Innovations and Frontiers in HPV Self-Sampling

Jane Montealegre, PhD
Associate Professor, Department of Behavioral Science

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.

1 new diagnosis every minute
1 new death every 2 minutes

Cervical cancer can be prevented.
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 women-years)

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

* and boys in countries where resources allow
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

CDC 2020
The U.S. is on track to eliminate cervical cancer as a public health problem in the next two to three decades.

Screening scale-up (90% coverage)  
'Elimination' year 2028

Status Quo / Vaccination scale-up (90% girls only)  
'Elimination' year 2038

Screening scale-up
< 1/100,000 year 2063

Time to elimination could be expedited by 10–13 years by achieving higher screening coverage.
Unfortunately, cervical cancer screening coverage has declined.

NCI, 2021
CDC Cancer Statistics Visualizations, 2022
Suk et al, Lancet Public Health, 2022
Several test options according to the current Cervical Cancer Screening Guidelines*

- **Pap Smear**
  - 21-65 Years
  - Every 3 Years

- **Pap Smear/High Risk HPV Co-test**
  - 30-65 Years
  - Every 5 Years

- **PRIMARY High Risk HPV TEST** (Preferred)
  - 25-65 Years
  - Every 5 Years

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**Barriers to accessing care**

**Fragmented healthcare system**

**But all prone to the same barriers to Screening**

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Suk et al, JAMA Network Open, 2022
Montealegre et al, Gyn Onc 2014
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
It’s time
Shifting Paradigms

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

<table>
<thead>
<tr>
<th></th>
<th>Pooled Estimates</th>
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<tbody>
<tr>
<td><strong>Sensitivity</strong></td>
<td></td>
</tr>
<tr>
<td>Self-collected</td>
<td>96%</td>
</tr>
<tr>
<td>Provider-collected</td>
<td>96%</td>
</tr>
<tr>
<td><strong>Specificity</strong></td>
<td></td>
</tr>
<tr>
<td>Self-collected</td>
<td>79%</td>
</tr>
<tr>
<td>Provider-collected</td>
<td>79%</td>
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</tbody>
</table>

Increased Participation

<table>
<thead>
<tr>
<th></th>
<th>Self-Sampling Participation</th>
<th>Control Participation</th>
<th>Difference</th>
<th>Relative Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mailed kits</td>
<td>24%</td>
<td>10%</td>
<td>13%</td>
<td>2.5</td>
</tr>
<tr>
<td>Door-to-Door</td>
<td>93%</td>
<td>53%</td>
<td>39%</td>
<td>1.9</td>
</tr>
<tr>
<td>Offer at Clinic</td>
<td>50%</td>
<td>22%</td>
<td>28%</td>
<td>2.3</td>
</tr>
</tbody>
</table>

Arbyn et al, Lancet Oncol, 2018
Costa et al, Br J Cancer, 2022
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: Self-Sampling for **HPV** to Improve **Prevention** of Cervical Cancer

Anticipated FDA approval: 2024-2025 (?)
New possibilities:
Opportunistic Clinic-Based Self-Sampling
New Possibilities: Mailed Self-Sample HPV Testing

Screening from the privacy of your own home! ¡Detección temprana en la privacidad de tu 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 lléve la a una clínica de Harris Health
4. Receive your results
   Reciba sus resultados

Underscreened patients (n=2,268)

Educational phone call to encourage cervical cancer screening

Educational call + Mailed self-sample HPV test kit

Educational call + Mailed kit + Telephone assistance from Patient Navigator

Funding: NIMHD R01MD30175 (Montealegre)

Montealegre et al. Trials 2020

PRESTIS Study
New Possibilities:
Community-Based Self-Sample HPV Testing

Funding: MD Anderson Community Outreach and Engagement Fund for Underserved Texans (Montealegre)
How do we prepare?

- Adopt and Integrate Primary HR-HPV Testing
- Build capacity and referral networks to provide clinical follow-up
- Implement strategies to ensure equitable access to care along the screening to treatment continuum
- Adapt and develop strategies to ensure contextual fit
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
Thank you!
¡Muchas gracias!