Antibiotic stewardship practices and drug quality in private pharmacies in Lao PDR: a mixed-methods study

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Summary

Background Private pharmacies are the primary access point for antibiotics in Lao PDR, yet they are frequently implicated in the unregulated dispensing that drives antimicrobial resistance. Regulatory non-compliance is often attributed to professional negligence, overlooking the structural constraints of the private sector.

Methods We conducted a mixed-methods assessment of 32 private pharmacies across three provinces of Lao PDR, combining physicochemical analysis of antibiotic quality, standardized Good Pharmacy Practice (GPP) audits, and in-depth semi-structured interviews. The triangulated design enabled comparisons of objective supply chain quality with provider knowledge and dispensing behaviors.

Findings The inventory audit (n = 689) revealed a high prevalence of WHO AWaRe Watch-group antibiotics (32.9%), unregistered formulations (14.8%), no pharmacy reached the 85-point GPP threshold. Class 2 pharmacies had a higher prevalence of unregistered antibiotics than Class 1 (adjusted prevalence rate ratio:1.64, 95% CI: 1.01–2.66). Qualitative analysis identified two themes that may explained these patterns. First, frontline providers lack familiarity with core stewardship terminology (e.g., "antimicrobial"), limiting engagement with national policy. Second, pharmacists reported dispensing sub-therapeutic doses or unregistered generics to accommodate patients' purchasing power.

Interpretation Private pharmacies in Lao PDR operate under a dual burden of terminological disconnection and economic precarity. Our findings suggest that regulatory enforcement alone is insufficient to address the trade-offs faced by pharmacists, who may face a choice between dispensing suboptimal regimens or denying primary care. Strengthening stewardship may require adapting educational curricula to bridge the translational gap and expanding financial protection to reduce the economic pressure for suboptimal dispensing.

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Introduction

Antimicrobials have been used to prevent and treat infections in humans and animals caused by microorganisms. However, antimicrobial resistance (AMR) has emerged as a pressing global health crisis, severely undermining their effectiveness.[1] AMR caused 1.27 million deaths and contributed to 4.95 million worldwide in 2019; if uncontrolled, it could lead to 10 million deaths annually by 2050.[2,3] The AMR crisis is primarily driven by inappropriate consumption, particularly self-medication, which can lead to treatment failure, drug toxicity, and the acceleration of resistance.[4] In many

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Research in context

Evidence before this study

We searched PubMed, Embase, and gray literature, including reports from international organizations and the Lao Ministry of Health, for studies published up to 3 April 2026 with the terms "antibiotics", "non-prescription", "stewardship", "good pharmacy practice", "pharmacy", "pharmacist", "low-income countries", "middle-income countries", and "Lao PDR". Existing evidence shows widespread non-prescription antibiotic dispensing across many low- and middle-income countries, including the Lao People's Democratic Republic (Lao PDR), alongside weak regulatory enforcement and gaps in pharmacists' knowledge. Previous studies in Lao PDR have also documented the presence of substandard antibiotics, including products with sub-therapeutic active pharmaceutical ingredient content, although falsification remains uncommon. However, few studies have combined drug quality testing, with assessments of Good Pharmacy Practice (GPP) regulatory compliance, and qualitative investigation of dispensing practices. To our knowledge, limited evidence exists on how frontline pharmacies interpret antimicrobial stewardship policies or how economic constraints shape dispensing behaviors.

Added value of this study

In this mixed-methods study with 32 private pharmacies across different classes of private pharmacies and three geographically distinct provinces of the Lao PDR, we combined the physicochemical analysis with antibiotic samples with standardized GPP regulatory auditing, and in-depth qualitative interviews. Whilst regulatory noncompliance was widespread, most samples met pharmacopeial standards, suggesting a disconnect between regulatory compliance and antibiotic quality. Our findings also indicate that frontline pharmacists may have limited familiarity with stewardship terminology, and that the dispensing of incomplete antibiotic courses and unregistered products can reflect response to patient affordability constraints. By integrating quantitative and qualitative data, this study provides a more comprehensive account of how regulatory, economic, and knowledge-related factors interact to shape antibiotic use in the private sector.

Implications of all the available evidence

Taken together with existing evidence, our findings suggest that strengthening antibiotic stewardship in Lao PDR requires approaches that go beyond regulatory enforcement. Interventions should consider the practical realities of pharmacy practice, including communication barriers around stewardship concepts and the economic constraints faced by patients and providers. Future research should evaluate context-adapted stewardship interventions and examine how regulatory and educational strategies can be aligned to improve dispensing practices without compromising access to health.

low- and middle-income countries (LMICs), antibiotics are often available for purchase without a medical prescription.[5–8] This accessibility is often facilitated by the inadequate regulation enforcement, which remains a significant driver of misuse.[4,5,9] In the Lao People's Democratic Republic (Lao PDR), national antibacterial consumption reported to the WHO Global Antimicrobial Resistance and Use Surveillance System, compiled from annual importation and domestic production volumes, ranged from 18 to 30 DDD per 1000 inhabitants per day between 2019 and 2023.[10] Much of this dispensing takes place in private retail pharmacies, which therefore represent a key target for stewardship efforts.[11]

In Lao PDR, private pharmacies are integral to the health system, providing essential medications and advice in areas underserved by hospitals,[12–15] and operate independently of the public referral network of health centers and district, provincial, and central hospitals.[16] As the health system's first point of contact for infections, their adherence to appropriate dispensing practices is critical.[17] Yet, these pharmacies often operate outside the clinical guidance,[14,18,19] facilitating self-medication practices that compromise patient and population safety.[12,14] Prescribing authority in Lao PDR is restricted to physicians and dentists, and antibiotics are classified as prescription-only medicines that pharmacists may not legally dispense without a prescription[16,20]; the widespread dispensing of antibiotics without prescriptions[9,14] therefore reflects an enforcement gap rather than a legislative one.

The consequences of this regulatory gap extend beyond mere administrative non-compliance. Community pharmacies are legally required to procure medicines exclusively from licensed suppliers (i.e., authorized domestic manufacturers, registered import-export companies, and official wholesalers) with all products registered with the Food and Drug Department (FDD) and accompanied by invoices recording batch numbers and expiry dates[20,21]; imported medicines originate mainly from Thailand, Vietnam, China, and India. Procurement outside these licensed channels increases the risk of circulation of substandard and falsified drugs.[22] Defined by the WHO as authorized products that fail to meet quality standards or falsified products that deliberately misrepresent their identity, substandard and falsified antibiotics pose a threat to population health.[23–25] In Lao PDR, a prevalence survey found that nearly 20% of samples failed to meet pharmacopeial content limits, although no falsified products

were detected among the samples tested.[26] Substandard antibiotics may contain subtherapeutic or supratherapeutic doses of the active pharmaceutical ingredient (API).[27] These low dosages are particularly dangerous because they are insufficient to eliminate the target pathogen but high enough to exert selective pressure,[23] fueling the emergence of resistant strains.[23–25]

To mitigate these risks, Lao PDR has made significant strides in strengthening its stewardship infrastructure, launching a national AMR surveillance program in 2018 and implementing a National Strategic Plan on AMR 2019–2023[28] and 2026–2035[29] and local antimicrobial prescribing guidelines.[12,14] Central to this strategy is also the adoption of Good Pharmacy Practice (GPP) as the primary regulatory benchmark for community pharmacies. Defined by the WHO and International Pharmaceutical Federation as the global standard for quality assurance, GPP mandates rigorous protocols across four domains: physical environment, storage conditions, documentation, and dispensing quality.[30] However, although the FDD has legally mandated these standards, the extent of their implementation in practice remains unclear.

Previous studies in the region have largely examined single dimensions: pharmacist practices and regulatory compliance without medicine quality testing.[31] These constructs are related but distinct; a pharmacy may comply with regulatory standards yet stock poor-quality products, or fall short of standards while its stock meets pharmacopeial limits. No study has assessed all three simultaneously, leaving the relationship between dispensing behavior and medicine quality unexamined. To address this gap, we examined three linked dimensions: regulatory compliance through standardized GPP audits, the physicochemical quality of antibiotics through laboratory analysis, and pharmacists' stewardship knowledge and dispensing practices through in-depth interviews. By linking these datasets, we aim to explore the relationship between regulatory adherence and the prevalence of unregistered or substandard medicines in the community.

Methods

Study design and setting

We conducted a cross-sectional mixed-methods study from April to August 2024 to evaluate community pharmacy practices and antibiotic quality in Lao PDR (Fig. 1). The study employed a stratified sampling design, drawing from 13 districts across three provinces selected to represent distinct socio-economic and geographical profiles: Vientiane capital (central urban economic hub), Luang Prabang (northern site with mixed urban-rural characteristics), and Champasak (southern rural, resource-constrained setting). The study protocol was executed through a collaborative framework involving the Lao Tropical and Public Health Institute (Lao TPHI), the Lao FDD of the Lao Ministry of Health, the Bureau of Food and Drug Inspection (BFDI), and the NUS Lao PDR Programme.

Participants and sampling strategy

Private community pharmacies were stratified by licensure status into Class 1 (comprehensive service, typically urban, managed by a pharmacist with a university degree) and Class 2 (limited service, typically rural, run by an assistant pharmacist). Class 3 pharmacies, which may operate without a pharmacist and are authorized only in remote areas pending planned phase-out,[21] were excluded, as were facilities closed on the survey date. A target sample of 32 pharmacies was recruited using stratified random sampling; allocation across provinces was designed to ensure geographic representation within available resources rather than proportionality to the underlying pharmacy population. Six of the 30 initially selected pharmacies (all Class 2; four without eligible dispensing staff present, two closed at visit) were replaced by the nearest eligible pharmacy within a 2-km radius. No pharmacy declined participation. Participants for the qualitative component included one dispensing pharmacist or assistant pharmacist from each site, selected via convenience sampling. This study was designed as an exploratory mixed-methods assessment integrating pharmacy inspections, qualitative interviews, and laboratory analysis. Given the resource-intensive nature of field and laboratory procedures, a pragmatic sample of 32 pharmacies was selected to capture variation across geographic and socioeconomic contexts rather than to provide nationally representative estimates. Participating pharmacies gave written informed consent and were informed that the assessment was for research purposes. Details, including the sampling frame and the sample size calculation for the laboratory component, are provided in the Supplementary Materials.

Good pharmacy practice inspection

A specialized inspection team from the FDD evaluated compliance using the GPP checklist covering four domains: premises/hygiene, documentation, storage/quality assurance, and service quality (details provided in the Supplementary Materials). Compliance was scored on a 0–100 scale using an FDD inspection checklist (Supplementary Materials), with scores <85 defined as the minimum acceptable score in the GPP inspection instrument used by FDD to define a non-compliant pharmacy. Study visits were unannounced, and assessments carried no regulatory consequence for participating pharmacies. GPP assessments were conducted by FDD personnel using an adapted checklist, none of whom had previously inspected the participating pharmacies. There is at present no routine

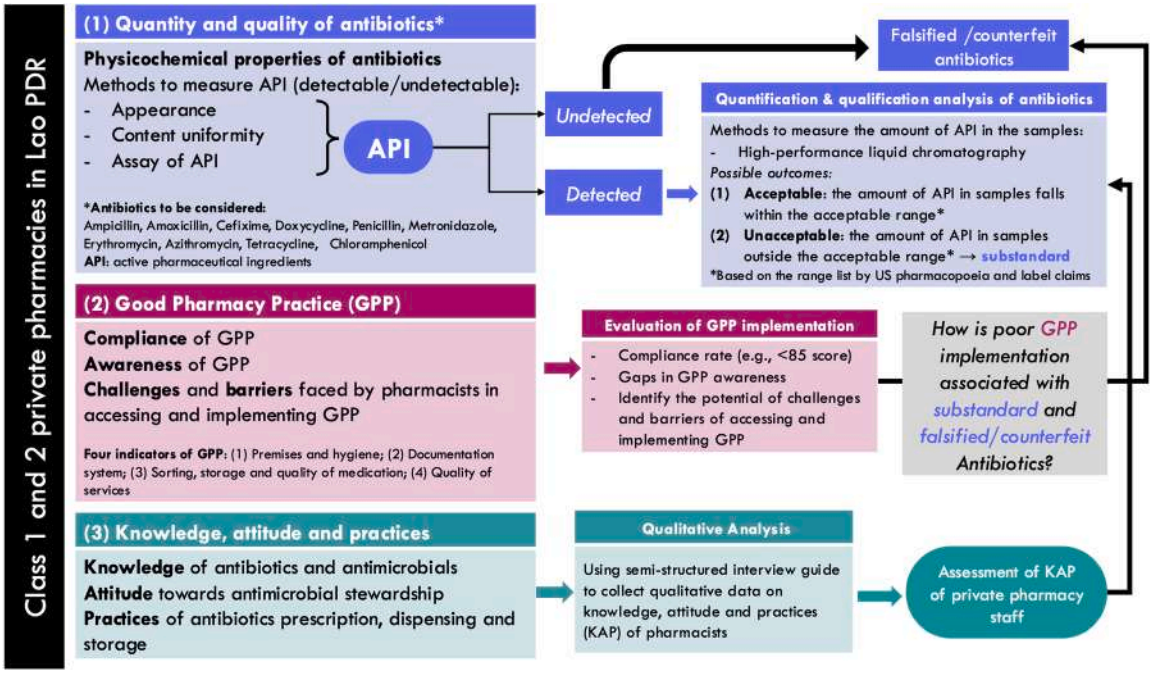


Fig. 1: **Conceptual framework for integrating the quality and quantity of antibiotics, regulatory compliance and behaviors in private pharmacies in Lao PDR.** The study employs a mixed-methods design across three data fields. (1) Antibiotic quality assessment. Samples are screened for physical defects and analyzed via high-performance liquid chromatography to detect active pharmaceutical ingredients (API). Products are classified as acceptable, substandard (outside pharmacopeial limits), or falsified/counterfeit (undetectable API). (2) Good Pharmacy Practice (GPP). Pharmacies are audited across four domains to determine a quantitative compliance score (<85 indicating noncompliance). (3) Knowledge, Attitudes, and Practices (KAP). Semi-structured interviews assess pharmacist stewardship behaviors. The framework posits that regulatory non-compliance (low GPP) and poor stewardship knowledge are structural drivers of the circulation of substandard antibiotics.

programme of GPP or antimicrobial stewardship inspection in Lao PDR.

Semi-structured interviews

Semi-structured in-depth interviews (30–45 min) were conducted with the responsible dispensing staff member at each pharmacy to assess knowledge of antimicrobial resistance (AMR), stewardship practices, and operational challenges. Interviews were conducted separately from the GPP inspection by trained researchers rather than inspectors. All interviews were audio-recorded following written informed consent. Saturation was monitored during data collection and was deemed reached by the thirtieth interview, with the final interview yielding no new codes.

Antibiotic sampling and laboratory analysis

To assess product quality, ten tracer antibiotics were targeted, representing beta-lactams (ampicillin, amoxicillin, and cefixime), tetracyclines (doxycycline, tetracycline), macrolides (erythromycin, azithromycin), and other classes (penicillin V, metronidazole, and chloramphenicol). All ten tracer antibiotics were targeted at each pharmacy. Sampling was restricted to products in stock at the time of the visit. Procurement was unblinded: samples were purchased openly by BFDI from shelf stock, restricted per protocol to FDD-registered products, with a minimum of 60 dosage units per sample in original packaging. Samples were coded immediately upon acquisition using a unique 9-digit alphanumeric code, and laboratory analysts were blinded to the source pharmacy and province. In total, 310 antibiotic samples underwent physicochemical analysis at the National Center for Food and Drug Analysis (NCFDA) (sample size calculation in Supplementary Materials). Sampled products, restricted per protocol to FDD-registered products and predominantly generic formulations, underwent visual inspection for packaging integrity followed by quantitative chemical analysis (high-performance liquid chromatography). The active pharmaceutical ingredient (API) content was quantified to determine compliance with pharmacopeial standards (USP/BP). Samples were classified as substandard if the API content fell outside the acceptable assay range (typically 90–110%). All antibiotic products held in each pharmacy at the time of the visit were recorded, yielding 689 products across the 32 sites. These

products were categorized into Access, Watch, and Reserve groups according to the 2023 WHO AWaRe classification[30]; given the absence of Reserve group agents in the audited inventory, analysis focused on the proportion of Access versus Watch group antibiotics to evaluate stewardship adherence.

Data analysis

We employed a convergent mixed-methods analytical framework. Quantitative data (GPP compliance scores, antibiotic inventory audits, and API assay results) were cleaned and validated using Microsoft Excel. Statistical analyses were performed using R statistical software (version 4.5.1). Descriptive statistics (means, standard deviations, median, interquartile range and frequencies) were calculated to characterize pharmacy demographics and inventory composition. We fitted an exploratory Poisson regression model with log link to examine associations between pharmacy characteristics and the rate of unregistered antibiotics per pharmacy. The, logarithm of the total number of audited antibiotics per pharmacy was included as an offset, so that exponentiated coefficients are prevalence rate ratios (PRRs), interpretable as the relative prevalence of unregistered products per audited antibiotic. Province and pharmacy class were included as covariates. The Pearson dispersion statistic was 1.41, indicating mild overdispersion; a negative binomial model produced equivalent estimates without improved fit. Because pharmacies were sampled within 13 districts, we assessed the sensitivity of inference to district-level clustering using a cluster bootstrap (5000 resamples of districts) and cluster-robust standard errors, and assessed the influence of individual pharmacies using Cook's distance (Supplementary Table S5). The API assay results were analyzed against pharmacopeial acceptance limits (typically 90–110%), with outliers visualized to identify substandard products. Qualitative data were transcribed independently by the two researchers present at each interview and reconciled, translated into English by researchers familiar with the pharmaceutical context, and verified against the Lao originals by bilingual FDD technical experts, with discrepancies resolved collaboratively to preserve conceptual equivalence. Transcripts were analyzed using an inductive thematic approach following the six-step framework by Braun and Clarke,[32,33] coded and analyzed by VL and KP, who coded independently and resolved discrepancies through discussion to consensus with reference to the original Lao transcripts; VL, a native Lao speaker, cross-checked coded excerpts against the originals, and themes were reviewed by senior qualitative researchers at Lao TPHI. The quantitative and qualitative datasets were triangulated during the interpretation phase to explore the divergence between regulatory compliance (GPP) and actual dispensing practices.

Ethical approval

The study protocol was approved by the National Ethics Committee for Health Research (NECHR) of Lao PDR (NECHR No. 055/NECHR), dated 3rd May 2024. Written informed consent was obtained from all participants. Participants had the right to end their participation in research at any time and under any conditions that made them feel uncomfortable.

Reflexivity

VL, DC and TK conducted interviews in Lao. All interviewers are experienced qualitative researchers trained in conducting individual in-depth interviews. VL, SK, DC, TK and DD have professional experience in pharmacy and expertise in GPP and AMR. All authors have diverse backgrounds and experience; hence, regular discussions throughout the study phase that emphasized individual reflexivity were essential in ensuring that the interviews and data analysis were approached objectively.

Role of the funding source

This study (Project 100024) was funded by the International Center for Antimicrobial Resistance Solutions (ICARS), which also provided advice on data collection. KP, SK, and NV were supported by the National University of Singapore Lao PDR Programme at the Saw Swee Hock School of Public Health, which provided technical support for research activities.

Results

A total of 32 private pharmacies were enrolled across the three study provinces (Table 1). The majority of participating pharmacies were classified as Class 1 pharmacies (71.9%) and were located in urban settings (78.1%). Rural pharmacies were concentrated in Champasak (40%) and Luang Prabang (30%), and pharmacies in Vientiane Capital were all urban. The responsible dispensing staff member was a licensed pharmacist in 27 of 32 pharmacies (84.4%) and assistant pharmacist in 5 (15.6%) at the time of survey, with a median professional experience of 9.0 years (interquartile range [IQR]: 3.0–19.8 years). Physical accessibility to secondary care varied considerably, with the median distance to the nearest hospital ranging from 1.1 km in the capital to 2.4–2.6 km in the provinces.

A quantitative assessment of GPP revealed noncompliance, with a mean cumulative GPP score of 58.8 (standard deviation [SD] 10.8) out of 100. No surveyed pharmacy achieved the 85-point threshold. Private pharmacies in the southern province of Champasak achieved the lowest mean compliance (50.2, SD 10.8 versus 63.4, SD 7.8, in Luang Prabang and 62.1, SD 9.3, in Vientiane capital, Kruskal–Wallis p-value = 0.010) (Table 2 and Fig. 2c). An inventory audit of 689 distinct antibiotic products (median: 18.0 products per site, IQR

Pharmacy characteristics	Total (N = 32)	Champasak (N = 10)	Luang Prabang (N = 10)	Vientiane capital (N = 12)
Pharmacy classification[a]				
1	23 (71.9%)	6 (60.0%)	8 (80.0%)	9 (75.0%)
2	9 (28.1%)	4 (40.0%)	2 (20.0%)	3 (25.0%)
Responsible staff member: licensed pharmacists, n (%)	27 (84.4%)	9 (90.0%)	9 (90.0%)	9 (75.0%)
Years of experience as a pharmacist				
median (IQR)	9.0 (3.0–19.8)	9.0 (3.8–20.0)	12.0 (9.0–21.0)	6.0 (2.0–9.5)
Type of location				
Urban, n (%)	25 (78.1%)	6 (60.0%)	7 (70.0%)	12 (100%)
Peri-urban or Rural, n (%)	7 (21.9%)	4 (40.0%)	3 (30.0%)	0 (0%)
Distance to nearest hospital (km), median (IQR)	2.40 (0.24–3.80)	2.40 (1.35–3.20)	2.55 (1.65–3.88)	1.08 (0.15–3.88)

IQR, interquartile range; N, total number of pharmacies; n, number of pharmacies in subgroup. [a]Pharmacy classification is determined by the Lao Ministry of Health based on the qualification of the licensee and scope of service: Class 1 pharmacies are typically larger, urban facilities authorized to stock a wider range of pharmaceuticals; Class 2 pharmacies are generally smaller community outlets with a more restricted formulary, often serving rural populations; Years of experience are missing for n = 2 pharmacists.

Table 1: **Characteristics of pharmacies and pharmacists.**

14.0–25.5) identified a high prevalence of Watch-group and unregistered antibiotics (per pharmacy values in Supplementary Table S4). Unregistered antibiotics accounted for a median of 14.8% (IQR 7.5–21.0) of the stock per pharmacy, consistent across all three provinces despite the disparities in GPP scores (Table 3). Class 2 pharmacies had a higher rate of unregistered antibiotics compared with Class 1 pharmacies (adjusted prevalence rate ratio [PRR] 1.64, 95% CI: 1.01–2.66; $p = 0.048$) (Table 3); the point estimate was stable across sensitivity analyses (Supplementary Table S1), and this association should be regarded as hypothesis-generating. A predominance of penicillins was recorded across all provincial cohorts, and substantial volumes of macrolides and cephalosporins were also identified. WHO AWaRe "Watch" group antibiotics constituted a median of 32.9% (IQR 24.1–41.4) of audited stock (Table 2 and Fig. 2b); neither pharmacy class nor province was associated with "Watch" group prevalence (Supplementary Table S6). Despite poor GPP scores, the majority of samples (99.5%) demonstrated adequate quality, with API content within the pharmacopeial acceptance range (90–110%). However, one sample from the "Watch" group, antibiotic Cefixime, was substandard, containing less than 30% of the labeled API content, while a Tetracycline sample exhibited an API of >115% (Fig. 2d).

Familiarity with antibiotics and with stewardship terminology

Pharmacists demonstrated functional clinical knowledge alongside limited command of the terminology used in national stewardship guidelines. Clinical knowledge was evident in some participants' handling of treatment boundaries. Most participants correctly stated that antibiotics are ineffective against fungal infections, distinguished antifungal from antibacterial indications, and most correctly rejected discontinuing antibiotics when symptoms subsided. However, this practical competence did not translate into a command of a broader stewardship lexicon. When queried on the term antimicrobial, 31 of 32 participants (96.9%) could not correctly define it: *"I don't understand what is antimicrobial"* (P9, pharmacist, Champasak). Other respondents confused antimicrobials with antivirals, with specific diseases, or with individual antibiotics. Thus, the gap was not the absence of clinical knowledge but a mismatch between the vocabulary of national AMR policies and the working language of frontline practice,

Pharmacy performance	Total (N = 32)	Champasak (N = 10)	Luang Prabang (N = 10)	Vientiane capital (N = 12)
GPP score[a], mean (SD)	58.8 (10.8)	50.2 (10.8)	63.4 (7.84)	62.1 (9.30)
Antibiotic stock in the pharmacies				
Total antibiotics audited (n)	689	173	238	278
Antibiotics audited per shop, median (IQR; range)	18.0 (14.0–25.5; 7–49)	18.0 (13.25–22.8; 7–25)	24.5 (15.0–28.8; 11–41)	16 (14.0–29.5; 10–49)
Unregistered antibiotics[b] per shop, median % of total antibiotics audited (IQR)	14.8% (7.5–21)	16.0% (9–19.2)	12.8% (9.4–16.4)	18.3% (5.5–22.7)
Antibiotics that are WHO AWaRe "Watch" products[c] per shop, median % of total antibiotics audited (IQR)	32.9% (24.1–41.4)	31.0% (24.9–35.3)	33.3% (24.9–41.9)	31.5% (25.4–41.6)

GPP, Good Pharmacy Practice; IQR, interquartile range; SD, standard deviation; range, minimum–maximum. [a]The Good Pharmacy Practice (GPP) score is calculated based on the Lao PDR Food and Drug Department inspection checklist (0–100 scale). A score of ≥85 is required for regulatory compliance, and scores <85 indicate non-compliance. [b]Unregistered antibiotics are defined as pharmaceutical antibiotic products lacking a valid registration number from the Lao PDR Ministry of Health at the time of audit. [c]The WHO AWaRe tool classifies antibiotics into three groups to guide stewardship: (1) Access (first-line treatments), (2) Watch (agents with higher resistance potential), and (3) Reserve (last-resort options for multidrug-resistant organisms). No "Reserve" antibiotics were found in the surveyed sites.

Table 2: **Regulatory compliance scores and antibiotic inventory composition of private pharmacies stratified by province.**

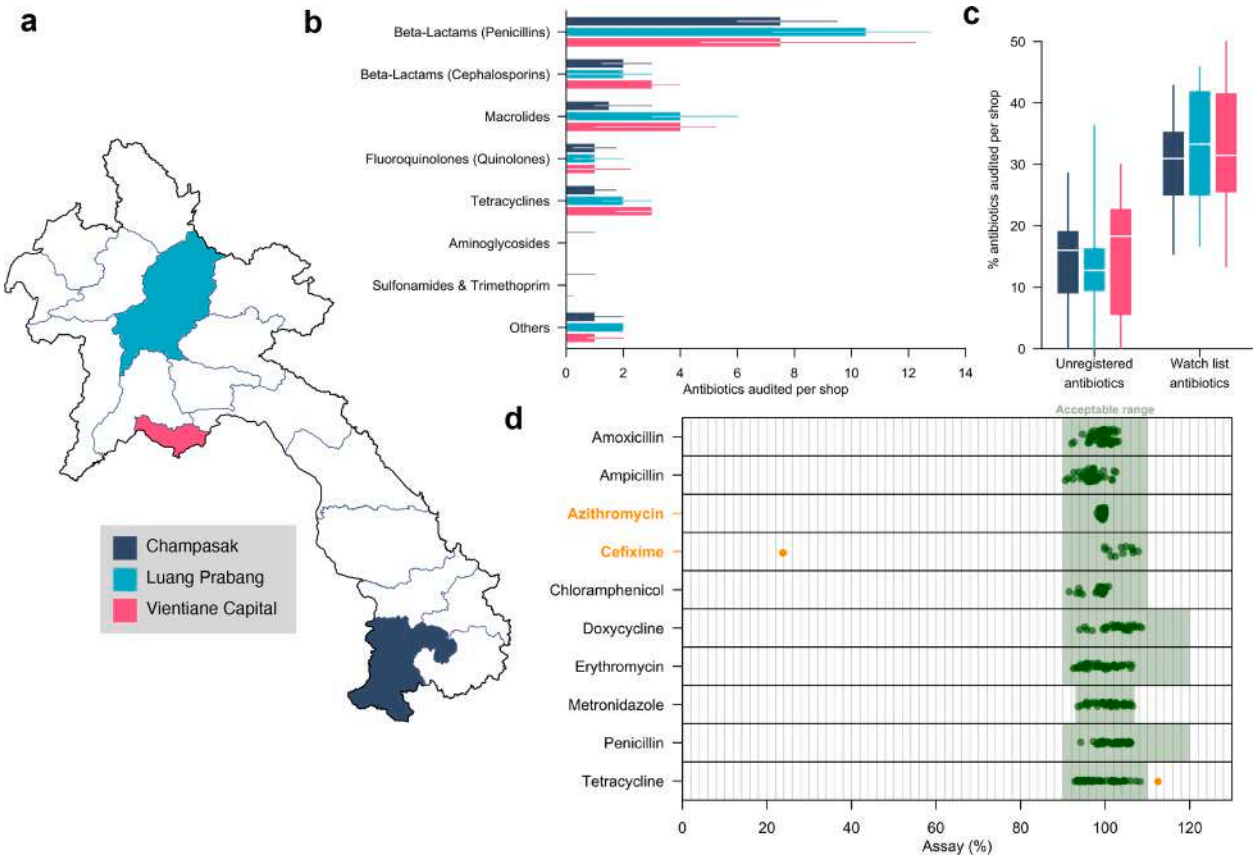


***Fig. 2:* Geographic distribution, antibiotic stock composition, Good Pharmacy Practice performance, and quality assessment of antibiotics in community pharmacies across three Lao provinces.** (a) Map of Lao PDR highlighting the three study provinces: Champasak (dark blue), Luang Prabang (light blue), and Vientiane Capital (pink). (b) Median percentage of antibiotic pharmacology classes audited per shop, stratified by province. The inset boxplot shows the percentage of unregistered and WHO AWaRe "Watch" group antibiotics per shop across the provinces. (c) Boxplots of Good Pharmacy Practice (GPP) scores for all studied pharmacies and stratified by province. The box indicates the interquartile range (IQR), the solid horizontal line is the median, the dashed red line is the mean, and the dashed gray line is the 85-point minimum score for meeting the GPP standards. (d) Active pharmaceutical ingredient assay content (%) for sampled antibiotics. The green shaded region represents the acceptable pharmacopeial range. Dots represent individual samples; orange dots highlight outliers for Cefixime (substandard) and Tetracycline (over-potent). Antibiotic names in orange (Azithromycin, Cefixime) are on the WHO AWaRe "Watch" group antibiotics.

which may limit providers' engagement with stewardship guidance framed in policy terminology.

Economic consideration in dispensing

Participants described dispensing as a continuous negotiation between professional judgment and commercial viability, with economic considerations shaping decisions at three ares[1]: the dispensing counter,[2] the quantity dispensed, and[3] the sourcing of stock.

Gatekeeping under consumer demand

Pharmacists described attempting to triage patients (e.g., asking for symptoms before dispensing and referring serious cases to doctors), indicating that professional identity as assessor and advisor remains intact in principle. In practice, this gatekeeping was constrained by consumer demand in a competitive market. Patients frequently requested specific antibiotics by prior familiarity, and participants reported that refusing such requests carried a direct commercial cost: *"If we don't sell, they will come to another pharmacy. [we] follow patient demand or they are dissatisfied."* (P5, pharmacist, Champasak). Respondents described the loss of sale and clientele as the consequence of enforcing prescription requirements (Supplementary Figure S2).

Dispensing to the purchasing power of patients

The quantity dispensed was frequently set by what patients could afford rather than by the clinical regimen. Participants reported routinely dispensing incomplete courses, *"bought only 2-3 tablets only"* (P28, pharmacist, Luang Prabang) and initiating the rationing themselves: *"they do not have enough money, they ask to take it for only 1 day"* (P26, pharmacist, Luang Prabang). Participants are confronted with the choice of denying treatment entirely or providing a partial dose that fits

Variables	Unadjusted PRR[a] (95% CI)	Adjusted PRR[a] (95% CI)	p-value
Province			
Champasak	*Reference*		
Luang Prabang	1.01 (0.59–1.73)	1.21 (0.68–2.14)	0.513
Vientiane capital	0.95 (0.56–1.60)	1.10 (0.63–1.91)	0.734
Pharmacy classification[a]			
1	*Reference*		
2	1.55 (0.98–2.45)	1.64 (1.01–2.66)	0.048

PRR, prevalence rate ratio; CI, confidence interval. Poisson regression of the count of unregistered antibiotics per pharmacy with log(total antibiotics audited) as offset; n = 32 pharmacies. [a]Pharmacy classification is determined by the Lao Ministry of Health based on the qualification of the licensee and scope of service: Class 1 pharmacies are typically larger, urban facilities authorized to stock a wider range of pharmaceuticals; Class 2 pharmacies are generally smaller community outlets with a more restricted formulary, often serving rural populations. [b]Unregistered antibiotics are defined as pharmaceutical antibiotic products lacking a valid registration number from the Lao PDR Ministry of Health at the time of audit.

Table 3: **Association between pharmacy characteristics and rate of unregistered antibiotics[b] from multivariable Poisson regression.**

the patient's economic means. This dispensing-to-budget pattern suggests a coping mechanism that educational interventions alone are unlikely to address or dismantle without accompanying financial protection mechanisms for patients.

Sourcing under margin pressure

The same affordability constraint extended upstream to inventory decisions, although sourcing priorities varied: some participants reported ordering on quality from established companies and wholesalers, while others applied price-led rules within the registered market. As one respondent explained, *"If there is the same API from two importing companies that are both registered, but the other companies are cheaper, we choose the cheaper one. Nowadays, the price is important"* (P1, pharmacist, Champasak). Where infrastructure allowed, the majority of respondents adhered to physical storage guidelines, describing glass cabinets or air-conditioned environments to prevent degradation consistent with the Premises domain of GPP. In lower-income settings, however, affordability led stocking decisions, and unregistered products entered through demand and shortage: P23 (assistant pharmacist, Luang Prabang) linked the chain directly, reporting that *"quality medicine is expensive and cannot be sold"* and "because of [a] shortage [of the] drug, we need to buy unregistered, and because they are cheaper". Some participants also relied on informal channels, including van distributors, to stock specific brands patients prefer, consistent with the unregistered antibiotics identified in the inventory audit (Fig. 2b and Table 2). Notably, low-cost dispensing was sometimes framed as a clinical strategy rather than a commercial one: *"I would recommend that they take a cheaper one so that they can be sure that they will take the full course of the medication"* (P26, pharmacist, Luang Prabang), positioning affordability as a means of securing treatment completion rather than undermining it.

Discussion

The mixed-methods approach adopted in our study revealed insights into GPP compliance, antibiotic quality, and pharmacist practices in Lao PDR. AMR poses a growing threat to global health, with LMICs like Lao PDR bearing a disproportionate burden due to weak healthcare systems, limited resources, and unregulated pharmaceutical practices. Private pharmacies in Lao PDR serve as critical access points for healthcare, especially in rural areas where access to hospitals and other formal health facilities is limited. These pharmacies are often the first point of contact for communities seeking treatment and medications, reflecting a broader trend observed across LMICs, where private sector health services are pivotal yet underregulated.

Triangulating the physicochemical, regulatory, and behavioral datasets suggests a plausible explanatory pathway: the prevalence of Watch-group antibiotics may reflect patient demand for perceived-stronger broad-spectrum agents; low scores in the dispensing and documentation domains (Fig. 2c and Supplementary Figure S2) may reflect commercial adaptation to a market where strict stewardship is penalized by loss of clientele rather than a knowledge deficit; and the presence of unregistered products aligns with sourcing strategies aimed at affordability rather than accidental supply chain leakage. However, the previous National Strategic Plan on Antimicrobial Resistance (NSP) and guidelines[28,29,34] appear disconnected from the operational reality of Lao private pharmacy practice. While the NSP prioritizes high-level stewardship governance, our findings suggest that its implementation may be obstructed by a translational gap in the nomenclature used in the NSP and by stewardship's reliance on patients' purchasing power. First, the widespread inability of frontline providers to define core concepts like antimicrobial suggests that the technical lexicon used in the NSP has not been operationalized in the community, and educational interventions based on this terminology may be ineffective. Second, pharmacists reported dispensing sub-therapeutic doses or unregistered antibiotics to accommodate patient affordability, suggesting a response to economic constraints rather than a failure of professional ethics. The prevalence of Watch-group agents in pharmacy stock mirrors hospital point-prevalence surveys in Lao PDR, where 80% of inpatient antibiotic prescriptions were broad-spectrum and only half were Access-group agents.[35]While the first NSP focused on core pillars like surveillance and stewardship, the current NSP-AMR 2026–2035 adopts a 10-year, two-phased framework that shifts the focus toward long-term sustainability and institutionalization through domestic financing.[29]

The educational disconnect is not unique to the Lao setting in our study. A recent multi-country assessment across Africa by Agiri and colleagues[36] identified similarly that only half of pharmacy staff received formal

stewardship training, resulting in significant knowledge gaps among private dispensers compared to their public-sector counterparts. This suggests widespread inadequacies in undergraduate curricula to translate high-level AMR concepts into the practical lexicon of community pharmacy across several African nations,[36] specifically in Uganda,[37] and Nepal,[38] not just a gap in Lao PDR.

Furthermore, the commercial architecture of the private sector actively erodes the pharmacist's capacity for stewardship. The antibiotic dispensing patterns identified in our study are not unique to the Lao context but rather reflect a persistent global challenge. A recent systematic review by Li and colleagues covering 52 countries estimated the pooled prevalence of non-prescription antibiotic dispensing at 63.4%, higher in LMICs.[39] The commercial pressure identified in our participants corroborates the findings across 28 African nations,[36] where patient demand and high out-of-pocket costs were identified as primary drivers of non-prescription dispensing. In both contexts, the role of the pharmacists is structurally compromised by the financial necessity to secure the sale, consistent with the hypothesis that antibiotic misuse in LMICs is often an economic symptom rather than a clinical choice. Participants in our study described a *merchant-customer* dynamic that supersedes the *pharmacist-patient* relationship, with pharmacists noting the customers trust doctors' prescription but tend to refuse pharmacists' recommendations. Pharmacists also stock WHO AWaRe "Watch" group antibiotics in their facilities, not out of negligence, but to satisfy patients' demands; although we note that neither pharmacy class nor province was associated with Watch-group prevalence in our audit, suggesting this demand operates across the sector rather than in identifiable subgroups. If they attempt to enforce prescription rules or ask about symptoms, they risk not only losing the sale but losing the customer entirely. Thus, dispensing without a prescription function less as a regulatory violation than as an adaptation to a market that values speed and access over clinical oversight, pressuring the pharmacists to act against guidelines and weakening their gatekeeping role.[39,40] In parallel, the accessibility and quality of public primary care must improve so that health centers offer a realistic alternative to pharmacy self-medication for common infections; extending the national antimicrobial prescribing guidelines, introduced for hospital care in 2021, to health center and community pharmacy practice would give first-contact providers a shared standard.[35]

Strengths and limitations

The primary strength of this study lies in its mixed methods triangulation, which integrates physicochemical analysis, regulatory auditing, and qualitative analysis to provide a holistic assessment of the pharmacy sector.[41] Unlike standard KAP surveys that rely solely on self-reported data,[42,43] our inclusion of objective laboratory analyses helped address social desirability bias and quantify the prevalence of substandard and unregistered medicines circulating in the market. Furthermore, the mixed-methods design enabled us to move beyond descriptive statistics to explanatory mechanisms; by coupling quantitative GPP scores with in-depth interviews, we explored how constraints on patient purchasing power and terminological gaps drive regulatory noncompliance.[36–39] Geographically, the stratification across Vientiane capital and provincial districts captures urban-rural disparities, ensuring the findings reflect the diverse socioeconomic realities of the Lao health landscape.[12,14,44] Consequently, this study establishes an empirical baseline for the Lao FDD to design targeted interventions that address both the structural and individual determinants of antimicrobial resistance.

However, our study has several limitations that necessitate cautious interpretation. First, the sample size of 32 pharmacies, although appropriate for a resource-intensive mixed-methods design, limits statistical power and generalizability; as allocation across strata was not proportional and no sampling weights were applied, estimates describe the sampled pharmacies rather than the national pharmacy population, and the findings should therefore be interpreted as exploratory and hypothesis-generating rather than nationally representative. The exclusion of Class 3 outlets and the replacement of six ineligible Class 2 pharmacies by eligible facilities both plausibly bias observed practice upward, making our compliance findings conservative. Second, the cross-sectional design provides a static snapshot of pharmacy practices, precluding the assessment of temporal trends in antibiotic dispensing. Third, the laboratory analysis was restricted to oral solid dosage forms, excluding injectables and pediatric formulations. As injectables are often implicated in high-risk usage patterns, their exclusion may underestimate the total burden of compromised antibiotics.[45] Quality testing was further restricted to ten tracer antibiotics for which validated analytical methods and certified reference standards were available locally, and because sampling was limited to registered products, the quality of unregistered antibiotics in circulation (and of agents captured in the inventory audit but not tested, including sulfonamide-trimethoprim combinations and fluoroquinolones used for urinary tract infections) remains unknown. Additionally, while our sampling covered three diverse provinces, the exclusion of remote northern border regions, where transboundary trade introduces distinct regulatory challenges, limits the generalizability of the findings nationwide. Fourth, the qualitative component relies on self-reported data from pharmacists. While we attempted to mitigate response bias through triangulation with

objective inventory audits and laboratory analyses, the potential for social desirability bias in interview responses regarding dispensing protocols remains. Relatedly, although visits were unannounced and assessments carried no regulatory consequence, observation by FDD personnel and the open purchase of samples may have induced reactivity; any such bias would likely improve observed practice, making our compliance findings conservative. Finally, the sample size for physicochemical testing was constrained by the specific market dynamics of Lao PDR; the limited variety of manufacturing batches available on pharmacy shelves restricted the breadth of our quality testing. Future research should employ longitudinal surveillance and broader geographic sampling to fully capture the dynamics of the informal pharmaceutical market.[45]

This study questions the narrative that the mishandling of antibiotics in Lao PDR is merely a consequence of professional negligence. Instead, our study reveals that the pharmacy sector is burdened by terminological disconnection and economic precarity. Previous high-level plans on AMR have struggled to translate technical stewardship concepts into the operational understanding of community providers,[12,14,28,29,34] while patient poverty pushes pharmacists to prioritize affordability over clinical guidelines.[3,46] Interventions that focus solely on punitive regulatory enforcement overlook the trade-offs faced faced by pharmacists, who may face a choice between dispensing a sub-therapeutic dose to an indigent patient or denying care entirely.[47] To bridge these gaps, future interventions should be designed and tested beyond simple compliance checks. Candidate strategies suggested by our findings include: adapting antimicrobial stewardship curricula to replace abstract policy language with practical, symptom-based algorithms that pharmacists can easily communicate to patients[48]; tightening supply chain integrity to reduce the informal distribution networks that introduce unregistered and high-potency (e.g., AWaRE "Watch" list) antibiotics enter pharmacies[49,50]; and expanding financial protection mechanisms for outpatient care,[50] without which pharmacists may remain caught between dispensing sub-therapeutic doses and denying access.[50,51] These remain hypotheses for policy evaluation rather than demonstrated solutions. Ultimately, effective antimicrobial stewardship in the private sector is unlikely to be achieved through regulation alone.[52] Our findings suggest it will also require aligning policy language with provider reality, so that the gatekeepers of the health system are supported to protect the communities they serve.[51]

Conclusion

Private pharmacies in Lao PDR are key providers of antibiotic access and face structural and economic constraints that may limit adherence to optimal stewardship. Although most quality-tested antibiotics met pharmacopeial standards, the presence of unregistered products and wide availability of WHO AWaRe "Watch" antibiotics indicate gaps in regulatory implementation. Addressing these challenges may require combining enforcement with context-adapted training and financial protection mechanisms, hypotheses that warrant testing in intervention studies.

Contributors

VL, KP, and DD designed the study and led the overall data interpretation. SK, NV, SS, BS, and BK also participated in the study design. VL, SK, NV, BS, and KP drafted the article and did the data analysis and model building. VL, SK, NV, DC, TK, BS, and DD accessed and verified the data. All authors interpreted the results and critically revised the manuscript for scientific content. VL, KP, and DD have full access to all the study data. All authors had the final responsibility to submit the manuscript for publication.

Data sharing statement

All data used in this study can be downloaded from the cited references. The codes used to generate these analyses are available at https://github.com/kieshaprem/lao-pharmacy-amr.

Editor note

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Declaration of interests

All other authors involved in the research have confirmed that they had no commercial or financial interests that could potentially create a conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.lanwpc.2026.102028.

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