

Clinical trial shows first evidence that anal cancer is preventable

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A large, international clinical trial led by doctors at the University of California, San Francisco indicates that a vaccine to prevent anal cancer is safe and effective, according to a study reported in the Oct. 27, 2011 issue of *New England Journal of Medicine*.

Though [anal cancer](#) is less common than other forms of the disease in the United States, the number of cases has increased in recent years, and is particularly common among men who have sex with men and HIV-infected individuals.

Anal cancer is caused by infection with [human papilloma virus](#) (HPV), the most common sexually-transmitted pathogen in the United States. The virus also causes [cervical cancer](#) in women, and the vaccine is already approved and routinely recommended to prevent this condition. The new clinical trial suggests that the same vaccine would also protect men, and likely women, against anal cancer.

In the 1990's, UCSF established the Anal Neoplasia Clinic at the UCSF Helen Diller Family Comprehensive Cancer Center, the world's first clinic devoted to promoting research, awareness, screening and prevention of anal cancer. UCSF professor Joel Palefsky, MD, FRCPC, who founded and directs the clinic, led the clinical trial, and has recently founded a new professional society devoted to the study of the disease.

"Almost six thousand people every year in this country are diagnosed with anal cancer, and more than 700 people die from the disease," said

Palefsky. "What this trial showed is that those cancers and deaths could be prevented."

The trial involved a group of 602 men who have sex with men from Australia, Brazil, Canada, Croatia, Germany, Spain and the United States all of whom had at least one, but no more than five, sexual encounters and who were between the ages of 16-26 years. All were randomized into groups that either received a placebo or a three-shot injection of the vaccine [Gardasil](#), which protects against HPV 16 and 18, the most common HPV types involved in anal cancer, and HPV 6 and 11, the most common types in anogenital warts. The patients were enrolled in the trial from 2006-2008, and they were followed for three years after their last shot.

As described in the paper, the vaccine proved effective at reducing anal infections with HPV and precancerous lesions known as high-grade anal intraepithelial neoplasia, which are anal cancer precursors. The trial showed that the vaccine reduced the incidence of these cancer precursors by nearly 75 percent among those who had not been previously exposed to any of the HPV types in the vaccine. Among those who were previously exposed to one or more of the types in the vaccine, the vaccine reduced the incidence of the precancerous lesions by 54 percent.

"Based on these data, the vaccine works well to prevent HPV infection and precancerous anal disease, and will likely prevent anal cancer in men," said Palefsky. "The ideal time to begin vaccination would be before initiation of sexual activity, but vaccination may also be useful after initiation of sexual activity."

An earlier study led by Palefsky's coauthor Anna Giuliano at the H. Lee Moffitt Cancer Center and Research Institute in Tampa, FL showed that the HPV vaccine effectively protects both heterosexual men and men

who have sex with men against external genital warts. The new study adds to the body of evidence supporting routine HPV vaccination of young males, said Palefsky.

This week, a group known as the Advisory Committee on Immunization Practices (ACIP), which is convened by the Department of Health and Human Services and the Centers for Disease Control and Prevention, met in Washington, D.C. to consider how it recommends HPV vaccine for [men](#).

On Tuesday, the ACIP group voted to change their policy on the vaccine, which they previously "recommended," which means that it was approved and available to people if they want it. Individuals could order it, but it would have been up to insurance companies if they wanted to reimburse for the vaccine or not.

After weighing the clinical evidence, including the data presented in the [New England Journal of Medicine](#) paper this week, ACIP voted to make HPV vaccinations "routine" for boys up to the age of 21 years. This means the [vaccine](#) will be placed on routine schedule of vaccines and insurance companies will be obligated to cover it.

More information: The article, "HPV Vaccine against Anal HPV Infection and Anal Intraepithelial Neoplasia" by Joel M. Palefsky, Anna R. Giuliano, Stephen Goldstone, Edson D. Moreira, Jr., Carlos Aranda, Heiko Jessen, Richard Hillman, Daron Ferris, Francois Coutlee, Mark H. Stoler, J. Brooke Marshall, David Radley, Scott Vuocolo, Richard M. Haupt, Dalya Guris, and Elizabeth I.O. Garner appears in the Oct. 27, 2011 issue of the New England Journal of Medicine.

Provided by University of California, San Francisco

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