Comparison of a Portable Colposcope with State of the Art Cervical Screening in the U.S., Peru, and Tanzania

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Disclosures

- This work is supported by NIH R01 CA195500 and NIH R01 CA193380
- I have no financial relationships or conflict of interest to disclose.
Who are we?

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Duke BME

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Duke Statistics

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Duke BME

Max Kellish
Duke BME

Guillermo Shapiro
Duke ECE
Leisegang Optik-2
$20,000USD

Canon SX50HS
US $500USD

Colposcopy/Cervicography
Where?

DUKE

KCMC

La Liga

IFCPC 2017 World Congress
Why do we need this?
Cervical Cancer in Peru

KEY STATS.

About 4,636 new cervical cancer cases are diagnosed annually in Peru (estimations for 2012).

Cervical cancer ranks as the 1st cause of female cancer in Peru.

Cervical cancer is the 1<sup>st</sup> most common female cancer in women aged 15 to 44 years in Peru.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Peru</th>
<th>South America</th>
<th>World</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual number of new cancer cases</td>
<td>4,636</td>
<td>45,008</td>
<td>527,624</td>
</tr>
<tr>
<td>Crude incidence rate&lt;sup&gt;a&lt;/sup&gt;</td>
<td>31.3</td>
<td>22.2</td>
<td>15.1</td>
</tr>
<tr>
<td>Age-standardized incidence rate&lt;sup&gt;a&lt;/sup&gt;</td>
<td>32.7</td>
<td>20.3</td>
<td>14.0</td>
</tr>
<tr>
<td>Cumulative risk (%) at 75 years old&lt;sup&gt;b&lt;/sup&gt;</td>
<td>3.4</td>
<td>2.0</td>
<td>1.4</td>
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</table>

Data reported as of 15 Mar. 2015

http://www.hpvcentre.net/statistics/reports/PER.pdf
Cervical Cancer in Tanzania

KEY STATS.

About 7,304 new cervical cancer cases are diagnosed annually in Tanzania (estimations for 2012).

Cervical cancer ranks* as the 1st leading cause of female cancer in Tanzania.

Cervical cancer is the 1st most common female cancer in women aged 15 to 44 years in Tanzania.

Table 3: Cervical cancer incidence in Tanzania (estimates for 2012)

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Tanzania</th>
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<th>World</th>
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<td>7,304</td>
<td>45,707</td>
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<tr>
<td>Crude incidence rate*</td>
<td>30.6</td>
<td>25.8</td>
<td>15.1</td>
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<tr>
<td>Age-standardized incidence rate*</td>
<td>54.0</td>
<td>42.7</td>
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<tr>
<td>Cumulative risk (%) at 75 years old*</td>
<td>5.8</td>
<td>4.6</td>
<td>1.4</td>
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http://www.hpvcentre.net/statistics/reports/TZA.pdf
Study Design

A Pilot Comparison of the POCkeT Colposcope and Standard-of-Care Cervical Screening At 3 Centers
Clinical Study Protocol at Duke

Speculum Placement

Leisegang Optik 2

Pocket Colposcope

Images with each scope
(white and green light)

5% Acetic Acid
White and Green images

5% Acetic Acid
White and Green images

Randomized Image Pairs

Standard of Care Biopsy with
Image Quality and Visual Diagnosis

Blinded Image Interpretation
Modified Reid Index
Lesion Margin, Color,
Vessels, Impression

Images with each scope
(white and green light)
Clinical Study Protocol at KCMC

- Speculum Placement + 5% Acetic Acid
- VIA Impression
- 35mm Camera (Canon SX50HS)
- Pocket Colposcope
- 5% Acetic Acid
- Randomized Image Pairs
- Image Quality and Visual Diagnosis (Pathology only if indicated)
- Blinded Image Interpretation

Modified Reid Index
Lesion Margin, Color, Vessels, Impression
Clinical Study Protocol at La Liga

Speculum Placement + 5% Acetic Acid

Goldway 2000 image

Pocket Colposcope image

5% Acetic Acid

Lugol’s Iodine

Images with each scope
(Lugol’s and Acetic acid)

Randomized Images Pairs

Standard of Care Biopsy with Image Quality and Visual Diagnosis

Blinded Image Interpretation

Modified Reid Index
Lesion Margin, Color, Vessels, Impression
Representative Images - Duke

<table>
<thead>
<tr>
<th></th>
<th>Normal</th>
<th>LSIL</th>
<th>HSIL</th>
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<tr>
<td>Pocket</td>
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<td>Acetic Acid</td>
<td>Acetic Acid</td>
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<tr>
<td>Leisegang</td>
<td>Green</td>
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Representative Images - Peru

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<td></td>
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<td>Lugol’s Iodine</td>
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<td>Goldway</td>
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<td><img src="image8" alt="Image" /></td>
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### Representative Images - Tanzania

<table>
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<th>Normal</th>
<th>LSIL</th>
<th>HSIL</th>
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<tbody>
<tr>
<td>Pocket</td>
<td>Acetic Acid</td>
<td>Acetic Acid</td>
<td>Acetic Acid</td>
</tr>
<tr>
<td>Canon</td>
<td></td>
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</table>

**Acetic Acid**
Image Concordance: Duke

n=276, 3 clinicians

Level of Agreement (%)

Portable Colposcope vs. Standard of Care
Portable Colposcope vs. Pathology
Standard of Care vs. Pathology

CIN-  CIN+
<table>
<thead>
<tr>
<th>(3 clinicians) Cut Off $\geq$ CIN 1</th>
<th># of image pairs</th>
<th>Level of Agreement (%)</th>
<th>kappa</th>
<th>p-value</th>
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<tbody>
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<td>276</td>
<td>72.1</td>
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<td>Portable Colposcope vs. Pathology</td>
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<td>58.7</td>
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<td>63.4</td>
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<table>
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<th>(n=276, 3 clinicians) Cut Off $\geq$ CIN 1</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
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<td>66.0</td>
<td>48.2</td>
<td>71.6</td>
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<td>Standard of Care Colposcope vs. Pathology</td>
<td>77.8</td>
<td>43.0</td>
<td>66.0</td>
<td>57.6</td>
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</tbody>
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Image Concordance: Peru

n=280, 4 clinicians

Level of Agreement (%)

- Portable Colposcope vs. Standard of Care
- Portable Colposcope vs. Pathology
- Standard of Care vs. Pathology
# Image Concordance: Peru

<table>
<thead>
<tr>
<th>(4 clinicians)</th>
<th>Cut Off ≥ CIN 1</th>
<th># of image pairs</th>
<th>Level of Agreement (%)</th>
<th>kappa</th>
<th>p-value</th>
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<table>
<thead>
<tr>
<th>(n=274, 4 clinicians)</th>
<th>Cut Off ≥ CIN 1</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
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<tbody>
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<td>Portable Colposcope vs. Pathology</td>
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Image Concordance: Tanzania

n=150, 3 clinicians

Portable Colposcope vs. Standard of Care

Level of Agreement (%)
Overall Pooled Image Concordance

n=706, 7 clinicians, 3 sites
n=598, 7 clinicians, 3 sites

Level of Agreement (%)
### Overall Pooled Image Concordance

<table>
<thead>
<tr>
<th>(7 clinicians)</th>
<th>Cut Off ≥ CIN 1</th>
<th># of image pairs</th>
<th>Level of Agreement (%)</th>
<th>kappa</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Portable Colposcope vs. Standard of Care Colposcope</td>
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<table>
<thead>
<tr>
<th>(n=598, 7 clinicians)</th>
<th>Cut Off ≥ CIN 1</th>
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<th>Specificity</th>
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<th>NPV</th>
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<tbody>
<tr>
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<td>70.7</td>
<td>45.1</td>
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<td>41.3</td>
<td>63.4</td>
<td>62.3</td>
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</table>
Conclusions

Reasonable Image Concordance between devices and clinicians in all three countries
Comparative Diagnostic Accuracy with comparative sensitivity & specificity between device and SOC
Imaging Quality that is equivalent to high-end colposcopy
Low Cost – Approximately $500USD
Portable – Connectivity to laptop, tablet, or smartphone
Easy to Use
Secure Image Transmission and Storage – Cloud Based
Timely Expert Consultation – Local and Worldwide
Image Database for Educational programs and QI
Potential for Computer Algorithms
Potential for Speculum Free Imaging
LEEP or Hysterectomy

Cancer Therapy

HPV Prescreen ➔ POckeT ➔ Onsite Treatment Cryotherapy or Cold Coagulation
“THE IDEA THAT SOME LIVES MATTER LESS IS THE ROOT OF ALL THAT’S WRONG WITH THE WORLD.”

Dr. Paul Farmer, Partners in Health