

Quality of Antimalarial Drugs in East Africa: A Systematic Review

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Background: The use of poor quality drugs will have multiple consequences with an extended hazard of growing drug-resistant strains.

Purpose: The review aimed to provide the quality status of antimalarial drugs in East Africa.

Data Source: PubMed, Scopus, Web of Science, and Google Scholar were searched from September 5 to September 12, 2021.

Study Selection: The review included articles available as original research targeted at evaluating the quality of antimalarial drugs. For inclusion, data on at least one of the following quality control parameters were required: packaging and labeling, hardness, friability, weight variation/uniformity of weight, disintegration, dissolution, and assay/percentage purity. Mendeley citation manager version 1.19.4 was used to avoid duplication and organize references, and titles and abstracts were primarily used for screening.

Data Extraction: The sample collection site, drug name, and the quality control parameters tested were retrieved from the selected studies.

Data synthesis: Totally, 300 antimalarial drug samples from Ethiopia, Kenya and Tanzania were included in this review. No antimalarial drug tested failed the identification and disintegration test. However, 15.93% (36/226), 5.00% (15/300), and 1.90% (3/158) of antimalarial samples failed the dissolution, assay and mass uniformity test, respectively. Moreover, amodiaquine and sulfadoxine/pyrimethamine samples failed dissolution and assay tests. In addition, amodiaquine samples failed the mass uniformity test. However, artemether/lumefantrine and quinine passed all quality control parameters tested. Overall, 19.67% (59/300) of antimalarial drug samples did not meet at least one quality control parameter. And the higher failure rate was reported for sulfadoxine/pyrimethamine accounting for 52.86% (37/70).

Conclusions: An unneglected amount of antimalarial drug failed to meet at least one quality control parameter. Strengthening pharmaceutical management systems, including post-marketing surveillance, and providing the resources required for medication quality assurance, are recommended.

Keywords: antimalarial drugs, quality control, coartem, artemether/lumefantrine, assay, dissolution, East Africa

Introduction

Malaria is a life-threatening mosquito-borne disease caused by *Plasmodium* species and spread by the bites of infected female Anopheles mosquitoes. Fever, headache, chills, and vomiting are symptoms of the disease, and if left untreated, can lead to morbidity and death.¹ According to the WHO 2020 report, there were approximately 229 million malaria cases worldwide. The majority of cases were from Africa and Asia.²

In the 1990s, malaria became more prevalent in Sub-Saharan Africa, owing to growing resistance to chloroquine and sulfadoxine-pyrimethamine.³ This tendency was likely worsened by the use of poor quality antimalarial medications.⁴

There are two management principles for malaria: prevention (vector control, drug prophylaxis, and potential use of a vaccine) and treatment in which drugs play a role.⁵ Currently, Artemisinin-based combination therapies (ACTs) are

becoming the center for managing malaria.⁶ Successful malaria management is achieved through early diagnosis and immediate treatment with quality ensured medicines.³

Medicines are crucial parts of healthcare systems and patient care. Patients, physicians, caregivers, and communities must have confidence in the pharmaceuticals they are using, and the pharmaceuticals needs to be genuine and satisfy the appropriate quality standards.⁷ Safety, quality, and efficacy of medicines are the criteria utilized to control pharmaceuticals.⁸ The quality of drugs is particularly vital,⁹ and almost 15% of drugs circulated on the market are counterfeit.¹⁰ The problem of counterfeiting is well recognized within the African region, and in other parts of the developing world.¹¹ Nowadays, among 12 antimalarial drugs utilized in the world, eight have been counterfeited.¹² The use of poor quality antimalarial will have multiple consequences with an extended hazard of growing drug-resistant strains of malaria.¹³

A study conducted in 2008 on six malarious countries reported that 35% of antimalarial samples were substandard and failed to comply quality control parameter of either assay or dissolution.¹⁴ A survey conducted by WHO in six African countries in 2011 showed that from 267 tested samples, 28.5% of them failed to meet specifications for different quality control parameters of identification test, assay, dissolution and mass uniformity test.¹⁵ Similarly, a study conducted in Kenya detailed antimalarial drugs had higher failure rate (26.8%) than antibiotics (5.3%).¹⁶ Another study conducted in Kenya in 2000 reported 3.9% and 69.7% of sulfadoxine/pyrimethamine products failed assay and dissolution tests, respectively.¹⁷ Although poor quality anti-malarial drugs have been reported so far in various parts of Africa, there is no comprehensive estimate of the quality status of anti-malarial drugs in the East African region. Therefore, the current review aimed to provide the quality status of antimalarial drugs in selected East African countries through a systematic review of existing evidence.

Methods

Search Method

The review followed the steps recommended in the Preferred Reporting Items for Systematic reviews and Meta-Analyses¹⁸ (Figure 1). The studies were identified from PubMed, Scopus, Web of Science, Google Scholar and other data bases. A manual search from Google was done for grey literature screening. The search was conducted from September 5 to September 12, 2021.

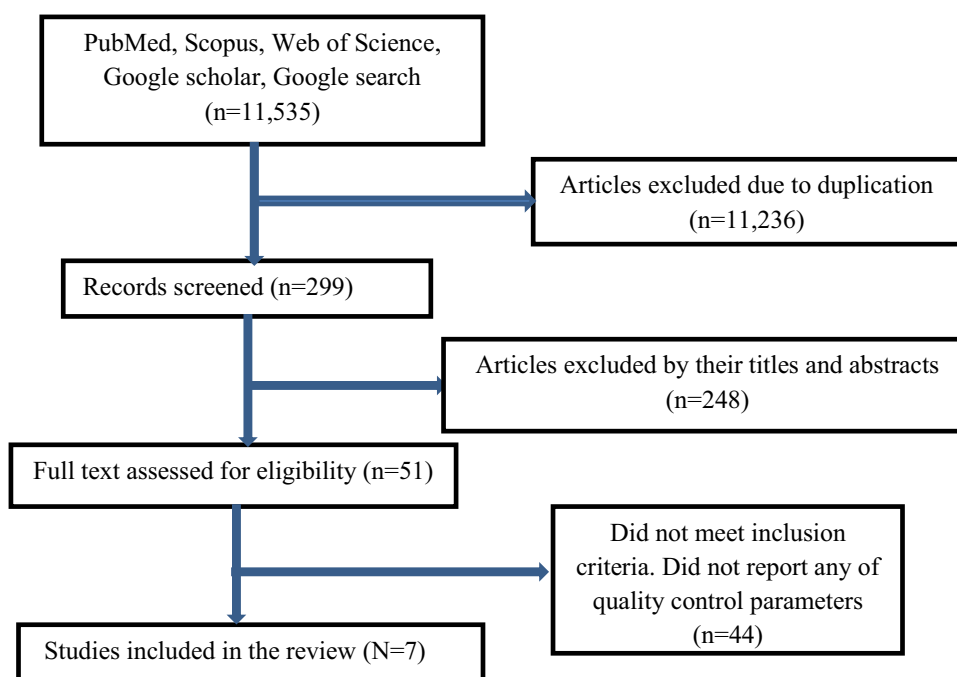


Figure 1 PRISMA of included studies.

The search terms used were quality evaluation, quality control, antimalarial drugs, chloroquine sulphate, coartem, artemether/lumefantrine, artemisinin combination therapy, sulfadoxine/pyrimethamine, fansidar, quinine, amodiaquine, artesunate and amodiaquine co-packed tablet, hardness, friability, weight variation, uniformity of weight, disintegration, dissolution, assay, purity, East Africa. The search terms were constructed in line with the Medical Subject Headings (MeSH) using important connector words. A detail of search strategy for some databases is available in [Supplementary File 1](#). The software Mendeley citation manager 1.19.4 version was used to avoid duplication and organize references.

Selection of Studies, Methodological Quality of Included Studies and Data Extraction

Primarily, titles and abstracts were used for screening, and the remaining articles were subjected to full review to extract essential components.

The data were extracted in Microsoft Excel. Data extraction was handled by MG and GH by using the data extraction form in excel. The data retrieved from the selected studies include the name of the primary author, year of publication, journal, volume, sample collection site, drug name, number of brands included in the study, laboratory test performed (packaging and labeling, identity test, assay, dissolution, uniformity of mass, friability, hardness, content uniformity and disintegration).

After removing irrelevant articles, MG, GH and BU independently reviewed for data quality and methodological validity using a standardized methodological quality evaluation instrument obtained from MEDQUARG guideline¹⁹ ([Supplementary File 2](#)). Any disagreement was handled by consulting SS.

Inclusion and Exclusion Criteria

Studies available as original research aimed to evaluate the quality of the antimalarial drug, whether it is published or unpublished, studies written in English, and studies conducted in East Africa were included in this review. Data on at least one of the following quality control parameters had to be available for inclusion: packaging and labeling of pharmaceuticals, hardness, friability weight variation/uniformity of weight, disintegration, dissolution and assay/ percentage purity. Editorial and case reports were excluded.

Quality Assessment Parameters for Antimalarial Drugs

The parameters used for quality assessment were packaging and labeling of antimalarial drugs, hardness, friability, weight variation/uniformity of weight, disintegration time, dissolution and assay or percentage purity.

Data Synthesis and Analysis

The data extracted from included articles were imported into a Microsoft Excel spreadsheet and presented in the form of tables and figures. Summary results were presented by frequency and percentage using tables and figures.

Results

Search Result

Initially, 11,534 articles were accessed from electronic databases of PubMed, Scopus, Web of Science, Google Scholar, Google search and other data bases. The titles and abstracts of 299 records were screened for eligibility after duplicates were removed. Of 299 studies, 248 were excluded after the title and abstract were reviewed. The remaining articles were assessed for full-text review. And 44 articles were excluded because of not related to quality evaluation of anti-malarial drugs and assess safety and efficacy of antimalarial drugs. Finally, 7 studies were included in the review.^{20–26}

Characteristics of Studies

The articles included in this review were conducted in three countries. Ethiopia,^{20,21,26} Tanzania,^{22,24} and Kenya^{23,25}). Around 50% (n=159) of the samples included in this review were collected from Ethiopia and 48 (16.00%) included samples were collected from Kenya ([Table 1](#)).

Table 1 Distribution of Samples by Country

Country	Quantity of Sample Obtained
Ethiopia	159 (53%)
Tanzania	48 (16%)
Kenya	93 (31%)
Total	300

Quality Control Parameters Tested

All studies included in the review were conducted on the quality control parameters of packaging and labeling. Except for one study,²⁶ all conducted the identification test. All of the included studies were done an assay test. Except for one study,²³ of the studies evaluated the dissolution test. In this review, 300 samples of different antimalarial drugs were included (Table 1).

Drugs Included in the Review

In this review, different brands of antimalarial drugs were included. Artemether/lumefantrine (artefan, artemine, IPCA, coartem), sulfadoxine/pyrimethamine (sulphadar, tansidar, tansin, malostat, neopyrin, laridox, tansimax, orodar, medo-doxin, malareich, fansidar), artesunate +amodiaquine co-packed product, chloroquine (APF, cadila, Epharm), quinine (QSM300, quini, quinine remedica) and amodiaquine tablets were included (Table 2).

Sample Collection Site and Types of Pharmacopeias Used to Test Drug Quality

The samples were collected from hospital pharmacies, health center pharmacies, drug stores, wholesales pharmacies, and retail outlet pharmacies (Table 3).

Different Pharmacopeias were utilized to evaluate the quality of antimalarial drugs. The commonly used pharmacopeias were USP, Combination of USP and BP, International Pharmacopeia (Table 3).

Types of Analytical Techniques Used and Quality Control Parameters

Four different analytical techniques were utilized to evaluate the quality of antimalarial drugs. High-Performance Liquid Chromatography (HPLC) was used for assay and identification tests. UV-spectroscopy was also used to perform quality control test for assay (Table 4).

Quality Control Tests of Anti-Malarial Dugs Included in the Review

All the seven studies included in this review evaluated the packaging and labeling of antimalarial drugs. Of the 300-samples of antimalarial drugs tested for packaging and labeling, 3 (1.00%) failed to comply with packaging and labeling of pharmaceuticals. Chloroquine phosphate (3-sample) was the one that failed to comply (Table 2).

All of the antimalarial drugs included in the review had active pharmaceutical ingredients (Table 2).

Of the 300-samples, 15-samples failed to comply with the assay test. And amodiaquine tablets (10-samples) and Sulfadoxine/pyrimethamine (5-samples) were the antimalarial drugs that failed to comply (Table 2).

Three samples, 1.90% (3/158), failed to comply with the mass uniformity test. Amodiaquine tablets (3-samples) were the tablets that failed to comply with the mass uniformity test. Only one sample of Sulfadoxine/pyrimethamine failed to comply with the friability and hardness test (Table 2).

Of 300 samples of antimalarial drugs included in this review, 15.9% (36/226) of the samples failed to comply with the dissolution test. Sulfadoxine/pyrimethamine (30-samples) and amodiaquine tablet (6-samples) was the samples failing to comply with the test (Table 2).

Table 2 Quality Control Parameters Evaluation of Antimalarial Drugs Included in the Review

No.	Drugs Name	Quality Control Parameters Tested and Number of Tablets Failed to Comply with the Test										% of Faller
		Total Sample	Packaging Labeling	Identity	Assay	Dissolution	Mass Uniformity	Friability	Hardness	Content Uniformity	Disintegration	
1	Artemether/ lumefantrine	117	0	0	0	0	0	0	0	NA	0	0%
2	Sulfadoxine/ pyrimethamine	70	0	0	5 (7.14%)	30 (42.86%)	0	1 (1.43%)	1 (1.43%)	NA	0	52.86% (37/70)
3	Amodiaquine tablet	44	0	0	10 (22.73%)	6 (13.64%)	3 (6.82%)	0	0	NA	0	43.18% (19/44)
4	Chloroquine phosphate	44	3 (6.82%)	NA	0	0	0	0	0	NA	NA	6.82% (3/ 44)
5	Quinine	16	0	NA	0	0	NA	0	0	0	NA	0%
6	ACTs	9	0	0	0	0	NA	NA	NA	NA	NA	0%
	Overall % faller	300	1.00%(3/300)	0%	5.00%(15/ 300)	15.93%(36/ 226)	1.90%(3/158)	1.00%(1/ 100)	1.00%(1/ 100)	0%	0%	19.67%(59/ 300)

Table 3 Sample Collection Site for Tested Drugs and Utilized Pharmacopeia Method for Quality Control Test

Primary Author	Sample Collection Site	Utilized Pharmacopeia
Belew et al ²¹	Hospital, health center, whole sales and drug store	International Pharmacopoeia
Amin et al ²³	Wholesalers pharmacies	USP
Hebron et al ²²	Commercial drug distributors and medical departments	USP and BP
S Abuye et al ²⁰	Retail outlet pharmacies	USP
Minizi et al ²⁴	Wholesalers pharmacies	USP
Hussien B. ²⁶	Hospital, HC and private pharmacy.	USP and BP
Ndwigah, S et al ²⁵	Public and private facility	USP

Abbreviations: HC, health center; USP, United State pharmacopeia; BP, British pharmacopeia; EP, European pharmacopeia; JP, Japanese pharmacopeia.

Table 4 Analytical Techniques Used for Quality Control of Antimalarial Drugs

Analytical Technique	Quality Control Parameters
HPLC (High Performance Liquid Chromatography)	Assay and identification tests
UV-spectrophotometer	Assay
GPHF (Global Pharma Health Fund)Minilab	Assay and disintegration
TLC (Thin Layer Chromatography)	Identification test

Specific Antimalarial Drug Quality and Quality Control Tests

Seventy samples of sulfadoxine/ pyrimethamine were tested for different quality control parameters, and 52.86% (37/70) samples failed to comply with at least one quality control parameter tested. 42.86% (30/70) of them failed the dissolution test, and 7.14% (5/70) of them failed the assay test (Table 2). Of 44 tablets of amodiaquine tested for quality, 43.18% (19/44) of them failed to comply with at least one quality control parameter. From these parameters, 22.73% (10/44) of them failed the assay test, and 13.64% (6/44) of them failed the dissolution test.

Forty-four samples of chloroquine were included in this review, and 6.82% (3/44) of them failed to comply with at least one parameter of the quality control test. Three of the tablets failed the packaging and labeling inspection (Table 2).

From different quality control parameters tested for the antimalarial drugs included in this review, the highest faller rate was reported for the dissolution test (15.93%), followed by the assay test accounting for 5.00% (Table 2).

As per this review, 19.67% (59/300) of antimalarial drugs failed to comply with at least one quality control parameter. Of the different quality control parameters tested, the dissolution test encountered the higher faller rate (15.93%), followed by the assay test accounting for 5.00% (Table 2).

Discussion

When determining whether medicine is substandard, damaged, or counterfeit, visual inspection of packaging and labeling is essential. Some products contain genuine active pharmaceutical ingredients, but packaged in fake packaging.²⁷ The WHO checklist for physical characteristics, packaging and labeling information, or the USP tool for visual inspection of medicine were used in all studies included in the review to inspect packaging and labeling.^{28,29} All tablets passed the packaging and labeling of pharmaceuticals, except three samples of chloroquine phosphate tablets. The study conducted on the malarious world reported that out of 9348 anti-malarial samples, 30.1% (2813) failed chemical/packaging quality tests.³² To identify the products, HPLC was utilized to compare the retention times of the analyzed drug peak to those of

a reference standard (RS). Product peak retention time and RS chromatogram peak retention times were compared and determined to be similar.²⁰ All drugs under investigation passed the identification tests.

The assay test is used to determine how much active pharmaceutical ingredients are present in a dosage form and its critical quality control parameter. Of the 300-antimalarial drug samples tested for percentage purity, 15-samples failed the test. The tablets that failed the assay test were amodiaquine 22.73% (10/44) and sulfadoxine/pyrimethamine 7.14% (5/70). A study conducted in South-East Nigeria on the quality of anti-malarial reported that 60 (37%) of the anti-malarial drugs tested did not meet the USP specifications for the amount of active ingredients.³¹ The ability of a drug to dissolve is a crucial part of its evaluation, and it is one of the quality control tests for ensuring product uniformity and batch-to-batch equivalence.³⁰ According to the current review, 226-samples of antimalarial drugs were examined for dissolution. In contrast, 36 (15.93%) antimalarial drugs failed the dissolution test. The samples that failed the dissolution test were sulfadoxine/pyrimethamine (30/70) and amodiaquine (6/44). The finding is comparable with the study conducted in six malarious countries in 2008 reported that, in total, 35% (73/210) of the samples were substandard and failed either the TLC or the dissolving tests. Failure by TLC, dissolution, or both of the individual pharmaceutical kinds, happened in 38% of SP and 48% of amodiaquine.¹⁴ Uniformity of weight or content uniformity is used to ensure the consistency of dosage units. And each unit in a batch should have a drug substance within a range around the label claim.³⁰ Of 158 samples tested for mass uniformity, 1.93% (4/158) of them failed to comply with the test.

Disintegration, friability and hardness tests are the quality control parameter for tablets. Tablets must maintain their integrity from the time they are manufactured till they reach the patients, and they must not break apart during long shipments on boats and in trucks.⁹ The disintegration, friability, and hardness tests were performed in three studies. And the majority of the samples met the requirements. The friability and hardness tests for the sulfadoxine/pyrimethamine tablet were failed to comply. Overall, 19.67% of samples (59/300) failed at least one quality control parameter. The faller is higher for sulfadoxine/ pyrimethamine and amodiaquine. However, the quality control tests for artemether/lumefantrine and quinine were in line with the specification. The majority of antimalarial drugs failed the dissolution and assay tests, which is a critical quality control parameter.

Strength and Limitations

The review tried to assess the quality of antimalarial drugs circulating in East Africa from existing evidence. However, the availability of limited data results in difficulty in including more articles. In addition, quantitative analysis and heterogeneity of the articles were not performed.

Conclusions

Overall, 19.67% of the sample failed to meet at least one of the quality control parameters. Amodiaquine and sulfadoxine/pyrimethamine samples had a higher faller rate than others. However, artemether/lumefantrine and quinine samples passed all quality control tests. The dissolution test had the highest faller rate among the quality control parameters, followed by the assay.

Data Sharing Statement

The data set used for analysis is available from the corresponding author upon request.

Disclosure

The authors disclose no conflicts of interest in this work.

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