

## Exploring the feasibility of HPV self-collected sampling

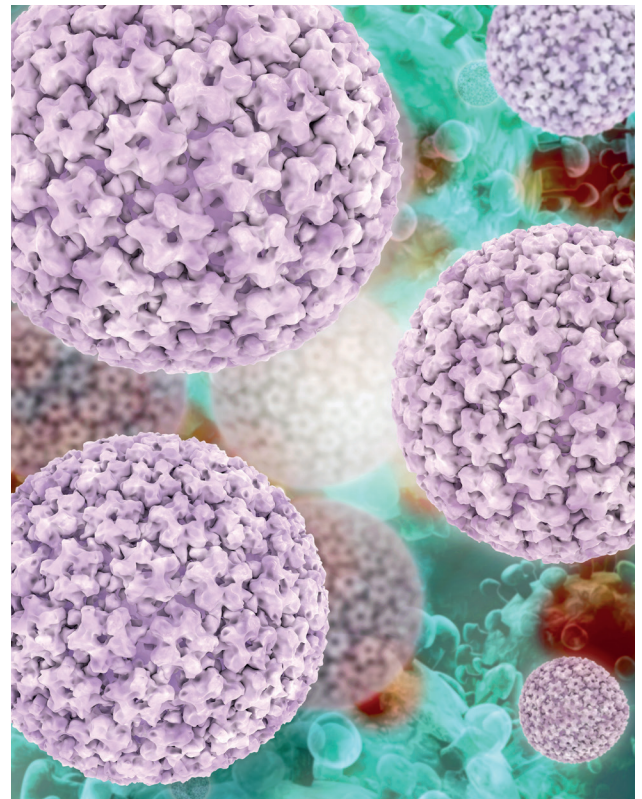
By Lauren M. Tom, BSN, MS, FNP-BC and Deborah Baresic, BSN, MS, WHNP-C

According to the American Cancer Society, about 13,170 new cases of invasive cervical cancer are expected to be diagnosed in the United States in 2019, and 4,250 cervical cancer-related deaths are expected to occur.<sup>1</sup> More than 99% of cervical cancers develop as a result of persistent infection with high-risk HPV (hrHPV) strains.<sup>2</sup> The succession from HPV infection to cancer follows a predictable sequence: transmission, persistence, progression to cell dysplasia and pre-cancer, and invasion.<sup>3,4</sup> Cervical cancer virtually never develops without positive hrHPV status, specifically HPV 16, 18, or other high-risk strains.<sup>2,4</sup> Most cervical cancers and related deaths occur in women who have not been adequately screened, followed up, or treated for the disease.<sup>4</sup>

A growing body of evidence supports the feasibility of hrHPV testing as a primary cervical cancer screening (CCS) method for some women.<sup>4,5</sup> In 2014, the FDA approved one HPV test for primary CCS.<sup>5</sup> In 2015, the Society of Gynecologic Oncology and the American Society of Colposcopy and Cervical Pathology issued an interim guide for healthcare providers (HCPs) who choose to use HPV testing for primary CCS.<sup>5</sup> In August 2018, the United States Preventive Services Task Force released new CCS recommendations: The use of hrHPV testing every 5 years for women aged 30-65 was added while retaining the other screening options of cervical cytology alone every 3 years or co-testing (cervical cytology and hrHPV testing) every 5 years.<sup>6</sup> Recommendations from the American College of Obstetricians and Gynecologists do not currently include this new option.<sup>7</sup>

### Is self-collected HPV sampling a feasible option for CCS?

Self-collected HPV sampling kits used in clinical studies



consist of a Q-tip or brush with an outer shell similar to a tampon that is self-inserted into the vagina. This outer shell prevents sampling from the vulva and lower vagina and limits vaginal contaminants. After the brush is rotated internally, the entire device is withdrawn, and the end of the inner brush is placed in a transport medium to be sent to a laboratory.<sup>8</sup> Women have proved to be competent in self-collected sampling.<sup>9-15</sup> Studies have shown similar sensitivity in detecting hrHPV when samples are self-collected versus HCP-collected.<sup>8,10,11,16</sup>

Self-collected HPV testing offers the potential to reach women who lack access to care or who do not seek CCS because of embarrassment, discomfort with the procedure, or past experiences of discrimination in the healthcare setting.<sup>12,15,17-19</sup> However, several factors must be considered to determine the feasibility of self-collected HPV sampling as an option for CCS.

### Will women utilize self-collected HPV testing?

Overall, studies have indicated that women are satisfied with the experience of self-collected HPV testing. Rates of return of self-collected samples in these studies have varied because of the use of different methods to engage participants and the use of different comparators.

Investigators of a study conducted in rural Canada

recruited 818 women from family practice clinics who were overdue for CCS.<sup>20</sup> The women were randomized to receive (1) a self-collected HPV kit mailed to their home (n = 335), (2) a mailed reminder to make a Pap test appointment (n = 335), or (3) standard-of-care opportunistic screening (n = 152). Of the 335 women who received a self-collected HPV kit, 70 (21%) self-sampled and returned the kit. In the other two groups, 37 (11%) of the 331 women who received a reminder letter scheduled and underwent a Pap test and 13 (8.5%) of the 152 women in the control group underwent CCS. Among the 70 women in the group who self-sampled and returned the kit, 56 (80%) reported that they would be very likely to choose self-collected sampling in the future.

A study in the Mississippi Delta area focused on women who had not had CCS for at least 3 years.<sup>9</sup> Community health workers went door to door offering women the choice of a free Pap test voucher or a self-collected HPV kit. A total of 119 women participated in the study, with 77 (64.7%) choosing self-collection kits and 42 (35.3%) choosing a Pap test voucher. Of the women who chose the kits, 62 (80.5%) returned the samples; of those who chose the Pap test vouchers 17 (40.5%) completed screening.

In a study conducted in Minnesota, researchers investigated the feasibility of recruiting women via advertising on a social networking site to promote the use of HPV self-collection kits, as well as to survey them about their perceptions of self-collection.<sup>13</sup> Women were offered the opportunity to participate in self-collection and complete an online survey or to just complete the online survey. A total of 197 women were enrolled, with 67 agreeing to participate in both the self-collection and survey and 130 completing the survey only. Of the 67 women who were sent kits, 62 (92.5%) returned them for testing. Most women who self-collected a sample reported favorable perceptions about self-collection, including ease of sampling (87.1%), absence of pain during sampling (72.6%), and privacy (85%). Women who returned the sample and completed the survey received a \$50 gift card as compensation.

A community outreach approach was used to evaluate the feasibility and acceptability of self-collection HPV testing among Hopi women residing on a reservation in Arizona.<sup>15</sup> Flyers and informational brochures about the self-collected HPV test were posted in public places, handed out face to face at community events, and distributed door to door during a health education campaign. The flyer was also circulated by email, pub-

lished in tribal newsletters, and aired as a public service announcement on the tribal radio station. Among 353 participants, 329 (93.2%) returned a self-collection kit. Satisfaction with self-sampling was high; 96% reported sampling was easy, 87% reported no discomfort, and 62% reported that they preferred self-sampling to receiving a Pap test from an HCP. Reasons for preferring self-sampling were privacy, reduction in embarrassment, and convenience. As with the study conducted in Minnesota, 13 women who returned their sample received a gift card.<sup>15</sup>

These studies and several others have demonstrated that women are willing and capable of using self-collected HPV testing.

Although no CCS was done, a qualitative study used focus groups to ascertain 25 women's perceptions about self-collected HPV testing; these women all resided in a rural community in Ontario, Canada.<sup>21</sup> After attending a brief information session on self-collected HPV testing, the women were asked for their initial perceptions. Perceived advantages of self-collected HPV testing included convenience, privacy, and ease of self-sampling. In addition, the women thought that self-sampling would eliminate the embarrassment and discomfort associated with having an HCP obtain the sample. Perceived disadvantages involved concerns about the reliability of the test and confidence in one's ability to self-collect properly. The women expressed a need for more information about HPV testing and self-collection before they would feel comfortable and confident in using self-sampling. Barriers that self-sampling could not address included (1) a lack of awareness about the importance of screening in the prevention and early detection of cervical cancer and (2) a fear of cancer.

These studies and several others have demonstrated that women are willing and capable of using self-collected HPV testing. Most women in the studies who

completed such testing reported ease of use and satisfaction with the method, and liked aspects such as privacy, decreased embarrassment, and convenience.

Primary HPV testing has growing support as an acceptable cervical cancer screening option for some women; self-collected HPV tests are an option worth exploring for women who struggle with access to care and other barriers.

### Beyond the sampling: Which issues still need to be resolved?

Return rates for self-collected kits in these studies ranged from 21% to 93.2%. Compensation with a gift card likely helped achieve high sample return rates. The intensive multi-component community awareness strategy, along with the gift card, achieved the highest return rate (the one achieved in the Hopi women study). This approach is labor intensive and incurs costs, but it may be needed to ensure participation in this type of screening.

Systems to ensure that women receive their test results and have access to follow-up for abnormal findings is important. Women may have increased access to CCS with self-collected HPV testing, but if they must surmount financial, geographic, or other barriers to deal with abnormal results, then self-testing does not have much benefit. In addition, not all barriers to screening can be resolved with self-collected HPV testing. Women who are not aware of the benefits of CCS for prevention and early detection of cancer are not likely to seek screening via any method.

### What are the implications for practice?

Primary HPV testing has growing support as an acceptable CCS option for some women; self-collected HPV tests are an option worth exploring for women who struggle with access to care and other barriers. The opportunity to improve CCS rates among hard-to-reach populations is promising. The future for self-collected HPV testing depends on acceptance of primary HPV testing for CCS, continued awareness campaigns, development of strategies to achieve good self-collected sample kit return rates, and availability of resources for follow-up and treatment when needed.

The June 2018 National Association of Nurse Practitioners in Women's Health (NPWH) **Position Statement: Cervical Cancer Screening<sup>A</sup>** provides several recommendations for HCPs who provide care for women aged 21 years or older.<sup>22</sup> HCPs should identify those subpopulations in the community they serve who are at risk for not undergoing regular CCS and follow-up and advocate for culturally appropriate outreach. Regardless of CCS method used, HCPs should educate women about the importance of screening, use effective reminder and follow-up systems, and establish resources for referral and treatment. If self-collected HPV testing is utilized in the future, it will provide HCPs with one more tool to reach women and to decrease cervical cancer morbidity and mortality rates. ●

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