

New research reveals extent of poor-quality antimalarial medicines in South American countries

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Two articles recently published in *Malaria Journal* shed new light on the quality of antimalarial medicines circulating in countries in the Amazon Basin in South America. Researchers from the Promoting the Quality of Medicines (PQM) program, a cooperative agreement between the U.S. Agency for International Development (USAID) and the U.S. Pharmacopeial Convention (USP), in conjunction with country partners, coordinated these studies in the context of the Amazon Malaria Initiative (AMI).

"Though several studies in recent years have assessed the quality of antimalarial medicines circulating in Africa and Asia, there have been no comprehensive studies looking at the situation in the Americas," said Patrick Lukulay, Ph.D., vice president of Global [Health Impact](#) Programs at USP and director of the PQM program. "This region has been largely overlooked, perhaps because of a perception that substandard and counterfeit medicines pose less of a threat in these countries. However, the findings in one of the studies in which medicines were assessed in the private and informal sectors in two countries indicate that poor-quality medicines are indeed a serious concern for antimalarials. The data from the other study suggests that the systematic implementation of basic, rapid and low-cost quality testing helps in reducing the prevalence of poor-quality medicines on the market."

The first study, Quality of Antimalarials Collected in the Private and Informal Sectors in Guyana and Suriname, assessed the quality of circulating antimalarial medicines in the private (licensed pharmacies, wholesalers and distributors) and informal (unlicensed shops and [convenience stores](#)) sectors. No information was previously available about the quality of these medicines. Though antimalarials are usually distributed through public health facilities at no cost in these countries, the private and informal sectors thrive in Guyana and Suriname—particularly in the remote interior regions where the presence of public facilities is limited or nonexistent, and large populations of workers in the gold mining and logging industries live. Buying from these facilities poses increased risk of access to and use of non-recommended treatments and/or poor-quality products, which can have serious repercussions on patients' health.

In Guyana, 45 of 77 (58 percent) of antimalarial medicines were found to be of poor quality. Visual and physical inspection unveiled 30 failures and analytical tests revealed 18; a medicine failing more than one test was considered a single failed medicine. Visual and physical inspections provide valuable information about the physical appearance and labeling of medicines, and in many cases these inspections can detect counterfeit medicines. Quality control tests assess critical quality attributes of a medicine, such as identity, content, impurities and dissolution, among others. Of particular concern was the proportion of monotherapy (single drug) treatments failing quality control tests in Guyana (43 percent). This included a high failure rate for artesunate monotherapy, a treatment not recommended by the World Health Organization (WHO) for *Plasmodium Falciparum* [malaria](#), the most common type of malaria in the interior of Guyana. WHO recommends artesunate combination therapy for *Plasmodium Falciparum*.

In Suriname, 86 percent of the samples collected were Artecom[®], and only this antimalarial was analyzed. All Artecom samples lacked a label

claim for the content of one of the components—primaquine—which resulted in an automatic failure of visual and physical inspection. Inadequate labeling is problematic because it renders it impossible for patients to know the dosage of the medicine they are taking, which could lead to ineffective treatment. Additionally, undeclared strength of primaquine poses a safety concern to individuals who are glucose-6-phosphate dehydrogenase deficient. This antimalarial medicine was also found in Guyana; it is not registered in the countries nor is part of their national treatment guidelines. All samples in Guyana and Suriname were collected between June and August 2009.

"These findings point to significant problems in the quality of antimalarials available in private and informal sector facilities in Guyana and Suriname," said Lawrence Evans, Ph.D., the study's lead author. "Besides the presence of medicines not included in the World Health Organization malaria treatment guidelines, the ease with which medications were procured without accurate diagnosis poses another major risk to patients' safety. In addition, this could have serious implications for the development of drug-resistant strains of Plasmodium parasites, particularly Falciparum, as novel treatments are not foreseeable in the near future."

The second study, Implementation of Basic Quality Control Tests for Malaria Medicines in Amazon Basin Countries: Results for the 2005-2010 Period, looks at the quality of malaria medicines in seven South American countries over a five-year period. In this study, basic analytical tests were utilized as a rapid and low-cost screening mechanism to identify substandard or [counterfeit medicines](#). Performing basic tests is the first stage in a quality control framework developed by PQM for use in developing countries.

From 2005 to 2010, the quality of a total of 1,663 malaria medicines sampled in Bolivia, Brazil, Colombia, Ecuador, Guyana, Suriname and

Venezuela was evaluated. The medicines sampled comprised all the therapies included in countries' therapeutic guidelines, and were mostly collected from the public sector (1,445, or 86.9 percent). In all, 193 (11.6 percent) were found not to meet quality specifications, of which only 51 (three percent) failed analytical tests; these values compare favorably with results reported for other regions of the world. None of the artemisinin derivatives failed basic analytical tests. Most failures were found during visual and physical inspections, and most of those were due to expired medicines. Under the storage conditions prevailing in many of these areas (e.g., high temperatures and high humidity), medicines of good quality could degrade faster, and the risk of consuming degraded substandard medicines increases if utilized beyond their expiration date. The highest rates of expired products were found in Bolivia and Colombia, both of which addressed this problem by better controlling their inventory, and in subsequent years no expired medicines were reported in these countries. During 2009 and 2010 a dramatic decrease in poor-quality medicines was observed.

The authors also identified areas that need to be strengthened. This includes performing confirmatory testing, a critical component of the quality control framework proposed by PQM, which was not implemented thoroughly. These tests are performed at a qualified laboratory and utilize validated methodologies to assess compliance with quality specifications. Basic analytical tests should be used for screening purposes, and need to be followed by confirmatory testing on subsets of the sampled medicines. In addition, sampling should include the private and informal sectors when these are prevalent. By not performing confirmatory testing methodically and/or assessing only the public sector, some poor-quality medicines may still go undetected. Finally, the official medicine control laboratory and the medicines regulatory authority, both of which are crucial to ensuring proper execution of quality monitoring activities and prompt implementation of corrective actions, should always be included.

"This comprehensive study provides the first documented regional information on the quality of malaria medicines in the Americas. Of relevance is that all participating countries adopted the same methodology to assess the sampled medicines—something that has never been done before in this region," said Victor Pribluda, Ph.D., lead author of the study. "This is significant because use of consistent methodology promotes collaboration and exchange of information between countries, a hallmark of the holistic approach implemented by AMI to prevent and control malaria in the region."

More information: To read the full studies, visit: www.malariajournal.com/content/11/1/203/abstract and www.malariajournal.com/content/11/1/202/abstract

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