

Cost, availability and affordability of antibiotics in Islamic Republic of Iran

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Abstract

Background: Cost, availability and accessibility can influence the patterns of antibiotic use, adherence to prescriptions and the development of antimicrobial resistance.

Aim: To assess the cost, availability and affordability of antibiotics in Islamic Republic of Iran using the WHO access, watch and reserve classification.

Methods: We analysed secondary data for March 2023 to March 2024 on cost, availability and affordability of antibiotics in Islamic Republic of Iran, using the WHO access, watch and reserve classification. Cost and affordability were compared between the access, watch and reserve antibiotic groups using the Kruskal–Wallis and Mann–Whitney U tests. $P \leq 0.05$ was considered statistically significant.

Results: Most injectable antibiotics were unaffordable while most oral formulations were affordable. Among the injectables, streptomycin was the cheapest (15 000 IRR/defined daily dose), followed by procaine-benzylpenicillin (82 325 IRR/defined daily dose), while temocillin was the most expensive (25 828 000 IRR/defined daily dose). However, streptomycin and temocillin were not in the essential medicines list. Among the orals, nitrofurantoin was the cheapest (12 370 IRR/defined daily dose) while linezolid was the most expensive (1 030 558 IRR/defined daily dose). There were statistically significant differences in prices ($P = 0.007$) and affordability ($P = 0.035$) between the access, watch and reserve groups. Affordability was significantly lower for the reserve group of antibiotics ($P = 0.04$).

Conclusion: Our findings show that although access antibiotics remain largely affordable, watch group antibiotics were used excessively. Targeted policies are needed on the pricing, production, distribution, and prescription of antibiotics in Islamic Republic of Iran to promote rational use and curb antimicrobial resistance.

Keywords: antibiotic, AWaRe classification, availability, affordability, cost, access, watch, reserve, Iran

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Introduction

Antimicrobial resistance (AMR) is a global public health threat that undermines the prevention and treatment of infectious diseases (1). In 2021, AMR was responsible for an estimated 1.14 million deaths worldwide – more than HIV/AIDS and malaria combined (1). In Islamic Republic of Iran, AMR accounted for 6928 deaths attributable to AMR and 25 419 associated deaths (2), exceeding fatalities from transport injuries, neurologic disorders, chronic respiratory diseases, unintentional injuries, and digestive diseases. Treating resistant microbial infections often requires more expensive medicines, longer hospital stays, and more intensive care, leading to higher health care costs. AMR-related infectious diseases can cause significant productivity losses due to increased morbidity and mortality, resulting in substantial economic impact (3).

WHO launched the Global Action Plan (GAP) on AMR in 2015, endorsed by the World Organisation for Animal Health (WOAH) and Food and Agriculture Organization (FAO). The GAP guides countries in developing and implementing national action plans to combat AMR (4). One strategic objective of the GAP focuses on optimising antimicrobial use in humans, animals, and plants through antimicrobial stewardship (AMS) (5), which is included in the National Action Plan (NAP) of Islamic Republic of Iran.

The access, watch, and reserve (AWaRe) classification, introduced by WHO in 2017, is a cornerstone of AMS, classifying antibiotics into 3 groups: access, watch, and reserve. WHO recommends that access antibiotics account for at least 70% of total consumption and that prescribers prioritise effective treatment (6,7).

The Iran Food and Drug Administration (IFDA) reported an increase in national antimicrobial consumption from 51.60 defined daily doses (DDD) per 1000 inhabitants per day (DID) in 2020 to 67.4 DID in 2022, with watch group use increasing from 49.4% to 53.1% (8).

Affordability – determined by medicine prices, insurance coverage, household income, and clinical indication – directly affects access, as poor affordability can lead to incomplete treatment courses and worsen AMR (9). No previous studies in Islamic Republic of Iran have assessed antibiotic availability, cost, and affordability in relation to AWARe. This study addresses that gap by evaluating cost, availability and affordability of antibiotics distributed nationally, to generate evidence for strengthening antimicrobial stewardship policies and practices.

Methods

Study setting

The Islamic Republic of Iran Council for the Review and Compilation of the Official Drug approves authorised medicines for the market (10). The IFDA regulates all aspects of the pharmaceutical sector, including drug registration, pricing, marketing, distribution, rational use, counterfeit prevention, national formulary, and pharmacy practice (11). Data submitted to IFDA are subject to strict guidelines and rigorous review to ensure compliance with safety and efficacy standards.

Study design

We conducted a cross-sectional study using secondary data from the IFDA for the official Iranian year 2023, (1 March 2023–1 March, 2024). The variables included all antibiotics classified under the anatomical therapeutic chemical (ATC) subgroup J01 (antibiotics for systemic use) registered and distributed in 2023. Data were collected on antibiotic counts, marketing authorisation holders (MAHs), consumption measured in defined daily doses (DDD), and costs in Iranian Rials (IRR), categorised by antibiotic class, route of administration (oral and injectable), and the WHO AWARe classification (access: first-line treatments; watch: higher resistance risk; reserve: last-resort options for severe infections).

The study used the 2023 WHO AWARe classification, the 23rd WHO Model List of Essential Medicines (EML), Iran's National Essential Medicines List (NEML), and the WHO ATC/DDD index (12–14). Medicine prices were obtained from the IFDA website, and 2023 sales data were obtained from the Amarnam database, which compiles annual distributor reports used by IFDA (15,16).

To calculate the cost of DDD per product/brand in Iranian rial per DDD, we used the public price of the antibiotic, its pack size (number of units), strength, and DDD. The generic-based pharmaceutical system of Islamic Republic of Iran sets uniform prices for medicines with the same active ingredient, dosage form, and strength, determined centrally by IFDA. The average cost per DDD was

then calculated for each antibiotic across all the products/brands. The highest and lowest costs per DDD were also recorded.

The highest and lowest cost per DDD for each antibiotic were used to calculate the cost ratio and percentage cost variation. The cost ratio was calculated by dividing the highest cost per DDD by the lowest cost per DDD. The percentage cost variation was calculated as the difference between the highest and lowest cost per DDD expressed as a percentage (17). Antibiotic affordability was calculated according to WHO and Health Action International (HAI) definitions (18,19). The Iranian Ministry of Labour has set the minimum monthly wage for 2023 at 54 million IRR (20). The affordability threshold was set at the daily wage based on this amount ($\approx 1\,800\,000$ IRR). If the lowest cost per DDD of an antibiotic was below the minimum daily wage, it was considered “affordable”.

Statistical analysis

Data were extracted from the IFDA price database and the Amarnam sales database and analysed using Microsoft Excel and SPSS version 26. The distribution of the quantitative variables was assessed both graphically and statistically. As the data were skewed, results were reported as the median and inter-quantile range (IQR; 25th–27th percentile). The Mann-Whitney U and Kruskal-Wallis tests were applied to compare the median cost per DDD and the number of MAHs across AWARe categories. For oral antibiotics, the reserve group was excluded from testing, because only one sample was available. Fisher's exact test was used to evaluate differences in the proportion of affordable antibiotics among AWARe categories. $P \leq 0.05$ was considered statistically significant.

Ethics considerations

Since the dataset comprised secondary, aggregated, and non-identifiable data, publicly available to the principal investigators through their authorised access to the IFDA system, and used in accordance with applicable regulations, ethics approval was not required for this study

Results

Availability of antibiotics

This study identified and analysed the distribution of 30 injectable (Table 1) and 25 oral (Table 2) antibiotics categorised as: injectable (36% access, 53% watch, 10% reserve) and oral (52% access, 44% watch, 4% reserve). A significant proportion (67%) of injectable antibiotics fell under ATC subgroups J01D (27%), J01C (23%), and J01X (17%) (Figure 1a). Among these, 21 (70%) were listed on EML, and 18 (60%) were included in the NEML, based on data from 86 MAHs. Most oral antibiotics belonged to J01C (20%) and J01M (20%), followed by J01F (16%) and J01D (12%) (Figure 1b). Of these, 19 (76%) were on the WHO EML, and 13 (52%) were on Islamic Republic of Iran NEML, produced by 173 MAHs.

Table 1 Availability, cost, cost ratio, variation and affordability of injectable antibiotics by AWaRe category, Islamic Republic of Iran, 2023

AWaRe category	Antibiotic	Anatomical therapeutic chemical code	Defined daily dose	Average cost (IRR/defined daily dose)	Cost ratio	Cost variation (%)	Affordable	On essential medicines list	On non-essential medicines list	Marketing authorization holder number
Access	Amikacin	J01GB06	1.00	585 700	2.8	179	Yes	Yes	Yes	3
	Ampicillin	J01CA01	6.00	2 228 400	3.0	200	No	Yes	Yes	2
	Ampicillin/Sulbactam	J01CR01	6.00	1 219 200	1.0	0	Yes	No	Yes	2
	Cefazolin	J01DB04	3.00	59 814	1.0	1	Yes	Yes	Yes	6
	Clindamycin	J01FF01	1.80	588 450	1.5	55	Yes	Yes	Yes	7
	Cloxacillin	J01CF02	2.00	616 400	1.0	0	Yes	Yes	Yes	1
	Co-trimoxazole	J01EE01	20UD	302 660	1.0	0	Yes	Yes	Yes	2
	Gentamicin	J01GB03	0.24	448 900	2.7	171	Yes	Yes	No	4
	Metronidazole	J01XD01	1.50	592 800	1.0	0	Yes	Yes	No	2
	Benzathine benzylpenicillin	J01CE08	3.60	700 500	1.0	0	Yes	Yes	Yes	2
	Procaine benzylpenicillin	J01CE09	0.60	89 325	1.0	0	Yes	Yes	Yes	1
Watch	Azithromycin	J01FA10	0.50	605 100	1.0	0	Yes	Yes	Yes	1
	Cefepime	J01DE01	4.00	1 863 467	1.8	83	No	No	No	3
	Cefotaxime	J01DD01	4.00	800 600	1.4	38	Yes	Yes	Yes	3
	Ceftazidime	J01DD02	4.00	1 160 533	1.4	35	Yes	Yes	Yes	5
	Ceftizoxime	J01DD07	4.00	1 900 600	1.4	44	No	No	No	4
	Ceftriaxone	J01DD04	2.00	386 100	1.5	51	Yes	Yes	Yes	5
	Ciprofloxacin	J01MA02	0.80	941 310	1.3	32	Yes	Yes	Yes	4
	Imipenem/Cilastatin	J01DH51	2.00	4 358 400	1.0	0	No	Yes	No	6
	Levofloxacin	J01MA12	0.50	168 150	3.0	200	Yes	No	No	3
	Meropenem	J01DH02	3.00	3 250 350	1.3	32	No	Yes	Yes	6
	Piperacillin/Tazobactam	J01CR05	14.00	1 984 423	1.0	3	No	Yes	Yes	1
	Streptomycin	J01GA01	1.00	15 000	1.0	0	Yes	No	No	1
	Teicoplanin	J01XA02	0.40	1 723 700	1.0	0	Yes	No	No	1
	Temocillin	J01CA17	4.00	25 828 000	1.0	0	No	No	No	1
	Tobramycin	J01GB01	0.24	280 800	1.0	0	Yes	No	No	1
	Vancomycin	J01XA01	2.00	1 126 400	1.0	0	Yes	Yes	Yes	3
Reserve	Colistin	J01XB01	9.00	3 678 100	1.6	64	No	Yes	No	3
	Linezolid	J01XX08	1.20	1 637 250	1.0	0	Yes	Yes	Yes	2
	Tigecycline	J01AA12	0.10	3 064 000	1.0	0	No	No	No	1

AWaRe = access, watch, reserve

Cost and affordability of antibiotics

The cost and affordability of antibiotics is summarised in Table 1 (injectables) and Table 2 (orals). Among injectable antibiotics, streptomycin – an aminoglycoside in the watch group – had the lowest cost at 15 000 IRR/DDD, but was excluded from both the WHO and Islamic Republic of Iran EMLs and was supplied by only one MAH. Procaine-benzylpenicillin was the next cheapest at 82 325 IRR/DDD, while temocillin had the highest cost at 25 828 000 IRR/DDD and was absent from both essential lists. Im-

ipenem/cilastatin, another watch beta-lactam, was priced at 4 358 400 IRR/DDD and had 6 MAHs.

In the oral category, nitrofurantoin was the cheapest at 12 370 IRR/DDD and was included in both the WHO and national EMLs, while linezolid – the most expensive at 1 030 558 IRR/DDD – appeared on both lists with 7 brands. Fosfomycin, a watch antibiotic, cost 785 900 IRR/DDD but was absent from both essential lists and had 4 MAHs. Overall, most injectable antibiotics were unaffordable, whereas most oral formulations were affordable.

Table 2 Availability, cost, cost ratio, variation, and affordability of oral antibiotics by AWaRe category, Islamic Republic of Iran, 2023

AWaRe category	Antibiotic	Anatomical therapeutic chemical code	Defined daily dose	Average cost (IRR/ defined daily dose)	Cost ratio	Cost variation (%)	Affordable	On essential medicines list	On non-essential medicines list	Marketing authorization holder number
Access	Amoxicillin	J01CA04	1.50	98 494	2.3	127	Yes	Yes	Yes	8
	Ampicillin	J01CA01	2.00	36 908	1.0	0	Yes	Yes	Yes	1
	Amoxicillin/ clavulanic acid	J01CR02	1.50	149 657	3.0	200	Yes	Yes	Yes	5
	Clindamycin	J01FF01	1.20	498 267	4.3	330	Yes	Yes	No	7
	Cefalexin	J01DB01	2.00	145 890	1.7	69	Yes	Yes	Yes	8
	Co-trimoxazole (tab)	J01EE01	4UD	33 644	1.3	32	Yes	Yes	Yes	6
	Co-trimoxazole (susp)	J01EE01	8UD	112 080	1.0	0	Yes	Yes	Yes	3
	Cloxacillin	J01CF02	2.00	74 640	1.1	5	Yes	Yes	Yes	2
	Doxycycline	J01AA02	0.10	25 700	1.4	40	Yes	Yes	Yes	4
	Metronidazole	P01AB01	2.00	110 344	1.0	0	Yes	Yes	No	15
	Tetracycline	J01AA07	1.00	49 200	1.0	0	Yes	Yes	No	3
	Phenoxymethylpenicillin	J01CE02	2.00	54 333	3.4	237	Yes	Yes	No	2
	Nitrofurantoin	J01XE01	0.20	12 370	1.0	0	Yes	Yes	Yes	1
Watch	Azithromycin	J01FA10	0.30	151 351	17.9	1695	Yes	Yes	Yes	19
	Cefixime	J01DD08	0.40	71 137	8.1	706	Yes	Yes	Yes	7
	Clarithromycin	J01FA09	0.50	136 371	2.3	134	Yes	Yes	No	7
	Ciprofloxacin	J01MA02	1.00	50 133	1.7	71	Yes	Yes	Yes	16
	Cefuroxime	J01DC02	0.50	65 900	1.1	13	Yes	Yes	No	16
	Erythromycin	J01FA01	2.00	249 600	1.4	40	Yes	Yes	Yes	4
	Gemifloxacin	J01MA15	0.32	168 100	1.0	0	Yes	No	No	5
	Levofloxacin	J01MA12	0.50	46 733	1.2	21	Yes	No	No	20
	Moxifloxacin	J01MA14	0.40	152 272	1.0	0	Yes	No	No	2
	Ofloxacin	J01MA01	0.40	31 147	1.1	11	Yes	No	No	8
	Fosfomycin	J01XX01	3.00	785 900	1.0	0	Yes	No	No	4
Reserve	Tigecycline	J01XX08	1.20	1 030 558	1.0	0	Yes	Yes	Yes	7

AWaRe = access, watch, reserve

Figure 1 Percentages of antibiotics by anatomical therapeutic chemical subgroups: (A) injectable formulations and (B) oral formulations

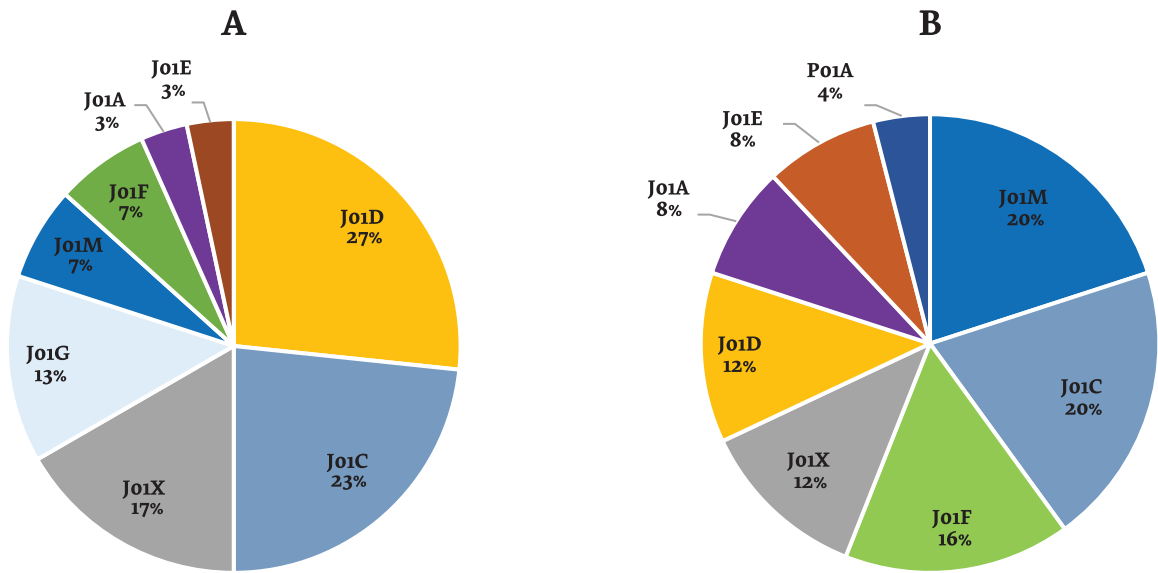


Table 3 Relationship between cost, marketing authorization holders and affordability of oral and injectable antibiotics by AWARe category, Islamic Republic of Iran, 2023

Formulation	Access	Watch	Reserve	P
Oral				
Number of antibiotics	13	11	1	
Average cost (IRR per defined daily dose)	Median = 74 640 (IQR: 36 908–112 080)	Median=136 371 (IQR: 50 133–168 100)	Median= 1 030 558 (IQR: 1030558–1030558)	0.19*
Total marketing authorization holders	Median = 4.0 (IQR: 2.0–7.0)	Median = 7.0 (IQR: 4.0–16.0)	Median = 7.0	0.048*
Affordability	13 (100%)	11 (100%)	(IQR: 7.0–7.0)	> 0.99**
Injectable				
Number of antibiotics	11	16	3	
Average cost (IRR per defined daily dose)	Median = 590 814a (IQR: 44 8900–700 500)	Median = 1 143 466.5 (IQR: 495 600–1 942 511.5)	Median= 3064000a (IQR: 1 637 250–3 678 100)	0.045*** (H value = 6.22)
Total marketing authorization holders	Median = 2.0 (IQR: 2.0–4.0)	Median = 3.0 (IQR: 1.0–4.5)	Median = 2.0 (IQR: 1.0–3.0)	0.75*** (H value = 0.57)
Affordability	10 (90.9%)	10 (62.5%)	1 (33.3%)	0.75***
Total				
Number of antibiotics	24	27	4	
Average cost (IRR per defined daily dose)	Median = 147 773.5a (IQR: 64 486.5–89 632)	Median = 386 100 (IQR: 136 371–1 723 700)	Median = 2 350 625a (IQR: 1 333 904–3 371 050)	0.007*** (H value = 9.79)
Total marketing authorization holders	Median = 3.0 (IQR: 2.0–6.0)	Median = 4.0 (IQR: 2.0–7.0)	Median = 2.5 (IQR: 1.5–5.0)	0.52*** (H value = 1.32)
Affordability	23 (95.8%)ab	21 (77.8%)a	2 (50.0%)b	0.035***

* Statistical analysis by Mann-Whitney U test (Group reserve not included because only one sample was available); ** Statistical analysis by Fisher Exact test; *** Statistical analysis by Kruskal-Wallis test; a Significant difference; IQR = Interquartile range

With 7 MAHs (all generics), clindamycin had a cost ratio of 1.5 and a 55% cost variation. In contrast, ampicillin and levofloxacin – with 2 and 3 MAHs, respectively – showed the highest cost ratio of 3 and a 200% cost variation among injectables. In the oral market, levofloxacin had the largest number of MAHs ($n = 20$), followed by azithromycin ($n = 19$), both listed in the WHO and national EMLs. The average cost ratio for antibiotics in Islamic Republic of Iran was 1.89, with azithromycin recording the highest cost ratio at 17.9 and an exceptional 1695% cost variation. Quinolones and macrolides predominated in oral watch antibiotics, while cephalosporins were the most common injectables.

Relationship between marketing authorisation holders, cost and affordability with AWARe category and route of administration

In Table 1, the cost, number of MAHs, and affordability of antibiotics were compared across access, watch, and reserve groups, separately for oral and injectable formulations.

Among oral antibiotics, the median cost of watch group medicines was higher than those of access group medicines; however, this difference was not statistically significant ($P = 0.19$). The median number of MAHs was significantly higher for watch group antibiotics ($P = 0.05$).

In contrast, for injectable antibiotics, the median cost was significantly higher in the watch and reserve groups than in the access group ($P = 0.05$). In contrast, no statis-

tically significant differences were observed in the median number of MAHs among injectable formulations ($P = 0.75$). Affordability was highest for access injectables (90.9%), followed by watch (62.5%) and reserve (33.3%) groups.

When all formulations were combined, the overall median cost differed significantly across AWARe categories ($P = 0.01$), while affordability was significantly lower among reserve group antibiotics ($P = 0.04$). These results suggest that although access antibiotics were largely affordable, watch and reserve antibiotics, particularly injectables, were associated with a higher financial burden for patients.

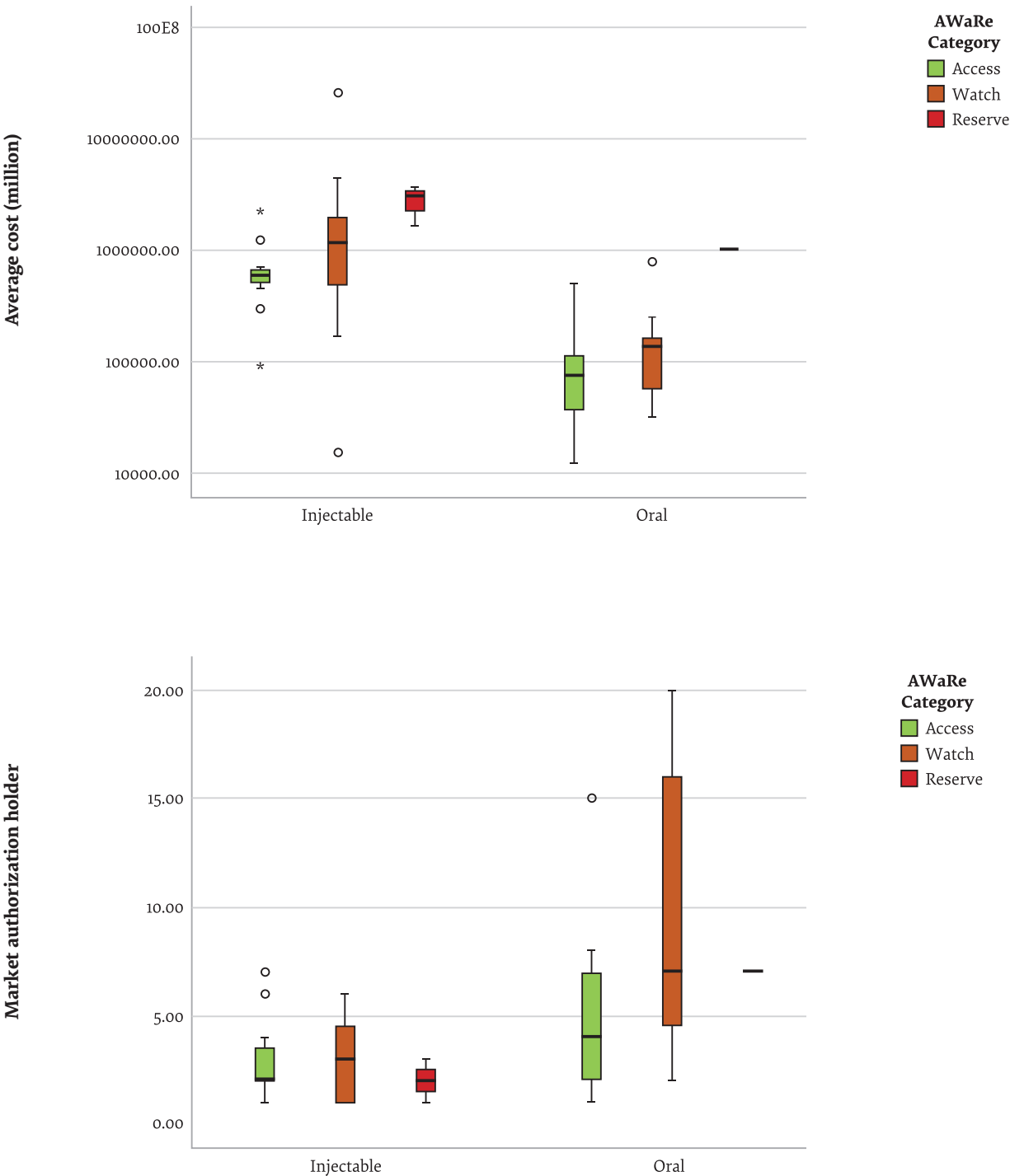
The cost distribution and the number of MAHs across AWARe categories are shown in Figure 2. Overall, injectable antibiotics had significantly higher median costs than oral formulations, particularly within the reserve group (Figure 2a).

In terms of market presence, oral antibiotics had a greater number of MAHs than injectables, especially in the watch group (Figure 2b), indicating wider availability for oral formulations.

Discussion

This is the first nationwide analysis in Islamic Republic of Iran to examine affordability of antibiotics by distribution channel based on the WHO AWARe classification, alongside comparative assessments of costs and regula-

Figure 2 Distribution of average cost (A) and marketing authorization holder number (B) of antibiotics, Islamic Republic of Iran, 2023



tory context. Our findings showed that a significant proportion of injectable (53.3%) and oral (48.3%) antibiotics were in the watch group, underscoring the extensive use of this category. Cost differences between oral watch and access was minimal, while half of the antibiotics in the reserve group met the affordability threshold.

A key strength of this study is its nationwide assessment of antibiotic affordability stratified by AWaRe category and route of administration, enhancing generalisability and allowing for international comparison. It also adhered to STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines to ensure transparency and rigour (21).

There are 4 important implications for policy and practice arising from our findings. First, watch group antibiotic use is excessive, consistent with reports from Qatar and Nepal, both showing high watch group use. WHO 2024 report on antibiotic consumption found that approximately 57% of the consumed DDDs of antibiotics in Islamic Republic of Iran were in the watch group (22,23,8). Macrolides (mainly azithromycin), fluoroquinolones, and third-generation cephalosporins were major contributors, reflecting regional trends (24). According to the WHO report, Islamic Republic of Iran is the second-highest consumer of third-generation cephalosporins, after Bangladesh. Conversely, second-generation cephalosporin use in Islamic Republic of Iran is minimal due to the inclusion of only one such agent in the Iran Drug List (IDL), whereas countries like Germany, Cyprus, Hungary, Poland, and Spain rely more on these agents (8). Revising the IDL to include more access group and second-generation cephalosporins from the WHO EML could help balance prescription patterns.

The persistently high watch antibiotic consumption since the COVID-19 pandemic, coupled with the exclusion of many from the essential medicines list, underscores the need for regulatory action (25). Excessive use of watch group antibiotics increases the risk of AMR, particularly when many are not subject to effective regulation through inclusion in the EML. In Islamic Republic of Iran, half of the watch group antibiotics, including 7 out of 10 oral antibiotics and 8 out of 19 injectable antibiotics, are absent from the national EML. Therefore, the IFDA should align supply and distribution policies with AWARe priorities and the national EML, giving preference to access antibiotics. Specific measures could include mandatory registration of watch group antibiotics in the tracing, tracking, and authentication control (TTAC) system for real-time monitoring.

Second, there was no significant difference in the price per DDD of oral antibiotics between access and watch groups, unlike findings from Jordan (26). However, when assessed per treatment course, some watch antibiotics may be less costly, as reported in Cameroon (27). The average cost ratio in Islamic Republic of Iran was 1.89 (1.4 for injectables, 2.5 for orals), which is within the WHO threshold (< 3) and lower than in Jordan, Cameroon, and Ethiopia (28). This likely reflects local production of antibiotics, although imported brands like zithromax drive extreme price variation; azithromycin had a cost ratio of 17.9 and a cost variation of 1695%. As seen in Spain and Italy, adjusting prices or introducing copayments may help reduce overuse (29,30).

Third, with the exception of parenteral ampicillin, all access antibiotics were within the affordability threshold. Surprisingly so were half of the reserve group – a result that contradicts WHO's expectation that these medicines should remain least accessible and reserved for last-line use. This may reflect domestic production in Islamic Republic of Iran, which lowers market prices and increases availability. These results highlight the need to revise antibiotic pricing and manufacturing pol-

icies for reserve antibiotics. Pricing could be linked to AWARe category and consumption patterns rather than being based solely on production cost.

As this analysis used the national minimum wage without considering subsidies or insurance coverage, actual affordability may be higher. Future studies should incorporate these policy considerations for a more accurate assessment of access.

Fourth, 60% of MAHs produce watch antibiotics. Among these, azithromycin and levofloxacin had the highest number of MAH (19 and 20, respectively). Nitrofurantoin, an access antibiotic, is produced by only one company in Islamic Republic of Iran, contributing to its limited market availability. Although other access agents such as penicillin V and cloxacillin are produced domestically, production of nitrofurantoin by other manufacturers could provide long-term benefits, given its sustained effectiveness against uncomplicated lower urinary tract infections, and the country's high urinary tract infections burden (31–34). Policy measures to encourage this shift could include subsidies for importing raw materials used in manufacturing access group antibiotics.

Beyond pricing, availability and prescription behaviours, enhancing patient education and enforcing robust regulatory measures are essential to promote rational antibiotic use. Comprehensive awareness campaigns targeting healthcare professionals and the public, complemented by robust legislative frameworks, are essential for strengthening antibiotic stewardship efforts and reducing antimicrobial resistance. Experiences from Sweden, United Kingdom, Australia and France show that integrated AWARe-based strategies can optimise prescription and reduce inappropriate use, providing practical models for informing antibiotic policy development in Islamic Republic of Iran (35–38).

Study strengths and limitations

A key strength of this study is its nationwide assessment of antibiotic affordability stratified by AWARe category and route of administration, enhancing generalisability and allowing for international comparison. The study adhered to STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines to ensure transparency and rigour (21).

The limitations include the absence of real-time antibiotic consumption data and the absence of hospital-level analyses and prescription audits; future research should incorporate both to improve accuracy and strengthen policy guidance.

Conclusion

Watch group antibiotics were used excessively, with no significant price differences from access antibiotics and cost ratios within the WHO threshold. Access group antibiotics were the most affordable, followed by watch and reserve groups. The large number of producers and the low price of

watch antibiotics are key factors driving their high use. In addition to affordability and prescription patterns, patient education and regulatory measures also play a crucial role in promoting rational antibiotic use. There is an urgent need

for policy reforms and targeted regulatory interventions on antibiotic production, supply, demand, pricing and monitoring in Islamic Republic of Iran.

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