



## Integrating HPV self-collect into primary care to address cervical cancer screening disparities

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### ABSTRACT

Human papillomavirus (HPV) self-collect shows promise to increase cervical cancer screening rates in underscreened populations, such as Somali patients, but little is known about how to integrate such an approach in primary care. In this study, primary care providers and staff who provide primary care services to Somali women were asked for their views on integrating HPV self-collect into routine care to address cervical cancer screening disparities. Thirty primary care providers and staff participated in semi-structured interviews exploring their views on HPV self-collect and their anticipated needs or barriers to implementing this approach into the clinic generally and with specific patient populations, such as Somali women. A thematic analysis using the constructivist version of grounded theory was undertaken. Providers and staff anticipate positive patient reaction to the option of HPV self-collect, and were interested in using this approach both for Somali patients and for all patients in general. HPV self-collect was viewed as straightforward to integrate into existing clinic workflows. Providers largely lacked awareness of the evidence supporting primary HPV testing and HPV self-collect specifically, sharing concerns about effectiveness of self-collect and the lack of a physical exam. Providers felt clinic-wide staff education and patient education, along with strategies to address disparities, such as cultural and linguistic tailoring would be needed for successful implementation. Integrating HPV self-collect as an option in the cervical cancer screening process in a primary care clinical encounter offers considerable opportunity to address health disparities and may benefit all patients.

### 1. Introduction

Compared to the general U.S. female population, immigrant and refugee women have disproportionately higher incidence and mortality rates from cervical cancer that are largely attributable to suboptimal screening participation (Jemal et al., 2011; Bray et al., 2018). Among Somali immigrant women, cervical cancer screening rates are strikingly poor; only 25 %-50 % of Somali women are up-to-date with screening, (Minnesota Community Measures, 2017; Ben et al., 2013; Pratt et al., 2020). compared with 82 % for the U.S. general female population (CDC, 2017). A complex set of barriers contribute to low screening rates

among Somali women, including limited health literacy, (Pavlish et al., 2010) lack of knowledge about cancer in general, (Carroll et al., 2007; Al-Amoudi et al., 2015) cultural and religious beliefs, (Pavlish et al., 2010; Bigby et al., 2010; Khaja et al., 2010; Degni et al., 2012; Johnson et al., 2009) and limited awareness about HPV and cervical cancer (Carroll et al., 2007; Al-Amoudi et al., 2015; Abakporo et al., 2018; Downs et al., 2010; Otanez and Torr, 2018). Other contributing factors include mistrust of healthcare providers and systems (Pavlish et al., 2010; Downs et al., 2010; Dailey and Krieger, 2017). Modesty concerns are also significant (Raymond et al., 2014; Pratt et al., 2017). Providers do not always feel skilled or confident to provide care to Somali women

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who have been circumcised (Chalmers and Hashi, 2000; Johnson-Agbakwu et al., 2014; Braddy and Files, 2007; Jacoby and Smith, 2013). Novel screening strategies are needed to address barriers and increase screening rates in Somali women.

Guideline-recommended cervical cancer screening strategies in the U.S. include options for screening with Pap tests and/or human papillomavirus (HPV) tests. Primary or 'HPV-only' screening is a preferred strategy in both the 2018 United States Preventive Services Taskforce (Curry et al., 2018) (ages  $\geq 30$  years) and the 2020 American Cancer Society ( $\geq 25$  years) screening guidelines (Fontham et al., 2020). The 2021 World Health Organization (WHO) guidelines recommend primary HPV-based screening for cervical cancer, (WHO, 2021) and multiple countries (e.g., Australia, The Netherlands, and the United Kingdom) have introduced primary HPV screening into their national screening programs (Bruni et al., 2022). Primary HPV screening is more sensitive than Pap for detecting cervical precancers, yet the transition to primary HPV screening in U.S. clinics and health systems has been slow. An additional advantage of primary HPV screening is the potential for patient-collected samples. Unlike Pap, HPV testing can be performed on either clinician-collected or self-collected samples, with comparable effectiveness for detecting cervical precancers (Canfell et al., 2017; Arbyn et al., 2018; Polman et al., 2019). Multiple studies have shown that HPV self-collect is effective in reaching women who otherwise delay or opt out of cervical cancer screening (Costa et al., 2023). The WHO recommendations include HPV self-collect as an option for HPV-based primary screening, (World Health Organization, 2022) and HPV self-collect has been deployed as a cervical cancer screening strategy in countries outside of the U.S (Serrano et al., 2022). For Somali women, HPV self-collect may address barriers related to modesty. A 2015 study showed that HPV self-collect was feasible and acceptable among Somali women, and that women who were mailed self-collect kits were 14 times more likely to undergo cervical cancer screening than women receiving usual care (brief education and recommendation to attend their clinic for Pap) (Sewali et al., 2015).

Research on HPV self-collect has primarily focused on home-based, mail-in kits, (Arbyn et al., 2018) yet accessing mail-based healthcare can be a barrier for some patient populations, especially if there are literacy concerns (Pavlish et al., 2010). If self-collect could be offered at primary care visits, there would be opportunities for providers to directly address patient concerns and provide education. information to address those barriers relating to knowledge about cancer, (Carroll et al., 2007; Al-Amoudi et al., 2015) and the limited awareness about HPV and cervical cancer specifically (Carroll et al., 2007; Al-Amoudi et al., 2015; Abakporo et al., 2018; Downs et al., 2010; Otanez and Torr, 2018).

Implementation science (IS) offers the conceptual frameworks and methods necessary to help identify barriers and facilitators to integrating HPV self-collect in primary care, and has been used to identify strategies for successfully implementing cancer control practices into clinical care (Neta et al., 2015). The Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2015) focuses on five key implementation domains: intervention, outer setting, inner setting, characteristics of individuals and process of implementation. In this study, we utilized CFIR to guide semi-structured interviews with providers, staff and administrators in two primary care clinics in the Minneapolis metropolitan area of the U.S. These two clinics are participating in a pragmatic clinical trial to assess the effectiveness of a tailored implementation of primary care clinic-based HPV self-collect that aims to reduce cervical cancer screening disparities among Somali women. The aim of these formative interviews was to understand provider and clinic staff views on HPV self-collect and their anticipated needs or barriers to implementing this approach into the clinic generally and with specific patient populations, such as Somali women.

## 2. Methods

Primary care providers, administrators and staff participated in semi-structured interviews, exploring their views on HPV self-collect and their anticipated needs or barriers to integrating this approach into the clinic setting and clinical encounter.

### 2.1. The Isbaar project

The interviews were conducted in the context of a pragmatic clinical trial, titled '*Reducing cervical cancer screening disparities in Somali immigrant women through a primary care based HPV self-sampling intervention*', or the Isbaar Project ('isbaar' is the Somali word for screening). The Isbaar Project is a Hybrid Type 2 effectiveness-implementation study to assess the effectiveness and implementation of a patient-centered, culturally-tailored HPV self-collect intervention for Somali women (the study protocol paper is forthcoming). The project will evaluate changes in Somali women's cervical cancer screening rates after implementing HPV self-collect in three primary care clinics in Minneapolis, Minnesota. The main study hypothesis is that implementing HPV self-collect in primary care clinics will lead to increased uptake of cervical cancer screening in Somali women. Here we report on initial interviews with providers, administrators, and staff, conducted to refine the intervention implementation strategies. The interview participants are from two clinics, as the third clinic was recruited to take part in the study after the interviews were completed.

### 2.2. Study population

A convenience sample of 30 primary care providers, administrators, and staff from two urban primary care clinics (15 participants per clinic) were recruited to take part in one semi-structured interview between February–August 2022 (see Table 1). One clinic is part of the University of Minnesota Family Medicine Residency Program, and the other is a Federally Qualified Health Center. Providers included physicians, nurses and nurse practitioners, midwives, physician assistants, and resident physicians. Staff included patient care staff, medical assistant, case manager, clinic supervisor/manager, call center, or project manager. Administrators were general leaders in the clinic in director or executive level roles, many of whom also served in clinical roles.

### 2.3. Study instrument

The CFIR was used to inform the development of the interview guide (see Table 2). The interview guide explored views on the use of HPV self-collect, the context in which it would be implemented, anticipated reactions from patients and views on the processes for implementation. Questions explored views on integrating HPV self-collect into the clinic, and included questions about how to be responsive to the needs of Somali patients specifically.

### 2.4. Data collection

The interviews were conducted by an experienced interviewer (FH, KF, CBB), who received training from the lead author (RP). Interviews were conducted virtually, using Zoom, and took approximately 30 min. Participants were also asked a brief set of questions on their demographics, clinic role, and years working in the clinic.

### 2.5. Data analysis

Interview data were transcribed verbatim and analyzed with the assistance of Nvivo 12 software.<sup>58</sup> Two study team members coded the transcripts systematically (RP, SX), and met regularly to review the emerging analysis and develop the codebook using a process of consensus. The analysis process was informed by the social

**Table 1**

Descriptive characteristics of clinic staff, administrators and providers who were interviewed in Minneapolis, Minnesota between February–August 2022.

	n	%
Total	30	100
Gender Identity		
Female	26	87
Male	2	7
Non-binary / non-conforming	1	3
Missing/declined	1	3
Age		
18–29	6	20
30–39	5	17
40–49	4	13
50–59	9	30
60–69	4	13
Missing/declined	2	7
Race		
American Indian / Alaska Native	1	3
Asian	2	7
Black / African origin	6	20
White / Caucasian	20	67
Missing/declined	1	3
Years Working at Clinic		
< 1 year	2	7
1–4 years	14	47
5–10 years	7	23
11–15 years	1	3
16–20 years	1	3
>20 years	2	7
Missing/declined	3	10
Job Role at Clinic		
Leadership*	7	23
Providers**	14	47
Staff***	9	30

\*Director or executive level role.

\*\*Physician, nurse, nurse practitioner, midwife, physician assistant, or resident physician.

\*\*\*Patient care staff, medical assistant, case manager, clinic supervisor/manager, call center, or project manager.

constructivist approach to grounded theory (Charmaz, 2014). This approach allows for themes and sub-themes to emerge from the data, while also considering the broader context, including key literature, or theoretical frameworks, (Charmaz, 2014) such as CFIR. The emerging analysis was presented to a broader group of research team members, and the study community advisory board, to further ensure the rigor of the analysis.

### 2.6. Human subjects

The University of Minnesota Institutional Review Board provided ethical approval for the conduct of this study (STUDY00012408, SITE00001416). University of Washington IRB approval was granted through a reliance agreement with the University of Minnesota (STUDY00013359). The study is registered with [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT05453006) (NCT05453006).

## 3. Findings

Here we present the findings from the analysis organized by main themes and associated subthemes, respectively. Additional illustrative quotes can be found on [Table 3](#).

### 3.1. Views on HPV self-collect

Most participants had not heard of HPV self-collect prior to the interview, although most had experience with patient self-collected samples in general. During the interview, the interviewer provided information about HPV self-collect for those who were unfamiliar. There

**Table 2**

Semi-structured interview guide administered to study participants in Minneapolis, Minnesota between February–August 2022.

Thank you for agreeing to participate in an interview today. As you likely know, your clinic has agreed to take part in study where HPV self-sampling will be offered to patients who are due for cervical cancer screening as an option for completing their screening. This may mean there are some changes that need to happen to make this work well for everyone here. I'm interested in your views about HPV self-sampling and your feedback will be helpful as we plan to implement HPV self-sampling as an option for cervical cancer screening here at the clinic.
1. Before we get started today can you please describe for me a bit about your role at the clinic and how long you have been here?
2. Now I would like to ask you some questions about using methods like HPV self sampling here at the clinic. Can you share what experiences have you had or observed in using patient collected samples in your practice or at this clinic?
3. Have you heard of HPV self sampling for cervical cancer screening before? If no – provide a brief explanation. <i>Prompt: What are your thoughts about HPV self-sampling?</i>
4. What do you think about offering the option of HPV self collected patient samples as part of cervical cancer screening at this clinic? <i>Prompts: Any particular concerns about it? Any particular advantages to using self-sampling?</i>
5. Do you have any thoughts or concerns about the evidence for using HPV SS? <i>Prompts: What else would you want to know more about in relation to HPV SS? Do you feel it offers a the same quality as a Pap test?</i>
6. I would now like to ask you a few questions about how patients might see HPV self-sampling as an option for cervical cancer screening. How do you think Somali patients at this clinic might react to be offered the option of HPV self-sampling for cervical cancer screening? <i>Prompt: Why do you think that?</i>
7. What information or education do you think Somali patients might need as they consider if they want to use the option of HPV self-sampling as an option for cervical cancer screening?
8. How do you imagine other patient populations in your clinic react to the idea of HPV self-sampling?
9. As we plan to implement HPV self-sampling as an option for cervical cancer screening we imagine this could mean there are some changes that need to happen to make this work well for everyone here at the clinic. Based on your role and experience, what do you think needs to happen for HPV self sampling to be successfully offered as an option for cervical cancer screening here? <i>Prompts: Are there structural changes that might be needed? What else do we need to know?</i>
10. We know everyone in the clinic has a part to play in the care workflow. Again based on your role and experience, how would adding the option for HPV self-sampling for cervical cancer screening impact the work you do?
11. Please share with me how you would see HPV self-sampling best fitting into your current workflow around cervical cancer screening? <i>Prompts: Who might offer it? Which role would be best placed to support this? How would it fit into the clinical encounter the best? Where would the sampling be most easily done?</i>
12. How well do you think an approach like HPV SS fits in this setting? <i>Prompts: Do you think there is leadership support?</i>
13. Can you describe for me what kinds of processes are typically used at the clinic for implementing new changes? <i>Prompts: How well do you see that working? What could improve that?</i>
14. When you are making changes, how do you usually get feedback about how well that is going? <i>Prompts: What would work well for getting feedback about this change?</i>
15. What training do you think will be needed for clinic providers or staff to help support implementation of HPV self sampling?
16. How do you feel about HPV self sampling being offered as an option for cervical cancer screening at the clinic? <i>Prompts: How do you feel about the plan to implement the intervention in your setting? Do you have any feelings of anticipation? Stress? Why?</i>
17. How confident are you that you will be able to successfully implement HPV self sampling as an option for cervical cancer screening?
18. How confident do you think your colleagues feel about using the intervention?
19. Do you have any other thoughts you would like to share on how we might best implement HPV self-sampling as an option for cervical cancer screening in primary care?

was a great deal of support for HPV self-collect as a routine option in the cervical cancer screening process for all patients, and for specific populations who may have been less engaged in cervical cancer screening. It was seen as an easy tool, offering choice to patients, and a way to reach those who were not currently open to Pap tests and pelvic exams.

I think it is absolutely wonderful. I think that more women are likely to do a self-screening. Then they come in and get screened by a provider to be honest with you. I think that the element of privacy is absolutely...is absolutely important to a lot of Somali women. I think

**Table 3**  
Illustrative quotes from interview participants, including administrators, staff and providers, collected in Minneapolis, Minnesota between February–August 2022.

Main Theme	Illustrative Quotes
Views on HPV Self-Collect	<i>Yeah, we've done patient collected samples for STI screening, and I'm like, for, you know, for initial evaluation of like yeast infections if people want to avoid a vaginal exam. But primarily for STI screening. I would say we've done self collected samples for many, many years. So not just vaginal but rectal, oral—we've done a lot of self samples and self swabbing for that, and we just teach people how to do that, and then they can do it themselves. And I'll allow that for, you know, an initial vaginitis work up to for somebody who's super, super nervous about vaginal exams. (Clinic 2, Provider)</i>
Perceived Patient Response/Reaction	<i>I think that there's subsets of the population that would be all in favor. I anticipate that there will be people that are "no way, no how." And then with a large bucket in the middle, so representative, your typical bell shape curve don't have any experience at other clinics or other organizations with this, and so I can only speak in generalities. (Clinic 1, Leadership)</i>  <i>I do think that a potential worry is, will there be the perception that this is sub-optimal care right? "So why are you asking us this question? Aren't you supposed to do it the other way? Isn't that the right way the better way and now you're doing it differently and you're doing it with us? Is that the cheaper way or this faster way or something that isn't quite as good as the standard way?" So I would anticipate we will have thoughtful questions that span the whole gamut. (Clinic 2, Provider)</i>  <i>Well, I mean I think both my Somali patients and my transmen both probably I would guess that they would be in favor of it. I think both groups have been leery to have pap tests done in clinic, particularly by male providers, so my guess is that they will appreciate the option. I think one of it questions people have is, you know can you explain this well to me like, how I do this technique so that I get it a good test and so I think that would be something. I think that both groups would want to make sure that they knew how to do it, that they could kind of be guided through the process of how to self-sample. (Clinic 2, Provider)</i>
Patient and Provider Education	<i>We know that our Somali community has, you know, unfortunately, there's a lot of misunderstanding, miseducation, miss of whatever in there, you know, out there within that community, and I know, we are struggling, we struggle, and we want to make sure that we are, you know, educating them correctly. So I think that, if this is one, one thing that we can help, do, I think we need to really, I think we should do it, I think that there will be there's going to have to be a lot of that education piece and how to break that ice within that community. To say that this, you know, this is so important, and this is, you know, hopefully the fact that you know, you get to do it yourself will help, help with that. (Clinic 2, Staff)</i>  <i>Everything has to be in Somali language. Yeah, not English. I know that's just common and, you know, you'd think that it would be a no brainer. But there's so many things that we give patients that are in English and, you know, they just take it and stuff in their bag, and that's it. But I think every, all the materials have to be very clearly explained in Somali at a, you know, at an appropriate level of understanding. (Clinic 1, Provider)</i>  <i>I do think though anytime you roll something out you absolutely have to have very strong why's, right? There's generally a mistrust in the healthcare system that it's doing things so that it costs less or we make more money and so being very clear that we're doing this because we believe our patients aren't adequately screened for cervical cancer. (Clinic 2, Provider)</i>

**Table 3 (continued)**

Main Theme	Illustrative Quotes
Integration into Routine Primary Care	<i>I think to be able to implement it at clinic, I think just making providers like nursing staff and patients just aware that it's an option and having good like, guidance, and how to do the swab and good education about that. It's just as high quality as doing a pap smear, I think are important, otherwise, I don't think there's a lot of barriers to implementing it. You know, we have all of the like, equipment and swabs already in the lab capability. Like I don't see that being a factor at all. I think it's more just education piece for staff and patients. (Clinic 2, Provider)</i>  <i>We have to have the ability to just have it in the room. Like saying, it's like you know I'm imagining the way this will happen is I'll be seeing a woman for headaches or something I'll look in their chart and they'll say hey you're due for a pap smear so you know I'll come back next year for that. Oh, you know, there's a really easy way, to do it now. All you have to do is, is this, and just put it in here just this like, and but if I have to go and get it somewhere else, if I have to order it, and then go find this special thing and all kinds of extra things versus right now pap smears are in the rooms, you know. And I can just reach and grab it, you know. So if I can grab it put a label on and say here it is. I'm just going to step out you do it and you just leave it right here, and I put a little thing, you know, so they're just making it super easy, even to the extent that I can leave and not come back again because I'm not going to interpret the test right away. (Clinic 2, Leadership)</i>  <i>MAs do a lot. A lot a lot a lot around here. I think there's you know they can they may possibly have to know how to do it too, when nurses aren't available. There may be someone else who comes in or during a visit that that the provider may say, this needs to be done, and nurse may be busy already, so I don't know. You know the MAs may also have to know how to educate the patient to get it done. (Clinic 1, Leadership)</i>  <i>So this you know, I think to explain the why. You know, whatever, whatever the process is to explain, the why this is important is going to be really important in terms of the process. There are several key meetings that would be important to have someone like yourself to come and describe what it is, and how this is going to impact patients or the clinical flow. (Clinic 1, Leadership)</i>  <i>I think that we are motivated to provide cancer screening. And also we want, we know that our Somali women have lower rates of cancer screening and higher rates of cervical cancer. And are motivated to other, you know, reach out to patients in other ways. So I think absolutely can be implemented. (Clinic 2, Leadership)</i>

privacy is just really, really more inclusive for the patients. (Clinic 1, Staff Member)

Many participants were also clear that they needed more information about the evidence supporting HPV self-collect specifically and primary HPV screening in general, including test sensitivity, efficacy, and the required management or triaging for positive results. Some participants expressed concern about the implications of doing fewer physical exams, in relation to missing concerns that might be identified in a physical exam.

### 3.2. Perceived patient response/reaction

Participants anticipated patients would be positive about being offered HPV self-collect. It was thought patients would feel empowered by being able to collect their own sample, and it would be seen as a good option for patients who are underscreened, have a history of trauma or abuse, have anxiety, learning difficulties or are gender diverse. There was some concern that some patients may view self-collect as a lesser option, and therefore feel they were being offered suboptimal care.

When discussing Somali patients specifically, participants felt HPV self-collect could overcome common barriers to cervical cancer screening, including modesty concerns. Participants shared that for many Somali patients, discomfort was compounded by the experience of female genital circumcision, which could make the physical exam less comfortable, both physically and emotionally.

It might help me to get more females will participate to do this test. That's what I believe because in our culture and religion females don't any want contact with males unless it's necessary. And this test will be like brief screening and they don't see the benefit this test will have because they more focusing, oh, I don't want to, I don't want any males see me or something going bad. (Clinic 1, Provider)

### 3.3. Patient and provider education

Participants felt there would be a need to educate patients on the evidence for using HPV self-collect, compared with screening by a provider. Participants also felt that for underscreened groups, such as Somali women, patient education should be accompanied by education on the value of cervical cancer screening in general, including the importance of following up on abnormal test results. Participants described the need to have clear directions on how to self-collect the HPV sample, including having information available in English and Somali, diagrams/visual materials, and if possible, also making instructions available in audio or video formats.

I would say that just instructions, very clear instructions about how to use it, and also translated materials just because we know that the majority of our population English is not their first language. And maybe even video demonstrations would be nice, because I know that some individuals cannot read either. So just having multiple ways of transferring that material to them. (Clinic 1, Staff Member)

Participants were clear that in order to integrate HPV self-collect into routine care, there was a need to educate all providers and staff, including interpreters, on why HPV self-collect was being used, the evidence for HPV self-collect compared to current approaches or Pap or Pap/HPV co-testing on provider-collected samples (participating clinics had not yet adopted primary HPV testing on provider-collected samples into standard care), and how to implement this approach. This would involve information on how to offer the test and the required workflow.

### 3.4. Preparation for change

The key features of change process that has been previously used in the clinic when integrating a new practice were described by participants as often starting with leadership level buy-in and decision making, which may involve working with an organizational board or with the system in which the clinic is embedded. Following the decision to implement a change, clinic champions or leads were typically identified to spearhead the change process. These champions or leads would help to ensure the changes were reviewed in clinical operations meetings, where there is the opportunity to address system level changes and to determine how a new activity would fit in the current workflow. Participants described the need for system level changes that were consistent with the system expectations around billing, labeling of samples and the impact on quality measures.

Following these strategic decisions preparing for change, there would typically be a rollout plan, which would include a plan for communication throughout the clinic and addressing education needs. Participants appreciate the use of 'cheat sheets' about new workflows, or 'talking points' to help guide new conversations with patients. Participants shared the value of having a clear timeframe for implementation and a way in which to review early implementation efforts and adjust as needed.

Yeah, so usually, typically, with a process change like this we usually take a little bit of time to roll it out, because what ends up happening is we educate patient care staff separately, then we educate the providers. And so it would, oftentimes, we're the first ones to know that this change is coming, because we'll provide support for the providers, it's like, sometimes almost more important that we know the process, just so we can walk through it. (Clinic 2, Staff Member)

Some participants shared that the process of change requires sustained and repeated education and review, particularly as the primary care environment may have many competing priorities and changes at any one time. When asked to share their level of confidence in being able to implement HPV self-collect in their clinic environment, most were optimistic, as it was seen as easily compatible with other clinic practices and current workflows.

Participants were asked to share how they assessed the success of implementing new practice changes at their clinics. Participants described reviewing patient data and eliciting feedback from providers, medical assistants and patients, to gather information on how a new practice was being implemented and experienced. Data would be reviewed at ongoing quality improvement committees, which were usually engaged in assessing the effectiveness of new practices that were implemented in the clinic, including reviewing data and using processes such as Plan-Do-Study-Act (PDSA) cycles and daily huddle meetings.

When discussing the involvement of various roles within the clinic, participants were clear that involving all staff and providers, including leadership, front desk staff, members of the care team, the lab, and interpreters, was essential in the success of implementing a new clinic process. It was particularly noted that medical assistants are often a first point of care in discussing screening, and at times are filling in to support other members of the care team.

MAs do a lot. A lot a lot a lot around here. I think there's you know they can they may possibly have to know how to do it, too. when nurses aren't available. There may be someone else who comes in or during a visit that the provider may say, this needs to be done, and nurse may be busy already, so I don't know. You know the MAs may also have to know how to educate the patient to get it done. (Clinic 1, Leadership)

### 3.5. Integration into routine primary care

Overall, participants were positive about HPV self-collect being integrated into their current workflow as it was largely seen as consistent with current practices around other patient self-collected samples. Some provider participants felt they would only offer HPV self-collect as an option should provider sample collection be declined, as they considered it a lesser option. Participants described the importance of having a patient-centered process for HPV self-collect. Participants wanted to have access to talking points or scripts that offers accurate and culturally appropriate information for talking with patients. One participant, who identified as Somali, shared their hope that the clinic could also do community-level education and outreach that might lead to Somali patients proactively asking for the self-collect option.

Yeah, so I would educate them and tell them when you go there. And you have your doctor's appointment. Ask them if they can do self-testing, and I can educate them that for the community. (Clinic 2, Provider)

Participants described what they felt would be needed to successfully undertake self-collect during the clinic encounter. This included having processes that ensured the correct supplies (swabs and instructions) were located in exam rooms, and aids to identify the correct swab type. Most suggested that the patient would do self-collection in the exam room, with the provider stepping out of the room. Some felt patient bathrooms that were set up for sample collection would also be possible,

but only in an environment where there were ample private bathrooms. Participants shared the importance of having changes made to the electronic health records (EHR) to help support implementation, including with health maintenance reminders. Some felt their existing EHR was consistent with implementing HPV self-collect.

#### 4. Discussion

The integration of HPV self-collect into routine primary care was seen as a desirable strategy for cervical cancer screening, not just for Somali patients, but for all patients. The Isbaar Project will be one of the first studies to evaluate the potential of HPV self-collect beyond home-based, mail-based outreach, as a promising approach for in-person use during the clinical encounter in primary care. Offering HPV self-collect within the clinic visit was identified as having the potential to address barriers specific to Somali patients, such as education about cancer, modesty, (Raymond et al., 2014; Pratt et al., 2017) and reluctance to have pelvic exams, (Chalmers and Hashi, 2000; Berg and Underland, 2013) and that these barriers were also common to many different patient groups. It was seen as an option that was patient-centered and empowering, and would not only address disparities but also have clinic-wide appeal.

Despite this enthusiasm, there are knowledge gaps in primary care around HPV self-collect specifically, and about HPV primary testing in general. The CFIR describes the concept of ‘relative advantage’, where the merits of a new intervention are compared with alternatives, and ‘evidence strength and quality’. This study shows that despite clear relative advantages, there would be a need to address provider concerns about the strength and quality of evidence supporting HPV self-collect for cervical cancer screening. If, for example, providers perceive self-collect as only being appropriate if a provider exam is declined, this could limit uptake, highlighting the need for provider education.

As clinics explore integrating HPV self-collect into primary care, it will be important to monitor impact on disparities for underscreened patient populations over time. While there might be a great benefit in utilizing a strategy to address disparities that can be used for all patients, it will be important to ensure the racial and ethnic disparities seen in Pap uptake (Jemal et al., 2011; Bray et al., 2018) are not inadvertently replicated in HPV self-collect. This is likely best achieved through continued focus on reducing disparities, and using strategies such as developing or providing access to culturally- and linguistically-tailored self-collect instructions.

Offering HPV self-collect in routine primary care was seen as having a high degree of consistency with what CFIR would describe as ‘inner setting concerns’, compatible and comparable to other self-testing procedures, a high priority area and straightforward to implement. This is also consistent with the CFIR domain of process or implementation, with clinics outlining robust processes for embedding new changes, from the use of champions, existing quality improvement mechanisms and approaches to evaluation and monitoring. Settings that have low levels of awareness or use of primary HPV testing may have more systemic barriers to overcome regarding HPV self-collect. The barriers noted in this study include system or leadership buy in, and the need to build systems (such as the EHR or health maintenance approaches) to support the integration of primary HPV testing.

##### 4.1. Limitations

This qualitative study focused on two clinic settings in an urban setting in the upper Midwest. As such it may not be generalizable to other settings or contexts. The participants in this study are part of an intervention project, which will implement HPV self-collect into routine primary care, so participants may have been predisposed towards HPV self-collect due to their involvement in the broader study. Participants may have had dual roles, for example, be a clinician and an administrator. In this study we asked participants to provide answers in relation

to the role they primarily identified with, which may be a limitation. Finally, this study does not report on the direct views or experiences of patients being offered HPV self-collect as part of cervical cancer screening processes.

##### 4.2. Conclusion

Integrating HPV self-collect in the cervical cancer screening process in the primary care clinical encounter offers considerable opportunity to address disparities and may benefit all patients. It was viewed as highly compatible and implementable with current primary care practices. Importantly, however, implementation should include provider and patient education, and also focus on strategies to address disparities, such as cultural and linguistic tailoring for Somali and other priority patient populations.

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#### CRediT authorship contribution statement

**Rebekah Pratt:** Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Christina Bliss Barsness:** Methodology, Formal analysis, Writing – review & editing, Project administration, Data curation, Investigation. **John Lin:** Writing – review & editing, Project administration, Methodology. **Jay Desai:** Writing – review & editing, Methodology, Conceptualization. **Kristi Fordyce:** Writing – review & editing, Project administration, Investigation, Formal analysis, Data curation. **Rahel Ghebre:** Writing – review & editing, Conceptualization. **Faiza Hassan:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Anisa Ibrahim:** Writing – review & editing, Conceptualization. **Tim Ramer:** Writing – review & editing, Conceptualization. **Adam Szpiro:** Writing – review & editing, Conceptualization. **Bryan J. Weiner:** Writing – review & editing, Methodology, Conceptualization. **Serena Xiong:** Writing – review & editing, Formal analysis. **Sophia Yohe:** Writing – review & editing, Conceptualization. **Rachel L. Winer:** Writing – review & editing, Conceptualization.

#### Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

#### Data availability

Data will be made available on request.

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