



Global Regulation of Antibiotic Sales Through Antimicrobial Stewardship Initiatives

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ABSTRACT:

Antibiotics have played a crucial role in reducing the prevalence of infectious diseases, yet their irrational use has led to the growing threat of antimicrobial resistance (AMR), which significantly impacts global health, particularly in developing countries. Conventional infections are getting harder to treat with conventional antibiotics, which raises healthcare costs and puts a strain on finances, particularly for lower-income families. AMR is estimated to be the cause of 700,000 deaths per year. Self-medication is one form of misuse that hastens the emergence of resistant pathogens. The AWaRe classification, which divides antibiotics into Access, Watch, and Reserve categories to help inform treatment choices, was created by the World Health Organization (WHO) to encourage the prudent use of antibiotics. Additionally, poor-quality and fake medications lead to treatment failures, especially in environments with limited resources. Inadequate drug regulation makes this problem worse. Antibiotic Stewardship Programs (ASPs) are essential in the fight against antimicrobial resistance (AMR). Overuse of antibiotics in developed nations is a problem brought about by patient expectations, long-standing prescription practices, and insufficient surveillance systems. The efficacy of ASP in developing countries is hampered by inadequate resources, subpar diagnostics, self-medication, and lax regulatory frameworks. The problem is made more difficult by political unrest, healthcare fragmentation, and financial limitations. Better education, stricter laws, more efficient use of resources, and international cooperation in the fight against AMR are all necessary to address these issues.

Introduction

Antibiotics have significantly mitigated the prevalence of common infectious diseases and have become imperative in a wide range of medical interventions. Irrational use of antibiotics plays a pivotal role in the emergence and spread of antimicrobial resistance, which is now a major menace to global health. It is mainly affecting the developing countries^[1]. It is approximated that about 7,00,000 people die of antibiotic resistance every year worldwide. The major cause for the accelerated development and dissemination of antibiotic resistance is the cumulative volume of antibiotic utilization. Conventional infections that were initially treated with antibiotics have become difficult to treat with standard first-line antibiotics because of antimicrobial resistance^[2]. The notable shortcoming of antimicrobial resistance is that the cost of therapy will increase, which ultimately leads to a financial burden on

the patients, especially the middle class and less affluent families. Misuse and overconsumption, especially through self-medication, have led to the loss of the capability of the antibiotics to fight infectious diseases and have resulted in the emergence of resistant species^[3].

The WHO has classified antibiotics into three categories: Access, Watch and Reserve (AWaRe). It was developed in the year 2017 by the WHO expert committee on the selection and use of essential medicines. It mainly aims at monitoring antibiotic utilization and monitoring the effects of stewardship. Access – It focuses on promoting the use of first-line antibiotics for conventional infections. E.g., Amoxicillin, Ampicillin, Benzathine Penicillin. Watch – It focuses on promoting judicious use of antibiotics that have higher resistance potential so that they can be reserved for specific situations. E.g., third-generation cephalosporins, fluoroquinolones. Reserve –



Its emphasis on restricting the use of last-line antibiotics for multi-drug-resistant infections so that they can be used as the ultimate line of defense. E.g.: Polymyxins, Tigecycline, Fosfomycin [4].

Substandard and counterfeit antimicrobial drugs can lead to failure of therapy. This can be because of sub-therapeutic or nonexistent active pharmaceutical ingredients, adverse reactions due to overdosing, or the existence of toxic ingredients. The challenge with substandard and counterfeit drugs is more prominent in low-income and developing countries. These countries face these kinds of issues majorly due to inappropriate regulation over dispensing of drugs and manufacturing of drugs [5].

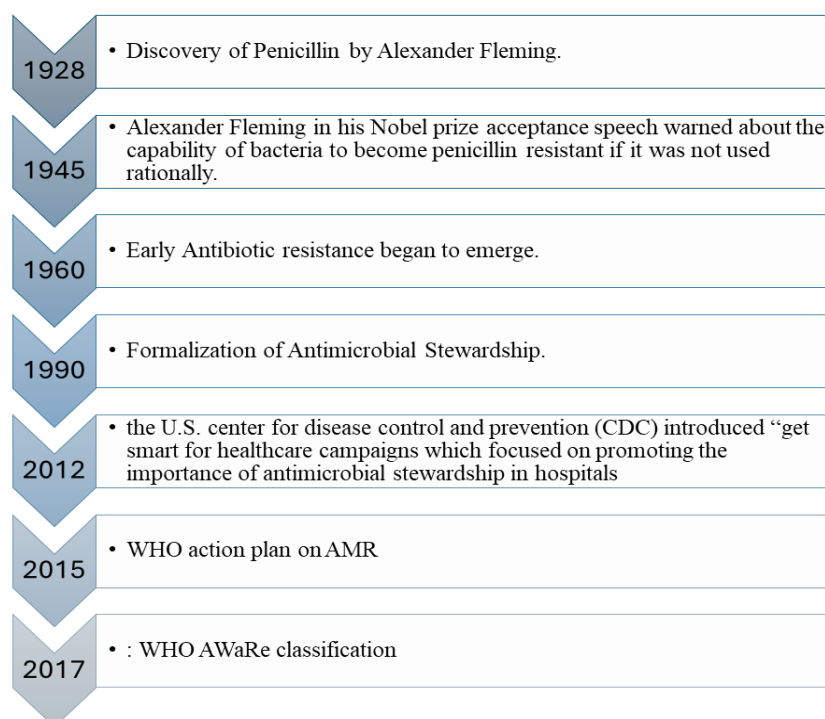
In the pre-antibiotic era (before 1928), people often died due to infectious diseases such as tuberculosis, syphilis and pneumonia. After the discovery of penicillin, *Staphylococcus aureus* was the first organism to develop resistance [6]. Newer antibiotics were discovered in the period of 1940-1960s, but multi-drug-resistant pathogens emerged. Multi-drug-resistant *Mycobacterium tuberculosis* was the first among them, followed by penicillin-resistant *Neisseria gonorrhoeae* and methicillin-resistant *S.aureus* [7]. Then came the era of

superbugs. Vancomycin-resistant enterococci emerged and multi-drug-resistant *Pseudomonas aeruginosa* and *Acinetobacter* posed problems in the healthcare settings. The modern-day crisis involves carbapenem-resistant Enterobacteriaceae, colistin-resistant *E. coli*, and *Candida auris*, which is a drug-resistant fungus that has been spreading globally [8].

Regulation around the world

History:

- The World Health Organization has been engaged in the vanguard against the growing antimicrobial resistance worldwide. It has introduced various guidelines and programs with a vision to decrease antimicrobial resistance. Antimicrobial stewardship (AMS) is one among them. This program was introduced when antimicrobial resistance was identified as a major public health conundrum. The concern of antimicrobial resistance has been validated since the discovery of antibiotics.



**WHO Antimicrobial Stewardship Program:**

Program Name	Year	Key Components	Reference
WHO Global Action Plan on AMR (GAP-AMR)	2015	Five strategic objectives: improve awareness, strengthen surveillance, reduce	[09]
WHO Guidelines on AMS in Human Health	2019	Evidence-based AMS strategies include audit and feedback, formulary restriction, education, and multidisciplinary teams for hospitals and healthcare settings.	[10]
WHO Model List of Essential Medicines (AWaRe classification)	2017	Categorizes antibiotics into Access, Watch, and Reserve (AwaRe) groups to support monitoring and promote responsible use	[11]
Global Antimicrobial Resistance Surveillance System (GLASS)	2015	Collects standardized AMR data globally, integrating lab-based surveillance and epidemiological data	[12]
Infection Prevention and Control (IPC)	2016	Promotes hand hygiene, environmental cleaning, equipment sterilization, and safe clinical practices to reduce infections	[13]
World Antimicrobial Awareness Week (WAAW)	2015	Annual campaign to improve public and professional awareness and understanding of AMR and responsible antimicrobial use	[14]
AMS Toolkits and Implementation Frameworks	2019	Provides core elements, checklists, training modules, and practical guidance for implementing AMS programs in hospitals and primary care	[15]

Antimicrobial Stewardship in Developed Countries

The United States: The US FDA plays a vital role in advocating antimicrobial stewardship in the United States. It focuses on ensuring the safe and efficient use of antimicrobials both in humans and animals. Antimicrobial susceptibility testing devices were introduced to provide guidance for healthcare professionals regarding choosing appropriate antibiotic therapy in support of stewardship programs. The FDA commences regulation of antimicrobials, from approving and labeling antimicrobials to promoting research and innovation regarding the development of new antibiotics [16]. The veterinary feed directive came into effect on January 1, 2017 with a vision to ensure antibiotics are used only when necessary. The Veterinary Feed Directive (VFD) was implemented with an aim to regulate the use of antibiotics in animal feed. Risk

Evaluation and Mitigation Strategies (REMS) was introduced with a vision to ensure that the benefits outweigh the risks of antibiotics being used, especially for certain high-risk antibiotics [17].

China: China has a high burden of antimicrobial resistance. The Chinese government, in collaboration with healthcare institutions and international organizations, has implemented various initiatives to promote rational use of antibiotics and fight AMR [18]. China has banned the use of certain antibiotics in animal feed as growth promoters. A national action plan on AMR was launched to address the growing threat of AMR. China's antimicrobial resistance surveillance systems monitor antibiotic use. It also monitors antimicrobial resistance patterns across the country. The Chinese government strictly asks hospitals to conduct antibiotic prescription audits and report the data. There



are prescribed limits for outpatient and inpatient antibiotic use^[19].

Europe: Europe has a well-established antimicrobial stewardship program. The European One Health Action Plan against AMR was introduced with an objective to address AMR through a One Health approach covering human and animal health. It aimed to strengthen international collaboration on AMR. EU legislation on veterinary medicines and medicated feed restricts the use of antibiotics in animals and ensures that antibiotics are used under veterinary supervision only^[20]. ECDC Antimicrobial Resistance Surveillance (EARS-Net) monitors AMR in invasive bacterial infections across the European Union. EARS-Net is an EU-wide surveillance system for monitoring antimicrobial resistance. It tracks AMR trends, identifying emerging threats and launching AMR plans^[21]. ECDC Antimicrobial Consumption Surveillance (ESAC-Net) tracks antibiotic consumption in humans. ESAC-Net is a European surveillance network that monitors antibiotic consumption across the EU^[22]. European Antibiotic Awareness Day is observed on November 18th every year to raise awareness regarding antibiotic resistance^[23].

Antimicrobial Stewardship in Developing and Lower Middle-Income Countries (LMICs)

India: India has a high health burden due to misuse of antibiotics and limited availability of healthcare infrastructure. The National Action Plan on AMR, launched in the year 2017, intends to improve awareness and understanding of AMR, reduce infection, and promote rational use of antibiotics in humans and animals. ICMR has established an Antimicrobial Stewardship Program in hospitals across the country^[24]. ICMR has also launched the National Antimicrobial Resistance Surveillance Network (NARS-NET), which monitors AMR trends across the country. NARS-NET is a surveillance network established by government or health regulatory organizations with an aim to collect, analyze, and share data related to AMR. The collective data from hospitals, clinics, or lab reports are uploaded to a central database, which analyzes any outbreaks and alerts the public. The National Center for Disease Control plays a key role by promoting public awareness and capacity building^[25]. The Food Safety and Standards Authority of India (FSSAI) monitors the use of antibiotics in the animal food sector to prevent the spread

of resistance. FSSAI is a regulatory body that ensures the safety and standard of food across India. They perform functions like regulating food standard licensing and registration, consumer awareness and training, and food safety monitoring^[26].

Ghana: Antibiotic stewardship in Ghana, like in many other countries, is a vital aspect of public health aimed at ensuring the proper use of antibiotics to prevent antibiotic resistance. In Ghana, the overuse and misuse of antibiotics in both healthcare and agricultural settings are contributing to a growing threat of antibiotic-resistant infection, which can make infections harder to treat and increase mortality rates. Ghana has developed policies aimed at limiting the misuse of antibiotics, such as the National Policy on Antimicrobial Resistance (AMR)^[27]. This policy lays out strategies to monitor, control, and promote the rational use of antibiotics in healthcare. However, enforcement of these policies is often unstable due to limited resources, incomprehension, and weak healthcare infrastructure. Ghana is working to improve surveillance systems for antibiotic use and resistance. However, the country still faces challenges in collecting and analyzing data on the extent of antibiotic resistance due to limited laboratory capacity and resources. Boosting surveillance systems will provide better data for evaluation^[28].

Chile: Antibiotic stewardship in Chile has gained substantial attention in recent years, as the country has worked to address the risky hazard of antimicrobial resistance (AMR). Chile has designed a National Action Plan on Antimicrobial Resistance (AMR), which outlines strategic actions to combat AMR. The plan reflects the World Health Organization's (WHO) Global Action Plan on AMR and focuses on elevating antibiotic prescribing, upgrading surveillance, and encouraging public awareness. The plan is an intersectoral approach involving various government agencies, healthcare providers, agricultural sectors, and the public^[29]. The Ministry of Health in Chile has established guidelines for the intended use of antibiotics in hospitals and primary care settings. Hospital antibiotic stewardship programs (ASPs) are being executed to ensure that antibiotics are prescribed only when required and in the correct dosages and durations. The goal is to reduce unnecessary or inappropriate use, which aids to the development of resistant bacteria. Chile has adopted clinical guidelines for treating common infections, which include



recommendations for the rational use of antibiotics. These guidelines are regularly updated based on emerging resistance patterns^[30]. Chile has secured its surveillance systems to monitor AMR patterns. The Chilean National Program for Surveillance of Antimicrobial Resistance helps track resistance trends in both human health and animal health. Surveillance data is used to update national policies and modify treatment guidelines accordingly^[31]. Chile has begun taking steps to regulate the use of antibiotics in animal husbandry more effectively. In 2018, the Agriculture and Livestock Service (SAG) implemented a law that requires the prescription of antibiotics for veterinary use. This regulation aims to reduce the uncontrolled use of antibiotics in agriculture^[32].

Uganda: Antimicrobial stewardship (AMS) in Uganda is a vital concern given the worsening hazard of antimicrobial resistance (AMR), which poses a critical challenge to the healthcare system and public health. AMR occurs when bacteria, viruses, fungi, and parasites become resistant to the drugs that had eliminated them or impeded their growth. This makes infections harder to treat, leading to longer hospital stays, more high-cost treatments, and elevated mortality. In Uganda, as in many other developing countries, AMR is escalated by factors such as overuse and misuse of antibiotics, knowledge gaps, and limited resources. Uganda has developed a National Action Plan (NAP) on Antimicrobial Resistance, which aligns with the World Health Organization's (WHO) Global Action Plan to combat AMR. The goal of the NAP is to lower the emergence and spread of AMR through a multi-sectoral approach involving human health, animal health, agriculture, and the environment. The action plan aims at enhancing the oversight and regulatory frameworks for antibiotic use, supporting the rational use of antibiotics in both healthcare and agriculture, and strengthening surveillance systems to inspect AMR patterns^[33]. Uganda has also made efforts to support AMR surveillance, although the country still faces significant gaps in terms of resources and infrastructure^[34]. The Uganda National Health Laboratory Services (UNHLS) and the Ministry of Health (MOH) collaborate with international organizations like the WHO and the Centers for Disease Control and Prevention (CDC) to monitor AMR trends. Surveillance data is critical in informing treatment guidelines and the development of policies to

curb AMR. In Uganda, some hospitals have started implementing antibiotic stewardship programs, particularly in major referral hospitals such as Mulago National Referral Hospital. However, limited laboratory capacity, specifically in rural areas, remains a challenge to extending effective surveillance^[35]. Hospital antibiotic stewardship programs (ASPs) are vital for reducing unnecessary antibiotic use and enhancing patient outcomes. These programs aim to promote the rational use of antibiotics by developing and implementing guidelines for prescribing antibiotics, monitoring antibiotic prescribing patterns in hospitals and providing feedback to healthcare providers, and conducting training for healthcare workers on pertinent antibiotic use and the potential harm of AMR^[36].

Sudan: Antimicrobial stewardship (AMS) in Sudan is an emerging field of focus due to the intensifying threat of antimicrobial resistance (AMR), which poses critical threats to public health. Like many developing countries, Sudan faces challenges in implementing effective antibiotic stewardship, including healthcare resource constraints, inadequate regulatory enforcement, and high rates of inappropriate antibiotic use in both healthcare and agricultural sectors. However, there are ongoing efforts to confront these issues and diminish the impact of AMR. Sudan has developed a National Action Plan (NAP) on Antimicrobial Resistance, which is aligned with the World Health Organization's (WHO) Global Action Plan to address AMR. The goal of the NAP is to reduce the spread of antimicrobial resistance by encouraging the rational use of antibiotics, enhancing surveillance, and raising awareness about AMR. Key priorities outlined in the NAP include strengthening regulatory frameworks and improving the enforcement of antibiotic prescription laws, increasing surveillance of antibiotic use and resistance patterns, and upgrading public education and training of healthcare providers on the appropriate use of antibiotics^[37]. Sudan has established regulations governing the sale and dispersion of antibiotics. The National Medicines and Poisons Board is responsible for regulating pharmaceuticals, including antibiotics, in Sudan. However, one of the major challenges is the weak enforcement of these regulations. Antibiotics are often sold over-the-counter without prescriptions in many parts of the country, which leads to misuse and overuse. Strengthening enforcement, increasing monitoring of drug outlets, and conducting



periodic inspections are necessary to curb the illegal sale of antibiotics and reduce inappropriate use^[38]. In some of Sudan's major hospitals, efforts have been made to create antibiotic stewardship programs (ASPs) to promote the rational use of antibiotics. These programs aim to ensure that antibiotics are prescribed based on

standard procedure and the appropriate clinical indications, monitor antibiotic prescribing patterns and provide suggestions to healthcare providers, and provide training to healthcare professionals on the principles of antimicrobial stewardship, appropriate prescribing practices, and AMR^[39].

Antibiotic Stewardship in other countries.

Country	Existence of ASP	Key stakeholders involved	Implementation level	Challenges Noted
Canada	Yes	Health Canada, Public Health Agency, hospitals	National/Provincial	Variation across provinces, data integration issues
Germany	Yes	Federal Ministry of Health, hospitals	National	Outpatient sector engagement, regional differences
Japan	Yes	Ministry of Health, hospitals	National	Aging population, overprescription in outpatient care
Brazil	Yes	ANVISA, Ministry of Health	National	Over-the-counter (OTC) misuse, lack of enforcement
Mexico	Yes	COFEPRIS, hospitals, private sector	National	OTC sales, limited surveillance
Nigeria	Limited/Developing	NCDC, teaching hospitals	Pilot/Local Initiatives	Regulatory gaps, low awareness, limited funding
Cambodia	Emerging	Ministry of Health, NGOs	Project-based	Weak enforcement, informal providers
Afghanistan	Very Limited	WHO, NGOs, public hospitals	Not Structured	Conflict, lack of policy, informal drug market
Bangladesh	Developing	DGHS, Ministry of Health	National Action Plan	Poor regulation, high antibiotic misuse, informal sales



Challenges to Implementation of Antimicrobial Stewardship Programs:

Antibiotic stewardship program challenges in developed countries:

Antibiotic stewardship programs (ASPs) are essential in combating antimicrobial resistance (AMR), even in developed countries, as these programs aim to optimize antibiotic use to improve patient outcomes, reduce adverse effects, and slow the development of resistance. While developed nations generally have more resources and infrastructure for implementing ASPs, several challenges persist. Below are some of the key challenges faced by ASPs in developed countries:

Antibiotic Overuse and Misuse

Patient Expectations: In many developed countries, patients often expect antibiotics for various conditions, particularly viral infections where antibiotics are ineffective. This demand for antibiotics can pressure healthcare providers to prescribe them unnecessarily, even when they are not needed.

Prescribing Habits: Despite evidence supporting the benefits of appropriate antibiotic prescribing, some healthcare providers may have ingrained practices that favor the use of antibiotics for common infections like respiratory tract infections. Changing these habits requires sustained education and awareness campaigns for healthcare professionals.

Empirical Prescribing: In cases where rapid diagnoses are challenging, healthcare providers may prescribe broad-spectrum antibiotics "just in case" to cover a wide range of potential pathogens, even when the infection is likely viral or can be better targeted with a more specific treatment^[40].

Antimicrobial Resistance (AMR) Surveillance and Data

Fragmented Surveillance Systems: Even in developed countries, AMR surveillance can be fragmented across different healthcare settings (hospitals, outpatient clinics, long-term care facilities, etc.). This fragmentation makes it challenging to gather consistent, national-level data on resistance patterns and to make real-time, evidence-based prescribing decisions.

Resistance Data Delays: The time lag in receiving AMR data can delay responses and hinder decision-making. Early identification of emerging resistance patterns is critical to preventing widespread issues, but limited resources and infrastructure for real-time surveillance can impede this^[41].

Integration of ASPs into Routine Practice

Lack of Staff or Resources: ASPs often require a dedicated team, including infectious disease specialists, pharmacists, microbiologists, and other healthcare providers. In some developed countries, there may be a shortage of trained professionals or insufficient funding to implement or expand these teams, particularly in smaller healthcare settings or rural areas^[42].

Workload and Time Constraints: Healthcare providers, especially in busy hospitals or primary care settings, may find it challenging to prioritize ASPs alongside other urgent tasks. Time pressures can lead to less thorough reviews of antibiotic prescriptions or a lack of follow-up on stewardship interventions.

Electronic Health Records (EHR) Limitations: While EHRs have made data collection and management easier, many systems do not have built-in tools that support real-time decision-making for antibiotic prescriptions. The integration of clinical decision support tools into EHRs is crucial but can be challenging due to system limitations, lack of standardization, and high implementation costs^[43].

Antibiotic Resistance in Hospitals and Healthcare Settings

Healthcare-associated Infections: Hospitals and long-term care facilities often serve as hotspots for resistant infections, particularly in patients with complex medical conditions, weakened immune systems, or those requiring prolonged care. Managing antibiotic resistance in these settings requires stringent infection control measures, such as isolation protocols and hand hygiene practices, alongside stewardship efforts.

Frequent Use of Broad-Spectrum Antibiotics: In hospitals, broad-spectrum antibiotics are frequently used to manage complex infections, which can contribute to the development of resistance. Even with stewardship programs in place, the use of broad-spectrum agents for empirical treatment remains common^[44].



Antibiotic Use in Surgery and ICU: The use of antibiotics in surgical prophylaxis and intensive care units (ICUs) is another area where stewardship programs face challenges. While there is a push to use the narrowest spectrum possible and to limit durations of antibiotic courses, the need for effective prophylaxis in high-risk patients complicates stewardship efforts [45].

Outpatient Antibiotic Prescribing

Primary Care Prescribing Habits: In developed countries, much of the antibiotic overuse occurs in outpatient settings, particularly in primary care. Studies have shown that a significant number of antibiotics are prescribed for conditions like viral infections (e.g., colds, flu, sore throats) where antibiotics are not effective. Changing the behaviour of primary care physicians and other outpatient clinicians requires addressing patient expectations and providing more robust diagnostic support [46].

Public Awareness and Education

Patient Demand and Misinformation: Despite public health campaigns, many patients in developed countries still expect antibiotics for conditions that do not require them. Misconceptions about the necessity of antibiotics and a lack of understanding about AMR persist, which can lead to non-compliance with stewardship recommendations.

Misinformation on social media: The spread of misinformation about antibiotics and their effectiveness via social media and other online platforms further complicates public education efforts. Correcting these misconceptions and educating the public about the dangers of overusing antibiotics is a challenge for both health authorities and stewardship programs [47].

Antimicrobial stewardship program challenges in developing and underdeveloped countries:

Antibiotic stewardship programs (ASPs) play a critical role in managing and curbing antimicrobial resistance (AMR) by promoting the rational use of antibiotics. However, in developing and underdeveloped countries, the implementation and success of these programs face several significant challenges due to resource constraints, lack of infrastructure, and other systemic issues. Below are the key challenges in antibiotic stewardship programs in developing and underdeveloped countries:

Limited Healthcare Resources

Shortage of Trained Personnel: Many developing and underdeveloped countries face shortages of healthcare workers, including doctors, nurses, pharmacists, and microbiologists. This makes it difficult to establish and maintain effective ASPs, as these programs require trained personnel to monitor and guide appropriate antibiotic use, provide education, and evaluate prescribing practices.

Insufficient Infrastructure: Many healthcare facilities, particularly in rural areas, lack the necessary infrastructure for proper infection prevention and control (IPC) measures, which are closely linked to the effectiveness of ASPs. Inadequate facilities and limited access to diagnostic tools make it challenging to implement stewardship programs that rely on accurate diagnosis and proper treatment regimens [48].

Lack of Diagnostic Capacity

Limited Access to Diagnostic Tools: In many low- and middle-income countries, healthcare providers lack access to modern diagnostic tools, such as microbiology labs and point-of-care testing. Without the ability to quickly and accurately diagnose infections, doctors often rely on empirical treatment (broad-spectrum antibiotics), which contributes to overuse and inappropriate antibiotic prescribing.

Delayed Results: Even when diagnostic tests are available, delays in laboratory results can lead to prolonged use of antibiotics, as clinicians may prescribe broad-spectrum antibiotics while awaiting test results [49].

Over-the-Counter (OTC) Antibiotic Sales and Self-Medication

Widespread Self-Medication: In many developing and underdeveloped countries, antibiotics are available over-the-counter (OTC) without a prescription, leading to widespread self-medication. Patients often purchase antibiotics for self-diagnosed conditions, contributing to misuse and the development of resistance [50].

Informal Drug Markets: Antibiotics are often sold in informal drug markets or by street vendors without proper regulation. This creates a situation where antibiotics are easily accessible, even for conditions where they are not needed, exacerbating the problem of AMR [51].



Cultural Factors and Patient Expectations

Patient Demand for Antibiotics: In many developing countries, patients often demand antibiotics, especially for common viral infections like colds and flu, where antibiotics are ineffective. The belief that antibiotics are the cure for a wide range of ailments persists, and healthcare providers may feel pressured to prescribe antibiotics to meet patient expectations.

Lack of Public Awareness: Many people in developing countries are not fully aware of the risks of antibiotic misuse and AMR. Cultural beliefs and practices around medicine and health care can also influence the demand for antibiotics and contribute to non-compliance with prescribed regimens^[52].

Inadequate Regulatory Frameworks and Enforcement

Weak Regulatory Systems: In many developing and underdeveloped countries, regulations surrounding the sale and prescription of antibiotics are often weak or poorly enforced. The lack of strong regulatory frameworks and enforcement mechanisms allows antibiotics to be freely sold without prescriptions, further contributing to inappropriate use.

Corruption and Non-Compliance: Even when regulations exist, corruption or lack of political will can hinder enforcement. Pharmacies and drug vendors may not follow guidelines, and informal or black-market sales of antibiotics may continue unchecked^[53].

Economic Constraints

Limited Funding for AMS Programs: Many developing countries face budgetary constraints that make it difficult to allocate sufficient resources for implementing and maintaining ASPs. There may be limited financial support for staffing, training, monitoring, and the purchase of essential diagnostic tools or antibiotics.

Cost of Medicines: Even when guidelines for appropriate antibiotic use are in place, the cost of certain antibiotics, particularly newer or second-line agents, may be prohibitively high. This can lead to the use of cheaper, broad-spectrum antibiotics or the self-medication of low-cost alternatives that may not be the most appropriate^[54].

Infection Control and Surveillance Challenges

Weak Infection Prevention and Control Measures: Effective ASPs require strong infection control practices to prevent the spread of resistant infections in healthcare settings. In many developing and underdeveloped countries, infection control measures are inadequate or not consistently implemented, which can undermine the effectiveness of stewardship efforts^[55].

Limited Surveillance Systems: Surveillance systems for AMR in developing countries are often underdeveloped or fragmented. Lack of data on the extent of resistance and the prevalence of resistant infections makes it difficult to assess the impact of stewardship programs and adapt strategies accordingly. The absence of comprehensive, national-level surveillance data also hinders policymakers' ability to implement targeted interventions^[56].

Fragmented Healthcare Systems

Lack of Coordination Across Healthcare Settings: In many developing countries, healthcare systems are fragmented, with limited communication between primary care, hospitals, and rural healthcare settings. This fragmentation can lead to inconsistent antibiotic prescribing practices, with little oversight or feedback on usage across different healthcare levels.

Multiple Providers: Patients often see multiple healthcare providers for the same condition (e.g., visiting different clinics, pharmacies, or traditional healers), leading to fragmented care and inconsistent antibiotic use. This lack of coordinated care can make it difficult to track and optimize antibiotic prescriptions^[57].

Resistance in Agriculture and Animal Use

Widespread Use of Antibiotics in Agriculture: In some developing countries, antibiotics are used extensively in agriculture for purposes such as disease prevention and growth promotion in livestock. The use of antibiotics in animals, particularly in the absence of veterinary supervision, is a significant contributor to AMR. The lack of regulations in the agricultural sector exacerbates the problem, as resistant bacteria in animals can be transmitted to humans through the food chain.

Lack of Awareness Among Farmers: Many farmers may not be aware of the risks associated with the overuse of antibiotics in animals or may lack access to



alternatives like vaccines or improved farming practices that reduce the need for antibiotics [58].

Political and Social Instability

Instability and Conflict: Governmental unrest, war, and conflict in some developing and underdeveloped countries create major obstacles to the implementation of effective healthcare programs, including AMS. Interference of health services, lack of access to essential

medications, and the failure of medical services infrastructure make it harder to execute and sustain stewardship programs [59].

Migration and Refugee Crises: Large movements of people due to conflict, poverty, or natural disasters can lead to the spread of resistant infections across borders, further complicating AMR control efforts [60].

Challenge Category	Key issues
Limited Healthcare Resources	<ul style="list-style-type: none"> - Shortage of trained healthcare professionals (pharmacists, ID specialists) - Inadequate infrastructure and hospital capacity for ASP implementation
Lack of Diagnostic Capacity	<ul style="list-style-type: none"> - Scarcity of microbiology labs - Limited access to rapid diagnostics - Delays in test results hinder evidence-based prescribing.
OTC Antibiotic Sales and Self-Medication	<ul style="list-style-type: none"> - Easy availability of antibiotics without prescription - Lack of pharmacist regulation - Self-medication driven by convenience or economic reasons
Cultural Factors and Patient Expectations	<ul style="list-style-type: none"> - Social norms encouraging antibiotic use for minor illnesses - Patient pressure on providers to prescribe antibiotics
Inadequate Regulatory Frameworks and Enforcement	<ul style="list-style-type: none"> - Weak or absent policies on antibiotic stewardship - Poor enforcement of existing laws on prescription-only use
Economic Constraints	<ul style="list-style-type: none"> - Insufficient government and donor funding - Competing healthcare priorities (e.g., maternal care, infectious diseases) - High cost of ASP setup
Infection Control and Surveillance Challenges	<ul style="list-style-type: none"> - Poor implementation of IPC guidelines - Inadequate AMR surveillance systems - Underreporting of resistance data
Fragmented Healthcare Systems	<ul style="list-style-type: none"> - Lack of coordination among public, private, and informal sectors - Inconsistent ASP implementation across facilities
Resistance in Agriculture and Animal Use	<ul style="list-style-type: none"> - Excessive use of antibiotics in livestock - Lack of regulation in veterinary medicine - Cross-resistance from animal to human AMR
Political and Social Instability	<ul style="list-style-type: none"> - Disruption of healthcare services due to conflict or unrest - Limited prioritization of AMR during emergencies - Brain drain of skilled professionals



Discussion

The findings of this assessment draw attention to the critical role that community pharmacists can and have to play in addressing the global crisis posed by antimicrobial resistance (AMR). As essential health care workers, pharmacists are regularly the primary point of contact for sufferers in search of medical directives, in particular in low- and middle-income nations (LMICs) where access to physicians can be controlled.

This role places pharmacists in a unique position to induce antibiotic use definitely or negatively, relying on their expertise, attitudes, and practices. The evaluation regularly suggests that at the same time as community pharmacists typically have core knowledge of antibiotic resistance and recognize its seriousness. This disconnect between knowledge and conduct is a principal subject matter throughout the literature and is stimulated by using a couple of frequently overlapping factors.

Moreover, the evaluation points to systemic problems that exacerbate irrational antibiotic shelling out. Many pharmacists report insufficient access to up-to-date scientific recommendations, continuing professional development possibilities, and guidance from public health structures. The lack of regular training and reinforcement of antibiotic stewardship standards means that pharmacists may depend heavily on empirical expertise or previous practices. Furthermore, in a few settings, there is a blurred line between the pharmacist's function and that of the prescriber, further complicating efforts to promote rational antibiotic use.

The mindset of pharmacists in the direction of antibiotic stewardship is generally high quality, with many expressing concerns over growing resistance tiers and an enthusiasm to make contributions to answers. However, positive attitudes on my own do not guarantee appropriate behaviour, particularly when pharmacists function in environments lacking the structural guide to act consistent with their assurance. This includes weak enforcement of pharmaceutical laws, restrained inspection mechanisms, and low penalties for non-compliance.

From a practical viewpoint, the reviewed studies screen variations in the way antibiotics are distributed. Many pharmacists admit to distributing antibiotics for viral infections or without assessing the total scientific picture,

which can result in therapeutic failure, adverse outcomes, and the acceleration of resistance. This is particularly tricky in instances in which there is minimal conversation among pharmacists and different healthcare providers. Inadequate referral structures, inadequate documentation, and a loss of shared electronic health facts further contribute to uncoordinated care and bad antimicrobial oversight.

The evaluation indicates that addressing the distance between knowledge and exercise requires a comprehensive strategy. Educational interventions remain critical, but they have to be ongoing, realistic, and context-precise. Integrating antibiotic stewardship into pharmacy curricula and making it a requirement for licensure renewal can assist in reinforcing desirable practices. Simultaneously, rules ought to be sustained in restriction of non-prescribed sales, supported by regular monitoring, penalties for non-compliance, and incentives for ethical exercise.

Collaboration is a vital future approach. Pharmacists should be included in national and nearby antimicrobial stewardship packages along with physicians and nurses. Strengthening interprofessional relationships can promote the transfer of statistical data and shared choice-making in patient care. Moreover, virtual tools, which include e-prescribing structures and cell apps presenting medical opinions, can aid pharmacists in making informed decisions.

Limitations in the studies reviewed need to additionally be stated. Most of the literature to be had is cross-sectional, relying heavily on self-suggested records, which may be difficult to bias. Future studies need to prioritize longitudinal and intervention-based designs to better recognize the long-term effectiveness of tutorial and regulatory interventions. Additionally, qualitative research exploring pharmacists' lived studies can provide richer insights into the contextual and psychological elements influencing their practices.

Conclusion

This review establishes the important role that community pharmacists occupy within the broader effort to fight antibiotic resistance. Although demonstrating relevant information and a usually effective mindset towards antimicrobial stewardship, their actual practices often diverge from validated guidance. The massive



dispensing of antibiotics without prescriptions, coupled with insufficient affected person training and susceptible regulatory oversight, keeps fueling improper antibiotic use in lots of settings.

Reconciling the differences between know-how and exercise is paramount. This calls for complex methods that consist of non-stop expert schooling, stronger enforcement of pharmaceutical laws, and integration of pharmacists into country-wide antimicrobial stewardship packages. Policymakers should prioritize the implementation of context-unique interventions that keep in mind financial constraints, patient behaviour, and healthcare infrastructure. Additionally, utilizing digital equipment and promoting interprofessional collaboration can elevate pharmacists' capability to make knowledgeable, evidence-based decisions.

Empowering pharmacists via supportive structures, clear guidelines, and ongoing education is not merely useful. With collective actions from governments, professional bodies, healthcare institutions, and groups, network pharmacists can emerge as principal triggers in the worldwide fight against antimicrobial resistance.

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