

# BMJ Open Attitudes and factors affecting acceptability of self-administered cervicovaginal sampling for human papillomavirus (HPV) genotyping as an alternative to Pap testing among multiethnic Malaysian women

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## ABSTRACT

**Objective:** The objective of this study was to determine the attitudes and acceptability of self-administered cervicovaginal sampling compared with conventional physician-acquired Papanicolaou (Pap) smear among multiethnic Malaysian women.

**Method:** A cross-sectional study was carried out via interviewer-administered surveys from August 2013 through August 2015 at five government-run, urban health clinics in the state of Selangor. Subjects were participants from an ongoing community-based human papillomavirus (HPV) prevalence study who answered a standard questionnaire before and after self-sampling. The cervicovaginal self-sampling for HPV genotyping was performed using a simple brush ('Just for Me'; Preventive Oncology International, Hong Kong). Detailed data on sociodemographics, previous Pap smear experience, and attitudes towards self-administered cervicovaginal sampling were collected and analysed. Acceptability was inferred using a five-item Likert scale that included six different subjective descriptives: experience, difficulty, convenience, embarrassment, discomfort or pain, and confidence in collecting one's own sample.

**Results:** Of the 839 participants, 47.9% were Malays, followed by 30.8% Indians, 18.8% Chinese and 2.5% from other ethnicities. The median age of the participants was 38 years (IQR 30–48). Some 68.2% of participants indicated a preference for self-sampling over the Pap test, with 95% indicating willingness to follow-up a positive result at the hospital. Age, ethnicity and previous Pap test experience were significant independent factors associated with preference for self-sampling. The older the individual, the less likely they were to prefer self-sampling (adjusted OR 0.94, 95% CI 0.90 to 0.98). The Chinese were less likely to prefer self-sampling (72.6%) than the Malays (85.1%) (adjusted OR 0.57, 95% CI 0.33 to 0.98,  $p=0.004$ ). Participants who had never undergone a Pap smear were also more likely to prefer self-sampling

## Strengths and limitations of this study

- This is one of the largest studies to systematically assess the acceptability of cervicovaginal self-sampling as an alternative to Papanicolaou (Pap) smear in a population with low screening uptake.
- The study cohort consisted of a convenience sample from healthcare clinics, possibly introducing bias, as it excluded those who may not attend healthcare facilities for a variety of reasons.
- This study could not assess and compare the sensitivity and specificity of the screening methods—that is, human papillomavirus genotyping versus Pap smear.
- The attitudes of those who declined to join the study may have introduced bias to the results.

(88.5%) than women who had undergone a previous Pap (80.9%) (adjusted OR 0.06, 95% CI 0.35 to 0.87).

**Conclusions:** Overall, urban Malaysian women from multiethnic backgrounds found self-sampling to be an acceptable alternative to Pap smear.

## INTRODUCTION

Cervical cancer is the second most common cancer among Malaysian women with an incidence of over 16 per 100 000 and mortality of over 8 per 100 000.<sup>1 2</sup> While there is no population-based cervical cancer screening programme in Malaysia, the government has supported opportunistic screening by providing free Pap smear tests since 1995. The uptake of Papanicolaou (Pap) tests among Malaysian women remains suboptimal, with

less than half (47.3%) of the population having undergone one.<sup>3</sup> Many reasons have been cited for the lack of participation in cervical cancer screening, including cost, embarrassment, fear, lack of knowledge and lack of time.<sup>4–7</sup> In 2010, the Malaysian government started a national school-based human papillomavirus (HPV) immunisation programme.<sup>8</sup> Despite the success of the national HPV vaccine programme, with more than 90% of 13-year-old school girls being vaccinated,<sup>9</sup> more comprehensive coverage and increased uptake of cervical screening remains important for at least another 30–40 years to adequately prevent the development of cervical cancer in the Malaysian population.

In communities where uptake of conventional cervical screening by cytology has been low, self-sampling may offer an attractive alternative. Unlike Pap smear tests, this procedure can be carried out by the individual themselves without the help of a physician or medical staff. This means that other logistical barriers involved with Pap test screenings, such as long waiting times in hospitals, inadequate number of and inexperienced cytologists, and unequal distribution of healthcare resources,<sup>10</sup> can be overcome, making it a more efficient and cost-effective option.<sup>11–12</sup> There is a variety of self-samplers available which allows different methods of screening for cervical cancer. Generally, they are divided into brush-based and lavage-based self-sampling devices most commonly used for HPV genotyping but are also suitable for cervical cytology and detection of biomarkers associated with cervical premalignant or malignant diseases.<sup>13–14</sup> Studies have shown a rise in participation from non-respondents to screening programmes when self-sampling methods are introduced.<sup>15–20</sup> However, owing to sociocultural and religious differences, it was important to assess the value of self-sampling in a multi-ethnic Asian community such as Malaysia. This study aimed to explore the attitudes and perception before and after the process of self-sampling for HPV genotyping to determine acceptability in comparison with the Pap smear test among a multiethnic population.

## METHOD

### Participants

Volunteers for this cross-sectional study were recruited via convenience sampling between August 2013 and August 2015 from five government-run general practice clinics (Klinik Kesihatan Pandamaran, Klinik Kesihatan Ampang, Klinik Kesihatan Bandar Botani, Klinik Kesihatan Batu 9, and University Malaya Medical Centre), which are located in Selangor, the most developed state in Malaysia with a high level of urbanisation. Subjects were participants from an ongoing community-based HPV prevalence study (The Malaysian HPV Prevalence Study), who were recruited during their visits to the health clinics for primary care services, including immunisation and routine health checks, and while accompanying family members to these clinics.

Participants aged between 18 and 60 years old who agreed to perform self-sampling joined this study. The exclusion criteria were pregnancy, menstruation, acute illness or never having been sexually active. This study received approval from the Medical Research Ethics Committee (NMRR-13-444-14609) and the University of Malaya Medical Ethics Committee (MREC989.32). Written informed consent was obtained from all participants. All patient responses were kept confidential.

### Cervicovaginal self-sampling and assessment

Participants were invited to perform self-sampling on their own using a simple brush ('Just for Me'; courtesy of Preventive Oncology International, Hong Kong). An image of the brush can be seen in figure 1. Instructions on how to use the self-sampler were given to the participants. Briefly, participants were instructed to gently push the brush to the top of the vagina with one leg on a chair. The brush is turned a few times to the left and then the right before being removed completely. After withdrawal, the brush is rubbed on to the Preventive Oncology International FTA<sup>®</sup> card provided with the kit and sealed in an envelope. The FTA<sup>®</sup> card is a solid media specimen transport card and therefore eliminates problems encountered with alcohol-based liquids, temperature exposure and transportation difficulties.<sup>21</sup> A questionnaire developed in a previous study<sup>22</sup> was modified and translated into Malay and Mandarin so it could be applied to our multilingual population (see online supplementary material file). It was administered before and after the procedure. The preassessment was intended to evaluate the initial response of the participants when they were introduced to the kit and later compared with their actual experience, which was recorded during the post-assessment. Acceptability indices for the self-administered cervicovaginal sampling included six items: experience, difficulty, convenience, embarrassment, discomfort or pain, and confidence (as shown in table 1). A five-item Likert scale was used in the pre- and post-self-sampling questionnaire, where 5 was the most favourable response and 1 the most disagreeable. A positive response towards self-sampling (deemed as acceptable) was defined based on participant responses of 4 or 5 points using the Likert scale. After self-sampling, we also inquired about participants' preference for HPV testing: prefer self-sampling; no preference (agreeable to both); prefer Pap testing. Sociodemographic information was collected via interviewer-administered questionnaire and included information on age, ethnicity, highest attained education, marital status, smoking status and previous Pap testing experience.

### Statistical analysis

Cronbach's  $\alpha$  coefficient which ranges from 0 to 1 was used to ascertain internal consistency of the questionnaire. A low value shows poor reliability or consistency among the items within the construct and a value of at



**Figure 1** The 'Just for Me' self-administered cervicovaginal sampling brush, courtesy of Preventive Oncology International, Hong Kong.

least 0.7 is generally needed to show good reliability. McNemar's test was used for correlated proportions to measure any significance in the change of acceptability after self-sampling. Categorical variables were compared using  $\chi^2$ . Continuous variables were described using medians, as most of the variables were assumed to be not normally distributed in the population, and compared using the Mann-Whitney U test. Participants who indicated that they preferred self-sampling as well as those who did not have any preference (agreeable to both methods) were categorised into 'prefer self-sampling' and compared against participants who preferred the Pap test. Multivariable logistic regression analysis including age, highest attained education, ethnicity, marital status, smoking status and previous Pap testing experience was conducted to determine independent predictors of preference for self-sampling. A p value of <0.05 was considered to be significant. Data was analysed using SPSS V.20.

## RESULTS

### Participant characteristics

A total of 839 women were interviewed and the median age of the study participants was 38 years (IQR 30–48). Most (82.7%) of the study population were premenopausal, aged 50 years old and below. Malay women represented the largest ethnic group (47.9%), followed by Indians (30.8%), Chinese (18.8%) and other races (2.5%), with 86.3% being married. Over half (57%) of the participants were employed, while 35.2% were full-time home-makers. Secondary education had been completed by 62.1%. Only 11.8% of women reported a monthly household income of more than RM5000 (US \$1100). Out of the 839 women, 76% had heard of the Pap smear before, with 63.1% having undergone a Pap test. Most of the women (81.9%) who had undergone a Pap smear test did so in the 5 years preceding the study.

Factors positively associated with previous experience of Pap testing include higher education level ( $p < 0.05$ ),

**Table 1** Indices of the five-item Likert scale for each of the categories

Likert scale	1	2	3	4	5
Experience	Very bad	Bad	Neither	Good	Very good
Difficulty	Very hard	Hard	Neither	Easy	Very easy
Convenience	Very inconvenient	Inconvenient	Neither	Convenient	Very convenient
Embarrassment	Very embarrassed	Embarrassed	Neither	Not embarrassed	Not embarrassed at all
Discomfort/pain	Severe discomfort/pain	Some discomfort/pain	Neither	No discomfort/pain	No discomfort/pain at all
Confidence	Not at all confident	Unconfident	Neither	Confident	Very confident

older age ( $p<0.05$ ) and higher income ( $p<0.05$ ). Of the women who had never undergone a Pap test, primary barriers stated were lack of awareness (13%), lack of time (10%), no existing symptoms (6.6%) and fear (5.1%) (data not shown).

### Self-administered cervicovaginal sampling is acceptable

Both pre- and post-questionnaires showed a high internal consistency, with a Cronbach's  $\alpha$  value of 0.796 for the pre-questionnaire and 0.862 for the post-questionnaire. In the pre-questionnaire, more than half of the participants gave a positive response (score 4 or 5 on the Likert scale) for all six items tested: experience, ease of procedure, convenience, embarrassment, comfort and confidence. Table 2 shows the pre- and post-test proportions of women who found self-sampling acceptable (answered 4 or above on the Likert scale). Most women's perceptions changed significantly after experiencing self-sampling in that, after self-sampling, most reported the procedure to be easy (84.5%), convenient (86.3%) and not painful (78.2%) and expressed confidence about collecting their own samples correctly (79.6%).

Overall, the above findings indicate that there was an increase in all six indices of acceptability after self-sampling. In the post-questionnaire, it was also revealed that the vast majority (91.8%) of the participants would be willing to self-sample if it was made the only cervical cancer screening option available. Most (95.2%) participants expressed willingness to go for a follow-up should they obtain a positive result. Approximately two-thirds (60.0%) preferred to carry out self-sampling at home, and almost half (49.1%) would prefer to pick up the self-sample kit at a nearby clinic.

### Self-sampling versus conventional Pap test

After the procedure, 68.2% of the participants were reported to have a preference for self-sampling compared with 13.5% who preferred Pap smear tests, while 14.1% stated no preference (agreeable to both methods). There were no significant differences in preference for self-sampling based on education level, smoking and marital status (table 3). Women who preferred self-sampling were significantly younger than their counterparts who preferred the Pap test. Ethnicity also

influenced preference for self-sampling, with the Chinese less likely to prefer self-sampling than the Malays (OR 0.57, 95% CI 0.33 to 0.98). For a sensitivity analysis, the group of women were split into those who had and had not previously undergone Pap tests. It was found that prior experience of undergoing a Pap test had a significant impact on the preference ( $p=0.01$ ). Among the women with no prior experience of Pap testing, self-administered cervicovaginal sampling was preferred over physician sampling in 75% of participants.

### DISCUSSION

To our knowledge, this is one of the largest studies where acceptability of self-sampling was systematically assessed before and after the procedure was carried out in a multiethnic Southeast Asian population. In this study, 98% of the participants were within the screening age population (21–65 years old), where 40% of the participants had not undergone a Pap test in the past 3 years or more, and 36% of participants had never had a Pap test. Cervical cancer, the second most prevalent cancer among Malaysian women, is preventable, and an estimated 70% of new cases can be prevented by screening and early detection.<sup>23 24</sup> Unfortunately, the overall uptake of the Pap smear in Asian countries, including Malaysia, is still poor.<sup>4–7 25</sup> Lack of awareness was the main reason cited by the participants in this study for never having undergone Pap smear tests before this. This is also the most commonly cited reason in other countries such as Turkey, Bangladesh, Gabon and Korea.<sup>26–29</sup> Therefore, increasing awareness of and education about cervical cancer screening is necessary and independent of the modality of screening. While self-swabs and other self-sampling devices have been examined and reported to be reliable<sup>6</sup> and not inferior to specimens obtained by physicians,<sup>30</sup> it is necessary to investigate the perception and acceptability of self-sampling among multiethnic Malaysian women, especially potential users who have never undergone Pap testing.

Generally, participants found self-sampling to be highly acceptable. Negative perceptions regarding the use of self-sampling reported before experience with collection decreased after having experienced the self-collection first-hand. The acceptability scores indicated

**Table 2** Percentage of women who found self-sampling acceptable (answered 4 or above on the Likert scale)

	Pre-questionnaire, N (%)	Post-questionnaire, N (%)	p Value*
Good experience	588 (70.1)	686 (81.7)	0.004
Easy to do	570 (67.9)	709 (84.5)	<0.001
Very convenient	647 (77.1)	724 (86.3)	0.021
Not embarrassing	716 (85.3)	740 (88.2)	0.267
No discomfort	426 (50.8)	656 (78.2)	<0.001
Very confident	567 (67.6)	668 (79.6)	0.003
Overall median score	4.333	4.833	

\*Derived using McNemar's test. p Values <0.05 were considered significant.



**Table 3** Factors associated with preference for self-sampling

Participant characteristic	Overall (N)	Preferred self-sampling	Preferred Pap test	p Value*	OR†	95% CI
Age	38	37 (30–47)	43 (31–52)	0.001‡	0.98‡	0.96 to 1.00
Education level						
Basic	89	77 (86.5)	12 (13.5)	0.714	1.00§	
Secondary	436	362 (83.0)	74 (17.0)		0.72	0.35 to 1.48
Tertiary and above	160	133 (83.1)	27 (16.9)		0.67	0.30 to 1.52
Ethnicity						
Malay	335	285 (85.1)	50 (14.9)	0.004‡	1.00§	
Indian	213	183 (85.9)	30 (14.1)		1.09	0.65 to 1.83
Chinese	117	85 (72.6)	32 (27.4)		0.57‡	0.33 to 0.98
Other	20	19 (95.0)	1 (5.0)		2.24	0.29 to 17.55
Marital status						
Single	82	66 (80.5)	16 (19.5)	0.433	1.00§	
Married	603	506 (83.9)	97 (16.1)		1.41	0.76 to 2.60
Smoking						
Never	642	532 (82.9)	110 (17.1)	0.112	1.00§	
Current or former	40	37 (92.5)	3 (7.5)		2.38	0.70 to 8.13
Previous Pap experience						
Yes	434	351 (80.9)	83 (19.1)	0.010‡	1.00§	
No	243	215 (88.5)	28 (11.5)		1.46	0.88 to 2.41

Values are median (IQR) or N (%).

\* $\chi^2$  test was used to compare categorical variables, whereas the Mann-Whitney test was used to compare age.

†OR for preference for self-sampling compared with preference for Pap testing, derived using a multivariable logistic regression model mutually adjusted for age, highest attained education, ethnicity, marital status, smoking status and previous Pap test experience.

‡Results were considered to be significant, as the p value was <0.05, or 95% CI for OR did not include 1.00.

§Reference indicator.

that the participants were highly confident in collecting their own samples. This is similar to studies undertaken in Sub-Saharan Africa<sup>31</sup> and Finland.<sup>19</sup> Interestingly, in studies where physician sampling was compared directly with self-sampling, women trusted the physician sampling more and had lower confidence in their own competency.<sup>22–32</sup> In our study, the level of education was significantly associated with confidence, and, surprisingly, those with a higher level of education were less confident about self-collection. There could be several explanations for this. It can be postulated that those with a higher education tend to overthink and question their abilities more. Education programmes designed to show the validity of self-collection may help to alleviate any concerns raised by doubtful participants. Another reason could be that women with higher education were more comfortable with a professional carrying out the test rather than themselves. This is contradictory to studies showing that education level did not have a significant impact on self-sampling acceptability.<sup>33</sup> The majority (68.2%) of the women surveyed preferred self-sampling compared with physician-sampled Pap smear tests after carrying it out. This is not surprising, as issues such as embarrassment and inconvenience could be overcome with the use of self-samplers, enabling women to do it independently in the comfort of their own homes. These results are in line with those of previous studies.<sup>22–34–38</sup> However, prior experience with Pap testing or the absence of any previous experience may have influenced this decision. The results indicated that

physician sampling was less likely to be preferred than self-administered cervicovaginal sampling for women who have never undergone Pap testing. This result matched a similar study<sup>25</sup> in which patients with no history of Pap testing were more inclined to self-sampling. This finding has important implications, as one of the target groups for improving cervical screening rates is non-attendees or those that have not participated in screening in any form.

It is worth noting that the different religions and cultures among Malaysian women did not influence the acceptability of self-sampling. This is in agreement with previous findings,<sup>39–40</sup> which also reported that cultural or religious beliefs were not a barrier to screening participation. Although in agreement with these findings, Padela *et al.*<sup>41</sup> noted that there was a fatalistic attitude related to negative religious coping, whereby individuals felt that health issues were a penance from God, which resulted in decreased willingness to undergo Pap testing. Therefore, while religious beliefs did not appear to influence acceptability of self-sampling, problems related to fear of the diagnosis should still be addressed when trying to implement self-administered cervicovaginal sampling. In this study, self-sampling was found to be a very acceptable tool even before it was carried out. The results also suggest that age and ethnicity are important predictors in this study to determine preference for self-sampling. When planning a community-based model for cervical cancer prevention, the involvement and proper management by the local government administration

and community leaders is vital for its success. This was exemplified in the work by 130 communities in China.<sup>42</sup> A similar approach should be considered so that the resources, planning and massive screening is carried out efficiently and successfully in Malaysia.

### Study strengths and limitations

One of the strengths of this study is its large sample size and the diversity of the population surveyed in terms of social and demographic characteristics. However, the findings might not accurately represent the whole Malaysian population because the participants mostly consist of women in urban areas from a developed state and not women in rural areas. Furthermore, the study population was recruited from women who came to the health centres, resulting in those unable to come because of logistical barriers being missed. Thus, the results represented women who had reasonable health-care access. Despite this, nearly 40% had not previously received a Pap test, indicating that access alone does not completely explain the poor screening participation rates in Malaysia. However, because of this design feature, further studies are needed to assess the attitudes of the rural Malaysian population towards self-administered cervicovaginal sampling and its acceptability, as this may represent one of the feasible alternatives to broad screening in remote areas. It is possible even with our findings in women who have access to health-care and hospitals that others in rural areas might not necessarily find self-sampling acceptable for different reasons such as traditional mind sets or cultural taboos.

### CONCLUSION

This study, which examined the acceptability of self-administered cervicovaginal sampling among Malaysian women, has shown encouraging results. Overall, Malaysian women from different backgrounds found the self-sampling method to be an acceptable alternative to traditional Pap smears, hence increasing the options for expanded cervical cancer prevention strategies in this population.

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