

# Regional Guidance document for the development and implementation of Antimicrobial Stewardship Programs

1<sup>st</sup> Edition



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# Foreword

Antimicrobial resistance (AMR) is not only a health issue causing significant morbidity and mortality, it is also an economic matter world over. Left unchecked, it will be responsible for 10 million people dying every year and a reduction of 2% to 3.5% in Gross Domestic Product (GDP) by 2050. This is unacceptable. The situation gets worse in low-income and middle-income countries, including sub-Saharan Africa where the fragile health systems have low capacity to detect and manage the scourge. The higher cost of second-line drugs forms an added burden to their weak economies. Overuse or inadequate therapies of antibiotics both play a role in the development of anti-microbial resistance. The reasons for this irrational use of the antimicrobials are vast and therefore need a focused and systematic approach to deal with the problem.

There is consensus that to stem the worsening situation of AMR, there is a need to initiate systemic and sustained effort to reduce irrational use of antimicrobials. Antimicrobial stewardship (AMS) is one of the key strategies to overcome resistance. It involves the careful and responsible management of antimicrobial use by a multi-professional effort.

This guidance document provides a framework for implementing strategies to control AMR. It identifies the key components of successful implementation of AMS, namely: Research and Development, Regulation and Manufacturing, selection of pharmaceuticals; procurement, supply and distribution; and diagnostics, prescribing medicine and dispensing and responsible use of medicines. For each component, the very well-thought out gaps are identified and possible solutions suggested. These gaps form the foundation blocks for systems strengthening towards sustainable AMS.

The success of a stewardship program in an organization needs to account for: motivation at all levels of the organization to improve outcomes for patients with infections, prevent avoidable harm related to antimicrobial prescribing and recognition of the potential and actual impact of antimicrobial resistance. The principles needed to achieve the goals are the elements of an AMR Stewardship program. The guidance discusses the stewardship elements which include: leadership commitment, governance structure, accountability and drug expertise, reporting, monitoring and evaluation, education and training, communication, quality improvement, and action.

Many times, plans are proposed with unrealistic or little consideration of where and when to apply the suggested strategies. This obviously leads to failure. The guidance document provides a list of suggested interventions discussed by level of service and resources available for use. An elaborate monitoring and evaluation strategy are included to provide the basis for objectively determining the status and level of success reached in achieving the set objectives.

The East, Central and Southern Africa Health Community (ECSA-HC) is humbled to have coordinated the development of this important document for the East African Region, but it may be applied to other parts of sub-Saharan Africa. This is in line with the mandate given to ECSA-HC by its Member States to implements programs aimed at encouraging efficiency and relevance of health services, towards the attainment of the highest standards of health for the populations in the region. It is also in line with the aspirations of the UN Sustainable Development goals which address AMR and good health.

ECSA-HC would like to wish all stakeholders involved in the implementation of this guidance document success. The fight against AMR requires tireless and committed involvement of all stakeholders and a joint effort.

**Professor Yoswa Dambisya**  
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# Abbreviations and acronyms

<b>ACDC</b>	Africa Centre for Disease Control and Prevention	<b>LIMS</b>	Laboratory information management system
<b>AFENET</b>	African Field Epidemiology Network	<b>LQMS</b>	Laboratory quality management systems
<b>AMAs</b>	Antimicrobial Agents	<b>MDRO</b>	Multidrug resistant organisms
<b>AMR</b>	Antimicrobial Resistance	<b>MO</b>	Medical Officer
<b>AMS</b>	Antimicrobial stewardship	<b>MTCs</b>	Medicines and therapeutics committees
<b>AMU</b>	Antimicrobial Use	<b>NGOs</b>	Non-governmental organizations
<b>ASG</b>	Antimicrobial Stewardship Guidance document	<b>PDSA</b>	Plan-Do-Study-Act
<b>ASLM</b>	African Society for Laboratory Medicine	<b>PPP</b>	Public private partnership
<b>ASM</b>	American Society of Microbiology	<b>PPS</b>	Point prevalent surveys
<b>AWaRe</b>	Access, Watch and Reserve	<b>QA Models</b>	Quality assurance models
<b>CDC</b>	United States Centres for Disease Control and Prevention	<b>R&amp;D</b>	Research and development
<b>CMEs</b>	Continuous Medical Education	<b>SLIPTA</b>	Stepwise Laboratory Improvement Towards Accreditation
<b>CO</b>	Clinical officer	<b>SSI</b>	Surgical site infections
<b>CPD</b>	Continuous professional development	<b>UNGASS</b>	United National General Assembly (UNGASS);
<b>DDD</b>	Defined Daily Dose System	<b>URTI</b>	Upper respiratory tract infection
<b>DHIS</b>	District Health Information System	<b>UTI</b>	Urinary tract infection
<b>DJCC</b>	ECSA-HC Director's Joint Consultative Forum	<b>WHA</b>	World Health Assembly
<b>DOT</b>	Days of Therapy	<b>WHO</b>	World Health Organization
<b>EAC-HSC</b>	East African Community Health and Scientific Conference		
<b>ECSA-BPF</b>	ECSA Health Community, Best Practices Forum		
<b>ECSA-HC HMC</b>	ECSA-HC Health Ministers Conference		
<b>ECSA-HC</b>	The East, Central and Southern Africa Health Community		
<b>GCLP</b>	Good Clinical and Laboratory Practice		
<b>GDP</b>	Gross Domestic Product		
<b>GHSA</b>	Global Health Security Agenda		
<b>GMP</b>	Good Manufacturing Practice		
<b>HMT</b>	Health Management Team		
<b>ICAN</b>	Infection Control Africa Network		
<b>ID physician</b>	Infectious diseases physician		
<b>IPC</b>	Infection Prevention and Control		
<b>KAPS</b>	Knowledge attitude and practices survey		



## Glossary

**Antimicrobial agents (AMAs):** are agents that kills microorganisms or stops their growth. Antimicrobial medicines can be grouped according to the microorganisms they act primarily against. For example, antibiotics are used against bacteria, and antifungals are used against fungi.

**Antimicrobial Resistance (AMR):** is the ability of a microbe to resist the effects of medication that once could successfully treat the microbe.

**Antimicrobial stewardship (AMS):** is a coordinated program that promotes the appropriate use of antimicrobials (including antibiotics), improves patient outcomes, reduces microbial resistance, and decreases the spread of infections caused by multidrug-resistant organisms.

**Antimicrobial Stewardship Guidance (ASG):** is a guidance document for developing National Antimicrobial stewardship Guidelines, provides a framework for implementing strategies to control AMR.

**“AWaRe”:** This is a WHO classification of antibiotics in its Essential Medicines List into Access, Watch and Reserve (AWaRe) groups. **Access group** - includes antibiotics that have activity against a wide range of commonly encountered susceptible pathogens while also showing lower resistance potential than antibiotics in the other groups. **Watch group** - includes antibiotics that have higher resistance potential and includes most of the highest priority agents among the Critically Important Antimicrobials for Human Medicine and/or antibiotics that are at relatively high risk of selection of bacterial resistance. **Reserve group** - includes antibiotics and antibiotic classes that should be reserved for treatment of confirmed or suspected infections due to multi-drug-resistant organisms.

**Continuous Medical Education (CMEs):** Refers to a specific form of continuing education (CE) that helps those in the medical field maintain competence and learn about new and developing areas of their field

**Defined daily dose (DDD):** is a statistical measure of drug consumption, defined by the World Health Organization (WHO) Collaborating Centre for Drug Statistics Methodology.

**Global Health Security Agenda (GHSA):** is a multi-partner and multi-country initiative that targets to reduce health threats from infectious diseases outbreaks through prevention, timely detection and response strategies.

**Member States (MS):** is a state/country that is a member of East African Community or the East, Central and Southern Africa Health Community.

**Regional:** East African Community and the East, Central and Southern Africa Health Community.

# Executive Summary

This Guidance document on Implementation of Antimicrobial Stewardship: Regional Guidance document for the development and implementation of Antimicrobial Stewardship Programs is intended to act as a blueprint to provide a guide into the development of National Antimicrobial Stewardship programs in the countries. The document provides a guide on the key 'what to do' and to 'how to' guiding actions on setting up AMS programs at the National, sub-national and community levels of health systems.

Effective antimicrobial drugs are prerequisites for both preventive and curative measures, protecting patients from potentially fatal diseases and ensuring that complex procedures, such as surgery and chemotherapy, can be provided at low risk. Yet systematic misuse and overuse of these drugs in human medicine and food production have put every nation at risk. Without harmonized and immediate action on a global and regional scale, the world is heading towards a post-antibiotic era in which common infections could once again kill. Alert to this crisis, the May 2015 World Health Assembly adopted a global action plan on antimicrobial resistance.

At a regional level, monitoring the use of antimicrobial agents is critical to inform sustainable implementation of antimicrobial stewardship programmes which heavily depend on stable systems, infrastructure, capacity, and interventions relevant for human and animal health and plant production. Strengthening the systems, infrastructure, capacity, and interventions span multiple levels for example at: global and regional level: how new antibiotics are introduced to the market, labelled, priced, distributed and used; national level: legislation, regulation and national treatment guidelines; hospital level: optimizing the use of antibiotics for patients in hospitals; and at community level: fostering access and appropriate use at health care access points and in animal health through awareness raising and targeted interventions. Establishing antimicrobial stewardship programs in the countries will be critical to ensure rational and appropriate use of medicines.

Antimicrobial stewardship is a coordinated program that promotes the appropriate use of antimicrobials (including antibiotics), improves patient outcomes, reduces microbial resistance, and decreases the spread of infections caused by multidrug-resistant organisms. There is limited information and models that can demonstrate successful implementation of antimicrobial stewardship in resource limited settings. Consequently, it is critical that the models proposed will be able to support a sustainable antimicrobial stewardship program that evaluates, incorporates and strengthens the components in the framework for implementing antimicrobial stewardship; research and development; regulation and manufacturing; selection; procurement, supply, and distribution; and diagnostic, prescribing medicine, dispensing and responsible use.

The document covers the following areas: -

**Part 1 - Background:** this section provides background on the burden of antimicrobial resistance globally, regionally and in each country and provides the rationale of setting up AMG programs within the countries.

**Part 2 - Components of Stewardship:** this section provides the foundational and infrastructural components for ensuring availability of medicines that are properly regulated, proper diagnostics and systems that are fundamental setting effective AMG programs. These components include: research and development, regulation and manufacturing, supply chain management covering drug selection, procurement, supply, and distribution and diagnostics, prescriptions, dispensing and appropriate use. In each of the components, the document has identified critical gaps in the systems, proposed strategies to address the gaps and taken stock of the available resources within the countries, regionally and internationally.

**Part 3 - Elements of a Stewardship program:** this section describes the essential elements for antimicrobial stewardship programs in the hospital settings, administrative levels (national and sub-national) and community settings. The document has identified the core elements accounting for needs of the countries in the region. The core elements covered in this document are; leadership commitment, governance structure, accountability and drug expertise, reporting, education and training, communication, quality improvement. For each core element, the ASG has defined the core element, required actions and the roles and responsibilities for the various levels of leadership.

**Part 4: Actions and effective interventions:** this part had documented the effective interventions required to implement AMS programs. The document provides a description of actions to be taken at various levels of service delivery and administrative levels in order to effectively promote and implement a good AMS program. These interventions have further been structured by the technical areas of cares including pharmacy driven interventions, infection and syndrome specific Interventions, diagnostic driven interventions and education.

**Part 5: Monitoring and evaluation:** The M&E framework outlines the indicators, outcomes/results following implementation of the actions and interventions proposed in the document. It outlines how the proposed strategies are expected to yield outcomes. The section is meant to monitor, evaluate and report on the progress of implementation of the interventions.

**Part 6: Resource Mobilization:** resource mobilization refers to all activities involved in securing new and additional resources. The section covers the suggested opportunities for resource mobilization for AMS Program through internal sources from the member states, external donor institutions and development partners. Stewardship activities can be incorporated within existing programs at the Ministry of health and other institutions. Many government programs may already have a stewardship element imbedded in their routine activities.

**Part 7: Risk assessment and Management:** Risk management involves identification, monitoring and managing potential risks in order to minimize the negative impact they may have on the implementation of AMS program. The document has identified a number of anticipated risks and risk mitigation strategies.

This edition of ASG covers human health aspects. The next edition will cover animal health AMS.

# **PART 1**

# **Background**

## Introduction

Over the years, antibiotics have reduced the burden of infectious diseases and have become critical in many medical interventions such as surgery and organ transplants making the development and widespread use of antimicrobial agents (AMAs) among the most important public health intervention over several years. Widespread use of AMAs in medicine has enhanced expression of human pathogens resistant to these agents resulting in increased selective pressure which has been seen as microorganisms rapidly develop resistance to AMAs<sup>1</sup>.

The loss of efficacy of AMAs against common pathogens has not only led to a shift towards more expensive antimicrobial agents but also to increased morbidity and mortality in low-income and middle-income countries, where affordability of second-line drugs restricts their use. The intensity of the emergence of resistance is driven by a population's volume of consumption of AMAs, whether use is appropriate or not.

It is estimated that in 2009, more than 3 million kilograms of antimicrobials were administered to human patients in the United States. While the life-saving benefits of antimicrobials are indisputable, the consequences of use and misuse must also be considered. Major concerns related to the use of antimicrobials are increasing resistance, increased healthcare costs and higher incidence of infection (*Clostridium difficile*). While much of the discussion focuses on overuse, there is also evidence of adverse outcomes associated with inadequate antimicrobial therapy. Continued rise in resistance could lead to 10 million people dying every year and a reduction of 2% to 3.5% in Gross Domestic Product (GDP) by 2050, and this would cost the world up to 100 trillion USD<sup>2</sup>.

The WHO global report on AMR indicates that resistance of common bacteria has reached alarming levels in many parts of the world. Furthermore, the report shows high proportions of resistance to third-generation cephalosporins and carbapenems: up to 54% among *Escherichia*

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<sup>1</sup> Laxminarayan R, Duse A, Wattal C, Zaidi AKM, Wertheim HFL, Sumpradit N, et al. Antibiotic resistance-the need for global solutions. *Lancet Infect Dis.* 2013; 13:1057–1098. doi: 10.1016/S1473-3099(13)70318-9.

<sup>2</sup> Jim O'Neill. Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations. The Review on Antimicrobial Resistance, 2014. [https://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations\\_1.pdf](https://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf).

coli and *Klebsiella pneumoniae*<sup>3</sup>. The Global Antibiotic Resistance Partnership conducted by the Uganda National Academy of Sciences recently revealed worsening trends of resistance and diminishing effectiveness of antibiotics in Uganda. Some affordable drugs, such as penicillin G and cotrimoxazole, have been reported to have resistance at or near 100%. A study conducted to review the situation of AMR situation in East Africa increased resistance reported among commonly-used antibiotics (ampicillin, gentamicin and ceftriaxone), raising concern that these antibiotics may no longer be useful for treating moderate or severe bacterial infections in East Africa<sup>4,5</sup>.

Antimicrobial resistance is strongly associated with antibiotic prescribing patterns. Studies show that up to 50% of antimicrobial use is inappropriate including the use of antibiotics for the treatment of infections not caused by bacteria, treatment of culture results reflecting colonization or contamination rather than infection, misuse of broad-spectrum courses longer than is necessary and prescription of antimicrobials in inappropriate doses. The occurrence of antibiotic resistance is substantial in long term care facilities with studies indicating that antibiotic use is common with annual prevalence rates ranging from 47% to 79% and part of the prescribed antibiotics are unnecessary<sup>6</sup>.

The available evidence suggests that the global consumption of antibiotics in humans has risen in the past two decades, primarily driven by an increased use in low and middle-income countries. At the same time, there has been a shift towards the use of broad-spectrum and last-resort antibiotics (Klein et al 2018). From the World Health Organization report on antimicrobial consumption published in November 2018 indicated, only six out of forty-seven countries in Africa submitted data on consumption representing 9% of the total number of countries that collected and submitted data. This is partly due to the lack of national surveillance systems to support the continuous collection of data on the use of antimicrobial agents. According to the report, the total antibiotic consumption was highest for the United Republic of Tanzania (27.3 DDD per 1000 inhabitants per day) followed by Burkina Faso (13.8 DDD per 1000 inhabitants per day), Côte d'Ivoire (10.7 DDD per 1000 inhabitants per day) and Burundi (4.4 DDD per

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<sup>3</sup> World Health Organization. Antimicrobial resistance: global report on surveillance. WHO Press: Geneva, Switzerland; 2014.

<sup>4</sup> Ampaire L, Muhindo A, Orikiriza P, et al. A review of antimicrobial resistance in East Africa. *African Journal of Laboratory Medicine*. 2016;5(1), a432. <http://dx.doi.org/10.4102/ajlm.v5i1.432>.

<sup>5</sup> Wangai FK, Masika MM, Lule GN, Karari EM, Maritim MC, Jaoko WG, et al. (2019) Bridging antimicrobial resistance knowledge gaps: The East African perspective on a global problem. *PLoS ONE* 14(2): e0212131. <https://doi.org/10.1371/journal.pone.0212131>

<sup>6</sup> van Buul LW, van der Steen JT, Veenhuizen RB, et al. Antibiotic use and resistance in long term care facilities. *J Am Med Dir Assoc*. 2012 Jul;13(6):568.e1-13. doi: 10.1016/j.jamda.2012.04.004.

1000 inhabitants per day). With respect to the classification of antibiotic consumption based on the WHO AWaRe (Access, Watch and Reserve) categories showed that the proportions of antibiotics in the Access category relative to the total consumption in Burkina Faso, Burundi and Côte d'Ivoire were 75%, 90% and 82%, respectively, while the Watch group accounted for 24%, 10% and 16%, respectively. The United Republic of Tanzania showed a different pattern with antibiotics in the Access and Watch groups making up 56% and 22%, respectively, of the total consumption. Consumption of the Reserve group of antibiotics were not identified in any of the four countries (World Health Organization; 2018).

Improving use of antibiotics through antibiotic stewardship is one of the key interventions necessary to curb the further emergence and spread of antimicrobial resistance (AMR). It is also important for ensuring appropriate treatment.

## Purpose

At a regional level, monitoring the use of antimicrobial agents is critical to inform sustainable implementation of antimicrobial stewardship programmes which heavily depend on stable systems, infrastructure, capacity, and interventions relevant for human and animal health and plant production. Strengthening the systems, infrastructure, capacity, and interventions span multiple levels for example at: global and regional level: how new antibiotics are introduced to the market, labelled, priced, distributed and used; national level: legislation, regulation and national treatment guidelines; hospital level: optimizing the use of antibiotics for patients in hospitals; and at community level: fostering access and appropriate use at health care access points and in animal health through awareness raising and targeted interventions. There is limited information and models that can demonstrate successful implementation of antimicrobial stewardship in resource limited settings. Consequently, it is critical that the models proposed will be able to support a sustainable antimicrobial stewardship program that evaluates, incorporates and strengthens the components in the framework for products development from manufacturing to consumption (research and development; regulation and manufacturing; selection; procurement, supply, and distribution; and diagnostic, prescribing medicine, dispensing and responsible use) strengthening the systems and foundational components of implementing antimicrobial stewardship WHO (figure 1.1)<sup>7, 8</sup>.

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<sup>7</sup> Antimicrobial stewardship programmes in health-care facilities in low- and middle-income countries. A practical toolkit. Geneva: World Health Organization; 2019.

<sup>8</sup> Global Framework for Development & Stewardship to Combat Antimicrobial Resistance. WHO/EMP/IAU/2017.08 (revised 19 October 2017)

## COMPONENTS IN THE FRAMEWORK FOR IMPLEMENTING ANTIMICROBIAL STEWARDSHIP

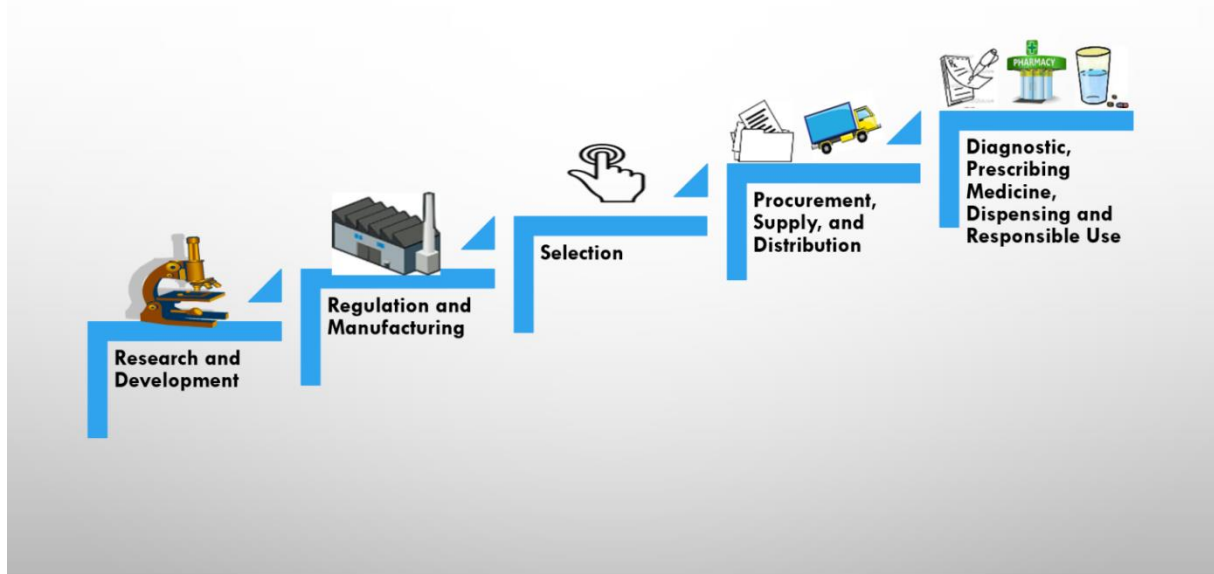


Figure 1.1. Products lifecycle and linkage to Antimicrobial stewardship (source: WHO/EMP/IAU/2017.08)

This Guidance document on implementation of Antimicrobial Stewardship: Regional Guidance document for the development and implementation of Antimicrobial Stewardship Programs is intended to act as a blueprint to provide a guide into the development of National Antimicrobial Stewardship programs in the countries within the region. The document provides a guide on the key 'what to do' and to 'how to' guiding actions on setting up AMS programs at the National, sub-national and community levels of health systems. The basis of the document is on the pillars highlighted above on product development (below referred to as components) and the core-elements of AMS.



# **Part 2**

## **Components of Antimicrobial Stewardship**

# 2

## Components of Antimicrobial Stewardship

This section provides the foundational and infrastructural components for ensuring availability of medicines that are properly regulated, proper diagnostics and systems that are fundamental setting effective antimicrobial stewardship programs. The section links the products lifecycle and the antimicrobial stewardship to include the following components include: research and development, regulation and manufacturing, supply chain management covering drug selection, procurement, supply, and distribution and diagnostics, prescriptions, dispensing and appropriate use.

### Component 1: Research and Development

The concept of research and development involves the development of new antimicrobial medicines, diagnostic tools, vaccines and other interventions for detecting, preventing and controlling antimicrobial resistance. Research and development fundamentally support the access pillar in antimicrobial stewardship by promoting the availability of innovative means of preventing and controlling anti-microbial resistance. The World Health Organization (WHO) set up a new product development partnership with the Global Antibiotic Research and Development Partnership to develop new antibiotic treatments while endeavouring to ensure sustainable access. While the development of new drugs is important to ensure sustained therapy choices, development of new therapies has been affected negative by several factors that hinder new investments in drug development. These include limited funding for basic research, government commitment to research, lack of motivation to new molecules discovery, regulatory issues, and problems with drug safety that lead to product withdrawals among others. Navigating novel products or technologies through the existing regulatory pathways with evolving regulatory environment as scientific discovery advances. Investors are not motivated to develop new drugs owing to uncertainty of the regulatory process unless there is clear evidence of the products safety and effectiveness.<sup>9</sup> WHO published a list of antibiotic-resistant priority

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<sup>9</sup> Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation. Breakthrough Business Models: Drug Development for Rare and Neglected Diseases and Individualized Therapies: Workshop Summary. Washington (DC): National Academies Press (US); 2009. 2, Current Model for Financing Drug Development: From Concept Through Approval. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK50972/>. Accessed on 20<sup>th</sup> May 2019

pathogens containing 12 families of bacteria that pose the greatest threat to human health. This was drawn to guide and promote research and development (R&D) of new antibiotics, as part of WHO's efforts to address growing global resistance to antimicrobial medicines<sup>10</sup>. Countries require a nationally driven R& D that includes: -

- Research on vaccines, diagnostics and production
- Alternative medicines

Table 2.1 below shows gaps in research and development, proposed strategies, roles and responsibilities (regional leadership, national leadership, sub-national leadership, healthcare institution and community leadership), and available resource to be leveraged.

**Table 2.1: Gaps and strategies: Research and development**

Gaps	Strategies and Solutions	Leadership Responsibilities	Resources Available
<b>Limited investment in research and development</b>	<ul style="list-style-type: none"> <li>▪ Advocacy for Buy-in and ownership on research agenda.</li> <li>▪ Develop a national research agenda for the country for AMR/U</li> </ul>	National Regional, International, National, County and Hospital, Communities	Regional organization (EAC Health Research Commission; ECSA, Academic institutions, Research Institutions
	<ul style="list-style-type: none"> <li>▪ Develop Country guidelines on advocacy and communication strategy on antimicrobial resistance</li> </ul>	National	National Council of Science and Technology. Academia and Research institutions.
<b>Lack of Motivation for New Molecules development</b>	<ul style="list-style-type: none"> <li>▪ Incentivising drug developers including patenting</li> </ul>	National	Availability of regulatory bodies
<b>Limited analytical capacity</b>	<ul style="list-style-type: none"> <li>▪ Build analytical capacity in data analysis interpretation of results, and design of data collection tools through training programs.</li> <li>▪ Establish the use of existing systems with analytical capabilities</li> </ul>	Regional, International, National, Sub-national and County	Regional and national research institutions WHONET system has analytical capabilities
<b>Translation of research findings to actionable policies and practices</b>	<ul style="list-style-type: none"> <li>▪ Engage communication experts to translate technical research finding into policy briefs and recommendations</li> </ul>	Regional, International, National, Sub-national and County	Engage health communication experts at the regional, national and county level
<b>Lack of data on alternative medicine treatment options</b>	<ul style="list-style-type: none"> <li>▪ Support research on alternative treatment options and foster collaboration between researchers and alternative medicine community</li> </ul>	Regional and National	Engage regional research institutions who support alternative medicine
<b>Absence of strong research background in medical professional training</b>	<ul style="list-style-type: none"> <li>▪ Cultivate inclusion of research in the curriculum of training programs</li> </ul>	Regional and National	Academic institutions to incorporate programs form research into training programs
<b>Lack of policies on generated data use and dissemination. Limited data sharing between various disciplines on research findings</b>	<ul style="list-style-type: none"> <li>▪ Develop protocols for reporting and dissemination of data locally.</li> <li>▪ Establish interphase that connects data generators and the users.</li> <li>▪ Foster collaboration between researcher's, program managers and policy makers.</li> </ul>	National Regional, International, National, County and Hospitals	IRBs International meetings – UNGASS, WHA, ICAN, Regional Conference, (ECSA-BPF, DJCC/HMC; EAC-HSC), and National Fora
<b>Lack of robust monitoring and evaluation system to</b>	<ul style="list-style-type: none"> <li>▪ Establish indicators for monitoring stewardship interventions and design a system for AMR stewardship</li> </ul>	Regional and National	Surveillance system Medicines and therapeutic programs

<sup>10</sup> <https://www.who.int/news-room/detail/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed>

facilitate generation of routine data			Health Management Information systems-DHIS
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UNGASS – United National General Assembly (UNGASS); WHA-World Health Assembly; ICAN - Infection Control Africa Network; ECSA-BPF – ECSA Health Community, Best Practices Forum, DJCC -ECSA-HC, Director’s Joint Consultative Forum, ECSA-HC HMC - Health Ministers Conference; EAC-HSC – East African Community Health and Scientific Conference

## Component 2: Regulation and Manufacturing

Regulation entails efforts to enforce policies that determine whether new medicines can be approved and how they are used in the treatment and prevention of human disease. In developed world, drug development is legislated and implemented by the regulating bodies such as the Federal Drug Agency in the United States and European Medicine Agency in Europe.<sup>11</sup> Pharmaceutical manufacturing processes can contribute to antimicrobial resistance through the following key routes:

- releasing antibiotics into the environment in wastewaters,
- irrational use in humans and in Livestock industry when used for prophylaxis and feed boosters; and
- manufacturing antibiotics with insufficient levels of the active antibiotic ingredient.

**Regulation and manufacturing** fundamentally support the access pillar in antimicrobial stewardship because they serve as the gatekeeper for the influx of new antimicrobial. Excessive and stringent regulations and guidelines implemented by regulatory bodies for clinical trials can impede the availability of new drugs in the process of safeguarding the public from harm. Contrary to manufacturing that needs to be monitored as the emission to the environment and wastewater can contribute to the increase in antimicrobial resistance. Recommend enforcement of good manufacturing practices and post market surveillance of antimicrobial agents.

The table 2.2 below shows gaps in regulation and manufacturing, proposed strategies, roles and responsibilities (regional leadership, national leadership, sub-national leadership, healthcare institution and community leadership), and available resource to be leveraged.

**Table 2.2: Gaps and strategies in regulation and manufacturing**

Gaps	Strategies and Solutions	Leadership responsibilities	Resources Available
Weak regulation on practices related to drugs administration	<ul style="list-style-type: none"> <li>▪ Enhance inspection of antimicrobial dispensing units and pharmacies</li> <li>▪ Develop harmonized tools for assessing compliance to regulatory standards</li> <li>▪ Engaging in PPP to enhance enforcement and reduce malpractices</li> <li>▪ Public education and awareness of the public on risks associated with purchase of medicine without a prescription</li> </ul>	Regional and National	Regional and international accreditation organizations Rebate programs e.g. National Health Insurance Fund National regulatory bodies Guidelines for harmonization of regulation of medicine-EAC

<sup>11</sup> Global Framework for Development & Stewardship to Combat Antimicrobial Resistance. [http://www.who.int/phi/implementation/research/WHA\\_BackgroundPaper-AGlobalFrameworkDevelopmentStewardship.pdf](http://www.who.int/phi/implementation/research/WHA_BackgroundPaper-AGlobalFrameworkDevelopmentStewardship.pdf)

	<ul style="list-style-type: none"> <li>Conduct operational/implementation research e.g. Knowledge attitudes and Practices (KAP) studies, point prevalence studies (PPS) etc</li> </ul>		
International trade barriers that restrict full country level participation	<ul style="list-style-type: none"> <li>Country level engagements into rational decisions on international trade barriers</li> </ul>	Regional and National	Regional organizations to which countries subscribe that may negotiate to address trade barriers
Excessive and stringent regulations and guidelines impeding on availability of new drugs	<ul style="list-style-type: none"> <li>Stringent but friendly regulatory frameworks and approval processes for new drugs and clinical trials</li> </ul>	National	Regional and international accreditation organizations Rebate programs e.g. National Health Insurance Fund National regulatory bodies
Lack of effective enforcements of policies and guidelines for Good Manufacturing Practices (GMP)	<ul style="list-style-type: none"> <li>Adopting and harmonizing the guidelines for GMP per country</li> </ul>	National	National regulatory bodies Guidelines for harmonization of regulation of medicine-EAC
Inadequate enforcement quality assurance and monitoring programs for rational use	<ul style="list-style-type: none"> <li>Carry out monitoring activities for compliance to stewardship standards.</li> <li>Standardized guidelines to support stewardship including QA models</li> <li>Champion hospital accreditation programs</li> <li>Accreditation and certification of hospitals to enforce compliance to standards</li> <li>Licensing and re-licensure of the health facilities</li> </ul>	National, Sub-national, and Hospitals	Accreditation bodies and programs; regulatory bodies
Inadequate enforcement regulations to control waste management of pharmaceuticals	<ul style="list-style-type: none"> <li>Develop and strengthen policies to regulation of waste disposal</li> <li>Establish safe disposal programs at sub-national levels to support hospitals and community health units</li> <li>Advocate for safe disposal of antimicrobial agents in the community</li> </ul>	Regional and National	Community health structures Pharmaceutical waste disposal structures

QA models - quality assurance models

## Component 3: Supply Chain Management

### Selection, procurement, supply, and distribution

Antimicrobial stewardship program cannot succeed without improvement of supply chain for antimicrobials, reagents and related supplies. An ineffective supply chain can lead to a shortage of supplies which is linked to disease outbreaks inappropriate use, anti-microbial resistance and contributes to the circulation of counterfeit or substandard products. The primary objective of an efficient supply chain should be to ensure that the right medicine is given to the right patient, at the right time and the right price.

There are three broad strategies that experts and stakeholders such as non-governmental organizations (NGOs), governments, academics, and industry representatives expect pharmaceutical companies to use to improve the effectiveness and efficiency of supply chains in low to middle-income countries. These strategies include: -

- demand planning;
- ensuring sufficient, uninterrupted supply; and
- strengthening the distribution chain

The management of supply chain is therefore organized around selection, quantification, procurement and distribution.

**Medicines selection** is a critical factor in the successful implementation of access to antimicrobials which has implications for antimicrobial stewardship. Medicines selection should include assessment of the evidence-base for the medicine choice and pharmacoeconomic evaluations. Decisions around the selection of medicine for inclusion on a formulary or medicines list should also consider issues such as access and implementation. Governments must guarantee uninterrupted access to essential medicines of assured quality.

**Forecasting and quantification** information should form the basis of antimicrobial procurement. Accurate quantification requires data from various sources including antimicrobial consumption and prescription patterns. Also, in order to maintain the quality of antimicrobials, all stakeholders in the supply chain must comply with the applicable legislation and regulations. All activities in the supply chain must comply with Good distribution and Good Storage Practices.

Ensuring a strong supply chain of reliable diagnostic tests, reagents, and consumables is one of the key factors for creating a sustainable, strong system on AMR surveillance and antimicrobial use. Hence, efficient systems for managing **drug procurement and distribution** should be put in place to avoid interruptions in supply or wastage.

Table 2.3 below shows gaps in selection, procurement, supply, and distribution proposed strategies, roles and responsibilities (regional leadership, national leadership, sub-national leadership, healthcare institution and community leadership), and available resource to be leveraged.

**Table 2.3: Gaps and strategies in supply chain management**

Gaps	Strategies and Solutions	Leadership Responsibilities	Resources Available
<ul style="list-style-type: none"> <li>▪ Lack of evidence at regional level that guide inclusion of the antimicrobials on the essential medicine list</li> </ul>	<ul style="list-style-type: none"> <li>▪ Strengthen AMR surveillance to guide selection of antimicrobials</li> </ul>	Regional/National	Structures for AMR Surveillance
<ul style="list-style-type: none"> <li>▪ Stockout/shortage of laboratory reagents and consumables</li> </ul>	<ul style="list-style-type: none"> <li>▪ Strengthen the supply chain</li> </ul>	National/Sub national	National drug management authorities in each country
<ul style="list-style-type: none"> <li>▪ Counterfeit or substandard antimicrobials in the supply chain</li> </ul>	<ul style="list-style-type: none"> <li>▪ Ensure pre and post market surveillance for antimicrobials in the country is conducted</li> </ul>	Regional/National	Regulatory bodies for drugs
<ul style="list-style-type: none"> <li>▪ Inaccurate forecasting and quantification of antimicrobial requirements due to lack of accurate data</li> </ul>	<ul style="list-style-type: none"> <li>▪ Develop a national database on antimicrobial consumptions</li> </ul>	National/Sub national	Training programs on supply chain management
<ul style="list-style-type: none"> <li>▪ Lack of updated essential medicines list and formularies</li> </ul>	<ul style="list-style-type: none"> <li>▪ Update the essential medicines list based on efficacy, safety, quality and cost effectiveness</li> </ul>	National	Essential drug list available
<ul style="list-style-type: none"> <li>▪ Inadequate communication between the end users and the procurement department</li> </ul>	<ul style="list-style-type: none"> <li>▪ Improve communication between the end users and the procurement department</li> </ul>	National/Sub national	Medicines and therapeutic committees available in countries to guide essential medicines list
<ul style="list-style-type: none"> <li>▪ Inadequate technical capacity for the supply chain management</li> </ul>	<ul style="list-style-type: none"> <li>▪ Capacity building on supply chain management</li> </ul>	National	Training programs on supply chain management

## Component 4: Diagnostic, prescribing dispensing and responsible use of medicine

**Diagnostics:** One of the critical elements for improving antimicrobial stewardship and drug development is the rapid and accurate identification of the pathogens, as well as rapid and accurate antimicrobial susceptibility testing. Effective antimicrobial stewardship is closely linked with the ability to make correct diagnoses. Incorrect diagnoses can lead not only to overuse or misuse of antibiotics, particularly the critical broad-spectrum antibiotics, but also to poor outcomes for patients resulting from failure to treat the actual disease present. Therefore, investments in laboratory quality management systems and aggregated patient information management systems will ensure quality assured testing. Lack of laboratory reagents and consumables, which makes proper testing, diagnosis, and treatment difficult or impossible, even when appropriate laboratory equipment is available.

Physicians then face the hard decision of treating patients using antimicrobial agents to the best of their knowledge rather than based on an accurate diagnosis from test results. The speed of diagnostic testing is a critical factor in effective antimicrobial stewardship. Typical turnaround time using traditional microbiological testing methods is 48 to 96 hours for pathogen identification, followed by an additional 48 to 72 hours for antimicrobial drug-susceptibility testing. The cost for the diagnostic test and weak sample referral systems can be barriers to access leading to un-informed prescription by clinicians. Initial treatment decisions may be made empirically before diagnostic testing results are available. Critical goals of antimicrobial stewardship can be achieved through faster and more accurate diagnostic testing reducing time to appropriate antibiotics, reducing unnecessary use of antibiotics, and informing decisions regarding antibiotic de-escalation or discontinuation. Addressing this gap in the supply chain of diagnostic tests can make the difference between the appropriate use of antibiotics and overuse or inappropriate use. Additionally, more significant investment in rapid quality assured diagnostics and their integration into clinical practice as one of the key strategies. Integration of diagnostics with other stewardship interventions, to provide fast, accurate identification and susceptibility testing will achieve better clinical outcomes and timely streamlining and de-escalating of empiric broad-spectrum antibiotics in severely ill patients. Inadequate staffing, insufficient training in microbiology skills and supervision of health personnel, lack of access to rapid diagnostic facilities to support treatment decisions. There is need for continuous interaction between the laboratory, clinicians and patients on availability of diagnostic tests and establishment of facility level structures like MTC, stewardship committees to guide diagnostic and prescribing patterns and requirements

**Prescribing, dispensing and responsible use:** Pharmacies should operate under a license and the full-time management and supervision of a registered pharmacist. Pharmacists should play a central role in community education and advising patients on the correct use of medicines. Pharmacists should assume a leadership role in the rational use of medicines in both the healthcare and community environments. Only licensed practitioners may prescribe and dispense antibiotics. A prescription or verbal instructions of an authorized prescriber known to the managing pharmacist are necessary to purchase antibiotics from a hospital or private pharmacy, and unregulated over-the-counter sales are not the primary concern of national antibiotic stewardship. Antimicrobials should only be sold with a prescription, and this should be

strictly enforced in all pharmacies. Local incentive structures should be examined to identify factors influencing prescription practices. Methods of payment and reimbursement should be in line with standard treatment guidelines to discourage irrational use. Promotional activities by pharmaceutical companies should be regulated and monitored to prevent the industry from misinforming patients and from offering financial incentives to providers.

The practice of allowing prescribers to practice medicine, and own pharmacies and diagnostic laboratory facilities propagates the abuse and conflict of interest that impacts implementation of antimicrobial resistance and regulation of appropriate use. National standard treatment guidelines should incorporate proper training and supervision of health personnel and for mechanisms to make diagnostic support available. Hospitals should have prescribing guidelines for treatment and prophylaxis for common infections relevant to the patient population, the local antimicrobial resistance profile and the surgical procedures performed in the institution. Community health workers and volunteers that bridge the gap of access in the remote and rural community health centers, server as prescribers without any credentials or treatment guidelines for prescribing and dispensing antimicrobials. Some countries have instituted training programs; upon completion of the program, the community health workers and nurses can apply for a license to prescribe and dispense medicines, with prescribing at primary care level being competency-based as opposed to occupation-based. In situations where, medical practitioners are not available, nurses are further permitted to diagnose patients; symptomatic diagnosis and treatment guidelines should be provided as a guide for an area without the capacity for laboratory diagnostics and medical practitioner.

Table 2.4 below shows gaps in diagnostic, prescribing medicine, dispensing and responsible use, proposed strategies, roles and responsibilities (regional leadership, national leadership, sub-national leadership, healthcare institution and community leadership), and available resource to be leveraged.

**Table 2.4: Gaps and strategies in Diagnostic, prescribing medicine, dispensing and responsible use**

Gaps	Strategies and Solutions	Leadership Responsibilities	Resource Available
<ul style="list-style-type: none"> <li>▪ Inadequate laboratory capacity and resources staffing, infrastructure and data management</li> <li>▪ Lack of diagnostic guidelines, diagnostic stewardship and non-compliance to testing algorithms at health facilities</li> <li>▪ Inadequate prioritization of diagnostics</li> <li>▪ Lack of confidence in laboratory services by the clinicians</li> <li>▪ Long turnaround time for receipt of</li> </ul>	<ul style="list-style-type: none"> <li>▪ Strengthen laboratory capacity (including LIMS), staffing, infrastructure and data management.</li> <li>▪ Develop, customize, and disseminate guidelines and algorithms</li> <li>▪ Conduct diagnostic stewardship training for clinicians (include diagnostic stewardship in the training package for AMR</li> <li>▪ Sensitize patients about the importance of diagnosis before treatment</li> <li>▪ Task shift to enable nurses and phlebotomists to collect specimens</li> <li>▪ Improve laboratory clinician communication</li> <li>▪ Promote laboratory quality systems improvement and or/ accreditation including accreditation of microbiology services</li> <li>▪ Promote use of newer, simpler, and faster technologies</li> <li>▪ Promote sharing and use of AMR data</li> </ul>	<p>Regional, International, National, Sub-national, and County</p>	<p>Ongoing efforts to strengthen laboratory capacity and surveillance (GHSA, ACDC, Fleming Fund, ASM, ASLM, AFENET, US CDC, World Bank/ECSA)</p> <p>Lessons from PBF programs in Rwanda and Burundi</p>



laboratory culture results ▪ Inadequate sharing and utilization of AMR data	▪ Promote performance-based financing (PBF) for services		
▪ Prescribing antimicrobial agents without laboratory diagnostic	▪ Adherence of standard treatment guidelines, program treatment protocols ▪ Ensure laboratory antimicrobial sensitivity test results shall be mandatory	Regional/National	Regulatory bodies for drugs
▪ Selling antimicrobial agents without prescriptions	▪ Strengthens enforcement for the sale of antimicrobial agents	Regional/National	Regulatory bodies for drugs
▪ Knowledge gap on AMR and AMU	▪ Increase intervention for responsible use of antimicrobial agents to the community	Regional/National	Regulatory bodies for drugs

GHSa – Global Health Security Agenda, ACDC – Africa Centres for Diseases Prevention and Control, ASM – American Society of Microbiology, ASLM – African Society for Laboratory Medicine, AFENET – African Epidemiology Network, US CDC – United States Centres for Diseases Prevention and Control; AMU -Antimicrobial use; AMR- Antimicrobial resistance

# **Part 3**

## **Core Elements for Antimicrobial Stewardship Program**

# 3

## Core Elements for Antimicrobial Stewardship Program

An antimicrobial stewardship program is a systematic approach to implement a range of activities to achieve a goal. The activities can be basic, or complex considering available resources and should engage a range of leader, professionals, and stakeholders. The success of a stewardship program in an organisation needs to account for; motivation at all levels of the organization to improve outcomes for patients with infections, prevent avoidable harm related to antimicrobial prescribing and a recognition of the potential and actual impact of antimicrobial resistance.

A stewardship program needs clear lines of accountability and a structure within the organization that allows the implementation of interventions, support the scheme, monitor performance and account for performance on outcome measures. Lastly, it is essential that an education component is incorporated into the program to ensure participants buy in and knowledge of the goals. In 2019, the United States Centres for Disease Control and Prevention (CDC) published the Core Elements of Hospital Antibiotic Stewardship Programs, which outlines essential components for antimicrobial stewardship programs in the hospital setting<sup>12</sup>. There are variations to the Core elements in other acute care settings but very limited guidance on the community setting. The antimicrobial stewardship guidance document (ASG) will focus on elements in the acute care setting, administrative levels as well as the community setting. Listed are the core elements with modifications to account for needs of the East African region; leadership commitment, governance structure, accountability and drug expertise, reporting, monitoring and evaluation, education and training, communication, quality improvement, and action. For each core element, the ASG will define the core element and establish roles and responsibilities for levels of leadership.

### Core Element 1 - Leadership Commitment

Among the critical components of a stewardship program, are leadership commitment and culture of Antimicrobial use. Leadership commitment comprises of dedicating necessary human (designating a multidisciplinary team) resources, financial allocation, and information technology resources. Leadership support can take several forms and should include but not limited to the aspects described below.

- Evidence of leadership commitment may take the form of a **formal statement or policy** indicating that the organization (Region, National, Sub-National, and Healthcare facility) supports efforts to improve and monitor antimicrobial use.
- Formal statements carry more weight with staff than informal communications such as newsletters and e-mail. It is recommended that the formal statement should include **stewardship-related positions or collateral duties**.
- Subsequently, stewardship related positions should undoubtedly include **job descriptions and annual performance reviews**. This ensures that individuals with the assigned duties are given sufficient time to contribute to stewardship activities.

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<sup>12</sup> Core Elements of Hospital Antibiotic Stewardship Programs. <https://www.cdc.gov/antibiotic-use/core-elements/hospital.html>

- Lastly, leadership commitment should reflect allocated time and resources to support **training and education**.

As a part of the commitment, leadership should define where the organization needs to go with regards to stewardship using quantitative data on antimicrobial use to establish organizational outcomes. Members of the organization can then implement the vision and direction. Table 3.1 below describes actions of leadership commitment element, the corresponding level of leadership responsible for implementing the action and expertise needed.

**Table 3.1: Leadership commitment in AMR Stewardship**

Actions	Level	Role/ Responsibility
Formal or written statement to support stewardship activities to improve and monitor antimicrobial use	National and subnational	Senior leadership
Mobilize resources and budget for financial support to antimicrobial stewardship activities	National, Sub-national and institutional	Senior leadership
Designate a multidisciplinary stewardship team	National, Sub-national and institutional	Senior leadership
Establish stewardship-related duties in job descriptions and annual performance reviews for AMS team	National, Sub-national and institutional	Multidisciplinary stewardship team
Establish clear communication structures/ lines of authority on antimicrobial stewardship programs.	National, Sub-national and institutional	Senior leadership
Allocate time to participate in stewardship activities including training and education	National, Sub-national and institutional	Multidisciplinary stewardship team
Stewardship program performance review	National, Sub-national and institutional	Multidisciplinary stewardship team
Call to action for stewardship support	Regional	Regional organizations

## Core Element 2 – Governance Structures

### ***Organizational structure for AMS***

Following an organization's declared commitment to antimicrobial stewardship, the leadership needs to establish the governance structure for the stewardship program. The governance structure is key to sustainment of the program since it serves as the decision-making chain, authority, and oversight. Antimicrobial stewardship program governance structure covers the combination of individuals filling executive and management roles, program oversight functions and structure and policies that define management principles and decision making.

The governance structure at the **national level** would differ slightly based on how each country is structured. However, the general premise on governance should be through the lead Ministry of Health tasked with the responsibility on the AMR National Action Plan, mission and directing the country-specific outcomes. The national level is also responsible for ensuring a collaborative, integrated approach to animal and human antimicrobial stewardship interventions. The antimicrobial stewardship program committee at the national level comprises of a multidisciplinary team with clear terms of reference and defined lines of communication, reporting, and accountability. Subcommittees could also be designated to investigate and report on the antimicrobial stewardship plan.

At the **sub-national level**, organizations within the provinces/regions, counties, districts/sub-counties, and healthcare centres establishments play a vital role in operational oversight of antimicrobial stewardship program in support of national governance. The governance structure at the sub-national level should be responsible for taking the national strategic objectives and standards and adapting them to suit operational model and governance structures at the local level. They ensure budgets are set up to support stewardship activities; conduct situational analysis, prioritize and implement antimicrobial stewardship interventions and provide monitoring and evaluation functions to determine progress. The antimicrobial stewardship governance committee at the sub-national level consist of a multidisciplinary team of about 7-10 members depending on the local set up and availability of various expertise.

- Governance of antimicrobial stewardship typically falls within the **clinical leadership** functions of the heads of provincial/regions, counties and district/sub-counties departments of health as the case may be.
- Depending on resources and capacity, governance functions could include pharmaceutical and therapeutic monitoring, diagnostic stewardship, infection prevention and control monitoring in addition to antimicrobial stewardship.
- To leverage resources, organizations should consider using governance structures already in place that can accommodate antimicrobial stewardship activities.
- Successful stewardship programs in the healthcare facility have typically placed the antimicrobial stewardship governance within the Medicines and therapeutics committees (MTCs), infection prevention and control committees, hospital quality improvement team or patient safety governance structure and included within the hospital's quality and safety strategic plan.

The responsibility for implementing and managing the antimicrobial stewardship program resides with a multidisciplinary antimicrobial stewardship (AMS) team or committee. An example of a governance structure with reporting framework for an AMS team that could be adapted to the different hospital structures is shown in figure 3.1. It is important to have formal links established between AMS team, hospital executive (or equivalent), director of clinical services (or equivalent), drug and therapeutics committee (or equivalent), infection prevention and control committee (or equivalent). It is critical that the highest-ranking member of each department or committee represents the hospital on the AST to ensure translation of policy into action.

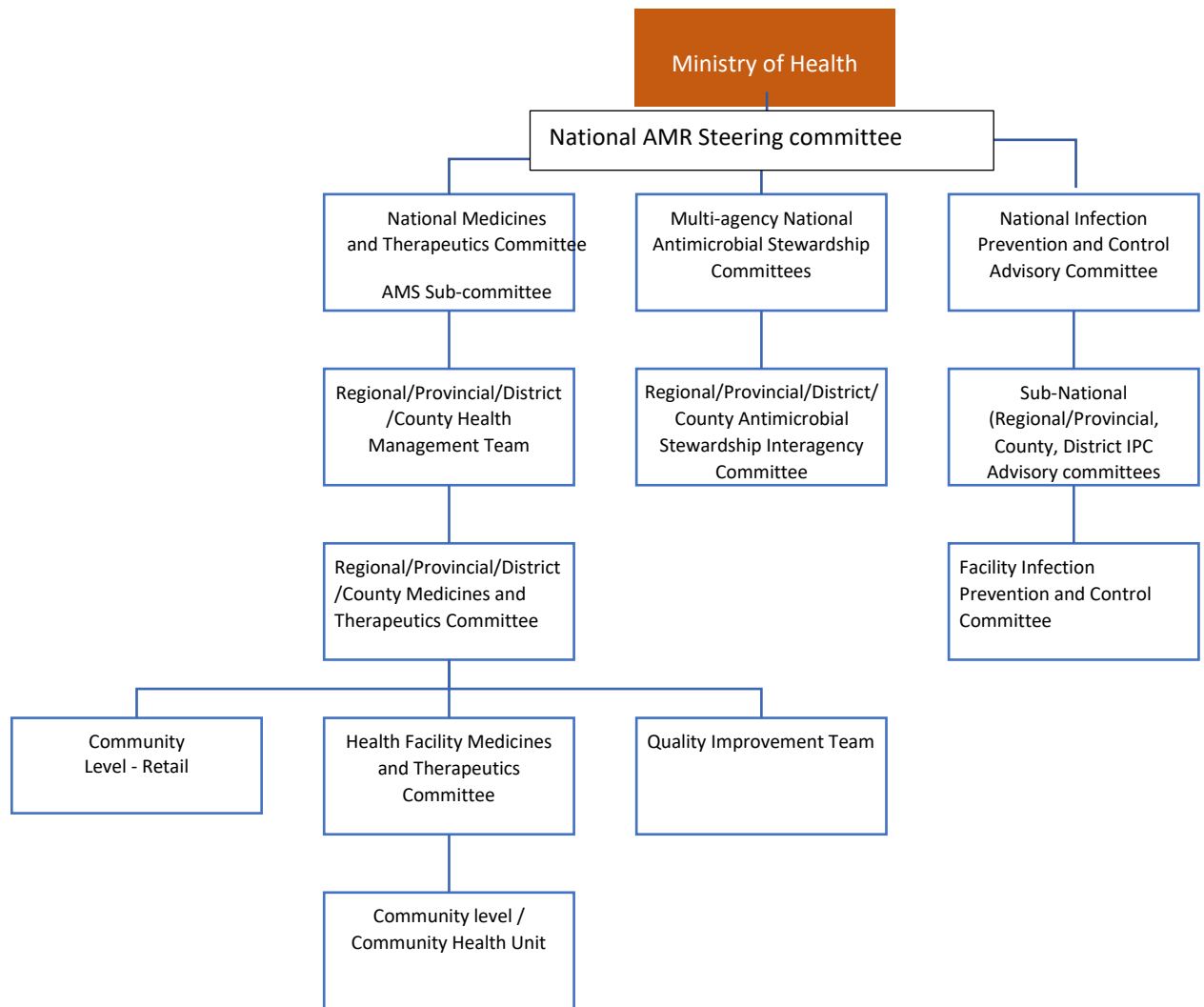


Figure 3.1(a): AMS Governance structure for the administrative and community levels

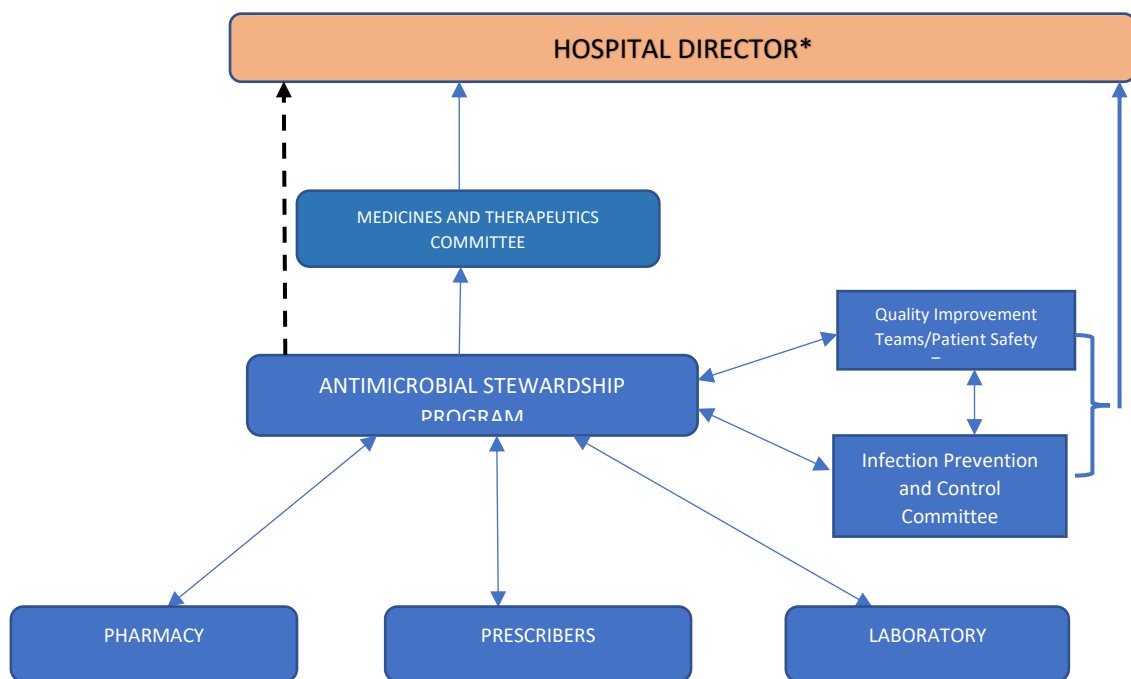


Figure 3.1(b): Facility level Governance structure for the antimicrobial stewardship program (service delivery level). \*Hospital director, Medical superintendent, Chief/Executive Director (hospital), Medical Officer in-charge

## Composition of AMS team

The recommended membership of the AMS team should ideally include a clinician, clinical microbiologist, clinical pharmacist, nurses (experienced in infectious diseases), patient safety manager, a laboratory technologist and information technologist (IT). As a minimum, the AMS team should include an appropriate clinician (a clinical microbiologist or infectious disease physician, if available), a pharmacist (clinical pharmacist with infectious disease training, if possible) and a microbiologist as core team members. The membership should be between 7 to 10 members. Where on-site infectious diseases (ID) physicians or clinical microbiologists are not available, the AMS team should be led by an interested clinician with a pharmacist. Where resources are scarce, and the above-described expertise is not available, facilities may negotiate appropriate external specialist advice (e.g. from the higher-level health facility) to support the local AMS team or appointed focal person (Table 3.2).

**Table 3.2: Proposed composition of antimicrobial stewardship committees at various levels of administration and service delivery**

Committee members	Level of Care					
	National AMS Committee/ TWG	National Referral	Regional/Province/ County referral (Level 5)	Sub-county/ District (Level 4)	Health Centres (Level 3)	Dispensaries (Level 2)
Clinical Microbiologist	✓	✓	+/-	-	-	-
Microbiologist	✓	✓	+/-	-	-	-
Lab technologist/ scientist	✓	✓	+/-	✓	✓	-
ID Physician/ physician	✓	✓	✓	+/-	-	-
MO	-	-	+/-	✓	✓	-
IPC focal person	✓	✓	✓	+/-	-	+/-
Clinical pharmacist/ Pharmacist	✓	✓	✓	-	-	-
Pharmacy technician/ assistant	-	-	-	+/-	+/-	+/-
Nursing	✓	✓	✓			
Clinical team (surgeon, paediatrician)	+/-	+/-	+/-	+/-	-	-
CO/AMO	-	-	-	+/-	✓	+/-
Epidemiologist	✓	✓	+/-	-	-	-
Management representative	✓	✓	✓	-	-	-
Animal health experts	✓					
Best fit		Under IPC/MTC/ Standalone	Under IPC/MTC/ Standalone	Under IPC/MTC/ Standalone	Under IPC/MTC/ Standalone	-

*ID-infectious diseases; MO- Medical officer (doctor); IPC – infection Prevention and Control; +/- the expertise may/may not be available at this level; CO- clinical officer; AMO – Assistant Medical Officer; Other specialists may be incorporated from time to time as needed and based on the countries' settings*

## Roles and responsibilities of AMS committee core members

As the prescribers of antibiotics, it is vital that clinicians are fully engaged in and supportive of efforts to improve antibiotic use in hospitals. Laboratory staff should guide the proper use of tests and the flow of results. They can also guide empiric therapy by creating and interpreting a facility cumulative antibiotic resistance (antibiogram). Information technology staff are critical to integrating stewardship protocols into existing workflow. For example, embedding relevant information and protocols at the point of care such as immediate access to facility-specific

guidelines at the point of prescribing; implementing clinical decision support for antibiotic use; creating prompts for action to review antibiotics in key situations and facilitating the collection and reporting of antibiotic use data.

Nurses can assure that specimen for cultures are taken before initiating the patient on new course of treatment with antibiotics. Besides, nurses review medications as part of their routine duties and can prompt discussions of antibiotic treatment, indication, and duration. Additionally, the pharmacists, infection preventionists/infection control experts and hospital epidemiologists should assist with prescriptions auditing, analysing, monitoring and reporting of resistance trends, educate staff on the importance of appropriate antibiotic use, and implement strategies to optimize the use of antibiotics. There is no consensus on staffing recommendations; however, hospitals with existing programs suggest that for every 100 acute beds, at least 10 hours of a senior pharmacist and 3.5 hours of lead clinician time per week should be dedicated to AMS team activities.

**Table 3.3: Roles of different members of the AMS team**

Designation	Responsibilities
Management	<ul style="list-style-type: none"> <li>• Formal constitution of AMS Team</li> <li>• Budget and plan for AMR</li> <li>• Advocate for the utilisation of laboratory services</li> </ul>
Physician/ Clinicians (prescribers)	<ul style="list-style-type: none"> <li>• Improve antibiotic prescription and use</li> <li>• Educate the patient and staff about AMR</li> <li>• Leadership role of AMS team</li> <li>• Review medications as part of their routine duties</li> </ul>
Pharmacist/ dispensers	<ul style="list-style-type: none"> <li>• Educate patients and staff on the importance of appropriate antibiotic use</li> <li>• Implement strategies to optimize the use of antibiotics</li> <li>• Auditing of prescription</li> <li>• Secretary of AMS team</li> <li>• Review medications as part of their routine duties</li> <li>• Managing antimicrobial supply chain (ensuring availability of antimicrobials)</li> <li>• Appropriate dispensing of medicines and advising on proper use</li> <li>• Communicate with prescribers on available medicines, dosages etc</li> <li>• Keeping documentation of antimicrobials consumptions</li> </ul>
Laboratory technologist	<ul style="list-style-type: none"> <li>• Guide the proper use of tests, timing &amp; quality of specimen collection and the flow of results</li> <li>• Generate an appropriate antibiogram</li> <li>• Observe quality standards in the laboratory including timely provision of results to guide on patient’s management</li> <li>• Ensure timely communication of laboratory results</li> </ul>
Information communication officers/health information/Record officer	<ul style="list-style-type: none"> <li>• Integrating stewardship protocols into existing systems.</li> <li>• Creating prompts for action to review antibiotics in key situations in the information management system</li> <li>• Facilitating the collection and reporting of antibiotic use by creating an appropriate communication platform</li> </ul>
Clinical microbiologist	<ul style="list-style-type: none"> <li>• Championing laboratory service utilisation by clinician including ensuring that cultures are performed before starting antibiotics</li> <li>• A facility cumulative antibiotic resistance (antibiogram) to guide treatment</li> <li>• Educating patients and staff on appropriate use of antibiotics</li> </ul>



	<ul style="list-style-type: none"> <li>Review medications as part of their routine duties</li> </ul>
<b>Nurse</b>	<ul style="list-style-type: none"> <li>Prompting medication review</li> <li>Ensuring appropriate administration of antibiotics</li> <li>Enhancing communication with other relevant departments e.g. laboratory teams, pharmacy teams and clinicians</li> <li>Prompt specimen collection for culture prior to administration of antimicrobials</li> <li>Health education on antimicrobial use and infections prevention</li> </ul>
<b>Epidemiologist/ Biostatistician</b>	<ul style="list-style-type: none"> <li>Analysing, interpreting and monitoring of resistance trends</li> <li>Checking data quality</li> </ul>

### Core Element 3 – Accountability and Drug Expertise

Successful programs have shown that accountability and drug expertise are critical for a successful stewardship program. The recommendation is to appoint a single leader who will be responsible for the stewardship program outcomes. Experience with successful programs shows that a physician leader is effective. To co-lead the program, a pharmacist responsible for improving antibiotic use is needed. Formal training in infectious diseases and antimicrobial stewardship would benefit stewardship program leaders. Locations with available resources and capacity have achieved success by hiring full-time staff to develop and manage stewardship programs; however, with limited resources options include the use of part-time and off-site expertise from other hospitals. The pharmacy and therapeutics committee should not be considered the stewardship team within a hospital if only performing its traditional duties of managing the formulary and monitoring drug-related patient safety, though in some smaller facilities the pharmacy and therapeutics committee may be expand its role to assess and improve antimicrobial use.

The stewardship leader and co-lead should be incorporated into the AMS governance structure and linked to the AST. The leader and co-lead should work with a team identified at the co-element two in order to enhance the stewardship program. There needs to be clear lines of accountability between the ASP governance structure and other existing governance structures; such as the clinical governance, drug, and therapeutics committee, infection prevention, and control committees.

The table below describes actions of accountability and drug expertise element, the corresponding level of leadership responsible for implementing the action and expertise needed.

**Table 3.4: Actions on Accountability and Drug Expertise**

Actions	Level	Expertise	Alternative expertise
Designate a leader to be accountable to the leadership for meeting established goals or targets	National, subnational and healthcare facilities	Infectious disease physician and pharmacist	In absence of either, identify an appropriate champion for the program
Training of AMR team leadership in antibiotic stewardship	National, Sub-national and institutional	Leadership skill and AMS training	
Appoint Pharmacy co-lead to improve the use of antibiotics within the facility	Health facilities	Clinical Pharmacist/ Pharmacist	Appropriate champion

Set the practice standards for assessing, monitoring and communicating patient outcomes	National, subnational and healthcare facilities	Multidisciplinary	
Establish an antimicrobial stewardship team	National, subnational and healthcare facilities	Multidisciplinary	

## Core Element 4 – Reporting

Reporting information collected on antibiotic use and resistance patterns to doctors, nurses and relevant staff on a regular basis serves as a reminder of why antimicrobial stewardship activities are essential. Regular reporting\* can occur within the organization but also reporting to external leadership levels who have responsibility for antimicrobial stewardship is encouraged. Ideally, reporting elements should focus: -

- On patient outcomes to assess the impact of interventions, identify potential areas for improvement, and provide feedback to clinicians.
- Antimicrobial resistance profiles (antibiograms)
- Documented treatment indications by prescribers
- Adherence to facility-specific treatment guidelines,
- Diagnostic tests(microbiological) and antibiotic susceptibility tests done
- Modified antibiotic choices to microbiological findings
- Monitoring resistance at the patient level (i.e., what percent of patients develop resistant super-infections)
- Monitor and evaluate clinical outcomes

\*Reporting could be done on weekly basis or regularly during the AMS committee meeting Responsibilities associated with stewardship program reporting actions differs at different levels of leadership. The table below describes actions of reporting element, the corresponding level of leadership responsible for implementing the action and expertise needed.

**Table 3.5: Reporting actions**

Action	Level	Expertise	Alternate Expertise
Harmonize the reporting system to ensure flow of information from Health Facilities to National and Regional	Regional, National and Health facilities	Clinician, Clinical Microbiologist	Pharmacists
Disseminate antibiogram and consumption information (antimicrobial agents used) by specific community within the country	National and Sub-national	Clinical Microbiologist, Pharmacists Infectious diseases specialists Laboratory professionals *Qualified Clinicians	Pharmacists Laboratory professionals *Qualified Clinicians
Provide guidelines to standardize antibiogram development	Regional National and Sub-national	Clinician, Clinical Microbiologist and Pharmacists	
Share AMR information (feedback) with all healthcare providers as well as leadership and any other stakeholders	Regional and National and Sub-National	Clinical Microbiologist, Pharmacists Laboratory professionals *Qualified Clinicians	Pharmacists Laboratory professionals *Qualified Clinicians
Develop/adopt standardized tools such as those for drug use evaluations or antibiotic audit forms for reviews	National and Sub-National	Clinical Microbiologist, Pharmacists *Qualified Clinicians	Laboratory professionals

\*Qualified - clinicians with training and experience in interpretation Antimicrobial susceptibility tests

Retrospective charts reviews could also be used based on pharmacy records or discharge diagnoses. It is also important to document interventions, provide feedback and track responses to feedback. Measure antibiotic use as either days of therapy (DOT) or defined daily dose (DDD).

## Core Element 5 – Education and Training

While education alone is not sufficient, it is vital to any successful antimicrobial stewardship program. Continued antimicrobial stewardship education should be provided to laboratory staff, physicians, pharmacists, nurses, other relevant staff, patients and communities. The tailored education and training should focus on microbiology skills, antibiotics resistance, antibiotic use and prescribing practice, Infection control. Educational programs can provide a foundation of knowledge that will work to enhance and increase acceptance of stewardship strategies. Tools such as the CDC Get Smart tool can be used to educate patients and family members

There are many options for providing education on antibiotic use such as:

- Educational presentations which can be done in formal and informal settings,
- Messaging through posters, fact-sheets, flyers and newsletters or electronic communication to staff groups.
- Reviewing de-identified cases with providers where changes in antibiotic therapy could have been made is another useful approach.
- Community engagements through local leadership using electronic and print media like community radios, television (TV), health talks and participation in community gatherings

A variety of web-based educational resources are available that can help facilities develop educational content. Tailored education has been found to be most effective when paired with corresponding interventions and measurement of outcomes.

The table below describes actions of reporting element, the corresponding level of leadership responsible for implementing the action and expertise needed.

**Table 3.6: Education and training actions on AMS**

Action	Level	Expertise
Develop, implement and integrate a training course on AMS within the existing training programs (pre- and in-service training)	Regional, National and Health facilities	Multidisciplinary team
Provide continuous professional development training	Regional, National and Health facilities	Multidisciplinary team
Establish AMS training program for communities that can be delivered by community health volunteers and health workers, media etc	Regional, National and Health facilities	Multidisciplinary team
Incorporate AMS elements into orientation package for new medical staff	Regional, National and Health facilities	Multidisciplinary team
Measure impact/effectiveness of training and education programs	Regional, National and Health facilities	Technical experts, M&E Specialists

## Core Element 6 – Communication

Communication is a vital component of the success of an antimicrobial stewardship program. There is evidence that shows that effective communication campaigns contribute towards promoting the rational use of antibiotics by prescribers and patients, as well as within the agriculture and food industries. Communication framework should contain: -

- Clear, straightforward communication that shows the vision and the benefits of the program, core clinical messages and mechanism for internal and external communication with stakeholders
- Additionally, certain design elements are recommended in a communication campaign to ensure effectiveness and impact; these include multi-pronged communication plans (Desk top job aides, IEC materials involving a mix of media channels, audience segmenting and audience-centric messaging, targeted messaging, the timing of campaign activities,
- Involvement of key opinion leaders and policy makers
- Phase-wise evaluation (formative, process, and summative evaluation) of the campaigns.

Clinical messages could be targeted to clinicians, prescribers, and patients (community). Identify and communicate to prescribers' specific situations where antibiotics should be withheld and guidance concerning the duration of antibiotic use, which is often an area of misuse. Face-to-face meetings with Medicine Therapeutic Committees (MTC) platforms for prescribers, where there is an opportunity for reflection about their prescribing practices, or attending multidisciplinary teams, web-ex conferences, call free call centres (telemedicine) are all critical in promoting learning about prudent prescribing. Table 3.7 below describes actions of communication element, the corresponding level of leadership responsible for implementing the actions and expertise needed.

**Table 3.7: Communication actions**

Action	Level	Expertise
Develop, implement and sustain an awareness campaign, communication messaging and targeted messaging on AMS	Regional and National, Sub-National	Technical experts, Health promotion experts; Risk communication experts, Media, opinion leaders and policy makers
Create and champion a sustainable system for knowledge management including capacity building	Regional and National, Sub-National	Technical experts, Health promotion experts; Risk communication experts
Disseminate evidence based best practice within and from different countries	Regional and National, Sub-National	Technical experts (Researchers, Academia etc), Health promotion experts; Risk communication experts
Develop a system with capability for early warning, alerts and notification within the antimicrobial stewardship process including cross-border communication	Regional and National, Sub-National	Technical experts (Public Health Specialist, Health Economist; Risk communication experts; ICT experts

## Core Element 7 – Quality Improvement

Quality improvement is an additional tool that can be incorporated into a stewardship program for interventions are continuously improved, and efforts sustained. There are several means of identifying areas of improvements that can be used at national or facility level. At the onset of

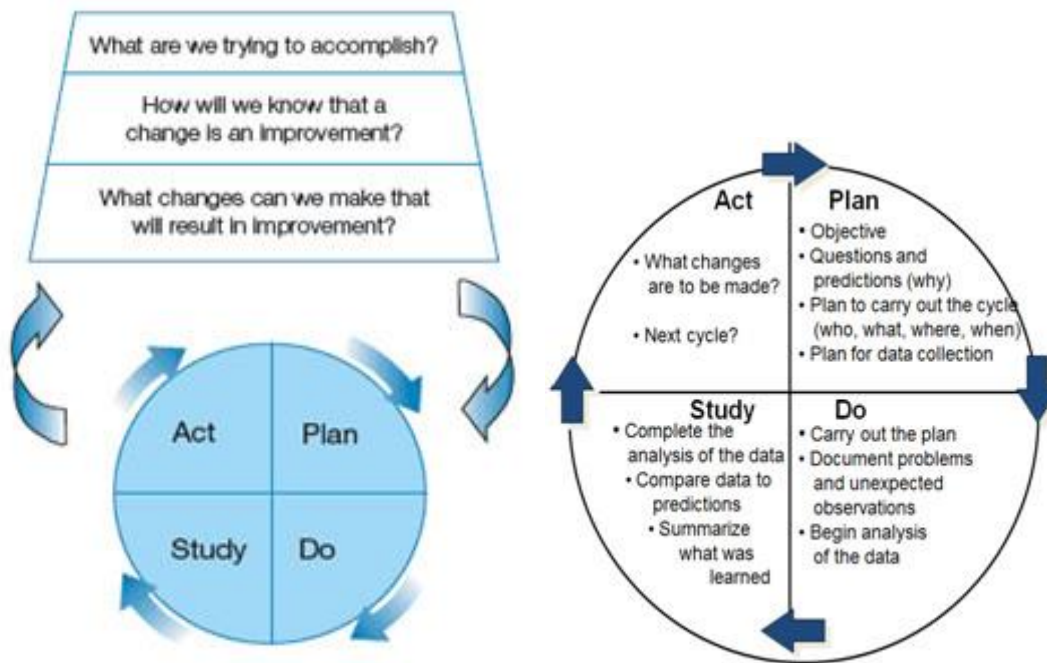
AMS program, a baseline assessment and risk assessments can identify areas of improvement whose implementation progress can be monitored regularly. Review of the AMS M&E Framework is another source for identification of areas of improvement. Client feedback platforms should be established at facility levels to track satisfaction levels. A system for measuring impact of interventions must be established.

Quality improvement should include but not limited to laboratory, clinical practice, prescription, dispensing and patient care. It should be clear on what is to be measured, the frequency of measurement and how the findings and improvements will be communicated. Standard tools should be used to measure and track quality improvement in the areas of quality management systems, timely and appropriate use of antibiotics, appropriate administration and de-escalation, data monitoring and stewardship infrastructure and availability of expertise at point of care.

Where new changes are proposed, it is recommended that they should be tested using experiential learning method, such as the Plan-Do-Study-Act (PDSA) cycle (Figure 3.2). Testing in quality improvement allows unforeseen problems to be resolved, and interventions to be evaluated and refined before full implementation into day-to-day operations. Each PDSA sequence should increase in scope and scale, and be analysed, allowing subsequent actions to be refined. Where change is proposed it is critical to outline the quality improvement steps; -

- Clearly establish the aim – What are you are trying to accomplish
- Establish a measure – How will we know that a change is an improvement
- Plan to improve – What changes can we make that will result in improvement
- A specific test of changes – Perform the PDSA cycle

Testing in quality improvement work allows unforeseen problems to be resolved, and interventions to be evaluated and refined before full implementation into widespread day-to-day operations. In general, testing should follow a sequence of Plan-Do-Study-Act (PDSA) cycles (Figure 3.2). Each sequence should increase in scope and scale, and be analysed, allowing subsequent tests to be refined. For example, a hospital AMS team decides to introduce a restricted antimicrobial formulary, with required prior phone approval from an ID physician before selected agents are dispensed. They would be wise to initially test the approval and dispensing process in a range of conditions. For example, they could work with one cooperative prescriber to see if the process works well at different times of the day, on weekends, and when different dispensing pharmacists or infectious diseases (ID) physicians are on duty. After making any necessary refinements, the team could then plan on including all respiratory patients, then all medical patients and so on.



**Figure 3.2. PDSA model for Improvement**

In addition to the PDSA, there are other available tools in quality improvement used to identify problems, resolve and measure if change has been achieved including process mapping, pareto diagrams, cause and effect diagrams (fish-bone). In all cases, the improvement process must be clearly documented as to what problem was identified and how it was improved as a source for preventative actions.

**Table 3.8: Quality Improvement**

Action	Level	Expertise
Develop/customize an M&E Framework for the AMS	Regional and National, Sub-National	Technical experts, M&E Experts
Conduct risk assessment/AMS audits to identify and prioritize areas of improvement		
Develop and implement standard tools for measuring and tracking Quality Improvement/continuous assessment	Regional and National, Sub-National	Technical experts, M&E Experts
Establish Quality Improvement Teams to implement and monitor identified improvement projects within the health facilities	Regional and National, Sub-National	
Establish client feedback mechanisms (suggestion box, surveys, hotlines) with results reviewed, improvements identified, implemented and communicated to users.	Facility	Technical experts

# **Part 4**

## **Stewardship program actions and interventions**

# 4

## Stewardship program actions and interventions

Implementation of AMS requires actions at various levels of service delivery. The summary below provides a description of actions to be taken at various levels of service delivery and administrative levels in order to effectively promote and implement a good AMS program.

### Systems level interventions

#### Regional level

Resources required	Interventions
<b>Limited resources</b>	<ul style="list-style-type: none"> <li>Promote the creation of regional AMR committees and technical working group with clear terms of reference</li> <li>Develop regional antimicrobial stewardship action plans</li> <li>Coordinate regional antimicrobial awareness campaigns</li> <li>Resource mobilization for AMR activities</li> <li>Promote regional research and development</li> </ul>
<b>Moderate resources</b> including resources for planning and dedicated staff	<ul style="list-style-type: none"> <li>Support inclusion of antimicrobial stewardship training in pre-service curriculums and develop and implement stand-alone courses</li> </ul>
<b>Resource intensive</b> and may require establishment of a formal program with trained staff and dedicated resources	<ul style="list-style-type: none"> <li>Track antibiotic use within the region and set regional targets for improvement</li> <li>Describe resistance patterns across the region to improve treatment guidelines and identify priority pathogens</li> <li>Develop systems for accreditation and certification to support adherence to standards</li> <li>Harmonization of regional GMP requirements</li> <li>Promote monitoring of antibiotic quality (pharmacovigilance, Post market surveillance)</li> <li>Conduct research and development in AMR</li> </ul>

#### National level

Resources required	Interventions
<b>Limited resources</b>	<ul style="list-style-type: none"> <li>Develop national action plan for AMR</li> <li>Establish multi-sectorial National AMR committees with clear terms of reference</li> <li>Develop a national AMR research agenda</li> <li>Mobilize resources for AMR</li> <li>Establish technical working group for AMS</li> <li>Coordinate national antimicrobial awareness campaigns</li> <li>Dissemination of research results, surveillance reports and AMS program reports.</li> <li>Promote research and development</li> </ul>
<b>Moderate resources</b> including resources for planning and dedicated staff	<ul style="list-style-type: none"> <li>Develop and ensure access to updated and evidence based national medicines formulary, standard treatment guidelines and essential medicines list</li> <li>Develop national guidelines for antimicrobial stewardship</li> <li>Conduct AMS program annual review</li> <li>Implement national infection prevention control guidelines</li> <li>Promote compliance to treatment guidelines</li> </ul>



	<ul style="list-style-type: none"> <li>▪ Develop and strengthen policies and procedures on regulation of access to reserve antimicrobials</li> <li>▪ Promote diagnostic stewardship</li> <li>▪ Inclusion of antimicrobial stewardship training course into the pre-service curriculums and develop stand-alone courses</li> </ul>
<p><b>Resource intensive</b> and may require establishment of a formal program with trained staff and dedicated resources</p>	<ul style="list-style-type: none"> <li>▪ Build laboratory capacity to strengthen AMS activities</li> <li>▪ Build pharmaceutical sector capacity</li> <li>▪ Enforce regulatory authority policies to promote prescription and dispensing</li> <li>▪ Develop a national research agenda on AMR and conduct research</li> <li>▪ Track antibiotic use and consumption to assess appropriateness and set national targets for improvement</li> <li>▪ Monitoring national resistance patterns to improve treatment guidelines and identify priority pathogens</li> <li>▪ Monitor antibiotic quality</li> <li>▪ Identify and address drivers of inappropriate prescribing behavior</li> </ul>

**Sub-national level\* (Regional/Provincial/County, sub-county administrative levels)**

Resources required	Interventions
<b>Limited resources</b>	<ul style="list-style-type: none"> <li>▪ Establish multi-sectorial subnational AMR committees with clear terms of reference</li> <li>▪ Establish linkages with the medicines and therapeutics committee and infection prevention control</li> <li>▪ Organize sub-national antimicrobial awareness campaigns</li> </ul>
<b>Moderate resources</b> including resources for planning and dedicated staff	<ul style="list-style-type: none"> <li>▪ Ensure access and monitor compliance to national medicines formulary, standard treatment guidelines and essential medicines list</li> <li>▪ Promote diagnostic stewardship</li> </ul>
<b>Resource intensive</b> and may require establishment of a formal program with trained staff and dedicated resources	<ul style="list-style-type: none"> <li>▪ Implement national action plan for AMR</li> <li>▪ Implement national guidelines for antimicrobial stewardship</li> <li>▪ Conduct operational research on AMR.</li> <li>▪ Implement national infection prevention control guidelines</li> <li>▪ Build diagnostic capacity to strengthen AMS activities</li> <li>▪ Build pharmaceutical sector capacity to ensure access to quality affordable and efficacious medicines and pharmaceutical care services</li> <li>▪ Comply with regulatory authority requirements to promote appropriate prescription and dispensing practices</li> <li>▪ Track and report sub national antibiotic use and consumption</li> <li>▪ Monitoring and reporting sub national resistance patterns to improve treatment guidelines and identify priority pathogens</li> <li>▪ Conduct in service antimicrobial stewardship training</li> <li>▪ Monitor and report antibiotic quality (pharmacovigilance and post market surveillance)</li> <li>▪ Identify and address drivers of inappropriate prescribing behavior</li> </ul>

**\*Administrative levels depending of country structures**

## Service delivery point (health facility) and community interventions

### *Policies that support optimal use*

#### **Hospital**

- Make sure they obtain the updated National clinical treatment guidelines derived from local data
- Make sure they obtain the National essential medicine list
- Make sure they obtain the National AMS guidelines (if available), or adopt either WHO or CDC AMS guidelines
- Make sure they comply to National medicines therapeutic committee guidelines
- Develop a hospital formulary with restrictions and pre-authorizations
- Develop surgical prophylaxis guidelines which adhere to appropriate antimicrobial use based on local data
- Make sure the empirical treatment is regularly reviewed based on local data from their setting.
- Ensure efficient procurement based on hospital formulary to promote consistent availability
- Make sure they fully comply with National IPC policy

#### **Community**

- Include appropriate use of antimicrobials in public education campaigns of the community health strategies
- Sensitize the community on the importance of hygiene and vaccination
- Community healthcare workers should not dispense antimicrobials

### *Implementing specific antimicrobial interventions*

Level of care	Interventions
<b>Hospital settings</b>	
<b>Broad interventions</b>	<ul style="list-style-type: none"> <li>▪ Formally establish and support antimicrobial stewardship committee with clear terms of reference</li> <li>▪ Establish antimicrobial stewardship rounds which include infectious disease specialist, clinical microbiologist and clinical pharmacist or pharmacist</li> <li>▪ Enhance communication and teamwork among stakeholders e.g. laboratory personnel vs. clinicians, pharmacists vs. clinicians</li> </ul>
<b>Pharmacy driven interventions</b>	<ul style="list-style-type: none"> <li>▪ Regular prescriptions audits (minimum twice a year) and provide feedback to prescribers</li> <li>▪ Enforce antimicrobial restrictions and pre-authorization as per hospital formulary and National medicine guidelines</li> <li>▪ Regularly conducts Drug use audits and provides feedback to stakeholders</li> <li>▪ Ensure antimicrobial expenditure analysis is done and the reports are shared to HMT meetings</li> <li>▪ Ensure antibiotic timeouts i.e. regular prompts to the clinicians to re-evaluate intravenous antibiotics every 48 to 72 hours especially among in-patients</li> <li>▪ Ensure regular prompts to clinicians on IV to oral conversion and dose adjustments</li> </ul>

	<ul style="list-style-type: none"> <li>▪ Ensure review of antibiotics based on culture and AST results</li> <li>▪ Strict compliance to surgical prophylaxis guidelines</li> <li>▪ Ensure compliance with treatment guidelines in terms of duration of treatment</li> <li>▪ Perform medication reviews by pharmacists for in- and outpatients</li> <li>▪ Ensure proper medication use counselling while dispensing</li> </ul>
<b>Infection and Syndrome Specific Interventions</b>	<ul style="list-style-type: none"> <li>▪ Develop and incorporate guidelines for management of high-risk infections and outbreaks such as multidrug resistant organisms (MDRO) and C. difficile into the standard treatment guidelines</li> <li>▪ Ensure harmonization of IPC and AMS teams towards comprehensive management of high-risk infections and outbreaks such as MDRO and C. difficile</li> </ul>
<b>Diagnostic driven interventions</b>	<ul style="list-style-type: none"> <li>▪ Capacitate the laboratory (staff, equipment, reagents, ICT) to offer correct and timely results to clinicians</li> <li>▪ Ensure uninterrupted provision of laboratory services</li> <li>▪ Enhance quality of laboratory services and adherence to laboratory standards</li> <li>▪ Generate hospital-specific antibiograms and laboratory utilization data every 3 to 6 months (depending on the flow of samples), and provide feedback to stakeholders for interventions</li> </ul>
<b>Education</b>	<ul style="list-style-type: none"> <li>▪ Train hospital staff on AMS using National AMS program/ curriculum</li> <li>▪ Induct students/interns/new staff on AMS practices</li> <li>▪ Conduct infection-specific CMEs e.g. UTI, SSI, URTI on AMS</li> <li>▪ Awareness creation among clinicians on conditions that often do not require antimicrobials</li> <li>▪ Provision of teaching materials/job aids e.g. algorithms</li> </ul>
<b>Community Settings</b>	
<b>Broad Interventions</b>	<ul style="list-style-type: none"> <li>▪ Public education on appropriate antimicrobial use</li> <li>▪ Provision of IEC materials about AMS e.g. posters, brochures, multimedia etc</li> <li>▪</li> </ul>
<b>Pharmacy Driven Interventions</b>	<ul style="list-style-type: none"> <li>▪ Public sensitization on the danger of self-medication i.e. buying antimicrobials without prescription</li> </ul>
<b>Infection and Syndrome Specific Interventions</b>	<ul style="list-style-type: none"> <li>▪ Provision of education on the importance of special interventions such as isolation of patients with high-risk/contiguous infection</li> </ul>

# 5 Monitoring and Evaluation Plan for the AMR Stewardship

The M&E plan is the framework which outlines the indicators to be used to monitor, evaluate and report on the progress of project implementation. It outlines how the proposed strategies are expected to yield outcomes.

COMPONENTS	STRATEGIES	KEY OUTCOMES/RESULTS	INDICATORS
Research and Development	Build analytical capacity in data analysis interpretation of results, and design of data collection tools through training programs	Improved capacity in AMR data analysis and interpretation of results	# of health personnel trained in AMR data analysis interpretation of results
	Develop National AMR Research Agenda for the country	Relevant Research agenda developed and implemented to influence policy reforms	Availability of National AMR research Agenda
	Develop country guidelines on advocacy and communication on AMR	Improved advocacy and communications on AMR	Availability of AMR Communication guidelines
	Engage communication experts to translate technical research findings into policy briefs and recommendations	Increased utilization of research findings to inform programmatic improvements	# of policy guidelines produced and disseminated
	Foster collaboration between researchers, program managers and policy makers		# of research studies on alternative treatment options supported
	Support research on alternative treatment options and foster collaboration between researchers and alternative medicine community	Increased availability of alternative treatment options from alternative medicine community	# of Countries supporting researches on alternative treatment options
	Cultivate inclusion of research in the curriculum of training programs	Improved research capacities	# of countries with research curriculum on training programs
	Develop protocols for reporting and dissemination of data locally		
	Establish indicators for monitoring stewardship interventions and design a system for AMR Stewardship	Improved AMR Stewardship	# of countries with designed system for AMR stewardship program
	Facilitate voluntary participation in operational research (OR)		

Regulation and Manufacturing	Enhance inspection of pharmacies and antibiotics selling outlets	Inspection of pharmacies and antibiotics selling outlets enhanced	% of pharmacies inspected per country % of pharmacies complying with National Antibiotic Regulation
	Develop harmonized tools for assessing compliance to regulatory standards	Harmonized tools for assessing compliance to regulatory standards developed	# of countries complying with harmonized regulatory standards
	Engaging in PPP to enhance enforcement and reduce malpractices	Enhanced enforcement and reduce malpractices through public private partnership (PPP)	# of malpractices reported per year
	Public education and awareness of the public on risks associated with purchase of medicine without a prescription	Increased public awareness on risks associated with purchase of medicine without a prescription	# Education and awareness campaigns conducted
	Develop and strengthen policies to regulation of waste disposal	Policies on regulation of antimicrobial waste disposal strengthened	# of countries with Policies on regulation of antimicrobial waste disposal
	Establish safe disposal programs at sub-national levels to support hospitals and community health units	Antimicrobial safe disposal programs established	# of countries with Antimicrobial safe disposal programs
	Advocate for safe disposal of antimicrobial agents in the community		
	Conduct OR (KAPS, PPS)	Improved knowledge on AMR	# of operational research (OR) studies conducted
	Formulate stringent but friendly regulatory frameworks and approval processes	Regulatory frameworks established	# of facilities with Regulatory frameworks established
	Adopting harmonizing the guidelines for Good Manufacturing Practices per country	Harmonized the guidelines for Good Manufacturing Practices per country	# countries with harmonized guidelines for Good Manufacturing Practices
Supply Chain: Selection, Procurement,	Involve required committed and motivated expertise	Enforced categorizing antibiotics according to WHO list of access, watch and reserve	# of countries with enforced categorization of antibiotics according

Supply, and Distribution		
Strengthen AMR surveillance to guide selection of antimicrobials	Strengthened AMR surveillance	to WHO list of access, watch and reserve
Capacity building on proper quantifications and forecasting	Improved capacity on proper quantifications and forecasting	# of countries with Improved capacity for quantifications and forecasting
Strengthen the supply chain	Strengthened the supply chain	# of countries with strengthened the supply chain
Ensure pre and post market surveillance for antimicrobials in the country is conducted	Improved pre and post market surveillance for antimicrobials	# of countries conducting pre and post market surveillance
Conduct surveys on availability, access and use of antimicrobials	Surveys on availability, access and use of antimicrobials	Availability of surveys reports on availability, access and use of antimicrobials
Capacity building on supply chain management	Improved capacity on supply chain management	# of staff trained on supply chain management
Update the essential medicines list based on efficacy, quality and cost effectiveness	Essential medicines list updated based on efficacy, quality and cost	# of countries with updated essential medicines list
Education and Training on Medicines selection		
Increase investment in diagnostics including reagents and supplies, laboratory quality management systems	Increased investment in diagnostics including reagents and supplies	# of stockouts of reagents and supplies
Promote laboratory accreditation including microbiology	Increased number of laboratories accredited	# of laboratories accredited
Conduct diagnostic stewardship training for clinicians (include diagnostic stewardship in the training package for AMR	Increased awareness on diagnostic stewardship among clinicians	# of clinicians trained on diagnostic stewardship
Diagnostic, prescribing medicine, dispensing and	Strengthen laboratory capacity (including LIMS), staffing, infrastructure and data management.	# of laboratories with approved staffing norms
		# of laboratories with adequate infrastructure for AMR Surveillance

responsible use (Access & Stewardship pillar)		
		# of laboratories with 3 stars and above * under the SLIPTA scheme
Develop, customize, and disseminate guidelines and algorithms	Guidelines customized and disseminated	# of Guidelines customized and disseminated
Develop Treatment guidelines to reflect the AWare categorization of antibiotics	Treatment guidelines reflecting the AWare categorization of antibiotics developed	
Strengthen the pharmaceutical supply chain to ensure uninterrupted supply of essential medicines	Strengthened the pharmaceutical supply chain	# of stockouts supplies of essential medicines
Conduct diagnostic stewardship training for clinicians (include diagnostic stewardship in the training package for AMR)	Improved knowledge and skills on diagnostic stewardship	# of countries with training programs on diagnostic stewardship # of clinician trained on diagnostic stewardship
Ensure access and availability to high quality and effective drugs for all patients needing them.	Improved access to high quality and effective drugs for all patients needing them.	# of stockouts of drugs
Sensitize patients about the importance of diagnosis before treatment	Increased awareness on the importance of diagnosis before treatment	# of countries with patients' sensitization programs on the importance of diagnosis before treatment
Improve laboratory clinician communication		# of laboratories utilizing newer, simpler, and faster technologies
Promote laboratory accreditation including microbiology		# of countries utilizing newer, simpler, and faster technologies
Promote use of newer, simpler, and faster technologies		# of countries sharing AMR Surveillance Data
Promote sharing and use of AMR data		
Promote performance-based financing (PBF) for services		

3 stars and above includes laboratories that have been accreditation using international standards (ISO15189; College of American Pathologists, CAP etc)

### Core Element 1 - Leadership Commitment

ACTIONS	KEY OUTCOMES/RESULTS	INDICATORS
Mobilize resources and budget for financial support to antimicrobial stewardship activities	Improved implementation of Antimicrobial Stewardship activities	Availability of written statement to support stewardship activities # of Antimicrobial stewardship activities implemented
Designate a multidisciplinary stewardship team	Established multidisciplinary stewardship team	# Personnel's constituting a multidisciplinary stewardship team
Establish stewardship-related duties in job descriptions and annual performance reviews for AMS team	Stewardship-related duties included in job descriptions	# of health facilities with Stewardship-related duties included in staff's job descriptions
Establish clear communication structures/ lines of authority on antimicrobial stewardship programs.	Communication structures established	Availability of clear communication structures/ lines of authority on antimicrobial stewardship programs.
Allocate time to participate in stewardship activities including training and education	Improved participation in stewardship activities	
Stewardship programme performance review	Improved implementation of the Stewardship programme	# of performance reviews conducted for the stewardship programme
Advocate for support for stewardship activities at countries and regional level	Call to action for stewardship support	Formal or written statement to support stewardship activities to improve and monitor antimicrobial use Availability of resources to support
<b>Core Element 2 –Governance Structures</b>		
ACTIONS	KEY OUTCOMES/RESULTS	INDICATORS
Formal constitution of AMS Team within the Member States	AMS team constituted	# of countries with AMS team constituted # of countries with AMS governance structure



Improve antibiotic prescription and use	Improved antibiotic prescription and use	# of facilities with improved antibiotic prescription and use
Educate patients and staff on the importance of appropriate antibiotic use	Increased awareness on appropriate antibiotic use	# of patients/staff trained on the importance of appropriate antibiotic use
Auditing of prescription	Improved prescription	# of facilities with proper audit systems for prescription
Managing antimicrobial supply chain (ensuring availability of antimicrobials)		# of facilities with stock out of antimicrobials
Communicate with prescribers on available medicines, dosages etc	Improved communications on available medicines, dosages	# of facilities with regular reports on available medicines, dosages
Keeping documentation of antimicrobials consumptions	Appropriate antibiograms generated	# of facilities with appropriate antibiograms
Ensure timely communication of laboratory results	Improved turn around time for laboratory results	Average turn around time
Review medications as part of their routine duties	List of medications reviewed	# of facilities with list of medications reviewed
Enhancing communication with other relevant departments e.g. laboratory teams, pharmacy teams and clinicians	Enhanced communication with other relevant departments e.g. laboratory teams, pharmacy teams and clinicians	# of facilities with enhanced communication with other relevant departments
Analysing, interpreting and monitoring of resistance trends	Improved AMR surveillance	# of facilities with routine systems for AMR surveillance
<b>Core Element 3 – Accountability and Drug Expertise</b>		
<b>ACTIONS</b>	<b>KEY OUTCOMES/RESULTS</b>	<b>INDICATORS</b>
Designate a leader and co-leader to be accountable to the leadership for meeting established goals or targets	Leader and co-leader designated	# of facilities with Leaders and co-leader designated
Training of AMR team leadership in antibiotic stewardship	Improved capacity in antibiotic stewardship	# of personnel trained in antibiotic stewardship
Appoint Pharmacy co-lead to improve the use of antibiotics within the facility	Pharmacy co-lead appointed to improve the use of antibiotics within the facility	# of facilities with Pharmacy co-lead appointed

Set the practice standards for assessing, monitoring and communicating patient outcomes	Improved patients' outcomes	# of facilities with standards for assessing, monitoring and communicating patient outcomes
<b>Core Element 4 – Reporting</b>		
<b>ACTIONS</b>	<b>KEY OUTCOMES/RESULTS</b>	<b>INDICATORS</b>
Harmonize the reporting system to ensure flow of information from Health Facilities to National and Regional	Enhanced flow of information from Health Facilities to National and Regional	Availability of harmonized reporting tools from Health Facilities to National and Regional
Disseminate antibiograms and consumption information (antimicrobial agents used) by specific community within the country	Antibiograms and consumption information by specific community disseminated	# Health facilities with defined antibiograms # Health facilities with antibiotic consumption information
Provide guidelines to standardize antibiograms development	Standardized Antibiograms Guideline developed	Availability of the standardized guideline for Antibiograms development
Share AMR information (feedback) with all healthcare providers as well as leadership and any other stakeholders	AMR information shared	# of multisectoral data sharing meetings convened # of publications made on AMR
Develop/adopt standardized tools such as those for drug use evaluations or antibiotic audit forms for reviews	Standardized tools for drug use evaluations developed	Availability of standardized tools for drug evaluations
<b>Core Element 5 – Education and Training</b>		
<b>ACTIONS</b>	<b>KEY OUTCOMES/RESULTS</b>	<b>INDICATORS</b>
Develop, implement and integrate a training course on AMS within the existing training programs (pre and in-service training)	Improved capacity on AMS	# of pre-service with integrated course on AMS # of in-service with integrated course on AMS # of CPD sessions conduct
Establish AMS training program for communities that can be delivered by community health volunteers and health workers, media etc	Increased awareness on AMR	# of communities trained on AMS
Incorporate AMS elements into orientation package for new medical staff	Impact/effectiveness of training and education programs documented	# of new medical staff oriented on AMS Availability of Impact/effectiveness Report
<b>Core Element 6 – Communication</b>		
<b>ACTIONS</b>	<b>KEY OUTCOMES/RESULTS</b>	<b>INDICATORS</b>
Develop, implement and sustain an awareness campaign, communication messaging and targeted messaging on AMS	Increased awareness on AMS	# of countries with active AMS awareness campaigns conducted
Create and champion a sustainable system for knowledge management including capacity building		

Disseminate evidence based best practice within and from different countries	Improved dissemination of evidence based best practice within and from different countries	# of fora convened to disseminate evidence based best practices
Develop a system with capability for early warning, alerts and notification within the antimicrobial stewardship process including cross-border communication	Improved capacity for early warning, alerts and notification within the antimicrobial stewardship process	# of early warnings and alerts received per quarter
<b>Core Element 7 – Quality Improvement</b>		
<b>ACTIONS</b>	<b>KEY OUTCOMES/RESULTS</b>	<b>INDICATORS</b>
Conduct risk assessment/AMS audits to identify and prioritize areas of improvement	Risk assessment conducted	# of countries conducted Risk assessment
Develop and implement standard tools for measuring and tracking Quality Improvement/continuous assessment	Tools for measuring and tracking Quality Improvement developed	Availability of tools for measuring and tracking Quality Improvement
Establish Quality Improvement Teams to implement and monitor identified improvement projects	Improved quality	# of Quality Improvement Teams established
Establish client feedback mechanisms (suggestion box, surveys, hotlines) with results reviewed, improvements identified, implemented and communicated to users.	Improved customer care	# of health facilities with established client feedback mechanisms



# Resource Mobilization

Resource mobilization refers to all activities involved in securing new and additional resources. It also involves better utilization of, and maximizing, existing resources. Resource mobilization for the Antimicrobial Resistance Stewardship Program involves getting stewardship activities into plans and budgets of the member state governments, institutions and agencies and development partners at different levels. Stewardship activities can be incorporated within existing programs at the Ministry of health and other institutions. Many government programs already have a stewardship element imbedded in their routine activities.

To be funded from the government fiscus or development partners, AMS should be included in relevant national policies and strategic plans. Member states should engage private institutions using PPP models to finance AMS

The key stakeholders who should be engaged to mobilize resources for the stewardship program are as follows:

- The ECSA Health Community and East African Community secretariat as the regional stewardship focal point.
- The Ministry of Health as the national stewardship focal point for all collaborative efforts.
- Development partners
- The national programs including the TB, AIDS and malaria control programs
- The National Medicines Regulatory Authority
- Professional councils for doctors, nurses, pharmacists etc
- Private and public health facilities
- Community based organizations.
- Institutions of Higher learning (including Public and Private Universities)
- Pharmaceutical, diagnostic and medical distributors
- Research organizations

Government funding can be utilized to support some stewardship activities if they are budgeted and planned for especially those that require limited and moderate resources. For resource intensive activities, additional funding could be sought for from different stakeholders.

**Table 6.1: Roles of the different stakeholders**

Level	Organization	Activities
<b>Regional level</b>	EAC, ECSA-HC and Africa CDC secretariat	<ul style="list-style-type: none"> <li>• Provide a linkage between member states and donors.</li> <li>• Provide technical assistance on how countries can increase resources for stewardship activities (domestic and external).</li> </ul>
<b>National level</b>	Ministry of health, Government programs, National Medicine Regulatory Agency	<ul style="list-style-type: none"> <li>• Plan and budget for stewardship activities</li> <li>• Increase domestic fund allocation to stewardship programs</li> <li>• Define pathways for private sector financing in the implementation of stewardship activities</li> <li>• Raise resources for stewardship activities by advocating for funds from potential donors</li> </ul>
<b>Health facility level</b>	Hospitals, health centres, Laboratories, pharmacies,	<ul style="list-style-type: none"> <li>• Ensure transparency and accountability of funds</li> <li>• Plan and budget for stewardship activities.</li> <li>• Advocate for funds for stewardship activities.</li> </ul>

# 7

## Risk Management

Risk management involves identification, monitoring and managing potential risks in order to minimize the negative impact they may have on the implementation of AMS program. The identified risks are analysed, risk mitigation strategies identified, implemented and monitored for their effectiveness.

Similarly, for the proposed AMS program to realize its full potential, there are risks that have to be anticipated and mitigation measures implemented to maximize its benefits. The Table below list some of the identified risks and proposed mitigation measures

**Table 7.1: Potential risks and mitigation measures**

Potential Risk	Mitigation Measures
<b>Inadequate budget to perform Antimicrobial Stewardship (AMS) activities</b>	Mobilise resource and Budget for Antimicrobial Stewardship (AMS) activities
<b>Lack of National AMR research Agenda</b>	Develop a National AMR research agenda
<b>Inadequate Human resource (laboratory, Pharmacy, clinicians, nurses etc) s</b>	Employ/deploy required human resources to perform AMS activities
<b>Frequent stock out of laboratory reagents, essential equipment and antimicrobials</b>	Strengthen supply chain systems to ensure accurate quantifications, optimum procurement and timely distribution of laboratory reagents, essential equipment and antimicrobials
<b>Existence of sub-standard medicines and diagnostics in the market</b>	Build capacity in GMP within the local Pharmaceutical Industries Establishing mechanism for monitoring compliance to GMP using structures like the National Drug Authority
<b>Poor quality of Diagnostic services</b>	Build capacity in laboratory quality management systems (LQMS) Enroll Laboratories in LQMS programs (accreditation, SLIPTA, GCLP)
<b>Outdated treatment guidelines, protocols, policies and formulary list</b>	Review, and update based on evidence and train relevant staff on treatment guidelines, policies, protocols, and formulary list
<b>Infiltration of market with counterfeit, falsified and unregulated medicines</b>	Enforcement of regulation and enhance pre-and post-market surveillance
<b>Lack of data on antimicrobial use and consumption</b>	Conduct and disseminate findings of Regional/National surveys on antimicrobial use and consumption
<b>Access to antibiotics without prescription</b>	Regulatory enforcement policies requiring prescription
<b>Poor intersectoral collaborations</b>	Fostering intersectoral collaborations with various stakeholders including incorporation of members from other relevant sectors into AMS committees
<b>Inadequate infrastructure</b>	In collaboration with other partners advocate for improved infrastructure where need
<b>Poor water and sanitation</b>	Through multisectoral collaboration enhance provision of safe water and sanitation facilities to citizens
<b>Inappropriate disposal of unused medication</b>	Educate the public and health care workers on proper disposal of unused medicine (remaining after change of treatment) Provide collection boxes in health facilities and pharmacies for disposing unused medicine