A randomized trial of a community health worker led intervention using HPV self-sampling to increase cervical cancer screening among minority women: Preliminary findings

Supported by:
Community Networks Program, Center to Reduce Cancer Health Disparities
National Cancer Institute; U54 CA153705
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SUCCESS Vision

Through increased cervical cancer screening we can eliminate cervical cancer health disparities in our local community

Contribute towards our nation’s ongoing effort towards the reduction and ultimate elimination of cancer health disparities

Team:

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CHWs
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Linabel López
How to reduce cervical cancer disparities

• Improve Access to Care
• Community Health Workers are effective!
• Need to find a better screening test than
• USPSTF 2012 Guidelines
  • women aged 30 to 65 year: screening with Pap smear every 3 years or with a combination of Pap and HPV testing every 5 years
• Emerging evidence suggests that HPV testing followed by cytology in women with positive HPV test results may be reasonable strategy
Cervical Cancer Screening:  

“Reduction of cervical cancer morbidity and mortality will require novel strategies for screening. Self-collected swabs for HPV testing...is one such strategy that holds promise for addressing the disparities in cervical cancer screening”

- Advantages of HPV self-screening
  - Do not need see a doctor!!
  - Can be done by the woman herself
  - Can be done even if having menses
  - May be more culturally appropriate
Outreach Core

From January to September 2013, we conducted
- 155 Community Events
  - 44 Health Fairs
  - 42 Community Presentations
  - 37 Information table
  - 9 radio interviews
  - 23 Community Advisory Board (CAB) meetings

In sum, we have reached over 10,000 individuals with our health messaging and motivated more than 30% of unscreened women to get a Pap smear.
Maria in Hispanic/Latino Site
Valentine in Little Haiti site
Linabell at South Dade site
SUCCESS Main Research

• **RCT of 600** women who have not been adequately screened for cervical cancer

• **Primary Outcome**: Self-reported cervical cancer screening at 6 months

• **Secondary Outcomes**: cervical cancer knowledge, access to care, time to follow-up and further testing among women having abnormal screens.

• **Subgroup analyses**: site and race/ethnic group
Recruitment

- 200 women at each site over 3 years
- Rapid eligibility screen in community based locations and if eligible contact info for follow up home visit
- FQHC sites with UM and CAB input decides best recruitment strategy
- UM research staff with CHWs follow up with participant, obtain consent and do baseline intake survey
- In ARM 2 and 3 CHWs do follow up educational session and do intervention
- UM staff do 6 month follow up survey
Role of Community in Study? They are doing the study!!

- Developed idea for study with us
- They find the women, do the education, and do the intervention
- They coordinate the CABs for us
  - Extremely valuable input (recruitment, results notification)
- Two Bi-weekly meetings
  - Leadership review progress, troubleshoot
  - UM CHEs meet with CHWs weekly review progress
- What does UM do?
  - Scientific leadership / clinical trial methodology
  - Do IC, initial and 6 month f/u
  - Bean counters, data management and analysis
  - Writing, posters, papers, etc
Success Main Research

Numbers from CHWs

Assessed Total: 3,842
HI=1,569   LH=1,222   SD=1,051

Eligible Total: 1005
HI=322   LH=396   SD=287
CHW in Arm 3 Education Session
HPV Sampler Kit
Cumulative Randomized by Site

Number of Participants Randomized

- LH
- HI
- SD
- Total

2011          2012                                                                    2013

Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep
Participants by Site

<table>
<thead>
<tr>
<th>Site</th>
<th>Goal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>LH</td>
<td>163</td>
<td>163</td>
</tr>
<tr>
<td>HI</td>
<td>165</td>
<td>165</td>
</tr>
<tr>
<td>SD</td>
<td></td>
<td>166</td>
</tr>
</tbody>
</table>
SUCCESS as of 10/31/2013

Enrollment

Assessed for eligibility (n= 3987)

Ineligible and excluded (n= 2981)
• Age <30 or >65 (n= 576)
• Race (n= 40)
• PAP ≤ 3 years (n= 1979)
• Pregnant (n= 113)
• Uterus removed (n= 273)

Eligible (n=1005)

Non-Participants
• Do not want to participate (n= 1)

Potential Participants (n= 1004)
• Informed Consent Intake Survey Completed (n= 494)
• Contact in Process (n= 510)

Randomization
n= 494

Community Outreach (n= 155)

Sites
Hialeah (n= 53)
Little Haiti (n= 57)
South Dade (n= 45)

CHW (n= 172)
Health education and Navigation

Sites
Hialeah (n= 55)
Little Haiti (n= 54)
South Dade (n= 63)

CHW+ choice of HPV self sampler (n= 167)

Sites
Hialeah (n= 57)
Little Haiti (n= 52)
South Dade (n= 58)

Total Randomized by Sites
Hialeah (n= 165)
Little Haiti (n= 163)
South Dade (n= 166)
Completed 6-month follow up
persons > 9 months after enrollment, $N=331$

- Outreach Only: 90% completed, 10% pending
- CHW Navigation: 90% completed, 10% pending
- CHW and HPV Sampling: 90% completed, 10% pending
# HPV Positivity Rate

<table>
<thead>
<tr>
<th>Site</th>
<th>Arm 3-HPV pos=23 of N=87*</th>
<th>Arm 3 %</th>
<th>HPV samplers from EI</th>
<th>EI %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hialeah</td>
<td>7/32</td>
<td>21%</td>
<td>4/27</td>
<td>15%</td>
</tr>
<tr>
<td>Little Haiti</td>
<td>12/33</td>
<td>36%</td>
<td>11/38</td>
<td>29%</td>
</tr>
<tr>
<td>South Dade</td>
<td>4/22</td>
<td>18%</td>
<td>5/19</td>
<td>26%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>23/87</strong></td>
<td><strong>26%</strong></td>
<td><strong>20/84</strong></td>
<td><strong>24%</strong></td>
</tr>
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