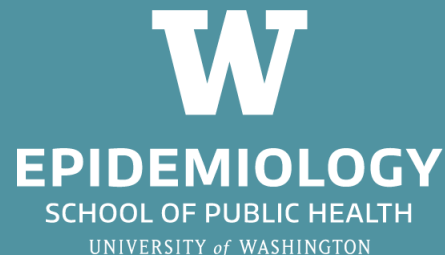


The STEP-2 Trial Flash Talk: Challenges and Lessons From the Pilot Phase

Rachel Winer, Amanda Petrik, Jasmin Tiro
NIH Collaboratory Steering Committee Meeting
May 29, 2025



OUTLINE

- Project overview & timeline
- Successes
- Challenges
- Lessons learned

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)

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

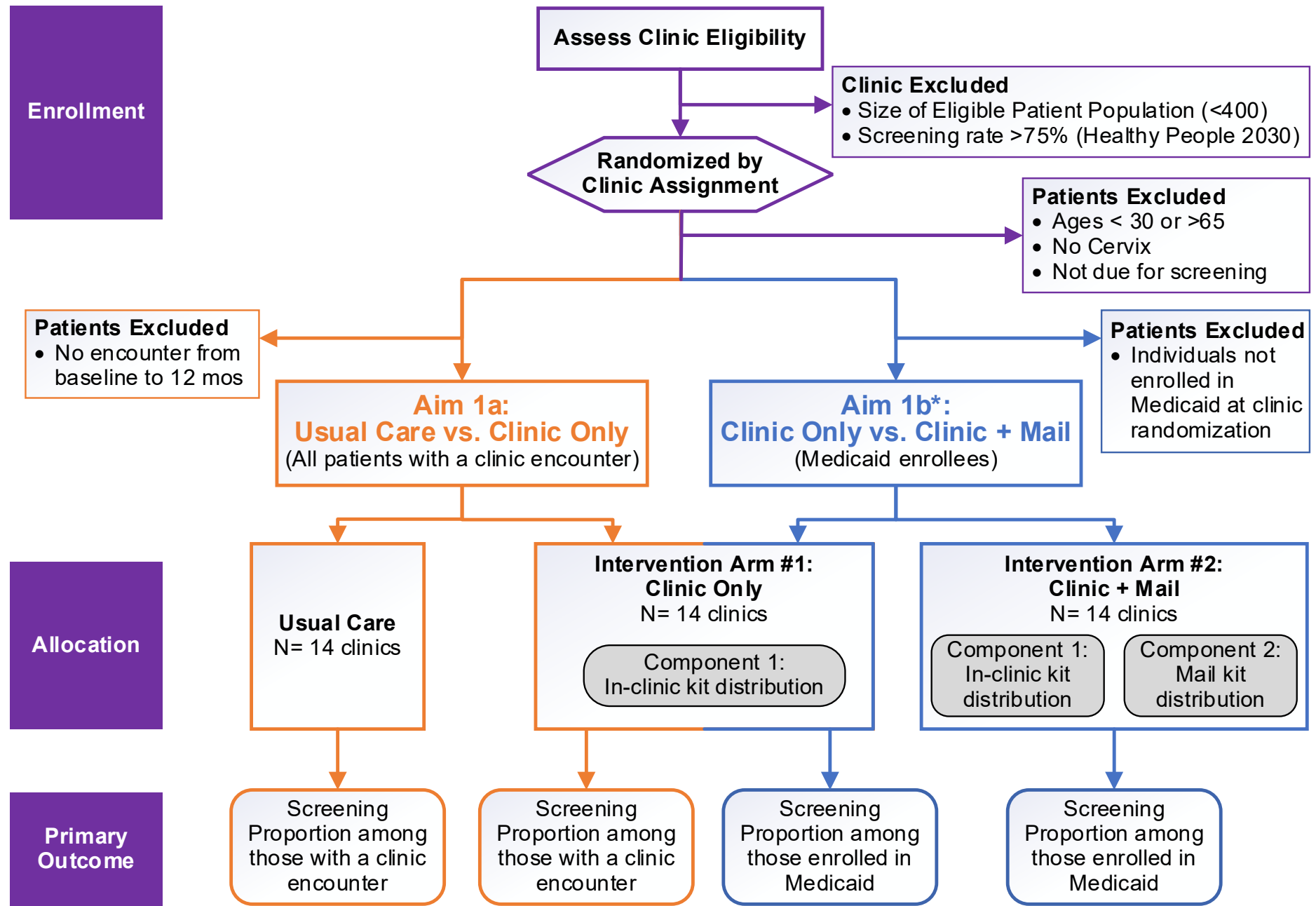
Pilot

- Develop, test, and refine the HPV self-sampling interventions & implementation strategies
- 2 FQHCs clinics & 3 health plans

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 (visited clinic & has a medical record number) and **unestablished patients** (assigned by health plan to clinic/provider but never visited clinic)



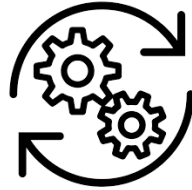
***Clinic + Mail vs. Usual Care is a secondary analysis, restricted to Medicaid enrollees**

IMPLEMENTATION STRATEGIES



Practice Facilitation Guide

- Step-by-step guide to help champion assemble team and modify workflows/ protocols based on clinic preference



Clinic Readiness Tool

- Champion & team assess available resources & current staff roles/ responsibilities supporting screening delivery; strength & weaknesses of current workflows
- What must be adjusted to integrate HPV self-sampling?



Patient-Centered Materials (Boot Camp Translation / Listen, Empower, Co-create [LEC]) for clinic & mail distribution approaches

- Informational flyer about HPV role in cervical cancer, importance of screening, new screening modality (self sampling)
- Modified informational video with QR code to instructions
- Kit Instructions
- Text reminders
- Tip sheets for staff to answer common patient questions



Clinician / Staff Webinars

- General info about cervical cancer, importance of screening, new modality HPV self-collection (e.g., how different from Pap tests)
- Communication skill building (clinician recommendation, staff instruct on kit use, explaining test results)
- Modified follow-up pathways (e.g., Pap for other high-risk HPV+ results)



Implementation Toolkit for mailing

- Step-by-step guide to help health plans & clinics work together to maximize mailed kit reach

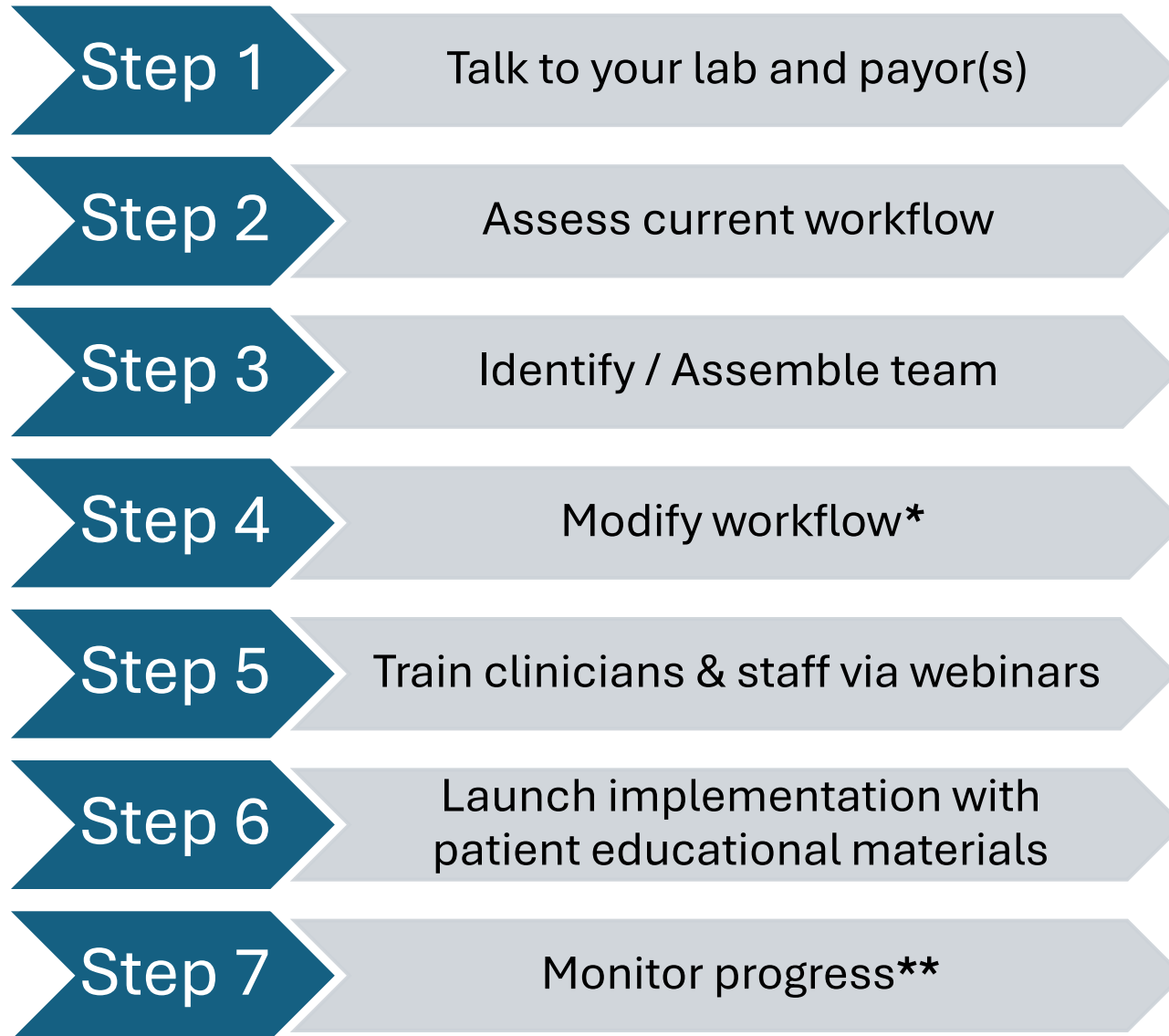
SUCCESSSES

- Convened Advisory Board & held quarterly meetings
- Engaged 2 FQHCs & 3 Health Plans
- Implementation strategies developed/refined and ready for testing in pilot:
 - ✓ Clinic readiness tool
 - ✓ 3 clinic/clinician training webinars
 - ✓ Patient-facing materials
 - ✓ Practice facilitation guide for implementing in-clinic HPV kit distribution
 - ☐ Implementation toolkit for mailed HPV kits (drafted; feedback & approval expected in June)
- On track for launching the in-clinic and mailed HPV self-sampling pilots in August

Version 1: Facilitation Guide



Practice
Facilitator
(appointed by
healthcare
system)
leads execution
of steps

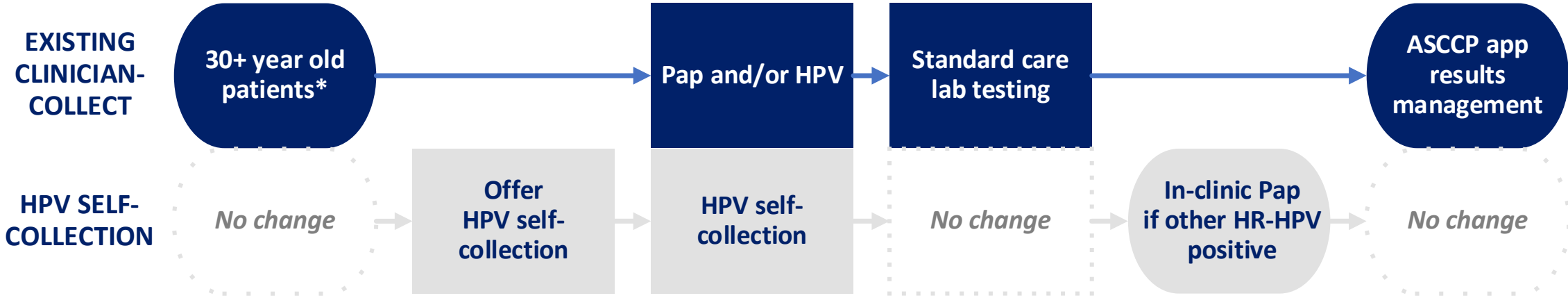


** Program EHR order & Reports communicating results to clinician & patient*

*** Program reports on cervical screening metrics to include kit completion*

Example Clinical Workflow Re-design Data Visualization

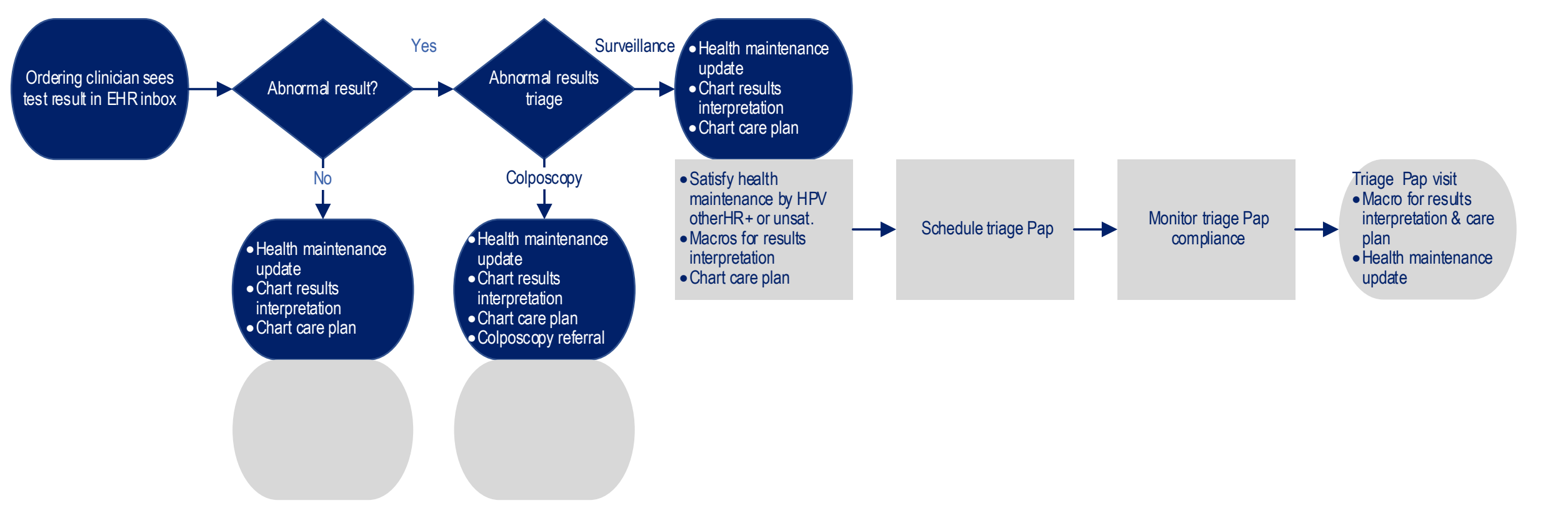
Overall



* 30+ years old if following USPSTF guidelines. 25+ years old if following ACS guidelines.

Example Clinical Workflow Re-design Data Visualization

Management of Abnormal HPV Self-Collection Results



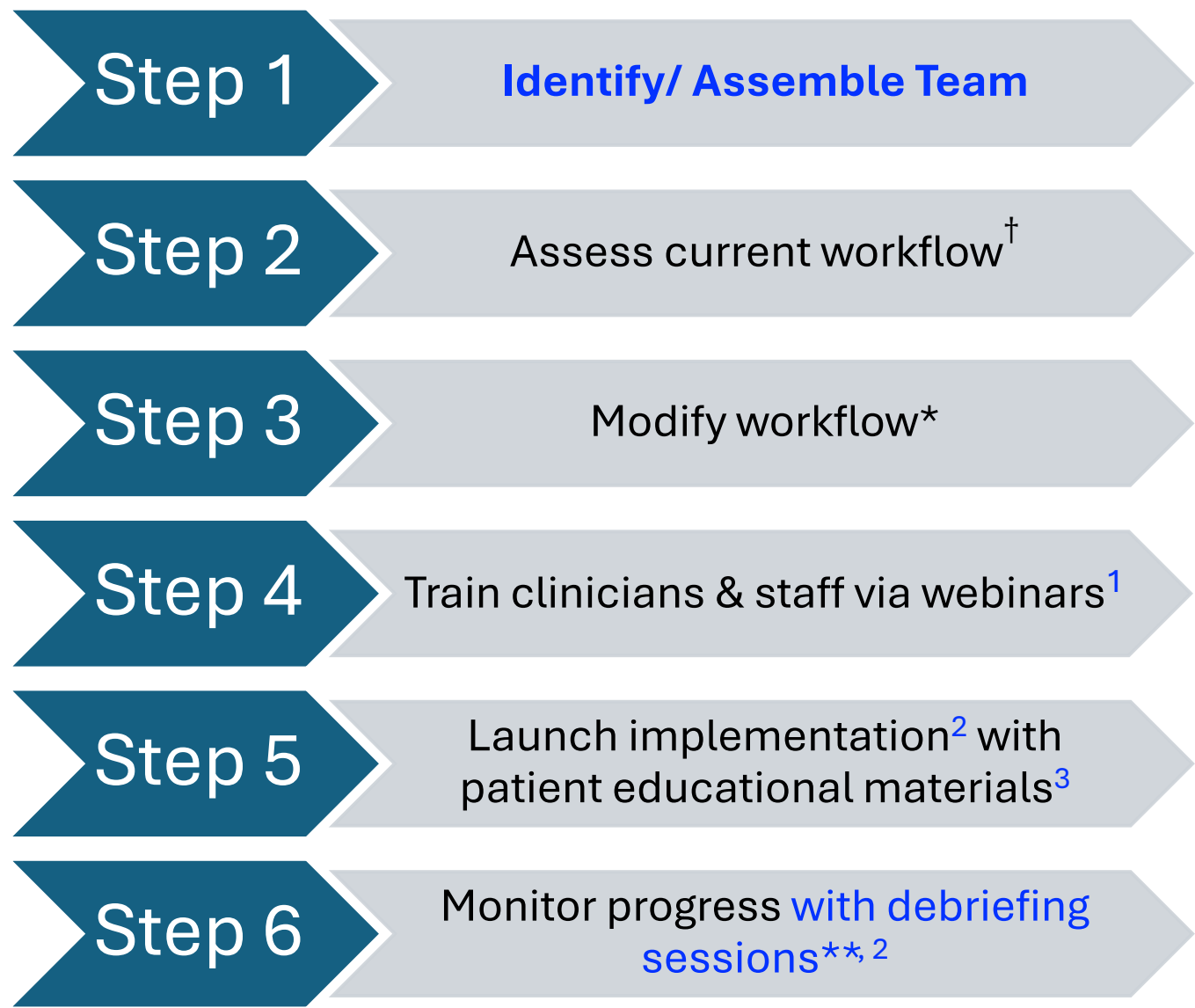
Feedback from Advisory Committee & Qualitative Interviews

- ❖ Think carefully about how practice facilitators are selected by the healthcare organization – suggest a 2 co-leads: clinician champion knowledgeable of cervical screening process & administrative lead experienced in quality improvement (e.g., process to change lab and IT)
- ❖ Assemble team first to minimize communication frustrations/ delays; typical team members: clinician champion, QI admin, lab liaison, IT specialist, medical assistant
- ❖ Support clinic team with brief *How To* and *FAQ* documents for daily use
- ❖ Don't reinvent wheel... use STI (CT / NG) self-collect instructions and staff training
- ❖ Provide facilitator with templates to run the launch meeting and debrief sessions (project recap, results from performance analysis, questions to solicit feedback)

Version 2. Facilitation Guide



Practice Facilitator
(recommend 2 co-leaders: Clinical champion & QI admin lead)
leads execution of steps



Identify/ Assemble Team

Step 1

Assess current workflow[†]

Step 2

Modify workflow*

Step 3

Train clinicians & staff via webinars¹

Step 4

Launch implementation² with patient educational materials³

Step 5

Monitor progress with debriefing sessions^{**}, 2

Step 6

[†] Use Clinic Readiness Tool

* Program EHR order & Reports communicating results to clinician & patient

¹ Reinforce training with *How To* tip sheets (eligibility criteria & follow-up protocol for in-clinic Pap)


² Provide templates (slides, session format)

³ Mimic CT/NG low literacy instructions

** Program reports on cervical screening metrics to include kit completion

TYPES OF MATERIALS


PATIENT-FACING MATERIALS

HPV Self-Test Get screened for cervical cancer today! 

What is the HPV self-test?

The HPV self-test is an easy way to check if you have HPV. You can do this test instead of a Pap, which collects cells from your cervix.


The HPV self-test is for **women ages 30-65** years old. You take your own sample from your vagina. It works just as well as when a doctor does the test.



HPV (*human papillomavirus*) is a common virus that can cause cervical cancer. The HPV self-test looks for HPV in cells collected from your vagina. If HPV is found, it can lead to early cell changes in the cervix. Treating these changes early can prevent or stop cancer.

Why should I do the HPV self-test?

Getting tested for HPV helps **PREVENT** cervical cancer!



It's fast, easy, and doesn't hurt! Most people find it simple. No need for a pelvic exam, and it only takes 20 seconds!

It's private and convenient! You can do it in the clinic bathroom or at home, depending on how you got the test.

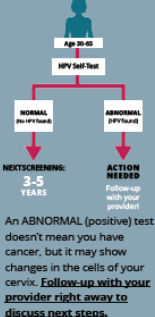
Protect Your Health! Prevent cervical cancer by completing your HPV self-test today!

Source: www.PreventHPVCancer.com

What happens after I do the HPV self-test?

Return your sealed sample to the provider at the clinic or by mail, depending on how you got the test.

Your sample will go to a lab, and you will get your results within two weeks.





Normal (no HPV found): Next screening: 3-5 years.

Abnormal (HPV found): Action needed: Follow-up with your provider.

An ABNORMAL (positive) test doesn't mean you have cancer, but it may show changes in the cells of your cervix. **Follow-up with your provider right away to discuss next steps.**


Fact Sheet

HPV Self-Test Instructions 

Package contents: A HPV Self-Test, B Biohazard bag, C Envelope. 

1. Wash hands
2. Twist and pull out swab
3. Get comfortable
4. Insert swab to red mark and rotate
5. Close the swab and write date
6. Put in envelope
7. Drop your sealed sample in the mail. Or give your sealed sample to the provider.

Reminder: Do not use this test if you're pregnant!

For more information, please call: (503) 352-6000  [Insert Logo]

Instructions

[Date]
[Address]

Dear (Patient's Name),

At HealthPoint we care about your health. To make sure you are up-to-date on your cervical cancer screening, we are partnering with your health plan, Community Health Plan of Washington (CHPW), to send you an HPV self-test. You can do this test instead of a Pap, which collects cells from your cervix.

Here's what you need to know:

- **What is HPV?** HPV (*human papillomavirus*) is a common virus. Some HPV viruses can cause changes in cervical cells.
- **What is the HPV self-test?** The HPV self-test looks for HPV in cells from your vagina. If HPV is found, it can lead to cell changes in the cervix. Finding and treating these changes early can prevent or stop cancer from growing.
- **Who should take this test?** Women ages 30-65 can use this test instead of a Pap.
- **How does it work?** You'll collect your own vaginal sample using the swab in the kit. It works just as well as when a doctor does the test. It's fast, easy, and doesn't hurt. You can do it at home!
- **How to do the test?** The test kit will have simple instructions to follow.

When you get your HPV test kit in the mail, please do the test and mail it back right away! Your provider will notify you if your result is normal (negative). If your result is abnormal (positive), your provider will call you about next steps. An abnormal result doesn't mean you have cancer, but it's important to follow up with your provider right away. If you have any questions or need help, please call us at xxx-xxx-xxxx.

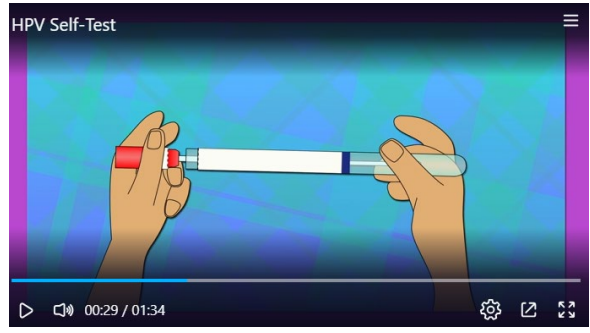
At HealthPoint, we are here to give you the best care and support you. **Protect your health by completing the HPV self-test!**

Your HealthPoint and Community Health Plan of Washington (CHPW) Care Team,

HealthPoint
955 Powell Ave SW
Renton, WA 98057
<HP phone number>
www.healthpointchc.org/

CHPW Customer Service
1111 Third Ave, Suite 400
Seattle, WA 98101
1-800-440-1561 (TTY: 711)
www.chpw.org/

Introductory Letter




Video

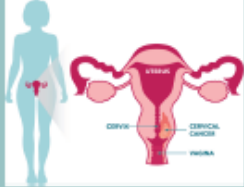

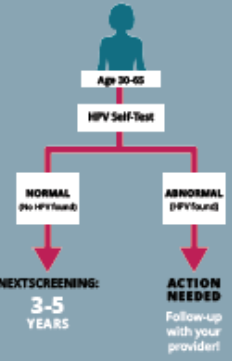
PROVIDER-FACING MATERIALS


FAQs

Talking points

FACT SHEET (front page)

HPV Self-Test Get screened for cervical cancer today! 

What is the HPV self-test?	Why should I do the HPV self-test?	What happens after I do the HPV self-test?
<p>The HPV self-test is an easy way to check if you have HPV. You can do this test instead of a Pap, which collects cells from your cervix.</p> <p>The HPV self-test is for women ages 30-65 years old. You take your own sample from your vagina. It works just as well as when a doctor does the test.</p>  <p>HPV (<i>human papillomavirus</i>) is a common virus that can cause cervical cancer. The HPV self-test looks for HPV in cells collected from your vagina. If HPV is found, it can lead to early cell changes in the cervix. Treating these changes early can prevent or stop cancer.</p>	<p>Getting tested for HPV helps PREVENT cervical cancer!</p>  <p>It's fast, easy, and doesn't hurt! Most people find it simple. No need for a pelvic exam, and it only takes 20 seconds!</p> <p>It's private and convenient! You can do it in the clinic bathroom or at home, depending on how you got the test.</p> <p>Protect Your Health! Prevent cervical cancer by completing your HPV self-test today!</p> <p><small>Source: www.PreventHPVCancers.com</small></p>	<p>Return your sealed sample to the provider at the clinic or by mail, depending on how you got the test.</p> <p>Your sample will go to a lab, and you will get your results within two weeks.</p>  <p>NORMAL (no HPV found) NEXT SCREENING: 3-5 YEARS</p> <p>ABNORMAL (HPV found) ACTION NEEDED: Follow-up with your provider</p> <p>An ABNORMAL (positive) test doesn't mean you have cancer, but it may show changes in the cells of your cervix. Follow-up with your provider right away to discuss next steps.</p>

For more information, please call: **(503) 352-6000**  [Insert Logo]

© 2023 Created by the STEP-2 Project with funding from the National Cancer Institute (U23CA270196)

Clinic Name • Address • City, State, Zip Code

Highlights



- Participants emphasized the need for widespread, clear, and accessible information about HPV, cervical cancer, and screening options like the HPV self-test
- Preferred terminology: “self-test” “self-screening”, “autoprueba”
- Simple and clear fact sheet with visuals
- Clarifies what is the HPV self-test, who it is for, why should it be done, why is the self-test a good option, what happens after the self-test is completed
- Emphasize prevention of cancer
- Discuss follow-up if you have an abnormal result





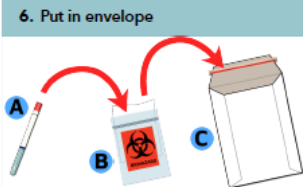
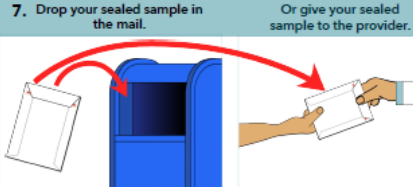
FACT SHEET (back page)

LIMITED WORD INSTRUCTIONS


HPV Self-Test Instructions

Package contents: **A** HPV Self-Test, **B** Biohazard bag, **C** Envelope

SCAN FOR VIDEO INSTRUCTIONS  

1. Wash hands 
2. Twist and pull out swab 
3. Get comfortable 
4. Insert swab to red mark and rotate 
5. Close the swab end and write date 
6. Put in envelope 
7. Drop your sealed sample in the mail. Or give your sealed sample to the provider. 

Reminder: Do not use this test if you're pregnant!

For more information, please call: (503) 352-6000  [Insert Logo]

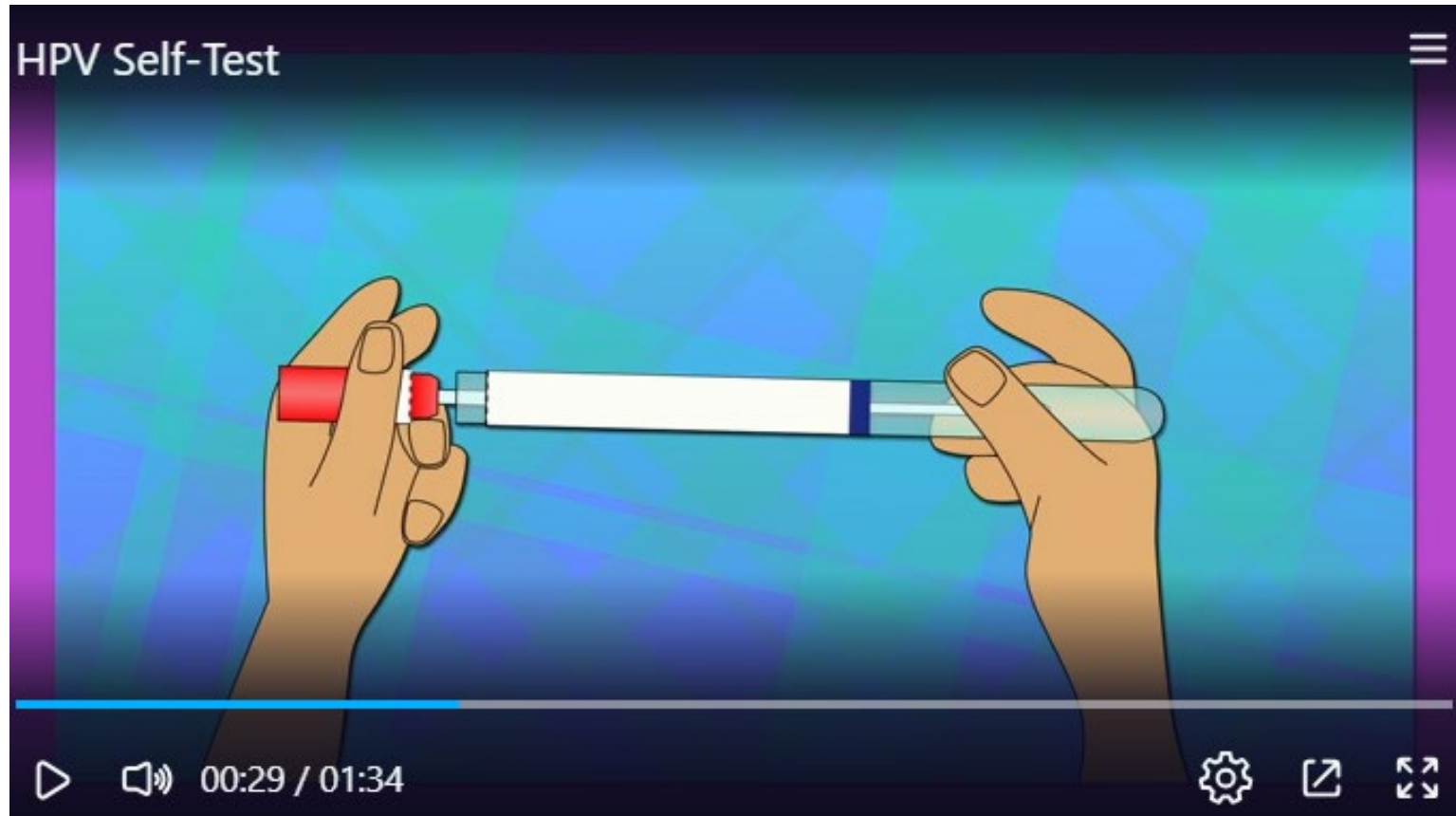
© 2025 Created by the STEP-2 Project with funding from the National Cancer Institute (1UGCA190286)

Clinic Name • Address • City, State, Zip Code

Highlights

- Create simple and clear instructions with visuals including animated video
- Uses more images and fewer words to describe the HPV self-test process
- Includes QR code for video of self-test instructions
- Includes washing your hands

VIDEO (How to Complete HPV Self-Test)



Video modification: 0:23 – 1:13

<https://research.kpchr.org/preventhpvcancers/Videos>

CHALLENGES

- One of our pilot FQHCs unexpectedly withdrew from the study (due to internal health system organizational factors)
 - Quick pivot to a back-up clinic is in progress
- Need to test multiple pathways for the mailed kit distribution intervention
 - 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)

LESSONS LEARNED

- Value of engaging early with multiple health systems & health plans
 - Onboarding takes longer than expected
 - Clinics/plans may drop out, even after engagement
- Need to be flexible & responsive to needs of FQHC and health plan partners
 - Quick pivots necessary
 - Engagement with clinic/health plan partners, patients, advisory board to co-design practical and relevant implementation strategies

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	
Using community-centered research methods				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