

Supporting immunization decision-making in low- and lower-middle-income countries

International Vaccine Access Center | Johns Hopkins Bloomberg School of Public Health

CONTENTS

OVERVIEW	1
BACKGROUND	1
OBJECTIVES	1
APPROACH	2
LIMITATIONS.....	2
METHODS	3
DEFINING DECISION-MAKING.....	3
LITERATURE SEARCH.....	3
STAKEHOLDER AND INITIATIVE MAPPING.....	5
RESULTS	5
INTERPRETATION AND SUMMARY	14
DECISION-MAKING INITIATIVES	14
COUNTRY AND REGIONAL APPROACHES.....	15
KEY TAKEAWAYS AND RECOMMENDATIONS	15
CONCLUSION.....	17
APPENDICES	18

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OVERVIEW

This project, funded by the Wellcome Trust, was conducted by JHSPH/IVAC in the summer of 2019 and provides a brief landscape of the types of initiatives funded to support immunization decision-making efforts in low- and lower-middle-income countries, particularly countries ever eligible for Gavi support.

Scope: We defined “decision-making” as the synthesis of clinical, epidemiological, policy, and behavioral research, data, and expert opinion to ensure effective delivery of vaccines and immunization services to priority target populations, and focused—for this assessment—on introduction decision-making rather than implementation decision-making.

Approach: We reviewed publicly available peer-reviewed and gray literature, supplemented with key informant discussions and institutional knowledge, and mapped results to decision-making considerations, partner/initiative types, global goal alignment, and level of investment.

Findings: Decision-making initiatives historically focused on one antigen, but recent shifts to a more comprehensive approach recognize that few countries consider introduction of one vaccine at a time, absent any competing priorities. Future efforts likely need to shift to viewing new vaccine introduction as a package, within the broader child health domain. Specific inclusion of capacity building has also been limited in existing and past initiatives; cultivating skills such as leadership, change management, and stakeholder engagement are crucial to sustainable decisions in a world with many competing priorities. Funders should consider how to prioritize community- and country-driven, context-sensitive initiatives that approach immunization decision-making with an emphasis on integration, sustainability, and capacity strengthening. Key areas lacking support are life course immunization—considering age groups beyond infants and young children—and middle-income countries, historically ineligible for financing support and left out of decision-making support initiatives.

BACKGROUND

Immunization decision-making is defined as the synthesis of clinical, epidemiological, policy, and behavioral research, data, and expert opinion to ensure effective delivery of vaccines and immunization services to priority target populations. The lines between decision-making and implementation are often blurred, and activities to support better decisions do not always capture the important nuances that build country capacity for future scenarios.

Nonetheless, an array of donors and partners have been engaged in immunization policy and program initiatives in recent years, conducting projects to support or strengthen country-level decision-making. To better understand this landscape and identify potential areas in need of donor and partner engagement, we conducted a two-pronged assessment of both the global landscape and specific country approaches.

OBJECTIVES

- Summarize publicly available information on donor-supported country-level decision-making initiatives
- Map existing funders, advisors, and implementing partners engaged in supporting decision-making-related efforts in low- and middle-income countries (LMICs)
- Synthesize evidence to identify gaps in support and/or opportunities for future engagement

APPROACH

Landscape assessment

To assess global and regional support for and engagement in decision-making among low- and lower-middle-income countries, we considered:

- Key stakeholders involved in immunization decision-making at global, regional, and country levels (i.e. donors/funders, implementers, advisory groups)
- Donor-funded decision-making initiatives and obvious gaps
- Gaps or opportunities in decision-making funding

We conducted a literature review to methodically search the body of published, peer-reviewed literature on donor/funder investments in initiatives that support or enable immunization decision-making in LMICs. Initiatives could be country-focused, regional, or global. Information abstracted through this review enabled us to identify key funding or implementing stakeholders, priority areas (geographic, topical, etc.) among and across stakeholders (stratified by donors/funders and implementers), peak funding/implementation periods and their alignment with global initiatives or benchmarks. These and other outputs from the review were incorporated into a matrix.

We supplemented the review with a targeted search of grey literature and institutional knowledge of past and current initiatives that involve decision-making support.

Country decision-making approaches

We developed brief, high-level summaries of immunization decision-making approaches, stakeholder roles, and, where possible, integration with other health and non-health intervention decisions in two LMIC, India and Bangladesh, as well as the AFRO Regional Immunization Technical Advisory Group. Understanding the context-specific approaches LMICs and regional bodies employ to balance competing budgetary and programmatic priorities—including immunization, other preventive health measures, and non-health programs—and weigh sometimes complex evidence for new vaccines may help to inform strategies for further funder and Gavi engagement with current and transitioning countries.

To this end, we reviewed available literature to identify existing published articles outlining decision-making approaches in LMICs, supplemented with targeted searches of grey literature, institutional knowledge, and key informant discussions where possible.

LIMITATIONS

While we aimed to be as comprehensive as possible in this review, we recognize a number of limitations. Across all aspects of this initiative, we are limited to that information that is published, either in peer reviewed or grey literature, and identified in some way as supporting immunization decision-making and/or policy.

Our search terms aimed to cast a wide net and gather as many potentially relevant papers as possible from the peer-reviewed and grey literature. However, in some cases content was not captured through this search. In order to maintain the systematic approach as much as possible, we continued with our initial approach but do note that there is likely a body of relevant literature not captured. In a future review, conducted under more ideal conditions, we would propose expanding the number of search term tests to ensure all relevant literature is captured and incorporated.

We included two grey literature databases in our review as well—again, with the aim of keeping our approach as systematic as possible—but affirm that these databases are far from comprehensive resources. The content of interest for this landscape assessment is often unpublished, and may only appear on a listing of projects on an organizational website or not at all. We relied heavily on institutional knowledge and conversations with key informants to identify additional initiatives and funders to include in this review. However, there is little to no detail available on many of these efforts. In part, this is attributable to sensitivities around external support for decision-making efforts; in some settings, there are significant concerns about undue influence in country decisions, particularly from international entities. Additionally, many of these efforts are likely included under a larger umbrella project not specifically defined as supporting decision-making, limiting our ability to identify them

through the literature review and manual searches. For a future review, additional key informant interviews would help capture the many nuances that are not documented in scholarly or grey literature, both because decision-making may not have been a primary objective and because decision-making-related engagement may not have been highlighted due to potential sensitivities.

Finally, while we recognize that implementation decision-making considerations—how to actually roll out a new vaccine in the national immunization program; plan and conduct health worker trainings; develop information, education, and communication materials; and other key implementation steps—are equally critical components under the immunization decision-making umbrella, we determined that including both introduction decision-making and implementation decision-making would create too broad of a scope for this review and limit our ability to accurately and adequately detail the landscape and country experiences. Where possible and appropriate, we have included implementation advisors and implementation activities that are frequently considered as part of the pre-introduction decision phase (i.e., considerations of cold chain capacity, etc.), but do recognize that there are many partners and funders, and potentially different approaches at the country level, to address implementation decision-making. We do not address these in this assessment.

METHODS

DEFINING DECISION-MAKING

Decision-making for immunization is a complex, dynamic concept which can encompass a wide range of activities along the vaccine introduction continuum. For the purposes of this assessment, we considered the following working definition of immunization decision-making:

Synthesis of clinical, epidemiological, policy, and behavioral research, data, and expert opinion to ensure effective delivery of vaccines and immunization services to priority target populations.

This process typically includes considerations of disease burden, health need, and potential impact; cost effectiveness and financing; different vaccine formulations, products, and/or dosages; how to ensure equitable access to vaccines; social, political, and ethical factors affecting vaccine promotion and uptake; the logistics of introducing new vaccines and/or scaling up vaccine delivery efforts; monitoring and evaluation of immunization delivery and uptake efforts; and the long-term sustainability of immunization programs and systems for vaccine delivery.

While we recognize that immunization decision-making can include any or all of these considerations in a given setting, the line between immunization decision-making and immunization program implementation is often blurred. In this assessment, we focused primarily on pre-introduction decision-making, although there are components of implementation that are included given their overlap between both the pre- and post-introduction decision phases.

LITERATURE SEARCH

We conducted a systematic review of the scholarly literature and a complementary, non-systematic review of the grey literature to identify peer-reviewed studies, technical guidance, and policy documents addressing decision-making processes around immunization and related programs.

Databases

Our search was conducted across the following scholarly literature databases:

- PubMed
- Embase
- Health Systems Evidence Database
- Scopus
- Web of Science
- LILACS

We also searched grey literature databases OAlster and OpenGrey, and conducted targeted searches of document libraries for key funders, implementing partners, and technical groups, including, but not limited to: WHO, CDC Stacks, DFID, Gavi, UNICEF, PATH, Sabin Vaccine Institute, JSI, CHAI, the Task Force for Global Health, USAID, and PAHO.

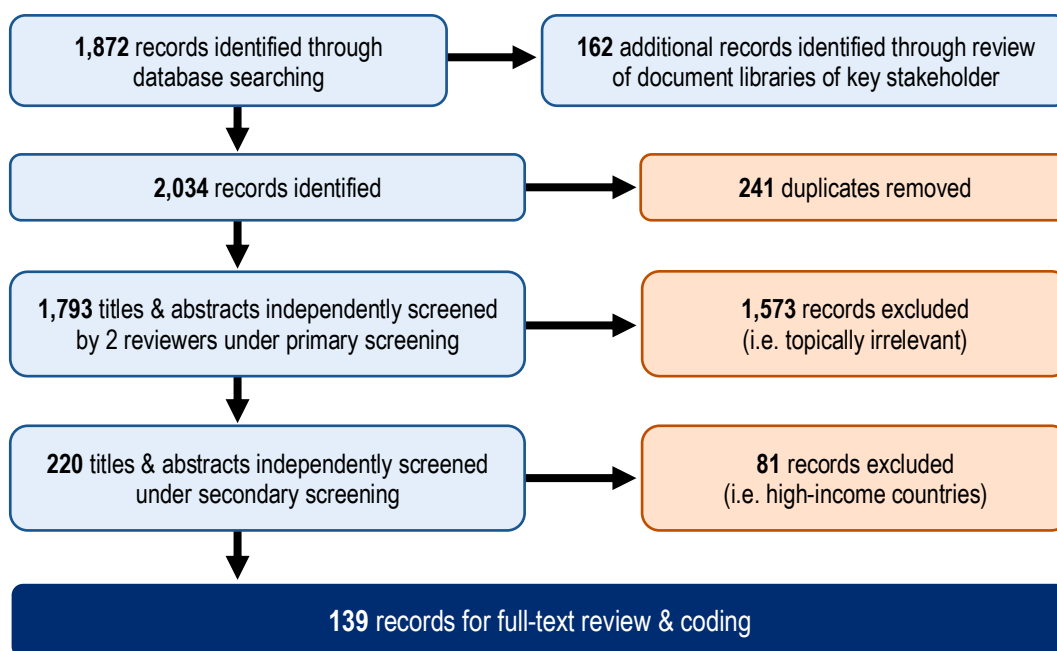
Search terms

("national" OR "country") AND ((immunization[MeSH Terms]) AND ("decision making" OR policy))

Inclusion criteria

- English-language articles and documents published between January 1, 2000 and April 30, 2019
- Address decision-making processes, policymaking, and/or funding efforts around national immunization systems and programs

Flowchart



Analysis

We developed a coding framework (Appendix) based on *a priori* knowledge of immunization programs, policies, and decision-making processes, as well as on the working definition of decision-making with respect to immunization. Documents selected for in-depth review were coded iteratively using NVivo 12 coding software, with new codes added to the framework as they emerge from the literature. Key data abstracted from the literature include:

- Key stakeholders (i.e. donors/funders, implementers, advisory groups) involved in immunization decision-making at global, regional, and country levels
 - How do they interact?
 - Gaps in interaction
- Decision-making-focused initiatives supported by Gavi and other donors/funders, which may include, but are not limited to:
 - Geographical, topical, and/or other gaps in funded initiatives;
 - Redundant or duplicative funding for specific antigens, target populations, and/or geographies;

- Capacity-building with respect to policy processes, interpreting data, enhancing data quality, and advocacy;
- Engagement with external partners in the immunization space;
- Building robust evidence bases for immunization decision-making;
- Modelling, forecasting, and planning;
- Budgeting and financial analysis;
- Preparing for public health emergencies;
- Assessing trade-offs between immunization and other health priorities; and
- Building, sustaining, and sharing of institutional knowledge and expertise
- Support for National Immunization Technical Advisory Groups (NITAGs) and other national stakeholders and entities involved in decision-making
- Initiatives or efforts requiring additional support

Based on these results—supplemented with institutional knowledge and grey literature targeted searching—we developed a matrix of partner engagement and potential areas of opportunity for further effort.

STAKEHOLDER AND INITIATIVE MAPPING

We mapped stakeholders and partners—those identified through the literature review and based on both subsequent targeted searches, institutional knowledge, and key informant insight—to core categories of engagement in order to identify areas with possible gaps in support:

- Donors – those providing funding to countries, partners, and initiatives
- Advisors (scientific, economics/financing, policy, implementation) – those providing technical expertise, guidance, or review
- Funded partners – partners funded to conduct project work
- Policy makers – entities responsible for developing/issuing recommendations or policies
- Advocates – entities conducting issues advocacy

Based on the analysis of the literature, we further identified (1) specific decision-making criteria used by NITAGs and other decision-making or -supporting entities, and (2) areas of current or potentially needed support in support of decision-making and improving immunization policies. We mapped the areas of potential support to key questions regarding the saturation of existing support—based on the literature, not necessarily on country input—and potential impact of these investments. Across all analyses, we summarize the results of the literature review and incorporate additional insight from institutional knowledge and key informant input.

RESULTS

Here we provide the results of the literature review, conversations with key informants, and review of institutional knowledge on support for decision-making and country approaches. Where appropriate, we have mapped these results to provide an evidence-informed approach to identifying gaps and opportunities for future engagement. These results are synthesized and summarized in the Tables 1-3 and Figure 1.

These results are blinded to avoid highlighting specific partners and initiatives and instead look holistically at the body of funding and funded efforts to support country immunization decision-making. We do, however, provide examples of initiatives, partners, and funders for each category.

Table 1: Mapping known funders, partners/stakeholders, and initiatives supporting country immunization decision-making by stakeholder type and role in decision-making support

Interpretation: Each partner, donor, or initiative identified through this assessment as funding or funded to support country immunization decision-making is classified by entity type/category (i.e. donor, multi-partner initiative, advisory group, etc.) and role in supporting decision-making (i.e. provide scientific advice, complete project work, develop policy recommendations, advocate, etc.). Examples of each category are included below.

- – No stakeholders and/or initiatives found to be working in this role
- – At least one stakeholder and/or initiative working in this role

PARTNER/INITIATIVE (BY TYPE)	ROLE IN IMMUNIZATION DECISION-MAKING							
	Donor <i>Fund countries or partners</i>	Advisor				Funded partner <i>Funded to complete project work</i>	Policy maker <i>Develop policies or recommendations</i>	Advocate <i>Conduct issues advocacy</i>
		Scientific	Economics/ financing	Policy	Implementation			
Known stakeholders by type/category <i>Partners, initiatives, or other stakeholders funding or funded to support immunization decision-making in LIC/LMIC</i>		<i>Provide technical expertise, guidance, or review</i>						
ADVISORY GROUPS/COMMITTEES <i>Example: WHO's Strategic Advisory Group of Experts (SAGE) on Immunization provides expert guidance and develops policies/recommendations to support country decision-making</i>	○	●	●	●	●	○	●	○
National Immunization Technical Advisory Groups (NITAGs)		●	●	●	●		●	
Regional Immunization Technical Advisory Groups (RITAGs)		●	●	●	●		●	
Advisory Committee A		●	●	●	●		●	
Advisory Committee B		●	●	●	●		●	
Advisory Committee C		●	●	●	●		●	
Advisory Committee D		●	●	●	●		●	
Advisory Committee E		●	●	●	●		●	
Advisory Committee F		●	●	●	●		●	
DONORS/FUNDERS <i>Example: The Bill & Melinda Gates Foundation funds partners and initiatives to support country-decision making, provides technical expert advice on key areas, and supports advocacy efforts. Government international development agencies like UK DFID and USAID are also included in this category.</i>	●	●	●	●	●	●	●	●
Donor/Funder A	●	●	●	●	●	●	●	●
Donor/Funder B	●	●	●	●	●	●	●	●
Donor/Funder C	●	●	●	●	●	●	●	●
Donor/Funder D	●	●	●	●	●	●	●	●
Donor/Funder E	●	●	●	●	●	●	●	●
Donor/Funder F	●	●	●	●	●	●	●	●
Donor/Funder G	●	●	●	●	●	●	●	●
GLOBAL CORE PARTNERS <i>Example: UNICEF funds initiatives, provides expert advice/guidance, and supports advocacy efforts</i>	●	●	●	●	●	●	●	●
Core Partner A	●	●	●	●	●	●	●	●
Core Partner B	●	●	●	●	●	●	●	●
Core Partner C	●	●	●	●	●	●	●	●

PARTNER/INITIATIVE (BY TYPE)	ROLE IN IMMUNIZATION DECISION-MAKING							
Known stakeholders by type/category <i>Partners, initiatives, or other stakeholders funding or funded to support immunization decision-making in LIC/LMIC</i>	Donor <i>Fund countries or partners</i>	Advisor				Funded partner <i>Funded to complete project work</i>	Policy maker <i>Develop policies or recommendations</i>	Advocate <i>Conduct issues advocacy</i>
		Scientific	Economics/ financing	Policy	Implementation			
		<i>Provide technical expertise, guidance, or review</i>						
GOVERNMENT ENTITIES <i>Example: The U.S. CDC funds initiatives like surveillance, provides expert advice/guidance, and develops recommendations.</i>	●	●	●	●	●	●	●	○
Government Ministries								
Government Health Agency								
Country Support Unit								
INTERNATIONAL NGOs <i>Example: PATH is funded to complete project work, provides technical advice/expertise, and conducts advocacy activities. Individual NGOs, like PATH, are part of some multi-partner initiatives/networks and may also have single-partner initiatives.</i>	●	●	●	●	●	●	○	●
International NGO A								
International NGO B								
International NGO C								
International NGO D								
International NGO E								
International NGO F								
International NGO G								
International NGO H								
International NGO I								
MULTI-PARTNER INITIATIVES/NETWORKS <i>Example: The Rotavirus Accelerated Vaccine Introduction Network (RAVIN) is a consortium consisting of IVAC, JSI, and CDC, and provides scientific, policy, and implementation advice to 8 Gavi-eligible countries, is funded to complete project work, and conducts advocacy. Other initiatives provide single-country support. ADIPs like PneumoADIP, RotaADIP, and the Hib Initiative are also included here. Individual partners may also be classified above as International NGOs, core partners, or others.</i>	○	●	●	●	●	●	○	●
Multi-partner Initiative A								
Multi-partner Initiative B								
Multi-partner Initiative C								
Multi-partner Initiative D								
Multi-partner Initiative E								
Multi-partner Initiative F								
Multi-partner Initiative G								
Multi-partner Initiative H								
Multi-partner Initiative I								
Multi-partner Initiative J								
Multi-partner Initiative K								

PARTNER/INITIATIVE (BY TYPE)	ROLE IN IMMUNIZATION DECISION-MAKING							
Known stakeholders by type/category <i>Partners, initiatives, or other stakeholders funding or funded to support immunization decision-making in LIC/LMIC</i>	Donor <i>Fund countries or partners</i>	Advisor				Funded partner <i>Funded to complete project work</i>	Policy maker <i>Develop policies or recommendations</i>	Advocate <i>Conduct issues advocacy</i>
		Scientific	Economics/financing	Policy	Implementation			
		<i>Provide technical expertise, guidance, or review</i>						
Multi-partner Initiative L								
Multi-partner Initiative M								
Multi-partner Initiative N								
Multi-partner Initiative O								
OTHER <i>Example: India's Immunization Technical Support Unit (ITSU) is funded to conduct project activities and provides technical expert advice/guidance.</i>	○	●	●	●	●	●	○	●
Professional Medical Societies								
Vaccine Manufacturers								
Country Support Units								
PARTNER INITIATIVES <i>Example: The Sabin Vaccine Institute's Sustainable Immunization Financing (SIF) initiative provides expert advice on economics/financing and policy for immunization decision-making, is funded to complete project activities, and engages in advocacy efforts. Sabin is also classified as an international NGO and may be part of multi-partner initiatives.</i>	○	●	●	●	●	●	○	●
Partner Initiative A								
Partner Initiative B								
Partner Initiative C								

Figure 1: Decision-making factors

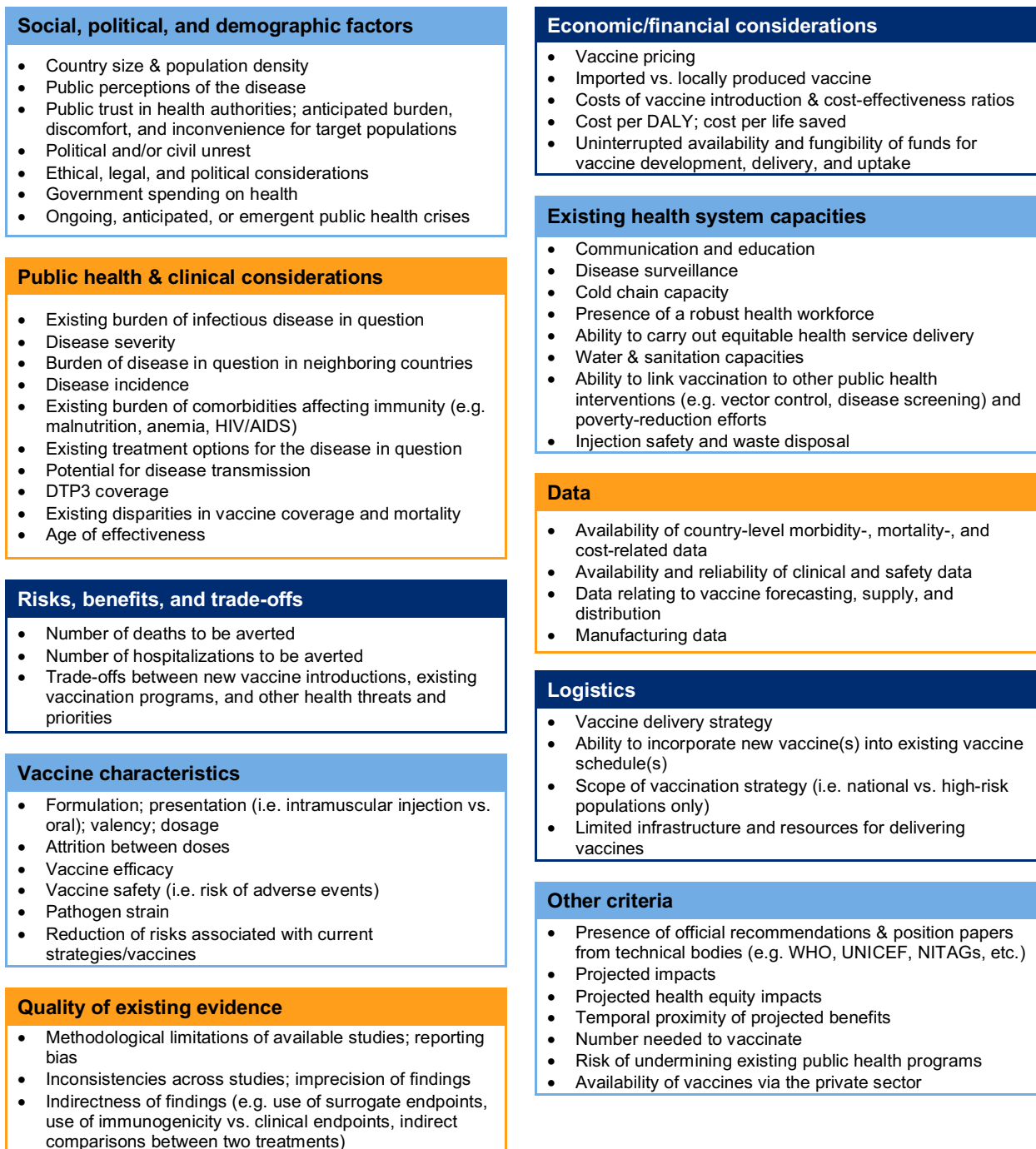


Table 2: Mapping priorities and areas of need identified through literature against known funding, partner prioritization, and potential impact

Interpretation examples:

Infants: This area has extensive recent and ongoing funding (dark gray, indicating a saturated space with lower opportunity for new investment); has been identified as a high priority by partners and funders, regardless of whether funding is associated (orange, indicating a priority area and potential opportunity for engagement); and has substantial potential for health and economic impact as a result of further investment.

Adults (life course): This area has little funding (orange, indicating opportunity for catalytic investment); that has been identified as a priority by some partners, despite limited funding being allocated (light grey, indicating moderate opportunity); and has moderate potential health and economic impact (light grey)

KEY

Potential opportunity for funder/partner engagement

Moderate opportunity (e.g. some existing funding, moderate impact)

Low opportunity (saturated space, not noted as a priority area)

	Funding	Funder/partner priority	Potential impact
	<i>Is area known to have current or recent past donor funding?</i>	<i>Has topic been identified as a donor or key partner (e.g. WHO) priority, regardless of funding availability?</i>	<i>What is the potential impact (i.e. lives saved, return on investment, etc.)?</i>
Key Populations			
Low-income populations			
Mobile populations; nomadic, scattered, and border-settled populations			
Migrant populations			
Healthcare personnel			
Non- and/or under-immunized children; children requiring "catch-up" vaccination			
Hidden populations (e.g. individuals living in remote areas, community newcomers)			
Adults (life course)			
Pregnant women			
Infants			
"Active refuser" populations			
"Hidden" urban poor population			
Technical Support			
Improving operational execution of supplemental immunization activities			
Improving national disease screening capacities			
Consider alternate indicators and inequality measures to understand immunization coverage challenges			
Support establishment of systematic, methodological, structured approaches to guide decision makers through considering all evidence			
Implementing community-based approaches to social mobilization, handling vaccine noncompliance, and addressing vaccine safety issues			
Develop approaches to address lagging immunization (esp. for low-income/underserved populations) in MIC and HIC			

KEY

Potential opportunity for funder/partner engagement

Moderate opportunity (e.g. some existing funding, moderate impact)

Low opportunity (saturated space, not noted as a priority area)

	Funding	Funder/partner priority	Potential impact
	<i>Is area known to have current or recent past donor funding?</i>	<i>Has topic been identified as a donor or key partner (e.g. WHO) priority, regardless of funding availability?</i>	<i>What is the potential impact (i.e. lives saved, return on investment, etc.)?</i>
Process (Structures) Support			
Strengthen the technical capacities of NITAGs			
Train secretariats and members on stakeholder mapping, working group functioning, systematic approaches to assess scientific evidence, writing policy briefs			
Assess NITAG outputs and outcomes			
Improve data/survey frequency to support better coverage estimates			
Improving use of data for evidence-based decision-making			
Integrate immunization decision-making with ongoing/other health systems strengthening efforts			
Strengthening monitoring capacities			
Improve engagement of community leaders/members in immunization decision-making			
Operationalize equity-based decision-making			
Characterize immunization decision-making in humanitarian and public health emergency contexts			
Understand linkages between country, system, and individual decision-making processes			
Characterize community-driven, bottom-up approaches to immunization policy and implementation			
Establishing vaccination policies for healthcare workers			
Program Support			
Strengthening program management			
Assessing future availability of essential therapies (e.g. ART)			
Increasing access to and demand for health services			
Improve collaboration between human and animal health sectors			
Support efforts to consider non-vertical programs			
Support initiatives led by LMICs and South-South exchanges			
Financing & Economics			
Assessing the cost-effectiveness of new vaccine introductions			
Establish clear financing policies and commitments from donors to help inform sustainable country decisions			
Assess alternate funding strategies to avoid disrupting policy and planning processes in recipient countries			
Sustainable immunization financing in MIC and Gavi-transitioning countries			
Other Health System Priorities			
Achieving universal immunization coverage			
Minimizing threats to health workers			

Table 3: Characteristics of countries reporting the existence of a NITAG

Countries reporting the existence of a NITAG	NITAG meets all criteria	Gavi country	Eligible for NVI support (2019)	World Bank income group	WHO region
Afghanistan				LIC	EMRO
Albania				UMIC	EURO
Algeria				UMIC	AFRO
Andorra				HIC	EURO
Argentina				HIC	AMRO
Armenia				UMIC	EURO
Australia				HIC	WPRO
Austria				HIC	EURO
Azerbaijan				UMIC	EURO
Bahrain				HIC	EMRO
Bangladesh				LMIC	SEARO
Belarus				UMIC	EURO
Belgium				HIC	EURO
Benin				LIC	AFRO
Bhutan				LMIC	SEARO
Bolivia (Plurinational State of)				LMIC	AMRO
Bosnia and Herzegovina				UMIC	EURO
Brazil				UMIC	AMRO
Bulgaria				UMIC	EURO
Burkina Faso				LIC	AFRO
Canada				HIC	AMRO
Chile				HIC	AMRO
China				UMIC	WPRO
Colombia				UMIC	AMRO
Costa Rica				UMIC	AMRO
Côte d'Ivoire				LMIC	AFRO
Croatia				HIC	EURO
Cuba				UMIC	AMRO
Czech Republic				HIC	EURO
Denmark				HIC	EURO
Djibouti				LMIC	EMRO
Dominica				UMIC	AMRO
Ecuador				UMIC	AMRO
Egypt				LMIC	EMRO
El Salvador				LMIC	AMRO
Estonia				HIC	EURO
Fiji				UMIC	WPRO
Finland				HIC	EURO
France				HIC	EURO
Georgia				LMIC	EURO
Germany				HIC	EURO
Greece				HIC	EURO
Guatemala				UMIC	AMRO
Honduras				LMIC	AMRO
Hungary				HIC	EURO
Iceland				HIC	EURO
India				LMIC	SEARO
Indonesia				LMIC	SEARO
Iran (Islamic Republic of)				UMIC	EMRO
Iraq				UMIC	EMRO
Ireland				HIC	EURO
Israel				HIC	EURO
Japan				HIC	WPRO
Jordan				UMIC	EMRO
Kazakhstan				UMIC	EURO
Kenya				LMIC	AFRO
Kiribati				LMIC	WPRO
Korea, Democratic People's Republic of				LIC	SEARO
Korea, Republic of				HIC	WPRO
Kuwait				HIC	EMRO
Kyrgyzstan				LMIC	EURO
Lao People's Democratic Republic				LMIC	WPRO

Countries reporting the existence of a NITAG	NITAG meets all criteria	Gavi country	Eligible for NVI support (2019)	World Bank income group	WHO region
Latvia				HIC	EURO
Lebanon				UMIC	EMRO
Libya				UMIC	EMRO
Lithuania				HIC	EURO
Luxembourg				HIC	EUO
Macedonia, The former Yugoslav Republic of				UMIC	EURO
Malaysia				UMIC	WPRO
Maldives				UMIC	SEARO
Mali				LIC	AFRO
Malta				HIC	EURO
Mauritania				LMIC	AFRO
Mexico				UMIC	AMRO
Moldova, Republic of				LMIC	EURO
Monaco				HIC	EURO
Mongolia				LMIC	WPRO
Montenegro				UMIC	EURO
Morocco				LMIC	EMRO
Mozambique				LIC	AFRO
Myanmar				LMIC	SEARO
Nepal				LIC	SEARO
Netherlands				HIC	EURO
New Zealand				HIC	WPRO
Nicaragua				LMIC	AMRO
Niger				LIC	AFRO
Niue				n/a	WPRO
Oman				HIC	EMRO
Pakistan				LMIC	EMRO
Palau				HIC	WPRO
Panama				HIC	AMRO
Papua New Guinea				LMIC	WPRO
Paraguay				UMIC	AMRO
Peru				UMIC	AMRO
Philippines				LMIC	WPRO
Poland				HIC	EURO
Portugal				HIC	URO
Qatar				HIC	EMRO
Romania				UMIC	EURO
Saudi Arabia				HIC	EMRO
Senegal				LIC	AFRO
Slovakia				HIC	EURO
Slovenia				HIC	EURO
Somalia				LIC	EMRO
South Africa				UMIC	AFRO
Spain				HIC	EURO
Sri Lanka				LMIC	SEARO
Sudan (the)				LMIC	EMRO
Suriname				UMIC	AMRO
Switzerland				HIC	EURO
Syrian Arab Republic				LIC	EMRO
Thailand				UMIC	SEARO
Tunisia				LMIC	EMRO
Turkey				UMIC	EURO
Uganda				LIC	AFRO
United Arab Emirates				HIC	EMRO
United Kingdom of Great Britain and Northern Ireland				HIC	EURO
United States of America				HIC	AMRO
Uruguay				HIC	AMRO
Uzbekistan				LMIC	EURO
Venezuela (Bolivarian Republic of)				UMIC	AMRO
Viet Nam				LMIC	WPRO
Yemen				LIC	EMRO
Zimbabwe				LIC	AFRO

Source: NITAG Resource Center; VIEW-hub

INTERPRETATION AND SUMMARY

DECISION-MAKING INITIATIVES

Current and recent initiatives

Informed by our literature review, conversations with key informants, and institutional knowledge, we mapped initiatives funded to support decision-making in LMICs.

Key components of efforts to support sustainable, cross-cutting immunization decision-making include, but are not limited to: prioritizing cross-domain engagement (e.g. scientific, economic, and implementation input); approaching decision-making as a holistic issue across immunization (rather than focusing exclusively on one antigen); incorporating country or community partners and input; included a significant and explicit capacity strengthening component; including some type of advocacy or agenda-setting activity to help cultivate political will and a longer-term enabling environment; and assessing geographic reach.

Decision-making initiatives such as those outlined above have historically focused on one antigen or disease, allowing for focused effort and technical expertise to achieve one goal without needing to draw on an extensive network of stakeholders and advisors—this approach helped to effectively advanced Hib and, to a slightly lesser degree, pneumococcal conjugate vaccine introductions. More recently, there has been a shuffling of priorities to take a more comprehensive approach, recognizing that few countries are considering just one vaccine at a time and can consider each antigen's introduction in a vacuum, absent any competing priorities. There is general consensus on the need to shift the way we look at immunization decision-making and how partners and donors support these efforts. This means considering new vaccine introduction as a package, rather than as individual antigens one at a time, in order to balance competing priorities and leverage planning and preparations to maximize efficiency. It also means looking at immunization as part of the broader child health and even overall public health space, rather than in a silo.

Capacity building and community input are additional areas that have been part of past initiatives but not necessarily a concrete, clearly defined and prioritized aspect. Some initiatives have recognized the importance of these efforts but do not necessarily include a clear plan and approach for implementing them. It is important to note that capacity building, and community engagement though to perhaps a lesser degree, requires substantial time to effectively carry out.

Future funders should consider how to prioritize community- and country-driven, context-sensitive initiatives that approach immunization decision-making with an emphasis on integration, sustainability, and capacity strengthening. Cultivating skills such as leadership, change management, and stakeholder engagement are crucial to sustainable decisions in a world with many competing priorities.

Priorities and gaps for decision-making support

Table 2 lists priorities and gaps identified through the literature review (column A), in many cases overlapping between both classifications during the period of the literature review (2000-2019). In some cases, populations identified as priorities have not necessarily had funding or targeted initiatives to respond—or at least not with published or publicly available information—and areas identified as gaps may have seen new interest in funding and establishing.

Additionally, we note that what is interpreted from the literature and other inputs (discussion with key informants, institutional knowledge) may not reflect what countries have identified as areas of need. Some areas identified as gaps may also have substantial investment or partner engagement, relative to other potential areas of investment or support. For example, cost effectiveness of immunization is regularly highlighted as an area for which countries need evidence to inform decision-making. We also

note that a number of partners have been supporting this analysis in recent years and helped to address this gap. Likely it remains a priority and identified from the country perspective because it often requires country-specific analysis, rather than considering analysis from neighboring or similar countries. Other economic analysis, particularly those like cost of illness studies, which inform cost-effectiveness calculations and other economic assessments, may benefit from further investment—both in conducting these studies and in synthesizing and identifying ways to support their utilization in countries considering new vaccines.

Key gaps and areas of potential funder/partner engagement in support of country, regional, and global decision-making are summarized below.

COUNTRY AND REGIONAL APPROACHES

India and Bangladesh, both Gavi-eligible lower-middle-income countries in the WHO South East Asia Region, have established NITAGs that meet the WHO-outlined criteria:

- Ministerial Decree or equivalent issued
- Terms of reference developed
- Standard operating procedures developed
- Declaration of Interest signed by all members
- Chairperson neither supervises nor reports to, directly or indirectly, the immunization programme or (preferably) the Ministry of Health
- NITAG has only technical advisory role
- NITAG composed of multi-disciplinary expertise

In both cases, as well, the NITAG engages a scientific subcommittee to provide in-depth subject matter expertise. This allows for targeted technical input, while the NITAG may take a broader, cross-disciplinary approach. Importantly, in both settings—as in all countries with by-definition NITAGs—the NITAG is not the final decision-making body, but rather operates as a recommending authority (although in Bangladesh, the role is slightly more involved). The Ministry of Health (or equivalent) then considers the recommendation and makes an official decision. Supporting multiple partners and in-country entities—including ministries, NITAGs and their subcommittees, and in-country scientific, economic, and programmatic actors, as well as advocates—to understand and apply evidence, evaluate options, and make informed recommendations is a critical area needing support in order to be institutionalized in many countries.

KEY TAKEAWAYS AND RECOMMENDATIONS

There are relatively few initiatives engaged in supporting immunization decision-making.

There are a relatively small number of organizations and initiatives supporting the decision-making process in countries, although they do provide a fair amount of antigen specific technical expertise. Some global core partners provide NITAG strengthening support; many NITAG-focused efforts prioritize the structure of the body rather than transferring skills or enhancing process awareness/familiarity. Past initiatives supporting decision-making have generally been in the broader context of accelerating vaccine introduction; many of these efforts are antigen-specific (e.g. focused on one vaccine, like Hib) or analysis-specific (e.g. focused on one type of project, like cost-effectiveness models). Although capacity building was an element of the early initiatives, many of the nuances of decision-making and appreciation of the efforts that needed to go on at a global or regional level were missing. Relatively little emphasis has been placed on fostering collaboration and integration with other functions or sectors.

There is a need to understand the drivers of country decisions in a broader context.

There has been limited assessment across countries to characterize the context-specific challenges and barriers that drive priorities. The vaccine process is often quite siloed, making integration with other programs and priorities a challenge. Some initiatives have sought to identify barriers and facilitators to

decision-making, but tend to look through a vaccine lens rather than the broader country priorities. Recent archetype analyses for adult and maternal immunization aimed to understand some of the broader contexts and drivers, such as health security or cost, and we understand that Gavi has done some preliminary research in this area, but the extent and specific details have not been publicly documented at the time of this analysis.

Immunization decision-making initiatives benefit from a comprehensive perspective across the continuum.

Many decision-making support initiatives have been siloed to one antigen or country, or have focused on one step in the extensive process of immunization introduction and implementation, rather than considering the full continuum of decision-making—advocacy and agenda-setting, introduction decision-making (including scientific, economic, policy, and implementation questions), program planning, implementation, and evaluation. Efforts to support this comprehensive look at new intervention introduction may help facilitate an evidence-based, systematic approach to decisions. The Total Systems Effectiveness (TSE) initiative—now CAPacity—may be one approach to help countries make informed decisions about which vaccines they will use and how to advance them, but this initiative has not been widely publicized to date.

Middle-income countries still need decision-making support.

Middle-income countries are often assumed to have sufficient capacity to make decisions and, in many cases, to finance their immunization programs and incorporate new antigens. While they may have technical expertise, other challenges, such as advocacy, agenda setting, and financing considerations may become all the more important. The priorities that inform decisions in these settings may differ from those in Gavi-eligible, low-income countries. For example, in many cases these countries face issues of high morbidity rather than high mortality, or have generally well-functioning systems but significant vulnerable populations missed by services entirely.

The type of support needed is shifting.

As countries transition from Gavi eligibility, the types of support—particularly around economics and financing—may need to shift. Analysis of an intervention's cost-effectiveness is typically a requirement for country decision-making, yet countries need an increasing degree of understanding of how to make the financial case in the context of competing priorities and leverage potentially interlinked priorities. Increasingly, to make the case for vaccines, the evidence will need to show not just the impact on disease, but the economic benefits (healthcare costs averted, improved productivity, etc.) and the value vaccines bring to addressing other priorities including Primary Health Care, equity, education, nutrition, poverty and more. As different populations across the life course are now being considered, expertise around the issues of other relevant sectors will become increasingly important.

There is a strong need to prioritize capacity building and identifying and addressing skills gaps.

As decisions become more complex and target groups move beyond the familiar infant populations, decision makers will need to problem solve and build networks—to recognize their own expertise gaps and understand how to reach out to those who can fill that gap. They will need to consider a broader view of immunization, integrating immunization decisions with other sectors. Although advocacy and agenda setting are not typically associated with decision-making, the reality is that a strong understanding of how to affect a theory of change is key to success. Decision makers need to lead, influence, communicate, advocate, and understand the broader picture to consider trade-offs. They need to understand the value of quality data and how to use it; current data initiatives may not be sufficient to help strengthen this area. Future initiatives should also look for ways to engage social scientists in decision-making processes.

Decisions are not always straight forward and appreciation of priorities within a country may help moderate decisions based on cost or cost effectiveness. Some initiatives provide guidance to countries on trade-offs, but do not have an in-country mandate to train countries on the findings. Nonetheless,

support tools are one way that countries can strengthen their decision-making capability. Others have helped countries navigate challenging decisions about product switching, but only in a small subset of countries. Still others include an explicit capacity building component and emphasize the need to integrate advocacy and decision-making to help accelerate decisions.

Immunization needs to be integrated with other health programs.

Health programs face an array of competing priorities. Rather than looking at vaccines a separate program, integrating with other programs and building stronger links to primary health care may be beneficial; links to health security and preparedness may also be of value. This requires an understanding of and engagement with multiple diverse stakeholders.

Immunization across the life-course needs to be prioritized.

Immunization decision-making support in LMIC has largely focused on infant populations, expanding to adolescents as HPV vaccine becomes the next priority for many countries. However, there is an often-unrecognized health and economic burden from vaccine preventable diseases among adults, warranting consideration of immunization across all phases of life. This will require a substantial shift not only in how decisions are made—what evidence is required and what thresholds must be met for a decision to be made—but also in how we communicate the value of vaccination and implement immunization programs in non-traditional populations. While life-course immunization has been identified as a priority by several global partners, funding to support decision-making in this space has not yet materialized. LMIC are typically averse to incorporating adult immunization without global recommendations or regional momentum.

There is a continued need to improve data quality and, where possible, frequency.

Decision-making bodies and immunization program officials rely on high-quality data, with a strong preference for local data. Partner analyses note that a lack of recent, reliable, high-quality data can have implications for decision-making, implementation, and monitoring. Data will also need to be fit for purpose to be able to answer questions in specific populations. Efforts to not only improve the quality and availability of data to inform decisions, but also increase awareness of and ability to identify and accurately and appropriately interpret epidemiological, economic, and programmatic data—and to recognize the implications of basing decisions on poor data—are increasingly critical.

CONCLUSION

Decision-making is context-specific and the immunization space is quite dynamic, particularly as we move beyond the traditional EPI vaccines and into different target populations. Future initiatives should recognize this and focus on building skills and defining approaches for effective evidence-based decision-making that can be adapted and applied in multiple situations based on the varying context and priorities of the country. There is an opportunity for funders to make lasting impact by investing in initiatives that emphasize capacity strengthening across the immunization continuum.

APPENDICES

[Appendix 1: Coding framework](#)

[Appendix 2: Annotated bibliography](#)

[Appendix 3: India case study](#)

[Appendix 4: Bangladesh case study](#)

[Appendix 5: AFRO RITAG case study](#)

[EndNote library](#)