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Does mailing unsolicited HPV self-sampling kits to women overdue for cervical cancer screening impact uptake of other preventive health services in a United States integrated delivery system?

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ABSTRACT

Women overdue for cervical cancer screening often have other preventive care gaps. We examined whether mailing unsolicited human papillomavirus (HPV) self-sampling kits to increase cervical cancer screening impacted receipt of other preventive services women were due for: mammography, colorectal cancer (CRC) screening, influenza vaccination, depression screening, and diabetic HbA1c monitoring. From 2014 to 2016, 16,590 underscreened women were randomized to receive a mailed kit or usual care Pap reminders within Kaiser Permanente Washington. We used logistic regression to estimate odds ratios (ORs) of preventive services receipt within 12-months between the intervention vs. control arms, and within the intervention arm (comparing those returning a kit vs. attending Pap vs. nothing), adjusting models for demographic variables. There were no significant between-arm differences in uptake of any of the preventive services: intervention vs. control: mammography OR = 1.01 (95% confidence interval:0.88–1.17), CRC screening OR = 0.98 (0.86–1.13), influenza vaccination OR = 0.99 (0.92–1.06), depression screening OR = 1.07 (0.99–1.16), HbA1c OR = 0.84 (0.62–1.13). Within the intervention arm, preventive services uptake was higher in women who completed cervical cancer screening vs. did not, with stronger effects for women who attended Pap: Pap vs. nothing: mammography OR = 11.81 (8.11–17.19), CRC screening OR = 7.31 (5.57–9.58), influenza vaccination OR = 2.06 (1.82–2.32), depression screening OR = 1.79 (1.57–2.05), HbA1c OR = 3.35 (1.49–7.52); kit vs. nothing: mammography OR = 2.26 (1.56–3.26), CRC screening OR = 5.05 (3.57–7.14), influenza vaccination OR = 1.67 (1.41–1.98), depression screening OR = 1.09 (0.89–1.33), HbA1c OR = 1.23 (0.57–2.65). Mailing HPV self-sampling kits to underscreened women did not negatively impact uptake of other preventive services. However, overall preventive service uptake was the highest among women who attended in-clinic cervical cancer screening.

1. Introduction

Most cervical cancers are preventable with human papillomavirus (HPV) vaccination and screening.(US Preventive Services Task Force et al., 2018; Saslow et al., 2012; Guo et al., 2018) In the U.S., cervical cancer mortality has significantly declined through routine screening, (Centers for Disease Control and Prevention CDC, 2011) yet approximately 1 in 4 people with a cervix (henceforth referred to as women) remain underscreened (overdue for guideline-recommended routine screening or never screened).(White et al., 2017; Cervical Cancer Screening, n.d.) More than 50% of cervical cancers diagnosed occur in underscreened women.(Leyden et al., 2005; Kinney et al., 1998; Janerich et al., 1995) Despite the availability of effective HPV vaccines, screening remains critical for cervical cancer prevention because HPV

Abbreviations: Body mass index, (BMI); Confidence intervals, (CI); Colorectal cancer, (CRC); Electronic medical record, (EMR); Fecal immunochemical test, (FIT); Fecal occult blood test, (FOBT); Hemoglobin A1c, (HbA1c); Healthcare effectiveness data and information set, (HEDIS); Home-based options to make cervical cancer screening easy, (HOME); Human papillomavirus, (HPV); Kaiser Permanente Washington, (KPWA); Odds ratios, (ORs); Papanicolaou screening, (Pap).

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vaccination uptake is suboptimal in the U.S.(Elam-Evans, 2020) and vaccines do not protect against all cancer-causing HPV types.

Previous studies suggested multiple barriers to screening uptake including lack of time or transportation, difficulties finding childcare or taking time off work, fear of pelvic exams, and prior negative experiences with screening. (Leyden et al., 2005; Oscarsson et al., 2008; Glasgow et al., 2000; Eaker et al., 2001; Waller et al., 2009; Goins et al., 2003) Non-clinic-based HPV kits could address these well-known barriers to cervical cancer screening. Previous studies demonstrated that non-clinic-based HPV kits increase cervical cancer screening participation, particularly in hard-to-reach populations.(Arbyn et al., 2018) However, one concern about offering non-clinic-based screening is that women who are underscreened for cervical cancer often have other important preventive care gaps,(Schueler et al., 2008; Wirth et al., 2014) and removing in-clinic visits could result in greater care gaps for other preventive health services, as attending in-clinic screening offers opportunities for interaction with healthcare providers. While women underscreened for cervical cancer are less likely to be engaged in other preventive care, a significant portion attend in-clinic visits with primary care providers. For example, we previously observed that one-third of 30–64-year-old women at Kaiser Permanente Washington (KPWA) (a U.S. integrated healthcare delivery system) who were overdue for cervical cancer screening had an in-clinic visit with a primary care provider within the prior year.(Malone et al., 2021)

We are unaware of studies that have evaluated whether non-clinic-based cancer screening modalities, such as fecal immunochemical test (FIT) kits for colorectal cancer (CRC) screening or HPV kits for cervical cancer screening, positively or negatively influence receipt of other recommended preventive services. Offering non-clinic-based screening could activate individuals to engage in other preventive services. For example, completing non-clinic-based screening may motivate individuals to adhere to other recommended preventive services. Furthermore, individuals who participate in non-clinic-based screening may have opportunities to receive other preventive services if they need to attend in-clinic follow-up after a positive result. On the other hand, unlike onsite health screening, non-clinic-based screening may reduce opportunities for individuals to attend other preventive services by removing the in-person visit in some cases.

To address this question, we used data from Home-based Options to Make cervical cancer screening Easy (HOME), a pragmatic randomized controlled trial of mailed HPV self-sampling kits in 30–64-year-old women who were overdue for cervical cancer screening within KPWA. (Winer et al., 2018) We selected five preventive services that are routinely recommended for all 30–64-year-old women or a subset based on age or health status and are included in KPWA's annual preventive services reminders birthday letter.(Bowles et al., 2016; Buist et al., 2017) These five preventive services are part of Healthcare Effectiveness Data and Information Set (HEDIS) quality metrics,(Cervical Cancer Screening, n.d.; Breast Cancer Screening, n.d.; Colorectal Cancer Screening, n.d.) and are often offered opportunistically during clinic visits: 1) mammography; 2) CRC screening; 3) influenza vaccination; 4) depression screening; and 5) hemoglobin A1c (HbA1c) testing for monitoring diabetes. We compared preventive services uptake over 12 months in women randomized to receive the self-testing kit versus usual care Papanicolaou (Pap) reminders. Additionally, we evaluated preventive services uptake among women in the intervention arm by their cervical cancer screening behavior: a) women who returned a kit but did not attend in-person Pap screening; b) women who attended in-person Pap screening regardless of returning a kit; and c) women who did not use a kit and did not attend Pap screening.(Winer et al., 2018)

2. Methods

We conducted a secondary analysis of data from the HOME trial. (Winer et al., 2018) The HOME trial was designed to compare cervical cancer screening uptake and detection and treatment of cervical precancers between two different strategies: 1) usual care Pap screening reminders plus adding a mailed HPV self-sampling kit (intervention group); and 2) usual care Pap screening reminders only (control group). (Winer et al., 2018) The HOME trial demonstrated that mailing HPV self-sampling kits to underscreened women increased cervical cancer screening uptake.(Winer et al., 2019)

The trial randomized 16,590 women who: 1) were aged 30–64 years, 2) had not had a hysterectomy, 3) had a primary care provider within KPWA's integrated delivery system, 4) had been continuously enrolled in KPWA for at least 3 years and 5 months, and 5) had not had a Pap test within 3 years and 5 months.(Winer et al., 2018) Women became eligible 5 months after receiving an annual preventive care birthday letter reminder indicating they were due or overdue for their Pap screening (no Pap test within the prior 3 years).(Winer et al., 2018) We allowed 5 months after women received their birthday letter reminders to ensure that our recruitment did not interfere with usual Pap screening outreach strategies.(Winer et al., 2018) Eligible women were identified using electronic medical record (EMR) data and enrolled under a waiver of informed consent. The trial was approved by KPWA and University of Washington institutional review boards.

The control arm received KPWA's usual care outreach, which includes an annual birthday letter with tailored recommendations and reminders for preventive care based on when they are due for services that are specific to their age and previous preventive services receipt; all women in the trial were reminded they were overdue for cervical cancer screening.(Winer et al., 2018) Additionally, there were clinician-targeted automatic alerts for preventive services, centralized outreach to inform women of care gaps and primary care outreach to bring in individuals who have care gaps, and opportunistic preventive care. (Winer et al., 2018; Buist et al., 2017) Women randomized to the intervention group received the same usual care outreach as the control arm and a mailed HPV self-sampling kit 5 months following their birthday letter, research information sheet, educational materials on how to self-collect and return a sample, and a prepaid return envelope addressed to the KPWA clinical laboratory.(Winer et al., 2018) The letter advised women to attend routine Pap screening regardless of whether they chose to complete the HPV self-sampling kit because HPV self-screening is not standard of care in the U.S. Kit use and Pap screening uptake was captured within six months after randomization from their EMR.

Women who received a recent Pap test prior to randomization or disenrolled from KPWA close to randomization were retroactively excluded from HOME analyses (n = 359). For the analysis of other preventive services uptake, we additionally excluded women who opted out of EMR review (n = 96), and women who died or disenrolled from KPWA during the 12-month follow-up period (n = 1917), leaving 14,218 women who were enrolled for at least 12-months after randomization. We compared uptake of the five preventive services by randomization arm, and by cervical cancer screening behavior within the intervention arm: a) women who returned a kit but did not attend Pap screening; b) women who attended Pap screening regardless of returning a kit; and c) women who did nothing.

We used EMR data to identify the first receipt of each preventive service within 12 months after randomization. Uptake of HbA1c testing was restricted to women with diabetes (n = 1036). For uptake of mammography and CRC screening, we used HEDIS definitions.(Breast Cancer Screening, n.d.; Colorectal Cancer Screening, n.d.) Mammography analyses were restricted to women who were between the ages of 52–64 years and not considered up-to-date per HEDIS at randomization (n = 3500).(Breast Cancer Screening, n.d.) Women were due for mammography if they had not had a mammogram to screen for breast cancer in the past two years. CRC screening analyses were restricted to women who were between the ages of 51–64 years and not up-to-date per HEDIS at randomization (n = 4482).(Colorectal Cancer Screening, n.d.) Women were due for CRC screening if they had not had a fecal occult blood test (FOBT) in the past year, a FIT test in the past 3 years,

flexible sigmoidoscopy or computed tomography colonography in the past 5 years, or a colonoscopy in the past 10 years.(Colorectal Cancer Screening, n.d.) There were no restrictions for influenza vaccination uptake or depression screening, as these services are recommended annually for all adults.

Our data were analyzed in aggregate due to human subjects restrictions on obtaining individual level data for HOME trial intervention arm women who did not return the home-based HPV kit.(Winer et al., 2018) Observations were at the level of the individual participant, with the woman as the unit of analysis, using frequency weighting in regression models. We fit a univariate logistic regression model for each exposure (randomization arm, or screening behavior subgroup within the intervention arm) and preventive service outcome (10 models total). The dependent variable was defined as a binary indicator of whether the health service was completed during the 12-month follow-up period. The independent variable of interest was defined as a binary indicator of randomization group, or three-level indicator of screening behavior within the intervention arm. Models estimated odds ratios (OR) and 95% confidence intervals (CI) for associations between using the preventive health services and either randomization arm or intervention subgroups. Statistical significance was defined as p-value <0.05 based on two-sided tests.

For between randomization arm comparisons, we fit unadjusted models, and models adjusted for covariates that were unbalanced between arms (chi-square test p-value <0.05). We considered the following demographic covariates extracted from the EMR, measured at randomization: age (30–39, 40–49, 50–59, 60–64); race (White, Asian or Native Hawaiian or other Pacific Islander, Black or African American, other, or unknown); ethnicity (Non-Hispanic, Hispanic, or unknown); length of health plan enrollment before randomization ($\geq$3.4 to $<$5 years, $\geq$5 to $<$10 years, or $\geq$ 10 years); time since last Pap test (attended Pap screening in the past $>$3.4 to $<$5 years, attended Pap screening in the past $\geq$5 to $<$10 years, attended Pap screening $\geq$10 years ago, or no recorded Pap test); women's U.S. Census block median household income(Onega et al., 2008) ($<$\$49,999, $\geq$\$50,000 to $\leq$\$74,999, $\geq$\$75,000 to $\leq$\$99,999, $\geq$\$100,000, or unknown); travel time from women's home to primary care clinic ($<$10 min, $\geq$10 to $<$20 min, $\geq$20 to $<$30 min, $\geq$30 min, or unknown); body mass index (BMI) ($<$24.9, $\geq$25 to $\leq$29.9, $\geq$30 to $\leq$34.9, $\geq$35 to $\leq$39.9, $\geq$40, or unknown); tobacco use (never, current, former, or unknown); Charlson Comorbidity Index(Charlson et al., 1987) (0, 1, 2, or $\geq$ 3); and randomization year.

For within-intervention arm comparisons, we adjusted for covariates that changed OR estimates by 10% or more when they were added individually to models.(Lee, 2014) The categorizations of some covariates were different from those used for between-arm comparisons, as aggregate data restrictions precluded cell sizes less than five: race (White or Non-White); enrollment length ($\geq$3.4 to $<$10 years or $\geq$ 10 years); time since last Pap test (attended Pap screening more than 3.4 years ago or no recorded Pap test); and Charlson Comorbidity Index (Charlson et al., 1987) (0, 1, or $\geq$ 2). Additionally, we were unable to assess potential confounding by ethnicity, BMI, tobacco use, and travel time from women's home to primary care clinic due to the aggregate data restrictions on cell sizes less than five. All remaining potential confounders were assessed for influenza vaccination and depression screening. All covariates except for ethnicity, median household income, BMI, tobacco use, Charlson Comorbidity Index, and travel time were assessed for mammography. For CRC screening, all covariates except for ethnicity, BMI, tobacco use, Charlson Comorbidity Index, and travel time were assessed. We could not assess any potential confounders for HbA1c testing.

3. Results

For influenza vaccination, depression screening, and HbA1c testing, regression analyses comparing randomization arm were adjusted for enrollment duration; all other covariates were balanced within the populations eligible for each of the five preventive services (Table 1).

In the comparison *by randomization arm*, preventive services uptake varied by service and ranged from 20.9% for depression screening to 79.9% for HbA1c testing among women who were randomized to the control group, with few differences between the intervention vs. control groups. Overall, no analyses showed significant differences between arms on any preventive services uptake (Table 2).

In the *within-intervention arm comparison*, preventive services uptake was higher in women who received cervical cancer screening using a kit or attending Pap screening than in women who did nothing (Table 3). Comparing women who attended Pap screening to women who did nothing, there were significant differences in uptake for all preventive services. All comparisons between women who completed a kit only and women who did nothing were significant, except for depression screening and HbA1c testing. We also compared preventive services uptake among women who attended Pap screening to women who completed the kit only (Table 4). All comparisons were significant, except for HbA1c testing and CRC testing adjusted for time since last Pap.

There were some important differences in preventive services uptake when evaluating screening modality selected. Mammography adherence was higher among women who attended Pap screening (79.3%) than in women who returned a self-sampling kit (44.3%) or did neither (26.6%). Compared with women who did neither, the adjusted odds of mammography adherence were 2.26 times greater (95%CI:1.56–3.26) for women who returned a kit only, and 11.81 times greater (95% CI:8.11–17.19) for women who attended Pap screening regardless of kit return. Across preventive services, uptake was higher among women who attended Pap screening than among women who completed a kit. The strongest association was observed for mammography adherence (adjusted OR = 5.23, 95%CI:3.18–8.59).

CRC screening adherence was higher among women who completed a kit only (48.7%; adjusted OR = 5.05, 95%CI:3.57–7.14) or attended Pap screening (59.3%; adjusted OR = 7.31, 95% CI:5.57–9.58) than women who did neither (15.1%). CRC screening adherence was not statistically significantly different when comparing women attending Pap screening to those completing kits (adjusted OR = 1.45, 95% CI:0.97–2.15).

Influenza vaccination uptake was also higher among women who completed cervical cancer screening (kit: 40.7%; OR = 1.67, 95% CI:1.41–1.98) (Pap: 45.8%; OR = 2.06, 95%CI:1.82–2.32) than women who did nothing (29.1%). Uptake was slightly higher among women who attended Pap screening than women who returned a kit only (OR = 1.23, 95%CI:1.02–1.48).

Depression screening was higher among women who attended Pap screening (32.1%; adjusted OR = 1.79, 95%CI:1.57–2.05) compared with women who did nothing (19.1%). Compared with women who returned a kit, the adjusted odds of depression screening were 1.64 greater (95% CI:1.32–2.04) for women who attended Pap screening.

HbA1c testing was higher among diabetic women who attended Pap screening (90.7%) than who did nothing (74.4%; OR = 3.35, 95% CI:1.49–7.52). Comparisons with kit returners were not statistically significant.

4. Discussion

This study evaluated the impact of unsolicited, mailed HPV self-sampling kits for cervical cancer screening on receipt of other preventive services. Among women in an integrated healthcare delivery system who were underscreened for cervical cancer, uptake of other recommended preventive services was low. We found no significant differences in uptake of other cancer screening (mammography and CRC screening), annual influenza vaccination, depression screening, and HbA1c testing for diabetic monitoring between women randomized to receive a mailed self-sampling kit versus usual care Pap screening reminders. Mailing HPV self-sampling kits to underscreened women

Table 1
Demographic characteristics of control and intervention group participants by preventive health services eligibility.

	Mammography (n = 3500)[a]		CRC screening (n = 4482)[b]		Influenza vaccination (n = 14,218)[c]		Depression screening (n = 14,218)[c]		HbA1c testing (n = 1036)[d]	
	Control (n = 1752)	Intervention (n = 1748)	Control (n = 2293)	Intervention (n = 2189)	Control (n = 7135)	Intervention (n = 7083)	Control (n = 7135)	Intervention (n = 7083)	Control (n = 522)	Intervention (n = 514)
Characteristic[e]	%	%	%	%	%	%	%	%	%	%
Age at randomization, y										
30–39	–	–	–	–	17.2	17.6	17.2	17.6	7.3	4.7
40–49	–	–	–	–	25.8	26.4	25.8	26.4	16.3	18.3
50–59	63.4	65.6	66.8	68.7	37.3	37.0	37.3	37.0	43.3	45.1
60–64	36.6	34.4	33.2	31.3	19.7	19.0	19.7	19.0	33.1	31.9
Race										
White	72.4	72.2	74.1	74.5	72.6	72.1	72.6	72.1	66.1	67.7
Asian or Native Hawaiian or other Pacific Islander	9.4	8.3	9.3	7.9	10.5	10.5	10.5	10.5	13.0	11.7
Black or African American	4.6	4.3	4.2	3.7	4.3	4.6	4.3	4.6	5.0	6.6
Other	5.6	6.5	5.7	6.8	6.6	7.3	6.6	7.3	11.5	10.3
Unknown	8.0	8.7	6.7	7.1	6.0	5.5	6.0	5.5	4.4	3.7
Ethnicity										
Non-Hispanic	87.8	87.6	89.3	88.8	89.2	89.6	89.2	89.6	86.8	91.2
Hispanic	4.6	4.3	4.6	4.6	5.0	5.0	5.0	5.0	8.8	5.3
Unknown	7.6	8.1	6.1	6.6	5.8	5.4	5.8	5.4	4.4	3.5
Length of health plan enrollment before randomization, y[f]										
3.4 to <5	20.6	22.6	21.4	23.6	23.9	23.9	23.9	23.9	27.2	19.8
5 to <10	23.7	25.2	23.1	24.4	28.5	30.4	28.5	30.4	20.9	25.3
≥ 10	55.7	52.2	55.5	52.0	47.6	45.7	47.6	45.7	51.9	54.9
Time since last Pap test (by length of enrollment), y										
Enrolled 3.4 to < 5										
No Pap test	79.7	76.0	76.0	72.3	67.5	65.8	67.5	65.8	68.3	70.6
> 3.4 to <5	20.3	24.1	24.0	27.7	32.5	34.2	32.5	34.2	31.7	29.4
Enrolled 5 to < 10										
No Pap test	47.1	46.0	45.7	42.7	28.7	29.7	28.7	29.7	28.4	30.8
> 3.4 to <5	37.0	39.2	40.4	45.9	58.1	57.0	58.1	57.0	56.0	53.1
5 to <10	15.9	14.7	14.0	11.4	13.1	13.3	13.1	13.3	15.6	16.2
Enrolled ≥ 10										
No Pap test	20.7	20.6	18.2	19.1	12.3	12.6	12.3	12.6	11.4	12.8
> 3.4 to <5	37.9	39.8	43.8	45.8	58.2	59.2	58.2	59.2	57.2	56.0
5 to <10	26.1	24.5	23.9	22.4	20.5	19.9	20.5	19.9	18.8	20.9
≥ 10	15.3	15.1	14.2	12.7	9.0	8.3	9.0	8.3	12.6	10.3
Women's census block: Median household income, $										
< 49,999	22.4	22.8	22.6	22.8	22.2	22.5	22.2	22.5	27.0	29.0
50,000-74,999	35.0	33.8	33.8	33.3	34.7	34.9	34.7	34.9	39.8	39.1
75,000-99,999	23.7	23.6	23.7	23.7	25.3	24.7	25.3	24.7	18.2	18.1
≥ 100,000	9.6	11.0	11.1	11.3	10.4	10.5	10.4	10.5	6.9	6.8
Unknown	9.2	8.9	8.7	9.0	7.4	7.3	7.4	7.3	8.0	7.0
Travel time from women's home to primary care clinic, min[g]										
< 10	33.7	32.4	33.5	32.7	32.5	32.9	32.5	32.9	34.5	*NA*
10 - < 20	40.1	43.5	39.5	41.9	41.3	41.9	41.3	41.9	38.9	*NA*
20 - < 30	14.4	13.8	15.0	13.9	14.4	14.3	14.4	14.3	13.4	*NA*
≥ 30	10.2	9.3	10.5	10.5	10.8	10.0	10.8	10.0	11.7	*NA*
Unknown	1.7	0.9	1.5	1.0	1.1	0.8	1.1	0.8	1.5	*NA*
BMI, kg/m^2[h]										
< 24.9	19.9	22.2	21.0	22.8	24.3	24.8	24.3	24.8	7.7	10.3
25–29.9	21.9	20.3	23.0	20.6	22.9	22.6	22.9	22.6	16.7	15.8
30–34.9	15.4	16.3	15.8	16.4	16.7	16.2	16.7	16.2	22.6	17.7
35–39.9	10.5	9.8	10.5	11.2	10.9	11.4	10.9	11.4	21.1	19.3
≥ 40	10.1	10.3	10.6	11.6	11.9	12.9	11.9	12.9	29.9	33.3
Unknown	22.2	21.1	19.1	17.4	13.3	12.1	13.3	12.1	2.1	3.7
Tobacco use										
Never	45.8	43.2	49.2	46.5	54.0	54.2	54.0	54.2	55.7	50.2
Current	14.6	17.0	13.9	15.6	12.6	12.6	12.6	12.6	13.6	15.4
Former	19.1	20.1	19.3	20.7	20.8	21.4	20.8	21.4	28.5	31.1
Unknown	20.4	19.6	17.6	17.2	12.7	11.8	12.7	11.8	2.1	3.3
Charlson comorbidity index score(Charlson et al., 1987)										
0	82.8	80.7	81.3	81.0	81.1	81.0	81.1	81.0	5.9	7.2
1	9.1	11.4	10.4	11.3	11.6	11.1	11.6	11.1	39.5	36.2
2	4.3	4.4	4.7	4.5	4.0	4.4	4.0	4.4	26.8	30.2
3+	3.8	3.5	3.6	3.2	3.3	3.5	3.3	3.5	27.8	26.5
Randomization year										
2014	63.4	62.0	58.6	58.2	52.3	52.5	52.3	52.5	57.1	55.8
2015	24.9	25.6	28.7	28.1	31.0	30.7	31.0	30.7	27.2	26.5
2016	11.8	12.4	12.7	13.8	16.6	16.8	16.6	16.8	15.7	17.7

Abbreviation: BMI, body mass index.

[a] Mammography analyses were restricted to women who were between the ages of 52 and 64 years and not considered up-to-date per HEDIS.(Breast Cancer Screening, n.d.)

[b] CRC screening analyses were restricted women who were between the ages of 51 and 64 years and not considered up-to-date per HEDIS.(Colorectal Cancer Screening, n.d.)

[c] There were no restrictions for influenza vaccination uptake or depression screening, as these services are recommended annually for all adults.

[d] Uptake of HbA1c testing was restricted to women with diabetes.

[e] Based on electronic medical record data.

[f] Chi-square tests indicated significant differences (p-value <0.05) in length of health plan enrollment between the intervention group and control group for influenza vaccination, depression screening, and HbA1c testing.

[g] Distributions of travel time to from women's home to primary care clinic are not available for participants in the intervention group of HbA1c testing due to cell sizes less than 5.

[h] Calculated as weight in kilograms divided by height in meters squared.

Table 2
Odds ratios (ORs) for preventive health services receipt by randomization arm.

Preventive health services by randomized arm	Received preventive health service[a] n (%)	OR, Unadjusted (95% CI)	OR, Adjusted[g] (95% CI)
Mammography[b]			
Control ($n = 1752$)	586 (33.4)	Ref	–
Intervention ($n = 1748$)	590 (33.8)	1.01 (0.88, 1.17)	–
CRC screening[c]			
Control ($n = 2293$)	544 (23.7)	Ref	–
Intervention ($n = 2189$)	512 (23.4)	0.98 (0.86, 1.13)	–
Influenza vaccination[d]			
Control ($n = 7135$)	2422 (33.9)	Ref	Ref
Intervention ($n = 7083$)	2377 (33.6)	0.98 (0.92, 1.05)	0.99 (0.92, 1.06)
Depression screening[e]			
Control ($n = 7135$)	1488 (20.9)	Ref	Ref
Intervention ($n = 7083$)	1556 (22.0)	1.07 (0.99, 1.16)	1.07 (0.99, 1.16)
HbA1c testing[f]			
Control ($n = 522$)	417 (79.9)	Ref	Ref
Intervention ($n = 514$)	396 (77.0)	0.85 (0.63, 1.14)	0.84 (0.62, 1.13)

[a] Uptake of the preventive health services were assessed in the 12 months after randomization.

[b] Mammography analysis was restricted to women ages 52 to 64 years and not considered up-to-date per HEDIS.(Breast Cancer Screening, n.d.)

[c] CRC analysis was restricted women ages 51 to 64 years and not considered up-to-date per HEDIS.(Colorectal Cancer Screening, n.d.)

[d] There was no age restriction for influenza vaccination uptake. Influenza vaccination is recommended annually for all adults.

[e] There was no age restriction for depression screening uptake. Depression screening is recommended annually for all adults.

[f] There was no age restriction for HbA1c testing, but the analysis was restricted to women with diabetes.

[g] Models for influenza vaccination, depression screening, and HbA1c testing were adjusted for length of health plan enrollment prior to randomization (≥3.4 to <5, ≥ 5 to <10, or ≥ 10 years).

increased cervical cancer screening (we previously reported that screening uptake was 26.3% in the intervention group versus 17.4% in the control group (Winer et al., 2019)) without negatively or positively impacting uptake of other preventive services for women in the intervention arm.

Among women randomized to receive HPV self-sampling kits, preventive services uptake was higher in women who completed cervical cancer screening than in women who remained underscreened. Similar to previous studies, (Wirth et al., 2014; González and Borrayo, 2011; Kang et al., 2018; Bertaut et al., 2018; Carlos et al., 2005; Carlos et al., 2004) we observed positive associations between cervical cancer screening attendance and both mammography and CRC screening. We also observed a positive association between cervical cancer screening and influenza vaccination, in contrast to a previous study that found no association using self-reported data from the population-based 2016 Behavioral Risk Factor Surveillance System survey.(Oancea and Watson, 2019)

Within the intervention arm, there were clinically important differences in preventive services uptake by whether women did nothing, returned the kit or attended in-person screening. Mammography, CRC screening, and influenza vaccination receipt was higher in women who returned the self-sampling kit vs. did nothing, suggesting that mailing kits may have activated some women to engage in other preventive care. However, each preventive service evaluated was higher for women who chose in-clinic screening vs. returning the self-sampling kit. This was especially pronounced for mammography, which is consistent with previous studies suggesting that women who attend Pap screening are more engaged in female cancer screenings than other types of cancer screenings.(Bertaut et al., 2018; Lo et al., 2013) Some women may have had a Pap test and mammography at the same clinic visit, as both screenings can be offered opportunistically. However, we did not have the ability to assess this with these data. Our within-intervention arm comparison suggests there will need to be additional strategies in place to improve uptake of other preventive services (particularly mammography) if non-clinic-based screening is introduced for women overdue for cervical cancer screening. For example, health systems may consider additional patient-, provider-, and/or health system-level strategies such as financial incentives,(Purnell et al., 2015; Constantinou et al., 2016) patient education,(Kurt and Akyuz, 2019; Naz et al., 2018) provider assessment and feedback,(Sabatino et al., 2012) and/or behavioral interventions to target other preventive services in conjunction with offering HPV self-sampling.(Thompson et al., 2020; Tatar et al., 2018)

All eligible women were enrolled into the HOME trial under a waiver of consent, with only 0.6% of women opting out of medical record review, reducing the likelihood of participation bias, recall bias,(Coughlin, 1990) Hawthorne effects,(Landsberger, 1958; McCambridge et al., 2014) and social desirability bias.(Edwards, 1953) Other strengths include the large sample size (except for HbA1c testing) and the novelty of looking at the effect of a screening outreach intervention on other preventive services. Also, we are unaware of any prior studies that have examined associations between Pap screening and depression screening or HbA1c testing for monitoring diabetes. Including HbA1c testing also offered a comparison of a preventive service that is used for routine monitoring in a subgroup of individuals with a chronic condition versus the other services used for prevention or early detection. In our study population, HbA1c testing uptake was relatively higher than uptake of the other preventive services.

Aggregate data restrictions limited our ability to adjust for demographic covariates with small cell size categories. Additionally, temporality between cervical cancer screening and other preventive services could not be established in the within-intervention arm comparison due to the overlapping time periods for assessing the exposure (cervical cancer screening uptake within 6-months post-randomization) and the outcomes (preventive service receipt within 12-months post-randomization). For example, a woman could have received her annual influenza vaccination before she returned a kit or attended Pap screening. While we cannot infer a causal relationship of using a HPV self-sampling kit or attending Pap screening on increased participation in other preventive services,(Hill, 1965; Rothman and Greenland, 2005) the temporality is less relevant in this context because our primary objective was to evaluate whether mailing HPV kits impacts adherence to other preventive service recommendations.

Table 3
Preventive health services receipt and odds ratios (ORs) for preventive health services receipt by intervention subgroup.

Preventive health services by subgroup of intervention[a]	Received preventive health service[b] n (%)	OR, Unadjusted (95% CI)	OR, Adjusted[c] (95% CI)
Mammography[d]			
Did nothing ($n = 1424$)	379 (26.6)	Ref	Ref
Completed the kit only ($n = 131$)	58 (44.3)	2.19 (1.52, 3.15)	2.26 (1.56, 3.26)
Attended Pap screening ($n = 193$)	153 (79.3)	10.55 (7.30, 15.23)	11.81 (8.11, 17.19)
CRC screening[e]			
Did nothing ($n = 1740$)	262 (15.1)	Ref	Ref
Completed the kit only ($n = 152$)	74 (48.7)	5.35 (3.79, 7.55)	5.05 (3.57, 7.14)
Attended Pap screening ($n = 297$)	176 (59.3)	8.21 (6.29, 10.71)	7.31 (5.57, 9.58)
Influenza vaccination[f]			
Did nothing ($n = 4997$)	1455 (29.1)	Ref	–
Completed the kit only ($n = 651$)	265 (40.7)	1.67 (1.41, 1.98)	–
Attended Pap screening ($n = 1435$)	657 (45.8)	2.06 (1.82, 2.32)	–
Depression screening[g]			
Did nothing ($n = 4997$)	955 (19.1)	Ref	Ref
Completed the kit only ($n = 651$)	141 (21.7)	1.17 (0.96, 1.43)	1.09 (0.89, 1.33)
Attended Pap screening ($n = 1435$)	460 (32.1)	2.00 (1.75, 2.28)	1.79 (1.57, 2.05)
HbA1c testing[h]			
Did nothing ($n = 398$)	296 (74.4)	Ref	–
Completed the kit only ($n = 41$)	32 (78.0)	1.23 (0.57, 2.65)	–
Attended Pap screening ($n = 75$)	68 (90.7)	3.35 (1.49, 7.52)	–

[a] Subgroups were defined by cervical cancer screening behavior in the 6 months after randomization.
[b] Preventive health services uptake was assessed in the 12 months after randomization.
[c] Models were adjusted for demographic, health, or health plan enrollment covariates that changed OR estimates by 10% or more. No adjusted OR are reported for outcomes where no covariate changed the OR by 10% or more.
[d] Mammography analysis restricted to women ages 52 to 64 years and not considered up-to-date per HEDIS.(Breast Cancer Screening, n.d.) Adjusted model adjusted for randomization year (2014, 2015 or 2016).
[e] CRC screening analysis was restricted to women ages 51 to 64 years and not considered up-to-date per HEDIS. (Colorectal Cancer Screening, n.d.) Adjusted model adjusted for time since last Pap screening (no recorded Pap test or attended Pap screening more than 3.4 years ago).
[f] There was no age restriction for influenza vaccination uptake, as the service is recommended annually for all adults.
[g] Depression screening uptake had no age restriction, as the service is recommended annually for all adults. Adjusted model adjusted for time since last Pap screening (no recorded Pap test or attended Pap screening more than 3.4 years ago).
[h] There was no age restriction for HbA1c testing uptake, but the analysis was restricted to women with diabetes.

Table 4
Preventive health services receipt and odds ratios (ORs) for preventive health services receipt comparing attended Pap screening to completed the kit only.

Preventive health services by subgroup of intervention[a]	Received preventive health service[b] n (%)	OR, Unadjusted (95% CI)	OR, Adjusted[c] (95% CI)
Mammography[d]			
Completed the kit only ($n = 131$)	58 (44.3)	Ref	Ref
Attended Pap screening ($n = 193$)	153 (79.3)	4.81 (2.95, 7.86)	5.23 (3.18, 8.59)
CRC screening[e]			
Completed the kit only ($n = 152$)	74 (48.7)	Ref	Ref
Attended Pap screening ($n = 297$)	176 (59.3)	1.53 (1.03, 2.27)	1.45 (0.97, 2.15)
Influenza vaccination[f]			
Completed the kit only ($n = 651$)	265 (40.7)	Ref	–
Attended Pap screening ($n = 1435$)	657 (45.8)	1.23 (1.02, 1.48)	–
Depression screening[g]			
Completed the kit only ($n = 651$)	141 (21.7)	Ref	Ref
Attended Pap screening ($n = 1435$)	460 (32.1)	1.71 (1.37, 2.12)	1.64 (1.32, 2.04)
HbA1c testing[h]			
Completed the kit only ($n = 41$)	32 (78.0)	Ref	–
Attended Pap screening ($n = 75$)	68 (90.7)	2.73 (0.93, 7.99)	–

[a] Subgroups were defined by cervical cancer screening behavior in the 6 months after randomization.
[b] Preventive health services uptake was assessed in the 12 months after randomization.
[c] Models were adjusted for demographic, health, or health plan enrollment covariates that changed OR estimates by 10% or more. Adjusted ORs are not reported for outcomes where no covariate changed the OR by 10% or more.
[d] Mammography analysis restricted to women ages 52 to 64 years and not considered up-to-date per HEDIS.(Breast Cancer Screening, n.d.) Adjusted model adjusted for randomization year (2014, 2015 or 2016).
[e] CRC screening analysis was restricted to women ages 51 to 64 years and not considered up-to-date per HEDIS. (Colorectal Cancer Screening, n.d.) Adjusted model adjusted for time since last Pap screening (no recorded Pap test or attended Pap screening more than 3.4 years ago).
[f] There was no age restriction for influenza vaccination uptake, as the service is recommended annually for all adults.
[g] Depression screening uptake had no age restriction, as the service is recommended annually for all adults. Adjusted model adjust for time since last Pap screening (no recorded Pap test or attended Pap screening more than 3.4 years ago).
[h] There was no age restriction for HbA1c testing uptake, but the analysis was restricted to women with diabetes.

Since this study was restricted to women who were underscreened for cervical cancer, the findings may not be applicable to cervical cancer screening-adherent women. The impact of mailing HPV self-sampling kits to women who are adherent to cervical cancer screening is still unknown. Gaps in preventive services could potentially be created by removing in-person Pap screening if non-clinic-based screening is introduced as an option for adherent women. Offering non-clinic-based screening for adherent women could result in greater care gaps for other preventive health services; however, gaps might not be as large if adherent women tend to be better about receiving their preventive services regardless of whether they select HPV kits or in-person Pap screening. The sample of this study was a subset of insured women with access to care at KPWA, which, like the underlying region of the U.S., has a high proportion of non-Hispanic White, higher income, and highly educated individuals. The study also had several limitations. All women in the study had insurance and access to healthcare; therefore, our findings may not be generalizable to other U.S. populations. Our results also may not be applicable to women with limited English proficiency, since women with an "interpreter needed" flag in their EMR were excluded. Finally, while the main study was a randomized trial, this substudy was limited to women due for each preventive service. Models adjusted for variables that were imbalanced between groups; however, it is possible that there is residual confounding.

5. Conclusion

Individuals who are overdue for cervical cancer screening remain a hard-to-reach population, even after removing barriers associated with in-person screening. While cervical cancer screening rates remained

low,(Winer et al., 2019) mailing HPV kits improved cervical cancer screening rates and did not result in reduced uptake of other recommended preventive services. Our within-intervention arm comparisons demonstrated differences in preventive services uptake by whether women did nothing, returned the kit or attended in-person screening. As health systems implement HPV self-testing for cervical cancer screening, they should identify additional targeted strategies to encourage and engage patients in other preventive services uptake.

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Declaration of Comepting Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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