

At-Home Screening for Cervical Cancer

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Prevent Cancer Dialogue
June 17, 2020



12,000

New cases of cervical cancer dx
each year in US

A map of the United States is shown against a dark background. The map is divided into two main color regions: a purple region on the left and a blue region on the right. The text is overlaid on the purple region.

>50%

**of these women are in the 25% of women
who are not up to date with screening.**



2018 USPSTF cervical cancer screening guidelines for women aged 30-65 years

3 options:

- 1) Pap every 3 years
- 2) Co-test (Pap & HPV) every 5 years
- 3) HPV alone (i.e. “primary HPV”) every 5 years



Alternative Screening Strategies

- With primary HPV screening (i.e., HPV alone) now a guideline-approved option, HPV self-sampling is an emerging strategy.
- Potential to increase access & eliminate need for a clinic visit for a majority of women.

Home-based self-sampling for HPV

- US studies demonstrate feasibility, acceptability & concordance with provider collected samples
- Population-based trials in countries with organized screening programs → self-sampling improves cervical cancer screening participation rates
 - High follow-up compliance after a HPV+ test
 - Higher yield of cervical precancers
- Several countries (Australia, The Netherlands) now include HPV self-sampling options for underscreened women.



Original Investigation | Obstetrics and Gynecology

Effect of Mailed Human Papillomavirus Test Kits vs Usual Care Reminders on Cervical Cancer Screening Uptake, Precancer Detection, and Treatment

A Randomized Clinical Trial

Rachel L. Winer, PhD, MPH; John Lin, BA; Jasmin A. Tiro, PhD; Diana L. Miglioretti, PhD; Tara Beatty, MA; Hongyuan Gao, MS; Kilian Kimbel, BA; Chris Thayer, MD; Diana S. M. Buist, PhD, MPH



Funding: National Cancer Institute - R01CA168598
ClinicalTrials.gov: NCT02005510



Study Overview

- Large, pragmatic RCT (n=19,851) to compare effectiveness of two programmatic approaches to increasing cervical cancer screening among overdue women at Kaiser Permanente Washington.
- First approach (control arm) was usual care – annual patient reminders and ad hoc outreach by clinics – to promote adherence to Pap screening.
- Second approach (intervention arm) included usual care PLUS mailed HPV self-screening kits.
- Fully integrated into the clinical delivery system

Your kit includes:

- Gloves
- 2 cotton swabs in separate wrappers
- A tube to hold the cotton swabs after you collect your sample
- A biohazard bag and a small, padded envelope for mailing your sample to us



Things to know before you collect your sample:

- Do not use the screening kit if you are pregnant.
- For best results, do not have sexual intercourse, douche, or use vaginal medications for 48 hours before collecting your sample.



1 Wash and dry your hands, then put on the gloves. Next, open the tube and take the first cotton swab out of the wrapper.



2 Spread apart the skin outside your vagina. With the other hand, gently push the cotton swab into your vagina as far as it will go without hurting—like you would with a tampon.



3 Rotate the cotton swab inside your vagina three full turns, keeping it as far inside as you can.



4 Take the cotton swab out of your vagina while spreading apart the outside skin.



5 Hold the cotton swab with your fingers and **break it in half**. Try not to touch the cotton tip.



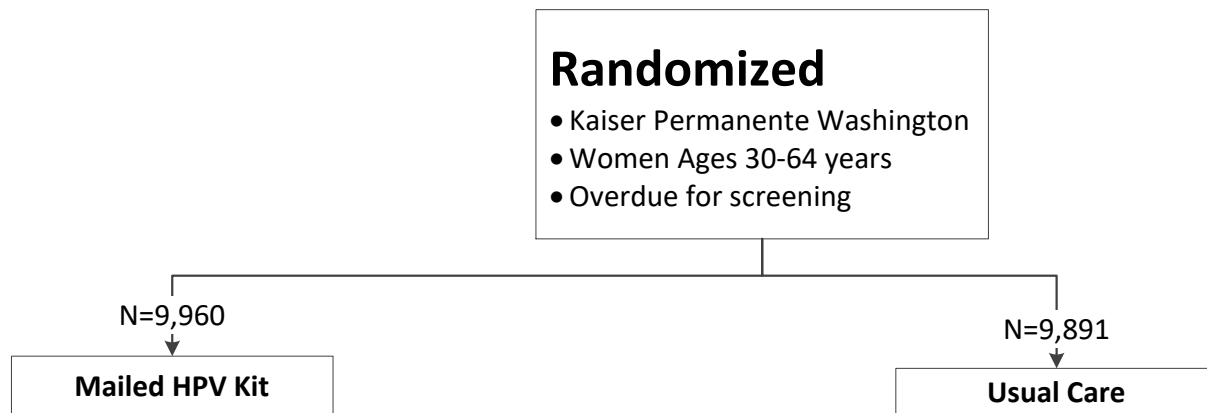
6 Put the cotton swab into the tube, then set the tube within easy reach. Throw away the broken end.



7 Take the second swab out of the wrapper, then **repeat steps 2-6**. When you're done, both swabs will be in the tube.

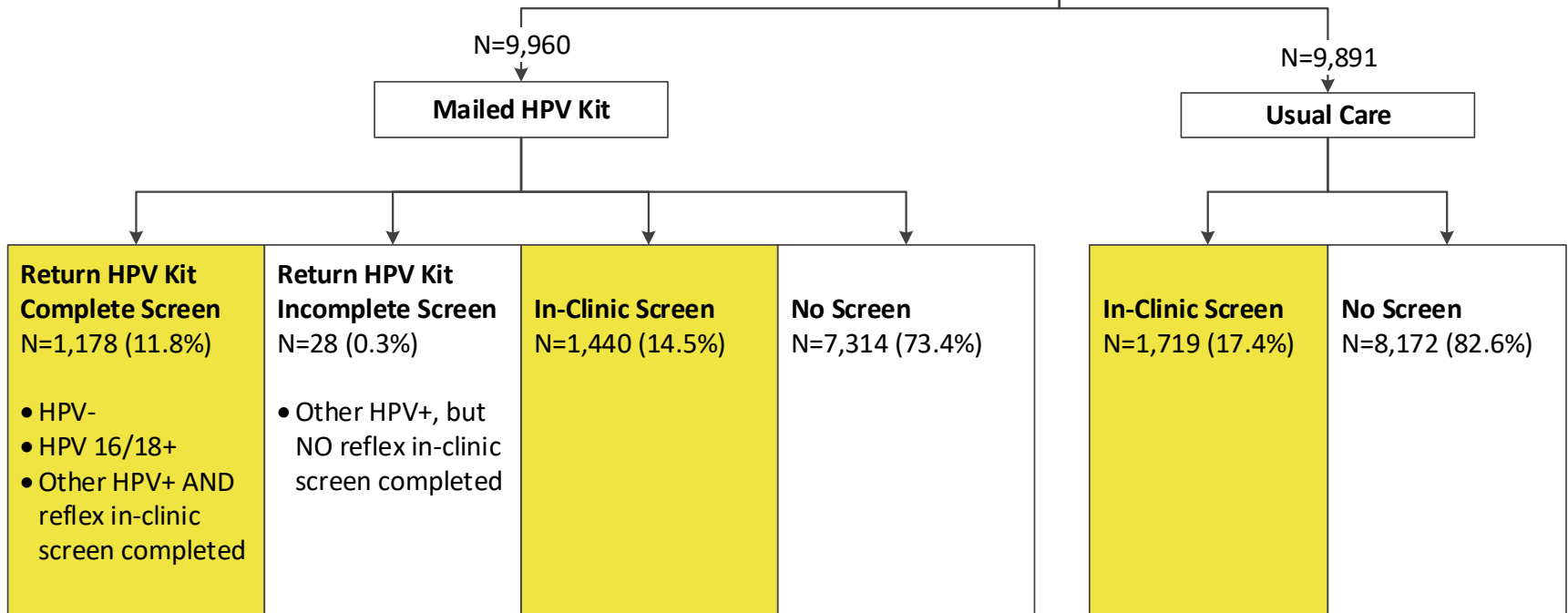


8 Close the tube, throw away the gloves, and wash your hands.



Randomized

- Kaiser Permanente Washington
- Women Ages 30-64 years
- Overdue for screening



Mailed HPV Kit

Usual care

RR (95% CI)

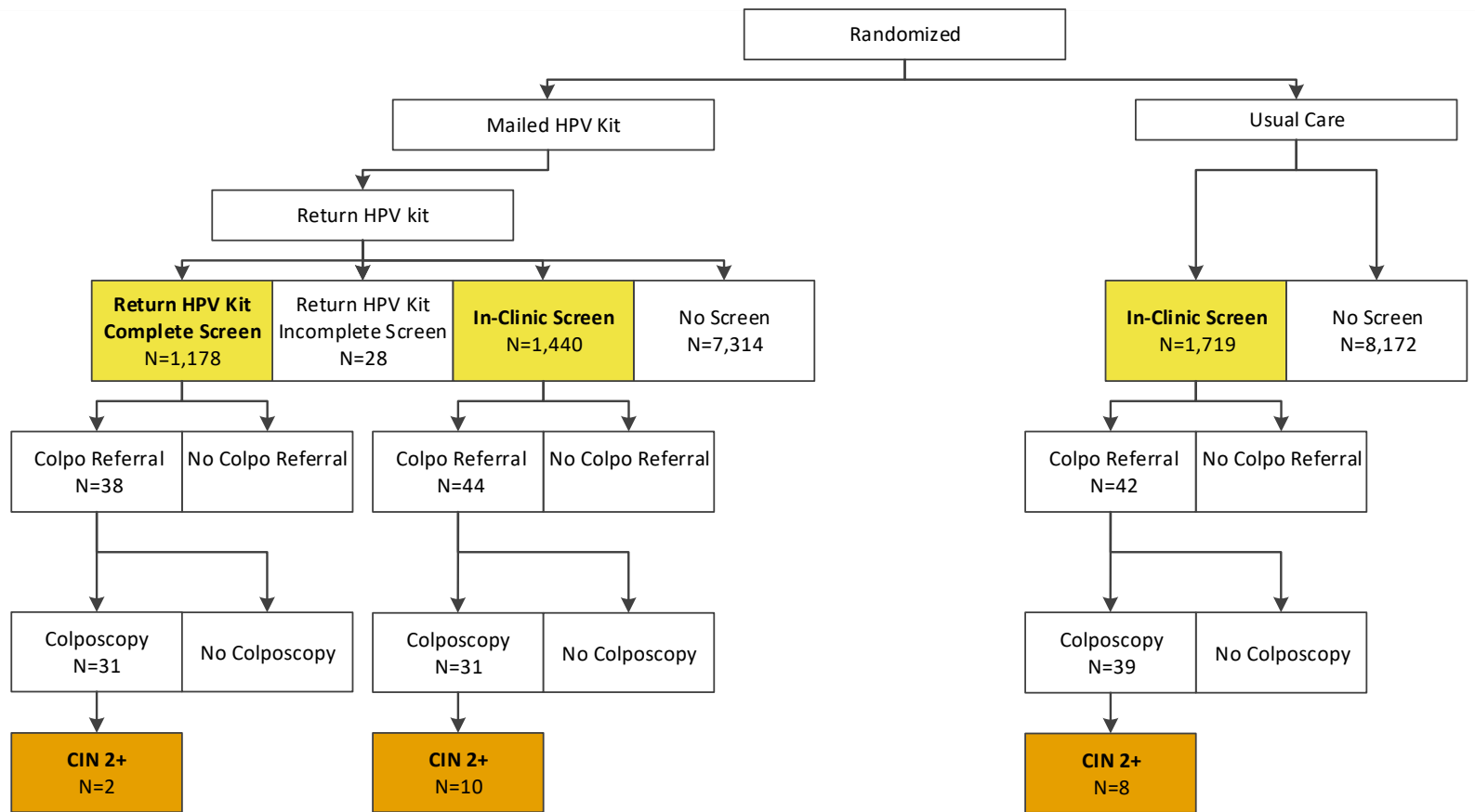
Screening uptake 2,618 (26.3%) 1,719 (17.4%) 1.51 (1.43-1.60)



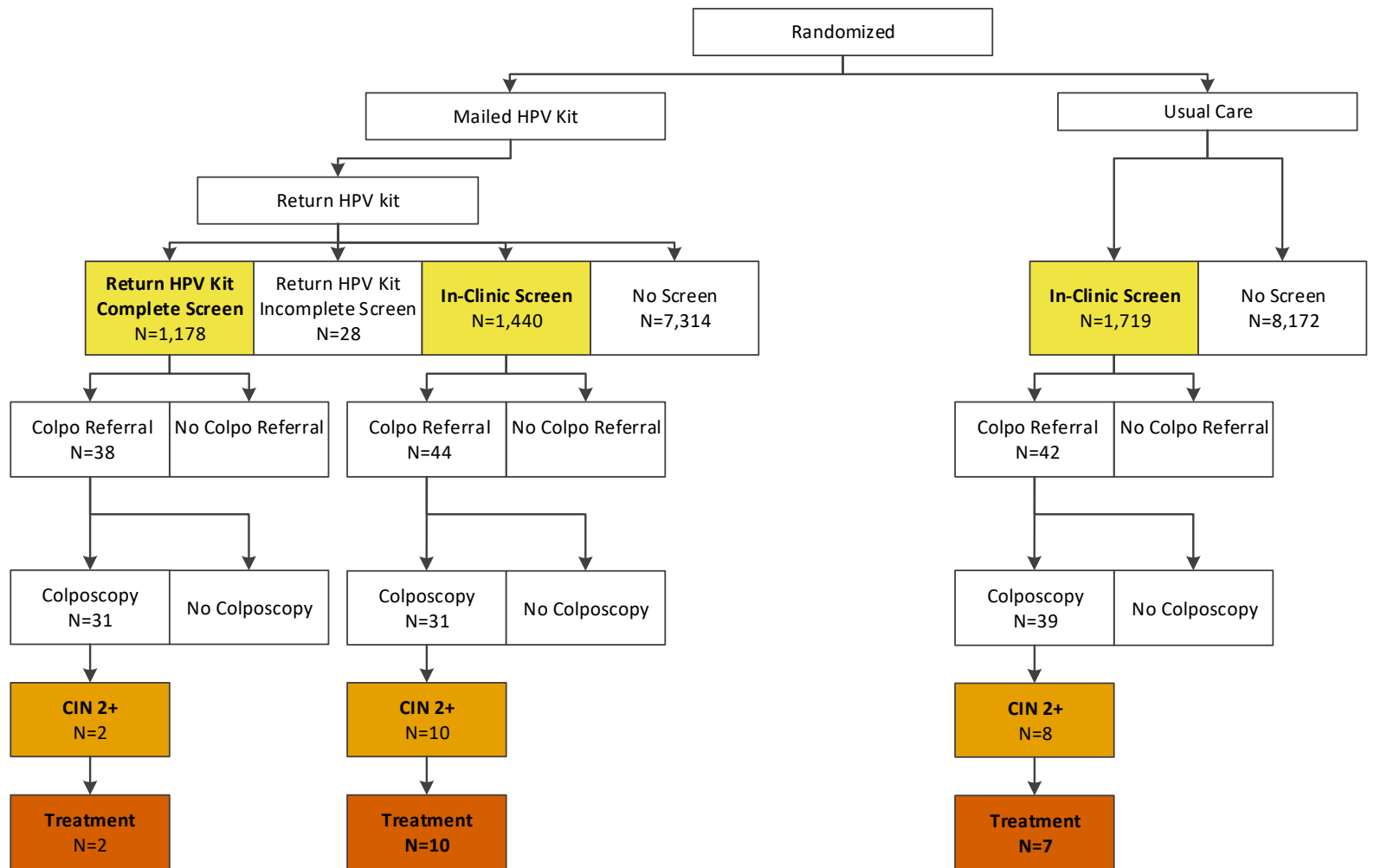
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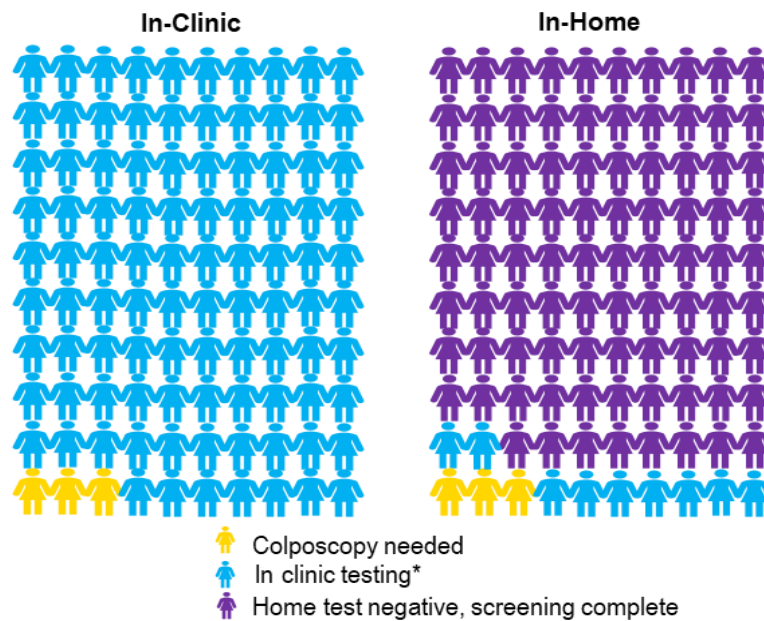
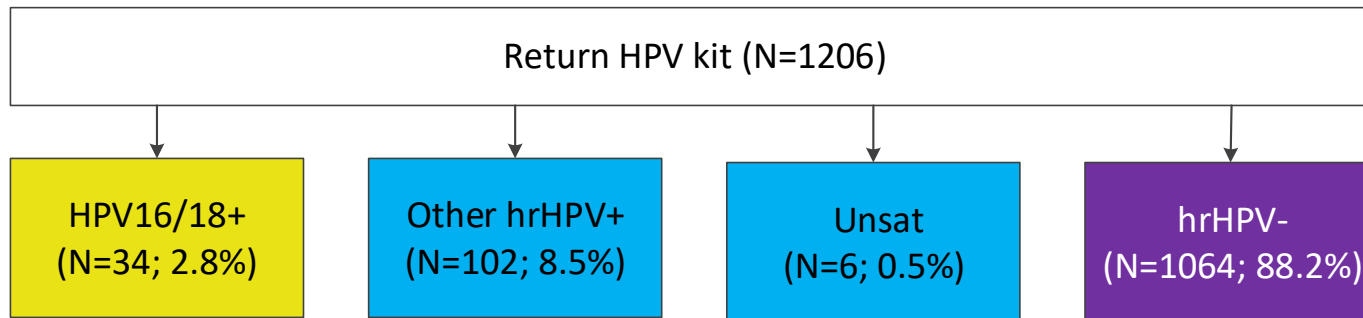
School of Public Health



	Mailed HPV Kit	Usual care	RR (95% CI)
Screening uptake	2,618 (26.3%)	1,719 (17.4%)	1.51 (1.43-1.60)
CIN 2+	12 (0.12%)	8 (0.08%)	1.49 (0.61-3.64)



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Screening uptake	2,618 (26.3%)	1,719 (17.4%)	1.51 (1.43-1.60)
CIN 2+	12 (0.12%)	8 (0.08%)	1.49 (0.61-3.64)
Treatment	12 (0.12%)	7 (0.07%)	1.70 (0.67-4.32)



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Understanding Patients' Perspectives and Information Needs Following a Positive Home Human Papillomavirus Self-Sampling Kit Result

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- 46 women interviewed (out of 75 invited) with HPV+ kit result
 - 38 completed all recommended follow-up
 - 8 did not complete all recommended follow-up

Reaction to Kit



Theme 1: Convenience of home-based test

"I actually thought it was pretty cool you could do something like that at home and just mail it in."

"A private way to take a test and find out about something. It didn't seem daunting to me or overwhelming."

Reaction to Positive Test Results

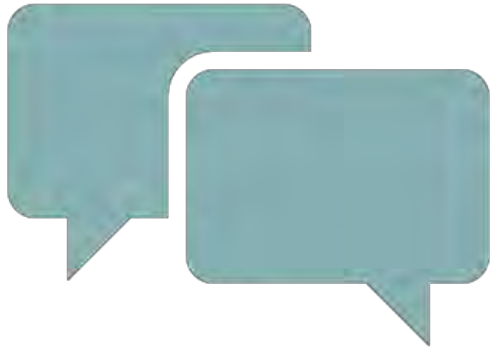


Theme 2: Anxious / sense of urgency to follow-up and discuss with provider.

"I had a follow up phone call from a nurse 3 days after getting the email. I had nobody to ask questions of ... So my lack of information caused panic."

"It made me feel like I needed to go in and see my doctor right away and have another test, which I did."

Reaction to Positive Test Results

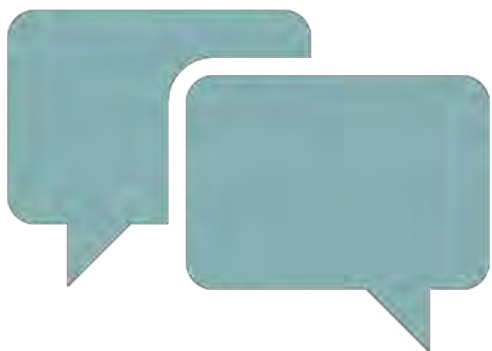


Theme 3: Poor understanding of results and subsequent information-seeking.

“I didn’t understand what I was reading on the internet ... so I made an appointment with the doctor.”

“Once I got the results online, I did look on the internet to kind of explain – because half of it said negative and the other part said positive, so I thought, what in the heck?”

Reaction to Positive Test Results



Theme 4: Surprise by results/Low perceived risk

"So when I tested positive - I'm 60 years old, it's not like I'm running around, I've had the same partner for 27 years - I was quite shocked when... she told me it was a STD, and I was about floored."

"I just had questions from beginning to end ... I've only been married to one person ... Why is this showing up now? I don't get it."

Understanding about different screening and follow-up strategies





Theme 5: Concern that HPV self-screening is inaccurate when Pap is normal

"If it's contradictory to my regular Pap smear... or maybe it's more specific. I just don't understand why they were different."

"I would rather them [other patients] go through a doctor than to use your kit, because I wouldn't want them to go through what I went through, but... if it worked and you guys got it better or... found out it was a tech or a machine problem... then yeah, I think doing it at home is so much better than going to the doctor. But not with the kit the way it is right now."


Reactions of women underscreened for cervical cancer who received unsolicited human papillomavirus self-sampling kits

[Colin Malone](#), [Jasmin A Tiro](#), [Diana SM Buist](#), [Tara Beatty](#), [John Lin](#), [Kilian Kimbel](#), [Hongyuan Gao](#), [Chris Thayer](#), [Diana L Miglioretti](#), [Rachel L Winer](#)  [Show less](#) 

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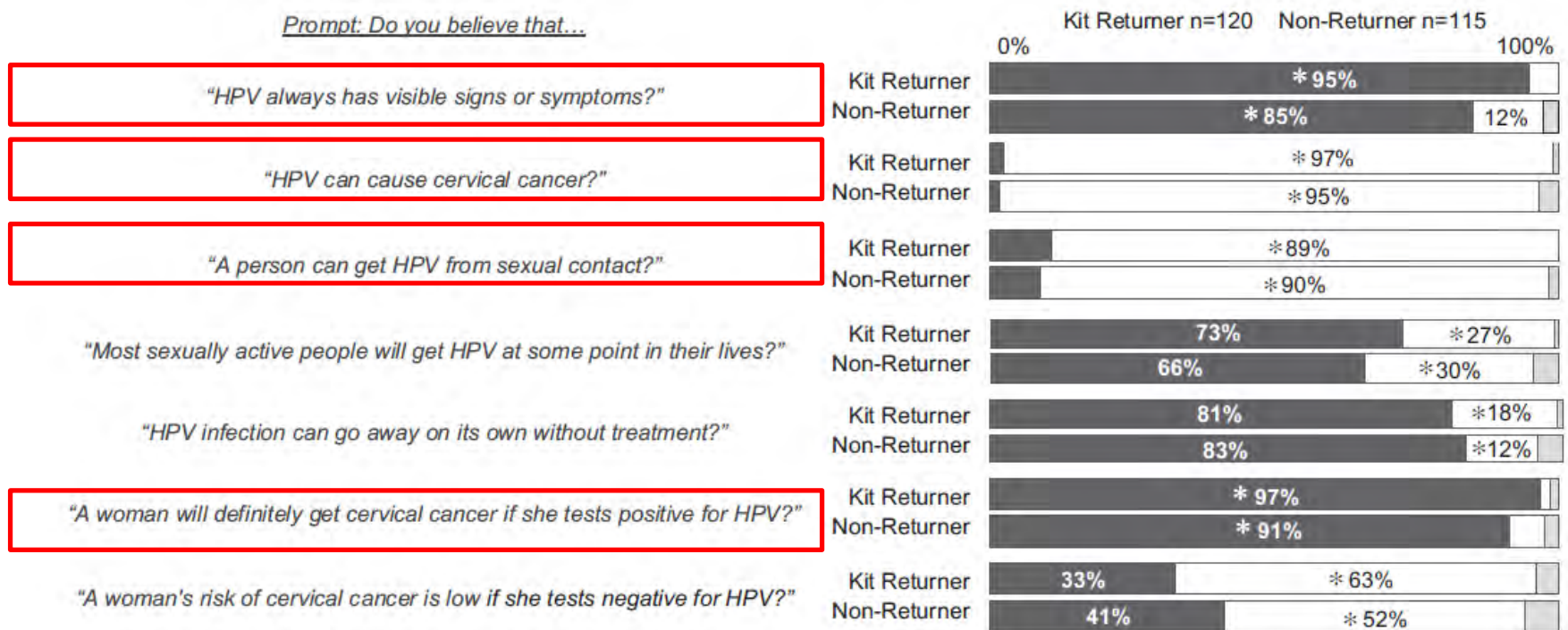
Compared 120 kit returners & 115 non-returners

HPV/Cervical Cancer Knowledge

HPV/Cervical Cancer Knowledge Items

Prompt: Do you believe that...

Legend:
 Yes
 No
 Missing
 Correct Response



HPV/Cervical Cancer Knowledge

HPV/Cervical Cancer Knowledge Items

Prompt: Do you believe that...

Legend:
 Yes
 No
 Missing
 Correct Response

Kit Returner n=120 Non-Returner n=115

0% 100%

"HPV always has visible signs or symptoms?"



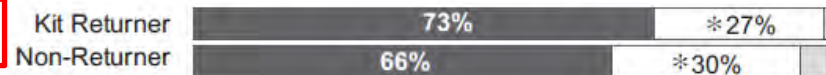
"HPV can cause cervical cancer?"



"A person can get HPV from sexual contact?"



"Most sexually active people will get HPV at some point in their lives?"



"HPV infection can go away on its own without treatment?"



"A woman will definitely get cervical cancer if she tests positive for HPV?"



"A woman's risk of cervical cancer is low if she tests negative for HPV?"

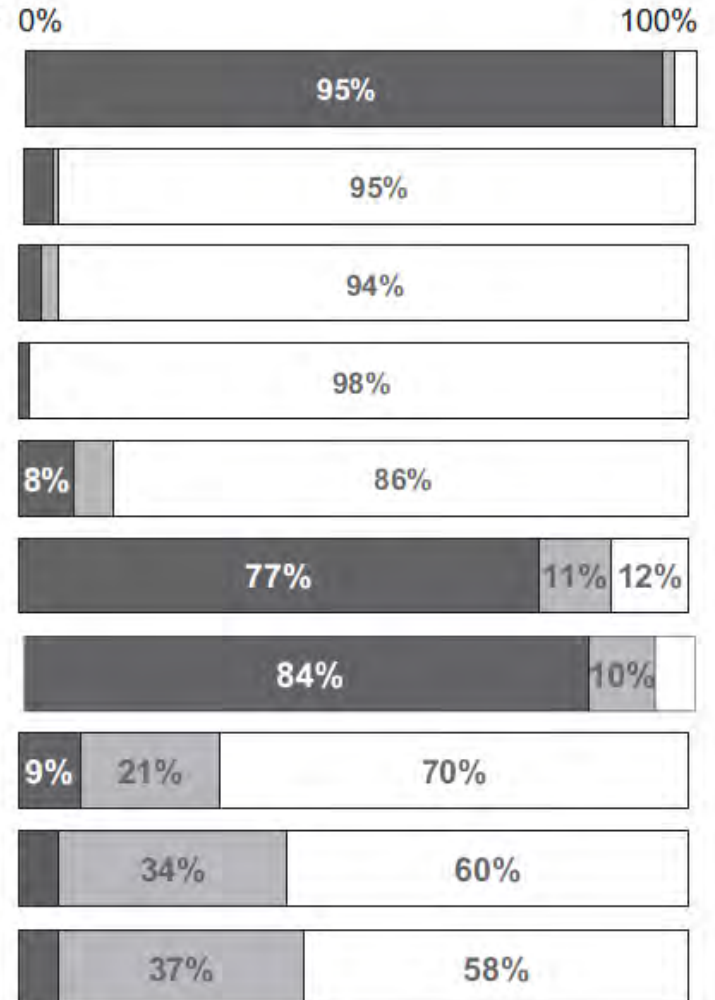


HPV Self-Sampling Experiences Items

Legend:
 Disagree + Strongly Disagree
 Neither Agree Nor Disagree
 Agree + Strongly Agree

Kit Returner n=120

Prompt: How much do you agree or disagree with the following statements?



"I am sure I got a good sample from my vagina using the swab."

"I felt in control of my health after using the kit."

"I trust HPV home screening kit test results."

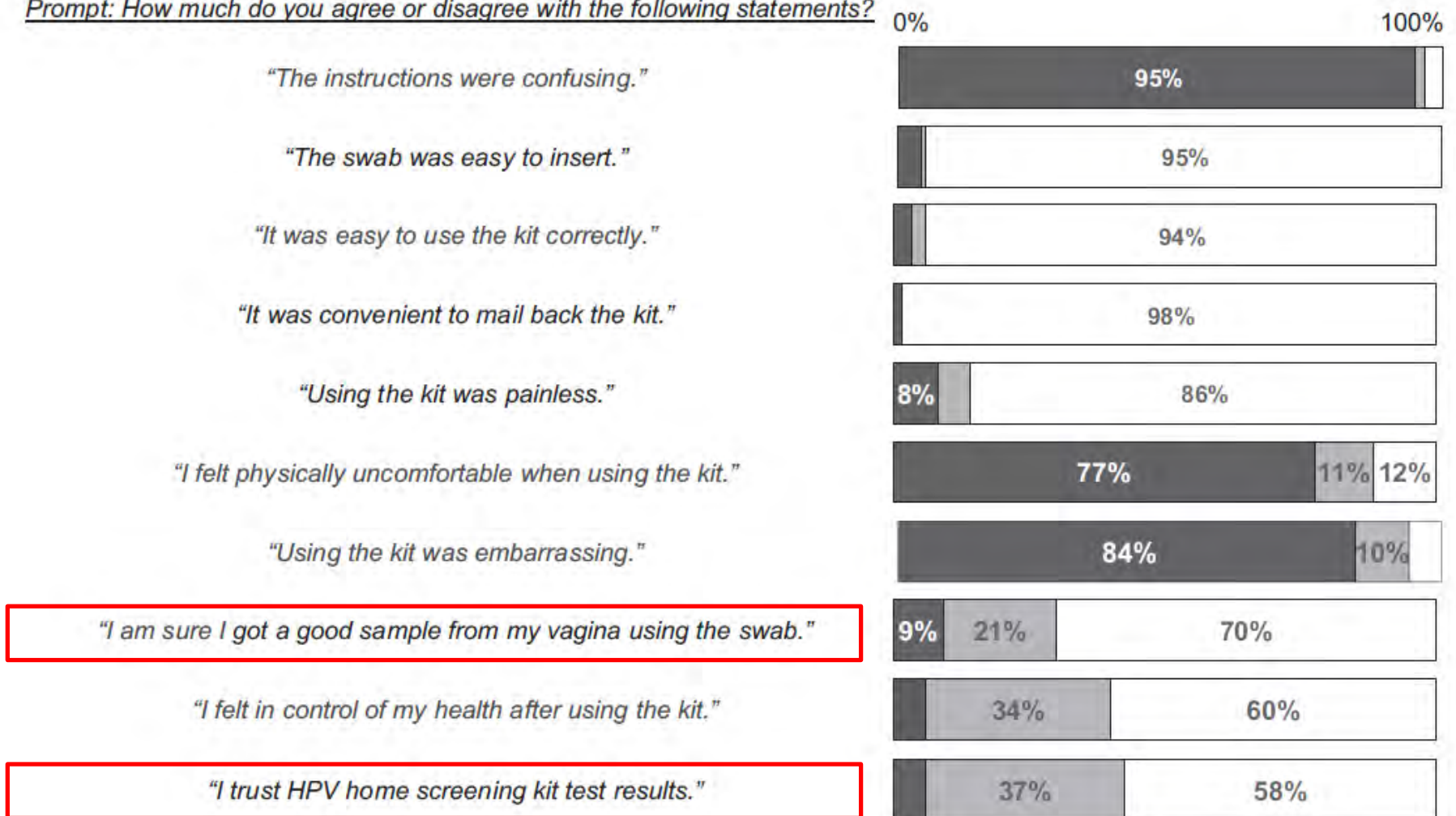


HPV Self-Sampling Experiences Items

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Kit Returner n=120

Prompt: How much do you agree or disagree with the following statements?



Main Findings

- Increased screening uptake by 50% compared to usual care
- No significant difference in CIN2+ detection or treatment
- Patient-centered: convenient & easy to use

Areas for improvement

- Improving patient education to address concerns about ability to use kits correctly & distrust in test results
- Closing systems gaps and improving patient and provider education to increase adherence to diagnostic follow-up after an HPV positive kit result

Future Steps

- What are potential implications for implementing primary HPV screening strategies that incorporate home-based self-sampling?
- How do we engage the hardest to reach women in cervical cancer screening?
- How can self-sampling be used to scale up cervical cancer screening in low- and middle-income countries?

Cervical Cancer in Low- and Middle-Income Countries

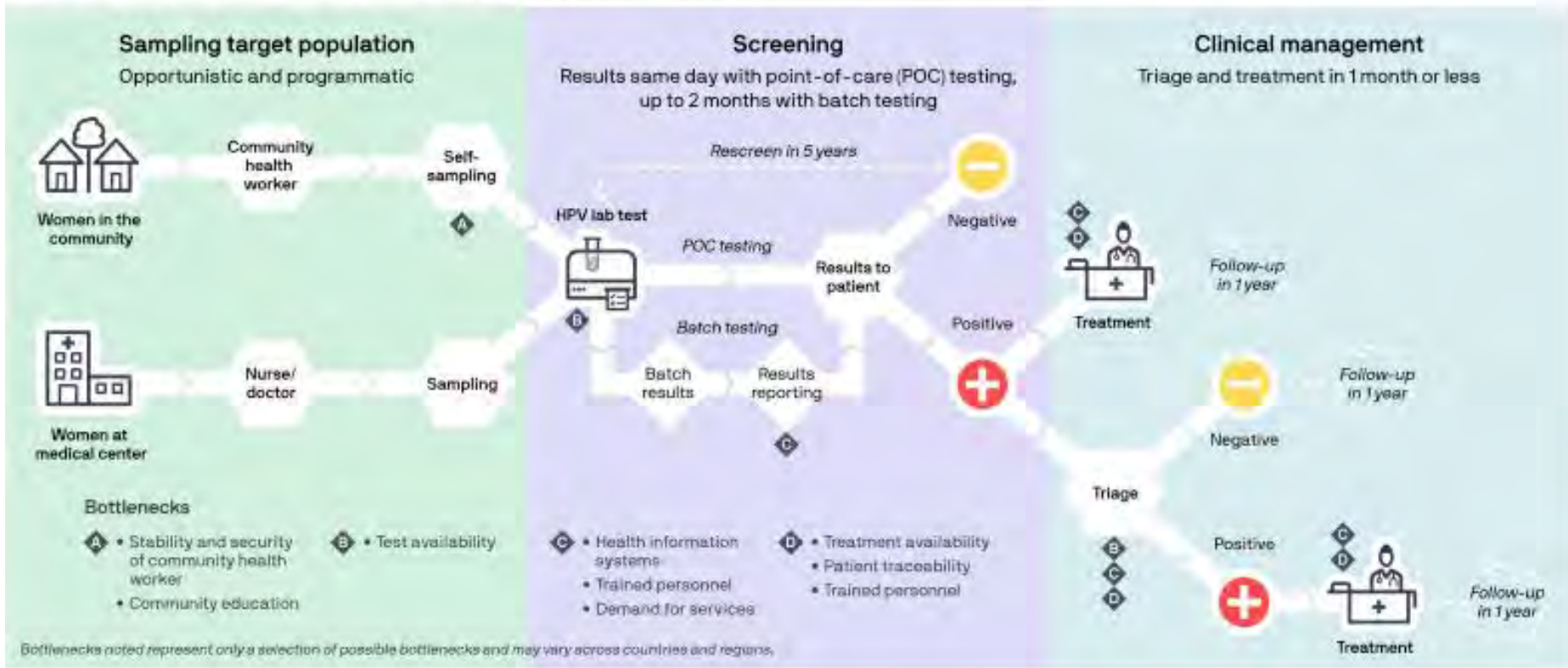
- Cervical cancer screening programs extremely difficult to implement in low-resource settings & most women in LMIC have not been vaccinated
- Unvaccinated women will generate 35-40 million cervical cancers over next 65 years
- 2018 WHO cervical cancer elimination goals include vaccination, screening, and treatment milestones by 2030:
 - Vaccination of 90% of girls <15 years
 - 70% of women aged 35-45 screened ≥ 1 /lifetime
 - Treatment of 90% of detected lesions

Cervical Cancer in LMICs

- Scaling-up screening could be improved with HPV self-sampling
- Will required organized approach tailored to country-specific needs

HPV-based cervical cancer screening program

Main interventions, ideal timelines, and bottlenecks



Thank you!