Clinician and Patient Acceptability of Self-Collected Human Papillomavirus Testing for Cervical Cancer Screening

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Abstract

Background: To evaluate clinician and patient attitudes toward home self-collected human papillomavirus (HPV) testing for cervical cancer screening.

Methods: Women aged 21–65 years were recruited for a randomized trial comparing home self-collected HPV testing to standard clinician-collected Pap screening. Participants were surveyed about their attitudes toward self-collected HPV testing. Clinicians performing cervical cancer screening in University of Washington medical clinics were also surveyed to determine their acceptability of self-collected HPV testing.

Results: Over half (59.1%) of the 1,769 women surveyed preferred self-collected HPV testing to cliniciancollected tests. Reasons most often cited were convenience or time saving (82.7%), and avoiding embarrassment or discomfort associated with pelvic exam (38.1%). Women who did not prefer self-collected HPV testing reported greater faith in clinician-collected samples (56.7%) or a desire for a clinic visit to address other issues (42.4%). One hundred eighteen (49.6%) of 238 physicians and midlevel providers surveyed completed the survey. The majority (78.0%) reported that they would recommend a self-collected HPV test if the test had qualities such as high sensitivity and cost effectiveness. Provider concerns mirrored those of patients, namely ensuring adequate sample collection and the opportunity to address other health concerns.

Conclusion: Patients and clinicians are supportive of self-collected HPV testing. However, concerns regarding adequacy of samples that are self collected and the desire to see a provider in a clinic setting for other health needs highlight areas that need to be addressed if self collection proves to be a viable option for cervical cancer screening.

Keywords: self-collected, HPV, Pap, cervical cancer, screening

Introduction

O VER THE LAST several decades human papillomavirus (HPV) testing has been extensively studied and validated as an important component of cervical cancer screening. Studies have demonstrated that as compared to primary Papbased screening, primary HPV testing (done on cliniciancollected samples) provides superior sensitivity (although lower specificity) for detection of high-grade squamous lesions.^{1,2}

Although clinical practice has not yet changed from cytology-based screening in the United States, recently published guidelines have supported the use of primary HPV testing, based on cervical samples obtained in clinics by healthcare workers, as an alternative to Pap screening for cervical cancer control.³ In addition, clinical trials and a meta-analysis have also shown that HPV testing performed on self-collected samples (collected from the vagina either in clinic or at home) provides similar results to that of testing using clinician collected cervical samples.^{4–6} Another large trial of self-collected HPV samples in countries outside the United States suggests that this approach is likely to increase the number of women participating in screening and potentially reduce costs so there is a great deal of interest in further research.⁷

Previous studies have suggested that women prefer selfcollected HPV samples for screening but little is known about whether this method would be endorsed by clinicians^{4,8,9} Endorsement by providers is of particular concern given recent reports that examined clinician attitudes toward other

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recent changes to the cervical cancer screening recommendations related to age of onset of screening, screening intervals, and use of HPV testing. Results from these surveys documented significant push back by clinicians to new recommendations for longer screening intervals and later onset of screening because of fear that such changes would result in less face to face contact with patients^{10,11}. Since at home selfcollected HPV testing may further reduce the number of women seeking in-clinic screening, it is possible that there will be serious objections by providers.

The present study was undertaken to evaluate both clinician and patient attitudes toward at home self-collected HPV testing as part of a National Institutes of Health funded randomized trial comparing clinician-obtained Pap tests to selfcollected HPV tests for cervical cancer screening.

Materials and Methods

Beginning in March of 2012, women aged 21–65 years presenting to two University of Washington clinics for routine cervical cancer screening were invited to participate in the HOPE (Home HPV or Pap Exam) trial, a prospective randomized trial to evaluate the accuracy and acceptability of home self-collected HPV testing compared to routine Pap testing. Additionally, women were recruited by direct mailing to University of Washington students and staff, local newspaper advertisements, local web advertisements, and community posted flyers.

Women who had prior screening within 1 year of enrollment, known immune suppression, were currently pregnant, had a hysterectomy, or a colposcopy procedure within 2 years or treatment of cervical dysplasia within 3 years were excluded from participation into the study. Wait times to schedule screening visits ranged from 3 days to 2 weeks for those seen in the research clinic and waits for specific University of Washington providers varied but detailed information is not available. After providing informed consent, women were randomized to receive either cervical cancer screening with a home self-collected HPV test, or a cliniciancollected Pap or Pap with HPV test per current guidelines.¹²

All subjects were seen by a clinician at enrollment and received a screening exam with collection of ThinPrepTM (Hologic 1996, Bedford, MA) sample from cervix. Subjects were then randomized to receive routine Pap test or home selfcollect HPV test for screening. If women were randomized to the self-collect arm then the ThinPrep sample obtained was held in lab and run only as a reflex test if needed. At end of the study visit, these subjects were given a self-collect kit. Brief instructions were reviewed regarding how to return the sample box via standard USPS priority mail. Subjects were informed that the kit contained one double-sided instruction sheet with collection instructions on one side and shipping instructions on second side. No additional education on self-collection procedure was provided. The kits contained two individually wrapped sterile Dacron polyester swabs and a container for the sample. No storage instructions required since the sample is kept at ambient temperature.

Women were asked to complete a written or online survey following their first screening visit. The survey consisted of ~40 questions regarding prior experiences associated with Pap testing, preferences for at home self-collected HPV testing or clinician-collected tests, and reasons for preferring one method of testing over the other. Participants were asked to complete all questions on the questionnaire regardless of which method of testing they preferred. Short answers to open-ended questions were summarized by thematic categorization. Data from participants who enrolled and completed surveys from the first round of screening are presented here. Subjects received up to \$50 (\$25 after study visit and \$25 after completion of the questionnaire) as incentive for enrollment.

Clinicians performing cervical cancer screening in University of Washington medical clinics were surveyed online regarding the acceptability of self-collected HPV screening. The short survey consisted of two sets of questions. The demographic questions included gender, years in practice, specialty, frequency of performing Pap screening, and knowledge of the HOPE study. The second set included questions aimed at determining the characteristics that clinicians felt were important for a screening test and whether clinicians would recommend an at home self-collected HPV test if such a test had these characteristics.

The survey invitation was sent by email to 238 internal medicine (n=78), family medicine (n=77), and obstetric and gynecology (n=51) physicians, nurse practitioners (n=25), and physician assistants (n=8) who had publically listed email addresses, worked within the University of Washington healthcare system, and had performed Pap exams between January 2013 and January 2014. Up to two reminder emails following the initial invitation were sent to encourage participation. Providers who consented to participate and completed the survey received a \$10 gift card.

Chi-square tests and uncorrected *p*-values were calculated for comparisons of patient and clinician factors associated with preferences for at home self-collected HPV testing or clinician-collected tests. Mantel–Haenszel tests for trend were calculated for ordered categorical factors such as patient and clinician age groups, education level, number of Paps in the past 5 years, household income level, years in practice by clinicians, and clinician frequency of Pap testing. *p*-Values ≤ 0.05 were considered statistically significant. Analyses were conducted using Stata version 14.1, EpiInfo 7.1.3, and SAS version 9.4.

All research activities were approved by the study data safety and monitoring board, the University of Washington (No. 7489 approved July 20, 2011 and No. 9028 approved November 20, 2013) and University of Minnesota Institutional Review Boards (No. 1109M04321 approved October 5, 2011).

Results

Patient acceptability survey

One thousand eight-hundred nineteen women enrolled in the HOPE study and 1,769 (97.3%) responded to the acceptability survey. The mean age of women completing the survey was 35.7 years (Table 1). Women in the self-collected HPV and clinician-collected test arms were comparable in terms of age, ethnicity, and race (data not shown). Over 58% of the responders reported two or more Pap screens in the past 5 years and 15.8% reported a previous diagnosis of a sexually transmitted infection. Twenty-nine percent of women overall reported receiving two or more doses of an HPV vaccination.

Table 2 summarizes the results of the patient acceptability survey. Over 59% of study participants indicated that they would prefer a self-collected HPV test to a clinician-collected

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TABLE 1. PATIENT DEMOGRAPHIC CHARACTERISTICS
and Medical History for Home HPV or Pap
EXAM STUDY TRIAL PARTICIPANTS ($N=1,769$)

% *Characteristic* n Age at baseline (years) Mean (standard deviation) 35.7 (11.9) Interquartile range 26 - 45Race American Indian/Alaska Native 21 1.2 195 11.5 Asian Native Hawaiian/Other Pacific 10 0.6 Islander Black/African American 165 9.8 White 1,210 71.6 More than one race 88 5.2 Ethnicity Not Hispanic or Latino 1.595 91.9 Hispanic or Latino 141 8.1 Education ≤High school 154 8.8 Some college or technical 521 29.7 or associate school Bachelor's degree 482 27.5 Graduate school 598 34.1 Number of Pap tests in past 5 years^a 244 13.9 0 1 483 27.52 3 425 24.2 307 17.5 4 +296 16.9 History ever diagnosed with a STI^a: Trichomonas 100 5.7Chlamydia 156 8.8 4.5 Gonorrhea 80 Genital herpes 110 6.2 Genital warts 73 4.1 Combined total 280 15.8 HPV vaccination^a 529 29.9 ≥ 2 shots

Missing information is as follows: race (4.5%), ethnicity (1.9%), education (1.4%), number of Pap tests in past 5 years (0.8%).

^aInformation is self-reported.

HPV, human papillomavirus; STI, sexually transmitted infection.

Pap test (40.9%). The most common reasons cited for preferring a self-collected HPV test were convenience or time saving (82.7%) and avoiding embarrassment or discomfort (38.1%) associated with a pelvic exam. The majority of women (74.0%) indicated that they would be more willing to participate in self-collected HPV screening if their provider recommended it. Women reported preference for cliniciancollected tests primarily for two reasons: they had more faith in provider-obtained samples (56.7%) and clinic visits allowed for discussion of other medical issues (42.4%).

Women who preferred the self-collected HPV test were more likely to report embarrassment (p < 0.001) or pain and discomfort (p=0.01) with a pelvic exam (Table 3). Preference for self-collected HPV testing increased with increasing level of education (p < 0.001) and household income (p < 0.001) as well as a need to take time off from work (p=0.009). However, women with a prior history of a sexually transmitted infection were less likely to prefer selfTABLE 2. PATIENT PREFERENCES FOR HOME HUMAN PAPILLOMAVIRUS TESTING VERSUS CLINICIAN-OBTAINED TESTING (N=1,769)

	<i>Total</i> , $N = 1,769$
Patient testing preference $(n = 1,759, 99)$.	4%)
Home HPV testing	1,039 (59.1)
Clinician-obtained Pap testing	720 (40.9)
Why do you prefer a self-collected test?	(n=1,039)
Logistics: more convenient, easier, time saving (%)	859 (82.7)
Experience: avoid embarrassment, discomfort (%)	396 (38.1)
Other (%)	18 (1.7)
If recommended by provider as an altern $(n=1,754, 99.2\%)$	ative would you be
More willing to use home HPV testing	1,297 (74.0)
Less willing to use home HPV testing	55 (3.1)
No effect on my choice of test	402 (22.9)
Why do you prefer a clinician-obtained	test? $(n = 720)$
More faith in provider sample/exam (%)	408 (56.7)
Other medical issues/face-to-face interaction (%)	305 (42.4)
Other (%)	40 (5.6)
Would any of the following make you m with home HPV testing? $(n=671)$	nore comfortable
Clinic confirmation that you performed the test correctly (%)	402 (59.9)
Phone call/email providing you with results and discussing any follow-up (%)	539 (80.3)
Option of a clinic visit to obtain a second test (%)	434 (64.7)

collected HPV testing (p = 0.04). Women who were assigned to and received a self-collected HPV test compared to those who were assigned to and received a clinician-collected test were more likely to prefer the self-collected HPV test (p < 0.001). Test preference did not vary significantly by age, need for child-care arrangement, out-of-pocket expenses, or clinic type (p > 0.05).

Women who were randomized to the self-collected HPV arm of the study reported positive experiences with the self-collected HPV test. Of 881 women, 97.7% indicated that the "instructions were easy to follow" and only 6.7% reported "trouble obtaining a sample" (data not shown).

Clinician acceptability survey

Of the 238 clinicians invited to participate, 118 (49.6%) consented and responded to the survey. Response rates were highest among gynecologists (64.7%) and were somewhat lower in family practitioners (41.6%) and physician assistants (14.3%). Respondents were mainly women (82.9%) and were 70.9% were internists or family practitioners (Table 4). Approximately half of respondents (47.5%) had been in practice <10 years. Approximately one-third reported performing Pap screening on a daily basis, and 64.1% of respondents reported prior knowledge of the HOPE study.

		Prefer clinician Pap	Prefer home HPV	р
	N=1,759	720 (40.9)	1,039 (59.1)	
Age				
<30	751	323 (43.0)	428 (57.0)	0.5
30-50	761	298 (39.2)	463 (60.8)	
51+	256	109 (42.6)	147 (57.4)	
Age at first pap				
≤20	1,178	469 (39.8)	709 (60.2)	0.06
21–24	364	156 (42.9)	208 (57.1)	
25+	129	62 (48.1)	67 (51.9)	
Experienced embarrassment at last Pap test				
No	1,355	597 (44.1)	758 (55.9)	< 0.001
Yes	355	106 (29.9)	249 (70.1)	
Experienced pain/discomfort at last Pan test				
No	1 1 2 8	488 (43 3)	640 (567)	0.01
Yes	584	216 (37.0)	368 (63.0)	0.01
Savually activa	501	210 (37.0)	500 (05.0)	
No	55	24(43.6)	31(564)	07
Ves	1 700	702 (41.1)	1 007 (58 0)	0.7
	1,709	702 (41.1)	1,007 (30.9)	
Education	154	92 (52 0)	71 (46.1)	-0.001
	154	83 (53.9)	/1 (40.1)	<0.001
Associate or technical school	521	224 (43.0)	297 (57.0)	
Bachelor's degree	482	191 (39.6)	291 (00.4)	
Graduate school	598	225 (37.6)	373 (62.4)	
History of prior STI(s)				
No	1,489	599 (40.2)	890 (59.8)	0.04
Yes	280	131 (46.8)	149 (53.2)	
Number of Paps in past 5 years				
0	244	103 (42.2)	141 (57.8)	0.11
1–2	908	355 (39.1)	553 (60.9)	
3	307	125 (40.7)	182 (59.3)	
4+	296	139 (47.0)	157 (53.0)	
Needed to take time off for last Pap				
No	1,103	479 (43.4)	624 (56.6)	0.009
Yes	620	229 (38.4)	391 (61.6)	
Needed to arrange child care for last Pap				
No children	1,189	492 (41.4)	697 (58.6)	0.6
Have children, no child care arrangement needed	461	185 (40.1)	276 (59.9)	
Yes	106	42 (39.6)	64 (60.4)	
Any other out-of-pocket expenses for last Pap				
No	1.341	547 (40.8)	794 (59.2)	0.8
Yes	353	142(40.2)	211(59.8)	0.0
Household income category	000	1.2(1012)	==== (0)(0)	
<\$10,000	353	183 (51.8)	170 (48.2)	<0.001
\$10,000	385	156 (40.5)	220 (50 5)	N0.001
\$35,000-99,999	333	123 (36.9)	229(5)(5)(5)(5)(5)(5)(5)(5)(5)(5)(5)(5)(5)(
>\$100,000	128	37(289)	91(711)	
Pendemization	120	57 (20.5))1 (/1.1)	
Salf collect	976	224(264)	557 (62 6)	<0.001
Clinician collected	0/0	524 (50.4) 406 (45 4)	337(03.0)	<0.001
	000	400 (43.4)	402 (34.0)	
	274	114 /41 ()	1(0 (50 4)	0.0
UW Medicine Clinics	2/4	114(41.0)	100 (58.4)	0.8
naroorview Research Clinic	1,485	000 (40.8)	8/8 (39.1)	

TABLE 3.	PATIENT C	HARAC	CTERISTICS	Associati	D WITH	PREFERENC	E FOR	Self-Collec	TED
	Home 1	HPV V	VERSUS CI	linician-O	BTAINED	TESTING (1	V = 1.75	59)	

UW, University of Washington.

Table 5 summarizes the characteristics of a screening test that were identified as important by clinicians. A higher percentage of clinicians indicated that patient acceptability was important (93.2%) compared to clinician acceptability (72.9%). The majority (78.0%) reported that they would recommend a self-collected HPV test if the test had qualities such as a high sensitivity and cost effectiveness. The most common reason cited for not recommending a self-collected HPV test was concern that a missed clinic visit could translate into a missed opportunity to address other health issues

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TABLE 4.	DEMOGRAPHIC CHARACTERISTICS OF CLINICIAN	V
	SURVEY PARTICIPANTS ($N=118$)	

TABLE 5. CLINICIAN SURVEY RESULTS REGARDING ACCEPTABILITY OF AT HOME HPV TEST

Characteristic	n	%
Sex		
Female	97	82.9
Male	20	17.1
Age (years)		
Median	41	
Range	27-72	
Degree		
MD	103	88.1
PA	1	0.8
NP	12	11.0
Years in practice		
<5	44	37.3
5–9	12	10.2
10–19	26	22.0
20+	36	30.5
Specialty		
Gynecology	28	23.9
Internal medicine	44	37.6
Family practice	39	33.3
Midwifery	1	0.9
Primary care/nurse practitioner	4	3.4
Women's health specialist	1	0.9
Frequency of Pap testing		
Daily	39	33.3
Weekly	41	35.0
Monthly	32	27.4
Yearly	5	4.3
Previous knowledge of Home HPV or Pap Exam study	75	64.1

Missing information is as follows: sex (n=1), degree (n=2), specialty (n=1), frequency of Pap testing (n=1).

(n=28). Other concerns included patient nonadherence to clinic-based follow-up, patients not coming in to the clinic for preventative exams, concerns about difficulty with sample collection or processing, and a desire to discuss the test results with a patient in clinic.

Additional chi-square test for trend analyses comparing responses by age and years of practice (data not shown) revealed that older clinicians >40 years (p=0.06) and those in practice longer >10 years (p=0.03) were somewhat more likely to list "patient able to obtain adequate sample" as an important characteristic for the screening test. Most survey respondents reported prior knowledge of the HOPE study, and survey responses for those with and without prior knowledge of the HOPE study were similar.

When subdivided by specialty, gynecologists were significantly less likely to recommend self-collected HPV testing (p=0.03). A "missed opportunity to address other health concerns" was the most common reason provided by gynecologists for not recommending a self-collected screening test (12 [67%] of 18 respondents). Ten percent of providers suggested additional characteristics that would be important for the self-collected test including: patient ability to understand results, ease of access to sample materials and testing, compliance with sample return, established frequency for testing, appropriate reminder systems in place, insurance coverage, stability of samples

	n	%
What characteristics are important for a	N=118	
cervical cancer screening test?		
Patient able to obtain adequate sample	107	90.7
Patient acceptability	110	93.2
Provider acceptability	86	72.9
Cost effectiveness	113	95.8
Sensitivity	115	97.5
Specificity	97	82.2
Other	12	10.2
If these characteristics were met, would	N = 118	
you recommend home HPV tests		
instead of clinician-obtained tests?		
Yes	92	78.0
Maybe	21	17.8
Probably not	5	4.2
Definitely not	0	0.0
For what age group would it acceptable	N = 112	
to use home HPV testing?		
Women <30 years	4	3.6
Women ≥30 years	26	23.3
Women of any age	82	73.2
Why would you not recommend home HPV testing?	$N=37^{\rm a}$	
Provider should perform test	0	0.0
Women may not return for other care	2	5.4
Adverse effects of lack of contact with patient	1	2.7
Missed opportunity to address other health issues	28	75.7
All of the above reasons	2	5.4
Other reasons	4	10.8

^aFrequencies reported for all participants who responded to this question regardless of whether or not they reported that they would recommend home HPV testing.

at room temperature, turnaround time, and positive and negative predictive values.

Discussion

Although a number of studies have shown that self-collected HPV tests are acceptable to patients, to our knowledge this is one of the first studies to also determine acceptability in clinicians. Our results suggest that self-collected HPV testing would be acceptable to clinicians if specific characteristics for a screening test could be met. However, this study also highlights clinician fears regarding missed opportunities to detect other health issues due to lack of a clinic visit. Limitations of this clinician survey include a small sample size, a 50% response rate that varied somewhat by specialty, and a study population of mostly nongynecologic academic clinicians who may be more willing to adopt new approaches to cervical cancer screening than those outside of an academic setting. More than one-third of clinician respondents had <5 years in practice (44 in total: 34 residents, 3 fellows and 7 faculties). As such, it is important to confirm these results in a larger, more diverse group of clinicians, including those in primary care as well as gynecologic specialties, to determine whether selfcollected HPV tests are similarly viewed.

Findings from this study are consistent with others that show that self-sampling is generally acceptable to patients.^{5,13,14} Over half the women in the clinician-obtained Pap arm of the study, and over 63% of women in the selfcollection arm of the study indicated they would prefer the option of self-collected testing; however, all participants were aware the study was evaluating a self-collected HPV screening test at recruitment, which may have resulted in overestimation of acceptability. Other limitations include the fact that this was a convenience sample, and that most (85%)participants were enrolled from a research clinic or at an academic institution. Despite this, our study population was similar to the general Seattle population in terms of race, ethnicity, and educational attainment. However, the views and preferences or participants in this study may not be generalizable to a specific population (United States Census Estimates July 1, 2015, www.census.gov/quickfacts/table/ RHI105210/5363000).

Since women who preferred self-collected HPV testing cited convenience and less embarrassment or discomfort as reasons for their preference, this supports the idea that self-collected samples could be an important alternative for women who may be reluctant to present to a clinic for routine screening.^{7,13,15,16} In a rural community in Ontario, Canada, under-screened women were twice as likely to participate in cervical cancer screening when offered self-collected HPV sampling kits compared to women who were invited to undergo Pap testing.¹⁴ In Argentina, offering self-collection of samples for HPV testing by community health workers during home visits resulted in a fourfold increase in cervical cancer screening uptake.⁷

Positive self-collected HPV test results may be helpful in encouraging women to then present to a clinic for further testing. For instance, among a group of underserved women in rural Appalachia, women more frequently returned for follow-up Pap test if their self-collected HPV test results were positive.⁹ Special populations such as lesbian/bisexual women and under-screened Swiss women (no Pap within 3 years) have been reported to have similar acceptance of self-collected testing.^{17–19}

An important consideration is the age at which a selfcollected HPV test can be offered if deemed suitable for use. In this study, most clinicians (73.2%) felt the self-collected HPV test would be acceptable for use at all ages. In the HOPE study protocol, all participants aged 21–65 years were randomized to a self-collected HPV test or clinicbased Pap. Given most clinician respondents reported some prior knowledge or experience with the HOPE study, this may have biased their response. Since current guidelines^{3,12} do not recommend the use of HPV testing for women aged <25 years, evaluation of whether the self-collected HPV test has similar accuracy and cost effectiveness in young women aged <25 years compared to women aged 25 years or older will need to be performed before self-collected HPV can be recommended for use across a wider age range.

Most women in the HOPE study reported that they would be more comfortable with a self-collected HPV test if a provider recommends this form of screening, if a clinic confirmed that the test was performed correctly, and if the provider contacted the patient to discuss the results, including any need for followup. Anhang studied a population of low-income, Hispanic uninsured women who indicated a preference for clinician collected samples (68%) over self-collect because they had more faith in the results; however, 21% of subjects indicated that self-collection would increase their likelihood of participation in screening.¹³ Similarly, in Victoria, Australia, women perceived self-sampling to be more convenient and less embarrassing and uncomfortable, but expressed concern that self-sampling would be less accurate than a clinician-collected Pap test.¹⁶

In our study, preference for self-collected HPV testing increased with education attainment and household income. Similar to our findings, in rural El Salvador, self-collection preference was associated with increased education and prior knowledge of HPV.²⁰ Further, a study of self-collected HPV tests in 3,863 women from India, Nicaragua and Uganda showed that acceptability was increased when providers prepared women for testing with education.²¹

Finally, a consistent finding between clinicians and patients was the need to ensure that patients had access to their healthcare provider to address other concerns. Integration of self-collected HPV tests into routine clinical practice, should they prove accurate and cost effective, will not only require education but also determining how to establish new clinical pathways for recommending and following up test results while ensuring continued access to a healthcare provider for other needs.

Conclusion

Home self-collected HPV screening tests are acceptable to patients and clinicians if the test is shown to be accurate, cost effective, and does not impact access to a healthcare provider for other health concerns.

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