

## Poor-quality antimalarial drugs threaten to jeopardize progress made in malaria control over past decade

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Poor-quality and fake antimalarial drugs are leading to drug resistance and inadequate treatment that is endangering global efforts made to control and eliminate malaria over the past 10 years, according to a review of the evidence published in The *Lancet Infectious Diseases*. In particular, the emergence of resistance to artemisinin drugs, currently the most effective treatment against malaria, on the Thailand-Cambodia border should be a wake up call, warn the authors.

Findings from the Review indicate that around 36% of antimalarial drugs analysed in southeast Asia were fake\*, while a third of samples in sub-Saharan Africa failed chemical testing for containing too much or too little of the <u>active ingredient</u>, potentially encouraging <u>drug resistance</u>.

"3.3 billion people are at risk of malaria, which is endemic in 106 countries. Between 655 000 and 1.2 million people die every year from Plasmodium falciparum infection. Much of this morbidity and mortality could be avoided if drugs available to patients were efficacious, high quality, and used correctly", explains Gaurvika Nayyar from the Fogarty International Center at the National Institutes of Health (NIH) in the USA, who led the research.

Nayyar and colleagues from the NIH analysed data from published and unpublished studies that looked at chemical analyses and the packaging of antimalarial drugs in sub-Saharan Africa and southeast Asia, where



the risk of contracting and dying from malaria is greatest.

Data from seven countries in southeast Asia including analysis of 1437 samples of seven malaria drugs, showed that over a third failed chemical testing, nearly half were incorrectly packaged, and about a third were fake.

Further analysis of data from 21 countries in sub-Saharan Africa including over 2500 <u>drug samples</u> showed similar results, with over a third failing chemical analysis and a fifth found to be fake.

Worryingly, say Nayyar and colleagues, this might only be the tip of the iceberg: "Despite a dramatic rise in reports of poor-quality antimalarial drugs over the past decade, the issue is much greater than it seems because most cases are probably unreported, reported to the wrong agencies, or kept confidential by pharmaceutical companies."

Worse still they say: "No reliable global estimates are available about the frequency of poor-quality antimalarial drugs because of no internationally accepted definitions of different types of poor-quality drugs; no globally standardised or statistically robust sampling schemes, testing protocols, and requirements for drug content; a dearth of funds; and no recognised international forum to provide technical and scientific guidance and oversight."

They conclude that several parallel interventions are needed to define and eliminate criminal production, distribution, and poor manufacturing. Their recommendations include increased investment in medicine regulatory authorities in Africa to encourage country ownership of the problem, adding that: "Currently, only three of the 47 malarious countries in Africa have laboratories that are equipped to chemically analyse antimalarial drugs."



In a linked Comment, Michael Seear from British Columbia Children's Hospital, Vancouver, Canada calls for more research to clarify the extent and cause of poor drug quality: "Drug quality is dependent on the overlapping effects of poor manufacturing standards, criminal counterfeiting, adulteration with inactive or toxic fillers, relabeling of time-expired drugs, and degradation during storage. Reliable research concerning counterfeiting is limited, and almost no information is available about the other four factors."

Moreover, he notes, the international response to the problem has been poor: "Construction of a balance between protection of intellectual property and the maintenance of drug quality has plagued the relation between WHO and the International Medical Products Anti-Counterfeiting Taskforce (IMPACT)...Hopefully, public health will be given more priority than are intellectual property rights and WHO will develop a clearly defined and widely accepted mandate in this area."

**More information:** Study online: <a href="www.thelancet.com/journals/lan">www.thelancet.com/journals/lan</a> ... (12)70064-6/abstract

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