Optimising human papillomavirus self-testing for high risk women

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ABSTRACT

Objectives Human papillomavirus self-tests that can be used at home and returned by mail may increase cervical cancer screening rates. Growing evidence suggests that self-test methods could increase screening for high-risk and hard-to-reach populations. The purpose of this study was to identify which self-test device women prefer and why.

Methods Four focus groups were conducted with 30 high-risk women in two rural and two urban counties in North Carolina. Women evaluated three self-test devices: the Pantarhei screener (a lavage that releases liquid into the vagina and re-collects fluid), the Qiagen cervical brush (a brush that women insert into the vagina and is turned around to collect cells) and the Fournier cervical self-sampling device (a tampon-like plastic wand).

Results The majority of women reported that they would use the brush (70%), followed by the wand (67%) and the lavage (43%). Women from urban areas appeared to prefer the brush, whereas women from rural areas endorsed the wand. Women reported liking the lavage because it seemed easy to use; they liked the wand because of its inviting colour (green), and liked the brush because of its small size and familiarity. Women reported disliking the lavage because the liquid seemed messy and unsanitary, disliked the wand due to the 15—20 recommended turns, and disliked the brush because it was short and the tip seemed abrasive.

Conclusions No one device was perfect, although suggestions for an optimal self-test most resembled the brush. These findings can be used to develop an optimal self-test collector for women.

Human papillomavirus (HPV) is a common infection that can be spread by sexual contact. Persistent infection with oncogenic types of HPV infection can cause cervical cancer, which is a leading cause of death for women worldwide,[1] and is the fourth leading cause of cancer among women in the USA.[2] Globally, underserved and lower socioeconomic status populations bear the greatest burden of cervical cancer.[3] African-American women are 50% more likely to be diagnosed with cervical cancer and twice as likely to die from the disease as Caucasian women.[4–6] In addition, cervical cancer incidence and mortality for Hispanic women is higher than for non-Hispanic women in the USA.[5]

Although cervical cancer is largely preventable through regular pap smear screening,[7] more than half of women diagnosed with cervical cancer have had infrequent or no screening.[8 9] One way to increase screening for the risk of cervical cancer among women who seldom or never get pap tests is to offer self-collection tests to test HPV that women can use from home and return by mail. A self-collection test, or self-test, collects HPV DNA using a device such as a vaginal swab, cytobrush, or vaginal lavage. HPV DNA screening through self-collection methods has high sensitivity and specificity for the detection of high-grade cervical precancer.[10 11] The accuracy of the self-collection devices that our focus groups examined has also been shown to be acceptable: brush (sensitivity 82.5%, specificity 93.6%),[11] tampon (sensitivity 94%, specificity 81%),[12] and lavage (sensitivity 81%, specificity 68%).[13] Although numerous studies report that women find self-collection methods acceptable and prefer them to physician-administered tests,[13 14] self-tests are not widely used in the USA. More importantly, little is known about what characteristics of self-tests women prefer. The purpose of this study was to identify which of three HPV self-test devices women prefer and to understand why they prefer one over the other.

METHODS

Participants

A trained moderator and note-taker (ARR and AKL) conducted in-depth, semi-structured focus groups with women in North Carolina until saturation was reached (four groups). Women were recruited from the waiting rooms of two county health departments using non-probability quota sampling. The moderators conducted two focus groups in an urban county (Wake) and two focus groups in a rural county (Harnett). Participants were English-speaking women between 30 and 65 years old, who were not currently pregnant, and who did not have a hysterectomy. Therefore, they were women at risk of cervical cancer and eligible to use an HPV self-collection test.

Procedures

Focus groups were held in private rooms at county health departments. Women provided informed consent before the discussions. Each focus group lasted approximately 90 min and was audio-tape recorded. Women received a US$30 check card for participation.

The focus group topical guide reflected input from an expert panel of faculty from medicine, psychology and public health, public health students and a focus group expert. General areas explored in the topical guide included: first impressions and likes and dislikes of each self-test, ways to improve self-test instructions, exploring reasons why women may or may not want to use

each self-test, and overall preference of which self-test they think most women would use.

Participants handled and saw demonstrations of how to use the following three self-test devices (accompanied by user instructions): the Qiagen cervical brush (Qiagen, Valencia, CA; formerly Digene Corporation) is a brush that women insert into the vagina and turn around five times to collect cells; the Fournier cervical self sampling device (Bay Point Group (BPG, LLC), Miami, Florida, USA) is a tampon-like plastic wand with an ejectable tip, which women are recommended to turn around 15–20 times to collect cells; the Pantarhei screener (Pantarhei Devices BV, The Netherlands) acts as a lavage, releasing liquid into the vagina and collecting the fluid back into the device to collect cells. Pictures of each collector appear in figure 1.

Women saw each self-test and user instructions one at a time. Each focus group presented the devices in a different order to distribute the potential order effects equally. Women completed a nine-question anonymous paper survey after each focus group discussion. The paper survey allowed us to ask close-ended questions that did not lend themselves to the discussions including, 'would you use the collector?', 'which one would you prefer to use?', 'which device do you think most women would prefer to use'. The institutional review board of the University of North Carolina at Chapel Hill approved the study protocol and materials.

Data analysis

We used qualitative analysis techniques to analyse the focus group data, which included the focus group recordings, detailed observation notes taken during the sessions, and debriefing session notes. Coding allowed for data reduction and categorisation of data into themes. Analysts developed a coding template and added codes as they emerged. To ensure coding reliability, the first coder (ARR) performed all coding and consistency checks throughout the process, and a second coder (AKL) re-analysed 25% of the data. After coding, we conducted thematic and content analysis. We used Fisher's exact test to examine whether rural and urban women differed in their willingness to use the devices. Statistical analysis of quantitative data were two-tailed conducted using SPSS 17.0.

A.Digene Cervical Brush
B.Fournier Self Sampling Device
C.Pantarhei Sampler

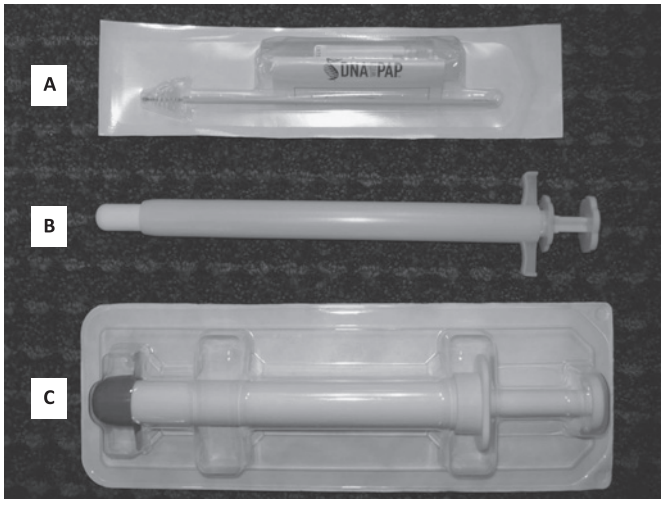

Figure 1 (A) Qiagen cervical brush. (B) Fournier cervical self sampling device. (C) Pantarhei screener.

RESULTS

Of the 30 women who participated in the focus group discussions, 66% were African American (n=20), 20% were Hispanic or Latina (n=6), and 13% were Caucasian (n=4). Approximately half of the women (47%, 14/30) were rural residents. All but one woman (97%, 29/30) said they had received pap smears in the past 4 years.

Paper survey

Most women believed that the self-test would work to prevent cervical cancer (87%, 26/30). When asked about one device at a time, most women reported that they would use the brush (70%) or the wand (67%) for home HPV self-testing. Fewer said they would use the lavage (43%) (table 1). More women from urban areas reported willingness to use the brush (87%), and more women from rural areas were willing to use the plastic wand (100%). However, even upon endorsing the use of the brush, two women listed contingencies indicating that they would use the brush 'if the tip was changed', and one woman indicated that she would use the wand 'if the collection did not require turning 20 times'.

When asked to choose among the three devices, women preferred the brush (60%) (table 2). Fewer women chose the lavage (17%) or the wand (20%). When asked, 'which device do you think most women would prefer to use', the majority of women again chose the brush (60%). One woman noted that neither she nor other women would be likely to use any of the devices.

Focus group discussions

The devices presented below are in order from the most to the least preferred. For each device, we report women's general impressions, their interest in use and their reasons for and against use. Finally, we present women's reflections on which device they prefer after seeing all three devices.

Brush

Women's comments suggested that they preferred the brush. Upon seeing the brush, many women made positive comments: 'I like this one', 'I do too'. They liked its small size, that the bristles on the side of the brush were soft, that it seemed similar to something they had seen doctors use, and that they only have to turn the brush around five times to collect a cell sample (table 3). Commenting on characteristics that they did not like about the brush, almost all women thought the tip of the brush would be painful, commented that it may cause bleeding, or said that the sharp point on the end might hurt them. Some women thought that it was too small and fragile, and many women were concerned that part of the brush might 'pop off' inside their vagina while in use. Women described the brush as a 'toothpick', 'an arrow' and '…like the straws you stir your coffee with'.

Reasons provided for brush use included that it seemed simpler and similar to what a doctor currently uses, that it is not

Table 1 Willingness to use HPV self-test devices, when evaluated separately

	Overall (n=30) (%)	Urban (n=16) (%)	Rural (n=14) (%)	p Value
Brush	70	87	50	<0.05
Wand	67	37	100	<0.001
Lavage	43	31	57	0.27

Three women spontaneously noted 'maybe' when asked whether they were willing to use the wand self-test, and were grouped with the 'no' category.
HPV, human papillomavirus.

Table 2 Willingness to use HPV self-test devices when evaluated at the same time

	Overall (n=30) (%)	Urban (n=16) (%)	Rural (n=14) (%)
Which device would you prefer to use?			
Brush	60	81	36
Wand	20	6	36
Lavage	17	6	28
I would not use any of them	3	6	0
Which device do you think most women would prefer to use?			
Brush	60	69	50
Checked both brush and wand	7	13	0
Wand	17	13	21
Lavage	13	0	29
I don't think most women would use any of them	3	6	0

Percentages may not sum to 100% due to rounding.
HPV, human papillomavirus.

so intimidating, and that it seemed sterile and uncomplicated. Reasons for non-use included that the tip looked painful and that it was flimsy, and many reported that they would use it if the tip were changed to a softer material.

Wand

Women's comments were evenly split in terms of likes and dislikes of the wand (table 3). Women thought that the plastic wand seemed simple and liked that it resembled both creams for vaginal infections and that it looked like a tampon, whereas others felt that it was complicated, that there seemed to be a lot of steps involved, and that it resembled a toy, namely a 'glow stick'. Another example of the contradictory nature of the perception of the wand is demonstrated in this woman's perception of its size, 'It's a little smaller than the other ones, but still intimidating a little'. Women voiced similar mixed thoughts about the appearance of the wand and the pain that the collector might cause. One perception that was shared unanimously throughout the focus groups was dislike of the mechanism of action recommendations, specifically that once inserted into the vagina, the wand needed to be turned 15–20 times to collect a cell sample. The 15–20 turns elicited laughter and overall discontentment with the collection instructions.

Reasons provided for wand use included that it seemed easy and that they liked the colour, whereas reasons provided for non-use included the 15–20 turns required and the length of the collector. Notably, one of the focus groups conducted in an urban county could not come up with any reasons that women may want to use it.

Lavage

Of the three self-test devices, women liked the lavage least. When queried on what they liked about it, women reported that it seemed easy to use and appeared that it would work well. A few women liked that the directions stated that the liquid inside was sterile and sanitary. However, most women disliked the lavage for the following reasons: it seemed messy; the liquid did not seem sterile; it was too big; it was not flexible; it seemed complicated; the appearance was off-putting and it seemed inaccurate (some speculated that it may not collect enough cells to test for HPV). The majority of comments centred around not liking the liquid in terms of its messiness, and many were concerned that the 'water' may not be sterile. Two women commented that companies may put something in the liquid that might inadvertently hurt women. In one focus group, the sight of the lavage sent the group into uncontrollable laughter at how big it appeared, and referred to it as 'a bike pump', 'a sex toy' and 'a turkey baster'.

Reasons provided for lavage use included that it was easy, seemed clean, and offered a familiar concept to douching. When asked, 'what are some reasons why women may or may not want to use it', again there were many more reasons provided for non-use of the lavage device, including the size (too big), the appearance, the messiness of the liquid, and the mechanism of action was intimidating with the suction function. Women wanted the appearance of the device changed including the white colour: 'soften it up so it's not so intimidating'.

Preference for device

After observing the characteristics of all three devices, women were asked which device they thought women would like better and why. Both urban and one rural county focus group endorsed the brush, because it seemed simple and easy, less invasive, and that it looked familiar to something the doctor uses. One rural county focus group most preferred the wand based solely on its appearance.

Although women most preferred the brush, they had several suggestions for improvements. Suggestions included: (1) change the tip to something softer or include more bristles at the top; (2) make the shaft a little thicker but not as thick as the other two devices; (3) develop a handle for the brush, creating a 'grip tip' to hold on to when turning the brush around; and (4) indicate on the brush where to stop when inserting into the vagina to prevent women from pushing the brush too far into the vagina.

DISCUSSION

It is important to note that of the three self-test devices, not one device was perfect as women made many suggestions for improvements. Overall, women liked the brush the most and the lavage the least. Women in this study desired a self-test brush that is easy to use, has a soft tip for cell collection, and is not too big, but also not too small or flimsy that it might break during use. In addition, they preferred an inviting colour that is not so vivid that it resembles a toy.

The strengths of this study include the focus group study design that allowed for an in-depth discussion of the devices and a chance for participants to see, hear and touch the three devices. The focus group setting made it possible to clarify responses and to probe for more information if needed. In addition, our sample size of 30 provided a reasonable number of women in which saturation could be reached. A limitation of this study is that, although women viewed and handled the devices, they did not actually use the devices to collect cervicovaginal cells. Our study would have been stronger if participants had been able to use the devices. However, motivation for use begins with first impressions. If a woman did not like the device upon first seeing it, it is unlikely that she would use it. Other limitations of this study include that the participants are not representative of the population and that our results are not generalisable. Like most qualitative research, the generalisability of our findings to other women in North Carolina or in the USA is not established by our study. Our present results are further limited to women's perceptions of each self-test device, rather than actual comparisons of self-test performance for the detection of high-grade cervical neoplasia or the optimal collection of cervicovaginal exfoliated cells. In addition, these results are among women who reported screening within the past 4 years and

Table 3 Major themes about likes and dislikes of three self-test devices

Device	Theme	Favourable quote	Unfavourable quote
Brush	Ease of use	'You only have to turn it five times.' 'It's easier.'	—
	Size	'I like that it's small.'	'I would like the handle to be a little longer.'
	Soft/painful	'The bristles are soft.'	'The tip is hard. It might hurt' 'It looks painful.' 'I would feel using that, myself is cutting my cervix to pieces. Am I going to cut myself?'
	Familiar/comfortable	'It's very similar to the brush that doctors use now to do the pap smear.' 'This looks familiar. It's similar to something that I've seen' 'I feel more comfortable using it. I like it.'	—
	Fragile	—	'It's flimsy.' 'That wire won't break off up in nobody will it?'
Plastic wand	Ease of use/Familiar	'It's kind of like a tampon, I already like it.' 'Simple, like using Monistat.'	'Seems like a lot of work.' 'Seems like there are a lot of steps involved.'
	Size	'It's not too big.' 'The shape is pleasing.'	'I don't like the size of it.' 'It's long… cut the tube down.' 'I wouldn't… I mean because I don't use tampons, and it's too long. I would be more comfortable with the brush.'
	Mechanism of Action	—	'No one is going to sit there and do that for 20 turns. They are going to tell you that they did it for 15—20 turns, but no one is going to actually do it for that many turns'
	Appearance	'The colour does make it very inviting… just the colour itself.' 'I like the color'	'That just doesn't even look right.' 'Now we see why they revamped the Monastat.'
	Discomfort	'It doesn't look too painful.'	'This one seems like it may hurt a little more because you are leaving it in longer and turning it.'
Lavage	Easy of use	'…looks easier to handle.' 'This one seems a little bit easier.' 'The directions were so easy that anybody could understand… how to use it.' 'I think it's a simple device.'	'…seems more complicated. I'm having to read the direction again just to make sure I would do that correctly.' '[comment in regards to written instructions for use where the self-test user is asked to lay down on the bed before inserting the device] You have to lay down on the bed to do this one with your legs up. You might as well come to the doctor.'
	Size	—	'It's too big.' 'It's too thick.' 'Make it skinnier.' 'There are some people who do not use tampons and they might not do this.'
	Sterility	'Where it says the sterile liquid, that kind of brings you piece of mind.' 'It looks more sanitary.'	'…to me it's not just water.' 'Is it really water?' 'How is that liquid going to stay sterile?'
	Mechanism of action	'To me, it's like a douche' [indicating approval]	'To me, it's like a douche' [indicating disapproval] 'I mean I'll try it and if I don't feel the suction. I'm all for it, but I do feel a lot of things down there and I do feel in my mind that I'm gonna feel… that I'm not going to like it.' 'I don't like the suction part idea either.' 'It's kind of messy'
	Appearance	—	'It does look kinda big and it reminds me of some kind of sex toy.' 'Overall the look is ugly.' 'It's too manly.' 'It reminds me of a turkey baster.' 'Looks like a douche.' 'Looks like a bike pump.' 'I don't like it at all.'
	Inaccurate	—	'…that's my concern, the accuracy.'
	Not flexible	—	'…feels more plastic, more harder.'

therefore work needs to be done among women who have not been screened regularly or at all. Finally, women in this study compared all three devices, whereas in a more typical situation they may have only been provided with exposure to one self-collection device. Therefore, it is possible that women might view some of the devices more favourably when seen in isolation than as a group.

A systematic review of 25 studies of HPV DNA self-collection found that women have been successful in collecting self-test samples, found self-testing acceptable, and reported self-sampling as a positive experience.[15] Furthermore, the quality of biological samples was generally similar to that of clinician-assisted sampling.[15] However, women in a previous study that focused on specific devices found a lavage to be difficult to use and questioned its overall efficacy.[16] Although women in our study did not have the opportunity to use the lavage, they also questioned its ease of use as well as its accuracy. In fact, our study found that women generally disliked the lavage compared with the other devices. Women in a study among Muslim women in London also preferred the swab over the lavage.[17] In another study conducted in the USA,[18] women expressed concern over the use of the swab, in particular they were afraid that the swab might break while in use. This concern was similar to those voiced about the brush in our focus group discussions.

Whereas we found evidence to support the projected use of self-test methods for the collection of HPV DNA, it is especially important that women tended to prefer the self-test over the pap test in other studies.[13—15 19—24] Together, these findings point towards HPV DNA self-testing as a feasible strategy to increase screening among women. Although a feasible screening strategy, another important point is that women had suggestions for improvements for all devices they saw and therefore no

Key messages

- HPV DNA self-testing may be a feasible strategy to increase screening among women.
- Of the three self-testing devices evaluated, no one device was perfect, although suggestions for an optimal self-test most resembled the brush.
- Developing optimal self-test devices that women prefer and enjoy using may increase HPV screening, identify women's HPV positivity and associated treatment for high-risk populations.

one device was found to be ideal. Suggestions of improvements from this study and others like it could be used to develop an optimal self-test device for women.

Although the preference for lavage did not vary by geographical location in our study, preference for the brush and wand did, with more rural women endorsing the wand and more urban women endorsing the brush. This finding is important and should be explored further. There is growing evidence that self-test methods of screening may work for high-risk hard-to-reach populations such as minority, foreign-born and medically underserved women.[25] Identifying self-test device preference and tailoring accordingly may be a necessary and advantageous step in an effort to increase screening and thus decrease cervical cancer rates among high-risk populations. Self-test device preference may vary on a whole host of demographic characteristics such as geographical place of residence (rural/urban), ethnicity and cultural background, which may need to be considered when tailoring devices to maximise uptake among certain populations. Future formative research should focus on the development of optimal self-test devices for these populations.

Our findings have implications not only for HPV self-test screening, but also broader implications for other self-testing methods. Self-tests for home screening have been developed for other sexually transmitted infections such as chlamydia, gonorrhoea and HIV. Home tests have increased screening utilisation for chlamydia and gonorrhoea.[26] Developing optimal self-test devices that women prefer and enjoy using may increase HPV screening, identify women's HPV positivity, encourage referral to cytological screening and associated treatment for high-risk populations. Priorities for future research include: (1) to understand better the differences in self-test device preference among varying populations in an effort to increase screening rates among high-risk groups; (2) the development of a larger study in which women have a chance to use the devices and assess their experiences in doing so; and (3) continued exploration of new self-collection methods that may increase screening for other sexually transmitted infections or pertinent health measures.

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Competing interests None declared.

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Contributors ARR and NTB collaborated in the writing of the manuscript. ARR, NTB, AKL, ACR and JSS were involved in the design and development of the study. ARR was the focus group moderator and AKL was the note-taker. ARR and AKL conducted the data analysis. JSS and NTB edited the manuscript before submission and offered helpful revisions and additions. All authors had full access to all of the data in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

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