

Cytopathology in focus: Self-collected Pap tests in the U.S. market

Recommended Reading

Christopher J. VandenBussche, MD, PhD

January 2020—The authors of an article published in the *Journal of the American Society of Cytopathology* participated in a public hearing at the Food and Drug Administration in January 2018. The hearing advised the FDA about what research would be required to demonstrate the safety and efficacy of a self-collected Papanicolaou test device. In the article, Staats, et al., review the literature on self-collected Pap tests. The authors also provide a review of published studies on self-collected HPV tests. They pose important questions that surround the self-collected Pap test; most remain only partially answered, given the limited evidence examining such tests in the literature (Staats PN, et al. Self-collected Papanicolaou tests in the United States market: more questions than answers. *J Am Soc Cytopathol.* 2019;8[6]:342-351).

A large body of observational data supports the effectiveness of the Papanicolaou test in reducing mortality from cervical cancer, yet over the past five years, eight million women ages 21 to 65, in the U.S. alone, were not screened for cervical cancer. Among the reasons are a lack of access, fear, and embarrassment. Women participating in self-collection studies often find self-collection to be more convenient, less uncomfortable, and less embarrassing than provider collection. For these reasons, even women who undergo regular screening may opt for self-collection over provider collection, should an FDA-approved self-collected Pap test become available.

The authors provide a meta-analysis to evaluate the performance of self-collected Pap tests reported in the literature. While the number of studies was limited, adequacy rates for self-collected Pap tests ranged from 86 percent to 100 percent. The concordance between self-collected Pap tests and provider-collected Pap tests ranged from 41 percent to 100 percent. The sensitivities of self-collected Pap tests for dysplasia were consistently lower when compared with the performance of provider-collected Pap tests. For some tests, sensitivity was reduced by half. Self-collected tests that involved a brushing method for collection were more sensitive than tests that involved a washing method, but they still demonstrated reduced sensitivities compared with provider-collected Pap tests.

The authors considered the impact that self-collected Pap tests would have on cervical screening using current screening data in the United States. They argue that the self-collected Pap test would be successful in reducing cervical cancer rates only if the technology were preferentially adopted by women who are otherwise not being screened, or are being inadequately screened. However, if women who are currently receiving provider-performed Pap collection opted to use self-collected Pap tests, it could contribute to an overall increased risk of cervical cancer in the population over time. The harm caused by this effect could outweigh the benefit of reducing the number of unscreened patients in the population. To alleviate this possible harm, the authors conclude that an FDA-approved self-collected Pap test should demonstrate a sensitivity that equals that of provider-collected Pap tests.

Dr. VandenBussche is an associate professor of pathology and oncology, Johns Hopkins University School of Medicine, Baltimore. He is a member of the CAP Cytopathology Committee.