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HEALTH EQUITY, HPV AND THE CERVICAL CANCER VACCINE

Joanna N. Erdman*

Technological innovation is primarily valued because it fills an existing health care gap. This is especially true respecting vaccines in the sexual health context. Behavioural and screening prevention are often seen as temporary measures until a vaccine is available.¹ Vaccines remove the need, and thus fill the gap, of imperfect prevention.

This article focuses on a different kind of health care gap: *health inequity*. It explores the relationship between technological innovation and health inequity. In particular, the article examines the relationship between the vaccine against human papillomavirus (HPV) infection, the cause of cervical cancer, and inequity in cervical cancer incidence and mortality.

In Canada, screening programs have drastically reduced the incidence of cervical cancer, but their benefits have been unequally distributed. Women of lower income and literacy, new immigrants, and aboriginal women remain significantly more likely both to develop and die of cervical cancer.² The tragedy of cervical cancer is thus not only that it is preventable. It is that prevention efforts have disproportionately failed the disadvantaged.

Technological innovation alone will not remedy this inequity. The HPV vaccine merely expands the available means for reducing or enhancing health inequity depending on its implementation.³ For this reason, the ar-

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1 Gregory D. Zimet, Rose M. Mays & J. Dennis Fortenberry, "Vaccines Against Sexually Transmitted Infections: Promise and Problems of the Magic Bullets for Prevention and Control" (2000) 27 Sexually Transmitted Diseases 49 at 49.

2 Canadian Cancer Society *et al.*, *Canadian Cancer Statistics 2007* (Toronto: Canadian Cancer Society/National Cancer Institute of Canada, 2007) at 17.

3 This analytic framework borrows from Paul H. Wise, "The Anatomy of a Disparity in Infant Mortality" (2003) 24 Annual Review of Public Health 341 at 345: "... medical progress alone can never guarantee equity in health outcomes. Rather, growing efficacy merely provides an expanded substrate for disparity reduction or enhancement, depending on patterns of provision." This frame-

title looks beyond technological innovation to focus on the Canadian HPV vaccination strategy. It asks: Who is intended to, and who in practice will, benefit from the vaccine? Will it be women with the least or greatest need? Will existing health disparities be reduced or enhanced?

The first part of the article discusses the legal significance of health inequity. The second part examines the health equity effects of the Canadian HPV vaccination strategy.

1. Health Inequity and its Legal Significance

Health inequity is defined as differences in health that “are not only unnecessary and avoidable, but ... unfair and unjust.”⁴ Health inequity thus does not refer to all differences in health, but focuses on a subset of differences. It refers to health disparities that are *unjust* because they are avoidable and thus unnecessary.

As argued by Paula Braveman, health inequities are identified by their systematic tracking of existing lines of social disadvantage, including socioeconomic status, race and sex.⁵ Disadvantaged population groups systematically experience worse health or greater health risks than more advantaged groups. Systematic association with social disadvantage renders health disparities unjust by positioning health distribution as neither avoidable nor necessary, but informed by relevant institutions that construct social disadvantage, and thus the health disparities that track it. Health inequity is located in the social institutions that systematically place already disadvantaged population groups at further disadvantage with respect to their health. One such institution is the health system. Health inequity is a function of how health policies and programs are designed and how health resources are distributed among population groups. In other words, health inequity implicates the ethical and legal principle of distributive justice.⁶ The cause

work “is intended to transcend disciplinary antagonisms between the realms of technical efficacy and social justice.” At 342-43.

4 M. Whitehead, “The concepts and principles of equity in health” (1992) 22 *International Journal of Health Services* 429 at 429.

5 Paula A. Braveman, “Monitoring Equity in Health and Healthcare: A Conceptual Framework” (2003) 21 *Journal of Health Population and Nutrition* 181 at 181.

6 *Ibid.* at 183.

and more importantly the responsibility for health inequity is located in government action, namely health policies and programs.

The concept of health inequity, and its consequences for government responsibility, is reflected in the equality rights under s. 15(1) of the Canadian *Charter of Rights and Freedoms*. Pre-existing disadvantage is identified as a contextual factor supporting a finding of government discrimination.⁷ The failure to recognize and address the needs of groups subject to preexisting disadvantage is an especially important indicator of discrimination in the health context. The Supreme Court has expressly dismissed the claim that governments are “entitled to provide benefits to the general population without ensuring that disadvantaged members of society have the resources to take full advantage of those benefits.”⁸ A claimed distinction between state-imposed and pre-existing disadvantage in the design of health policies and programs “bespeaks a thin and impoverished vision of s. 15(1). It is belied, more importantly, by the thrust of this Court’s equality jurisprudence.”⁹ Health policy cannot escape constitutional scrutiny because it is facially neutral. On the contrary, the neutrality of a policy, its unresponsiveness to pre-existing disadvantage, may render the policy discriminatory. Under s. 15(1), government must account for health policies and programs that place already disadvantaged social groups at further disadvantage with respect to their health and healthcare.¹⁰

Disparity in HPV-related diseases, in particular cervical cancer, is a striking instance of health inequity worldwide. A meta-analysis of 57 studies revealed an increased risk of approximately 100% between high and low social class categories for the development of invasive cervical cancer.¹¹ In Canada, women of lower income and literacy, new immigrants,

7 *Law v. Canada (Minister of Employment and Immigration)*, [1999] 1 S.C.R. 497 at 534, [1999] S.C.J. No. 12.

8 *Eldridge v. British Columbia (Attorney General)*, [1997] 3 S.C.R. 624 at para. 73, [1997] S.C.J. No. 86 [*Eldridge* cited to S.C.R.].

9 *Ibid.*

10 See *McKinney v. University of Guelph*, [1990] 3 S.C.R. 229, [1990] S.C.J. No. 122, wherein the Supreme Court of Canada held that the term “law” in Section 15(1) of the *Charter* is not confined to formal types of law-making such as statutes and regulations, but extends to government policies, programs and activities.

11 Seema Parikh, Paul Brennan & Paolo Boffeta, “Meta-Analysis of Social Inequality and the Risk of Cervical Cancer” (2003) 105 *International Journal of Cancer* 687 at 688.

and aboriginal women are more likely to both develop and die of cervical cancer.¹²

The HPV vaccine is widely regarded as one of the most important technological innovations in women's health.¹³ Government accountability extends, however, beyond the opportunity of technological innovation and policy objectives. It extends to the impact of an HPV vaccination policy on disadvantaged groups. Will the Canadian vaccination strategy benefit women with the greatest or least need? Will it ensure the best possible health for the advantaged at the expense of the disadvantaged? Will existing health disparities be reduced or enhanced? These are the questions of a health equity perspective, the questions of s. 15(1) of the *Charter*.

2. HPV, Cervical Cancer and the Canadian Vaccination Strategy

This part of the article examines the Canadian HPV vaccination strategy from a health equity perspective. Prior to describing the strategy, a brief review of the science of the human papillomavirus (HPV), cervical cancer and the HPV vaccine is provided.

A. The Science: HPV and Cervical Cancer

The human papillomavirus (HPV) is a diverse set of more than 100 different virus types. These viruses infect skin and mucous membranes. HPV, for example, causes benign skin warts. More than 40 HPV types are sexually transmitted and infect the anogenital (anus and genitalia) region. HPV is the most prevalent sexually transmitted infection.¹⁴ An estimated 75% of all sexually active women will be infected in their lifetime.¹⁵

12 *Supra* note 2.

13 "To market a drug" *The Vancouver Sun* (14 May 2007) A11: "When Finance Minister Jim Flaherty announced \$300 million in federal money for a program to vaccinate girls and young women against the human papillomavirus, it was hailed as the most important development in women's reproductive health since the pill."

14 National Advisory Committee on Immunization (NACI), "An Advisory Committee Statement (ACS): Statement on human papillomavirus vaccine" (2007) 33 Canada Communicable Disease Report 1 at 4: Estimated prevalence and incidence may vary because HPV "is not a nationally notifiable disease in Canada and, to date, no population-based studies have been published."

15 Society of Obstetricians and Gynaecologists of Canada, *Human Papillomavirus*:

Most infections are asymptomatic and transient. The immune system resolves the infection in a matter of months.¹⁶ Persistent infection over decades with two groups of HPV-types (high risk and low risk) leads to adverse health outcomes. This classification – high risk and low risk – is based on oncogenic potential or association with invasive cervical cancer.¹⁷ Low risk HPV types are associated with most anogenital warts and mild cervical dysplasia (precancerous cellular abnormalities). High risk HPV types are associated with cervical dysplasia, which if left undetected and untreated, may progress to cervical and other forms of cancer.¹⁸

HPV infection and cervical cancer can not therefore be conflated. While almost all cervical cancers can be traced to high risk HPV infection, the vast majority of high risk HPV infections clear spontaneously and will not develop into cervical cancer.¹⁹

B. Prevention Strategies: Sex, Screening and Vaccination

Three prevention strategies derive from the key role of HPV infection in the etiology of cervical cancer: sexual behaviour modification, screening and vaccination.

Sexual activity has been recognized as a factor of cervical cancer risk since the mid-nineteenth century, based on now controversial statements of its comparative incidence in prostitutes and nuns.²⁰ Sexual behaviour modification to reduce exposure to HPV, a sexually transmitted infection (STI),

the most common sexually transmitted infection (Ottawa: Society of Obstetricians and Gynaecologists of Canada, 2007) at 4.

16 The Public Health Agency of Canada reports that over 80% of HPV infections often acquired at an early age clear spontaneously within 18 months. See Public Health Agency of Canada, *Canadian Guidelines on Sexually Transmitted Infections 2006 Edition* (Ottawa: Public Health Agency of Canada, 2007).

17 See Nubia Munoz *et al.*, “Epidemiologic Classification of Human Papillomavirus Types Associated with Cervical Cancer” (2003) 348 *New England Journal of Medicine*, 518.

18 Cervical cancer is the primary malignancy. Other anogenital cancers (vulva, vaginal, anus and penile) and cancers of the mouth and upper throat are also associated with HPV infection.

19 *Supra* note 14 at 1, 3.

20 See e.g. Petr Skradanek, “Cervical Cancer in Nuns and Prostitutes: A Plea for Scientific Continence” (1988) 41 *Journal of Clinical Epidemiology* 577.

is one primary prevention strategy. Safer sex practices include delayed sexual debut, consistent condom use and reduced number of sexual partners. While the effectiveness of safer sex strategies for HPV infection is debated,²¹ this prevention strategy carries a significant advantage. It can engage with upstream determinants of sexual ill-health: social, institutional and other structural constraints underlying risk behaviours related to sexual health and well-being. This prevention strategy can thus work to create more supportive sexual health environments.

Screening and vaccination programs, in contrast, focus on the biomedical causes of HPV infection.

The “Pap” (Papanicolaou) smear test is one of the most successful screening tests in the history of medicine. Since its introduction in Canada, this secondary prevention strategy has dramatically reduced the incidence and mortality of cervical cancer.²² Screening allows for early detection, follow-up and treatment of precancerous abnormalities, a viable strategy in cervical cancer prevention because of the prolonged progression from infection to disease, an estimated ten years or longer.²³

Despite the success of screening programs, the decline in cervical cancer incidence in Canada has plateaued. In 2006, an estimated 1,350 new cases of cervical cancer and 390 cervical cancer-related deaths were reported.²⁴ Cervical cancer rates, more significantly, continue to vary according to indicators of social disadvantage: lower socioeconomic status, lower education level, birthplaces outside Canada and marginalized ethnicities. Women belonging to socially disadvantaged groups remain at a significantly higher risk of both developing and dying of cervical cancer.²⁵ Age-standardized rates of cervical cancer among Canadian Inuit women, for example, are three times

21 The Society of Obstetricians and Gynaecologists of Canada advises that as compared to other STIs – such as chlamydial infection, gonorrhea, syphilis, HIV infection and hepatitis B – fewer behavioural methods of HPV prevention have been shown to be effective. HPV infection is also unique in its risk of transmission with very few partners: up to 60% of women are infected by their first partner. See Marc Steben, “Prevention” (2007) 29:8 *Journal of Obstetrics and Gynaecology Canada* S23 at S23.

22 *Supra* note 14 at 11.

23 *Ibid.* at 4.

24 *Supra* note 2 at 20, 22.

25 *Ibid.* at 17.

higher than the national average. Elevated cervical cancer rates of 2 to 6 times are reported among aboriginal women in British Columbia, Saskatchewan, Manitoba and Ontario.²⁶

This disparity results not from individual but systemic risk: inaccessible screening and treatment. 60% of women diagnosed with cervical cancer in Canada have not been screened or have been inadequately screened.²⁷ Disadvantaged women are disproportionately represented among the unscreened and the untreated.²⁸ This is the consequence of multiple system barriers, including:

- opportunistic screening that relies on provider initiation,
- lack of primary care or female providers and restrictions on mid-level providers,
- lack of culturally competent care,
- language and literacy differences, and
- failure to address women's distrust, embarrassment and discomfort in accessing sexual health services.

One answer to the health inequity of screening programs is to reduce their importance. This can be accomplished by improving the effectiveness of primary prevention. Rather than focusing on sexual transmission, the newest primary prevention focuses on the proximal biomedical causes of HPV infection. The intervention: vaccination.

On July 10, 2006, Health Canada approved the vaccine Gardasil™ (Merck Frosst Canada Ltd.).²⁹ Based on the review of data respecting quality, safety, and effectiveness, Health Canada considered the benefit/risk profile

26 Health Canada, *Cervical Cancer Screening in Canada: 1998 Surveillance Report* (Ottawa: Public Works and Government Services, 2002).

27 K. Joan Murphy, "Screening for Cervical Cancer" (2007) 29:8 *Journal of Obstetrics and Gynaecology Canada* S27 at S27.

28 *Supra* note 14 at 14: "Failure to screen and failure to screen at the recommended interval are associated with low education and low socio-economic status, rural/remote residence and ethnicity." See also *supra* note 26 at ix: "Women who are older, immigrant or Aboriginal, or who have a lower socio-economic status are at higher risk of developing cervical cancer, as these groups show lower compliance with regular screening schedules."

29 Health Canada, *Notice of Decision for Gardasil™*, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/nd_ad_2006_gardasil_102682-eng.pdf>.

of the vaccine favourable for the prevention of HPV infection and associated diseases, including cervical cancer, vulvar and vaginal cancer, genital warts and precancerous lesions.³⁰ Gardasil protects against initial infection with two high risk HPV types (16 and 18) which cause approximately 70% of cervical cancers and two low risk HPV types (6 and 11) which cause approximately 90% of anogenital warts.³¹ On February 15, 2007, the National Advisory Committee on Immunization (NACI) issued a statement recommending the use of Gardasil™ for Canadian females between nine and twenty-six years of age.³² The HPV vaccine Cervarix™ (GlaxoSmithKline) is currently under Health Canada review.

The HPV vaccine carries the potential not simply to reduce but to effectively eradicate cervical cancer. Realization of this potential depends, however, on the extent to which women who have historically failed to benefit from screening programs can access the vaccine. The success of HPV vaccination depends on its health equity effects. Design and implementation of the Canadian HPV vaccination strategy is thus paramount to its success.³³

C. Implementation Challenges: Sex, Youth and Money

Three characteristics pose challenges to achieving the promised health equity benefits of the HPV vaccine: its characterization as a STI vaccine, its administration to young adolescents and its exceptionally high cost.

The HPV vaccine is characterized as protecting against diseases caused by infection with HPV, a sexually transmitted infection (STI).³⁴ As the vaccine is designed to prevent against initial HPV infection, it is ideally administered

30 Health Canada, *Summary Basis of Decision (SBD) Gardasil™ Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine Merck Frosst Canada Ltd.*, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/sbd_smd_2007_gardasil_102682-eng.pdf>. Health Canada's Summary Basis of Decision documents are intended to outline the scientific and regulatory considerations that factor into Health Canada regulatory decisions related to drugs and medical devices.

31 *Supra* note 14 at 2-3, 16.

32 *Ibid.* at 23.

33 See e.g. Debbie Saslow & Cosette M. Wheeler, "Human Papillomavirus Vaccines: Who Will Pay, Who Will Receive, When to Administer?" (2007) 17 *Ethnicity and Disease* S2-8.

34 Merck Frosst Canada Ltd., *Product Monograph: Gardasil* (Kirkland, QC: Merck Frosst Canada Ltd., 2006).

prior to exposure and thus sexual debut. The National Advisory Committee on Immunization recommends use of Gardasil for females “between 9 and 13 years of age, as this is before the onset of sexual intercourse for most females in Canada, and the efficacy would be greatest.”³⁵

Vaccine acceptance is based in part on perceived susceptibility or risk.³⁶ This factor may pose an implementation challenge for an STI vaccine administered to young adolescents.

In the case of an STI vaccine, risk of infection is associated with sexual and other social behaviours: early age of first sexual intercourse, higher numbers of or transient sexual partners, inconsistent condom use, having never married or not living with a sexual partner – traditional markers of sexual promiscuity. Women, and especially socially disadvantaged women, may be unwilling to associate themselves with such negatively stereotyped and stigmatized behaviours. This poses challenges for vaccination programs intended to target high risk women identified by markers of social disadvantage, such as socioeconomic status or ethnicity. Targeted programs may legitimate stereotypes or perpetuate stigma about the source of higher cervical cancer rates among these women: sexual and other risk behaviour inherent to the individual or population group rather than inaccessible screening and treatment, underlying systemic factors.³⁷

In the case of an STI vaccine administered to young adolescents, parents may be especially unwilling to acknowledge their child’s susceptibility to infection.³⁸ While evidence suggests that most parents will not object to vaccination on this ground,³⁹ the data is not disaggregated. The sexual transmission of HPV may be a stronger consideration in families and communities where premarital sex is strictly forbidden. It is, however, young women from these families and communities who are commonly denied

35 *Supra* note 14 at 23.

36 *Supra* note 1 at 51.

37 Anne Schneider & Helen Ingram, “Social construction of target populations: implications for politics and policy” (1993) 87 *American Political Science Review* 334 at 335.

38 Richard K. Zimmerman, “Ethical analysis of HPV vaccine policy options” (2006) 24 *Vaccine* 4812 at 4814.

39 Gregory D. Zimet, “Understanding and overcoming barriers to human papillomavirus vaccine acceptance” 18 *Current Opinion in Obstetrics and Gynecology* S23 at S24-25.

sexual health information, education and services, and who would therefore benefit most from vaccination.

Cost is also a significant factor in vaccine acceptance.⁴⁰ With a purchase cost of \$404.85,⁴¹ Gardasil is the most expensive vaccine ever developed for mass use.⁴² Poor and low income women are a large proportion of women systemically denied the benefits of screening. If women are required to privately pay for the vaccine, women with the greatest need will again be denied access to preventative care.⁴³ The HPV vaccine will contribute little to decreasing cervical cancer incidence and mortality if it is inaccessible to disadvantaged population groups with the greatest risk of developing and dying of cervical cancer.

D. The Canadian Strategy: School-Based Publicly-Funded Cancer Vaccination

The health equity challenges of the HPV vaccine are not insurmountable. On the contrary, the Canadian strategy is expressly designed to address these concerns. The strategy: school-based, publicly funded Cancer vaccination.

On March 19, 2007, the Federal Government announced that it would contribute \$258 million on a per capita basis to implement provincial and territorial HPV vaccination programs over the next three years.⁴⁴ In 2007, Nova Scotia, Newfoundland and Labrador, Prince Edward Island, and Ontario offered Gardasil on a voluntary basis with parental consent as part of school-

40 *Supra* note 1 at 51; *supra* note 38.

41 Andre Lalonde, "Cost-Benefit Analysis of HPV Vaccination" (2007) 29:8 Journal of Obstetrics and Gynaecology Canada S43 at S48. See also Patented Medicines Prices Review Board, "Report on New Patented Drugs – Gardasil," online: Patented Medicines Prices Review Board <<http://www.pmr-b-cepmb.gc.ca/english/view.asp?x=924&mp=572&pf=1>>. The introductory price of Gardasil is listed at approximately \$135 per dose with three doses required.

42 Abby Lippman *et al.*, "Human papillomavirus, vaccines and women's health: questions and cautions" (2007) 177 Canadian Medical Association Journal 484 at 485.

43 *Ibid.* at 486: "if and when evidence shows that an HPV vaccination program can be successfully implemented in Canada, it must be publicly funded. Lack of financial resources must not preclude any girl or woman from receiving what has been sanctioned by health officials."

44 James M. Flaherty, *The Budget Speech 2007: Aspire to a Stronger, Safer, Better Canada* (Ottawa: Department of Finance Canada, 2007) at 10.

based vaccination programs. The programs target girls in Grades 6, 7 or 8. British Columbia and Quebec are expected to begin school programs in 2008.

The Canadian strategy offers a number of advantages from a health equity perspective.

The strategy (with Merck's lead) re-characterizes and promotes the vaccine as a "cancer vaccine."⁴⁵ This re-characterization addresses two factors of vaccine acceptance: disease severity and perceived susceptibility.⁴⁶

Cancer relative to STIs is perceived as a more serious disease. In the Product Monograph for Gardasil, cervical cancer is described as a "serious and sometimes life threatening disease."⁴⁷ Provincial governments likewise emphasize the severity of cervical cancer in support of their vaccination programs. The Government of Newfoundland and Labrador, for example, describes the vaccine as "one of the first and most successful steps young women can take to prevent cervical cancer and we want them to have the best advantage to avoid this terrible disease."⁴⁸ The website of the Ontario Ministry of Health and Long Term Care reads, "Cervical cancer is a serious disease that affects far too many women in Ontario. The HPV vaccination will help protect your daughter from this terrible disease."⁴⁹

The focus on cervical cancer also affects perceived susceptibility. The GardasilTM Product Monograph describes cervical cancer as "start[ing] when a female catches certain types of HPV ... [y]ou or your child cannot get cancer of the cervix without first having an HPV infection."⁵⁰ It then proceeds to describe how "HPV is a common virus ... In the absence of vaccination, it is estimated that 75% of sexually active Canadians will catch Human Papillomavirus during their lifetime."⁵¹ The Product Monograph explains that "[w]hile most people clear the virus, those who don't can develop cervical cancer."⁵²

45 See e.g. *supra* note 39 at S24.

46 *Supra* note 1 at 51.

47 *Supra* note 34.

48 Health and Community Services, News Release, "Newfoundland and Labrador to Roll Out HPV Vaccination Program in September" (6 August 2007).

49 Ministry of Health and Long-Term Care, "About the HPV Vaccine," online: Ontario's Grade 8 HPV Vaccination Program, online:
<<http://www.hpvontario.ca/aboutonvaccine.html>>.

50 *Supra* note 34.

51 *Ibid.*

52 *Ibid.*

By emphasizing the high risk of HPV infection and the necessary link between HPV and cervical cancer, the Product Monograph intuitively builds a conflated perception of high risk for cervical cancer. It is interesting to note that the monograph describes those at risk for HPV, namely 75% of all sexually active Canadians, but not those at risk for cervical cancer. Like many cancers and unlike STIs, the development of cervical cancer is disassociated from personal fault or deviant sexual behaviour.

The strategy of framing Gardasil as a vaccine against a severe disease to which all women are susceptible provides the basis for universal school-based programs which by definition include the disadvantaged. On the website of the Ontario Ministry of Health and Long Term Care, it is explained that “[t]he HPV vaccination program is being implemented within First Nations communities in a manner consistent with the other publicly funded school-based vaccination programs ... All females in Grade 8 will be offered the HPV vaccine.”⁵³ School-based programs further remove the need for parents to expressly acknowledge the reasons for or to actively seek vaccination of their daughters, thereby diminishing access disparities on this basis.

The public funding of school-based programs also counters cost concerns. As reported in the *Ottawa Citizen*, with the announcement of its \$258 million contribution, the federal government stated: “This is an expensive vaccine and ... the whole purpose is to make it available to people across Canada, women and girls across Canada, regardless of their ability to pay.”⁵⁴

For these reasons, the Canadian vaccination strategy can be characterized as equity promoting.

E. Health Inequity: Of Continued Concern

As always, however, the solution itself proves problematic. In resolving one set of equity challenges, the Canadian strategy creates a new set. This section considers how school-based publicly-funded cancer vaccination programs may reduce rather than enhance health inequity, and how they may do so with more serious and lasting consequences.

Governments have not positioned vaccination programs as serving health equity or distributional goals. Rather than challenging ideological

⁵³ Ministry of Health and Long-Term Care, “FAQ,” online: Ontario’s Grade 8 HPV Vaccination Program <<http://www.hpvontario.ca/faq1.html>>.

⁵⁴ K. DeRosa, “Government announces cash for HPV vaccine” *The Ottawa Citizen* (17 April 2007) C5.

frameworks and existing definitions of public health priorities, governments have worked within existing efficiency rather than equity frameworks to gain public support. This may prove problematic on both ethical and efficiency grounds.

Women's health advocates have criticized the strategy of conflating HPV infection and cervical cancer – of creating the false perception of a cervical cancer epidemic – to secure public support for universal programs.⁵⁵ While a majority of women will be infected with HPV, the vast majority of infections will not develop into cervical cancer. Many of the young women who will receive the vaccination are at a low lifetime risk of developing cancer. This heterogeneity of risk renders the HPV vaccine different from other public health vaccines. In the Canadian context, modelling predicts that to avoid one case of cervical cancer will require the vaccination of 324 girls; to avoid one death from cervical cancer will require the vaccination of 729 girls – with life-long duration of vaccine protection.⁵⁶ These facts are reported to have affected parental perceptions of susceptibility. Parents may be unwilling to risk vaccination of uncertain immunity duration to prevent a disease unlikely to develop for decades and which may largely be protected against with screening, early detection and treatment. Less than half of Ontario parents consented to their daughters' vaccination in the first year of the province's program.⁵⁷

The following ethical questions are thus presented: Is it ethical to build a school-based vaccination program on the false perception of a public health crisis? Is it ethical if necessary and intended to ensure access for disadvantaged population groups?

The focus on cervical cancer also proves ethically problematic from a gender equity perspective. Locating the responsibility for sexual health in young women reinforces gender stereotypes. While cervical cancer is a sex-specific disease, the prevalence rate of HPV infection, the necessary cause of

55 *Supra* note 42 at 484: "There is no epidemic of cervical cancer in Canada to warrant the sense of urgency for a vaccination program initiated by the federal finance minister's announcement." See also Roberta Avery, "Risk of cervical cancer distorted, causes alarm" *The Toronto Star* (27 September 2007).

56 Marc Brisson *et al.*, "Estimating the number needed to vaccinate to prevent diseases and death related to human papillomavirus infection" (2007) 177 *Canadian Medical Association Journal* 464 at 466.

57 Judy Gerstel, "Perspectives on the HPV Vaccine" *The Toronto Star* (10 January 2008).

cervical cancer, is similar in men and women. There is a high rate of transmission of HPV in female partners of men with pre-existing penile warts, and HPV infection in men has been shown to contribute to HPV infection and subsequent cervical disease in women.⁵⁸ Vaccinating males could thus provide indirect health benefits for women, but also offer important protection against other cancers, precancerous lesions and genital warts, which affect both women and men. While the characterization of the HPV vaccine as a cancer rather than STI vaccine may serve important health equity goals, it risks reinforcing a gender stereotype that women should take sole responsibility for sexual health.⁵⁹ Australia, Mexico, and the European Union have all approved the use of the vaccine for use in males.

The Canadian vaccination strategy also raises concerns of inefficiency. The heterogeneity of risk for cervical cancer, and thus the vaccination of women at minimal risk and with negligible need, suggests that targeted implementation may be more efficient. Such is the dilemma of targeted programs: the risk of stigmatization versus the commitment of public funds to those with the greatest need.⁶⁰ In universal programs, public funding for cervical cancer prevention will be wasted on populations well protected by screening programs.⁶¹ Attributable additional lives saved will be few. Moreover, given that no provincial program is truly universal, these resources could be redeployed to disadvantaged populations with the real capacity to benefit. The program is thus not only wasteful, but inequitable: the vaccine benefits accrue to the advantaged at the expense of the disadvantaged.

Interestingly, these ethical and efficiency concerns are often countered by returning to an STI characterization of the vaccine. Women with minimal risk of developing cervical cancer nevertheless receive significant benefits

58 Anna R. Giuliano, "Human papillomavirus vaccination in males" (2007) 107 *Gynecologic Oncology* S24 at S26.

59 Inmaculada De Melo-Martín, "The Promise of the Human Papillomavirus Vaccine Does Not Confer Immunity Against Ethical Reflection" (2006) 11 *The Oncologist* 393 at 395.

60 Bernard Lo, "Human papillomavirus vaccination programmes" (2007) 335 *BMJ* 357 at 357.

61 *Supra* note 42 at 486: "We must be certain that spending an estimated \$2 billion to vaccinate a population of girls and women in Canada who are already mostly well protected by their own immune systems, safer sex practices and existing screening programs will not perpetuate the existing gaps in care and leave the actual rate of deaths from cervical cancer unchanged."

from the vaccine: they avoid the stigma of a STI, the pain and discomfort of genital warts, and the distress and invasive procedures associated with abnormal screening results and treatment. This re-characterization carries, however, significant risk. The shift from a cancer to a STI vaccine risks jeopardizing the very rationale for – and the associated health equity benefits of – a universal vaccination program.

A further counter-argument addressing efficiency concerns requires that an analysis account for public spending and savings of system-wide changes. Simply adding vaccination to existing screening programs may not be an efficient use of resources, but this is not the strategy. Research suggests that unless screening programs are modified, the immunization costs will strongly outweigh the health care resources, including treatment costs, saved through vaccination.⁶²

The National Advisory Committee on Immunization advises, for example, that “[a]s more females receive the vaccine the screening programs may be modified in either type and/or frequency of screening. This is an area requiring careful research and surveillance before guidelines can change.”⁶³ Careful research and surveillance is required because screening program modifications carry the greatest risk of adverse health equity effects.⁶⁴ Diversion from screening to vaccination may not only fail to reduce, but may enhance health inequity.

The vaccine is not a substitute for routine screening. It protects against infection with two high risk HPV types responsible for 70% of cervical cancer. The National Advisory Committee on Immunization thus advises that “women should still expect to take part in the currently recommended

62 Marc Brisson *et al.*, “The potential cost-effectiveness of prophylactic human papillomavirus vaccines in Canada” (2007) 25 Vaccine 5399 at 5406. See also Sue Goldie, “A public health approach to cervical cancer control: Considerations of screening and vaccination strategies” (2006) 94 International Journal of Gynecology and Obstetrics S95.

63 *Supra* note 14 at 24.

64 It is worthwhile to note that the Ontario Ministry of Health and Long-Term Care addresses screening program concerns on its HPV information website. “Maintaining and strengthening Ontario’s cervical cancer screening program continues to be a priority. Introducing the HPV vaccination program is in no way an indication of any intention to relax cervical cancer screening in Ontario.” *Supra* note 53.

cervical cancer screening programs.”⁶⁵ A shift in focus from screening to vaccination may leave disadvantaged women with greater risk of developing cervical cancer from remaining high risk HPV types. Screening also remains critically important for women already exposed to HPV or who do not receive the vaccine. Women who immigrate to Canada, for example, cannot benefit from school-based vaccination. Those who cannot privately afford the vaccine remain dependent on screening programs. The danger to be avoided is the neglect of successful screening programs for the promised but unrealized potential of universal vaccination. With a focus on primary prevention, governments may be even less inclined – the political will for cervical cancer exhausted – to implement repeated recommendations of expert groups for nationwide comprehensive organized screening to reach disadvantaged women.⁶⁶

More problematically, the shift from screening to vaccination represents a shift from the health system to disease-control interventions. A school-based vaccination program can be implemented as a vertical program without any spillover effects on health system structures that remain profoundly inequitable. This is unlike investment in screening, an often integrated component of comprehensive reproductive and sexual health care.⁶⁷ System level change could improve young women’s access to comprehensive sexual health education, information and services.⁶⁸ Linking the HPV vaccine with other sexual health interventions, including family planning and other STI prevention, may be an important opportunity to improve broader sexual health and well-being.

A focus on vaccine programs, without consideration of the systemic inequality in the health system, diverts attention away from government responsibility for existing health disparity. Women who die of cervical cancer in Canada are disadvantaged women ill-served by the current health system. A policy focused on a disease-specific technological innovation neglects the complex and enduring problem of system-wide health inequity.

65 *Supra* note 14 at 24.

66 *Supra* note 27.

67 Canadian Women’s Health Network, *HPV, Vaccines, and Gender: Policy Considerations* (Winnipeg: Canadian Women’s Health Network, 2007).

68 A.E. Pollack *et al.*, “Ensuring access to HPV vaccines through integrated services: a reproductive health perspective” (2007) 85 *Bulletin of the World Health Organization* 57 at 59.

Conclusion

Examination of the relationship between technological innovation and health inequity returns in conclusion to government responsibility. It is undisputed that the HPV vaccine is a most welcome innovation in women's health. Precisely for this reason, the Canadian strategy must ensure the vaccine's availability among disadvantaged population groups with the greatest need and thus capacity to benefit. The value of health equity must play an important role in government accountability. This is true both in setting the direction of health policy and in ongoing surveillance to ensure that health inequities are reduced rather than enhanced over time.

