



Global Vaccine Action Plan

2011–2020

WHO Library Cataloguing-in-Publication Data

Global vaccine action plan 2011-2020.

1.Immunization programs. 2.Vaccines – supply and distribution. 3.Health Promotion.
4.Research. 5.National health programs. I.World Health Organization.

ISBN 978 92 4 150498 0

(NLM classification: WA 115)

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Printed in the USA

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Foreword

The Global Vaccine Action Plan (GVAP) is a framework approved by the World Health Assembly in May 2012 to achieve the Decade of Vaccines vision by delivering universal access to immunization. The mission outlined in the GVAP is straightforward: improve health by extending by 2020 and beyond the full benefits of immunization to all people, regardless of where they are born, who they are, or where they live.

Overwhelming evidence demonstrates the benefits of immunization as one of the most successful and cost-effective health interventions known. Over the past several decades, immunization has achieved many things, including the eradication of smallpox, an accomplishment that has been called one of humanity's greatest triumphs. Vaccines have saved countless lives, lowered the global incidence of polio by 99 percent and reduced illness, disability and death from diphtheria, tetanus, whooping cough, measles, *Haemophilus influenzae* type b disease, and epidemic meningococcal A meningitis.

Further progress has been made in introducing vaccines against pneumococcal disease and rotavirus diarrhoea as well as vaccines which prevent chronic diseases such as liver and cervical cancer.

We are facing a pivotal moment in history. Right now, the global health community has an unprecedented opportunity to coordinate with governments to develop and implement plans and strategies that will improve the lives of millions of people around the world through universal access to appropriate vaccines.

Together, we can overcome the hurdles that remain in delivering vaccines to every corner of the planet. These powerful tools are already available to most, but not yet all, people. To extend immunization to everyone, the GVAP seeks to ensure adequate resources, develop supportive health systems and infrastructure, and work with countries to train health workers needed to reach remote and marginalized populations. The plan also articulates the need for a concerted effort to develop new and improved vaccines and technologies that will help maximize the benefits of immunization around the world for years to come.

This ambitious action plan to reach all people with the vaccines they need is the product of the Decade of Vaccines Collaboration, an unprecedented effort that brought together development, health and immunization experts and stakeholders. The powerful idea that vaccines work and save lives must now be shared with a much broader audience, using such vehicles as World Immunization Week and others to promote universal vaccination and help focus on current challenges related to immunization. While dedicated health workers immunize people daily in all countries, World Immunization Week gives countries and organizations additional, focused opportunities to raise public awareness of how immunization saves lives—during the same week, every year, in every country.

When they endorsed the GVAP, health officials of 194 countries also declared that the completion of polio eradication is a programmatic emergency for global health, asking for sufficient funding to complete the initiative. Polio eradication is an early, major milestone in the implementation of the GVAP.

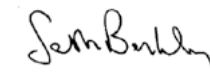
Our aim is to build on past achievements and use our know-how and experience to save more lives. This plan, that builds on the WHO-UNICEF Global Immunization Vision and Strategy, and the GAVI Alliance Strategy, provides the guiding

principles and strategic objectives that will enable immunization of more people against more diseases; introduce newly available life-saving vaccines and technologies; and coordinate immunization and other critical health interventions. The plan also suggests key targets for further research and development.

The Decade of Vaccines Leadership Council, along with all partners—governments and elected officials, health professionals, academia, manufacturers, global agencies, development partners, civil society, media and the private sector—are committed to achieving the ambitious goals of the GVAP.

Together we will track and measure progress through the GVAP and the UN Secretary General Global Strategy for Women’s and Children’s Health Accountability Frameworks.

Many more are expected to add their support in the future as the plan is translated and implemented at the country and regional levels. The success of this ambitious global plan will be one of the most enduring legacies for today’s children and the generations who follow them.



Dr. Seth Berkley
Chief Executive Officer
GAVI Alliance



Dr. Christopher Elias
President
Global Development Program
Bill & Melinda Gates Foundation



Mr. Anthony Lake
Executive Director
United Nations Children’s Fund (UNICEF)



Dr. Margaret Chan
Director General
World Health Organization



Dr. Anthony Fauci
Director
*US National Institute of Allergies
and Infectious Diseases*



Ms. Joy Phumaphi
Executive Secretary
African Leaders Malaria Alliance

Global Vaccine Action Plan

In May 2011, a report by the Secretariat on the global immunization vision and strategy was noted by the Sixty-fourth World Health Assembly.¹ During the discussions the vision for the Decade of Vaccines (2011–2020) and the development of a Global Vaccine Action Plan were welcomed. Subsequently, the Executive Board at its 130th session in January 2012 considered the Global Vaccine Action Plan and provided guidance.² The Board also adopted resolution EB130.R12 on World Immunization Week.³ The final plan was endorsed at the 65th World Health Assembly in May 2012.

¹ See WHO documents [A64/14](#) and [WHA64/2011/REC/2](#), summary records of the sixth meeting, section 2, the seventh meeting and the eighth meeting, section 2.

² See WHO documents [EB130/21](#) and [EB130/2012/REC/2](#), summary record of the eleventh meeting.

³ See WHO document [EB130/2012/REC/1](#) for the resolution, and for the financial and administrative implications for the Secretariat of the adoption of the resolution.

Introduction

The Global Vaccine Action Plan builds on the success of the Global Immunization Vision and Strategy, 2006–2015, which was launched in 2005 as the first 10-year strategic framework to realize the potential of immunization. Developing the plan has brought together multiple stakeholders involved in immunization, including governments and elected officials, health professionals, academia, manufacturers, global agencies, development partners, civil society, media and the private sector, to define collectively what the immunization community wants to achieve over the next decade. In total, the global consultation process reached over 1100 individuals representing more than 140 countries and 290 organizations, and included two special sessions to brief representatives of the Permanent Missions of the United Nations Offices and other Intergovernmental Organizations in Geneva and New York.



Developing the plan brought together more than 1100 individuals in 140 countries, representing 290 distinct organizations

Immunization is, and should be recognized as, a core component of the human right to health and an individual, community and governmental responsibility. Vaccination prevents an estimated 2.5 million deaths each year. Protected from the threat of vaccine-preventable diseases, immunized children have the opportunity to thrive and a better chance of realizing their full potential. These advantages are further increased by vaccination in adolescence and adulthood. As part of a comprehensive package of interventions for disease prevention and control, vaccines and immunization are an essential investment in a country's—indeed, in the world's—future.

Now is the time for showing commitment to achieving the full potential of immunization. The collective recognition of this opportunity has led the global health community to call for a Decade of Vaccines, in line with the requests made in resolution WHA61.15 on the global immunization strategy. The vision for the Decade of Vaccines (2011–2020) is of a world in which all individuals and communities enjoy lives free from vaccine-preventable diseases. The mission of the Decade of Vaccines is to extend, by 2020 and beyond, the full benefit of immunization to all people, regardless of where they are born, who they are or where they live.

The Global Vaccine Action Plan reiterates existing goals and sets new goals for the decade, proposes six strategic objectives and the actions that will support their achievement, and provides an initial estimate of resource requirements and return on investment. [Annex 1](#) summarizes recommended indicators to monitor and evaluate progress. Beyond the action plan, country, regional and global stakeholders need to take responsibility for specific actions, translate the action plan into detailed operational plans (updating both the action plan and the operational plans as new information becomes available), complete the development of an accountability framework for the Decade of Vaccines (2011–2020) and mobilize resources to ensure that the vision for the Decade of Vaccines becomes a reality. Accomplishing this will require global and national institutions to innovate and to change the way they work. [Annex 2](#) provides a summary of stakeholder responsibilities.



This century promises to be the century of vaccines

The last century was, in many respects, the century of treatment, resulting in dramatic reductions in morbidity and mortality, with the discovery and use of antibiotics as one of the biggest agents of change in health. This century promises to be the century of vaccines, with the potential to eradicate, eliminate or control a number of serious, life-threatening or debilitating infectious diseases, and with immunization at the core of preventive strategies. Ensuring that the vision for the Decade of Vaccines becomes a reality is a powerful step in that direction.



The vision

for the Decade of Vaccines (2011–2020) is of a world in which all individuals and communities enjoy lives free from vaccine-preventable diseases.

The Immunization Landscape Today

Important progress in the last decade

In the last 10 years, great advances have been made in developing and introducing new vaccines and expanding the reach of immunization programmes. More people than ever before are being vaccinated and access and use of vaccines by age groups other than infants is expanding. As a result of immunization combined with other health care and development interventions—including improved access to clean water and sanitation, better hygiene and education—the annual number of deaths among children under five years of age fell from an estimated 9.6 million in 2000 to 7.6 million in 2010, despite an increase in the number of children born each year.



The annual number of deaths among children under five years of age fell an estimated 2 million from 2000 to 2010

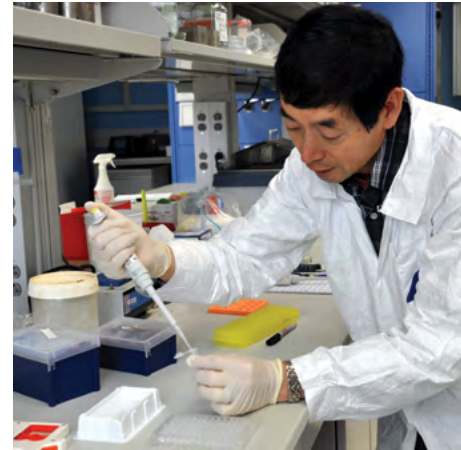
Immunization has helped drive this reduction in child mortality: coverage of vaccines that have been in use since the inception of the Expanded Programme on Immunization has expanded, and new vaccines have been introduced. Vaccines against hepatitis B and *Haemophilus influenzae* type b have become part of national immunization schedules in 179 and 173 countries, respectively; poliomyelitis is nearing eradication; and a large number of deaths from measles are being averted every year. The number of deaths caused by traditional vaccine-preventable diseases (diphtheria, measles, neonatal tetanus, pertussis and poliomyelitis) has fallen from an estimated 0.9 million in 2000 to 0.4 million in 2010.⁴

New and increasingly sophisticated vaccines that have become available in the last decade, including pneumococcal conjugate vaccine and vaccines against infection with rotavirus and human papillomavirus, are currently being rolled out globally. Efforts are being made to shorten the time lag that has historically existed in the introduction of new vaccines between high- and low-income countries. For example, pneumococcal conjugate vaccines were introduced in low-income countries approximately a year after being introduced in high-income countries.

Through an innovative international collaboration, an affordable conjugate vaccine against *Neisseria meningitidis* serogroup A was developed and is now in use in the African meningitis belt.

There are now licensed vaccines being used to prevent, or contribute to the prevention and control of, 25 vaccine-preventable infections (Table 1).


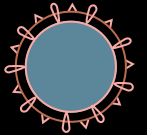
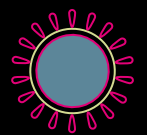
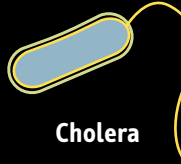

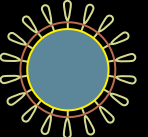
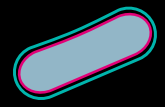
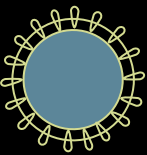

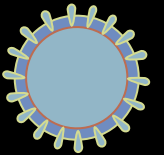

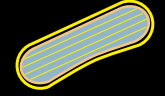
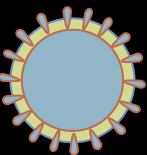

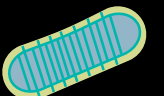
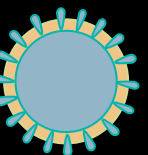
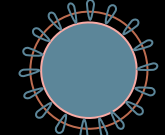
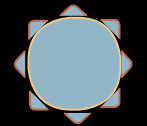
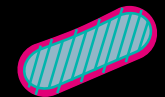

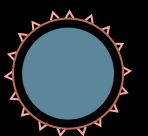
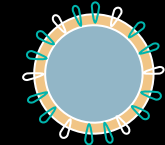
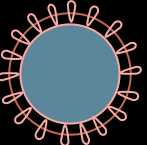
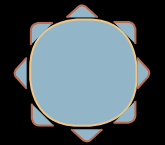
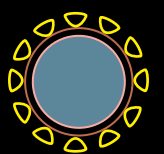
The strengthening by countries of national programmes, aided by improved support from and coordination among local, national, regional and international stakeholders, has succeeded in improving immunization coverage rates. Financing from domestic budgets allocated to immunization programmes has risen over the past decade, as has the flow of international resources dedicated to immunization. According to the immunization programme data for 2010,⁵ 154 of the 193 Member States report having a specific budget line item for immunization, and 147 have developed multi-year national plans to sustain the gains achieved, further enhance performance to reach desired goals and introduce appropriate new vaccines.



Efforts are being made to shorten the time lag that has historically existed in the introduction of new vaccines between high- and low-income countries

⁴ Sources for estimates: measles and neonatal tetanus, in World Health Statistics 2012, Geneva, World Health Organization, 2012; diphtheria and poliomyelitis, for 2000: http://www.who.int/healthinfo/global_burden_disease/estimates_regional_2000_v3/en/index.html (accessed 5 April 2012), for 2008: <http://apps.who.int/ghodata/> (accessed 5 April 2012); pertussis, WHO Secretariat provisional data.
⁵ http://www.who.int/immunization_monitoring/data/en/ (accessed 13 April 2012).

TABLE 1: VACCINE-PREVENTABLE INFECTIOUS AGENTS OR DISEASES

 Anthrax	 Measles	 Rubella	 Cholera	 Meningococcal Disease
 Influenza	 Diphtheria	 Mumps	 Tetanus	 Hepatitis A
 Pertussis	 Tuberculosis	 Hepatitis B	 Pneumococcal disease	 Typhoid fever
 Hepatitis E	 Poliomyelitis	 Tick-borne encephalitis	 Haemophilus influenzae type b	 Rabies
 Varicella and herpes zoster (shingles)	 Human papilloma-virus	 Rotavirus gastroenteritis	 Yellow fever	 Japanese encephalitis

Global and regional immunization initiatives have supported countries in building up their systems and introducing new vaccines. Global goals and milestones established through the Global Immunization Vision and Strategy 2006–2015, the United Nations Millennium Declaration, the United Nations World Summit for Children, the United Nations General Assembly Special Session on Children, and, more recently, the United Nations Secretary-General’s Global Strategy for Women’s and Children’s Health have stimulated expansion of national immunization programmes. In low- and middle-income countries these have been supported by initiatives such as the GAVI Alliance, the Global Polio Eradication Initiative, the Measles Initiative, the vaccine procurement services of UNICEF, and PAHO’s Revolving Fund for Vaccine Procurement.



Reaching underserved populations will be especially challenging, but inequities need to be tackled because these populations often carry a heavier disease burden

Significant unmet needs remain

Despite this progress, vaccine-preventable diseases remain a major cause of morbidity and mortality. Adoption of new vaccines by low- and middle-income countries (where disease burdens are often the highest) has been slower than in high-income countries. In 2010, for example, only 13% of the total high-income country birth cohort lived in countries that did not have pneumococcal conjugate vaccines in their immunization schedules. Of the total low-income country birth cohort, 98% lived in countries that did not have pneumococcal conjugate vaccines in their schedules.

Coverage gaps persist between countries, as well as within countries. The average coverage with three doses of diphtheria-tetanus-pertussis-containing vaccine and with measles-containing vaccine in low-income countries was 16% and 15% below that of high-income countries in 2010, respectively. However, this represents a positive trend in comparison with the coverage gap of 30% for both vaccines in the year 2000.

In some countries, coverage of measles-containing vaccine in rural areas is 33% lower than in urban areas. Similarly, the measles vaccine coverage rate for the richest fifth of the population in some countries is up to 58% higher than for the poorest fifth. Coverage can also be very low in settlements of the urban poor, especially in cities with transitory migrant populations, and in indigenous communities.

Geographical distance from health centres is not the only determinant of low coverage; inequities are also associated with other socioeconomic determinants, such as income levels and the educational status of the mother. A special geographic focus is needed on lower-middle-income countries with large populations, where the majority of the unvaccinated live. Reaching underserved populations will be especially challenging, but inequities need to be tackled because these populations often carry a heavier disease burden and may lack access to medical care and basic services, with the fragile economies of individuals and their families suffering a severe disease-related impact as a consequence.



16%
lower DTP3 coverage in low-income countries than in high-income countries in 2010

New opportunities and challenges for the Decade of Vaccines (2011–2020)

Individuals and communities, governments and health professionals have primary responsibility for exploiting the opportunities and confronting the challenges that this decade will bring. New and improved vaccines are expected to become available, based on a robust pipeline that includes several vaccines for diseases that are not currently preventable through vaccination. The introduction of new vaccines targeted against several important causes of major killer diseases, such as pneumonia, diarrhoea and cervical cancer can be used as a catalyst to scale up complementary interventions. In addition to reducing mortality, these new vaccines will prevent morbidity with resulting economic returns even in countries that have already succeeded in improving mortality rates. Innovations in existing vaccines will bring additional benefits, such as greater effectiveness, thermostability, easier administration and lower cost.

At the same time, the development of vaccines and other immunization innovations is facing increasingly complex manufacturing and regulatory processes, as well as rising research, development and production costs. As new vaccines (for example, against dengue and malaria) become available and underutilized vaccines (for example, those against cholera, human papillomavirus, rabies, rotavirus, rubella and typhoid) are administered more widely, supply and logistics systems—already burdened—will face an even greater need for innovations. Finally, the number of health workers, as well as their knowledge and skills, will need to be enhanced, better coordinated and better supervised. While the challenges are many, the introduction of new vaccines also represents an opportunity to strengthen immunization systems and to act as a catalyst to implement many of the required reforms. As national immunization investments increase, so must government oversight and accountability.



The number of health workers, as well as their knowledge and skills, will need to be enhanced

Immunization funding needs in the areas of research and development, procurement and delivery are expected to more than double in the coming decade. New and more complex vaccines will bring new funding requirements and countries will be confronted with difficult decisions in dealing with competing health priorities. Resources will need to be allocated more efficiently, with the relevant decisions guided by national priorities, capacity, clear information on the costs and benefits of choices, and improved financial management. Expenditures must be linked to outputs and impacts, showing a clear investment case for immunization.

As the economies of many low- and middle-income countries continue to grow, so will their potential to fund immunization. Countries that have relied on development assistance will be able to fund an increasing proportion of their immunization programmes, and may even, eventually, be able to fully sustain them. Some will be able to extend new financial and technical support to global immunization projects. At the same time, vaccine manufacturers in some of these countries will be expected to make an even more significant contribution to the supply of high-quality, affordable vaccines, spreading the sources of production more widely and increasing competition.

The growing availability of information and penetration of mobile telephone and social networks can boost public demand for immunization, and ensure that people are made aware of both the benefits derived from vaccines and their potential risks. The immunization community can take advantage of social networks and electronic media to more effectively allay fears, increase awareness and build trust.

The lessons learnt from past decades, the unmet needs, and the opportunities and challenges that this decade presents have been carefully considered in the formulation of the guiding principles, measures of success and recommended actions articulated in the following sections.



As the economies of many low- and middle-income countries continue to grow, so will their potential to fund immunization

Six Guiding Principles

Six principles have guided the elaboration of the Global Vaccine Action Plan.



1

COUNTRY OWNERSHIP

countries have primary ownership and responsibility for establishing good governance and for providing effective and quality immunization services for all.

2

SHARED RESPONSIBILITY AND PARTNERSHIP

immunization against vaccine-preventable diseases is an individual, community and governmental responsibility that transcends borders and sectors.

3

EQUITY

equitable access to immunization is a core component of the right to health.

4

INTEGRATION

strong immunization systems, as part of broader health systems and closely coordinated with other primary health care delivery programmes, are essential for achieving immunization goals.

5

SUSTAINABILITY

informed decisions and implementation strategies, appropriate levels of financial investment, and improved financial management and oversight are critical to ensuring the sustainability of immunization programmes.

6

INNOVATION

the full potential of immunization can only be realized through learning, continuous improvement and innovation in research and development, as well as innovation and quality improvement across all aspects of immunization.



These six fundamental principles can realistically and effectively guide the full spectrum of immunization activities throughout the Decade of Vaccines (2011–2020). Although the Global Vaccine Action Plan will need to be translated into specific regional, country and community contexts, these guiding principles are universally applicable and relevant to each of the Decade of Vaccines' goals and strategic objectives described below.

Measures of Success

The Decade of Vaccines is about taking action to achieve ambitious goals. Early in the decade, this means achieving already established elimination and eradication goals. It means dealing with the public health emergency constituted by wild poliovirus transmission in order to secure a world free of poliomyelitis. It also means assuring the global or regional elimination of measles, rubella and neonatal tetanus.⁶ Completing this agenda has never been more critical. Success will encourage the achievement of additional ambitious goals. Failure will mean millions of preventable cases of disease and death will continue to occur.

⁶ By 2015, achieve maternal and neonatal tetanus elimination (defined as less than one case of neonatal tetanus per 1000 live births) in every district, measles elimination in at least four WHO regions and rubella elimination in at least two WHO regions. By 2020, achieve measles and rubella elimination in at least five WHO regions.



By 2020, coverage of target populations should reach at least 90% national vaccination coverage and at least 80% vaccination coverage in every district or equivalent administrative unit for all vaccines in national immunization programmes





Later in the decade, success will be recorded in terms of the expansion of immunization services to meet vaccination coverage targets in every region, country and community. In 2015, the coverage of target populations should reach the goal of the Global Immunization Vision and Strategy, 2006–2015 of at least 90% national vaccination coverage and at least 80% vaccination coverage in every district or equivalent administrative unit (the marker for this being coverage for diphtheria-tetanus-pertussis-containing vaccines). By 2020, coverage of target populations should reach these levels for all vaccines in national immunization programmes unless alternative targets exist. Vaccine introductions should also be monitored, with the goal of at least 80 low- or middle-income countries introducing one or more appropriate new or underutilized vaccines by 2015. These technical accomplishments will not be sustained unless countries take full ownership of their routine immunization programmes (see [strategic objective 1](#) below).

During this decade millions of additional deaths and cases of disease should become preventable as a result of the development, licensure and introduction of new and improved vaccines and technologies for high-burden diseases. Specifically, progress towards the licensure and launch of vaccines should be tracked against one or more major pathogens not currently vaccine preventable (such as, cytomegalovirus, dengue virus, group A streptococcus, hepatitis C virus, hookworm, leishmania and respiratory syncytial virus) and at least one new platform delivery technology.



Meet vaccination targets in every region, country, and community

Goals of the Decade of Vaccines (2011–2020)

<p>Achieve a world free of poliomyelitis</p>		<p>Meet global and regional elimination targets</p>	
<p>Meet vaccination coverage targets in every region, country and community</p>		<p>Develop and introduce new and improved vaccines and technologies</p>	
<p>Exceed the Millennium Development Goal 4 target for reducing child mortality</p>			

If these immunization-specific goals are achieved, hundreds of millions of cases and millions of future deaths will be averted by the end of the decade, billions of dollars of productivity will be gained, and immunization will contribute to exceeding the Millennium Development Goal 4 target for reducing child mortality (and the target that succeeds it post-2015).



For example, it is estimated that if the coverage targets for introduction and/or sustained use of 10 vaccines alone (those against hepatitis B, *Haemophilus influenzae* type b, human papillomavirus, Japanese encephalitis, measles, meningococcus A, pneumococcus, rotavirus, rubella and yellow fever) in 94 countries during the decade are met, between 24 and 26 million future deaths could be averted compared with a hypothetical scenario under which these vaccines have zero coverage (see also Annex 4).

24-26
million future deaths
could be averted

Six Strategic Objectives

Continuous progress towards the following Six Strategic Objectives will enable the achievement of the goals of the Decade of Vaccines (2011–2020).



1

ALL COUNTRIES COMMIT TO IMMUNIZATION AS A PRIORITY.

Key indicators to monitor progress towards this strategic objective at the country level are the presence of a legal framework or legislation that guarantees financing for immunization and the presence of an independent technical advisory group that meets defined criteria.

2

INDIVIDUALS AND COMMUNITIES UNDERSTAND THE VALUE OF VACCINES AND DEMAND IMMUNIZATION AS BOTH THEIR RIGHT AND RESPONSIBILITY.

Progress towards increased understanding and demand can be evaluated by monitoring the level of public trust in immunization, measured by surveys on knowledge, attitudes, beliefs and practices.

3

THE BENEFITS OF IMMUNIZATION ARE EQUITABLY EXTENDED TO ALL PEOPLE.

Progress towards greater equity can be evaluated by monitoring the percentage of districts with less than 80% coverage with three doses of diphtheria-tetanus-pertussis-containing vaccine and coverage gaps between lowest and highest wealth quintile (or another appropriate equity indicator).

4

STRONG IMMUNIZATION SYSTEMS ARE AN INTEGRAL PART OF A WELL-FUNCTIONING HEALTH SYSTEM.

The strength of health systems can be evaluated based on dropout rates between the first dose of diphtheria-tetanus-pertussis-containing vaccine and the first dose of measles-containing vaccine. The quality of data is important for monitoring the functioning of a health system. Data quality can be evaluated by monitoring whether immunization coverage data is assessed as high quality by WHO and UNICEF.

5

IMMUNIZATION PROGRAMMES HAVE SUSTAINABLE ACCESS TO PREDICTABLE FUNDING, QUALITY SUPPLY AND INNOVATIVE TECHNOLOGIES.

Key indicators to monitor progress towards this strategic objective will be the percentage of routine immunization costs financed through government budgets and globally installed capacity for production of universally recommended vaccines within five years of licensure/potential demand.

6

COUNTRY, REGIONAL AND GLOBAL RESEARCH AND DEVELOPMENT INNOVATIONS MAXIMIZE THE BENEFITS OF IMMUNIZATION.

Key indicators of progress towards this strategic objective include proof of concept for a vaccine that shows greater or equal to 75% efficacy for HIV/AIDS, tuberculosis or malaria and the initiation of phase III trials for a first generation universal influenza vaccine. In addition, country research and development capacity can be measured by the institutional and technical capacity to manufacture vaccines and/or carry out related clinical trials and operational and organizational research.

Actions to Achieve Strategic Objectives

Achieving the vision and goals of the Decade of Vaccines (2011–2020) will only be possible if all stakeholders involved in immunization commit themselves to, and take action to achieve, the six strategic objectives; uphold the Decade of Vaccines guiding principles when implementing all the actions; and regularly monitor and evaluate progress towards both strategic objectives and goals using the indicators described above (see also Annex 1).

An accountability framework is needed that defines the methodology and source of data for these indicators, identifies which stakeholders will be responsible for what actions, and articulates the process and responsibilities for monitoring and evaluating progress over the course of the

Decade. The Global Vaccine Action Plan lays the groundwork for each of these elements. Further development and implementation of the accountability framework at country, regional and global levels could take place over the course of 2012 by leveraging the findings of

[the Commission on Information and Accountability for Women's and Children's Health](#) and aligning work, wherever possible, with other accountability efforts and initiatives by all stakeholders at the country level to deliver and monitor progress.



All stakeholders involved in immunization commit themselves to, and take action to achieve, the six strategic objectives

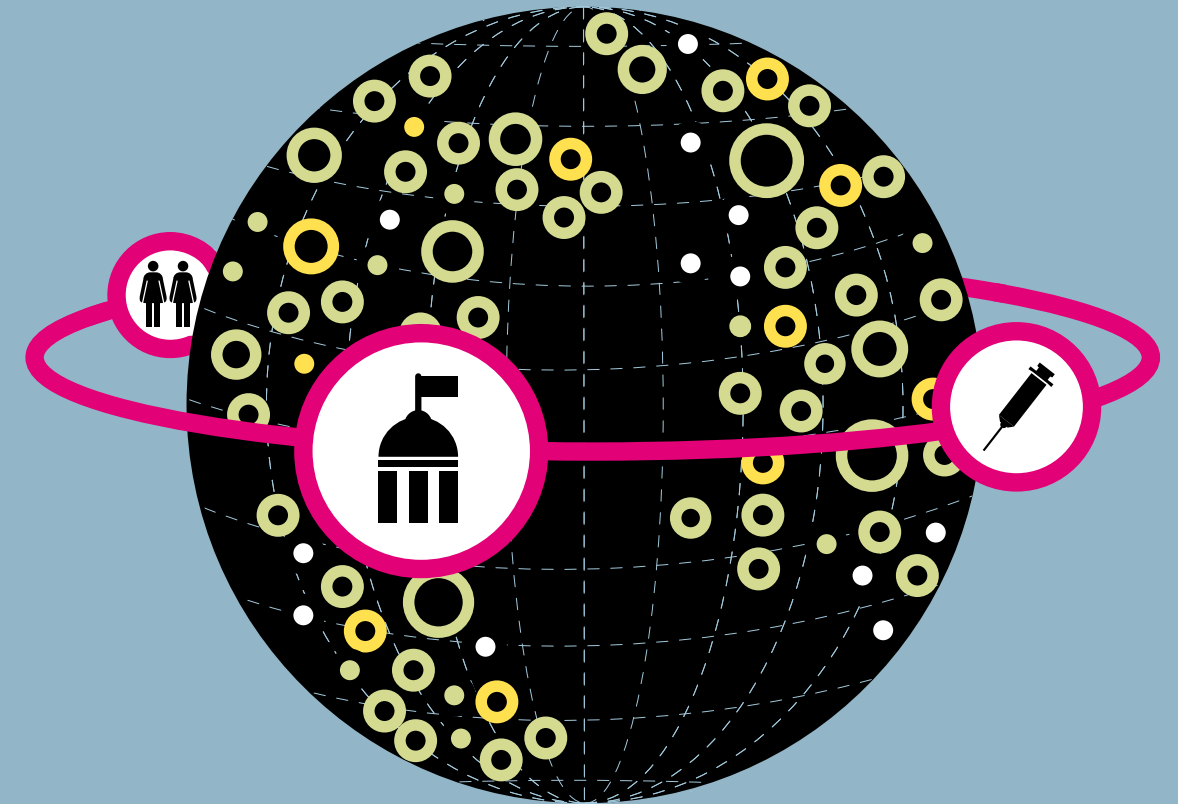
Strategic objective

1

All countries commit to immunization as a priority.

Committing to immunization as a priority first and foremost means recognizing the importance of immunization as a critical public health intervention and the value that immunization represents in terms of health and economic returns. Countries demonstrate a commitment to immunization by setting ambitious but attainable national targets and allocating adequate financial and human resources to programmes to achieve these targets; ensuring that their national immunization plans are fully integrated into national health plans, with appropriate budgets and formulated with the participation of all major stakeholders; and demonstrating good stewardship and implementation of their national health plans. Country commitment to immunization does not, however, imply that immunization programmes will be prioritized or funded at the expense of other vital health programmes.

National legislation, policies and resource allocation decisions should be informed by credible and current evidence regarding the direct and indirect impact of immunization. Much of the evidence base exists but does not reach policy-makers, as those who generate the evidence are not always those who interact with these decision-makers. Collaboration between, on the one hand, technical experts who generate the evidence and, on the other, the champions of immunization who construct context-specific messages that highlight the importance of immunization within health and social services, can unequivocally articulate the value of immunization and how immunization supports equity and economic development.



**All countries: Establish and sustain commitment to immunization;
Inform and engage opinion leaders on the value of immunization;
Strengthen national capacity to formulate evidence-based policies.**

Independent bodies, such as regional or national immunization technical advisory groups, that can guide country policies and strategies based on local epidemiology and cost effectiveness should be established or strengthened, thus reducing dependency on external bodies for policy guidance. These bodies can readily be supported by institutions or individuals charged with collating and synthesizing information required for informed decision-making. Regional support systems and initiatives, such as the PAHO ProVac initiative,⁷ can be expanded to support countries in strengthening their decision-making. It is important that national immunization technical advisory groups or their regional equivalents, engage with academia, professional societies, and other national agencies and committees, such as the vaccine regulatory agencies, national health sector coordination committees, and inter-agency coordination committees, in order to ensure a cohesive and coordinated approach to achieving national health priorities. Strong links between ministries of health, education⁸ and finance, as well as human resources and legislators are also essential for sustainable programme implementation.

Support and formal endorsement of national policies and plans at the highest political and administrative levels, nationally and subnationally, is considered essential for ensuring commitment and sustainability. Governments and elected officials are responsible for putting in place necessary legislation and budget allocations. As immunization is a strong indicator of the overall ability of the health system to deliver services, legislators should be encouraged to scrutinize, defend and closely follow immunization budgets, disbursements and immunization programme activities, both at the national level and within their respective constituencies. Civil society organizations can effectively advocate for greater commitment and hold governments accountable for commitments once they are made. Immunization programmes need to have management structures for programme implementation to be effective. Officials at the national and subnational levels responsible for implementation of the immunization plans can be held accountable for programme performance when they are sufficiently empowered to provide effective leadership and have the required management and programme monitoring skills.



Ensuring that national immunization plans are fully integrated into national health plans

For high- and middle-income countries, commitment to immunization should cover the same areas, but may also include maintaining or assuming the role of development partners. Together with global agencies, development partner countries can coordinate the sharing of information and best practices among countries, help bridge temporary funding gaps, and support capacity strengthening by working with stakeholders in different country settings.

TABLE 2: SUMMARY OF RECOMMENDED ACTIONS FOR STRATEGIC OBJECTIVE 1
ALL COUNTRIES COMMIT TO IMMUNIZATION AS A PRIORITY.



Establish and sustain commitment to immunization.	Inform and engage opinion leaders on the value of immunization.	Strengthen national capacity to formulate evidence-based policies.
<p>ENSURE legislation or legal framework in all countries, including provisions for a budget line for immunization, and for monitoring and reporting.</p> <p>DEVELOP comprehensive national immunization plans that are part of overall national health plans through a bottom-up process that includes all stakeholders.</p> <p>SET ambitious but attainable country-specific targets within the context of morbidity and mortality reduction goals.</p> <p>SCRUTINIZE, defend and follow more closely immunization budgets, disbursements and immunization programme activities.</p> <p>SUPPORT local civil society organizations and professional associations to contribute to national discussions on immunization and health.</p>	<p>EXPLORE models to promote collaboration between the stakeholders that generate evidence on immunization and those who use it in order to set priorities and formulate policies.</p> <p>DEVELOP and disseminate the evidence base on the public health value of vaccines and immunization and the added value of achieving equity in access and use of immunization.</p> <p>DEVELOP and disseminate the evidence base for the broad economic benefits of immunization for individuals, households, communities, and countries.</p> <p>INCLUDE immunization in the agendas of governing body meetings at all levels and in other social, health and economic forums.</p>	<p>CREATE, or strengthen existing, independent bodies that formulate national immunization policies (for example, national immunization technical advisory groups or regional technical advisory groups).</p> <p>DEVELOP more effective ways for national regulatory agencies, health sector coordination committees, and interagency coordination committees to support immunization programmes as part of disease control programmes and preventive health care.</p> <p>CREATE regional forums and peer-to-peer exchange of information, best practices and tools.</p> <p>CREATE expanded and more transparent mechanisms for aggregating, sharing and using information to monitor commitments.</p>

⁷ ProVac is a package of tools to support: (i) the estimation of cost-effectiveness and epidemiological and economic impact of new vaccines; (ii) training; and (iii) the strengthening of national infrastructure for decision-making.

⁸ Especially important for delivering immunization to older children and adolescents through school health programmes and for monitoring school entry requirements with immunization.

Strategic objective

2

Individuals and communities understand the value of vaccines and demand immunization as both their right and responsibility.

Significant improvements in coverage and programme sustainability are possible if individuals and communities understand the benefits and risks of immunization; are encouraged to seek services; are empowered to make demands on the health system; and have ownership of the planning and implementation of programmes within their local communities. Although there has generally been a high demand for vaccination services, accessing hard-to-reach populations, attaining higher coverage levels and achieving equity objectives may require additional approaches to stimulate demand for vaccination.

Generating individual, household and community demand will require using traditional platforms more effectively as well as new strategies to convey the benefits of immunization, emphasize immunization as a core component of the right to health and encourage greater use of services. New efforts could take advantage of social media and approaches used by commercial and social marketing efforts to promote immunization and address concerns. New mobile and Internet technologies should also be utilized, drawing on the experiences and successes of other innovative public health campaigns. Communications and social research to identify the barriers to and drivers of vaccination should inform the development of context-specific messages. Lessons on vaccines and immunization should be included in the primary school education curriculum. Multisectoral approaches that promote efforts, such as female education and empowerment, will help improve utilization of immunization and health services in general.



Significant improvements in coverage and programme sustainability are possible if individuals and communities understand the benefits and risks of immunization

Where appropriate, programme strategies could also include measures to provide an incentive both to households to seek immunization services and to health care providers to improve their performance in vaccinating children, particularly those that have not been reached previously. At the household level, conditional cash transfer programmes often include vaccination of children as a requirement for receiving household income transfers. There is evidence that such programmes may have a positive impact on immunization coverage rates, even in countries with high coverage rates, and particularly for more marginalized populations. Because conditional cash transfer programmes are often administered in countries as part of a broad package of social protection or poverty alleviation measures, these programmes provide an opportunity to link immunization programmes and health ministries with other broader development initiatives, including those administered by other ministries.

At the health facility level, both households and health care providers can be further motivated by in-kind gifts at the time of vaccination, or by giving performance-based financing bonuses to providers. There is some early evidence to suggest that performance-based financing of immunization services leads to increasing numbers of children being vaccinated, although more rigorous analysis of the impact of performance-based financing on immunization is still being carried out.

Providing incentives to health care workers and households through monetary and in-kind gifts has implementation challenges that need to be carefully addressed. These schemes need to respect the autonomy of beneficiaries. Social research is also needed to determine the conditions under which incentives contribute to improved coverage and the types and levels of incentives that are appropriate for a given context. Demand-generation activities must be coupled with mechanisms to ensure reliability of vaccine supply.

Some reasons for hesitancy are undoubtedly amenable to improved communications and advocacy initiatives designed to counteract growing anti-vaccination lobby groups and to increase understanding of the value of vaccines or of the danger of diseases. However, others are best addressed by ensuring the quality of the services provided. Individuals will be less hesitant to use services if they

Demand-generation activities must be coupled with mechanisms to ensure reliability of vaccine supply



perceive the quality of those services to be acceptable. They are more likely to come to vaccination sessions when scheduled services are convenient and predictably available; when practical counselling is offered about where and when to come for vaccination and why, and about what to expect following vaccination; when the health workers have a welcoming attitude; when waiting times are reasonable; and when services are offered without charge. Health care workers should receive training in effective communication to enable them to deal with the media and with local communities when there are reports of serious adverse events following immunization, in order to allay fears and tackle vaccine hesitancy.

Bringing about change will require the participation of individuals, households and communities in the development and implementation of all demand-generation strategies. It will also require new and stronger community-based advocates with local knowledge, credibility and the front-line experience necessary to drive change. The participation of in-country civil society organizations will be crucial to develop strong advocacy efforts and should be supported by capacity building. Here again, an effort that promotes collaboration between evidence generators and evidence users could provide training for champions and link with local social and professional networks, which are an important source of grass-roots immunization champions. This will especially be required as country programmes embrace a life-course approach to immunization. Current advocates must recruit new voices—potentially including educators, religious leaders, traditional and social media personalities, family physicians, community health workers and immunization champions. Researchers and technical experts will also have an important role in creating greater community awareness and providing credible responses to misinformation regarding immunization.

Generating individual and community demand will reinforce country commitment to vaccines and immunization ([strategic objective 1](#)). Activities to generate demand for vaccines and immunization should build on the broader movement in order to help people to hold their governments accountable for access to health services.



There is some early evidence to suggest that performance-based financing of immunization services leads to increasing numbers of children being vaccinated

**TABLE 3: SUMMARY OF RECOMMENDED ACTIONS FOR STRATEGIC OBJECTIVE 2
INDIVIDUAL AND COMMUNITIES UNDERSTAND THE VALUE OF VACCINES AND
DEMAND IMMUNIZATION AS BOTH THEIR RIGHT AND RESPONSIBILITY.**



Engage individuals and communities on the benefits of immunization and hear their concerns.

ENGAGE in a dialogue which both transmits information and responds to people’s concerns and fears.

UTILIZE social media tools and lessons learnt from commercial and social marketing efforts.

LEVERAGE new mobile and Internet-based technologies.

INCLUDE immunization in the basic education curriculum.

CONDUCT communications research.

Create incentives to stimulate demand.

CREATE incentives for households and health workers in favour of immunization, where appropriate, while respecting the autonomy of beneficiaries (for example, cash or in-kind transfers, bundling of services, media recognition).

CONDUCT social research to improve the delivery of immunization services and the ability to meet the needs of diverse communities.

Build advocacy capacity.

RECRUIT new voices, including those of educators, religious leaders, traditional and social media personalities, family physicians, community health workers, and trained immunization champions (among others).

TRAIN health-care workers in effective communication techniques, especially to address vaccine hesitancy and to respond to reports of serious adverse events following immunization in order to maintain trust and allay fears.

ENGAGE, enable and support in-country civil society organizations to advocate the value of vaccines to local communities and policy-makers and local and global media.

CREATE national or regional advocacy plans that involve in-country civil society organizations.

LINK global, national and community advocacy efforts with professional and academic networks.



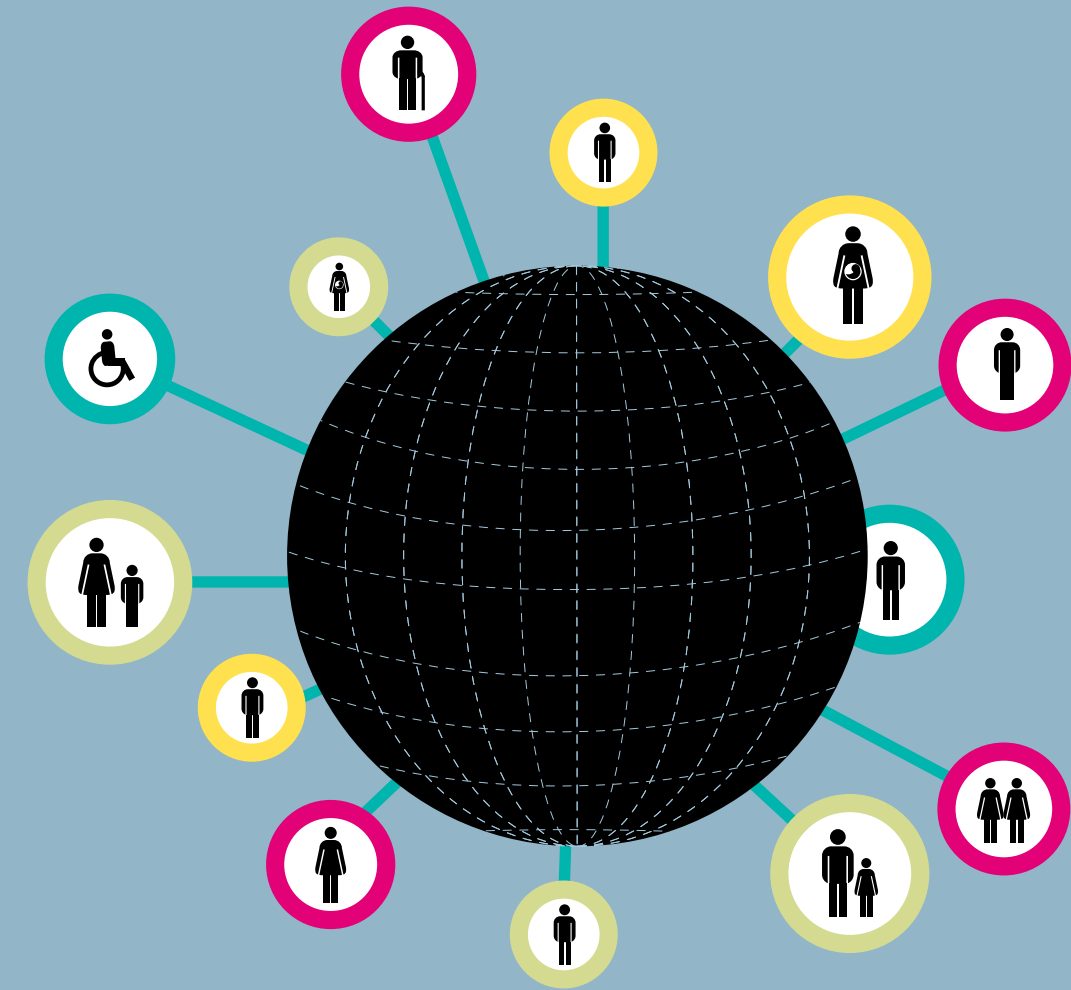
Strategic objective

3

The benefits of immunization are equitably extended to all people.

Today, four out of every five children receive at least a basic set of vaccinations during infancy and are therefore able to lead healthier, more productive lives. Unfortunately, this means one child in every five is not being reached. In this decade, the benefits of immunization should also be more equitably extended to all children, adolescents and adults. Achieving this strategic objective will mean that every eligible individual is immunized with all appropriate vaccines—irrespective of geographic location, age, gender, disability, educational level, socioeconomic level, ethnic group or work condition—thereby reaching underserved populations and reducing disparities in immunization both within and between countries. Because disease burdens tend to be disproportionately concentrated in more marginalized populations, reaching more people will not only achieve a greater degree of equity, but will also achieve a greater health impact and contribute to economic development. Furthermore, disease eradication and elimination goals cannot be met without achieving and sustaining high and equitable coverage.

In 2002, WHO, UNICEF and other partners introduced the concept of “Reaching Every District”, a first step toward achieving more equitable coverage. Through its various operational components, which include re-establishing outreach services, providing supportive supervision, engaging with communities, monitoring and use of data and district planning and resource management, the Reaching Every District strategy was able to expand the provision of immunization services. Similarly, initiatives aimed at disease eradication and elimination or rapid mortality reduction have used strategies, such as national or subnational immunization days (for poliomyelitis eradication) and supplementary immunization activities (for measles and rubella elimination,



Achieving this strategic objective will mean that every eligible individual is immunized with all appropriate vaccines—irrespective of geographic location, age, gender, disability, educational level, socioeconomic level, ethnic group or work condition

measles mortality reduction and neonatal tetanus elimination). More recently, strategies collectively referred to as periodic intensification of routine immunization have been used to extend immunization to the unreached, packaged together with other primary health care interventions.

Even these strategies continue to miss populations, for example those that reside outside traditional social and governmental structures. To sustain the gains of these historical efforts and to achieve and sustain disease control goals, the Reaching Every District strategic approach should be recast as “Reaching Every Community”. To attain more equitable coverage, the definition of community should be expanded beyond geographically defined communities. Reaching every community will mean aiming to encompass every eligible individual, even those beyond typical government outreach.

Reaching every community will call for an understanding of the barriers to access and use of immunization; it will also require the underserved to be identified, and micro-plans at the district and community levels to be reviewed and revised in order to ensure that these barriers can be overcome. The rapid expansion of information technology should be leveraged to establish immunization registries and electronic databases that will allow each individual’s immunization status to be tracked, timely reminders to be sent when immunization is due and data to be accessed easily to inform actions. The introduction of unique identification numbers could be a catalyst for the establishment of such systems.

Drawing on the experiences of successful poliomyelitis vaccination campaigns, decentralized planning and outreach should be used to reach populations that are remote or nomadic or that have been historically marginalized. New strategies for reaching the urban poor and urban migrants will also be necessary. Given the tenuous and evolving community structures and the inadequate security involved, new approaches to community outreach will be especially critical for reaching these groups. This is all the more true in view of the fact that sometimes the most unifying force in these urban and peri-urban areas is a shared and deep-seated mistrust of outsiders, especially governments.

The Reaching Every District strategic approach should be recast as “Reaching Every Community”



Implementing strategies to reach all underserved populations will require engagement with the nongovernmental sector, including civil society organizations and private sector organizations, and will need to involve all aspects of immunization including advocacy, social mobilization, service delivery and monitoring programme performance. To support such collaboration, governments should allocate increased resources to underserved communities and ensure that programmes have sufficient, well-trained personnel to execute strategies effectively. Partnerships across government sectors (for example, with educational institutions) and coordination with programmes that focus on vulnerable populations will be essential. In addition, efforts to provide high-quality immunization services to all children will need to continue unabated in order to protect gains already recorded.



Creating strategies for reaching individuals throughout their life course

There are other dimensions of equity that merit consideration during the Decade of Vaccines (2011–2020), including disparities between countries, adolescent and adult immunization, and immunization during emergencies.

Historically, it took decades before new vaccines used in high-income countries became available in low- and middle-income countries. Steps are being taken to address this inequity, including the introduction of new vaccines, with the support of the GAVI Alliance. However, much more needs to be done to sustain and extend these gains, particularly to middle-income countries.

A “life-course” approach must also be taken in order to make the benefits of immunization available to all those at risk in every age group. As diseases are being successfully controlled through infant immunization, the need to boost immunity to sustain and extend these gains is increasingly being recognized. In addition, new and existing vaccines that are beneficial for school children, adolescents and adults at special risk—such as health workers, immunocompromised individuals, animal handlers, and the elderly—for example, vaccines against human papillomavirus, influenza and rabies) are now available and being increasingly used. The success of efforts to eliminate maternal and neonatal tetanus and the benefits to both women and infants of influenza vaccination during pregnancy have increased interest in exploring the development of other vaccines that could be used during pregnancy (for example, group B streptococcus or respiratory syncytial virus vaccines). This will mean creating strategies for reaching individuals throughout their life course, and developing plans for the systems that will monitor and track progress.

Likewise, targeted plans are needed to ensure access to immunization during humanitarian crises, outbreaks and in conflict zones. These plans should include a focus on communication and provision for the development of vaccine stockpiles.

Social and operational research is needed to inform the design and test the effectiveness of the delivery strategies mentioned above. Key areas of focus for this research could include identifying the main causes of low coverage in particular areas and communities, assessing economic barriers to immunization, understanding the best approaches for reaching individuals of various ages, and assessing the most effective incentives for reaching different groups.



TABLE 4: SUMMARY OF RECOMMENDED ACTIONS FOR STRATEGIC OBJECTIVE 3
THE BENEFITS OF IMMUNIZATION ARE EQUITABLY EXTENDED TO ALL PEOPLE.

<p>Develop and implement new strategies to tackle inequities.</p>	<p>PREVENT and respond to vaccine-preventable diseases during disease outbreaks and humanitarian crises, and in conflict zones.</p>	<p>DEVELOP new approaches to community engagement for urban and peri-urban areas.</p>
<p>RECAST “Reaching Every District” to “Reaching Every Community” in order to deal with inequities within districts.</p>	<p>Build knowledge base and capacity for enabling equitable delivery.</p>	<p>TRAIN health workers and civil society organizations in engaging communities, in identifying influential people who can assist in planning, organizing and monitoring health and immunization programmes, as well as community needs, and in working with communities to meet those needs.</p>
<p>ENGAGE underserved and marginalized groups to develop locally tailored, targeted strategies for reducing inequities.</p>	<p>TRACK each individual’s immunization status, leveraging immunization registries, electronic databases and national identification number systems.</p>	<p>CONDUCT operational and social science research to identify successful strategies to reduce inequities and improve the quality and delivery of immunization services.</p>
<p>INTRODUCE appropriate new vaccines into national immunization programmes (see also objective 5).</p>	<p>TAKE advantage of community structures to enhance communication and deliver services (for example, traditional birth attendants, birth registries).</p>	
<p>ESTABLISH a life-course approach to immunization planning and implementation, including new strategies to ensure equity across the life span.</p>	<p>INVOLVE civil society organizations in community outreach and planning.</p>	

Strategic objective

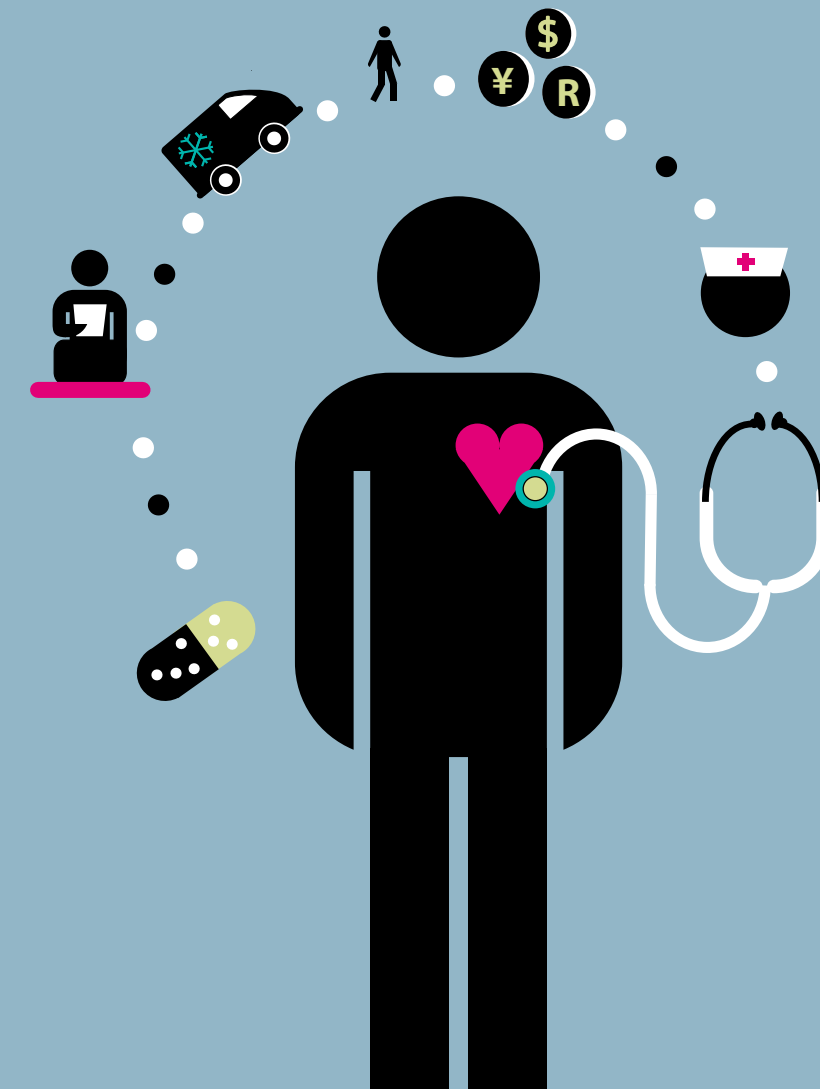
4

Strong immunization systems are an integral part of a well functioning health system.

The success of national immunization programmes in introducing new vaccines, attaining goals for quality, equity and coverage, and becoming financially sustainable depends upon a well functioning health system. The many interconnected components of an immunization system require multi-disciplinary attention in order to build a cohesive, non-fragmented and well-functioning programme that coordinates and works in synergy with other primary health care programmes.

Health systems encompass a range of functions from policy and regulation to information and supply chain systems, human resources, overall programme management and financing. Health systems include both the public and private sectors, and in some countries the private sector can play a valuable role in educating households about the need for and benefits of vaccination, as well as providing health care. Some of these functions have been dealt with in other sections of this document. This section discusses the actions required to foster greater coordination between immunization and other programmes within health systems and to strengthen the information, human resources, supply chain and logistics components of health systems.

Immunization service delivery should continue to serve as a platform for providing other priority public health interventions, such as those for vitamin A supplementation, deworming, and insecticide-treated bednets. Other priority programmes should also serve as a platform for delivering immunization. Every contact with the health sector should be used as an opportunity to verify immunization status and provide immunization where indicated. Furthermore,



Immunization service delivery should continue to serve as a platform for providing other priority public health interventions



Coordinating immunization with integrated primary health-care programmes may also facilitate social mobilization efforts

as new vaccines become available that target some but not all pathogens that cause particular syndromes, such as pneumonia, diarrhoea and cervical cancer, it is important that their introduction be an opportunity to scale up the delivery of complementary interventions. For example, the vaccines against pneumococcus and rotavirus should be complemented with other actions to protect, prevent and treat related respiratory and diarrhoeal diseases.

New vaccine deployment should therefore be accompanied by comprehensive disease-control plans both within countries and globally. Coordination of immunization with other services should take place at all levels of a country's programmes, involve outreach efforts and participation by health centres, and be a part of programme management. Coordinating immunization with integrated primary health-care programmes may also facilitate social mobilization efforts, helping to generate community demand for services ([strategic objective 2](#)) and address inequity ([strategic objective 3](#)). Additionally, efforts should be made to ensure that global vaccine programmes focused on eradication and elimination goals (for example, poliomyelitis and measles campaigns) do not operate in silos. The choice of mechanisms to promote greater interaction and coordination between different programmes should be made by countries according to their local context. The synergies and efficiencies as a result of integration and coordination will be particularly beneficial in countries with fragile health systems.

Access to timely high-quality information is essential for effective immunization. Critical information includes process indicators that allow programmes to monitor their performance and take corrective action, and outcome indicators that measure the impact of programmes. Output and impact indicators need to be analysed along with expenditures in order to identify bottlenecks and best practices and to gauge overall programme efficiency (value for money). Immunization information systems need to be linked to broader health information systems, while remaining readily accessible and meeting immunization programme needs.

Monitoring of immunization coverage and dropout rates has been in place since the launch of the Expanded Programme on Immunization to ensure programme effectiveness. Although the quality and timeliness of data reporting have improved steadily over the years, the quality of administrative coverage data is still inadequate in many countries. Furthermore, the use of data in order to take corrective action at district and community levels is still unsatisfactory. New approaches to immunization tracking through unique identification numbers (discussed in [strategic objective 3](#)) can improve the quality of immunization coverage data and facilitate the development of comprehensive immunization registries. New technologies, including hand-held communication devices and mobile phones, can support this effort and facilitate data sharing. Armed with higher-quality data and new data-analysis tools, programme managers at all administrative levels can use information to improve programme performance, allocate funding appropriately, and track progress more effectively.

Disease surveillance is critical for informing decision-making on the adoption of new vaccines and on the strategies for their use in their respective national programmes. Such surveillance is also essential for monitoring the impact of immunization and changes in disease epidemiology, and for supporting sustained use. Robust epidemiological data will also be crucial for understanding vaccine effectiveness and guiding priorities in the research and development community, and will help to identify the areas where research and development is most needed ([strategic objective 6](#)). Disease surveillance platforms need to be strengthened to improve the quality and sharing of information. This will include strengthening laboratory capacity for microbiological confirmation of diagnosis and for tracking the spread of diseases using molecular typing techniques.



On rare occasions, adverse reactions can affect the health of vaccine recipients. More frequently, coincidental health events can follow immunization and may be wrongly attributed to vaccines. In both instances, it is extremely important to detect and analyse promptly serious adverse events following immunization. To assist low- and middle-income countries in managing such important issues, WHO and its partners have developed the Global Vaccine Safety Blueprint. This strategic plan will enable the countries concerned to have at least minimal capacity for vaccine safety activities; it will also enhance capacity for vaccine safety assessment in countries that introduce newly developed vaccines, that introduce vaccines in settings with novel characteristics or that both manufacture and use prequalified vaccines; and it will establish a global vaccine safety support structure. Implementing the Global Vaccine Safety Blueprint strategies to build capacity for safety surveillance during the Decade of Vaccines (2011–2020) will ensure that everyone everywhere receives the safest vaccines possible and that safety concerns are not a cause of hesitancy in using vaccines.

Ensure that everyone everywhere receives the safest vaccines possible and that safety concerns are not a cause of hesitancy in using vaccines

The increasing complexity of immunization programmes and ambitious new goals, mean that more trained health workers are needed to manage the increased burden of work, including programme managers at the national and subnational levels as well as front-line workers who deliver services and interact directly with communities. Programme managers need to be equipped with technical knowledge about vaccines and immunization, as well as with management skills. Front-line health workers, who deliver not only vaccinations but also primary health care interventions and health education, need coordinated, comprehensive and very practical pre- and in-service training, with updated, relevant curricula and post-training supervision. Health-care workers need to be able not only to explain why immunization is important, but also to give advice to individuals and communities on nutrition, create a healthier environment and recognize the danger signs when someone falls ill. Immunization programmes should ensure that this training and supervision is effectively extended to community-based health workers. Civil society organizations can help with training and coordinating such workers.

Health workers can only be effective if sufficient supplies (vaccines, supplements and medicines) are available when they need them. The influx of new vaccines has outstripped the capacity of the current cold-chain system in many countries. Thus, supply chains and waste management systems urgently need to be expanded and made more efficient and reliable. They should be streamlined to maximize effectiveness. They should also take into account and make an effort to minimize the environmental impact of energy, materials and processes used for immunization both within countries and globally. The availability of new technologies provides the opportunity to innovate, not only to improve immunization supply chain management, but also to seek increased synergies with other sectors and supply systems for other health interventions. Another potential area of innovation concerns understanding the lessons learnt from private-sector practices and supply chain management. In addition, tasks that could be outsourced to private sector companies in order to create greater efficiency should be explored.



The availability of new technologies provides the opportunity to innovate



Front-line health workers need coordinated, comprehensive and very practical pre- and in-service training

It will be essential to ensure that immunization supply systems are staffed with adequate numbers of competent, motivated and empowered personnel at all levels. Likewise, improvements to health information systems should also support the management of resources, helping staff to ensure that adequate quantities of vaccines are always available to meet demand. Efforts to strengthen supply chains should be implemented in such a way that they benefit both immunization programmes and broader national health efforts.

Developing stronger, more efficient, comprehensive approaches to disease control and immunization will require health ministries to take the lead in strengthening and coordinating immunization programmes and health systems more broadly, including engaging civil society organizations, academia and private practitioners. They can draw on the expertise of academics to help develop and deploy new tools and approaches to service delivery. Civil society organizations can contribute to the development of integrated programmes so that they are aligned with local realities and incorporate community-based human resources. Communities can ultimately hold their governments accountable by demanding integrated services. Regional and global organizations can also help by ensuring that data and best practices are shared in and across countries and that country programmes have access to analytical tools. Development partners can provide supplemental financial resources if needed.



**TABLE 5: SUMMARY OF RECOMMENDED ACTIONS FOR STRATEGIC OBJECTIVE 4
STRONG IMMUNIZATION SYSTEMS THAT ARE AN INTEGRAL PART OF A
WELL-FUNCTIONING HEALTH SYSTEM.**

Develop comprehensive and coordinated approaches.

ENSURE that global vaccine programmes focusing on eradication and elimination goals (for example, poliomyelitis and measles campaigns) are incorporated into national immunization programmes and do not operate independently.

ENSURE that new vaccine deployment is accompanied by comprehensive plans to control targeted diseases.

ENSURE coordination between the public and private sectors for new vaccine introduction, reporting of vaccine-preventable diseases and administration of vaccines, and ensure quality of vaccination in the public and private sectors.

CONSIDER the inclusion of vaccines (as appropriate to national priorities) in health programmes across the life-course.

Strengthen monitoring and surveillance systems.

IMPROVE the quality of all administrative data concerning immunization and promote its analysis and use at all administrative levels to improve programme performance.

DEVELOP and promote the use of new technologies for collection, transmission and analysis of immunization data.

FURTHER strengthen and expand disease surveillance systems to generate information for decision-making, monitoring the impact of immunization on morbidity and mortality and changes in disease epidemiology.

ENSURE capacity for vaccine safety activities, including capacity to collect and interpret safety data, with enhanced capacity in countries that introduce newly developed vaccines.

Strengthen capacity of managers and frontline workers.

ENSURE that immunization and other primary health-care programmes have adequate human resources to schedule and deliver predictable services of acceptable quality.

INCREASE levels of pre-service, in-service and post-service training for human resources, and develop new, relevant curricula that approach immunization as a component of comprehensive disease control.

PROMOTE coordinated training and supervision of community-based health workers.

Strengthen infrastructure and logistics.

INNOVATE to improve cold-chain capacity and logistics, as well as waste management.

MINIMIZE the environmental impact of energy, materials and processes used in immunization supply systems, both within countries and globally.

STAFF supply systems with adequate numbers of competent, motivated and empowered personnel at all levels.

ESTABLISH information systems that help staff to track the available supply accurately.

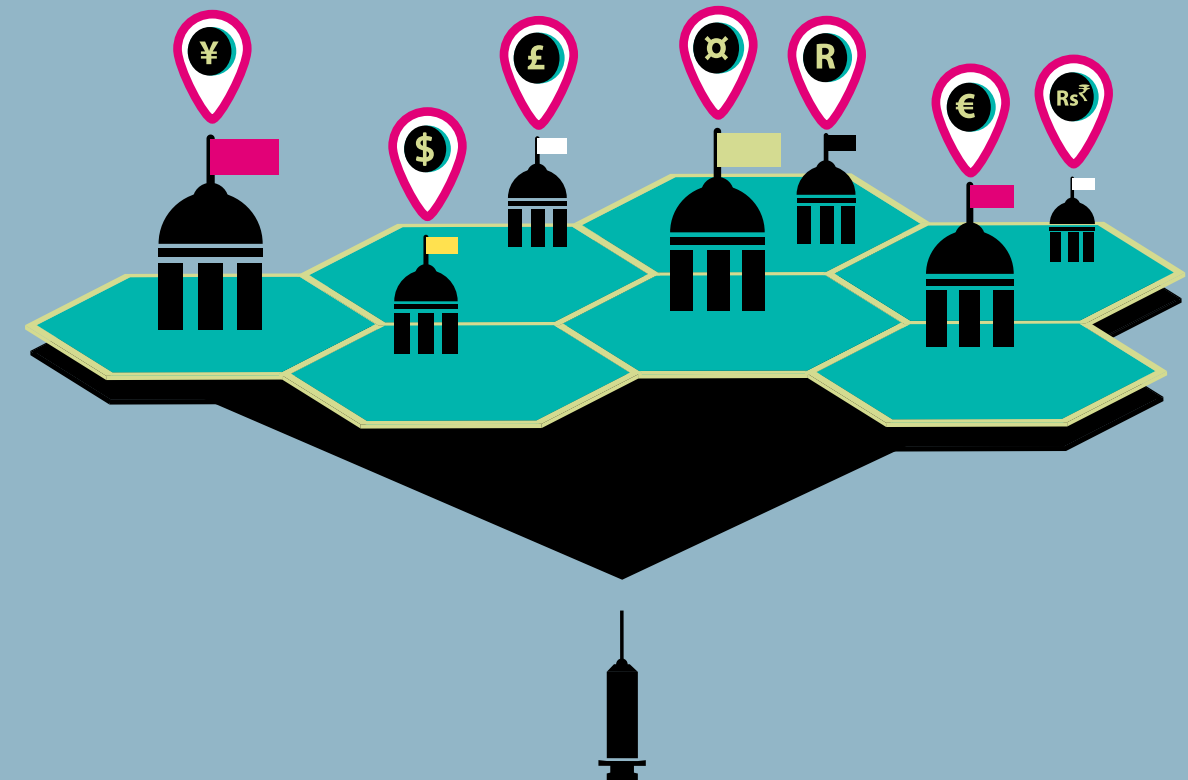
Strategic objective

5

Immunization programmes have sustainable access to predictable funding, quality supply and innovative technologies.

To meet goals of the Decade of Vaccines (2011–2020), actions must be taken both within countries and globally to increase the total amount of available funding for immunization from both countries and development partners. Countries should ensure the financial sustainability of national immunization programmes through regular evaluation of resource needs; efficiency in service delivery; availability of adequate domestic financing; and resource mobilization from development partners to meet any funding gaps. Governments also need to explore alternative and innovative financing mechanisms for health and immunization. Some countries have established trust funds or use dedicated tax revenues, among other strategies. In addition, it is important to move beyond budgets and into expenditures. Governments can improve vaccine access and prevent shortages of vaccines, immunization equipment or health workers by assuring that budgeted funds are disbursed in an ongoing and timely fashion that responds to programmes' needs.

Although the financing of immunization services is first and foremost a core responsibility of governments, development partners should support national strategies through more predictable, longer-term financing, and should also explore the next generation of innovative financing mechanisms. Emphasis needs to be placed on mutual accountability between countries and their development partners in terms of immunization financing. One possible



Actions must be taken both within countries and globally to increase the total amount of available funding for immunization



A crucial but often overlooked key driver underpinning all these interventions is the quality assurance of vaccines

approach is to undertake annual resource tracking of immunization financing from partners and governments alike. For both countries and development partners, evidence-based advocacy and policy efforts should be focused on obtaining a renewed commitment to past funding pledges.

There is also a need to improve the allocation, accountability and sustainability of funding. Coordinating funding support from development partners and other external sources to target national budget priorities will ensure that funds are addressing the most pressing country needs. Funding allocation strategies should be revised periodically to confirm they are achieving goals, such as eradication and elimination of disease, as quickly and as effectively as possible. Feedback loops should be established to enhance programme sustainability, results and impact. One potential methodology to explore is a pay-for-performance funding system. However, the merits of this approach must be balanced against the importance of ensuring the predictability of funding, the risks of creating perverse incentives, and the fact that implementation of such a scheme requires high-quality data. This would include linking international, national, and local funding distribution to specific performance metrics and leveraging the resulting metrics to promote programme improvement.

Innovative pricing and procurement mechanisms are needed to alleviate funding pressure and to support the development and scale-up of new and existing vaccines. Innovations will be particularly important for those lower-middle-income countries that do not have access to the PAHO, UNICEF and GAVI Alliance pricing and procurement mechanisms. Mechanisms to explore include differential pricing using new approaches to define price tiers and pooled negotiation or procurement methods for lower-middle-income countries. Current pooled procurement models exist in both the vaccines and pharmaceuticals markets. One example is the PAHO revolving fund pooled procurement and short-term credit mechanism. This and other models could be assessed and modified to best suit the needs of the lower-middle-income countries and the individual vaccine markets.

The provision of long-term sustainable funding will be an incentive to manufacturers, thereby improving supply security. In addition, supply-side interventions are needed. A growing proportion of affordable vaccines that are used to immunize the world's population are manufactured in middle- and lower-middle-income countries. In the coming decade, these countries will not only have a requirement to ensure the quality, safety and efficacy of vaccines used domestically, but also a growing global obligation to protect and enhance the security of the global immunization enterprise. Potential supply-side interventions to ensure quality, safety and efficacy include identifying and disseminating best practices in manufacturing and quality control, investing in research and development capabilities, and initiating technology transfers and co-development agreements.

A crucial but often overlooked key driver underpinning all these interventions is the quality assurance of vaccines. Good-quality assurance relies crucially on effective standardization, which ensures that each vaccine product can be manufactured consistently and also enables multiple manufacturers to make similar products of the same quality. Normative processes to achieve globally harmonized standards for vaccines already exist, including international biological reference materials, but action is needed to strengthen global standardization.



In addition, each country should develop the capacity to monitor and assure the safe use of vaccines, in line with the strategy defined in the WHO Global Vaccine Safety Blueprint initiative (as discussed under [strategic objective 4](#)). Action should also be taken to strengthen national regulatory systems and develop globally harmonized regulations in order to ensure that the increasing demand for regulatory reviews can be managed in an effective and timely manner. This is an issue not just for low- and middle-income countries involved in technology transfer, but also for regulatory agencies in high-income countries where expertise and resources need to be maintained. These supply-side interventions need to be based on solid business cases developed by countries to ensure the impact of these significant and long-term investments.

Making change happen with respect to sustainable funding will require commitments from governments and development partners to increase resources and improve programme efficiencies, as well as from additional countries joining the development partner ranks. Likewise, sustainable supply will require the multisectoral involvement of governments (for example, the science and technology, trade, industry and health sectors) in order to create an environment that helps suppliers to strengthen their capabilities. Emerging economies have a particularly important role to play in both cases, given their high rate of economic growth and the rapid expansion of the supply base there.

To increase alignment, activities currently performed by the UNICEF Supply Division and the GAVI Alliance to improve communication and coordination among countries, vaccine manufacturers and public-sector organizations should be further expanded. Countries need a forum where they can more clearly communicate expected demand for new vaccines and provide guidance on desired product profiles. This first-hand information would enable suppliers to make more informed product development and capacity planning decisions, thereby mitigating product development and supply risk. This information would also help development partners and other public-sector organizations to establish more defensible and reliable strategies and support plans. This forum could further be utilized to enable suppliers to accurately communicate the possible current and future range of pricing and supply to countries, and for countries to share information on and experience with vaccine procurement.



**TABLE 6: SUMMARY OF RECOMMENDED ACTIONS FOR STRATEGIC OBJECTIVE 5
IMMUNIZATION PROGRAMMES HAVE SUSTAINABLE ACCESS TO LONG-TERM FUNDING
AND QUALITY SUPPLY.**

Increase total amount of funding.	Improve allocation of funding in low- and middle-income countries.	Secure quality supply.
<p>ESTABLISH a commitment for governments to invest in immunization according to their ability to pay and the expected benefits.</p> <p>ENGAGE new potential domestic and development partners and diversify sources of funding.</p> <p>DEVELOP the next generation of innovative financing mechanisms.</p>	<p>STRENGTHEN budgeting and financial management in-country to better integrate financial and health care planning and priority setting.</p> <p>COORDINATE funding support from development partners and other external sources.</p> <p>EVALUATE and improve funding support mechanisms on the basis of their effectiveness in reaching disease goals.</p>	<p>BUILD and support networks of regulators and suppliers to share best practices and to improve quality assurance capabilities and quality control.</p> <p>DEVELOP tools to strengthen global standardization of manufacturing and regulatory processes.</p> <p>STRENGTHEN national regulatory systems and develop globally harmonized regulations.</p>
Increase affordability for middle-income countries.	<p>BASE funding on transparency and objectivity in order to ensure the sustainability of programmes.</p> <p>PROMOTE the use of cost and cost-benefit arguments in fund raising, decision-making, and in defence of immunization funding.</p> <p>EXPLORE pay-for-performance funding systems.</p>	<p>PROVIDE a forum where countries can communicate expected demand for vaccines and technologies and provide guidance to manufacturers on desired product profiles.</p>
<p>EXPLORE differential pricing approaches to define explicit criteria for price tiers and the current and future prices to be made available to lower middle-income and middle-income countries.</p> <p>EXPLORE pooled negotiation or procurement mechanisms for lower-middle-income and middle-income countries.</p>		

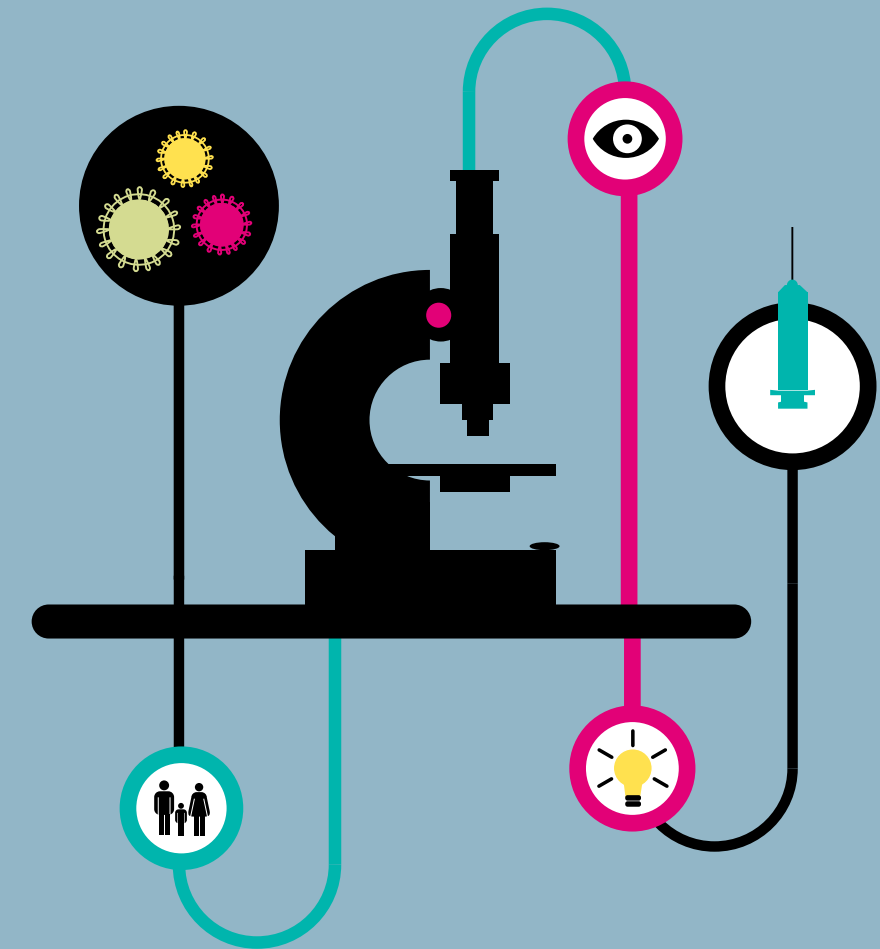
Strategic objective

6

Country, regional and global research and development innovations maximize the benefits of immunization.

In the coming decade, targeted and innovative research and development efforts are needed across discovery, development and delivery. Innovative research and development efforts will lead to: (1) identification of mechanisms of protection and pathogenesis; (2) well-defined and novel antigenic targets for development of new vaccines; (3) development of bio-processing, formulation, manufacturing and delivery technologies for new and improved vaccines; and (4) development of disease-burden and cost-effectiveness data for in-country decision-making.

WHO has conducted a detailed study of disease prioritization and the Institute of Medicine in the United States of America is in the process of developing a model designed to assist decision-makers in prioritizing preventive vaccines based on health, economic, demographic, programmatic and social impact criteria, as well as scientific, technical and business opportunities. The Decade of Vaccines collaboration has not undertaken a vaccine or disease prioritization exercise. To complement the above efforts, a spectrum of research and development needs is presented across discovery, development and delivery, from which stakeholders can choose to invest according to their own priorities and perceptions of the return on their investments.



Research is needed to accelerate development, licensing and uptake of vaccines that are currently in early development



Scientists from disciplines not previously engaged in vaccine research will need to be recruited

Across all research and development activities, increased engagement and consultation with end-users is needed to ensure that technologies and innovation are prioritized according to real demand and added value. New arrangements will also be required to facilitate the transfer of technologies and access to and sharing of associated information, while acknowledging and respecting intellectual property rights. In order to support this work and maximize its effectiveness of, scientists from disciplines not previously engaged in vaccine research (systems biology, nanotechnology, structural biology and metabolomics) will need to be recruited. Chemical and mechanical engineers, chemists and information technology specialists will also have key roles to play in this endeavour. In addition, capacity building and human resource development are needed in low- and middle-income countries to conduct research and development, including finding better ways to conduct operational research and evaluate immunization programmes. Research and development is being conducted in institutions of excellence in many low- and middle-income countries. This capacity is producing indigenous data, as well as fostering bilateral and multilateral collaboration in basic sciences and vaccine development. Capacity can be further strengthened through peer-to-peer training and exchanges between countries. Greater networking among research centres (from discovery to clinical trials) will facilitate the exchange of ideas and the efficient building of partnerships among institutions in high-, middle- and low-income countries.

Discovery and basic research will lay the groundwork for impact in future decades. Research at the interface between host and pathogen is needed to enable the development of new vaccines. Advancing knowledge of innate and adaptive immune responses will permit more rational vaccine design. Strengthening the understanding of immunologic and molecular characteristics of microbes through systems biology will permit the identification of new antigenic targets for vaccine development and effective ways of predicting protective immune responses and mechanisms of protection. Appropriate studies of host genetics and biomarkers will contribute to understanding the causes of variation in human population responses to vaccines, or susceptibility to adverse effects.

For the development of new and improved vaccines and vaccine technologies, the research and development community will benefit from adopting best practices in portfolio and partnership management, including the identification of early indicators of success and failure to inform milestone-based investments. The community should also consider new approaches to ensure promising vaccine candidates are advanced from discovery to development, particularly where market incentives are insufficient. This is especially important for vaccines to prevent “neglected” diseases.

Research is needed to accelerate development, licensing and uptake of vaccines that are currently in early development, including development of technologies for more efficacious and less expensive manufacturing of vaccines. Greater access to the technology and associated information for adjuvants and their formulation into vaccines is needed for advances in developing new and more effective vaccines. Non-syringe delivery mechanisms and vaccine packaging that best suit the needs and constraints of countries, as well as thermostable vaccines and new bioprocessing and manufacturing technologies, are priority research areas for accelerating the development of next-generation vaccines that are more effective, less expensive and easier to manufacture and deliver.



Non-syringe delivery mechanisms as well as thermostable vaccines are priority research areas

Additionally, the elaboration and aggressive pursuit of a global regulatory science agenda will improve manufacturing efficiency, better characterize products, improve clinical trial design and safeguard the highest standards for vaccine safety and efficacy. The challenge is considerable in achieving understanding of the adverse effects, finding ways to avoid them and yet not compromising the known efficacy of the existing product—and without incurring the costs of developing, testing and registering a new product. In this dimension, research on animal models and in vitro systems that better predict safety and efficacy would shorten the time for developing safe and effective vaccines and for making them available to communities. Knowledge of the correlates of protection and safety will greatly help to bring these second-generation products to licensure and use.

With respect to delivery, priority areas to improve programme efficiency and increase vaccine coverage and impact should include research on the use of effective information through modern communication technologies and social research in order to understand the cultural, economic and organizational determinants of immunization. Health economic analysis will guide the introduction and prioritization of vaccines, and hence representative epidemiological, immunological and operational studies and studies of vaccine impact will be needed.

Operational research on the most effective delivery approaches is also needed in order to overcome the challenges posed by life-course immunization (newborn, infant, adolescent, pregnant women, elderly, among others) and vaccination in emergency and outbreak situations. Research on immunological interference effects and optimization of delivery schedules will be required as more new vaccines are introduced into routine programmes and immunization is extended beyond the first year of life. In the case of special populations, such as pregnant women, confirmation of safety will be particularly important. Furthermore, research is required in order to develop bio-markers for validating immunization coverage estimates and enabling better measurement of population-level immunity profiles. In addition, research to develop field-usable and cost-effective diagnostic tools for establishing etiology that are suited for use at point-of-care in low-income countries will be valuable additions to improving surveillance quality.



Concerted action among the research community, manufacturers, health professionals, programme managers, national immunization technical advisory groups, vaccine regulatory agencies and development partners will be needed to attain the full potential of research and development in the next decade. Methods and arguments for prioritization and allocation of scarce resources will have to be agreed upon by these groups, balancing the tensions between country-driven choices and the need for large-scale research efforts and markets in order to sustain development and commercialization. Health professionals, programme managers, vaccine regulatory agencies and national immunization technical advisory groups can help to identify areas where innovations could be made, and assess their real demand and added value. Development partners can help promote a judicious allocation of some resources for research and development, according to the agreed priorities. The research community and manufacturers will have prime responsibility for promoting innovation and pursuing the research agenda defined above.



Operational research on the most effective delivery approaches is also needed in order to overcome the challenges posed by life-course immunization

**TABLE 7: SUMMARY OF RECOMMENDED ACTIONS FOR STRATEGIC OBJECTIVE 6
COUNTRY, REGIONAL, AND GLOBAL RESEARCH AND DEVELOPMENT INNOVATIONS
MAXIMIZE THE BENEFITS OF IMMUNIZATION.**



Expand capabilities and increase engagement with end-users.

ENGAGE with end-users to prioritize vaccines and innovations according to perceived demand and added value.

ESTABLISH platforms for exchange of information on immunization research and consensus building.

BUILD more capacity and human resources in low- and middle-income countries to conduct research and development and operational research.

INCREASE networking among research centres for efficient building of partnerships among the institutions of high-, middle- and low-income countries.

PROMOTE collaboration between traditional research disciplines and scientists from disciplines not previously engaged in vaccine research.

Improve programme efficiencies and increase coverage and impact.

RESEARCH the use of more effective information through modern communication technologies.

CONDUCT representative epidemiological, immunological, social and operational studies and investigations of vaccine impact to guide health economics analysis.

PERFORM operational research on improved delivery approaches for life-course immunization, and vaccination in humanitarian emergencies, so-called fragile States and countries in and emerging from conflict.

PERFORM research on interference effects and optimum delivery schedules.

PERFORM research to develop improved diagnostic tools for conducting surveillance in low-income countries.

Accelerate development, licensing and uptake of vaccines.

PROMOTE greater access to technology, expertise and intellectual property for adjuvants and their formulation into vaccines.

DEVELOP non-syringe delivery mechanisms and vaccine packaging that best suit the needs and constraints of national programmes.

DEVELOP thermostable rotavirus and measles vaccines.

DEVELOP new bioprocessing and manufacturing technologies.

DEVELOP a global, regulatory science research agenda.

ADOPT best practices in portfolio and partnership management for research and development.

Enable the development of new vaccines.

RESEARCH on the fundamentals of innate and adaptive immune responses, particularly in humans.

RESEARCH on immunological and molecular characteristics of microbes.

IMPROVE understanding of the extent and causes of variation in pathogens and human population responses to vaccines.



A spectrum of research and development needs is presented across discovery, development and delivery

Health Returns on Investment in Immunization

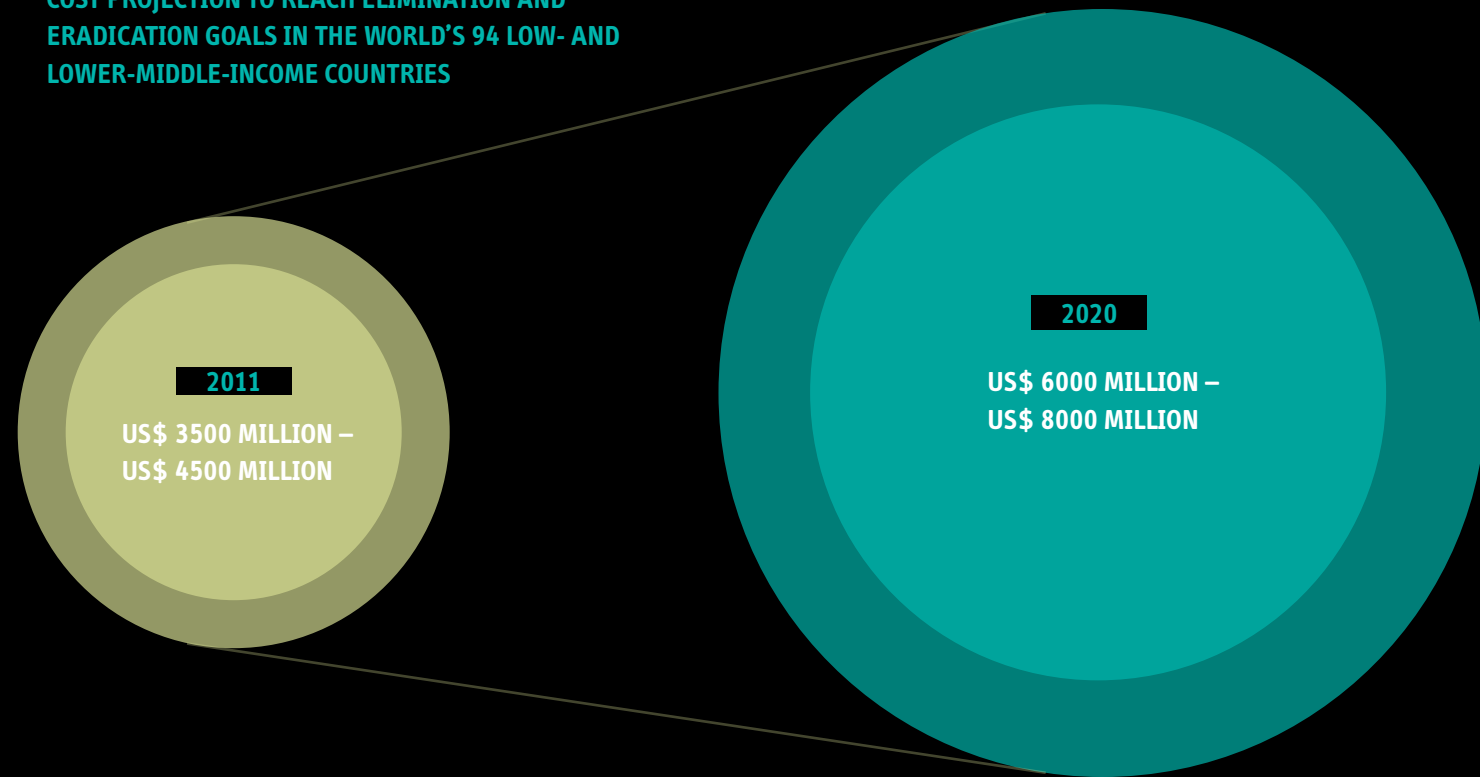
The Global Vaccine Action Plan has outlined a set of ambitious goals and strategic objectives for the decade to broaden the impact and reach of immunization across the globe. By extending coverage for existing vaccines, introducing new vaccines and pursuing elimination and eradication for specific diseases, millions of deaths can be averted and billions of dollars in economic benefit can be generated.



All stakeholders investing together will drive a significant health and economic impact

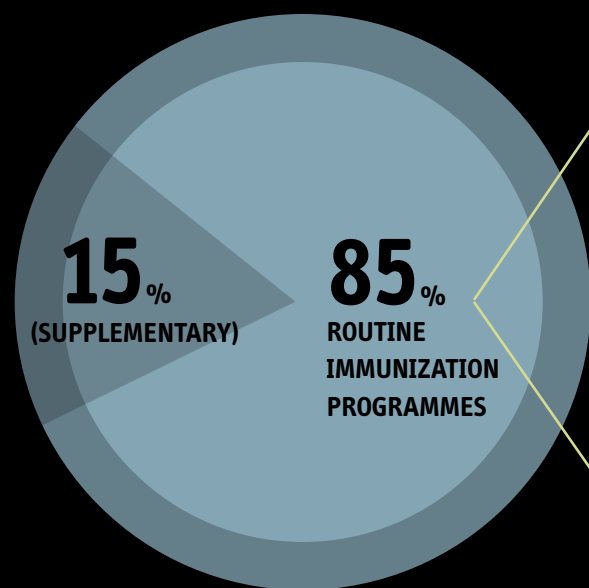


COST PROJECTION TO REACH ELIMINATION AND ERADICATION GOALS IN THE WORLD'S 94 LOW- AND LOWER-MIDDLE-INCOME COUNTRIES



COSTS CUMULATIVELY OVER THE COURSE OF THE DECADE (2011-2020)

US\$ 50 000 MILLION – US\$ 60 000 MILLION



SUPPLEMENTARY IMMUNIZATION ACTIVITIES for accelerated disease control and eradication and elimination efforts throughout the decade

COVERAGE EXAMPLES

2011 2020

PNEUMOCOCCAL VACCINE COVERAGE

8% 90%

PENTAVALENT VACCINE

50% 90%

UP TO FIVE ADDITIONAL VACCINES



It is projected that costs to sustain and scale up current immunization programmes, introduce new and underutilized vaccines, and conduct supplemental immunization activities to reach elimination and eradication goals in the world's 94 low- and lower-middle-income countries will rise from between US\$ 3500 million and US\$ 4500 million in 2011 to between US\$ 6000 million and US\$ 8000 million in 2020, costing approximately between US\$ 50 000 million and US\$ 60 000 million cumulatively over the course of the decade (from 2011 to 2020). The following estimates all pertain to these 94 countries.⁹

An estimated US\$ 42 000 million to US\$ 51 000 million of these costs (roughly 85% of the total) will support expanding routine immunization coverage and introducing additional vaccines to routine immunization programmes.¹⁰ For example, pneumococcal vaccine coverage for the birth cohort in the 94 countries is projected to go from 8% in 2011 to approximately 90% by 2020. Similarly, coverage with the pentavalent vaccine (against diphtheria-tetanus-pertussis hepatitis B and Hib) is projected to move from 50% in 2011 to more than 90% by 2020. To take another example, it is anticipated that up to five additional vaccines that are currently not licensed or widely used in low- and lower-middle-income countries will be introduced across many of the countries in the analysis during the decade: vaccines against cholera, dengue and malaria, inactivated poliovirus vaccine, and typhoid Vi conjugate vaccine. Delivery programmes will need to be strengthened to ensure they meet current needs, are well-maintained over the decade, have sufficient capacity to accommodate additional vaccines that are planned to be introduced, and facilitate immunization coverage aspirations across low- and lower-middle-income countries. As a consequence, the costs of annual routine immunization will increase from approximately US\$ 2500 million in 2011 to US\$ 7500 million by 2020.

Of these costs, an estimated cumulative figure of between US\$ 8000 million and US\$ 9000 million (the remaining 15% of the total) will be for supplementary immunization activities for accelerated disease control and eradication and elimination efforts throughout the decade, which will complement routine immunization programmes. This analysis assumes that these efforts will be focused on measles, meningococcus A meningitis, poliomyelitis, rubella, tetanus and yellow fever.

24-26
million future deaths
could be averted

⁹ Countries included in the scope of the costing analysis include 92 low- and lower-middle-income countries according to the July 2011 World Bank Classification (available at <http://www.icsoffice.org/Documents/DocumentsDownload.aspx?Documentid=474>, accessed 11 April 2012) in addition to two upper-middle-income countries (Azerbaijan and Cuba) which receive GAVI Alliance support for existing vaccines, but which have graduated from support for future vaccines.

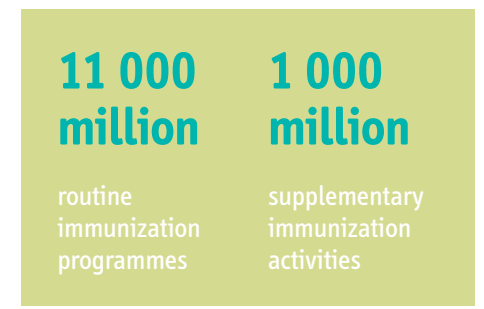
The costs described above for routine and supplementary immunization activities encompass the projected costs of the acquisition of vaccines and injection supplies, as well as the delivery of those vaccines and supplies, including transportation and cold chain logistics, human resources, training, social mobilization, surveillance and programme management. These costs do not include the additional costs or efficiencies that may be generated through the actions recommended in the global vaccine action plan where there is an insufficient evidence base for these costs at this time. Specifically, it does not include the additional cost of scaling up seasonal influenza vaccination or the additional resource needs for increased surveillance, increased civil society engagement, and current and additional technical agency support to implement the Global Vaccine Action Plan. Nevertheless, the costs do represent the majority of the cost of achieving the strategic objectives of the Decade of Vaccines (2011–2020).

The governments of low- and lower-middle-income countries will continue to play a pivotal role in meeting resource needs. Assuming that country funding for immunization grows in line with projected gross domestic product and all GAVI Alliance-eligible countries fully meet its co-financing requirements, it is estimated that the available funding from country governments for routine immunization and supplemental immunization activities could total approximately US\$ 20 000 million over the decade. In addition, if the GAVI Alliance renews its current level of funding for the 2016–2020 period, its resources will generate an estimated additional US\$ 12 000 million of funds for the decade, approximately US\$ 11 000 million for routine immunization programmes and approximately US\$ 1 000 million for programmes involving supplementary immunization activities. Based on these assumptions, country governments and the GAVI Alliance combined could provide a total of approximately US\$ 32 000 million in funding for the decade. These estimates could be considered the minimum available financing over the decade because they do not include contributions from development partners beyond that provided through the GAVI Alliance (owing to the considerable uncertainty surrounding future levels of development partner financing).

Meeting the estimated US\$ 18 000 million to US\$ 28 000 million in additional funding will require commitment from all stakeholders, with governments needing to continue making immunization a priority in resource allocation decisions; development partners needing to sustain and bolster access to

10 Diseases covered by the vaccines included in the scope of the costing analysis include: diphtheria-tetanus-pertussis, hepatitis B, *Haemophilus influenzae* type b, human papillomavirus, Japanese encephalitis, measles, meningococcus A, mumps, pneumococcus, poliomyelitis, rotavirus, rubella, tuberculosis and yellow fever.

If the GAVI Alliance renews its current level of funding for the 2016–2020 period, its resources will generate an estimated additional US\$ 12 000 million for the decade:



funding for immunization in spite of competing priorities; and the entire community needing to continue efforts to reduce the cost of vaccine acquisition and immunization service delivery.

All stakeholders investing together will drive a significant health and economic impact. Work to sustain or extend coverage of existing vaccines and efforts to introduce new vaccines, if undertaken together, have the potential to avert millions of future deaths, as well as hundreds of millions of cases of disease, and generate hundreds of billions of dollars in economic impact over the decade.

As an example of the potential impact of immunization, a sub-analysis of 10 vaccines, delivered during the decade, that represent an estimated US\$ 42 000 million of the US\$ 50 000 million to US\$ 60 000 million cost for the decade,¹¹ have the potential to avert in total between 24 and 26 million future deaths (Table 8) as compared with a hypothetical scenario under which these vaccines have zero coverage.¹²

11 Vaccines included in health benefits analysis cover the following diseases in countries representing 99.5% of the birth cohort of the 94 countries included in the costing analysis: hepatitis B, *Haemophilus influenzae* type b, human papillomavirus, Japanese encephalitis, meningitis A, pneumococcus, rotavirus, rubella, yellow fever and measles.

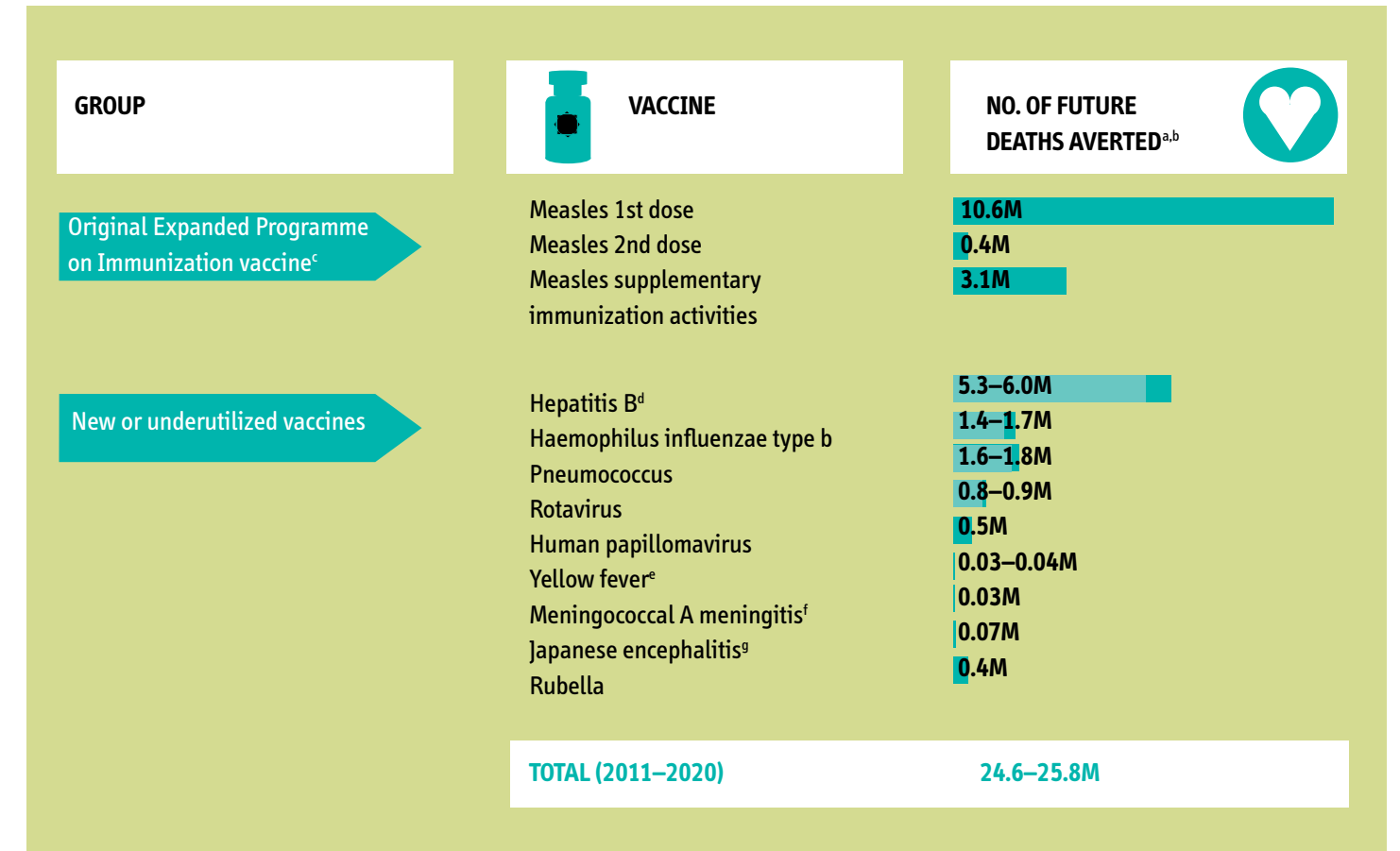
12 Data were insufficient to estimate morbidity averted through immunization in these countries.



The figures for deaths averted represent the full estimated benefits that can be achieved during the decade for these 10 vaccines, through sustaining or enhancing current immunization levels and introducing additional vaccines into the national immunization programmes of the selected countries, using no vaccination as the counterfactual. They are not limited to only the incremental benefits of the additional actions undertaken during the Decade of Vaccines (2011–2020).

The current projections of costs, available funding and health impact will evolve as additional analysis is completed and new and better data become available. Additional analysis will allow for the expansion of the scope described by this document, including increasing the number of diseases covered by the cost and health benefits analysis, quantifying impact on morbidity, quantifying economic benefits and further increasing the level of detail of costing and funding projections. Additional analysis is needed in order to better understand vaccine research and development costs and benefits, which are not included in the current projections. New and better data will, among other things, enhance the analysis with revised disease burden statistics, better vaccine price forecasts, improved population information and more consistent data across all countries. In addition, a process should be developed and maintained to allow for updates to cost, funding, and health and economic impact estimates at the country and global levels, ideally on an annual basis. This will facilitate enhanced planning, coordination and engagement among the many stakeholders that will be required to achieve the strategic objectives and goals of the Decade of Vaccines (2011–2020).

TABLE 8: TOTAL FUTURE DEATHS AVERTED, 2011–2020, ASSUMING NO VACCINATION AS THE COUNTERFACTUAL



a The estimated future deaths averted was developed by a working group that included staff from WHO, the GAVI Alliance, the Bill & Melinda Gates Foundation and PATH. The estimate uses a mix of static and dynamic cohort models and various data sources across the 10 vaccines, including the Lives Saved Tool. Vaccine coverage projections are from the GAVI Strategic Demand Forecast 4.0 (4 October 2011) and from the GAVI Adjusted Demand Forecast.
 b Ranges shown for estimates where alternative assumptions were considered for the scope of countries and the demand forecast.
 c Data were insufficient to allow estimation of deaths averted from BCG, diphtheria, tetanus or pertussis vaccines.
 d Scaled up in the decade 2001 to 2010.
 e Disease burden limited to only a few regions.
 f Same as above.
 g Same as above.

Continuing Momentum for the Decade of Vaccines (2011–2020)

Ensuring success throughout the Decade of Vaccines requires additional focus and action beyond the development of the Global Vaccine Action Plan. Four critical sets of activities will be required in order to translate the action plan into actions and results: development of tools for translation of the plan; development of a complete accountability framework; securing commitments from the stakeholder community; and communicating Decade of Vaccines opportunities and challenges.



Tools are needed [to] help stakeholders better understand how to translate the actions recommended in the action plan into the local context

Tools are needed that provide the full thinking behind the Global Vaccine Action Plan, together with details, to enable implementation. The production, publication and communication of these tools will help stakeholders better understand how to translate the actions recommended in the action plan into the local context.

The Global Vaccine Action Plan lays the groundwork for an accountability framework, which will be finalized with more detailed roles and responsibilities for stakeholders, a complete set of indicators, the methodology and data sources for each indicator detailed and baselines established where required. Investments are needed to improve data quality and develop more robust in-country monitoring and evaluation systems. Regular audits should be conducted to verify data quality. Progress should be reviewed annually, beginning in 2013, by country, the WHO regional committees and the Health Assembly.

Commitments aligned to the Global Vaccine Action Plan from countries, civil society organizations, multilateral agencies, development partners and vaccine manufacturers can transform the action plan from a document to a movement. Efforts to build these commitments and a strategy for coordinating them will be required at the global, regional and country levels. Appropriate channels must be identified and targeted communications developed to ensure that Decade of Vaccines messages reach and resonate with all stakeholders.

The period of time immediately following the Sixty-fifth World Health Assembly will be critical for ensuring that the agenda-setting translates into effective action. Key opportunities to sustain and build on the current momentum during the remainder of 2012 include the WHO regional committee meetings, the meeting of the Board of the GAVI Alliance, the UNICEF Executive Board meeting, the GAVI Alliance Partners' Forum and the Child Survival: A Call to Action summit.

The Decade of Vaccines collaboration was a time-limited effort that ended with the completion of the Global Vaccine Action Plan and related activities identified above. There will be no new structure to support the implementation phase of the Decade of Vaccines/Global Vaccine Action Plan. Lead stakeholders need to assume ownership to support implementation and progress monitoring.

WHO will play a leadership role for the action plan as the normative lead agency in global health, including the defining of norms and standards for production and quality control of vaccines, as well for strengthening immunization delivery, programme monitoring and surveillance systems. In collaboration with other stakeholders, the WHO Secretariat will also advocate for and provide technical support to Member States in promoting greater country ownership, creating synergies between immunization and other primary health-care programmes and implementing research, notably to increase programme efficiencies and impact.

The Decade of Vaccines collaboration was a time-limited effort that ended with the completion of the Global Vaccine Action Plan and related activities identified above



World Health Assembly Resolution

SIXTY-FIFTH WORLD HEALTH ASSEMBLY
WHA65.17 Agenda item 13.12 26 May 2012
Global Vaccine Action Plan
The Sixty-fifth World Health Assembly,

Having considered the report on the draft Global Vaccine Action Plan;¹ Recognizing the importance of immunization as one of the most cost-effective interventions in public health, which should be recognized as a core component of the human right to health;

Acknowledging the remarkable progress made in immunization in several countries to ensure that every eligible individual is immunized with all appropriate vaccines, irrespective of geographical location, age, gender, disability, educational level, socioeconomic level, ethnic group or work condition;

¹ Document [A65/22](#).



Applauding the contribution of successful immunization programmes in achieving global health goals, in particular in reducing childhood mortality and morbidity, and their potential for reducing mortality and morbidity across the life-course; Noting that the introduction of new vaccines targeted against several important causes of major killer diseases such as pneumonia, diarrhoea and cervical cancer can be used as a catalyst to scale up complementary interventions and create synergies between primary health care programmes; and that beyond the mortality gains, these new vaccines will prevent morbidity with resulting economic returns even in countries that have already succeeded in reducing mortality;

Concerned that, despite the progress already made, disease eradication and elimination goals such as the eradication of poliomyelitis, the elimination of measles, rubella, and maternal and neonatal tetanus cannot be met without achieving and sustaining high and equitable coverage;

Concerned that low-income and middle-income countries where the adoption of available vaccines has been slower may not have the opportunity to access newer and improved vaccines expected to become available during this decade; Alarmed that globally routine immunization services are not reaching one child in five, and that substantial gaps persist in routine immunization coverage within countries;

Recalling resolutions WHA58.15 and WHA61.15 on the global immunization strategy,
¹ Document A65/22. WHA65.17

TENTH PLENARY MEETING, 26 MAY 2012 A65/VR/10
1. ENDORSES THE GLOBAL VACCINE ACTION PLAN;
2. URGES MEMBERS STATES:

- (1) to apply the vision and the strategies of the Global Vaccine Action Plan in order to develop the vaccines and immunization components of their national health strategy and plans, paying particular attention to improving performance of the Expanded Programme on Immunization, and according to the epidemiological situation in their respective countries;
- (2) to commit themselves to allocating adequate human and financial resources to achieve the immunization goals and other relevant key milestones;
- (3) to report every year to the regional committees during a dedicated Decade of Vaccines session, on lessons learnt, progress made, remaining challenges and updated actions to reach the national immunization targets;

3. REQUESTS THE DIRECTOR-GENERAL:

- (1) to foster alignment and coordination of global immunization efforts by all stakeholders in support of the implementation of the Global Vaccine Action Plan;
- (2) to ensure that the support provided to the Global Vaccine Action Plan's implementation at regional and country level includes a strong focus on strengthening routine immunization;
- (3) to identify human and financial resources for the provision of technical support in order to implement the national plans of the Global Vaccine Action Plan and monitor their impact;
- (4) to mobilize more financial resources in order to support implementation of the Global Vaccine Action Plan in low-income and middle-income countries;
- (5) to monitor progress and report annually, through the Executive Board, to the Health Assembly, until the Seventy-first World Health Assembly, on progress towards achievement of global immunization targets, as a substantive agenda item, using the proposed accountability framework to guide discussions and future actions.

Annexes



Annex 1: Recommended Indicators

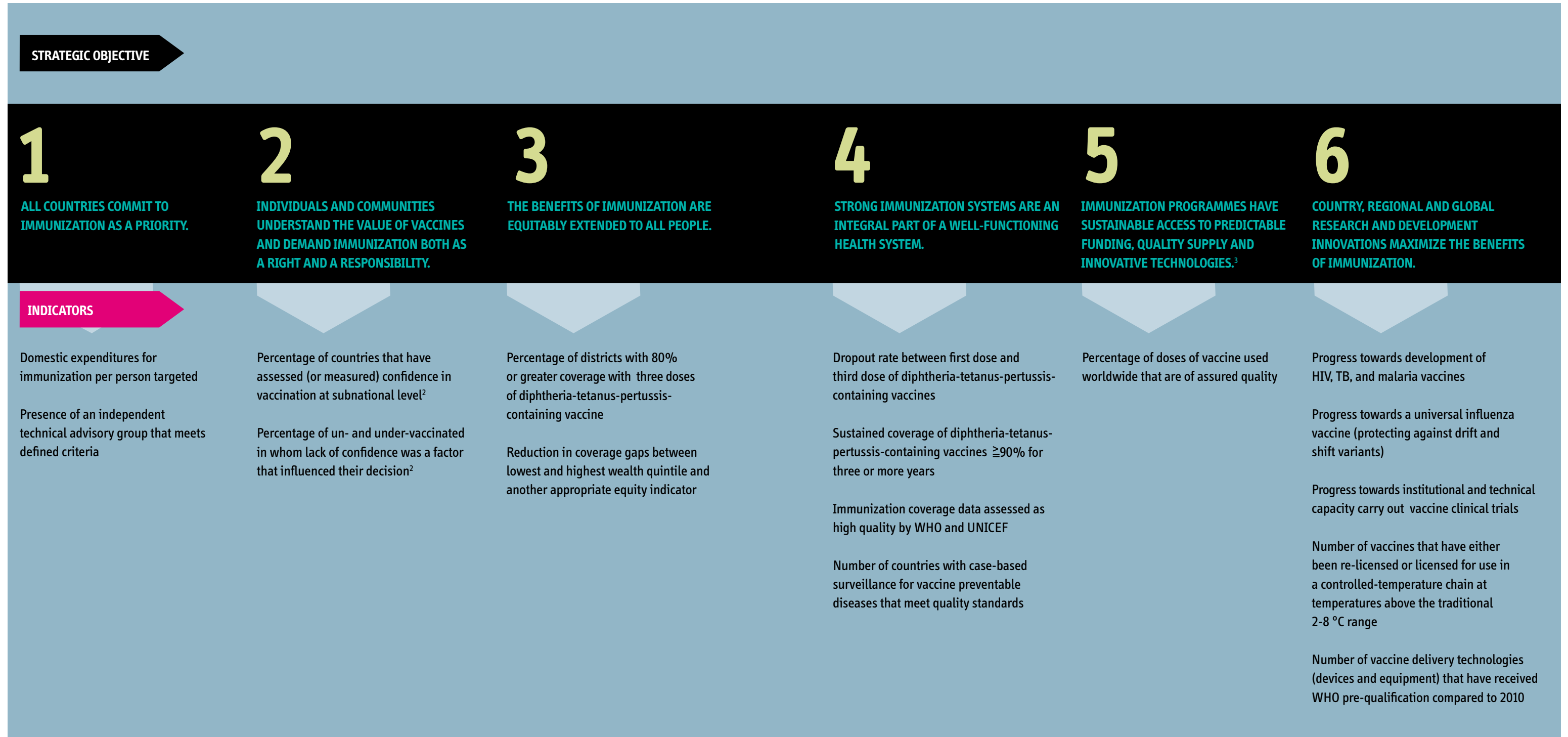
PROPOSED GOAL-LEVEL INDICATORS & TARGETS¹

GOAL	TARGET BY 2015	TARGET BY 2020
Achieve a world free of poliomyelitis	Interrupt wild poliovirus transmission globally (by 2014)	Certification of poliomyelitis eradication (by 2018)
Meet global and regional elimination targets	Neonatal tetanus eliminated in all WHO regions Measles eliminated in at least four WHO regions Rubella/congenital rubella syndrome eliminated in at least two WHO regions	Measles and rubella eliminated in at least five WHO regions
Meet vaccination coverage targets in every region, country and community	Reach 90% national coverage and 80% in every district or equivalent administrative unit with three doses of diphtheria-tetanus-pertussis-containing vaccines	Reach 90% national coverage and 80% in every district or equivalent administrative unit with all vaccines in national programmes, unless otherwise recommended
Develop and introduce new and improved vaccines and technologies	At least 90 low-income and middle-income countries have introduced one or more new or underutilized vaccines	All low-income and middle-income countries have introduced one or more new or underutilized vaccines Licensure and launch of vaccine or vaccines against one or more major currently non-vaccine preventable diseases Licensure and launch of at least one platform delivery technology
Exceed the Millennium Development Goal 4 target for reducing child mortality	Reduce by two thirds, between 1990 and 2015, the under-five mortality rate (Target 4.A)	Exceed the Millennium Development Goal 4 Target 4.A for reducing child mortality

¹ These proposed indicators will be presented to the WHO EB and World Health Assembly for final review in 2013. The Strategic Advisory Group of Experts on immunization will also consider the development and addition of indicators to monitor equity in access to vaccines between countries, and integration of immunization systems into broader health systems, respectively.



PROPOSED STRATEGIC OBJECTIVE-LEVEL INDICATORS



² Provisional indicator to be finalized based on outcomes of pilot assessment in selected regions

³ The report on progress will also include a narrative report on progress with vaccine supply, pricing and procurement.

Annex 2: Stakeholder Responsibilities

There is an opportunity to achieve real progress in the next decade. Realization of this potential is contingent upon all stakeholders having clearly defined and coordinated responsibilities. Primary responsibility is held by individuals and communities, governments and health professionals, as recipients and providers of immunization respectively. Other stakeholders also have an important role in achieving the objectives.





INDIVIDUALS AND COMMUNITIES, AS RECIPIENTS OF IMMUNIZATION, SHOULD DO THE FOLLOWING:

UNDERSTAND the risk and benefits of vaccines and immunization, viewing this as part of being a responsible citizen.

DEMAND safe and effective immunization programmes as a right from their leaders and government, and hold leaders and government accountable for providing them.

PARTICIPATE in public-health discussions and be involved in key decisions about immunization processes.

PARTICIPATE and contribute to the immunization delivery process and convey the needs and perspectives of their communities to the policy-makers.



GOVERNMENTS, AS THE MAIN PROVIDERS OF IMMUNIZATION, SHOULD DO THE FOLLOWING:

INCREASE support for national immunization programmes and ensure financial sustainability by 2020.

DEPENDING upon countries' income and as economies grow, fund an increasing proportion of domestic immunization programmes, progressing to the full funding of domestic programmes, and then funding global immunization efforts.

DEVELOP and introduce laws, regulations, and policies that support immunization programmes and a secure, high-quality supply base, if necessary.

DEVELOP region- and country-specific plans, together with other stakeholders in region/country.

PRIORITIZE and assume full ownership of national immunization programmes in order to create equity-driven programmes that reach every community.

WORK with stakeholders within and outside governments.

RESPOND with timely information when public concerns are raised about safety and efficacy to sustain public trust.

ENSURE immunization programmes are adequately staffed with personnel who are well trained and given appropriate incentives to manage the programme and deliver services.

INCREASE awareness of the importance of immunization to improve a population's health and its contributions to strengthening health systems and primary health care.

EFFECTIVELY CONVEY messages on vaccines to create demand.

ENGAGE in dialogue with communities and media and use effective communications techniques to convey messages about vaccines and to address safety concerns.

ENCOURAGE and support research on vaccines and vaccination issues; and encourage education at all levels on vaccines.

COLLABORATE regionally and internationally in advocacy programmes, evidence sharing, and coordinated preparedness.

PARTICIPATE in open dialogues with manufacturers to ensure affordability of current and new vaccines.



HEALTH PROFESSIONALS SHOULD DO THE FOLLOWING:

PROVIDE high-quality immunization services and information on them.

INTRODUCE vaccine educational courses on immunization at universities and institutions training health-care professionals as well as continuing education for all health-care providers (medical, nursing, pharmacy and public health practitioners).

IDENTIFY areas where immunization services could be improved and innovations made.

SERVE as proactive, credible voices for the value of vaccines and recruit other advocacy voices.

USE existing and emerging technologies to improve delivery and better capture information.

ENGAGE in dialogue with communities and the media and use effective communications techniques to convey messages about vaccines and to address safety concerns.



ACADEMIA SHOULD DO THE FOLLOWING:

PROMOTE innovation to accelerate the development of new and improved vaccines, contribute to the optimization of vaccine formulation and immunization programme logistics, and lay the groundwork for the impact of immunization in future decades.

PURSUE a multidisciplinary research agenda that focuses on transformational impact and is based on the needs of end users.

DEVELOP vaccines and technologies that will optimize and maximize vaccine delivery.

EMBRACE new ways of working that speed up scientific progress.

IMPROVE dialogue with other researchers, regulators and manufacturers in order to align actions and increase effectiveness in responding to local and global immunization challenges.

PROVIDE the core data, methods and arguments that help drive the continued prioritization of immunization both globally and locally.

ENGAGE more with systematic reviews to identify areas where solid scientific evidence exists (which should be the basis of health policies) and those areas where such evidence is lacking (which would be the basis for future primary research).

PROVIDE evidence and outline best immunization practices.

SUPPORT the development of manufacturing capabilities.

PROMOTE budget allocation for vaccine and immunization research.



MANUFACTURERS SHOULD DO THE FOLLOWING:

CONTINUE to develop, produce and supply innovative and high-quality vaccines that meet countries' needs.

SUPPORT research and an education agenda for immunization.

PARTICIPATE in open dialogues with countries and the public sector to ensure sustainable access to current and new vaccines.

CONTINUE to innovate manufacturing processes and pricing structures.

SUPPORT the media outreach for the Expanded Programme on Immunization to increase awareness.

SUPPORT rapid scale-up and adoption as new or improved vaccines emerge.

DEVELOP partnerships that support the growth of manufacturing capabilities and increase vaccine supply and innovation.

WORK in coordination with other partners on vaccine and immunization advocacy.



GLOBAL AGENCIES, SUCH AS WHO, UNICEF, THE WORLD BANK, REGIONAL DEVELOPMENT BANKS AND THE GAVI ALLIANCE, SHOULD DO THE FOLLOWING:

ADVOCATE for and provide technical support to promote country ownership.

STRENGTHEN national capabilities and regional infrastructure.

CONTINUE to define norms and guidelines to improve vaccine and immunization services, striving to achieve greater equity and sensitivity to gender and subpopulation (including, among others, minorities and age groups).

PROMOTE synergies between immunization and other health services as well with other sectors such as, education, economic development and financing.

FUND the provision of vaccines and immunization-related activities.

WORK with all stakeholders to improve technical assistance to strengthen immunization and other components of health systems.

ENCOURAGE, share and support evidence-based decision-making across the spectrum of development, health and immunization stakeholders.

ENGAGE partners to generate popular demand for immunization and support programme research and improvements.

PROMOTE the idea of sustainable national funding and engage rapidly emerging economies as funding partners.

DEVELOP mechanisms for mutual accountability that hold all governments, programmes and development partners responsible for committed levels of support.

PROMOTE a dialogue between manufacturers and countries to align supply and demand.

PURSUE innovative financing and procurement mechanisms that reinforce country ownership, and promote equity and affordability for low- and middle-income countries.



DEVELOPMENT PARTNERS, SUCH AS BILATERAL AGENCIES, FOUNDATIONS AND PHILANTHROPISTS, SHOULD DO THE FOLLOWING:

FULFIL institutional mandates and missions in the health field.

SUPPORT countries and regional entities to achieve national and regional goals, and contribute to the advancement of their priorities.

PROMOTE country ownership and country-led health, vaccine and immunization plans that include budgets for improving access to services and reducing the equity gap in coverage.

PROMOTE comprehensive, integrated packages of essential interventions and services that include vaccines and immunization and strengthen health systems.

PROVIDE predictable long-term funding aligned with national plans and encourage new and existing partners to fund vaccines and immunization.

BUILD civil society capacity and support civil society organization activities in countries.

PARTICIPATE in international advocacy through access to open evidence that can be shared.

MAINTAIN transparent and coordinated funding, accompanied by performance-based evaluation.



CIVIL SOCIETY, INCLUDING NONGOVERNMENTAL ORGANIZATIONS AND PROFESSIONAL SOCIETIES, SHOULD DO THE FOLLOWING:

GET INVOLVED in the promotion and implementation of immunization programmes at both country and global level.

PARTICIPATE in the development and testing of innovative approaches to deliver immunization services that reach the most vulnerable people.

FOLLOW national guidelines and regulations in the design and delivery of immunization programmes that fulfil the duty of accountability to national authorities.

EDUCATE, empower and engage vulnerable groups and communities on their right to health, including vaccines and immunization.

BUILD grass-roots initiatives within communities to track progress and hold governments, development partners and other stakeholders accountable for providing high-quality immunization services.

CONTRIBUTE to improved evaluation and monitoring systems within countries.

ENGAGE in country, regional and global advocacy beyond the immunization community to ensure vaccines and immunization are understood as a right for all.

COLLABORATE within and across countries to share strategies and build momentum for improved health, vaccines and immunization.

MEDIA SHOULD DO THE FOLLOWING:

UNDERSTAND the benefits of, and concerns about, immunization in order to accurately report on and effectively promote immunization programmes.

ENGAGE in country, regional and global advocacy beyond the immunization community to ensure vaccines and immunization are understood as a right for all.

USE effective communications techniques to convey messages about vaccines and to address safety concerns.



THE PRIVATE SECTOR SHOULD DO THE FOLLOWING:

SUPPORT the diversification of funding sources for immunization programmes (among others, private sector, insurance providers and patients).

ENGAGE in country, regional and global advocacy beyond the immunization community and serve as champions for immunization to ensure vaccines and immunization are understood as a right for all.

Annex 3: Costing and Funding Methodology and Assumptions

Projecting the costs and available finances for scaling up immunization in an effort to achieve the objectives of the Decade of Vaccines Collaboration Global Vaccine Action Plan, 2011-2020

OBJECTIVE

To project the financial resource availability and requirements to facilitate the vision delineated in the GVAP

METHODS

Projections of annual and cumulative total costs and financial flows were made to characterise the resource needs for delivering a range of existing and key pipeline vaccines over the decade in world's poorest countries where the benefits of immunization are expected to be greatest. The projections draw upon and consolidate information from existing forecasts and costing studies as well as country-specific data available from country immunization plans. The analysis focuses on projecting costs and financial flows likely to be available to cover those costs for vaccines and injection supplies, associated delivery efforts and immunization-specific system costs (e.g. cold chain). The financing projections model the domestic funding flows from country governments, support received through the GAVI Alliance, and other major sources of development assistance for immunization.



Introduction

A critical component in moving from a set of documents to action and results is an analysis of financial resource availability and requirements to facilitate the vision delineated in the GVAP. The remainder of this document provides an overview of the methodology and approach that underpins this analysis. Instead of covering all actions in the GVAP, this analysis focuses on the costs, projected financing, and resulting funding gap, under different scenarios, to immunize target populations in low and lower-middle-income countries with existing vaccines and upcoming vaccines that are expected to address significant disease burden in these countries.

Methods

COUNTRIES INCLUDED

While the Decade of Vaccines Collaboration (DoVC) is intended as a global enterprise, the immunization cost and financing projections analysis focused on 94 countries, consisting of all those classified as low (35) or lower-middle-income (57) by the World Bank in 2011, as well as two countries that are now in the process of graduating from GAVI eligibility and are classified as upper-middle-income countries.⁴ A table listing the specific countries included in this analysis can be found below. Due to data availability for key variables, the analysis sample consisted of 89 countries representing >99% of the total birth cohort of the original 94 countries. Of the 89 analysis countries, 57 are currently eligible for new GAVI support, 16 are countries that are currently graduating from GAVI support, and 21 countries are ineligible for GAVI support.

This analysis focuses on the costs, projected financing, and resulting funding gap, under different scenarios

>99%
of the total birth cohort of the original 94 countries represented

TABLE 9: COUNTRY SCOPE FOR ANALYSIS

Afghanistan	Malawi	Congo, Rep	Moldova	Tuvalu
Bangladesh	Mali	Côte d'Ivoire	Mongolia	Ukraine
Benin	Mozambique	Djibouti	Morocco	Uzbekistan
Burkina Faso	Myanmar	Egypt	Nicaragua	Vanuatu
Burundi	Nepal	El Salvador	Nigeria	Viet Nam
Cambodia	Niger	Fiji	Pakistan	West Bank & Gaza
CAR	Rwanda	Georgia	Papua New Guinea	Yemen
Chad	Sierra Leone	Ghana	Paraguay	Zambia
Comoros	Somalia	Guatemala	Philippines	Azerbaijan
Congo, DR	Tajikistan	Guyana	Samoa	Cuba
Eritrea	Tanzania	Honduras	São Tomé & Príncipe	
Ethiopia	Togo	Indonesia	Senegal	
Gambia	Uganda	India	Solomon Islands	
Guinea	Zimbabwe	Iraq	Sri Lanka	
Guinea-Bissau	Angola	Kiribati	Sudan, N.	
Haiti	Armenia	Kosovo	Sudan, S.	
Kenya	Belize	Lao, PDR	Swaziland	
Korea, DR	Bhutan	Lesotho	Syria	
Kyrgyzstan	Bolivia	Marshall Islands	Timor-Leste	
Liberia	Cameroon	Mauritania	Tonga	
Madagascar	Cape Verde	Micronesia	Turkmenistan	

WB INCOME CLASSIFICATION

- LIC
- LMIC
- UMIC

The analysis has focused on these countries in part because given highly constrained government spending on health in these countries, they are in a general sense least likely to have the financial capability to completely self-fund desired immunization services and, therefore will require the most support of the global community to achieve the objectives of the GVAP.

⁴ World Bank income classification released July 2011, based on 2010 GNI per capita. Low-income countries have a 2010 GNI per capita of US\$1005 or less. Lower-middle-income countries have a GNI per capita of between US\$1006 and US\$3975.

VACCINES INCLUDED

While all vaccines are important within the wider scope of the DoVC, the vaccines that have been included in the scope of this analysis are those vaccines that are for use in humans, currently available, and in many cases, widely used, along with newer vaccines that are expected to significantly address the vaccine-preventable disease burden⁵ within the 94 countries included in the country scope identified above. In addition to vaccines licensed and available today, the analysis also accounts for the expected introduction of several new vaccines over the course of the decade. Veterinary vaccines and vaccines primarily recommended for therapeutic use (e.g. Rabies vaccines) as well as vaccines predominantly employed outside of resource-poor settings (e.g. Seasonal Flu vaccines) were excluded from the analyses.

For the purposes of defining methods and identifying data sources, two (non-mutually exclusive) categories were used to classify the vaccines covered in the analysis: (1) Vaccines delivered via campaigns and associated with Accelerated Disease Control (ADC), Eradication, or Elimination initiatives and (2) Vaccines delivered through routine immunization programs. This categorization was helpful since delivery costs differ markedly depending on the delivery strategies (e.g. primarily through in-frequent vaccination campaigns versus the routine vaccination), and the timing and intensity of delivery efforts (that affect costs) differ depending on whether the vaccines/disease were associated with high-level global or regional eradication, elimination or ADC initiatives. The table below summarizes the vaccines/diseases in each of the categories.

The vaccination schedule and targeting strategies selected for each of these vaccines was based on global guidance (e.g. from WHO Position Papers, SAGE Guidance). While for pipeline vaccines where such information is often not available, assumptions about the delivery strategy as well as the expected timing of licensure were based on the advice of vaccine development experts particularly from relevant Product Development Partnerships. These were analytical assumption rather than pre-suppositions of guidance and decisions on the part of regulators and individual countries.

**TABLE 10:
VACCINE/DISEASE SCOPE FOR ANALYSIS**

<p>(1) ADC/ ELIMINATION/ ERADICATION VACCINES (DELIVERED VIA CAMPAIGNS)</p> <p>Conjugated Meningitis A Measles Oral Polio Vaccine (OPV) Rubella Tetanus Yellow Fever</p>
<p>(2) ROUTINE VACCINATION PROGRAMS</p> <p>Cholera (campaign) Conjugated Meningitis A Dengue (routine) Hepatitis B Human Papilloma Virus Inactivated Polio Vaccine (IPV) Japanese Encephalitis (routine and catch up) Malaria (routine) Measles (1st and 2nd dose) Non-penta DTP and inc. tetravalent combinations OPV Penta (DTP-HepB-Hib) Pneumococcal Rotavirus Rubella Tuberculosis (BCG) Typhoid (conjugate) (routine) Yellow Fever</p>

COST AND FINANCING COMPONENTS INCLUDED

For each of the above categories included in the analysis, costs were developed in three segments: vaccine and injection supplies, vaccine delivery (including capital cold chain operation costs) and capital investment in cold chain capacity. The vaccine delivery and capital investment in cold chain costs were then combined into a single *delivery* cost category.

DELIVERY COSTS FOR ROUTINE SERVICES INCLUDE:		DELIVERY COSTS FOR SUPPLEMENTAL CAMPAIGNS INCLUDE:
HUMAN RESOURCES (national, subnational, district and service levels)	VEHICLES AND TRANSPORT	OPERATIONAL COSTS OF CAMPAIGNS (incl. for epidemic response)
COLD CHAIN EQUIPMENT AND THEIR OVERHEADS (installation, energy, maintenance and repairs)	PROGRAMME MANAGEMENT	SOCIAL MOBILIZATION
	TRAINING AND CAPACITY BUILDING	DISEASE SURVEILLANCE
	SOCIAL MOBILIZATION, IEC AND ADVOCACY	TECHNICAL ASSISTANCE (at country level only)
	DISEASE SURVEILLANCE	

Costs refer to immunization-specific costs only and human resources costs for individuals partially dedicated to immunization. Other shared health system costs such as buildings were excluded. Total costs to sustain current gains and to incremental needs to scale up over the next decade were included.

Cost projections on a country-by-country basis were developed and aggregated for the categories of vaccines described in Table 2 covering the period 2011-2020. The assumptions and methodology for the baseline cost scenario are summarized below. In addition, low and high scenarios were created. All costs are presented in constant 2010 US\$.

For each of the vaccine groups included in the analysis, financing flows were projected from three financing sources: (i) Country Governments, (ii) the GAVI Alliance, and (iii) Other Development Partners (i.e. bilateral donors, multilateral agencies and philanthropic agents).

⁵ The list of vaccines was drawn from a previous effort undertaken by WHO on behalf of GAVI to characterize vaccines by public health priority. The terms of reference of this work are available here: http://www.who.int/immunization/sage/Categorization_Activity_SAGE.pdf. While the main findings from this work are summarized here: http://fr.gavialliance.org/resources/3_Vaccine_Investment_Strategy.pdf.

(1) Accelerated Disease Control (ADCs), Elimination and Eradication programs

The World Health Organisation (WHO) and United Nations Children’s Fund (UNICEF) lead the implementation of country-level programmes for a variety of disease control, eradication and elimination efforts to combat vaccine-preventable diseases (listed in [Table 10](#) above). These programmes produce plans and forecasts detailing the key activities, and the cost associated with the implementation of these programs.

These plans and forecasts have been used as the basis for projecting both the costs of vaccine and injection supplies, and vaccination delivery for each of these programmes over the decade as well as for other critical activities necessary for administering the programs.

(A) VACCINE COSTS

The target populations and planned timing of vaccination campaigns to achieve the relevant disease control, eradication or elimination goals over the course of the decade were taken from the plans as delineated by the programs. These were combined with estimates of current vaccine prices (provided by UNICEF Supply Division) to create forecasts of the vaccine/injection supply costs of these programs.

(B) DELIVERY COSTS

Delivery costs for the ADC, Eradication and Elimination programmes were separated into core costs incurred primarily by implementing partners to facilitate programs, *operational costs* to physically deliver vaccines and run the vaccination campaigns and *contingency funds* in the case of disease outbreaks.

Core costs cover critical activities—for example to stimulate demand (Social Mobilization) and to monitor the incidence and prevalence of disease (Surveillance) in affected countries. Core cost projections were also taken at face

value from the programme plans where available. In the absence of long-term projections for this cost component, recent core cost estimates were projected forward based on the programme forecasts. Operational costs encompass all running costs outside of vaccines and core costs to implement a vaccination campaign. Country-specific operational cost information recorded in comprehensive multi-year immunization plans (cMYPs) were used to generate metrics which were applied to the aforementioned forecasts to project the running costs of all planned campaigns. Finally, contingency funds include the resource needs to procure and manage vaccine stockpiles and monies held in reserve to implement reactive campaigns in the event of disease outbreaks — These amounts are based on historic needs and taper off over time as it is assumed the ADC, Elimination and Eradication programmes make progress towards their respective goals. These costs were also taken directly from programme plans.

(2) Routine Vaccination programmes

(A) VACCINE COSTS

Demand forecasts for traditional routine vaccines already on the market were estimated on a country-by-country basis using existing demand forecasts from WHO, UNICEF as well as GAVI (Strategic Demand Forecast version 4.0 and Adjusted Demand Forecast version 4.0). These demand forecasts were then combined with estimated prices to project the costs of these vaccines and related injection supplies. For GAVI-eligible countries, GAVI-like price forecasts were used on a disease-by-disease basis. For the non-GAVI lower-middle-income countries (LMICs) in the analysis, baseline prices were assumed to be held constant at the same differential between current GAVI prices and PAHO Revolving Fund prices. Using the demand forecasts and price forecasts, the acquisition costs of vaccines and associated supplies were projected.

For vaccines still in the pipeline, demand forecasts were developed based on expert input obtained through interviews with Product Development Partnership (PDP) representatives and other external stakeholders familiar with these vaccines under development. Expected acquisition costs for these vaccines were projected by applying these demand forecasts to a projected price per dose for each of the vaccines in this segment.

Projecting both the costs of vaccine and injection supplies, and vaccination delivery for each of these programmes over the decade



(B) DELIVERY COSTS

Delivery costs include the main components of routine immunization service delivery systems: human resources at all levels of the system and ongoing capacity building (training); the supply chain and logistics systems needed to store and transport vaccines (cold chain equipment, vehicles, transport...), and the cost of programme management (information systems, M&E...), social mobilisation and disease surveillance. The approach to estimate the delivery costs rested on separating those costs for *service delivery* and those costs for *vaccine delivery*.

The service delivery costs are those that are needed to implement the national immunization programme to deliver the immunization services. Information provided by countries in their *cMYPs* was the basis of the costing and financing estimates for delivery. Under the auspices of the Global Immunization Vision and Strategy (GIVS), countries launched a process to strategically plan for their national immunization programme including estimating the current and future costs required to reach the goals and targets of their programme. Based on the wealth of information available for approximately 65% of the countries (58) in scope, a bottom-up costing exercise using a standard ingredients approach to costing was undertaken by countries. From this sample of real data from countries, average unit costs by typology of country was used to impute missing

Countries launched a process to strategically plan for their national immunization programme including estimating the current and future costs required to reach the goals and targets of their programme

values for the remaining 35% of countries for which point estimates were not available. The needs for scaling up were derived from a variety of sources linked to the anticipated coverage projections and how countries have identified priorities, strategies and needs within their *cMYPs*.

The vaccine delivery costs are those that are needed to ensure adequate supply of vaccines through the health system and to store and transport vaccines in a safe and effective manner throughout the entire supply chain and logistics systems of countries (from the national vaccine store to a service delivery point in a health centre or outreach post). In other words, these encompassed all the cold chain costs for storing vaccines (whether the capital equipment or their recurrent overheads) and the logistics of transporting vaccines (whether the vehicles or their recurrent overheads).

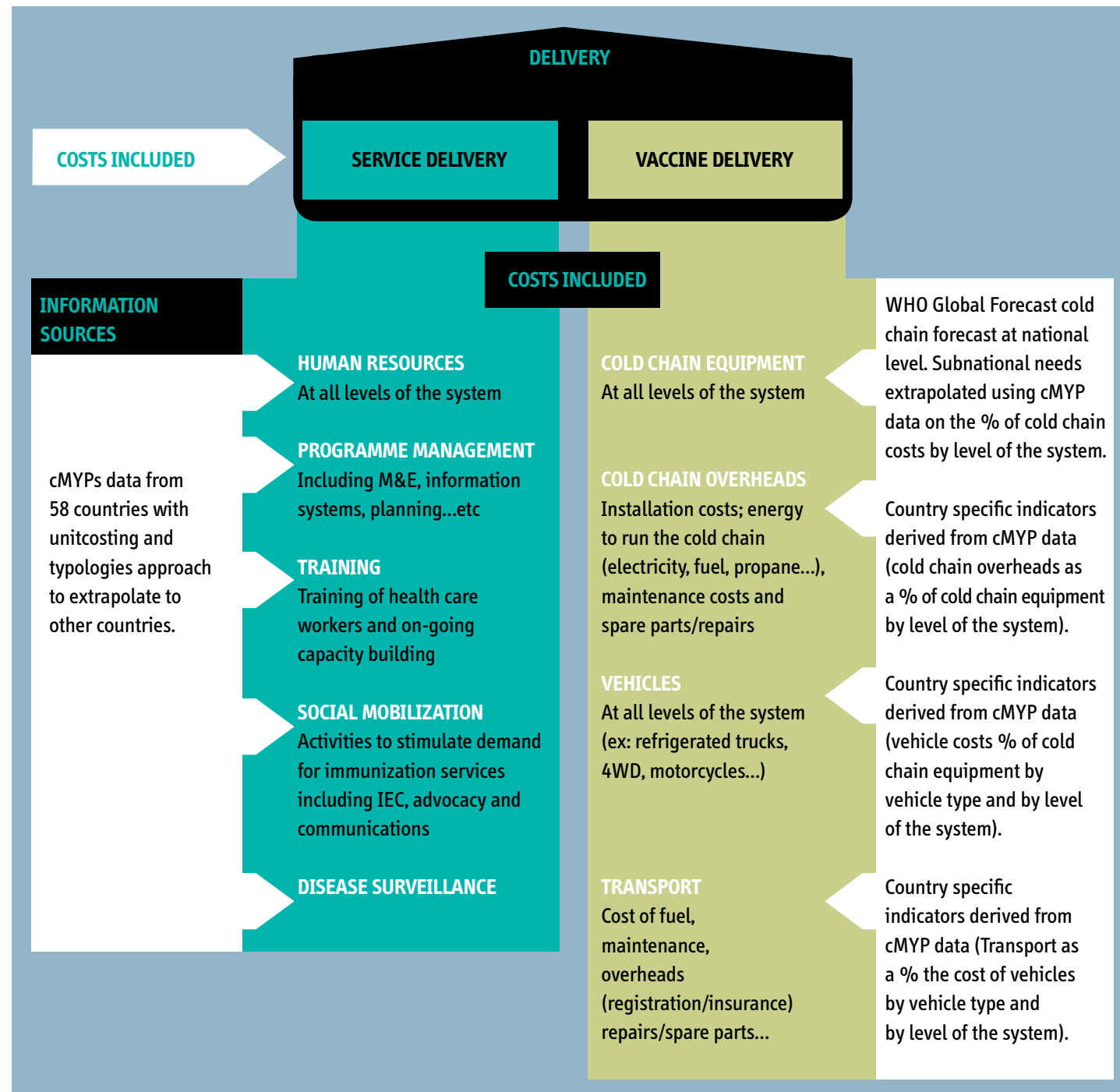
The WHO global forecast for cold chain and logistics is the basis of the costing for vaccine delivery. The global forecast tool estimates (using the same demand forecast assumptions for vaccines) the on-going needs to maintain the existing cold chain infrastructure in place along with the incremental needs to scale up needs to raise coverage and introduce new vaccines.

Incremental capital cold chain costs were analyzed on a country-by-country basis. Total expected volume of vaccines was compared to country-level cold chain capacity. If capacity was projected to exceed country capacity in a given year, incremental cold chain needed was estimated using relevant cost per volume cold chain benchmarks.

Due to its unique service delivery, HPV delivery costs were defined on the basis of findings from several pilot demonstration projects as reported by PATH.

65% of the countries undertook a bottom-up costing exercise using a standard ingredients approach to costing

TABLE 11: SUMMARY OF THE APPROACH TO ESTIMATE THE COST OF DELIVERY



Financing projections

Financing projections were developed across three main sources: public spending on health from government’s own sources, GAVI Alliance funding, and other development partners. These projections were calculated for the vaccines described in [Table 10](#).

(I) GOVERNMENT FLOWS FOR IMMUNIZATION

The methodology to project government flows for immunization rested on relying on the available financing data provided by countries in their national multi-year immunization plans (cMYPs). The analysis of this data was the basis of the government financing estimates for both vaccines and systems costs. For countries that did not have cMYP, a methodology of unit financing and typologies was applied in a similar fashion as done on the costing side. For SIAs, typologies were based on population groupings since the per capita investments by governments tend to be lower for midsize/larger countries (i.e. population ≥10 million) than much smaller countries (i.e. population <10 million)—mainly due to economies of scale that can be leveraged in the former. For government financing for routine vaccination services, rather than using a typology by population groups, the GAVI co-financing groupings were used that stratify countries since these groups provide a proxy of the ability to finance vaccines and immunization. This typology groups countries into Low-Income, Intermediate, Graduating and Non-GAVI.

In broad terms the method for projecting government flows involved generating a baseline estimate of government funding for the year 2010 derived from the cMYP data. This baseline estimate was projected forward between 2011 and 2020 based on IMF projections of real GDP growth. The assumption underlying the projection methods is that growth in the health budget of countries will grow at the same rate as economic growth. In other words, the base case funding assumes that governments will continue to provide the same share of the health budget for immunization as they currently do over time—despite the fact that in absolute terms, the amount governments contribute will increase in line with economic growth forecasts.

In the baseline scenario, no additional government funding was assumed to be available for the mainly new or pipeline vaccines that are not part of the traditional/basic EPI vaccines or those supported by GAVI (e.g. malaria, dengue vaccines)

(II) GAVI ALLIANCE FUNDING

For those vaccines delivered through campaigns and that are part of ADC activities but that are funded by GAVI, (i.e. MenA, yellow fever, rubella), GAVI Alliance funding was assumed to cover the full costs of the vaccines/injection supplies, while for operational costs, it was assumed that GAVI will provide funding at least equivalent to current levels (i.e. US\$0.30 per targeted person).

For routine GAVI-supported vaccines, GAVI's own financing projection assumptions were applied through 2020 to determine the amount of finances GAVI will provide for New Vaccine Support over the decade. The analysis does not include any GAVI funding that is and might be made available for delivery activities associated with routine vaccination programmes/systems.

(III) OTHER DEVELOPMENT PARTNER FUNDING

For routine programs, country-specific levels of other development partner funding (in a sample of 40 cMYPs that included programs with PCV, pentavalent, and rotavirus vaccines) were used to generate two population-weighted indicators: 1) OD partner financing of *vaccines* as a share of GHE; and 2) OD partner financing of *delivery* costs as a share of GHE by two population groups (<100 million and >100 million) using STATA10. Population-weighted averages were applied to each country in the model based on their population group, and multiplied by GHE to project over the period. This method assumes that 2010 levels of other donor support for vaccines and routine program delivery relative to GHE remain constant over time. This represents a baseline level of other donor financing, above which additional other partner financing for new vaccines might be added.

Other development partner funding aside from contributions to immunization that occur through GAVI Alliance funding have not been included for the purposes of this analysis.

Developing estimated future resource requirements

Vaccine acquisition costs and delivery cost projections have been combined with aggregated financing flow projections on an annual basis to estimate the funding gaps/incremental resource requirements on an annual basis needed to successfully scale up immunization programmes globally in line with the coverage targets outlined within the GVAP.

LIMITATIONS

This exercise does not analyse or attempt to approximate the cost of the implementation of the Global Vaccine Action Plan. The analysis described above is only an exercise to determine the vaccine acquisition and service delivery cost and resource availability for increasing coverage of existing vaccines and the introduction of new vaccines over the course of the decade.

The costs projections produced from this effort to do not include the agency overhead costs for the implementation and maintenance of the GVAP – there will be additional resources required for this activity.

Costs and funding for Research and Development activity are not captured in this analysis.

Costs and funding for Advocacy and Political Support activity are not captured in this analysis.

The approach taken for this exercise builds on existing sources of information and global projection of needs generated by different groups (e.g. Polio, Measles, etc) in order to leverage the best data available, when possible. Because of this approach, it is difficult to ensure a consistency in the methods throughout the work, and a complete mitigation of double counting risks.

The costs are limited to a priority set of countries although the aspirations of the Decade of Vaccine and GVAP are global.

While it is important to acknowledge the limitations of the analysis that was conducted, it is not believed that any of the limitations outlined above will alter the directional nature of the results of this exercise.

Annex 4: Health Impact Methodology and Assumptions

Projecting the total impact of vaccination administered between 2011–2020, relative to a no vaccination scenario, for selected vaccines



FORECAST IMPACT OF VACCINATION ADMINISTERED BETWEEN 2011–2020

A. SAMPLE DATA OUTPUT

Data shown for persons vaccinated for DoV impact scenario

GROUP	VACCINE-PREVENTABLE DISEASE	VACCINATION STRATEGY	NUMBER OF FUTURE DEATHS AVERTED	NUMBER OF DEATHS AVERTED PER 1,000 PERSONS VACCINATED
Original EPI vaccines	Measles – 1st dose	routine	10.6M	16.5
	Measles – 2nd dose	routine	0.4M	1.9
	Measles – SIA	campaign	3.1M	3.5
New or underutilized vaccines	Hepatitis B	routine	5.3-6.0M	8.3
	Hib	routine	1.4-1.7M	2.6
	Pneumococcal	routine	1.6-1.8M	4.3
	Rotavirus	routine	0.8-0.9M	3.1
	Human papillomavirus	routine	0.5M	15.1
	Yellow fever	routine	0.03-0.04M	0.2
	Meningococcal meningitis A	campaign & routine	0.03M	0.8
	Japanese encephalitis	campaign & routine	0.07M	0.1
	Rubella	campaign & routine	0.4M	0.4
	TOTAL (2011-2020)			24.6-25.8M

B. INDICATOR

Future deaths averted calculated over period of mortality risk in vaccinated cohorts, relative to a no vaccination scenario, for vaccines delivered during the period 2011–2020.

C. COUNTRIES

94 countries, consisting of all those classified as low (35) or lower-middle-income (57) by the World Bank in 2011, as well as two countries that are now in the process of graduating from GAVI Alliance eligibility and are classified as upper-middle-income countries were considered in scope for the purposes of this analysis. Due to data availability, 13 countries with small populations were omitted; it will not alter the directional nature of this analysis.

D. POPULATION PROJECTIONS

UN Population Division 2008 (hepatitis B, YF, NmA, JE, HPV, rubella) or 2010 (Hib, rotavirus, Sp, measles) revision.

E. COVERAGE PROJECTIONS

GAVI Strategic Demand Forecast 4.0, 4 October 2011; GAVI Adjusted Demand Forecast (SDF 4.4 October 2011 was used for the 73 GAVI eligible countries.) A different projection, however, was used for the non-GAVI eligible countries.

F. VACCINES AND VACCINATION STRATEGIES

G. MODEL SOURCE AND STRUCTURE

H. UNDERLYING DISEASE BURDEN

HEPATITIS B	Routine infant	Centers for Disease Control	Static natural history population-based cohort
HIB	Routine infant	Johns Hopkins University (Lives Saved Tool model)	Static cohort
PNEUMOCOCCAL	Routine infant	Johns Hopkins University (Lives Saved Tool model)	Static cohort
ROTA VIRUS	Routine infant	Johns Hopkins University (Lives Saved Tool model)	Static cohort
HUMAN PAPILOMAVIRUS	Routine 10-13 year old girls	Harvard University	Static cohort
YELLOW FEVER	Routine infant (following SIAs conducted prior to 2011)	GAVI (Long Range Cost and Impact model)	Estimate of 0.2 deaths averted per 1,000 vaccinated from a static cohort model estimate for Nigeria applied to projected numbers vaccinated during 2011-2020
MENINGOCOCCAL MENINGITIS	Routine infant + one-time SIA (all 1-29 year olds)	GAVI (Long Range Cost and Impact model)	Estimate of 1.04 (SIA) and 0.08 (routine infant) deaths averted per 1,000 vaccinated from a static cohort model estimate of the NmA investment case applied to projected numbers vaccinated by each strategy during 2011-2020
JAPANESE ENCEPHALITIS	Routine infant + one-time SIA (all 1-15 year olds)	PATH	Static cohort
RUBELLA	One-time SIA v (all 9 month-14 year old boys and girls)	UK Health Protection Agency Centre for Infections, CDC, WHO	Dynamic cohort
MEASLES Measles – 1st dose Measles – 2nd dose Measles – SIA	Routine infant Routine childhood Variable	WHO/Department of Immunization, Vaccines and Biologicals (2012)	Dynamic natural history model informed by surveillance data

HEPATITIS B	Pre-vaccination HBsAg serosurvey data (many countries)
HIB	WHO/CHERG 2008 under-5 pneumonia deaths (many countries) x pre-vaccination proportion radiographic pneumonia cases due to Hib (probe studies in 6 countries)
PNEUMOCOCCAL	WHO/CHERG 2008 under-5 pneumonia deaths (many countries) x pre-vaccination proportion radiographic pneumonia cases due to Sp (probe studies in 3 countries)
ROTA VIRUS	WHO/CHERG 2008 under-5 diarrhoea deaths (many countries) x pre-vaccination proportion severe gastroenteritis due to rotavirus infection (many countries)
HUMAN PAPILOMAVIRUS	Pre-vaccination retrospective surveys of women with invasive cervical cancer with use of molecular techniques to determine the proportion due to HPB and due to specific HPV genotypes (many countries)
YELLOW FEVER	Pre-vaccination 1993 study modelling the impact of vaccination in Nigeria during 1991-2026. Model based on several disease burden studies in Nigeria (one country, little comparable data elsewhere). Only epidemic disease burden considered. Impact based on marginal increase in coverage since year prior to start of GAVI support
MENINGOCOCCAL MENINGITIS	Based on a pre-vaccination prospective hospital surveillance study in Niger conducted during 1981-1996 (one country, little comparable data elsewhere)
JAPANESE ENCEPHALITIS	Based on a 2011 review of population-based surveillance studies. Some pre-vaccination some post-vaccination) (several countries)
RUBELLA	Pre-vaccination retrospective rubella serosurveys to determine age-specific incidence (many countries)
MEASLES	Case fatality ratios from Wolfson et al 2009 review of CFRs for children under five. CFRs for 5-9 years old assumed 50% of CFRs for 1-4 year olds and CFRs were assumed to be 0 above 10 years of age. Age distribution derived from case based surveillance data, using first dose coverage and regions as covariates

Annex 5: Countries and Organizations that Contributed to the Elaboration of the GVAP

ORGANIZATIONS WHOSE MEMBERS HAVE PROVIDED INPUTS AND COMMENTS TO THE GLOBAL VACCINE ACTION PLAN

GOVERNMENT ENTITIES:

Africa Regional Certification Commission, Albanian Institute of Public Health, Centro Nacional para la Salud de la Infancia y la Adolescencia de México, Chinese Centers for Disease Control, Chinese National Institute for Food and Drug Control, European Medicines Agency, Federación de Planificación Familiar Estatal, Forum des parlementaires africains et arabes pour la population et le developpement, Health Canada,

Indian Department of Biotechnology, Indian National Institute of Immunology, National Primary Healthcare Development Agency of Nigeria, Paul Ehrlich Institut, President's Emergency Plan for AIDS Relief, Dutch National Institute of Public Health & Environment, Sudan National Medicines & Poisons Board, U.K. Department of Health, U.K. Health Protection Agency, U.K. National Institute of Biological Standards and Control, U.S. Army, U.S. Centers for Disease Control and Prevention, U.S. Department of Defense, U.S. Department of Health and Human Services, U.S. Department

of State, U.S. Food and Drug Administration, U.S. National Institutes of Health - National Institute of Allergy and Infectious Diseases, Yemen Supreme Board for Drugs.

HEALTH PROFESSIONALS:

American Academy of Pediatrics, Asociación Mexicana de Pediatría, Confederación Nacional de Pediatría de México, Hôspital d' Enfants de Rabat, Indian Academy of Pediatrics, International Pediatric Association, Leiden University Medical Center, Sudan Pediatric Association, Uganda Paediatric Association.

ACADEMIA:

Aga Khan University, American Association for the Advancement of Science, Australian National Centre for Immunisation Research & Surveillance, Banaras Hindu University, Barcelona Centre for International Health Research, Barcelona Institute for Global Health, Center Esther Koplowitz, Centre for Health Sciences Training, Research and Development, Centro para Vacunas en Desarrollo de Chile, Centro de Investigación y de Estudios Avanzados del Instituto Politécnico Nacional, Chandigarh Post Graduate Institute of Medical Education and Research, Christian Medical College, Chulalongkorn University, Emory University Hospital, Fred Hutchinson Cancer Research Center, Fundacio Clinic per a la Recerca Biomedica, Georgia Institute of Technology, Gorgas Institute, Griffith University, Hospital Clínic, Indian Council for Medical Research, Indian International Centre for Genetic Engineering and Biotechnology, Infectious Diseases Research Institute, Institut Català d'Oncologia, Institut d'Investigacions Biomèdiques August Pi i Sunyer, Institut Pasteur, Institute of Medical Sciences, Instituto de Salud Pública Universidad Veracruzana, International Agency for Research on Cancer, International Centre for Diarrhoeal Disease Research

Bangladesh (ICDDR), Jawaharlal Nehru University, Johns Hopkins University, Jordan University Hospital, Karolinska Institute, London School of Hygiene & Tropical Medicine, Lund University, Mahidol University, Makerere University, Mali's Center for Vaccine Development, Marrakech Faculté de Médecine, Maxwell School of Syracuse University, Mayo Clinic Vaccine Research Group, Medical Research Council, Menzies School of Health Research, Methodist Hospital Research Institute, Molecular Biophysics Unit Indian Institute of Science, New York Academy of Sciences, Novartis Vaccines Institute for Global Health, Oswaldo Cruz Foundation, Pakistan's National Institute of Child Health, Pakistan's National Institute of Health, Princeton University, Ragon Institute, Rockefeller University, Sandra Rotman Centre for Global Health, Tehran University of Medical Sciences, The Wharton School University of Pennsylvania, Universidad Autónoma de México, Universidad Autónoma de Yucatán, Universidad Autónoma San Luis Potosí, Universidad del Valle de Guatemala, Universidad Peruana Cayetano Heredia, University College London, University of Alabama, University of Antwerp, University of California – San Francisco, University of Cape Town, University of Erfurt, University of Geneva, University

of Goettingen, University of Hong Kong, University of Kwazulu-Natal, University of Maryland, University of Melbourne, University of Michigan, University of Minnesota, University of Oxford, University of Philippines, University of Tennessee, University of Toronto, University of Warwick, University of Yaounde, Walter Reed/ Armed Forces Research Institute of Medical Sciences Research Unit Nepal, Wellcome Trust.

PRODUCT DEVELOPMENT PARTNERSHIPS:

Aeras—Global TB Vaccine Foundation, Dengue Vaccine Initiative, European Vaccine Initiative, International AIDS Vaccine Initiative, International Vaccine Institute, Malaria Vaccine Development Program, Malaria Vaccine Initiative, Medicines for Malaria Venture, Meningitis Vaccine Project, Tuberculosis Vaccine Initiative.

MANUFACTURERS:

Aridis Pharmaceuticals, Baxter, Bharat Biotech, BIO, Biofarma, Biological E, Bio-Manguinhos/Fiocruz, Biovac Institute, Birmex, Butantan Institute, Centro de Ingenieria y Biotecnología de Cuba, CNBG, Crucell Vaccines, Developing Countries Vaccine Manufacturers Network, GlaxoSmithKline Biologicals, Indian Immunological Limited, Inovio Pharmaceuticals, Intercell, International Federation of

Pharmaceutical Manufacturers and Associations, Laboratorio Emea, Merck, NasVax, Novartis Pharma AG, Novartis Vaccine Institute for Global Health, Novavax, Pfizer, Sanofi-Aventis, Sanofi-Pasteur, Serum Institute, Shanta Biotechnics Limited, Vaxinnate Corporation, Xiamen Innovax Biotech Co. Limited, Zydus Cadilla.

GLOBAL AGENCIES:

African Leaders Malaria Alliance, the GAVI Alliance, Partnership for Maternal, Newborn, and Child Health, United Nations Population Fund, UNICEF, United Nations, World Bank, World Health Organization and its regional offices.

DEVELOPMENT PARTNERS:

African Development Bank, Australian Agency for International Development, Bill & Melinda Gates Foundation, Canadian International Development Agency, European Union, Inter-American Development Bank, Japan International Cooperation Agency, Norwegian Agency for Development Cooperation, Spanish Agency for International Development Cooperation, Swedish International Development Cooperation Agency, U.K. Department for International Development, U.S. Agency for International Development.

CIVIL SOCIETY:

@Verdade, ACTION, Action for Global Health, ActionAid, Afro Global Alliance, Aga Khan Health Services, Agence de Médecine Préventive, Alternative Santé, American Association for Cancer Research, American Cancer Society, Inc., Americans for Informed Democracy, American Red Cross, American Society of Tropical Medicine and Hygiene, Asociación Lalla Salma de Lutte contre le Cancer, Association d'Assistance aux Développement, Associazione Italiana Donne per lo Sviluppo – Italian Association for Women in Development, BIO Ventures for Global Health, Carlos Slim Foundation, Catholic Relief Services, Center for Global Development, Center for Strategic & International Studies, Cestas – Centro di educazione sanitaria e tecnologie appropriate sanitarie, Civil Society Human and Institutional Development Programme, Clinton Health Access Initiative, Communication for Development Centre in Nigeria, Consortium of Christian Relief and Development Associations in Ethiopia, CORE Group, Ethiopian Catholic Secretariat, European Parliamentary Forum, European Public Health Alliance, Every Child by Two, Farmamundi, GAVI CSO Constituency, German Foundation for World Population (DSW), Ghana Coalition of NGOs in Health, Global Action for Children, Global

Commission on HIV and the Law, Global Eye, Global Health Advocates, Global Health Council, Global Health Technologies Coalition, Global Poverty Project, Health Action International, Health and Rights Education Program, Health Development Consultancy Services (HEDECS), HealthNet TPO, Interact Worldwide, International Council of Voluntary Agencies, International Federation of Red Cross and Red Crescent Societies, International HIV/AIDS Alliance, International Research Foundation for Development, Kaiser Family Foundation, Kenya AIDS NGOs Consortium, Kenya Community Health Network, Kenya Red Cross, Kid Risk, Inc., Knowledge Ecology International, Light Africa International, Lions Club International Foundation, Malaria No More, Management Sciences for Health, Millennium Development Goals Health Alliance, Médecins du Monde, Medecins Sans Frontières, Medicos del Mundo, Mundo Sano, Niger's Regroupement des ONGs et Associations du Secteur de la Santé, Nothing But Nets, ONE, Oxfam, Partnership for Maternal, Newborn, and Child Health CSO constituency, PATH, Philippine Foundation for Vaccination, Plan International,

Planeta Salud, Policy Cures, PSI, Réseau des Plates-formes nationales d'ONG d'Afrique de l'Ouest et du Centre, RESULTS, Results for Development, Rotary International, Sabin Vaccine Institute, Save the Children, Sightsavers, Soins de Sante Primaires en Milieu Rural, Stop AIDS Alliance, Strengthening Rights and Equality by Empowering Teams, Swaasthya, Task Force for Global Health, TB Alert, Terre des Hommes, The Centre for Health Policy, The Communications Initiative, The INCLIN Trust International, Union des ONG du Togo, Union for International Cancer Control, United Methodist Church General Board of Church and Society, United Nations Foundation, U.S. Fund for UNICEF, Vaccines for Africa Initiative, Welthungerhilfe, World Vision.

PRIVATE SECTOR:

Applied Strategies, Bernard Fanget Consulting, Boston Consulting Group, Codexis, Dynavax, Evergreen Associates, Global Health Strategies, GMMB, John Snow, Inc., Johnson & Johnson, Kleiner Perkins Caufield & Byers, Lion's Head Global Partners, Liquidia Technologies, McKinsey & Company, MedImmune, NeoVacs, S.A., PricewaterhouseCoopers, Weber Shandwick.

COUNTRIES THAT PROVIDED INPUTS AND COMMENTS TO THE GLOBAL VACCINE ACTION PLAN:

Afghanistan, Albania, Algeria, Angola, Argentina, Armenia, Australia, Austria, the Bahamas, Bangladesh, Barbados, Belgium, Belize, Benin, Bolivia (Plurinational State of), Botswana, Brazil, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Canada, Cape Verde, the Central African Republic, Chad, Chile, China, Colombia, Congo, Costa Rica, Cote d'Ivoire, Cuba, Cyprus, the Democratic Republic of Congo, Denmark, the Dominican Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea, Estonia, Ethiopia, Finland, the Former Yugoslav Republic of Macedonia, France, French Guiana, Gabon, the Gambia, Georgia, Germany, Ghana, Greece, Guatemala, Guinea, Guinea-Bissau, Haiti, Honduras, Hungary, India, Indonesia, Ireland, the Islamic Republic of Iran, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Kyrgyzstan, Lao (People's Democratic Republic), Lebanon, Lesotho, Liberia, Libya, Madagascar, Malawi, Maldives, Mali, Mauritania, Mauritius, Mexico, Monaco, Mongolia, Morocco, Mozambique, Myanmar, Namibia, Nepal, the Netherlands, Nicaragua, Niger, Nigeria, Norway, Pakistan, Panama, Papua New Guinea, Paraguay, Peru, the Philippines,

Poland, Portugal, Qatar, Republic of Korea, Russian Federation, Rwanda, Sao Tome and Principe, Saudi Arabia, Senegal, Serbia, Seychelles, Sierra Leone, Singapore, Somalia, South Africa, South Sudan, Spain, Sudan, Suriname, Swaziland, Sweden, Switzerland, the Syrian Arab Republic, Thailand, Timor-Leste, Togo, Trinidad and Tobago, Tunisia, Turkey, the Turks and Caicos Islands, Uganda, Ukraine, the United Kingdom of Great Britain and Northern Ireland, the United Republic of Tanzania, the United States of America, Uruguay, Uzbekistan, Venezuela (Bolivarian Republic of), Viet Nam, Yemen, Zambia, Zimbabwe.

Annex 6: The Monitoring and Evaluation/ Accountability Framework

Background

The Monitoring and Evaluation/Accountability Framework is a critically important element of the [Global Vaccine Action Plan \(GVAP\)](#). Recognizing the importance to closely monitor the GVAP implementation progress, the [World Health Assembly \(WHA\) resolution](#) called for annual reports on progress at each Regional Committee meeting and at the WHA, through the WHO Executive Board (EB).



IN DEFINING THE SCOPE OF THE M&E/A FRAMEWORK, THE GVAP REFERS TO THE NEED:

TO FINALIZE a complete set of GVAP indicators with the appropriate methodology and data sources for each indicator defined and baselines established, where required.

TO INVEST in improving data quality and developing more robust in-country monitoring and evaluation systems.

TO SECURE commitments aligned with the GVAP from different stakeholders, including countries, civil society organizations, multilateral agencies, private foundations, development partners, and vaccine manufacturers.

TO DEVELOP a mechanism for coordinating the implementation of these commitments at global, regional and national levels.

TO ENSURE annual reporting of progress at each Regional Committee meeting and at the WHA, through the WHO EB.

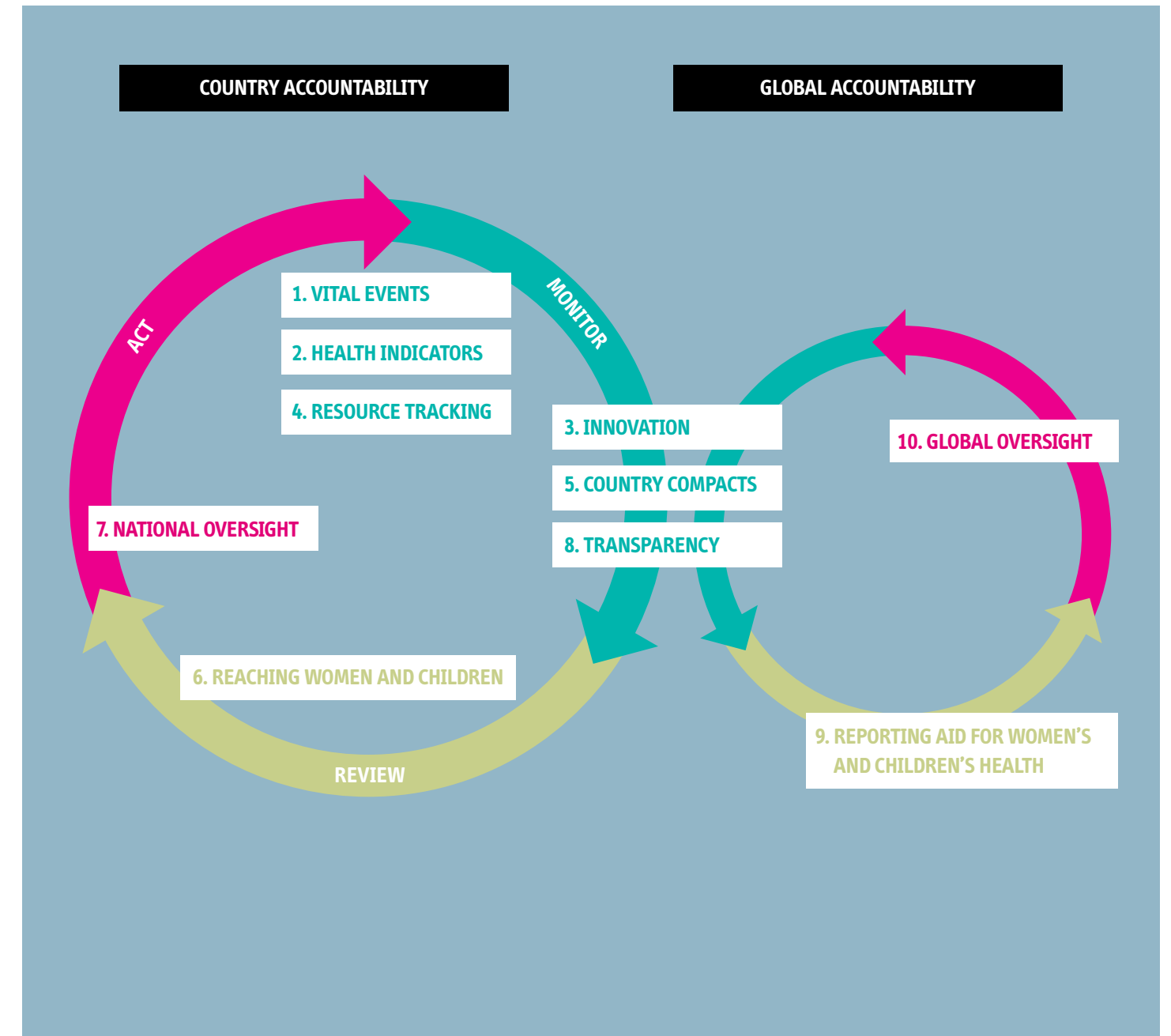
The Accountability Framework for the United Nations (UN) Secretary General’s Global Strategy for Women’s and Children’s Health

The GVAP calls for leveraging the recommendations of the Commission for Information and Accountability for Women’s and Children’s Health and aligning work, wherever possible, with other accountability efforts.

The Accountability Framework of the UN Secretary General’s Global Strategy for Women’s and Children’s Health refers to a cyclical process of monitoring, review and remedy/action to assess progress, document success, identify problems that need to be rectified and take prompt action as and where needed. This process needs to occur at the country and global levels as illustrated in Figure 1.⁶ To have a better oversight of progress an independent Expert Review Group (iERG)⁷ reports annually to the UN Secretary General on the results and resources related to the Global Strategy and on progress in implementation of the Commission’s recommendations. The Decade of Vaccines annual report that will be submitted to the WHA will also be shared with the iERG as information for their annual report to the UN Secretary General.

6 Commission on Information and Accountability for Women’s and Children’s Health. Keeping Promises, Measuring Results. World Health Organization 2011 (http://www.who.int/woman_child_accountability/en/)
 7 iERG members http://www.who.int/woman_child_accountability/iERG/members/en/

FIGURE 1:
THE ACCOUNTABILITY FRAMEWORK FOR THE UN SECRETARY GENERAL’S GLOBAL STRATEGY FOR WOMEN’S AND CHILDREN’S HEALTH



Proposed Process for the GVAP Monitoring and Evaluation / Accountability Framework

A similar cyclical process of monitoring, review, and recommendations for action is proposed for the GVAP M&E/A Framework. In addition to the national and global levels, another level of GVAP M&E/A at the regional level is required to accommodate the requirement of reporting annually to the WHO Regional Committees.

Using a similar framework allows for complementarity with the accountability process for the UN Secretary General Global Strategy for Women’s and Children’s Health and provides opportunities to leverage and/or use these processes for tracking and reporting on some of the aspects of GVAP. This applies in particular to the process to monitor commitments and resources as described in the related documents for this session. [Figure 2](#) illustrates the proposed GVAP M&E/A Framework process. Guidelines for making immunization commitments under the UN Secretary General Global Strategy for Women’s and Children’s Health framework can be found on each Decade of Vaccines (DoV) Collaboration Leadership Council website.

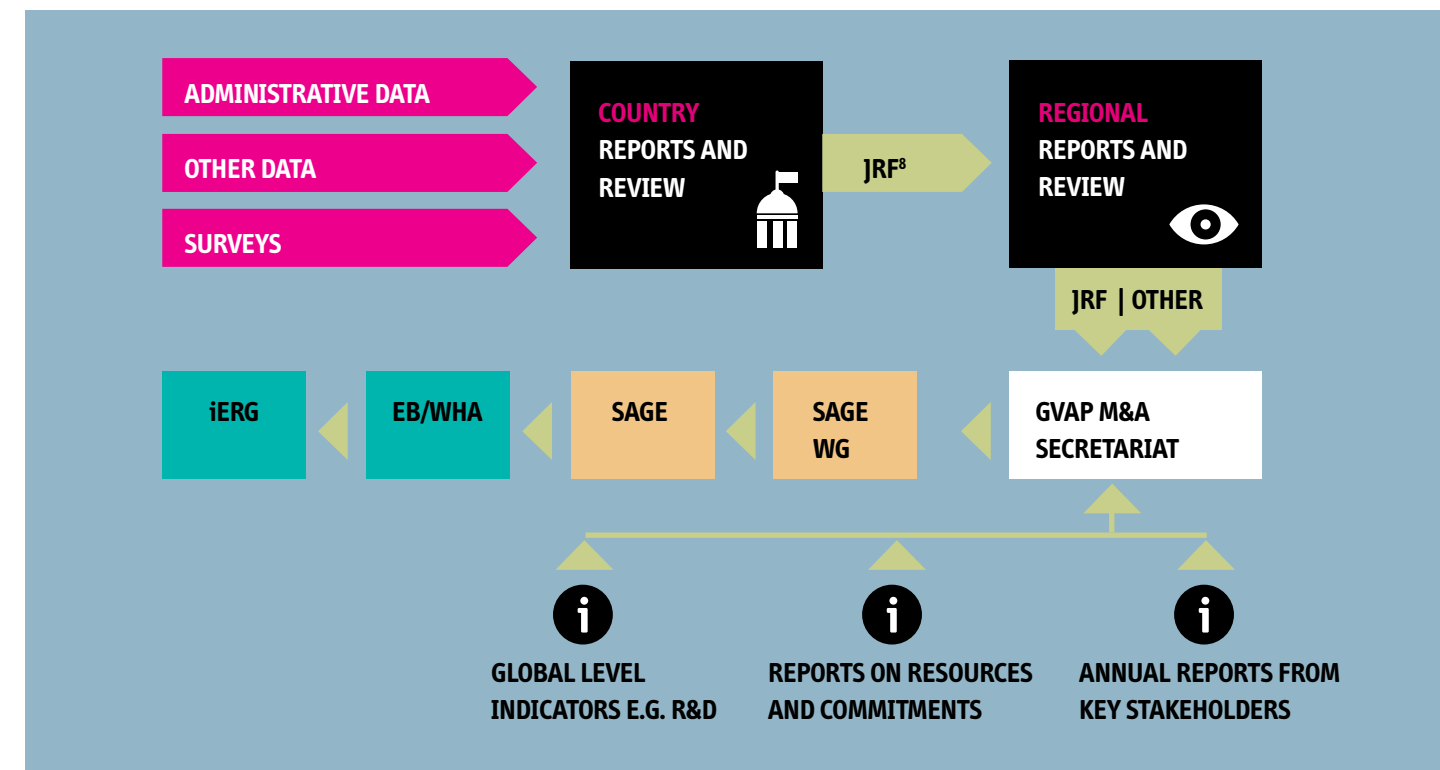
The GVAP M&E/A Framework will be applied to: (1) monitoring results (defined as progress against the GVAP Goals’ and Strategic Objectives’ indicators); (2) documenting and monitoring stakeholder commitments to GVAP and DoV; (3) tracking resources invested in vaccines and immunization; and (4) inclusion of independent oversight and review of progress, through the World Health Organization Strategic Advisory Group of Experts (SAGE) on Immunization, in the reporting to the governing bodies.

A final set of GVAP indicators ([see Table 12](#) and [Table 13](#)) was reviewed and approved by SAGE during their 6-8 November 2012 meeting, and will be presented to the WHO EB in January 2013 and the WHA in May 2013.

MONITORING COMMITMENTS AND RESOURCES:

The M&E/A Framework will also document and monitor stakeholders commitments to GVAP and track resources invested in vaccines and immunization.

FIGURE 2:
PROPOSED GVAP MONITORING AND EVALUATION/ACCOUNTABILITY FRAMEWORK




GLOBAL LEVEL: The annual review process will go through SAGE, the WHO EB and the WHA. The report will also be shared with iERG for their women’s and children’s health annual report to the UN Secretary General.

REGIONAL LEVEL: The WHO Regional Offices are developing their mechanisms for review and reporting to the Regional Committees. Regional Technical Advisory Groups on Immunization may take on that role, similar to the SAGE role at the global level.

COUNTRY LEVEL: The National Immunization Technical Advisory Groups (NITAGs) and the Interagency Coordination Committees (ICCs) could also assume roles of monitoring commitments and resources at the country level. This will be determined as countries continue to develop their national plans.

8 JRF is the WHO and UNICEF Joint Reporting Form.

TABLE 12: PROPOSED EXTENDED GOALS INDICATORS

	1. ACHIEVE A WORLD FREE OF POLIOMYELITIS			2. MEET GLOBAL AND REGIONAL ELIMINATION TARGETS		
INDICATORS	1.1. Interrupt wild poliovirus transmission globally	1.2. Certification of poliomyelitis eradication	2.1. Neonatal tetanus elimination	2.2. Measles elimination	2.3. Rubella/CRS elimination	
OPERATIONAL DEFINITION	No wild poliovirus isolated globally for at least 1 year, in the presence of certification quality AFP surveillance (annual non-polio AFP rate of at least 1/100,000 population < 15 years at national and sub-national level, with adequate stool specimens collected from at least 80% of AFP cases)	No wild poliovirus isolated globally for at least 3 years in the presence of certification quality AFP surveillance	< 1 NT case/1,000 live births in each district and maintenance of elimination based on annual WHO/UNICEF District Data Spreadsheet	Number of regions with 100% of countries having declared interruption of endemic measles virus transmission for a period of > 12 months in the presence of high quality surveillance The surveillance quality will be assessed as described in criteria for verification of elimination	Number regions with 100% of countries having declared interruption of endemic rubella virus transmission for a period of > 12 months without occurrence of CRS cases associated with endemic transmission in the presence of high quality surveillance	
DATA SOURCE/COLLECTION	National AFP surveillance systems + supplementary surveillance data where available (environmental surveillance or enterovirus surveillance through national lab networks)	Final national documentation on polio-free status submitted by NCCs and accepted by RCCs	WHO/UNICEF District Data Spreadsheet, and WHO validation report (based on LQA in worst performing district)	Each region has a verification commission which annually reviews the status of all countries	Each region has a verification commission which annually reviews the status of all countries	
BASELINE	2011: 650 WPV-confirmed cases reported from 16 countries	2011: National documentation on polio-free status accepted by RCCs in 168 out of 194 WHO member states (87%)	2010 (40 countries still to achieve elimination)	2010 (0/5 regions - AMRO, WPRO, EMRO, EURO, AFRO)	2010 (0/2 regions - AMRO, EURO)	
TARGET	2014	2018	2015	2015: 4 WHO regions 2020: 5 WHO regions	2015: 2 WHO regions 2020: 5 WHO regions	
MILESTONES	Track number of countries with national documentation of polio-free status, accepted by RCCs		10 countries eliminated NT by 2012; 22 countries eliminated NT by 2013; 36 countries eliminated NT by 2014; 40 countries eliminated NT by 2015	Monitor # and % of countries in each region that are verified as having eliminated diseases	Monitor # and % of countries in each region that are verified as having eliminated diseases	



3. MEET VACCINATION COVERAGE TARGETS IN EVERY REGION, COUNTRY AND COMMUNITY

INDICATORS

3.1. Reach 90% national coverage and 80% in every district or equivalent administrative unit with three doses of diphtheria-tetanus-pertussis containing vaccines

3.2. Reach 90% national coverage and 80% in every district or equivalent administrative unit for all vaccines in national programmes, unless otherwise recommended

OPERATIONAL DEFINITION

WHO UNICEF Estimates of National Immunization Coverage (WUENIC)* for national coverage;

District data:

- accept JRF admin data if WUENIC based on administrative coverage; missing district reports =indicator not met, encourage reporting;
- if WUENIC not based on administrative coverage, repeated measure (at least two

- surveys or special studies to document district coverage); early measure (2009 to 2015) and later measure (2016 to 2020)
- countries may choose to conduct surveys in selected “high risk” districts likely to have low coverage
- surveys should be conducted at least twice in the decade (baseline and one other time) but countries should aim for more frequent surveys

Determination of national and district level coverage as defined above

Indicator applies to all vaccines being used for country-wide, universal immunization (exception of HPV, where country-wide universal immunization of girls would be included)

Coverage refers to coverage with primary series of vaccine

For pneumococcal and rotavirus vaccines, this will be coverage with primary series by 12 months of age. For other vaccines, the exact measurement of coverage needs to be defined, but will be as reported in the WUENIC

DATA SOURCE/COLLECTION

WUENIC, JRF, surveys or special studies

WUENIC, JRF

BASELINE

2010 or early measure

2010 or early measure (for district data)

TARGET

2015 – all Member states

2020: All Member States

MILESTONES

Monitor trends in coverage

Monitor trends in coverage

	4. DEVELOP AND INTRODUCE NEW AND IMPROVED VACCINES AND TECHNOLOGIES				5. EXCEED THE MILLENNIUM DEVELOPMENT GOAL 4 TARGET FOR REDUCING CHILD MORTALITY
INDICATORS	4.1. Licensure and launch of vaccine or vaccines against one or more major currently non-vaccine preventable diseases	4.2. Licensure and launch of at least one platform delivery technology	4.3. Number of low-income and middle-income countries that have introduced one or more new or underutilized vaccines		5.1. Reduce under-five mortality rate
OPERATIONAL DEFINITION	Licensure relates to registration by a functional National Regulatory Authority (NRA) Launch is defined as addition of the vaccine to the national immunization schedule in one or more low or middle income countries (WB definition) and sustained for a period of at least 12 months. Excludes use only in the private sector. Includes vaccines in national schedule that may be selectively used in “at risk” populations	Licensure relates to registration by a functional NRA New platform delivery technology is defined as a new mechanism for delivering vaccines to individual recipients that facilitates coverage, improves performance, or reduces cost of vaccine or delivery, e.g. jet injectors, microneedles, aerosol etc. Launch as defined for new vaccine introduction (see above indicator)	Low- and middle-income countries= world bank classification 2012 Vaccine is added in national immunization schedule and used for a sustained period of at least 12 months (excluding those used only in the private sector and not in national immunization schedule; includes vaccines included in national schedule but for selective use at risk populations, e.g. seasonal influenza) New and underutilized vaccines refers to all vaccines that were not previously in national immunization schedule		Under-five mortality rate per 1000 live births
DATA SOURCE/COLLECTION	Annual surveys with NRA’s; JRF for launch of vaccine; WB for definition of low and middle income countries	Annual surveys with NRA’s; JRF for launch; WB for definition of low and middle income countries	World Bank, JRF		United National Interagency Group on Mortality Estimates (IGME)
BASELINE	0	0	2010		
TARGET	2020: one or more	2020: one or more	2015: at least 90 2020: all low and middle income countries		2015:2/3 reduction compared to 1990 2020: exceed 2015 target
MILESTONES	Incremental progress (i.e. number of products in phase 1, 2 or 3 clinical trials) on development to be reported and assessed by SAGE	Incremental progress on development (i.e. number of products in phase 1, 2 or 3 clinical trials) to be reported and assessed by SAGE	Monitor trends in vaccine introduction		Monitor trends

* WUENIC= WHO UNICEF Estimates of National Immunization Coverage

TABLE 13: PROPOSED EXTENDED STRATEGIC OBJECTIVE INDICATORS

1			2		
ALL COUNTRIES COMMIT TO IMMUNIZATION AS A PRIORITY			INDIVIDUALS AND COMMUNITIES UNDERSTAND THE VALUE OF VACCINES AND DEMAND IMMUNIZATION BOTH AS A RIGHT AND A RESPONSIBILITY		
INDICATORS			INDICATORS		
	1.1. Domestic expenditures for immunization per person targeted	1.2. Presence of an independent technical advisory group that meets defined criteria		2.1. Percentage of countries that have assessed (or measured) the level of confidence in vaccination at subnational level**	2.2. Percentage of un- and under-vaccinated in whom lack of confidence was a factor that influenced their decision**
OPERATIONAL DEFINITION	<p>Immunization expenditure from national domestic resources, as reported in the JRF</p> <p>Size of target populations as reported in JRF</p>	<p>National Immunization Technical Advisory Groups meeting all WHO criteria of functionality</p> <p>Criteria of functionality are as described in the WHO/UNICEF JRF</p>	OPERATIONAL DEFINITION	<p>Vaccination confidence: Trust in the usefulness and safety of vaccines and in the system that delivers them. Vaccination confidence exists on a continuum and is one of the factors that influences behavior ranging from acceptance to refusal.</p> <p>Determination, whether there been some assessment (or measurement) of the level of confidence in vaccination at subnational level.</p>	<p>Vaccination confidence: Trust in the usefulness and safety of vaccines and in the system that delivers them. Vaccination confidence exists on a continuum and is one of the factors that influences behavior ranging from acceptance to refusal.</p> <p>Determination of % of un- and under-vaccinated in whom lack of confidence was a factor that influenced their decision (this applies to all vaccines) and whether this % was measured or estimated.</p>
DATA SOURCE/COLLECTION	JRF	JRF	DATA SOURCE/COLLECTION	JRF	JRF
BASELINE	Reported expenditure for 2010	2010	BASELINE	TBD	TBD
TARGET	Increasing trend in country allocation to national immunization programmes	Functional National Immunization Technical Advisory Groups in all countries	TARGET	Increasing trend in the % of countries having assessed the level of confidence in vaccination at subnational level	Decreasing trend in the distribution of % of un- and under-vaccinated in whom lack of confidence is a factor at the national level.
MILESTONES	Monitor and report trends	Increasing trend in number of countries with functional NITAGs	MILESTONES	Monitor and report trends	Monitor and report trends

** Provisional indicator to be finalized based on outcomes of pilot assessment in selected regions.

3

THE BENEFITS OF IMMUNIZATION ARE EQUITABLY EXTENDED TO ALL PEOPLE

INDICATORS

3.1. Percentage of districts with 80% or greater coverage with three doses of diphtheria-tetanus-pertussis-containing vaccine

3.2. Reduction in coverage gaps between wealth quintiles and other appropriate equity indicator(s)

OPERATIONAL DEFINITION

Same process for determining district level coverage as for Goal 3

Determination of wealth index as defined in DHS and UNICEF Multi-indicator cluster surveys (MICS);

If wealth quintile is used should report coverage across all quintiles and not just lowest and highest quintile;

Data collection by repeated measure (special study or survey), with at least two measurements, early measure (2009-2015) and late measure (2016-2020)

DATA SOURCE/COLLECTION

JRF annual, or special studies/surveys for repeated measures

Household survey or special study representative of entire population

BASELINE

2010 or early measure

Early measure

TARGET

All countries with all districts $\geq 80\%$ DTP3 coverage by 2020

Increasing trend in equity in immunization coverage; Proposed target to align with GAVI targets: proportion of countries with $< 20\%$ difference in coverage between wealth quintiles 60% by 2015 and 75% by 2020

MILESTONES

Monitor trends in number of countries meeting the target

Increasing trend in equity in immunization coverage

4

STRONG IMMUNIZATION SYSTEMS ARE AN INTEGRAL PART OF A WELL-FUNCTIONING HEALTH SYSTEM

INDICATORS

4.1. Dropout rate between first dose (DTP1) and third dose (DTP3) of diphtheria-tetanus-pertussis-containing vaccines

4.2. Sustained coverage of diphtheria-tetanus-pertussis-containing vaccines 90% or greater for three or more years

OPERATIONAL DEFINITION

$((DTP1 - DTP3) * 100) / DTP1$

Countries sustaining coverage of 90% or higher for three consecutive years, based on WUENIC

DATA SOURCE/COLLECTION

WUENIC

WUENIC

BASELINE

2010

2010

TARGET

Decreasing trend in drop out rate

All countries by 2020

MILESTONES

Trends in drop-out rates

Increasing trend in number of countries sustaining coverage of 90% or higher

4

CONTINUED

INDICATORS

4.3. Immunization coverage data assessed as high quality by WHO and UNICEF

4.4. Number of countries with case-based surveillance for vaccine-preventable diseases

OPERATIONAL DEFINITION

Use qualitative assessment of data quality in WUENIC, based on nationally reported data, consistency in data on estimates of size of target population, and consistency between estimates from administrative and other data sources (surveys and other programmatic information)

countries reporting that they have established surveillance in the JRF and whose reports are included in WHO databases

Vaccine preventable disease surveillance will contain, at a minimum:

- country-wide surveillance for poliomyelitis, measles and neonatal tetanus;

DATA SOURCE/COLLECTION

WUENIC Grade of Confidence

JRF and surveillance reports to WHO

BASELINE

2010

TARGET

All countries to have high quality immunization coverage data by 2020

100% of countries for polio and measles surveillance by 2015

MILESTONES

Monitor trends in number of countries meeting the target

Increasing trend

5

IMMUNIZATION PROGRAMMES HAVE SUSTAINABLE ACCESS TO PREDICTABLE FUNDING, QUALITY SUPPLY AND INNOVATIVE TECHNOLOGIES***

INDICATOR

5.1. Percentage of doses of vaccine used worldwide that are of assured quality

OPERATIONAL DEFINITION

Number of doses of vaccines of assured quality used in a country / total doses of vaccines used in national immunization programme

Vaccines of assured quality include:

- Vaccines produced in a country with a functional national regulatory authority
- Vaccines prequalified by WHO

DATA SOURCE/COLLECTION

JRF; Assessment by the WHO team on quality, safety and standards for vaccines

BASELINE

2010

TARGET

100% of doses vaccines by 2020

MILESTONES

Increasing trend

***The report on progress will also include a narrative report on progress with vaccine supply, pricing and procurement.

6

INDICATORS

COUNTRY, REGIONAL AND GLOBAL RESEARCH AND DEVELOPMENT INNOVATIONS MAXIMIZE THE BENEFITS OF IMMUNIZATION.

6.1. Progress towards development of HIV, TB, and malaria vaccines

6.2. Progress towards a universal influenza vaccine (protecting against drift and shift variants)

6.3. Progress towards institutional and technical capacity carry out vaccine clinical trials

6.4. Number of vaccines that have either been re-licensed or licensed for use in a controlled-temperature chain at temperatures above the traditional 2-8 °C range

6.5. Number of vaccine delivery technologies (devices and equipment) that have received WHO pre-qualification against the 2010 baseline

OPERATIONAL DEFINITION

Number of HIV, TB, and malaria vaccine clinical trials assessing clinical efficacy completed and with results reported

Number of influenza clinical trials assessing clinically the breadth of protection completed and reported

Number of countries per WHO region having reported conduct of a vaccine clinical trials that meet quality standards (to be specified)

As defined in indicator

Four categories of equipment would be tracked:
 - Refrigerators and freezers
 - Cold boxes and vaccine carriers
 - Coolant packs
 - Temperature monitoring devices

DATA SOURCE/COLLECTION

WHO, NIH and other clinical trial registries

WHO, NIH and other clinical trial registries

WHO, NIH and other clinical trial registries

Reports from NRAs

PQS data base

BASELINE

Incremental above 2010

Incremental above 2010

TARGET

Proof of concept for a vaccine that shows greater or equal to 75% efficacy for HIV/AIDS, tuberculosis, or malaria vaccines

At least one vaccine providing broad spectrum protection against influenza A virus licensed

Every Region has a solid base of countries competent in hosting and managing vaccine trials

MILESTONES

Narrative report on progress in development of these vaccines

Narrative report on progress in development of these vaccines

Increasing number of vaccines

Increasing number of technologies

The SAGE Decade of Vaccines Working Group that will review the annual GVAP progress report will also consider the development and addition of indicators that measure equity in access to vaccines between countries, and an indicator to monitor integration of immunization systems into broader health systems.



Acknowledgements & Contacts

Approximately 1,100 participants from more than 140 countries and 290 organizations provided ideas, feedback, and comments to the Global Vaccine Action Plan.

This document was developed under the auspices of the Decade of Vaccines Collaboration Leadership Council, composed of Seth Berkley (GAVI Alliance), Margaret Chan (World Health Organization), Christopher Elias (Bill & Melinda Gates Foundation), Anthony Fauci (US National Institute of Allergy and Infectious Diseases), Anthony Lake (UNICEF), and Joy Phumaphi (African Leaders Malaria Alliance).

THE DECADE OF VACCINES COLLABORATION STEERING COMMITTEE GUIDED THE DEVELOPMENT OF THE GVAP:

Pedro Alonso (co-chair DoVC Steering Committee, the Barcelona Institute for Global Health), Ciro de Quadros (co-chair DoVC Steering Committee, the Sabin Vaccine Institute), Nicole Bates (co-chair Public & Political Support Working Group, Bill and Melinda Gates Foundation), Zulfiqar Bhutta (Aga Khan University), Lola Dare (The Centre for Health Sciences Training, Research and Development), Helen Evans (the GAVI Alliance), Lee Hall (National Institute of Allergy and Infectious Diseases), T. Jacob John (retired, Christian Medical College, Vellore, India), Jean-Marie Okwo-Bele (co-chair Delivery Working Group, the World Health Organization), Orin Levine (co-chair Global Access Working Group, Johns Hopkins Bloomberg School of Public Health), David Salisbury (co-chair Research & Development Working Group, the United Kingdom Department of Health), Anne Schuchat (National Center for Immunization and Respiratory Diseases, the U.S. Centers for Disease Control and Prevention), Peter A. Singer (co-chair Public & Political Support Working Group, Sandra Rotman Centre, University Health Network and University of Toronto), Lucky Slamet (the National Agency of Drug and Food Control,

Indonesia), Gina Tambini (the Pan American Health Organization), Jos Vandelaer (co-chair Delivery Working Group, UNICEF), and Sandy Wrobel (co-chair Global Access Working Group, Applied Strategies).

EIGHT WORKING GROUPS:

(Delivery, Global Access, Public & Political Support, Research & Development, Costing & Funding, Health & Economic Benefits, Monitoring & Evaluation/Accountability Framework Indicators, Communications) involving more than 100 participants have collaborated in the development of the document. More than additional 180 people participated in the working group discussions.

THE FOLLOWING INDIVIDUALS HAVE BEEN MEMBERS OF THE WORKING GROUPS:

DELIVERY WORKING GROUP CORE MEMBERS:

Amani Abdelmoniem (Ministry of Health, Sudan), Mercy Ahun (the GAVI Alliance), Shams el Arifeen ICDDRDB), Silvia Bino (Institute of Public Health, Albania), Brent Burkholder (CDC), Pradeep Haldar (Ministry of Health and Family Welfare, India), Clifford Kamara (the Sabin Vaccine Institute), Najwa Khuri-Bulos (Jordan University Hospital), Rebecca Martin (CDC),

Susan McKinney (USAID), Robert Steinglass (John Snow, Inc.), Liang Xiaofeng (Chinese CDC), John Wecker (PATH), Simon Wright (Save The Children UK).

More than 70 additional individuals participated in the discussions of the Delivery Working Group, and the following resource persons assisted the group: Teresa Aguado (WHO), Thomas Cherian (WHO), Rudi Eggers (WHO), Gian Gandhi (UNICEF), Ed Hoekstra (UNICEF), Steve Jarrett (UNICEF), Lidija Kamara (WHO), Patrick Lydon (WHO), Osman Mansoor (UNICEF), Carsten Mantel (WHO), Violaine Mitchell (Bill & Melinda Gates Foundation), Dragoslav Popovic (UNICEF), and Daniel Tarantola (WHO).

GLOBAL ACCESS WORKING GROUP CORE MEMBERS:

Girindre Beeharry (Bill & Melinda Gates Foundation), Kim Bush (Bill & Melinda Gates Foundation), David Cook (IAVI), Gerard Cunningham (Bill & Melinda Gates Foundation), Harkesh Dabas (Clinton Health Access Initiative), Patricia Danzon (The Wharton School, University of Pennsylvania), James Droop (the U.K. Department for International Development), Christopher Egerton-Warburton (Lion's Head Global Partners), David Ferreira (the GAVI

Alliance), Lauren Franzel (PATH), Björn Gillsater (UNICEF), Amanda Glassman (Center for Global Development), Shanelle Hall (UNICEF), Robert Hecht (Results for Development), Miloud Kaddar (WHO), Subhash Kapre (retired, the Serum Institute), Lothe Lene Jeanette (Norwegian Agency for Development Cooperation), Ian Lewis (UNICEF), Margie McGlynn (IAVI), Julie Milstien (University of Maryland), Neeraj Mohan (Clinton Health Access Initiative), Melinda Moree (BIO Ventures for Global Health), Mary C. Muduuli (African Development Bank), Raja Rao (Bill & Melinda Gates Foundation), Daniel Rodriguez (the Pan American Health Organization), Helen Saxenian (Results for Development), Meredith Shirey (UNICEF), Maya Vijayaraghavan (CDC), Melinda Wharton (CDC), Piers Whitehead (NeoVacs), Prashant Yadav (University of Michigan), Michel Zaffran (WHO). Johns Hopkins Bloomberg School of Public Health provided the support of Kyla Hayford to the group.

PUBLIC & POLITICAL SUPPORT WORKING GROUP CORE MEMBERS:

Geoff Adlide (the GAVI Alliance), Luis Barreto (retired, Sanofi Pasteur Canada), Shereen El Feki (Global Commission on HIV and the Law), David Gold (Global Health Strategies), Elizabeth Gore (UN Foundation),

Jennifer Kates (Kaiser Family Foundation), Kaia Lenhart (GMMB), Jesus Lopez-Macedo (UNICEF), Adrian Lovett (ONE), Maziko Matemba (Health and Rights Education Program, Malawi), Gregory Poland (Vaccine), Kammerle Schneider (IAVI), Kamel Senouci (Agence de Medecine Preventive), Nelson Sewankambo (Makerere University), Damian Walker (Bill & Melinda Gates Foundation), Peg Willingham (UN Foundation). Over 30 additional individuals participated in the discussions of the Public and Political Support Group. The working group received support from Stephanie Lazar, consultant to the Bill & Melinda Gates Foundation, and Lauren Leahy from the Sandra Rotman Centre.

RESEARCH & DEVELOPMENT WORKING GROUP CORE MEMBERS:

Alex von Gabain (Intercell), Bruce Gellin (U.S. Department of Health and Human Services), Jesse Goodman (Food and Drug Administration), Marie-Paule Kieny (WHO), Margaret Liu (ProTherImmune), Christian Loucq (International Vaccine Institute), Adel Mahmoud (Princeton University), Tom Monath (Kleiner Perkins Caufield & Byers), Gary Nabel (National Institutes of Health), Regina Rabinovich (Bill & Melinda Gates Foundation), Rino Rappuoli (Novartis Vaccines & Diagnostics), Steve Reed (Infectious Diseases

Research Institute), Adam Sabow (McKinsey & Company), Chris Wilson (Bill & Melinda Gates Foundation). Around 110 individuals participated in the discussions of the R&D Working Group.

DOV COSTING & FUNDING TECHNICAL WORKING GROUP:

Logan Brenzel (Bill & Melinda Gates Foundation), Hugh Chang (PATH and DOVC Secretariat), Santiago Cornejo (GAVI Alliance), Eliane Furrer (GAVI Alliance), Lauren Franzel (PATH), Gian Gandhi (UNICEF), Patrick Lydon (WHO), Carol Marzetta (Applied Strategies), Helen Saxenian (Results for Development), and Sandra Wrobel (Applied Strategies), with consultancy services provided by The Boston Consulting Group.

HEALTH & ECONOMIC BENEFITS WORKING GROUP:

Jessica Atwell (Johns Hopkins University), Dagna Constenla (Johns Hopkins University), S. Deblina Datta (the GAVI Alliance), Ingrid Friberg (Johns Hopkins University), Marta Gacic-Dobo (WHO), Sue Goldie (Harvard School of Public Health), Peter Hansen (the GAVI Alliance), Lisa Lee (the GAVI Alliance), Orin Levine (Johns Hopkins University), Meredith O'Shea (Harvard School of Public Health), Sachiko Ozawa (Johns Hopkins University), Susan Reef

(CDC), Meghan Stack (Johns Hopkins University), Peter Strebel (WHO), Chutima Suraratdecha (PATH), Steven Sweet (Harvard School of Public Health), Yvonne Tam (Johns Hopkins University), Emilia Vynnycky (Health Protection Agency), Damian Walker (Bill & Melinda Gates Foundation), Neff Walker (Johns Hopkins University), Steve Wiersma (WHO).

**MONITORING & EVALUATION/
ACCOUNTABILITY FRAMEWORK
INDICATORS WORKING GROUP:**

David Brown (UNICEF), Tony Burton (WHO), John Grove (Bill & Melinda Gates Foundation), Chung-Won Lee (CDC), Dragoslav Popovic (UNICEF), Daniel Thornton (GAVI Alliance), with consultancy services provided by The Boston Consulting Group.

COMMUNICATIONS WORKING GROUP:

Courtney Billet (NIAID), Hayatee Hasan (WHO), Hannah Kurtis (PAHO), Christian Moen (UNICEF), Jeffrey Rowland (the GAVI Alliance), Karen Lowry Miller (Bill & Melinda Gates Foundation).

The World Health Assembly in May 2011 and the WHO Executive Board in January 2012 reviewed the initial drafts of the GVAP and provided valuable inputs and guidance on the process and the content of the GVAP.

UNICEF organized a briefing of UN member states representatives on the 19 January 2012 in New York. Appendix 5 contains a list of all countries and organizations that have contributed to the document.

The DoV Collaboration Secretariat was responsible for preparing and managing the consultation process of the Global Vaccine Action Plan in close coordination with the Steering Committee and the Working Groups. The members of the Secretariat were: Magdalena Robert (Director), Altaf Lal (Technical Director), Hugh Chang (Advisor to Co-chairs), Enric Jané (Advisor to Co-chairs), Santiago Porto (Project Manager), Laura Moya (Working Group Coordinator for Delivery and Research & Development Working Groups), Laurie Werner (Working Group Coordinator for Global Access and Public and Political Support Working Groups), Laia Bertran (Project Officer), Richard Hatzfeld (Communications), Amy

Alabaster (Communications), Dan Epstein (Communications), Joan Tallada (CSOs Coordinator), Claudia Hernandez (Project Assistant), Yolanda Amat (Project Assistant), Desirée Van der Mei (Project Assistant), Monique Shields (Project Assistant).

The Steering Committee members endorse the Global Vaccine Action Plan and generally agree with its findings. The document represents a common vision of the Steering Committee, incorporating inputs from members of the different working groups, academia, civil society, and industry, and inputs received through various consultations. Naturally, not every view expressed in this document reflects the views of all individuals and institutions that participated in the development of the plan. Individuals and institutions might have different perspectives on some of the issues. The views expressed by individuals do not represent the position of the institutions to which they belong. The Steering Committee members would like to publicly thank all stakeholders engaged in this collaboration.

Questions about the Global Vaccine Action Plan can be directed to representatives from the Decade of Vaccines Collaboration Leadership Council agencies.



Bill & Melinda Gates Foundation
Email: media@gatesfoundation.org



GAVI Alliance
Email: info@gavialliance.org



National Institute of Allergy and Infectious Diseases (NIAID)
Email: ocpostoffice@niaid.nih.gov



United Nations Children's Fund (UNICEF)
Email: immunization@unicef.org



World Health Organization (WHO)
Email: vaccines@who.int

The Decade of Vaccines Collaboration Secretariat was hosted by:



