

UC San Diego
Moore's Cancer Center



The Promise of HPV Self-Testing

Thursday, April 18th, 2024

UC San Diego
MOORES CANCER CENTER



CERVICAL CANCER

Quality Improvement
Learning Collaborative

Session I: The Promise
of HPV Self-Testing

APRIL 18TH, 12PM PST



[tinyurl.com/hpv
selftesting](https://tinyurl.com/hpvselftesting)

Agenda

01	Welcome
02	The Promise of Self-Testing NCI Cervical Cancer 'Last Mile' Initiative: SHIP Trial
03	Spotlight: Updates from the Every Woman Counts Program
04	Closing and Action Steps

MEETING REMINDERS



AUDIO

Please make sure your line is muted unless you are asking a question during the q&a portion of the session.



CHAT

Use the chat to introduce yourself & ask questions throughout the session!

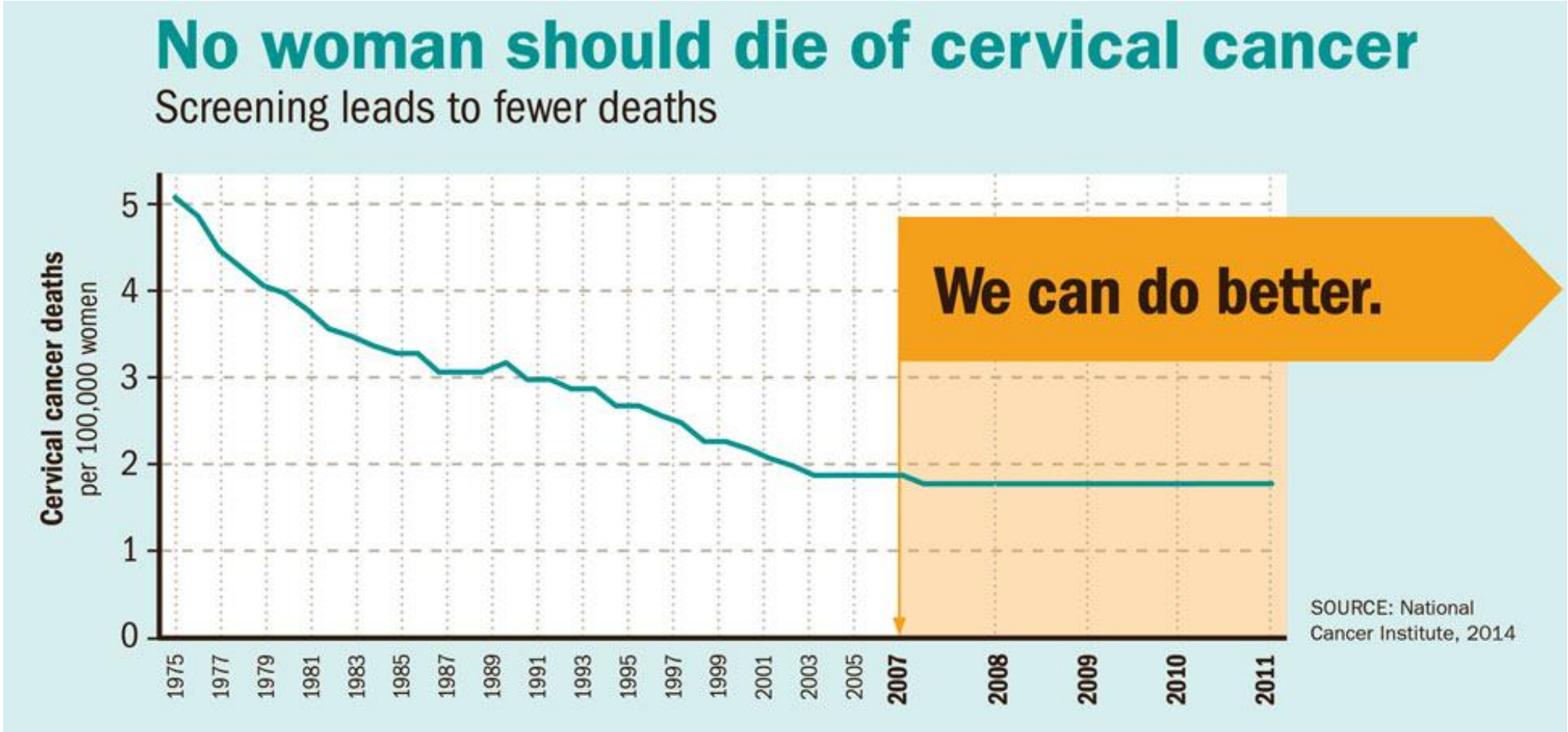


RECORDING

Slides, meeting recording and resources will be shared with all attendees

WELCOME TO THE FIRST SESSION OF 2024!

This collaborative is led by the Community Outreach and Engagement team of Moores Cancer Center. Our goal is to feature topics and speakers to help practitioners address the barriers to cervical cancer elimination in our San Diego-Baja region.



Cervical Cancer Quality Improvement Learning Collaborative

2023 Timeline

Session I:

- Spotlight on Vista Community Clinic: Improving Community Outreach for Cervical Cancer Screening
- Cervical Cancer Screening Needs Assessment

Session II:

- Enhancing and promoting inclusive cervical cancer screening for the entire San Diego community

Session III:

- Spotlight: Cervical Health on the Border



Update: Cervical Cancer in San Diego

2021 Cancer Stats:

- 118 cancer cases
- ~46% in Hispanic individuals
- 12% in Asian and Pacific Islander individuals
- ~3% Black/African American individuals
- ~81% aged 18-64
 - *Not Represented:*
 - Native American cancer burden
 - Middle East/North African descent
 - LGBTQIA+ identification

2017-2021 Cancer Stats:

- 624 cancer cases
- ~41% in Hispanic individuals
- 78% aged 18-64
- +13% in Asian and Pacific Islander individuals
- .32% in Native American individuals



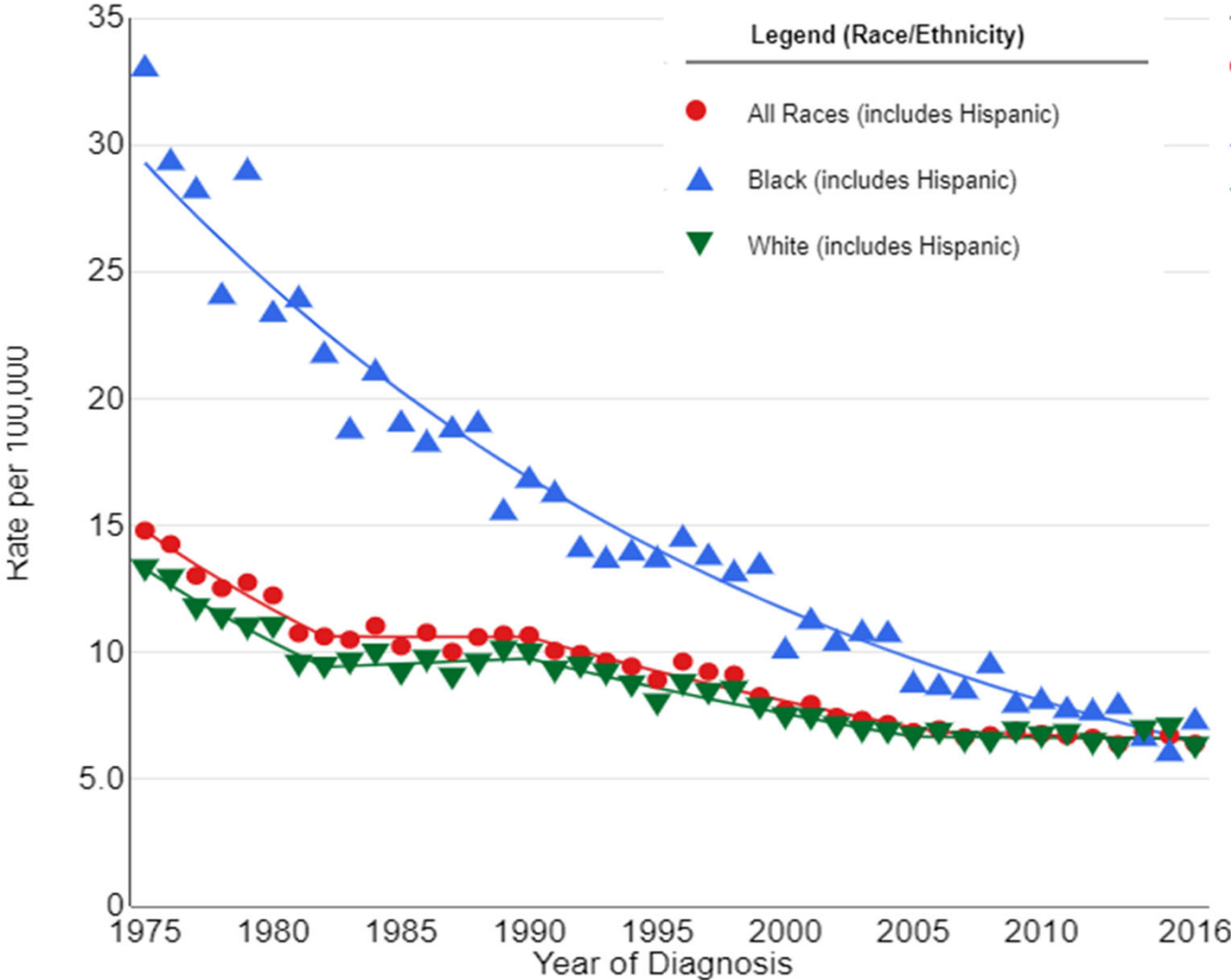
Data courtesy of the California Cancer Registry



The Promise of Self-Testing

NCI Cervical Cancer 'Last Mile'
Initiative: SHIP Trial

Cervical Cancer is Highly Preventable But is Still Not Fully Prevented!



(1975-2016, SEER data)

Background

- >13,000 women continue to be newly diagnosed and >4,000 women continue to die due to cervical cancer every year in the United States
- The full public health impact of prophylactic HPV vaccination on reducing cervical cancer rates will not be realized for at least another generation
- ***Over half of the incident cervical cancer*** cases in the US are among women who have been ***never screened*** or ***infrequently screened, and who do not participate in routine screening***
- ***This 'last mile' problem represents a significant cancer health disparity*** and needs to be addressed via concerted efforts to reduce and eventually eliminate cervical cancer as a public health problem in the United States

Background

Current US Guidelines for Cervical Cancer Screening Methods for Average-Risk Asymptomatic Women

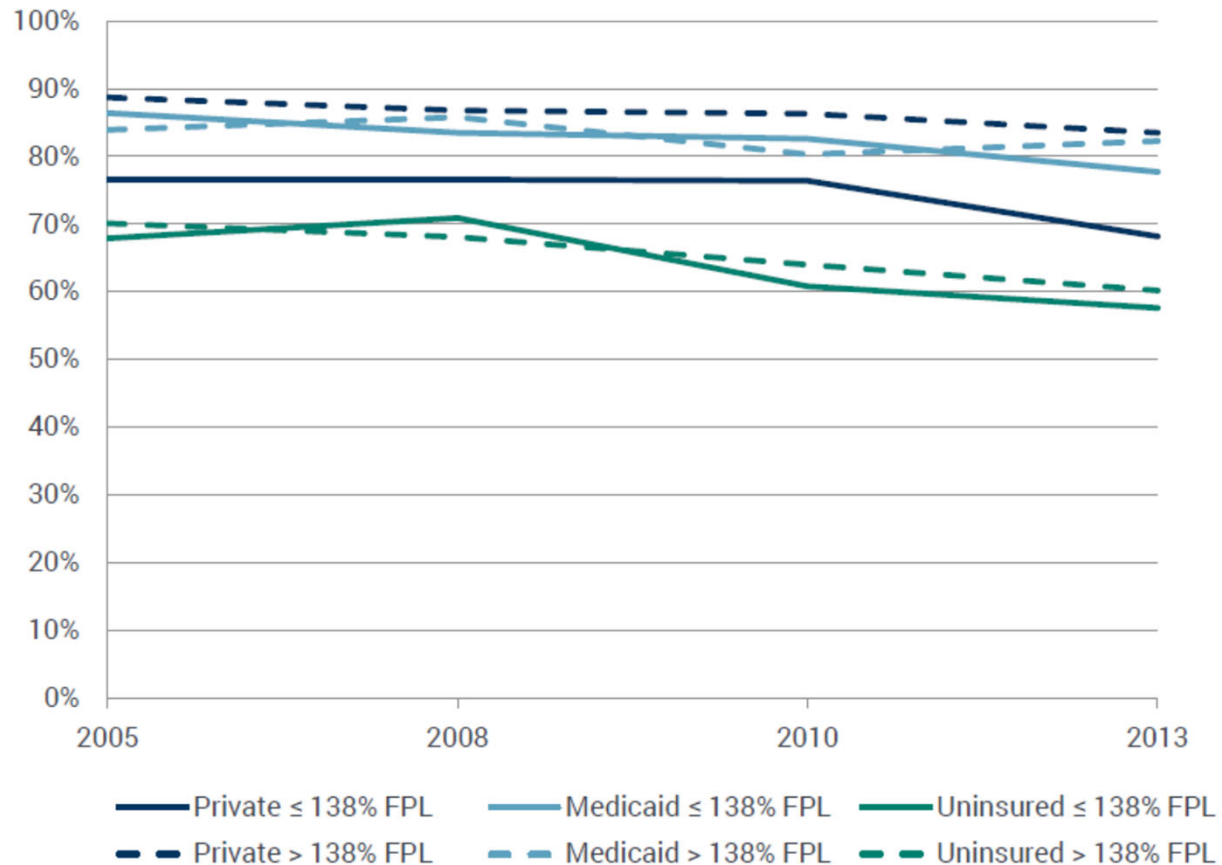
- **Age 21 to 29:** Every 3 years with Pap testing
- **Age 30 to 65:**
 - Every 5 years with HPV testing
 - OR** Every 3 years with Pap testing
 - OR** Every 5 years with co-testing (Pap testing + HPV testing)

(The U.S. Preventive Services Task Force states that HPV testing or Pap testing alone are preferred options compared with co-testing)

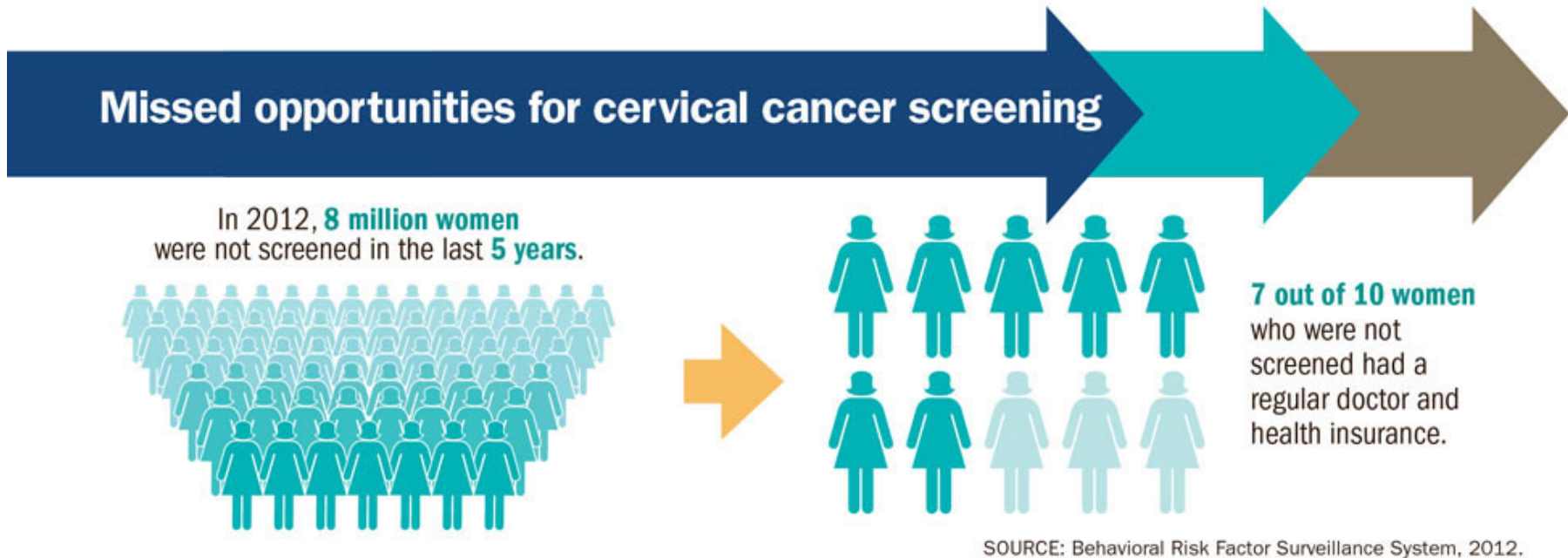
Background

Utilization of Cervical Cancer Screening remains suboptimal for ~3 out of 10 women

Percentage of Eligible Women Undergoing Screening in the Past Three Years, by Insurance Status



Background

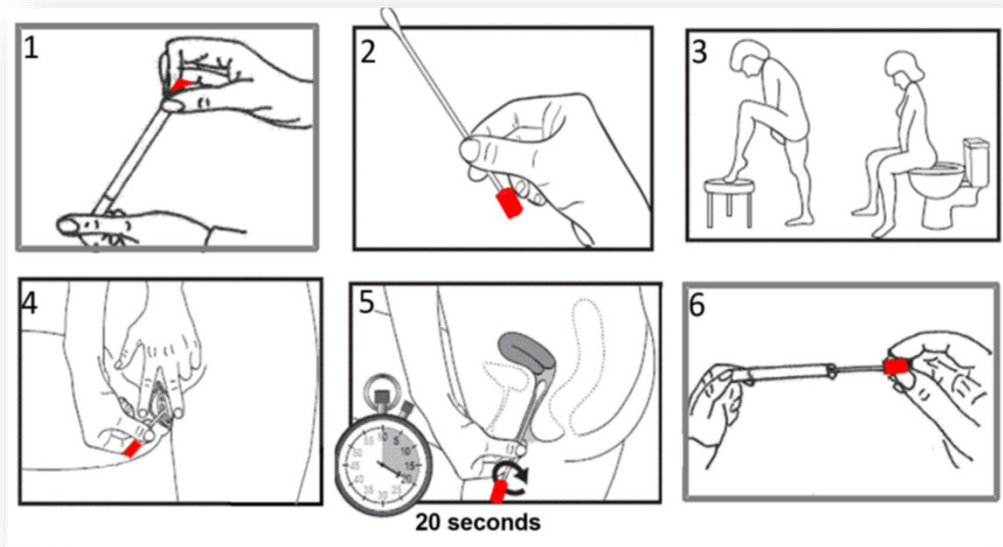


Women less likely to be screened:

- lower socioeconomic status and lower educational attainment
- racial/ethnic minorities and foreign-born
- residents of rural counties or areas with geographic inaccessibility to adequate screening services (e.g., Appalachia, Deep South, US-Mexico border region, Native American Reservations, Pacific/Outlying Islands)

Self Sampling for HPV testing

- Ease of collection
- When women choose (time, place)
- By themselves/in privacy
- No need for appointment or speculum examination
- Kits can be mailed back and forth, or can be brought back during other clinic visits



Self Sampling for HPV testing

Not a new concept – already offered to non-attenders of organized cervical cancer screening programs in Europe

Several studies have shown **high patient acceptability** for self-sampling-based cervical cancer screening

Other advantages of self-sampling-based cervical cancer screening

- HPV self-sampling increases uptake in nonattenders of regular screening
- Attendance to follow-up care after testing HPV positive by self-sampling is high
- Majority of women who actively declined screening indicated interest in self-sampling
- Direct offer of self sampling devices to women in communities that were under-screened generated high participation rates

Arbyn et al 2018, Snijders et al, 2012, Lim et al 2017, Nelson et al 2016, Duffy et al, 2017, Marlow et al, 2018

Self Sampling for HPV testing

- Meta-analyses of several observational studies and screening trials shows self-sampling-based HPV testing has
 - **higher sensitivity** compared to cytology
 - **comparable sensitivity** vs. clinician-collected sampling for PCR-based HPV testing
- Yet no clinical guideline in the US has incorporated a self-sampling strategy for HPV testing, primarily due to **lack of an FDA-approval of self-sampling for HPV testing as a standard of care or an alternative screening approach** for women who do not/cannot access clinic-based/speculum-exam-based cervical cancer screening

Arbyn et al 2018, Arbyn et al 2014, Cuzick et al 2006

NCI Cervical Cancer 'Last Mile' Initiative



Goal: *Overcome barrier of lack of FDA approval for self-collection approaches for HPV testing-based cervical cancer screening*



Approach: *Engage public and private sector stakeholders to facilitate regulatory approvals for self-collection*



Outcome: *Increase screening access and reduce cervical cancer incidence in underserved and high-burden populations*

<https://prevention.cancer.gov/lastmile>

General Contour of the Screening Trial (based on FDA input)

Participant enrollment; informed consent; provider collected specimen for HPV testing and liquid-based cytology

Mailing of HPV self-collection kits at home 2-3 days after clinic visit; to be returned in 2 weeks

Provider and self-collected specimen labeled with different/masked IDs sent to central laboratory for aliquoting

Aliquot order-balanced batches randomly assigned and sent to each participating company for HPV testing.

Women who are HPV positive on either specimen or have cytologic abnormalities will undergo colposcopy/biopsy and quality-assured histopathology

NCI Cervical Cancer 'Last Mile' Initiative: Key Activities

Facilitating discussions for regulatory approvals for self-collection

- Reviewing evidence on self-collection to inform regulatory pathways
- Facilitation of discussions between FDA and HPV assay manufacturers seeking approvals for self-collection approaches for primary HPV testing.

Self-collection for HPV testing to Improve Cervical Cancer Prevention (SHIP) Trial

- Nationwide multicenter clinical trial and associated studies
- Independent evaluation of multiple self-collection devices and HPV assays for usability, acceptability, accuracy, and effectiveness to inform implementation

Disseminating evidence on self-collection to change and inform clinical practice

- Partnerships with professional societies to update clinical practice guidelines after FDA approvals for self-collection
- Creating publicly-accessible repository of resources on self-collection

<https://prevention.cancer.gov/lastmile>

NCI Cervical Cancer ‘Last Mile’ Initiative

‘Self-collection for HPV testing to Improve Cervical Cancer Prevention’ (SHIP) Trial

Announcement of “SHIP” trial network on self-sampling for cervical cancer prevention at White House (Jan. 25, 2024)



As part of the Forum, National Cancer Institute (NCI) Director Kimryn Rathmell announced a new NCI-supported trial to drive progress on cervical cancer prevention. The brand new ‘Last Mile’ Initiative, Self-collection for HPV testing to Improve Cervical Cancer Prevention (SHIP) Trial Network aims to test the performance of multiple self-collection devices for HPV, the leading driver of cervical cancer, so that cervical cancer screening can be brought closer to the people in the communities that are behind on screening.

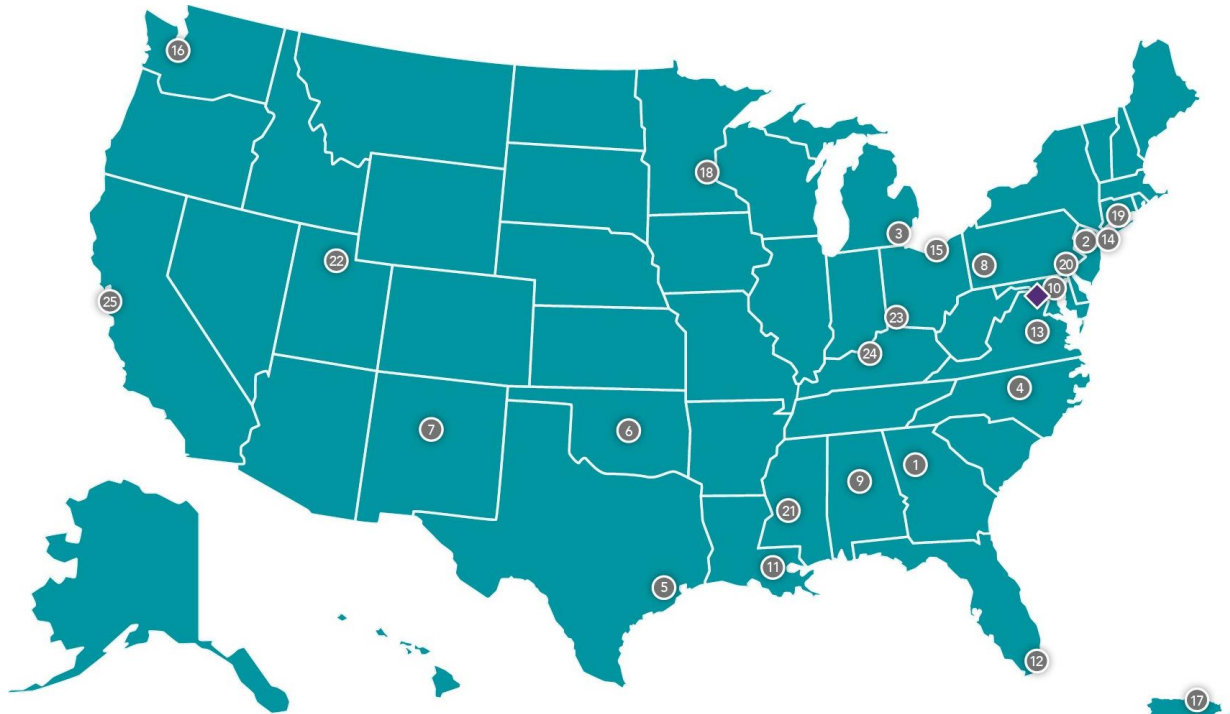
White House Cervical Cancer Forum (Jan. 25, 2024)

Self-collection for HPV testing to Improve Cervical Cancer Prevention (SHIP) Trial Network

- SHIP trial network is a great example of:
 - ✓ **Broad collaboration** – within research and beyond, including federal and private sector partners
 - ✓ **Addressing disparities**
 - ✓ **Engaging with the community**, beneficiaries of research

NCI Cervical Cancer ‘Last Mile’ Initiative

‘Self-collection for HPV testing to Improve Cervical Cancer Prevention’ (SHIP) Trial Network: **Study Sites**



20. University of Pennsylvania Abramson Cancer Center, Philadelphia, PA
21. University of Mississippi Medical Center, Jackson, MS
22. University of Utah Huntsman Cancer Institute, Salt Lake City, UT
23. University of Cincinnati College of Medicine, Cincinnati, OH
24. University of Louisville School of Medicine, Louisville, KY
25. University of California, San Francisco School of Medicine, San Francisco, CA

1. Emory University School of Medicine, Atlanta, GA
2. Rutgers New Jersey Medical School, Newark, NJ
3. University of Michigan Medical School, Ann Arbor, MI
4. University of North Carolina School of Medicine, Chapel Hill, NC
5. University of Texas MD Anderson Cancer Center, Houston, TX
6. University of Oklahoma Stephenson Cancer Center, Oklahoma City, OK
7. University of New Mexico Health Sciences Center, Albuquerque, NM
8. University of Pittsburgh Medical Center/Magee-Womens Hospital, Pittsburgh, PA
9. University of Alabama at Birmingham School of Medicine, AL
10. Johns Hopkins University School of Medicine, Baltimore, MD
11. Louisiana State University Health Sciences Center New Orleans, LA
12. University of Miami Sylvester Comprehensive Cancer Center, Miami, FL
13. Virginia Commonwealth University School of Medicine, Richmond, VA
14. Weill Cornell Medicine and New York Presbyterian Hospitals, New York, NY
15. Cleveland Clinic Ob/Gyn and Women’s Health Institute, Cleveland, OH
16. University of Washington School of Public Health, Seattle, WA
17. University of Puerto Rico Comprehensive Cancer Center, San Juan, PR
18. Minneapolis VA Healthcare System, Minneapolis, MN
19. Yale New Haven Health, New Haven, CT

NCI Cervical Cancer 'Last Mile' Initiative

Self-Collection for HPV testing to Improve Cervical Cancer Prevention (**SHIP**) Trial

Usability and Acceptability Testing of Devices

- Assessment of usability and acceptability of self-collection devices by individuals representing the intended-use population

Accuracy of Self-Collection Device-HPV Assay Combinations

- Cross sectional studies to evaluate accuracy of self-collection device and HPV assay combinations in a simulated home environment

Effectiveness of Self-Collection in Underserved and High-Burden Populations

- Mixed-methods approaches to evaluate effectiveness of self-collection to inform wider implementation

Features of SHIP Trial: Independent, non-competitive, parallel evaluations of multiple self-collection device-assay combinations.

<https://prevention.cancer.gov/lastmile>



EVERY WOMAN COUNTS

California Health Collaborative

Department of Health Care Services



AGENDA



About the Program



Health Educators



Clinical Coordinators



EWC Eligibility



Questions

ABOUT THE PROGRAM

Every Woman Counts (EWC) provides free breast and cervical cancer screening and diagnostic services to California's underserved individuals.

The mission of EWC is to save lives by preventing and reducing the devastating effects of cancer for Californians through education, patient navigation, screening, diagnosis, treatment referrals, and evidence-based interventions, with special emphasis on the underserved.

ABOUT THE PROGRAM

HISTORY -- FEDERALLY FUNDED

- The federal program is the [National Breast and Cervical Cancer Early Detection Program \(NBCCEDP\)](#)
- Every state has a program with a unique name and different eligibility criteria
- Every Woman Counts began in 1991 as a federally-funded program with 134 Primary Care Providers (PCPs) serving 30,000 women



ABOUT THE PROGRAM

HISTORY -- STATE FUNDED

Every Woman Counts (EWC)

- In 1994, the Breast Cancer Early Detection Program (BCEDP) was established with state funding
- The federal and state programs then merged into one known as Cancer Detection Programs: Every Woman Counts (CDP:EWC)
- Since 2012, the program has been known simply as EWC



Every Woman Counts

ABOUT THE PROGRAM

REGIONAL STRUCTURE

- 10 regions, each with a Regional Contractor (RC)
- Each RC has at least one HE and at least one CC



ABOUT THE PROGRAM

HOW DO WOMEN FIND OUT ABOUT EWC?

- Online Provider Locator (OPL)
 - <https://www.dhcs.ca.gov/services/cancer/EWC/Pages/ewc-clinic-locator.aspx>
- Health Educators
- 800 number
 - 1-800-511-2300
- From medical providers
- Word of mouth



Welcome to the Every Woman Counts Provider Locator! Use the search box below to locate an Every Woman Counts provider in your area. You can also call the EWC consumer 800# automated line at 1-800-511-2300 for 24-hour provider referrals.

You may be eligible for full health coverage under **Covered California**. Visit www.CoveredCa.com or call 1-800-300-1506 to find out.

Seeking treatment?

If you have already been diagnosed with breast or cervical cancer and are seeking treatment, you may qualify for free treatment services through the Breast and Cervical Cancer Treatment Program (BCCTP). For more information or to find a BCCTP enrolling provider, please call toll free 1-800-824-0088.

⚠ **Attention Internet Explorer users.** The EWC Provider Locator may not function as intended if your browser is in compatibility mode. Please turn off 'Compatibility View' in your browser settings.

Locate Providers Select Language ▾

Search

Zip code Enter your zip code to see the top 5 results in your area. Or you can use the Address Search below for more precise results.

Advanced Options

Address Street City

Distance 5 miles

I Would Prefer My Doctor To Speak ▾

I Would Prefer

Female Doctor Evening Hours Weekend Hours

Database Last Updated: Jul 10 2022 3:31AM

How did you find out about the Every Woman Counts (EWC) Program?

▾

HEALTH EDUCATORS

- Recruit EWC-eligible individuals to enroll into the program
- Collaborate with community leaders to offer small group health education classes
- Utilize a network of Community Health Workers (CHWs) to recruit individuals to attend health education classes, translate, and establish collaborations
 - Any individual can be a CHW
 - Paid volunteers
- Provide navigation services to individuals who are due for breast and/ or cervical cancer screening

CLINICAL COORDINATORS

- Registered Nurses
- Provide Training, Support and Clinical Technical Assistance for enrolled health care providers
- Recruit primary care providers based on Regional Needs Assessment
- Ensure provision of appropriate and timely breast and cervical cancer screening and diagnostic services
- Offer patient navigation to EWC-enrolled individuals and those who are ineligible for EWC, including individuals who need to be enrolled in the Breast and Cervical Cancer Treatment Program (BCCTP)
- Implement Evidence–Based Interventions (EBIs)

You can find your region's Clinical Coordinator on the DHCS website:

<http://www.dhcs.ca.gov/services/cancer/EWC/Pages/RegionalContractors.aspx>

EWC ELIGIBILITY

Age	<ul style="list-style-type: none">• Individuals with a cervix that are 21-65 years of age and older - cervical screening and diagnostic services.• Exceptions for individuals >65 for those with inadequate prior screening, or for ongoing surveillance for previous abnormalities
Residency	Must have a physical California address or, if homeless, a location where a recipient can be contacted and/or receive mail
Income	At or below 200% of federal poverty level
Insurance	Does not have any private or public insurance coverage, OR If insured, unable to afford deductibles, copays, or share of cost

EWC ELIGIBILITY

CONT.

200 Percent of the 2024 HHS Poverty Guidelines by Family Size (Department of Health and Human Services)		
Family Members Living in Household*	Monthly Gross Household Income	Annual Gross Household Income
1	\$ 2,510	\$ 30,120
2	\$ 3,407	\$ 40,880
3	\$ 4,303	\$ 51,640
4	\$ 5,200	\$ 62,400
5	\$ 6,097	\$ 73,160
6	\$ 6,993	\$ 83,920
For each additional member add:	\$ 897	\$ 10,760

See income criteria under EWC Program Information at dhcs.ca.gov

EWC CERVICAL CANCER COVERED PROCEDURES

Screening services:

- Pap test every three years starting at age 21 and older
- Pap test and HPV screening (co-test) or HPV alone every five years as an option for age 30 and older

Diagnostic services:

- HPV Genotyping (type 16, 18 and 45)

Colposcopy

- With or without biopsy
- With or without endocervical curettage

Follow –up until final diagnosis is reported

Free Treatment available through the Breast and Cervical Cancer Treatment Program (BCCTP)

Contact Us For More Information

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Every Woman Counts

(800) 511-2300

<http://dhcs.ca.gov/EWC>

Closing & Action Steps



1. Complete our survey for this CC QI LC Session I

- Your feedback matters! Let us know how we did

2. Cancer Prevention 101

- Reach out to our COE team at mcccoe@health.ucsd.edu

3. Sign up for the CC QI Learning Collaborative

- Recommend topics for our future sessions: <https://bit.ly/3LaPfc8>

4. Join us for our next meeting!

- Happening July 18th, 2024

Thank you!

Meeting recording, slides and resources coming soon!



mcccoe@health.ucsd.edu



<https://moorecancercenter.ucsd.edu/>



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