

Annex 3: Costing and Funding Methodology and Assumptions

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

OBJECTIVE

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

METHODS

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



Introduction

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

Methods

COUNTRIES INCLUDED

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

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

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

TABLE 9: COUNTRY SCOPE FOR ANALYSIS

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

WB INCOME CLASSIFICATION

- LIC
- LMIC
- UMIC

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

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

VACCINES INCLUDED

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

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

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

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

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

COST AND FINANCING COMPONENTS INCLUDED

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

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

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

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

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

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

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

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

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

(A) VACCINE COSTS

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

(B) DELIVERY COSTS

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

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

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

(2) Routine Vaccination programmes

(A) VACCINE COSTS

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

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

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



(B) DELIVERY COSTS

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

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

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

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

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

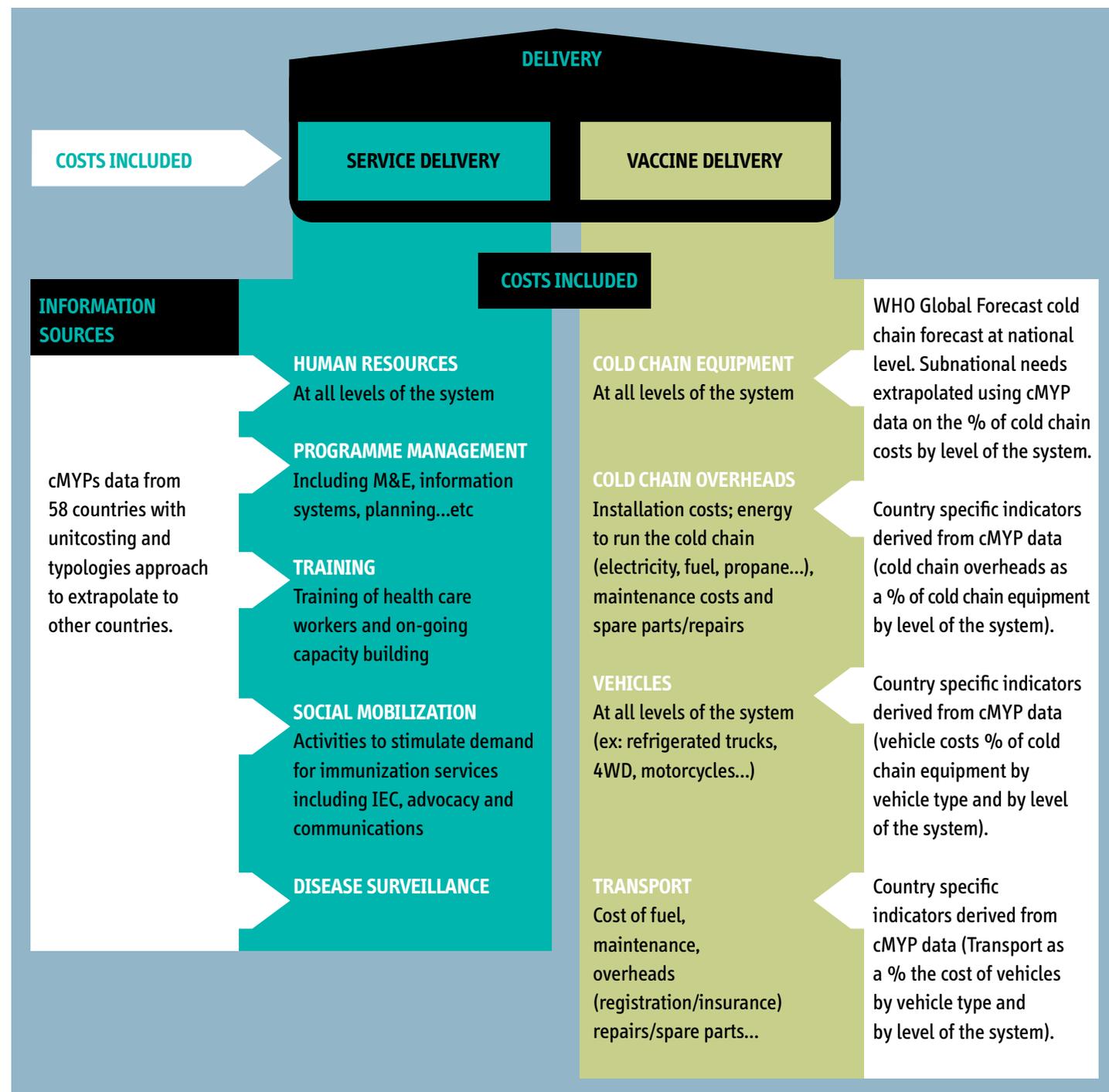
The WHO global forecast for cold chain and logistics is the basis of the costing for vaccine delivery. The global forecast tool estimates (using the same demand forecast assumptions for vaccines) the on-going needs to maintain the existing cold chain infrastructure in place along with the incremental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

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

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

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

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



Financing projections

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

(I) GOVERNMENT FLOWS FOR IMMUNIZATION

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

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

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

(II) GAVI ALLIANCE FUNDING

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

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

(III) OTHER DEVELOPMENT PARTNER FUNDING

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

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

Developing estimated future resource requirements

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

LIMITATIONS

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

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

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

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

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

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

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