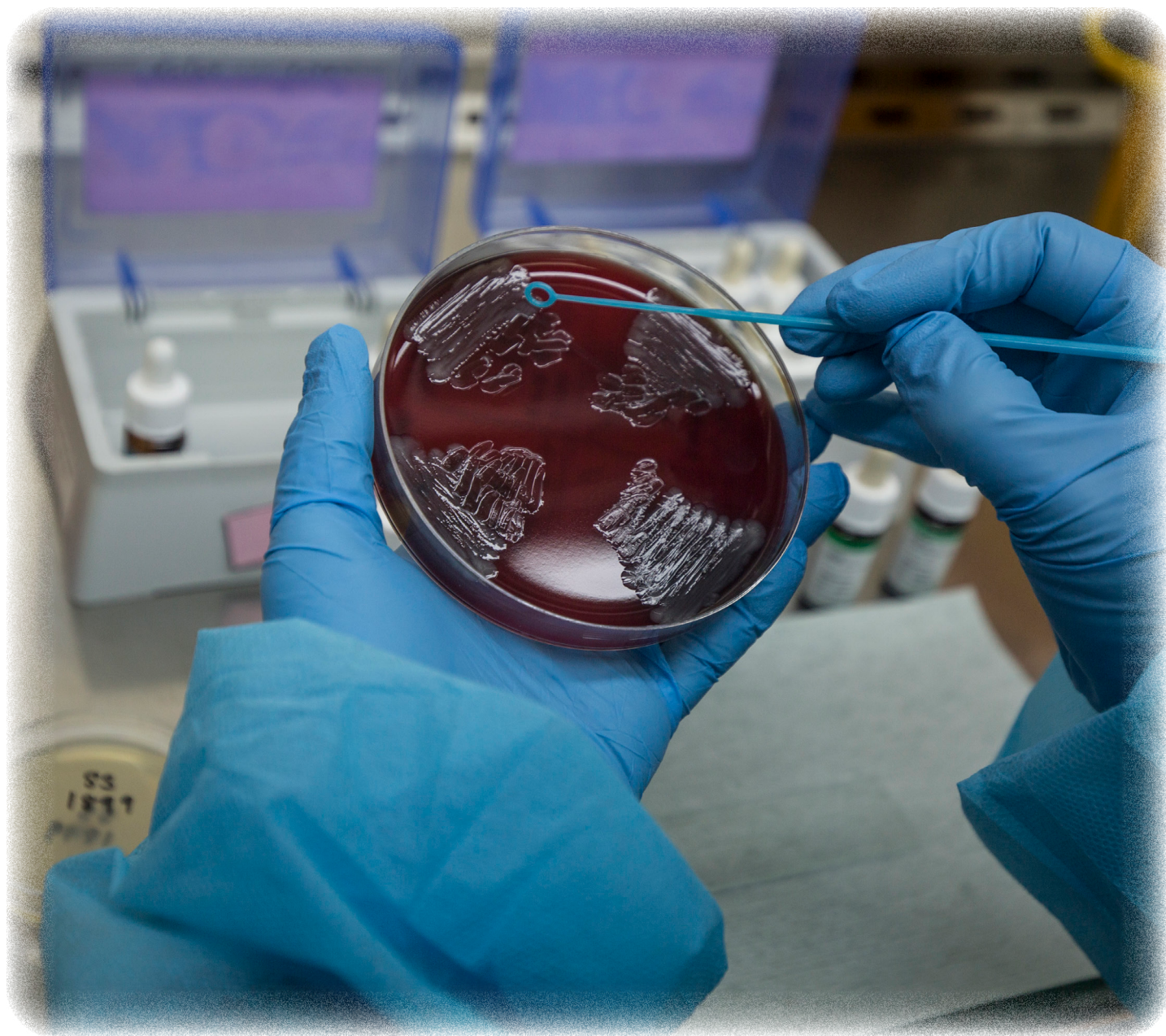


SPECIAL ISSUE ON ANTIMICROBIAL RESISTANCE



Antimicrobial resistance presents an increasing threat to public health globally. Strong commitment to antimicrobial stewardship by every stakeholder in the health system is needed to tailor the use of antimicrobials and mitigate resistance.

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SPECIAL ISSUE ON ANTIMICROBIAL RESISTANCE

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Insights and imperatives on antimicrobial resistance in the Eastern Mediterranean Region

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Antimicrobial resistance (AMR) has become entrenched across the Eastern Mediterranean Region (EMR)—undermining our health, our development and our security. Despite progress in developing AMR national action plans (NAP), strengthening infection prevention and control (IPC), and reporting AMR and consumption data to WHO's surveillance system, the AMR burden continues to increase. In 2021 alone, bacterial AMR was directly responsible for nearly 100 000 sepsis-related deaths in the Region—more than 1 in 6 of all sepsis deaths (2). These stark figures show that AMR is a systemic crisis requiring an urgent, coordinated response.

This special issue of the Eastern Mediterranean Health Journal (EMHJ) brings together evidence from EMR Member States, with studies on multidrug resistance, antibiotic consumption, stewardship gaps, availability, affordability, and community practices. Together, they provide a clear picture of the Region's challenges and opportunities for stronger policy and collaboration.

Sara et al, analysing the Iranian nosocomial infection surveillance data, report 72% multidrug resistance in bacterial isolates from hospital-acquired urinary tract infections, with the highest prevalence in *Acinetobacter* spp (97%). Mortality reached 42% overall and 60% among patients infected with *Candida* spp. (3).

It is well known that inappropriate use of antibiotics—particularly watch antibiotics with high resistance potential—is a key determinant of higher resistance rates (11). Studies from Tunisia and the Islamic Republic of Iran show that watch group antibiotics are being consumed at alarmingly high rates. In Islamic Republic of Iran, over 61% of hospital prescriptions in 2023–2024—compared to 44% in Tunisia in 2022—were from the watch category, with substantial preference for cephalosporins (44%) (4–7).

Abdulaziz et al, using data from Egypt's National Office for Handling and Reduction of Medication Errors (NOHARMe), found over 56 000 combined drug therapy problems and medication errors related to antimicrobials, mainly incorrect dosage or indication (96.7%). Alarmingly, 65.4% of the prescription errors involved watch antibiotics (8).

In Syria, Aldaef et al found that 62.2% of internally displaced persons used antibiotics without prescription,

and more than half used antibiotics prescribed for others (9). Although 70% of this population reported sufficient knowledge of antimicrobials, over half believed antibiotics are used to treat viral infections.

These findings emphasize the importance of public education and improved access to formal health care services in fragile settings. Emerging data from Gaza confirm that AMR is exacerbated by conflict, injuries and attacks on hospitals, laboratories and water systems (12).

The regulatory environment shapes the use of antibiotics. Azita et al show that in Islamic Republic of Iran, watch antibiotics are widely available and competitively priced, possibly contributing to their overuse (10). Azithromycin and levofloxacin are produced by nearly 20 manufacturers each, while nitrofurantoin—an effective access antibiotic—is produced by just one. Similar to recent findings in Jordan (13), this highlights the need for pricing reforms, production incentives for access antibiotics, and stricter controls on watch group sales. Pricing should reflect stewardship goals, not just production costs.

Encouragingly, Tunisia has consistently met the WHO target for access antibiotic consumption nationally, reaching 75% in 2023 (4). Integration of access, watch, reserve (AWaRe) classification into hospital formularies and the development of 47 stewardship indicators demonstrate a commitment to institutional accountability (5). Egypt's NOHARMe system offers a scalable regional model if real-time feedback can be incorporated (8). Iran's national formulary and centralised pricing system could also enable stewardship-linked regulation. Such initiatives should be harmonised and shared regionally as best practices.

At the global level, 2024 saw the United Nations General Assembly endorse a political declaration on AMR, with measurable targets (14). The World Health Assembly endorsed WHO's strategic and operational priorities on drug-resistant bacterial infections in human health (15) and adopted the first global IPC strategy, action plan and monitoring framework (16). In the same year, the fourth Global High-level Ministerial Conference in Jeddah endorsed the establishment of an AMR One Health learning hub, and the Kingdom of Saudi Arabia set up the regional AMR access and logistics hub (17).

As the updated global action plan on AMR (2026–2036) was formally adopted by Member States in May 2026, regional priorities identified in the technical paper adopted by Member States in 2024 must be emphasized (18,19). IPC progress must be sustained and scaled up. As agreed during the third ministerial conference in Oman in 2022, countries need to commit domestic funding for AMR NAP implementation with clear milestones and targets, using the One Health approach (1). Region-specific challenges that drive AMR—conflict, fragmented health systems, poor IPC and water, sanitation and hygiene (WASH)—must be addressed (20).

The studies in this issue highlight excessive use of watch antibiotics, stewardship gaps in hospitals and intensive care units, challenges in the private sector, and affordability pressures. These findings demand policy action: regulate over-the-counter antibiotic sales without harming essential access; expand public education campaigns targeting youth, communities, and NGOs; incentivize local production of access antibiotics; and ensure microbiology laboratory services and antibiotic supplies in conflict and humanitarian settings.

This issue also reveals major research gaps, including the impact of IPC, vaccination, and WASH on AMR; the effectiveness of NAP implementation; and social

and structural determinants. Systematic investment in operational and implementation science research mapped to the needs of our countries is required. A regional network of researchers across One Health, working closely with different stakeholders—including policymakers, programme managers, clinicians, and communities—can provide better insights and more effective solutions.

As global efforts are intensified towards accelerating implementation of the new global action plan, strengthening accountability and translating commitments into measurable outcomes at country level, the Eastern Mediterranean Region has both the evidence and the mandate to act. The studies in this special issue highlight the urgency to curb excessive use of watch antibiotics, strengthen stewardship, tackle affordability, and close research gaps. They also remind us that conflict and inequities amplify AMR risks in our Region. With UN and World Health Assembly commitments, and new regional hubs, the foundations for progress are in place. The task now is to translate commitments into measurable action—anchored in One Health, backed by domestic investment, and supported by collaboration. If we act decisively, the Region can help turn the tide against AMR; if not, the costs—to lives, health systems, and development—will only continue to increase.

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The Structured Operational Research and Training Initiative supporting antimicrobial resistance control in the Eastern Mediterranean Region

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Introduction

Operational research (often used interchangeably with implementation research) is the “science of doing better”. It is vital for assessing what works and what does not within health systems by examining how programmes, services and policies are applied in real-world settings, with the aim of improving them (1,2). For example, if a health clinic repeatedly experiences stockouts of antibiotics, operational research can explore why this happens and test solutions to fix it. Likewise, if patients wait too long for blood culture results before receiving effective antibiotics, operational research can help map the process and identify ways to reduce waiting time. Put simply, operational research provides a roadmap that will help health systems become more effective, more efficient and more responsive to people’s needs (3,4).

Operational research capacity-building is urgently needed globally to address major public health challenges such as antimicrobial resistance (AMR). An estimated 1.27 million deaths are directly attributable to, and 4.95 million deaths associated with, AMR each year (5). This places AMR alongside HIV and tuberculosis as one of the world’s most pressing public health threats. Eastern Mediterranean Region (EMR) countries have been confronted with AMR-associated challenges, potentially compromising the effectiveness of life-saving medicines and slowing down progress towards Universal Health Coverage (UHC) (6).

This commentary highlights the importance of strengthening operational research capacity for addressing AMR in the EMR and provides an overview of the support provided by the Structured Operational Research and Training Initiative (SORT IT), a global partnership supporting capacity-building of countries.

Strengthening operational research capacity in EMR

Despite the pressing problem of AMR in EMR countries, robust data on its burden, drivers and impact remain limited, compromising evidence-based action (6). Building

operational research capacity is vital to bridging the data gap and empowering countries to generate context-specific evidence locally on how best to prevent, diagnose and manage resistant infections within their settings.

Several factors underscore the urgency to build operational research capacity in the EMR:

High disease burden and fragile health systems

EMR countries report some of the highest AMR levels (6), with some, e.g. Somalia, Syria, Sudan, Yemen, also struggling with protracted conflict, displacement, forced migration, and resource limitation, which disrupt health systems and weaken surveillance, infection prevention and control, and AMR stewardship programmes. Operational research will help advance tailored and feasible solutions under such conditions.

Inappropriate use of antimicrobials

Over-the-counter availability of antimicrobials, irrational prescribing and self-medication are common. Operational research can help identify behavioural and system-level drivers of misuse and provide evidence to support the enforcement of stewardship policies for the improvement of prescription and dispensing practices.

Gaps in implementation of national and regional AMR strategies

National AMR strategies provide a framework for action (7), however, progress in funding and translating them into practice is uneven in the EMR. Operational research can provide tools for identifying bottlenecks and improving the application and effectiveness of policy interventions.

One Health and cross-sectoral complexity

AMR is a One Health challenge that spans human, animal and environmental health. It is therefore not just a hospital problem but a system-wide challenge. Operational research can provide the cross-sectoral and integrated evidence generation needed to guide multisectoral responses that will bridge the human, animal and environmental health continuum.

Sustainability and partnerships

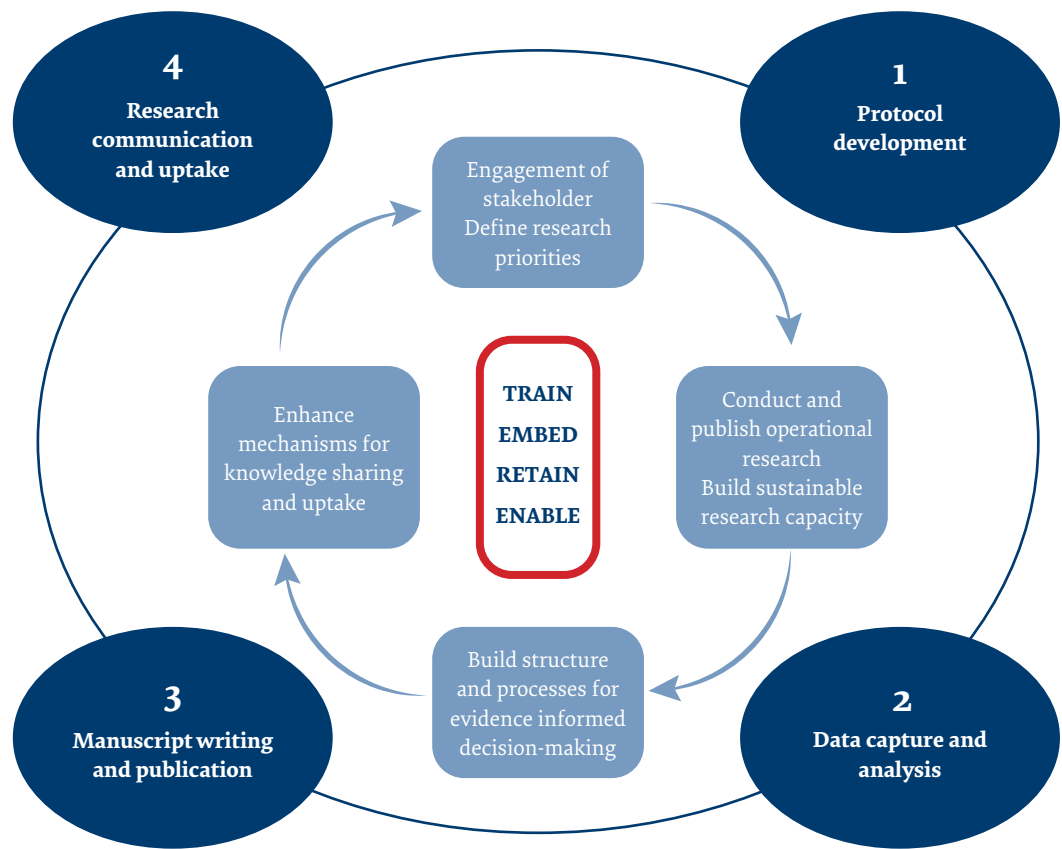
Strengthening operational research capacity will equip local researchers, institutions and ministries of health with the capacity to continuously produce and apply research evidence to public health policymaking and practice. This will reduce dependence on external expertise and promote cross-country learning, which are crucial for addressing AMR as a transnational issue. Although most countries have enrolled in AMR surveillance initiatives, reporting remains uneven, with concerns regarding data quality and representativeness. Strengthening operational research capacity will help bridge these surveillance and data gaps.

A proven model for building capacity in operational research

SORT IT, led by the UNICEF, UNDP, World Bank and WHO Special Programme for Research and Training in Tropical Diseases (TDR), and implemented with

partners, is a proven model for building operational research capacity (8). Since 2012, its operations have been expanded into 97 countries, 25 public health domains and 87 partner institutions across low-, middle- and high-income countries. SORT IT supports countries and institutions to become “data rich, information rich and action rich” for the improvement of public health (2). Its 10-12-month training cycle follows a learning-by-doing approach (Figure 1). Each trainee completes a research project with hands-on mentorship throughout the research cycle—from relevant research question development to publication and effective communication of findings to policymakers. This ensures that research generates evidence and publications as well as informs policy and practice (9). To ensure effectiveness, the SORT IT model integrates performance targets such as the 80-80-80-80 targets and the accountability metrics (8). A recent independent assessment of SORT IT publications covering observational studies across 72 countries and 24 thematic areas found that 90% of the publications were of good reporting quality (10).

Figure 1 The Structured Operational Research and Training Initiative (SORT IT) cycle (2025), spanning 10–12 months with integrated milestones and performance targets



The legacy of success of the SORT IT approach in AMR (2019–2025)

SORT IT has demonstrated significant impact in AMR across countries. The TDR annual metrics surveys indicate that 79% of 75 AMR studies conducted in African (Ghana, Sierra Leone, Uganda), Asian (Myanmar, Nepal) and Latin American (Colombia, Ecuador) countries have influenced policy or practice while simultaneously building leadership capacity in health research and strengthening health systems more broadly (11). Among the SORT IT trainees, 92% have continued to apply their skills to address AMR issues, 64% have completed additional research studies, and 36% are currently mentoring others in creating a new cohort of operational researchers. Over 50% of the trainees have applied their acquired skills in responding to outbreaks such as COVID-19 (12) and mpox (13), underscoring the crosscutting benefits to health systems.

Sustaining the momentum of success of SORT IT in tackling AMR in the Eastern Mediterranean Region

In 2024, Al Ain, in the United Arab Emirates (UAE), hosted a pioneering SORT IT programme in the EMR. The programme brought together 20 institutions from 10 countries, including the ministries of health, to address AMR in Egypt, Islamic Republic of Iran, Tunisia, and UAE. This programme was jointly implemented by TDR, United Arab Emirates University, Abu Dhabi Public Health Center, WHO Regional Office for the Eastern Mediterranean, WHO country offices, and SORT IT partner institutions. Eight country-relevant research studies were completed, addressing critical issues such as hand hygiene, antibiotic consumption, antibiotic resistance patterns in human and animal specimens, and the emergence of super fungal bugs like *Candida auris*. Some of the studies related to antibiotic consumption patterns and multidrug resistance in urinary tract infections in Islamic Republic of Iran and Tunisia are featured in this special issue of the EMHJ.

Sustaining this momentum requires localising the SORT IT model to country context and expanding it to other

domains. Successful examples already exist in Armenia (14) and Ukraine (15) on improving care for vulnerable populations; Kenya (16) on neglected tropical diseases and tuberculosis (TB); Pakistan (17) and Rwanda (18) on health systems; Sierra Leone and Liberia on outbreak resilience (19); India on TB and promoting training innovations; Ghana (20) and Nepal (21) on AMR; and the United Kingdom (22) on health protection and mental health.

Key strategic pillars for national adoption include focusing on national priorities, communicating research findings to decision-makers effectively, building and sustaining a pool of trained operational researchers, embedding capacity in national institutions for long-term sustainability, adapting the training model to available resources, and fostering global and regional collaborations. Adopting a 3-year structured SORT IT cycle would be ideal for the region:

- Year 1: Conduct baseline studies and use the findings for advocacy to decision-makers.
- Year 2: Provide technical support to implement findings.
- Year 3: Conduct follow-up studies to assess the impact of implemented actions.

This cyclical approach aims to ensure continuous improvement and measurable outcomes.

Countries striving to strengthen their health systems for UHC should build capacity nationally so they can generate and use evidence as needed. However, this can only be achieved if health systems policy- and decision-makers are empowered to use the results of real-world operational research for programming. Investing in people so they can effectively tackle AMR and other health system challenges towards the achievement of UHC is not a luxury, it is an essential step for equipping the health system with “the right people in the right place at the right time”.

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Progress and challenges in antimicrobial resistance control in the Eastern Mediterranean Region

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Introduction

Antimicrobial resistance (AMR) is an increasing global health threat, with profound implications for health systems, economies, sustainable development, and most importantly, people's lives. Globally, AMR was responsible for an estimated 1.14 million deaths in 2021, and projections suggest that it could cause up to 10 million annual deaths by 2050 if current trends continue unchecked (1). Evidence shows that COVID-19 pandemic accelerated the emergence and transmission of AMR, particularly in hospital settings (2).

The economic toll of AMR is equally alarming. The World Bank estimates that by 2030, AMR could cause a global Gross Domestic Product shortfall exceeding US\$ 1 trillion annually, with the greatest impact on low- and middle-income countries (3).

In the Eastern Mediterranean Region (EMR), 96 416 deaths were attributed to bacterial AMR in 2021, accounting for 17% of all deaths due to bacterial sepsis (4). The burden of AMR in the region is exacerbated by socioeconomic disparities, fragile health systems, conflict, displacement, weak health infrastructure, and high rates of antibiotic consumption. Under-5 children are disproportionately affected and they represent 35% of AMR-related deaths in the region (4).

This commentary highlights progress, persistent challenges and priority actions for the control of AMR in the EMR.

Regional diversity and vulnerability

The EMR comprises 22 countries and territories with varying income levels and health system capacities—11 middle-income, 6 high-income and 5 low-income. Although substantial disparities exist between national health system capacities and resources, including the peculiar challenges faced by 9 fragile, conflict-affected and vulnerable countries, 21 countries have developed national action plans (NAPs) on AMR control (5). During the annual Regional Committee meeting in 2024, EMR countries adopted a resolution for a collaborative approach to addressing AMR (6). The resolution calls for improved One Health governance, including costed and

budgeted NAPs; infection prevention and control (IPC); water, sanitation and hygiene (WASH); immunization improvements; access to essential health services through uninterrupted supply of antibiotics and diagnostics; and fit-for-purpose workforce. The resolution also identifies the need to incorporate AMR into emergency preparedness and response plans and integrate IPC and stewardship into primary care.

AMR governance and financing

NAP implementation by EMR countries remains uneven; only 4 countries have costed and budgeted plans based on 2024 data from the Global Database for Tracking Antimicrobial Resistance Country Self-Assessment Survey (TrACSS) (5). Monitoring and evaluation frameworks are weak and multisectoral coordination is often ad hoc. Domestic financing is limited, with many of the countries relying on external financial support for key activities. The region needs sustainable funding mechanisms and stronger capacity and accountability structures. The flagship initiatives of the WHO Regional Director on supply chain resilience and health workforce development offer strategic entry points to progress on governance and financing for AMR control (7).

AMR surveillance and data gaps

AMR surveillance systems have expanded. As of 2025, 22 EMR countries were reporting AMR data to the Global Antimicrobial Resistance and Use Surveillance System (GLASS) (8,9). However, concerns persist regarding data quality and representativeness. Blood culture testing rates are low and diagnostic stewardship is weak. Only a few EMR countries use AMR data to inform policy and operational decisions (8). Antimicrobial use (AMU) surveillance is similarly limited. While 21 countries are enrolled in GLASS-AMU, only 13 reported data in 2025. Subnational data are scarce, hindering targeted interventions. The lack of reliable data is particularly acute in fragile countries experiencing conflict and violence, where health systems are fragmented and under-resourced and the risks of emergent AMR are highest (8,10).

Antibiotic consumption and stewardship

EMR has been reported to have the highest per capita antibiotic consumption rates globally—21.8 defined daily doses per 1000 inhabitants per day in 2018, compared to the global average of 16.2 (11). Consumption increased by 114% in the region's middle-income countries between 2000 and 2018 (8,11). Point prevalence surveys in 7 countries have shown that 57% of hospitalised patients received at least one antimicrobial, third generation cephalosporins being the most prescribed (12). Alarmingly, only 21% of prescriptions were based on culture results and 39% lacked documented rationale. These findings underscore the need for improved AMR stewardship, diagnostics and provider education.

Antibiotic access and regulation

Antibiotic access and regulation remain uneven. Overuse is common in some settings while others face shortages due to weak supply chains and financial constraints. National essential medicines lists exist in 19 countries, but alignment with treatment guidelines and enforcement of regulations is inconsistent (8). Although restrictions on over-the-counter sales of antibiotic exist in most countries, enforcement is strong in only a few countries. Price disparities, low availability of generic medicines and reliance on fragile global supply chains for active pharmaceutical ingredients further complicate access. Regional initiatives such as pooled procurement and the use of digital tools such as Antibioigo offer potential pathways for improving access and stewardship (7,13).

IPC, WASH and vaccination

Given the dramatic impact of the COVID-19 pandemic and thanks to the new WHO global strategy, IPC has gained momentum recently (14). As of 2024, 16 EMR countries had an active national IPC programme, 19 had developed evidence-based guidelines aligned with international standards, and 13 were promoting multimodal strategies for IPC interventions (15). However, only 8 countries had a healthcare-associated infection (HAI) surveillance system, 10 countries had developed IPC curricula for in-service training, and 12 had IPC monitoring plans.

Basic WASH services are lacking in many health care facilities across the region, which impedes efforts to combat AMR and compromises equity and dignity for health care providers and recipients. The 2023 regional WASH estimates for health care facilities in the EMR shows that approximately 40% of facilities had inadequate hygiene services such as hand hygiene facilities at points of care and toilets, and 71% had improper waste management (16). Rural areas and fragile countries experiencing conflict and violence lag significantly behind. Investments in WASH infrastructure, particularly in health care settings, are urgently needed (8). Vaccination coverage is suboptimal. Pneumococcal vaccine is not included in several national

programmes and measles coverage has decreased post-pandemic (17). The success of typhoid conjugate vaccine in Pakistan, which extensively reduced drug-resistant cases from 65% to 44%, highlights the potential of vaccines in AMR control (8).

One Health and multisectoral coordination

The One Health approach is gaining traction, with 16 countries reporting multisectoral coordination mechanisms (5). However, only a few countries have fully operational systems (5), and there are challenges in aligning efforts through collaborations, strengthening One Health governance, and expanding cross-sectoral partnerships due to limited staffing and capacity in ministries of agriculture and environment (8). The One Health AMR learning hub proposed to be established in Saudi Arabia has the potential to become a great resource for supporting EMR countries in achieving progress through sharing of best practices and advancing evidence-based initiatives and actions (18).

AMR in emergencies and fragile settings

Fragile and conflict-affected countries face a disproportionate burden of AMR due to disrupted health systems, poor IPC, limited diagnostics, and lack of antimicrobial stewardship expertise. Humanitarian response programmes must integrate AMR considerations, and global funding mechanisms should prioritise these settings (8). Primary health care and emergency preparedness plans must include IPC and rational antibiotic use to ensure resilience. Replicable models for managing AMR in emergencies are needed, particularly in settings with high resistance rates and limited resilience.

The way forward in the EMR

EMR countries have made commendable progress in combating AMR, but urgent action is needed to scale-up and sustain current efforts. NAPs should be operationalised with realistic costing and integrated into national health plans. Strengthening primary care and embedding AMR stewardship across all levels of the health system is imperative in the long run. Pooled procurements, including under the flagship initiatives of the Regional Director, should complement regulatory reform (7). Scaling up IPC and WASH, especially in rural and underserved areas, and expanding vaccination coverage can help reduce the need for antibiotics. Substantial investment is essential to enhance surveillance and data use for decision-making, diagnostics and workforce development. Social and behavioural research as well as integration of these interventions into all levels of care and across sectors and organizations are critical. AMR should be considered a core concern during emergencies with tailored strategies for fragile and conflict-affected contexts.

In summary, EMR needs to adopt a people-centred health systems approach to addressing AMR in human health, while strengthening and aligning efforts across human, animal, agri-food, and environmental sectors. Only by investing in strategic priorities and focusing

response on equity and resilience can the region achieve the United Nations High-level Meeting target to reduce deaths due to bacterial AMR by 10% by 2030, against the 2019 baseline of 411 000 deaths in the EMR.

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A case for urgent action on fungal and anaerobic bacterial pathogens control in low- and middle-income countries

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The forgotten pathogens

Global health discourse has rightly prioritised antimicrobial resistance (AMR), tuberculosis and emerging viral pandemics (1). However, a dangerous blind spot remains. Fungal and anaerobic bacterial pathogens continue to be overlooked in international health strategies, funding frameworks and diagnostic roadmaps (2–3). This neglect disproportionately affects low- and middle-income countries (LMICs), where diagnostic limitations, surveillance gaps and therapeutic constraints already compromise patient outcomes (4). As a clinical microbiologist working in the Indian public health sector, I have witnessed firsthand the cost of this invisibility.

Recent estimates suggest that there are over 6.5 million invasive fungal disease cases annually, with approximately 3.8 million associated deaths (5). Invasive candidiasis, cryptococcal meningitis, aspergillosis, and mucormycosis are common among immunocompromised patients, intensive care unit admissions, transplant recipients, and individuals with uncontrolled diabetes (5). Anaerobic bacteria such as *Clostridium* spp., *Bacteroides fragilis* and *Fusobacterium* are implicated in intra-abdominal infections, necrotising soft tissue infections, surgical site infections, and sepsis, but are rarely identified in routine hospital diagnostics in LMICs. These pathogens contribute to prolonged hospital stays, inappropriate antimicrobial use and mortality, yet they receive little mention in global AMR conversations (6).

This commentary highlights the persistent neglect of fungal and anaerobic infections in global health policies, outlines the consequences for low- and middle-income countries, and proposes strategies to close the critical gaps.

The diagnostic barriers

There are several reasons for the persistent neglect. Fungal and anaerobic pathogens are diagnostically challenging. Fungal diagnostics require specialised tools—culture on Sabouraud media, galactomannan and β -D-glucan assays, or PCR-based platforms—that are largely available only at tertiary centres (5). Anaerobic

culture requires strict environmental control, which is lacking in most LMIC laboratories. As a result, both pathogen groups are underdiagnosed, creating the impression that they are rare or inconsequential (3).

The policy gaps

Fungal and anaerobic pathogen infections are systematically excluded from policy frameworks. The WHO Global AMR Surveillance System (GLASS) initially focused on a narrow set of aerobic bacteria. An early GLASS implementation protocol for *Candida* spp. was launched in 2019, and the fungi module began receiving data from countries in 2024 (6). However, uptake remains limited and fungal surveillance is still in its infancy in most LMICs. The essential diagnostics list includes only a handful of fungal tests and no anaerobic assays (7). National AMR action plans in LMICs often exclude fungal and anaerobic infections, and surveillance programmes rarely collect data on them, leaving health systems blind to their burden and trends. In India, even tertiary public hospitals lack anaerobic culture capacity, and fungal surveillance remains fragmented outside of HIV or transplant centres.

The funding neglect

There is little funding for the prevention and treatment of fungal and anaerobic infections. While tuberculosis, malaria and HIV receive structured support through global mechanisms such as the Global Fund and Gavi, fungal infections do not. A 2022 analysis by the Global Action Fund for Fungal Infections (GAFFI) found that fungal research and development received less than 1.5% of all infectious disease research funding (5), and anaerobic infections received less. This reinforces the neglect at global and national levels (2,5) and local underinvestment, which creates a cycle of silence and inaction.

Since the beginning of 2021, there has been a global surge in cases of COVID-19-associated mucormycosis. This predominantly affects individuals with compromised immunity and is especially notable among patients with poorly controlled diabetes mellitus or those who have received corticosteroid therapy (8). The rhino-orbital-cerebral form represents the most frequent

clinical manifestation of this invasive fungal infection. During the second wave of COVID-19 in India, more than 45 000 cases of mucormycosis were reported, many among young patients with uncontrolled diabetes (9). A recent study found mucormycosis in 6% of COVID-19 patients versus 1% in non-COVID-19 patients, underscoring the elevated risk of COVID-19-associated mucormycosis (10). During the pandemic, hospitals lacked access to timely diagnostics or antifungal drugs, leading to disfigurement and deaths. Anaerobic infections often go unrecognised, resulting in empiric use of broad-spectrum antibiotics, which accelerates resistance and drives costs higher. These infections are clinically significant, yet invisible in data, reports and funding streams (3).

Strategies for closing the gap

To correct the longstanding and detrimental imbalance in global health priorities, several coordinated global and national actions are urgently required to bring fungal and anaerobic bacterial infections into the core of public health strategies and AMR mitigation frameworks (11).

First, fungal and anaerobic pathogens must be explicitly integrated into antimicrobial resistance surveillance initiatives, including the WHO GLASS and equivalent national platforms, such as India's integrated disease surveillance programme. The WHO published a fungal priority pathogens list in 2022 to systematically guide research and public health investment, and *Candida* spp. is now tracked within GLASS. However, coverage remains limited, reporting is inconsistent across LMICs and anaerobic pathogens remain entirely excluded. The current surveillance mechanisms are predominantly centred on a limited panel of aerobic bacterial pathogens, and fail to capture the epidemiologic footprint and resistance trends of anaerobic organisms and fungal species. Expanding the scope of surveillance programmes would enable health authorities to generate meaningful data, guide empirical treatment protocols, monitor resistance patterns, and support evidence-based policymaking across LMICs (13,14). The expected impact of this expansion would be earlier case detection, more rational antimicrobial use and ultimately a measurable reduction in preventable morbidity and mortality.

Second, the WHO Essential Diagnostics List (EDL) should be revised and expanded to include a wider array of fungal and anaerobic diagnostic assays that are accessible, affordable and adaptable to LMIC health systems. While the current EDL includes several bacterial and parasitic diagnostics, fungal tests—such as lateral flow assays for cryptococcal antigen detection, chromogenic agar for *Candida* speciation, and β -D-glucan assays for invasive fungal infections—remain underrepresented. Anaerobic diagnostics, including culture kits for *Clostridium* and *Bacteroides* species, and nucleic acid amplification techniques for toxin detection, are not included in the list. Their inclusion is essential to support diagnostic stewardship and timely intervention

in resource-constrained settings (6,15). Improved diagnostic access would translate into earlier and more accurate case detection, reduced reliance on empirical regimens, shorter hospital stays, and improved patient outcome.

Third, governments—particularly LMICs—must allocate funds and provide policy support for workforce development in clinical microbiology, infectious diseases and laboratory medicine, particularly for microbiologists, infection control specialists and laboratory technicians. Establishing centres of excellence, enhancing continuous medical education and incorporating these areas into the undergraduate and postgraduate curricula will help establish a workforce that is capable of identifying, diagnosing and managing these infections effectively (16). Such investments will facilitate accurate diagnosis, rational antimicrobial use and effective infection control, thereby strengthening the resilience of health systems.

Fourth, donors and funding agencies should allocate resources for fungal and anaerobic diagnostic and therapeutic innovation research and development. Priority should be given to developing affordable, rapid and robust point-of-care tests tailored to the environmental conditions and epidemiologic needs of LMICs. Investments in vaccine development for high-risk fungal pathogens (e.g. *Aspergillus*, *Cryptococcus*) and the creation of broad-spectrum antifungal and anti-anaerobic agents is urgently needed to supplement the therapeutic channels that have remained stagnant for decades (2,17). Supporting implementation research and pilot programmes that scale up new diagnostic tools can help bridge the gap between bench innovation and bedside application. The expected outcome would be the availability of immediate and long-term innovations, ranging from low-cost diagnostics such as cryptococcal lateral flow assays (successfully deployed in South Africa to enable early detection and pre-emptive treatment) to novel therapies, which would reduce diagnostic delays, expand treatment options and directly lower mortality (18).

Fifth, national AMR action plans must evolve to comprehensively include fungal and anaerobic infections, ensuring their recognition across health policy instruments, procurement protocols, and clinical guidelines. This will require updating the standard treatment guidelines, establishing clear case definitions for surveillance and integrating fungal and anaerobic indicators into health information systems. Such action plans must be cross-sectoral and aligned with the One Health approach, recognising the interplay between human, animal and environmental reservoirs of antimicrobial resistance (1,12,19). Embedding these pathogens in the national AMR strategies would create a sustainable policy environment that ensures visibility, secures resources and leads to more comprehensive and effective AMR responses.

Conclusion

Fungal and anaerobic infections remain a silent yet deeply entrenched crisis in global health. Their persistent neglect undermines the equity and comprehensiveness of AMR strategies as well as the broader goals of Universal Health Coverage, health system strengthening and pandemic preparedness. LMICs—already strained by systemic resource limitations—are disproportionately burdened by this diagnostic and therapeutic void, which results in mismanagement, prolonged hospitalizations and preventable deaths. These pathogens, although not always headline-grabbing, cause insidious damage

as they are not visible in laboratory data, unrecorded in surveillance reports and unfunded in research and development portfolios (3,12,20). Addressing this gap is not merely a scientific necessity but a moral imperative. We call on WHO, donors and governments to explicitly integrate fungal and anaerobic pathogens into AMR strategies, surveillance systems, diagnostic guidelines, and funding priorities of low- and middle-income countries—so that no pathogen and no patient is left behind.

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Table 1 Gaps and recommended actions for addressing fungal and anaerobic bacterial infections in LMICs

Area	Current gaps	Proposed actions	Expected impact
Surveillance	- Limited fungal surveillance - Candida spp. included in GLASS since 2019, but reporting remains patchy - Anaerobic pathogens excluded - Data fragmented and disease burden underestimated	- Strengthen uptake of the GLASS fungi module - Expand scope to include broader fungal species and anaerobes - Mandate reporting in AMR action plans	- Earlier case detection - Improved treatment choices - Reduced empirical antibiotic use - Lower mortality
Diagnostics	- Limited or no access to fungal antigen assays (e.g. galactomannan, β-D-glucan), PCR and anaerobic culture facilities - Dependence on tertiary centres	- Expand WHO essential diagnostics list to include fungal and anaerobic tests - Subsidize procurement - Invest in regional laboratory capacity	- Earlier and more accurate diagnosis - Reduced empirical therapy - Improved stewardship - Shorter hospital stays
Policies and guidelines	- National AMR action plans rarely address fungal and anaerobic pathogens - Absence of clinical guidelines in many LMICs	- Update AMR policies to explicitly include these pathogens - Develop treatment guidelines tailored to LMIC settings	- Sustainable inclusion of neglected pathogens in health systems - Standardized treatment - Stronger AMR response
Funding and research and development	- Fungal research and development receives <1.5% of infectious disease research funding - Anaerobic infections receive negligible funding	Allocate funds for affordable point-of-care diagnostics and new therapies	- Development of rapid, low-cost tools - Improved therapeutic pipeline - Reduced diagnostic delays and mortality
Workforce capacity	- Limited training in fungal and anaerobic microbiology for laboratory and clinical staff - Lack of infection control integration	- Implement training programmes for microbiologists, infectious disease physicians and laboratory staff - Include modules in medical curricula	- Skilled workforce capable of accurate diagnosis - Rational antimicrobial use - Effective infection control
Community awareness	- Low awareness among health care workers and patients - Infections perceived as rare	Public health campaigns and clinician sensitization programmes	- Increased awareness - Earlier health-seeking - Reduced delays in diagnosis and treatment

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Unsupervised use of antibiotics in the State of Palestine

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Introduction

The world has been amazed since the introduction of the first antibiotic, penicillin, in 1928 (1). Subsequent introduction of streptomycin in 1943 marked another milestone in antibiotic innovation and discovery (2).

Before antibiotics, simple infections often led to severe complications and even death, but their advent changed the course of medical history, significantly reducing mortality rates (3). However, the emergence of antibiotic-resistant bacteria strains, primarily due to overuse and misuse of antibiotics, has raised global concerns, prompting a re-evaluation of our relationship with these drugs (4). In developed countries, supervision and advancements in the healthcare systems help tailor the use of antibiotics for their intended purposes and thus helping to mitigate antimicrobial resistance (AMR). However, in developing countries like the State of Palestine, the situation is different (5); antibiotics are frequently available over-the-counter without a prescription and patients are sometimes given inappropriate antibiotic prescriptions, and these have contributed widely to AMR (8).

Overprescription of antibiotics for conditions that do not require them, such as viral infections, and not completing prescribed antibiotic doses, are key contributors to AMR (6). Evidence shows that antibiotics are often dispensed without prescription in the State of Palestine and in several Middle Eastern countries (9). Many patients self-medicate using antibiotics purchased over-the-counter, and sometimes by sharing antibiotics within households (10). The lack of robust data collection systems and inadequate resources for identifying bacterial strains and antibiotic sensitivities in laboratories further complicate the situation (11).

Strategies to minimize AMR include prudent use of antibiotics, based on the antimicrobial stewardship guidelines, understanding the pharmacokinetics and pharmacodynamics of antibiotics, and performing diagnostic and antimicrobial susceptibility testing (7).

Médecins Sans Frontières' laboratories installed in the region often report alarmingly high levels of multi-drug-resistant bacteria, specifically among Enterobacte-

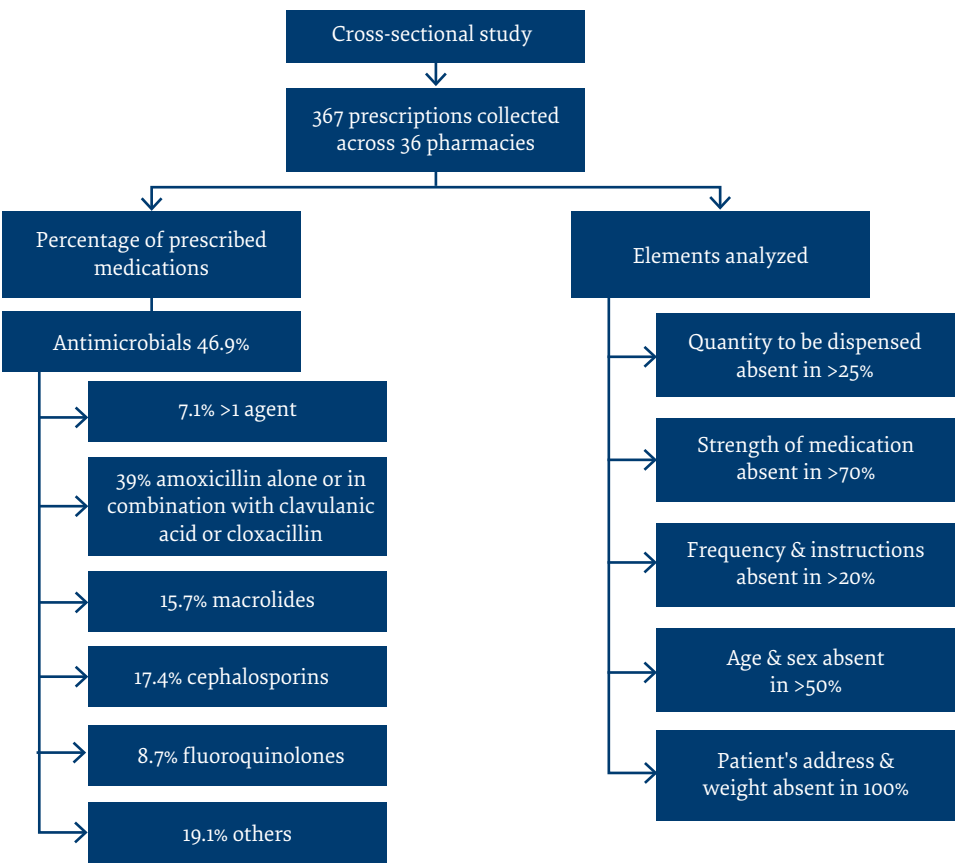
riaceae isolates to third-generation cephalosporins and carbapenems, as well as high prevalence of multi-drug resistant *Staphylococcus aureus* (12). A retrospective review of medical records at the European Gaza Hospital found poor adherence to current standards of care in severity assessment and management of community-acquired pneumonia (13). A broad range of antibiotic regimes were used without microbiological guidance, thus increasing the risk of antibiotic resistance. A prospective study by Al Jarousha et al, which collected blood specimens from neonates in 2 neonatal intensive care units in Gaza City, found a significant infection rate with multidrug-resistant *A. baumannii*, and it was associated with considerable mortality (14).

A cross-sectional study of bacterial isolates from burns units in Gaza found a high percentage of cultures positive for pathogens like *Pseudomonas aeruginosa* and *Enterobacter cloacae* (15). A notable finding was the high resistance of these isolates to common antibiotics, highlighting a significant challenge in treating infections in burns units. Similar results would likely be observed in the West Bank because of the comparable culture, locality and practices (16). A cross-sectional study in the West Bank by Al-Halawa et al revealed that 60% of pharmacists dispensed antibiotics without a prescription, indicating a similar trend in antibiotic use and practices (8). Another study in both the West Bank and Gaza identified the need for educational initiatives to improve the knowledge of physicians on the appropriate use of antibiotics, thus improving attitudes and practices (9).

One cross-sectional study that analysed prescriptions in Nablus, West Bank, reveals that antimicrobials are the most commonly prescribed medications, constituting 46.9% of all prescriptions, followed by nonsteroidal anti-inflammatory drugs or analgesics (40%). The study also found that the quality of prescription writing was deficient in certain aspects and needed improvement (17) (Figures 1 & 2).

WHO recommends that a prescription should include several key elements such as the patient's age, sex, address; frequency and amount of medication to be dispensed, and the handwriting should be legible (18). One study highlighted a concerning rate of omission of these

Figure 1 Flowchart of a cross-sectional study on prescriptions across pharmacies in Nablus, West Bank, State of Palestine.

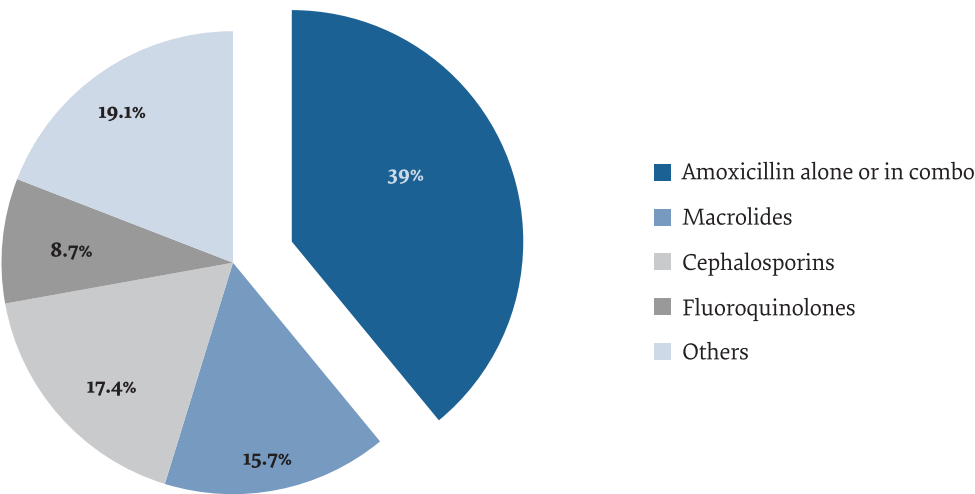


**Metronidazole was incorrectly classified as cephalosporin in the original article, leading to its exclusion from that class and its addition to "others". Same for "sulfamethoxazole + trimethoprim", which was also added to "others".*

**The percentage of azithromycin reported in the original article was miscalculated. The accurate percentage is 9.3%, bringing the total for the entire class of macrolides to 15.7%.*

**For frequencies, instructions and strengths, the percentages represent cases where these details were not fully specified for all prescribed drugs in the prescription.*

Figure 2 Percentage of specific antimicrobials dispensed across pharmacies in the city of Nablus, West Bank, State of Palestine.



**Metronidazole was incorrectly classified as cephalosporin in the original article, leading to its exclusion from that class and its addition to "others". Same for "sulfamethoxazole + trimethoprim", which was also added to "others".*

**The percentage of azithromycin reported in the original article was miscalculated. The accurate percentage is 9.3%, bringing the total for the entire class of macrolides to 15.7%.*

crucial elements in prescriptions (17). Although there is a scarcity of published research on antibiotic prescriptions in the State of Palestine, local observations suggest that at least 75% of patients in outpatient clinics and medical centres across the West Bank are given enteral or parenteral antibiotics for fever, irrespective of its cause. This practice has been observed among general practitioners, specialists and nurses. The commonly used antibiotics are ceftriaxone, cefazolin, meropenem, metronidazole, amoxicillin-clavulanic acid, piperacillin-tazobactam, and vancomycin. Ceftriaxone is the most frequently administered. A similar situation is believed to exist in Gaza. This trend is thought to be driven primarily by the ease of access to these medications, often supplied to physicians by pharmaceutical companies as incentives to prescribe their products, along with the financial benefits involved. The lack of patient education on AMR may have contributed significantly to this.

A cross-sectional study by Alagha et al indicated that 68.2% of hospitalized patients in Gaza were prescribed antibiotics, ceftriaxone being the most frequently used (47.5%) (19). Another study in Gaza reported excessive and often irrational antibiotic prescriptions and a lack of culture sensitivity (20). A study in Ethiopia revealed high use of ceftriaxone (59% prevalence). Its use was predominantly empirical at 79.5%, and 80.2% of the ceftriaxone prescriptions were deemed inappropriate (21). These findings are highly concerning and underscore the critical need for antibiotic stewardship programmes to manage usage, address resistance and decrease health care costs.

Antimicrobial residues found in various food types pose significant risks to human health and the environment, primarily due to antibiotic use in agriculture and animal husbandry (22). While these substances play crucial roles in disease prevention and in promoting growth in livestock, their presence in food products can adversely affect consumers. Such adverse effects include allergic reactions, antibiotic resistance and alteration of the natural gut microbiota (22). Shahid et al further elaborated that these residues can contribute to the emergence of antibiotic-resistant bacteria, posing a major public health challenge (23). Jayalakshmi et al highlighted the risk of reduced efficacy of antibiotics in treating human diseases due to the presence of antibiotic residues in the food chain (24).

Although cooking and processing can reduce the risk of ingesting certain antibiotics, they do not guarantee the complete breakdown of residues. The stability of antibiotics such as quinolones and β -lactams presents significant health risks because their residues can persist

in milk even after heat treatment, potentially reaching consumers (25,26).

Studies in the State of Palestine have found antibiotic residues in poultry meat samples, with an overall positive rate of 24% (27). In a study on raw dairy milk samples, a significant portion exceeded the maximum residual limits (MRLs) for β -lactams and tetracyclines. For instance, 22.2% of the samples tested for β -lactam residues were above MRLs, while 18.7% of the samples tested for tetracycline exceeded MRLs. This underscores the need for enhanced monitoring and regulation, especially in regions like the State of Palestine where specific regulations and monitoring systems are lacking (28).

In regions such as the State of Palestine, the unsupervised use of antibiotics, coupled with the inadequate monitoring of imported foods, poses a threat to food safety and human health. A review of 40 studies on antibiotic residues in foods from Arab countries, including the State of Palestine, has highlighted concerns about antimicrobial resistance and the need for improved monitoring and control measures. The study found evidence of antibiotic residues in some Palestinian milk samples, including β -lactams, tetracyclines and sulfamethazine, detected through initial quality assessments using SNAP test kits and in ultra-high temperature milk. However, limited resources have hindered further analysis (29).

Conclusions and recommendations

To address this critical issue of AMR effectively, the Ministry of Health and other authorities in the State of Palestine should implement stringent measures to prevent further deterioration of practices regarding antimicrobial use. More research is needed on microbial sensitivity to antibiotics and to provide data on AMR for developing evidence-based antibiotic prescription guidelines in the State of Palestine (17). There is a need to improve patient education regarding antibiotic use; develop or adopt clear guidelines on antibiotic prescription for viral illnesses, especially upper respiratory tract infections; enhance food monitoring and quantification to minimise antibiotic residues in food products; implement stricter regulations on outpatient parenteral antibiotic administration; and regulate the dispensing of antibiotics. These will require multisectoral collaborations to leverage resources and technical expertise.

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The rise of multidrug-resistant organisms in Sudan and Gaza amidst health system disruptions

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Keywords: antimicrobial resistance, multidrug resistance, antimicrobial stewardship, health system, Gaza, Sudan

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Introduction

Gaza and Sudan have experienced disruptions to their health systems in the past decades. The public health situation in Gaza has been critical due to the blockades since 2007 and the October 2023 Hamas-Israeli conflict. These have caused extensive damage to health care services and infrastructure, thereby pushing the health system to the brink of collapse (1). The current Sudan conflict, which began in April 2023, has affected the health infrastructure, leading to a broken health system with serious lack of essential medicines and medical equipment. Access to clean and safe drinking water and food has been a serious challenge to the health of the Sudan population, which is largely displaced (1,2). Over 70% of hospitals in the affected areas have become non-operational.

Beyond conflict-related injuries, Sudan is experiencing extensive infectious disease outbreaks, which further intensify the health care crisis (1). Antimicrobial resistance (AMR) is a major public health threat globally. Drug-resistant infections kill more than 1.27 million people globally each year, and averagely 92 800 in the Eastern Mediterranean Region, creating a heavy burden on health systems. An average of 3940 deaths are attributable to AMR yearly in Sudan, and 300 in Gaza (3). Multidrug-resistant organisms (MDROs) have increased significantly between 2000 and 2024, in Sudan and Gaza (3).

This commentary highlights the increase in multidrug-resistant bacteria in Sudan and Gaza and actions to minimise their occurrence.

Multidrug-resistant organisms in Sudan and Gaza

The Institute for Health Metrics and Evaluation estimates that in 2021, 2840–5030 deaths were attributable to AMR and 10 500–18 600 were associated with AMR in Sudan, with the highest deaths occurring among patients aged <5 years (4). Among the deadliest pathogen-

drug combinations in 2021 were methicillin-resistant *Staphylococcus aureus* (MRSA), carbapenem-resistant *Acinetobacter baumannii*, and *Streptococcus pneumoniae* (4). A recent study from the University of Gezira, Sudan, reported 39.3% prevalence of multidrug-resistant organisms, with *Staphylococcus aureus* and *Proteus* spp. having the highest MDR (5). Although Sudan was identified by the WHO Global Antimicrobial Resistance Surveillance System (GLASS) as a country with increasing AMR threat, the current conflict has severely limited the capacity to monitor and quantify resistance patterns (6).

Evidence from Gaza shows alarmingly high levels of AMR in clinical isolates and hospital wastewater. *Pseudomonas* was detected in 59.4% of water samples from 5 primary health care centres in Gaza, with high resistance to imipenem (84%) and piperacillin (84%), followed by aztreonam (31.6%) and gentamicin (28.9%) (7). New Delhi metallo- β -lactamase-resistant gene (NDM) was identified in 26% of the *Pseudomonas* isolates. This highlights the urgent need for effective water safety and AMR monitoring in health care facility (7). Furthermore, of 158 gram-negative bacilli isolates obtained from Al-Nasser Paediatric Hospital in the Gaza Strip, 58.9% were positive for ESBL production (8). The prevalence of ESBL production among the bacteria was estimated at 83% among *Klebsiella pneumoniae*, 62% among *E. coli*, and 33% among *P. aeruginosa*. The 2 *P. mirabilis* isolates were ESBL producers.

Findings in Sudan and Gaza are comparable to those in the WHO Eastern Mediterranean region (9,10). Both MDR gram-negative bacteria, including *Klebsiella pneumoniae*, *E. coli* and *Acinetobacter baumannii*, and gram-positive bacteria, including MRSA, have been identified among the most prevalent in the region, leading to significant morbidity and mortality. For instance, in Tehran, the most prevalent MDROs were *Acinetobacter* species and *P. aeruginosa*, while in Jordan, MRSA, *Escherichia coli*, *Pseudomonas*, *Citrobacter*, *Proteus* spp. and *Klebsiella* spp. were the most isolated MDROs (9).

Factors driving antimicrobial resistance in Sudan and Gaza

In Gaza, mass violence has resulted in a high burden of traumatic injuries with heavily contaminated wounds. Under extreme resource constraints, health workers have been compelled to prioritise life- and limb-saving interventions over infection prevention and control (IPC) and antimicrobial resistance (AMR) control (11). In Sudan, a recent study from the University of Gezira found that wound swabs accounted for 41.2% of MDR isolates (12).

During the October 2023 conflict, Al-Shifa, Al-Quds and Al-Ahli Arab hospitals collectively sheltered approximately 117 000 internally displaced persons. Severe overcrowding, combined with the collapse of water and sewage systems and the displacement of over 1.5 million people into unsanitary environments, significantly increased the risk of infectious transmission (13).

The emergence of MDROs in Sudan and Gaza is closely related to the misuse and availability of antibiotics, a common phenomenon also observed in similar environments like Syria (14). In Sudan, antibiotics have been widely available for purchase without a prescription, leading to irrational use as a major cause of resistance. Before the war, only 27% of facilities in Sudan had antimicrobial stewardship (AMS) programmes, and currently, none of these programmes is functional (11). Shortage of essential medicines, the circulation of counterfeit drugs and overburdened clinicians relying on broad-spectrum antibiotics without microbiological guidance further exacerbate the problem (11).

In Gaza, prolonged blockade has restricted access to antibiotics, with availability decreasing to as low as 45%, and the denials at border crossings have led to the expiration of diagnostic reagents and medicines, limiting targeted antimicrobial therapy (11,13).

Weak IPC practices, compounded by overcrowding, represent another major driver. By 2024, more than 70% of hospitals in Sudan were damaged or closed, and before the conflict, most health workers lacked access to IPC guidelines (11,15). In Gaza, overcrowded hospitals serving both as shelters and care facilities further worsen the crisis, with wounded patients often untreated on floors and exposed to hospital-acquired infections (13). During the 2018 Great March of Return protests, nearly all admitted gunshot patients developed resistant infections (16).

Diagnostic capacity is also severely compromised. In Sudan, 79% of doctors do not rely on microbiology results due to cost and limited access. The collapse of laboratory surveillance, shortage of supplies and dysfunction of microbiological services have led to the emergence and spread of MDROs (11,15).

Perspectives on the short-, medium- and long-term strategies to prevent AMR in Sudan and Gaza

The critical intersection of humanitarian crises and health system disruptions in Sudan and Gaza highlights the need to integrate AMR mitigation strategies into ongoing responses (17). AMS activities, led by the ministries of health and supported by partners, could be integrated across all levels of care to encourage responsible use of antibiotics. This may include antimicrobial prescription practice monitoring, routine audits, multidrug-resistant organism surveillance, capacity building for health workers, and contextualised implementation of standard guidelines for patient management, depending on the level of care (17).

Evidence suggests that effective stewardship programmes can enhance awareness, perceptions and practices among health care professionals regarding appropriate antibiotic use, thereby potentially limiting unnecessary prescriptions within hospital settings (13). This is believed to be more effective when integrated with effective IPC practices, such as hand hygiene, environmental sanitation and proper waste management (5), thus reducing the transmission of MDROs.

Strengthening microbiology capacity and pathogen surveillance at all levels to address MDROs may be effective, particularly in active conflict settings. This may include rebuilding critical laboratory infrastructure and ensuring continuous capacity-building for relevant staff, because robust surveillance is essential for early detection and for monitoring the spread of MDROs. Implementing patient surveillance upon hospital admission has served as an effective tool for early detection of treatment failures, which may be an indicator of underlying MDRO infection or potential hospital outbreak (5), although feasibility may be doubtful in conflict settings due to limited resources.

In the mid-term, implementation of key activities aimed at building resilient health systems would be helpful, as outlined by the Regional Committee for the Eastern Mediterranean (17–19). Supporting health system recovery for MDRO mitigation post-crisis arguably requires focusing on strengthening local capacities to prevent and manage MDRO infections, alongside outbreak preparedness for core national priority pathogens. Arguments in favour of effective recovery and resilience often highlight the importance of integrating routine risk assessments, particularly in high-risk facilities, to identify and bridge gaps in practice. This viewpoint supports the re-establishment and strengthening of national and facility-based pathogen surveillance, alongside other AMR-related recoveries, including water, sanitation and hygiene infrastructure. A strengthened health system is inherently better positioned to maintain

essential services while concurrently responding to resistant infections, potentially reducing morbidity and mortality associated with MDR pathogens (18).

Policy frameworks like the AMR national action plans for Sudan and Gaza remain critical documents that embed AMR actions, including monitoring antibiotic use, increasing access to diagnostics and enhancing care at the primary level. However, the action plans for both Sudan and Gaza are not up-to-date. Sudan's action plan expired in 2020, while Gaza's plan expired in 2024. This creates a policy gap. Revising the action plans, based on current realities, may provide a better policy environment

for addressing the problem of increasing MDROs in Sudan and Gaza (16,18).

In the long-term, antimicrobial stewardship capacity-building could be incorporated into the core training curriculum for health workers toward achieving sustainable recovery. Integrating this concept early in medical education may better prepare the healthcare workforce in Sudan and Gaza conceptually and practically to combat multidrug resistance (19).

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Readiness of national reference laboratories in the Eastern Mediterranean Region for antimicrobial resistance surveillance systems

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Abstract

Background: National reference laboratories are central to antimicrobial resistance surveillance, yet their capacities vary widely across the Eastern Mediterranean Region.

Aim: To assess the readiness of national reference laboratories in the Eastern Mediterranean Region for antimicrobial resistance surveillance.

Methods: From November 2019 to June 2020 and from December 2024 to February 2025 we collected and analysed data relating to antimicrobial resistance surveillance capacities of national reference laboratories from the 22 countries and territories in the WHO Eastern Mediterranean Region. We compared the paired binary indicators using the 2-sided exact McNemar test ($P < 0.05$) and analysed the secondary Global Antimicrobial Resistance and Use Surveillance System data for 2017–2023.

Results: Only 3 national reference laboratories had the full public health capacity. Limited confirmatory and reference testing, poor data integration and use, shortage of skilled workforce, and suboptimal quality assurance mechanisms were the major gaps identified. Fungal diagnostic capacity was a critical and largely neglected gap. There were no statistically significant within-country changes among the 9 countries included in the longitudinal comparison. The Global Antimicrobial Resistance and Use Surveillance System data suggest gradual strengthening of surveillance infrastructure.

Conclusion: There is an urgent need to strengthen the core functions of national reference laboratories in the Eastern Mediterranean Region to better support antimicrobial surveillance systems.

Keywords: antimicrobial resistance, reference laboratory, surveillance, GLASS, Eastern Mediterranean

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Introduction

The Global Research on Antimicrobial Resistance (GRAM) project estimated that, in 2021, 4.71 million of the 7.75 million deaths caused by bacterial infections were associated with drug-resistant infections, including 1.14 million attributable deaths (1). In the Eastern Mediterranean Region (EMR), bacterial antimicrobial resistance (AMR) was associated with 380 000 deaths, including 92 800 attributable deaths in 2021. Projections indicate that AMR-attributable deaths could increase by nearly 70%, reaching 3.24 million by 2050 (1).

AMR surveillance is a key pillar of the WHO Global Action Plan (GAP), to generate data for evidence-based policies and interventions (2). As international efforts intensify to strengthen AMR surveillance systems, access to high-quality and timely laboratory services remains essential for cost-effective interventions, including infection prevention and control and antimicrobial stewardship (3).

National reference laboratories (NRLs) are central to laboratory-based surveillance networks. They provide

leadership and technical support to surveillance site laboratories (SSLs), standardise laboratory practices, and serve as referral hubs for complex and specialised testing (4,5). Through the Global Antimicrobial Resistance and Use Surveillance System (GLASS), launched in 2015, WHO highlighted the importance of nationally adapted surveillance systems built around functional coordination mechanisms, NRLs and SSLs networks (6). WHO further supported this role through its 2020 guidance for NRLs, which outlines key functions in reference testing, standardisation, training, data analysis, evaluation, and research (4).

In alignment with the GAP on AMR, endorsed during the 68th World Health Assembly in 2015, several consultative workshops have supported the development and implementation of national AMR action plans (NAPs) across EMR countries, including the strengthening of NRLs and laboratory networks (7). However, NRLs remain a weak link in AMR surveillance systems in many resource-constrained settings, particularly in countries affected by conflict, political instability and economic volatility. As a result, surveillance data are often

underutilised, and challenges related to data quality and inefficient reporting further limit their use for policy and public health (8,9).

To the best of our knowledge, no systematic assessment of NRLs has been conducted across the EMR within the context of AMR surveillance systems. This paper therefore documents the public health, operational and technical capacities of NRLs, identifies critical gaps affecting their ability to support health systems, and proposes context-specific, actionable solutions to inform targeted laboratory strengthening strategies.

Methods

The WHO Regional Office for the Eastern Mediterranean (WHO/EMRO) conducted 2 regional cross-sectional surveys to assess the core AMR surveillance capacities of NRLs in the EMR. Although the tools included a broader set of questions than those reported here, this analysis focused on public health, operational and technical capacities. Secondary data on 3 core indicators – national coordinating centres (NCC), designation of NRLs and SSLs – were obtained from GLASS reports for 2017–2023 to assess country-reported progress in these areas (10).

Cross-sectional surveys

The surveys covered the following 2 domains and the second survey included selected questions, used with permission, from a tool previously developed by the WHO Western Pacific Regional Office (WHO/WPRO):

Public health capacities: This domain assessed the ability of NRLs to effectively support the national AMR surveillance network, specifically SSLs, in alignment with WHO recommendations (4), including reference/confirmatory testing, guidance and standardisation, training and capacity building, evaluation and monitoring, and data collection and analysis.

Operational and technical capacities: This domain evaluated the technical and operational infrastructure of NRLs using key components of the laboratory quality management system (LQMS) (13), including availability of standard operating procedures (SOPs), internal quality control, external quality assessment (EQA), minimum staffing, laboratory information systems (LIS), and supply chain management.

The second survey placed particular emphasis on assessing fungal diagnostic capacity within NRLs.

Data collection and analysis

The questionnaires were distributed by email from November 2019 to June 2020 and from December 2024 to February 2025 to national GLASS focal points, directors of central public health laboratories, and/or directors of AMR NRLs across the 22 countries and territories in the region. Automated validation checks were used to prevent data entry errors and responses were returned to national focal points for verification before analysis. Survey responses were analysed across the 2 core domains using a standardised framework informed by WHO guidance and international best practices (4,11). Only the 9 countries that participated in both surveys were included in the longitudinal comparison. Common paired binary indicators were compared using the 2-sided exact McNemar test and the comparative results were presented as counts. Statistical significance was set at $P < 0.05$. Findings were interpreted cautiously given the small matched sample.

Ethics considerations

This survey assessed institutional laboratory capacities and did not involve human participants, patient data or human biological specimens. The work was conducted as part of a WHO-coordinated regional survey of national reference laboratories in the Eastern Mediterranean Region. In accordance with WHO procedures, the survey was reviewed and approved through WHO’s internal clearance process.

Results

Response to the surveys

We received responses from 20 countries for the first survey, and 11 countries for the second survey (Table 1). Two high-income countries (HICs) participated only in the second survey and were therefore excluded from the comparative analysis. The remaining 9 countries classified as middle- (MICs) and low-income countries (LICs) participated in both surveys and were retained to allow for direct comparison.

Findings from the first survey

Basic laboratory capabilities and infrastructure

Nine of the 20 respondents, including all 4 HICs and 5 of the 11 MICs, reported adequate budget for laboratory

Table 1 Description of respondent countries and territories based on the income level

Income level	Number	
	First survey (2020)	Second survey (2025)
High-income countries	4	2
Middle-income countries	11	7
Low-income countries	5	2
Total	20	11

operational services. Twelve countries, including all 5 LICs and 7 MICs, reported regular shortages of laboratory supplies. Budget adequacy was closely linked to sustainable provision of consumables.

All 4 NRLs in HICs and 5 NRLs in MICs reported automation for AMR testing, including identification and antimicrobial susceptibility testing (AST), and the use of molecular diagnostics to detect resistance patterns. In contrast, none of the NRLs in LICs reported having such capabilities. All the LICs consistently reported electricity and water supply interruptions, posing additional challenges to regular and reliable laboratory operations.

Public health capacities

Only 3 (all HICs) of the 20 NRLs reported full capacity across all assessed public health functions. Among the assessed domains, data collection and analysis were the weakest, with only 9 of 20 NRLs meeting the expected requirements to support a functional AMR surveillance

system. In contrast, training and capacity building, and guidance and standardisation were the most consistently reported strengths: 18 of 20 NRLs reported providing training to staff, conducted on average twice per year, while 16 of 20 NRLs reported disseminating guidance through protocols, policies or standard operating procedures (Figure 1A).

Operational and technical capacities

Operational and technical capacities varied widely across the countries and territories. The strongest domain was the availability of SOPs, reported by 17 of the 20 laboratories. Minimum staffing requirements were not met, with only 7 of 20 NRLs meeting the recommended benchmark of at least one qualified medical microbiologist and one epidemiologist, irrespective of the income level. Ten of 20 countries reported using laboratory information systems (LIS) to support AMR surveillance (Figure 1B).

Figure 1A Public health capacities in respondent EMR countries (N = 20), 2019–2020

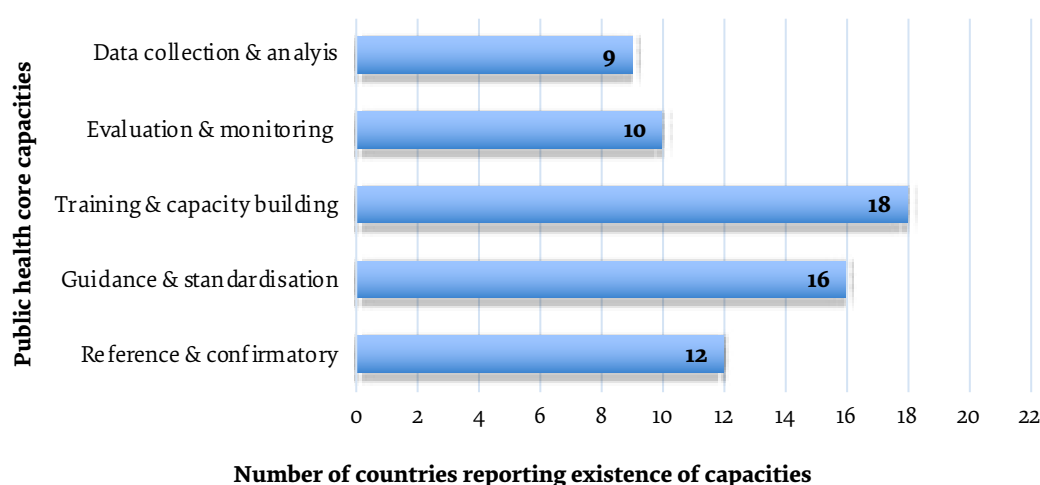
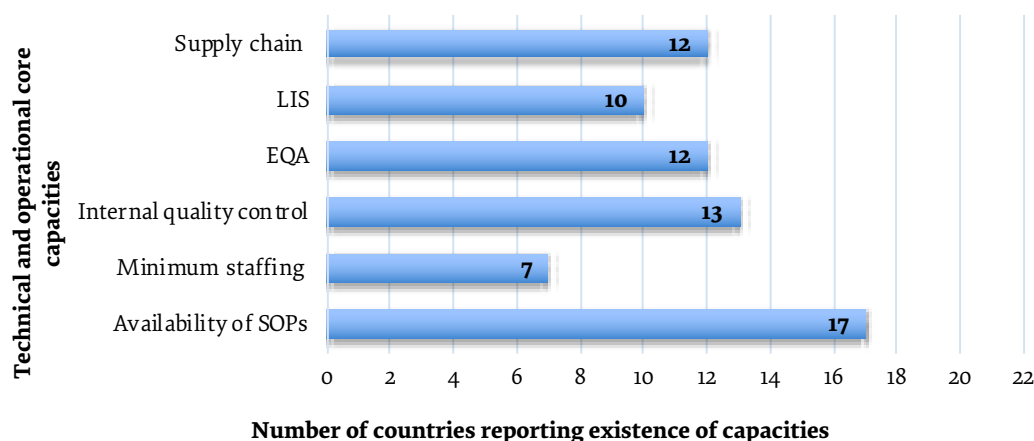


Figure 1B Technical and operational core capacities in respondent EMR countries (N = 20), 2019–2020



SOPs = standard operating procedures; LIS = laboratory information system; EQA = external quality assessment

Comparison across surveys

Comparative analysis among the 9 countries that responded to both surveys did not detect statistically significant within-country changes in any of the paired indicators. Descriptively, availability of laboratory information systems increased from 1 in 9 in 2020 to 2 in 9 in 2025 ($P = 1.000$), automated systems increased from 7 in 9 to 9 in 9 ($P = 0.500$), shortage of laboratory supplies increased from 6 in 9 to 9 in 9 ($P = 0.250$), and availability of medical microbiologists increased from 4 in 9 to 6 in 9 ($P = 0.500$). In contrast, participation in external quality assessment programmes decreased from 9 in 9 to 6 in 9 ($P = 0.250$), and availability of epidemiologists decreased from 6 in 9 to 2 in 9 ($P = 0.125$) (Figure 2). Although these descriptive patterns may suggest contextual shifts in selected operational capacities, they should be interpreted cautiously, because none of them reached statistical significance and the matched sample was small; therefore, they do not constitute evidence of confirmed temporal trends.

Fungal diagnostic capacity

The second survey incorporated an additional module to assess the capacity of NRLs for fungal pathogen identification and antifungal susceptibility testing. Of the 9 NRLs surveyed, 8 (2 LICs and 6 MICs) reported lacking fungal diagnostic services. Key barriers to fungal diagnostic services included shortage of trained mycologists, absence of national policies and standardised diagnostic guidelines, and limited essential diagnostic supplies such as antifungal discs and fungal culture kits. Other challenges included lack of standardised quality control strains and generally low clinician awareness of fungal diagnostics, thus limiting the integration of fungal diagnostics into routine surveillance.

Findings of the GLASS reports

Data from the GLASS reports (2017–2023) showed a statistically significant upward trend over time ($P < 0.05$) in GLASS enrolment, establishment of NCC and designation of NRLs, indicating gradual yet meaningful progress in surveillance capacity across EMR countries (Figure 3).

Discussion

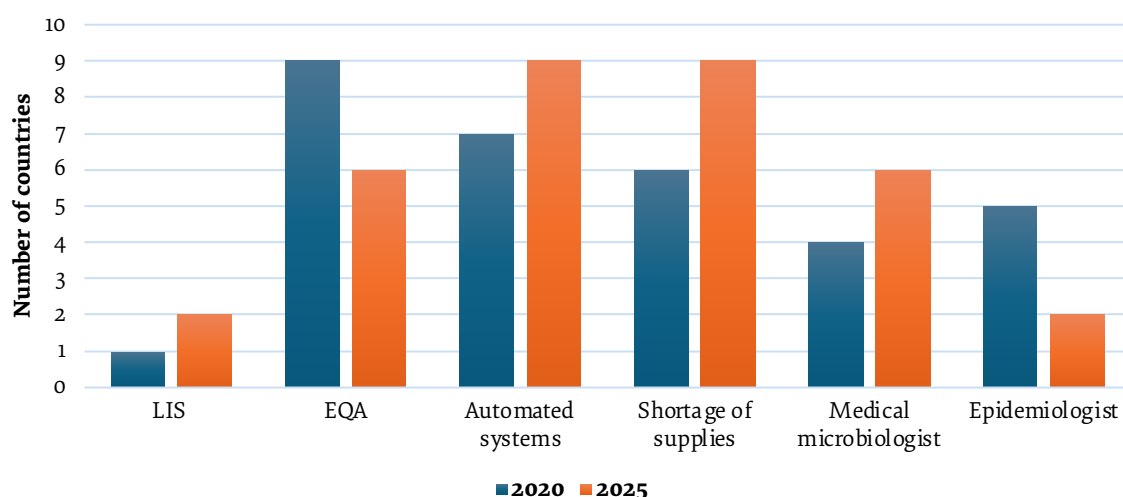
Our study shows critical deficiencies in the public health, technical and operational capacities of NRLs, with marked variability across EMR countries and territories. Only 3 of the 20 NRLs assessed reported full capacity across all evaluated domains, all of which are in HICs and rely heavily on automated, digitalised systems that enable high throughput and quality-assured data generation.

The key themes emerging from the study are discussed, along with proposed solutions, as follows:

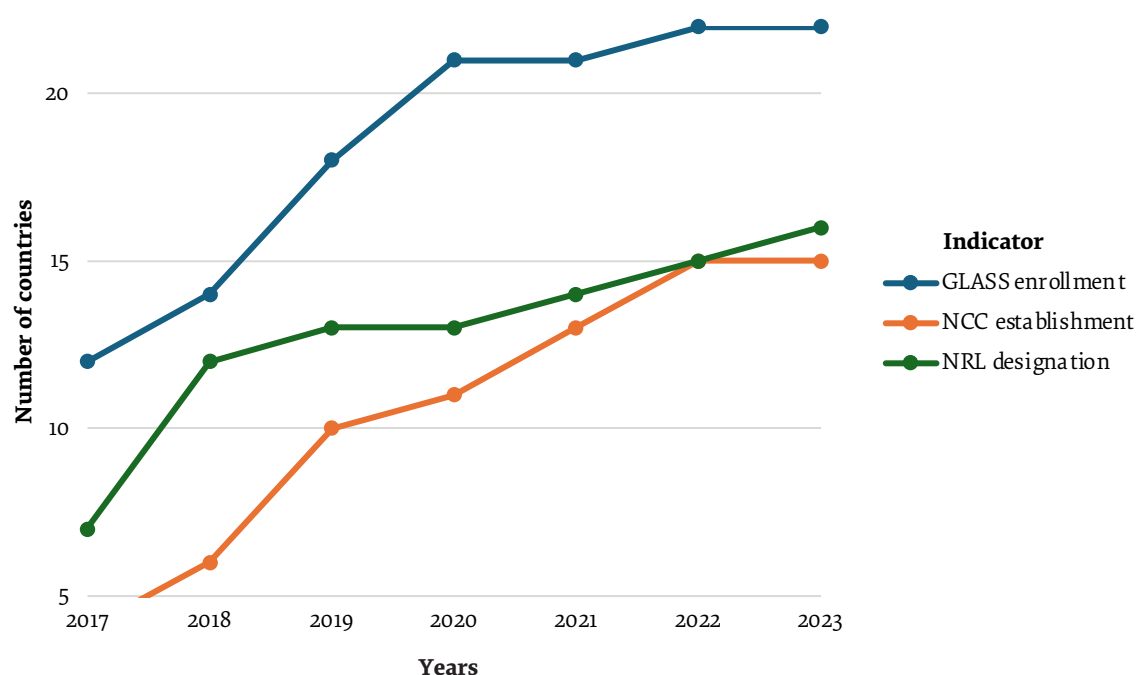
Limited confirmatory and reference testing capacity

NRLs fell short in their ability to perform confirmatory testing beyond the genus level and to characterise resistance mechanisms using advanced technologies. Specifically, 7 (5 from LICs) of the 20 assessed NRLs reported the absence of automated identification/AST systems, and 8 of 20 lacked molecular diagnostic capacity. This limits the ability of NRLs to detect a broad spectrum of clinically relevant bacterial pathogens, particularly those that are difficult to identify, using conventional culture-based methods. AST remains challenging across NRLs in the EMR due to limited access to up-to-date knowledge, shortage of trained medical microbiologists and inadequate essential antimicrobial discs. These challenges are reflected in the EMR external quality assessment (EMR-EQA) report, which highlights

Figure 2 Comparison of the 9 countries that responded to the first (2020) and second survey (2025)



LIS = Laboratory information system; EQA = external quality assessment

Figure 3 Progress on key AMR surveillance indicators, EMR, 2017–2023

NCC = National Coordinating Centre; NRL = National Reference Laboratory; GLASS = Global Antimicrobial Resistance and Use Surveillance System

suboptimal performance among NRLs, findings comparable to those reported by WHO Regional Office for Africa (WHO/AFRO) external quality assessment programme (12,13).

Many EMR countries and territories harnessed COVID-19 emergency funding and political momentum to enhance molecular diagnostic capacity through investments in PCR and genomic sequencing technologies, alongside targeted bioinformatics training. Although integration of these platforms into national laboratory systems remains incomplete, as reflected in the second survey, their increased use marks a pivotal step towards institutionalising molecular AMR testing. This is particularly significant in LMICs where such technologies were previously inaccessible (14,15).

However, the adoption of advanced technologies in LMICs remains challenging due to high costs, gaps in infrastructure and maintenance, and limited workforce bioinformatics competency. The development and deployment of locally manufactured, cost-effective and context-adapted *invitro* diagnostic solutions—designed to withstand suboptimal infrastructure and fluctuating temperatures—are widely discussed in the literature as a feasible alternative (16).

Poor data integration and use

Our results revealed substantial gaps in data management and reporting infrastructure. Paper-based systems remain dominant in 50% (10/20) of the countries and territories assessed, a finding consistent with patterns reported in other resource-constrained settings, where paper-based systems hinder real-time data exchange and analysis (17). Conversely, while 10 of 20 countries

and territories reported using LIS, significant challenges persist. As noted by Yadav et al, these challenges include poor infrastructure, frequent system shutdowns, limited backup and data protection mechanisms, risk of data loss, inconsistencies, and lack of standardisation across LIS platforms (18). All these factors impede timely validation, analysis and dissemination of surveillance data to national stakeholders and are reflected in the quality of data submitted to the GLASS platform, which are often incomplete, inconsistent and insufficient to accurately represent the national burden of AMR (10).

An additional barrier affecting the efficiency and national representation of AMR data is the limited referral systems and integrated data reporting tools connecting NRLs and SSLs, often because of financial constraints and data privacy concerns. Free tools such as WHONET and SEDRI-LIMS may help mitigate financial gaps. However, in the EMR, WHONET remains largely confined to basic data entry and GLASS reporting, while features such as antibiograms and disaggregated analysis remain underused (19,20). The underuse of WHONET features may partly reflect concerns about data privacy and security, although these are increasingly being addressed through encryption and anonymisation (21).

Shortage of skilled workers

Only 7 out of 20 countries reported having a medical microbiologist and an epidemiologist in their NRLs. This shortage of skilled staff has been reported by WHO/AFRO (22) and may be linked to decreasing interest in laboratory medicine as a specialty and brain drain, particularly in LMICs (23). National and regional strategies to assess workforce capacities both qualitatively and quantitatively

are critical to ensure alignment between staffing plans and national health service delivery priorities (24).

Sub-optimal quality assurance mechanisms

Participation in external quality assessment is a critical indicator of the operational and technical competence of NRLs (15). Recognising its importance, WHO/EMRO established a regional external quality assessment system (REQAS) in 2007. A 2022 REQAS report indicates that 70% (14/20) of participating laboratories met acceptable performance standards. However, consistent participation remains a challenge, primarily due to prolonged emergencies and international embargoes that have disrupted infrastructure, procurement and delivery of essential reagents and specimens (12).

National external quality assessment schemes provide tangible evidence of quality oversight (8). However, our survey indicates that only 50% of the countries and territories have established formal mechanisms such as national external quality assessment schemes, audits or structured inspection systems. This may reflect limited financial and human resources or weak data management systems (25). Alternative mechanisms, such as inter-laboratory comparisons, audit sample reviews or the use of surrogate organisms or materials aligned with national laboratory policies and budgets, may help address these systemic challenges (26). Targeted investments in external quality assessment will help reduce dependency on external support, promote sustainability and strengthen overall resilience of the national laboratory systems (25).

Limited capacity for the diagnosis of fungal infections

Despite the increasing burden of invasive fungal infections globally, diagnostic capacity remains profoundly inadequate in many resource-constrained settings (27). Consistent with this concern, our study identified substantial gaps in fungal diagnostic capacity among participating NRLs, particularly in LMICs. These findings suggest that fungal diagnostic services remain largely outside routine reference laboratory functions in most participating countries and territories. They highlight the need for laboratory strengthening strategies aligned with local epidemiology, antifungal resistance patterns and health system realities, with emphasis on workforce development, diagnostic infrastructure and quality assurance.

Similar findings from other settings suggest that these gaps reflect a broader regional and global challenge rather than isolated country level deficiencies (28,29). WHO has reinforced the importance of addressing this gap through the publication of the fungal priority pathogens list in 2022, which advocates stronger national diagnostic capacity to improve detection, surveillance and response (30). However, progress remains limited by shortage of trained mycologists, limited adoption of newer diagnostic approaches, reduced sensitivity of some molecular methods in low-burden specimens, and

constrained access to antifungal agents (31–33). These limitations weaken surveillance, limit the evidence base for treatment guidelines, impair detection of emerging antifungal resistance, and may delay the recognition of invasive fungal infections in routine clinical practice (34).

A pragmatic, phased approach is therefore needed. At the minimum, NRLs should be able to support standardised fungal microscopy and culture, facilitate referral for species level identification where in-country capacity is limited, and ensure access to antifungal susceptibility testing for priority pathogens. Strengthening fungal diagnostics will require the inclusion of mycology in national laboratory policies and essential diagnostics planning, dedicated training and mentorship for laboratory staff and clinicians, and stringent quality assurance procedures (30–34). Where full in-country capacity is not immediately feasible, phased expansion through referral networks and centres of expertise may provide a realistic intermediate pathway towards full integration of fungal diagnosis into national surveillance systems.

Minimal progress over the years

The paired comparison between the 2 surveys indicates persistent gaps rather than clear improvement. Although exact McNemar testing did not show statistically significant within-country changes, modest increases were observed in the uptake of automated systems and the availability of medical microbiologists, increasing from 7 in 9 to 9 in 9 countries and from 4 in 9 to 6 in 9 countries, respectively. These changes are contextually relevant but should be interpreted as descriptive rather than confirmed temporal trends. Although several countries leveraged the COVID-19 pandemic to strengthen their laboratory systems, despite its disruption to AMR surveillance, critical constraints persist (14). Shortage of laboratory supplies became universal among the 9 matched countries in the second survey, and the availability of epidemiologists decreased markedly from 6 in 9 to 2 in 9 countries and territories.

Together, these findings reveal the continuing weaknesses in workforce composition, quality-related functions and supply chain. They highlight the need for dedicated budget allocations and clear career pathways to support retention, motivation and sustained technical capacity development (24). The findings are consistent with evidence that investments in laboratory systems can generate returns that substantially exceed their costs (23). Conversely, reductions in public health funding, including for NRLs, are likely to increase long-term health care expenditures and deepen health inequities (35).

Study limitations

As with any self-assessment, this study has several inherent limitations. The data relied on the knowledge and interpretation of the respondents who completed the questionnaires, which may have introduced variability in reporting. Additional challenges include potential

misinterpretation related to language barriers and incomplete responses, with some questions unanswered. The comparative findings should be interpreted with caution. The smaller number of participating countries in the second survey has reduced the statistical power to detect anything other than large within-country differences. Therefore, the absence of statistical significance should not be equated with evidence of stability or the absence of meaningful contextual change. Despite these limitations, the findings provide a valuable overview of the current capacity and highlight important areas for targeted improvement.

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Conclusion

There is an urgent need to strengthen not only the operational and technical capacities of NRLs, but also their public health functions, which remain underdeveloped and poorly integrated with national programmes. Priority actions include sustainable domestic financing, comprehensive national laboratory policies supported by clear legal and strategic frameworks, fit-for-purpose workforce development, sustainable oversight through national external quality assessment, integration of molecular platforms into national laboratory strategies, strengthened referral pathways and quality assurance systems, and enhanced fungal diagnostic capacity through targeted investments in expertise, infrastructure and reagents.

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Four-year analysis of antimicrobial resistance patterns in Iraq

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Abstract

Background: This is the first nationwide assessment of resistance patterns among WHO target pathogens in Iraq.

Aim: To analyse antimicrobial resistance patterns over 4 years in Iraq, based on data from the national surveillance system.

Methods: Using the WHONET software, we collected and analysed 238 973 clinical specimens from the 106 antimicrobial resistance surveillance sites across Iraq, for 2020–2023, from the Iraqi national surveillance system. The data were analysed using SPSS version 26.

Results: Resistance to carbapenem by *Acinetobacter baumannii* increased markedly, reaching 80% in 2023. Resistance to third-generation cephalosporins was notably high among *Acinetobacter baumannii* (88.5–92%) and *Escherichia coli* (88.0%) while methicillin-resistant *Staphylococcus aureus* was at 74.0%. Multidrug resistance and extensively drug-resistant profiles for *Acinetobacter* spp. and *Klebsiella pneumoniae* increased, particularly extensively drug-resistant *Acinetobacter* spp. (66%). Resistance to last-line reserve antibiotics, such as colistin and tigecycline, increased significantly in 2023, suggesting an increasing threat to the efficacy of these critical agents.

Conclusion: These findings indicate that several key pathogens in Iraq have surpassed the critical resistance thresholds, thus limiting the effectiveness of commonly used empirical therapies and narrowing treatment options. Strengthening antimicrobial stewardship and prescription practices is essential to curb resistance and protect the efficacy of treatment regimens.

Keywords: antimicrobial resistance, antibiotic, antimicrobial surveillance, bacteria, antimicrobial stewardship, Iraq

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Introduction

Antimicrobial resistance (AMR) is a growing threat globally, leading to longer hospital stays, higher treatment costs and increased mortality. It disrupts routine care and strains health systems. WHO warns that AMR could cause 10 million deaths annually by 2050 if left unchecked (1). The 2024 annual statistical report of the Iraqi Ministry of Health (MOH) ranks bacterial infections as the seventh leading cause of mortality nationwide (2). And WHO statistics shows that Iraq has reached an alarming level of bacterial resistance across its health care settings (3).

In Iraq, infections caused by resistant strains of bacteria such as *Staphylococcus aureus*, *Escherichia coli* and *Klebsiella pneumoniae* have been linked to high mortality rates (4–6). A 2022 WHO report ranks Iraq fifth among 86 countries in methicillin-resistant *Staphylococcus aureus* (MRSA) prevalence (7). These infections are harder and costlier to treat. National studies report high rates of antibiotic-resistant *Acinetobacter baumannii*, especially in hospital and military settings across Iraq (8–10).

The WHO Access, Watch and Reserve (AWaRe) classification groups antibiotics into 3 categories: Access for first-line use, Watch for limited use due to resistance risk and Reserve as last resort options for severe, drug-resistant infections (1). Unfortunately, an Iraqi

study revealed widespread colistin (reserve antibiotic) resistance among *A. baumannii* isolates from Baghdad, driven by mobile genetic elements (11).

AMR is fuelled by inappropriate prescriptions, self-medication and antibiotic use for livestock (12,13). Poor infection prevention and control facilitates the spread of resistant microbial strains in communities and health care settings (14). In Iraq, most physicians in public hospitals and pharmacists in community pharmacies prescribe antibiotics frequently and empirically without relying on culture and sensitivity tests (12,15,16). A review of 37 Iraqi studies found widespread antibiotic misuse, with pharmacists often dispensing without prescriptions. Residues in meat and water constitute environmental risks. Although there are regulations, implementation remains limited (17).

Antimicrobial surveillance helps detect resistance, guides treatment and improves outcomes. Studies on AMR trends inform public health policies and support infection control as well as optimisation and targeting of resource allocation for interventions (18). Effective AMR management depends on strong surveillance and reliable data. Timely resistance insights guide treatment, curb misuse and improve outcomes, while quality control ensures accurate monitoring and targeting of public health interventions (3).

Established in 2019, the Iraqi National Coordination Center (NCC) and Reference Laboratory leads AMR surveillance efforts through sites that monitor resistance and support timely public health actions. Data from the centre have been reported to the Global Antimicrobial Resistance and Use Surveillance System (GLASS) since inception, aiding resistance tracking (18).

Although several studies have explored bacterial profiles associated with AMR in Iraq, most of them were conducted in single sites or limited to individual provinces (6,8,9,11,15). This is the first nationwide study to profile WHO-designated indicator bacteria in Iraq using national surveillance data. The findings highlight the role of standardised surveillance in guiding therapy, shaping policy and detecting outbreaks, in alignment with the United Nations Sustainable Development Goals (SDGs). The study objective was to identify antimicrobial resistance patterns in Iraq over a period of 4 years, based on the national surveillance system.

Methods

This retrospective study used AMR data collected through the national surveillance system administered by the Department of Antimicrobial Resistance, Directorate of Public Health, Iraqi Ministry of Health. WHONET software was used to facilitate the systematic collection, monitoring and reporting of AMR data at the national level. The software was used to collate national AMR data from 106 sites in 19 directorates across 16 out of the 18 provinces in Iraq in 2023. Each surveillance site (hospital) had 2 focal persons for AMR activities—a pharmacist and a laboratory bacteriologist—who had been trained by MOH and WHO. Clinical specimens were collected from hospital patients, and data on resistant bacteria were recorded using the software. These data are submitted monthly to the national coordinating centre for aggregation and analysis.

We analysed archived data for 2020–2023 to assess AMR trends based on the WHO GLASS framework. Clinical specimens were cultured on media appropriate to type (e.g. blood, MacConkey, chocolate, or cystine-lactose-electrolyte-deficient CLED agar), incubated at 35–37°C for 18–24 hours, and examined for colony morphology and gram stain. Bacterial identification was done using biochemical methods, manual disk diffusion or automated systems (VITEK 2/Render), depending on available laboratory resources (19).

Following identification, antimicrobial susceptibility testing (AST) was conducted and the results were interpreted according to the Clinical and Laboratory Standards Institute (CLSI) breakpoints, with isolates categorized as susceptible (S), intermediate (I) or resistant (R). Results were recorded in the respective laboratory information systems and transmitted to the national AMR surveillance platform.

Inclusion and exclusion criteria

Only bacterial isolates with complete AST data were included in the study. Eligible specimens were required to originate from human clinical sources, such as blood, urine, respiratory tract, or wound. Bacterial culture isolates collected from all AMR surveillance sites across Iraq were analysed. Samples were obtained from patients attending health facilities, including inpatients and outpatients. All age groups were included. Data collection forms with incomplete information were excluded from the analysis. To prevent duplication, repeated isolates from the same patient were removed, and only the first bacterial isolate per patient was considered.

Ethics considerations

The study proposal was approved by the Ethical Committee at the University of Baghdad College of Pharmacy, Iraq. All data were anonymised, with patient identifiers removed to ensure confidentiality.

Statistical analysis

All the data were deidentified prior to analysis and imputed into Excel sheets, including organism names, dates of isolation, antibiotic agents, and corresponding susceptibility results. The dataset was subsequently cleaned to remove duplicate entries, incomplete records and implausible values. Descriptive statistics, including percentages of resistance, were computed using the SPSS version 26. Resistance prevalence was calculated as the proportion of resistant isolates among the total number tested for each antimicrobial agent. These rates were analysed to detect resistance patterns and temporal variations during the study period (2020–2023). Because the focus was on resistance percentages rather than inferential comparisons, descriptive statistics were sufficient. Figures were generated using Microsoft Excel.

Results

This study analysed 238 973 clinical specimens collected from patients attending hospitals during 4 consecutive years: 131 420 in 2023; 79 556 in 2022; 20 830 in 2021; and 7167 in 2020.

Antimicrobial surveillance sites in Iraq

Between 2020 and 2023, Iraq witnessed a substantial expansion in AMR surveillance capacity, with the number of public surveillance sites increasing from 22 in 2020 to 106 across 19 health directorates and 16 provinces by 2023. This expansion included the establishment of new public surveillance sites alongside the introduction of private laboratories into the national monitoring network. The inclusion of Erbil in 2023 with 7 public sites marked a notable extension in the northern region.

MRSA and *Escherichia coli* resistance to 3rd generation cephalosporins

Overall, resistance to third generation cephalosporins among *Escherichia coli* decreased, from 94.7% in 2020

to 85.5% in 2021 and 84% in 2022, before increasing to 88% in 2023. Methicillin-resistant *Staphylococcus aureus* showed more pronounced fluctuations, with resistance decreasing from 95.5% in 2020 to 84.6% in 2021, increasing to 87% in 2022, and then decreasing sharply to 74% in 2023 (Figure 1).

Acinetobacter, Klebsiella Pneumonia and Pseudomonas Aeruginosa resistance to carbapenem

Acinetobacter baumannii showed a progressive increase in carbapenem resistance, from 66% to 80% between 2020 and 2023. *Klebsiella pneumoniae* exhibited a variable trend, with resistance decreasing from 64.3% in 2020 to 51.6% in 2021, then gradually increasing to 61.8% by 2023. In contrast, *Pseudomonas aeruginosa* maintained relatively stable resistance rates, decreasing slightly to 50% in 2021 and increasing to 54% in 2023 (Figure 2).

Multiple drug resistance, extensive drug resistance and pan-drug resistance

Between 2020 and 2023, multidrug-resistance by *Acinetobacter* spp. increased from 71% to 78%, while MDR *Klebsiella pneumoniae* peaked at 65% in 2021 before decreasing to 58%. MDR *Escherichia coli* and *Enterococcus faecium* fluctuated modestly (38–47% and 34–40%, respectively), and MDR *Pseudomonas aeruginosa* and *Staphylococcus aureus* remained stable. Extensively drug-resistant (XDR) *Acinetobacter* spp. increased to 66%, whereas XDR *Klebsiella pneumoniae* decreased from 45% to 35%. Possible pan-drug resistant (PDR) strains were rare,

with *Acinetobacter* spp. increasing from 4% to 8%; other species showed minimal change (Figure 3).

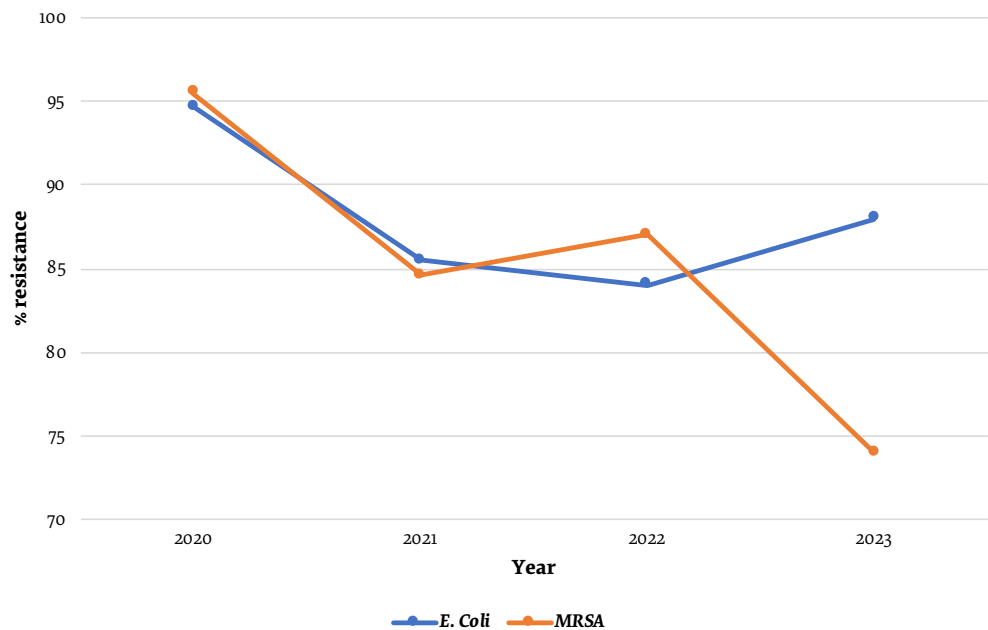
Resistance of Acinetobacter baumannii to common antibiotics

Resistance patterns of *Acinetobacter baumannii* from 2020 to 2023 was persistently high across multiple antibiotic classes. By 2023, resistance exceeded 80% for cefotaxime (91.9%), ampicillin/sulbactam (92.0%), ceftriaxone (88.5%), ceftazidime (84.1%), ciprofloxacin (81.8%), cefepime (81.6%), imipenem (80.6%), and meropenem (80.5%). Aminoglycosides such as gentamicin (76.5%) and amikacin (62.0%) showed considerable resistance, while levofloxacin and trimethoprim/sulfamethoxazole followed similar trends, reaching 75.6% and 70.1%, respectively, in 2023 (Table 1).

Resistance trend to 3 available reserve antibiotics

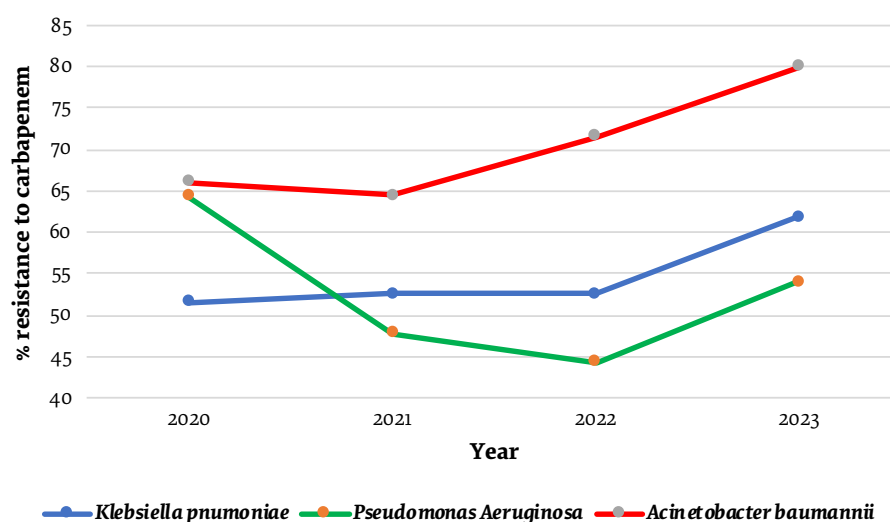
From 2020 to 2023, there were notable shifts in the overall resistance to reserve antibiotics. Resistance to colistin remained stable at 23.8% between 2020 and 2022, followed by a sharp increase to 44% in 2023. Tigecycline resistance hovered around 10.4% through the first 3 years, then more than doubled to 23.5% in 2023. In contrast, linezolid resistance showed relative stability, ranging from 9.4% to 11.7% during the same period (Figure 4).

Figure 1 Percentage infection with methicillin-resistant *Staphylococcus aureus* or *Escherichia coli* resistant to 3rd generation cephalosporin



The 2 metrics are indicators for the United Nations Sustainable Developments Goals

Figure 2 Percentage resistance of 3 indicator bacteria (*Acinetobacter*, *Klebsiella pneumoniae* and *Pseudomonas aeruginosa*) to carbapenem



Discussion

Antimicrobial surveillance sites

This is the first nationwide study on WHO-designated indicator bacteria in Iraq, based on thousands of clinical specimens from the national AMR surveillance system. Between 2020 and 2023, AMR centres were launched in 16 of 18 provinces, enabling data transmission to the Ministry of Health via WHONET. By 2023, surveillance had covered 90 public hospitals and 16 private laboratories, reflecting Iraq's increasing efforts to strengthen AMR monitoring and epidemiologic infrastructure. Because only isolates with complete AST data were included, the dataset reflects testing performed using standardised methods across all contributing laboratories, which helps reduce inter-laboratory variability and limit the influence of external confounders on the observed resistance patterns.

The United Arab Emirates maintained a more extensive network of 317 surveillance sites, including 84 hospitals, 233 health centres or clinics and 45 microbiology laboratories distributed across all the 7 emirates (20). Iraq needs to expand its AMR surveillance network to a broader range of public and private health facilities, enabling comprehensive monitoring of resistance patterns and facilitating early detection of potential outbreaks.

Bacterial resistance to 3rd generation cephalosporins

Ceftriaxone is currently among the most commonly used empirical injectable antibiotics in Iraq (21). The 2023 surveillance report highlights persistently elevated resistance rates to third generation cephalosporins, with *Escherichia coli* exhibiting an alarming resistance prevalence of 88%. Similarly, a study conducted in the northern province of Duhok, which analysed 454 clinic

specimens collected between 2017 and 2020, reported high levels of *Escherichia coli* resistance to multiple antibiotics, including third generation cephalosporins—cefepime (63.3%) and ceftriaxone (63.9%)—as well as ampicillin (88%) (4).

Our analysis revealed that *Acinetobacter baumannii* exhibited very high resistance rates to third generation cephalosporins—specifically cefotaxime (92%) and ceftriaxone (88.5%)—which remain among the most commonly administered empirical antibiotics in Iraq (22). These findings indicate the limited clinical efficacy of third generation cephalosporins. In addition to *Acinetobacter baumannii* resistance, a previous Iraqi study (2012) reported that several prevalent bacterial pathogens—including *Escherichia coli*, *Streptococcus* spp., *Klebsiella* spp., *Pseudomonas aeruginosa*, *Proteus* spp., and *Staphylococcus* spp.—exhibited resistance to third generation cephalosporins, with rates ranging from 52.6% to 100% (23). Therefore, the empirical use of cephalosporins in this context may offer limited clinical benefit while imposing a significant economic burden on the health system.

Bacterial resistance to carbapenem

Meropenem, a commonly prescribed watch antibiotic for MDR infections in Iraq, showed high resistance rates: *Acinetobacter* spp. (88%), *Klebsiella pneumoniae* (61.8%) and *Pseudomonas aeruginosa* (54%). A 2023 Baghdad study found *Escherichia coli* had 96% resistance to imipenem, indicating poor efficacy (24). Another study reported that 51.5% of *Pseudomonas aeruginosa* isolates from Baghdad hospitals were resistant to carbapenems, with meropenem resistance (50%) slightly higher than imipenem (39.7%) (25).

Several Iraqi studies have attributed the high rate of carbapenem resistance to widespread inappropriate antibiotic use, particularly empirical prescription

Figure 3 Multidrug resistance (A), extensive drug resistance (B) and pan-drug resistance (C) trends of 6 common bacteria, Iraq (2020–2023)

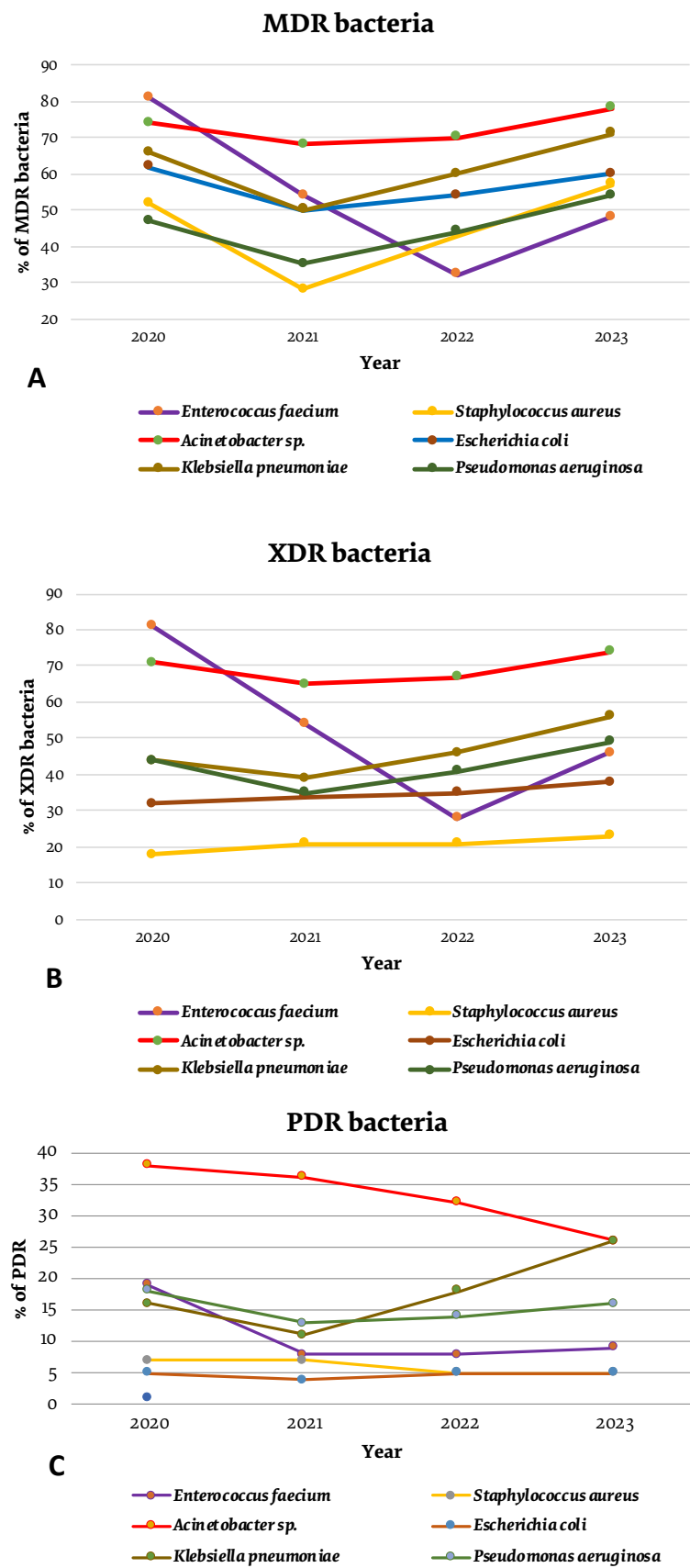


Table 1 Percentage resistance of *Acinetobacter baumannii* to common antibiotics, Iraq (2020–2023)

Antibiotic name	2020	2021	2022	2023
Ampicillin/Sulbactam	50.0	N/A	91.4	92.0
Cefotaxime	98.7	93.0	94.6	91.9
Ceftriaxone	95.2	79.8	89.8	88.5
Ceftazidime	86.4	83.2	81.4	84.1
Ciprofloxacin	N/A	68.2	77.6	81.8
Cefepime	79.2	75.5	79.4	81.6
Imipenem	74.9	68.3	72.8	80.6
Meropenem	79.1	66.9	74.8	80.5
Gentamicin	72.2	67.0	68.3	76.5
Levofloxacin	78.8	58.4	72.0	75.6
Trimethoprim/ Sulfamethoxazole	68.2	54.7	65.4	70.1
Amikacin	N/A	62.0	59.4	62.0

N/A= not applicable (not measured)

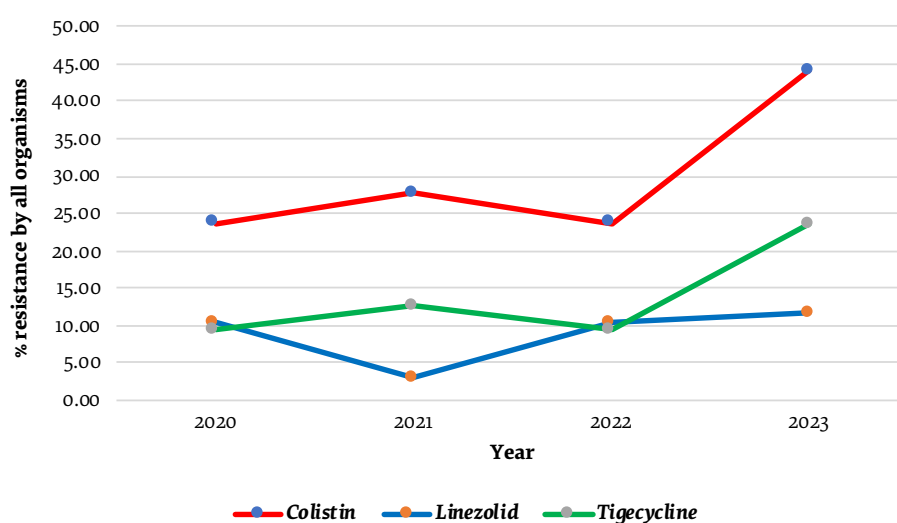
practices that bypass preliminary culture and sensitivity testing (26,27). A recent review of Iraqi studies highlights multiple official directives by the Ministry of Health to limit meropenem prescription until culture and sensitivity results are available (17). However, these antibiotic stewardship efforts face challenges in clinical practice; some physicians continue to prescribe meropenem empirically—particularly in urgent cases—because of the time required to obtain laboratory test results, which may be several days.

MDR, XDR and PDR of *Escherichia coli* and MRSA

This study applied WHO indicator 3.d.2, tracking resistance in *E. coli* to third generation cephalosporins and MRSA—2 common, fast-growing pathogens.

Between 2020 and 2023, Iraq saw a general decrease in resistance levels. MDR bacteria resisted at least 1 drug in 3 or more classes; XDR resisted all but 1 or 2; PDR resisted all, leaving no effective treatments (28). Between 2020 and 2023, *Escherichia coli* showed consistently high MDR rates (50–62%), with possible XDR increasing from 32% to 38%, signalling increasing treatment challenges. PDR remained low (4–5%).

A Ramadi-based study of 120 urinary tract infection cases confirmed extensive resistance among uropathogenic *Escherichia coli* (UPEC) strains—over 90% to third generation cephalosporins and piperacillin, 82.9% to fluoroquinolones and up to 68.2% to aminoglycosides. Imipenem remained largely effective (7.3% resistance) (29).

Figure 4 Resistance trend to 3 common reserve antibiotics by all organisms, Iraq (2020–2023)

These findings indicate the need for stronger stewardship and updated treatment protocols. *Staphylococcus aureus* showed a sharp increase in MDR from 28% in 2021 to 57% in 2023, with XDR steady at 21–23% and PDR low (5–7%). Despite worsening resistance, some treatment options remain.

Four Iraqi studies confirmed widespread resistance in *S. aureus* and coagulase-negative staphylococci. An Iraqi study analysing 200 blood samples collected from public and private hospitals between 2018 and 2019 identified *Staphylococcus aureus* as the causative agent in 14.4% of septicæmia cases (30). Another Iraqi study found *S. aureus* (10.36%) as the leading post-maxillofacial surgery pathogen, with over 65% resistance to key antibiotics. MDR MRSA strains showed >90% resistance to penicillin and 91.1% to erythromycin (31). Mohammed and colleagues evaluated 290 clinical samples upon hospital admission, reporting that *S. aureus* accounted for 22.4% of isolates, with 95.4% of strains resistant to oxacillin and methicillin—confirming widespread MRSA prevalence (32).

Awayid et al analysed MRSA strains from patients with skin, wound and burn infections between January and September 2020 and reported extreme multidrug resistance among MRSA isolates—exceeding 90% for both penicillin and erythromycin (5). Coagulase-negative *Staphylococcus* spp. showed resistance to most tested antibiotics, including levofloxacin, azithromycin and tetracyclines. In severe cases, meropenem was used with vancomycin or cephalosporins due to resistance to standard injectables (15).

These findings reveal widespread multidrug-resistant *Staphylococcus* spp. in Iraq and indicate an urgent need for stronger stewardship and targeted infection control.

MDR, XDR and PDR of *Acinetobacter baumannii*

During the 4 years of our study, *Acinetobacter* species showed the highest resistance in Iraq, with MDR rates of 74–78%, XDR reaching 74% in 2023 and PDR peaking at 38% in 2020 and remaining high at 26% in 2023. Multiple Iraqi studies have also reported the escalating MDR of *Acinetobacter baumannii*, particularly in hospital environments. Al-Samaree analysed isolates from Baghdad hospitals and found high resistance rates to several antibiotics, notably 94% to piperacillin, while colistin retained partial efficacy with 20% resistance—though emerging resistance was noted (8). A case of osteomyelitis caused by multidrug-resistant *Acinetobacter baumannii* was reported in an American military setting in Iraq. The infection was successfully treated with tigecycline, indicating the potential—yet underexplored—therapeutic role of this agent in managing bone infections (9).

Al-Kadmy and colleagues characterised *A. baumannii* isolates from hospital surfaces, revealing 100% resistance to gentamicin and ciprofloxacin, whereas colistin and tigecycline remained fully effective at that time. This

study of 120 isolates in Baghdad found colistin resistance genes linked to mobile genetic elements, indicating caution in its use (10).

These findings align with national data identifying *Acinetobacter baumannii* as Iraq's most resistant pathogen and reinforces the need for culture and sensitivity testing before treatment.

Acinetobacter species remains an AMR threat in the region. A 2024 study in United Arab Emirates (UAE) analysed 17 564 isolates over 12 years and reported nearly 50% decrease in MDR and XDR rates between 2010 and 2021—contrasting Iraq's steady resistance levels. However, carbapenem-resistant strains (CRAB) still posed serious risks, linked to higher mortality, intensive care unit (ICU) admissions and longer hospital stays (20). The notable decrease in resistance levels among *Acinetobacter* spp. in the UAE suggests more effective antibiotic stewardship and dispensing practices than those observed in Iraq.

A study in Saudi Arabia found widespread environmental contamination by carbapenem-resistant *A. baumannii* in ICU, medical and surgical units. Many isolates were international clones, indicating the urgent need for strict hygiene and infection control (33). Another Saudi Arabia study analysed the incidence, outcomes and predictors of *A. baumannii* infections in 8 ICUs in 5 geographically diverse cities. The study found that infection rates were higher in university and military hospitals, especially those with larger bed capacity and more ICU isolation rooms. Notably, mechanically ventilated patients had a 10-fold increased risk of infection, highlighting the role of invasive procedures and hospital infrastructure in driving transmission (34). *Acinetobacter baumannii* poses a major threat across Iraq and the Middle East due to its high resistance to commonly used watch antibiotics.

Resistance trend to 3 available reserve antibiotics

Surveillance data show increasing resistance to Iraq's reserve antibiotics—colistin (44%) and tigecycline (23.5%)—indicating the urgent need for stricter stewardship to protect their effectiveness. In addition to its increasing resistance profile and high cost, numerous local, regional and global studies have documented serious adverse effects associated with colistin use, including respiratory failure, nephrotoxicity and acute renal failure (35–38). Therefore, colistin and other reserve antibiotics should be preserved as last-line treatments for MDR, XDR or possible PDR pathogens—such as *Acinetobacter baumannii*, and resistant strains of *Escherichia coli*.

Tackling AMR requires a coordinated, multisectoral approach involving engagement between the healthcare, policy and public sectors. Priorities include responsible antimicrobial use, stronger surveillance, research for new treatments, and raising public awareness (39).

Study limitations

This study has several limitations. The study was limited to samples and culture results obtained from public health care settings, primarily government hospitals. The Ministry of Health provides AMR data as cumulative annual aggregates without disaggregation by individual reporting sites. This limited our ability to conduct sub-analyses confined to the original (2020) surveillance centres and may have limited the granularity of our findings. Site-specific variations in resistance patterns could not be assessed, which may affect the interpretation and generalisability of the results.

Conclusion

This 4-year national analysis provides the most comprehensive overview until date of antimicrobial resistance patterns in Iraq, and highlights several critical, data-supported concerns. *Acinetobacter baumannii* consistently showed the highest resistance burden,

with carbapenem resistance reaching 80% and third generation cephalosporin resistance exceeding 88–92% by 2023. *Klebsiella pneumoniae* and *Pseudomonas aeruginosa* showed substantial carbapenem resistance (61.8% and 54%, respectively), while *Escherichia coli* maintained persistently high resistance to third generation cephalosporins (88%). The MDR and XDR profiles further highlight the severity of resistance, particularly among *Acinetobacter* spp., where XDR levels increased to 66%. Alarming, resistance to reserve antibiotics increased sharply in 2023, with colistin resistance reaching 44% and tigecycline 23.5%. These findings collectively indicate that several key pathogens in Iraq have surpassed critical resistance thresholds, limiting the effectiveness of commonly used empirical therapies and narrowing treatment options. Continued investment in laboratory capacity, standardised AST practices and timely reporting will be essential to detect emerging resistance trends and guide evidence-based clinical and public health interventions.

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Seven-year analysis of national antibiotic consumption in Tunisia

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Abstract

Background: Monitoring national antibiotic consumption is essential to strengthen antimicrobial stewardship and efforts to combat antimicrobial resistance.

Aim: To assess annual antibiotic consumption in Tunisia from 2016 to 2023.

Methods: Using SPSS version 27, Spearman correlation, the WHO defined daily dose per 1000 inhabitants per day and the WHO access, watch and reserve classification, we analysed national antibiotic consumption data in Tunisia for 2016 to 2023.

Results: Overall antibiotic consumption increased from 31.6 defined daily dose per 1000 inhabitants per day in 2016 to 32.4 in 2023, with lower values for 2019–2022 ($P = 0.096$). Private sector consumption consistently exceeded public sector levels and access group antibiotics were the most consumed (78% in 2016, 65% in 2021 and 75% in 2023). Beta-lactam penicillins was most consumed (exceeding 60% in most years), followed by macrolides, lincosamides and streptogramins ($\approx 10\%$ in most years), while oral antibiotics represented 98% of total consumption.

Conclusion: The predominance of generics indicates the need for vigilant antimicrobial stewardship to prevent cost-driven overuse and mitigate resistance. There is a need to strengthen national antibiotic use surveillance, including in private sector facilities, and promote a more rational use of antibiotics.

Keywords: antibiotic consumption, antimicrobial resistance, AWaRe classification, antibiotic surveillance, Tunisia

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Introduction

Since their discovery in 1928, antibiotics have been a cornerstone of modern medicine, saving millions of lives worldwide. However, the rapid emergence of antibiotic-resistant bacteria now threatens to reverse these gains (1,2). Resistance is primarily driven by inappropriate antibiotic use in human and animal health, compounded by inadequate hygiene and infection prevention, which together reduce the effectiveness of existing antibiotics and increase health care-associated infections (2). The development of new antibiotics has stagnated, with only 8 new antibiotic agents introduced between 2017 and 2019, most offering limited clinical benefits (3). According to the 2019 Global Antimicrobial Resistance Research Project, antibiotic resistance is estimated to cause up to 39 million deaths by 2050 (4). If no action is taken, deaths attributed to antimicrobial resistance (AMR) could surpass those caused by the leading diseases, such as cancer (4,5).

In response to this increasing threat, Tunisia's Ministry of Health, in collaboration with the Ministry of Agriculture, Water Resources, and Fisheries, launched the National Action Plan to Combat Antimicrobial Resistance (NAP-AMR) in 2019 (6). This plan is structured around 4 strategic pillars: raising awareness,

strengthening research and monitoring, improving infection prevention and control, and optimising antimicrobial use in human and animal health. The National Agency for Medicines and Health Products leads the fourth pillar, overseeing annual monitoring of national antibiotic consumption in defined daily doses (DDD) per 1000 inhabitants per day, using the WHO access, watch and reserve (AWaRe) classification.

This study analyses annual trends of antibiotic consumption in Tunisia from 2016 to 2023, expressed as DDD per 1000 inhabitants per day, stratified by sector (public and private), pharmacological class, and the WHO AWaRe classification.

Methods

Study design

We conducted a cross-sectional study to analyse annual national antibiotic consumption in Tunisia, expressed as DDD per 1000 inhabitants per day, from 2016 to 2023. The study population comprised the total Tunisian population for each year from 2016 to 2023, as estimated by the United Nations.

Antimicrobials were classified according to the anatomical therapeutic chemical (ATC) classification

system. Only products listed in the WHO ATC/DDD 2024 index (WHO Collaborating Centre for Drug Statistics Methodology) were included. The DDD is the assumed average maintenance dose per day for a drug's main indication in a 70 kg adult (7). By convention, results are expressed in DDD per 1000 inhabitants per day for each year, stratified by sector (public/private), pharmacological class, and AWaRe classification. To obtain the relative consumption of antibacterials by AWaRe categories (%), the 2023 AWaRe classification was applied (8).

Data for this study were collected from the National Agency for Medicines and Health Products database (SIAMED). Procurement data were obtained from 2 sources: the Central Pharmacy of Tunisia for imported medicines, and annual declarations from local manufacturers for locally manufactured medicines intended for the national market.

Antibiotics procurement data were extracted from SIAMED software, containing validated records of imported and locally manufactured antibiotics distributed in Tunisia. Annual data were organised into Microsoft Excel tables and entered into the WHO-provided Excel tool, which contains embedded macros to calculate DDD per 1000 inhabitants per day. To ensure data accuracy, all manual entries were systematically double-checked, and consistency and logic checks were performed on the final dataset before analysis.

Data analysis

To express the data in DDD per 1000 inhabitants per day, we used the Excel tool provided by WHO. This tool integrates all antimicrobial antibiotic agents and their codes from the latest ATC/DDD version (2024). The tool can calculate the DDD of 5 classes of antimicrobials: antibacterials (ATC J01, A07AA, P01AB); antimycotics and antifungals for systemic use (J02, D01B); antivirals for systemic use (ATC J05); drugs for the treatment of tuberculosis (ATC J04A); and antimalarials (ATC P01B). This study included systemic antibiotics (J01) and nitroimidazole derivatives (P01AB).

DDD per 1000 inhabitants per day was calculated for each antibiotic and stratified by year, sector (public and private), pharmacological class, route of administration and the WHO AWaRe classification. Percentage consumption was calculated as the proportion of each antibiotic's DDD per 1000 inhabitants per day relative to the total consumption. In addition, trends of antibiotic consumption from 2016 to 2023 were performed using Spearman correlation. Statistical analyses were conducted using SPSS version 27, and $P < 0.05$ was considered statistically significant.

Ethics considerations

As the data were aggregated at the national level and contained no identifiable patient information, ethics approval was not required.

Results

Overall antibiotic consumption in Tunisia

Overall antibiotic consumption in Tunisia increased from 31.6 DDD per 1000 inhabitants per day in 2016 to 32.4 in 2023, with lower values from 2019 to 2022 ($P = 0.096$) (Figure 1a). When disaggregated by sector, private sector consumption consistently exceeded public sector levels, increasing from 19.6 DDD per 1000 inhabitants per day to 28.0 DDD per 1000 inhabitants per day over the study period ($P = 0.132$). In contrast, public sector consumption decreased from 12.0 DDD per 1000 inhabitants per day in 2016 to 4.4 in 2023 ($P = 0.028$) (Figure 1b).

Locally manufactured antibiotics accounted for about 70% of the total consumption.

Antibiotic consumption by AWaRe classification

During the study period, access group antibiotics represented most national consumption, accounting for 78% in 2016, 65% in 2021, and 75% in 2023 (Figure 2). Watch group antibiotics comprised 24% in 2016, peaked at 30% between 2020 and 2022, and decreased to 22% in 2023. Reserve group use remained 1% throughout, while non-recommended antibiotics accounted for up to 4% of total consumption.

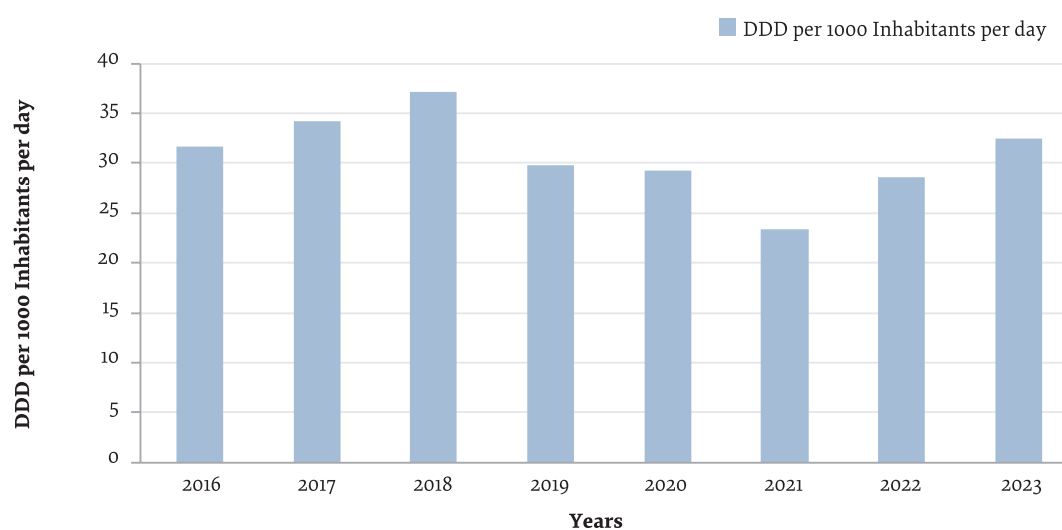
Antibiotic consumption by pharmacological class

Beta-lactam penicillins (J01C) dominated antibiotic consumption, exceeding 60% in most years, except 2021 and 2022, where they represented 52% and 56%, respectively (Table 1). Macrolides, lincosamides and streptogramins (J01F) ranked second, averaging approximately 10% of total consumption, but increasing to 14%, 18% and 15.2% in 2020, 2021 and 2022, respectively. Cyclines (J01A) followed, accounting for 6.1% to 11.1% of use, while quinolones (J01M) remained stable at 5–8.6% over the study period.

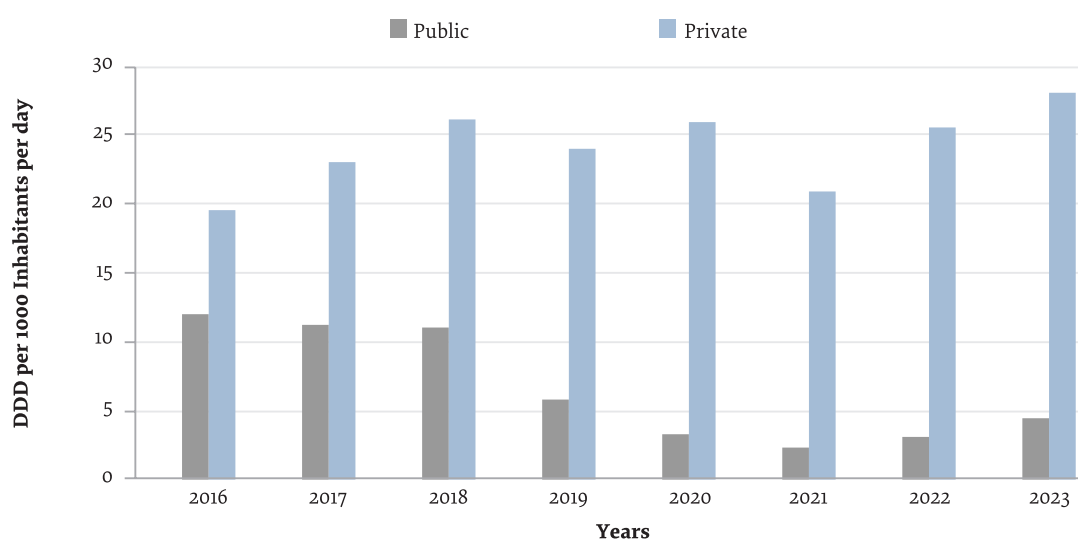
Antibiotic consumption by route of administration

Oral antibiotics represented 98% of total consumption. Between 4 and 6 antibiotic agents accounted for 75% of the total oral consumption each year. In 2018, 4 out of the 5 most-used oral agents belonged to the access group; by 2021, this proportion decreased to 3 of 6. Amoxicillin and amoxicillin/clavulanic acid together represented more than 70% of oral antibiotic consumption and exceeded 80% in 2018 and 2023.

For parenteral antibiotics, amoxicillin/clavulanic acid and gentamicin—both from the access group—accounted for 75% of total use. Quantitatively, access group antibiotics made up more than 60% of parenteral consumption, while qualitatively, about half of the antibiotic agents were from the access group, and the remaining (50%) from the watch group.

Figure 1a Overall antibiotic consumption in Tunisia (defined daily dose per 1000 inhabitants per day), 2016–2023

DDD = Defined daily dose

Figure 1b Overall antibiotic consumption in Tunisia by sector (public and private) (defined daily dose per 1000 inhabitants per day), 2016–2023**Table 1 Antibiotic consumption in Tunisia by pharmacologic class (%), 2016–2023**

Pharmacologic class	2016	2017	2018	2019	2020	2021	2022	2023
Beta-lactams, penicillins	63.3	56.6	65.0	63.3	62.7	52.8	55.8	64.5
Macrolides, lincosamides and streptogramins	9.2	10.2	9.5	9.0	13.9	18.1	15.2	10.8
Tetracyclines	7.9	11.1	6.1	7.9	5.9	8.0	8.9	8.2
Quinolones	7.9	8.0	8.0	7.7	5.8	8.2	8.6	5.0
Other beta- lactams	5.1	11.5	5.0	4.7	4.4	5.4	6.1	4.8
Antibiotic combinations	0.0	0.0	2.3	2.8	3.6	3.9	2.1	3.5
Amoebiasis agents – nitroimidazole derivatives	1.3	1.2	1.4	2.1	2.0	1.8	1.8	1.6
Sulfonamides and trimethoprim	0.0	0.0	1.1	0.9	0.6	0.8	0.5	0.7
Aminoglycosides	0.3	0.6	0.5	0.5	0.4	0.5	0.4	0.4
Other antibiotics	1.3	1.0	0.9	1.1	0.7	0.5	0.7	0.3

Discussion

Overall antibiotic consumption

The overall consumption of antibiotics in Tunisia increased slightly from 31.6 to 32.4 DDD per 1000 inhabitants per day between 2016 and 2023, peaking in 2018, followed by a marked decrease notably between 2019 and 2022, particularly during the COVID-19 pandemic. By 2023, consumption again exceeded 30 DDD per 1000 inhabitants per day, although the overall trend was not statistically significant ($P > 0.05$).

To place Tunisia's consumption levels in context, we compared national data with 5 countries representing a spectrum of antibiotic use: the Netherlands (lowest consumer in Europe), Greece (highest in Europe), Jordan (a WHO Eastern Mediterranean Region country with demographic and geographical similarities to Tunisia), Egypt (another Eastern Mediterranean Region country in North Africa), and Islamic Republic of Iran (highest antibiotic consumer in the Eastern Mediterranean Region region) (9,10). In 2023, Tunisia's consumption was about 4 times higher than that of the Netherlands and slightly higher than that of Greece, but lower than those of Jordan, Egypt and Islamic Republic of Iran, where antibiotic consumption was nearly double Tunisia's levels (Figure 3).

Figure 3 shows a reduction in antibiotic consumption during 2020–2021 in Tunisia, The Netherlands, Greece, and Jordan, likely reflecting the impact of pandemic-related public health measures such as lockdowns and physical distancing. For Egypt and Islamic Republic of Iran, comparable data prior to 2020 were unavailable.

High antibiotic consumption is strongly correlated with high resistance levels, while low consumption is associated with lower resistance (11). International comparisons show that The Netherlands has low resistance, whereas Greece and Tunisia have high resistance rates (12,13). In this study, we examined resistance rates in these countries for 3 bacterial species classified by WHO as critical in the Bacterial Priority Pathogens List (BPPL) (14): *Klebsiella pneumoniae* (carbapenem-resistant), *Escherichia coli* (resistant to third-generation cephalosporins), and *Acinetobacter baumannii* (carbapenem-resistant).

In 2021, the resistance rate of carbapenem-resistant *Klebsiella pneumoniae* was below 1% in The Netherlands, over 50% in Greece, and around 30% in Tunisia (15,16). Similarly, resistance to third-generation cephalosporins in *Escherichia coli* was <10% in The Netherlands, 10–25% in Greece, and around 15% in Tunisia (15,16). For *Acinetobacter baumannii*, carbapenem resistance was <1% in The Netherlands, >50% in Greece, and ≈90% in Tunisia (15,16). All 30 clinical *A. baumannii* isolates from 3 hospitals in Baghdad carried both chromosomally encoded bla_{OXA} 51-like and bla_{OXA} 23-like genes (17). A 2022 genomic study in Iraq similarly found that 98.3% of *A. baumannii* strains were carbapenem-resistant, a rate close to that in Tunisia and consistent with regional trends (17,18).

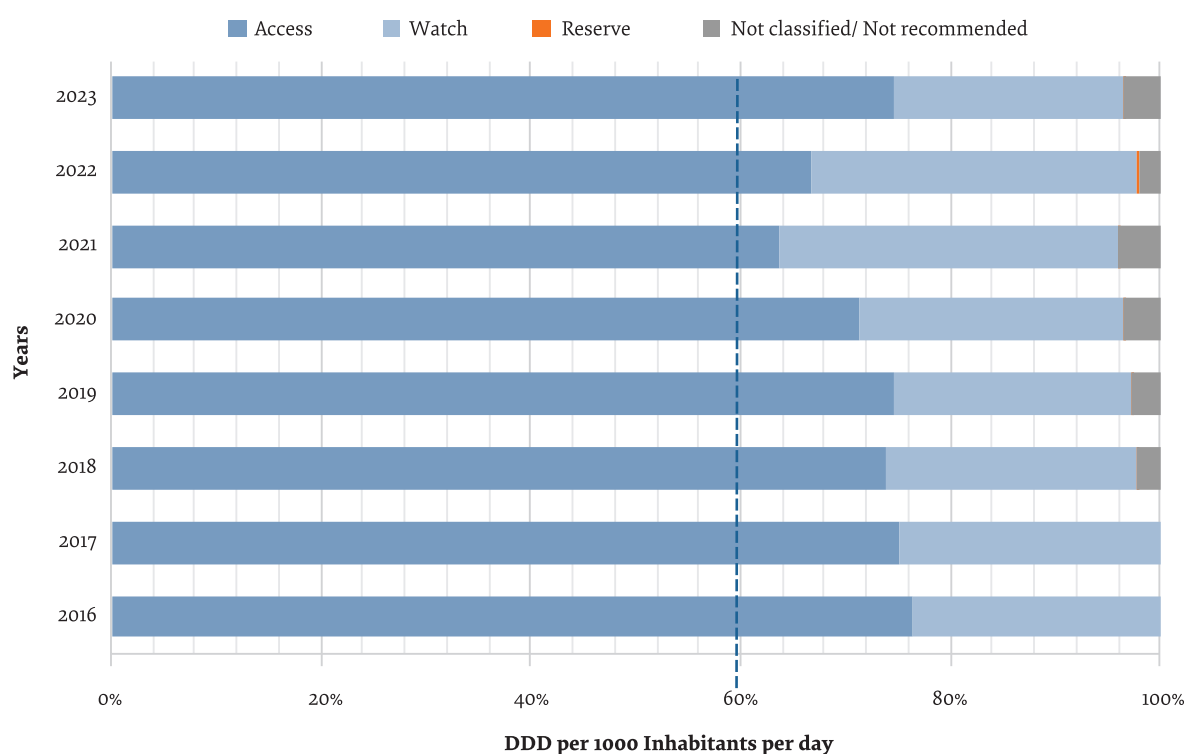
Antibiotic consumption in the private sector consistently exceeded public sector use, largely because private pharmacies serve most of the general population, while the public sector is limited to public hospitals. Antibiotics in public hospitals are dispensed strictly by prescription, whereas enforcement of prescription regulations in the private sector is inconsistent (19). Prescribers in public health care facilities are restricted to a hospital formulary, which excludes certain antibiotics available in the private sector such as oral amoxicillin/clavulanic acid, one of the most frequently consumed antibiotics (20). Prescription and dispensing practices also differ, with more structured antimicrobial stewardship programmes typically present in the public sector. These factors likely contributed to the significant decrease in public sector antibiotic use during the study period ($P < 0.05$), reflecting the impact of the NAP-AMR, which emphasises stewardship and rational use in public institutions (6).

This study showed that consumption of locally manufactured antibiotics significantly outweighed that of imported ones. This reflects substantial sectoral growth since the 1980s, driven by government incentives, with the number of manufacturing units increasing from 3 in the 1990s to 44 in 2023. Most locally produced antibiotics are lower-cost generics, making them more affordable than imported originator brands. Many originator antibiotics are manufactured locally under licence or by companies established in Tunisia (e.g. amoxicillin, azithromycin). Tunisia's robust quality control system ensures that imported and local antibiotics meet strict efficacy and safety standards. However, the predominance of generics underscores the need for vigilant antimicrobial stewardship to prevent cost-driven overuse and mitigate resistance, while balancing support for local production with strong regulatory oversight.

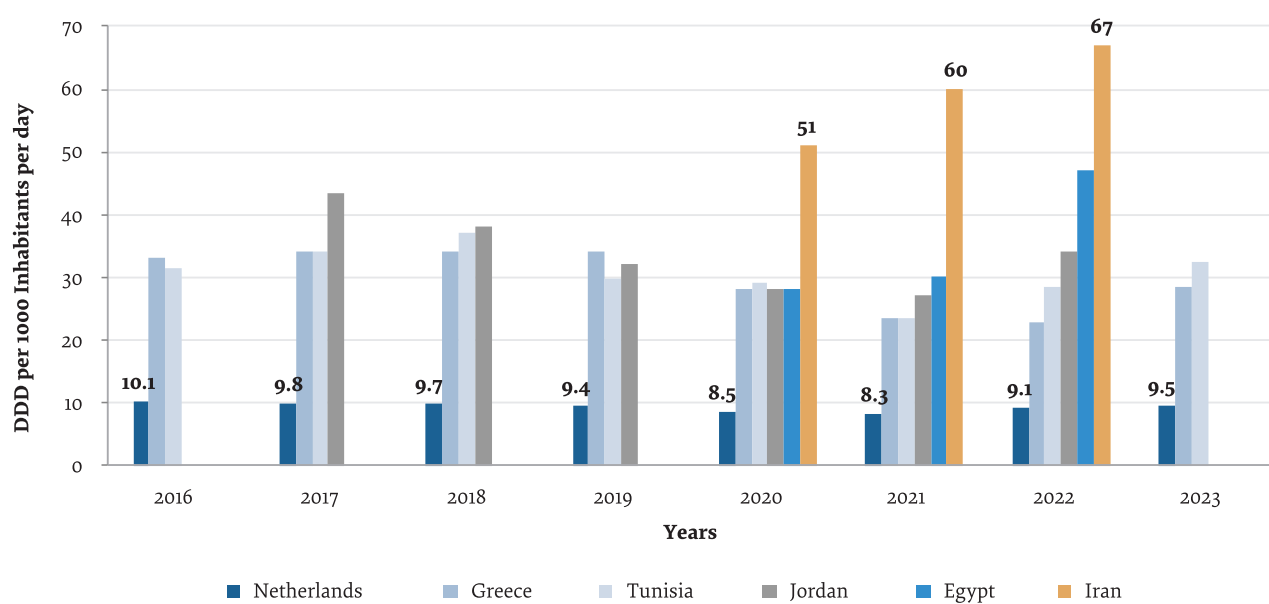
Annual consumption in Tunisia according to the AWaRe classification

In line with WHO recommendations, access group antibiotics should account for at least 60% of total national antibiotic use (21). Our study found that Tunisia's antibiotic consumption met this benchmark, exceeding 75% in most years of the study period, except for 2020, 2021 and 2022 (65%). This was largely due to the predominant consumption of penicillin class antibiotics, which consistently represented over 60% of total consumption, except in 2021. During the COVID-19 pandemic, watch group consumption increased, compared to access group use. Consumption of the reserve group remained below 1%, although it is worth noting that only 9 agents of the 30 reserve group antibiotics listed in the WHO AWaRe classification are available in Tunisia (8).

A notable factor influencing these changes was the introduction of azithromycin into the list of oral antibiotics in 2020. Azithromycin quickly accounted for 75% of oral antibiotic consumption, ranking third, after amoxicillin and amoxicillin/clavulanic acid and reaching 15% of total consumption in 2021. During the early days of the pandemic, azithromycin use in COVID-19 management ap-

Figure 2 Antibiotic consumption in Tunisia by AWaRe classification, 2016–2023

AWaRe = access, watch, reserve

Figure 3 Comparison of antibiotic consumption in Tunisia with selected countries (defined daily dose per 1000 inhabitants) per day

DDD = Defined daily dose

peared in an open-label non-randomised trial in France, sparking debate about its role, generally in combination with chloroquine. Several studies indicated that azithromycin has antimicrobial, antiviral and immunomodulatory effects, suggesting it as a potential COVID-19 therapeutic (22).

In Tunisia, the National Agency for Medicines and Health Products implemented a monitored emergency use of unregistered and investigational interventions (MEURI) procedure, allowing off-label prescription of hydroxychloroquine and azithromycin under strict monitoring (23). The RECOVERY study, a major international trial, concluded that azithromycin had no clinical benefit in hospitalised COVID-19 patients, leading to revisions in treatment protocols, including the removal of azithromycin from Tunisia's COVID-19 guidelines (24–26). Increased azithromycin use likely contributed to a decrease in access group consumption and the increase in watch group usage.

In our study, azithromycin consumption in Tunisia increased by 128.9% from 0.89 DDD per 1000 inhabitants per day in 2019 to 2.04 DDD in 2020, then increased by a further 37.0% in 2021 to its peak, stabilised in 2022, then decreased by 30.6% in 2023 (1.94 DDD). Overall, consumption increased by 117% between 2019 and 2023. In comparison, Greece saw a 13% increase between 2019 and 2020 followed by an 18.3% decrease through 2023, while The Netherlands recorded a continuous 18.5% decrease (9). The sharp increase in Tunisia from 2020 to 2022 likely reflects empirical COVID-19 use, suggesting misuse. Although consumption decreased in 2023, it did not return to pre-pandemic levels, indicating a degree of rationalisation but still requiring targeted stewardship programmes. Unlike Tunisia, The Netherlands maintained low and decreasing consumption, aligned with strict reduction policies. Greece's consumption remained relatively stable but high compared with the European average, reflecting persistent macrolide use (9).

This study systematically analysed national antibiotic consumption trends in Tunisia, expressed in DDD per 1000 inhabitants per day, from 2016 to 2023. The dataset,

compiled from import procurement records and declarations from local manufacturers and documented by the National Agency for Medicines and Health Products, covered 100% of national antibiotic use, providing a robust basis for policy development and stewardship interventions to optimise antimicrobial use.

However, the aggregated nature of the data did not allow assessment of prescription practices, dispensing patterns or insurance coverage, and there was no disaggregation by public and private health care facilities.

To address these gaps, the National Agency for Medicines and Health Products, in collaboration with WHO, the World Bank, the National Health Insurance Fund and the Central Pharmacy of Tunisia, has initiated a study to strengthen national surveillance, by incorporating additional variables such as funding sources, reimbursement status and geographic distribution. In 2023, the agency integrated the AWaRe classification into the hospital nomenclature to support pharmacists in promoting appropriate antibiotic use (20). In 2021, it also launched an antimicrobial stewardship strategy, training 33 hospital pharmacists from public hospitals and private clinics (27,28).

In 2024, work began on developing 47 antimicrobial stewardship indicators – 16 structural, 20 process, and 11 outcome – to monitor hospital implementation of antimicrobial stewardship programmes. Eight outcome indicators focus specifically on antibiotic use in hospitals. Once validated by the AMR committee and the Ministry of Health, these will be rolled out nationally to support antimicrobial stewardship implementation.

Conclusion

This study on antibiotic consumption in Tunisia between 2016 and 2023 described national consumption trends, including a decrease during the COVID-19 pandemic, and access group accounting for more than 60% of total use. The results identified priority areas for intervention to promote a more rational use of antibiotics, namely public awareness campaigns and strengthened antimicrobial stewardship in hospitals.

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Antibiotic consumption patterns in Iranian teaching hospitals

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Abstract

Background: There is a lack of national data on antibiotic consumption by teaching hospitals in Islamic Republic of Iran based on the WHO access, watch and reserve categorisation.

Aim: To quantify antibiotic consumption by teaching hospitals in Islamic Republic of Iran.

Methods: We analysed antibiotic consumption data for March 2023 to March 2024 across all 248 teaching hospitals in the 10 regions of Islamic Republic of Iran, using the WHO-defined daily dose methodology and the access, watch and reserve categorisation.

Results: Median antibiotic consumption was 299 defined daily dose per 100 admissions per day. Hospitals in Region 10 had the highest overall consumption (24.3% of total consumption), while Region 7 showed the highest use of reserve group antibiotics. Across all hospitals and regions, watch antibiotics were the most used (61%), followed by access (37%) and reserve (2%). Ceftriaxone 1 g and cefazolin 1 g were the most frequently used (11% of total consumption each), followed by meropenem 1 g injection (8.8%) and vancomycin 0.5 g (7%).

Conclusion: Our findings show high reliance on watch antibiotics, extensive cephalosporin use and prevalent parenteral formulations. There is a need to assess the appropriateness of antibiotic use in Iranian teaching hospitals in order to strengthen antibiotic stewardship.

Keywords: antibiotic consumption, AWaRe classification, teaching hospital, antimicrobial stewardship, defined daily dose, Iran

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Introduction

Antimicrobial resistance (AMR) is driven mainly by inappropriate and excessive antimicrobial use for humans and animals and is a major global health threat (1,2). The slow pace of antibiotic development further exacerbates this problem (2). In 2019, bacterial AMR alone caused 1.27 million deaths, exceeding the combined toll of HIV/AIDS and malaria (3).

Recognising its severe health and economic effects, the World Health Assembly (WHA) endorsed the WHO Global Action Plan on AMR in 2015 (4). In 2024, at the 79th United Nations General Assembly (UNGA) High-Level Meeting on AMR, global leaders approved a political declaration, committing to a clear set of targets and actions that include reducing the estimated 4.95 million annual human deaths associated with AMR by 10% by 2030 (5).

About 30% of human antibiotic use is considered inappropriate; and more than two-thirds occur in hospitals, especially among inpatients, thus accelerating

bacterial resistance (6,7). Effective responses require context-specific action plans supported by robust data on the magnitude and determinants of antibiotic use (4). Antibiotic use is measured using defined daily dose (DDD): “the assumed average maintenance dose per day for a drug used for its main indication in adults” (8). For comparability across settings, WHO recommends using DDD per 1000 inhabitants per day (also called DID) for population-level estimates, and DDD per 100 admissions, DDD per 100 bed-days, or DDD per 100 patient-days for hospital-level use (9).

International data show wide variations in antimicrobial consumption. In 2021, the European Union/European Economic Area average use was approximately 17.3 DDD per 1000 inhabitants per day, compared with 67.6 in Islamic Republic of Iran, which, according to WHO, has the highest reported human antibiotic consumption among 63 reporting countries; national use increased from 33 DID in 2000 to 67.6 in 2022 (10,11). Although cross-sectional studies have examined community and outpatient consumption patterns in Islamic

Republic of Iran, national hospital consumption has not been assessed (12-17).

To facilitate rational use, the WHO Expert Committee on the Selection and Use of Essential Medicines classifies antibiotics into access, watch, reserve (AWaRe) groups to support antibiotic stewardship and tracking (18). Following WHO recommendations, Islamic Republic of Iran adopted the Global Action Plan and developed a national action plan for AMR (2016–2021) (19). While AMR surveillance exists in the country, systems to monitor antimicrobial use in hospitals remain limited. Understanding antibiotic use within healthcare settings, particularly teaching hospitals, is critical to inform stewardship.

In this context, we conducted the first national study to quantify hospital antibiotic use across all 248 teaching hospitals over 12 months (March 2023 – March 2024). The objectives were to describe the consumption in DDD (WHO anatomical therapeutic chemical index 2023) and DDD per 100 admissions, and consumption by WHO AWaRe category.

Methods

Study setting

Islamic Republic of Iran has 31 provinces and 63 medical universities under the Ministry of Health and Medical Education, organised into 10 regions. Approximately 1100 hospitals operate nationally; 248 (23%) of which are teaching hospitals affiliated with these universities. All 248 teaching hospitals in Islamic Republic of Iran were included to ensure complete national coverage. These hospitals follow national guidelines for antibiotic use and maintain electronic real-time records through health information systems (HIS).

Study design

This cross-sectional study analysed hospital antibiotic consumption across all teaching hospitals in 10 regions, using admissions as the denominator. We included systemic antibacterials (ATC J01) available in the national market. Data on consumption (March 2023–March 2024) were collected from all 248 teaching hospitals using a standardised Microsoft Excel proforma. The study population was defined by the number of patients admitted to these hospitals during the study period. The WHO AWaRe classification, which categorises antibiotics into access, watch, and reserve groups based on their resistance potential and public health importance, was used for analysis and to assess stewardship.

Data were collected by trained hospital pharmacists using a structured Excel file with 2 worksheets: (i) antibiotic data (J01 subgroup, generic name, code, ATC code, dosage, route of administration, DDD, and units consumed); and (ii) hospital indicators (number of beds and admissions). This file, accompanied by a user guide, was distributed to medical universities, which trained

hospital staff to complete and submit the form every 6 months. Each university compiled the hospital data and forwarded them to regional universities. Regional aggregated datasets were then submitted to the Iran Food and Drug Administration (IFDA) for accuracy checks and final compilation at the national level.

The database included: hospital name; antibacterial subgroup (ATC J01) including tetracyclines (J01A), penicillins (J01C), other beta-lactams (J01D), sulfonamides and trimethoprim (J01E), macrolides/lincosamides/streptogramins (J01F), aminoglycosides (J01G), quinolones (J01M), and other antibacterials (J01X); number of antibiotics consumed; route of administration (oral or parenteral); and number of admissions during the study period. Two additional variables were added: the DDD for each antibiotic according to the WHO ATC/DDD index 2023, and the corresponding WHO AWaRe category (8,18).

Statistical analysis

Data from all universities were compiled in Microsoft Excel. Antibiotic consumption was expressed in DDD and DDD per 100 admissions. For each antibiotic, the DDD was calculated using the formula:

$$\text{DDD} = \frac{\text{number of antibiotic doses (tablets/injections) consumed} \times \text{quantity of antibiotics per dose (in grams)}}{\text{WHO Unit DDD of the antibiotic}}$$

Antibiotic consumption density (ACD) was defined as :

$$\text{ACD} = \frac{\text{total DDD for the antibiotic} \times 100}{\text{number of admissions during the given period (9)}}.$$

The DDD per 100 admissions was calculated for each antibiotic and aggregated by ATC J01 subgroup. ACDs were also aggregated for the 10 regions, with national and regional medians and interquartile ranges (IQRs) reported. DDD per 100 admissions was further stratified by , antibiotic class, and AWaRe category. The proportion of antibiotics in the access, watch and reserve groups was calculated as a percentage of the total DDDs.

Ethics approval

Ethics approval was granted by the Research Institute for Pharmaceutical Sciences, Tehran University of Medical Sciences (IR.TUMS.TIPS.REC.1402.185; 11 March 2024) and the Union Ethics Advisory Group, Paris, France (EAG 03/24; 2 February 2024). Informed consent was waived.

Results

Patient admissions and antibiotic consumption by defined daily dose

Table 1 summarises total DDD and ACD (DDD per 100 admissions) for March 2023 to March 2024 across 248 teaching hospitals in 10 regions. There were 6.1 million admissions and 18.2 million DDD consumption in total. Region 10 recorded the highest consumption (24.3% of the total consumption),

Table 1 Antibiotic consumption in Iranian teaching hospitals (defined daily dose per 100 admissions), March 2023–March 2024

	Overall	Hospital region										Interquartile range
		1	2	3	4	5	6	7	8	9	10	
Defined daily dose (million)	18.2	1.6	1.5	1.2	1.3	1.5	2.1	1.4	1.2	1.9	4.4	1.3–1.8
Antibiotic consumption per 100 admissions	299	317	374	294	131	227	362	242	232	296	561	235–362
ATC J01 subgroup												
Tetracyclines	5	5	4	6	2	5	6	3	2	4	16	3–6
Penicillins	21	18	13	16	11	21	27	16	11	22	54	14–22
Cephalosporins	136	140	188	131	54	108	162	111	116	131	222	112–162
Sulfonamides	2	1	2	3	1	1	1	2	1	1	6	1–2
Macrolides	44	67	49	33	25	27	66	23	35	57	59	29–57
Aminoglycoside	11	9	15	13	5	7	11	8	13	14	14	8–14
Quinolone	41	33	48	45	15	28	45	40	21	24	114	25–45
Other antibacterials**	43	44	55	47	18	30	44	39	33	43	76	35–47

ATC = anatomical therapeutic chemical classification

** This group comprises antibacterials with various modes of action not classified in any of the groups: glycopeptide antibacterials, polymyxins, steroid antibacterials, imidazole derivatives, nitrofurantoin derivatives.

Table 2 Antibiotic consumption by AWARe category and route in Iranian teaching hospitals, March 2023–March 2024

AWARe category	Total		Oral		Parenteral	
	Defined daily dose (million)	Percentage	Defined daily dose (million)	Percentage	Defined daily dose (million)	Percentage
Access	6.8	37.4	2.0	38.6	4.9	37.1
Watch	11.0	60.5	3.0	60.3	7.0	60.5
Reserve	0.4	2.0	0.05	1.1	0.3	2.4
Unclassified	0	< 0.01	0	< 0.01	0	0.00
Total	18.2	100%	5.05	100%	12.2	100%

while regions 3 and 8 consumed about 1.2 and 1.3 million, respectively (6–7% of the total). The national median ACD was 299 DDD per 100 admissions (IQR 235–362), ranging from 131 (Region 4) to 561 (Region 10).

Cephalosporins had the highest ACD (median 136; IQR 112–162), representing 45% of total DDD, while sulfonamides had the lowest (median 2; IQR 1–2), representing 1% of the total.

Antibiotic consumption by AWARe and route

Table 2 and Figure 1 present AWARe-grouped consumption and route (oral vs parenteral). Across all hospitals, access antibiotics accounted for 37% of DDD, watch 61%, and reserve 2%. A similar distribution was observed across both routes of administration and all 10 regions. Overall, 72% of antibiotics were given parenterally. While Region 10 had the highest total DDD consumption, Region 7 had the highest proportional reserve use (4%).

Figure 2 illustrates the consumption of ATC J01 antibiotic subgroups as a percentage of total use across all 248 teaching hospitals. Cephalosporins accounted for the largest share (44%), followed by “other” antibiotics, including vancomycins, colistimethate and linezolid (17%)

and macrolides (15%). Sulfonamides and tetracyclines were the least consumed subgroups (1% each).

The top 10 most consumed antibiotics are listed in Table 3. Ceftriaxone 1 g and cefazolin 1 g were the most frequently used, each accounting for approximately 11% of the total consumption, followed by meropenem 1 g injection (8.8%), and vancomycin 0.5 g (7%). Six of the 10 most consumed antibiotics belonged to the watch category.

These findings are consistent with the overall AWARe distribution and highlight the dominant role of cephalosporins and other watch antibiotics in Iranian teaching hospitals.

Discussion

This is the first national study to assess antibiotic consumption across all 248 teaching hospitals in Islamic Republic of Iran. A total of approximately 18.2 million DDDs were dispensed to just over 6 million patients, equivalent to 299 DDD per 100 admissions. The highest DDD per 100 admissions was in Region 10 and the lowest was in Region 4. Antibiotics from the watch group accounted for 61% of total use. Cephalosporins

Figure 1 Total Regional defined daily dose of J01 antibiotics by AWaRe category in Iranian teaching hospitals

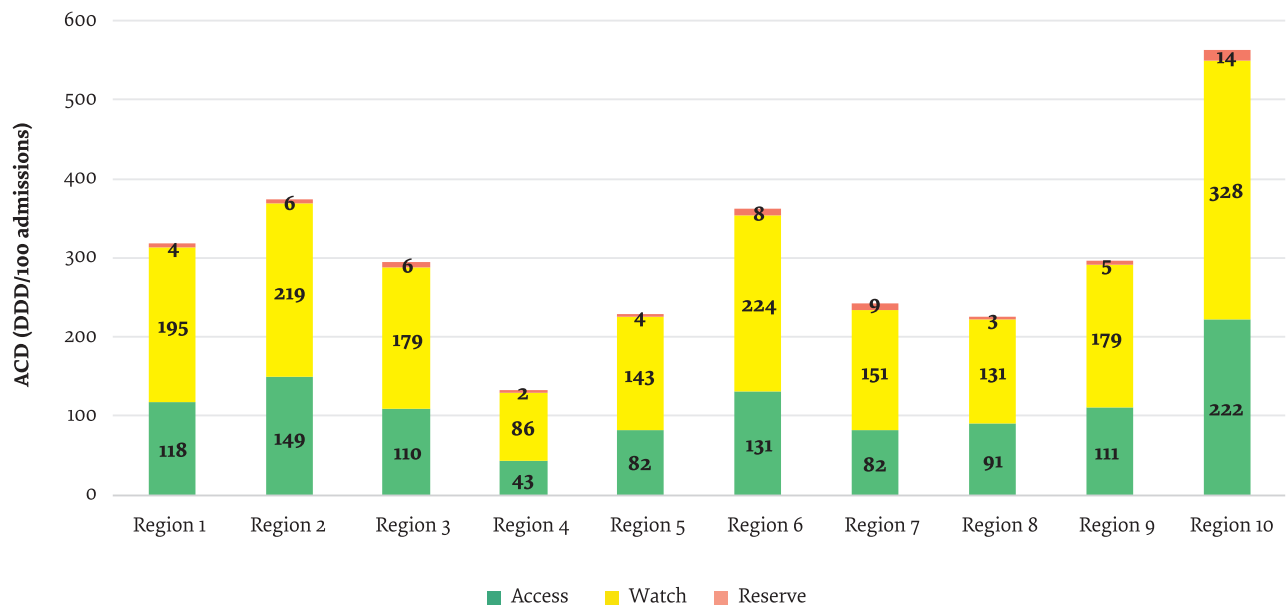


Figure 2 Percentage consumption by ATC J01 antibiotic subgroups in Iranian teaching hospitals (n = 8.1 million DDD)

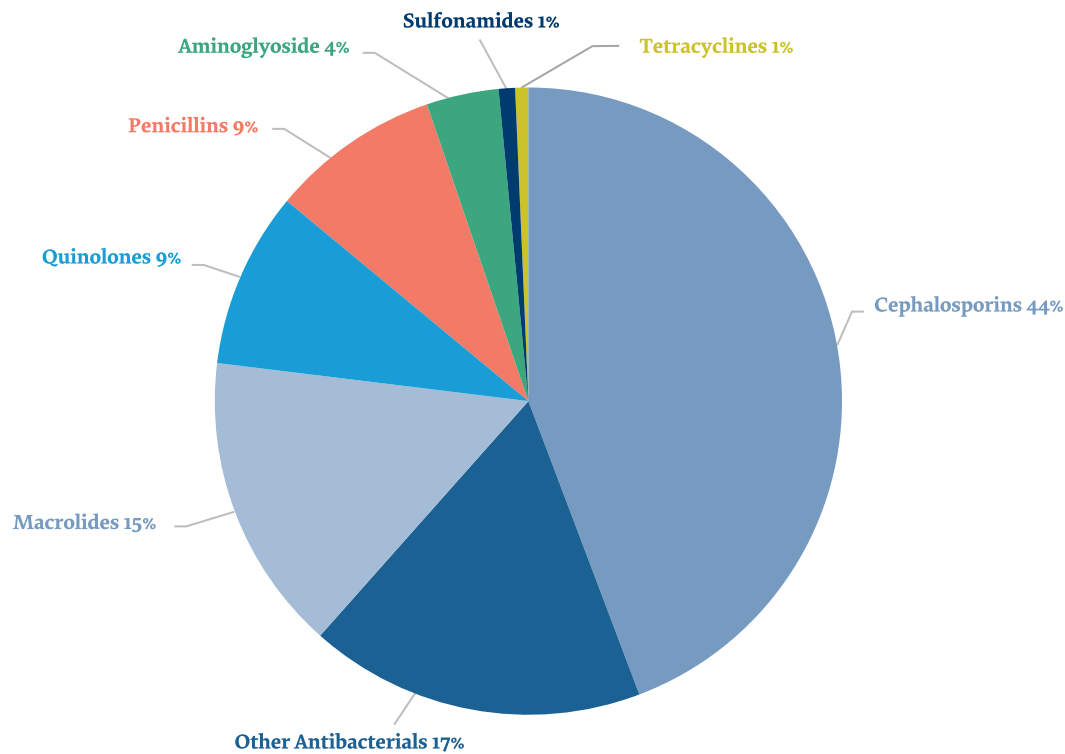


Table 3 Top 10 most consumed antibiotics in Iranian teaching hospitals, March 2023–March 2024 (DDD, million)

Generic name	AWaRe class	Route of administration	Defined daily dose (million)	Percentage of total antibiotics consumed
Ceftriaxone 1 g	Watch	Parenteral	2.0	10.9
Cefazolin 1 g	Access	Parenteral	2.0	10.8
Meropenem 1 g	Watch	Parenteral	1.6	8.8
Vancomycin g	Watch	Parenteral	1.3	6.9
Clindamycin 150 mg/1mL 2 mL	Access	Parenteral	1.0	5.6
Metronidazole 5 mg/1mL 100 mL	Access	Parenteral	0.7	3.9
Cefalexin 500 mg	Access	Oral	0.5	3.
Ciprofloxacin 500 mg	Watch	Oral	0.5	2.9
Levofloxacin 5 mg/1mL 100 mL	Watch	Parenteral	0.5	2.8
Levofloxacin oral tablet 500 mg	Watch	Oral	0.4	2.5

(44%) were the most consumed antibiotic subgroup, while sulfonamides and tetracyclines were the least consumed (1% each). Parenteral administration was the most common route of administration, constituting 72% of total use.

The study's findings have important public health implications. First, in the absence of international reference standards for ACD, it is difficult to determine whether the 299 DDD per 100 admissions is acceptable, high, or low. However, it provides a solid national baseline for future monitoring. Literature shows that both DDD/100 patient-days and DDD/100 admissions are valid measures. In Region 2, 119.2 DDD/100 patient-days were reported, and during the first 6 months of the COVID-19 pandemic, 121.6 DDD/100 patient-days were recorded (20,21). In Qatar, consumption reached 228.9 DDD/100 bed-days, and a systematic review found a pooled hospital-wide ACD of 586 DDD per 1 000 hospital days (22,23). Direct comparison is challenging because denominators differ between studies. For DDD/100 admissions, however, our findings show higher consumption than in Malaysia (167.49 DDD/100 admissions) but lower than in France (341 DDD/100 admissions) and the Netherlands (377 to 386 DDD/100 admissions) (24–26). This places Iran's hospitals at the higher end of global consumption.

Second, watch antibiotics represented 61% of total consumption, compared with 37% for access. This pattern aligns with findings in other low- and middle-income countries (LMICs), including Nepal and Qatar (22,27). WHO recommends that $\geq 60\%$ of antibiotic consumption should come from the access group (18). Over-reliance on watch drugs increases the risk of antimicrobial resistance. To address this, we propose 3 stewardship interventions: (i) introducing AWaRe colour-coding in electronic prescriptions to prompt physicians to consider access alternatives; (ii) mandatory registration of watch antibiotics in the TTAC (tracking, traceability, and control) system; and (iii) exploring economic levers such as higher co-payment for watch antibiotics, as used successfully in Spain (28).

Third, cephalosporins – particularly third-generation agents – were the most consumed subgroup (44%), consistent with other studies from Islamic Republic of Iran and the Eastern Mediterranean (29,30). Islamic Republic of Iran reports the second-highest consumption of third-generation cephalosporins after Bangladesh (10). Such use is associated with resistant *Enterobacterales*, linked to higher morbidity and mortality, especially in neonatal sepsis and LMICs (31). A shift in consumption towards second-generation cephalosporins would help mitigate this risk. The predominance of parenteral administration (72%) may reflect clinical severity of cases or prescription bias towards injectables, both of which increase health care costs. These findings emphasise the urgent need to strengthen stewardship programmes in teaching hospitals, which have been shown to reduce antibiotic use and improve outcomes (33,34).

The absence of integrated monitoring that links consumption data with clinical outcomes and resistance trends highlights a critical policy gap. Establishing a national system to routinely capture antibiotic use alongside patient profiles and AMR patterns is essential for evidence-based evaluation and guideline updates.

This study has several strengths and some limitations. Its main strength is the comprehensive coverage, notably data from all 248 teaching hospitals across 10 regions, providing a nationally representative analysis, disaggregated by class, dosage and route of administration.

Key limitations include the lack of data on hospitalisation duration, which prevented calculation of DDD per 100 patient-days. Instead, DDD per 100 admissions was used, as recommended by WHO when patient-day data is unavailable. The study did not explore reasons behind regional variations in antibiotic use, such as hospital capacity, disease burden, or prescription practices. Future studies should aim to collect clinical and hospital-level data, including patient-days and resistance patterns, to better explain consumption differences and support targeted stewardship interventions.

Conclusion

This study provides the first national baseline on hospital antibiotic consumption in Islamic Republic of Iran, identifying critical areas of concern and establishing reference values for future monitoring. The ACD of 299 DDD per 100 admissions serves as a benchmark for interpreting antibiotic use, although its interpretation remains limited without global reference standards and hospitalisation duration data.

The overuse of watch group antibiotics (61%) and the preference for cephalosporins (44%) highlight the need for strengthened antibiotic stewardship programmes to align with WHO recommendations and promote judicious use. Regional variations and the predominance of parenteral administration (72%) suggest heterogeneity

in prescription practices and potential over-reliance on injectables, with cost and patient care implications. Linking antibiotic use with clinical indications and resistance patterns will be crucial for data-driven policymaking and combating AMR at the national level.

These findings and recommendations have been shared with all medical universities and physicians. The Ministry of Health has adopted the recommendation to incorporate AWARe colour-coding into electronic prescription systems. At the time of writing this paper, the other 2 recommendations – mandatory registration of watch antibiotics in the TTAC system and pricing/reimbursement interventions – were under consideration. A repeat of this study in 24 months will evaluate the impact of these measures on antibiotic consumption.

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Point prevalence of antibiotic use in teaching hospitals in Tunisia

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Abstract

Background: Improving the rational use of antibiotics is critical to limiting the development and spread of antimicrobial resistance.

Aim: To assess the prevalence and types of antibiotic use and the association with patient characteristics in 2 teaching hospitals in Tunisia.

Methods: Using a modified WHO point prevalence survey protocol, we collected data on the prevalence of antibiotics use and types and classes of antibiotic used from the medical records of 1028 patients hospitalized at the medical, surgical and intensive care units of 2 teaching hospitals in Sfax Governorate, Tunisia. We analysed the data using SPSS version 26. $P \leq 0.05$ was considered statistically significant.

Results: The prevalence of antibiotic use was 26.8%, with an average of 1.7 antibiotics used per patient. Of the 466 antibiotic types used, 156 (35.4%) belonged to the access group and 277 (59.4%) to the watch group. Antibiotic use was highest (39.8%) among children aged <5 years and males had 30% higher chances of receiving antibiotics. Antibiotic use was higher among patients in high-risk wards than those in non-high-risk wards and among patients in intensive care units than in non-intensive care units. We found that 79.2% of the antibiotics were used empirically; watch antibiotics were used empirically in 78.7% of the patients.

Conclusion: The frequent use of watch group antibiotics for empirical treatment and the significantly higher antibiotic use among children and the elderly indicate the need to re-assess prescription practices in these and other hospitals, enhance prescription education, and develop standard guidelines for optimising antibiotic use in Tunisia.

Keywords: antimicrobial, antimicrobial resistance, AWaRe, antibiotic, teaching hospital, Sfax, Tunisia

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Background

WHO has recognized antimicrobial resistance (AMR), which is primarily driven by overuse and misuse of antimicrobials, as a major public health threat (1–3). Improving the rational use of antimicrobials, particularly antibiotics, is therefore critical to limiting the development and spread of AMR (4). The increasing incidence of AMR threatens health security in the WHO Eastern Mediterranean Region (EMR) (5) and data on antibiotic use by humans between 2000 and 2018 show that EMR had the highest increase in antibiotic consumption rates among all WHO regions (6).

The most recent data (2021) show that 4267 (64.4%) of the 6629 deaths due to bacterial sepsis in Tunisia were associated with bacterial AMR and 1067 (25.0%) were attributable to AMR (7). An analysis of 101 countries show that antibiotic consumption rates in Tunisia were almost 10 times higher than the lowest rates observed in all other countries (6). Among 9 countries that submit-

ted data to the WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS) in 2022, Tunisia reported the fourth highest per capita consumption of antibiotics in the EMR (8).

The defined daily dose (DDD) method and the anatomical therapeutic chemical (ATC) classification system are increasingly being used to compare antibiotic use and to monitor and research international drug use (9). Continuous monitoring of antibiotic use at the hospital level is difficult in many countries (10), therefore, gathering data at a specified period every year using a standardised WHO point prevalence survey method (10) is considered a feasible alternative in low- to middle-income countries. The point prevalence survey offers an opportunity to assess antibiotic use by departments and wards, to guide stewardship programmes, compare antibiotic use over time, and understand the impact of interventions while easing the workload associated with continuous data collection (10,11).

In Tunisia, only a few studies have examined the use of antibiotics in hospitals. Two national surveys conducted in 2005 and 2012 were limited to antibiotic use among patients with hospital-acquired infections (12,13) and other studies were limited to antibiotic use for respiratory infections or infections due to specific bacteria (14). One study in 2019 investigated antimicrobial use among all hospitalised patients in 2 tertiary care hospitals in South Tunisia (15) and the WHO classification of essential antibiotics within the access, watch and reserve groups (AWaRe) was not used in this study. Data from a multi-country point prevalence survey in EMR in 2019 show that 46.5% of hospitalised patients in Tunisia received at least one antimicrobial (3). The study shows that access antibiotics constituted 46.7% of all antibiotics used.

Tunisia implemented a national action plan on AMR in 2019–2023, which included appropriate use of antibiotics as one of the key strategic pillars, in alignment with the WHO global action plan (16).

In this context, this study was conducted in 2023 to evaluate antibiotic use in Tunisia. The specific objectives were to: (a) estimate the point prevalence of antibiotic use among hospitalised patients in 2 teaching hospitals in Tunisia; (b) describe the proportion of access, watch and reserve antibiotics used, and (c) assess the association between antibiotic use and patient characteristics.

Methods

Study setting and participants

Tunisia is a lower-middle-income country located in North Africa with an estimated population of over 12.3 million (17). Sfax is the second most populated city in the country with a population of over one million as of 2022 (18). We conducted the study in Hedi Chaker and Habib Bourguiba university teaching hospitals in Sfax Governorate between 20 February and 11 March 2023. These hospitals have 30 wards with 1519 beds, including 80 intensive care unit (ICU) beds and 66 high-risk beds.

Patients hospitalized in the medical and surgical wards, including neonatal, paediatric and adult wards, at 8.00 am on the day of the survey were included in the study. The wards were classified into ICUs and non-ICUs and into high-risk and non-high-risk. High-risk wards included haematology, oncology, burns, transplantation, and infectious diseases wards, where antibiotic use is usually high. Patients in long-term care wards, accident and emergency departments, day-surgery wards, and daycare wards were excluded.

The exposure variables were age groups (< 30 days, 1 month≤1 year, 1≤5 years, 5≤18 years, 18–64 years, ≥65), sex (male, female), ward type (medical/surgical, high-risk/non-high-risk, ICU/non-ICU). The outcome variables were antimicrobial and antibiotic use (yes/no); prevalence of antibiotic use; number of antibiotics used; access, watch, reserve categories; type of use (empirical/targeted). Table 1 presents the key definitions used in the study.

Study design

We used the WHO methodology for point prevalence survey on antimicrobial use in hospitals (10). As recommended, the point prevalence survey collects data on the prevalence of antimicrobial use, antibiotic classes and types of antibiotic use, from the medical records of all hospitalised patients at 8.00 am on the survey day, which aligns with the standard approach of including the maximum number of eligible patients present at the time of the survey.

Physicians trained in data collection visited each ward during one of the 20 survey days. Each ward was surveyed only once on a single day to minimise the effect of the movement of patients between wards and hospitals. The data collectors obtained the total number of patients in the ward at 8.00 am to calculate the number of eligible patients. From these eligible patients, they created a list of all patients receiving antimicrobials at 8.00 am, for whom they collected detailed antimicrobial use data. Patients who were started on antimicrobials after 8.00 am or stopped before 8.00 am on the survey day were excluded.

We collected the data using relevant sections of the WHO point prevalence survey protocol, particularly, the ward assessment tool, the patient case report form and the antimicrobial use form (10). We avoided sections that were not aligned with our study objectives, namely, hospital assessment tool, health care-associated infections tool and organisms and antibiotic susceptibility.

Data analysis

The study investigators validated a random sample of 20% of the data before analysing it with SPSS version 26, Stata and OpenEpi (19). We performed descriptive analyses using frequencies and proportions and used Chi-square test to compare the distribution of AWaRe antibiotic categories between empirical and targeted therapies. We conducted binomial regression to assess the association between antibiotic use and patient characteristics [age groups, sex and type of ward (medical/surgical, high-risk/non-high-risk and ICU/non-ICU)] by calculating the crude prevalence ratios (cPR) and adjusted ratio (aPR) with 95% confidence intervals (95% CI). $P \leq 0.05$ was considered statistically significant.

Ethics approval

We obtained oral consent from the patients before they participated in the study, in addition to obtaining permission from the directors of each hospital and the heads of each department to use their medical records. Ethics approval for the study was obtained from the Ethical Committee of Southern Tunisia (CPP SUD N° 0571/2023) and the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease, Paris, France (EAG 07/24). No patient identifiers were collected and hospital names were removed from the data before analysis.

Table 1 Key definitions used in the study

Terminology	Originator brands
Empirical therapy	If a patient received an antibiotic not based on a microbiological report, it was considered an empirical therapy (10)
Targeted therapy	If a patient received antibiotics based on a microbiological report, it was considered a targeted therapy (10)
Prevalence of antibiotic use	The proportion of patients receiving at least one antibiotic belonging to any antibiotic group defined above at 8 am on the day of the survey during the survey period. $\text{Prevalence of antibiotic use} = \frac{\text{No of patients receiving at least one antibiotic} \times 100}{\text{Total no of patients surveyed}}$
WHO AWaRe classification	Access antibiotics include mostly narrow-spectrum antibiotics recommended as essential first or second-choice empiric treatment options with lower resistance potential than antibiotics in the other groups (23). Watch antibiotics include antibiotics that have higher resistance potential and are prioritized as key targets of stewardship programs and monitoring, while Reserve antibiotics include “last resort” antibiotics that should be reserved for the treatment of multidrug-resistant organisms (23). At the 2024 United Nations General Assembly (UNGA) High-Level Meeting on AMR, countries endorsed a political declaration thereby committing that they would achieve at least 70% antibiotic use from the Access category by 2030 (34).

Results

Of the 1028 eligible patients, 486 were female (47.3%) and most patients (543 or 52.8%) were aged 18–64 years (Table 2). A total of 286 patients (27.8%) (95% CI = 25–30.4) received at least one antimicrobial medicine, of whom 276 (96.5%) received antibiotics, 10 received antivirals, 23 antifungals and 2 antiparasitic agents.

The prevalence (95% CI) of antibiotic use was 26.8% (24.2–29.7) (Figure 1). A total of 466 antibiotics were used, with an average of 1.7 antibiotics per patient. One hundred and thirty-one (47.5%) patients received more than one antibiotic.

Access, watch and reserve antibiotics

Among 276 patients who received antibiotics, 158 (57.2%) received at least one antibiotic from the access group, 198 (71.1%) from the watch group and 12 (4.3%) from the reserve group. Among patients who received at least one watch antibiotic, 66 (33.3%) received 2 or more watch antibiotics.

Of the 466 antibiotics used, 156 (35.4%) belonged to the access group and 277 (59.4%) to the watch group. A total of 369 antibiotics (79.2%) were prescribed empirically. There were significant differences between the proportion of AWaRe categories used for empirical and targeted treatments ($P < 0.001$).

One hundred and forty-eight (89.7%) of the access antibiotics were used empirically, 218 (78.7%) of the watch antibiotics were used empirically, and 12 (85.7%) of the reserve antibiotics were used for targeted treatments (Table 3).

Association between antibiotic use and patient characteristics

Antibiotic use was highest among children aged <5 years (39.8%) (Table 4). The males had 30% higher chances of receiving antibiotics, although there was no significant difference when adjusted for type of ward and age. The adjusted analysis showed that antibiotic use was significantly higher among other age groups than adult patients aged 18–64 years. Antibiotic use was higher among patients in high-risk wards (aPR = 2.2; 95% CI = 1.6–2.9) than among patients in non-high-risk wards and among patients in ICUs (aPR = 1.4; 95% CI = 1.04–1.9) than among patients in non-ICUs.

The use of more than 2 antibiotics (28.6% vs 14.5%, $P = 0.025$) and the use of more than one watch antibiotic (38.1% vs 21.4%, $P = 0.019$) were significantly higher among patients in high-risk wards than among patients in non-high-risk wards. There was no significant difference between the use of more than 2 antibiotics and more than one watch antibiotic between the medical and surgical wards, ICUs and non-ICUs, or between males and females. Although 26.9% of patients aged 5–18 years were prescribed more than 2 antibiotics, compared to an overall average of 16.7%, the differences in the use of more than 2 antibiotics were not statistically significant between the different age groups.

Discussion

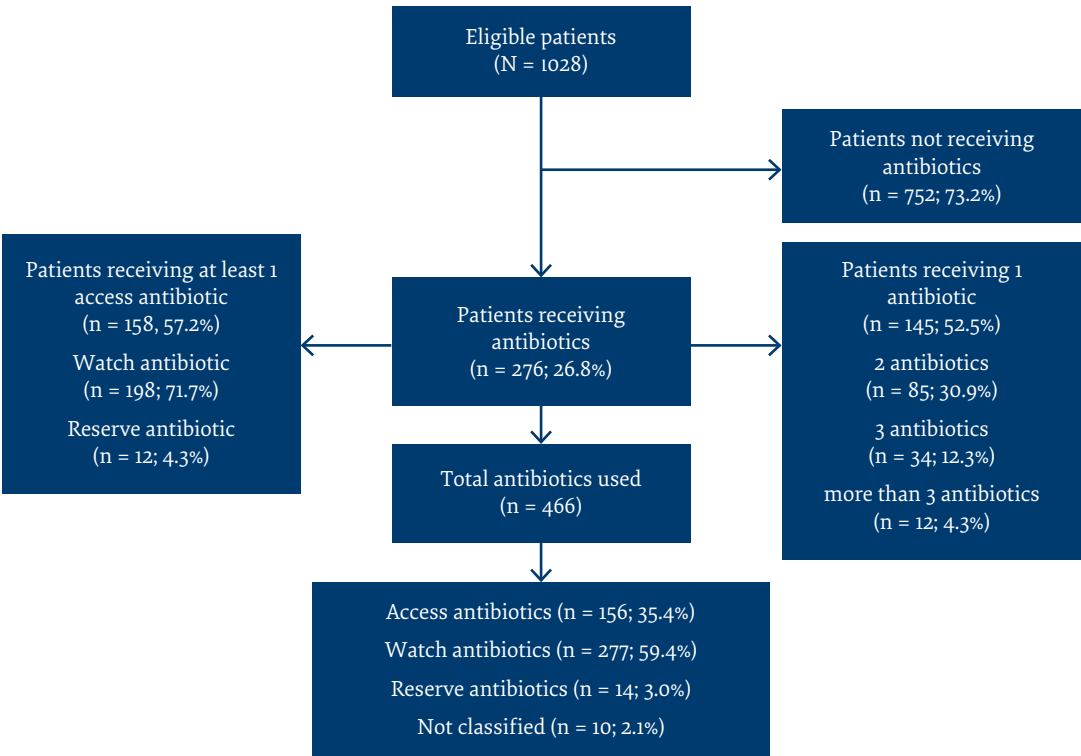
This study assessed the prevalence of antibiotic use among patients admitted to 2 tertiary care hospitals in Sfax Governorate of Tunisia in 2023. Two of the key findings have public health and programmatic implications. One, antibiotic use was significantly higher among children and the elderly and this has implications for patient

Table 2 Antibiotic use and patients characteristics, Tunisia, 2023

Characteristic	N	%
Age (years)		
< 30 days	48	4.7
1 month≤1 year	98	9.5
1≤5 years	40	3.9
5≤18 years	75	7.3
18–64 years	543	52.8
≥65	224	21.8
Sex		
Male	542	52.7
Female	486	47.3
Medical/surgical ward		
Medical	695	67.6
Surgical	333	32.4
Risk categorization of ward		
High-risk	87	8.5
Non-high risk	941	91.5
Place of admission		
ICU	83	8.1
Non-ICU	945	91.9
Total	1028	100

High-risk wards – including haematology, oncology, burns, transplantation, and infectious diseases wards, where antibiotic use is usually high
ICU = intensive care unit

Figure 1 Prevalence of antibiotic use among patients treated in 2 teaching hospitals, Tunisia, 2023



Note: Antituberculosis drugs are not included in the AWaRe classification

Table 3 Empirical and targeted use of antibiotic use among patients treated in 2 teaching hospitals, Tunisia, 2023

AWaRe group	Empirical use N (%)	Targeted use N (%)	Total N (%)	Statistics
Access	148 (89.7)	17 (10.3)	165 (100)	$\chi^2 = 48.94$ df = 2 P ≤ 0.001*
Watch	218 (78.7)	59 (21.3)	277 (100)	
Reserve	2 (14.3)	12 (85.7)	14 (100)	
Total	368 (80.7)	88 (19.3)	456 (100)	

High-risk wards – including haematology, oncology, burns, transplantation, and infectious diseases wards, where antibiotic use is usually high

ICU = intensive care unit

Table 4 Association between patients' characteristics and antibiotic use in 2 teaching hospitals, Tunisia, 2023

Characteristic	Total	Antibiotic use		aPR	95% CI
		N	%		
Age (years)					
< 30 days	48	17	35.4	1.7	1.1–2.7*
1 month≤1 year	98	41	41.8	2.3	1.7–3.1 *
1≤5 years	40	16	40	2.0	1.3– .1 *
5≤18 years	75	26	34.7	1.6	1.1–2.4 *
18–64 years	543	106	19.5	Ref (1)	–
≥65	224	70	31.2	1.6	1.2–2.0*
Sex					
Male	542	164	30.3	1.2	0.9–1.5
Female	486	112	23	Ref (1)	–
Medical/surgical ward					
Medical	695	205	29.5	1.04	0.8–1.3
Surgical	333	71	21.3	Ref (1)	–
High-risk/non-high-risk ward					
High-risk	87	42	48.3	2.2	1.6–2.9*
Non-high risk	941	234	24.8	Ref (1)	–
ICU/Non-ICU					
ICU	83	31	37.5	1.4	1.04–1.9*
Non-ICU	945	245	25.9	Ref (1)	–
Total	1028	276	26.8		

aPR = Adjusted prevalence ratio; CI = confidence interval; Ref = reference category; ICU = Intensive care unit

*Statistically significant

safety. Two, empirical use of watch antibiotics was substantial, suggesting the need for training and stringent measures to review their use by hospital stewardship teams.

Antibiotic use among children and elderly

The prevalence of antibiotic use (26.8%) reported in this study is lower than the most recent estimate of 46.5% in 2019 (3), possibly as a result of the antibiotic stewardship efforts including training, formation of stewardship teams and restrictions. The use of antibiotics was significantly higher among children, adolescents and the elderly than among adults aged 18–64 years. More than 25% of patients aged 5–18 years received more than 2 antibiotics, which may be an indication of inappropriate use, given the high empirical use. This resonates with a previous systematic analysis that showed increasing use of antibiotics among paediatric populations in low- and mid-

dle-income countries (27). A recent study from the United States of America shows that antibiotic use was most inappropriate among paediatric patients in ICUs and that consultation by infectious disease specialists was associated with lesser inappropriate orders (28).

Prolonged inappropriate empirical use of antibiotics may result in poor outcomes including an increased risk of *Clostridium difficile* infection (29). There is a tendency to overuse antibiotics for the elderly especially in ICUs, even when there is very little indication (20,30). Emerging evidence has associated early use of antibiotics in ICUs without bacterial culture with excess mortality (20). In our study, more than 10% of elderly patients (≥65 years) received more than 2 antibiotics. Overuse of antibiotics is often associated with AMR, which disproportionately affects the elderly, compared to other age groups (31). With an increasingly ageing community, it is important

to emphasize the need for dosage adjustments, targeted antibiotic use, and frequent review of antibiotics used among elderly patients in Tunisia, to mitigate drug interactions and adverse neurologic and toxic cardiac effects of antibiotics (32).

Empirical use of watch antibiotics

During the 2024 United National General Assembly, countries, including Tunisia, agreed to ensure that by 2030 70% of all antibiotics used at the national level are access (22). Tunisia reported 66.7% in 2022 (8), however, we found 35.4% in our study, lower than 46.7% reported by a similar study in 2019. Also, 33.3% of patients who received watch antibiotic received more than one watch antibiotic, indicating inappropriate or excess antibiotic use especially considering the higher proportion of empirical antibiotic use.

In our study, 79.2% of antibiotics were prescribed empirically, similar to a 2019 report (3). Another study reported 89.7% empirical use of access antibiotics, as first line antibiotics with low resistance potential (23). Higher empirical use of watch antibiotics may indicate inappropriate or overuse, suggesting the need to limit their use based on culture and sensitivity results (24). Previous systematic reviews and meta-analyses have associated inappropriate empirical antibiotic use with higher mortality (25). It is encouraging to see that most of the reserve antibiotics were used for targeted treatments, and this may be linked to the strict restrictions of their use in the country (26). Similar restrictions can be applied to selected watch antibiotics like quinolones and macrolides to reduce inappropriate use, especially in empirical therapy, alongside persuasive interventions like education for prescribers and audit with feedback (26).

Study strengths and limitations

To our understanding, this is the first published study in the last 5 years in Tunisia that estimated the prevalence of antibiotic use in a hospital using a standardised WHO point prevalence study method. The study was conducted when Tunisia's national action plan was due for review, and these results may be helpful in evaluating certain

objectives of the plan and in providing directions for future interventions. The study complied with the STROBE guidelines for reporting epidemiological observational studies (33).

However, this study has some limitations. One, due to resource constraints we could not collect clinical diagnosis data for all patients including their antibiotic resistance details. If available, these details would have helped in assessing the appropriateness of antibiotic use against clinical case mix and existing guidelines. Two, we measured only a point estimate and, therefore, could not conduct cause and effect analysis. These two limitations are inherent in all point prevalence surveys because of their cross-sectional design. Three, the findings on prevalence of antibiotic use cannot be generalized to the whole country because the study covered only 2 hospitals in one city; antibiotic use may differ from hospital to hospital due to various factors. However, our findings will be helpful in identifying appropriate interventions to improve antibiotic use in these and other similar hospitals.

Conclusion

This study examined antibiotic use patterns in Tunisia in 2023. It reports frequent use for empirical treatment, predominance use of watch antibiotics and use of multiple antibiotics. Although the overall prevalence of antibiotic use was lower than previously reported, the higher empirical use of watch antibiotics indicates the need for careful monitoring to avoid overuse. To address these issues and reduce AMR risks, we suggest creating national empirical therapy guidelines for common infections in Tunisia and to limit the empirical use of selected watch antibiotics to specific indications. We recommend the use of available point of care rapid diagnostic tests to rule out bacterial infections (e.g. C-reactive protein), wherever possible, to reduce unwanted empirical antibiotic use. More investments are needed in developing better point of care rapid bacteriology tests which can support clinical decisions. There is a need to continuously educate physicians, especially those working in paediatric and elderly care, ICUs and high-risk wards, on proper antibiotic prescription practices and the dangers of overuse.

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Gaps in HIV treatment and care in Morocco

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Abstract

Background: HIV remains a public health concern in Morocco, with persistent gaps in early diagnosis and retention in care, particularly outside major urban centres.

Aim: To describe HIV care delivery and patient outcomes at a referral centre in Safi, Morocco.

Methods: We collected and analysed sociodemographic, clinic and biological data of 283 HIV-confirmed patients who were actively followed up between December 2018 and December 2021 at the HIV referral centre of Mohamed V Provincial Hospital, Safi, Morocco.

Results: Sexual transmission accounted for 91.1% of infections. At diagnosis, 53.6% were asymptomatic. Treatment coverage was 92.6%. Median CD4 cell count increased from 351 cells/mm³ at initiation to 597 cells/mm³ after 12 months. Viral suppression increased from 45.8% at 3 months to 88.0% at 12 months. Of the patients, 10.2% were lost to follow-up, 6.7% died and 3.6% were transferred to other centres.

Conclusion: Although treatment coverage and virologic outcomes were high among the patients, late diagnosis, loss to follow-up and mortality remain important challenges, indicating the need for interventions to address the underlying challenges.

Keywords: HIV, diagnosis, sexual transmission, antiretroviral therapy, retention in care, Morocco

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Background

Globally, HIV continues to pose a major public health challenge despite sustained advances in prevention, testing, and antiretroviral therapy (ART). In the Eastern Mediterranean Region (EMR), coverage of HIV services remains below global averages, contributing to delayed diagnosis and gaps in continuity of care (1). In Morocco, an estimated 23 500 people were living with HIV in 2025, including 47% women and 1 080 children aged < 15 years. In 2023, 950 new HIV infections and 400 AIDS-related deaths were reported and national HIV prevalence was estimated at 0.08%. Mother-to-child transmission remains a critical concern, with a rate of 7% at 6 weeks, exceeding the national elimination target of < 5% and indicating missed opportunities along the prevention and care cascade (2).

Within this national context, the HIV referral centre in Safi, a coastal city in central-western Morocco, serves a predominantly rural and socioeconomically vulnerable population, where HIV-related stigma remains high and access to specialised services is limited. Service delivery is further constrained by limited human and material resources, restricted access to diagnostics, and challenges in maintaining long-term patient follow-up. This study describes HIV care delivery at the referral centre in Safi, with a focus on organisational resources, patient characteristics, and gaps in care, to inform strategies for improving patient care.

Methods

We conducted a descriptive, retrospective study at the HIV referral centre of Mohamed V Provincial Hospital in Safi, Morocco. The study aimed to describe the organisation of the centre, available resources, and patient cohort characteristics.

The HIV referral centre was established by the Ministry of Health in late 2018 and began operations on 25 November 2018. It provides care for people living with HIV in the Safi region, including ART initiation, routine clinical and biological monitoring, and follow-up. Care is delivered by a general practitioner trained in HIV management, supported by a nurse and a therapeutic mediator from the AIDS Fighting Association. Consultations are held twice weekly, with follow-up scheduled at one month, 3 months, and then every 6 months according to patients' clinical and biological status. Patients requiring specialised hospital care are referred to Mohammed VI University Hospital in Marrakesh. The hospital laboratory performs routine biochemistry, haematology, and immunoserology testing, including CD4 cell count and viral load monitoring. Microbiology, mycology, and histopathology testing are not available on site. Multidisciplinary care involves pulmonology, gynaecology, neurology, paediatrics, gastroenterology, and intensive care services.

All patients with confirmed HIV diagnoses, established by Western blot or viral load testing, who

were actively followed between December 2018 and December 2021 were included ($n = 283$). Patients with incomplete medical records were excluded.

Sociodemographic, clinical, and biological data were systematically extracted from patient medical records using standardised data collection forms. Variables included age, sex, marital status, literacy level, mode of HIV transmission, clinical stage, treatment regimen, CD4 cell count, and viral load at baseline and during follow-up. Data were entered and analysed using Microsoft Excel 2019.

Patient confidentiality and anonymity were maintained throughout data collection, in accordance with national HIV management guidelines and ethics requirements for medical research. Ethics approval was obtained from the Ethics Committee of Mohamed V Provincial Hospital in Safi, Morocco. Given the retrospective nature of the study, the requirement for informed consent was waived for the review of anonymised patient records, in accordance with national regulations.

Results

Between December 2018 and December 2021, 283 patients were managed at the centre: 66.0% were urban residents, and 58.0% were female (sex ratio 0.72). The mean age was 33.3 ± 18.4 years (range: 4 months–74 years). Most of the patients were enrolled in 2019, and 130 (45.9%) had previously been followed at other referral centres. Among newly diagnosed patients, 87.6% attended the referral centre within one month (mean interval: 11 ± 7.5 days). Heterosexual transmission accounted for 91.1% of cases, followed by same-sex transmission (6.0%) and mother-to-child transmission (3.0%). At diagnosis, 53.6% of the patients were asymptomatic, and 46.4% presented with clinical signs or HIV-related opportunistic infections.

Baseline CD4 testing was performed in 85.0% ($n = 130$) of newly diagnosed patients. Of those tested, 33.8% ($n = 44$) had CD4 counts < 200 cells/mm³ (mean: 351 cells/mm³; range: 50–900). CD4 testing at first consultation was performed in 80.8% ($n = 105$), of whom 60.9% had CD4 counts > 500 cells/mm³. Viral load testing was performed in 91.5% of new patients ($n = 140$; mean: 533,386 copies/mL, range: 2,000–1,200,000) and in 90.0% of referred patients ($n = 117$). Viral suppression was achieved in 82.1% of referred patients ($n = 96$), while 17.9% had detectable viremia (mean: 76,543 copies/mL; range: 5,000–400,000).

Overall, 92.6% of the patients ($n = 262$) initiated ART, most commonly a 2-nucleoside reverse transcriptase inhibitor plus one non-nucleoside reverse transcriptase inhibitor regimen (88.8%), followed by 2-nucleoside reverse transcriptase inhibitor plus protease inhibitor (5.8%) and 2-nucleoside reverse transcriptase inhibitor plus integrase inhibitor regimens (5.4%). Tenofovir disoproxil fumarate, emtricitabine, and efavirenz were the most frequently prescribed regimen. After 6 months of treatment, viral suppression was achieved among

70.9% of the patients, and 44.4% had CD4 counts > 500 cells/mm³.

During follow-up, 6.7% ($n = 19$) of the patients died, with 89.5% ($n = 17$) of deaths occurring among patients classified as WHO clinical stage C, and 14 had CD4 < 100 cells/mm³. Of the patients who died, 68.4% ($n = 13$) had not initiated ART, and pulmonary tuberculosis was the most frequent cause of death. Loss to follow-up occurred among 10.2% of patients ($n = 29$). Additionally, 3.6% ($n = 10$) were transferred to other facilities because of geographic proximity ($n = 4$), hospitalisation requirements ($n = 3$), or specialised care needs ($n = 2$).

Discussion

This study describes HIV care outcomes and gaps at a regional referral centre in Safi, Morocco, highlighting patterns of transmission, stage at diagnosis, treatment uptake, virologic response, and patient retention. Despite high antiretroviral therapy coverage and favourable virologic outcomes, late presentation, loss to follow-up, and mortality remain important challenges.

The predominance of heterosexual transmission is consistent with national and regional data from Morocco and other EMR countries, where heterosexual contact remains the main route of HIV transmission (3,4). The high proportion of patients presenting with clinical manifestations at diagnosis reflects persistent gaps in early HIV detection, despite progress in public awareness campaigns and systematic screening programmes (5). High ART uptake and favourable immunovirologic outcomes in this cohort are in line with national reports indicating improved access to ART and good treatment adherence (4,6,7). However, patient retention remains suboptimal, with a substantial proportion of patients (10.2%) lost to follow-up, potentially compromising treatment continuity and clinical outcomes. Evidence from other settings indicates that targeted interventions, such as structured phone follow-ups and community engagement, are associated with improved retention in care (8).

Mortality in this cohort was comparable to, or slightly lower than, rates reported in other Moroccan studies (4,7,9). Importantly, most fatalities occurred among patients with advanced disease, indicating the critical importance of earlier diagnosis and prompt ART initiation. At the national level, women account for nearly half of people living with HIV in Morocco, and mother-to-child transmission rates remain above elimination targets (2). The higher proportion of women in the Safi cohort may reflect differential health-seeking behaviour. However, it may also point to increased vulnerability linked to local socioeconomic and cultural factors. Addressing gender-related barriers is essential for tailoring HIV prevention and care strategies to the local context.

Although most patients initiated ART within 7 days of diagnosis, delays in treatment initiation persisted for a subset of patients, reflecting ongoing operational constraints within the care pathway. And, although

standard biological monitoring was implemented in accordance with national recommendations, some investigations required referral because of local laboratory limitations, particularly for serologic testing and tuberculosis diagnostics (10). These constraints represent a structural barrier to comprehensive HIV care and may contribute to delayed diagnosis and management of opportunistic infections.

Patients receiving care at the Safi Referral Centre underwent standard biological evaluation prior to ART initiation. This assessment included all Ministry of Health-recommended laboratory parameters, with the exception of serologic testing (hepatitis B/C, syphilis, toxoplasmosis, CMV) and the GeneXpert MTB/RIF assay, which were unavailable in the laboratory facility. Reliance on external laboratories for these essential tests reflects a structural limitation in regional HIV care delivery. Framing this as a systemic barrier highlights the need for investment in diagnostic infrastructure and resource allocation, as timely diagnosis and comprehensive management of opportunistic infections remain compromised without addressing these gaps.

Morocco has implemented a national antiretroviral therapy programme funded by the Ministry of Health in collaboration with international partners (11). The programme provides free ART to all enrolled patients. The recommended first-line regimen combines 2 nucleoside reverse transcriptase inhibitors (NRTIs) – tenofovir disoproxil fumarate (TDF) plus lamivudine (3TC) or emtricitabine (FTC) – with an integrase strand transfer inhibitor (INSTI), dolutegravir (DTG). This regimen was selected for its high efficacy, favourable tolerability, and simplified dosing that improves adherence. Treatment selection considers treatment history, clinical and biological status, comorbidities, and anticipated adherence. Second-line regimens are available for cases of virological failure, intolerance, or contraindications (Table 1). Specific protocols are also in place for paediatric patients and for co-infections, adjusted for age, weight and associated conditions (10).

Among 277 patients, 246 adults (88.8%) and all 6 children received first-line ART, while only 10 adults (3.6%) required second-line therapy. In our cohort, more than half of infections were detected through asymptomatic screening, while the remainder were identified after clinical presentation, reflecting better access to testing than reported in other national and regional reports. However, further progress is needed to meet programme targets.

The treatment regimens implemented at Safi centre followed the Ministry of Health guidelines. Immunovirological monitoring demonstrated encouraging outcomes, with a high proportion of patients achieving viral suppression after 12 months of treatment, results comparable to those reported in other national studies (4,6,7). However, this remains below the UNAIDS 95-95-95 target of 95% viral suppression, highlighting the need for strengthened adherence support and service delivery improvements (12). Adherence data were not stratified by urban versus rural residence, which may mask potential equity gaps and limit assessment of socio-geographic influences on treatment outcomes.

Patient follow-up outcomes revealed that most patients maintained regular care at the referral centre, while a proportion were lost to follow-up (LTFU). LTFU definitions vary across studies (13,14). This study applied the WHO definition of loss to follow-up as missing scheduled appointments for ≥ 3 months (15). The observed rate remains concerning. Although specific predictors such as distance to clinic, literacy level, and socioeconomic status were not systematically assessed, these factors are known to affect retention in care. Exclusion of patients with incomplete medical records may also have introduced selection bias towards individuals more engaged in care or with better baseline health status. Their absence represents a limitation of this study and highlights an important area for further operational research.

The cohort demonstrated a mortality rate comparable to national findings but lower than rates reported in other Moroccan studies (4,16). Critically, most deaths occurred among patients with advanced disease, underscoring the life-saving importance of early HIV diagnosis and rapid ART initiation. Beyond late presentation, other potentially preventable factors, including delays in treatment initiation, limited management of opportunistic infections, particularly tuberculosis, and barriers to continuous follow-up, likely contributed to mortality. These findings support the need for earlier testing, prompt initiation of effective and well-tolerated regimens, and strengthened integration of HIV and TB services to reduce mortality and improve long-term survival.

Conclusion

This study provides an overview of HIV management in Safi Province, Morocco, highlighting key epidemiologic and clinical characteristics, treatment patterns, and

Table 1 Second-line antiretroviral therapy regimens

First-line regimen	Second-line regimen
TDF + (3TC or FTC) + DTG	AZT + 3TC + LPV/r
AZT + 3TC + DTG	TDF + (3TC or FTC) + LPV/r
TDF + (3TC or FTC) + (EFV or NVP)	AZT + 3TC + DTG
AZT + 3TC + (EFV or NVP)	TDF + (3TC or FTC) + DTG

patient outcomes. Despite high antiretroviral therapy coverage, challenges persist, including late diagnosis, high loss-to-follow-up rates, and a predominantly young, female, and socioeconomically vulnerable population.

Strengthening community-based interventions, such as peer navigation, follow-up by trained health care workers, and individualised counselling, may improve adherence and retention. Expanding early testing campaigns

in underserved areas and integrating HIV screening into existing health services may facilitate timely diagnosis and treatment. Tailoring these strategies to local epidemiologic and sociocultural contexts may improve patient outcomes, reduce mortality, and support Safi Province in achieving national and international HIV targets.

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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

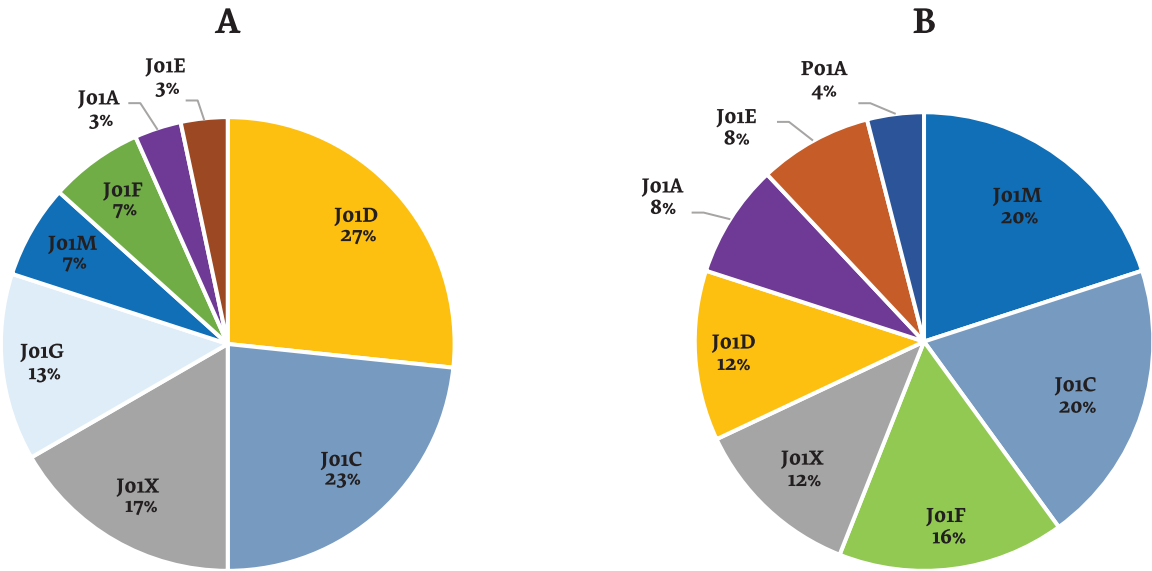


Table 3 Relationship between cost, marketing authorization holders and affordability of oral and injectable antibiotics by AWARe category, Islamic Republic of Iran, 2023

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.

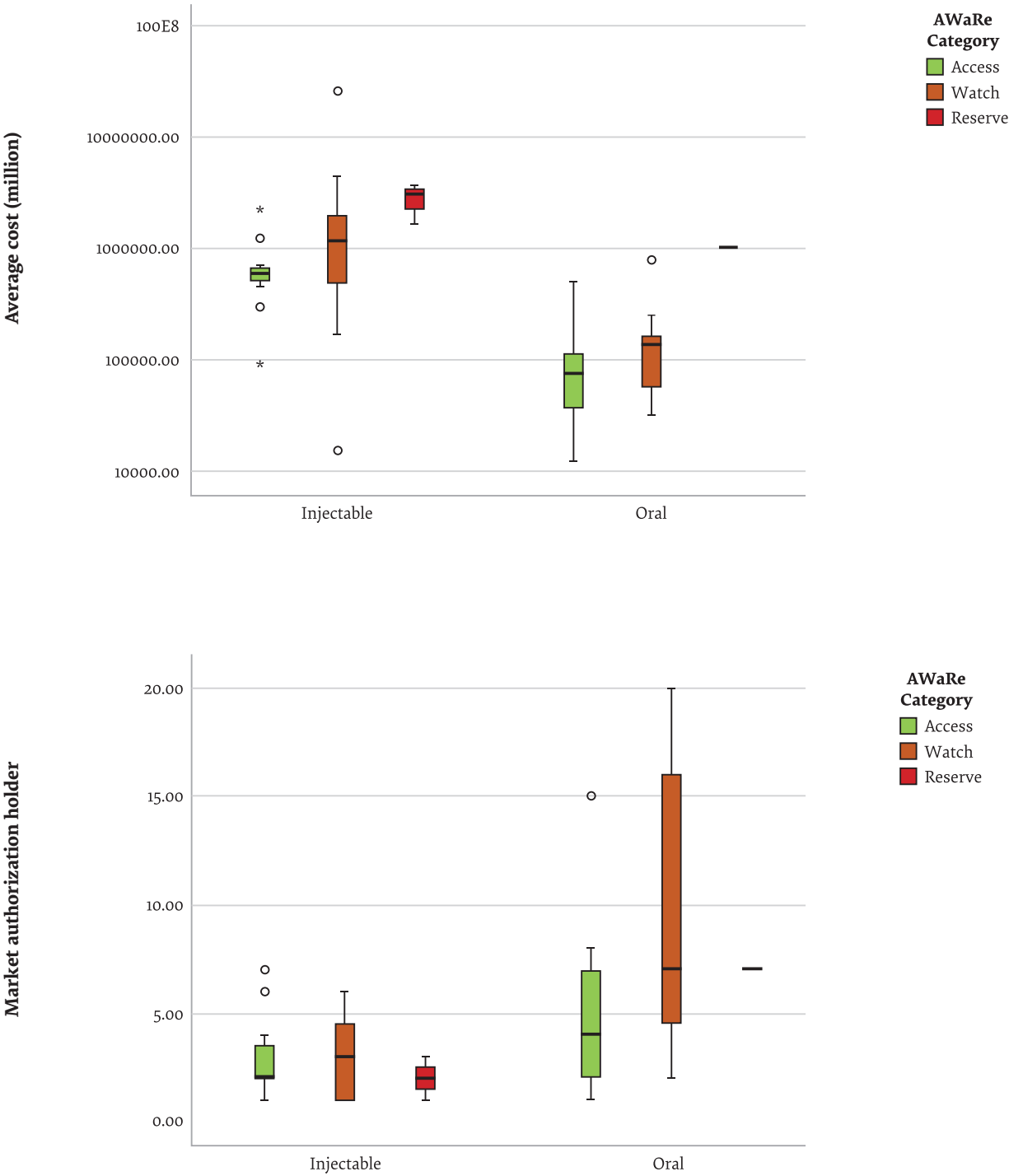
The cost distribution and the number of MAHs across AWARe categories are shown in Figure 2. Overall, injectable antibiotics had significantly higher median costs than oral formulations, particularly within the reserve group (Figure 2a).

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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A cross-sectional study of antibiotic prescription patterns in India using the WHO AWaRe classification

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Abstract

Background: Primary health centres represent the initial point of contact with the health system for most patients, and they account for a large proportion of antibiotic prescriptions in India.

Aim: To evaluate the pattern of antibiotic prescriptions at a primary care centre in India based on the WHO AWaRe framework.

Methods: From September to November 2024, we collected and analysed data from 525 participants who presented to the outpatient pharmacy of an urban primary health centre in Thiruvananthapuram, Kerala, India, and received a doctor's prescription. Data collected included prescription details, demographic characteristics, disease duration, and relevant clinical history. We assessed the compliance of the prescriptions to the WHO AWaRe guidelines.

Results: One hundred and forty-six (27.8%) of the 525 prescriptions analysed contained antibiotics. Access group antibiotics accounted for 51.4% and watch group accounted for 48.6%. No reserve antibiotic was prescribed. The most frequently prescribed antibiotics were amoxicillin-clavulanic acid (34.2%), followed by azithromycin (22.6%) and ciprofloxacin (17.1%). Non-adherence to the WHO AWaRe guidelines was observed in 56.2% of cases.

Conclusion: Our findings show lower usage of access group antibiotics than the recommended target of 70% by WHO. Stronger antimicrobial stewardship initiatives and prescriber training are needed to improve rational antibiotic use in this setting.

Keywords: antimicrobial resistance, antibiotic prescription, AWaRe, primary health care, antimicrobial stewardship

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Introduction

Antimicrobial resistance (AMR) is a growing threat to global health security. It reduces the ability of health systems to manage common microbial infections effectively. The magnitude of the AMR crisis is profound, with an estimated 4.95 million deaths in 2019, of which 1.27 million were directly attributable to bacterial resistance (1). Recent global forecasts suggest that the deaths attributable to AMR could reach 1.91 million by 2050 (2). This burden is particularly significant in low- and middle-income countries (LMICs) where inappropriate and excessive use of antibiotics are major drivers of AMR (1,3,4).

India is one of the largest consumers of antibiotics globally, yet, the gaps in regulation and surveillance systems in the country remain a concern (5,6). Inadequate infection control practices and uncontrolled access to antibiotics have further contributed to the increasing burden of antimicrobial resistance in the country (6).

The Kerala Antimicrobial Resistance Strategic Action Plan (KARSAP) launched in 2018 emphasises rational antibiotic use, infection control and adherence to institutional antibiotic policies. As part of this initiative,

the Antibiotic Smart Hospital (ASH) programme was introduced to encourage responsible antibiotic use across health care facilities (7,8).

WHO introduced the Access, Watch, Reserve (AWaRe) framework to promote the rational use of antibiotics. The framework categorises antibiotics into 3 groups: *Access* (first-line options with lower resistance potential), *Watch* (higher resistance risk, requiring careful monitoring), and *Reserve* (last-resort drugs for multidrug-resistant infections). It provides evidence-based recommendations for empiric antibiotic use for 34 common infections, promoting shorter treatment durations, early intravenous-to-oral switch strategies, and symptomatic care without antibiotics where appropriate (9,10).

For most patients, the primary health centre (PHC) represents the initial point of contact with the health system and accounts for a large proportion of antibiotic prescriptions in India (11). Antibiotic prescription rates are high, with frequent use of broad-spectrum watch antibiotics and less frequent use of recommended first-line access antibiotics. Inappropriate antibiotic use is common, particularly for conditions like respiratory infections, fever and diarrheal disease (11).

Antibiotic use patterns vary across India, necessitating localised interventions to address specific prescription challenges (12,13). Application of the AWARe classification for research in India is necessary for effective antimicrobial stewardship interventions.

The WHO global action plan on antimicrobial resistance highlights key objectives: increasing awareness, strengthening surveillance and research, and promoting the rational use of antibiotics (14). These priorities indicate the need for studies that provide region-specific data on antibiotic prescription patterns and support antimicrobial stewardship efforts.

This study aims to bridge the evidence gap by analysing antibiotic prescription patterns in a primary health centre in Thiruvananthapuram, Kerala, using the AWARe classification. It examined the antibiotic prescription rate, type of antibiotics and the appropriateness of prescribed antibiotics based on WHO recommendations.

Methods

This cross-sectional study was conducted at the Integrated Family Health Center, Pangappara, an urban training PHC affiliated with the Government Medical College, Thiruvananthapuram, Kerala, India. This PHC was selected for its feasibility, it serves approximately 150 000 individuals across 11 wards and has an 8-bed inpatient unit. It functions as an academic training centre for medical and allied health students.

The health care team consists of 6 consultants, 3 postgraduate residents and 7 house surgeons. Specialty outpatient services are provided on designated days and include general medicine, general surgery, ear, nose and throat (ENT), gynaecology, paediatrics, psychiatry, respiratory medicine, ophthalmology, physical medicine, dermatology, and dentistry. Not all these specialties operate daily, therefore, the types of patients present in the clinic vary by the day of the week.

Data collection

All patients who consulted a doctor and proceeded to the hospital pharmacy to obtain medication were invited to participate in the study. Patients who came for regular replenishment of medicines for non-communicable diseases were excluded from the study.

Data collection was conducted from 1 October 2024 to 30 November 2024. During each study visit, 25 consecutive patients presenting to the outpatient pharmacy with a prescription were included in the study. A total of 22 study visits were conducted between 10.00 am and 12.00 pm, which are the peak outpatient hours. The researcher was stationed at the outpatient pharmacy, but the prescribing doctors were unaware of the study.

The sample size was estimated as 461, based on the assumed 50% prevalence of antibiotic prescription and a non-response rate of 20%. A total of 550 prescriptions were enrolled, of which data from 525 were used for analysis.

Data collection involved capturing photographs of patient prescriptions for analysis and administering a structured questionnaire to gather demographic information and patient history, including previous antibiotic use. Parental consent was obtained for participants <18 years old. All collected data were anonymised to ensure confidentiality and securely stored throughout the study.

The dependent variables included the antibiotic prescription rate and adherence of prescriptions to AWARe recommendations. The independent variables included the patient's age and gender, and the illness for which the prescription was issued. These variables were analysed to assess the prescription patterns and their relationships with demographic and clinical factors.

Data analysis

The data were analysed using SPSS version 25. Descriptive statistics were used to summarise the demographic characteristics, antibiotic prescription patterns and adherence behaviours. Frequencies and percentages were calculated for variables such as age group, gender distribution and illness category. The proportion of antibiotics in the prescriptions was calculated to determine the prevalence of antibiotic use. Prescribed antibiotics were categorised into access, watch and reserve groups based on the AWARe classification and their distributions were analysed to assess compliance with WHO guidelines (9,10).

Compliance of antibiotic prescriptions to AWARe recommendations for specific clinical conditions were assessed. Prescriptions were considered compliant if the selected antibiotic matched the recommended first- or second-line agent for the diagnosed condition. Cross-tabulations were conducted to examine the distribution of antibiotic prescriptions across age groups, gender, illness, and AWARe classification.

Ethics considerations

The Institutional Ethics Committee of AHRI approved the study (AHRI/IEC/219/Jan2024). Written informed consent was obtained from all participants before data collection and the data were anonymised and securely stored to ensure confidentiality. Statistical results were presented in aggregate form, ensuring that individual patients could not be identified.

Results

A total of 525 patients were included in the study after data cleaning. The majority (40.0%) were aged 18–40 years and females were 54.9%. Respiratory infections were the most common diagnoses (49.9%), followed by minor injuries (18.1%) and skin infections or diabetic ulcers (9.1%) (Table 1).

Compliance with AWARe recommendations

A total of 525 prescriptions were analysed. Antibiotics were prescribed in 146 cases (27.8%), while the remaining

Table 1 Demographic characteristics and clinical presentation of study participants

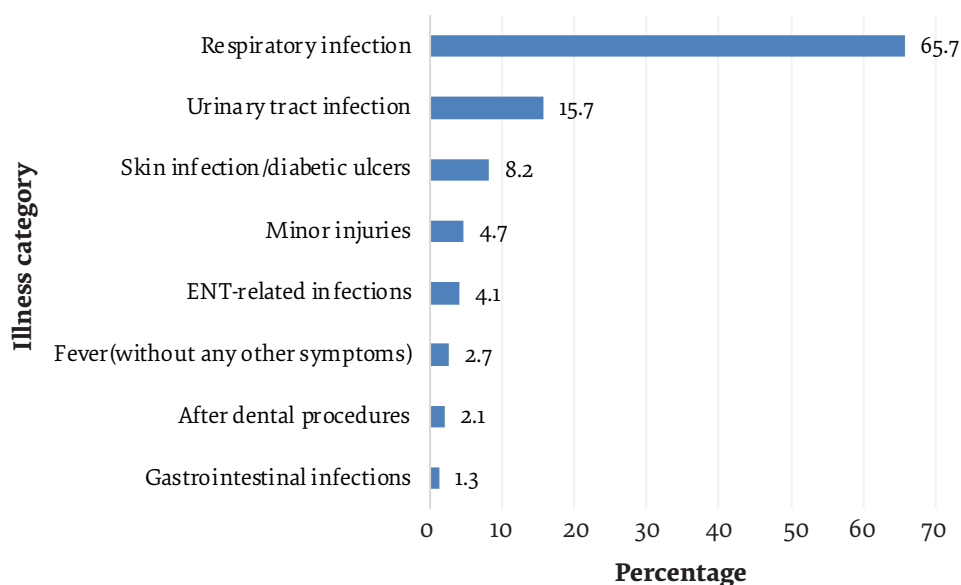
Variable	Frequency (N = 525)	Percentage
Age group (years)		
<18	118	22.5
18–40	210	40
41–60	125	23.8
>60	72	13.7
Gender		
Male	237	45.1
Female	288	54.9
Clinical presentation		
Respiratory infection	262	49.9
Fever	20	3.8
Urinary tract infection	28	5.3
Gastrointestinal infection	34	6.5
Ear, nose and throat-related illness	9	1.7
Minor injuries	95	18.1
Dental procedure-related	13	2.5
Skin infections/diabetic ulcer	48	9.1
Diagnosis not recorded	16	3.1

patients received symptomatic treatment without antibiotics (Table 1). Among the 146 antibiotic prescriptions recorded, 43.8% (n = 64) complied with AWARe recommendations for the diagnosed condition, while 56.2% (n = 82) did not comply.

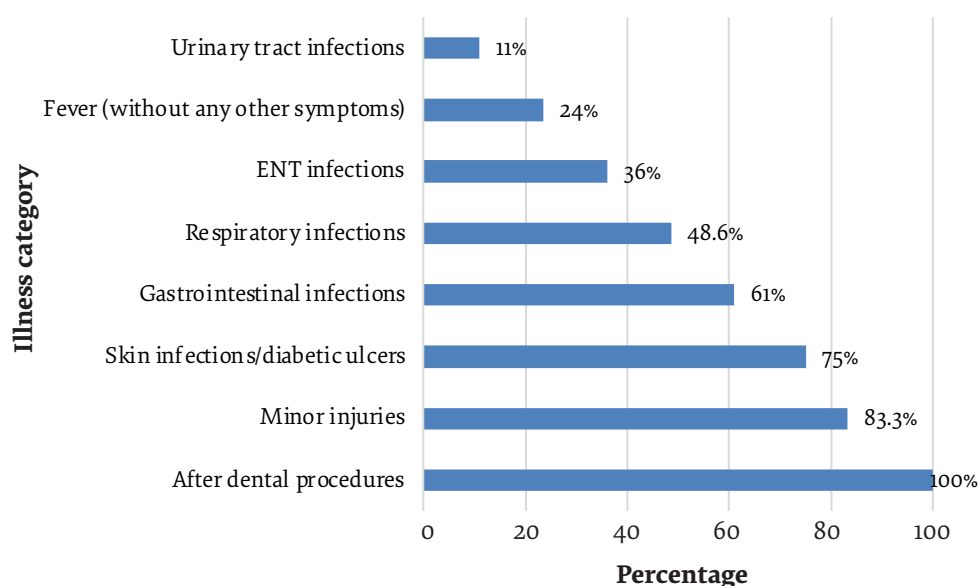
Compliance with AWARe recommendations varied by illness category. Most urinary tract infection prescriptions (91.3%) showed non-compliance with the

recommendations, skin infections and diabetic ulcers showed 75% compliance, and all dental prescriptions were compliant. Respiratory and gastrointestinal infections showed a more balanced distribution of compliant and non-compliant prescriptions (Figure 2).

Among the 146 antibiotic prescriptions, 51.4% (n = 75) belonged to the access group, while 48.6% (n = 71) were in the watch group.

Figure 1 Antibiotic prescription across illness categories

Note: Values represent the percentage of antibiotic prescriptions linked to each illness category.

Figure 2 Compliance with AWaRe recommendations by illness type

Distribution of prescriptions by AWaRe and illness type

The use of access (46.3%) and watch (53.6%) antibiotics was almost the same for respiratory infections, while urinary tract infections were mainly treated with watch antibiotics (69.6%). The most frequently prescribed antibiotic was amoxicillin-clavulanic acid (34.2%), primarily used for respiratory infections (Table 3). Among the watch antibiotics, azithromycin (22.6%) and ciprofloxacin (17.1%) were the most commonly prescribed, often for respiratory and urinary tract infections. Nitrofurantoin (0.7%) and cloxacillin (0.7%), both access antibiotics recommended for urinary tract infections and skin infections, respectively, were prescribed less frequently.

Discussion

This study evaluated antibiotic prescription practices for various illnesses using the WHO AWaRe classification and describes patterns of antibiotic use in a primary health care setting. Overall, antibiotics were prescribed in 27.8% of encounters, with almost equal distribution of access and watch antibiotics. Notably, no antibiotic from the reserve group was prescribed, as expected in a PHC setting. Respiratory infections accounted for the majority of antibiotic prescriptions, followed by urinary tract infections.

A recent systematic review of antibiotic prescription practices in Indian primary health care settings reported a pooled antibiotic prescription prevalence of 65%, with frequent use of broad-spectrum watch antibiotics and relatively low use of access antibiotics (11). In contrast, the antibiotic prescription rate in our study (27.8%) was considerably lower which shows that prescription prevalence is steward-aligned and within the appropriate

range. Patterns of high watch antibiotic use have been reported in other outpatient studies in India (15-17).

A secondary analysis of antibiotic prescription patterns in primary health care settings across India, China and Kenya reported a higher use of watch antibiotics in India and China, whereas access or narrow-spectrum antibiotics were more commonly used in Kenya (16). In this study, the most frequently prescribed antibiotic was amoxicillin-clavulanic acid, mainly used for respiratory infections. Among the watch group antibiotics, azithromycin was the most frequently prescribed and was commonly used for respiratory infections. However, azithromycin is not recommended as a first- or second-line treatment for most respiratory infections, including pharyngitis, sinusitis, community-acquired pneumonia, and chronic obstructive pulmonary disease (10). WHO guidelines recommend the use of access antibiotics as first-line treatment options to reduce the risk of AMR (19,10). Similar prescription patterns have been reported in other studies (15,17), which highlight the frequent use of antibiotic for self-limiting conditions such as upper respiratory tract infections, undifferentiated fever and other viral illnesses. The reasons for this may include the lack of point-of-care diagnostic tools, lack of access to treatment guidelines and inadequate training on antimicrobial stewardship in primary care settings (11,16,17).

The most commonly prescribed antibiotics for urinary tract infections in this study were ciprofloxacin (17.1%) and norfloxacin (5.5%), both belonging to the watch group. However, WHO guidelines recommend amoxicillin-clavulanic acid, nitrofurantoin and trimethoprim-sulfamethoxazole as the preferred first-line treatments for lower UTIs (9,10). Fluoroquinolones were commonly prescribed for UTIs although nitrofurantoin is the recommended first-line agent. Global surveillance through the WHO GLASS 2025 report indicates high and increasing fluoroquinolone resistance

Table 2 Distribution of prescriptions by AWaRe and illness type

Illness type	Total antibiotic prescriptions (n)	Access n (%)	Watch n (%)
Respiratory infection	97	45 (46.3)	52 (53.6)
Urinary tract infection	23	7 (30.4)	16 (69.6)
Skin infection/diabetic ulcer	12	9 (75)	3 (25)
Dental procedure-related	7	7 (100)	0
Ear, nose and throat-related illness	6	2 (33.3)	4 (66.7)
Minor injuries/other illness	6	6 (100)	0
Fever	4	3 (75)	1 (25)
Gastrointestinal infection	2	0	2 (100)

Note: Illness categories are not mutually exclusive; therefore, percentages for access and watch antibiotics are calculated using the total number of antibiotic prescriptions within each illness category (row-wise denominator).

Table 3 Distribution of prescribed antibiotics during the study period (n = 146)

Generic antibiotic	Frequency (n)	Percentage (%)
Amoxicillin-clavulanic acid	50	34.2
Azithromycin	33	22.6
Ciprofloxacin	25	17.1
Doxycycline	13	8.9
Amoxicillin	10	6.8
Norfloxacin	8	5.4
Cefixime	3	2.1
Ceftriaxone	2	1.4
Cloxacillin	1	0.7
Nitrofurantoin	1	0.7

among multiple pathogens, including *E. coli*, *Klebsiella pneumoniae*, *Salmonella spp.*, and *Neisseria gonorrhoeae*, with levels frequently exceeding 30–70%. These findings reinforce the need to limit ciprofloxacin use in primary care to prevent further increase of resistance (11).

Reserve antibiotics, categorised by WHO as last-resort options to be used for multidrug-resistant infections, were not prescribed in this study, aligning with antimicrobial stewardship goals. The WHO South-East Asia Regional Roadmap (2025–2030) highlights the need to strengthen AMR surveillance, antimicrobial stewardship and diagnostic capacity at primary health care settings, highlighting the need to improve antibiotic stewardship in primary care (19).

Study limitations

This study has several limitations, including its single centre design, lack of microbiological confirmation of infections, and the potential influence of seasonal variations on prescription patterns. The study evaluated antibiotic prescription patterns in an outpatient primary health care setting, and, therefore, the findings may not

reflect prescription practices in inpatient or tertiary care settings. The study was limited to prescription analysis and did not include follow-up of patients, therefore, clinical outcomes of antibiotic treatment could not be evaluated.

Recommendations

It is worthwhile to note the absence of reserve group antibiotics among the 146 antibiotic prescriptions at the PHC. However, 56.2% of the prescriptions were non-compliant with WHO guidelines, and access and watch group antibiotics were used almost equally (51.4% vs 48.6%). This requires targeted antimicrobial stewardship interventions.

The National Health Mission should encourage and incentivise PHCs to meet the 70% total access group antibiotic use through periodic antibiotic prescription audits. There is a need for the standardisation of UTI treatment, as 92.3% of the prescriptions were non-compliant with AWaRe guidelines. Point-of-care diagnostic stewardship for C-reactive protein should be subsidised for patients presenting with respiratory infections to differentiate between bacterial and viral infections. The frequent use of watch antibiotics (53.6%) among patients with respiratory infections in this study justifies the use of point-of-care C-reactive protein, as many of these infections were likely viral.

Digital AMR stewardship support systems can be implemented. With the implementation of the eHealth system, prescriptions are issued digitally at most PHCs in Kerala. When a watch or reserve antibiotic is selected, an automatic warning system can be integrated that requires justification for such selection, and displays lower-group antibiotic alternatives.

A pharmacist AMR stewardship partner system can be implemented. The pharmacists in Kerala could be empowered as AMR stewards, and they could seek clarification from the physician when watch or reserve antibiotics are prescribed where an access group antibiotic is the recommended first-line.

Conclusion

This study highlights high level reliance on watch antibiotics (48.6%) and less than the 70% WHO target for access group antibiotics. Non-compliance to the AWARe recommendations was observed in 56.2% of prescriptions, mainly due to the use of other antibiotics

than the recommended first-line options, particularly for respiratory and urinary tract infections. Strengthening antimicrobial stewardship programmes, improving prescriber training and reinforcing adherence to WHO guidelines are essential to optimise antibiotic use and mitigate AMR in primary care settings.

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Knowledge, attitudes and practices regarding antibiotic use among internally displaced persons in conflict-affected Syria

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Abstract

Background: Evidence on antibiotic use among internally displaced persons in conflict-affected Northwest Syria remains scarce.

Aim: To assess knowledge, attitudes and practices regarding antibiotic use among internally displaced persons in Northwest Syria.

Methods: We collected data from 630 individuals, aged ≥ 18 years, living in 12 internally displaced persons camps, in April 2022, through face-to-face interviews, using a WHO-validated questionnaire adapted for Syrian context. We analysed the data using SPSS version 26 and conducted univariate and multivariate logistic regression to assess associations between respondent characteristics and key outcomes. $P < 0.05$ was considered statistically significant.

Results: Of the 630 participants (58.1% female; median age 38 years), 66.5% had received at least one antibiotic prescription in the past year. Females were more likely than males (odds ratio 2.89; 95% confidence interval 1.10–7.40; $P = 0.02$), and single participants less likely than married participants (OR = 0.29; 95% CI: 0.10–0.84, $P = 0.02$), to have used a prescribed antibiotic. Antibiotic misuse was common: 62.2% used antibiotics without a prescription, 51.6% used antibiotics prescribed for others and 39.4% did not complete their recommended dosage. The proportion of participants who obtained antibiotics without prescription increased from 64.8% before to 79.0% after displacement ($P < 0.001$). Of the participants, 69.8% had sufficient knowledge of, and 59.2% had positive attitude towards, antibiotic use.

Conclusion: Although most participants reported having sufficient knowledge of antibiotics, misconceptions and inappropriate use were common. Targeted and evidence-based interventions are needed to improve antibiotic use practices and to support antimicrobial stewardship among internally displaced persons in Northwest Syria and other similar settings.

Keywords: antibiotic, antimicrobial resistance, internally displaced person, Idlib, Syria

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Introduction

Antimicrobial resistance (AMR) is a significant global health threat, contributing to substantial morbidity and mortality due to infectious diseases worldwide. In 2019, WHO estimated that AMR directly caused 1.27 million deaths and contributed to nearly 5 million more globally (1). Despite this burden, the drivers and manifestations of AMR vary considerably across regions and populations (2).

In the Eastern Mediterranean Region, AMR is fuelled by widespread misuse and overuse of antibiotics, weak antimicrobial stewardship, limited laboratory capacity, disrupted health care systems and protracted humanitarian crises (3,4). In conflict-affected settings, these challenges are magnified by population displacement, overcrowding, poor sanitation and interrupted treatment courses, all of which

facilitate the development and transmission of resistant pathogens (5,6).

The Syrian conflict, which has caused 874 000 excess deaths has worsened public health conditions, affecting neighbouring countries in the Middle East and Europe (7,8). Even before the war, widespread over-the-counter antibiotic sales contributed to AMR in Syrian Arab Republic, a practice still common in many developing nations (6,9). Many internally displaced persons (IDPs) reside in camps or informal settlements in the northwest (8). These settings are characterised by high population density, inadequate water and sanitation facilities, and fragile health care delivery, creating conditions conducive to infectious diseases and inappropriate antibiotic use (6).

Despite the severity of AMR, data on its prevalence in the Syrian Arab Republic are scarce, and little is known about antibiotic knowledge, attitudes and practices (KAP), particularly among IDPs in the northwest (6).

This study assessed the KAP related to antibiotic use among IDPs living in camps in northwest Syria and the sociodemographic factors associated with misuse.

Methods

Study setting

Northwest Syria, the last region outside the now-deposed government's control, has experienced mass displacement and long-term conflict. It is home to 4.2 million people, including 1.2 million living in camps (16). Since 2011, health care services have deteriorated due to shortages of workers, medications and advanced treatments (16). The area includes Idlib Province and northern Aleppo.

Study design

This cross-sectional study was conducted in 12 IDP camps in Idlib Province, Northwest Syria, from 9 to 20 April, 2022, using convenience sampling. Participants were eligible if they were aged ≥ 18 years and resided in IDP camps in Idlib Province. Most of them completed the questionnaire; a few refused and were excluded.

The sample size calculation was based on an estimated 700 000 IDPs and prevalence estimates of knowledge and positive attitudes of 46.1% and 40.6%, respectively (17). Using a 95% confidence level and 5% margin of error, the minimum required sample was 382, increased to 698 to account for non-responses (17).

A WHO-validated survey questionnaire, adapted for Syrian context, was used to collect data (17). It covered: sociodemographic characteristics (camp region, residence type, gender, age, marital status, pre-displacement city, education, employment, income, household size and health care access); antibiotic use and self-medication (14 questions on past-year antibiotic prescriptions, reasons for non-completion, self-medication, treated conditions and use of previously prescribed antibiotics); knowledge and attitudes (16 questions on knowledge and attitude statements rated on a 5-point Likert scale); and health care provider practices (4 questions assessed on a 5-point Likert scale).

Ten medical students (7 males, 3 females) from the University of Idlib conducted face-to-face interviews. A pretest of the questionnaire was conducted among 19 participants, who were excluded from the analysis, and based on their feedback it was revised for improved clarity and cultural appropriateness.

The primary outcome was antibiotic prescription frequency (prescribed antibiotics at least once in the past year). Self-medication was assessed in 3 ways: use of antibiotics without a prescription, non-completion of prescribed or unprescribed courses and acquisition of antibiotics without a prescription before and after displacement.

Responses were scored 0 or 1 and categorised using the median as a cut-off point (17): knowledge (9 items) and attitudes (7 items).

Statistical analysis

Data were collected electronically via KoBoToolbox, cleaned in Excel, and analysed using SPSS version 26. Continuous variables were reported as means (standard deviation) and/or medians [interquartile range (IQR)], and categorical variables as frequencies and percentages. Univariate and multivariate logistic regression were used to assess associations between respondent characteristics and key outcomes, including antibiotic prescription, self-medication, knowledge, and attitudes. $P < 0.05$ was considered statistically significant.

Ethics considerations

This study complied with the principles of the Declaration of Helsinki and was approved by the University of Idlib Ethical and Scientific Research Committee and the General Administration of Idlib Province camps. Participation was voluntary, and verbal informed consent was obtained from all participants. No incentives were offered.

Results

Participant demographics

Of the 697 invited participants, 67 declined, yielding a 90.3% response rate. Among the 630 respondents, 41.9% ($n = 264$) were male and 58.1% ($n = 366$) female. The median age was 38 years (IQR: 27–50) and median household size was 6 (IQR: 4–9). Most participants (84.3%) were married, and nearly two-thirds (64.9%) lived in tents (Table 1).

Antibiotic prescription, use and self-medication

A total of 419 participants (66.5%) reported receiving at least one antibiotic prescription in the past year. Of these, 11.5% used antibiotics once, 15.8% used them twice, and 64.7% used them 3 or more times. Non-completion of prescribed courses was reported by 39.4% (165/419), most commonly due to perceived recovery (86.7%).

Self-medication was reported by 62.2% (392/630), and over half of these (52.3%) did so more than 3 times in the past year. The most frequently self-treated conditions were sore throats (46.1%) and cold/flu (15.7%).

Half of all respondents (51.6%) had used antibiotics prescribed for another family member; 59.7% reused antibiotics for similar symptoms, and 31.9% for unrelated illnesses.

Association with antibiotic prescription practices

Logistic regression showed significant associations between antibiotic prescription and gender and marital status. Females were nearly 3 times more likely than males to use prescribed antibiotics (OR = 2.89; 95% CI: 1.1–7.4, $P = 0.02$), while singles were 71% less likely than married individuals (OR = 0.29; 95% CI: 0.10–0.84, $P = 0.02$). No other significant associations were found (Table 2).

For self-medication, unmarried individuals were less likely to use antibiotics without a prescription (OR = 0.62; 95% CI: 0.4–0.91, $P = 0.03$). The proportion using

Table 1 Sociodemographic characteristics of participants (N = 630)

Characteristic	N	%
Camp location		
Idlib	173	27.5
Maarrat Misrin	53	8.4
Sarmada	87	13.8
Dana	77	12.2
Atmeh	122	19.4
Kafr Takharim	43	6.8
Salqin	33	5.2
Harem	42	6.7
Type of residence		
Informal shelter	221	35.1
Tent	409	64.9
Gender		
Male	264	41.9
Female	366	58.1
Age group (years)		
18–30	224	35.6
31–40	152	24.1
41–50	118	18.7
51–65	114	18.1
> 65	22	3.5
Marital status		
Single	47	7.5
Married	531	84.3
Widowed	46	7.3
Divorced	6	1.0
City of residence before displacement		
Idlib	279	44.3
Damascus	1	0.2
Homs	14	2.2
Daraa	2	0.3
Aleppo	97	15.4
Hama	236	37.5
Other	1	0.2
Highest educational level		
Primary school	168	26.7
Secondary school	212	33.7
High school	46	7.3
Tertiary (under/postgraduate)	38	6.0
No formal education	166	26.3
Hama	236	37.5
Other	1	0.2
Employment status		
Employed	155	24.6
Unemployed	475	75.4
Job position (if employed)		
Health sector	5	3.2
Education sector	7	4.5

Table 1 Sociodemographic characteristics of participants (N = 630)

Characteristic	N	%
Manual professions	26	16.8
Trading	16	10.3
Daily worker	85	54.8
Other	16	10.3
Monthly household income (US\$)		
≤ 50	87	13.8
51–100	362	57.5
101–300	160	25.4
≥ 300	21	3.3
Able to reach a medical point easily		
Yes	489	77.6
No	141	22.4

antibiotics without a prescription increased from 64.8% before displacement to 79.0% after displacement ($\chi^2=1\ 84.7$, $P < 0.001$).

Multivariate analysis indicated that females (OR = 0.59; 95% CI: 0.39–0.88, $P = 0.01$), single individuals (OR = 0.43; 95% CI: 0.27–0.68, $P < 0.001$), and those with limited health care access (OR = 0.50; 95% CI: 0.34–0.75, $P = 0.001$) were less likely to use antibiotics without a prescription. No other significant associations were observed.

Knowledge of antibiotic use

The median knowledge score was 4 (IQR: 3–6); 69.8% ($n = 440$) had sufficient knowledge. Nearly 60% correctly identified antibiotics as effective against bacteria; however, 51.1% mistakenly believed they were effective against viruses, and 57% thought they accelerated recovery from coughs and colds (Table 3).

Regarding side effects, 90.1% recognised the need to stop antibiotics if adverse reactions occur. However, only 32.7% knew that antibiotics disrupt normal bacterial flora, and 32.1% were aware of their effect on healthy skin and gut bacteria. Knowledge levels were significantly associated with camp location ($P = 0.02$) and education ($P = 0.04$).

Attitude towards antibiotic use

The median attitude score was 3 (IQR: 2–4); 59.2% ($n = 373$) had a positive attitude, while 40.8% ($n = 257$) did not. Only 42.2% agreed that a prescription should be required to obtain antibiotics, and 44.8% reported completing antibiotic courses even when they felt better.

About 24.1% considered it acceptable to obtain antibiotics from friends or relatives. Nearly half (49.7%) believed antibiotics help with coughs lasting more than a week, and 78.9% considered them an appropriate treatment for sore throats (Table 3).

Attitudes varied significantly by gender ($P = 0.004$) and education level ($P = 0.007$). Negative attitudes were more common among females (45.6%) than males (34.1%) ($\chi^2 = 8.4$, $P = 0.002$). Positive attitudes increased with education, reaching 78.9% among highly educated

participants. Those with sufficient knowledge were more likely to have positive attitudes ($\chi^2 = 6.5$, $P = 0.01$), although the correlation was weak ($r = 0.14$, $P < 0.001$).

Opinions on prescription practices

Most participants expressed satisfaction with health care providers' efforts to explain antibiotic use (Table 3). Approximately 73.5% reported that doctors provided adequate explanations, and 93.3% noted similar efforts from pharmacists. Some 81.2% believed that doctors carefully assessed the necessity of antibiotics, whereas 25.1% felt that prescriptions were influenced by patient expectations.

Discussion

Antibiotic use among IDPs in camps in northwest Syria was high, with 66.5% of participants obtaining at least one prescription in the past year. While most participants demonstrated sufficient knowledge (70%) and positive attitudes (59.2%) toward antibiotic use, misuse was widespread: 62.2% used antibiotics without a prescription, 51.6% used antibiotics prescribed for others, and 39.4% did not complete their prescribed courses. Refugees and displaced populations are particularly vulnerable to antibiotic misuse and AMR due to limited health care access, weak antimicrobial stewardship programmes, low awareness, overcrowding and inadequate sanitation (15). The WHO Global Evidence Review on Health and Migration notes that displaced people may avoid care due to stigma, transport barriers and fear of deportation, while armed conflicts further exacerbate these risks (15,17).

Our findings align with previous studies among Syrian refugees in neighbouring countries, which reported high AMR rates. Carbapenemase-producing *Enterobacteriaceae* were found to be more common among Syrian refugees than among local populations (11,12). Multidrug-resistant infections occurred in 19% of ill Syrian children, affecting the urinary tract, surgical sites and bones (13). Similarly, a Finnish study found that more than half of Syrian refugees carried multidrug-resistant organisms, including 20.9% with

Table 2 Multivariate analysis of predictors of participants who consumed prescribed antibiotics during the last year

Characteristic	Total (N = 630)	Consumed prescribed antibiotics (n = 211)	OR	P	95% CI	
					Lower	Upper
Type of residence						
Informal shelter	221	77 (36.5%)	1.00	0.90	0.44	2.52
Tent	409	134 (63.5%)	1.05			
Gender						
Male	264	104 (49.3%)	1.00	0.02*	1.12	7.46
Female	366	107 (50.7%)	2.89			
Age group (years)						
< 38	331	116 (55.0%)	1.00	0.20	0.74	4.11
≥ 38	229	95 (45.0%)	1.75			
Marital status						
Married	531	170 (80.6%)	1.00	0.02*	0.10	0.84
Single	99	41 (19.4%)	0.29			
Highest educational level						
						0.54
Primary school	168	69 (32.7%)	1.00	0.16	0.71	6.95
Secondary school	212	65 (30.8%)	2.22			
High school	46	10 (4.7%)	1.54			
Tertiary (under/postgraduate)	38	12 (5.7%)	0.88			
No formal education	166	55 (26.1%)	0.28			
Employment status						
Employed	155	60 (28.4%)	0.29	0.02*	0.10	0.84
Unemployed	475	151 (71.6%)				
Job position (if employed)						
						0.33
Health sector	5	3 (5.0%)	1.00	0.13	0.67	20.47
Education sector	7	1 (1.7%)	0.66			
Manual professions	26	10 (16.7%)	0.20			
Trading	16	9 (15.0%)	1.52			
Daily worker	85	33 (55.0%)	3.73			
Other	16	4 (6.7%)	2.3			
Monthly household income (US\$)						
						0.27
≤ 50	87	33 (15.6%)	1.00	0.06	0.02	1.08
51–100	362	116 (55.0%)	0.14			
101–300	160	53 (25.1%)	0.29			
≥ 300	21	9 (4.3%)	0.23			
Household size						
< 6	235	86 (40.8%)	1.00	0.26	0.69	3.62
≥ 6	395	125 (59.2%)	1.59			
Able to reach a medical point easily						
Yes	489	166 (78.7%)	1.00	0.48	0.54	3.67
No	141	45 (21.3%)	1.41			

OR = odds ratio; CI = confidence interval; P < 0.05 indicates statistical significance; *Statistical significance

methicillin-resistant *Staphylococcus aureus* (14). Although our study population were IDPs and not cross-border refugees, these findings underscore the vulnerability of displaced Syrians to AMR and the urgent need for targeted interventions. In our setting, gender, education, camp location and marital status were associated with

differences in knowledge and practices; poor education and inadequate water, sanitation and hygiene likely contributed to overuse (17). Coordinated action is required to adapt health care frameworks to the realities of Northwest Syria.

Table 3 Participants' knowledge, attitudes and opinions on health care providers' antibiotic prescribing practices (%)

Statement	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Knowledge of antibiotic use					
A. Action and use (correct statements)					
1- Various antibiotics are required to treat different illnesses.	7.5	10.0	11.6	38.6	32.4
2- Antibiotics are effective against bacteria.	2.7	7.5	30.8	38.3	20.8
3- Antibiotics can kill bacteria normally found on the skin and in the digestive tract..	5.4	22.1	40.5	20.8	11.3
B. Action and use (incorrect statements)					
4- Antibiotics speed recovery from many coughs and colds.	10.5	22.7	9.8	37.3	19.7
5- Antibiotics are useful for the most coughs and colds.	7.0	16.5	8.4	44.1	24.0
6- Antibiotics are effective against viruses.	7.9	16.0	23.7	36.2	16.2
C. Side effects (correct statements)					
7- If adverse reactions occur while on antibiotics, the medicine should be stopped immediately.	2.2	4.0	3.7	34.9	55.2
8- If an antibiotic causes a skin reaction, avoid using that specific antibiotic again.	4.0	7.0	6.0	25.1	57.9
9- Antibiotics can disrupt the body's natural bacterial balance (flora).	8.6	15.2	43.5	23.0	9.7
Attitudes towards antibiotic use					
Positive attitude items					
1- I always complete the prescribed antibiotic course, even if I feel better.	21.7	30.3	3.2	22.1	22.7
Negative attitude items					
2- It is acceptable to obtain antibiotics from relatives or friends without seeing a doctor.	37.3	36.0	2.5	17.6	6.5
3- I prefer to buy antibiotics from a pharmacy without a prescription.	22.7	31.6	3.5	26.0	16.2
4- I prefer to keep antibiotics at home for future use.	14.9	15.2	1.4	41.4	27.0
5- If I feel better after a few days, I sometimes stop taking antibiotics before completing the course of treatment.	14.4	21.0	2.1	38.1	24.4
6- I prefer to use an antibiotic if I have a cough lasting more than one week	15.4	28.7	6.2	29.7	20.0
7- I prefer to use an antibiotic when I have a sore throat.	7.3	7.6	6.2	42.1	36.8
Opinions on healthcare providers' prescribing practices					
1- Pharmacists often explain how antibiotics should be used.	2.1	3.3	1.3	35.2	58.1
2- Doctors often take time during consultations to explain how antibiotics should be used.	10.2	10.3	6.0	36.5	37.0
3- Doctors often prescribe antibiotics because patients expect it.	24.4	42.1	8.4	10.5	14.6
4- Doctors often carefully consider whether antibiotics are needed.	2.1	5.4	11.3	43.3	37.9

The 66.5% prescription rate observed here exceeds those reported in Qatar and Iraq, but lower than those in Lebanon and Kuwait (18–21). The prevalence of self-medication (62.2%) is higher than in other Syrian regions, Kuwait, and Oman, yet lower than in Saudi Arabia (22). Accessibility and affordability of antibiotics remain concerns, and overprescription may be driven by insufficient training, patient pressure, fear of litigation, financial incentives or time constraints (25). In Syrian Arab Republic, 13.8% of pharmacies are reportedly operated by unqualified personnel, facilitating unsafe and unregulated sales (26).

More than two-thirds (69.8%) of the participants had sufficient antibiotic knowledge, aligning with other Syrian studies (23,27). However, misconceptions persist: 51.1% believed antibiotics treat viruses, and 57% thought they accelerate recovery from colds. Comparable misconceptions have been reportedly globally (21,23,28). Studies in Libya and Saudi Arabia found that 26.5% and 56.9% of participants, respectively, knew antibiotics do not treat viral infections (29,30). In northwest Syria, 39.5% stopped antibiotics early, and 51.6% used other family member's prescriptions, similar to Qatar and Kuwait (17,21,27).

Attitudes toward antibiotic use varied: 59.2% had a positive attitude, lower than regional averages (20). Lower education was associated with poorer antibiotic knowledge, consistent with findings elsewhere (23,31). The protracted Syrian conflict may have widened these gaps.

Implications for practice, policy and research

Unregulated antibiotic access remains a persistent challenge. Enforcement of prescription-only regulations, public awareness campaigns, and improved provider-patient communication are urgently needed (32). While most participants were satisfied with health care providers, one-quarter believed doctors prescribed antibiotics based on patient expectations. A Syrian study found all surveyed pharmacists ($n = 147$) dispensed antibiotics without a prescription (33). Targeted interventions, proven to have been effective in other settings, should focus on the public and health care workers (23). Collaborative efforts between the Ministry of Health, nongovernment organisations, and humanitarian actors should prioritise: limiting public access to antibiotics; improving access to qualified health care; providing education and training on appropriate antibiotic use; and strengthening AMR surveillance and monitoring systems.

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Study strengths and limitations

This study is among the first in Northwest Syria to examine knowledge, attitudes, and practices regarding antibiotic use among IDPs, providing valuable baseline data to guide interventions (6). However, the collapse of the national health care system has affected data reliability. Convenience sampling was necessary, but the shared demographic characteristics of camps in the region may support generalisability within northwest Syria. The cross-sectional design limits causal inference, and responses may have been affected by recall or social desirability bias. Further qualitative and mixed-methods research is recommended to explore the behavioural drivers of antibiotic misuse in this population.

Conclusion

Although most IDPs in Northwest Syria demonstrated sufficient knowledge about antibiotics, misuse remains common. Addressing AMR in this context will require interventions that account for the region's disrupted health care system and the realities of displacement. Broader national studies are needed to explore sociocultural drivers of misuse and inform context-specific antimicrobial stewardship strategies for the evolving health care in the Syrian Arab Republic.

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Fatal adverse reactions to injectable ceftriaxone sodium in Syrian Arab Republic

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Abstract

Background: Reports of fatal adverse reactions to ceftriaxone sodium have raised serious safety concerns in Syrian Arab Republic, yet evidence describing fatal outcomes remains limited.

Aim: To describe and characterise fatal adverse reactions associated with ceftriaxone sodium administration in Syrian Arab Republic.

Methods: We conducted a retrospective analysis of 14 fatal cases of ceftriaxone-associated adverse reactions reported to the national pharmacovigilance system in Syrian Arab Republic from 2018 to 2023.

Results: Fourteen ceftriaxone sodium-associated fatal ADR cases were identified, including one maternal-foetal case, accounting for 15 deaths. Most fatalities resulted from immediate anaphylactic reactions following intravenous or intramuscular administration. Fatal outcomes included maternal-foetal death, Stevens-Johnson syndrome with multiorgan failure and anaphylaxis occurring during an intradermal allergy test.

Conclusion: Fatal adverse reactions to ceftriaxone were predominantly rapid and unpredictable, underscoring the need for careful allergy assessment, close patient monitoring and adherence to safe administration practices.

Keywords: ceftriaxone, fatal adverse reaction, anaphylaxis, pharmacovigilance, Syria

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Background

Ceftriaxone sodium is a widely used third-generation cephalosporin antibiotic with broad-spectrum activity against gram-positive and gram-negative bacteria (1). Developed in the 1980s, ceftriaxone is commonly used for the treatment of meningitis and is widely prescribed for lyme disease, respiratory tract infections such as pneumonia, and complex intra-abdominal, urinary tract, skin, and joint infections (2–5). In cases of infection with beta-lactamase-producing bacteria, ceftriaxone is often combined with sulbactam, a beta-lactamase inhibitor, to broaden its antimicrobial spectrum (6).

Despite its widespread use, concerns have been raised regarding the safety profile of ceftriaxone, particularly hypersensitivity reactions (1). A pharmacovigilance study analysing paediatric adverse drug reaction (ADR) reports in China identified ceftriaxone as one of the cephalosporins most frequently associated with serious ADRs (7).

Globally, the incidence of hypersensitivity reactions to cephalosporins, including ceftriaxone, ranges from 1% to 3%, while reported rates of anaphylaxis range from 0.001% to 0.1%. Patients with a history of allergy to cephalosporins or penicillins are at increased risk, underscoring the importance of obtaining a comprehensive allergy history before administration (8,11–13).

Higher rates of adverse drug reactions have been reported among females, adults, and patients receiving intravenous administration, highlighting the need for vigilant clinical monitoring in these groups (12,14–16). In addition to patient-related factors, drug quality has been identified as a potential contributor to adverse reactions. A previous study reported that all tested Syrian ceftriaxone products contained leachable substances from rubber closures, with 47.46% exceeding the threshold of toxicological concern (17).

Although skin testing is commonly used to assess hypersensitivity, it may yield false-negative results because it relies on native compounds, whereas allergic reactions may be triggered by hapten formation during intravenous administration or drug metabolism (9,18).

In recent years, reports of fatal hypersensitive reactions to ceftriaxone have increased in Syrian Arab Republic, raising serious safety concerns. However, regional data describing fatal cases remain limited. This study aimed to characterise 14 fatal cases of ceftriaxone-associated adverse reactions in Syrian Arab Republic, including one maternal-foetal death, and to identify key risk factors, administration patterns, and potential contributing factors. By analysing these cases, we seek to improve clinical awareness, inform safer prescription and administration practices, and support the development of evidence-based guidance on the appropriate use of ceftriaxone.

Methods

A retrospective study was conducted using anonymised data from the ADR database of the Directorate of Drug Research and Control at the Syrian Ministry of Health. The analysis included all documented fatal ADR cases associated with ceftriaxone sodium between 2018 and 2023. Fourteen cases were identified, accounting for a total of 15 fatalities, including one maternal-foetal death. We extracted data on patient age and sex, clinical indication, route of administration, ceftriaxone dose, concomitant use of sulbactam, time to reaction onset, and cause of death.

Ethics considerations

This study was based on anonymised ADR data provided by the Syrian Ministry of Health and did not involve direct interaction with study participants. As the analysis relied solely on routinely collected pharmacovigilance data with no identifiable personal information, informed consent and ethics approval were not required.

Results

This study identified 14 fatal ADR cases associated with ceftriaxone sodium in Syrian Arab Republic, accounting for 15 deaths, including one maternal-foetal case. The study population included 7 males and 7 females, with ages ranging from 3 to 75 years. The most common indication for ceftriaxone use was respiratory tract infection ($n = 5$; 35.7%), followed by pyelonephritis, abscess, enteritis, and preoperative infection prevention ($n = 1$ each; 7.1%). In the remaining cases, the indication for treatment was not specified.

Deaths were due to anaphylactic shock ($n = 8$; 57.1%), followed by cardiac arrest ($n = 4$; 28.6%), multi-organ failure secondary to Stevens–Johnson syndrome ($n = 1$; 7.1%), and acute renal failure with congestive heart failure ($n = 1$; 7.1%).

The majority of ADRs occurred immediately after injection ($n = 11$; 78.6%), including one fatal reaction during an intradermal allergy test. Delayed response was observed in 3 cases, with 2 occurring after 2 days (14.3%) and one after 7 days (7.1%). Ceftriaxone doses ranged from 500 to 1500 mg, with 1000 mg being the most frequently administered dose ($n = 7$, 50%). Ceftriaxone was administered without sulbactam in 12 cases (85.7%), while 2 patients (14.3%) received ceftriaxone combined with sulbactam.

Table 1 summarises the individual cases, including patient characteristics, indication, dosage, route of administration, time to response, cause of death, and relevant clinical notes.

Several cases indicate the severity and diversity of the fatal reactions observed. A 28-year-old woman (case 2) in her ninth month of pregnancy developed anaphylactic shock after the sixth dose of ceftriaxone, resulting in maternal and foetal death. A 75-year-old man (case 7) developed Stevens-Johnson Syndrome (SJS) 7 days after

receiving ceftriaxone combined with sulbactam, which progressed to multi-organ failure. An 8-year-old girl (case 11) experienced fatal anaphylactic shock during an intradermal allergy test.

Discussion

The fatal cases identified in this study provide important insights into the spectrum of severe adverse reactions associated with ceftriaxone administration (Table 1). Anaphylactic shock was the predominant cause of death, underscoring the critical importance of thorough allergy assessment and careful consideration of previous hypersensitive reactions before initiating treatment. Although some cases involved concomitant administration of sulbactam, the common factor across all fatal events was exposure to ceftriaxone sodium.

The maternal-foetal fatality observed in this study highlights the particular vulnerability of pregnant patients, as anaphylactic shock may have severe consequences for both mother and foetus. This case underscores the need for heightened vigilance, cautious prescription, and close monitoring when ceftriaxone is administered during pregnancy.

Fatal anaphylactic reactions were not limited to first exposure, it occurred after multiple doses in several cases, indicating the unpredictable nature of hypersensitive reactions, which may arise at any stage of treatment. Delayed reactions were also observed, suggesting that immune-mediated mechanisms may evolve over time, particularly in IgE-associated beta-lactam hypersensitivity (1).

The occurrence of fatal anaphylaxis during an intradermal allergy test further indicates that such procedures do not eliminate risks and may provoke severe reactions. This finding reinforces the need for appropriate emergency preparedness whenever allergy testing is performed (15).

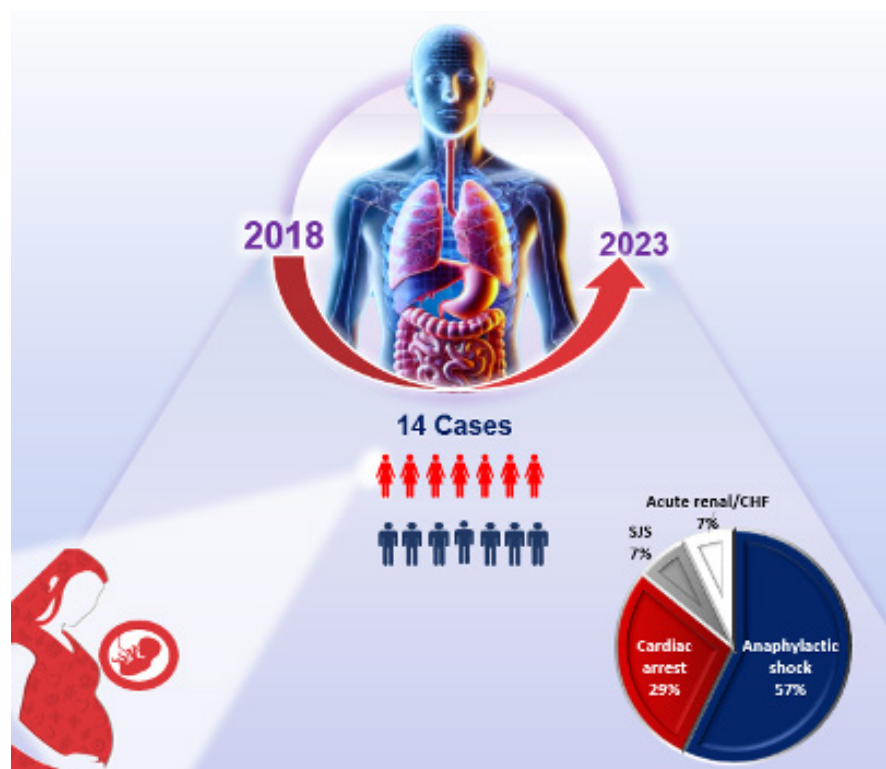
In addition to clinical risk factors, drug quality may have contributed to the observed reactions. Previous analysis of Syrian ceftriaxone products demonstrated the presence of leachable substances from rubber closures in all tested vials, with 47.46% exceeding the threshold of toxicological concern (17). These substances may potentiate IgE-mediated immune responses and increase the risk of severe hypersensitivity, highlighting the importance of rigorous pharmaceutical quality control and clinical risk assessment.

Limitations of the study

A key limitation of this study is its reliance solely on fatal ADR cases reported to the Syrian Ministry of Health pharmacovigilance system. Fatal cases that were unreported or incompletely documented may have been missed, potentially leading to an underestimation of the true burden of ceftriaxone-associated fatal reactions. Strengthening pharmacovigilance systems and improving the completeness and timeliness of adverse

Table 1 Fatal adverse reactions associated with ceftriaxone sodium (N = 14)

Case No.	Sex	Age (years)	Route of administration	Indication	Dose	Sulbactam co-administration	Time to reaction onset	Cause of death	Adverse reaction and fatality description
1	M	7	IM	Not specified	Not specified	No	Immediate	Anaphylactic shock	Developed anaphylactic shock after injection; admitted to hospital but died.
2	F (mother)	28	IV	Not specified	1000 mg	No	Immediate after 6th dose	Anaphylactic shock	Drug withdrawn and patient hospitalised; foetal death occurred first, followed by maternal death.
3	N/A	Foetus	N/A	N/A	N/A	N/A	N/A	Foetal death	Foetal death secondary to maternal anaphylactic shock.
4	M	18–65	IV	Not specified	1000 mg	No	Immediate after 5th dose	Anaphylactic shock	Anaphylactic shock developed after administration; no concomitant medications reported; patient did not survive.
5	F	17	IV	Respiratory infection	1000 mg	No	2 days after 4th dose	Anaphylactic shock	Developed anaphylactic shock 2 days after drug administration, resulting in acute hypoventilation; patient was ventilated but did not survive.
6	F	17	IV	Respiratory infection	1000 mg	No	2 days after administration	Anaphylactic shock	Anaphylactic shock occurred 2 days after administration; patient did not survive despite interventions.
7	F	43	IM	Tonsillitis and allergic asthma	1000 mg	No	Immediate	Anaphylactic shock	Anaphylactic shock occurred within minutes; resuscitation unsuccessful.
8	M	75	IM	Acute bronchitis	1500 mg	Yes	7 days after administration	Multi-organ failure due to SJS	Developed toxic epidermal necrolysis after ceftriaxone-sulbactam; progressed to multiorgan failure; no prior drug allergy reported.
9	M	35	IM	Not specified	Not specified	No	Immediate	Cardiac arrest	Hypersensitivity reaction led to cardiopulmonary arrest; patient died on arrival at hospital.
10	F	65	IM	Not specified	Not specified	No	Immediate	Cardiac arrest	Hypersensitivity reaction resulted in cardiopulmonary arrest; patient died on arrival at hospital.
11	M	Not specified	IM	Respiratory infection	1000 mg	No	Immediate	Cardiac arrest	Developed shock and circulatory collapse; died despite CPR.
12	F	8	ID	Enteritis	Not administered	Yes	Immediate	Anaphylactic shock	History of drug allergy; fatal anaphylactic shock occurred during intradermal allergy test.
13	F	3	IV	Pyelonephritis	500 mg	No	Immediate	Acute renal failure and CHF	Developed severe oedema, unconsciousness, renal failure, and congestive heart failure.
14	M	36	IV	Preoperative infection prevention	1000 mg	No	Immediate	Anaphylactic shock	Developed anaphylactic shock, later pneumonia in ICU; patient died.
15	M	40	IM	Abscess	1000 mg	No	Immediate	Cardiac arrest	Developed urticaria and itching followed by cardiac arrest; hydrocortisone administered; patient died; classified as anaphylaxis.

Figure 1 Fatal adverse reactions due to ceftriaxone sodium in Syrian Arab Republic

event reporting would support more accurate assessment in future studies.

Conclusion

It remains unclear whether ceftriaxone-associated allergic reactions observed in this study were due to poor drug quality (including purity), inappropriate dosing, or improper methods of administration. Concerns have been raised regarding the presence of leachable

substances in Syrian ceftriaxone products, which may exacerbate hypersensitivity risks. Reducing the risk of severe adverse reactions requires strengthened quality control measures, including monitoring for leachable substances from rubber closures, as well as thorough allergy evaluations based on detailed patient history and hypersensitivity testing. Close clinical observation after administration, with immediate access to emergency resuscitation equipment, is also essential.

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Medication errors and therapy problems may drive antimicrobial resistance in Egypt

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Abstract

Background: Antimicrobial resistance is a challenge in Egypt and the potential contributors are medication errors and drug therapy problems involving antimicrobial agents.

Aim: To analyse, for corrective actions, antimicrobial-related drug therapy and management errors reported to the Egyptian National Office for Handling and Reduction of Medication Errors.

Methods: We analysed data on antimicrobial-related drug therapy and management error reported to the National Office for Handling and Reduction of Medication Errors by 46 hospitals in 2 Egyptian governorates between January 2020 and November 2024. Using descriptive statistics, and based on the WHO access, watch and reserve classification, we summarised the error types and antimicrobial agents involved.

Results: Of the 162 638 valid error reports, 57 592 (35.4%) involved antimicrobials, of which 98.2% were combined drug therapy and management errors. The most common errors were related to prescription (96.7%), including dosing regimen (43.1%) and incorrect indication (33.8%). The most frequently implicated agents were ampicillin/sulbactam (12.0%), levofloxacin (11.5%), ceftriaxone (9.0%), and cefotaxime (7.2%). Watch group antibiotics accounted for 65.4% of the errors, followed by access (27.8%) and reserve (5.7%).

Conclusion: Our findings provide important baseline data for strengthening antimicrobial stewardship in Egypt. Appropriate policies are needed to minimise antimicrobial-related errors, improve rational use of antimicrobials, strengthen antimicrobial surveillance, and mitigate the risk of inappropriate watch group prescriptions in Egypt.

Keywords: antimicrobial resistance, medication errors, drug therapy problems, prescription, patient safety, AWaRe classification, antimicrobial stewardship, NOHARMe, Egypt

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Background

National Office for Handling and Reduction of Medication Errors

The National Office for Handling and Reduction of Medication Errors (NOHARMe) system was established in Egypt in 2014 as a national framework for reporting medication errors and drug therapy problems. Currently managed by the Egyptian Drug Authority (EDA), the system is used by public hospitals and primary health care units. Clinical pharmacists examine patient files to detect drug therapy problems or medication errors before submitting them to NOHARMe.

A medication error is defined as any avoidable incident that could result in improper medication use or patient injury while the medication is under the control of the patient, health care provider, or consumer (1). A drug therapy problem refers to any undesirable patient event involving, or suspected to involve, drug therapy that interferes with treatment goals and requires professional judgment to resolve (2).

The primary goal of NOHARMe is to provide a systematic tool for collecting, reviewing, and analysing reports on drug therapy problems and medication errors at the national level. This analysis generates statistics on the most frequently involved drugs, common errors, stages of occurrence, and error severity (3). The resulting insights help identify trends and inform corrective actions to prevent recurrence.

NOHARMe facilitates the exchange of experiences among hospitals and provides recommendations to health care practitioners to reduce medication errors. Corrective measures may include developing guidelines for good pharmacy practice, issuing newsletters, or implementing regulatory actions such as ministerial decrees. Similar reporting systems are implemented globally, including the Institute for Safe Medication Practices Medication Error Reporting Program (ISMP MERP) and MEDMARX in the United States, the National Reporting and Learning System (NRLS) in the United Kingdom, and ISMP Canada (4–7). All these emphasise standardised reporting and systematic analysis to improve practice and patient safety.

To ensure consistency, NOHARMe uses a coding system to classify drug therapy problems and medication errors, published on the Egyptian Drug Authority (EDA) website. This approach establishes a common terminology, minimising variations in report quality and enabling integration into a unified national programme (8). To enhance the reliability and usability of the collected data, hospital pharmacists receive practical training on how to use the system for data entry and analysis.

Antimicrobial misuse

Antimicrobial misuse is a significant global concern, contributing to the increase in antimicrobial resistance (AMR). WHO has prioritised this issue, emphasising the need for clear antimicrobial use policies and antimicrobial stewardship initiatives (9). In 2017, WHO introduced the AWaRe classification to promote responsible antibiotic use, according to which antibiotics are categorised into “Access”, “Watch”, and “Reserve” groups based on their potential to cause resistance. This classification, updated biennially, supports local, national, and international efforts to combat resistance (10).

This report presents insights on antimicrobial misuse reported through the NOHARMe system from January 2020 to November 2024, which could be used to inform corrective actions and improve practice, contributing to global efforts to combat AMR and promote patient safety. By understanding the prevalence and nature of antimicrobial-related errors, health systems can implement targeted interventions to reduce misuse and enhance patient outcomes.

Methods

Study design and setting

This retrospective study examined antimicrobial-related data submitted by clinical pharmacists with varying qualifications and experience to NOHARMe from January 2020 to November 2024. A convenience sample was drawn from hospitals in 2 Egyptian governorates – one coastal and one in the Delta region – selected because of their high reporting compliance. The sample included data from 20 hospitals in the coastal governorate and 26 in the Delta governorate, consisting mainly of inpatients, with a smaller proportion of outpatients.

The data was assessed for completeness, and any submission missing the antimicrobial name or type of drug therapy problem or medication error was excluded.

Data collection

The data were retrieved from the NOHARMe system, which receives standardised data entry forms from hospitals reporting drug therapy problems and medication errors. The form was designed by the NOHARMe unit within the EDA to facilitate uniform data collection and entry. Uploading the forms to the system enabled easy retrieval of cumulative hospital-level data for analysis.

The form includes hospital identifiers and patient information (initials, file number, age, and sex); the reporting system is designed to exclude full patient names to protect confidentiality. It also records the hospital department where the event occurred, the date the event was detected, and the name of the clinical pharmacist who identified and reported the event. Each event could involve one or more drugs, reported as the main drug and, where applicable, a second drug (e.g. in drug–drug interactions). Drug names are usually reported using generic (non-proprietary) names, except when errors involved look-alike or sound-alike medications, in which case both generic and trade names are recorded.

Events were categorised as drug therapy problems, medication errors or combined drug therapy problems and medication errors.

- For drug therapy problems only events, the form captured drug therapy problem type (based on reference codes), problem description, clinical pharmacist recommendations/interventions, references used, and physician acceptance status (accepted, rejected, or pending).
- For medication errors only events, the form captured stage and type of error (based on reference codes), a description of the error, actions taken, the possible cause, and whether or not the error reached the patient.
- For combined drug therapy problem and medication error events, all the above information was recorded.

Drug therapy problem reference codes were grouped into 7 main categories, further divided into 27 subcategories. Medication error reference codes were divided into 7 error categories: ordering/prescription (27 subcategories), preparation (5), storage (2), transcription (8), dispensing (10), administration (13), and monitoring (2).

Data analysis

Microsoft Excel was used for the descriptive analysis, using pivot tables and graphs to assess the frequency and distribution of drug therapy problems or medication errors. Descriptive statistics included both absolute and relative (percentage) frequency counts. All antimicrobial-related reports were analysed first, followed by a detailed analysis of combined drug therapy problem and medication error events. Patient demographic data, event descriptions, pharmacist recommendations/interventions, references, physician acceptance status, and possible error causes were excluded from this analysis.

Ethics considerations

All information in this report was kept confidential by the EDA, including the identities of patients and reporters, which were never disclosed. Approval for the analysis and publication was obtained from the EDA Chairman following legal consultation.

Results

A total of 235 138 reports were collected from 46 hospitals between January 2020 and November 2024. After excluding 72 500 (30.8%) incomplete submissions, 162 638 (69.2%) valid reports analysed. Of these, 57 592 (35.4%) were associated with antimicrobial agents. Among these, 305 (0.5%) were classified as drug therapy problems only, 708 (1.2%) as medication errors only, and 56 579 (98.2%) as combined drug therapy problems and medication errors.

Among the 305 drug therapy problems only reports, the majority involved monitoring (n = 157; 51.5%) or adherence problems (n = 148; 48.5%). Of the 708 medication errors only reports, most occurred during the ordering/prescription stage (n = 487; 68.8%), followed by administration (n = 146; 20.6%), transcription (n = 31; 4.4%), dispensing (n = 19; 2.7%), preparation (n = 13; 1.8%), monitoring (n = 9; 1.3%), and storage (n = 3; 0.4%).

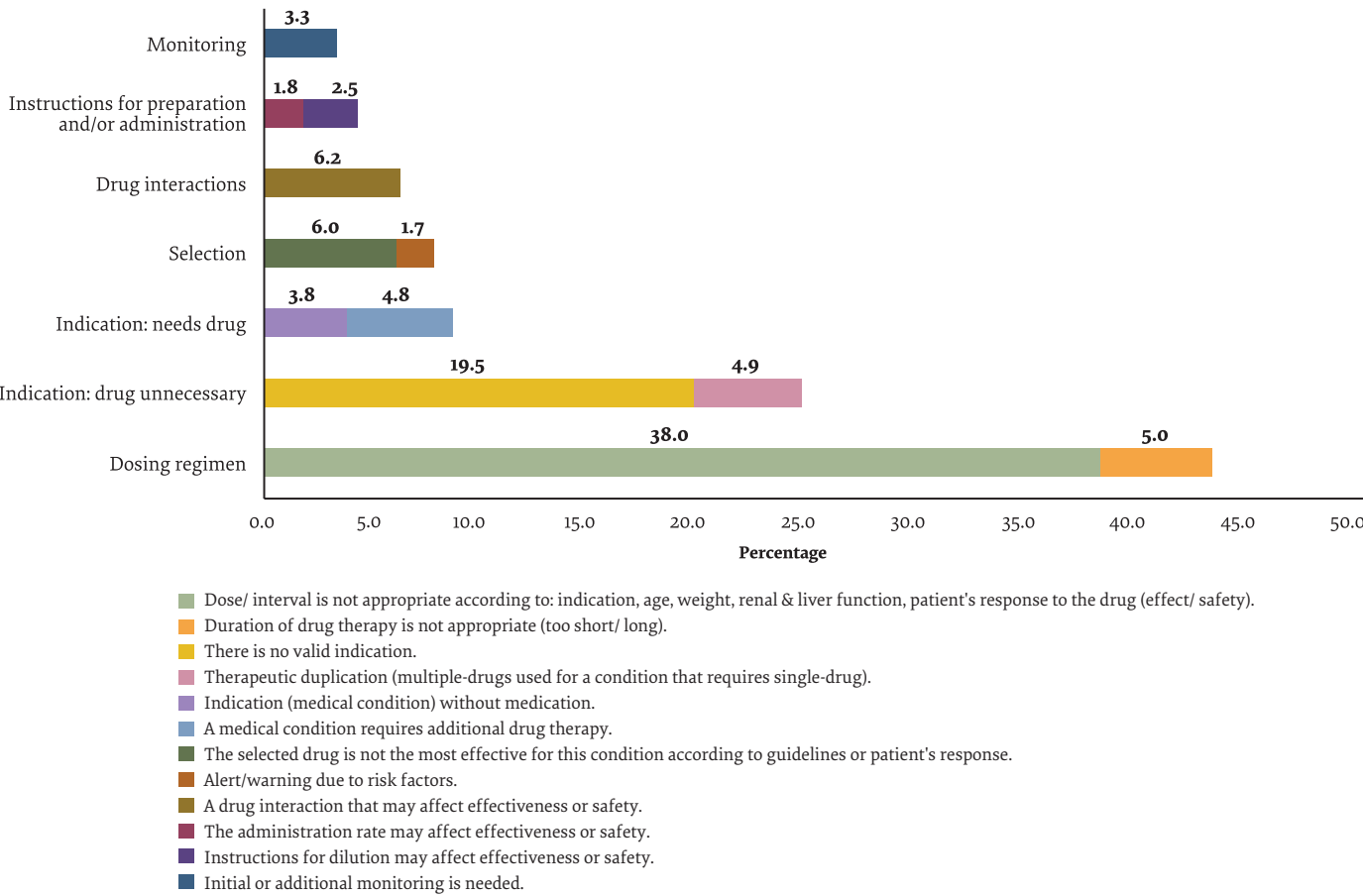
In the 56 579 combined drug therapy problems and medication errors events, dosing regimen problems were most frequent (n = 24 384; 43.1%), including inappropriate dose or interval (n = 21 530; 38.1%) and inappropriate duration (n = 2 854; 5.0%). Indication-related problems followed (n = 19 123; 33.8%), including no valid indication

(n = 11 042; 19.5%), therapeutic duplication (n = 2767; 4.9%), need for additional therapy (n = 2704; 4.8%), and indication without corresponding medication (n = 2160; 3.8%). Other categories included selection issues (n = 5129; 9.1%), drug interactions (n = 3499; 6.2%), preparation/administration instructions (n = 2563; 4.5%), and monitoring problems (n = 1881; 3.3%).

Most combined drug therapy problems and medication errors occurred during prescription (n = 54 698; 96.7%), with the remainder occurring during monitoring (n = 1881; 3.3%). These data are illustrated in Figure 1.

The combined drug therapy problems and medication errors involved 58 282 individual antimicrobial entries (main or second drugs). Analysis using the WHO Anatomical Therapeutic Chemical (ATC) classification level 2 (Figure 2) showed that antibacterials for systemic use were most common (n = 52 922; 90.8%), followed by antiprotozoals (n = 1513; 2.6%), antivirals (n = 1378; 2.4%), antimycotics (n = 981; 1.7%), anthelmintics (n = 630; 1.1%), and antidiarrhoeals (n = 479; 0.8%) (11). Other drug classes accounted for ≤ 0.2% of the reports, including antimycobacterial agents, anti-infective eye drops, and topical antifungals.

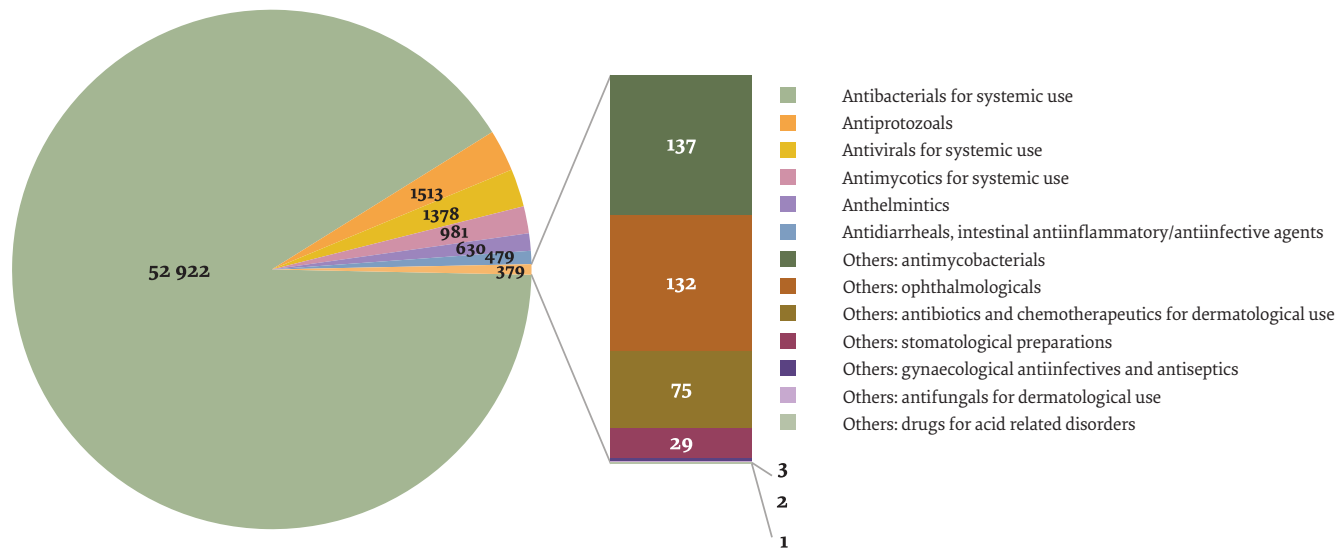
Figure 1 Relative frequency of drug therapy problems and medication errors by problem category and type (relative to the total count of combined drug therapy problems and medication errors)



Notes:

- Only DTPs with a relative reporting frequency of more than 1% are shown.
- The percentages shown in the figure do not add up to 100%.

Figure 2 Reporting frequency by antimicrobial class (ATC level 2)



- Notes:
- Frequencies are shown for the 6 most reported level 2 ATC groups in the pie chart.
 - The remaining groups are combined under the category 'Others' in the stacked bar.
 - All values represent reporting frequencies.
 - The legend lists all ATC level 2 groups sorted in a descending order of reporting frequency. The top 6 correspond to the pie chart colours, while the remaining 7 correspond to the bar chart colours.

Figure 3 Reporting frequency for ATC level 3 groups

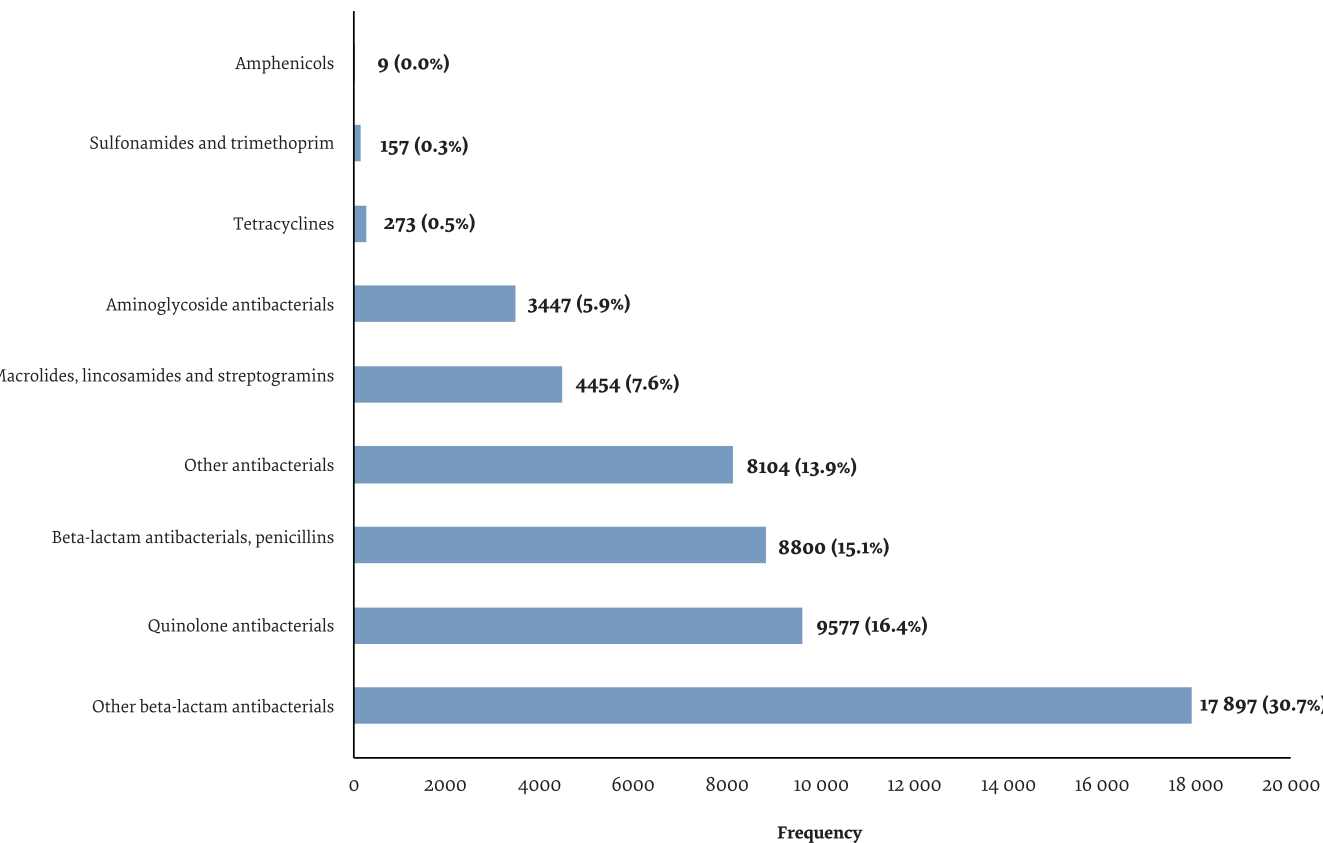
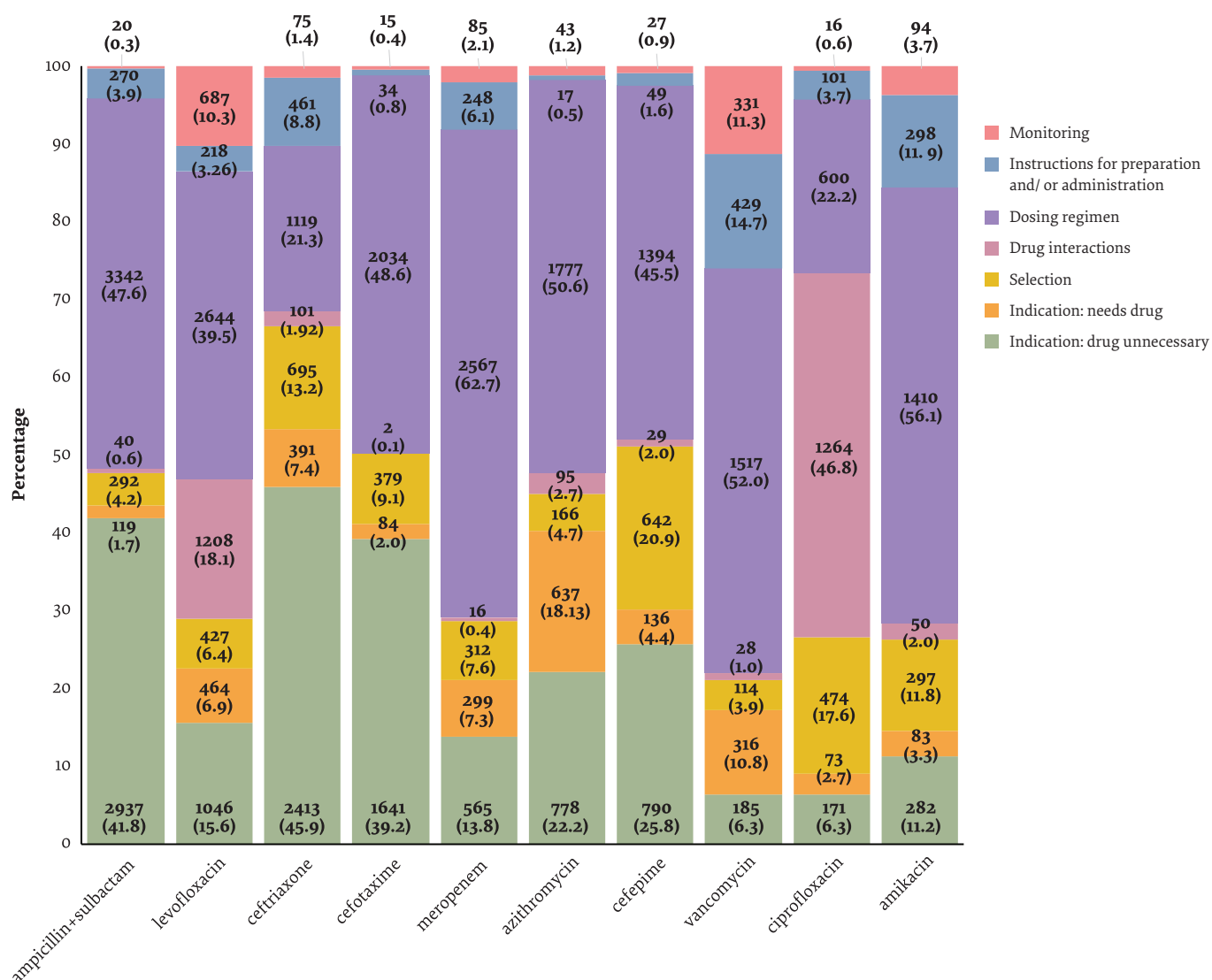


Figure Most frequent drugs involved in drug therapy problems and medication errors

Further classification of antibacterial by ATC level 3 (Figure 3) revealed that other β -lactam antibacterials were the most prevalent ($n = 17\,897$ 30.7%), followed by quinolones ($n = 9577$ 16.4%), β -lactam antibacterial (penicillins) ($n = 8800$ 15.1%), and other antibacterials ($n = 8104$ 13.9%). Macrolides, lincosamides, and streptogramins accounted for 4454 (7.6%), aminoglycosides for 3447 (5.9%), and other categories (e.g. tetracyclines, sulfonamides/trimethoprim) combined accounted for less than 0.5% of reports.

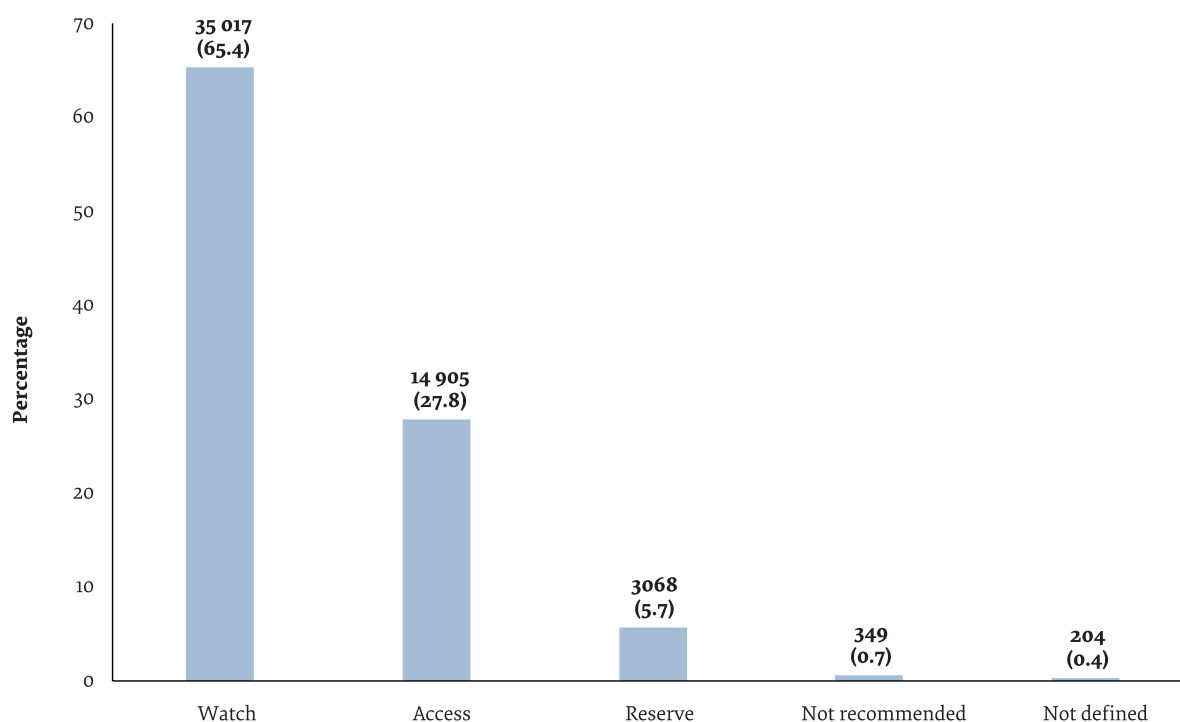
The most frequently reported drugs associated with drug therapy problems and medication errors were ampicillin/sulbactam ($n = 7020$; 12.0%), levofloxacin ($n = 6694$; 11.5%), ceftriaxone ($n = 5255$; 9.0%), cefotaxime ($n = 4189$; 7.2%), meropenem ($n = 4092$; 7.0%), azithromycin ($n = 3513$; 6.0%), cefepime ($n = 3067$; 5.3%), vancomycin ($n = 2920$ 5.0%), ciprofloxacin ($n = 2699$; 4.6%), and amikacin ($n = 2514$; 4.3%). Other drugs included metronidazole ($n = 2372$ 4.1%), linezolid ($n = 2328$; 4.0%), gentamicin ($n = 934$; 1.6%), fluconazole ($n = 842$;

1.4%), hydroxychloroquine ($n = 762$; 1.3%), ceftazidime ($n = 680$; 1.2%), acyclovir ($n = 673$; 1.2%), amoxicillin/clavulanic acid ($n = 622$; 1.1%), ivermectin ($n = 616$; 1.1%), and colistin ($n = 612$; 1.0%). Drugs such as nitazoxanide, clarithromycin, and piperacillin/tazobactam each accounted for <1.0%. Figure 4 shows the top 10 drugs associated with drug therapy problems and medication errors and the most frequently encountered event types for each drug.

Antibiotics submitted to the NOHARMe database and listed in the WHO AWaRe classification were grouped and analysed, showing that the watch group accounted for the majority of drug therapy problems and medication errors ($n = 35\,017$; 65.4%), followed by the access group ($n = 14\,905$; 27.8%), the reserve group ($n = 3068$; 5.7%), not-recommended combinations ($n = 349$; 0.7%), and unspecified antibiotics ($n = 204$, 0.4%). Figure 5 presents reporting frequencies for AWaRe categories.

Based on error category (whether the event reached the patient), 8785 (15.3%) did not reach the patient, while

Figure 5 Reporting frequency by AWaRe category (shown as absolute frequencies and as percentages of all antimicrobials involved in combined DTPs/MEs)



12 059 (21.1%) reached the patient, and 36 443 (63.61%) had an unknown status.

Discussion

This five-year descriptive analysis of 162 638 events reported to the NOHARMe database found antimicrobial drug therapy problems and medication errors to be highly prevalent. Among all reported antimicrobials, systemic antibacterials accounted for the largest share associated with drug therapy problems and medication errors. Ampicillin/sulbactam was the most frequently reported antibiotic, followed by levofloxacin, then ceftriaxone. Approximately two-thirds of antibiotics involved in drug therapy problems and medication errors belonged to the WHO watch category. Most antimicrobial drug therapy problems and medication errors occurred at the prescription stage, with dosage regimen errors being the most common type, followed by inappropriate indications. In nearly all cases in which errors reached patients, 99.0% caused no harm.

Regarding prevalence, more than one-third of all submissions were antimicrobial-related, and 90.8% of the antimicrobials involved were systemic antibacterials. This finding is consistent with a previous analysis of the NOHARMe database, which concluded that antibiotics were the top class involved in medication errors (19.4%) (12). A systematic review of medication errors in

the Middle East found that anti-infectives were the most frequently reported group (13). Similarly, a cross-sectional study in Saudi Arabia showed that 22.1% of the total reported medication errors were antimicrobial errors (14).

Few studies have compared the antibacterial drug therapy patterns commonly involved in medication errors among countries in the region. Our findings are broadly comparable to a Saudi Arabian study, in which amoxicillin/clavulanate and ceftriaxone were most frequently implicated agents (14). However, our results differed slightly, with ampicillin/sulbactam, levofloxacin and ceftriaxone being the most frequently reported agents. These differences may be a reflection of variations in antimicrobial prescription patterns between the 2 countries, with prescription trends potentially influencing the frequency of medication errors in the reported agents. This assumption is supported by a point prevalence survey conducted at Mansoura University Hospital, which revealed that aminopenicillins (with or without β -lactamase inhibitors) were the most commonly prescribed antimicrobials, followed by third-generation cephalosporins and fluoroquinolones (15) – a pattern similar to the antibiotics associated with drug therapy problems and medication errors in our analysis. Another point prevalence survey in 18 Egyptian hospitals reported that third-generation cephalosporins were the most prescribed (28.7% of prescriptions), followed by penicillin with β -lactamase inhibitors (19.7%) (16).

Our analysis found that the majority of drug therapy problems and medication errors occurred at the prescription stage, a pattern reported consistently in studies from diverse settings worldwide. A retrospective review of medication errors reported to the Malaysian national reporting system over 4 years showed that prescription errors accounted for more than two-thirds of reported errors (17). Another study in the United States of America reported that 53.0% of errors were caused by prescription – a figure similar to previous NOHARMe findings (18,12). In Egypt, practitioners cite several causes of prescription errors, primarily lack of experience or training, followed by increased workload, distractions, and low adherence to national and international antibiotic guidelines (12,19,20). Regarding the pattern of drug therapy problems and medication errors detected in our analysis, inappropriate dose or dosing intervals made up the largest proportion of the reported events, followed by medication with no valid indication. This finding is consistent with the Saudi and Malaysian study results, where antimicrobial dosing errors were the most commonly reported types of errors (14,17).

Using the WHO AWaRe classification, watch antibiotics predominated in drug therapy problems and medication errors (65.4%) over access (27.8%), likely reflecting inpatient prescription patterns. This aligns with global point prevalence survey data from Egypt showing 65.0% watch versus 30.0% access use in adult inpatients (21). Notably, this high watch antibiotic use coincides with limited knowledge of the AWaRe classification: in one survey, only 13.4% of 500 Egyptian prescribers had AWaRe lists, underscoring the need to distribute these lists and train prescribers to optimise antibiotic use (19).

The AWaRe classification provides a practical framework to track antimicrobial misuse, particularly in high-risk categories (watch and reserve), while supporting data collection for national and global AMR strategies in line with WHO objectives. These findings provide important baseline data for antimicrobial stewardship efforts in Egypt. To our knowledge, this is the first study to characterise antimicrobial drug therapy problems and medication errors in Egypt nationally and to analyse the antibiotics involved, using the WHO AWaRe classification.

Acknowledgments

We sincerely thank the pharmacists who reported drug therapy problems and medication errors to NOHARMe; their commitment to patient safety strengthens the national database and supports improvements in medication practices. We also acknowledge the leadership of the Egyptian Drug Authority Chairman in advancing Egypt's pharmaceutical industry.

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Conflict of interest: None declared.

Study limitations

While our analysis was based on substantial, valid data, the findings may not be generalisable across Egypt because the sample was non-random and drawn from only 2 governorates. The reliance solely on pharmacist-reported errors may have introduced bias and underreporting. Some 63.6% of submitted events did not include information on whether the errors reached the patient, which limited the ability to analyse error severity. Incomplete reports represented a missed opportunity for analysis. This limitation could be addressed through enhanced training on the reporting system.

Recommendations

Prescription errors can be reduced through tailored strategies, such as educational programmes for prescribers, computerised decision-support tools, and enhanced pharmacist involvement in patient care (22). The predominance of watch group errors in our results indicates that targeted policies are needed to strengthen rationalisation of antibiotic use and mitigate the risk of inappropriate watch group prescription.

The reporting system should be optimised to enhance the completeness and accuracy of data submissions, thereby reducing instances of incomplete or missing information. Providing further training for existing users and promoting adoption among new users from other health care facilities would strengthen overall system effectiveness.

Further research is warranted to clarify the relationship between antimicrobial prescription patterns and the incidence of reported antimicrobial medication errors.

Conclusion

NOHARMe provides a wealth of information on the patterns of antimicrobial drug therapy problems or medication errors, enabling preventive measures and corrective actions to address irrational antimicrobial use in participating Egyptian hospitals. The study highlights the persistent observation that prescription errors are the most common, with the dosing errors showing the highest prevalence. Categorising antibiotics according to the AWaRe classification revealed higher prevalence of errors in the watch group.

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A review of the burden, resistance patterns and outcomes of hospital-acquired infections in Saudi Arabia

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Abstract

Background: Hospital-acquired infections remain a major problem in Saudi Arabia, contributing to increases in morbidity, mortality and health care costs.

Aim: To review evidence on the epidemiology, risk factors and outcomes of hospital-acquired infections in Saudi Arabia hospitals.

Methods: Following PRISMA 2020 guidelines and narrative synthesis approach, we searched PubMed/Medline and Web of Science, as well as the databases of Google Scholar, Multidisciplinary Digital Publishing Institute, and Springer Nature, for articles published between 2015 and 2025 on hospital and health care-associated infections in Saudi Arabia. We appraised the quality of the studies using the Newcastle-Ottawa scale, Joanna Briggs Institute and risk of bias in non-randomized studies of interventions tools.

Results: Surgical site infections were $\leq 1\%$, but higher among caesarean section cohorts ($\approx 4.7\%$). Gram-negative pathogens (*Klebsiella*, *E. coli*, *Pseudomonas*, *Acinetobacter*) were predominant, with $\approx 41\%$ multidrug resistance and $\approx 25\%$ extensive resistance. Risk factors for infection included intensive care unit stay, use of invasive devices, diabetes, and prolonged procedures. Bundle adherence was high ($\approx 94\text{--}100\%$), but hand hygiene compliance lagged ($\approx 76\%$). Reported outcomes included longer intensive care unit stay, increased antibiotic use and high mortality in severe central line-associated bloodstream infection cases.

Conclusion: Hospital-acquired infections in Saudi Arabia are predominantly associated with the use of invasive devices and driven by resistant gram-negative bacteria. Although national surveillance and bundle programmes have helped improve infection prevention in hospitals, there is a need for strict adherence to antimicrobial stewardship guidelines, enforcement of hand hygiene practices and uniform surgical site infection surveillance methods.

Keywords: hospital-acquired infection, nosocomial infection, antimicrobial resistance, intensive care unit, infection prevention, Saudi Arabia

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Introduction

Healthcare-associated infections (HAIs), also referred to as hospital-acquired infections, are infections contracted during care that were not present or incubating at the time of admission. HAIs occur frequently and contribute to prolonged stay, excess mortality and increased health system costs (1). Common HAIs include central line-associated bloodstream infections (CLABSI), catheter-associated urinary tract infections (CAUTI), ventilator-associated pneumonia/events (VAP/VAE), and surgical site infections (SSI). The burden of HAIs is amplified by antimicrobial resistance, including methicillin-resistant *Staphylococcus aureus* (MRSA) and carbapenem-resistant *Acinetobacter baumannii* (2).

Globally, HAIs threaten patient safety and health system sustainability. WHO estimates that 7% of hospitalised patients in high-income countries and up to 15% in low- and middle-income countries acquire HAIs (3). In the United States of America (USA), 1 in 31 inpatients is affected (4), while Europe records 8.9 million cases annually, causing disability-adjusted-life-years (DALYs)

comparable to influenza, tuberculosis and HIV/AIDS (5). These infections cause preventable morbidity and high health care costs.

An estimated 10–12% of inpatients in the Eastern Mediterranean Region (EMR) have HAIs due to shortcomings in the health system such as limited resources, weak infection prevention and control and high-level antimicrobial resistance (3). Cross-border spread of resistant pathogens in the region is often fuelled by instability, forced migration and medical tourism. Intensive care units (ICUs) particularly report extremely high infection levels (6).

Saudi Arabia presents a distinct context. Its rapidly expanding health sector faces additional strain from Hajj and Umrah participants, thus heightening the risk of communicable disease transmission (7). To improve disease monitoring, the Ministry of Health launched the Health Electronic Surveillance Network (HESN), modelled after the USA National Healthcare Safety Network (NHSN) (8). Despite the progress made until date, national and single centre data still show a

significant burden of device-associated infections, driven by multidrug-resistant gram-negative organisms and inter-facility variations in care protocols.

Existing studies on HAIs in Saudi Arabia remain fragmented, are mostly single centre, narrow in scope and inconsistent in surveillance practices. A comprehensive synthesis is therefore needed to benchmark performance internationally, guide antimicrobial stewardship and strengthen national infection prevention and control (IPC) strategies.

This systematic review synthesised published evidence on HAIs in Saudi Arabia between 2015 and 2025. It examined the incidence and prevalence rates, pathogen distribution and antimicrobial resistance profiles, risk factors, implemented IPC strategies, and associated clinical and economic outcomes.

Methodology

Study design

This was a systematic review with narrative synthesis, reported in accordance with PRISMA 2020. A meta-analysis was not performed because of substantial clinical and methodological variations across the eligible studies (e.g. study design, setting, population, case definition, denominator, and outcome measure) and incomplete reporting of variance estimates required for statistical pooling.

The review question was formulated using the population, intervention/exposure, comparator, outcomes, study design (PICOS) framework:

The population included patients of all ages hospitalised in Saudi Arabia. The intervention/exposure included hospitalisation, invasive procedures (catheterisation, surgery, mechanical ventilation), or other healthcare exposures. The comparator, where applicable, included patients without HAIs or international benchmarks. The outcomes were the incidence and prevalence of HAIs; pathogen distribution and antimicrobial resistance (AMR); risk factors; infection prevention and control (IPC) interventions; morbidity, mortality, and costs. The study design included observational studies (cross-sectional, cohort, case-control), outbreak investigations, surveillance analyses, and interventional studies. The review question was: “What is the epidemiology, risk factor profile, antimicrobial resistance pattern, and clinical impact of HAIs in Saudi Arabia between 2015 and 2025?”

Search strategy

Electronic search was conducted on PubMed/Medline and Web of Science. To reduce the risk of missing locally published evidence, we also screened Google Scholar as a supplementary source (the first 200 results sorted by relevance, with duplicate removal and title/abstract screening) and conducted targeted searches on Multidisciplinary Digital Publishing Institute and Springer Nature to identify potentially relevant studies in Saudi Arabia not indexed in the main bibliographic

databases. Reference lists of included articles were searched for additional eligible studies.

We searched articles published from January 2015 to March 2025 using search terms combined controlled vocabulary (MeSH/Emtree) and free-text keywords with Boolean operators. Core concepts were HAIs (hospital-acquired, healthcare-associated, nosocomial, CLABSI, CAUTI, VAP, SSI), antimicrobial resistance (multidrug-resistant, MRSA, ESBL, carbapenem-resistant, *Acinetobacter baumannii*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*), and location (Saudi Arabia).

An example search string was ("Saudi Arabia"[Mesh] OR Saudi[tiab]) AND ("hospital-acquired infection"[tiab] OR "healthcare-associated infection"[tiab] OR "nosocomial infection"[tiab] OR CLABSI[tiab] OR CAUTI[tiab] OR VAP[tiab] OR "surgical site infection"[tiab]) AND ("antimicrobial resistance"[tiab] OR MRSA[tiab] OR ESBL*[tiab] OR "carbapenem-resistant"[tiab] OR *Acinetobacter*[tiab] OR *Klebsiella*[tiab] OR *Pseudomonas*[tiab]). the filters were English; 2015–2025; humans.

Eligibility criteria

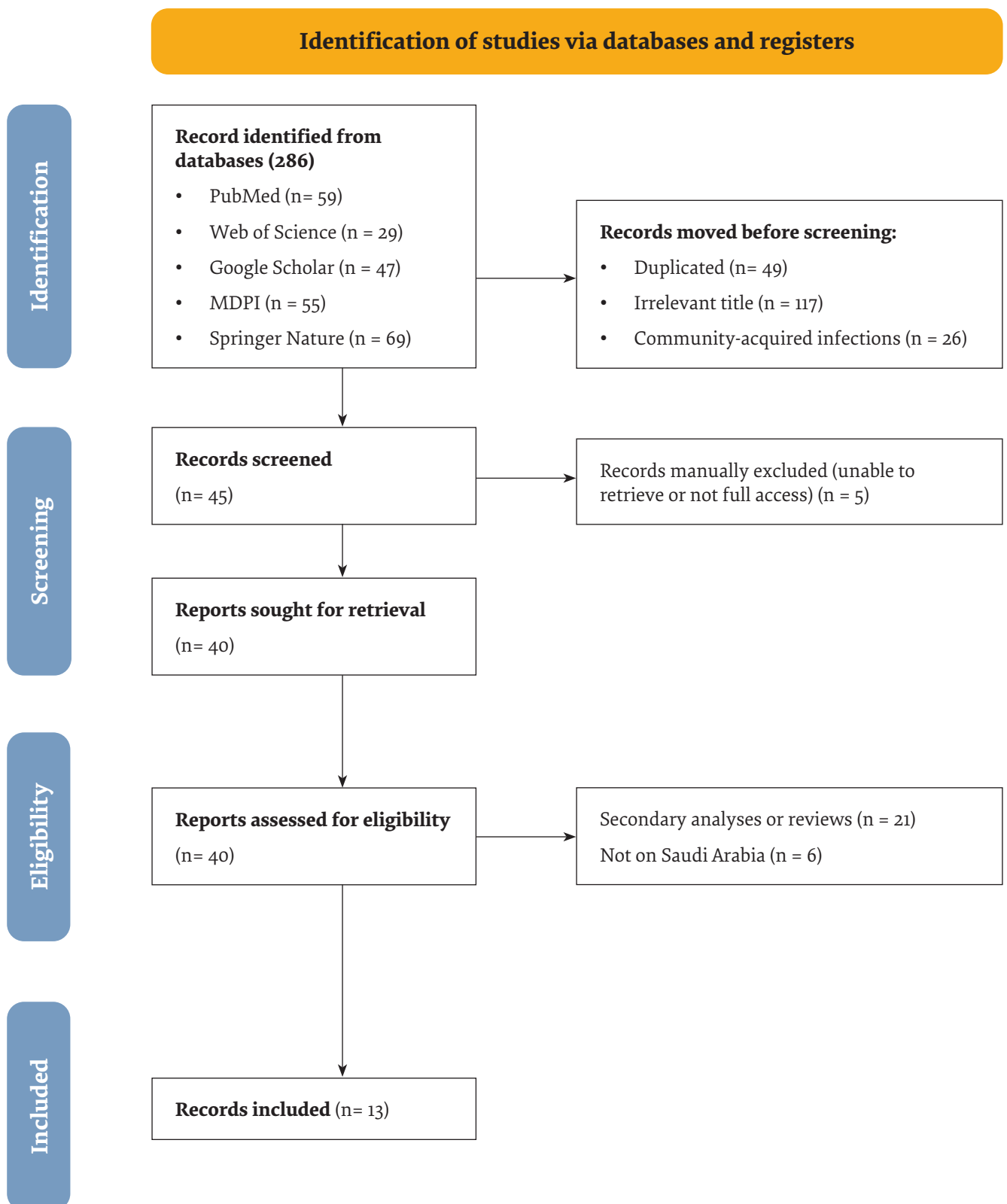
We included studies conducted in Saudi Arabia; published between 2015 and 2025; reporting hospital/healthcare-associated infections in any hospital setting (especially ICU) including incidence, prevalence, pathogens/AMR, risk factors, outcomes, or infection prevention and control interventions; and observational, surveillance, outbreak investigation, or interventional designs. Studies outside Saudi Arabia, or on non-hospital/community infections, editorials/commentaries, and studies without extractable HAI outcomes were excluded. However, one study reporting hospital-acquired venous thromboembolism (VTE) was retained solely as a comparative patient-safety outcome to illustrate shared surveillance and bundle-implementation considerations; it was not included in the HAI incidence estimates. Narrative or systematic reviews, scoping reviews, case reports with <5 patients, studies limited to community-acquired infections, and grey literature were also excluded.

Study selection

The initial search retrieved 286 records. After removing 49 duplicates, 237 remained. Screening of titles/abstracts excluded 192 records, which did not meet the criteria. Forty-five full text articles were assessed; 32 were excluded (27 reviews or secondary analyses; 5 inaccessible). Thirteen studies met the eligibility criteria and were included in the final synthesis (Figure 1).

A standardised extraction sheet (Microsoft Excel) was piloted and applied independently by 2 reviewers to extract data on bibliographic details (authors, year), study design and setting, population characteristics (sample size, age group, clinical ward or ICU), HAI type (e.g. CLABSI, CAUTI, ventilator-associated events, VAE, or ventilator-associated pneumonia, VAP, depending on the surveillance definition used in each study, SSI), microbial and resistance profile (pathogens, resistance mechanisms, genotypes), epidemiologic metrics (incidence density,

Figure 1 PRISMA flow chart for the study



prevalence, outbreak magnitude, attributable mortality), risk factors (patient, procedural, environmental, system-level), IPC interventions (bundles, surveillance, stewardship, outbreak containment), and clinical or economic outcomes (mortality, morbidity, length of stay, costs). Disagreements were resolved through consensus or third-party adjudication.

Quality appraisal

Methodologic quality was assessed using validated tools appropriate for the design, including Newcastle–Ottawa scale (NOS) for cohort and case–control studies (Ottawa Hospital Research Institute), JBI checklist for prevalence studies for cross-sectional designs (JBI), and ROBINS-I tool for quasi-experimental and interventional studies (26,28,29). Each study was rated as low-, moderate- or high-risk of bias.

Data synthesis

Given the substantial heterogeneity in the study designs, populations, surveillance definitions or denominators, and outcome measures, we conducted a systematic review with narrative synthesis. We summarised the study findings using descriptive statistics (e.g. ranges and medians of reported incidence or prevalence) and structured thematic synthesis for risk factors and IPC interventions. A quantitative meta-analysis was not undertaken because the data was not sufficiently comparable and key variance parameters were inconsistently reported.

Results

Characteristics of synthesised studies

Thirteen studies (2015–2025) from Riyadh, Qassim/Unaizah, Taif, Jeddah, Hail, Mecca, and Eastern Province were synthesised (Table 1). The designs covered surveillance, cohorts, outbreaks, colonisation, paediatrics, and AMR analyses. The study settings spanned the Ministry of Health, National Guard, university, and private hospitals. The populations included adults in ICUs, paediatrics, surgical ward patients, and health care workers (Table 1).

The overall study quality ranged from low to moderate (Tables 4,5,6). Most single-centre observational studies were rated as moderate risk of bias, due to limited control of confounding and incomplete reporting of key denominators or variance estimates (Tables 5 and 6). By contrast, the national and multicentre surveillance analyses (e.g. HESN-based datasets) were assessed as lower risk of bias and, therefore, provide higher confidence for the national device-associated HAI incidence estimates. Findings on specific risk factors and IPC intervention effects should be interpreted with greater caution when

derived from small cohorts or before–after designs where secular trends cannot be excluded (Table 4).

Incidence and prevalence of HAIs

The national HESN benchmark rates reported for adult ICUs were 2.57 CLABSI per 1000 central line-days, 1.08 CAUTI per 1000 urinary catheter-days and 4.21 ventilator-associated events per 1000 ventilator-days (8,30). Across individual hospital studies, reported ranges were 1.1–2.6 per 1000 device-days for CLABSI, 0.5–1.1 for CAUTI, and 1.1–2.97 for ventilator-associated pneumonia/events where reported (9–11). These estimates indicate that device-associated HAIs remain the predominant HAI burden in Saudi Arabia ICUs (12).

Pathogen distribution and antimicrobial resistance

In all the designs, gram-negative organisms were predominant: *Klebsiella pneumoniae*, *Escherichia coli*, *Pseudomonas aeruginosa*, and *Acinetobacter baumannii*. Less common, but significant gram-positive organisms were MRSA and enterococci, which were found in the paediatric and intensive care units (Table 1). The resistance rates were alarming: up to 68% of the carbapenem resistance in *Acinetobacter*, and approximately 37% in *Pseudomonas* (10). The distribution of aminoglycoside resistance genes was extremely high in Taif *P. aeruginosa* isolates (17). Genomic correlation between carbapenem-resistant *A. baumannii* on the surfaces and patient isolates in Jeddah ICUs was confirmed by environmental surveys (18). The Eastern Province reported colonisation of the cleaning staff with MRSA (9.4%) and Enterobacteriaceae (15.6%) (13).

Risk factors

The risk factors at the patient level included prolonged ICU stay, higher severity of illness (e.g. APACHE II), advanced age, and comorbidities (e.g. diabetes, hypertension, chronic kidney disease) (Table 2) (14,15). Procedure- and device-related factors included prolonged device use (central line, urinary catheter, or mechanical ventilation), emergency insertion and incomplete adherence to bundle elements (9,11). Previous antimicrobial exposure and colonisation with multidrug-resistant organisms were associated with HAI occurrence in several studies (Table 2). One of such studies was a cohort-evaluated hospital-acquired venous thromboembolism; because VTE is not an infection, it is treated as a comparative patient safety outcome in the discussion section (16).

Infection prevention and control interventions

The HESN system helped harmonised surveillance definitions and reporting at the national level. In the Unaizah hospital study, bundle adherence was high for device-associated infection bundles (VAP/VAE bundle 94%, CLABSI bundle 100%, CAUTI bundle 99%, and SSI bundle 99%), while hand hygiene compliance was 76%, based on the routine compliance reports and audits of the hospital infection control unit for 2021 (9).

Table 1 Data extraction

Study	Setting & design	Population	HAI type	Key microbes/ resistance	Core findings
Nour 2017	Quasi-experimental, Mecca	281 HCWs (ED)	MERS-CoV	Viral	↑ Knowledge & practice; training improved response
Daowd 2025	Retrospective, Riyadh tertiary	33,237 admits	VTE (HA-VTE)	–	0.03% incidence; older, immobile, surgical patients at risk
Alsheddi 2023	MOH surveillance (106 hospitals)	ICU/dialysis/surgery	CLABSI, CAUTI, VAE, SSI	–	CLABSI 2.6; CAUTI 1.1; national benchmarks set
Alrebish 2023	Retrospective, Unaizah	3,944 surgeries	CLABSI, CAUTI, VAP, SSI, MDRO	MDRO 2.8/1k pt-days	Low HAI rates; HH 76%—needs improvement
Kilani 2024	Chart review, 74 MOH hospitals	1,003 cases	VAE, CLABSI, CAUTI, SSI	GNB 74% (Kp, Ab); fungi 22% (C. auris)	217 outbreaks; CFR 47.5%; ICU/COVID link
Alrabiah 2016	Retrospective, Riyadh	39 pediatric HA-MRSA	MRSA (BSI, pneumonia, SSTI)	mecA/PBP2a	15% mortality; prior surgery major risk
Balkhy 2020	Pooled MNGHA surveillance	1,333 pts	CLABSI, VAP, CAUTI, SSI	GNB 63%, MRSA 27%, VRE 20%	↑ AMR; stewardship gaps persistent
Albudayri 2024	Riyadh ICU	21 CLABSI pts	CLABSI	VRE 33%, Candida 29% (C. auris)	76% mortality; elderly with CVCs vulnerable
Alqurashi 2025	Cross-sectional, Eastern Province	96 cleaners	Colonization	MRSA 9%, Enterobacteriaceae 16%	ICU/OR contamination; HH training key
El Far 2023	Taif hospital	100 P. aeruginosa isolates	HAI-related	AME genes, aminoglycoside R 18–31%	Resistance profiling only
Yasir 2022	Jeddah ICU, env. survey + WGS	361 isolates	Env. contamination	CRAB genes (blaOXA, blaADC)	ICU reservoirs identified
Saleem 2022	Hail ICU	1,078 admits	CAUTI	Klebsiella 20%	Seasonal pattern; long-term catheterisation = risk
Abalkhail 2021	Qassim HCWs	213 HCWs	General HAI precautions	–	Knowledge 68%, practice 73%; training needed

Clinical and economic outcomes

HAIs prolonged ICU stay, drove antimicrobial use and raised mortality. CLABSI mortality reached 76% in one Riyadh ICU (11). Paediatric MRSA showed 15% mortality, 10% complications (14). The Ministry of Health outbreaks had 47.5% fatality, 66.1% with COVID-19 co-infection (12). High costs, although rarely measured, were associated with longer stays, expensive drugs and outbreak control.

Methodological characteristics

National surveillance enabled benchmarking but lacked case-mix adjustment (8,12). ICU cohorts offered details but were single-centre and less generalisable (9,11,15). Laboratory studies provided resistance data but no patient outcomes (17,18). The knowledge, attitude and perception surveys exposed health care worker gaps but did not measure infection rates (19,20). One study on hospital-acquired VTE (16) reported the application of surveillance or bundle tools to infectious and non-infectious

Table 2 Risk factors for HAIs in Saudi Arabia compared with international evidence

Source (country/setting)	HAI type/outcome	Study design / population	Key risk factors/predictors reported
Alrabiah et al, 2016 (Saudi Arabia; tertiary hospital, Riyadh)	Hospital-acquired MRSA infection (paediatric)	Retrospective chart review; ≤14 years; n = 39	Male sex; previous surgery; previous hospitalisation; high PICU admission and sepsis in HA cases (as reported by authors)
Saleem et al, 2022 (Saudi Arabia; ICU setting)	CAUTI/catheter-associated bacteriuria with MDR pathogens	Retrospective review of catheterised ICU patients	Longer ICU stay; prolonged urinary catheterisation; immunosuppressive drug use; irrational antibiotic exposure; patient age and sex were associated in some analyses (as reported by authors)
Rosenthal et al, 2024 (ISID Guide; multicountry synthesis)	Device-associated HAIs (CLABSI, CAUTI, VAP)	Synthesis of international surveillance and guideline evidence	Consistently reported determinants include severity of illness, prolonged device days, emergency insertion, suboptimal aseptic technique/maintenance, and limited staffing/training; these factors underpin prevention bundle recommendations.

harms. Overall, the designs were complementary but heterogeneous (Table 1).

Discussion

Comparison with international benchmarks

The national HESN benchmarks (CLABSI 2.57 per 1000 central line-days; CAUTI 1.08 per 1000 urinary catheter-days; and VAE 4.21 per 1000 ventilator-days) provide an important reference point for Saudi Arabia’s adult ICUs (8). International comparisons should be interpreted cautiously because surveillance definitions, ICU case mix and denominators vary. However, when contrasted with multicountry pooled estimates from low- and middle-income settings reported by the International Nosocomial Infection Control Consortium (INICC) (e.g. pooled mean CLABSI ≈4.5 per 1000 CL-days and VAP ≈12 per 1000 ventilator-days in pooled LMIC surveillance), the Saudi Arabia benchmark rates appear lower, consistent with the presence of national surveillance and bundle implementation (21–23). Conversely, the NHSN adult medical-surgical ICU CLABSI rates reported in the United States of America are around a median of 0.8 per 1000 central line-days, highlighting an opportunity for improvement (21) (Table 3).

Pathogen ecology and antimicrobial resistance

In line with the national and international reports, gram-negative pathogen, especially *Acinetobacter baumannii*, *Klebsiella pneumoniae*, *Escherichia coli*, and *Pseudomonas aeruginosa* dominate HAIs in Saudi Arabia (27). The resistance trends are disastrous: carbapenem resistance was 68% in *A. baumannii* and 37% in *P. aeruginosa* (10). These rates are equivalent to the European CDC alerts on carbapenem-resistant *Acinetobacter* and *Klebsiella* in southern and eastern Europe (25). Genomic evidence of the environment of Jeddah revealed that clonal associations between surface isolates and patient infections occurred, which proves that hospitals are reservoirs of the resistant organisms (18). Paediatric MRSA still plays a role in nosocomial infections, and it is important to highlight

that gram-positive pathogens are still clinically relevant despite gram-negative pre-eminence.

Determinants of infection risk

The vulnerabilities that were consistently reported across cohorts in Saudi Arabia include patient-level vulnerabilities: ICU admission, invasive devices, comorbidities, and previous antibiotic exposure (10,11 14,15). Hand hygiene compliance, which averaged approximately 76% with a hospital-wide programme (9), knowledge, attitude and perception survey (gaps in knowledge and practice among health care workers) (19,20), and colonisation among cleaning staff (13) were system-level determinants. Investigations of outbreaks conducted by the Ministry of Health in 2020–2021 describe the surge-era pressures of staffing shortage, supply shortage and heavy use of devices, which contributed to the ICU clusters (12).

Infection prevention and control performance

IPC performance was variably reported by the studies. Where available, compliance with device-associated infection bundles was high, whereas hand hygiene compliance was more modest and inconsistently measured or reported (9). Evidence suggests that sustained audit-and-feedback, availability of trained IPC personnel and institutional leadership support are important enablers of effective IPC implementation. Because most IPC performance data were derived from single centre retrospective reports, these findings should be interpreted with caution and validated through multicentre prospective evaluations.

Clinical and economic burden

The prevalence of HAIs in Saudi Arabia was associated with prolonged ICU hospitalisation, development of antimicrobial resistance and mortality (11,15). In a cohort of Riyadh ICUs, the mortality rate was above 70% in CLABSI cases (11), whereas the national outbreaks surveillance reported a fatality rate of about 50% in 2020–2021 (12).

Although few studies directly measured the costs, the findings suggest that these outcomes would strain the

Table 3 International benchmark comparison for device-associated HAIs

Metric (per 1000 device-days unless noted)	Saudi Arabia (HESN adult ICU benchmark)	LMIC pooled estimate (INICC; illustrative)	High-income benchmark (illustrative)	Notes on comparability
CLABSI (per 1000 central line-days)	2.57	≈4.55	≈0.8 (NHSN median, adult medical-surgical ICU)	Definitions and ICU mix vary; interpret directionally
CAUTI (per 1000 catheter-days)	1.08	≈2.91	Typically <1–2 in many adult ICU reports	Surveillance definitions/denominators differ by system
VAE/VAP (per 1000 ventilator-days)	4.21 (VAE)	≈11.96 (VAP)	Not directly comparable (VAE vs VAP)	VAE surveillance differs from VAP case definitions; use caution

Sources: HESN benchmarks from Alsheddi et al, 2023; INICC and NHSN illustrative values from Rosenthal et al, 2024 (ISID Guide chapter on CLABSI).

budget, because of the long hospital stays, consumption of expensive reserve antimicrobials, and containment of outbreaks (9). The addition of hospital-acquired venous thromboembolism surveillance (16) indicates that infection control infrastructure may be used to support broader patient safety efforts. The similarities in bundle adherence dilemma in infectious and non-infectious events justify the necessity of an integrated safety culture, instead of programme silos. International findings show that HAIs cost billions of dollars per year in health systems (3-5), and the situation in Saudi Arabia is perhaps not an exception, as the use of broad-spectrum and last-line agents was recorded.

Comparative patient safety outcome (hospital-acquired VTE)

One cohort study addressed hospital-acquired venous thromboembolism. Although VTE is not an infection, it was retained as a comparative patient safety outcome because it shares key system level determinants with HAIs (e.g. prolonged hospitalisation or immobility, risk stratification and bundle-driven prophylaxis and audit). It is therefore discussed to contextualise the broader patient-safety role of surveillance and compliance monitoring rather than as part of the HAI burden estimates (16).

Unique Saudi context

The annual Hajj and Umrah pilgrimages pose a unique challenge (7), and mass events can cause high patient turnover and increase the risk of communicable and device-related diseases. Although not all the studies discussed this, the history of outbreaks during pilgrimages highlight the need for surge-prepared IPC systems. The increasing growth of health care in Saudi Arabia by public and private entities introduces heterogeneity in IPC implementation (24).

Conclusion and recommendations

In Saudi Arabia, health care-associated infections remain a persistent patient safety challenge. The burden is concentrated on device-associated infections in intensive care units and is compounded by antimicrobial resistance and resource use. National surveillance benchmarks suggest rates that are lower than many pooled estimates from low- and middle-income settings, yet higher than those reported in many high-income settings, indicating opportunities for improvement through strengthened IPC, surveillance and antimicrobial stewardship.

Based on the synthesis of evidence, 6 strategic priorities emerge. One, there is a need to scale up nationwide programmes to rationalise antibiotic use, supported by local antibiograms and rapid diagnostics. Two, to strengthen hand hygiene and IPC culture, we must raise compliance from 70–80% to $\geq 90\%$ through sustained audits, feedback and behavioural change interventions among staff, including the cleaners. Three, there is a need to expand and unify surveillance by extending HESN to private and specialised hospitals and ensuring uniform case definitions and transparent benchmarking. Four, there is a need to leverage genomic epidemiology by incorporating environmental and molecular surveillance into outbreak investigations to detect reservoirs and transmission chains. Five, it is essential to build surge capacity by developing IPC contingency frameworks tailored for Hajj, Umrah and future pandemics, emphasising staffing resilience, device supply security and rapid auditing. Six, there is a need to address research gaps by prioritising underexplored areas such as neonatal units, transplant populations and economic analyses of the cost burden of HAIs to inform long-term system planning.

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An imperative for antimicrobial stewardship education through One Health and interprofessional education in the Eastern Mediterranean Region

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Dear Editor,

I would like to highlight critical gaps in antimicrobial stewardship (AMS) education in the Eastern Mediterranean Region (EMR) and emphasise the need for structured, competency-based training aligned with One Health and interprofessional education approaches.

Antimicrobial resistance (AMR) poses a significant public health threat worldwide, including in the EMR. Regional and global reports have consistently identified inappropriate antibiotic prescription patterns and limited stewardship training as persistent challenges in the region (1,2). In response to this increasing threat, WHO developed a health worker competency framework on AMR, which defines the core competencies needed to support appropriate antimicrobial use, and provides a curriculum guide for standardising training and assessment tools for undergraduate medical education (1). Apart from the WHO resources, other educational opportunities are available online, including workshops, e-learning courses and educational websites (3–5). Moreover, stewardship curricula are available through different organizations (6,7), including the Open University's antimicrobial resistance course, which offers open access training on AMR and stewardship principles.

Despite the availability of these global frameworks and resources, AMS education in the EMR remains fragmented and inconsistently implemented. In most medical schools, AMR content is confined to isolated microbiology, pharmacology or public health courses, with limited interdisciplinary integration and minimal competency-based assessment. Educational outcome evaluation is often inadequate, leaving graduates insufficiently prepared to prescribe antimicrobials responsibly or to advocate for stewardship practices in clinical settings (8).

Encouraging but limited examples highlight the feasibility of improving AMS education in the region. In Egypt, for example, a structured elective course titled “antibiotic prescribing etiquette” has significantly improved the knowledge, attitudes and behaviours of medical students regarding antibiotic use (8). Selected universities in Saudi Arabia have integrated WHO's online stewardship course into their undergraduate programmes (9). Although these initiatives are promising, they remain isolated and have not yet translated into systematic regional adoption.

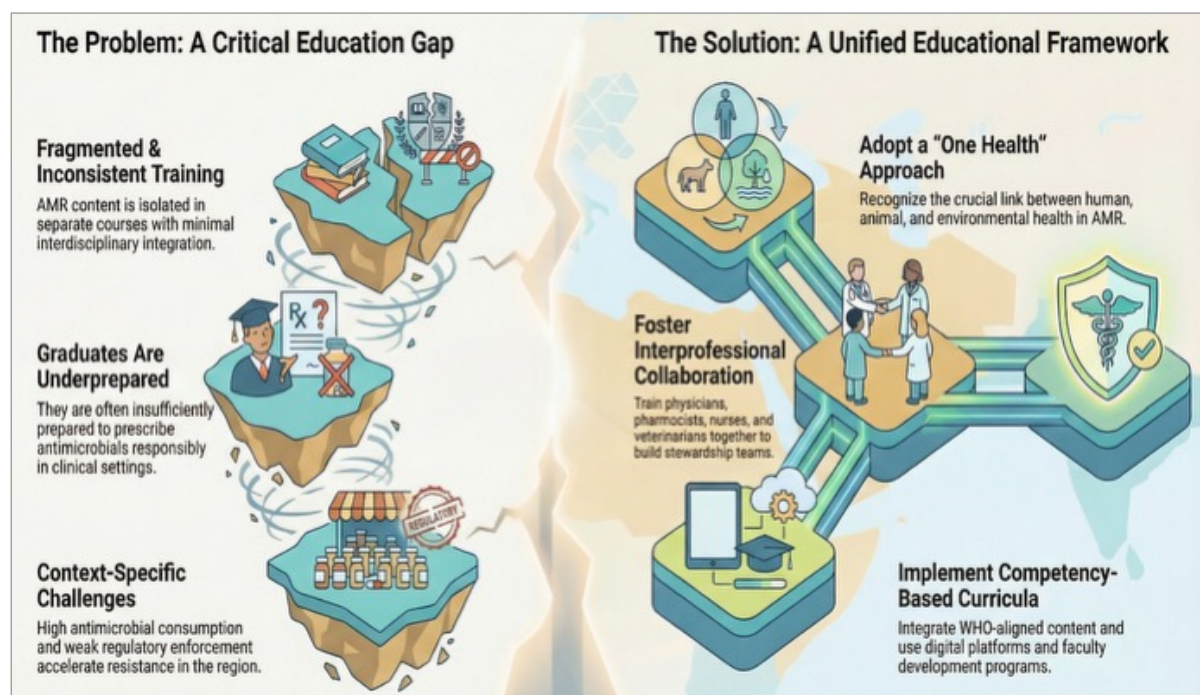
The EMR faces context-specific challenges that accelerate AMR, including high antimicrobial

consumption, limited access to diagnostics and weak regulatory enforcement. Although some countries have developed national action plans aligned with WHO guidelines, the educational and capacity-building components are often underemphasised. Experts in the region have advocated for an inclusive academic approach, and studies have suggested regular curriculum updates to improve antimicrobial use (10,11). A recent report by the WHO Regional Office for the Eastern Mediterranean highlighted the importance of strengthening education and training initiatives across the EMR, particularly for early-career prescribers (2).

AMS implementation requires collaboration among various health care professionals, including physicians, pharmacists, nurses, microbiologists, and veterinarians (Figure 1). The One Health approach, which recognises the interconnection between human, animal and environmental health, provides a relevant framework for addressing antimicrobial resistance. Adopting this approach and fostering interprofessional collaboration have been central to successful stewardship initiatives in several EMR countries (12). Blended educational models that combine online learning with in-person and interprofessional activities, may offer a practical mode for delivering AMS education in the region. Engaging medical education experts and faculty, along with securing political commitment, is vital for effective educational initiatives.

Strengthening AMS education requires deliberate integration of WHO-aligned content into competency-based curricula across the health disciplines. Interprofessional education, digital learning platforms, faculty development programmes, and train-the-trainer models can help expand teaching capacity. Aligning AMS competencies with accreditation standards and professional licensing requirements would further support sustainability and accountability.

In conclusion, strengthening antimicrobial stewardship education is vital to addressing the increasing AMR in the EMR. Universities and academic institutes should play a central role in integrating AMS into the health professions curricula and aligning educational efforts with national and global priorities. Faculty support is critical to sustain AMS and AMR initiatives and translate educational content into practice. Academic institutions can also lead advocacy and awareness activities that promote responsible antimicrobial use among health care professionals and students. Positioning AMS education

Figure 1 Gaps and solutions in antimicrobial resistance education

within the One Health and interprofessional framework will provide practical and scalable pathways for capacity building in the region. Coordinated action by academic, policymaking and accreditation institutions is urgently

needed for a competent workforce and to preserve the effectiveness of antimicrobials.

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A call for coordinated action to strengthen regional pharmacovigilance systems in the Eastern Mediterranean Region

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Dear Editor,

Pharmacovigilance is a critical pillar of safe and effective health systems, yet it remains a neglected component of many national strategies in the Eastern Mediterranean Region (EMR) (1). Despite the increasing complexity of therapies and the widespread use of multidrug regimens to treat conditions such as tuberculosis, cancer, HIV/AIDS, and non-communicable diseases, adverse drug reactions (ADRs) are frequently underreported and inadequately addressed in routine care (2).

We wish to highlight this persistent gap and call for systematic and coordinated implementation of existing strategies of the WHO Regional Office for the Eastern Mediterranean (WHO/EMRO).

Recently, we analysed over 25 tuberculosis cases from 4 provinces in southern Morocco and found a significant ADR burden, primarily comprising hepatotoxicity and neurotoxicity, which often led to treatment interruption and non-adherence (3). Although these findings are local and not generalisable, they illustrate systemic challenges reflected across EMR countries. WHO considers an ADR reporting rate of at least 200 per million population per year as a minimum standard (6). Reporting in Türkiye was as low as 2 reports per million in 2008, and despite recent progress, it only reached 84–99 reports per million in 2017–2020, still below the WHO benchmark (7).

Evidence shows that many EMR countries fall well below this threshold. In Afghanistan, Bahrain and Qatar, the number of ADR reports per year has at times been negligible or even zero (8). By contrast, many European

countries—through systems such as EudraVigilance, supported by robust infrastructure that combine spontaneous reporting with active surveillance and digital platforms—consistently exceed the 200 per million standard. These differences indicate an urgency for coordinated action at the regional level to strengthen pharmacovigilance in the EMR (4). We recommend the following actions: a regional task force established by WHO/EMRO to coordinate the efforts, allocation of seed funding to support pilot electronic reporting systems in high-burden countries, harmonized ADR reporting tools and regional digital platforms for real-time surveillance, joint regional training for healthcare providers and pharmacovigilance officers, leveraging existing success stories from Egypt and Saudi Arabia as models, and drawing on global precedents such as the European Union's EudraVigilance to demonstrate feasibility (5).

National tuberculosis programmes and ministries of health should prioritise integrating pharmacovigilance into essential public health services, particularly in resource-constrained settings (6). We call on WHO/EMRO to take the lead in mobilising the resources, coordinating stakeholders and ensuring that pharmacovigilance becomes a core pillar of patient safety in the EMR.

By investing in collaborative pharmacovigilance systems, EMR countries can improve patient safety and treatment outcomes, detect early signs of drug resistance, and enhance trust in health systems.

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Bridging the adverse drug reaction reporting gap to strengthen pharmacovigilance systems in low- and middle-income countries

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Keywords: pharmacovigilance, adverse drug reaction, ADR, LMIC

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Dear Editor,

The public health system faces a major crisis because adverse drug reaction (ADR), which is often under-recognised, causes avoidable medical complications and fatalities while generating global health care expenses. Menang et al established that low- and middle income countries (LMICs) experience most of this burden because their pharmacovigilance systems operate with insufficient funding, inadequate staffing and weak organisational structures, which often fail to identify and address medication safety concerns (1). The increasing number of medicines distributed throughout LMICs fall short of safety monitoring systems. The absence of medication monitoring has created an unsafe environment, placing vulnerable patients at increased risk.

Health care professionals, particularly in LMICs, encounter multiple obstacles hindering ADR reporting, including of heavy workloads, limited education, inadequate reporting systems, and legal concerns. However, these obstacles are not equally spread throughout the various regions. Therefore, conventional solutions cannot address them. Health professionals in South Asia encounter knowledge deficiency, while in sub-Saharan Africa, systemic failure is the challenge (1). Mohsin et al reported an estimated <5% rate of model-based actual ADR events occurring across multiple LMICs, thus highlighting the severity of the surveillance deficit (2).

Public and private sector organisations require customised context-based solutions to address the current challenges. The educational curriculum for health professionals needs to include pharmacovigilance training, from undergraduate education through post-graduate professional development. Jusot et al reported that repetitive pharmacovigilance training led to better quantity and quality of ADR reporting in sub-Saharan Africa (3). However, implementation of these advancements remains limited in many settings, because feedback operations are often discontinued, indicating

that to sustain reporting, there is a need for supportive regulatory frameworks for educational programmes.

Beyond educational interventions, structural and technological strategies are also essential to strengthen pharmacovigilance systems. The framework designed by WHO for pharmacovigilance assessment uses 3 main performance indicators to measure system effectiveness: population-based reporting rates, signal detection rate and structured feedback (4). An evaluation of pharmacovigilance systems in 51 developing nations showed that national programmes achieved an average score of 17.2 out of 63 points on WHO pharmacovigilance indicators, highlighting substantial gaps in core systems management (4). The WHO pharmacovigilance indicators receive their highest scores from countries that maintain national pharmacovigilance centres and national advisory boards (4). Thus, national regulatory frameworks in LMICs require fundamental enhancement through strategic partnerships with international organisations.

Digital platforms can enable organisations to use scalable solutions that will help them reach their objectives through ADR surveillance. Mobile reporting systems decrease administrative work requirements while enabling users to access remote locations. In a cluster-randomised trial across 367 Ugandan health care facilities involving over 2400 medical staff, the Med Safety application achieved a 73% relative increase in ADR reporting, compared with pre-intervention baseline (5). However, reporting rates may decline when active regulatory oversight is withdrawn, because digital tools function as an operational monitoring element that requires sustained human supervision.

In conclusion, improving ADR reporting in LMICs is a public health imperative. The establishment of a reliable pharmacovigilance system that safeguards at-risk populations across the world requires educational programmes that integrate digital technological advancements, regulatory monitoring and global cooperative efforts.

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First meeting of the expert advisory group on the development of Pakistan's priority pathogen list

Keywords: antimicrobial resistance, AMR, priority pathogen list, antibiotic, Pakistan

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Introduction

Antimicrobial resistance (AMR) has been implicated in nearly 60% of hospital-associated sepsis cases and more than 50% of neonatal mortality cases (1). AMR is projected to cause 1.91 million deaths annually by 2050, primarily among the elderly, and an estimated loss of up to US\$ 3.4 trillion in global Gross Domestic Product annually by 2030, if urgent preventive actions are not taken (2).

A nationally adapted priority pathogen list (PPL) is essential because it reflects the local epidemiologic and AMR trend needed to identify pathogens of greatest concern to a country's health system (3). PPL is a cornerstone of public health surveillance programmes, as it provides local data and evidence. It is very helpful for strengthening surveillance of AMR and health care-associated infections, for guiding health care policy and infection prevention strategies, and for prioritizing health research and development.

In July 2025, WHO and the Pakistan National Institute of Health held an expert advisory group meeting to discuss the draft national PPL.

Summary of discussions

In 2021, over 41% of AMR-attributable deaths in the Eastern Mediterranean Region occurred in Pakistan, where antimicrobial consumption is among the highest in the region, exceeding the regional and global averages (4). In 2022, only 24 health care facilities contributed to the WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS) (5).

Pakistan's national disease surveillance system had previously faced significant challenges; therefore, the development of a Pakistan-specific PPL offers great benefits. It will guide AMR surveillance and control efforts, support vaccine and drug development, improve antimicrobial stewardship, and make the health system more resilient and better equipped to combat the AMR crisis. To be effective, the PPL should be dynamic and updated regularly. To ensure that surveillance and AMR data from laboratory networks are reliable, there is a need to strengthen laboratory diagnostics capacity across Pakistan through a phased approach that begins with pathogens most easily identified using routine laboratory methods.

The PPL is not a replacement for the list of notifiable diseases, but a complementary tool that focuses on multidrug resistant organisms of greatest public health importance. It is a tool to inform national policy and priority-setting and enhance alignment with broader infectious disease control efforts. It is therefore important to integrate PPL with other health programmes and ensure that it is actionable, context-specific and regularly updated.

Next steps

Responses from participants will be analysed and refined, after which a virtual discussion will be held to review and agree on priority pathogens to include in the national PPL.

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State of Kuwait Prize for the Control of Cancer, Cardiovascular Disease and Diabetes in the Eastern Mediterranean Region

The State of Kuwait Prize for the Control of Cancer, Cardiovascular Disease and Diabetes in the Eastern Mediterranean Region is one of several Foundation awards, administered by the World Health Organization. It acknowledges the work of well-known scientists, researchers or dedicated people who have greatly contributed to the advancement of public health.

Purpose

The purpose of the prize is to recognize individuals who have made outstanding contribution(s) to the prevention, control or research on cancer, cardiovascular disease and diabetes.

Eligibility

There will be a maximum of three recipients per year, per disease group. Interested individuals must have made outstanding contribution(s) to the prevention, control and research on cancer, cardiovascular disease and diabetes. Current and former members of the WHO Secretariat shall not be eligible to receive the prize, and the candidature of a deceased person should not be submitted to the Foundation Committee, unless death occurs after making the nomination. A candidate who has been awarded previously, and has been re-nominated after several years, will only be eligible if a new contribution has been made. Candidates are more likely to receive the prize if they:

- contribute to the successful formulation and implementation of national policy and strategy for one or more of the cancer, cardiovascular disease and diabetes disease groups; and
- submit documentary evidence that research and other programmes have been translated into policy and have contributed to improvements in the prevention and/or control of one or more of the three disease groups.

Note

- To facilitate the assessment of their work, candidates will be requested to upload documentation in support

of their application, illustrating how they made substantive contribution to prevention, control or research in one or more of the three disease groups.

- The Foundation committee reserves the right to request further information from applicants to better assess their application

Nature of the prize and attribution

The prize consists of a bronze medal and a sum of money, which will be presented to the recipient, or their representative, in case of absence, by the Committee Chair during the Regional Committee for the Eastern Mediterranean.

Deadline for submission

The deadline for the submission of applications and nominations for the 2026 State of Kuwait Prize for the Control of Cancer, Cardiovascular Disease and Diabetes in the Eastern Mediterranean Region is **15 July 2026**.

Prize timeline

August 2026: A list of shortlisted candidates will be sent to the national health administrations for endorsement.

October 2026: The Regional Committee for the Eastern Mediterranean will decide on the recipients of the prize for 2026.

October 2027: Chair of the Regional Committee for the Eastern Mediterranean will present the award to recipients during the 74th Session of the Regional Committee.

For more information, please visit:

<http://kuwaitprize.emro.who.int/>

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