Clinical Breast Exam Screening Program by Trained Laywomen in Malawi

Lily Gutnik MD MPH
Personal Background

- **Academic training:** Current Surgery Resident at University of Utah,
- **Fogarty fellowship site:** UNC Project Malawi, Lilongwe Malawi 2014-15
- **Fogarty project title:** Clinical Breast Exam Screening Program by Trained Laywomen
- **Primary mentors:** Satish Gopal MD MPH, Clara Lee MD MS

Agnes Ntoya 2/8/1948 - 2/2/2017
Study Objectives

Aim 1: To train laywomen as breast health workers to perform screening clinical breast exams (CBE) and to educate patients on breast cancer in Lilongwe health clinics.

Aim 2: To assess feasibility and acceptability of CBE screening in Malawi as a possible future strategy for early breast cancer detection in this setting.

Aim 3: To assess clinical outcomes for CBE, including proportion of women with detectable abnormalities and subsequent pathologic diagnoses.
Breast Health Workers (BHW)

<table>
<thead>
<tr>
<th>BHW</th>
<th>Age</th>
<th>Marital Status</th>
<th>Highest Educational Attainment</th>
<th>Most Recent Work Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>22</td>
<td>Single</td>
<td>College</td>
<td>Assistant primary school teacher</td>
</tr>
<tr>
<td>2</td>
<td>27</td>
<td>Married</td>
<td>Secretarial school, certificate in information technology</td>
<td>Administrative assistant in private hospital</td>
</tr>
<tr>
<td>3</td>
<td>36</td>
<td>Married</td>
<td>Teacher's college and certification</td>
<td>Completed teaching certification</td>
</tr>
<tr>
<td>4</td>
<td>58</td>
<td>Married</td>
<td>Secretarial school</td>
<td>Corporate administrative assistant</td>
</tr>
</tbody>
</table>
Training
Study Design and Flow

Eligible Women:
- ≥30 years old
- No prior breast cancer or breast surgery
- Clinic attendance for reasons other than a breast concern

Breast Cancer Talk in Clinic Waiting Room:
- 1 STI Clinic
- 2 General Medicine
- 1 Colposcopy
- 1 Family Planning/Antenatal

Recruitment, enrollment after clinic visit, BHW performs CBE in private exam room

Normal CBE
- Randomized to Ultrasound
- Randomized to Physician Exam

Abnormal CBE
- Physician Exam
  - Concordant Exam
    - FNA/Core Needle biopsy for all palpable masses
  - Discordant Exam
    - Ultrasound

Randomized to Ultrasound
Results: Aim 1: Training Laywomen

Pre-Post survey
pre-training knowledge increased from 49% to 91% correct (p<0.0001),

CBE:

<table>
<thead>
<tr>
<th>BHW CBE</th>
<th>Physician CBE Abnormal</th>
<th>Physician CBE Normal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal (n=60)</td>
<td>29 (48.3%)</td>
<td>31 (51.7%)</td>
</tr>
<tr>
<td>Normal (n=45)</td>
<td>2 (4.4%)</td>
<td>43 (95.5%)</td>
</tr>
</tbody>
</table>

- Sensitivity: 93.5% (95% CI 78.6-99.2%)
- Specificity: 58.1% (95% CI 46.1-69.5%)
- Positive predictive value: 48.3% (95% CI 35.2%-61.6%)
- Negative predictive value: 95.6% (95% CI 84.9-99.5%)
Results Aim 2: Feasibility and Acceptability

2,288 women approached for study participation
- 83% attended educational talk
- 17% did not attend educational talk

1220 (53%) of women eligible

1,068 (47%) of women not eligible
- 95% ≤30 years of age
- 2% clinic attendance for breast concern
- 1% history of breast surgery
- 2% deemed not eligible by study staff although reason not documented

1,000 (82%) women accepted CBE and study participation
- Acceptance varied across clinics from 71%-86% (p=0.001)
- Educational talk attendance was associated with higher CBE participation (83% vs 77%, p=0.012).

220 (18%) women declined CBE and study participation
- 69% lack of time
- 16% feeling ill/tired
- 4% lack of interest
- 3% tending to child
- 3% fear of cancer diagnosis
- 5% other reasons

175 Talks attended by:
- 2,860 women
- 1,435 men

1,068 (47%) of women not eligible

220 (18%) women declined CBE and study participation
- 69% lack of time
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- 4% lack of interest
- 3% tending to child
- 3% fear of cancer diagnosis
- 5% other reasons

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## Participant Characteristics

<table>
<thead>
<tr>
<th></th>
<th>All women (n=1000)</th>
<th>CBE normal (n=933)</th>
<th>CBE abnormal (n=67)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, years (SD)</td>
<td>37.2 (8.0)</td>
<td>37.2 (8.0)</td>
<td>36.5 (8.1)</td>
<td>0.447</td>
</tr>
<tr>
<td>Family history of breast cancer, n (%)</td>
<td>23 (2.3)</td>
<td>18 (1.9)</td>
<td>5 (7.5)</td>
<td>0.015</td>
</tr>
<tr>
<td>Has children, n (%)</td>
<td>962 (96.2)</td>
<td>902 (96.7)</td>
<td>60 (89.6)</td>
<td>0.003</td>
</tr>
<tr>
<td>Post-menopausal, n (%)</td>
<td>110 (11.0)</td>
<td>99 (10.6)</td>
<td>11 (16.4)</td>
<td>0.142</td>
</tr>
<tr>
<td>Currently breastfeeding, n (%)</td>
<td>139 (13.9)</td>
<td>130 (13.9)</td>
<td>9 (13.4)</td>
<td>0.909</td>
</tr>
<tr>
<td>Currently using contraception, n (%)</td>
<td>550 (55.0)</td>
<td>530 (56.8)</td>
<td>20 (29.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Had breast concerns in past 30 days, n (%)</td>
<td>103 (10.3)</td>
<td>58 (6.2)</td>
<td>45 (67.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Breast lump</td>
<td>6 (0.6)</td>
<td>0 (0)</td>
<td>6 (13.3)</td>
<td>0.004</td>
</tr>
<tr>
<td>Nipple discharge</td>
<td>12 (1.2)</td>
<td>2 (3.4)</td>
<td>10 (22.2)</td>
<td>0.003</td>
</tr>
<tr>
<td>Breast pain</td>
<td>33 (3.3)</td>
<td>9 (15.5)</td>
<td>24 (53.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Breast Itching</td>
<td>57 (5.7)</td>
<td>45(77.6)</td>
<td>12 (26.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mean age at onset of menses, years (SD)(^a)</td>
<td>15.0 (1.8)</td>
<td>15.1 (1.6)</td>
<td>15.0 (1.8)</td>
<td>0.93</td>
</tr>
<tr>
<td>Mean age at birth of first child, years (SD)(^b)</td>
<td>22.3 (6.4)</td>
<td>22.4 (6.3)</td>
<td>20.4 (4.3)</td>
<td>0.82</td>
</tr>
<tr>
<td>Mean age at menopause, years (SD)(^c)</td>
<td>50 (6.1)</td>
<td>47.1 (6.1)</td>
<td>46.1 (6.2)</td>
<td>0.65</td>
</tr>
</tbody>
</table>

CBE=clinical breast exam. SD=standard deviation. \(^a\)870 women (812 CBE normal, 58 CBE abnormal) reported age at onset of menses. \(^b\)948 women (888 CBE normal, 60 CBE abnormal) reported age at birth of their first child. \(^c\)82 women (73 CBE normal, 9 CBE abnormal) reported age at menopause.
Results Aim 3: Clinical Outcomes

29 women with abnormal screening CBE and abnormal physician exam

19 recommended to have pathologic sampling

- 15 breast lesions
  - 7 fibroadenoma
  - 2 normal/benign
  - 2 dysplasia
  - 1 galactocele
  - 1 abscess
  - 2 declined diagnostic procedure

- 4 axillary lesions
  - 1 Kaposi sarcoma
  - 1 tumoral calcinosis
  - 2 declined diagnostic procedure

10 not recommended to have pathologic sampling

- 8 breast lesions
  - 5 breast pain
  - 2 breast infection
  - 1 breast asymmetry

- 2 axillary lesions
  - 2 lymph nodes <1cm


**Presentations:**


Lessons Learned & Advice

- What’s the way forward?
- Capitalize on Every Opportunity
- Relationships are the key
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