

# Study: HPV vaccines are safe and generate protective antibody levels in young cancer survivors

November 10 2021, by Matt Windsor

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Wendy Landier, Ph.D. Credit: Frank Couch

New research by investigators at the University of Alabama at Birmingham and Emory University is the first to report that the two

widely used vaccines against human papillomavirus, or HPV, are safe and generally well tolerated by cancer survivors. The researchers also found that the immunogenicity of the vaccines in cancer survivors was comparable to the general population. The study results were published Nov. 9 in *The Lancet Child & Adolescent Health*.

Survivors of childhood cancers are at increased risk of developing subsequent HPV-related cancers, in part because they can experience prolonged immunosuppression during and after active treatment. According to one [2013 study](#), female survivors of pediatric and young adult cancers have a 40 percent higher risk of subsequent HPV-related cancers compared with females in the general United States [population](#), while male [cancer](#) survivors have a 150 percent higher risk.

But the uptake of HPV vaccines among young cancer survivors is lower than that of the general population. According to [previous research](#) by the same investigators at UAB and Emory, the strongest predictor of HPV [vaccine](#) non-initiation in cancer survivors was lack of health care provider recommendation for the vaccine. Some vaccines do not generate as strong an immune response in individuals who have received cancer treatment, which could be one reason providers have been hesitant to strongly recommend HPV vaccination to patients who are cancer survivors. Another potential obstacle is the fact that HPV vaccination is not currently part of routine oncologic follow-up care.

The new study is the first phase 2 clinical trial to evaluate the safety and immunogenicity of the HPV vaccine in young cancer survivors. It enrolled 436 participants ages nine to 26 who were between one and five years post-cancer therapy. The study found that antibody responses against HPV types 16 and 18—the two primary causes of HPV-related subsequent cancers—were noninferior to comparable groups in the general population. The safety profile in participants was similar to the general population as well. The most common cancer represented among

participants was leukemia (47 percent), and 14 percent of participants had undergone hematopoietic cell transplantation.

"These findings support incorporation of the HPV vaccine into routine oncologic follow-up care for all young cancer survivors," said Wendy Landier, Ph.D., co-principal investigator of the study and first author of *The Lancet Child & Adolescent Health* article, who is a professor in the Division of Pediatric Hematology/Oncology in the UAB Marnix E. Heersink School of Medicine and the UAB School of Nursing. Landier is also deputy director of the UAB Institute for Cancer Outcomes and Survivorship.

"When a young cancer [survivor](#) faces the diagnosis of a subsequent cancer, this is devastating not only for the survivor, but also for their family and for the health care providers who worked so hard to treat the primary cancer," Landier said. "The ability to prevent subsequent HPV-related cancers is now within our grasp. Routine administration of this safe and effective cancer-prevention vaccine to childhood cancer survivors should substantially reduce their risk of developing HPV-related subsequent cancers."

Landier and article senior author James Klosky, Ph.D., of Emory University, who is also co-principal investigator for the clinical trial, are now at work on a National Cancer Institute-funded clinical trial of an intervention aimed at improving HPV vaccine uptake in childhood cancer survivors by focusing on pediatric oncology health care providers.

Landier and Klosky became interested in HPV vaccinations among young cancer survivors soon after the first quadrivalent HPV vaccine was approved by the U.S. Food and Drug Administration in 2006. "We both worked clinically with childhood cancer survivors, and we were excited about the possibility of a vaccine that could prevent HPV-related

cancers in this population," Landier said. "We also wondered whether these young cancer survivors would be able to mount an immunological response to the vaccine similar to that of their healthy peers in the general population. As we worked on our grant proposal, we became very aware of the low uptake of the HPV vaccine in the general population, compared to that of other vaccines, and we wanted to understand whether low HPV vaccination rates would also be a problem in young cancer survivors."

## **Study details**

The researchers received funding support to examine these questions from the National Cancer Institute, which led to the initiation of this clinical trial in 2012. The trial enrolled participants through June 2018, and the final follow-up occurred in July 2020. A noninferiority trial is designed to determine if serum antibody levels in trial participants are similar to or better than the antibody levels found in a comparable efficacy trial—in this case, the efficacy trials used for HPV vaccine licensure. Participants enrolled through March 1, 2016, received the quadrivalent, or HPV4, vaccine, which protects against four types of HPV. Subsequent participants received the nonavalent, or HPV9, vaccine, which protects against nine HPV types. Noninferiority criteria were met for each age/sex subgroup in the trial except against HPV type 18 in older females (ages 16–26) receiving the HPV9 vaccine. (The HPV4 vaccine is no longer used in the United States, but it is still authorized for use in some other countries, Landier says.)

One or more adverse effects were reported by 55 percent of participants: 51 percent of those receiving the HPV4 vaccine and 59 percent of those receiving HPV9. The most common adverse effect was injection site pain, although the proportion of cancer survivors reporting injection-related adverse effects (pain, swelling, redness) was significantly lower than the general population. The proportion of cancer survivors reporting

nausea and fatigue was significantly higher than the general population.

"We used a noninferiority design because an efficacy trial was not feasible in the cancer survivor population due to the large numbers of participants—thousands—required for efficacy [trials](#), and the fact that half of our targeted population consisted of children and younger adolescents, in whom an efficacy trial would not have been feasible," Landier said. "We also had the advantage that immunogenicity studies had already been conducted in the general population for all the age/sex groups that we were targeting among the [cancer survivors](#). This allowed us to make direct comparisons to each age/sex subgroup within the [general population](#). This is important because immunogenicity to the HPV vaccine is known to vary by age and sex, with younger patients and males producing higher antibody titers than older patients and females, respectively."

**More information:** Wendy Landier et al, Immunogenicity and safety of the human papillomavirus vaccine in young survivors of cancer in the USA: a single-arm, open-label, phase 2, non-inferiority trial, *The Lancet Child & Adolescent Health* (2021). [DOI: 10.1016/S2352-4642\(21\)00278-9](#)

Provided by University of Alabama at Birmingham

Citation: Study: HPV vaccines are safe and generate protective antibody levels in young cancer survivors (2021, November 10) retrieved 25 April 2023 from <https://medicalxpress.com/news/2021-11-hpv-vaccines-safe-antibody-young.html>

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