Paper-based device spots falsified or degraded medications

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A team of researchers has developed a simple, inexpensive, paper-based device to test medicine for quality and adulteration. Credit: Lieberman and Bliese

The developing world is awash in substandard, degraded or falsified medications, which can either directly harm users or deprive them of needed treatment. And with internet sales of medications on the rise, people everywhere are increasingly at risk. So, a team of researchers has developed a simple, inexpensive paper-based device to screen suspicious

medications.

The researchers will present their work today at the 252nd National Meeting & Exposition of the American Chemical Society (ACS). ACS, the world's largest scientific society, is holding the meeting here through Thursday. It features more than 9,000 presentations on a wide range of science topics.

"People who don't have access to the best-quality medicines also don't have as many resources to buy the analytical instrumentation to detect the quality problems," says Marya Lieberman, Ph.D. "Instead of a $30,000 instrument, we've developed a $1 paper card. We designed the card so it would be as easy and inexpensive to use as possible."

Medications can be compromised in many different ways. For example, they may be bulked up with fillers, or they can degrade because they are stored improperly. Identifying poor-quality medications is challenging, as inspectors may not know in advance what chemical adulterants or degradation products they need to look for. Plus, bad-quality medications may contain at least some of the active ingredient, so simply detecting the presence of the real medication isn't enough to rule out issues.

In this study, Lieberman of the University of Notre Dame, along with Hamline University undergraduate Sarah Bliese, developed a card to detect falsified or degraded antibiotics such as ciprofloxacin or ceftriaxone, both of which the World Health Organization lists as "essential." To screen for a variety of potential quality issues, the researchers included 12 lanes separated by wax barriers on the paper device. Each lane contained a different set of reagents to detect materials or functional groups found in active pharmaceutical ingredients, degradation products or common fillers.

To run a sample, the researchers crush a pill and rub the resulting powder across all 12 lanes, and then dip the bottom of the paper card in water for three minutes. The water wicks up the lanes, bringing reagents into contact with the powder. Colors are formed when the reagents interact with the pharmaceutical, filler or degradation product. The researchers then compare the color pattern from the sample with the color patterns obtained from high-quality pharmaceutical products. The comparison can be done by eye or with an image-analysis program on a smartphone.

Ceftriaxone is sensitive to heat and breaks down if storage temperatures climb too high. As an experiment, the researchers subjected ceftriaxone to high temperatures and ran the card test, simultaneously analyzing the degradation products via liquid chromatography-mass spectrometry. They verified that the colorimetric pattern for the degraded antibiotic was different from that of the correctly stored product. In addition to these tests on the pure active ingredient, Lieberman and Bliese analyzed dozens of real-world samples of ceftriaxone from Kenya and Uganda.

Unscrupulous makers of falsified medication sometimes add colorants containing toxic heavy metals to their products to make the illicit pills more closely resemble their legitimate counterparts, Bliese says. So, in a related project at Hamline University, Bliese and Deanna O'Donnell, Ph.D., are exploring whether a portable X-ray fluorescence spectroscopy device can scan pills for these substances.

In June, Lieberman and Bliese traveled to Kenya to test a new paper card which can detect substandard antibiotics. While Lieberman is currently focusing her work on the developing world, she says her cards could be applicable worldwide to perform, for example, the analysis of herbal medicines and nutritional supplements. "Sometimes those 'herbal products' are actually spiked with pharmaceuticals," she explains. "The paper test cards could be a defense against this." Bliese says her next

project will be to develop a paper test card to help first responders identify drugs of abuse and differentiate them from household products or legitimate medicines.

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