Vaccine 37 (2019) 7527–7529

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Commentary

National immunization programme development and vaccine legislation

Shawn H.E. Harmon [a,*], Noni E. MacDonald [b]

[a] Faculty of Law and Department of Pediatrics, Faculty of Medicine, Dalhousie University, Halifax, Nova Scotia, Canada
[b] Department of Paediatrics, Dalhousie University, IWK Health Centre, Halifax, Canada

1. Introduction

The global health community's long-evolving partnership with individual countries – most recently under, though not limited to, Gavi, the Vaccine Alliance – has resulted in national immunization program (NIP) capacity-building and new vaccine introduction, particularly in low-income countries over the past decade [1,2]. This partnership has resulted in greater financial and practical support for NIPs [2], but, as Berkley recently observed [3], countries transitioning out of Gavi support must take increasing ownership of their NIPs to ensure long-term success and sustainability. Indeed, this necessity for country ownership to increase uptake and efficacy is universal.

To encourage the necessary political support for immunization, Berkley advocates the adoption of legislation. This may indeed send a strong social message about the importance of immunization to health and wellbeing, and it may additionally signal that the government is prepared to invest appropriately in public health [4], but actors, whether they are only starting to take ownership of their NIP or have long maintained ownership, must embark on the legislative journey in full appreciation of the demands and ramifications. This necessitates a sober assessment of the alternatives to law and the limits of the law (i.e., legislation will not necessarily overcome vaccine hesitancy, mistrust of medical professionals, technical capacity shortfalls, or financial or vaccine acquisition limitations).

If legislation is ultimately the route favoured, public officials must consider even more carefully the nature and content of their legislative intervention. This paper highlights some of the policy demands imposed by a legislative approach. Importantly, it does not highlight all the elements that would be useful for inclusion in the legislation itself, but rather five broad preparatory matters that we believe are particularly salient to the immunization setting.

2. Key considerations when contemplating vaccine legislation

NIPs are critical components of the public health environment. They are (or can be) an effective and cost-efficient healthcare intervention that has multiple salutary consequences. And like other controversial areas of healthcare (e.g., reproductive medicine, abortion treatment, transplantation medicine, medical assistance in dying), immunization *probably does* warrant a legislative foundation to help regularize the field and highlight its integration within the broader socially accepted healthcare system.

The dangers of adopting legislation (in any setting) are that it will be mis-directed, poorly designed, and inadequately supported by robust institutions. A danger of adopting vaccine legislation is that it will be too strongly shaped by reactions to vaccine hesitancy and the 'junk science' that drives some of that resistance. There are many examples of reactionary legislative responses to socio-medical scandals; the result of these interventions has been a plethora of narrow, siloed instruments that, in the end, do not much improve the target practice space, or the broader health setting [5]. (For example, many laws adopted in reaction to biobanking offered neither effective nor necessary protection of the interests at stake [6].) Other dangers are that legislation will add to institutional complexity and fragmentation, making an already crowded policy space more labyrinthine, frame NIPs so they cannot be amended responsively, narrow existing programs, or result in resources being drawn away from other important public health programs.

Ultimately, if legislation is considered the best way forward – and it may well be – then a number of matters must be thoughtfully addressed, some general and some bespoke to vaccination. Here, we highlight five, noting at the outset that these matters require sustained and sensitive multi-stakeholder collaboration, with participants being public health and immunization experts, policymakers, funders, healthcare providers, scholars from multiple disciplines, and representatives from diverse elements of civil society, including youth, elders, and traditionally marginalized groups.

Objectives: Actors must design a defensible communication strategy so that clear social objectives and policy aims can be collaboratively articulated [7]. This is an obvious but sometimes overlooked or under-elaborated task. It is important not only for identifying challenges and barriers to achieving the stated social aims of the legislation (which ought to be broader than merely increasing vaccine uptake), but also for defining the ambitions and parameters of the legislation and its measures for success. Importantly, this objectives exploration must be *explicit, collaborative, and iterative* if it hopes to result in clearly understood challenges and barriers, socially acceptable and impactful aims, and

* Corresponding author at: Weldon Law Building, Rm 331, Dalhousie University, 6061 University Avenue, Halifax, NS B3H 4R2, Canada.
E-mail address: shawn.harmon@dal.ca (S.H.E. Harmon).

https://doi.org/10.1016/j.vaccine.2019.09.102
0264-410X/

robust mechanisms for overcoming the former and realizing the latter. Barriers relevant to a given jurisdiction might be normative (i.e., countervailing norms), technical (i.e, lack of scientific or health service/delivery capacity), or social (i.e., low societal acceptance). Common barriers that will almost inevitably need to be confronted and overcome include:

- under-developed healthcare systems and/or unevenly distributed services (i.e., immunization-access problems);
- insufficient resources (financial, technical, staffing/expertise) to appropriately deliver an effective NIP;
- mistrust of key actors (e.g., physicians, researchers, public health authorities, local government etc.);
- social resistance stemming from countervailing political agendas that encourage vaccine hesitancy.

This collaborative and participative process should result in an instrument which positions the NIP in the broader public health system (demonstrating its integration with other systems aimed at good health) [8]. It should also position vaccination in the human rights setting. In this regard, vaccination should be identified as a key mechanism available to governments wishing to meet their obligation to make real the so-called 'right to health', which has been characterized as including the right to preventative interventions [9]. In other words, the law might characterize vaccination simultaneously as a right of citizens made possible by health research and innovation, a duty of citizens as an element of the social contract, and a duty of government to provide and sustain in an equitable manner. This is not often done clearly and directly, though there are examples of such linking to human rights in low- and middle-income countries.

Values: Actors should identify and define core values applicable to the immunization framework. Moral values are important to the realization of good governance, particularly where human health and wellbeing are implicated [10]. However, values are often assumed rather than explicit, and are often extremely opaque or hidden, and therefore invisible. Sometimes, when they are stated, they are nonetheless under-operationalized, and therefor remain rhetorical [11]. Values should be explicit, defined, and linked to legal principles and statutory mechanisms of action. And again, this design function ought to be approached as a collaborative undertaking involving multiple stakeholders.

Space is insufficient to explore these values here, but, at base, some generally applicable values might be solidarity, beneficence, and equity. Values that inform the framework – its institutions and actions – should include transparency, accountability, proportionality, flexibility, and evidence-based decision-making. As with the characterization process identified above, duties might be emphasized, including those of individuals to contribute to the health of their communities, and to not serve as sources of risk or ill-health.

Institutions: The legislative framework should erect and structure sound institutions and processes. One of the most important is the National Immunization Technical Advisory Group (NITAG), which will not likely already be grounded in an existing statute [12], and with respect to which the following, at a minimum, should be addressed [12]:

- composition (number of members, expertise of members, organizational structure);
- member independence (i.e., tenure, how members are appointed and removed, how conflicts are handled);
- committee independence (i.e., whether the committee can act unilaterally);
- procedures for conducting business and making decisions (i.e., single annual meeting, multiple meetings, in-camera versus open, etc.);
- process for acquisition and use of evidence (i.e., powers to investigate (call on stakeholders, compel evidence, obtain data/documents) and undertake consultations);
- authority (i.e., nature of decisions, how they are delivered, to whom recommendations and decisions are delivered, if the decisions are binding on the national immunization programme, etc.);
- reporting (i.e., reports mandated, report format, to whom reports are furnished, etc.);
- reflexivity (i.e., metrics for measuring NITAG impact and success, means for the NITAG to revise its practices).

By attending to these matters, the legislation will ensure that the NITAG is independent, expert, accountable and flexible, all of which supports sustainability. Of course, the NITAG is not the only significant institution. Others are (1) national and subnational agencies or bodies that assess (new) drugs and make recommendations to government about their inclusion on formularies identifying publicly-funded medicines, (2) procurement bodies or committees, (3) chief public health officers or medical officers of health, (4) regional immunization officers (who are tasked with applying the NIP and making decisions necessary to ensure good community health given local socio-economic and geographic conditions, including the presence of traditionally marginalized and vector communities). To maximize effectiveness, legislation will need to adopt a joined-up perspective, taking notice of, and perhaps amending, how these different operators within the shared space of public health work and interact.

Mandatory components: Attention must, of course, be paid to the nature of the NIP itself. More specifically, will the legislation make the NIP, or parts of it, mandatory? Actors should not leap too quickly to adopt a hard mandatory NIP, for such can encourage resistance to vaccination and a backlash against the NIP. Evidence on the effect of mandatory approaches is patchy, and there may be significant unintended consequences of adopting a mandatory approach [13]. Nonetheless, there are some advantages to making certain elements of the NIP mandatory, even if sanctions do not form a strong element of the framework [13]. If mandatory immunization *is* the preferred route, careful thought, planning, and follow-up are critical. Pertinent questions include [13]:

- Is there a problem with uptake rates, and what lies behind this problem?
- Is this the right solution at this time in this socio-economic/political context, and what might need to be done to minimize and/or respond to any public backlash to this approach that might be anticipated?
- What components of the NIP need to be mandatory, and do they fit the culture and context?
- Do other strategies need to be part changes to the NIP?
- Will the shift to a mandatory NIP be supported by an increase in resources to deliver the NIP, and will other public health actions be compromised?
- What is the consequences for vulnerable or traditionally marginalized populations?
- What should be the position of a no-fault vaccine injury compensation scheme?

Case-studies: Finally, there is the (preliminary) issue of understanding the nature, operation and social significance of existing legislation addressing immunization. Research is needed on a wide range of questions that are pertinent to the legislative option:

- How is existing vaccine legislation approached (i.e., its nature and structure)?

- Does it facilitate the building of public health policy and/or scientific capacity?
- Does it helpfully stabilize immunization policy or expert institutions?
- Does it create sites of domestic and/or international collaboration and partnership, thereby offering improved public health networking and harmonization?
- Does it measurably increase immunization coverage and/or the social acceptance of vaccination?

Some research on the legislative aspects of immunization has already been undertaken in relation to Latin America [14,15], certain European states [16,17], and three Caucasus/Black Sea countries [18]. Empirical research on the governance of NITAGs and NIPs in members of the Global NITAG Network (GNN) has also been undertaken through the NITAG Environmental Scan Project (MacDonald, Harmon, Faour, et al.). But, as has already been observed [3,13], much more empirical research is needed to better understand how this setting works, how law might best be deployed, and what mechanisms are most effective in achieving policy objectives.

3. Conclusion

Given the many challenges faced by NIPs in the current sociopolitical milieu, legislative intervention may look like an attractive option, and it may indeed be an effective option. However, actors should not settle on the legislative route too quickly, nor, more importantly, should the process of crafting legislation be rushed. As demonstrated above, there are many social, political, and technical questions, and they must be tackled in a collaborative, multidisciplinary manner that is sensitive to macro and micro contexts (e.g., culture, political setting, key institutions and relationships, etc.). Further, the process needs to proceed at a thoughtful pace; immunization strategy and governance is a complex policy subject that is not amenable to simplistic solutions with short-term aims.

In 2017, the Strategic Advisory Group of Experts on Immunization (SAGE) recommended that a comprehensive global audit should be undertaken to document the ways in which legislation and regulation have been used to promote or undermine immunization at the national level [19]. This, it was felt, would allow actors to identify how legislation can be best applied in different contexts to strengthen immunization systems. This work has begun, but only partially. We suggest that immunization governance more holistically understood (i.e., as implicating public health legislation, immunization legislation/policies, actor regulation (e.g., physician, pharmacist), national procurement practices, etc.) must be examined, together with the broader public and global health (and health justice) architecture, with a view to identifying local, national, and international individual and systemic barriers and bottlenecks that undermine the effectiveness of legal instruments, and additional policy levers that may compliment them. This should be done through both individual and comparative case studies relying on multiple disciplines applying multiple methods of investigation using a wide range of agreed indicators.

As a final note, we believe that this research could and should be integrated with collaborative capacity-building with key national stakeholders so that NIPs and their regulatory architecture can be developed across regions in cohesive and complimentary ways. The ambition to do this work, and to generate new insights, exists, but financial and logistic support is needed to pursue it.

4. Author declaration

The authors warrant that the article is the authors' original work, hasn't received prior publication, and isn't under consideration for publication elsewhere.

Funding

None.

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.

Acknowledgements

None.

References

[1] GAVI, Annual Progress Report 2017; 2017, at file:///C:/Users/sh999086/Downloads/Gavi-Progress-Report-2017.pdf.
[2] GVAP Secretariat, Global Vaccine Action Plan Secretariat Annual Report 2017; 2017, at https://www.who.int/immunization/sage/meetings/2017/october/3_GVAP_SecReport2017.pdf.
[3] Berkley S. Political will and vaccine legislation. Vaccine 2018;37:4838–9.
[4] SAGE, 2018 assessment report of the global vaccine action plan; 2018, at https://apps.who.int/iris/bitstream/handle/10665/276967/WHO-IVB-18.11-eng.pdf?ua=1.
[5] Laurie G. Liminality and the limits of law in health research regulation: what are we missing in the spaces in-between? Med Law Rev 2016;25:47–72.
[6] Laurie G. Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law. Hum Genet 2011;130:347–56.
[7] Hallworth M, Parker S, Rutter J. Policy making in the real world: evidence and analysis, 2011.
[8] WHO. Draft thirteenth general programme of work, 2019–2023, A71/4; 2018, at http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_4-en.pdf?ua=1.
[9] UNHCHR. Fact sheet no. 31: the right to health; 2008, at https://www.ohchr.org/Documents/Publications/Factsheet31.pdf.
[10] Harmon S. Control of reproductive treatment and research: from the moral to the political to the legal – and back again? In: Smith J, Papaioannou T, editors. The limits of governance: the challenge of policy-making for the life sciences. p. 79–104.
[11] Harmon S. Ethical rhetoric: genomics and the moral content of UNESCO's "universal" declarations. J Med Ethics 2008;34(11):e24. https://doi.org/10.1136/jme.2008.024166.
[12] Harmon S, Faour D. NITAG environmental scan: report on NITAG governance frameworks, 2019.
[13] MacDonald N, Harmon S, et al. Mandatory infant & childhood immunization: rationales, issues and knowledge gaps. Vaccine 2018;36:5811–8.
[14] Trumbo SP, Janusz CB, Jauregui B, McQuestion M, Felix G, Ruiz-Matus C, Andrus JK, Quadros CD. Vaccination legislation in Latin America and the Caribbean. J Public Health Pol 2013;34(1):82–99. https://doi.org/10.1057/jphp.2012.66.
[15] McQuestion Michael, Garcia Ana Gabriela Felix, Janusz Cara, Andrus Jon Kim. National legislation and spending on vaccines in Latin America and the Caribbean. J Public Health Pol 2017;38(1):3–15. https://doi.org/10.1057/s41271-016-0052-x.
[16] SABIN. Legislative landscape review: legislative approaches to immunization across the european region; 2018.
[17] Attwell K, Drislane S, Leask J. Mandatory vaccination and no fault vaccine injury compensation schemes: An identification of country-level policies. Vaccine 2019;37(21):2843–8. https://doi.org/10.1016/j.vaccine.2019.03.065.
[18] Trumbo S, Silver D, et al. Strengthening legal frameworks for vaccination: the experiences of Armenia, Georgia, and Moldova. Vaccine 2019;37(35):4840–7.
[19] Strategic Advisory Group of Immunization Experts. 2017 assessment report of the global vaccine action plan; 2017. Recommendation 8b.