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Strengthening vaccination frameworks: Findings of a study on the legal foundations of National Immunization Technical Advisory Groups (NITAGs)

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ABSTRACT

In 2017, the Strategic Advisory Group of Experts on Immunization's Assessment Report of the Global Vaccine Action Plan noted the need to "*better document the ways in which legislation and regulations have been used to promote or undermine immunization at the national level*". Despite National Immunization Technical Advisory Groups (NITAGs) now existing in over 134 countries worldwide, there has been very little academic consideration of their legal underpinnings. In this paper, we compare the legal foundations and authority of 28 NITAGs from the six WHO Regions. All are members of the Global NITAG Network. We categorize the NITAGs based on their legal foundation and on the authority granted to them by their government, organizing them into a taxonomy of models. We then propose legal considerations for governments contemplating establishing or reforming a NITAG.

1. Introduction

There is a growing belief that legislation makes an important (indeed critical) contribution to the legitimization of national immunization programs (NIPs), signaling political acceptance of their social significance, securing and stabilizing their existence, and encouraging country ownership [1,2], and, ultimately, citizen buy-in through improved vaccination uptake and public health. For example, the Global Vaccine Action Plan (GVAP) has identified the establishment of immunization laws as an indicator of national commitment to immunization [3]. In the Pan-American region, it has been reported that legislation helped Latin American and Caribbean immunization programs, particularly with respect to national spending [4]. In the European region, it has been reported that legislation adopts a varied approach to mandates depending on country context, with no single approach commended [5]. Ultimately, despite the perceived importance of legislation, there is little understanding of the diverse approaches to vaccination legislation across national borders globally [6,7], which led the Strategic Advisory Group of Experts on Immunization (SAGE) to issue a call at the global level for "*better* [documentation of] *the ways in which legislation and regulations have been used to promote or undermine immunization at the national level*" [8].

Related to this, in 2017, there was a call from the Global NITAG Network (GNN) for more research into the legal foundations of National Immunization Technical Advisory Groups (NITAGs) worldwide [7]. NITAGs are envisioned as expert committees that provide independent, evidence-based, scientific and/or technical advice to governments and health authorities on vaccination, new vaccines, and immunization policy [9,10]. By December 2017, some 124 countries reported the existence of a NITAG, with 82 self-reporting that their NITAGs complied with the WHO's six 'process indicators', being: (1) the existence of a legislative or administrative basis for the NITAG; (2) the existence of formal, written terms of reference; (3) the implementation of a conflict of interest policy; (4) the representation of at least five areas of expertise on the NITAG; (5) the holding of a meeting at least once per year; and (6) the circulation of the meeting's agenda at least

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one week prior to each meeting [11,12]. By August 2019, 158 countries reported the existence of a NITAG within their jurisdiction that generally complied with the definition offered by the WHO, [12] and 114 of these countries self-reported that their NITAGs complied with the WHO's six 'process indicators' [13]. However, despite some attention to their processes and assessment, there has, to date, been little attention paid to the legal underpinnings of NITAGs.

Given the two above-noted shortcomings in evidence and insight, and given the calls issued by SAGE and the GNN, we undertook the NITAG Environmental Scan, a pilot project aimed at improving our understanding of NITAG governance, and the significance, if any, of particular governance structures on immunization program content or delivery of GNN member NITAGs across different WHO regions. The following sections describe the project and its methods, and report on some of the findings as they relate to NITAG foundation.

2. The project

The NITAG Environmental Scan was designed as a qualitative project with the broad objectives of exploring the foundation of GNN member country NITAGs so that policymakers and decision-makers would have heretofore unavailable information that may empower them to improve their immunization architecture and better harmonize that architecture and related practices across jurisdictions, thereby improving the conditions for achieving the vision of the Decade of Vaccines [8]. It was funded by a small contract from the WHO's Department of Immunization, Vaccines and Biologicals (IVB), and it received ethical scrutiny and ethics approval from the Research Ethics Board of the IWK Health Centre in Halifax, Nova Scotia, Canada (Ethics Approval No. 1023718).

3. Methods

Data collection within the NITAG Environmental Scan was pursued through three main avenues. The first and primary means was a secure online survey that was developed iteratively by the research team, with questions and structure refined through team interactions. The survey was pilot tested for comprehensibility and answerability with the help of five reviewers from three different WHO regions, all of whom were familiar with NITAGs. This resulted in amendment of questions to enhance clarity, and restructuring to improve overall flow. All GNN country members (40 as of June 2018) were invited to participate in the survey through a national representative drawn from the GNN Secretariat list, who would enter the survey via a password-protected portal. The survey was available in English and French as all GNN countries in 2018 reported a capacity to respond in at least one of those two languages. The survey was open from June 2018 to September 2018, with three reminders issued by the GNN Secretariat. Given that the main objective of the survey was to collect primary feedback from country experts, it included three components: (1) tick-box questions that could be tabulated quantitatively using simple descriptive statistics; (2) free-text comments that were analyzed qualitatively for specific jurisdictional insights and themes by the two lawyers on the team (SH, DH); and (3) requests for legal and/or policy instruments (which were provided to us either via URL or email).

The second means of data collection – supplemented by the survey itself – was to gather and examine primary governance instruments. Instruments were submitted in a range of languages. While several had official or semi-official translations, most non-English instruments were not translated in their entirety, largely due to the prohibitive cost and the time demands of translating so many instruments from so many languages. To minimize the impact of this limitation, we adopted a pragmatic approach to translation. The team undertook an initial 'rough translation' using Google Translate and Deepl, which permitted identification of key elements or provisions of the instruments. If further elaboration was felt necessary, these sections were translated at the WHO so that precise/reliable wording was obtained. The final scripts were then subject to legal text analysis (by SH and DF) with the aim of identifying provisions addressing NITAG membership, structure, authority, etc. [14].

The final means of data collection, meant to further minimize the impact of the above limitation, was to conduct desktop research in pursuit of pertinent secondary sources (e.g., governmental explanatory notes, recommendations, policies, articles, studies, or comments), primarily in relation to specific case-study countries. In doing so, we reviewed national government webpages (e.g., Ministries of Justice, Health, Public Health Agencies, online legislation registries), a range of legal repositories (e.g., Vaccine European New Integrated Collaborative Effort (VENICE), International Labor Organization's National Legislation database (NATLEX)), UN, WHO and regional health organization policy webpages, and academic literature accessed through Google Scholar, WestLaw and WorldLII. This was then subjected to selected follow-up outreach to national experts to verify results and/or seek clarity around certain aspects of the instruments provided.

4. Results

Of the 40 GNN member countries invited to participate, responses were received from 28, representing a response-rate of 70%. For all but one country, respondents answered all or most of the questions (i.e., no single question suffered from consistent non-responsiveness, and the survey did not exhibit drop-out in the progression from start to finish). Drawing on World Bank classifications, responses were received from six low-income, five lower-middle-income, six upper-middle-income, and 11 high-income countries, representing all six of the WHO regions (Table 1: Country Respondents). Based on survey responses and our review of legal documents, 23 of 28 of the respondent countries (82%) reported the existence of legislation or regulation relating to their national immunization program (NIP) (Table 2: Legal and Policy Instruments).

A taxonomy of three categories of foundation was developed: formal; informal; and evolutionary (Table 3: Taxonomy of NITAG Foundations). Twenty-seven of the 28 respondents fall within one of these three broad foundational categories; for Tanzania, a category could not be assigned. As categorized, the foundations for these NITAGs are strongly skewed toward an informal foundation (74% (20/27)), with most reliant on an executive instrument (e.g., Ministerial Decree or Statement), and fewer on a departmental policy statement, or similar administrative tool. Only five NITAGs (5/27 (18.5%)) were assessed to be grounded in legislation or regulation. For more on the countries represented in each category, see Table 4: Evidence on NITAG Foundation.

Of the 28 respondent countries, we were supplied with or able to locate and directly analyse 18 NITAG foundational instruments (i.e., instruments that founded or otherwise enabled or structured the NITAG). For the remaining 10 NITAGs, we relied on statements made by our survey respondents, with corroboration, when possible, from relevant policy statements or other authoritative documents. Based on the evidence, four general models of authority

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Table 1
Country Respondents.

Table 1 Country Respondents			
Country Flag	**GNN Country Member**	**WHO Region**	**Income Level**
	Albania	European	Upper-Middle
	Argentina	Americas	High
	Armenia	European	Upper-Middle
	Australia	Western Pacific	High
	Belgium	European	High
	Canada	Americas	High
	Chile	Americas	High
	China	Western Pacific	Upper-Middle
	Côte d'Ivoire	African	Lower-Middle
	Ethiopia	African	Low
	Germany	European	High
	Indonesia	South-East Asia	Lower-Middle
	Jordan	Eastern Mediterranean	Upper-Middle
	Kazakhstan	European	Upper-Middle
	Latvia	European	High
	Maldives	South-East Asia	Upper-Middle
	Nepal	South-East Asia	Low
	Nigeria	African	Lower-Middle
	Sri Lanka	South-East Asia	Lower-Middle
	Sweden	European	High
	Tanzania	African	Low
	Timor-Leste	South-East Asia	Lower-Middle
	Togo	African	Low
	Uganda	African	Low
	United Kingdom	European	High
	United States	Americas	High
	Uruguay	Americas	High
	Zimbabwe	African	Low

were developed: advisory; directive; hybrid; and collaborative (Table 5: Models of NITAG Authority).[1] Using these models, we found that 24 NITAGs were advisory (24/28 (86%)); two were hybrid; one was directive, and one was collaborative. Moreover, there was no strong correlation between NITAG authority and the nature of the NITAG's foundation, with the exception that the directive and hybrid NITAGs all had a formal foundation (based in statute and statutory instrument). Advisory NITAGs, by contrast, were grounded in all foundation types (Table 6: NITAG by Authority Model and Legal Foundation).

Amongst the NITAGs where authority was advisory, the instruments expressed or signaled this (soft) authority in different ways. In some, the authority was explicitly stated. For example, the Terms of Reference for Sweden's NITAG states that "[the NITAG] is advisory and has no decisive role."[15,16,17] More commonly, less explicit terms were used, including references to the subject NITAG offering "advice" or "opinions" (e.g., Armenia, Ethiopia, Uganda), or making "recommendations" (e.g., Belgium, China, Cote d'Ivoire, Ethiopia).

As noted, only one directive NITAG was found – Germany – and 'directiveness' was achieved by requiring the government to fund and/or place into the NIP vaccines recommended by the NITAG. Hybrid NITAGs have a combination of directive and advisory powers depending on vaccine and/or context. Our review found two hybrid NITAGs, those from the UK and USA, both of which have complex histories, and both of which are grounded in both statute and statutory instruments (i.e., they are formally founded). In the USA, NITAG recommendations are binding with respect to paediatric vaccinations. Under paragraphs 8 and 9 of its 2018 Charter, ACIP *shall* establish, review, and revise the list of vaccines administered to children and youth through the national Vaccines for Children Program (which list *shall* be used by the CDC to purchase and deliver paediatric vaccines), and ACIP recommendations adopted by the CDC *must* be covered by private health plans [18]. In the UK, recommendations are directive in response to, inter alia, a request from the Secretary of State.

Only one example of a collaborative NITAG was found: Canada's National Advisory Committee on Immunization (NACI). NACI's collaborative character is a direct result of the federal government being constitutionally unable to establish a directive NITAG because responsibility for healthcare delivery (and immunization programs) rests with the provinces. The constitutional division of jurisdiction with respect to health in Canada makes the founding of even an advisory NITAG contingent. As such, NACI must negotiate its influence with each of the 13 provincial and territorial authorities. Thus, NACI recommendations may or may not be

[1] We acknowledge that 'authority' can mean several things, and in the immunization setting, has several facets. For example, it can refer to: scientific authority (e.g., opinions around vaccine safety, efficacy, and quality having a sufficient evidence-base and coming from sufficiently credentialed individuals); social authority (e.g., opinions around vaccine authorization, and what considerations will undergird that assessment, having a sufficiently wide consensus); legal authority (e.g., bodies or decisions having some socially sanctioned and publicly recorded power to adopt a course of action or enforce a decision); and moral authority (e.g., bodies or decisions having a foundation in, or clear connection to, the advancement of human wellbeing as socially and logically understood). In the present case, we are referring to the NITAGs' legal authority; their empowerment to make a decision and see it complied with by those responsible for taking action on the ground.

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Table 2
Legal and Policy Instruments.

Respondent Member	No. of Insts.	Instrument Type	Instrument Title or Description (mostly unofficial translations of title) † = Received/Located Official or Semi-Official English Translation	Origin Language
Albania	1	Statute	On Prevention & Fighting Infection and Infectious Diseases	Albanian
Argentina	3	Statute	Law No. 22.909: Establishing a General Regimen for Vaccination	Spanish
		Decree	Ministerial Res. 258/2013: National Immunization Commission	Spanish
		Regulation	Ministerial Res. 258/2013 Regulations	Spanish
Armenia	2	Decree	Government Decree on National Immunization Program for 2016–2020	Armenian
		Decree	Minister of Health Decree N 2907, November 1 2013	Armenian
Australia	3	Statute	National Health Act 1953	English
		Regulation	National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)	English
		Terms of Reference	ATAGI Terms of Reference	English
Belgium	5	Decree	Royal Decree 2007/22420 Creating the High Council on Health	French
		Decree	Ministerial Decree 2007/22843 Approving the Rules of Procedure on the High Council of Health	French
		Regulation	Regulations on vaccinations and infectious Diseases	French
		Decree	Royal Decree Rendering Poliomyelitis Vaccination Obligatory	French
		Court Decision	2013 Decision of the Belgian Court of Appeal upholding mandatory Polio vaccination	Dutch
Canada	3	Statute	Immunization of School Pupils Act (Ontario)	English
		Statute	Public Health Act (New Brunswick)	English
		Statute	Public Health Act (Québec)	English†
		Terms of Reference	NACI Terms of Reference	English
Chile	3	Decree	Ministry of Health Decree 2028 Creating Advisory Committee on Vaccines and Strategies of Immunization	Spanish
		Decree	Various decrees on obligatory vaccination	Spanish
		Terms of Reference	CAVEI Terms of Reference	Spanish
China	2	Regulation	Decision on Amending the Regulations on the Administration of Vaccine Circulation and Vaccination	Chinese
		Regulation	Opinions of the General Office of the State council on Further Strengthening Vaccine Circulation and Vaccination Management	Chinese
Côte d'Ivoire	1	Decree	Decree 226 Regarding the Creation, Organisation, Properties, and Functioning of the National Committee of Independent Experts for Vaccination of Côte d'Ivoire	French
Ethiopia	1	Terms of Reference	Ethiopian NITAG Terms of Reference	English
Germany	1	Statute	Act on the Reform of the Communicable Diseases Law	English†
Indonesia	4	Decree	Decree of ITAGI 2006	Indonesian
		Decree	Decree of ITAGI 2010	Indonesian
		Decree	Decree of ITAGI 2013	Indonesian
		Decree	Decree of ITAGI 2015	Indonesian
Jordan	0	*No instruments received*		
Kazakhstan	2	Decree	2012 Decree 116, On the Establishment of the National Advisory committee on Immunization	Kazakh / Russian
		Decree	2013 Decree No 119: Amendments and Additions to . . . List of Diseases against which Prophylactic Vaccinations are carried out. . .	Kazakh / Russian
Latvia	2	Statute	Statute of the National Council for Immunization	Latvian
		Statute	Vaccination Regulations	Latvian
Maldives	1	Statute	Public Health Protection Bill	English
Nepal	2	Statute	Immunization Act	English†
		Terms of Reference	Nepal National Committee on Immunization Practices Charter	English
Nigeria	0	*No instruments received*		
Sri Lanka	0	*No instruments received*		
Sweden	2	Statute	Infection Prevention Law	Swedish
		Terms of Reference	Reference Group for National Vaccination Programs	Swedish
Tanzania	0	*No instruments received*		
Timor-Leste	0	*No instruments received*		
Togo	1	Decree	Decree No. 2015–096 Regarding the Creation and Composition of the Technical Consultant Group on Vaccination (GTCV)	French
Uganda	2	Statute	Immunisation Act 2017	English
		Decree	Ministerial Statement Establishing the National Immunization Technical Advisory Group (NITAG)	English
United Kingdom	3	Statute	Vaccine Damage Payments Act 1979	English
		Regulation	The Health Protection (Vaccination) Regulations 2009	English
		Terms of Reference	Joint Committee on Vaccination and Immunisation Code of Practice 2013	English
United States	4	Statute	Social Security Act	English
		Statute	Public Health Service Act	English
		Statute	National Childhood Vaccine Injury Act of 1986	English
		Terms of Reference	Advisory Committee on Immunization Practices (ACIP) Charter	English
Uruguay	4	Decree	Decree No. 716: Creation of a New Integrated the Vaccination Advisory Commission	Spanish
		Decree	Decree No. 234: Evaluation Carried Out by the Vaccination Advisory Commission in Relation to Needs of Integration	Spanish
		Decree	Decree of 19 September 2005: Incidence and Prevalence of Hepatitis B in our Country	Spanish
		Terms of Reference	Vaccination Advisory Commission: Strategic Vision and Standard Procedures	Spanish
Zimbabwe	1	Statute	Public Health Act	English

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Table 3
Taxonomy of NITAG Foundations.

Formal	• Relies on statute or a statutory instrument (e.g., regulations adopted pursuant to an enabling statute). • Typically requires some form of formal democratic or participative action at commencement (i.e., introduction and debate in, and passage through, an elected body). Statutory bodies are also often characterized by formal authorization, a stated remit and limitations, and/or oversight together with metrics for measuring compliance with its remit or advancement of its social objective. This, in turn, provides the body with a degree of organizational stability. • Typically necessitates legislative action to revoke or significantly reform the foundation or the operation of the body. This arguably provides the potential for a 'stronger' regulatory body insofar as its clear scope of action and boundaries, both fortified in difficult-to-amend legal instruments, can shield it from executive interference and embolden it to pursue its objectives transparently and stoutly.
Informal	• An executive instrument (e.g., a decree or statement of a president or minister of health), or executive policy (e.g., a statement or policy document of an executive branch, department or minister) is the basis for the body's existence and operation. • While a decree can sometimes be viewed as a formal legal instrument (and is so considered in many jurisdictions), these instruments are also defensibly characterized as policy instruments subject to change with relative ease (i.e., without the formalities of debate and vote within an elected body). • Expected to exhibit a greater ease of introduction and institutional development, and to result in an organization with a greater ease of disbandment/discontinuation. • Assume such instruments are adopted with shorter lead-times, put in place and operationalized with less accompanying public debate.
Evolutionary	• Less structured process; generally formed by way of convention and practice over time. • May be a lack of clarity as to how the body was originally established, or an alteration as to the scope of its functions, though an informal origin and a range of functions based on convention is likely. • Key characteristic that differentiates this type of foundation from the others is the long-standing existence and slow evolution of the organization, with its functions expanding, contracting, or otherwise changing over time as conditions and expectations alter. These bodies may perform a range of duties, some of which are NITAG-like, or they may have changed their practices to become NITAG-like.

followed by any (or all) of Canada's subnational jurisdictions, and some of its resources will be expended trying to mold the 13 immunization programs into a 'national' program. Note that the UK may also fit this model with respect to actions in relation to Scotland, Wales and Northern Ireland.

5. Discussion

The NITAG Environmental Scan of 28 GNN member countries revealed that most were founded informally, not by statute, and, in terms of their authority, most are advisory in nature. While we anticipated that a statutory foundation would be in the minority, the extent of non-legislative foundation was higher (74%) than one might have expected. This may simply be a reflection of the countries who responded, but the popularity of the informal approach might also be driven by the flexibilities identified in our category definitions. An informal foundation can mean greater responsiveness to changing needs, and ease of alteration of remits, but it can also make the organization less authoritative and more precarious. In centralized systems, a founding Presidential or Ministerial decree may result in the NITAG being associated with the decreeing politician, rendering the NITAG's longevity or authority uncertain after the founder's term has expired, especially in jurisdictions without a tradition of a non-partisan public service.

With respect to authority, being an advisory NITAG offers the primary benefit of encouraging strongly independent, evidence-based advice on immunization without undue consideration of the political, which is largely somebody else's bailiwick. Moreover, the NITAG can participate in the policy decision-making process relating to the NIP without requiring the government to relinquish authority over that policy field. This flexibility may be highly desirable in countries with (for example) limited financial resources, difficulties in vaccine procurement (e.g., common stock-outs) or delivery, or a shortage of qualified medical practitioners to administer the vaccines. A significant drawback to being an advisory NITAG parallels the benefits: it is the government, rather than the independent expert body, which makes the final decision on NIP content. This gives rise to the risk that decisions will be driven by reasons other than medical evidence (e.g., political expediency, financial considerations, moral objections such as those raised in some jurisdictions to the HPV vaccine [19]). Advisory NITAGs *may* also be seen as less authoritative than directive NITAGs, although this certainly need not be the case: some of our respondents indicated that their advisory NITAG recommendations were regularly taken seriously by the government, and would, as a matter of common course, be accepted.

The benefits and drawbacks to being a directive NITAG are roughly the inverse of the advisory model. Final decisions about vaccination policy are being made by notionally neutral experts rather than elected governments, which will arguably be expected to have a broader and more nuanced perspective. Having said that, it is arguable that decisions made by experts with the scientific, medical, and statistical training required to understand and critique the relevant evidence will more closely track the evidence and provide greater health benefits to society, than decisions made by politicians beholden to a range of countervailing interests. A potential pitfall for directive NITAGs is that making a scientifically and medically sound decision in a context where the government lacks the means to act on the NITAG's directions will likely serve only to undermine the NITAG's authority, and possibly even the NIP more generally.

Hybrid NITAGs offer a mix of the above benefits and drawbacks. By limiting the scope of NITAG recommendations which are binding, governments have the opportunity to maximize the implementation of independent and evidence-based immunization policy while addressing concerns such as the potential for financial burden (e.g., the UK's limiting of binding recommendations to those issued in response to a question from the Secretary of State). A binding mandate with a reduced scope may also be more politically viable (e.g., the USA's limiting of binding recommendations to paediatric vaccinations). However, these qualifications on the NITAG's authority *may* serve to restrict the NITAG's independence or effectiveness. For example, if the UK Secretary of State simply fails (or refuses) to issue questions to the NITAG, then the NITAG is unable to exercise its binding recommendation power, meaning that UK vaccination policy would be decided by government instead of independent experts – completely undermining the primary benefit of a hybrid model.

While collaborative NITAGs may exemplify some of the characteristics of (most likely) advisory NITAGs, it is difficult to think about 'benefits' and 'drawbacks' in the same proactive or agency-based way as the others. In some respects, the existence of this model is not a matter of political or legal choice, but rather the consequence of a particular pre-existing legal or constitutional order which imposes itself upon the actors, generating its own conven-

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Table 4
Evidence on NITAG Foundation.

Country	WHO Region	World Bank Income Level	Foundation				
			Formal		Informal		Evo.
			Statute	Statutory Instrument	Executive Instrument	Policy	Practice
Albania	European	Upper-Middle	✓				
Argentina	Americas	High			✓		
Armenia	European	Upper-Middle			✓		
Australia	Western Pacific	High			✓		
Belgium	European	High			✓		
Canada	Americas	High				✓	
Chile	Americas	High			✓		
China	Western Pacific	Upper-Middle			✓		
Côte d'Ivoire	African	Lower-Middle			✓		
Ethiopia	African	Low			✓		
Germany	European	High	✓				
Indonesia	South-East Asia	Lower-Middle			✓		
Jordan	Eastern Med.	Upper-Middle			✓		
Kazakhstan	European	Upper-Middle			✓		
Latvia	European	High			✓		
Maldives	South-East Asia	Upper-Middle			✓		
Nepal	South-East Asia	Low	✓				
Nigeria	African	Lower-Middle				✓	
Sri Lanka	South-East Asia	Lower-Middle					✓
Sweden	European	High				✓	
Tanzania	African	Low	Unclear foundation				
Timor-Leste	South-East Asia	Lower-Middle			✓		
Togo	African	Low			✓		
Uganda	African	Low				✓	
United Kingdom	European	High	✓	✓			
United States	Americas	High	✓	✓			
Uruguay	Americas	High			✓		
Zimbabwe	African	Low				✓	

Table 5
Models of NITAG Authority.

Type	Description
Directive	Governments and/or health authorities or decision-makers are bound to implement the NITAG's recommendations on vaccines.
Advisory	Governments and/or health authorities may implement NITAG recommendations, but are not legally bound to do so.
Hybrid	Governments and/or health authorities or decision-makers are bound to implement decisions or recommendations only under certain circumstances (e.g., the NITAG may issue binding recommendations for certain diseases or populations, or under certain conditions).
Collaborative	Governments or health authorities receive advice from the NITAG but it sits within a fragmented political/legal environment, and a complex and multi-level healthcare system, such that the central/national government is unable to act unilaterally either with respect to the NITAG or healthcare more generally.

Table 6
NITAG by Authority Model and Legal Foundation.

Country	Authority Model	Legal Foundation
Albania	Advisory	Statute
Argentina	Advisory	Executive Instrument
Armenia	Advisory	Executive Instrument
Australia	Advisory	Executive Instrument
Belgium	Advisory	Executive Instrument
Chile	Advisory	Executive Instrument
China	Advisory	Executive Instrument
Côte d'Ivoire	Advisory	Executive Instrument
Ethiopia	Advisory	Executive Instrument
Indonesia	Advisory	Executive Instrument
Jordan	Advisory	Executive Instrument
Kazakhstan	Advisory	Executive Instrument
Latvia	Advisory	Executive Instrument
Maldives	Advisory	Executive Instrument
Nepal	Advisory	Statute
Nigeria	Advisory	Policy
Sri Lanka	Advisory	Practice
Sweden	Advisory	Policy
Tanzania	Advisory	Unclear
Timor-Leste	Advisory	Executive Instrument
Togo	Advisory	Executive Instrument
Uganda	Advisory	Policy
Uruguay	Advisory	Executive Instrument
Zimbabwe	Advisory	Policy
Germany	Directive	Statute
United Kingdom	Hybrid/Collaborative	Statute and Statutory Instrument
United States	Hybrid	Statute and Statutory Instrument
Canada	Collaborative	Policy

tions and inertias. Since legislative reform of collaborative NITAGs into explicitly advisory, directive, or hybrid is highly impracticable (at least in the example we uncovered), countries with such NITAGs will likely need to seek other ways to strengthen their NITAG and/or NIPS.

As a final note, we acknowledge the limitations of this study. The foundation and authority taxonomies developed to categorize the NITAGs in each of these 28 respondent countries might need to be revisited and refined if applied to all 158 countries with NITAGs. Additionally, further categories might need to be added. For example, no small country (with a population under 500, 000) was included, and no regional small-country NITAG such as that which exists in the Caribbean participated. One might expect the latter to be collaborative in authority and informal in foundation, but the dynamic might be quite different than Canada's, and so a bespoke assessment is warranted. Overall, however, assessing NITAG foundation and authority in all countries claiming to have a NITAG would be a mammoth undertaking, and it is unclear what new information could be found. The array of countries from the GNN that participated in this survey included a range of country sizes,

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all six WHO regions, and all categories of World Bank income levels. Hence the survey findings and taxonomies/models developed would likely hold, even if more were surveyed.

6. Conclusions

A key message for those advocating for vaccine legislation, and for those contemplating same, is that, beyond the NIP itself, the architecture supporting that NIP is critical and deserving of careful thought. Indeed, it may be equally deserving of a legislative foundation that helps to shield it from the vicissitudes of politics. A key component of that architecture is a NITAG, and careful consideration of the nature of that NITAG is warranted, and, again, ought to be expressed clearly in any vaccine legislation that might be adopted. The salutary effects of doing so are several.

First, explicit expression of the NITAG's remit and capacities (i.e., authority) forces legislators to *consider* the NITAG's authority, and to make a decision about the role that independent, evidence-based, expert opinions will play in determining national public health and immunization policy. There may be valid jurisdiction-specific reasons for favouring one authority model over another, but this choice should be a conscious one made publicly so that the benefits and drawbacks can be weighed and appreciated.

Second, both this process and the formal recognition itself provides certainty regarding the role of the NITAG and how it is expected to conduct itself. Some of our evidence exposed an uncertainty that could create tensions – or more explicit problems – down the road. For example, a number of respondents indicated that their NITAG recommendations were 'binding'. However, a review of the relevant foundation documents revealed that they were, in fact, advisory. This may point to a social/politically accepted difference in de facto and de jure power, or it may expose a discrepancy that has not been obvious to date only because NITAG recommendations have routinely been accepted by the government. If the latter, this discrepancy may prove problematic should future governments or politicians disregard NITAG recommendations.

Ultimately, while encouraging governments to explicitly consider the foundation type and authority model for their NITAG, we expect that the overall effect of these features on NIP effectiveness will depend on specific national conditions, including, potentially, the extent to which the NITAG engages with publics. Future comparative research relying on a bespoke assessment framework can help verify the specific costs, benefits, and overall value of one model over another. The point here is that NITAG foundation and model are immensely worthy matters for the expenditure of research/political/policy/legislative capital when designing or reforming the national vaccine space.

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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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