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## Expanding Free School-based Human Papilloma Virus (HPV) Vaccination Programs to Include School-aged Males in Nova Scotia, Canada

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## Abstract

Bill 70 (*HPV Vaccine Act*) was presented to the Nova Scotia House of Assembly with the aim of expanding the current Nova Scotia school-based HPV vaccination program to include males. In recent years, increased awareness of HPV and HPV-caused cancers has led to the implementation of school-based female HPV vaccination programs across Canada. Changing guidelines, based on recent evidence, suggest that males should also be included in these programs. Program expansion to include males aims to reduce the prevalence of HPV-causing cancers and their ensuing costs, to promote equal access to healthcare services, and to make Nova Scotia a leader in HPV prevention. Support from the Canadian public and high profile political actors along with pressure from other provinces and interest groups, including the Society of Obstetricians and Gynaecologists of Canada, influenced the passing of the *HPV Vaccine Act*. In order to implement this reform, the provincial financial commitment to the previous HPV program was expanded to cover the cost of male vaccination.

*Le projet de loi 70 (Loi sur les vaccins contre le papillomavirus), dont l'objet est d'étendre aux garçons le programme de vaccination contre le papillomavirus humain (PVH) en vigueur actuellement dans les écoles de Nouvelle Écosse, a été présenté devant l'Assemblée parlementaire de la province. La prise de conscience récente du rôle du PVH comme facteur de risqué dans de nombreux cancers a conduit à la mise en place de programmes de vaccination scolaires pour les filles partout au Canada. Des données empiriques récentes ont conduit à modifier les recommandations de pratiques pour ouvrir ces programmes aux garçons. L'objectif d'une telle ouverture des programmes est de diminuer la prévalence (et les coûts) des cancers provoqués par le PVH, ainsi que de renforcer l'égalité d'accès aux soins et de placer la Nouvelle Écosse à la pointe de la prévention du PVH. Une opinion publique canadienne favorable, ainsi que le renfort d'acteurs politiques majeurs et la pression venue d'autres provinces et de groupes d'opinion, comme la Société des Obstétriciens et Gynécologues du Canada, ont contribué au vote de la loi sur la vaccination PVH. La province a augmenté son engagement financier dans le programme PVH afin de couvrir le coût des vaccins pour les garçons.*

### Key Messages

- Recent research on Human Papilloma Virus (HPV) infection and its relationship to cancers in both men and women has led to updates of the national recommendations to expand current school-based HPV vaccination programs to include school-aged males into the programs that vaccinate school-aged females.
- Nova Scotia was the third province in Canada to include all males into their school-based HPV vaccination program (after Prince Edward Island and Alberta). Positive results from preliminary evaluations and program acceptance, helped to create an environment in which Bill 70: *HPV Vaccine Act* passed in the Nova Scotia legislature.
- Six Canadian provinces (Prince Edward Island, Alberta, Nova Scotia, Manitoba, Ontario, and Québec) have now expanded their school-based HPV vaccination programs to include all males.

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### Messages-clé

- *Afin de tenir compte des résultats récents de la recherche sur le papillomavirus humain (PVH) et son rôle dans les cancers masculins et féminins, la version actualisée des recommandations nationales étend les programmes de vaccination scolaires PVH, pour l'instant réservés aux filles, aux garçons d'âge scolaire.*
- *La Nouvelle Écosse est la troisième province canadienne à ouvrir son programme de vaccination scolaires PVH aux garçons (suivant l'Île du Prince Édouard et l'Alberta). Les résultats préliminaires encourageants des évaluations et du bon accueil fait aux programmes ont produit un environnement propice au vote du projet de loi 70 : Loi sur les vaccinations PVH à l'Assemblée de Nouvelle Écosse.*
- *Au total, six provinces canadiennes (Île du Prince Édouard, Alberta, Nouvelle Écosse, Manitoba, Ontario, et Québec) ont maintenant élargi leur programme de vaccination scolaire PVH aux garçons.*

## 1 BRIEF DESCRIPTION OF THE HEALTH POLICY REFORM

Private member's bill, Bill 70: *An Act to Expand the School Vaccination Program to Include the Human Papilloma Virus (HPV) Vaccine for Boys*<sup>1</sup> (*HPV Vaccine Act*) passed its second reading in the Nova Scotia House of Assembly on 1 April 2015. The bill aimed to expand the current school-based vaccination program in Nova Scotia, which provided free HPV vaccination only to school-aged females in the province, to also include free and accessible HPV vaccination for school-aged males. Prior to Bill 70, HPV vaccination of school-aged males in the province was voluntary and paid out of pocket by families.

HPV is a virus that can be sexually transmitted and can infect and have long-term effects on individuals of both sexes. While in many cases of infection, the HPV virus is cleared without medical intervention or serious consequences, HPV infection is associated with and is a cause of cervical, head and neck (including oropharyngeal), anal, and penile cancers and can also lead to the development of anogenital warts. HPV vaccines are developed to specifically target and limit the transmission and infection of highly virulent strains of HPV within the population and those that are associated with important outcomes such as anogenital warts.

HPV vaccination is an important tool to prevent the spread of HPV via sexual transmission, as barrier methods of contraception (e.g., condoms) do not prevent all forms of skin-to-skin contact that are capable of viral transmission. Public knowledge regarding effective HPV prevention has been reported as low. In a recent study in the United States on knowledge surrounding HPV prevention, the majority of participants (52.6%) incorrectly answered that condom use was effective in preventing HPV (Jesse *et al.* 2015). Therefore, additional strategies, such as HPV vaccination, are necessary to prevent the spread of HPV within the population.

Even though vaccination is an effective way to prevent HPV, many studies have identified that lack of knowledge surrounding HPV vaccination and risks are important barriers to vaccination acceptance. Studies conducted among a sample of the general Canadian population observed that 17.4% of surveyed parents did not feel they had adequate knowledge surrounding HPV vaccination (Gilbert *et al.* 2016). Similarly, a study that looked at parents who accepted and declined HPV vaccination for their daughters in Québec indicated that parents did not feel they had adequate information about the HPV vaccine (Krawczyk *et al.* 2015a; 2015b). In Nova Scotia, school-based programs with public health nurses were found to be beneficial in increasing uptake and engagement (Whelan *et al.* 2014), suggesting that school-based vaccination programs for HPV may help prevent the spread of HPV.

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<sup>1</sup>The term "males" will be used throughout the health reform analysis.

## 2 HISTORY AND CONTEXT

The association between HPV and cervical cancer has long been hypothesized (zur Hausen 1976). A 1999 study by Walboomers and colleagues, using new technologies, determined the worldwide prevalence rate of HPV in cervical cancers to be 99.7%—the highest attributable fraction reported for any major human cancer. This large attributable fraction reinforces the need to implement HPV vaccination programs and to expand programs that were already in place in order to minimize the prevalence of this necessary agent in cervical cancer progression.

In order to prevent HPV infection and its associated cancers, HPV vaccines were developed against the strains of HPV that most frequently cause cancer (HPV 16 and 18) and anogenital warts (HPV 6 and 11). In 2006, HPV4 (Gardasil®), which protects against HPV strains 6, 11, 16, and 18, was licensed for use in Canada for both males and females. School-based vaccination programs for females were implemented across Canada during 2007-2010 targeting school-aged females in grades 4-8, indicating that vaccination would also be beneficial in protecting heterosexual males from contracting HPV through herd immunity provided by vaccinated females.

In 2012 and again in 2015, the National Advisory Committee on Immunization (NACI) updated their recommendations to include male vaccination (NACI 2012; 2015), given Gardasil®'s ability to prevent infections with HPV 6 and 11, which are common causes of anogenital warts, and the increasing evidence to support a relationship between HPV and certain forms of cancer in males (NACI 2015). While most provinces had not yet expanded their programs to males despite the NACI recommendation, Prince Edward Island (PEI) and Alberta did so in 2013.<sup>2</sup> In addition, in December 2015, the province of Québec announced that it would also provide free vaccination to school-aged males starting 1 September 2016 (Gouvernement du Québec 2015). Manitoba also released plans to expand its provincial program in October 2015 (Province of Manitoba 2015). Preliminary evaluations of the expanded program in PEI have observed vaccine uptake of 79.0% among males, a similar uptake to what was reported in the first year of the HPV vaccination program implementation for girls (McClure *et al.* 2015).

Cost-effectiveness must also be taken into account when decisions are made regarding allocation of provincial funds. Cost-effectiveness studies conducted outside of Canada have reached different conclusions. Several systematic reviews highlight current limitations in the cost-effectiveness literature and advocate for more research on the topic (Ben Hadj Yahia, Jouin-Bortolotti and Dervaux 2015; Giraldi, Martinoli and d'Alessandro 2014; Jiang *et al.* 2013; Marsh *et al.* 2014; Sinisgalli *et al.* 2015; Suijkerbuijk *et al.* 2017). Increasing immunization rates among girls was concluded to be the most cost-effective strategy, due

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<sup>2</sup>In 2015, British Columbia also expanded its HPV program to include males, but only to vulnerable males, specifically, men-who-have-sex-with-men, males who “are questioning their sexual orientation”, HIV positive, street involved, in youth custody, or in care of the Ministry of Children and Family Development (B.C. Centre for Disease Control 2015) and therefore will not be considered throughout this paper.

to herd immunity for heterosexual males alone (Brisson *et al.* 2011). One study conducted in Canada (Graham *et al.* 2015) concluded that increasing coverage to include males would decrease health care costs in the long term, but it does not take into account herd immunity from covering females. Given that further evidence is needed to conclusively address the cost-effectiveness of programs in Canada, the reform's acceptance was not likely based on clear evidence from cost-effectiveness studies.

### 3 GOALS OF THE REFORM

#### 3.1 Stated

The transcript of the second reading of *The HPV Vaccine Act* (Bill 70) states that the expansion of school-based HPV vaccination programs to include school-aged males aims to prevent oropharyngeal cancers, provide equal HPV prevention to males and females, and reduce the long-term cancer care costs to Nova Scotia.

#### 3.2 Implicit

In addition to the above mentioned stated goals, the government of Nova Scotia sees additional benefits resulting from expanding the program to include males. First, Nova Scotia will be in compliance with the current recommendations by both the Society of Obstetricians and Gynaecologists of Canada and NACI. Thereby, Nova Scotians will receive improved access to healthcare resources and preventative programs (Blake 2013; NACI 2015).

In addition to working towards the stated goals, expanding HPV vaccination to include school-aged males will lessen the burden of unmentioned HPV-causing cancers in males, including penile and anal cancers. This reform also increases the potential for herd immunity, which will lessen the potential for HPV transmission as fewer individuals will be susceptible to HPV infection (Government of Nova Scotia 2015).

Increasing access to HPV vaccination to school-aged males is also seen as promoting equity and equal access to prevention. This will occur by providing access to HPV vaccination to all males; although, this will have the largest impact on increasing equity to the men-who-have-sex-with-men (MSM) population, which does not benefit largely from herd protection of vaccinated females. This is due to the fact that herd effects from vaccinating females would be minimal on HPV transmission within this population. Therefore, MSM could see a decline in HPV transmission and its long-term effects following program expansion. This program will also improve access among individuals with lower socioeconomic status (SES) who, prior to program expansion, would have to pay out of pocket for HPV vaccination. This out-of-pocket expense was cited as a barrier in a national survey as a reason that parents did not vaccinate their sons against HPV (Perez *et al.* 2015). By including school-aged males in the province-wide school-based HPV vaccination program, Nova Scotia will decrease inequalities in access to prevention, particularly among MSM and

lower SES populations, even though it must be noted that an income-tested program was never envisioned or discussed.

## 4 FACTORS THAT INFLUENCED THE ADOPTION OF THE REFORM

### 4.1 From the governmental agenda to the decision agenda

Following the updated 2012 NACI guidelines for HPV vaccination of males, expansion of HPV vaccine programs in place had to be evaluated across Canada (NACI 2012). While this issue might have been on the governmental agenda of Nova Scotia, there was minimal urgency, as program expansion was not being widely advocated. While the problem at hand was clearly defined and some evidence supported program expansion to decrease the incidence of HPV infection (Blake 2013; NACI 2012), there was minimal political motivation to make any changes to the status quo regarding HPV programs and no evidence-based proposals had been presented to feasibly address the lack of a universal HPV vaccination program in Nova Scotia.

Motivation to move the policy forward to the decision agenda came from policy changes in other Canadian provinces, clear proposals presented by respected politicians with personal commitments to the issue, and successful implementation of program expansion (McClure *et al.* 2015). First, expansion of the HPV vaccination program was adopted in PEI and in Alberta in 2013 and recent findings reported that expansion was adopted by 79.0% of eligible males in PEI (McClure *et al.* 2015). This would put pressure on the remaining Canadian provinces to expand their programs and to provide equivalent services to their constituents. In the spring of 2015, veteran member of the legislative assembly (MLA), Gordie Gosse introduced the clear proposal to the Nova Scotia legislature after being diagnosed with cancer caused by HPV infection. The proposal itself was similar to what had been successful in PEI, was in compliance with national recommendations, and was to be added to a currently successful program.

### 4.2 How and why the decision was made

The mandate of the Nova Scotia Ministry of Health Promotion and Protection is to ensure that the current and future health needs of all Nova Scotians are and will be met. On 1 April 2015, the Nova Scotia Health Authority was created to efficiently and effectively plan for the long-term health of Nova Scotians, and expanding HPV vaccination to include school-aged males was one of the programs included in their initial budget (Finance and Treasury Board of Nova Scotia 2015). This program fits the mandate of the authority and reflected the current scientific evidence on vaccine effectiveness. In addition, the *HPV Vaccine Act* (Bill 70) was proposed by a veteran elected official, who had a personal story

about the impact of not providing HPV vaccination for males, which undoubtedly increased the pertinence of the proposal.

In addition to the above mentioned factors, the province of Nova Scotia has a history of being a leader on HPV prevention, being the first province to provide publicly funded HPV vaccination to school-aged females in 2007 from the federal fiscal incentive (Ministry of Health Promotion and Protection 2007). Finally, the public health care system of Canada is valued for its attempts to provide equal care and foster equal health to all Canadians. In the case of the evidence in support of providing publicly funded HPV vaccination to school-aged males as well as females, this is consistent with the Canadian determination to obtain equality in access to health and health services.

## 5 HOW THE REFORM WAS ACHIEVED

### 5.1 Policy instruments

The *HPV Vaccine Act* (Bill 70) passed its second reading of the Nova Scotia Legislature on 1 April 2015 and public funding for HPV vaccination for school-aged males was included in the provincial budget on 8 April 2015 (2015a; 2015b). This financial commitment will allow for the expansion of the school-based HPV vaccination program.

### 5.2 Implementation plans

As the school-based vaccination infrastructure was in place previously, the costs of expansion were minimal. In order to achieve the goal of the *HPV Vaccine Act* (Bill 70), males in grade 7 were included in the school-based HPV vaccination programs along with females. Details on HPV vaccination and make-up procedures for missed vaccinations have been added to Nova Scotia's Student Immunization Program information booklets and consent forms (2015c). Media outlets reported that the cost of expansion was estimated to be \$492,000, which was to be covered within Nova Scotia's budget for vaccination programs (Fraser 2015; Grant 2015).

### 5.3 Communication plans

Communication was achieved through press releases and pamphlets that were created for dissemination to parents and guardians of school-aged children in Nova Scotia (2015b; 2015c). The peer-reviewed literature in Canada reported successful implementation of program expansion in PEI (McClure *et al.* 2015), mostly (52.6%) positive opinions from the Canadian public on HPV vaccinations (Feinberg *et al.* 2015), and a lack of knowledge by parents on the availability of HPV vaccination for males (Perez *et al.* 2015). Additional literature and barriers to uptake have summarized the difficulty in promoting HPV vaccination program adoption in males (Radisic *et al.* 2017), which could be barriers to program success.



## 6 EVALUATION

There was no program or impact evaluation concretely outlined to determine the success of the school-based HPV vaccination program expansion. In order to evaluate the program, Nova Scotia could implement studies of HPV vaccine coverage, like in PEI (McClure *et al.* 2015), studies of the prevalence of anogenital warts, like in Australia within a network of sexual health clinics (Ali *et al.* 2013), and long-term studies on rates of HPV-caused cancer in the general population of Nova Scotia and in specific populations that are predicted to show the most direct impact from this program (e.g., MSM populations).

## 7 STRENGTHS, WEAKNESSES, OPPORTUNITIES AND THREATS

Table 1 presents a summary of the strengths, weaknesses, opportunities, and threats associated with the expansion of the publicly-funded school-based HPV vaccination program to include males in Nova Scotia. Issues of effectiveness, costs, politics, and equity are considered.

Table 1: SWOT Analysis

STRENGTHS	WEAKNESSES
<ul style="list-style-type: none"> <li>• The intervention complies with national-level recommendations (NACI 2015; Blake 2013).</li> <li>• It is supported by current scientific evidence.</li> <li>• HPV vaccination had some (52%) positive support from commenters on online Canadian media articles (Feinberg <i>et al.</i> 2015).</li> <li>• No additional cost is reported for the Nova Scotia Ministry of Health budget as costs will be supplied from the current budget.</li> </ul>	<ul style="list-style-type: none"> <li>• The program will incur additional costs and limit the remaining resources available for Nova Scotia's health budget.</li> </ul>

OPPORTUNITIES	THREATS
<ul style="list-style-type: none"> <li>• The program promotes equality of health care.</li> <li>• Being one of the first provinces to expand their HPV program, Nova Scotia will continue to be a leader in HPV prevention strategies among the Canadian provinces.</li> </ul>	<ul style="list-style-type: none"> <li>• Program expansion has the potential to decrease HPV coverage among females via increasing reliance on herd immunity; however, this is unlikely.</li> <li>• The financial commitment to the program will minimize the remaining available resources for other public health services (\$492,000 was included in the budget for this program (Fraser 2015; Grant 2015)).</li> <li>• Barriers and decreased uptake for expansion of HPV vaccination to include males has been reported in the peer-reviewed literature (Radisic <i>et al.</i> 2017).</li> <li>• More information is needed regarding the cost-effectiveness of this program expansion and whether this is the best use of public health funds.</li> </ul>

## 8 CONCLUSION

Nova Scotia's decision to expand its HPV vaccination program to include school-aged males has met little controversy. Its support is founded in scientific evidence, national recommendations, and political pressure for the project, which allowed for swift and commendable action on the part of Nova Scotia.

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