Opportunities and Challenges in the Elimination of Cervical Cancer

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INNOVATIONS VI
In Cancer Prevention and Research Conference
OCTOBER 2-3, 2023 · MOODY GARDENS HOTEL AND CONVENTION CENTER · GALVESTON, TEXAS

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Disclosures

I have no conflicts of interest to disclose.

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The global burden of cervical cancer is high

1 new diagnosis every minute

1 new death every 2 minutes

Cervical cancer can be prevented

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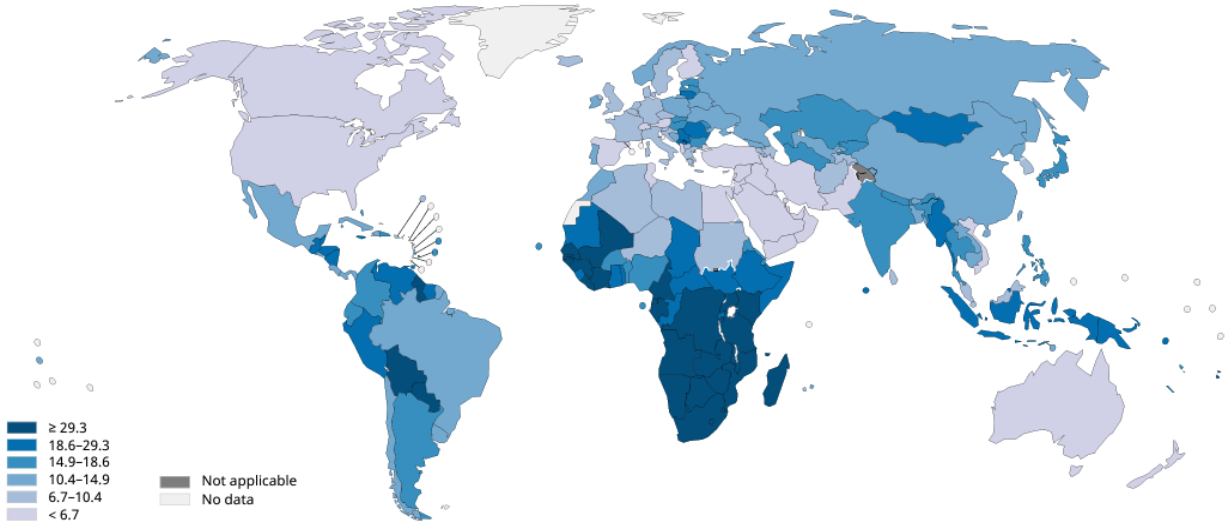
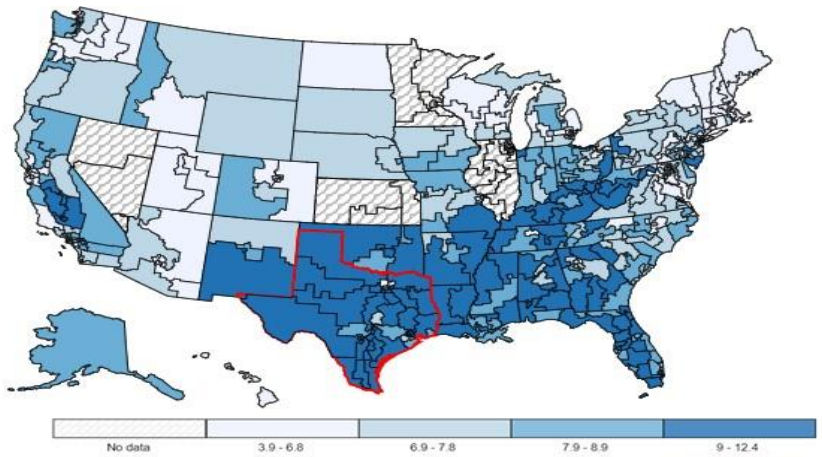
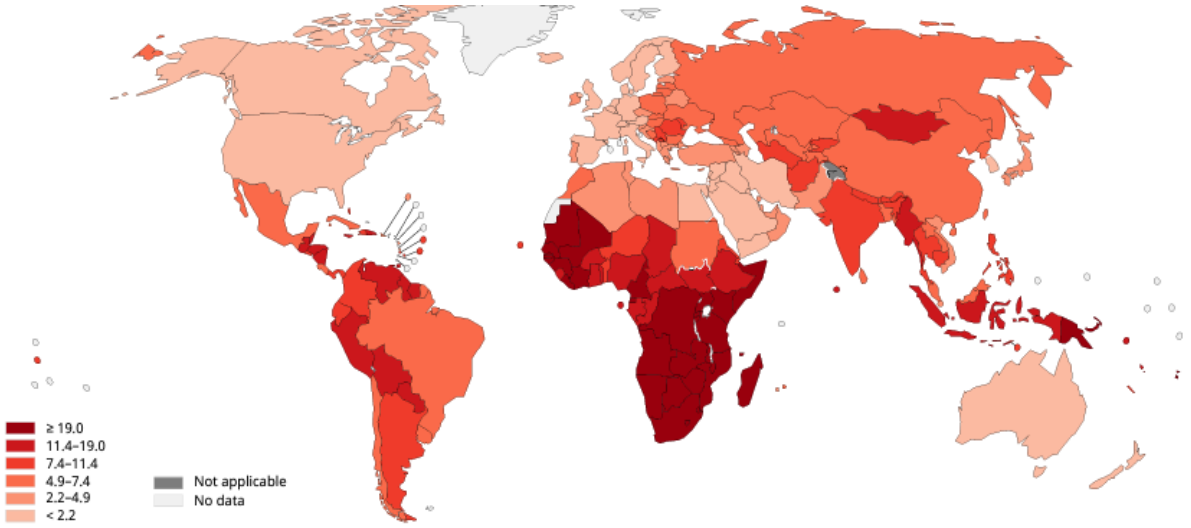
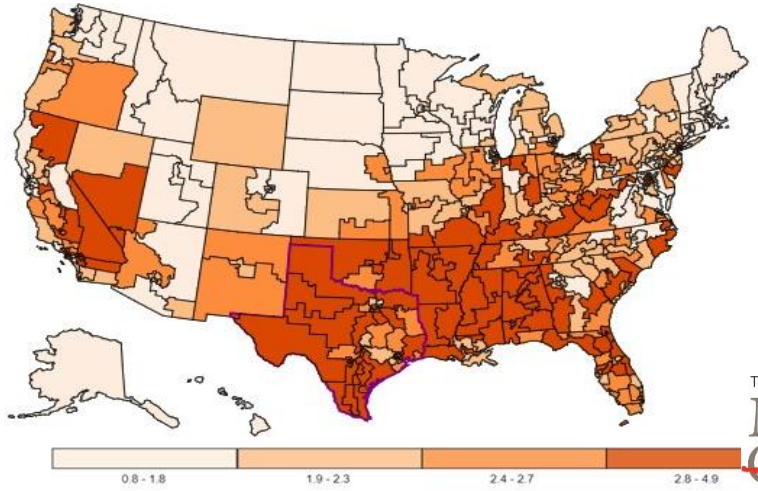
Cervix Cancer: *A Marker of Inequity, Globally and Locally*







Globocan 2020



CDC 2020

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* and boys in countries where resources allow

90%

of girls* fully vaccinated with HPV vaccine by age 15

70%

of persons screened with a high-performance test

90%

of persons identified with cervical disease receive treatment

Global Strategy

to achieve the elimination of cervical cancer as a public health problem

(incidence ≤ 4 per 100,000 person-years)

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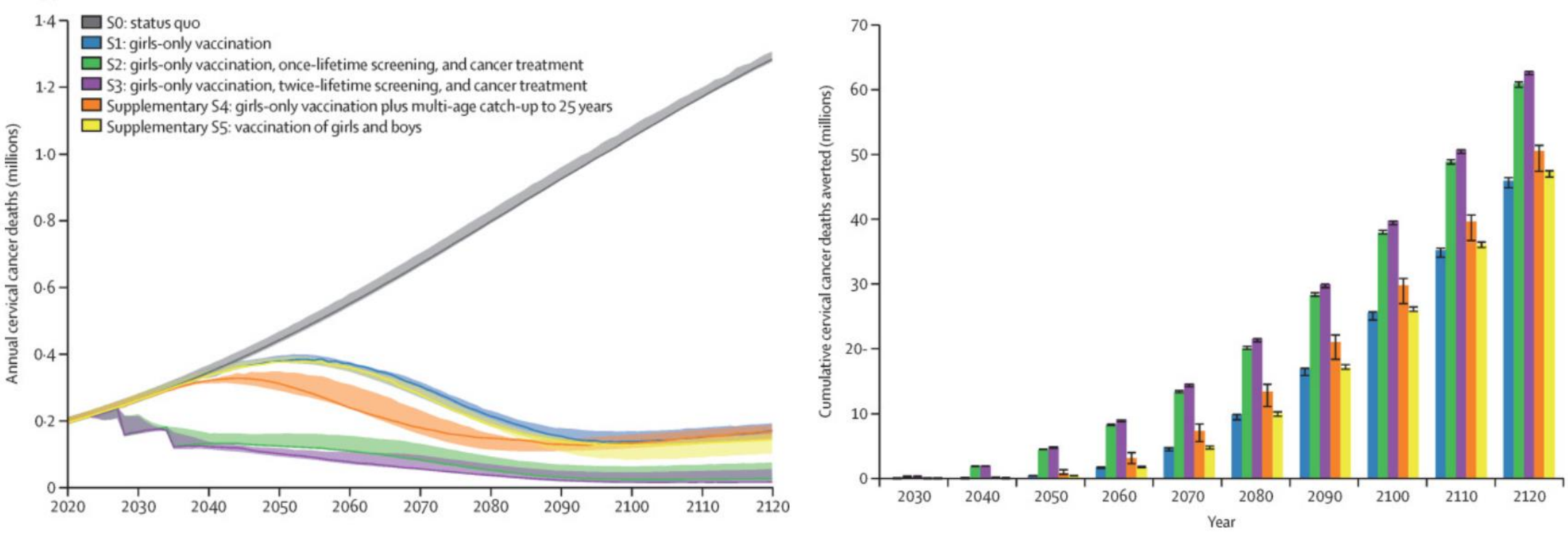
Elimination Modeling



Achieving the 90-70-90 targets by 2030 would result in over 62 million cervical cancer deaths averted by 2120.

Canfell et al, Lancet, 2020

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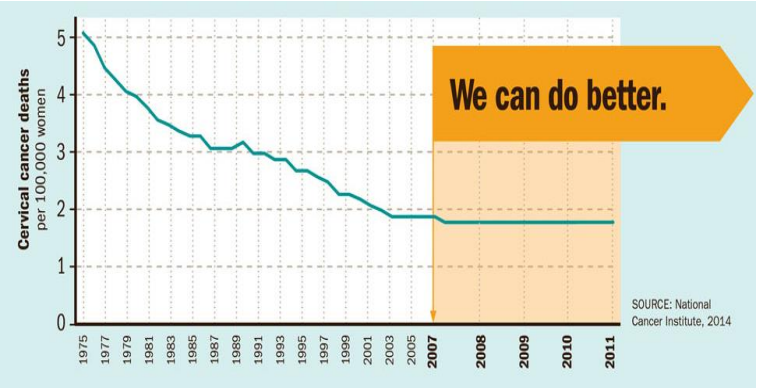
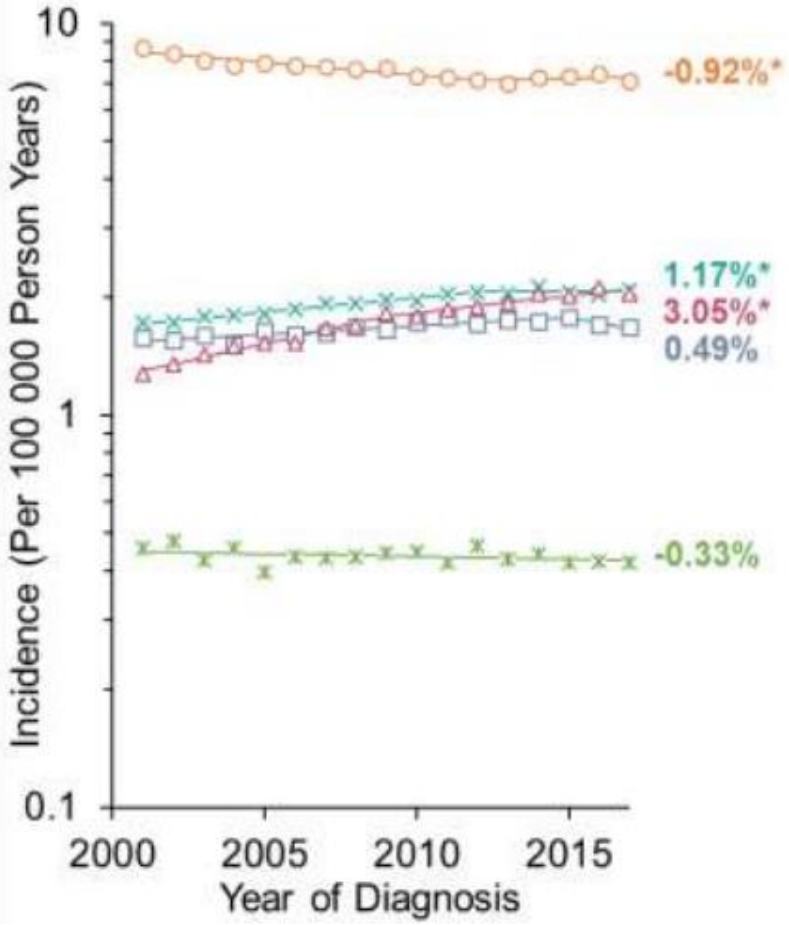
In an era in which world leaders have committed to eliminate cervical cancer…

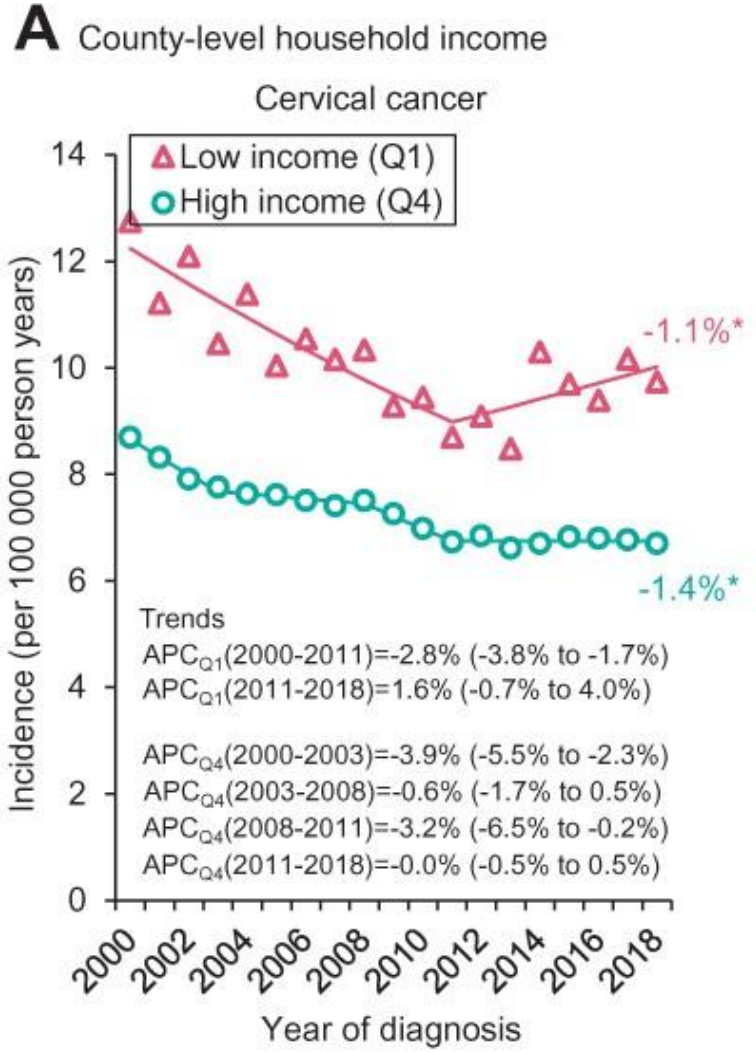
the U.S. is losing ground



NCI, 2014

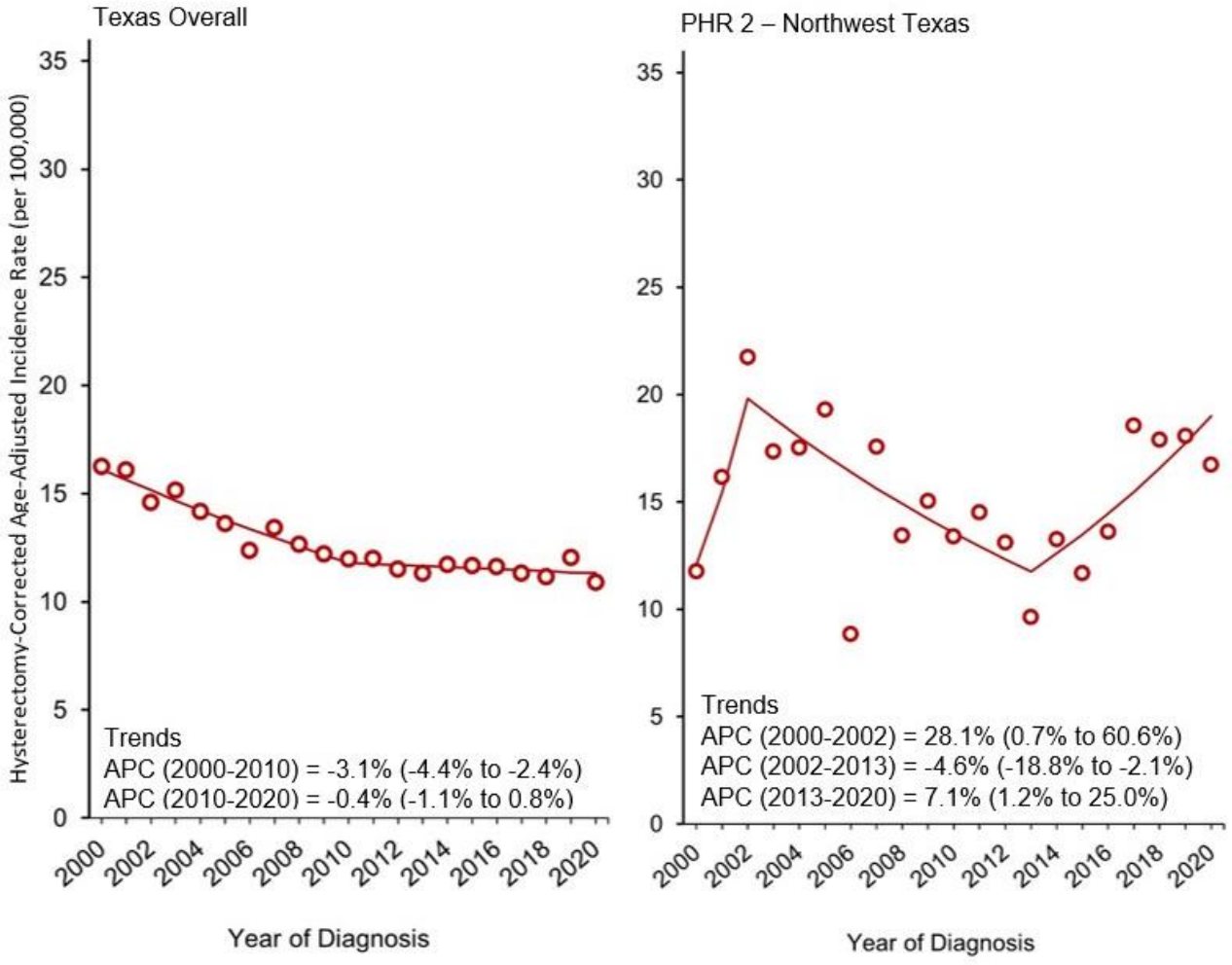


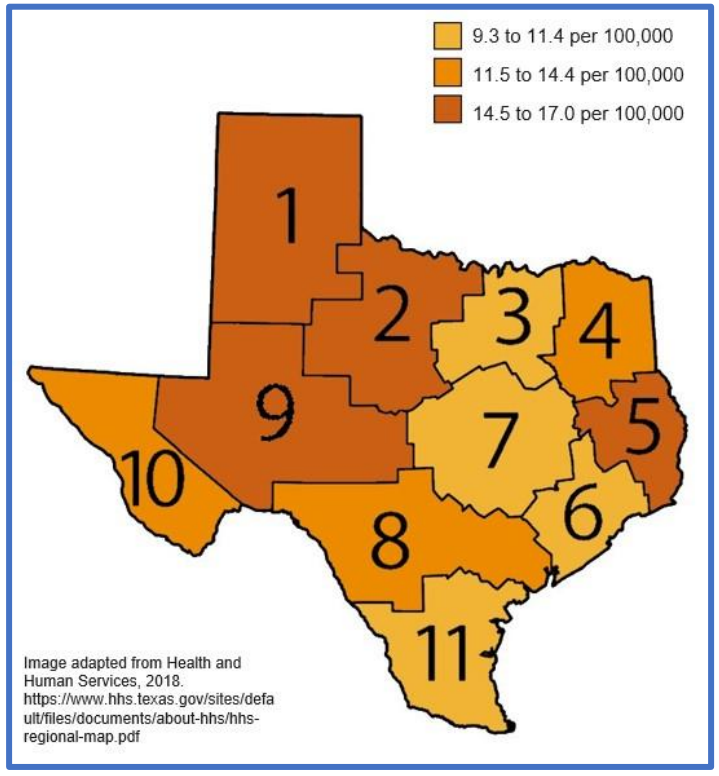
Deshmukh et al, JNCI 2021



Lin et al, JNCI Cancer Spectrum, 2022

And the trends are similar in Texas





Trisha Amboree, PhD
PRESTIS Postdoctoral Fellow

CPRIT Conference Poster presentation

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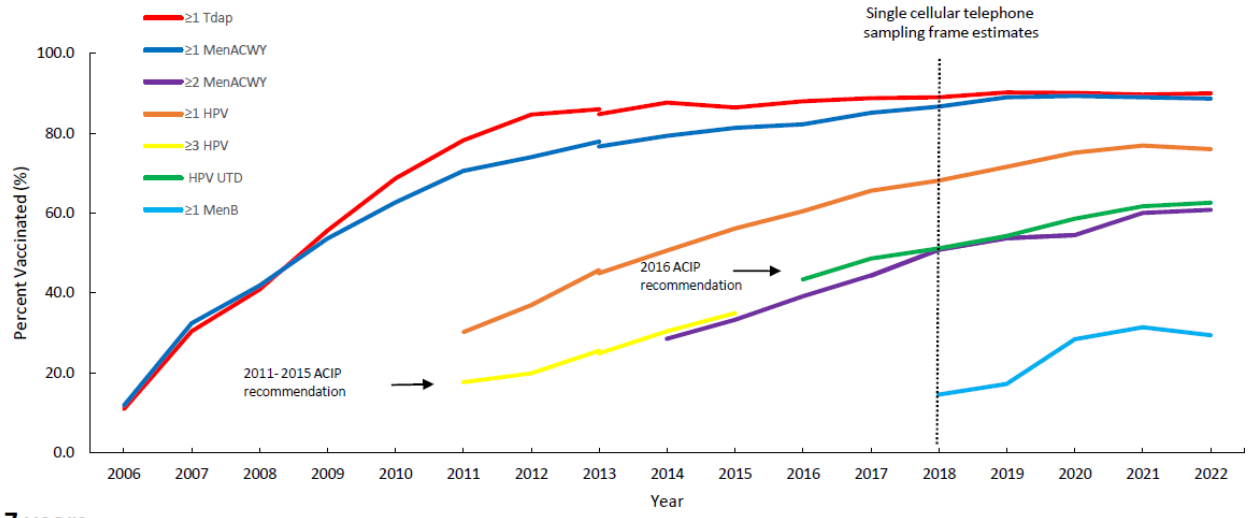
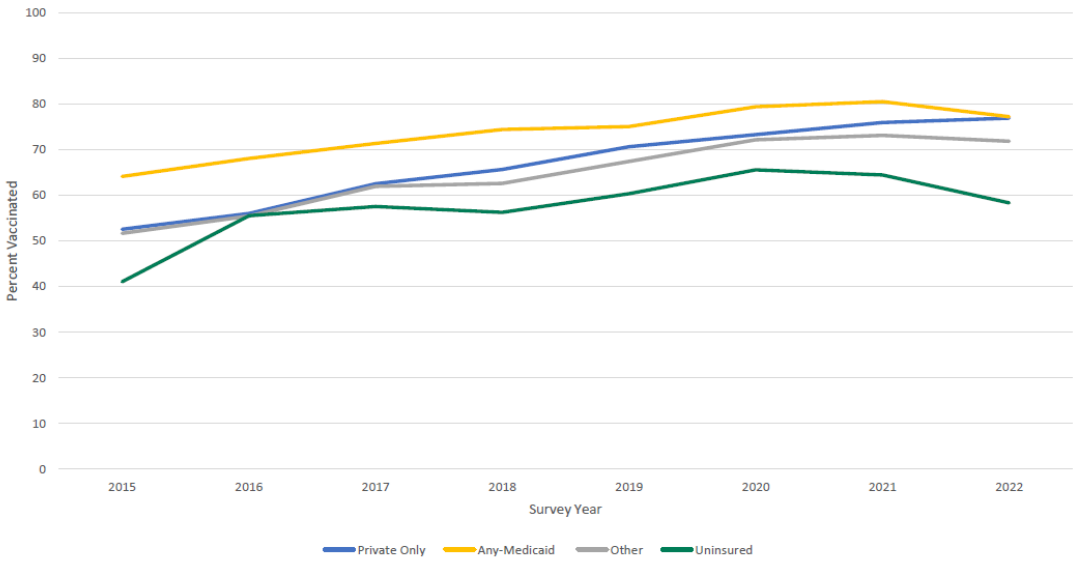
There is slowing uptake of the HPV Vaccine.

Estimated vaccination coverage with selected vaccines and doses* among adolescents aged 13-17 survey year—National Immunization Survey-Teen§, ¶, United States, 2006-2022



Estimated vaccination coverage with ≥1 human papillomavirus (HPV) vaccine among adolescents 13-17 years, by Health Insurance Status— National Immunization Survey–Teen (NIS-Teen), United States, 2015-2022.



And there are significant disparities

In particular, lower HPV vaccine coverage among uninsured children and teens.

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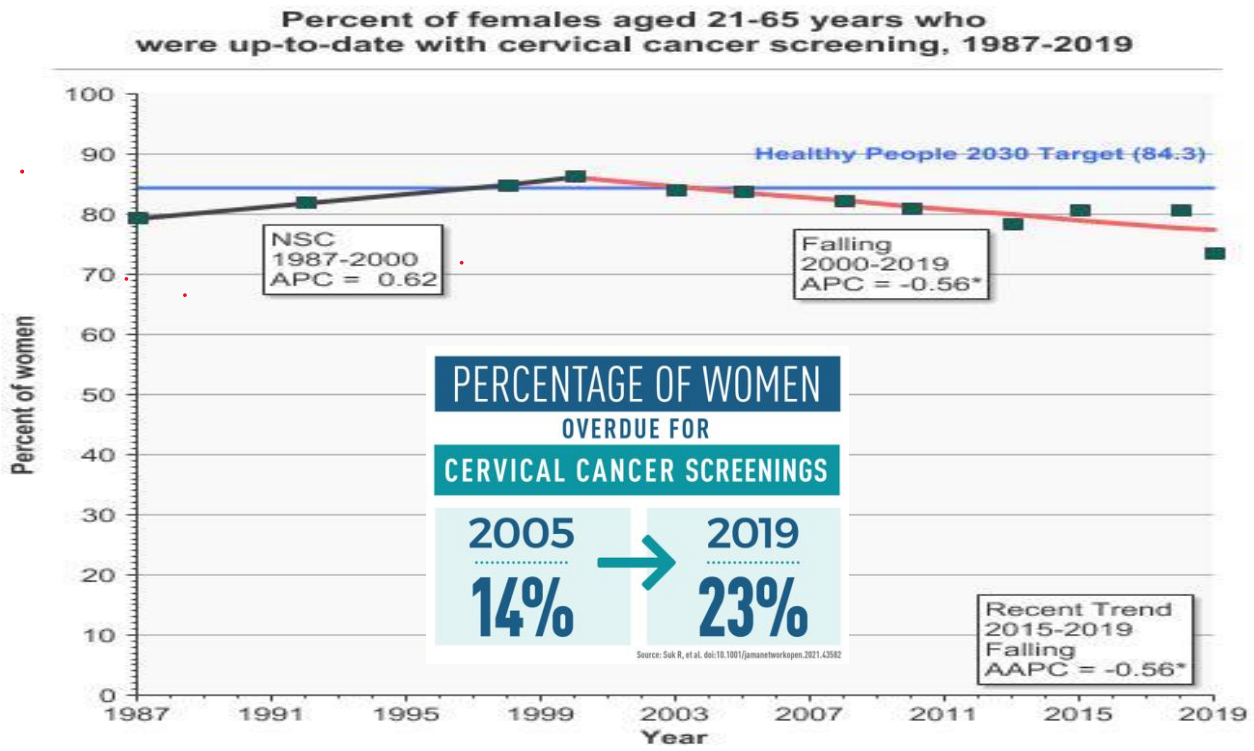
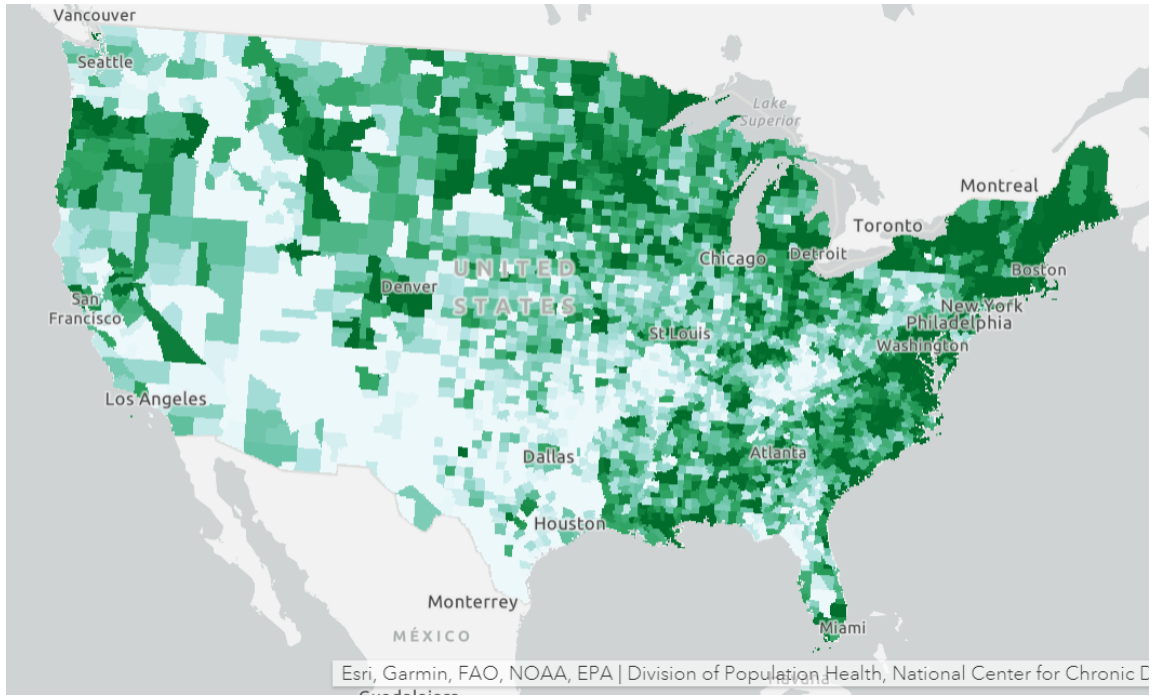
Cervical cancer screening coverage has declined.





Rates of overdue cervical cancer screening in 2019 by sociodemographic group

Racial and ethnic groups	
Non-Hispanic Black	22%
Non-Hispanic White	20%
Other (including Alaska Native and American Indian)	27%
Georgraphic groups	
Rural women	26%
Urban women	23%
Health insurance status	
Uninsured	42%
Public insurance	28%
Private insurance	18%

And the disparities are *profound.*

NCI, 2021
CDC Cancer Statistics Visualizations, 2022
Suk et al, Lancet Public Health, 2022

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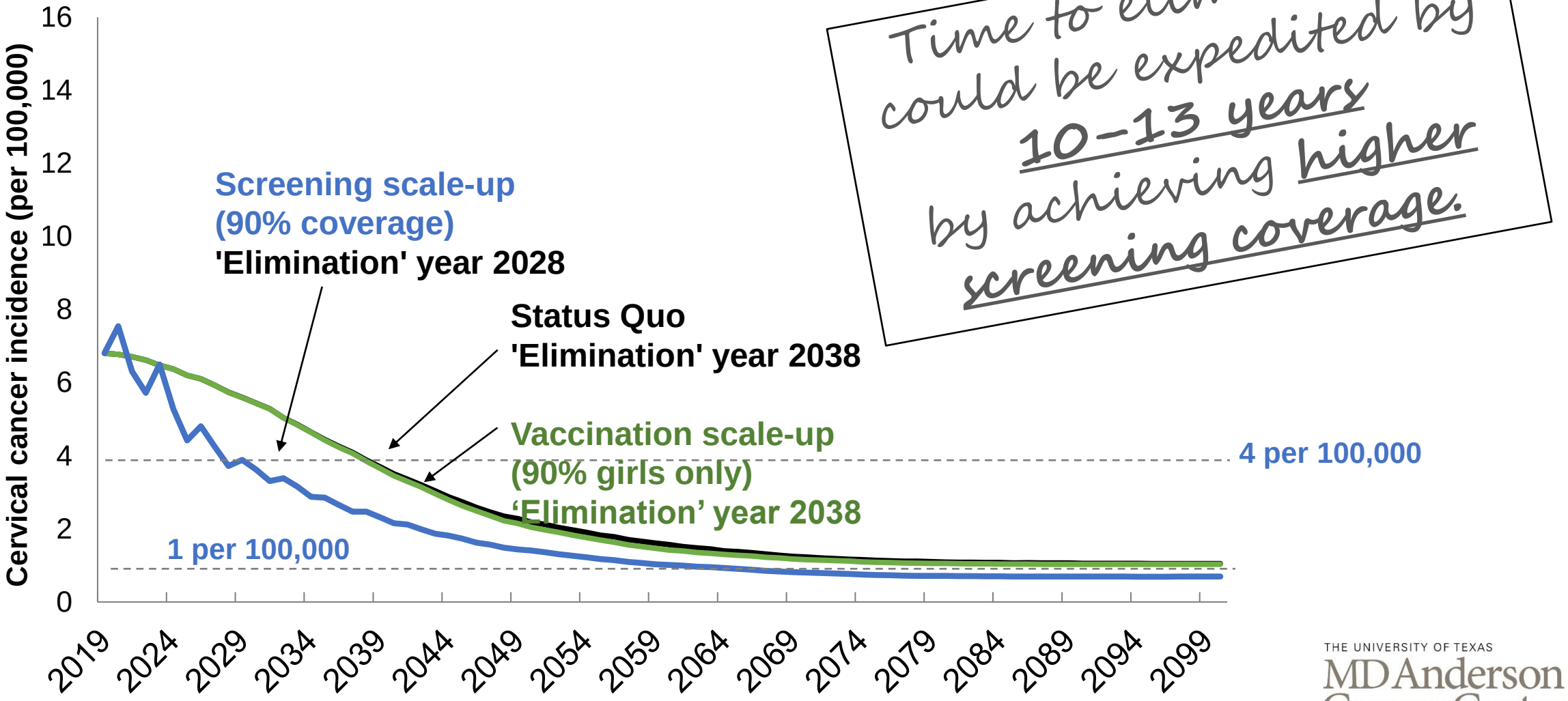
Nonetheless, the U.S. can eliminate cervical cancer as a public health problem in the next two to three decades.



Time to elimination could be expedited by 10–13 years by achieving higher screening coverage.

Burger et al, Lancet Public Health, 2020

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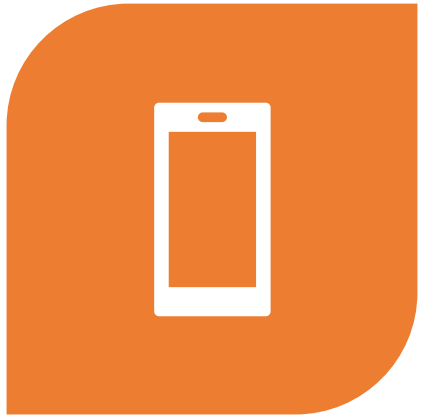
How are we going to get there?



HARNESS INNOVATIONS

ACCELERATE AND SCALE-UP IMPLEMENTATION

FOCUS ON EQUITY

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Several test options according to the current *Cervical Cancer Screening Guidelines**

Pap Smear (cytology)	Pap Smear/High Risk HPV Co-test	PRIMARY High Risk HPV TEST *(Preferred)*
• 21-65 Years • Every 3 Years	• 30-65 Years • Every 5 Years	• 25-65 Years • Every 5 Years

Shifting Paradigm to Primary HPV

Primary HPV screening tests for HPV first, followed by a triage test such as cytology, colposcopy, and/or HPV genotyping if the initial test is positive.

Shifting Paradigms:

Primary HPV testing is superior to cytology in terms of:

- Improved sensitivity for CIN3+ over cytology alone (↑ detection by 50%)
  (Minimally lower sensitivity over co-testing for CIN3+, but not for cancer diagnosis*)
- High negative predictive value → high reassurance rate for women with a negative HR-HPV test
- Ability to be conducted on self-collected samples
- Improved access

*Gage JC et al, J Natl Cancer Inst, 2014
Arbyn et al, Lancet Oncol, 2018

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But still certain trade-offs to acknowledge

Lack of specificity

- Triage test needed to determine management of HPV+

Requires integrated infrastructure to assure appropriate follow-up of test results

Only 2 FDA-approved tests

- Many health systems are currently using an HPV testing assay that is approved from co-testing but not primary HPV testing

Slide borrowed from Debbie Saslow, PhD, ACS

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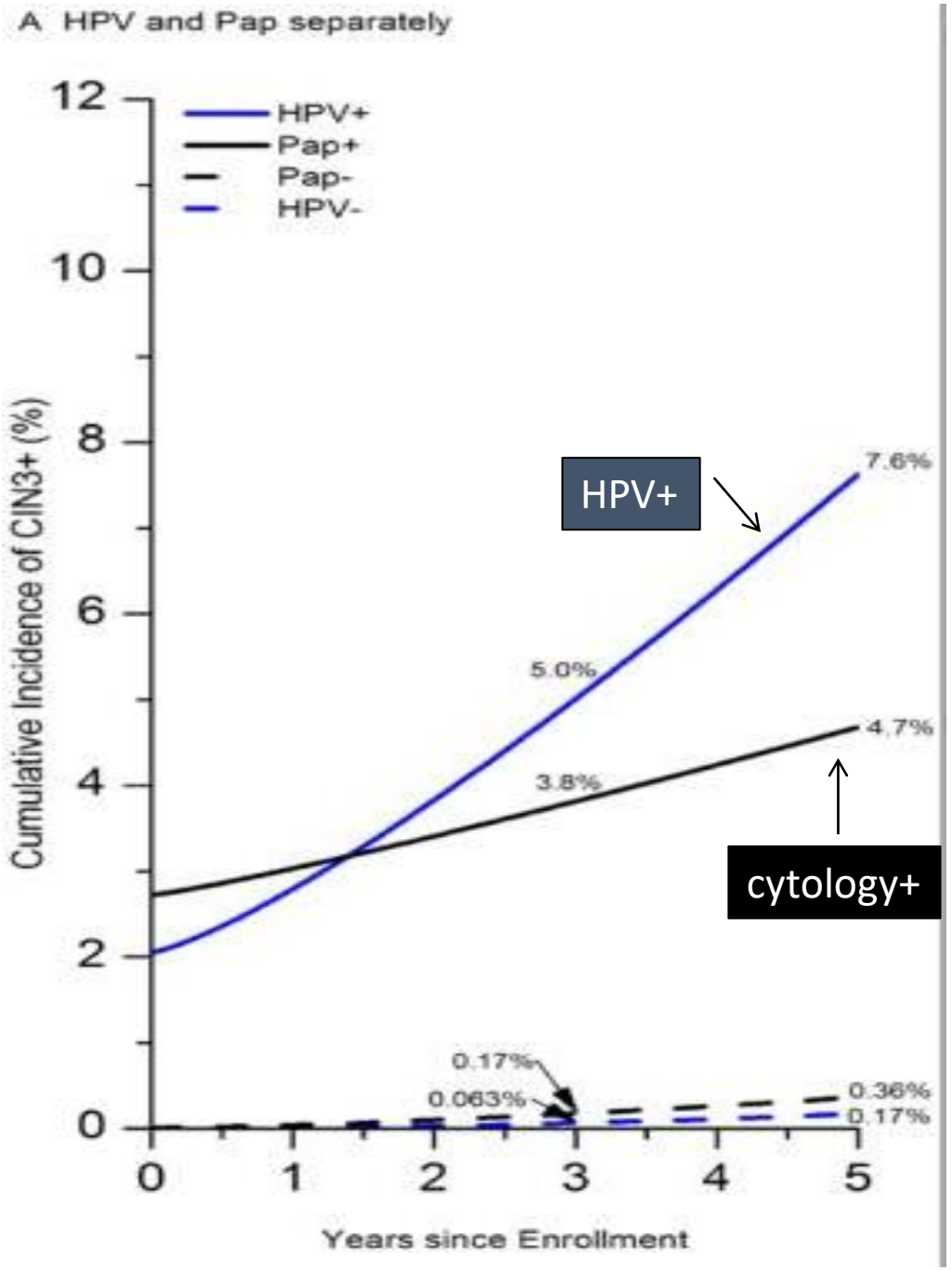
Primary HPV testing predicts risk of CIN3+ better than cytology



Katki et al, J Low Genit Tract Dis. 2013
Slide adapted from Debbie Saslow, PhD, ASC

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Primary HPV Screening is the Most Cost-Effective Approach

Modeling study based on 99,549 patients with co-testing followed over 3 years.

Screening Modality	Cases of CIN3+ Detected	Number of Colposcopies	Cost
Primary HPV Screening	294	2422	$3.47 M
Primary Cytology	285	2966	$4.80 M
Cotesting	308	2988	$5.85 M

Jin XW, et al. J Gen Intern Med. 2016 | Slide adapted from Debbie Saslow, PhD, ACS.

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Current Screening Guidelines for Average-risk Individuals

	American College of Obstetricians and Gynecologists (ACOG), 2020	US Preventive Services Task Force (USPSTF), 2018	American Cancer Society (ACS), 2020
Age to start screening	**21**		**25**
Screening test options and intervals	**Ages 21-65:** Cytology alone every 3 years OR **Ages 21-29:** Cytology alone every 3 years **Ages 30-65:** Cytology plus HPV testing every 5 years OR **Ages 21-29:** Cytology alone every 3 years **Ages 30-65:** HPV testing alone every 5 years		**Ages 25-65+ Preferred:** HPV testing alone every 5 years OR **Acceptable:** Either Cytology plus HPV testing every 5 years OR Cytology alone every 3 years
Age to end screening	**65** if 3 consecutive negative Pap tests OR 2 negative cytology plus HPV tests OR 2 negative HPV tests AND no abnormal tests within the prior 10 years with the most recent within the prior 5 years AND no CIN2+ within the prior 25 years		

Slide adapted from Debbie Saslow, PhD, ACS.

Shifting Paradigms:

Primary HPV testing is superior to cytology in terms of:

- Improved sensitivity for CIN3+ over cytology alone (↑ detection by 50%)
  (Minimally lower sensitivity over co-testing for CIN3+, but not for cancer diagnosis*)
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- Ability to be conducted on self-collected samples
- Improved access

*Gage JC et al, J Natl Cancer Inst, 2014
Arbyn et al, Lancet Oncol, 2018

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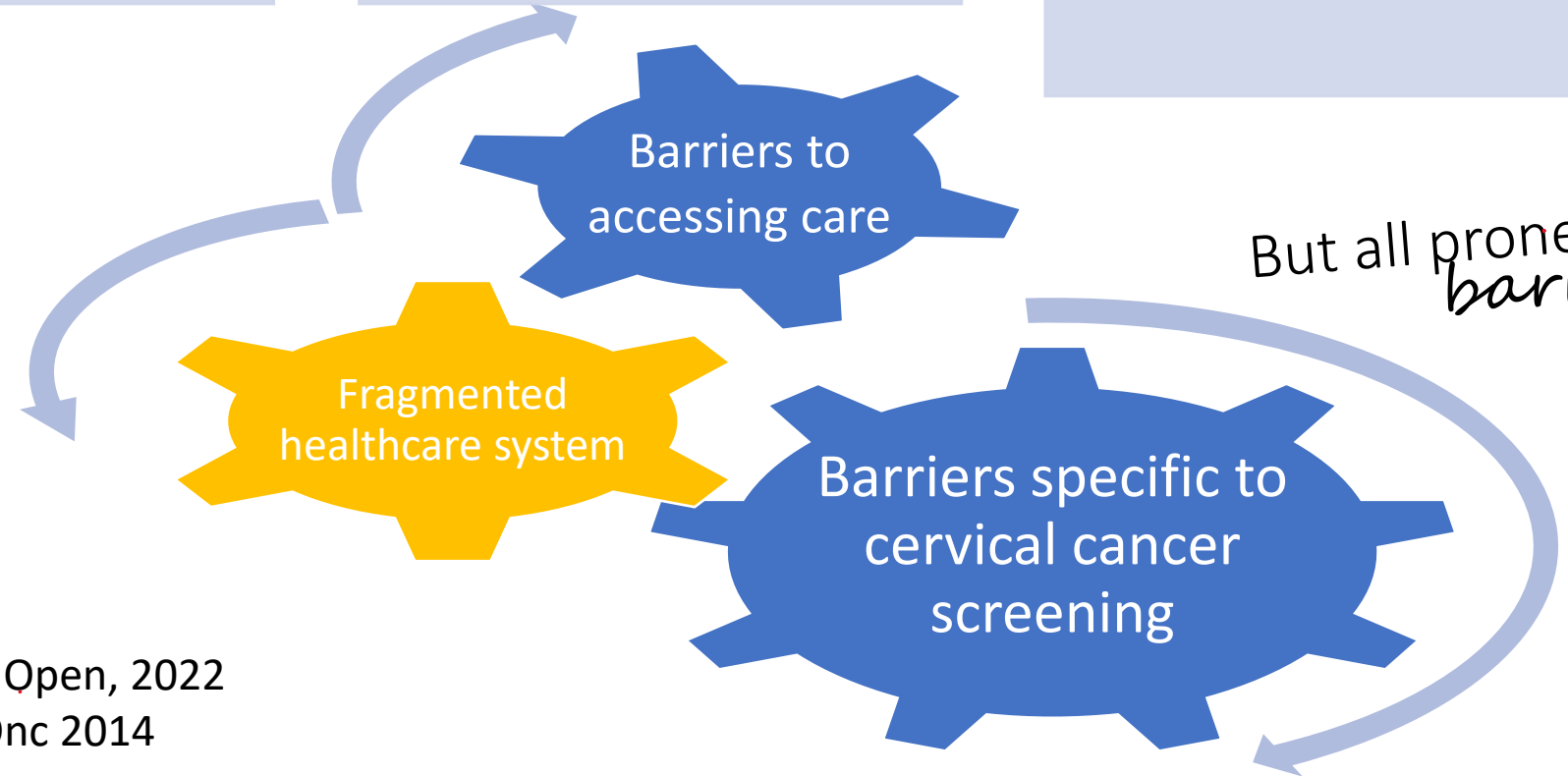
Currently, there are several test options

Pap Smear	Pap Smear/High Risk HPV Co-test	PRIMARY High Risk HPV TEST (*Preferred*)
• 21-65 Years • Every 3 Years	• 30-65 Years • Every 5 Years	• 25-65 Years • Every 5 Years



But all prone to the same *barriers to Screening*

Suk et al, JAMA Network Open, 2022
Montealegre et al, Gyn Onc 2014

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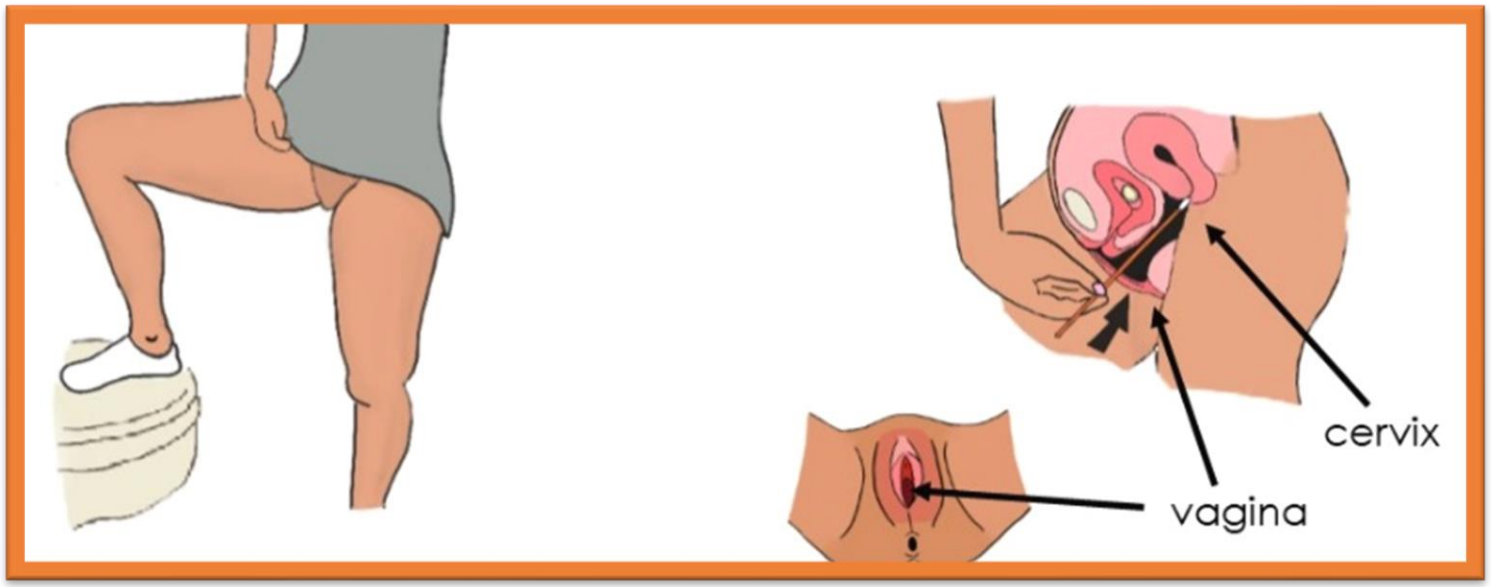
It's time

Pap Smear	Pap Smear/High Risk HPV Co-Testing
• 21-65 Years • Every 3 Years	• 30-65 Years • Every 5 Years

Paradigm Shift

PRIMARY High Risk HPV TESTING (Preferred)

- 25-65 Years
- Every 5 Years
- ***Performed on samples collected by a provider or by self***



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What is the evidence for self-sample HPV testing?

Sensitivity and specificity of self-sample HPV test is similar to provider-collected HPV test

Relative parameters, comparing HPV testing with self- versus provider-collected samples

Assay	Clinical Endpoint	# studies	Ratio (95% CI)			
			Sensitivity	Specificity	Test positivity	Positive Predictive Value
PCR	CIN2+	17	0.99 (0.97-1.02)	0.98 (0.97- 0.99)	1.00 (0.94-1.06)	0.97 (0.90-1.04)
	CIN3+	8	0.99 (0.96-1.02)	0.98 (0.97-0.99)		0.90 (0.78-1.05)

	Pooled Estimates
Sensitivity	
Self-collected	96%
Provider-collected	96%
Specificity	
Self-collected	79%
Provider-collected	79%

Pooled sensitivity and specificity using PCR Assays

Arbyn et al, Lancet Oncol, 2018

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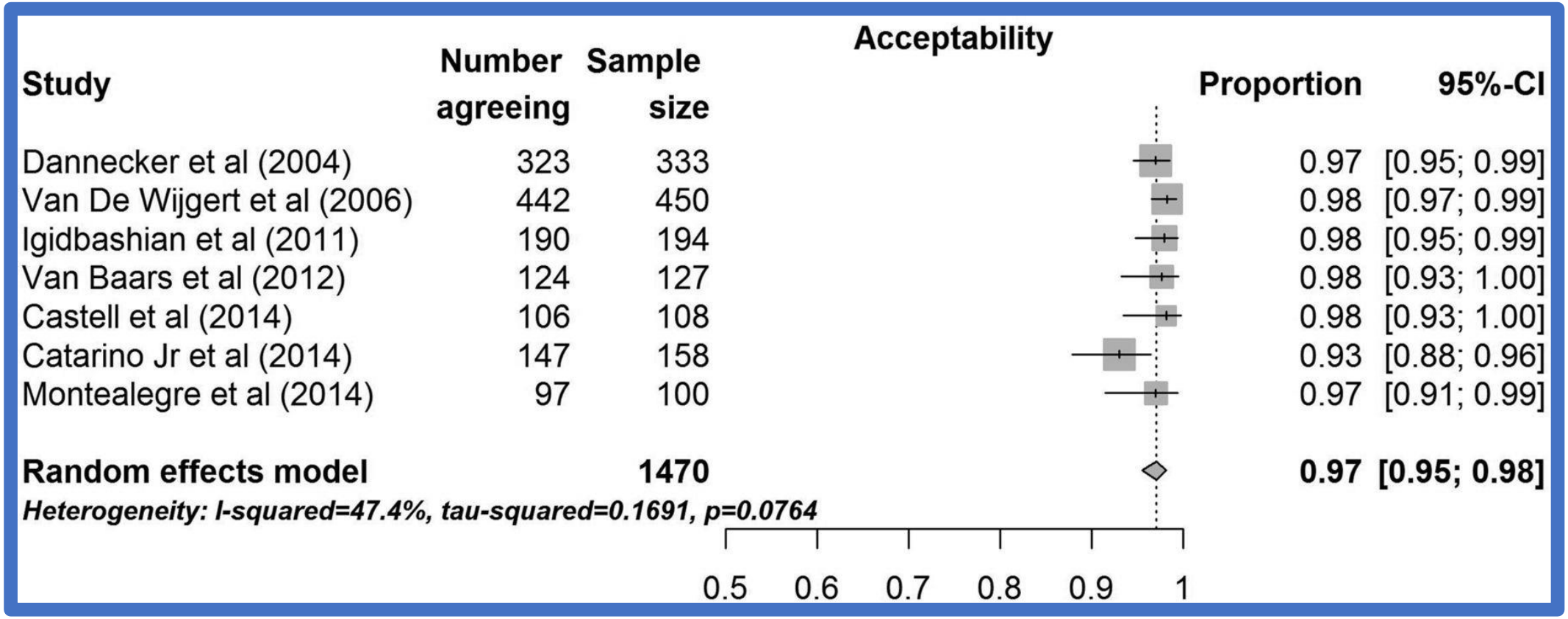
Self-sampling is highly acceptable to women.



Nelson et al, Sex Transm Infect, 2017

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Self-Sampling Increases Participation in Cervical Cancer Screening

	Self-Sampling Participation	Control Participation	Difference	Relative Participation
Mailed kits	24%	10%	13%	2.5
Door-to-Door	93%	53%	39%	1.9
Offer at Clinic	50%	22%	28%	2.3

Pooled relative participation:
2-fold increase

Costa et al, Br J Cancer, 2022

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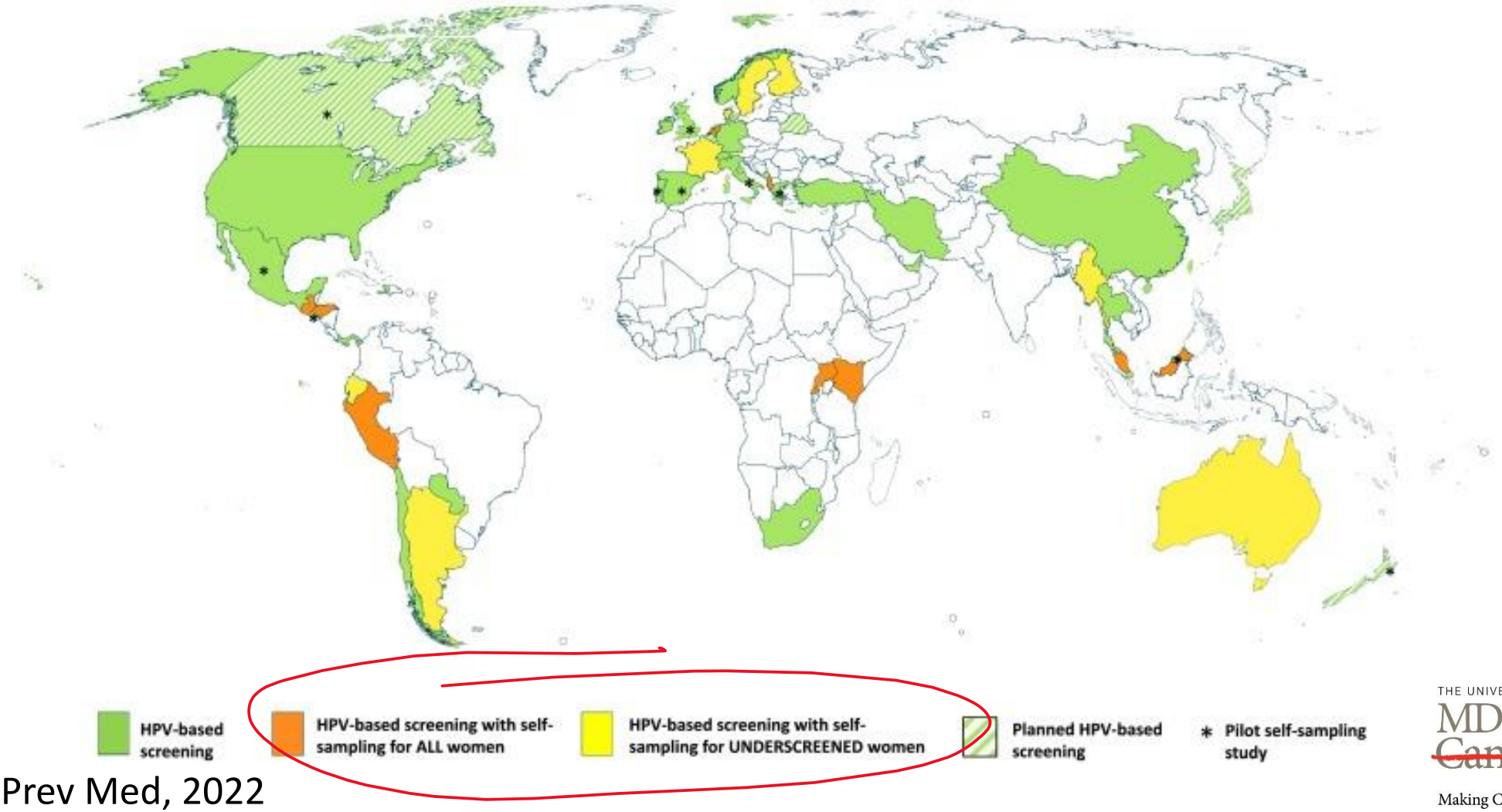
Increasingly used in national cervical cancer screening programs

Self-Sampling in National Cervical Cancer Screening Programs



Serrano et al, Prev Med, 2022

Regulatory Landscape of Self-Sampling in the U.S.

Goal: FDA approval of home-based self-sampling

‘Last Mile’ Initiative by National Cancer Institute

Public-private partnership to validate at-home self-sample HPV testing for FDA approval

SHIP Trial: **S**elf-Sampling for **H**PV to **I**mprove **P**revention of Cervical Cancer

Anticipated FDA approval: 2024-2025 (?)

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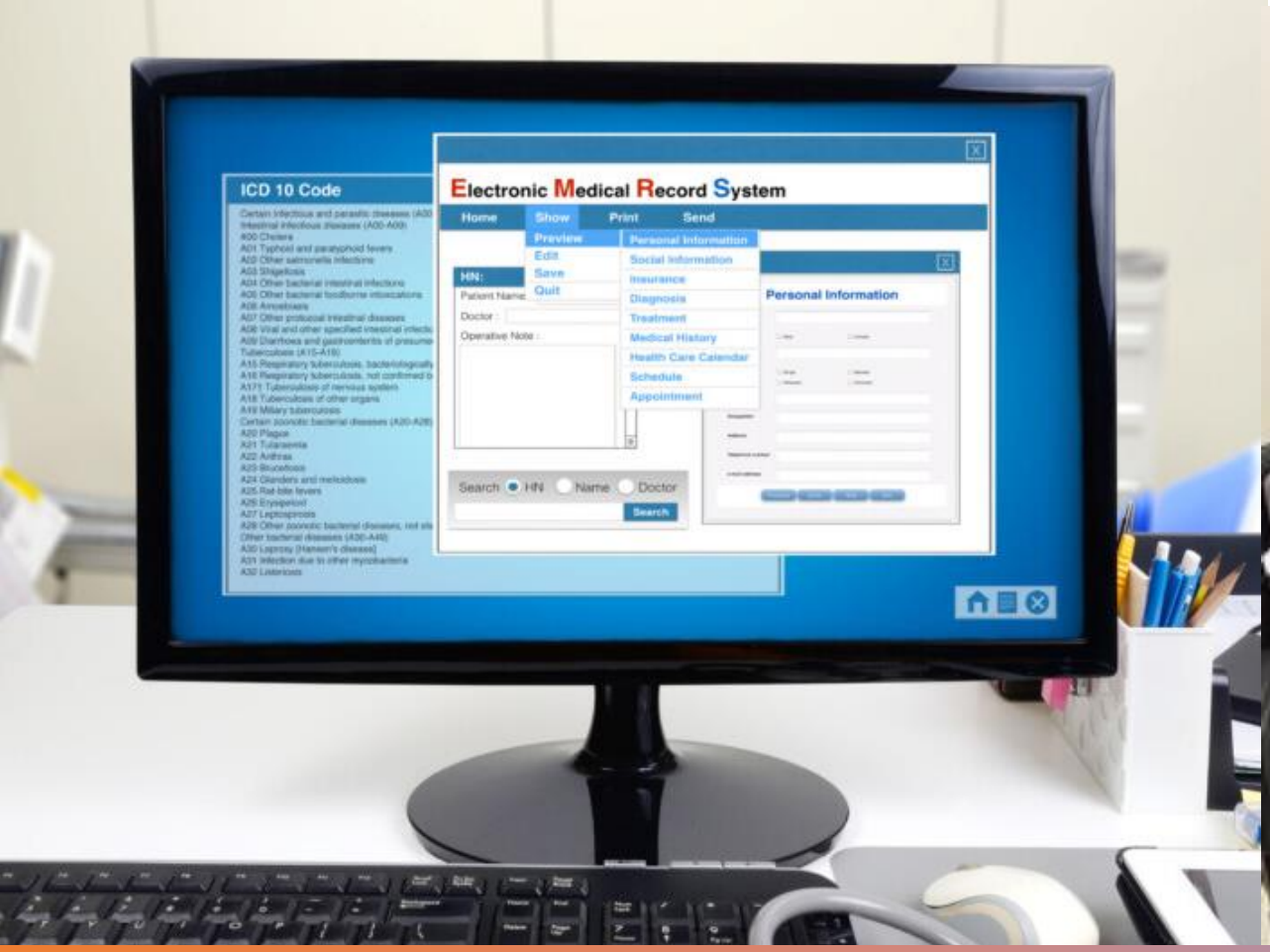
New possibilities.

At-home screening



New possibilities:

Opportunistic Clinic-Based Self-Sampling

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New possibilities:
Community-based screening

Montealegre et al, J Immigr Minor Health 2014

Erin Kobetz, PhD, University of Miami

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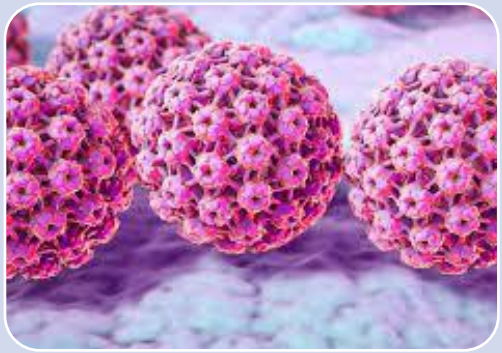
How do we prepare?



Facilitate adoption and integration of primary HR-HPV testing

Build collaborative networks, capacity at decentralized facilities, and access to patient navigation to ensure clinical follow-up

Implement contextually-relevant strategies to ensure broad and equitable reach of primary HR-HPV Testing

Develop new technologies to dramatically and equitably increase access

Develop contextually-relevant strategies

PRESTIS Study

Mailed self-sample HPV testing for underscreened patients in a safety net health system

Montealegre et al. Trials 2020

Funding: NIMHD R01MD30175 (Montealegre)

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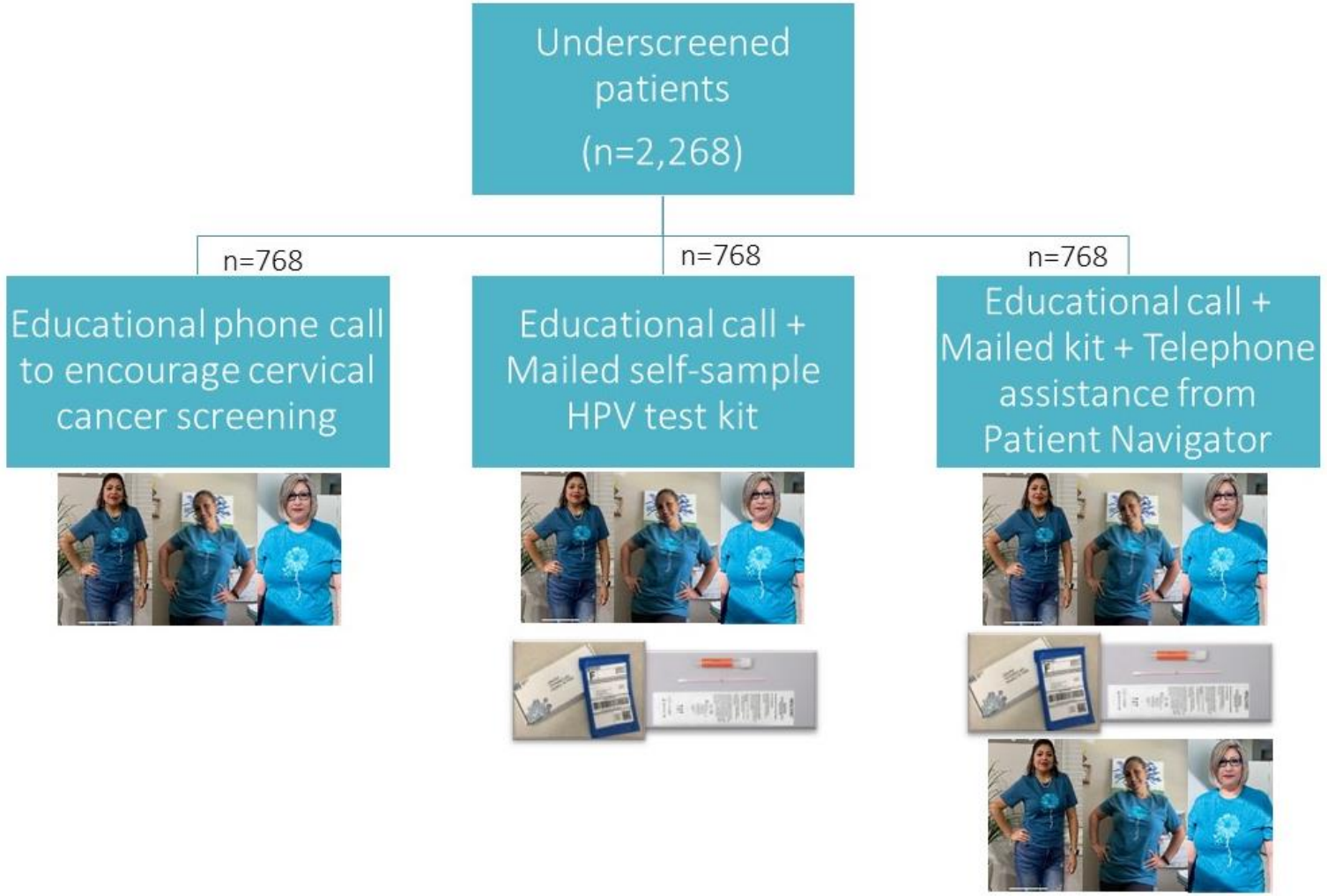
Develop contextually-relevant strategies



PRESTIS Study

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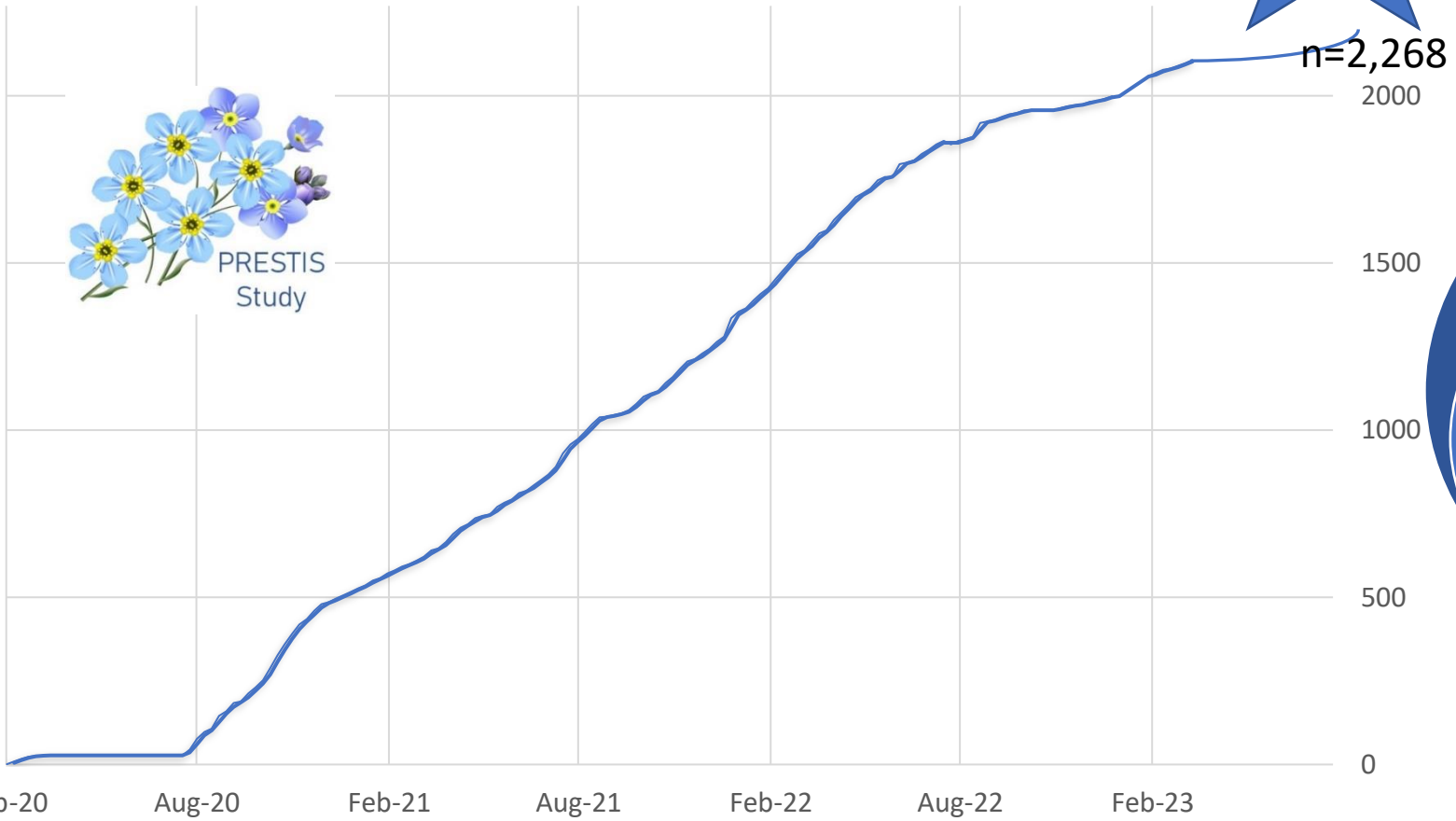
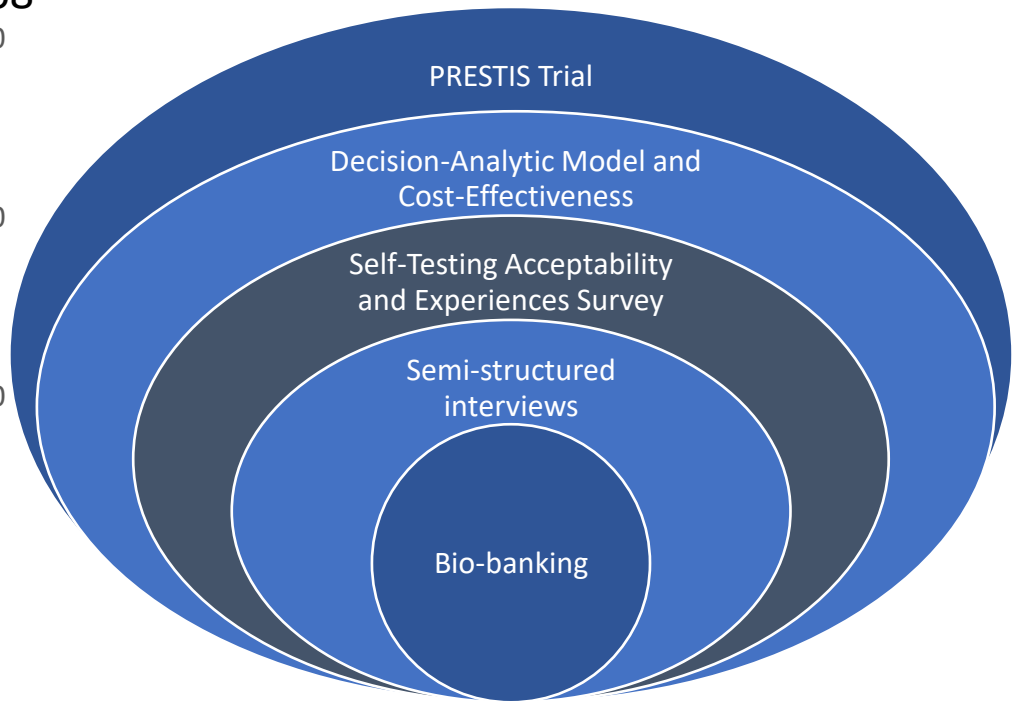
Develop contextually-relevant strategies

100 %





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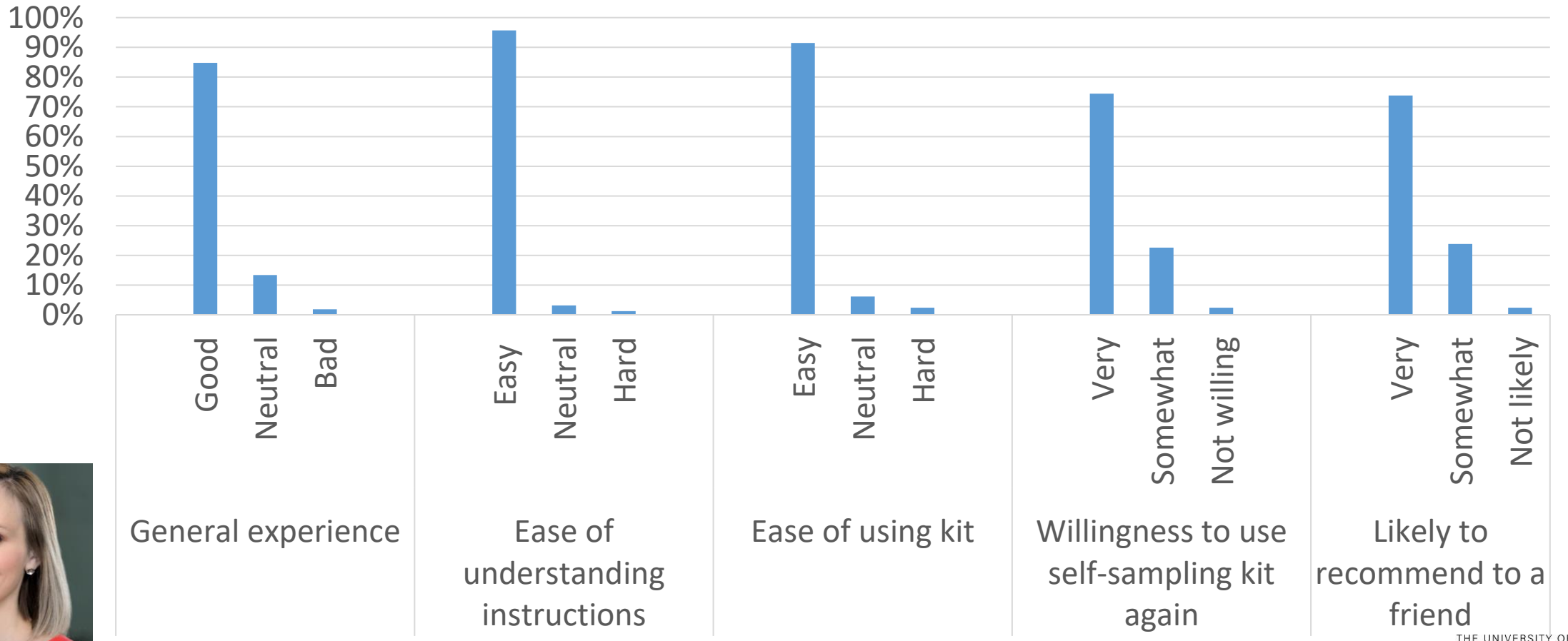
Develop contextually-relevant strategies



Susan Parker, MPH

Parker SL et al, Elife, 2023; Parker SL et al Amer J Prev Med, *Under Review*

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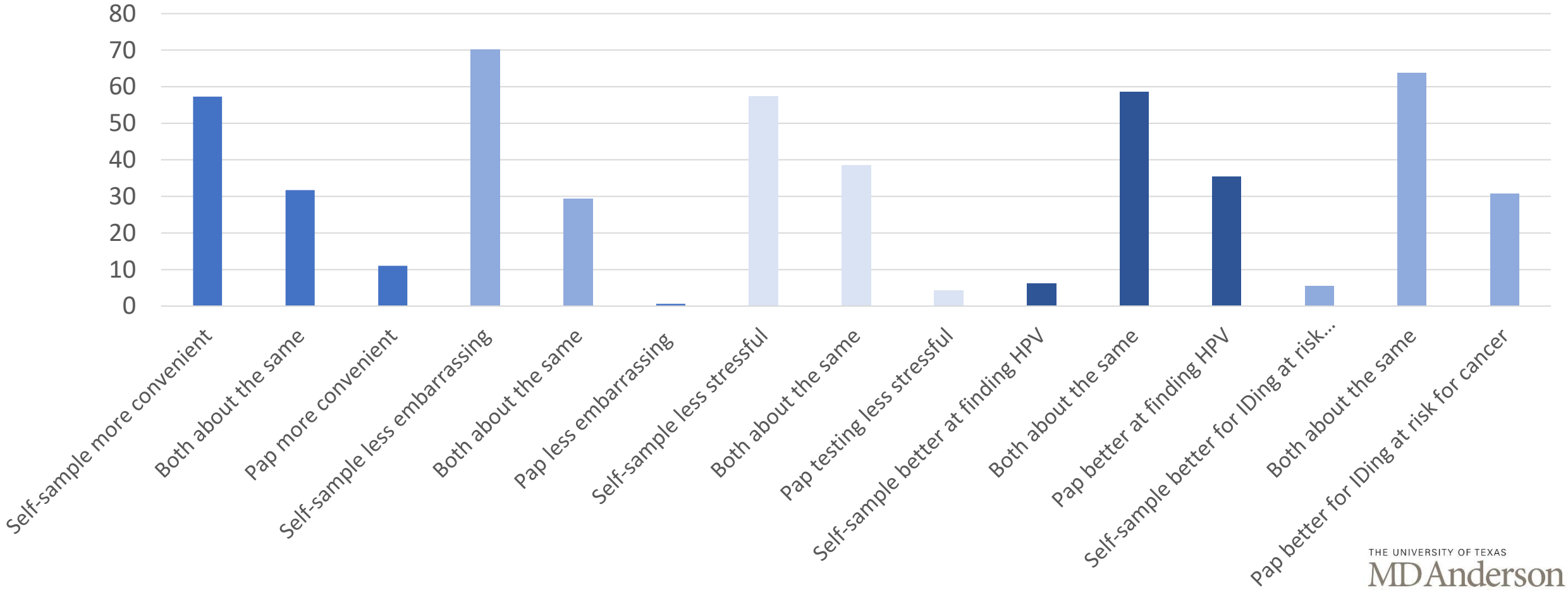
Develop contextually-relevant strategies



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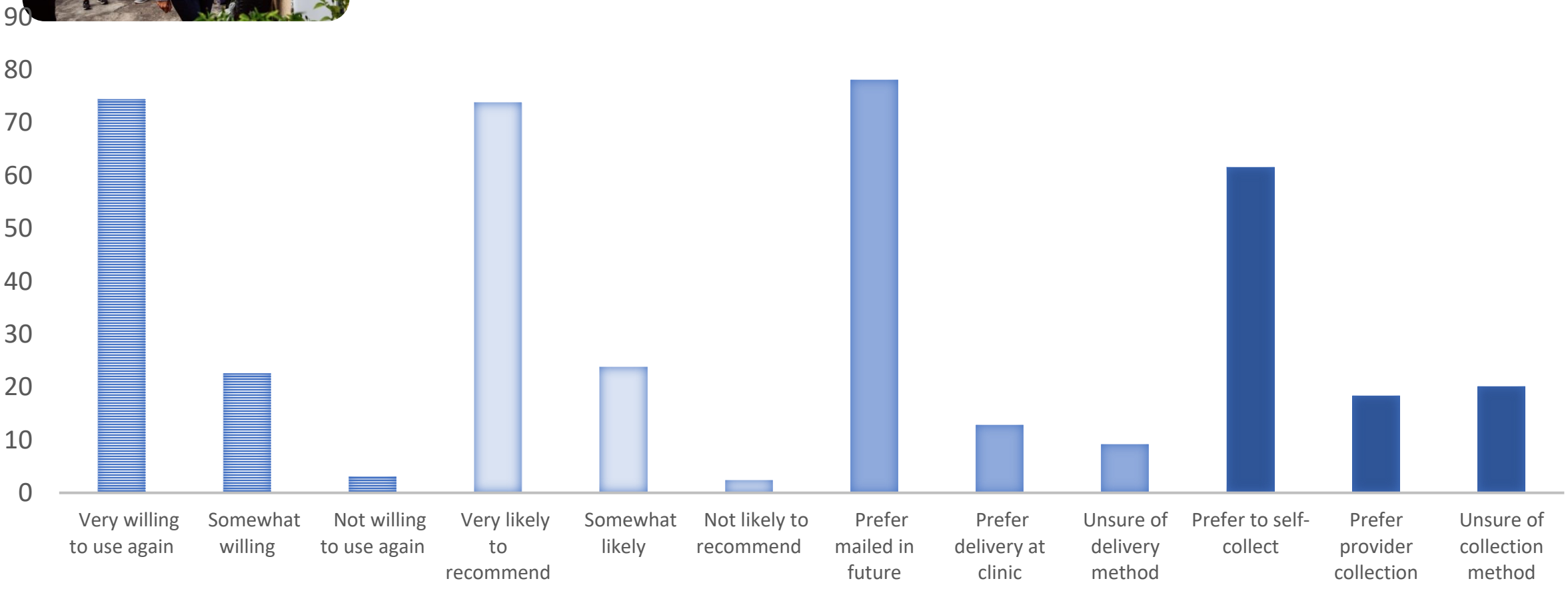
Develop contextually-relevant strategies



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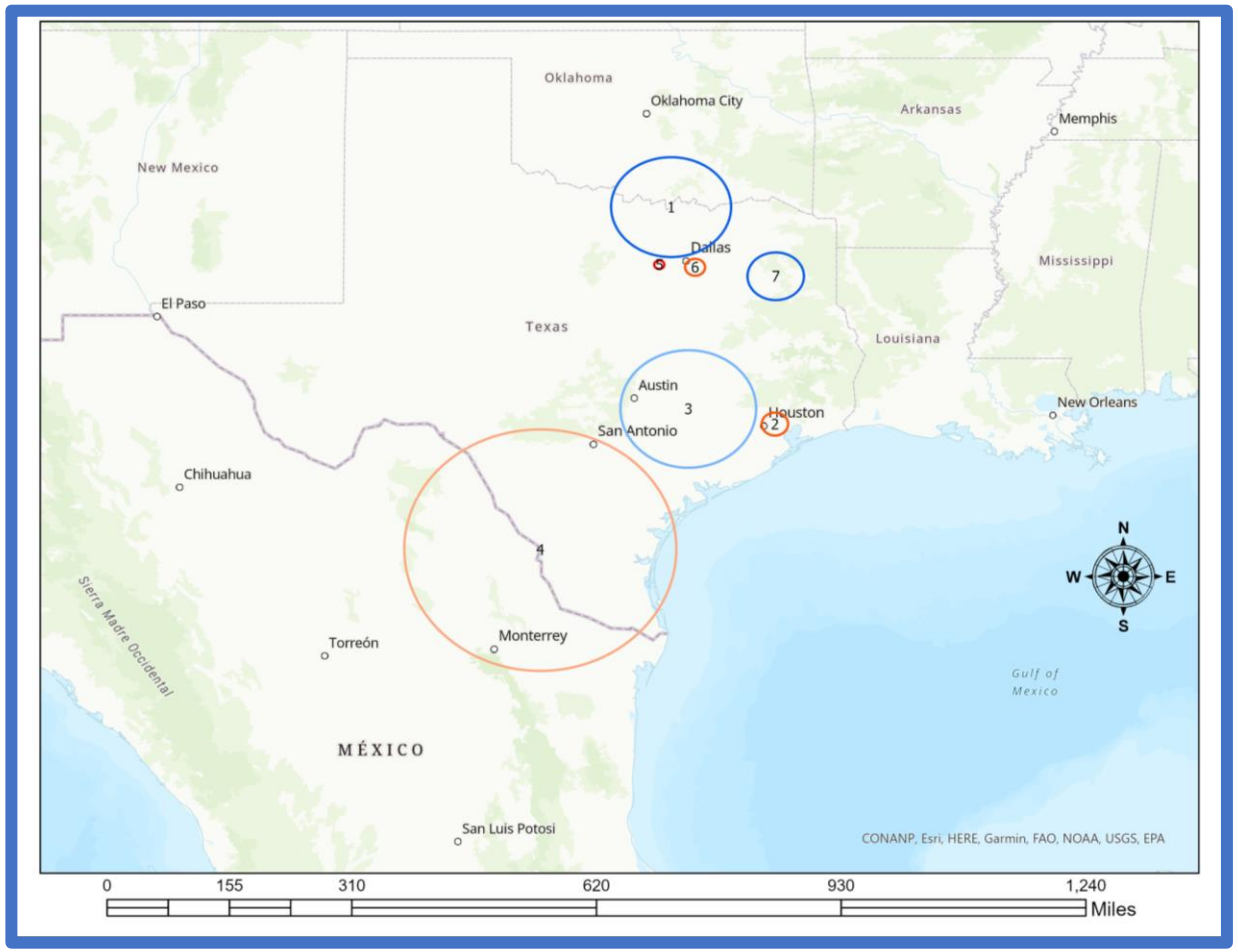
Develop contextually-relevant strategies



Pilot Study: Self-Sampling in Public Emergency Departments

Itunu Sokale, PhD, CPRIT Postdoctoral Fellow

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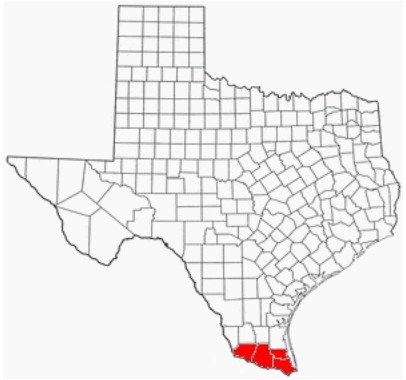
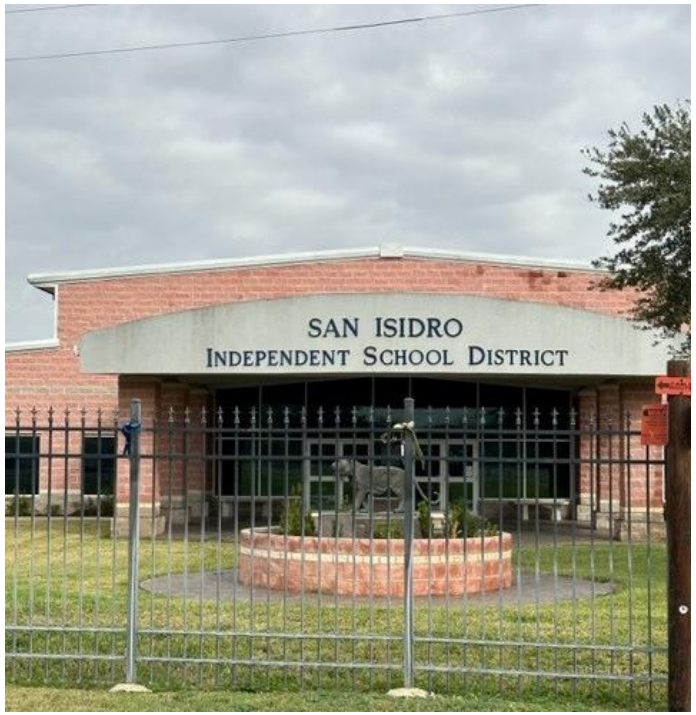
Develop and test contextually-relevant strategies





Prevención en sus manos

Prevencion en sus Manos

Funding: MD Anderson Community Outreach and Engagement Fund for Underserved Texans (Montealegre)

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Develop contextually-relevant strategies

Research and demonstration projects in this area are critical

- How do we use self-sampling in outreach?
- What are effective strategies to implement self-sampling?
- How do we ensure clinical follow-up?
- What strategies are cost-effective?
- How do we integrate self-sampling in clinical settings?
- What are effective communication strategies?

Texas can and should lead the way!

CPRIT

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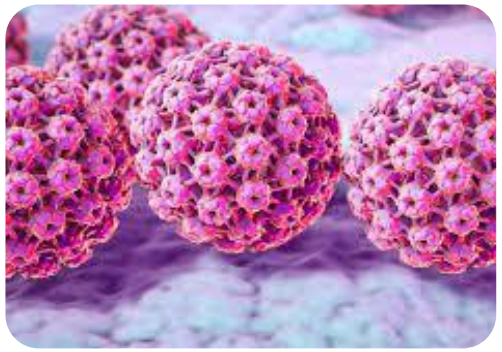


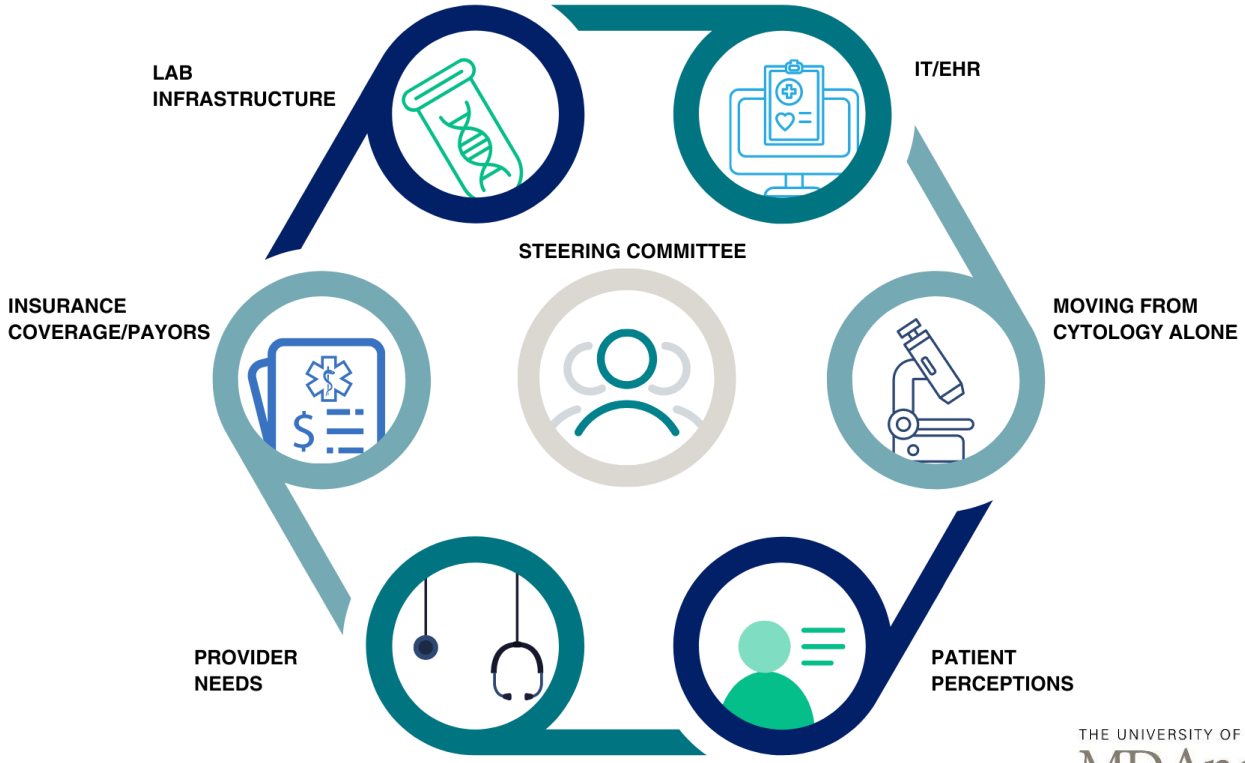
Adopt and Integrate Primary HPV Testing

American Cancer Society | National Roundtable on Cervical Cancer

Primary HPV Screening Initiative

- Create a **comprehensive roadmap with recommendations and tools** to support the transition to primary HPV screening in the United States over the coming years as described in the ACS Cervical Cancer Screening Guideline (2020)

- Determine the actors who will be responsible for implementation



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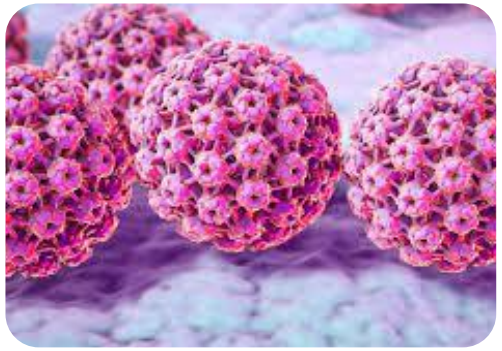
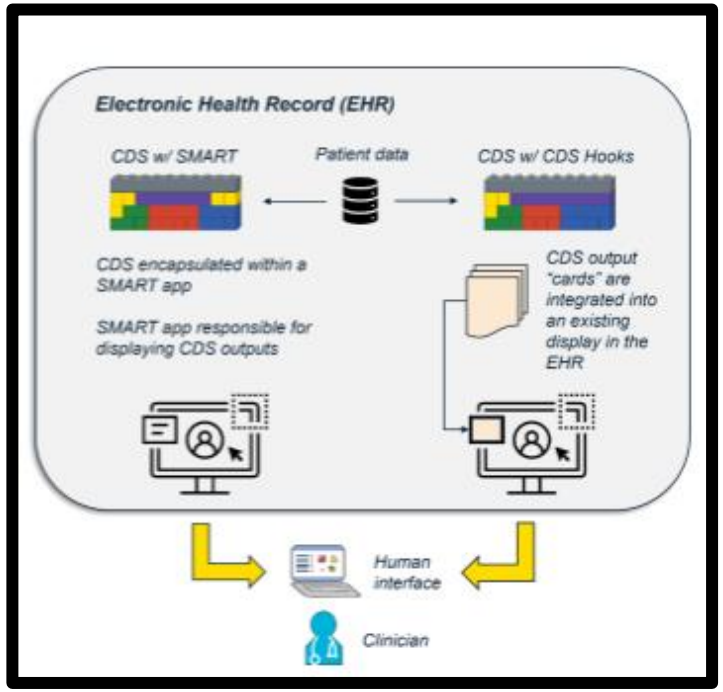
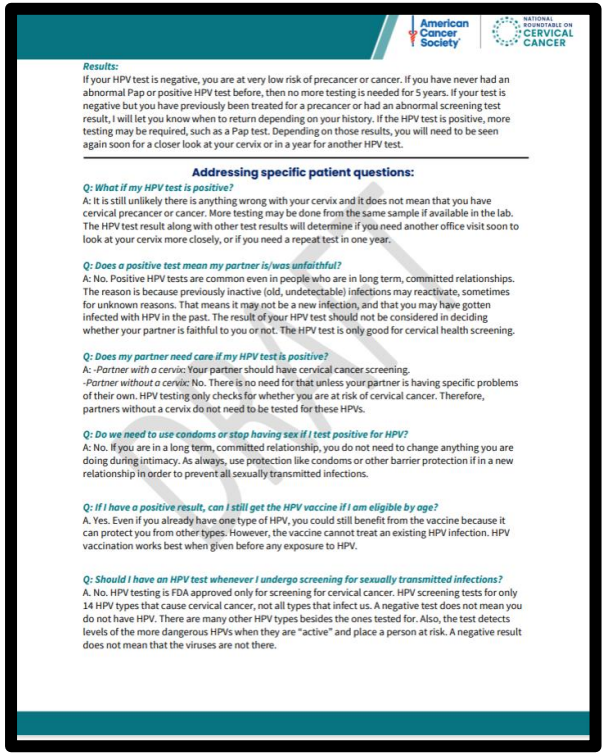


Adopt and Integrate Primary HPV Testing

- Patient/Consumer Education (51.62%)
- Provider/Clinician Education (51.11%)
- Stigma (46.51%)
- Primary HPV/ Self-Sampling Prep (45.94%)
- Access (44.44%)





Results:
If your HPV test is negative, you are at very low risk of precancer or cancer. If you have never had an abnormal Pap or positive HPV test before, then no more testing is needed for 5 years. If your test is negative but you have previously been treated for a precancer or had an abnormal screening test result, I will let you know when to return depending on your history. If the HPV test is positive, more testing may be required, such as a Pap test. Depending on those results, you will need to be seen again soon for a closer look at your cervix or in a year for another HPV test.

Addressing specific patient questions:

Q: What if my HPV test is positive?
A: It is still unlikely there is anything wrong with your cervix and it does not mean that you have cervical precancer or cancer. More testing may be done from the same sample if available in the lab. The HPV test result along with other test results will determine if you need another office visit soon to look at your cervix more closely, or if you need a repeat test in one year.

Q: Does a positive test mean my partner is/was unfaithful?
A: No. Positive HPV tests are common even in people who are in long term, committed relationships. The reason is because previously inactive (old, undetectable) infections may reactivate, sometimes for unknown reasons. That means it may not be a new infection, and that you may have gotten infected with HPV in the past. The result of your HPV test should not be considered in deciding whether your partner is faithful to you or not. The HPV test is only good for cervical health screening.

Q: Does my partner need care if my HPV test is positive?
A: *-Partner with a cervix:* Your partner should have cervical cancer screening.
-Partner without a cervix: No. There is no need for that unless your partner is having specific problems of their own. HPV testing only checks for whether you are at risk of cervical cancer. Therefore, partners without a cervix do not need to be tested for these HPVs.

Q: Do we need to use condoms or stop having sex if I test positive for HPV?
A: No. If you are in a long term, committed relationship, you do not need to change anything you are doing during intimacy. As always, use protection like condoms or other barrier protection if in a new relationship in order to prevent all sexually transmitted infections.

Q: If I have a positive result, can I still get the HPV vaccine if I am eligible by age?
A. Yes. Even if you already have one type of HPV, you could still benefit from the vaccine because it can protect you from other types. However, the vaccine cannot treat an existing HPV infection. HPV vaccination works best when given before any exposure to HPV.

Q: Should I have an HPV test whenever I undergo screening for sexually transmitted infections?
A. No. HPV testing is FDA approved only for screening for cervical cancer. HPV screening tests for only 14 HPV types that cause cervical cancer, not all types that infect us. A negative test does not mean you do not have HPV. There are many other HPV types besides the ones tested for. Also, the test detects levels of the more dangerous HPVs when they are "active" and place a person at risk. A negative result does not mean that the viruses are not there.

What CPT code is used for high-risk HPV testing for primary screening?	Is CPT 87624 a Category I code?	What is the 2023 Medicare Payment Rate for CPT code 87624?
CPT code 87624.	**Yes, CPT 87624 is a Category I CPT code.**	**The 2023 Medicare Payment Rate for CPT code 87624 is $35.09.**
Decisions about the specific code(s) to report are the responsibility of the performing laboratory.	Other categories of codes (e.g., Category III) may not be recognized by all payors and could create coverage and reimbursement challenges.	Medicaid and private payor reimbursement rates may vary.

DO'S	DON'TS
DO highlight technology and research advancements to support moving towards primary HPV screening.	DON'T stress that there is a test being taken away from the traditional screening paradigm (the Pap test).

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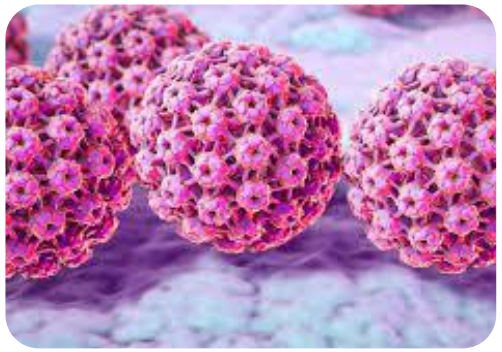

Adopt and Integrate Primary HPV Testing

Iterative process of developing an implementation roadmap:

- Demonstration projects in safety net health systems

Serve a large proportion in of socioeconomically disadvantaged individuals in the U.S.

Often serve predominantly racial/ethnic minority populations

Socioeconomically disadvantaged, racial/ethnic minority women shoulder a disproportionate burden of cervical disease.

CPRIT

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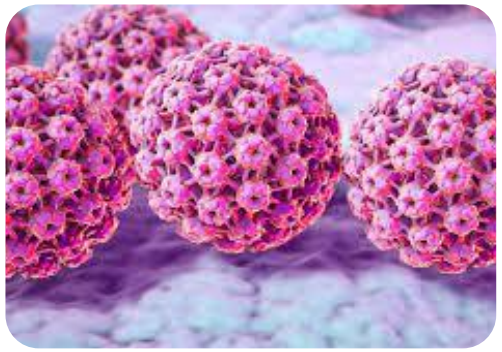

Adopt and Integrate Primary HPV Testing

Why safety nets?

Patient-level barriers:

- Language barriers
- Low literacy
- Unstable housing
- Distrust of healthcare system
- Access and economic barriers

System-level barriers:

- Significant resource constraints
- Patients with complex health needs (i.e., competing priorities)
- Unique payer mix
- High proportion of uninsured patients

If we don't design for safety nets health systems, they will be left behind and disparities will become exacerbated.

Implementation plans must be focused on equity.

Texas can and should lead the way!

CPRIT

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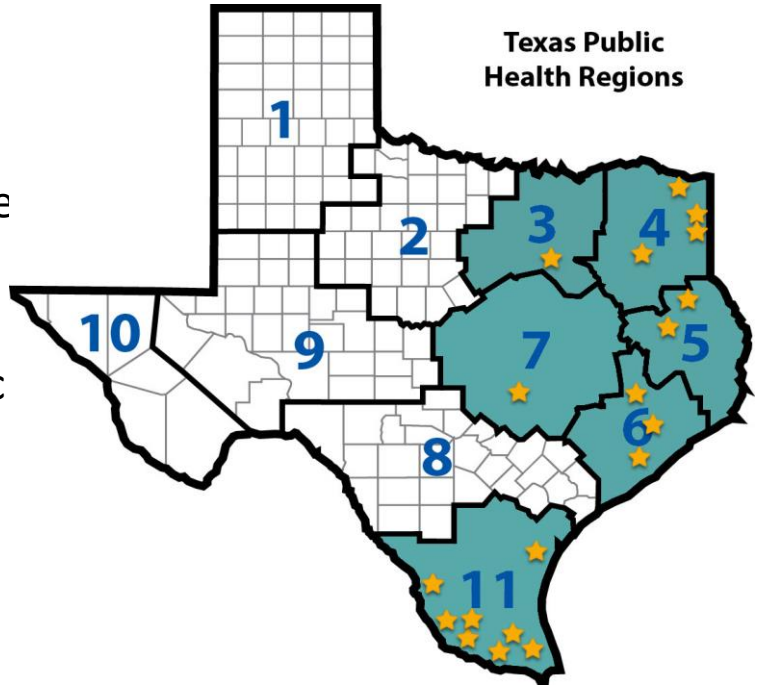
Build collaborative networks

CPRIT Investments have already started this

Program for Reducing Cervical Cancer

- Thirteen collaborating Federally Qualified Health Centers/Community Clinic/Mobile Clinic systems with 24 individual clinics Located in 16 countie in six Public Health Regions in Texas
- Five academic partners from UT System: UTHSC at Tyler, UTRGV School of Medicine, UTHSC School of Public Health Houston, UTHSC School of Public Health - Brownsville Regional Campus, UT Dell School of Medicine

CPRIT



Drs. Kathleen Schmeler, Ellen Baker, and Melissa Varon
CPRIT PP150012, PP190014, PP220037

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Build and decentralize capacity

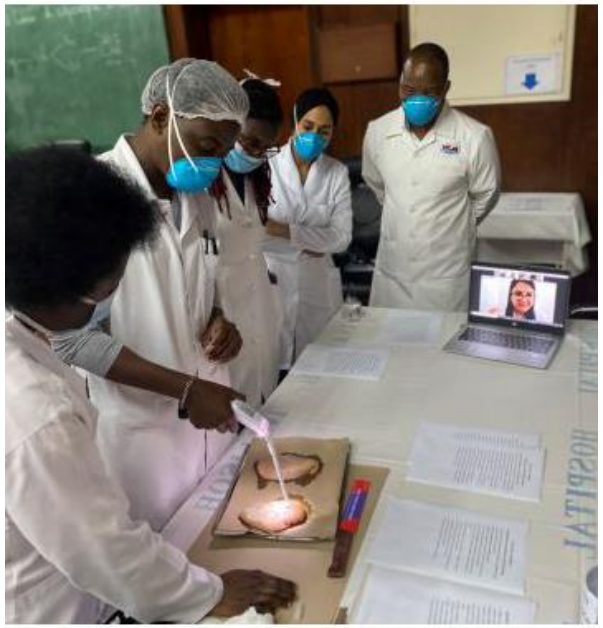
Project ECHO

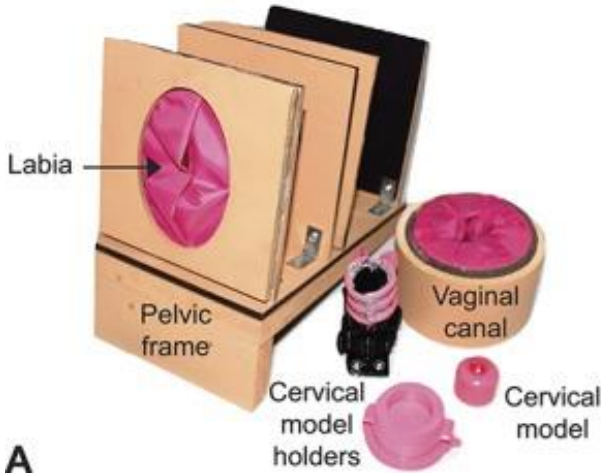
Extension for **C**ommunity **H**ealthcare **O**utcomes

Capacity building through telementoring

CPRIT

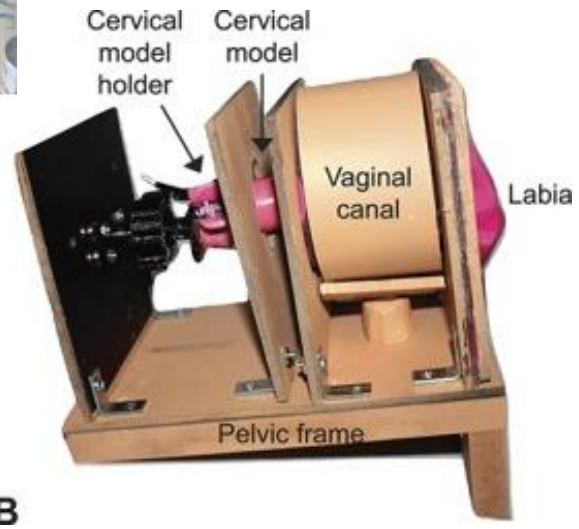
Build and decentralize capacity





Colposcopy capacity building

In local and regional safety net health systems



CPRIT PP150012, PP190014, PP220037 (PD: Schmeler)

Parra et al, Obstet Gynecol, 2019

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Build patient navigation programs

CPRIT

Ensure that persons with HPV + test receive appropriate follow-up for diagnosis and treatment

Program for Reducing Cervical Cancer
CPRIT PP150012, PP190014, PP220037
(PD: Schmeler)

Maria Daheri, RN and Patient Navigation Team
Harris Health System/Community Network for Cancer Prevention
CPRIT PP140028, PP17004, PP210007 (PDs: Montealegre, Jibaja-Weiss)

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Develop new technologies

Currently, two FDA-approved HPV tests

Expensive

Require sophisticated laboratory infrastructure

Roche cobas® HPV Test

BD Onclarity™ HPV Assay

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Develop new technologies

Critical need for point-of-care (POC) tests

Laboratory testing conducted close or at the site where patient care is provided.

Rapid
Precise
Low-cost
Require minimal training

Cepheid® Xpert ® HPV Test

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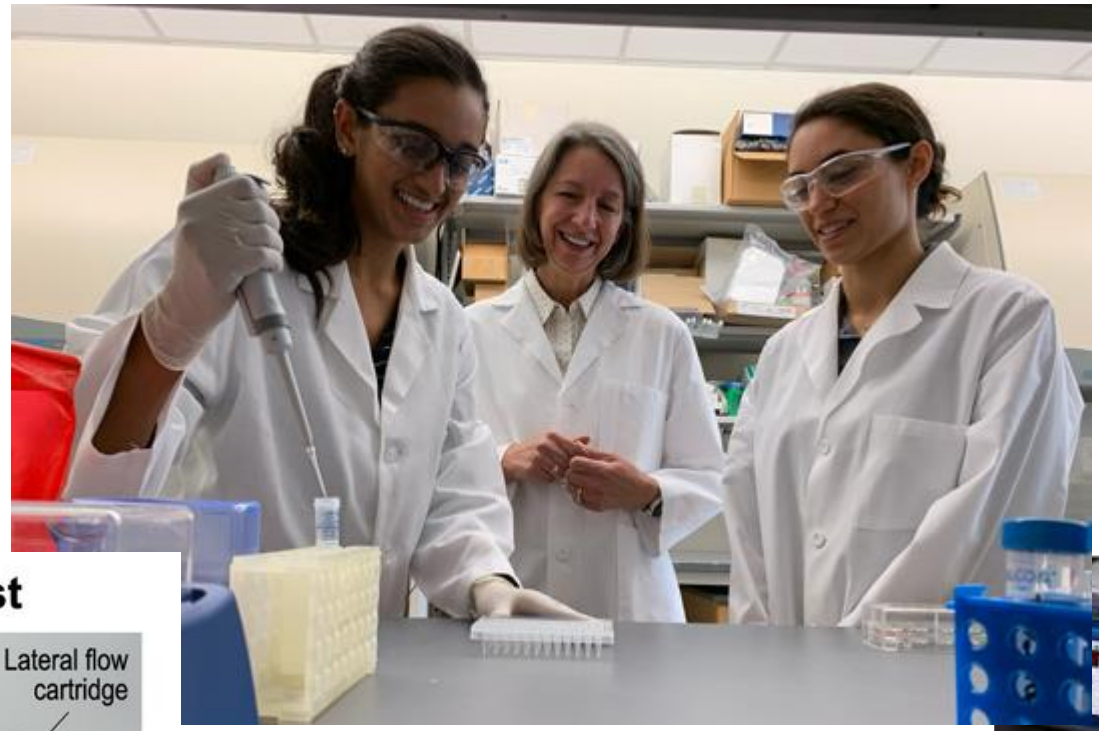
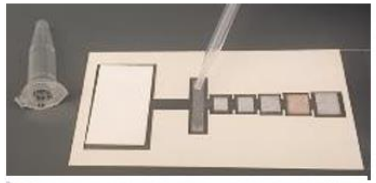
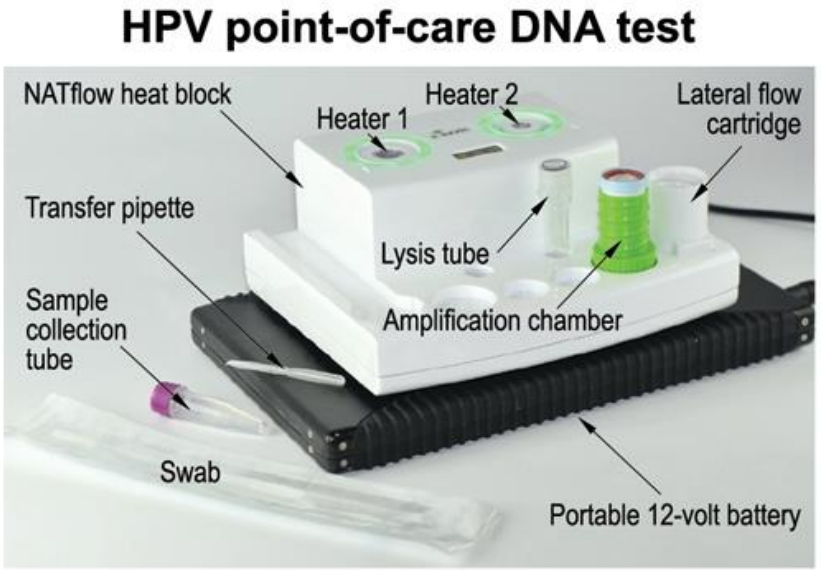
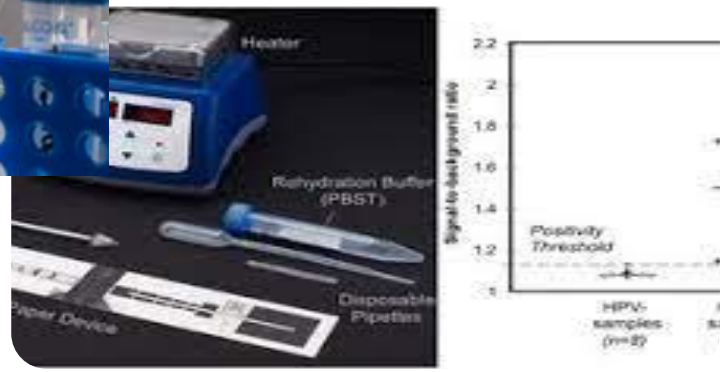
Develop new technologies









Rebecca Richards-Kortum, Rice University;
Kathryn Kunrod, White House Office of Science and Technology Policy

Kunrod et al, Science Trans Med, 2023
Smith et al, Lab Chip, 2023

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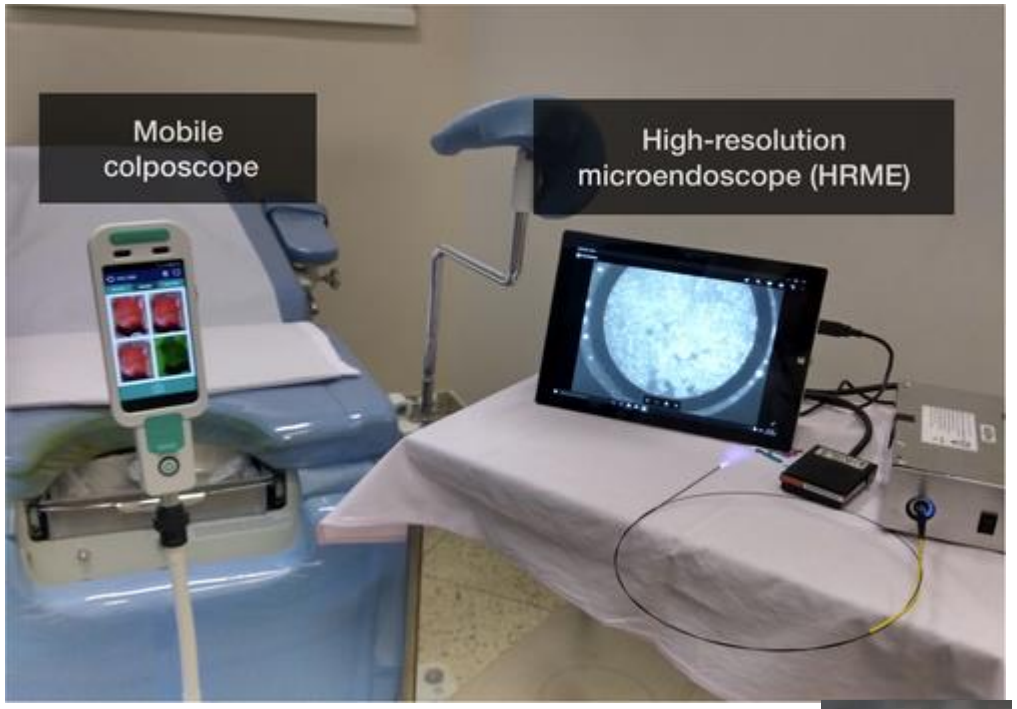
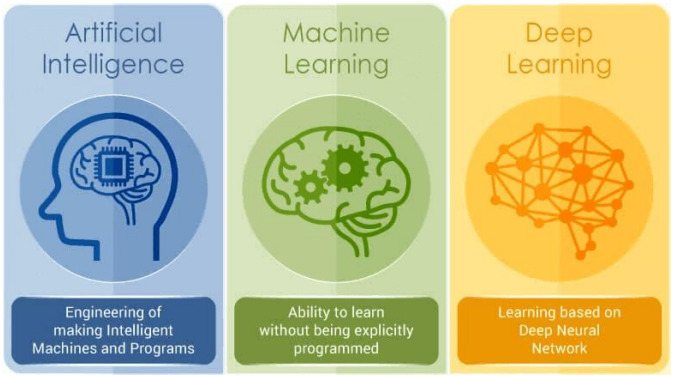
Develop new technologies

Need for low-cost point-of-care diagnostic technologies

Pocket Colposcope (Beta), Duke University Global Health Institute





Role for AI

Drs. Rebecca Richards-Kortum and Kathleen Schmeler

Hunt et al, Int J Cancer, 2022

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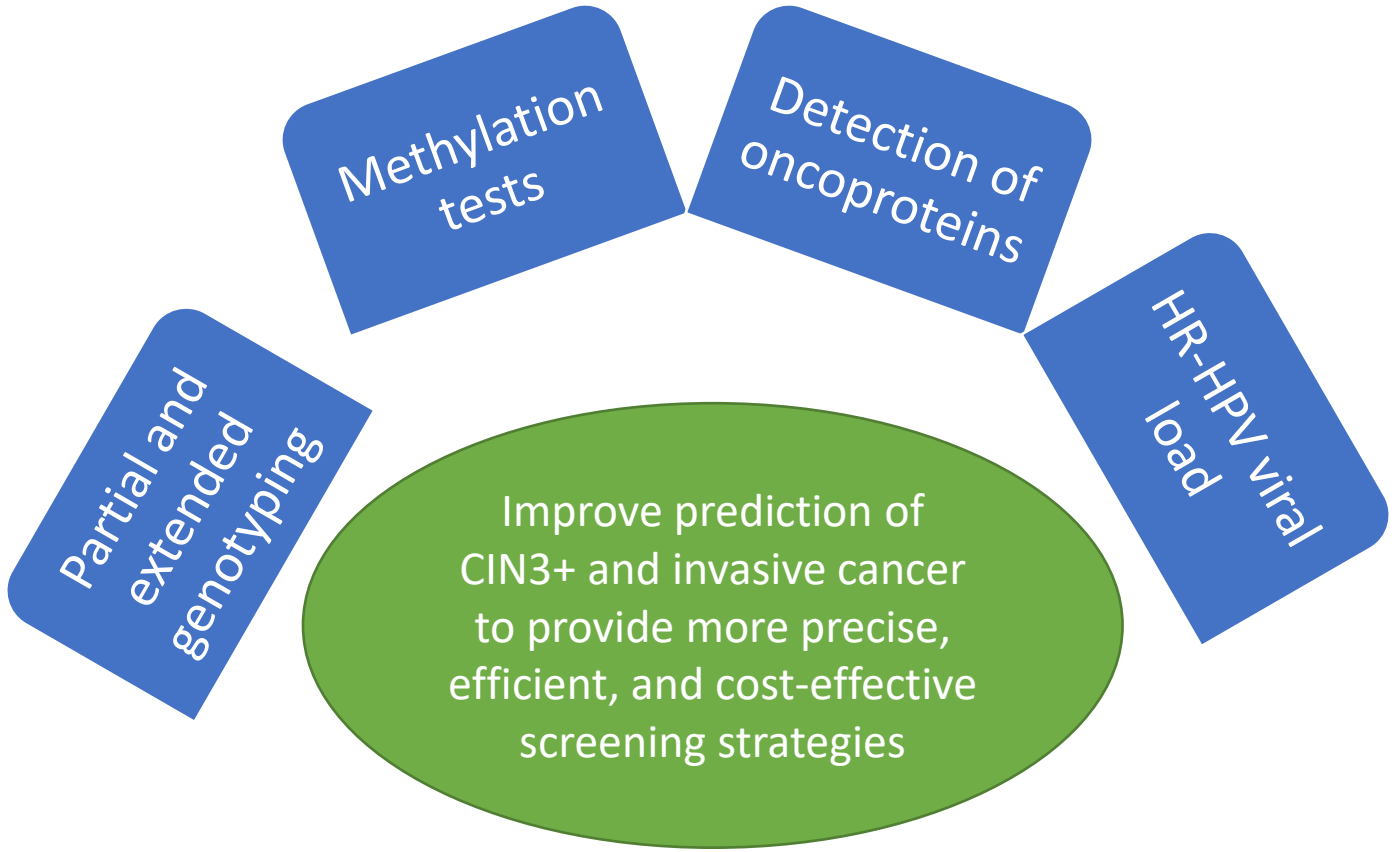
Develop new technologies

Need for molecular triage tests in HPV screening strategies

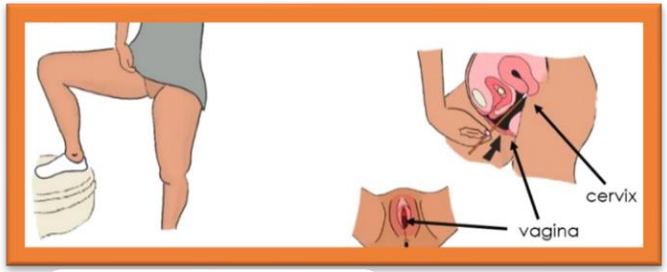
HPV testing ↓ specificity

Need for tests to more accurately identify persons for colposcopy and minimize clinically irrelevant findings.



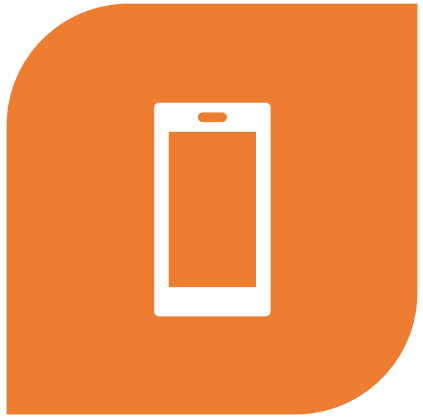
Taghavi et al, Frontiers Oncol, 2023

Photo credit: Felipe Lopez Photography



A Vision for the Future

Texas will lead the way!



HARNESS INNOVATIONS

ACCELERATE AND SCALE-UP IMPLEMENTATION

FOCUS ON EQUITY

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

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Thank you!

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MUSC
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