OFFICIAL TITLE: Reducing cervical cancer screening disparities in Somali immigrant women through a primary care based HPV self-sampling intervention

SHORT TITLE: HPV Self-Sampling in Somali Women (Isbaar Project)

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Study Exempt from IDE requirements

Study Part 2 device intervention determined to be a nonsignificant risk (NSR) device by University of Minnesota institutional review board as it does not meet the definition of a significant risk (SR) device under §812.3(m) of the investigational device exemptions (IDE) regulation (21 CFR 812).

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1. **SUMMARY OF CHANGES – PROTOCOL**

#	Date	Change
1.		
2.		
3.		
4.		
5.		

TABLE OF CONTENTS

1. BACKGROUND

1.1 Study Disease(s)

Somali women have one of the highest rates of cervical cancer in the world (24 cases annually per 100,000).[1,2] Nearly all cervical cancers can be prevented by identifying and removing pre-cancerous lesions caused by high-risk human papillomavirus (HPV). In the U.S. the proportion of Somali immigrant women who are up-to-date with guideline-recommended cervical cancer screening ranges from 25%-50%,[3–5] compared with 82% for the U.S. general female population.[6] Low screening rates contribute to increases in cervical cancer incidence, late-stage diagnoses, treatment burden, and mortality.[7–9] These prevention disparities are caused by a range of factors, including health literacy challenges,[10] limited awareness about HPV and cervical cancer,[11–15] reluctance to use preventive health care due to misperceptions about health care costs (even with insurance coverage),[10] cultural or religious beliefs,[12,16–18] and patient concerns related to modesty.[14] Additionally, health care providers do not always feel skilled or confident to provide Pap tests on circumcised Somali women.[19–21] Physical barriers in circumcised women can also lead to poor access for conducting accurate cervical examinations,[22] which can reduce provider confidence.[23]

1.2 Rationale

The U.S. Preventive Services Task Force (USPSTF) guidelines include HPV testing alone (primary HPV screening) as a recommended cervical cancer screening strategy in women aged 30-65 years.[24] With primary HPV screening *self-screening is an emerging option,* because HPV tests (unlike Pap tests) can be performed on self-collected samples. HPV self-sampling is accurate for detecting precancerous cervical lesions,[25] and effective in reaching women who otherwise delay or opt out of screening,[26–28] including Somali immigrant women.[29] While research in this area has focused primarily on home-based, mail-in self-sampling kits,[26–28,30] there is an untapped opportunity to utilize HPV self-sampling in primary care settings. Offering HPV self-sampling in primary care could effectively increase cervical cancer screening rates in Somali women by positioning providers to address screening barriers,[31] enabling clinics to opportunistically fit in HPV self-sampling with other appointments, and providing an alternative modality for circumcised women.[32]

2. OBJECTIVES

2.1 Aim 1

Utilizing the Consolidated Framework for Implementation Research (CFIR) and Social Cognitive Theory (SCT), identify patient-, provider-, clinic-, and systems-level barriers and facilitators to inform refinement of implementation strategies to promote Somali women's uptake of HPV self-sampling.

2.2 Aim 2 (primary objective)

Using a difference-in-difference design to compare between-period changes in Somali women attending intervention (clinics implementing the HPV self-sampling option as standard of care) versus control primary care clinics, assess the effect of implementing HPV self-sampling on women's completion of cervical cancer screening.

2.2.1 Aim 2 (secondary objective)

Assess the effects of implementing HPV self-sampling on cervical cancer screening uptake in all patients.

2.3 Aim 3

Utilizing mixed methods and the Reach Effectiveness Adoption Implementation Maintenance framework (RE-AIM), assess the HPV self-sampling implementation strategies used by the clinics and develop a comprehensive implementation science based framework of the processes and strategies needed to implement HPV self-sampling in primary care for Somali patients and all other patients.

3. PATIENT SELECTION

3.1 Inclusion Criteria

3.1.1 Aim 1

Focus groups:

(a) Identify as a Somali woman

(b) Between ages of 30-65 years and eligible for cervical cancer screening

Clinic interviews:

(a) Administrators, physicians, nurses, interpreters, community health workers (CHWs), and medical assistants (MAs), employed at intervention clinics

3.1.2 Aim 2

Primary objective:

(a) Identify as a Somali woman

(b) Between ages of 30-65 years

(c) Due or overdue for routine cervical cancer screening

(d) Receiving care at intervention clinics (MHealth Fairview Smiley's Family Medicine clinic, Community-University Health Care Center (CUHCC), or People's Center Clinics and Services) or control clinics (across the MHealth Fairview system)

Secondary objective:

(a) Between ages of 30-65 years

(b) Due or overdue for routine cervical cancer screening

(c) Receiving care at intervention clinics (MHealth Fairview Smiley's Family Medicine clinic, Community-University Health Care Center (CUHCC), or People's Center Clinics and Services) or control clinics (across the MHealth Fairview system)

3.1.3 Aim 3

Patient interviews:

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(a) Between ages of 30-65 years

(b) Participated in HPV self-sampling for cervical cancer screening at an intervention clinic

Clinic interviews:

(a) Administrators, physicians, nurses, interpreters, CHWs, and MAs, employed at intervention clinics

3.2 Exclusion Criteria

3.2.1 Aim 1

(a) Focus groups: None
(b) Clinic interviews: None

3.2.2 Aim 2

(a) Opted out of research in the electronic health record

3.2.3 Aim 3

(a) Patient interviews: None
(b) Clinic interviews: None

3.3 Inclusion of Women and Minorities

3.3.1 Aim 1

Focus groups:

The goal of the focus groups is to assess barriers and facilitators to inform refinement of implementation strategies to promote Somali women's uptake of HPV self-sampling, so participants will be restricted to female sex Somali individuals who meet our study eligibility requirements. Non-English speaking participants will be included, specifically Somali speakers.

Clinic interviews:

Clinic interviews will be restricted to administrators, physicians, nurses, interpreters, CHWs, and MAs, employed at intervention clinics. The ethnic/racial composition will largely reflect the ethnic/racial composition of the employees at each clinic.

3.3.2 Aim 2

Primary objective:

The goal of the primary objective is whether in-clinic HPV self-sampling improves cervical cancer screening completion among Somali women. Because cervical cancer only affects people with a uterine cervix, the study population will be composed of female sex Somali individuals who meet our study eligibility requirements.

Secondary objective:

The goal of the secondary objective is whether in-clinic HPV sampling improves cervical cancer screening completion among all patients. Because cervical cancer only affects people with a uterine cervix, the study population will be composed of female sex individuals who meet our study eligibility requirements. Race and ethnicity are not eligibility requirements for participation, so the ethnic/racial composition of our study population will largely reflect the ethnic/racial composition of female patients of M Health Fairview, CUHCC, and People's Center Clinics and Services.

3.3.3 Aim 3

Patient Interviews:

The goal of the patient interviews is to assess the HPV self-sampling implementation strategies used by the clinics and develop a comprehensive implementation science based framework of the processes and strategies needed to implement HPV self-sampling in primary care for both Somali patients and all other patients, so participants

will include female sex individuals who meet our study eligibility requirements. Non-English speaking participants will be included, specifically Somali speakers as this study is targeting Somali women.

Clinic interviews:

Clinic interviews will be restricted to administrators, physicians, nurses, interpreters, CHWs, and MAs, employed at intervention clinics. The ethnic/racial composition will largely reflect the ethnic/racial composition of the employees at each clinic.

3.4 Inclusion of Children

3.4.1 Aim 1

Focus groups:

We are not enrolling individuals younger than age 30. As of 2022, USPSTF cervical cancer screening guidelines[9] recommend primary HPV screening commence at age 30 years .

Clinic interviews:

All health professionals are adults; as such, children will not be included in this study aim.

3.4.2 Aim 2

We are not enrolling individuals younger than age 30. As of 2022, USPSTF cervical cancer screening guidelines[9] recommend primary HPV screening commence at age 30 years.

3.4.3 Aim 3

Patient interviews:

We are not enrolling individuals younger than age 30. As of 2022, USPSTF cervical cancer screening guidelines[9] recommend primary HPV screening commence at age 30 years.

Clinic interviews:

All health professionals are adults; as such, children will not be included in this study aim.

4. STUDY PROCEDURES

4.1 Subject Recruitment and Screening

4.1.1 Aim 1

Focus groups:

Focus group participants will be recruited from partnering clinics and in the community through local mosques or community organizations.

Clinic recruitment at each intervention clinic may happen in several ways: a) clinic staff mentioning the study and providing recruitment flyers at the clinic for distribution, b) the bilingual research facilitator tabling in the clinic lobby with recruitment flyers, and c) community outreach through contacts at local mosques and community organizations connected to the Somali community

Participants will be screened for eligibility and provided the information sheet about the study either in person (if recruitment is in person at the clinic or community site) or

remotely. In the case of remote screening and consenting, the process will occur over the phone or Zoom; the information sheet will be sent by email or a link provided over Zoom. After being screened and consenting to participate, participants can select if they prefer to participate in a focus group conducted in either English or Somali, choose a focus groups time/date and format (virtual or in-person) and will fill out a demographic survey over phone with the research facilitator or through a Qualtrics or REDCap link sent via text or email.

Clinic interviews:

Administrators, physicians, nurses, interpreters, CHWs and MAs will be recruited at each clinic by working with clinic leadership to identify potential participants. All potential participants will be clearly informed that participation is voluntary and will not affect their position at the clinic. The goal will be to recruit 15 participants at each clinic.

4.1.2 Aim 2

Unless patients indicated in the medical record that they do not wish to have their records used for research purposes, under a waiver of consent and HIPAA authorization inclusion and exclusion criteria data will be programmatically extracted from the EHR in both intervention and control clinics (age, history of sub-cervical hysterectomy, cervical cancer screening / diagnostic / treatment history and results, etc.).

4.1.3 Aim 3

Patient interviews:

Patients who complete the self-sampling option will be given study contact information by the clinic (by flyer, verbally or mailed letter) so they can reach out to the study team if they would like to participate in a short interview.

Clinic interviews:

Administrators, physicians, nurses, interpreters, CHWs and MAs will be recruited at each clinic by working with clinic leadership to identify potential participants. All potential participants will be clearly informed that participation is voluntary and will not affect their position at the clinic. The goal will be to recruit 10 participants at each clinic.

4.2 Procedures

4.2.1 Study Design

Aim 1

Patient focus groups, and individual provider or clinic staff interviews will be conducted.

Aim 2

Three primary care clinics (M Health Fairview Clinic - Smiley's, Community-University Health Care Center (CUHCC) and People's Center Clinics & Services) will implement HPV self-sampling as part of standard care for cervical cancer screening for all patients. Programmatically extracted data from these clinics will be compared to cervical cancer screening rates in M Health system clinics that do not implement HPV self-sampling.

Aim 3
Patient 1:1 interviews, and individual provider or clinic staff interviews will be conducted.

4.2.2 Study Procedures

Aim 1:
Patient focus groups and individual provider or clinic staff interviews will be conducted.

Focus groups (n=40 – 80 participants):
We will collect focus group data from Somali women, between 30-65 years of age. The age range reflects the current guidelines for women who should receive cervical cancer screening with primary HPV testing. Five to eight focus groups (up to 10 participants each) will be conducted with Somali women.

Focus groups will be conducted in two parts.

- First, we will ask about knowledge about HPV and cervical cancer, screening experiences and views on HPV self-sampling, what influences their decision making about screening, and their experience with clinic providers.
- During the second part of the focus groups, we will provide brief information on HPV self-sampling to help inform the discussion. Participants will be asked their views on how self-sampling could best be implemented in primary care, including their perspectives on barriers and facilitators, informational needs, tailoring of instructions, and how it would best fit in the clinic visit.

Participants will receive $50 for participating. The focus groups will last approximately 90 minutes.

Focus groups will be held either in a virtual format or in one of the following venues: (1) at MHealth Fairview Smileys Family Medicine Clinic or the People's Center in a private room (hereafter referred to as partner clinics); (2) a private room at a community center or mosque. Some participants might feel more comfortable in a remote format versus in-person setting and vice versa.

Clinic interviews (n=30)
We will collect interview data from 30 individual provider or clinic staff, including physicians, nurses, interpreters, CHWs, and medical assistants (MAs). Each interview is estimated to take between 30-45 minutes. The interview guide will include views on HPV self-sampling in the context of primary care, views on Somali women's needs and resources about cervical cancer screening and HPV self-sampling (e.g., patient education needs), the role of staffing, workflow, current protocols, knowledge and beliefs about HPV self-sampling, how individuals anticipate the best processes for approaching implementation and demographic questions.

Data from focus groups and interviews will inform implementation strategies to promote uptake of HPV self-sampling in primary care for Somali women.

Aim 2:

Three primary care clinics (M Health Fairview Clinic - Smiley's, Community-University Health Care Center (CUHCC) and People's Center Clinics & Services) will implement HPV self-sampling as part of standard routine care for cervical cancer screening for all patients, as a new usual care option for cervical cancer screening.

The study team will support the clinics in the implementation process as part of a quality improvement initiative. Findings from Aim 1 will be used to guide the development of the self-sampling components, including refinement of existing self-sampling instructions, the creation of new culturally tailored patient information materials, training materials for providers, workflow guidance, referral processes, and guidance on reporting and communication.

Data collection: Demographics, provider and patient characteristics, healthcare utilization (whether HPV self-sampling offered/completed, questions, or problems patients may have had with HPV self-sampling, screening history, gravidity/parity, receipt of preventative services like mammography or colorectal screening, etc.), health information (e.g. circumcision status, BMI, co-morbity index, etc.), screening utilization, Pap and HPV test results, colposcopies, biopsy results (to identify CIN 2+ cases), and CIN 2+ treatment will be programmatically extracted from the EHR (in both intervention and control clinics).

Control clinics: All other M Health Fairview primary care clinics in the metro area will be included as control clinics. Control clinics will have passive participation and their only involvement will be that data will be pulled from these clinics from the M Health Fairview research data warehouse.

Aim 3:

We will ask patients who participated in the self-sampling, and administrators, physicians, nurses, interpreters, MAs, and CHWs at each participating clinic, to identify their experience of implementation. We will use these data to identify barriers and facilitators for implementing HPV self-sampling, and needs for ongoing sustainability. Participants who were included in Part 1 can also be included in Aim 3.

Patient interviews (n=30):

Patients who did the self-sampling option will be interviewed throughout the study implementation phase. Interviews will explore views on HPV self-sampling and demographic questions. In addition, women with abnormal results will be asked about their experience and of the resultant care. The sample will be a convenience sample, recruited throughout the study. Participating clinics will provide patients who do self-sampling the contact information for study staff and instructions of how to get in touch if interested in participating in the follow-up interview.

Clinic interviews (n=30):

The participants will include administrators, physicians, nurses, interpreters, CHWs and MAs. The semi-structured interview guide will explore provider and staff perspectives on the reach of HPV self-sampling in the clinic, the perceived effectiveness of the HPV self-sampling intervention, the adoption of HPV self-sampling across the clinic, including barriers and facilitators to provider practice, views on the self-sampling implementation strategies used, and provider views on the ongoing maintenance of self-sampling, including intention to continue to implement the strategy, and what resources –

financial, training or staff related – would be needed to ensure successful ongoing delivery. Demographic information from interviewees will also be collected. Interviews are expected to take around 30 minutes in length, and will be audio recorded.

4.3 Early Termination

Subjects will not be terminated from the study by the study investigators; however, subjects may choose to decline some or all study procedures. All subject withdrawals will be documented.

5. STATISTICAL CONSIDERATIONS

5.1 Power Analysis

For our primary outcome analysis (Aim 2), we expect to enroll 1,130 Somali patients in each of the pre- and post-intervention cohorts divided between the three intervention clinics and 4,550 Somali patients in each of the pre- and post-intervention period cohorts in the control clinics. Preliminary data from the two intervention clinics suggests that 15% of Somali patients in the pre-intervention cohort will be screened during the study period, and a somewhat lower screening rate of 11% in the control clinics. Based on results from our prior HOME trial in underscreened women,[30] we assume the screening rate in the intervention clinics will increase by at least 9% (from 15% to 24%) in the post-intervention period and will not change in the control clinics. Assuming accrual and screening times are uniformly distributed over the study periods, we estimate 98% power to detect an effect of the intervention in the difference-in-difference analysis. We will still have 80% power if the intervention increases the rate of screening by only 6% (from 15% to 21%). These power calculations are conservative in that they are based on an assumption of independent data, and we expect some overlap between the pre- and post-intervention cohorts in each clinic, and additional intervention clinic (CUHCC). The induced correlation will increase study power since the contrast of interest will be between correlated observations.

5.2 Planned Enrollment (Aim 2, primary objective)

ANTICIPATED/PLANNED ENROLLMENT for ENTIRE STUDY: Number of Participants (*must provide exact numbers. i.e. no range)*			
Ethnic Categories	**Sex/Gender**		
	Females	Males	Total
Hispanic or Latino	0	0	0
Not Hispanic or Latino	5,680	0	5,680
Ethnic Categories: Total of All Participants	5,680	0	5,680
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	5,680	0	5,680
White	0	0	0
More Than One Race	0		0
Racial Categories: Total of All Participants	5,680	0	5,680

5.3 Analysis Plans

5.3.1 Analysis plan relevant to Aim 1

Focus groups will be audio recorded and both translated and transcribed, using experienced staff from whom we have an established track record of receiving high quality translations. Interview data will be audio recorded and transcribed verbatim. A thematic analysis based on the socially constructivist version of grounded theory will be conducted.[33–35] This approach allows for the identification of emergent themes alongside consideration of knowledge from the literature, the SCT constructs (focus groups), and the CFIR domains (interviews). Data analysis will be conducted by a minimum of two members of the research team, including Dr. Pratt, with frequent cross-checking across emergent themes. NVivo12[36] software will be used. Any disagreement in themes or coding will be addressed through consensus building. The analysis process will include a rigorous process of the identification and refinement of emergent themes. Uniquely, our research team has always ensured that one of the two coders is a Somali research team member. In our experience, this deepens the process of reviewing emerging themes, and ensures the analytic process thoughtfully considers and integrates perspectives from both a Somali and non-Somali analyst.

5.3.2 Analysis plan relevant to Aim 2

We will use difference-in-difference methods to compare between-period changes in screening completion in women in the intervention and control clinics. Between-period changes in intervention clinic women will be compared with between-period changes in control clinic women over the same time frame to control for secular trends in screening completion that could potentially confound the comparison if it were conducted only in the intervention clinics. Validity of the difference-in-difference approach depends on the reasonable assumption that secular trends equally affect screening uptake in women in both groups of clinics. Our primary outcome analysis will include Somali patients only. A secondary outcome analysis will include all patients.

The 12-month pre-intervention period is February 20, 2022 through February 19, 2023. The 12-month post-intervention period is February 20, 2023 through February 19, 2024. During each period, eligible individuals are identified through the EHR. Including a full 12 months for each pre and post period minimizes the risk of bias from confounding seasonal factors.

The primary outcome of screening completion is defined as either: a) receiving Pap and/or HPV testing by a clinician, or b) self-sampling HPV-negative or HPV16/18+; or c) self-sampling positive for other HR-HPV types or unsatisfactory, and returning for a follow-up Pap test to complete the screening episode. For individuals with other HR-HPV or unsatisfactory test results on self-sampling, a follow-up Pap test is required. Therefore, our criterion specifies that if the Pap test is not completed, the individual will not be considered completely screened. Individuals who initiate screening during the 12-month pre- or post-intervention period are allowed up to 3 months after the screening initiation date to complete the screening episode, if necessary (e.g., returning for a follow-up Pap test after self-sampling positive for other HR-HPV types or unsatisfactory). Analyses will model time to initiating a completed screening episode.

To analyze the data using a difference-in-difference approach, we will fit a Cox proportional hazards model with time to initiating a completed screening episode as the outcome, $\lambda(t \dashv | X_i,W_i,Z_i)=\lambda(t)\exp\{\beta_1 X_i+\beta_2 W_i+\beta_3 X_i W_i+\beta_4 Z_i+ \beta_5 Z_i W_i \}$, where $\lambda(t)$ is the baseline hazard function indexed by time on study in the pre- or post-intervention study period, X_i is an indicator of

pre-intervention (X_i=0) or post-intervention (X_i=1) cohort, W_i is an indicator of study (W_i=0) or control (W_i=1) clinic, and Z_i is a vector that includes adjustment for patient covariates, e.g., age, time since last cervical screen. We will use robust standard errors to account for correlation between observations in the pre- and post-intervention cohorts (i.e, women who are due for screening during the pre-intervention period and are seen again in the post-intervention period prior to being screened). A similar model will be used for the secondary outcome of screening initiation, and for the secondary objective these analyses will be applied to the larger cohort of all women (not just Somali-American women).

We will report the proportions completing necessary in-clinic follow-up within 3 months after an abnormal kit result by screening history, and we will summarize the numbers of women that opt for clinician-administered, self-sampling, and no screening in the intervention group (primary: Somali-American women, secondary: all women)

5.3.3 Analysis plan relevant to Aim 3

We will use a mixed methods approach to develop a RE-AIM based analysis[38–40] of clinic and patient perspectives on implementation (see Table 3). We will also draw on SCT and CFIR, as used in Aim 1, to inform the qualitative component of the RE-AIM analysis. First, we will ask patients, administrators, physicians, nurses, interpreters, MAs, and CHWs at each clinic to identify their experience of implementation. We will use these data to identify barriers and facilitators for implementing HPV self-sampling, and needs for ongoing sustainability. Finally, we will use a mixed methods approach to analyze data across each RE-AIM component. Each step of the analysis will be reviewed and refined by the CAB.

The analytical process will happen in two stages. In stage one, the interview data will be translated and transcribed. A thematic analysis will be conducted, following the rigorous process outlined in Aim 1.[33] The resultant thematic analysis will be integrated into stage two. In stage two, a mixed methods approach will be used to consolidate data collected across Aims 1-3. The analysis will be shared with the CAB throughout the analytic process, allowing for extensive input from the CAB, with a particular focus on how to address issues of cervical cancer screening disparities for Somali women.

6. ADVERSE EVENTS: REPORTING REQUIREMENTS

6.1 Determination of Study Risk

This is a minimal risk study assessing a new standard care medical intervention.

6.2 Reporting Adverse Events

Not applicable. Aims 1 and 3 entail qualitative focus groups and interviews. Aim 2 outcome measures will assess standard care utilization by electronic medical record (EMR) extraction.

6.3 Reporting the Intensity of an Adverse Event

Not applicable.

6.4 Reporting the Relationship of an Adverse Event to intervention

Not applicable.

7. STUDY OVERSIGHT AND DATA REPORTING / REGULATORY REQUIREMENTS

7.1 Protocol Review

The protocol and informed consent forms for this study will be reviewed and approved in writing by the University of Minnesota Institutional Review Board before any individual is enrolled in this study.

7.2 Informed Consent

Aim 1: In compliance with 45 CFR part 46, informed consent will be obtained from all participants via verbal consent under a waiver of documentation of consent .

Aim 2: All consent will be conducted in compliance with Code of Federal Regulations, Title 45, Part 46 (45 CFR part 46). To reduce participation bias, we will request a waiver of informed consent and a waiver of HIPAA Authorization to identify, enroll and collect data for all participants.

Aim 3: In compliance with 45 CFR part 46, informed consent will be obtained from all participants doing patient interviews by written or electronic informed consent and for clinic provider interviews via verbal consent under a waiver of documentation of consent.

7.3 Changes to Protocol

Any protocol modifications will be approved by the Principal Investigators and approved by the IRB before the revision or amendment may be implemented. The only circumstance in which the amendment may be initiated without regulatory approval is for a change necessary to eliminate an apparent and immediate hazard to the participant. In that event, the investigators will notify the IRB in writing per current IRB rules.

7.4 Data and Safety Monitoring Plan

This is a minimal risk study with no medical intervention. There is no data safety and monitoring committee for this study.

Aims 1 and 3: There is a small risk that some participants will experience distress in talking about cervical cancer screening, due to stigma or worry about cancer in the Somali community. The study team will mitigate this through providing clear communication about the study, being available to talk through concerns prior to study participation and offering support should distress occur.

All Aims present the potential risk of loss of confidentiality. We will minimize the risk of loss of confidentiality by keeping data secure.

HIPAA compliance: For Aim 1, HIPAA compliance is not applicable. For Aim 2 and Aim 3 patient interviews, participant data will be extracted from the intervention clinics and designated control clinics in the M Health Fairview Health system. As such, their participation is subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security standards. For Aim 3 clinic provider and staff interviews, HIPAA compliance is not applicable. All relevant staff have completed required HIPAA training and all research activities will be conducted incompliance with the HIPAA standards.

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