Pocket Colposcope:

Analysis of Bringing Elements of Referral Services to Primary/Community Care



BASS CONNECTIONS



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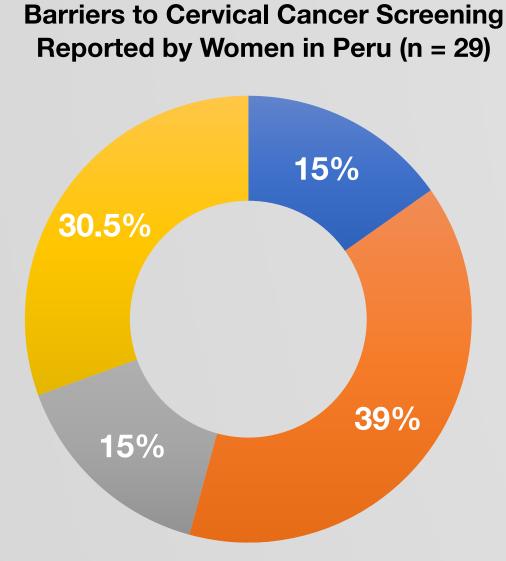
BACKGROUND

- 84% of new cervical cancer cases worldwide occur in low- and middle-income countries¹
- Three-visit cancer care paradigm (screening, diagnosis, treatment) is ineffective for low-resource settings, with high lost-to-follow-up rates at each stage
- Colposcope: device used to screen for abnormal cells in cervix
- Pocket Colposcope (Fig. 1): low-cost, accessible, and FDAcleared device that rivals state-ofthe-art colposcopes



Bass Connections aims to investigate how to transform three visit cervical cancer care paradigm, with a focus on implementing the Pocket Colposcope

PREVIOUS RESEARCH



- Lack of Awareness Money Access to Care Fear Fig. 2: Results of survey distributed to women at the La Liga Contra el Cáncer clinic in Lima, Peru

- 2016-17: Global Value Chain analysis of the Pocket Colposcope introduction in Peru² Identified key leverage points
- 2017-18: Assess patient & physician attitudes toward Pocket Colposcope in Peru
- Conducted patient surveys (Fig. 2), focus group with midwives, & training sessions with physicians

RESEARCH OBJECTIVES

2018-19 GOAL: To create a road map on implementing transformative technologies into an innovative healthcare model to reduce cancer disparities, with a focus on cervical cancer and the Pocket Colposcope. This roadmap requires assessment of clinical acceptability, market for the Pocket Colposcope, and policy considerations.

- 1. CLINICAL ACCEPTABILITY: Assess patient and provider attitudes to evaluate clinical acceptability of the Pocket Colposcope
- 2. MARKET ANALYSIS: Build an understanding of the market for the Pocket Colposcope
- 3. POLICY FRAMEWORK: Assess opportunities and barriers to implementing the Pocket Colposcope in the context of regulation, reimbursement, and ethical and liability concerns

1. CLINICAL ACCEPTABILITY

To assess patient/provider attitudes about the cervical cancer screening paradigm and Pocket Colposcope, we designed three surveys to be implemented at the Duke 1J Gynecological Clinic and community clinics in NC.

Survey #	Setting	Target Audience	Purpose
1	Community clinics in North Carolina	Patients who are not currently using Pocket Colposcope	 Assess patients' barriers to cervical cancer screening/care Gauge patients' care preferences
2	Community clinics in North Carolina	Providers who are not currently using Pocket Colposcope	 Assess providers' experience/training in colposcopy and willingness to learn to use new colposcopy device Evaluate providers' attitudes toward image counseling
3	Duke 1J Gynecological Clinic	Patients enrolled in clinical trial for Pocket Colposcope	 Assess patient preferences between Pocket Colposcope and traditional, state-of-the-art digital colposcope

2. MARKET ANALYSIS

To evaluate the market opportunity for the Pocket Colposcope, we calculated the serviceable obtainable market (SOM), serviceable available market (SAM), and total addressable market (TAM).

Serviceable Available Market (SAM) Breakdown³

4,000

1,300

4,100 new family

9,400 new units sold annually

SAM/SOM Revenue Trends Industry Report #'s (BCC 2013) 2021 2020 2019 2020 Serviceable Available Market \$10.8M \$11.6M \$12.4M 11,600 12,400 # Units / Year Price (\$) / Unit \$1,000 \$1,000 \$1,000 \$1,000 \$1,000

Value Proposition for Provider: New revenue stream by adding colposcopy

 Screening coverage at only 80.5% in the US⁴ ■ 10 procedures pays off device (OB/GYN avg. 72 procedures/yr)

Serviceable Obtainable Market Calculated at 25% Penetration Rate

SOM \$4.6M 2.3k units/yr **SAM: \$9.4M** 9,400 units/year **TAM: \$532M** @ 7% CAGR

3. POLICY FRAMEWORK

The feasibility of performing biopsy was introduced as a major ethical concern and potential reimbursement barrier. To follow up on this finding from the medical ethics panel, we arranged a demonstration performed by an OB/GYN.

LEGAL PANEL

- Importance of language Statistical power for studies
- Transparency regarding device performance Procedure for ensuring
- hygiene Informed consent

COMMON THEMES

- Regulations around telemedicine
- Providers' liability concerns Insurers prioritize avoiding multiple visits
- Context of use is important Barriers to task-shifting

MEDICAL ETHICS PANEL

- for further studies on device performance and task-shifting
- Potential harms of overtreatment Ethics around task-

shifting

STAKEHOLDERS IN WASHINGTON, D.C.

 Securing code for reimbursement is critical Regulations around which providers can perform colposcopy Availability of broadband in rural areas

Recommendations

Feasibility of biopsy

Preliminary results from a demonstration of biopsy with the Pocket Colposcope indicate that collection of a histopathology sample is feasible.

RESULT: ROADMAP

MARKET ANALYSIS

- Main audience consists of OB/GYNs replacing equipment or looking for alternative ways to expand their practice to rural areas, along with family practice **ACCEPTABILITY** physicians expanding their scope of practice.
 - Profitability for providers is crucial for successful implementation of the device.

POLICY FRAMEWORK

- Assessing feasibility of conducting biopsy with the Pocket Colposcope is crucial for determining whether a reduction in points of care is possible.
- Regarding task-shifting, a process of amending insurance coding could allow non-physician providers to be reimbursed.
- Ensuring adequate physician compensation and reimbursement is pivotal.
- Important to analyze how integrating the Pocket Colposcope affects all steps of the cervical cancer care paradigm, such as biopsy.
- Context of use can strengthen the case for implementation of the Pocket Colposcope in certain settings.

FUTURE DIRECTIONS

CLINICAL ACCEPTABILITY

 Use IRB-approved surveys and in-depth interviews to evaluate patient and provider acceptability of the Pocket Colposcope in community care settings at in low-income areas of North Carolina.

MARKET ANALYSIS

Working with the

reimbursement system and

insurance companies is key

to provider acceptability.

Understanding who and

trust is key to patient

which procedures patients

acceptability. Even seemingly

unimportant aspects such as

the appearance of a medical

device can influence patient

perceptions of a procedure.

- Analyze cost efficacy in low-income community health settings by evaluating staffing models and efficiency levels from provider use of the Pocket Colposcope
- Analyze quantitative costing data to construct detailed curation of raw data

POLICY FRAMEWORK

- Determine what policy needs must be addressed to implement the Pocket colposcope in community care settings in NC and begin the transition to a decentralized model of cervical cancer screening/care
- Construct policy briefs on conventional cervical cancer screening/care paradigm

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