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# Patient Satisfaction With Human Papillomavirus Self-Sampling in a Cohort of Ethnically Diverse and Rural Women in Yunnan Province, China

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**Objective:** Rural Yunnan Province is one of the most ethnically, culturally, and religiously diverse regions in China. The majority of its women have never been screened for cervical cancer. It is not known whether women would feel comfortable and ultimately even prefer using a human papillomavirus (HPV) self-swabbing method.

**Methods:** In a 6-day period, 3,600 women were taught the role of HPV in cervical cancer. They were then given self-swabbing instructions. After obtaining their specimens, 600 women were interviewed about their experience with HPV self-testing. The women were of the Yi, Hui, Dai, and Han ethnicities.

**Results:** The overwhelming majority of the women surveyed understood the self-sampling instructions (588/600, 98%) and felt comfortable carrying out the self-sampling procedure (584/600, 97%). Significantly more women (389/600, 64.8%) preferred self-sampling to having the provider (211/600, 35.2%) obtain the sample ( $\chi^2 = 105.61, p < .05$ ). Women who preferred self-sampling did so primarily because they felt capable of obtaining the specimens ( $n = 80$ ) or that it was a more convenient way to be tested ( $n = 79$ ). The medical expertise of the provider ( $n = 74$ ) and concerns over the accuracy of the test ( $n = 88$ ) shifted some women's preference toward a provider-obtained sample.

**Conclusions:** There are 400+ million Chinese women who have never had a cervical cancer screening. Self-testing has the potential to significantly increase the number of women tested. Despite the diversity of the

women screened, the majority felt comfortable self-sampling and preferred self-swabbing to provider testing.

**Key Words:** HPV, self-swab, cervical cancer, China

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Currently, there are no national cervical cancer screening programs in China. Only 10%–30% of Chinese women report having ever had cervical cancer screening.<sup>1</sup> As such, more than 400 million Chinese women have never been screened for cervical cancer. This lack of screening has led to a high incidence of cervical cancer (15.3/100,000) and a relatively high mortality rate of 4.57/100,000.<sup>2</sup> In contrast, the incidence of cervical cancer in countries with organized cervical cancer screening programs is significantly lower. For example, in the United Kingdom, the incidence of cervical cancer is 7.1/100,000 with a mortality rate of only 1.8/100,000.<sup>3</sup> In 2014, the number of new cervical cancer cases in China was more than 102,000, with more than 30,400 deaths. In general, women living in rural areas of China are less likely to report ever having a cervical cancer screening, and mortality rates from cervical cancer are up to 48% higher in rural areas.<sup>1,4</sup>

Human papillomavirus (HPV) accounts for almost all cases of cervical dysplasia and cancer.<sup>5</sup> The prevalence of HPV infection varies among different ethnicities and geographic regions. In China, the most common high-risk genotypes are 16, 18, 52, 58, and 59.<sup>6,7</sup> The Yunnan Province is a geographically and highly ethnically diverse region in Southwest China, with a population of more than 48 million.<sup>8</sup> Yunnan is a relatively underdeveloped province and, at the time of this study, contained several poverty-stricken counties.<sup>9</sup> The prevalence of high-risk HPV (hrHPV) within the Yunnan Province ranges from 7.1% to 27.4%, which is highly dependent on the ethnicity of the women tested.<sup>10</sup> Because of the level of development, complex geography and dispersed population across the rural parts of the majority of Yunnan Province, the conventional, multistep screening process of screening with a Pap smear, colposcopy-directed biopsy, and subsequent treatment of women diagnosed with cervical dysplasia is too resource intensive for this low-income region.

Human papillomavirus DNA testing has been studied as a less burdensome screening method in low-resource settings.<sup>11,12</sup> To further reduce the medical provider burden, patient-obtained “self-swabs” for HPV DNA have been studied. A recent meta-analysis by Arbyn et al.<sup>13</sup> and Nelson et al.<sup>14</sup> showed HPV DNA testing of self-samples to have similar sensitivity and specificity to clinician-obtained specimens when used in conjunction with polymerase chain reaction (PCR) based testing systems. As such, the World Health Organization supports HPV testing in either provider obtained specimens or self-swab specimens in women 30 years and older.<sup>15</sup> Another meta-analysis by Nelson et al.<sup>14</sup> examined whether women found self-swabbing acceptable and/or preferable to provider obtained specimens. They looked at 37 studies that included more than 18,000 participants in 24 countries and found that 97% of women found self-sampling to be

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acceptable. In addition, 59% of women preferred self-sampling over provider sampling. To date, there have been 3 published studies that have examined the acceptability of self-sampling in Chinese women.<sup>16–18</sup> Two of these studies were performed in the Shanxi Province and the third was in Beijing. Ninety-nine percent of the women in Shanxi Province are Han Chinese and 94.7% of women in Beijing are Han. No previous studies have examined acceptability of self-sampling in ethnic minorities in China.

### STUDY DESIGN

Before the initiation of the study, institutional review board approval had been obtained from the United Family Hospitals' investigational review board (Beijing, China). During a 6-day period in July 2018, 3,600 Chinese women aged 35–65 years participated in a rapid, high-volume, see-and-treat cervical cancer screening study in 3 different medical clinics in the Yunnan province, Kunming Municipality, Xundian County. Local health officials had notified potential patients in the preceding weeks. Between 480 and 980 women were screened per day. Most women screened were ethnically Yi, Hui, and Dai.

After obtaining informed consent, the subjects received a brief explanation of HPV and its role in cervical cancer. They were then given both verbal instructions and an instruction sheet that contained illustrations on how to obtain a self-sampled vaginal specimen. In groups of 10–12 women, they were led by a female nurse to a semiprivate room with a large table in the center. The women were instructed to place the HPV collection vial on the table and remove the collection brush (careBrush) from its packaging. They were then instructed to lower their pants and insert the swab in their vagina, to twist the swab 3 times, and then insert the swab into their collection container. Women who had difficulty inserting the swab intravaginally were assisted by the nurse. Using this collection method, between 100 and 150 women were tested per hour. Upon exiting the collection room, a subset of the women ( $n = 600$ ) were interviewed using a short questionnaire to assess their opinion of self-swabbing. Interpreters were available to interview the women in their preferred dialect. Interviewers were able to ask follow-up questions to clarify responses. To prevent selection bias, as soon as an interviewer was available, the next woman in line was interviewed. None of the women selected to be interviewed refused.

Women who tested positive for hrHPV were then evaluated by digital colposcopy and treated with either cryotherapy or loop electrosurgical excision procedure if necessary. The results of this cervical cancer screening study have been previously reported.<sup>19</sup>

A sample size calculation was performed based on data regarding patient preference of self-swabbing provided by the meta-analyses performed by Arbyn et al.<sup>14</sup> and Nelson et al.<sup>14</sup> It was determined that a sample size of at least 372 women would be needed to identify a 10% difference in patient preference of self-swabbing or provider-collected swabs.

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### RESULTS

Nearly all of the women surveyed reported that they understood the self-sampling instructions (588/600, 98%), felt comfortable self-sampling (584/600, 97%), and 97% (581/600) found this to be an acceptable method of testing. Most women were confident that they were able to obtain an adequate specimen (552/600, 92%) and significantly more women preferred self-sampling (389/600,

65%) to provider (211/600, 35%) collection ( $\chi^2 = 105.61, p < .05$ ). The most common reasons that women preferred self-swabbing were as follows: (1) they felt capable of obtaining the specimen; (2) they felt that it is more convenient to obtain a self-swab than having to get a provider obtained specimen; and (3) they felt that it was less embarrassing than having a provider obtain the specimen. Importantly, none of the patients expressed embarrassment regarding obtaining self-swabs. Conversely, fewer women preferred provider obtained specimens because they believe them to be more accurate (88/600, 14.7%) or they preferred provider-obtained specimens because they wanted someone with more experience (74/600, 12.3%) to obtain the specimen. The mean age of women preferring self-swabbing (46.64 years) was not statistically significant ( $p = .46$ ) from those women who preferred provider sampling (47.15 years).

### DISCUSSION

As the largest and most populous of the low- to middle-income countries in the world, China carries a large burden of cervical cancer. The need for a cost-effective and high-volume cervical cancer screening strategy is especially crucial as more than 400+ million Chinese women have never had screening. Previous studies have demonstrated that HPV DNA screening for cervical cancer is cost-effective, efficient, effective, and versatile.<sup>20,21</sup> The results of this study show that the women studied are overwhelmingly accepting of self-swabbing for HPV. Their acceptance is highlighted by their comfort performing self-sampling and their perception that they were able to obtain adequate specimens. Even more importantly, they felt that it was more convenient and less embarrassing to self-sample rather than having to get provider-obtained swabs.

Self-sampling has the potential to reduce cervical cancer screening costs, as it eliminates the need for a highly skilled medical provider in the initial screening process. Self-sampling can increase the number of women who can be screened, and it also can reduce the amount of time needed to screen large numbers of women.

China is an ethnically, culturally, geographically, and socio-economically diverse nation. Although more than 90% of Chinese are ethnically Han, China has more than 50 ethnic groups and more than 100 million non-Han Chinese. Non-Han Chinese women are (on average) less educated, poorer, and are more likely to live in rural communities.<sup>22</sup> In addition, women of non-Han ethnicity are less knowledgeable regarding the benefits of cervical cancer screening, are more skeptical regarding cervical cancer screening, and are less likely to have been screened for cervical cancer.<sup>22,23</sup> The 3 previous studies conducted in China that have examined acceptability of self-collection studied only Han women.<sup>16–18</sup> In contrast, our study was performed with women predominantly of the Yi, Hui, and Dai ethnicities. The Yi, Hui, and Dai are generally considered socially conservative (with potentially less sexual partners), and this may contribute to a low rate of HPV infection in this population.<sup>15</sup> However, despite their social conservatism, this study demonstrated that with proper education and instruction, women of non-Han ethnicities are highly accepting of the self-swab cervical cancer screening.

One strength of our study was the method by which women obtained the self-swabs. Women self-swabbed in groups of 10–12 women under the guidance of a female nurse. Any woman who had difficulty with obtaining her specimen was given assistance. The benefit of this method is that it facilitated fast, high-volume collection of specimens (100–150 specimens/hour) and helped ensure that the specimens were obtained correctly. This likely explains why 97% of the women felt comfortable self-sampling and why 92% of women felt that the specimen they obtained were adequate. In contrast, a study by Tisci et al.<sup>17</sup> in the Shanxi province examined how well women followed a 7-step set of

instructions that was given to them verbally before they were asked to perform at self-swab. Only 50.8% recalled 5 of the 7 steps and only 12.8% remembered all 7 steps. It is not surprising, therefore, that they reported that only 52% of their study's participants felt comfortable obtaining self-swabs. They concluded that it was necessary to have a "trained and trusted medical person" present for the women to feel comfortable enough to perform the self-swab and to prevent injury as some women attempted to insert the swab in their urethra or anus.<sup>17</sup> Our study might be criticized because of the lack of privacy afforded to patients. However, as pointed out by Guan et al.,<sup>16</sup> "there may be a cultural difference in the need for privacy. In rural China, where communal bathrooms and showers are more common, women may have a different threshold for privacy than women in other cultures."<sup>16</sup> In addition, it should be noted that none of the 600 women surveyed said that they found self-swabbing in this communal setting to be embarrassing. Future studies should be conducted in different cultures to validate this group self-swab technique before it is implemented in screening protocols.

Another strength of our study is that data were derived from patient interviews rather than a written questionnaire. Although this may introduce interviewer bias, it allowed for a better understanding of the patients' responses and allowed responses from less literate women.

There are several significant limitations regarding this study: as this study was conducted concurrently with a high-volume, rapid, see-and treat cervical cancer screening program, during which up to 980 women were screened daily, it was not logistically possible to gather significant demographic information including parity, income level, or level of education. In addition, prior knowledge and attitudes regarding HPV and cervical cancer screening were not assessed. Another limitation of this study was that the questionnaire used during this study has not been psychometrically validated.

It also should be noted that very few of the women had previously been screened for cervical cancer. As such, the vast majority had never experienced a provider obtained swab. Therefore, they were comparing one known experience (self-swabbing) to an unknown experience (provider swabbing) when they were giving their preference.

Lastly, another limitation of our study is that the self-swabs were tested with the careHPV system (Qiagen, MD), which is a signal amplification system. The careHPV system was developed with support from the PATH and Gates Foundations and was designed specifically for use in low-resource settings. It is a simple, fast, low-cost, and robust method for HPV testing.<sup>24</sup> It is also semiportable, and each careHPV system can run 90 specimens in approximately 3 hours for \$4–\$6 per specimen. However, a meta-analysis by Arbyn et al.<sup>25</sup> published shortly after the completion of our study showed that hrHPV assays based on PCR were as sensitive on self-samples as on clinician samples to detect cervical intraepithelial neoplasia 2+ or 3+ lesions.<sup>25</sup> However, hrHPV assays based on signal amplification were slightly less sensitive on self-samples as compared with provider samples when using signal amplification systems such as careHPV.<sup>25</sup> Unfortunately, when this study was performed, no portable, low-cost, high-volume, rapid PCR-based hrHPV detections systems were commercially available. Since this study was performed, however, this type of system has become available (AmpFire System, Atila, CA).<sup>26</sup>

## CONCLUSIONS

Self-swabbing has the potential to significantly increase the number of women screened for cervical cancer. The method of self-swabbing described in this article has the potential to rapidly screen many women. In addition, despite the ethnic diversity of

the women screened, a majority felt comfortable self-sampling and preferred self-swabbing to provider testing.

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