Enhancing Skin Cancer Early Detection and Treatment in Primary Care

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Principal Investigator:	Sue Flocke, Ph.D.
	Department of Family Medicine Oregon Health & Science University 3181 SW Sam Jackson Park Road Portland, OR 97239 Phone: (503) 494-4404 Email: flocke@ohsu.edu
Participating Investigator(s):	Elizabeth Berry, M.D. Department of Dermatology Oregon Health & Science University 3303 S. Bond Avenue Portland, OR 97239 Phone: (503) 418-3376 Email: **berryel@ohsu.edu** Alex Verdieck Devlaeminck M.D. Department of Family Medicine Oregon Health & Science University 3181 SW Sam Jackson Park Road, FM Portland, OR 97239 Phone: (503) 494-5187 Email: **verdieck@ohsu.edu** Sancy Leachman, M.D., Ph.D. Department of Dermatology Oregon Health & Science University 3303 S. Bond Avenue Portland, OR 97239 Phone: (503) 418-3376 Email: leachmas@ohsu.edu
Statistician:	Shuling Liu, PhD Department of Family Medicine Oregon Health & Science University 3181 SW Sam Jackson Park Road, FM Portland, OR 97239 Phone: 503-494-4991 Email: liushu@ohsu.edu

Minimal Risk Protocol Template

1) Protocol Title

Enhancing Skin Cancer Early Detection and Treatment in Primary Care

2) Objectives

This mixed method study will evaluate whether a multicomponent education strategy improves the ability of Primary Care Providers (PCPs) to identify and triage skin cancer. This study will be deployed in two OHSU family medicine clinics: one OHSU Family medicine rural-based clinic and one urban underserved Federally Qualified Health Center (FQHC) clinic. Baseline data and those not participating in the training will serve as controls.

3) Background

Cutaneous melanoma (CM) is a potentially life-threatening form of skin cancer that is increasing in incidence. In the last three decades, incidence rates have more than tripled, and CM currently stands as the fifth most common invasive cancer in the United States.[1,2] According to estimates by the American Cancer Society (ACS), there will be nearly 100,000 new cases of CM and about 7,650 deaths due to melanoma in 2022 alone. The ACS expects that 1,640 of these new cases will occur in Oregon, which consistently ranks among the top ten states in the nation for CM incidence.[2] Unlike other common malignancies, melanoma is most often evident directly on the skin's surface, which lends the opportunity to improve early recognition with the goal of decreasing mortality.

If diagnosed early, both CM and other types of skin cancers are often curable. For distant metastatic disease, however, the prognosis is substantially worse. Stage I CM disease carries a five-year survival rate of 99%. For stage IV CM, however, the five-year survival rate drops to 30%.[3] In addition to higher mortality rates, late-stage disease is also associated with increased morbidity and increased health care costs. For example, late-stage tumors require wider excision margins, sentinel lymph node sampling, increased imaging surveillance, and may necessitate the use of expensive and potentially toxic therapies in the treatment or adjuvant setting.[4]

The early detection of melanoma through simple, noninvasive screening practices has a considerable potential to reduce the burden of this disease. In Oregon, there are few dermatologists in the areas of highest incidence, so PCPs are in a unique position to recognize and treat or triage skin cancers.[5,6] However, PCPs have identified barriers to their ability to diagnose skin cancer, including knowledge gaps, paucity of time and lack of clinical workflows for routine screening and electronic health record (EHR) support tools to facilitate screening.[7-9] Dermoscopy (using a device with polarized light and magnification to visualize underlying skin structures) and EHR tools designed to facilitate skin screenings can help overcome these barriers but are rarely used in PCP settings.[10-12] We hypothesize that providing PCPs with the appropriate training and tools to screen for and recognize melanoma will facilitate diagnosis of more skin cancers at earlier

stages. Our team has already developed and demonstrated the efficacy of a PCP education intervention (Melanoma Toolkit for Early Detection, MTED)[13] and is poised to deploy this toolkit in the pilot study outlined in this protocol.

4) Study Design

This study is a mixed method pilot study to determine whether multicomponent education module improves the ability of Primary Care Providers (PCPs) to identify and triage skin cancer. The main independent variable is the multicomponent education for clinicians. This is primarily a feasibility study to evaluate the engagement and uptake of the training and change in skin cancer screening behavior on the part of clinical teams. We hypothesize that exposure to the intervention will increase clinician knowledge, increase the use of a SKLIP dermoscopy device to facilitate capture of high-resolution dermoscopy images, and increase screening for skin cancer.

Outcomes:

- Uptake of the training and performance of skin cancer screening processes measured by proportion of clinicians invited to participate in the educational intervention that complete the training modules; use of the Epic smart tool and dotphrases.
- Clinicial knowledge measured through pre- and post-tests implemented during live (in-person or virtual) training.
- Use of the risk assessment tool measured through EHR data.
- Identification of suspicious lesions measured through EHR data.

We hypothesize that the multicomponent education strategy will result in the diagnosis of more skin cancers at earlier stages. Primary endpoints of the study include the pre- and post-intervention: number of melanomas biopsied, mean and median Breslow depth of melanomas biopsied, number of other malignant skin tumors biopsied, total number of referrals to dermatology, number of referrals to dermatology for concerning moles, and number of OHSU PCPs who access the Melanoma Toolkit for Early Detection (MTED), an online Continuing Medical Education training. There will be two comparison groups: OHSU PCPs receiving the intervention, OHSU PCPs not exposed to the intervention.

5) Study Population

a) Number of Subjects

This study will be conducted at two primary care clinics. Within these two clinics, there are approximately 80 clinicians (e.g. MD, NP, PA, DO, APP).

We will invite all advanced practice providers (MD, NP, PA, DO) at these two clinic sites to participate in the multicomponent educational intervention, up to 40 clinicians per site. These clinicians will take part in the surveys imbedded in the Toolkit, surveys pre-and post-training, and live (in-person/virtual) trainings. Thus, we will recruit approximately 40 clinicians within the 2 clinics for the active intervention.

We will observe the in-person trainings and take detailed fieldnotes. We expect approximately 40 clinicians will participate in each training.

We will interview approximately 5-10 members per site within the clinic.

We will extract EHR data collected from patients from within these two clinics for the year prior and for 1-year post training implementation (2/1/2022-9/30/2024). We estimate up to 200 individuals with biopsies per year, per clinic. For a subset of patients, we will conduct a chart review to affirm use of specific devices to photograph lesions and biopsy results that are not readily ascertainable from EHR data alone.

b) Inclusion and Exclusion Criteria

Two OHSU primary care clinics will be assigned to receive exposure to the melanoma early detection intervention. Baseline data and clinicians at the two clinics who do not receive the intervention will serve as study comparators.

We will be using secondary EHR data from the study clinics. Biopsy and referral data will be extracted from EHR from patients within these two primary care clinics who were screened, referred, biopsied for potential skin cancer and/or diagnosed with melanoma. Data from all other patients seen in these clinics during the time period will be included for comparison. These data will be electronic health record (EHR) data from patients between the ages of 18 and 110 with an encounter in one of the study clinics. A subset of this data will undergo a chart review to affirm use of specific devices to photograph lesions and free text biopsy results and/or interpretation.

We may observe all in-person trainings. There are no inclusion/exclusion criteria for training observation. All training participants will be 18 years or older and are required to speak English during the training and in their occupations.

Qualitative interviews will be conducted with clinicians who receive the intervention. These individuals are all aged 18 years or older and all practice members speak English. No patients will be interviewed for this research.

Exclusion criteria: No one will be intentionally excluded.

c) Vulnerable Populations

This study will not target vulnerable populations, but they may be included in the EHR data. EHR data may include patients under 18, those who may be pregnant or decisionally impaired.

d) Setting

This study will be conducted at OHSU and deployed at two clinics: one OHSU Family medicine rural based clinic and one urban underserved FQHC clinic. Study information will be collected using EPIC data fields to assess biopsy rates, uptake of risk assessment and health maintenance (HM) reminders and use of e consult and formal consultation. Qualitative data will be collected

using semi-structured qualitative interviews via in-person, phone or video calls. We will also conduct and observe in-person trainings.

The population health team at OHSU will pull EHR data from OHSU primary care clinics. They will provide a de-identified dataset to OHSU researchers for analysis. No OHSU data will leave OHSU.

e) Recruitment Methods

Study staff will submit an inquiry for research engagement per the Department of Family Medicine's current Standard Operating Procedure. DFM research leadership and clinic leadership will confirm the participation of each clinical site. Then, with clinic leadership support, advanced providers from each site will be invited to participate in the multicomponent educational intervention.

We will email leaders at each of the sites and ask for permission to observe the trainings and take fieldnotes. A reminder invite to the in-person training will be shared with clinic leadership, and will be emailed to the participating clinic members (see recruitment materials). This email will remind participating clinic members of the upcoming training and include and a copy of the information sheet. During the live training, we will ask participants for their email addresses so that we may remind them to complete the training post-test and to invite them to complete the online portion of the trainings. (See supplemental materials).

Patients are not being directly recruited to this study however, patient level EHR data will be used to evaluate the impact of the intervention as outlined in the primary endpoints above.

We will invite and potentially interview all clinicians but will stop once saturation[14] is reached and no new information is being gleaned. In exchange for participation in the one hour interview, clinician member participants will receive a $100 Amazon gift card.

f) Consent Process

As the risks to the clinic staff are minimal, we will request IRB approval to provide study information sheets. Clinicians who participate in the intervention will receive a study information sheet describing their participation in the in-person training, online learning modules (MTED), the possibility of participating in qualitative interviews, and how data will be used to answer study questions.

For the qualitative training observations, we will ask for permission to join the trainings and take field notes. This study poses a minimal risk to participants, and as such, a formal consent process is not required for observation.

For the qualitative interviews, we request a waiver of written consent. This request is justified, since if signed, the signature would be the only thing that would identify the interviewee in study records. We will avoid using names during the interviews. If names are used, they will be scrubbed from the transcript during the transcribing process. The research team will make clear that the interviewee does not need to participate in the interview and there are no repercussions for saying no. Prior to an interview, practice members will receive an Information Sheet stating the purpose of the study and explaining their rights as a participant in the study. The study team will answer any questions about the study, obtain verbal consent, and ask

permission to record the interview. If a participant agrees to be interviewed but not audio-recorded the interviewer will take notes during the interview and write them up shortly afterwards. Participants will also be instructed that they can request the audio recording to be stopped at any point during the interview.

We are requesting a waiver of authorization and consent for secondary analysis of EHR data in this research, as patients are not actively recruited. We believe this study meets the necessary requirement for a waiver of authorization and consent as: 1) the research involves no more than minimal risk to the subjects; 2) the waiver or alteration will not adversely affect the rights and welfare of the subjects as it involves no more than a minimal risk of loss of confidentiality; and, 3) the research could not practicably be carried out without the waiver or alteration because it would not be possible to consent the number of patients whose EHR records are needed to answer the study question.

6) Study Procedures & Schedule of Events

The multi-component educational intervention includes the following:

Training:

Group Training:

Group training sessions will consist of an initial training and an one hour follow up refresher training on how to use the SKILP device and identifying Melanoma. The in-person trainings are designed as lunch and learn sessions. The initial training will include how to use the MTED, how to use a SKLIP dermoscopy device, how to use the Epic health maintenance reminder tool to document a high-risk patient, and how to triage. We will support workflow restructure to involve use of Epic tools, SKLIP devices, etc. but are unable to assess changes to workflow itself. PCPs will receive education on how to use a collection of skin cancer-specific SmartPhrases in Epic. These SmartPhrases contain resources such as a melanoma risk stratification tool, skin cancer after visit summary, and templates for biopsies and skin exams. An accompanying PowerPoint document explains how to access and use the SmartPhrases, as well as provides instructions on how to satisfy billing codes and health maintenance reminders. The training is tailored to PCPs but may be delivered to the entire healthcare team (nursing staff and medical assistants) to facilitate implementation.

The follow up refresher training will follow the same format as the initial training and will contain similar content as the initial training (See Dermoscopic Red Flags of Melanoma Powerpoint in Supplemental Materials).

Live trainings may be in-person or virtual, but will not be recorded. We will use a sign-in sheet to collect names and email addresses of those who attended the in-person trainings so that we may follow up with them and provide a link to the online portion of the trainings and to measure expose of the training.

Lunches will be provided at all group training sessions, along with SKLIP devices at the intial training and educational materials. Pre- and post-training tests will be given during the initial in-person training session to measure uptake of the training. These tests will be distributed through an email about the upcoming training (see supplemental materials) and a QR code that

partctipants can access through their phones or laptops during the training. A pre-recorded version of the trainings will also be available to accommodate busy schedules.

Refresher trainings:
For those that complete the initial training we will offer short refresher trainings via a series of 5 emails that contain refresher material from the initial training and will be designed to increase practice and repetition of identification of skin-related pathologies. Emails will include a link to a short Qualtrics survey to measure uptake of training information.

We will email all partcipants of the intial training and offer the refresher materials and the option to opt out of the short trainings. Surveys are under development and will be uploaded for IRB review prior to sending out to participants.

Training observation:

A study team member will sit quietly during the in person trainings, and will listen and observe what happens, and take jottings or notes. The study team will not collect PHI and no identifiers will be recorded. The observers' field notes will focus on training content, questions, and discussion. Following the training, the researcher will type and prepare detailed fieldnotes. The original jottings will be destroyed after the final typed fieldnotes are prepared.

Online Training/Education:

The Melanoma Toolkit for Early Detection (MTED) is a Continuing Medical Education training that PCPs from the intervention arm of the study will be encouraged to complete as part of the intervention. Participants will be provided with a link by email to complete the training within the online platform. The Toolkit contains various Epic tools (SmartPhrases, the melanoma risk stratification framework, a skin cancer-specific after visit summary) and a self-paced online curriculum (see IRB #19372 – "Educational Program for the Early Detection of Melanoma in Oregon"). A separate copy of the online curriculum and surveys has been made specifically for this study to avoid cross-contamination of data. Knowledge will be assessed among the intervention participants as pre-post intervention evaluations. Knowledge and confidence assessments are embedded in the online learning MTED modules (as pre- and post-test surveys) and have demonstrated improvement in PCP melanoma knowledge and confidence in a prior study (Orfaly 2021). This information will allow us to measure the level of uptake of the curriculum and track any changes in overall referral and biopsy numbers of Toolkit-trained PCPs. The data will always be assessed as an aggregate and never on an individual provider basis. Individual PCPs will be de-identified and will create a unique ID. Those who complete the MTED training can request CME upon completion.

Interviews:

The study team will conduct interviews from the two study sites. We will invite everyone who participated in the first training to the interviews. Interview will last up to one hour and will take place outside of regular work hours.

Using a semi-structured interview guide, the interviewer will ask participants questions designed to increase our understanding of approaches to screening for melanoma, current systems in place, barriers to implementation, perceptions around skin cancer training and education, uptake of training and how it influenced delivery of care. No personal health information (PHI) will be collected. Interviews will take place in-person, over the telephone or video all using an OHSU-approved platform. If Webex or GoToMeeting (videoconferencing) is used to record the conversation, the recording meeting file (MP4 video file format) will be converted to an audio-file (MP3), and the original file will be immediately destroyed. Audio-recording from interviews will be professionally transcribed. If video is recorded, we will convert the video file to be audio-only, share that audio with the transcriptionist, and destroy the original video file.

Subsequent interview guides will be informed by the participation in the multi-educational training opportunities and will be submitted for IRB approval before they are conducted.

EHR Data: The majority of data for this study will be drawn from the EHR to document clinician screening for skin cancer during routine primary care outpatient visits.

Data collection will include three main time periods: 12 months of baseline data; 2-3 months of active intervention; and 12 months of post intervention data.

For a subset of patients, we will obtain patients' MRN to conduct a chart review. De-identified data are insufficient to identify medical photography, which requires opening charts to review the photographs. Biopsy interpretation are also embedded in the patient's chart, which we will review. Any new EHR data will be linked through a separate crosswalk and scrubbed for analysis.

Table 1 includes the indicators from the EHR that will be collected to evaluate the impact of the intervention and other co-variates of interest and their data source.

Quantitative analytic data will include a study ID for clinicians so that we can determine exposure of the clinician to the intervention. No patient level identifiers will be used in this study.

Table 1

Data Class	**Examples include, but are not limited to:**	**Data source**
Clinician characteristics	sex, age, degree (MD, DO, NP, PA, resident), years of practice	Public faculty data

Encounter information	Encounter date, encounter type, clinician ID, reason for visit, level of service, clinic ID, Department ID, encounter ICD9/10 problems, encounter CPT codes, encounter payor(s), skin cancer screening performed, use of skin cancer screening tool, use of SKLIP, biopsy performed, referral to dermatology, econsult to dermatology. Use of skin cancer dot phrase, Established vs. new patient. Patient characteristics age, sex, race, ethnicity.	EHR, chart review
biopsy info/ pathology	Biopsy result, number of biopsies performed, number of skin lesions biopsies, Breslow thickness	EHR, chart review
Clinician knowledge and confidence	MTED pre- and post-evaluations,	From IRB approved Surveys (***IRB #19372*** – *"Educational Program for the Early Detection of Melanoma in Oregon").*
practice pattern, referral practice	qualitative Interviews	Coded qualitative interview transcripts

Schedule of Events

	Pre- Intervention		Intervention (~3 months)		Post-Intervention (~12 months)	
Procedures	**Present**	**Apr 2023**	**Apr&May 2023**	**Aug – Oct 2023**	**Oct - Dec 2023**	**Jan - Sep 2024**
Pre-intervention EHR Data pull	x					
Develop training materials	x					
Recruitment	x					
Initial Training			x			
Online Training			x	x	x	
Refresher trainings					x	
Intervention EHR Data pull			x			
Interview guide finalized				x	x	
Qualitative interviews				x	x	
Online survey (MTED) data pull				x	x	
Post- Intervention EHR Data pull					x	x
Data analysis					x	
Dissemination (manuscripts, results in clinicaltrials.gov, etc.)					x	x

7) Data and Specimens

a. Handling of Data and Specimens

The online surveys containing the knowledge assessments will be administered using Qualtrics, an OHSU approved survey application. The research faculty and staff who have access to the application for data management and analytic purposes are all trained in and comply with research ethics and policies related to research data confidentiality, privacy and security as part of their employment at OHSU. PCPs invited to complete the online training and knowledge assessments will generate a unique ID that will be requested each time a test is completed. Participants who request CME will need to provide names and email address but this data will not be linked to data collected in pre- and post-tests or unique ids.

Interviews will be transcribed and will not include interviewees' names during the interview and will be scrubbed during transcription process. If a third-party transcription service is used, we will go through OHSU approved vendor Landmark, for which we already have a contract in place. The audio files from interviews will be destroyed after the transcript is checked for accuracy.

All qualitative data (interviews and fieldnotes) will be stored in a password protected computer file on a secure workstation at OHSU and access is restricted to study personnel. Notes will not include identifying information about the clinic, health care providers, or patients. Access to data will be restricted and require OHSU ID/password authentication. Their study ID number will be used to be able to link the interview information with the EHR and clinician performance data.

No patients will be individually identifiable for analyses. Each patient will be assigned a unique identification number that is not based on any personal identifiers by the OHSU population health analysts (not part of the research team). OHSU data population health analysts will retain the crosswalk between identifiers and patient data, but not share it with the research team

For a subset of patients, we will obtain patients' medical records number (MRN) to conduct a chart review. The MRN will be linked to a patient's unique ID number in a separate document not for analysis. MRNs will not be recorded in any datasets used for analysis.

We will ensure proper protections are in place to securely transfer and store these data within OHSU to prevent disclosure. The limited data set will be analyzed by biostatisticians employed by the OHSU department of family medicine. All data will be stored on secure servers and password protected computers at OHSU. We have previous experience conducting these types of studies.

b. Sharing of Results with Subjects

Results of the study will not be shared with subjects. All findings will be reported in aggregate.

Meta data including codebook/data dictionary and a document describing data used in publications will be added to a repository for 10 years.

8) Data Analysis

Quantitative Data: Univariate descriptive statistics will be examined for all variables from the MTED pre- and post- evaluation survey. Comparison between data collection timepoints will be completed using Chi-square test (categorical), ANOVA (continuous), or Kruskal-Wallis one-way ANOVA test (continuous variables that are not normally distributed). Standard qualitative analysis techniques will be used for coding open-ended questions.

Descriptive statistics will be used to report screening, biopsy and referral characteristics at each data collection time points. Means, standard deviations will be reported for normally distributed continuous variables and medians and interquartile ranges (IQR) will be reported for non-

normally distributed ones. Frequencies and percentages will be calculated for categorical variables. The main comparison is between clinicians in the multicomponent educational intervention arm vs. clinicians at the same sites that do not have exposure to the multicomponent educational intervention. These two groups of clinicians are examined using a pre-post study design to evaluate outcomes including change in risk assessment, biopsy referral and identification of skin cancers. Linear mixed-effects regression models adjusting for clustering effects within study sites and other potential confounders will be used to compare the intervention and control arms in screening, biopsy and referral characteristics outcomes from baseline to post-intervention. A p-value < .05 will be considered statistically significant.

Qualitative data analysis: The study team will meet regularly to review fieldnotes and transcribed data and listen to and discuss key segments of the recorded interviews. Analyzing qualitative data as it is collected is crucial to monitoring data quality, refining interview guides, and monitoring theme saturation. This ongoing process will be used to track emerging themes and create a coding template to be used for more in-depth analysis. We will follow the 5-phase analysis strategy described by Miller and Crabtree (describing, organizing, connecting, corroborating/ legitimizing, representing).[14,15] We will use an immersion-crystallization approach[16] in which the team reads and discusses the data for each participant (immersion) to identify key findings (crystallization); first to identify key themes within each "case", and then to identify cross-case findings.

9. Monitoring

9.1 Data Quality

Quality control procedures for this data include routine (i.e., quarterly) monitoring by the Principal Investigator of:

1. the removal of direct identifiers from information contained with the EHR data and Qualtrics data;
2. the documentation of investigator access to the Qualtrics;
3. any conditions that may negatively impact the confidentiality of information contained within the research registry.

9.2 OHSU Knight Cancer Institute Data & Safety Monitoring Plan

This study is under the oversight of the Knight Cancer Institute's Data and Safety Monitoring Committee (DSMC) as described in the Knight institutional Data & Safety Monitoring Plan (DSMP). The Knight DSMP outlines the elements required to ensure the safety of clinical study participants, the accuracy and integrity of the data and the appropriate modification of cancer-related clinical research for which significant benefits or risks have been discovered or when the clinical study cannot be successfully concluded. The Knight DSMP also describes the methods and procedures for ensuring adequate oversight of cancer-related research at OHSU.

As described in the Knight DSMP, regardless of a study's risk level and any specific Knight oversight in place, the Investigator is singularly responsible for overseeing every aspect of the design, conduct, and final analysis of his/her investigation. The DSMC is responsible for conducting Quality Assurance audits on CI approved protocols. This low risk investigator-initiated study may be randomly audited by the

DSMC audit team.

10) Risks and Benefits

a. Risks to Subjects

The primary risk to subjects is related to the small possibility of disclosure of legally protected personal health information (PHI) via EHR data acquisition or qualitative data collection (i.e., interviews). This potential risk will be described in the Information Sheet. Identities of interviewees will not be disclosed in study documents.

b. Potential Benefits to Subjects

Clinicians exposed to the intervention may gain additional knowledge and expertise for diagnosing and managing skin cancers. Practice members who attend the group training in person will receive a lunch and participating clinics may receive at least 1 SKLIP dermoscopy device for every 2 clinicians in the intervention clinics. SKLIP devices may be kept by clinics at the conclusion of the intervention.

Participants who are invited and complete a one time inteview will receive $100 dollar Amazon gift card.

c. Ethical and Regulatory Requirements

a. Protocol Review

The protocol and informed consent form for this study must be reviewed and approved in writing by the OHSU Knight Cancer Institute (Knight) Clinical Research Review Committee (CRRC) and appropriate Institutional Review Board (IRB) prior to any patient being registered on this study.

b. Changes to Protocol

Any modification of this protocol must be documented in the form of a protocol revision or amendment signed by the principal investigator and approved by the CRRC and 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 patient. In that event, the investigator must notify the CRRC and IRB in writing within 5 working days after the implementation.

c. Privacy, Confidentiality, and Data Security

Study staff will be trained to handle data securely for this study. Only staff members who have completed OHSU's required CITI and IRB trainings will be allowed to conduct study activities. The study PI, Dr. Sue Flocke will be responsible for ensuring that all individuals have satisfied this requirement and will monitor completion of any renewals or additional trainings over the course of the study.

<u>EHR Data:</u> Our protocol and procedures for using EHR data ensures no patients are individually identifiable for analyses. Data will be destroyed three years after completion of all study activities.

<u>Training observations:</u> fieldnotes from observations will be de-identified prior to analysis and saved at OHSU on secure, password-protected servers, including the X drive, Sharepoint or OneDrive. Research staff have training and expertise in high-quality data management and project operations.

Interview data: To minimize risks related to qualitative data analysis, any identifying information will be removed during transcription and signed informed consent will not be obtained. The audio (or video) files from interviews will be destroyed once transcribed. The interviews contain no questions about PHI, though prior to the interview participants' name, email, and phone number may be collected. Access to data will be restricted and require OHSU ID/password authentication. Transcribed data will be destroyed after three years of completion of all study related activities. All files will be stored on the OHSU approved cloud storage software and behind a password and OHSU firewall. Data will be destroyed three years after completion of all study activities.

d. Maintenance of Records

If the investigator relocates or for any reason withdraws from the study, the study records must be transferred to an agreed upon designee, such as another institution, another investigator, or to OHSU Knight Cancer Institute Clinical Research Management. Records must be maintained according to sponsor or FDA requirements. State requirements specific to this protocol.

e. Inclusion of Women, Minorities and Children

No OHSU Knight Cancer Institute study will focus on any particular gender, racial or ethnic subset. No subject will be excluded from the study on the basis of gender, racial or ethnic origin. Male, female and minority volunteers will be recruited for this study from the general population and approximately 50% men and 50% women will be studied.

The projected gender, racial and ethnic composition of the study will represent that of the Oregon population of patients seen in one OHSU Family Medicine rural-based clinic and one urban underserved Federally Qualified Health Center (FQHC) clinic.

Table 2: Projected Accrual for the Present Study - Estimated using total unique patients seen in an Oregon Family Medicine rural-based clinic from 1/1/21-12/31/21 time frame

Ethnic Category	**Sex/Gender**			
	Females	Males	Unknown	Total
Hispanic or Latino	331	209		4.9
Not Hispanic or Latino	5092	3898		81.8
Unknown	828	630		13.3
Ethnic Category: Total of all subjects*	6251	4737		100.0
Racial Category				
American Indian or Alaskan Native	75	57		1.2
Asian	90	35		1.1
Black or African American	36	39		0.7
Native Hawaiian or other Pacific Islander	19	10		0.3
White	4994	3853		80.5

Ethnic Category	Sex/Gender			
	Females	Males	Unknown	Total
More than one race	212	132		3.1
Unknown	825	611		13.1
Racial Category: Total of all subjects*	6251	4737		100*

Table 3: Projected Accrual for the Present Study - Estimated using total unique patients seen in an Oregon Family Medicine urban underserved FQHC from 1/1/21-12/31/21 time frame

Ethnic Category	Sex/Gender			
	Females	Males	Unknown	Total
Hispanic or Latino	561	437		8.5
Not Hispanic or Latino	5367	3678		80.0
Unknown	842	897		11.5
Ethnic Category: Total of all subjects*	6670	5012		100.0
Racial Category				
American Indian or Alaskan Native	94	47		1.2
Asian	321	242		4.8
Black or African American	417	302		6.2
Native Hawaiian or other Pacific Islander	38	22		0.5
White	4700	3579		70.9
More than one race	340	229		4.9
Unknown	760	591		11.6
Racial Category: Total of all subjects*	6670	5012		100*

Source: Adapted from U.S. Census Bureau, 2010 *Totals may not equal 100 due to rounding.

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