

Module 2: Components of AMS



Objectives

By the end of this module, you should be able to:

1. Describe the AMS components
2. Describe the relationship between the AMS components
3. Outline for each component the gaps, strategies, resources and responsibilities
4. State the principles of diagnostic stewardship, optimal prescribing, dispensing and responsible use of antimicrobials



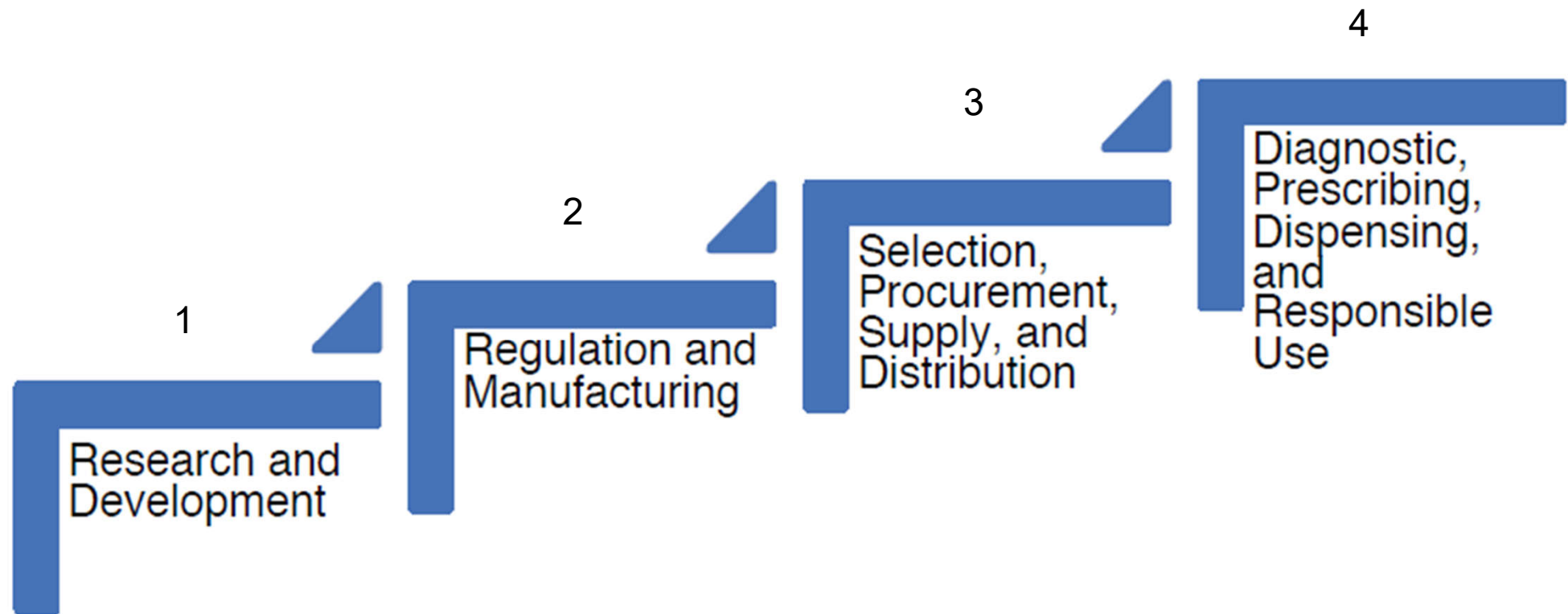
Overview of AMS Components

- In an integrated approach to optimising antimicrobial use in the context of UHC, WHO has stated the following components to be integral in AMS: Regulation of antimicrobial agents, supply chain management, access to antimicrobials and use, AMR surveillance, immunisation, and infection prevention and control (IPC).
- In the Kenyan context, we consider research and development and manufacturing as key components that have been overlooked elsewhere, and we incorporate them in our stewardship guidelines, in addition to the WHO components
- In addition, developing and utilizing a Monitoring and Evaluation (M&E) framework is essential throughout the implementation of the core elements, ensuring progress is tracked, challenges are identified, and improvements are continuously informed by data.



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Components of AMS



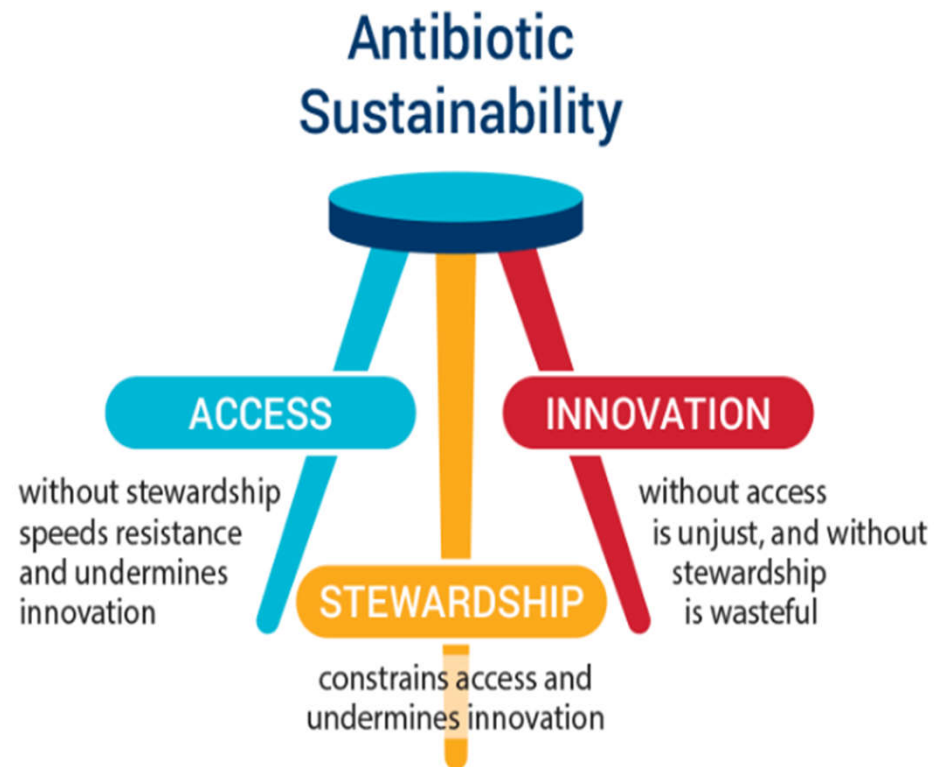
The Framework of AMS

The AMS framework is built on a delicate balance between 3 pillars that ensure the sustainable use of antibiotics:

- 1. Research and development (innovation)** involves advancing new antimicrobials
- 2. Access** entails establishing doorways for millions of people to obtain antimicrobials when they need them
- 3. Stewardship** hinges on efforts to maintain the effectiveness of existing medicines.



The Framework of AMS...



Hoffman S, Outterson K. JLME (2015)



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The Framework of AMS...

- Access to antimicrobials without consideration for conservation and innovation, is likely to speed up resistance,
- AMS, on the other hand, can constrain access and undermine innovation.
- Furthermore, innovation without access is unjust, and access without conservation wasteful.
- AMS programs should aim to strike a balance between the 3 pillars (particularly in resource-limited settings), ensuring that access to essential antimicrobials is preserved and expanded where needed.



1. Research & Development (R&D)

- Involves the development of new **Antimicrobials, Diagnostic tools, Vaccines, and Interventions** for preventing and controlling AMR.
- R&D fundamentally supports the stewardship & access pillars, by promoting the availability of effective antimicrobials against resistant pathogens.
- In 2024, WHO released a Bacterial Priority Pathogens List focusing on 15 pathogens in human health, to guide global R&D priorities in AMR.
(<https://www.who.int/publications/i/item/9789240093461>)



WHO Bacterial Priority Pathogens List, 2024

Critical group	High group	Medium group
 <i>Acinetobacter baumannii</i> carbapenem-resistant	 <i>Salmonella Typhi</i> fluoroquinolone-resistant	 Group A Streptococci macrolide-resistant
 Enterobacterales third-generation cephalosporin-resistant	 <i>Shigella</i> spp. fluoroquinolone-resistant	 <i>Streptococcus pneumoniae</i> macrolide-resistant
 Enterobacterales carbapenem-resistant	 <i>Enterococcus faecium</i> vancomycin-resistant	 <i>Haemophilus influenzae</i> ampicillin-resistant
 <i>Mycobacterium tuberculosis</i>, rifampicin resistant^a ^a RR-TB was included after an independent analysis with parallel criteria and subsequent application of an adapted MCDA matrix.	 <i>Pseudomonas aeruginosa</i> carbapenem-resistant	 Group B Streptococci penicillin-resistant
	 Non-typhoidal <i>Salmonella</i> fluoroquinolone-resistant	
	 <i>Staphylococcus aureus</i> methicillin-resistant	
	 <i>Neisseria gonorrhoeae</i> third-generation cephalosporin, and/or fluoroquinolone-resistant	



WHO bacterial priority pathogens list, 2024 (Organization, W.H, 2024).

Challenges of R&D

Key gaps	Proposed Strategies	Resources Available
Lack of defined AMR research agenda	Develop a research agenda guided by global research agenda for AMR/AMS	Existing regional and local research institutions
Uncoordinated research on AMR/AMS	Consolidate and develop an inventory for ongoing and completed research on AMR/AMS	NASIC, NACOSTI
Limited funding for AMR and AMS research	Increase government funding, strengthen local, regional, and international partnerships, incentivize private sector investment	Government funding, partners
Inadequate research infrastructure such as laboratories, diagnostic tools, and data systems	Infrastructure development, strengthen diagnostic capabilities, and invest in digital health solutions	Government funding, partners
Limited collaboration between research institutions	Establish research networks, promote regional and international collaborations	NASIC, Research institutions
Weak intellectual property protection and innovative management systems	Strengthen IP laws and support innovation management	Kenya Intellectual Property Institute



2. Regulation and Manufacturing

- Pharmaceutical manufacturing processes can contribute to AMR through two key routes:
 - manufacturing antimicrobials with insufficient levels of the active antimicrobial ingredient.
 - releasing antimicrobials into the environment in pharmaceutical waste
- Regulation is done through:
 - Ensuring the manufacturing of high-quality antimicrobials & dispensing of antimicrobial agents based only on prescriptions (PPB)
 - Ensuring compliance of waste management related to pharmaceutical/ antimicrobial production (NEMA)
- Regulation and manufacturing supports the AMS access pillar.



Challenges of Regulation and Manufacturing

Key gaps	Strategies and solutions	Resources available
Low compliance to existing regulation of pharmaceutical manufacturing	Advocacy and Enforcement	PPB National Quality control Laboratory
Weak post market surveillance of pharmaceutical products	Strengthen post-market surveillance	Pharmacovigilance online platform for reporting
Low compliance with pharmaceutical waste management guidelines	Advocacy and enforcement	NEMA PPB



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3. Selection, Procurement, Supply and Distribution

Supply chain is a network of individuals, organisations, activities, resources, and technologies involved in the delivery of a product from the source to the intended institutions

Supply chain inadequacies result in antimicrobial shortages. These may lead to:

- Inadequate disease control,
- Inappropriate antibiotic use e.g. violating the AWaRe classification of antimicrobial agents and,
- The circulation and use of counterfeit or substandard antimicrobials resulting from erratic supply of active pharmaceutical ingredients

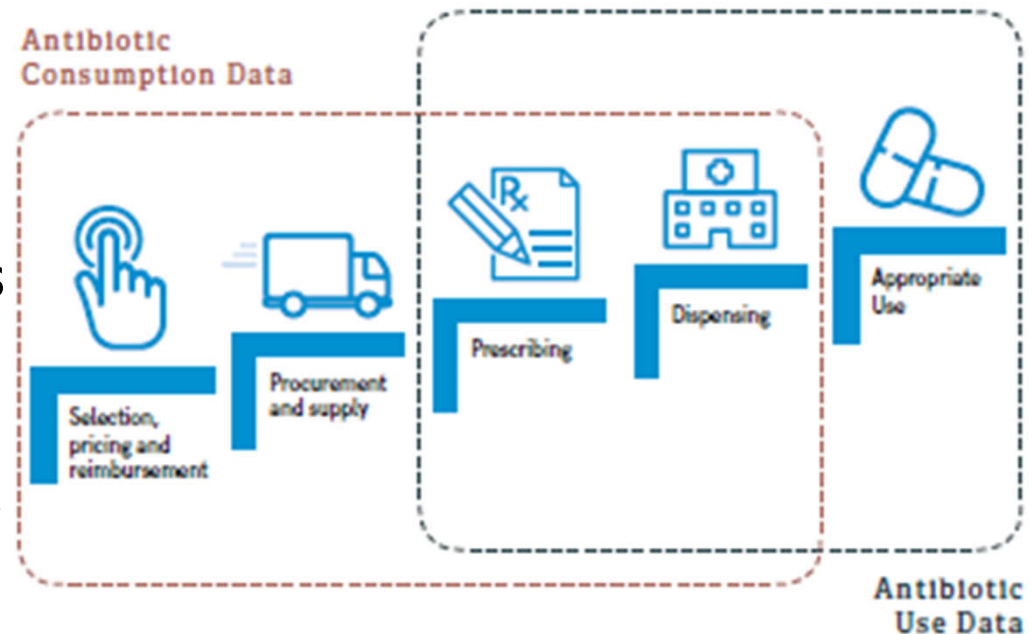


3. Selection, Procurement, Supply and Distribution...

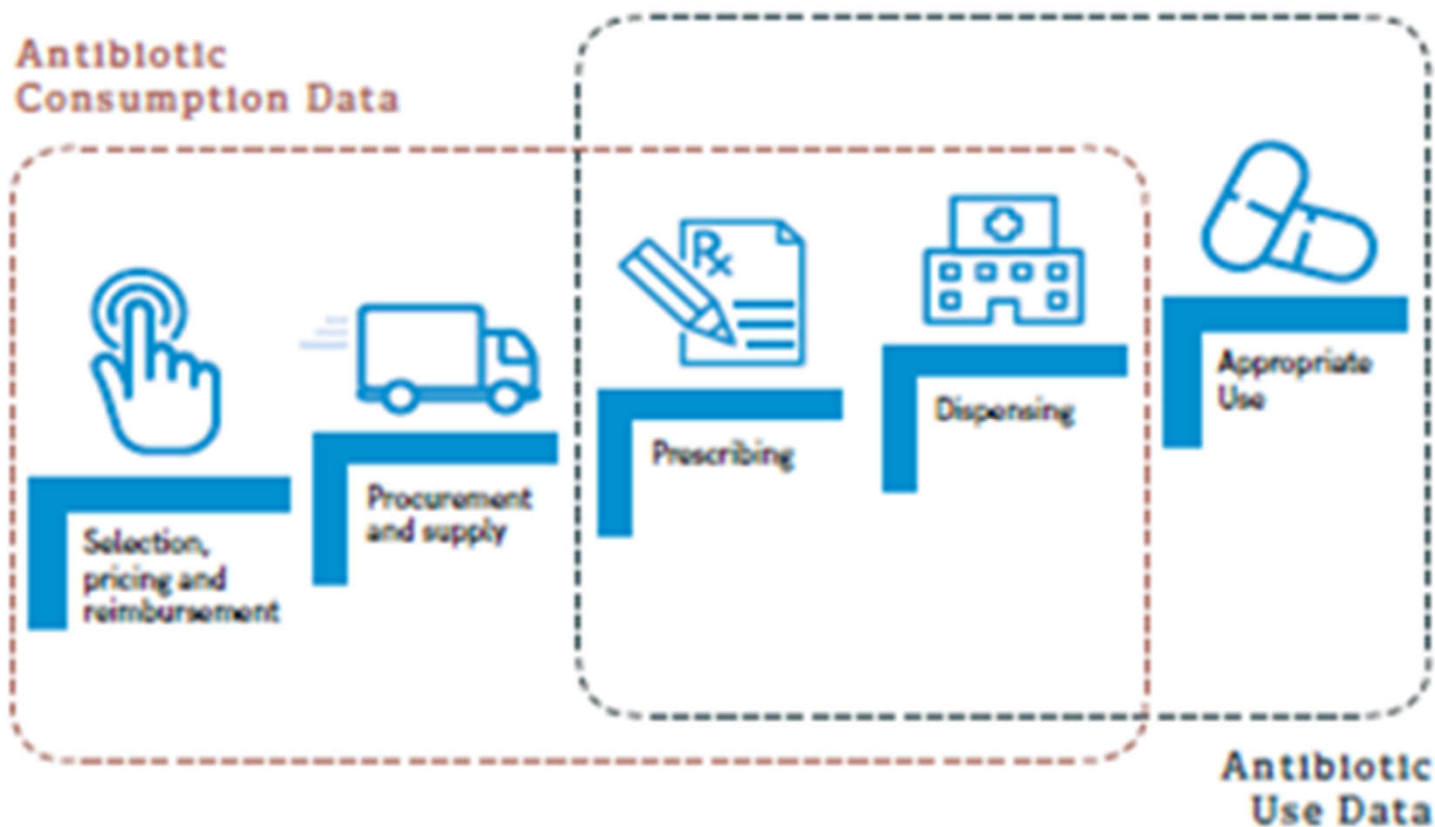
Process of supply chain

1. Selection:

- It is critical to access pillar.
- Selection should be guided by the current Essential Medicines List, formulary, and guidelines whose development should be evidence-based, and developed by multi-disciplinary team.



3. Selection, Procurement, Supply and Distribution...



3. Selection, Procurement, Supply and Distribution...

2. Procurement:

An efficient procurement system is essential for ensuring the uninterrupted supply of quality-assured antimicrobials while minimizing wastage.

Best practice:

- Forecasting/ planning: To ensure that the right products are available at the right time and in the right quantities - preventing stock-outs and wastages.
- Validation of the sources to ensure access to quality products.

3. Supply and distribution:

These processes are complex and prone to inefficiencies.

Best practice:

- Ensure that the right medicine is delivered to the right patient, at the right time, and at the right price — all the way to the point of care, including the last mile of distribution (such as remote or underserved areas).



Challenges of Supply Chain

Key gaps	Strategies and solutions	Resources available
Financial constraints	Budgeting and cost effective procurement	Facility improvement fund, Budgetary allocations
Inventory management challenges	Training and capacity building Advanced inventory management systems	Partners supporting the training HMIS in facilities- has an inventory module
Supply chain logistics disruptions Transportation issues	Diversify suppliers and contingency plans Streamline custom procedures to reduce bureaucratic delays for importing essential medicines.	KEMSA
Security and theft	Enhanced security measures and accountability systems(regular audits)	Office of auditor general, Internal audit mechanisms



4. Diagnostics, Prescribing, Dispensing and Responsible Use

- To effectively combat AMR, it is essential to understand the roles of diagnostic stewardship, rational prescribing and dispensing and responsible use of antimicrobials
- Each of these components plays a critical role in ensuring that antimicrobials are used appropriately to preserve their efficacy



Diagnostic Stewardship

- **Definition:** Diagnostic stewardship refers to a series of coordinated guidance and interventions to improve appropriate use of microbiological diagnostics to guide therapeutic decisions (*WHO Manual on Diagnostic Stewardship, 2016*)
- **Objectives**
 - Promote appropriate, timely diagnostic testing, including specimen collection and pathogen identification
 - Support patient management guided by timely microbiological data.
 - Support provision of accurate and representative AMR surveillance data to inform treatment guidelines



Challenges: Diagnostics

Key Gaps	Strategies and Solutions	Resources available
Limited of capacity to conduct reliable and timely microbiological diagnostics	- Strengthen capacity at county and sub county level - Strengthen sample referral system to all facilities	- MOH - County government - Implementing partners
Prohibitive cost of providing Microbiology services	- Build an economic case for reagents - Investment and insurance - Encourage patients to register to NHIF/SHIF - KEMSA to stock Microbiology reagents	- County government - NHIF/SHIF - KEMSA
Inadequate HR capacity - No. and training of trained and competent Personnel	- Complying with staffing norms and standards - Identify and train staff on microbiology processes	- National antimicrobial resistance surveillance training curriculum:2020 - Integrated ECHO learning platform - Onsite mentorship programs
Over-reliance on Empirical Treatment	- Strengthen diagnostic stewardship - Sensitize clinicians during clinical laboratory interface meetings and integrated ward rounds	- Diagnostic stewardship- A clinician's handbook on appropriate use of microbiologic diagnostic test - National antimicrobial stewardship guidelines for health care settings in Kenya: 2020



Slide 21

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consider re-ordering to slide 21

Kelly Alexander, 01/07/2025

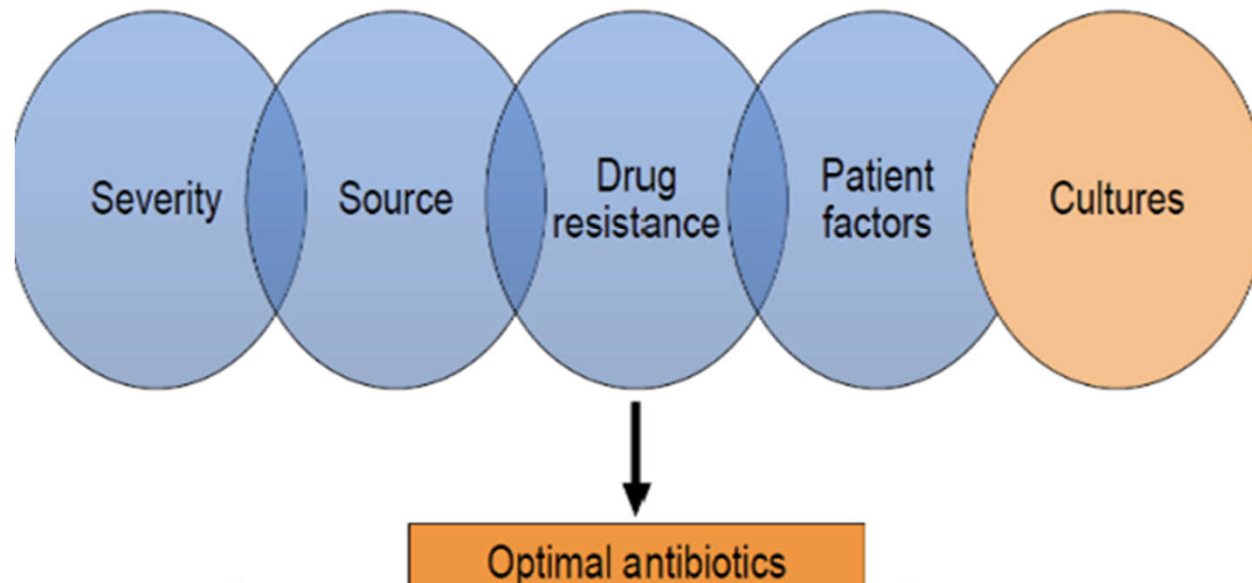
Principles for Optimal Prescribing

- Tentative diagnosis is made based on comprehensive history and examination
- Based on severity, antimicrobials are used empirically when an infection is suspected before microbiologic data is available to support the diagnosis
- When determining the most effective empiric therapy you must consider:
 - Severity of illness
 - Source of infection
 - Antimicrobial resistance
 - Patient factors e.g. Comorbidities
 - Likely pathogen



Principles for Optimal Prescribing...

An informed choice



Principles of Optimal Prescribing

- Based on identification of the pathogen and susceptibility results definitive therapy should be instituted.
- Assess need for
 - Escalation
 - De-escalation
 - Discontinuation
 - Changing the route of administration



Challenges: Prescribing

Key Gaps	Strategies and Solutions	Resources available
Limited training in antimicrobial stewardship, leading to inappropriate prescribing practices.	Ongoing education	National AMS guidelines
Commercially driven prescribers and Patient demand can pressure practitioners to prescribe antibiotics, even when they are not necessary	Create public awareness on AMR and AMS	National AMR communication Strategy
Inconsistent access to up-to-date clinical guidelines can result in improper antimicrobial prescribing	Access to updated clinical guidelines for healthcare providers	Clinical guidelines and drug formularies
Lack of access to essential and vital medicines including antimicrobials	Procurement of essential antimicrobials based on the AWaRE categorization	National Government, County Governments, KEMSA



Dispensing and Responsible Use

- Review of prescription to ensure **appropriate use** of antimicrobials
i.e. *the right antimicrobial, for the right indication (right diagnosis), the right patient, at the right time, with the right dose, duration and route*
- Utilize **medication use counselling** to emphasize importance of adherence to antimicrobial therapy – take medication as recommended and complete dose
- Advice on correct handling and storage as well as proper disposal of unused medication
- Provide **education** on responsible use of antimicrobials, discourage use for management of viral infections



Challenges: Dispensing and Responsible Use

Key Gaps	Strategies and Solutions	Resources available
Weak regulation of community pharmacies	Inspection of pharmacies Empowerment to implement AMS Strengthen regulations to ensure antibiotics are dispensed only with a valid prescription	PPB Professional societies (PSK)
Economic incentives to sell more antibiotics	Improve dispensing practices through continuous education and access to updated clinical guidelines	PPB MoH
Weak surveillance of antimicrobial use	Enhancing existing platforms for monitoring e.g. LMIS and DHIS2 data collection and surveillance	MoH NPHQL Donor programmes e.g. HIV, TB
Lack of public awareness about the dangers of AMR leading to misuse of antimicrobials	Public health campaigns to educate the community on AMR	Community Health Promoters



Key Points

- AMS is a coherent set of actions which promote the responsible use of antimicrobials.
- R&D support the AMS & access pillar by promoting the availability of antimicrobials
- Regulation and manufacturing support the AMS access pillar, as they serve as the gatekeepers for antimicrobials.
- Supply chain is a network involved in the delivery of a product from the source to the intended end users. The processes include selection, procurement, supply and distribution.
- To effectively combat AMR, it is essential to understand the roles of diagnostic stewardship, rational prescribing and dispensing and responsible use of antimicrobials



The End



***You have come to the end of this module. Kindly attempt module
2 quiz before proceeding to module 3***