

New dipstick speeds trachoma diagnosis in the field



Courtesy of Helen J Lee, PhD

Devon Schuyler

TESTING for *Chlamydia trachomatis* – the bacterium that causes trachoma – is so impractical in developing-world countries that the World Health Organization (WHO) recommends a simplified clinical grading system for detecting the disease. But now a new, inexpensive assay has shown some early success at making highly accurate diagnoses in remote areas.

“It’s a very promising and interesting tool. It bridges one of the biggest limitations of infection detection through laboratory means, which is that you need very complicated sampling methodology, and then you need to transfer the samples to highly sophisticated laboratories. It could add important information to the current clinical grading used in the field,” said Silvio P Mariotti MD, head of the WHO’s trachoma programme, in an interview with *EuroTimes*.

In a study published in *The Lancet* (May 13, 2006;367:1585-1590), researchers tested a point-of-care assay on more than 600 children living in Tanzania. Local health workers assessed the children using both the assay and the WHO method. For comparison, the group also sent an eye swab from each patient to a laboratory in the UK for PCR testing.

The researchers found that the assay was significantly more accurate than the WHO method for detecting trachoma.

“The test predicted the presence of *C. trachomatis* infection much more accurately than the clinical sign diagnosis that is currently used,” said Helen J Lee PhD, the lead author of the study.

She pointed out that not only was the testing carried out in villages with no electricity or running water, but that local personnel in Tanzania were able to perform the test perfectly with less than two hours of training.

Dr Lee, who is associate professor of medical biotechnology, University of Cambridge, predicted that the assay would play a role in rapid screening of populations for trachoma, allowing programme managers to target antibiotic treatment to communities

that most need it.

She said that although the assay is not yet commercially available, it is being used in further research studies.

High-tech test in a low-tech environment

Researchers recruited 664 children aged one to nine years old into the study by conducting house-to-house surveys in several villages in Tanzania. The villages included in the study were reported to have relatively high prevalence of trachoma in children, but had never received mass treatment with azithromycin.

Four local health workers received an hour’s worth of training on how to use the assay. These workers took two swabs from the subtarsal conjunctiva of each child: one for testing with the assay, and one to be sent for PCR testing. An ophthalmic nurse with extensive experience in grading trachoma graded signs of trachoma using the WHO simplified trachoma grading system.

The total number of children who tested positive for *C. trachomatis* infection using PCR was 19 per cent. The assay was significantly more likely than the simplified WHO grading system to produce results that agreed with those from PCR testing, with greater sensitivity (84 per cent vs. 64 per cent), specificity (99 per cent vs. 80 per cent), and positive predictive value (97 per cent vs. 44 per cent). Inter-agreements and intra-agreements between the four healthcare workers were very high: 99 per cent and 95 per cent, respectively.

Dr Lee and a team of scientists developed the point-of-care assay at the University of Cambridge, and went on to form a US-based company called Diagnostics for the Real World. The company will begin marketing a *Chlamydia* rapid test for sexually transmitted diseases in Europe in the spring of 2007, according to Dr Lee. The company plans to sell the trachoma assay, which is very similar to the STD test, at a low cost in developing-world countries.

Dr Lee is making plans in collaboration with the WHO and non-governmental

organisations to use the assay in other parts of Sub-Saharan Africa, regions of North Africa where the prevalence of trachoma is low, and Australia, Nepal and Mexico.

A better use of resources

David Mabey MD of the London School of Hygiene & Tropical Medicine, who is one of Dr Lee’s co-authors, emphasised that the assay requires further study.

“I think it needs to be evaluated in different settings with different prevalence of infection to see if it performs similarly, and then we need to look at cost effectiveness of different ways of using this and comparing that with the current WHO system of assessment based on clinical signs,” he said.

If the assay continues to prove effective, Dr Lee said that it could help healthcare workers target azithromycin treatment to the communities that really need it.

“Trachoma is a disease affecting the poorest of the poor. Therefore, it is important to focus the scarce resources in these communities to treat infected individuals,” she said.

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Pictured above from left to right:

Recruitment of Masai children in Rosalini, Hai District, Tanzania in September 2006; Dr Helen Lee & Mr Claude-Edouard Michel at laboratory of Diagnostics Development Unit (University of Cambridge, Department of Haematology, UK) presenting the point-of-care assay based on Simple strip format with an improved sensitivity due to a patented signal amplification technology; and training of health worker at Sanya Station, Hai District. Local health workers can reliably perform the assay with just one hour’s training