

## **A Woman-centered Approach for Cervical Cancer Prevention**

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Addressing disparities in the global cancer burden is a key part of the post-2015 global development agenda. Cervical cancer is emblematic of that disparity, with almost 90% of cases and cancer-related deaths occurring in low and middle-income countries (LMICs). Many LMICs lack the health care infrastructure required for cytology-based screening and referral colposcopic diagnosis, which have dramatically reduced the disease burden in wealthier countries. The World Health Organization (WHO) recommends adoption of alternative protocols that employ low-cost and simple-to-use screening technologies and treat all women who are positive based on these tests. One strategy – highly sensitive human papillomavirus (HPV) testing – has been shown to reduce the incidence and mortality from cervical cancer when coupled directly with outpatient treatment for women with HPV-positive results. More recent guidelines have moved back from this “screen & treat” approach, given concerns about overtreatment. The American Society of Clinical Oncology (ASCO) recently released guidelines recommending that HPV be used as a screening test, followed by triage with Visual Inspection with Acetic Acid (VIA) to confirm the presence of lesions. While this may decrease overtreatment, VIA remains a poor triage test because of low sensitivity and specificity and low quality of interpretation. There is a need for a triage test that is low-cost, easy-to-use and will provide reliable results at the point-of-care.

This presentation will discuss our multipronged, approach to addressing these barriers to cervical cancer screening and management. The first component is a patient-centered device that reimagines the pelvic exam, for self-cervix imaging without the need of the speculum and which can be used in combination with self-HPV screening to triage women who need diagnostic colposcopy. The Callascope has been tested in Durham, NC and in Accra, Ghana and achieves cervix visualization of 83% for provider-based imaging without the speculum, and 95% for self-based imaging while enabling 2x patient comfort. The second component includes a Pocket Colposcope, a low-cost high-quality, portable colposcope, that packages all the features of a \$15,000 standard of care colposcope into a hand-held device. The Pocket colposcope enables multi contrast, and imaging at multiple magnifications and has been validated in clinical investigations on > 1000 patients in hospitals across the globe and an international image concordance study found to the Pocket Colposcope to be comparable to a standard colposcope when compared to the gold standard, pathology. The third component is a machine learning algorithm for automated, and accurate decision-making that overcome limitations of no-uniform provider experience or lack of access to a provider who can interpret the images. The algorithms apply feature-extraction and machine learning methods to leverage multiple sources of contrast. Preliminary results achieve sensitivity, specificity, and accuracy of 81.3%, 78.6%, and 80.0%, respectively, when used to distinguish cervical intraepithelial neoplasia (CIN+) relative to normal and benign tissues. These results are superior to three expert providers (77% sensitivity, 51% specificity, and 63% accuracy) with experience ranging from 15-40 years. When the Pocket colposcope and machine-learning algorithms can be followed immediately with treatment using a portable thermocoagulator, which has been recently approved by the WHO for cervical cancer ablation. In summary, a three-visit model (screening, diagnosis and treatment) can be consolidated to a single visit. The majority of women (98 out of 100) can complete the screening process at home with self-HPV and self-imaging. A small subset would then attend a health facility, ideally near her home to receive confirmatory diagnosis with the Pocket Colposcope followed by treatment. These results demonstrate the potential for this multi-pronged solution to put women at the center of the solution in resource-limited settings. This model could pave the way for women-centered approaches for other sexual and reproductive health challenges.