



...supporting international communities in their efforts to build and sustain healthy families

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Portable colposcopy

In 1997, Family Health Ministries began developing an inexpensive, battery-powered, portable colposcope. A colposcope is a telescope with a short focal length that is used to examine a woman's cervix with a greenⁱ and/or a white light when she is suspected of having a precancerous lesion on her cervix.

Conventional colposcopes are not available in many communities around the world because they are expensive, dependent on electricity and difficult to transport because of their size and weight. FHM decided to try to design this portable instrument specifically to help meet a need in low-resource settings where cervical cancer screening is not widely available.

The latest version of our portable colposcope was named the 'CerviScope' by a team of students led Theo Tam and it is currently being evaluated in Ethiopia, Malawi and Guatemala. Cervical cancer prevention programs in Pakistan, India, Nigeria, Kenya, Tanzania, Argentina, Honduras, Nicaragua and Haiti have also asked to participate in the field testing of FHM's CerviScope.

CERVICAL CANCER PREVENTION IN HAITI

Among resource-poor nations, Haiti has one of the highest incidences of and mortality from cervical cancer. This understanding prompted FHM to partner with the community of Leogane, Haiti, to develop a cervical cancer prevention program in 1993.

Today FHM's program is developing and testing a variety of novel screening strategies with the goal of expanding access to preventive therapies and reducing the morbidity and mortality of cervical cancer in Haiti. The importance of this work was recently highlighted by a study co-sponsored by PAHO and the CDC, which estimated that without better screening strategies in low-resource communities that the number of cervical cancer deaths could double in the Caribbean by 2030.

FHM has been conducting these studies involving colposcopy, HPV DNA screening and liquid-based cytology in collaboration with the Duke School of Biomedical Engineering, Qiagen Corporation & Cytoc Corporation.

PORTABLE COLPOSCOPY

Because conventional colposcopes are bulky, heavy, electricity-dependent and expensive, many communities around the world have relied on examining a woman's cervix with the naked eye, a technique known as VIA. FHM hopes to provide health care workers in low-resource communities with a colposcope that is inexpensive, lightweight and electricity-independent.

Contact FHM to obtain principal investigator Dr. David Walmer's short research summary on Non-inferiority Evaluation of the CerviScope (11/07).

CERVISCOPE SPONSORSHIP

FHM is looking both for financial sponsors and healthcare providers to help us place these devices in communities around the world for field testing. Because of special machining, the 1st 15-20 prototypes will cost us ~\$1000 to place in the field. If this field-testing is successful, we expect mass production of the units to bring the cost down to under \$500.

If you are interested in being a sponsor or a field-testing site, please contact FHM's research coordinator at 919-382-5500 or at Jackie.Ndirangu@FamilyHM.org. In early July 2008, FHM received its first sponsor for a colposcope, which is being by Serving in Mission clinic in Lagano, Ethiopia. A second colposcope was shipped to Guatemala in September 2008.

DEVELOPMENT HISTORY

Phase 1:

In 1997, David Walmer, MD, PhD & Gus Rodriguez, MD created Family Health Ministries' first portable colposcope by combining surgical loupes, a bicycle halogen headlamp and a green camera filter. The portable colposcope was then evaluated in the dysplasia clinic at Duke University Medical Center.

The study was conducted by having Dr. Eva Littman (above and left) examine the cervix with the portable colposcope and then with the standard colposcope. She recorded her findings after each exam. Dr. Rodriguez then examined the cervix with the standard colposcope, unaware of Dr. Littman's findings. Forty seven women with CIN I - III were screened. The sensitivity of the portable colposcope to detect cervical lesions compared with the standard colposcope (same examiner) was 96.5%. There was a greater difference in the interobserver variability (11.6%) using the standard colposcope for both exams than there was between the portable and the standard colposcope.

This work was published in a supplement of the *Journal of Acquired Immunodeficiency Syndrome* in October of 2004. The scope was then modified through a collaboration with Marcus Henderson & David Katz and evaluated in Haiti. Although the device functioned well, it was not widely accepted by clinicians because it put too much weight on the bridge of the examiner's nose.

Phase 2:

In 2006, Theo Tam, Ram Balasubramanian, Adnan Haider, Gauravjit Singh and Wynn Xiao Wu approached Dr. Walmer about working with FHM and entering the portable colposcope in the CURES competition at Duke University, which is sponsored by Dr. Bob Malkin and *Engineering World Health*. The students worked with FHM to design a lighter instrument and to develop a business plan to market and distribute the instruments. The students named the device the CerviScope as part of their marketing plan and they won 1st place in the competition, which gave them and FHM \$100,000 in resources to take the next steps.

Phase 3:

As an outreach of those resources, FHM worked with ATI, an engineering firm in Cary, NC, to finalize the design of the CerviScope and to ship prototypes to communities around the world for field testing. Testers will be asked to contribute comments for improving future versions of the device.

Phase 4:

FHM submitted a grant to PATH to compare the efficacy of the CerviScope to VIA and to conventional colposcopy. PATH looked at the scope and decided that this trial was not needed & that we should proceed directly from usability testing to producing a marketable scope and doing research designed to reduce the incidence of cervical cancer in low resource communities.

iWhen it has been painted with acetic acid, the cervix appears translucent under a green light except where there is dysplasia. Cervical dysplasia is a pre cancer HPV oncogenic stage