

Study in Nigeria finds one in ten malaria drugs are poor quality

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Credit: CDC

A rigorous analysis of more than 3,000 antimalarials purchased in Enugu, Nigeria found 9.3% to be of poor quality, according to new research published in *PLOS ONE*.

Researchers found 1.2% of the samples to be falsified and 1.3% to be degraded, but raised bigger concerns about 6.8% being of substandard

manufacture, leaving patients at risk of not receiving the correct treatment dose and potentially contributing to the development of resistance to the main drug used to treat malaria.

The drug quality team of the Artemisinin-based Combination Therapy (ACT) Consortium at the London School of Hygiene & Tropical Medicine analysed 3,024 [antimalarials](#) containing artemisinin (the component that makes malaria treatment effective) from Enugu Metropolis, South East Nigeria, which has a population of 3.3 million. Nigeria is the single most heavily malaria-burdened country in the world, with 48 million malaria cases and 180,000 deaths per year.

Dr Harparkash Kaur, from the London School of Hygiene & Tropical Medicine, lead investigator of the drug quality programme of the ACT Consortium, said: "Although these results raise concerns, they are reassuring in comparison with previous reports that found that more than 35% of antimalarials in sub-Saharan Africa failed chemical content analysis - in other words, were poor quality. This may be because those reports predominantly used a "convenience" approach to select samples for analysis, which may not be representative of the places where patients buy their medicines."

The team purchased medicines from 421 outlets in Enugu including pharmacies, patent medicine vendors, and public health facilities. In addition to "convenience" sampling, which lacks systematic guidance on which outlets to sample from, samples were also bought from a representative sample of outlets. Two approaches were used in the representative sampling: a covert approach, using "mystery clients" in which researchers pretended to be patients with malaria, or their relatives, asking to buy medicines; and an "overt" approach, where researchers told vendors openly that they were going to analyse the quality of their malaria medicines.

Each sample was analysed in three independent laboratories in the UK and USA and classified as acceptable quality, falsified (fake drugs which do not contain the stated active pharmaceutical ingredient or API), substandard (which contain inadequate amounts of the active ingredients), or degraded (decomposition of the API by poor storage conditions, such as heat and humidity).

All three sampling methods detected falsified drugs, but the prevalence was higher in samples purchased using the convenience approach.

Falsified samples contained chemicals other than the stated API, such as chlorzoxazone (a muscle relaxant), ciprofloxacin (an antibiotic) or acetaminophen (a commonly used painkiller).

The team also identified artemisinin-based monotherapy tablets, which are no longer recommended by the World Health Organization because they do not include the partner compound that makes it an effective artemisinin-based combination therapy. Some of these monotherapies were also falsified.

Substandard or degraded drugs were more prevalent than falsified ones in Enugu. Poor quality drugs were frequently found in patent medicine vendors - also known as drug shops, which are the main source of treatment for most patients - rather than in pharmacies.

Study co-author Prof. Obinna Onwujekwe from the University of Nigeria, Enugu said: "The results show that the health system actors should be eternally vigilant in Nigeria and in other countries to ensure that sub-standard drugs do not impede or erode gains made in [malaria treatment](#). Drug regulatory authorities and their partners should intensify drug quality monitoring activities with appropriate sanctions for defaulters."

The ACT Consortium's large drug quality programme, which has analysed over 10,000 samples from six [malaria](#) endemic countries over five years, has recently published results from Tanzania and Cambodia, where substandard medicines were of similar concern but where no falsified medicines were found. Results from Equatorial Guinea, Ghana and Rwanda will be published in the next few months.

More information: Harparkash Kaur, Elizabeth Louise Allan, Ibrahim Mamadu, Zoe Hall, Ogochukwu Ibe, Mohamed El Sherbiny, Albert van Wyk, Shunmay Yeung, Siân Clarke, Isabel Swamidoss, Michael D Green, Prabha Dwivedi, Maria Julia Culzoni, David Schellenberg, Obinna Onwujekwe. Quality of Artemisinin-Based Combination Formulations for Malaria Treatment: Prevalence and risk factors for poor quality medicines in public facilities and private sector drug outlets in Enugu, Nigeria. *PLOS ONE*. DOI: [10.1371/journal.pone.0125577](https://doi.org/10.1371/journal.pone.0125577)

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