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HPV Self-sample Program Evaluation in US Health System

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*I have no conflicts of interest to report

Kaiser Permanente Washington Health Research Institute

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Vaginal HPV Self-Sampling has Not Been Recommended United States Guidelines

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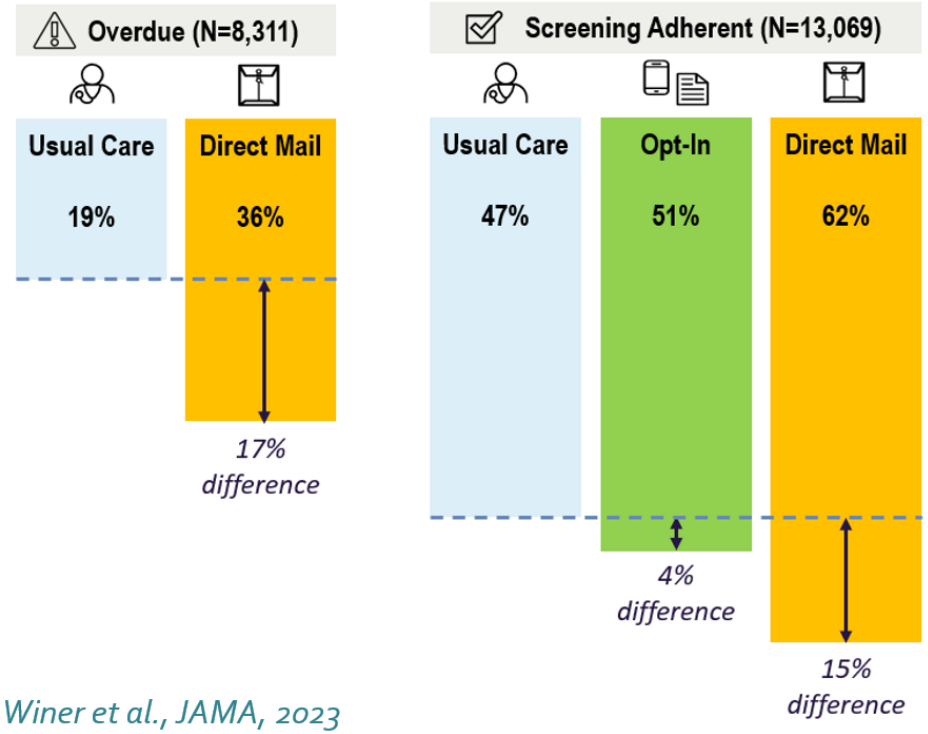
- To help change this we conducted a pragmatic randomized controlled trial at Kaiser Permanente Washington with 30,000 individuals aged 30-64 at average risk and due or overdue for cervical cancer screening.
- The STEP trial showed that direct mailing of HPV self-sampling kits to significantly increased screening uptake
- **The program included both direct mailing PLUS opportunistic in-clinic distribution of HPV self-sample kits**
- **This presentation is a mixed methods evaluation of the Kaiser Permanente Washington program**

Self-Testing options in the Era of Primary HPV screening for cervical cancer (STEP) trial
National Cancer Institute
R01CA249375, Green, Winer, 2020-2022



Winer et al., JAMA, 2023

We performed both Quantitative and Qualitative Assessments

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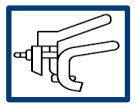
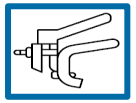
Pre-Program (January 1, 2022 – June 30, 2022)



Clinician collected (HPV reflex, HPV/Pap combined, Pap only)

Post-Implementation (October 1, 2023 – March 31, 2024)



Cervical screening, clinician collected (HPV reflex, HPV/Pap combined, Pap only)



Mailed HPV self-sample tests



In-clinic distribution of HPV self-sample tests

Safety Net System For Follow-up of Positive Self-Sample HPV Tests

Quantitative evaluation compared the pre to post program :

1. Cervical cancer screening rates
2. Percent with high-risk HPV 16,18 and the percent completing colposcopy, percent with other high-risk HPV completing Pap testing
3. Differences in screening uptake by population characteristics

Qualitative evaluation (interviews with associate medical directors, site visits)

1. Program acceptability, facilitators, challenges, and opportunities for improvement

- The overall population included more than 120,000 individuals assigned female at birth and age 30-64 with a cervix
- About 72,000 (62%) were current for screening and did not need screening in both time periods
- **38% were either due or overdue (N = 48511 pre and 47,333 post) and needed screening**

Characteristics of individuals ages 30-64 at average risk due or overdue for cervical cancer screening during the pre and post periods

	Pre self-collect HPV program (7/1/22-12/31/22)	Post self-collect HPV program (10/1/23-3/31/24)
	N=48511	N=47333
Age		
Age Mean(SD)	49.2	48.8
Race N(%)		
Asian	11.3%	11.2%
Black or African American	5.4%	5.7%
Hawaiian/Pacific Islander	0.7%	0.7%
White	60.9%	59.3%
Native American/Alaska Native	1.2%	1.4%
More than one race	3.0%	3.1%
Other	3.4%	3.4%
Unknown/missing	14.1%	15.4%
Ethnicity N(%)		
Hispanic	6.0%	6.3%
Non-Hispanic	81.2%	80.0%
Unknown/missing	12.8%	13.8%
Language N(%)		
English	87.8%	87.6%
Spanish	0.7%	0.9%
Other	3.8%	3.8%
Unknown/missing	7.7%	7.8%
Primary care clinician or obgyn visit within 12 months prior to index date		
Yes	57.8%	57.9%

Screening Uptake* Pre- versus Post- Program Among Individuals Ages 30-64 Due or Overdue for Cervical Cancer Screening

(does not include individuals current for screening during this time period)

	Pre self-collect HPV program (7/1/22-12/31/22)	Post self-collect HPV program (10/1/23-3/31/24)	Absolute difference	p-value
Screening completion				
Due or Overdue for Cervical Cancer Screening	N=48511	N=47333		
Screening complete during observation period N(%)	7200(14.8%)	8067(17.2%)	867(2.2%)	
Completed Screening	14.8%	17.0%	**2.2%**	**<.0001**
Type of Screening Completed				
Cervical clinician-collected	7200(100%)	5053(62.6%)	-2147	<.0001
Vaginal self-collected	NA	3014(37.4%)		NA

*this includes: 1. HPV reflex 2. HPV/pap combined or 3. pap only

HPV, human papilloma virus; NA, not applicable; Pap, Papanicolaou

The source of cervical cancer screening changed dramatically

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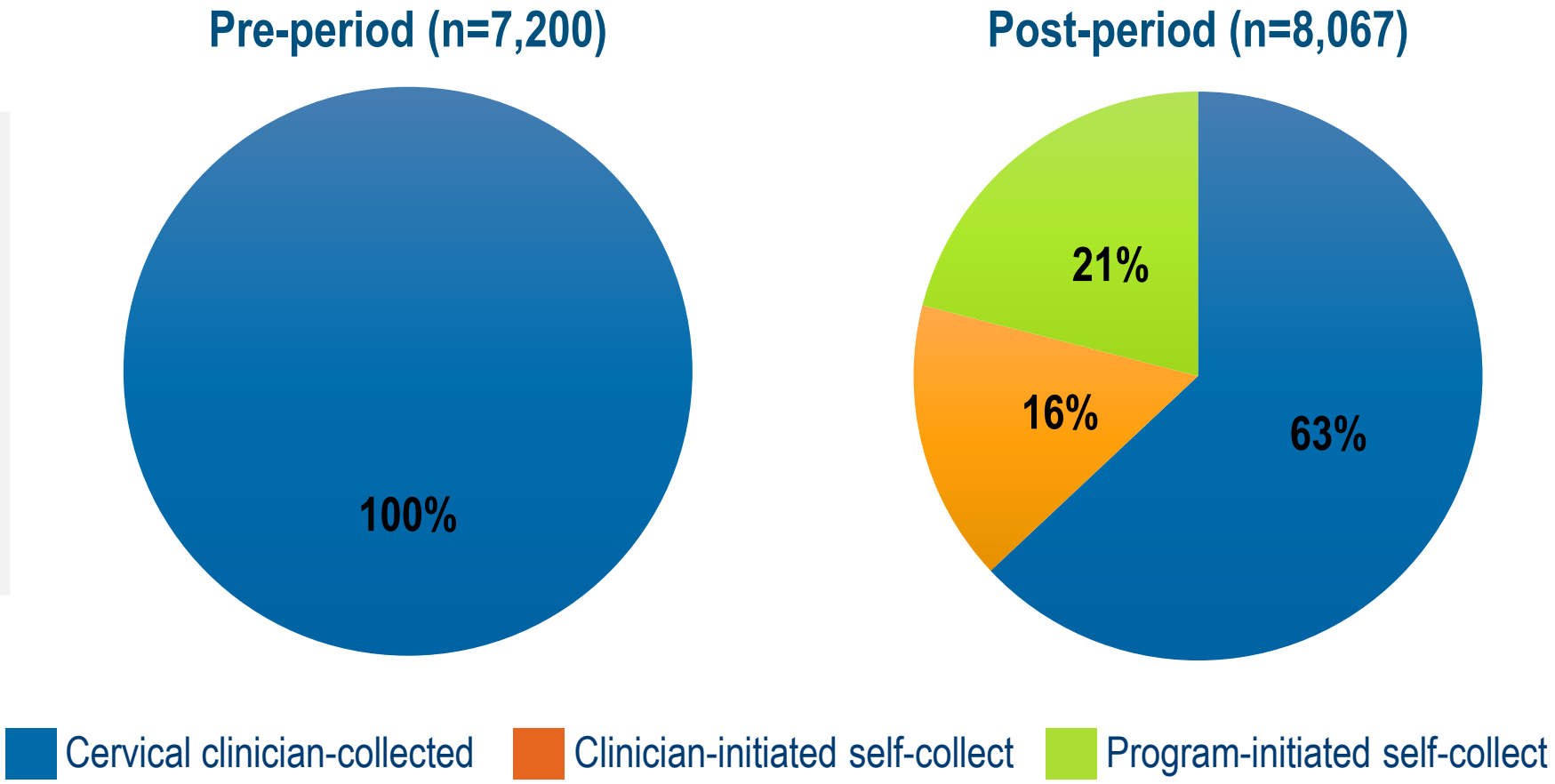
Cervical cancer screening rates by modality, before and after implementation of the self-collect HPV program

Key message

- The number of cervical clinician-collected screenings decreased from 7,200 to 5,053 (while screening completion increased by 2%)



One quarter of kits mailed during the post-period were completed

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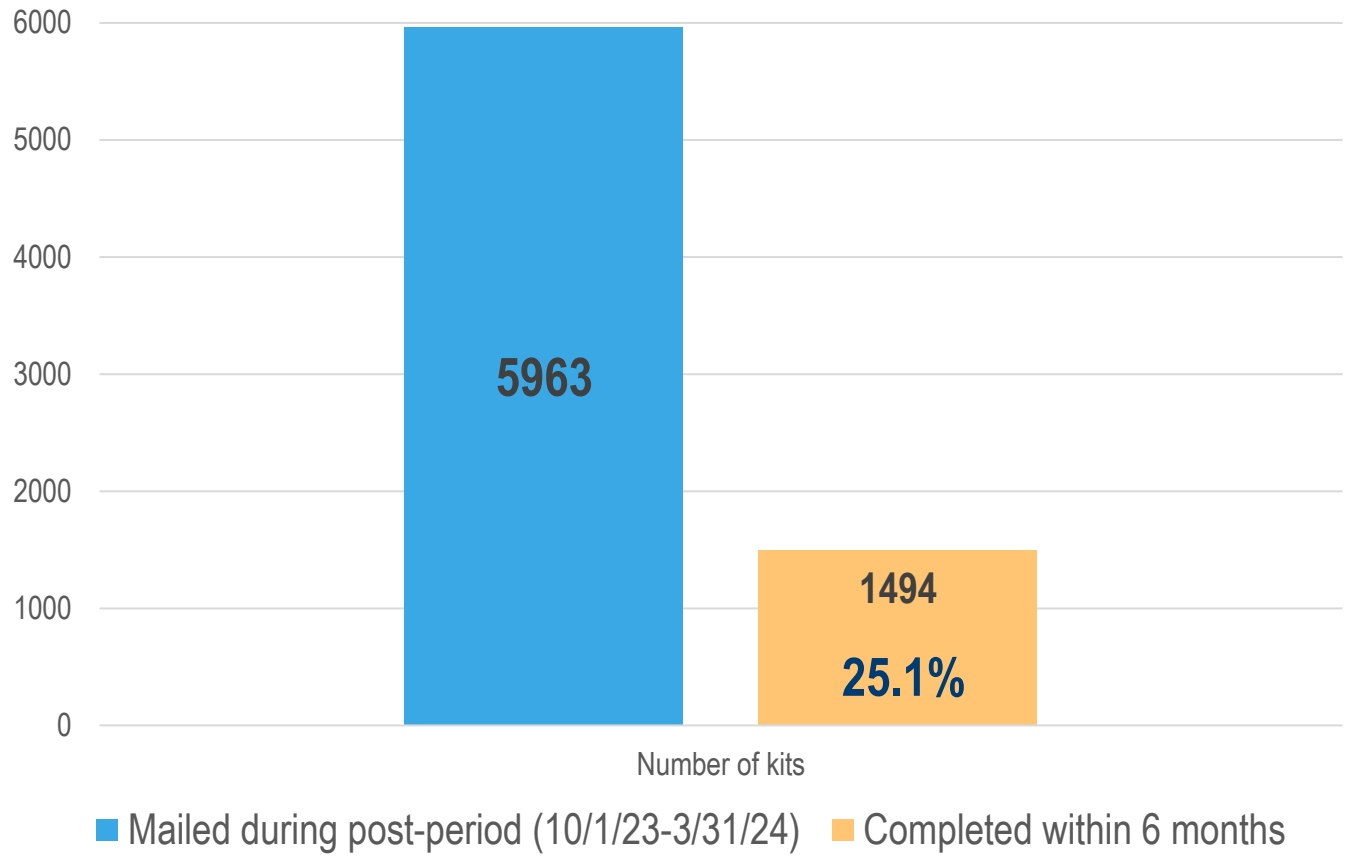

Follow-Up Testing for Positive Tests

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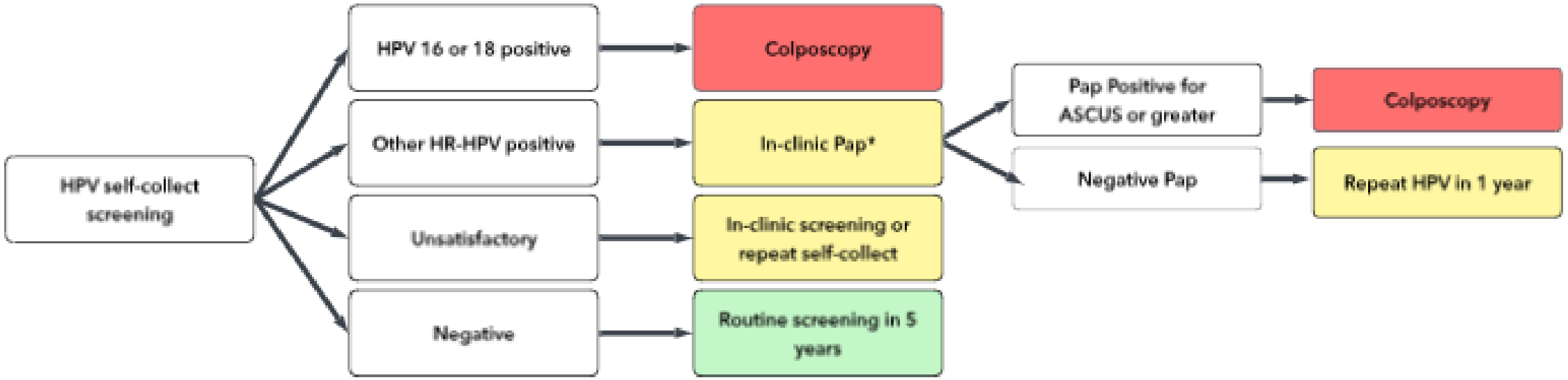
	Pre-period	Post-period
Total screened	7,200	8,067
HPV positive 16/18 (%)	36 (0.5%)	62 (0.8%)*
Colposcopy completed n(%)	18 (50.0%)	47 (75.8%)
HPV positive other subtypes n(%)	114 (1.6%)	350 (4.3%)*
Pap completed n(%)	114 (100%)	287 (82.0%)

* Clinician and self-collect combined In the post-period, 24 16/18 positive tests and 156 other HPV positive tests were self-collect HPV tests

Key messages

- Follow-up for 16/18 was higher after program implementation, likely due to the presence of a safety net nurse.
- Follow-up for other high-risk HPV subtypes was lower in the post-period because fewer people were screened with HPV reflex pap screens

Follow-up testing and screening*



*Manage per American Society for Colposcopy and Cervical Pathology ASCCP Concensus Guidelines

Screening rates increased for patients of all races

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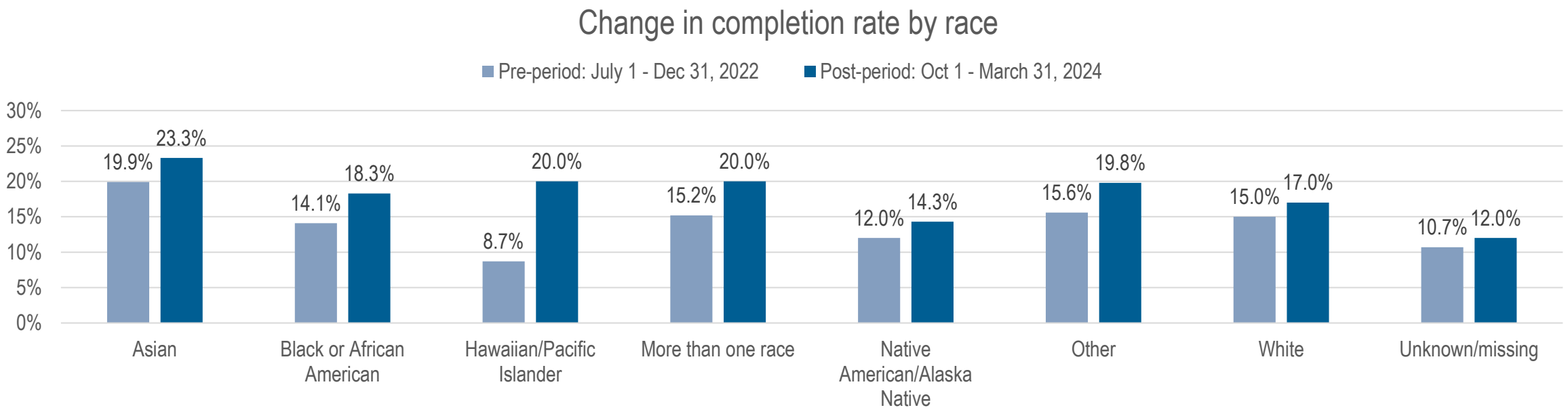
Key message

- Screening rates went up for all race categories, and some groups with the lowest baseline screening rates had the largest increases in screening
- These results suggest self-collect HPV may help minimize racial disparities in cervical cancer screening



Screening rates increased for people with varying screening histories

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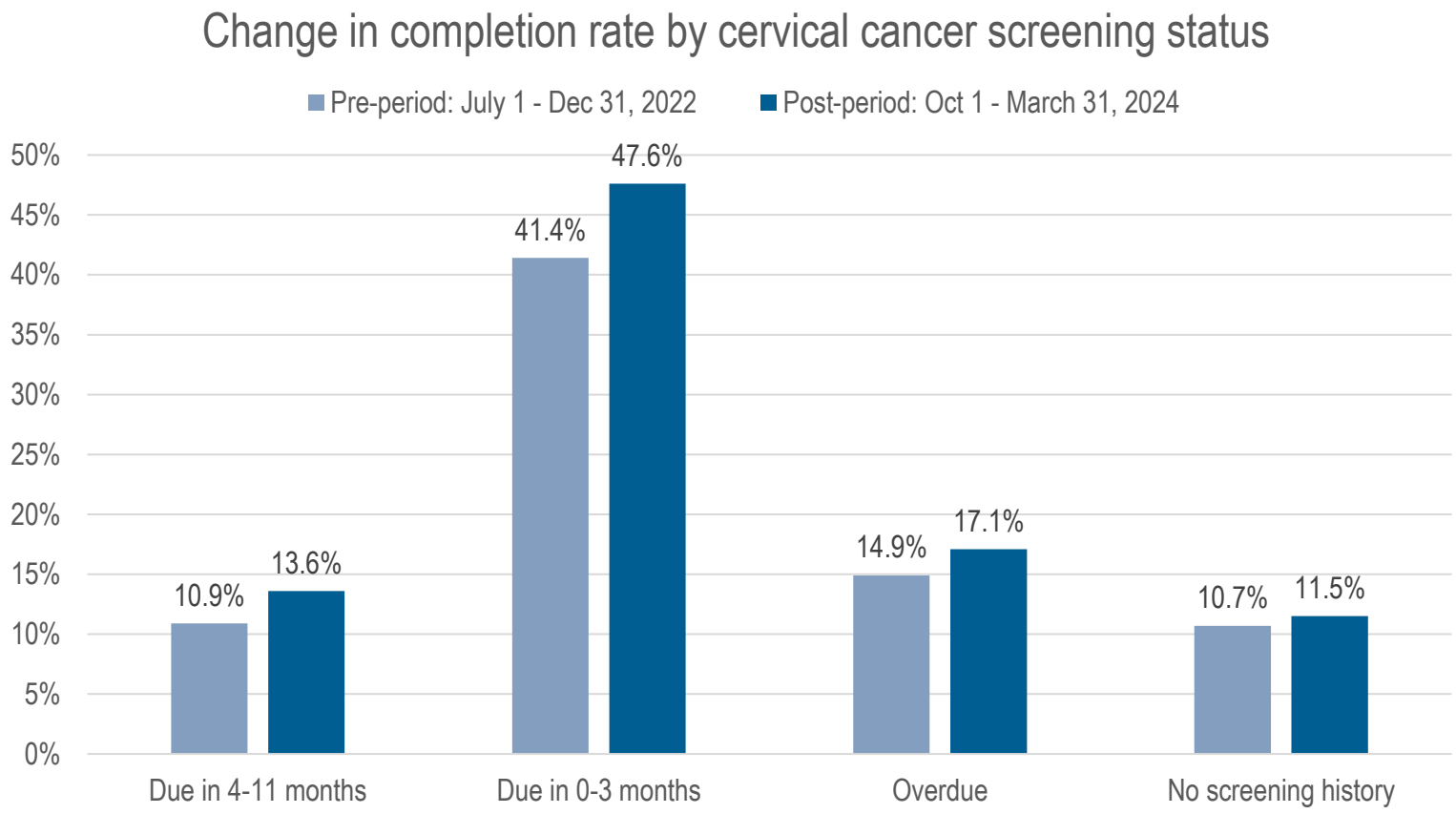
Cervical cancer screening rates before and after implementation of the self-collect HPV program

Key message

- Screening rates increased for people with different cervical cancer screening histories, but the largest increases were for those coming due in 0-3 months



Clinician Acceptability

THEME Clinician Acceptability	
Subthemes	**Illustrative Quotes**
Opportunities	
Most clinicians view the program favorably	*“Best thing ever,” “the HPV self-collect program changed my practice,” “I hand them out like candy”*
Male clinicians appreciate the test	*“There's more likelihood that women would rather do self-collection than a male provider doing an exam, so I think it's easier to for me to sell it because, otherwise they would have booked an appointment with another provider.”*
Saves time, is efficient	*"People can do it at home or at the end of a visit that has nothing to do with their cervix, and it doesn't require a lot of extra time"* *“It also saves appointments for other sicker patients to be managed.”*

Key message

- In clinic distribution was highly acceptable

Clinician Knowledge, Attitudes, and Practices with HPV Self-Sample Program Interviews with Clinic Medical Directors and Site Visits

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Theme – Clinician Acceptability	
Subthemes	**Illustrative Quotes**
Challenges	
Concerns about accuracy	*That's a question I am unclear on, is it as sensitive as cervical collection in the clinic?"*
Worry about missing something	*"Never examining with eyes can cause us to miss other concerns: lichen sclerosis, skin cancer, etc. and doesn't give women a sense of reassurance. I don't want women to feel a pelvic exam is a bad thing!"*
Non-adoption because of lack of information	*"Using kits in clinic- didn't know that was an option. Should put the kits in the drawer with the FIT kits. There's just no workflow for this."*

Key takeaways

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- After implementation of the HPV self-sample program, screening rates increased and traditional clinician-collected cervical HPV testing decreased. This suggests that the program met its goals of increasing cervical cancer screening and also decreased pelvic exams.
- The Safety-Net nurse program resulted in increased colposcopy follow up rates
- Clinicians found the program highly acceptable, but they had gaps in knowledge about HPV self-sampling and recommended follow-up.
- Recommendations
  - Additional and ongoing education and training
  - Optimization of workflows
- Next steps: Improve program, re-evaluate, and compare to other health systems

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Thank You



Other recommendations (some are in process)

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- Mail a pre-letter explaining what they will be receiving (unless the patient has requested – portal communications only) – OK to have both
- Change kits instructions to make it more obvious that the date of completing the test needs to be filled in. Can also highlight the date line on the specimen tube label
- See if a smaller box can be used for mailing and returning the kits (problems with postal boxes, waste)
- Develop FAQs for patients – so they understand that HPV testing is a more accurate test than pap testing and the importance of follow up for positive tests.
- Model costs from a business perspective – for decisions on how best to operationalize the program

Appendix: Problems were identified and solved during the post period and beyond

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Challenges and updates in 2024

- May: Fixed coding in health maintenance that was incorrectly counting screening due dates for people moving from Q3y pap in their 20s to Q5y HPV in their 30s (was giving extra time too early).
- June: Decision that clinicians offering self-collect in clinic should place a new order (rather than use the bulk order) to improve tracking of mailed vs. in clinic sc.
- Nov/Dec: At program launch decided to exclude people who were due before 1/1/18 (to avoid overwhelming lab). Took this out of the coding in Dec and were expecting some throttling to limit how many kits would go out at once but the throttling didn't work, and 9,000 kits went out end of Nov/beginning of Dec. A few hundred additional kits were mailed in but then the team halted additional mailings through the end of 2024.
- Kits and those with mold were not processed
- Nov/Dec: Changed logic for who was considered "due soon" and added to the bulk order from due in 12 months to due in 6 months. The bulk order expiration date was also extended to 12 months to avoid expiring orders.
- Upcoming: team is working on timing of when a kit is re-mailed out to someone still due for screening.