Patient Acceptance of Self-Sampling for Human Papillomavirus in Rural China

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■ **Abstract**

Objective. To test a new survey instrument and determine the acceptance and potential barriers of cervicovaginal self-sampling for high-risk human papillomavirus in rural Chinese women.

Materials and Methods. Data from thirteen survey questions assessed acceptance of the self-sampling procedure. Pain, comprehension, and cultural beliefs were potential barriers evaluated by the survey.

Results. A total of 1,560 women were surveyed. The average and mode number of steps of the self-sampling procedure recalled was 5 (out of 7). Ninety-one percent preferred performing the test at a clinic versus their home. The major barrier encountered was related to the educational level of the women.

Conclusions. The measure performed well in this population. The self-collection brush was well accepted by these women. Education is the largest hurdle to overcome in implementing a self-sampling screening program. ■

Key Words: HPV, self-sampling, acceptance

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The incidence of cervical cancer varies widely among and within regions throughout the world [1, 2]. This is attributable in large part to the variable access to cytologic screening programs to detect and treat preinvasive disease of the cervix [3]. For example, although the age-adjusted mortality rate from cervical cancer in The People's Republic of China (4.29/100,000) is slightly greater than that of the United States [4], rates in rural provinces such as Shanxi Province where screening is rarely performed are much higher (52/100,000) [5, 6]. Traditional cytologic screening using the Pap smear is complex and expensive. Less expensive methods that do not require as great a health care infrastructure such as self-sampling for high-risk types of human papillomavirus (HPV) [7] have been proposed. HPV is recognized as the principal cause of cervical cancer and its precursors.

The Shanxi Province Cervical Cancer Screening Study (SPOCCS) was designed to determine the sensitivity and specificity (critical in low-resource settings) of six screening technologies to develop low-cost screening for rural China [8]. SPOCCS II conducted further screening investigations as well as continuing work in HPV self-sampling. [7, 9–12]

The study team determined that a specialized measure of patients' acceptance specific to cervicovaginal self-sampling was required due to the invasive and personal nature of the test. It is hypothesized that women will have various barriers preventing them from feeling comfortable performing the test. Examples of perceived barriers include their husbands' disapproval, cultural practices, and general feelings of personal discomfort when touching themselves.

Measures of patient acceptance of medical procedures have been developed and tested in the past [13–15]; however, a specific measure for cervicovaginal self-sampling has only recently been studied [16].

This study has three objectives:

- Test a newly developed measure for patient acceptance of cervicovaginal self-sampling (self-sampling for HPV).
- Determine barriers associated with HPV self-sampling.
- Establish the level of acceptance for the self-sampling procedure within a group of unscreened rural Chinese women.

The hope is that through this research, self-sampling technology can be applied in a culturally sensitive and educationally appropriate manner.

MATERIALS AND METHODS

The human subject review boards of both the Cleveland Clinic Foundation and the Cancer Institute/Hospital of the Chinese Academy of Medical Sciences in Beijing approved the study. Development of the measure was aided by the pilot phase of SPOCCS II where 215 women were surveyed. This pilot tested the survey and the feasibility of the SPOCCS II protocol. The initial measure was created and then translated into Chinese by Y.H. Shen, one of the co-authors, to pilot the questionnaire.

The results of the survey pilot were then combined with the results from a focus group to develop the final survey instrument. The focus group was comprised of eight women receiving treatment at the Cancer Institute/Hospital, Chinese Academy of Medical Sciences, Beijing, China. The primary duties of the focus group were to review the survey for the completeness of answer choices and for comprehension of the questions themselves. Y.H. Shen moderated the group. Demographic data were collected as a component of SPOCCS II, not as part of this survey. Utilizing the same patient identification number for all aspects of the study enabled study personnel to match demographic data with the survey results.

Women aged 35 to 50 years of age were recruited from Yangcheng County and Xiangyuan County, Shanxi Province, The People's Republic of China for enrollment in the SPOCCS II protocol. Eligible subjects must have had a uterine cervix and may not have been screened for cervical neoplasia in the past 10 years. Informed consent was obtained from interested and eligible women in conjunction with consent for SPOCCS II. As part of the SPOCCS II protocol study participants were asked to complete a self-sample for HPV using a small cervical sampling brush (Digene Corp., Gaithersburg, MD) and a specific technique developed for SPOCCS II [8].

Figure 1 contains the directions for the self-test. The instructions for performing the self-test were given verbally to groups of women immediately preceding their performing the test. The women preformed the test and were observed for what types of difficulties they had following the procedure.

As women left the clinic approximately 16% were systematically selected to complete the self-sampling survey. Women whose last digit of their ID number ended in a two or an eight in Xiangyuan County and a one or a six in Yangcheng County were chosen for an interview. ID numbers were assigned sequentially as the women came to the clinic to be screened. All women who were asked to complete the survey did so. The interviewers were trained by two of the co-authors, Y.H. Shen and Donna Fife. They made sure the interviewers understood the meaning of the questions, the correct way to ask each question, and how to accurately explain the questions.

The survey consisted of 13 questions split into two types. One type explored issues surrounding the self-sample, whereas the other measured knowledge about HPV and cervical cancer.

Reliability data were also gathered on a sample of 23 women at two time points separated by 2 weeks. At each time point, the women were given instructions for

1. Open the transport container, hold the plastic end of the self-test with your dominant hand so that it is pointing toward you.
2. Open the outside of your vagina and insert the brush.
3. Point the tip towards your lower back, hold the brush steady and straight, slowly insert the brush into your vagina.
4. Continue to insert until you feel resistance (the length of the brush handle still outside the vagina should approximate the length of your thumb).
5. Once you meet resistance gently turn the entire self-test brush in a circle 3-5 times.
6. Remove the brush from your vagina, put it into the transport container.
7. Bend the handle until it snaps, screw the top on the container and dispose of the handle.

Figure 1. Self-test directions.

the self-test, performed the self-test, and answered the same survey questions. At each time point, two independent raters simultaneously coded the women's responses.

Analysis

All analyses were conducted using the Statistical Package for the Social Sciences (SPSS, Inc., Chicago, IL). Interrater reliability was assessed both with a measure of association, Cohen's kappa, and a measure of agreement, total percent agreement. This dual method was employed since kappa is influenced by prevalence and total percent agreement is influenced by chance agreements. By examining both indicators a more complete assessment of rater consistency may be obtained. In addition, these methods were used at both time points to determine if interrater reliability would improve as raters became more proficient at scoring the surveys. Test-retest reliability was assessed in a similar fashion using the scores of one of the raters; Cohen's kappa and total percent agreement were computed. Descriptive information, including frequencies and measures of central tendency, when applicable, were computed for all survey variables and for variables related to the women's background. χ^2 tests were used to examine associations between levels of comfort performing the self-test and those demographic variables, which had adequate variation, including age and education level.

RESULTS

As described in Table 1, the 1,560 surveyed women ranged in age from 32 to 51 years, with a median age of 40.8 years (SD = 4.31 years). Ninety-nine percent of the women were married, and 79.6% had completed 9 years of school. One quarter of the surveyed women were high-risk HPV positive. These demographics were comparable to those found in the total SPOCCS II population.

Overall the self-sampling device was well accepted by these women, and none of the women refused to self-sample. In 12.5% of the women pain and bleeding after doing self-sampling was reported. A smaller percentage (2.4%) than originally expected reported feeling uncomfortable touching their genitals. Additionally, there does not seem to be any evidence to suggest that their husbands would reject them performing this test. The number one reason cited for women not doing the test is thinking they are not ill (42%; 95% CI = ± 0.375).

Table 1. Demographics

Demographic characteristic	(*n* = 1,560)	SPOCCS II (*n* = 8,000)
Gender, % female	100	100
Age, median (SD)	40.8 (+4.31)	40
Marital status, % married	99	98.4
Education, % with 9 years	79.6	80.4
HPV status, % high-risk HPV positive	25.4	23.7

SPOCCS, Shanxi Province Cervical Cancer Screening Study; HPV, human papillomavirus.

Table 2. Number of Steps Recalled

No. of steps recalled	% Who recalled only that no.	Cumulative %
2	0.2	100
3	1.0	99.8
4	13.0	98.8
5	50.8	85.8
6	22.2	35.0
7	12.8	12.8

Frequencies showed when surveyed, both the average and the mode number of steps recalled by the women were 5 (of 7 steps) of the self-sampling procedure. Table 2 shows the percentages of women by the number of steps remembered. Eighty-five and eight tenths percent of the women recalled at least five steps. Thirty-five percent recalled at least six steps and 12.8% recalled seven steps. The three steps that were missed with the greatest frequency were: continue to insert until resistance, 76%; point the tip toward lower back, hold the brush steady and straight, insert into vagina, 43.5%; and open the outside of your vagina and insert the brush, 31.5%. Although this may look discouraging all the women clearly inserted the brush.

As previously mentioned, a goal of this study was to test this newly developed measure. Although the survey only had 13 actual questions, each question had many parts for a total of 67 study variables. As it would be difficult to list reliability data for each individual item, Table 3 summarizes the reliability data.

Interrater reliability testing showed that the raters improved over time. Each kappa increased at time two. Looking at the interrater reliability we were able to determine that mutual exclusivity was not achieved in two of the answer choices resulting in problems with coding (steps two and three both say insert the brush). Negative kappas were found for these questions. Because we know that the women inserted the brush we are confident that this coding error can account for the percentages of women recorded as forgetting these steps. Therefore, the result of recalling on average 5 of 7 steps may

Table 3. Reliability Data

	Time 1		Time 2	
Interrater reliability	Kappa	Percent agreement	Kappa	Percent agreement
Range	−0.31 to 1.00	47.8–100	0.42–1.0	78.3–100
Average (all variables)	0.81	88.4	0.88	89.75
	Rater 1			
Test-retest reliability	Kappa	Percent agreement		
Range	−0.16 to 1.0	39.1–100		
Average (all variables)	0.71	87.4		

not be completely accurate, but the ambiguity is easily corrected by achieving mutual exclusivity within the answer choices.

Table 4 lists other survey-measured factors that were associated with self-sampling. Included are women's experiences with the procedure, barriers to the test, and indicators of acceptance.

Difficulties arose when the women attempted the self-sample. These women had trouble understanding the directions for performing the self-sample. When the women were asked what would make understanding the directions easier, 95% said that a more graphic explanation would have helped. The level of education and technologic exposure were far less than anticipated, leaving the women unable to safely and independently collect the sample. Problems included contamination of the sampling brush, difficulty locating their vagina, spillage of the transport medium, and trouble distinguishing between the top and the bottom of the transport container. The study staff observed these difficulties during the self-collection process and took steps to insure the women's safety.

Forty-two percent responded saying most women would not perform the test unless they felt ill. Seventeen percent said the test was embarrassing. Eighty-seven percent had heard of cervical cancer, of these, 92% were afraid of getting cervical cancer, 16.7% were worried about having HPV, and 85% did not know why testing

Table 4. Factors Associated with Self-Sampling (*n* = 1,560)

	% Yes	CI
Women's experience with self-sampling		
Someone read or explained the directions to them	99.9	99.875–99.925
A more graphic explanation of the directions would have made understanding the directions easier	95.1	95.075–95.125
I prefer to do the test at the clinic than at home	91.1	91.075–91.125
Did you experience pain while performing the test	12.6	12.575–12.625
Did you bleed when you performed the test	12.4	12.375–12.425
Barriers for the women in our study		
I do not know why HPV testing is important	84.7	84.675–84.725
I was uncomfortable touching my genital area	2.4	2.375–2.425
I felt that the test might not be safe	2.1	2.075–2.125
I thought that the brush was not clean	0.8	0.775–0.825
I was afraid of hurting myself while performing the test	0.8	0.775–0.825
I did not understand how to perform the test	0.4	0.375–0.425
Hypothesized barriers for other women as relayed by the women in our study		
Woman does not think she is ill	42.4	42.375–42.424
The cost of the test is too high	12.0	11.975–12.025
Many people do not believe in the medical sciences	10.4	10.375–10.425
She will not do the test because she is afraid	5.2	5.175–5.225
She will not be able to read the directions	0.8	0.775–0.825
Her husband will not want her to do the test	0.4	0.375–0.425
The test may be experimental	0.4	0.375–0.425
Indicators of acceptance		
Are you afraid of having cervical cancer	91.9	91.875–91.925
Have you heard of cervical cancer	86.9	86.875–86.925
I took the test because I wanted to protect myself from disease	50.4	50.375–50.425
Believe that other women will accept the test	48.6	48.575–48.625

HPV, human papillomavirus.

for HPV was important. Ninety-one percent said they would prefer to perform the test at a clinic versus their home. Presenting reasons for this desire were imbedded in the women's comfort level with the test.

Finally, some demographic group comparisons were conducted on women's comfort level with self-sampling. Table 5 lists the comparisons that were possible given the lack of demographic variability in these data. Approximately half of all women reported being "comfortable" or "very comfortable" performing the self-sampling. There were no differences in comfort among older versus younger women. There were, however, significant differences based on education. An examination of the frequencies seems to indicate that women with more education were more likely to be comfortable performing the test.

DISCUSSION

For women who live in areas where medical contact and funding is limited one of the hopes is that self-sampling for the high-risk subtypes of HPV infection can aid health workers in the identification of women who are at high risk for cervical cancer. HPV has been identified in virtually 100% of cervix cancers worldwide [17]. With HPV being a primary cause of cervical cancer, it follows that if you can identify women with high-risk HPV it should be possible to prevent most cervical cancer from developing.

The survey used in this study was developed in response to questions raised by the SPOCCS II protocol; this was the first time the survey was used in a clinical trial. In addition to examining the acceptance and potential barriers of cervicovaginal sampling, the study team wanted to test this newly developed survey instrument. As we expanded our studies into diverse cultures we began to question whether acceptance of self-sampling in one culture could determine acceptance in another and if the barriers to uptake of self-sampling would differ based on cultural values, norms, or religious beliefs. This survey instrument was developed to aid in this assessment. In an attempt to aid in the validation of the measure, general rules of survey development were followed [18], a focus group was employed, and the measure was plot tested before use in the full study.

Table 5. Group Comparisons of Comfort Using Self-Sampling Test

	% Comfortable	% Uncomfortable	χ^2	Phi/Cramer's V
Age				
≤40.76	52.1	47.9	0.04	−0.00
≥40.77	51.6	48.4		
Education				
No school	52.4	47.6		
Primary	48.4	51.6		
Middle school	51.3	48.7	7.95	0.07[a]
Beyond middle	59.6	40.4		

[a] $p < .05$

Initial evaluations from the pilot study showed the directions for performing the self-sample had been administered to the women using a variety of methods. These methods ranged from someone reading the directions to the women to the women reading the directions for themselves and then having someone explain them. Even though the directions seemed to be thoroughly explained and 98.6% of the women surveyed reported understanding the directions, none of these women could describe the entire procedure back to the interviewer, thus implicating a problem in the directions themselves, the way they were explained, or how the women interpreted the request for restatement of the procedure. The ability to restate or recall directions is important when trying to assess the depth to which directions are understood. The interviewers spoke the same dialect as the women and were trained on how to administer the questionnaire and explain the questions while retaining the intended meaning.

A focus group of women similar to those surveyed in the pilot study was formed to aid further development of the survey before SPOCCS II. Focus groups have been shown to be an effective tool for data collection within Chinese populations [19]. However, translation has been problematic when Chinese focus groups have been used. To minimize this, the moderator was Chinese and spoke the same dialect as the women in the group. She was then able to translate the data, while maintaining the integrity and accurateness of its content. The women in the focus group reported having concerns about cervical cancer but not knowing enough about the disease to understand why screening was important. They were helpful in identifying barriers to self-sample performance.

Focus groups provide critical information for the development of survey instruments. These groups can offer valuable insight into cultural differences and the religious and ethnic barriers they face. Our focus group also revealed it is equally important not to assume the barriers. Some of the things we assumed would be issues for the women in China were not. For example, they did

not seem uncomfortable touching their genitals, and on the converse we knew the education level was low but we did not expect the absolute lack of anatomical awareness we found. The women in the focus group also played an integral role in the translation process.

A trained and trusted medical persons presence was necessary for the women to feel comfortable enough to perform the test. Additionally, the local health care nurse or barefoot doctor was needed to prevent injury. There were women who attempted to insert the self-sample brush into their urethra and anus. Implementing a self-sampling screening program while useful in a medically remote population like the rural villages in China must be accompanied by an extensive educational effort. For these women in China their low level of education and poor understanding of their own bodies and lack of technological exposure presented major hurdles for this research, while demonstrating that medical interventions must be accompanied by education. Even though there have been great advances in education in China recently, these older women received very inferior education, if any. Any educational program will have to address the lack of anatomical knowledge and the gaps between what these women's knowledge is and what they must know to take advantage of technology that could help reduce their rates of cervical cancer. Even some very basic things like plastic bottles and screw on tops need to be introduced. These items that we encounter every day are completely foreign to these women. Another barrier to educational success is the fact that these women live at a basic subsistence level leaving little room for thoughts on health maintenance. Obviously the great limiting factor in any health education program is the willingness of the participants. These women expressed an interest in gaining additional information about their health and their bodies. It is also the case that the Chinese health system is optimal for the type of village-specific education that these women need. The local doctors within each village are trusted by the women and could help to construct programs that would fit into their lives and address their concerns. In addition to the central importance of education we also believe that an improved self-sampling device may prove to be safer, more effective, and more intuitive in its use, than the brush used in this study.

The test re-test procedure placed this measure under further scrutiny. Through this process two flaws in the design were found. A new question following question 7 will be added to future versions. Question 8 will now read, "If your choice was to perform the test at home or not at all which would you choose?" This issue was not resolved within this cohort of women. They told us performing the test at the clinic is preferable but clinics are scarce in many low-resource settings, therefore it is important to know if going to the clinic were not an option would they perform the test. A lack of mutual exclusivity within the answer choices for the original question 8 was also discovered through the test re-test process. Answer choice b and c both contain the phrase "insert the brush". Coding of this question was inconsistent between the two raters we used for the test re-test. In future versions each step will be separate and counted by itself.

Although scientifically the premise is good that self-sampling technology could have a major impact on the incidence of cervical cancer, barriers exist that may prevent women from feeling comfortable enough to use the test. The women in our study clearly felt other women would not perform the test unless they felt ill, and although the women we sampled expressed a fear of getting cervical cancer they did not understand that this test would help prevent them from getting the disease. If women for whatever reason will not or cannot perform the self-sample the fact that it could save lives by triaging care becomes irrelevant.

Studies have assessed the acceptance of home screening for chlamydial genital infection. The women screened were in London. They were sent sampling kits in the mail and were asked to perform a vulvar swab. Unlike the HPV self-test no insertion of the swab into the vagina was necessary. The response rate for the women asked to perform vulvar swabs was 31%. Some women commented on their uncertainty that they performed the test correctly, and one woman commented on the fact that taking the test was "quite personal" [20]. Women in northeast Thailand were asked to use a self-scraping devise to test themselves for cervical cancer. Their acceptance of the procedure was evaluated by a questionnaire. Most of the women were not convinced that the devise they used was safe or accurate. Half the women said that they would rather have a doctor perform the test and would not recommend it to a friend or neighbor. These women have more medical exposure than the population in rural China and they still had worries about the safety of the devise [21].

Because little is known about the reaction of women in rural settings to self-sampling and especially the acceptance of self-sampling for HPV, this measure has been developed. Self-sampling technology can save lives if women use the test. It will be necessary to mount

educational campaigns in areas where self-sampling for HPV could potentially be used for primary screening. In China since the work units are so organized it would behoove anyone to use the local health care worker in each village to help initiate sampling among the village women. We feel that this person would be able to ease the discomfort these women expressed and may help create the possibility for home self-sampling. Low levels of education have been found as a barrier for other screening procedures such as self-breast examination [22]. However, by utilizing the resources at hand it may be possible to lessen its effect. Information gathered on the acceptance of and barriers to the performance of the self-sampling will be invaluable in exploring the feasibility of implementing a self-sampling screening program to detect high-risk HPV or other yet to be tested biomarkers.

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Appendix A

Questionnaire of women's experience with the HPV-self test

Patient ID#_____

The purpose of this survey is to gain knowledge from women about their experience using the self-test for human papilloma virus (HPV). The investigators want to know what you think of the test. Your answers will be kept confidential, and they will in no way affect your care or current study participation. Please be as honest and forthcoming as you can. The more information we know the better the health care women will receive.

1. How were the directions explained to you? (Circle all that apply).
   a. I read the directions to myself.
   b. Someone read the directions to me.
   c. Someone explained the direction to me.

2. Which of the following would have made understanding the directions easier? (Circle all that apply).
   a. Pictures and more detailed explanation. If yes, what specific pictures would you have liked?_____.
   b.Video
   c. A more graphic explanation of the directions
   d. Less technical language in the directions.
   e. I would have preferred to read the directions in private.
   f. Other_____

The next three questions ask about feelings or sensations you had before, during or after, you took the test. When answering these questions please think about your experience. Your answers can help us to make this test more comfortable.

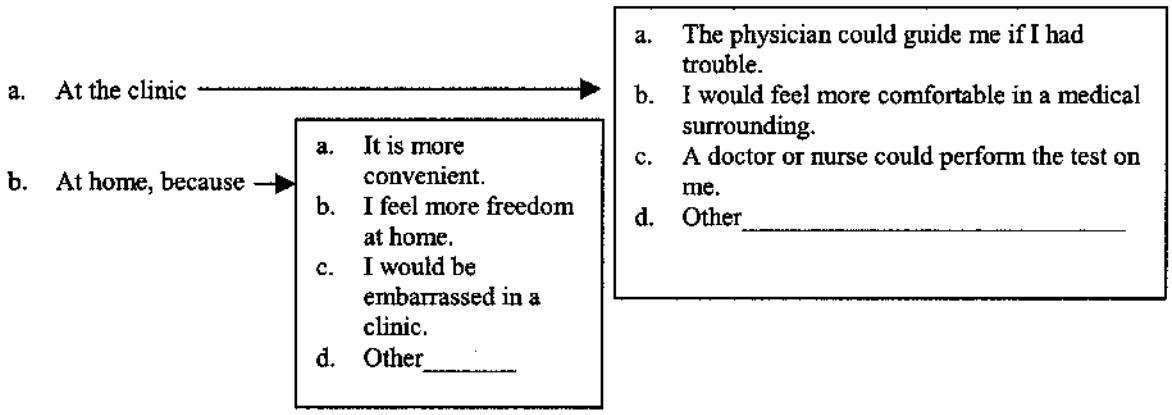
3. Many people have concerns when they use this test. I am going to read a list of these concerns. Please tell me if you had any of these.
   a. I felt that the test might not be safe.
   b. I was afraid that I would hurt myself while performing the test.
   c. I thought that maybe the brush was not clean.
   d. I did not understand how to perform the test.
   e. I was uncomfortable touching my genital area.
   f. Other. Please explain it:_____

4. Did you feel pain when you used the test?
   a. A lot b. A little c. No

5. Did you bleed when you used the test?
   a. A lot b. A little c. No

6. How comfortable were you performing the test?
   a. Very comfortable
   b. Comfortable
   c. Not comfortable

7. If you had a choice would you prefer to perform the test at home or at a clinic?



8. If your choice was to perform the test at home or not do the test at all which would you choose?

a. I would perform the test at home.
b. I would not perform the test.

Now that you have answered questions about your experience using the self-test, I am going to ask you two questions that will help us to identify problems with the test procedure. As before please be as honest as you can. This information will help us create a better health program.

9. I want you to describe to me the self-test procedure. Please describe the test as if you were teaching someone else how to do it. I will give you a sample test that you can use to help you describe the steps of the procedure.

a. Open the transport container, hold the plastic end of the self-test with your dominant hand so that it is pointing toward you, then open the outside of your vagina and insert the brush.
b. Point the tip towards your lower back, hold the brush steady and straight slowly, then insert the brush into your vagina.
c. Continue to insert the test until you feel resistance. Once you meet resistance gently turn the entire self-test brush in a circle 3-5 times.
d. Remove the brush from your vagina, put it into the transport container, bend the handle until it snaps, screw the top on the container, and dispose of the handle.

10. Through conversations with other women age 35-50 we have identified issues that they think could effect the use of this test. I will read a statement to you and then ask you if you think it could prevent women from performing the self-test. Answer Yes, if you think it could be a problem or No, if you do not think that women will be affected by it.

a. The women might not perform the test because she does not think that she is ill.
b. She hasn't time when the medical group comes here.
c. She will not be able to read the directions.
d. Her husband will not want her to do the test.
e. She won't do the test because she is afraid.
f. Many people do not believe in the medical sciences, so they would not do the test.
g. The cost is too high.
h. Someone thought they will be the experimental things, not the patients.

The final set of questions are about cervical cancer and Human papilloma virus. We would like to know how much you know about them. Answer as honestly as possible; we hope to use this information to construct better educational programs about these diseases.

8. Have you heard about cervical cancer?
   a. Yes
   b. No

9. Are you concerned about any of the following?
   b. Having cervical cancer.
   c. Being ill.
   d. Having Human Papilloma Virus.
   e. Dying
   f. Other people being sick.

10. People have a variety of reasons why they take this test. Which of the following apply to you?
   a. I want to protect myself from disease.
   b. I am concerned that I may have HPV.
   c. I am concerned that I might have cervical cancer.
   d. Someone in my family had cervical cancer.
   e. Someone in my family died of cervical cancer.
   f. I know someone with HPV.
   g. I want to help improve health care for women.
   h. I want to help improve medical technology.
   i. I am taking the test because I am part of a medical study.

11. Tell me why testing for Humanpapillomavirus (HPV) is important?
   a. HPV causes cervix cancer.
   b. HPV is cervix cancer.
   c. HPV testing is not important if you see your doctor regularly.
   d. HPV can kill you.
   e. I do not know why it is important.

Number of investigator:|__|__|