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Rapid Field Assay for Artemisinin Drug Quality

Summary

Artemisinin-based combination therapies (ACT) are the first line malaria treatment recommended by WHO. Drug quality of ACTs in many areas of the world, however, represents a significant concern; with many drugs in the supply chain containing inadequate levels of active pharmaceutical or no active pharmaceutical at all. A rapid field test for drug quality therefore represents an important development in ensuring adequate specification of these vital medications.

Applications

- A fast and low cost *in situ* colorimetric test detecting artemisinin levels in malaria drugs.

Benefits

- Rapid, simple, stable and portable. Ideal for field use.
- Semi-quantitative.
- Easy to read.

Background

Malaria is a significant public health burden, particularly in low and middle-income countries. In order to combat the disease, artemisinin derivatives (ARTs) were developed as anti-malarial drugs. However, due to the growing concern of resistance to ARTs, WHO no longer recommends the use of artemisinin derivatives in isolation. As a result, artemisinin-based combination therapies (ACT) are now the frontline therapy in malaria. Although the artemisinin component in ACTs remain expensive and because of the demand, the risk of counterfeit or substandard ACTs reaching the market is high. This has led to the undertreatment and an increasing threat of resistance to this drug class.

Systematic studies have demonstrated that the prevalence of substandard drug can be up to 37% in certain malaria-endemic territories and although the amount of true counterfeit drug remains low, a significant subset of drug in the supply chain is not fit for purpose. Current methods for testing artemisinin content in drugs including liquid-chromatography coupled to mass-spectrometry are expensive, sophisticated and cannot be used in the field. A simple means of assessing ACT quality therefore represents a clear unmet need.

Technology and its advantages

A simple, robust, rapid and portable field test to provide a semi-quantitative assessment of artemisinin drug quality has been developed at LSHTM. This two-step assay simply involves dissolving the drug in the supplied buffer and spotting on to a cartridge to give a colorimetric readout.

The assay has been confirmed as being highly specific to artemisinin, having been tested against a total of 80 other drugs common in malaria endemic settings. These include other antimalarial drugs, commonly used excipients, antiretroviral drugs and other frequently used drugs from the WHO essential drugs list.

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Validation has been performed using 100 samples of ACTs collected in Africa and Asia. The assay is therefore ideally suited as a first-line field test to assure the quality of ACTs in resource-poor, malaria-endemic settings.

Inventors

Dr Harparkash Kaur joined the London School of Hygiene & Tropical Medicine (LSHTM) in 2001 is a founder member of the artemisinin combination therapy consortium. She is the director of the LSHTM Bioanalytical facility and the lead investigator of the drug quality project. She was an elected chartered chemist, fellow of the Royal Society of Chemistry in 1999 (CChem FRSC) and designated a chartered scientist (CSci) in 2005.

Dr. Jean-Robert Ioset is a discovery manager at the institute of tropical neglected disease (DNDi). He has authored more than 40 publications in the field of natural product chemistry, anti-infective drug discovery and counterfeit drugs.