

Vaccine brings hope, questions

FDA on verge of approving drug to protect against cervical cancer

By Rebecca Vesely, STAFF WRITER

Physicians on the front lines of treating cervical cancer are expressing elation that the Food and Drug Administration as early as next week could approve a vaccine shown to protect against the disease.

But they also said the benefits of the vaccine likely won't be seen for a decade or more, because it is most effective among young girls who are not sexually active. And they expressed concern the women and girls who need the vaccine most may not have access to it.

"It's a very important first step, and it will make a big difference in the fight against cervical cancer," said Dr. Linda Engelstad, director of the breast and cervical cancer control program at the Alameda County Medical Center. "How it plays out in public health and how to get it to the people who are the highest risk isn't clear yet."

On May 18, a federal advisory panel unanimously recommended that the FDA approve Gardasil, a vaccine developed by Merck that blocks four strains of the human papillomavirus, or HPV. The FDA is expected to approve the vaccine by Thursday.

HPV is the most common sexually transmitted disease in the country, infecting 20 million men and women. For most people, HPV goes away on its own, but for some women, HPV can lead to cervical, vaginal and vulvar cancers if it isn't caught and treated. About 15,000 women develop cervical cancer each year nationwide and 4,000 die from the disease. Worldwide, it is the second most common cause of cancer deaths in women.

In a 10-year clinical trial involving 27,000 patients, Gardasil was found to be 100 percent effective against two strains of HPV, which cause about 70 percent of cervical cancer cases. Gardasil was also effective in preventing HPV strains that result in most genital wart cases. The federal advisory panel deemed the vaccine safe and effective for women and girls ages 9 to 26.

Because the vaccine is most effective when given to girls before they are sexually active, physicians said a huge effort is needed to get the vaccine to those who can most benefit — girls ages 9 to 13.

"Most of these young girls haven't seen a gynecologist at this age," said Dr. John Chan, a gynecological oncologist at Stanford University and Lucile Packard Children's Hospital. "Pediatricians and family practitioners will have to be involved."

The vaccine is administered via three injections given over a period of six months. The cost is between \$300 and \$500, and it is unclear whether it will be covered by insurance companies or public health programs.

Dr. Adekemi Oguntala, an adolescent medicine physician at Children's Hospital and Research Center Oakland, said for most of the girls she treats, the vaccine would come too late.

"I see these girls six months to a year after they've started having sexual relations with people," Oguntala said. "When I do Pap smears, I end up telling them they have HPV."

The Pap test screens for malignant cells or cell changes, including precancerous cervical lesions, that might develop into cervical cancer, and is usually performed as part of a routine annual pelvic exam. Gardasil is not effective once a woman already has HPV.

Oguntala and other physicians said that even if the vaccine is approved and distributed within the next few months, as expected, they won't likely see the benefits of Gardasil for a decade or more. An untreated case of HPV typically takes 10 years to develop into cervical cancer. HPV is extremely contagious, and may not show up on a Pap test for two years.

Stigma still surrounds cervical cancer. Highland Hospital in Oakland holds cervical cancer screenings every Saturday, and detects about 40 to 50 cases per year, of which about 10 to 15 cases are invasive and untreatable, Engelstad said.

"We spend a lot of time educating women, some who are reluctant to come in and fear the tests will affect their fertility," she said. "Occasionally, women's husbands don't want them to come in for treatment."

The hospital's Pathfinders program has a team of volunteers who track down women who don't show up for cervical and breast cancer screenings. This can involve intensive legwork, going door to door and making phone calls to reach women who may not have a fixed address and are often uninsured, Engelstad said.

"This is one of the cancers with major health disparities and outcomes," she said. "This is the population that would most benefit from the vaccine."

The advisory committee on immunization practices at the Centers for Disease Control and Prevention is slated to discuss how Gardasil will be administered on June 29. The 15-member committee, which schedules the administration of vaccines in this country, could recommend guidelines for vaccination, including universal inoculation in girls of a certain age.

It will be up to states, however, to decide who should get the vaccine. The California Legislature would have to pass a law to mandate its use, said a spokeswoman for the state Department of Health Services.

Bay Area physicians said a public health campaign, with financial support for the state, will be necessary to offset the cost of the vaccine and show parents that their children can benefit.

The benefits of the vaccine are already evident, physicians agreed.

"What happens is it gets people talking," Oguntala said. "With teens, if you don't bring it up, they don't want to talk about it."