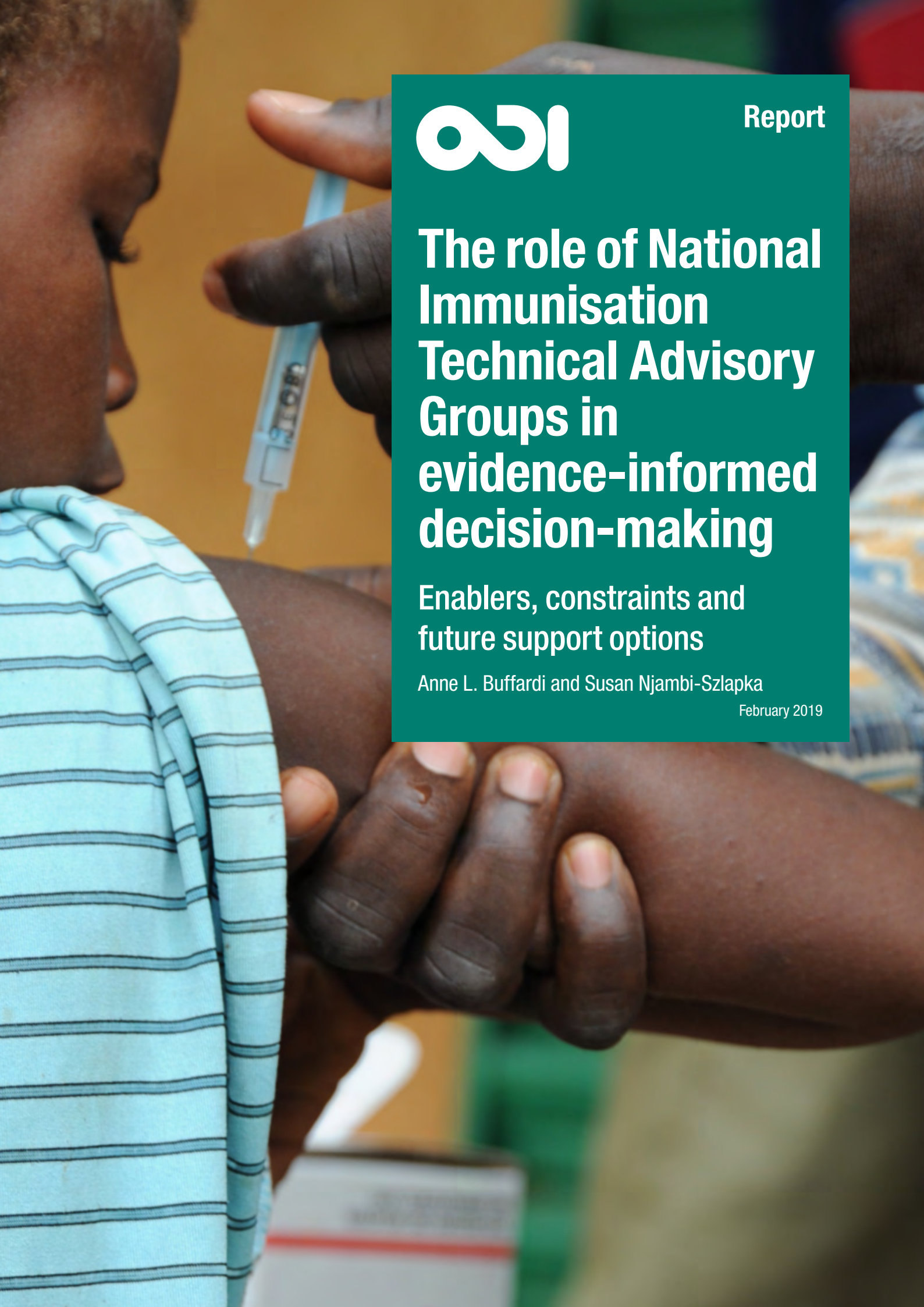

Report

The role of National Immunisation Technical Advisory Groups in evidence-informed decision-making

Enablers, constraints and future support options

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Cover photo: a child receives the MenAfriVac™ shot in Burkina Faso. Credit: Flickr/World Health Organization.

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Acronyms

BMGF	Bill & Melinda Gates Foundation
CDC	Centers for Disease Control and Prevention
CoI	conflict of interest
DFID	Department for International Development (UK)
EIDM	evidence-informed decision-making
EPI	Expanded Programme on Immunization
GNN	Global NITAG Network
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
GVAP	Global Vaccine Action Plan
HPV	human papilloma virus
HTA	Health Technology Assessment
ICC	Inter-agency Coordinating Committee
iDSI	International Decision Support Initiative
IPV	inactivated polio vaccine
MDG	Millennium Development Goal
MoF	ministry of finance
MoH	ministry of health
NGO	non-governmental organisation
NIP	National Immunisation Programme
NITAG	National Immunisation Technical Advisory Group
NRC	NITAG Resource Center
PAHO	Pan American Health Organization
PATH	Program for Appropriate Technology in Health
RITAG	Regional Immunisation Technical Advisory Group
SAGE	Strategic Advisory Group of Experts on Immunization
SDG	Sustainable Development Goal
SIVAC	Supporting Independent Immunization and Vaccine Advisory Committees initiative
ToC	theory of change
TWG	technical working group
UHC	universal health coverage
WHO	World Health Organization

Executive summary

National Immunisation Technical Advisory Groups (NITAGs) are multidisciplinary groups of national experts who provide independent, evidence-informed advice to policy-makers on vaccine-related issues. At the close of the 10-year SIVAC (Supporting Independent Immunization and Vaccine Advisory Committees) initiative, the external evaluation concluded that newer NITAGs would continue to need support for at least a decade, and that future support would need to be better harmonised across donors and aligned with national systems.

Following that evaluation, the Wellcome Trust and the World Health Organization (WHO) initiated a scoping exercise to determine how different types of NITAGs could be supported in the coming years. This involved a two-day NITAG stakeholder workshop, rapid document review and consultations with WHO staff and NITAGs from 11 countries. This report presents the findings of that process, written for organisations who are familiar with and considering supporting the next phase of NITAGs' development, NITAG members, and national and global stakeholders with which NITAGs engage.

To illustrate national decision-making processes and NITAGs' role within them, the report presents nested pathways of change developed by workshop participants. Country examples highlight the iterative nature and national variation in these processes; the lack of contestation over types of evidence and NITAG recommendations; the central role that financing plays in determining if, when and how NITAG recommendations are implemented; and the positioning of these technical advisory groups within political processes where they may have to make decisions based on incomplete evidence.

Four enabling areas contribute to NITAGs' ability to inform these national decision-making processes and provide evidence-informed recommendations on vaccine-related issues. NITAGs require secured funding, adequate support from the secretariat, independence, and trusting, mutually engaging relationships with key immunisation stakeholders. Yet, countries continue to face constraints in each of these areas, challenges which in many cases are well recognised but persistent.

Four actionable support options will help to enable NITAGs' basic functioning and could improve their effectiveness and efficiency:

- financial resources for basic secretariat functioning
- training, coaching and mentoring
- documenting experiences, sharing lessons and networking across NITAGs
- improving access to tools, guidance documents, research evidence and systematic reviews.

A future priority for NITAGs established in the last decade is strengthening relationships, particularly with ministries of health, and further integrating their work into national decision-making processes. These aspirations have a large relational element, distinct from the technical and administrative emphasis that has been the focus of much NITAG support in the past. Furthermore, these efforts will need to be driven by NITAGs themselves. Concrete steps for NITAGs and national stakeholders could include:

- establishing institutional relationships with key bodies
- formalising the post-recommendation process with the ministry of health (MoH)
- demonstrating the contribution and value of NITAGs
- leveraging experts to raise the profile of the NITAG
- capitalising on immunisation programme activities and processes.

Donors, the WHO and the Global NITAG Network (GNN) will continue to play

important roles in supporting core NITAG functions and the expansion and embedding of NITAGs' role in evidence-informed decision-making processes. To jointly move this work forward, three interdependent actions are most pressing:

- Donors need to define their roles and more actively coordinate among themselves.
- Donors also need to be more explicit in communicating what they can fund and how NITAGs can access these resources.
- The WHO and the GNN need to clarify the 'ask' to donors and develop an investment case with defined national, regional and global support activities.

At the workshop, discussions began regarding which institutions are best placed to lead strategy development and fund-raising efforts, and how technical organisations (i.e. WHO and Centers for Disease Control and Prevention (CDC)) and donor organisations (i.e. Gavi, Wellcome Trust and the Bill & Melinda Gates Foundation) relate to one another. This too needs to be resolved.

Further discussions about the next phase of NITAG development must consider broader shifts that affect NITAGs directly, as well as the enabling environment in which they work. These changes include the expansive Sustainable Development Goals (SDGs) agenda and universal health coverage efforts, donor transitions and an increasingly crowded vaccine arena.

1 Introduction

National Immunisation Technical Advisory Groups (NITAGs) are multidisciplinary groups of national experts who provide independent advice to policy-makers on issues related to immunisation and vaccines, based on evidence and the national context (Adjagba et al., 2015; WHO, 2018). The Global Vaccine Action Plan (GVAP) 2011–2020 and 2017 World Health Assembly resolution call on governments to establish and strengthen these advisory bodies, acknowledging their pivotal role in decision-making and in achieving national health goals. Although the number of NITAGs doubled between 2010 and 2016, the mid-term review of the GVAP noted the need for accelerated progress in order to meet the goal of a functional NITAG in all countries by 2020 (WHO, 2017).[1]

At the close of the 10-year SIVAC initiative, the external evaluation concluded that newer NITAGs would continue to need support for at least a decade, and that future support would need to be better harmonised across donors and aligned with national health system considerations and other decision-making processes (Howard et al., 2018). Following the evaluation, the Wellcome Trust and the WHO initiated a scoping exercise to determine how different types of NITAGs could be supported in the coming years, and this report presents the findings of that process. The report is written for organisations who are familiar with and considering supporting the next phase of NITAGs' development, NITAG members, and national and global stakeholders with whom NITAGs engage.

In the last eight years, a growing number of articles have documented NITAG internal structures and ways of working (see *Vaccine* 28(1), 2010, which is entirely devoted to the topic, and also Duclos et al., 2013; Adjagba et al., 2015; Ricciardi et al., 2015; Adjagba et al., 2017). Decision-making processes, both within NITAGs and more broadly within national governments, are less clear (Bryson et al., 2010; Gessner et al., 2010; Ricciardi et al., 2015). This aspect of their work is increasingly being recognised as critical to NITAG effectiveness, particularly as they move beyond basic functioning; yet, the role of different actors in strengthening evidence-informed decision-making processes is not well defined.

First on Adjagba et al.'s (2015) list of recommendations for creating and strengthening future NITAGs is to reinforce institutional integration to promote sustainability and credibility. They use the term 'careful positioning' of the NITAG in the decision-making process (2015: 594). Similarly, the SIVAC evaluation noted that NITAGs 'need to be integrated in decision-making processes in a way that balances independence and influence' but there was 'little consensus on how NITAGs could better complement other decision-making bodies' like Inter-agency Coordinating Committees (ICCs) or Health Technology Assessment (HTA) (Howard et al., 2018: 1540).

The scoping exercise aimed to advance thinking and multi-stakeholder dialogue about these issues and to identify concrete next steps that could be taken by different actors. For NITAGs and other national stakeholders, these actions

1 The WHO defines a functional NITAG as meeting the following process indicators: (1) legislative or administrative basis for the advisory group; (2) formal written terms of reference; (3) at least five different areas of expertise represented among core members; (4) at least one meeting per year; (5) circulation of the agenda and background documents at least one week prior to meetings; (6) mandatory disclosure of any conflict of interest. For small countries, the GVAP goal may be met through a regional body (Regional Immunisation Technical Advisory Group (RITAG)). As of 2016, 83 WHO member states met all six criteria, 122 met the first or second criteria, and 129 countries reported the existence of a NITAG (WHO, 2017).

related to strengthening relationships, including establishing institutional linkages, formalising the post-recommendation process with their respective ministries of health (MoHs) and demonstrating the value of NITAGs in evidence-informed decision-making. For donors, key next steps included clearly communicating what could be funded and how to access these resources. Reciprocally for the WHO, this entailed clarifying the funding request to donors and developing an investment case, with defined national, regional and global activities, costs and value.

It is important to note at the outset that discussions regarding the future of NITAGs are situated within larger transitions at national and international levels, and developments in evidence-informed decision-making more broadly. Relative to the Millennium Development Goals (MDGs), the wide-ranging SDG agenda – which includes efforts to expand universal health coverage (UHC) as the cornerstone of the health SDG – has brought a stronger systems orientation to development and raised a much more expansive set of issue areas for national governments to address. At the same time, Gavi and other global health initiatives have begun transitioning countries off external support (Silverman, 2018). As such, governments are having to prioritise between more investments than existing national resources may be able to cover.

In parallel, over the last decade there has been heightened attention in international development paid to the role evidence can play in these decision-making processes (Shaxson et al., 2016). Indeed, the rapid growth of NITAGs can be seen as reflective of these dual trends towards increased national ownership and evidence-informed decision-making. More recently, the WHO has initiated discussions regarding the use of HTA within the context of UHC, as a policy tool for systematically evaluating the properties, effects and impacts of health interventions in order to allocate finite resources and ensure equitable access (WHO, 2016). Although HTA is not a new approach, its use in low- and middle-income countries has been limited, and is rarely conducted through a formal, independent body (Kriza et al., 2014; Babigumira, 2016; Siegfried et al., 2017). Efforts to support the next phase of NITAG development, therefore, must take place within these broader considerations that affect NITAGs directly, and indirectly, through the enabling environment in which they work.

2 Approach

The core activity of this scoping exercise was a two-day NITAG stakeholder workshop at Wellcome Trust in London in October 2018, which aimed to develop a shared vision among participants of NITAG functionality and sustainability, and to articulate the processes of change towards these goals (Annex A). Preparatory work ahead of the meeting included a rapid document review (Annex B); in-person and remote consultations with Geneva-based WHO staff supporting NITAGs and the Global NITAG Network (GNN), two of whom had previously worked for SIVAC; and semi-structured telephone interviews with NITAGs in nine countries, including GNN members. The country interviews aimed to better understand future opportunities and challenges for different types of NITAGs, the types of support that would be most useful, national decision-making processes and the NITAGs' relationships to other groups, including their respective MoHs. This set of countries was identified by the WHO and covered a range of income groups, regions and Gavi eligibility and transitioning status. These NITAGs also varied in their date of establishment from the mid-1960s to 2013. Overall, the NITAGs present at the London workshop and many of those interviewed represent more established groups; the experiences of new NITAGs and those operating in fragile and conflict-affected settings may be different.

Using the data gathered during the interviews and the document review, we created draft diagrams illustrating pathways of change, which served as the basis for group discussions at the October workshop. These diagrams aimed to help participants jointly conceptualise pathways through which particular outcomes could be achieved. Identifying key steps and relationships can help to surface gaps and assumptions, and clarify points of agreement and disagreement. These visual representations provide a road map for change processes, and can be used to guide and monitor progress towards intended goals, and to communicate these processes to others. They aim to distil core elements of change processes and, as such, are simplified depictions of what are often quite complex processes. We used a nested approach, developing separate diagrams for distinct areas that then feed into one another.

Each diagram illustrated ways in which NITAGs could work towards: (1) secured funding; (2) adequate support from the secretariat; (3) independence; (4) recognition by relevant stakeholders; (5) evidence-informed decision-making processes within the NITAG itself; and (6) within broader evidence-informed decision-making processes at the national level. These priority areas were identified by the WHO, and the wording and specific steps along these change processes were taken directly from the NITAG simplified assessment tool, which identifies 22 indicators of NITAG functionality, quality and integration into decision-making processes.

Each of the pathways of change was interrogated and revised during the workshop. Participants also identified different possible types (what), mechanisms (how) and sources (who) of support that could help NITAGs work towards these outcomes in the coming years, and revised an additional pathway of change around one particular means through which support could be offered: the creation of a regional support hub. The primary changes made to the pathways of change during the workshop related to the nature of interactions between NITAGs and other stakeholders, the need to demonstrate NITAGs' impact and value, the role of capacity-building in strengthening evidence-informed decision-making and use of an evidence-to-recommendation framework, and distinctions between technical and administrative secretariat functions.

Following the workshop, we conducted interviews with two additional countries to understand in greater depth the role of NITAGs

in national decision-making processes and their relationships with other bodies, including those involved in HTA efforts, which had not been explicitly raised previously. This report presents the perspectives of workshop participants and interviewees, and our analysis of the constraints and opportunities for NITAGs at this time. The subsequent sections of this report present the pathways of change, potential future roles and support options for NITAGs. The final section highlights key actions for donors, the WHO and the GNN.

3 What is the role of NITAGs in national health decision-making?

NITAGs provide evidence-informed recommendations related to immunisation issues, which can serve to strengthen health policy and programmes, with the ultimate goal of improving population health. NITAGs are embedded within a broader decision-making process through which they interact with core national institutions, predominantly the ministry of health (MoH). Other groups may engage in national processes as well, including professional associations, citizens' groups, private industry, academia and other advisory and issue-specific groups or initiatives.

Figures 1 and 2 present nested evidence-informed decision-making processes, whereby a policy question or need is identified for the NITAG to review, the NITAG follows a series of steps to issue an evidence-informed recommendation, which is then considered as part of a broader national policy process, where it may be weighed relative to other health investments and priorities in other ministries. The diagrams are not meant to be prescriptive, but rather reflect NITAG intentions of how evidence-informed decisions could be made. Each country context and NITAG is unique and specific country processes will certainly vary.

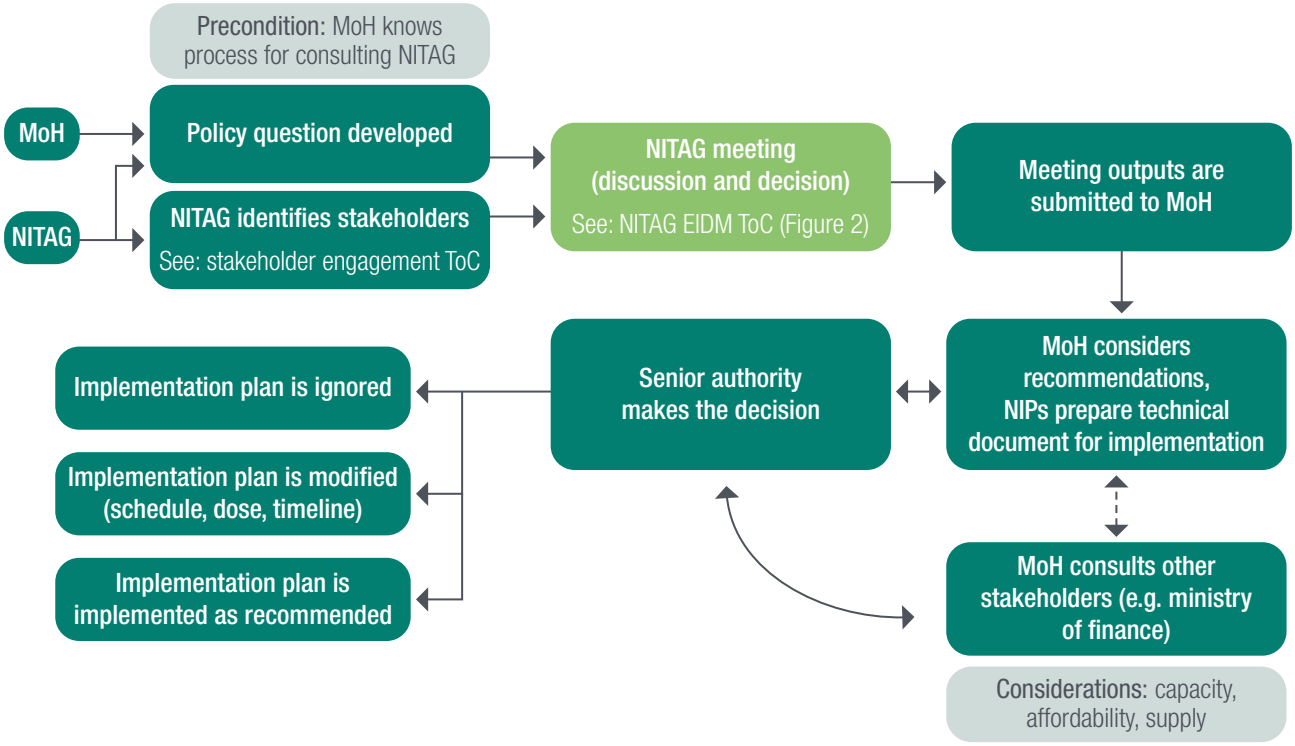
3.1 The national evidence-informed decision-making process

As illustrated in Figure 1, NITAGs typically enter into this decision-making process in one of two ways: a policy question or need may be identified by the MoH and the NITAG will be asked to advise on the matter; alternatively, the NITAG will identify an issue that it feels should be raised with the MoH. As a precondition for these initial steps to be taken, officials at the MoH must be aware of the existence and the role of the NITAG, and of the process for issuing a request and responding to a recommendation. Following the ministerial decree that establishes the NITAG, these additional processes will need to be developed and interpersonal relationships cultivated with key people at the MoH. To some extent, this sensitisation and relationship-building process will be an ongoing endeavour as staff change over time.

Once a policy question has been identified, the NITAG will then follow its own internal evidence-informed decision-making process, illustrated in Figure 2 and discussed in greater depth in the following subsection. Once they have reached a decision, the NITAG will then submit written recommendations to a designated high-level official in the MoH. In order for NITAG recommendations to be actionable, there must be an adequate supply of the vaccine, it must be affordable and there must be sufficient institutional capacity to implement the vaccine schedule.

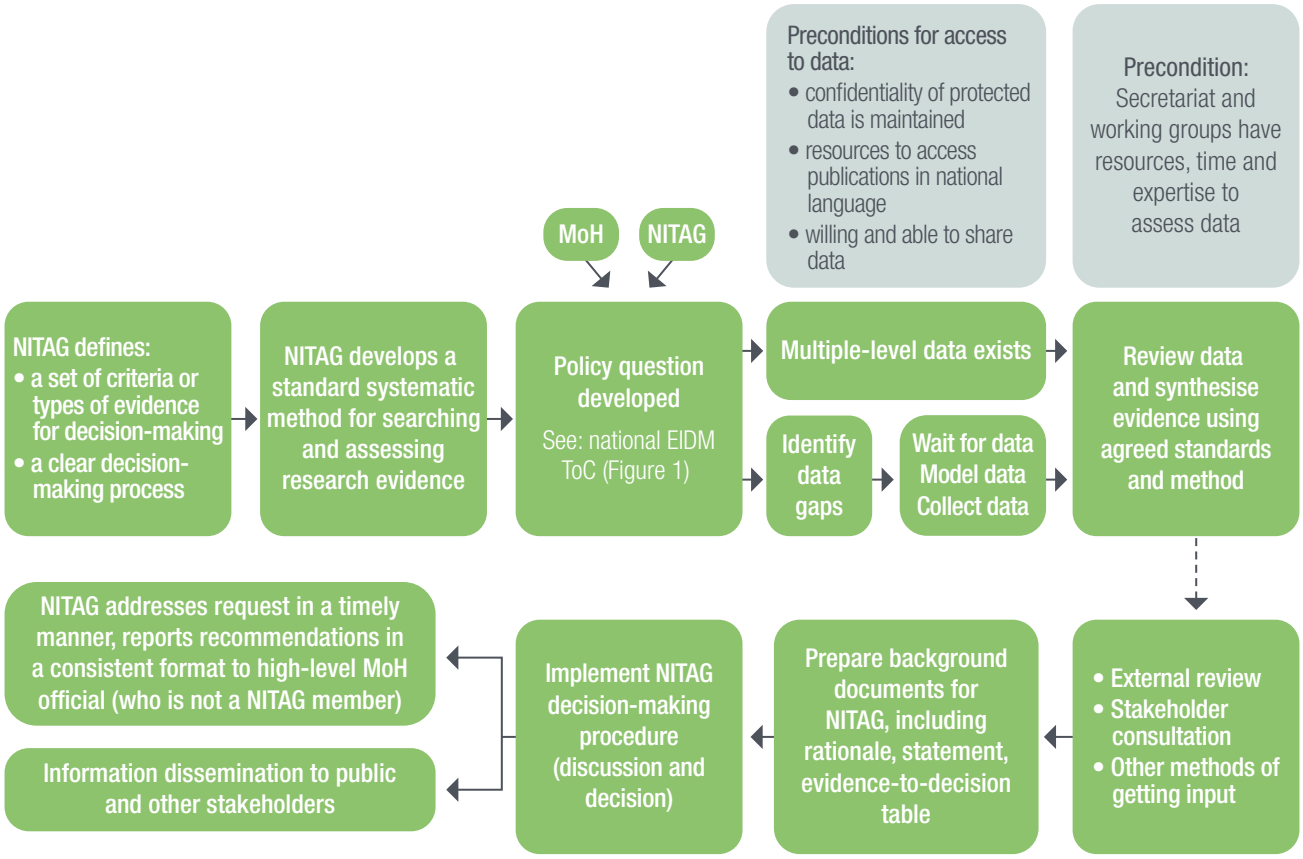
As the MoH considers the NITAG recommendation, the National Immunisation Programme (NIP) will prepare technical documents to guide implementation, so it is clear what would be required if the recommendation is approved. The MoH may also consult other relevant stakeholders, particularly the ministry of finance (MoF). A senior authority will then choose one of three courses of action: execute the implementation plan as recommended, ignore the implementation plan and the NITAG's recommendation, or modify the plan, which may involve changing the vaccine schedule.

Figure 1 Illustrative national evidence-informed decision-making process



Note: as articulated by workshop participants. NIP=National Immunisation Programme

Figure 2 Illustrative NITAG evidence-informed decision-making process



Note: as articulated by workshop participants.

3.2 The NITAG evidence-informed decision-making process

As illustrated in Figure 2, the process for the NITAG to issue evidence-informed recommendations begins by establishing procedures: defining a set of criteria or types of evidence and a clear assessment and decision-making process, including a standard, systematic method for searching and assessing evidence. Once a policy question is developed, these procedures are then applied. The background evidence review is dependent on the existence of multiple-level data (i.e. national statistics, surveillance data, national or regional studies), identification of where gaps exist and a strategy to address these gaps. This may involve waiting for data to become available, modelling projected effects and/or collecting new data. Accessing data requires resources to obtain publications, including those in the national language, the willingness and ability of data holders to share their information, and procedures for maintaining the confidentiality of protected data. Even if data is available, the NITAG secretariat and technical working groups (TWGs) must have the resources, time and expertise to access it, apply a standard, systematic method to review and synthesise the body of evidence, and prepare background documents for the NITAG to discuss. Preparation of these documents may also involve stakeholder consultation, external review or other inputs. The NITAG will then deliberate and reach a decision according to the defined decision-making procedure.

3.3 Decision-making processes in practice

The selected set of country interviews offers insights into how these processes manifest themselves in practice and vary across different national contexts.

For newer NITAGs and those in lower income countries, the process tended to begin with a request from the MoH, rather than the NITAG initiating evidence inquiries and recommendations themselves – although they expressed a desire to be more proactive in this way in the future. More established NITAGs offered examples where they issued recommendations in response to disease outbreaks, considered vaccines in the pipeline and identified other issues they perceived as needing attention. In two additional cases, the NITAG review and decision-making process was initiated by regional recommendations and through conversations between the NITAG and the National Regulatory Authority. The initial request process was often formal, but not always. An MoH may make a verbal request in a meeting, for instance. During the workshop, participants discussed the opportunity to incorporate recommendations from the Strategic Advisory Group of Experts on Immunization (SAGE) in planning NITAG activities. After SAGE recommendations are made, Regional Immunisation Technical Advisory Groups (RITAGs) could be charged with distilling regional implications and NITAGs could subsequently discuss the national implications.

To address the policy question, in the countries with which we spoke, TWGs often conducted the background review and assessment. The process of evidence synthesis is resource intensive and requires a specific skill set. This initial review step was followed by a meeting of the full NITAG to deliberate and reach a decision.

In terms of the types of evidence required, NITAGs are clear about what they need. Scientific evidence appears to be considered first, with economic analyses considered at a later stage, still informing the NITAG's recommendation. Many interviewees also mentioned looking to WHO guidance as part of the evidence review process.

There were no examples of having to resolve conflicting pieces of evidence. In some cases, existing evidence may be considered to be insufficient to make a decision, in which case the NITAG may decide to gather more evidence, or to launch and carefully evaluate a demonstration project before making a more comprehensive recommendation. Multiple articles have highlighted cost-effectiveness and economic analysis data as being particularly lacking; this concern did not emerge as a prominent theme in the interviews. Workshop participants discussed the need for NITAGs to solicit the MoH for improved access to and higher quality surveillance data as a key piece of evidence for decision-making.

In terms of evidence assessment, application of a systematic approach (i.e. GRADE: Grading of Recommendations Assessment, Development, and Evaluation) appears uncommon. Indeed, among European NITAGs, use of systematic reviews was required by 58% of the 26 NITAGs surveyed; 19% used quality appraisal tools for systematic reviews, and only 15% the GRADE methodology specifically (Hombach, 2018 citing Takla et al., 2015). Workshop participants mentioned that, in the context of imperfect or little information, it was often not feasible to use this framework. NITAGs use the information that is available to them; even where evidence gaps are clear, they may not have the resources to fill those gaps (i.e. commission new studies). Interviewees did not mention the use of a standardised evidence-to-recommendation framework, which was raised at the workshop as an important but underused tool.

Multiple countries characterised the internal NITAG decision-making process and their interactions with the MoH (and in some cases MoF) as iterative processes. In one example, a newer NITAG developed its workplan with the MoH so that prioritisation discussions began from the outset. In several countries, information requests and dialogue between the NITAG and ministries continued after a recommendation was issued. For example, the MoF may follow up with the NITAG to ask for further cost–benefit analyses. Several interviewees also noted that while more extensive financial calculations may take place following the recommendation, the NITAG was broadly aware of what was financially possible, and also considered implementation logistics and programme capacity when developing recommendations, so that they were in line with what the NITAG thought would be financially and institutionally feasible.

Two middle-income countries emphasised the importance of demonstrating national burden of disease to justify the investment of introducing a new vaccine. One noted that they do not recommend a vaccine simply because it is available; the allocation of public resources for a vaccine rather than for other priorities must be warranted. A populous middle-income country with a local manufacturer assessed its ability to produce a sufficient supply of the vaccine under consideration and the feasibility of technology transfer as central to their deliberation process. A small country that had recently transitioned out of Gavi support emphasised the importance of having a separate budget for vaccines and a line item specifically for vaccine procurement to ensure that these resources did not get diverted elsewhere.

Countries varied in the extent to which the NITAG has direct interactions with the MoF, or whether these interactions took place through the MoH. They also varied in terms of the number of bodies from which approval needed to be granted. In some cases, the ministries could make the final decision. In others, a recommendation needed additional approval by the national development planning bureau and/or the parliament. Interviewees were not familiar with HTA processes and did not discuss specific bodies tasked with prioritising national resources, other than the ministries.

In one country, the national MoH and MoF would approve, finance and roll out the introduction of new vaccines for the first two years, after which time provinces would be responsible for both financing and implementation. The NITAG was not involved in these subsequent subnational processes. Another country was in the midst of a decentralisation process and expressed uncertainty regarding the extent to which that would affect the NITAG's membership (i.e. requests for provincial representatives), role and/or the implementation of its recommendations.

There were no examples of contestation over NITAG recommendations. When asked to give an example of when a recommendation was not adopted, interviewees indicated that it was always for financial reasons rather than substantive disagreements with the recommendation itself. Workshop participants identified one outcome as the 'implementation plan is ignored'. Interviewees spoke instead of implementation delays, which varied from several years to a decade or more. Financial constraints may also contribute to modifications of a NITAG recommendation: reducing the number of doses, for example. A decision may be affected by the timing of the recommendation in the fiscal cycle, in which case implementation may be planned for the following cycle. The NITAG's ability to make

recommendations may also be affected by short timelines, when an MoH deadline does not allow sufficient time (typically several months) for the NITAG to establish a working group, synthesise and assess the evidence, and develop a recommendation.

The role of Gavi at this phase of the process was raised by several interviewees. In one case, after the MoH had initially rejected the NITAG recommendations, Gavi assurance of funding resulted in the fractional inactivated polio vaccine (IPV) recommendations being adopted by the MoH. In another country, the MoH saw an opportunity to secure Gavi funding and faced a deadline for this request, so they did not consult the NITAG for its recommendations. In a third instance, the human papilloma virus (HPV) vaccine was implemented because of a Gavi requirement, rather than a NITAG recommendation. In some cases, at the beginning of the national decision-making process, once the government identifies the potential need for a new vaccine, they initiate negotiations with Gavi to first ensure that funding is available before consulting the NITAG to offer their technical recommendations.

In contrast to the initial request, which was typically formalised, the follow-up process once a recommendation was issued by the NITAG to the MoH appeared to be informal or undefined. Several interviewees were unclear about the extent to which NITAG communications were subsequently shared throughout the MoH with all the relevant people; uncertain whether or not action was being taken on a previous recommendation; and confused about whether a recommendation was not going to be recommended or would simply take time before it would be implemented.

Taken together, these experiences of evidence-informed decision-making in practice highlight four key themes. First, these processes are iterative in nature and vary cross-nationally. Second, there is little contestation over types of evidence and NITAG assessments and recommendations, which is not always the case in other issue areas.[2] Third, finances play a central role in the implementation of recommendations. And finally, while NITAGs are technical advisory groups oriented around scientific evidence, they may have to make decisions based on incomplete evidence, and they operate within political processes. We now turn to factors that enable and constrain NITAGs' ability to advance evidence-informed decision-making.

2 The lack of contestation may in part reflect the countries selected for interviews. Adjagba and colleagues (2015) observed that competition and mistrust between ministries and between the MoH and the NITAG has blocked the establishment of some NITAGs. In general, there is a greater consensus on methods and types of evidence in the health sector compared to other fields like international development.

4 What enables and constrains NITAGs' ability to fulfil their mandate?

If the core mandate of NITAGs is for multidisciplinary groups of national experts to provide independent, evidence-informed advice to policy-makers on issues related to immunisation – as illustrated in the previous section – several core elements are perceived to be necessary for them to be able to fulfil this role. As framed by workshop participants, a NITAG should:

- be sustainable through secured, adequate funding
- receive adequate support from the secretariat for conducting activities
- issue independent recommendations
- interact with stakeholders in a trustful and mutually engaged way
- implement its own evidence-informed decision-making procedures in a timely manner, reporting recommendations in a consistent format to a designated high-level official in the MoH.

When NITAGs have the funding and capacity to gather and analyse information, deliberate and make recommendations without conflicts of interest, and interact with relevant stakeholders, they are then able to act as an influential advisory body in national health decision-making processes. The five elements listed above are interdependent, and without any one dimension the intended role of NITAGs may be compromised. That said, like all groups and organisations, NITAGs go through a developmental process, and their functioning, quality and integration into policy processes typically evolve and deepen over time, as has been the case with older NITAGs (Duclos, 2010). These elements do, however, require continuous inputs and are not 'completed' at a single point in time.

The pathways or theories of change leading to each of these areas, as refined in the workshop, are included in Annex C and briefly summarised in turn below. These pathways reflect steps that a NITAG could take and, in some cases, has taken in order to support each enabling area. Specific roles for different actors are discussed in the section 'How could NITAGs be strengthened to fulfil their mandate?' As in the previous section, we describe how these processes have played out in different countries. Since the NITAG evidence-informed decision-making procedures were covered above, this section focuses on the remaining four areas.

First, NITAG sustainability requires **secured adequate funding**, with the aim of having at least one full-time secretariat post based in the MoH,[3] with a line item in the budget. The assumption is that high-income countries should be able to cover NITAG activities within their MoH budgets. In order to secure this funding, the secretariat must create a work plan based on a national needs assessment, identify potential sources of funding for different activities (which could include national and international sources) and submit proposals for this work (see Annex C: Figure C.1).

3 In some countries, it may be more feasible for the funds for this post to be channelled through a professional association or non-governmental organisation (NGO) rather than directly through the MoH, for contractual reasons.

Workshop participants viewed the ability of a NITAG to secure funding as a reflection of its demonstrated value and recognition as an authoritative body. They saw a role for more evaluations of NITAGs' work and assessments of their cost-effectiveness and value for money as a way to enhance their recognition by the MoH. In turn, this was thought to increase buy-in and financial investment in the NITAG. Developing country-specific investment cases is also a key next step to secure funding from international sources, and was considered to be time sensitive, within an increasingly crowded health landscape, in order to capitalise on the recent momentum NITAGs have generated.

Country interviews echoed findings from the SIVAC evaluation (Howard et al., 2018) that secured funding for one secretariat staff member was not currently feasible for many MoH budgets. In all the low-income countries with which we spoke, NITAG activities are supported through external funds, and secretariat staff time is typically shared with other programmes rather than there being one full-time person dedicated to the NITAG. These interviewees expressed concerns regarding sustainable funding for a secretariat in the future. In one low middle-income and one upper middle-income country, NITAG activities are supported by the US Centers for Disease Control and Prevention (CDC). In other middle- and high-income countries with which we spoke, core NITAG activities are indeed funded directly through MoH budgets. In some cases, these countries rely upon external funds for international travel – to GNN meetings, for example – since travel funds are not available through the ministry.

Second, NITAG functioning also requires **adequate support from the secretariat.** Workshop participants identified administrative secretariat functions such as taking minutes and organising meetings, as well as the ability to prioritise agenda items, engage experts and maintain internal and external communication. They distinguished these skills from technical or scientific secretariat functions, which require staff time to attend meetings and conduct activities, and particularly the ability to source and analyse evidence, and develop background documents for the NITAG to review and discuss (see Annex C: Figure C.2).

Countries that lack a full-time secretariat indicated that the constraint was financial, rather than the lack of people with these required skill sets. Higher-income countries spoke more about the need for a stronger scientific secretariat function, again more related to finances and time. Some countries have collaborated with universities to supplement this function, so that literature reviews are conducted by students. One chair mentioned learning about a NITAG librarian post in a neighbouring country from which they have received training and expressed a desire for this type of resource to assist with evidence synthesis.

The third area – NITAGs issue **independent recommendations** – requires that the group be independent from special interest groups and from the MoH, and follow a systematic process for making evidence-based recommendations. The former requires terms of reference, a defined membership selection process and standard operating protocols, which specify that NITAG core members are not under the direct authority of the MoH and that the chair and core members serve in their own capacity as individuals, rather than as representatives of institutions. Moreover, the NITAG must present and manage conflicts of interest, both apparent and real (see Annex C: Figure C.3).

Multiple countries found the term 'independence' problematic and instead characterised their relationship with the MoH as interdependent.[4] They clarified the relationship as working 'with' rather than 'for' the ministry, with neither entity giving or taking orders from the

4 One country with which we spoke has had an embedded NITAG located within the MoH for more than 50 years. The membership (n = 38) and mandate of this group is much larger than most NITAGs, covering communicable diseases more broadly. Their embeddedness was perceived to be an advantage, in that the NITAG recommendation is in fact *the* authoritative decision, which ensured implementation. Furthermore, immunisation is considered as part of broader prevention strategies and discussed alongside other communicable disease issues, rather than separately. They felt the breadth of representation included in the NITAG enabled meaningful debate and discussion, which limited biased decisions.

other, and with the MoH not having power over NITAG members. Therefore, they interpreted the NITAG's ability to issue independent decisions as more about managing conflicts of interest and strengthening evidence-informed decision-making processes. One country highlighted the importance of the chair's ability to convene meetings as needed and lead the membership recruitment process.

Interviewees and workshop participants noted that in both low- and high-income countries many NITAG members are involved in vaccine trials in some way, which may exclude a large proportion of the available pool of national vaccines experts in certain decisions. In some cases, members do not have an understanding of what a conflict of interest entails and therefore do not declare it. For some countries, an issue that remains contentious is the inclusion of representatives from industry and the question of how this can be reconciled with their conflict of interest.

Finally, the fourth enabling area is a **trustful, mutually engaging relationship with key immunisation stakeholders.** Workshop participants characterised this as a two-way communication process on key issues and agenda topics, technical matters, draft recommendations, vaccines under development and implementation issues. This process is expected to enhance the adoption of NITAG recommendations and facilitate dissemination and implementation of recommendations. Establishing these relationships requires the NITAG to identify key stakeholders and their (potential) roles, for example, as a liaison member, ex officio, working group member or external reviewer. Participants envisioned this engagement throughout the decision-making process, with the secretariat taking the lead on external stakeholder engagement before recommendations are made and NITAG members being responsible for engagement after recommendations are issued, collaborating with others to disseminate and communicate the advice (see Annex C: Figure C.4).

Workshop participants identified eight stakeholder groups: professional societies or associations, academia, civil society and NGOs, the general public, subnational health structures, other government entities (i.e. regulators, department of defence), funders and industry.[5] In practice, NITAG relationships with stakeholder groups outside the government appear to be focused on the first two groups and predominantly driven by member representation. These relationships are linked through particular NITAG members who are active in professional associations, who work for universities or who sit on other advisory committees. NITAGs may draw on the expertise of academics and members of professional associations (paediatric associations were mentioned most often), but this is typically done on an as-needed, individual basis, rather than through formal institutional relationships. One interviewee noted the importance of informal communication for stakeholder engagement, as a means of creating trust.

There was no evidence of overt conflict between the NITAG and other entities, or divergence of recommendations. One country noted that the paediatric association recommended a longer list of vaccines than are on the current government schedule. There were no examples of direct NITAG interaction with other national advisory bodies, and some interviewees were unclear as to ICC processes. In several middle-income countries, interviewees mentioned a growing role of the private sector in health care. Some NITAGs may call on individual industry experts as part of evidence gathering and review processes, but NITAG interactions appear to be less common with this sector.

5 Mounier-Jack et al. (2017) identified the following programmes supporting decision-making for new interventions/ vaccines in low- and middle-income countries: WHO, Gavi, US CDC, iDSI (BMGF, DFID, RF), PATH, ProVac (BMGF, PAHO), WHO SAGE, RITAGs, NITAGs, other regional bodies (cited in Cook, 2018).

These experiences reflect much of what has already been identified in the literature.[6] The recent SAGE review of NITAG activities, too, notes similar constraints, including lack of funding, workplans, assessment of conflict of interest and human resources, insufficient training on evidence-based review processes, limited access to literature and publications (including as a result of language) and recognition of the NITAG by the MoH (Hombach, 2018 citing WHO, 2017).

Thus, there appears to be a shared understanding of NITAGs' core mandate, enabling areas, and key factors – some persistent – which constrain NITAGs' ability to function as intended.

6 Previous articles have highlighted gaps in the five core enabling areas: (1) funding; (2) human resources in NITAG secretariats; (3) management of conflicts of interest from manufacturers, MoH and WHO; (4) NITAG decision-making processes including transparency, data availability, quality review of evidence and routine incorporation of affordability aspects; and (5) relationships with MoH, other advisory groups, professional associations and subnational authorities (Gessner et al., 2010; John, 2010; Senouci et al., 2010; Brenzel, 2012; Duclos et al., 2013; Adjagba et al., 2015; Howard et al., 2018).

5 What potential future roles do NITAGs envision for themselves?

Looking forward, the end of SIVAC marks a transition point for NITAGs. Since 2000, there has been a rapid uptake of new vaccines (Kallenberg et al., 2016) and, as noted at the outset, the number of NITAGs has doubled in the last decade. The Global NITAG Network was formed, and regional and bilateral interactions among NITAGs have increased. Moving from a phase of establishment and new vaccine introduction, the next phase for NITAGs created in the last decade could be characterised as one of embedding and expansion.[7]

When asked where they saw NITAGs in the next 5–10 years, the most prominent theme among workshop participants and interviewees was strengthening relationships with other entities, particularly the MoH, and further integrating NITAG activities in national decision-making processes. They would like to see greater visibility of NITAGs in the health sector, continuous communication with EPI (Expanded Programme on Immunization) programmes and MoHs, and enjoying the trust of the medical fraternity and the confidence of the general population. They envisioned NITAGs integrated into national research agendas, which in part could help build capacity and attract scientists.

Most countries expressed a desire to expand their NITAG's current role in various ways. Some indicated that they would like to be more proactive in identifying issues rather than solely responding to ministry requests. NITAGs that had been established for a longer period characterised a shift from previous emphasis on new vaccine introduction to modifications of existing vaccines schedules, and expanding the focus beyond the EPI programme to look at vaccines for adolescents (which has already begun with recent HPV vaccine introductions), the elderly and adults. Some NITAGs indicated a desire to be more engaged in matters beyond the point of issuing a recommendation, concerned with whether and how the recommendation was implemented, including vaccine coverage rates. Others were clear about the bounded nature of the NITAG's scope, ending with a recommendation, although they acknowledged that the success of the NITAG was largely reflected in the implementation of their recommendations.

Interviewees and workshop participants also expressed a desire for more frequent communication, peer support, knowledge sharing and documentation of experiences, both within and across countries.

7 We distinguish between an establishment phase and an embedding and expansion phase to highlight a desired shift expressed by stakeholders involved in this scoping exercise, and changes in the broader immunisation landscape identified in the literature, from a dominant orientation in previous years towards new vaccine introduction and establishment of new NITAGs to a desire to be further integrated in national processes and address a broader range of vaccine-related matters. Some of the activities involved in both 'phases' are ongoing (i.e. training, networking, engagement in national processes). Moreover, this characterisation reflects NITAGs where previous support has primarily been directed. Some NITAGs have been functioning for more than half a century. Another 69 countries do not currently have, or have access to, a NITAG.

In terms of future changes and improvements, lower-income countries reiterated the importance of adequate funding for a dedicated NITAG secretariat position as crucial to their future. NITAG capacity for evidence-informed decision-making was a prominent theme in workshop discussions, including the capacity to conduct research, access to information and the ability to synthesise this evidence. They noted that, while NITAGs' credibility is based on evidence-informed decision-making, the extent to which individual groups have the capacity to uphold these high standards varies considerably. To a much lesser extent, interviewees mentioned strengthening internal NITAG decision-making processes or adopting GRADE, when the evidence base was strong enough to apply this framework. When the evidence base was weaker, several countries mentioned they would need additional funding to commission or conduct research studies. Workshop participants raised the possibility of alternatives to GRADE so as not to disregard 'good enough' evidence.

These aspirations for NITAGs are set within a broader context that is also in the midst of multiple transitions. Interviewees mentioned future NITAG challenges as related to the implementation of their recommendations and functioning of the EPI programme, both of which were outside their direct control. Even more broadly, they identified factors that affect the availability of national and international resources, MoH functioning and, indirectly, NITAGs' work: for example, Argentina's currency drop in September 2018, Nepal's decentralisation processes, Jordan's responsibilities for Syrian refugees, and potential future country reclassifications as income levels rise, with corresponding implications for external funding.[8] Thus, there appears to be a shared recognition of the interdependence of NITAG activities, immunisation programmes, health systems and broader national and international factors. Exactly how to approach some of these bigger challenges remains an open question.

8 Indeed, the GVAP highlighted many of these factors as influencing the context in which decisions are made and vaccines delivered: economic uncertainty, conflicts and natural disasters, displacement and migration, and infectious disease outbreaks, as well as growing levels of vaccine hesitancy and stockouts (WHO, 2017). Within the field of vaccines itself, Adjagba and colleagues (2015) characterise the arena as becoming more complex in terms of vaccine schedules, expansion of focus from children to other population groups, a growing number of manufacturers, and pricing that varies according to supply, demand and ability to pay. SAGE has emphasised the need for a multidimensional, system-wide approach that aligns immunisation with broader efforts related to the SDGs, health system strengthening and universal health coverage and antimicrobial resistance efforts (WHO, 2017), echoing Brenzel's (2012) assertion that planning and budgeting for NIPs cannot be done in isolation from the rest of the health system.

6 How could NITAGs be strengthened to fulfil their mandate?

To enable this next phase of NITAG development, there are multiple courses ahead, some more immediately actionable than others. Previous research and recent GVAP and SAGE recommendations have identified support needs and options, including activities offered through SIVAC, intended to strengthen three *types of capacity*: organisational and administrative, relational, and technical.[9] They classify multiple *channels or mechanisms* that could and have been used to strengthen these capacities, such as exchange visits and study tours, co-analysis, contracting national or international consultants, accessing a pool of trainers and evaluators, twinning, and cross-national, regional and global collaboration. *Sources* of support include other NITAGs, other national organisations, RITAGs, donors, international organisations and the GNN.[10]

Four areas of support are comparatively straightforward and actionable in the short to medium term. These are not new areas of need and efforts to address most are underway to varying degrees; however, as Howard et al. (2018) note, if they are not addressed, they threaten NITAG sustainability and could potentially undermine previous investments. To borrow terminology from the MDGs, these areas of support represent the unfinished agenda of the establishment phase of this recent NITAG era. We then turn to support needs related to the next phase of NITAG development, embedding and expansion. Annex D presents support options that workshop participants identified in relation to national evidence-informed decision-making processes and the NITAG enabling areas.

9 *Organisational and administrative capacity* includes meeting logistics and invitations, following standard operating procedures and a visible and physical secretariat office with an experienced immunisation professional. *Relational capacity* relates to the ability to prioritise agenda items, reach consensus, have the authority to engage academic personnel and form working groups and maintain strong communication channels with relevant stakeholders, particularly the EPI programme manager. *Technical capacity* requires the skills to identify available data, coordinate appropriate evidence and technical background documents for review, properly assess immunisation situations (including evaluating the implications for the organisation, infrastructure and finances), define target populations, develop structured recommendations, evaluate NITAG outputs and outcomes, respond to a tender to obtain funding for a study, and conduct horizon scanning to develop surveillance in advance of licensure and research on costs or current burden of disease (Hall, 2010; Senouci et al., 2010; Adjagba et al., 2015, 2017; Howard et al., 2018).

10 In the last year, GVAP and SAGE have made similar recommendations in terms of future NITAG strengthening, including technical capacity-building by levering regional and national expertise, global tools and resources, WHO regional office support to promote information exchange and peer support (WHO, 2017), tailored guidance, mentoring, support in expanding NITAGs' scope beyond introduction of new vaccines to include critical review and optimisation of existing vaccine programmes, and fostering collaborations between countries and at regional and global level (Hombach, 2018 citing WHO, 2017).

6.1 Supporting the unfinished agenda of the establishment phase of NITAGs

This first set of NITAG support options will help to enable NITAGs' basic functioning and could improve their efficiency and effectiveness. Support needs include:

1. **Financial resources for basic secretariat functioning.** This clearly remains a pressing need for countries whose immunisation programmes are not fully self-sustaining. If it is feasible to fund NITAG activities – particularly a full-time secretariat post – through Gavi's Health System and Immunisation Strengthening fund, this is the most logical mechanism. Discussions about NITAG financial sustainability would then be a part of broader immunisation transition planning, providing a stronger link between NITAGs, the MoH and the MoF.

   For this to take place, donors need to clarify if and how NITAGs can access financial resources for basic secretariat functioning. This may require NITAGs to prepare detailed budgets and to coordinate with MoH staff and/or the WHO so these needs are included as part of broader resource requests. Investment cases are discussed further in the final section on action steps.
2. **Training, coaching and mentoring.** This type of capacity-strengthening support could range from periodic training for new members and short courses on cost-effectiveness to longer term twinning arrangements. Participants noted evidence synthesis (drawing on existing ProVac tools), the role of economic evidence in decision-making, evidence-based processes to develop recommendations, and skills in distilling findings into accessible policy recommendations as particularly important training needs.

   To expand existing training and mentoring, NITAGs need to articulate to the WHO and RITAGs their specific needs and what they are able to offer to other groups. The WHO and RITAGs can play a matching function and/or directly provide this support. NITAGs established within the last decade offer a growing resource to offer practical advice and mentoring to newer NITAGs based in countries whose national contexts may be more similar to their own than long-standing NITAGs in Europe and North America. Examples of these South–South exchanges include Mozambique NITAG support to Angola, Indonesia support to North Korea and Myanmar, Zimbabwe support to Malawi and Sri Lanka support to Timor-Leste. Some NITAGs may be able to offer in-kind support. A modest level of funding may still be required for travel and for the GNN secretariat or RITAGs to provide technical support and facilitate cross-NITAG linkages.
3. **Documenting experiences, sharing lessons and networking across NITAGs.** The recently established GNN provides an excellent platform for horizontal exchanges across NITAGs. Sub-regional networks could be expanded, again with the WHO playing an initial matching function, but sustained interaction would need to be driven by NITAGs themselves.

   Workshop participants and some interviewees expressed a strong desire for more documentation of NITAG activities, impacts (reductions in vaccine-preventable disease) and estimates of their value for money. These assessments could be presented as short briefs to enable NITAGs to learn from one another, as well as improve awareness and demonstrate their value to national decision-makers and the broader public. If these efforts are pursued, it will be important to distinguish communication products explicitly aimed at showcasing success, from a balanced and critical appraisal of NITAG activities, costs and outcomes, which, like all evaluations, is likely to show areas of both achievement and improvement.

   New operational research could also assess the relative value of different training approaches in different contexts. Much of the published research and evaluation on NITAGs to date appears to be focused on a similar set of relatively well-established groups; it may be worth broadening the set of countries to better understand NITAGs in other settings. Further research on how NITAGs relate to national decision-making processes should focus much

more on other actors in these processes: MoH, MoF, subnational entities and other key stakeholder groups (ICC, disease-specific groups, professional associations, universities).

To continue knowledge sharing and networking, the GNN will need to be adequately resourced to cover staff time and expenses associated with convening meetings. Operational research and documentation of NITAG experiences could be coordinated globally so similar questions are being investigated in purposively selected countries, and subsequently researched by national actors, including academics. Similarly, NITAG communication templates could be developed by the WHO and then adapted at the national level. These research and communication activities would require additional funding.

4. **Improving access to tools, guidance documents, research evidence and systematic reviews.** The NITAG Resource Center (NRC) has already made great strides in centralising relevant documents and facilitating access to resources. Workshop participants suggested consolidating core guidance documents and lessons into a NITAG 'bible', including how guidance and training have been adapted in different countries. They also felt that more could be done to leverage academic partnerships and share research and systematic reviews, concerned that NITAGs were duplicating each others' efforts. NITAGs could draw on evidence from neighbouring countries with similar epidemiological contexts, and globally share 'context free' evidence like systematic reviews and data on adverse effects. Interviewees expressed a desire for the latest scientific evidence.

   To further improve access to information, the GNN and RITAGs could proactively disseminate new research and systematic reviews as they become available. Reciprocally, research that is conducted at the national level by universities and ministries should be added to the NRC. Including a request for recent research as part of regular reporting may help to streamline this process. The WHO and the GNN could share background documents from SAGE meetings so that NITAGs are aware of current processes and recommendations.

   As with training and facilitating networks, maintaining an updated repository of resources will require sufficient funding. Given the limited level of staffing at the WHO, expanding the scope of their involvement in any of these latter three areas would require more resources than are currently available.

In addition to types and sources of support, the workshop included a more detailed discussion of one support mechanism in particular: the potential creation of a regional support hub to provide more intensive NITAG support (see Annex C: Figure C.5). Drawing on global guidance and existing material, this hub would aim to build capacity on commissioning and synthesising research and evaluation, facilitate interaction across NITAGs to share good practices and lessons learnt, develop longer-term twinning arrangements and provide in-person and remote support to individual NITAGs on specific issues. For the regional hub to be established, regional needs and priorities would need to be mapped out, based on NITAG support requests, evaluation findings and WHO regional offices and RITAG suggestions. Seed funding for a planning grant could be used for this needs assessment process and to identify potential hub models. Longer-term funding would then need to be secured and a host institution selected through a competitive recruitment process.

Workshop participants and one interviewee also felt that the role of existing RITAGs could be enhanced to support the latter three areas as well. RITAGs could attend the launch of new NITAGs. They could better promote what they can offer to individual countries. This offer could include both advisory and technical support, as well as advocating at the national level for strong NITAG roles, leveraging the high profile of many RITAG members. The WHO should take the lead in clarifying the roles and information flows between the GNN secretariat, RITAGs and the regional support hub.

6.2 Supporting the embedding and expansion phase of NITAG development

As discussed earlier, a key future priority identified by NITAGs is strengthening relationships with different stakeholders, particularly the MoH, and better integrating their work into national decision-making processes, with the aim of increasing the likelihood that their recommendations will be implemented. Support needs related to these priorities are less straightforward than the four areas discussed above. NITAGs face a tension because their success is dependent on factors that have traditionally been beyond their scope (and indeed will remain outside their direct control). Moreover, increasing engagement in policy processes and adopting more of an advocacy orientation is a departure from their positioning as an independent advisory body.

To date, NITAG decision-making processes and recommendations have not been contested. If NITAGs engage more in broader prioritisation processes, they will increasingly face competing priorities. These shifts are underway, and vaccines are already weighed against other potential investments, but NITAGs have been less directly involved in these processes, mostly affected by them. If NITAGs become more integrated in national decision-making processes, their role – and to a certain extent, their ways of working – may change. Strengthening relationships and integration efforts have a large relational element, distinct from the technical and administrative emphasis that has been the focus of much NITAG support in the past. Furthermore, these efforts will need to be driven by NITAGs and other national actors, as there may be limits as to the extent to which external actors can facilitate these changes.

NITAGs' aspiration to expand the scope of their activities – to proactively take up issues, extend to other population groups, convene more working groups, and consider modifications and implementation of vaccines that have already been introduced – will require more members and/or more time from members and the secretariat. NITAGs may quickly reach the limits of a volunteer model if demands on their time exceed what they are able to offer. As institutions lose core funding and some academics face increasing pressure to fund their positions, people's time may become a scarcer resource. Turnover of members who have individual relationships with key external stakeholders may limit the NITAGs' influence if institutional relationships are weak.

Despite these challenges, there are multiple concrete steps that could be taken. NITAGs could **establish institutional relationships** with key bodies – universities, professional associations and other advisory bodies in particular – rather than relying on individual relationships and ad hoc requests. This shift could facilitate the type of two-way, trustful, mutually engaging relationships to which workshop participants aspired. It could also serve as a way to engage different groups throughout the NITAG decision-making process, rather than simply at the end through dissemination activities. This would enable greater information flows and knowledge sharing, which in turn could increase the evidence base on which NITAGs could draw.

NITAGs could also **formalise the post-recommendation process with the MoH**, similar to the initial request process, so that the NITAG is aware that the recommendation has been received and knows what next steps are being taken, if any. In both cases, this formalisation should not be interpreted as neglecting the interpersonal element of relationships and policy processes, which will remain instrumental in facilitating NITAGs' work. These relationship-building efforts will require time, both in terms of person hours and in terms of building trust.

As noted, there was a strong desire among workshop participants to **demonstrate the contribution and value of NITAGs** to national decision-makers. The accessible briefs could highlight their role and achievements. Documenting the process by which recommendations are generated would enhance the transparency of NITAGs' work, which was thought would build public trust, particularly in countries where vaccine hesitancy presents a challenge. Relatedly, the NITAG could engage the media to raise its profile. This would require a communication strategy, media training and guidelines on who could communicate on the group's behalf (i.e. only the chair).

Workshop participants also suggested that NITAGs **leverage experts** and external contacts from established NITAGs who are integrated in national decision-making to meet with governments where NITAGs are less involved in vaccine decisions. They can draw on well-respected academics to increase the profile of the NITAG, including recruiting them as members as a potential way to enhance the group's influence.

Participants suggested that NITAGs **capitalise on EPI programme activities and processes** – for instance, including a review of the NITAG as part of EPI reviews. NITAGs could be codified within the EPI programme and/or seek legislation to support the process of implementing recommendations. The NITAG chair and the EPI manager could jointly present the work of the NITAG to other colleagues in the MoH.

The growing evidence base on the use of evidence to inform decision-making has identified individual, interpersonal, institutional and broader contextual factors that can facilitate and hinder evidence use (Orton et al., 2011; Sumner et al., 2011; Liverani et al., 2013; Oliver et al., 2014; Punton, 2016).[11] It highlights the salience of national context and extent of cross-national variation (Woelk et al., 2009; Nutley et al., 2010; Rodríguez et al., 2015). This work underscores that there is not one support option to strengthen evidence-informed decision-making processes.[12] Indeed, a panel discussion at the 2017 GNN meeting in Berlin illustrated the differences in how NITAGs in different country contexts have tried to strike a balance between integration and independence (MacDonald et al., 2017). The forthcoming comparative case study of the role of NITAGs in strengthening national vaccine policy and decision-making in Armenia, Ghana, Indonesia, Nigeria, Senegal and Uganda will help to deepen understanding of these processes, representing the first of what could be a series of studies to investigate and document these efforts across different types of NITAGs.

Donors and the WHO could support national evidence-informed decision-making processes through similar mechanisms identified in the previous section: financing and facilitating cross-national exchanges and training, and coordinating and funding operational research and communications materials. As noted, however, strengthening relationships and integration will need to be led by national actors, particularly the NITAG chair and secretariat.

11 Individual-level factors include pre-existing beliefs, identity, past experience, mental models and confirmation bias. Interpersonal (relationship and network) factors refer to the type and nature of relationships between evidence producers and evidence users (i.e. researchers and policy-makers). Organisational-level factors relate to 'cultures' of evidence use, including time to access and appraise research, management of information (i.e. silos, staff turnover and institutional memory) and path dependence. Broader, systems-level factors include *policy ideas and narratives*: extent of consensus on the nature of the problem and appropriate responses, international discourses on domestic policy, novelty; *policy actors and networks*: extent to which the ruling party is ideologically driven, special interests, level of bureaucracy, professionalism and capacity to process evidence; and *national context and institutions*: democratic openness, academic and media freedom, norms on consultation, centralisation, established structures to link researchers and policy-makers.

12 In recent years, there have been several large bilateral initiatives to strengthen evidence uptake and use in low- and middle-income countries. These are intensive, multi-year endeavours, which can give a sense of the scale of effort required and offer tangible lessons that could potentially be adapted. For example, based on the efforts of a government department in South Africa to strengthen evidence-informed decision-making, Wills and colleagues (2016) offer practical guidance and organisational assessment tools that may be useful to NITAGs.

7 Actions and conclusions

The previous section presented support needs and activities involved in further embedding NITAGs in national decision-making processes. It discussed the roles that donors, the WHO, RITAGs, NITAGs and other national actors could play in addressing these areas. We conclude with key action points that workshop participants identified for donors, the WHO and the GNN to jointly move this work forward.

Workshop participants reinforced persistent calls for donors to improve the sustainability of their support through the regional hub, twinning approaches, peer-to-peer learning and international support mechanisms in order to bring countries to a level of self-sufficiency, after which time they can assume NITAG costs themselves. They identified three pressing action points for donors, the WHO and the GNN.

As a critical first step in improving sustainability, participants identified the **need for donors to define their roles and more actively coordinate among themselves**, echoing a key recommendation of the SIVAC evaluation (Howard et al., 2018). They suggested that, if NITAGs' scope is to include programme implementation considerations, UNICEF is a key player that should be involved in these discussions. Creating a core group of NITAG champions from interested organisations could help to coordinate efforts, raise the profile of NITAGs, strengthen the ability of these individuals to advance investment cases within their institutions and provide a centralised contact point with which GNN representatives could liaise. At a national level, donor–NITAG communications could be improved by inviting NITAG chairs to relevant donor meetings and including NITAGs in Gavi joint appraisal processes.

Second, workshop participants requested that donors – and Gavi in particular, given their central role in the vaccine landscape – **be more explicit in what they can fund and how NITAGs can access these resources**, including more detailed information that should be included in the investment case. If specific donors are unable to fund particular activities – for instance, NITAG secretariat or WHO positions, travel, research or communications materials – this should be clearly communicated to the WHO and to NITAGs so they can pursue alternative options. In particular, workshop participants requested clarification on the availability of funding to reinforce national surveillance systems, to support RITAGs and to compile the NITAG 'bible'.

Third, alongside greater clarification from donors on what is feasible to fund, participants emphasised the **need for the WHO and the GNN to clarify the 'ask' to donors and develop an investment case** for national, regional and global support activities. They envisioned discrete packages of support tailored to individual NITAGs' developmental stage and linked to a broader strategy of capacity-strengthening and national integration. The investment case should demonstrate the value of NITAGs' role in evidence-informed decision-making with concrete examples of the costs, activities and impacts as a result of previous NITAG efforts, including NITAG costs relative to overall immunisation budgets. It should identify particular needs, activities to address those needs, intended outcomes and clear accountability mechanisms. The national component of the investment case should be driven by GNN members so that it reflects the realities of different NITAGs. The

pathways of change diagrams could serve as the basis for developing country-specific plans, drawing on existing workplans and NITAG self-assessments and external evaluations which have been initiated in the last few years. RITAGs could lead regional assessments, informed by SAGE recommendations. These national and regional cases would link to a global strategy that covers the GNN and other international-level activities and clarifies how national, cross-national, regional and global efforts relate to one another.

Some people have expressed frustration that resource needs have not been adequately addressed despite repeated calls for more sustainable support. The persistence of these needs suggests that reiterating these requests will do little to change the status quo. Greater specificity from NITAGs and the WHO regarding defined national, regional and global activities, costs and value, and greater clarity from donors regarding what is feasible to fund and how, may offer a productive way forward.

At the workshop, discussions began regarding which institution(s) is/are best placed to lead strategy development and fund-raising efforts, and how technical organisations (i.e. WHO and CDC) and donor organisations (i.e. Gavi, Wellcome Trust and the Bill & Melinda Gates Foundation) relate to one another. If a NITAG core group is created, as suggested above, that would be a logical place to resolve these discussions, and to agree on a plan of action and timeline. Preparing the investment case will be time-consuming, so some existing activities may need to be postponed, reduced and/or dedicated resources secured for these efforts.

In addition to these more time-sensitive actions, workshop participants identified several other areas of action that could be taken. Donors could also raise awareness among high-level officials of NITAGs' value to MoHs; and make evidence that they fund more readily available. The WHO and the GNN could advocate for NITAGs at national and global levels; document, synthesise and disseminate knowledge; and further facilitate cross-NITAG interactions. Concrete steps related to these areas are presented in Annex E.

Looking ahead, there are clear avenues to ways forward, some of which have been known for some time but not addressed. Other tensions and potential shifts in the next phase of NITAG development will be more experimental. Historically, the immunisation field has been at the forefront of many public health advances and the wave of millennial global health initiatives. Proactively learning from NITAGs' roles in national policy processes as universal health coverage becomes more institutionalised offers the opportunity to continue this legacy and leadership.

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Annex A Workshop agenda and participant list

NITAG stakeholder workshop

Wellcome Trust, London

4–5 October 2018

This workshop is part of a programme of work to help the WHO and donor organisations understand how NITAGs could best be supported to provide evidence-based recommendations to ministries of health on immunisation policy, and the role and needs of the Global NITAG Network (GNN). It will draw on previous and ongoing research to describe best practice in NITAGs' functionality and what they require to be sustainable.

The workshop's specific objectives are to discuss and agree:

- a shared vision of NITAG functionality and sustainability
- the processes of change for NITAGs to attain functionality and sustainability
- a realistic timeline including stakeholder involvement for this vision
- the final agenda for the Global NITAG Network meeting.

Thursday 4 October 2018	
09:00	Coffee
09:30	Introductions and participants' hopes for the workshop
09:50	The role of NITAGs from a global policy-making perspective • Joachim Hombach (WHO) • Ole Wichmann (STIKO)
10:20	NITAGs: overview of lessons learnt to date • Presentations from Anthony Harnden (JCVI), Jahit Sacarlal (Mozambique) and Daniel Stecher (Argentina)
10:45	Coffee
11:15	Visioning: in 10 years' time, what could effective NITAGs look like? • Buzz groups and plenary discussion
11:45	Understanding how NITAGs function: presentation of interim research findings and outline theories of change • Louise Shaxson/Susan Njambi-Szlapka (ODI)
12:30	Plenary discussion and reflections on the morning
13:00	Lunch
14:00	Refining NITAG theories of change • Group work
15:15	Tea
16:00	Defining progress markers • Continuation of group work
17:00	Close

Friday 5 October 2018	
08:30	Coffee
09:00	Summary of day 1 • Kathy Cavallaro (WHO consultant)
09:15	Developing an action plan • Facilitated discussion in plenary
10:00	Coffee
10:30	Drafting an agenda for the Global NITAG Network • Plenary discussion
11:30	Evaluations
12:00	Wrap-up and close

	Participant name	Affiliation
1	Kathleen Cavallaro	Consultant, formerly Centers for Disease Control and Prevention
2	Steve Cochi	Centers for Disease Control and Prevention
3	Amanda Cohn	Centers for Disease Control and Prevention
4	Kori Cook	Wellcome Trust
5	Jonathan Crofts	Public Health England
6	Antoine Durupt	World Health Organization
7	Andrew Earnshaw	Public Health England
8	Nathalie El Omeiri	Pan American Health Organization
9	Stephen Hadler	Task Force for Global Health
10	Anthony Harnden	University of Oxford, Joint Committee on Vaccination and Immunisation (JCVI), UK
11	Louise Henaff	World Health Organization
12	Joachim Hombach	World Health Organization
13	Natasha Howard	London School of Hygiene and Tropical Medicine
14	Erin Kennedy	Centers for Disease Control and Prevention
15	Stacey Knobler	Sabin Vaccine Institute
16	Ranjana Kumar	Gavi, the Vaccine Alliance
17	Sophie Matthewson	Gavi, the Vaccine Alliance
18	Joe Miller	Wellcome Trust
19	Sandra Mounier-Jack	London School of Hygiene and Tropical Medicine
20	Rudzani Muloiwa	Vaccines for Africa
21	Jahit Sacarlal	Universidade Eduardo Mondlane, Comité de Peritos para a Imunização (CoPI), Mozambique
22	Sushmita Sarkar	Wellcome Trust
23	Zoe Seager	Wellcome Trust
24	Abby Shefer	Centers for Disease Control and Prevention
25	Rupa Singh	BP Koirala Institute of Health Sciences, Nepal National Committee on Immunization Practices (NCIP)
26	Daniel Stecher	Dirección de Control de Enfermedades Inmunoprevenibles, Ministerio de Salud, Comisión Nacional de Inmunizaciones (CoNaIn), Argentina
27	Christoph Steffen	World Health Organization
28	Jennifer Stuart	UK Department of Health and Social Care
29	Ole Wichmann	Robert Koch Institute, Ständige Impfkommission, German Standing Vaccination Committee (STIKO)

Annex B List of documents reviewed

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Additional documents were gathered for Honduras, Kenya, Thailand and Viet Nam.

Web resources

Gavi
www.gavi.org/about/programme-policies/co-financing/

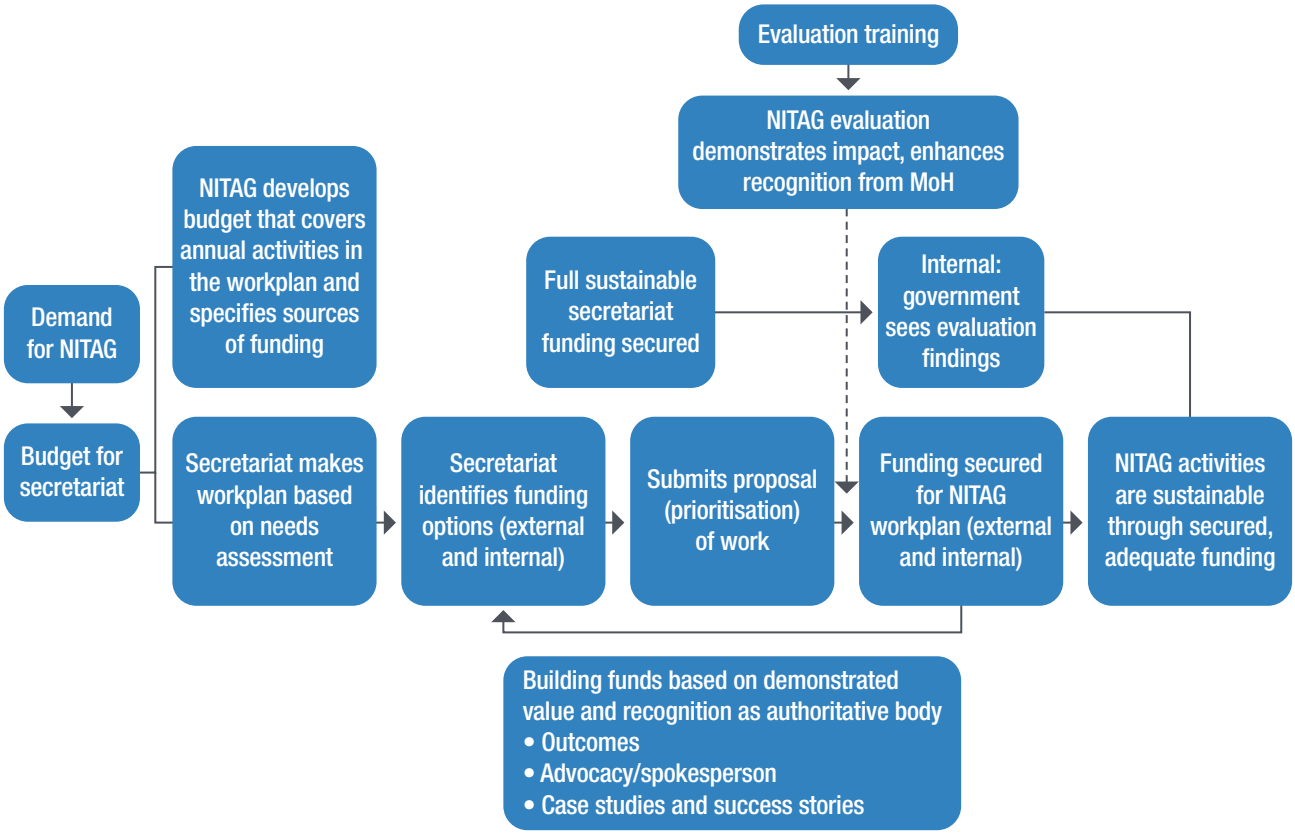
NITAG Resource Center
www.nitag-resource.org/

Wellcome Trust
https://wellcome.ac.uk/what-we-do/our-work/vaccines
https://wellcome.ac.uk/what-we-do/our-work/programmes-and-initiatives-africa-and-asia

World Health Organization
www.who.int/immunization/en/
www.who.int/immunization/sage/national_advisory_committees/en/
www.who.int/immunization/policy/sage/en/
www.who.int/immunization/policy/position_papers/en/
www.who.int/immunization/global_vaccine_action_plan/en/
www.who.int/immunization/programmes_systems/interventions/en/
www.who.int/immunization/programmes_systems/sustainability/en/
www.who.int/immunization/programmes_systems/financing/en/
www.who.int/immunization/programmes_systems/sustainability/transition/en/
www.who.int/immunization/programmes_systems/sustainability/mic_strategy/en/
www.who.int/universal_health_coverage/en/

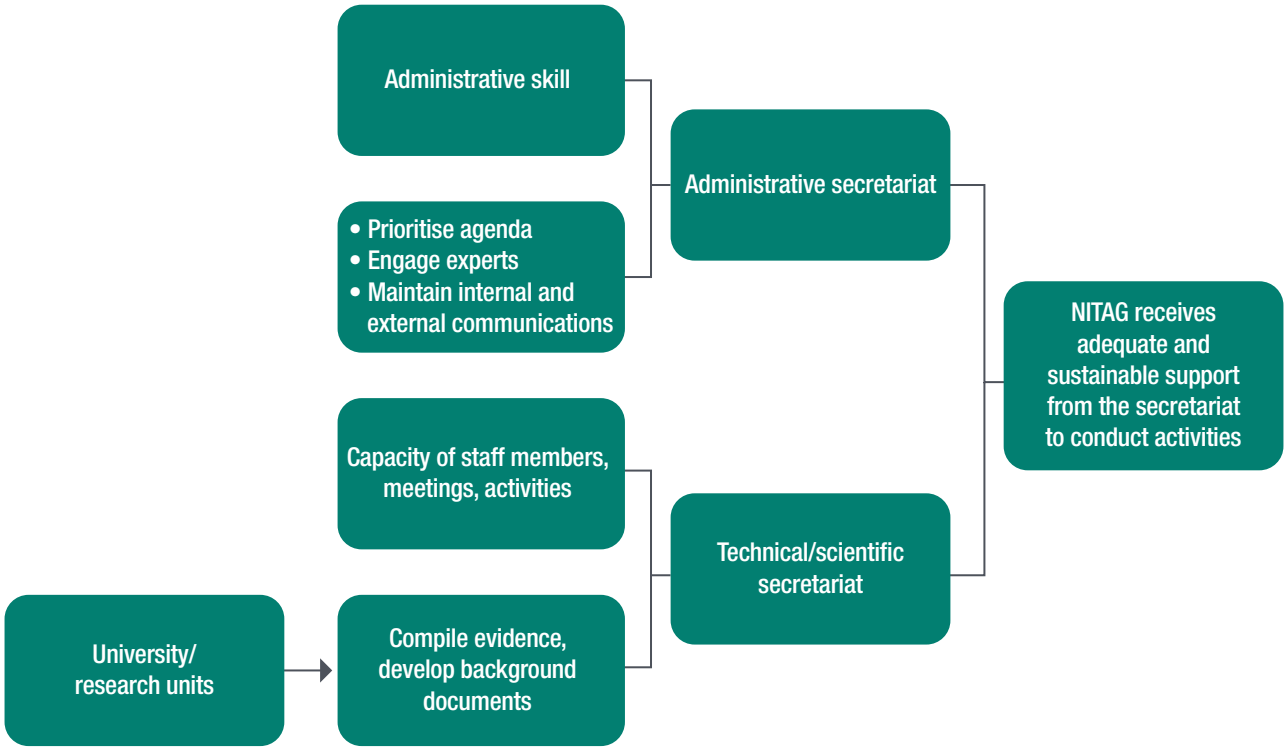
Annex C Pathways of change for NITAG enabling areas and the regional support hub

Figure C.1 NITAG is sustainable through secured funding



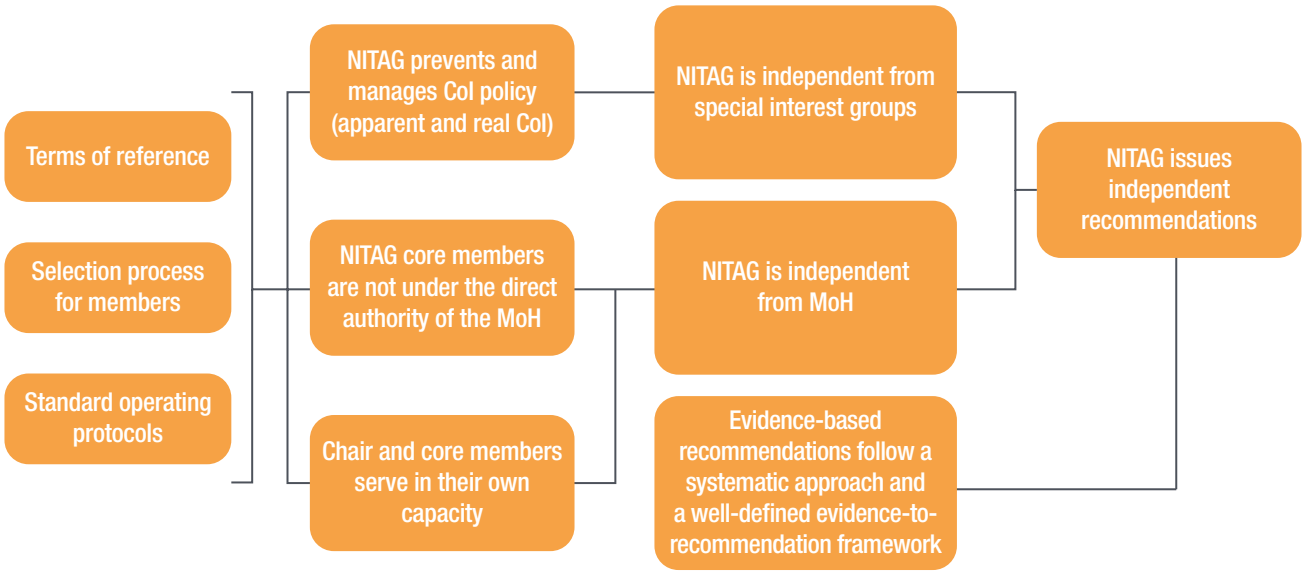
Note: as articulated by workshop participants.

Figure C.2 NITAG receives adequate support from the secretariat



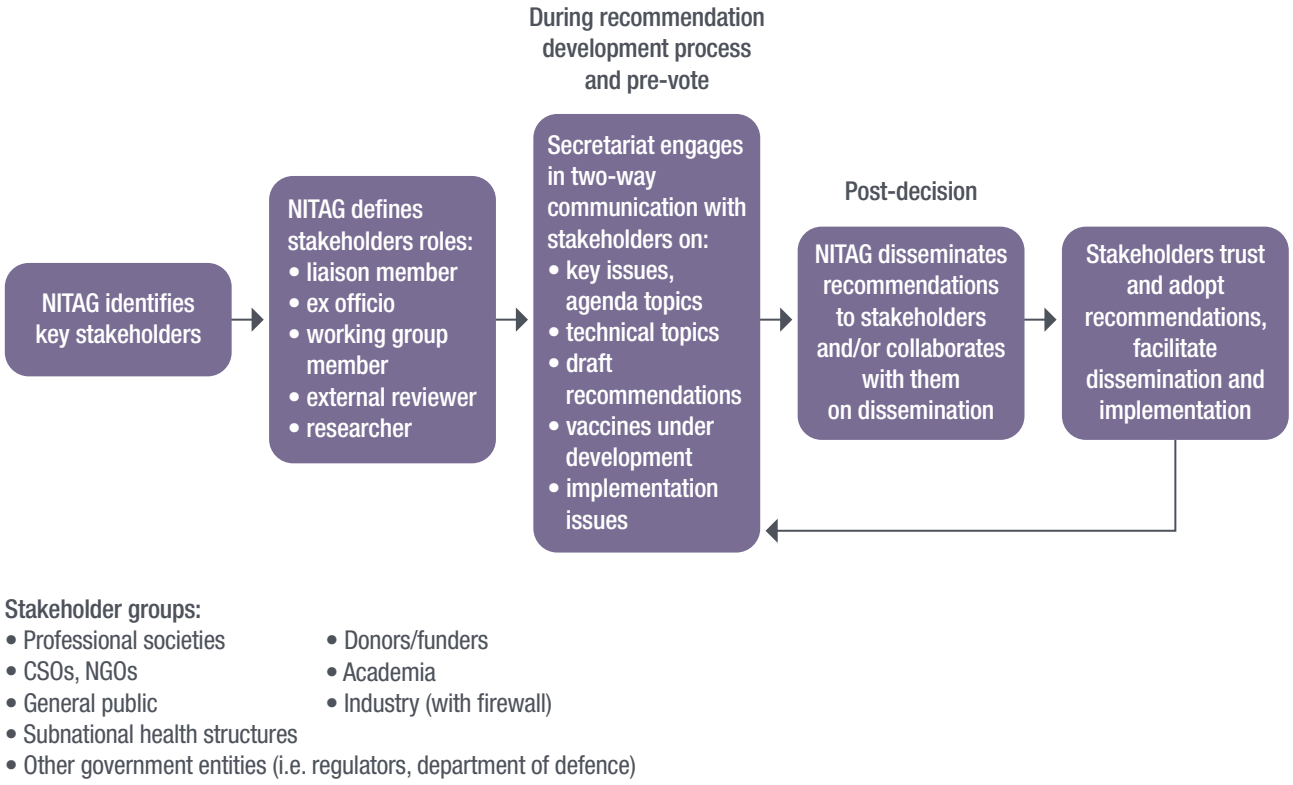
Note: as articulated by workshop participants.

Figure C.3 NITAG issues independent recommendations



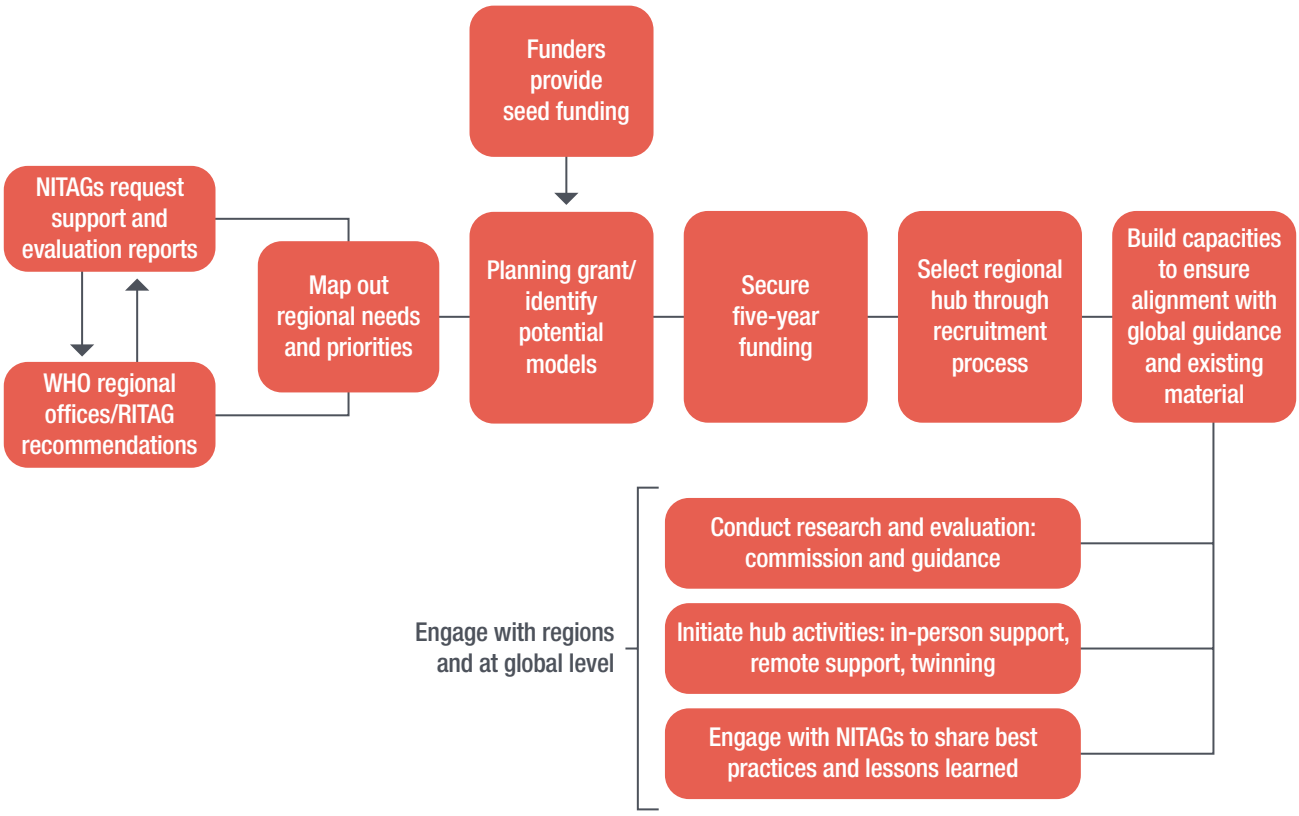
Note: as articulated by workshop participants.

Figure C.4 NITAG and stakeholders are trustfully, mutually engaged



Note: as articulated by workshop participants.

Figure C.5 NITAG regional support hub



Note: as articulated by workshop participants.

Annex D Options to support NITAGs' mandate and enabling areas

NITAG mandate and enabling areas	Support options
NITAG implements its own evidence-informed decision-making procedures and informs national policy processes	• Funding to train secretariat staff • Training and capacity-building, ProVac and similar tools • Regional support hub, regional dossier, international expertise, twinning, funding • Strengthening working groups • Training in how to synthesise and write policy briefs • Training in evidence-based reviews/GRADE • Improve standard operating procedures for handling urgent requests • Improve consideration of economic analysis • Strengthen stakeholder engagement
NITAG is sustainable through secured funding	• Gavi funding possible in 73 countries • HIC should have funding • Leverage academic partnerships • Defined line item in MoH budget • Bilateral agencies and foundations • Role for industry? (independence, inappropriate influence?)
NITAG receives adequate support from the secretariat	• NITAG secretariat having a line item in MoH budget (critical) • Secretariat is provided with support for training and evaluation to reinforce this • Administrative support to strengthen capacity of secretariat staff members for collection, analysis and interpretation of new data
NITAG issues independent recommendations	• Training: materials for reference, templates for terms of reference (will need to be adapted) • Remote support • Person-to-person learning: workshops, GNN for sharing information, observing SAGE, RITAGs
NITAGs and stakeholders are trustfully, mutually engaged	• Secretariat engage in two-way communications: consultation mechanism, resources to support scoping, human resources within the secretariat with time for implementation • Post-decision: NITAG disseminates recommendations to stakeholders: communication channels, consistent format for dissemination and recommendations (i.e. what to include, how to present, etc.), human resources to disseminate, best/good practices shared • NITAG describes role for each stakeholder: mapping tool, engagement strategy/ communication, applying principles (SIVAC training), help desk or hotline for regional hub
NITAG regional support hub	• Strong coordination in place, funding for one coordinator at regional level • Partners collaborate • NITAGs are active: Gavi-eligible countries allocate funding to attend training for regional hub • Mature NITAGs exist and are willing to be twinned: availability of expertise, assessment done • Training material is developed and endorsed by NITAG community

Note: as identified by workshop participants.

Annex E Additional actions for donors, the WHO and the GNN

Additional donor actions

As well as defining roles and coordination and clearly communicating funding options, workshop participants identified two other steps donors could take: **advocating for NITAGs with national decision-makers and improving access to evidence they are funding**.

The access and close relationships that donors have with some governments offers an opportunity for donors to raise awareness among high-level officials of NITAGs' existence, role and value to MoH work, highlighting their use of evidence in doing so, and the comparatively very low cost of NITAGs relative to overall immunisation budgets. A final and less prominent point was a request for donors, who fund and themselves generate valuable evidence that NITAGs could use in their own decision-making and advocacy, to make this evidence more readily available.

Additional WHO and GNN actions

Beyond clarifying the 'ask' to donors and developing an investment case, workshop participants identified three other areas of action.

Participants saw a role for the WHO to **advocate for NITAGs at national and global levels**. Assessments of NITAG impact and cost-effectiveness could be used to demonstrate the contribution of NITAGs to national stakeholders, particularly in countries without existing NITAGs and where they are less integrated in national decision-making processes. Participants also recommended that regional WHO offices advocate for NITAGs as the norm in EPI programmes.

The remaining action points for the WHO and the GNN relate to the latter three actionable support options: training and mentoring, documenting experiences and networking, and improving access to information. In order to expand existing activities in these domains, the WHO and the GNN could further **document, synthesise and disseminate knowledge**. Participants saw a role for the WHO to develop a systematic way to identify NITAG knowledge gaps and implications for evidence-informed decision-making. They suggested that more articles related to NITAGs be submitted to peer-reviewed journals, again mentioning NITAG impacts and cost-effectiveness. As noted in the body of the report, a NITAG 'bible' could synthesise existing knowledge and resources, and new research and documentation could be conducted or commissioned.

Finally, the WHO and the GNN could further **facilitate cross-NITAG interactions**. Specifically, they could ask mature NITAGs to commit to longer-term in-kind support and 'twinning' with nascent NITAGs. Another opportunity for interaction would draw on the joint appraisal assessment and include NITAG progress monitoring an agenda item for RITAG meetings.

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