



The role of National Immunization Technical Advisory Groups (NITAG) in strengthening health system governance: Lessons from three middle-income countries—Argentina, Jordan, and South Africa (2017–2018)

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ABSTRACT

Introduction: Toward the Global Vaccine Action Plan 2020 goal, almost 90% of countries have established a National Immunization Technical Advisory Group (NITAG). However, little is known about NITAG's contributions to governance.

Methods: In 2017–2018, a two-step, qualitative retrospective study was conducted. Jordan (JO), Argentina (AR), and South Africa (SA) were selected owing to government-financed NITAGs from middle-income countries (MICs), geographic diversity, and a vaccine introduction with NITAG support. Country case studies were developed, collecting data through desk review and face-to-face key informant interviews (KIIs) from Ministry of Health (MoH) and NITAG. Case studies were analyzed together, to assess governance applying the European Observatory on Health Systems and Policies framework focusing on transparency, accountability, participation, integrity, and policy capacity (TAPIC).

Results: Document review and 53 KII (22 AR, 20 SA, 11 JO) showed NITAGs played a pivotal role as advisors promoting a culture of evidence-informed policies. NITAGs strengthened governance, although practices varied among countries. Meetings were conducted behind-closed-doors, participation restricted to members, only in one country agendas, and recommendations were public (AR). To increase participation, policy capacity, and transparency, countries considered adding experts in communications, advocacy, and economics. AR and SA contemplated including community members. NITAGs functioned autonomously from the government, with no established internal or external monitoring or supervision. NITAG meeting minutes allowed the review of integrity, adherence to terms of reference, standard operating procedures, and conflict of interest (Col). For the most part, NITAGs abided by their mandates. Significant issues were related to the level of MoH support and oversight of Col declaration and documentation.

Conclusions: Systematically implementing governance approaches could improve processes, better tailor policies, and implementation. The long-term survival and resilience of NITAGs in these countries showed they play a significant role in strengthening governance. Lessons learned could be useful to those promoting country-driven evidence-informed decision-making.

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Abbreviations: ACIP, American Committee on Immunization Practices USA; AFR, African Region; Col, Conflict of Interest; ICC, Coordinating Committees; JO, Jordan; KI, Key Informant; KII, Key Informant Interview; MIC, Middle Income Country; MoH, Ministry of Health; NIP, National Immunization Program; NITAG, National Immunization Technical Advisory Group; NRA, National Regulatory Agency; PAHO, Pan American Health Organization; SAGE, Strategic Advisory Group of Experts on Immunization, WHO; SA, South Africa; SIVAC, Supporting Independent Immunization and Vaccine; SOP, Standard Operating Procedures; TOR, Terms of Reference; WHO, World Health Organization.

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1. Introduction

Many countries have instituted National Immunization Technical Advisory Groups (NITAGs) to provide recommendations on immunization policy to Ministries of Health [1,2]. The 2011–2020 Global Vaccine Action Plan (GVAP) objective that “all countries having a functional NITAG by 2020” further engaged World Health Organization (WHO) regions, Member States and global experts in establishing NITAGs [3],[4]. The WHO and global partners have provided leadership and support to countries to create, strengthen and promote collaboration among NITAGs [5–7]. According to the WHO/UNICEF Joint Reporting Form (JRF), as of 2019, 170/194 (88%) of countries reported having a NITAG, a significant increase from 99/194 (51%) in 2012 [2],[8],[9]. In the global movement towards delegating certain government functions (e.g., policy research, evaluation, and analysis) to advisory bodies, NITAGs may play a significant role in the policymaking process and exert influence on the adoption of vaccines [10–12]. NITAG terms of reference and mandates fit a rational policy-making model, in which recommendations for policy decisions are based on a structured and comprehensive approach. NITAG’s purpose is to provide independent, evidence informed advice to policymakers and program managers on issues related to immunization, vaccines, and technologies. Moreover, in many instances, NITAG recommendations consider what works’ in their countries’ context, in addition to technical and scientific evidence [13]. WHO and global partners have collaborated with countries to strengthen NITAGs’ decision making capacity and have proposed indicators to assess NITAGs [14–16]. Given the challenges governments face in terms of research, evaluation, and analytic capacity, there is a recent focus on governance, including a plurality of actors, and achieving a more distributed policy advisory system [17]. Some experts have issued recommendations to increase the transparency of NITAG recommendations and their communication [18,19]. The World Bank (WB) states that governance comprises the traditions and institutions by which a country exercises authority. WB’s definition of governance includes the capacity of the government to formulate and implement sound policies effectively [20]. Therefore, governance is policy-centric and implies a systematic way of making and implementing decisions [21]. Good governance is built by good practices (empowerment, inclusion, participation, integrity, transparency, and accountability) [22,23]. NITAG members are multidisciplinary national experts who provide independent, evidence-informed vaccine policy recommendations to national health authorities. NITAGs may strengthen governance by being integrated into the decision-making structure when providing strategic advice [21,24,25]. The European Observatory on Health Systems and Policies developed a method to assess health systems governance through case study presentations and a framework, incorporating the five attributes of good governance: transparency, accountability, participation, integrity, and policy-making capacity (TAPIC) [23]. The analysis of these attributes can be applied in a variety of settings; for example, to study advisory groups such as NITAGs to document good practices, identifying problems, and providing a measure of the level these qualities are practiced. Developing frameworks to assess the immunization policy-making processes, particularly in middle income countries (MICs), is one of the aspects that global partners are actively working on to guide the strengthening of NITAGs [14],[26–28]. In 2017, the World Health Organization (WHO) and the U.S. Centers for Disease Control and Prevention (CDC) initiated consultations around their mutual interest in assessing NITAGs beyond the JRF functionality indicators [4],[8]. CDC was interested in describing policy-making processes leading to vaccine introduction in MICs. That were both

country-driven and supported by NITAGs with an established record of advising decision-makers. The overall goal of this assessment was to understand the contribution of MIC NITAGs to policy and governance while describing the immunization policymaking process, the integration of NITAGs to MoH in that process, and NITAG contributions to good governance in those countries. In addition to MICs, the countries receiving substantial assistance from the international community for the introduction of vaccines can potentially benefit from the case studies, providing real-world experiences on the processes that need to be in place to transition out of external support.

2. Methods

Investigators implemented a two-step, qualitative, retrospective case study design. The first step involved the development of country case studies [19], while the second step was to synthesize findings from these case studies by applying the TAPIC governance framework [23]. Eligibility The assessment focused on good governance practices in MICs with a record of policy success. Policy success was understood as MoH recently endorsing and implementing a NITAG recommendation to introduce a vaccine. WHO Regional Offices and other partners collaborated in the selection of the three countries. The criteria for country selection were: (1) MIC not eligible for Global Alliance for Vaccine and Immunization (Gavi) support; (2) different WHO regions; (3) the existence of country-led immunization policy-making processes without significant external support; (4) at least one vaccine introduced in 2014–2015 with the involvement of a NITAG. The countries selected were the Republic of South Africa (SA—WHO African Region), Argentina (AR—WHO Americas Region), and Jordan (JO—WHO Eastern Mediterranean Region). MoHs and NITAGs in all three countries accepted the invitation to participate and to collaborate in this assessment.

2.1. Data collection

2.1.1. Case studies

First, to develop country case studies, the investigators conducted desk reviews of relevant NITAG and MoH documents and semi-structured face-to-face interviews with key informants (KIs) involved in the policymaking process [29]. Data collection took place from September 2017 to June 2018. The purpose of the desk review was to obtain relevant information about each country’s policymaking process. The documents reviewed included the NITAG charter, terms of reference (ToRs), standard operating procedures (SOPs), membership, and criteria for member selection. Other documents of interest were the agendas and meeting minutes documenting the recommendations on the specific new vaccine introduced, and the relevant National Immunization Program (NIP) documents for policy implementation. The purpose of the key informant interviews (KIIs) was to obtain in-depth insight into the phases leading to policy formulation and implementation, and NITAG integration that could inform NITAG contributions to good governance. Sampling was purposive. Interviewees included the individuals who had first-hand knowledge of the actual process of the NITAG establishment and functioning, the process of policymaking, and the policy dialog between the NITAG and the government. Those interviewed included the NITAG Chair, NITAG members, NITAG Secretariat, officials from the NIP, MoH, and Ministry of Finance (MoF); and other immunization stakeholders involved in the immunization policymaking process, such as national regulatory agencies. The Secretariat is the technical agency appointed by the MoH to provide scientific and administra-

tive support to the NITAG. A CDC researcher developed the interview guide, which included several topics related to the composition and functioning of NITAGs, the immunization policymaking process, dialogue between NITAG and MoH, NITAG's embedment, and integration into the policymaking process. Supporting Independent Immunization and Vaccine Advisory Committees Initiative (SIVAC) tool served as a general guide in developing the questions related to the characteristics of NITAG [30]. The interview guide was pre-tested to check for clarity, flow, redundancy, and appropriateness for a 60-minute interview, and revisions were made accordingly. The number of KIIs to be conducted was not decided at the beginning of the study. Instead, data collection was finished once information saturation had been reached (i.e., when no new information or themes emerged). All data collection activities were conducted in collaboration between the countries' MoHs, NITAGs, WHO and Country Offices (CO), and the CDC. With assistance from WHO COs, local consultants contacted the KIs, scheduled appointments, and collected documents for the review. In AR and SA, all interviews were conducted in the local official language (Spanish and English, respectively). However, in JO, some interviewees preferred Arabic, and others preferred English. In the latter case, English was chosen by the KIs in Jordan as a courtesy to investigators who did not know Arabic, even when simultaneous translation capabilities were available. Researchers took notes and audiotaped the discussions during the conversations. Recordings were transcribed verbatim in the original language, using MS Word, and the text was edited to anonymize the interviews. Transcriptions in Arabic were translated into English. Only one KI from JO opted out of the discussion. Critical documents for the desk review were available in all the countries, and the country reports included data from all the KIs, and the information collected was included in the case studies.

2.2. Data analysis

2.2.1. Case studies

Collaborating with the CDC, each country team developed a report for their country, based on the qualitative analysis and the triangulation of information from both the interviews and documents, using NVivo software for contextual analysis. Investigators examined the policymaking process by tracing the stages of the introduction and implementation of the last vaccine incorporated into each country's NIP schedule. The case studies discussed the policy process culminating in the introduction of rotavirus (JO), human papillomavirus (SA), and meningococcal ACWY (AR) vaccines. The written reports were shared with WHO, MoH, and NITAG focal points in the respective countries.

2.2.2. Good governance attributes

The second step involved reviewing and synthesizing the case studies and applying the TAPIC framework for analysis. One of the investigators (MSP) was responsible for this step because this person developed the protocol and the interview guide, conducted or participated in all the face-to-face KIIs (except for two in SA), and had the most in-depth knowledge of the data and case reports. Using the TAPIC framework as a guide (summarized in Table 1), the reviewer conducted a line by line analysis of each report, abstracting relevant sections and quotes to illustrate each TAPIC attribute. The abstracted narratives and quotes from the three case studies were further analyzed to synthesize the results found for each TAPIC category [23]. To ensure that appropriate review and input was received from all collaborators, the manuscript underwent several rounds of critical appraisal and validation. The country consultants, who were principal authors of the country reports, reviewed the first draft, made comments, and validated the information included in the synthesis. A second draft was developed

and distributed to WHO country offices in JO and SA and Regional PAHO office (for AR), as well as the NITAG Chairs, and MoH focal persons in each country. All co-authors reviewed and provided suggestions to the second draft. After an internal review at the CDC, the third draft was sent to all co-authors for final approval.

2.2.3. Confidentiality/protection of privacy

This study received a non-research determination from the CDC Human Subjects Office; WHO COs requested permission from the MoHs to conduct the assessment, and it was granted in writing. The MoHs and NITAGs actively participated in the evaluation by sharing relevant documents with the investigators for the desk review. The WHO local consultants received training on the protection of privacy. No names were recorded during data abstraction. Participants received information describing the study before the interview, and KIs had a chance to ask questions. The participation of KIs was voluntary; written consent was obtained from KIs before the interviews. KIs were made aware of their opportunity to review the transcripts to delete any part they did not want to be quoted in the case studies. The names of KIs were recorded in the forms, but investigators did not use KI names in any analysis. Only a table with the list of KIs' positions and institutions was included in the case studies. Documents, recordings, and paper copies of the completed interviews were stored at the respective WHO COs in a locked cabinet. All data transfers were handled, using an encrypted share drive. Electronic databases were stored on a password-protected CDC laptop with an encrypted hard drive. MoH, WHO, and CDC own the data, which will only be shared with the consent and approval from all stakeholders.

3. Results

In Table 2 a summary is presented of the type and number of key informants interviewed in each country.

In all three countries (AR, JO, and SA), the MoH had formally established a NITAG; all the advisory groups functioned independently without government oversight. NITAG evidence-informed recommendations were not binding, and NITAGs themselves were not engaged in final decision-making or policy implementation. Each MoH was involved in other stages of the policymaking process, such as reviewing advice given by the NITAG, participating in policy design, endorsement, implementation, monitoring, and evaluation. Interviewees from the MoHs agreed that health policy should be well-informed, unbiased, evidence-based, and locally relevant. As described below, although public health decision-making was centralized and occurred at the national level, governance attributes were different in each participating country. Attributes of governance based on the TAPIC framework. The findings of AR, SA and JO NITAG governance attributes of transparency, accountability, participation, integrity, and capacity are presented in Table 3. Table 3 also summarizes recommendations discussed during the interviews to strengthen NITAG governance attributes.

3.1. Transparency

In SA and JO NITAGs, none of their working documents were in the public domain. The AR NITAG posted their vision and purpose, list of members, ministerial decree, ToRs, meeting agendas, and recommendations with relevant background documentation (i.e., technical presentations on the MoH website and published relevant information on the Global NITAG resource center website) [31],[2]. In SA and AR, NITAG sessions were audiotaped, but the transcripts were not shared beyond the Secretariat. None of the NITAGs produced annual reports, workplans, or policy briefs. In all the participating countries, each NITAG's deliberation, and deci-

Table 1

Attributes of Good Governance* used in the assessment of Argentina, Jordan, and South Africa NITAGs (2017–2018).

Governance attribute	Description of good practices	Contribution to good governance	NITAGs and good governance
Transparency Decisions, positions, opinions, or views are traceable, well-defined, shared	Entails institutions informing the public and other actors about the processes, the reasons by which recommendations and decisions are made. Transparency involves regular reporting, open meetings, and producing information in useful, easily understood formats.	Helps to build trust	NITAG's procedures include dissemination of agendas, processes, and decisions in a way that information is translated, so the public can easily understand (e.g., by promoting access on the MoH/NITAG website). NITAG's deliberation sessions are open, allowing input, feedback, and appeals to recommendations from other interested parties. Evidence-based criteria and economic studies are used to support recommendations.
Accountability Mechanisms for reporting to principals, regulators, rules and possible sanctions	Implies a relationship between an actor (e.g., an agency) and a forum (e.g., a legislature) in which the actor must inform the other party of decisions, explain choices, and may impose mandates and sanctions (i.e., conflict of interest, standards, codes of conduct).	Helps to manage conflict of interest, promotes regulations, and sets standards	NITAG has ultimate accountability to NIP, the senior management in MoH. However, NITAGs are relatively autonomous and independent, which contributes to their legitimacy. NITAG's ability to manage conflicts of interest for all members and other non-members, such as academics participating in NITAG working groups.
Participation Affected parties engaged in decision-making	Relevant parties have access to decision-making and power so that they acquire a meaningful stake in the work of the institution, creating policies that are just and effective. Participation promotes collaboration and coalition building.	Helps with legitimacy, ownership, and equity, while highlighting areas of conflict	NITAG's structure is allowing relevant parties, stakeholders, partners, civil society, and those affected by the decisions to have the opportunity for involvement and participation in the process and formulation of recommendations.
Integrity Clear personnel policies in place (job descriptions, roles, and responsibilities and transparency in hiring, tenure, etc.)	Facilitated when there are clear roles and responsibilities; the processes of representation and the methods for decision-making and enforcement are understood by all members and institutions apply those. Integrity involves predictability, anti-corruption, ethics, and the rule of law (legislative mandate. Clear procedures and organizational roles, mission, and purposes facilitate honesty. Internal audits, budget, processes, regulatory functions, and goals support integrity).	Helps with good management	NITAG's adherence to terms of reference, mandates, rules, roles, responsibilities, mission, and goals.
Capacity Ability, skills, and experience for research, advising and policy analysis	This attribute implies policies with resources in pursuit of societal goals. Political ideas undergo a process to become workable and well-designed policies. There is an understanding of legal and budgetary issues, efficient use of resources, and training.	Helps to avoid poor policy outcomes	NITAG's technical capacity and resources to exercise their functions (e.g., individuals with high-level expertise in evidence-based methodologies, public health, economics, and social values). Integration with MoH to provide guidance, education materials, tools, and evaluation indicators to support the implementation of the recommendations. Awareness of budgetary implications of NITAG's proposals.

NITAG – National Immunization Technical Advisory Group.

* Adapted from European Observatory on Health Systems and Policies framework in Greer et al. 2016.

Table 2

Type and number of key informant interviewed by country.

Key Informant type	Number of Interviews by Country		
	Argentina (AR)	Jordan (JO)	South Africa (SA)
NITAG Chair	1	1	1
NITAG Core member*	4	2	3
NITAG Non-Core member	8		
NITAG Secretariat	1	1	1
NIP	3	4	1
MoH	2	1	9
Finance	1	1	1
NRA	1	1	1
WHO	1		1
Other**			2
Total	22	11	20

* Only those designated as core members are involved in the NITAG's decision-making process.

** Both in SA: Ministry of Education (HPV implementation); BioVac (vaccine procurement).

sions could be traced by reviewing meeting minutes, which provided an insight into the different criteria and the primary considerations that lead to recommendations. Governments published decisions about immunization policies through implementation guidelines, updated vaccine schedules, and communication mate-

rials that were available to technical staff, and in some cases, to the public on the MoH websites.

3.2. Accountability

There were no robust systems instituted for the monitoring and evaluation of the quality, credibility, availability of NITAGs immunization recommendations. Beyond the indicators reported to the JRF, there were no other established indicators routinely collected, such as those proposed by Blau et al. [14], or Greer et al. [23], which include measurement of the impact of a NITAG's contributions; the importance of a measure of impact was mentioned by an interviewee in JO. Although in SA in 2010 Shoub et al. [33], measured the uptake of NITAG vaccine recommendations adopted by the MoH (75%) and also provided some of the reasons why NITAG recommendations were not endorsed by the MoH, this measurement has not been repeated.

Meanwhile, AR had defined that immunization surveillance data would be used to evaluate the impact of strategies proposed by the NITAG. However, any evidence that this had been put into operation was lacking [32]. The policy on intellectual and financial conflict of interest (Col) for NITAG members and working groups involves individuals signing written declarations that should be kept up to date [34]. The countries had developed guidelines

Table 3
Summary of Findings and Recommendations to Strengthen NITAG Governance by TAPIC Attribute.

NITAGs and Good Governance TAPIC Attribute	Countries Practices			Recommendations
	Argentina	South Africa	Jordan	
Transparency	NITAG deliberation/sessions were closed, but on occasion outside experts were invited to attend NITAG produced detailed agendas, meeting minutes on deliberation and decisions, documenting their internal process, different criteria, type of evidence, and the major considerations leading to recommendations NITAG contributions could be traced, to a certain extent, in Government publications: immunization policies and guidelines, updated vaccine schedules, communication materials available to technical staff, and in some cases, to the public on the MoH websites. MoH/NITAG website linked to the Global NITAG resource center's website provided access to NITAG vision, purpose, list of members, ministerial decree, ToRs, meeting agendas, recommendations and relevant background documentation (i.e., technical presentations) [31],[2].			Evaluate, adapt good practices from WHO SAGE on Immunization, other leading and matured NITAGs (e.g., ACIP, STIKO, JCVI) Use available information such as NITAG documents, records of advice and guidance to produce work plans, policy briefs, annual handbooks, or summary reports Further define and share criteria used for decision-making, technical background documents considered in NITAG deliberations, the process for evidence-to-recommendation, and its framework. Involve communication experts to aid the dissemination of meaningful NITAG information to the public.
Accountability	No robust system to M&E the quality, credibility, availability of immunization recommendations and policies Impact of strategies proposed by the NITAG to be measured using MoH surveillance system data. Stecher et al. (2014) [32]. All countries had guidelines, procedures, and rules in place to address conflict of interest (COI). Policy on intellectual and financial COI applied to NITAG members and working groups and involved individuals signing written declarations [34]. The responsibility to ensure members' compliance with the COI policy lay on the NITAG Secretariat (JO, AR) or the NITAG Chair (SA). COI policy implemented for several years. Implementation of stepwise rotation to ensure institutional memory and a smooth transition when members leave and new MoH's appointees arrive Some members interested in exercising oversight functions over the NIPs while other members understood assuming accountability functions over the MoH would likely interfere with or overstep their advisory mission			Establish indicators to measure NITAG contributions to Governance over time Share the responsibility to monitor compliance, manage, resolve and improve COI policy with MoH or other governance groups Strengthen support and oversight of NITAG processes and adherence to ToRs, SOPs, and COI Define NITAGs' mission-related to supporting M&E, and its role in recommending, selecting reliable indicators, designing tools, participating in actual activities related to M&E.

Table 3 (continued)

Participation	Countries Practices			Recommendations
	Argentina	South Africa	Jordan	
NITAG members were highly committed and participation was high during regular and extraordinary meetings, frequency of which had increased. Only MoH-appointed members participated in NITAG's sessions, and only those designated as core members were involved in the NITAG's decision-making process leading to recommendations NITAGs hesitated to include external participants (e.g., civil society organizations, community advocates, and other stakeholders) in deliberations AR and SA NITAGs concerned the inclusion of other actors with diverse views or priorities, increasing internal conflict or harming the ongoing NITAG process to achieving consensus.		SA NITAG and MOH expressed trust for vaccines was decreasing among some religious groups. Concerned religious leaders from Islamic and Jewish councils suggested that their participation in NITAG meetings discussing vaccine introductions would help them to advocate for vaccine acceptance in their communities.		Set up a process of consultation with stakeholders, opening participation in deliberations of relevant actors from civil society Consider the participation of a wide range of stakeholders and civil society in NITAG sessions. Examine procedures to increase participation that do not put at risk current good decision-making practices Promote consultations with religious and other community leaders when addressing specific topics sensitive to the public.
	NITAG non-core members selected among five regional NIP managers who contributed valuable input on the feasibility of NITAG's recommendations. Those managers remained engaged after policy endorsement to support subnational programs during the implementation phase	SA MoH was considering expanding the involvement of NITAG members to include experts in programmatic implementation. The SA NITAG also advocated for the inclusion of the Biovac Institute, a public-private partnership, to advise NITAG on issues related to vaccine procurement.		Incorporate social scientists, communication experts, as NITAG members to better advise MoH on issues related to vaccine confidence, community perceptions, and attitudes towards vaccines. Improve the feasibility of NITAGs recommendations, accelerate MoH's endorsement and enable successful policy implementation by encouraging the participation of expert on economics, logistics, procurement, and other programmatic aspects
Integrity	Countries Practices			Recommendations
	Argentina	South Africa	Jordan	
NITAG members highly aware of the existing terms of references, purpose, codes of conduct, membership eligibility, roles and responsibilities, and the duration of memberships. Recommendations were decided by consensus in SA and AR, and by majority rule in JO. These NITAGs met the WHO UNICEF JRF functionality indicators (8). NITAGs' mandates were limited to immunization and providing advice to MoH regarding vaccines, vaccine-preventable diseases, and supported the NIP. NITAGs primary mission was to facilitate a transparent, evidence-informed policy-making process by issuing recommendations to the Government upon assessing the available evidence on existing, new, and emerging vaccines and technologies. NITAGs were clearly distinguished from the National Regulatory Agencies (NRA), Inter-Country Committees (ICC), and disease-specific committees. However, some of the NITAG members participated in other committees.		NITAGs evolved from Immunization Committees established soon after their NIPs institution (JO in 1985 and SA in 1993)		Revisit NITAGs' mission SOP, TOR, roles, and responsibilities periodically to ensure relevance to the current policy context, priorities, and challenges confronted by NITAGs and NIP.

(continued on next page)

Table 3 (continued)

Capacity	Countries Practices			Recommendations
	Argentina	South Africa	Jordan	
	NITAG members were highly trained, experienced professionals dedicated to designing recommendations, that aligned technical aspects to countries' political contexts to ensure policy success MoHs highly valued NITAGs capacity. Governments trusted, viewed NITAGs evidence informed recommendations as an important asset and integrated NITAGs' advice to the policymaking process. In time of crisis, NITAGs' capacity made them resilient and able to fulfill their mission and continue to respond effectively despite of shifting political, economic, and technical environments. NITAGs were considering membership beyond traditional medical and public health expertise, to improve their capacity for policy analysis, incorporating critical economic and programmatic factors when assessing policy options. All NITAGs agreed on the value of having an economist as a member Since none of these MICs was eligible for GAVI funding [35], their NITAGs were eager for their MoH sharing budget information, when considering the introduction of vaccines.			
	The case of AR, where regional NIP managers were already NITAG non-core members, highlighted the value of considering the operational and programmatic aspects during deliberations and when issuing recommendations. Those NIP managers played a crucial role in NITAG-MoH integration, before and after the issuance of advice, and provided continued participation and contributions at different stages of the policy cycle.	The Government of SA was considering the inclusion of program experts as NITAG members to increase their capacity to address implementation issues in better tailor their policy recommendations.	NITAG in JO considered including a communication expert to translate scientific evidence to policymakers and the public. An economist was considered essential to assess affordability and leading policy dialogue with MoF.	Increase NITAGs capacity by promoting a comprehensive synthesis of critical economic and programmatic aspects to their recommendations, which could improve integration with MOH and lead to improved policy design and implementation.
	PAHO ProVac initiative sponsored an exchange between AR NITAG and MoH with the US Advisory Committee on Immunization Practices (ACIP) and CDC, which later guided the restructuring of the AR NITAG. [23]. ProVac also supported Centers of Excellence to support NITAGs and MOH in the Region. Participation in GNN [25,26]		EMRO Workshops on evidence-based policymaking and exchanges of good practices through the Global NITAG Network (GNN) were some examples of the much-appreciated WHO assistance. Participation in GNN	Engage, participate in GNN meetings, activities

defining CoI, a written CoI declaration form or affidavit, and how to proceed when a CoI arose. In all participating MICs, there were rules for early termination in case of misconduct or significant CoI. The responsibility to ensure members' compliance with the CoI policy was with the NITAG Secretariat (JO, AR) or the Chair (SA). SA and AR did not express any concerns with the process and emphasized that they have been rigorously implementing the CoI policy for several years. However, in JO, the NITAG was considering to improve their capacity to monitor and enforce proper compliance. NITAGs were implementing a process of stepwise rotation when members leave, and the new MoH's appointees arrived to ensure institutional memory and a smooth transition. This process allowed for the continuity and accountability of activities because many of the terms of the current core members expired at the same time (SA, AR). Some NITAG members (AR, SA) expressed an interest in exercising oversight functions over the NIP's policy implementation. Those members considered advocating access to specific MoH data that would allow them to supervise the program's performance. However, other members thought assuming accountability functions over the MoH would likely interfere with or overstep their advisory mission.

3.3. Participation

In each country, only the NITAG members appointed by the MoH and only those designated as core members were involved in the NITAG's decision-making process leading to recommendations. Occasionally, the NITAG Chairs would invite experts to provide information on a particular topic; however, the meetings were closed to the public in all three countries. NITAGs hesitated to include external participants (e.g., civil society organizations, community advocates, and other stakeholders) in deliberations. For the NITAG members interviewed in AR and SA, their foremost concern about the inclusion of other actors in NITAG sessions was the possibility of additional and more diverse views or priorities increasing internal conflict or harming the ongoing NITAG process to achieving decisions by consensus. In AR, NITAG non-core members were selected among five regional NIP managers who contributed valuable input on the implementation aspects of NITAG recommendations. The same NIP managers remained engaged after the policy endorsement to support subnational programs during the implementation phase. According to one government official, the SA MoH was considering expanding the involvement of NITAG members to include those with expertise in programmatic implementation. The SA NITAG also advocated for the inclusion of the Biovac Institute, a public–private partnership, to advise NITAG on issues related to vaccine procurement. NITAGs in both SA and AR were looking into ways to balance the benefits of civil society participation while avoiding dissenting views, which may result in conflict and inefficiency in deliberations. For example, a SA NITAG member expressed that trust for vaccines was decreasing because of the concern among Islamic and Jewish groups to being vaccinated against measles due to concerns the vaccine contained pork ingredients and animal they are forbidden to eat. Leaders of those religious councils endorsed vaccines and were interested in participating in NITAG meetings when vaccine introductions were discussed, to become better informed and being able to advocate among those in their communities who refused vaccines. NITAG and MoH were considering their request.

3.4. Integrity

NITAG members were aware of the terms of references, their purpose, codes of conduct, membership eligibility, roles and responsibilities, and the duration of memberships. In two coun-

tries, immunization committees were established as soon as their NIPs were instituted (JO in 1985 and SA in 1993). Their NITAGs evolved from those committees. However, the first committee in AR was created much later (2000). The governments had revised or enhanced NITAGs' ministerial decrees, ToRs, and SOPs (JO in 2009, AR in 2013, and SA in 2015). In all three countries, NITAGs' mandates were limited to immunization and provided advice to MoH regarding vaccines, vaccine-preventable diseases, and supported the NIP. In general, NITAGs primary mission was to facilitate a transparent, evidence-based policy-making process by issuing recommendations to the government upon assessing the available evidence on existing, new, and emerging vaccines and technologies. NITAGs in these countries were clearly distinguished from the National Regulatory Agencies (NRA), Inter-Country Committees (ICC), and disease-specific committees. However, some of the NITAG members participated in other committees.

3.5. Capacity

For the most part, NITAG members were highly trained, experienced professionals. They also worked tirelessly to design policies that would align technical aspects to their country's political contexts to ensure policy success. In SA, a NITAG member had also been former member and Chair of the WHO's Strategic Advisory Group of Experts (SAGE) on Immunizations [36]. NITAG members from JO and AR valued the support provided by the WHO Regional Offices to strengthen the policymaking processes and the country's capacity to issue recommendations. Workshops on evidence-based policymaking and exchanges of good practices through the Global NITAG Network were some examples of the much-appreciated WHO assistance. The Pan American Health Organization's (PAHO) ProVac initiative sponsored an exchange between AR NITAG and MoH with the US Advisory Committee on Immunization Practices (ACIP) and CDC, which later guided the restructuring of the AR NITAG [37],[38]. NITAG members from AR appreciated PAHO's ProVac establishing regional centers of excellence to support vaccine-related health economic studies used by NITAG and MoH for decision-making [39],[26]. NITAGs were considering a more inclusive membership, beyond traditional medical and public health expertise, to improve their capacity for policy analysis, incorporating critical economic and programmatic factors when assessing policy options. The NITAG in JO considered including a communication expert. NITAGs agreed on the value of having an economist as a member and Jordan's example of their fiscal space analysis to introduce rotavirus vaccine was a good example of the benefits of having an economist when making recommendations.

4. Discussion

In the three MICs assessed, NITAGs played a pivotal role as advisors, strengthening and promoting a culture of evidence informed policies and strengthening health systems governance in their countries. Governments regarded NITAG members as highly capable experts, facilitating evidence in formed decisions, whose influence reached their respective WHO Regional level. We found that NITAG policy analyses and recommendations had supported policymakers, implementers, evaluators, and policy champions within the country. NITAGs in these countries participated significantly in the policymaking process as integral bodies, contributing to the introduction of most of the vaccines in the NIP schedules, while providing other technical support. NITAGs displayed similarities and differences in the critical Governance attributes assessed, the major areas for improvement being on transparency, accountability and participation. We highlight the strengths and weaknesses

and share some of the recommendations discussed during the interviews.

Transparency: Practices to strengthen transparency varied among the countries. NITAGs had made thoughtful efforts towards transparency by recording sessions, detailing areas of agreement and conflict, and the process by which members reached consensus. NITAGs' available documents (agendas, meeting minutes) were a gateway to understanding NITAG and MoH dynamics and integration, the interactions with working groups and experts. Through these documents it was also possible to trace each NITAG framework, the policy process, and how evidence based recommendations were achieved and shared with the MoH. All NITAGs expected their policy analysis and recommendations to support a larger group of policymakers, implementers, evaluators, and policy champions. The major weakness was the absence of comprehensive documentation (work plan, policy briefs, annual handbook, or summary). The absence of compelling evidence or proper documentation (work plan, policy briefs, annual handbook, or summary), and together with the fact that deliberations were conducted behind closed doors and attended solely by NITAG members, could open the risk for questioning the transparency of the decisionmaking process and recommendations. Among other committees, the US ACIP and the WHO Strategic Advisory Group of Experts on Immunization (SAGE) publish their recommendations on their web sites. On that regard AR was making an excellent effort to disseminate relevant documents produced by their NITAG, making them available on the MoH website. Other strategies to enhance transparency could include outlining the following in the NITAG SOP and ToR: defining criteria used for decision-making, describing the process for an evidence-to-recommendation framework, and preparing technical background documents for NITAG deliberations.

Accountability: Documentation of compliance with Col policy and the establishment of enforcement of accountability mechanisms are essential for good governance. NITAG members considered of value having a written Col policy to protect NITAG reputation of being independent, credible, and free from competing interests. NITAG members believed compliance with Col policy increased legitimacy and acceptance of their policy decisions and improved relationships with stakeholders who advocated for better scrutiny of the policy process. Among the concerns was the robustness of Col enforcement, given that accountability, essential for good governance, relied exclusively on the NITAG Secretariat or the Chair. Some members thought accountability meant ensuring continuity, institutional memory, and resilience, which were at risk when members were replaced. Some had implemented a mechanism of stepwise rotation to facilitate a good transition. However, the merit of that policy had not been assessed. An area of interest was developing and implementing indicators to measure NITAG performance, the impact of NITAG recommendations, and their contributions to the NIPs and to good governance. There were some efforts to implement indicators beyond those reported to the JRF, to measure the contributions of more mature MIC NITAGs. Accountability is an area in which collaboration between MoH and NITAG could prove valuable if the right balance is achieved to avoid overstepping of the NITAGs' advisory mission. Since NITAGs functioned relatively autonomous from the government, more robust oversight of NITAG processes and adherence to ToRs, SOPs, and Col could play a role in strengthening governance.

Participation: To enrich the breadth of experience and provide more comprehensive evidence based decision-making, NITAGs proposed broadening membership to include experts in communication, finance, economics, program implementation, and civil society. Admitting outside audiences into NITAG or MoH deliberations could enforce NITAG and MoH's commitment for more rigorous, open, and transparent decisions than the current practices.

To address the issue of vaccine confidence, SA was assessing the inclusion of religious and other community leaders in deliberations, while the JO NITAG emphasized the need of communication experts to appropriately address.

Integrity: Clarity among NITAG and MoH members about mandates, methods of selecting members, procedures, roles, and purposes could improve the management of the policy process. NITAGs would benefit from MoH revisiting the mission and ToRs to provide more explicit guidance, which could be better adapted to the current policy context, priorities, and challenges.

Capacity: The policy-making capacity of MIC countries could be strengthened by NITAGs more comprehensive synthesis of the critical economic and programmatic aspects of potential recommendations, which could improve policy design and implementation. Implementation was mostly under the MoH national and jurisdictional responsibilities. The government of SA was considering the inclusion of program experts as NITAG members to increase the capacity to address implementation issues in policy recommendations. The case of AR, where regional NIP managers were NITAG non-core members, highlighted their value when considering operational and programmatic aspects during deliberations, when issuing recommendations and during implementation; this practice provided NITAG contributions at the different stages of the policy cycle.

5. Limitations

There were several limitations to this study. During the initial phase, NITAG Chairs, and WHO COs reviewed the accuracy of the data from the interviews included in the country reports and the reports themselves. The results were also examined by the CDC and researchers from all three countries. However, the analysis and the synthesis of the governance attributes were conducted by only one researcher. Even though the reviewers were able to point out ambiguities and resolve disagreements, the abstraction of the reports and analysis itself was not repeated by another investigator to further ensure reliability.

6. Conclusions

In all three countries, the governments appreciated the value added by NITAGs. This benefit was mainly to fulfil their mandate and provide independent advice regardless of shifting political, economic, and technical environments. NITAGs contributed to policy analysis and influenced, to some extent, policy design and implementation, saving valuable time, resources, and contributing to policy success and good governance. Moreover, NITAGs supported good governance by providing input to guide efficiency, resilience, and effectiveness of the policy process [12]. Interviewees mentioned the need for robust indicators to appropriately monitor and evaluate mature, good functioning NITAGs from MICs and their contributions to MoH and good governance. The long-term survival of these three MIC NITAGs can be regarded as a success. The fact that governments considered non-binding recommendations made by NITAGs, indicated that authorities had entrusted NITAGs and valued their advice. Governments stood by NITAG recommendations even when their recommendations were contrary to internal or external groups' guidance or even pressure. An aspect that must not be overlooked is the legacy of these NITAGs. The rich and unique traditions, impressive work, and the achievements undertaken over the decades were significant assets in AR, JO, and SA. The history and lessons learned in each country should be registered and shared with the next generation of NITAG members, governments, and others committed to the advancement of public health. Systematically implementing sound gover-

nance approaches, including monitoring and evaluation, can lead to improved processes, well-tailored policies, and efficient policy implementation.

Disclaimer

The findings, opinions, conclusions, and assertions contained in this consensus document are those of the individual members. They do not necessarily represent the official positions of any participant's organization (e.g., government, university, or corporations) and should not be construed to represent any Agency determination or policy.

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Maria S. Panero: Conceptualization, Data curation, Formal analysis, Writing - original draft. **Najwa Khuri-Bulos:** Validation, Writing - review & editing. **Cristián Biscayart:** Validation, Writing - review & editing. **Pablo Bonvehí:** Validation, Writing - review & editing. **Wail Hayajneh:** Validation, Writing - review & editing. **Shabir A. Madhi:** Validation, Writing - review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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References

- [1] Duclos P. National Immunization Technical Advisory Groups (NITAGs): guidance for their establishment and strengthening. *Vaccine* 2010;28 (Supplement 1):A18–25. <https://doi.org/10.1016/j.vaccine.2010.02.027>.
- [2] NITAG Resource Center. Available: <http://www.nitag-resource.org/>.
- [3] Global Vaccine Action Plan 2011–2020 [Internet]. 1st ed. Geneva: World Health Organization; 2013. https://www.who.int/immunization/global_vaccine_action_plan/GVAP_doc_2011_2020/en/.
- [4] SAGE April 2017 National Immunization Technical Advisory Groups: Background Paper. https://www.who.int/immunization/sage/meetings/2017/april/1_NITAGs_background_document_SAGE_April_2017.pdf.
- [5] Takla A et al. Characteristics and practices of National Immunisation Technical Advisory Groups in Europe and potential for collaboration, April 2014. <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=21049>.
- [6] Bell S et al. Value and effectiveness of National Immunization Technical Advisory Groups in low- and middle-income countries: a qualitative study of global and national perspectives. <https://doi.org/10.1093/heapol/czz027>.
- [7] Ba-Nguz A et al. Supporting national immunization technical advisory groups (NITAGs) in resource-constrained settings. New strategies and lessons learned from the Task Force for Global Health's Partnership for influenza vaccine introduction. *Vaccine* 2019;37(28):3646–53. <https://doi.org/10.1016/j.vaccine.2019.05.046>.
- [8] WHO/UNICEF Joint Reporting Form. Available at https://www.who.int/immunization/monitoring_surveillance/routine/reporting/en/.
- [9] Duclos P et al. Progress in the establishment and strengthening of national immunization technical advisory groups: analysis from the 2013 WHO/UNICEF joint reporting form, data for 2012. *Vaccine* 2013;31(46):5314–20. <https://doi.org/10.1016/j.vaccine.2013.08.084>.
- [10] Munira SL, Fritzen SA. What influences government adoption of vaccines in developing countries? A policy process analysis. *Soc Sci Med* 2017;65 (8):1751–64. <https://doi.org/10.1016/j.socscimed.2007.05.054>. Elsevier.
- [11] Nielson S. Knowledge utilization and public policy processes: a literature review. IDRC Evaluation Unit; 2001. Available: <https://bit.ly/2Zca6Ey>.
- [12] Jones H. A guide to monitoring and evaluating policy influence. Working and discussion papers. Overseas Development Institute; February 2011. [Available: <https://bit.ly/2wfpjmw>].
- [13] Sanderson I. Evaluation, policy learning and evidence-based policy making. *Public administration*, vol. 80, no. 1. p. 1–22, 2002. Available: <https://bit.ly/3bZaZET>.
- [14] Blau J et al. Indicators to assess National Immunization Technical Advisory Groups (NITAGs). *Vaccine* 2013;31:2653–7. <https://doi.org/10.1016/j.vaccine.2013.01.047>.
- [15] van Zandvoort K et al. Strengthening national vaccine decision-making: assessing the impact of SIVAC Initiative support on national immunisation technical advisory group (NITAG) functionality in 77 low and middle-income countries. *Vaccine* 2019;37(3):430–4. <https://doi.org/10.1016/j.vaccine.2018.11.070>.
- [16] Mosina L et al. Building immunization decision-making capacity within the World Health Organization European Region. *Vaccine* 2020;38(33):5109–13. <https://doi.org/10.1016/j.vaccine.2020.05.077>.
- [17] Evans B, Wellstead A. Policy dialogue and engagement between non-governmental organization and government: a survey of processes and instruments of Canadian policy workers. *Central Eur Publ Policy* 2013;7(1). <https://digitalcommons.mtu.edu/social-sciences-fp/7/>.
- [18] Editorial – Recommendations for strengthening NITAG policies in developed countries. *Vaccine* 2015;33(1):1–2. <https://doi.org/10.1016/j.vaccine.2014.10.035>.
- [19] Howard N et al. The role of National Immunisation Technical Advisory Groups (NITAGs) in strengthening national vaccine decision-making: a comparative case study of Armenia, Ghana, Indonesia, Nigeria, Senegal and Uganda. *Vaccine* 2018;36(37):5536–43. <https://doi.org/10.1016/j.vaccine.2018.07.063>.
- [20] World Bank Governance Indicators. Home page. Available: <https://bit.ly/2wHvx83>.
- [21] Mikkelsen-Lopez I, Wyss K, de Savigny D. An approach to addressing governance from a health system framework perspective. *BMC Int Health Hum Rights* 2011;11:13. <https://bit.ly/39ekXzj>.
- [22] Sundaram JK, Clark MT. Does good governance always boost development? Article published in World Economic Forum collaboration with Project Syndicate. Available: <https://bit.ly/38P8PVK>.
- [23] Greer SL, Wismar M, Figueras J, editors. Strengthening health system governance: better policies, stronger performance. European observatory on health systems and policies series: Open University Press; 2016. p. 57–84. <https://apps.who.int/iris/bitstream/handle/10665/329515/9780335261345-eng.pdf>.
- [24] Siddiqi S, Masud TI, Nishtar S, Peters DH, Sabri B, Bile KM, et al. Framework for assessing governance of the health system in developing countries: gateway to good governance. *Health Policy* 2009;90:13–25. <https://doi.org/10.1016/j.healthpol.2008.08.005>.
- [25] Mayer IS, van Daalen CE, Bots PWG. Perspectives on policy analysis: a framework for understanding and design. *Int J Technol Policy Manage* 2004;4 (2). <https://doi.org/10.1504/IJTPM.2004.004819>.
- [26] Bryson M, Duclos P, Jolly A. Global immunization policy-making processes. *Health Policy* 2010;96(2):154–9. <https://doi.org/10.1016/j.healthpol.2010.01.010>.
- [27] Gessner BD, Duclos P, DeRoeck D, Nelson EAS. Informing decision-makers: experience and process of 15 national immunization technical advisory groups. *Vaccine* 2010;28S:A1–5. <https://doi.org/10.1016/j.vaccine.2010.02.025>.
- [28] Ricciardi GW, Toumi M, Weil-Olivier C, Ruitenber EJ, Dankó D, Duru G, et al. Comparison of NITAG policies and working processes in selected developed countries. *Vaccine* 2015;33(1):3–11. <https://doi.org/10.1016/j.vaccine.2014.09.023>. Epub 2014 Sep 23.
- [29] Yin R. Case study research and application: design and methods. Los Angeles: Sage; sixth ed.; 2018. <https://bit.ly/2X1fxUD>.
- [30] SIVAC, AMP HPID, Evaluating National Immunization Technical Advisory Groups (NITAGs). Performance–Practical Tool; Jan 2016.
- [31] CoNaIn, (NITAG) Argentina. MoH website: <https://bit.ly/2sSpRjZ>.
- [32] Stecher D, Gaiano A, Biscayart C, Gentile A, Gonzalez Ayala S, Lopez E, et al. National immunization commission: strengthening evidence-based decision making in Argentina. *Vaccine* 2014;32:1778–80. <https://doi.org/10.1016/j.vaccine.2014.01.080>.
- [33] Schoub BD, Ntombenhle J, Ngcobo NJ, Madhi S. The National Advisory Group on Immunization (NAGI) of the Republic of South Africa. *Vaccine* 2010;28:31–4. <https://doi.org/10.1016/j.vaccine.2010.02.029>.
- [34] Bélisle-Pipon JC, Ringuette L, Cloutier AI, Doudenkova V, Williams-Jones B. Conflicts of interest and the (in)dependence of experts advising government on immunization policies. *Vaccine* 2018;36:7439–44. <https://bit.ly/31JTLc6>.
- [35] Gavi - The Vaccine Alliance - Eligibility. <https://www.gavi.org/types-support/sustainability/eligibility>.
- [36] WHO Strategic Advisory Group of Experts on Immunization, website: <https://bit.ly/2TvB5WO>.

- [37] Jauregui B, Sinha A, Clark AD, Bolanos BM, Resch S, Toscano CM, et al. Strengthening the technical capacity at country-level to make informed policy decisions on new vaccine introduction: lessons learned by PAHO's 27 Initiative. *Vaccine* 2011;29(1):1099–106. <https://doi.org/10.1016/j.vaccine.2010.11.075>.
- [38] Advisory Committee on Immunization Practices (ACIP), website: <https://bit.ly/2PDCGZL>.
- [39] Toscano CM, Jauregui B, Janusz CB, Sinha A, Clark AD, Sanderson C, et al. ProVac Network of Centers of Excellence. Establishing a regional network of academic centers to support decision making for new vaccine introduction in Latin America and the Caribbean: the ProVac experience C12-8. *Vaccine* 2013;31 (Suppl3). <https://doi.org/10.1016/j.vaccine.2013.05.033>.