lowing myocardial infarction was firmly established, like the causal association of oncogenic HPV strains, high-grade lesions and cervical cancer. Moreover, certain antiarrhythmic drugs were shown to suppress this ventricular ectopy, much as the HPV vaccine has been shown to decrease the risk for high-grade cervical lesions. However, later randomized trials showed that these antiarrhythmic drugs were associated not with an improved survival rate, but rather with a worsening one. These points would appear to reinforce the sagacious message of the commentary by Abby Lippman and colleagues that careful evaluation of the evidence, much still lacking, is required before intelligent decisions regarding public policy can be made.[2]

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The debate surrounding the HPV vaccine[1] might be characterized by 2 slogans: "Just do it" versus "What's the hurry?" The HPV vaccination program's supporters see any potential reductions in cervical cancer deaths as sufficient justification for starting the program immediately. Others point to unanswered questions about the real-world costs and the effectiveness and safety of a vaccination campaign, and they caution that we need to wait for better data.

There is a natural quasi-experiment on which Canada can capitalize, with 4 provinces (Ontario, Nova Scotia, Prince Edward Island, and Newfoundland and Labradour) serving as the early intervention group and the remaining provinces and territories as the delayed control group. As health authorities across the country set up patient registries to systematically track and monitor the results of their HPV vaccination programs, we can start to answer vital real-world questions about the uptake of vaccination programs, the rates and severity of adverse effects and the impacts of the new vaccination initiatives on rates of Pap smear screening. Jurisdictions in the delayed control group can use the lessons learned by the early intervention group to refine their programs before they are launched, and we will be able to compare the experiences of the 2 groups on a number of factors.

Using controlled delays to evaluate the effectiveness of health programs is not new. In 1946, when faced with a dire shortage of streptomycin and a large number of patients with tuberculosis, British authorities randomly assigned patients to early or delayed intervention groups.[2] The drug shortage coupled with the scientific uncertainty about the overall benefits and risks of streptomycin, created an experimental situation and thus produced vital information to optimize treatment.

Implementing HPV vaccination programs at different times in Canada may not be the ideal "organized implementation infrastructure"[3] for which some in the oncology community have called, but why not let pragmatism rule the day? We can learn from the experience of early adopters and gather and analyze new real-world data on the vaccination programs as they become available. For any rigorous evaluation program to be successful, health planners must coordinate their activities and set up the right data systems to capitalize on Canada's natural quasi-experiment.

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The commentary by Abby Lippman and colleagues on the planned vaccination of Canadian girls aged 9–13 years with the HPV vaccine raises "questions and cautions"[1] for physicians, parents and citizens of Canada. As a physician who trained in the late 1970s with gynecologic-oncologist Hugh Allen, I have witnessed both the devastating effects of advanced cervical carcinoma[2] and the dramatic reduction in the incidence of this disease with Pap smear screening.[3] As a parent, I would worry that if I had a daughter aged 9–13 years (I have sons) she could not give informed consent to HPV vaccination by herself.[4] Predicated on my expectation that she could be educated about the importance of Pap smear screening and safe sexual practices and would comply at least with Pap smear screening, I would advise her that HPV vaccination was not necessarily in her best interest. As a citizen, I believe that funding for women's health promotion should be directed to improving educational initiatives about Pap smear screening and safe sexual practices and to starting a public education campaign concerning the largely preventable breast and ovarian cancers related to the *BRCA* gene mutations,[5] which are much more common killers of women than cervical cancer.

As a physician, parent and citizen, I support vaccination for herd immunity;[6] however, my obligation to my daughter would supersede my obligation to others. When one of my patients asks, "What would you do if I (or my daughter) was your daughter?" I usually respond, "But you are not my daughter (or wife or sister)." In this case, however, I would respond, "I would be uncomfortable with you being vaccinated against HPV at this time."

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[Three of the authors respond:]

We wrote our commentary[1] hoping to initiate a broader discussion about how limited public resources are allocated, about the kinds of questions and concerns that might be addressed before programs are initiated and about the place of HPV vaccinations in an overall cervical cancer prevention policy that is already having success in Canada through the use of Pap smear testing. We maintain this focus here.

We thank James Mansi for responding for Merck Frosst but note that he does not actually address our concerns directly. We acknowledge the points he has raised; however, even adding the 3 components Mansi includes in the "new standard of care" (proper education, continued Pap smear testing and post-vaccination surveillance) will still leave a vaccination program insufficient. We also need — at the least — much improved cervical cancer screening programs and vaccine registries, as well as better knowledge of the prevalence of HPV strains and of the duration of protection before we consider mass vaccination programs. Moreover, we must determine whether and how vaccinating girls and women (who are already mostly well protected by their own immune systems, safer sex practices and existing screening programs) would actually change the inequitable death rates from cervical cancer in Canada.

That Eduardo Franco and colleagues would consider our cautionary position "irrelevant and untenable" is most puzzling. We are pleased to see that James Brophy, by contrast, finds it "sagacious." The precautionary principle is one that many people apply in assessing public health programs (see www.sehn.org/precaution.html for a discussion of this principle). Furthermore, we clearly stated that HPV was a necessary — but not sufficient — cause of cervical cancer; what, then, is the purpose of Franco and colleagues' example of smoking and lung cancer?

More importantly perhaps, we never questioned the selection of young women aged 15–25 years for participation in studies of the vaccine's efficacy, nor did we question the facts that immune responses in adolescents may be stronger than those in young adults and that vaccination is of maximal benefit when used for pre-exposure prophylaxis. We did ask, however, if 5 years of trials provided enough information to proceed with a mass vaccination program given that the vaccine's effectiveness rates are just starting to be known. (In response to Alex Ferenczy, we point out that our comment about the trials available for review was based on data presented by Lisa Rambout and colleagues:[2] only 3 of the 6 studies meeting their inclusion criteria for systematic review were of the quadrivalent vaccine. This would seem to be a "handful.")

Nevertheless, and notwithstanding the "utmost scientific rigour" of the randomized controlled trials (although Brophy has raised some interesting issues about this), about half of the 50 000 girls and women in the vaccine trials participated in studies of the bivalent HPV vaccine, Cervaris, which we did not discuss in our commentary. As well, the published report of the study by Reisinger and colleagues describes the experiences with Gardasil of only a limited number of girls aged 9–15 years (617 in the vaccinated group, 322 in the control group), which is the main age range for immunization in Canada, and provides data only on immunogenicity and short-term safety, not on efficacy.[3] Thus, conflating all of the girls and women who were studied with this very small group of particular interest is inappropriate.

Alan Cassels repeats, while most others ignore, the basic question our commentary raised for discussion: Why begin mass vaccinations now? Where is the evidence base for this important public health decision? The letter writers who confuse the issue of epidemics with details of the ways in which women with cervical cancer suffer deflect this question. They also perhaps ignore the current gaps in care that may explain why many women ultimately diagnosed with invasive cervical cancer did not have a Pap smear test when it was due despite having received care from physicians in the previous 5 years (Ms. Kathleen Decker, CancerCare Manitoba: personal communication, 2007).

Women, and men, suffer in myriad ways, and public health policies need to focus on where best to allocate finite resources, not only on an individual level but also with regard to population needs. This means that cost-effectiveness and lost opportunity costs are usually taken into account. As Schiffman has pointed out in the US context, "It is worth debating ... whether immediate, universal coverage is a greater public health priority ... than other needs ... competing for the same resources."[4] We need to have this debate in Canada. In addition, with regard to Jeff Nisker's distinction between individual decisions about the use of the vaccine and public policies about a program of vaccinations, we need to emphasize that both personal and population health care must always be based on the primary principle of "do no harm."

Wynia recently wrote that "this vaccine still faces plenty of questions."[5] We hope readers will continue to discuss these questions and the place of HPV vaccination in a broad sexual and reproductive health perspective and to accept alternative viewpoints generously and in reasoned fashion, even ones that question supposedly "established" wisdom.

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