Delivering Immunization in the Next Decade

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1. INTRODUCTION

Immunization programmes have been in place in countries for over 30 years, following the inception of the Expanded Programme on Immunization in 1974. Subsequently, they have been boosted by several regional and global initiatives, including the Universal Children Immunization Initiative in the 1990s. Over the last decade, the GAVI Initiative launched in 2000 and more recently the Global Immunization and Vision and Strategy, 2006-2015, have stimulated interest and investment in child immunization. Yet, a substantial proportion of each annual birth cohorts do not benefit from available vaccines, and immunization programmes remain isolated from other components of primary health care. Health services have yet to acquire the capacity to introduce new vaccines on a wide scale and prepare for the expansion of the constantly growing array of vaccines intended to be beneficial to infants, older children, adolescents and adults, and there are growing concerns about inequities affecting the most disease-prone populations—in particular the poor and underserved communities in low and middle-income countries.


GIVS was launched in 2006 as the first-ever 10-year framework to fully realize the potential of immunization in controlling morbidity and mortality from vaccine preventable diseases. The GIVS overarching goal to reducing global morbidity and mortality by two-thirds in 2015 compared to 2000 levels allowed to estimate that immunization has the potential to contribute 25% to the achievement of MDG4. To achieve this goal, countries were expected by 2010 to reach 90% national immunization coverage and 80% in every district or equivalent administrative unit, and reduce measles deaths by 90% over the Year 2000. By 2010, GIVS had succeeded as a rallying point globally and was well adopted by many countries as an over-arching strategic framework for immunization, through a recommended and comprehensive menu of 24 distinct strategies and 98 priority activities. The global framework was used to develop regional immunization strategies and by many countries to develop comprehensive, fully-costed, multi-year national plans for immunization. Several companion documents were developed to support the implementation of the strategies in GIVS, including the Global Framework for Immunization Monitoring and Surveillance, the New and Underutilized Vaccine Introduction Action Plan and the Measles Control Strategic Plan.

Some of the successful outcomes of GIVS include i) the development of new recommendations for routine immunization for children, adolescents and adults; ii) expansion of use of new vaccines in the developing countries, particularly with support from GAVI and innovative financing mechanisms such as
The International Finance Facility for Immunization (IFFIm) and Advance Market Commitment (AMC) for pneumococcal vaccine that were successfully piloted; iii) the launch of the synergistic approaches to pneumonia, diarrhoea and cervical cancer control, where vaccination formed one of a package of interventions and iv) the establishment of a sentinel site surveillance networks for invasive bacterial diseases and rotavirus diarrhoea as a platform for surveillance for diseases targeted by new vaccines;

The GIVS framework was also perceived to have some weaknesses, including the following: i) insufficient articulation of basic assumptions around vaccine availability and financial feasibility of immunization programmes; ii) insufficient engagement of country level policy-makers, programme managers, civil society organization and professional societies in drafting GIVS; iii) while GIVS emphasized the need to consider immunization within the larger health systems context, follow up action to re-establish immunization as a core component of primary health care was not taken was inadequate; iv) though the vision statement envisaged a world in which immunization was valued, the follow up actions to realize this vision were insufficient.

Among the reasons for these shortcomings was that documents and action plans developed to support the implementation of the strategies articulated in GIVS did not receive the required visibility. In addition, while GIVS provided a framework for developing country multi-year plans for immunization, they were not always linked to data emanating from programme reviews, were often disconnected from other health plans, both in terms of planning cycles and insufficient attempts to seek and create synergies between programmes. These plans often remain stand-alone documents failing to position immunization firmly within the context of primary health care. Having reached the mid-point of its implementation lifespan, the experience gained from the first five years of GIVS can be applied to the refocusing and expansion of efforts underway, the introduction of innovative remedies to noted obstacles, and the projection of an even more ambitious vision for the coming decade.

The Decade of Vaccines, 2011-2020: A Comprehensive Venture to Advance Immunization for Everyone

The Decade of Vaccines (DoV) is proposed as a vision for using the next ten years to achieve further immunization goals and key milestones in the discovery, development and delivery of lifesaving vaccines, focusing on children and the poor and striving towards a world without fear of disease. Whereas in the past century, considerable protection was achieved through vaccination, many inequities remain. Providing the same benefits to everyone everywhere must be the aim. Achieving this aim, based on the centrality of individual country needs and decisions, will require:

- establishing a strong demand for vaccination through a broad and sustained recognition of the value of vaccines;
- building stronger systems for the delivery of immunization services;
- creating the right incentives to ensure an adequate supply of affordable vaccines; and
- cultivating a robust scientific enterprise to produce innovation that realizes the power of immunization to improve the health status and quality of life of people around the world.

This vision, which builds on, learns the lessons of, and extends the fundamentals and time period of the GIVS framework, develops an overall strategy that amplifies GIVS through four key components:

1. Strengthening **Public Support and Demand** for vaccination, through increased public awareness of the societal and economic benefits of immunization and highlight the moral imperative to make it
available to all segments of society, particularly to the most vulnerable. In doing so, it will seek to re-establish immunization as a core component of primary health care.

2. Expanding the reach of Delivery programs to ensure that all persons at risk, particularly children, benefit from the protection that vaccines can provide, no matter where they live. Robust delivery systems with an adequately trained, competent and committed work-force will be central to ensuring the sustained high performance of the program.

3. Maintaining a strong pipeline of Research and Development (R&D) to harness the cutting edge of new science to produce new vaccine solutions and associated technologies and address the most pressing health needs and the programmatic constraints in developing countries.

4. Exploring a variety of strategies to ensure Global Access to sufficient supplies of vaccines of assured quality at prices that will facilitate the introduction and sustained use to meet the demand for equitable access and programmatic constraints in developing countries.

This document, to be further elaborated with active participation from Governments, the private health sector and civil society, takes a focus on the Delivery component of the Decade of Vaccines. To be fully developed by the end of 2011, it will be extended by action plans defining the roles and responsibilities of national and international actors; it will set goals, timelines and indicators to measure progress and promote accountability; it will be supported by a costing and financing plan. These documents will be submitted for review and approval to the May 2012 65th World Health Assembly.

II. DELIVERING IMMUNIZATION DURING THE DECADE 2011-2020

Immunization Delivery refers to the centrality of demand-driven, country-lead approaches and action in immunization based on equity, responsibility and accountability in a spirit of self-reliance and gradual self-sufficiency to achieve commonly shared global immunization goals. National programmes in low and medium income countries will benefit most from committed and sustained international cooperation in the formulation, dissemination and application of norms and standards of best practice, the acquisition of quality vaccines and technologies, and fair co-financing.

Overall Delivery Goal:

The goal of the Delivery stream of the Decade of Vaccine is, throughout the life-course, to achieve equity in the delivery of effective and safe immunization along with other essential primary health care interventions in order to prevent, control, eliminate or eradicate vaccine-preventable diseases.

Guiding Principles:
Over the decade, 2010-2020, the main focus of Immunization Delivery, therefore, will be to strengthen country capacities to deliver immunization services to all people, following five guiding principles:

- National ownership, responsibility and accountability in extending safe and effective immunization to their target populations;
• Greater equity and equality in access to immunization both within and across countries, with a particular focus on populations in greatest need;
• Ready and rapid access to new vaccines, technologies and products to meet national, regional and global disease burden reduction;
• Alignment of immunization with other primary health care interventions; and
• Preparedness and response to special needs created by unusual events, including humanitarian emergency action and the emergence of epidemics.

Internationally, greater reliance on decisions made by low and middle-income countries should guide technical and financial support. Official Development Assistance Agencies as well as international non-governmental organizations organization, including foundations, academic entities and not-for profit institutions have a critical role to play in combining resources to facilitate country-led strategies and decision-making.

III. The Delivery Strategy

The DoV Delivery Strategy aims at five objectives under which figure recommended approaches and, for each of them, essential activities. These objectives serve as a structure to the present Strategy, as follows:

Objective 1: Achieve equity in the use of vaccines: reaching every community with vaccination through complementary delivery methods that engage all appropriate health service providers in the public, private and non-governmental sectors; ensuring that the poorest and least-served are reached; building capacity and demand for the wider use of new vaccines; and strengthening the efforts to eradicate polio and eliminate measles and maternal and neonatal tetanus.

Objective 2: Uphold Immunization as a Human Right: creating, increasing and sustaining community trust in immunization and awareness of this right; and focusing on underserved and marginalized communities by shifting the current emphasis on “Reaching Every District” to “Reaching Every Community”.

Objective 3: Seek synergies with Immunization as a key component of primary health care: putting increased emphasis on disease burden reduction; encompassing the multiplicity of interventions needed to achieve this reduction with vaccines as an entry point or a complement to other interventions; and participating in collaborative efforts to renovate and strengthen overall health systems.

Objective 4: Develop immunization systems able to meet the challenge: improving systems and tools for generating evidence, monitoring programme performance and use of data for action; training, deploying and supporting adequate human resources for programme management and implementation; and building, maintaining and sustaining regular immunization procurement, delivery and effective supply systems.
Objective 5: Bolster National Self Reliance and Partnerships: Strengthening structures and processes for countries to develop immunization policy, strategies, and best practices; promoting greater ownership, political commitment, accountability and self-reliance of immunization programs; enabling formation of collaborative endeavors and engaging actors with a variety of expertise across different sectors; achieving sustainable immunization financing and sound financial management; and establishing national structures and enforcing processes for accountability.

An additional element, **Costing**, will work across these main objectives to establish the costs and funding required to meet Immunization Delivery goals and targets specifically in low and lower-middle income countries, and estimate the anticipated funding gap for the Decade in the specific DoV-Delivery component.

**Objective I. Achieve Equity in the Use of Vaccines**

Achieving equity in the use of vaccines will require not only improvements in some current practices applied to disease control, elimination, eradication, but also innovations to enhance delivery and utilization of services. Although global immunization services reach more than 80% of targeted recipients, wide disparities continue to exist both within and across countries. Immunization programmes reach children in most countries at least four times during their first year of life, thus providing the most comprehensive outreach of any public health service. They also create opportunities and provide a vehicle to incorporate other health interventions for greater health benefits. Furthermore, immunization can be more effective by incorporating it with other existing platforms.

Despite high rates of coverage, millions of infants and other targeted groups remain un-vaccinated or fail to receive all their recommended doses, leaving them exposed to preventable disease and death. To achieve greater equity in immunization it will be necessary to further address the special needs of marginalized or underserved populations. For that it will be necessary to evaluate and plan specific interventions to address the issues that are the result of social-economic status, race and ethnicity, gender, and health status. Additional ways need to be found to bolster demand and improve services to reach these children who are often the ones who fail to receive any public health services whatsoever.

Further efforts will be made to vaccinate those children older than one year of age. Reaching children during the second year of life can be a clear indicator of a health system’s capacity to effectively expand to deliver services. Vaccines are now increasingly more available to provide all age groups with long term protection against detrimental health effects of communicable diseases. While immunization contributes to lowering mortality, morbidity and disability in all age groups, these efforts can have an even more dramatic impact by controlling outbreaks and achieving regional/local elimination or even global eradication of some vaccine preventable diseases.

Key approaches towards achieving equity in immunization during the Decade of Vaccines are outlined below:

**Approach 1.1.: Develop a life course orientation to immunization**

Historically, vaccinations have been targeted primarily to children less than one year of age. This has resulted in a substantial decline in childhood mortality. It is increasingly recognized, however, that
vaccinating at older age groups can be critical, in boosting the effects of the infant doses, catching up infants who missed scheduled vaccines, or indeed, providing the first opportunity for deliver primary vaccinations. Recent WHO recommendations are that children receive two doses of measles vaccine, with the second dose being given after 12 months, either via routine services or mass vaccination activities. The effect of several vaccines given in infancy (e.g., DTP) is boosted by a second dose later in life. Vaccines such as HPV target girls aged 9 to 13 years of age, and additional vaccination services must be developed for this age group. Many other vaccines are beneficial to school children, adolescents, adults, the elderly, and to workers in specific professions (e.g., health workers, armed forces or animal handlers) demonstrating the need for the expansion of vaccination services to all age groups.

Administering Hep B, polio and other vaccines at birth has been a challenge in many countries and the effort to do so must be further strengthened. Compliance with school-entry immunization requirements and the comprehensive vaccination of health workers and other at-risk groups of people has been sub-optimal. Older age groups have had low level of compliance with immunization, including for seasonal influenza and influenza pandemic preparedness. Thus, throughout the Decade, countries will determine and regularly update a comprehensive vaccination schedule and a road map for timely administration of the vaccinations over the entire life course of for their populations.

Activities 1.1.:
- Develop, propagate and apply a method to determine the need for the vaccination of new age groups and other target groups. Formulate the risk benefit ratio of vaccinating each particular group with the specific vaccine.
- Build national / international capacity to apply this method to the specific national context.
- Identify delivery methods and strategies for informing, creating and responding to demand for reaching new target populations (new-borns, second year of life, adolescents, adults), while developing integrated packages of preventative health intervention delivery for these other age groups.
- While retaining the primary focus of the immunization programme on infants and mothers, expand the regular immunization schedule for all age groups and high risk groups, as determined by the countries.

Approach 1.2.: Bridge immunization gaps by overcoming barriers to equitable access.
Globally, 82% infants received three doses of DTP in 2009 leaving 23.5 million infants at risk for morbidity and mortality of vaccine preventable diseases. At the same time 122 out of 193 WHO member states reached at least 90% of their infants nationally and 45 countries reached at least 80% of DTP3 coverage in all their districts in 2009. Although immunization is among the most equitable health interventions, disparities between countries and within countries continue to exist, due to inadequate services, social and economic exclusions, among other factors.

DHS and MICS data show that, generally, the underserved populations with lower immunization status and bear a heavier burden of disease. This is correlated to living conditions, literacy and nutrition status. Consequently, the underserved populations have the greatest opportunity for gains in survival and development outcomes if services, including immunization, are provided to and used by them. Hence, provision of services to under-served populations—even at greater cost, is cost-effective. This is also
true for countries with high coverage that are missing to vaccinate their most vulnerable population groups.

As it strives for greater equity in immunization, each country will identify risk factors for missed opportunities and underlying causes of disparities affecting their population, developing strategies specifically designed to reduce the differences as they relate to immunization coverage. Countries will use current monitoring, surveillance and survey data to further analyse both the risks and underlying factors of exclusion or non-compliance. Risk factors may include: educational attainment of the mother; mother not being protected against tetanus; delivery not performed by skilled birth attendants; marginalization in urban areas; geographical isolation; financial obstacles; such system failures as lack of vaccines and qualified health workers; lack of knowledge of immunization benefits among, and demand from the underserved population; and insufficient use of demographic data including birth registration. Often, marginalized children are not accounted for in the national and sub-national data, as may be the case for orphans, street children, children detained with mothers or children in mobile, displaced or refugee populations. Underlying causes may invoke systemic denial or neglect of service provision to certain individuals or communities on the basis of discrimination as may be related to such factors as: social, cultural, economic and religious characteristics; political affiliation; racial or ethnic origin; or migrant status. Providing immunization as a human right to these most vulnerable population is a means to protect both individual and public health. Inequity and disparities in vaccination coverage among children as well as older age groups are multi-faceted problems calling for multi-sectorial responses.

Through the systematic conduct of barrier analyses, the Decade of Vaccines creates an opportunity to determine where immunization gaps exist, what risk factors and underlying causes they are associated to and which of these demand corrective actions that are under the purview of immunization services. Other reasons for inequity and disparity may require the intervention of other branches of health services, sectors of government and civil society organization. Immunization programmes should use the evidence they have collected and analyzed to alert such other actors and help induce and effect the needed structural or systemic changes within the means available to them.

Strategically, to reach equitably the entire population, alternate or mixed vaccination delivery methods need to be adopted and, to maximize their health benefits, to be associated with other primary health care interventions. Most children are reached today through the existing, established health services offering quality vaccination and other health services routinely through fixed facilities or in an outreach mode. Additionally, mass vaccination campaigns have been used to successfully boost the population immunity and to provide additional opportunities for polio eradication, and measles accelerated control. Increasingly, countries with weak health systems are recognizing this approach as a means to reach the previously unreached populations. More recently, countries have successfully implemented special days or weeks (called Child Health Days or Mother & Child Health Weeks) to deliver an array of preventative health interventions, including vaccinations. Meticulous follow up of missed scheduled vaccinations, the use of community mobilization, and taking full advantage of all vaccination opportunities are all important factors in improving delivery.

While celebrating the success of immunization programmes to date it is understood that new generation vaccines require delivery within a comprehensive health promotion and disease control framework which is to ensure maximal benefit and community acceptance. PCV and RV are two current examples of vaccines that particularly benefit from being delivered as part of comprehensive pneumonia and diarrhoea control programmes. However, over the next decade, as vaccines against HPV, malaria,
dengue, and TB become available and are introduced, the need to deliver vaccines as integral components of health promotion and comprehensive disease control programmes will only grow. With vaccines as a vital element of these programmes, the global vaccine community is in a position partner in these programmes and maximize their overall health impact.

Activities 1.2.:

- Use data on disease burden surveillance, survey and administrative immunization coverage, vaccine supply (particularly at district and facility levels), and micro-planning to identify population size, location and risk factors as well as underlying causes associated with low immunization coverage or high dropout rates.
- Conduct health-seeking behavior, opportunity and barrier analyses to determine motivation, constraints in demand, and patterns of utilization of immunization services.
- Undertake corrective action within the programme- based on the nature and magnitude of the barriers to immunization - including review and revision of communication strategies, greater sensitivity to risks and underlying determinants of low coverage, systematic review and update of micro-plans at the health facility or district level for all immunization services, and more efficient use of human and financial resources.
- Ensure that health professionals serve as change agents and understand, promote, and efficiently communicate the benefits of immunization.
- Develop, implement, and periodically review and collaboratively revise national health and social policies, laws, and programmes that address disparity and inequity issues as they relate to barriers to immunization.
- Appropriate funds and implement strategies to reach underserved populations.
- Establish effective follow up of vaccination defaulters through individual or community mechanisms.
- Utilize any contact a person may have with the health services as an opportunity to vaccinate, eliminating missed opportunities and shifting from a regimented to an opportunistic, encompassing and appealing approach.
- Develop a mechanism at global level for monitoring progress of reducing the disparities between and within countries.

Approach 1.3.: Introduce and expand the use of new vaccines, as determined by country-led, evidence-based decisions in the context of comprehensive health promotion and disease control interventions

The introduction of Haemophilus Influenzae type b (Hib) vaccine in developing countries has gained traction in spite of initial delays, with 158 countries having introduced this vaccine. To date though, only 38% of the 2009 global birth cohort currently lives in a country with nationwide availability of Hib, as China, India, Nigeria and Indonesia, comprising 45% of the developing country birth cohort, have yet to introduce this vaccine as part of their routine schedule.

Progress with the introduction of pneumococcal conjugate and rotavirus vaccines has been slow with respectively 42 and 23 countries having introduced them and only 11% of the 2009 global birth cohort living in a country with nationwide availability of either of these vaccines. The recent launch of the Advance Market Commitment (AMC) to encourage the development and production of pneumococcal
Conjugate vaccines (PCV) is predicted to contribute to accelerated uptake in GAVI-eligible countries. The AMC has secured up to 60 million doses of PCV per year for a 10 year period at an initial price of US $7 per dose, with price dropping to a maximum of $3.50 per dose once the AMC funds are used up.

Human Papilloma Virus (HPV) vaccines were licensed in 2006 and 2007 and have been introduced to date in 26 countries. Pilot projects conducted to introduce HPV vaccines in developing countries have shown the challenges for establishing a new platform for routine immunization of adolescents. There are licensed vaccines available against epidemic diseases, such as meningococcus, yellow fever, typhoid and cholera, but they vary greatly in their use. A meningococcal A conjugate vaccine that protects against group A meningococcus infections, cause of a majority of deadly outbreaks in the 25 countries of the "meningitis belt", has been introduced on a large scale in Burkina Faso, Mali and Niger in September 2010.

The Decade of Vaccines affords the opportunity to expand to all populations at risk the use of newly developed vaccines as well as others, such as cholera, typhoid and influenza vaccines that are available and licensed but under-utilized. Additionally, the Decade may see the advent of new formulations of existing vaccines or new vaccines currently under development—one or more vaccines against tuberculosis and malaria among them—which may become effective public health tools. To accomplish implementation of new and underused vaccines within a comprehensive health promotion and disease control framework, a transformative approach is required with the engagement of diverse stakeholders at district, national, regional, and global levels, and the establishment of collaborative endeavors to inform the policy process, support evidence-based decision-making, recognize and create efficiencies, and mobilize political will and financing. In all situations, the decision to introduce the use of new vaccines should rest with national authorities on the basis of quality information and careful evaluation of the readiness of immunization services to procure and deliver such new products in an effective, safe and sustainable fashion.

Recognizing that new vaccines do not address the entirety of major public health problems such as pneumonia and diarrhoea, more comprehensive disease prevention and control strategies are being elaborated where vaccination is just one element. Indeed, new vaccines currently introduced in public health programmes in low and medium income countries, such as those against Hib, pneumococcal pneumonia, rotavirus diarrhoea and meningitis A, offer only partial protection against these agents and none against other agents which may cause similar diseases but for which vaccines are currently unavailable. WHO and UNICEF have articulated a new "Global Action Plan for Pneumonia" (GAPP), with the aim to "Protect, Prevent, and Treat" combining vaccination and other primary health care interventions. There is increasing recognition that the association of the introduction of new vaccines with health promotion, care and treatment has multiple advantages: (1) It responds to community demands for care when vaccine fails; (2) It lends itself to creating community awareness about the fact that a particular disease for which a vaccine against a particular agent may be caused by other agents against which no vaccination is yet available; (3) It enhances health-seeking behaviours; (4) It fosters greater collaboration across the public and private health sector; and, importantly; (5) It has a greater impact on disease burden among communities that have routinely lesser access to public health and medical services. For these reasons, among others, country health programs will increasingly use innovative comprehensive health packages to reduce morbidity and mortality of vaccine-preventable diseases in an efficient and affordable way.
Activities 1.3:

- Identify appropriate alternatives or complements to fixed delivery methods and outreach services, to ensure that the target populations receive timely vaccinations and other interventions in every community, at least four times a year for children.
- Strengthen global and local structures and management capacity to process data and information for decision-making.
- Collect and analyze the evidence and document the mix of interventions that provides the best outcomes in specific settings and, under the leadership of the Ministry of Health, involve all relevant stakeholders in the design, planning, implementation, and evaluation of the comprehensive disease package to ensure availability of adequate resources and capacity.
- Define an integrated package of interventions by age group that can be delivered to prevent and control diseases that reflect country priorities.
- Define and establish a clear structure of accountability for all stakeholders, based on a stakeholder mapping.
- Support establishment and strengthening of coordination across programmes both nationally and internationally.
- Strengthen coordination between immunization and other programmes for better planning and implementation of coordinated interventions at the district level.
- Identify, inform and channel community demand to guide country decisions by making integrated vaccine preventable disease prevention and control known and used.
- Train, motivate, and supervise health workers at all levels of the health system to ensure effective delivery of comprehensive health interventions.
- Pool the financial, logistical, and human resources from various programs at field level to provide comprehensive interventions that maximize the impact of the resources.
- Utilize operations research and monitoring and evaluation to continuously adapt and improve the quality of the combined interventions and integrated health services.
- Use of all/appropriate health, nutrition, environmental, and education service delivery contacts to promote, provide and monitor immunization coverage to minimize missed opportunities.

Approach 1.4.: Prevent and respond to vaccine preventable diseases in outbreaks and humanitarian crises

Successfully preparing and responding to outbreaks, a vital component of immunization, requires effective surveillance systems, response mechanisms, impact mitigation, and effective management and coordination. These programs must be in line with national policies and international health regulations. Humanitarian crises expose vulnerable populations to increased risks of outbreaks and create a need for immediate vaccination responses. Valuable lessons have been learned in conducting campaigns which can be applied to epidemics and humanitarian emergencies. Experience from disease-control activities for polio, measles, maternal and neonatal tetanus, yellow fever, Japanese Encephalitis and epidemic meningitis demonstrates that when appropriate policies, programmes and resources are in place, targeted populations can be reached for immunization even in the most difficult and remote areas where routine health services are not readily available.
Countries at risk for epidemics need preparedness plans and financial resources firmly established in their overall immunization plan and services. Similarly, capacity is required at regional and global levels to prepare for a rapid and appropriate response to emergencies and natural disasters since that response involves the rational use of vaccines. Stockpiles of key vaccines that can be accessed by countries in a timely manner will play a crucial role in ensuring an effective response to contain epidemics and ensure equitable access to life saving vaccines. In the case of influenza, a global laboratory network monitors the circulating virus strains and all countries have developed preparedness plans for coping with a pandemic. WHO, UNICEF, vaccine manufacturers and research institutes will continue to support the development of national preparedness plans. These plans should include national, regional or global stockpiles of vaccines against measles, yellow fever, Japanese Encephalitis, polio, meningitis, cholera vaccines and H1N1 influenza. The experience obtained from the response to the 2009-2010 influenza pandemic should inform the preparation of and response to future health crises at the global, regional and country levels.

**Activities 1.4.:**
- In insecure and conflict areas, utilize all opportunities of relative calm for health workers to safely vaccinate and deliver other interventions to underserved populations.
- Develop and disseminate policy and guidance on use of vaccines in response to humanitarian emergencies, on vaccines of regional importance and on vaccines against epidemic-prone diseases.
- Develop and sustain national, regional and global capacity to respond to pandemic flu and other communicable disease epidemics due to new emerging agents.
- Support efforts to increase capacity at country level to conduct rapid risk analysis following an outbreak and develop an outbreak response preparedness plan.
- Strengthen regulatory capacity to respond to urgent needs for epidemic preparedness and response.
- Develop, coordinate and implement plans and funding to ensure access by countries to a stockpile of key vaccines for both epidemic control and pre-emptive campaigns.
- Maintain an effective surveillance system linked to the Global Alert and Response Network enabling the appropriate and timely use of vaccines in the context of emerging or threatening epidemics, and share information globally.

**Approach 1.5.: Achieve global and regional goals for accelerated disease control, elimination and eradication**

Global and regional eradication or elimination initiatives have been undertaken to rapidly decrease morbidity and mortality from specific diseases, and in the case of eradication to make the causal agent extinct. New regional goals for accelerated disease control, for meningitis, Japanese Encephalitis, Yellow Fever or hepatitis, may be set in future.

The eradication of small pox and other, on-going campaigns for disease elimination and eradication have shown that campaigns are a highly effective method of disease control particularly when the targeted population has been identified and appropriate means are available. The benefits of eradication are permanent and accrue after a finite cost whereas costs of controlling the same disease must be maintained indefinitely, and the costs are on-going. A time-limited goal of eradication allows...
mobilization of support more readily than a control program. However, the strain placed by eradication and elimination campaigns on health systems including human and financial resources, combined with epidemiological and technical issues, may limit the possibility of eradication. These programmes have developed tools and models to improve programme planning and management and enabled immunization services to be brought to even the most hard-to-reach communities providing an equitable and cost effective means of distributing multiple child survival interventions.

The success of any eradication/elimination initiative is based on 5 principles: (1) A dynamic adaptively managed, global coordination; (2) An efficacious, safe, and affordable vaccine; (3) Uncomplicated surveillance standards with clear performance indicators; (4) Robust, affordable diagnostic tests; and (5) International accreditation and certification mechanisms.

Disease control and eradication initiatives have given rise of highly performing surveillance and laboratory networks systems, along with collection, interpretation and use of data for programme guidance that have proved crucial for overall immunization programs.

Furthermore, these initiatives have made available tools and models that can improve program planning and management. These programmes have enabled immunization services to be brought to even the most hard-to-reach communities providing an equitable and cost effective means of distributing multiple child survival interventions. Disease targeted campaigns should contribute to the strengthening of health system, by providing physical equipment, skilled human resources, the assisting with institutional arrangements and operating procedures, and avoid draining resources from routine immunization and primary health care as a whole. For those diseases for which eradication goals have been set, implementation should have the additional aim of strengthening routine immunization and integrated disease surveillance.

Activities 1.5.:
- Strive to achieve the existing disease control goals
- Increase national responsibility for and accountability to the agreed global and regional goals.
- Forge effective partnerships involving governments, development agencies, as well as civil society, including private entities and foundations, for financing, advocacy and technical expertise.
- Establish a reliable supply of safe and effective vaccines to meet demand and create procurement mechanism that provide predictable and stable supply volume at optimal cost.
- Optimize the use of accelerated disease control, elimination and eradication resources and capacity, in order to simultaneously strengthen routine immunization and surveillance system in the hardest to reach areas.
- Sharpen tools and models to guide the accelerated control, elimination, and eradication programmes.

Objective II. Uphold Immunization as a human right
Past efforts to engage communities in immunization has often been seen and defined as garnering public “support” for programmes that were designed and implemented with limited say by those who
are the main intended beneficiaries of these efforts. To enroll community support has been attempted through various mechanisms: creating public awareness about the benefits of immunization, mobilizing community and political leaders in advocating for services, and the use of community-based structures to host immunization sessions. These efforts have yielded some degree of success but the high proportion (one in five) of children who, each year, do not benefit from full immunization with currently available vaccines indicates a critical shortcoming of national programmes. In 2002, the Reaching Every District (RED) approach was developed and introduced by WHO, UNICEF and other partners in the GAVI Alliance to improve immunization systems in areas with low coverage. Far from being a programme, or separate initiative, the approach outlined five operational components that are specifically aimed at improving coverage in every district: re-establishment of regular outreach services; supportive supervision: on-site training; community links with service delivery; monitoring and use of data for action; better planning and management of human and financial resources. The RED approach encourages countries to use coverage data to make an analysis of the distribution of unimmunized infants, and thereby prioritize districts with poor access and utilization of immunization, while districts are encouraged to make microplans to identify local problems and adopt corrective solutions. Concurrently, national reporting mechanisms shifted from national aggregates to district-based averages. Since 2003, 53 developing countries have started implementing RED to various degrees, mostly low and middle income countries in Africa and south and south-east Asia.

Building on this experience, the Decade of Vaccines aims to hone in on the 10-20% of each annual birth cohort within each district who, in the shadow of district-based averages, constitute the “tolerable” proportion of unvaccinated infants. Obstacles to reaching these children are often not related to geographical complexities but to social distance: a large proportion of under-served communities may be found everywhere and characterized by poverty, stigma and discrimination as is often the case for slum dwellers, migrant workers and ethnic minorities. The right to be immunized, as a component of the right to health granted to all children at their birth, belongs to these marginalized communities as it does to all people and states have obligations to progressively fulfill this right within the maximum amount of resources available to them. To fulfill this right is sound for individual and public health. As the Decade of Vaccines aims to combine vaccination with other primary health care interventions and to expand the age groups targeted for immunization, several approaches can be applied by states in fulfilling their obligations, including: (1) creating, increasing and sustaining community trust in immunization and awareness of immunization as a right; and (2) focusing on underserved and marginalized communities by shifting the current emphasis on “Reaching Every District” to “Reaching Every Community”.

**Approach 2.1.: Create, increase and sustain community trust in immunization and awareness of their rights**

Every effort will be made to shift the perception and attitude of communities from awareness and acceptance of immunization to active demand for a service to which they are entitled. Data shows that community participation in immunization programmes results in higher coverage and ultimately reduces the incidence of vaccine-preventable diseases. Communities and individuals are more likely to actively participate in, support and demand immunization services if they are convinced of the value of vaccination and trust the providers and delivery system. A successful immunization programme depends upon safe and effective vaccines delivered through available, accessible, affordable, acceptable and quality services that are culturally and socially appropriate. Communities and individuals deserve to be cognizant of the benefits of these services and their right to them.
Continued advocacy, social mobilization, and communication by health system providers—both governmental and non-governmental—will increase public awareness of their right to immunization and of the benefits thereof. Evidence-based communication strategies will be developed. Perceptions, opinions and cultural specificity of population groups will be taken into consideration and related barriers to vaccination redressed. Health providers will gain effective communication skills to promote the benefits and provide accurate and timely information on vaccination. Of particular concern is widespread misinformation propagated by anti-vaccination lobbies about unproven risks of immunization. Measures will be taken on the global and national level to propagate evidence-based information in transparent ways that communicate the benefits and side effects associated with the use of vaccines, reduce unfounded risk perception and maintain demand for immunization.

States should take the necessary steps, to the maximum of their available resources, available individually and through international assistance and cooperation, to deliver, as a matter of priority, immunization as a minimum obligation. It must demonstrate that every effort has been made to use all resources possible in this effort.

Activities 2.1.: Create, increase and sustain community trust in immunization and awareness of their right
- Systematically collect data on community demands for and contribution to immunization and other elements of primary health care via surveys, focus groups with opinion leaders, mothers’ groups.
- Ensure that parents, caregivers and target populations are informed about the benefits of timely immunization.
- Stimulate and sustain demand by maintaining and continually updating advocacy, mobilization and communication strategies and activities that recognize immunization as a human right.
- Enlist community participation in communication of immunization benefits and by using new-born and defaulter tracking.
- Reinforce public trust in immunization and effectively prevent and/or contain strategies and messages by anti-vaccination groups.
- Address concerns and review side effects of vaccination by effectively managing any adverse events following immunization, and communicate regarding these transparently and professionally and in a timely manner.

Approach 2.2.: Focus on underserved and marginalized communities: shifting the current emphasis on “Reaching Every District” to “Reaching Every Community”

An enabling social network can assist in engaging and supporting individuals to demand services for themselves and their families. Health workers will be informed, motivated, trained, supervised and mentored to extend their services to underserved communities, regardless of social, economic or civil status. This will be accompanied by guarantees to marginalized communities that using immunization and other primary health care services will not create ground for further discriminatory measures such as poor treatment within the health care setting or administrative sanctions towards those who may not be documented residents within the health system’s catchment area. To this end, immunization programmes will form a close partnership with key stakeholders in marginalized communities - such as local politicians, religious leaders, civil society organizations, community group leaders, and parents.--- encouraging them to take part in creating a supportive social environment. Individuals and communities
experiencing unequal treatment from state or non-state actors on the basis of such attributes as age, gender, political, behavioural, financial, or social status will receive particular attention from partners committed to deliver immunization as a human right.

Given the need for multiple doses of most antigens and the introduction of new vaccines for infants and older age groups, advanced planning and financing for immunization services need to be sustained and continually promoted. In order to create, increase, and sustain immunization demand, services need to be: (1) readily available and accessible (e.g., time-appropriate scheduling with communities/clients for immunization sessions and organizing outreach); (2) acceptable to clients (which includes linking public and private services and addressing any potentially prohibitive cost issues); (3) monitored and supervised for performance, using data at all levels for improved follow-up and coverage of target populations; and (4) equipped with potent vaccines of assured quality that are available at the point of contact between health care workers and clients.

In order to reach currently underserved individuals and communities, the “Reach Every District” strategic approach, recast as “Reaching Every Community,” with micro-planning can place greater emphasis on undocumented temporary residents, displaced populations, migrants, people living in poverty and those who, more generally, are marginalized and unaccounted for.

Activities 2.2.:

- Engage with civil society and other key stakeholders on issues important to underserved and marginalized communities, securing the stewardship of community leaders.
- Partner with communities through existing or new mechanisms for dialogue so that communities are aware of immunization as a right and involved with processes of decision-making affecting them.
- Construct and market a package of interventions best suited to underserved and marginalized communities and create social and attitudinal changes among health workers and professional associations as key sources of information and responses to the health needs and demands of these communities.
- Recast the “Reach Every District” strategic approach as “Reaching Every Community” with greater specificity in micro-planning, access, response to demands from underserved and marginalized communities, monitoring and reporting.
- Identify innovative, community-based approaches for newborns (e.g. for birth doses) and defaulter tracking and coverage monitoring.
- Ensure that through direct participation or the intervention of civil society organizations that the community voice is heard at both national and international levels when health priorities are being defined or discussed.
- Facilitate interaction between communities and political leaders centered on recognition of immunization as a human right.

Objective III. Seeking synergies: Immunization as a key component of primary health care
Immunization programmes were established in the 1970s on the recognition that life-saving vaccines were available but not utilized systematically in most low and medium-income countries and that ongoing maternal and child health services were unable to promptly expand immunization as a result of structural, systemic and financial constraints. Over the years, the Expanded Programme on Immunization succeeded to reach a significant proportion of eligible children—in fact the highest ever proportion of infants reached by any public health service. Along with this, however, most national immunization programmes had developed in isolation from other primary health care delivery services, a trend which was later accentuated through the end of last century by the inception of new immunization initiatives often qualified as vertical programmes. International funding and technical organizations agencies and foundations have favoured immunization over broad-based primary health care programmes for several reasons, including: the impact of vaccines on disease burden reduction; the performances of, and relative strength of monitoring and accountability mechanisms developed over the years by immunization programmes; and the hope that strong immunization programmes would contribute directly or indirectly to the revitalization of primary health care; and the development of new vaccines and technologies promising of additional health gains. In the new millennium, several global initiatives were launched which added impetus to large-scale targeted public health interventions with little connectivity across them and insufficient investment in the strengthening of health systems on which increasing demands were made.

Economic recession affecting disproportionately low and middle income countries, the deepening gap between the need for structural reforms within the health sector severely affected by declining human resources availability have resulted in a quasi stalemate. Health systems cannot deliver efficiently primary health care services while disease-targeted global initiatives face tremendous constraints in further scaling-up and sustaining their efforts through overburden health systems and the ever-shrinking qualified human resources for health. National immunization programmes suffer from this dual jeopardy. In a context of growing competition for global financial resources and insufficient funding from national governments, the further expansion of immunization coverage amongst children and the multiplicity of newly emerging target populations usually not reached by immunization programmes necessitates new alliances and cooperation across health departments which have until now operated in silos.

Today and increasingly over the coming decade, immunization programmes will have to seek synergies with other initiatives in health and social development. For each partner engaging in sectoral and cross-sectoral collaboration, the challenge is to benefit from, and contribute to these synergies while not placing at risk the hard-won acquisitions of years of work in isolation from one another. Positive synergy has been defined as the effect of combined actions whereby the impact of the whole exceeds the sum of its individual parts. Negative synergy may occur when such an approach is poorly conceived and constraints to efficiency and effectiveness offset the benefits yielded from the combination of actions.

The technical and operational rationale for and approaches to combining immunization with other health promotion, prevention, care and treatment, the association of selected interventions and the broadening of community demands has been laid out in earlier Approach 1.4. This approach will call for systemic adjustments and changes in health provider’s skills, understanding, attitudes and practices are laid out below. The underlying intent here is to ensure greater and diverse responses to community health needs while preserving and expanding the effectiveness and impact of each of the chosen interventions contributing to the reduction of disease burden resulting from available and newly introduced vaccines.
Approach 3.1.: Broaden the scope of targeted disease burden reduction through interventions combined with vaccine delivery

These measures should be implemented as part of an integrated package of effective, feasible and affordable interventions that are based on national contexts and that emphasize the most vulnerable populations. A package of simple interventions will protect individuals by lowering the risk for specific preventable diseases as: micronutrient deficit (through the administration of Vitamine A); vector-borne diseases, in particular malaria (through the distribution and use of impregnated bednets); helminth infections (e.g. periodic distribution of anti-helminthic drugs); and other causes of disease burden that can be reduced through the use of commodities or medicines delivered along with vaccines to children and adults. Such interventions have been successfully implemented during the last decade, taking the opportunity of polio eradication or measles elimination campaigns or outreach routine immunization activities. The array of combined interventions could be broadened upon establishing the evidence that it is efficient and effective and does not overburden the logistics of delivery of immunization, thus acting in positive synergy.

Many interventions in a comprehensive health package fall within the scope of health ministries, but some will require close collaboration with other sectors and non-governmental organizations. Collaborative interventions must be prioritized at the policy and financial level, to ensure that an environment conducive to interventions is in place and that resources are available. At the same time, delivery of key interventions needs to be integrated at the point of care with guidance and participation from community leaders and civil society. In settings with high morbidity and mortality, emphasis will be given to interventions that will maximize morbidity and mortality reduction while recognizing the goal of upholding every person’s right to access prevention and effective treatment against health threats that extend beyond vaccine-preventable diseases.

Activities 3.1.:

- Actively identify community priorities through community dialogue and comprehensive planning efforts.
- Use service delivery contacts during fixed, outreach, mobile and campaign or Child Health Day activities to provide a locally agreed package of high impact interventions along with immunization.
- Communicate country programme needs to global immunization partners to establish norms and standards of best practice and secure financial support.
- Implement, monitor and evaluate packages of combined health interventions based on community priorities with coordinated national, global and donor support.
- Conduct operational research to seek maximum efficiency, effectiveness and sustainability of combined interventions through alternate or complementary mechanisms.

Approach 3.2.: Participating in collaborative efforts to renovate and strengthen overall health systems, in particular human resources for health

Immunization and other ongoing disease control programmes benefiting from significant national and international funding are constrained by numerous systemic barriers affecting the health sector, including uncertain political commitment, fragmented and often competing health initiatives, inadequate infrastructure, limited human resource capacity, weak monitoring and evaluation,
insufficient attempts to enhance and respond to public demand and sub-optimal allocation and use of available financial resources. The growth of disease targeted programmes in the last decade has prompted initiatives to revitalize health systems through global initiatives in support of which several analytical and planning frameworks have been put forward. The WHO Health System “Building Blocks” will serve here as a convenient framework for determining points of congruence between immunization programmes and other entities within and outside health systems with which synergy can be created. Good health systems build on: (1) Efficient **health services**, delivering effective, safe, quality personal and non-personal health interventions to those who need them, when and where needed, with minimum waste of resources; (2) A well-performing **health workforce**, working in ways that are responsive, fair and efficient to achieve the best health outcomes possible, given available resources and circumstances; (3) A well-functioning **health information system**, ensuring the production, analysis, dissemination and use of reliable and timely information on health determinants, health systems performance and health status; (4) A well-functioning health system ensures equitable access to **essential medical products**, **vaccines** and **technologies** of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use; (5) A good **health financing** system raising adequate funds for health, in ways that ensure people can use needed services, and are protected from financial catastrophe or impoverishment associated with having to pay for them; and (6) **Leadership and governance**, ensuring strategic policy frameworks exist and are combined with effective oversight, coalition-building, the provision of appropriate regulations and incentives, attention to system-design, and accountability.

**Activities 3.2.: Participating in collaborative efforts to renovate and strengthen overall health systems, in particular human resources for health**

- Nationally, engage all National immunization actors in health situation analyses, policy development, strategic development and financing plans with a focus on primary health care.
- Review systematically the present and future needs and capacity of immunization programmes against the six building blocks of Health Systems and perform a gap analysis.
- Identify core functions of actors contributing to primary health care and inventory their goals, strategies, methods and resources to determine common goals and beneficiary populations, points of congruence and complementarities likely to generate mutual benefits in the form of greater efficiency, effectiveness and impact.
- Lay out a progressive pathway to closely monitor collaboration with other primary health care actors (public, non-governmental and private).
- Globally, harmonize international cooperation for health guided by country needs and choices, facilitating the pooling of resources and aligned accountability processes to ease the use of these resources.
- Create and nurture collaborative links across leading global health initiatives to ensure mutual learning, greater coordination and flexibility in support extended to countries.
- Develop and implement mechanisms of accountability on the national and international levels that are subscribed to by governments, non-governmental
organizations and the private sector with the intent to prevent and redress the misuse of resources.

- Safeguard the pivotal role of immunization services at the core of primary health care delivery.

**Objective IV. Develop immunization systems able to meet the challenge**

Strengthening immunization system performance and monitoring, as part of a functioning health system, is the foundation to achieve and sustain coverage targets, sustainably reduce disease and mortality, and successfully introduce new vaccines. Yet, despite their relative maturity, immunization programmes in many countries have become fragile even as they face new challenges. Many of the shortcomings of immunization can be related to management issues, insufficient use of information for decision-making and impact monitoring, weaknesses in human resources, shortcomings in procurement, supply and logistics, and perfunctory financial management. These failings can undermine sustained country commitment, transparent accountability and the attainment of self-reliance.

As an integral part of the health system, immunization can be viewed as a developmental challenge that requires a systems approach. The many interconnected components of an immunization system require multi-disciplinary attention to build a cohesive, non-fragmented and well-performing programme. Certain of these components have been neglected for a variety of reasons, including in some cases institutional preferences of partner agencies, formulaic prescriptions and an absence of a learning culture to identify and diffuse innovative ideas.

At the outset of the Decade, early action will be undertaken and sustained to translate political commitment to immunization into sound management of all facets of immunization programmes, across all resource areas—human resources, information, supply and logistics, and finances.

**Approach 4.1.: Improve systems and tools for generating evidence, monitoring programme performance and use of data for action**

Currently, in many countries, national ownership and investments in surveillance and monitoring are limited. Surveillance and monitoring are often constrained by lack of capacity and viewed as responding to pressures from and under the control of external partners rather than national institutions.

Monitoring of immunization coverage and drop-out rates has been in place since the onset of Expanded Programme on Immunization (EPI) in the 1970s. While the quality and timeliness of reporting has improved steadily over the years, in many developing countries, administrative reports of coverage are not accurate and coverage is assessed mainly through periodic surveys. Real time and high quality coverage data at all administrative levels is required for timely corrective actions and optimal programme performance.

Generating evidence, monitoring and evaluating performance should be seen in the context of the broader health system and requires local use of data for action. Monitoring the performance of immunization programmes also requires careful surveillance of Vaccine Preventable Diseases (VPDs), based on sound epidemiological practices grounded with quality laboratory confirmation. Monitoring a
number of aspects of the immunization components of primary healthcare programmes includes the monitoring of coverage and drop-out rates, supply chain, financial and human resources, Adverse Events Following Immunization (AEFI) and periodic comprehensive programme reviews. Immunization monitoring also provides opportunities to harmonize with other Maternal and Neonatal Child Health (MNCH) activities such as the use of monitoring indicators and supportive supervision practices.

Surveillance provides data to inform decisions on introduction of new vaccines and potential need to adjust current immunization programs, and measure the impact of vaccines on the burden of disease and monitor changes in disease epidemiology. In many developing countries, the VPD surveillance has moved from aggregate reporting of diseases that often produced incomplete and poor quality data, to case-based surveillance with laboratory confirmation with the polio eradication and measles control initiatives. More recently a new platform for sentinel site surveillance for invasive bacterial diseases and rotavirus diarrhea was established. Strengthening surveillance data requires focus on improving the quality, completeness and timeliness of reporting of data and better coordination and integration, where appropriate, with wider disease surveillance systems, such as the Integrated Disease Surveillance Projects. Data from disease surveillance may not always provide comprehensive data on the disease burden. These data, however, can be used in mathematical models to generate disease burden projections. Coverage and expenditure data can be added to the models to estimate the impact and cost-effectiveness of immunization.

New technologies, including handheld communication devices, provide the opportunity to establish comprehensive immunization registries and improve the quality of administrative data. Periodic surveys will still serve to validate administrative data, particularly where vital registration data for the target population are sub-optimal, and provide additional data that may be used to evaluate determinants of immunization coverage and inform programme planning. Several other elements should also be monitored, including supply chain performance, adverse events, budget execution, training practices and human resource performance. These various vectors of monitoring data should be cross-analyzed to provide a more comprehensive picture of programme performance.

With an increasing number of products being developed specifically for developing country markets and by manufacturers in developing countries where systems for post-marketing surveillance are weak or non-existent, capacity to monitor AEFI and investigate and promptly respond to reports of deaths or severe adverse events following immunization is essential to maintain public confidence in the programme. Most developing countries are limited in their capacity to monitor AEFI and systems to do this need to be established urgently.

Improving the quality and use of data for informing national policies, programme planning at all levels and documenting the impact of the programme would serve to improve the situation. This calls for a greater coordination with national statistical institutes to improve the quality of target population data and a better collaboration with the national health information systems to join forces in data quality improvement efforts including the monitoring and evaluation of immunization and surveillance data quality in a broader context.

**Activities 4.1.:**
- Enhance the effectiveness and use of tools (including models) for estimating immunization coverage and equity, disease burden, vaccine impact and cost-effectiveness.
Create disease surveillance platforms for diseases targeted for eradication/elimination or diseases that occur in outbreaks; sentinel site surveillance to define epidemiology, generate evidence for decision-making; and monitoring trends for non-epidemic diseases.

Ensure coverage analysis and data use at all levels (including active local monitoring through RED and new approaches to reach every community).

Develop indicators for monitoring HSS performance related to immunization and tools to facilitate use of data.

Maintain AEFI monitoring systems, including investigation and response to unexpected severe adverse events.

Use state-of-the-art information systems and technologies to integrate monitoring, tracking and supply.

Foster cross-border and international collaborative disease control efforts and sharing of data.

Approach 4.2.: Train, deploy and support adequate human resources for programme management and implementation

Initiatives in health workforce development in the last decade have resulted in new insights into what works in planning, managing, educating and supporting health workers. Nevertheless, there remain critical shortages of health workers in the poorest countries, as well as inadequate pre and in-service education, lack of motivation and underperformance of the health workforce. These issues are linked in terms of workforce development: management in the health sector is frequently weak which leads to a failure to implement health workforce plans, or to monitor progress where changes are put in place. Some cadres, such as community health workers, pharmacists and CSOs, have considerable potential to assume more extensive tasks and responsibilities and enhance care delivery. Given that salaries are low in many countries, and health workers at all levels perform other jobs in addition to their public sector position, appropriate incentives will be determined in each case to encourage health workers to take on additional tasks and responsibilities.

Good management requires competent managers who are able to improve workforce climate, be supportive supervisors, and teach others to be so too, collect, understand and share data related to the workforce and health outcomes and advocate for improved staffing and budgets. A better understanding of workforce data will enable managers to plan for adequate staffing of vaccine programs.

At a health sector level, integration will be facilitated when joint stakeholder groups are convened to discuss common interests. Those involved in vaccination should be part of the stakeholder groups that guide workforce development, including the metrics that will be used to monitor progress.

Health workers are unlikely to be working in only one program, even though funding is often program based. Helping all cadres of health workers, including Community Health Workers (CHWs) where appropriate, to consolidate their learning and practice requires identifying the competences they require to be excellent practitioners and devising curricula for pre and in-service training that address these. Becoming more specific about the tasks that health workers are expected to carry out permits a different style of workforce analysis and planning, in which each area of care has staff competent to carry out all of the tasks required by that area of care. In a national context where action to improve
productivity is urgently needed, a study of skills mix, tasks and competence could provide a framework for realigning workforce planning and adopting a more rational approach to staff deployment and teamwork. Such an approach offers an opportunity to bring together those with an interest in task shifting and establish a robust monitoring and evaluation system that can ensure broad based operational learning. In addition, the formalization of task shifting permits a rational approach to supportive legislation as needed.

Advances in ways of delivering ‘just-in-time’ information to health workers and managers are exponential. New ways of supervising staff – for example with PDA based checklists – have been developed and field tested and can be applied to public health where feasible. Telephone information delivered to health workers when they need it is known to work well, and can be used for all cadres, including CHWs. In pre-service education, learning approaches have to encourage self-directed and peer-to-peer learning using a range of technologies and moving away from classroom based learning. These new approaches have to be continued into in-service courses too, with learners becoming able to solve problems in a complex environment by seeking their own information.

The private for profit and not-for-profit sector will be involved in augmenting the human resource inadequacies and shortages in the public health sector. Charters for their categorization and engagement; and guidelines to ensure compliance and accountability will be developed to guide their inclusion in the health development of communities. This would promote aid effectiveness, ownership, alignment, and harmonization, management of results and mutual trust and accountability.

Throughout the Decade, in conjunction with existing global initiatives on health workforce development, new insights will be applied into what works in planning, managing, educating and supporting existing governmental and non-governmental health workers—including private health providers, both formal and informal. Sufficient numbers of competent health workers, equitably deployed and supported by strong health systems, will be trained, retrained and deployed to manage and implement immunization programs. New approaches will be applied to support learning through pre- and in-service education, and lack of motivation and underperformance will be addressed through supportive supervision and the creation of fair incentives.

**Activities 4.2.:**
- Establish benchmarks for skill sets, job accountabilities, remuneration and size of human resources required for programme management and implementation.
- Invest in management of the workforce at all levels of the health system in conjunction with global and national initiatives on human resources for health.
- Promote integration across all public health activities including immunization and adopt possible task shifting, as needed.
- Monitor capacity needs and use competences to identify, implement and monitor potential task shifting, as well as required team skill sets.
- Involve non-governmental health providers, including the private sector in immunization promotion and delivery.
- Apply pre-service and in-service training and supportive supervision for immunization staff (including use of adult learning methods and peer to peer approaches)
- Seek and apply innovative and fair incentives and other means to motivate health workers to ensure effective delivery of comprehensive health interventions and design and apply tools for assessing human resources performance.
**Approach 4.3.: Build, maintain and sustain regular immunization procurement, delivery and supply systems**

The cold chain and logistics systems established, strengthened and maintained over the past 30 years has been the backbone of the immunization programmes. It has also served as a model for many other public health interventions. This network of policies, equipment and people operating against precise yet simple rules has enabled immunization programmes to protect over 80% of the world’s infants with basic vaccines. Accurate forecasting of vaccine, cold chain and other supplies has continuously improved over time.

Over the years, the cold chain was strengthened to reach further out: staff were continuously trained to ensure adherence to essential vaccine management standards; better, more reliable equipment was introduced and safer injection practices were promoted. These logistics systems were however conceived and established thirty years ago, before computers were widely used, before sophisticated tracking and management tools were available and when most vaccines cost less than US$ 1 per dose. Until today, many persistent system inefficiencies could be overcome by maintaining high stock levels and tolerating high wastage rates. Today, however, several new vaccines are being introduced and these are more costly than traditional ones. High wastage and high levels of stocks are no longer financially bearable. Single dose vaccine presentations are increasingly being used to reduce wastage. This has a substantial impact on the storage and transport capacity that is required at each level of the cold chain. Recent vaccine management assessments have highlighted that the systems are not in place in countries to accommodate introduction of new, more costly, more bulky vaccine: The current systems do not have the ability to evolve rapidly enough; quick fixes are usually the approach taken to address challenges; and human resources currently available are not sufficient nor sufficiently trained to plan for and manage these new challenges.

Early in the Decade, managers must acquire the ability to maintain lower stock levels, reduce wastage, accurately forecast vaccine requirements, and prevent equipment break-downs or malfunctions so that eligible populations can access and make use of high quality and safe immunization services.

**Activities 4.3.:**

- Ensure that forecasting and planning methods to deliver timely, effective and efficient vaccinations of good quality with all vaccines in the national immunization schedule are in place.
- Enable vaccinators to knowledgeably and competently give all scheduled vaccines to target populations.
- Expand scheduled immunization services to function effectively in decentralized settings, and in private and non-governmental health services.
- Ensure delivery systems can deliver other health interventions and work in harmony with other relevant disease-control initiatives.
- Ensure that product characteristics suit needs and constraints of countries.
- Develop and implement effective and efficient supply systems, based on early planning and forecasting.
- Integrate vaccine supply into health supply systems, wherever possible.
- Minimize environmental impact of immunization equipment and supplies, including systematic waste disposal methods.
- Promote state-of-the-art information systems and technologies.

**Objective V. Bolstering national self reliance and partnerships**

Traditionally, ownership of immunization programs has been closely linked to the level of government funding, suggesting that more government funding ensures greater ownership. However, ownership needs to be considered within a wider context that will take into account numerous other factors that may ultimately affect level of programme funding. The strength and resilience of national institutions and structures, good government stewardship, with autonomous decision-making and accountability at all levels, is all vital to achieving increased national ownership. Many low and middle income countries depend on external support for key elements of their immunization programmes; however, this support is generally vertically coordinated and managed, leading to inefficient use of resources, duplication of efforts, potential competition between departments and minimization of the impact.

Although governments, donors and partners are increasingly committed to greater mutual programmatic and financial accountability, beneficiary communities are usually not involved. Health personnel responsible for delivering the services do not feel sufficiently accountable to the communities. As demand for immunization services increases, greater accountability will be expected by beneficiary communities, both fiscal and in terms of programmatic performance.

Collective action of all stakeholders pursuing common immunization goals will improve efficiency and outcomes. This is in line with the five principles of the Paris Declaration on Aid effectiveness, namely ownership, alignment, harmonization, management for results, and mutual accountability. These principles inspired the International Health Partnership (IHP) launched in September 2007 with the aim of scaling up coverage and use of health services, and delivering improved outcomes against the health related MDGs and universal outcome commitments. The same principles were further enhanced by the 2008 Accra Agenda for Action.

To bolster national self-reliance and partnerships successfully during the Decade, efforts will be made to: strengthen structures and processes for developing immunization policy, strategies, and best practices; promote greater political commitment, ownership, accountability and self-reliance of immunization programs at all levels; recognize the drivers/mechanisms that enable and hinder effective collaboration at community, national, regional, and global levels; broaden engagement of civil society and communities; and achieve sustainable immunization financing and sound financial management.

**Approach 5.1.: Strengthen structure and processes for developing immunization policy, laws, regulations and best practices**

Immunization policies, laws, regulations and standards of best practice for public health will be developed nationally, taking into account national health priorities and capacities, rather than solely responding to global and regional recommendations that may be insufficiently sensitive to local realities. Building and strengthening national structures and processes able to deliver these tools are essential.
steps towards the promotion of greater national ownership of and commitment to immunization while improving capacity and reducing external dependency of the national programme in technical, managerial and financial terms.

In the context of immunization, a new and expanding array of institutions, agencies and groups have been established in low and medium income countries although both structures and processes put in place need considerable strengthening. These include national policy advisory groups, experts committees on immunization, ethical committees, national regulatory authorities, pharmacovigilance centres, procurement agencies and national pharmacies. These entities are often established by and operate under the purview of the state—most often the Ministry of Health. Non-state actors such as private vaccine manufacturers, communities represented by Civil Society Organizations or patient safety organisations are not always invited or committed to contribute to the development of and adherence to national policy, norms and standards.

To strengthen immunization-related policy, norms and standards some countries have established National Technical Advisory Groups (NITAG). These groups act as both a technical resource and a deliberative body to guide national authorities and policy makers towards evidence-based decisions. They are intended to bring increased scientific rigor, ownership and credibility to the immunization policy formulation, independent from political or personal interests. While the majority of industrialized countries have NITAGs, many low and middle-income countries still lack functioning NITAGs or have none at all.

There is also a demonstrated need for independent and functional regulatory authorities able to address issues relevant to the quality, efficacy and safety of vaccines used or to be used by national immunization programmes. To this end, most countries rely on a National Regulatory Agency (NRA) on either the national or inter-country level. The roles of regulatory agencies are to develop a long-term confidence in quality of product released on the national market and to allow better accountability of and response from manufacturers when problems arise. A five steps capacity building initiative has been developed and supported since 1996 by the WHO and several partners, including: the United States Agency for International Development (USAID); the UK Department for International Development (DFID); the World Bank, AusAID; US Food and Drugs Administration (USFDA); The Bill & Melinda Gates Foundation (BMGF), The European & Developing Countries Clinical Trials Partnership (EDTCP) as well as other development, funding and technical entities.

From a National Immunization Programme (NIP) perspective, norms and standards of national best practice need to be informed by international normative frameworks, adapted locally, promoted, adhered to and monitored. The guidance for strategic planning, such as the comprehensive multi-year plan (cMYP) for immunization developed by WHO and UNICEF which GAVI requires in support of grant application, need fine-tuning. Harmonizing cMYPs, health sector strategic plans and the national budgeting process calls for additional international guidance, methods and tools which, in turn, can be adapted and applied in countries. Normative frameworks should be shouldered by laws and regulations defining obligations and accountability of state and non-state actors in the production and delivery of effective and safe vaccines and in the application of standards of immunization.

By decade’s end 2020, all low and middle-income countries will have functioning and active NITAGs and NRAs, a strong planning process of NIPs, pharmacovigilance systems and procurement agencies. NITAGs recommendations will be translated into respective national immunization and vaccine policy.
Activities 5.1.:

- Develop structures and processes to generate and use evidence for formulating policies, strategies and best practices ensuring that only vaccines of assured quality are used in national programmes.
- Promote national enactment and monitoring of legislation and regulations aimed at universal access to and use of safe and effective immunization.
- Establish and efficiently use NITAGs with the active involvement of local academia, research institutes, professional associations and civil society organizations in NITAGs.
- Create tools and processes NITAGs can use to develop, update and monitor immunization multi-year (cMYP) and annual plans and ensure that NITAGS receive periodic briefings on immunization program performance and program budget performance.
- Build functional National Regulatory Agencies (NRA), national pharmacovigilance capacity and procurement agencies for vaccines at country or inter-country levels and strengthen processes for regulation of vaccines and
- Assert country ownership on vaccine and immunization policy formulation.
- Forge functional relations between established NITAGs and NRAs.
- Promote programme learning (including operations research) to identify and disseminate best practices, using national teaching facilities as appropriate.

Approach 5.2.: Promote greater political commitment, ownership, accountability and self-reliance of immunization programmes at all levels

Political commitment for immunization programmes is often manifested as support from the highest levels (e.g., President, Prime Minister, and Minister of Health). Although this positive development cannot be underplayed, the engagement of the Head of State is often ceremonial and the broader political engagement, particularly at the subnational levels that is required for programme success may be lacking. This is particularly important because the trend towards decentralization of health services, including immunization, dictates the need to refocus efforts to ensure political commitment at the district or local government level. It may even be more beneficial to focus on “Societal Commitment” that will take into consideration the importance of numerous other stakeholders ranging from religious leaders to parents and caretakers. This should contribute towards achieving increased ownership of the immunization programs, thereby leading to greater cooperation, participation, and ultimately even increased government funding.

Over the next decade, it is expected that low and middle income countries will lead the formulation of national policies, strategies, and plans that will ensure equitable access to, and uptake of existing and new vaccines by children, women of childbearing age and other vulnerable populations such as young people, adults exposed to particular risks as a result of behavioral or professional factors and the elderly. Immunization programmes will be driven by the needs, demands and entitlements of beneficiary populations, and Government and non-Governmental entities engaged in immunization will be expected to fulfill their responsibility for delivering vaccines within the maximum availability of their resources and the norms and standards applicable in the country. All actors will subscribe to the principle of mutual accountability and contribute to the collective learning of ways to alleviate obstacles to immunization and respond better to community needs and demands.
Within and beyond the span of the Decade, National immunization programs will be linked to other disease prevention and control programs, and in close consultation with parliaments, communities, donors and other stakeholders, especially CSOs and the private sector. Country-based partnerships for immunization will contribute to greater national self-reliance in decision making and operational terms. To this end, the drivers and mechanisms that enable or hinder effective collaboration at community, sub-national and national levels will be reviewed jointly by all actors. Rules of engagement and mutual accountability will be established and periodically reviewed collaboratively. International development cooperation and funding agencies will act collectively to help strengthen national capacity to plan, implement, monitor and evaluate national immunization programs through country-established systems and procedures.

Activities 5.2.:
- Internationally, develop and introduce approaches to enhance national and local government ownership of the immunization program.
- Nationally, provide immunization guidance for sub-national levels in keeping with broader health sector reform.
- Develop and introduce indicators to monitor self-reliance including the efficiency of national immunization governance, collaborative endeavours and the tracking of resource use.
- Undertake landscape analysis, including assessment of pre-existing relationships, degree of stakeholder capacity and engagement and ability to commit and efficiently use resources.
- Create rules, incentives, and guidance for participation and coordination of stakeholders and creation of efficiencies.
- Enable coordinated and inclusive policy dialogue and decision-making at district, national, regional and global levels to facilitate evidence-based country decision-making and implementation of vaccine introduction and related disease control initiatives.
- Invest in appropriate and effective partnership mechanisms allowing for full range of engagements from the informal to contract driven.
- Strengthen coordination among stakeholders to maximize synergies within comprehensive disease control initiatives.
- Engage other government sectors (e.g., Planning, Finance, Education).
- Include professional associations, CSOs, faith-based organizations, industry, private sector in strategic development and decision-making, monitoring and evaluation.
- Establish new ways to engage collaboratively with the private health sector, including and beyond the pharmaceutical industry.
- Document, monitor and evaluate the adequacy, participatory nature, transparency, timeliness and efficiency of national and sub-national decision-making processes around vaccine use.
- Revise decision-making processes, correct the course of action as may be needed, continue evaluation and disseminate and implement lessons learned.

Approach 5.3.: Broaden engagement of civil society and communities
Civil Society Organizations (CSOs) may be non-governmental organizations, community-based groups/or partnerships, professional associations, faith-based groups, and academic or technical institutions. Civil Society (CS) plays a major role in immunization around the world, helping to ensure that programmes maintain an appropriate balance that strengthens routine immunization services and infrastructure, achieves targets (e.g., polio, measles, meningitis), and enables introduction of new vaccines. CS delivers a high proportion of health care (including immunizations) to populations with the greatest challenges, particularly marginalized, underserved or hard to reach rural and urban groups.

Some shortcomings in current CS involvement include an under-appreciation of its roles in planning, implementation, monitoring, and evaluation. One result is that CS involvement may be *ad hoc* rather than planned. Additionally, there appears to be mistrust of CS on the part of many public sector officials and officials may not be clear on what CSOs are most important to involve. In some areas, CSOs may view each other as competitors for limited resources and not coordinate their activities. With the potential for many new vaccines, some of which may target individuals outside the traditional infant population, it will be increasingly important to ensure that CS is involved in the full range of immunization activities, from policy development through resource mobilization and accountability, service delivery, surveillance, operational research, and monitoring and evaluation.

Through unique connections with target communities and the population at large, CSOs can be important advocates in resource mobilization and increasing demand for services at local, national and international levels as well as stimulating action within communities. In addition, CSOs can provide important feedback and perspectives about on-the-ground realities to inform discussions on key policy issues. CS serves an important watchdog role to ensure that governments and other entities (e.g., multilateral institutions) are held accountable for meeting their obligations and expressed commitments.

**Activities 5.3.:**
- Involve NGOs and community leaders/groups in local Inter-Agency Coordinating Committees (ICCs), and monitor community contributions to improving services.
- Engage civil society at various levels in service delivery, technical assistance, and advocacy, and monitor their contributions to improving services.
- Systematize approaches to securing the support of community leaders (including religious leaders, retired health workers).
- Identify innovative, community-based approaches for newborns (e.g. for birth doses) and defaulter tracking and coverage monitoring.

**Approach 5.4.: Achieve sustainable immunization financing and sound financial management**
In many countries today, more is spent on immunization than on all public health services combined. Newer and underutilized vaccines are pushing costs up to an estimated US$30-50 per fully immunized child. So far, for most low and middle income countries, most of the requisite funding and technical support have come from external donors. Governments are investing at a far slower rate, resulting in widening fiscal gaps and growing donor dependency.

Despite the Paris Declaration, IHP+ and other agreements, the greater share of most national immunization budgets is still executed by partners (ie, the donor funds are off–budget, invisible to governments and parliaments). National financial management systems are chronically budget weak. Only a few immunization programme managers can estimate the true current cost per fully immunized child in
their countries because they do not follow programme expenditures. Thus, the efficiency of the programmes is unknown and there is little or no budget oversight or accountability. This sets up a low-level equilibrium trap. Since true costs are unknown, annual immunization budgets are, at best, increased in incremental fashion; at worse they are static, decreasing or non-existent.

Poor financial management and high donor dependency are thus interrelated problems. They must be addressed together if governments and other domestic stakeholders are to invest more in immunization and reach the sustainable financing goal (Defined by GAVI as: “... the ability of a country to mobilize and efficiently use domestic and supplementary external resources on a reliable basis to achieve current and future target levels of immunization performance in terms of access, utilization, quality, safety and equity”.)

New business practices are needed- new ways to share and cross analyze information and to use that information to solve problems and optimize performance. These new practices are needed not only within and across ministries but also between government and parliament. Some governments are already tracking their health expenditures through output- based and performance-based budgeting reforms. These approaches generate in-year reports which often contain vaccine coverage as a leading health sector indicator. Interagency Coordinating Committees and other coordinating bodies will begin actively monitoring not only external expenditures but also trends in the national financing picture.

Even if an immunization investment case is properly made, and even if budget performance is maximized, most countries will still need to develop new, long-term financing solutions. The tools available include revenue earmarks, risk-pooling (insurance) mechanisms, long-term development loans and debt relief (HIPC) funding. Engaging more elected officials, CSOs, private businesspeople and other stakeholders- at both national and sub-national levels- will help mobilize new domestic resources. In a number of countries, sub-national governments are forming their own immunization operational budgets as part of ongoing decentralization processes. In other settings, national immunization trust funds are emerging. The funds are managed by public-private boards, the beneficiary is the routine immunization program and its purpose is to protect lives. In the coming decade, immunization will spear-head implementation of slow-moving budget and decentralization reforms and engage more groups in innovative resource mobilization strategies with spillovers to other health programs.

Activities 5.4:
- Create an enabling environment for financial sustainability, including cost-effectiveness guidelines and tools, budget lines for vaccines and other costs.
- Ensure sustainable and sufficient national financing, with links to funding initiatives (co-financing, sustainable immunization financing).
- Establish effective costing, budgeting, financial management processes and audit oversight.
- Establish financial tracking systems and strengthen national and sub-national accountability.
- Build national capacity to achieve financial self-sufficiency, adapting existing tools for training and development such as the comprehensive Multi-year Plans for Immunizations (cMYP), and using existing cost-effectiveness tools such as the ProVac tool used by the PAHO Immunization Project to build national capacity to
make evidence-based decisions on new vaccines introduction, the tool for Marginal Budgeting for Bottlenecks (MBB), the Unified Health Model (UHM), and others.

- Enhance national rapid response mechanisms for emergencies and epidemics.
TO BE CONSIDERED WHEN PREPARING THE DELIVERY ACTION PLAN:

Improving performances to achieve the goals of the Decade of Vaccines

Achieving the Delivery goal of the Decade of Vaccines will call for improvements of performances both nationally and internationally. The main factors that will govern the performance of Immunization Delivery in-country over the Decade are:

1. The building/strengthening of a resilient immunization delivery system, anchored as a key element of Primary Health Care, and staffed with skilled and motivated human resources;
2. Greater innovation to meeting immunization goals and targets and reaching the poorest and least-served populations, and enhancing drives towards disease control, elimination and eradication;
3. A further strengthening of the focus on morbidity and disease burden reduction, recognizing immunization as one of several essential public health interventions, and reducing substantially mortality, morbidity and disability due to pneumonia, diarrhea, meningitis and other diseases for which licensed vaccines exist or will become fit for public health use during the decade;
4. A stronger element of measurement, determining results and linking these to a greater commitment to immunization services from national and international leaders
5. Implementing vaccination of all target groups, going beyond immunization for infants and children to include adolescents and adults, in accordance with national immunization schedules
6. A greater role for qualified private and other non-governmental entities in the delivery of immunization services to complement governmental health programmes in remote rural areas and ever-increasing urban populations;
7. Early and sustained leadership of country decision-makers in vaccine production and use, taking account of the evolving position of countries with rapidly evolving economies and large populations, such as Brazil, Russia, India, China; and
8. Engagement of civil society organizations in countries and globally, to ensure growing and sustained demand for immunization services.

IV. Priority Setting

(not covered in this draft)
V. Next steps

(not covered in this draft)