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How fake drugs cause the spread of untreatable TB in developing countries



In December 2011, Dr. Zarir Udwadia, one of India's leading tuberculosis doctors, reported in a medical journal that he had four tuberculosis patients that were resistant to all treatment, <u>The Wall Street Journal reported</u>. By January, he had a dozen such cases, and 15 soon after.



In this Oct. 22, 2012 photo, a tuberculosis patient is given an injection in New Delhi.

The Journal's investigation found that in 18 sites around India, 6.7 percent of TB patients tested were drug-resistant. In one Mumbai clinic alone, about 28 percent of TB patients were incurable with standard medicines.

Tuberculosis, a disease that destroys lung tissue, is more commonly associated with the Victorian era than with the modern age. Today, TB can be cured with several heavy rounds of antibiotics, but the emergence of drug-resistant strains of the disease in India and other countries around the world have raised alarm among health workers.

One culprit in the rise of untreatable TB is counterfeit drugs, which can undermine treatment efforts by packing insufficient active ingredients to fully kill off bacteria, breeding new, stronger super-strains of the disease. Though the scourge of counterfeit malaria drugs has shaken up the public health world in recent years, researchers are now turning their attention to fake TB drugs, as well, as cases of drug-resistant TB have emerged in both the developing world and in higher-income cities such as

London and Moscow.

A <u>new study published</u> in the International Journal of Tuberculosis and Lung Disease found that 16.6 percent of tuberculosis drugs in Africa, 10.1 percent in India and 3.9 percent in other middle-income countries were "failures," meaning they had less than 80 percent of the active ingredient necessary to treat the disease.

"The biggest determinant of drug quality is wealth [of the country]," said one of the study's lead authors, Roger Bate, an economist who researches international health policy with the American Enterprise Institute.

The study analyzed drugs in 17 countries -- those that are home to about 60 percent of the world's total cases of multidrug resistant TB. Over the past five years, teams of researchers have been purchasing antibiotics at random pharmacies in each of the countries and testing the medicines' active ingredients. (To find the samples for middle-income countries, researchers visited Bangkok, Beijing, Istanbul, Moscow and Sao Paulo.)

When patients take these fake drugs, they remain sick longer or die. In some patients, germs multiply and morph into new strains, making them harder and more expensive to treat.

The authors suspect that the number of fake drugs in Africa is so high because few of the drugs there are "registered," meaning authorized to be sold by a relevant drug agency. (It's virtually impossible to find unregistered pharmaceuticals in the United States, for example, because of FDA regulations.) Non-registered drugs are generally more dangerous, but they can proliferate in countries where regulatory bodies are weak.

"Countries with high levels of unregistered drugs show a lack of competency in customs to prevent products from entering the country," Bate said. "African regulators are less competent at doing their jobs."

But simply stopping the flood of fake drugs into each country won't entirely fix the problem, the authors say, because there's a difference between drugs that are designed to deceive patients and those that are simply poorly made or stored. Creating a so-called falsified medicine, which has little or no active ingredient, can be considered a criminal act. But then there are the drug companies that make mistakes, pills that are stored improperly, mislabeled bottles or sloppy compounding, among other potential errors.

"Often, these bad drugs are just poorly made or poorly stored," Bate said. "If all you do is beef up customs, you're not going to deal with the legal substandard products on the market."

To catch bad batches of drugs, Bate recommends trying a tactic similar to the international community's response to fake malaria drugs -- setting up strong donor and in-country facilities to test the medicines before they're sold.

"Right now, most TB doctors are just assuming that there's not a problem with medicines," he said. "If someone's not reacting, they keep giving them the drug in hopes it will start working."

Comments