



GLOBAL FRAMEWORK FOR IMMUNIZATION MONITORING AND SURVEILLANCE

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A decorative graphic consisting of a grid of thin teal lines. The grid is composed of vertical lines on the left side and horizontal lines across the bottom, creating a frame for the text below.

G F I M S

global framework for immunization
monitoring and surveillance

The global immunization partners have a vision of a world that, by 2010, benefits from an integrated epidemiological, laboratory and programme monitoring network dedicated to optimizing the surveillance of vaccine-preventable diseases (VPDs) and monitoring of immunization programme performance. This network will provide the high quality information needed to measure the impact of vaccines and maximize their safe, effective and equitable use at country, regional and global levels to reduce or eliminate the burden of VPDs.

In response to this challenge, the World Health Organization (WHO) has developed a Global Framework for Immunization Monitoring and Surveillance – GFIMS. The GFIMS vision, as described in this document, is an extension of the Global Immunization Vision and Strategy 2006–2015 (GIVS) which specifically called for the articulation of:

a global plan for reliably monitoring the goals of the global strategy through an approach that builds sustainable monitoring capacity within the country, particularly at the district level; such a plan would outline a strategic approach for strengthening coverage monitoring, surveillance, and laboratory capacity for vaccine-preventable diseases by building on existing systems within countries and, at the same time, emphasizing high performance and accuracy.¹

Decision-makers need to decide on how best to immunize more people against more diseases,

introduce newly available life-saving vaccines and technologies, and provide other critical health interventions during immunization contacts in a manner that will maximize effectiveness, impact on the VPD burden and ensure efficiency in resource allocation. They need high quality data on which to base these decisions.

Organizations that provide funding to immunization programmes also need comprehensive, high quality data on programme performance and surveillance to measure the impact of vaccine use on the VPD burden and justify their public health investments.

There is, therefore, a rapidly growing urgency to provide high quality data to meet these needs. It is these needs that are the driving force behind the commitment to strengthen and expand the monitoring infrastructure of VPD surveillance and immunization programmes.

The global framework, as described in this document, has two **target audiences**:

- country-level programme and surveillance decision-makers and planners, and
- organizations that provide funding to immunization programmes.

This document defines and describes the essential components of the global framework, factors contributing to changes in the VPD surveillance and programme monitoring landscape, goals and objectives, the anticipated impact of reaching these goals and also the risks of failing to reach them by 2010.

¹ GIVS – Global Immunization Vision and Strategy 2006–2015.

Geneva, World Health Organization, 2005 (WHO/IVB/05.05), page 64.

http://www.who.int/vaccines-documents/DocsPDF05/GIVS_Final_EN.pdf

ESSENTIAL COMPONENTS OF GFIMS

The needs and aims that comprise the global framework include:

- the need to bring all VPD surveillance and programme monitoring together into a broad, unified framework that links with, and builds upon, the strengths and successes of polio surveillance and other surveillance systems already in existence;
- the aims to be reached and activities to be planned to realize the GFIMS vision for VPD surveillance and programme monitoring by 2010;
- recognition of the central role of VPD surveillance and programme monitoring in assuring successful control and/or elimination of VPDs.

FACTORS CONTRIBUTING TO CHANGES IN THE SURVEILLANCE AND PROGRAMME MONITORING LANDSCAPE FOR VPDs

The surveillance and programme monitoring landscape for VPDs is undergoing rapid changes that highlight the need: a) to formulate a new common vision among immunization partners, and b) to give direction to VPD surveillance and immunization programme monitoring. These changes have been shaped by a number of factors, including:

- increased emphasis on achieving high routine immunization coverage (one of the four Strategic Areas of GIVS)²;
- the availability of new vaccines and financing options for introduction of new vaccines;
- the need to sustain surveillance and programme monitoring to support the ongoing goal of polio eradication;
- new global goals, such as the GIVS goal to reduce measles mortality by 90% by 2010 (compared with 2000)³;
- new international health regulations that require countries to establish and maintain surveillance capacity to detect and provide notification of diseases of global health importance; and
- the threat of emerging or pandemic diseases.

Goals and objectives

The global framework has goals and objectives at the global, regional, national and service delivery levels, as outlined below.

01 To link epidemiological and laboratory surveillance (where technically and logistically appropriate):

- a) for all VPDs, including diphtheria, influenza, measles, mumps, pertussis, polio, rubella and congenital rubella syndrome (CRS); and
- b) for diseases such as Japanese encephalitis (JE), meningococcal meningitis and yellow fever in specific regions.

² Protecting more people in a changing world, Strategic Area I. In *GIVS – Global Immunization Vision and Strategy 2006–2015*. Geneva, World Health Organization, 2005 (WHO/IVB/05.05), pages 29–38.

³ *GIVS – Global Immunization Vision and Strategy 2006–2015*. Geneva, World Health Organization, 2005 (WHO/IVB/05.05), page 26.

02 To provide programmatic data to monitor ongoing immunization coverage trends and other measures of programme performance; to use these data to maintain coverage achievements and reach additional children — especially the hard-to-reach and minority or disadvantaged populations — through routine and outreach services.

03 To provide a surveillance and monitoring network to facilitate the completion of polio eradication and certification, to support the achievement of the regional measles elimination and measles mortality reduction goals, and to document the elimination of neonatal tetanus.

04 To build surveillance capacity at country level for disease burden estimates and impact monitoring in preparation for new or recently introduced vaccines (such as *haemophilus influenzae* type b [Hib], JE, meningococcal conjugate, pneumococcal conjugate and rotavirus), as well as monitoring of VPDs that are initially clinically silent, such as hepatitis B and human papillomavirus.

05 To expand and link existing laboratory networks for viral and bacterial diseases, including the polio and measles laboratory networks and other regional and local networks (e.g. the Paediatric Bacterial Meningitis Network and sentinel surveillance networks for pneumococcal and rotavirus disease), to include other priority VPDs (see also No. 1 above).

06 To link with other infectious disease surveillance and programme monitoring systems by providing a common platform at country level on an «as needed» basis for early detection and response to non vaccine-preventable emerging infections and disease outbreaks.

07 To link with other initiatives to develop global surveillance for seasonal, avian and pandemic influenza to ensure the appropriate and timely use of vaccines in the context of emerging or threatening epidemics (see also No. 1 above).

Reaching the goals

The following outcomes are anticipated if the global framework succeeds in reaching the above goals.

01 By using surveillance and monitoring data to inform and direct public health action, the unacceptably high global disease burden due to VPDs⁴ will be further reduced.

02 A more compelling case can be made for a more equitable distribution of currently available or new vaccines, already widely used in the industrialized world, to occur in disease-endemic developing countries.

03 By linking the extensive global VPD surveillance network with the associated vaccine-delivery infrastructure of national immunization programmes, epidemics of global health

⁴ It is currently estimated that approximately 2.5 million children under five years of age die every year as a result of VPDs.

importance — such as seasonal and pandemic influenza, epidemic meningitis, and other infectious disease threats — will be detected and rapid response will follow.

Failing to reach the goals

The risks, if the goals of the global framework fail to be reached by 2010, are outlined below.

01 There will be insufficient data on which to make accurate estimates of the VPD burden; the effects of VPDs would thus be underestimated.

02 Financial and human resources would be used inefficiently.

03 There would be an inability to fine-tune programme direction; this would force programme managers to attempt to direct their programmes without requisite data.

04 Vaccine impact would be poorly measured; this would result in an excessive reliance on modelling.

05 Opportunities to build national and regional surveillance and monitoring capacity (e.g. bacterial disease surveillance networks) would be lost.

06 VPD outbreaks would not be detected adequately so preventable cases and deaths could occur.

07 Capacity to detect new and emerging agents would be deficient.

Health staff in every district should have the capacity not only to monitor programme and routine immunization coverage, conduct disease-specific surveillance and implement outbreak detection and response, but also to use the information acquired thereby in taking decisions and implementing action.

This document emphasizes the role that immunization plays in strengthening health systems through the overall benefits that accrue by building human resource capacity, improving logistics and securing financial resources.

The global framework focuses on **two key areas** that require ongoing support and expansion:

GFIMS Strategic Area A:

Surveillance of vaccine-preventable diseases

GFIMS Strategic Area B:

Immunization programme monitoring.

In each of these **areas**, the document cites the related GIVS strategies and activities (inset boxes) and describes the main components of a functioning system and its basic requirements. The key surveillance and programme monitoring activities are outlined in each section as «**aims**». These activities must all be included and budgeted for in national comprehensive multi-year plans for immunization (cMYPs), annual plans of action, and proposals made to funding organizations and partners.

PURPOSE OF THE DOCUMENT

All public health intervention programmes require constant monitoring and feedback on performance to enable programme managers to monitor the quality of programme performance and direct or modify their interventions to meet the changing environment. Furthermore, decisions on the inclusion of a new public health intervention – such as the introduction of a new vaccine – require critical information on the disease burden and epidemiology, as well as the expected cost-effectiveness and impact of the intervention itself. In immunization programmes, performance monitoring is dependent on two key items of information: a) vaccination coverage – that is, the number of doses of vaccine delivered to the target group; and b) disease surveillance data – that is, data on reduction of the disease burden targeted by the vaccines.

In the final section of the GIVS document, *The Way Forward*, the need for accompanying documents to GIVS to be developed was expressed:

Several frameworks and instruments will be needed to translate the vision and strategies laid out in this document into national or institutional policy, planning, implementation, monitoring and evaluation. These will include ... [a global plan for reliably monitoring the goals of the global strategy through](#)

an approach that builds sustainable monitoring capacity within the country, particularly at the district level; such a plan would outline a strategic approach for strengthening coverage monitoring, surveillance, and laboratory capacity for vaccine-preventable diseases by building on existing systems within countries and, at the same time, emphasizing high performance and accuracy.⁵

This document, describing the Global Framework for Immunization Monitoring and Surveillance (GFIMS), is a response to that need. With its global perspective, the global framework is a rallying point for Member States and immunization partners and donors. It has two [target audiences](#):

- country-level programme and surveillance decision-makers and planners, and
- organizations that fund immunization programmes.

For the decision-makers and planners, the global framework will ensure that the level of surveillance reached in global polio eradication efforts and programme acceleration is not only built on, but further adapted and integrated for other VPDs, epidemic-prone disease surveillance and programme monitoring.

For the funding organizations, the global framework will supply comprehensive and high quality monitoring data on programme perform-

⁵ GIVS – *Global Immunization Vision and Strategy 2006–2015*. Geneva, World Health Organization, 2005 (WHO/IVB/05.05), page 64.

ance; these organizations need this information to measure the impact of vaccine use on the VPD burden and thus justify their public health investments.

The objectives of this document are outlined below.

01 To define a broad vision for VPD surveillance and immunization programme monitoring for 2010 by:

- a) describing the current status, including the achievements and limitations of surveillance and the need to bring all VPD surveillance together in a broad, unified framework that links with – and builds on – the strengths and successes of polio surveillance and other surveillance systems already in existence;
- b) defining: i) the need for countries to have accurate data on which to base rational, data-driven decisions on their vaccination programmes, and ii) the need for programme acceleration and introduction of new vaccines;
- c) outlining standard components and defining key elements that should be in place for adequate surveillance and programme monitoring;
- d) describing the rationale for building and maintaining VPD surveillance and immunization programme monitoring capacity at all levels; and
- e) identifying areas of collaboration and coordination with other public health surveillance and programme monitoring systems.

02 To articulate the aims that should be reached to realize the GFIMS vision for VPD surveillance and programme monitoring by 2010.

03 To act as an advocacy tool by informing partners, donors and Member States of the central role of VPD surveillance and programme monitoring in assuring successful control or elimination of VPDs.

VPD surveillance and immunization programme monitoring have to be viewed in the context of the health system – that is, as a part of overall health system monitoring and surveillance. While recognizing this imperative, this document can only provide a general framework for the larger perspective, based on the extensive experience gained to date with VPDs.

BACKGROUND AND CONTEXT

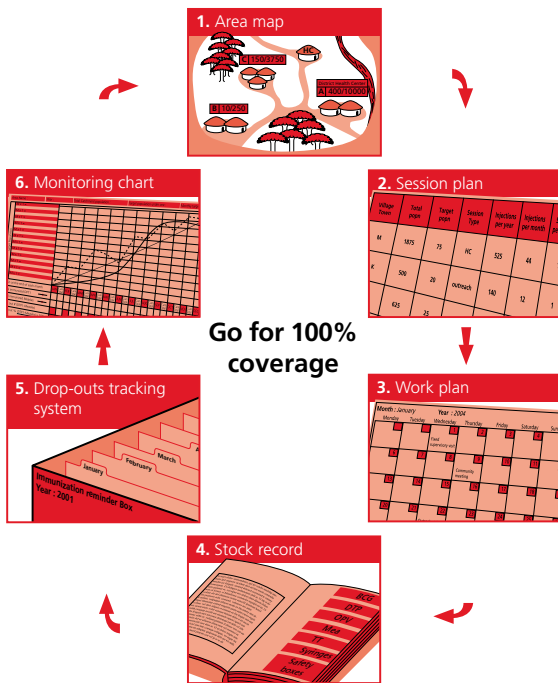
The surveillance landscape for VPDs is changing rapidly due to a number of factors, including those outlined below.

01 Increased emphasis on routine immunization coverage. «Protecting more people in a changing world» is one of the four GIVS Strategic Areas⁶. The GIVS goal for all countries to reach at least 90% national vaccination coverage, with

⁶ GIVS – Global Immunization Vision and Strategy 2006–2015. Geneva, World Health Organization, 2005 (WHO/IVB/05.05) – GIVS Strategic Area I, page 29.

at least 80% vaccination coverage in every district (or equivalent administrative level) by 2010, highlights the need to strengthen routine coverage monitoring at the district level. Along with initiatives such as the Reaching Every District (RED) strategy, the implementation of strategies to reach this goal requires accurate and timely programme monitoring to be in place.

Put these RED tools into action



The Reaching Every District (RED) strategy addresses common obstacles to increasing immunization coverage such as poor quality district planning and inadequate monitoring and supervision of health workers.

Credit: WHO

02 Availability of new vaccines and/or financing options for vaccine introduction. Countries are faced with an unprecedented array of new vaccines to be introduced. These vaccines may be either already licensed or at an advanced stage of development. These factors, together with the financial support from the GAVI Alliance (GAVI)

for new and under-used vaccine introduction, underscore the need for countries to develop surveillance systems that are able to provide disease-burden data. Such data will enable evidence-based decisions on introduction issues to be made and the impact of introduction to be monitored. To introduce new policies for existing vaccines – promoting optimal use and extending coverage to include additional age and risk groups – will require that: a) existing surveillance systems be expanded to include diseases prevented by new vaccines, b) laboratory networks be strengthened, and c) the capacity to monitor the impact of both new and existing vaccines be built up.

03 The ongoing global goal of polio eradication.

Despite the advanced stage of polio eradication, the ongoing high-quality surveillance of acute flaccid paralysis (AFP) and polio laboratories will need to be maintained until global certification is achieved, even in the absence of large numbers of polio cases.



A doctor examines a young boy with leg paralysis in a rural courtyard in Agra, India. After a thorough physical examination, she counsels the parents on physical therapy and arranges for a follow-up visit.

Credit: WHO/R. Kumar

04 New global goals. To help achieve and monitor the new GIVS measles mortality reduction

goal of 90% reduction in measles deaths by 2010 compared with 2000, countries need to strengthen or establish case-based, laboratory-supported measles or febrile rash illness surveillance systems.

05 New international health regulations (IHR).

The new regulations, approved by the World Health Assembly⁷ in 2005 have entered into force in June 2007. These regulations stipulate that a single case of poliomyelitis due to wild type poliovirus, smallpox or human influenza caused by a new subtype must be reported to WHO. Furthermore, if other VPDs, such as yellow fever or meningococcal disease, constitute a public health emergency of international concern (based on an algorithm given in Annex 2 of the *International Health Regulations 2005*⁸), WHO should be notified. The new IHR require that State Parties establish and maintain core capacities for surveillance (at the local, intermediate and national levels) able to detect and provide notification of diseases of global health importance. The IHR on surveillance, Article 5.1, states that:

Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1.

Countries and regions have already started to implement the IHR by assigning national and regional IHR focal points and revising guidelines and plans for assessments of national surveil-

lance systems. As progress is made for national, regional and global surveillance and monitoring systems to meet the IHR requirements, mutually beneficial opportunities emerge for collaboration in the concomitant strengthening of VPD surveillance and monitoring, and the provision of guidance to countries.

06 The threat of emerging or pandemic diseases.

With the increase in threat from diseases, such as severe acute respiratory syndrome (SARS) and pandemic influenza, the ability to call on surveillance officers posted at the grass-roots level will be critical to early-case finding, notification and rapid response.

07 Multiple partners and donors. Given the factors above, partners and donors are increasing their requests for regular programme monitoring and surveillance information on progress in VPD control. Separate channels of external and specified surveillance funding for respective VPDs can create imbalances and funding gaps for cross-cutting functions. A unified vision of VPD surveillance and monitoring – endorsed by partners and donors – would increase efficiency and help identify funding gaps.

These changes in the surveillance and monitoring landscape all highlight the need to formulate a new vision that is common to immunization partners and gives direction to VPD surveillance and immunization programme monitoring. The interplay of different circumstances and trends, furthermore, provides a compelling incentive to take steps towards an integrated surveillance framework.

⁷ World Health Assembly Resolution WHA58.03

⁸ *International Health Regulations 2005* can be found at http://www.who.int/csr/ihr/IHRWHA58_3-en.pdf

Over the past decade, considerable progress has been made in establishing global, regional and national systems for VPD surveillance, including extensive laboratory networks and immunization programme-performance monitoring, such as the WHO/UNICEF Joint Reporting Form (JRF) and regional immunization monitoring systems. These systems have been instrumental in measuring and/or estimating vaccination coverage and the impact of immunization on the global VPD disease burden. They have also provided critical data to: a) guide public health policy, b) assess the impact of strategies, and c) inform immunization programme adjustments and improvements.

The progress achieved has been supported, in large part, by substantial amounts of targeted human and financial resources from the polio eradication and measles-mortality reduction initiatives.

This support has been primarily concentrated at the national and sub-national levels in less developed countries where existing infrastructures are weakest, both in terms of programme monitoring and implementation. The global and regional disease surveillance network has generated crucial information for successfully guiding these VPD-specific initiatives; on a limited basis it has also supported the detection, prevention and control of epidemics of diphtheria, haemorrhagic fevers (Ebola, Marburg), meningitis, rubella, and vector-borne diseases such as dengue and yellow fever. More recently, this network has served as a first line of defence for early detection, response and investigation of outbreaks of avian influenza.

SURVEILLANCE AND PROGRAMME MONITORING GOALS

The goals and objectives for the global, regional, national and service delivery levels are outlined below.

- 01** Link epidemiological and laboratory surveillance where technically and logistically appropriate:
 - a) for all VPDs, including diphtheria, influenza, measles, mumps, pertussis, polio, rubella and CRS; and
 - b) for diseases such as JE, meningococcal meningitis and yellow fever in specific regions.
- 02** Provide programmatic data to monitor ongoing immunization coverage trends and other measures of programme performance; use these data to maintain coverage achievements and reach additional children – especially the hard-to-reach and minority or disadvantaged populations – through routine and outreach services.
- 03** Provide a surveillance and monitoring network to facilitate the completion of polio eradication and certification, to support the achievement of the regional measles elimination and measles mortality reduction goals, and to document the elimination of neonatal tetanus.
- 04** Build surveillance capacity at country level for disease-burden estimates and impact monitoring in preparation for new or recently introduced vaccines (such as Hib, JE, meningococcal conjugate, pneumococcal conjugate and rotavirus), as well as monitoring of VPDs that are initially clinically silent, such as hepatitis B and human papillomavirus.

05 Expand and link existing laboratory networks for viral and bacterial diseases, including the polio and measles laboratory networks and other regional and local networks (e.g. the Paediatric Bacterial Meningitis Network and sentinel surveillance networks for pneumococcal and rotavirus disease), to include other priority VPDs (see also No. 1 above).

06 Link with other infectious disease surveillance and programme monitoring systems by providing a common platform at country level on an «as needed» basis for early detection and response to non-vaccine preventable emerging infections and disease outbreaks.

07 Link with other initiatives to develop global surveillance for seasonal, avian and pandemic influenza to ensure the appropriate and timely use of vaccines in the context of emerging or threatening epidemics (see also No. 1 above).

Reaching the goals

The following outcomes are anticipated if the global framework succeeds in reaching the above goals.

01 By using surveillance and monitoring data to inform and direct public health action, the unacceptably high global disease burden due to VPDs⁹ will be further reduced.

02 A more compelling case can be made for a more equitable distribution of currently available or new vaccines, already widely used in the

industrialized world, to occur in disease-endemic developing countries.

03 By linking the extensive global VPD surveillance network with associated vaccine delivery infrastructure of national immunization programmes, epidemics of global health importance – such as seasonal and pandemic influenza, epidemic meningitis, and other infectious disease threats – will be detected and rapid response will follow.

Failing to reach the goals

The risks if the global framework fails to reach the above goals by 2010 are outlined below.

01 There will be insufficient data on which to make accurate estimates of the VPD burden; the effects of VPDs would thus be underestimated.

02 Financial and human resources would be used inefficiently.

03 There would be an inability to fine-tune programme direction; this could force programme managers to attempt to direct their programmes without the requisite data.

04 Vaccine impact would be poorly measured; this could result in an excessive reliance on modelling.

05 Opportunities to build national and regional surveillance and monitoring capacity (e.g. bacterial disease surveillance networks) would be lost.

⁹ It is currently estimated that approximately 2.5 million children under five years of age die every year as a result of VPDs.

06 VPD outbreaks would not be detected adequately so preventable cases and deaths could occur.

07 Capacity to detect new and emerging agents would be deficient.

GUIDING PRINCIPLES

Guiding principle 1: Integrating programme monitoring and VPD surveillance in the health systems context

Disease surveillance and programme monitoring are an integral component of the health system and, as such, are affected by the barriers and challenges to the health system as a whole. The health system's ability to deliver a service such as immunization is often constrained by a number of barriers that are encountered throughout the health system. Moreover, disease surveillance and programme monitoring themselves affect the health system and, when they do not function well, can have a sector-wide detrimental impact. A key component of endeavours to improve monitoring and surveillance is to eliminate or alleviate these barriers.

Fundamental system-wide barriers which directly affect the quality of disease surveillance and programme monitoring include:

- inadequate physical structures, equipment and supplies;
- deficient information collection and transmission systems;
- severe human resource shortages;
- a lack of political and/or financial commitment;
- inadequate quality assurance and accreditation mechanisms for laboratories.

While disease surveillance and programme monitoring benefit from an effective health system, they can contribute to the strengthening of the system by alleviating information obstacles within it.

One of the key system-wide barriers is the severe shortage of human resources due to the lack of motivated, trained, supervised and adequately paid health staff. Effective planning, use and management of human resources in VPD surveillance and programme management can contribute to the health system as a whole. This can be achieved by investing in capacity-building for the human resources at district and health facility levels, by capitalizing on investments already made in polio eradication, and through a sector-wide approach that links and collaborates with other public health interventions.



Long-lasting insecticidal nets provide protection against malaria.

Credit: WHO/S. Hollyman

Integrating programme monitoring and VPD surveillance in the health system context aligns with GIVS Strategic Area III – to integrate immunization, other linked health interventions and surveillance in the health systems context. Strategic Area III emphasizes the role of immunization in strengthening health systems through the benefits that accrue to the whole system as a result of building human resource capacity, improving logistics and securing

financial resources. This health system based approach delivers national immunization programmes with a great potential to contribute to the achievement of Millennium Development Goal Four (MDG 4).

Guiding principle 2: Capacity-building at district and health facility levels

As mentioned under Guiding principle 1 above, investing in human resources through capacity-building can significantly contribute to the alleviation of one of the key system-wide barriers. This investment should be made at all levels though it is most critical at the district and health facility levels. This is because, in most countries, the health workers at the district and health facility levels are the first contact with the community – it is they who deliver services, provide health information and obtain feedback from the community.

Every district should therefore have the capacity to conduct programme and routine coverage monitoring, disease-specific surveillance, and detect and respond to outbreaks. The importance of capacity-building at the local level is underscored in the 2005 IHR where the capacity to detect, report and immediately implement preliminary control measures at the local community and health facility levels is defined as one of the core capacity requirements.

National programmes will be more effective if peripheral operating units (district teams and health facilities) are able to use information for action and decision-making to improve coverage and monitor impact and programme management.

Effective training, supervision and motivational strategies for management of human resources are therefore critical at the district and health facility levels.



A maternal and neonatal lot quality assurance (LQA) training session in West Bengal, India
Credit: WHO/J.Vandelaer

GIVS Strategy 12: Improve management of human resources

- Inventory human resource needs and determine how existing trained immunization personnel can best contribute their skills and experience to new immunization and health systems goals, and engage nongovernmental organizations and the private sector in the delivery of immunization.
- Plan for and provide sufficient, adequately paid and trained human resources and match human and financial resources to actual programme needs.
- Through improved and secure living and working conditions, training and incentives (including career advancement, improved salaries and family support), motivate health workers in inaccessible or insecure areas to reach all eligible populations.
- Ensure that supportive supervision to these health workers is resourced, prioritized, reliably conducted and monitored.

Guiding principle 3: Assuring quality data

Although surveillance is a means to monitor a disease control programme, the surveillance system itself should also be monitored and evaluated over time, as should other cross-

cutting health system issues. Monitoring of the surveillance system involves regular reviews of its processes and objectives to ensure that they meet surveillance needs and that these needs are clearly defined and appropriate.

It is also important to regularly collect system monitoring information on selected indicators in the following five key areas that incorporate the core functions of surveillance:

- detection and notification capacity,
- data systems and communications,
- event-based investigation, verification and risk analysis,
- laboratory proficiency and accreditation, and
- managerial/supportive activities (e.g. timeliness and completeness).

The data quality audit (DQA) developed with GAVI support to further assess the quality of data within the routine programme reporting system has been expanded by WHO into a data quality self-assessment (DQS) methodology. The DQS allows countries to diagnose constraints within their reporting systems and identify appropriate remedial steps.

Guiding principle 4: Linkage with other surveillance and monitoring systems

Several surveillance and monitoring functions – detection, analysis, data management, analysis and reporting – are common to all health programmes. Linkage with other systems to strengthen surveillance and monitoring makes sense since it can reduce duplication, time and cost while increasing the efficient use of the often limited human and financial resources and physical structures. Linkage should neither compromise the quality of VPD surveillance nor over-burden existing health systems. By con-

trast, linkage should be appropriate and efficient and provide «added value» to achieve mutual benefit.

GIVS Strategy 13: Assess and develop appropriate interventions for integration

- At the global level, develop standardized methods for monitoring and evaluating the efficiency, effectiveness and impact of combined interventions, and adapt them for use at the district and service delivery level.

GIVS Strategy 14: Maximize the synergy from integrating interventions

- Monitor and evaluate the incremental efficiency, effectiveness and impact of combined interventions and their means of delivery; apply these findings in order to continuously improve the combined intervention, increase the range of joint interventions, and contribute to long-term financial sustainability.

GIVS Strategy 15: Sustain the benefits of integrated interventions

- Establish joint financing, monitoring and evaluation functions.
- Pool the resources needed to cover operational and other costs.
- Advocate for further synergy and explore additional linkages

Linkage with other VPD surveillance and monitoring efforts

The different components of VPD surveillance should be consolidated and integrated at all levels under a broad, unified framework; this should include integration with existing surveillance systems. Linkage that builds on the financial, human and infrastructural investments already made for polio eradication is the most obvious step to take. In many countries – particularly low-income and least-developed countries where disease-surveillance systems are not fully developed – AFP surveillance systems

have been expanded to report on other VPDs including measles, neonatal tetanus and yellow fever. An example of this is the integrated disease surveillance (IDS) in Africa. As discussed below, (under GFIMS Strategic Area A, Status) the polio laboratory network at country, regional and global levels served as the backbone in the establishment of measles/rubella laboratory capacity. Both the polio and measles laboratory networks can be further expanded to include laboratory investigation of other VPDs. The data management and communication components of the polio and measles surveillance systems can also serve as the foundation for a more inclusive surveillance system. An example of linking surveillance networks would be to link JE with polio and measles/rubella. Surveillance of acute encephalitis syndrome for JE has strong parallels with AFP surveillance for polio; the measles/rubella laboratory network can be capitalized on to provide serological confirmatory testing for suspected JE cases. Linking the three surveillance programmes presents an opportunity to increase efficiency.

Linkage with non-VPD specific surveillance and monitoring

VPD surveillance and monitoring should be linked to priority health programmes, including those dealing with diseases with medium-term and long-term prospects for prevention with new or improved vaccines (medium-term prospects related to malaria; long-term prospects to human immunodeficiency virus [HIV] and tuberculosis [TB]). Linkage provides enormous opportunities to reach at least three MDGs on time – i.e. MDGs 4 and 5 related to reduction of child and maternal deaths and MDG 6 on reduction of the HIV, TB and malaria burdens. Linkage can improve surveillance and monitoring programmes by improving: a) the management

of surveillance information for new vaccines, and b) outbreak detection and response.

Coordination and collaboration with those involved in pandemic preparedness at the global level is essential to harmonize activities and prevent the duplication of effort.

All five RED components – re-establishing outreach services, linking with communities, supervision, use of data for action and district resource planning – involve the use of surveillance and monitoring data. Collaboration with other programmes in the implementation of data-related components of an integrated RED strategy – that includes malaria and child survival interventions – has the potential to impact on child mortality and the achievement of MDG child-survival goals.

GIVS Strategy 24: Include vaccines in global epidemic preparedness plans and measures

- Maintain an effective surveillance system linked to the Global Alert and Response Network enabling the appropriate and timely use of vaccines in the context of emerging or threatening epidemics, and share information globally.

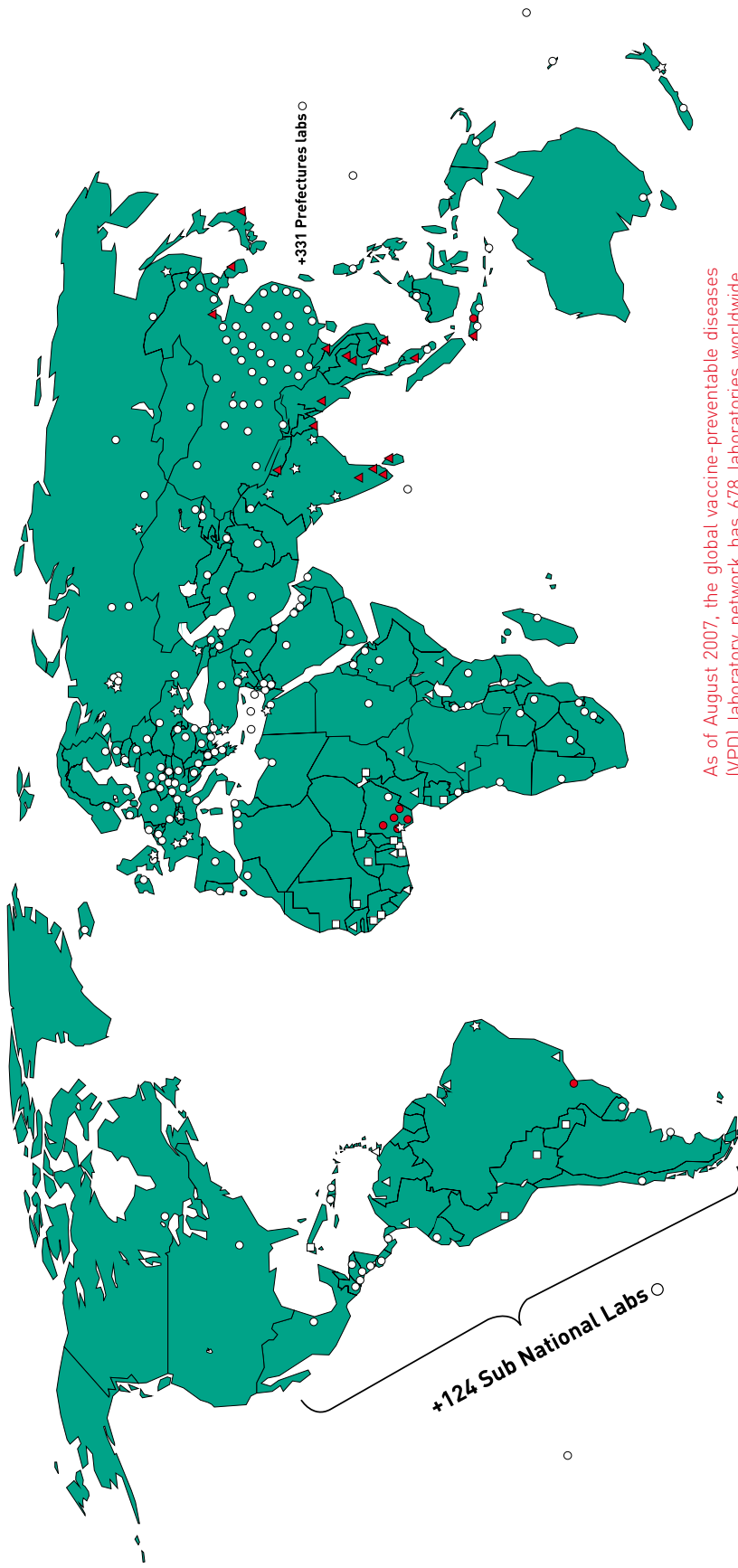
Outreach sessions and linkage with communities are two RED strategy components with a high potential impact. In many countries, outreach sessions provide 40–60% of the childhood immunizations. Outreach sessions reach populations with the lowest level of health services and should include scheduled visits to deliver public-health interventions such as insecticide-treated nets (ITNs) and intermittent preventive treatment in infants (IPTi) for malaria, and vitamin A supplementation and antihelminthics for child survival. In addition, outreach sessions provide an excellent opportunity to col-

Global vaccine-preventable diseases laboratory network

WHO Labs/Institutes testing for:

- ☆ Polio only (22)
- Measles/rubella only (543)
- Polio and measles/rubella (109)

- Measles/rubella and yellow fever (14)
- △ Polio, measles/rubella and yellow fever (13)
- ▲ Polio and/or measles/rubella and JE



As of August 2007, the global vaccine-preventable diseases (VPD) laboratory network has 678 laboratories worldwide. This network has the capacity for the diagnostic testing of polio, measles, yellow fever, rubella, and Japanese encephalitis. In addition, a number of these VPD laboratories have used the breadth of their diagnostic capacity to identify unknown viruses, including the virus causing SARS.

The designation employed and the presentation of material on this map do not imply the expression of any opinion whatsoever on the part of the secretariat of the World Health Organization concerning the legal status of any country.

lect and examine community information about populations that have the highest-mortality and lowest-coverage rates for EPI and other child survival practices and interventions. The RED component – linking with communities – provides an opportunity to discuss data interpretation based on community data collected during outreach and fixed sessions.

Immunization programmes should interface and collaborate with the Health Metrics



Mobile vaccination teams visit parks, bus and railway stations, as well as river and sea terminals to vaccination street children and other high-risk populations who may not attend school or do not have access to community vaccination sites. Credit: American Red Cross

Network (HMN), a major WHO framework for strengthening surveillance and health information systems at the country level and, when appropriate, with academic centres of excellence. The latter can be a valuable resource not only for training and strengthening capacity but also for providing data that is useful in understanding the epidemiology and burden of a local disease.

GIVS Strategy 19: Provide access to immunization services in complex humanitarian emergencies

- Include vaccine-preventable diseases in integrated surveillance and monitoring systems established in response to complex emergencies.

Linkage with the private-sector health care

In countries with a significant proportion of private-sector health care and immunization services, linkage with the private sector to obtain coverage data, for example, is critical. In most countries, the private sector health providers play an important role in VPD case detection. This sector of the health care services has to be engaged in comprehensive disease surveillance for the full extent of the disease burden to be perceived. The means have to be found for private clinicians and other health care providers to: a) provide regular updates on VPD surveillance and programme monitoring, and b) report appropriately and regularly to the public health programme.

Guiding principle 5: Assuring financial sustainability

GIVS Strategy 21: Ensure adequate and sustainable financing of national immunization systems

- Strengthen national capacity for financial planning both within the immunization programme itself and the ministry of health as a whole.
- Coordinate immunization financing through the Interagency Coordinating Committees to ensure adequate and appropriate donor support to national governments.

Solid and sustainable financing is required to ensure continuous availability of all data needed to achieve current and future immunization goals of disease surveillance and programme monitoring.

Substantial financial support for immunization programme monitoring and VPD surveillance should be, primarily, the responsibility of nation-

al governments who should be urged to provide this support in a sustainable way. External support – provided through well-coordinated and efficient investments in monitoring and surveillance systems – is needed mainly in the lowest income countries. In some cases external support is required to jump-start surveillance activities. An important issue is to find a suitable balance between the allocation of resources for building management information systems that include surveillance and monitoring at national and district levels, and resources for systems that preferentially benefit global and research perspectives, e.g. high-cost surveys and «high-science» sentinel sites/studies.

The international partners currently supporting vaccination programmes globally should provide guidance to countries on the inclusion of VPD surveillance as a standard component of their multi-year plans, budgets, proposals, and GAVI applications. The objectives are: a) to ensure that surveillance for new vaccines is initiated as a standard practice before the vaccine is introduced, b) to provide baseline information on disease burden, and c) to continue surveillance to evaluate impact following vaccine introduction.

Maintaining, improving and expanding global surveillance and monitoring capacity for VPDs and the immunization programme will only be possible with continued international commitment to ensure the necessary financial support for expanding human resources and laboratory capacity, as required. The comparatively small investment in surveillance and monitoring systems is an important prerequisite to ensure that the main interventions – routine and supplementary vaccination activities – have the desired impact, are well-guided and efficiently implemented. Global polio eradication has shown that

it is possible to build an efficient global surveillance system in resource-poor countries at relatively minimal cost compared to the cost of the intervention itself. Global VPD surveillance and monitoring efforts, particularly in low-income developing countries, have increasingly been strained by expectations and demands to expand existing systems to incorporate surveillance for the introduction of new vaccines. Existing VPD surveillance systems are also expected to serve as a platform for detection and response to emerging infectious disease threats, such as avian influenza. However, these additional expectations have not as yet been backed up by additional resources.

OUTLINE OF STRATEGIC AREAS

The global framework has two key strategic areas that require ongoing support and expansion.

GFIMS Strategic Area A:

Surveillance of vaccine-preventable diseases

GFIMS Strategic Area B:

Immunization programme monitoring

For each of these areas, this document cites the relevant GIVS strategies and activities and describes the main components and basic requirements for a functioning system. The « aims » listed in each section are key surveillance and monitoring activities and should be included and budgeted for in national comprehensive cMYPs, in annual plans of action and in proposals made to funding organizations and partners.

CONTEXT AND BACKGROUND

It is critical to have an effective disease surveillance system for programme planning, priority setting, resource mobilization and allocation. Disease surveillance has many purposes, including:

- establishing the VPD burden;
- monitoring progress towards disease eradication, elimination and/or control goals;
- assuring rapid detection and response to disease events of public health concern;
- documenting short-term and long-term effects of vaccination on disease burden and epidemiology, thereby monitoring programme effectiveness;
- detecting shifts in types or sub-types of organisms causing disease.

In most cases, VPD surveillance systems already exist for diseases targeted by the traditional EPI vaccines¹⁰. However, these systems need to be maintained, improved, and expanded to meet the increased demand for accurate disease-burden data and vaccine impact data. In areas where VPD surveillance is globally inadequate – for example, in the surveillance of bacterially invasive disease – the systems have to be not only globally conceptualized with input from regions and Member States, but also created, funded and expanded; this may take several years.

A key component of surveillance is to monitor impact of immunization on disease incidence.

GIVS Strategy 16: Strengthen monitoring of coverage and case-based surveillance

- Expand the existing surveillance systems (such as polio and measles surveillance) in order to progress towards effective case-based surveillance for vaccine preventable diseases, i.e., both existing vaccine preventable diseases and diseases for which vaccines are anticipated.

GIVS Strategy 17: Strengthen laboratory capacity through the creation of laboratory networks

- Expand the existing laboratory networks (including the polio and measles laboratory network and other regional and local networks such as the Paediatric Bacterial Meningitis Network and the networks established by GAVI's Accelerated Development and Introduction Plans for pneumococcal and rotavirus vaccines) to include other priority diseases.
- Assure the training, equipment, reagents and quality control procedures needed to sustain high quality diagnostics for all vaccine-preventable diseases and other priority diseases.
- At the global level, develop new diagnostic tests, tools and procedures to improve both field-based and laboratory confirmation of diagnoses.

GIVS Strategy 18: Strengthen the management, analysis, interpretation, use and exchange of data at all levels

- Regularly review district indicators of performance, including risk status for vaccine-preventable diseases and use surveillance and monitoring data to advocate for improved access to, and quality of, immunization.
- Monitor the quality and performance of coverage monitoring and surveillance systems through surveys, monitoring of performance indicators, data quality assessments, disease modelling and supportive supervision.

¹⁰ BCG, DTP, measles and polio vaccines.

For this, reliable epidemiological data (e.g. case-fatality ratios, incidence rates and seroprevalence data) are needed. The specific data requirements are, however, dependent on the nature of the disease and the modelling approach used.

Developing models and processes to estimate disease burden and monitor the impact of immunization on disease burden is a useful exercise in itself as the process requires the establishment of disease-reduction goals that need to be monitored. Furthermore, the global and regional burden of disease estimation is a key decision-making component for WHO in making recommendations on vaccine introduction and in preparing investment cases to facilitate donor decisions in support of vaccine introduction in eligible countries. Although modelling provides critical information, it is important that sensitive surveillance systems be developed to ensure that the immunization strategy accomplishes the objectives for which it has been designed – that is, that it has an impact on disease burden.

GIVS Strategy 8: Strengthen country capacity to determine and set policies and priorities for new vaccines and technologies

- Strengthen country capacity to assess disease burden and the cost and cost-effectiveness of new vaccines and technologies through the use of standard tools.

Linkage with other surveillance and monitoring systems is highlighted as a guiding principle (see above, *Guiding principle 4*). Building on systems that already exist assures an increase in efficiency and effectiveness, with better coordination and information-sharing.

The laboratory, a critical component of VPD surveillance, is needed to provide accurate and

timely data for decision-making and action. Participating laboratories – preferably public health laboratories rather than laboratories in academic institutions – have a defined role in VPD control and prevention; they have strong links to ministries of health, immunization programmes and WHO. Efficient quality-assurance programmes are key factors in assuring sensitive laboratory-based surveillance, participation and compliance with annual WHO accreditation processes and proficiency testing. Network laboratory staff must be trained to use globally standardized tests and procedures. Network laboratories must be underpinned by global expert-reference laboratories that provide the ultimate expert technical knowledge. The goal for most diseases is for every country to have a proficient national laboratory that can process both virological and bacterial specimens. Small countries, where this may not be possible, should have access to such a service.



Accredited laboratories of assured quality are critical for the confirmation and molecular characterization of vaccine-preventable diseases.
Credit: WHO

Most vaccines likely to be introduced within the developing world in the coming five years will provide protection against diseases that have an appropriate surveillance system, based at a laboratory sentinel site, to detect specific pathogens associated with different clinical syn-

dromes. Sentinel sites provide decision-makers with evidence/disease burden information that: a) supports decisions on vaccine introduction against these diseases, and b) serves as a basis for monitoring the impact of these vaccines. Ideally, two to three years' worth of baseline data are required to mitigate season-to-season and year-to-year variability in disease incidence. Appropriate sentinel-disease surveillance should therefore precede vaccine introduction by two to three years.

GIVS Strategy 9: Ensure effective and sustainable introduction of new vaccines and technologies

- Expand surveillance of diseases that can be prevented by new vaccines, and strengthen laboratory capacity to monitor the impact of these new vaccines on disease patterns and programme operations.

It is critical to develop standardized information and notification systems that collect data at the local level and report to higher levels. Quality indicators for the surveillance and monitoring systems, organized by district, help keep the focus on strengthening national and district systems and enable real-time monitoring. EPI has been extremely successful in developing such systems; other programmes could benefit from EPI's experience by building on its platforms for data collection and feedback (such as bulletins at several levels). Other programmes – malaria and child survival in particular – should consider collaborating with EPI to institute an annual information mechanism similar to the EPI Joint Reporting Form.

Monitoring immunization safety is an essential component of programme monitoring, both to assess and ensure safety of vaccine delivery and to ensure the quality and safety of the vaccines used. Immunization safety can be partly ad-

dressed through monitoring of immunization injection supplies, vaccine storage and preparation practices, as well as through surveillance of adverse events following immunization (AEFI). AEFI surveillance ensures timely action to address real and perceived vaccine-safety concerns that could otherwise have a potentially negative impact on vaccination coverage. AEFI surveillance also allows for the collection of quantitative data that can be used to assess the role of safety concerns when coverage is below target.

GIVS Strategy 5: Improve vaccine, immunization and injection safety

- Establish surveillance and response to adverse events following immunization, both for existing vaccines and for new vaccines as they are introduced into national schedules.
- Be responsive to potential vaccine safety issues and address these urgently.

STATUS

By virtue of tremendous political and financial commitment over the past 25 years, the polio eradication initiative has made a large investment in strengthening immunization and surveillance systems (both in the infrastructure and at a human level). The existing polio field and laboratory surveillance networks are essential to the accomplishment of eradication and certification; they must be maintained until certification – for the next five years at least or even beyond – in order to meet the surveillance quality standards set out by the polio eradication initiative and the global and regional certification commissions. This period represents an opportunity, not only for polio surveillance to be expanded to include surveillance of other VPDs but also for other accelerated disease-control

efforts to continue to bring their own resources to the joint VPD surveillance network at country level. Polio surveillance activities will require continued external funding during this period. In many countries, particularly the least developed and low-income countries where disease surveillance systems are not fully developed, AFP surveillance systems have already been broadened (e.g. IDS in Africa) to include the reporting of other VPDs, including measles, neonatal tetanus and yellow fever. Case-based surveillance using laboratory confirmation of suspected cases is currently available globally for polio and, to a lesser degree, for measles and rubella (laboratory confirmation is not required for neonatal tetanus). In many countries, the more intensive measles surveillance has uncovered background transmission of rubella, as both measles and rubella fit the same case definition of fever and rash illness; many laboratories also test measles IgM negative samples for rubella. In countries where no rubella vaccination is offered, the number of rubella cases found incidentally in the course of measles surveillance often leads to increased interest in rubella control. Global measles morbidity data is not uniformly well reported; the countries most affected rarely report on measles mortality. An estimation process is therefore used to determine the reduction in mortality. An important caveat to note is that two factors – the inconsistent quality of available data and the estimation process – impute levels of uncertainty to any estimates. These margins of uncertainty should be carefully measured and reported.

Similar to measles, yellow fever surveillance exists in many endemic countries and requires clinical investigation and reporting of each case, as well as collection of a serum sample for yellow fever IgM testing from every suspect

case that meets the standardized case definition. Neonatal tetanus surveillance needs to be strengthened; it requires strong community support that includes the ability to detect and report neonatal mortality in the community at health-facility level.

Global virological VPD laboratory networks, with appropriate capacity at the global, regional, national and sub-national levels, currently provide crucial support to global polio eradication for regional elimination and accelerated control of measles and rubella, and for yellow fever control (in the African Region). The proven track record of the global polio and measles/rubella laboratory networks presents opportunities for continued expansion – for example, building appropriate surveillance capacity to support the wider use of existing vaccines (Hib) and the anticipated introduction of new vaccines such as dengue, human papillomavirus, JE, pneumococcal and meningococcal conjugate vaccines and rotavirus. Specific emphasis should be placed on the expansion of global bacteriological laboratory capacity, especially in light of the surveillance needs of diseases prevented by newer and soon-to-be-introduced bacterial vaccines such as Hib, pneumococcus and meningococcal vaccines, and the need to define the role and potential of other vaccines such as typhoid vaccine in disease-endemic countries. This will also ensure that the serotype composition of the vaccines used – pneumococcus, for example – is best suited to country situations.

In developing countries, prior to the introduction and use of Hib vaccine in the early 2000s, surveillance of invasive bacterial diseases was limited. Due to the lack of disease-burden information from Hib surveillance and difficulties in routinely diagnosing the disease, many coun-

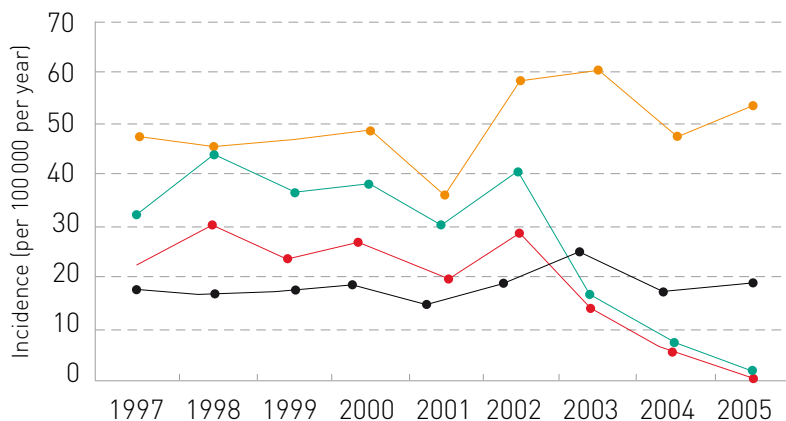
tries did not recognize the importance of Hib as a cause of childhood mortality and disability. As developing countries introduced Hib vaccine into their programmes, the need for ongoing surveillance was recognized. In several regions, sentinel sites were established to document the impact of the vaccination programme by monitoring trends in disease occurrence. In the African Region support for paediatric bacterial meningitis surveillance (PBMS) was provided to one laboratory per country – usually to the laboratory associated with the main teaching or national reference hospital. Cerebrospinal fluid (CSF) samples were investigated for pathogens, specifically Hib, *S. pneumoniae* and *N. meningitidis*. This proved helpful in most countries where data recorded the local presence of these pathogens; it allowed for estimation of the disease burden using simple rapid assessment tools and documented vaccine impact by showing the decline of Hib meningitis cases against the steady rise in case counts of *Streptococcus pneumoniae* meningitis. This surveillance was not population-based and included only re-

ferred patients from across the country; it was, however, useful in identifying disease trends in hospital/referred patients.

For the surveillance of AEFIs, WHO has developed generic guidelines that can be adapted to local resources and systems. Reporting is usually case-based. However, in many settings resources may only permit case-based reporting for pre-defined serious events (i.e. events that are potentially fatal or result in hospitalization, permanent disability or death) or clusters of events, while common and minor events may only be reported in an aggregate format from the peripheral level to the sub-national and national levels. Active surveillance, based on a search for selected medical events or active follow-up of vaccines, is particularly useful for specified events and short duration (e.g. during a mass immunization campaign or for a limited period following introduction of a new vaccine or expansion of an existing vaccine to a new target population). In all cases, surveillance may either be countrywide or limited to sentinel reporting

Sentinel surveillance: Decline of Hib meningitis compared to *Streptococcus pneumoniae* meningitis following introduction of Hib conjugate vaccines, children <5 years, Malawi – 1997-2005

- Hi Blantyre City
- Sp Blaantyre City
- Hi Blantyre rural
- Sp Blantyre rural



Source: College of Medicine & Wellcome Trust Laboratory at the Queen Elizabeth Central Hospital, AMP, MOH/PBM network sentinel site: Blantyre Malawi

sites or geographical regions; the latter may be considered in the early phases of establishing the surveillance system.

AIMS

01 | General surveillance

- Globally establish guidance on surveillance standards for all VPDs (using current and new vaccines), including standardized case definitions, case ascertainment and reporting, data management, and analysis and standard surveillance performance indicators. Each country to carefully adapt the standards to meet national needs in accordance with its disease-control priorities, objectives and strategies.



WHO-recommended standards for surveillance of selected vaccine-preventable diseases

- Develop general guidelines and standards for using mathematical modelling for disease burden and mortality estimation; include clear instructions on how to measure and report on uncertainty in such estimates. Ensure that these guidelines are peer-reviewed.
- Produce and annually update disease burden estimates for VPDs; monitor progress towards the GIVS goal of two-thirds reduction in global childhood morbidity and mortality due to VPDs by year 2015, compared to 2000.
- Make compatible basic disease burden estimation tools available to countries to assist them in taking decisions on introducing new vaccine/s or changes in their vaccination programmes.

- Establish a monthly global feedback bulletin for monitoring progress towards the achievement of global disease control, surveillance and coverage goals.
- Develop guidelines for defining key indicators for all VPD surveillance assessment and monitoring in order to monitor and evaluate the systems themselves.

02 | Disease-specific surveillance

Polio

- Reach and maintain a level of AFP surveillance that is adequate to interrupt wild poliovirus transmission in all Member States.
- Through advocacy with Member States and donor agencies, maintain current levels of AFP and polio field surveillance staff as well as logistics, laboratory and supportive staff during the eradication and post-eradication phases.

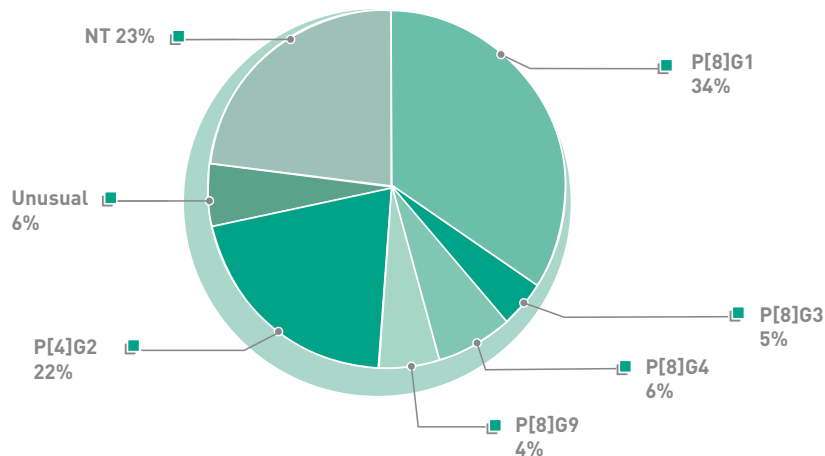
Measles, rubella, neonatal tetanus and CRS

- Aim to establish and maintain a countrywide, active, case-based, laboratory-supported rash and fever surveillance system to deliver data to the set standards in all Member States.
- Initiate mortality surveillance, where possible, to directly measure measles and neonatal tetanus mortality.
- Establish and maintain CRS surveillance to the set standards in regions where a simultaneous rubella elimination goal exists.

03 | Laboratory network

- With the support of partners, establish and maintain regional and global laboratory networks to support the surveillance

Pie chart showing proportions of Rotavirus genotypes circulation in Latin America between 1996 and 2005. Molecular surveillance of rotavirus genotypes is critical for monitoring the impact of rotavirus vaccine introduction in the region.



Laird et al., 2006; Castello et al., 2004; Urbina et al., 2004; Parra et al., 2005; Mascarenhas et al., 2006; Volotão et al., 2006; countries data, 2005-2006.

networks, in order to: a) establish disease burden, and b) monitor the impact of introduction of new vaccines or vaccination strategies, including changes in serotype and/or genotype or molecular epidemiology, and disease epidemiology of targeted pathogens.

- Establish global and regional bacteriological reference laboratories to support and assure the quality of national laboratory networks, evaluate currently available assays and, where appropriate, introduce and evaluate new laboratory technologies such as polymerase chain reaction (PCR) and field-based rapid assays.
- Establish disease-specific global laboratory standards for quality assurance, proficiency testing, accreditation and standard operating procedures to ensure accuracy and validation of laboratory information; include new VPDs.
- Where feasible, link regional/global integrated new vaccine laboratory networks to the regional/global polio and measles/rubella networks, particularly for laboratory support

and supervision, data management and reporting.

- Strengthen laboratory data management and establish mechanisms for communication and coordination to facilitate exchange of information: a) between sites, and b) between sites and local decision-makers.
- Provide global and regional capacity to develop and coordinate the new laboratory networks.

04 | New vaccine and sentinel surveillance

- Strengthen WHO headquarters and regional laboratory and surveillance capacity (skills, human resources and equipment) to support surveillance of diseases prevented by newer vaccines, in order to coordinate the surveillance activities at the global and regional levels and provide technical assistance to countries.
- Establish sentinel surveillance systems, using standardized methodologies to document the baseline disease burden and

monitor the impact of the vaccines, in preparation for the introduction of Hib, pneumococcal, rotavirus, epidemic meningitis and JE vaccines. Each country to have sufficient sentinel surveillance sites to provide at least a measure of the impact of vaccination.

- Expand the scope of the sentinel surveillance sites by including surveillance for additional VPDs as appropriate, including mechanisms for surveillance of new medium-term vaccines.
- Establish guidelines and methods to determine the impact of vaccination against infections so as to generate baseline estimates of disease burden and the impact of vaccination. Focus on diseases such as hepatitis B and human papillomavirus infections that are largely imperceptible or asymptomatic in the acute phase but have long-term consequences on health.

05 | Integrated disease surveillance

- Initiate or improve the quality of notification of VPDs; expand reporting of diseases such as pertussis and diphtheria. Where appropriate use well established AFP reporting systems in both private and public-sector facilities to enhance reporting of other VPDs.
- Where possible, improve the integration of VPD surveillance with surveillance systems that are related to other disease-control programmes such as HIV/AIDS, malaria control or TB.
- Create linkage with global influenza laboratory networks wherever appropriate.

06 | AEFI surveillance

- Establish a network of sentinel countries to monitor safety of newly introduced vaccines and ensure that:
 - a) information about potential adverse events related to new vaccines is collected and analysed in a systematic manner, and
 - b) adequate information on the safety profile of new vaccines is available post-licensure to support the vaccination policy and recommendations.
- Strengthen global AEFI monitoring through collaboration with the WHO Collaborating Centre for International Drug Monitoring (the Uppsala Monitoring Centre) to enhance the management of vaccine safety data and ultimately to ensure timely detection and analysis of vaccine safety signals.



CONTEXT AND BACKGROUND

In immunization programme monitoring, data on the process and outcome of the intervention itself is collected and analysed to provide valuable quantitative and qualitative information on programme performance. In most countries, monitoring of the overall health system includes immunization programme monitoring, often as part of a larger compilation of data from the service delivery level. These data generally include the demographics of people attending the health facilities, the services offered to them, the procedures followed and the medicines/vaccines provided. In some countries, other child-health interventions are recorded simultaneously with the vaccination tallies; this provides valuable information. The monitoring data are generally compiled and transmitted to higher levels once a week or once a month. In addition, annual summary reports provide feedback on the availability, capacity, training and status of staff, and include annual summary figures of disease occurrences, procedures and visits. Within an immunization programme, the five components generally outlined in the planning process are service delivery, surveillance, vaccine management and logistics, advocacy and communication and, finally, programme management. Monitoring of each of these components provides the manager with the broad programmatic information he/she requires. The cornerstone of programme monitoring – measuring vaccination coverage and dropout levels – falls within the service-delivery component. The area of vaccine management and logistics monitoring is receiving increasing attention and is described below. In the more difficult areas to monitor – programme management performance, advocacy

and communication – proxy and health-system indicators are generally used; these include staffing levels, budget flows and the quantity of communication material produced. These areas are, however, being increasingly monitored by using programme management indicators (such as timeliness of disbursement of funds to district and service delivery levels or the proportion of districts that have held a quarterly supervisory meeting during the past year), advocacy and communications indicators (such as the existence of immunization communication plans at each level or the presence of community volunteers/mobilizers during immunization sessions), and supervision indicators (such as the proportion of districts with a supervision plan or the proportion of planned supervisory visits that have actually been conducted).

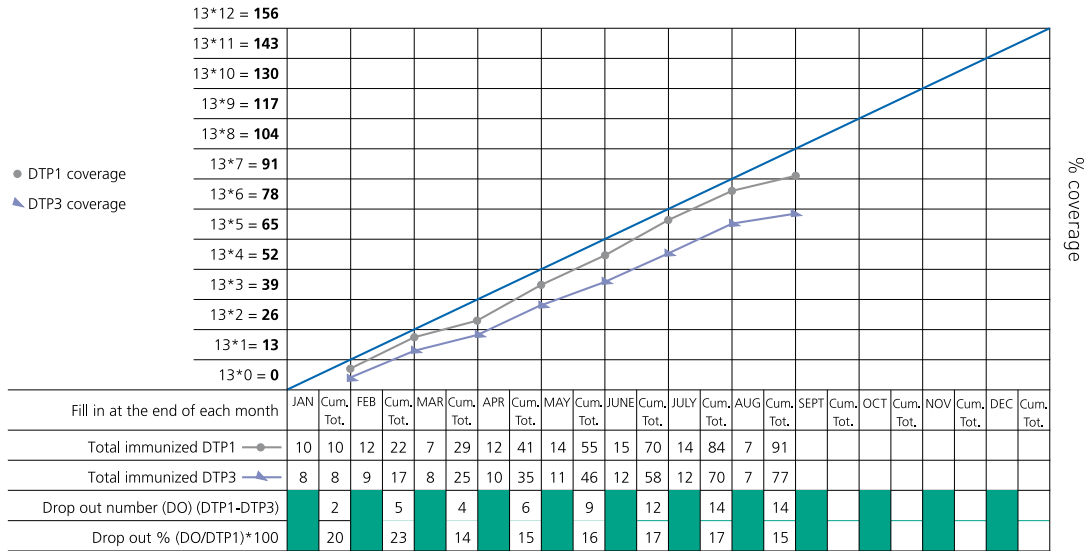
GIVS Strategy 6: Improve and strengthen vaccine-management systems

- Build capacity for effective vaccine management through training, supervision and the development of information systems in order to ensure the safety and potency of vaccines up to the point of use.
- Conduct accurate demand forecasting at national and district levels to ensure the uninterrupted supply of assured quality vaccines, auto-disable syringes and safety boxes, and new types of equipment as they become available. Forecasting should be reviewed regularly to respond to changing delivery strategies.

GIVS Strategy 18: Strengthen the management, analysis, interpretation, use and exchange of data at all levels

- Contribute to the development of better tools (e.g. computer software) for monitoring coverage of vaccines and linked interventions, vaccine and logistics management, and disease surveillance, to better support data entry, analysis, feedback, and utilization for programme management.

Example of an immunization monitoring chart



Cum. Tot. = Cumulative total

Source: WHO

ROUTINE COVERAGE

Routine vaccination coverage rates are generally used to describe the proportion of the targeted population that has been vaccinated. This information is valuable at every level of the programme; it provides a rough estimate of the proportion of the population that remains susceptible to the disease targeted by the vaccine.

Further analysis of coverage data allows the programme to develop plans for reaching those who have been missed or who have initiated, but not completed, a vaccination series (i.e. drop-outs). It is not only geographical barriers, but also social, economic, cultural and ethnic barriers and service delivery gaps that can prevent vaccination. In planning human and other resources within the programme, coverage should be considered as a proxy for staff workload. At the health facility level, coverage data may be a powerful motivator to health workers and a valuable tool in feedback to communities.

At district level, coverage can be used to target outreach and fixed facility immunization sessions; immunization coverage assessments can identify programme weaknesses that need to be addressed.

Monitoring vaccination coverage is a critical component of monitoring programme performance. It should be a key function of surveillance staff, together with improving the quality and use of data at peripheral levels and synergy with other programme monitoring. In using service statistics to estimate coverage, it is essential to have reliable and consistent estimates of the catchment populations, based on population-census projections.

Coverage estimates based on service statistics should be periodically validated using results from population-based surveys, such as a demographic health survey (DHS) or the UNICEF multiple indicator cluster survey (MICS) that should be conducted every three years.

A critical component of vaccination programmes is the uninterrupted flow of assured quality vaccines whose potency is maintained up to the point of delivery. Any interruption to this flow of vaccines can result in children being turned away from a vaccination site without having been vaccinated. To ensure that this does not happen, an effective monitoring system must be in place. Monitoring of vaccine management includes the monitoring of: a) central and regional vaccine stores, b) vaccine arrivals and shipments, c) vaccine distribution and use, d) vaccine wastage, and e) temperatures in the cold chain.

Given the expense of establishing and maintaining a number of disease-specific or programme-specific personnel in all parts of all districts, it is logical to collaborate with other public health programmes to promote common monitoring mechanisms. For example, malaria, HIV, TB, Integrated Management of Childhood Illness (IMCI), and EPI programmes could work together to jointly support programme and information aspects related to outreach services and the RED strategy. Linking programme monitoring for joint interventions is one of the guiding principles for achieving effective disease surveillance and programme monitoring. This topic has been addressed above (*see Guiding principle 4*).

Programme reviews are conducted at regular intervals to establish a situational analysis of programme components. Reviews provide (mostly) qualitative information that allows for re-orientation and renewal of the components. Reviews may focus on a specific component of an immunization programme (e.g. AFP surveillance) but are more frequently designed to assess various programme components simul-

taneously. A programme review is commonly accompanied by a pre-review survey (such as a coverage survey) to add a quantitative component, or a desk review of research papers, travel reports, consultant reports and/or an associated assessment, such as a cold-chain inventory, related to the immunization programme.

GIVS Strategy 7: Evaluate and strengthen national immunization programmes

- Conduct regular immunization programme evaluations at local, district and national levels and provide feedback on performance, obstacles and new opportunities to all partners

The general purpose of a programme review is to assess the level of performance and identify constraints and bottlenecks encountered in the provision of immunization services in a country.

A review identifies areas with exemplary practices in immunization and related services. This allows other areas to learn and benefit from such practices. Recommendations can also be made, on the basis of a review, to enhance future performance of immunization services in the sustainable control of VPDs and ensure maximum impact on child survival.

In addition, an EPI review is a valuable tool in increasing the visibility of a programme – both within the country and externally. As such, the advocacy opportunity presented by an EPI review should not be underestimated; it should be included in the planning and implementation of the review. Similarly, further advocacy should be planned around the follow-up visits that may be conducted some time after the review to determine whether or not its recommendations have been implemented.

STATUS

In an effort to strengthen collaboration and minimize the reporting burden, WHO and UNICEF jointly established a standard questionnaire that has been used since 1998 to collect information on an annual basis from Member States. The development of this questionnaire – the Joint Reporting Form (JRF) – was based on a process of consensus between staff from UNICEF, WHO and selected ministries of health. The trends of national immunization coverage are a key component of the JRF and, over the past five years, have established a valuable time-series of national coverage. Initially several countries did not complete the JRF and this caused gaps in the system. In the past two years, however, 99% of the Member States have completed it. Increasingly these data are forming the basis on which to judge a country's performance. In some cases donors such as GAVI rely on these figures to drive their performance-based support.

On the global level, coverage monitoring by vaccine should continue to be included in the annual WHO/UNICEF JRF to maintain official country-reporting cycles. The frequency, however, should be increased to a quarterly cycle, starting with the high-priority countries and focusing on the improvement of data quality. At district, sub-national and national levels, coverage monitoring should be conducted at least monthly; this would allow for rapid

detection and resolution of problems in the delivery or quality of the programme.

Countries that are eligible to receive support from the GAVI Fund¹¹ use JRF coverage data in submitting their applications for support and, also, subsequently in their annual progress reviews. In an attempt to standardize country vaccination data provided from different sources, WHO and UNICEF have formed a group to evaluate available data; on the basis of these data, the group reaches agreement on a «best» estimate of coverage.

This process originally included data points that varied hugely within some countries or, without apparent reason, had wide variations from year to year. Over the past four years, however, since the creation of this group, the data reported through UNICEF and WHO have become much more consistent, both year-by-year and from different sources in the same year.

GIVS Strategy 16: Strengthen monitoring of coverage and case-based surveillance

- Improve coverage monitoring of vaccines and other linked health interventions and the use of information at district and local levels through strengthening human resource capacity, monitoring the quality of data, improved tools for data compilation, feedback and supervision.

¹¹ See http://www.gavialliance.org/Support_to_Country/Who_can_Apply/index.php

The methods that WHO and UNICEF use in reviewing national estimates of coverage for inclusion in the annual «WHO/UNICEF estimates of coverage» are available in the public domain¹², together with an audit trail of how the estimates were derived for each country. Prior to official publication, each country receives its estimates for comment/reaction and has the opportunity to study its data in an annual country-consultation process. This process and its results are reviewed and approved by an independent expert panel.

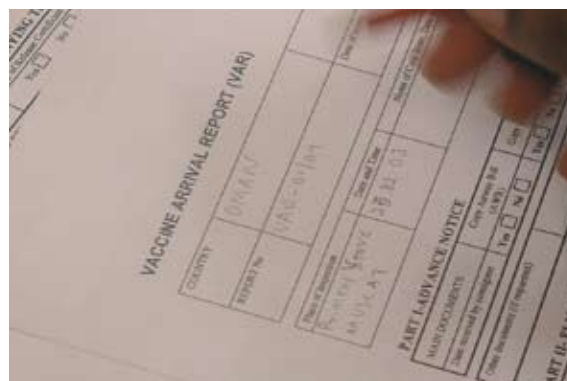
In addition to routine coverage data, the JRF collects data on:

- annual incidence of selected VPDs,
- nationally recommended immunization schedules,
- sources of vaccines,
- immunization coverage,
- immunization-system indicators,
- supplementary immunization activities.

In order to reach the global vaccination goals, it is critical – from a global and a partnership perspective – to increase coverage in several countries with large populations and optimize the contribution of immunization to MDG 4. There is great interest in monitoring progress more frequently and thoroughly in these countries and they are being encouraged to establish or maintain reporting systems that are able to provide data to their national health authorities and inter-

ested parties globally.

With the introduction of stock management and temperature recording systems, vaccine management monitoring has been firmly established at health facility levels. Frequently, however, this information is neither analysed nor transmitted to the next level to obtain a collective view of vaccine stock levels (including stock-outs) and wastage. With the introduction of more expensive vaccines, programme efficiency and reduced vaccine wastage have become even more important and additional emphasis has been placed on these systems. Computer systems are increasingly being placed at provincial and national levels to maintain drug and vaccine information systems and allow for more careful management of delivery and ordering.



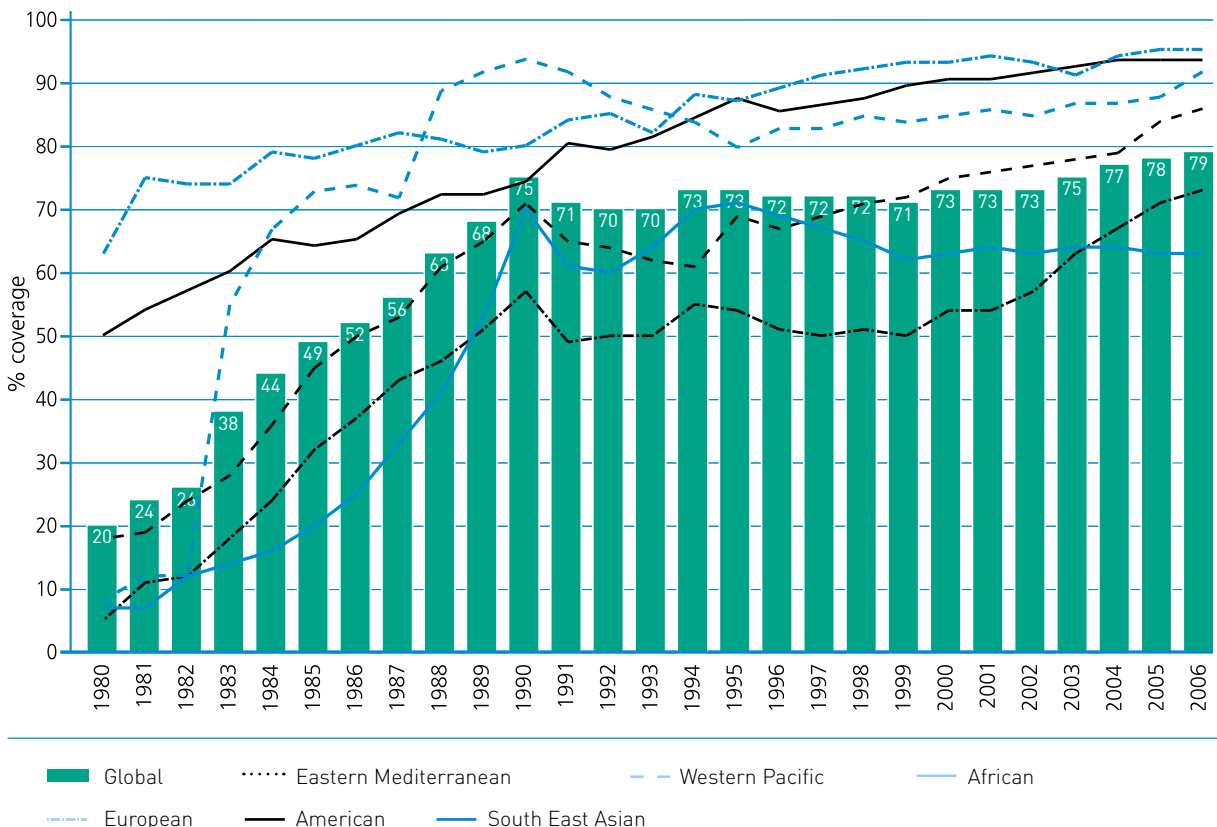
The vaccine arrival report monitors international shipments of vaccines to ensure that shipping guidelines are followed and that vaccine quality is maintained by encouraging increased ownership of the procurement process by all the parties involved.
Credit: WHO/U. Kartoglu

¹² See <http://www.who.int/vaccines-documents/GlobalSummary/GlobalSummary.pdf>

Immunization visits are more commonly being seen as «healthy child» contacts and several additional interventions and preventive measures are being implemented at the same time. Similarly, outreach programmes no longer provide a single intervention – immunization only – but include additional services to the children attending. Monitoring systems increasingly capture data on joint programme interventions in a unified recording system. For example, a tally sheet for vaccine doses administered may also provide space to record the provision of a dose of vitamin A or replies to questions such as whether or not the child slept under a mosquito net the previous night.

One of the purposes of jointly monitoring multiple health interventions is to determine if these interventions support each other and work in synergy. While merging interventions can be expected to improve efficiency, it is important to follow the quality indicators of the surveillance/monitoring system in tracking the «value for money» and effectiveness of integrating initiatives. Programme reviews are currently conducted in the anticipation of revising or creating a multi-year plan or in the face of a specific programme problem. Sometimes a detailed desk review of the status of immunization will suffice as a situational analysis prior to a planning cycle. Most developing-country im-

Global Immunization 1980-2006, DTP3 coverage



Source: WHO/UNICEF estimates, 2006. 193 WHO Member States. Data as of February 2007.

munization programmes conduct a comprehensive programme review regularly — approximately every five years.

AIMS

01 | Coverage monitoring

- Regularly – at least once a month – all countries to monitor coverage and vaccination indicators (e.g. drop-out rates) at national and local levels to monitor programme performance and direct corrective action as necessary.
- Strengthen the use of data through regular training and supportive supervision to ensure that health staff have the ability to monitor and interpret basic trends at every level where data are collected, collated or analysed.
- Countries to maintain standardized tools (e.g. tally sheets and registers) to record and transmit programmatic data, data items and reporting frequencies in each country; put systems in place to transmit data from one level to the next.
- Countries to report annually on the progress made in their immunization programmes — using the WHO/UNICEF JRF – based on the administrative collection of data and any coverage surveys conducted.
- As an integral part of the JRF include monitoring the quality of data, based on an agreed set of indicators. Where possible, data reported in the JRF should be the «gold-standard» of coverage reporting and should form the basis of all monitoring of vaccination programmes required by partners and funders. In countries

where differences between reported and estimated data exist, put activities in place to ensure their convergence.

- Review the data items of the WHO/UNICEF JRF every two years with a view to:
 - a) streamlining them in regard to the data needs at all levels, and b) minimizing the burden on the countries.
- Periodically conduct a high quality, nationally representative household survey to provide estimates of coverage. Validate estimates based on service statistics against the coverage estimates.

02 | Vaccine management

- Within the existing cascading system of reporting from service delivery level to national level, countries should institute a system for monitoring stock – at least at national and provincial/sub-national stores. This should allow for the monthly reporting of stock levels and stock-outs of vaccines, syringes and safety boxes, regulation of vaccine distribution and peripheral wastage monitoring.
- The national vaccine store manager should complete vaccine arrival forms and send them back to the shipping agent. These data should be nationally collated and reported to the national EPI manager and the interagency coordinating committees (ICCs). Where feasible, implement a monitoring system through the national regulatory authority (NRA) mechanism to determine the quality of vaccines on arrival in the country.
- Conduct effective vaccine store management assessments at least every five years or when a major change in the programme is being planned (such as the

introduction of a new vaccine).

- Maintain an inventory of the cold-chain equipment used in the immunization programme, outlining type and age of equipment, operating temperatures, power source and storage capacity.

03 | Joint interventions

- Monitor public health interventions that are jointly planned and implemented; use indicators that measure: a) each component separately, and b) the synergy of their joint implementation.

04 | Programme reviews

- To be effective, design and implement programme reviews internally, within a country; only use external support (including consultants) to support a process owned and managed by the country.
- Conduct reviews of specific components of the immunization programme (e.g. a cold-chain review) either when specific questions need to be addressed or specific areas of need have been identified. However, where possible, make a comprehensive assessment of the programme, taking into consideration the interplay between all its components rather than looking at each component in isolation.
- Based on EPI reviews, provide recommendations that are specific and actionable and put in place an agreed process to follow up on their implementation. Ideally, incorporate the recommendations within the cMYP updates.



Regular programme reviews are important for monitoring the level of performance and identifying constraints and bottlenecks encountered in the provision of immunization services at country level
Credit: WHO/R. Eggers

To achieve the VPD control objectives it is critical to ensure funding for disease surveillance. Moreover, investing in disease surveillance makes the public health system more effective and efficient – surveillance can, for example, lead to detection of a local epidemic early enough for control to be both more effective and less costly in terms of dollars expended and lives claimed. Apart from the health sector, epidemics can be costly because of their impact on several aspects of the economy, particularly productivity and international trade and tourism. To contain a disease, borders – intra-national or international – are ineffective. Investment in surveillance and public health is, therefore, a wise move – not only for the country in which the epidemic may be occurring, but also for the countries to which it might spread. Beyond its role in controlling devastating epidemics, surveillance is important in controlling and preventing endemic diseases that reduce productivity and can be costly to manage.

Effective programme monitoring can make the public health system more efficient and result in cost savings. Monitoring vaccine wastage, for example, can identify problem areas and reduce wastage. Allocating resources for programme monitoring ensures efficient use of the available resources and leads to significant cost savings either for the countries or for the donors that purchase their vaccines. Timely and reliable coverage monitoring can identify areas or populations that are highly susceptible to diseases such as measles. The occurrence of an outbreak and potential spread of such diseases can thus be prevented by vaccinating those identified. It should be noted that the proportion of resources needed to ensure adequate surveillance and programme monitoring is minimal in comparison to programme costs. In the polio

programme, for example, the total operational cost of its global laboratory network (including the 75% covered by national resources) is approximately 2% of its external costs.

Funding for VPD surveillance is declining and there is no coordinated strategy to mobilize resources for surveillance of the classic and new VPDs. Current funding is generally disease specific – each VPD has a separate channel of external and specified surveillance funding. This can create imbalances; it neither provides for more unspecified funding to fill gaps at the local level nor does it strengthen the cross-cutting functions of VPD surveillance. There are limited resources that allow for funding of cross-cutting and support functions of VPD surveillance. Possible resources from GAVI are, at present, limited to the countries eligible for GAVI support; this often leaves needy middle-income countries without external support.

AIMS

Funding for disease surveillance and programme monitoring

- Establish advocacy and partnering networks with donor agencies to raise funds for surveillance and monitoring.
- Establish alternative and sustainable funding sources (external funding in some countries) with immunization partners and funders to build on AFP surveillance to ensure that, by 2010, funds from non-polio sources cover at least 50% of the VPD surveillance system costs coming through WHO.
- Ensure that countries not only include funding for the relevant activities in their

national multi-year plans of action but also specify funding for all critical activities, including the establishment and/or maintenance of adequate bacteriological laboratory facilities.

- Co-finance provincial supervision and RED with other programmes (such as malaria, child survival or HIV) that have a need to implement RED-type public health sub-systems (outreach, supervision, district planning, data for action, contact with the community) to achieve high coverage in all districts.

The GFIMS, as described in this document, was prepared in consultation with immunization partners and endorsed by the Strategic Advisory Group of Experts (SAGE) in November 2006. Subsequent to publication, it will be widely distributed and procedures for further discussion will be initiated. Copies will be sent to WHO country offices and ministries of health to assure its availability at the national level, as well as to interested parties among global and regional partners.

An important and urgent next step is to develop a budget to cover human and financial resource needs to implement the goals and objectives of the global framework, at the country, regional and global levels. Discussion of the global framework should be included in EPI meeting agendas, particularly at regional and inter-country levels, as well as at meetings of EPI managers and regional working groups.

To convey the urgency of its message, this document encompasses a limited time-frame. The aims and activities outlined, however, should not be similarly confined but rather implemented and maintained beyond these time limits.

GFIMS AT COUNTRY LEVEL

It is expected that this GFIMS document will provide countries with encouragement and guidance in updating their cMYPs to include key surveillance and monitoring components in their strategic planning. The cMYP process is an opportunity to cost the necessary components of the surveillance and monitoring system. In countries where functioning surveillance and monitoring systems are already in place, this document aims to encourage maintenance and

expansion of these systems and, where possible, increase integration with other disease surveillance and disease-control programme monitoring. In the case of new vaccines or new monitoring systems (e.g. vaccine management monitoring), the steps outlined will provide further direction to the initiation of appropriate system developments.

In national ICC discussions this document should serve as a reference guide to investment in surveillance and monitoring by in-country immunization partners and, mainly, by the ministry of health itself. In planning for additional GAVI support to countries, especially in terms of the recently approved health systems support, countries and ICCs are encouraged to include additional resources for surveillance and immunization programme monitoring in their proposals. These resources should be sufficient to ensure that high quality data are available to decision-makers for results-oriented measurements of immunization programme impact, in terms of both immunization coverage and reduced disease burden.

The use of data at district and service-delivery levels, where direct action can be taken to rectify any programmatic or reporting problems, is the ultimate objective of all monitoring and surveillance. Capacity-building at these levels, to obtain, analyse and act upon relevant data, is the fundamental goal of the global framework. In countries that have not yet taken the following actions, the specific tasks outlined below should be considered to be «next steps» in implementing the global framework.

- In a joint activity between the immunization programme and the epidemiology and data sections, use the GFIMS:

- a) to do in-country assessment of surveillance and monitoring of core capacities, needs and opportunities for integration, as a component of the *IHR 2005* requirements;
- b) to check which areas of programme monitoring and VPD surveillance are functioning well and which are deficient;
- c) to decide which new approaches to monitoring and surveillance can be considered.
- Where needs are identified, ascertain the cost of meeting these needs and take every opportunity to mobilize resources. For GAVI-eligible countries, programme monitoring and surveillance support may be considered under the funding window for Health Systems Strengthening.
- Establish a firm link between the immunization programme, the epidemiology or health information systems and the laboratory support units at all levels within the country. Ideally, these teams should be in continuous contact with each other; alternatively, regular meetings to provide updates should be considered.
- Ensure that immunization programme and VPD surveillance data are regularly reviewed and acted upon within the EPI team. This should be extended to ICC meetings, organizational or agency staff meetings and intercountry EPI managers' meetings.
- Institute regular information and data review meetings at sub-national and district levels, possibly in connection with existing supervisory or training activities.

GFIMS AT THE REGIONAL LEVEL

The WHO regional offices are primarily responsible for the provision of technical assistance in countries to develop and maintain the surveillance and monitoring systems. In cases where regions have taken the lead in developing surveillance systems (e.g. regional rotavirus-surveillance laboratory networks), their experience and know-how should be made available to other regions where those skills and experiences may be lacking.

Secondly, the WHO regional offices play a crucial role in the regular collection and collation of data from countries and thereby affect the improvement of data quality and completeness. Standardized reporting formats and frequencies, together with regional data-checking activities, are a cornerstone of accurate reporting. Where new systems are being developed, or the integration of existing surveillance and monitoring systems are being planned, it is essential that the regional focus for coordination, collation and synthesis of data and country support is sustained and further enhanced.

Finally, the quality assurance and accreditation of national laboratories remain key functions of regional staff.

GFIMS AT THE GLOBAL LEVEL

Further to compiling this document outlining the vision and need for high quality surveillance and monitoring systems, WHO headquarters aims to update and/or develop technical guidelines on each of the areas of work described. It plans

to outline the necessary standards and indicators of surveillance and monitoring and assist in the development of standardized procedures for the reporting and analysis of programme and surveillance data. Global standardization and coordination will be needed, particularly in the area of newly established surveillance and monitoring systems, such as the bacteriological laboratory sentinel sites for Hib and pneumococcal surveillance. WHO will ensure that leadership is provided in the establishment of these systems.

Using this document as an advocacy tool, global level partners are called upon to mobilize resources for VPD surveillance and immunization programme monitoring, including the maintenance of existing, functioning systems, such as AFP surveillance for polio. This will allow potential funding organizations to better understand the complexity and breadth of the systems and be able to contribute to the vision of the global framework.

CONCLUSION

With the SAGE endorsement and wide country and partner buy-in to the global framework, it is anticipated that a foundation will be laid upon which the GFIMS vision can be realized. Having stated the case for VPD surveillance and immunization programme monitoring, further interactions with other surveillance and programme monitoring systems can similarly be sought and effectively implemented.

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