

implement a research project to determine the feasibility of establishing a network of community-based health care teams with the capability of performing smartphone-based digital cervicography in Tanzania.

**Methods:** The project was carried out with an expert team in Kilimanjaro and Arumeru district hospital (Arumeru district) between October 2013 and March 2015. In total we have recruited 500 clients from Arumeru district hospital (a semi-rural site). After the subject underwent VIA and smartphone-based digital cervicography, and the non-expert health team had recorded their diagnosis and treatment plan, the digital image was sent by SMS to the expert site for review. The image was then sent to the expert reviewer for diagnosis and the result was then recorded and transmitted via SMS back to the peripheral site only after the team had recorded and stored their initial diagnosis result. The expert diagnosis was to inform and dictate what the final diagnosis will be and this was communicated to the client and acted on as per protocol with respect to cryotherapy or referral for LEEP excision/other intervention or simply for planned surveillance.

**Findings:** Interim analysis of the first 250 patients indicated that there was full agreement between nurse and expert diagnosis on 94.6% of images. A significantly higher number of women with abnormal cervical lesions were HIV positive. The nurse-run digital cervicography team had overwhelmingly positive feedback about the use of the mHealth based system for capacity building and quality assurance.

**Interpretation:** iPhone-based digital cervicography and SMS image transfer provide a reliable and sustainable strategy for maintaining and upgrading skills of non-expert cervical cancer screening teams and strengthen the ability of non-expert (nurses) to accurately diagnose abnormal cervical lesions.

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### A real world feasibility study for using HPV test as primary screening technology for cervical cancer screening in rural China

Y. Zhao<sup>1</sup>, F. Chen<sup>1</sup>, X. Zhang<sup>1</sup>, F. Zhao<sup>1</sup>, G. Gao<sup>2</sup>, F. Zheng<sup>2</sup>, W. Chen<sup>1</sup>, Y. Qiao<sup>1</sup>; <sup>1</sup>National Cancer Center, Cancer Hospital of Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, CN, <sup>2</sup>Xinmi Maternal and Child Health Care Hospital, Xinmi, CN

**Background:** The national cervical cancer screening program for rural women has been expanded to 10 million Chinese women every year since 2012, which was based on VIA/VILI and Pap smears. In low resource settings, the efficiency of VIA/VILI and Pap smears in real world were unsatisfactory and it is difficult to set up effective screening systems. HPV test is now recommended as primary screening. A low cost, rapid and simple test came into market recently (careHPV™ test; QIAGEN Gaithersburg Inc). Success of setting up a high quality screening system by HPV test requires good performance when operated by personnel with limited laboratory experience. This study aims at evaluating the feasibility of implementing the rapid HPV test as primary screening tool for cervical cancer screening by local health workers in rural China.

**Methods:** Women living in rural areas of Xinmi, Henan Province were invited. Women fulfilled the informed consent were randomized into 3 arms and screened by careHPV test, Pap smears or VIA/VILI separately. Any positive and 10% negative women were referred to colposcopy. Directed biopsy and/or ECC were performed if necessary. A laboratory-inexperienced local worker was trained by technician from NCC/CHCAMS. All the screening procedures were performed by local health workers. The final diagnoses were based on a histopathology expert from NCC/CHCAMS. Some of the screened women and rural health

workers were invited to finish a questionnaire. The Institutional Review Board for human research subjects at NCC/CHCAMS approved the study. SPSS 13.0 software and chi-square test were used for data analysis. Test level was adjusted by Bonferroni test.

**Findings:** 900 women had careHPV test, 560 underwent VIA/VILI and 579 had Pap smears. The overall detection rate for CIN2+ was 0.64%. The positive rates for HPV test, VIA/VILI and Pap smears were 10.6%, 17.9% and 5.7% respectively ( $p < 0.001$ ). The detection rates for CIN2+ showed no statistically difference ( $p=0.937$ ). The false negative for CIN1 was 50% in Pap smears group. The compliance of careHPV group was significantly higher ( $p < 0.001$ ). 266 women and 25 health workers finished the questionnaire. 9.1% women with VIA/VILI complained about the pain (careHPV 4.5%, Pap smears 2.3%). The vast majority women (97%) and all the health workers preferred HPV test irrespective of the cost.

**Interpretation:** After a simple training, experience-limited personnel could operate careHPV test appropriately. The referral rate of HPV test is proper for population screening in real world. Our study proved HPV test is possible to implement in rural areas technically and acceptable to the women and rural health workers. It also implied that free and good quality screening methods may improve the coverage for government initiated programs.

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### Acceptability of cervical cancer screening using a self-collected tampon for HPV testing among HIV-infected women in Pretoria, South Africa

P.C. Adamson<sup>1</sup>, A. Medina-Marino<sup>2</sup>, F. Kinkel<sup>3</sup>, M. Huchko<sup>4</sup>; <sup>1</sup>School of Medicine, University of California, San Francisco, San Francisco, CA/US, <sup>2</sup>Foundation for Professional Development, Pretoria, ZA, <sup>3</sup>Department of Family Medicine, University of Pretoria, Pretoria, ZA, <sup>4</sup>Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF School of Medicine, San Francisco, CA/US

**Background:** Cytology-based screening programs face multiple barriers to successful implementation and broad uptake. Self-collection of cervical specimens for HPV testing has been suggested as one method for increasing cervical cancer screening coverage. We sought to describe the acceptability of self-collected HPV specimens using a tampon compared to Pap smears among HIV-infected women attending an HIV treatment clinic in Pretoria, South Africa.

**Methods:** We conducted a prospective study at one government HIV treatment clinic in Pretoria, South Africa. The study population consisted of 325 HIV-infected women, 25 years or older, seeking care at the clinic and without chart documentation of a cervical cytology result within the past three years. A study clinician performed a pelvic exam and obtained a cervical brush specimen. All study participants received instructions, and then performed a tampon self-collection. The specimens would be used for cytology and to evaluate the performance of a molecular test. After the collection, each participant completed a questionnaire to assess her experiences with both collection methods. The acceptability survey utilized a Likert scale, from 1 (most favorable) to 5 (least favorable), to assess user experiences related to privacy, embarrassment, pain, discomfort, and care for both collection methods. A direct comparison of preferred method was also assessed. Results are reported as proportions and are analyzed using Z-test and Chi-square test statistics.

**Findings:** When compared directly, 179 (55.4%) of women preferred the clinician-collected method and 144 (44.5%) preferred the tampon method ( $p = < 0.01$ ), excluding two missing values.

There were no differences between the participants' perceptions of privacy ( $p=0.62$ ), embarrassment ( $p=0.17$ ), physical discomfort ( $p=1.0$ ), or pain ( $p=0.36$ ) between the tampon and clinician-collected methods. However, more women reported feeling "very well cared for" during the clinician-collected method, compared to the tampon-collection ( $p < 0.01$ ). Most women ( $n = 261$ ; 80.3%) were willing to collect the tampon at home and bring the specimen with them into the clinic. In our study population, 146 (44.9%) women were familiar with using tampons. About half of the women (182; 56%) reported that carrying the tampon for an hour was "very easy," while 62 (19.1%) reported some difficulty with using the tampon.

**Interpretation:** Slightly more women preferred a clinician-collected swab compared to a self-collected tampon in our study population. While there were no differences in relation to privacy, pain, or discomfort, the clinician-collected method allowed women to feel better cared for, which might have driven the observed difference in preference. Therefore, tampon-collected specimens could be a viable alternative for those patients who do not wish to undergo a pelvic examination or who prefer home-collection as a means for cervical cancer screening.

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### Brief quality improvement interventions are effective in changing mid-level provider prescribing behavior in a developing country context

R.R. Korom<sup>1</sup>, S. Onguka<sup>2</sup>, P. Halestrap<sup>3</sup>, M. McAlhaney<sup>3</sup>, M.B. Adam<sup>3</sup>; <sup>1</sup>Penda Health, Boston, MA/US, <sup>2</sup>Kabarak University, Nairobi, KE, <sup>3</sup>Kijabe Hospital, Kijabe, KE

**Background:** Quality improvement processes are important globally. There is a paucity of effectiveness trials of quality improvement processes in primary care settings in developing countries. Our aim in this study was to assess the effectiveness of brief educational interventions for improving diagnosis and management of common conditions, particularly in the area of antibiotic prescribing practices. We hypothesized that brief educational sessions would be effective at improving provider quality for common outpatient illnesses.

**Methods:** We conducted a multi-site, pre-post effectiveness study of staged interventions among outpatient mid-level providers at two peri-urban medical facilities in Kenya. Study participants included accredited Clinical Officers employed at the sites. We deployed three educational interventions on the management of urinary tract infection (UTI) to both sites in a non-randomized fashion. First, a clinical practice guideline was introduced via a formal educational session. Second, investigators facilitated peer-to-peer chart review to provide feedback on guideline adherence. Third, recently published locally relevant antibiotic resistance data was reviewed with providers in an educational session. Charts of female patients between the ages of 14–49 who were given a diagnosis of UTI were audited before and after each intervention. These charts were scored using a binary scale on a series of five quality metrics. Auditors used strict chart extraction tools, but were not blinded to the stage of intervention. The primary outcome was the change in provider prescribing behavior on the antibiotic prescription quality metric. The secondary outcome was a composite score of all five metrics. Fisher's exact test was used to compare performance on the primary outcome for the pre- and post-intervention stages. A two-tailed Student's *t*-test was used to compare the composite quality scores. Approval for this study was granted by the Kijabe Hospital Ethics Committee.

**Findings:** Pre-intervention charts were reviewed in a combined analysis across both sites ( $N = 147$ ). Recommended prescribing

practices were followed in 19% of charts reviewed prior to any educational intervention. The mean quality metric composite score during this period was 2.140 ( $SD = 0.87$ ) on a five-point scale. 143 charts were reviewed in the post-intervention period ( $N = 143$ ). Recommended prescribing practices were followed in 41% of charts following the intervention (Fisher's exact test = 0.000039,  $N = 290$ ,  $p < 0.001$ ). The mean quality metric composite score during this period increased to 2.72 ( $SD = 1.07$ ), ( $t(290) = 4.949$ ,  $p < 0.001$ ).

**Interpretation:** The results of the first phase of this quality improvement effectiveness study suggest that brief educational interventions are effective in changing provider prescribing behavior and improving quality across multiple metrics. This study provides a foundation to implement additional quality improvement interventions in outpatient community practices in low- and middle-income countries.

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### A point-of-care device for the rapid diagnosis of tuberculosis

S. Wong<sup>1</sup>, P.K. Drain<sup>2</sup>, C. Klapperich<sup>3</sup>; <sup>1</sup>Boston University, Boston, MA/US, <sup>2</sup>Massachusetts General Hospital/Harvard Medical School, Boston, MA/US, <sup>3</sup>Biomedical Engineering, Boston, MA/US

**Program/Project Purpose:** Despite being a largely curable disease, tuberculosis infected 8.6 million people and killed 1.3 million in 2012. These grim statistics are largely due to low detection rates—approximately 60% of suspected TB cases go undiagnosed and untreated because there is no fast and accurate way to detect TB. We aim to develop a simple-to-use, inexpensive, and rapid point-of-care TB diagnostic for use in low-resource settings where TB is most prevalent.

**Structure/Method/Design:** For years, TB diagnostics has remained surprisingly stagnant. Recently, a new option became commercially available: a lateral flow assay that functions like a home pregnancy test. The test—Determine™ TB LAM Ag test (Alere Inc.)—diagnoses TB by detecting lipoarabinomannan (LAM), a cell wall glycolipid of *Mycobacterium tuberculosis* that is shed into the urine of persons with active TB. Although initially promising, numerous clinical evaluations have convincingly demonstrated that the test's sensitivity is too low to accurately diagnose the general TB population. The problem is likely that urinary LAM concentrations are naturally present at levels too low to be immunodetectable. Some studies, however, suggest that a 10-fold increase in LAM concentration could dramatically improve its immunodetectability. We developed a method to pre-concentrate LAM without sophisticated laboratory equipment (e.g., centrifuge) to enhance its downstream immunodetection. Our technology can be easily translated to a battery-powered, point-of-care platform and readily integrated with a test like Determine™ to leverage the diagnostic's simplicity and commercial availability. To pre-concentrate LAM, we applied localized heat to a paper-based device to enhance urine evaporation and LAM concentration. We proved the feasibility of this strategy by concentrating bromophenol blue (BPB) in water and LAM in water or urine using a commercial resistive heater (as the localized heat source) heated to 220°C with a benchtop power supply. BPB and LAM were quantified via spectrophotometry and immunoblotting, respectively.

**Outcomes & Evaluation:** Initial tests to concentrate BPB in water by heating the paper strip for 10 minutes resulted in a 19-fold concentration of BPB ( $19.2 \pm 3.5$ ;  $n=3$ ). Concentrating LAM in water for 10 minutes resulted in a 21-fold increase in LAM ( $21.4 \pm 1.5$ ;  $n=3$ ). The comparable degree of concentration of BPB and LAM in