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## **Draft global immunization strategy**

The draft global immunization strategy in its entirety is submitted herewith to the Health Assembly for its consideration.<sup>1</sup>

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<sup>1</sup> See document A58/12 for the Secretariat's report, draft resolution and executive summary.

# **DRAFT GLOBAL IMMUNIZATION VISION AND STRATEGY**

**Strategic Framework for 2006-2015**

# VISION

## A world in 2015 in which:

- immunization is highly valued
- every child, adolescent and adult has equal access to immunization as provided for in their national schedule
- more people are protected against more diseases
- immunization and related interventions are sustained in conditions of diverse social values, changing demographics and economies, and evolving diseases
- immunization is seen as crucial for the wider strengthening of health systems and major element of efforts to attain the Millennium Development Goals
- vaccines are put to best use in improving health and security globally
- solidarity among the global community guarantees equitable access for all people to the vaccines they need.

## Guiding Principles

The following guiding principles have inspired the formulation of the draft global strategy:

**Equity and gender equality.** All people - without distinction of race, religion, political belief, economic or condition - have a right to equal access to the needed vaccines and interventions.

**Ownership, partnership and responsibility.** Goals are commonly agreed and pursued by governments and their partners, joined by international solidarity, which engage in coordinated activities determined by national plans.

**Accountability.** Stakeholders and actors in immunization are publicly accountable for their policies and actions.

**Assured quality and safe products and services.** All products made available meet internationally recognized standards of quality and safety, and services are delivered according to best practices.

**Strong district-based immunization systems.** Interventions and their monitoring at district level ensure local commitment and ownership and the appropriate adaptation of the programme to local needs and circumstances.

**Sustainability through technical and financial capacity building.** Financial and technical self-reliance is a target for national governments and partners working collectively, with continuing incremental infrastructure building.

**Policies and strategies based on evidence and best practices.** The choice of policies, strategies and practice is informed by data from operational research, surveillance, monitoring and evaluation, disease burden and impact assessments, and economic analyses, and by the sharing of lessons and experiences from countries in similar circumstances.

# 1. CONTEXT

## 1.1. Introduction

1.1.1. Immunization is a cost-effective and life-saving intervention which prevents needless suffering through sickness, disability and deaths. It benefits all people – not only through improvements in health and life expectancy but also through its social and economic impact at the global, national and community level. In today's increasingly interdependent world, acting together against vaccine-preventable diseases of public health importance and preparing for the possible emergence of diseases with pandemic potential will contribute significantly to improving global health and security.

1.1.2. Immunization and the other linked health interventions that can be easily implemented with immunization to the benefit of both, will contribute significantly to the achievement of the Millennium Development Goals by improving health, especially among children and women, and contributing to poverty reduction and development efforts.<sup>1</sup> Specific goals that will benefit from widespread immunization include:

- 1.1.2.1. Reduce child mortality by two-thirds between 1990 and 2015 (MDG4), measured inter alia by using as an indicator the proportion of one-year old children immunized against measles;
- 1.1.2.2. Improve maternal health by reducing the maternal mortality ratio by three-quarters between 1990 and 2015 (MDG5); and
- 1.1.2.3. Combat HIV/AIDS, malaria and other diseases (MDG6) by halting and beginning to reverse the incidence of malaria and other major diseases.

1.1.3. The Global Alliance for Vaccines and Immunization (GAVI), together with its fundraising arm The Vaccine Fund (VF), has also set milestones for selective immunization goals. These include:

- 1.1.3.1. By 2010 or sooner, all countries will have routine immunization coverage at 90% nationally with at least 80% coverage in every district;
- 1.1.3.2. By 2007, all countries with adequate delivery systems will have introduced hepatitis B vaccine; and
- 1.1.3.3. By 2005, 50% of the poorest countries with the highest disease burden and adequate delivery systems will have introduced Hib vaccine.

1.1.4. A further immunization goal was set by the Fifty-sixth World Health Assembly in 2003 in response to presentations on the need for global preparedness in the event of an influenza pandemic, urging Member States to increase immunization against influenza among all people at high risk, reaching 75% coverage by 2010. Countries which do not yet have a national influenza vaccination policy should establish one and draw up and implement a national preparedness plan for an influenza pandemic. Preparedness for pandemics should be further strengthened through improved national surveillance and laboratory capacity.

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<sup>1</sup> Immunization is playing an important role in reaching the goals outlined in the UN General Assembly Special Session for Children (2002) by reducing morbidity and mortality among all age groups. This document builds upon those immunization and disease reduction goals, including: ensure full immunization of children under one year of age at 90% nationally, with at least 80% coverage in every district or equivalent administrative unit; the global eradication of polio by 2005; the elimination of maternal and neonatal tetanus as a public health problem by 2005; the reduction of measles mortality by half between 1999 and 2005; and the extension of the benefit of new and improved vaccines and other preventive health interventions to children in all countries as appropriate.

- 1.1.5. This document sets out a unifying vision and strategies for 2006-2015 which is intended to stimulate collective action and to ensure commitment by governments and immunization partners. It establishes a common strategic platform for countries and immunization partners, supports a comprehensive approach to planning and urges a broader approach to immunization programmes. It is a vision that focuses not only on new vaccines and technologies for future introduction, but also on ways of strengthening the current immunization system so that it can maximally deliver currently available vaccines as well as underutilized or new vaccines and other technologies. The vision also focuses on the need to strengthen surveillance and other measurement systems in order to identify high-risk and underserved populations where additional efforts are needed, and to monitor progress. In view of the marked differences between countries' strengths and weaknesses, countries and their partners are encouraged to use this document to reflect on the policies and strategies most suited to their individual needs and circumstances.
- 1.1.6. The document offers a broad strategic framework rather than a detailed strategic plan. Building on the vision and strategic directions proposed and informed by data available nationally and internationally, countries will be invited to examine their options, establish priorities, set objectives and targets, elaborate a national strategic plan, project their resource needs and the availability of resources, and formulate monitoring and evaluation frameworks. Towards this aim, WHO, UNICEF, multilateral and bilateral partners, NGOs and the private sector will further strengthen their coordination in order to collaborate effectively with countries in this endeavour. To support this national planning process, the present the draft global strategy will be underpinned by guidance documents and technical support.

## **1.2. History and impact**

- 1.2.1. The immense scientific achievement of vaccines and immunization, targeting children and women of childbearing age in all countries, represents one of the most successful and cost-effective public health interventions in history. Immunization has eradicated smallpox, substantially reduced morbidity and mortality from diphtheria, pertussis, tetanus and measles, and is on the verge of eradicating polio. Since its inception in 1974, the Expanded Programme on Immunization (EPI) has provided guidance and recommendations to national authorities on how to design, develop, and manage immunization services to efficiently deliver needed immunizations. Meanwhile, during the 1980s, the global push to achieve Universal Childhood Immunization (UCI) resulted in the establishment of national systems of immunization and rapidly rising immunization coverage.
- 1.2.2. Immunization services must be sustainable since over 100 million children are born every year and need to be immunized. Moreover, in an increasingly globalized world, the global community has a clear interest in the widespread use of current vaccines as well as the rapid development of new vaccines against emerging diseases. The establishment of strong national immunization services in many countries over recent years has ensured that today over 70% of the world's targeted population is reached with immunization. As a result, it is estimated that immunization carried out in 2003 alone will prevent more than 2 million deaths from vaccine-preventable diseases and an additional 600 000 hepatitis B-related deaths (from liver cirrhosis and hepatoma) that would otherwise have occurred in adulthood among the children immunized in 2003.

- 1.2.3. Despite these achievements, global commitment to immunization has not been sustained in all countries. In 2003 worldwide, an estimated 27 million infants and 40 million pregnant women remained in need of immunization. In that same year, it is estimated that 28 million children (27% of all births) were born in 32 countries where immunization coverage is less than 70%, including 10 million in countries with coverage under 50%. In 2003, only 28% of developing countries reported that all districts had achieved over 80% coverage among infants with the basic three doses of diphtheria-tetanus-pertussis (DTP) vaccine. Moreover, beyond infancy, children, adolescents and adults do not yet fully benefit from the protection provided through immunization against diseases affecting them. For example, diseases such as measles, rubella and meningitis can cause deafness, hearing loss and other permanent disabilities which can only be prevented by immunization. These disabilities have a direct impact on efforts to meet the MDGs on poverty reduction (MDG1) and primary education (MDG2).

### **1.3. Strength through partnerships**

- 1.3.1. Global partnerships, such as GAVI/VF and the Measles Partnership, have been created in order to attain shared goals. Such partnerships bring together major stakeholders in immunization from the public and private sectors, including the vaccine industry.
- 1.3.2. Initiatives for eradication of poliomyelitis, reducing measles mortality and elimination of maternal and neonatal tetanus have shown that partnerships enable immunization services to be brought to even the most hard-to-reach communities. Through the Global Polio Eradication Initiative, for example, countries have clearly demonstrated the capacity to achieve high vaccination coverage rates and conduct high performance disease surveillance, even in areas affected by political turmoil or other difficult circumstances. However, accessing hard-to-reach populations on a regular basis and those affected by outbreaks and emergency situations requires specially designed strategies.
- 1.3.3. The global polio eradication initiative has not only achieved great progress towards its set goals but has had a wider impact on health service delivery. It has explored new ways to engage communities in health actions benefiting them; succeeded in involving private partners and the commercial sector in immunization efforts; created high quality information systems; systematized logistics and the financial management of field programmes; and stimulated the establishment of surveillance mechanisms supported by laboratory networks. In order to build on the experience of the polio initiative, the most effective way to sustain the gains derived from polio eradication will be to gradually incorporate polio activities into disease prevention, control and surveillance, while using the valuable experience accumulated through this initiative to inform the development of future health policies and programmes.
- 1.3.4. The success of immunization depends on a sustainable and reliable supply of affordable vaccines of assured quality. Globally, 24 suppliers and more than 60 vaccines are on the WHO list of suppliers pre-qualified to supply vaccines on the international market. Although temporary shortages in global supply do occur, resulting in national stockouts, overall the outlook for the vaccine supply market is more positive than it has been for the past decade. The engagement of partnerships involving countries, international organizations and public and private industry partners will go a long way towards resolving this issue.

#### **1.4. New vaccines and technologies**

- 1.4.1. Efforts are under way to develop new vaccines against major infectious diseases (including malaria, HIV/AIDS and tuberculosis). Meanwhile, many other new vaccines and technologies are already licensed or at an advanced stage of development (including rotavirus and pneumococcal vaccines), and other vaccines are readily available but underused. Activities to ensure the safety of immunization are also being implemented (such as the use of auto-disable syringes) and the subject is becoming a top priority for countries.
- 1.4.2. By the end of 2003, 134 out of 165 (81%) developing countries and economies in transition had successfully introduced hepatitis B vaccine into their national immunization schedules and 63 (38%) had introduced Hib vaccine. In low-income countries, these new vaccine introductions were greatly facilitated by support from GAVI/VF.
- 1.4.3. During the period 2006-2015, countries may be faced with an unprecedented array of new vaccines and technologies for introduction. To ensure that countries can make rational, evidence-based decisions about the choice of new vaccines and technologies, current gaps in knowledge (including disease burden, the cost-effectiveness of various strategies, and regulatory issues) will have to be filled.

#### **1.5. Financing**

- 1.5.1. In low-income countries, especially in sub-Saharan Africa, overall health services are desperately under-financed. In some countries, basic health services receive less than US\$ 10 a year per capita — against a requirement of US\$ 30-40 a year per capita. Although immunization financing should be primarily a national public responsibility, many low-income countries rely heavily on international assistance for this. As a result, financing can be volatile and vulnerable to shifts in donor priorities. In response, a number of innovative financing mechanisms have been developed, including the Pan-American Health Organization's Revolving Fund for Vaccine Procurement and the Vaccine Independence Initiative, GAVI/VF, as well as the inclusion of immunization in country Poverty Reduction Strategic Papers (PRSPs) and Sector-Wide Approaches (SWAPs).
- 1.5.2. Immunization is a highly cost-effective and relatively inexpensive health intervention. The overall cost of immunization, however, including the procurement of new vaccines, new vaccine formulations and technologies, is expected to rise sharply in the future. The expansion of vaccination schedules to include new vaccines has greatly increased the amount of resources that need to be mobilized. Although some relief may be obtained over time as the larger amounts of vaccine to be procured leads to greater competition among manufacturers and a reduction in price, experience has shown that it takes several years before increased demand for new vaccines is matched by lower prices. Meanwhile, the rising cost of immunization delivery needs to be added to the cost of vaccines; logistics and labour are becoming more expensive, and the extension of services to populations that are currently not being reached will need additional resources.
- 1.5.3. Securing the financing for the introduction of new vaccines and increasing coverage with existing vaccines will test all countries and their partners. Ways need to be found to maximize the cost-effectiveness of contacts with immunization services (such as spreading the cost of these contacts across relevant health initiatives) and to strengthen national capability to project financial needs and obtain the required resources.

- 1.5.4. Evidence-based policy decisions will have to be taken on the “affordability” of vaccines in relation to the reduction of disease burden. In view of this, it will be critical to reinforce the benefits of vaccines and immunization and to highlight their importance as a highly valued component of primary health care. In both relative and absolute terms, governments and immunization partners may have under-invested in immunization, partly due to expectations that vaccines would always remain no more than a few cents per dose. Over recent years, traditional vaccines, whilst remaining relatively inexpensive, have for a variety of reasons increased in price. New vaccines will be even more expensive, while continuing to provide an excellent public health intervention.
- 1.5.5. It is anticipated that in the near future, additional broad-based funding mechanisms such as the front-loading of immunization support through international financing facilities may enable further expansion of support through GAVI/VF or other channels. Meanwhile, the returns from investments made in different health sector areas will be maximized through the proposed linkage of other disease-targeted interventions with immunization, to the benefit of both.

## **1.6. Contribution to overcoming of system-wide barriers**

- 1.6.1. Increasingly, immunization will help to overcome barriers to equitable health-service delivery and sector-wide development, and will benefit from those efforts. The benefits include better public health and improved efficiency of public health services. Immunization services inevitably experience the constraints that affect the health system as a whole, but they can help significantly in overcoming system-wide barriers through the strengthening of district teams and their capacity to make optimal use of the resources and opportunities available locally. In turn, sector-wide approaches to strengthening cross-cutting areas such as human resources management, financing, logistics, public-private partnerships and information sharing can clearly benefit immunization. For example, immunization relies on a sector-wide approach to obtain a share of national and international funding sources as well as national accounting and financing systems. At the same time, immunization can also contribute experience in fund-raising as well as the capacity to engage local donors. Similarly, while immunization benefits from a sector-wide approach to medium- and long-term planning and financing of logistics, it can contribute considerable experience of managing transportation, health care waste disposal and the cold chain system as well as having an overall structure and systems in place. The inclusion of immunization services as a key component of health system development will greatly enhance efforts to achieve greater integration of services and long-term financial sustainability.

## **1.7. Strong monitoring, surveillance and evaluation capacity**

- 1.7.1. Over the past decade, considerable progress has been made in establishing systems for monitoring and surveillance of coverage rates and trends of vaccination and its impact on vaccine-preventable diseases, and in using those data for guiding public policy, strategies and programmes. Through extensive and growing laboratory networks, for poliomyelitis and measles has not only generated crucial information for guiding the respective eradication and mortality reduction initiatives, but has also supported the prevention and control of epidemics of, for instance, meningitis, diphtheria, rubella and vector-borne diseases such as dengue and yellow fever. In countries vulnerable to such epidemics, the combination of effective national laboratories and regional reference centres where further laboratory investigations can be conducted has proved to be an important and effective



public health tool. These systems have enormous potential to provide a platform for the development of mechanisms to detect both emerging infections and outbreaks of disease. With the expanded use of underutilized vaccines (e.g., Hib, rubella, yellow fever) and the targeting of additional diseases over the coming decade (e.g., rotavirus, pneumococcal disease and meningococcal disease), case-based surveillance for all vaccine-preventable diseases and, more generally, monitoring and evaluation of immunization systems will enhance national and global ability to adapt strategies to evolving needs. Such information will help determine their cost-efficiency and cost-effectiveness, strengthen accountability at all levels and, together with the Global Alert and Response Network for emerging diseases and epidemics, contribute to global health and security.

## **1.8. Links to other interventions**

- 1.8.1. Immunization services are often widely available and potentially can support, and be supported by, additional health interventions. The combined delivery, or integration, of linked health interventions is a more effective way of achieving common health goals. For example, the benefits of combining immunization with two other interventions, namely vitamin A supplementation and the distribution of insecticide-treated bednets for malaria prevention, are increasingly being seen. Integration may also involve combining prevention and care services — offering timely immunization and treatment through a single delivery channel. In some cases, disease-targeted activities have the potential to expand the benefits of immunization contacts. At fixed health facilities, immunization is often combined with other services such as growth monitoring, nutritional advice, information on preventive care, referral of the child for medical conditions, and reproductive and sexual health care for the mother. However, efforts are needed to ensure that these interventions are also integrated into outreach immunization activities.
- 1.8.2. For those who are responsible for national planning, integration means bringing together the management and support functions of different sub-programmes, and ensuring the complementarity between different levels of care (as highlighted in The World Health Report 2005). The integration of immunization services with other health interventions will require an evidence base to guide policies, strategies and investments, as well as a means to evaluate the impact of linked interventions. Access to integrated services needs to be systematized in order to maximize the benefits to mothers and children attending health facilities.

## **1.9. Preparedness for global epidemics and emergencies**

- 1.9.1. Some vaccine-preventable diseases occur periodically in the form of widespread regional epidemics, only to fade away for several years before reoccurring. Examples of these epidemic diseases include meningococcal meningitis, yellow fever and Japanese B encephalitis. Countries at risk of epidemics need preparedness plans that are firmly rooted in their overall immunization plan and services. Similarly, capacity is required at country and global levels to prepare for a rapid and appropriate response to emergencies and natural disasters since that response may involve the rational use of vaccines. In the case of influenza, a global laboratory network monitors the circulating virus strains and all countries need up-to-date preparedness plans for coping with a pandemic. Many national preparedness plans, however, do not exist, are out of date, or lack practicality. Governments, WHO, UNICEF, vaccine manufacturers and research institutes are currently

involved in efforts to support the development of national preparedness plans and to expand capacity for production of influenza vaccine worldwide, including work on the development of a new vaccine against virus strains with pandemic potential.

#### **1.10. Responding to needs: the draft global strategy**

- 1.10.1. Immunization services throughout the world have achieved remarkable progress to date, mainly through a focus on infants and with only a limited number of vaccines available to developing countries. However, over the past two decades coverage levels have stagnated at suboptimal levels in many countries. Globally, out of every four children born each year, one will not receive commonly available vaccines and, as a result, will be exposed to morbidity, disability, stunted growth or premature death that could have been averted by timely immunization.
- 1.10.2. The draft global strategy proposes to sustain immunization to those who are currently reached, extend immunization to those who are currently unreached and to age groups beyond infancy, introduce new vaccines and technologies and link immunization to other health interventions as well as to the development of the overall health system. It places immunization firmly within the context of sector-wide approaches to health, highlighting the way immunization can both benefit from and contribute to health system development and the alleviation of system-wide barriers.
- 1.10.3. This document offers a framework within which national policies, programmes and action plans can be elaborated. The draft global strategy takes on the challenges of increasing access, the target population, and the range of products that will become available. It outlines what needs to be done at global, country and service delivery level, in a way that can be adapted for regional and national strategic plans. It offers the potential to use available budgets more efficiently and to ensure better coordination across all stakeholders towards the reduction of vaccine-preventable diseases, disability and deaths.

## 2. GOALS

2.1.1. Between 2006 and 2015, all those working on immunization and related product development should strive to prevent morbidity and mortality by achieving the following goals and targets:

**2.1.2. By 2010 or earlier:**

- **Increase coverage.** Countries will reach at least 90% national vaccination coverage<sup>2</sup> and at least 80% vaccination coverage in every district or equivalent administrative unit.
- **Reduce measles mortality.** Globally, mortality due to measles will have been reduced by 90% compared to the 2000 level<sup>3</sup>.

**2.1.3. By 2015 or earlier:**

- **Sustain coverage.** The vaccination coverage goal reached in 2010 will have been sustained.
- **Reduce morbidity and mortality.** Global childhood morbidity and mortality due to vaccine-preventable diseases will have been reduced by at least two-thirds<sup>4</sup> compared to 2000 levels.
- **Ensure access to vaccines of assured quality.** Every person eligible for immunization included in national programmes will have been offered vaccination with vaccines of assured quality according to established national schedules.
- **Introduce new vaccines.** Immunization with newly introduced vaccines will have been offered to the entire eligible population within five years of the introduction of these new vaccines in national programmes.
- **Ensure capacity for surveillance and monitoring.** All countries will have developed the capacity at all levels to conduct case-based surveillance of vaccine-preventable diseases, supported by laboratory confirmation where necessary, in order to measure vaccine coverage accurately and use these data appropriately.
- **Strengthen systems.** All national immunization plans will have been formulated as an integral component of sector-wide plans for human resources, financing and logistics.
- **Assure sustainability.** All national immunization plans will have been formulated, costed and implemented so as to ensure that human resources, funding and supplies are adequate.

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<sup>2</sup> Referring to vaccines containing all antigens given to children under one year of age, those containing measles antigen for children up to two years of age, and those given to women of child-bearing age, as provided for in national immunization schedules. In the case of newly introduced vaccines, these should have been introduced in a country's national schedule for at least five years..

<sup>3</sup> This provisional goal has been proposed and will be finalized during 2005.

<sup>4</sup> This goal correlates with Goal 4 of the Millennium Development Goals with its target of reducing the under-five mortality rate by two-thirds between 1990 and 2015. It is expected that the additional reduction in mortality will be achieved through effective case management. Assuming a rapid increase in access to vaccines, including the introduction of new vaccines and the greater use of underused vaccines, it is expected that the two-thirds reduction in mortality due to vaccine-preventable diseases will be mainly achieved through a 70% to 80% reduction in the number of deaths from currently vaccine-preventable diseases (i.e. measles, pertussis, diphtheria, tetanus, illness due to *Haemophilus influenzae* type b infection), once coverage reaches 90% and a 40% to 50% reduction in deaths from diseases that are expected to be prevented by new vaccines in the near future (i.e., against rotavirus and pneumococcal infection). This estimation will be revised over time as better projections are developed and better data become available.

### 3. REALIZING THE VISION

- 3.1. The draft global strategy comprises four main areas with 24 component strategies. The strategic approaches are: protecting more people in a changing world; introducing new vaccines and technologies; integrating immunization, other linked health interventions and surveillance in the health systems' context; and immunizing in the context of global interdependence.
- 3.2. **Strategic area 1: Protecting more people in a changing world** covers the key strategies needed to reach more people with immunization services, especially those who are hard to reach and those who are eligible for newly introduced vaccines.
- 3.3. **Strategic area 2: Introducing new vaccines and technologies** focuses on the need to promote the development of high priority new vaccines and technologies and to enable countries to decide on and proceed with their introduction.
- 3.4. **Strategic area 3: Integrating immunization, other linked health interventions and surveillance in the health systems' context** emphasizes the role of immunization in strengthening health systems through of the benefits that accrue to the whole system as a result of building human resource capacity, improving logistics and securing financial resources. The aim is to link immunization with other potentially life-saving interventions in order to accelerate reduction in child mortality. The component strategies also aim to improve disease surveillance and programme monitoring so as to strengthen not only immunization programmes but the health system as a whole, and to ensure that immunization is included in emergency preparedness plans and activities for complex humanitarian emergencies.
- 3.5. **Strategic area 4: Immunizing in the context of global interdependence** builds on the recognition that equity in access to vaccines and related financing and equal availability of information are in every country's interest. The component strategies in this area aim to increase awareness of, and respond to, the reality that every country is vulnerable to the impact of global issues and events on vaccine supply, financing, collaboration of partners, communication and epidemic preparedness.
- 3.6. Each strategic area is characterized by a brief statement on current knowledge, experience and key challenges. This is followed by an outline of the specific aims, strategies and key actions that may be considered in developing national strategic plans. In this way, the proposed strategies create a framework for national, institutional and local planning and budgeting. In addition, they are intended to provide a framework in which partner support can operate. The focus is on what needs to be done and how this may be achieved, recognizing that the final choice of strategies will be made by individual countries, based on their capacity, priorities and the projected availability of resources.

## **An expanded role**

The draft global immunization vision and strategy:

- provides a vision with broad strategic directions for national policy and programme development, in the context of support to immunization programmes by all partners.
- extends the reach of immunization beyond infancy to other age groups and beyond the existing confines of immunization programme into other settings, while maintaining the priority of vaccination in early childhood;
- encourages a package of interventions to reduce child mortality.
- contributes to global preparedness against the threat of emerging pandemics.
- commits all to unprecedented efforts to reach the "hard-to-reach".
- promotes data-driven ways of solving problems for improving programme effectiveness.
- prepares the ways for the introduction and widespread use of new and underused vaccines and technologies, all of which will require long-term financial planning.
- promotes the development of case-based surveillance for all vaccine-preventable diseases with expansion of laboratory networks for viral and bacterial diseases.

## **4. Strategic area 1: Protecting more people in a changing world**

### **4.1. Challenges**

- 4.1.1. Most of the children currently unreached by immunization live in the least-developed countries, which carry a disproportionate share of the world's disease burden. However, there are unreached populations and immunization system failures in every country. Although immunization services have been strengthened in many countries and succeed in averting many deaths, there is continuing concern at the failure to achieve high immunization coverage in every district. At the global level, and in some regions, immunization coverage (measured by coverage among infants with three doses of DTP) has stagnated since the early 1990s. Although progress has been achieved since then, in 2003 coverage remained below 50% in 12 countries, all of them in Africa. In 2003, over 27 million children worldwide were not immunized during their first year of life and will remain vulnerable to vaccine-preventable diseases unless comprehensive multi-year national and district plans are developed, implemented and monitored. Both national and district level planning will have to prioritize not only underserved populations and areas but also accessible but unreached urban and peri-urban populations, and develop specific strategies to reach them.
- 4.1.2. Valuable lessons have been learned, which can be applied to strengthen immunization services. Experience from disease control activities for polio, measles, neonatal tetanus, yellow fever and epidemic meningitis demonstrates that when appropriate policies, programmes and resources are in place, children and women can be reached with immunization even in the most difficult and remote areas and where routine health services are not readily available.
- 4.1.3. However, in many countries, insufficient and inadequately planned financial resources and poor budgetary and financial management compromise the sustainability and expansion of health and immunization services. Poor management and economic crises have led to funding deficits, resulting in inadequate resources at local levels for supervision, training of staff, and logistical support, as well as the cancellation of outreach services in some areas.
- 4.1.4. In many countries, underserved populations remain unreached due to poor planning, ineffective delivery strategies or weak implementation. All too often, countries lack national and district level immunization workplans; and the district-level management that exists is often overburdened, untrained or weak. Poor management in some countries is evidenced by high dropout rates and by missed opportunities for immunization. Immunization schedules in many countries do not cover age groups beyond infancy. Elsewhere, countries often do not have effective strategies in place to reach these other age groups (e.g., school-aged children, adolescents and adults). As a result, the full potential of available vaccines is not being realized.

- 4.1.5. Countries also need to ensure that they have efficient vaccine management systems and logistics. Vaccine quality must be maintained at every stage of the continuum between manufacture and administration of the vaccine. The storage and transportation of vaccine after arrival in a country are the weak links in the supply and delivery chain. Meanwhile, the availability of heat-stable vaccines, which are often sensitive to freezing, brings new challenges as well as more cost-effective approaches which can reduce dependency on the traditional cold chain.
- 4.1.6. Immunization safety is another critical issue for immunization programmes. As a preventive intervention, immunization is wholly reliant on the acceptance, understanding and trust of those who use the services. Immunization safety (including vaccine quality and safety, injection safety and safe injection waste disposal) is therefore a critical component of the trust placed by clients in immunization services.
- 4.1.7. Meanwhile, the promotion of immunization as a key public health strategy is currently not utilized to its full capacity. As a result, many people remain unaware of the risks of vaccine-preventable diseases and/or the benefits of immunization, and immunization has become increasingly undervalued.

## 4.2. Aims

- 4.2.1. To achieve a minimum of four immunization contacts with all infants, especially among hard-to-reach populations (geographically, socially or culturally), using a district-based approach that provides immunization through fixed sites, outreach services, mobile teams, supplementary immunization and the private sector;
- 4.2.2. To expand immunization beyond infancy to other age groups to maximize the impact of existing vaccines;
- 4.2.3. To use appropriate strategies to reach at-risk populations in order to rapidly reduce disease burden and to prevent and respond to epidemics and outbreaks; and
- 4.2.4. To strengthen vaccine management practices, including logistics, to ensure the availability of safe and effective vaccines at all times.

## 4.3. The component strategies

### **4.3.1. Strategy 1: Use a combination of approaches to reach everybody targeted for immunization**

- 4.3.1.1. Efforts to ensure that everyone is reached with immunization services will require the political and financial commitment of all stakeholders. Immunization can be delivered through routine services and/or supplementary activities. Most countries, industrialized and developing countries alike, use a combination of these approaches in order to respond appropriately to changing disease patterns or to rapidly increase herd immunity through high immunization coverage. A balanced approach which combines routine and

supplementary immunization will avoid any potential diversion of attention and resources. By methodically building on the experience gained from polio eradication activities, maternal and neonatal tetanus elimination and measles control/elimination, and ensuring coordinated and comprehensive planning and resource availability, countries will be able to avoid the fragmentation of immunization activities and ensure sustained high coverage with current and new vaccines.

4.3.1.2. In countries or districts where existing strategies have produced high vaccination coverage and good access to health services, care should be taken to sustain these gains by maintaining the human, financial and programmatic support. In all cases, pursuing the “Reaching Every District” (RED) approach described in Strategy 3, will be a key factor in efforts to maintain the coverage reached.

#### 4.3.1.3. Activities:

- Strengthen national commitment to ongoing immunization services through policy and strategy development that also includes human resources and financial planning with national budget allocations in the context of a wider health sector strategic plan;
- Formulate and implement comprehensive multi-year national strategic plans and annual workplans to deliver reliable services based on data analysis and problem solving. The plans and budgets should cover all areas supporting the national immunization programme including routine vaccination, accelerated disease control activities, introduction of new vaccines, surveillance, laboratory support, financing, logistics, vaccine management, cold chain management, social mobilization and communication;
- Sustain high vaccination coverage, where it has been achieved, by ensuring that adequate support is maintained for existing systems;
- Develop appropriate national strategies to immunize children who were not immunized during infancy; and
- Where and when appropriate, include supplementary immunization activities as an integral part of the national plans to achieve national goals.

### 4.4.1. Strategy 2: Increase community demand for immunization

4.4.1.2. Coverage increases if there is community demand and well-informed confidence in the benefits and safety of immunization and in the need to adhere to a prescribed schedule. The availability of adequate means of communicating these benefits to the public and the existence of responsive and reliable health services delivering an integrated health care package will stimulate the demand needed to drive the programme forward.



#### 4.4.1.3. Activities:

- Engage community members, NGOs and interest groups in immunization advocacy and implementation;
- Assess the existing communication gaps in reaching all communities and develop and implement a communication and social mobilization plan as part of the comprehensive multi-year plan based on these assessments. The plan should include ways of targeting unreached communities, establishing well-informed community demand, and addressing the problem of immunization refusal; and
- Provide regular, reliable, and safe immunization services that match demand.

### 4.5. Strategy 3: Ensure that unreached people are reached in every district at least four times a year

- 4.5.1 Under normal circumstances, it is possible to fully immunize children with at least four contacts with immunization services during their first year of life. However, some children remain unreached for reasons of geographic isolation, lack of information, the social or cultural environments in which they live, or active discrimination to which they are subjected. Therefore, special measures are needed to overcome all these barriers. Reaching unreached urban populations will become an important component of this strategy as urbanization and informal settlements place urban children increasingly at risk of missing out on immunization.

#### **Five operational components needed to Reach Every District (RED):**

- **Re-establishment of regular outreach services**
- **Supportive supervision: on-site training**
- **Community links with service delivery**
- **Monitoring and use of data for action**
- **Better planning and management of human and financial resources.**

- 4.5.2. Strengthened efforts and additional resources may be required to establish or expand outreach services through a combination of short-term and longer-term approaches (e.g. mobile services combined with the creation or revitalization of permanent services). Underserved populations and areas will be prioritized and, through the use of the Reach Every District (RED) approach, efforts will be directed to achieving greater equity in the availability and delivery of immunization services. The design and maintenance of strong outreach services with the capacity for the successful introduction of new policies and interventions are dependent on specific knowledge and skills among immunization providers as well as regular supportive supervision. To meet this need, integrated and regular district-based training, supervision and follow-up, together with the creation and periodic assessment of supervision standards, targets and plans will aim to ensure the timeliness and quality of services. In addition, it is important that financial resources, logistic support and supplies should be regularly available to ensure that district teams are able to fulfill their role.

**4.5.3. Activities:**

- Through micro-planning at the district or local level, map (geographically, socially, culturally) the entire population in order to identify and reach the unreached target populations at least four times a year;
- Reduce the number of immunization drop-outs (incomplete vaccination) through improved management, defaulter tracing, and social mobilization and communication during immunization contacts and avoid missed opportunities to vaccinate;
- Strengthen the managerial skills of national and district immunization providers and managers and develop and update supervisory mechanisms and tools; and
- Provide timely funding, logistic support and supplies for programme implementation in every district.

**4.6 Strategy 4: Expand vaccination beyond the traditional target group**

- 4.6.1. Expanding the benefits of immunization to population groups other than infants and women of childbearing age — for example, to older children for booster doses and to adults for epidemic prevention and control — has the potential to prevent even more morbidity and mortality and to increase global security against impending pandemics. In developing countries today, routine immunization services are only offered to infants and women of childbearing age. As a result, children and women who are not immunized on schedule remain susceptible to vaccine-preventable diseases and may benefit from vaccines only when supplementary vaccination activities are carried out (against measles or polio, for example). However, in the intervening period, those who remain unimmunized may not only acquire but also spread such diseases.
- 4.6.2. In addition, booster doses may be required in order to consolidate immunity against diseases such as diphtheria, tetanus and pertussis, while a second opportunity to receive measles vaccine may imply reaching out routinely to children older than one year. Other vaccines (for example, against influenza) and interventions (for example, vitamin A and iron supplementation) are of direct benefit to children and adults, and in particular to those who for reasons of age, ongoing illness or disability are at greater risk than others of acquiring severe forms of infection.
- 4.6.3. The expansion of immunization services beyond the current age groups is no small task. It requires efforts to gather and analyse the information needed to support policies and investments, as well as the possible reorientation or creation of services targeting these new populations. The benefits of such efforts are two-fold: the reduction of preventable morbidity and mortality in individuals who have been immunized; and the establishment of systems that can be used in the event of emerging epidemics affecting children and adults alike.

#### **4.6.4. Activities:**

- As part of national policy and strategy development, define target populations and age groups for vaccination appropriate to the national situation, making the protection of those outside the infant age group an integral component of immunization services; and
- Apply standard tools to assess the cost-effectiveness of different immunization schedules and strategies in a range of demographic, geographic and epidemiological settings.

### **4.7. Strategy 5: Improve vaccine, immunization and injection safety**

4.7.1. Safe immunization requires safe and potent vaccines, safe injection practices and adequate sharps waste disposal, and rapid action when adverse events occur following immunization. Immunization safety provides a model and sets standards of practice applicable to the wider spectrum of injections performed in the health care setting.

#### **4.7.2. Activities:**

- Procure vaccines only from sources that meet internationally recognized quality standards;
- Ensure long-term forecasting for existing and new vaccines by improving vaccine management skills;
- Achieve national self-reliance in quality assurance and regulatory oversight to meet global standards, and promote and further strengthen existing programmes that support this (in particular, scientific evaluation, capacity building, public education, training and communication);
- Introduce, sustain and monitor safe injection practices, including the use of autodisable (AD) syringes and other safe methods of vaccine administration, and thereby contribute to the enforcement of safe injection practices and health care waste disposal;
- Establish surveillance and response to adverse events following immunization, both for existing vaccines and for new vaccines as they are introduced into national schedules; and
- Be responsive to potential vaccine safety issues and address these urgently.

### **4.8. Strategy 6: Improve and strengthen vaccine management systems**

4.8.1. One of the main challenges that immunization programmes face today is the need to ensure that vaccines are not damaged due to mishandling after their arrival in the country. The transport and storage of vaccines under controlled temperatures is important to ensure

their safety and potency. At the same time, vaccines must reach all those they are intended for, including those living in remote and underserved areas. Poor vaccine stock management at all levels, poor vaccine handling and storage and high wastage contribute to the poor performance observed in immunization programmes. In many countries, the continuing disintegration of cold chain and vaccine distribution mechanisms has prompted efforts to improve vaccine management systems and to strengthen the immunization programme infrastructure.

- 4.8.2. An additional challenge is the need to ensure adequate supplies of vaccine and equipment nationwide without disruption. Inefficient vaccine management systems — including poor stock management, poor quality of vaccine handling and storage and high wastage — contribute substantially to low programme performance. Between 2006 and 2015, cold chain equipment will need to be replaced at least once. Meanwhile, the introduction of new vaccines will require new strategies and additional cold storage capacity.
- 4.8.3. Recent developments such as the improved heat stability of vaccines, increased awareness of the need to prevent freezing, and the availability of vaccine vial monitors (VVMs) on most vaccines supplied through UNICEF have opened the way for innovative approaches in vaccine management which have the potential to reduce dependency on the traditional cold chain.
- 4.8.4. The logistics of immunization also require adequate and well-functioning transportation and communication systems, currently often deployed solely for immunization programmes. This investment should increasingly be considered in the context of an expanded package of linked health interventions, allowing for cost-sharing, joint training and effective management.

#### 4.8.5. Activities:

- Conduct accurate demand forecasting at national and district levels to ensure the uninterrupted supply of assured quality vaccines, AD syringes and safety boxes, and new types of equipment as they become available. Forecasting should be reviewed regularly to respond to changing delivery strategies;
- 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;
- Increase access and coverage through a "safe chain" approach which includes taking vaccines beyond the cold chain, using a VVM-based vaccine management system; and
- Move towards coordinated and sector-wide financing and management for transportation and communications.

## 4.9. Strategy 7: Evaluate and strengthen national immunization programmes

4.9.1. The performance of immunization activities will be guided by disease surveillance, coverage monitoring and management information. These are addressed in Strategic Area Three in view of their strong linkages to system-wide disease and management monitoring processes. In addition, the design, reorientation, further expansion and validation of immunization strategies will be informed by focused immunization programme evaluations and operations research. Information arising from programme reviews and other forms of evaluation will be shared widely in a spirit of transparency and accountability towards all involved.

#### **4.9.2. Activities:**

- Conduct regular immunization programme evaluations at local, district and national levels and provide feedback on performance, obstacles and new opportunities to all partners; and
- Where appropriate, perform operations research and evaluation of “what works” to improve the delivery of immunization and to make systems more effective, efficient and equitable in order to improve immunization coverage.

## **5. Strategic area 2: Introducing new vaccines and technologies**

### **5.1. Challenges**

- 5.1.1. Many major breakthroughs are occurring in the development of new vaccines and technologies. Through the support of the Global Alliance for Vaccines and Immunization (GAVI) and The Vaccine Fund, major progress has been made in making new vaccines available in low-income countries. These advances are revolutionizing the way vaccines are conceptualized, manufactured, presented and administered. It is critical that the setting of research priorities and financial investments take into account the needs of both developed and developing countries and, within these countries, of populations that are the most vulnerable to ill health and premature death.
- 5.1.2. Combination vaccines that include DTP with other antigens (e.g., hepatitis B and Hib) offer opportunities to simplify immunization delivery and are expected to become increasingly available during the next decade. However, the availability of different combination vaccines will pose new challenges for immunization programmes. Difficult choices will have to be made not only between monovalent vaccines and more expensive combination vaccines, but also between the different combination vaccines available.
- 5.1.3. While existing vaccines (such as Hib, yellow fever, influenza, Japanese B encephalitis and rubella vaccines) are readily available but underused, new vaccines against rotavirus, pneumococcus, meningococcus, and human papilloma virus (HPV) are in advanced stages of testing or already being introduced on limited scale. At the same time, new vaccines are being developed against major infectious pathogens such as malaria, HIV/AIDS, pandemic influenza and tuberculosis, as well as against some of the “orphan” infectious diseases, including leishmaniasis and hookworm infestation.
- 5.1.4. In addition, various new immunization-linked methods and products are being developed to increase the ease, safety and efficacy of immunization delivery. It is anticipated that several of these — for example, new formulation methods to increase vaccine stability, devices for the non-injectable administration of vaccines, and rapid biomedical tests to monitor and evaluate the impact of immunization — will be helpful in accomplishing the decade goals. Once tested, these new methods and devices will have to be brought to the market at affordable prices if they are to be used widely in low-income countries.
- 5.1.5. Decisions on the introduction of new or underutilized vaccines and new technologies must be based on country disease burden and priorities and on what is affordable and sustainable within the budgeting and planning context. Countries should be empowered to evaluate their own needs and priorities for new and underutilized vaccine and technologies. Critical issues will include how new vaccines can help immunization systems reach more people and stimulate community, country and partner commitment to sustaining access to these products in the long term at affordable costs. The introduction of new vaccines will also require countries to reassess their immunization schedules, including the need for booster doses, immunization at school entry, and the immunization of adolescents and adults.

- 5.1.6. Partners, according to their mandates, will continue to fulfill their roles towards regulating and assuring the quality and availability of these products through the strengthening of regulatory and delivery systems. For countries where the introduction of new vaccines will be co-financed by external sources, this must involve collaboration between governmental and non-governmental entities, international development and technical agencies, other interest groups, and the private sector. The role of partner coordinating bodies such as the Interagency Coordinating Committees (ICCs) will be critical in efforts to coordinate partner inputs as well as to ensure the long-term operational and financial sustainability of immunization services after the introduction of new products. The early involvement of ministries of finance and of the national political leadership will be necessary to ascertain that the availability of financial resources will match the planned commitments in the long term.
- 5.1.7. Finally, despite the momentum to develop new vaccines and formulations, there are also disincentives to the development of vaccines perceived as low-profit products for developing country markets. As a result, research agendas are often tailored to the needs of wealthier countries instead. To overcome these barriers will require new approaches to stimulate and support research, development and regulatory processes across the world, together with an increased focus on capacity building in developing countries and the development of public and private financing mechanisms that create incentives for technical cooperation, other forms of partnership and fair competition.

## 5.2

### Current and future vaccines and technologies

#### Current vaccines

- DTP and DTP-based combinations \*
- Measles \*
- Polio (OPV and IPV) \*
- BCG \*
- *Haemophilus influenzae* type b \*
- Hepatitis B \*
- Tetanus toxoid\*
- Rubella \*
- Mumps\*
- Yellow Fever \*
- Japanese B encephalitis (inactivated and live) \*\*
- Pneumococcus (polysaccharide and conjugate) \*
- Meningococcus (polysaccharide and conjugate) \*
- Influenza \*
- Hepatitis A \*
- Varicella \*
- Rabies \*\*
- Cholera (inactivated and live) \*\*
- Typhoid \*\*

#### New or improved vaccines anticipated by 2015

- Rotavirus °
- Human papilloma virus °
- Pneumococcus (improved conjugate or protein-based) °
- Japanese B encephalitis (improved) °
- Meningococcus A (multi-serotype conjugate) °
- Measles (aerosol) °
- Polio (inactivated vaccines based on Sabin strains) °
- Polio (monovalent OPV type 1) °°
- Dengue °°
- Group A Streptococcus °°
- RSV °°
- Shigella °°
- ETEC °°
- Typhoid (conjugate) °°
- West Nile Fever °°
- SARS °°
- Malaria °°
- DTaP (with two P antigens) °°
- New combinations of existing

<ul style="list-style-type: none"> <li>• Rift Valley Fever **</li> <li>• Tick borne encephalitis **</li> <li>• Pseudomonas **</li> </ul> <p><i>* Available for immediate use in routine immunization</i></p> <p><i>** Available for specific regions or circumstances</i></p> <p><b>Available but underused immunization supportive technologies:</b></p> <ul style="list-style-type: none"> <li>• Vaccine Vial Monitors (VVMs) on all vaccines</li> <li>• Pre-filled injection devices</li> </ul>	<p>vaccines °°</p> <ul style="list-style-type: none"> <li>• Influenza for pandemic response</li> </ul> <p>° <i>Late stage of development</i></p> <p>°° <i>Licensing expected in 2010-2015</i></p> <p><b>New immunization supportive technologies anticipated by 2015:</b></p> <ul style="list-style-type: none"> <li>• Jet injectors</li> <li>• Vaccine patches</li> <li>• Vaccine nasal sprays</li> <li>• Vaccine aerosols</li> <li>• Thermostable vaccines</li> </ul>
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## 5.3. Aims

- 5.3.1. To empower countries to evaluate the need and establish priorities for introducing newly available vaccines and technologies through strengthening their capacity to make decisions based on disease burden, economic analysis, and the feasibility of introduction;
- 5.3.2. To ensure that countries have an adequate supply of new vaccines and technologies to meet their needs and have access to the corresponding financial resources;
- 5.3.3. To ensure that new vaccines will be offered to the entire eligible population within five years of the introduction of these new vaccines in national programmes; and
- 5.3.4. To ensure that future vaccines of public health importance are researched, developed and made available, particularly for disadvantaged populations with high disease burden.

## 5.4. The component strategies

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

- 5.4.1.1. The possible addition of a new vaccine or new technology to an immunization delivery system requires careful consideration of disease burden in relation to other public health priorities and programmatic feasibility. In addition, mechanisms to ensure the long-term



financial sustainability of the new vaccine or technology need to be in place prior to introduction. The promising development of several new vaccines makes it even more important to help countries determine which of these represents the best opportunity for the investment of limited national resources, in particular which product will be easiest to integrate into immunization systems and has the potential to provide the greatest public health benefit.

#### **5.4.1.2 Activities:**

- Strengthen country capacity to assess disease burden and the cost and cost-effectiveness of new vaccines and technologies through the use of standard tools;
- Characterize the optimal product formulations and schedules to maximize impact and minimize cost and operational difficulties;
- To assist the country decision-making process, build an evidence base of country experience and methodology at the international level for each new vaccine and technology; and
- Ensure that the long-term financial requirements from national governments and supporting partners are fully understood and committed to prior to the introduction of new vaccines.

#### **5.4.2. Strategy 9: Ensure effective and sustainable introduction of new vaccines and technologies**

- 5.4.2.1. Once the decision is made to introduce a new vaccine or technology, the introduction process must be carefully planned and implementation evaluated in order to avoid the risk of overloading and weakening immunization services. Within five years of introducing a new vaccine, countries will aim to reach coverage levels similar to those achieved with other antigens administered simultaneously in the immunization schedule. Key components in the successful introduction of a new vaccine include efforts to increase public awareness and education, both on the new vaccine and the disease prevented, health worker training and the adequate preparation of the logistics and reporting systems. The introduction of new vaccines will require the improvement of surveillance, including the improvement of laboratory facilities. This may require international technical cooperation.

#### **5.4.2.2. Activities:**

- Integrate the introduction of each new vaccine into countries' multi-year sector-wide plans and provide a financial analysis;
- Ensure adequate training of health workers and vaccine managers at all levels and prepare the logistics and reporting systems;
- Produce appropriate information, education and communication (IEC) materials to ensure good understanding of the benefits of new vaccines or technologies, and their acceptance by parents, communities and health workers;
- Ensure that within five years of introduction the coverage of the new vaccine reaches the same level of coverage as for other vaccines given at the same time; and
- 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.

#### **5.4.3. Strategy 10: Promote research and development of vaccines against diseases of public health importance**

- 5.4.3.1. In order to gain the maximum benefits from immunization, efforts are needed to promote the research and development of new vaccines, especially against diseases that cause the highest morbidity and mortality, and to guide the global development agenda for vaccines, technologies and operational research. Countries have a key role to play in defining their priority needs and contributing to the production and analysis of data that will inform and guide the global research agenda. In turn, countries also need to ensure that information generated by research is taken into account in the development of national policies.
- 5.4.3.2. Since the establishment of the WHO/EPI schedule in 1984, many things have changed: polio and measles are on the wane; much more is known about existing vaccines, including the burden of pertussis and, in some countries, diphtheria in older children and adults. Research will be needed to optimize schedules in order to maintain long-term immunity against those infections. New vaccines are being introduced which will target adolescents and young adults, with strategy implications that are not yet clear. As the scope of immunization programmes broadens, there is a need to re-examine the epidemiology of infections for which vaccines exist or will be licensed in the next 5-10 years. The characteristics and performance of those vaccines will require carefully designed and conducted clinical trials and post-licensure evaluations, for which capacity in developing countries remains scarce.

#### 5.4.3.3. Activities:

- Produce local evidence to influence and prioritize public and private investments in new vaccines and technologies;
- Engage local public health authorities and research communities in defining research agendas relevant to countries which bear a disproportionate share of the disease burden;
- Strengthen the capacity of developing countries to undertake the research and development of new vaccines and technologies, including conducting high quality clinical trials and post-licensure evaluation;
- Generate geographically and epidemiologically representative clinical data on vaccine effectiveness and conduct demonstration projects of post-licensure evaluations of the impact of vaccination on child survival;
- Engage the global research and development community, including vaccine manufacturers, in the design and production of new vaccines against infectious diseases of public health importance, especially in developing countries; and
- Research and develop evidence-based policies for immunization schedules and strategies as new vaccines and vaccine presentations (e.g., vaccine aerosols) and technologies are introduced.

## **6. Strategic area 3: Integrating immunization, other linked health interventions and surveillance in the health systems' context**

### **6.1. Challenges**

- 6.1.1. Immunization services operate within the health systems context and are, like all health care interventions, profoundly affected by the barriers and challenges encountered by the health system as a whole. The ability of health systems to deliver services such as immunization is often constrained by lack of political and financial commitment, a severe shortage of human resources, inadequate physical infrastructure and equipment, weak monitoring and information systems, lack of management skills, weak social mobilization and previous experience of unmet demand. However, efforts to strengthen immunization services can also help reduce barriers to the equitable delivery of health services and strengthen the health system as a whole. These efforts should be seen as part of a renewed international effort to scale up health services to meet the health-related MDGs by 2015.
- 6.1.2. In the process of health system development, system-wide barriers can be alleviated in areas such as human or financial resources planning and management, outreach services and community mobilization. Immunization can both contribute to these improvements and benefit from them. System-wide barriers such as political and financial commitment (Strategic Area Four), physical infrastructure and equipment (Strategic Areas One and Three) and social mobilization (Strategic Areas One and Four) are key areas where immunization both relies on the overall benefits which a sector-wide approach can bring and contributes experience and resources in a range of different areas. The critical area of human resources is another. The lack of well motivated, trained, supervised and adequately paid health staff — compounded in many countries by both AIDS deaths and the impact of the brain drain — is a major constraint on both immunization and the health system as a whole. A sector-wide approach is essential to provide a better career structure and work environment for health workers as well as improved pay, welfare and other incentives to ensure increased motivation and better deployment of staff. While benefiting from this, immunization services can also contribute through experience in training and effective supervision, as well as in the management of the delivery of services, including the ability to reach populations even in remote, often impoverished areas. Immunization can also contribute a potential source of trained and experienced health workers from the polio eradication programme — many of them trained in surveillance activities — who will soon become available for other priority disease activities in developing countries.
- 6.1.3. Immunization can also help alleviate system-wide barriers by capitalizing on its well-established access to children and women, through linking immunization with the delivery of other essential health interventions. Effective efforts to use immunization contacts as a

key opportunity for links with other child survival approaches such as Integrated Management of Childhood Illnesses (IMCI) and the delivery essential health interventions such as vitamin A, deworming and bednets would have a rapid impact in reducing child mortality. Immunization is an integral component and often acts as the mainstay of maternal and child health services. Immunization contacts provide a regular opportunity for communities to access additional preventive and curative information, as well as goods and services in support of child health, primary care and reproductive health. For example, vitamin A and other micronutrients, bednets and de-worming treatments have all been successfully distributed both through supplementary and routine polio or measles immunization activities.

- 6.1.4. In addition to the direct health benefits there are other potential advantages in combining targeted health interventions. The expanded provision of locally appropriate, preventive and curative services may result in increased trust by the community in the health system as more of their demands are met. Well planned linkages between interventions may lead to the pooling of human and financial resources and reduce intervention-specific costs if transport and distribution mechanisms are shared. The diversification of these services may also have a positive impact on coverage of both immunization and other interventions delivered at the same time. However, careful planning is needed to ensure well-planned and well-resourced linkages in order to avoid excessive demands on peripheral health personnel and unmet expectations. Linkages between health interventions delivered through fixed health facilities and/or outreach services should be systematically planned and documented and, where successful, scaled up. These developments should occur within the context of a wider strategy for strengthening health systems.
- 6.1.5. Meanwhile, efforts to strengthen surveillance, monitoring and evaluation offer another key opportunity to alleviate system-wide barriers through providing better data to improve health system management. In order to improve the efficiency and effectiveness of surveillance systems at the national level, the management and sharing of data on vaccine-preventable diseases should be part of an integrated surveillance and health information network. The expansion and strengthening of surveillance for vaccine-preventable diseases also provides a critical first line of defence against emerging diseases and diseases of epidemic potential. High performance disease surveillance is needed to detect disease outbreaks, define disease burden, guide policies, strategies and activities, and assess the impact of immunization. Accurate monitoring of immunization coverage is necessary to measure success in delivering vaccines and to determine causes for the continuing incidence of the disease.
- 6.1.6. Finally, in the event of complex humanitarian emergencies due to conflict or natural disasters — when contact with immunization services is often lost — the early re-establishment of immunization services can contribute to the process of re-building damaged health systems. In addition to including immunization in emergency preparedness planning and activities, surveillance for vaccine-preventable diseases should be included in integrated surveillance and monitoring systems established in response to the complex emergency.

## 6.2 Aims

- 6.2.1. Contribute to a sustained enabling environment in the health sector in which every person can be immunized to achieve the disease control goals set by countries, and where immunization services interact with the entire health sector in a way that enhances the performance of both;

- 6.2.2. In joint action with all areas of the health sector, address system-wide barriers such as human resource capacity, logistics and overall financial resources;
- 6.2.3. Explore, plan and implement appropriate linkages between immunization and other interventions tailored to the local context and aim to reach high coverage both for immunization and other child survival activities, and establish joint programme management systems to ensure sustainable linkages; and
- 6.2.4. Strengthen and expand disease surveillance, coverage monitoring and management information systems to support policy and programme decisions and local action.

## 6.3. The component strategies

### 6.3.1. Strategy 11: Strengthen immunization programmes within the context of health systems development

6.3.1.1. Opportunities exist to align immunization programmes structurally and functionally within the health system in ways that are mutually strengthening. Focusing on improving capacity at the district level for human or financial resources planning and management, outreach services and community mobilization provides an entry point for the alleviation of system-wide barriers. Efforts will also be needed to identify policy groups and develop collaborative links between them; to establish common understanding around relevant policy contexts; to reach agreement on compatible aims relating to immunization and health system development; to develop causal links between policy content in immunization and health system development as a basis for evidence-based policy-making; and to strengthen policy-making structures, systems, skills and values.

#### 6.3.1.2. Activities:

- Through regular analysis of district-wide data, document key factors for the success and failure of immunization activities and share these findings with others involved in health systems development;
- Participate actively in collective efforts to shape sector-wide policies and programmes, while preserving the central role of immunization in the context of sector-wide policies and programmes; and
- Use the experience gained in health systems development as an opportunity to position immunization services in a way that ensures the maximum benefit for all people.

### 6.3.2. Strategy 12: Improve management of human resources

- 6.3.2.1. In many countries, the performance of immunization and other health services is hampered by the lack of qualified and experienced staff who are suitably skilled and equipped to reach out to the entire population. The delivery of health services is often undermined by human resource problems such as the inappropriate deployment of staff, inadequate training, low pay and poor supervision. As a result, even with the greatest motivation, health workers may not be able to provide the minimum four contacts per year to the infant population eligible for immunization. Moreover, health staff often have to carry out their duties in conditions of insecurity. Governments have a duty to ensure that appropriate conditions are in place to ensure that health workers are able to perform their work fully, including efforts to minimize the risks to which they are exposed.
- 6.3.2.2. These critical human resource issues need to be addressed not only by immunization programmes but on a system-wide level as well. One potential source of trained and experienced health personnel is the polio eradication programme, which has built up a vast pool of highly committed workers who will gradually become available for other immunization or disease surveillance and control activities as the polio eradication initiative draws to an end. There is a need to tap this wealth of human resources in developing countries. This will require well-performing structures and human resources management so that the contribution of these key health workers can be recognized and they can be redeployed and supported in the long-term. This pool of workers should be considered for gradual integration in immunization and the wider health sector to work on other national priority programmes.

#### 6.3.2.3. Activities:

- 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 NGOs 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; and
- Ensure that supportive supervision to these health workers is resourced, prioritized, reliably conducted and monitored.

### 6.3.3. Strategy 13: Assess and develop appropriate interventions for integration

- 6.3.3.1. Potential linked interventions must be demonstrated to be mutually beneficial, cost-efficient and cost-effective. To meet this need, they should be assessed in terms of their operational and programmatic suitability. In particular, there is a need to consider the

opportunity cost and effort both to the person seeking health care and to the health care provider.

#### **6.3.3.2. Activities:**

- Develop and field-test potential joint interventions according to national and regional priorities to assess their feasibility, safety and potential impact on disease reduction, and document these findings;
- Tailor integrated packages of interventions to local needs and feasibility, and ensure that they are mutually supportive and designed to meet demand; and
- 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.

#### **6.3.4. Strategy 14: Maximize the synergy from integrating interventions**

6.3.4.1. Once potential linked interventions have been identified and evaluated, the joint programme activities should be carefully planned and executed to maximize the benefits. Areas of overlap and duplication should be identified and minimized to the benefit of both interventions, and common activities streamlined. Efforts to link immunization with other essential health interventions will lead to improved efficiency in public health services, broaden the partnership base, and contribute to long-term financial sustainability.

#### **6.3.4.2. Activities:**

- Include joint interventions in multi-year and annual plans, ensuring the acceptance and participation of all stakeholders within the programmes, the district management teams and the community;
- Formulate and implement as part of these plans integrated training plans based on training needs assessments and appropriately developed training materials;
- Implement interventions jointly, choosing from fixed, outreach, mobile, Child Health Day (CHD) and Supplementary Immunization Activity (SIA) approaches. Special emphasis should be placed on outreach and mobile teams in situations where they represent the best means of contact between hard-to-reach populations and health services; and
- 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.



### **6.3.5. Strategy 15: Sustain the benefits of integrated interventions**

6.3.5.1. In the long term, links between priority child survival interventions and approaches, including IMCI, and immunization services will require the ultimate harmonization of policy and programme development and implementation as well as resource allocation.

#### **6.3.5.2. Activities:**

- Bridge different programmes in global agencies and within countries by formalizing a management structure that facilitates coordination and efficiency without disregarding programme-specific needs;
- Establish joint financing, monitoring and evaluation functions;
- Pool the resources needed to cover operational and other costs;
- Remain attentive to community-perceived needs and provide quality information to secure sustained community support; and
- Advocate for further synergy and explore additional linkages.

### **6.3.6. Strategy 16: Strengthen monitoring of coverage and case-based surveillance**

6.3.6.1. Coverage monitoring and case-based surveillance are central to programme management. Lack of data as well as poor quality data and data analysis are well-known system-wide barriers. Both surveillance and coverage monitoring require efforts to build human capacity for field surveillance and for the collection, compilation, analysis, interpretation and use of data. Vaccine coverage and other monitoring systems can be improved through data quality self-assessments, better systems to compile and analyse data, and regular feedback to district and local levels. In addition, the expansion and strengthening of vaccine-preventable disease surveillance can ultimately be used to detect emerging infections and other priority diseases, and contribute to strengthening overall disease surveillance.

6.3.6.2. The introduction of new vaccines and technologies will require the expansion of existing surveillance systems to include diseases prevented by new vaccines and the strengthening of laboratory capacity to monitor the impact of these new vaccines. As resources and laboratory testing capacity increase, surveillance for new vaccines will eventually become case-based surveillance, with laboratory confirmation where appropriate. Surveillance needs to be implemented well in advance of the introduction of any new vaccine, in order to provide information on disease burden, serotype prevalence and vaccine selection, as well as the baseline information needed to judge the effectiveness of the vaccine.

6.3.6.3. Surveillance, monitoring and evaluation are integral components of successful immunization systems, but require a system-wide infrastructure to succeed. This includes

adequate transport, communications, materials, methods and logistics for specimen collection and dispatch, as well as funds for operating expenses for surveillance.

#### **6.3.6.4. Activities:**

- 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;
- 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; and
- At the global level, develop and provide countries with new methodologies to estimate the burden of disease in order to obtain more accurate estimates of disease and to monitor vaccination coverage and programme performance towards achieving national, regional and global goals.

### **6.3.7. Strategy 17: Strengthen laboratory capacity through the creation of laboratory networks**

6.3.7.1. Laboratory capacity and networks will be strengthened in order to ensure their ability to not only confirm cases of vaccine-preventable diseases but also to determine the causes and establish the disease burden of other priority diseases. National laboratories will be an integral component of regional networks. A basic infrastructure and logistics system will be vital and can be expanded for other VPDs by expanding existing laboratory networks and by ensuring adequate transport, communications, materials, methods and logistics for specimen collection and dispatch, and funds for operating expenses and quality control procedures.

#### **6.3.7.2. Activities:**

- 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 (ADIPs) 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; and
- At the global level, develop new diagnostic tests, tools and procedures to improve both field-based and laboratory confirmation of diagnoses.

### **6.3.8. Strategy 18: Strengthen the management, analysis, interpretation, use and exchange of data at all levels**

- 6.3.8.1. The management and sharing of information underpin all surveillance, monitoring, and evaluation components. At the country level, data management for vaccine-preventable diseases should be part of an integrated surveillance and health information framework with the potential to provide information on a range of national priority diseases. Data management will be strengthened through capacity building, training and the use of frequent and regular supervision. Appropriate tools will be developed for local use, which will facilitate standardized and ad hoc data analyses. National immunization programmes should seek linkages with other health programmes (e.g., malaria, IMCI, HIV/AIDS and TB) to improve the national health information system.
- 6.3.8.2. Efforts are under way to improve the efficiency and timeliness of the registration of births and deaths (vital registration) in an effort to ensure that more children are able to benefit from health care, education and other public services to which they are entitled. Immunization services can use these data to monitor coverage and impact as they do in countries where birth registration achieves high coverage. In turn, the increasing demand for immunization may motivate parents to register their child soon after birth.

#### **6.3.8.3. Activities:**

- Contribute to the design of integrated management information systems and improve data management through regular training, monitoring and feedback at the local level;
- 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;
- 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, cleaning, analysis, feedback, and utilization for programme management;
- Monitor the quality and performance of coverage monitoring and surveillance systems through surveys, monitoring of performance indicators, data quality assessments, disease modeling and supportive supervision; and
- Collaborate with civil authorities in advocating for increased registration of births and deaths.

### **6.3.9. Strategy 19: Provide access to immunization services in complex humanitarian emergencies**

6.3.9.1. In complex emergencies such as wars, natural disasters and civil conflict, immunization can play a critical role in preventing disease and deaths in already difficult circumstances, as well as preventing the potential spread of disease to neighbouring populations. This timely intervention can also provide an early signal of humanitarian concern for populations under stress and lays the cornerstone for the rehabilitation or reconstruction of devastated health systems.

6.3.9.2. Since emergencies and disasters are, by their very nature, difficult to predict, adequate contingency plans and appropriate supplies should be maintained at global and regional levels.

#### **6.3.9.3. Activities:**

- Include immunization-related issues in rapid situation assessment of complex emergencies;
- Incorporate immunization services in emergency preparedness plans and activities;
- Re-establish immunization services in populations affected by complex emergencies and link these services to the rehabilitation of health systems;
- Create global capacity to advise on appropriate immunization strategies in complex emergencies and natural disasters; and
- Include VPDs in integrated surveillance and monitoring systems established in response to complex emergencies.

## 7. Strategic area 4: Immunizing in the context of global interdependence

### 7.1. Challenges

- 7.1.1. The interdependence between low-, middle- and high-income countries, between sectors of human development, and across components of immunization programmes, requires a global vision of how resources such as the global supply of vaccines can best be secured and used equitably. Components that have proven to be essential to ensure an adequate global supply of assured quality vaccines include accurate forecasts, financial planning, appropriate contracting, and adequate stock management and distribution systems.
- 7.1.2. A continuing issue of concern is the divergence of vaccine markets, which has occurred mainly due to factors such as cost, differences in disease burden and concerns about possible side-effects. As a result, developing countries today increasingly provide different vaccine antigens or different vaccine formulations than those provided in the industrialized countries. This divergence has profound implications for the grouped procurement systems operated by UNICEF and the Pan American Health Organization (PAHO), which enable national immunization programmes in developing countries to obtain vaccines at reduced prices and to be included in aggregated short- and long-term forecasts to industry which help ensure the availability of vaccines. These schemes will face difficulty in procuring, well in advance of their use, products that are increasingly diversified and costly, when their introduction remains heavily dependent on both reliable forecasting of national needs and efficiency in implementation.
- 7.1.3. As many new and more costly vaccines become available in the future, governments will face hard choices about which vaccines to include in the national immunization schedule. Efforts to determine whether a vaccine is "affordable" or not will depend very much on the perceived value of vaccines, which, even at higher prices, are expected to remain a highly cost-effective intervention. A key challenge over the next 10 years will be to reduce the financial barriers to high population coverage with existing and new vaccines, and to ensure that both governments and partners adopt policies and take actions that favour stable and adequate financing for vaccines and immunization in the future.

#### **How much will it cost ?**

##### ***An illustrative example***

Costing an immunization vision is not a straightforward exercise. Any estimate will be subject to uncertainty in the data and methods used to estimate costs, as well as around the choice of interventions each country would choose to achieve the draft global strategy. These costs will also be sensitive to the availability and future prices of underused and new vaccines, as well as the availability of funds to finance continuous expansions and improvements of immunization systems.

Given these uncertainties, and based on existing data and methods, preliminary estimates were made of current spending on immunization, as well as the cost of scaling up immunization efforts between the years 2006 and 2015 in 117 of the poorest countries.<sup>1</sup> The impact that scaling up immunization could have on the mortality attributable to vaccine-preventable diseases was also estimated.

The broad assumptions of this illustrative example are that each country will aim to reach 90% routine coverage by 2015, including campaigns as appropriate;<sup>2</sup> and will introduce available and safe vaccines, including new vaccines expected to be widely available during the period 2006-2015.<sup>3</sup>

Results suggest that in the year 2000, approximately US\$ 1 billion was spent on routine immunization for the delivery of basic vaccines. By 2006, costs are expected to have doubled as countries are expanding their immunization schedules with underused vaccines and accelerated measles mortality reduction campaigns. By 2015, the annual costs of reaching all the goals outlined in the illustrative example are estimated to be three times those of 2006.

Achieving the goals outlined in the illustrative example will require at least a doubling of current financing for immunization if we assume a continuation of current investments by national governments and external donors and new international funding for immunization (e.g., GAVI).

However, such costs are not without a good return on investment, particularly in terms of the contribution to achieving the MDG child mortality reduction goal (MDG4). In 2000, immunization prevented 1-2 million child deaths in a single year. By 2015, this will more than double, preventing 4-5 million child deaths per year. The full benefits of sustaining current immunization efforts — and scaling them up — could prevent more than 38 million premature deaths in 2006-2015. At an average cost per death averted of under US\$ 1000, immunization continues to be one of the best health investments available.

The numbers cited above should be considered as indicative and preliminary in nature. Efforts are ongoing to improve these estimates.<sup>4</sup> More definitive figures will be available in 2006.

1. All costs referred to include shared health systems costs.

2. Includes campaigns for rapid mortality reduction (tetanus, measles); and in conjunction with the introduction of new or underused vaccines (rubella, yellow fever, and meningococcal A). Also included are the costs of the final stages of polio eradication, the bulk of which is for campaigns.

3. Include Hib, HepB, Yellow Fever, rubella, and second dose measles vaccines as "underused vaccines", and rotavirus, pneumococcal, meningococcal A and JE vaccines as "new vaccines". We do not include the vaccine costs for provision of a booster dose of DTP, and we assume that OPV use will cease in 2010, and do not include any costs associated with the use of IPV.

4. Further methodological details are available in: Wolfson L, and Lydon P, (2005) *Methodology for Estimating Baseline and Future Levels of Costing (and Impact) for the Global Immunization Vision and Strategy 2005 - 2015, Draft 1.1. WHO mimeograph.*

7.1.4. Appropriate co-financing strategies will be developed to reduce the financial barriers to the introduction of new and existing vaccines and technologies. In addition, efforts will be made to ensure that external financial support to countries is provided in ways that strengthen national capacity to gradually assume financial responsibility for immunization. GAVI/VF have a key role to play in this effort.

7.1.5. The dramatic changes in the information and communication environment that have occurred globally over the past decade — mainly due to the globalization of the media and pervasive access to internet-based information — have had both a positive and negative impact on public perceptions about vaccines. The frequency of concerns about vaccine safety has increased as interested parties share their concerns globally, and in turn appreciation of the value of immunization appears to have waned. On the other hand, information on the benefits of immunization can now reach more people more rapidly and help ensure that care givers are better informed about the choices and options available to them.

7.1.6. Finally, global interdependence has increased the vulnerability of people everywhere to the uncontrolled spread of diseases through epidemics of national or global proportions. Infectious diseases can easily and quickly spread from country to country (e.g. polio). Vaccines already exist to prevent or control some of these diseases, and others are likely to

become available in the next decade. Local, national and global preparedness against epidemics has become a critical step in safeguarding global health and security.

## 7.2. Aims

- 7.2.1. Increase awareness of and respond to the reality that every country is vulnerable to the impact of global issues and events on vaccine supply, financing, partner collaboration, communication and epidemic preparedness; and
- 7.2.2. Strengthen and coordinate partnerships at global and national levels in support of immunization programmes.

## 7.3. The component strategies

### 7.3.1. Strategy 20: Ensure reliable global supply of affordable vaccines of assured quality

- 7.3.1.1. The success of immunization depends on a sustainable supply of affordable vaccines of assured quality. Inadequate vaccine procurement, inaccurate forecasting and late ordering create obstacles for the immunization programme. Collaboration between countries, vaccine manufacturers and international supply agencies should be strengthened to ensure that global demand is identified and actions taken to meet that demand.
- 7.3.1.2. Ultimately, the price of vaccines will to some extent depend on the ability of the global community to address the difficult process of forecasting vaccine needs and making available the appropriate vaccine antigens and formulations — a strategy which requires effective partner and country interaction.

#### 7.3.1.3. Activities:

- Ensure long-term forecasting for existing and new vaccines through close collaboration between international agencies, donors and vaccine manufacturers;
- Develop global standards and methods for testing the quality, safety and efficacy of vaccines and other biologicals;
- Promote the production of affordable vaccines of assured quality by vaccine manufacturers in developing and developed countries; and
- Promote the emergence of multiple manufacturers from industrial and developing countries to provide an adequate supply of affordable vaccines of assured quality (both existing and new vaccines) and immunization materials.

### **7.3.2. Strategy 21: Ensure adequate and sustainable financing of national immunization systems**

7.3.2.1. Achieving financial sustainability for immunization, in order to sustain gains in disease reduction, improve coverage and introduce new products, will require the mobilization of new resources both from within countries and from the international community. The principles or criteria for donor participation in the funding process need to be delineated. In addition, clear criteria and principles are needed to define the appropriate interactions between partners and national immunization programmes when the introduction of new or underutilized vaccines and/or technologies is under consideration.

#### **7.3.2.2. Activities:**

- Strengthen national capacity for financial planning both within the immunization programme itself and the ministry of health as a whole;
- Commit increased and sustained national budget allocations for vaccines, on the basis of improved understanding of the value of vaccines in public health;
- Encourage local and district level contribution to health services and immunization programmes through interaction with local businesses and interests;
- Mobilize international solidarity to secure and sustain financing for immunization, including long-term commitments by existing public and private funding entities and new long-term financial mechanisms in support of the research, development, production and use of new vaccines; and
- Coordinate immunization financing through the ICCs to ensure adequate and appropriate donor support to national governments.

### **7.3.3. Strategy 22: Improve communication and dissemination of information**

7.3.3.1. Communication must be improved in order to ensure that the public, policy-makers, and health workers understand the vital importance of immunization for the health of both children and adults. This is essential both in ensuring support for the current immunization programme and in providing information about the introduction of new vaccines or technologies to a national schedule. As delivery systems become more complex and the diversity of products available increases, the demand for clear guidance on programme preferences will also intensify. In view of the globalization of the media, including widespread access to internet-based information, it is of critical importance to make use of the available media both to provide evidence-based information about the value of immunization and to counter false information about vaccine safety issues.



#### **7.3.3.2. Activities:**

- Develop new ways of using the globalized media, including the internet, to build public awareness of the benefits of immunization;
- Produce quality and timely information on the benefits of immunization and associated risks and develop key messages to promote immunization according to national needs and priorities; and
- Through regional and global channels, document and systematically communicate the experience gained by countries that have added new vaccines and technologies.

#### **7.3.4. Strategy 23: Define and recognize the roles, responsibilities and accountability of partners**

7.3.4.1. Global partners should provide leadership and coordination, particularly in setting global goals, lead global advocacy efforts to ensure that immunization remains high on the international health agenda, and support research to facilitate the introduction of new vaccines and technologies and to improve immunization programmes. Immunization partners also play an important role at national and regional levels through various partner coordinating mechanisms such as the ICCs.

#### **7.3.4.2. Activities:**

- Negotiate and define the roles and responsibilities of key immunization partners at the global level on a regular basis, to ensure both accountability and efficient coordination;
- Set global immunization goals jointly and in consultation with countries to ensure the full commitment of all parties;
- Obtain global concurrence on policies, norms and standards for immunization and additional interventions;
- Provide leadership in global advocacy and ensure that immunization remains high on the global health agenda by raising awareness of the importance and benefits of immunization among governments, donors and in the global community;
- Develop and actively participate in regional and national partnership bodies (such as ICCs) to support implementation, provide ongoing technical assistance and monitor progress in countries; and
- Support epidemiological and operational research on vaccines and immunization.

### **7.3.5. Strategy 24: Include vaccines in global epidemic preparedness plans and measures**

7.3.5.1. Vaccine-preventable diseases may occur in epidemic form, whether localized or affecting a region, a country or the whole world. Of the vaccines available to prevent or contain such epidemics, some are insufficiently used (e.g., yellow fever in endemic countries), others are under improvement (e.g., Japanese B encephalitis, cholera), and others may be made available only in limited supplies and after the time needed required for their formulation and production (e.g. influenza). In addition, other vaccines against diseases of epidemic potential may become available by 2015 (e.g., SARS, dengue). In line with their commitment to strengthen epidemic alert and response capacity, countries and international organizations are in the process of formulating national preparedness plans for epidemic control. However, developing countries have a number of structural and functional obstacles to overcome before they become fully prepared to face such events. Immunization programmes are important potential contributors to epidemic preparedness and response at the national and global levels through: surveillance; vaccine procurement and delivery; promotion of safe immunization practices and logistic outreach.

#### **7.3.5.2. Activities:**

- Develop global and country-specific epidemic preparedness and prevention plans relevant to specific diseases;
- Develop and implement plans and funding for a stockpile of key vaccines for both epidemic control and pre-emptive campaigns; and
- 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; and
- Strengthen regulatory capacity to respond to urgent needs for epidemic preparedness and response.

## 8. THE WAY FORWARD

- 8.1. This section focuses on the actions needed to facilitate the global implementation of the draft global strategy: consultations to ensure that countries apply the guiding principles to their own strategic planning through strategies tailored to individual needs, capacity and resources; securing the early engagement of immunization partners; concerted strengthening of the capacity of immunization services at the district level, especially in low-performing countries; establishment of a knowledge base about successfully linked health interventions as a resource for their potential scaling up; development of an evaluation and review process to measure progress up to 2015; and production and dissemination of supportive documentation detailing plans and policies as well as further information on technical issues.

### **Consensus development and national commitment**

- 8.1.2 National and regional consultations are already using the draft global strategy as a basis for elaborating policies and plans tailored to their specific needs, capacity and resources. In doing so, countries will require the commitment of governments, including not only ministries of health but also ministries overseeing planning, finance, education and local government, who have a key role to play in health matters. It will require the engagement of programme managers as well as the close involvement of partners from civil society and the private commercial sector. Underlying assumptions for progress towards the draft global strategy goals include efforts involving partnerships at all levels to improve management, develop and implement appropriate advocacy strategies, and monitor and evaluate results. While these partnerships have a significant role to play at the regional and global levels, it is at the country level that they can have a major impact. In an effort to maximize the value of this role, crucial efforts will be needed to strengthen the ICCs in order to improve coordination.

### **Strengthening district capacity for implementation of the draft global strategy with a focus on low-performing countries**

- 8.1.3 The implementation of the draft global strategy relies on efforts at the district level. To meet this need, support will be needed at the district level to help identify and overcome constraints on the delivery of immunization, to deploy human and financial resources in ways that best meet local needs, and to use local data to inform such decisions. A key priority in district plans and activities will be efforts to reach out to underserved communities and to engage the participation of communities in these efforts.
- 8.1.4. Countries have reached different stages of progress towards their immunization goals. Those that have demonstrated their capacity to improve and sustain the coverage and quality of immunization will deserve continued support for their activities as they further improve their performance and introduce new vaccines. Special efforts will be devoted to low-performing countries in order to accelerate progress. To this end, national, regional and global consultations will set priorities for action, taking into account the extent of national commitment and gaps in immunization delivery, implementation capacity and financing. In low-performing countries, concerted action by national and international stakeholders will seek to alleviate constraints affecting not only the performance of immunization services but the health system as a whole.

### **Experimentation and scaling up of integrated interventions**

- 8.1.5. In areas of proven integration (e.g., malaria control and routine immunization), countries and partners are encouraged to actively pursue and support joint planning, implementation and monitoring of these activities.
- 8.1.6. Building on new knowledge derived from operational research and practical experience, new operational linkages will be created between immunization and other health interventions. Combined interventions which have proven to be efficient, effective and sustainable will be replicated on a wider scale and new pathways explored to further enhance the catalytic role of immunization. Joint management, financing, monitoring and evaluation mechanisms for linked interventions will be explored to ensure improved coordination, both within immunization programmes and between them and other health sector initiatives.

### **Evaluation, review, adjustment**

- 8.1.8. Over the 10-year period covered by the draft global strategy, periodic progress reviews and selected probes into specific issues arising in the course of implementation will inform the shaping and re-shaping of policies and programmes. A mid-term evaluation of the draft global strategy will be conducted in 2010 and an end-term review in 2015.
- 8.1.9. The reliable evaluation of programme performance and impact will require the improvement of current monitoring and evaluation methods as well as the development of new ones. Moreover, efforts will be needed to strengthen national and international capacity to apply appropriate and up-to-date monitoring and evaluation methods. Such efforts will result both in the establishment of new measurable targets, against which progress can be reliably measured, and in greater accountability for the use of national and international resources.

### **Development of accompanying documents**

- 8.1.10. 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:
- 8.1.11. Companion technical documents for national use describing in greater detail key issues such as comprehensive multi-year planning, including financing; human resources planning; medium- and long-term vaccine procurement forecasts; priorities for research and development; progress and impact indicators; and monitoring and evaluation frameworks;
  - 8.1.12. Projected global financial needs and consolidated monitoring and evaluation targets and indicators, based on the range of national plans and budgets;
  - 8.1.13. Formulation of national and regional comprehensive multi-year strategic plans that set targets, define strategies and provide human and financial plans, emphasizing accountability and the decentralization of decision-making authority and resources to the district level;
  - 8.1.14. A global plan for reliably monitoring the goals of draft 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;

- 8.1.15. National, regional and global financing plans; and
- 8.1.16. A global development and research strategy responding to the current and anticipated needs of the draft global strategy.
- 8.1.17. The strategic options outlined above are not exhaustive. The draft global strategy should be seen not as a detailed blueprint but rather as an evolving plan. As the strategy and vision unfold over the next 10 years, new challenges will arise and new responses and innovations will be needed.