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\$15,000 "Cure it!" Lemelson-MIT Student Prize Graduate Winner

Callascope imaging device for cervical cancer diagnosis and a smartphone algorithm to classify cervix images as normal or pre-cancerous

The Challenge: Invasive cervical cancer affects the lives of half a million women worldwide each year, and has a higher than 50% mortality rate.¹ The majority of these deaths occur in low- and middle-income countries (LMICs).² In contrast, in the United States, cervical cancer incidence and mortality rates have decreased by 70% over the last 70 years due to early detection and treatment of the pre-invasive disease.³ This slow growing disease is, in fact, preventable when caught in its early stages.

Typically, screening for cervical cancer begins with a Pap smear to test for abnormal cells. If found, the next step is to view the cervix with a colposcope, a low powered microscope. If an abnormality is seen, the third step is to biopsy for pathology. This model of screening and diagnosis, however is costly and often not practical to implement in medically underserved regions due to lack of resources and technologies.

Currently, in most low-resource settings, cervical cancer is screened by visual inspection with the human eye, but the absence of image capture and magnification can lead to higher levels of inaccurate diagnoses. In addition, most gynecologists use a speculum (typically an antiquated, hard metal device) to dilate the vagina for examination. This device has been shown to be a significant reason why women avoid cervical cancer screening, due to anxiety, fear, discomfort, pain, embarrassment, and/or vulnerability during the procedure. This is especially true of women with vaginismus, an involuntary tightening of the vagina, often due to sexual abuse. The fact that the majority of women dying of cervical cancer are located in LMICs correlates with a

¹ Ferlay J, S.I., Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray, F. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11. Lyon, France: International Agency for Research on Cancer. 2013.

² Scarinci, I.C., et al., Cervical cancer prevention: new tools and old barriers. Cancer, 2010. 116(11): p. 2531-42, and Freeman, H.P.a.W., B. K. Excess cervical cancer mortality: A marker for low access to health care in poor communities. National Institutes of Health; 2007. Report No.: 05-5282.

³ Group, F.I.S., Quadrivalent vaccine against human papillomavirus to prevent high-grade cervical lesions. N Engl J Med, 2007. 356(19): p. 1915-27 and Paavonen, J., et al., Efficacy of human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine against cervical infection and precancer caused by oncogenic HPV types (PATRICIA): final analysis of a double-blind, randomised study in young women. Lancet, 2009. 374(9686): p. 301-14.

report from the World Health Organization that documents women's health issues in LMICs having the highest sexual violence rates worldwide.⁴

The Solutions: Mercy's primary invention is a high quality, low-cost, speculum-free device for cervical cancer prevention and screening. The device is called the Callascope and it's designed to resemble the shape of a Calla Lily, with a stem and mechanical introducer for expanding the vaginal walls in order to obtain accurate visualization of the cervix. Mercy also designed a narrow channel along the stem of the device to inject acetic acid, which is a contrast agent used to visualize areas of pre-cancer on the cervix. The device is easily inserted like a tampon, either by a physician or the woman herself, and it is fitted with a consumer-grade light source and camera to take images of the cervix from inside the body. This is a novel idea, considering that current low-cost imaging is taken from outside of the body. The invention's small design makes it ultra-portable and its autoclavable plastic material allows for sterilization and reuse. Compared to traditional, clinical colposcopes, the Callascope is 100X less expensive.

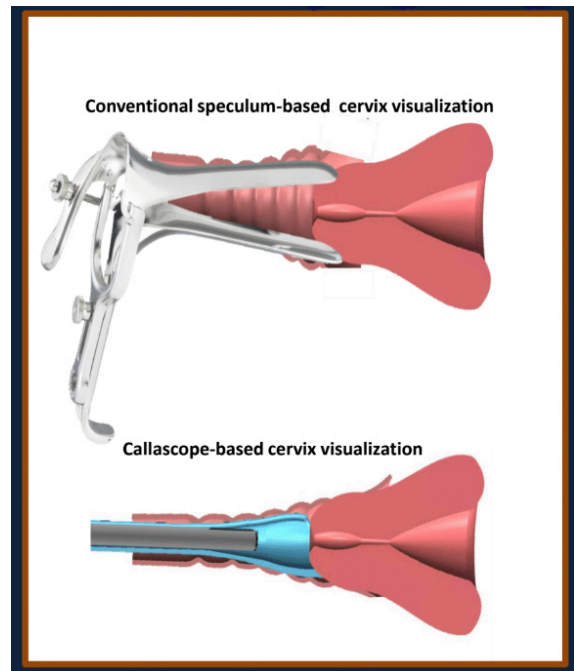


Figure 1: Cervix imaging with conventional speculum showing expansion of entire vaginal canal for imaging (top). Cervix imaging with Callascope showing expansion of vaginal canal closest to the cervix for imaging (bottom).

The Callascope is coupled with Mercy's second invention, an algorithm that uses machine learning to classify cervix images as normal or pre-cancerous. The algorithm can be deployed on a smartphone application and is based on objectively quantifiable cervix image features. Images from 134 colposcopy patients have shown that the algorithm has superior sensitivity and specificity compared to expert colposcopists. The Android application is HIPAA compliant for imaging and data storage.



Figure 2: Callascope camera and introducer with mobile imaging application deployed on an Android tablet showing a cervix.

Commercialization: Mercy's lab group has partnered with 3rd Stone Design, a product development firm specializing in consumer and medical health products. From that partnership, a startup called Athoria was created to license and commercialize the Callascope. Mercy is also in the process of forming a for-profit entity called Calla Health Technologies to house the intellectual property related to the Callascope. She and her team are negotiating with a contract manufacturer and distributor who has operations in over 30 countries for cervical pre-cancer therapy devices.

For LMICs, Mercy envisions a top-down approach targeting direct sales to the Ministry of Health and non-governmental organizations looking to establish or enhance their cervical cancer screening programs. In high-income countries, Mercy plans to target private and public clinics looking to expand their existing practice to rural obstetricians. The revenue stream will come from Callascope sales and from a subscription-based mobile application software with a tiered pricing level strategy.

Mercy has worked to establish relationships with international non-profit organizations that specialize in bringing healthcare innovations to the people who need them most. In addition, several physicians have been brought on board to implement the device in clinical studies. A predicate device, the Pocket Colposcope, has already obtained FDA 510(k) clearance and the Callascope is expected to go through a similar process.

⁴ <https://www.who.int/reproductivehealth/publications/violence/24159358X/en/>