Southern African HIV Clinicians Society
3rd Biennial Conference
13 - 16 April 2016
Sandton Convention Centre
Johannesburg

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Self-collected vs. Provider-collected Samples For Cervical Screening Using Xpert HPV

Abstract # 208

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14 April 2016
Disclosure

• These data were presented, in part, at the 30th International Papillomavirus Conference, Lisbon, Portugal, 2015
Estimated cervical cancer incidence worldwide (2012)
Xpert HPV (GeneXpert, Cepheid)

- Xpert HPV is a point-of-care rtPCR test for 14 hrHPV types:
  - HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68
- 1-hour run time
- All reagents contained in single cartridge
- No cold chain required
- Multichannel instruments available
Rationale

• The availability of Xpert HPV should expand access to cervical cancer screening through HPV “test-and-treat” strategies

• It is critical to understand how this test performs in HIV-infected women

• HPV self-testing may also improve screening coverage and should be investigated, including within HPV test-and-treat paradigms
Objectives

• To determine agreement between self- and provider-collected samples using Xpert HPV

• To evaluate the sensitivity, specificity, and agreement beyond chance of Xpert HPV as compared to Digene HC2 in HIV-infected women
Methods

• **Design:** Cross-sectional performance validation study

• **Population:** HIV-infected women 25-65 years
  - Not pregnant
  - No cervical HSIL
  - No treatment for HSIL

• **Setting:** Urban hospital and mobile clinic

• **Sample size:** 350
350 eligible HIV+ women enrolled

Self-collected specimen & pelvic examination

Self- & provider-collected Xpert HPV
Self- & provider-collected HC2
Pap smear
Statistical Analysis

• For this interim report (N=150) on accuracy of self-collected vaginal swabs for Xpert HPV we calculated:
  • Agreement beyond chance (Cohen’s Kappa statistic)
  • Percent agreement among positives between self-collected and provider-collected swabs
### Demographic Characteristics

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>39 years [35-44]</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>&lt; High school</td>
<td>39%</td>
</tr>
<tr>
<td>Completed high school</td>
<td>48%</td>
</tr>
<tr>
<td>Completed tertiary education</td>
<td>13%</td>
</tr>
<tr>
<td><strong>Employed</strong></td>
<td>75%</td>
</tr>
<tr>
<td><strong>Receiving ART</strong></td>
<td>98%</td>
</tr>
<tr>
<td><strong>CD4+ cell count, median [IQR]</strong></td>
<td>437 cells/uL [285-613]</td>
</tr>
<tr>
<td><strong>HIV-1 viral load &lt; 200 copies/mL</strong></td>
<td>72%</td>
</tr>
<tr>
<td><strong>Prior pap smear</strong></td>
<td>77%</td>
</tr>
</tbody>
</table>
Agreement Between Self- & Provider-Collected Xpert HPV

<table>
<thead>
<tr>
<th></th>
<th>Self-collected</th>
<th>Provider-collected</th>
<th>Kappa (95% CI)</th>
<th>Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any hrHPV</td>
<td>45%</td>
<td>37%</td>
<td>0.65 (0.52-0.77)</td>
<td>83%</td>
</tr>
<tr>
<td>HPV16</td>
<td>8%</td>
<td>6%</td>
<td>0.74 (0.53-0.96)</td>
<td>97%</td>
</tr>
<tr>
<td>HPV18/45</td>
<td>12%</td>
<td>8%</td>
<td>0.69 (0.48-0.89)</td>
<td>95%</td>
</tr>
<tr>
<td>HPV31/33/35/52/58</td>
<td>26%</td>
<td>20%</td>
<td>0.66 (0.51-0.80)</td>
<td>88%</td>
</tr>
<tr>
<td>HPV 51/59</td>
<td>8%</td>
<td>6%</td>
<td>0.61 (0.34-0.87)</td>
<td>96%</td>
</tr>
<tr>
<td>HPV39/68/56/66</td>
<td>18%</td>
<td>15%</td>
<td>0.80 (0.67-0.93)</td>
<td>95%</td>
</tr>
</tbody>
</table>
Conclusions

• We observed robust agreement between self- and provider-collected Xpert HPV samples
• There was also greater cellularity and increased hrHPV detection in self-collected samples
• Our preliminary results suggest a potential role for self-collected samples in future HPV test-and-treat programs