



STRATEGIES AND OPPORTUNITIES AROUND CERVICAL CANCER AND HPV VACCINATION

SPEAKERS:

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MODERATOR:

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Presentation Agenda

01

Cervical Cancer in Texas

02

Strategies and
Opportunities for HPV
Vaccination

03

Strategies and
Opportunities for
Cervical Screenings



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

 **UTHealth Houston**
School of Public Health

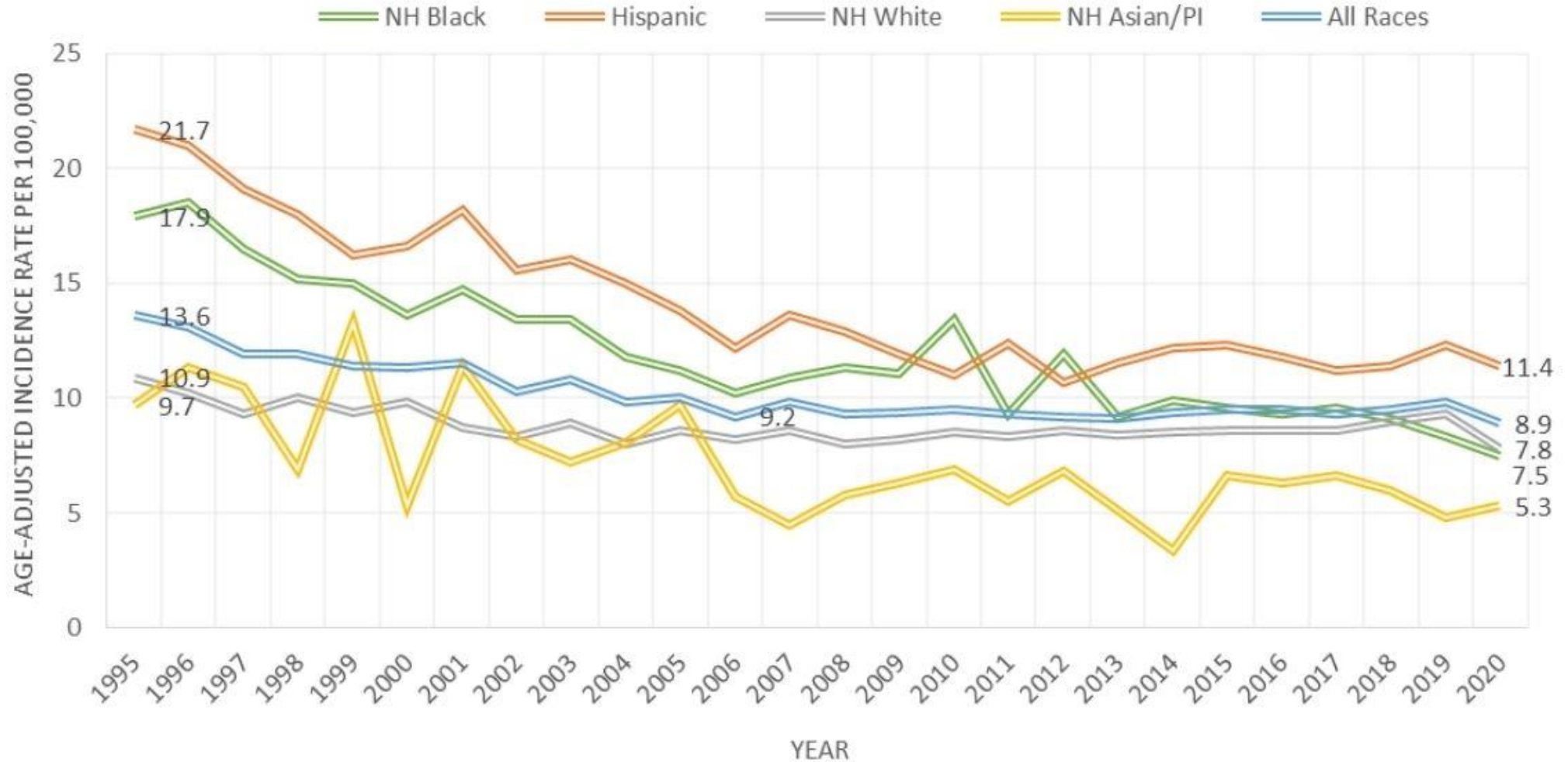
THE UNIVERSITY OF TEXAS
MDAnderson
Cancer Center
Making Cancer History[®]

Cervical Cancer Facts

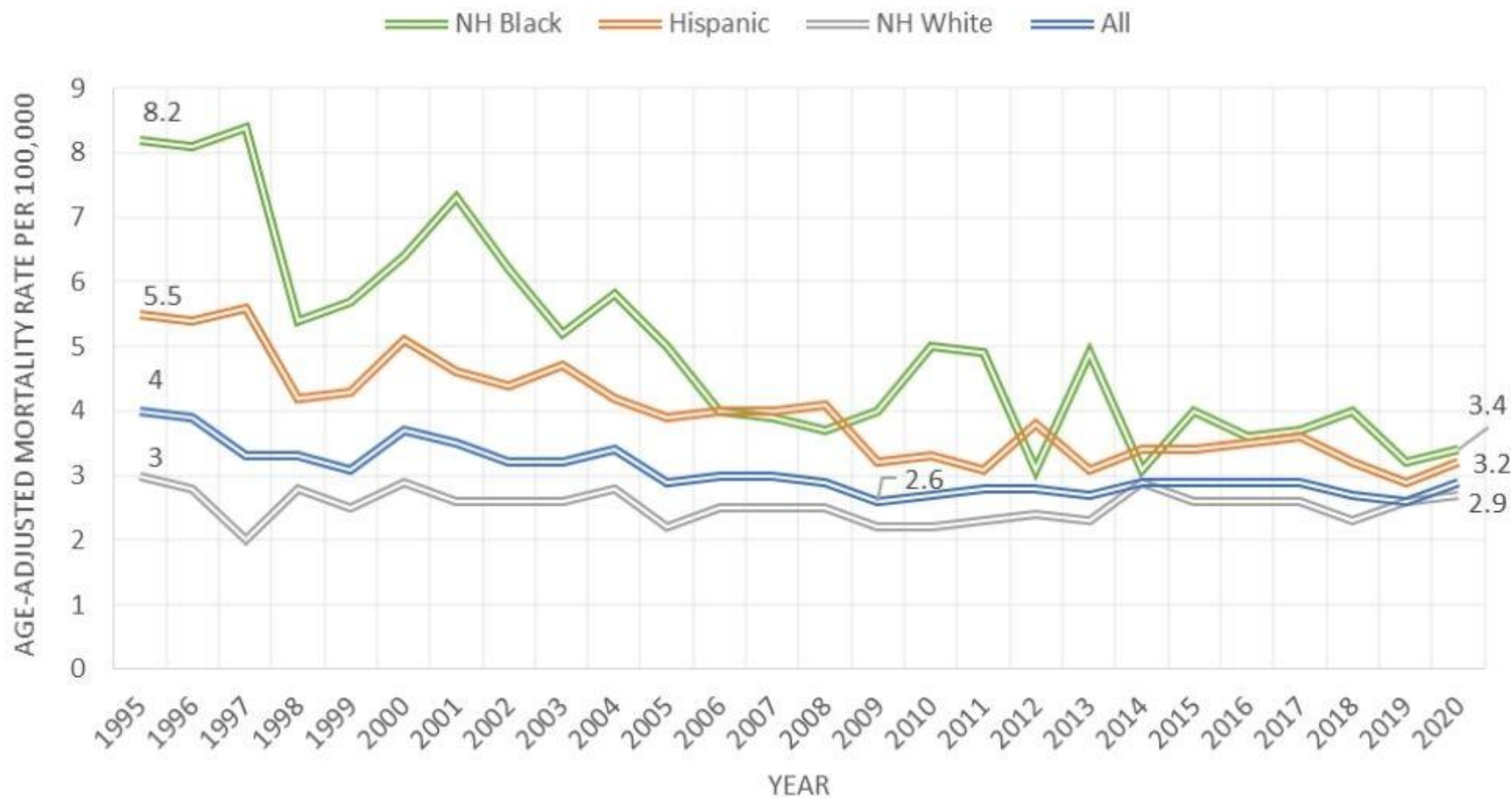
- The main cause of cervical cancer is a persistent human papillomavirus (HPV) infection.
- Most cervical cancers can be prevented through HPV vaccination (90%).
- 9 out of 10 cervical cancers can be prevented through regular screening.

Cervical cancer is almost entirely preventable through widespread HPV vaccination and regular cervical screenings.

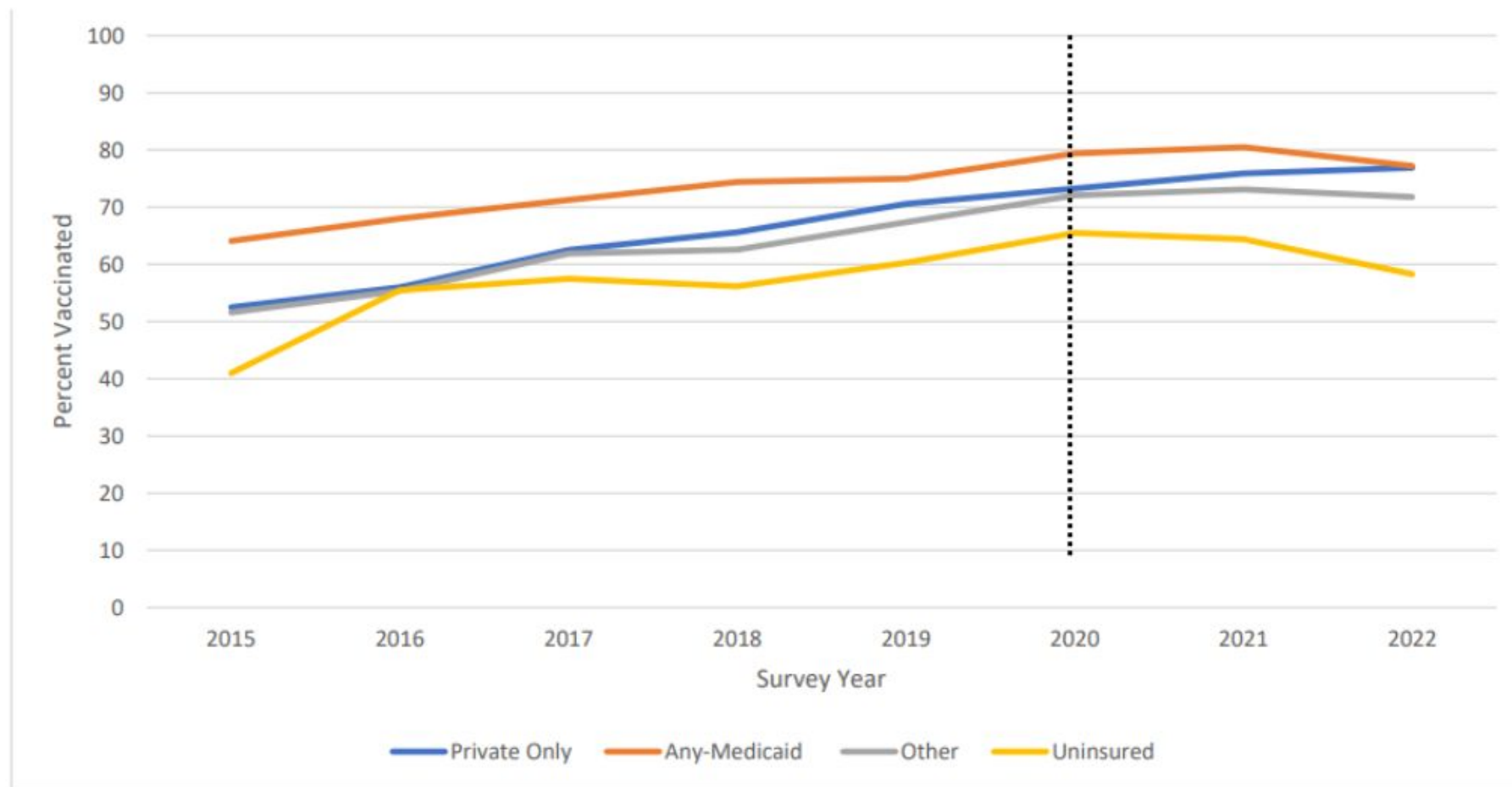
Invasive Cervical Cancer Incidence Rate Trends in Texas, by Race 1995 - 2020



Cervical Cancer Mortality Rate Trends in Texas, by Race , 1995 - 2020



Estimated Vaccination Coverage with ≥ 1 HPV vaccine among Adolescents aged 13-17 years, by Health Insurance Status*

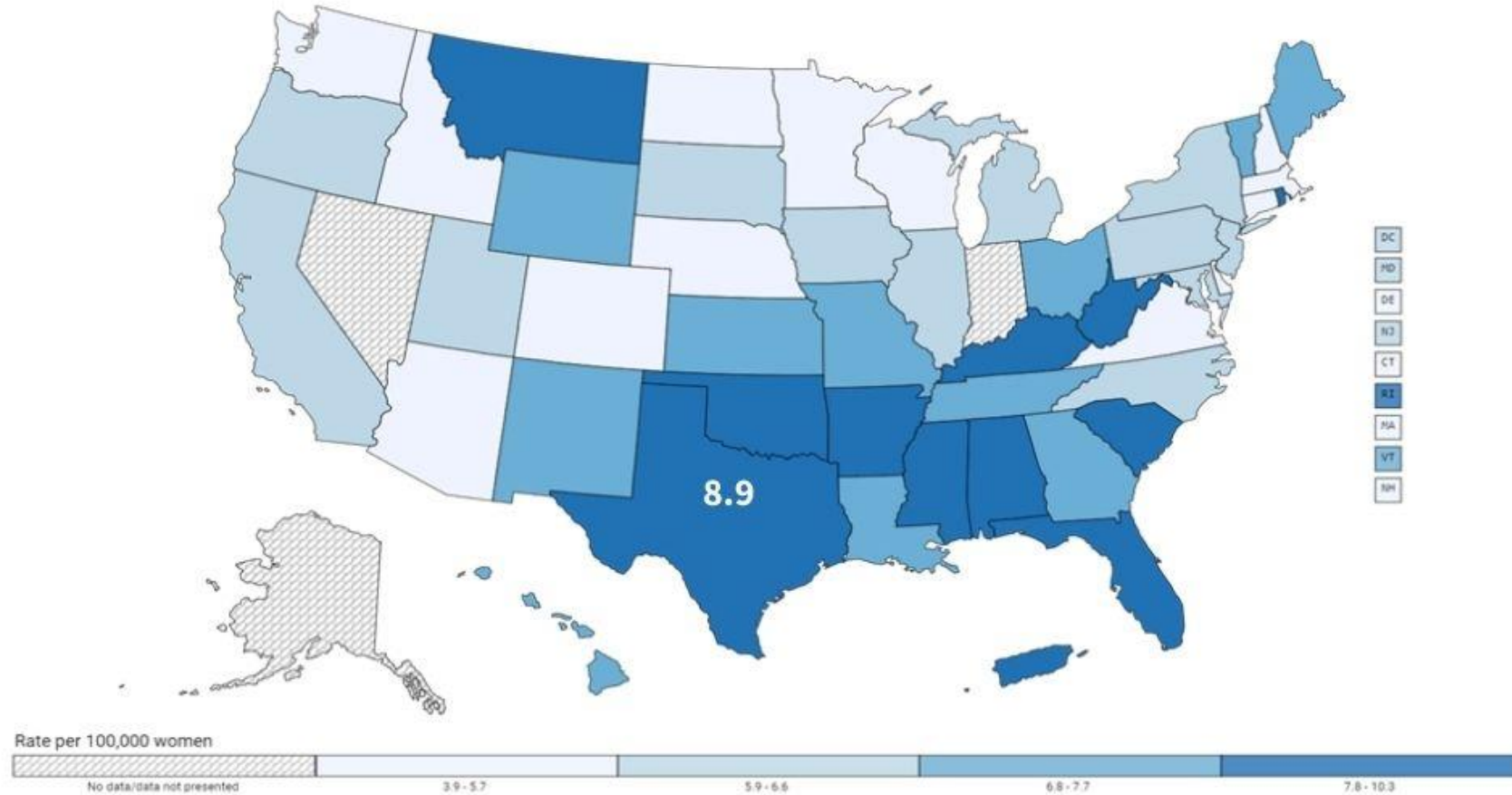


*Adolescents' health insurance status was reported by parent or guardian. "Other insurance" includes the Children's Health Insurance Program, military insurance, Indian Health Service, and any other type of health insurance not mentioned elsewhere.

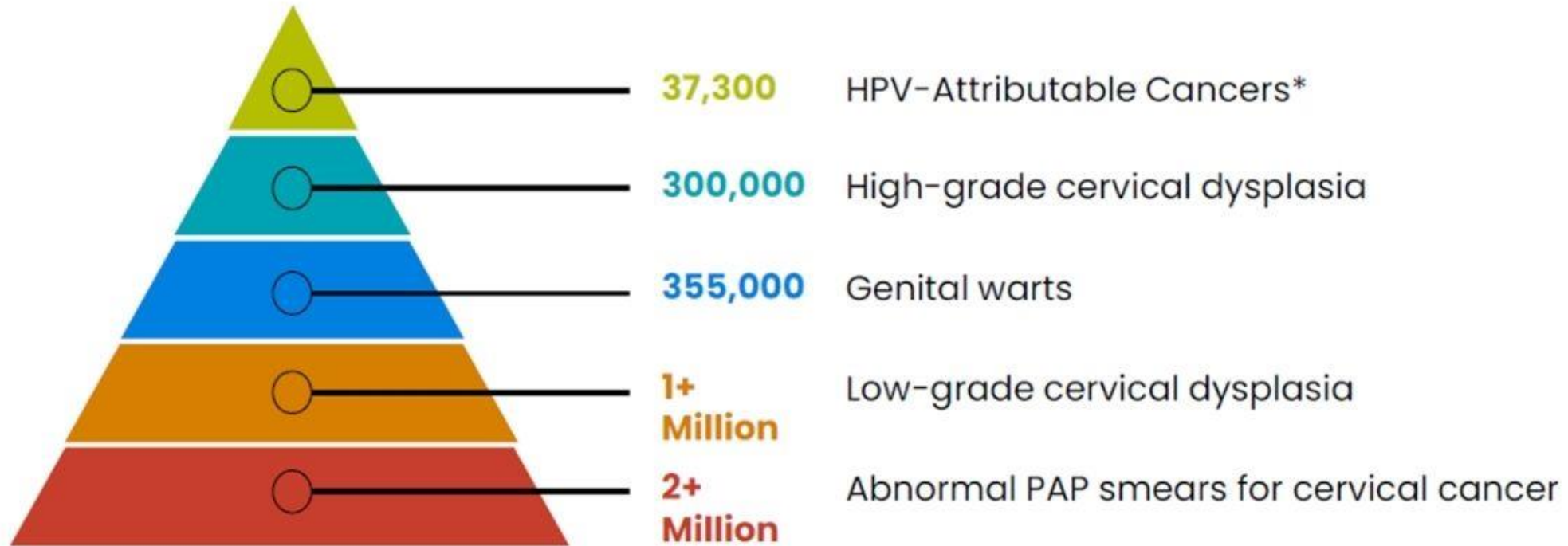
Source: National Immunization Survey Teen (NIS-Teen), United States 2015-2022

Rate of New Cervical Cancers in the United States, 2020

Estimated 50,126 people diagnosed with cervical cancer Jan 2015-Dec 2019



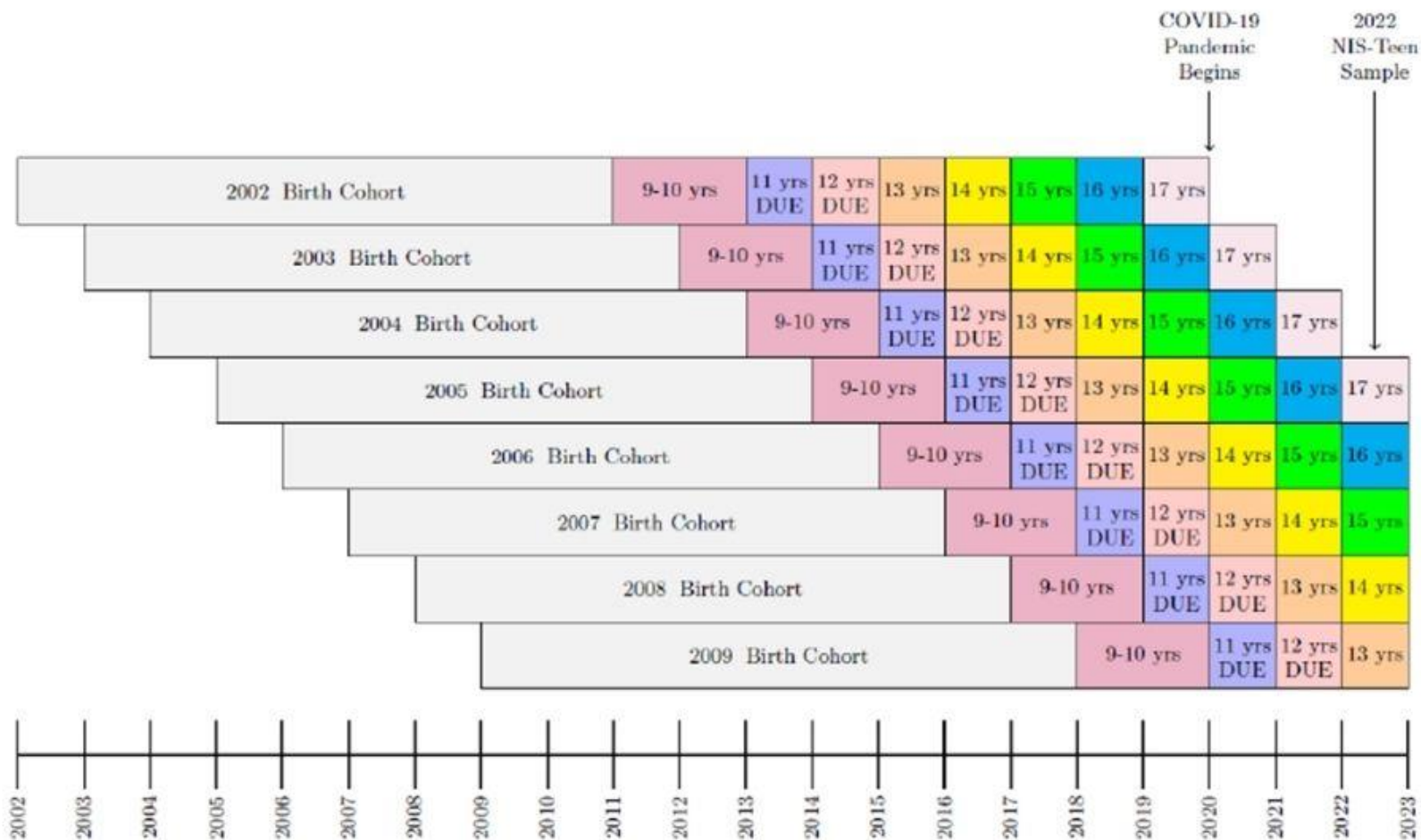
HPV Multiple Impacts on Population Health



* Source: <https://www.cdc.gov/cancer/hpv/statistics/cases.htm>

NOTE: Data are from population-based cancer registries participating in CDC's National Program of Cancer Registries (NPCR) and/or the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program for 2014 to 2018, covering 98% of the U.S. population.

2022 NIS - Teen MMWR Analysis Plan

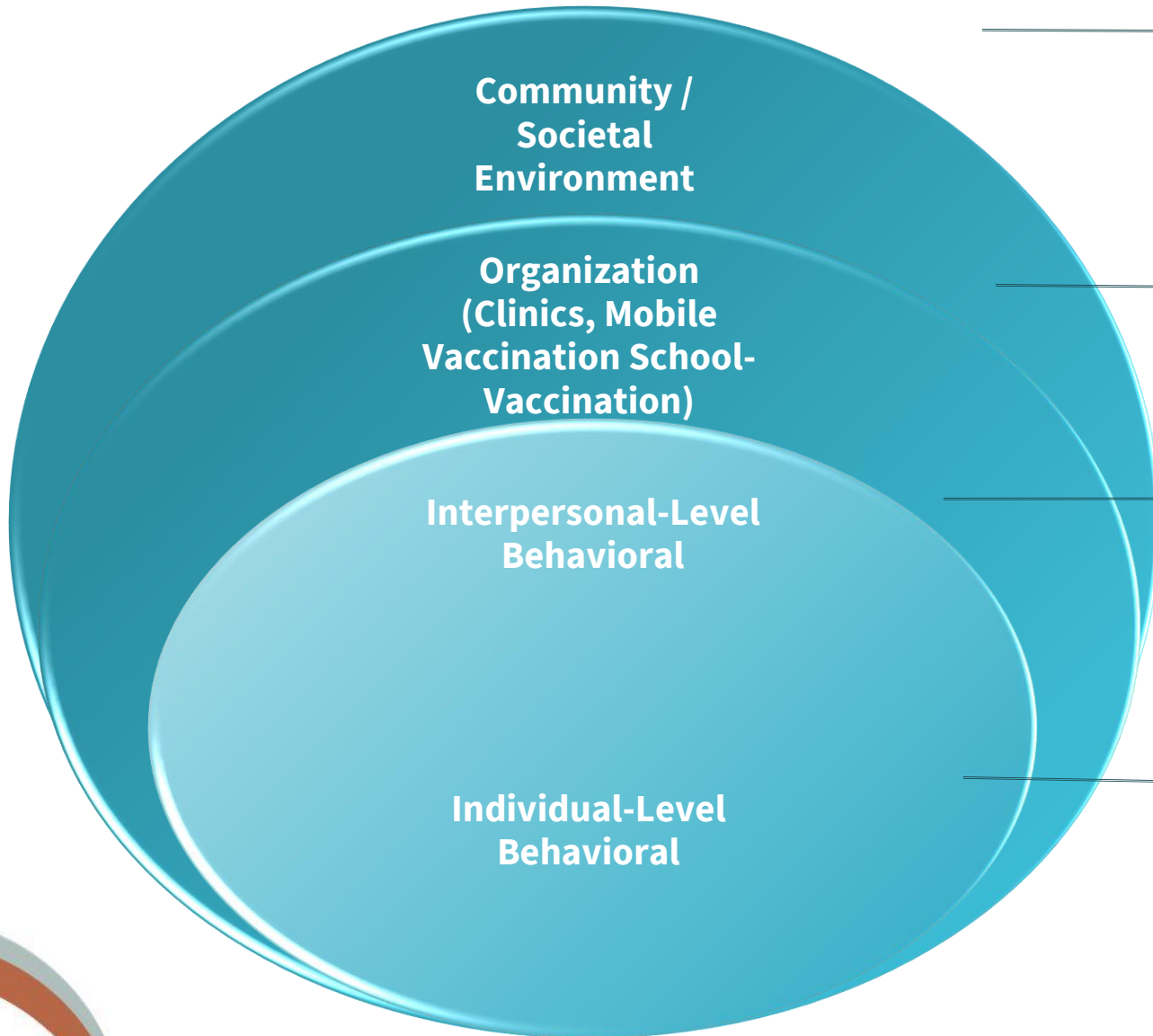


- Traditional cross-sectional analysis of coverage among teens aged 13-17 years
- Birth cohort analysis of coverage by age groups to capture recent changes in vaccination coverage during the COVID-19 pandemic.



STRATEGIES AND OPPORTUNITIES FOR HPV VACCINATION

Factors Influencing HPV Vaccination are Complex



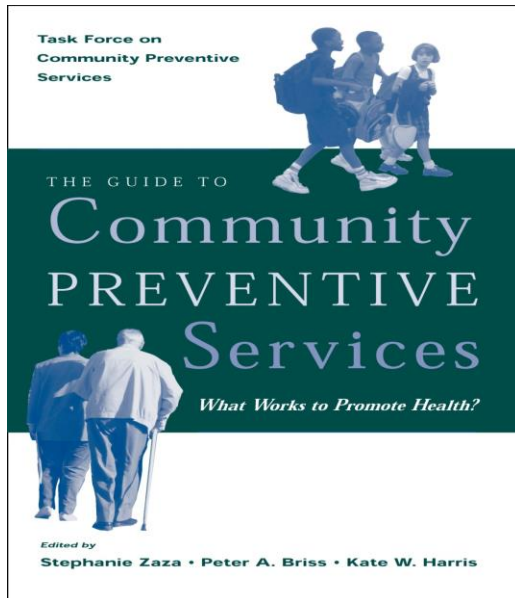
- HPV vaccination policies
- Immunization Registries
- Information sharing environment
- (e.g., social media)

- Clinic leadership
- Healthcare team structure
- EHR capability

- Provider recommendation
- Provider-patient (parent) communication
- Peer/Family influences

- Perceived/Actual Cost
- Didn't know about HPV vaccination
- Perceived safety
- Perceived benefits/ risks
- Misinformation

Evidence-Based Strategies to Increase Vaccination



The Guide Ratings

- ✓+ **Strong evidence**
- ✓ **Sufficient evidence**
- ? **Insufficient evidence**

Source: Guide to Community Preventive Services. Vaccination.
<https://www.thecommunityguide.org/topics/vaccination.html>

		Vaccination
Provider- or System-based Interventions	Health Care System-Based Interventions Implemented in Combination	✓ +
	Provider Assessment and Feedback	✓ +
	Provider Education when Used Alone	?
	Provider Reminders	✓ +
	Standing Orders	✓ +
	Immunization Information Systems	✓ +
Increasing Community Demand for Vaccinations	Client Reminder and Recall Systems	✓ +
	Client or Family Incentive Rewards	✓
	Vaccination Requirements (for schools, child care and college attendance)	✓ +
	Community-Based Multicomponent Interventions	✓ +
Enhancing Access to Vaccination Services	Vaccination programs in WIC settings	
	Home visits	✓ +
	Reducing Client Out-of-Pocket Costs	✓ +
	Provider Education when Used Alone	?
	Clinic-Based Education when Used Alone	?
	Community-wide education when Used Alone	?
	Client-held paper immunization records	?
	Monetary Sanction Policies	?

The Adolescent Vaccination Program (AVP):

A Clinic-Based Multicomponent Strategy to Increase HPV Vaccination

MPIs: Drs. Savas, Shegog, and Vernon



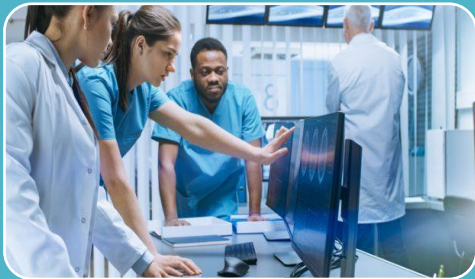
AVP HOUSTON (RP150014 & PP140183)

Goal: Develop and evaluate the multicomponent AVP intervention aimed at improving HPV vaccination initiation and completion through strategies aimed at systems, providers, and parents, implemented in a large diverse clinic system. Avg. of 111,126 patients ages 11-17 per year; 80% commercial insurance.



AVP SAN ANTONIO (PP180089)

Goal: Adapt and evaluate the multicomponent AVP intervention to increase HPV vaccination initiation and completion through implementation of the evidence-based AVP in San Antonio. Avg. of 6,771 patients ages 11-17 per year; 85% commercial insurance.

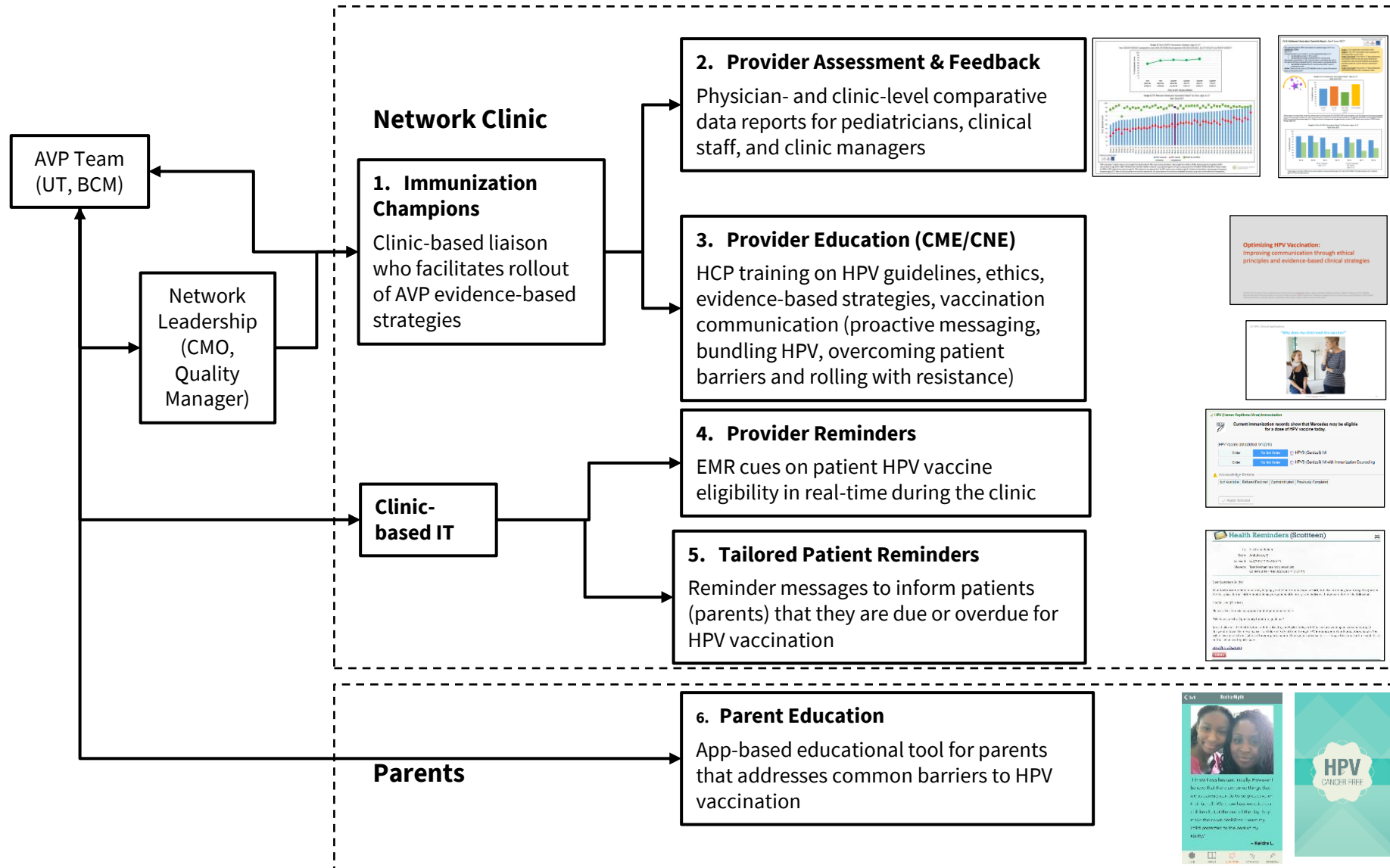


AVP IMPLEMENTATION TOOL (AVP-IT) (PP190041)

Goal: Support AVP scale-up by developing an AVP implementation support tool (AVP-IT) to facilitate implementation and sustainment of the evidence-based AVP intervention adapted for a safety-net clinic system in Houston. Provides guidance on implementing AVP strategies that is tailored to the clinic profile (e.g. EHR platform, existing HPV strategies, and other clinic and patient-related factors)

Funding: CPRIT RP150014 (PDs: Savas, Vernon), PP140183 (PDs: Savas, Shegog, Vernon), PP180089 (PDs: Savas, Shegog, Vernon) & PP190041 (PDs: Savas, Shegog)

Adolescent Vaccination Program (AVP)



AVP Houston: Formative work with Physicians

➤ **Pediatrician barriers**

Insufficient knowledge about HPV and HPV-related diseases

Perceived that there was no immediate need to vaccinate younger adolescents

Belief that they need to disclose to parents that the HPV vaccine is not required for school

Extra time to talk to vaccine-hesitant parents is a barrier

➤ **Pediatrician-reported parental barriers**

Not knowing or understanding the diseases the vaccine prevents

Wanting to wait until the child was older (child not having sex)

Wanting to wait until more was known about the long-term effects (the vaccine was too new)

AVP Houston: Key Findings Regarding System-Level Changes

After reaching 80% vaccination rates in clinics, it was much harder to get the clinic rates higher

Facilitators to Systems Changes

- The Chief Medical Officer (Clinic system leader) was essential to facilitating system changes required to support the A&F. provider reminders and recalls, and patient reminders.
- The CMO identified an assistant (another MD with an interest in EHR optimization projects), and nurse lead. This core leadership team worked to align resources and staff buy-in throughout the system
- This leadership team facilitated identifying clinic champions at each of the 51 clinics

Barriers / Limitations

- Pediatricians reporting barriers that included concern about vaccine safety, efficacy, or financial burden on patients reported significantly lower odds of initiation ($p < 0.05$).³
- Significantly higher odds of vaccination initiation among patients when pediatricians used a bundled, presumptive HPV recommendation rather than singling out HPV vaccination ($p < 0.05$).⁴

³ Farias AJ, Savas LS, Fernandez ME, et al. Prev Med. 2017.

⁴ Savas LS, Farias AJ, Healy MC, et al.. Journal of Applied Research on Children, 2021.

AVP Implementation in Large Clinic Network in Houston

- A pre-and post-test time series analysis established the AVP effect on intervention outcomes¹

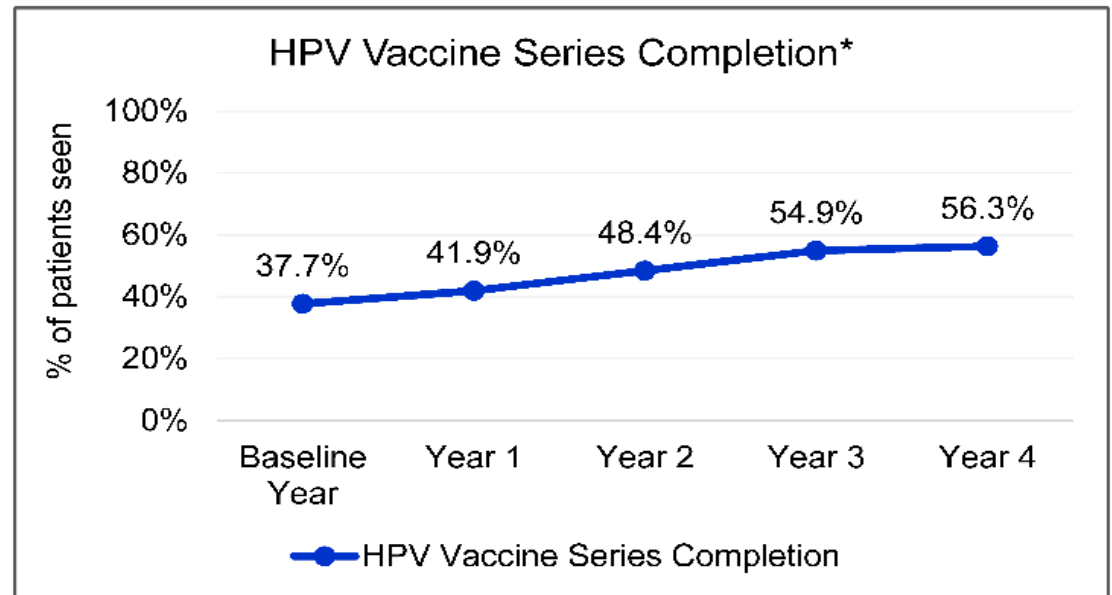
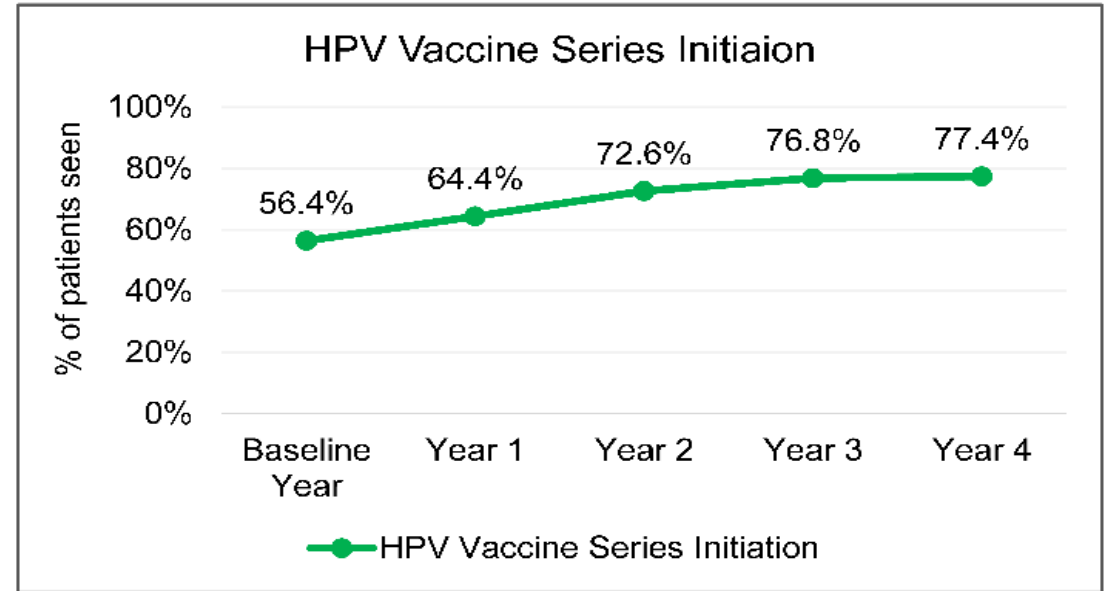
Initiation rates increased from 56.4% to 77.4%

Completion rates increased from 37.7% to 56.3%

- Acceptability and feasibility assessment of the AVP HPVcancerFree app among parents revealed increased positive attitudes toward HPV vaccination.²

¹ Vernon SW, Savas SL, Shegog R, et al. JARC. 2020.

² Shegog R, Savas LS, Healy CM, et al. Hum Vaccin Immunother. 2022.



*completion use the 2- or 3-dose recommendation

Key Findings Regarding System-Level Changes

AVP San Antonio

After reaching 80% vaccination rates in clinics, it was much harder to get the clinic rates higher
No decline in HPV vaccination rates was detected during the COVID 2020 Pandemic period

Facilitators to Systems Changes

- Buy-in from the Medical Director and clinic leadership helped to obtain 100% physician participation in CME

Barriers to Systems Changes

- A new EHR that did not have the same capabilities as Epic
 - (electronic provider reminders were not possible and there was little ability for customization of patient reminder campaigns)
- High turnover and difficulty engaging staff during the COVID-19 pandemic
- System-level interruptions due to the transition from Athena to Epic EHR

AVP Implementation in Large Clinic Network in San Antonio Outcomes (2018-2022)

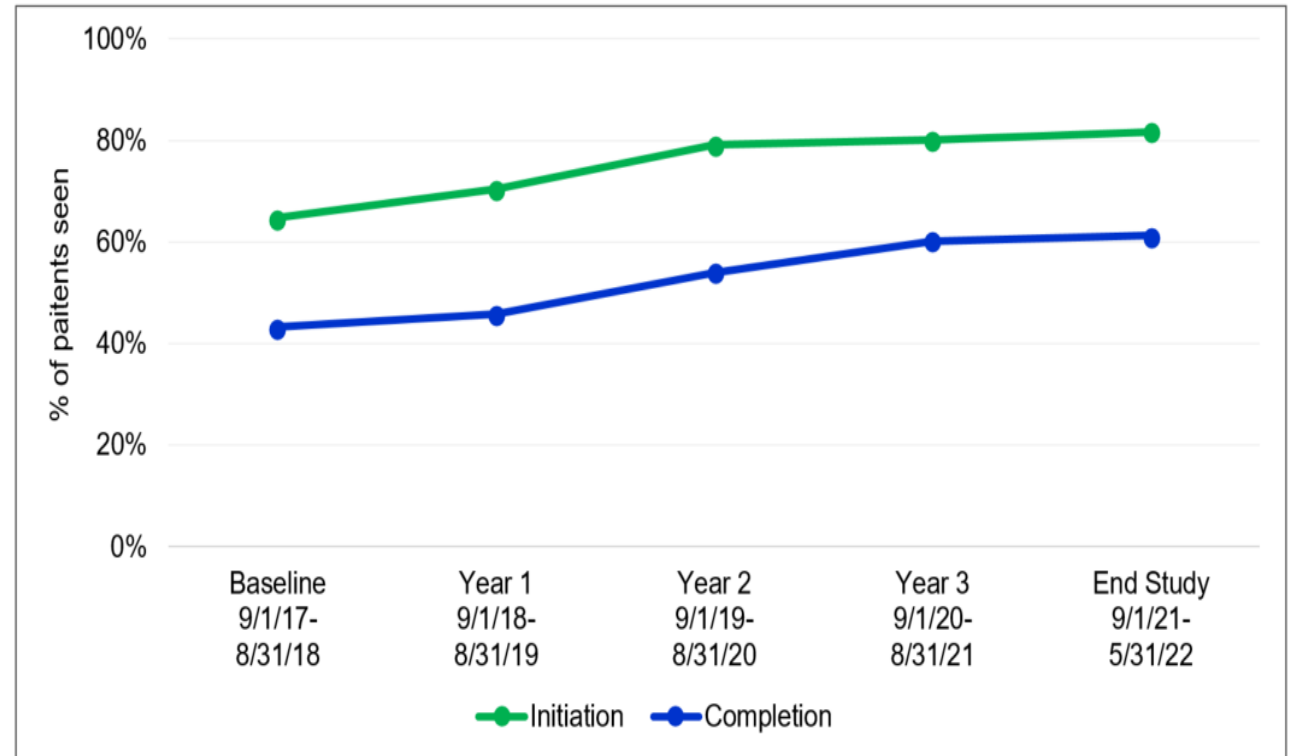
- A pre-and post-test time series analysis established the AVP effect on intervention outcomes

Initiation rates increased from 64.7% to 81.6%

Completion rates increased from 43.2% to 61.3%

- The AVP effectively increased HPV vaccination rates among male and female patients in a small clinic network in the San Antonio Area (6,771 patients ages 11-17).

San Antonio Network HPV Vaccination Initiation and Completion Rates for Patients Ages 11-17



HARRISHEALTH
SYSTEM



Conceptual model

LEGACY
COMMUNITY HEALTH

HPV Vaccination in Safety Net Systems



Funding: CPRIT PP170099 (PDs: Jibaja-Weiss, Montealegre), PP190051 (PDs: Montealegre, Jibaja-Weiss) & PP220038 (PDs: Montealegre, McGee)

Why safety-net health settings?



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



Uninsured patients face increased barriers to HPV vaccination and nationally have the lowest coverage of HPV vaccination



Socioeconomically disadvantaged, racial/ethnic minority women shoulder a disproportionate burden of HPV-associated disease.

Goals

Goal 1

Increase the proportion of pediatric patients who **initiate** the HPV vaccine series.

Goal 2

Increase the proportion of pediatric patients who **complete** the HPV vaccine series.



Dose 1

Ages 9-12 (on-time)

Ages 13-14 (catch-up)

Ages 15-18 (late)



Dose 2

6-12 months later



Dose 3

For ages ≥ 15 yrs

Priority Populations

Pediatric patients and their parents/caregivers

Boys and Girls

Ages 9 -12 (On-time)

Ages 13-14 (Catch-up)

Ages 15-18 (Late)



Pediatric providers

Physicians

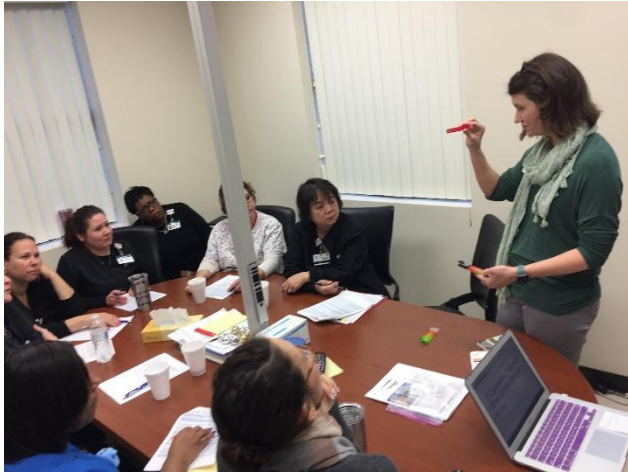
Nurses

Medical assistants

Other clinic staff



Setting: All Pediatric, Family Practice, and School-based Clinics



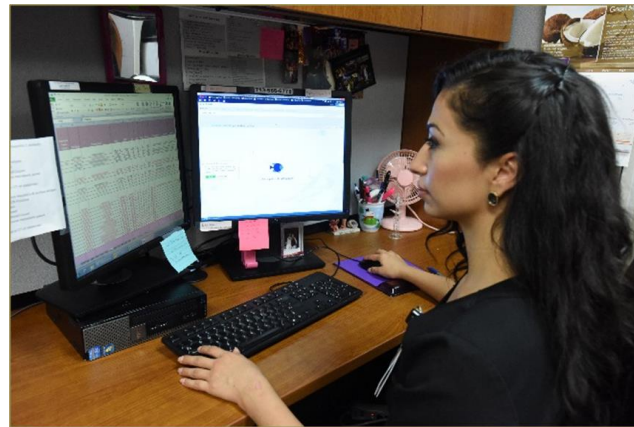
Multi-Component Program

1) Patient/Parent Education:
Linguistically- and culturally-
targeted patient/parent priming
videos at the point-of-care

2) Provider training and practice
facilitation

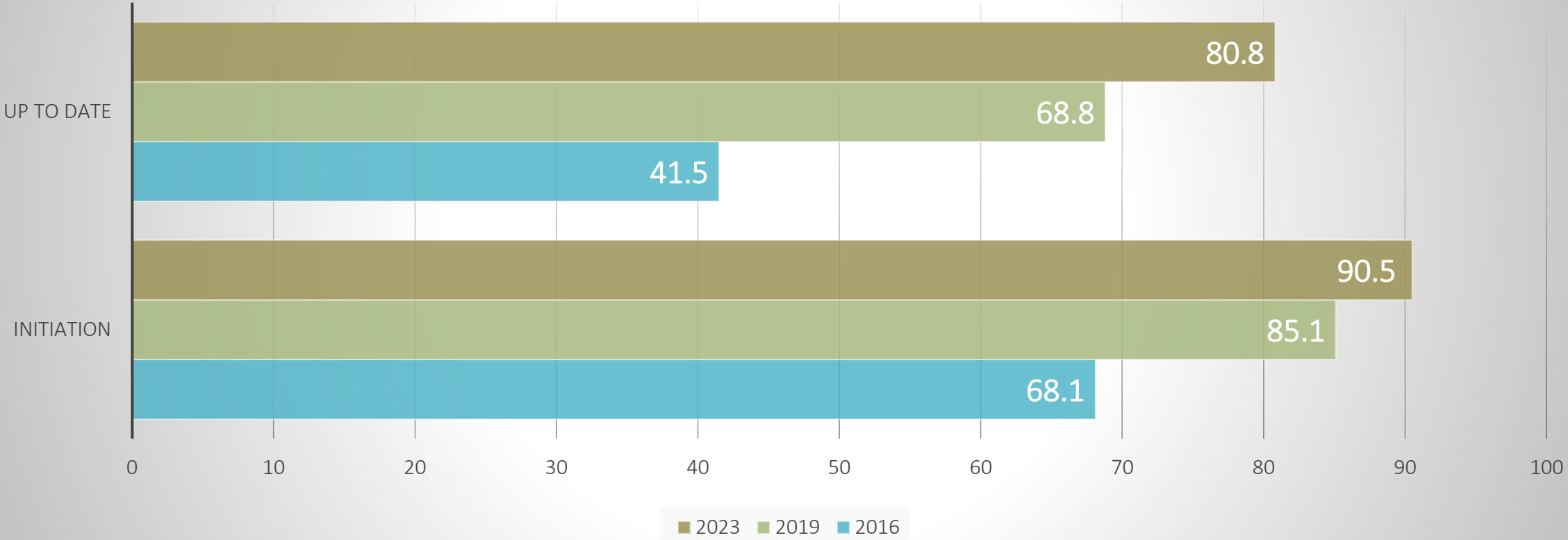
3) Assessment and feedback

4) Tiered Patient Navigation,
tracking, & reminder/recall

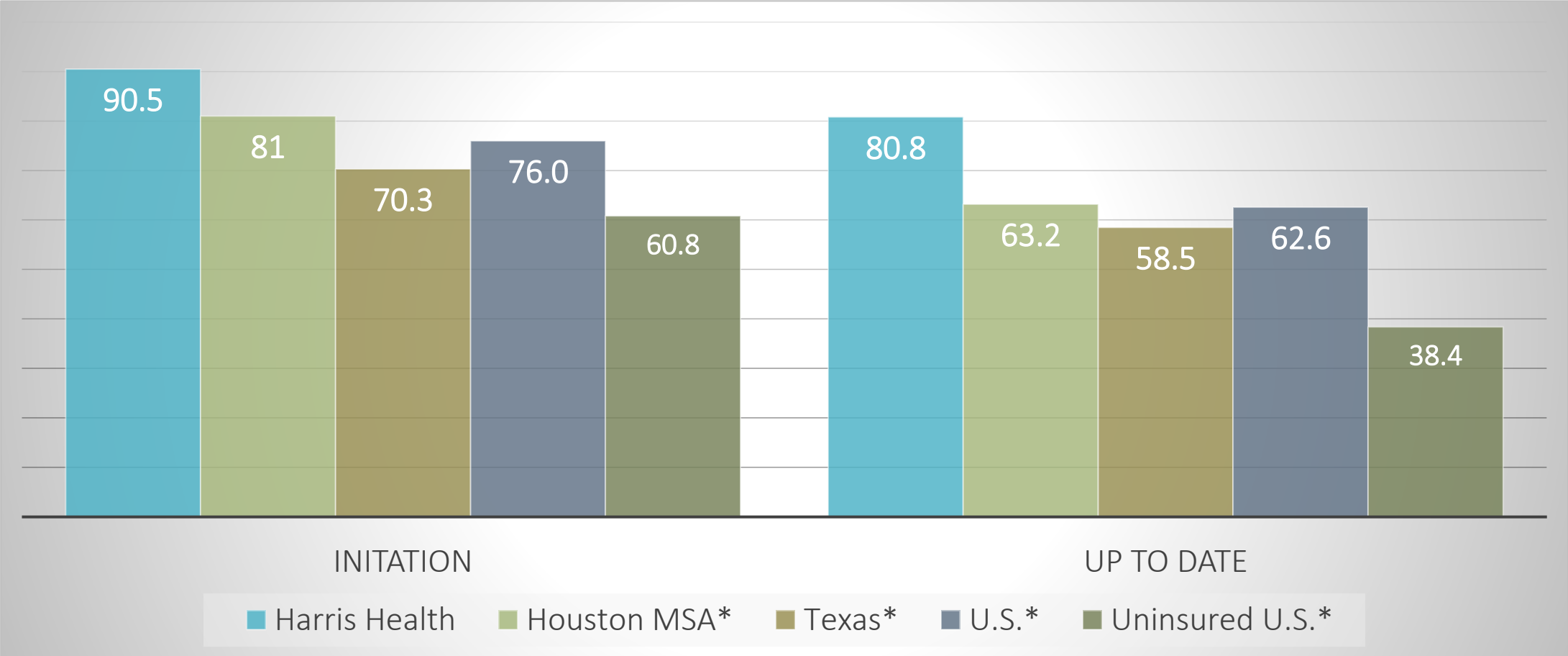


Results

HPV Vaccine Initiation and Completion among Harris Health System Patients Ages 11-18 Years, 2016-2021



Comparative HPV Vaccination Rates, Adolescents 13-17 Years



*CDC, NIS-Teen 2022



Valbona Health Center, 84% completion



C.E. Odom Pediatric and Adolescent Health Center, 83% completion

HARRISHEALTH SYSTEM

*7 of 13 clinics reached >80% up-to-date
HPV vaccination*

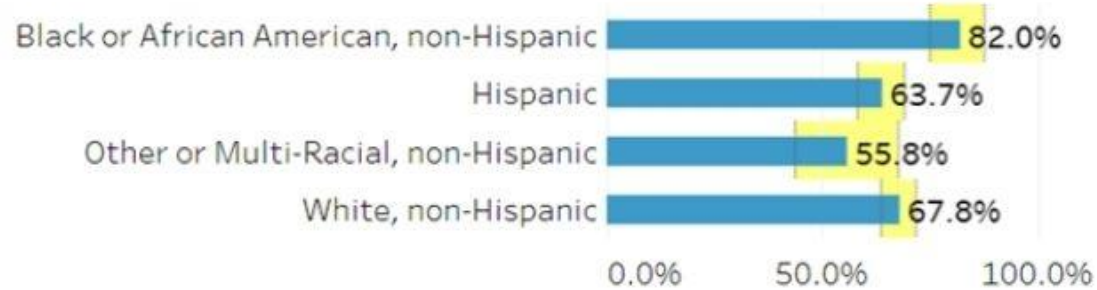


STRATEGIES AND OPPORTUNITIES FOR CERVICAL SCREENINGS

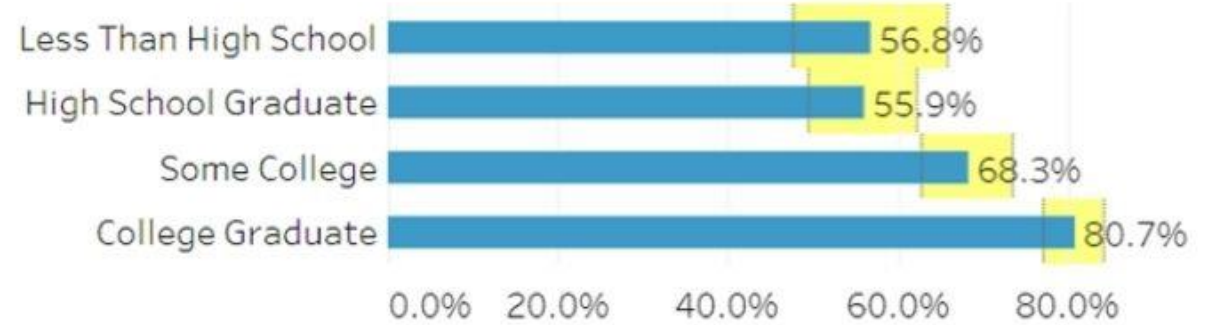
Disparities in Cervical Cancer Screening

Estimated % Population Reporting Having a Pap Test in the last 3 years, 2020, Texas

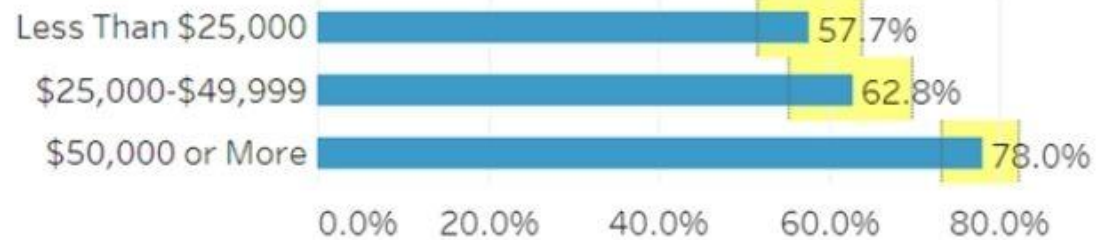
RACE/ETHNICITY



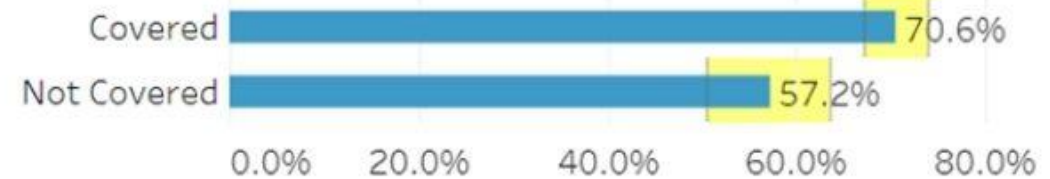
EDUCATION



HOUSEHOLD INCOME

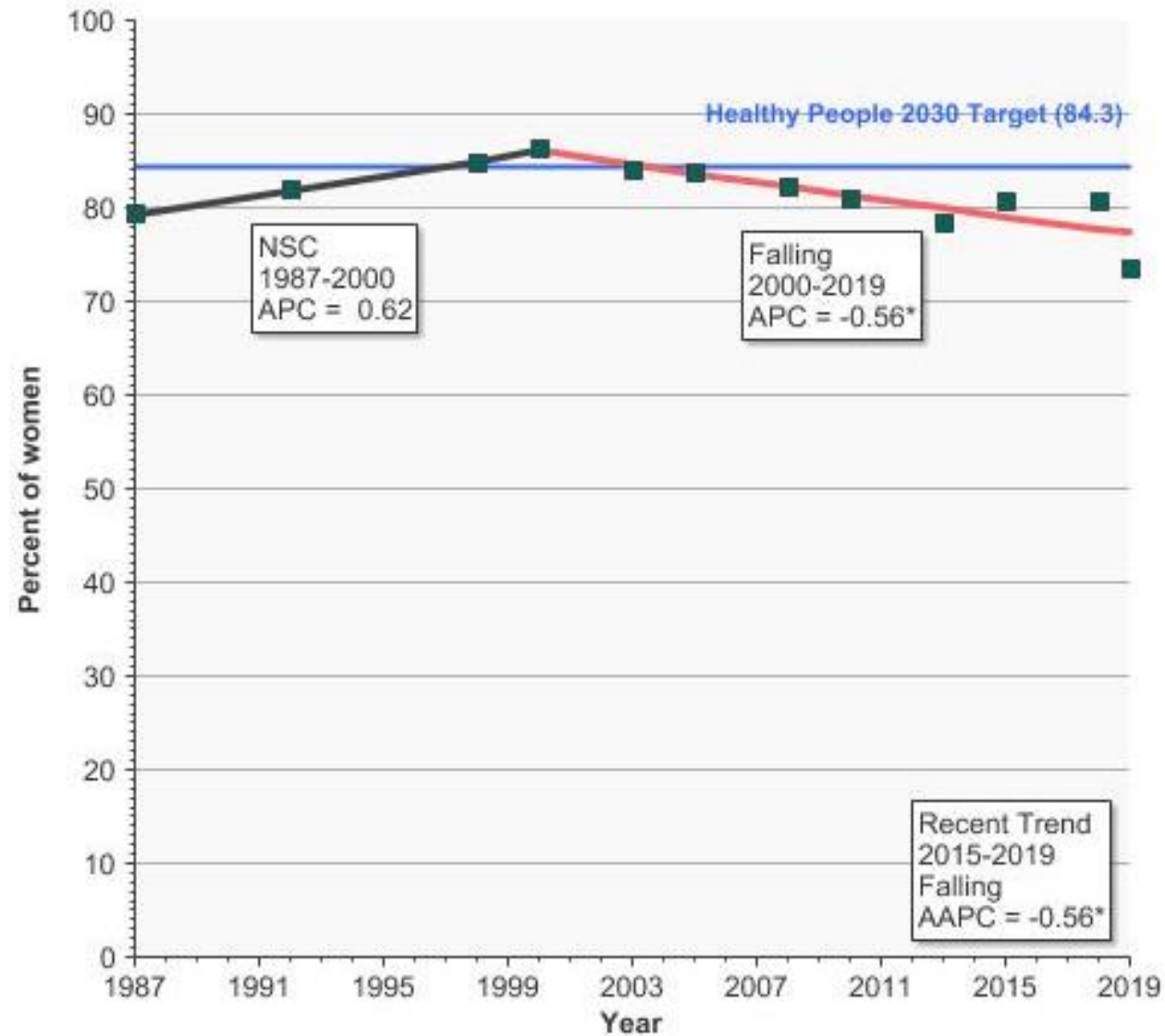


HEALTH CARE COVERAGE



Source: Behavioral Risk Factor Surveillance System (BRFSS)

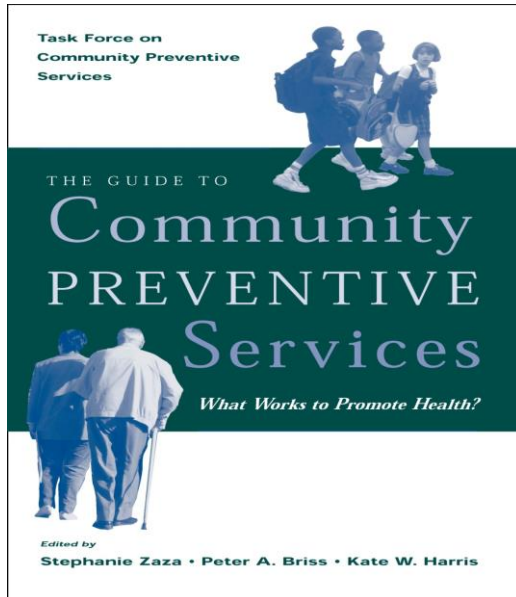
Percent of females aged 21-65 years who were up-to-date with cervical cancer screening, 1987-2019



HP 2030 Target C-09: 84.3%

Source: Centers for Disease Control and Prevention, National Center for Health Statistics. National Health Interview Survey.

Evidence-Based Strategies to Increase Cervical Cancer Screening



The Guide Ratings

- ✓+ **Strong evidence**
- ✓ **Sufficient evidence**
- ? **Insufficient evidence**

Source: Guide to Community Preventive Services. Vaccination.
<https://www.thecommunityguide.org/topics/vaccination.html>

		Cervical Cancer Screening
Client-Oriented Interventions	Client Reminders	✓+
	One-on-One Education	✓+
	Reducing Structural Barriers	✓+
	Small Media: Videos, print material to inform & motivate, tailored or general	✓+
	Client Reminders	✓+
Increase Demand & Access	Community Health Workers	✓+
Increase the Demand for Services	Patient Navigation Services	✓
Provider-Oriented Interventions	Provider Assessment and Feedback	✓
	Provider Reminder and Recall Systems	✓+
	Multicomponent Interventions	✓+
	Mass Media	?
	Group Education	?
	Client Incentives	?
	Reducing Client Out-of-Pocket Costs	?
Provider Incentives	?	

SEMM Adaption & Expansion Intervention Components 2011-2013

Community-Based Recruitment

**CHWs Deliver
Education**
(1-to-1)

**CHWs Deliver
Education**
(Group Education)

Education
In-person

Health Coach Navigation/CHW

Navigates participants - support to remove barriers and assist in scheduling cancer screenings/vaccinations



A CHW-delivered bilingual breast and cervical cancer screening, and HPV vaccination, program prioritizing medically underserved women 21 years and over, particularly Latinas.

Cervical Cancer Screening

Multicomponent Interventions	✓+
Community Health Workers	✓+
Patient Navigation Services	✓
• Client Reminders	✓+
• One-on-One Education	✓+
• Reducing Structural Barriers	✓+
• Group Education	?
Small Media: Videos, print material to inform & motivate	✓+

SEMM: Education & Telephone Navigation: 2011-2013

- 391 Women participated in at least 1 navigation call
- 3 Navigation calls, on average, were completed before an appointment made
- 4.2 Navigation calls made until an appointment was completed



SEMM adapted from *Cultivando la Salud* & evaluated in a community-based randomized trial and proven effective.¹

SEMM Cervical Screening Effectiveness :

ITT Protocol: OR 1.91 (1.27, 2.88)

Per Protocol: OR 3.09 (1.88, 5.08)

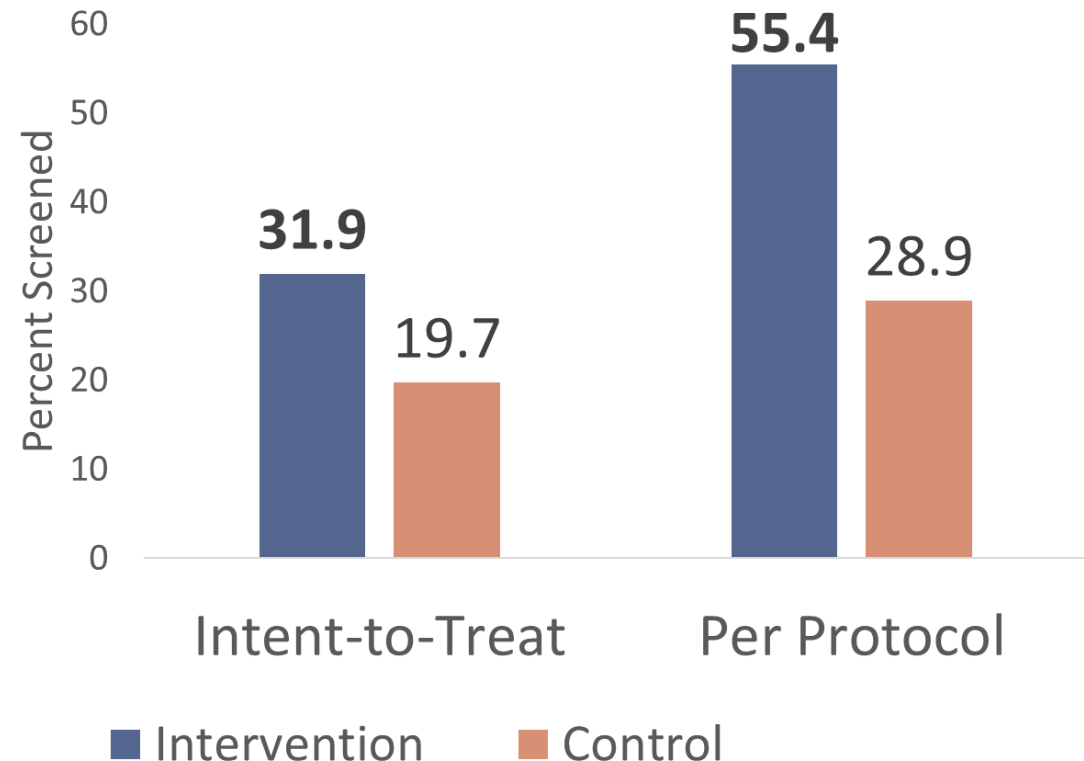
SEMM Breast Screening Effectiveness:

ITT OR 2.04 (1.44, 2.88)

Per Protocol OR 2.17 (1.48, 3.18)

(CPRIT-funded: PP110081)

Savas, PI



^a Adjusted for Age, insurance, family history of cervical cancer, and self-efficacy

^b Adjusted for age and self-efficacy

1. Savas LS, Heredia NI, Coan SP, Fernandez, ME. Effectiveness of a community health worker-delivered intervention to increase breast and cervical cancer screening among medically underserved Hispanics. E-Poster, Oral Presentation presented at World Cancer Congress; October 4, 2018; Kuala Lumpur, Malaysia.

SEMM Adaption & Expansion Intervention Components 2015-2019

SEMM Adaption & Expansion Intervention Components 2019-2023

Community & Clinic-Based Recruitment

Community & Clinic-Based Recruitment

**CHWs Deliver
Education
(1-to-1)**

**CHWs Deliver
Education
(Group Education)**

Educ.
In-person

Educ.
Telephone

Health Coach/LHW
Navigates participants - support to remove barriers
and assist in scheduling cancer
screenings/vaccinations

Social Marketing Campaign

Zoom Education



Funding: CPRIT PP PP160047, PP190061
(PD: Savas, LS)



Salud en Mis Manos
Health in My Hands

Most Common Barriers Reported by Participants

Original SEMM (2011-2013) (Adaptation of CLS)

SEMM (2015-2019)

SEMM (2019-2023)

Reported to Navigators

1. Lack of Insurance
2. Lack of “Gold Card”
3. Lack of time/ busy
4. Transportation

1. Lack of time/ busy
2. Cost
3. Do not know where to go
4. No Insurance

1. Cost
2. Lack of time/ busy
3. Do not know where to go
4. Transportation

Reported on Follow-up Surveys

1. Money
2. Transportation
3. Work
4. No “Gold Card”
5. Insurance
6. No Time

1. Cost
2. No Insurance
3. Do not know where to go
4. Lack of time/ busy
5. Keeps putting it off
6. Transportation

Ongoing analysis

SEMM Participants Reached and Served

2015 -2019

2019 -2023

SEMM Education & Navigation Results	# women
Reach & Served	
Assessed for unmet B&C cancer prevention needs	8,176
Received CHW-delivered B&C cancer education	4,402
In need of mammography	3,134
In need of Pap screening	3,126
In need of an HPV vaccine	308
Opted into SEMM health coach navigation services	3,818
Health coaching calls made to participants	8,277

CPRIT: PP160047

SEMM Education & Navigation Results	# women
Reach & Served	
Assessed for unmet B&C cancer prevention needs	9,822
Received CHW-delivered B&C cancer education	7,268
In need of mammography	3,146
In need of Pap screening	3,682
In need of an HPV vaccine	351
Opted into SEMM health coach navigation services	4,149
Health coaching calls made to participants	15,282

CPRIT: PP190061

The SEMM-Dissemination and Implementation Assistance (SEMM-DIA) Program

The AVP-Implementation Tool

Next Steps: To develop implementation support strategies to facilitate the delivery of these evidence-based programs to support EBI scale-up and sustainment.

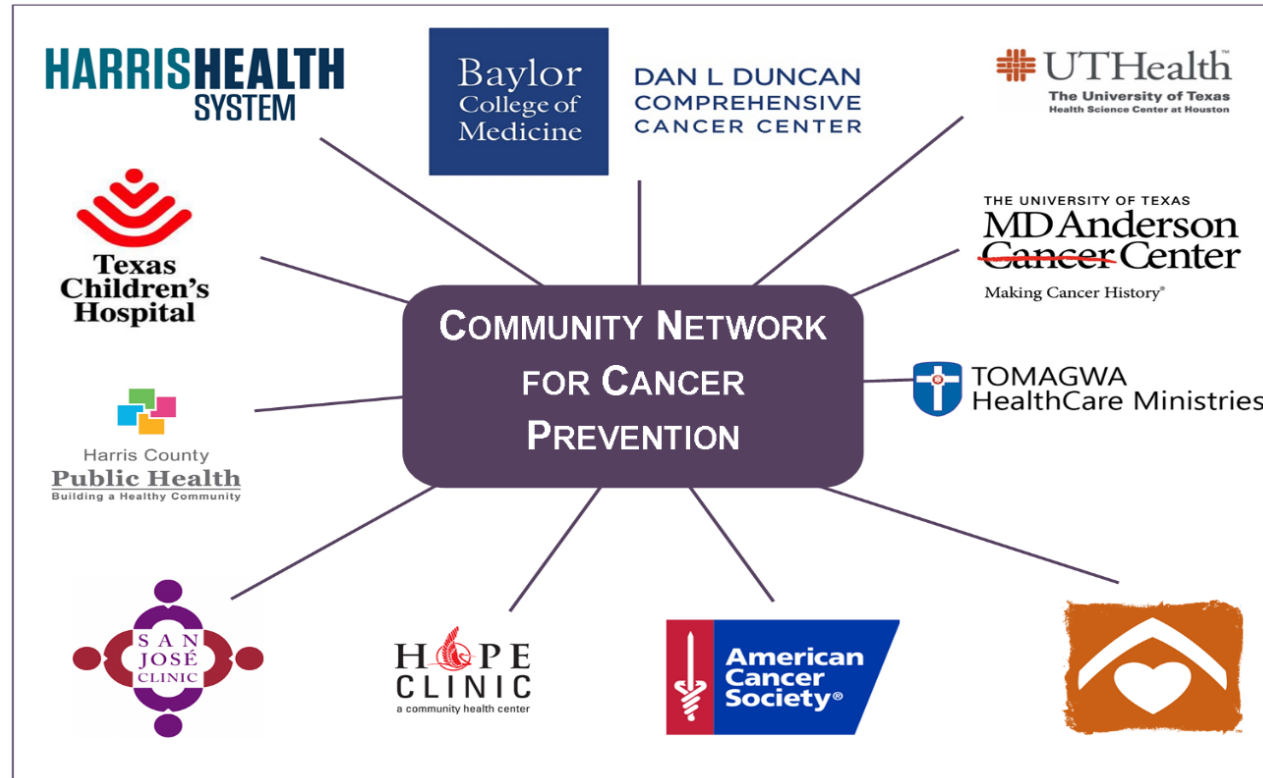
CPRIT PP190061.

CDC Prevention Research Center (Cooperative Agreement Number: 1U48DP006408-01-00)

Savas, L.S., Loomba, P., Shegog, R., Alaniz, A., Costa, C., Adlparvar, E., Allicock, M.A., Chenier, R., Goetz, M., Markham, C.M., & Fernandez, M.E. (2023). Using Implementation Mapping to increase uptake and use of Salud en Mis Manos: A breast and cervical cancer screening and HPV vaccination intervention for Latinas. *Frontiers in Public Health*, 11..

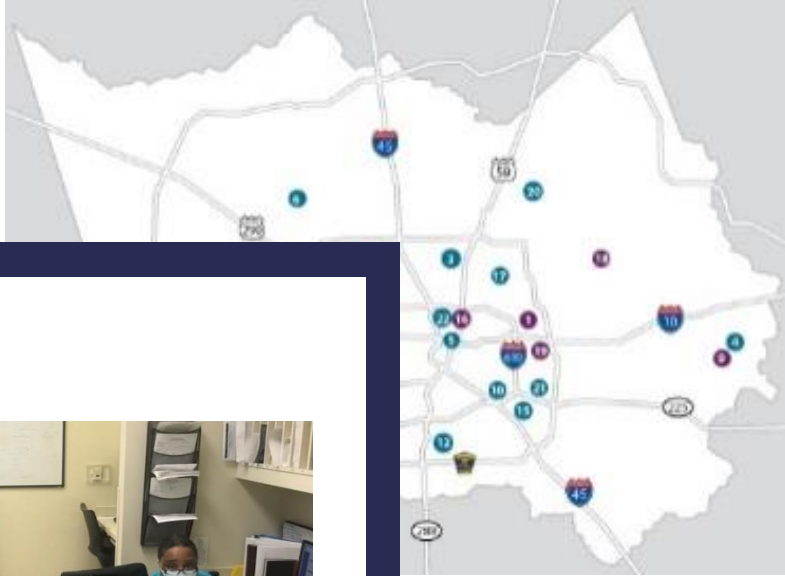
Cervical cancer screening in safety net health systems

Initial program in 2010: Established the Community Network for Cancer Prevention (CNCP)



Funding: CPRIT PP100201 (PD: Jibaja-Weiss), PP140028 (PD: Jibaja-Weiss), PP170094 (PDs: Jibaja-Weiss, Montealegre) & PP21007 (PDs: Montealegre, Jibaja-Weiss)





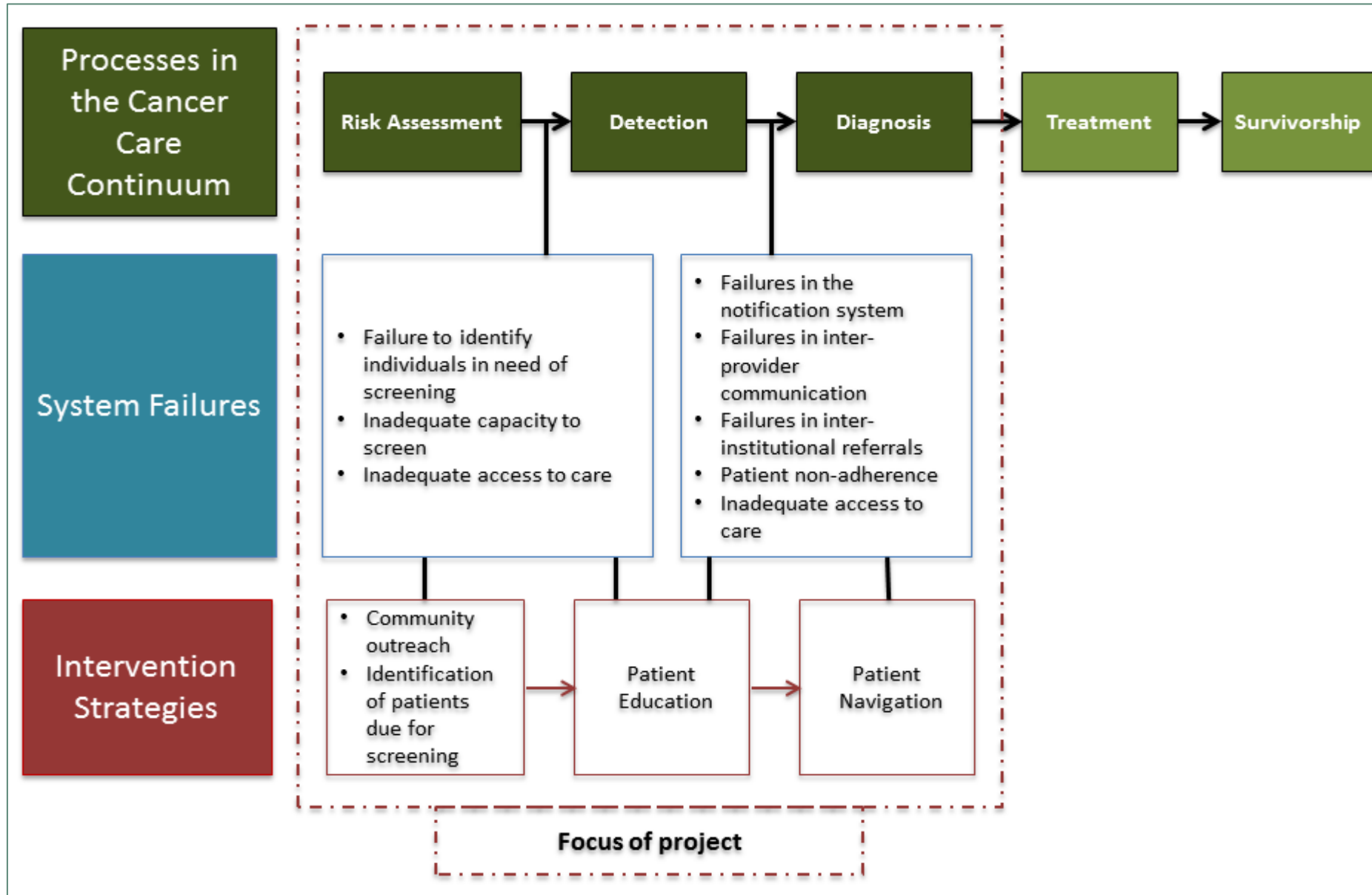
Partnership with Harris Health System, 3rd largest safety net health system in the U.S.
(>125,000 cervical cancer screening-eligible patients)



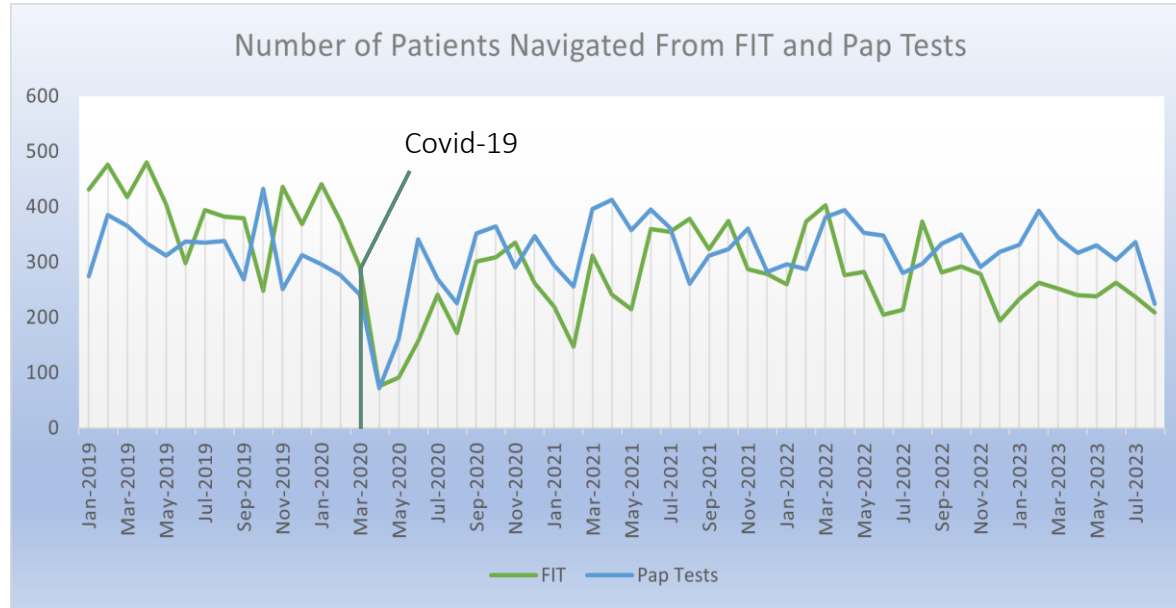
HARRISHEALTH
SYSTEM



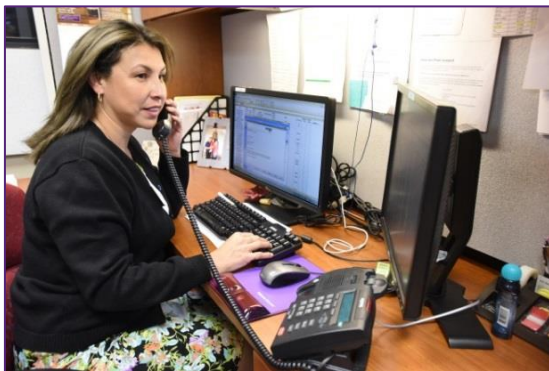
Approach



Results



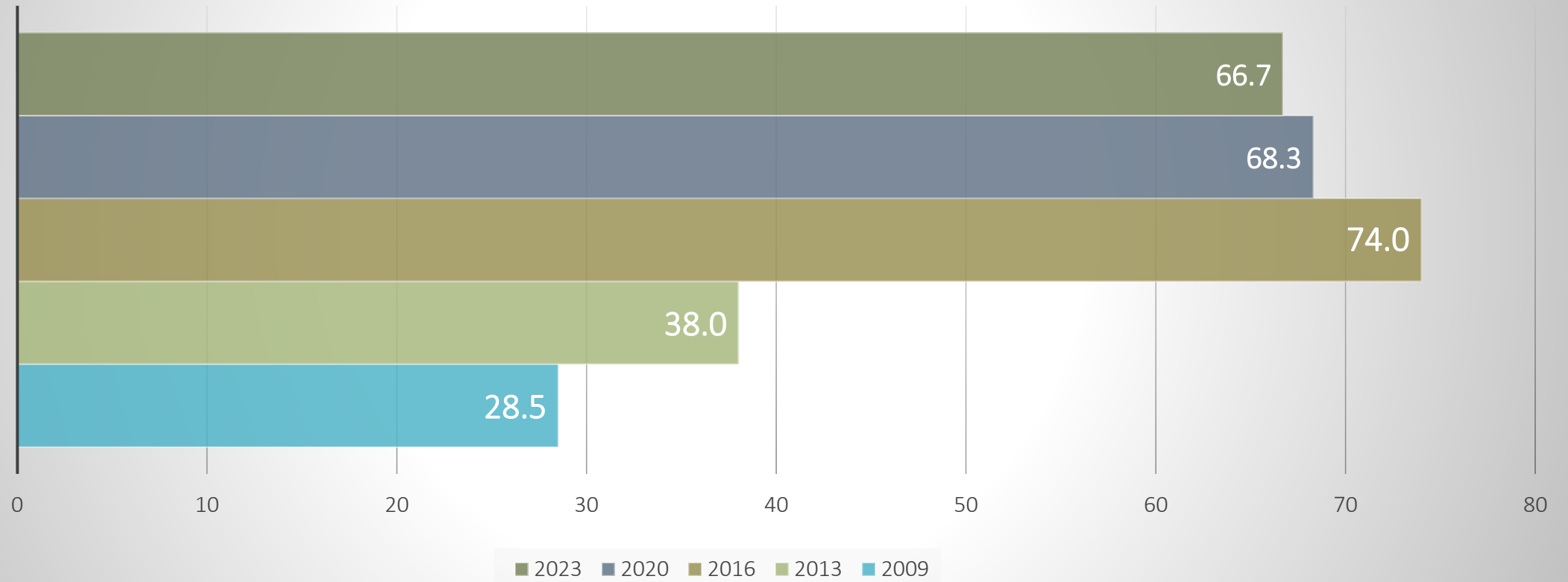
Outreach and education to community residents about the importance of screening and access navigation to CNCP clinical partners

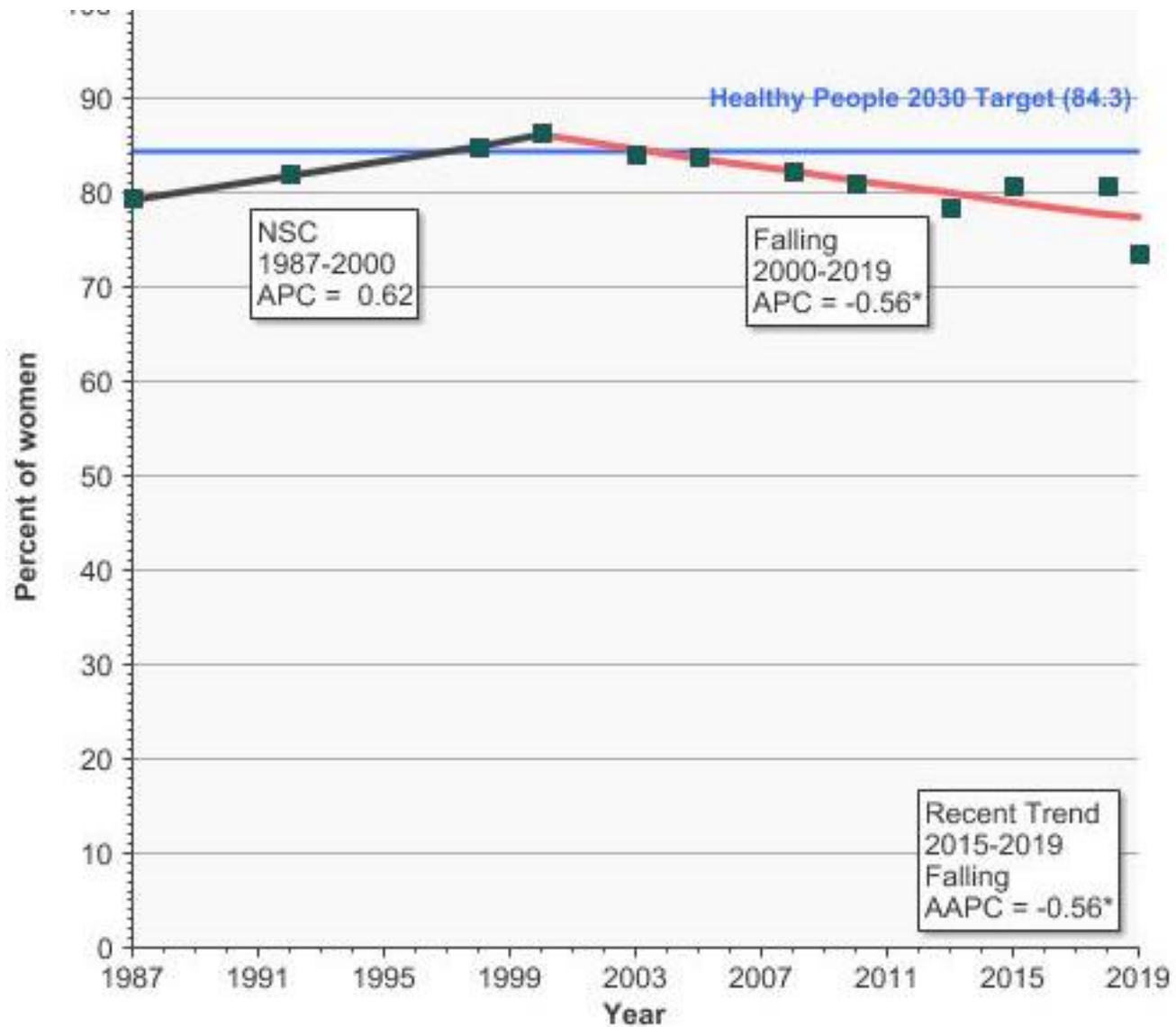


Navigate ~400 patients with an abnormal cervical cancer screening test each month

Results

Cervical Cancer Screening Completion among Harris Health System Patients
Ages 21-65 Years, 2009-2023



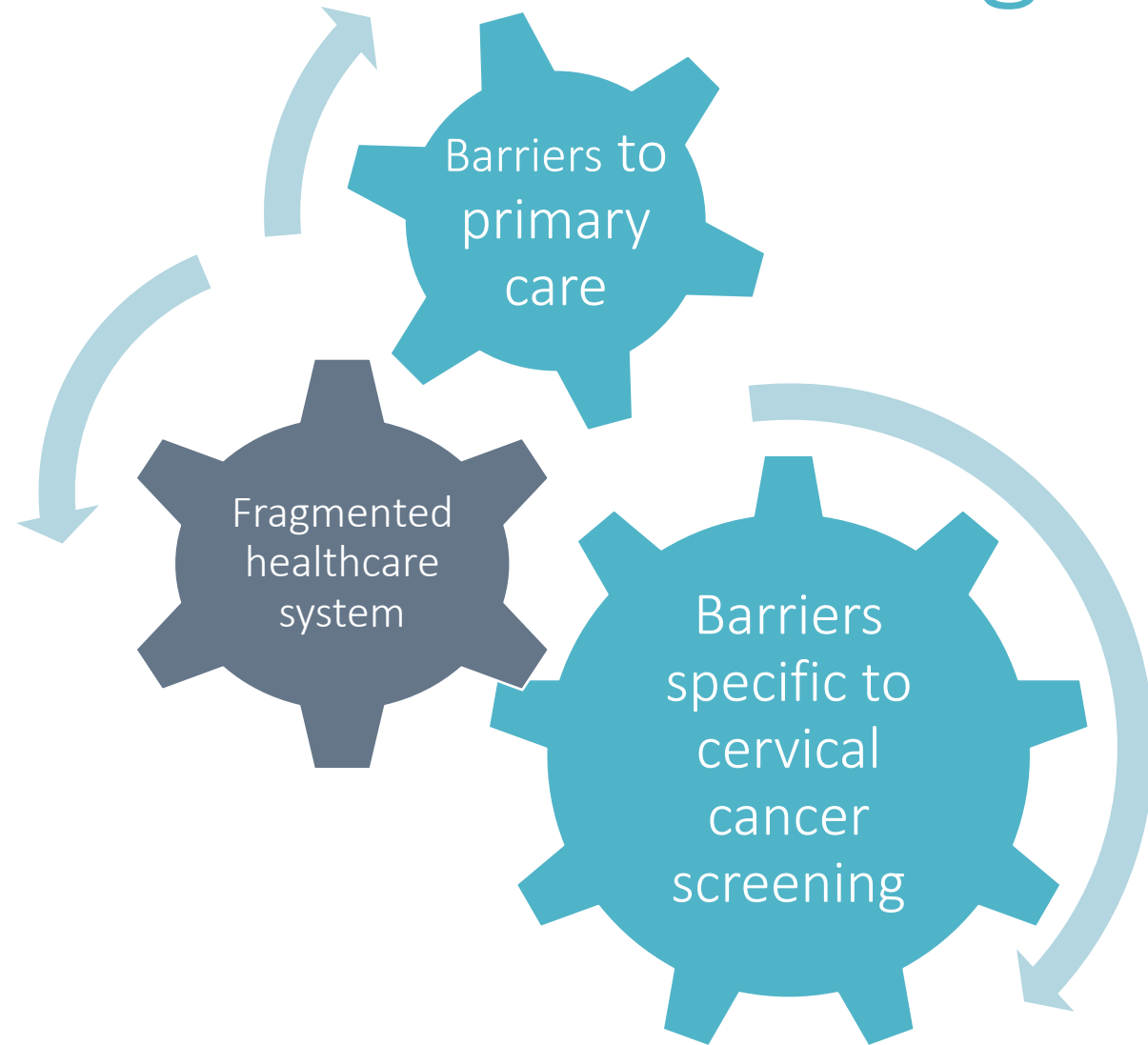


Challenges

Early on: dramatic improvement of cervical cancer screening coverage.

More recently: stagnation and declining coverage, consistent with national trends

Barriers to Cervical Cancer Screening



- Currently available interventions to increase provider-delivered screening are insufficient and inadequate to address existing barriers.

Pap Smear

- 21-65 Years
- Every 3 Years

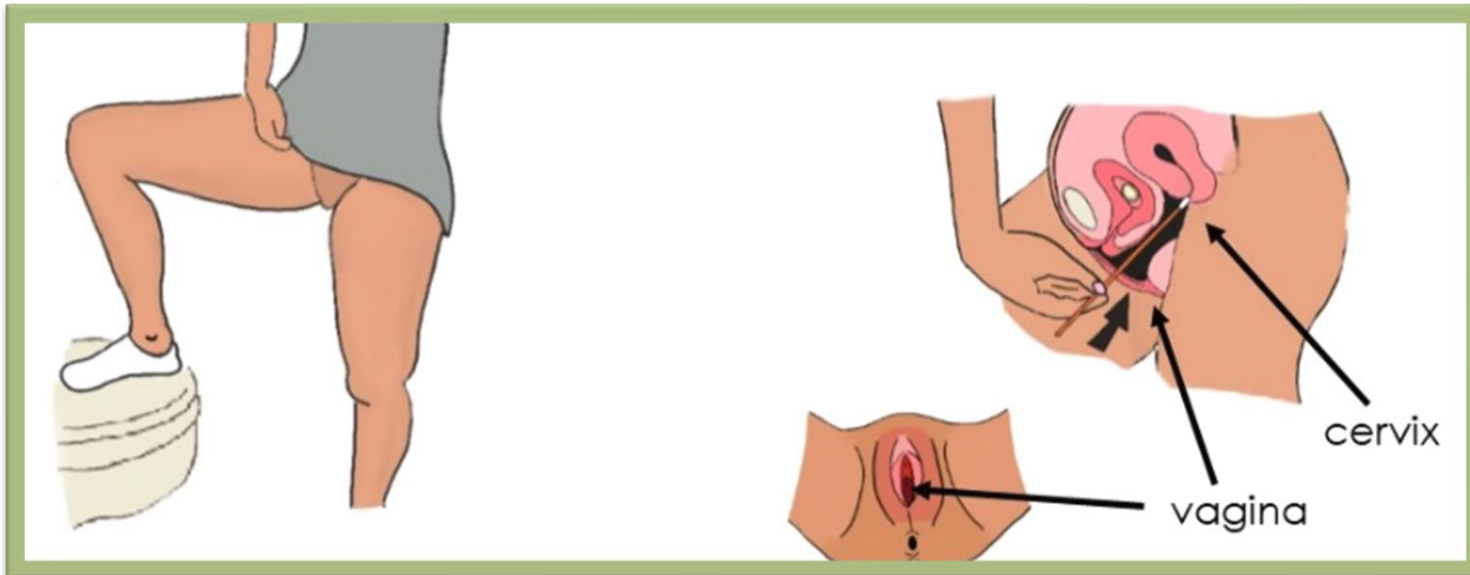
Pap Smear/High Risk HPV Co-Testing

- 30-65 Years
- Every 5 Years

PRIMARY High Risk HPV TESTING (Preferred)

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

Paradigm Shift



Shifting Paradigms

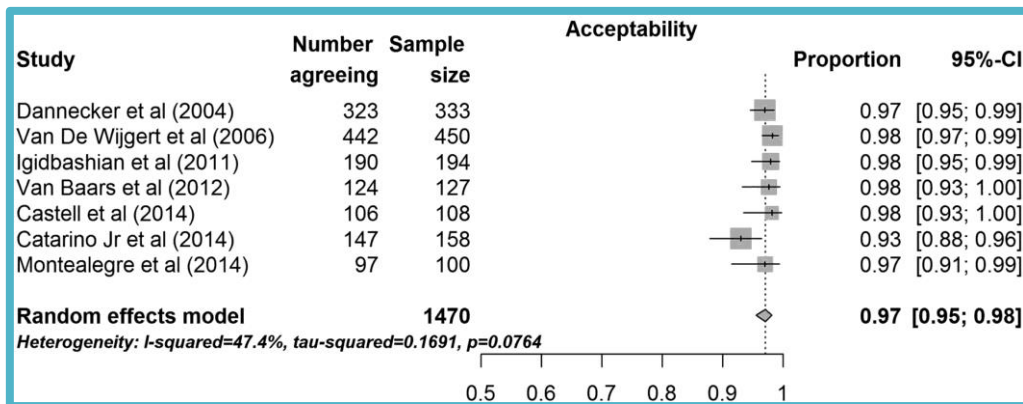
Equivalent sensitivity and specificity for detecting high-grade pre-cancer

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

Increased Participation in global settings

	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

High levels of acceptability



Arbyn et al, Lancet Oncol, 2018
 Costa et al, Br J Cancer, 2022
 Nelson et al, Sex Trans Infect, 2017

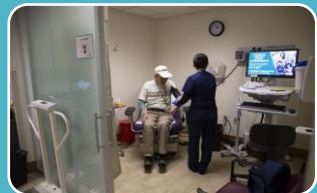
What about U.S. Safety Net Health Systems?



Serve a large proportion 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.

Safety net patients may face barriers that hinder effectiveness of mailed self-sample HPV testing kits:

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

The PRESTIS Trial: Prospective Evaluation of Self-Testing to Increase Screening



Effectiveness

Role of patient
navigation

Acceptability
And Experiences

Cost-
effectiveness

PRESTIS Trial

Screening from the privacy of your own home!
¡Detección temprana en la privacidad de su hogar!



1
Read the information
Lea la información



2
Collect your sample
Tome su muestra



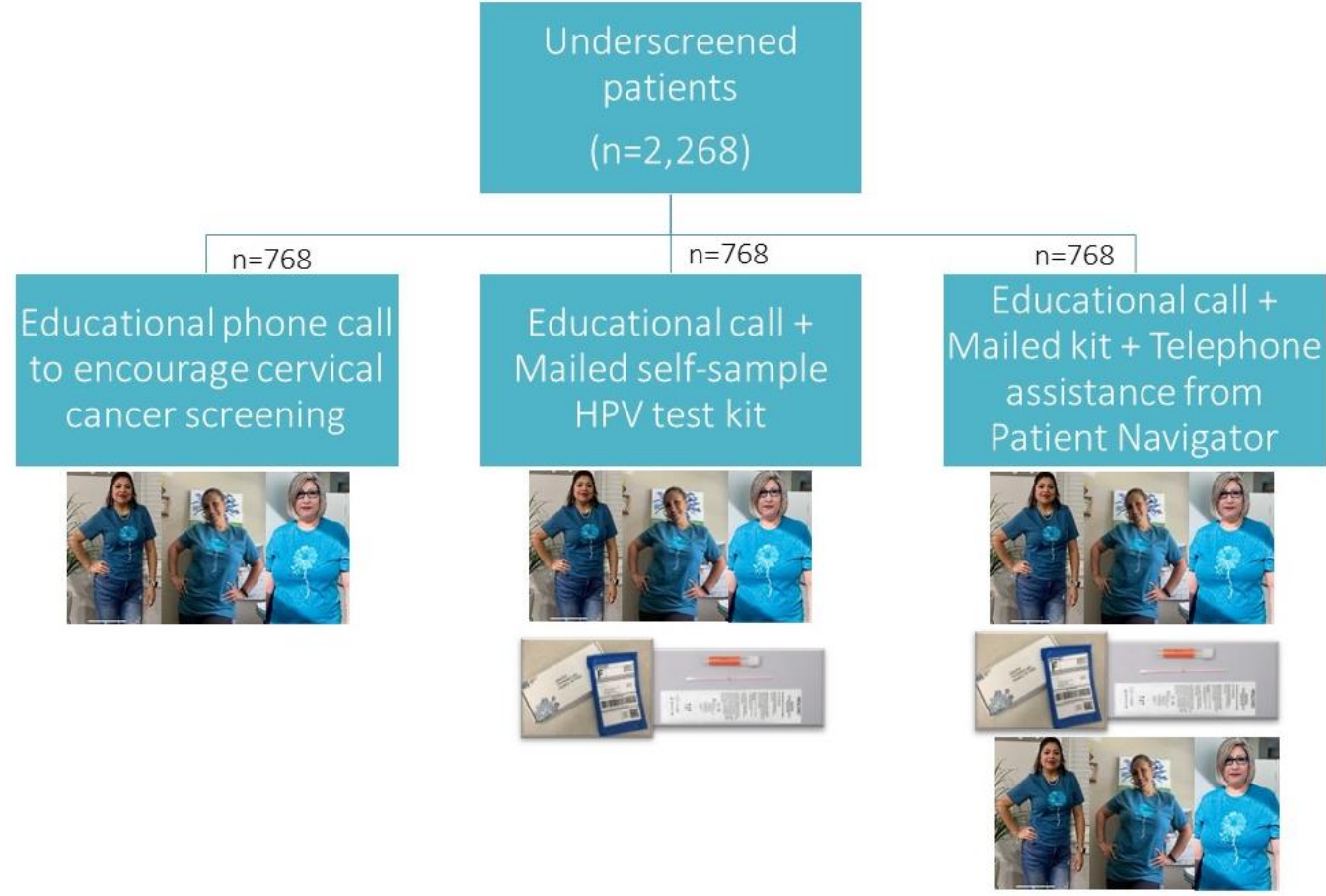
3
Place your sample in the mail **or** drop it off at your Harris Health clinic
Mande su muestra por correo o llévela a una clínica de Harris Health



4
Receive your results
Reciba sus resultados

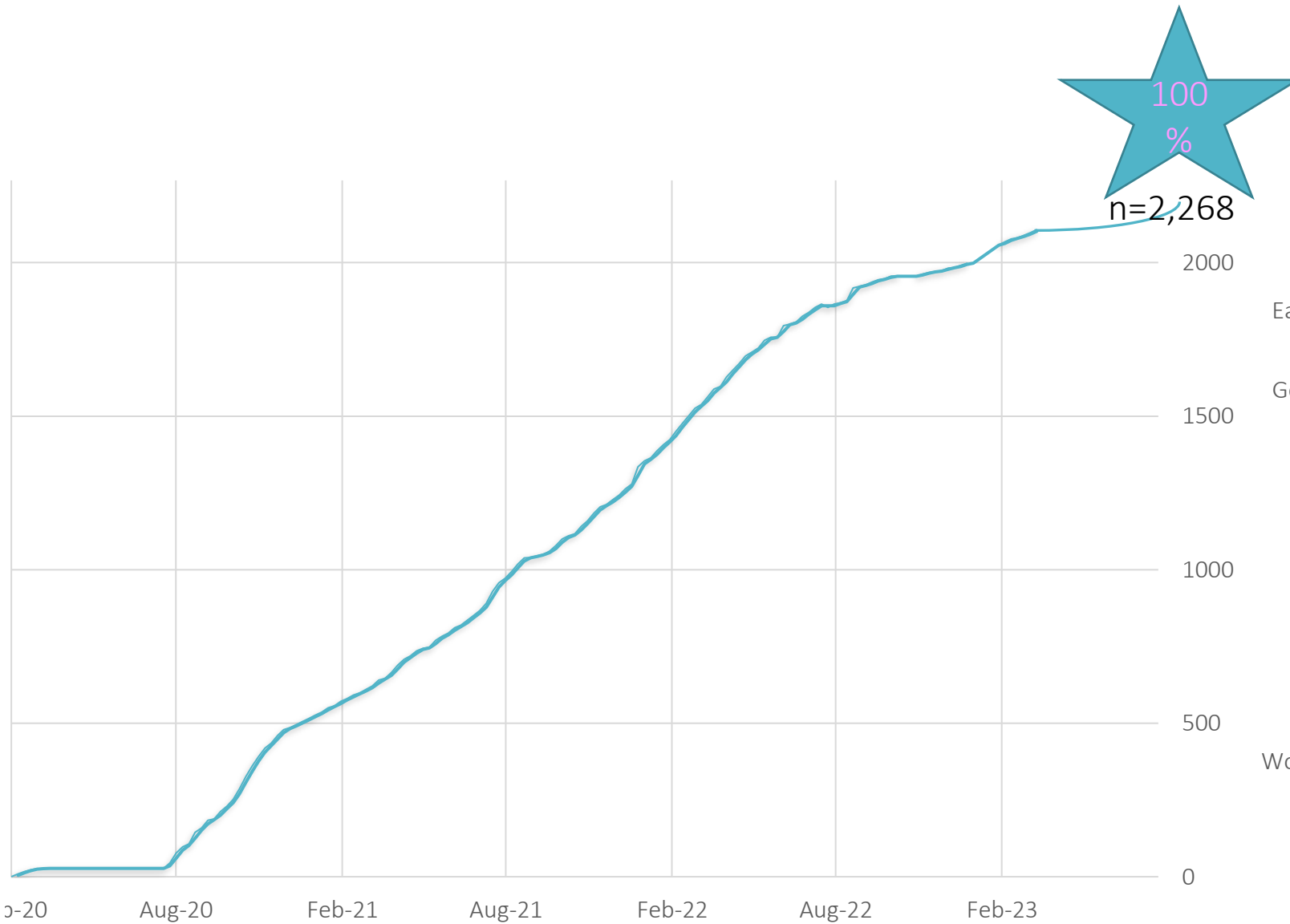


Montealegre et al. Trials 2020

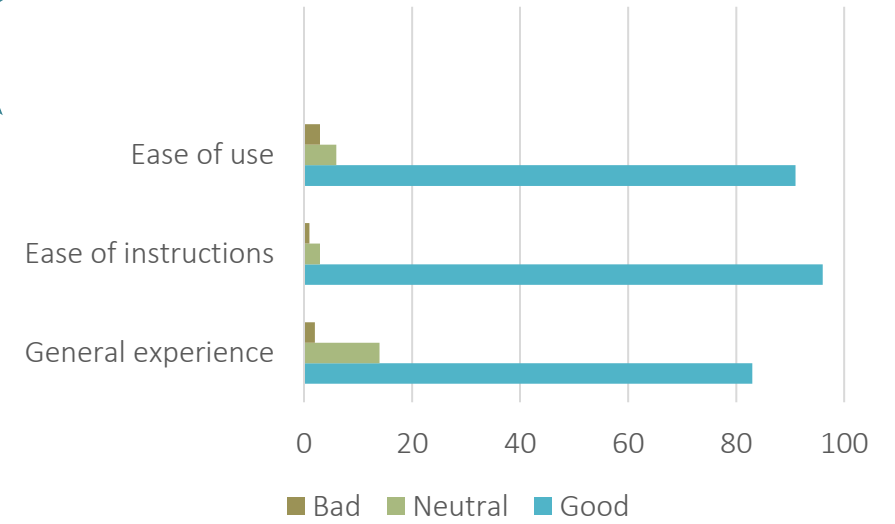


Funding: NIMHD R01MD30175 (Montealegre)

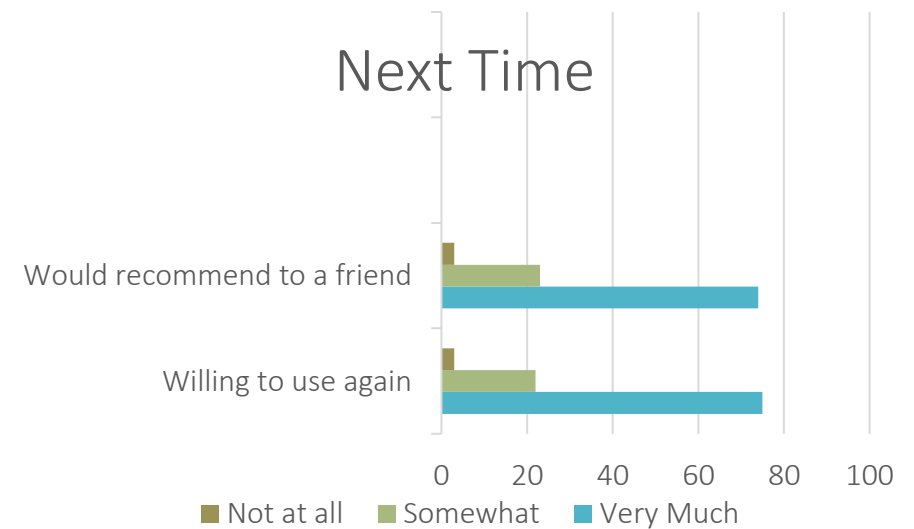
Interim Results



Experience



Next Time



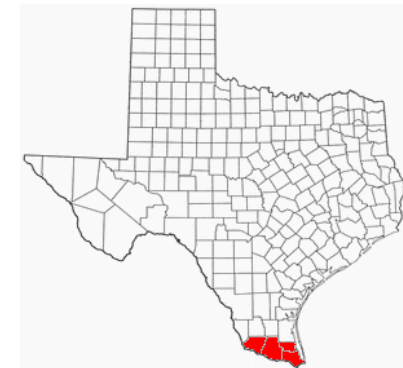


New
Opportunities
(once FDA
Approved):
Health System-
Based
Interventions

New Opportunities (once FDA approved): Community-based Interventions



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



New Collaborative Opportunities (once FDA approved):

Build on the evidence-base and experiences of currently-funded CPRIT programs and expand their reach through primary HPV-testing with self-sampling