Researchers detecting low quality antimalarial drugs with a lab-on-paper

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Access to high-quality medicine is a basic human right, but over four billion people live in countries where many medications are substandard or fake. Marya Lieberman of the Department of Chemistry and Biochemistry at the University of Notre Dame and Abigail Weaver a postdoctoral associate in the University's Department of Civil Engineering and Environmental and Earth Sciences took up the challenge of how people in developing countries could detect low quality antimalarial drugs without expensive equipment and without handling dangerous chemicals.

The solution they developed involves using paper cards, embedded with reagents, that carry out 12 colorful chemical tests all at once on a solid sample. The colors show whether a medicine contains the expected ingredients and whether fillers or substitute drugs have been added.

Weaver's and Lieberman's research demonstrated that a library of chemical color tests embedded on a paper card can presumptively identify formulations corresponding to very low quality antimalarial drugs. The presence or absence of chloroquine (CQ), doxycycline (DOX), quinine, sulfadoxine, pyrimethamine, and primaquine antimalarial medications, in addition to filers used in low-quality pharmaceuticals, are indicated by patterns of colors that are generated on the test cards. Test card sensitivity for detection of these pure components ranges from 90 percent to 100 percent with no false positives in the absence of pharmaceutical.

These easy-to-use cards will help people in the developing world identify suspicious medications before they harm patients. Tests are simple and inexpensive enough to be carried out in clinics, pharmacies, and ports of entry and could provide a screening method to detect suspicious medicines throughout the supply chain.

In previous research the Lieberman group developed paper tests for antibiotics like amoxicillin.

"The antimalarial drugs are different chemically so we couldn't use that card for this project," Lieberman said. "Gail developed a new card and tested samples with formulations corresponding to high quality products or low quality products, and we measured whether the test card could identify the bad formulations correctly and whether good formulations were mis-identified as bad ones."

Now that they have developed the test cards, Lieberman and Weaver are working to get them out of the lab and into the world.

"Our immediate next step is to test antimalarial drugs collected by collaborators in Southeast Asia to see whether the test cards can detect good and bad pills in that sample pool," Lieberman said. "Next is to use the cards in an ongoing screening program in Kenya. It's going to require a big push on manufacturing so we can produce larger numbers of cards at even lower cost, as well as development of sophisticated software to enable a computer to read the test results using just a cell phone photograph of a test card. And we can't lose track of the need to remove low quality products from the market; this requires additional chemical analysis of suspect products and close coordination with the national medical regulatory agency.

"Working with the Purdue College of Pharmacy and Moi Teaching and Referral Hospital (MTRH) in Kenya, we are setting up a laboratory at

MTRH that can conduct confirmatory testing of suspicious pharmaceuticals. This site will act as a sentinel to detect low quality medicines in Western Kenya. Companies like Merck, Lilly, and Waters made generous donations of analytical instruments and funding to make this project possible. Our goal is to greatly reduce the time it takes to identify low quality products in the supply chain so the medical regulatory authorities can take action to protect the health of patients in Kenya and neighboring countries."

The paper appears in a Supplement to the *American Journal of Tropical Medicine and Hygiene* entitled "The Pandemic of Falsified Medicines: Laboratory and Field Innovations and Policy Perspectives." The special issue includes 17 papers on detection technologies and methods, data from field surveillance, and policy recommendations describing how public health authorities and decision makers can monitor the scope of the problem, identify problems at all stages of the pharmaceutical supply chain, and improve the quality of medications

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