

# **Sustainable Access to Vaccines in Middle-Income Countries (MICs): A Shared Partner Strategy**

## **Report of the WHO-Convened MIC Task Force**

**March 2015**

### ***Executive Summary***

Over the past decade, access to vaccines in middle-income countries (MICs) has been much debated. This focus on MICs has been fuelled by the realization that the majority of poor people and vaccine-preventable deaths are now in MICs and by a concern that this group of countries may be missing out on opportunities to introduce new vaccines, with donors focused on low-income countries (LICs). In light of the increased international attention to this issue and at the request of SAGE, in June 2014 WHO convened a Middle-Income Country Task Force to develop a coordinated strategy and plan of action.

To gain additional clarity on the nature of the problem, the Task Force's re-assessed immunization performance in all MICs. This analysis revealed that the great majority of vaccine-preventable disease burden is currently concentrated in donor-supported MICs, and that this group is the main driver of the lag in immunization performance in MICs relative to LICs, including in the fraction of the birth cohort with access to new vaccines. The notion that MICs have fallen behind donor supported countries may thus not well capture the issues at stake.

A comprehensive look at MICs performance shows that MICs are far from attaining the GAVAP targets. While forty MICs are well supported by Gavi, another sixty-three countries do not benefit from a unified international strategy. In these countries, vaccine-preventable disease burden and numbers of unvaccinated children are relatively low compared to the Gavi MICs, but substantial and unacceptable nonetheless. Many of these countries have strong systems and the potential to make rapid gains if key barriers are removed.

It is on this latter group, the non-Gavi countries, that the MIC Task Force has decided to focus its MIC Strategy, mainly on the grounds of complementarity and global equity. Given the dynamic donor landscape and the anticipated exit of countries from Gavi support in coming years, it is envisaged that the MIC Strategy will also eventually benefit Gavi-graduated countries. The strategy will focus on an initial period from 2016-2020 coinciding with the remaining years of the Decade of Vaccines. For a second period (2021-2025), the Task Force proposes to develop as necessary an adapted strategy accounting for changes in the immunization and development landscape.

The Task Force has undertaken a careful study of both the needs of non-Gavi MICs and the types of support currently provided to these countries by immunization partners. Based on this and on a modelled analysis of impact, the Task Force has agreed that its strategy should address both new vaccine introduction and immunization coverage. The proposed MIC Strategy focuses on four main areas: i) strengthening evidence-based decision-making; ii) enhancing political commitment and ensuring financial sustainability of immunization programmes; iii) enhancing demand for and equitable delivery of immunization services; iv) improving access to timely and affordable supply. Within each of these broad areas, the Task Force has identified a set of focus activities and lead agencies.

Each area of the strategy is important in its own right and will contribute to the overall objectives of raising and sustaining equitable immunization coverage and enabling introduction of new vaccines. But the Task Force also believes that the elements of the strategy work together in important ways. In particular, many of the planned activities can be seen as enhancing and consolidating vaccine demand from MICs, which, in conjunction with interventions on the supply side, will help give MICs

access to more affordable and secure supply, the strongest area of concern. Access to more affordable supply can in turn allow countries for which vaccine prices have been an obstacle to introduce and sustain coverage of needed vaccines.

The non-Gavi MICs are a diverse group with varying needs. The Task Force therefore designed the strategy as a menu of options, from which countries will be able to choose the kinds of assistance that they identify as priorities. In providing this assistance, the strategy would emphasize collaboration among MICs and peer-to-peer learning. This and other aspects of strategy implementation will require innovation in the way participating organizations work to enable greater collaboration and flexibility.

Acting as secretariat of the Task Force, WHO has estimated the total cost of the support activities included in the MIC Strategy and evaluates this investment at approximately \$20 million per year for the 2016-2020 period. This relatively low cost reflects the strategy's focus on targeted technical assistance to remove important obstacles while relying heavily on countries own resources to achieve their immunization goals. The Task Force is also exploring innovative approaches to increasing the credibility and market impact of MICs vaccine funding. This mechanism, which could involve a development bank, would be based primarily on the budget commitments of participating countries and would thus depend critically on country commitment. The Task Force will proceed with assessing the cost effectiveness aspect of the funding needs once the visibility to country demand improves.

The proposed MIC Strategy will be discussed at the SAGE meeting in April 2015 and subsequently fine-tuned in light of feedback and further consultation with countries, regions, and immunization partners. The Task Force will also begin discussions with potential donors and, if there is sufficient interest in supporting the strategy, turn to developing a detailed implementation plan.

## **Background**

Over the past decade, access to vaccines in middle-income countries (MICs) has become a much debated issue. At the heart of the “MICs issue” is the reality that two thirds of the world’s poor now live in MICs. This is a dramatic change from the 1990s when 93% of poor people lived in low-income countries (LICs).<sup>1</sup> This issue has also been viewed through the lens of global disease burden and immunization performance: MICs account for 60% of global under-five deaths, as well as similar or greater shares of vaccine-preventable deaths and unvaccinated children (DTP3).<sup>2,3,4</sup>

In the immunization field, an important impetus for a MICs focus has been a concern that these countries, excluded from or facing the loss of donor support, may be missing out on opportunities to introduce important vaccines. The World Health Assembly (WHA) and the WHO Strategic Advisory Group of Experts on immunization (SAGE) have repeatedly called upon the WHO secretariat and the international community to more rigorously investigate obstacles to and mobilize resources for sustainable access to vaccines in MICs.<sup>5</sup> Also, the Global Vaccine Action Plan (GVAP)—endorsed by WHA in 2012—calls for innovation in pricing and procurement models for MICs. The cause of these countries has been championed by the regions of the Americas, Europe and the Eastern Mediterranean.

As the MIC issue gained the attention of immunization agencies, SAGE recognised the increased response. Yet, in November 2012, SAGE pointed to the absence of a clear strategy and action plan in this area and warned that it could lead to ineffective and inefficient use of scarce resources and an inequitable focus on some geographical areas.<sup>6</sup>

## **The MIC Task Force**

In light of these trends and in response to the SAGE recommendation, the WHO secretariat convened a Task Force on sustainable access to vaccines in MICs in June 2014 and tasked it with: i) reviewing the performance of MICs in immunization; ii) refining understanding of the needs of MICs and taking stock of ongoing activities to address these needs; iii) defining a shared strategy, action plan, and monitoring and evaluation framework to enhance sustainable access to vaccines in MICs; iv) acting as an information-sharing and coordination forum across immunization agencies active in MICs. The Task Force is intended to be an inclusive forum for engaging stakeholders as well as a mechanism for generating political will.

Several agencies are represented in the MIC Task Force: the Agence de Médecine Préventive, the Bill and Melinda Gates Foundation, the Gavi Secretariat, the Sabin Vaccine Institute, the Task Force for Global Health, UNICEF Programme and Supply Divisions, WHO (headquarters, PAHO/AMRO, EURO, and EMRO) and the World Bank. (For details on membership, see Annex I.) The work of the MIC Task Force is supported by the Bill and Melinda Gates Foundation, which is also funding analytical work by the Results for Development Institute in support of the Task Force.

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<sup>1</sup> Poverty and Inequality World Bank database (2011). Also see: Sumner A (2012): “Where Do The World’s Poor Live? A New Update”, IDS WORKING PAPER Volume 2012 No 393, and Glassman A, Duran D, Sumner A (2011): “Global health and the new bottom billion: what do shifts in global poverty and the global disease burden mean for Gavi and the Global Fund?”. Center for Global Development, Working Paper 270.

<sup>2</sup> Results for Development analysis, 2014.

<sup>3</sup> These realities reflect in part the shortcomings of the Gross National Income (GNI) per capita measure used to define these country income categories—and to determine eligibility for many forms of international assistance. This measure both fails to capture many aspects of development status and ignores altogether how income and the fruits of development are shared.

<sup>4</sup> Levine O, Bloom D, Cherian T, De Quadros C, Sow S, Wecker J, Duclos P, Greenwood B (2011): The future of immunisation policy, implementation, and financing. *Lancet*, pp55-56.

<sup>5</sup> SAGE November 2008, 61st WHA May 2008, SAGE November 2010.

<sup>6</sup> SAGE Meeting, November 2012, Meeting Report <http://www.who.int/wer/2013/wer8801.pdf?ua=1> (accessed 13.05.2014).

Since its inception, the MIC Task Force has met over teleconferences and in person. In addition, the Task Force has conducted consultations with countries, CSOs, industry, and partners.<sup>7</sup> The Task Force's findings and recommendations have been presented at the SAGE GVAP working group in March 2015 and will be discussed at SAGE in April 2015.

### ***Re-assessing the "MICs issue"***

In the past, analysis of MICs performance in immunization has been framed in terms of rate of new vaccine adoptions compared to donor funded LICs. In order to gain additional clarity on the nature of the problem, the Task Force reviewed the performance of all 103 middle-income countries<sup>8</sup> against GVAP targets for which data were readily available. The Task Force believed a comparison against agreed absolute standards would be more meaningful and ambitious than relative comparison of MICs to LICs. Also, using the GVAP framework, rather than studying new vaccine introductions alone, allows a more comprehensive understanding of MICs performance.<sup>9</sup> Full results of the analysis performed will be presented at SAGE in April 2015 and available thereafter on the SAGE website.

In brief, the analysis showed that, overall, MICs have considerable work to do to meet the GVAP Decade of Vaccines targets:

- i) Almost 90% of polio cases in 2014 were in MICs: there were cases in Pakistan, Nigeria, Iraq, Syria, and Cameroon;
- ii) India, Nigeria, Indonesia, Algeria, Zambia still suffer considerable measles deaths, while Nigeria, China, India, Indonesia, Pakistan, and Angola had the highest number of reported cases in 2013;
- iii) Only 19 MICs, including China and Egypt, have reduced under-five mortality by two thirds since 1990;
- iv) 38 MICs have DTP3 coverage below 90% and more than half fail to meet targets for coverage equity;
- v) 20% of MICs had not introduced any of six priority new or underused vaccines by the end of 2013;<sup>10</sup>
- vi) Trends in domestic expenditure fall short of targets and, finally;
- vii) Only about 40% of MICs have functional national technical advisory bodies on immunization ("NITAGs").<sup>11</sup>

The re-assessment also highlighted that there is significant heterogeneity across the entire group of MICs and that a more granular assessment is warranted. This analysis showed that; i) no sub-group of MICs, defined by region, income, or Gavi status, is meeting all GVAP targets; ii) the great majority of vaccine-preventable deaths are in Gavi countries, particularly India and Nigeria, but also poorer Gavi-eligible MICs; iii) the American and European regions are the best performers; iv) non-Gavi MICs are on average performing better than Gavi-supported MICs; v) upper-middle-income countries are performing consistently better than lower-middle-income countries.

Given past concern that MICs might be lagging behind donor-funded LICs in new and priority vaccine introduction, the Task Force looked carefully at this issue while recognizing the limits of such assessment. The Task Force concluded that while the MICs as a group do lag in the fraction of children reached with some important new vaccines, notably the pneumococcal conjugate and

<sup>7</sup> Two regional consultations were organised (EUR and EMR) as well as meetings with CSOs and industry associations (IFPMA, DCVMN). Partners have also been surveyed.

<sup>8</sup> Based on World Bank definition of countries with gross national income (GNI) per capita of US 1,046 to 12,745.

<sup>9</sup> For instance in recognition of country independent decision making vis-à-vis new vaccine introductions also based on local mortality/morbidity and cost- effectiveness considerations.

<sup>10</sup> These vaccines are PCV, rotavirus, HPV, IPV, Japanese encephalitis, and yellow fever.

<sup>11</sup> As assessed by compliance with six indicators on the WHO/UNICEF joint reporting form.

rotavirus vaccines, this lag is driven primarily by a few large countries. These large countries—with the exception of China—are still Gavi-supported and include India, Nigeria, Indonesia, and Pakistan.

The Task Force believes that this analysis represents an important reframing of the so-called “MICs issue”: the challenges MICs face in reaching globally agreed immunization targets are real, but these challenges are not well captured by the notion that these countries have fallen behind donor-supported countries.

### ***Scope of a MIC Strategy***

Faced with developing a coherent strategy for action and making the best use of limited resources, the Task Force agreed to use the following principles to drive its own recommendations on scope and priorities: maximize health impact, maximize value for money, address inequities within and among countries, consider technical and political feasibility, and complement existing and planned efforts.

With these principles in mind, the most important decision that the Task Force made was to focus its efforts on MICs not receiving support from Gavi. Although the 40 Gavi MICs currently have the greater share of vaccine-preventable disease burden (88%), they are well supported to address this burden and to move toward the GVAP goals. In contrast, the remaining 63 MICs benefit neither from major donor support nor from a unified international strategy. These countries are where the MIC Task Force can have the greatest impact.

The non-Gavi MICs shares of people living in poverty, disease burden, unimmunized children, while relatively modest as a fraction of the global total, are nonetheless considerable, and unacceptable as well as a challenge to GVAP’s elimination goals. China, Brazil, and South Africa are among the top 20 countries in numbers of people living on less than \$1.25/day.<sup>12</sup> There are an estimated 152,000 vaccine-preventable deaths in non-Gavi MICs every year. Globally, non-Gavi MICs represent 20% of pneumococcal pneumonia cases, 10% of resulting mortality, and 13% of pneumonia DALYs. Of these cases, 75% occur in countries that have not introduced PCV, while 67% of deaths in non-Gavi MICs happen in countries without PCV.<sup>13</sup> These countries also represent 28-32% of global cervical cancer mortality and morbidity.<sup>14</sup> About 2.6 million children in these countries fail to receive all three doses of DTP, 2.4 million are not immunized against measles, and almost 32 million do not receive three doses of PCV. Some non-Gavi MICs have unacceptably low coverage rates. Eight countries, with a total birth cohort of 2.7 million, have below 80% national MCV1 coverage,<sup>15</sup> and six have below 80% DTP3 coverage.<sup>16</sup>

These countries, in general, have stronger health systems and immunization programs than poorer countries, making rapid gains possible if critical obstacles were removed. Moreover, as non-Gavi MICs include 30% of the global birth cohort, strengthening the capacity of these countries to introduce new vaccines and increase coverage could help to consolidate vaccine demand and contribute to healthy markets, potentially benefiting Gavi and non-Gavi MICs alike.

The Task Force also recognised that the non-Gavi group of MICs would change over time, with up to 24 countries possibly losing Gavi support by 2020. The share of vaccine-preventable deaths in MICs occurring in countries not receiving Gavi support is likely to grow from 12% in 2014 to 37% in 2020 and possibly as much as 82% in 2025.<sup>17</sup> While the Task Force agreed that Gavi is best placed to

<sup>12</sup> Andy Sumner (2012): “Where Do The World’s Poor Live? A New Update”, IDS WORKING PAPER Volume 2012 No 393.

<sup>13</sup> Mortality from WHO CHERG data. Morbidity source: TRIVAC v. 2.0 (dataset includes 183 countries), based on unpublished, country-level 2008 Global Burden of Disease estimates.

<sup>14</sup> GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11

<sup>15</sup> WUENIC coverage data, 2013. Vanuatu, Syria, Iraq, South Africa, Marshall Islands, Gabon, Lebanon, Dominican Republic (in order of lowest to highest coverage).

<sup>16</sup> WUENIC coverage data, 2013. Marshall Islands, Syria, South Africa, Vanuatu, Iraq, Gabon (in order of lowest to highest coverage).

<sup>17</sup> India, Nigeria, Pakistan, and Indonesia are projected to have graduated from Gavi support by this date.

support eligible and graduating MICs, it concluded that graduated countries should be fully in its scope and that the MIC Strategy should seek to anticipate and address the needs of these countries after the end of Gavi support.<sup>18</sup> Thus, in focusing on non-Gavi MICs, the Task Force aims to address the needs of a group of countries that, over the medium and long term, may grow to encompass most of the world's poor and many of the greatest immunization challenges.

Reflecting the GVAP goals and its own analysis of the potential contribution of increased coverage to alleviating the burden of vaccine-preventable disease, the Task Force also agreed that it was important to address both new vaccine introduction and coverage of existing vaccines. This choice was further supported by consultations with countries and WHO regional offices.

Finally, the Task Force agreed to work on two time horizons. For a first period aligned with the GVAP timeframe (2015-2020), the Task Force developed a detailed strategy to help non-Gavi MICs, possibly including a first set of Gavi-graduated countries, to reach GVAP targets. For a second period (2021-2025), the Task Force proposes to develop as necessary an adapted strategy accounting for changes in the immunization and development landscape. These changes could include a new global vision of immunization beyond GVAP, graduation of new countries from Gavi (and perhaps exit of some countries from middle-income status), and possibly a new country classification framework for determining allocation of donor support relying less on GNI per capita.<sup>19</sup>

### ***Focus of a MIC Strategy: needs, gaps, and solutions***

The MIC Task Force has analysed the needs of non-GAVI MICs, assessed current efforts by international partners to meet these needs, and identified remaining gaps. A detailed description of sources used for this work is provided in [Annex II](#). A detailed mapping of current ongoing partner efforts in MICs is available in [Annex III](#).

The Task Force's review suggests that the most important unmet needs for these countries are in four main areas: i) Evidence-based decision-making; ii) Political will and national immunization financing; iii) Demand for and delivery of immunization; and iv) Access to timely and affordable vaccine supply. Based on this analysis, the group has developed a package of activities that could be offered to countries. These activities, along with coordination mechanisms, targets and indicators, as well as timelines, constitute the proposed MIC Strategy. The draft strategy is summarized in tabular form on page 16 of this report; more details on the proposed activities can be found in Annex IV.

It is important to note that the activities proposed for the MIC Strategy, which are described in the following sections, are a mixture of existing activities that can be expanded to help additional countries and a few key new initiatives. Of note, much of the debate on access to vaccines in MICs has focused on prices. While the Task Force recognizes the crucial importance of affordability as an obstacle, especially to new vaccine adoption, it believes that a more comprehensive approach that addresses coverage as well as new vaccine introduction and promotes affordability through both supply and demand-side measures is more likely to be productive.

### ***1- Strengthened decision making for timely and evidence-based immunization policy***

Informed decision-making on vaccine introduction and other areas of immunization policy is crucial for all countries, but particularly important for countries that fully fund their immunization

<sup>18</sup> The Task Force also recognized that the global community may have a responsibility to monitor and support Gavi's efforts to ensure successful graduation. It agreed that graduating countries would be 'watched', and the Task Force would remain available to play a role should the Gavi Alliance identify any added value in its engagement.

<sup>19</sup> Saez, Catherine. "New Quiet Initiative To Improve Drug Access In Middle-Income Countries, Change Country Classification System." *Intellectual Property Watch*. 25 February 2015. Available at: <http://www.ip-watch.org/2015/02/25/new-secret-initiative-to-improve-drug-access-in-middle-income-countries-change-country-classification-system/> (last accessed 03/03/2015).

programmes.<sup>20</sup> In these countries, adoption and related decisions are likely to be more country-owned and less reliant on international recommendations, and strong cases need to be made to secure sufficient domestic resources to sustainably fund programmes.

Immunization partners have agreed that NITAGs are important structures of the decision making process, while recognizing that NITAGs are not always sufficient for sound decision-making. GVAP calls on all countries to put in place functional NITAGs by 2020, yet in 2013 only 38% of non-Gavi MICs had done so.

Although a sound decision-making process can result in a decision not to adopt a WHO-recommended vaccine, as justified by local epidemiological, economic, or other considerations, such a process can ensure that recommended vaccines are promptly and rigorously considered for national introduction and that, where introduction is warranted, a strong case is made to policy-makers.<sup>21</sup> Recognizing country ownership of vaccine adoption decisions, GVAP also calls on countries to introduce one or more new or underutilized vaccine by 2020. As of December 2013, 34 non-Gavi MICs representing 54% of countries in the group and 64% of the group's birth cohort have adopted one or none of six high-priority new vaccines analysed.<sup>22</sup> Fourteen non-Gavi MICs, accounting for 22% of countries and 6% of the group's birth cohort, have adopted none of the six vaccines.

Several partners are active in strengthening national decision-making processes through supporting evidence-based policy recommendations, disease burden measurement, economic analysis, tools development, training, advocacy, technical assistance, and recent analyses have documented the impact of these efforts.<sup>23,24</sup> While global efforts in this area can benefit all countries, targeted country efforts are currently limited to Gavi or PAHO countries, leaving a clear gap for non-Gavi MICs. Recognizing this gap as well as the availability of active initiatives and tested tools to address this need, the MIC Task Force proposes to build on current efforts and past experience to extend services to a broader range of non-Gavi MICs.

Strengthened decision-making on immunization policy plays a crucial role in the overall MIC Strategy, as it underpins—and logically precedes—mobilization of domestic political will and financing, contributes to increased and more credible demand for vaccines (and thus lower prices), and supports efforts to strengthen immunization systems and combat hesitancy. The relationship between the different arms of the strategy is discussed at greater length in the last section of the report.

## **2- Increased political commitment & financial sustainability of immunization programmes**

Non-Gavi MICs must rely primarily or exclusively on domestic resources to purchase vaccines and fund immunization services. Inadequate national financing—in some cases reflecting insufficient political will— as well as inefficient use of available resources may limit both new vaccine

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<sup>20</sup> It is important to recognize that NITAGs should advise not only on introduction of new vaccines but also on optimization of existing schedules and other aspects of immunization policy.

<sup>21</sup> Countries may decide not to introduce a vaccine because they believe disease burden is relatively low, or because other interventions are a more appropriate or cost-effective way to address the burden. Many MICs have more effective health systems and thus curative services than most LICs, which may reduce the potential benefit of some vaccines. Finally, countries may decide not to introduce some useful vaccines because they are not cost-effective or affordable at current prices. Decisions made on this basis could be reversed if countries had access to lower prices.

<sup>22</sup> PCV, rotavirus, HPV, IPV, Japanese encephalitis, and yellow fever. Year of introduction of selected vaccines, as of 31 December 2013. Immunization, Vaccines and Biologicals, World Health Organization. Database available for download at: [http://www.who.int/immunization/monitoring\\_surveillance/data/en/](http://www.who.int/immunization/monitoring_surveillance/data/en/).

<sup>23</sup> Adjagba, A., Senouci, K., Biellik, R., Batmunkh, N., Faye, P. C., Durupt, A., ... & da Silva, A. (2015). Supporting countries in establishing and strengthening NITAGs: Lessons learned from 5 years of the SIVAC initiative. *Vaccine*, 33(5), 588-595.

<sup>24</sup> For more on strengthening country-level decision-making, please see: Jauregui, B., Sinha, A., Clark, A. D., Bolanos, B. M., Resch, S., Toscano, C. M., ... & Andrus, J. K. (2011). Strengthening the technical capacity at country-level to make informed policy decisions on new vaccine introduction: lessons learned by PAHO's ProVac Initiative. *Vaccine*, 29(5), 1099-1106.



introduction and immunization coverage. This issue has been raised several times by countries and agencies in the context of MIC Task Force consultations.

Data on domestic immunization expenditures in non-Gavi MICs are limited in coverage and quality, and the Task Force recognized the need to work more intensively with MICs on tracking resources and documenting budget performance. The available data demonstrate, however, that the share of government resources devoted to the purchase and delivery of vaccines varies widely across MICs, from a maximum of 0.47% of general government expenditure (GGE) in Paraguay to a minimum of 0.01% in China. There is no currently agreed target level for domestic financing, but if the median share of GGE spent on vaccines in the PAHO region (0.06%) is taken as a benchmark, 35 non-Gavi MICs, representing 72% of the group's birth cohort, currently fail to meet this standard.<sup>25</sup>

In addition, GVAP calls for all countries to have standard budget line items for vaccines and immunization programmes in their national or health sector budgets, which can contribute to higher and more predictable immunization funding.<sup>26</sup> Almost all non-Gavi MICs (54 of 63) have met this target,<sup>27</sup> but only 46% of non-Gavi MICs have increased domestic expenditure on immunization, as required by a second GAVP target.

Finally, consultations with WHO regions strongly reinforced the importance of helping countries to mobilize additional domestic resources for immunization as well as the scope for using resources more efficiently.

Several agencies support countries to enhance national funding to immunization through advocacy, technical assistance, peer exchanges, and training, but, here again, these activities primarily benefit Gavi or PAHO countries.<sup>28</sup> Drawing on existing expertise and tools, the Task Force proposes to expand existing services to non-Gavi MICs.

### **3- Enhanced demand for & equitable delivery of immunization services**

In addressing coverage, the Task Force further noted that both the delivery of immunization services—the reach and efficiency of programmes—and demand for these services were important, especially in light of growing concerns over vaccine hesitancy. It therefore proposes activities in both areas.

#### *Addressing Vaccine Hesitancy and Building Community Demand for Vaccines*

In order to achieve and maintain high uptake, the vaccine community needs to sustain both public and provider confidence in vaccines and their benefits. “Vaccine hesitancy”, which refers to delay in acceptance or refusal of vaccines despite availability of vaccination services, has been flagged as an area of concern since 2011.<sup>29</sup> A recent SAGE Working Group on the issue noted that hesitancy is complex and context-specific and is influenced by factors such as complacency, convenience and

<sup>25</sup> This is an illustrative example to demonstrate how a benchmark might be used in practice. The American region was chosen as a benchmark for its high performance in vaccine coverage and introduction of new and under-utilized vaccines. Health spending was calculated as a percentage of 2012 GGE using data from 2012 Joint Reporting Forms and the IMF's *World Economic Outlook* database. This analysis excludes nine non-Gavi MICs due to insufficient data (Iraq, Libya, Maldives, Mexico, Micronesia, Montenegro, Palau, Serbia, and Syria).

<sup>26</sup> Lydon et al (2008) Government financing for health and specific national budget lines: The case of vaccines and immunization. *Vaccine* 26: 6727-34. Available at: [http://www.who.int/immunization/programmes\\_systems/financing/analyses/JVAC\\_8255\\_LydonP.pdf](http://www.who.int/immunization/programmes_systems/financing/analyses/JVAC_8255_LydonP.pdf).

<sup>27</sup> Joint Reporting Forms, 2013.

<sup>28</sup> McQuestion, M., Gnawali, D., Kamara, C., Kizza, D., Mambu-Ma-Disu, H., Mbwangue, J., & de Quadros, C. (2011). Creating sustainable financing and support for immunization programs in fifteen developing countries. *Health Affairs*, 30(6), 1134-1140. Information on EURO's work with graduating countries was obtained from Osman Niyazi Cakmak, MIC Task Force member.

<sup>29</sup> WHO (2012). Meeting of the Strategic Advisory Group of Experts on Immunization, November 2011 – conclusions and recommendations. *Weekly Epidemiological Record*, 87, 1-16.



confidence.<sup>30</sup> SAGE recognized that this is a rapidly changing global problem that requires global attention and has called for countries to establish the capacity to deal with hesitancy and for partners to support them.<sup>31</sup>

While it is currently difficult to measure and locate vaccine hesitancy and thus quantify the extent of the problem in non-Gavi MICs, country consultations confirmed that vaccine hesitancy is an important concern that could jeopardize sustained vaccine coverage of existing vaccines as well as new vaccine introductions. People in MICs, like those living in high-income countries, have better access to curative medicines and are thus less likely to die of communicable diseases than people in LICs. This is likely to be one of the factors eroding the perceived benefit of immunization. In addition, MICs tend to adopt similar practices to HICs and are thus influenced by hesitancy behaviours we are witnessing in richer settings.<sup>32</sup>

While there are various country-level attempts to address vaccine hesitancy, there are few international initiatives. The European Regional Office (EURO) has begun to work in this area through technical assistance, guidelines and tools (Tailoring Immunization Programmes – TIPs tool) based upon evidence from behavioural economics, the medical humanities, psychology, and neuroscience.<sup>33</sup> The London School of Hygiene and Tropical Medicine has created a Vaccine Confidence Index, which is a global surveillance tool to identify and track rumours and misinformation related to immunization.<sup>7</sup> Most of this work though is only at its inception and currently focuses on HICs or LICs.

Given remaining gaps globally and for MICs in particular, the MIC Task Force proposes to make this a core area of the MIC Strategy, building organizational capacity, conducting research, and developing tools in line with the SAGE recommendations. The Task Force believes that hesitancy may be easier to understand and managed in institutionally stronger MICs than in low-income settings and results of this work could benefit LICs and HICs alike.

### *In-country supply chain & data systems*

Given the complexity of immunization systems and the need to limit the number of activities in the strategy, the Task Force chose to focus on two areas on the delivery side that stood out in country and partner consultations and which seemed particularly amenable to international assistance: supply chain and data systems.

According to data on wastage rates, stock-outs, and coverage, and scores on WHO Effective Vaccine Management (EVM) assessments, the Task Force estimates that at least 28 non-Gavi MICs, representing 32% of the birth cohort, face supply chain issues.<sup>34</sup> MICs are facing significant challenges in their vaccine logistics systems, given the burden of introducing new vaccines that are often more costly and require greater storage capacity. Countries have to properly manage smaller, but sufficient stockpiles, reduce wastage, accurately forecast vaccine requirements, and prevent

<sup>30</sup> Report of the SAGE Working Group on Vaccine Hesitancy. 1 October 2014. Available at: [http://www.who.int/immunization/sage/meetings/2014/october/1\\_Report\\_WORKING\\_GROUP\\_vaccine\\_hesitancy\\_final.pdf](http://www.who.int/immunization/sage/meetings/2014/october/1_Report_WORKING_GROUP_vaccine_hesitancy_final.pdf).

<sup>31</sup> SAGE MICs report.

<sup>32</sup> More information on consultations is available upon request.

<sup>33</sup> EURO. "European Immunization Week – Guidelines for national planning. Available at: [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0003/84297/EIW2011\\_guidelines\\_update.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0003/84297/EIW2011_guidelines_update.pdf?ua=1). Since Bulgaria established TIP in 2012, the Ministry of Health has developed plans to introduce new tools to strengthen the quality of discussion regarding immunization between general practitioners and families, to improve curricula and training of Roma health mediators to optimize their role in promoting immunization, and to revise the school-entry vaccination policy and develop lessons on vaccines and infectious diseases. See EURO. "TIP implementation in Bulgaria." Available at: <http://www.euro.who.int/en/health-topics/communicable-diseases/poliomyelitis/activities/tailoring-immunization-programmes-to-reach-underserved-groups-the-tip-approach/tip-country-projects/tip-implementation-in-bulgaria>.

<sup>34</sup> This number includes countries with a third or more blank responses on the 2013 JRF; those that do not report having a systems for monitoring adverse events; and those with a high share (60% or greater) of private health expenditure.

equipment breakdowns. Embedded in this issue is a need to strengthen human resources and the training and motivation of supply chain workers to ensure competency and low turnover rates.<sup>35</sup>

Similarly, country consultations revealed that health information systems are weak in many MICs. Basic data, for example on immunization coverage or vaccine needs and stocks, are often not reliable or available in a timely manner, and are not always well used by managers to improve performance. The result could be lower coverage, either because unreached populations are not identified or because of vaccine distribution problems.<sup>36</sup>

Based on a number of criteria, including incomplete reporting on the JRF, lack of an adverse events monitoring system, and high reliance on the private sector for health service delivery, the Task Force estimates that 46 non-GAVI countries, representing 84% of the birth cohort, may benefit from assistance with data systems.<sup>37</sup>

Various agencies are currently working in these areas, according to the Task Force's mapping, but few are working in non-Gavi MICs. The Task Force proposes to make use of these existing initiatives and tools and to focus particularly on human resource strengthening—helping countries to improve their own capacity to manage data and supply chains. The Task Force proposes to achieve this to a large extent through peer-to-peer learning. Two areas of focus might be data systems in rapidly growing urban areas, a particular concern for many MICs, and the implementation of electronic immunization systems, where guidance is badly needed. Electronic immunization systems that are linked with civil registries have contributed significantly in improving immunization data quality in the European region.<sup>38</sup>

#### **4- Improved access to affordable and timely supply**

The affordability of new vaccines, especially for non-Gavi MICs and countries soon to lose Gavi support, has been a big concern for the past few years.<sup>39</sup> At the 67<sup>th</sup> World Health Assembly in 2014, dozens of countries requested greater price transparency, information on cost of production, support for improving negotiation capacity, and access to lower prices.<sup>40</sup> The limited price information that is available shows a wide variation in prices currently paid by non-Gavi MICs and consultations conducted by the Task Force confirmed that prices are one of the main preoccupations of countries.<sup>41</sup>

In these consultations, countries also raised the issue of sustained access to supply: indeed, according to the 2014 GVAP assessment report, 40% of low- and middle-income countries have

<sup>35</sup> Zaffran, M., Vandelaer, J., Kristensen, D., Melgaard, B., Yadav, P., Antwi-Agyei, K. O., & Lasher, H. (2013). The imperative for stronger vaccine supply and logistics systems. *Vaccine*, 31, B73-B80. Available at: [http://www.who.int/immunization/sage/meetings/2013/november/3\\_stronger\\_vaccine\\_supply\\_and\\_logistics\\_systems.pdf](http://www.who.int/immunization/sage/meetings/2013/november/3_stronger_vaccine_supply_and_logistics_systems.pdf)

<sup>36</sup> PATH. "Fact Sheet". *Better Immunization Data Initiative*. Available at: [http://bidinitiative.org/wp-content/uploads/BID\\_factsheet\\_02\\_Final.pdf](http://bidinitiative.org/wp-content/uploads/BID_factsheet_02_Final.pdf)

<sup>37</sup> This number includes countries with a third or more blank responses on the 2013 JRF; those that do not report having a systems for monitoring adverse events; countries that do not meet the district coverage equity target; those with less than 80% coverage of MCV1 and DTPs; those with more 50% urban population; and those with a high share (60% or greater) of private health expenditure.

<sup>38</sup> In Georgia, electronic registries are integrated with the civil registries and have managed to reach 15% more children that were not captured before. Most EUR countries that have established immunization registries are able to collect data on vaccines, generate reminders and recall vaccination notices for each client, provide official vaccination forms upon request, and allow vaccination coverage assessments. See Johansen, K., Lopalco, P. L., & Giesecke, J. (2012). Immunisation registers—important for vaccinated individuals, vaccinators and public health. *Euro Surveill*, 17(16), 2-4.

<sup>39</sup> Médecins Sans Frontières (2015). Right Shot: The Right Shot: Bringing down barriers to affordable and adapted vaccines. Available at: <http://www.msfaccess.org/content/right-shot-bringing-down-barriers-affordable-and-adapted-vaccines>.

<sup>40</sup> Makinen, M., Kaddar, M., Molldrem, V., & Wilson, L. (2012). New vaccine adoption in lower-middle-income countries. *Health policy and planning*, 27(suppl 2), ii39-ii49.

<sup>41</sup> WHA67.

<sup>41</sup> V3P. Database, reports, and analyses. Available at: [http://who.int/immunization/programmes\\_systems/procurement/v3p/platform/database/en/](http://who.int/immunization/programmes_systems/procurement/v3p/platform/database/en/).

suffered national-level stock-outs of at least one vaccine that lasted at least one month. Twenty-one non-Gavi MICs experienced such stock-outs, accounting for 15% of all the low- and middle-income countries with national level stock-outs. Non-Gavi countries are also struggling to secure supply for new vaccine introductions and reported difficulties securing responses to tenders for new introductions.<sup>42</sup>

As mentioned above, in recent years the tendency has been to consider the issue of access to affordable and timely supply for MICs in isolation, and several initiatives have been launched recently to address it, including UNICEF's MICs tender and WHO's Vaccine Price, Product Procurement initiative (V3P). The MIC Task Force has concluded that a more comprehensive approach that addresses both demand and supply-side constraints to affordable supply is more likely to bear fruit. This broader approach would nevertheless include activities more specifically focused on price and supply (see below).

### *Increasing procurement skills and knowledge*

Previous studies have identified inefficient procurement as an important barrier to MICs obtaining competitive prices and reliable supply of new and traditional vaccines.<sup>43</sup> Technical assistance on procurement options and practices is a way to improve the efficiency of procurement, especially in self-procuring countries (currently 16 non-Gavi MICs including 11% of the non-Gavi MICs birth cohort), but also in mix-procuring countries. It is important to recognize that inefficient procurement can reflect deep-seated deficiencies in public-sector management or corruption.

A few organizations are currently helping MICs improve procurement practices, the effort is very limited due to unclear roles and responsibilities, limited capacity and country scope. This is an important area where the Task Force is determined to increase effort through a collaboration among UNICEF, WHO and possibly the World Bank to strengthen procurement knowledge and skills. The Task Force proposes to do this through increased peer learning among countries, development of missing tools (such as updated procurement guidelines) and provision of targeted technical assistance to countries most in need.

### *Access to price and contract information*

Vaccine price is a major factor in deciding whether and when to adopt new vaccines. Without information on prices paid by comparable countries—and information on contract terms—decisions about vaccine adoption are often delayed or misinformed.<sup>44</sup> Price transparency is also a way for countries to ascertain whether they are paying equitable prices. Analysis of national price databases and other medicine price mechanisms have shown positive effects on access to medicines, including the uptake of higher quality medicines, more favourable results from contract negotiations, changes in national pricing policies, and decreased prices.<sup>45</sup>

Information on vaccine prices is particularly important for self-procuring MICs countries, which deal directly with manufacturers and have limited financial resources available for vaccine purchase.

There are currently four main initiatives—UNICEF's and PAHO's publication of prices awarded in their vaccine tenders, WHO's V3P, and MSF's advocacy and analysis on vaccine prices<sup>46</sup>—aimed at

<sup>42</sup> EMRO or EURO MIC Task Force country consultations. More information available upon request.

<sup>43</sup> Makinen et al (2012) New vaccine adoption in lower-middle income countries. *Health Policy and Planning* 27: ii39-ii49.

<sup>44</sup> Results for Development, Inc. (2011). Synthesis Report of New Vaccine Adoption in Low-Middle Income Countries (available at [http://www.who.int/immunization/programmes\\_systems/financing/analyses/Obstacles\\_to\\_New\\_Vaccine\\_Adoption\\_in\\_LMICs.pdf](http://www.who.int/immunization/programmes_systems/financing/analyses/Obstacles_to_New_Vaccine_Adoption_in_LMICs.pdf)).

<sup>45</sup> Hinsch, M., Kaddar, M., & Schmitt, S. (2014). Enhancing medicine price transparency through price information mechanisms. *Global Health*, 10, 34.

<sup>46</sup> MSF. (2015). *The Right Shot: Bringing down barriers to affordable and adapted vaccines*. Available at: <http://www.msfaccess.org/content/right-shot-bringing-down-barriers-affordable-and-adapted-vaccines>.

giving countries more information on vaccine prices. Given recent investment in these initiatives and broad political support for their implementation (e.g. SAGE 2014),<sup>47</sup> the Task Force believed they should continue as part of a broader MIC Strategy.

#### *Access to revolving funds*

Assurance that suppliers will be paid on time is important to obtain lower vaccine prices, but some MICs face uncertainties in their annual budgetary allocation processes that make it difficult to ensure timely payment. Some also have legal restrictions on prepayment, while others cite access to hard currency as a barrier.<sup>48</sup>

Revolving funds such as PAHO's and the UNICEF Vaccine Independence Initiative (VII) provide a line of credit to member countries unable to produce funding for a vaccine purchase at the time needed, allowing countries greater flexibility in payment terms and preventing supply disruptions. It should be noted that a revolving fund only addresses timing issues: if countries do not repay in full, the revolving fund will not be sustainable. The PAHO Revolving Fund credit line is available to all participating countries and territories in the AMR region, but cannot be expanded to other regions. UNICEF's VII is currently used by 18 countries (four countries and 13 Pacific Islands) due to a small capital base. The VII has had only one default in its 24-year history.<sup>49</sup>

Even with these funds, there is a large unmet need for pre-financing support. UNICEF SD has generally received, on average, \$100 million worth of pre-financing requests annually. More than half of the requests are for immunization supplies, and the majority of requests are unmet. By 2020, UNICEF SD expects to receive more than \$225 million in pre-financing requests annually, 75% of which will continue to be for immunization-related commodities.<sup>50</sup>

A solution to payment issues in MICs could be to give more MICs the option to draw on revolving funds. A recent UNICEF Executive Board decision has authorized expansion of VII's capital base to \$100 million,<sup>51</sup> provided sufficient resources become available. There is great potential for VII to benefit many more countries. In line with this opportunity, the Task Force proposes to continue existing efforts in this area.

#### *Product registration requirements*

Inefficient and widely varying processes for registering vaccines, including WHO-prequalified vaccines, create an important obstacle to the introduction of new vaccines, lengthening timelines and driving up costs for countries and suppliers. The barrier that distinct and sometimes onerous registration requirements pose is almost certainly greater for lower-cost manufacturers (who have fewer in-country staff to negotiate these processes).<sup>52</sup> At a minimum, 30 non-Gavi MICs, representing 48% of countries, could benefit from streamlined regulatory processes to expedite

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<sup>47</sup> Through the 2014 GVAP report, SAGE recommends that: i) countries change the rules of the game on vaccine affordability, to create transparency which is in their interest. They can do this by making pricing information publicly available, and by collaborating with WHO and all technical agencies to develop solutions; ii) technical partners support countries to improve the transparency of vaccine pricing. Technical agencies themselves should do everything possible to share pricing data. This report is available at: [http://www.who.int/immunization/global\\_vaccine\\_action\\_plan/SAGE\\_DoV\\_GVAP\\_Assessment\\_report\\_2014\\_English.pdf?ua=1](http://www.who.int/immunization/global_vaccine_action_plan/SAGE_DoV_GVAP_Assessment_report_2014_English.pdf?ua=1).

<sup>48</sup> Gavi. Country needs assessment of Access to Appropriate Pricing for Gavi graduates and non-Gavi LMICs.

<sup>49</sup> UNICEF. "Vaccine Independence Initiative (VII)." Available at: [http://www.unicef.org/pacificislands/immunization\\_2881.html](http://www.unicef.org/pacificislands/immunization_2881.html).

<sup>50</sup> UNICEF (2015). Executive Board first regular session. "Recommendation to the Executive Board: Extension and expansion of the Vaccine Independence Initiative and its revolving fund". Available at: [http://www.unicef.org/about/execboard/files/2015-PL5-VII\\_and\\_revolving\\_fund-ODS-EN.pdf](http://www.unicef.org/about/execboard/files/2015-PL5-VII_and_revolving_fund-ODS-EN.pdf).

<sup>51</sup> UNICEF. VII and Revolving Fund Expansion: Informal Board Session. January 2015. Presentation available at: [http://www.unicef.org/about/execboard/files/VII\\_Expansion\\_Informal\\_Board\\_2015\\_01\\_20.pdf](http://www.unicef.org/about/execboard/files/VII_Expansion_Informal_Board_2015_01_20.pdf).

<sup>52</sup> Consultation with DCVMN at annual conference, November 2014.

access to prequalified and other priority vaccines.<sup>53</sup>

The Task Force discussed possible solutions to this issue, taking into account on-going initiatives to establish global norms and standards, understand regulatory pathways, and align regulatory requirements and pathways, while recognizing their limitation in geographic or vaccine scope. The Task Force proposes to focus over the long term on continued efforts to streamline and align requirements for vaccine registration regionally and globally, which would alleviate these constraints while preserving country autonomy.<sup>54</sup> In the shorter term, expedited processes for prequalified vaccines could be a useful compromise.<sup>55</sup> The recent experience with facilitating introduction of IPV as part of the Polio Endgame, during which the WHO Regulatory Strengthening and Vaccine Assessment Prequalification teams coordinated efforts to ensure timely registration of prequalified vaccines in some countries, was well received by both countries and manufacturers.<sup>56</sup>

### *Pooled procurement and access to external procurement services*

External procurement services, for example through UNICEF Supply Division, can be a useful option for MICs that have limited procurement capacity. When the use of external procurement services also allows pooling of demand, it can help smaller countries that lack the individual market power to generate competitive bids. Even for large countries, pooled procurement can in theory provide greater market leverage and better access to reliable, affordable supply. The use of external procurement services can also help suppliers by eliminating the need to negotiate separately with each country. The Task Force recognises that not all countries will choose this option and that countries will use external procurement services in different ways. Some countries currently choose to use the UNICEF Supply Division or the PAHO Revolving Fund (see below) as routine channels for vaccine procurement, while others make use of these services on an ad hoc basis (for instance as procurement agent of last recourse if unable to access sufficient quantities of vaccine). Some countries see the use of external procurement services, including pooled procurement, as a long-term strategy, as is the case for many countries in the Americas region, while others may see it as short-term expedient as they build their own procurement capacity.

The use of external procurement services could benefit a wide variety of non-Gavi MICs outside the Americas region (where pooled procurement through PAHO is already the norm for many countries), including fully self-procuring MICs, MICs that use ‘mixed procurement modalities’, and small MICs with low bargaining power. In addition, countries that already procure individually through UNICEF could gain additional benefits from pooled procurement, if the barriers to effective demand consolidation could be overcome. Overall this covers all countries outside of PAHO (43) representing 68% of non-Gavi MICs and 77% of the group’s birth cohort.<sup>57</sup>

There are currently several initiatives in this area. The PAHO Revolving Fund for the Americas region, which combines pooled procurement with a revolving fund line of credit and technical assistance to countries, remains one of the most successful and well-known examples of pooled procurement. The Revolving Fund has increased the accuracy of vaccine demand forecasts and ensured timely

<sup>53</sup> Estimate of countries in need was developed through conversations with WHO HQ/HIS/EMP/RHT/RSS team. Estimated range: 30-50 non-Gavi MICs (48-79% of countries).

<sup>54</sup> This includes required information in dossiers, registration procedures and perhaps also other aspects of the process.

<sup>55</sup> In principle these measures would allow vaccines to be adopted more quickly in some countries, where registration is currently an important obstacle. More importantly, by allowing more suppliers to participate in national procurement processes, they could make some markets more competitive and reduce prices. The impact will be greatest over the medium term, when developing country manufacturers are expected to enter markets for additional important vaccines, including rotavirus, pneumococcal conjugate, and HPV.

<sup>56</sup> This work is still ongoing and a full assessment of its impact is not yet available. However, preliminary observations show that: i) several countries accepted the WHO prequalification as basis for accelerated registration of vaccines, reducing timelines from over 1 year to a few months; ii) up to present, no country has delayed introduction because of a registration issue; iii) both countries and WHO strengthened their capacities and got accustomed to/improved the expedited procedure, increasing the likelihood of its use in future.

<sup>57</sup> WHO HQ/HIS/EMP/RHT/RSS team.

payment, thereby building supplier confidence and reducing price fluctuations. It has also strengthened domestic commitment to immunization, built regional solidarity, and enhanced bargaining power with suppliers. It has almost certainly played a crucial role in the region's impressive immunization performance, including in the introduction of new vaccines.<sup>58,59</sup>

UNICEF, for its part, offers a range of procurement services to non-GAVI MICs, including: i) Reference pricing in instances where a self-procuring MIC requests UNICEF to negotiate prices on its behalf, e.g. as part of a reference pricing scheme; ii) single-country tendering in instances where a MIC requests specific vaccines for which UNICEF does not have a pre-existing long-term framework agreement or tender against which it can award additional MICs quantities; iii) multi-country tendering (pooled procurement) in instances where volumes from multiple MICs can be pooled and tendered together. UNICEF procures traditional vaccines (e.g. BCG, OPV, DTP, measles, MR) on behalf of a wide range of non-Gavi MICs: in some cases, this demand can be pooled by integrating it into existing tenders. UNICEF has recently procured newer vaccines such as PCV and rota through a pooled MICs tender and IPV for non-Gavi MICs through a separate pooled tender. In both cases, manufacturers have offered tiered pricing mainly based on country income.

UNICEF's MICs tender has not so far been as successful as hoped. Although preliminary analysis suggests several contributing factors, concern over the credibility of the demand that underpin such a tender has emerged as a crucial impediment to greater participation of suppliers. Overcoming this will require greater certainty not only about the timing of vaccine introduction by participating countries, but also about the availability of sustained funding and the timeliness and reliability of payment. An important lesson from this experience is that the benefits of pooled procurement can only be realized if substantial progress can be made in consolidating demand—many of the activities included in the MIC Strategy can contribute to this goal. Similar considerations apply to another recent effort in this area: the attempt by WHO EMRO to create a new regional pooled procurement mechanism.

The Task Force discussed extensively the way forward in this area and agreed: i) to develop and disseminate lessons learnt from current and past procurement initiatives for MICs, including the UNICEF MICs tender and the EMRO pooled procurement initiative; ii) to focus on activities that would contribute to consolidating demand (e.g. harmonization of product choices, expedited product registration, strengthening of country commitment and financing) through a strong collaboration between WHO, UNICEF, and other partners; iii) to explore further the potential of alternative tendering strategies and solutions with deeper engagement of manufacturers, including the possibility of new MICs pooled procurement efforts underpinned by greater demand consolidation; iv) to continue existing procurement services for MICs through the PAHO RF and UNICEF.

### *Influencing market dynamics*

The MIC Task Force also discussed measures to influence vaccine markets as a way of increasing access to timely and affordable supply. All MICs would benefit from lower prices and more secure supply that more competitive vaccine markets could bring, especially for new vaccines currently supplied by only one or two manufacturers. In addition, countries that rely on domestic production might benefit from measures that facilitate development of new vaccines by their producers. There are currently about 12 producing countries among the non-Gavi MICs.<sup>60</sup>

<sup>58</sup> PAHO. "Pan American Health Organization Revolving Fund." Available at: [http://www.who.int/immunization/newsroom/PAHO\\_Revolving\\_Fund\\_FINAL.pdf](http://www.who.int/immunization/newsroom/PAHO_Revolving_Fund_FINAL.pdf).

<sup>59</sup> Tambini G1, Andrus JK, Fitzsimmons JW, Roses Periago M. (2006): Regional immunization programs as a model for strengthening cooperation among nations. *Rev Panam Salud Publica* 20:54-9.

<sup>60</sup> Argentina, Brazil, Bulgaria, China, Egypt, Iran, Mexico, Romania, Serbia, Thailand, TFYR of Macedonia, Venezuela (Source: WHO/EMP/RSS/ NRA group, 2014)



Several agencies and organizations are currently working to influence vaccine markets through both demand- and supply-side interventions (particularly to improve the supply base). This work includes negotiations with manufacturers, procurement policy, push and pull incentives for manufacturer investment, and advocacy. Some of the most important initiatives seek to accelerate the entry of emerging manufacturers into markets for important new vaccines. Of note, Gavi is currently working to identify potential options to provide Gavi-graduated countries with access to appropriate prices (the ATAP initiative). This initiative is also looking into possible inclusion of non-Gavi LMICs.

The Task Force acknowledged the considerable work in this area while noting that most of it focuses primarily on the Gavi market. The Task Force also noted that many of the interventions included in the MIC Strategy will influence markets, mainly by consolidating demand. Given this context, the Task Force proposes to make use of existing mechanisms such as the UNICEF and PAHO revolving fund tender processes and to encourage organizations working with manufacturers, including the Bill & Melinda Gates Foundation, to include provisions benefitting non-Gavi MICs in access agreements.

## The MIC Strategy

<b>Goal</b>	Enhance sustainable access to vaccines for populations in middle-income countries to meet GVAP targets			
<b>Driving Principles</b>	<p>The MIC Strategy is driven by GVAP principles of country ownership, shared responsibility, integration, sustainability &amp; innovation. In addition, it seeks to:</p> <ul style="list-style-type: none"> <li>• Address inequities within and among countries</li> <li>• Maximize health impact</li> <li>• Consider technical and political feasibility</li> <li>• Maximize value for money</li> <li>• Complement existing and planned efforts</li> </ul>			
<b>Country Scope</b>	All middle-income countries not supported through the Gavi Alliance			
<b>Objective</b>	Raise and sustain equitable immunization coverage & enable new vaccine introductions			
<b>Focus areas</b>	<p><b>Strengthened decision making</b> for timely and evidence-based immunization policy &amp; programmatic choices</p> <p>Through:</p> <ul style="list-style-type: none"> <li>• Establishing &amp; strengthening NITAGS</li> <li>• Strengthening national capacity to generate evidence for decision-making</li> </ul>	<p><b>Increased political commitment &amp; financial sustainability</b> of immunization programmes</p> <p>Through:</p> <ul style="list-style-type: none"> <li>• Strengthening legislative basis for immunization</li> <li>• Advocating for immunization to achieve set immunization spending targets</li> <li>• Mobilizing national resources and increasing efficiency in resource use</li> </ul>	<p><b>Enhanced demand for &amp; equitable delivery of immunization services</b></p> <p>Through:</p> <ul style="list-style-type: none"> <li>• Addressing vaccine hesitancy &amp; building community demand</li> <li>• Strengthening in country supply chain &amp; data systems</li> </ul>	<p><b>Improved access to affordable and timely supply</b></p> <p>Through:</p> <ul style="list-style-type: none"> <li>• Increasing procurement skills and knowledge</li> <li>• Increasing access to revolving funds</li> <li>• Harmonizing product choice &amp; registration processes</li> <li>• Increasing price Information</li> <li>• Strengthening pooled procurement options</li> <li>• Influencing market dynamics</li> </ul>
<b>Strategic enablers</b>	<p>Country commitment to and investments in immunization</p> <p>Coordination among international and local partners</p> <p>International and national advocacy &amp; country-to-country peer learning</p> <p>Strong monitoring &amp; evaluation efforts</p>			

### ***The strategy as a whole: implementation and impact***

The Task Force believes that the activities outlined here make up a coherent and comprehensive package of assistance to MICs as they strive to meet the GVAP goals. The proposed services and new initiatives address the major needs articulated by MICs and work together to strengthen each step on a path to meeting the goals, from rigorous decision-making through access to affordable supply and sustainable financing to strengthened immunization delivery systems.

The strategy, if successfully implemented, would help countries achieve the GVAP goals and reduce the burden of vaccine-preventable disease through three main causal channels. First, by strengthening immunization decision-making, it would make it more likely that countries consider adding new vaccines to their immunization programmes in a timely fashion and do so where the evidence supports such a choice. Second, by addressing important weaknesses in immunization delivery and combatting vaccine hesitancy, the strategy would help to increase coverage of both new and old vaccines. Third, by enhancing and consolidating MIC vaccine demand while at the same time addressing the supply side of vaccine markets the strategy would give many MICs access to lower vaccine prices. This, and the strategy's advocacy work on domestic financing, would in turn allow some countries for whom cost and financing have been obstacles to introduce important new vaccines. Lower prices for already introduced vaccines would free up resources that could be used for other immunization needs or for other health priorities.

The importance of demand consolidation—and the extent to which many of the activities making up the MIC Strategy could contribute to it—became clear during the Task Force's discussion on pooled procurement. Pooled procurement can be a powerful tool for achieving both lower prices and more secure supply, but its benefits will be limited unless manufacturers can be offered the prospect of predictable demand backed by secure financing and timely payment. Timely and rigorous introduction decisions, sustainable domestic financing, streamlined and aligned processes for vaccine registration, and access to revolving funds when needed are a critical part of the solution. These factors, which are also crucial for countries that choose to self-procure, can work hand-in-hand with other activities to influence vaccine markets, such as access agreements with suppliers and on-going efforts to ease the entry of new suppliers and make key markets more competitive.

Although the strategy addresses many of the most important needs of MICs, it is important to acknowledge what it does not or cannot do. It does not tackle directly the social determinants that underlie disparities in access to immunization as well as other health services. It can help only at the margin where problems in immunization systems and decision-making stem from deep-seated weaknesses in governance and institutional capacity. Perhaps most importantly, although advocacy—for domestic financing, for immunization in general—can play an important role, an international strategy can only do so much to create political will where it is lacking. Finally, the strategy only proposes very limited and catalytic external immunization financing for MICs, mainly for targeted technical assistance. Instead, it relies on building sustainable domestic financing and facilitating lower vaccine prices to help countries pay for needed vaccines.

The MIC Strategy is focused on non-Gavi MICs and is intended to complement Gavi's strategy for its eligible and graduating countries. It does so in three ways. First, it extends important services to and attempts to address critical challenges faced by a group of countries that have never had access to these kinds of assistance through Gavi. Second, it can provide some continuity of support to countries that have graduated from Gavi and thus help to ensure that the investments Gavi has made in these countries are sustained and extended. The details of this transition will depend on choices made by the Gavi Alliance Board this spring, as it reviews its eligibility, graduation, and co-financing policies and a policy to ensure access to affordable prices for graduated countries (ATAP). Third, by helping to strengthen and consolidate demand from non-Gavi MICs, the MIC Strategy can

complement the efforts of Gavi and its partners to influence important vaccine markets and thus assure affordable and sustainable supply for all developing countries.

Twenty-four countries are currently expected to graduate from Gavi support by 2020 and thus enter the ambit of the MIC Strategy within the initial 2016-2020 period.<sup>61</sup> Sixteen of these countries crossed Gavi's eligibility threshold and began the graduation process in 2011, after the eligibility policy was revised; eight more countries have begun graduation since. A further eight countries are currently projected to enter graduation between 2016 and 2020, and thus to lose Gavi support during the second MIC Strategy period, 2021-2025. Some of these countries are very large: Indonesia began graduation in 2011, Nigeria entered this year; India and Pakistan are among the countries expected to graduate before 2025. The entry of these countries will thus have profound implications for the MIC Strategy and it is important to analyse the extent to which the proposed activities will address their needs or if changes to the Strategy would be required.

In general, the current set of graduating countries, most of which are projected to have introduced five or more new vaccines from Gavi portfolio by the time they graduate, are in a good position to sustain the gains achieved with Gavi support. In many respects, the needs of the graduating countries are similar to those of the current non-Gavi MICs: some need help with self-procurement or with removing obstacles to continued procurement through UNICEF; although most have established NITAGs, some would benefit from further help in strengthening decision-making; many have weak regulatory agencies. The MIC Strategy is well positioned to help in these areas. Although most of the current graduating countries have quite high immunization coverage, 9 of 24 had DTP3 coverage below 90% in 2013 and four—Nigeria, Indonesia, Congo, and Ukraine had coverage persistently below 80%. The strategy's measures to address vaccine hesitancy and strengthen selected aspects of immunization systems can help, but probably cannot by themselves remedy these more deep-seated deficiencies in immunization performance. Finally, analyses carried out by the Gavi Secretariat as part of the current review of graduation policy show that a subset of graduating countries face a serious challenge in rapidly scaling up domestic spending to pay for large vaccine portfolios as Gavi support is withdrawn. This is a challenge unique to this subset of Gavi graduates, which the MIC Strategy can do little to ease in the short run. Approaches to mitigating the fiscal risk facing some graduating countries will be considered by the Gavi Board in June.

The MIC Strategy should reflect the characteristics of the countries it is intended to serve, particularly their greater capacity and autonomy, but also their heterogeneity. For this reason, the Task Force envisions the strategy as a menu of services from which countries could request assistance, focusing on areas that they themselves identify as priorities. Although the details of implementation remain to be worked out, many of the proposed activities will emphasize collaboration among MICs and peer-to-peer learning as much as technical assistance provided from the centre. To reflect greater capacity and autonomy, countries would also be asked to cover the greatest share in the cost of the strategy: technical assistance, when it is requested, would be subsidized rather than provided for free.

The WHO secretariat has estimated the potential cost of the various components of the strategy, working from information provided by agencies currently involved in similar activities. These estimates must be considered preliminary, as the actual cost will depend on country demand for these services, but the total annual cost of implementing the package described here is expected to be about \$20 million. This relatively low cost reflects the strategy's focus on targeted technical

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<sup>61</sup> Gavi is currently reviewing its eligibility and graduation policies—decisions taken by the Gavi Alliance Board in June of 2015 could affect the precise timing of the end of financial support for specific countries, as well as nature of Gavi's engagement with graduated countries.

assistance to remove important obstacles while relying heavily on countries own resources to achieve their immunization goals.<sup>62</sup>

The Task Force is exploring an innovative approach to increasing the credibility and market impact of MICs vaccine funding. This mechanism, which could involve a development bank, would be based primarily on the budget commitments of participating countries and would thus depend critically on country commitment.

The potential impact of the MIC Strategy, if fully implemented, is difficult to estimate, as the strategy would not directly provide vaccines or immunization services but act to remove obstacles to higher immunization performance. Yet, the Task Force believes that the package of activities in the strategy can contribute to alleviating a substantial fraction of the remaining burden of vaccine-preventable disease in the non-Gavi MICs, which is estimated at about 150,000 deaths per year in 2014, rising to about 530,000 deaths in 2020 if the 24 countries (including Nigeria) expected to lose Gavi support by then are included.<sup>63,64</sup> Even if the strategy were not implemented, countries would continue to improve immunization delivery and introduce new vaccines, albeit more slowly: a simple analysis, using the LiST model and based on linear extrapolation of trends over the last five years, suggests that perhaps 50,000 lives would be saved in current non-Gavi MICs over the initial strategy period (2016-2020) by such a continuation of current rates of improvement, in addition to those saved by 2013 levels of immunization.<sup>65</sup> If all current non-Gavi MICs that have not already done so introduced the pneumococcal conjugate and rotavirus vaccines while increasing coverage of these and the vaccines already in their portfolios to high levels by 2020, as many as 200,000 more deaths could be averted over this five-year period by pneumococcal conjugate, rotavirus, and Hib vaccination alone. A substantial number of additional lives could be saved by introduction of HPV and increased coverage of measles and Hep B vaccines. This estimate can be seen as representing an upper bound on the potential incremental impact of the MIC Strategy. A more modest scenario, in which the recent rates of adoption of the pneumococcal conjugate and rotavirus vaccines are doubled by implementation of the strategy, might prevent 60,000 deaths over current trends.

These estimates are intended only to give a sense of the potential impact of the strategy, if it were broadly implemented and led to substantial improvement in country performance. More precise and country-specific estimate will be possible once countries have prepared specific plans and defined priority areas of work within the strategy.

The Task Force envisions that the impact of the strategy would be monitored through existing GVAP channels, using the already agreed targets and indicators. A grant oversight mechanism could be established to monitor implementation of the strategy and provision of assistance to countries.

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<sup>62</sup> The already planned resource mobilization for VII is not included in the preliminary estimate of incremental costs for the MIC Strategy. Combined with estimated potential impact, the proposed funding investment will be evaluated for its cost effectiveness.

<sup>63</sup> Estimates for the baseline year are based on WHO CHERG data for deaths from diarrhoea, measles, meningitis, and pneumonia. Estimates for 2020 assume that vaccine-preventable deaths grow in proportion to birth cohorts. It should be kept in mind that currently available vaccines can prevent only some of these deaths even at high coverage, as they provide protection against only some strains or serotypes of some of the pathogens that can cause these illnesses and, especially in the case of the rotavirus vaccine, are not 100% effective.

<sup>64</sup> The Task Force has also analysed data from the TRIVAC model on vaccine-preventable morbidity in non-Gavi MICs, but at this time estimates are available only for pneumococcal disease.

<sup>65</sup> This and the other impact estimates presented in this paragraph are derived by applying estimates of lives saved per 1000 children vaccinated in Gavi countries (L.A. Lee et al (2013). The estimated mortality impact of vaccinations forecast to be administered during 2011–2020 in 73 countries supported by the GAVI Alliance. Vaccine 31S:B61-B72), adjusting for the difference in average under-five mortality between Gavi countries and the current non-Gavi MICs, and applying these adjusted rates to projected numbers of people immunised with pneumo, rota, and Hib in the three scenarios. These impact numbers are similar to estimates derived from an independent LiST analysis of vaccine impact in the non-Gavi MICs carried out by Results for Development for the Task Force.

### ***Next steps***

The MIC Task Force is submitting its strategy for discussion at SAGE in April 2015. The proposed strategy will then be fine-tuned to reflect SAGE feedback as well as continued consultation with regions, countries, and participating agencies. The Task Force will also need to begin concrete discussions with potential donors to ascertain their interest in supporting these efforts. Depending on the outcome of these discussions, the Task Force will then move to defining how the strategy would be implemented: how countries would request assistance, how countries and partner organizations would work together, how donor funds would be managed, and how the various activities and participating organizations would be monitored, and evaluated. The implementation plan should also define a clear exit strategy, a timetable or set of criteria for ending support to countries. The Task Force recognizes the opportunity that the MIC Strategy offers for innovation in the way its participating organizations work with each other and with countries.



## Annex I: Membership of the MIC Task Force

1. AMP	<ul style="list-style-type: none"> <li>Alex Adjagba, Director SIVAC Initiative</li> <li>Jean-Bernard Legargasson, Program Leader , Health Economics and Medical Anthropology</li> </ul>
2. BMGF	<ul style="list-style-type: none"> <li>John Yang - Senior program officer, Vaccine Delivery</li> <li>Greg Widmyer - Deputy director, Vaccine Delivery</li> </ul>
3. Gavi Secretariat	<ul style="list-style-type: none"> <li>Aurelia Nguyen – Director, Policy &amp; Performance</li> <li>Santiago Cornjeo – Senior Specialist</li> </ul>
4. Sabin	<ul style="list-style-type: none"> <li>Mike McQuestion - Director, Sustainable Immunization Financing</li> <li>John Andrus, - Executive Vice President</li> </ul>
5. Task Force for Global Health	<ul style="list-style-type: none"> <li>Alan R. Hinman - Director for Programs, Center for Vaccine Equity</li> </ul>
6. UNICEF PD	<ul style="list-style-type: none"> <li>Gian Gandhi - Senior Health Specialist (Policy &amp; Partnerships), Immunization Unit, Health Section</li> </ul>
7. UNICEF SD	<ul style="list-style-type: none"> <li>Heather Deehan - Chief of the Vaccine Centre</li> </ul>
8. WHO HQ (Chair) and Regional Offices	<ul style="list-style-type: none"> <li>Michel Zaffran - Coordinator, EPI, FWC/IVB</li> <li>Tania Cernuschi - Technical Officer, Vaccine Pricing, Supply, Procurement, FWC/IVB/EPI</li> <li>Niyazi Cakmak - EURO - Technical Officer, Communicable Diseases, EU/RGO/DCE/VPR/VPI</li> <li>Cuauhtemoc Ruiz-Matus - Regional Adviser AMRO</li> <li>Daniel Rodriguez - Advisor, Revolving Fund Management, AMRO/FGL/IM</li> <li>Nadia Teleb- Regional Adviser, EMRO</li> <li>Peter Beyer, Senior Advisor, HQ/HIS/EMP/PHI</li> </ul>
9. World Bank	<ul style="list-style-type: none"> <li>Karima Saleh – Senior Health Economist, Health, Nutrition &amp; Population</li> </ul>

## Annex II: Main information sources for assessment of needs and mapping of current activities

- Literature review, including as main sources a Synthesis Report of New Vaccine Adoption in Low-Middle Income Countries by Results for Development (2011); Gavi graduation assessments and LMIC assessments done as part Gavi's ATAP work; WHO/UNICEF Effective Vaccine Management country reports; and peer-reviewed articles.<sup>66</sup> These sources included studies of the following countries: Albania, Angola, Armenia, Azerbaijan, Bhutan, Bolivia, Cabo Verde, China, Cote d'Ivoire, Ecuador, Egypt, Georgia, Ghana, Guyana, Honduras, Indonesia, Kiribati, Kosovo, Lao PDR, Lesotho, Micronesia, Moldova, Mongolia, Morocco, Nigeria, Panama, Papua New Guinea, Philippines, Rep. Congo, Samoa, Sao Tome and Principe, South Africa, Sri Lanka, Sudan, Swaziland, Syria, Thailand, Timor-Leste, Tunisia, Turkey, Ukraine, Uzbekistan, Vanuatu, Vietnam, West Bank and Gaza, Zambia.
- A survey of needs and current support activities in the following countries: Morocco, Jordan, Egypt, Libya, Palestine, Iran, Iraq, Lebanon, Syria, Tunisia, Albania, Belarus, Kazakhstan, Hungary, Bulgaria, Serbia, Bosnia & Herzegovina (Federation and Republic).
- An in depth analysis of eight geographically diverse "sentinel" countries: non-Gavi or Gavi-graduating MICs with either a high absolute burden or a high rate of vaccine-preventable disease and, in some cases, other special characteristics: Philippines, Egypt, Cape Verde, South Africa, Thailand, Ecuador, Indonesia, and Angola.<sup>67</sup>
- Finally, this work was vetted through consultations with the European and Eastern Mediterranean WHO regional offices and their member countries and bilateral discussions with several partners.<sup>68</sup>
- Survey and interviews with the following agencies: Agence de Médecine Préventive (AMP), Bill & Melinda Gates Foundation (BMGF), Clinton Health Access Initiative (CHAI), Gavi, Harvard Global Health Institute, Johns Hopkins University International Vaccine Access Center (IVAC), Médecins Sans Frontières (MSF), National Institute for Health and Care Excellence (NICE) International, Sabin Vaccine Institute, Task Force for Global Health (TFGH), UNICEF Programme & Supply Division, United States Agency for International Development (USAID), World Bank, WHO headquarters, and the following WHO regional offices: the Eastern Mediterranean Region (EMRO), the European Region (EURO), the Pan American Health Organization (PAHO), the South-East Asia Region (SEARO), and the Western Pacific Region (WPRO).

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<sup>66</sup>R4D's report is available at

[http://www.who.int/immunization/programmes\\_systems/financing/analyses/Obstacles\\_to\\_New\\_Vaccine\\_Adoption\\_in\\_LMICs.pdf](http://www.who.int/immunization/programmes_systems/financing/analyses/Obstacles_to_New_Vaccine_Adoption_in_LMICs.pdf).

<sup>67</sup> Analysis is available upon request.

<sup>68</sup> Detailed results of these assessments are available upon request.

## Annex III: Mapping of ongoing support activities in MICs

One of the mandates of the MIC Task Force was to conduct a mapping of support activities by immunization partners targeting MICs. The mapping has two main goals: to understand the level of engagement of partners in MICs and to highlight how these activities could better respond to the needs of MICs. Activities are therefore colour coded according to the below categories:

- The activity is “sufficient, to be continued”: the activity is working well and is likely to achieve impact if continued. Activities that have just been started are also classified in this category.
- The activity “could be expanded /strengthened”: the activity is working well and could be continued, but it probably requires support to strengthen and/or expand actions to achieve greater impact in MICs.
- The activity “requires modifications”: the activity as-is is not likely to yield sufficient results and might require some changes and adjustments to achieve greater impact in MICs.
- “Not applicable, not enough information”: the classification is not applicable or there is not sufficient information to classify the activity.

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 Sufficient, to be continued	 Could be expanded/strengthened	 Requires modifications	 Not applicable, not enough information
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## 1. Strengthened decision making

### Establishing & strengthening NITAGS

Form of assistance	Org.	Activity name & Description	Countries covered	Challenges & limitations	Successes & development	Collaboration
TA, Financing, Training	AMP	<b>SIVAC</b> - Support countries to set up or strengthen NITAGs (activities include in-country TA and training, promotion of NITAG collaboration and a resource centre for knowledge sharing)	19 LICs & MICs	- Support limited to Gavi countries, with limited funding outside of Gavi countries - Challenges: need solid institutional integration to guarantee financial sustainability and resistance to political turmoil ; scarcity of HR in secretariats & lack of national experts  More info on challenges & successes on: <a href="http://www.sciencedirect.com/science/article/pii/S0264410X14016697">http://www.sciencedirect.com/science/article/pii/S0264410X14016697</a>	- In several countries, new NITAGs have impacted on recent vaccine decisions - Developed countries reported a positive impact from SIVAC activities - There is demand from countries - Resource centre for knowledge sharing - Activities could be extended to other non-Gavi countries	WHO HQ, WHO Regions, BMGF, PAHO, WAHO, Sabin, CDC, existing NITAGs
Technical and management assistance, Advocacy	CHAI	<b>New Vaccine Introduction (NVI):</b> - Evidence-based NVI decision-making for antigen prioritization - Strengthening government working groups - Data analysis support (sometimes also including assessment and support in improving data collection mechanism)	MICs: Nigeria, Cameroon, Vietnam, India		- Depending on funding availability, impact, priorities and other considerations, CHAI may consider supporting MICs where CHAI has a country office, but no existing vaccine programs.	
TA, Training	NICE	<b>International Decision Support Initiative (iDSI) :</b> - Build capacity in the generation of evidence about the cost effectiveness of technologies and the use of evidence in health policy - Currently in pilot phase (Philippines)	LICs & MICs	- Not vaccine-specific - Lack of locally-generated evidence - Lack of institutional processes to consider evidence in a transparent and accountable manner - Currently in development and difficult to assess impact on MICs and on immunization	- The network is growing, so iDSI will have capacity to increase current work in country or engage in new initiatives, where activities align with the remit and objectives of iDSI. - Still gathering ideas, eg. idea of floating hubs that share expertise in particular regions	HITAP, BMGF, DFID, Rockefeller Foundation, World Bank
TA, Capacity building	WHO & Gavi	<b>Gavi graduation assessments</b> - Conducted by Gavi (Secretariat and Alliance partners) to develop plans for successful country graduations - Include analysis of NITAG performance - Technical assistance available through Alliance partners during the plan implementation phase	Gavi-graduating countries	- Limited to Gavi-graduating countries. - To date (Mar 2015), mostly conducted in countries close to graduation (5 out of 11 assessments conducted in countries graduating in 2015/16), with reduced time available for making programme adjustments	Partner wide effort for a comprehensive approach to graduation	AMP
Advocacy, TA, Meetings, Training, Financing, Cooperation	WHO (regions)	- Sub-regional NITAG (eg. RTAG in EURO (ETAGE)) - Normative guidance on establishment and strengthening of NITAGs - Support on vaccine related legislations (support provided through SIVAC, a WHO collaborating centre)	All countries	In principle available to all countries, but limited resources to proactively engage with non Gavi countries (HR and financial)	- Role of NITAG particularly relevant in self-procuring MICs	NITAGs, Regional TAGs, CDC

	Sufficient, to be continued		Could be expanded/strengthened		Requires modifications		Not applicable, not enough information
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## Generating evidence for decision-making

Form of assistance	Org.	Activity name & Description	Countries covered	Challenges & limitations	Successes & development	Collaboration
TA	AMP	- Analysis of costing and financing of routine immunization and NUVI - Sentinel site disease surveillance for clinical and lab confirmed cholera (Africhol) - Use of economic evaluations for decision-making (training)	Ghana, Cameroon, Cote d'Ivoire, Nigeria, South Africa	- Decision making tools and scientific evidence often limited (eg. BoD)	Working with tools that go beyond the simple CEA analysis (eg BoD, affordability analyses, budget impact analyses ...)	
Financing	BMGF, IHME	<b>The Global Burden of Diseases, Injuries, and Risk Factors Study (GBD)</b> - Produces annual updates to critical information and data such as the effects of different diseases that kill people prematurely and cause ill health, comprehensive estimates of the disease burden attributable to different risk factors and changing disease patterns	All countries	- Data related to vaccines is limited	Large and detailed scientific effort to quantify levels and trends in health	
Financing, Tool development, Data collection & dissemination	BMGF	<b>Portfolio of studies</b> - Large portfolio of studies in epidemiology, etiology and burden of disease targeting vaccine-preventable diseases	Various MICs in several regions	- No public access to the repository		Several partners
Tool development,	Gavi	<b>Disease dashboard</b> - Using empirical evidence to measure the impact of vaccination in Gavi-supported countries	Gavi-countries	- Not created yet, being developed		WHO
TA, Training, Financing, Advocacy, Meetings, Analyses	JHU IVAC	- Data for decision-making: supporting NITAG data needs for PCV and RV, synthesize data, cost of illness studies, etc. - Policies and recommendations: policy surveys, advocacy support on IPV in MICs - Global disease burden on PCV, Hib, Mening. and RV: data synthesis for RV ; TA, funding, and training for global disease burden [data collection] for PCV, Hib, meningitis ; Pneumonia etiology studies in 7 countries (incl. South Africa, Thailand, Zambia)	Data for decision-making: India, Nigeria, others as requested. BoD: work in about 13 MICs	- Limited number of countries		
Tool development, TA, Training, Advocacy	PAHO	<b>ProVac &amp; ProVac International Working Group (ProVac IWG)</b> - To strengthen economic analyses leading to informed decision-making on introduction of new and underutilized vaccines - Key activities include: Economic evaluation & evidence (costs, benefits, cost-effectiveness; Tools & methodologies; Technical assistance and training	7 countries outside of PAHO (ProVac IWG)	- Outside of PAHO, the use of ProVac is limited to 7 countries and 3 regions (AFR, EMR, EUR) - Funding is limited	- 33 studies completed in 22 countries - Country-led effort, strong country-ownership - ProVac could be expanded to other countries with additional funding	AMP, Sabin, PATH, CDC, WHO, BMGF
TA, Financing	TFGH	- Burden of influenza - Introduction of influenza immunization for high risk groups, especially pregnant women	Laos, Nicaragua, Armenia, Morocco	- Limited to influenza - Limited to 4 MICs	- Expansion to an additional 2-8 countries over the next few years (number dependent on funding)	CDC, BMGF
TA, Financing,	WHO (regions)	<b>Disease burden</b> - Synthesis of all available published and unpublished (eg. on JE ) disease burden studies, Hepatitis B serosurveys, Hepatitis B birth dose assessment - Assessment of BoD for new vaccines to be introduced - Assess population immunity (eg. MR), conduct EPI & VPD surveillance reviews	Some countries of the regions	- Some activities limited to Gavi-countries - Limited funding and resources for regional or country studies which are often requested as evidence for decision making	- Need further resources to increase scope of activities and channel TA to countries	
Guidelines, Tool development, TA, Coordination	WHO	<b>Cost analyses and the broader economic impact of vaccination</b> - Assess the broader economic impact of vaccination: value-added of the vaccine and its economic, social, fiscal etc. impact for the country - Provides evidence for decision-making to get vaccines on the agenda: CEA, CE analysis, tools (eg. TRIVAC and C4P for HPV) - TA on cost-effectiveness analysis for new vaccines.: e.g. Vaccine effectiveness studies, Vaccine impact assessment studies, Regional network for Surveillance of diseases	All countries	- Lack of data and evidence - Funding is limited - Some tools are used in Gavi-countries only (even though available to all, eg. C4P)	- Particularly relevant to MICs - The area needs further research - WHO is equipped with technical skills and mandate to increase range of TA to non-Gavi MICs, but requires additional resources (HR and financial)	AMP
Guidelines, TA	WHO (HQ)	Policies recommendations: eg. vaccine introduction guidelines and tools, recommendations for routine immunization, multidose vial policy, vaccine position papers, evidence generation on disease burden, optimizing delivery schedules	All countries		- Used to inform decision-making - Publicly available online	


 Sufficient, to be continued	 Could be expanded/strengthened	 Requires modifications	 Not applicable, not enough information
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## 2. Increased political commitment & financial sustainability

### Strengthening national immunization financing, resource mobilization and programme efficiency

Form of assistance	Org.	Activity name & Description	Countries covered	Challenges & limitations	Successes & development	Collaboration
TA, evaluation	AMP	- Analysis of costing and financing of routine immunization and NUVI - In-country and remote technical support to cMYP costing tools	Gavi West African countries	Limited number of countries	Similar approaches could inform spending on immunization and improve costing of immunization in target countries	BMGF, WHO, Gavi
Analyses, Advocacy, Training	JHU IVAC	<b>Decade of Vaccines Economics (DOVE)</b> analyses - Advocacy for financing, parliamentary forums (India, Pakistan), briefings, landscape analysis - Dengue vaccine financing workshops	About 13 MICs	Limited number of countries	<i>No information on need or possibility to strengthen/expand activity</i>	
Advocacy, TA, Training	Sabin	<b>Sustainable Immunization Financing (SIF)</b> - Support to collective action by public sector counterparts within and across countries to increase budget transparency and accountability, develop sustainable financing mechanisms for immunization and enact legislation assuring public financing for immunization - Done through national and subnational briefings, advocacy events, peer exchanges between countries, costing studies and other participatory action research activities	22 Gavi-countries	- To date limited to Gavi-eligible countries - Challenges: limited fiscal space; chronic dependency on external funding; opacity about health spending; difficulties to change public financial management practices; difficulties to measure actual immunization costs and set budget benchmarks (immunizations and other basic services delivered in integrated fashion); lack of knowledge on future vaccine costs	- Increased budget transparency in 11/22 SIF countries to date - Immunization legislation under active development or passed in 19/22 SIF countries - There is increased demand from countries - Expanding to other countries (incl. non-Gavi MICs) - Promotes country ownership	BMGF, Gavi
TA, Financing	TFGH	Support for funding of maternal influenza immunization	Laos, Nicaragua	- Limited to influenza - Limited to 2 MICs	Expansion to an additional 2-8 countries over the next few years (number dependent on funding)	CDC, BMGF
Technical & Management Assistance, Financing	WHO & Gavi	<b>Gavi graduation assessments</b> - Conducted by Alliance partners to develop plans for successful country graduations - Include ensuring sufficient scale up of national immunization financing - Technical assistance available through Alliance partners during the plan implementation phase	Gavi-graduating countries	- Limited to Gavi-graduating countries. - Up to present (Mar 2015), mostly conducted in countries close to graduation (5 out of 11 assessments conducted in countries graduating in 2015/16), reducing time available for programme adjustments	Partner wide effort, comprehensive approach to graduation	UNICEF, Sabin, CHAI, WB (since 2015), several partners
Training	WHO EURO	- Training on resource mobilization to improve national capacities: development of a toolkit and training programme - Training on improving programme efficiency - Developing normative guidance	MICs in the region	Limited funding	Normative guidance developed by the region may be used by other regions after adaptation to regional context	
TA, Training, Advocacy	WHO	<b>Comprehensive Multi-year Plans (cMYPs), advocacy and TA</b> Technical assistance for preparation of multiyear plans for immunization including costing and planning of financial needs WHO regions: advocacy for allocating more government resources of EPI, capacity building to improve financial sustainability of the programmes, fiscal space analyses, immunization programme costing studies, support on financial management for immunization: health accounts	All countries	- Theoretically available to all MICs, but main demand comes from Gavi-countries (this is a Gavi-requirement) - Limited funding available to non-Gavi MICs	Would be a useful tool to have for MICs	Gavi, AMP, CHAI, several partners
TA, Coordination, Meetings, Analyses	World Bank	- Economic and financial analyses, including allocative efficiency analyses, technical efficiency analyses, Public Expenditure Tracking Surveys (PETS)	All MICs eligible for support	- Not vaccine-specific - The Bank is not sector specific, so loans or grants to immunization would have to be linked to the broader country plan.		



 Sufficient, to be continued	 Could be expanded/strengthened	 Requires modifications	 Not applicable, not enough information
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## Catalytic funding for NUVI

Form of assistance	Org.	Activity name & Description	Countries covered	Challenges & limitations	Successes & development	Collaboration
Financing, TA	WHO (HQ)	<b>IPV introduction</b> - Catalytic support for IPV introduction for non-Gavi MICs - Funding for start-up costs - 12 months catalytic procurement	Selected countries	- Limited to the identified countries - Activity in progress and long-term impact is not yet known	- Exceptional, unprecedented support dedicated to some MICs (16) to meet Endgame timelines - Enabled to speed up introduction of IPV	GPEI, TFGH
Financing, Technical and management assistance	World Bank	<b>Innovative financing</b> - eg. the AMC and IFFIm - Has historically been a convener and facilitator for discussions on innovative financing instruments for immunization - In 2015 the Bank will convene a group of stakeholders to explore new innovative financing solutions, purchasing solutions and market shaping models to increase sustainably financed access to vaccines in the short to medium term	Mainly Gavi-countries	So far limited to Gavi-countries	New ideas for innovative financing could be explored in the future (incl. bridge funding)	Gavi

	Sufficient, to be continued		Could be expanded/strengthened		Requires modifications		Not applicable, not enough information
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## Emergency funding





Form of assistance	Org.	Activity name & Description	Countries covered	Challenges & limitations	Successes & development	Collaboration
Funding	BMGF	\$24.8 M to UN agencies for Ebola response	West Africa	Exclusive focus on outbreaks and acute crisis relief		UN agencies
TA, Training	CDC	<b>Emergency Response and Recovery Branch</b> provides technical support for rapid assessment and surveillance, develops planning resources and technical guidelines, and training to strengthen HRH capacity	Bosnia and Herzegovina, Colombia, El Salvador, Iraq, Jordan, Marshall Islands, Micronesia, Palau, Samoa, Swaziland	Not vaccine-specific	Could expand capacity-building efforts to include immunization in long-term crises	OFDA, UNCHR, UNICEF, WHO, NGOs
Funding, Supplies, Expertise	EU	Emergency funding for outbreak response (€60M since March 2014) and for reinforcing capacity of governments to deliver vital public services (€210M)	All	Focus on outbreak response	Focus on capacity-building could be expanded to include long-term crisis support	MSF, ICRC, UNICEF and WHO
Funding, Advocacy	Gavi	- Flexible funding processes, ceilings, and channels, as well as technical support for affected countries - Access to price for organizations vaccinating in emergency situations: Gavi has encouraged manufacturers to offer their vaccines at the “Gavi price” to organizations vaccinating in emergencies,	Gavi countries, Palestine	- Funding is limited to Gavi-countries - The call on manufacturers has not yet generated positive responses		UNICEF, WHO
Funding	International Committee of the Red Cross	<b>Disaster Relief Emergency Fund (DREF)</b> : loans or grants that can be authorized and released in 24 hours. Argentina, Bosnia & Herzegovina, Botswana, Bulgaria, China, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Hungary, Kazakhstan, Macedonia, Montenegro, Namibia, Panama, Paraguay, Peru, Philippines, Romania, Seychelles	Many countries (listed on the left)	Exclusive focus on acute crisis relief	- Critical resources for immediate disaster response - Rapid release of funds	
Campaigns, Education, Service delivery	International Relief and Development	<b>Outreach Services for Iraqi Refugees (OSIR)</b> <b>Health Linkages and National Networks (HLNN)</b> <b>Health Support to Syrian Refugees in Jordan (HSSR)</b>	All; strong presence in Syrian refugee camps in Jordan	Involved in corruption scandal in Iraq (Jan 2015)	Supports capacity building	UNHCR
Funding, Campaign coordination, Guidelines	UN	- OCHA manages <b>Central Emergency Response Fund (CERF)</b> , capped at \$30 million/crisis (allocated to UN agencies including WHO) and <b>country-based pooled funds</b> (e.g. Common Humanitarian Fund in Sudan) - <b>UNHCR</b> funds and coordinates emergency vaccination campaigns, with funding and procurement assistance from <b>UNICEF</b> (focusing on measles and polio campaigns) - <b>UNICEF Emergency Programme Fund (EPF)</b> : since 2006, ceiling of \$75M / biennium	Several, incl.: Bosnia & Herzegovina, Colombia, Guatemala, Iraq, Jordan, Lebanon, Paraguay, Philippines, Syria	Funding needs at an all-time high, straining existing mechanisms	UNICEF experienced in vaccine procurement could be leveraged to assist integrated refugees access immunization services	WHO
Funding, coordination	USAID	<b>Office of Foreign Disaster Assistance</b> provides funding to support immunization campaigns during disasters	All disaster-affected countries	Exclusive focus on campaigns	Provides technical and regional expertise; could be expanded to support RI in long-term crises	UNICEF, WHO
Fundraising, Management and distribution of funds	WHO	- Emergency funds including <b>African Public Health Emergency Fund</b> and <b>South East Asia Regional Health Emergency Fund</b> - Country offices help to raise funds for immunization of refugees outside camps - Proposal for establishment of emergency fund and global health worker cadre endorsed by Executive Board (Jan 2015)	All		Strong financial and programmatic coordination arm; work with integrated refugees could be expanded	Several partners
Funding	World Bank	<b>Emergency Primary Health Care Restoration Project</b> : - To improve access to primary health care services among Lebanese populations impacted by the Syrian crisis - Call for creation of new pandemic emergency facility, Jim Yong Kim (Oct. 2014)	Lebanon	Not for refugees	Addresses impact of refugee crises on host country health systems	

 Sufficient, to be continued	 Could be expanded/strengthened	 Requires modifications	 Not applicable, not enough information
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### 3. Enhanced demand for and equitable delivery of immunization services





#### Addressing vaccine hesitancy & building vaccine community demand

Form of assistance	Org.	Activity name & Description	Countries covered	Challenges & limitations	Successes & development	Collaboration
Tool development, Research	LSHTM	<b>Vaccine confidence project:</b> - A global surveillance system to identify and track rumours and misinformation related to immunization - Development of a Vaccine Confidence Index	All countries	In development	In development	BMGF
Diagnostic tools	WHO EURO	- Developed TIP ( <b>T</b> ailoring <b>I</b> mmunization <b>P</b> rogramme) Toolkit to identify behavioural determinants of vaccination (and barriers) - Sample survey questions to assess the specific determinants of vaccine hesitancy developed by the SAGE working group	All countries in the region	- As a new tool, the TIP needs to be evaluated, validated and possibly modified, in particular in LICs % MICs beyond EUR. Needs to be adapted to be used globally - Requires advocacy for social mobilization - Requires funding for expansion - Requires more research and tools - Sample survey questions remain to be validated, in particular in low- and middle income settings	- Discussions with partners and stakeholders are ongoing to advance the use of the TIP tool/survey question - CDC expressed particular interest in supporting the evaluation and adaption of the TIP tool/survey question	WHO HQ, CDC, UNICEF
Communication	WHO EURO	<b>Mobile phone app</b> in 2013 to allow parents to track their child immunization (addresses a consistently reported reason for hesitancy: lack of reminder or recall system)	All MICs in the region	Useful communication tool, though not directly related to vaccine hesitancy	Useful communication tool No information on need or possibility to strengthen and expand activity	
Technical and management assistance	WHO & Gavi	<b>Gavi graduation assessment missions</b> Conducted by Alliance partners to develop plans for successful country graduations. Include: developing national immunization communication plan, to address vaccine hesitancy &/or to develop AEFI and risk communication. Technical assistance available through Alliance partners during plan implementation phase	Gavi-graduating countries	- Limited to Gavi-graduating countries. - Up to present (Mar 2015), mostly conducted in countries close to graduation (5 out of 11 assessments conducted in countries graduating in 2015/16), reducing time available for programme adjustments	Partner wide effort for a comprehensive approach to graduation	AMP, UNICEF, several partners
Advocacy	WHO	<b>World Immunization Week (WIW)</b> The SAGE Vaccine Hesitancy Working Group concluded that the World Immunization Week, in the scope of WHO, is an opportunity to build positive public dialogue around vaccines and immunization	All countries	- Further support and promotion of WIW is needed, in particular by partners and stakeholders such as civil service organizations - More financial support would be helpful to regional offices	WIW has been established as global brand with positive messaging around vaccines and immunization	WHO HQ, WHO Regions, several partners & stakeholders
Policy, Strategy, Guidance	WHO (HQ)	<b>SAGE Working Group on Vaccine Hesitancy</b> - Several documents and papers published by the SAGE working Group on vaccine hesitancy: vaccine hesitancy landscape study, systematic review of determinants of vaccine hesitancy and the mentioned report of the SAGE Working Group on Vaccine Hesitancy which is in the process of being published as a special issue of the journal Vaccine.	All countries	Need to validate tools to assess vaccine hesitancy as well as strategies to address it	- Existence of a definition of vaccine hesitancy - Creation of a matrix on determinants of vaccine hesitancy - Indicators to measure vaccine hesitancy have been tested and now included in JRF - Increased recognition of this issue at the international level	WHO EURO, Vaccine hesitancy Working Group members
Training	WHO	Sub-regional trainings on managing vaccine safety concerns, capacity building, communication strategy (eg. Immunization week) and media training ; Development of e-learning tools on vaccine hesitancy	All countries	Several initiatives are ongoing to develop training modules on vaccine hesitancy. These initiatives need to be aligned	Discussions initiated with WHO HQ, WHO EURO, UNICEF, LSHTM, Public Health Canada, other	WHO EURO, CDC, UNICEF
Research, Implementation, Guidelines	Various	Several initiatives are starting or ongoing in countries and involve a wide range of actors: NVAC Working Group on vaccine hesitancy, China MoH, China CDC, Belize, German Federal Centre for Health Education, NCIRS Australia, Romania NIPH, UK Department of Health, US CDC, Canadian Association for Immunization Research and Evaluation, Canadian Pediatric Society, GPEI, BMGF, Robert Wood Johnson Foundation, Canadian Center for Vaccinology, Harvard University, JHSPH, Ottawa Hospital Research Institute, University of Sydney, University of Washington School of Medicine, VAX Northwest, UNICEF, WHO, WHO EURO, vaccine Industry, ...	All countries	- Few examples of concrete actions relating to vaccine promotion/acceptance exist - Not enough global vaccine reporting or surveillance systems currently measuring demand-side indicators, such as vaccine hesitancy - Efforts are disparate and the issue is complex - Funding is limited. Grants often focus on the supply side of immunization but only a few projects funded to work on demand-side factors (e.g. vaccine acceptance, confidence and hesitancy)	- Many advisory committees and organizations have started to deal with the issue of vaccine hesitancy, including encountering and defining the problem of lack of confidence in vaccines, gathering information on the problem and suggesting potential strategies to deal with this issue.	Several partners

	Sufficient, to be continued		Could be expanded/strengthened		Requires modifications		Not applicable, not enough information
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## Strengthening supply chains

Form of assistance	Org.	Activity name & Description	Countries covered	Challenges & limitations	Successes & development	Collaboration
TA, Training	AMP	- <b>LOGIVAC</b> : Supply chain pre-service and in- service trainings (in country or in the LOGIVAC Centre in Benin) - <b>EPIVAC®</b> : One-year on-the-job training programme in applied vaccinology and management of immunization systems for district medical officers	Nigeria, Senegal, Cameroon, Cote d'Ivoire, Mauritania	Limited to Francophone sub-Saharan African countries	- Currently being expanded to Anglophone countries (hub in Rwanda) - Could be further expanded	UNICEF, Gavi, WHO
Financing,	Gavi	<b>Global immunization supply chain strategy</b> - Focuses most intensively on the country level - Focuses on system redesign, as well as 4 key elements of immunization: supply chain managers, supply chain management & improvement plans, supply chain dashboards, cold chain equipment	Gavi-countries	- Vaccine volume increases over time and stretches existing supply chain capacity - Limited to Gavi-countries		WHO, UNICEF, BMGF
Modelling, Analysis	JHU IVAC	<b>HERMES</b> (Highly Extensible Resource for Modelling Event-Driven Supply Chains) analysis. - Immunization system redesign	Vietnam, Thailand, India, Senegal	Limited number of countries	<i>No information on need or possibility to strengthen/expand activity</i>	Gavi BMGF
Advocacy, Research	MSF	<b>Vaccine adaptability &amp; service delivery</b> - Promoting improvement of vaccine products and improved packaging - Conducting research on thermostability of the Tetanus vaccine (through MSF's research arm, Epicentre); - Conducting in-country epidemiological research (eg. Niger) - Vaccine delivery & immunization campaigns	LICs & MICs	Challenges: there is a need for simplified dosing schedules, heat-stable vaccines, easy to administer (eg. Uniject) ; and there is a need for vaccines that better target epidemiological needs of developing countries		
Tool development, TA	UNICEF SD	<b>VIVA project (Visibility for Vaccines)</b> : - Link country level stock data with scheduled deliveries in a manner that provides a visual overview of projected stock levels - Identify risks of vaccine stock outs/overstocking well in advance to allow for corrective action	All countries. Test countries: The Philippines and Botswana	- Still being developed - Countries are not necessarily aware of the tool. Activity could benefit from communication, advocacy and TA to countries	- Publicly accessible online. An internet interface for all stakeholders to upload, visualize and comprehend the data easily	
TA, Training, Other	USAID	Cold Chain: In-country TA , capacity building, and training in cold chain & logistics	11 countries	Activities limited to some countries		
Technical and management assistance	WHO & Gavi	<b>Gavi graduation assessment missions</b> Conducted by Alliance partners to develop plans for successful graduation. Include: - Capacity strengthening (based on EPI review and EVM) - Improvements in cold chain and logistics as part of strategy to improve immunization coverage - Present LOGIVAC trainings if necessary (AMP) - MLM training identified as priority actions in Graduation plan when relevant	Gavi-graduating countries	- Limited to Gavi-graduating countries. - To date (Mar 2015), mostly conducted in countries close to graduation (5 out of 11 assessments conducted in countries graduating in 2015/16), with reduced time available for making programme adjustments	Partner wide effort for a comprehensive approach to graduation.	AMP, UNICEF, several partners
Technical and management assistance, Financing	WHO & UNICEF	<b>Immunization Supply Chains &amp; Logistics</b> - Cold chain logistics planning & management, including normative guidance, support on design of cold chain infrastructure, repair and maintenance, strengthening & improving cold chain capacity, cold chain assessment for new vaccines introduction, sub-regional meetings on strengthening vaccine management, advocacy and TA to priority countries to develop SOPs. - Information system: stock management (eg. VSSM), Cold Chain Equipment (CCE) management, temperature monitoring, web-based cold chain equipment inventories, accelerated adoption of new technologies, data analysis support - Procurement support for cold chain equipment (UNICEF SD, PAHO RF, CHAI)	All countries	Funding is mainly limited to Gavi countries and technical support to non-Gavi MICs is limited		USAID, PATH, CHAI, AMP
Technical guidelines, Advocacy, Monitoring	WHO	<b>Effective Vaccine Management (EVM) Initiative</b> - Provide materials and tools needed to monitor and assess vaccine supply chains and help countries to improve their supply chain performance (TA & online) - Technical and financial support for EVM assessment, developing of EVM improvement plans, capacity building and resource mobilization, follow up, re-assessment, etc.	All countries	- Available to all but mainly implemented in Gavi-countries (this is a Gavi requirement) - Implementation in MICs would require additional funding		USAID, PATH, CHAI, AMP
TA, Financing, Analyses	World Bank	<b>Supply chain strengthening</b> - Engagement in supply chain strengthening (including working with the private sector) to improve the efficiency and (cost)-effectiveness of supply chains - Best indicators for improved supply chains developed and revised using data from analytic work	All MICs eligible for support	- Not vaccine-specific - The Bank is not sector specific, so loans or grants to immunization would have to be linked to the broader country plan		

 Sufficient, to be continued	 Could be expanded/strengthened	 Requires modifications	 Not applicable, not enough information
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## Strengthening data systems

Form of assistance	Org.	Activity name & Description	Countries covered	Challenges & limitations	Successes & development	Collaboration
TA, Financing	AMP	<b>African Cholera Surveillance Network: Africhol</b> - Development of databases and data management tools on cholera disease burden in Africa through a network of surveillance sites (collecting data on demography, symptoms and risk factors in 20 sites in 11 countries) - Forum to share information on activities and develop tools for surveillance sites	11 countries in AFR	- Limited to Cholera - Limited to Africa	Data gathered serves to inform decisions on optimal interventions for cholera prevention and control, including vaccination	BMGF
Financing, Data collection & dissemination	PATH	<b>Project “Better Immunization Data” (BID)</b> - Areas of work: national immunization registries, automated report generation, supply chain system tools, use of barcodes, supportive supervision, community micro-training... - Develop immunization management information system components (built upon existing information system tools where they exist) and demonstrate effectiveness and scalability - Identify and extend best practices and create replicable models - Create a learning network of countries	Tanzania, Zambia	Currently limited to 2 countries	- Empower countries to enhance immunization through improved data collection, quality, and use - Expansion and dissemination of tools planned for 2016	BMGF, WHO, WHO AFRO, Gavi, UNICEF, MoH
Technical and management assistance	WHO & Gavi	<b>Gavi graduation assessment missions</b> - Conducted by Alliance partners to develop plans for successful country graduations - Include strengthening data management systems and relevant use of data for decision making - Technical assistance available through Alliance partners during plan implementation phase	Gavi-graduating countries	- Limited to Gavi-graduating countries. - To date (Mar 2015), mostly conducted in countries close to graduation (5 out of 11 assessments conducted in countries graduating in 2015/16), with reduced time available for making programme adjustments	Partner wide effort for a comprehensive approach to graduation	AMP, UNICEF, several partners
Coordination, Research, Data collection & dissemination	WHO	<b>JRF, WHO info repository</b> - HQ: Data collection and monitoring: Global data collection and dissemination, Global coordination, Research to improve monitoring and evaluation - Regions: support on collection and analysis of EPI/VPD data (JFR)	All countries	There is often more information available for Gavi-countries.		UNICEF
TA, Training, Financing, Surveillance, Tool development, Guidelines	WHO (regions)	<b>Surveillance networks, data sharing and e-registries, eg:</b> - Pharmacovigilance: surveillance of Adverse Events Following Immunization (AEFI) - Advocacy and support on implementation of immunization electronic/nominal registries and coordination (eg. PAHO ISIS), establishment of sentinel surveillance systems, surveillance networks, web-based surveillance reporting system, EPI reporting system, HR capacity building, sharing all data collection tools, strengthening capacity of national AEFI committee to conduct causality assessment and foster data sharing	All countries	- Technical support to non-Gavi MICs is limited - Limited knowledge and sharing of best practices regarding the implementation of e-registries - Support could be extended with additional funding - Need to strengthen expertise at country level	E-registries and improved data systems are considered key areas for some regions	
TA, Guidelines, Tool development	WHO (HQ)	<b>Surveillance &amp; Laboratory capacity</b> - Measles surveillance; RV surveillance and laboratory networks - Rotavirus and Global Invasive Bacterial Vaccine Preventable Diseases (IB-VPD) surveillance and laboratory networks	All countries	MICs would need financial support to start surveillance (eg. small seed money) and technical support	There is interest and demand from countries	CDC
TA, Guidelines, Coordination	WHO (HQ)	<b>Information systems</b> - Norms and standards, guidance on ICTs (including on e-registries), information sharing, coordination - Coverage survey manual and use of home based records - Technical support for software development for selected African countries - Assessing and improving immunization data quality	All countries	- Funding is limited - Implementation and TA for MICs is not foreseen	Still in development	CDC, BMGF, Gavi
Tool development, Communication	WHO (HQ)	<b>TechNet: online platform</b> - Practitioner network - Reference library	All countries		Still in development	BMGF
Data collection, Analyses	World Bank	<b>HealthStats</b> Data collection and analysis: 2014 Development Indicators/ Development Data Platform/HealthStats	All MICs eligible for support	- Not vaccine-specific - Loans or grants to immunization would have to be linked to broader country plan	<i>No information on need or possibility to strengthen/expand activity</i>	

 Sufficient, to be continued	 Could be expanded/strengthened	 Requires modifications	 Not applicable, not enough information
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## 4. Improved access to affordable and timely supply

### Increasing procurement skills and knowledge

Form of assistance	Org.	Activity name & Description	Countries covered	Challenges & limitations	Successes & development	Collaboration
TA	CHAI	Support for vaccines supply planning and procurement, especially for new vaccines	MICS: Nigeria, Cameroon, Vietnam, India	Limited to 4 Gavi-MICs	- In-country in-depth support - No information on need or possibility to strengthen/expand activity	
Procurement, Coordination, Financing	PAHO RF	<b>PAHO Revolving Fund</b> - Component of the TA on immunization in the Region. Pooled Procurement on behalf of Member States in the Americas Region. - Assist countries on demand planning, procurement, regulatory alignment, claim management (e.g. cold chain rupture)	PAHO countries	Only for PAHO Member States	- 41 countries and territories actively participating. - Established 35 years ago	
TA, Training	PAHO RF	<b>Forecasting</b> - Capacity building on vaccine and supplies forecasting - Update on vaccine markets to Member States (presentations and reports )	PAHO developing countries	- Limited to PAHO developing countries	With additional funding, PAHO could also support other WHO RO with TA	CDC
Implementation , Tool development	UNICEF SD	<b>Supply &amp; forecasting</b> - Follow and present key information on products, including pipeline products. - Publication of market updates with revised supply & demand update per vaccine - Forecast spreadsheet, monitoring - Annual manufacturers consultations	All countries, data on vaccine demand is from UNICEF- procuring countries	- Market updates limited to a few products - Takes only into account demand coming from countries procuring through UNICEF	Raises flags regarding upcoming market shortages	
Technical and management assistance	WHO & Gavi	<b>Gavi graduation assessments</b> - Conducted by Alliance partners to develop plans for successful country graduations - Include: TA and identification of bottlenecks; TA on improved procurement systems (Armenia, Azerbaijan, Uzbekistan); capacity building (e.g. international tenders) - Technical assistance available through Alliance partners during the plan implementation phase	Gavi-graduating countries	- Limited to Gavi-graduating countries. - Limited availability of procurement expertise to advise countries during missions	- Partner wide effort for a comprehensive approach to graduation - TA initiatives are considered important and to be continued	Gavi, UNICEF SD, several partners
Technical Assistance	UNICEF & WHO	<b>Vaccine Procurement Systems Assessments/Vaccine Security Missions</b> - Review of vaccine procurement systems, performance evaluation and identification of strengths and weaknesses - Orient countries on the changing vaccine market and support them in the development of accurate forecasting and timely and reliable funding	All countries	Limited to ad hoc missions, based on specific country request	- Provides recommendations for strengthening the vaccine procurement system	
TA, Financing, Analyses	World Bank	<b>Public procurement reform:</b> reviews the procurement legislative environment, institutional capacity, identifies bottlenecks and provides technical assistance in best practice examples.	All countries	- Not vaccine-specific - The Bank is not sector specific, so loans or grants to immunization would have to be linked to the broader country plan.		
TA, Training, Meeting	WHO (regions)	- TA on forecasting, harmonizing product/registration requirements and procurement legislation - Collaborating with UNICEF SD on procurement of vaccines for MICs - Capacity building on improving efficiency of procurement - Enhance capacity of MIC to procure vaccine through ICB (international competitive bidding) and local procurement - Idea of regional workshops (on procurement, vaccine security) being explored and developed	All countries	- Procurement rules and practices can prevent procurement options (e.g. national regulations conflicting with UNICEF's rules) - Technical support to non-Gavi MICs is limited - No dedicated funding or support mechanism for non-Gavi MICs for providing technical assistance	- Procurement through UNICEF needs to be further explored for some countries - Need more in-country TA - No workshop confirmed yet	UNICEF SD
Other	WHO (HQ)	Facilitate dialogue on supply availability	All countries	- Ad hoc-support, disease-specific - Challenges: Information and analyses on demand & supply forecasting are limited		



 Sufficient, to be continued	 Could be expanded/strengthened	 Requires modifications	 Not applicable, not enough information
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## Increasing access to revolving funds

Form of assistance	Org.	Activity name & Description	Countries covered	Challenges & limitations	Successes & development	Collaboration
TA	JHU IVAC	<b>Basket Fund</b> Documentation and technical support on basket funds in Lagos State	Nigeria: Lagos state	Very limited in scope	Looking to work more on an innovative financing mechanism in Asia.	
Technical and management assistance, Coordination, Procurement	PAHO RF	<b>PAHO Revolving Fund</b> - Established in 1979, the Revolving Fund (RF) offers a credit line to countries (60 days) - The RF acts as a line of credit, allowing governments to pay for vaccines after receipt of the order - Facilitate the use of local currency for the reimbursement of invoices (almost all countries already prepay or reimbursed the revolving fund in US\$) - RF working capital has grown significantly over the years through increased volumes of vaccine purchases and the compounding effect of a 3% service fee applied to each order - In 2014, the RF had a purchase value of \$575 M and a capital fund of \$130 million	PAHO countries	Limited to PAHO countries	- It is atypical to see countries with default payments - With today's capitalization level and projected purchases using the credit line, every participating country/territory has access to maximum US\$10 millions of credit - Most countries (36) place 100% of orders using the credit (revolving fund), and the rest use a mix (pre-payment and credit) - Currently, no extra capitalization is needed to cover expected purchases by credit in the next 2 years, at least	
Implementation, Financing, Tool development	UNICEF SD	<b>Vaccine Independence Initiative (VII)</b> - Revolving fund that acts as a line of credit, allowing governments to pay for vaccines after receipt of the order - Funds are used by UNICEF to purchase vaccines directly from the manufacturers. The revolving fund is then reimbursed when governments pay UNICEF for the vaccine order (generally 60-75 days following product delivery)	All countries with whom UNICEF has a programme of work may apply. Current use: 13 Pacific Island countries, Kenya, Niger, Cabo Verde, Chad, Lao PDR and Nigeria currently evaluating at the ministerial level. In 2014, quite a number of countries 'graduated' from use and are now procuring through standard procurement services	- Countries are often not aware that they can access this support - Need fundraising to raise capital base	- Particularly helpful to countries with issues with access to hard currency, cash flows and high vaccine prices due to high transportation costs and small demand. Has been used for countries to also service their co-financing requirements. - 1 default in 24 years which was subsequently remedied - In February 2015, UNICEF Executive Board has approved extension and expansion of allowable capital base from \$10 million to \$100 million, subject to available specific-contributions	

	Sufficient, to be continued		Could be expanded/strengthened		Requires modifications		Not applicable, not enough information
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## Harmonizing product choice & aligning registration processes

Form of assistance	Org.	Activity name & Description	Countries covered	Challenges & limitations	Successes & development	Collaboration
TA, Assessment	AMP, WHO	<b>NRA financial assessment</b> Project launched by WHO. Objectives: Estimate the costs of vaccine regulation for national medical authorities in target countries; Identify appropriate fee systems in the regulation of vaccines; Improve the financial sustainability of national medical authorities. Timeline: 2013 - 2017	China, India, Indonesia	Currently in 1 <sup>st</sup> phase of the project. Impact is unknown	Will potentially cover 16 developing and developed countries worldwide	WHO country offices, NRAs
Financing	WHO, IVI, Sabin, JHU, IVAC	<b>Dengue Vaccine Initiative (DVI)</b> - Key activities related to NRA include technical assistance, training, convening of NRAs (through the support of WHO, to endemic countries that expressed interest in evaluating and licensing the candidate dengue vaccines) - DVI was established to enable the policy environment and country readiness for accelerated introduction of dengue vaccines in endemic countries	Brazil, Thailand, Malaysia, Columbia, Mexico, Vietnam, Indonesia, Philippines	Limited to dengue		BMGF
TA, Training, Coordination, Guidelines	Global and Regional Regulatory Networks	<b>AVAREF and DCVRN</b> AVAREF: regional network of regulators and ethicists aimed at strengthening in-country capacity for the regulation of clinical trials including ethical approval. Focuses on development of procedures and protocols for the review of clinical trial applications and evaluation. Such procedures are aligned and adopted in all countries of the network. It also focuses on organizing joint reviews of clinical trial applications and eventually to review marketing authorization applications DCVRN: global network of MICs with fairly developed regulatory capacity. They collaborate among members to discuss concerns and difficulties faced for the evaluation of marketing authorization applications for novel vaccines (eg. Dengue). In collaboration with DVI, an international consultation will be organized for information sharing in the context of registration of dengue vaccines. DCVRN members are working on the development of points to consider documenting the rationale/ lack of rationale to require local clinical trials for the registration or evaluation of variations of imported vaccines. Such points to consider may be included as an annex in the revised version of the WHO clinical guidelines planned to be updated in 2015	- AVAREF: impacts at regional level in 20 countries - DCVRN impacts all countries	Requirements of local clinical trials is more a political issue than technical, the availability of points to consider will provide a framework on the rationale for such requirements but will not ensure the change in policy in individual countries Lack of funding for DCVRN	These initiatives represent effective mechanisms to facilitate the regulatory processes	WHO HQ, AFRO and NRAs
Training, Guidelines	WHO	<b>Global Learning Opportunities</b> - Course on regulatory framework for clinical trials - Course on non-clinical and quality evaluation of data for marketing authorization Based on the outcome of the regulatory framework surveys and the guidance document produced, a course for implementation of such guidance will be developed on regulatory framework for registration of medicines		Lack of funding	Could also address best procedural practices in registration	WHO, RO
TA, Coordination, Assessment	WHO	<b>Facilitating registration of IPV vaccines</b> Joint reviews were conducted in SEARO and AFRO using the collaborative procedure proposed by WHO for registration of prequalified vaccines under the leadership of the vaccines assessment group in PQT. In EMRO WHO/RSS offered to conduct a joint review of the CTD dossiers required by countries that follow a full review procedure for registration of vaccines independently of whether they are prequalified or not	Selected countries in AFR, SEAR and EMR	- Joint review of registration files necessary but not sufficient to ensure timely registration of vaccines - Additional disharmonized requirements and complicated procedures may impact actual timeframe for registration	- Joint reviews are a successful mechanism to provide technical support and increase capacity in countries - No information on need or possibility to strengthen/expand activity	WHO and NRAs


Sufficient, to be continued
  Could be expanded/strengthened
  Requires modifications
  Not applicable, not enough information

TA, Training, Coordination, Guidelines	WHO (HQ & AFRO)	<b>GMRH &amp; AMRH</b> Global Medicines Regulatory Harmonization (GMRH) initiative and the African Medicines Regulatory Harmonization Programme (AMRH): - Supports regional coordination and capacity building for medicines regulatory harmonization - Includes development of harmonized protocols for medicines registration, institutional development and strengthening of National Medicines Regulatory Authorities to improve medicine registration efficiency and transparency, and improve quality management systems	Countries in AFR	- Limited to AFR - Complicated area of work	Would increase access, availability and affordability -No information on need or possibility to strengthen/expand activity	BMGF, World Bank, Nepad, DFID, National Regulators
Research, Guidelines	WHO-(HQ)	<b>Facilitating regulatory pathways</b> - Internet search and survey on marketing authorization regulations in HIC, MIC and LMIC to assess requirements regarding registration of emergency vaccines (fast track provisions), requirements for local clinical trials for the registration/variation approvals of imported vaccines, provisions for acceptance of expedited registration procedure for prequalified imported vaccines - Work with manufacturers to assess constraints for registration and management of variations in countries using their vaccines Outcome of this work will support the development of guidance documents on model regulatory frameworks that would include provisions for reliance on other NRAs, for rapid registration of emergency products, reliance on WHO in the case of prequalified vaccines, etc.	HICs, MICs, LMICs	Will not provide information on actual administrative procedures followed in countries	- Seek understanding of major bottlenecks and differences between countries to devise interventions - No information on need or possibility to strengthen/expand activity	WHO, NRAs, RO and manufacturers
Guidelines Training	WHO (HQ)	<b>Norms and standards</b> - Development and establishment (through the ECBS) of global technical specifications on the quality, safety and efficacy of vaccines - Development and establishment (through the ECBS) of global reference preparations to support regional or national standards activities - Implementation workshops to help align regulatory requirements and to help build capacity of both NRAs and manufacturers	All countries	Insufficient resources to meet demands	WHO standards used by NRAs and used to define technical basis of PQ process. The greater the implementation, the greater the alignment of regulatory requirements	NRAs
Coordination, Guidelines	WHO (HQ)	<b>Vaccine Prequalification</b> - Review of general production process and quality control procedures, testing of consistency of lots, site auditing, and reliance on the NRA responsible for the regulatory oversight of the vaccine - Uses vaccine safety and efficacy data relevant to the target population - Vaccines meet specific programmatic needs, reflected by tender specifications: i.e. VVM type, presentation, labelling, packaging, etc.	All countries	Complicated process that can deter manufacturers to prequalify their products	- Ensures vaccines used in programmes are safe and effective - List of PQ vaccines available online	NRAs
TA, Training, Planning, Monitoring, Fundraising, Guidelines	WHO	<b>NRA strengthening</b> - NRA planning workshops - Plan and conduct in-country assessment to develop Institutional Development Plans (IDP), monitor progress - For manufacturing countries: plan and develop road map for vaccine prequalification - Organize trainings by or twinning with well-resourced and functional NRAs with least developed NRAs - Help graduating countries strengthen their NRAs, potentially in preparation for self-procurement or domestic production (Gavi-graduating countries only) - Provide standard methodology and tools - Develop document on Good Regulatory Practices to be later endorsed by ECBS and ECPP	All countries	- Need additional funding and resources at national level - Countries need more technical support	Currently there are 36/43 (84%) functional NRAs in producing countries	Gavi, BMGF, USAID

 Sufficient, to be continued	 Could be expanded/strengthened	 Requires modifications	 Not applicable, not enough information
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## Increasing access to price information

Form of assistance	Org.	Activity name & Description	Countries covered	Challenges & limitations	Successes & development	Collaboration
Technical and management assistance	CHAI	Negotiation support with manufacturers of cold chain equipment and access to price information for antigens and cold chain equipment	MICs: Nigeria, Cameroon, Vietnam, India	- Limited to 4 Gavi-MICs - Challenges: lack of publicly available information; need for more price data per manufacturer and per presentation	<i>No information on need or possibility to strengthen/expand activity</i>	
Advocacy	MSF	<b>The Right Shot &amp; Advocacy work</b> - Advocacy for price transparency - Providing basic understanding of pricing strategies and detailed information about vaccine product information and prices - Also promoting availability of vaccine price information via marketing & communication (press releases, crowdsourcing, etc.)	All countries, especially MICs	Challenges: Price information is hard to find, making data-comparability difficult ; the vaccine market lacks transparency	2 <sup>nd</sup> edition published in 2015	
Procurement, Communication	PAHO RF	<b>Vaccine prices</b> Publication of vaccine prices	PAHO countries	- Price information limited to PAHO developing countries - No volume disclosed - WAP, not real price per manufacturer	- Participation in V3P - Recognized as a contributor to price transparency - Often used as reference prices	
Procurement, Communication	UNICEF SD	<b>Vaccine prices</b> Publication of vaccines pricing - UNICEF SD publishes both contract awards and vaccine prices.	All countries, especially Gavi-countries	- Price information mainly limited to Gavi countries - Volumes by manufacturers not disclosed	- Participation in V3P - Recognized as an important contributor to price transparency - Often used as reference prices	
Tool development, Advocacy, Training, Data collection & dissemination	WHO	<b>V3P: Vaccine Price Product and Procurement</b> - Providing an online and publicly accessible database of vaccine price information, as well as product, price, and procurement information through an information repository and resource gateway - Price information shared by countries through the online platform or through the JRF - Advocacy through WHO regions and through Gavi graduation assessment missions and plans	All countries, especially MICs	- Limited participation from countries - Complexity of vaccine prices limit quantitative analyses	- 26 countries submitted price info in 2014 - Example of impact: Georgia has successfully used info for price negotiation - New GVAP indicator added: number of countries reporting prices per region as well as a price indicator	BMGF, UNICEF, PAHO, WHO EURO


 Sufficient, to be continued	 Could be expanded/strengthened	 Requires modifications	 Not applicable, not enough information
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## Strengthening pooled procurement options

Form of assistance	Org.	Activity name & Description	Countries covered	Challenges & limitations	Successes & development	Collaboration
Procurement, Coordination	PAHO RF	<b>PAHO Revolving Fund</b> - Pooled procurement of vaccines and immunization supplies - Provide countries with: continuous supply, quality products, affordable prices	PAHO countries	Limited to PAHO countries	Successful regional pooled procurement mechanism.	Individual AMR country governments
Procurement, Implementation	UNICEF SD	<b>MICs New Vaccine Tender</b> - Issued in Dec 2012. For PCV, Rota and HPV for delivery during the period 2013-2015. - Purpose: accelerate introduction of new vaccines in MICs, expand market of priority new vaccines, and establish reference prices.	All MICs	- Lack of commitment/credible demand from countries - Low participation from manufacturers - Manufacturers ask for non-disclosure of prices	- A handful of countries have or are in the process of introducing PCV, Rota and HPV as a result of the tender [Philippines (PCV, Rota), Albania (PCV), Palestine (PCV), Cook Islands (HPV)] - UNICEF SD is re-evaluating the mechanism	Individual country governments
Procurement	UNICEF SD	<b>UNICEF Procurement Services</b> - Aggregating multi-year demand forecasts and pooling procurement of vaccines + devices on behalf of individual countries, development partners and global initiatives. - Handling fees are charged in order to defray the incremental direct and indirect costs that UNICEF incurs by providing services	All countries  Gavi-countries (for Gavi-supported vaccines), plus ~20 non-Gavi MICs (mainly for basic/traditional vaccines + devices)	Need communication and procurement TA to countries, maybe through partners (e.g. understand requirements for pooled procurement)	- Offers the world lowest vaccine prices to Gavi-countries - Favourable prices for other countries for basic/traditional vaccines + devices	Gavi, GPEI, MRI, Individual country governments, NGOs
Procurement, Advocacy, Coordination, Guidelines, Training	WHO EMRO	<b>PVP</b> - Approved in 2011 and launched in 2008. - Exploring the idea of a pooled procurement mechanism for countries of the EMR. - First stage: encourage countries to procure through UNICEF SD. This phase is on progress. - 2nd stage: countries to join the PVP mechanism, managed by EMRO. MoU have been sent to countries.	All countries of the region, especially MICs	Limited country commitment. The RO is waiting for stronger commitment from countries to move forward.	- The following countries have been procuring through UNICEF SD: Morocco, Lebanon. Egypt, Syria and Iraq have been also utilizing services of UNICEF SD on ad hoc basis. - The following countries have signed MoUs to participate in PVP: Lebanon and Iraq - Initiatives and ideas to help countries move forward could be explored	UNICEF SD, UNICEF MENARO PAHO, CDC, WHO HQ Individual EMR country governments

## Influencing market dynamics

Form of assistance	Org.	Activity name & Description	Countries covered	Challenges & limitations	Successes & development	Collaboration
Financing, Other	BMGF	BMGF actively engages in a number of initiatives working with several MIC manufacturers to support product development, product affordability, supply security and product PQ	MICs with domestic supply (eg. India, China, Indonesia, Brazil) and MICs where products are licensed or recommended		All countries benefit from entry of new products and manufacturers	Gavi
Technical and management assistance	CHAI	<ul style="list-style-type: none"> <li>- Support developing country manufacturers enter or expand their presence in Gavi markets</li> <li>- Price negotiations with manufacturers</li> <li>- Support company's capacity for navigating PQ process</li> </ul>	Gavi-countries	<ul style="list-style-type: none"> <li>- Limited to Gavi countries</li> <li>- Challenges: developing country manufacturers not close to PCV production (&gt; 5 years away) ; processes are long and impact of TA on timeline is limited</li> </ul>	<ul style="list-style-type: none"> <li>- CHAI could play a role in non-Gavi MICs</li> <li>- CHAI could provide more TA to manufacturers for WHO PQ process.</li> <li>- With the support of partners, CHAI has generated over US\$1 billion in savings via negotiating lower vaccine prices for developing countries.</li> </ul>	Gavi, several partners
Technical and management assistance, Financing, Advocacy	Gavi	<b>Supply &amp; procurement strategy</b> <ul style="list-style-type: none"> <li>- Engagement with manufacturers to advocate for expansion of capacity and new product development</li> <li>- Use of market shaping instruments: e.g. volume guarantees; prepayments</li> </ul>	Gavi-countries	Creation of competitive markets is highly dependent on R&D success and long-term manufacturer commitment to vaccine development. It will not provide immediate relief	Market shaping role of Gavi may benefit MICs (creating healthy vaccine markets with competition which drives down prices)	UNICEF SD, BMGF, WHO
Advocacy, Procurement, Financing	Gavi	<b>ATAP: Access to Appropriate Prices</b> <ul style="list-style-type: none"> <li>- Explore ideas and implement actions to provide access to appropriate prices in countries graduated from Gavi support (e.g., tendering mechanism; payment mechanism)</li> <li>- Seek commitments from manufacturers to continue providing access to the Gavi price to graduated countries for a set period of time</li> <li>- Explore the possibility to extend actions to non-Gavi LMICs</li> </ul>	Gavi-graduated countries	<ul style="list-style-type: none"> <li>- Focused on Gavi-graduated countries</li> <li>- Focused on near and mid-term (although can lay a foundation for long-term)</li> <li>- Incomplete participation of manufacturers on price commitments (in terms of time and vaccines covered), and potential requirement to procure through PAHO or UNICEF</li> </ul>	<ul style="list-style-type: none"> <li>- Currently being drafted and discussed</li> <li>- Could include non-Gavi LMICs</li> </ul>	UNICEF SD and other partners
Meetings, Analysis	Harvard Global Health Institute	<b>Pricing policies &amp; strategies</b> <ul style="list-style-type: none"> <li>- Research, analysis, and convening around options, policies and approaches to pricing in MICs</li> <li>- Convened two workshops of stakeholders in March and July 2014 to discuss this topic</li> <li>- Following the July workshop, it was decided to create a Working Group (WG) to focus the discussion on more technical aspects of the pricing debate, and this work is ongoing</li> <li>- Pending satisfactory progress by this WG, third workshop of stakeholders may be convened in the first half of 2015</li> </ul>	All MICs	<ul style="list-style-type: none"> <li>- No publicly available information on this work</li> <li>- Need to increase awareness of product options, prices paid in other countries, and conditions linked to various prices.</li> <li>- Need further research and analysis to understand components of vaccine prices</li> </ul>		Several partners
Funding	USAID	<b>Research</b> <ul style="list-style-type: none"> <li>- Support to vaccine research development projects on malaria and HIV (IAVI)</li> </ul>	All countries		USAID has supported malaria vaccine research for 20 years, contributing to successfully moving vaccines from the lab into field trials	IAVI, several partners
Advocacy, TA, Training,	WHO	<b>Local production</b> <ul style="list-style-type: none"> <li>- HQ: supporting technology transfer for 13 countries for influenza</li> </ul>	HQ: 13 countries EMRO: Egypt, Iran,		<i>No information on need or possibility to strengthen/expand activity</i>	

 Sufficient, to be continued	 Could be expanded/strengthened	 Requires modifications	 Not applicable, not enough information
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Monitoring		vaccine - EMRO: supporting Iran and Egypt for improving production capacity; supporting technology transfer for Egypt and Iran for influenza vaccine & IPV	Pakistan, Tunisia, Morocco			
Guidelines, Coordination	WHO (HQ)	<b>Product development</b> - WHO Preferred Product Characteristics (PPC) - Includes activities such as: collaboration, standards & guidelines, promotion of vaccine R&D (eg. MenA, VIMT on Malaria) - No direct involvement in tech transfer, except through initiatives with other partners, like PATH (eg. MenA) or for influenza - Works to strengthen NRAs, including in producing countries	LICs & MICs	Need to strengthen NRAs		
TA, Research	WHO (HQ)	<b>Research Agenda</b> - Strengthen country capacity to carry out implementation research - Monitor and map implementation research activities - Provide a platform for researchers to share results	All countries			
Policy analyses, TA, Financing	World Bank Group	- Analyses of financing and procurement of commodities and vaccines during provider payment and more broadly health financing reforms, in particular, the transition from supply to demand financing (e.g. introduction of health insurance) within often highly fragmented health systems - International Finance Corporation (IFC)	- Case study countries to be selected - IFC: China, India, Brazil	- Not limited to vaccines - IFC pharma portfolio does not yet include vaccines, but does include APIs and finished generic formulations, as well as an investment fund	Assessment available in Q3/2015	Gavi



#### Annex IV: Detailed list of proposed activities of MIC Strategy

Strengthened decision making for timely and evidence-based immunization policy & programmatic choices		Increased political commitment & financial sustainability of immunization programmes		Enhanced demand for & equitable delivery of immunization services		Improved access to affordable and timely supply	
<i>Continue existing efforts</i>						<i>Increasing access to RF &amp; strengthening pooled procurement options</i> <ul style="list-style-type: none"> <li>Continuing activities of the PAHO revolving fund for the American region</li> <li>Continuing to conduct single country tenders at the request of countries</li> </ul>	PAHO RF
						<i>Increasing price Information</i> <ul style="list-style-type: none"> <li>Continuing sharing of price information through pooled procurement mechanisms</li> <li>Continuing data collection and dissemination through the V3P</li> <li>Continuing advocacy work for greater price transparency</li> </ul>	WHO, PAHO RF, UNICEF, MSF
<i>Increase scope of existing efforts</i>				<i>Strengthening in country supply chain &amp; data systems</i> <ul style="list-style-type: none"> <li>Promoting the use of the comprehensive EVM strategy and building capacity</li> <li>Optimizing supply chain systems through the use of private sector engagement and innovative partnerships</li> <li>Creating a peer learning platform on national immunization data</li> <li>Providing targeted support that focuses on the introduction of e-registries and other data challenges identified (harmonization, urban immunization, private sector engagement...)</li> </ul>	WHO, SABIN	<i>Increasing access to RF</i> <ul style="list-style-type: none"> <li>Expanding the capital base of Vaccine Independent Initiative (VII) through 2020</li> <li>Increasing country subscription to VII through proactive outreach</li> <li>Increasing access of countries to commercial markets bank guarantees</li> </ul>	UNICEF, WHO
		<ul style="list-style-type: none"> <li>Establishing &amp; strengthening NITAGs, including through the development of an international network of NITAGs</li> <li>Strengthening national capacity to generate evidence for decision-making including through provision of limited operational funding to countries</li> </ul>	WHO, SABIN, AMP	<ul style="list-style-type: none"> <li>Strengthening legislative basis for immunization</li> <li>Advocating for immunization to achieve set immunization spending targets (to be developed)</li> <li>Targeted advocacy and technical assistance for resource mobilization and increased efficiency in resource use</li> </ul>	WHO, SABIN	<i>Harmonizing product choice &amp; registration processes</i> <ul style="list-style-type: none"> <li>Developing and establishing WHO norms and standards</li> <li>Facilitating alignment of registration requirements and simplification of registration procedures, including through the use of 'facilitated/expedited process' for prequalified vaccines</li> <li>Facilitating registration of PQ vaccines through collaborative agreements with NRAs</li> </ul>	WHO

*New  
proposed  
efforts*

*Addressing vaccine hesitancy &  
building community demand  
through:*

- Creating a network of centres of excellence to build the necessary expertise for country support
- Developing and strengthening tools addressing vaccine hesitancy
- Evaluating and tailoring the TIP framework to middle income settings

WHO,  
AMP

*Increasing procurement skills and knowledge*

- Supporting south-to-south vaccine procurement learning through an annual Exchange Forum , regional workshop, and a vaccine Procurement Network
- Providing in-country technical assistance on procurement, including through the establishment of a pool of vaccine procurement experts
- Developing vaccine procurement guidelines & advocating for public procurement reform
- Strengthening demand-supply information exchange through current initiatives

UNICEF,  
WHO,  
and WB  
(TBD)

*Strengthening pooled procurement options*

- Synthesizing lessons learnt from ongoing efforts (UNICEF MICs tender, PAHO RF, EMRO PVP)
- Piloting a new tendering approach focusing on country demand consolidation possibly at regional level

*Influencing Market Dynamics*

- Encouraging the use of access agreements to the benefit of non-Gavi MICs including through the Gavi ATAP initiative
- Influence market dynamics through UNICEF and PAHO RF tendering processes

## Annex V: Acronyms

AMP.....	Agence de Médecine Préventive
AMRO.....	WHO Regional Office for the Americas
ATAP.....	Access to appropriate prices
BCG vaccine.....	Bacillus Calmette-Guerin vaccine (tuberculosis)
BID.....	Better Immunization Data
BMGF.....	Bill & Melinda Gates Foundation
CHAI.....	Clinton Health Access Initiative
CHERG.....	Child Health Epidemiology Reference Group
CSO.....	Civil society organization
DCVMN.....	Developing Countries Vaccine Manufacturers Network
DTP3 vaccine.....	Diphtheria-Tetanus-Pertussis vaccine
EMRO.....	WHO Regional Office for the Eastern Mediterranean
EURO.....	WHO Regional Office for Europe
EVM.....	Effective Vaccine Management
GGE.....	General government expenditure
GVAP.....	Global Vaccine Action Plan
HPV.....	Human papillomavirus vaccine
HVAC.....	Heating, ventilation, air-conditioning
IARC.....	International Agency for Research on Cancer
IDS.....	International Debt Statistics
IFPMA.....	International Federation of Pharmaceutical Manufacturers & Associations
IPV.....	Inactivated poliovirus vaccine
IVAC.....	Johns Hopkins University International Vaccine Access Center
JRF.....	WHO/UNICEF Joint Reporting Form
LICs.....	Low income countries
LMICs.....	Lower middle income countries
OPV.....	Oral poliovirus vaccine
MCV1.....	Measles-containing vaccine
MICs.....	Middle income countries
MR vaccine.....	Measles-Rubella vaccine
MSF.....	Médecins Sans Frontières
NICE International.....	National Institute for Health and Care Excellence International
NITAG.....	National Immunization Technical Advisory Group
NRA.....	National Regulatory Authority

NUVI .....	New and Under-utilized Vaccines Implementation
PCV .....	Pneumococcal conjugate vaccine
PAHO .....	Pan American Health Organization
PQ.....	WHO pre-qualified product
RF .....	Revolving fund
SAGE.....	Strategic Advisory Group of Experts on Immunization
SEARO.....	WHO Regional Office for South-East Asia
TA .....	Technical assistance
TFGH.....	Task Force for Global Health
TIP .....	Tailoring Immunization Programme
UNICEF PD .....	United Nations International Children’s Fund, Programme Division
UNICEF SD .....	United Nations International Children’s Fund, Supply Division
USAID .....	United States Agency for International Development
V3P Project.....	Vaccine Product, Price and Procurement Project
VII .....	Vaccine Independence Initiative
VPD.....	Vaccine-preventable death
WHA .....	World Health Assembly
WHO.....	World Health Organization
WPRO .....	WHO Regional Office for the Western Pacific
WUENIC.....	WHO/UNICEF Estimates of National Immunization Coverage