Innovations and Frontiers in HPV Self-Sampling

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Making Cancer History®





VIRTUAL
SUMMIT SERIES

Harnessing the Power of Innovation to Improve Cancer Prevention and Early Detection

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## Disclosures

I have no conflicts of interest to disclose.



The global burden of cervical cancer is high



new diagnosis every minute
 new death every 2 minutes

## Cervical cancer can be prevented











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

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# How are we going to get there?







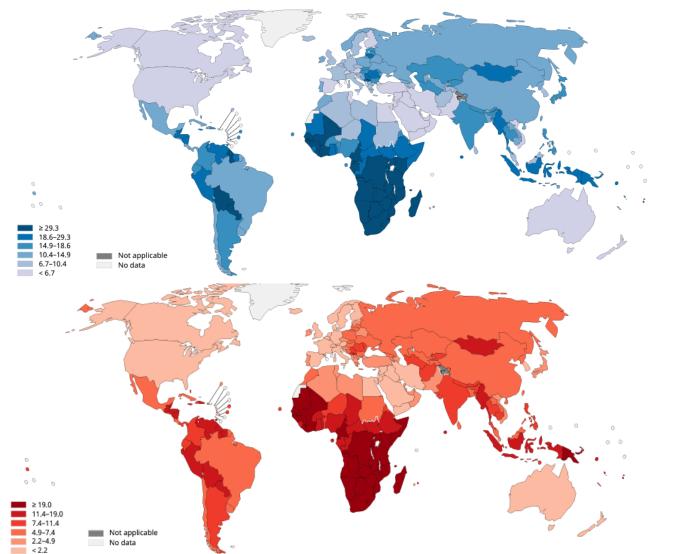
#### HARNESS INNOVATIONS

#### ACCELERATE AND SCALE-UP IMPLEMENTATION

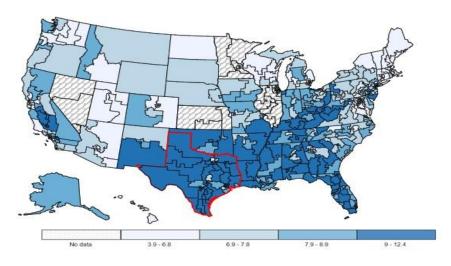
#### FOCUS ON EQUITY

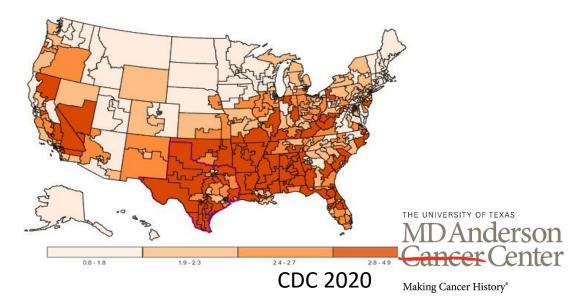


## Cervix Cancer: A Marker of Global Inequity



Globocan 2020





Time to elimination could be expedited by <u>10-13 years</u> by achieving <u>higher</u> <u>screening coverage</u>. The U.S. is on track to eliminate cervical cancer as a public health problem in the next two to three decades. 16 Cervical cancer incidence (per 100,000) 14 12 Screening scale-up (90% coverage) 10 'Elimination' year 2028 8 Status Quo / Vaccination scale-up (90% girls only) 6 'Elimination' year 2038 4 per 100,000 4 Screening scale-up < 1/100,000 year 2063 2 1 per 100,000 0  $-20^{2} - 20^{2} -$ 

Burger et al, Lancet Public Health, 2020

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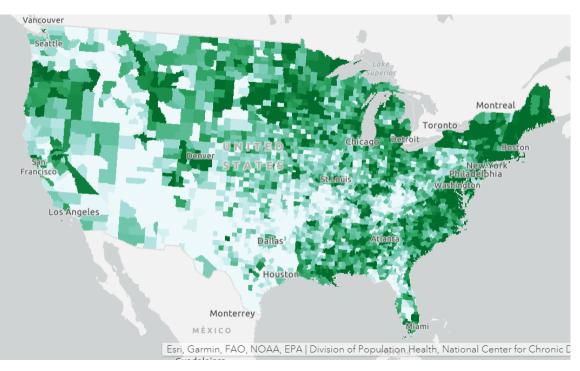
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# Unfortunately, cervical cancer screening coverage has declined.

Percent of females aged 21-65 years who

were up-to-date with cervical cancer screening, 1987-2019 100 90 Healthy People 2030 Target (84:3) 80 NSC Falling 1987-2000 2000-2019 70 APC = 0.62 $APC = -0.56^{\circ}$ Percent of women 60 50 40 30 20 Recent Trend 2015-2019 10 Falling AAPC = -0.56\* 0 1987 1991 1995 1999 2003 2007 2011 2015 2019 Year

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



Rates of overdue cervical cancer screening in 2019 by sociodemographic group

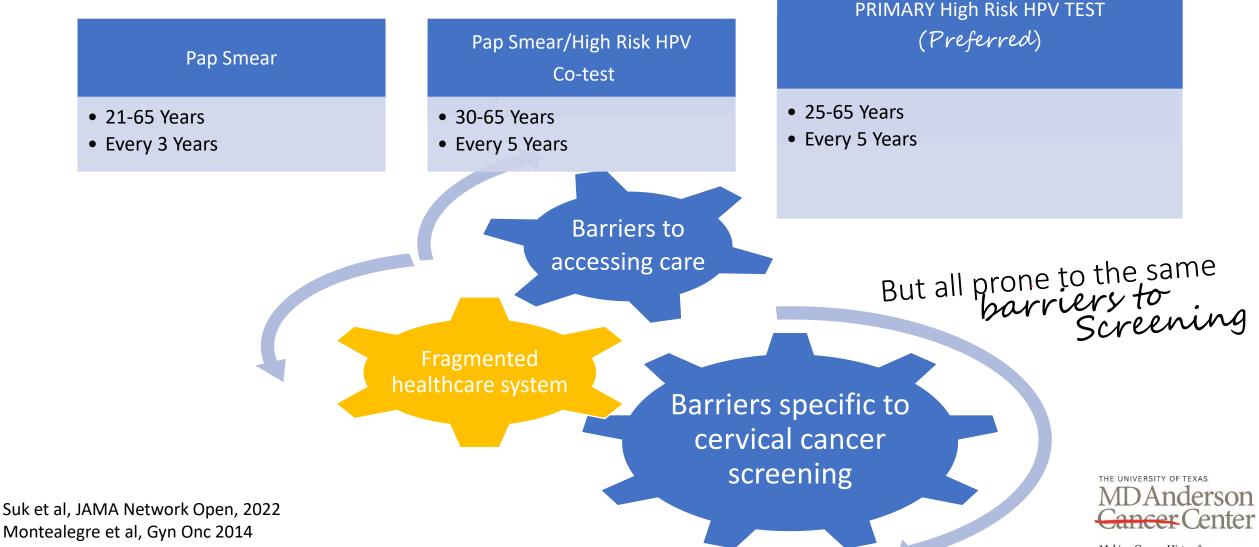
Racial and ethnic groups		
Non-Hispanic Black		
Non-Hispanic White		
Other (including Alaska Native and American Indian)		
Georgraphic groups		
Rural women		
Urban women		
Health insurance status		
Uninsured		
Public insurance		
Private insurance	18%	

And the disparities are

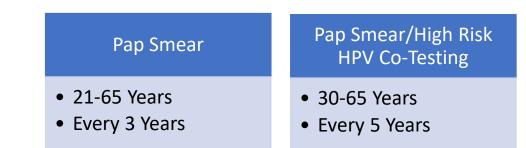
disparities are *profound*.



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



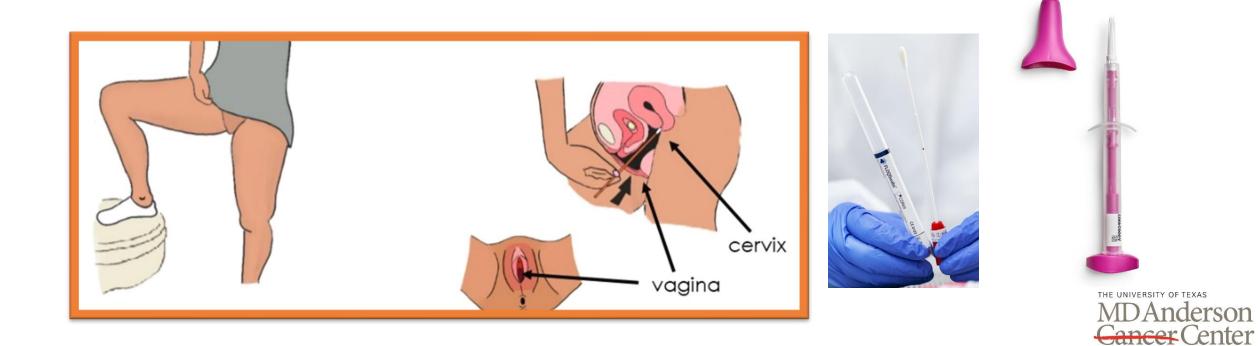




#### PRIMARY High Risk HPV TESTING (Preferred)

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

Paradigm Shift



## Shifting Paradigms

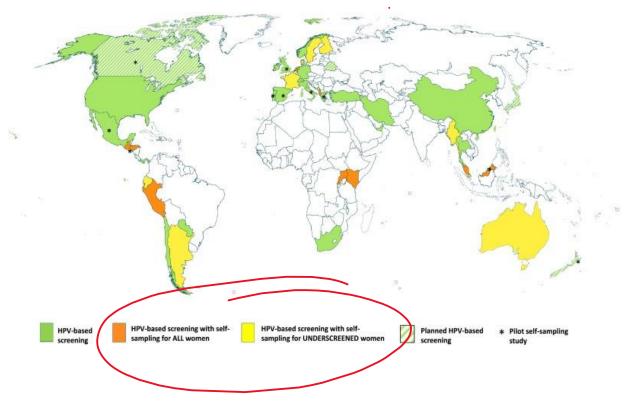
## Equivalent sensitivity and specificity for detecting high-grade pre-cancer

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

#### Increased Participation

	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

#### Self-Sampling in National Cervical Cancer Screening Programs



Arbyn et al, Lancet Oncol, 2018 Costa et al, Br J Cancer, 2022 Serrario 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: <u>Self-Sampling</u> for <u>H</u>PV to <u>Improve</u> <u>Prevention</u> of Cervical Cancer

Anticipated FDA approval: 2024-2025 (?)



## New possibilities. Opportunistic Clinic-Based Self-Sampling





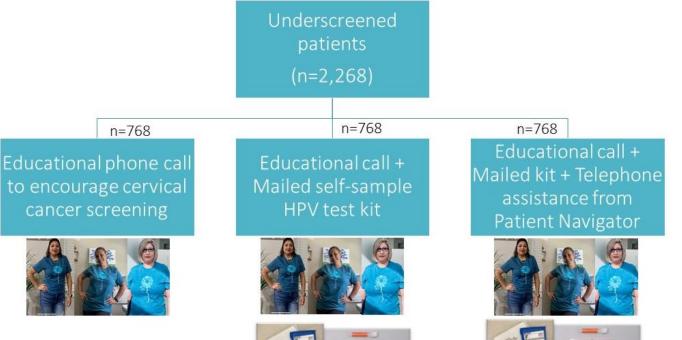
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## New Possibilities. Mailed Self-Sample HPV Testing













Montealegre et al. Trials 2020

Funding: NIMHD R01MD30175 (Montealegre)

New Possibilities. Community-Based Self-Sample HPV Testing









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



How do we prepare?

**Build capacity** 

and referral

networks to

provide clinical

follow-up







Implement strategies to ensure equitable access to care along to screening to treatment continuum

Adopt and Integrate Primary HR-HPV Testing



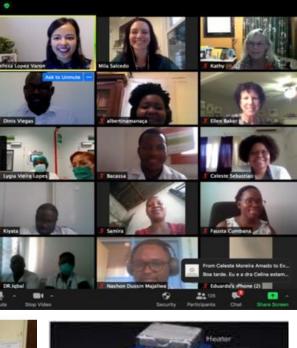
# CONTINUE TO INNOVATE

# And harness the power of innovation

to improve cancer prevention & achieve health equity.









Kunrod et al, Science Trans Med, 2023 Salcedo et al, Int J Gyn Cancer, 2019 Smith et al, Lab Chip, 2023





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