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

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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 incidence rates (World) in 2018, breast, all ages

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Estimated age-standardized mortality rates (World) in 2018, breast, all ages

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Data source: GLOBOCAN 2018 Graph production: IARC (http://gco.iarc.fr/today) World Health Organization



Cancer in Peru

Estimated age-standardized incidence and mortality rates (World) in 2018, Peru, females, all ages



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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 *new
- Competition
 with prizes for
 top producers

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 I 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 aspa 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 <u>ó</u> 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.

CASOS

LISTA DE VERIFICACIÓN DE HABILIDADES CLÍNICAS Y DE ORIENTACIÓN EN EXAMEN CLINICO DE MAMAS

		CASOS				
	PASO/TAREA					
a.	ORIENTACIÓN PREVIA AL EXAMEN CLINICO DE MAMAS	1	2	3	4	5
	1) ¿Saludó a la paciente con respeto y amabilidad?					
	 ¿Realizó una breve orientación sobre el despistaje de cáncer de mama (tamizaje)? 					
	 ¿Solicitó a la paciente su permiso para realizarle el examen clínico mamario? 					
	4) ¿Evaluó los conocimientos de la mujer sobre el examen clínico de mama?					
	5) ¿Respondió las inquietudes de la paciente sobre el examen clínico?					
	6) ¿Describió el procedimiento antes de realizarlo y describió las posibilidades de hallazgos clínicos (normal, tumor)?					
HAB Sat	ILIDAD/ACTIVIDAD DESEMPEÑADA ISFACTORIAMENTE					
b.	INTERROGATORIO-ANAMNESIS	1	2	3	4	5
	 ¿Realizó una breve historia clínica incluyendo si le han realizado el ECM anteriormente? 					

Clinical History for Breast Health

Coversità Persona Levrono Cerrenta Calabito Integra

PROGRAMA DE PREVENCION Y CONTROL DE CANCER DE MAMA HISTORIA CLINICA

DATOS GENERALES					
Nombre del establecimiento				Nº Historia Clínica	
Primer Apellido Segundo Ap	ellido	Nombres	DN	Tipo de Seguro	
Dirección / Comunidad			Distrito	Teléfono	
Fecha de nacimiento Edad (años)		Establecimient	o de referencia	Fecha de consulta	
¿Has escuchado acerca de la prevención d	lel cáncer de marr	na de un promo	tor(a) de salud?		
No Si, en una sesión educativa establecimiento de salud	en el	Si, en una sesió en mi comunida	n educativa S ad i	i, a través del contacto ndividual con el promotor	
ANAMNE SI S					
Motivo de consulta: Por tamizaje	Por sint	tomas mamaric	Por Por	referencia	
		D/1	//A D	uración	
Relación con ciclo menstrual: SI	NO	Peso:	Kg. Talla:	mt.	
ANTECEDENTES MAMARIOS:					
Exámenes previos: Biopsia 🔲 Mamogra	afia 🗌 Ecograf	fía 🗌 Fecha:	/_/_ Resultad	0:	
Mastitis Otros:					
Edad menarquia: A	Edad menopaus	sia:	A G	P	
Uso de anticonceptivos: SI NO	Tipo: Oral	Inyectable	Duración:	M/A	
Terapia de reemplaza hormonal: SI	NO Edad p	rimer embaraz	o: Años Lactancia	Matema: SI NO	
ANTECEDENTES PERSONALES Y FAMI	LIARE \$:				
Historia personal de: Cáncer de mama: S	I 🗌 NO 🗌	Cáncer de ova	rio: SI NO O	tro cáncer:	
Historia de familiar directo de: Cáncer de	e mama: Si 📃 M	NO Cánc	er de ovario: Si 📃 N	0 Otro cáncer:	
Habitos: Tabaco: SI NO Alcohol: SI NO					
EXAMEN CLINICO DE MAMA:			/ \		
CARACTERISTICAS DEL TUMOR	Mama	Mama		\backslash / \backslash	
Tumor palpable Tamaño Tumor 1	cm	cm			
Tamaño Tumor 2 Consistencia del tumor (blando, duro, pétreo,	cm	cm	Derecha	Izquierda	
fluctuante)			11	• Î •	
Tumor es movible (sí o no)			Nul V /	20 \ / / /	
Forma del tumor (redondo, oval, dismortico) Bordes del tumor (regular, irregular)			$ \langle \rangle \rangle / \rangle$		
Ganglio (axilar, supraclavicular)					
Secreción por pezón (color)					
Retracción (pezón, piel)	_		$ \langle / \rangle \rangle$	• . 5/1 \ 7 • 1	
Eczema (pezón, areola)			I X Y	· · · · ·	
Eritema o edema (pezón, piel)			6 3	6 1	
"Piel de naranja"			Distancia del pezón	cm. Distancia del pezóncm.	
* 100	DE SEGURO				
USUARIO (PAGANTE) 3 ESSALUD 5 SA SEGURO INTEGRAL (SIS) 4 SOAT 6 SA	NIDAD FAP NIDAD NAVAL	7 SANIDAD EP 8 SANIDAD PNP	9 PRIVADOS 10 OTROS		

	IMPRESIÓN CLINICA:			
	Normal Anormal no tumoral Tumoral o sospechoso de cáncer			
	Especificar:			
	BAAF REALIZADO: Fecha:///			
	Nódulo 1:			
	Características del aspirado:			
	Quístico: Incoloro 🗌 Lechoso 🗌 Sanguinolento 📄 Purulento 🗌 Otro:			
	No quístico: Grumoso 📄 Pastoso 📄 Sanguinolento 📄 Grasoso 📄 Otro:			
	Nº Aspirados: Nº láminas: Nº láminas coloreadas Tinción con Hematoxilina SI 📃 NO 💭			
	Resultado de Evaluación inmediata: Muestra adecuado: No 🔄 SI:			
	Complicaciones inmediatas: No 🔲 SI:			
	BAAF REALIZADO: Fecha://			
	Nódulo 2:			
	Características del aspirado:			
	Quístico: Claro Lechoso Sanguinolento Purulento Otro:			
	No quístico: Grumoso Pastoso Sanguinolento Grasoso Otro:			
	Nº Aspirados:Nº láminas:Nº láminas coloreadas:Tinción con Hematoxilina SI NO			
	Resultado de Evaluación inmediata: Muestra adecuado: No 📃 SI:			
	Complicaciones inmediatas No SI:			
1				
	Describir:			
	Referencia a:			
	ESTUDIOS COMPLEMENTARIOS:			
	Mamografia: Fecha:/ Resultado:			
	Ecografia: Fecha:/ Resultado:			
	DIAGNÓSTICO DEFINITIVO (CODIFICACIÓN CIE-10)			
	MANEJO:			
	Control Fecha control:/ BAF Referencia			
	Tratamiento para otro problema mamario Tratamiento			
	Nombre del Profesional. Sello y Firma			
	nonne de riveronañ dela Tinna			

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 page 2 of flowchart for clinical management based on cytological findings

Fine Needle Aspiration (FNA) Biopsy



Study Groups





Training







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.





FNA Slide Evaluation– Trujillo and Lima Peru, June 2019





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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.

<u>Ultrasound</u>:

• 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)

	Women receiving CBE* Annual average	Abnormal Result	%
All ages	20,636	174	0.8%
40–69 years	6,382	119	1.9%

*CBE: Clinical breast exam

**Preliminary data

Evaluation clinical breast exam histories in the 23 participating health centers

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

*Trujillo, preliminary data

Evaluation of clinical breast exam clinical histories

Reason for visit	N = 808 (%)		
Screening	382 (47.3)		
Breast symptoms	334 (41.3)		
Referral	41 (5.1)		
Information unavailable	51 (6.3)		



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
- Atypicals FNAs of 10:
 - 4 invasive (Stage unknown)
 - 1 Stage IIIB and 1 Stage IV
- 10 diagnosed cancers (Stage undetermined)



Preliminary Findings (2017–2018)

	Total	Women 40– 69 years
CBE (annual average)	20,636	6,382
Abnormal (annual average)	174	119
%	0.8%	1.9%
Atypical 2017–18 (N total)	4	10
FNA suspicous for cancer 2017–18 (N)	16	21
Annual breast cancer detection (per 100,000)	50.9	127.4

• 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.

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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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October 7th 2019, meeting introducing model to Central American MOHs, Antigua, Guatemala





Future Plans











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 followup 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.





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Carolyn Bain cbain@path.org







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



Training of nurses in palliative care units, 4 hospitals

Several regions of Peru



Manuals, flip charts and participant information booklets

