

Quick, low-tech HPV test used in rural areas

An inexpensive, rapid HPV DNA test effectively detected significant cervical precancers in women screened in rural areas of China, according to a study published in the October issue of *Lancet Oncology*.

Cervical cancer rates have dropped sharply in industrialized nations with the advent of wide cervical cancer screening programs (utilizing Pap tests and, more recently, combination Pap/HPV tests), but the disease continues to be a large problem in the developing world. 85% of cervical cancer cases are estimated to occur in poor countries that lack the means (including adequate laboratories and trained staff) to implement their own screening programs.

Enter careHPV, an HPV DNA test being developed by QIAGEN (formerly Digene) that's largely based on the hybrid capture 2 (HC2) HPV test currently marketed by the company. In the U.S., HC2 is distributed as the digene HPV Test and is currently approved by the FDA for use (along with a Pap test) for primary cervical cancer screening in the U.S. with women age 30 and over. The test is also used with younger women who have unclear Pap test results (such as ASC-US) to help clinicians sort out which patients need additional diagnostic procedures.



Unlike HC2, though, careHPV is designed for use by minimally trained technicians in remote areas, even those that lack running water and electricity. Results can be obtained in under three hours, allowing same-day treatment when needed.

In research done with over 2,500 women in rural China, Dr. You-Lin Qiao and colleagues report the two tests showed similar sensitivity in detecting significant cervical lesions (CIN 2 or higher): careHPV detected 90% of cervical precancers and cancers, while HC2 found 97% of lesions. Specificity (avoiding a false positive result) was also comparable in this study, at 84% with careHPV and 86% with HC2, respectively.

careHPV also fared better in finding cervical disease than visual inspection with acetic acid (VIA), a relatively inexpensive method of cervical cancer screening favored in many developing areas. With VIA, acetic acid is applied to the cervix (which turns abnormal tissue white), and the area is inspected with the naked eye and bright lights. In this study, VIA's sensitivity in detecting cervical precancers was only 41%.

The authors conclude that careHPV holds promise for cervical cancer screening in regions where other approaches may not be practical. Unanswered questions include the feasibility of self-sampling with this technology and, despite the test being designed for use in the developing

world, whether or not such technology might also benefit poor areas within industrialized nations.

Reference

Qiao Y-L, et al. A New HPV-DNA Test for cervical cancer screening in developing regions: a cross-sectional study of clinical accuracy in rural China. *The Lancet Oncology*, 2008. 9:929-36.