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'Long-term questions' ignored in rush to give HPV shots: critics

Doctors set to endorse vaccine for little girls

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The group representing Canada's 2,500 pediatricians and other specialists who care for children is set to endorse having little girls vaccinated against the sexually transmitted virus that causes cervical cancer.

But in the rush to inoculate, some critics say important questions have been ignored, such as how effective is the vaccine in the youngest girls and how long will immunity last?

The vaccine against human papillomavirus, or HPV, has been called a milestone in public health. But the only vaccine now approved in Canada -- Merck Frosst's Gardasil -- has been tested on fewer than 1,200 girls aged nine to 15. GlaxoSmithKline is also testing an HPV vaccine.

So far, Merck has data showing the vaccine is effective for five years in girls and women aged 16 and older.

"If we immunize nine-year-old girls and the protection conferred by the vaccine lasts approximately 10 years, that will mean that we will have a susceptible population of 19-year-old women, a cohort that demonstrates the highest rate of HPV infection," says Ryan Melnychuk a molecular virologist, ethicist and fellow in Dalhousie University's department of bioethics.

"How do you reach that population for a booster? If you cannot reach that population for boosters, your program will probably not be that successful. These questions must be considered now," he said in an e-mail. "Long-term questions -- duration of protection, efficacy, safety, etcetera -- appear to have been ignored in this recommendation."

The federal government has pledged \$300 million for HPV vaccine funding. But the National Advisory Committee on Immunization (NACI) recommendation in February that all girls and women aged nine to 26

be routinely vaccinated "would mean vaccinating over five million females, at a cost of \$2 billion for the vaccine alone," according to a recent article in the Canadian Medical Association Journal. Given in three shots over six months, Gardasil costs about \$405.

The Canadian Paediatric Society is reviewing the NACI recommendations. "We expect to be endorsing them shortly," said Dr. Robert Bortolussi, chairman of the

society's infectious disease and immunization committee.

"The vaccine promises to be highly, highly effective at preventing cervical cancer. That's one milestone in health care, to be able to eliminate a cancer by way of a vaccine."

Gynecologists say the most frequent question they hear now is, where can I get the shot? About 14,300 doses of Gardasil were dispensed by retail drugstores in Canada in the first two months of this year, compared to 9,552 prescriptions in the first five months the vaccine was available last year, according to IMS Health Canada.

"What's the rush on this one? This is not a public-health emergency," says Abby Lipman, a professor of epidemiology at McGill University and chair of the Canadian Women's Health Network.

"We have no idea how long the protection would last, we don't know if boosters are needed, we don't have any indication to suggest that the same people who are at risk of cervical cancer now because of system failures (in Pap screening) will actually get vaccinated."

"My cynical side says this looks like a fast and very headline-grabbing way (for the Harper government) to say they're paying attention to women's health. This is not a high issue on women's health agendas."

An estimated 1,400 women are diagnosed with cervical cancer in Canada each year, and about 400 will die from the disease. More than 90 per cent of cervical papillomavirus infections go away on their own. Cancer develops in a minority of women, and the disease today is rarely fatal in Canada.

Whether to inoculate "is a no-brainer," says Dr. Michael Shier, chief of gynecology and director of the colposcopy unit at Toronto's Sunnybrook Health Sciences Centre. Dr. Shier, a leading Canadian investigator in both Merck and GlaxoSmithKline's HPV vaccines, says there is no more awful way to die than from cervical cancer. "Women usually die in extreme pain because these cancers metastasize throughout the body."

Dr. Shier says the time to vaccinate is before girls become sexually active, and that the safety data for Gardasil "shows that it is unbelievably safe."

He says Merck and GlaxoSmithKline's HPV vaccines are the most studied vaccines in the history of medicine, "with huge numbers of people being vaccinated and scrutinized like never before." Gardasil was tested in more than 20,500 women aged 16 to 26. The most common side-effects are pain and swelling at the injection site, fever, nausea, dizziness, vomiting and fainting.

But side-effects not seen in clinical trials may emerge only once the vaccine is used more widely, researchers caution.

Doctors say the vaccine will help to ease not just the burden of cervical cancer, but the expense and anxiety that come with an abnormal Pap smear.

More than five million Pap tests are performed each year in Canada and about eight per cent, or 400,000, are abnormal.

But a leading U.S. researcher says there is no magic age at which to vaccinate.

In the U.S., up to 10 per cent of 11- and 12-year-olds will have HPV 16 and 18 infections. "Nine-year-olds will be smaller, but there will still be some at nine who will have infections," says Dr. Diane Harper, a physician and scientist at Dartmouth Medical Center who led some of the largest international trials of Gardasil.

HPV is contracted not just through sexual intercourse, but also through skin-to-skin contact. "That can be genital-to-genital, genital-to-finger, genital-to-mouth - which as parents we don't want to think about," Dr. Harper says.

But, "it's not like it's an airborne flu, where you have to vaccinate everybody who is going to be in contact with everyone else," says Dr. Harper.

"It really is one where you have a wide range, and it doesn't make a lot of sense to mandate that everybody has to have it at one particular age, because you don't know."

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