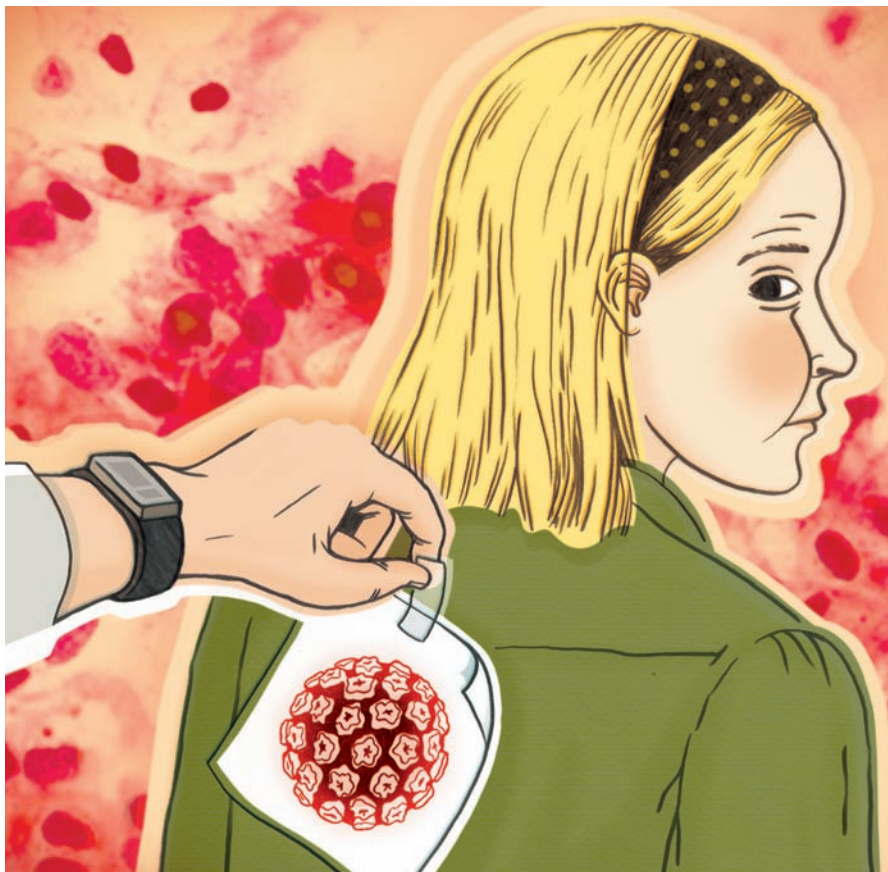


HEALTH > LOCAL ADVANCEMENTS IN STAYING WELL



# COST CAUSE

The HPV vaccine protects against cancer—but its high price may limit availability **BY SALLY JAMES**

**WHEN A NEW VACCINE** protecting against cervical cancer was approved by the Food and Drug Administration (FDA) last June, it was hailed as a breakthrough by health officials here and around the country. Among those most pleased with the approval was Seattle scientist Laura Koutsky, Ph.D., and others from Harborview and the University of Washington who helped design and carry out the exhaustive tests, involving thousands of women, required to bring the new vaccine, Gardasil, to the FDA.

Gardasil offers protection against four strains of the sexually transmitted human papillomavirus (HPV)—two of which cause about 70 percent of cervical cancer cases. (HPV is the most common sexually transmitted infection in the United States,

and at least 50 percent of sexually active men and women acquire genital HPV infection at some point in their lives.) Many Seattle women were the guinea pigs for the research that proved its effectiveness.

While enthusiasm for the vaccine hasn't dimmed, months after its approval Gardasil is snarled within state, federal and insurance reimbursement knots. It is available only to a limited population, and its high cost is one reason.

"Because of the price, I am concerned that some lower-income young women may have a delay in getting it," Koutsky comments.

Public health veteran Jeff Duchin, M.D., Chief of Communicable Disease Control for

Public Health—Seattle & King County, calls the public process for getting vaccines to consumers "embarrassing," both because of the time it takes and the distribution method, which results in some consumers receiving it sooner than others.

Vaccinations used to be cheap public health measures, often completed before a child entered public school. But Gardasil joins a new slate of vaccines, including vaccines to prevent pneumonia and meningitis, which are far more expensive and aimed at a different age group.

Gardasil, from the New Jersey-based pharmaceutical company Merck, is given in three doses and has a base cost of about \$360. Consumers pay more than that, because their own doctor or clinic will add a charge for the three office visits required to administer the vaccine. At the University of Washington's student health center, the total charge is \$525. Last summer, the National Centers for Disease Control approved Gardasil for all females ages 9 to 26 and has recommended routine immunization for girls ages 11 and 12.

Because the four viruses the vaccine protects against—as well as two others that

## COST OF VACCINES

	PUBLIC PURCHASE	PRIVATE PURCHASE
POLIO	\$10.82	\$22.80
MENINGOCOCCUS	\$68	\$82
HPV	N/A	\$360

Note: Many vaccines are part of the state's universal vaccine program. These are available at no cost to qualified recipients. The federal Vaccines For Children program sets the public purchase cost of vaccines; the private purchase is the charge for vaccines to practitioners who do not participate in the VFC. Both public and private practitioners may add a charge for an office visit and administrative costs.

## BUSINESS AND MARITIME LITIGATION, 45 YEARS STRONG.

Our experience in business litigation provides our attorneys with the edge in transactional, anti-trust, tax, securities, insurance, real estate and estate planning. Our respected immigration team serves individuals and businesses worldwide. You'll also find expert environmental and family law practices.

Visit our Web site at [Mikkelborg.com](http://Mikkelborg.com) and find out who we really are.

**MIKKELBORG**  
BROZ | WELLS | FRYER PLLC  
ATTORNEYS AT LAW

1001 FOURTH AVENUE SUITE 3600  
SEATTLE WA 98154  
206-623-5890  
email: [mail@mikkelborg.com](mailto:mail@mikkelborg.com)  
[www.mikkelborg.com](http://www.mikkelborg.com)



## HEALTH > LOCAL ADVANCEMENTS IN STAYING WELL

cause genital warts—are sexually transmitted, a patient's sexual history, or lack of one, becomes a crucial part of the decision about whether or not to get the vaccine. The Henry J. Kaiser Family Foundation reports the age of first intercourse is about 17 for American girls. Young women who are in their 20s and have been sexually active can still benefit—which is why the CDC recommends vaccination up to age 26. Few women, even if they are sexually active, are infected with all four of the virus types in the vaccine, so a woman will receive benefit from the vaccine if it protects her against even a single virus.

No one can predict just how patients and their doctors will parse the price of the vaccine against the potential benefit to each individual.

During this session, the state legislature is expected to take up the issue of paying for this vaccine for all Washington girls up to age 19. Washington is one of only a handful of states that pay for most required childhood vaccines, once they are included on what is called the "universal" list. The Department of Health has estimated it will cost \$6.5 million from the state's general fund, as well as money from a federal program, to provide this vaccine in the first year. If approved by the legislature, the money should begin to flow this summer.

State Rep. Shay Schual-Berke is a physician and a member of the House health care committee. She says it is too early for her to know how she will vote if the governor's final budget includes the request for HPV vaccine money.

"The policy question here is why HPV instead of something else for the next dollar," she explains. She is hoping that forecasters can provide data on how much the state will save in future medical costs if all female children are immunized. "For example, how do I decide about buying HPV or buying a proven high-school dropout prevention program for kids of color?" she asks.

While some observers in the public health community expect legislative approval, they also caution that the growing expense of vaccines, and their teen and adult target ages, raises new public policy questions of how vaccines should be financed.

Affordability has become a personal issue—at least temporarily—for 20-something women who face the dilemma of whether or not to pony up nearly \$500 or

wait until insurance companies cover the vaccine. While they wait, if they are sexually active, they could be exposed to these viruses.

Some women paid cash last fall for themselves or their daughters, according to doctors and clinics who were offering the shots. Three of the largest health insurance companies in our state, Regence, Premera and Group Health Cooperative, all announced by October that they would cover the vaccine immediately. However, as consumers often find out, the individual fine print of specific plans offered by employers may or may not cover preventive care such as vaccination.

For that reason, it is likely that thousands of Washington women still won't be able to get reimbursement for the shots.

Women struggling to make ends meet could not get the vaccine at the county's public health clinics right away, but Duchin says his agency hopes it will be available by spring or summer through the state's universal vaccine program. Merck has a mechanism to get Gardasil to those who cannot afford it, but only through private physicians who are willing to buy the vaccine themselves and then seek product replacement afterward.

"There is always an uncomfortable delay between vaccines being recommended and actually being available," Duchin notes.

**FOR SCIENTIST KOUTSKY**, the path toward a vaccine began when she started studying the human papillomavirus family as part of her graduate work at the University of Washington. She received a doctorate in epidemiology and published some research on what she calls the "early events" that happen to a woman's cervix after HPV infection.

Kathrin Jansen, Ph.D., a Merck scientist at the time, heard Koutsky's presentation about the viruses at a scientific conference. The two women hit it off, and when Merck was ready to begin developing a vaccine in 1994, it was Koutsky they asked to head the clinical trials.

As Koutsky explains, it was her own research on who gets HPV and how the disease progresses in the target age group that Merck wanted to use to help their scientists design and develop their vaccine program. Using Koutsky's data, they could then jointly decide exactly how to develop clinical trials that would be definitive. The collaboration



of Koutsky and Jansen earned them a “Chutzpah” award from television’s Oprah for helping women around the world.

In 2002, Koutsky was the lead author on the seminal paper in *The New England Journal of Medicine* that proved the concept of the vaccine. One more phase, clinical trials, had to be concluded—with more than 12,000 women participating around the world—before Merck won FDA approval. Competitor GlaxoSmithKline has a competing vaccine, Cervarix, that may win FDA approval this year.

Women will still need PAP tests for cervical cancer screening even if they get these vaccines, and Koutsky’s latest research target is to develop improved and more accurate screening tests.

While researchers move on to different targets, and Gardasil makes its slow progress through state and federal budgets, patients and doctors still have to make decisions about the vaccine. Seattle gynecologist Robin Cole, M.D., says she will recommend the vaccine to her own teen daughter. Another Seattle mother, Mari Stobbe, is a survivor of cervical cancer. She welcomes the vaccine for her four daughters, ages 20, 18, 12 and 9.

Because the vaccine is most beneficial if given before a patient begins sexual activity, or when she has had limited activity, sex has become part of the Gardasil discussion. In some parts of the country, social conservatives have argued against routine use of the vaccine, suggesting that it will encourage early sexual activity.

Others object to the notion that children need protection against a sexually transmitted disease. And cultural attitudes about sexuality are likely to complicate the vaccine’s introduction worldwide, where an estimated 250,000 women die of cervical cancer every year. In the United States, because of the effective screening of PAP smears, most women do not die of cervical cancer.

Near Ballard, at the offices of the non-profit global health organization PATH, researchers are already working to try to smooth the introduction of the vaccine in four pilot countries: Vietnam, Uganda, India and Peru. They received a grant of about \$28 million from the Bill and Melinda Gates Foundation to help countries understand the potential for the vaccine and find practical ways of making it available. ⑤

AllSeattleCondos.com Seattle-RealEstate.com

The only two sites you need for Seattle Real Estate

The #1 Coldwell Banker Team in Seattle...Two years running!

THE REPPOND TEAM

(206)295-1771

COLDWELL BANKER BAIN ASSOCIATES

**Start the new year with a holistic approach to your family’s health care.**

Call 206-834-4100 today to make an appointment to see a health care provider at our beautiful new clinic.

Naturopathic Medicine • Nutrition  
Immune Wellness Clinic • Homeopathy  
Acupuncture and Oriental Medicine • Counseling

**BASTYR CENTER**  
FOR NATURAL HEALTH  
*the teaching clinic of Bastyr University*

3670 Stone Way N.  
Seattle, WA 98103  
[www.BastyrCenter.org](http://www.BastyrCenter.org)