NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

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

Principal Investigators
Rachel Winer, PhD, MPH; Amanda Petrik, PhD; and Jasmin Tiro, PhD

Sponsoring Institution
University of Washington

NIH Institute Providing Oversight
National Cancer Institute (NCI)

Program Official
Pamela Marcus, PhD, MS (NCI)

Project Scientist
Aubrey Villalobos, DrPH, MEd (NCI)

Collaborators
- University of Chicago
- Kaiser Permanente Center for Health Research (Northwest)
- Kaiser Permanente Health Research Institute (Washington)
- HealthPoint Community Health Center
- SeaMar Community Health Centers
- Community Health Center of Snohomish County
- Tri-Cities Community Health
- Molina Healthcare
- Community Health Plan of Washington

ABSTRACT

The 29.3 million patients receiving care in US federally qualified health centers (FQHCs) have much lower cervical cancer screening rates than the national average. Self-collect for human papillomavirus (HPV) testing is an evidence-based cervical cancer screening method with high potential to reduce screening barriers. Self-collect kits can be distributed at clinics or mailed to patients' homes. Despite recent FDA approvals, FQHCs face significant barriers to implementing HPV self-collect. The STEP-2 trial will evaluate multilevel interventions for integrating HPV self-collect into FQHCs that leverage FQHC-Medicaid partnerships. In the planning phase, the study team will use community-engaged research and stakeholder input to adapt and pilot test multilevel interventions to support distribution of HPV self-collect kits in clinic and by mail. In the implementation phase, the study team will conduct a cluster randomized pragmatic trial to compare the effectiveness of the interventions for increasing cervical cancer screening. At least 42 FQHC clinics in Washington will be randomly allocated to 3 arms: usual care, in-clinic HPV self-collect distribution, or in-clinic plus mailed kit distribution. The mailed component will be administered by 2 Medicaid health plans. The primary outcome is the proportion of eligible patients who complete screening. The 2 primary comparisons will be usual care vs in-clinic distribution and in-clinic distribution vs in-clinic plus mail distribution. To minimize bias, each comparison will include distinct but overlapping patient populations (for example, all patients seen in clinic, Medicaid enrollees who established care with the clinic). A cost-effectiveness analysis will compare in-clinic distribution vs usual care and in-clinic plus mail distribution vs in-clinic distribution alone. The study team will use the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework and the Practical Implementation Sustainability Model (PRISM) to evaluate the interventions through mixed methods. The STEP-2 trial will be the first in the United States to determine the effectiveness and cost-effectiveness of HPV self-collect for increasing cervical cancer screening in FQHC settings. Results of the study will inform broad-scale implementation of HPV self-collect across FQHCs and other safety net clinics in the United States to reduce disparities in cervical cancer screening.

WHAT WE'VE LEARNED SO FAR

Challenge	Solution
Integration of lab results into the electronic health record (EHR) was not seamless; clinic staff were unfamiliar with how to import results and found the task onerous.	For the pilot, the study team worked with clinic staff and leadership to develop a clear protocol for importing results. For the main trial, the study team is working with system-level health IT programmers to build a lab-EHR interface that mimics existing protocols for other external labs.
In a pilot test of mailing letters to Medicaid enrollees who were assigned to a clinic but had not yet had a clinic encounter ("unestablished") to encourage them to establish care, yield was very low.	The study team revised the eligibility criteria and denominator for the clinic vs clinic + mail comparison to include only Medicaid enrollees with an encounter at their assigned clinic in the prior 2 years. This modification aligns with clinical workflows and stakeholder priorities while preserving the overall study design.

"Being part of the NIH Collaboratory has helped us think more intentionally about trial conduct in the context of real clinical workflows, how clinics and health plans have worked together in the past, and emerging factors affecting Medicaid patients. This engagement has strengthened our approach to designing strategies for downstream implementation." — Dr. Rachel Winer

"For investigators planning a pragmatic trial, we advise you to keep the intervention as aligned as much as possible to routine care practices while still answering a meaningful research question. If the trial includes implementation or cost-effectiveness questions, begin collecting those data from the start." — Dr. Jasmin Tiro

"Investigators should expect usual care to evolve, and build flexibility into your protocol, operations, and communication plan with clinics. It also helps to build in early collaboration with clinical and community partners, because pragmatic trials depend on fit with real-world workflows and patient needs." — Dr. Amanda Petrik

SELECTED PUBLICATIONS & PRESENTATIONS

- Presentation: NIH Pragmatic Trials Collaboratory Onboarding Meeting (2025)
- Poster Presentation: Engaging Stakeholders to Create an HPV Self-Collection Practice Facilitation Guide (2025)

See the complete set of STEP-2 resources.