Where there is no mammogram:
A model for the early detection of breast cancer in low resource areas, lessons from Peru

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Specializing in designing, developing, and scaling solutions in five core areas:

- Vaccines
- Diagnostics
- Drugs
- Devices
- Health systems
With a focus on:

- Cancer
- Diabetes
- Diarrheal disease
- Early childhood development
- Epidemic preparedness
- Heart disease
- HIV/AIDS
- Human papillomavirus
- Influenza
- Japanese encephalitis
- Malaria
- Maternal and newborn care
- Neglected tropical diseases
- Nutrition
- Sexual and reproductive health
- Tuberculosis
- Water, sanitation, and hygiene
Breast cancer detection model presentation

1. Background Breast Cancer
2. Rationale for early detection model
3. Community Education
4. Clinical Breast Exam
5. Triage Ultrasound
6. Fine Needle Aspiration Biopsy
7. Preliminary Results
8. Lessons Learned & Future Plans
Background:
Breast Cancer
Estimated age-standardized mortality rates (World) in 2018, breast, all ages
Rationale for early detection model
Rationale for early detection model

• Mammography is a financial and technical challenge.

• Mammography is less effective in young women due to dense tissue.

• IARC and WHO report self exam does not reduce mortality and should not be used as a prevention method.

Black and Richmond, Globalization and Health (2019) 15:3

https://doi.org/10.1186/s12992-018-0446-6
Rationale for early detection model

• Clinical breast exam (CBE) demonstrated down-staging in a randomized trial in India.

• A study in sub-Saharan Africa showed that CBE has cost-benefit when compared to mammograms; 10 times less expensive for same impact.

• In Malaysia the introduction of CBE in public programs over a period of 4 years, achieved a reduction in late stages from 60% to 30%.
A sustainable model of care

Community-based Breast Health Project, 2011–present

• Detecting breast cancer where mammograms are not available to all women; goal to downstage.

• Partnership international experts (Fred Hutch, UCSF, UW,), Peruvian health providers to develop materials and conduct trainings.

• Pilot in Pacasmayo: 2011–2014

• Expansion in Trujillo: 2016–present

• This model focuses on socialization and education, training professionals, facilitating access to clinical breast exam, utilizing ultrasound as triage and fine-needle biopsy to detect breast cancer.
Map of Trujillo – expansion to 9 health networks
Community education
1. Community Education

- Training Community Health Workers
- Didactic Materials: Flipchart, training manuals, and video
- Goal: Motivate women to come for CBE
Community Health Worker Trainings 2017 - 2018

- 121 Health workers trained
- Flipcharts distributed
- Registration forms for sessions
- Competition with prizes for top producers

[Image of people participating in a training session]
Clinical Breast Exam
2: Clinical Breast Exam (CBE)

- Primary Level training
- Palpable masses referred to trained doctor for second CBE and possible triage ultrasound, fine-needle aspiration biopsy.
Training in Trujillo

• **Trained Health Professionals:**
  - 224 Professional midwives
  - 15 Doctors

• **Trainers:**
  - Breast Oncologists from Nationa and Regional Cancer Institutes (INEN & IREN-Norte)

• **Training modality:**
  - Training manuals
  - Theory, pre-test, post-test
  - Breast models/ live patients
  - CBE checklist
  - Clinical history breast health
### Checklist for Clinical Breast Exam (CBE)

#### ANEXO I: LISTA DE VERIFICACIÓN ECM

**A. LISTA DE VERIFICACIÓN DE HABILIDADES CLÍNICAS**

Instrucciones: Coloque un X en el recuadro cuando la tarea ha sido realizada satisfactoriamente, una X si no se realiza de manera satisfactoria y N/O si no se observó el desempeño de dicha habilidad o tarea.

- **Satisfactorio**: Realiza el paso o tarea de conformidad con las pautas o el procedimiento estándar.
- **No Satisfactorio**: Incapaz de realizar el paso o tarea de conformidad con las pautas o el procedimiento estándar.
- **No Observado**: Paso, tarea o habilidad no desempeñada por el participante durante la evaluación hecha por el capacitador clínico.

#### LISTA DE VERIFICACIÓN DE HABILIDADES CLÍNICAS Y DE ORIENTACIÓN EN EXAMEN CLÍNICO DE MAMAS

<table>
<thead>
<tr>
<th>PASO/TAREA</th>
<th>CASOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. ORIENTACIÓN PREVIA AL EXAMEN CLÍNICO DE MAMAS</td>
<td></td>
</tr>
<tr>
<td>1) ¿Saludó a la paciente con respeto y amabilidad?</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>2) ¿Realizó una breve orientación sobre el despistaje de cáncer de mama (tamizaje)?</td>
<td></td>
</tr>
<tr>
<td>3) ¿Solicitó a la paciente su permiso para realizarse el examen clínico mamario?</td>
<td></td>
</tr>
<tr>
<td>4) ¿Evaluó los conocimientos de la mujer sobre el examen clínico de mama?</td>
<td></td>
</tr>
<tr>
<td>5) ¿Respondió las inquietudes de la paciente sobre el examen clínico?</td>
<td></td>
</tr>
<tr>
<td>6) ¿Describió el procedimiento antes de realizarlo y describió las posibilidades de hallazgos clínicos (normal, tumor)?</td>
<td></td>
</tr>
</tbody>
</table>

#### HABILIDAD/ACTIVIDAD DESEMPEÑADA SATISFACTORIAMENTE

<table>
<thead>
<tr>
<th>INTERROGATORIO-ANAMNESIS</th>
<th>1 2 3 4 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) ¿Realizó una breve historia clínica incluyendo si le han realizado el ECM anteriormente?</td>
<td></td>
</tr>
</tbody>
</table>
Clinical History for Breast Health

DATA DEMográficas
Nombre del establecimiento: ____________________________
Fecha: ____________________________

PRIMER APLICADO
Nombre: ____________________________
Fecha: ____________________________

SEGUNDO APLICADO
Nombre: ____________________________
Fecha: ____________________________

HISTORIA CLINICA
Fecha de consulta: ____________________________

SINTOMAS
- Sensación de un nódulo en el pecho:
- Sensación de molestias en el pecho:

IMPRENSIÓN CLÍNICA:
- Normal:
- Anormal no tumoral:
- Tumoral o sospechoso de cáncer:

BAFF REALIZADO:
- Fecha: ____________________________

Título 1:
Características del aspirado:
- Clínico: ____________________________
- No clínico: ____________________________

Título 2:
Características del aspirado:
- Clínico: ____________________________
- No clínico: ____________________________

CONTROL POST BAFF:
- Fecha: ____________________________

Referencia:

EXAMEN CLÍNICO DE MAMA:

CARACTERÍSTICAS/DESCRIPCIÓN
- Número palpado:
- Enlargimiento:
- Sensación de dolor:
- Sensación de quemazón:
- Sensación de sangrado:
- Sensación de fastidiar:
- Sensación de sensible:
- Sensación de otros:

DIAGNÓSTICO DEFINITIVO (CODIFICACIÓN CIE-10):

MANEJO:
- Control:
- Fecha control:
- BAFF:
- Referencia:

Nombre del profesional, Sello y Firma:
Triage ultrasound
Triage Ultrasound

1. Detect cysts (and drain them)
2. Decide whether to biopsy
3. Help locate mass to biopsy
4. Training included image review
Flowchart for Triage Ultrasound of FNA

See "Decision Making Tool for Ultrasound" for criteria for clinical and imaging-based suspicion of breast cancer.

1. **Focal finding (CBE+)** at Level I clinic: Refer to Level II hospital for evaluation
2. **Level II clinical evaluation:**
   - **No focal finding (CBE-):** Follow up
     - Recommend follow-up at Level II Hospital at 3 months
   - **Focal finding (CBE+):** Screen for cancer
     - Evaluate with Ultrasound
       - **Suspicious for cancer**
         - FNA with Referral: Refer pt directly to Level III hospital
       - **Complex cyst** Fluid and solid components
         - No FNA Refer pt directly to Level III hospital
       - **Simple cyst** Fluid component only
         - Cyst drainage To finalize care for pt. Do not send drainage for cytological evaluation
       - **Benign mass**
         - FNA Send sample to Level III hospital for cytological evaluation
3. **Annual CBE (regular screening):** At her local Level I health facility

See page 2 of flowchart for clinical management based on cytological findings.
Fine Needle Aspiration (FNA) Biopsy
FNA biopsy training in 2014, Trujillo, Peru
Fine-needle aspiration (FNA) biopsy

• Training to take biopsy and smear the slide.

• Stain the slide and review under microscope to ensure adequate sample.

• Challenges:
  • Staining protocols, slide labeling and quality control.
  • Transporting slides.
  • Reporting pathology results within two weeks.
Preliminary Findings
Evaluation in Trujillo

Information about clinical breast exam:

- Routine data, aggregated by GERESA.
- Manual extraction of data from 800 clinical records from midwives and doctors.

Ultrasound:

- Five readers evaluated the 233 ultrasounds completed and compared the results with the results of fine-needle biopsy and BIRADS.

Fine-needle biopsy:

- Ron Balassanian and Roberto Ruiz-Cordero visit Trujillo, Peru June 2019 to review FNA slides and assess quality of the samples. Further analysis pending.

*Preliminary data
Clinical breast exam data in Trujillo, 2017–18, data from regional Ministry of Health (GERESA)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Women receiving CBE* Annual average</th>
<th>Abnormal Result</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ages</td>
<td>20,636</td>
<td>174</td>
<td>0.8%</td>
</tr>
<tr>
<td>40–69 years</td>
<td>6,382</td>
<td>119</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

*CBE: Clinical breast exam
**Preliminary data
Evaluation clinical breast exam histories in the 23 participating health centers

<table>
<thead>
<tr>
<th>Clinical breast exam (CBE) in medical records</th>
<th>Total N = 808 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average age (SE)</td>
<td>39.9 (13.1)</td>
</tr>
<tr>
<td>Average BMI (SE)</td>
<td>27.9 (4.6)</td>
</tr>
<tr>
<td>Age at first pregnancy</td>
<td>21.0 (6.4)</td>
</tr>
<tr>
<td>Average number of children (SE)</td>
<td>2.4 (1.6)</td>
</tr>
<tr>
<td>Received information about the CBE program</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>225 (27.8)</td>
</tr>
<tr>
<td>Yes, education session in the clinic</td>
<td>419 (51.9)</td>
</tr>
<tr>
<td>Yes, education session in the community</td>
<td>43 (5.3)</td>
</tr>
<tr>
<td>Si, individual contact with health promoter</td>
<td>24 (2.9)</td>
</tr>
<tr>
<td>No information provided</td>
<td>97 (12.0)</td>
</tr>
<tr>
<td>Abnormal CBE (midwife) (N=610)</td>
<td>373 (61.1)</td>
</tr>
<tr>
<td>Abnormal CBE (doctor) (N=198)</td>
<td>195 (98.5)</td>
</tr>
</tbody>
</table>

*Trujillo, preliminary data
### Evaluation of clinical breast exam clinical histories

<table>
<thead>
<tr>
<th>Reason for visit</th>
<th>N = 808 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening</td>
<td>382 (47.3)</td>
</tr>
<tr>
<td>Breast symptoms</td>
<td>334 (41.3)</td>
</tr>
<tr>
<td>Referral</td>
<td>41 (5.1)</td>
</tr>
<tr>
<td>Information unavailable</td>
<td>51 (6.3)</td>
</tr>
</tbody>
</table>

*Trujillo, preliminary data*
Ultrasound: Comparisons between observers
Ultrasound/ Fine Aspiration Needle Biopsy: 2017–2018

• 199 patients received triage ultrasound.
  • 90 patients no biopsy needed.
  • 77 patients biopsy performed and no suspicious findings.
    • 31 suspicious findings:
      21 breast cancers diagnosed and 10 atypical.
Stages for malignant and atypical FNA diagnosis

- 1 ductal carcinoma in situ
- 1 Stage IIA
- 8 Stage IIIB
- 1 Stage IV
- Atypical FNA of 10:
  - 4 invasive (Stage unknown)
  - 1 Stage IIIB and 1 Stage IV
- 10 diagnosed cancers (Stage undetermined)
## Preliminary Findings (2017–2018)

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Women 40–69 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBE (annual average)</td>
<td>20,636</td>
<td>6,382</td>
</tr>
<tr>
<td>Abnormal (annual average)</td>
<td>174</td>
<td>119</td>
</tr>
<tr>
<td>%</td>
<td>0.8%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Atypical 2017–18 (N total)</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>FNA suspicious for cancer 2017–18 (N)</td>
<td>16</td>
<td>21</td>
</tr>
<tr>
<td>Annual breast cancer detection (per 100,000)</td>
<td>50.9</td>
<td>127.4</td>
</tr>
</tbody>
</table>

- **CBE**: Clinical breast exam; **FNA**: fine-needle aspiration biopsy
- The information in this table comes from various sources: GERESA, patient records, ultrasound analyses, FNA study.
Discussion

• Community education can facilitate an early demand.

• CBE program and referral system for tissue diagnosis requires a lot of organization but can be done at low-cost.

• The large mobilization needed in health system, but it is necessary in order to lower the stage at detection; now only 18% are in early stages.

• It is essential to have good data in order to be able to evaluate the program well.
Lessons learned
Areas for Improvement

1) Support from the national Ministry of Health.
2) Patient tracking systems.
3) Capturing women 40–69 years for screening.
4) Selection of health professionals for training.
5) Adequate practice time to reach high skill level.
6) Feedback to midwives at primary level.
7) Normalizing activities (competition with outbreaks).
Working Well

1) Local and regional coordination.

2) Training cascade (international, national, regional, local).

3) Standardized and higher-quality CBE.

4) “This is a model that helps reach a larger population, in particular those who live in remote areas.”

5) “The model allows for an alliance among different health professionals.”
Top cancer per country, estimated age-standardized mortality rates (World) in 2018, females, all ages

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Data source: GLOBOCAN 2018
Graph production: IARC
World Health Organization
October 7th 2019, meeting introducing model to Central American MOHs, Antigua, Guatemala
Future Plans
Patient Journey 2020

- Digital tracking with tablets
- Improved provider-patient messaging
- Increased access to screening through peer patient engagement
Utilizing Digital Solutions to Improve Patient Tracking

- EMR: Health workers enter data in tablets, allowing real-time follow-up.
- Accurate patient information will decrease time between detection and treatment.
- Ensure no women are lost to follow-up.
- Strengthen the health system’s overall capacity at the facility and district-level.
Improving provider communication with patients

- Train providers in psychological/emotional aspects for “bedside manner” which can:
  - Increase patient adherence to screening process & treatment plan.
  - Improve the patient’s mental health & emotional well-being.
Peer patient engagement

- Women who receive positive result during screening and complete necessary follow-up and treatment are trained to become ‘peer navigators’.
- These peer patient navigators recruit women from their social circles to undergo screening, provide basic education and support as friends and family complete the screening process.
Many thanks to our collaborators

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  Vivien Tsu, PhD,
  Tara Hayes-Constant, PhD, NP

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Thank you for attending!

Carolyn Bain
cbain@path.org
PATH
Patient Navigation

• Pacasmayo Pilot
  Women diagnosed, were not receiving treatment

• Navigation program designed and implemented to accompany women

• 55 Patient navigators trained during 2017-2018

• Training materials, manuals
Palliative Care

Training of nurses in palliative care units, 4 hospitals
Several regions of Peru

Manuals, flip charts and participant information booklets