New Research Validates At-Home Cervical Cancer Screening Device

The device, recently approved by the FDA, is as effective as an in-clinic screening and has the potential to increase accessibility for patients, says Colorado University associate professor Christine Conageski, MD.

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A new at-home self-collection device is taking aim at the screening gap for cervical cancer, and new research, spearheaded by a University of Colorado School of Medicine faculty member, demonstrates it's both safe and effective.

"Studies have shown that half of new diagnoses of cervical cancer are those that were not screened in the preceding five years. That tells us that cervical cancer has really become a disease of access: access to the vaccine for prevention, access to cervical cancer screening, and follow up management of the first abnormal screen," says Christine Conageski, MD, MSc, associate professor of obstetrics and gynecology, the principal investigator for the SELF-CERV trial, which sought to validate use of the device, called the Teal Wand.

The U.S. Food and Drug Administration approved the Teal Wand in early May, following the trial, which was completed at 16 medical sites across the country, including CU, and confirmed that the self-collected samples have the comparable performance as clinician-collected samples and detects precancer 96% of the time while also providing a preferred experience to traditional methods.

Acting on a preventable cancer

Researchers estimate that a quarter of women are not up to date on their cervical cancer screening, commonly known as a pap smear. For those at average risk, the U.S. Preventative Services Task Force recommends screening for cervical cancer every three years in women aged 21 to 29 years and five years for women aged 30 to 65 years.

"It's been a big challenge to boost those numbers," says Conageski, a CU Cancer Center physician. "We've not seen the number of cervical cancer cases in the U.S. budge in the better part of five years, and it's because screenings are not reaching those who are at greatest risk."

Cervical cancer is typically linked to certain types of human papillomavirus (HPV), which is passed through sexual contact. While many people are infected with HPV, only a small percentage will develop cervical cancer. Still, screenings are crucial in detecting HPV, cells that may develop into cancer, and cancer. Early intervention, Conageski says, is key to saving lives.

“Ultimately, we want to decrease cervical cancer rate, and we hope that this work is going to be part of that,” she says.

“If we can make screening more accessible to those that we’re not currently reaching, that is ultimately going to drive cervical cancer rates down, because cervical cancer is an almost 100% preventable cancer,” Conageski continues. “At this point, we have vaccines to prevent the initial HPV infections, and then we have excellent screening technology. And so, I almost feel like if a patient gets cervical cancer, it’s some sort of failure on the system.”

In the SELF-CERV trial, 86% of the more than 600 participants said they’d be more likely to stay up to date with cervical cancer screening if they could do them at home and over 90% said they preferred the self-collection method that the Teal Wand provided.

Moving beyond barriers

There are a range of barriers to in-clinic testing, Conageski and fellow researchers say, including logistical hurdles and emotional deterrents, like fear or discomfort of the pelvic examination — but the device seemed to help overcome many of them.

Participants of the trial were mailed a kit with instructions that allowed them to easily and comfortably collect the sample and return it to a lab. Participants also underwent a clinician speculum exam so that researchers could compare effectiveness.

In surveys, 32% of participants said they delayed screenings due to time, 32% said they were uncomfortable with the exam, and 32% also reported financial issues as a reason for delay.

“With the Teal Wand, it took 90% of patients less than five minutes to complete the sample collection and 60% of patients less than two minutes, so it’s a quick and easy process. You can fit this into your schedule, whenever that may be, and avoid having to schedule an appointment,” Conageski says.

Wide implementation of the device could also be a net positive for physicians and health care systems. Conageski says instead of completing a pap smear test, a physician could focus on other aspects of the patient’s health during their visit and both parties could feel relief that the at-home collection method could be trusted.

“Overall, we wanted to make sure that a device like this lived up to the reliability a patient could expect in-clinic,” she says. “Now, we’ll look at some implementation science and figure out how to integrate this technology into systems across the country, maybe even starting here in Colorado.”

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