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To cite this article: Omeed Darweesh , Brian Godman & Amanj Kurdi (21 Apr 2026): Non-prescription antibiotic dispensing and counseling practices in Iraqi community pharmacies: implications for antimicrobial stewardship and resistance containment, Expert Review of Anti-infective Therapy, DOI: [10.1080/14787210.2026.2663104](https://doi.org/10.1080/14787210.2026.2663104)

To link to this article: <https://doi.org/10.1080/14787210.2026.2663104>



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Published online: 21 Apr 2026.



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# Non-prescription antibiotic dispensing and counseling practices in Iraqi community pharmacies: implications for antimicrobial stewardship and resistance containment

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## ABSTRACT

**Background:** To assess the prevalence, characteristics, dispensing practices, and counseling behavior of non-prescription antibiotic dispensing among Iraqi community pharmacies to inform antimicrobial stewardship (AMS) policy.

**Research design and methods:** A cross-sectional simulated client study was conducted among 696 pharmacies across five Iraqi provinces. Standardized scenarios of upper respiratory tract infection were used to evaluate dispensing behavior, counseling quality (defined as whether staff provided key counseling components including enquiry about symptoms, allergy status, dosage instructions, and treatment duration), and antibiotic class distribution according to the WHO-AWaRe framework. Data were analyzed using descriptive and multivariable logistic regression.

**Results:** Antibiotics were dispensed without prescription in 80.6% (95%CI:77.6–83.5%) of the visits. Access antibiotics accounted for 60.8% (95%CI:56.9–65.0%) and Watch agents for 39.2% (95%CI:34.9–43.1%), with amoxicillin-(26.4%), amoxicillin–clavulanate-(30.7%), and azithromycin-(25.5%) most common. Counseling was poor; only 15% (95%CI:12.3–18.3%) of the providers asked any clinical question and only 7.7% (95%CI:5.5–9.9%) enquired about allergy history. Non-pharmacist staff (nurses) were significantly more likely to dispense antibiotics without prescription compared with pharmacists (OR = 5.7; 95%CI:3.2–10.1).

**Conclusions:** Non-prescription antibiotic dispensing and minimal counseling remain widespread in Iraqi pharmacies. Effective AMS in Iraq will require phased, system-level approaches, including strengthened regulatory enforcement, workforce support addressing all pharmacy personnel, and integration of community pharmacies into national AMR strategies.

## PLAIN LANGUAGE SUMMARY

Antimicrobial resistance (AMR) happens when bacteria stop responding to antibiotics, making infections harder to treat. In many countries, including Iraq, people can still buy antibiotics from community pharmacies without a prescription, which increases the risk of resistance. This study looked at how often and how responsibly antibiotics were sold in 696 pharmacies across five Iraqi cities. Researchers found that in over 80% of visits, antibiotics were given without a prescription. Nearly 40% were drugs that the World Health Organization classifies as higher-risk 'Watch' antibiotics. Most pharmacy staff did not ask important clinical questions or check for allergies before dispensing. These results show the urgent need for better antibiotic control and community pharmacy personnel training. Trained pharmacists could play an important role in improving antibiotic use in Iraq; however, our findings also show that other staff, including nurses, are often involved in dispensing antibiotics in community pharmacies. Ensuring safe and appropriate antibiotic use will therefore require clear regulations, proper oversight, and monitoring systems that address the practices of all personnel involved in medicine supply.

## ARTICLE HISTORY

Received 3 November 2025  
Accepted 17 April 2026

## KEYWORDS



Antimicrobial resistance; community pharmacy; non-prescription antibiotic dispensing; antimicrobial stewardship; simulated client methodology


## 1. Introduction

Antimicrobial resistance (AMR) is a major global health threat [1]. Without urgent and coordinated action, AMR could cause up to 10 million deaths annually by 2050 [2,3]. In low- and middle-income countries (LMICs), the burden of AMR is strongly driven by inappropriate antibiotic use in ambulatory care, particularly the dispensing of antibiotics without a valid prescription in community settings [4–6]. This undermines

antimicrobial stewardship (AMS) efforts and accelerates the spread of resistant pathogens, particularly in settings with limited stewardship resources [7–13].

According to recent global systematic reviews, the pooled prevalence of non-prescription antibiotic dispensing in community pharmacies exceeds 60%, reaching as high as 95% in some LMICs, with the majority of sales related to upper respiratory tract infections (URTIs) that are typically viral and

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 Supplemental data for this article can be accessed online at <https://doi.org/10.1080/14787210.2026.2663104>.

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self-limiting [4,5]. Such practices contribute to antimicrobial misuse and accelerate resistance development [4].

In Iraq, inappropriate antibiotic use is widely reported across healthcare settings, including empirical prescribing in hospitals, self-medication among the public, and non-prescription antibiotic sales in community pharmacies [14–18]. Inappropriate use has resulted in AMR becoming a leading cause of mortality in Iraq [14,19]. The Iraqi Ministry of Health's Antimicrobial Resistance National Action Plan (NAP, 2018–2022) acknowledges the urgent need to optimize antimicrobial use and strengthen stewardship activities across the One Health spectrum to reduce AMR in Iraq [19]. However, implementation remains challenging due to weak regulatory oversight, fragmented surveillance, and limited training in AMS principles among healthcare professionals (HCPs). Pharmacists and nurse-led clinics working in community settings in Iraq often serve as the first point of contact for patients seeking treatment, especially for common respiratory infections, and their practices play a critical role in shaping antibiotic consumption patterns nationally [17]. In Iraq, the dispensing of medicines is governed by national pharmaceutical legislation under the authority of the Ministry of Health. Within this framework, antibiotics are legally classified as prescription-only medicines and are intended to be supplied by licensed community pharmacies upon presentation of a valid prescription issued by a registered physician [19]. Community pharmacies are required to operate under the supervision of a registered pharmacist, and the non-prescription sale of antibiotics is not permitted under national regulations. However, regulatory oversight and enforcement remain inconsistent across regions. National and international assessments have documented challenges related to inconsistent inspections, limited enforcement of sanctions, and fragmented regulatory accountability, resulting in discrepancies between the formal regulatory framework and routine dispensing practices, particularly in outpatient and community pharmacy settings [15,20].

Community pharmacies are uniquely positioned to influence antibiotic use given their accessibility, trusted status, and frequent interactions with the public [21–23]. However, community pharmacies in Iraq operate within a fragmented regulatory environment characterized by weak inspection capacity, limited accountability mechanisms, and strong commercial and patient-driven pressures to supply antibiotics without prescriptions [5,14,15,24]. In addition, although community pharmacies operate under the legal supervision of licensed pharmacists, who hold professional responsibility for pharmacy practice and regulatory compliance, the community pharmacy workforce in Iraq is heterogeneous, often without clear differentiation of scope of practice or effective professional supervision [15,17]. This regulatory ambiguity contributes to variability in dispensing behavior and undermines the consistent application of AMS principles at the community level [17]. This means that the day-to-day dispensing of medicines may involve multiple cadres of personnel working within the pharmacy, including pharmacists, nurses, and pharmacy assistants. Consequently, antibiotic dispensing practices observed in community pharmacies may reflect the behaviors and knowledge of the broader pharmacy workforce rather than pharmacists alone. Recognizing this workforce structure

is important when assessing dispensing practices and designing antimicrobial stewardship interventions in community pharmacy settings. Qualitative studies among Iraqi community pharmacies reveal that such practices are often justified by perceived patient need, diagnostic uncertainty, and the belief that antibiotics are safe and effective for most infections [15]. At the same time, gaps in knowledge about antibiotic resistance and insufficient awareness of the World Health Organization (WHO) AWaRe classification system have been reported across Iraq and other LMICs, further exacerbating inappropriate dispensing [24,25]. Having said this, a recent study by Alkadhimi et al. (2024) [26] in Iraq found that community pharmacists are favorable toward ASPs; however, their role is limited. This needs to be addressed to reduce current high levels of AMR in Iraq [26]. The WHO's Global Action Plan on AMR, endorsed by all member states, urges countries to ensure that at least 60% of antibiotic consumption comes from the 'Access' group, agents with a lower resistance potential, while restricting the inappropriate use of 'Watch' and 'Reserve' antibiotics, which has now been increased by the United Nations General Assembly on AMR to 70% [27]. However, global and regional evidence indicates that community pharmacies disproportionately supply Watch group antibiotics, including macrolides and broad-spectrum  $\beta$ -lactams, which accelerate AMR development [5,28].

Against this background, understanding current antibiotic dispensing behaviors in Iraq's community pharmacies is vital to inform future effective stewardship strategies. Earlier studies in Iraq examining antibiotic sales without a prescription have provided valuable qualitative insights. However, these were largely limited in geographic scope, often restricted to a single city, and reliant on self-reported or interview-based data, which may not accurately capture real-world practices due to issues with sociability desire bias [14,15,25]. Furthermore, these studies did not comprehensively evaluate differences across regions, staff qualifications, or the types of antibiotics dispensed, nor did they quantify antibiotic use according to WHO AWaRe classifications [14,15,25]. To address these gaps, the present study employed an established, objective approach designed to assess authentic dispensing behavior to evaluate the extent and nature of non-prescription antibiotic sales, counseling practices, and antibiotic classes supplied among community pharmacies across multiple Iraqi provinces [29]. A comprehensive assessment of current dispensing practices is therefore needed to inform antimicrobial stewardship programmes (ASPs) among community pharmacies in Iraq [23,30,31]. To guide the study and its policy relevance, a pragmatic conceptual framework was adopted linking observed community pharmacy practices to AMS intervention pathways. Within this framework, inappropriate non-prescription antibiotic dispensing reflects gaps in regulatory governance and enforcement; the type of antibiotics supplied, particularly use of Watch agents, reflects stewardship and guideline adherence failures [27]; counseling and clinical enquiry practices indicate deficiencies in professional competence and training [21]; and variation by staff qualification highlights workforce and scope-of-practice issues [17,24].

Together, these domains align with four core AMS levers in community settings [19,23]: (i) regulatory enforcement and accountability, (ii) stewardship-aligned antibiotic selection using the WHO AWaRe framework, (iii) education and training to improve counseling and clinical assessment, and (iv) integration of community pharmacy data into national AMR surveillance systems. This framework underpins the study objectives and informs the identification of targeted, pharmacist-led AMS interventions appropriate for the Iraqi context.

## 2. Method

### 2.1. Study design and setting

This cross-sectional study employed Simulated Client Methodology (SCM) to objectively evaluate antibiotic dispensing practices among community pharmacies in Iraq [29]. The simulated client method was selected to capture actual dispensing practices and counseling behaviors in community pharmacies, including non-prescription antibiotic supply, which are not recorded in routine prescription or administrative datasets and would therefore not be observable using secondary data sources. The SCM is widely recognized as one of the most robust approaches for assessing real-world health-care provider behavior, minimizing reporting and observation bias [29]. The study was conducted between November 2024 and April 2025 (a period that overlaps with seasons in which respiratory infections are more commonly reported in Iraq) across five major urban centers in northern and central Iraq: Erbil, Sulaymaniyah, Kirkuk, Tikrit, and Baghdad. These locations were purposefully selected to represent diverse geographic, demographic, and socioeconomic contexts, collectively accounting for approximately 25% of the total Iraq's population of ~47.0 million. The inclusion of multiple provinces was intended to overcome the limitations of prior Iraqi studies [14,15], which were often restricted to single cities and relied primarily on qualitative or self-reported data. Details regarding consent requirements and the ethical justification for waiving individual consent from pharmacy personnel are provided in the Ethics statement section, consistent with the use of a SMC and the absence of identifiable personal data collection.

### 2.2. Study population and sample size

The target population comprised registered, licensed community pharmacies (CPs) operating under the supervision of the Syndicate of Iraqi Pharmacists. Pharmacies situated within hospital premises or unlicensed outlets were excluded. The minimum sample size was estimated at 366 CPs, calculated using a 95% confidence level ( $Z = 1.96$ ), an assumed prevalence of 0.5 (50%) for inappropriate antibiotic dispensing, and a 5% margin of error [32]. A prevalence of 0.5 was selected because it yields the maximum sample size when the true prevalence is uncertain, which is recommended for prevalence studies [33,34]. Because the primary objective was to estimate the prevalence of non-prescription antibiotic dispensing rather than to test a specific hypothesis, a formal power calculation was not seen as necessary. However, to enhance reliability and

generalizability, a simple random sampling strategy was applied to select 696 community pharmacies from a comprehensive registry of 7,550 licensed outlets across the five study provinces, obtained from the Syndicate of Iraqi Pharmacists, which served as the sampling frame. Within each selected pharmacy, the staff member on duty, whether a licensed pharmacist, nurse, or pharmacy assistant, was included, allowing the study to examine variations in dispensing behavior by professional background. Moreover, although the minimum required sample was 366, we intentionally sampled a larger number of pharmacies ( $n = 696$ ) to (i) increase the precision of the prevalence estimate and (ii) support planned subgroup estimates by city and staff professional category. With  $n = 696$ , the expected half-width of the 95% confidence interval around a prevalence estimate is narrower than with  $n = 366$  (improving precision for the primary outcome), and the larger sample provides more stable estimates within key strata [35]. In addition, the larger sample supported regression analyses and subgroup comparisons [36]. For example, based on the achieved group sizes (approximately 475 pharmacists and 215 nurses), the study had high power to detect practically meaningful differences in dispensing prevalence between these groups (e.g.  $\geq 12\%$ -point differences at  $\alpha = 0.05$ ) [32], while acknowledging that the study was not designed for fine-grained comparisons in small subgroups. The primary aim, however, remained estimation of the overall prevalence of non-prescription antibiotic dispensing.

### 2.3. Study outcomes: simulated client scenario and data collection

The primary outcomes of this study were to determine the extent and nature of antibiotic dispensing in community pharmacies without prescription. Data were collected using SCM, a validated behavioral research technique in which trained individuals enact predefined scenarios to objectively assess provider practices under real-world conditions. This approach minimizes social desirability bias and has been widely applied in LMICs to evaluate the appropriateness of antibiotic prescribing and dispensing [29,37,38].

For this study, a standardized simulated scenario was developed based on prior literature and refined using the structured questionnaire provided in *Supplementary File 1* [37–39]. The scenario involved a client requesting advice for a 20-year-old sibling at home experiencing mild sore throat, low-grade fever, and dry cough for two days, symptoms consistent with a viral upper respiratory tract infection (URTI) [11,40,41]. The simulated client scenario focused on an uncomplicated URIs because URIs are a common driver of inappropriate antibiotic use and a recognized target for AMS interventions. National evidence from Iraq consistently shows that antibiotics are frequently used for mild respiratory symptoms despite their predominantly viral and self-limiting nature, contributing substantially to avoidable antimicrobial exposure and resistance development [14–16]. From a policy perspective, reducing unnecessary antibiotic use for URIs is explicitly aligned with Iraq's NAP on AMR [19], which prioritizes optimization of antibiotic use in ambulatory care and community pharmacy settings where the majority of antibiotics are accessed.

Internationally, the WHO and UN AMR declarations identify URTIs as a key target condition for reducing inappropriate antibiotic consumption, particularly of Watch antibiotics, due to their high volume and low clinical justification [27,42].

To assess the threshold at which antibiotics were dispensed, three levels of escalation demands were applied, based on prior research [43]. Consistent with previous SCM studies [29,38], at the conclusion of each interaction, the client asked, 'Are you a pharmacist?' to prompt the provider's self-identification. Responses were recorded verbatim (e.g. *pharmacist, nurse, or pharmacy assistant*) and coded as categorical variables in subsequent regression analyses to examine whether professional background, as a proxy for knowledge, was associated with antibiotic dispensing behavior. The simulated clients were final-year pharmacy students who underwent two days of intensive, standardized training facilitated by a clinical pharmacist and the study supervisor. The training incorporated scenario role-play exercises, guidance on neutral and consistent case presentation, and detailed instructions on the accurate and timely completion of post-visit data forms. To ensure data quality and minimize recall bias, each simulated client completed the structured questionnaire immediately after each pharmacy visit. Completed forms were subsequently reviewed by a trained field coordinator, who conducted regular debriefing sessions and performance feedback to reinforce standardization. To ensure methodological standardization, all simulated clients followed a single scripted scenario with predefined symptoms and escalation prompts. Training included review of the scenario script and role-play exercises to ensure consistent case presentation. A structured data collection tool with predefined response options was used to minimize subjectivity (Supplementary File 1). The scenario and questionnaire were piloted in 15 pharmacies before full implementation, and completed forms were reviewed regularly by a field coordinator to maintain consistency across simulated clients. Given the covert nature of the SCM and the use of predefined categorical variables, formal inter-rater reliability statistics were not calculated; however, these multi-level training, piloting, and supervisory procedures are consistent with best practice recommendations for SCM studies in pharmacy and primary care research [29] and are widely used to ensure data reliability. Although audio recording was intentionally avoided to maintain the covert nature of the SCM visits, these multi-level validation procedures ensured consistency, reliability, and adherence to study protocols across all encounters.

All antibiotics dispensed were classified according to the World Health Organization (WHO) AWaRe framework, which categorizes agents into Access, Watch, and Reserve groups based on their resistance potential and public-health importance [27,44]. This system provides a globally standardized benchmark for evaluating antibiotic use and supports the United Nations General Assembly (UNGA) AMR target that at least 70% of antibiotic consumption in any setting should derive from the Access category [42]. To evaluate the quality of counseling practices following antibiotic dispensing, data were collected on whether community pharmacy staff provided guidance/advice regarding the correct use of the dispensed antibiotic, including information on dosage, route of

administration, frequency, and/or duration of therapy during the consultation. In addition, data were also collected on whether providers engaged in pre-dispensing clinical inquiry, such as asking about additional symptoms, past medical history, allergy status, or concurrent medication use, to determine the extent to which appropriate patient assessment and antimicrobial stewardship principles were applied in routine practice. Consequently, counseling quality was operationally defined a priori using a structured checklist based on antimicrobial stewardship and patient safety principles. Counseling components were then categorized into: (i) pre-dispensing clinical assessment (enquiry about symptoms, allergy status, medical history, or concurrent medicines), and (ii) post-dispensing instructions (dosage, frequency, route of administration, and treatment duration). Each component was recorded dichotomously (present/absent) using predefined response options in the data collection tool (Supplementary File 1). No composite score was calculated; instead, individual components were analyzed separately to allow transparent reporting of specific counseling gaps. To minimize subjectivity, only explicit and clearly articulated counseling elements were coded as present. Ambiguous, incomplete, or implied statements (e.g. vague advice without a stated dose or duration) were coded as absent. Where uncertainty arose, entries were reviewed during routine supervisory checks to ensure consistent interpretation across simulated clients. In addition to antibiotics, simulated clients recorded any other medicines supplied during the encounter. These were classified descriptively (e.g. antipyretics, analgesics, cough and cold preparations) to contextualize dispensing behavior; however, formal assessment of appropriateness or interaction risk was beyond the scope of the current analysis.

#### 2.4. Data analysis

Data were analyzed using descriptive and inferential statistics. Frequencies and percentages were reported for categorical variables, while continuous variables were summarized as mean (standard deviation, SD) or median (interquartile range, IQR), depending on data distribution. The overall prevalence of antibiotic dispensing without prescription was computed and subsequently stratified by key study covariates. To identify factors independently associated with antibiotic dispensing without prescription, a multivariable logistic regression model was fitted with antibiotic dispensing (yes/no) as the dependent variable. Covariates were selected a priori based on existing literature and contextual relevance and included staff professional category (pharmacist, nurse, pharmacy assistant), city (Erbil, Sulaymaniyah, Kirkuk, Tikrit, Baghdad), and provider's gender. These variables were chosen to capture differences in professional training, regulatory enforcement across regions, and potential demographic influences on dispensing behavior. Adjusted odds ratios (ORs) with 95% confidence intervals (CIs) were reported. Before model estimation, multicollinearity diagnostics were conducted using variance inflation factors (VIFs), all of which were below the accepted threshold, confirming the absence of multicollinearity. Model fit was evaluated using standard goodness-of-fit diagnostics appropriate for logistic regression. Given the large sample size

and binary outcome, the model was considered adequate for estimating associations between covariates and dispensing behavior. Sensitivity analyses were intentionally limited, as the primary aim of this study was to estimate the prevalence of non-prescription antibiotic supply rather than to make causal inferences. Stratified descriptive analyses by staff professional category and city were undertaken to examine the stability of prevalence estimates across key subgroups. More extensive sensitivity analyses, such as alternative model specifications or interaction testing, were not performed, as these were beyond the scope of the study objectives. All analyses were performed using STATA version 15 (StataCorp LLC, College Station, TX, U.S.A.). Ethical approval for the study was obtained from the Ethics Committee of Al-Kitab University, Iraq (Approval No. AKU-Pharm-2024-011).

### 3. Results

#### 3.1. Characteristics of participating community pharmacies

A total of 696 community pharmacies (CPs) across five Iraqi provinces were included in the study. Of the staff encountered, 68.2% ( $n = 475/696$ ) were licensed pharmacists, and 30.9% ( $n = 215/696$ ) were nurses (Table 1). Males accounted for 59.6% ( $n = 415/696$ ) of participants. The largest share of visits occurred in Kirkuk (30.6%,  $n = 213/696$ ), followed by Erbil (28.2%,  $n = 196/696$ ) (Table 1).

#### 3.2. Prevalence and pattern of antibiotic dispensing without a prescription

Of the 696 pharmacies visited, 561 (80.6%; 95%CI: 77.6–83.5%) dispensed at least one antibiotic without a valid prescription. Among the antibiotic dispensing encounters, 83.1% ( $n = 466/561$ ) provided antibiotics immediately after symptom description (demand level 1), and 11.2% ( $n = 63/651$ ) did so after the client requested ‘something stronger’ (demand level 2) (Table 2).

#### 3.3. Types and classes of antibiotics dispensed without a prescription

Across all non-prescription encounters, 561 antibiotics were supplied.  $\beta$ -lactams were the most frequently dispensed class (26.4%,  $n = 148/561$  for penicillins; 30.7%,  $n = 172/561$  for  $\beta$ -lactam/ $\beta$ -lactamase inhibitor combinations), followed by macrolides (27.1%,  $n = 152/561$ ) and cephalosporins (10.3%,  $n = 58/561$ ) (Table 2). Within these groups, the most common individual agents were amoxicillin – clavulanate (30.7%,  $n = 172/561$ ), amoxicillin (26.4%,  $n = 148/561$ ), and azithromycin (25.5%,  $n = 143/561$ ), with smaller proportions for clarithromycin (1.1%,  $n = 6/561$ ) and third-generation cephalosporins (7.8%,  $n = 44/561$ ) (Table 2). Fluoroquinolones (2.5%,  $n = 14/561$ ), including levofloxacin and ciprofloxacin, were dispensed less frequently, while aminoglycosides, tetracyclines, lincosamides, and sulfonamides collectively accounted for <2% (Table 2). According to the WHO AWaRe classification, Access antibiotics comprised 60.8% ( $n = 341/561$ ) (95%CI:56.9–65.0%) of those dispensed and Watch antibiotics 39.2% ( $n = 220/561$ ) (95%CI:34.9–43.1%). No Reserve antibiotics were supplied. Most antibiotics were dispensed for oral administration (92.9%,  $n = 646/561$ ), with only 7.1% provided parenterally ( $n = 50/561$ ). Recommended treatment duration ranged from one to ten days, with the majority advising 4–7 days (67.6%,  $n = 379/561$ ), while 27.3% ( $n = 153/561$ ) recommended  $\leq 3$  days (Table 2), suggesting inconsistent duration guidance across providers.

#### 3.4. Counseling and patient assessment practices

Although nearly all providers (99.0%,  $n = 555/561$ ) offered some form of instructions during dispensing, the depth and accuracy of counseling varied considerably. Only 15.3% ( $n = 86/561$ ) (95%CI: 12.3–18.3%) of staff asked additional clinical questions prior to dispensing (Table 3). Among these, half (50%,  $n = 43/86$ ) enquired about allergy or medication sensitivity, 40.7% ( $n = 35/86$ ) about respiratory symptoms (Table 3). Whilst 50.0% ( $n = 43/86$ ) of the 86 providers who asked any additional clinical questions inquired specifically about allergy status, this accounted for only 7.7% (95%CI:5.5–9.9%) of all antibiotic dispensing encounters ( $n = 43/561$ ), highlighting a critical gap in routine safety screening prior to dispensing.

**Table 1.** Baseline characteristics of the 696 community pharmacies, stratified by the status of dispensing antibiotics without a prescription.

Variables	Total, % (N = 696)	Antibiotics supplied	
		Yes (N = 561, 80.6%; 95%CI:77.6–83.5%)	No (N = 135, 19.4%; 95%CI:16.5–22.3%)
Gender*			
Male	59.6% (415)	81.2% (337; 95%CI:77.4–85.0%)	18.8% (78; 95%CI:15.0–22.6%)
Female	40.4% (281)	79.7% (224; 95%CI:75.0–84.5%)	20.3% (57; 95%CI:15.6–25.0)
Staff profession's type**			
Pharmacist	68.2% (475)	75.2% (357; 95%CI:71.3–79.1%)	24.8% (118; 95%CI:20.9–28.7%)
Nurse	30.9% (215)	93.0% (200; 95%CI:89.6–96.5%)	7.0% (15; 95%CI:3.5–10.4%)
Pharmacy Assistant (technician)	0.9% (6)	66.7% (4; 95%CI:12.5–99.5%)	33.3% (2; 95%CI:2.0–85.7%)
Cities**			
Kirkuk	30.6% (213)	73.7% (157; 95%CI:67.7–79.7%)	26.3% (56; 95%CI:20.3–32.3%)
Erbil	28.2% (196)	70.4% (138; 95%CI:64.0–76.9%)	29.6% (58; 95%CI:23.2–26.0%)
Sulaymaniyah	17.2% (120)	86.7% (104; 95%CI:80.5–92.8%)	13.3% (16; 95%CI:7.2–19.5%)
Baghdad	17.0% (118)	100% (118; NA)	0% (0; NA)
Tikrit	7.0% (49)	95.8% (47; 95%CI:92.1–99.5%)	4.2% (2; 95%CI:0.5–7.9%)

(Notes) \* indicate statistically non-significant difference ( $p > 0.05$ ); \*\* indicate statistically significant difference ( $p < 0.05$ )-obtained from the multivariable logistic regression.

**Table 2.** Characteristics of 561 antibiotics dispensed without a prescription among the 696 community pharmacies.

Variables	% (N)	95% Confidence interval
<b>Demand Level</b>		
1	83.1% (466)	80.0–86.2%
2	11.2% (63)	8.6–13.9%
3	5.7% (32)	3.8–7.6%
<b>Antibiotic names and classes</b>		
Beta-lactam/beta-lactamase-inhibitor	30.7% (172)	26.8–34.5%
• Amoxicillin/clavulanic acid	30.7% (172)	
Penicillins	26.4% (148)	22.7–30.0%
• Amoxicillin	26.4% (148)	
Macrolides	27.1% (152)	23.4–30.8%
• Azithromycin	25.5% (143)	
• Clarithromycin	1.1% (6)	
Cephalosporins	10.3% (58)	7.8–12.9%
• First-generation-cephalosporins	2.0% (11)	
• Second-generation-cephalosporins	0.5% (3)	
• Third-generation-cephalosporins	7.8% (44)	
Fluoroquinolones	2.5% (14)	1.2–3.8%
• Ciprofloxacin	0.7% (4)	
• Levofloxacin	1.8% (10)	
Lincosamides	0.7% (4)	0.1–1.4%
• Clindamycin	0.5% (3)	
• Lincomycin	0.2% (1)	
Tetracyclines	0.7% (4)	0.1–1.4%
• Doxycycline	0.2% (1)	
• Tetracycline	0.5% (3)	
Aminoglycosides	0.9% (5)	0.1–1.7%
• Gentamicin	0.9% (5)	
Carbapenems	0.2% (1)	0.01–0.5%
• Meropenem	0.2% (1)	
Rifamycins	0.2% (1)	0.01–0.5%
Sulfonamide-trimethoprim-combinations	0.4% (2)	0.1–0.9%
• Sulfamethoxazole/trimethoprim	0.4% (2)	
<b>AWaRe (WHO)</b>		
Access	60.8% (341)	56.9–65.0%
Watch	39.2% (220)	34.9–43.1%
<b>Duration of treatment</b>		
≤3 days	27.3% (153)	23.6–31.0%
4–7 days	67.6% (379)	63.7–71.4%
>7 days	5.2% (29)	3.3–7.0%
<b>Route of administration</b>		
Oral	92.9% (646)	88.2–96.8%
Parenteral	7.1% (50)	5.1–9.3%

**Table 3.** Counseling practices and inquiry patterns for the 561 antibiotics supplied/sold without prescriptions among the 696 community pharmacies.

Variables	% (N)	95% Confidence Interval
Advice on how to take the supplied antibiotic		
Yes	99.0% (555)	94.7–100%
No	1.0% (6)	0.2–4.0%
Asked any other questions		
Yes	15.3% (86)	12.3–18.3%
No	84.7% (475)	81.7–87.7%
Types of other questions asked (N = 86)		
Respiratory Symptoms (e.g. fever, dry/wet cough)	40.7% (35)	30.1–51.3%
Allergy and Medication Sensitivity	50.0% (43)	39.2–60.1%
Medical History and Chronic Conditions (e.g. hypertension, diabetes)	5.8% (5)	0.7–10.9%
Lifestyle and Behavioural Factors (e.g. smoking status, body weight)	3.5% (3)	0.4–7.5%

When stratified by professional cadre, pharmacists (14.3%;  $n = 51/357$ ) and nurses (16.5%;  $n = 33/200$ ) demonstrated comparable enquiry rates, whereas pharmacy assistants (50%;  $n = 2/4$ ) asked questions in half of the observed encounters. However, this difference was not statistically significant, as the small number of pharmacy assistants limited meaningful comparison. In addition to antibiotics, other medicines were frequently co-dispensed during the encounters. In 25.1% (141/561) of visits, no additional medicines were supplied alongside the antibiotic. Among encounters with co-dispensing, paracetamol was the most commonly supplied medicine (25.8%), followed by cough and cold preparations, including antitussives and combination products. These patterns suggest that antibiotics were often provided as part of a broader symptomatic treatment package rather than being reserved for clearly indicated bacterial infections.

### 3.5. Factors associated with non-prescription antibiotic dispensing

Multivariable analysis revealed that staff qualification and geographic location were statistically significant factors associated with non-prescription antibiotic dispensing (Table 1). The likelihood of dispensing antibiotics without prescription differed significantly by profession type (global  $p < 0.001$ ). Pharmacies staffed by non-pharmacist personnel were significantly more likely to supply antibiotics without prescription compared with those managed by licensed pharmacists (OR = 5.7; 95%CI: 3.2–10.1). Specifically, 93.0% ( $n = 200/215$ ) of nurses and 75.2% ( $n = 357/475$ ) of pharmacists engaged in non-prescription dispensing (Table 1). Significant regional variation in non-prescription antibiotic dispensing was observed. Dispensing was significantly more frequent in Baghdad (100%,  $n = 118/118$ ) and Tikrit (95.8%,  $n = 47/49$ ; OR = 10.2; 95%CI: 3.9–25.5) compared with the reference region, Kirkuk (73.7%,  $n = 157/213$ ). Higher odds were also observed in Sulaymaniyah (86.7%,  $n = 104/120$ ; OR = 2.9; 95%CI: 1.5–5.4), whereas Erbil showed no statistically significant difference relative to Kirkuk (70.4%,  $n = 138/196$ ; OR = 0.86; 95%CI: 0.55–1.40). Overall regional differences were statistically significant (global  $p < 0.001$ ) (Table 1). Gender (female vs. male) was not a statistically significant predictor after adjustment for other variables (OR = 1.2; 95%CI: 0.76–1.8). The direction and magnitude of associations observed in the multivariable model were consistent with stratified descriptive analyses by profession and region.

## 4. Discussion

### 4.1. Key findings

This nationwide simulated client study provides the first multi-province quantitative assessment of antibiotic dispensing practices among Iraqi community pharmacies. The findings reveal that non-prescription antibiotic sales remain common, occurring in more than four out of five pharmacy visits (80.6%). This high rate was despite existing regulations designating antibiotics as prescription-only medicines. These results underscore a critical gap between policy and practice and

indicate that the regulatory enforcement of dispensing laws remains weak across all regions of Iraq. The observed prevalence is substantially higher than that reported in earlier qualitative or city-specific studies in Iraq, which documented non-prescription sales rates of 35–78% in Baghdad, Basrah and Erbil [15,25]. This may be because community pharmacists taking part in qualitative studies may downplay this activity aware of the current regulations [45]. The inclusion of five major provinces, representing roughly one-quarter of the national population, provides robust, generalizable evidence that inappropriate and illegal antibiotic supply is systemic and widespread throughout Iraq rather than a localized problem. While global evidence provides important context [4,5,46], the exceptionally high prevalence observed in this study is best understood through Iraq-specific structural determinants. Despite antibiotics being legally classified as prescription-only medicines, enforcement of pharmacy regulations in Iraq remains weak, with limited inspection capacity, inconsistent penalties, and fragmented accountability between regulatory bodies [14,15,20]. In practice, this regulatory vacuum has normalized non-prescription antibiotic sales across provinces, resulting in widespread divergence between national policy and routine community pharmacy practice.

### 4.2. Patterns of antibiotic supply and AWaRe distribution

The antibiotics most frequently dispensed without prescription in our study were amoxicillin, amoxicillin – clavulanate, azithromycin, and 3<sup>rd</sup>-generation-cephalosporins, representing the most widely used broad-spectrum agents. Notably, 39.2% of dispensed antibiotics belonged to the WHO Watch category, which includes antibiotics associated with a higher resistance potential and for which their use should be restricted. While Access antibiotics accounted for 60.8%, this falls short of the WHO and UN General Assembly AMR target of 70% Access antibiotics [42]. The predominance of oral formulations (92.9%) reflects patient self-treatment behavior and accessibility of this formulation of antibiotics. In the Iraqi context, this pattern is likely reinforced by prescriber and dispenser perceptions that broader-spectrum antibiotics are more effective or more acceptable to patients, alongside limited awareness and operationalization of the WHO AWaRe framework within community pharmacy practice [15]. Unlike hospital settings, where stewardship oversight could have been better established, community pharmacies in Iraq operate largely outside structured AMS governance, allowing Watch antibiotics to be routinely supplied without clinical justification [14]. To date, there is lack of published studies in Iraq that have explicitly assessed the distribution of antibiotics dispensed without prescription in community pharmacies using the WHO AWaRe classification. Existing Iraqi evidence relevant to AWaRe patterns has instead been derived from hospital-based prescribing studies or from non-prescription antibiotic supply in other outpatient settings [17,18]. For example, a multicentre point prevalence survey of hospital antibiotic prescribing in the Kurdistan Region of Iraq reported high use of broad-spectrum antibiotics, including agents classified within the Watch group,

indicating suboptimal alignment with stewardship principles in inpatient care settings [18]. Similarly, a recent simulated client study conducted in nurse-led clinics in Iraq demonstrated frequent non-prescription supply of broad-spectrum antibiotics, many of which fall within the Watch category, although AWARe-specific reporting was not undertaken [17]. In community pharmacy settings, qualitative evidence has also highlighted widespread dispensing of broad-spectrum antibiotics in response to patient demand, suggesting a predominance of Watch group agents; however, these studies did not quantitatively classify antibiotics according to the AWARe framework [15]. Against this background, the present study provides the first quantitative assessment of non-prescription antibiotic supply in Iraqi community pharmacies explicitly framed within the WHO AWARe classification, thereby addressing an important evidence gap and enabling direct benchmarking against national and global stewardship targets.

#### 4.3. Counseling and clinical assessment practices

Although 99% of pharmacy personnel offered some counseling advice, the quality and clinical relevance of counseling were limited. Only 15% asked additional questions prior to dispensing, and less than 8% enquired about allergies, which is an essential step in safe prescribing. Within Iraq, inadequate counseling appears closely linked to workforce composition and operational realities in community pharmacies. Qualitative evidence indicates that many privately owned pharmacies rely on nurses or assistants for medicine supply, particularly during extended opening hours, often with limited on-site pharmacist supervision [15]. In such settings, antibiotic dispensing is frequently conducted as a transactional activity with minimal clinical engagement, resulting in limited patient assessment and undermining safe antibiotic use, a pattern also observed in simulated-client studies in comparable outpatient settings [17]. Pharmacists, while more likely to provide advice than nurses or assistants, still exhibited major knowledge gaps and inconsistent patient interaction. This pattern parallels the results from nurse-led clinic settings in Iraq [17], suggesting that across both sectors, frontline healthcare providers frequently rely on empirical practice rather than evidence-based guidance. The absence of structured AMS training, combined with commercial and workload pressures, appears to reinforce a transactional rather than clinical model of patient care. Although counseling practices were quantified using predefined indicators, consistent qualitative patterns were observed across simulated client encounters. Interactions were typically brief and transactional, with minimal probing beyond the initial request for antibiotics. When counseling occurred, it most often consisted of simple dosage instructions, while enquiries about symptom duration, allergy status, or concurrent medicines were rarely initiated. In several encounters, antibiotics were supplied immediately following the request, with little or no verbal exchange/interaction afterward. These observations help contextualize the quantitative findings and suggest that counseling in community pharmacy settings is frequently treated as an optional rather than integral component of antibiotic supply. Such interaction styles

may reflect time pressures, commercial incentives, and limited stewardship training [25], and are likely to undermine safe and appropriate antibiotic use. Importantly, it should be noted that inadequate counseling and limited clinical assessment have important patient safety implications, including increased risks of allergic reactions, incorrect dosing or duration, drug interactions, and inappropriate antibiotic exposure that may contribute to adverse events and AMR. The frequent co-dispensing of antibiotics with symptomatic treatments such as paracetamol and cough and cold preparations further indicates that antibiotics are routinely positioned as adjuncts to symptomatic care for self-limiting respiratory illnesses, reinforcing patterns of unnecessary antibiotic exposure.

#### 4.4. Determinants of inappropriate dispensing

The present study identified both professional background and geographic location as key determinants of inappropriate antibiotic dispensing without prescription in Iraq. Importantly, although pharmacists are the legally responsible license holders for community pharmacies in Iraq, our findings indicate that nurses were responsible for a substantial proportion of dispensing encounters. This observation underscores that inappropriate antibiotic dispensing in community pharmacies cannot be attributed solely to pharmacists but reflects the practices of the broader pharmacy workforce involved in medicine supply. Pharmacies staffed by non-pharmacist personnel, primarily nurses, were almost six times more likely to dispense antibiotics without prescription compared with those managed by licensed pharmacists. This finding is consistent with earlier qualitative research in Iraq and across other LMICs, which revealed that knowledge gaps, limited stewardship training, and lower confidence in clinical decision-making among non-pharmacist staff contribute substantially to inappropriate antibiotic use [15,24]. Non-pharmacist staff often view antibiotics as benign, multipurpose agents suitable for a broad range of self-limiting conditions, reflecting misperceptions about antibiotic safety and necessity that persist in the absence of professional supervision [5,47]. The predominance of non-pharmacist dispensing in Iraq's private pharmacy sector may also reflect economic pressures and structural gaps in regulatory enforcement. In many privately owned pharmacies, nurses or assistants operate in the absence of a supervising pharmacist, particularly during extended hours, enabling the sale of antibiotics as a routine commercial transaction rather than a clinical decision [17]. In Iraq, these commercial pressures are intensified by the predominance of privately owned community pharmacies operating within highly competitive urban markets. Qualitative evidence indicates that pharmacy income is largely derived from medicine sales rather than remuneration for professional or cognitive services, creating strong financial incentives to meet patient demand for antibiotics [17]. In the absence of routine regulatory audits, consistent inspection, or enforceable sanctions, non-prescription antibiotic dispensing has become a normalized and economically rational practice within community pharmacies, despite being clinically inappropriate and contrary

to national regulations [17,20]. This commercialization of antibiotic supply highlights the urgent need to strengthen professional accountability and licensing oversight within Iraq's community pharmacy network alongside improve knowledge and skills of community pharmacists [25,46]. Overall, non-prescription antibiotic dispensing in Iraq is also influenced by access barriers within the health system. Limited availability of primary care services, long waiting times in public facilities, and out-of-pocket costs for private consultations may encourage patients to seek treatment directly from pharmacies [15,20]. These factors, combined with weak regulatory enforcement, contribute to the normalization of non-prescription antibiotic supply.

Marked regional disparities further illustrate the uneven enforcement of pharmacy laws and stewardship frameworks. The extremely high dispensing rates observed in Baghdad (100%) and Tikrit (95.8%) contrast sharply with lower rates in Erbil (70.4%) and Kirkuk (73.7%) likely reflects differences in local enforcement intensity, market density, and regulatory oversight across Iraqi provinces. National and international assessments have highlighted substantial sub-national variability in inspection capacity and regulatory implementation within Iraq, which may contribute to divergent community pharmacy practices [20]. Provinces such as Baghdad and Tikrit, characterized by high population density and dense concentrations of privately owned pharmacies, exhibited near-universal non-prescription antibiotic dispensing, consistent with evidence linking competitive urban pharmacy markets to higher levels of inappropriate antibiotic supply [15,28].

By contrast, comparatively lower dispensing rates observed in Erbil and Kirkuk may reflect stronger professional norms, differences in regional governance arrangements within the Kurdistan Region of Iraq, and closer links between community pharmacies, academic institutions, and professional training centers, factors that have been associated with more conservative antibiotic dispensing behaviors in similar settings [17,25].

The absence of significant gender differences in dispensing behavior suggests that these practices are systemic and culturally embedded, rather than dependent on individual characteristics. This aligns with findings from global meta-analyses showing that contextual and institutional factors such as workload, profit motives, and regulatory laxity exert stronger influence on antibiotic sales than provider demographics [5,24]. In Iraq, inappropriate antibiotic dispensing largely reflects structural factors rather than individual noncompliance. The predominance of privately owned community pharmacies operating in competitive retail markets creates financial incentives to meet patient demand for antibiotics [15]. These pressures are compounded by regulatory gaps, including limited inspection capacity and inconsistent enforcement, resulting in a disconnect between national policy and routine dispensing practices [20]. Similar patterns have been reported in other low- and middle-income settings where policy restrictions are weakly enforced [28]. Addressing these drivers therefore requires coordinated regulatory enforcement, stewardship training, and professional accountability mechanisms.

#### 4.5. Implications for antimicrobial resistance and stewardship

Interpreted through the conceptual framework outlined in the introduction, our findings highlight how regulatory, professional, and stewardship gaps in community pharmacy practice converge to drive inappropriate antibiotic use in Iraq, necessary for Iraq's ongoing efforts to combat AMR and to operationalize its NAP on AMR (2018–2022). The widespread non-prescription sale of antibiotics observed across community pharmacies, particularly the high proportion of Watch antibiotics (39.2%), represents a substantial challenge to achieving both national and global antimicrobial stewardship (AMS) objectives. The high proportion of macrolides, fluoroquinolones, and  $\beta$ -lactam/ $\beta$ -lactamase inhibitor combinations dispensed without prescription is particularly concerning as these Watch-group antibiotics have been repeatedly implicated in the rapid emergence of resistance among *Escherichia coli*, *Klebsiella pneumoniae*, and *Staphylococcus aureus* organisms already demonstrating carbapenem-resistant and extended-spectrum  $\beta$ -lactamase (ESBL) phenotypes across the Eastern Mediterranean region [48]. Local surveillance data from Iraq have confirmed increasing rates of multidrug-resistant Enterobacterales, exceeding 60% in some tertiary hospitals, suggesting that community-level misuse likely contributes to hospital-level resistance burdens [14].

In Iraq, community pharmacies represent one of the most consistently accessible healthcare professionals, particularly in contexts where access to primary care physicians is constrained by cost, long waiting times, and geographic availability [20]. Despite this accessibility, the potential contribution of community pharmacists to AMS remains underutilized due to limited formal authority, weak integration into national AMR strategies, and insufficient regulatory and institutional support for pharmacist-led stewardship activities [15,19]. Strengthening pharmacist leadership within community settings, supported by clear scope-of-practice definitions and regulatory enforcement, therefore represents a critical and context-specific opportunity for improving antibiotic governance and promoting responsible antibiotic use in Iraq [14,18]. Unlike nurse-led clinics [17], where inappropriate antibiotic prescribing often stems from diagnostic uncertainty, community pharmacy dispensing is predominantly driven by consumer demand, economic incentives, and a lack of enforcement [5]. The finding that almost 80% of pharmacists supplied antibiotics after only a brief symptom description, without adequate assessment or counseling, highlights that knowledge of stewardship principles remains superficial, despite growing global attention to the AWaRe framework and responsible antibiotic use [24]. In many LMICs, including Iraq, community pharmacies are often the first point of contact for patients due to barriers in accessing primary care, such as long waiting times and consultation costs [46,49–51]. However, this advantage is offset by widespread inappropriate prescribing by other healthcare providers [4,17], reinforcing that a total ban on non-prescription antibiotic sales would be counterproductive. Instead, international experience supports a regulated, stewardship-oriented model that empowers trained pharmacists to supply a limited range of Access antibiotics for defined conditions.

Examples from Canada, New Zealand, and the United Kingdom show that such models improve patient outcomes, satisfaction, and timeliness of care while maintaining antibiotic oversight [31]. Pharmacists in LMICs have also become increasingly involved in educating prescribers and participating in AMS programs, improving prescribing quality and communication with patients [21,52,53]. Evidence from Iraq and neighboring countries confirms that structured educational interventions for community pharmacists can significantly reduce inappropriate antibiotic dispensing and enhance patient counseling [24,26,54]. Internationally, community-based stewardship initiatives have proven highly effective when pharmacists are empowered and supported by clear policy frameworks [25,32]. Educational and regulatory reforms such as mandatory prescription audits and public awareness campaigns have led to 20–40% reductions in non-prescription antibiotic sales within five years [11,40]. In the Republic of Srpska, stricter community pharmacy monitoring combined with updated infectious disease guidelines markedly reduced non-prescription antibiotic dispensing [55]. Similarly, pharmacist- and patient-targeted education campaigns in Indonesia led to a significant decline in such practices [56].

In Iraq, stewardship initiatives have largely focused on the hospital sector, leaving community pharmacies underutilized. Expanding AMS to the community level, supported by standardized national guidelines, digital prescription tracking, and continuing professional development (CPD), is essential to bridge this gap. Furthermore, Iraq's fragmented, privately dominated pharmaceutical market and weak integration with primary care systems exacerbate AMR risks by allowing antibiotics to circulate outside formal clinical governance [14,19]. According to the WHO and FAO One Health framework, AMR containment demands a coordinated, multisectoral approach spanning human, animal, and environmental health [57]. Yet, community pharmacies in Iraq remain largely absent from national AMR surveillance systems, including GLASS [14]. Incorporating pharmacy dispensing data into these networks would enable real-time monitoring of antibiotic consumption and early detection of inappropriate use. Furthermore, the involvement of nurses in medicine supply indicates that stewardship interventions must consider the broader workforce involved in dispensing practices. Taken together, these findings reinforce that addressing AMR in Iraq requires a paradigm shift from viewing community pharmacies solely as contributors to antibiotic misuse, to recognizing them as critical partners in AMR containment as seen in other countries [21–23,31]. By investing in pharmacist-led stewardship training, surveillance integration, and AWaRe-aligned practice standards, Iraq can substantially enhance its capacity to reduce inappropriate antibiotic use and align with global AMR containment goals.

#### **4.6. Policy implications and strategies to mitigate AMR**

The findings from this study highlight the urgent need for coordinated policy reforms to address inappropriate antibiotic dispensing in Iraq's community pharmacies and strengthen AMS capacity. Given that community pharmacies are the main point of antibiotic access for the population, they should be repositioned as key actors within Iraq's AMR response,

rather than peripheral providers. Regulatory actions should prioritize the establishment of a stewardship-oriented dispensing model, supported by clear national protocols, community pharmacy personnel training, and defined clinical pathways for managing minor infections. Given that nurses were involved in nearly one-third of dispensing encounters in this study, stewardship strategies should not focus solely on pharmacists but should also address the wider community pharmacy workforce. Training programs, regulatory guidance, and supervision mechanisms should therefore ensure that all personnel involved in medicine supply operate within clear antimicrobial stewardship frameworks under pharmacist oversight. Evidence from high- and middle-income countries demonstrates that allowing trained pharmacists to dispense selected Access antibiotics under regulated conditions can maintain patient access while improving prescribing safety and compliance [31]. This approach represents a practical alternative to complete prohibition, which has limited feasibility in LMIC contexts. Feasible stewardship interventions in Iraq include strengthening pharmacy inspections and expanding antimicrobial stewardship training through existing professional and regulatory structures [19,20]. More resource-intensive reforms, including remuneration for pharmacist-led clinical services or regulated pharmacist-only access to selected antibiotics, are likely to require phased implementation and alignment with broader health system financing reforms. Evidence from Iraq and comparable settings indicates that, in the absence of effective regulatory enforcement and mechanisms to address market-driven financial incentives within privately owned community pharmacies, isolated policy reforms are unlikely to result in sustained reductions in inappropriate antibiotic use [15,28]. At the system level, digital prescription validation and monitoring tools are needed to ensure accountability and generate data for surveillance. Integrating community pharmacy dispensing data into Iraq's national AMR surveillance system, and ultimately into WHO GLASS, would provide real-time insights into antibiotic utilization patterns and enable early detection of misuse trends. Sustained investment in continuing professional development (CPD) is equally critical. Embedding AMS and AWaRe-aligned training modules into pharmacy curricula and professional licensing requirements would strengthen pharmacists' knowledge and stewardship skills [24,26,54].

Moreover, public awareness campaigns aligned with WHO's World Antimicrobial Awareness Week could reduce self-medication and shape responsible health-seeking behavior. Finally, successful implementation of these strategies will require multisectoral collaboration involving the Ministry of Health, Iraqi Pharmacists Syndicate, academic institutions, and international partners, underpinned by the One Health framework [57]. However, given the inherent limitations of pharmacy-based consultations, including the absence of diagnostic testing and microbiological confirmation, unrestricted access to a wide range of antibiotics in community pharmacies is unlikely to support appropriate or targeted treatment. Strengthening regulations to restrict non-prescription access to selected antibiotics, particularly broad-spectrum and Watch agents, while limiting any pharmacist-led supply to clearly

**Table 4.** Recommended strategies to improve antibiotic use and reduce antimicrobial resistance in Iraq.

Level	Strategic action	Rationale and expected impact	Supporting references
Regulatory	Implement a regulated stewardship model allowing trained pharmacists to dispense a limited list of Access antibiotics for specified minor infections under defined clinical protocols.	Balances patient access and resistance control; avoids the unintended consequences of a total ban while ensuring responsible antibiotic supply.	[4,17,31]
Regulatory	Introduce digital prescription validation and audit systems linking pharmacies with primary care and national AMR databases.	Enables real-time monitoring of antibiotic use and improves regulatory oversight to identify high-risk areas.	[11,14,40]
Educational	Integrate antimicrobial stewardship (AMS) and WHO AWaRe training modules into undergraduate curricula and continuing professional development (CPD) programmes.	Builds pharmacist competence in stewardship, improves counseling and clinical assessment, and reduces inappropriate dispensing.	[24,26,46,54]
Professional	Establish national pharmacy AMS guidelines supported by the Iraqi Pharmacists Syndicate and Ministry of Health.	Provides clear standards for antibiotic dispensing, counseling, and referral, ensuring consistency across community pharmacies.	[14,19,21]
Public	Conduct sustained public awareness campaigns on AMR and appropriate antibiotic use, aligned with WHO's <i>World Antimicrobial Awareness Week</i> .	Reduces self-medication and patient demand for antibiotics without prescription.	[11,40,56]
System-level	Integrate community pharmacy dispensing data into Iraq's national AMR surveillance system and WHO GLASS.	Strengthens AMR monitoring across human, animal, and environmental sectors in line with the One Health framework.	[14,57]
Collaborative	Foster multisectoral partnerships among the Ministry of Health, professional bodies, academia, and international agencies to coordinate AMR policy implementation.	Promotes sustainability, harmonizes stewardship initiatives, and aligns Iraq's approach with global AMR control priorities.	[21–23,31,57]

defined Access antibiotics under national protocols may represent a more feasible and safer stewardship approach. Such measures should complement, rather than replace, physician-led diagnosis and laboratory-supported treatment pathways. The coordinated efforts, summarized in Table 4, would transform Iraq's community pharmacy sector from a major source of antibiotic misuse into a central pillar of national and regional AMR containment efforts.

#### 4.7. Strengths and limitations

This study represents the first multi-province, quantitative assessment of non-prescription antibiotic supply in Iraqi community pharmacies using a SCM. The use of simulated client methodology was necessitated by the absence of comprehensive, accessible community pharmacy prescription or dispensing datasets in Iraq, particularly for non-prescription transactions. While this limits direct linkage to patient-level clinical outcomes, SCM provides a robust approach for evaluating real-world practice in settings where routine data do not capture informal antibiotic supply. By incorporating pharmacies across five major provinces and using a standardized scenario reflecting a common upper respiratory tract infection, the study provides robust, generalizable insights into real-world dispensing behaviors. The SCM approach, widely regarded as the gold standard for assessing provider behavior, minimizes recall and social desirability bias, yielding more accurate estimates than self-reported or interview-based studies [29]. The inclusion of both pharmacist and non-pharmacist providers also allowed examination of professional practice differences that have not been systematically studied in Iraq before.

However, several limitations should be acknowledged. First, the study was limited to urban pharmacies, and findings may not fully represent practices in rural or remote areas, where healthcare access and regulatory oversight differ. Second, only a single clinical scenario (URTI) was assessed; dispensing behaviors may vary with other infection types or levels of perceived severity. Third, although simulated clients were carefully

trained, subjective interpretation of counseling quality could not be entirely eliminated. Furthermore, although formal inter-rater reliability coefficients were not calculated, the use of scripted scenarios, standardized training, piloting, immediate post-visit recording, and supervisory review ensured a high level of consistency across simulated client encounters. Moreover, the cross-sectional design captures behavior at one point in time and may not account for seasonal or policy-related changes in antibiotic sales. Additionally, data collection coincided partly with months when respiratory symptoms are more prevalent, which may have increased patient presentations for upper respiratory tract infections. While this could have influenced the volume of antibiotic requests, it is unlikely to alter the study's central conclusions, as antibiotics are not routinely indicated for uncomplicated viral respiratory infections, and the findings primarily reflect dispensing and counseling behaviors rather than disease incidence. Moreover, this study assessed dispensing behavior at the community pharmacy level rather than examining the professional competencies of individual staff members in detail. Although dispensing encounters in this study involved multiple categories of personnel, the manuscript places greater emphasis on pharmacists because they are the legally licensed owners and supervisors of community pharmacies in Iraq and therefore hold professional and regulatory responsibility for dispensing practices within these settings. This accountability is particularly relevant in the context of AMR and AMS, where pharmacists are expected to play a central role in ensuring appropriate antibiotic use and compliance with national regulations. At the same time, recognizing the involvement of nurses in medicine supply within community pharmacies indicates that these workforce dynamics should be considered when interpreting the study findings and when designing future AMS interventions targeting community pharmacy practice. Finally, this study did not assess antimicrobial resistance – associated morbidity or mortality, as estimating such outcomes requires microbiological and population-level mortality data that were beyond the scope of the simulated client

design and study objectives. Despite these limitations, we believe this study provides highly credible, policy-relevant evidence on antibiotic dispensing practices in Iraq and offers a scalable methodological framework for ongoing national AMR surveillance and intervention evaluation.

#### 4.8. Conclusion

This national study demonstrates that non-prescription antibiotic dispensing remains pervasive across Iraqi community pharmacies, with limited patient assessment and poor counseling practices. The widespread use of Watch antibiotics poses a clear threat to antimicrobial resistance control and underscores significant gaps in community-level stewardship. Community pharmacies represent a potentially important but currently underutilized resource for antimicrobial stewardship in Iraq. Although pharmacists are the legally responsible license holders for community pharmacies and therefore hold professional accountability for dispensing practices, our findings indicate that other personnel, including nurses, are also involved in a substantial proportion of antibiotic dispensing encounters. This workforce dynamic has important implications for antimicrobial resistance containment, as inappropriate antibiotic supply by multiple categories of staff may further increase unnecessary antimicrobial exposure in the community. While regulated pharmacist-led antimicrobial stewardship models have been proposed internationally, their feasibility and effectiveness in Iraq is contingent upon addressing underlying systemic barriers, including weak regulatory enforcement, reliance on medicine sales within privately owned pharmacies, workforce constraints, and limited integration of community pharmacies into national AMR governance structures. In this context, incremental and system-aligned measures such as strengthening enforcement of prescription-only regulations, expanding stewardship training through existing professional bodies, and piloting pharmacist-led roles within clearly defined and supervised frameworks that also consider the broader pharmacy workforce may represent more realistic pathways to impact. Integrating pharmacies into national AMR surveillance systems, strengthening AMS training, and improving public awareness are essential next steps. However, without parallel reforms to regulatory capacity and economic incentives, these measures alone are unlikely to achieve sustained reductions in inappropriate antibiotic use. Recognizing community pharmacists as potential partners in AMR containment while acknowledging the roles of other staff such as nurses involved in medicine supply must therefore be accompanied by enforceable governance, professional accountability, and phased implementation strategies to translate this potential into meaningful improvements in antibiotic governance in Iraq.

#### Acknowledgments

The authors would like to express their sincere gratitude to selected group of final-year pharmacy students from the College of Pharmacy, Al-Kitab University, for their invaluable contribution to data collection and fieldwork during this study. Their professionalism, commitment, and adherence to the study protocol were instrumental in ensuring the quality and reliability of the

data obtained through the simulated client methodology. We also extend our appreciation to the College of Pharmacy, Al-Kitab University, for its continuous academic support and facilitation of ethical approvals. The authors gratefully acknowledge the constructive collaboration and dedication demonstrated by all participating students and staff throughout the project.

Authors A. Kurdi, O. Darweesh and B. Godman all made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

#### Author contributions

CRediT: **Omeed Darweesh:** Conceptualization, Data curation, Methodology, Writing – original draft, Writing – review & editing; **Brian Godman:** Conceptualization, Investigation, Methodology, Writing – original draft, Writing – review & editing; **Amanj Kurdi:** Conceptualization, Formal analysis, Investigation, Methodology, Validation, Writing – original draft, Writing – review & editing.

#### Funding

This paper was not funded.

#### Declaration of interests

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

#### Reviewer disclosures

Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

#### Ethics statement

Ethical approval for this study was obtained from the Ethics Committee of Al-Kitab University, Iraq (Approval No. AKU-Pharm-2024-011). The study employed a simulated client methodology (SCM), a recognized and ethically accepted approach for assessing real-world healthcare practices, particularly where self-reporting or observation may introduce bias and where regulatory compliance is limited [29,38]. The SCM approach enables direct observation of provider behavior in natural settings, making it especially suitable for evaluating antibiotic dispensing without prescription, behaviors that may otherwise be concealed when providers are aware of being studied. Obtaining informed consent prior to data collection would have compromised the study's validity by altering behavior and introducing social desirability bias [59,60]. Accordingly, the Ethics Committee waived the requirement for individual informed consent, citing the study's minimal risk to participants. No personal identifiers were recorded, and all data were anonymized prior to analysis. In line with international ethical guidance for noninvasive observational research using covert methods, individual debriefing was not undertaken to preserve anonymity and avoid punitive consequences. However, aggregated, anonymized findings will be shared with relevant national stakeholders to inform antimicrobial stewardship (AMS) and regulatory policy. This waiver and methodology are consistent with ethical precedents from similar SCM-based studies in LMICs evaluating antibiotic use in pharmacies and clinics, which have contributed valuable evidence to AMR policy and governance frameworks [28,38,59].

## Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request. Due to the sensitive nature of the simulated client methodology and the need to protect the anonymity of participating pharmacies and staff, the dataset is not publicly available. Aggregated, de-identified data may be shared with qualified researchers or public health authorities for purposes of verification or further analysis, subject to institutional and ethical approval.

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