

Health Equity Implications of Excluding Boys and Vulnerable Young Men from Ontario's HPV Immunization Program

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On April 21, 2016, Ontario became the 6th province to include boys in a universal vaccination program against the cancer-causing human papillomavirus (HPV),^{1,2} following Quebec,³ Alberta,⁴ Nova Scotia,⁵ Prince Edward Island,⁶ and Manitoba.⁷ Starting in September 2016, grade 7 boys and girls are eligible to receive the quadrivalent HPV vaccination, resolving a gender inequity issue that has existed since the female-only program was implemented in 2007.⁸⁻¹³

Action on this important issue has been long overdue given that HPV vaccination has been shown to be 90-100% effective at preventing "high-risk" oncogenic (cancer-causing) HPV-16 and 18 infections, as well as "low-risk" HPV infections associated with anogenital warts (AGW) in *both* men and women.¹⁴⁻¹⁷ Since implementation of female vaccination programs in 2007 by over 50 countries worldwide, oncogenic HPV infection rates have reduced by 68%,¹⁶ leading to a 92-97% reduction in high-grade pap abnormalities, as well as reductions in any cause colposcopy, cervical biopsy, and definitive cervical therapy by 20%, 22%, and 42% respectively.¹⁵ In males, HPV vaccine efficacy has been relatively understudied compared to females. However, a recent multinational double-blinded randomized control trial involving over 4000 participants found quadrivalent HPV vaccination in HPV-naïve males aged 16 to 26 to be 90% effective at preventing AGW and 86% effective against persistent HPV-6, 11, 16 or 18 infections, resulting in 78% reduction in incidence of anal intraepithelial neoplasia.¹⁷

HPV infects 3 in 4 sexually active Canadians during their lifetime.¹⁴ While prevalence is bimodal in women (peaking <25 and >45 years old), it seems to be uniformly high in adult men of all ages.⁸ In females, persistent infection with oncogenic subtypes is associated with almost all cases of cervical cancer, as well as 40% of vaginal and vulvar cancers.^{14,18,19} In males, HPV is associated with up to 90% of anal cancers (AC), 50% of penile cancers, 35% of oropharyngeal cancers (OPC), 25% of oral cavity cancers (OCC), as well as 90% of AGW.^{14,19} While overall cancer rates in North America have generally slowed, rates of AC and OPC have increased, with AC rates nearly tripling.¹⁹⁻²¹ In Canada, the greatest increase in cancer incidence between 1997-2008 occurred in AC.²² Furthermore, the incidence of HPV-associated OPC has increased while all other non-HPV-associated OPC have decreased.²³ In fact, the burden of HPV-related head and neck cancer has been shown to be up to ~4x higher in men compared to women in some studies.^{8,20} Specifically, in Ontario, the incidence of HPV-related OCC in men over 20 has increased 1.4x from 1997-2006,

surpassing rates of HPV-unrelated OCC.²⁴ Men are key participants in HPV infection, both as patients and vehicles for transmission, and despite being affected by HPV as often as women, men have been unjustly excluded from comparable screening and prevention strategies,⁸ leading to a disproportionate HPV-associated burden in men over the last decade.

The nearly decade-long delay in including boys has been partly fueled by flawed theoretical assumptions inherent to the concept of herd immunity, which relies on immunizing high rates of females to provide passive immunity to non-immunized males.^{8,9,25} This model gives rise to several health inequity concerns, and relies on the false premise that sexual contact only occurs between men and women, and only occurs between Canadians while inside Canada.

Firstly, inconsistency in vaccination coverage has important herd immunity implications. Accurately estimating vaccination coverage in Ontario is known to be challenging and such estimates should be regarded with caution.²⁶ Coverage rates in Toronto are approximately 65% in girls,^{14,27} and albeit vaccination rates seem to be on an upward trend in Ontario, studies estimating HPV coverage report considerable variability, ranging from 59-80%, falling below the Canadian Immunization Committee benchmark of >80%.²⁸⁻²⁹

Furthermore, Ontario's health units exhibit large variations in population size (0.3-20.5% of Ontario's population) and are therefore subject to a great degree of over-estimation.²⁸⁻²⁹ Notable intra-regional inequities within very large regional units cannot be accounted for and thus pose a considerable risk of being masked by overall high coverage rates.²⁸ This is particularly concerning, given the odds of reporting a lack of knowledge about HPV infection and benefits of vaccination are higher in Hispanic, Black, and other marginalized races and socio-economic sectors of society.³⁰

Inclusion of males in vaccination programs should contribute to more effective bidirectional herd immunity effects. However, the issue of vulnerable male populations is augmented by the fact that there has been lack of awareness among health care providers regarding the impact of HPV infections in young boys and men, resulting in parents of young boys being 2.5x less likely to receive a recommendation for HPV vaccination by physicians.^{30,31} Alongside the nine-year exclusion of boys in the Ontario HPV vaccination program, young boys and men have been unjustly left behind, supporting calls for inclusion of a male HPV vaccination catch-up program in Ontario, similar to programs initiated in Quebec³ and British Columbia.³²

Secondly, perhaps the most overlooked health inequity inherent to the female-only herd immunity HPV vaccination model is that it entirely excludes gay, bisexual, and other men who have sex with men (GBMSM) in addition to persons living with HIV. This is particularly concerning given the significantly higher rates of HPV infection, subsequent cancers, as well as associated psychosocial burden in these vulnerable populations relative to the general population.³³⁻³⁶ Even if immunization rates in women reached 100%, the HPV chain of transmission would still be maintained through GBMSM,^{8,37} and thus these populations have been disproportionately left at risk by female-only vaccination programs.

In Toronto, 88.4% of HIV-positive and 77.9% of HIV-negative GBMSM tested positive for any type of HPV, and two-thirds (65.3%) of the HIV-positive, and half (50.7%) of the HIV-negative participants had infection with high-risk HPV types including HPV 16/18.³⁸ In a similar US study, 61% of HIV-negative and 93% of HIV-positive GBMSM tested positive for HPV.³⁹ In fact, HIV transmission has been shown to be associated with the presence of HPV in 21-37% of HIV infected women as well.⁴⁰ Persons living with HIV are especially vulnerable since their immunocompromised status leaves them at a higher risk of developing HPV-related cancers.⁴¹ In comparison to the general population, high prevalence of anal HPV infection among GBMSM and HIV-positive men is associated with 44x and 60x higher incidence of AC, respectively.^{14,33,34} Furthermore, in Australia's decision to publicly finance routine vaccination of boys, the greatest impact was expected to be among GBMSM.³⁶

Accordingly, other provinces, including Quebec³ and British Columbia³² fund special catch-up programs for these high-risk vulnerable populations up to the age of 26, whom would otherwise incur an out-of-pocket expense of \$400-600 per vaccination^{27,42-44}. Several lines of evidence support this. While HPV vaccination has maximal efficacy if provided before HPV exposure, it still has very good efficacy with ~70% reduction in infection and subsequent cervical lesions in women with serological evidence of previous HPV infection compared to >90% effectiveness in HPV naïve women.^{45,46} In the aforementioned male HPV vaccination trial, quadrivalent HPV vaccination was still 44.7-59.4% effective in males with evidence of previous exposure as well as GBMSM.¹⁷ Moreover, HPV vaccination has been shown to be safe and over 94% immunogenic in HIV-positive individuals with no effect on HIV viral load nor CD4+ count,^{47,48} and has been shown to reduce anal precursor lesions and AC by 50-78% in HIV-negative MSM.⁴⁸ With several trials currently running, data in HIV-positive MSM are not yet available.⁴⁸ However, based on the established immunogenicity in HIV-positive individuals and increased HPV prevalence, the Centers for Disease Control and Prevention, as well as the HIV Medicine Association of the Infectious Disease Society of America recommend vaccination for all HIV infected males 13-26 years old.^{48,49}

Given that GBMSM and persons living with HIV have higher rates of HPV infections as well as subsequently induced cancers,^{35,36} it is foreseeable that these populations will likely represent a greater cost burden per capita to the health

care system than the general population. These populations have been left out for the past nine years of vaccination programs that only cover females, thus increasing their risk of HPV-related cancers. Several cost-effectiveness analyses, including studies specific to Ontario, have already shown value in including boys in HPV vaccination programs.^{8,9,21,41,50-53} Cost-benefit of prevention programs are often described as a measure of disease burden called the quality adjusted life year (QALY) with <\$50,000 per QALY defined as an acceptable threshold.⁹ For reference, the female-only Ontario HPV vaccination program started in 2007 was shown to be highly cost-effective, at <\$10,000 per QALY.⁵⁴ The only prominent study assessing HPV vaccination in GBMSM in the US found clear cost-effectiveness in individuals not previously exposed to HPV (\$15,290 QALY), but still found acceptable cost-effectiveness (\$37,830 QALY) in MSM between ages 20 to 26 despite previous exposure to HPV.³⁷ Notably, further improved cost-effectiveness (QALY consistently <\$30,000) was found by inclusion of a 40% HIV-positive rate in MSM populations, and this study only assessed cost-benefits associated with AC and AGW.³⁷ Thus, further cost-effectiveness would be expected with inclusion of HPV associated OPC, OCC and penile cancer.

While praise should be given to the Ontario government for finally resolving some of the health inequity issues of a female-only vaccination program, there are populations still at risk that have yet to be addressed by the province's new universal policy. We strongly implore the government of Ontario to address these inequities affecting young male populations at the highest risk for HPV infection and subsequent cancers who are still unjustly left behind. A vast amount of HPV related cancers for men and women can be prevented across Ontario. If we are quick to respond, we can reduce the burden of HPV-related cancers to a broad range of populations, including those most at risk, GBMSM and those living with HIV. There is strong evidence that funding a catch-up program for high-risk vulnerable populations of GBMSM and persons living with HIV up to the age of 26 is warranted and necessary from a clinical, scientific, social and ethical perspective. We call upon the Minister of Health and Long-Term Care in Ontario to immediately ameliorate this issue by providing a publicly funded program to vaccinate young GBMSM and those living with HIV. Our call to the Ontario government is supported by the Canadian Cancer Society,¹⁴ the Society of Obstetricians and Gynecologists of Canada,⁵⁵ the Canadian Cancer Advocacy Coalition,⁵⁶ Toronto Public Health,²⁷ the National Advisory Committee on Immunization,¹⁹ and Public Health Ontario and the Provincial Infectious Diseases Advisory Committee on Immunization.⁵⁷

We encourage anyone who is interested in this issue to reach out to the primary authors about how to get further involved. You may also sign a petition at <https://www.change.org/p/the-honourable-dr-eric-hoskins-minister-of-health-and-long-term-care-publicly-fund-hpv-immunization-program-for-boys-and-young-men-particularly-gay-bisexual-and-other-msm-and-those-living-with-hiv>

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