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Shapiro, G. K., Guichon, J., Prue, G., Perez, S., & Rosberger, Z. (2017). A multiple streams analysis of the decisions to fund gender-neutral HPV vaccination in Canada. *Preventive Medicine*, 100, 123-131.

Published in:
Preventive Medicine

Document Version:
Peer reviewed version

Queen's University Belfast - Research Portal:
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Accepted Manuscript

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PII: S0091-7435(17)30137-8
DOI: doi: [10.1016/j.ypped.2017.04.016](https://doi.org/10.1016/j.ypped.2017.04.016)
Reference: YPMED 4994
To appear in: *Preventive Medicine*
Received date: 5 December 2016
Revised date: 3 April 2017
Accepted date: 9 April 2017

Please cite this article as: Gilla K. Shapiro, Juliet Guichon, Gillian Prue, Samara Perez, Zeev Rosberger , A Multiple Streams analysis of the decisions to fund gender-neutral HPV vaccination in Canada. The address for the corresponding author was captured as affiliation for all authors. Please check if appropriate. Ypped(2017), doi: [10.1016/j.ypped.2017.04.016](https://doi.org/10.1016/j.ypped.2017.04.016)

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**A Multiple Streams analysis of the decisions
to fund gender-neutral HPV vaccination in Canada**

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Funding: This work was funded by the Canadian Cancer Society Research Institute (CCSRI; Grant# 704036). GS was supported by the CIHR Vanier Canada Graduate Scholarship and Queen Elizabeth II Diamond Jubilee Scholarship programs.

Conflict of Interest: Zeev Rosberger reports personal fees from Merck as a consultant on two occasions (November and April, 2015) unrelated to the submitted work. The remaining authors declare no conflict of interest.

Word Count: Abstract 198 words; Manuscript 5,344.

Abstract

In Canada, the human papillomavirus (HPV) vaccine is licensed and recommended for females and males. Although all Canadian jurisdictions fund school-based HPV vaccine programs for girls, only six jurisdictions fund school-based HPV vaccination for boys. The research aimed to analyze the factors that underpin government decisions to fund HPV vaccine for boys using a theoretical policy model, Kingdon's Multiple Streams framework. This approach assesses policy development by examining three concurrent, but independent, streams that guide analysis: Problem Stream, Policy Stream, and Politics Stream. Analysis from the Problem Stream highlights that males are affected by HPV-related diseases and are involved in transmitting HPV infection to their sexual partners. Policy Stream analysis makes clear that while the inclusion of males in HPV vaccine programs is suitable, equitable, and acceptable; there is debate regarding cost-effectiveness. Politics Stream analysis identifies the perspectives of six different stakeholder groups and highlights the contribution of government officials at the provincial and territorial level. Kingdon's Multiple Streams framework helps clarify the opportunities and barriers for HPV vaccine policy change. This analysis identified that the interpretation of cost-effectiveness models and advocacy of stakeholders such as citizen-advocates and HPV-affected politicians have been particularly important in galvanizing policy change.

Keywords

Canada, cancer prevention, health policy, human papillomavirus, men's health, Kingdon Multiple Streams framework, policy analysis, vaccination, vaccine policy

Introduction

Most Human Papillomavirus (HPV) infections are asymptomatic and regress in 6-18 months but persistent infection can cause cancer and anogenital warts and can result in morbidity and mortality in females and males (Forman et al. 2012; Giuliano et al. 2014). The prevention of HPV has therefore become a prominent public health priority. Three vaccines, the bivalent (Cervarix®, GlaxoSmithKline; protecting against HPV 16/18), quadrivalent (Gardasil®, Merck; protecting against HPV 6/11/16/18), and nonavalent (Gardasil®9, Merck; protecting against HPV 6/11/16/18/31/33/45/52/58) have been developed to protect against HPV infections and are approved for use (Public Health Agency of Canada 2016; Centers for Disease Control and Prevention 2010). In Canada, the quadrivalent and nonavalent vaccines have been licensed for females and males (aged 9-26); the bivalent vaccine is licensed only for females (aged 9-45). Health Canada recommends that people receive the vaccines as school-aged children in order to provide the highest level of immunogenicity and to protect them before they become sexually active (Public Health Agency of Canada 2012). As of March 2017, all Canadian provinces and territories fund HPV school-based programs for girls, and six provinces have funded HPV vaccination for boys (Shapiro, Perez, and Rosberger 2016) and three have announced that they will commence funding in September 2017 (CBC News 2017; Government of British Columbia, 2017; Government of New Brunswick, 2017).

As other jurisdictions decide whether to adopt the policy of funding HPV vaccine for boys, it is important to draw upon an understanding of the foundations of this policy change (Eggertson 2012; Stanley 2014). A small but growing literature investigates decision-making processes in health policy and systems in low, middle and high-income countries (Greathouse et al. 2005; Koon et al. 2013). In a systematic review of national decision-making concerning adopting new vaccines, Burchett and colleagues write, “There is a need for more research exploring decision-making processes for vaccine adoption, particularly considering how decisions are made, rather than merely who was involved” (Burchett et al. 2012, ii70). To attempt to meet that need, this paper analyzes the underlying factors that have led to decisions to fund HPV vaccination for boys in Canada using a theoretical model of policy change. We use Kingdon’s Multiple Streams (MS) framework to explore the policy decisions to fund HPV vaccination for boys because this

theory offers a broad and multifaceted approach to conceptualize the issues that encourage decision-making and policy change (Kingdon 2011).

Methodology

In 2008, Walt and colleagues commented on the absence of theoretical frameworks in health policy analysis. The authors argued that, “explicit attention to theory development could benefit public policy practice by deepening our understanding of causality and by bringing coherence to a fragmented body of knowledge”; they highlighted the utility of Kingdon’s MS framework among others (Walt et al. 2008, 311). Kingdon’s MS framework addresses how certain policies emerge on the public agenda and are considered by decision-makers while others languish (Thurber 2011). Kingdon’s MS framework has been applied to investigate diverse issues in health policy development (Cairney 2007; Greathouse et al. 2005). It describes policy development as occurring because of three concurrent, but independent, streams. The *Problem Stream* analyzes whether an issue has been identified as a problem that is amenable to human control (i.e. in this case, by examining whether HPV and its associated diseases constitute a health problem). The *Policy Stream* describes the suitability of the proposed solutions for a problem (i.e. by examining whether HPV vaccination of males is an appropriate policy solution in Canadian jurisdictions). Thirdly, the *Politics Stream* describes the political context whereby policy is determined (i.e. by examining the perspective of important stakeholders). When these three streams come together at critical junctures— a problem is recognized, a solution is developed, and political impetus arises — then a ‘policy window’ opens, thus creating opportunity for policy development (Kingdon 2011).

Results

(1) Problem stream: Identifying HPV as a problem for males

HPV has been identified as a health problem in males. HPV is the most common Sexually Transmitted Infection (STI) among males and females (Anic and Giuliano 2011). HPV prevalence in men has been reported to be consistently higher than in females due to the poorer

natural immune response men have to HPV infection compared to females (Giuliano et al. 2011). Individuals can be unaware that they have contracted HPV because HPV infection is often asymptomatic (Anic and Giuliano 2011). The human papillomavirus becomes a health problem when it causes different sequela such as genital warts and cancer.

Epidemiologists have described a growing burden of HPV-associated cancers in men and have warned about the increasing incidence of anal, penile, rectal and oropharyngeal cancers (Palefsky 2010; Stanley 2012; Alemany et al. 2016). Early research suggests that HPV is associated also with sinonasal, conjunctiva, and lacrimal sac cancer (Zhao, Guo, and Zhang 2016; Knör et al. 2015; Afrogheh et al. 2016). HPV-related diseases, including precancerous lesions that require treatment and genital warts, significantly impair psychosocial wellbeing and health-related quality of life (Dominiak-Felden et al. 2013). Moreover, the HPV-related cancer burden in males falls more heavily on an already disadvantaged group; MSM are more susceptible to HPV-associated diseases (Zou et al. 2014; Latini et al. 2014; Glick et al. 2014; Egan v. Canada 1995).

HPV infection in sexually active heterosexual men is problematic also because males can transmit HPV to their female partners. HPV in women is responsible for cervical cancer and can cause vulvar, vaginal, anal, rectal, and oropharyngeal cancers (Palefsky 2010; Public Health Agency of Canada 2016). An association between HPV treatments has also been reported with miscarriage and preterm birth (Maria et al. 2015; Yang et al. 2013; Bonde et al. 2014), though further research is required. HPV infection has been associated with a higher risk of HIV acquisition (Houlihan et al. 2012). HPV infection can be transmitted by a pregnant woman to her foetus, resulting rarely in recurrent respiratory papillomatosis (Palefsky 2010).

The conditions caused by HPV in men, women and infants are largely preventable (Crosignani et al. 2013). However, no early detection measures are currently available to males (e.g. screening or HPV DNA testing) and not all males are included in a government funded prevention strategy (e.g. vaccination).

(2) Policy stream: Identifying HPV vaccination of males as an appropriate policy solution for Canada

To investigate whether HPV vaccination is an appropriate policy solution, we examine the suitability, equity, acceptability, and cost-effectiveness of this solution in Canada.

Suitability. The safety of the HPV vaccines has been determined in multiple randomized controlled trials and epidemiological reviews (Ferris et al. 2014; Palefsky et al. 2011; Vichin et al. 2015). Adverse events are rare. Most reported reactions concern pain at the injection site, which typically resolves in less than five days (Shearer 2011; Ferris et al. 2014). Extremely rare adverse events include flu-like symptoms (e.g. fever) and anaphylaxis (Brotherton, Zuber, and Bloem 2016).

The HPV vaccine has been shown also to be efficacious. In well-controlled trials, HPV vaccination prevented persistent infections (Ferris et al. 2014), and the HPV vaccine has been found to confer cross-protection against other HPV strains in females (Tabrizi et al. 2014; Wheeler et al. 2012). Recent studies have shown that the proportion of high-grade cervical intraepithelial neoplasia lesions caused by HPV 16 and 18 have declined only among women who received the HPV vaccine (Crosignani et al. 2013; Hariri et al. 2015).

Even though there are fewer studies of the vaccines' preventative effect in males (because the vaccine was initially approved only for females), all indications are that the vaccines demonstrate comparable immunogenicity for both sexes (Hillman et al. 2012; Stillo et al. 2015). The emerging literature on HPV vaccines in males has demonstrated the safety and non-inferior immunogenicity in males (Castellsague et al. 2015; Iversen et al. 2016; Lehtinen et al. 2016; Van Damme et al. 2015; Van Damme et al. 2016; Yang and Bracken, 2016). Pinto et al. (2016) found that vaccinating males induces HPV antibodies in the oral cavity in the majority of males, though it is still unclear whether antibody levels will provide long-term protection against infection. We may not see a direct reduction in cancer incidence in males for a number of years because cancer is a disease of latency; however, all available evidence anticipates a decline of HPV-associated cancers in males in the future because of HPV vaccination (Ferris et al. 2014).

Because of its safety and efficacy profile, the HPV vaccine has been licensed by Health Canada since 2006 for females and since 2010 for males (Public Health Agency of Canada 2012). HPV vaccination for boys is a feasible solution because boys can easily be vaccinated against HPV within existing school-based vaccination programs in Canada (Canadian Immunization Committee 2014). Moreover, the implementation of a gender-neutral HPV vaccination program will likely be less confusing to the public (Zimet and Rosenthal 2010; Stanley 2012).

Equitability. Funding HPV vaccination for males will increase equity. The argument for vaccinating only girls and protecting boys by the resulting herd immunity, assumes that males are exclusively heterosexual. MSM do not benefit from this policy and are at higher risk of HPV infection (Zou et al. 2014; Latini et al. 2014; Glick et al. 2014). Targeting MSM is cost effective, particularly if MSM receive the HPV vaccine at an early age (Kim 2010; Lin et al. 2017). The United Kingdom addressed this inequity in 2015 by recommending the vaccine for men who identify as gay or bisexual up to age 45 in genitourinary medicine and HIV clinics (Department of Health and Public Health England 2014). Similarly, since September 2015, the province of British Columbia provides the HPV vaccine to male youth who are in custody and care institutions or who identify as MSM (Brotherton, Zuber, and Bloem 2016), though it will offer the vaccine to all boys commencing in September 2017 (Government of British Columbia, 2017). British Columbia's selective approach had practical and ethical problems previously identified (Shapiro, Perez, and Rosberger 2016; Shapiro et al. 2015), including that it unfairly requires school-aged males to self-identify as homosexual to receive a health benefit. The province of Quebec has adopted an inclusive approach by funding the HPV vaccine both for MSM (under age 26) and all boys (in Grade 4) (Gouvernement du Québec 2016).

Some researchers argue that a female only HPV vaccination policy disadvantages not only MSM, but all males who must rely on herd immunity for protection (Stanley 2012).

Problematically, even though girls in Canada may receive the vaccine at no cost, they are not doing so at levels that adequately confer herd immunity. For example, though uptake varies by jurisdiction (e.g. 52.6% in Nunavut to 89.3% in Newfoundland and Labrador), only 72.3% of 12-14 year old girls in Canada received even one dose of the HPV vaccine in 2013 (Gilbert et al. 2016). Moreover, even if herd immunity were achieved in Canada, it would not protect

Canadian males who have sexual relationships with partners who are, or have come from, outside Canada. A policy that requires males to rely on females for protection from HPV is not equitable. Moreover, such a policy also treats women unequally by placing the burden to protect men on women (Crosignani et al. 2013).

Acceptability. Canadian studies report high acceptability of HPV vaccination for males. For example, a questionnaire conducted in a mid-size Ontario city revealed that mothers supported HPV vaccination for their daughters or sons (77.8% and 70.7% respectively) in their early teens; however, mothers were less willing to consent to vaccination of their younger children, 9 or 10-year-old daughters or sons (41.5% and 38.3%) (Lenehan et al. 2008). Ogilvie et al. (2008) examined acceptability of HPV vaccination for boys (N=1381) across Canada and found that 67.8% of Canadian parents planned to vaccinate their sons but acceptability varied (from 61.7% in British Columbia/Yukon to 79.8% in Atlantic Canada) (Ogilvie et al. 2008).

In studies examining uptake after 2012 when the HPV vaccine was recommended for males in Canada, the results have been mixed. McClure et al. (2015) found uptake was high (i.e. 79%) in P.E.I. after the public program was instituted (McClure et al. 2015). By contrast, Perez et al. (2016) surveyed a national sample of Canadian parents at two time points (N=3117, N=1427), when only P.E.I. and Alberta funded male vaccination. These researchers found less than 3% of parents reported that their 9-16 year-old sons received the HPV vaccine. Importantly, the vast majority of parents were in the early stages of vaccination adoption suggesting that many parents did not know that HPV vaccination is recommended for boys (Perez et al. 2016).

A number of barriers to acceptability by parents have been identified in the literature and include not receiving a recommendation from a health professional (Newman et al. 2013), lack of knowledge regarding the availability and recommendation of the HPV vaccine (Lenehan et al. 2008), negative attitudes towards vaccination (Ogilvie et al. 2008), as well as cost and logistical issues (Newman et al. 2013). Adolescents may also object to the vaccine due to generic vaccination concerns such as fear of needles (Hilton et al. 2013), or believing there is no need for HPV vaccination because they are not sexually active (Forster et al. 2012). Some Canadians may perceive that if the government has not funded a vaccine then it is unnecessary (Scheifele et

al. 2014).

Cost-Effectiveness. “Cost-effectiveness” is a term used to justify both funding and not funding HPV vaccination for males. The Alberta Ministry of Health stated that vaccinating boys is cost-effective: “Expanding the HPV program to males can save lives, reduce disease and reduce future health care costs in Alberta...The cost savings from this preventative effort could represent cost-savings to the health care system of over \$13.4 million” (Alberta Health 2014). Similarly, the Deputy Chief Public Health officer of P.E.I., Dr. Lamont Sweet, reportedly said, “The new program won’t cost more than the original [girls only] vaccination program” (CBC News 2013). By contrast, other provinces justify not funding HPV vaccine for boys claiming that such funding is *not* cost-effective (CTV Montreal 2014; Eggertson 2012). Many provinces have not made their cost-effectiveness analyses available publicly, which prevents them from being evaluated and compared.

Most studies modeling cost-effectiveness have reported that vaccinating boys is less cost-effective than increasing HPV uptake in females, particularly when there is moderate to high coverage in females (Brisson, Van de Velde, and Boily 2009; Brisson et al. 2011; Chesson et al. 2011; Jit et al. 2008; Pearson et al. 2014; Seto et al. 2012). By contrast, some studies have found male HPV vaccination to be cost-effective, particularly with lower estimated vaccine cost and greater estimated efficacy (Brisson et al. 2016; Burger et al. 2014; Elbasha and Dasbach 2010; Elbasha et al. 2007; Graham et al. 2015; Haeussler et al. 2015). There is substantial heterogeneity in the methodology and model parameters of different cost-effectiveness analyses (Pink et al., 2017). The main drivers of cost-effectiveness of gender-neutral vaccination has been the assumed vaccine and administration costs, whether cost reductions related to all HPV-related diseases were considered, whether female coverage was sub-optimal, whether herd immunity effects from girls were considered, and wider socio-economic considerations (Burger et al., 2014; Crosignani et al. 2013; Olsen and Jorgensen 2015; Jiang et al. 2013; Kim et al., 2007; Kotsopoulos et al. 2015; Pearson et al., 2014). Almost all models do not take into account sexual relationships with individuals from other jurisdictions, where HPV vaccination uptake rates in females vary widely, from non-existent to high coverage. Sexual relations with

unvaccinated people from other jurisdictions is a particularly important consideration in Canada given high rates of international travel and immigration.

Modification to vaccine type (e.g. quadrivalent or nonavalent), dosing schedules, and cost of the HPV vaccine can strongly influence cost-effectiveness estimations. Moreover, the World Health Organization (WHO) and the National Advisory Committee on Immunization (NACI) recommended decreasing the HPV vaccine dose from three to two doses (for individuals 9-14 years of age). Some evidence indicates that fewer number of doses (i.e. two or even one) may be sufficient (Sankaranarayanan et al. 2015; WHO 2014). Future cost-effectiveness analyses of male HPV vaccination should also examine recent vaccination rates across Canada, natural immunity (Elbasha and Dasbach 2010), herd immunity (Pearson et al. 2014), errors in vaccine administration (Hibbs et al., 2015), nonavalent vaccination (i.e. 9 HPV types and their associated disease) (Durham et al. 2016; Laprise et al. 2016; Largeton et al. 2017), changes to screening programs (Brisson et al. 2016), two dose schedule (Laprise et al. 2014), sexual behaviour and partnership duration (including early sexual initiation, sexual relationships with partners from other jurisdictions, paying for sex, and the MSM population) (Kim 2010; Van de Velde et al. 2012), possible waning vaccine protection (Jit et al. 2008; Laprise et al. 2014), marginal administration costs (Durham et al. 2016), the burden of non-cervical diseases (e.g. including anus, rectum, and oral/oralopharyngeal cancers as well as anogenital warts) (Burger et al. 2014; Chesson et al. 2011; Laprise et al. 2014), and HPV-related infant prematurity as a result of treatment for Cervical Intraepithelial Neoplasia (Ryser et al. 2015; Soergel et al. 2012; Olsen and Jorgensen 2015; Isidean et al. 2015). While some of these factors have been examined by some authors, we know of no study that has modeled and assessed all these factors simultaneously. Like Pink and colleagues, we advocate that studies report their assumptions and the impact of simplifying assumptions (Pink et al., 2017). Further, an updated systematic review that compares and contrasts these cost-effectiveness analyses is also merited.

(3) Politics Stream: Identifying the perspective of important stakeholders

The Politics Stream analyzes the political context and the perspectives and partisan influence of stakeholders in the decision arenas (Nowlin 2011). Interest groups can promote or block a policy change (Kingdon 2011). Groups that have a stake in the political debate about HPV vaccination for boys in Canada include the federal and provincial governments, the scientific and medical community, civil society, the media, pharmaceutical companies and school boards.

Government. Canadian provinces and territories are responsible for providing health care to people in Canada (The Constitution Act 1867). Nevertheless, the federal government plays an important role in setting agendas, providing funding, and approving drugs for market. In 2007, the federal government allocated \$300 million over three years to fund the HPV vaccine for girls (Steben 2008). The current federal government has not announced whether it will fund HPV vaccination for boys (Eggertson 2012). Individual elected representatives have advocated for HPV vaccine funding for boys, such as federal opposition Member of Parliament Peter Kent (Thornhill, Ontario), and Member of the Legislative Assembly of Nova Scotia, Gordon Gosse, both personally affected by HPV-related cancer (Payton 2014).

The Public Health Agency of Canada supports two committees that recommend vaccine use in Canada, namely NACI and the Canadian Immunization Committee (CIC). NACI - an advisory committee of scientific experts - first recommended HPV vaccination for females in 2007 and expanded its recommendation to include males (aged 9 to 26) in 2012 (Public Health Agency of Canada 2016). The CIC - an advisory committee of federal, provincial and territorial health authorities- is mandated to consider vaccine cost, alignment of vaccine programs, and acceptability (Canadian Immunization Committee 2014). In 2007, the CIC highlighted the goal of the HPV vaccination program as reducing the incidence of cervical pre-cancer and cancer (Canadian Immunization Committee 2007); in 2014, the CIC broadened the objective to include reducing other HPV-related diseases and recognized the impact of HPV on males (Canadian Immunization Committee 2014). NACI recommends male vaccination and the CIC favours funding HPV vaccination for boys where it is feasible, cost-effective, and acceptable.

Scientific and Medical Community. The scientific and medical community overwhelmingly agree that HPV vaccination is safe and effective, and that preventing HPV-related disease in

males is desirable, bar a minority of objections (Leon 2008; Harper and Demars 2014; Lippman et al. 2007). The Canadian Medical Association supports public funding for vaccinating males (Sagan 2014). The Canadian Pharmacists Association writes that “the lack of access to HPV vaccination programs for young men in Canada is needlessly putting the health of Canadians at risk” (Canadian Pharmacists Association 2015). The Federation of Medical Women of Canada has argued that vaccinating boys makes sense when there is a low uptake among girls (Eggertson 2012). The Canadian Paediatric Society has also recommended male HPV vaccination (Moore 2015). Recently, the Society of Obstetricians and Gynaecologists of Canada (SOGC), Society of Canadian Colposcopists, the Society of Gynecologic Oncology of Canada, and the College of Family Physicians of Canada, published a joint statement on the safety of HPV vaccination (SOGC et al. 2015). They explained that HPV is related to cancers that affect females and males, though the statement emphasized female vaccination (SOGC et al. 2015).

Civil society. Many Canadian organizations favour HPV vaccine and male vaccination. For example, the Canadian Cancer Society called the HPV vaccine “a game changer” (Canadian Cancer Society 2013, 10). Immunize Canada, a consortium of professional organizations guided by the Canadian Public Health Association, and a citizens’ group, HPV Canada, have supported HPV vaccination for males (HPV Canada 2015). When, in February 2015, the HPV vaccine was disparaged in a Canadian newspaper with the largest circulation, the *Toronto Star*, doctors, public health experts and researchers formed a coalition that became the Canadian Alliance to Support Immunization (CASI). Their denunciation of the misleading article helped lead to its retraction (Guichon and Kaul 2015; Chantal 2015). However, some anti-vaccination groups in Canada, such as Vaccine Choice Canada, continue to oppose HPV vaccine for both sexes.

Media. Sensational articles about HPV have been published in the Canadian media including *Macleans*’ cover story “Our girls are not guinea pigs”, and the aforementioned *Toronto Star*’s “A wonder drug’s dark side”, and *Le Devoir*’s “Urgent call for a moratorium on HPV vaccination in Quebec” (Gulli, George, and Intini 2007; Bruser and Mclean 2015; Rail, Molino, and Lippman 2015). Reading negative reports has been found to influence parents to refuse to vaccinate their children (Nan and Madden 2012; Gollust et al. 2010).

A 2009 content analysis of Canadian and U.S. national news coverage of HPV found that, in Canada, 28% of articles about the HPV vaccine were negative, whereas 43% were neutral and 29% were positive (Abdelmutti and Hoffman-Goetz 2009). A 2016 Canadian content analysis, conducted after NACI's recommendation to vaccinate boys, found that the proportion of newspaper articles in Canada that mentioned HPV vaccination for boys significantly increased between 2012 and 2014; nevertheless, only half of all those articles discussed HPV vaccination for boys (Perez et al. 2016).

Social media is another forum where HPV vaccination concerns can be voiced and circulated to Canadian audiences quickly. Sites such as Twitter quickly disseminate misinformation regarding HPV (Dunn et al. 2015). Some research has evaluated online comments to news articles (Feinberg et al. 2015), blogs or online discussion forums (Penta and Baban 2014, Keelan et al. 2010, Nan and Madden 2012), YouTube videos (Ache and Wallace 2008, Briones et al. 2012), and Twitter (Mahoney et al. 2015, Bahk et al. 2016, Dunn et al. 2015, Zhou et al. 2015, Surian et al. 2016). The balance of positive and negative content and type of concerns expressed appears to vary by social media platform and requires further investigation and surveillance.

Pharmaceutical Companies. Pharmaceutical companies, GlaxoSmithKline and Merck, are also stakeholders that directly influence the policy debate by setting the vaccine price in each province. They also lobby for their vaccines to be licensed, recommended, marketed, and publicly funded in Canada. In 2008, Gardasil received the Prix Galien Canada Innovative Product Award, which recognized its contribution to patient care in Canada (Prix Galien Canada 2008). The commercial promotion of vaccines is limited in Canada by law; advertisements must follow strict federal content regulations (Food and Drugs Act 1985; Scheifele et al. 2014); nevertheless, pharmaceutical companies invest in marketing their products and Canadians are often exposed to HPV vaccination through other countries' advertisements (e.g. in magazines and internationally read newspapers). The pharmaceutical industry works also with scientists by funding research, including HPV vaccination trials. Although academic participation in drug-related science is important for innovation, understandable concern arises about relationships between researchers and industry (Lewis et al. 2001). Pharmaceutical companies also give funds to medical societies. For example, Merck provided the SOGC with an unrestricted grant (\$1.5

million) to educate Canadians about HPV; the SOGC reported using peer-reviewed work to do so (Page 2007).

School boards. Because school aged children are typically vaccinated in school in Canada (Guichon et al. 2013), school boards are a notable stakeholder in this debate. Soon after provinces announced HPV vaccination program for girls, some Roman Catholic bishops publicly discouraged HPV vaccination, encouraging “a proper education in chastity” (Wingle 2007) and abstinence (Smith et al. 2008). Twelve school districts in Alberta, Ontario and the Northwest Territories banned the vaccine from being administered in publicly funded schools (Guichon et al. 2013). The HPV vaccine ban negatively affected HPV vaccination uptake because girls whose easy access was blocked by Catholic school boards were less likely to receive the vaccine than other girls. HPV vaccine bans caused particular hardship to girls with a lower socio-economic status (Musto et al. 2013). Because of advocacy which created pressure for the school trustees (Cotter 2014), and the publication of Bednarczyk et al.’s (2012) research disproving the notion that administration of HPV vaccine is associated with sexual activity (Bednarczyk et al. 2012), all school boards reversed their bans by May 2014 (HPV Canada 2015; Guichon et al. 2013). Nevertheless, this issue remains salient; in September 2014 the Calgary Catholic School District continued to include the Alberta episcopal letter that discourages HPV vaccination in the health information package for parents (Blackwell 2014). No new publicly-funded Catholic school board barriers have been reported regarding boys and HPV vaccination.

A study by McClure et al. (2015) in P.E.I. found that students (girls and boys) in the English Language School Board were more than twice as likely as students in the French Language School Board to receive all three doses of the HPV vaccine (McClure et al. 2015). Although the authors postulated that this finding is probably related to socio-demographic differences, more research is needed to examine the reasons that different linguistic school boards have varying HPV vaccine uptake (McClure et al. 2015).

Discussion

To date, few countries have publicly-funded HPV vaccination programs for boys: Australia (since 2013), Austria (since 2014), Barbados (since 2013), Canada (six jurisdictions; since 2013, with an additional three regions announcing programs to commence September 2017), Israel (since 2015), New Zealand (since 2017), Italy (since 2017), Liechtenstein (since 2016), Switzerland (i.e. The Republic and Canton of Geneva, since 2016), and the United States (Brotherton, Zuber, and Bloem 2016; Cancer Council Victoria 2016; ECDC 2016; Efrati 2015; Favato 2017; Freyer 2016; HPV Information Centre 2016; Shapiro et al. 2016; New Zealand Ministry of Health 2017). Because Canada is an international leader in funding HPV vaccination for boys, analyzing what led to policy development in Canada may inform health care policy and practice on a national and international level. This paper used Kingdon's MS framework to examine diverse factors that were (or were not) involved in incorporating boys into HPV vaccination programs in Canada. Kingdon's MS framework theorizes that all three streams must be open for policy change to occur (i.e. a problem is recognized, a solution is developed, and political impetus arises (Kingdon 2011). Accordingly, any one factor—such as insufficient research, public demand, or a strongly opposed stakeholder—can derail policy change.

Analysis from the Problem Stream identified that HPV causes HPV-associated cancers and anogenital warts in men, that males can transmit HPV to their sexual partners and that offspring can be negatively affected. The incidence of HPV-associated cancers has been increasing in Canada and worldwide. To build on the available evidence, future research should evaluate and monitor the cross-protection, possible type replacement, safety and efficacy of the HPV vaccines in males.

Analysis from the Policy Stream identified that vaccinating boys is a suitable and equitable solution that has precedent in the universal female HPV vaccination program. While acceptability of HPV vaccination among boys in some provinces (e.g. P.E.I) appears strong, greater research is required to understand why provincial uptake varies. The most contentious factor has been cost-effectiveness analyses, which have varied depending on models and methodologies. Crucial to cost-effectiveness analyses is the vaccine price that provinces and territories negotiate with pharmaceutical companies, which is not public knowledge and inclusion of additional costs. Lowering vaccine costs through price negotiations and reducing

delivery costs (by administering more than one vaccine at the same time) is a current priority to reach cost-effectiveness for male HPV vaccination (Baussano et al. 2014). Indeed, Australia has obtained a lower vaccine price for males compared to females (Brotherton, Zuber, and Bloem 2016). Moreover, the availability of funds also appears to have been crucial for policy change in some provinces. For example, P.E.I. appears to have had existing funds in the Department of Health and Wellness budget and a relatively small population of boys to be vaccinated. In Alberta, the Alberta Cancer Prevention Legacy Fund likely helped address the cost barrier (Alberta Health Services 2016). Moving to a two or one-dose regime also makes the HPV vaccination program more affordable; this change likely affected Nova Scotia's decision to include boys, which coincided with the decision to offer only two doses to girls and boys (Fraser 2015). Cost-effectiveness, though an important factor, should not be the only consideration for initiating a vaccine program. Future research could expand on this evaluation of the policy stream by incorporating related criteria considered in the advisory process of immunization recommendations (e.g. adequateness of vaccine supply) (Nijsten et al. 2016).

The Politics Stream identified relevant stakeholders and their positions. The scientific and medical communities favour funding male vaccination, and have recently advocated for male vaccination publicly. The federal and provincial/territorial agencies favour funding male vaccination, though some provinces have emphasized the importance that the vaccine be cost-effective for males. Pharmaceutical companies have strongly promoted male vaccination. Generally speaking, the Canadian media and civil society have positively assessed the HPV vaccine; however, male HPV vaccination has been less visible in the media compared to female vaccination, some notable news articles have caused a stir, and anti-vaccine groups are active in this debate. Lastly, a number of Catholic school districts opposed HPV vaccination in the past, banning or discouraging female vaccination. The momentum required to overturn the Catholic school vaccine bans (predominantly in Alberta where local, national and international media coverage favoured in-school HPV vaccination) may have created a 'window of opportunity' for HPV vaccination in boys.

Although Kingdon's MS framework offers a broad and multifaceted approach, it is not exhaustive. It would be useful for future research to evaluate other (high and low income)

countries and conduct international comparisons, which necessitates taking into account the potential role of policy diffusion (Shipan and Volden, 2012). It would also be helpful to extend this research by considering other policy frameworks that examine decision-making (Koon et al., 2013; Walt et al. 2008). For example, there is a burgeoning field examining how health policy systems research could be more directly embedded into the decision-making sphere (Koon et al., 2013). The WHO and collaboration among National Immunization Technical Advisory Groups on immunization (NITAGs) are well positioned to lead improvements in the use of evidence in policy decision-making and make informed immunization decisions for their local contexts (Adjagba et al., 2015; Perronne et al., 2016). Because there is little overlap in the decision-making processes of NITAGs (Nijsten et al., 2016; Ricciardi et al., 2015), future research could inform the development of an international standard for an evidence-based process of decision-making for immunization policy. Such research should advance the conceptual decision-making framework for policy analysis.

Conclusion

As of March 2017, nine Canadian provinces offered, or intend soon to offer, publicly funded school-based HPV vaccination for males and females, albeit with slight variations. This paper's analysis identified that the interpretation of cost-effectiveness models, herd immunity calculations, and advocacy by stakeholders (including citizen-advocates and HPV-affected politicians) have been particularly important in galvanizing policy change. There are multiple, simultaneously ongoing policy debates regarding HPV vaccination in Canada and other developed countries on matters such as: how many doses children should receive, at what age children should receive the vaccine, which vaccine should be administered, and whether the HPV vaccine should be funded for high-risk boys only. Because Kingdon's MS framework helps focus and analyze such public health decisions, it may be useful in future policy research on the implementation of HPV vaccination programs for boys in Canada and internationally.

Acknowledgments

The authors thank Antonia Maoini and Daniel Weinstock for their helpful comments on an earlier version of this article.

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ACCEPTED MANUSCRIPT

Highlights

- Canada is an international leader in funding HPV vaccination for school-aged boys.
- Kingdon's framework helps clarify the landscape that led to male HPV vaccination.
- HPV is problematic for males, their sexual partners, and offspring.
- Male vaccination is suitable, equitable, and acceptable; however, cost-effectiveness is debated.
- Stakeholders including citizen-advocates and HPV-affected politicians were important in galvanizing policy change.