Do you approve of spending $300 million on HPV vaccination?

NO

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Women in North America most at risk of developing and dying from invasive cervical cancer are those for whom Papanicolaou testing has "failed"[1]: either they were not tested within the recommended time frame or they did not have follow-up and appropriate interventions. Although women in this situation are often already marginalized by poverty and lack access to primary care, many who do enter the health system remain inexplicably untested.[2] This raises the question: will vaccination itself make a substantial difference in the lives of the women in Canada most likely to develop and die from invasive cervical cancer? Current evidence creates serious doubts.

Adding value?

As with all new technologies, new vaccines need to be evaluated to determine whether using them will improve upon what is already available and, if so, at what cost.[3] Many provinces currently lack linked cancer and screening registries or well-developed organized screening programs; follow-up on abnormal Pap smear results is erratic; and outreach programs struggle for funding. It is legitimate, then, to question the rushed introduction of school-based vaccination programs before appropriate evaluation of what vaccinations would contribute to existing programs that are themselves in need of resources and support. It is also unfortunate that programs were introduced in an atmosphere of confusion and misunderstanding that arose from vast pharmaceutical advertising and marketing campaigns creating "fear [of cancer] and cheer [about the vaccine]."[4] These erroneous "end cervical cancer" promotions eclipsed public education about issues such as the actual low prevalence of oncogenic strains of human papillomavirus (HPV), the very high rate of spontaneous clearance of infections, and the slow progression of infections.

Data to support public health agencies and individuals in making reasoned decisions about immunizations are limited. The published trial of Gardasil focusing on young girls ages 9-15, the group targeted specifically for school-based immunizations in Canada, reported only on short-term immunogenicity and safety, not efficacy.[5]

Broader context

Immunization is not the only approach to preventing cervical cancer in Canada; secondary prevention through Pap testing has already reduced mortality.[6] There is, moreover, added value associated with health care visits for Pap testing. For many women, these visits provide opportunities for counseling about contraception and preconception, screening for sexually transmitted infections, health assessments, and health promotion with regard to smoking and nutrition.

Certainly, the costs (financial and other, private and public) of Pap testing and programs for its delivery, of subsequent interventions for those with true- and false-positive test results, and of the personal effects of invasive cervical cancer warrant attention. But we cannot overlook how cervical cancer screening—and vaccination—occur within a broad reproductive and general health care context that often does not serve women well. Consequently, any renewed attention to cervical cancer as a "preventable disease" will remain problematic as long as discussions of prevention narrow to an artificial debate between those apparently "for" and those accused of being "against" a vaccine. We need to consider vaccinations not in isolation, but as part of an overall reproductive and sexual health strategy within which reduction in the already relatively low frequency of substantial morbidity and mortality from cervical cancer (compared with other cancers affecting women throughout life) is but one objective.

Simply adding vaccinations to current practices for reducing the burden of cervical cancer can have net costs in the millions of dollars for many years to come.[7] Yet there has been no public debate about whether vaccination as an add-on is the best use of resources in light of

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The parties in this debate will have the opportunity to refute each other's arguments in Rebuttals to be published in an upcoming issue.

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possible alternatives needing funding (eg, enhanced and improved Pap smear screening to capture women now missed; further developing other approaches, including direct HPV testing[8] and liquid-based cytology; establishing registries to monitor Pap testing programs and to record rare side effects to the vaccine; and tracking those who, if vaccinated, might need booster shots in the future).

The high projected costs of vaccination programs suggest that their benefits—and cost-effectiveness—will be most unlikely to be realized in countries such as Canada unless there are substantial changes to existing screening and treatment programs.[7,9] But we must be cautious about simply replacing ongoing activities to offset the cost of immunizations and first obtain all the evidence needed for policy making, including evidence on potential lost opportunity costs: what works now, even if it is in need of improvement, must not be inappropriately sacrificed. As well, we need to be cautious so that hastily introduced mass vaccinations do not lead to iatrogenic effects that might occur if, for example, those vaccinated have a false sense of security about their chances of developing cancer and thereby become less vigilant in getting Pap tests and using measures to reduce their risk of sexually transmitted infections.[10]

Cautious approach

Given the many unknowns and unplanned-for matters already highlighted by others,[11,12] we continue to advocate a cautious public health approach to mass immunization programs, an approach that avoids the rush to vaccinate girls and that is, instead, based on solid evidence that immunization will actually be able to attain the goals those promoting it have described and that girls' and women's overall sexual and reproductive health needs will be met. This approach will require consideration of the health services available, of the educational needs of the target population, of the data on cost-effectiveness, and of the lost opportunity costs in setting public health policy for a nonepidemic condition for which there are (changing) secondary prevention measures.

We are not against the vaccine, and we are dedicated to promoting women's health. We firmly believe that prevention is always better than treatment. But prevention must be done with full consideration of all of its components. At this time, it remains difficult to justify spending $300 million on a rushed vaccination-only program when funds to build up the necessary public health infrastructure have yet to be provided, and many pertinent questions that could readily be addressed remain unanswered. We have the time to proceed cautiously, and we should.

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Competing interests

None declared

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CLOSING ARGUMENTS

- Before launching a population-based HPV vaccination program, we need to know more about the prevalence of and risk of exposure to oncogenic HPV, as well as the real-world effectiveness of the vaccine.
- The goals of the vaccination program should be clarified to permit development of the most appropriate and sustainable immunization policies.
- New resources should go to improve programs coordinating innovative outreach and follow-up for cervical cancer screening, including a public education campaign.