Health Care Personnel's Perspectives on Human Papillomavirus (HPV) Self-Sampling for Cervical Cancer Screening: A Pre-Implementation, Qualitative Study

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Abstract

Background: Persistent infection with high-risk human papillomavirus (hrHPV) types are well-documented causes of cervical cancer. Since the implementation of cervical cancer screening methods (e.g., Pap tests), cervical cancer rates have declined. However, Pap tests are still unacceptable to many women and require complex infrastructure and training. Self-sampling techniques for collecting HPV specimens (or "HPV self-sampling") have been proposed as a possible alternative to overcome these barriers. The objective of this study was to understand various health care personnel's perspectives on the potential implementation of an HPV self-sampling practice in US primary care settings.

Methods: Between May – July 2021, a study invitation was emailed to various health care professional networks across the Midwest, including a snowball sampling of these networks. Eligible participants were invited to a 45-60 minute Zoom-recorded interview session and asked to complete a pre-interview survey. The survey collected sociodemographics on age, occupation, level of educational attainment, race/ethnicity, gender, and an awareness of HPV self-sampling. The semi-structured interview was guided by the Consolidated Framework for Implementation Research and asked participants about their views on HPV self-sampling and its potential implementation. All interviews were audio-recorded, transcribed, and analyzed using NVivo 12.

Results: Key informant interviews were conducted with thirty health care professionals - 13 health care providers, 6 clinic staff, and 11 health care leaders - from various health care systems. Most participants had not heard of HPV self-sampling but reported a general enthusiasm for wanting to implement it as an alternative cervical cancer screening tool. Possible barriers to implementation were knowledge of clinical evidence and ease of integration into existing clinic workflows. Potential facilitators included previous adoption of similar self-sampling tools (e.g., stool-based testing kits) and key decision-makers.

Conclusion: Although support for HPV self-sampling is growing, its intervention's characteristics (e.g., advantages, adaptability) and the evidence of its clinical efficacy and feasibility needs to be better disseminated across US primary care settings and its potential adopters. Future research is also needed to support the integration of HPV self-sampling within various delivery modalities (mail-based vs. clinic-based).

Contributions To The Literature

- This novel study captures perspectives from health care professionals on the probable implementation of an HPV self-sampling practice.
- Several perceived multilevel barriers to HPV self-sampling were noted, including: (1) at the institutional level, the need for additional clinic resources and education; (2) at the patient level, ensuring the validity of self-collected samples; and (3) at the test level, the variability of test kits which could induce user error.
- While support for HPV self-sampling among health care personnel is growing, additional efforts are needed to disseminate the clinical efficacy and feasibility of this new screening tool in US primary care settings.

Introduction

Persistent infections with high-risk human papillomavirus (HPV) types (e.g., 16, 18) are well-documented causes of cervical cancer.[1] In 2021, an estimated 14,480 new cases of cervical cancer occurred in the United States[2], resulting in health care costs associated with testing, treatment, and management of cervical malignancies.[3] As

the second-highest annual medical expenditure for U.S. women ($37.7 billion)[4], wide-ranging public health efforts must be employed to address the burden of cervical cancer. Since the implementation of cervical cancer screening (CCS) methods, such as cervical cytology (or “Pap test”), cervical cancer rates have markedly declined.[5–7] Yet, Pap tests are still unacceptable to many women, impose high operational costs, and require complex infrastructure and training.[7–9]

Self-sampling techniques for the collection of HPV specimens have been proposed as an acceptable and effective alternative to overcome some of these barriers.[10–16] Empirical studies examining the efficacy of HPV self-sampling have shown significant improvements in cervical cancer screening rates among women.[12, 17–19] In countries with organized cervical cancer screening programs (e.g., Great Britain), HPV self-sampling has already been employed as an adjunct strategy for increasing primary cervical cancer screening.[20, 21] HPV self-sampling has been shown to be effective in reaching women who otherwise delay or opt-out of cervical cancer screening.[22–25] In studies examining acceptability and preference, many women report a high acceptability of self-collected HPV tests, and in some cases, women indicated a higher preference for self-collected HPV tests than provider-collected tests.[26–29] Multiple cost-effectiveness analyses have also found that self-collected HPV testing had a lower lifetime cost and a higher quality-adjusted life expectancy than Pap test screening.[30–32] These findings suggest that HPV self-sampling is a potentially cost-saving and effective strategy to increase cervical cancer screening among women who may not readily undergo routine Pap tests. However, most research in this area has focused on mail-based self-sampling kits[20–24, 33], and an untapped opportunity exists to utilize clinic-based HPV self-sampling in health care systems.[34] Providing clinic-based HPV self-sampling may help resolve common issues related to the mailing of samples (e.g., missing samples) and patients’ questions around how to conduct the self-collection (e.g., visual tutorials provided by clinic staff).

Currently, the United States Preventive Services Task Force (USPSTF) recommends three cervical cancer screening options for women ages 30–65 based on clinic-based and clinician-obtained samples: 1) cervical cytology every 3 years or 2) a high-risk human papillomavirus (hrHPV) test every 5 years or 3) a hrHPV testing in combination with cervical cytology (co-testing) every 5 years.[35] Notably, the USPSTF recommendation for hrHPV testing (primary HPV testing) was approved in 2018, with a recent similar guideline adoption by the American Cancer Society (ACS) in 2020.[36] Primary HPV testing is increasingly being incorporated into screening and follow-up guidelines for cervical cancer.[37] Nevertheless, health systems still experience slow adoption of primary HPV testing due to the recency of approved evidence-based guidelines.[38]

To date, no pre-planning or pre-implementation study has been conducted to assess if HPV self-sampling – whether as a mail-based or clinic-based practice – can be used to facilitate primary HPV testing in the US. Guided by the Consolidated Framework for Implementation Research (CFIR)[39], this qualitative study aimed to describe perspectives of health systems leaders, primary care clinicians, and clinic staff on the potential implementation of an HPV self-sampling practice in primary care clinics.

Methods

Study population and procedures

Health care professionals across three personnel types – health systems leaders, providers, and clinic/lab staff – were recruited and interviewed for the study. Health systems leaders included individuals who were medical directors and operating officers embedded within a health system. Providers included primary care clinicians,

general medical practitioners, obstetrics/gynecologists, nurse practitioners, and physician assistants employed in primary care settings. Clinic and/or lab staff included lab staff, nursing staff, and community health workers embedded within a primary care setting. A study invitation was emailed to the listserv of the health care professional networks across the Midwest. The email invitation included information on the study, motivation of the research team, and compensation for completing the interview. Some participants were also identified and recruited through snowball sampling. All participants were required to meet the following eligibility criteria: 1) read and write in English; 2) be 21 years or older; and 3)currently employed in a health care system or primary care setting. All interviews were video recorded along with field notes and conducted over Zoom over 45–60 minutes with one or two female research team members (FH, RP, SX). Before each interview, verbal consent was obtained from all participating individuals. All participants were compensated with a mailed $50 gift card.

Study measures and interview guide

All participants completed a short survey prior to their interviews. The survey, administered online through Qualtrics, assessed age, occupation, level of educational attainment, race/ethnicity, gender, and an awareness of HPV self-sampling (yes/no). The semi-structured interview guide was organized by three CFIR domains: intervention characteristics, inner setting, and process (Table 1). Questions around the intervention characteristics were intended to capture health care personnel's perceptions (e.g., advantages, adaptability, barriers) of HPV self-sampling. Potential implementation considerations were covered with questions in the latter two domains (inner setting, process). Before study recruitment, the interview guide was pilot tested with two primary care providers (not included in the study sample). All study protocols and materials were submitted for IRB approval and deemed exempt.

Table 1
Key informant interview guide and questions mapped onto CFIR domains.

CFIR DOMAIN(S)	Core Questions	Prompts
INTERVENTION CHARACTERISTICS – Evidence Strength & Quality; Relative Advantage	1. What are your views on using self-collected HPV testing as a potential option for cervical cancer screening?	Would you like to have it as an option you could offer patients? Why or why not? Do you see any other particular advantages or disadvantages to HPV self-sampling?
INTERVENTION CHARACTERISTICS – Evidence Strength & Quality; Relative Advantage	2. In your view, what do you think patients would think of self-collected HPV testing as an option for cervical cancer screening?	What about the patients who participate less?
INTERVENTION CHARACTERISTICS – Adaptability	3. Do you think a mailed HPV self-sampling intervention would work within the context of your clinical setting? Why or why not?	What kinds of changes or alterations do you think will need to be made to mailed HPV self-sampling so that it will work effectively in your setting?
INTERVENTION CHARACTERISTICS – Adaptability	4. HPV self-sampling could also be completed in the clinic during a clinic visit. Do you think an in-clinic HPV self-sampling intervention would work within the context of your clinical setting? Why or why not?	What kinds of changes do you think will need to be made to clinic-based HPV self-sampling so that it will work effectively in your setting?
INNER SETTING – HPV Self-Sampling Awareness	5. Have you heard about self-collected HPV testing as an option for cervical cancer screening?	
INNER SETTING – Implementation Climate **(Subconstruct - Compatibility)**	6. How well would a mail-based HPV self-sampling intervention fit with existing work processes and practices in your setting?	Can you describe how mail-based HPV self-sampling would best be integrated into current processes?
INNER SETTING – Implementation Climate **(Subconstruct - Compatibility)**	7. How well would a clinic-based HPV self-sampling intervention fit with existing work processes and practices in your setting?	Can you describe how clinic-based HPV self-sampling would best be integrated into current processes?
INNER SETTING – Readiness for Implementation **(Subconstruct - Access to Knowledge & Information)**	8. What kind of information do you think decision makers would need if they were to consider implementing HPV self-sampling?	
PROCESS – Engaging **(Subconstruct - Opinion Leaders)**	9. Who are the key decision makers that would influence if HPV self-sampling would be used in your clinical context?	Do you know if your health system has discussed adopting this new method for cervical cancer screening? Why or why not?

Data analysis

Two researchers (NA, SX), both trained by a qualitative research expert (RP), independently coded a subset (10) of the interview transcripts. They double-coded the data to ensure consistency, then met to discuss, review, and adjudicate any differences in coding. Coding differences were resolved through reviewing the data and developing a

consensus on the central themes. A social constructivist grounded theory approach was used to identify meta-themes, themes and subthemes in the data, allowing for the emergent findings to be loosely situated in the CFIR framework.[40, 41] Although the CFIR was used as a guiding framework, every attempt was made to retain the subjective meaning expressed by the respondents in the presentation of the study results. Ongoing discussions and consensus decision-making regarding the organizing codebook within the research team validated the rigor of the qualitative analysis. All interview data were organized, managed, and coded using NVivo 12 software.[42]

Results

Participants

Thirteen health care providers (n = 13, 43.3%), six clinic/lab staff (n = 6, 20.0%), and eleven health care leaders (n = 11, 36.7%) participated in the interviews (Table 2). The majority of participants were aged 40 and older (n = 19, 63.3%), non-Hispanic White (n = 25, 83.3%), female (n = 27, 90.0%), college-educated (n = 28, 93.3%), and had never heard of HPV self-sampling (n = 17, 56.6%). Most health care providers worked in an academic health center, whereas clinic/lab staff worked in community health centers, and health care leaders were predominantly from managed care organizations (e.g., payors, health plans).

Table 2
Study Participant Demographics (N = 30)

Sociodemographic Variables	Health Care Providers N = 13 n (%)	Clinic/Lab Staff N = 6 n (%)	Health Care Leaders* N = 11 n (%)	Total Sample N = 30 n (%)
Age Range	–	1 (16.7)	–	1 (3.3)
18–29	3 (23.1)	3 (50.0)	1 (9.1)	7 (23.3)
30–39	7 (53.8)	1 (16.7)	6 (54.5)	14 (46.7)
40–49	2 (15.4)	–	1 (9.1)	3 (10.0)
50–59	1 (7.7)	1 (16.7)	–	2 (6.7)
60+				
Race/Ethnicity	12 (92.3)	3 (50.0)	10 (90.9)	25 (83.3)
Non-Hispanic White	1 (7.7)	1 (16.7)	–	2 (6.7)
Black/African-American	–	2 (33.3)	–	2 (6.7)
Asian	–	–	1 (9.1)	1 (3.3)
Hispanic	–	–	–	–
Other				
Gender	11 (84.6)	6 (100.0)	10 (90.9)	27 (90.0)
Female				
Health System Type	6 (46.1)	2 (33.3)	1 (9.1)	9 (30.0)
Academic Health Center	4 (30.8)	4 (66.7)	3 (27.3)	11 (36.7)
Community Health Center	3 (23.1)	–	1 (9.1)	4 (13.3)
Hospital-based System	–	–	6 (54.5)	6 (20.0)
Managed Care Organization				
Highest Level of Education	13 (100.0)	4 (66.7)	11 (100.0)	28 (93.3)
College Graduate				
HPV Self-Sampling Awareness	3 (23.1%)	6 (100.0)	8 (72.7)	17 (56.7)
No				

*Age data were not available for three health care leader respondents.

Intervention characteristics – relative advantages of HPV self-sampling

Compared to traditional cervical cancer screening (CCS) methods, participants reported many important potential advantages to offering HPV self-sampling within health care systems. At the institutional level, these benefits included increased reach and follow-up, especially among those who are traditionally underscreened due to personal barriers, such as limited English proficiency, low health literacy, and/or financial and structural barriers.

"From a total population health management standpoint, it would have some advantages, especially when it's targeted to groups with lower rates, in particular certain racial/ethnic minority groups or patients in specific demographics of gender minority, and patients who have the history of trauma who don't feel comfortable with the [Pap test] procedure, but would feel comfortable with a tampon-like self-collection modality. In all likelihood, I think that it [HPV self-sampling] would be really high yield." (Leader)

Several respondents also perceived HPV self-sampling to be an important trauma-informed CCS tool, given the full control patients would be able to have over their own screening experiences.

Meanwhile, at the provider level, reducing stress and saving clinicians more time to conduct other clinical interactions were the most important advantages.

"*As the provider, I don't like having to do some exams, if I don't need to because it does take a lot of time to set up. It would be really nice to just be able to [have the patient] come in and do everything they needed to do."* (Provider)

Respondents also reported perceived personal and procedural advantages to HPV self-sampling at the patient-level. The most commonly cited personal advantages were ease of use, efficiency (not needing a provider to initiate the collection), comfort, privacy, and cost-saving. Some provider participants also perceived that HPV self-sampling could help to empower and cultivate patient's interest and proaction in their own health.

"When somebody gets a screening result that says it's abnormal, that [could help them see that] they could be at higher risk [for the disease], so in that moment then their readiness to do a more invasive procedure is higher." (Leader)

Some respondents, moreover, discussed significant procedural advantages to the self-sampling approach, such as its ability to mitigate invasiveness and pain, and reduce time and burden for both patients and providers.

Intervention characteristics – adaptability (e.g., advantages of mail-based vs. clinic-based approaches)

Specific advantages to the adaptability of HPV self-sampling – either within the context of a mailed-based approach or a clinic-based approach – were also reported. The most important advantage to the mail-based approach was that it would be relatively easy to be integrated into existing workflows, but only if the implementing health care system has experience and success with past mailed campaigns and interventions.

"We have in the past done some panel management where we're going through and see where people are due for various things and then do a phone and mail outreach to try to get people to come in, etc. I could see that we could easily pull patients who are eligible or due for cervical cancer screening and mail them kits." (Leader)

Due to the recent COVID-19 pandemic, many health care systems had also pivoted to providing virtual care and telemedicine to their patients. Nearly all participants reported that their patient portals and electronic medical record (EMR) databases had been strengthened as a result. They noted that mailing HPV self-sampling kits would

complement the telehealth services they were already offering to patients; the adoption of the mail-based approach, they perceived, would be ideal and feasible because it was leveraging an already extant infrastructure.

In contrast, the biggest advantage to offering clinic-based HPV self-sampling is its opportunistic nature – that is, allowing patients who are already coming into the clinic for other preventive care needs (e.g., a sore throat or flu shot) to simultaneously complete or take a self-sampling test kit home with them. Respondents working in health systems, where particular mailed campaigns have not been successful with certain patient populations (e.g., highly-mobile), were most enthusiastic about this approach. Several provider participants shared that the clinic-based approach would ease some of their concerns around not having in-person/physical visits if the mail-based approach was instituted. They also noted that if any patient concerns around the self-collection arose at the clinic, they could address, advise, and troubleshoot those concerns in a timelier fashion.

"It would be better if it's done in the clinic where somebody can be there and support it, and answer any questions – until women kind of get to the point where they have confidence and do it themselves." (Provider)

Additionally, the adoption of the clinic-based approach into existing workflows was perceived to be practical - as some clinicians stated, it would be similar to instituting lab orders (e.g., urine samples, blood draws) and could be completed within one clinic visit.

"If you're able to have lab staff do it, then the patient could come in anytime. And just like a urine sample. They could just go into the bathroom, do it, and then drop it off." (Lab staff)

Inner setting – implementation climate

Awareness of HPV self-sampling

An overwhelming majority of respondents had not heard of HPV self-sampling. Once it was described, many of them perceived the tool favorably, particularly its potential to narrow racial and ethnic disparities in cervical cancer screening, and were excited to support the integration of it into their practices and health plans. Some providers also viewed HPV self-sampling as an alternative to traditional CCS tools; however, they did not perceive it as a primary screening tool.

"I think an all-in approach is necessary to address some of these disparities and to have that [HPV self-sampling] as another tool, so that when somebody you know at the point of care, declines a Pap test, they can have another option." (Provider)

Despite the low level of awareness, a handful of providers had heard of HPV self-sampling and were already piloting the tool within their practices. Those who were piloting these services also reported positive support and satisfaction from many of their patients.

Barriers to HPV self-sampling

Most participants supported HPV self-sampling; however, many of them had reservations about the challenges to its implementation. These barriers were identified at the institutional, patient, and test levels. At the institutional level, the following challenges were noted: (1) need for additional clinic resources (including the need to support follow-up care), (2) need for additional education of both providers and patients; (3) availability of test-kits; (4) disruption to clinic workflows; (5) interference with existing preventive care and routine practices; (6) disjointed labs and clinics;

(7) lack of telehealth services; (8) perceived lack of CCS rates and performances from partners and competitors; and (9) negative past experiences with self-testing interventions.

At the patient-level, the most commonly perceived barrier was the accuracy of self-collection. Several provider participants shared that patients' perceptions and abilities to collect viable samples for HPV testing could be a potential hurdle to taking up HPV self-sampling effectively. They worried that (1) patients may believe that their self-collected samples will not be as sufficient or valid as a clinician-collected sample, preventing them from actually initiating the self-collection (perception); and (2) that patients may not be able to perform the self-collection accurately, resulting in samples that would not be conducive for analysis (ability).

The most important contributing factor to a patient's ability to self-collect, as reported by health care personnel participants, was their self-efficacy – that is, having sufficient confidence, training/education, and comfort to collect a sample on their own even under constraints.

"I think all women will have varying degrees of feeling comfortable with swabbing themselves. I could see people struggling with tampons, so I can see that being a challenge. I think just offering support and saying you don't have to do this. This is just an option that we have now, and I can walk you through it, and you can try it out and I'm here to help you with it. I think that [support] could be really helpful, particularly the guidance of it." (Leader)

Most respondents believed that if patients were not trained to develop this individual capacity, they would likely not take up HPV self-sampling. Language was also a reported barrier to establishing self-efficacy within patients. Provider participants shared that if multilingual educational resources around HPV self-sampling were not available, racial/ethnic groups could be disproportionately served. A few respondents suggested that having community health workers to assist and provide tutorials on the self-collection process can help mitigate this issue.

"*I think many of my BIPOC patients would be all for it but with the language barrier there's just a need for a lot of continuing education. But once the idea is there, that you could just do HPV screening, it'll be good."* (Provider)

"*If someone did self-sampling a number of times and they felt comfortable doing it, you know, another thing we could even explore is a community health worker bringing it to somebody at their homes having them do it, and being kind of like on site and then taking it back, that might be another effective way of doing it as well."* (Leader)

Several provider participants shared that older patients may be more resistant to HPV self-sampling – as it would require more training, counseling and buy-in to get them onboard with this tool. They believed that younger patients would be more likely to adopt this tool as they were perceived to be more mobile, having more time constraints, and exhibiting lower learning curves. Some participants also mentioned that community support could be important to some racial and ethnic groups. For example, if some patients report positive attitudes and experiences with HPV self-sampling and share this information within their networks, other individuals within their communities may be more likely to initiate HPV self-sampling. Hence, a lack of community buy-in could be a potential barrier to widespread adoption.

"There's a lot of stigma for women who are getting/accessing health care services. Because of the different practices that happen in different communities, some women will rely on their peers, network to kind of inform her." (Leader)

Some participants also reported that HPV self-sampling may pose a challenge to patients with variable sexual anatomies, such as those with circumcisions and imperforate hymens. One provider respondent also shared that

HPV self-sampling may not be appropriate for patients with physical disabilities, as the self-collection does require physical functioning to perform and collect vaginal samples.

"I think about the mobility challenges potentially in someone who is postmenopausal with arthritis or other sorts of things that might make it more difficult for them to insert the swabbing." (Provider)

Some participants also perceived HPV self-sampling could create additional patient burden. For example, if some patients were already experiencing challenges with coming into the clinic and navigating health care services, they would be less likely to initiate HPV self-sampling as it would require additional effort.

"If a self-collection is going to not give us the cells and it has to be recollected then the patient is having to deal with that situation twice. So the disadvantage for that would be putting the patient in an even more uncomfortable position because now they're having to deal with two swabs instead of one." (Lab staff)

Several respondents additionally shared that it could be challenging to motivate patients, who have a strong reliance and trusted relationship with their provider, to initiate HPV self-sampling – as these types of patients would much rather defer to traditional CCS methods that require clinician-collected samples.

Test-level barriers

HPV self-sampling test kit characteristics were also noted as potential barriers to implementation. Provider participants were most concerned with the level of evidence around the validity of self-collected samples. Many respondents cited that if self-collected samples were not as valid as clinician-collected samples, they would not support the use of the tool.

Specifically, they had concerns about the possibility of self-collected samples creating false negatives and hesitancy around adopting HPV self-sampling if it had lower sensitivity than traditional CCS methods.

"I wonder about the technicality of the test as far as its specificity and sensitivity. Is it as good when done within certain parameters you know? That's one potential thing especially when it's rolled out." (Provider)

Similarly, many participants had strong reservations about the potential for high user error. Respondents shared that if the test kits were too complicated (containing too many steps, requiring too many instructions), the opportunity for patients to make missteps along this process would be manifold and could lead to incorrect or insufficient samples. They suggested simplifying self-collection instructions into digestible formats (videos/illustrations) and instituting some feedback mechanisms (between patients and providers) that appropriately identified correctly collected samples.

"It would be nice to have instructions in multiple languages, and maybe even the option of a video or a diagram. If there is like a contact person that could explain and just make sure that education is there, that would be helpful in supporting the patient." (Provider)

Other factors that could also contribute to user error included the types of self-collection instruments and their requirements for sample viability. The concerns raised by respondents about the collection instruments (e.g., lavage, brush) were based on their usability factors (i.e., perceived user-friendliness). Some participants believed that the lavage would be more difficult to use since it required several steps to collect and prepare a solution. Meanwhile, others thought that a brush could pose more challenges as it may feel more uncomfortable for some patients.

“I think a big barrier could be the brush. If a patient can’t tolerate a bigger brush, she might not do it. Maybe if there is a guided path brush that is flat, that might be easier to do.” (Provider)

Barriers to achieving sample viability were organized into two categories: (1) required composition of a viable sample, and (2) procedural requirements to maintain a viable sample. Many respondents inquired about the amount and types of cells (cervix only, cervicovaginal, or other) required for a sufficient sample.

“I do have some concerns with it. If it is a molecular test that doesn't require a lot of cells. But does it require the patient to get the swab on the cervix? My concern then is if the patient will be able to get it up that far by themselves to get the right type and amount of cells?” (Lab staff)

Regarding procedural requirements, several concerns were raised about the shelf-life and ability of test kits to maintain sample viability during transport. Specific transport barriers included the ability to protect the integrity of samples in extreme temperatures, prevent contamination, and/or be stored for an extended period of time before testing.

Several potential costs associated with the implementation of HPV self-sampling were also reported. These included (1) costs incurred from hiring additional personnel to support implementation and follow-up, and (2) HPV self-sampling test kits not being covered by programs like the National Breast and Cervical Cancer Early Detection Program or health plans. In addition to the costs, some regulatory challenges were also brought up. Provider participants, who were aware of HPV self-sampling, knew that the approach is not currently an approved standard of care; this regulation, they cited, remains the biggest barrier to integration. Other test-level concerns included the lack of FDA-approved HPV self-sampling tests and the potential for overtesting or overscreening in patient populations.

Specific barriers to mail-based vs. clinic-based HPV self-sampling

Specific challenges were also noted about the clinic- and mail-adapted HPV self-sampling approaches. Two barriers were identified for the clinic-based approach: (1) if health systems contained a policy that prevented onsite self-collection (e.g., exam rooms and bathrooms are not deemed sanitary); and (2) if no infrastructure is available to support onsite collection (e.g., curtains in exam rooms). In contrast, three specific barriers to the mail-based approach were identified by participants. The concerns included: costs, lack of privacy, and mailing logistics. Several respondents stated that if the mail-based approach is adopted, significant institutional funding would be required to coordinate mailing logistics and cover mailed kits (e.g., postage, envelopes). Another barrier to the mail-based approach is the lack of privacy within the homes of patients to perform the self-collection. Having no safe and privately available space for patients to conduct the self-collection may make it less likely that they complete the self-sampling. A few provider participants shared that the lack of resident/home privacy could also create a potential for patients to be stigmatized and shamed for sexual activity if people are able to identify that they were initiating HPV self-sampling (such as neighbors or parents opening the mailed test-kits of patients).

“Many people live in congregate or intergenerational households. Maybe with partners who may or may not always be supportive. So when the test gets sent out, is it confidential? Because even though it's a screening tool, somebody might think it's a pregnancy test or that there's something wrong that you've got an infection, which could cause stigma. These are potential unintended side effects of mailing and how confidential they are, especially for people that don't live by themselves or don't want anyone to know what they are doing.” (Provider)

Finally, many health care personnel discussed several challenges with the logistics of the mail-based approach (particularly within the context of past and unsuccessful mailed interventions). They shared that obtaining a consistent mailing address in highly mobile patient populations was often difficult. When test kits and clinic information were mailed to these patients, they had already moved, so the test kits were lost or returned to the clinic. In cases where mailed test kits did successfully reach patients, they were often misplaced or lost by patients. Overwhelmingly, many respondents did not support the idea of blindly mailing out HPV self-sampling test kits to patients.

Process – planning & engaging (e.g., decision-making)

Most respondents shared that their health systems operated on a hierarchical leadership model when it came to the process of approving and instituting a new EBP. Senior executive leaders – such as chief operating officers (COOs), chief medical officers (CMOs), chief health officers or clinic/unit/department managers – were frequently cited as the most important decision makers. These leaders were primarily responsible for packaging and presenting all the information (evidence, cost-effectiveness, feasibility, implementation guide) to health systems stakeholders about approving a new EBP. The curation of evidence for institutional approval often involved a collaborative effort between these leaders, their implementation staff, and payers. Implementation staff, identified as providers/clinicians, lab staff, and EMR personnel, were needed to provide insights and planning on the actual integration of the EBP. Meanwhile, health care personnel working within payor organizations, such as public health analysts and health plan/economic researchers, played an important role in building the business case (cost/benefits, setup of reimbursement rates) of the EBP. Once approval is secured, key implementation staff will lead the scale out of the EBP. Several respondents shared that the duration of approval to integration can range from half a year to as long as three years.

Readiness for implementation

Many participants shared that multiple sources of information and evidence were needed from senior health care leaders to package a convincing argument for the approval and adoption of HPV self-sampling. These included: whether the EBP has been adopted by their local competitors and/or partners; been shown to be cost-effective; demonstrated clinical efficacy, feasibility, and effectiveness; been adopted and recommended as a screening strategy by national clinical guidelines (such as American College of Obstetricians and Gynecologists, ACOG; American Society for Colposcopy and Cervical Pathology, ASCCP; American Society of Clinical Oncology, ASCO; United States Preventive Services Task Force, USPSTF) and local clinical guidelines; been approved by regulatory bodies (Clinical Laboratory Improvement Amendments, CLIA; US Food and Drug Administration, FDA); and been instituted into payment plans (Centers for Medicare & Medicaid Services, CMS) and clinic performance metrics (National Committee for Quality Assurance, NCQA; Healthcare Effectiveness Data and Information Set, HEDIS). One surprising and novel criterion that some health systems are considering as part of their approval package was if the EBP specifically focused on closing racial/ethnic disparities, that is, if the EBP had demonstrated efficacy in reducing disparities in care.

Discussion

This study provided an in-depth assessment into health care personnel's perspectives on HPV self-sampling, using CFIR to guide exploration of factors for its potential implementation within US primary care settings. These key informants identified numerous barriers and facilitators to the potential adoption of an HPV self-sampling practice. The barriers and facilitators related to a number of CFIR domains: intervention characteristics, inner setting, and

process. Of most salience to the pre-planning context of HPV self-sampling, however, was the intervention characteristics; the other domains were less present across all interviews.

As reported in the literature, multiple barriers to traditional Pap test screening exist. These include psychosocial issues such as embarrassment, pain and discomfort associated with a pelvic exam, and practical issues such as difficulty finding the time to have the test or an acceptable (e.g., gender-concordant) doctor.[43] Counter to the psychosocial and practical issues associated with Pap tests, HPV self-sampling was perceived by all health care personnel to be easier to use, more efficient, comfortable, private, and cost- and time-saving. Of most importance to health care personnel, was the tool's potential ability to increase reach, especially within underscreened populations, due to its perceived acceptability and decreased invasiveness. Many meta-analyses have demonstrated that HPV self-sampling effectively increases cervical cancer screening compliance in hard-to-reach populations.[44–46] The high acceptability and preference of self-collected HPV tests among women, further, have been well documented in many large randomized controlled trials.[22, 26, 27]

While health care personnel were enthusiastic about HPV self-sampling, they held reservations around how it should be implemented within health care systems. Most agreed that adapting it into a clinic-based or mail-based context would increase reach; however, they were less sure about implementing a combined approach and whether that would be most effective. As discussed by participants, several disadvantages and advantages existed within both delivery approaches. Implementation barriers to the mailed approach specifically included: (1) mailing and laboratory logistics (e.g., lost kits, privacy); (2) disruption to clinical workflows; (3) additional follow-up and lack of linkage to health systems (including follow-up care); and (4) extra costs. Most of these implementation issues are not new and have been consistently reported in HPV self-sampling intervention studies[47, 48] and other mailed, self-service testing models (e.g., HIV self-testing, mailed fecal immunochemical tests).[49–52]

In contrast, fewer implementation barriers to the clinic-based approach were noted, but those that were noted centered around the question of whether the health system had policies and infrastructures to support onsite self-collections. The lack of perceived barriers reported for this approach may be a function of the limited research on clinic-based HPV self-sampling. To date, only one pilot study (i.e., ROSE 1.0) has implemented HPV self-sampling onsite in a primary care setting.[34] The preliminary results of this study found that engagement, completion of HPV self-sampling and follow-up amongst women was high. The optimistic findings from this pilot study align with health care personnel's perceived advantages of the clinic-based approach, such as its ability to institute higher compliance, lower user error rates, and quicker turnaround time.

Regardless of the delivery approach, convincing decision-makers and developing acceptable implementation strategies within a health care system remain key to advancing the adoption of HPV self-sampling. The most salient adoption barrier amongst key decision makers was having sufficient information to build a compelling case for HPV self-sampling. As demonstrated in prior studies, key influencers' capacity to sell an intervention, provide support, spell out roles for key staff, and reflect on implementation progress are important for successful implementation.[53, 54] Information of most interest for key decision-makers included clinical efficacy (e.g., test characteristics of HPV self-sampling), feasibility, and effectiveness, and adoption and recommendation of HPV self-sampling as a screening strategy by both national and local clinical guidelines. With the increased movement at the federal level to reduce disparities in care[55], some key decision makers were also beginning to call for evidence of the intervention's impact to reduce racial/ethnic disparities. Strategies that tailor to these leaders, therefore, should be included in any implementation plan to integrate HPV self-sampling within health care systems.

When implementing a complex health care intervention like HPV self-sampling, it is important to understand and anticipate potential barriers and facilitators. As reported in a large, pragmatic mail-based HPV self-sampling trial in the US, several implementation issues were noted.[48] These included: complicated mailing and laboratory logistics; disruption to clinical workflow; and a lack of linkage to health systems (including follow-up care) – all of which are barriers also identified in this study. Conducting interviews with key stakeholders in a health care system prior to implementation and applying an implementation framework like the CFIR, can enable researchers and practitioners in health care systems to identify and plan for such contingencies that may affect the successful uptake of HPV self-sampling. Overall, these findings have the potential to inform future cervical cancer screening priorities and practices, as well as add to the emerging body of evidence that uses CFIR to examine pre-implementation processes.[56, 57]

Strengths and limitations

The strength of this study was the inclusion of various health care personnel to reveal several views. Use of the CFIR also helped to identify factors that could impede or facilitate the implementation success of an HPV self-sampling practice.[39] These results further contribute to the growing evidence and literature on CFIR applications within pre-implementation studies. This research also carried with it the limitations of qualitative research, including limited generalizability due to the selectivity of the sample and the limited number of interviewees. Using a semi-structured interview guide could have also introduced some investigator bias that may influence the data collection, analysis, and interpretation. To minimize this issue, the research team did conduct some respondent validation (i.e., member checking) of the results with a subset of interviewees through oral presentations.

Conclusion

Support for HPV self-sampling among health care personnel is growing; however, additional efforts are needed to disseminate the clinical efficacy and feasibility of this new screening tool in US primary care settings. Specific consideration around the intervention's characteristics, such as its relative advantage over other traditional CCS methods, its clinical evidence and feasibility, and adaptability may help to facilitate and speed up the application and adoption of HPV self-sampling. Further research is also needed to support the integration of HPV self-sampling within various delivery modalities (mail-based vs. clinic-based).

Abbreviations

ACOG
American College of Obstetricians and Gynecologists
ACIP
Advisory Committee on Immunization Practices
ACS
American Cancer Society
ASCCP
American Society for Colposcopy and Cervical Pathology
ASCO
American Society of Clinical Oncology
CCS
Cervical Cancer Screening

CDC
Centers for Disease Control and Prevention
CFIR
Consolidated Framework for Implementation Research
CLIA
Clinical Laboratory Improvement Amendments
CMO
Chief Medical Officer
CMS
Centers for Medicare & Medicaid Services
COO
Chief Operating Officers
COVID-19
Coronavirus Disease 2019
EMR
Electronic Medical Record
EBP
Evidence-Based Practice/Program/Policy
FDA
US Food and Drug Administration
FQHC
Federally-Qualified Health Center
HEDIS
Healthcare Effectiveness Data and Information Set
hrHPV
High-risk Human Papillomavirus
HPV
Human Papillomavirus
IRB
Institutional Review Board
NCQA
National Committee for Quality Assurance
USPSTF
United States Preventive Services Task Force

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

All authors have indicated they have no potential conflicts of interest todisclose.

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Authors' contributions

SX conceived of the idea for the study and oversaw the research. SX, RG, SK, DL, SM, and RP constructed and refined the study protocol. SX conducted, acquired, and managed the data. SX, FH, and NA were involved in the data collection and analysis. SX drafted, refined, and revised the manuscript, and is the guarantor of this paper. All authors, edited, read, and approved the final manuscript.

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