2 to 3 more countries including WPRO) in the RWRS
Countries have conducted a review of injections practices and new policy are in place to improve and sustain injection safety in immunization	3 countries conducted injection safety assessment and develop policy to strengthen injection safety in immunization settings	4 countries conducted injection safety assessment	Injections safety policies are in place in all 11 Member States
Countries store their vaccine in compliance with WHO recommendations for Effective Vaccine Store Management (EVSM)	4 countries have conducted assessments and implemented plans for improvement	7 countries conducted assessment and implemented activity plan to strengthen EVSM	11 countries conducted assessment and implemented activity plan to strengthen EVSM
Countries have policy on safe disposal including safety box to dispose needle right after injection and technologies or/and practices for final disposal that do not harm the community and the environment	One country conducted study on risk associated with needle pullers	One country conducted study on risk associated with needle pullers	One country has introduced the needle puller nationwide

Plans

IVD assists countries in the Region in establishing a system for licensing of products and product facilities, surveillance for the vaccine performance in field conditions, lot release, use of laboratory testing when needed, regular inspection and compliance with good manufacturing practice (GMP) and evaluation of clinical trial data in licensing decisions. To make sure that manufacturers comply with these parameters, the countries are also supported in having a competent and functioning independent NRA.

SEAR pioneered vaccine capacity building with the NRAs. Since 2001, IVD has assessed all the NRAs in the Region as well as having assisted national counterparts in implementing institutional development plans. The NRAs of the three producing countries are today in compliance with WHO recommendations to regulate safety, quality and efficacy of locally manufactured vaccines. Ultimately, these NRAs will also be able to take on

additional responsibilities in the WHO PQ process that are now conducted by WHO. Over the past 10 years, IVD has also built a strong database of nearly 350 NRA specialists, covering each of the six functions. Assessments and Institutional Development Plan monitoring has also been conducted. This strategy has greatly contributed to the capacity building of the NRAs, as well as building networks that will be instrumental in a decentralized framework.

IVD also supports countries in responding promptly, efficiently and with scientific rigour to vaccine safety issues with the potential to affect, in the short or long term, national immunization programmes. Additionally, the IVD team helps monitor the safety of vaccines during clinical testing and fosters the development of improved AEFI surveillance systems across the Region. With the introduction of new vaccines, particularly with combination formulation vaccines, AEFI monitoring, investigation and causality assessment have become increasingly important issues across the Region.

Analysis of nationally reported AEFI is still limited, and hence needs further strengthening. Ten countries currently have guidelines and reporting systems in place and eight countries have established national AEFI committees. National EPI managers and NRA experts have received training through the global training network (GTN) centre for AEFI in Sri Lanka. Over the 2010-2013 period, IVD will prioritize training in investigation and causality assessment including procedures for post-mortem investigation. In this regard, IVD will develop a guideline for vaccine AEFI post-mortem investigation. IVD will also encourage national AEFI committee representative to join expert networks on causality assessment and will engage those national AEFI committee members in reviewing system in other countries so as to build capacity and share experiences across countries.

Another growing regional focus is increasing the safe and appropriate use of injections, especially with new vaccines of different formulation that will require revision of the open vial policy and changes in practice for safe injection. In this area IVD will guide countries in formulating national policies, as well as supporting training and capacity building. Following the needle puller risk assessment study conducted in Bangladesh, a pilot project will also be launched to test the equipment over a one year period. It is expected that once all operational and safety issues related to the use of the needle puller are addressed, the country will implement the needle puller nationwide.

With the introduction of more expensive new vaccines, wastage minimization has also become an increasingly important consideration in the Region. Vaccine wastage is attributed to multiple causes. Better vaccine management practices, better cold chain monitoring and the use of WHO open vial policy, among others, are ways in which to minimize waste. SEAR has hence also supported the review of vaccine management procedures in four countries using the WHO/UNICEF assessment tool. The outcomes of this assessment led to upgrading of the central storage facility in several countries. WHO will continue this support by consolidating achievements through in-country technical visits and by initiating similar work in priority countries.

Lastly, WHO is seeking to expand its global NRA capacity building strategy from vaccines to medicines, with priority on the Global Fund to Fight AIDS,

Tuberculosis and Malaria (GFATM) medicines. IVD has hence initiated formal NRA assessments in selected countries to assess regulatory systems for medicines and vaccines. The central location of Thailand between WHO's Western Pacific and South East Asia is an ideal location for WHO to support not only producing country in SEAR but also producing countries in WPRO, including China, Vietnam, South Korea and the Philippines. The decentralization of technical expertise from HQ, combined with SEAR's decentralization of technical staff to WCO Thailand will contribute to creating a WHO regulatory technical hub for medical supply, serving both SEARO/WPRO Regions. It will also greatly enhance WHO collaboration with existing economic forums and their regulatory task forces. Further consultation with HQ, Regional offices and national counterparts will be held in early 2010 to address the growing number of medical products submitted to WHO for PQ. The outcomes of these consultations will pave the way for the decentralization of expertise from HQ to SEAR and country offices, hence better serving Member States.

ABBREVIATIONS

AEFI	Adverse events following immunization
AFP	Acute flaccid paralysis
CCS	Country Cooperation Strategies
CIP	Coverage improvement plan
DTP	Diphtheria, Tetanus and Pertussis vaccine
EPI	Expanded Programme for Immunization
GAP	Global Action Plan for the laboratory containment of wild polioviruses
GAVI	Global Alliance for Vaccines and Immunization
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GIVS	Global Immunization Vision and Strategy
GPW	General Programme of Work
GTN	Global Training Network
Hib	Haemophilus influenza type b (a bacterium)
JE	Japanese encephalitis
MCV	Measles-containing vaccine
MDGs	Millennium Development Goals
MR	Measles-rubella vaccine
MTSP	Medium-Term Strategic Plan
NCL	National Control Laboratory
NNT	Neonatal tetanus
NRA	National Regulatory Authority
OPV	Oral polio vaccine
R&D	Research and Development
RED	Reach Every District
SEA	South-East Asia
SEAR	South-East Asia Region
SIA	Supplementary immunization activity
VDPV	Vaccine-derived poliovirus
UNICEF	United Nations Children's Fund
VPD	Vaccine-preventable disease
WHO	The World Health Organization
WPV	Wild polio virus