FDA approves first self-test collection kit for HPV

May 16 2024, by Dennis Thompson

The U.S. Food and Drug Administration has approved a kit that will allow women to collect their own vaginal sample for HPV screening, a move that could increase early detection in those at risk for cervical cancer.

Women will be able to swab themselves in privacy at a doctor's office, clinic or pharmacy, and the sample will then be sent off for analysis.

More than half of U.S. women diagnosed with cervical cancer have never been screened or screened only infrequently for the virus, the kit's maker Roche said in a news release announcing the approval on May 15 2024.

"With vaccinations, innovative diagnostic tools and screening programs, achieving the WHO's goal of eliminating cervical cancer by 2030 is within reach," Roche Diagnostics CEO Matt Sause said. "Our HPV self-collection solution helps support this goal by reducing barriers and providing access to HPV screening by allowing people to privately collect their own sample for HPV testing."

Each year, about 11,500 U.S. women are diagnosed with cervical cancer and about 4,000 women die from it, according to the U.S. Centers for Disease Control and Prevention.

HPV is the known cause of more than 95% of cervical cancers, Roche added.

"Almost all cervical cancers are caused by persistent infection with certain types of HPV," Dr. Karen Knudsen, CEO of the American Cancer Society (ACS), said in a statement. "Self-collection can expand access to screening and reduces barriers, which will give more people the

opportunity to detect, treat and ultimately survive cancer."

Most primary care doctors don't test for HPV. Instead, women are most often screened by gynecologists during a pelvic exam, a procedure to which some don't have access and others find too intrusive and embarrassing.

"Roche's self-collection solution can help reduce these barriers by offering an alternative to clinician collection procedures, while also providing accurate and reliable results," Roche said.

The HPV test itself is already covered by private insurance, Medicare and Medicaid, Roche told the *Washington Post*.

"This literally just opens up another option for a different demographic of people that might not feel comfortable, that might not have access [and] may not have time" to get tested otherwise, Irene Aninye, chief science officer for the Society for Women's Health Research, told the *Post*.

The ACS recommends that cervical cancer screening begin at age 25, and that women ages 25 to 65 have an HPV test every five years.

Studies done for the past two decades have found that self-collection for HPV testing is feasible and acceptable, and that women can collect samples as well as their physicians, the ACS said.

"Self-collection was not FDA-approved at the time our current guideline was released, but we now expect a minor update to the guideline to note that primary HPV testing via clinician-collected sample or self-collection is acceptable," said ACS Chief Scientific Officer Dr. William Dahut.

"We anticipate self-collection will play an increasingly prominent role in

cervical cancer screening once regulatory and clinical prerequisites are in place and as supporting evidence continues to accumulate," Dahut added.

The approval could also open the door for at-home collection of samples.

Teal Health received FDA breakthrough designation last week for an at-home cervical cancer screening device called the Teal Wand. Women would collect their own sample at home, then send it to a lab to be tested for HPV.

The designation grants Teal Health priority status from regulators when clinical trials wrap up and the data is submitted to the FDA.

"No more stirrups, no more speculum," the Teal Health website promises. "The Teal Wand replaces the need for an in-office pap smear using stirrups, a speculum and a hard plastic brush or broom. With self-collect, you are in control."

More information: The National Cancer institute has more on cervical cancer.

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