

# Of National Immunization Technical Advisory Groups (NITAGs), Evidence, and Decisions on Public Vaccination Programs: Lessons from Canada



## A Propósito de Comissões Técnicas de Vacinação (CTV), Evidência e Decisões sobre Programas Públicos de Vacinação: Lições do Canadá

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### INTRODUCTION

In late 2018, Portugal's parliament decided to include universal meningitis B and rotavirus vaccination while also adding human papillomavirus vaccinations for boys in Portugal's National Vaccine Program. This decision was taken relatively quickly, which drew criticism from many stakeholders within the country's health sector. The Portuguese Ordem do Médicos suggested that the decision lacked "[appropriate] analysis and agreement based on scientific evidence", with the Portuguese Director-General of Health similarly signalling that while study into the merits of universal vaccination with meningitis B continued, evidence did not support the deployment of rotavirus universally in the Portuguese context.<sup>1</sup> This controversy was resolved in late 2019 with the inclusion of these vaccines in the National Vaccine Program in line with a recommendation by Portugal's National Immunization Technical Advisory Group to the Directorate-General of Health. This provided the requisite evidence that supported the Government's policy, which justified their waiting for the completion of the technical appraisal.<sup>2</sup>

Portugal's experience on this topic is not unique. Population-level decisions around vaccines in many countries are often divided between arms-length National Immunization Technical Advisory Groups (NITAGs) that are mandated to provide independent, evidence-informed advice on their use, and government policymakers, who ultimately decide which vaccines should be publicly funded and how they might be deployed. Case studies abound of vaccines recommended for broad use that are shelved or only partly deployed for lack of resources or political will, or—in the converse case, a roll-out more aligned as a popular measure instead of considerations of scientific evidence or epidemiologic context.

Canada's own experience with quadrivalent human papillomavirus (qHPV) vaccine in the mid-2000s demonstrated

how the best advice of a NITAG, in this case Canada's National Advisory Committee on Immunization (NACI), played a limited role in the overall scope and initial roll-out of the vaccine owing to a complex mix of policy considerations and pressures around funding, public perception, and influential stakeholders.<sup>3</sup>

This article explores the role of NITAGs and their best practices, and then applies these considerations to the Canadian experience to encourage governments to recommit to implementing vaccinations on the basis of provided evidence and guidance.

### AN INTRODUCTION TO NITAGs

NITAGs aim to provide independent review of the evidence concerning the efficacy, effectiveness, and safety of a vaccine, as well as country-specific or regional data on the burden of the disease in the population and where possible, the cost-effectiveness of including the vaccine in the national immunization program. Following extensive review, NITAGs then make recommendations for how vaccines might be incorporated into public health immunization programs with the goal of maximizing public health benefit. One objective of the Global Vaccine Action Plan has been the establishment of NITAGs in all countries by 2020 to inform vaccine policy and reduce reliance of countries on guidance provided by external bodies.<sup>4</sup>

The World Health Organization (WHO) has developed six key process indicators for NITAGs to ensure they have sufficient independence from government and industry interests, necessary expertise, and an effective process. These indicators are as follows:

- The NITAG has a legislative/administrative basis;
- Formal written terms of reference are in place;
- A conflict of interest policy is implemented;
- Members from at least five different areas of

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expertise are included (e.g., infectious diseases, public health, epidemiology, health economics, immunology, pediatrics, internal medicine);

- NITAG meets at least once a year;
- Meeting agenda and background papers are circulated ahead of the meeting.<sup>5</sup>

In their role, NITAGs must strike a balance between independence from political or other influence and ensuring sufficient integration with government policy. Different countries employ different models to address this tension; some NITAGs exist within the Ministry of Health with membership requiring approval by the ministry, while others are only supported by a secretariat in the Ministry of Health. Transparency in independence is similarly addressed in various ways, with some NITAGs opening their meetings to the public, such as the United States Advisory Committee on Immunization Practices (ACIP), others with closed meetings that include non-voting representatives from professional organizations (e.g., NACI in Canada) or others that publish meeting minutes on public websites (as in the United Kingdom).<sup>4</sup>

As of 2017, 99/194 (51%) countries, including Portugal, reported that they met all six NITAG process indicators, an increase from 63 countries in 2012.<sup>5</sup> While this is good progress, it is unlikely that the GVAP goal of all countries having a functional NITAG by 2020 will be achieved within the upcoming year.<sup>4</sup>

## TENSIONS REVISITED

The decision to roll out qHPV vaccine in Canada in 2006 had parallels with the recent Portuguese experience. In this instance, the recommendation of a NITAG (Canada's NACI) around the use of qHPV was issued in early 2007 alongside a federal budget decision to fund the purchase of qHPV vaccine by provincial governments, which are responsible for funding and administering immunization programs in Canada. The funds were to come from a budget allocation for \$300 million Canadian dollars (€200 million) earmarked to support activities under Canada's National Immunization Strategy, which until the issuance of the budget announcement had been telegraphed as support for federally coordinated immunization activities as opposed to direct vaccination purchase.<sup>3</sup>

While this was, in retrospect, a positive decision that has led to Canada's leadership in rolling out qHPV vaccination, that this budget decision occurred contemporaneous to the release of the 2007 NACI recommendation gave rise to negative media coverage questioning the haste and safety by which the vaccine was brought forward. The involvement of a representative from a pharmaceutical company in lobbying for an extension to funding that was subsequently earmarked for qHPV purchase was of concern. Additionally,

the subsequent decision by four provinces to apply for and deploy qHPV programs during the 2007–2008 school year also resulted in a situation where NACI's 2008 follow-up statement on qHPV, which was intended to inform provincial program planning, came across instead as a NITAG playing catch-up after the fact.<sup>3</sup>

Much of the conflict in timelines relates to the situation that arose in Portugal in that the decisions to fund and deploy vaccinations in both countries were ultimately political decisions, which are often taken opportunistically. The deliberative process of NITAGs, plus limited funding for their activities, can conflict with a need for speed and political expediency. The result is that governments may end up taking decisions that are not made in full confidence of the independent scientific body.

The converse also occurs where a government decision to deploy a vaccine may be delayed long after the NITAG has issued its recommendation, particularly if it is perceived as politically challenging. One such example concerns gender-neutral qHPV vaccination in Canada, where a NACI recommendation to include boys in vaccination programs was issued in 2012 but was only first taken up by some provinces in 2015 and 2016.<sup>6</sup>

## CONCLUSION

The independence and deliberative processes undertaken by NITAGs are essential to developing recommendations that ensure that safe and effective vaccines are deployed in an optimal manner within various national contexts. However, so long as such groups remain advisory to political decisions that are taken, there will always exist a material risk that expediency will trump scientific consensus.

Canada's experience with qHPV may have led to widespread coverage with a vaccine widely regarded as safe and effective, but the approach to the decision demonstrated a certain disregard for the NITAG's processes, represented an untested use of funds originally earmarked for other activities, and may have driven greater hesitancy through the haste and confusion. Portugal's recent events will be similarly assessed over time but serve as another example in continuing discussions around the role and importance of NITAGs and how best to balance their independence, deliberations, and advice with the urgent demands of policy and political process.

## CONFLICTS OF INTEREST

The authors have no conflict of interest to declare.

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