Cervical Cancer Self-Collection for Southeast Asian Immigrant and Refugee Women

NCT05286749

8-8-2023

Title:
Community Health Outreach to Increase Cervical Cancer Education and Self-Collection Screening (CHOICESS) Program for Southeast Asian Immigrant and Refugee Women in Wisconsin

Team Members

Primary Investigator
Jessica Dalby, MD Associate Professor University of Wisconsin SMPH Department of Family Medicine and Community Health 1100 Delaplaine Ct., Madison, WI 53715 Phone: (608) 263-3111 Email: jessica.dalby@fammed.wisc.edu

Collaborators	**Organization**	**Role on Project**	**Email**
Tana Chongsuwat, MD	UW-Madison SMPH	Postdoctoral Research Associate	chongsuwat@wisc.edu
Mayhoua Moua	Milwaukee Consortium for Hmong Health	Community Partner	mkehmonghealth@gmail.com
Kaitlin Sundling, MD	UW-Madison SMPH/Wisconsin State Laboratory of Hygiene	Cytologist	ksundling@wisc.edu
Joshua Faulkes	UW-Madison Wisconsin State Laboratory of Hygiene	Cytology Supervisor	jdfaulkes@slh.wisc.edu

Protocol Version History

Protocol Version	Version Date	Summary of Revisions Made	Rationale
1.0	11/16/21	Initial version	
2.0	08/02/22	Study site location change Timeline Sample handling and analysis Sharing of Data Incentives	Capacity and equipment Feasibility and recruitment Original lab lacking LDT validation required Additional of laboratory with necessary LDT validation Change in gift card amount
3.0	03/22/23	Timeline Study personnel	Simplicity of timeline Increase FTE for Jessica Dalby and removal of Megan Fitzpatrick as Co-PI
4.0	08/08/23	Expansion of inclusion ethnicities Consent process	Expansion of recruitment pool for feasibility in enrolling enough participants Accommodations for special ethnic groups with limited English proficiency and low reading literacy

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STATEMENT OF COMPLIANCE

I confirm that I have read this protocol. I will comply with the IRB-approved protocol, and applicable regulations, guidelines, laws, and institutional policies.

I agree to ensure that all staff members involved in the conduct of this study are informed about their obligations in meeting the above commitment.

Name	**Signature**	**Date**
Name	**Signature**	**Date**
Jessica Dalby		**08/08/23**

Jessica Dalby, MD
Principal Investigator

SYNOPSIS

Study Title	Community Health Outreach to Increase Cervical Cancer Education and Self-Collection Screening (CHOICESS) Program for Southeast Asian Immigrant and Refugee Women in Wisconsin
Brief Summary	The primary purpose of this study is to determine whether educational workshops paired with self-collected high-risk human papillomaviruses (hrHPV) screening will increase participation in cervical cancer screening among Southeast Asian refugee and immigrant populations in Wisconsin compared with offering clinician-collected screening (total sample size: 250 participants). We hypothesize that participation in cervical cancer screening will be higher among women in the intervention group as compared to the control group.
Number of study sites	1
Study Design	Workshops are randomized to either a control or intervention group.
Primary Objective	To evaluate whether educational workshops paired with self-collected hrHPV screening will increase participation in cervical cancer screening among Southeast Asian refugee and immigrant populations in Wisconsin compared with offering clinician-collected screening.
Secondary Objective(s)	To evaluate participant satisfaction with the educational workshops using satisfaction surveys.
Research Intervention(s)	**Control** workshops are workshops where participants are provided education on standard-of-care for cervical cancer screening such as pap smear and HPV testing through clinician-collection methods using speculum and cervical swabs. **Intervention** workshops are workshops where participants are provided all the same education as control as well as additional education on self-collection for HPV-only testing using vaginal swab as an additional method. After each workshop, each group will be offered to participate in their assigned group's screening method (clinician-collected or self-collected).
Device used on study (including any IND/IDE #)	Evalyn® Brush (Rovers® Medical Devices, Netherlands) Regulation Number# 884.4530 Roche Cobas4800 HPV Test System (Roche Molecular Systems Inc., Rotkreuz, Switzerland)
Study Population	Southeast Asian Immigrant and Refugee (Karenni, Karen, Burmese, and Hmong) Women in Wisconsin, aged 25-65, eligible for cervical cancer screening.
Sample Size	240
Study Duration for individual participants	Subject participation is limited to the workshop session, post-workshop cervical cancer screening, and follow-up contact on results of screening tests.
Study Specific Abbreviations/ Definitions	ASCCP, Society for Colposcopy and Cervical Pathology; CHW, community health worker; FDA, Food and Drug Administration; HCP, health care provider; hrHPV, high-risk human papillomaviruses; LMP, last menstrual period; MCHH Milwaukee Consortium for Hmong Health; ROI, release of information

1. INTRODUCTION

1.1 Background

Despite effective screening and early treatment options, 311,000 women die of cervical cancer worldwide every year.[1] In the United States, Hmong-American immigrant women experience incidence and mortality rates four times those of their non-Latina white counterparts and have alarmingly low participation in cervical cancer screening.[2] With the third highest Hmong population in the US, Wisconsin's minority communities face similar health disparities.[1] Factors such as modesty, fatalism, lack of knowledge, and lack of access impede participation in screening and treatment for cervical cancer. These barriers can be attributed to cultural beliefs, patriarchal family/clan structure, language barriers, and mistrust or lack of experience in the Western medical system.[3,4]

In women 25 and over, screening for cervical cancer screening through testing for high-risk human papillomaviruses (hrHPV) has been found to be more sensitive than cytology and effective in preventing cervical cancer.[5] **Self-collection** has been a proposed strategy to reach under-screened women worldwide. Recent systematic reviews and meta-analyses have shown that offering hrHPV self-collection at home to non-attendees can significantly increase attendance and the detection of high-grade cervical lesions, compared to currently widely-used reminder letters for clinician-based screening.[6,7] Most studies have found at least a doubled response rate to submitting a self-sample versus scheduling an on-site pap smear, even among under-screened populations.[8-10] Furthermore, with improved hrHPV polymerase chain reaction (PCR)-based testing technology, the sensitivity for detection of human papillomavirus (HPV) infections is comparable in most self-collect samples when compared to clinician-collected samples. Kaiser Permanente ran a similar study across 20,000 women who were behind on their screening and found that 50% more women chose to return a self-sample than schedule an in-office screen. A large population-based cervical cancer self-collected study in Argentina found that HPV-based screening doubles the detection rate ratio (DRR) for HPV screening.[9] These studies have led some countries, such as Australia, to institute a self-collection option nationally.[8,10] Furthermore, our previous work in rural Zimbabwe found that community-based screening using self-collected samples increased participation in cervical cancer screening from a baseline of 5% to 82% participation.[11-13] As part of a comprehensive cervical cancer screening program, the utilization of self-collected samples has advantages from both a public health and individual participant perspective. Some of the barriers to screening can be mitigated by self-collection, and resources can be better allocated to participants at the highest risk of developing cervical cancer.

1.2 Rationale

The effectiveness of offering self-collection sampling options to Southeast Asian refugee and immigrant populations to improve cervical cancer screening participation has not been investigated. The Milwaukee Consortium for Hmong Health (MCHH), supported by the Well Woman Program, has had success increasing participation in breast cancer screening through outreach and education activities. However, it continues to have **limited success** engaging women in cervical cancer screening. We have established a partnership with MCHH to develop innovative cervical cancer workshops that combine community health worker (CHW)-led engagement with self-collected hrHPV screening, with the primary objective of increasing participation, awareness, and engagement in cervical cancer screening and treatment activities among this population.

2. STUDY OBJECTIVES AND ENDPOINTS

Objectives	Endpoints
Primary	
• To evaluate whether educational workshops paired with self-collected hrHPV screening will increase participation in cervical cancer screening among Southeast Asian (Hmong, Burmese, Karen, and Karenni) refugee and immigrant populations in Wisconsin compared with offering clinician-collected screening.	• Uptake of cervical cancer screening using a self-collect device vs. clinician-based screening.
Secondary	
• To evaluate participant satisfaction with the educational workshops using satisfaction surveys.	• Participant satisfaction as determined using qualitative methods.
• To evaluate participant willingness to use self-collection as method for screening.	• General willingness to use a HPV self-collect device at home and/or as the preferred collection method for cervical cancer screening, assessed via mixed methods survey.

3. STUDY PARTICIPANTS

Study participants in this project include participants recruited for cervical cancer CHW-led educational workshops led by MCHH. Participants can be either Hmong, Karen, Burmese or Karenni speaking and are recruited by MCHH with a particular focus on those who are behind or have never had cervical cancer screening. The main objective is to provide education to these participants on cervical cancer prevention and screening with subsequent invitation for immediate post-workshop sample collection for cervical cancer screening.

4. NUMBER OF PARTICIPANTS

Total number of study subjects: 250.

5. INCLUSION AND EXCLUSION CRITERIA

5.1 Inclusion Criteria

- Female (assigned female at birth, regardless of gender identity)
- Ages 25-65
- Fluent understanding in English, Karen, Burmese, Hmong or Karenni.

5.2 Exclusion Criteria

- Prior hysterectomy
- Impaired decision-making capacity
- Pregnancy

6. SPECIAL POPULATIONS

Those who lack consent capacity, the mentally ill, prisoners, cognitively impaired persons, children, and employees will not be included in this research study.

7. RECRUITMENT METHODS

Participants will be identified and recruited by MCHH using several recruitment strategies.

7.1 Verbal Communication

Word of mouth among participants, family members, and the Southeast Asian community will be used. Participants will be encouraged to contact MCHH for further details and specifics about the research study.

Announcements at church service will be done by CHWs at local churches frequented by Southeast Asian immigrant and refugee communities. Announcements will be scripted and will include key eligibility, criteria, length of workshop, location of study site, type of remuneration, and contact details for further information.

7.2 Telephone Recruitment

The study team will call potential participants using a list of community members who have previously sought services through MCHH. Attempts to reach participants will be two times over a two-week period. All initial discussion with participants from recruitment lists, or when potential subjects contact the study team via other recruitment methods, will include a brief description of the study's purpose, eligibility criteria, and participant involvement will be reviewed. This must also include a statement that participation is voluntary. The screener will ask the caller if she has any questions and whether they are interested in participating. After all questions have been answered, the study team member will ask if the potential subject is interested in proceeding to the next step in recruitment for the study. Potential subjects will answer pre-screening questions using an IRB-approved script. Information collected from potential subjects who fail pre-screening will be destroyed at the end of the study period. Potential subjects who meet all pre-screening criteria will be invited to a particular workshop day in order to go through the consent process.

7.3 Participant Remuneration

All participants regardless of their participation in the post-workshop screening for cervical cancer or the post-workshop satisfaction survey will receive a $25 gift card.

8. CONSENT PROCESS

The informed consent process will make clear that participation in any and all aspects of the study are voluntary, and that participants may end their participation at any time.

The informed consent process will be conducted following all federal and institutional regulations relating to informed consent. Informed consent will be obtained at the beginning of participation through the following process:

- A link to a pre-record video will be provided to each participant at the time of recruitment. This video will be created prior to the start of the study which CHWs employed through MCHH will provide consent information using the pre-approved oral script.
    - If the CHW does not speak the spoken language, then an the CHW would follow the script in English and a translator would then translate the information to the participant language.
- Upon arrival to the study, participants will be asked if they have seen the pre-recorded video:
    - If any participant reports the video was not viewed – it will be shown to all participants.
    - CHW provides a summary about the study, study activity, and consent items, then answering any questions which may arise.

    - If the CHW does not speak the spoken language, then an the CHW would provide the information in English and a translator would then translate the information to the participant language. Questions or comments will also be translated back to the CHW to be answered. The translator will serve as witness to ensure that study materials and consent were understood by the participant.
- It will be noted in a participant's study record noting they provided verbal consent.

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Participants will be informed of random assignment into two groups: standard-of-care control group and intervention group. Due to the nature of this study, we will not disclose which group the participant belongs to although will provide a debrief session at the end of the study about what information could not be given at the time of consenting, and why they could not be told at that time.

Participants will not be told the full procedures prior to enrollment due to the need to test the hypothesis in this study. Participants in the control group are initially only provided educational materials about the standard of care for cervical cancer screening. While self-collection may or may not be known by the workshop participants in the control group, this is not standard of practice nor usually recommended by clinicians. Whereas the intervention group is provided additional materials about self-collection in the core educational material and is offered as a screening option immediately at the end of the workshop. The uptake of cervical cancer screening by workshop participants at the end of the workshop will then be compared between these two groups to determine.

The informed consent process will include contact information for the PI, who can be contacted if participants or potential participants have questions or concerns.. Informed consent forms will be available in written English, Hmong, or Karenni for reference only. All participants will have access to the pre-recorded video in their native language for reference.

9. PROCESS TO DOCUMENT CONSENT IN WRITING

This study requests of waiver of written documentation of consent

- A written script of the information will be provided orally.
- Pre-recorded video of oral script will be available to all participants for future reference.
- Research presents no more than minimal risk of harm to subjects.
- The research involves no procedures for which written consent is normally required outside of the research context.

This consent requests an alteration of the consent process (HRP-410) due to the following criteria:

- The study involves no more than Minimal Risk to the participants based on clinical standard of care.
- The study could not be practically carried out without the alteration. Participants will be blinded to which group they are randomized in order measure participation rates based on which type of screening method they are offered (clinician-collection vs self-collection)
- The alteration will not adversely affect the rights and welfare of the subjects. Participants will be provided the risks of each collection method in detail during the workshops. If a participant declines the type of screening they are offered will then be offered the other screening method.
- Subjects will be provided the additional pertinent information after participation.
- High proportion of participants in this study population have no or low reading or writing literacy in English or the native language.

10. SETTING

The location where the research team will conduct the research will be at MCHH's community center (1802 W Walnut St, Milwaukee WI 53205). The space has been previously used by MCHH to conduct larger workshops

in-person and can accommodate any necessary physical spacing needed for respiratory infection control. In addition, the community space has two private rooms to accommodate needs for participant privacy.

11. STUDY INTERVENTION

This randomized controlled trial will be done in partnership with MCHH. Previous partnership with MCHH and UW-Madison researchers developed cervical cancer educational workshops designed by CHWs to provide innovative mixed-modality education consisting of pictographs, flipcharts, videos, and hands-on models. These workshops to be conducted in Hmong, Karen, and Burmese and Karenni languages were tested in mock workshops with Hmong and Karenni participants and through a community advisory panel prior to dissemination. This approach caters to the unique culture and communication styles of Southeast Asian immigrant and refugee populations.

All workshops will be conducted by the CHWs on the study team. If the CHW is not fluent in the target language (such as Karen or Burmese), then the CHW will conduct all study activities in English with a translator available to translate all activities.

All participants attending a workshop will be randomized as a group to either a control or intervention group. Workshops in the control group will provide education recommending standard of care (clinician-collected hrHPV testing and cytology screening). Workshops in the intervention group will be offered the same education with additional education on the option of self-collection (HPV testing only) for their screening method. All participants will have the same basic demographic information collected in MCHH's standard intake form with an additional question on current barriers to screening.

Participants will self-select which workshop day they would like to attend depending on their preferred language. Participants can attend any available date a workshop is being offered until filled. Participants will be blinded to knowing which workshops are control or intervention groups. Participants during consent will be made aware there are two different groups and the difference between the intervention and control group is the education provided and screening method offered at the end of the education session. Participants will be provided the full study details at the end of their participation.

We anticipate a total of thirty workshops, fifteen of which will be control and fifteen of which will be intervention, will be planned in total over a sixteen-month period (Table 1). All workshops will have 8 participants recruited due to limited space of the community center, time, and to accommodate physical spacing needs. There will be two workshop sessions per day (one in the morning and one in the afternoon).

Table 1. Planned Number of Hmong and Karenni Participants in the Intervention and Control Workshops

Intervention Workshop	**1**	**2**	**3**	**4**	**5**	**Total**
Hmong	**8**	**8**	**8**	**8**	**8**	**40**
Karenni	**8**	**8**	**8**	**8**		**36**
Karen	**8**	**8**	**8**			**24**
Burmese	**8**	**8**	**8**			**24**
Control Workshop						
Hmong	**8**	**8**	**8**	**8**	**8**	**40**
Karenni	**8**	**8**	**8**	**8**		**36**
Karen	**8**	**8**	**8**			**24**
Burmese	**8**	**8**	**8**			**24**

After workshop conclusion, participants will be offered same-day on-site cervical cancer screening depending on assignment in the control or intervention group (clinician-collected screening or self-collection screening, respectively). Participants, regardless of engagement in screening, will then complete a post-evaluation workshop survey (consisting of two surveys, see Appendix C).

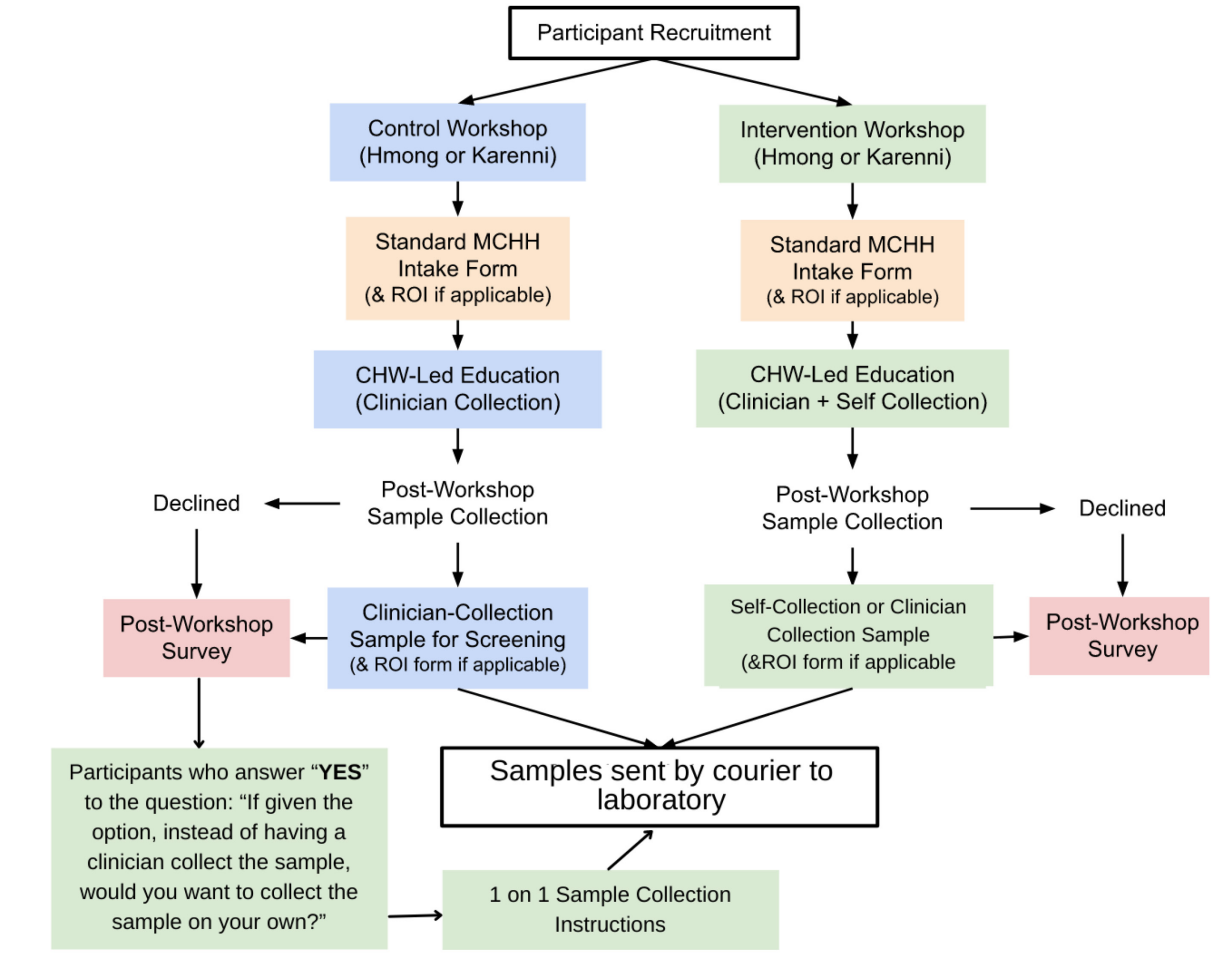
Due to ethical concerns and our hypothesis that this population is less likely to do cervical cancer screening if offered clinician-collected screening only. Participants in the control workshops who answer “yes” on the survey to the question “If given the option, instead of having a clinician collect the sample, would you want to collect the sample on your own?,” will be subsequently offered self-collection for their screening method. CHWs will provide to these participants a 5-minute 1-on-1 instruction tutorial on self-collection, translated handout, private room to collect a sample, and then samples sent to the laboratory per protocol.

Similarly, participants will be made aware during the education of the self-collection method, that this is not a usual method that is offered in many clinical practices. If a participant were to visit their usual primary care doctor for an exam, a pelvic examination to obtain a clinician-collected cervical swab for HPV testing and pap smear is the usual method which they should anticipate. We are offering self-collection as studies show growing validity of HPV self-sampling, particularly among hard-to-reach populations.[14-18] With this understanding, self-collection will be offered and encouraged although if participants desire clinician-collection instead this is option will also made available.

The final part of the study is to fully explain the purpose of the study to each participant, including why subjects could not be informed of all study procedures prior to, and during the study up to that point. The study procedures in question were providing standard-of-care education on cervical cancer screening to both groups and additional information on self-collection for HPV screening to the intervention group. The education on the option for self-collection is withheld from the control group. This information could not be disclosed to the study participants prior to the end of the study to effectively measure participations rates for self-swab if they are provided the education or education is withheld.

Full workflow of design for participation in workshops and post-workshop screening is outlined in Figure 1.

Figure 1. Participant Engagement Workflow



12. STUDY TIMELINES

Subject participation is limited to the workshop session, post-workshop cervical cancer screening and surveys, and follow up call from CHWs on results of screening tests (if indicated).

- Duration of participation involvement is estimated to be between two to three hours.
- Activities involved is primarily attendance at a 45-minute workshop followed by post-workshop survey (estimate to complete in three- to five-minutes)
- Participants who opt for screening for cervical cancer after workshop completion will spend an additional 30 to 60 minutes waiting for sample collection. Actual time for sample collection will be between five- to ten- minutes.
- Participants will be contacted by phone regarding their results on screening tests by MCHH CHWs. Those with positive results will be asked to return to the community center to discuss the results in-person with CHWs, with a clinician available by virtual methods.

Anticipated duration to enroll all study participants will be over 16 months. Estimated date for researchers to complete this study (including primary analysis) is over 24 months starting from IRB approval.

A research subject will be defined as “enrolled” in the study when they meet the following criteria:

- The subject has been consented by study staff.
- The PI has verified that the subject meets all of the inclusion criteria.
- The PI has verified that subject meets none of the exclusion criteria.
- The subject has been assigned to the protocol by study staff.

The project period is estimated to be two years from date of IRB approval. Table 2 summarizes the activities and evaluations that will take place during the project, over a 24-month time period, and which subject participants are involved with them.

Table 2. Study Calendar

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Activities																								
Develop Recruitment Strategy	X	X																						
Recruitment			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X					
Monthly Workshops					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X					
Follow-up on Screening Results					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Evaluation																								
Participation Rates					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X				
Post Workshop Surveys					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X				

13. PROCEDURES INVOLVED

13.1 Project Activities

13.1.1 Pre-Participation Intake

Intake will be done upon recruitment, after informed consent it obtained and prior to start the assigned workshop. Forms to be used are the standard intake forms used by MCHH for previous workshop participations and gathers information such as demographics, primary care physician (PCP), and insurance coverage (full intake form in Appendix A). Intake forms are assigned an ID # which will be used to extract data for this research program. Ms. Mayhoua (MCHH Director) will maintain original intake forms at the MCHH community center and participant identities to the study ID separately from other data. Following information from the intake form will be collected for this research program:

- ID Number
- First and last initials
- Workshop Date
- Ethnicity
- Date of Birth
- Gender
- Month and year of previous Pap Test
- Type of Insurance
- Answer to the following question “What reasons may be stopping you from getting a Pap Test?” (options below)

[ ] No symptoms	[ ] I don’t want to know the results
[ ] No transportation	[ ] Childcare
[ ] Too expensive/No insurance	[ ] No family history of cervical cancer
[ ] I don’t know where to go	[ ] My doctor never mentioned it
[ ] Spouse will not allow it	[ ] Embarrassed
[ ] I’m too busy/No time	[ ] Long wait to get an appointment
[ ] I am afraid it will hurt	[ ] None

If a participant has a PCP, MCHH can fax or mail the results of their screening tests directly to their PCP. For participants who do not have a PCP and would like to establish with one, a list of available providers in the area accepting new patients will be obtained prior to the start of the research study.

Providers accepting new patients will be oriented by phone by a research team member prior to the start of the study. They will be provided with a brief overview of the research study and purpose. In addition, when receiving participant results on cervical cancer screening, cover letter will include a brief overview of the research project, purpose, recommend follow-up, and need for patient to establish as a new patient to their clinic.

13.1.2 Workshops

All workshop materials were previously developed through a partnership with Dr. Chongsuwat and MCHH, with support through a community advisory panel. Workshops consist of translated materials into Hmong, Burmese, Karen and Karenni, with methods that include flip charts, video, and hands-on models to provide education on cervical cancer screening and prevention. Materials were developed to target mother-daughter pairs although for this research will target only women age 25 to 65 which is the target for HPV only screening (versus co-testing HPV and pap smear). Participants self-select which workshop day they would like to participate in

although are blinded which group the workshop belongs to. Workshops are differentiated based on belonging to the control or intervention group.

- **Control** workshops are workshops where participants are provided education on standard-of-care for cervical cancer screening such as pap smear and HPV testing through clinician-collection methods using speculum and cervical swabs.
- **Intervention** workshops are workshops where are participants are provided all the same education as control as well as additional education on self-collection for HPV only testing using vaginal swab as an additional method.

13.1.3 Post-Workshop Survey Collection

All participants after education session, regardless of participation in post-workshop screening for cervical cancer, will answer questions on two separate surveys. The MCHH post-workshop evaluation survey (MCHH-PES) has been used previously after workshops that were hosted by MCHH. The UW Health Post-Workshop Satisfaction Survey (UW-PSS) will be an additional survey done to cover remaining questions on participant satisfaction.

13.1.3.1 MCHH Post-Workshop Evaluation Survey (MCHH-PES)

Data collected on the original intake form by MCHH includes the following questions (Figure 3) and will be collected in this study in the same format. Survey will be administered verbally by CHWs in the participants native language. Paper copies of the survey will remain with MCHH and responses copied into Qualtrics survey and continued with questions in the next section (13.2.2. UW Health Researchers Post-Workshop Satisfaction Survey).

Figure 3. MCHH-PES Questions

Participant Evaluation

After today's workshop, how likely are you to...?	Not likely		Neutral		Very Likely
1. Receive a Pap/Pelvic exam this year or as recommended?	1	2	3	4	5
2. Spread the word about the screenings available to your family members?	1	2	3	4	5
3. To encourage your family members to get screened?	1	2	3	4	5
4. Practice healthy behaviours that can reduce your risks for cervical cancer?	1	2	3	4	5

13.1.3.2 UW Health Post-Workshop Satisfaction Survey (UW-PSS)

Additional survey questions will be administered verbally by CHWs and answers recorded in Qualtrics for data collection. Responses will not be linked to the study ID or other identifiable information. Theme of survey questions is below (full survey in Appendix C):

- Comfort with method (either self-collection or clinician-collection)
- How likely would the participant get screening for cervical cancer again?
- If self-collection (or clinician-collection) was an option, would they have preferred this method.

- If not getting screening today, will they go for screening in the near future?
    - If not why? Where?
- Understanding of instructions (self-collection)

13.1.4 **Post-Workshop Sample Collection**

Immediately after workshops, participants will be offered same-day opportunity to engage in cervical cancer screening either through clinician collection (if in the control) or self-collection (if in the intervention group). Participants who do not desire screening through the program will be encouraged to attend cervical cancer screening with their local health department or provider.

Pregnant women will be excluded from this study if they are known to be pregnant at the time of screening, although additional measures will be taken prior to sample collection for women unaware of pregnancy status. All participants will be asked the date of their last menstrual period (LMP). Participants will be requested to provide a urine sample for on-site urine pregnancy testing if more than six weeks from LMP unless post-menopausal or meeting criteria of relative certainty a woman is not pregnant. CDC 2016 Selective Practice Recommendations for reasonable certainty states, a health care provider can be reasonably certain that women is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is ≤7 days after the start of normal menses
- has not had sexual intercourse since the start of last normal menses
- has been correctly and consistently using a reliable method of contraception
- is ≤7 days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and <6 months postpartum[14]

Results of the urine pregnancy test will be provided immediately to the participant and if positive, excluded from the remaining of the study although still counted as a participant. Due the possibility that participants who are pregnant and included in the study (educational workshops only, will not be included in either screening method– clinician-collected or self-collection). For risks involved with the educational workshop portion of the study:

- The research involves no more than minimal risk to pregnant women and fetuses.
- The research holds prospect of direct benefit to the pregnant women, the prospect of direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus.
- The educational workshops on cervical cancer provided potential benefit by prevention of cervical cancer in the woman and reduction of morbidity and mortality which may have subsequent benefit to the fetus.

Physicians from UW- Madison will be made available to assist in either group with CHWs as approved translators to guide collection.

13.1.4.1 **Self-Swab Vaginal Samples**

Participants will be provided a private area of their choice (exam room or bathroom) to self-collect vaginal samples. Device which will be used is the Evalyn® Brush (Rovers Medical Devices, Netherlands) which has FDA and CLIA approval. The device is self-directed by the participant and will include translated instructions in Hmong, Karen, and Burmese and Karenni. Instructions will also be provided to all participants orally. The device is neither implanted nor creates a potential for serious risk to the health, safety, or welfare of the subject. A picture of the device and instructions for self-collected provided by the manufacturer are included in Appendix B. There are no known potential serious risks to the health, safety, or welfare of the subject. Dr. Chongsuwat will be available onsite to answer any questions or concerns participants have during the self-collection process.

13.1.4.2 **Clinician-Collected Cervical Samples**
The provider (Dr. Chongsuwat) will obtain a sample in the normal standard fashion using speculum to collect cervical samples. Samples will be collected in ThinPrep vials for Pap smear and HPV testing.

Self-collected samples will be packaged for disposition and transported to the Penn State Health Medical Group Laboratory for processing and evaluation. Clinician-collected samples will be packaged for disposition and transport to the WSLH lab for processing and evaluation. There are no known potential serious risks to the health, safety, or welfare of the subject.

If participants have a primary care provider and did not sign a ROI form at intake and at this time would like their results sent to their provider, a ROI form will be offered to be filled out and signed.

13.1.5 **Sample handling and analysis**

Clinician-collected samples will be labeled with study ID, participant initials, date of collection and source of collection (cervix) and transported via approved courier to the Wisconsin State Laboratory of Hygiene (WSLH).

Self-collected samples collected using the Evalyn self-collection device will be transferred to a ThinPrep vial for storage and transport. The vial will be labeled with study ID, participant initials, date of collection and source of collection (vaginal self) and transported via approved courier to the Penn State Health Medical Group Laboratory.

13.1.5.1 **HPV testing**
All samples will be processed at the WSLH (if cervical clinician-collected) or Penn State Health Medical Group Laboratory (if vaginal self-collected) and tested for the presence of 14 oncogenic/high-risk HPV genotypes 16, 18, and other (31,33,35,39,45,51,52,56,58,59,66,68) using the CLIA-certified Roche Cobas4800 HPV Test System (Roche Molecular Systems Inc., Rotkreuz, Switzerland) according to the manufacturer's instructions. Negative samples with the process control (β-globin) DNA concentration that does not fall within Roche's pre-determined range will be considered technically inadequate.

Samples will be pre-aliquoted into properly barcoded 13ml round bottomed sarstedt tubes (2ml) for HPV primary testing according to the Roche Cobas HPV Test package insert. All samples will be run on the Roche Cobas 4800 (for a full HPV workflow following the package insert guidelines). Unsatisfactory results will be run a second time per laboratory standard operating procedure. Results of the sample will be reported to MCHH using standard operating and HIPAA procedures. All HPV Test run results will be analyzed and checked for quality by the Cytology Supervisor.

13.1.5.2 **Pap Smear testing**

Cytological studies, including cell counts, will be performed on the remaining material in the ThinPrep vials following WSLH standard operating procedure, summarized as follows. Mono-layer smears will be generated on the CLIA-certified Hologic T-5000 platform and stained with Hologic PAP stain using WSLH stain quality controls. Initial screening will be performed by WSLH staff cytotechnologists and quality control screening will be performed by a qualified QC Technologist with five years or more of experience in GYN cytology. Abnormal slides will be reviewed by staff pathologists. Unsatisfactory study samples will be reprocessed at the discretion of the WSLH Cytology Director. All cytology samples will be assessed for 1) adequacy (>5,000 cells per slide, estimated based on ten fields counted at 400x magnification) and, 2) diagnoses according to Bethesda System. Clinician-collected cytology cases will be evaluated as part of the routine clinical flow and results reported to MCHH. Cytological results will be grouped as the diagnosis of atypical squamous cells of undetermined significance or higher (ASC-US+) and as high-grade dysplasia (HG cytology). Histological results will be grouped as the diagnosis of cervical intraepithelial neoplasia 2 or higher (CIN2+), cervical intraepithelial neoplasia 3 or higher (CIN3+), and cervical carcinoma (CA).

13.1.5.3 Reporting of results

All results of the samples will be reported to MCHH using standard operating procedures.

For vaginal self-collected samples collected using the Evalyn self-collection device, processed by the Penn State Health Medical Group Laboratory, additional wording will include “This test was developed and its performance characteristics determined by Penn State Health Milton S. Hershey Medical Center laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This lab is certified under CLIA-88 as qualified to perform high complexity lab testing. .”

For cervical samples collected by a clinician using the Dacron Brush and stored in ThinPrep vials, CLIA-certified and FDA-approved analysis of the liquid cytology on Hologic T-5000 platform and HPV genotype analysis on the Roche COBAS platform will be used.

13.1.6 **Follow-up on results**

Samples from screening will be sent via courier to the respective laboratory and results forwarded to MCHH to follow up on results. All participants will be contact by phone regarding their results. Participants with positive results will be asked to return to the community center to discuss the results in-person with MCHH CHWs with a clinician from the study team available virtually to answer any questions. Two attempts will be made to call the participant via phone and if still not reached, a letter will be mailed to the participant’s home.

All participants regardless of results will be provided a printed copy of their results via mail or in-person. If a participant does not have a preferred primary care clinic, additional resources will be given on available providers in the area accepting new patients. If participants filled out an ROI form at intake, all results as well as brief letter describing the study will be faxed or mailed to the health care clinic. Guidelines for appropriate follow up by Society for Colposcopy and Cervical Pathology (ASCCP) standards are outlined through an online web application, mobile app, and website (asccp.org/management-guidelines). These management guidelines will be followed for interpreting risk of pathology and recommendation of follow up needs.

14. COMPARISON OF USUAL CARE AND STUDY PROCEDURES

Standard of care for women recommended by the ASCCP is screening for cervical cancer starting at age 21 with pap smear every three years and then co-testing (HPV and pap smear) starting at age 30. American Cancer Society (ACS) recommends screening starting at age 25 with primarily HPV only every five years. Both societies recommend for screening to continue until age 65 unless history of abnormal results or hysterectomy unrelated to cervical dysplasia.

These research procedures follow standard of care as expected for care delivered to participant population at UW-Madison/UW Health, regarding clinician collection of samples for cervical cancer screening. In both the intervention and control arms of the study, participants will be offered the opportunity for cervical cancer screening via a licensed health care professional. The intervention is education and use of self-collection for HPV only testing using vaginal swab as an additional method to usual care, i.e., pap smear and HPV testing through clinician-collection methods using speculum and cervical swabs (control).

Overall, research has shown self-collection HPV testing as an acceptable method for screening especially in hard-to-reach populations, although concerns remain on potential for false negative results.[15-19] Participants will be informed of this risk and encouraged if opting for self-collection through this method to follow-up with their primary care physician for additional screening per recommended guidelines. Reporting of results will further specify this comparison to standard procedure (outlined in section 13.1.5.3 Reporting of Results).

Otherwise follow up recommendations based on results for clinician-collection (outlined in section 13.1.5 Follow up on Results) is also standard of care, and there will be no delay in care or treatment as a result of being in this study.

If patients have a primary care clinic, their results will not automatically flow into their electronic health record. If an ROI for the PCP has been filled out (see section 13.1.1 and 13.1.3), copy of the results and recommendation for next steps will be provided for continuity of care. Participants will also receive a paper copy of their results to maintain for their own records.

15. WITHDRAWAL OF PARTICIPANTS

Subjects are free to withdraw from participation in the study at any time upon request.

Subjects who sign the informed consent form and who do not attend the workshop will be replaced. Subjects who sign the informed consent form, and who attend some or all of the workshop, but do not complete surveys or screening, or are withdrawn or discontinued from the study, will not be replaced.

16. DATA MANAGEMENT AND CONFIDENTIALITY

16.1 Project Data Collection

Standardized data collection forms (e.g., source documents, standardized assessment forms, etc.) are used to ensure data collected are consistent and compliant with the protocol and IRB application.

Data collection is the responsibility of study team members under the supervision of the Principal Investigator (PI). The PI is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the recorded and reported data.

All data collection forms must be completed in a legible manner; any missing data will be explained. Data entry errors will be corrected with a single line through the incorrect entry and the correct data is entered above/near the correction. All changes will be initialed and dated.

16.2 Data Storage and Maintenance

Data will be stored in compliance with HIPAA regulations on encrypted UW research servers in the Department of Family Medicine and Community Health All records including study enrollment information will be housed in compliance with regulations indefinitely until the analysis is complete. The process of destroying of these records post-analysis will comply with applicable UW or policies for research records.

The study ID, date of workshop attendance, age, zipcode, type of screening done, and screening results will be stored in REDCap Institute for Clinical and Translational Research (ICTR). Portable devices will be used to access secure web-based application of ICTR's RedCap. No data will be stored locally on the device. Only encrypted devices will be used.

Research Electronic Data Capture (REDCap) is a largely self-service, secure, web-based application for building and managing data collection forms. REDCap provides data management functionality by allowing the development of instrument and surveys to support data capture for research studies.

Post-workshop survey results will be stored in Qualtrics and not linked to study ID, results will be entirely anonymous. Paper copies of the intake form will be stored in a locked location at the Milwaukee Consortium for Hmong Health.

16.3 Confidentiality

There is a slight risk of loss of confidentiality of participant information to subjects enrolled on study. Records will be linked to study ID. Participant identification information will be stored separately and maintained with MCHH for purposes of contacting follow up results. Any information regarding participations will be kept confidential, and to the extent permitted, will not be publicly available. Information collected will be stored on secure, password-protected electronic systems and access will be limited to those involved directly on study.

17. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS

Subject confidentiality and privacy are strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. This confidentiality is extended to cover testing of biological samples in addition to the demographic information relating to subjects. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence.

All research activities will be conducted in as private a setting as possible. Individual rooms will be available at the research site for answering intake questions, obtaining informed consent, survey data collection, and for sample collection. During workshops, participants will be asked to not to disclose any comments, questions, or feedback provided by other participants to anyone outside of the study setting.

All study staff engaged in the conduct of this project have completed training on the protection of human subjects and the Health Insurance Portability and Accountability (HIPAA) Privacy Rule. In addition, all key personnel (i.e., Principal Investigator, individuals involved in identifying/recruiting subjects, obtaining informed consent, or interacting and intervening with subjects) have undergone Good Clinical Practice (GCP) training.

Information about study subjects will be kept confidential and managed according to HIPAA requirements. All subjects will sign a combined informed consent and HIPAA authorization form that includes specific privacy and confidentiality rights. Study data will be maintained per federal, state, and institutional data policies.

Authorized representatives of the following groups may need to review this research as part of their responsibilities to protect research subjects: representatives of the IRB and UWCCC (funding agency). The clinical study site will permit access to such records.

18. SHARING OF RESULTS

Each participant who undergoes cervical cancer screening after the workshop, either through clinician collection (if in the control) or self-collection (if in the intervention group), will be contacted by a CHW or other staff member of MCHH, and the participant's results will be given to her. Recommendations will be for all women to present in-person although if declines, results will be given via telephone. All results will also be mailed to the participant and preferred primary care provider (if applicable).

Dissemination of findings in this study will be made available in a journal that is yet to be determined although will be funded through the sponsor agency and in an open access journal. Authorship plans will include at minimum, Drs. Tana Chongsuwat, Megan Fitzpatrick, Jessica Dalby, and Ms. Mayhoua Moua as authors, order of authorship to be determined. Subject's identity will remain confidential on presentation of data or publication.

19. DATA AND SPECIMEN BANKING

NA

20. STUDY ANALYSIS

20.1 Statistical Hypothesis

Participation in cervical cancer screening will be higher among women in the intervention group as compared to the control group.

20.2 Sample Size Justification

For this pilot study, we will enroll 250 participants, which is based on the feasibility of the number of workshops possible during the program length, funding, and resources available through MCHH.[9] Power estimates are based on comparing the rate of participation between the intervention arm (participants offered self-collected hrHPV) and the control arm (participants offered clinician-collected screening). Estimates of screening rates for the Hmong women population (percent that have had a clinician-collected screening in the last 2-3 years) range from 61- 81%. As we do not have estimates for rates for Karenni, Karen, Burmese, or Hmong women, we will use these estimates for participation rates in the control arm. The table below shows the detectable participation rates (and differences between proportions) for the intervention arm for different combinations of power (1-β) and values for the control arm from 0.61-0.81, for the hypotheses H0: $P \leq p_0$ vs. H1: $P > p_0$, where p_0 is the rate of participation in the control arm, for a sample size of 250 (125/arm), with a one-sided level 0.05 binomial test.

	Detectable Participation Rate (Difference)		
Control		Power	
Participation Rate	0.80	0.85	0.90
0.61	0.77 (0.16)	0.78 (0.17)	0.79 (0.18)
0.71	0.85 (0.14)	0.86 (0.15)	0.87 (0.16)
0.81	0.93 (0.12)	0.93 (0.12)	0.94 (0.13)

As an example, if there is a participation rate of 0.81 for those offered clinician-collected screening, we will be able to detect a rate of 0.93 (a difference of 0.12) in the participants offered self-collected hrHPV with a one-sided level 0.05 binomial test with a power of 0.85.

20.3 Statistical Methods

20.3.1 **Primary Outcome Measures and Analysis:**

The primary outcome measure is uptake of cervical cancer screening. The results will be reported through summary statistics of the number of participants in each group subsequently engaging or seeking out cervical cancer screening either through services offered after workshop education or self-reported desire to follow up through their community health care provider. Comparisons between the study arms will be based on a binomial test. The analysis will indicate if participants offered additional self-collection education would be more willing to engage in cervical cancer screening. Summary statistics will also include uptake of screening differentiated by reported ethnicity.

20.3.2 **Secondary Outcome Measures and Analysis**

Qualitative survey data will be obtained through pre- and post-workshop surveys to evaluate the impact of the educational workshops.

Further statistical support for this program will be obtained through consultation with statisticians in the UW-Madison SMPH and/or UW Carbone Cancer Center Biostatistics Shared Resource. For quantitative data, differences will be tested with Wilcoxon Rank-Sum tests for continuous or ordinal categorical data, Chi-Squared tests for unordered categorical data, and binomial tests for dichotomous data.

21. POTENTIAL BENEFITS TO PARTICIPANTS

Potential benefits of the study are linked to the goal of the project – providing access to an alternative method for cervical cancer screening through self-collection for HPV testing. In addition, all participants will benefit by participating and attending cervical cancer workshops in their native language, led, and sponsored by a trusted community organization. This research has the potential to reduce barriers to screening for vulnerable

populations such as immigrant and refugee women or other women who do not feel comfortable with clinician-collection for screening.

22. RISKS TO PARTICIPANTS

This protocol is considered to have a minimal risk to participants. Potential risks of the both collection methods (clinician-collected and self-collection)are mild physical discomfort, pain and temporary increase in vaginal spotting lasting 1 - 2 days. Risks will be minimized by explicit translated instructions on how to use the device. Additional risk of undetected cervical dysplasia is dependent on screening test sensitivity.

This research protocol does subject participants to increased risk of false negative screening tests than usual standard of care. Self-collection has a small increase in false negatives compared to clinician collection due sample errors. In a study by Tranberg et al., concordance for HPV detection between self-collected samples and clinician-collected samples shows 89% agreement (81% sensitivity, 92% specificity), which is an acceptable concordance to justifying offering self-collection to participants in this study.[20]

23. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF THE PARTICIPANTS

The Principal Investigators (Drs. Fitzpatrick and Dalby) will be responsible for reviewing and monitoring all study data and any adverse events. The Principal Investigator will meet with study personnel at least monthly to evaluate study progress, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, and other factors that can affect study outcomes. All unanticipated problems and adverse events that require reporting to the IRB will be reported to the University of Wisconsin Madison (UW) Health Sciences-IRB (HS-IRB).

24. ECONOMIC BURDEN TO PARTICIPANTS

Potential costs to participants is travel to and from the community center.

25. RESOURCES AVAILABLE

Will the research be conducted outside School of Medicine and Public Health or UW Hospitals and Clinics (e.g. the researcher does not have an SMPH research feasibility attestation for this study)?	X☐ **YES** (complete 25.1) ☐ **NO** (remove text below, but retain this section)

Feasibility of recruiting:

- Estimates of Hmong, Karen, and Burmese and Karenni women in the Milwaukee area was calculated by using published data from 2019 by the Pew Research Center and population estimate of 50.52% in the US population are women.
- Number of Hmong women in the Milwaukee area age 30 to 64 is approximately 2001.
- Number of Burmese women in the Milwaukee area age 30 to 64 is approximately 1273.
- Estimate recruitment will be 80 Hmong, 48 Karen, 48 Burmese and 64 Karenni participants
- These are not true estimates of the number of women in the population we are recruiting from due to age and specific ethnicity. Inclusion of women in this study is between age 25-65 and Hmong, Karen, Burmese or Karenni. Karenni and Karen is a smaller ethnic group commonly grouped together with other ethnic groups categorized in the general Burmese ethnic group.
- Potential participants the research team has access to is not yet determined, although MCHH routinely recruits for and conducts educational workshops in which 368 participants were recruited between July 1, 2020 and June 30, 2021.
- Additional resources and networks will be provided through collaboration with the City of Milwaukee Health Department.

Personnel:

- All personnel who will engage in the study will have appropriate experience, credentials, and training.
- All personnel will have sufficient time available to conduct the research:
    -
    - Primary Investigator Dr. Jessica Dalby will commit 5% of FTE to the research project.
    - Collaborators Dr. Tana Chongsuwat and Mayhoua Moua will commit 20% of FTE each to the research.
- All personnel will perform study activities commensurate with their job description and scope of practice and will be appropriately supervised and monitored.

Space and Facilities:

- Appropriate approvals and safeguards are/will be in place for both clinical and non-clinical space and facilities where study activities may occur. Type and risk-level of procedures have been accounted for when selecting space and facilities.
- Location of research activities will be at MCHH's community center with adequate space to conduct workshops activities as well as post-workshop cervical cancer screening.

Availability of medical or psychological resources:

- There will be a medical professional on site for support during and after workshop activities.
- There will be referral to primary care clinicians or other community providers for support of any additional medical or psychological needs as a result of this research study. Anticipated psychological need will be minimal. More than minimal medical need is anticipated for follow-up of abnormal results, this is anticipated and addressed in the protocol.

26. MULTI-SITE RESEARCH

NA

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28. APPENDICES

APPENDIX A: Milwaukee Consortium for Hmong Health Cervical Cancer Workshop Intake Form

MILWAUKEE CONSORTIUM FOR HMONG HEALTH

Participant Intake Form
Cervical Cancer

Office Use:
ID#
CHW:
Grant:
Date:

Personal Information:

First Name: _____ Middle Initial: _____ Last Name: _____
Phone Number: _____ Cell or Landline (circle one) Email: _____
Address: _____ Apt./Unit #: _____
City: _____ State: _____ Zip Code: _____
Date of Birth: _____/_____/_____ Gender: ◯ Male ◯ Female Ethnicity: _____

Medical History:

Month and year of previous Pap test:
_____/_____ (mm/yyyy) ◯ Never ◯ Unknown
Do you need help getting a Pap test? ◯ Yes ◯ No
What type of insurance do you have? ◯ Private ◯ Medicaid ◯ Medicare ◯ None
◯ Other: _____
Who is your primary doctor? _____ Primary Care Location: _____

What reasons may be stopping you from getting a Pap test?

◯ No symptoms
◯ No transportation
◯ Too expensive/No Insurance
◯ I don't know where to go
◯ Spouse will not allow it
◯ I'm too busy/No time
◯ I am afraid it will hurt
◯ I don't want to know the results
◯ Childcare
◯ No family history of cervical cancer
◯ My doctor never mentioned it
◯ Embarrassed
◯ Long wait to get an appointment
◯ None

Participant Evaluation

After today's workshop, how likely are you to…?

	Not likely		Neutral		Very Likely
1. Receive a Pap/Pelvic exam this year or as recommended?	1	2	3	4	5
2. Spread the word about the screenings available to your family members?	1	2	3	4	5
3. To encourage your family members to get screened?	1	2	3	4	5
4. Practice healthy behaviours that can reduce your risks for cervical cancer?	1	2	3	4	5

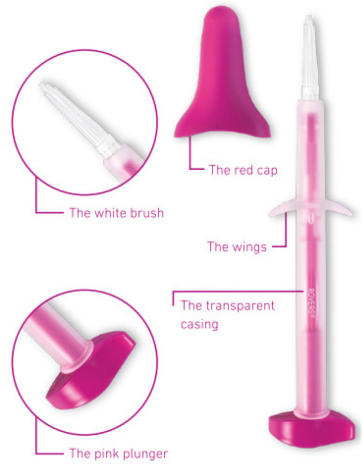
Other comments/questions about Cervical health:

_____

_____

Revised: 7/2019

APPENDIX B: Evalyn® Brush (Rovers® Medical Devices, Netherlands) and Instructions



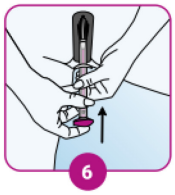
Wash your hands before usage.

Remove the Evalyn Brush from the packaging. Do not throw the packaging away, as it is necessary for sending the Evalyn Brush to the laboratory after usage.

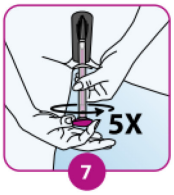
Press the sides of the pink cap with your thumb and index finger to remove the pink cap from the Evalyn Brush. Ensure that you do not touch the white fibres of the Evalyn Brush with your hands!

Obtain the sample whilst in a standing position. Assume a comfortable stance (e.g. as if you were about to insert a tampon).

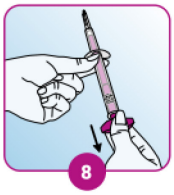
Spread your labia with one hand, and with the other, insert the Evalyn Brush into your vagina until the wings touch your labia.



Hold the transparent casing with one hand, and with your other hand, push the pink plunger in the direction of the transparent casing. You will hear and feel a click when the brush is in the right position with the pink plunger directly against the casing.



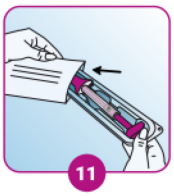
Turn the pink plunger five rotations in the same direction. After each rotation, you will hear a click. This helps you count the rotations. After turning the plunger five times, carefully remove the Evalyn Brush.



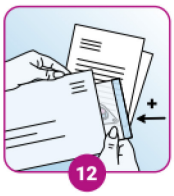
Hold the transparent casing with one hand, and with your other hand, pull on the pink plunger until the white brush disappears into the casing. When doing so, do not touch the top part of the Evalyn Brush above the wings.

Hold the transparent end to ensure the white brush does not extend again. Place the pink cap back on the Evalyn Brush using your thumb and index finger. You will hear a click when it is properly in place.

Put the Evalyn Brush back inside the packaging.



Place the packaging containing the Evalyn Brush into the plastic bag provided and seal it.



Use the return envelope to send the plastic bag containing the Evalyn Brush together with other required information.

APPENDIX C: UW Health Researchers Post-Workshop Satisfaction Survey (UW-PSS)

Due to the number of skip logics, the survey is best viewed through Qualtrics
Link: https://uwmadison.co1.qualtrics.com/jfe/form/SV_bQT22KcJ9g7Qklw

Community Health Outreach to Increase Cervical Cancer Education and Self-Collection Screening (CHOICESS) Program among Burmese and Hmong Women in Wisconsin.

This post-workshop participant survey is designed to be filled out with the guidance of Community Health Workers.

Please do not have the participant fill this information on their own.

Please copy the below information from the paper MCHH intake form:

Section A

After today's workshop, how likely are you to....?

	Not Likely	Somewhat unlikely	Neutral	Somewhat likely	Very Likely
1) Receive a Pap/Pelvic exam this year or as recommended?	○	○	○	○	○
2) Spread the word about the screenings available to your family members?	○	○	○	○	○
3) To encourage your family members to get screened?	○	○	○	○	○
4) Practice healthy behaviors that can reduce your risks of cervical cancer?	○	○	○	○	○

What workshop did the participant attend?

- ● Clinician-collection education → Continues to Section B
- ○ Self-collection education → Skip to Section D

Section B

Did the participant get screening for cervical cancer today? (Clinician Collected)

- ● Yes
- ○ No → Skip to Section C

Section B (continued)

How comfortable did you feel with this method?

- ◯ Extremely comfortable
- ◯ Somewhat comfortable
- ◯ Neither comfortable nor uncomfortable
- ◯ Somewhat uncomfortable
- ◯ Extremely uncomfortable

How likely would you get screening for cervical cancer again?

- ◯ Extremely likely
- ◯ Somewhat likely
- ◯ Neither likely nor unlikely
- ◯ Somewhat unlikely
- ◯ Extremely unlikely

In the workshop you attended today, we did not discuss self-collection as an option.

If self-collection was an option, would you have preferred this method?

- ◯ Yes
- ◯ Maybe
- ◯ No

Any remaining questions you have about the workshops or about cervical cancer?

Survey End

Section C

Will you get screening for cervical cancer in the near future (within the next year)?

- ◯ Yes
- ◯ Maybe
- ◯ No

Do you have any concerns with getting screening for cervical cancer?

Where would you go to get cervical cancer screening?

- ◯ My usual doctor or other clinician
- ◯ The health department
- ◯ Will return to the community center
- ◯ Another health care provider (not yet found)
- ◯ Not sure yet

Section C (continued)

In the workshop you attended today, we did not discuss self-collection as an option.

If self-collection was an option, would you have preferred this method?

- ○ Yes
- ○ Maybe
- ○ No → Any remaining questions you have about the workshops or about cervical cancer? **Survey End**

At this time - please provide a quick 1 on 1 instruction on self-collection for cervical cancer screening.

After the participant is done, please return to complete the remainder of this survey.

- ○ Patient agreed and collected a self sample → Skips to to Section E
- ○ Patient declined a self sample today → Any remaining questions you have about the workshops or about cervical cancer? **Survey End**

Section D

Did the participant get screening for cervical cancer today? (Self Collected)

- ○ Yes, clinician collection → Skips to to Section F
- ○ Yes, self-collection → Skips to to Section E
- ○ No → Skips to to Section G

Section F

How comfortable did you feel with this method?

- ○ Extremely comfortable
- ○ Somewhat comfortable
- ○ Neither comfortable nor uncomfortable
- ○ Somewhat uncomfortable
- ○ Extremely uncomfortable

How likely would you get screening for cervical cancer again?

- ○ Extremely likely
- ○ Somewhat likely
- ○ Neither likely nor unlikely
- ○ Somewhat unlikely
- ○ Extremely unlikely

Any remaining questions you have about the workshops or about cervical cancer?

Survey End

Section E

How comfortable did you feel with this method?

- ◯ Extremely uncomfortable
- ◯ Somewhat uncomfortable
- ◯ Neither comfortable nor uncomfortable
- ◯ Somewhat comfortable
- ◯ Extremely comfortable

How likely would you do self-collection for cervical cancer screening again?

- ◯ Extremely unlikely
- ◯ Somewhat unlikely
- ◯ Neither likely nor unlikely
- ◯ Somewhat likely
- ◯ Extremely likely

Would you have preferred a clinician to help with the collection?

- ◯ Do not prefer
- ◯ Prefer slightly
- ◯ Prefer a moderate amount
- ◯ Prefer a lot
- ◯ Prefer a great deal

Did you have any confusion with the instructions?

- ◯ No
- ◯ Yes

How likely are you to recommend this method to others?

- ◯ Extremely unlikely
- ◯ Somewhat unlikely
- ◯ Neither likely nor unlikely
- ◯ Somewhat likely
- ◯ Extremely likely

Any remaining questions you have about the workshops or about cervical cancer?

Survey End

Section G

Will you get screening for cervical cancer in the near future (within the next year)?

- ◯ Yes
- ◯ Maybe
- ◯ No

Do you have any concerns with getting screening for cervical cancer?

Where would you go to get cervical cancer screening?

- ◯ My usual doctor or other clinician
- ◯ The health department
- ◯ Will return to the community center
- ◯ Another health care provider (not yet found)
- ◯ Not sure yet

Any remaining questions you have about the workshops or about cervical cancer?

Survey End