MAAP
Mapping AMR & AMU Partnership

ANTIMICROBIAL RESISTANCE SURVEILLANCE GUIDANCE FOR THE AFRICAN REGION

A Guide on the Collection, Management and Analysis of Data for Antimicrobial Resistance, Consumption, and Use in Africa

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The Fleming Fund
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UKaid
from the British people

AfricaCDC
Centres for Disease Control and Prevention

ECOWAS

ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE

ABBREVIATIONS	
Africa CDC	Africa Centres for Disease Control and Prevention
AMC	Antimicrobial Consumption
AMR	Antimicrobial Resistance
AMRCC	Antimicrobial Resistance Coordinating Committee
AMRSNET	Antimicrobial Resistance Surveillance Network
AMR-SS	AMR Surveillance System
AMS	Antimicrobial Stewardship
AMU	Antimicrobial Use
ASLM	African Society for Laboratory Medicine
ASP	Antimicrobial Stewardship Program
AST	Antibiotic Susceptibility Testing
ATC	Anatomical Therapeutic Chemical
AU	African Union
AWaRe	Access, Watch, and Reserve
CDW	Central Data Warehouse
CLSI	Clinical and Laboratory Standards Institute
CMS	Central Medical Store
CSF	Cerebrospinal fluid
CSO	Civil Society Organization
DDD	Defined daily dose
DID	DDD per 1,000 inhabitants per day
DRI	Drug Resistance Index
ECDC	European Centre for Disease Prevention and Control
ECOWAS	Economic Community of West African States
ECSA-HC	East, Central & Southern Africa Health Community
EQA	External Quality Assessment
EUCAST	European Committee on Antibiotic Susceptibility Testing
FAO	Food and Agriculture Organization
FBO	Faith-based organization
GAP	Global Action Plan
GLASS	Global Antimicrobial Resistance Surveillance System
HIS	Health Information System
HMIS	Hospital Management Information System

ABBREVIATIONS	
ID	Infectious Diseases
INN	international nonproprietary name
IPC	Infection Prevention and Control
KII	Key Informant Interview
KPIs	Key Performance Indicators
LIMS	Laboratory Information Management System
LMIC	Low- 0r Middle-Income Country
MAAP	Mapping Antimicrobial Resistance and Antimicrobial Use Partnership
M&E	Monitoring and Evaluation
MoH	Ministry of Health
MPP	Medicinal Product Package
NAP	National Action Plan
NCCU	National-level central coordinating unit
NGO	Non-Governmental Organization
NRL	National Reference Laboratory
PHA	Public Health Agency
PHI	Public Health Institute
PPS	Point Prevalence Surveys
QA	Quality assurance
QC	Quality control
SCC	Site coordinating committee
SOP	Standard Operating Procedure
TB	Tuberculosis
TOR	Terms of reference
TWG	Technical Working Group
UNEP	United Nations Environment Programme
WAHO	West Africa Health Organization
WOAH	World Organisation of Animal Health
WHO	World Health Organization

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FOREWORD

Antimicrobial resistance (AMR) is a critical global health and development threat, directly responsible for an estimated 1.27 million deaths in 2019. The misuse and overuse of antimicrobials in humans, animals, and plants are primary drivers of this growing resistance. While AMR affects countries worldwide, its impact is particularly severe in low- and middle-income regions, where poverty and inequality exacerbate its consequences.

In Africa, the threat of AMR is particularly acute, with significant implications in public health, agriculture, and the environment. In response to this threat, the Fleming Fund Regional Grant Phase I, led by the African Society for Laboratory Medicine (ASLM) and supported by its strategic partners, The Africa Centres for Disease Control and Prevention (Africa CDC), The East, Central, and Southern Africa Health Community (ECSA-HC), and The West African Health Organization (WAHO), focused on enhancing data availability for AMR and Antimicrobial Consumption (AMC) in 14 countries across West, East, Central, and Southern Africa. Analyzing retrospective data from 2016-2018, the initiative identified significant gaps in AMR testing capabilities across the 14 countries, lack of access to bacteriology services, and a critical need for stronger antibiotics, diversification of antibiotic use, and better integration of clinical and laboratory data to effectively combat AMR in the region.

Building on this foundation, this Antimicrobial Resistance Surveillance Guidance for the African Region provides a vital framework to address some of these challenges. This document offers comprehensive guidance for troubleshooting and strengthening AMR surveillance across the continent, improving our understanding of AMR trends, and ultimately ensuring the capacity to detect, monitor, and respond effectively to AMR threats. By standardizing surveillance practices and fostering collaboration across the region and in all sectors, the guidance aims to build robust systems equipped to tackle the complexities of AMR surveillance. The guidance focuses on enhancing AMR surveillance system and lays the groundwork for incorporating data from multiple sectors to improve the overall AMR surveillance strategy using the One Health approach. Not only does it guide national efforts but also aligns them with regional and global strategies, contributing to a coordinated response to this growing threat. Countries are encouraged to utilize this guidance and adapt it to their national priorities.

This initiative reflects the collective efforts and shared vision of key partners, including the Africa CDC, ECSA-HC, and WAHO. The consortium commits to offering leadership and support to all African Union (AU) member states in their efforts to establish and strengthen AMR surveillance systems. This support will include capacity-building initiatives, providing training and guidance on key components of AMR surveillance such as data management, analysis, and reporting. In particular, Africa CDC and ASLM will provide the infrastructure and resources for the Continental Central Data Warehouse (CDW), ensuring the security and efficient management of the vast AMR data generated across the continent.

As we move forward, let us focus on establishing a robust and effective surveillance system that supports the collection of large quantities of quality AMR/C/U data, strengthening evidence-based decision-making, and fosters sustainable practices to mitigate the threat of AMR in Africa. By doing so, we can safeguard human and animal health, protect our environments, and contribute to the global fight against AMR.

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General Disclaimers

The Antimicrobial Resistance Surveillance Guidance for the African Region is intended to provide a framework for the establishment, operation, and strengthening of AMR surveillance systems across African Union member states. While every effort has been made to ensure the accuracy and relevance of the information contained within this guidance, the authors and contributing organizations do not make any guarantees or representations regarding its completeness, applicability, or suitability for specific local contexts.

The guidance serves as a reference document and should not be considered legally binding. It is designed to be adapted to fit the unique epidemiological, infrastructural, and resource conditions of each country. Users are encouraged to consult local experts, regulatory authorities, and stakeholders to ensure alignment with national policies, priorities and practices.

The ASLM, Africa CDC, ECSA-HC, WAHO and other collaborating partners are not liable for any direct, indirect, or consequential losses or damages arising from the use or misuse of this guidance. The inclusion of specific organizations, products, solutions or services does not imply endorsement by the authors or affiliated institutions. This guidance should be used as a tool to enhance national and regional AMR surveillance efforts, in conjunction with locally relevant resources and expertise.

ACKNOWLEDGEMENT

The Antimicrobial Resistance Surveillance Guidance for the African Region represents the culmination of the collaborative efforts from numerous countries, individuals and organizations committed to addressing the growing threat of AMR across the African continent. We extend our deepest gratitude to the people of the United Kingdom for their unwavering support through the Fleming Fund. We also thank the Africa CDC, ASLM, ECSA-HC, and WAHO for their invaluable support and expertise in developing this guidance.

We are especially grateful to the experts from the participating African countries - Cameroon, Eswatini, Gabon, Ghana, Kenya, Malawi, Nigeria, Sierra Leone, Tanzania, Uganda, Zambia, and Zimbabwe – for their critical reviews, contributions and validation of this guidance. Their insights and dedication have been instrumental in shaping this guidance.

This guidance is a testament to the power of partnership and a shared vision in tackling one of the most urgent public health challenges of our time: Antimicrobial Resistance.

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BACKGROUND

1. BACKGROUND

1.1 ANTIMICROBIAL RESISTANCE, ITS PUBLIC HEALTH RELEVANCE AND BURDEN IN AFRICA

Antimicrobials are medicines, including antibiotics, antivirals, antifungals, and antiparasitics, that are used to prevent and treat infections in humans, animals, and plants. Antimicrobial Resistance (AMR) arises when bacteria, viruses, fungi, and parasites no longer respond to these medicines, rendering them ineffective and making infections more difficult to treat (1). This resistance increases the risk of disease spread, severe illness, disability, and death. Although AMR is a natural phenomenon driven by genetic changes in pathogens, it is significantly accelerated by human activities such as the misuse and overuse of antimicrobials in healthcare, agriculture, and animal husbandry.

AMR is a global challenge impacting countries across all income levels, with severe consequences in low- and middle-income countries (LMICs) due to weak healthcare and surveillance systems, and inequalities (1) (2). AMR threatens modern medicine by making infections harder to treat, thereby increasing risks in critical procedures like surgeries and cancer chemotherapy. This undermines patient safety and treatment efficacy, complicating healthcare delivery worldwide. The situation is exacerbated by a critical global shortage of new antibiotics due to insufficient research and development pipeline (3).

On the other hand, AMR also has profound economic implications. The World Bank projects that AMR could lead to an additional US$ 1 trillion in healthcare costs by 2050 and cause annual gross domestic product (GDP) losses between US$ 1 trillion and US$ 3.4 trillion by 2030 (4).

The significant health impacts and economic costs of AMR highlight the urgent need for coordinated global efforts. Key strategies include prevention of infections, ensuring universal access to quality diagnosis and treatments, using antimicrobials responsibly, and investing in strategic information systems as well as research and development for new vaccines, diagnostics, and medicines. By prioritizing these strategic areas, we can combat AMR, safeguard public health, and preserve the advancements of modern medicine.

AMR is a critical public health issue in Africa, driven by factors such as limited surveillance data and inadequate access to effective medicines (2) (6). This challenge is exacerbated by socioeconomic conditions, healthcare infrastructure limitations, and unique regional factors that contribute to the growing threat of AMR on the continent.

In 2019, a World Health Organization (WHO) systematic analysis estimated 1.05 million deaths in Africa associated with AMR, with 250,000 deaths directly attributable to it (2). The study identified third-generation cephalosporin-resistant Klebsiella pneumoniae and methicillin-resistant Staphylococcus aureus as the leading pathogen-drug combinations responsible for deaths attributable to AMR in 25 and 16 countries, respectively.

This challenge is compounded by Africa's rapid growth despite significant health burdens, including epidemics of HIV, Tuberculosis (TB), Malaria, and emerging threats such as Ebola and COVID-19. Furthermore, extensive use of antimicrobials in agriculture and livestock farming contributes to the spread of resistant bacteria from animals to humans through food chains and environmental contamination via animal waste (7) (8).

In response to these challenges, the Fleming Fund Regional Grant, through the Mapping Antimicrobial Resistance and Antimicrobial Use Partnership (MAAP) Phase I, led by the African Society for Laboratory Medicine (ASLM) and supported by various strategic and technical partners, aimed to enhance data availability for spatiotemporal mapping of AMR in

Fourteen African countries across West (Burkina Faso, Ghana, Nigeria, Senegal, Sierra Leone), East (Kenya, Tanzania, Uganda), Central (Cameroon, Gabon), and Southern Africa (eSwatini, Malawi, Zambia, Zimbabwe). By collecting, digitizing and analyzing historical data from 2016-2018, the program established baselines and trends for AMR and AMC, identified key drivers, and highlighted gaps in surveillance. These efforts aimed to strengthen future data collection, analysis, and reporting capabilities across the region.

The findings provided critical insights into the AMR burden and AMC across the 14 African countries, where most existing AMR data is based on statistical modeling. Key findings are presented in the figure 1:

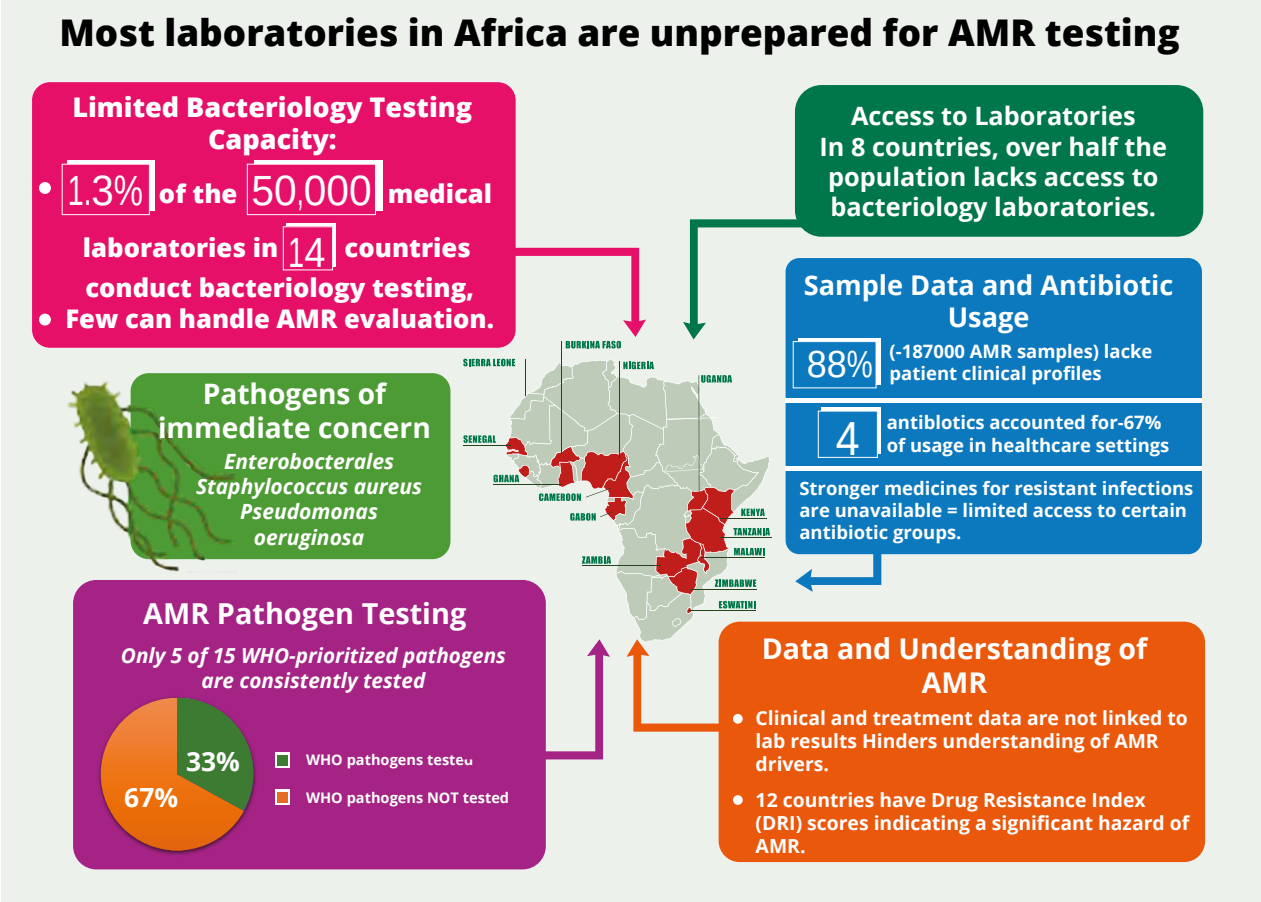


Figure 1: Key findings from MAAP Phase 1

This lack of robust and continuous surveillance data impedes the assessment of treatment efficacy and understanding of resistance drivers in Africa. While many countries face challenges in establishing AMR surveillance systems, valuable AMR data has been collected over decades but remains largely inaccessible for large-scale analysis. Digitizing and aggregating this data can help establish AMR patterns across various pathogen-drug combinations and reveal spatiotemporal trends. Additionally, linking AMR, AMC and AMU data and patient information can uncover AMR drivers and enhance our understanding of treatment efficacy for evidence-based policy, improving antimicrobial use and stewardship, and enhancing patient care. Without reliable data, it is challenging to monitor AMR patterns, identify threats, and take action.

1.2 ANTIMICROBIAL CONSUMPTION AND USE

Antimicrobial Consumption (AMC) and Antimicrobial Use (AMU) are terms that are often used interchangeably, but they represent different concepts. AMC refers to the total amount of antimicrobials used within a specified setting (e.g. national, hospital, or community health care level) over a specified period based on aggregated data from sources like imports, wholesalers, insurance, or facility dispensing or procurement records. In contrast, AMU focuses on whether antimicrobials are prescribed appropriately, for the right infections and according to treatment guidelines (e.g. if required laboratory tests and clinical assessments were done prior to issuing a prescription, and if the right antimicrobial was prescribed at the correct strength & frequency, over an appropriate duration, to treat the right indication as per country guidelines and if the patient correctly/completely consumed the prescribed antimicrobial) (5). Therefore, it is crucial to distinguish between these terms to accurately understand and address antimicrobial stewardship (AMS). Refer to figure 2 for more details distinguishing AMC and AMU.

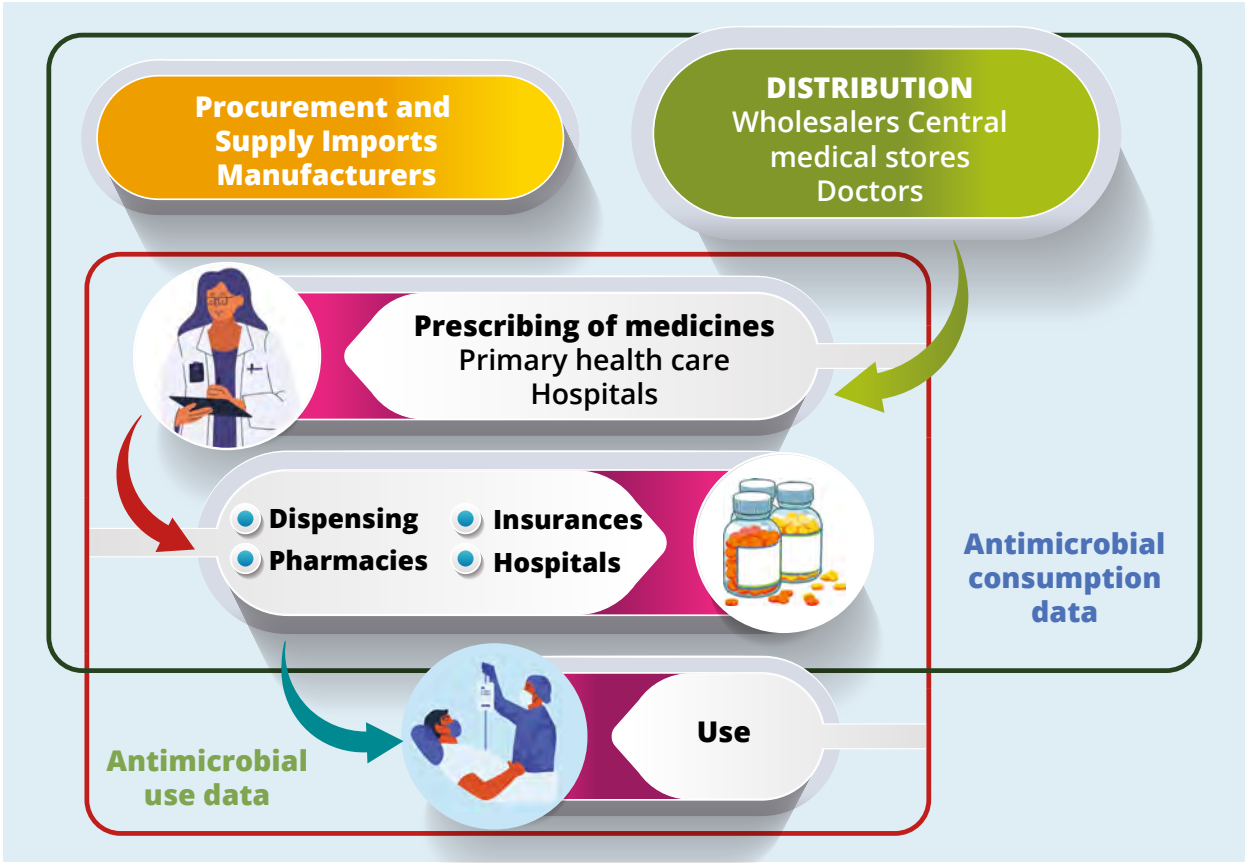


Figure 2: Supply chain of antimicrobials and illustration of sources of AMC and AMU data.

1.3 ANTIMICOROBIAL RESISTANCE SURVEILLANCE TYPES AND APPROACHES

In the context of public health, surveillance refers to the continuous, systematic collection, collation, analysis, and interpretation of health-related data, and its timely dissemination (9). It serves as an early warning system for outbreaks, monitors disease trends (e.g., AMR), assesses intervention effectiveness, tracks progress toward health goals, and informs planning and evaluation of public health policies and strategies. AMR surveillance involves monitoring pathogens resistance profiles and monitoring antimicrobial use (AMC/AMU) to obtain reliable information.

There are two primary approaches to AMR surveillance:

- **Comprehensive Surveillance:** Involves monitoring a specified disease or pathogen across the entire at-risk population, capturing data on all infection cases. It is generally limited to collecting basic data, such as date of birth, gender, location, specimen type, and resistance pattern.
- **Sentinel Surveillance:** Collects data from a specific representative population to serve as an indicator for the larger population. It is ideal for prolonged, detailed data collection, and detecting emerging resistance using a targeted approach.

The feasibility of collecting whole or representative sample varies by country and setting. When comprehensive surveillance is impractical, sentinel surveillance can provide reliable data when the correct methodologies are utilized. Optimizing resources is essential in enhancing a country's surveillance capacity.

AMR surveillance can be collected either continuous or episodic; the choice between the two is dependent on the availability of resources. Irrespective of whether surveillance is continuous or episodic, surveillance may be defined as either passive or active:

- Passive surveillance is a continuous, cost-effective monitoring method. Healthcare providers voluntarily report cases based on a list of reportable diseases provided by their health department, though the data is less detailed.
- Active surveillance proactively seeks out reports of specific diseases or microbes, ensuring more complete data. While it provides more detailed and comprehensive data, it is also more resource-intensive and costly to implement.

Essential Steps for AMR, AMC and AMU Surveillance

1. Define the public health question, target population, and sampling methods.
2. Standardize procedures and tools for collecting and reporting test results.
3. Train staff in sample collection, data management, and information dissemination.
4. Record and share antimicrobial susceptibility test (AST) results through laboratory information systems.
5. Record and share AMC data from aggregated data sources and AMU data from patient-level clinical records.
6. Implement quality assurance for data collection and analysis to guide clinical decisions and AMS.

In relation to antimicrobial usage, surveillance involves two main types of data collection: quantitative and qualitative. Quantitative data, known as AMC, measures the amount, timing, and location of antimicrobial use and is typically collected routinely. Qualitative data, referred to as AMU, explores the reasons, users, and methods behind antimicrobial use, often gathered through surveys.

Key aspects of AMR, AMC and AMU surveillance are described in figure 3:

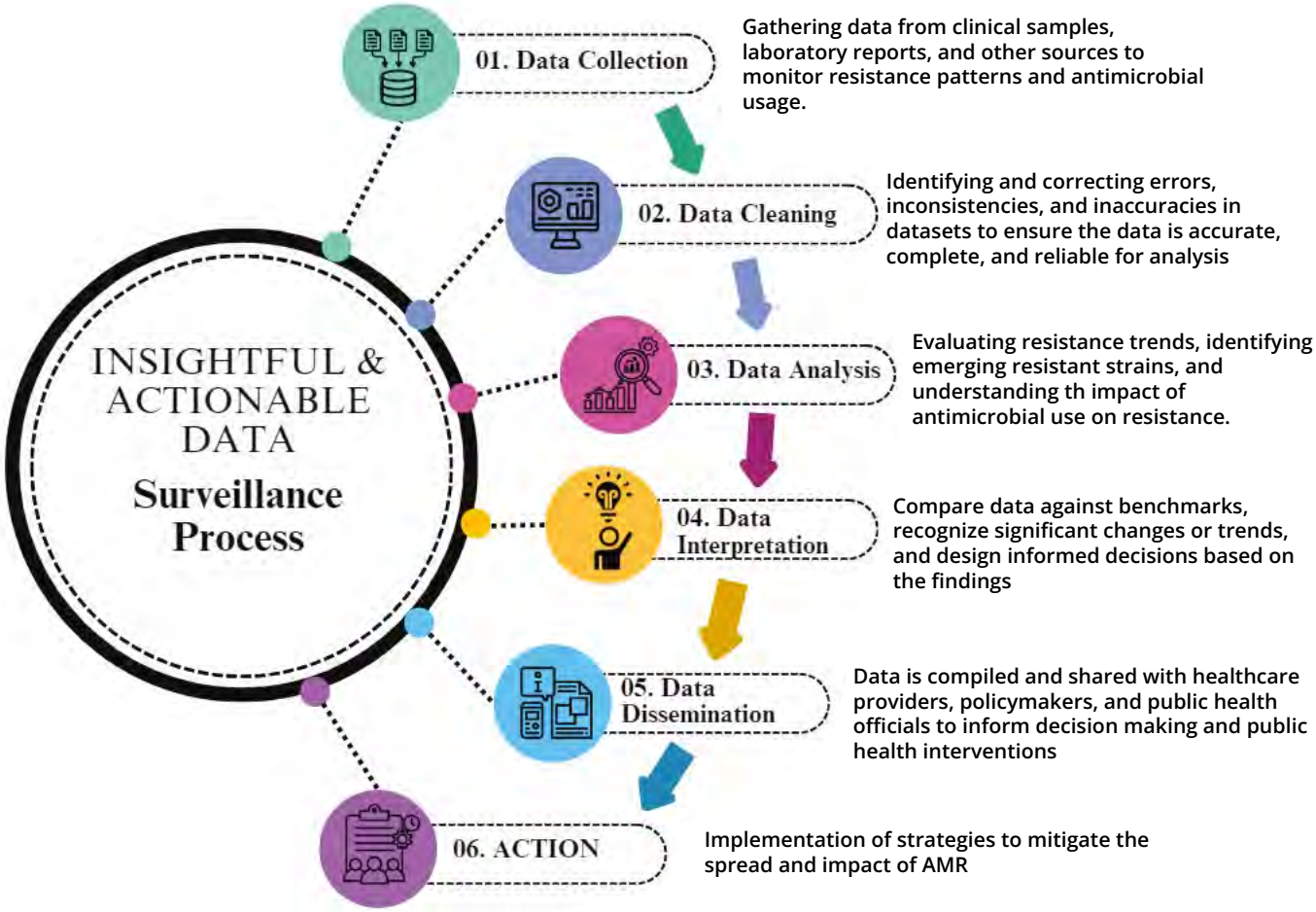


Figure 3: AMR, AMC and AMU surveillance aspects and processes.

1.4 OVERVIEW OF THE IMPORTANCE OF AMR SURVEILLANCE IN AFRICA

The incidence of AMR varies globally, with the most severe impact in LMICs, particularly those in Africa. Understanding AMR's health and economic burden, including mortality rates and surveillance is critical (10). Gathering information on antimicrobial use will support efforts to ascertain the need for new antimicrobials and priority interventions to preserve efficacy of existing ones. To support the design of effective interventions to curb AMR in Africa, concerted efforts are required to enhance data management, diagnostic capacity and coordinated surveillance across all levels.

Key impact activities that AMR and AMC/AMU surveillance can support include:

1. Ensuring early detection of novel and emerging resistance patterns to ensure the management and control of outbreaks of resistant infections, through timely interventions and adjustment of treatment protocols.
2. Establishment and operationalization of AMS programs (ASPs), to develop and enforce policies to optimize antimicrobial use and minimize misuse.
3. Development and implementation of policies, action plans and regulations to address AMR, utilizing local data.

4. Provision of quality healthcare, through development of tailored antimicrobial treatment guidelines and protocols, national formularies and essential lists (medicine and diagnostic), guided by local resistance patterns.
5. Supports the monitoring and evaluation of intervention and program impacts.
6. Guides resource allocation, informs emergency responses, and ensures that interventions are effective and prioritized.
7. Enhancing Global Health Security, through supporting the prevention of global pandemics of resistant infections by ensuring the identification and mitigation of spread of resistance pathogens across borders.

1.5 CHALLENGES/LIMITATIONS IN AMR SURVEILLANCE IN AFRICA

Establishing comprehensive and robust AMR surveillance systems (AMR-SS) in Africa is not void of challenges that must be mitigated. The table 1 highlights some of these challenges and limitations:

Challenge	Description
Inadequate AMR-SS	Fragmented and inconsistent data collection; limited laboratory capacity; lack of standardized protocols; limited surveillance sites, and accredited laboratories.
Data gaps & limited technological infrastructure	Largely paper-based information systems; limited interoperability of electronic data systems; inadequate diagnostic technologies; low AST utilization; not all WHO priority pathogens tested; poor to no linkage of laboratory to patient information.
Insufficient funding & resources	Resource constraints affect laboratory infrastructure, staffing, and training.
Lack of regulatory enforcement & policies	Weak enforcement of policies and regulations to govern the use of antimicrobials; slow implementation of NAPs, mainly due to inadequate resources and political commitment.
Challenges in AMC & AMU monitoring	Widespread informal medicine markets and self-medication (including over-the-counter use), complicates the accurate monitoring of AMC and AMU.
Agricultural practices & environmental challenges	Suboptimal surveillance in agriculture and livestock sectors; poor handling and disposal contributes to environmental contamination and spread of AMR.
Barriers to collaboration	Inadequate coordination among countries and organizations leading to fragmented efforts; varying commitment, capacity, and legal frameworks affecting regional strategies.
Human resource constraints	Shortages of trained professionals in laboratory and epidemiology; high staff turnover leads to gaps in expertise to sustain surveillance programs; limited training opportunities and resources, presents a risk of underreporting or misreporting.

1.6 PURPOSE AND OBJECTIVES OF THE GUIDANCE

Collaboration between governments, local and international organizations, implementing partners, and the private sector, is required to realize a comprehensive Africa AMR-SS. This guidance aims to strengthen AMR surveillance in Africa by improving the quality, volume and relevance of AMR-related data for informed decision making. This effort will build on the existing Africa CDC's Antimicrobial Resistance Surveillance Network (AMRSNET).

Broad objectives of the guidance:

- Improve Data Quality & Quantity: Enhance the collection of large volumes of quality AMR data, its analysis, and dissemination.
- Build Surveillance Networks: Strengthen Africa's capacity for early detection and response to AMR.
- Inform Strategies & Policies: Use AMR, AMC, and AMU data to guide surveillance strategies and policy decisions.

Specific objectives of the guidance:

1. Standardizing data collection and analysis methods within and across countries to enable comparability.
2. Provision of guidance to improve early detection and response to AMR.
3. Provide a useful resource for outlining training, capacity building, supervision, monitoring, and evaluation of surveillance activities.

1.7 SCOPE OF THE GUIDANCE

AMR threatens human, animal, plant, and ecosystem health and its rapid spread highlights the importance of a "One Health" approach, which integrates multiple sectors, disciplines and communities to balance and optimize the health across these key sectors (9). While this guidance primarily focuses on establishing and enhancing human health AMR-SS, it emphasizes the importance of integration of data from other sectors to improve the overall AMR surveillance strategy using the One Health approach.

1.8 INTENDED READERSHIP AND USERS OF THE GUIDANCE

The key readership and users of this continental guidance encompasses a diverse range of stakeholders across various sectors. These stakeholders play crucial roles in implementing, managing, and utilizing the surveillance data to combat AMR and include:

1. National and Regional Health Authorities: Ministries of Health (MoH), Public Health Institutes (PHI)/ Public Health Agencies (PHAs), National Central Coordination Units (NCCU), AMR coordinating committee (AMRCC) or any other assigned committee or body to manage AMR containment.
2. Human healthcare providers and institutions: Hospitals, clinics, microbiology laboratories, pharmacies.
3. National, sub-national and facility AMS and infection prevention and control (IPC) programs/ committees.
4. Policymakers and legislators.
5. Regulatory bodies across the One Health lead sectors.
6. Research and Academic Institutions: Universities and research centers, epidemiologists.
7. International and Regional Organizations: WHO, World Organization for Animal Health (WOAH), African Union (AU), Food and Agriculture Organization (FAO), United Nations Environment Program (UNEP) etc.
8. Public health Non-Governmental (NGOs) and Civil Society (CSOs) Organizations
9. Pharmaceutical and Biotechnology Industries.
10. Funding Agencies and Implementing Partners.
11. General public and media.

2

SUMMARY OF AMR SURVEILLANCE SYSTEM ESTABLISHMENT IN THE AFRICA REGION

2. SUMMARY OF AMR SURVEILLANCE SYSTEM ESTABLISHMENT IN THE AFRICA REGION

This guidance is intended to complement, not replace, international and local guidelines, manuals, and existing national structures and strategies. Countries are encouraged to use the guidance outlined in this document, summarized in the flowchart in figure 4, to plan the establishment of their AMR-SS. A phased approach, informed by each country's situational analysis (which includes determining strengthens, weaknesses, opportunities and threats), is recommended for effective implementation. As countries develop their human health AMR-SS, they should also consider how to integrate surveillance in animal health and environmental sectors, based on their specific contexts and the current state of systems in these sectors. Incorporating a One Health approach from the outset will strengthen the overall capacity to contain AMR effectively.

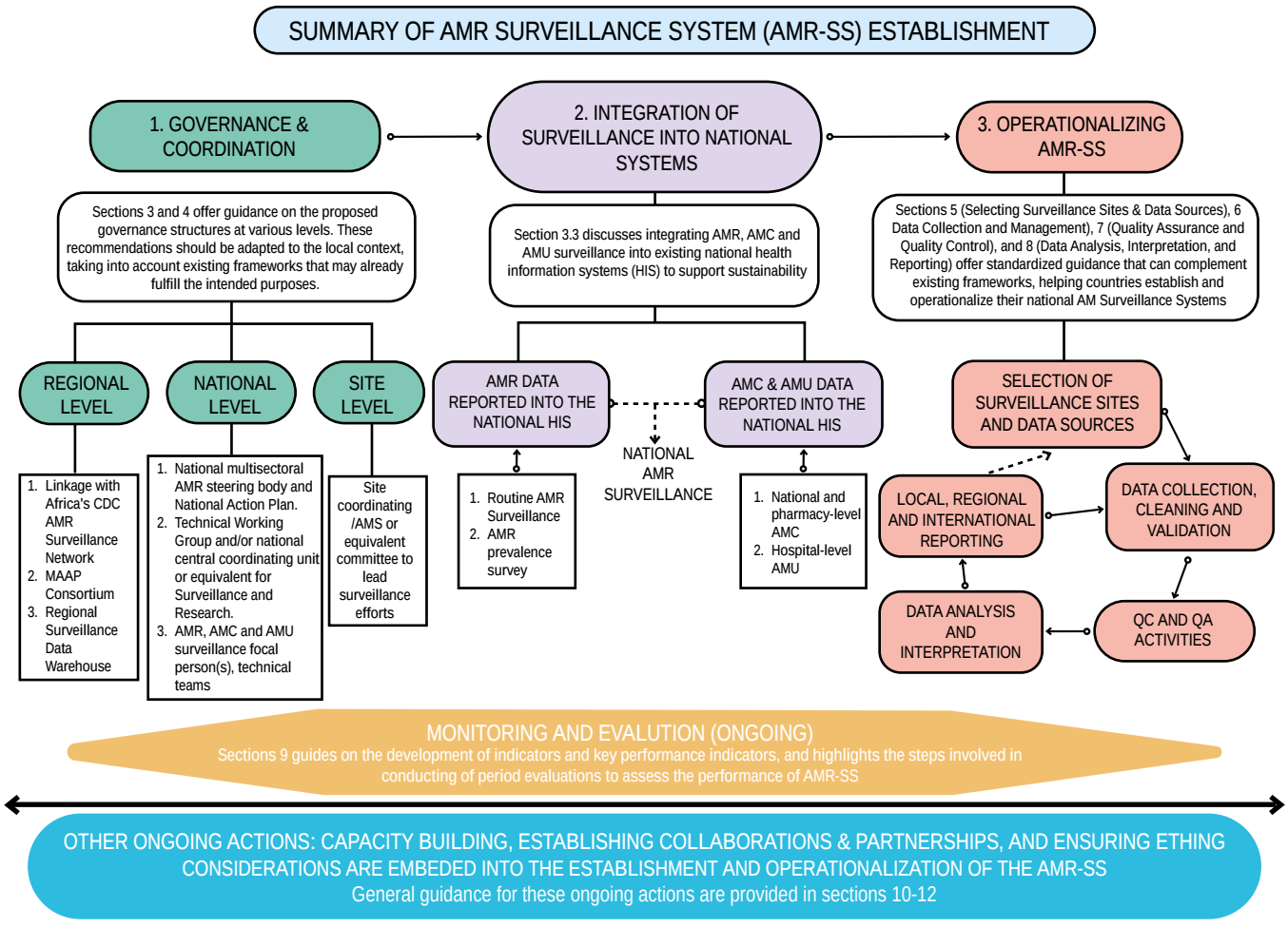


Figure 4: Flow chart providing a summary guide of the essential elements for establishment of national AMR-SS.

3

SURVEILLANCE DESIGN AND APPROACHES

3. SURVEILLANCE DESIGN AND APPROACHES

Key Takeaways:

- **Routine Surveillance:** Focuses on isolate-based and sample-based data, with WHO recommending the broader sample-based approach for a comprehensive understanding of AMR trends.
- **AMR Prevalence Surveys:** Complement routine surveillance by prospectively identifying cases with standardized methods, enhancing data quality and representativeness.
- AMC and AMU surveillance generates essential data that, when integrated with AMR surveillance, offer a comprehensive understanding of AMR. AMC, reported as DDD per 1,000 inhabitants per day, systematically tracks the quantity of antimicrobials used, while AMU focuses on usage patterns, typically gathered through Point Prevalence Surveys (PPS).
- National AMR Surveillance Systems: Requires national and sub-national structures, including coordinating units, reference laboratories, and centralized data warehouses.
- **Continental Collaboration:** Leveraging existing regional networks will enhance national laboratory capacity, standardize AMR, AMC, and AMU surveillance practices, and establish a solid foundation for future AMR containment efforts in Africa.
- **Integration with Health Systems:** Integrating AMR surveillance into existing national health information systems ensures comprehensive tracking, better resource utilization, and supports sustainable AMR strategies.

3.1 APPLICATION OF ROUTINE (PROSPECTIVE) AND PERIODIC PREVALENCE SURVEYS

In this guidance the terminology used will be in line with the WHO Global Antimicrobial Resistance Surveillance System (GLASS)-AMR, AMC and AMU guidance and refers to the different types of AMR and antimicrobial medicine surveillance data, as highlighted in figure 5:

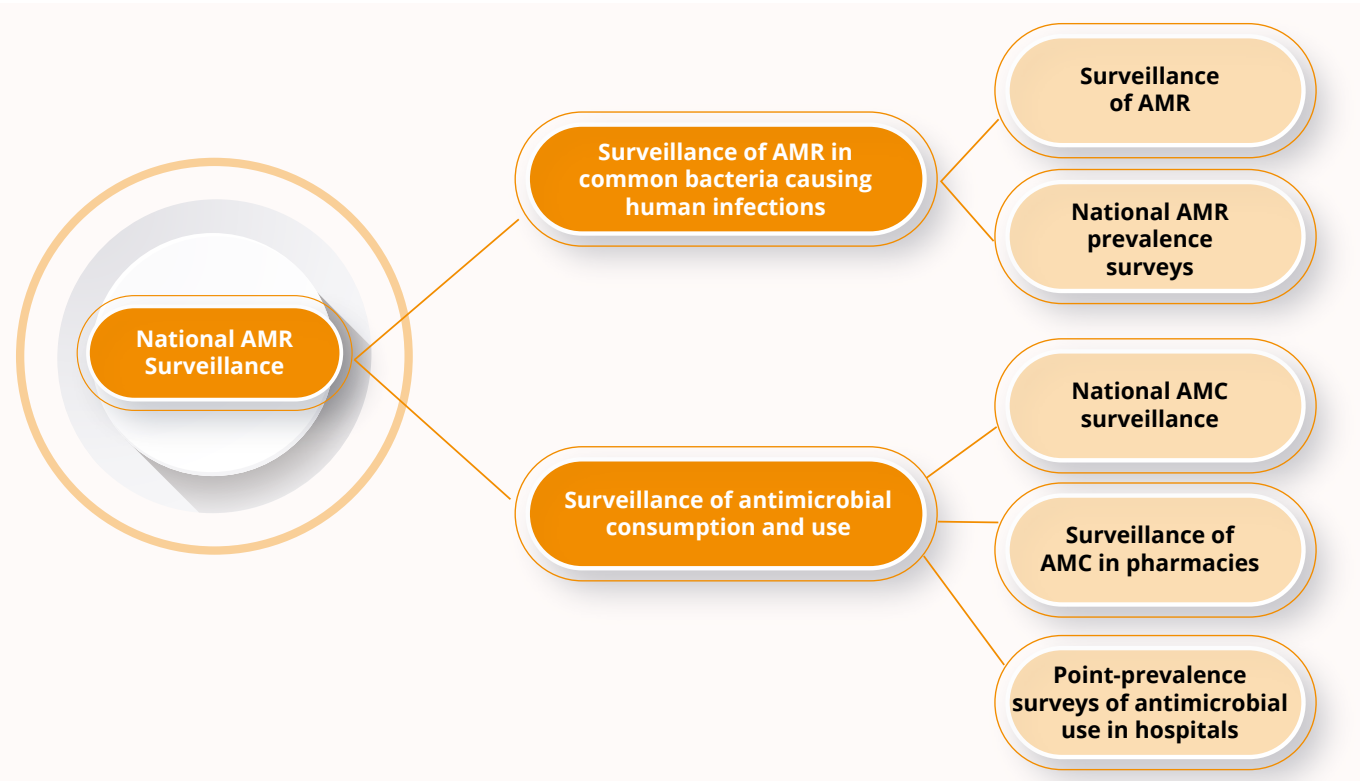


Figure 5: Overview of national AMR surveillance components

i. Routine (continuous, prospective) surveillance

Routine surveillance describes the continuous collection, analysis and interpretation of AMR-related data on an ongoing basis. Cases are prospectively and actively identified, using standardized case definitions, and the selection of surveillance sites is prospectively defined to achieve national representativeness and data accuracy.

- Isolate-based data focuses on patients with laboratory-confirmed infections by target pathogens. It provides details on the proportion of infections resistant to specific antimicrobials.
- Sample-based data encompasses the entire patient population from whom clinical specimens are collected. It accounts for those with confirmed infections, as well as cases with no microbial growth or growth of other organisms, offering a broader view of infection frequency and resistance patterns in the patient population. Isolate-based data are a subset of sample-based data.

While both data types (isolate-based and sample-based) can be reported to GLASS, WHO encourages the use of sample-based data.

ii. AMR prevalence surveys

These refer to a systematic targeted, cross-sectional collection of data to assess the prevalence of AMR at a specific point in time within a defined population or setting. These surveys compared to routine surveillance, are narrower and more focused, designed to provide a snapshot of AMR in a particular location or population. They are conducted periodically (e.g. annually, biennially) rather than continuously. The variables collected for the national AMR prevalence surveys are the same as for the routine surveillance approach. AMR prevalence surveys are a complementary strategy to improve quality, completeness, and representativeness of data.

iii. AMC and AMU Surveillance

WHO's strategies for AMC and AMU surveillance emphasize the importance of understanding how antimicrobials are consumed and used across different settings, which is vital for informing AMR containment strategies.

AMC surveillance involves the systematic collection of data on the quantity of antimicrobials consumed over time, usually at the national level. This data is often reported as Defined Daily Doses (DDD) per 1,000 inhabitants per day, helping to monitor trends in AMC and identify potential areas of misuse or overuse.

AMU surveillance focuses on the patterns of antimicrobial use, particularly in healthcare facilities, and aims to identify prescribing practices and the appropriateness of antimicrobial therapies. This type of surveillance can be carried out through Point Prevalence Surveys (PPS). PPS are cross-sectional studies conducted at specific points in time to assess the proportion of patients receiving antimicrobials in a given setting, such as hospitals or outpatient clinics. These surveys provide insights into the prescribing practices and help identify areas for improvement in ASPs.

Together, AMC and AMU surveillance provide critical data that when integrated with AMR surveillance, offers a comprehensive understanding of the drivers of AMR. This integration is essential for developing targeted interventions to promote rational use of antimicrobials and reduce the burden of AMR.

3.2 ESTABLISHING A ROBUST AMR SURVEILLANCE SYSTEM AT CONTINENTAL, NATIONAL AND SUB-NATIONAL LEVELS

In 2015, the WHO released its Global Action Plan (GAP) to address the AMR crisis, urging countries to develop their own National Action Plans (NAPs). The GAP outlines five strategic objectives, including surveillance and research. Following the adoption of

the GAP on AMR, the WHO developed a series of AMR-related manuals to guide countries in implementing effective surveillance and response strategies. The establishment of GLASS was a key milestone in this effort, providing a standardized global framework for AMR data collection and reporting. Subsequently, WHO released various manuals, including the GLASS manuals, which offers detailed guidance on setting up national AMR-SS, and manuals on AMC and AMU surveillance (11) (12) (13). These resources were designed to help countries build capacity, ensure data comparability, and strengthen global efforts to monitor and combat AMR.

Therefore, to align with global efforts to combat AMR, each country should establish a national multisectoral AMR steering body to govern policy direction, develop, review, monitor, and implement the NAP on AMR. This national AMR steering committee will establish technical working groups (TWGs) with clear terms of reference (TOR), to oversee the implementation of the strategic objectives within the NAP-AMR. In countries with devolved/decentralized government systems, sub-national AMR steering bodies should be established to oversee NAP implementation at sub-national levels.

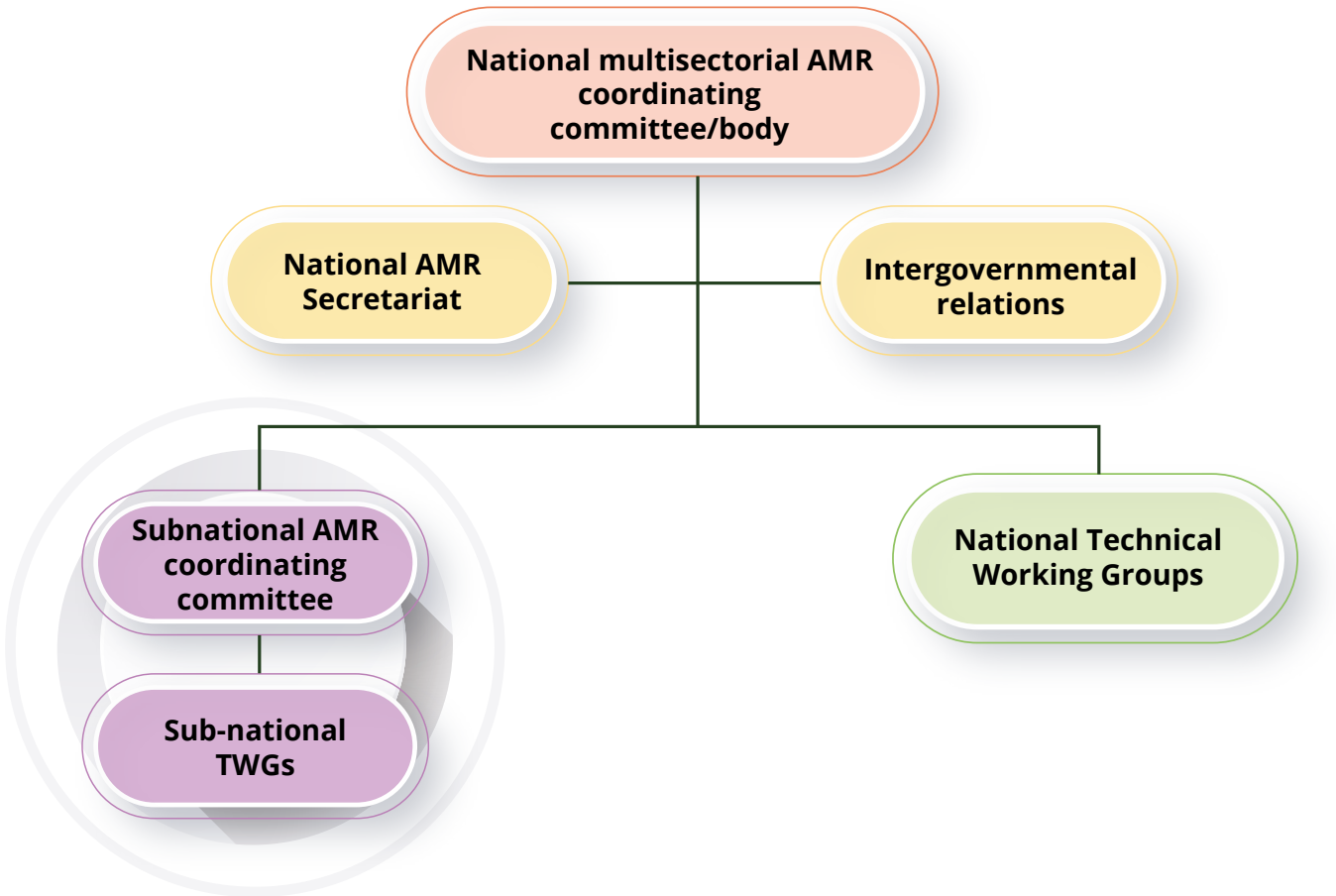


Figure 6: Suggested National Structure for AMR Coordination

Within the country's overall structure overseeing the implementation of the NAP-AMR, there should be a TWG responsible for surveillance and research activities. To ensure a robust AMR-SS is established at both country and continental (regional) levels, certain core components must be supported at both levels:

Country level

- Establishment of a national central coordinating unit (NCCU) (this can be any other committee/ body as designated at national level) to oversee the national surveillance program, gather national AMR, AMC and AMU data and handles its analysis and dissemination.
- Establishment of clear legal and regulatory frameworks to support this coordination unit/ body to ensure AMC and AMU data collection, reporting, and use are standardized and enforced.
- Each country should designate at least one National Reference Laboratory (NRL) to promote good laboratory practices and support laboratories within the national AMR-SS.
- A focal point should be designated to coordinate AMR surveillance activities within the NRL.
- A national focal point should be designated to coordinate AMC and AMU surveillance activities, this focal point may sit within the MoH AMR secretariat, committee or TWG or other nationally designated body such as the national pharmaceutical regulatory body with links to the national AMR coordination committee/body.
- Assessment of the AMR, AMC and AMU surveillance capacity, identification of gaps and development of a national surveillance strategy.
- The country should have an established central data warehouse (CDW).
- Enrollment of one or more surveillance sites to collect basic demographic, clinical, epidemiological, and microbiological and antimicrobial use data from patients.
- Enrollment of national AMC data sources of aggregated data, such as importers or wholesalers, hospitals or pharmacies, or health insurance companies.
- Governance and coordination structures with clear TORs must be established to support the above components.

Regional/Continental level

- Build national laboratory capacity in African countries to conduct AST.
- Facilitates access to standardized methodologies for conducting laboratory-based AMR surveillance, as well as national and pharmacy-based surveillance on AMC and AMU.
- Promote advanced and specialized testing of selected pathogens by regional reference laboratories or collaborating centers.
- Leveraging off AMRSNET to provide comprehensive support for the establishment and strengthening of AMR-SS across Africa. Which will include ensuring ongoing capacity building, data standardization, data integration, and advocacy, enabling African countries to better monitor and combat AMR
- Build the foundation for future studies on the containment of AMR.

3.3 INTEGRATING AMR, AMC, AND AMU SURVEILLANCE INTO EXISITING NATIONAL HEALTH INFORMATION SYSTEMS

Integrating AMR, AMC and AMU surveillance into existing national health information systems (HIS) is strongly advised, as it enhances the ability to track and respond to AMR, enabling a more comprehensive approach that facilitates timely and effective interventions and sustainable efforts to combat AMR.

Benefits of integration:

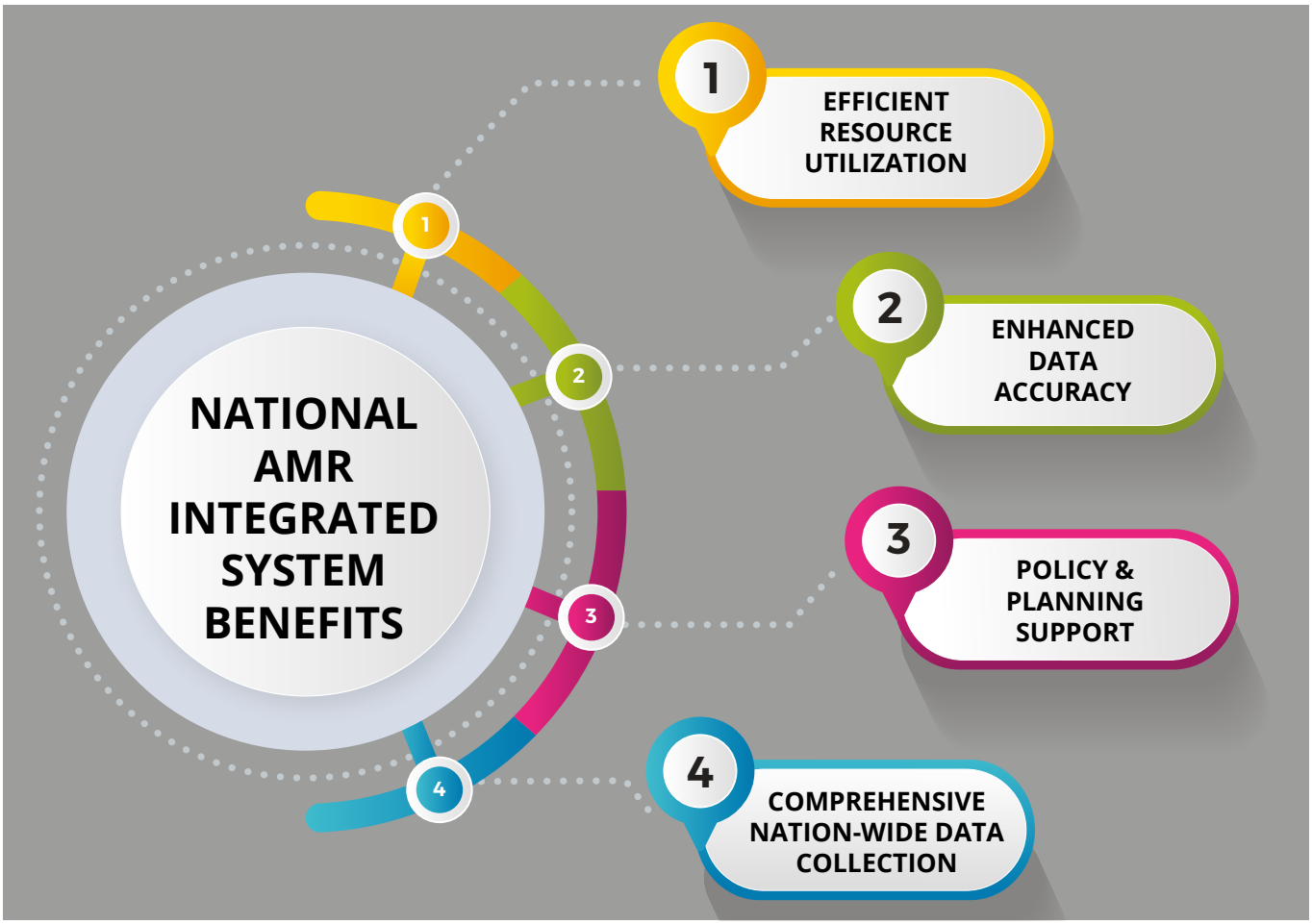


Figure 7: Benefits associated with establishing national AMR integrated systems for AMR surveillance

A national integrated system will pool data from various healthcare facilities, laboratories, pharmacies and sectors, providing a comprehensive view of AMR, AMC and AMU trends. This approach facilitates informed decision-making, enhances accuracy through standardized protocols, and enables real-time data access for timely analysis. Ideally, the AMR-SS should be embedded within the country's existing integrated HIS, which already gathers surveillance data on diseases such as HIV, TB, malaria, and emerging infectious diseases, as well as data from outbreak investigations, epidemiological surveillance, academia research, and biorepositories. By leveraging existing HIS, countries can avoid duplication, optimize resources, support sustainability, and ultimately provide policymakers with critical insights and evidence to develop and implement effective AMR strategies and interventions.

Steps for successful integration:

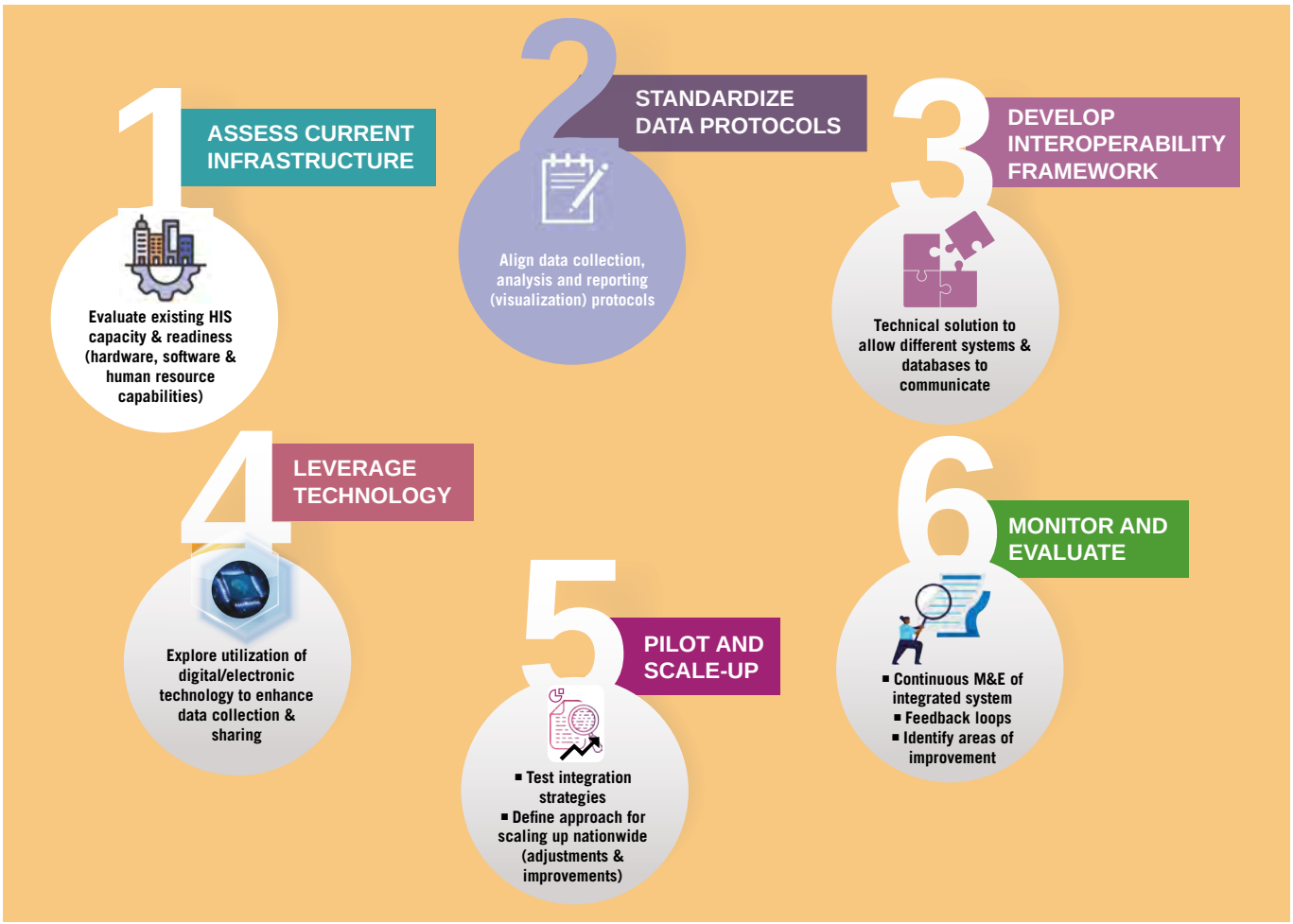


Figure 8: Stepwise approach to establishing national intergrated AMR surveillance systems

In addition to the steps highlighted in figure 8 the following areas also need to be considered:

- Capacity building and training: Invest in training healthcare professionals, laboratory personnel, and IT staff to ensure adequate skills for surveillance efforts.
- Collaboration with stakeholders: Engage key stakeholders, including government agencies, healthcare providers, laboratories, and international partners, to ensure a coordinated approach to AMR, AMC and AMU surveillance. Collaboration fosters shared goals and resource pooling.
- Establishment of governance structures: Create clear governance frameworks, with defined roles and responsibilities, to oversee the integration process, ensuring accountability, data privacy, and security.

4

GOVERNANCE AND COORDINATION MECHANISMS FOR DATA SHARING AND USE

4 GOVERNANCE AND COORDINATION MECHANISMS FOR DATA SHARING AND USE

Key Takeaways:

- **National and Regional Governance:** Establish National Central Coordinating Unit (this can be any country assigned structure such as the AMRCC) and similar regional bodies with clear TORs to lead AMR, AMC, and AMU data sharing, utilization, situational analyses, strategic planning, and to ensure alignment of sectors.
- **National Reference Laboratories (NRLs):** NRLs support AMR surveillance through specialized testing, outbreak investigations, and quality control and assurance across all surveillance sites.
- **Sentinel Sites:** Serve as primary data collection points, feeding data directly to the CDW (Central Data Warehouse) for consolidation and onward transmission to the continental data repository for further processing and analysis.
- **Continental Coordination:** Key for unified AMR governance, ensuring consistency, collaboration and effective communication across national efforts, promoting a unified approach to AMR, AMC and AMU data governance and sharing.

4.1 ESTABLISHMENT OF GOVERNANCE STRUCTURES AND COORDINATION MECHANISMS FOR DATA SHARING AND USE

This section will highlight the recommended structures and coordination mechanisms which countries, and regional teams must establish to ensure effective governance for AMR data sharing and utilization. The goal is to improve public health outcomes and AMR management. Below are the governance levels;

1. Governance bodies at national and regional levels
Country level:

- A NCCU, or other committee/body as designated at national level (such as the AMRCC), should be established, with TORs and a governance framework.
- A technical team should be established, responsible for setting national priorities for AMR pathogens, AMC and AMU surveillance, capacity building and strengthening quality assurance.
- National coordinator(s)/ focal person(s) for AMR, AMC, and AMU surveillance designated from key institutions, such as the MoH or PHI/PHA. The coordinator(s), supported by a technical team, should lead efforts in training, standardization, and quality assurance, potentially serving as the technical team leader(s).

The NCCU's roles and responsibilities must be clearly defined with formal TORs. It should include technical experts and key stakeholders. Typical members might include representatives from Ministries responsible for; human health, animal health and the environment, academia, research, among other key stakeholders.

The NCCU's primary functions are:

- Conducting situational analyses and eligibility assessments of the country's AMR, AMC, and AMU surveillance capacity and sustainability.
- Developing and overseeing national strategic plans for AMR, AMC and AMU surveillance, monitoring and evaluation.
- Extending strategic oversight to include IPC policies, treatment guidelines, and regulation of antimicrobial agents.

A NRL must be established to support laboratories within an AMR surveillance system. It should provide reference testing to all AMR surveillance sites including other laboratories that isolate, detect, identify bacterial species, confirm and characterize AMR mechanisms.

A NRL has four reference functions:

1. Primary analysis of samples (when necessary); specialized and confirmatory testing for identification; serotyping by analyzing samples and identifying species, including subtyping.
2. Confirmation and characterization of AMR mechanisms, including analyses that cannot be performed at surveillance sites.
3. Outbreak investigation.
4. Quality control (QC) and quality assurance (QA).

Continental level:
To establish a robust continental AMR-SS in Africa, it is essential to create well-structured continental coordination bodies that ensure alignment, collaboration, and coherence across nations. Drawing from the successful governance model of the other regional governance structures, such as the European Centre for Disease Prevention and Control (ECDC), a centralized coordinating entity in Africa can be built from existing regional AMR networks (AMRSNET and the Economic Community of West African States (ECOWAS)). This entity would serve as a platform for harmonizing surveillance standards, facilitating data sharing, and providing technical guidance to national AMR-SS. By leveraging and integrating the strengths of regional networks, this continental body would enhance the effectiveness of AMR, AMC, and AMU surveillance across the continent, fostering a unified approach to combating AMR and supporting evidence-based policymaking at both national and regional levels.

2. Surveillance (sentinel) sites governance
Sentinel sites should establish organizational structures that integrate with existing facility and laboratory systems to manage surveillance activities. In this guidance, we refer to this structure as the Site Coordinating Committee (SCC). However, the functions of this committee may already fall under the mandate of an existing facility structure (such as an AMS committee) or be assigned to any other designated committee responsible for managing surveillance activities.

Each sentinel site must have a SCC with a clearly defined TOR. The SCC should include key representatives such as the site leader, facility administrator, data manager, laboratory personnel, pharmacist, and relevant public health specialists. The site leader will be responsible for reporting to the NCCU. The SCC, led by the site coordinator, is responsible for:

- Collaborating with the national technical team to analyze the site's current capacity and sustainability.
- Planning strategic priorities for the site.
- Overseeing AMR surveillance implementation and reporting on key indicators.

The SCC also supports on-site training for AMR surveillance procedures, develops locally adapted standard operating procedures (SOPs), and ensures QC through regular audits. They work with the national team to establish internal QA, aiming to progress to external assessments. Effective communication channels must be maintained to provide AMR results to practitioners and summarized data to stakeholders, while anonymized case-level data should be reported to the NCCU. The SCC will work closely with other existing facility structures, to support overseeing other aspects, such as compliance to IPC policies, and treatment guidelines.

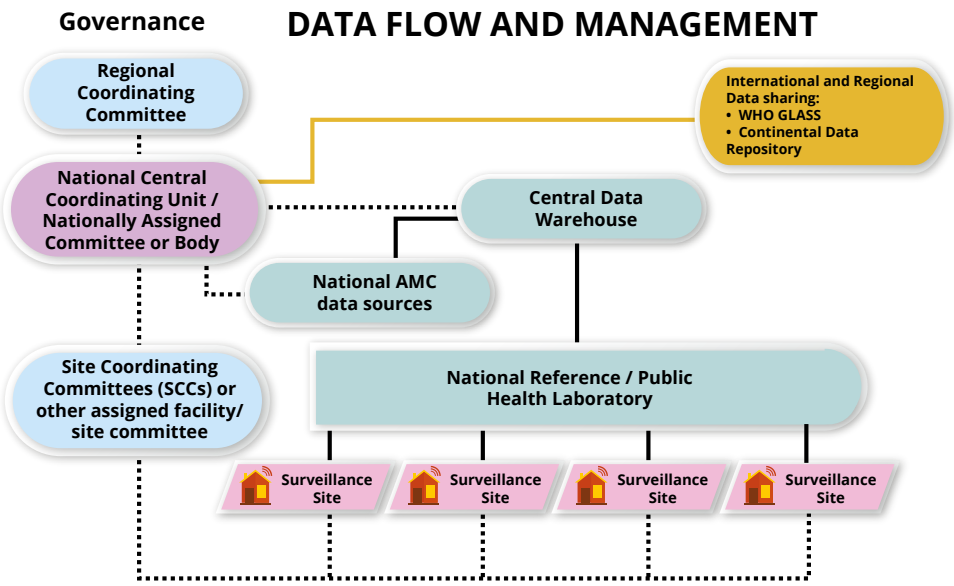


Figure 9: Simplified diagram of governance and data sharing and transmission in the AMR Surveillance System

5

SELECTING SURVEILLANCE SITES AND DATA SOURCES

5. SELECTING SURVEILLANCE SITES AND DATA SOURCES

Key Takeaways:

- Site Selection for Laboratories (Sentinel Sites): Use NCCU-defined criteria, situational analysis and eligibility tool to choose AMR surveillance (sentinel) sites, ensuring geographic, socioeconomic, and epidemiological diversity. Regularly update selection.
- AMC Data: Conduct KIIs to understand antimicrobial pathways, utilizing responses to design a flow chart of antimicrobial routes. Additionally, collect AMC data from pharmacies (hospital and community) within laboratory catchments. and use questionnaires to assess data collection readiness. Finalize AMC data sources with NCCU and MoH.
- AMU Data: Gathered from hospitals and pharmacies through prescription and patient records.

This section will outline the process for selecting surveillance sites and data sources for AMR, AMC, and AMU data collection. It is important to ensure comprehensive coverage across various sectors, including public, private, and faith-based organizations (FBOs), to capture a more accurate and representative picture of antimicrobial use and resistance. General considerations should focus on inclusivity and diversity of healthcare settings to enhance the reliability of the data.

5.1 APPROACH

Laboratories

Selection of AMR surveillance sites should be based on a criterion defined by NCCU. An initial situational analysis or laboratory mapping exercise should be utilized to pinpoint potential sites for AMR sentinel surveillance. The NCCU should lead the site selection process transparently, with input from all relevant stakeholders when appropriate.

The selected surveillance sites and the network should account for variations in geography, socioeconomic factors, demography, disease epidemiology (including co-morbidities like HIV), and ecological factors such as climate, rainfall, and land use. Additionally, the approach should encompass both rural and urban distributions and include participation from both private and public sectors to ensure a comprehensive understanding of AMR dynamics across diverse settings and to address disparities in access and resource.

Relying solely on one level of healthcare, such as referral hospitals, will not provide an accurate representation of the country's AMR situation.

Medicine Supply Chain/Pharmacies

To characterize the pathway through which the antimicrobials get to patients in the country, Key Informant Interviews (KIIs) should be conducted with relevant stakeholders that may include the NCCU, MoH's departments responsible for health products and technologies, medicine/pharmaceutical regulatory authority, manufacturers, wholesalers/ distributors, health insurers, and the central medical store (CMS). See annex 2 for the medicines supply chain KII.

i. National-level AMC data

National AMC data can be gathered from existing supply chain data sets, depending on the availability and accessibility of aggregated information. To enhance accuracy, data should be collected as close as possible to the time of antimicrobial consumption (as highlighted in figure 10). Therefore, the NCCU should aim to incorporate data from pharmacies and map these locations for future national surveillance, as it targets data sources closer to the patient. Involving both private and public sector players in this effort is essential for comprehensive coverage. Given the complexities and multi-agency coordination required to obtain detailed data from lower levels of the supply chain of antimicrobials, countries can start with aggregated AMC data from higher levels of the supply chain, such as importers and local manufacturers or wholesaler/distributor. This phased approach allows for incremental improvements in data collection, gradually building a more robust, accurate and inclusive surveillance system.

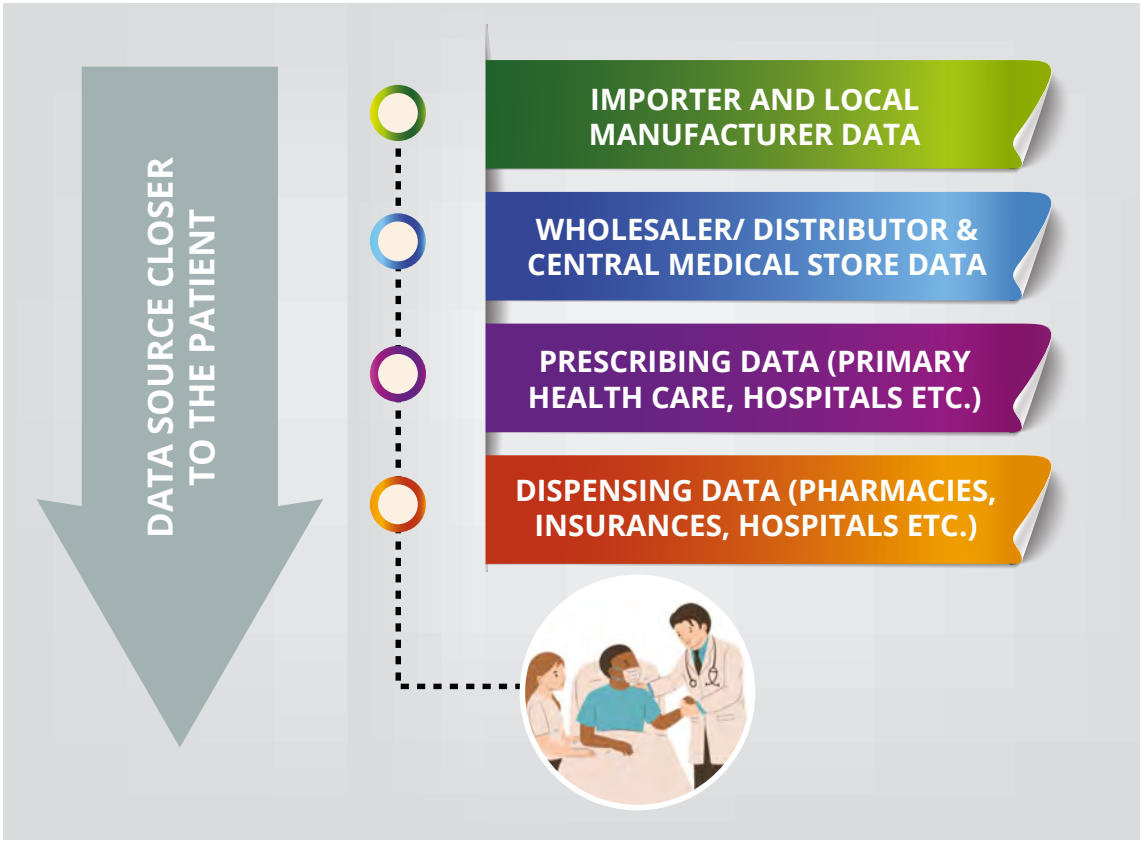


Figure 10: Overview of National AMC data sources, highlighting sources closest to the point of consumption for more accurate estimates.

ii. Pharmacy-level AMC data

AMC data is to be obtained from the pharmacies that are co-located within an agreed catchment with the selected AST laboratories in the country. Additional AMC data should be collected from the community pharmacies nominated by the co-located pharmacies based on their proximity to the AST laboratories and/ or because they serve as preferred patient medicine or backup sources in case the main hospital pharmacy experiences stock outs.

iii. Antimicrobial Use data

AMU data should be collected from the recruited hospitals and provided from the facilities prescription and patient medical records.

5.2 SET CRITERIA

The criteria for selection of these sites are outlined below with reference to the tools to support the process.

Laboratories

a. In-country, the laboratory network should be initially mapped with support from the NCCU.
b. Create an inventory of laboratories in the tiered network, with capabilities to identify pathogens and conduct AST.
c. Conduct laboratory capabilities assessments using the laboratory eligibility assessment tool (see annex 1). The assessment tool will obtain site-specific details and assess the laboratories on five aspects:
   - Specimen management practices
   - Quality management systems implementation
   - Commodities and equipment management practices
   - Laboratory information systems.
   - Personnel and training

d. Assign each laboratory a readiness score for AMR surveillance based on information gathered from the criteria defined in the laboratory eligibility assessment tool, which provides scoring information for each response (annex 1).
e. Select laboratories based on the above self-reported information, considering other factors such as representation in relation to geography, socioeconomic factors, demography, disease epidemiology, and ecological factors, rural and urban distributions, participation from both private and public sectors, as well as laboratory rankings.
f. Regularly, NCCU should conduct these assessments to update the country's laboratory network.

Pharmacies and medicines stores

a. Review of the KII responses should be conducted by the assigned AMC surveillance focal person and the NCCU (see annex 2).
b. Develop a flow chart to illustrate the route through which antimicrobials get to the patient designed, mapping out the potential sources of data.
c. Mapping of pharmacies should be conducted with assistance from the pharmacy regulatory body.
d. Pharmacy/medicine supplier questionnaire (see annex 3) should be filled in by the mapped agencies, to assess the availability and readiness to collect AMC data.
e. The final selection of AMC data is made by the NCCU and MoH, with consideration of the percentage representation of total consumed antimicrobials in the country.

6

DATA COLLECTION AND DATA MANAGEMENT

6. DATA COLLECTION AND DATA MANAGEMENT

Key Takeaways

- Comprehensive Data Collection: The section outlines processes for collecting AMR, AMC, and AMU data. Providing standardized procedures aimed at emphasizing the importance of gathering accurate and complete data across healthcare settings.
- Key Data Elements: Provides essential variables for AMR, AMC and AMU data collection. Countries are called upon to review and adapt these variables based on their national priorities.
- Aligning National Priorities to Guidelines: Countries are encouraged to align their data collection efforts with WHO guidelines, while adjustments should be made to reflect national priorities and available capacities.
- Data Management & System Integration: Recommends standardized tools and protocols provided for efficient data management and real-time reporting. Discusses the importance of integration of data systems with a national CDW which is critical for comprehensive analysis and dissemination of findings
- Sampling Strategies: Highlights the role of prevalence surveys for AMR and AMU and the need for effective sampling strategies.
- Reporting: Calls for data submission to WHO's GLASS and regional repositories to support global, continental and national surveillance.

This section will describe the data collection process in the country for AMR, AMC and AMU data.

6.1 KEY DATA ELEMENTS

i. AMR data variables

The key data variables and elements to be collected fall under patient demographics, clinical profile/ information, specimen information, culture result (no growth/ contamination/ pathogen), AST result, resistance mechanism, antimicrobial usage, laboratory information (see annex 4 for full list of key AMR variables).

When collecting individual-level data for AMR prevalence surveys additional information will be collected e.g., hospital name, ward or department, patient diagnosis, medical history, referral, antimicrobial therapy, etc.

ii. AMR surveillance targets

In 2023, WHO GLASS updated priority pathogens list and associated specimen types for global surveillance of AMR (see table 2). NCCU should review and adopt these lists, while considering national priorities and available capacities to detect and report these pathogens.

Table 2: GLASS target pathogens and specimen types

Target Pathogens	Specimens					
	Blood	Cerebrospinal fluid (CSF)	Urine	Stool	Lower Respiratory Tract	Urethral, Cervical, Rectal, and Pharyngeal Swabs
Acinetobacter spp.	✓	✓			✓	
Escherichia coli	✓	✓	✓		✓	
Klebsiella pneumoniae	✓	✓	✓		✓	
Pseudomonas aeruginosa	✓	✓			✓	
Staphylococcus aureus	✓	✓			✓	
Streptococcus pneumoniae	✓	✓			✓	
Neisseria meningitidis	✓	✓				
Haemophilus influenzae	✓	✓			✓	
Salmonella spp. (non-typhoidal)	✓			✓		
Salmonella enterica serovar Typhi	✓			✓		
Salmonella enterica serovar Paratyphi A	✓			✓		
Shigella spp.				✓		
Neisseria gonorrhoeae						✓

Priority specimen types: Priority pathogen will be reported only when isolated from the defined priority specimen types. These specimen types are blood, urine, faeces (stool), urethral, cervical swabs, CSF, specimens from the lower respiratory tract, and non-urogenital samples (rectal and pharyngeal).

Priority Pathogens: In human health, 12 families of bacterial pathogens have been prioritized for AMR surveillance globally, as shown in table 2. Annex 5 provides a full list of specimen types for each pathogen and antimicrobials to be tested against them. In addition to these pathogen lists, WHO in 2024 released a list of 15 families of antibiotic-resistant pathogens grouped into critical, high, and medium priority for public health measures, and research and development (see table 3). Countries should customize their priority pathogen lists based on national priorities and available capacities.

Table 3: WHO priority pathogen list 2024

Pathogen	Resistance	Priority
Acinetobacter baumannii	Carbapenem-resistant	Critical
Enterobacterales	Carbapenem-resistant, ESBL-producing	Critical
Mycobacterium tuberculosis	Rifampicin-resistant	Critical
Salmonellae Typhi	Fluoroquinolone-resistant	High
Shigella species	Fluoroquinolone-resistant	High
Enterococcus faecium	Vancomycin-resistant	High
Pseudomonas aeruginosa	Carbapenem-resistant	High
Non-typhoidal Salmonellae Typhi	Fluoroquinolone-resistant	High
Neisseria gonorrhoeae	Cephalosporin-resistant, Fluoroquinolone-resistant	High
Staphylococcus aureus	Methicillin-resistant	High
Group A Streptococci	Macrolide-resistant	Medium
Streptococcus pneumoniae	Macrolide-resistant	Medium
Hemophilus influenzae	Ampicillin-resistant	Medium
Group B Streptococci	Penicillin-resistant	Medium

iii. AMC data variables

The core AMC variables and elements to be collected include product name, pack size, strength, route, and number of packs (see annex 6 for full list of variables). Countries should review and customize data variables according to their national priorities.

iv. AMU data variables

The key variables and elements for AMU data collection are grouped into several categories, each focusing on critical aspects of patient care and treatment patterns. These categories include patient demographics, clinical profile/information (diagnosis, indication, specimens collected etc.), culture results, AST results, antimicrobial use (product name, dosage, route, frequency, and duration). A full list of variables has been provided in annex 7. Countries should review and customize data variables according to their national priorities.

v. AMC and AMU data scope

The scope of antimicrobials that will be surveilled will include the WHO core monitoring Anatomical Therapeutic Chemical (ATC) medicine categories for AMC surveillance, which are J01 (antibiotics for systemic use), A07AA (antibiotics for alimentary tract) and P01AB (Nitroimidazole derivatives for protozoal diseases), see table 4 below for details of antimicrobial classes for surveillance. Considering national priorities for AMC and AMU surveillance, countries can tailor their monitoring focus to align with specific antimicrobial agents that are most relevant to their public health needs.

Table 4: WHO core and optional medicine classes for AMC surveillance.

ANTIMICROBIAL CLASS	ATC	MONITORING
Antibacterials for systemic use	J01	Core
Antibiotics for alimentary tract	A07AA	Core
Nitroimidazole derivatives for protozoal diseases	P01AB	Core
Antifungals	J02	Optional
Antimycotics	D01BA	Optional
Antivirals	J05	Optional
Antimycobacterials for treatment of tuberculosis	J04A	Optional
Antimalarials	P01B	Optional

Note: For AMU studies, currently only J01 antibiotics are recommended to be collected according to the WHO methodology for point prevalence survey on antibiotic use in hospitals, and only those administered through oral, parenteral, rectal or inhalation routes (12).

6.2 METHODS FOR DATA COLLECTION

6.2.1 AMR data collection

i. Sentinel surveillance

Laboratories enrolled in the national AMR surveillance network will prospectively collect and report data in real time or at a frequency set by the NCCU. AMR data can be collected using either paper-based tools, such as laboratory registers/logs, standardized data forms, while electronic tools can be Laboratory Information Management System (LIMS), Hospital Management Information System (HMIS), WHONET, standardized Microsoft Excel™ templates, ODK forms, LabBook, among others. AMR surveillance data collected using LIMS, HMIS, ODK forms can be reported in real-time to the national CDW, while data collected using other tools require NCCU to define reporting frequency. Use of paper-based tools often presents retrieval and data quality challenges, thus not encouraged. NB: For sites that do not yet have suitable tools for efficient data management and reporting in place, there are solutions such as WHONET, a free Windows-based database software developed by WHO collaborating center for AMR surveillance, for microbiology data management and analysis.

Another cost-free option for electronic AMR data entry is SEDRI-LIMS. This is an open-source, microbiology-focused LIMS sponsored by the Wellcome Trust that is designed to streamline data entry, adapt to existing laboratory workflows and seamlessly integrate with its environment. It also has built-in support for WHONET export so that, when used in conjunction with the WHONET tool, data entered into the LIMS as part of the normal workflow can be exported to GLASS automatically without duplicate entry.

The WHO GLASS AMR data collection methodology for routine sample and isolate-based AMR surveillance is recommended for all participating countries, as well as the AMR prevalence studies (13). The GLASS method defines minimum data variables to be collected and reported. Countries are advised to collect additional variables aligned to their national AMR surveillance objectives.

A standardized SOP has been developed to provide stepwise guidance on the data entry and management, ensuring that all relevant data is collected for reporting to the country's CDW, regional repository and the WHO GLASS (see annex 8 for SOP01 for data collection and management).

1. Ensure all tools being used to collect AMR data have all the key variables captured. (refer to key data variables in annex 4).
2. The core patient data that should accompany any request for AST are as follows: unique identifier; age; gender; specimen type; date of specimen collection; date of admission; and patient location type status (inpatient vs.

outpatient). NB: additional information may be collected according to local and national protocols. Refer to annex 8, for SOP01 on data collection and management, and annex 9 for SOP02 which details data entry and reporting using WHONET software.

3. The data collected and entered or captured should be reviewed, cleaned and transmitted in real-time, or as per the set submission frequencies, to the national and regional repositories. Each row of the dataset should represent an individual patient's results. Where the laboratory or hospital issues unique patient identifiers, it is possible to track and deduplicate records.
4. Annually review and submit the AMR surveillance data collected to the WHO's GLASS.
5. The CDW in the country should be maintained by the national reference/public health laboratory, with the aim of collating national AMR data for analyses, dissemination, and use to inform national and sub-national policies and practices, and for global dissemination to WHO GLASS.

ii. Sampling strategies

Functional AMR surveillance systems aim to generate high-quality, representative data. To achieve this, it is crucial to select surveillance sites across different healthcare system tiers and conduct routine sampling and testing in both inpatient and outpatient departments, ensuring a representative patient mix for laboratory-based AMR surveillance. Health-seeking habits, access to healthcare, and the number and distribution of surveillance sites can significantly affect AMR rates and should be considered when interpreting AMR trends using routine laboratory-based surveillance. To address potential biases in laboratory-based AMR surveillance, AMR prevalence studies are recommended as a complementary surveillance approach.

iii. AMR prevalence studies

The population under survey includes all patients seeking care at health care facilities who meet the infection case definition. Survey sites are selected to be national representative using WHO approved protocols.

6.2.2 AMC data collection

AMC data collection will follow the WHO GLASS AMC methodology to ensure that all relevant data is captured for reporting to WHO GLASS (14). Tools for AMC data collection can be paper-based or electronic. Paper-based AMC data collection tools include pharmacy medicine card or registers, standardized data forms, while electronic tools include pharmacy/ inventory management systems, HMIS, AMC or MAAP tools, standardized Excel™ templates, among others. It is possible to set up AMC reporting direct to the national CDW in real-time, by integrating the electronic database to CDW (this will require enabling an IT solution). This would be possible for electronic pharmacy systems or data entered prospectively into the AMC or MAAP tools. While data collected using other tools e.g. standardized Excel™ templates require NCCU to define reporting frequency. As with AMR data, the use of paper-based tools often presents retrieval and data quality challenges, thus not promoted. NB: For sites that do not yet have suitable tools for efficient data management and reporting in place, the MAAP tool is recommended.

A standardized SOP has been developed to provide stepwise guidance on the data entry and management of AMC, ensuring that all relevant data is collected for reporting to the country's CDW, regional repository and the WHO GLASS (see annex 10 for SOP03 on AMC data collection and analysis).

1. Countries should produce a list of all medicinal product packages (MPPs) for the antimicrobial agents with marketing authorization in the country. For each uniquely identified MPP, a range of information needs to be systematically collected to calculate the quantity of the active ingredient (substance) in a package. In addition, the correct application of the ATC and DDD methodology performed to obtain the number of DDD contained in one MPP (refer to SOP03 in annex 9).
2. For each MPP reported in the registry, consumption is expressed as the total number of packages imported, sold or dispensed (depending on the data source used to extract the consumption data) during a defined period.

This can be stratified by health care sector and level, if this information is available.

3. Each antimicrobial substance should be named, preferably using the international nonproprietary name (INN).
4. Map all the unique molecule name and formulation combination with additional information such as WHO ATC5 code, WHO DDD, and WHO Access, Watch, and Reserve (AWaRe) categorization.
5. The data collected and entered or captured should be reviewed, cleaned and transmitted in real-time, or as per set submission frequencies, to the national and regional repositories. Enter all the standardized variables including antimicrobial names, salt, formulation, WHO ATC5, WHO DDD, and WHO AWaRe (refer to key data variables in annex 6). Each row of the dataset should represent an individual patient. Where the pharmacy or hospital issues unique patient identifiers, it is possible to track and deduplicate records.
6. Annually review and submit the AMC surveillance data collected to the WHO GLASS.
7. Where national AMC data is housed within the pharmacy regulatory body or other agency. The NCCU should ensure the integration of the data system with the CDW in the country. This will enable AMR and AMC comparative analysis to be performed, dissemination of comprehensive finding, and used to inform national and sub-national policies and practices, and for global dissemination to WHO GLASS.

6.2.3 AMU data collection

AMU data is collected from the recruited hospitals and provided from the facilities prescription and patient medical records. The WHO methodology for point prevalence survey on antibiotic use in hospitals is recommended to be used by all recruited surveillance sites in the country (12). A standardized SOP has been developed to provide stepwise guidance on the data collection of AMU (see annex 11 for SOP04 on AMU data collection and analysis).

1. Patient sampling: Based on the size of the hospital the following patient sampling can be employed:
   - < 500 total inpatient beds, include all eligible patients in the wards
   - 500-800 total inpatient beds, one out of two patients per ward
   - 800 total beds, one out of three patients per ward

   To obtain the final list of eligible patients, ordered them alphabetically starting with their Surname and perform random selections of patients, while maintaining consistency e.g., every 1st, 2nd or 3rd patient.
2. Inclusion, exclusion and scope of antimicrobials for data collection are outlined in SOP04 (annex 11).
3. There are 3 data collection tools: Hospital questionnaire (type and size of the hospital), ward level data (type of ward, number of eligible & included patients, characteristics of ward), and the patient level data (patient information, antimicrobial use information and therapy details),

A One Health AMR data management system should be enabled by the NCCU to support the visualization of the AMR data submitted to CDW from across sectors and to simplify the process of collating and validating data for submission to GLASS.

6.3 DATA CONFIDENTIALITY, PRIVACY, AND SECURITY

Ensure patient data is anonymized or deidentified to protect privacy in line with global standards like GDPR (General Data Protection Regulation) and national regulations. Surveillance data containing personal identifiers must be protected with secure file management, including the encryption of computers and other storage devices, data encryption and adherence to organizational and governmental requirements. Data managers should be trained in these secure practices to ensure safe data sharing at national, continental, and international levels, while maintaining data integrity and confidentiality. Promoting interoperability and adopting harmonized standards will reduce risks associated with data sharing.

Countries must implement robust cybersecurity measures to protect AMR surveillance data from unauthorized access, adhering to international protocols such as ISO/IEC 27001. In addition, countries are required to establish clear legal agreements defining the rights, responsibilities, and liabilities for data sharing, ensuring compliance with ethical data use principles (see section 12 on ethical considerations). Consider conducting regular audits of data management practices to ensure compliance with standards and identify areas for improvement.

6.4 DATA ACCESSIBILITY AND SHARING

Balance the need for open data sharing with the protection of sensitive information. Invest in capacity building to enhance data management and security skills among healthcare workers. Obtain necessary ethical approvals for data access and sharing, particularly when sharing sensitive or personal health information.

Countries must establish data sharing/use agreements (DSAs/DUAs) that outline the terms and conditions of data sharing, including restrictions on use, data security measures, and responsibilities of data recipients. Ensure that data is used solely for the purposes specified in the agreement, such as public health monitoring and research.

Where possible, make AMR data publicly available to enhance transparency and foster trust. This can be done through public health websites or open-access databases. Provide access to relevant stakeholders, including healthcare professionals, researchers, policymakers, and public health organizations, while respecting data privacy and confidentiality.

At the continental level, the central data repository has the responsibility to prevent unauthorized access, use, or disclosure of shared data, ensuring that all information remains accurate and properly utilized. To fulfill this responsibility, the repository will implement robust security measures, including physical, electronic, and managerial safeguards, aligned with international standards and best practices. These measures will not only protect the data received from individual countries but also ensure that it is securely processed, stored, and shared. The repository will work closely with national data providers to uphold data integrity and confidentiality, ensuring that all data security protocols are consistently applied across the continent.

7

QUALITY ASSURANCE AND QUALITY CONTROL

7 QUALITY ASSURANCE AND QUALITY CONTROL

Key Takeaways:

- QA vs. QC: QA ensures quality through systematic activities; QC focuses on operational techniques. Both are vital for ensuring high laboratory standards are achieved.
- EQA: Essential for validating laboratory performance and achieving accreditation.
- It is essential that countries ensure national regulation of the following practices to support AMR-SS: clinical practice (through implementation and enforcement of Antimicrobial Stewardship Programs); laboratory practice (ensuring licensing, accreditation, and compliance with standards; and pharmacy practice (regulate dispensing, enforce sales rules, and implement pharmacovigilance).

7.1 IMPLEMENTING QUALITY ASSURANCE/ CONTROL PROCESSES

Quality assurance (QA) refers to the systematic activities and programs put in place to ensure that quality requirements for laboratory processes and outputs are met. While quality control (QC) involves the operational techniques and activities used to fulfill quality requirements. These processes are integral to maintaining high standards in laboratory testing and data collection.

QA activities should be led by the national coordinator and technical team in-country, in conjunction with external organizations as appropriate.
QA in countries should include the following:

i. Countries must ensure that they have in place SOPs for sample collection, handling, processing, and reporting, and that they are adhered to. This helps ensure consistency and reliability across different laboratories. SOPs should be regularly updated and aligned with international standards, such as the Clinical and Laboratory Standards Institute (CLSI), the European Committee on Antimicrobial Susceptibility Testing (EUCAST) and ISO17025. At a core level, all site procedures should be undertaken according to SOPs, adapted from national or regional SOPs, and other guidelines.

ii. Regular training sessions and competency assessments for laboratory personnel are essential to maintain proficiency in AST. Training should cover the latest techniques, equipment handling, and adherence to SOPs.

iii. Conducting regular internal audits and quality checks helps identify areas for improvement and ensures compliance with established procedures. This includes checking the calibration of equipment, reviewing test results, and verifying the accuracy of data entry. In a facility setting, standardization and investigation should be assessed through standard quality control procedures, ensuring completeness of the data and investigations requested, through audit assessment and feedback. Such as, hospital level data on all admissions are required to assess, for example, the diagnosis of all patients and whether those with an infectious syndrome were appropriately investigated. At a core level, the quality of clinical sampling and the data acquired should be subject to internal quality assurance assessment through the national coordinator and technical team.

iv. Documentation and record keeping: Accurate documentation of all procedures, test results, and corrective actions is crucial for traceability and accountability. Good record-keeping practices facilitate the review and analysis of data, contributing to continuous quality improvement.

v. Participation in external quality assessments (EQA).

In relation to in-house QC activities, the following should be implemented:

i. Maintain bacteriology reference control strains: Use control strains of known susceptibility to verify the accuracy of AST results. Regularly test these control strains alongside clinical samples to ensure test performance is within acceptable limits.
ii. Reagent and media quality: Ensure that all reagents and culture media are tested with control strains when prepared or opened for use; they are stored correctly, with regular checks for expiration dates and contamination. Using high-quality reagents and media is essential for obtaining reliable test results.
iii. Equipment calibration and maintenance: Regular calibration and maintenance of laboratory equipment, such as incubators, autoclaves, and spectrophotometers, are vital to ensure accurate readings and prevent equipment-related errors.

7.2 EXTERNAL QUALITY ASSESSMENT (EQA) PROGRAMS FOR LABORATORIES

EQA is a system for validating laboratory performance and includes programs that provide an independent assessment (by an external and objective agency) by comparing the laboratory results with other laboratories and reference standards. EQA is essential, and all laboratories should participate in a formal EQA scheme for all tests performed.

Traditional proficiency testing is the most cost-effective and useful EQA method. This involves dispatch of test isolates to laboratories, to be processed using the normal testing methods by staff who routinely handle such samples. Results are submitted to the EQA provider, which provides feedback and allows comparison with results from other laboratories. If participation in formal proficiency testing is not possible, adequate EQA may be achieved through a combination of within country retesting / rechecking and internal QC procedures, with periodic external observation of practices and procedures by qualified personnel from NRLs. All laboratories should be encouraged to work towards full accreditation (e.g. using the WHO Step wise Laboratory Improvement Process Towards Accreditation in the African Region (SLIPTA) (15)).

The benefits of laboratories EQA include:

- Proficiency testing helps identify areas needing improvement and validates the accuracy of testing procedures.
- EQA programs facilitate inter-laboratory comparisons, allowing laboratories to benchmark their performance against peers and identify discrepancies in testing methodologies.
- They provide detailed feedback on laboratory performance, highlighting strengths and areas for improvement. Laboratories are encouraged to implement corrective actions based on this feedback to enhance their quality systems.
- Participation in EQA programs can support laboratories in achieving accreditation, such as ISO 15189 for medical laboratories, which demonstrates compliance with international standards and enhances credibility.

Therefore, all AMR surveillance laboratories in a country should be enrolled into microbiology EQA schemes. These EQA efforts will contribute to improved data quality and the ability of the country to use and report accurate AMR data.

7.3 NATIONAL REGULATION OF CLINICAL, LABORATORY, AND PHARMACY PRACTICE

Effective regulation of clinical, laboratory, and pharmacy practices is essential to ensure the implementation of a comprehensive and robust AMR-SS. The relevant national regulatory frameworks should focus on the following aspects:

Clinical Practice
Healthcare facilities must have in place ASPs, with the appropriate governance structures established

and operational. These programs must incorporate diagnostic stewardship and have strong links with the facility IPC programs. It is recommended that the facility appoint AMS focal persons to coordinate the ASP activities, who will hold the responsibility of providing regular updates to the national (+/- subnational) AMR coordinating body (such as the AMRCC).

These facility-based committees, overseeing the implementation of the ASP, should have clear TOR and action plans that should incorporate the following key activities:

- Development and enforcement of guidelines for the diagnosis and treatment of infectious diseases. This will helps standardize care and promote the appropriate use of antimicrobials.
- Coordination and implementation of continuous medical education, development, and certification for practitioners, ensuring they remain informed about the latest AMR trends and treatment protocols.
- Strengthening the clinical-laboratory interface, enhancing communication and collaboration of the multidisciplinary team.

Laboratory Practice

Laboratories should be licensed and accredited by national authorities to ensure they meet quality standards. Accreditation bodies, such as national health ministries or independent organizations, should regularly assess laboratories. Furthermore, these regulatory agencies should monitor laboratory compliance with QA/QC standards, SOPs, and biosafety protocols to maintain high testing quality.

Pharmacy Practice

Pharmacy/medicine regulatory bodies must ensure that all operational medicine dispensing outlets are licensed and accredited by national authorities. Furthermore, strict regulations are in place to safeguard the sale of antimicrobials. Tight enforcement of these regulations should in turn restrict over-the-counter sales without prescriptions, thereby reducing inappropriate use. The regulatory bodies should also ensure the implementation of essential medicine lists and pharmacovigilance systems to monitor and report adverse reactions and resistance patterns associated with antimicrobial use.

8

DATA ANALYSIS, INTERPRETATION AND REPORTING

8. DATA ANALYSIS, INTERPRETATION AND REPORTING

Key Takeaways

- **Data Analysis for AMR, AMC, and AMU:** Provides details on AMR, AMC and AMU analysis which can employ a range of tools from MAAP, WHONET and R Software to EPI Info 7. Introduces standardized methodologies and procedures, including assessing pathogen resistance, drivers of AMR, Drug Resistance Index (DRI), AMC using Defined Daily Doses (DDD), analyzing trends based on WHO classifications and routes of administration, AMU descriptive analysis etc.
- **Data Reporting Framework:** Emphasizes standardized templates, rigorous data validation, regular reporting intervals, and strong privacy measures to ensure data integrity and confidentiality.
- **Data Visualization and Dashboards:** Interactive and user-centric dashboards are crucial for making complex data accessible to a wide range of stakeholders, ensuring informed decision-making at all levels.
- **Channels of Reporting:** Advocates for digital platforms with secure data sharing capabilities, supplemented by paper-based reporting where necessary, supported by feedback loops and comprehensive stakeholder training.

8.1 DATA ANALYSIS

8.1.1 Antimicrobial Resistance data analysis

Data is transferred into the country's CDW (repository) through an online application for further analysis. The following core analysis will be performed (refer to annex 12 for SOP05 on AMR data analysis and dissemination):

i. Preliminary data review to check for data completeness, accuracy, and redundancy. Data summarization should be conducted on the following parameters: quantum of cultures (total cultures, valid cultures [total number of clinical samples appropriately collected, handled, and processed, leading to the accurate growth of microorganisms representative of the patient's infection], positive cultures, or positive cultures with AST results); level of pathogen identification; inappropriate testing [AST conducted without clinical justification, on improper samples, or using incorrect methodologies]; clinical information; culture characteristics; specimen characteristics; and identified pathogens.

ii. Descriptive analysis to assess distribution by specimen types, age group, gender, patient locations, departments, pathogens reported. This can be included in generating inferential statistics.

iii. AMR rates: Determine the extent (proportion or percentage) to which a pathogen is resistant to a particular antimicrobial agent or class, determined by the proportion of isolates that are non-susceptible (i.e., either intermediate or resistant) over a one-year period:

AMR rate = No. of non-susceptible isolates / No. of tested isolates [CI 95%]

iv. Resistance patterns and prevalence of multidrug resistance (MDR), Extensive drug resistance (XDR) and Pan drug resistance (PDR)

v. Drivers of AMR: To determine the associations between AMR and its potential drivers at country- and patient-levels.

vi. Drug Resistance Index (DRI): Optional analysis to assess the relationship between AMU and AMR through the DRI.

$$DRI = \sum (\text{Resistance Rate}_{i,j} \times \text{Antibiotic Use Fraction}_{i,j})$$

where:

- *i* is the specific pathogen.
- *j* is the antibiotic or class of antibiotics.
- Resistance Rate $_{i,j}$ is the percentage of isolates of pathogen *i* that are resistant to antibiotic *j*.
- Antibiotic Use Fraction $_{i,j}$ is the proportional

usage or consumption of antibiotic *j* (out of total antibiotic use) for pathogen *i*.

An SOP has been provided with stepwise guidance for the preparation and conversion of AMR surveillance data files using WHONET Baclink for Analysis (refer to annex 13: SOP06).

8.1.2 Antimicrobial Consumption data analysis

As AMC data is directly entered into the MAAP tool, the data can be transferred into Excel™ for further analysis from the backend (refer to annex 9 for SOP03 on AMC data collection and analysis).

The MAAP tool is designed to take the input i.e., data expressed in number of packages, and will produce an output of data expressed in DDD at the substance level., through the following calculation:

DDD AMC Analysis: DDD's are calculated as follows:

$$\text{Number of DDDs} = \frac{\text{Total milligrams used}}{\text{DDD value in milligrams*}}$$

**WHO approved DDDs for antibiotics:* https://www.whocc.no/atc_ddd_index/

Where total grams of the antimicrobial used is determined by summing the amount of active ingredient across the various formulations (different strengths of tablets, or capsules, syrup formulations) and pack sizes. Once AMC is converted to standard DDDs, the data is further analyzed as described in SOP03 (annex 10). The analysis will produce the following output data: into the below standard units:

i. National level data as DDDs/1000 inhabitants/ day (DID)
ii. Pharmacy level data as DDD/100 patient admissions
iii. Monthly AMC trend split by:
    - AMC by WHO ATC classification: The ATC classification is a system to classify active medical substances according to defined standards. The active medical substances are divided into different groups according to the target organ or system and their therapeutic, pharmacological, and chemical properties.
    - AMC by WHO AWaRe categorization: The AWaRe categorization of antibiotics is a framework designed to promote optimal use of antibiotics and combat AMR. It classifies antibiotics into three groups—Access, Watch, and Reserve—based on their necessity, potential for resistance, and public health impact. This categorization is essential for surveillance of AMC as it helps in monitoring and guiding appropriate antibiotic use.
    - AMC by route of administration (Oral vs Parenteral vs Rectal vs Inhalation)
    - AMC by mono drug therapy versus combination drug therapy
    - AMC by formulation type (Oral Solids vs. Oral Liquids)

8.1.3 Antimicrobial Use data analysis

AMU data will we analyzed using Excel™ as described in SOP04 (annex 11), covering the following core areas:

i. Descriptive analysis to assess occupancy, prevalence of antimicrobial prescribing, distribution by antimicrobial types, age group, gender, patient locations, departments etc.
ii. AMU by individual antimicrobial molecule, WHO ATC classification, WHO AWaRe categorization, and route of administration (total for hospital and disaggregated by ward)
iii. Indication and compliance assessment
iv. AMR correlations

8.2 TOOLS FOR DATA ANALYSIS AND VISUALIZATIONS

8.2.1 AMR Data Analysis and Visualization

1. WHONET Software: A critical tool in the global effort to combat AMR, offering advanced capabilities to support microbiology laboratory data management and analysis. WHONET was used in MAAP Phase 1, supporting data management and integration, providing standardization and advanced data analysis.
2. R Software- AMR Package: Specialized tool within the R programming environment tailored for the analysis and visualization of antimicrobial resistance data. It provides a comprehensive

set of functions and tools to facilitate advanced statistical analysis, data visualization, and modeling related to AMR.

3. MS-Excel: Spreadsheet application that offers basic tools for organizing, analyzing, and visualizing data, including AMR data. While Excel may not be as specialized as dedicated statistical software, it provides essential functionalities for preliminary analysis and visualization of AMR trends.
4. One Health AMR Surveillance System- Integrated with National CDWs: This system is designed to enhance surveillance efforts by linking data across these sectors and integrating them into national central data warehouses for comprehensive analysis and action.
5. Statistical Analysis System (SAS): Software suite widely used for advanced analytics, business intelligence, and data management across various industries, including healthcare and pharmaceuticals. SAS can be leveraged for the analysis of AMR data, providing powerful tools for statistical modeling, data integration, and visualization.
6. EPI Info 7: Supports public health professionals in data management, analysis, and visualization. While primarily known for its epidemiological applications, EPI Info 7 can also be utilized for the management and analysis of AMR data.
7. Other recommended platforms: SEDRILIMS, DHIS II,

8.2.2 AMC and AMU Data Management Tools

1. AMC Tool: An open-source program designed to calculate AMC, analyze, and manage antimicrobial consumption data. The tool is the successor of ABC Calc.
2. Global Point Prevalence Survey (Global PPS): A collaborative initiative aimed at monitoring and evaluating antimicrobial prescribing practices in healthcare facilities across different regions and countries. The initiative provides standardized methodology and data analysis on antimicrobial use.
3. MAAP tool: The tool encompasses a set of methodologies, standardized protocols, and data collection instruments employed by the MAAP initiative.

8.3 GLOBAL AND REGIONAL SURVEILLANCE NETWORKS

Existing global surveillance networks for AMR and AMC play a crucial role in combating the growing threat of resistant pathogens and optimizing antimicrobial use worldwide. These networks facilitate collaboration, data sharing, and strategic planning at international, regional, and national levels. They support the following functions:

- Standardization and harmonization of data
- Early detection and monitoring of AMR and AMC trends
- Informed decision-making and policy development
- Capacity building and technical support
- Facilitating research and innovation
- Promoting global and regional cooperation and collaboration
- Benchmarking and performance evaluation
- Public awareness and advocacy
- Supports the implementation of the GAP on AMR
- Enhancing pandemic preparedness and overall Global Health Security

This highlights the importance and urgency for the Africa region to establish a surveillance network for the continent, borrowing from the experiences and lessons from these existing global and regional networks.

Examples of key surveillance systems and networks

1. European Antimicrobial Resistance Surveillance Network (EARS-Net), coordinated by the ECDC, monitor AMR in Europe by collecting and analyzing data on resistance patterns among clinical isolates of bacteria from invasive infections. The ECDC also coordinates the monitoring of AMC in Europe through the European Surveillance of Antimicrobial Consumption Network (ESAC-Net).
2. Central Asian and Eastern European Surveillance of Antimicrobial Resistance (CAESAR), monitors AMR and AMC in healthcare settings across

Central Asia and Eastern Europe.

3. Latin American Network for Antimicrobial Resistance Surveillance (Rede Latinoamericana de Vigilancia de la Resistencia a los Antimicrobianos [ReLAVRA]), is a collaborative initiative aimed at monitoring and addressing AMR across Latin American countries.
4. South East Asia Regional Antimicrobial Resistance Initiative (SEAR-AMI), is a network, coordinated by the WHO Regional Office for South-East Asia, supporting member countries in building and strengthening AMR, AMC and AMU surveillance systems. SEAR-AMI focuses on standardizing data collection and reporting, sharing best practices, and fostering regional collaboration to combat AMR.
5. The Western Pacific Regional Antimicrobial Consumption Surveillance System (WPRACSS) and the Western Pacific Regional Antimicrobial Resistance Surveillance System (WPRARSS) are initiatives aimed at monitoring AMR and AMC across countries in the Western Pacific Region.
6. The Africa CDC's AMRSNET is mandated to support the establishment and strengthening of AMR surveillance systems, which also encompasses AMC and AMU surveillance, across Africa. It facilitates the coordination of surveillance efforts, standardizes data collection and reporting, and promotes collaboration among member states. AMRSNET aims to build a robust regional network that enhances the quality and consistency of AMR data.
7. ECOWAS, through its health agency WAHO, is mandated to coordinate and strengthen AMR surveillance, including AMC and AMU, across its current 15 member states in West Africa. This includes harmonizing policies, building capacity, and promoting data sharing among member states.
8. WHO GLASS, launched in 2015, the first global collaborative effort to standardize AMR and AMC surveillance. GLASS collaborates closely with the AMR and AMC regional networks listed above.

8.4 VISUALIZATION/DASHBOARD

The primary objective is to facilitate the comprehension and analysis of AMR, AMC and AMU data through the development of sophisticated and yet user-friendly dashboards. These dashboards should be designed to distill complex data sets into actionable insights that can be easily interpreted by a diverse range of stakeholders, from policy makers and public health officials to clinical practitioners.

Components

1. **Interactive Dashboards:** The design of these dashboards should prioritize flexibility and interactivity, allowing users to explore data in a way that aligns with their unique needs and objectives. By incorporating features such as customizable views, filters and capabilities for delving deeper into specific data points, stakeholders can engage with the data at a macro and micro level. This not only enhances the engagement, but it also empowers the users to uncover specific trends and patterns relevant to their decision-making processes.

2. **Visual Elements:** Effective data visualization relies on a strategic selection of visual elements. Elements such as line charts, for example, are particularly useful for illustrating trends over time while bar charts can highlight comparative data across different regions or demographics. Geographic representations such as heat maps and choropleth maps are invaluable in displaying regional variations in resistance rates, providing a visual context that can help identify areas of concern or success. Additionally, the use of infographics and pie charts can convey key statistics and proportions rendering complex data more digestible.

3. **User-Centric Design:** Given the diverse range of users accessing these dashboards, it is essential to design with the end user in mind. A user-centric approach ensures that the dashboards are intuitive and accessible, reducing the learning curve for non-technical users. This includes the use of plain language, clear instructions, and logical navigation paths. Moreover, dashboards should be responsive and accessible on various

devices ensuring that stakeholders can access the information they need where they need it.

4. **Data Accuracy and Updates:** The reliability of the data presented in the dashboards is paramount. To maintain accuracy, data should be integrated in real time or updated at regular intervals with version controls and time stamps clearly indicated. This transparency helps in trust in the data, enabling stakeholders to make informed decisions using the most current information available.

5. **Accessibility:** Ensuring that dashboards are accessible to all users is a critical consideration. This includes compliance with international accessibility standards, providing alternative text descriptions for visual elements and ensuring that there is compatibility with assistive technologies such as screen readers. An accessible design not only broadens the potential user base but also demonstrates a commitment to inclusivity.

8.5 DATA REPORTING

The objective of is to establish a robust and consistent data reporting framework that supports the reliable and timely submission of AMR, AMC and AMU data. This framework should accommodate the diverse needs of different reporting entities while ensuring that the data is collected, processed and transmitted in a manner that maintains its integrity and confidentiality.

Framework Elements:

1. **Standardized Templates:** A standardized approach to data collection is crucial in ensuring consistency across reporting entities. By providing a unified reporting template aligned with established protocols, stakeholders can submit data that is uniform in structure and content. This standardization simplifies aggregation and data analysis at a national or regional level facilitating comparison and trend analysis. The templates should be designed to capture all necessary data elements while also being adaptable to accommodate the specific contexts of different reporting entities.

2. **Data Validation:** To ensure the accuracy and reliability of reported data, a two-tiered validation process should be employed. Automated validation checks can quickly identify obvious errors or inconsistencies, while a subsequent manual review by trained personnel can catch more nuanced issues. This dual approach helps maintain high standards of data quality, ensuring that the information used for analysis is both accurate and comprehensive.

3. **Frequency of Reporting:** The reporting framework should be structured around clearly defined reporting intervals, such as monthly or quarterly submissions. These intervals are designed to balance the need for timely data with the capacity of the reporting entities to collect and submit accurate information. Clear communication of submission deadlines and the establishment of a feedback loop can help ensure that data is submitted on time and any issues are promptly addressed.

4. **Anonymization and Confidentiality:** Protecting the privacy and confidentiality of individuals is a core principle of the data reporting process. All reported data should be anonymized, removing any personally identifiable information to comply with relevant data protection regulations. This process not only safeguards patient privacy but also builds trust among stakeholders, encouraging more open and accurate data sharing.

5. **Reporting Tools:** The effectiveness of the reporting framework is enhanced by the tools used to submit and process data. Electronic reporting tools that integrate with the existing systems can streamline the reporting process, reducing the potential for manual entry errors and improving efficiency. These tools should be user-friendly, with features such as real-time error detection and guided submission processes to support accurate and timely data

entry.

8.6 CHANNELS OF REPORTING

The objective is to define a secure and efficient system for the transmission and sharing of AMR, AMC and AMU data, ensuring that the data reaches the relevant stakeholders in a timely manner while maintaining its integrity and security. Below are some of the channels for reporting AMR, AMC and AMU data.

1. **Digital Platforms:** The use of secure web portals and API's (application programming interface) is essential for efficient submissions in the current digital age. These platforms should be designed to facilitate easy access for all stakeholders, with robust security measures such as end-to-end encryption and multi factor authentication to protect the data during transmission. The availability of mobile optimized platforms further enhances accessibility, allowing stakeholders to submit or access data from any location.

2. **Data Sharing Platforms:** Centralized data repositories play a crucial role in the aggregation and analysis of reported data. These platforms should be scalable and interoperable, supporting seamless data exchange across different systems and regions. By maintaining a unified dataset, these repositories enable more comprehensive analysis and facilitate the sharing of insights across a wider network of stakeholders.

3. **Paper-Based Reporting (if necessary):** While digital tools are the preferred method for data reporting, it is important to provide alternatives for facilities that lack digital infrastructure. Standardized paper forms can ensure that data collected in these contexts, is consistent with the digital submissions, while protocols for the digitization of paper-based data can help integrate it into the central data repository systems.

4. **Feedback Loops:** Establishing a feedback loop is essential for maintaining data quality and supporting automated feedback reports can provide immediate insights into the quality of submitted data, highlighting any errors or discrepancies that need to be addressed. Regular communication with stakeholders through channels such as webinars or newsletters can further support this process, keeping stakeholders informed and engaged.

5. **Training and Support:** The success of the reporting system depends on the ability of stakeholders to use it effectively. Comprehensive training programs, including workshops, e-learning modules, and detailed user manuals, are essential for building the necessary skills and knowledge. Ongoing support through a dedicated help desk ensures that stakeholders can receive assistance when needed. Minimizing disruptions and maintaining efficiency of the reporting process.

9

MONITORING AND EVALUATION

9. MONITORING AND EVALUATION

Key Takeaways

- **Developing Indicators:** This section purposes to introduce the establishment of a robust M&E framework to track AMR surveillance progress and impact. Indicators should span around the core elements of AMR-SS structure, public health priorities, core functions, and support functions. Countries are called to use the WHO-provided indicators and KPIs (annex 14) to develop their own with the aim of monitoring performance and addressing issues. NCCU should agree on and review indicators annually, adjusting as needed.
- **Conducting Periodic Evaluations:** Provides guidance on scheduling regular evaluations based on the M&E plan to ensure systems remain effective and aligned with national AMR goals. Countries are to use evaluations to make timely adjustments and improve the surveillance system.

9.1 DEVELOPING INDICATORS TO MONITOR PROGRESS AND IMPACT OF AMR SURVEILLANCE EFFORTS

Monitoring and evaluation (M&E) play a crucial role in AMR surveillance systems by ensuring that objectives are met, and activities remain on track. An effective M&E framework should involve pilot testing of any new surveillance methods and tools, continuous review of implementation steps, and necessary adjustments to improve processes. Establishing a robust M&E framework helps countries enhance their national AMR-SS and boost their capacity to participate in the WHO GLASS. This is especially beneficial for resource-limited countries aiming to strengthen their surveillance capabilities. By identifying potential issues early, M&E enables timely recommendations and adjustments to enhance system effectiveness.

M&E provides a comprehensive view of the program's progress, from initial conditions to the achievement of objectives. By integrating M&E from the start, planners and implementers are encouraged to set realistic goals aligned with building a sustainable system.

A national AMR-SS encompasses several elements, that a country may choose to be targeted for development, monitoring, and evaluation:

- AMR-SS structure: Including core components such as the NCCU, at least one NRL, and designated surveillance sites.
- Public health priorities: Defined objectives such as priority pathogens and infections to be surveilled.
- Core functions: Quality aspects of the system, including case detection, data collection, analysis, and reporting.
- Support functions: Facilitating implementation through standards, guidelines, and training.

To achieve the desired outcomes, a surveillance program requires resources (inputs) and development of activities (processes), leading to results (outputs). Identifying indicators for each element is essential for measuring success.

Sample indicators have been provided by WHO (see annex 14) to monitor these elements effectively (16). These indicators have been grouped according to development metrics and provide verification measures/ Key Performance Indicators (KPIs) for national planners. These KPIs are used to monitor progress and identify sentinel sites where problems are arising, and more detailed investigation is needed to understand why the indicators are not being met. These measures will aid in supporting surveillance sites to achieve the KPIs by providing them with the necessary support.

In-country indicators should be agreed at the inception of AMR surveillance and reviewed annually by the NCCU. Countries may adopt a tiered approach to apply relevant indicators at different stages of surveillance system development, adjusting strategies as the system evolves. Once the indicators have been set, the NCCU should determine how often evaluations will occur (e.g., annually, biannually). The frequency should reflect the system's needs and resource availability.

9.2 CONDUCTING PERIODIC EVALUATIONS

With the developed clear M&E plan the NCCU can schedule periodic evaluations of the AMR-SS implementation. Conducting periodic evaluations of AMR-SSis crucial for ensuring these systems remain effective, responsive, and aligned with the national AMR containment goals as outlines in the country's NAP. The flowchart in figure 11 provides a comprehensive guide on how to conduct these evaluations:

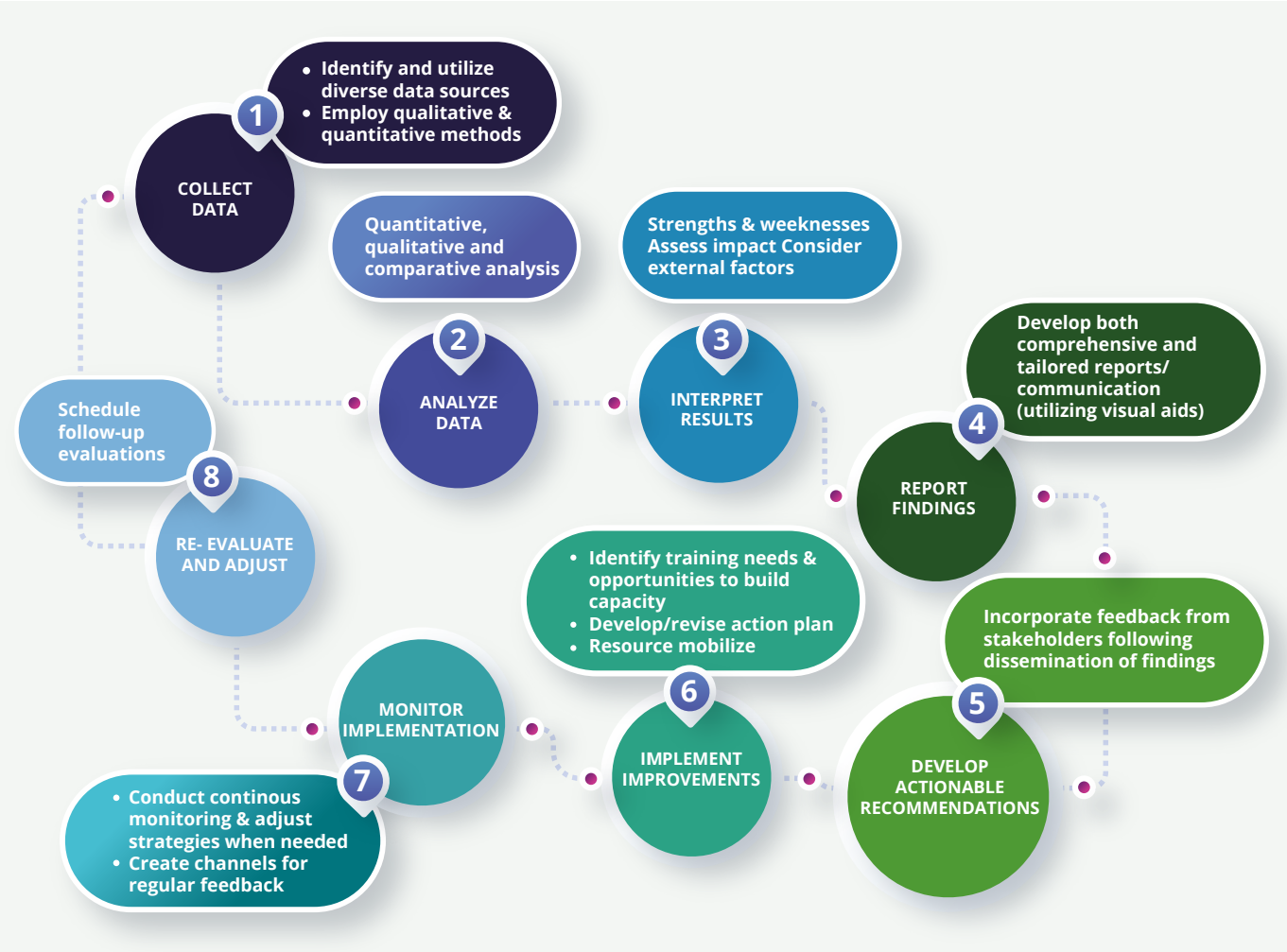
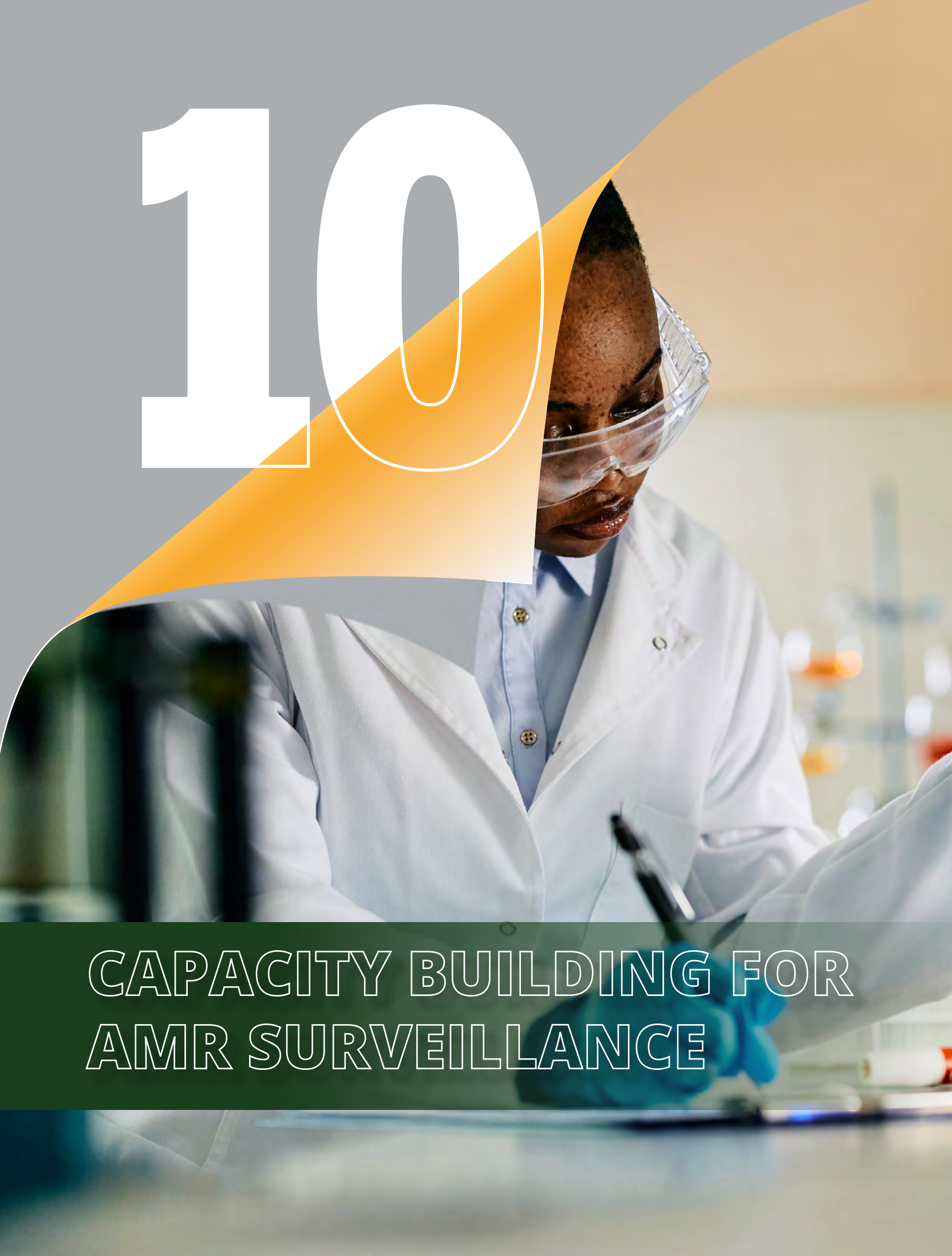


Figure 11 Flowchart providing a comprehensive guide on how to conduct AMR-SS evaluations

10



CAPACITY BUILDING FOR AMR SURVEILLANCE

10. CAPACITY BUILDING FOR AMR SURVEILLANCE

Key Takeaways

- **Training Programs:** Encourages the development of a multisectoral AMR training curriculum covering AMR basics, surveillance methodologies, laboratory techniques, data management, and antimicrobial stewardship. Utilization of workshops, e-learning, professional associations, and mentorship for effective training.
- **Strengthening Laboratory Capacity:** Calls on the expansion of AMR surveillance sites and ensuring participation in national EQA programs. Discusses the upgrading of facilities, implementation of QA/QC protocols, and provision of specialized training. Encourages countries to foster collaboration through a network of laboratories and use innovative solutions.
- **Clinical and Pharmacy Practice:** Highlights the need for enforcement of regulatory frameworks for antimicrobial sale and distribution; integration of AMR training in educational programs; implementation of medication review protocols; and calls on pharmacies to report dispensing data to support AMR surveillance and targeted interventions.

10.1 TRAINING PROGRAMS

It is recommended that countries develop a multisectoral AMR surveillance training curriculum. The aim of which is to harmonize the delivery of AMR surveillance training content across the sectors. Training programs are essential for developing a skilled workforce capable of effectively managing and implementing AMR-SS. A comprehensive training approach focuses on enhancing the technical skills of healthcare professionals, laboratory and pharmacy personnel, and public health officials involved in AMR activities.

Key topics to be covered include:

- Basics of AMR and its implications
- Introduction to AMC and AMU
- One Health approach to addressing AMR
- AMR, AMC and AMU surveillance methodologies and data collection
- Laboratory techniques for identifying resistant pathogens
- Quality control and assurance
- Data management, analysis, and interpretation
- Use of AMR data for decision-making and policy formulation
- IPC measures and interventions, including hospital acquired infection surveillance
- ASPs and responsible use of antimicrobials in clinical practice
- Monitoring and evaluation
- AMR research

The country can also employ several strategies aimed at delivering targeted trainings:

- Workshops and seminars to provide hands-on training in AMR detection, data analysis, and interpretation. Engaging experts to share insights and best practices.
- Self-paced e-learning training that will provide learners with a flexible option to go through

modules and courses. Furthermore, it will increase accessibility and reach of participants across the country, especially in resource-limited settings.

- Collaboration with professional associations to include modules within their Continuous Professional Development (CPD) programs.
- Develop an in-country mentorship program, for more experienced staff to mentor others, providing them with guidance and support, fostering knowledge transfer and skill development.
- Countries should explore the role of online platforms such as Zoom™ and Microsoft Teams™ for delivery of trainings including ECHO sessions.

10.2 STRENGTHENING LABORATORY CAPACITY FOR AMR TESTING AND ANALYSIS

The NCCU should regularly engage in activities to expand the country's AMR surveillance network, with the aim of increasing the number of surveillances sites across human health, animal health, and environmental sectors. The country is recommended to set clear targets in the NAP in relation to the number of surveillance sites that are targeted to be enrolled, considering the guidance provided on sentinel site selection. These sites will also be required to participate in the national microbiology EQA programs and refer isolates to reference laboratories for quality control, based on the established isolates referral criteria. Furthermore, the NCCU should ensure that baseline assessments are conducted using the standardized laboratory assessment tools.

Following this, joint action plans between NCCU and surveillance sites should be developed to improve detection and surveillance capacities, conduct periodic mentorship and support supervision visits, and training, among other interventions.

The NCCU and the technical team, should ensure that the country's laboratory capacity is undergoing continuous strengthening by setting up plans to:

1. Upgrade laboratory facilities to meet international standards. Ensuring the availability of essential equipment, reagents, and supplies for AMR testing.
2. Implementation of strict QA and QC protocols to maintain accuracy and reliability in AMR testing. Regularly participate in EQA programs to benchmark against global standards.
3. Provide specialized training for laboratory technicians and scientists on advanced AMR testing techniques and equipment handling. Foster expertise in molecular diagnostics, susceptibility testing, and resistance mechanism identification.
4. Create a network of laboratories at regional and national levels to facilitate data sharing and collaboration (including sample referral). Develop standardized protocols for sample collection, processing, and reporting to ensure consistency across laboratories.
5. Optimize the use of available resources by implementing innovative solutions such as automated systems. Leverage technology to improve efficiency and reduce turnaround times.

10.3 GUIDANCE FOR IMPROVED AND REGULATED CLINICAL AND PHARMACY PRACTICE

Enhancing clinical and pharmacy practices is vital for combating AMR effectively. Establishing guidelines and regulatory frameworks ensures that healthcare providers adhere to evidence-based practices, promoting the responsible use of antimicrobials.

Figure 12 provides key strategies that should be implemented to improve clinical practice and provides some activities that should be prioritized within these strategies.

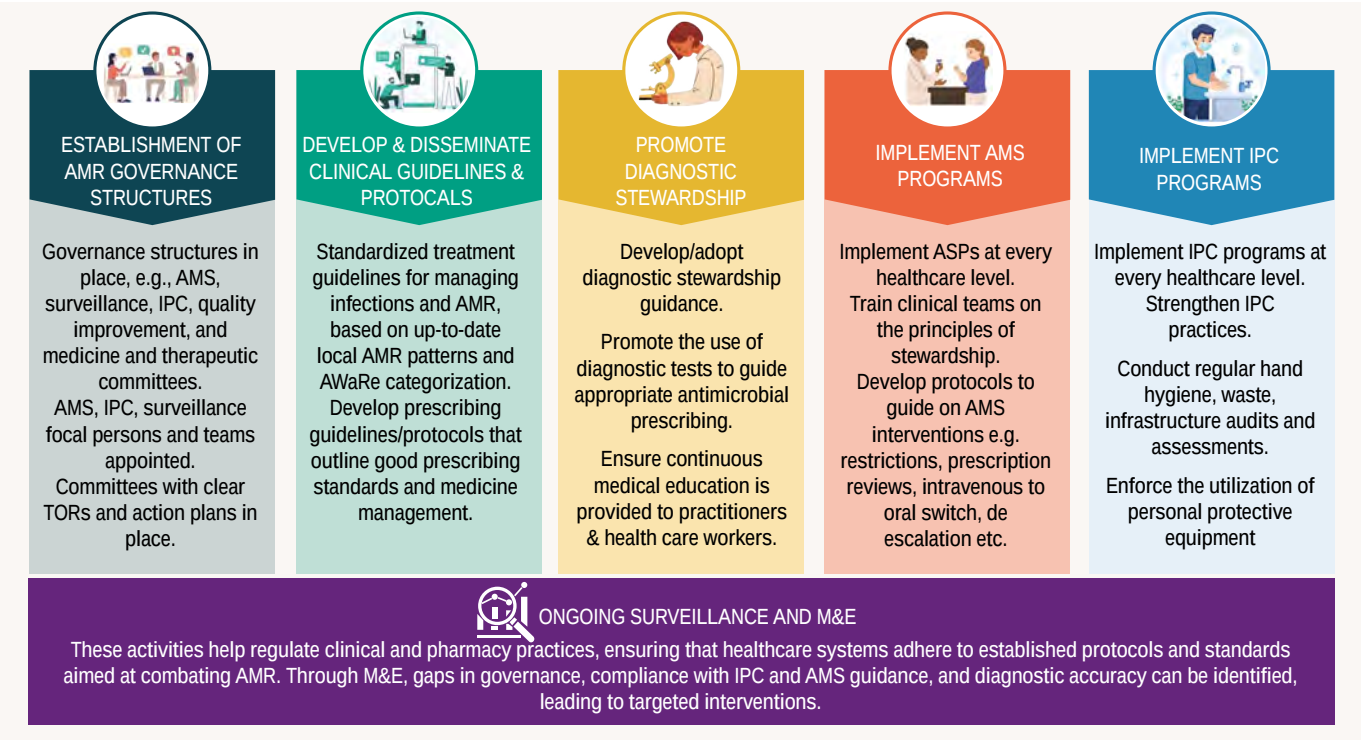


Figure 12: Suggested key strategies to support AMR containment in clinical practice.

Below are some key strategies for ensuring the regulation of pharmacy practice, which is a key area to ensure the enforcement of stewardship practices:

1. Establish regulatory frameworks for the sale and distribution of antimicrobials. Enforce prescription-only policies to prevent over-the-counter sales of antibiotics.
2. Incorporation of AMR training within the pre- and in-service curricula for pharmacists, enforcing the importance of responsible dispensing practices. Encourage pharmacists to provide guidance on appropriate antimicrobial use to patients.
3. Implement medication review protocols to assess patient adherence and optimize antimicrobial therapy. Provide counseling to patients on the importance of completing prescribed antimicrobial courses, avoiding self-medication with antimicrobial agents, and on the appropriate disposal procedures for unused antimicrobials.
4. Encourage pharmacies to participate in AMR surveillance efforts by reporting dispensing data and trends. Utilize this information to identify patterns of inappropriate use and target interventions.

11

COLLABORATION & PARTNERSHIPS; AND FUNDING & SUSTAINABILITY

11. COLLABORATION & PARTNERSHIPS; AND FUNDING & SUSTAINABILITY

Key Takeaways

- **Collaboration and Partnerships:** To enhance global AMR surveillance through knowledge exchange, standardized methods, and pooled resources.
  - ✓ Key Collaborators: Quadripartite alliance (WHO, FAO, WOAH, UNEP), CDC, WHO's GLASS, regional organizations (AU, IGAD), and international partners.
  - ✓ Benefits: Strengthen integrated AMR surveillance systems and coordinate global actions while supporting local needs.
- **Funding and Sustainability:** Call to secure and maintain financial resources for effective AMR surveillance systems.
  - ✓ Strategies: Diversify funding sources, engage international donors, develop sustainable business models, integrate AMR into health policies, and build local capacity.
  - ✓ Focus: Ensure long-term sustainability through continuous advocacy, cost-effective approaches, and regular M&E.

11.1 COLLABORATION AND PARTNERSHIPS

International collaboration and partnerships are crucial in combating AMR as they facilitate knowledge exchange, standardize methodologies, and pool resources, ultimately enhancing global surveillance capabilities. These collaborative efforts are essential for building robust and effective AMR-SS that can operate across borders and address the complex, interconnected nature of AMR.

Key among these is the Quadripartite alliance, comprising the WHO, the FAO, WOAH, and UNEP. This alliance emphasizes the importance of the One Health approach, which recognizes the interconnectedness of human, animal, and environmental health. By working together, these organizations aim to promote integrated AMR-SS and coordinate joint action plans that align with global guidelines while providing critical support to individual countries.

In addition to the Quadripartite, several other key players share similar goals and offer valuable resources and technical expertise. These include the Centers for Disease Control and Prevention (CDC), WHO's GLASS, the United Nations, and existing surveillance networks like AMRSNET, ECOWAS, and EARS-Net. NGOs, international partners, and regional organizations, including Africa CDC and African Union – Interfrican Bureau for Animal Resources (AU-IBAR) and the Intergovernmental Authority on Development (IGAD), alongside national PHIs/PHAs, are pivotal in coordinating efforts and ensuring that surveillance systems are tailored to the specific needs and contexts of different regions.

Collaborating with academia and research entities locally, regionally, and internationally is also vital for advancing the AMR agenda. Utilizing AMR, AMC, and AMU surveillance data advances research across several critical areas, including the development of new therapeutics and diagnostics, further standardization of surveillance protocols, the understanding of transmission mechanisms, and forecasting of trends. This comprehensive approach informs clinical practices, shapes public health policies, and supports the creation of effective containment strategies. Countries should focus on publishing findings in regional and international journals, ensuring that Africa data informs the global discourse of AMR. High-quality manuscripts, standardized data collection methods, and regional networks

will enhance meaningful comparisons, while open-access journals ensure wider accessibility, especially for LMICs. Additionally, integrating multidisciplinary and multisectoral (human health, animal health, and environmental) expertise, conducting economic assessments, and promoting implementation science will further maximize the use of surveillance data. By translating research into practice and engaging with international collaborators, Africa can contribute significantly to global AMR efforts, helping to close knowledge gaps, drive evidence-based decision making, and strengthen regional and global health outcomes.

By leveraging the strengths and resources of these diverse partners, the global community can enhance its ability to detect, report, monitor, and respond to AMR threats, ensuring a more coordinated and effective approach to safeguarding public health.

11.2 FUNDING AND SUSTAINABILITY

Securing and sustaining funding is critical to the success of the Africa AMR-SS. To achieve this, a comprehensive strategy, spanning across the One Health sectors – human health, animal, and environment, must be implemented to map out and diversify funding sources. It is essential that AMR-SS activities are included in the annual workplans and budgets of each sector to ensure coordinated and sustained efforts. This strategy should prioritize targeted interventions and advocacy to secure consistent government funding, while also actively engaging international donors and enhancing partnerships with the private sector to ensure a robust and diversified financial base. Additionally, leveraging existing funding sources such as the Global Fund, World Bank, and other international and local initiatives targeting malaria, HIV, TB, and emerging infectious diseases will further strengthen resource availability.

However, securing initial funding is only part of the challenge. To ensure the long-term sustainability of the AMR-SS, clear and strategic measures must be established. These measures include developing country-specific sustainable business models that align with national priorities, integrating AMR-SS into health policies, and embedding AMR surveillance activities into routine operations across the sectors. Routine M&E activities should also be performed to track progress and adjust strategies as needed. Continuous advocacy is essential to expand and strengthen AMR-SS, while implementing cost-effective approaches will ensure resources are utilized efficiently. Engaging the private sector can bring in additional investment and innovation to support these efforts.

Additionally, building local capacity in both surveillance and financial management is crucial for maintaining the system's effectiveness and sustainability over time. By adopting these strategies, Africa can establish a resilient and enduring AMR-SS that not only addresses current challenges but also remains adaptable and durable in the face of future threats.

12

ETHICAL CONSIDERATIONS

12. ETHICAL CONSIDERATIONS

Key Takeaways:
Purpose: Ensure AMR surveillance respects ethical standards and protects rights while contributing to public health.

Key Considerations:

- Data Privacy: Safeguard patient data and adhere to data protection regulations.
- Equity and Fairness: Ensure fair resource distribution and inclusivity.
- Transparency: Promote clear communication and accountability.
- Appropriate Use: Use data only for intended public health purposes.
- Avoid Stigmatization: Prevent misuse of data that could harm specific groups or communities.

12.1 GENERAL CONSIDERATIONS

AMR, AMC and AMU surveillance are critical components in the global effort to combat the spread of resistant pathogens. While these activities provide essential data for public health decision-making and policy development, they also raise several ethical considerations that need to be carefully managed. Ethical considerations are vital for ensuring the integrity and effectiveness of surveillance efforts. By prioritizing ethical practices, surveillance systems can contribute to better public health outcomes, inform policymaking, and contribute to the global fight against AMR while still respecting the rights and dignity of individuals and communities involved. The following are the key ethical considerations that must be addressed when establishing surveillance systems and networks:

1. Ensuring privacy and confidentiality of patient data and adhering to strict data protection regulations to prevent unauthorized access and misuse of sensitive health information. Compliance with ethical board requirements, including obtaining informed consent for the use of personal health data in surveillance activities, where this is recommended and necessary.
2. Ensuring equity, justice and fairness is crucial, including the equitable distribution of resources for surveillance and access to surveillance data, across different regions to ensure comprehensive participation and benefit. Furthermore, surveillance efforts and distribution of interventions (e.g., vaccines, diagnostics and treatments) must be inclusive and protect vulnerable populations who may be disproportionately affected by AMR.
3. Maintenance of transparency and accountability through promotion and dissemination of clear and accurate information on AMR, its risks, and how and why surveillance data is collected and monitored. Furthermore, establishing mechanisms in-country and in the region to hold organizations and governments accountable for maintaining quality and integrity in the provision of health care and in addressing surveillance findings.
4. Surveillance data should only be used exclusively for its intended purposes, such as public health monitoring and research, and not for punitive or discriminatory measures against individuals or groups. It's essential to have ethical reviews and approval processes in place, where deemed necessary, to safeguard against misuse and ensure that data handling upholds the highest ethical standards.
5. It is crucial to establish appropriate mechanisms and checks to ensure that data collected and reported does not lead to stigmatization of certain groups or communities. Safeguards must be in place to protect the privacy and dignity of individuals and communities, ensuring that data use promotes health equity rather than reinforcing stereotypes or discrimination.

12.2 PUBLISHING AMR SURVEILLANCE DATA FOR SCIENCE AND ACADEMICS

The ethical use of AMR surveillance data in scientific or academic publications is crucial to ensuring that data is handled responsibly and transparently. Researchers must adhere to principles of data privacy, especially when working with sensitive information that could potentially identify individuals, healthcare facilities, or countries. It is essential to anonymize or aggregate data to protect the privacy of patients, communities, or nations involved in AMR surveillance. Researchers should seek prior consent and approval from relevant national and local authorities before using AMR data, ensuring that it is utilized in accordance with local and international data protection laws. Ethical guidelines also require transparency in acknowledging the source of the data, giving due credit to the institutions and individuals who contributed to its collection.

In addition to privacy concerns, the equitable sharing of AMR data is critical for fostering collaboration and trust within the scientific community. AMR surveillance data often results from collective efforts between governments, institutions, and researchers, and publications should reflect this collaborative spirit. Data should not be misused to unfairly criticize or blame countries or institutions, especially those with limited resources or infrastructure. Instead, the publication of AMR data should aim to promote public health improvements, advocate for more effective interventions, and inform policies without jeopardizing the interests of any contributors. By adhering to these ethical principles, researchers can ensure that AMR surveillance data is used to advance science and public health responsibly and constructively.

13

CONCLUSION

13 CONCLUSION

The Antimicrobial Resistance Surveillance Guidance for the African Region is a pivotal resource designed to guide Africa's efforts in combating AMR. This first edition represents a significant step towards harmonizing and enhancing AMR, AMC and AMU surveillance practices across the continent.

This guidance provides a comprehensive framework for systematically collecting, managing, and analyzing data on AMR, AMC, and AMU. Through standardized procedures and guidelines, it aims to strengthen both national and regional surveillance systems, ensuring data reliability and accuracy. Implementing this guidance will facilitate a more coordinated and effective response to the growing challenge of AMR.

The recommendations within this guidance are designed to be adaptable to diverse national contexts, promoting the development of robust surveillance systems tailored to specific country's needs. It emphasizes collaboration between countries, sectors, and stakeholders, underscoring the importance of a unified approach to AMR surveillance.

In essence, this guidance is more than a guide; it is a call to action for all African nations to prioritize AMR surveillance and take decisive steps towards safeguarding public health. By adhering to the outlined standards and actively participating in the collective efforts, countries can significantly contribute to the global fight against AMR, support the global security agenda, and ensure a healthier future for generations to come.

REFERENCES

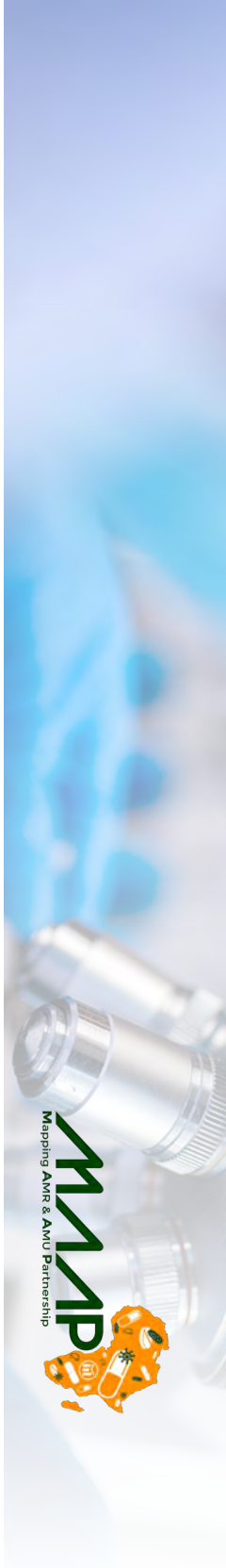
1. World Health Organization. Antimicrobial resistance. World Health Organization. [Online] November 21, 2023. https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance.
2. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Murray, Christopher JL, et al. 2022, The Lancet, pp. Volume 399, Issue 10325, 629-655.
3. The global threat of antimicrobial resistance: science for intervention. Laxminarayan, R., et al. 2016, The Lancet Infectious Diseases, pp. 16(11), 1193-1210. doi:10.1016/S1473-3099(16).
4. World Bank. Drug-Resistant Infections: A Threat to Our Economic Future. World Bank. [Online] 2017. https://documents1.worldbank.org/curated/en/323311493396993758/pdf/final-report.pdf.
5. Gordon, Claire. Technical Bulletin: Surveillance & AMU. [Online] April 2020. [Cited: June 01, 2021.] https://www.flemingfund.org/wp-content/uploads/29e140d66670221b9d95aaaa108ef03e.pdf.
6. Expanding antibiotic, vaccine, and diagnostics development and access to tackle antimicrobial resistance. Laxminarayan, Ramanan , et al. 2024, The Lancet, pp. Volume 403, Issue 10443, 2534 - 2550; https://doi.org/10.1016/.
7. Antibiotic Use in Agriculture and Its Consequential Resistance in Environmental Sources: Potential Public Health Implications. Manyi-Loh, Christy, et al. 2018, Molecules, p. 23(4): 795.
8. Global trends in antimicrobial use in food-producing animals: 2020 to 2030. Mulchandani, Ranya, et al. 2023, PLOS Global Public Health, p. 3(2): e0001305. https://doi.org/10.1371/journal.pgph.0001305.
9. World Health Organization. Glossary of health emergency and disaster risk management terminology. World Health Organization. [Online] 2020. https://iris.who.int/handle/10665/331716. License: CC BY-NC-SA 3.0 IGO.
10. Antimicrobial Resistance in the WHO African Region: A Systematic Literature Review 2016–2020. Gahimbare, Laetitia, et al. 2024, Antibiotics, p. 13(7):659. https://doi.org/10.3390/antibiotics13070659.
11. World Health Organization. Global Action Plan on Antimicrobial Resistance . [Online] 2015. [Cited: December 23, 2020.] https://apps.who.int/iris/bitstream/handle/10665/193736/9789241509763_eng.pdf?sequence=1.
12. World Health Organization. WHO Methodology for Point Prevalence Survey for antibiotic use in hospital. Version 1.1. [Online] 2018. https://apps.who.int/iris/bitstream/handle/10665/280063/WHO-EMP-IAU-2018.01-eng.pdf?ua=1.
13. World Health Organization. GLASS manual for antimicrobial resistance surveillance in common bacteria causing human infection. [Online] 2023. https://iris.who.int/bitstream/handle/10665/372741/9789240076600-eng.pdf?sequence=1.

14. GLASS Methodology for surveillance of national antimicrobial consumption. World Health Organization. [Online] 2020. https://iris.who.int/bitstream/handle/10665/336215/9789240012639-eng.pdf?sequence=1.
15. WHO Regional Office for Africa. WHO Guide for the Stepwise Laboratory Improvement Process Towards Accreditation in the. World Health Organization Africa Region. [Online] 2015. https://www.afro.who.int/sites/default/files/2017-06/guide-for-the-slipta-in-the-african-region071115.pdf.
16. World Health Organization . World Health Organization . National antimicrobial resistance surveillance systems and participation in the Global Antimicrobial Resistance Surveillance System (GLASS): A guide to planning, implementation, and monitoring and evaluation. [Online] 2016. https://iris.who.int/bitstream/handle/10665/251554/WHO-DGO-AMR-2016.4-eng.pdf?sequence=1&isAllowed=y.
17. World Health Organization. WHO report on surveillance of antibiotic consumption: 2016-2018 early implementation. [Online] 2018. [Cited: December 23, 2020.] https://apps.who.int/iris/bitstream/handle/10665/277359/9789241514880-eng.pdf?ua=1.
18. Global antibiotic consumption 2000 to 2010: an analysis of national pharmaceutical sales data. Van Boeckel, Thomas P, et al. 8, 2014, The Lancet Infectious Diseases , Vol. 14, pp. 742-750.
19. Global increase and geographic convergence in antibiotic consumption between 2000 and 2015. Martinez, Elena M, et al. 15, 2018, Proceedings of the National Academy of Sciences, Vol. 115, pp. E3463-E3470.
20. National Antibiotic Consumption for Human Use in Sierra Leone (2017–2019): A Cross-Sectional Study. Kanu, Joseph Sam, et al. 2, 2021, Tropical Medicine and Infectious Disease, Vol. 6, p. 77.
21. National Antimicrobial Consumption: Analysis of Central Warehouses Supplies to In-Patient Care Health Facilities from 2017 to 2019 in Uganda. Namugambe JS, Delamou A, Moses F, Ali E, Hermans V, Takarinda K, Thekkur P, Nanyonga SM, Koroma Z, Mwoga JN, Akello H, Imi M, Kitutu FE. 2, 2021, Tropical Medicine and Infectious Disease, Vol. 6, p. 83.
22. Point prevalence survey of antibiotic use and resistance at a referral hospital in Kenya: findings and implications. Okoth, Caleb , et al. 3, 2018, Hospital Practice, Vol. 46, pp. 128-136.
23. Antibiotic use in Kenyan public hospitals: Prevalence, appropriateness and link to guideline availability. Maina, Michuki, et al. 2020, International Journal of Infectious Diseases, Vol. 99, pp. 10-18.
24. Dispensing of Antimicrobials in Kenya: A Cross-sectional Pilot Study and Its Implications. Mukokinya, Mwasi Mary Ann, et al. 2, 2018, Journal of Researc in Pharmacy Practice , Vol. 7, pp. 77-82.
25. The Surveillance of Antimicrobial Resistance in Africa: Challenges and Opportunities. Ncube, L. K., Solanki, G. C. and Kularatne, R. 2023, African Journal of Microbiology Research,, pp. 17(3), 135-145.
26. National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on the Long-Term Health and Economic Effects of Antimicrobial Resistance in the United States. Combating Antimicrobial Resistance and Protecting the Miracle of Modern Medicine. [book auth.] Engineering, and Medicine, et al. National Academies of Sciences. Washington (DC) : National Academies Press (US), 2021, p. 4. Strengthening Surveillance.
27. Antimicrobial resistance containment in Africa: Moving beyond surveillance. Anyaegbunam, Zikora Kizito Glory, et al. 2024, Biosafety and Health, pp. Volume 6, Issue 1; ISSN 2590-0536; https://doi.org/10.1016/j.bsheal.2023.12.003.
28. World Health Organization. Global antimicrobial resistance and use surveillance system (GLASS) report 2022. World Health Organization. [Online] 2022. https://iris.who.int/bitstream/handle/10665/364996/9789240062702-eng.pdf?sequence=1.
29. World Health Organization. Laboratory assessment tool. World Health Organization. [Online] 2012. https://www.who.int/publications/i/item/WHO-HSE-GCR-LYO-2012.2.
30. World Health Organization. World Health Organization. Diagnostic stewardship: a guide to implementation in antimicrobial resistance surveillance sites. [Online] 2016. https://www.who.int/publications/i/item/WHO-DGO-AMR-2016.3.


ANNEXES

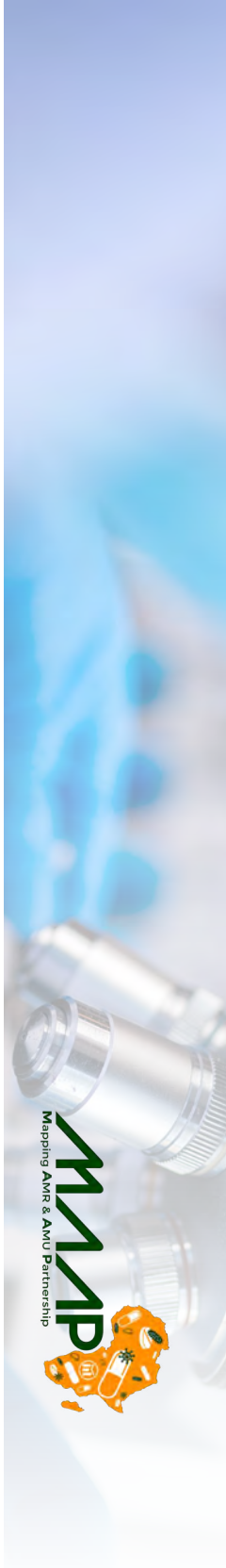
ANNEX 1: LABORATORY ELIGIBILITY QUESTIONNAIRE

Section A: Laboratory details questions	Response (Select or Type in Answer)	Scoring
A.1 What is the name of the laboratory? [Enter response as plain text]		Not scored
A.2a Which County/Region is the laboratory based in?		Not scored
A.2b What is the address of the laboratory? (Enter exact address, nearest landmark or street intersection)		Not scored
A.3 Is the laboratory routinely conducting antimicrobial susceptibility testing?		Not scored
A.4 What is the laboratory's level of service? (Select from drop down)		Not scored
A.5 What is the laboratory's affiliation? (Select from drop down)		Not scored
A.5 Is the laboratory co-located in a clinical facility?		Not scored
A.6 Is a pharmacy co-located with the laboratory?		Not scored
A.7 Did the laboratory serve as a national AMR surveillance site (at any time)?		Not scored
A.8 Is your country participating in the World Health Organization's Global Antimicrobial Resistance Surveillance System (WHO GLASS)?		Not scored
Part 1: Commodity and Equipment questions	**Response (Select or Type in Answer)**	**Scoring**
1.1 Does the laboratory have a regular power supply with functional back-up, in place at all times?		Score 1 for "Yes" and 0 for "No
1.2 Does the laboratory have a continuous water supply in place at all times?		Score 1 for "Yes" and 0 for "No
1.3 Does the laboratory have certified and functional biosafety cabinet, in place at all times?		Score 1 for "Yes" and 0 for "No
1.4 Does the laboratory have automated methods for bacterial identification in place?		Score 1 for "Yes" and 0 for "No
1.5 Does the laboratory have automated methods for antimicrobial susceptibility testing in place?		Score 1 for "Yes" and 0 for "No
1.6 Does the laboratory test for mechanisms of antimicrobial resistance?		Score 1 for "Yes" and 0 for "No
Part 2: Quality Assurance (QA), Accreditation & Certification questions	**Response (Select or Type in Answer)**	
2.1a Is the laboratory implementing quality management systems?		Score 1 for "Yes" and 0 for "No
2.1b If you answered 'yes' to question 2.1a: What quality management tools did the laboratory utilize? (e.g., LQMS, SLIPTA, SLMTA, mentoring, others)		Score 1 if at least one of those tools were used



2.2a Has the laboratory received a quality certification?		Score 1 for "Yes" and 0 for "No
2.2b If you answered 'yes' to question 2.2a: What kind of quality certification did the laboratory receive? (e.g., SLIPTA, College of American pathologists)		None
2.2c If you answered 'yes' to question 22.b: What was the laboratory's level of quality certification (e.g., star rating for SLIPTA certified laboratories)?		None
2.3a Has the laboratory been accredited by a national or international body at any time?		Score 1 for "Yes" and 0 for "No
2.3b If you answered 'yes' to question 2.3a: What was the name of the accreditation body/bodies?		None
2.4 Has the laboratory participated in an inter laboratory comparison or external quality assessment (EQA) scheme for pathogen identification and AST at any time?		Score 1 for "Yes" and 0 for "No
2.5 Has the laboratory utilized reference strains to verify that stains, reagents, and media are working correctly at any time?		Score 1 for "Yes" and 0 for "No
2.6 Does the laboratory maintain records of QC results?		Score 1 for "Yes" and 0 for "No
2.7 Is there a quality focal person in your laboratory?		Score 1 for "Yes" and 0 for "No
2.8 Does the laboratory follow standard operating procedures (SOPs) on pathogen identification and AST methodology?		Score 1 for "Yes" and 0 for "No
2.9 Does the laboratory comply with any standards (e.g., CLSI, EUCAST, others) for reporting AST results?		Score 1 for "Yes" to any standard and 0 for "No
Part 3: Personnel & Training	**Response (Select or Type in Answer)**	
3.1 Does the laboratory have at least one qualified microbiologist in place?		Score 1 for "Yes" and 0 for "No"
3.2 Does the laboratory have a laboratory scientist/technologist /technician experienced in microbiology with skill set in bacteriology in place?		Score 1 for "Yes" and 0 for "No"
3.3 Does the laboratory have up to date complete records on staff training and competence records for the microbiology tests they perform in place?		Score 1 for "Yes" and 0 for "No"
Part 4: Specimen Management	**Response (Select or Type in Answer)**	
4.1 Does the laboratory follow a defined standard operating procedure (SOP) for specimen collection and testing?		Score 1 for "Yes" and 0 for "No"
4.2 Does the laboratory comply with specimen rejection criteria for rejecting inadequate specimens?		Score 1 for "Yes" and 0 for "No"
4.3a Does the laboratory have information on the annual average number of specimens processed for culture and sensitivity?		Score 1 for "Yes" and 0 for "No"

4.3b If you answered 'yes' to question 4.3a: What was the average number of specimens processed for bacterial culture per year?		None
4.3c If you answered 'yes' to question 4.3a: What was the annual average number of specimens that yielded bacterial growth and were processed for susceptibility tests?		None
Part 5: Laboratory Information System & Linkage to Clinical Data	**Response (Select or Type in Answer)**	
5.1 Is a specimen (laboratory) identification number assigned to patient specimens received?		Score 1 for "Yes" and 0 for "No"
5.2a Is there a system/database to store patient data (demographic, clinical & specimen)?		Score 1 for "Yes" and 0 for "No"
5.2b If you answered 'yes' to question 5.2a: What type of data was captured in the system/database?		Score 1 for each positive response (max total being 3)
5.2c If you answered 'yes' to question 5.2a: What was the format for storage of information?		Score 1 for paper; 2 for mixed (E/P; E/P/O; others; mixed) and 3 for electronic (max score being 3)
5.2d If you answered 'yes' to question 5.2a: What is the location of this database, or where can this database be accessed from?		Score 1 for other; 2 for clinic and 3 for lab (max score being 6)
5.3a Are patient demographics and clinical information captured on test request forms?		Score 1 for "Yes" and 0 for "No"
5.3b If you answered 'yes' to question 6.3b: Are test request forms stored and retrievable?		Score 1 for "Yes" and 0 for "No"



ANNEX 2: MEDICINE SUPPLY CHAIN KII

Medicine Supply Chain Key Informant Interview (KII)	
1. Domestic Producers and Importers	**Response**
1.1 What quantity/proportion of antimicrobials are produced/manufactured (if any) within the country?	
1.2 If domestically produced what manufactured quantity is later exported?	
1.3 What quantity/proportion of antimicrobials are imported?	
1.4. What proportion (if any) are then re-exported?	
2. Procurement, Storage & Distribution	
2.1. Are there any specific regulations regarding procurement and/or storage of antimicrobials?	
Public sector	
2.2 Who supplies to the public sector (names of the companies/organizations)?	
2.3 What role (if any) does the Central Medical Stores (CMS) play in the procurement, storage and distribution of antimicrobials in the country?	
2.4 What quantity/proportion of antimicrobials is purchased by public healthcare facilities from CMS and what quantity/proportion from wholesalers/other suppliers? (specify who these other suppliers are)	
2.5 How do public facilities procure and receive their antimicrobial supplies?	
Private sector	
2.6 Who supplies to the private sector (names of the companies/organizations)?	
2.7 What quantity/proportion of antimicrobials is purchased by private healthcare facilities from CMS and what quantity/proportion from wholesalers/other suppliers? (specify who these other suppliers are)	
2.8 How do private facilities procure and receive their antimicrobial supplies?	
Donor Funded Supply	
2.9 Is there any donor support for procurement of antimicrobial in the country?	
2.10 If yes to the above, who are the donors and what are the procedures regarding import and distribution of donated antimicrobials?	
2.11 Which sector(s) is supported with supplies procured through donor agencies?	
2.12 If there is donor support, are antimicrobials sourced locally or imported?	

2.13 Does the available donor data indicate specific country antimicrobial consumption? Do these procurement mechanisms fit in with the countries regulatory systems and WHOs recommended surveillance practices? or are there challenges?	
2.14 What proportion/quantity of antimicrobials are procured/supplied from donor programs; and using which mechanisms are such products procured e.g. WAMBO for The Global Fund, pooled procurement mechanisms etc.	
2.15 What are the requirements and procedures for suppliers to import/export antibiotics in the country?	
3. Data and Information Systems	
3.1 What information systems are currently in use at national level for managing data on antimicrobials?	
3.2 Are the systems manual or electronic?	
3.3 What type of information is captured using these systems? (e.g. generic names, dose strengths, formulations, pack size, brand names and volumes)	
3.4. Does the country have a centralised data source for all antimicrobials that are imported/exported?	
3.5 What are the available data sources to quantify antimicrobial consumption at facility level (records from pharmacies, data from health insurance programs, prescribing records of physicians, dispensing records of pharmacists etc.)?	
3.6. What are the available data sources to quantify antimicrobial consumption at sub – national level (records from pharmacies, data from health insurance programs, prescribing records of physicians, dispensing records of pharmacists etc.)?	
3.7 What are the available data sources to quantify antimicrobial consumption at the national level (records from pharmacies, data from health insurance programs, prescribing records of physicians, dispensing records of pharmacists etc.)?	
3.8 What challenges (if any) are faced in terms of data availability of antimicrobials?	
3.9 Do public sector healthcare providers have HMISto monitor and retrieve data of logistics of antimicorbials? How is it managed and what data does it gather and for what use?	
4. Informal Supply Chains	
4.1 Is there an estimate of the antimicrobial black-market size in the country?	
4.2 Are there any mechanisms utilized by relevant authorities to track and trace illegally imported antimicrobials in the country?	

ANNEX 3: PHARMACY/MEDICINE SUPPLIER ELIGIBILITY QUESTIONNAIRE

Pharmacy/medicine supplier Eligibility Questionnaire	
A. General information	**Response**
1. What is the name and complete address of your pharmacy/institution?	
2. Does the pharmacy house or is it co-located with a laboratory?	
3. Does the pharmacy/institution have relevant certification/ accreditation (in example by the pharmacy board/ regulatory authority etc.)	
4. Does the pharmacy/institution have the following in place at any time? (select response from drop-down) a. At least one pharmacist b. At least one pharmacy technician	
5. Are there SOPs in place for entering issues / sales of antimicrobials?	
B. Antibiotic Consumption Data	**Response**
6. Are the following data at the pharmacy/medicine store stored electronically? (State Y/N for each)	
a. Sales of antimicrobials to patients/customers	
b. Purchases (from wholesalers/distributors/open markets etc.)	
c. Current stock in hand of antimicrobials (at end of month)	
d. No electronic records are maintained	
7. If answer is NO to Q6, does the pharmacy/medicine store manually hold paper-based data for medicines? (State Y/N for each)	
a. Sales of antimicrobials to patients/customers	
b. Purchases from wholesalers/distributors/open markets etc.	
c. Current stock in hand of antimicrobials (at end of month)	
8. What records can be used for prospective data extraction for antimicrobial sales? (State Y/N for each option)	
a. Sales invoices / prescriptions to customers/patients (sell-out)	
b. Supplier invoices received by pharmacy (sell-in)	
c. Any other (please state)	
9. What kind of stock control system does the pharmacy/medicine store maintain? (State Y/N for each option)	

a. Issues/ sales book	
b. Stock card/Bin Card	
c. Electronic	
d. Any other (please state)	
10. In the case of dispensing antimicobials to patients, can the pharmacy trace if there was a prescription?	
11. Based on the data held, will it be possible to obtain real time disaggregated data for the following fields	
a. Antimicrobial name	
b. Antimicrobial strength _Value	
c. Antimicrobial strength_Unit	
d. Formulation	
e. Pack size_Value	
f. Pack size_Unit	
g. Brand	
h. Quantity issued out/in	
i. Balance stock (after transaction is complete)	
j. Recipient (facility, department, patient type)	
C. Antimicrobial Use data	**Response**
1. Does the facility use an electronic prescribing system?	
2. If yes to Q12, is the electronic prescribing system linked to: a. The laboratory system to enable access to AST results b. The pharmacy dispensing system to access antimicrobial issuance information?	
3. Does the pharmacy dispensing data system hold patient disaggregated data (patient level)?	
4. Do the dispensing records hold data on:	
a. Diagnosis	
b. Type of infection	
c. Empirical or treatment	
5. For facilities with paper-based records, is there a unique identifier that links patient files/treatment sheets with: a. Laboratory reports? b. Pharmacy dispensing records?	

ANNEX 4: Key AMR Variables

Variables	Mandatory/ Optional	Description
Patient laboratory variables		
1. Patient code	Mandatory	Unique identifier for the patient.
2. Specimen type	Mandatory	Name of the specimen collected (e.g., blood, urine).
3. Specimen site	Mandatory	The anatomical site from where the specimen was collected (e.g., throat, wound).
4. Date of specimen collection	Mandatory	Date when the specimen was obtained from the patient.
5. Culture results (no growth/ contaminated/ pathogen name)	Mandatory	The outcome of the culture test, such as no growth, contamination, or specific pathogen identified.
6. AST Results	Mandatory	Antimicrobial susceptibility test (AST) results indicating antibiotics the pathogen is susceptible or resistant to.
7. AST Standard	Mandatory	The standard or guideline used for interpreting AST results (e.g., CLSI, EUCAST).
8. Resistance mechanism (if available)	Optional	Known resistance mechanism, such as beta-lactamase production.
Patient demographic variables		
1. Patient code	Mandatory	Unique identifier for the patient, same as the laboratory patient code.
2. Patient sex	Mandatory	Sex of the patient (male or female).
3. Patient age or date of birth	Mandatory	Age or birthdate of the patient.
4. Patient location	Mandatory	Patient's location at the time of admission (ward name, outpatient etc.)
5. Patient department/specialty	Mandatory	The hospital department or specialty where the patient is receiving care.
6. Patient admission date	Optional	The date when the patient was admitted to the hospital.
7. Patient discharge date	Optional	The date when the patient was discharged from the hospital.
8. Patient level of education	Optional	The highest education level completed by the patient.
9. Patient weight and height	Optional	Patient's body weight and height, relevant for dosage calculations.
10. Pregnancy status	Optional	Whether the patient is pregnant (for female patients).
11. Premature birth	Optional	Whether the patient was born prematurely (for neonates and infants).
12. Patient transferred from another clinical set-up	Optional	Indicates if the patient was transferred from another healthcare facility.
Patient clinical/health variables		
1. Primary complaint	Mandatory	The primary health issue or complaint presented by the patient.
2. Primary diagnosis at admission	Mandatory	The main diagnosis made upon the patient's admission.
3. ICD code	Mandatory	The International Classification of Diseases (ICD) code for the patient's diagnosis.
4. Comorbidities	Optional	Any coexisting medical conditions the patient may have.
5. Antibiotic treatments prior to sampling: name & duration	Optional	Details of any antibiotics prescribed before sample collection, including the name and treatment duration.
6. Presence of an indwelling medical device at time of sampling; type of device	Optional	Whether the patient had a medical device (e.g., catheter) inserted at the time of sampling, and the type of device used.

Variables	Mandatory/ Optional	Description
7. Origin of infection - community acquired or hospital acquired	Optional	Whether the infection was acquired in the community or in the hospital (nosocomial infection).
8. Patient outcome at discharge (recovered/ deteriorated/ dead etc.)	Optional	The patient's health outcome at discharge.
Laboratory-specific variables		
1. Laboratory's level of service (Reference/ Regional/ Intermediate/ District/ Community/Other)	Mandatory	The classification or tier of the laboratory based on its service level.
2. Laboratory's affiliation (MoH/ Private/ NGO/ Other)	Mandatory	The administrative or organizational affiliation of the laboratory.
3. Laboratory co-location with clinic/ hospital/pharmacy	Mandatory	Whether the laboratory is physically located alongside a clinic, hospital, or pharmacy.
4. If laboratory served as a national AMR surveillance site at any time	Mandatory	Whether the laboratory has participated in national antimicrobial resistance surveillance.
5. Facility & Equipment related variables	Mandatory	Variables related to the facility's infrastructure and equipment.
6. Quality Assurance (QA), accreditation & certification related variables	Mandatory	Variables related to laboratory accreditation, certification, and quality assurance measures.
7. Personnel & training related variables	Mandatory	Variables concerning laboratory staff qualifications and training.
8. Specimen management related variables	Mandatory	Variables regarding how specimens are handled and managed.
9. Laboratory information system & linkage to clinical data	Mandatory	Whether the laboratory has an information system and how it links to clinical data.
Facility-specific variables		
1. Ownership of facility (public/ private/ FBO/ partnership/ mission/ military, etc.)	Optional	The ownership or type of healthcare facility (e.g., public, private, FBO, military).
2. Level of facility (primary, secondary, tertiary)	Optional	The level or tier of the healthcare facility (primary, secondary, or tertiary care).
3. Facility co-location with pharmacy/ laboratory	Optional	Whether the facility is physically co-located with a pharmacy or laboratory.
4. Number of inpatient beds	Optional	The total number of inpatient beds in the facility during the specified year(s).
5. Number of admissions	Optional	The number of patient admissions in the facility during the specified year(s).
6. Number of outpatient visits	Optional	The number of outpatient visits during the specified year(s).
7. Presence of ID Department	Optional	Whether the facility has an infectious diseases (ID) department.
8. Number of ID physicians	Optional	The number of infectious disease physicians at the facility.
9. Number of ID nurses	Optional	The number of infectious disease nurses at the facility.
10. Presence of AMS program	Optional	Whether the facility has an antimicrobial stewardship (AMS) program.
11. Frequency of AMS meetings	Optional	How often does the AMS program hold meetings.
12. Presence of Medical Therapeutic Committee (MTC)	Optional	Whether the facility has a Medical Therapeutic Committee.
13. Frequency of MTC meetings	Optional	How often does the MTC hold meetings.

Variables	Mandatory/ Optional	Description
14. Presence of IPC committee	Optional	Whether the facility has an Infection Prevention and Control (IPC) committee.
15. Frequency of IPC meetings	Optional	How often does the IPC committee meet.
16. Number of bacterial cultures processed	Optional	The number of bacterial cultures processed by the laboratory in the specified year(s).
17. Number of fungal cultures processed	Optional	The number of fungal cultures processed by the laboratory in the specified year(s).
18. Number of positive cerebrospinal fluid cultures	Optional	The number of positive cerebrospinal fluid (CSF) cultures in the specified year(s).
19. Number of positive blood cultures	Optional	The number of positive blood cultures in the specified year(s).
20. Number of negative cultures	Optional	Total number of clinical samples that were processed for bacterial growth in a laboratory but did not result in the growth of any microorganisms in the specified year(s)
21. Number of contaminated samples	Optional	Total number of clinical samples that were compromised by the unintended introduction of external microorganisms during collection, handling, or processing, in the specified year(s)
20. Format for storing patient laboratory records	Optional	The format (e.g., electronic, paper) in which patient laboratory records are stored.
21. Format for storing patient clinical records	Optional	The format (e.g., electronic, paper) in which patient clinical records are stored.

ANNEX 5: Specimen, pathogen and antimicrobial combination

Specimen	Pathogens under surveillance	Antimicrobial group (ATC)	Antimicrobials to report
Blood	*Acinetobacter spp.*	Tetracyclines Aminoglycosides Carbapenems Polymyxins	Tigecycline, minocycline Gentamicin, amikacin Imipenem, meropenem, doripenem Colistin
	E. coli and K. pneumoniae	Sulfonamides and trimethoprim Fluoroquinolones Third-generation cephalosporins Fourth-generation cephalosporins Carbapenems Polymyxins	Co-trimoxazole Ciprofloxacin, levofloxacin Ceftriaxone, cefotaxime, ceftazidime Cefepime Imipenem, meropenem, ertapenem, doripenem Colistin
	P. aeruginosa	Third-generation cephalosporins Combinations of penicillins, including betalactamase inhibitors Aminoglycosides Carbapenems Polymyxins	Ceftazidime Piperacillin/tazobactam Gentamicin, amikacin, tobramycin Imipenem, meropenem, doripenem Colistin
	S. aureus	Beta-lactamase resistant penicillins Second-generation cephalosporins	Oxacillin Cefoxitin
	S. pneumoniae	Beta-lactamase sensitive penicillins Beta-lactamase resistant penicillins Third-generation cephalosporins Sulfonamides and trimethoprim Macrolides	Penicillin G Oxacillin Ceftriaxone, cefotaxime Co-trimoxazole Erythromycin
	Salmonella spp.	Fluoroquinolones Third-generation cephalosporins Carbapenem	Ciprofloxacin, levofloxacin Ceftriaxone, cefotaxime, ceftazidime Imipenem, meropenem, ertapenem, doripenem
	Salmonella enterica serovar Typhi and Salmonella enterica serovar Paratyphi A	Amphenicols Penicillins with extended spectrum Sulfonamides and trimethoprim Fluoroquinolones Third-generation cephalosporins Macrolides	Chloramphenicol Ampicillin Co-trimoxazole Ciprofloxacin, levofloxacin Ceftriaxone, cefotaxime, ceftazidime Azithromycin

Specimen	Pathogens under surveillance	Antimicrobial group (ATC)	Antimicrobials to report
CSF	*S. pneumoniae*	Beta-lactamase sensitive penicillins Beta-lactamase resistant penicillins Third-generation cephalosporins Sulfonamides and trimethoprim	Penicillin G Oxacillin Ceftriaxone, cefotaxime Co-trimoxazole
	N. meningitidis	Beta-lactamase sensitive penicillins Rifamycins Fluoroquinolones Third-generation cephalosporins	Penicillin G Rifampicin Ciprofloxacin Ceftriaxone, cefotaxime
	H. influenzae	Penicillins with extended spectrum Combinations of penicillins, including beta-lactamase inhibitors Third-generation cephalosporins Sulfonamides and trimethoprim	Ampicillin Amoxicillin-clavulanic acid Ceftriaxone, cefotaxime Co-trimoxazole
Urine	*E. coli and K. pneumoniae*	Nitrofuran derivatives Penicillins with extended spectrum Sulfonamides and trimethoprim Fluoroquinolones Third-generation cephalosporins Fourth-generation cephalosporins Carbapenems Polymyxins	Nitrofurantoin (for E. coli) Mecillinam Co-trimoxazole Ciprofloxacin, levofloxacin Ceftriaxone, cefotaxime, ceftazidime Cefepime Imipenem, meropenem, ertapenem, doripenem Colistin
Stool	*Salmonella spp.*	Sulfonamides and trimethoprim Fluoroquinolones Third-generation cephalosporins Carbapenems	Co-trimoxazole Ciprofloxacin, levofloxacin Ceftriaxone, cefotaxime, ceftazidime Imipenem, meropenem, ertapenem, doripenem
	Shigella spp	Sulfonamides and trimethoprim Fluoroquinolones Third-generation cephalosporins Macrolides	Co-trimoxazole Ciprofloxacin, levofloxacin Ceftriaxone, cefotaxime, ceftazidime Azithromycin

Specimen	Pathogens under surveillance	Antimicrobial group (ATC)	Antimicrobials to report
Lower respiratory tract	*pneumoniae*	Beta-lactamase sensitive penicillins Beta-lactamase resistant penicillins Third-generation cephalosporins Sulfonamides and trimethoprim	Penicillin G Oxacilline Ceftriaxone, cefotaxime Co-trimoxazole
	H. influenzae	Penicillins with extended spectrum Combinations of penicillins, including betalactamase inhibitors Third-generation cephalosporins Fluoroquinolones Sulfonamides and trimethoprim	Ampicillin Amoxicillin-clavulanic acid Ceftriaxone, cefotaxime Ciprofloxacin, levofloxacin Co-trimoxazole
	S. aureus	Beta-lactamase resistant penicillins Second-generation cephalosporins	Oxacillin Cefoxitin
	Acinetobacter spp.	Tetracyclines Aminoglycosides Carbapenems Polymyxins	Tigecycline, minocycline Gentamicin, amikacin Imipenem, meropenem, doripenem Colistin
	E. coli and K. pneumoniae	Sulfonamides and trimethoprim Fluoroquinolones Third-generation cephalosporins Fourth-generation cephalosporins Carbapenems Polymyxins	Co-trimoxazole Ciprofloxacin, levofloxacin Ceftriaxone, cefotaxime, ceftazidime Cefepime Imipenem, meropenem, ertapenem, doripenem Colistin
	P. aeruginosa	Third-generation cephalosporins Combinations of penicillins, including betalactamase inhibitors Aminoglycosides Carbapenems Polymyxins	Ceftazidime Piperacillin/tazobactam Gentamicin, amikacin, tobramycin Imipenem, meropenem, doripenem Colistin
Urethral, cervical, rectal, pharyngeal swabs	*N. gonorrhoeae*	Third-generation cephalosporins Macrolides Aminocyclitol Fluoroquinolones Aminoglycosides	Ceftriaxone, cefixime Azithromycin Spectinomycin Ciprofloxacin Gentamicin

ANNEX 6: Key AMC Variables

Variables	Description
Country	Name of the country where is the site
Site Name	The name of the site or pharmacy where the transaction takes place. It identifies the location of the antimicrobial dispensing or distribution.
Site Type	Hospital Pharmacy / Community Pharmacy
Sector	Private / FBO /Public
Date of transaction	Date on which sales/dispensing/consumption of antibiotic was recorded in dd/mm/yyyy format
Antibiotic Name	Molecule name of the antibiotic sold/consumed
Salt	Such as Ethylsuccinate, Hippurate, Mandelate or None
Combination	Monotherapy and Combination therapy
Antibiotic Strength	The potency of the antibiotic, indicating the concentration of the active ingredient (e.g., 250 mg, 500 mg, 40 mg/2 ml). Ensure all the strength information especially for syrups, suspensions or injectables is captured per ml
Antibiotic Strength Units	The units used to express the strength of the antibiotic, such as milligrams (mg), grams (g), or international units (IU).
Brand	The commercial brand name of the antibiotic, as marketed by pharmaceutical companies. This is essential for recognizing and differentiating products.
Route of Administration	Oral, Parenteral, Rectal, Inhalation powder, and Inhalation solution
Pack size	Number of tablets, bottles, ampoules, vials, etc in a pack
Pack volume	Applicable only in case of Syrups, Suspension, or Parenteral formulations
Quantity issued	Quantity of packs sold/consumed
Recipient Unit	The specific department or unit within the recipient facility where the antibiotic is being dispatched or utilized, aiding in targeted distribution analysis.

ANNEX 7: Key AMU Variables

Variable Category	Variable Name	Description
Patient Demographics	Patient ID	A unique identifier assigned to each patient.
	Age	Patient's age, recorded in years.
	Sex	Patient's gender (Male/Female/Other).
	Weight	Patient's weight, often in kilograms, to calculate dosage.
Hospital Information	Hospital ID	Unique identifier for the hospital where the patient is being treated.
	Ward Type	Type of ward where the patient is located (e.g., ICU, surgical ward, medical ward, pediatric ward).
	Bed Number	The specific bed number assigned to the patient.
	Date of Admission	The date when the patient was admitted to the hospital.
Antimicrobial Prescription	Antimicrobial Name	The specific name of the antimicrobial prescribed.
	ATC Code	Anatomical Therapeutic Chemical (ATC) classification code for the antimicrobial, which provides a standardized way to describe the substance.
	Dosage Form	Form in which the antimicrobial is administered (e.g., tablet, injection, suspension).
	Dose	The amount of antimicrobial prescribed per administration (e.g., 500 mg, 1 g).
	Frequency	How often the antimicrobial is administered (e.g., twice a day, every 8 hours).
	Route of Administration	The method by which the antimicrobial is delivered to the patient (e.g., oral, intravenous, intramuscular).
	Indication	The clinical reason for prescribing the antimicrobial (e.g., pneumonia, urinary tract infection, prophylaxis).
	Indication Type	Indicates whether the use is for treatment, prophylaxis, or other purposes (e.g., empirical, targeted).
	Start Date	The date when the antimicrobial therapy began.
	End Date	The planned or actual date when the antimicrobial therapy was discontinued.
Microbiological Data	Culture Results	Results of microbiological cultures (e.g., positive, negative, pending).
	Pathogen Identified	Specific pathogen identified in the culture, if applicable (e.g., E. coli, Staphylococcus aureus).
	Susceptibility Testing	Results of antimicrobial susceptibility testing (e.g., sensitive, resistant, intermediate).
Outcome Measures	Length of Hospital Stay	The total number of days the patient stayed in the hospital.
	Treatment Outcome	Outcome of the antimicrobial treatment (e.g., cured, improved, unchanged, deteriorated).
	Adverse Events	Any adverse events or side effects reported during antimicrobial treatment.

Variable Category	Variable Name	Description
Additional Variables	Prescriber ID	Unique identifier for the healthcare professional who prescribed the antimicrobial.
	Stewardship Program Involvement	Whether the antimicrobial use was reviewed or monitored by an antimicrobial stewardship program.
	Compliance with Guidelines	Whether the antimicrobial prescription aligns with local or international treatment guidelines.
	Previous Antimicrobial Exposure	Any history of antimicrobial use in the past 3 months prior to the current treatment.
	Empirical vs. Targeted Therapy	Indicates whether the antimicrobial therapy was started empirically or after identifying a specific pathogen.
	Prophylaxis Indication Duration	The duration of antimicrobial use for prophylaxis, especially in surgical cases.
	Antimicrobial Combination Therapy	Information on whether combination therapy was used and details about additional antimicrobials prescribed.

ANNEX 8: Standard Operating Procedure (SOP) for AMR Surveillance Data Collection and Management: SOP01

Title: Standard Operating Procedure (SOP) for AMR Surveillance Data Collection and Management	
SOP code: SOP01	Effective Date: August 1st 2024
Owner:	Issue Date:
Approver:	Number of pages:

1. Purpose

Antimicrobial resistance (AMR) data collection at a surveillance site is crucial for understanding and monitoring the AMR trends across levels to guide antimicrobial stewardship interventions. This SOP provides standardized guide for AMR data collection and management using standardized AMR data tools. In laboratory-based surveillance of AMR, bacteriology data generated through routine testing becomes valuable AMR surveillance data.

2. Scope

This SOP covers AMR data collection, management and reporting to national and regional surveillance systems. Procedures described are those for data collection, data entry, data quality assurance, data storage, data security and data reporting. The procedures should be adapted based on data systems in use at surveillance sites.

3. Responsible Persons

This SOP applies to all personnel involved in data collection, entry, and management using standardized data tools and systems for AMR surveillance.

- Data Collectors: Ensure accurate and timely collection of data.
- Data Entry Personnel: Enter data accurately into electronic tools
- Data Managers: Oversee the data entry process and ensure data integrity; train data collectors

4. Procedure

4.1. AMR Data Collection and Entry

- Use standardized tools to collect and enter AMR surveillance data.
- Implement data quality checks as outlined in section 4.4.
- These tools may include laboratory information management systems, hospital management

information systems, MS- Excel data collection tools, WHONET software and laboratory registers.
- Data collected using electronic systems has more advantages over paper-based data.
- Data collection tools should collect the minimum data variables as defined by the national, regional and global AMR surveillance systems.
- Minimum data variables for AMR surveillance include unique patient identifier, age, sex, patient location, patient department, date of admission, specimen collection date, specimen type, test result, AST results.
- To assure quality of AMR surveillance data collected, regular review and analysis for KPIs should be defined.
- Collect, enter and report AMR surveillance data regularly; frequencies as defined in the national, regional and global strategies.
- For data entry and reporting using WHONET software, refer to SOP02.
- Ensure that any data that needs clarification is questioned with the relevant laboratory staff.

4.2. AMR Data Storage, Privacy and Security
- Local data storage, privacy and security policies apply to AMR surveillance data collected.
- Paper-based data records should be securely stored considering risks of fire, theft and flooding.
- Electronic records stored in local servers should be backed-up periodically in external drives or cloud servers.
- To conform to patient confidentiality policies, all records should be encrypted, and unique identifiers used in place of names.

4.3. AMR Data Reporting to National or Regional Surveillance Centers
- AMR surveillance data can be reported to national and regional surveillance centers in real-time using HMIS, LIMS, WHONET and DHIS II linked to a central data warehouse.
- Periodically data can also be reported in various formats such as SQLite, .xlsx, .csv and .txt file formats.
- Perform data transformations and conversions per surveillance system requirements and submit the AMR surveillance data records.

4.4. Quality Control
- Periodically audit a subset of AMR surveillance data records entered manually for any transcription errors.
- Audit core variables using summary statistic functions in tools such as MS- Excel™ for accuracy and completeness.
- Validate data entries against source documents to ensure consistency.
- Where massive errors are detected in AMR data records, consider data recollection, re-entry together with other corrective actions to avoid recurrence.

4.5. Training
- Provide regular training sessions for all personnel involved in data collection and entry.
- Update training materials as needed to reflect changes in procedures.

5. Document Control
Version: 1.0
Effective Date: [Date]
Review Date: [Date]
Approval: [Approving Authority]

ANNEX 9: Standard Operating Procedure (SOP) for AMR Surveillance Data Collection and Reporting Using WHONET Software: SOP02

Title: Standard Operating Procedure (SOP) for AMR Surveillance Data Collection and Reporting Using WHONET Software	
SOP code: SOP02	Effective Date: August 1st 2024
Owner:	Issue Date:
Approver:	Number of pages:

1. Purpose

Antimicrobial resistance (AMR) data collection at a surveillance site is crucial for understanding and monitoring the AMR trends across levels to guide antimicrobial stewardship interventions. This SOP provides standardized guide for AMR data collection and reporting to national or regional levels using WHONET to ensure consistent and accurate surveillance of AMR.

2. Scope

This SOP covers basics of using WHONET software for data collection and reporting. Topics in scope include downloading and installing WHONET software, updating already installed WHONET software, creating a standard laboratory configuration file, data entry into a laboratory in WHONET and reporting data using WHONET.

3. Responsible Persons

This SOP applies to all personnel involved in data collection, entry, and management using WHONET for AMR surveillance.

- Data Collectors: Ensure accurate and timely collection of data.
- Data Entry Personnel: Enter data accurately into WHONET.
- Data Managers: Oversee the data entry process and ensure data integrity.

4. Procedure

4.1. WHONET Software Download and Installation

- Download and install the latest version of WHONET software from http://www.whonet.org/software.html.
- Once downloaded, double click on WHONET set up file in the downloads folder and follow the onscreen instructions to set up and install the program.
- If the software is already installed, update to the latest version using the help section of the software.
- Detailed guidance on downloading and installing WHONET software can be found in the link: https://whonet.org/training.html.

4.2. Creating a laboratory configuration

- If a laboratory configuration has been sent to you, download, copy, open the WHONET folder on your computer > Click on "My computer"> click on "C" drive. Then click and open the "WHONET" folder and paste the configuration file.
- Double-click on the WHONET icon on your desktop.
- A list of laboratory configurations currently defined will be displayed. If you wish to set up a new laboratory, click on "New Laboratory".
- In the window that is displayed, select your "Country" and for "Laboratory name", type in the official name of the laboratory. For the "Laboratory code", enter an abbreviation of the code.

4.2.1. Configure antibiotics

- Click on Antibiotic Tab.
- Select in the drop-down menu the guideline to use in AST results interpretation (CSLI or EUCAST).
- Choose Disk or MIC or Etest as the test method.
- Select the antibiotics from the "WHONET antibiotics list to the "local antibiotics list.
- Use the ↔ arrow to move antibiotics across the lists as desired or double click on antibiotic.

4.2.2. Configure locations (Optional)

- Click on the Location tab.

- Click edit to add or delete institutions and departments on the right side.
- Click ok to save changes.
- Note: Institution and departments are editable while the location types are not editable.

4.2.3. Configure data fields

- Click on data fields tab.
- Click on modify lists.
- Uses the arrows ↔ to move data fields from either WHONET or Created lab.
- Identify the fields that are of interest for the purpose of this data collection exercise (compare with the WHONET template fields).
- Ensure there is consensus among the laboratory staff on the specific information that is to be captured under one specific field.
- Apply caution with the following fields that may lead to confusion, as their respective meanings may vary considerably from one laboratory to another: ID number, Lab number, Code, Patient ID, Patient lab ID, specimen number, sample number, etc.
- Match each field of interest from the manual records, with the exact field it refers to in the WHONET template (e.g. if the lab is recording the Patient lab ID under 'ID number', please record it in WHONET as Patient lab ID).
- Develop an in-house record of the matching as it will come in handy for everyone entering data in this laboratory.
- Double-check the information to make sure field matching is accurate, and information around interlinking manual records and facility records is also correct.
- When you add a data field it appears at the bottom of the list.
- Click 'OK'.

4.3 Data Entry

- Launch WHONET: Go to C drive/WHONET (click on the WHONET icon).
- Go to File/Open laboratory, select the laboratory you want to open, and click on Open laboratory.
- If the laboratory is yet to be configured follow the steps outline above or within the WHONET training package available at: https://whonet.org/training.html.
- Click on Data entry/Open data file.
- Choose the appropriate data file (C drive/ WHONET/ Data) and select the specific data file for this laboratory.
- Enter the data as it is in the manual records (e.g. laboratory register).
- Ensure that any data that needs clarification is questioned with the relevant laboratory staff.
- Date: enter the data using the following format: MM/DD/YYYY (age will be automatically calculated the date of birth is entered).
- Some data fields will require selection from a dropdown list.
- Once all data fields are entered, click on save isolate. There are three (3) save options available:

i. Save the isolate: Choose this option to continue with a new patient.

ii. Save the isolate and continue with the same specimen: Choose this option to enter results from another AST test on the same specimen (called 'specimen site' in our template) from the same patient.

iii. Save the isolate and continue with the same patient: Choose this option to enter AST results on the same patient, but from another specimen (called 'specimen site' in our template).

- Click on view database at periodically during data entry to ensure your data is captured on WHONET.
- In the event you are required to stop data entry, ensure you finish the isolate you are working on, save it and click Exit or just close the window.

4.4 Data Back-Up

- Save data entries regularly to prevent loss.
- Perform routine back-ups of the WHONET data files to a secure location: cloud or external drives.

4.5 WHONET Data Reporting to National or Regional Surveillance Centers

- AMR surveillance data can be reported in SQLite, .csv and .txt file formats.
- SQLite file can be found in the WHONET folder> Data folder.
- To convert SQLite file to .csv or .txt.

- Click on the Data Entry tab> Combine, export or encrypt data file tab.
- Select the data file export.
- Select Output format in the drop-down menu.
- Input new data file name.
- Select preferred location to save the file and click “Combine tab”.
-

4.6 Quality Control

4.6.1 Data Review and Validation:

- Periodically review entered data for accuracy and completeness.
- Validate data entries against source documents to ensure consistency.
- Document findings and corrective actions taken.

4.7 Training

- Provide regular training sessions for all personnel involved in data collection and entry.
- Update training materials as needed to reflect changes in procedures.

4.8 WHONET Data Back-Up

- Save data entries regularly to prevent loss.
- Perform routine backups of the WHONET database to a secure location.

5 Related Documents

- SOP01: AMR Surveillance Data Collection and Management
- SOP05: AMR Data Analysis and Dissemination
- SOP06: Preparation and Conversion of AMR surveillance data files using Baclink for Analysis using WHONET

6 Definition of terms and Abbreviations

- CSLI- Clinical and Laboratory Standards Institute
- EUCAST- European Committee on Antimicrobial Susceptibility Testing
- WHONET- Windows-based database software developed by WHO for the management and analysis of microbiology laboratory data.

7 References

John Stelling. (2016). WHONET manual. Brigham and Women’s Hospital WHO Collaborating Centre for Surveillance of Antimicrobial Resistance Boston, Massachusetts.

8 Document Control

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Approval: [Approving Authority]

ANNEX 10: Standard Operating Procedure (SOP) for AMC Surveillance Data Collection and Analysis: SOP03

Title: Standard Operating Procedure (SOP) for AMC Surveillance Data Collection and Analysis	
Target: Antimicrobial consumption data – data collection, quality control, and analysis	
SOP code: SOP03	**Effective Date:** August 1st 2024
Owner:	**Issue Date:**
Approver:	**Number of pages:**

1. Purpose

Antimicrobial consumption (AMC) data collection at a surveillance site is crucial to better understand the patterns and amount of antibiotics used at the site, which can inform policies, regulations and interventions to guide antimicrobial stewardship interventions. This SOP provides standardized guide for AMC data collection and reporting to national or regional levels to ensure consistent and accurate surveillance of AMC, cleaning, and analysis.

2. Scope

This SOP covers basics of AMC data collection and reporting. Topics in scope include: Mapping AMC data, data collection, data entry in MAAP, creation of master file, data analysis, and quality control

3. Responsible Persons

This SOP applies to all personnel involved in data collection, cleaning, and analysis of AMC surveillance data.

- Data Collectors: Ensure accurate and timely collection of data.
- Data Entry Personnel: Enter data accurately into WHONET.
- Data Managers: Oversee the data entry process and ensure data integrity.

4. Procedure

4.1. Mapping AMC data and data collection

- Data collectors to identify the existing paper-based (such as registers, stock-cards, bin-cards) or electronic data recording systems in the facilities.
- Capture the available data in an MS Excel for the list of variables documented in table 1. In case any of the variable is not available in the data recording systems in the facility those should be marked to ensure completeness or quality of available data can be monitored

Variables	Description
Country	Name of the country where is the site
Site Name	Name of the pharmacy
Site Type	Hospital Pharmacy / Community Pharmacy
Sector	Private / FBO / Public
Date of transaction	Date on which sales/consumption of antibiotic was recorded in dd/mm/yyyy format
Antibiotic Name	Molecule name of the antibiotic sold/consumed
Salt	Such as Ethylsuccinate, Hippurate, Mandelate or None
Combination	Monotherapy and Combination therapy
Antibiotic Strength	such as 250, 125, 40 mg/2 ml; Ensure all the strength information especially for syrups, suspensions or injectables is captured per ml
Antibiotic Strength Units	Milligram, International Units, or Milligram per Litre etc
Route of Administration	Oral, Parenteral, Rectal, Inhalation powder, and Inhalation solution
Pack size	Number of tablets, bottles, ampoules, vials, etc in a pack
Pack volume	Applicable only in case of Syrups, Suspension, or Parenteral formulations
Quantity issued	Quantity of packs sold/consumed

4.2. Create a standardized antibiotic master file

- List all available antibiotics in an excel workbook with their generic names, salt, and their available formulations
- Map all the unique molecule name and formulation combination with additional information such as WHO ATC5 code, WHO Defined Daily Dose (DDD), and WHO AWaRe
- All the standardized variables including antibiotic names, salt, formulation, WHO ATC 5, WHO DDD, and WHO AWaRe are uploaded to the MAAP tool.

4.3. AMC data entry in the MAAP tool

- Enter the data collected in the MS excel in 4.1. lists all the variables along with the description to be included in the MAAP tool for data collection
- Data entry personnel to capture the variables as identified in the registers, stock cards or electronically monitored antibiotic sales/ consumption information in the MAAP tool. Selected variables such as WHO ATC 5, WHO DDD, and WHO AWaRe to be automatically sourced (based on MAAP tool capability) from the master file created in step 4.2. In case automatic fill is not possible, data entry personnel to enter these manually in the MAAP tool along with other data points.

Variables	Description	Information source
Country	Name of the country where is the site	Manual entry
Site Name	Name of the pharmacy	Manual entry
Site Type	Hospital Pharmacy / Community Pharmacy	Manual entry
Sector	Private / Public	Manual entry
Date of transaction	Date on which sales/consumption of antibiotic was recorded in dd/mm/yyyy format	Manual entry
Antibiotic Name	Molecule name of the antibiotic sold/consumed	Manual entry
Salt	Ethylsuccinate, Hippurate, or Mandelate; Default is blank	Manual entry
ATC5 Code	A unique code assigned to a medicine according to the organ or system it works on and how it works. The classification system is maintained by the World Health Organization (WHO)	Automatic fill (Source: Master file)
Combination	Monotherapy and Combination-therapy	Manual entry
Antibiotic Strength	such as 250, 125, 40 mg/2 ml; Ensure all the strength information especially for syrups, suspensions or injectables is captured per ml	Manual entry
Antibiotic Strength Units	Milligram, International Units, or Milligram per millilitre etc	Manual entry
Route of Administration	Oral, Parenteral, Rectal, Inhalation powder, and Inhalation solution	Manual entry
Pack size	Number of tablets, bottles, ampoules, vials, etc in a pack	Manual entry
Pack volume	Applicable only in case of Syrups, Suspension, or Parenteral formulations	Manual entry
Quantity issued	Quantity of packs sold/consumed	Manual entry
WHO Defined Daily Dose	The assumed average maintenance dose per day for a drug used for its main indication in adults	Automatic fill (Source: Master file)
WHO AWaRe	Antibiotics are classified into three groups, Access, Watch and Reserve, considering the impact of different antibiotics and antibiotic classes on antimicrobial resistance, to emphasize the importance of their appropriate use; Antibiotics which are not listed in any of the above-mentioned categories are marked as “Uncategorized”	Automatic fill (Source: Master file)

4.4. Data Analysis:

- For each data entry total sold/consumed milligrams per antimicrobial were divided against the standard DDD value issued by WHO to obtain total DDDs (World Health Organization, 2020).
- Different metrics are applicable for analysis based on the data source for example:

o To analyze national level antibiotic consumption the metric used is:

DDDs/1000 inhabitants/day (DID) = (Total DDDs consumed/number of days in the data year) * (1000/Country population in the year of analysis)

o To analyze antibiotic consumption for in-patients the metric used is:
DDD/100 patient admissions = (Total DDDs consumed in-patient in an year/number of days in the data year) * (100/number of in-patient in the year of analysis)

- Based on the AMC DDD analysis following analysis can be conducted to further drill down the consumption pattern:

o Monthly AMC trend for each facility split by:
  - ☐ AWaRe category
  - ☐ Route of administration
  - ☐ Mono drug therapy vs combination drug therapy

o Ratio of DDDs by route of administration
  - ☐ Oral vs Parenteral vs Rectal vs Inhalation
  - ☐ Oral Solids vs. Oral Liquids

5. Quality Control

5.1 Data Review and Validation:

- Periodically review entered data for accuracy and completeness
- Validate data entries against source documents to ensure consistency.
- Document findings and corrective actions taken

5.2 Training

- Provide regular training sessions for all personnel involved in data collection and entry.
- Update training materials as needed to reflect changes in procedures.

6. Definition of terms and Abbreviation

AMC – Antimicrobial Consumption
DDD – Defined Daily Dose

7. Document Control

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ANNEX 11: Standard Operating Procedure (SOP) for AMU Surveillance Data Collection and Analysis: SOP04

Title: Standard Operating Procedure (SOP) for AMU Surveillance Data Collection and Analysis	
Target: Antimicrobial use data – data collection, quality control, and analysis	
SOP Code: SOP04	Effective Date: August 1st 2024
Owner:	Issue Date:
Approver:	Number of pages:

1. Purpose

Antimicrobial Use (AMU) data collection at a surveillance site is crucial to better understand the patterns and how antimicrobials used across the site, this is conducted through Point Prevalence Surveys (PPS). This information will inform policies, regulations and interventions to guide antimicrobial stewardship (AMS) interventions. This SOP provides a standardized guide for AMU data collection (utilizing the PPS methodology) and reporting to ensure consistent and accurate surveillance of AMU, cleaning, and analysis.

- Identify and monitor rates of antimicrobial prescribing in hospitalized patients
- Identify differences between prescribing rates between the different hospital departments, hospitals, regions and countries
- Determine variation in antibiotics, dose and indications across the different locations
- Furthermore, PPS can help to identify targets for quality improvement in antibiotic prescribing, identify interventions to promote better stewardship of antibiotics to assist the fight against antimicrobial resistance and assess the effectiveness of interventions through repeated surveys.

2. Scope

This SOP covers basics of AMU data collection and reporting. Topics in scope includes planning for AMU data collection, data entry, data analysis, and quality control

3. Responsible Persons

This SOP applies to all personnel involved in data collection, cleaning, and analysis of AMU surveillance data.

- Data Collectors: Ensure accurate and timely collection of data.
- Data Managers: Oversee the data entry process and ensure data integrity.

4. Procedure

4.1. Planning for AMU data collection

- The structuring and coordination of the PPS is managed by a Hospital Coordinator/Hospital Investigator/AMS focal person. Their roles include:
  - Coordination of the surveys.
  - Reports results to hospital management and national coordinator.
  - Apply for ethical clearance.
  - Identify and support investigators.
- Select an investigator team, which can include physicians, including infectious disease specialists, microbiologists and laboratory officers, infection control practitioners and nurses, pharmacists, data managers and IT.
- The hospital coordinator/investigator trained in the WHO PPS methodology will be responsible coordinating any cascade training.
- Prior to survey the whole investigational team will conduct a pilot study reviewing clinical notes of 10 patients. This will allow the team to agree on data extraction procedure to reduce bias. Each investigator to collect data independently and later compare for internal validity.
- Data collection in the entire hospital should be conducted in a maximum of three consecutive weeks. Should be made as short as possible and all wards meeting criteria should be included.
- Each ward must be surveyed in a day.
- Surveys should be avoided on weekends and holidays. Staff and elective procedures reduced on these days.

4.2. Patient sampling

Based on the size of the hospital the following patient sampling can be employed:

- < 500 total inpatient beds, include all eligible patients in the wards.
- 500-800 total inpatient beds, one out of two

patients per ward.
- 800 total beds, one out of three patients per ward.

4.3. Patient Inclusion Criteria

- Only patients who are hospitalized in the ward at 08:00 on the day of the survey should be included in the survey.
- All neonates born before 08:00 on the day of the survey are included and counted separately from their mother, that is mother and baby count as two different patients, if applicable.
- All patients meeting the eligibility criteria should be included in the survey irrespective of whether they are receiving antibiotic treatment or not.

4.4. Patient Exclusion Criteria

- All day care patients must be excluded, such as:
  - Patients undergoing treatment or surgery and are discharged the same day.
  - Patients seen at outpatient departments.
  - Patients in the emergency room.
  - Outpatient dialysis patients.
  - Discharged patients who remain as lodgers while waiting for transportation/clearance.
  - Parents/relatives of admitted children who reside as lodgers in the ward to nurse them.
  - Patients receiving outpatient parenteral antibiotic therapy (OPAT).

4.5. Antibiotic Inclusion & Exclusion Criteria

- Include if the patient is on antibiotic therapy at 08:00 on the day of the survey.
- Exclude if the antibiotic therapy is initiated after 08:00 on the day of the survey.
- Exclude if the antibiotic therapy was stopped before 08:00 on the day of the survey
- Special cases:
  - If the patient is on antibiotic therapy at 08:00 on the day of the survey but the antibiotic is not administered daily, then the antibiotic should still be reported. This includes, for example, patients with renal impairment with reduced dosing frequency or long-acting antibiotics that are administered with prolonged intervals, e.g., 48 hourly or more.
  - Single-dose regimes, such as gentamycin in combination with other antibiotics, should be included if the dose was given within 24 hours prior to 08:00 on the day of the survey.
  - If the patient is on treatment with antibiotic A at 08:00 on the day of the survey but the treatment is changed to antibiotic B at 10:00, then only antibiotic A should be reported
- Antibiotics to be included – Annex XI – WHO Methodology: https://www.who.int/publications/i/item/WHO-EMP-IAU-2018.01
- The list mainly covers antibiotics in the JO1 Anatomical Therapeutic Chemical (ATC) WHO category.
- The facility may decide to include any other category of antimicrobials based on interest e.g., antifungals (J02).
- Antimicrobials administered through oral, parenteral, rectal or inhalation routes are included in the survey.
- Exclude topical applications, eye drops, ear drops, and vaginal suppositories.

4.6. Data Collection

There are three sets of data collection tools to use to collect the following information:

1. Hospital questionnaire – type and size of the hospital

Hospital ID/Name:	Hospital type/level: Primary/Secondary/Tertiary/Specialized
Survey Start Date:	Survey End Date:
Hospital Ownership: Public/Private not-for-profit/ Private for-profit /other	Hospital Total Beds:
Hospital ICU beds:	Hospital Acute Beds:
Hospital High Risk beds:	Hospital annual admissions:
Hospital annual patient days:	Hospital Included beds:
Eligible patients:	Included patients:
Patient sampling details:	

2. Ward level data - Type of ward, No. of eligible & included patients, Characteristics of ward

Date of survey	
Ward Investigator:	
Ward ID/Name:	
Ward Type: Paediatric: Paediatric medical ward (PMW) Paediatric surgical ward (PSW) High risk paediatric ward (PHRW) Paediatric intensive care unit (PICU) Neonatal: Neonatal medical ward (NMW) Neonatal intensive care unit (NICU)	Adult: Adult medical ward (AMW) Adult surgical ward (ASW) High risk adult ward (AHRW) Adult intensive care unit (AICU) Mixed ward (MXW)
Total number of beds: on the ward present at 08:00 am on day of PPS split up by activity NB: For mixed departments, fill the total number of patients corresponding to each of the encountered activities	
Ward total patients: Total number of patients present in the ward at 08:00	
Ward eligible patients: Number of eligible patients present in the ward at 08:00 NB: For mixed departments, fill the total number of patients corresponding to each of the encountered activities	
Ward included patients: Number of patients included in the survey. This is the number of eligible patients minus patients who did not give consent to participate in the survey.	

3. Patient level data:

	Data variable	Data details
	Patient information	• Patient identifier • Sex • Age • Weight (paediatric) • Admission date
	Antimicrobial information	• Antimicrobial count (number of antimicrobials prescribed for patient) • Antimicrobial name documented and INN name • Start day of treatment • Dose (standardized in mg) • Number of doses per day (frequency) • Route of administration (oral, parenteral, inhalation, rectal etc.)
	Indication data	• Indication for therapy (treatment for CAI or HAI, prophylaxis - medical or surgical etc.) • Surgical prophylaxis duration and site • Diagnosis and documentation of this in notes
	Additional information including microbiology information	• Whether a sample has been tested • Results of the microbiology sample testing (specimen type, culture results (organism, AST result) • Is the prescription compliant with local prescribing guidelines • Comments (to include details of treatment e.g., switch of therapy based on microbiology results, previous treatments etc. • Prescriber variables (optional)

4.7. Ensuring standardized data elements

- List all available antibiotics in an MS-Excel™ workbook with their generic names, salt, and their available formulations.
- Map all the unique molecule name and formulation combination with additional information such as WHO ATC5 code, and WHO AWaRe.
- Agree on standard way to record data elements, options are highlighted below and see WHO codes values https://www.who.int/publications/i/item/WHO-EMP-IAU-2018.01:

Data Element	Data Options
Name of medicine	Antimicrobial name as per approved INN name
Date of start of therapy	DD/MM/YY
Duration of therapy	7, 5, 3, stat
Route	Parenteral (P), Oral (O) Rectal (R), Inhalation (INH)
Unit dose	Grams (g), milligram (mg), international units (IU) etc.
Dose frequency	Twice a day (1), three times a day, every 2 days (0.5), stat etc.
Prophylaxis	Indicate whether surgical or medical: See coded list: https://www.who.int/publications/i/item/WHO-EMP-IAU-2018.01
Diagnosis	See coded list of diagnosis: https://www.who.int/publications/i/item/WHO-EMP-IAU-2018.01

4.8. Data Cleaning and Analysis:

- Data Cleaning: Review the collected data for accuracy and completeness.
- Organize data into relevant categories: Group antimicrobial agents by class, indication, administration route, and patient demographics (e.g., age, gender, comorbidities).

4.8.1 Descriptive analysis: Percentage hospital/ward occupancy (disaggregated further by age and sex distribution). Calculate the prevalence of antimicrobial use, determining the proportion of patients receiving antimicrobials within the study population. Assess the distribution of different antimicrobial classes and usage patterns across various wards or department.

4.8.2 Indication and compliance assessment: Determine whether antimicrobials were used according to guidelines, based on the indication (e.g., therapeutic, prophylactic). Identify instances of guideline compliance or deviations

4.8.3 AMR correlations: Link antimicrobial use to resistance patterns. Analyze the relationship between the types of antimicrobials used and the prevalence of resistant organisms within the same setting.

4.8.4 Disaggregation of AMU data (total for hospital and disaggregated by ward/specialty):

- AMU by individual antimicrobial molecule, to present the top utilized antimicrobials, including utilizations as Mono drug therapy vs combination drug therapy.
- AMU by WHO ATC classification
- AMU by WHO AWaRe categorization

AMU by route of administration: Oral vs Parenteral vs Rectal vs Inhalation, and Oral Solids vs. Oral Liquids

5. Quality Control

5.1 Data Review and Validation:

- Periodically review entered data for accuracy and completeness
- Validate data entries against source documents to ensure consistency.
- Document findings and corrective actions taken

5.2 Training

- Provide regular training sessions for all personnel involved in data collection and entry.
- Update training materials as needed to reflect changes in procedures.

6. Definition of terms and Abbreviation

AMU – Antimicrobial Use
ATC – Anatomical Therapeutic Chemical
AWaRe – Access, Watch, and Reserve

7. Document Control

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ANNEX 12: Standard Operating Procedure (SOP) for AMR Data Analysis and Dissemination: SOP05

Title: Standard Operating Procedure (SOP) for AMR Data Analysis and Dissemination	
Target: For Laboratory Data - Data Analysis, Reporting and Dissemination	
SOP code: SOP05	Effective Date: August 1st 2024
Owner:	Issue Date:
Approver:	Number of pages:

1. Purpose

This SOP provides general stepwise instructions for AMR surveillance data analysis and dissemination to influence local, national and global policies on AMR prevention and containment. AMR surveillance data use remains low due to limited capacities for AMR data analysis

2. Scope

This SOP covers AMR data review for cleaning and validation, analysis and dissemination of analysis findings. The procedures should be adapted based on data management and analysis tools in use locally, nationally or at regional level

3. Responsible Persons

This SOP applies to all personnel involved in AMR data management using standardized data tools and systems for AMR surveillance.

- Data Collectors: Ensure accurate and timely collection of data.
- Data Entry Personnel: Enter data accurately into electronic tools
- Data Analysts: Lead data review- cleaning and validation and analysis using tools such as MS-Excel, WHONET, R, SAS and STATA.
- Data Managers: Oversee the data entry process and ensure data integrity, training of data collectors and entry personnel, oversee data review, analysis and dissemination
- Clinical Microbiologists: Review AMR surveillance data for technical inaccuracies
- Epidemiologists: Guide AMR data analysis and interpretation

4. Procedure

4.1 Data collation

- This is done to create a unified local, national or regional data set for the period under review
- This step is not necessary if all data is stored in a single database from where a unified dataset can be downloaded
- Review data files received from multiple sources for consistencies in file structure
- Perform relevant data transformations and conversions where inconsistencies are noted
- Note: Where standardized tools are used to collect, enter and transmit AMR surveillance data, no transformations or conversions are required
- Perform data encryption for data files received with personal information.
- Process the files and merge the files using R-software, MS-Excel or WHONET.

4.2 AMR Data Cleaning and Validation

- AMR surveillance data cleaning and validation requires involvement of multiple stakeholders: infectious disease specialists, clinical microbiologists, epidemiologists, M& E specialists and data management teams
- Review and clean AMR data with ease using MS-Excel or R- software.
- Use basic descriptive statistics to uncover data structure issues and technical inaccuracies
- Adopt with modification a five-step data cleaning and validation approach

4.2.1 Remove duplicates and irrelevant data records

- Use GLASS methodology for removing duplicate records
- Drop irrelevant data records i.e. records not deemed important for analysis. Both national and regional AMR surveillance systems focus is on select priority pathogens from select specimen types.
- Records deemed not priority can be dropped at this step

4.2.2 Fix data structural issues

- Structural errors may arise from inconsistencies in data formats, missing values, incorrect data types, naming conventions, typos, or incorrect capitalization.
- Step undertaken to standardize data in-puts across all surveillance variables

4.2.3 Review data for technical inaccuracies

- Technical inaccuracies of focus are those around pathogen-drug combination, to ensure priority pathogens isolated were tested against the correct antimicrobials
- Use national, regional and global surveillance guidance documents

4.2.4 Address missing data

- Records with missing data can be dropped or filled based on inputs in other data variables e.g. using patient department to fill patient location type
- This however should be done with care and with team consensus

4.2.5 Validate the cleaned data records

- This final step is performed to quality assurance purposes with involvement of all stakeholders
- Use MS-Excel filter and pivot table functions
- Drop records found with errors at this point

4.3 AMR Data Analysis

- AMR data analysis can be performed using MS-Excel, WHONET, R- AMR package, SAS and STATA
- Process data for analysis with available analysis tools
- To process data for analysis using WHONET, refer to SOPs on data conversion using BacLink and data analysis using WHONET software.
- Begin analysis with descriptive statistics to summarize key characteristics of the AMR data
  Total records and distribution by specimen types, surveillance sites, age group, gender, patient locations, departments, pathogens reported
  Analyze data for resistance patterns and prevalence of multidrug resistance (MDR), Extensive drug resistance (XDR) and Pan drug resistance (PDR) (Magiorakos, A.P., et al., 2012)
- Proceed to consider data analysis for inferential statistics such as;
  Analysis of the relationship between patient demographics (age, gender, etc.) and AMR.
  Use appropriate statistical tests to determine the significance of observed trends or associations. This might include chi-square tests, t-tests, or regression analysis depending on the nature of the data.
- Perform the optional data analysis to assess correlation of AMU to AMR (this should be considered based on the availability of population representative data)

$$DRI = \sum (\text{Resistance Rate}_{i,j} \times \text{Usage Fraction}_{i,j})$$

where:

i is the specific pathogen.
j is the antibiotic or class of antibiotics.
Resistance Rate$_{i,j}$ is the percentage of isolates of pathogen *i* that are resistant to antibiotic *j*.
Antibiotic Use Fraction$_{i,j}$ is the proportional usage or consumption of antibiotic *j* (out of total antibiotic use) for pathogen *i*.

4.4 AMR Data Presentation/Visualization

- Present the analyzed AMR data using bar charts, line graphs, heatmaps, or other visual representations to enhance understanding.
- AMR data can also be presented inform of antibiograms
- Antibiogram is a visual representation of the susceptibility or resistance of bacterial isolates to different antibiotics.
- Calculate and include the percentage of isolates that are susceptible, intermediate, or resistant to each antibiotic reported
- Consider isolates tested >30 times against an antibiotic
- Enhanced antibiograms can be generated by stratifying data by patient type and hospital department
- Refer to CLSI M39 to detailed guidance on development of antibiograms

4.5 Reporting and Dissemination

- Prepare quarterly AMR surveillance bulletins and annual reports for dissemination to stakeholders
- Prepare and disseminate policy briefs based on data analysis findings

4.6 Continuous Improvement

- Provide regular feedback to surveillance sites and implement continuous quality improvement actions based on data review and validation findings
- Conduct regular training sessions for all teams involved in data management

5. Related Documents

- SOP01: AMR Surveillance Data Collection and Management
- SOP02: AMR Surveillance Data Collection and Reporting Using WHONET Software
- SOP06: Preparation and Conversion of AMR surveillance data files using Baclink for Analysis using WHONET

6. Definition of terms and Abbreviations

Dataset: A dataset is a collection of separate pieces of data that is treated as a single unit by a computer. Datasets often represent data in the form of a data table, in which columns represent variables and rows represent data values corresponding to each data unit.

7. References

- Clinical and Laboratory Standards Institute. (2014). Analysis and presentation of cumulative antimicrobial susceptibility test data. 4Ed.
- Magiorakos, A. P., et al. (2012). Multidrug-resistant, extensively drug-resistant and pandrug-resistant bacteria: an international expert proposal for interim standard definitions for acquired resistance. Clinical microbiology and infection: the official publication of the European Society of Clinical Microbiology and Infectious Diseases, 18(3), 268–281. https://doi.org/10.1111/j.1469-0691.2011.03570.x
- WHO. (2023). Global AMR and AMU Surveillance System (GLASS) manual 2.0. https://iris.who.int/bitstream/handle/10665/372741/9789240076600-eng.pdf?sequence=1

8. Document Control

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ANNEX 13: Standard Operating Procedure (SOP) for Preparation and Conversion of AMR surveillance data files using Baclink for Analysis using WHONET: SOP06

Title: Standard Operating Procedure (SOP) for Preparation and Conversion of AMR surveillance data files using Baclink for Analysis using WHONET	
SOP code: SOP06	Effective Date: August 1st 2024
Owner:	Issue Date:
Approver:	Number of pages:

1. Purpose

This SOP provides guideline for preparation and conversion of AMR surveillance data files for analysis or reporting using WHONET software. This applies to institutions using Laboratory Information Management System (LIMS) to enter data and institutions managing AMR data in Microsoft excel. This will avoid repeated data entry of already available data in excel or LIMS

2. Scope

This SOP covers steps for preparation and conversion data files. These include: inspecting data file and preparing files for BacLink conversion, starting BacLink, configuring a new file format, running the conversion and getting started in WHONET.

3. Responsible Persons

- Data Collectors: Ensure accurate and timely collection of data.
- Data Entry Personnel: Upload data accurately into WHONET.
- Data Managers: Oversee the data entry process and ensure data integrity.

4. Procedures

4.1 Inspect and Prepare Data file for BacLink Conversion

- Open the data file in excel by double clicking the file or using the MS Excel "Import Data" function for .txt and .csv files
- Inspect and clean data file. Examples;
  Deduplication of records to achieve one isolate per patient
  Split columns. E.g. Age data column entered as 57 years should be split into two; age and age units
  Standardize entries in data variables: organism names, departments, patient locations, gender
  Date formats
- Ensure data to be converted begins in the cell A1
- Save the file as tab delimited text file
- Click on "File", "Save as". Instead of using the default "Excel Workbook" format, click on "Save as type" and select the option "Text (Tab delimited) (*.txt)".

4.2 Start BacLink

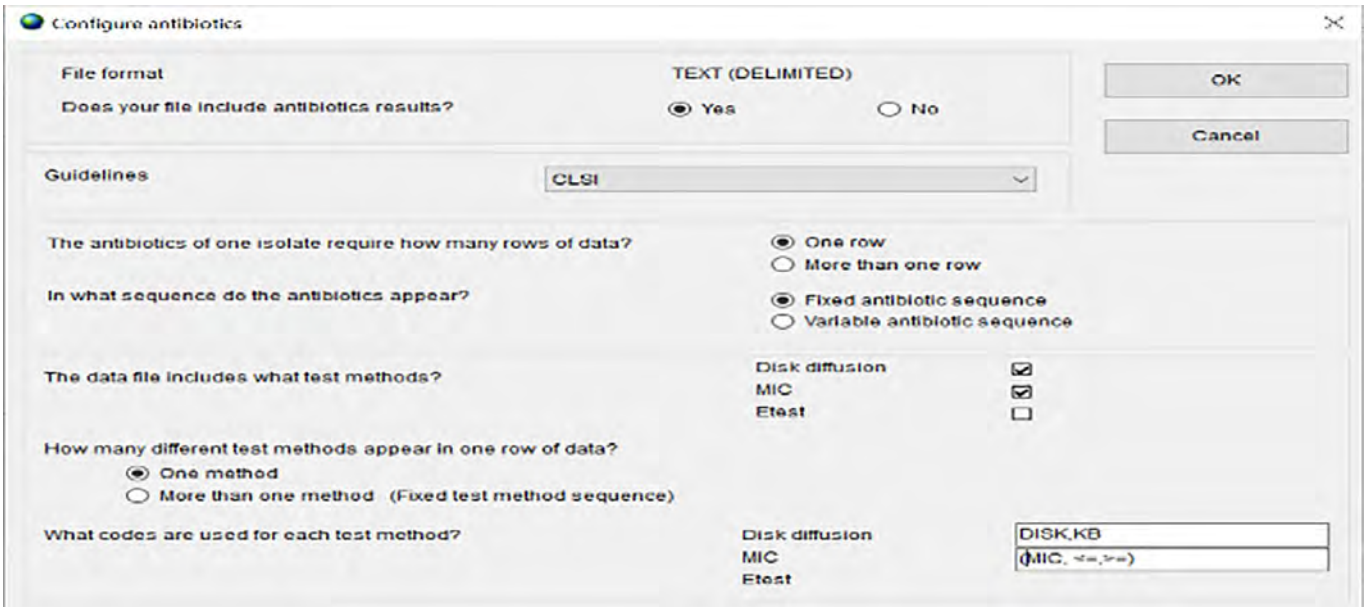
- Start the BacLink program by double-clicking on the BacLink shortcut icon installed on your desktop.

4.3 Configuring a new file format

- To convert the file saved, you need to give BacLink enough details for it to perform the conversion. To do this, click on "New Format". This should open the file format window.
- From the drop-down box, select the Country.
- Next enter the Laboratory Name and up to three characters for the Laboratory Code
- Click on the File Structure button and select the format "Text (Tab delimited)".
- Next select the File location as c:\whonet5\data. If the data file is stored elsewhere click "Browse" to select the location folder
- Next select or input the precise File name

4.4 Configure Antibiotics

- Click on "Antibiotics" and give "Yes" response to the question on if the data file contains antibiotics results.
- Next select the guideline used or to be used to interpret the AST results (CLSI or EUCAST)
- Next select appropriate responses to subsequent sections based on your file structure as shown on fig. 1.



- Click Ok and "Yes" or "No" to subsequent question

4.5 Configure Data Fields

- Click "Data Field" tab at the bottom to configure data fields for conversion
- On the pop window, click "select a sample data file"
- Select the file and open it
- Define the relationship between the WHONET fields and your data fields.
- To do this, click on a WHONET field on the left, and then click on the corresponding field on the right.
- Next click the "=" sign in the middle, OR double click on the matching field
- If you make a mistake, you can use the option "None of the below" to remove an incorrect match.
- After matching Data fields, proceed to match and define antibiotics.
- Click "Add antibiotics at the bottom to add antibiotics, guided by the data file.
- Click on the undefined antibiotics and click define antibiotic.
- After you select the correct antibiotic, click on "OK". Proceed to define all the other antibiotics as well. When finished, your screen should look like the below.
- Click on "OK" to return to the file format configuration screen, and "OK" again to return to the main configuration screen.

4.6 Saving the Configuration

- Click on "Save" and give a name to the new BacLink configuration. BacLink automatically adds ".cfg" to the filename that you give.
- Then click on "Exit" to leave the configuration area. The new configuration will appear on your list of BacLink file formats

4.7 Run Data Conversion

- Click on "Begin conversion". BacLink will display results from the conversion of the first three isolates in the original data file to allow for visual inspection of the accuracy of conversion.
- When the conversion is finished, BacLink may alert it encountered some codes that it did not recognize. Click "Yes"
- BacLink displays all the different codes that it did not recognize
- Highlight each row at a time and click on "Define codes" to see the screen with a list of all of the unrecognized codes.
- Double click on the first code to define it OR highlight the code and click "Define code".
- BacLink will now suggest a number of possible matches for the code. Click on the correct match, and then "OK".
- If you do not see the code listed, then use the search box to look for the correct code.
- Continue until all codes are defined.
- Re-run conversion to include the newly defined codes in the data file
- A warning message pops that says "the WHONET

file that you want to create already exists, do you want to replace it? Answer "Yes".
- Click "Next" and "Next" again to finish the conversion. BacLink returns to the main BacLink screen because all of the undefined codes were resolved.
- Click on "Exit" to leave BacLink and proceed to WHONET.

4.8 Getting Started with WHONET

- Double-click on WHONET icon on the desktop to begin WHONET.
- Create a new laboratory configuration to access the file converted in BacLink
  Click on "File" and click "Create a laboratory from a data file", to create a new laboratory configuration based on the converted data file
  In the pop window, select the country, input laboratory name and code.
  Click "Data files" to select the data file to use in creating the new laboratory configuration, and click "OK"
  WHONET proceeds to create a matching laboratory configuration. When completed, the program asks if you want to review the new configuration. Answer "Yes".
  Review "Antibiotics", "Locations" and "Data fields"
  After you explore these screens, click on "Save" to leave the configuration program.
  Note: After creating the configuration utilizing the shortcut described above, you can make any further edits, such as any modifications to the antibiotic breakpoints and profiles, with Modify laboratory in the same way as any WHONET laboratory configuration.
- Inspect the converted data file using the new laboratory configuration
  Click on "Data Entry", "Open data file", and choose the file
  Click on "View database" to review the file structure and records in the data file. WHONET displays the complete contents of the data file created by BacLink.
  Inspect the file to see if there are any possible errors – in the dates, codes, antibiotic results, etc.
  When finished, click on "Continue" and "Exit" to return to the main WHONET screen. Then "File", "Exit" to leave WHONET completely.

5 Related Documents

- SOP01: AMR Surveillance Data Collection and Management
- SOP02: AMR Surveillance Data Collection and Reporting Using WHONET Software
- SOP05: AMR Data Analysis and Dissemination

6 References

BacLink Excel and text file configuration. https://whonet.org/WebDocs/BacLink.8_Data_imports_configuration_Excel_and_text_file_configuration.pdf

7 Document Control

Version: 1.0
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ANNEX 14: Sample indicators for M&E of national AMR-SS

N	Indicator	Definition	Type	Value (National Level)
Surveillance structure				
1	Presence of a NCCU	NCCU with mandate, ToRs, and a responsible person (focal point) is established	Input	NCCU established (Y/N)
2	NCCU with the mandate for sharing information with GLASS	Mandate to participate in GLASS has been delegated by the relevant national authority	Input	NCC mandate includes sharing data (Y/N)
3	National plan for AMR surveillance	Strategic and operational plan for implementing and strengthening AMR surveillance, including participation in GLASS	Input	National plan exists (Y/N)
4	Presence of a National Focal Point (NFP)	NFP is designated and communicating with GLASS	Input	National GLASS focal point designated (Y/N)
5	Budget for AMR surveillance	Identified national budget to support the national AMR surveillance system	Input	National budget for AMR surveillance (Y/N)
6	National Reference Laboratory (NRL)	At least one NRL is designated with terms of reference to support national AMR surveillance system	Input	NRL for AMR designated (Y/N)
7	Number of AMR surveillance sites	Number of sites fulfilling requirements to collect and report data on patients and AST	Input	# of targeted sites established (n of N)
8	Existence of documented roles & responsibilities	Roles and responsibilities are well-documented at each level of the surveillance system	Process	Documentation of roles exists (Y/N)
9	Collaboration of sectors other than human health	Intersectoral collaboration with other sectors (animal health, agriculture, water, sanitation) with regular meetings	Process	Regular meetings take place (Y/N)
10	Functional network of surveillance sites	Existence of a network with regular information exchange and experience sharing	Process	Regular reports generated and sent (Y/N)
Public health priorities targeted for surveillance				
11	Priority specimen types included in AMR surveillance	Number of prioritized specimen types included in national targets	Output	% of sites with target specimens included
12	Priority pathogens	Number of prioritized pathogens in the national targets	Output	% of sites with target pathogens included
13	Priority pathogen-antimicrobial combinations	Number of prioritized pathogen-antimicrobial combinations in national targets	Output	% of sites with target combinations included
14	Priority pathogen-antimicrobial combinations (GLASS)	Number of prioritized pathogen-antimicrobial combinations in GLASS targets	Output	% of sites with GLASS targets included

N	Indicator	Definition	Type	Value (National Level)
Core functions & Quality of Surveillance				
15	Surveillance sites with standard case definition	Proportion of sites with standard case definitions for AMR episodes	Input	% of sites using standard definitions
16	Completeness of data reported	Proportion of reports with no missing required information	Output	% of sites submitting complete reports
17	Timeliness of submission of surveillance reports	Proportion of sites submitting reports to the next higher level on time	Output	% of sites submitting reports on time
18	Routine validation of surveillance data	Existence of routine validation of data at national and surveillance sites	Process	% of sites with routine validation
19	Existence of regular feedback	Presence of a feedback mechanism between surveillance sites and the next higher level	Process	Feedback mechanism in place (Y/N)
20	National strategy informed by AMR surveillance	National body receives AMR data and discusses implications for the national strategy at least once a year	Outcome	Discussion mechanism in place (Y/N)
21	Capacity to detect and notify unusual AMR events	Inclusion and reporting of unusual AMR events in the surveillance system	Process	% of unusual AMR events notified (Y/N)
22	Confirmation of unusual type of AMR	Capacity to confirm unusual AMR types within the laboratory or at a reference laboratory	Process	% of labs with confirmation capacity (Y/N)
23	Mechanism for AMR outbreak detection	Ability to detect and notify potential AMR outbreaks in hospitals	Process	% of sites with outbreak detection
24	National laboratory QA programme	Internal QA programme organized and implemented in all labs providing data to the national system	Process	% of labs with QA programme implemented
25	External quality assurance system (EQA)	National AMR programme organizes EQA for all laboratories participating in the national system	Process	% of labs participating in EQA
26	NRL participation in EQA	NRL participates in an internationally recognized EQA organized or supported by a regional reference laboratory or network	Process	NRL participates in EQA (Y/N)
27	EQA performance of laboratories	Proportion of laboratories passing the EQA proficiency test	Process	% of sites passing EQA PT

N	Indicator	Definition	Type	Value (National Level)
Support functions (guidelines and training)				
28	AMR surveillance standards and guidelines	Availability of AMR surveillance standards and guidelines in line with the GLASS manual	Input	% of sites applying standards (Y/N)
29	Availability of good communication lines	Proportion of surveillance sites with functional communication facilities	Input	Y/N national level, % of sites
30	Availability of budget line for surveillance activities	Evidence of a budget line for surveillance activities including resources for training, communication, etc.	Input	Y/N national level, % of sites
31	Surveillance staff trained in AMR surveillance	Training of surveillance staff in AMR surveillance including GLASS methodology	Process	# of training sessions, % of trained staff
32	Clinical staff trained in AMR surveillance	Training of clinical staff in AMR surveillance including GLASS methodology	Process	# of training sessions, % of trained staff
33	Laboratory personnel trained in AMR surveillance	Training of laboratory personnel in AMR surveillance and techniques according to GLASS requirements	Process	# of training sessions, % of trained staff
34	Supervision conducted at surveillance sites	Proportion of sites with supervision conducted	Process	Supervision mechanism in place (Y/N)


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