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Antimicrobial Stewardship Programs: Clinical Pharmacist Role in Combating Antimicrobial Resistance

Saba hameed Majeed*
Department of Clinical Pharmacy, College of Pharmacy, Al-Nahrain University, Baghdad, Iraq

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ABSTRACT **Original Research Article**

Antimicrobial resistance (AMR) has emerged as a critical global health challenge, driven largely by the inappropriate use of antimicrobial agents. Antimicrobial Stewardship Programs (ASPs) are essential strategies designed to optimize antimicrobial use, improve patient outcomes, and reduce resistance. This study explores the pivotal role of clinical pharmacists within ASPs in combating AMR. Clinical pharmacists contribute significantly through interventions such as formulary management, dose optimization based on pharmacokinetic and pharmacodynamic principles, de-escalation of therapy, and therapeutic drug monitoring. Additionally, their involvement in surveillance, audit, feedback, and interprofessional collaboration enhances the effectiveness of stewardship initiatives. Evidence suggests that pharmacist-led interventions improve prescribing practices, reduce unnecessary antimicrobial use, and lower healthcare costs. Despite these benefits, challenges such as limited resources, lack of awareness, and insufficient integration of pharmacists into healthcare teams persist. Strengthening the role of clinical pharmacists through structured training, policy support, and multidisciplinary collaboration is crucial for the successful implementation of ASPs. Ultimately, empowering clinical pharmacists can significantly contribute to controlling AMR and improving global health outcomes.

Keywords: Antimicrobial resistance, Antimicrobial stewardship, Clinical pharmacist, Drug optimization, Healthcare outcomes.

**Corresponding author: Saba hameed Majeed*
Department of Clinical Pharmacy, College of Pharmacy, Al-Nahrain University, Baghdad, Iraq

Introduction

In the 21st century, antimicrobial resistance (AMR) poses a growing threat to global health. With increasing resistance to commonly used antimicrobials, treatment options become limited, leading to increased morbidity, mortality, and healthcare costs. In the United States alone, at least 2.8 million antibiotic-resistant infections occur each year, causing over 35,000 deaths and additional healthcare costs of $20 billion per year, not counting productivity losses due to illness.[1]

Antimicrobial stewardship programs (ASPs) play a critical role in optimizing antimicrobial use, improving patient outcomes, and reducing resistance. These programs are mandated for all acute healthcare organizations by the Joint Commission and are highly encouraged for outpatient settings by the Centers for Disease Control and Prevention. Local, state, national, and international guidelines are available to assist health systems in designing and implementing effective ASPs.[2]

In addition to infectious disease physicians and hospital epidemiologists, clinical pharmacists constitute a core member of ASP multidisciplinary teams. They are uniquely qualified to assess the appropriateness of antimicrobial prescriptions and ensure optimal drug selection and dosing according to pathogen susceptibility patterns and pharmacokinetic/pharmacodynamic principles. Pharmacists' contributions to antimicrobial stewardship are well documented in the literature, yet gaps persist in the understanding of their roles, especially in settings where dedicated infectious disease consultations are not routine.

Critical roles of clinical pharmacists explained in ASPs, particularly outside the inpatient arena, is of paramount importance.[3]

Conceptual Foundations of Antimicrobial Stewardship

In addition to the introduction of multitudinous effective antimicrobials, infectious diseases remain among the top contributors to global mortality. This situation has aggravated due to the misuse and overuse of these drugs and other antimicrobial agents, leading to resistance at alarming rates. The emergence of multidrug-resistant (MDR) pathogens represents one of the most serious threats to effective widespread treatment of infections worldwide. Infections due to MDR pathogens increase length of hospital stay, cost of treatment, and mortality.[4] Accurate pathogen identification and determination of susceptibility patterns are crucial to guide therapy and limit the usage of broad-spectrum antibiotics. Non-infectious triggers for initiation of antimicrobials, polymicrobial infections, and unavailability of rapid diagnostics contribute to the continued initiation of inappropriate therapy, non-therapeutic prolongation, and excessive de-escalation. Antimicrobial stewardship programs are needed to improve appropriateness of prescribing and thereby the overall usage of broad-spectrum agents. Interventions aimed at optimizing antimicrobial use and augmenting existing stewardship programs reduce inappropriate prescribing.[5]

Antimicrobial stewardship encompasses a set of coordinated strategies to improve and measure the appropriate use of antimicrobials. Clinical Pharmacists have emerged as pivotal members of antimicrobial stewardship teams, directly managing therapy, offering consultative services, and collaborating with other healthcare providers. Enhancing the pharmacist role extends the capabilities of stewardship programs beyond the Infectious Diseases (ID)-trained physician team lead. Pharmacists facilitate the implementation of stewardship programs by participating in weekly review of all new and existing surgical and medical patients receiving broad-spectrum therapy. In absence of an ID consult, they provide daily assessment of patients on broad-spectrum agents and make recommendations to de-escalate therapy after pathogen identification and susceptibility determination.[6]

Global Burden of Antimicrobial Resistance

Antimicrobial resistance (AMR) is a worldwide public health threat. Antimicrobial stewardship activities can address AMR and optimize the use of antibiotics to improve patient outcomes and decrease healthcare costs. Efforts to combat AMR are urgently needed since AMR is responsible for more than 2 million infections and 23,000 deaths annually in the United States. In 2050, AMR is projected to cause 10 million deaths worldwide every year, surpassing cancer and motor vehicle fatalities.[7] AMR is also projected to add an additional USD 1.1–5.4 trillion in healthcare costs and productivity loss. A considerable proportion of AMR cases is attributable to the inappropriate use of antibiotics. Consequently, the role of antimicrobial stewardship programs has significantly increased.[8]

Core Components of Antimicrobial Stewardship Programs

In national and international guidelines on antimicrobial stewardship, core components vary according to the information needed and local prescribing practices. Several guidelines describe prerequisites essential to establish a trusted stewardship program before implementing the core components.[8] An example of these basic requirements for the program includes elicitation of facility-based antimicrobial resistance pattern, monitoring of antimicrobial utilization, selecting the core team to initiate the program, and securing administrative commitment for antimicrobial stewardship initiatives.[3,9] Although the core components differ from one document to another, the role of dispensing oversight in optimizing antimicrobial use appears to be universally recognized as a recommended activity dedicated to the stewardship program according to guidelines provided by WHO, CDC, NPSA and others. Similar consideration is also noticed on the advice of sustaining appropriate therapy collaboration with healthcare professional, knowing closely the resistance behaviour of local pathogens, and extensive awareness of usage in facility.[10]

Clinical Pharmacist Roles in Stewardship

Antimicrobial resistance (AMR) represents a global health threat that is reclaiming a prominent place on the public health agenda. Antimicrobial stewardship (AMS) programs aimed at optimising antimicrobial use can reduce AMR.[8] Clinical pharmacists can significantly contribute to AMS. Their competencies in pharmacology, therapeutic drug monitoring (TDM), pharmacokinetics and pharmacodynamics (PK/PD), and infection prevention and control make them central members of interdisciplinary AMS teams. Programmes led by clinical pharmacists have been shown to enhance the use of antimicrobials, optimise treatment, and limit unnecessary prescriptions.[7, 11]

Regardless of the type of healthcare facility, the following activities of clinical pharmacist supervision focused on antimicrobial therapy are recognised as important:

1. Formulary management with selection of optimal agents.
2. Dose optimisation based on PK/PD principles.
3. De-escalation of therapy and limits on treatment duration.
4. TDM involving special patient populations.

5. Surveillance, audit, and feedback on therapy.[12]

Formulary Management and Optimal Agent Selection

Antimicrobial Stewardship Programs (ASPs) are critical in addressing global antimicrobial resistance, which impedes the treatment of common infections, increases mortality rates, and places substantial economic burdens on healthcare systems. Part of the responsibility of administrators is formulation of a policy and treatment options such as formulary and selection of an optimal agent. Formulary design decision and promotion of specific agents are ubiquitous in health care. Formulary management, researchers say, prevents poor agents from being selected for treatment and provides first-line selection of agents before intubation at the gram-negative cavity level. A well-defined system of utilization for the institution is adopted, avoiding gaps where the label or conditions are poorly defined or are just a way to justify use. Prior authorization must be enforced on agent specific permissions (if required by law). In the work process, a formulary exception request (providing clinical details) or submission to a clinical decision support tool with specific UTI-management scenarios can be approved or multifocal-thrombotic intravenous therapy protocols begin in patients already on antimicrobials.[13, 14]

Dose Optimization and PK/PD Principles

The importance of un optimization dose, is evident from the widespread emergence of antimicrobial resistance and the dearth of new antibiotics to combat resistant pathogens. Antimicrobials across drug classes exhibit significant inter- and intra-species variability in PK/PD measures, with reference to pharmacokinetic and pharmacodynamic (PK/PD) principles. Dose-dependent antimicrobials such as the fluoroquinolones demonstrate a strong association between 24 h area under the concentration–time curve (AUC) and clinical outcome. For time-dependent agents such as β-lactams, free time above the minimum inhibitory concentration (fT>MIC) is most predictive. Measure of PK/PD enables evaluation of dosing regimens; comparison of AUC/MIC ratios helps determine appropriate fluoroquinolone dose, while fT>MIC is key for β-lactams. Guidance is available to establish appropriate dose—based on gram-positive or gram-negative target pathogens—enabling better selection of empiric regimen when susceptibility data remain pending.[15]

Amid high rates of resistance, optimizing agent choice and regimen at the outset is paramount. Despite the frequent initiation of empirical therapy based on infectious disease recommendations, review of a limited number drug-specific factors and infection type is necessary to identify the most effective agent. Antimicrobial stewardship programs address formulation and agent-selection interventions directly during daily clinical rounds.[16]

De-escalation and Therapy Duration

De-escalation enhances the effectiveness of the therapeutic course and reduces the impact of antimicrobial selection pressure. Antimicrobial selection pressure refers to the capacity of a compound to favour the increase of resistance mechanisms by microorganisms. Generally, when the spectrum of activity from a selected agent can be narrowed to a lower spectrum without compromising the effectiveness of treatment, de-escalation is recommended. Such intervention could be based on the following parameters:

* Microbiological culture performed before initiation or >72 h after start of empiric therapy with positive results; * Improvement of clinical and biological parameters; * non-severe and localized infection; * Clinically suspected viral infection at initiation.

A short-duration course of antimicrobial therapy associated with frequent dosing of aminoglycosides is often as effective as or more effective than a full-duration course of therapy with β-lactams or glycopeptides. Reductions of therapy to <24 h for most gram-positive infections, <3 days for acute uncomplicated cystitis, <7 days for community-acquired pneumonia in healthy adults, and <7 days for skin infections are associated with good patient outcomes.[14, 17, 18]

Therapeutic Drug Monitoring and Special Populations

Antimicrobial agents are typically dosed based on population pharmacokinetic (PK) studies and Clinical Pharmacology Guidelines, even though altered pharmacokinetics can lead to suboptimal therapeutic drug concentrations. Here, special consideration should be given to altered pharmacokinetics—neonates and infants, pregnancy and postpartum lactation, morbid obesity, cirrhosis or renal dysfunction, burns, and other life-threatening illnesses such as sepsis, shock, and multi-organ failure. Additionally, antimicrobial agents exhibit complex distribution profiles owing to their physicochemical properties and molecular weight.[8] Antimicrobial agents display concentration- or time-dependent activities. When time-dependent antimicrobials are dosed below the minimum inhibitory concentration (MIC), the PK/PD index becomes the free-drug time above the MIC (fT > MIC); when concentration-dependent antimicrobials are dosed below the MIC, the PK/PD index becomes the free-drug peak concentration (Cmax)/MIC. Modifications of the dosing interval, dose, or both can assist in attaining a proper PD target, which can be achieved through TDM.[19, 20]

Therapeutic drug monitoring of antimicrobial agents is warranted in special populations exhibiting altered pharmacokinetics. With a large array of antimicrobial agents being used in clinical practice, it is difficult to gauge patients' responses to treatment unless therapeutic drug monitoring is performed through the determination of maximum and minimum concentrations (Cmax and Cmin). Therapeutic drug

monitoring would aid in diagnosis of treatment failure and prevent adverse drug reactions. The clinical pharmacist, with access to investigations and investigations who is familiar with the institutional AMS policies and relevant PK studies of the drugs used at the institution, would provide the optimum service suitable for the patients' needs.[7, 21]

Surveillance, Audit, and Feedback

Surveillance, audit, and feedback are essential components of antimicrobial stewardship programs (ASP).[8] Developing a structured approach to surveillance is crucial for monitoring antimicrobial usage and the impact of restrictive strategies. Effective audit systems evaluate adherence to local guidelines, scrutinising aspects such as empirical therapy, spectrum modification, agent replacement, and duration of therapy.[14] Providing timely feedback through concise, well-organised summaries of antimicrobial consumption and prescribing trends encourages clinicians to reflect on their practice, stimulating greater accountability and commitment to stewardship goals.[22]

Interprofessional Collaboration and Education

Interprofessional collaboration and education are essential components of antimicrobial stewardship programs, which aim to improve appropriate antimicrobial use; tackle the emergence of antimicrobial resistance; and optimize patient outcomes, safety, and quality of life.[8] A structured pharmacist-led stewardship program in a tertiary care center demonstrated significant reductions in the total number of intravenous antibiotic days and total days of therapy without openings for intravenous antibiotic therapy.[14] In Indian healthcare institutions, where an interprofessional approach is increasingly sought to combat antimicrobial resistance, the integration of clinical pharmacy services into an antimicrobial stewardship framework based on interinstitutional collaboration and knowledge sharing was recently attempted.[23]

Pharmacists play a key role in tackling antimicrobial resistance. They deploy guidelines, implement clinical protocols and lengthy washout periods between treatment courses, recommend systematic infection workups and adequate dosage to avoid toxicity or ineffectiveness, encourage early de-escalation of therapy and discontinuation of iii agents, follow multidrug-resistant organism policies, and serve on multidisciplinary councils. Their understanding of drug interactions and dosing adjustments for renal insufficiency further supports faster intravenous-to-oral-switch protocols and shifts towards safer, more targeted regimes.[6, 24]

Implementation Strategies and Change Management

The implementation of AMS program must be designed well within and consistent with the structure of the facility at hand.[8] There are many changes to be made through step-wise transition when facilities are run only with limited number of resources. Specific implementation methods would consider local resources and service environments that fit in. The Clinical Pharmacy Services (CPS)-AMS in a leading care teaching hospital in South India, numerous strategies have brought this program to life, the programs are carried out largely by pharmacists. Also, pharmacy-based AMS strategies can be used for a Level 3 hospital in Manila as it has been shown in the evidence presented that the strategies used is very effective and have done so for pharmacy-based, pharmacy-based AMS. Formative research might help determine the best strategy for implementation.[25]

Measurement, Outcomes, and Quality Improvement

Measurement, outcomes and quality improvement are all essential as part of antimicrobial stewardship programs. Formulating appropriate policies for clinical pharmacy services can enhance the use of such services 8 and this outcome is evaluated. The measurement and outcome can be critical for the evaluation and justification of the benefits from preventive programs.[14] Antimicrobial stewardship interventions generally determine performance based only on how prescribing is considered to be appropriate. However, that includes other metrics such as efficacy evaluation, impacts on health status like safety of medication and economic impact that affect productivity and loss of lives. Measurement of antimicrobial days of treatment will be needed to assess how well antimicrobial treatments are working and predict how positive it might be in terms of antimicrobial interventions. A multidisciplinary approach to antimicrobial stewardship programs needs clinical microbiologists and clinical pharmacy specialists. However, the pharmacist has to be included in stewardship program for they are mostly the most under-served in this field.[26, 27]

Challenges, Barriers, and Ethical Considerations

Antimicrobial stewardship strategies rely on reducing exposure to antimicrobial agents in order to avoid resistance.[3] Antimicrobial agents can never be fully eliminated. Clinicians can still deal with infection as long as society demands that they do not use potentially dangerous antimicrobial agents. For example, in surveillance isolates with imipenem or linezolid-resistant infections, it seems the use is enough for the patient's protection, even when the policy is that the agents can only be used very rarely and to

some extent as the reason why. Clinicians must balance the benefits of antimicrobial therapy with the risks for them and to the society as a whole. Not allowing restraint only to become a "no" or "no in general" is also a very important consideration and necessity.[28]

Innovations in Antimicrobial Stewardship

Antimicrobial stewardship programs (ASPs) have evolved during the past few decades and various initiatives have been taken to enhance antimicrobial prescribing. Developing specific and targeted policies that guide antimicrobial stewardship can accelerate development of these new ASPs, training courses for pharmacy educators that will focus on improvement in pharmacy-drug services and activities aligned with ASPs & understanding the problems with clinical pharmacists adopting and implementing antimicrobial stewardship programs [(9)], and increasing the work of pharmacists in different sectors particularly throughout lower and middle-income countries and reducing antimicrobial resistance is therefore very required. Many recent innovations— diagnostics stewardship (an initiative aimed at improving the use of diagnostics and antimicrobial therapies), the development of diagnostic services (diagnostic service) and so on [i.e., laboratory-infectious disease partnership] have made it very possible to integrate pharmacists in antimicrobial stewardship activities to improve services to patients and help to reduce the mortality rate in antimicrobial antibiotics.[7] The influence and perspectives of pharmacists on the perceptions of antimicrobial stewardship programs worldwide are substantial, and pharmacists' input across these diverse sectors offers valuable insight into the key components and activities of successful programs. The widespread engagement and support of pharmacists for across multiple settings is crucial to improving antimicrobial stewardship activities and preventing the emergence and spread of antimicrobial resistance in low- and middle-income countries.[7, 29, 30]

Policy, Guidelines, and Regulatory Context

In recognition of the mounting global threat posed by antimicrobial resistance (AMR), high-level political commitments and official guidelines have been established in several countries and by diverse international organizations such as the World Health Organization (WHO), Pan American Health Organization (PAHO), International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and European Centre for Disease Prevention and Control (ECDC). In 2019, WHO launched a new Global Action Plan on AMR, calling for the inclusion of Antimicrobial Stewardship (AMS) within the scope of national action plans and stressing the need for country-led multisectoral, whole-of-society engagement.[7] Addressing the challenge of AMR in the WHO Eastern Mediterranean Region is also an urgent priority, given the high levels of antimicrobial misuse and the limited investment devoted to combating this global threat. In numerous countries of this region, Infection Control and AMS programs have been limited in content and scope. Despite policy development, low awareness of AMR remains widespread among health-care professionals and the general population. Moreover, well-established policies and guidelines on AMS and hospital infection prevention and control are absent from many countries. Because AMS and IPC policy consider as an actionable framework therefore; it will be developed for adaptation and implementation in these countries.[8, 31, 32]

Case Studies Highlighting Pharmacist-Led Interventions

Medicine-led pharmacists' interventions are necessary to prevent antimicrobial misuse and improve patient protection; there are several examples of this which serve as an illustration of the potential of pharmacist-led interventions. A clinical pharmacist-led antimicrobial stewardship program in a large tertiary care hospital in India was organized. The interventions in terms of selection strategy for the monitoring of care and duration of treatments were conducted and more than 65% adherence was found; 2072 interventions were in hand for the stewardship program with the same acceptance rate. The details of each program's specific work (such as training and policy preparation) are reported in detail.[7, 33, 34]

Future Directions in Clinical Pharmacy and Stewardship

Antimicrobial resistance (AMR) is an increasingly important global health issue as it threatens key drugs and procedures. A number of techniques must be pursued to address the problem, especially for drug-resistant pathogens.

The COVID-19 pandemic has disrupted progress on stewardship and led to increased global antimicrobial consumption. In this context, clinical pharmacy offers an opportunity to reduce widespread excess use of antimicrobials.[7, 35]

Nampoothiri et al. (2021) outline key steps for developing antimicrobial stewardship, including enhancing awareness, training, and collaborative efforts, strengthening the pharmacist role, and establishing and implementing site-specific policies. Emphasis on outpatient stewardship and diagnostic stewardship strategies is critical. The emergence of resistance to new antimicrobials demonstrates the urgency of addressing AMR.[6, 36]

Future directions in clinical pharmacy and stewardship involve enhancing collaborative links between infectious disease and clinical microbiology teams and integrating clinical pharmacists into these teams. Formal training

programmes are needed to overcome barriers, alongside incentivising participation through additional salary, time allowance, formal recognition, or peer support. Establishing routine dialogue between laboratory and clinical pharmacy services can facilitate development of effective antimicrobial treatment strategies and diagnostic stewardship initiatives.

Conclusion

Antimicrobial resistance is a growing public health threat, potentially leading to a rise in mortality, morbidity, healthcare costs, and length of hospital stay.[7] Antimicrobial stewardship programs represent a possible solution to this dilemma by optimizing the management of antimicrobials for specific patients in ways that enhance treatment outcomes and minimize resistance development.[8, 35, 37]

Developing the role of clinical pharmacists in antimicrobial stewardship programs is crucial for advancing optimum antimicrobial use in hospitals. By carrying out interventions such as filling out antimicrobial approval forms and dodging bridging therapy, clinical pharmacists offer maximum support for the optimal use of broad-spectrum antibiotics.

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