Self-Testing for Cervical Cancer in Priority Populations (STEP-2)

New NIH Collaboratory Trial Overview

January 8, 2025

OUTLINE

- STEP-2 Research Team & Advisory Board
- Project Overview
- Project Status
- Success, challenges & potential hurdles
- Data sharing plan

STEP-2 RESEARCH TEAM

University of Washington Team:
- Rachel Winer, Contact PI
- John Lin, Lead Project Manager

University of Chicago Team:
- Jasmin Tiro, MPI
- AJ Jose, Project Manager, Practice Facilitator

KPNW CHR Team:
- Amanda Petrik, MPI
- Rich Meenan, Co-I
- Jamie Thompson (BCT), Co-I
- Jen Rivelli, Spanish-speaking tailoring of materials
- Anna Edelmann, Project Manager
- Liz Shuster, Analyst

KPWA HRI Team:
- Beverly Green, Co-I
- Susan Shortreed, Biostatistician
- Melissa Anderson, Biostatistician
- Kris Hansen, Project Manager

ADVISORY COMMITTEE

- **Sarah Feldman -** Brigham & Women's Hospital, Harvard Medical School
- **Erin Hafer -** Community Health Plan of WA
- **Carolyn Halley -** HealthPoint
- **Lauren Harriett -** University of Chicago
- **Christian Hill -** Virginia Garcia
- **Yogini Kulkarni-Sharma -** Molina
- **Connie Mao -** University of Washington
- **Donna Oliver -** WA Department of Health
- **Gilma Pereda -** Cervivor, Inc.
- **Sally Retecki -** Care Oregon
- **Lisa Soltani -** El Rio Health
- **Susan Vadaparampil -** ACS, Moffitt Cancer Center

PROJECT OVERVIEW

Work with Medicaid health insurance plans & federally qualified health centers (FQHCs) in WA & OR to implement and evaluate 2 HPV self-sampling intervention strategies (in-clinic distribution with or without mailed distribution)

STEP-2 CLINICAL TEAMS

Oregon:

- Care Oregon Medicaid Health Plan (pilot/ full trial)
- Virginia Garcia Community Health Centers (pilot/ full trial)
- Multnomah County (full trial)

Washington:

- Molina Medicaid Health Plan (pilot/ full trial)
- Community (Medicaid) Health Plan Medicaid (pilot/ full trial)
- HealthPoint (pilot/ full trial)
- SeaMar Community Health Centers (full trial)
- Cowlitz (full trial; tentative)
- NeighborHealth (full trial; tentative)

GOALS OF 2-YEAR PILOT & 4-YEAR FULL TRIAL

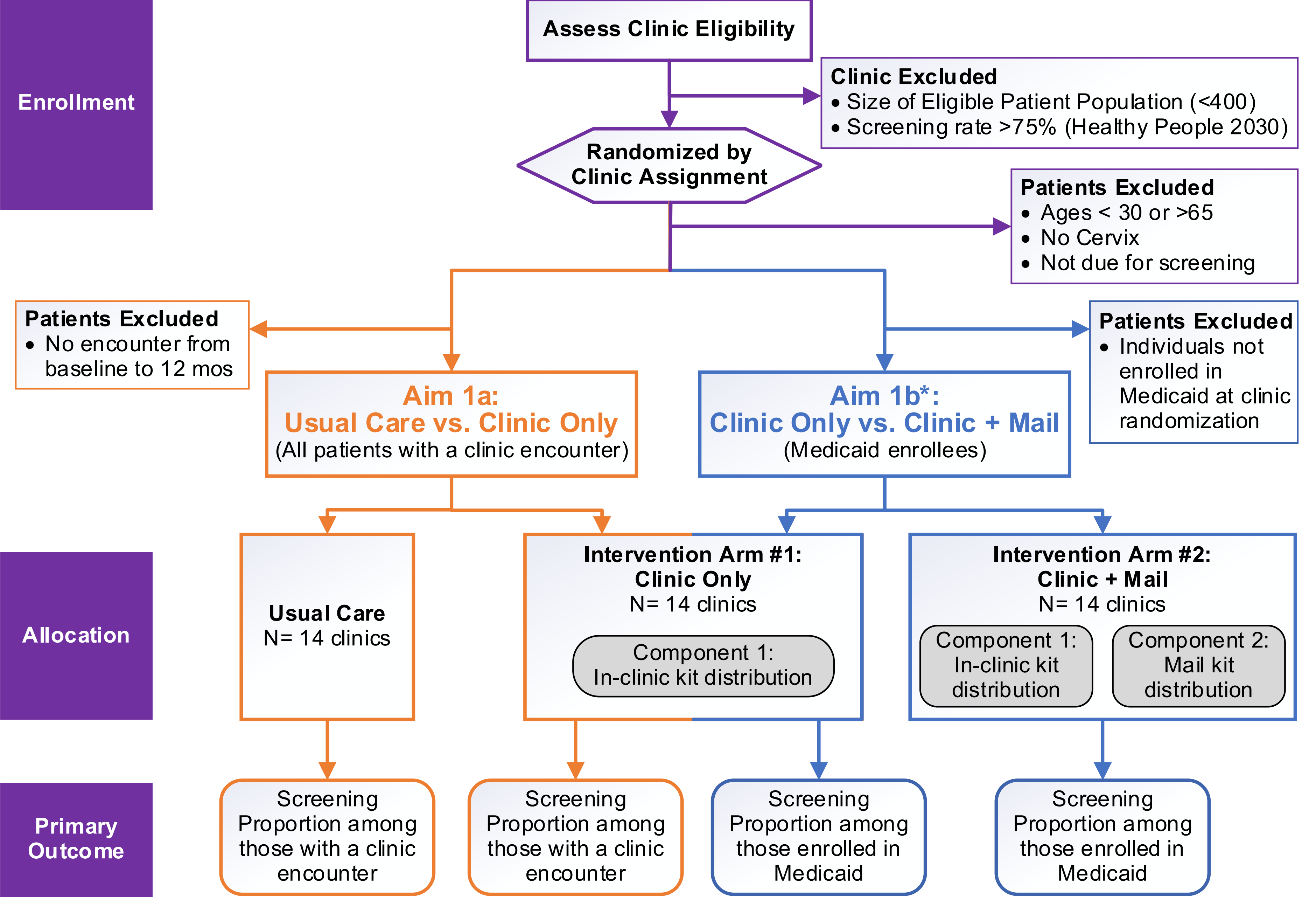
Pilot

- Develop, test, and refine the HPV self-sampling interventions & implementation strategies
- 2 FQHCs (1 clinic in each health system) & 3 health plans in WA & OR

Full trial

- Cluster randomized pragmatic trial in 42 FQHC clinics
- Clinics randomized to Usual Care, in-clinic distribution *only*, or in-clinic *plus* mailed distribution
- Evaluate comparative effectiveness; cost effectiveness; and acceptability, adoption, implementation & maintenance

Medicaid enrollees includes established patients (had recent clinic visit) and unestablished patients (assigned to clinic/provider & never visited; or no recent visit)



***Clinic + Mail vs. Usual Care is a secondary analysis, restricted to Medicaid enrollees**

IMPLEMENTATION STRATEGIES

Clinic Readiness Tool
- Champion & clinic team assess available resources & current staff roles/ responsibilities supporting cervical cancer screening delivery

-Strengths & weaknesses of current protocols / workflows; what must be adjusted to integrate HPV self-sampling?

Practice Facilitators & Facilitation Guide

- Options on how to modify workflows/ protocols based on clinic team preference

Patient-Centered materials (BCT)
- Pamphlet about HPV role in cervical cancer, importance of screening, new screening modality (self sampling)

- Kit Instructions (for use in clinic & in mailings)

- Staff instructions, Text reminders

Clinician / Staff Webinars
- Basic cervical cancer facts, new modality (accurate, equivalent to clinician-collected tests), adjusted follow-up protocols

- Communication skill building (screening recommendation, answering patient questions (difference Pap vs. HPV tests), explaining test results

Implementation Toolkit for mailing

- Instructions on how health plans & clinics can collaborate to maximize mailed kit reach

Revised Figure 3. Conceptual Model based on Theories of Health Beliefs, Relational Coordination, & Diffusion of Innovations

Implementation Strategies | **Determinants of Behavior Change** | **Outcomes**

PRISM

External Context:
External policies and financial incentives (FDA, CMS, NBCCEDP), clinical practice guidelines

Internal Context (Clinic & Health Plan Level):
Staff turnover, quality improvement capacity, readiness/ resistance to change

Patient

- Patient-centered materials
- Mailed kit – cue to action

Perceived Risk
Knowledge
Beliefs (Choice, Convenience)
Intention

- Clinician recommend kit
- Staff instruct on how to use kit

Clinician & Team

- Practice facilitator + debriefing sessions
- Clinic readiness tool
- Facilitation guide (step-by-step protocols & training manuals)
- Clinician/staff webinars

Knowledge
Positive attitude
Communication
Self-Efficacy
Resources

Health Plan

- Implementation toolkit (collaborate with clinics, mail kits to patients)

Resources
Staff Capacity
Partnerships

RE-AIM:
Reach
Effectiveness
Adoption
Implementation
(Adaptation)
Maintenance

STEPS Facilitation Guide (In Clinic Distribution)

Practice Facilitator Leads Execution of Steps

With support from Research Team via **Debriefing Sessions**

- Step 1 — Talk to your lab
- Step 2 — Assess current workflow
- Step 3 — Identify/Assemble Team
- Step 4 — Modify workflow*
- Step 5 — Train Clinic Staff**
- Step 6 — Implement
- Step 7 — Monitor Progress***

Steps 2–4: **Clinic Readiness Tool**

* Program EHR order, Result report

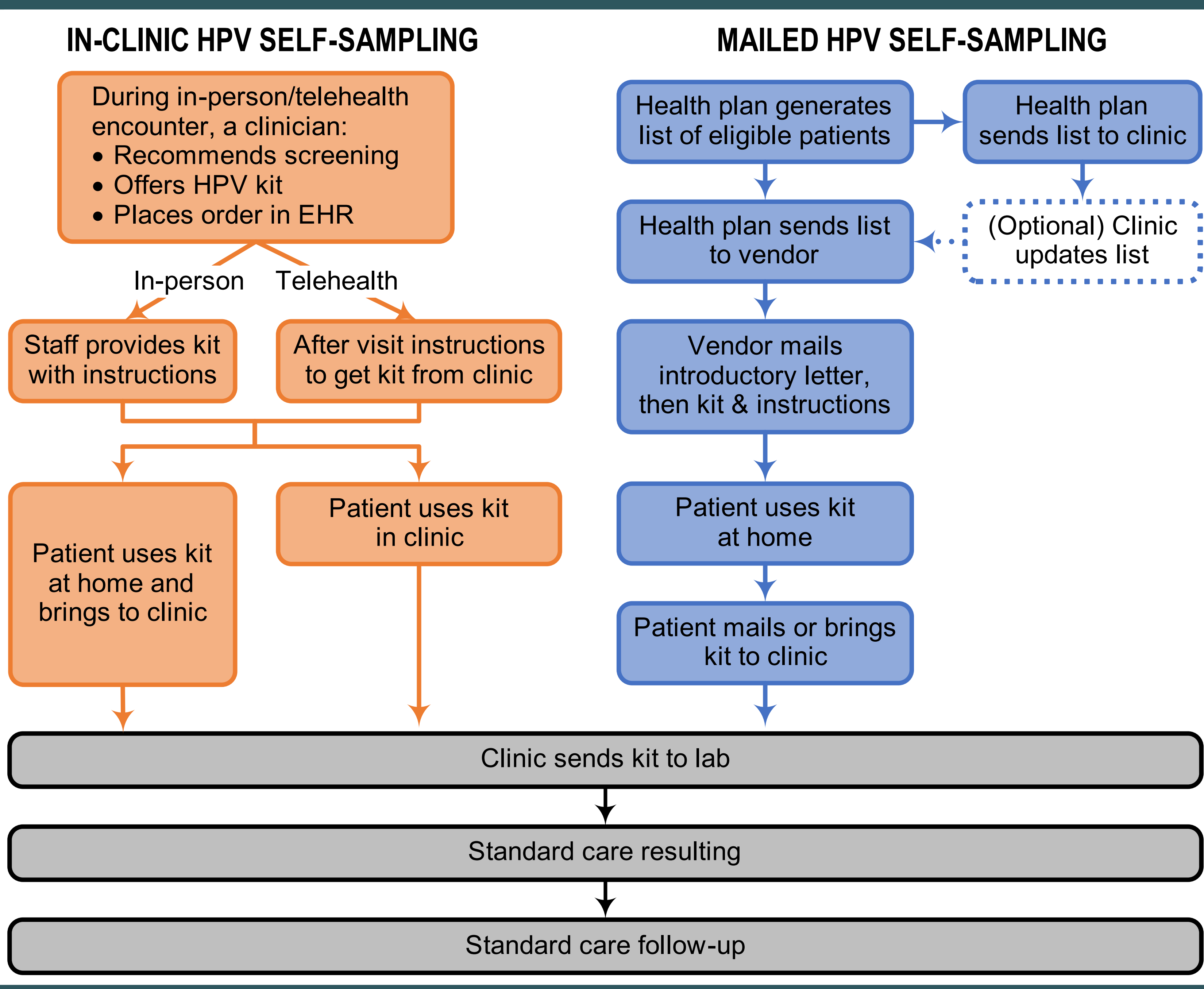
Step 5: **Webinars** **How To Tip Sheets

Step 6: **BCT Patient-Centered Materials** (also feeding into Webinars)

*** Program UDS reports to include kit completion

Figure 4.
Pathways for In-Clinic and Mailed HPV Self-Sampling

NOTE: the Implementation Toolkit teaches the health plan & clinic about how they are working together to mail kits to eligible patients.



Implementation Toolkit (Mail Distribution)

Step	Activity	Resource
Step 1	Form Health Plan & Clinic Partnership	**Webinar Module 1**
Step 2	Generate/ Refine patient list*	*Protocol to refine list among plan & clinic before hand off to vendor (optional)
Step 3	Mail kits, Batch order	**BCT Patient-Centered Materials**
Step 4	Patient return kit to clinic	**BCT Patient-Centered Materials**
Step 5	Clinic staff review kit & send to UW lab**	**Protocols to update order, place lab req, send results
Step 6	Results reporting (UW to clinic to patient**)	**BCT Patient-Centered Materials**; **Webinar Module 3**
Step 7	Clinic manage abnormal results***	**Webinar Module 3**

*** How To Tip Sheets

BCT in the STEP-2 Study

Refine patient-facing materials (English, Spanish) via a community-engaged approach

Refine/co-create patient-facing materials (e.g., videos, reminder text, phone messages, clinician communications) to be tailored and centered around patients' informational needs

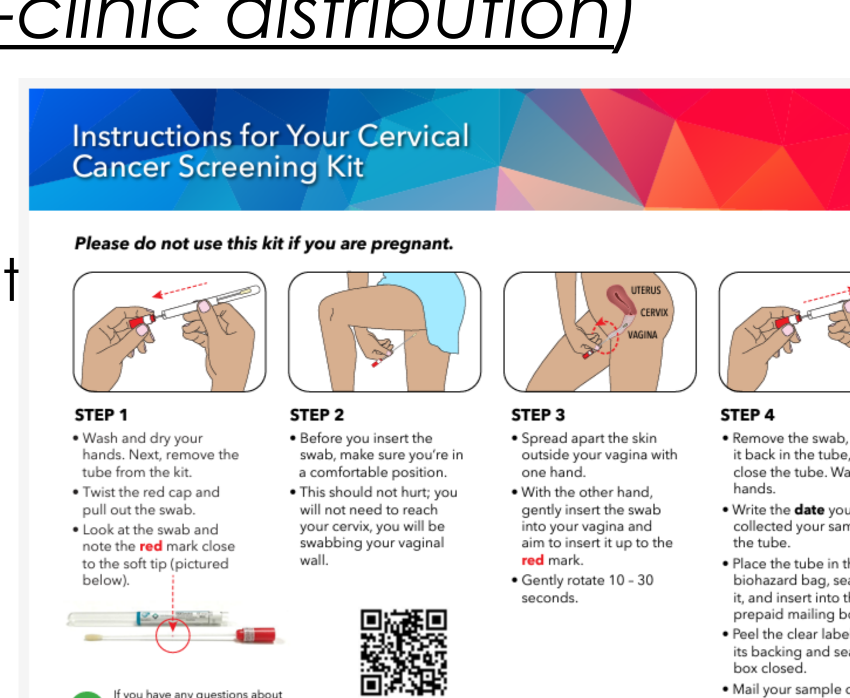
- Preferred messages (e.g., importance of HPV screening, what is HPV self-testing, how to do it)
- Preferred modality for delivering of outreach messages and reminders (e.g., text, video, patient portal)

Purpose

Develop messages to motivate patients to get screened using HPV self-testing

Co-create/revise materials about the HPV self-test that are tailored for priority populations *(<u>for mailing and in-clinic distribution</u>)*

- Limited word instructions
- Fact sheets / pamphlets
- Letters (introductory and follow-up regarding result
- Reminders (e.g., text, postcard, patient portal)
- Clinic posters
- FAQs (script for providers to talk to patients)
- Short animated instructional video



What is Boot Camp Translation?

Community Engagement Approach

1. Engages participants in translating health information into ideas, messages, and materials that are understandable and meaningful to community members
2. Iterative schedule of in-person meetings and short, focused phone calls (requires about 20–25 hours of participant time over 4–12 months)

**A typical schedule includes a full day retreat followed by 2–3 additional 2–4 hour face-to-face sessions, interspersed with 4–8 thirty-minute phone calls.*

Participating Clinics

HealthPoint

- **English** language
- 12-15 participants (patients, clinic staff, health plan staff)
- Washington

Virginia Garcia

- **Spanish** language
- 12-15 participants (patients, clinic staff, health plan staff)
- Oregon

Format for Community Engagement

Main	Follow-Up #1	Follow-Up #2
In-person session	Virtual session*	Virtual session*
5 to 6 hours	1 hour	1 hour
$100	$25	$25
Expert presentations + brainstorming & breakout sessions	Review of draft messages and materials	Review of draft messages and materials

Timeline

Clinic Kick-Off

BCT Planning + Preparation

BCT Participant Recruitment

BCT In-Person Session

BCT Follow-Up Sessions

September	October	November	December	January	February	March

Pilot begins in **August 2025**

UG3 Timeline

Aim	Milestones	Year 1				Year 2			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
		5-24 7-24	8-24 10-24	11-24 1-25	2-25 4-25	5-25 7-25	8-25 10-25	11-25 1-26	2-26 4-26
Interest-holder engagement	Assemble Interest-holder Advisory Board & hold quarterly meetings								
Project Planning	Formalize collaboration with 2 FQHC clinics and 3 health plans for the Phase 1 pilot								
Establish Workflow	Outline in-clinic and mailing workflows and protocol options to implement HPV self-sampling								
1. Adapt implementation strategies to integrate HPV self-sampling	Refine clinic readiness tool, practice facilitation guide, and webinars for clinics								
	Refine implementation toolkit for health plans								
2. Conduct Bootcamp Translation (BCT)	Recruit & host patient BCT sessions (English & Spanish)								
	Tailor patient-facing materials								
3. Conduct pilot in 2 FQHC clinics and 3 Medicaid health plans	Report baseline data from pilot clinics and health plans								
	Pilot test interventions (in-clinic and mailed HPV self-sampling) and implementation strategies (clinic readiness tool, practice facilitation guide, webinars, implementation toolkit, and tailored patient facing materials)								
	Assessment of the pilot intervention's implementation, reach and effectiveness based on the number of kits handed out in clinic or mailed, returned, and completed								
Transition to Phase 2	Onboard health plans and clinics for Phase 2 & deploy clinic readiness tool								
	Finalize Phase 2 trial design: update power analyses, sample size estimates, and protocol								

SUCCESSES

- Convened Advisory Board & held quarterly meetings
- Engaged 2 FQHCs & 3 Health Plans
- Refined and deployed Clinic Readiness Tool at both FQHCs
- Refined facilitation guide & webinars; Gathering feedback from interest-holders (early 2025)
- BCT is on track for February launch

Challenges Scorecard

Challenge	Level of Difficulty*					
	NA	1	2	3	4	5
Regulatory issues (e.g., IRBs, consent)			X			
Study design issues (e.g., ICC, power, sample size, confounders)					X	
Infusing health equity across the research life cycle, including enrolling a diverse and representative population				X		
Engaging with patient partners to inform the study		X				
Engaging with clinicians and health systems and health plans to identify or recruit participants					X	
Engaging with clinicians and health systems and health plans to deliver the intervention					X	
Data access (e.g., approval, privacy, security) and data management planning			X			
EHR integration and/or data extraction, including data management and quality assessment				X		
Collecting multi-level prospective data, including PROs			X			
Optimizing intervention sustainability and planning for sustainment					X	

*Your best guess: 1 = little difficulty; 5 = extreme difficulty

POTENTIAL HURDLES TO UH3 TRANSITION

- Logistics of onboarding 42 clinics & deploying Clinic Readiness Tool for full trial
  - However, nesting of clinics within 6 health systems will mitigate burden
- Ensuring integrity of the in-clinic plus mailed distribution arm
  - Considerable variability across Medicaid health plans (e.g., costs/incentives, whether they will mail kits to both established and unestablished patients, and how they will run the mailed program – type of vendor)

Data Sharing – Planning Phase

- *What is your current data sharing plan and do you foresee any obstacles?*
- *What data you are planning to share from your project (individual-level data, group-level data, specific variables/outcomes, etc.)?*

-We plan to share de-identified individual-level quantitative data from patient screening outcomes & clinician surveys, and de-identified qualitative data from patient interviews and clinic/health plan debriefing sessions.

-Patient screening outcome data & clinician survey data should be straightforward and easy to deidentify; qualitative data from patient interviews/clinic & health plan debriefing sessions will be more difficult to deidentify , but we do not foresee obstacles.

-Data will be shared in the Dryad repository.

- *What information did the IRB require about how the data would be shared beyond the study in order to waive informed consent, if applicable?*

-The IRB did not have any requirements because the data will be deidentified.