

BMJ Open Quality of antibiotics purchased on Bioko Island and four mainland districts of Equatorial Guinea: a cross-sectional medicine-quality survey

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ABSTRACT

Objectives Antibiotics are essential chemotherapeutic agents for treating bacterial infections and vital for curbing mortality and morbidity. However, their misuse, overuse and sub-therapeutic dosing resulting from poor-quality medicines contribute to antimicrobial resistance (AMR), which is recognised as one of the leading global public health threats.

Design Cross-sectional medicine-quality survey using mystery-client sampling.

Setting Public and private medicine outlets on Bioko Island and four mainland districts of Equatorial Guinea, surveyed in 2018.

Participants 424 medicine outlets that were open during the survey window, from which 901 antibiotic samples were purchased.

Primary outcome measures The proportion of antibiotic samples (amoxicillin, ampicillin, ciprofloxacin, gentamicin and tetracycline formulations) classified as acceptable, substandard or falsified by active pharmaceutical ingredient content, measured by high-performance liquid chromatography with diode-array detection against US pharmacopoeia tolerance limits; bioavailability was assessed by dissolution testing for a subset of samples.

Results The results indicate substantial concern regarding antibiotic quality. Only 33.2% (n=299) of samples were of acceptable quality, while 61.2% (n=551) were substandard and 5.7% (n=51) were falsified. Quality patterns were comparable between Bioko Island and the mainland, with no statistically significant regional differences (overall χ^2 p=0.43). The substandard proportion was 62.1% (95% CI 58.2% to 65.9%) on Bioko Island and 59.0% (95% CI 53.2% to 64.6%) on the mainland; the falsified proportion was 6.0% (95% CI 4.4% to 8.1%) and 4.9% (95% CI 3.0% to 8.1%), respectively.

Conclusions The findings of this study identify quality concerns affecting the essential antibiotics available in Equatorial Guinea, with comparable patterns observed across both Bioko Island and the mainland. The results support a review of national policies governing the importation and distribution of essential medicines and argue for establishing routine post-market surveillance through the Baney Reference Laboratory, which is well-positioned to serve as the national hub for medicine quality assurance. Strengthening this regulatory capacity will

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study used nationwide mystery-client sampling of all outlets open at the time of the survey, across Bioko Island and four mainland districts.
- ⇒ Active pharmaceutical ingredient content was quantified by validated high-performance liquid chromatography with diode array detection against US pharmacopoeia tolerance limits.
- ⇒ A subset of samples underwent dissolution testing, assessing bioavailability and not content alone.
- ⇒ Fieldwork was conducted in 2018, so the findings represent a baseline rather than the current market.
- ⇒ Outlet-level information was incomplete for some samples, which limited outlet-based comparisons.

safeguard public health and contribute to global efforts to address AMR.

INTRODUCTION

Antibiotics are essential chemotherapeutic agents for the treatment of bacterial and some parasitic infections. They have substantially reduced global morbidity and mortality from diseases such as pneumonia, tuberculosis, malaria and diarrhoeal illness.^{1–3} The global antibiotics market is projected to grow steadily, reaching an estimated value of US\$74 billion by 2033, driven primarily by the rising burden of bacterial infections.⁴ However, their effectiveness is increasingly compromised by antimicrobial resistance (AMR), now recognised as a major global health threat, particularly in Africa.⁵ AMR is estimated to cause approximately 1.2 million deaths annually worldwide, and substantial associated economic consequences. Up to 10 million annual deaths are predicted by 2050, if current trends continue.⁶

Resistance is driven by inappropriate treatment practices, suboptimal dosing,

incomplete treatment courses and poor adherence, as well as exposure to poor-quality medicines.⁷ These factors result in sub-therapeutic drug concentrations that favour the survival and propagation of resistant strains.⁸ Although inappropriate antimicrobial use is widely acknowledged as a primary driver of AMR, the contribution of poor-quality medicines remains poorly characterised mainly due to lack of data.⁹ Recent surveys from neighbouring Central African countries have documented poor-quality antibiotics using comparable field methods. A mystery-client survey in three Cameroonian cities found an overall substandard-or-falsified prevalence of 7.9%, concentrated in the informal sector.¹⁰ An analysis of antibiotics in the Democratic Republic of the Congo classified 25% as substandard, again with markedly higher failure in informal than formal outlets.¹¹ A 2024 systematic review estimated the pooled prevalence of substandard and falsified (SF) medicines in Africa at 22.6%, with antibiotics among the most affected classes.¹² No antibiotic-quality survey has been published for Equatorial Guinea, which this study addresses.

The WHO estimates that around 10% of medicines in low- and middle-income countries (LMICs) are substandard or falsified, representing an annual economic loss of approximately US\$30.5 billion.¹³ Substandard medicines are authorised products that fail to meet quality specifications, often containing incorrect amounts of the stated active pharmaceutical ingredient (API).^{9 14} Falsified products may contain no active ingredient, the wrong ingredient or incorrect quantities. Both can lead to treatment failure, toxicity and increased mortality, and may directly contribute to AMR through sub-therapeutic exposure.^{13 15 16}

Antibiotics and antimalarials are among the most commonly reported poor-quality medicines.¹³ A meta-analysis of 96 studies estimated the overall prevalence of SF medicines of 13.6% in LMICs, with antibiotics accounting for 12.4%.¹⁶ A recent systematic review reported that the prevalence of SF antibiotics in Africa was as high as 44.6%.¹² In many settings where infectious diseases are endemic, antibiotics are widely available without prescription and are frequently produced at low cost, increasing vulnerability to poor manufacturing practices and falsification. Despite this, data on antibiotic quality remain limited. In one study of 35 samples purchased from Ghana, Nigeria and the UK, all amoxicillin products met quality standards, whereas 60% of co-trimoxazole samples failed.¹⁷ In this study, all samples were purchased without a prescription, consistent with the widespread over-the-counter availability of antibiotics in this setting, itself a recognised driver of misuse and of selective pressure toward resistance.¹⁸

Weak regulatory systems, limited enforcement capacity and inadequate quality surveillance sustain the circulation of poor-quality medicines, particularly in resource-constrained settings. This underscores the urgent need to assure medicine quality across both high- and low-income settings, while new and effective therapeutics are being

developed. To help address this evidence gap, this study evaluated Equatorial Guinea (EG).

METHODS

Patient and public involvement

This study did not involve any patients as it set out to assess the quality of antibiotics available for purchase at various outlets on Bioko Island and four districts of Río Muni, EG.

Identification of medicine outlets

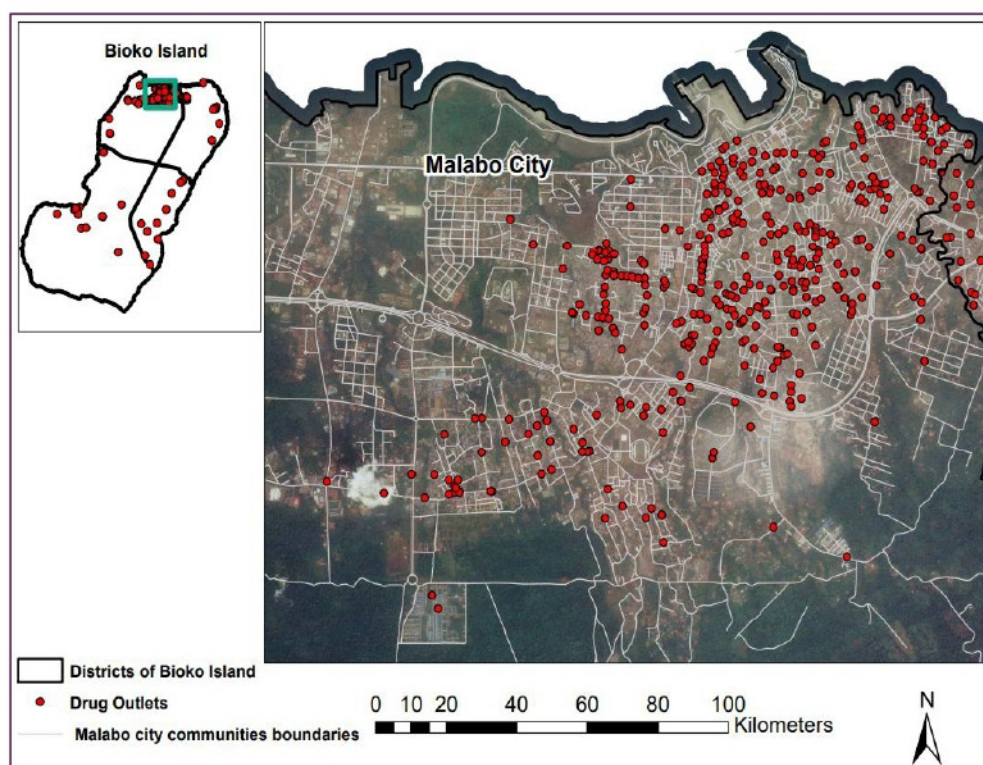
A census of medicine outlets was first conducted in June 2013 as part of the antimalarial quality assessment.¹⁹ This was supplemented in 2018 with updated outlet information obtained through routine programmatic operations. In total, 714 outlets were identified, including brick-and-mortar pharmacies, health centres, consulting rooms, hospitals, markets, mobile vendors and medicine kiosks across Bioko Island and four mainland locations. All outlets that were open for business at the time of the survey were visited (n=424; 59%), and medicine samples were purchased using a mystery-shopping approach (figure 1A,B; online supplemental table 1).¹⁹ Outlet categories were recorded, but the formal registration status of individual outlets was not systematically captured and could not be verified. Outlets were not randomly sampled; the survey sought to visit every outlet open during the survey window, a census of open outlets rather than a probability-based sample.

Acquisition of antibiotic samples

The study design and analysis methods reported in this manuscript were informed by guidelines, including the conduct of surveys of the quality of medicines published by WHO and the checklists of criteria for designing and reporting of medicine quality studies.^{19–21} Samples of antibiotics were purchased from the 424 outlets using a ‘mystery client’ approach over 25 days between 25 September and 14 November 2018.

Four pairs of surveyors, overseen by two supervisors, were trained to visit the medicine outlets and purchase a sample of each brand of antibiotic available. Sampling was weighted approximately five private outlets to one public facility, reflecting the higher number of private outlets in the country. Surveyors approached the provider, feigning that they or a family member were sick with fever symptoms and needed medications. They requested to see all medicines that the provider recommended before purchasing a course of treatment. A total of 901 antibiotic formulations consisting of amoxicillin (capsules, suspensions and co-formulations with clavulanic acid), ampicillin capsules, ciprofloxacin (tablets and infusions), injections of gentamicin and tetracycline tablets were purchased across the surveyed outlets, with the brand, formulation and dosage of each sample recorded (online supplemental table 2). The overall sample selection flow is summarised in online supplemental figure 1.

A



B

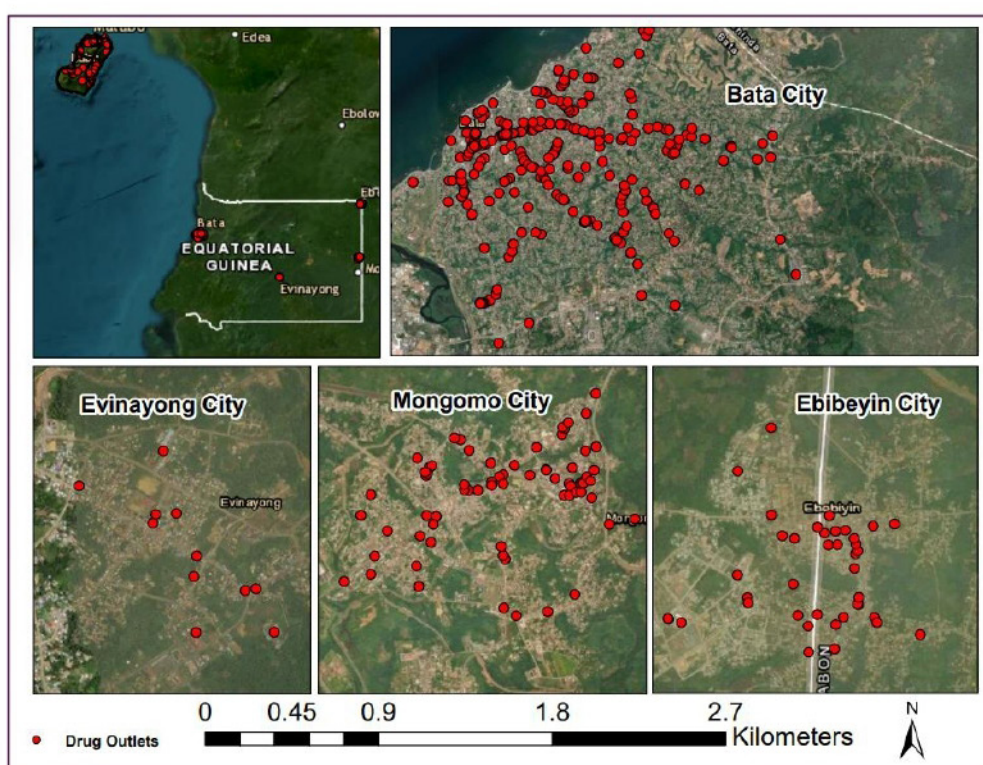


Figure 1 Distribution of outlets on (A) Bioko Island and (B) Río Muni Mainland visited to purchase samples of antibiotic medicines.

Data entry

Information about the individual samples was recorded using mobile tablets programmed to note brand name, selected active pharmaceutical ingredients (SAPIs), dose form, outlet, district, date of purchase, name of stated manufacturer, country of manufacture, batch number, date of manufacture, expiry date, number of tablets per packet and price paid.

Sample processing, laboratory analyses and classification of quality

The antibiotic samples were placed in individual zip-lock bags and labelled with the unique outlet and product codes before being stored safely at room temperature (air-conditioned) in a locked room. Subsequently, all samples were despatched to the LSHTM bioanalytical facility for further processing and chromatographic analyses. Visual inspection of purchased samples consisted of taking digital photographs of packaging and contents, followed by checking the sample information with data collected in the field. Visual inspection was used to document packaging and product characteristics and was not applied as an independent criterion for classification; quality was determined solely by high-performance liquid chromatography (HPLC)-measured active-ingredient content against USP tolerance limits.²² Capsules and tablets were weighed, and their dimensions recorded, followed by confirmatory laboratory analyses for content and dissolution testing for bioavailability.

Chemicals, materials and instruments

Reference standards of the SAPIs—amoxicillin, potassium clavulanate and ampicillin were purchased from Sigma-Aldrich, UK. Ciprofloxacin, gentamicin and oxytetracycline hydrochloride reference standards were acquired from the European Directorate for the Quality of Medicines & HealthCare. Laboratory consumables, including solvents, columns and vials, were purchased from Thermo Fisher Scientific, UK. The HPLC with diode array detection (HPLC-DAD) system (Thermo Scientific Dionex Ultimate 3000) was also supplied by Thermo Fisher Scientific, Hemel Hempstead, UK. A Pharma Test PT 017 dissolution apparatus was from the Pharma Test Group, Hamburg, Germany.

Laboratory analyses

High-performance liquid chromatography-diode array detector conditions

Quantitative analyses were carried out using the HPLC-DAD system and separation of each SAPI was achieved using an Acclaim 120 C₁₈, 5 µm, 120 Å 150X4.6 mm column (Fisher Scientific UK, Leicestershire, UK), using eluent composition, flow rate and detection wavelength as outlined in publications.^{12 22–25} The authenticity of the detected peaks was determined by comparison of retention time, spectral extraction and spiking the sample with commercially available pure reference standards of each API in the formulation.¹⁷ A calibration curve of each

SAPI was generated by Chromeleon (Thermo Scientific Dionex Chromeleon 6.8 Chromatography Data System) using known amount of the reference standard. For each sample, a duplicate set of constituent tablets or capsules was analysed twice (total number of measurements=4) and a mean of the values was recorded. To validate the HPLC method for amoxicillin, ampicillin, tetracycline, gentamicin and ciprofloxacin, procedures and parameters were ensured to follow the International Council for Harmonisation guidelines for bioanalytical assay methods. Linearity (r^2) of 0.05–50 µg/mL ≥ 0.998; the limits of detection and quantification were determined using signal-to-noise ratios of 3:1 and 10:1, respectively; intra-day precision (RSD) 2.0%–10.0%; inter-day precision (RSD) 3.0%.

Laboratory API content

The substance of each formulation was determined by dissolving an appropriate quantity of the sample in a suitable solvent to obtain a nominal concentration of 1 mg/mL. The resulting solution was centrifuged and the supernatant further diluted prior to injection onto the HPLC column. The content of each sample (capsules, tablets, injectables or suspensions) was quantified based on the concentration of the stated API, expressed as a percentage. This was calculated by comparing the measured concentration in each sample with the labelled dose and multiplying by 100. The percentage of each stated API was used to classify sample quality according to the tolerance limits defined in the USP-24²⁶ (online supplemental table 3). Samples were classified as acceptable if the measured API content fell within the specified limits and as substandard if values were either above or below these limits. Samples in which the stated API was not detected, but where other unspecified compounds were potentially present, were classified as falsified.

Dissolution analyses of formulations and compliance with tolerance limits

Dissolution testing was performed in accordance with the in vitro dissolution protocols specified in the relevant USP monographs for each tablet and capsule formulation.²⁶ No corresponding monographs are available for infusion or injectable preparations. Amoxicillin and ampicillin capsules, as well as ciprofloxacin and tetracycline tablets, were analysed using a Pharma Test PT 017 dissolution apparatus. The release of the API into the dissolution medium over time was quantified by HPLC-DAD using the analytical method described above.

Statistical analysis

Proportions of samples classified as acceptable, substandard and falsified are reported with 95% CIs. The multi-variable Poisson model was fitted on complete cases with non-missing covariate data, so the model sample (n=899) is marginally smaller than the full descriptive sample (n=901). Differences in the distribution of sample quality between Bioko Island and the mainland were assessed

using Pearson χ^2 tests across the full two-by-three contingency table of region and quality classification, and separately for the binary contrast of poor-quality (substandard or falsified combined) against acceptable samples. A p value below 0.05 was considered statistically significant. Analyses were performed in Stata 18 SE (StataCorp, College Station, TX, USA). In addition to these descriptive comparisons, poor quality (substandard or falsified vs acceptable) was modelled as a function of region (Bioko vs mainland), antibiotic class, dosage form and manufacturer-country group. Because poor quality was a common outcome, adjusted prevalence ratios were estimated using Poisson regression with cluster-robust SEs to account for the sampling of multiple products per outlet. ORs are not reported as the primary measure because, for a common outcome, they would exaggerate the association relative to the prevalence ratio. 95% CIs are presented throughout.

RESULTS

Chemical quality of antibiotic formulations

Content analyses determined using HPLC-DAD

The majority of samples were purchased from outlets in the main districts of EG, including Malabo (the capital city) on Bioko Island and Bata on the Río Muni mainland. Table 1 reports classification by API content measured by HPLC-DAD; dissolution testing results are presented separately in online supplemental table 6.

The overall quality of samples of antibiotics (n=901) purchased on Bioko Island (n=618) and Río Muni mainland (n=283) were analysed for content in the laboratory using HPLC-DAD. Classification of results adhering to the pharmacopoeia tolerance limits revealed that a higher percentage of samples purchased on Bioko Island were substandard (n=384, 62.1%) compared with the mainland (n=167, 59.0%) online supplemental table 4. Greater numbers of falsified antibiotics were found on Bioko Island (n=37/618, 6.0%) than on the mainland (n=14, 4.9%). These differences between regions were not statistically significant (overall region by quality χ^2 p=0.43; poor-quality vs acceptable p=0.25; falsified samples p=0.64), indicating comparable distributions of sample quality across Bioko Island and the mainland. The 95% CIs for the overall proportions were 30.2% to 36.3% (acceptable), 57.9% to 64.3% (substandard) and 4.3% to 7.4% (falsified).

Quality of individual antibiotic formulations purchased in EG are charted in figure 2. Less than 10.0% of amoxicillin capsules were of acceptable quality (7.1%; n=14/197), most were substandard (88.3%; n=174/197) and less than 10 were falsified (4.6%; n=9/197). Greater number of amoxicillin suspensions were of acceptable quality (66.7%; n=14/21) and the rest were substandard (33.3%; n=7/21).

Quality of individual antibiotic formulations was further categorised according to the region of purchase, Bioko Island or Río Muni Mainland, as shown in figure 3.

In the multivariable model, the quality of antibiotics did not differ between Bioko and the mainland (adjusted prevalence ratio 1.02, 95% CI 0.96 to 1.09). Antibiotic class was the dominant determinant of quality: relative to ciprofloxacin, the adjusted prevalence ratio of poor quality was 8.93 (95% CI 6.05 to 13.16) for ampicillin, 8.46 (95% CI 5.74 to 12.46) for amoxicillin-clavulanic acid, 8.36 (95% CI 5.70 to 12.26) for amoxicillin, 7.86 (95% CI 5.33 to 11.58) for tetracycline and 4.61 (95% CI 3.01 to 7.07) for gentamicin (figure 4). Manufacturer-country group carried only a small independent association after adjustment for class (India 1.18, 95% CI 1.03 to 1.36; Nigeria 1.19, 95% CI 1.05 to 1.36, vs Spain); because manufacturer country is taken from the packaging label, which is unreliable for falsified products and unstated for many samples, these associations are presented descriptively rather than as evidence of manufacturing origin. Poor-quality prevalence by district, grouped by region with 95% CIs, is shown in figure 5. Findings were unchanged in sensitivity analyses using the full recoverable sample and the recorded-outlet subset.

Amoxicillin formulations

Penicillin in the form of amoxicillin is the most prescribed antibiotic and a greater number of capsules were purchased on the island (n=142) than on the mainland (n=55) and their quality was found to be comparable; acceptable was 7.0% (10/142) versus 7.3% (4/55); substandard was 88.0% (125/142) versus 89.1% (49/55) and falsified was 4.9% (7/142) versus 3.6% (2/55). Most number of suspensions of amoxicillin were purchased on Bioko Island (n=18) and 61.1% (11/18) were of acceptable quality 38.9% (7/18) were substandard. All of the ones purchased on the mainland (n=3) were of acceptable quality 100.0% (3/3). The third formulation purchased was amoxicillin and clavulanic acid, of which 43 tablets were purchased on the island and 8 on the mainland. None of them were of acceptable quality; 74.4% (32/43) from the island and 62.5% (5/8) were substandard; 25.6% (11/43) from the island and 37.5% (3/8) from the mainland were found to be falsified.

Ampicillin

Capsules of ampicillin were also not found to be of acceptable quality; they were either substandard, 92.4% (110/119) from the island and 95.1% (77/81) from the mainland; or falsified, 7.6% (9/119) from the island and 4.9% (4/81) on the mainland.

Ciprofloxacin

Tablets (n=216) and infusions (n=8) of ciprofloxacin purchased on the island or mainland did not reveal any to be falsified. The tablets 89.1% (114/128) from the island and 90.9% (80/88) from the mainland were of acceptable quality; 10.9% (14/128) from the island and 9.1% (8/88) were substandard. Of the ciprofloxacin infusions, 6 of 7 (85.7%) from the island and 1 of 1 (100.0%) from the mainland were of acceptable quality; 1 of 7 (14.3%) from

Table 1 Overall quality of antibiotic formulations purchased in Equatorial Guinea (EG) and at outlets in districts of Bioko Island and Río Muni Mainland of EG

Formulation	Classification	Overall in EG	Quality of samples from Bioko Island % (number/district total)				Quality of samples from Río Muni Mainland % (number/district total)			
			Malabo	Baney	Luba	Bata	Ebibeyín	Evinayong	Mongomo	
Amoxicillin capsules (n=197)	Acceptable	7.1% (n=14)	7.9% (10/126)	0	0	10.0% (4/40)	0	0	0	
	Substandard	88.3% (n=174)	86.5% (109/126)	100.0% (10/10)	100.0% (6/6)	90.0% (36/40)	100.0% (7/7)	100.0% (1/1)	71.4% (5/7)	
	Falsified	4.6% (n=9)	5.6% (7/126)	0	0	0	0	0	28.6% (2/7)	
Amoxicillin suspensions (n=21)	Acceptable	66.7% (n=14)	58.8% (10/17)	100.0% (1/1)	0	100.0% (2/2)	0	0	100.0% (1/1)	
	Substandard	33.3% (n=7)	41.2% (7/17)	0	0	0	0	0	0	
	Falsified	0	0	0	0	0	0	0	0	
Amoxicillin/clavulanic acid tablets (n=51)	Acceptable	0	0	0	0	0	0	0	0	
	Substandard	72.5% (n=37)	76.3% (29/38)	60.0% (3/5)	0	66.7% (4/6)	0	0	50.0% (1/2)	
	Falsified	27.5% (n=14)	23.7% (9/38)	40.0% (2/5)	0	33.3% (2/6)	0	0	50.0% (1/2)	
Ampicillin capsules (n=200)	Acceptable	0	0	0	0	0	0	0	0	
	Substandard	93.5% (n=187)	91.3% (94/103)	100.0% (11/11)	100.0% (5/5)	94.1% (64/68)	100.0% (6/6)	100.0% (1/1)	100.0% (6/6)	
	Falsified	6.5% (n=13)	8.7% (9/103)	0	0	5.9% (4/68)	0	0	0	
Ciprofloxacin tablets (n=216)	Acceptable	89.8% (n=194)	90.2% (92/102)	90.9% (20/22)	50.0% (2/4)	90.8% (59/65)	90.0% (9/10)	100.0% (2/2)	90.9% (10/11)	
	Substandard	10.2% (n=22)	9.8% (10/102)	9.1% (2/22)	50.0% (2/4)	9.2% (6/65)	10.0% (1/10)	0	9.1% (1/11)	
	Falsified	0	0	0	0	0	0	0	0	
Ciprofloxacin suspensions (n=8)	Acceptable	85.7% (n=7)	83.3% (5/6)	100.0% (1/1)	0	0	100.0% (1/1)	0	0	
	Substandard	14.3% (n=1)	14.3% (1/7)	0	0	0	0	0	0	
	Falsified	0	0	0	0	0	0	0	0	
Gentamicin injections (n=111)	Acceptable	50.5% (n=56)	46.7% (36/77)	57.1% (4/7)	100.0% (2/2)	63.2% (12/19)	100.0% (2/2)	0	0	
	Substandard	43.2% (n=48)	45.5% (35/77)	42.9% (3/7)	0	31.6% (6/19)	0	100.0% (1/1)	100.0% (3/3)	
	Falsified	6.3% (n=7)	7.8% (6/77)	0	0	5.3% (1/19)	0	0	0	
Tetracycline tablets (n=97)	Acceptable	14.4% (n=14)	19.1% (13/68)	14.3% (1/7)	0	0	0	0	0	
	Substandard	77.3% (n=75)	76.5% (52/68)	71.4% (5/7)	0	82.4% (14/17)	66.7% (2/3)	0	100.0% (2/2)	
	Falsified	8.3% (n=8)	4.4% (3/68)	14.3% (1/7)	0	17.6% (3/17)	33.3% (1/3)	0	0	
Not necessary. *Not needed										

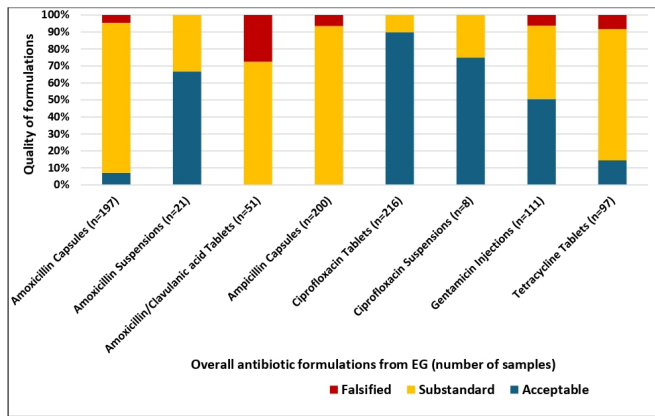


Figure 2 Overall quality of the antibiotics purchased in Equatorial Guinea (EG).

the island was substandard and none were purchased on the mainland.

Gentamicin

Gentamicin injections, used to treat serious bacterial infections, were purchased from both island and mainland locations. Of the samples collected on the island, 48.8% (42/86) were of acceptable quality, 44.2% (38/86) were substandard and 7.0% (6/86) were falsified. Among mainland samples, 56.0% (14/25) were of acceptable quality, 40.0% (10/25) were substandard and 4.0% (1/25) were falsified.

Tetracycline

Tetracycline tablets were available at both locations on EG and only the ones purchased on the island 18.7% (14/75) were of acceptable quality; 76.0% (57/75) from the island and 81.8% (18/22) from the mainland were substandard; 5.3% (4/75) from the island and 18.2% (4/22) from the mainland were falsified.

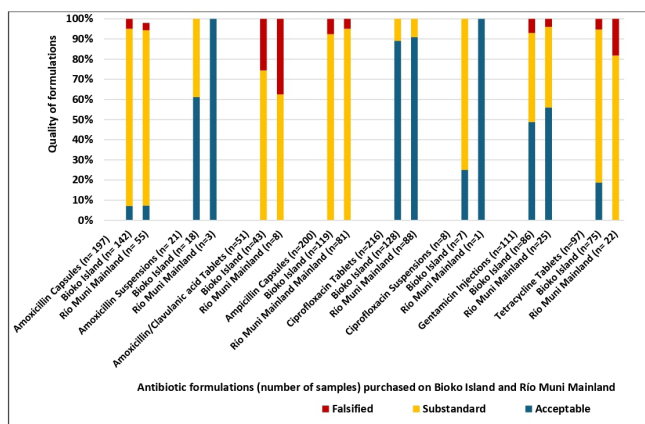


Figure 3 Quality of various antibiotics purchased on Bioko Island and Río Muni Mainland, Equatorial Guinea.

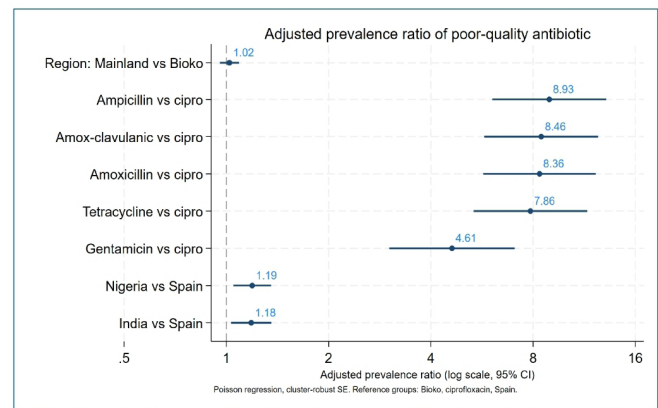


Figure 4 Adjusted prevalence ratios of poor-quality antibiotics from the multivariable Poisson model with cluster-robust SEs (reference groups: Bioko, ciprofloxacin and Spain).

Antibiotic quality and purchase price

No clear association was observed between the retail price of antibiotic formulations and their pharmacopeial quality. Within each antibiotic class, price ranges overlapped substantially across acceptable, substandard and falsified samples, in several cases identically. Price is therefore not a reliable indicator of quality in this setting, and these findings reinforce the case for active post-market surveillance over reliance on market-based proxies.

Dissolution analyses

Dissolution analysis can only be carried out following the in vitro dissolution testing protocols detailed in the authorised monographs outlined in pharmacopoeias for a given formulation.

12 samples per antibiotic, randomly selected from those classified as acceptable or substandard, were subjected to dissolution testing. Authorised USP tolerance limits are shown in online supplemental table 5 which were used to

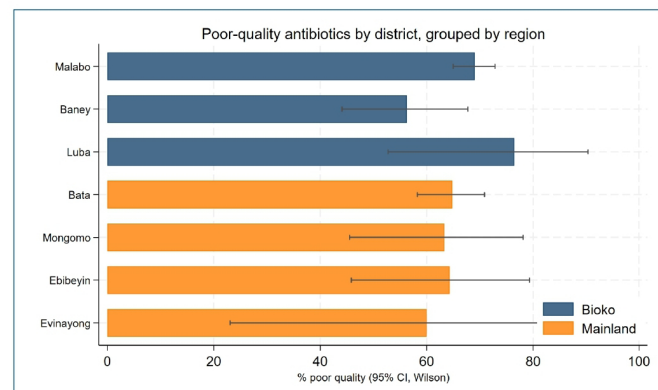


Figure 5 Prevalence of poor-quality antibiotics by district, grouped by region (Bioko Island and Río Muni mainland), with 95% CIs.

indicate whether the formulation was compliant (yes) if it dissolves within the specified time to release the specified amount of API, not (no) and the results are summarised in online supplemental table 6: brand name, outlet type, where the sample was purchased, country of manufacture, batch number, expiry date and per cent of stated active ingredient detected (SAPI %) as well as compliance with pharmacopoeia tolerance limits indicated as yes or no (in red).

Falsified antibiotic samples

Overall, 51 samples (5.7%; 51/901) were found to contain either no stated active pharmaceutical ingredient (SAPI) or less than 10.0% SAPI and were therefore classified as falsified. Online supplemental table 7 shows that the majority were purchased from pharmacies (38 of 51; 74.5%), with the remainder from clinics (n=4), medicine kiosks or botiquines (n=3), health facilities (n=3), market or street vendors (n=2) and one outlet whose type was not recorded (n=1). Because pharmacies also accounted for the large majority of all sampled outlets, this concentration reflects the sampling frame rather than a higher pharmacy risk: 77.6% of all antibiotic samples were purchased at pharmacies, and the proportion of pharmacy samples classified as falsified (5.4%) was comparable to that at other outlet types (range 4.7%–10.3%). Throughout, falsified was applied as an operational, content-based classification (API absent or below 10% of the stated amount); intent was not established and packaging was not authenticated, so the term is used in this operational sense, with the exception of the Augmentin batches matching WHO Medical Product Alert N°11/2019, for which independent corroboration exists.

DISCUSSION

The circulation of SF antibiotics in Africa represents a major public health concern, with recent estimates indicating prevalences of 12.4%–44.6%.^{12 16} Although direct quantitative evidence remains limited, there is strong biological plausibility that SF antibiotics contribute to AMR, thus highlighting the need for robust data on antibiotic quality.^{27 28}

The study presented here determined the quality of the main classes of antibiotics (n=901) purchased from 424 outlets, including brick-and-mortar pharmacies, health centres, consulting rooms, hospitals, markets, mobile vendors and medicine kiosks across Bioko Island. Samples purchased using the mystery client method included penicillins (269 amoxicillin formulations; 200 ampicillin capsules), fluoroquinolones (224 ciprofloxacin formulations) and aminoglycosides (111 gentamicin injections), as well as 97 tetracycline tablets. The four antibiotic classes evaluated in this study are included in the Lista de Medicamentos Esenciales de Guinea Ecuatorial (LIMEGE), the national essential medicines list published by the Ministry of Health and Social Welfare, which designates amoxicillin, ampicillin, ciprofloxacin,

gentamicin and tetracycline for use across hospitals and health centres.²⁹ Four of the five are also included on the WHO Model List of Essential Medicines³⁰; tetracycline is not on the current WHO Model List, though the related compound doxycycline is listed. These are not specialty or elective drugs; they are the medicines the national health system depends on for routine treatment of common bacterial infections. The LIMEGE has not been revised since its fourth edition in 2012, 6 years before the completion of this study and still used today, which may itself reflect broader challenges in pharmaceutical governance and regulatory capacity that contribute to the quality problems documented here.

The overall results from the antibiotic quality assessment indicate cause for concern as 33.2% (n=299) of total samples were of acceptable quality, 61.2% (n=551) were substandard and 5.7% (n=51) were falsified. Hence, more than two-thirds of the antibiotics sampled in EG were either substandard or falsified. The quality of fluoroquinolones (n=224), ciprofloxacin tablets and infusions was found to be of acceptable quality, and no falsified samples were identified.

The reliability of these results is informed by the use of the mystery client sampling approach, which provided robust estimates of the quality of antimalarial medicines in earlier studies on Bioko Island and in Enugu, Nigeria.^{19 31 32} The mystery client approach has a lower inherent risk of sampling bias as drug outlets are unaware of the survey.

Dissolution profiles are expected to align with the quantity of SAPI detected, such that formulations meeting pharmacopoeial content specifications should also demonstrate acceptable bioavailability as indicated by dissolution testing. In this study, the measured SAPI content generally served as a reliable indicator of compliance in dissolution analyses, suggesting that most formulations would deliver the intended therapeutic dose. However, notable exceptions were observed. An amoxicillin sample (brand name *E.MOXCLAV*; batch no. 1602890; labelled as manufactured in Egypt), purchased from a pharmacy in Malabo, contained only 29.9% of the SAPI yet complied with dissolution requirements. Despite its low SAPI content, its dissolution performance suggested that the active ingredient was released in a manner consistent with acceptable bioavailability. In contrast, a ciprofloxacin sample (brand name *Ciprolif*; batch no. 170751; labelled as manufactured in China), obtained from a market in Ebibeyin, contained 91.3% SAPI but failed dissolution testing. This failure indicates that, despite an apparently adequate drug content, the formulation in terms of binding would likely deliver a sub-therapeutic dose in vivo, potentially contributing to the development of AMR.

Such discordance between content and dissolution results has been reported previously. For example, sulfadoxine–pyrimethamine antimalarial formulations obtained in Pakistan, implicated in worsening a malaria epidemic in Afghan refugee camps, were found to meet

pharmacopeial limits for content but failed dissolution testing.³³

Amoxicillin is a penicillin and a member of the beta-lactam group. The other β -lactams from this study, the ampicillin capsules, were mostly substandard (93.5%) or falsified (6.5%). β -lactams are active against many gram-positive, gram-negative and anaerobic organisms while exerting little toxicity towards human cells. The amoxicillin combination with clavulanic acid, a β -lactamase inhibitor, is used as a broad-spectrum antibiotic to treat a wide range of bacterial infections, including upper and lower respiratory tract infections and infections of the skin and soft tissue.³⁴ The formulation of greatest concern identified in this study was amoxicillin-clavulanic acid (AMOX/CLAV; n=51), for which none of the samples met acceptable quality standards; 27.5% (n=14) were falsified and 72.5% (n=37) were substandard. In comparison, studies from Kenya have reported a lower prevalence of substandard AMOX/CLAV formulations (37.7%).³⁵ These findings are consistent with alerts issued through the WHO Medical Product Rapid Alert system, which notifies Member States of dangerous SF medical products and calls for heightened vigilance and strengthened regulatory action by national medicines regulatory authorities and Ministries of Health to safeguard public health and medicine supply chains.³⁶

The fieldwork for this study was conducted in 2018 and these data should therefore be interpreted as a baseline snapshot of that period rather than a description of current conditions. Since then, EG has undertaken reforms to its pharmaceutical supply chain through the Ministry of Health and Social Welfare, including changes to importation channels and the operationalisation of the Baney Reference Laboratory. The impact of these reforms on the quality of medicines reaching outlets has not been formally assessed, and no comprehensive medicine quality survey has been published in EG since this fieldwork. The 2018 data presented here therefore remain the most recent comprehensive assessment of antibiotic quality in the country and provide the baseline against which future evaluations of regulatory reform can be measured.

These antibiotic findings can be placed in the context of two prior surveys of medicine quality conducted in the same setting using the same mystery client method. The 2013 survey of antimalarial quality on Bioko Island reported 9.0% of samples as substandard or falsified.³² The 2018 follow-up survey of antimalarials, conducted by the same field team and covering both Bioko and the mainland, reported 59.5% of samples as substandard or falsified.¹⁹ The present antibiotic data, also from 2018, show that 66.9% of antibiotic samples were either substandard (61.2%) or falsified (5.7%). Taken together, the three studies describe a marked deterioration in the quality of medicines circulating in the country between 2013 and 2018 across two unrelated therapeutic classes, suggesting a broad weakening of the pharmaceutical supply chain during that period rather than a class-specific issue. The

comparison also indicates that, in 2018, antibiotic quality was at least as poor as antimalarial quality despite the latter being subject to dedicated programmatic attention through the Bioko Island Malaria Elimination Programme (BIMEP). This argues that antibiotic quality assurance deserves its own surveillance architecture rather than being assumed to follow from antimalarial efforts. The overall proportion of substandard or falsified antibiotics observed here is high relative to recent regional surveys, which reported 7.9% in Cameroon¹⁰ and 25% in the Democratic Republic of the Congo¹¹ and above the 22.6% pooled African estimate.¹² Two features warrant caution in that comparison: outlet-level information was incomplete for some samples, and those regional surveys found poor quality concentrated in the informal sector, whereas the falsified products here were concentrated in formal pharmacies; this divergence should be read against the incomplete outlet denominator rather than treated as a settled contrast. BIMEP is a long-running malaria control and elimination programme delivered as a public-private partnership between the Government of Equatorial Guinea, private-sector partners and MCD Global Health.

Detection of falsified Augmentin batches matching WHO Medical Product Alert N°11/2019

Eight of the falsified amoxicillin-clavulanic acid samples identified in this study were labelled as Augmentin and carried batch numbers 562626 or 762837, both of which were flagged in WHO Medical Product Alert N°11/2019 as falsified products circulating in West and Central Africa.³⁷ These samples were purchased from pharmacies in Malabo, Bata, Mongomo, and from a first-aid facility and a clinic in Baney, demonstrating that products subject to the WHO alert were in circulation across both Bioko and the mainland at the time of sampling. The recurrence of the same batch numbers across multiple outlets and districts is consistent with shared upstream distribution channels rather than isolated points of entry. Detection of these specific batches in the EG market provides direct evidence that the WHO alert system identified products which had reached this national supply chain, and supports closer coordination between EG's regulatory authorities and WHO surveillance to enable timely response when alerts are issued.

Among the 51 falsified samples, the country of stated manufacture and the type of outlet show recognisable patterns. India accounts for the largest share of falsified stated origins among the labelled samples (predominantly amoxicillin labelled as Healmoxy from Maxheal Pharmaceuticals), followed by Nigeria (predominantly ampicillin labelled as Petsow Laboratories), Great Britain (associated with Augmentin) and China. By outlet type, pharmacies account for 74.5% of falsified samples in this dataset, with the remainder from clinics, medicine kiosks or botiquines, health facilities and market or street vendors. The concentration of falsified products in formal pharmacies rather than informal vendors warrants

particular attention because patients have stronger expectations of product authenticity in those settings. A parallel breakdown of outlet type for the substandard subset was not possible because outlet-level information was not consistently recorded for those samples. This concentration should be interpreted against the sampling frame: because the great majority of all samples were purchased from pharmacies, a larger absolute number of falsified products would be expected there even if the rate of falsification per outlet type were similar, so the raw share reflects where sampling was concentrated rather than a demonstrably higher risk specific to pharmacies.

Limitations in ensuring quality of medicine

Several limitations should be considered. Of the 714 outlets identified through the 2013 census and supplemented in 2018, only 424 (59.0%) were open at the time of survey visits and available for sampling; the quality profile of products in the remaining 290 outlets is therefore unknown. Sample sizes for certain subgroups were small, particularly ciprofloxacin infusions (n=8), limiting the precision of these estimates. The subset of samples selected for dissolution testing was intended for illustrative purposes and was not designed to be representative. In addition, the study did not include bacterial isolates; therefore, the relationship between substandard antibiotics in this setting and AMR patterns is inferred rather than directly measured. Mobile and street vendors are itinerant and few were trading during the survey window, so that outlet type is under-represented; in addition, packaging was not authenticated and manufacturers were not contacted, and because multiple samples were taken per outlet the observations were clustered within outlets.

Public health implications

For policy, the findings argue for an update to the LIMEGE, which has not been revised since its 2012 fourth edition, and for a review of the registration and importation pathways through which the antibiotics assessed here reach EG. The Baney Reference Laboratory is well positioned to serve as the national hub for post-market surveillance of essential medicines, with capacity already in place for the analytical methods used in this study. Beyond the essential-medicines list, post-market surveillance of medicine quality can be embedded within EG's developing response to AMR under the WHO Global Action Plan framework, in line with wider efforts to strengthen such plans across the WHO African Region.³⁸ The Baney Reference Laboratory, the national reference laboratory of Equatorial Guinea (recognised by WHO for COVID-19 testing), is well placed to serve as the national hub for routine post-market surveillance as that architecture develops. They also point to the need to strengthen the national medicines regulatory framework, including routine quality control of imported medicines. In EG this responsibility rests with the Directorate-General of Procurement, Pharmacies, Biomedical Laboratories and Blood Banks of the Ministry of Health and Social Welfare,

which oversees the registration, importation and distribution of medicines and the authorisation and inspection of pharmacies and laboratories; because essentially all antibiotics on the market are imported, quality assurance depends on the controls it applies at importation and on subsequent post-market surveillance. The Ministry has been actively strengthening these controls, including ongoing nationwide pharmacy inspections to verify that registration and importation documentation is in order and, where necessary, enforcement action against non-compliant outlets; our findings reinforce the value of sustaining and expanding this work alongside routine post-market quality surveillance.

For clinical practice, prescribers in EG should be aware that the amoxicillin-clavulanic acid available in the market at the time of this study was uniformly unacceptable by content, with more than a quarter falsified. Where amoxicillin-clavulanic acid is clinically required, sourcing from facilities with verified supply chains, and counselling patients on the need to complete courses obtained from such sources, becomes especially important. The uniformly unacceptable quality of amoxicillin-clavulanic acid here is consistent with dissolution failures reported elsewhere in the region; in eastern Ethiopia, 60% of amoxicillin-clavulanic acid samples were pharmaceutically non-equivalent to their comparator on dissolution.³⁹ A content-based survey such as this cannot distinguish substandard manufacture from post-manufacture degradation. Several of the most affected formulations, notably amoxicillin-clavulanic acid and reconstituted suspensions, are heat- and moisture-sensitive,³⁴ and prolonged storage under the high ambient temperatures and humidity typical of this setting can itself reduce active ingredient content. Poor storage along the supply chain and at the point of sale may therefore contribute to the low quality observed, alongside any weaknesses in manufacturing or regulatory oversight; these mechanisms are not mutually exclusive and both are plausible here.

For research, the priority is a longitudinal surveillance programme that allows the impact of any subsequent regulatory reforms to be quantified, and studies that link sub-therapeutic antibiotic exposure to bacterial resistance patterns in clinical isolates from the same setting. Expanding the assessment to other essential medicines beyond antimalarials and antibiotics, particularly antihypertensives, antidiabetics and antiretrovirals, would build the broader picture needed for regulatory prioritisation.

CONCLUSION

The quality of antibiotics available on Bioko Island and the Río Muni mainland in Equatorial Guinea warrants attention, with a substantial proportion of samples found to be substandard or falsified. Sustained investment in medicine quality surveillance remains challenging in resource-limited settings, but the findings of this study provide an evidence base to support strengthening of national pharmaceutical policies governing medicine

importation and distribution. Ensuring the quality of essential medicines is both a national priority and a critical component of global health efforts to prevent the emergence and spread of AMR.

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Data availability statement Data are available upon reasonable request. If the data are released to unvetted persons they may use it to produce counterfeit medicines.

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