

Introduction and value proposition

There has been increasing recognition of vaccine-access challenges in middle-income countries (MICs) and the need for increased action, particularly in countries that are not eligible for or have transitioned out of Gavi support. This is driven by the fact that MICs account for 69% of zero-dose children¹ and 67% of vaccine-preventable deaths. Gavi-transitioned or non-Gavi-eligible MICs account for 22% of the total zero-dose children and 14% of the total vaccine-preventable deaths^{i,ii}.

Over the past decade, MICs have demonstrated strong ownership and national commitment to their immunization programmes, resulting in meaningful progressⁱⁱⁱ. However, partner support to non-Gavi-eligible and Gavi-transitioned MICs has been limited. Continued country leadership backed by increased, coordinated partner support to the full breadth of MICs will help accelerate progress and ensure country and global immunization objectives are achieved.

Middle-income countries (MICs) include both lower middle- and upper middle-income countries. For the 2021 fiscal year, the World Bank defines lower middle-income countries (LMICs) as economies with a gross national income (GNI) per capita, calculated using the World Bank Atlas method, of between US\$1,036 and US\$4,045 and upper middle-income countries (UMICs) as those with a GNI per capita of between US\$4,046 and US\$12,535.

There are 50 LMICs and 56 UMICs. Of these countries, 17 are Gavi-transitioned and 28 are still Gavi-eligible. The remaining 61 countries are non-Gavi-eligible.

Source: World Bank, 2020.

1. Zero-dose children defined as number of surviving infants not receiving DTP1

The next decade (2021–2030) will bring additional challenges to immunization programmes in MICs. In many MICs, coverage rates are backsliding, new vaccine introductions are lagging behind, domestic vaccine financing is growing slowly, and significant inequities in service delivery remainⁱⁱⁱ. By 2030, 35 countries, representing 42% of the global birth cohort, will have transitioned from Gavi support, greatly increasing their domestic vaccine financing requirements². Further, new regional epidemics and global pandemics, such as those of Ebola, measles and COVID-19, threaten to overwhelm immunization infrastructure and exacerbate existing challenges.

The potential health impact of improving immunization outcomes in Gavi-transitioned and non-Gavi-eligible MICs is substantial. Modelling suggests that the introduction of pneumococcal conjugate vaccine (PCV) and vaccines for rotavirus and human papillomavirus (HPV) in Gavi-transitioned and non-Gavi-eligible MICs in 2020 could have saved an estimated 70,000 lives if 90% coverage had been reached, and increasing coverage for existing vaccines to 90% could have saved another estimated 16,000 lives³.

The World Health Assembly (WHA)^{iv} and the WHO Strategic Advisory Group of Experts on Immunization (SAGE)^{v vi} have called upon the WHO Secretariat and the international community to investigate obstacles and mobilize resources to support sustainable access to vaccines in MICs. Considerable efforts by immunization stakeholders at all levels have gone into identifying challenges and mapping existing support to MICs, as documented in the 2015 SAGE-endorsed Shared Partner MIC Strategy^{vii}.

Following those efforts, initial steps have been taken to address MIC vaccine-access challenges. WHO regions have developed MIC-specific strategies and platforms to facilitate cross-country collaboration backed by meaningful domestic political support^{viii}. Meanwhile, countries have signed up for ambitious agendas such as cervical cancer elimination. And donors have expressed interest in supporting Gavi-transitioned and non-Gavi-eligible MICs, as demonstrated in the Gavi 5.0 MICs strategy which allocated US\$281 million for the 2021–2025 period to support such countries.

While the COVID-19 pandemic has presented immense challenges to countries' health systems, it has also reinforced domestic and international interest in supporting immunization by demonstrating the linkages between robust health systems and economic security. In addition, it may be possible to leverage mechanisms such as the COVAX Facility^{ix}, which is designed to ensure access to COVID-19 vaccines in all interested countries, to address other MIC immunization challenges once the pandemic has subsided.

2. Based on Gavi 4.0 eligibility rules as of 2020

3. See Annex 1 for details of 2020 vaccine-preventable disease modelling in MICs

Through the IA2030 priority-setting process, countries, international organizations and industry have all identified vaccine access in MICs as a critical issue. If the global IA2030 targets are to be reached, MICs must not be left behind and forgotten. The heterogeneity of contexts and challenges in MICs makes it difficult to develop a single approach, and most actions identified in the IA2030 Strategic Priorities should be applied as appropriate in each country context. However, given the breadth of challenges, actions with the highest impacts should be prioritized. Based on the outcomes of comprehensive, multi-year consultations with countries, regions, industry and partners, this strategic document identifies the areas where additional action has the greatest potential to significantly improve access to vaccines over the next decade in MICs.

Strategic Priority Goal and Objectives

Goal

MIC immunization programmes are adequately supported by countries and partners, resulting in the acceleration of new vaccine introductions, reduction of inequities in service delivery and coverage, and improved programme sustainability.

Objectives

- Increase the number of MICs that have successfully introduced two or more of PCV, HPV, rotavirus and COVID-19 vaccines and ensure no countries drop newly introduced vaccines from their schedules
- Stabilize high coverage rates in countries already or at risk of backsliding and reduce significant coverage inequities
- Increase financial and technical resources made available to MICs and ensure that new support is well coordinated with existing regional and global efforts

Context and challenges

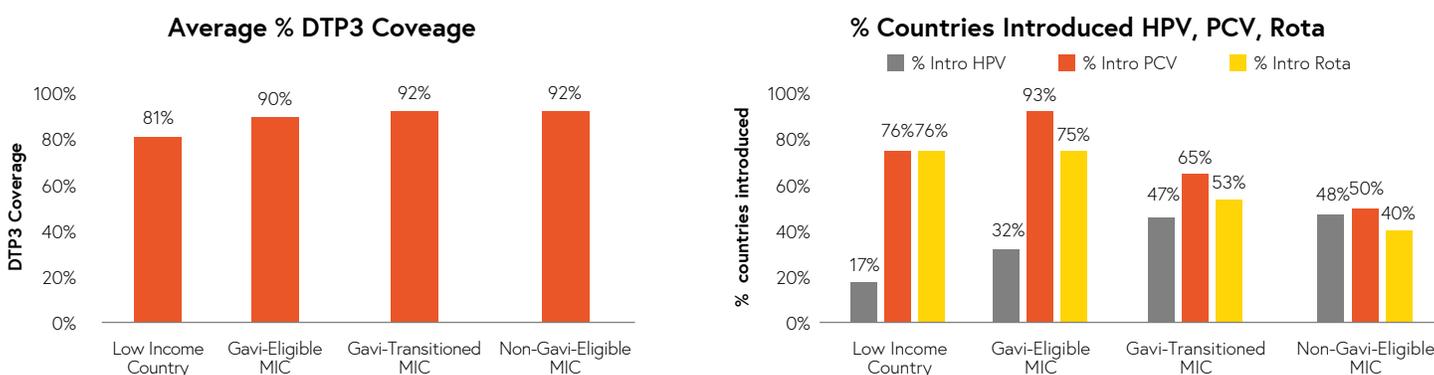
Current State of Immunization in MICs

While the 45 Gavi-eligible and Gavi-transitioned MICs have a greater share of the MIC vaccine-preventable disease burden than non-Gavi-eligible MICs (79% versus 21%)ⁱ, they already benefit from donor and partner support to reach the IA2030 goals. In contrast, the remaining 61 non-Gavi-eligible MICs historically have not received significant funding or internationally coordinated strategic support. Globally, non-Gavi-eligible MICs account for 20% of pneumococcal pneumonia cases, 10% of associated mortality and 13% of disability-adjusted life years (DALYs) lost to pneumonia. These countries also account for 28–32% of global cervical cancer mortality and morbidity. About 2.6 million children in these countries do not receive all three doses of DTP, almost 32 million do not receive three doses of PCV, and 2.4 million are not vaccinated against measlesⁱⁱ. In addition, adult immunization programmes are nearly non-existent in these countries.

MICs are heterogeneous and no one approach will work for all MICs. Strategies need to be tailored to each country. For example, in the Region of the Americas, where many countries have already introduced two out of the three PCV, HPV and rotavirus vaccines, improving the affordability of vaccines to sustain introductions may be a higher priority than introducing new vaccines. Coordinating new support through regional mechanisms will help to ensure that activities are tailored and country priorities are being supported.

Relative to their Gavi-supported counterparts, non-Gavi-eligible MICs have significantly lower rates of introduction of PCV and rotavirus vaccines, despite having higher incomes and greater DTP3 coverage (Figure 1). Once global HPV supply becomes less constrained, Gavi countries are expected to surpass non-Gavi-eligible countries in HPV introductions as well. Approximately 29 million children living in non-Gavi-eligible MICs do not have access to at least two of the three HPV, PCV or rotavirus vaccines.

Figure 1. Immunization outcomes by MIC segment



	Low Income Country	Gavi-Eligible MIC	Gavi-Transitioned MIC	Non-Gavi-Eligible MIC
# Countries	29	28	17	58
% Global Birth Cohort	16%	38%	7%	30%

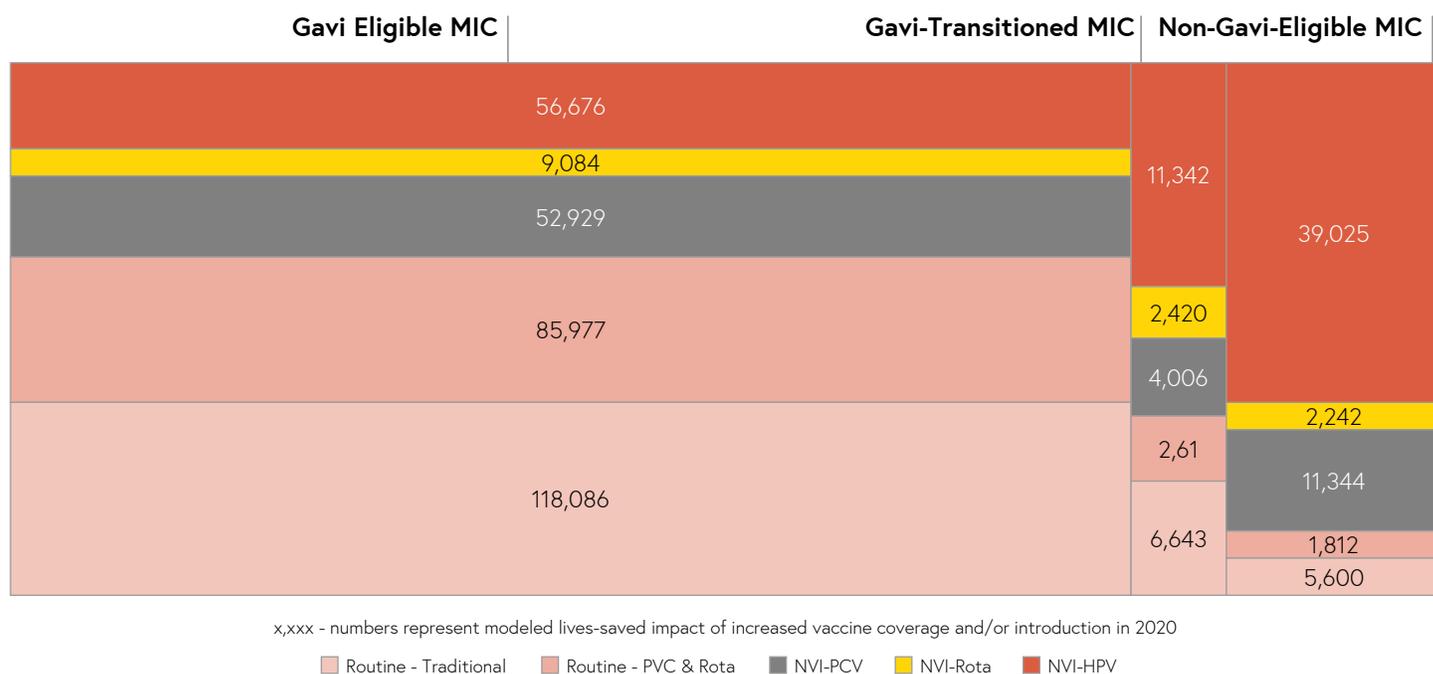
DTP3 coverage based on 2019 WUENIC estimates; universal country introduction based on 2020 IVAC ViewHub; income categories based on 2020 World Bank definitions.

Modelling suggests that the introduction of PCV, HPV and rotavirus vaccines in non-Gavi-eligible and Gavi-transitioned MICs in 2020 could have saved 70,000 lives if 90% coverage had been reached (Figure 2), with 70% of these averted deaths attributable to HPV vaccination⁴. A significant proportion of the lives that could be saved by new vaccine introductions are concentrated in a small number of high-population countries (Table 1). For example, new vaccine introductions in China (HPV, PCV, rotavirus), Indonesia (HPV, rotavirus), Philippines (HPV, PCV, rotavirus) and Egypt (HPV, PCV, rotavirus) could have saved an estimated 47,000 deaths, representing 67% of lives that could have been saved by introductions in this set of MICs.

4. Impact of HPV immunization accounts for future averted deaths in adulthood due to immunization in 2020

Increasing coverage for vaccines already being delivered is also critical. For traditional vaccines protecting against diphtheria, tetanus, pertussis, measles, *Haemophilus influenzae* type b (Hib), and hepatitis B, increasing coverage to 90% in 2020 could have saved an estimated 12,000 lives in non-Gavi-eligible and Gavi-transitioned MICs. While increasing coverage of PCV and rotavirus vaccines in countries having already introduced them could have saved another 4,000 lives⁵.

Figure 2. Estimated numbers of lives saved by vaccine introductions and increased coverage in MICs



'Routine': impact of increasing coverage to 90% in countries having already introduced these vaccines; 'NVI': impact of introducing and reaching 90% coverage in countries where the vaccine has not been introduced nationwide. 'Traditional' vaccines include those protecting against diphtheria, tetanus, pertussis and measles, *Haemophilus influenzae* type b (Hib), and hepatitis B. See Annex 1 for details of modelling.

There is a need to reach more zero-dose children to ensure that every child receives the necessary vaccinations throughout their life. As of 2019, MICs have the largest zero-dose child population (9.5 million, 69%). Approximately 2.9 million of these children live in Gavi-transitioned or non-Gavi-eligible MICs, accounting for 21% of the zero-dose child population. Furthermore, in 32 of the 63 countries classified as middle-income in both 2000 and 2019, the population of zero-dose children grew. In 2019, Over half of zero-dose children (8.9 million, 64%) lived in 10 countries: Angola, Brazil, Democratic Republic of the Congo (DRC), Ethiopia, India, Indonesia, Mexico, Nigeria, Pakistan and the Philippines. As of 2020, Angola and Indonesia have transitioned out of Gavi support, while India and Nigeria are transitioning. Brazil, Mexico and the Philippines have never been Gavi-eligible.

5. See Annex 1 for details of vaccine-preventable disease modelling

Table 1: Top opportunities for new vaccine introductions and coverage impacts in non-Gavi-eligible or Gavi-transitioned MICs.

Country	Potential number of lives saved by new vaccine introductions in 2020	Missing introductions
China	33,885	PCV, HPV, rotavirus
Indonesia	8,361	HPV, rotavirus
Philippines	4,948	PCV, HPV, rotavirus
Egypt	3,878	PCV, HPV, rotavirus
Russian Federation	3,423	HPV, rotavirus
Other (73 countries)	12,815	--

Country	Potential number of lives saved by increased coverage in 2020
Angola	5,342
Indonesia	3,245
China	2,352
Philippines	1,232
South Africa	1,176
Other (73 countries)	2,969

Limited political will, inadequate domestic financing, and unaffordable vaccine prices are major barriers limiting both new vaccine introductions and immunization coverage. Non-Gavi-eligible MICs are particularly vulnerable to these challenges as they must rely primarily on domestic resources for vaccine procurement and delivery. On average, procurement of HPV and PCV vaccines accounts for 22% and 34%, respectively, of non-Gavi-eligible MICs' vaccine budgets. In some countries, the cost of either vaccine might be as much as 70% of total vaccine spending^x. These high procurement costs prevent countries from introducing vaccines, or constrain funding available for service delivery improvements. Access to affordable pricing in MICs is often limited by a variety of challenges such as poor access to and use of market intelligence, low vaccine product flexibility and acceptance, and inefficient product regulatory and procurement processes.

Limited access to global support during the COVID-19 pandemic threatens the abilities of MICs to introduce a COVID-19 vaccine and to resume regular vaccination activities, such as other new vaccine introductions and service delivery improvements. Mechanisms such as the COVAX Facility and COVAX Advanced Market Commitment (AMC) have been set up to provide support for the introduction, procurement and delivery of a COVID-19 vaccine. However, further fiscal and technical assistance will be required to help vulnerable immunization programmes. WHO and UNICEF estimate that, during 2021-2023, US\$655 million is needed in Gavi-transitioned or non-Gavi-eligible MICs to address polio and measles immunization gaps caused by COVID-19-related disruption^{xi}.

The international COVID-19 pandemic response will expand partner support to MICs and also has the potential to lay the foundation for long-term support beyond COVID-19. Through the COVAX AMC, 22 non-Gavi-eligible MICs will be eligible to receive COVID-19 support. In addition, other self-financing MICs will participate in global mechanisms such as UNICEF procurement, or use WHO prequalification in an expanded way to facilitate registration. Many MICs will be engaging partners in a meaningful way for the first time and the following approaches should be considered to ensure that, where feasible, COVID-19 vaccine preparedness and delivery support is leveraged to facilitate future non-COVID-19 vaccine introductions:

- Familiarize country decision-makers with global partner mechanisms and support long-term alignment between country and international processes (e.g. helping countries meet UNICEF vaccine procurement requirements or streamline regulatory processes).
- Identify the best tools, establish evidence-based decision-making processes, and improve data-sharing practices that can be leveraged to strengthen immunization systems.
- Strengthen the role of regional mechanisms to increase intra- and inter-region information sharing and cooperation (e.g. joint decision-making, regulatory review).

Current MIC Initiatives

Efforts to achieve IA2030 objectives in MICs should be designed to respond to the diverse needs of MICs and leverage existing interventions established at the regional and country levels. A number of WHO countries and regions have already developed MIC-focused strategies. These platforms not only provide valuable cross-country collaboration and information-sharing opportunities but also help to mobilize domestic support. Where beneficial, countries, regions and partners should work to complement existing or planned initiatives. Examples of regional initiatives include:

- In the **Region of the Americas**, the ProVac Initiative aims to improve evidence-based decision-making for vaccination, while the Caribbean Regulatory System has been established to support regulatory harmonization across countries.
- In the **African Region**, efforts have been made to establish multiple sub-regional pooled procurement mechanisms (e.g. for Small Island Developing States, Southern African Development Community), while the African Vaccine Regulatory Forum (AVAREF) strengthens regulatory capacity and improves cross-country regulatory coordination in Africa^{viii}.
- In the **European Region**, efforts have been made to build political will (e.g. Southern Eastern European Health Network Ministers' commitment to a regional MICs Strategy on Immunization^{xiii}) and to strengthen evidence-based decision-making.

- In the **South-East Asian Region**, the Association of South-East Asian Nations (ASEAN) Vaccine Security and Self-Reliance working group was established to promote regional vaccine security, build vaccine confidence, share best practices, and to develop, implement and monitor strategic immunization plans.
- In the **Western Pacific Region**, processes have been put in place to expedite regulatory approval for products with WHO prequalification and stringent regulatory approval.
- In the **Eastern Mediterranean Region**, efforts have been made to harmonize regulatory processes (e.g. via self-assessment workshops for national regulatory authorities in Egypt, Jordan, Lebanon and Saudi Arabia).

Global initiatives: At the global level, several initiatives actively support MICs. Examples include the Vaccine Independence Initiative (VII), Market Information for Access to Vaccines (MI4A), the Learning Network for Countries in Transition (LNCT), the Vaccine Procurement Practitioners Network (VPPN), and preparation of a MICs Financing Facility. Partners also provide support to countries for strengthening of National Immunization Technical Advisory Groups (NITAGs), policy guidance and procurement. Although these activities have increased national capacities, overall funding and coordination of country support is limited. IA2030 and Gavi 5.0 (see below) provide an important opportunity to enhance these regional and global efforts in a more coherent and better-funded approach.

Gavi 5.0 support for MICs: Gavi and partners have drafted a comprehensive approach to support MICs. Initial support from Gavi will focus on preventing backsliding in Gavi-transitioned countries, as well as leveraging the COVAX AMC to build relationships with select non-Gavi-eligible MICs and provide a platform for future new vaccine introductions. A more comprehensive MICs approach will gradually be rolled out and include a MICS Financing Facility to help countries procure vaccines at sustainable prices. Through this approach, Gavi and UNICEF will provide significant procurement experience, but additional technical support is needed to ensure countries successfully implement the new vaccine introduction.

Key Areas of Focus

Given the breadth of challenges in MICs, country and partner efforts should focus on specific IA2030 Strategic Priorities most likely to drive impact: **SP2: Commitment and Demand**, **SP3: Coverage and Equity**, **SP5: Outbreaks and Emergencies** and **SP6: Supply and Sustainability**. Additional support, resourcing and coordination are critically needed in these areas, particularly for Gavi-transitioned and non-Gavi-eligible MICs.

Across the four MIC focus Strategic Priorities, actions identified in the relevant annexes should be applied as appropriate for each country context. A few of those actions are emphasized below as particularly important and of potentially high impact in MICs. Where possible, these recommendations should be built upon or complement existing initiatives of countries, regions and partners, such as those outlined in Section 3. Activities across all Strategic Priorities should be made transparent to help ensure sharing of best practices and to promote collaboration across peers.

Supply and Sustainability

Ensure that the supply of and access to vaccines meet country needs and that vaccines are introduced in a timely manner, regardless of a country's wealth, and at prices that are affordable

Key Evidence and Gaps

Over recent decades, market-shaping interventions have helped to accelerate access, reduce vaccine prices to improve affordability, and incentivize innovation to meet the needs of countries, especially for those procuring through the Pan-American Health Organization (PAHO) Revolving Fund and UNICEF. Yet many needs remain unmet, especially for self-procuring MICs which do not have their own robust procurement mechanisms or are not able to access pooled procurement schemes. These countries have experienced delays in introducing new vaccines, due to factors including unaffordable prices, inefficient tendering and procurement processes, and limited use of market intelligence^{viii}.

Strategic interventions

- **At the global level**, there is a lack of alignment on a strategy to achieve healthy and sustainable MIC markets, which limits effective collaboration across partners. Partners should **further institutionalize efforts to develop global MIC vaccine market assessments and track MIC-specific market-shaping goals**, as is done for Gavi-eligible and UNICEF-procuring countries.
- Limited access to product and market intelligence can negatively impact strategic procurement decisions. **Current efforts to disseminate product and market intelligence should be strengthened to improve country decision-making** on issues such as new vaccine introductions, product switches and procurement channels. NITAGs and RITAGs should continue to be supported and trained to better access and interpret market dynamics and collaborate more closely with neighbouring countries. Increasing the role of NITAGs and RITAGs in procurement discussions can improve flexibility around product choice and improve market competition.
- Inefficient pre-licensure and post-approval regulatory processes (e.g. redundant local laboratory testing requirements) increase procurement costs and delay access to vaccines. **Strengthening cross-regional and sub-regional initiatives that aim to improve registration practices and harmonization** could help address these issues. Possible actions include twinning countries with mature regulatory systems with countries possessing less sophisticated national regulatory systems, and documenting key successes and challenges in countries that have enhanced their regulatory capacity. Cross-country platforms can also be used to expand use of the WHO Collaborative Registration Programme. Increased access to data on country regulatory requirements would also help inform international harmonization efforts and enable suppliers to increase the speed and geographic scale of their product registrations, leading to improved access.

- **Effective market access mechanisms already used in Gavi-supported countries should be expanded and innovative incentives should be developed** to increase manufacturers' motivation and ability to supply MICs. For example, encouraging more manufacturers to develop post-Gavi transition pricing commitments, such as Access to Affordable Price Commitments^{xiii}, can improve country financial forecasting, programme sustainability, and supplier competition.
- Country access to affordable, quality vaccines and related equipment (e.g. cold chain) is often limited by sub-optimal procurement practices. **MICs should focus on improving their procurement processes** by removing financing or legal barriers such as those limiting access to affordable products and preventing effective multi-year forecasting and tendering. Further, where it would allow for significant cost savings or product access benefits, MICs should consider procurement through UNICEF or other mechanisms.
- **Scaling up existing cross-border collaboration platforms will help countries more successfully implement the above recommendations.** There are a number of emerging platforms, such as the Small Island Developing States in the African Region and the South-Eastern Europe Health Network in the European Region, LNCT and the VPPN, from which learnings can inform future collaboration efforts. Resources should be dedicated to developing the capacities of cross-border platform secretariats and working groups to share best practices within and across different regional communities (e.g., EURO Cross-Border Collaboration Report^{xiv}). Such collaborations can focus on a variety of activities, such as information sharing, joint market scanning, and group, coordinated or centralized procurement, where appropriate and feasible.

Commitment and Demand

Strengthened decision-making for timely and evidence-based immunization policy and increased political and financial commitment to immunization programmes

Key evidence and gaps

Securing political commitment for sufficient domestic immunization resourcing and developing robust decision-making systems is particularly critical for countries that self-finance their immunization programmes. Strong evidence-driven cases and decision-making processes need to be developed to secure sufficient domestic resources and effectively implement vaccine programme improvements.

Strategic Interventions and Operationalization

- **Supporting development of country-specific investment cases and advocacy packages** could encourage sustainable investment in immunization programmes, especially if they help promote cross-sectoral dialogue outside of ministries of health (e.g., parliamentarian forum briefings). Improving data transparency and reporting on MIC immunization spending, for example through the Joint Reporting Forum, will also help global and country advocacy.

- Introductions, product switches and other programmatic decisions face delays as a result of weak decision-making and technical capacities. To help strengthen these processes, efforts can **build upon existing decision-making support mechanisms**, such as the Global NITAG Network and NITAG Resource Centre, RITAGs, WHO National Immunization Strategy process, and the CAPACITI and CHOICE capacity-building projects. Further, frameworks and tools can be developed at the global level to help countries develop national approaches to evaluate cost-effectiveness of various product options.
- In many countries, institutionalized decision-making processes do not exist, leading to inefficient and slow decision-making. Without a clear pathway for decision-making, even technically capable programmes will falter. Partners who work on specific technical capacity-building projects should ensure that they are coordinated and working together to **develop country-owned, coherent decision-making pathways**.
- Decision-making and advocacy are stymied when appropriate data and evidence are unavailable in MICs. Partners should work with countries to **identify where missing data is preventing key decisions such as product switches or new vaccine introductions from being made, so that the relevant country or regional studies can be supported**. In some cases, effective regional data does exist but countries are unaware or unsure how to leverage such information. The impact of this support can be made most effective by promoting information exchange and collaboration between NITAGs, RITAGs, and other cross-country platforms.
- **MICs have robust, influential civil society organizations (CSOs) that should be more effectively engaged to further the political prioritization of immunization issues**. CSOs can be valuable allies in efforts to build community trust, generate demand for immunization services, and address vaccine hesitancy^{xv}.

Coverage and Equity

Ensuring everyone has meaningful access to safe and effective vaccines regardless of their geographical location, age, education, socioeconomic status, or any gender-related obstacles

Key evidence and gaps

Although the Global Vaccine Action Plan (GVAP) aimed to achieve high national coverage and geographical equity, these global goals have not been met. In many countries high coverage co-exists with and hides significant sub-population inequities^{xvi}. Generating strong community demand and addressing hesitancy issues will be fundamental to addressing these service gaps. Key underserved populations include the urban poor, hesitant, remote rural and conflict-affected populations, as well as mobile populations such as migrants, internally displaced persons, refugees, nomads and pastoralists.

Strategic interventions

- **Improving access to lower prices and more affordable vaccines** will free up resources and allow countries to invest more in immunization system strengthening. Strategies and activities to help achieve this have been identified in Section 4.1.
- **Immunization strategies need to be tailored to reach zero-dose and under-vaccinated children.** Rights-based approaches need to be adopted to prioritize underserved and missed populations. There is also a need to increase global and country knowledge of pro-equity policy, frameworks and monitoring systems, as well as country capacity to translate such policies into practice. Such initiatives need to be fully integrated into national health policies and plans. Reducing the number of zero-dose and under-vaccinated children should become a critical performance measure for the reduction in immunization and primary health care inequities and attainment of universal health coverage. Given its high levels of infectivity and the visibility of outbreaks, measles can serve as a tracer of zero-dose children and underserved communities.
- Immunization programmes need to **better understand the broader social and environmental determinants of those being missed or under-vaccinated.** Scientific research and community engagement strategies can help identify the barriers and social factors that influence vaccine-seeking behaviour. Analysis of local-level coverage and specific population groups can also generate insights that can be used to develop, cost and implement targeted strategies.
- **Pro-gender strategies and interventions should be supported.** Approaches could include: widening the audience for information, education and communication strategies; strengthening and sustaining social mobilization in under-immunized and zero-dose communities; making adjustments to service provision based on community perspectives of quality; and increasing local support and promoting a shared sense of purpose and accountability.
- Where increasing rates of vaccine hesitancy limits community demand for immunization and exacerbates coverage inequities, partners can **promote sharing of vaccine hesitancy best practices across MICs.** For example, lessons learned from country and international initiatives, such as the European Region's Tailoring Immunization Programmes (TIP) tool^{xvii}, could be shared broadly.

Outbreaks and Emergencies

Immunization programmes should (1) anticipate, prepare for, detect, and rapidly respond to vaccine-preventable and emerging disease outbreaks, and (2) ensure immunization service delivery during acute emergencies and among communities affected by conflict, disaster and humanitarian crisis

Key evidence and gaps

Humanitarian crises, including armed conflict and natural disasters, are expected to become more common and many unvaccinated children live in conflict-affected countries. Climate change is also likely to impact human health through environmen-

tal and social changes resulting from migration and displacement. As of 2020, there are 21 states identified by the World Bank as being in conflict or fragile⁶; 10 of these are non-Gavi-eligible or Gavi-transitioned MICs: Libya, Iraq, Kosovo, Lebanon, Venezuela, Kiribati, Marshall Islands, Micronesia, Timor-Leste and Tuvalu.

Strategic interventions

- Timely access to vaccines is challenging for countries facing unpredictable outbreaks. Improved coordination may **enable MICs to more quickly access global stockpiles to rapidly respond to outbreaks**. Supporting fast-track authorization and introduction of other regulatory flexibilities for timely access to new vaccines in emergency situations will also be beneficial.
- Children affected by conflict suffer disproportionately from disease outbreaks^{xvii}. Further, certain countries facing humanitarian crises and serious economic challenges face insufficient support in procurement of vaccines. This issue could be alleviated by **expanding the 'Humanitarian Mechanism' to increase the number of products included and participating suppliers**^{xix}.

Implementation and Next Steps

In order to reach the global IA2030 goals and improve access to vaccines in MICs, it will be critical for countries, regions and partners to demonstrate strong leadership in the areas highlighted in this document. In the first years of the next decade, countries will be focused on COVID-19 responses and vaccine introduction. However, it is important that relatively high-impact, low-cost actions to improve non-COVID-19 immunization outcomes are still carried out. Where feasible, COVID-19 vaccine preparedness and delivery support should be leveraged to facilitate future non-COVID-19 vaccine introductions.

Many of the suggested strategic interventions in this document already exist to some extent and do not need to be developed anew. Rather, key learnings, tools, and existing regional and global coordination mechanisms should be reinforced to ensure that the right support is provided, tailored to country needs and strengthened as needed. Additional coordination between countries, regions and partners will help maximize the impact of these interventions. Aligning on more specific, time-bound targets for MICs, re-establishing a MICs immunization coordination forum, improving information sharing, and development of joint plans of action are just some of the steps that can be taken to accelerate progress.

Vaccine introductions and service delivery improvements take time and the next decade will be critical for vaccine access in MICs. If efforts to lay the foundation for improved vaccine access were delayed, this would jeopardize the ability of countries to meet the IA2030 goals and put MICs at risk of being left further behind. Access challenges and potential solutions have been well documented and researched. It is now up to countries, regions and partners to ensure that all children, regardless of country income status, have equitable access to life-saving vaccines.

6. <http://pubdocs.worldbank.org/en/888211594267968803/FCList-FY21.pdf>

Annex 1: Modelling vaccine-preventable deaths in 2020

Model Objective: A simple model was developed to estimate the number of lives saved by new vaccine introductions and increases in coverage (to 90%) in a single year for select vaccines. The model is meant to provide a point-in-time estimate of the lives-saved impact of vaccine introduction and coverage increase interventions in middle-income countries.

Methodology: Two types of interventions were modelled: (1) increasing coverage to 90% for those vaccines that had already been introduced and (2) introducing a new vaccine and then immediately reaching 90% coverage. If the coverage of an already introduced vaccine was already greater than 90%, the impact of a coverage increase was not considered.

The following vaccines were analyzed: "traditional" vaccines, representing vaccines protecting against diphtheria, tetanus, pertussis, measles, *Haemophilus influenzae* type b (Hib), and hepatitis B, as well as newer vaccines such as pneumococcal conjugate vaccine (PCV) and vaccines for rotavirus and human papillomavirus (HPV). The impact of increasing HPV coverage in countries that have already introduced it was not modelled due to lack of available coverage data.

Intervention Impact Formula: The formula to calculate the proportional impact of coverage increases and/or new vaccine introductions was based on the method used in the Lives Saved Tool (LiST). For a given vaccine intervention (e.g. HPV introduction or measles coverage increase), the number of disease-specific deaths in a given year was multiplied by $R_{i,j,a,t}$ (see below formula) to determine the lives-saved impact. For all infections except HPV, the number of disease-specific deaths in a given year was based on under-five disease-specific deaths in each country. For HPV, the estimates were based on female cervical cancer deaths of all ages. The lives-saved impact of HPV immunization accounts for future averted deaths in adulthood due to immunization in 2020.

$$R_{i,j,a,t} = [l_{i,j,a} \times (C_{i,a,t} - C_{i,a,0}) / (1 - l_{i,j,a,0} \times C_{i,a,0})] \times AF_{i,j,a}$$

- $R_{i,j,a,t}$ = proportional impact in mortality from cause of death j for children in age band a caused by intervention i at time t
- $l_{i,j,a}$ = intervention effectiveness (i.e., vaccine efficacy)
- $AF_{i,j,a}$ = affected fraction (i.e., vaccine serotype coverage)
- $C_{i,a,t}$ = coverage at time t

Data Sources: The following data sources were used:

- Disease-specific deaths: Global Burden of Disease (GBD), 2017
- Vaccine introduction status: International Vaccine Access Center (IVAC) VIEW-hub, 2020
- Vaccine coverage rates: WHO WUENIC estimates, 2019
- Gross national income (GNI): World Bank, 2020
- Efficacy and Affected Fraction: Lives Saved Tool (LiST) and WHO position papers on measles and cervical cancer

Results: Modelling suggests that the introduction of PCV, HPV and rotavirus vaccines in non-Gavi-eligible and Gavi-transitioned MICs in 2020 could have saved 70,000 lives if 90% coverage had been reached (Figure 2). For traditional vaccines protecting against diphtheria, tetanus, pertussis, measles, *Haemophilus influenzae* type b (Hib), and hepatitis B, increasing coverage to 90% in 2020 could have saved an estimated 12,000 lives in non-Gavi-eligible and Gavi-transitioned MICs. While increasing coverage of PCV and rotavirus vaccines in countries having already introduced them could have saved another 4,000 lives.

Resources

Key Resources

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