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

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- I have no financial relationships or conflict of interest to disclose.













Who are we?



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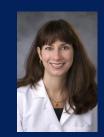
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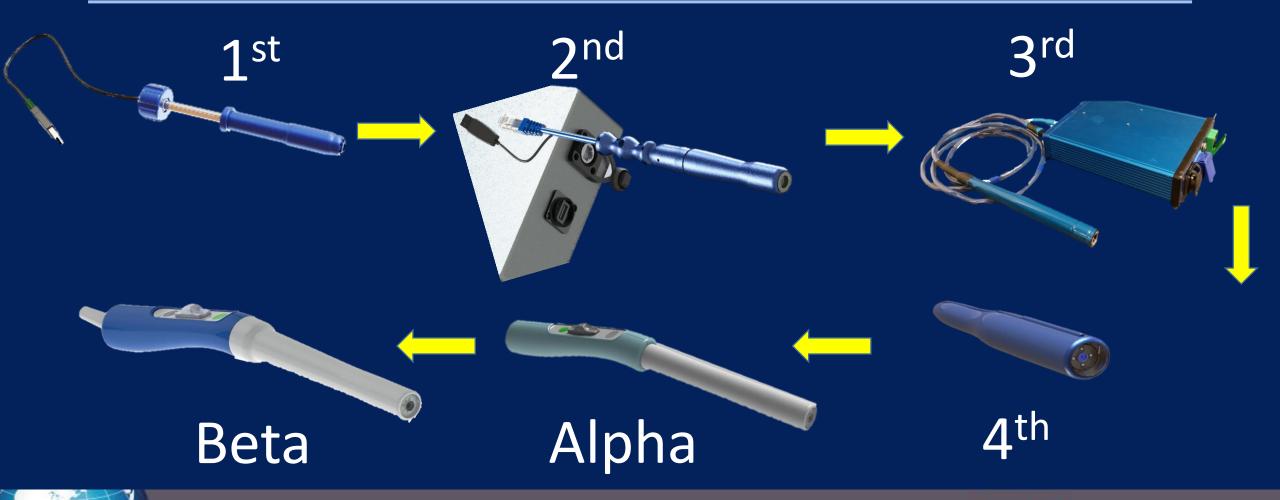
Guiillermo Shapiro Duke ECE







The Pocket Colposcope Evolution









Colposcopy/Cervicography



Canon SX50HS US \$500USD







Where?













La Liga







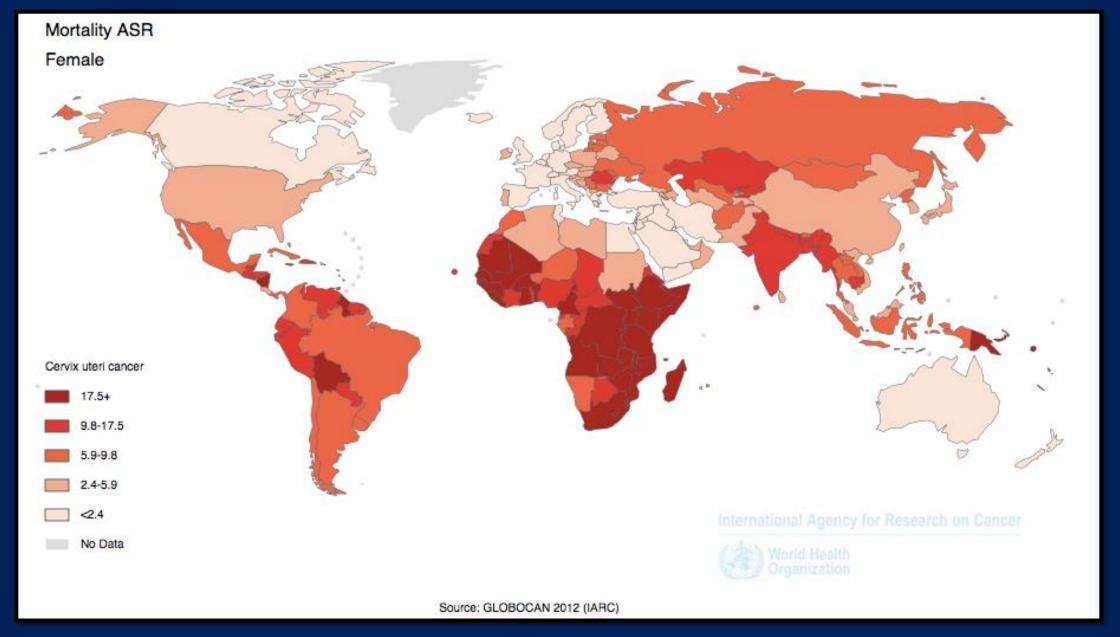
DUKE

Why do we need this?















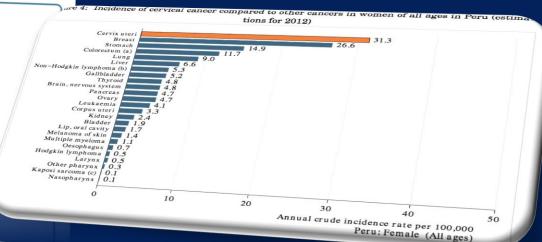
Cervical Cancer in Peru

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^{th} most common female cancer in women aged 15 to 44 years in Peru.



	Indicator			
	Annual number of new cancer cases	Peru	South	
	or tide incidence rate ^a	4,636	South America	World
	Age-standardized incidence rate ^a		45,008	527,624
	Cumulative risk (%) at 75 years old ^b	31.3	22.2	
•	901g	32.7	20.3	15.1
		3.4	2.0	14.0
				1.4

http://www.hpvcentre.net/statistics/reports/PER.pdf







Cervical Cancer in Tanzania

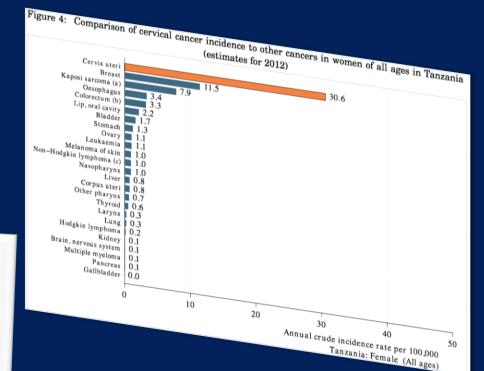
KEY STATS.

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

Cervical cancer $\mathbf{ranks*}$ as the $\mathbf{1}^{st}$ leading cause of female cancer in $\mathbf{Tanzania}$.

Cervical cancer is the $\mathbf{1}^{th}$ most common female cancer in women aged 15 to 44 years in Tanzania.

Table 3: Cervical cancer incidence in Tanzania (estimates for 2012) Indicator Annual number of new cancer cases Tanzania Eastern Africa World Crude incidence ratea 7,304 45,707 Age-standardized incidence rate a527,624 30.6 Cumulative risk (%) at 75 years old^b 25.8 15.1 54.0 42.7 14.0 5.8 4.6 1.4



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



Randomized Image Pairs



Standard of Care Biopsy with Image Quality and Visual Diagnosis



Blinded Image Interpretation

Modified Reid Index Lesion Margin, Color, Vessels, Impression







Clinical Study Protocol at KCMC



____ Speculum Placement + 5% Acetic Acid

VIA Impression



35mm Camera (Canon SX50HS)





5% Acetic Acid

Pocket Colposcope

Randomized Image Pairs



Blinded Image Interpretation

Image Quality and Visual Diagnosis (Pathology only if indicated)



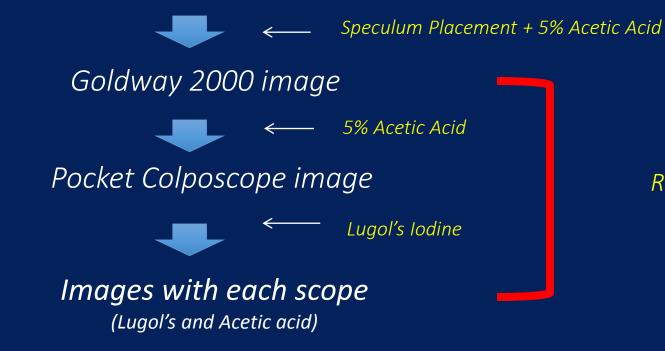
Modified Reid Index Lesion Margin, Color, Vessels, Impression







Clinical Study Protocol at La Liga



Standard of Care Biopsy with Image Quality and Visual Diagnosis



Randomized Images Pairs



Blinded Image Interpretation

Modified Reid Index Lesion Margin, Color, Vessels, Impression







Representative Images - Duke

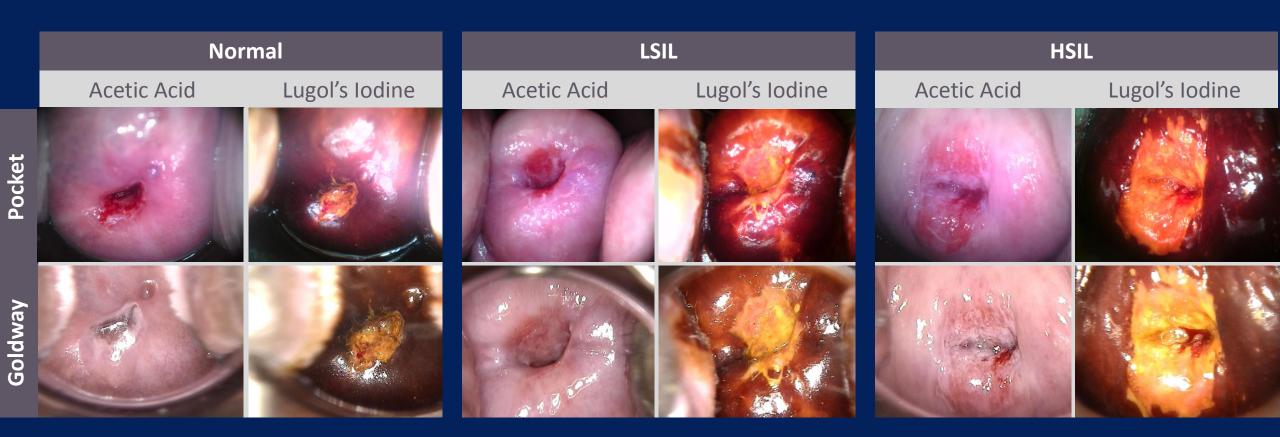








Representative Images - Peru









Representative Images - Tanzania









Image Concordance: Duke

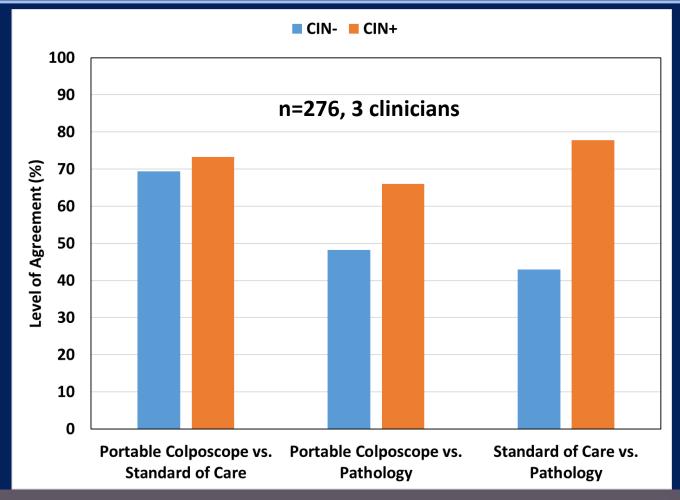






Image Concordance: Duke

(3 clinicians) Cut Off ≥ CIN 1	# of image pairs	Level of Agreement (%)	kappa	p-value
Portable Colposcope vs. Standard of Care Colposcope	276	72.1	0.3949	0.00009
Portable Colposcope vs. Pathology	276	58.7	0.1437	0.0085
Standard of Care Colposcope vs. Pathology	276	63.4	0.2157	0.0001

(n=276, 3 clinicians) Cut Off ≥ CIN 1	Sensitivity	Specificity	PPV	NPV
Portable Colposcope vs. Pathology	66.0	48.2	71.6	50.0
Standard of Care Colposcope vs. Pathology	77.8	43.0	66.0	57.6





Image Concordance: Peru

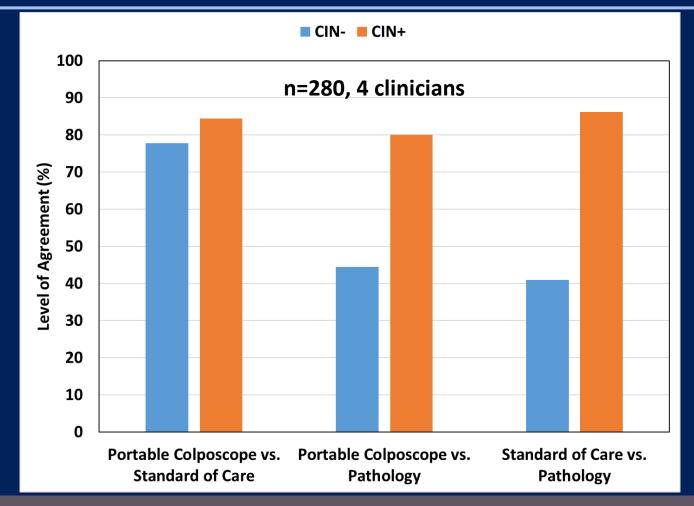






Image Concordance: Peru

(4 clinicians) Cut Off ≥ CIN 1	# of image pairs	Level of Agreement (%)	kappa	p-value
Portable Colposcope vs. Standard of Care Colposcope	280	82.5	0.5937	0.00009
Portable Colposcope vs. Pathology	274	61.3	0.2396	0.00009
Standard of Care Colposcope vs. Pathology	274	62.4	0.2646	0.00009

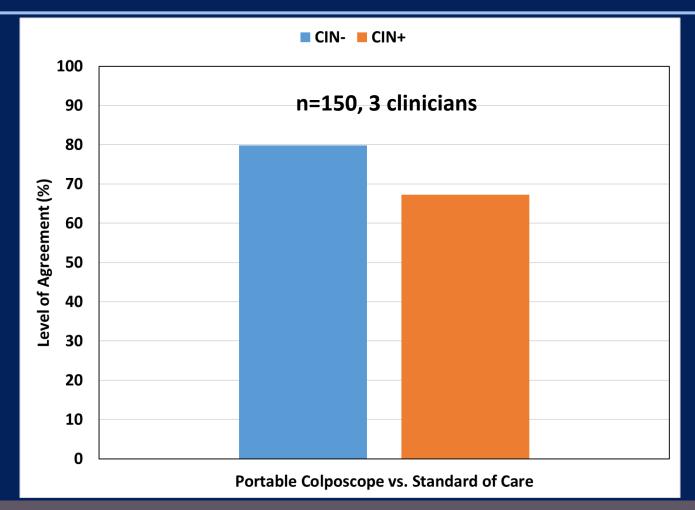
(n=274, 4 clinicians) Cut Off ≥ CIN 1	Sensitivity	Specificity	PPV	NPV
Portable Colposcope vs. Pathology	80.0	44.4	56.5	71.1
Standard of Care Colposcope vs. Pathology	86.2	41.0	56.9	76.6







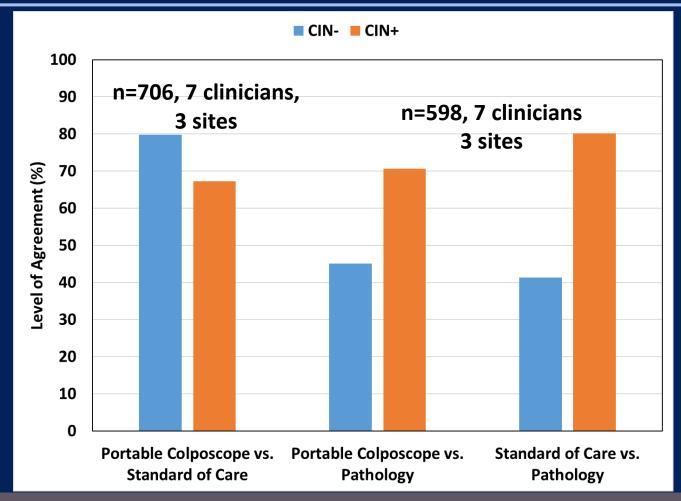
Image Concordance: Tanzania







Overall Pooled Image Concordance







Overall Pooled Image Concordance

(7 clinicians) Cut Off ≥ CIN 1	# of image pairs	Level of Agreement (%)	kappa	p-value
Portable Colposcope vs. Standard of Care Colposcope	706	76.8	0.5132	0.00009
Portable Colposcope vs. Pathology	598	59.4	0.1603	0.00009
Standard of Care Colposcope vs. Pathology	598	63.0	0.2232	0.00009

(n=598, 7 clinicians) Cut Off ≥ CIN 1	Sensitivity	Specificity	PPV	NPV
Portable Colposcope vs. Pathology	70.7	45.1	61.9	54.8
Standard of Care Colposcope vs. Pathology	80.2	41.3	63.4	62.3







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





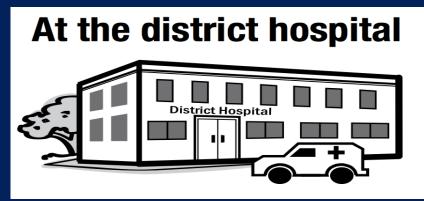




HPV Prescreen > POCkeT > Onsite

Treatment Cryotherapy or Cold Coagulation

LEEP or Hysterectomy



Cancer Therapy











