FDA Approves HPV Tests That Allow for Self-Collection in a Health Care Setting

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On May 14, the Food and Drug Administration (FDA) expanded the approvals of two tests that detect cancer-causing types of human papillomavirus (HPV) in the cervix. Both tests are used as part of screening for cervical cancer.

Under these expanded approvals, people can now be offered the option to collect a vaginal sample themselves for HPV testing if they cannot have or do not want a pelvic exam. However, the collection, which involves a swab or brush, must be done in a health care setting, such as primary care offices, urgent care, pharmacies, and mobile clinics.

The tests included in the approvals are Onclarity HPV, made by Becton, Dickinson and Company (BD), and cobas HPV, made by Roche Molecular Systems.

Until now, screening for cervical cancer in the United States has required a sample of cells collected from the cervix during a pelvic exam performed by a health care professional. But the availability of a self-collection option in health care settings should help widen access to screening, said Vikrant Sahasrabuddhe, M.B.B.S., Dr. P.H., of NCI's Division of Cancer Prevention.

Increased access to HPV testing is a particular need for certain populations among which rates of cervical cancer screening continue to be low, Dr. Sahasrabuddhe said.

"These [current] approvals are only a first step in what we think will be a much wider set of future approvals, once we gather additional evidence," he said.

Those future approvals, he continued, will hopefully come as a result of the NCI-led "Last Mile" Initiative. Last Mile is intended to accelerate the development and approval of self-collection approaches for HPV testing, including self-collection in people's own homes. Research supported by the initiative, in fact, helped lead to the recent expanded approvals.

As a part of Last Mile, a nationwide clinical trial program has been launched called SHIP (Self-collection for HPV testing to Improve Cervical Cancer Prevention). The trial will test whether self-collection in a home setting works as well as collection by a clinician in a health care setting,

continued Dr. Sahasrabuddhe, who leads the Last Mile Initiative and SHIP Trial.

Making home-based sample collection an option, he said, “will hopefully widen access to screening even further.”

Cervical cancer screening is not always accessible

Currently, almost 30% of eligible people with a cervix (women and people assigned female at birth) in the United States can’t or don’t get screened for cervical cancer at the recommended intervals.

In addition, far fewer people than recommended are getting HPV vaccines, which provide nearly 100% protection against cancer-causing types of HPV, explained Nicolas Wentzensen, M.D., Ph.D., of NCI’s Division of Cancer Epidemiology and Genetics, an expert on cervical cancer screening and management.

As a result, about 11,500 people in the United States are diagnosed with cervical cancer each year. Half of all new cases are in people who were not screened or inadequately screened as recommended by current guidelines.

Expert groups, including the U.S. Preventive Services Task Force, recommend that starting in their 20s, people with a cervix start getting screened for cervical cancer.

However, some people—such as those experiencing poverty, living in rural areas, or from racial and ethnic minority populations—tend to slip through the screening cracks, said Dr. Sahasrabuddhe.

One big problem, he explained, is that there are “many health care deserts across the country where people still don’t have access to a regular health care provider.”

And access isn’t the only barrier to cervical cancer screening, he added. People may have personal preferences, religious or cultural beliefs, a history of trauma, or disabilities or medical conditions that prevent them from getting a pelvic exam performed by a health care provider, he explained.

In addition, Dr. Wentzensen said, “there are many providers who can’t do [pelvic exams] or don’t have the infrastructure to do them.”

Expanding the uses of self-collection

For the tests covered by the expanded approvals, people collect their samples using a swab or a brush. There is no change, however, to how the tests look for the presence of HPV.

Having approved self-collection tests brings the United States closer to how cervical cancer screening is offered in several other countries, said Dr. Sahasrabuddhe, including the Netherlands,

Denmark, Sweden, and Australia, where testing using self-collected samples is widely used.

The SHIP Trial Network was launched in early 2024. The network's 25 clinical sites cover a wide range of health system settings nationwide that have the potential to enroll geographically, socioeconomically, racially, and ethnically diverse participants.

The study will examine the accuracy of vaginal self-collection performed in a simulated home environment offered during a clinic visit, compared with cervical samples collected by a health care provider during the same visit. SHIP will also collect data from participants about the acceptability of their experience and whether they would prefer to use self-collection in the future.

The initial participants will be people who have a scheduled colposcopy—an examination of the cervix performed when precancerous or cancerous changes are already suspected. At later stages, the trial will be extended to people without any known cervical changes receiving routine cervical cancer screening in clinics. A major effort of the trial will be to reach under-screened people from underserved populations with a high risk of cervical cancer.

Data from SHIP will be submitted to the FDA, with the eventual goal of extending the current limited approvals to home-based sample collection, Dr. Sahasrabuddhe explained.

An important first step

While expanding access to HPV screening is vital for reducing the number cervical cancer cases, it isn't the only thing needed, explained Dr. Wentzensen.

"Screening is only one piece of the full pathway to prevention," he said.

For example, if a screening test detects cancer-causing HPV in the cervix, additional visits to a health care provider may be needed to determine if there are precancerous cells that need to be removed and, if so, eventually having that procedure. "At each of these steps, [the prevention process] can break down," he said.

But for now, the limited self-collection approvals "are a great first step," Dr. Wentzensen continued. "And if these tests get approved for home use, it's going to enable even more access to screening."

Regularly Updating Cervical Cancer Screening Guidelines

NCI researchers are part of several national and international efforts to continuously update guidelines for health care providers on performing cervical screening and management. In the United States, one such initiative is called the Enduring Guidelines Effort, which includes representatives from federal health agencies, professional societies, and patient advocates.

As part of Enduring Guidelines, experts are already working on how to incorporate self-collection

for HPV testing into existing guidelines for providers, in concordance with the requirements laid out in the recent FDA approvals.

“Previously, we updated the guidelines every 7 to 10 years, but the field is moving so fast that that approach to guideline development has become outdated, and more rapid guidelines updates are necessary,” Dr. Wentzensen said.

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