Practical malaria tests promise results in remote regions

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You're in a small village in Mali. You have a fever, headaches and nausea, classic signs of malaria.

The most sensible thing would be for a technician at a clinic to prick your finger and examine the blood under a microscope. More likely, they'll simply assume you have malaria and hand you the medicines.

Most healthcare workers in remote African communities are ill-equipped, lacking the training or tools necessary to make sophisticated diagnoses. But indiscriminately treating all infections with malaria drugs is a sure way to exacerbate resistance to valuable drugs.

Confronted with this problem, scientists are scrambling to develop diagnostic tools that are practical and easy to use in even the most resource-poor settings.

In November, Johns Hopkins University scientists reported the first successful screening technique based on DNA from saliva or urine samples, rather than from blood. Researchers from the Geneva-based Foundation for Innovative New Diagnostics (FIND) have also devised a DNA-based test that, unlike other molecular tests, does not have to be sent away to a lab.

"Bedside tests that can detect DNA and are quite cheap are the potential future," says David Bell, a malaria diagnostics expert at the World Health Organization.

Rapid tests—usually dipsticks that work like pregnancy tests—detect proteins that are produced by malaria parasites. The tests are simple and effective, and about 40 million of them were made in 2006. But their quality is inconsistent, and manufacturing flaws, such as differences in the quantity of reagents and components, affect their sensitivity (*Nat. Rev. Microbiol.* **4**, 682–695; 2006).

The most accurate blood test detects the parasite's nucleic acids. But the technique is expensive and samples have to be sent to trained technicians in far-off labs.

FIND's new test, called loop-mediated isothermal amplification, or LAMP, is an inexpensive DNA test that any health worker with a heating source and basic lab skills and materials could use. The test will be ready for manufacturing in mid-2008, says Mark Perkins, chief scientific officer of FIND.

But highly sensitive assays such as LAMP can also detect parasites in people who are just carriers of the parasite and do not require treatment. In endemic regions there may be many of these individuals, and scientists will need to decide how best to use the tests there.

The saliva- and urine-based test, which must also be sent to labs, may prove more effective for research. In many countries where needles are taboo and AIDS is rampant, it can be difficult to convince healthy people to undergo a blood test. A less invasive technique would allow researchers to collect samples, for instance to track emerging drug resistance in a community.

The test needs to be validated, however. Malaria parasites aren't normally found in urine or saliva, so the researchers don't know why they found the traces of parasite DNA in those samples.

Emily Waltz, New York

Companies balk at California's patent rules for stem cell research

California is set to adopt rules that will guarantee public return on its state-funded stem cell research, requiring grantees to share patented materials, send a portion of revenues to the state and guarantee cheap treatments to Californians.

But the rules, which could set the tone for other state-funded science programs, are too restrictive and might put off companies, industry representatives warn.

The regulations are more stringent than the federal Bayh-Dole Act, which doesn't mandate revenue sharing or treatment access.

"The stem cell program in California launched two experiments. The obvious one is the research being done, and the other is an enormous policy experiment," says Jesse Reynolds, project director on biotechnology accountability at the Oakland-based nonprofit Center for Genetics and Society.

The state is finalizing patent rules for nonprofit grantees and the companies that work with them, and will begin enforcing them once the first grants are awarded in February 2007. Requirements for companies are expected to follow later in 2007.

Nonprofits and commercial ventures will both be required to notify the California Institute for Regenerative Medicine, established by the state to oversee grants, when their state-funded research results in a publication or patent and to freely share research materials—cell lines, compounds or DNA sequence information—they develop. The state will also receive a share of the revenues from licensing agreements and sales of therapies developed.

Although the biomedical industry has questioned whether some of the material-sharing policies are feasible, it has reserved its harshest criticisms for rules on discounted pricing and broad access.

Under the proposed rules, companies must make treatments developed using state-funded research accessible to Californians who don't have health insurance and at a discount through the state's healthcare plans.

Companies may decide not to license patents if they have to provide deep discounts on their products, says David Gollaher, president of the California Healthcare Institute, which represents more than 250 biomedical companies and research institutions.

Mary Maxon, deputy vice chair of the California Institute for Regenerative Medicine, says companies shouldn't worry and that specific access proposals will be judged on an individual basis. "You sign a contract saying you'll provide these things, but we won't tell you how to do it. We don't want you to go out of business," she says.

Reynolds says the industry is also worried about the precedent California could set. Nine other states fund or plan to fund stem cell research, and their intellectual property approaches vary vastly. Connecticut, for example, receives royalties on commercial developments but other terms are negotiable. Illinois's plan resembles California's but the specifics have not yet been determined.

"If California's policy works," Reynolds says, "then when other policies are revisited, it could set a precedent."

Brandon Keim, New York