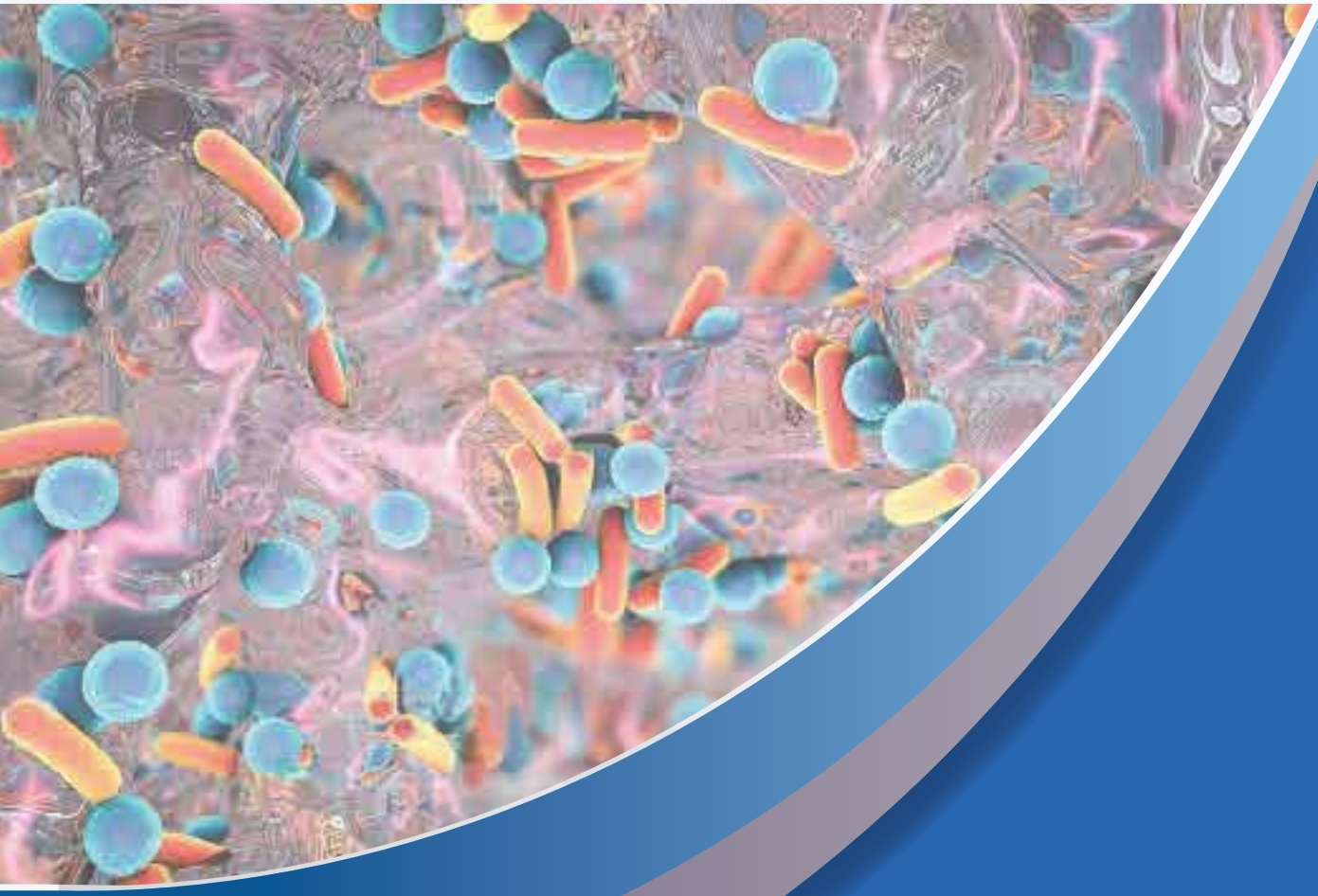
THE UNITED REPUBLIC OF TANZANIA

NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE FRAMEWORK



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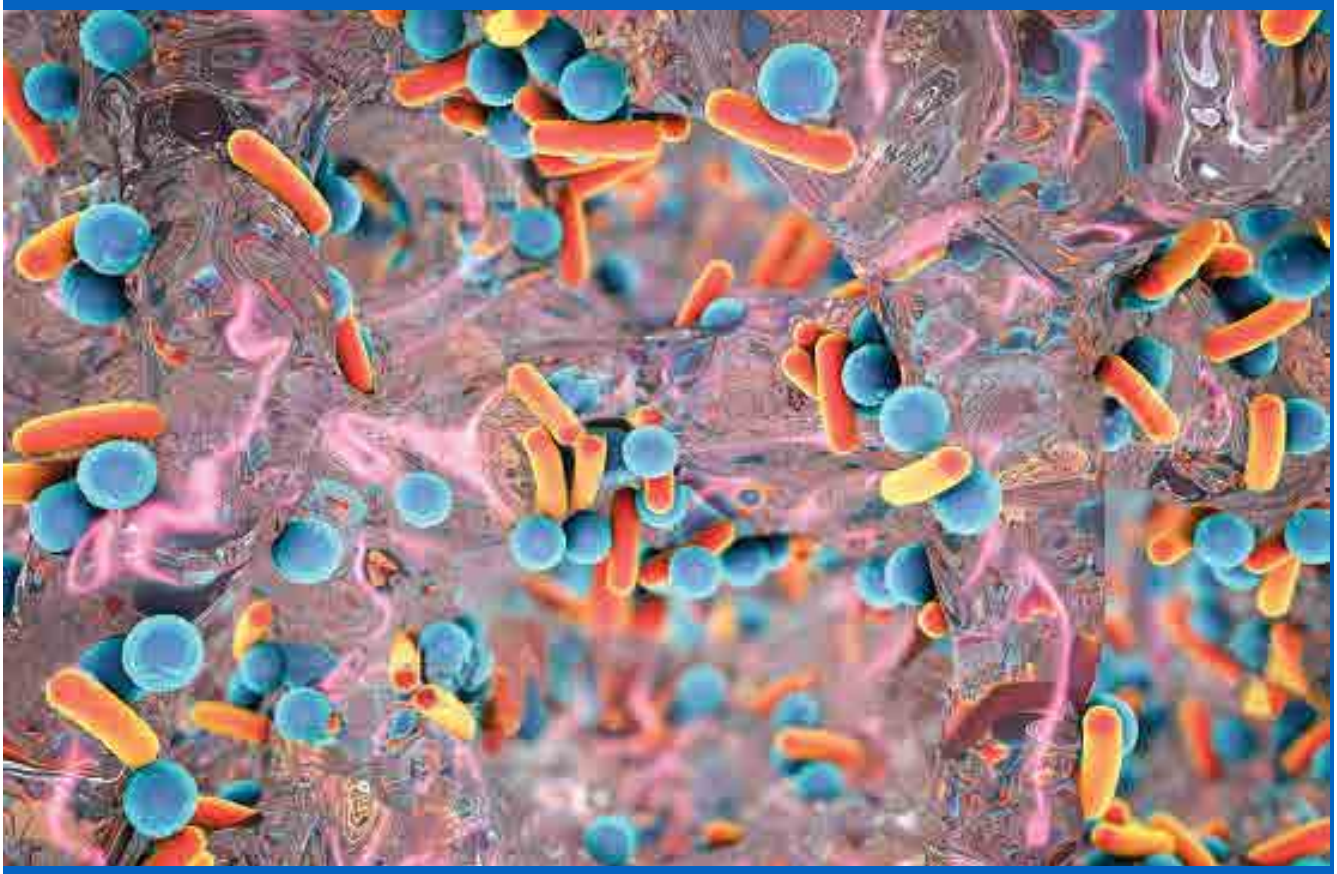

AUGUST, 2018

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LIST OF ACRONYMS AND ABBREVIATIONS

AMR	Antimicrobial resistance
AMU	Antimicrobial Use
AST	Antimicrobial susceptibility testing
BMC	Bugando Medical Centre
BSI	Blood-stream infections
CUHAS	Catholic University of Health and Allied Sciences
CDC	Center for Disease Control
CLSI	Clinical and Laboratory Standard Institute
DDD	Daily Defined Dose
DEC	Diarrhea genic *E.coli*
DVC	Director of Veterinary Services
EAC	East African Community
EDTA	Ethylene diamine Tetra acetic Acid
EQA	External quality assurance
ESBL	Extended-spectrum beta-lactamases
EUCAST	European Committee on Antimicrobial Susceptibility Testing
FAO	Food and Agriculture Organization of the United Nation
GARP	Global Antibiotic Resistance Partnership
GDP	Gross Domestic Products
GLASS	Global Antimicrobial Resistance Surveillance System
IPC	Infection prevention and control
MCC	Multi-sectoral Coordination Committee
MNH	Muhimbili National Hospital
MoHCDGEC	Tanzania Ministry of Health, Community Development, Gender, Elderly and Children
MoLF	Ministry of Livestock and Fisheries
MRSA	Methicillin-resistant *Staphylococcus aureus*
MUHAS	Muhimbili University of Health and Allied Sciences
NAP	National Action Plan on antimicrobial resistance
NCC	National coordinating committee
NHLQATC	National Health Laboratory Quality Assurance and Training Centre

NGO	Non-Governmental Organization
OHCEA	One Health Central and East Africa
OIE	World Organization for Animal Health
PC	Pharmacy Council
PMO	Prime Minister's Office
PO-RALG	President's Office Regional Administration and Local Government
PRA	Participatory Rapid Appraisal
PT	Proficiency testing
QMS	Quality Management System
SADC	Southern African Development Community
SOP	Standard operational procedure
SSI	Surgical site infection
STI	Sexual transmitted infection
SUA	Sokoine University of Agriculture
TFDA	Tanzania Food and Drugs Authority
TVLA	Tanzania Veterinary Laboratory Agency
TWG	Technical Working Group
USAID	United States Agency for International Development
URT	United Republic of Tanzania
UTI	Urinary tract infection
VMU	Veterinary Medical Use
VPO	Vice President's Office
WB	World Bank
WHO	World Health Organization

DEFINITION OF TERMS

Antimicrobials: An agent or substance, derived from any source that acts against any type of microorganism such as bacteria, mycobacteria, fungi, parasite, and viruses

Antimicrobial resistance: The ability of microorganisms to multiply or persist in the presence of an increased level of an antimicrobial agent relative to the susceptible counterpart of the same species.

Drug-resistant infections: Describes infections caused by organisms that are resistant to treatment, including those caused by bacteria that do not respond to antibiotics

Surveillance of antimicrobial resistance: Collection, validation, analyses and reporting of relevant clinical, microbiological and epidemiological data on antimicrobial resistance in targeted pathogens from different sources (e.g. humans, animals, food, environment), and on relevant antimicrobial use in humans and animals, and then applying the results to slow down or halt the development of resistance.

Veterinary medical use: Administration of an antimicrobial agent to an individual or a group of animals to treat control or prevent infectious disease.

Treat: Administer an antimicrobial agent to an individual or a group of animals showing clinical signs of an infectious disease;

Control: Administer an antimicrobial agent to a group of animals containing sick animals and healthy animals (presumed to be infected), to minimise or resolve clinical signs and to prevent further spread of the disease;

Prevent: Administer an antimicrobial agent to an individual or a group of animals at risk of acquiring a specific infection or in a specific situation where infectious disease is likely to occur if the drug is not administered

FOREWORD

Over the recent years, Antimicrobial Resistance (AMR) has become an increasingly important aspect for both animal and human health. Bacterial resistance to antimicrobials has shown to have serious economic impact in such a way that potent drugs are becoming ineffective resulting in loss of life for humans and animals as well as loss in agricultural product within the food chain.

Trend has shown an increase in usage of Antimicrobials in human health, animal health and production of aquaculture and other farming systems. Misuse and overuse of these antimicrobials directly impact on the environment with negative ecosystem health. In recognition of this problem, the Government of the United Republic of Tanzania realized the need to join global initiatives to combat AMR by ratifying different consensus as agreed at different global levels through multi-sectoral approach.

Development of this AMR surveillance framework has been a collaborative effort from various partners and stakeholders and was spearheaded by the Ministries responsible for human and animal health (Ministry of Health, Community Development, Gender, Elderly and Children, and Ministry of Livestock and Fisheries) in close collaboration with other key stakeholders at local and international level. The framework will help to streamline AMR surveillance activities in human health, agriculture and environment sectors in the country.

It is therefore anticipated that, this framework will be effectively implemented, monitored and reviewed regularly in response to the experiences gathered from its utilization. Besides, the sustainability of this framework depends on the extent to which new practices on antimicrobial use will be embedded in the whole society.

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ACKNOWLEDGEMENT

The National Antimicrobial Resistance (AMR) Surveillance Framework marks an important milestone in addressing challenges associated with AMR and Antimicrobial Use (AMU) that are increasingly becoming a major concern within public health, agricultural, and environmental sectors. The processes of developing the AMR surveillance plan considered situation analysis reports regarding AMR in public health, and agricultural sectors.

The National AMR Multi-sectoral Coordinating Committee (MCC) wishes to acknowledge technical contributions from the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC), the Ministry of Livestock and Fisheries (MoLF), the Ministry of Agriculture (MoA), Vice President's Office (VPO)-Environment, the Prime Minister's Office (PMO) (One Health Coordination Desk) as well as the World Health Organization. The list of experts is attached as appendix I.

In addition the MCC wishes to acknowledge the support from the American Society for Microbiology (ASM) and Food and Agriculture Organization (FAO) of the UN that enabled the AMR Surveillance and Research Technical Working Group to accomplish this AMR Surveillance framework.

Prof. Muhammad Bakari Kambi

CHIEF MEDICAL OFFICER AND CHAIRPERSON NATIONAL ANTIMICROBIAL RESISTANCE MULTI-SECTORAL COORDINATING COMMITTEE

Antimicrobial resistance (AMR) is a major global threat to human and animal health, and it endangers modern human and veterinary medicine. Whilst the direct use of antimicrobial agents in human health is recognized as a major contributor to antimicrobial resistance in human pathogens, there are circumstances where antimicrobials used in both food-producing and companion animals are key contributing factors. Surveillance and reporting of AMR and AMU is a global health priority.

It is anticipated that, the National Antimicrobial Resistance Surveillance Framework in human, animals, crops, food and environment will comprehensively mitigate the AMR and antimicrobial misuse in these sectors. The purpose of this AMR surveillance framework is to comprehensively and in a systematic manner collect, collate and generate information that will mitigate the AMR and antimicrobial misuse (AMU) in the country through effective monitoring of pathogens, AMU, antimicrobial sensitivity testing, antimicrobial residues and enhancing the prudent use of antimicrobials through communication of outcomes to the public.

The strategic objectives of this framework are aligned with the National AMR Action Plan based on national needs and priorities. The framework has highlighted strength, weakness, opportunity and challenges of the existing AMR/AMU governance system in the country. In this framework, priority pathogens and antimicrobial agents for surveillance purposes have been identified based on prevalence, incidence levels, zoonotic and food borne illness potential and pathogenicity. In addition, the identified priority organisms have shown the potential to develop or are known to have developed antimicrobial resistance that is of concern to human, animal, crop and environmental health.

Methods for AMR data collection are clearly defined in this framework and it differs from sectors. Both passive and active surveillance will be used to collect and analyze AMR epidemiological data. In this framework, standardized laboratory methods will be employed in order to obtain valid AMR surveillance data in the country. In view of this, standardized AMR sampling protocol and laboratory testing methods are described. Data management and sharing system has been sought to ensure that AMR information is shared to a range of stakeholders for action.

CHAPTER ONE

INTRODUCTION

Antimicrobial agents are powerful and effective drugs in the fight against infectious disease caused by bacteria, viruses, fungi and parasites [1,2]. Since discovery in the nineteen forties, antibiotics have contributed to dramatic reduction in morbidity and mortality from bacterial infections. However, increased use of antibiotics worldwide has been associated with a global rise of Antimicrobial Resistance (AMR), which threatens the return to pre-antibiotics era, where a common bacterial infection may once again result in death. AMR develops when strains of micro-organisms evolve to survive exposure to antimicrobial agents.

In many resource-limited settings including Tanzania, there is high burden of infectious diseases and antibiotics are widely used and save lives [3]. However, in these settings antimicrobial agents are inappropriately used which eventually leads to emerging of antibiotic resistance due to selection pressure. It is difficult to address irrational uses of antibiotics in resource-limited settings due to lack of diagnostic tools. In addition, antimicrobial substances are widely used in animals for growth promotions which further fuel existing AMR problem [4]. Coupled with irrational antibiotic uses; spurious, falsified, and counterfeit antimicrobial often slip into the drug supply chain [4].

Antimicrobials for Veterinary Medical Use (VMU) are intended for treating, controlling and preventing infectious diseases in chickens, cattle and to a lesser extent in pigs, sheep and goats. Emerging commercial aquaculture with eminent antimicrobial use in production may further exacerbate resistant microorganism's selection. In addition to the presence of antimicrobial metabolites in organic fertilizers used for crops, these agents are used directly in horticulture and cashew production [5-7]. Similarly, low quality water with potential antimicrobials from waste-water treatment plants in urban areas is used for horticulture irrigation [9]. Furthermore, feed additives containing enzymes, growth promoters, antimicrobial agents and probiotics are used in livestock feeds. The VMU and misuse of antimicrobials in human, animal and crop sectors, and its metabolites in organic fertilizers directly impact on the environment with negative ecosystem health.

Estimates of total annual global antibiotic consumption in agriculture vary considerably due to lack or existing weak surveillance and data collection systems in many countries and they range from around 63,000 tonnes to over 240,000 tonnes [10]. However, it is clear by any measure that antimicrobial use is widespread, on a scale at least equivalent to use in humans, and is projected to increase. Van Boeckel et al. estimated that global consumption of antimicrobials in agriculture will increase by 67 percent from 2010 to 2030, and consumption of antimicrobials amongst the Brazil, Russia, India, China and South Africa will increase by 99 percent in that same time period. [11] Globally, AMR will cause shortfall in Gross Domestic Products (GDP) ranging between US $1 - 3.4 trillion annually from the year 2030 with the current AMR trend [12]. It is estimated that approximately 10 million people will die annually by the year 2050 given the current scenario [13]. Similarly, the annual global GDP may be reduced by 2.5 - 3% in 2050 relative to a base-case scenario with no AMR effects. In Low-Income Countries (LICs), AMR frequently occurs in microorganisms that are likely to be transmitted in the community such as *Mycobacterium,* Neisseria *gonorrhoea* [14], *Vibrio* infections and *Campylobacter* [15].

According to Food and Drug Administration (FDA) (2011), between 50 and 70 percent of medically important antimicrobials in humans are also used in livestock. Studies suggest that 75-90 percent of tested antimicrobials are excreted from animals un-metabolized and enter sewage systems and water sources thus contaminating the ecosystems. In this scenario, animal wastes can contain resistant bacteria and antimicrobials that could then foster the emergence of resistance in bacteria beyond those in animal guts – including bacteria that may pose a greater risk to humans and animals [10]. Manure from farm animals is often used on crops as a fertilizer which has been shown to create resistance.

In the United Republic of Tanzania (URT), agriculture contributes to at least 30% of the national GDP and 67% of the total employment. The livestock industry contributed about 13%, to the Agricultural GDP and 7.9% to the National GDP in 2015. Despite low contribution of livestock sector to the regional agriculture GDP, the livestock population and distribution has been increasing steadily ranking first in the EAC and SADC. The scenario of antimicrobials usage in human and animal health in Tanzania is similar to other developing countries.

CHAPTER TWO

JUSTIFICATION FOR AMR SURVEILLANCE

The Joint External Evaluation (JEE) report of IHR core capacities conducted in the Tanzania Mainland in 2016 indicated a lack of capacity for AMR detection and surveillance of infectious caused by AMR pathogens. The FAO Assessment Tool for Laboratory and AMR Surveillance System (ATLASS) Progressive Indicator Pathway score for AMR surveillance system in the country indicated to be level 1, which is mostly due to a lack of standardized methods in laboratories practicing AST and data collection for the monitoring of indicators of AMR for animals, agriculture and environment. The findings of these independent and joint reports clearly indicated the country's capability to manage AMR and their associated threats is below the global recommended levels, underscoring the need to address challenges related to AMR and hence the developments of this surveillance framework.

Moreover, the framework is intended to compliment the requirements of the National Action Plan for AMR (2017-2022) that outlines AMR and AMU surveillance and monitoring activities as one of the key component to be addressed nationally. In the URT, legislations regulating antibiotic use as well as monitoring and control of their residues are not adequately enforced (Nonga et al., 2009). The inadequacy probably explains the reported high rates of antimicrobial resistance in human, animals and residues in animal products, crops and the environment.

In Tanzania, there is no surveillance guideline governing the use of antimicrobials and their associated effects in human, food producing animals, plant and environment. Individual researchers and scientists from different institutions in Tanzania have been working on AMR, but their research findings are not well coordinated to influence policy. Therefore, the purpose of this AMR surveillance framework is to comprehensively and in a systematic manner collect, collate and generate information that will mitigate the AMR and antimicrobial misuse in these sectors through effective monitoring of pathogens, Antimicrobial use (AMU), antimicrobial sensitivity testing, antimicrobial residues and enhancing the prudent use of antimicrobials through communication of outcomes to the public.

Laboratory based AMR surveillance is required for national action plan in the monitoring of emergency and spread of antimicrobial resistance. The generated data will be essential to inform and direct policy on AMR. The ultimate goal of this AMR surveillance Framework is to enable standardized, comparable and validated data on AMR to be collected, analyzed and shared, in order to inform decision-making, drive local and national action and provide the evidence base for action and advocacy.

While recognizing the global importance of drug resistance among viruses, fungi and parasites, this framework focuses on common bacteria causing infections in Tanzania but, will also consider pathogens identified globally as priority organisms for the early implementation of AMR surveillance. It is anticipated that activities which improve the isolation, identification, susceptibility testing and reporting of these organisms will eventually support development of clinical diagnostics for other pathogens.

CHAPTER THREE

SURVEILLANCE OF ANTIMICROBIAL RESISTANCE IN HUMAN

3.1 SITUATIONAL ANALYSIS OF AMR IN HUMAN

The most important problem associated with infectious disease is the rapid development of AMR that threatens the effective treatment and prevention of an ever-increasing range of infections caused by bacteria. Developing countries including Tanzania that bear 95% of the global burden of infectious diseases rely on empirical antimicrobial treatment to counteract these infections [16]. Tied with burden of infectious diseases, in Tanzania very high rates of resistance have been observed in bacteria that cause common health-care and community-acquired infections [17,18] and alternative options are very expensive to afford. Furthermore, infections due to these multi-drug resistant organisms are associated with increased mortality and morbidity [19].

Bacterial pneumonia, bloodstream infections (BSI), urinary tract infections (UTI), bacterial sexually transmitted infections, and healthcare-associated infections such as methicillin-resistant *Staphylococcus aureus* (MRSA) are among the important bacterial infections requiring antibiotics prescription. Data generated from individual researches and scientists from different institutions, shows enormous burden of antimicrobial resistant pathogens causing these infections [20-22]. Despite availability of data from individuals' researches, there is lack of unified standardized AMR surveillance system to determine the burden of AMR pathogens countrywide.

Studies have often reported very serious BSI requiring immediate antibiotic treatment with prevalence/ incidence rate of 10% in children under 14 years; 13.9% in children under 7 years; 7.5% in children under three years; and 14% in both children and adults [20, 23-25]. Neonatal sepsis rate has been reported as high as 39% of neonates admitted in neonate unit [26]. Most of bacterial isolates reported were highly resistant to commonly prescribed antibiotics; overall 60-80% of all Gram-negative isolates were resistant to Cotrimoxazole; 62.7-100% resistant to ampicillin, up to 67% resistant to gentamicin, 49% resistant to third generation cephalosporin and 14-49% were Extended spectrum beta-lactamases (ESBL) producers [23, 26-28]. A recent study from Tanzania Island, reported that six of seven *Salmonella typhi* isolates from BSI were multidrug resistant [24]. In the North-Western part of Tanzania mainland, *Salmonella* spp. were sensitive to ceftriaxone and imipenem, while being 84%, 69.2%, 38%, and 8% resistant to chloramphenicol, ampicillin, sulfamethoxazole/trimethoprim and ciprofloxacin respectively [21]. High levels of resistance of Gram positive bacteria from BSI were observed in penicillin G (70.6% - 91%) [23] whereas other study reported 28% of MRSA[26].

UTI is the second most common site of infection after Acute Respiratory Infection (ARIs) in the community and incidence varies by age, gender and health status. The prevalence in Tanzania varies from 13.9% in pregnant women to 39.7% among under-fives [20, 29- 31]. In all in country previous studies, *E. coli* was the most common cause of UTI, followed by *Klebsiella pneumoniae*. More than 85% of all isolates were resistant to ampicillin, 77% to Cotrimoxazole, 14-51% to Ceftriaxone, 14-27% to Ciprofloxacin [20, 29-31]. Generally, there has been an increasing trend of bacteria to become resistant to most prescribed antibiotics. Among *E. coli* isolates from urine; amoxicillin-clavulanate resistance has been increasing from 31.4% in 2004

[32] to 69.6 % and 85.7% in 2010 and 2014, respectively [20, 33]. Resistance trend to gentamicin among *E. coli* isolated from urine specimens has been found to range from 8.6% in 2004 to more than 44% in 2011at Muhimbili National hospital (MNH) [20, 32].

Resistance rate of *E. coli* to ciprofloxacin an alternative empirical treatment of UTIs when resistance to Cotrimoxazole is over 20% was found to be between 8.1% and 30.4% at Bugando Medical center (BMC) and MNH respectively [20, 31]. The rate of resistance of *E. coli* to ceftriaxone at BMC was found to increase from 14% in 2009 to 29.4 % in 2011 [29, 31] while at MNH, 49.3% and 50% of *E.coli* were resistance to ceftazidime and cefotaxime, respectively [20]. Two studies at MNH on Enterobacteriaceae causing hospital and community UTI found 23.8 - 45.2% of all isolates were ESBL producers [17, 20].

Surgical site infection (SSI) is among the common hospital acquired infections in developing countries. In Tanzania, *S. aureus*, *E.coli*, *K. pneumoniae*, *Acinetobacter* spp and *Pseudomonas aeruginosa* are among the predominant pathogens causing SSI. Recent studies from referral and tertiary hospitals reported 18.8% and 44% of *Staphylococcus aureus* isolates respectively [22, 34-35]. Moreover 71% [35] and 79.3% [22] were ESBL producers. The majority of *Acinetobacter baumannii* isolates from SSI at MNH, were highly resistant (73% to 100%) to most antimicrobial agents and 60% appeared to be [37]moderately sensitive to imipenem [22].

Previous studies in Tanzania revealed multi-drug resistant bacteria in diarrheal disease etiologic agents with 38% of diarrheagenic *E. coli* (DEC) found to be multi-resistant [36-37] and *Shigella* isolates were resistant to several antimicrobial agents. A recent study in Dar es Salaam found DEC displayed high rates of resistance to Cotrimoxazole (90.6%) and ampicillin (96.9%) while 56.2% found moderately resistant to chloramphenicol. At the same time *Shigella* spp. showed high rate of resistance to Co-trimoxazole (93.3%) [38]. Another study from a health facility in North-Western, Tanzania on susceptibility pattern of *Shigella* from patients with dysentery found highly resistant to tetracycline, Trimethoprim-Sulphamethoxazole, ampicillin and chloramphenicol [39].

Neisseria gonorrheae is often resistant to first-line antibiotics but data on antimicrobial resistance of *Neisseria gonorrheae* etiologic agent for gonorrhea are scarce. The study done in 2013, showed high resistance rates of *N. gonorrhea* to ciprofloxacin (77.7 % which had replaced Cotrimoxazole as first line [40].

Despite availability of these data on resistance patterns of different pathogenic bacteria, generalization of the findings is very difficult due unequal sample size representation and different study methodology. Therefore, having one systematic surveillance system across the country could shed light on the burden of antimicrobial resistance.

Currently the laboratory capacity in Tanzania is depicted by the existence of policy for ensuring quality of laboratory diagnostic capacities. The national laboratory quality standards/guidelines have been established, some laboratories at referral level participate in international EQA schemes, staff at all levels (Regional, Zonal and Reference Laboratories) have been trained in laboratory practices for isolation, identification and antimicrobial susceptibility testing (AST) performance. To date five referral laboratories including NHLQATC, have been accredited by SADCAS under ISO 15189, however 3 of them the microbiology section was not included

for accreditation. There is a program involving regional, special and some of faith based laboratories on accreditation process through SLMTA of which 48 Laboratories are enrolled in the program. However, there is limited laboratory diagnostic capacity for culture and AST at regional and district level often due to supply chain and human resource issues.

3.2 GOAL AND OBJECTIVES

Surveillance of AMR in human is critical for providing data on the extent and trends of the AMR problem. In Tanzania, there is no AMR surveillance in the context of a One Health approach which in turn limits national efforts to tackle AMR. Through the National Action Plan (NAP) on Antimicrobial Resistance 2017-2022, the national surveillance system for AMR will be established. Laboratory-based surveillance is required for national action in the monitoring of AMR and its spread. For reliable microbiological and AST, it is imperative to equip laboratories with equipment, reagents and human resource. Furthermore, a coordinated mechanism for AMR reporting will be established in order to share information in one health approach.

3.2.1 GOAL OF AMR SURVEILLANCE SYSTEM

The primary goal of this AMR surveillance system in human is to generate evidence on the burden of AMR among priority pathogens isolated in hospitals from in-patients and outpatients who have been referred for laboratory testing

3.2.2 STRATEGIC OBJECTIVES

The goal of antimicrobial resistance surveillance will be met through the following strategic objectives

i. Conduct routine AST on pathogens isolated from specimens of inpatients and/or outpatients with clinical infections at surveillance hospitals

ii. Establish monthly reporting of AST results and patient data from surveillance sites to National Health Laboratory Quality Assurance and Training Centre (NHLQATC)

iii. Establish regular and systematic communication of AST results from testing laboratories to clinical providers, infection prevention and control (IPC) and stewardship committees as described in this document

iv. Analyze, interpret, and publicly report annual AMR surveillance data in a written report at each surveillance site

v. Participate in global AMR surveillance through reporting to WHO

3.3 SURVEILLANCE METHODS

3.3.1 ROAD MAP FOR AMR SURVEILLANCE IMPLEMENTATION

The implementation period for the Tanzania AMR Surveillance System will be during 2018–2021. Five health facilities are proposed for phase I roll-out AMR surveillance with potential expansion to additional ten facilities in phase II and phase III during this period (2018 – 2021). Before initiation of AMR surveillance, laboratory assessment will be conducted to establish the capacities of facilities. This assessment will then give a true picture of which surveillance sites to be included in phase I, II and III from the list in table 1. Program success in initial phase will guide scaling-up of the surveillance sites. Extension of AMR surveillance to include other facilities will occur when

laboratories are functioning at acceptable capacity. After 6-months of surveillance activities, a formal program evaluation to assess challenges and program revision shall be performed with support from local and international stakeholders. This process will repeat every 12-months as additional sites are added (Appendix II)Table

1: List of proposed sites for AMR surveillance implementation

S/N	Surveillance site	Region
1	Muhimbili National Hospital	Dar es Salaam
2	Mbeya Referral Hospital	Mbeya
3	Bugando Medical Centre	Mwanza
4	Kilimanjaro Christian Medical centre	Moshi
5	Ndanda Hospital	Mtwara
6	Temeke Regional Referral Hospital	Dar es Salaam
7	Kibong'oto Hospital	Moshi
8	Amana Regional Referral Hospital	Dar es Salaam
9	Maweni Regional Referral Hospital	Kigoma
10	Mawenzi Regional Hospital	Kilimanjaro
11	Mount Meru Regional Hospital	Arusha
12	Musoma Regional Hospital	Mara
13	Mbeya Regional Hospital	Mbeya
14	Seketule regional Hospital	Mwanza
15	Mnazi mmoja Referral Hospital	Zanzibar
16	Sumbawanga Regional Hospital	Rukwa
17	Morogoro Regional Hospital	Morogoro
18	Dodoma Regional Hospital	Dodoma
19	Mpanda Regional Hospital	Katavi
20	Kitete Regional Hospital	Tabora
21	Kagera Regional Hospital	Kagera
22	Shinyanga Regional Hospital	Shinyanga
23	Benjamini Mkapa Hospital	Dodoma
24	MUHAS Academic Medical Centre	Dar es Salaam
25	Ifakara Referral Hospitals	Morogoro

3.3.2 SURVEILLANCE ROLL-OUT SITE PREPARATION

Prior to participation in AMR surveillance, facility´s laboratory will be assessed using standardized laboratory assessment tool for AMR to assess Laboratory capacity in microbiology section including record keeping, organization, personnel, facility, equipment, purchasing /inventory, quality control (QC)/quality assurance (QA), basic bacteriology, human resources and information systems. There shall be training of trainer on AMR surveillance who will be used to provide mentorship to the laboratories participating in AMR surveillance.

In preparation for the initiation of surveillance, extensive sensitization and training on the AMR surveillance strategy and procedures will be conducted for hospital administration and relevant clinical and laboratory personnel from selected sentinel sites. Hospital administrators will be requested to designate AMR site coordinators from both the clinical and laboratory departments and ensure that the program can be actively promoted. Laboratories will be trained on surveillance requirements and procedures for culture, identification, AST, quality control, external quality assurance, data reporting, and all relevant standard operating procedures (SOPs).

The AMR site coordinators will attend a sensitization workshop where the AMR surveillance system strategy, as defined in this document, will be described in detail. Additional on-site meetings and orientation will be held to familiarize clinicians with good specimen collection practices, increase awareness of the national AMR surveillance system, allow laboratorians to review the format and implications of AST results provided to clinicians, alert clinicians to the availability of hospital AMR data, and foster clinician-laboratory communication for discussion of AMR organisms in individual patients, the hospital system, and the region.

In the initial implementation period, participating laboratories will be provided with guidance on surveillance and reporting requirements, laboratory methodology, and QA as outlined in standard operating procedures (SOPs) for specimen collection, laboratory culture, and AST. Participating hospitals will also be asked to provide data regarding the catchment population (e.g., number of patients seeking care, demographics). Key activities during roll-out of AMR surveillance are summarised in Table 2. A reverse EQA (confirmatory testing at NHLQATC) will be conducted quarterly in-addition to EQA panel provided by the external provider be conducted quarterly

Table 2: Steps and key activities during roll out AMR surveillance

S/N	Key Activities
1	Conduct meeting to review/harmonize the proposed AMR surveillance plan draft, assessment tools, SOPs and other manuals
2	Develop standard operating procedures (SOPs) for AMR surveillance
3	Assessment of National Reference Laboratory for AMR surveillance implementation
4	Technical support of National Reference Laboratory for AMR surveillance implementation
5	Assessment of proposed AMR surveillance sites (labs and Hospitals)
6	Conduct workshop for proposed AMR surveillance sites
7	AMR training workshop for clinician
8	Disseminate the AMR surveillance, tools, SOPs, manuals, and forms
9	Establish an electronic system for AMR data repository
10	Equip the national laboratory with equipment for bio-bank/bio repository
11	On site train of AMR surveillance sites personnel on culture, identification and AST for priority pathogens
12	Develop the master list for the materials/reagents/items, required for AMR surveillance and supply mechanism to ensure constant availability
13	Initiate implementation of AMR surveillance at site level
14	Provide mentorship and supportive supervision to facilities implementation of AMR surveillance
15	Train laboratory personnel, on AMR QA program
16	Institute EQA for AMR testing basing on the WHO guidelines and ISO standards to participating laboratories
17	Support implementation, of EQA AMR scheme for appointed laboratories
18	Report for AMR data to national and Global surveillance sites

3.4 DESCRIPTION OF SURVEILLANCE STRATEGY

3 .4.1 ROUTINE CLINICAL SURVEILLANCE METHODOLOGY

In this surveillance, the primary method for surveillance of AMR organisms will be routine inpatient and out-patient collection of clinical specimens at participating hospitals. Specimens will be cultured and AST performed on all isolated pathogens. For all specimens positive for a priority organism(s), patient and laboratory data shall be reported into a laboratory information management system capable of facilitating reporting requirements (Figure 1). A standard data collection tool [Appendix II] will be used to record all surveillance data. AMR surveillance data will be entered into WHONET software and/or a computerized database at surveillance site level and also saved as hard copy at surveillance site.

AST results will then be returned to clinicians, IPC and AMR teams. All isolates from each surveillance site will be stored at-70 °C for future studies. Collected data will then be submitted to NHLQATC, which will make it available to the AMR Unit in the Ministry of Health to generate reports and policy. Isolates with unusual, unexpected or indeterminate resistance patterns shall be sent to NHLQATC for confirmatory testing and AST. Every 10th isolate from each site shall be send to NHLQATC for QA. NHLQATC also will conduct aggregated data reporting to WHO completing the global component of the surveillance system.

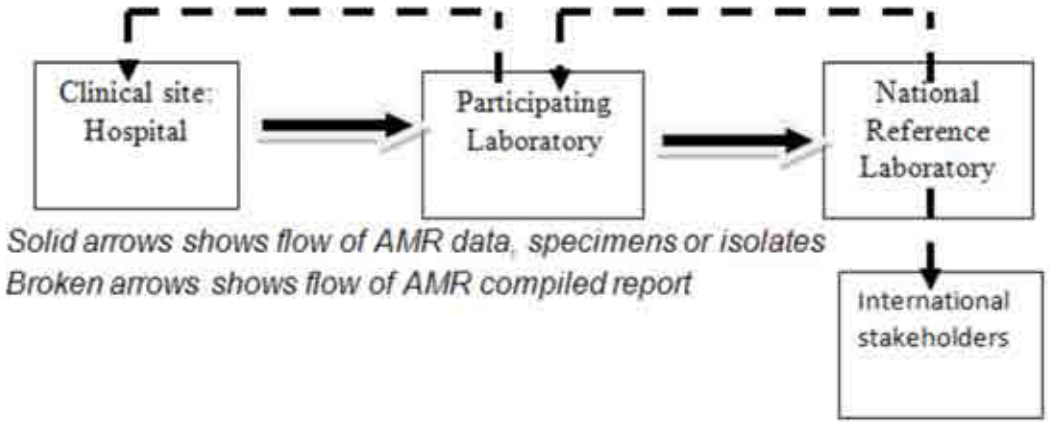

Figure 1: Simplified diagram of AST data sharing and isolate/sample transmission in the Antimicrobial Resistance Surveillance System

3.4.2 PRIORITY SPECIMENS, ORGANISMS AND ANTIBIOTICS

Priority specimens for AMR surveillance in Tanzania include urine, blood, stool, cerebral spinal fluid (CSF), wound swabs/pus, and genital swabs (urethral and cervical). The first priority specimens for AMR surveillance for this surveillance plan shall be blood and urine cultures. This will then be followed up by other priority specimens once laboratories have been able to accurately report AST from urine and blood priority pathogens. The choice of priority specimens to follow may be revised during surveillance based on the capacity of laboratories to process the priority specimen and surveillance implementation. Priority pathogens to be considered for AMR surveillance in Tanzania include current GLASS list for global reporting and bacteria causing common infections in the country [table 3].

AST will be conducted according to the guidelines of the Clinical and Laboratory Standards Institute (CLSI) and the NHLQATC will provide standard operating procedures (SOPs) to the sites or review and harmonize the SOPs currently in use at the participating laboratories. The priority organisms and antimicrobials for which susceptibility testing will be conducted are shown in table 4. However, the list of antibiotics is not exhaustive, facilities will be required to test all antibiotics highlighted in their SOP, but only listed on table 4 will be reported to Global Antimicrobial Resistance Surveillance System (GLASS).

Principle for consideration of bacteria-antimicrobial drug combinations selection will be based on: compliance with GLASS manual, recommended first-line treatment or surrogate substances for AMR, and AST international guidelines.

Table 3: Priority surveillance pathogens by specimen for Tanzania AMR surveillance

Specimen	Laboratory case definition	Priority organisms for surveillance
Blood	Isolation of pathogen from blood	*E. coli, K pneumoniae, A. baumannii, S. aureus, S. pneumoniae, Salmonella* spp.
Urine	Significant growth in urine specimen[a]	*E. coli, K. pneumoniae*
Stool	Isolation of *Salmonella*[b] or *Shigella* spp. from stool	*Salmonella* spp, *Shigella* spp.
Urethral and cervical swab	Isolation of *N. gonorrhoeae*	*N. gonorrhoeae*
CSF	Isolation of *S. pneumoniae* and *N. meningitidis*	*S. pneumoniae and N. meningitidis*
Wound swabs/pus	Isolation of pathogens from swabs	*E. coli, K. pneumoniae, A. baumannii, S. aureus. Pseudomonas*

[a] Pure culture according to local laboratory practice. Catheter samples excluded.
[b] Diarrhoeal surveillance is for non-typhoid salmonella species; for local clinical purposes, typhoid and paratyphoid should be included.

Table 4: Priority pathogens-antimicrobial combinations for Tanzania AMR surveillance

Pathogen	Antibacterial class	Antibacterial agents that may be used for AST[a,b]
Escherichia coli	Sulfonamides and trimethoprim	Co-trimoxazole
	Fluoroquinolones	Ciprofloxacin or levofloxacin
	Third-generation cephalosporins	Ceftriaxone or cefotaxime and ceftazidime
	Fourth-generation cephalosporins	Cefepime
	Carbapenems	Imipenem, meropenem, ertapenem or doripenem
	Polymyxins	Colistin
	Penicillins	Ampicillin

Klebsiella pneumoniae	Sulfonamides and trimethoprim	Co-trimoxazole
	Fluoroquinolones	Ciprofloxacin or levofloxacin
	Third-generation cephalosporins	Ceftriaxone or cefotaxime and ceftazidime
	Fourth-generation cephalosporins	Cefepime
	Carbapenems	Imipenem, meropenem
	Polymyxins	Colistin
Acinetobacter baumannii	Tetracyclines	Tigecycline or minocycline
	Aminoglycosides	Gentamicin and amikacin
	Carbapenems	Imipenem, meropenem
	Polymyxins	Colistin
Staphylococcus aureus	Penicillinase-stable beta-lactams	Cefoxitin
Streptococcuspneumonia e	Penicillins	Oxacillin , Penicillin G
	Sulfonamides and trimethoprim	Co-trimoxazole
	Third-generation cephalosporins	Ceftriaxone or cefotaxime
Salmonella spp.	Fluoroquinolones	Ciprofloxacin or levofloxacin
	Third-generation cephalosporins	Ceftriaxone or cefotaxime and ceftazidime
	Carbapenems	Imipenem, meropenem
Shigella spp.	Fluoroquinolones	Ciprofloxacin or levofloxacin
	Third-generation cephalosporins	Ceftriaxone or cefotaxime and ceftazidime
	Macrolides	Azithromycin
pseudomonas	Tetracyclines	Tigecycline or minocycline
	Aminoglycosides	Gentamicin and amikacin
	Carbapenems	Imipenem, meropenem
	Polymyxins	Colistin
Neisseria gonorrhoeae	Third-generation cephalosporins	Cefixime, Ceftriaxone
	Macrolides	Azithromycin
	Aminocyclitols	Spectinomycin
	Fluoroquinolones	Ciprofloxacin
	Aminoglycoside	Gentamicin
Neisseria meningitidis	Third-generation cephalosporins	Ceftriaxone
	Macrolides	Azithromycin
	Fluoroquinolones	Ciprofloxacin
	Phenicols	Chloramphenicol

[a] Listed substances are priorities for resistance surveillance in each pathogen but might not be first-line treatment options. [b] One or more of the drugs listed may be tested.

3.5 SURVEILLANCE STANDARDS

Minimum AMR surveillance laboratory capabilities are outlined in Table 5. Laboratory surveillance sites must meet the technical laboratory skill, QC, EQA, and data management minimum capabilities to participate in the AMR Surveillance System. A standardized assessment tool will be used to assess each proposed site. The assessment will be used to both determine eligibility to participate and to identify any deficient areas to be addressed prior to surveillance start.

Table 5: Minimum requirements for laboratory participation as a surveillance site in the AMR Surveillance System

Capacity	Minimum Requirements
Technical laboratory skills	· Identify priority organisms and perform AST in accordance with EUCAST and/ or CLSI standards · Perform AST by using disc diffusion, semi-automated, or manual testing for minimum inhibitory concentration and gradient diffusion
Quality control	· Utilize a NHLQATC-approved QC system · Maintain QC data records for potential review by NHQATC
External quality assurance	· Participate in a recognized EQA program · Achieve acceptable performance reviews on periodic EQA dispatches
Data management	· Make commitment to collect and report good-quality data in accordance with reporting timelines · Employ staff trained in collecting, analyzing and reporting epidemiological, clinical and laboratory data · Dedicate time for staff member(s) to regularly input, analyze, and report data
Hospitals' clinical and laboratory departments	· Willingness to participate · Adequate physical infrastructure and equipment · Adequate existing human resources · Microbiology expertise among laboratory staff · Patient populations - patient admissions and out-patient attendance) · Information Systems

3.5.1 CLINICAL SPECIMEN COLLECTION AND TRANSPORT STANDARDS

As part of routine clinical care, clinicians at participating hospitals will send a sample(s) for culture and AST from inpatients and outpatients with suspected infection to the laboratory accompanied with standardized laboratory requisition form [Appendix III]. The laboratory requisition form includes the minimum patient data that shall be submitted with a clinical specimen including the following elements which are necessary for AMR surveillance data analysis:

- Hospital / Facility Name
- Patient Name
- Unique Patient Identifier (e.g. Patient Medical Record Number)

- Date of Birth [or Age]
- Sex
- Inpatient / Outpatient
- Patient Ward / Location
- Admission Date
- Specimen Type
- Date of Specimen Collection

For consistency quality specimen collection, AMR focal person at each hospital ensures that physician and other healthcare workers are provided with SOPs for specimen collection and transport. Laboratory will assess and accept submitted specimens based on acceptance criteria. It is the laboratory's responsibility to ensure that clinicians have the appropriate containers and materials for priority specimen collection and that an adequate supply of these materials is maintained at all times. Laboratorians who suspect that specimen collection SOPs are not being followed (e.g., high level of specimen contamination with environmental organisms, hemolyzed samples) should meet directly with the clinical team to review collection procedures.

3.5.2 PATIENT SAMPLING STANDARDS

The clinical sampling for AMR surveillance shall be guided by the syndromic diagnosis for which patient is being treated. This supports interpretation of the data to guide empiric therapies in the situation if only clinical treatment failures or the most seriously ill patients are investigated. Sentinel site laboratories will also process other samples; however, capacity building and data collection should initially focus on priority specimen as a core function.

3.5.3 LABORATORY STANDARDS

3.5.3.1 PATHOGEN ISOLATION AND IDENTIFICATION

Specimen culture and testing for antimicrobial susceptibility will be done by sentinel site laboratories. Isolates with unusual susceptibility profiles, or of uncertain identification, shall be referred to the NRL for AMR as well as a proportion of all isolates for QC purposes. Reporting for AMR surveillance shall focus on the 10 national priority pathogens with the eight WHO priority pathogens included, as described in the GLASS manual and national priorities. These include:-

- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Acinetobacter baumannii*
- *Staphylococcus aureus*
- *Neisseria meningidis*
- *Streptococcus pneumoniae*
- *Salmonella* spp.
- *Shigella* spp.
- *Pseudomonas*
- *Neisseria gonorrhoeae*

The pathogens shall be identified by using relevant biochemical and/or serological tests following SOPs

3.5.3.2 ANTIMICROBIAL SUSCEPTIBILITY TESTING

AMR surveillance shall include the following bacteria-antimicrobial drug combinations in compliance with the GLASS manual (table 6). Antimicrobial susceptibility testing for priority pathogens shall be carried out in line with Clinical Laboratory Standards Institute (CLSI) guidelines, using the disc diffusion method.

The laboratories shall document whether isolates are susceptible, intermediate or resistant (S/I/R) according to clinical breakpoints defined by CLSI together with the zone sizes (mm) to allow for retrospective adjustment if new breakpoints are set. As the laboratory performance becomes acceptable, minimum inhibitory concentrations (MICs) may be determined by broth dilution (manual or automated) or gradient diffusion tests such as E-Tests. MIC values shall be recorded. These shall happen after reviewing with the labs that will be part of this surveillance system to see if this is feasible. When a new drug is introduced into clinical practice, laboratories will routinely test susceptibility to the drug in order to identify emerging resistance. Laboratory staff will be trained to recognize unusual or unexpected findings in routine samples. They will also be instructed to inform NHLQATC when this happens and if needed request technical assistance.

3.5.4 QUALITY CONTROL

Surveillance laboratories will be required to follow the guidelines for microbiology laboratory Quality Control (QC) as published by WHO (WHO 2003) or CLSI. Laboratories will review the components of their QC system with NHLQATC in the initial assessment. Internal quality control (IQC) is a routine procedure undertaken by laboratories to ensure quality of tests. IQC procedures shall be set up by laboratory management on regular periodic basis for tests they perform, and the results shall be recorded and discussed with all staff members. QC procedures must be practiced for each testing method used by the laboratory. Each test kit should have a set of positive and negative controls that are to be included in each test run. QC data sheets and summaries of corrective action shall be retained for documentation.

- These are be reviewed and checked periodically by the NHLQATC.
- Supervisory review shall be performed for out-of-range QC results and laboratories shall document corrective action that was taken on all QC failures.

IQC should cover all steps of each diagnostic test from the collection of specimen to the transmission of the results, as well as media production and maintenance of equipment. IQC testing should be performed regularly with each laboratory determining the frequency depending on the load of specimens it receives for antimicrobial susceptibility testing. Ideally, each batch of AST should be accompanied by an IQC. Laboratory equipment should be assessed on a regular basis to ensure maintenance and quality.

The use of reference bacterial strains as recommended by standard guidelines on AST such as CLSI and will contribute to the monitoring of the accuracy of the results. If the results for the control strain are accurate, i.e. all antimicrobial agents are in the control range, the procedure is assumed to be accurate and so AST may be performed on significant isolates. If the zones produced by the QC strains are out of the expected ranges, the technical personnel should try to determine the possible sources of the error and should troubleshoot the causes. If additional assistance is needed the sites will request assistance if they are unable to resolve the error on

their own from NHLQATC. IQC must be performed prior to initiating AST on the isolates. The control strains for the laboratories will be purchased from the American Type Culture Collection (ATCC) and the National Collection of Type Cultures (NCTC).

3.5.5 EXTERNAL QUALITY ASSURANCE

EQA is a system for validating laboratory performance using an external, objective agency. All laboratories participating in AMR surveillance shall participate in a formal EQA scheme for all tests performed. Proficiency testing (PT), re-testing (rechecking) and on site evaluation shall be used as EQA methods where laboratories process samples/isolates using the normal testing methods by staff who routinely handle such samples. PT results must be reported according to instructions and submitted within required deadlines to agency implementing EQA, which provides feedback and allows comparison with results from other laboratories.

Laboratories will also undergo an in-person visit by NLQATC at least twice yearly to review EQA and QC performance, assess all aspects of laboratory testing required to isolate and identify priority organisms and to detect resistance, assess data management quality, and answer questions that the laboratory might have. Each laboratory manager or head of laboratory must deal with unacceptable PT results, and corrective action must be taken and documented. The lab manager shall review EQA results and conduct root cause analysis and correction when corrective action failure occurs.

In retesting and rechecking EQA, every 10th isolate from each surveillance sites will be send to NHLQATC for rechecking, and feedback will be provided for corrective action. In addition, during onsite evaluation visit, stored isolated will be picked randomly and retested for QA.

For sustainability of EQA program during surveillance period, capacity need be built at NQLATC to ensure consistent supply of PT materials to participating laboratories. At the beginning of the surveillance, PT will be conducted twice a year, retesting of isolates at NQLATC from surveillance site will be performed quarterly. On site visit evaluation retesting will depend on the number of visits to the surveillance sites.

3.5.6 ISOLATE REPOSITORY AND CONFIRMATORY TESTING

Zonal laboratories will serve as repository for priority AMR isolates from all participating laboratories in that zone. Once a month, sites will send AMR priority isolates to the zonal laboratories for isolate repository. Prior to and during transport, isolates will be stored, in accordance with SOPs at -20°C or -80°C. The repositories will be equipped with ultra-low freezers, generator and a robust electronic specimen tracking system with bar-coding to allow for retrieval of bacterial isolates overseen by a freezer manager. This resource will be a key asset in promoting nationally relevant research as it will house isolates and sources in the AMR surveillance network. Once a quarter, every 10% isolate found to have a priority AMR organism sent for repositories will undergo confirmatory testing. The zonal laboratories will investigate any discrepant results for correction.

3.5.7 PROCUREMENT OF ESSENTIAL REAGENTS, SUPPLIES AND EQUIPMENT

Participating laboratories are responsible for ensuring appropriate inventory management of all necessary reagents, supplies and equipment for isolation, identification and AST of priority pathogens. Laboratories are also responsible for adhering to and keeping records of proper equipment maintenance. Participating laboratories will require training on inventory management, supply chain management system, and equipment maintenance. In addition, NHLQATC will maintain a listing of quality supplies and suppliers. The laboratory will follow ISO guidelines for total quality system implementation to monitor the consumption of reagents and supplies and to restock these in sufficient time so that regular activities are not interrupted and MOHCDGEC will ensure timely repair and preventive maintenance of equipment.

3.5.8 REPORTING STANDARDS

Reporting of results requires efficient data management at both surveillance sites and national levels. QC will be incorporated at every stage, with automated data validity checks and rules, as well as audit to check data consistency, completeness and accuracy. Confidentiality will be protected and data security measures should be in place. The site coordinator ensures individual case-level anonymized data are submitted to the NHLQATC with health facility data. These include the total number of patient episodes and the total number of samples processed in the laboratory. The NHLQATC should feedback sentinel site data at least quarterly to healthcare administration, clinical and laboratory staff, to support continued engagement with AMR surveillance.

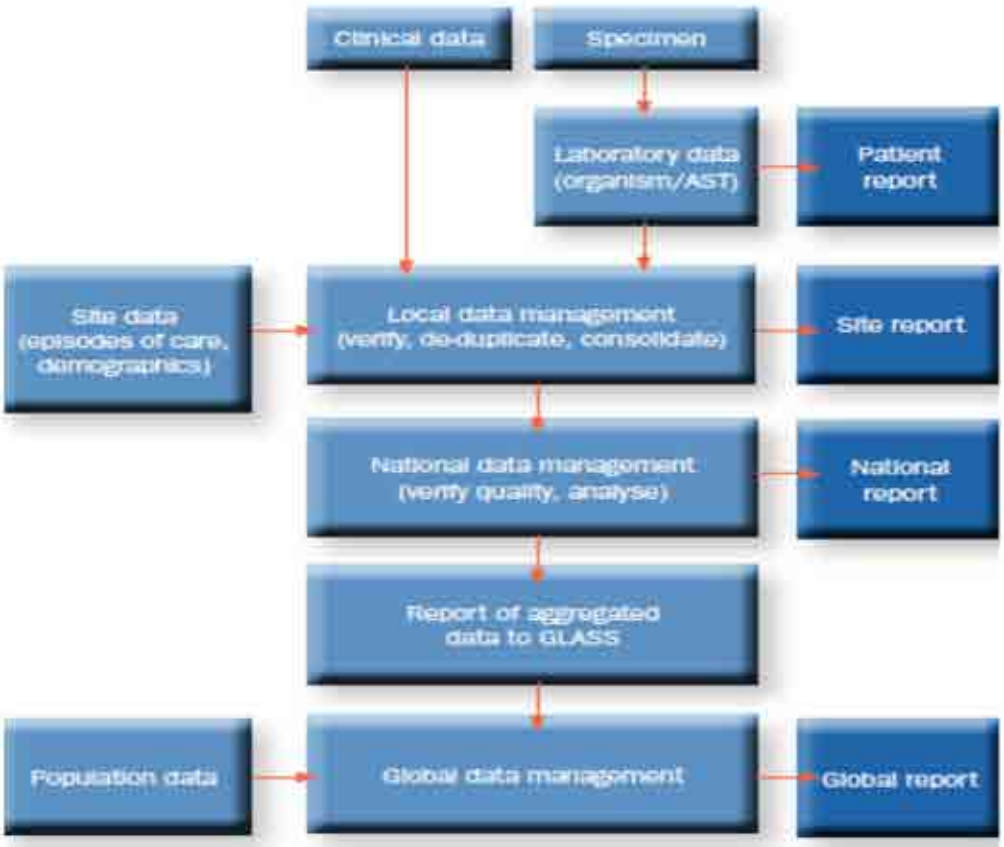

Figure 2: Data flow for AMR surveillance

3.5.8.1 DATA STANDARDS

The validity and efficiency of data collection, transmission, and analysis is a principle concern of any surveillance program. Prior to transmitting the monthly data files to the NHLQATC the data will be reviewed by the laboratory manager at the surveillance site to ensure that data is complete, valid, and in line with AMR surveillance system reporting requirements. AS Per the SOP for Data Management, data files shall be submitted using a uniform filename format that includes laboratory code that has been designated for each laboratory, month, and year.

Participating surveillance sites shall enter patient and laboratory data into data management software and shall report AST results specifically linked to patient infections and reported with some clinical data. This reporting standard is referred as patient-based surveillance. Under patient-based surveillance, AST results shall not be reported if they are from a duplicate specimen or if multiple specimens are submitted for culture during the course of a single patient infection.

Patient-based surveillance strives to count the AST profile of each individual infection only once. For example, if patient with sepsis had blood cultures drawn at two separate times throughout the course of their infection, and *E. coli* was isolated from both of their blood cultures, the results of both the first and second *E.coli*-positive blood cultures would be returned to the clinicians, but only the results of the first *E.coli*-positive blood culture would be reported into the AMR surveillance system. If the same patient has a subsequent blood culture positive for a different organism (e.g., *K. pneumoniae*), or if the original organism is later found in another specimen type (e.g., *E. coli* in urine), both these incidents would be counted as separate infections and each reported to the AMR surveillance system. To ensure repeat culture and AST results from a duplicate or subsequent specimen are removed from the AMR surveillance system, de-duplication of non-unique infections will be performed annually by the data manager at the NHLQATC. Each laboratory must also save all electronic files on a local computer or data server as a back-up.

3.5.8.2 SURVEILLANCE SITE REPORTING

In addition to the prompt entry of laboratory results into the record system [e.g. laboratory logbook, laboratory information management system (LIMS)) and return of all routine laboratory culture and AST results to clinical teams, laboratories will transfer the results of all priority AMR organisms from the record system in to WHONET.

Although laboratory data alone (e.g. organism and AST of all isolates) could be reported to the AMR surveillance system in what is referred to as laboratory-based or isolate-based surveillance, it is more informative to include some clinical data which is specifically linked to a patient's infection. This is referred to here as patient-based surveillance.

The following patient and laboratory data elements should be reported for each priority organism isolated from priority specimens of patients in the outpatient / inpatient / both outpatient and inpatient departments:

- Hospital / Facility Name
- Unique Patient Identifier (e.g. Patient Medical Record Number)
- Patient Date of Birth (or Age)

- Patient Sex
- Inpatient / Outpatient
- Patient Ward / Location
- Admission Date (for inpatients)
- Date of Specimen Collection
- Specimen Type
- Pathogen Identification
- Gram Stain
- AST line-listed data (e.g. minimum inhibitory concentration and/or inhibition zone diameter) for each antibiotic tested
- AST interpretation: Susceptible (S), Intermediate (I), and Resistant (R) classification

AMR data will be entered into WHONET. The data manager at the NHLQATC will assist laboratories in data management setup and training. The NHLQATC will also provide sites with a paper-based standard reporting tool [Appendix IV] to capture results prior to electronic entry into WHONET. Laboratory technicians should also use the paper-based tool when technical problems arise with WHONET. Procedures for data entry, storage, and export/transfer are provided in the SOP for Data Management.

On a monthly basis, the raw, line-listed data in the WHONET will be transmitted electronically to the data manager at the NHLQATC. The following should also be reported monthly in order to calculate denominators:

- Total number of specimens processed for each priority specimen type
- Total number of culture-negative specimens for each priority specimen type

Once a year, surveillance laboratories will be asked to provide updated estimates of hospital and population data, including:

- Number and demographics of patients seeking care (separately for inpatient and outpatient)
- Size and demographics of population served by hospital

3.5.8.3 ANTIBIOGRAM CREATION

The laboratory shall create individualized hospital reports, such as antibiograms, to assist in the overall understanding of AMR organisms in that hospital and community. On annually, each surveillance laboratory will use their own AMR data to create their hospital's antibiogram. The antibiogram shall be shared with the relevant clinical departments and hospital committees at the hospital in order to increase understanding of AMR organisms prevalent in that hospital and community, to impact treatment policies at the health facility, and to encourage continued participation in the surveillance system. Guidance on how to create hospital AMR report will be provided to each laboratory by the data manager at the NHLQATC.

3.5.8.4 NATIONAL AND GLOBAL REPORTING

AMR data from surveillance sites will be centrally stored and managed at NHLQATC which will be responsible for conducting data quality checks and data analysis, generating official AMR reports, and providing long-term data storage. Data files received from surveillance laboratories will be reviewed for data quality and will undergo any necessary cleaning and de-duplication prior to importation into the nationwide database. The nationwide database will be backed-up bi-weekly by the data manager at the NRL. Reporting of aggregate national and regional AMR data may be used to efficiently prioritize resources and inform policies directed at control of antimicrobial resistance. The following aggregated data will be included in the reports for each priority specimen type (i.e., blood, urine, stool, etc.):

- Total number of submissions of that specimen type
- Number of culture-negative submissions of that specimen type
- Number of submissions positive for each priority pathogen, by:
    - Pathogen type
    - Patient age group
    - Patient sex
    - Time in hospital at time of specimen collection (< 2 days OR > 2 days)
- All AST results for each priority organism-specimen combination, by:
    - Patient age group
    - Patient sex
    - Time in hospital at time of specimen collection (< 2 days OR > 2 days)

Reports will be published and distributed by MCC at least once yearly, and if indicated, special interim reports or focused analyses will be published. Every 12 months, data from all sites will be aggregated at NHLQATC and reported to WHO in accordance with the WHO Global Antimicrobial Surveillance System protocol

3.7 SURVEILLANCE OF ANTIMICROBIAL USE

One of the major activities in the AMR National Action Plan is the surveillance of the use of antimicrobials. Data on the use and consumption of antimicrobials have a number of uses, including:

- To relate exposure to antimicrobials to the development of antimicrobial resistance
- To identify and provide early warning of problems relating to changes in exposure and utilization and to develop interventions to address problems identified
- Monitoring the outcomes of interventions aimed at changing exposure
- Assessing quality of prescribing against practice guidelines
- Raising awareness in health professionals, consumers and policy makers about the issues of antimicrobial resistance and the contribution of inappropriate use of antimicrobials in humans

3.7.1 MONITORING OF ANTIMICROBIAL CONSUMPTIONS

WHO methodologies for the monitoring of antimicrobial consumption will be used both at the national and facility levels. At the national level, data collection will be done mainly using the import data. Hence, the antimicrobial consumption data at national level will be collected periodically at:

- TFDA - as most of the legal imports are recorded by TFDA including individual imports. The data base will provide the data for all antimicrobial imports to the private sector
- MSD - as a Public Procurement Agency is likely to have reasonable documentation of purchases of antimicrobials distributed to public health facilities and Faith Based Organization
- Local Manufacturers – to provide data on the produced antimicrobial which have been sold locally in a specified period of time and which are excluded from TFDA and MSD systems.

This methodology will provide antimicrobial consumption data at product level which would accordingly provide consumption in terms of packages. The number of grams contained in each package of the given product can be determined as per WHO guidelines which can be divided by the DDD value in grams to get the total number of Daily Defined Dose (DDDs) for that product. To get the estimate of the country consumption for each of the selected products, the collected data on packages converted into DDDs will be further converted into the DDDs/1000inhabitants/day (DID).

Core Set of Antimicrobial under Surveillance

The WHO surveillance program focuses only on antimicrobials for systemic use. Topical antimicrobials are excluded.. Therefore the following group of antibacterials as per the Anatomical Therapeutic Chemical (ATC) classification system are included in the consumption surveillance.

Antimicrobial	WHO Classifications
Antibacterials	J01
Antibiotics for alimentary tract	A07AA
Nitroimidazole derivatives for protozoal diseases	P01AB

3.7.2 MONITORING ANTIBIOTIC USE IN HOSPITALS

Monitoring antibiotic consumption and use at the facility level, the WHO Methodology for Point Prevalence Survey on Antibiotic Use in Hospitals will be used. The tool was piloted in Mwananyamala Regional Hospital and Muhimbili National Hospital in April, 2018.

The WHO methodology collects basic information on all hospitalized patients that are of relevance for treatment and management of infectious diseases. The methodology includes core and optional indicators including:

- Indication for antibiotic prescribed
- Antibiotic prescribed to patient (non-proprietary names, dose, duration, indication etc.)
- Type of prescriber

- If antibiotic is in National Essential Medicines List
- If sample has been taken for microbiology diagnostics
- Type of specimen for microbiology diagnostics
- Isolated organism
- Resistance phenotype etc.

The data obtained will be used to estimate the antibiotic use in hospitals, assess the implementation of standard treatment guidelines, evaluate the impact of stewardship programmes and inform on antibiotic prescribing trends. The information will support Policy Makers, managers, hospital therapeutic committees and Practitioners to raise awareness on prescribing practices in health professionals and design interventions on improving antibiotic use.

3.8 MONITORING AND EVALUATION OF AMR SURVEILLANCE

Monitoring and evaluation of the Country AMR Surveillance System will be established. The evaluation team will be identified (local and external evaluator), with representation from the MCC, NHLQATC, Universities, development partners and some participating laboratories. Evaluation of the program will be guided by the objectives and surveillance system structure. The evaluation team will work together to design an evaluation that will be used to describe and improve program performance and determine the effect of the program. Surveillance system evaluation will be conducted by using an established framework for program evaluation, such as those available from CDC (CDC 1999). Results of the evaluation will be published by the MCC in a special report, and decision makers will use the findings to make adjustments to the Country AMR Surveillance System.

Key Performance Indicators

Key Performance Indicators (KPIs) are used to monitor progress and identify significant problems at sentinel sites where more detailed investigations are needed to understand why the indicators are not being met. The purpose of this investigation is to support sentinel sites to achieve the KPIs. List of key performance indicators for evaluation and monitoring [Box 1]

Box 1: Indicators for a well-functioning sentinel surveillance site

- >80% of all patients admitted with an infectious syndrome are correctly sampled
- >95% of all samples sent for investigation include the physician's clinical diagnosis
- <10% of samples culture an organisms which is not clinically significant (a contaminant)
- >95% of priority pathogens are correctly identified by the sentinel site laboratory (tested against the gold-standard of the coordinating AMR laboratory or by EQA assessment)
- >95% of the resistance profiles are correctly identified by the sentinel site laboratory (tested against the gold-standard of the coordinating AMR laboratory or by EQA assessment)
- <3 month lag time for reporting all AMR data to the NCC

CHAPTER FOUR

SURVEILLANCE OF ANTIMICROBIAL RESISTANCE IN ANIMAL, AGRICULTURE

4.1 SITUATIONAL ANALYSIS IN ANIMAL, PLANTS AND ENVIRONMENT

4.1.1 SITUATIONAL ANALYSIS IN ANIMAL

Domestic animals suffer from high burden of infectious disease such as bacterial, protozoan, fungi and viral. The most common bacterial diseases are Contagious Bovine Pleuropneumonia in cattle, Contagious Caprine Pleuropneumonia in goats and major tick-borne protozoan diseases of cattle namely; East Coast Fever and Anaplasmosis which are treatable with antimicrobials. Also, Salmonellosis, Colibacillosis, Mycoplasmosis, Infectious Coryza and Coccidiosis in chickens are common infections. These, in addition to non-specific infections and preventive management require use of antimicrobials [41].

Studies have reported drug residues in beef, eggs and milk. Antimicrobial use in veterinary services may be grouped into therapeutic, metaphylactic (timely mass medication), prophylactic and for growth promotion. Farmers may use antimicrobials in animals to compensate for poor farm management practices, lack of formal veterinary services, lack of regulatory capability and because of the prevalent animal diseases. Under these practices, it is likely that farmers are unaware of potential negative effects of antibiotic overuse in animals [7, 42-44].

Commercial chicken and cattle production accounts for most of the veterinary drug use in the URT including antimicrobials. The most common antimicrobials used are oxytetracycline, amprolium, sulphonamides, chlortetracyclines, doxycycline, flumequine, penicillins, neoxyvital, trimazine and tylosin [7, 45-46]. In aquaculture, resistance to tetracycline, trimethoprim, amoxicillin, streptomycin, chloramphenicol, and erythromycin have been reported [47].

Information from few researches conducted in Tanzania, showed a considerable number of multidrug resistant bacteria known to cause mastitis in lactating cows [48]. High levels of resistance have been reported to penicillin G, chloramphenicol, streptomycin and oxytetracycline among *Staph. hyicus, Staph. intermedius and Staph. aureus*. Similar resistance results to amoxicillin and clavulanic acid combination, sulpha-methoxazole and neomycin have been found in poultry products contaminated with E. coli isolates [49]. An increasing trend is the incidence of antimicrobial resistance in multidrug resistant *E. coli, Klebsiella pneumoniae, Staph. aureus* and Salmonella in food animals in Tanzania [50]. The same authors indicated an increase in methicillin resistant *Staphylococcus aureus* (MRSA) and extended-spectrum beta-lactamase (ESBL) in the food animal sector in Tanzania.

Similarly, high prevalence of antimicrobial resistance of *E. coli* and *Campylobacter spp* isolates from animals have been reported in Tanzania for ampicillin, Amoxicillin + Clavulanic acid, gentamicin co-trimoxazole, tetracycline, amoxicillin, erythromycin, cefuroxime, norfloxacin and ciprofloxacin [50]. Antimicrobial resistant *Campylobacter* in food animals in Tanzania was reported from isolates in pigs, dairy, and beef cattle with specific resistance to ampicillin, gentamicin, streptomycin, erythromycin, tetracycline, ciprofloxacin, nalidixic acid, azithromycin, chloramphenicol, and tylosin [51]. Resistance of *Campylobacter* isolates from ducks in Morogoro on cefuroxime sodium, tetracycline, Ampicillin, erythromycin, gentamicin,

cloxacillin and amoxicillin have been reported [49]. In 2014, other studies revealed a high number of resistant *E. coli* and *Enterococci* isolates from wildlife and cattle in Tanzanian wildlife ecosystems [52]. Antimicrobial resistance has also been reported in isolates from fish and aquatic environment.

4.1.2 SITUATIONAL ANALYSIS in PLANTS

Bacterial diseases of plants are less prevalent than diseases caused by fungi and viruses. Antimicrobial agents for prophylactic treatment of bacterial diseases of plants are limited in availability, use and efficacy, and the therapeutic use is largely ineffective. Where studies have been conducted, the most applications have been by spray treatment with tetracycline and streptomycin been the most commonly used antimicrobial agents. In Tanzania, however, the most commonly used antimicrobial agents are Sulphur preparations and specifically in horticulture and in cashew nuts (orchards) [6-7, 9].

4.1.3 SITUATIONAL ANALYSIS in ENVIRONMENT

Antibiotic resistant bacteria are found in animals that have traditionally not been given antimicrobials, such as wild-caught animals, fish and crops. However, bacteria in the environment may carry resistance genes. Some may have natural resistance because of genetic diversity, but some may be because of selection from antibiotic residues washed as effluent into water bodies through rain [53]. Antimicrobials may be released into the environment from human, animals and crop sources, through excretion, disposal of unused or expired compounds, medical wastes, effluents from pharmaceutical industries, discharge from wastewater treatment facilities, leakage from septic systems and agriculture. Other pathways for dissemination are via land application of human and animal wastes, surface runoff and unsaturated zone transport.

Once in the environment, like any other organic chemicals, their efficacy depends on their physicochemical properties, prevailing climatic conditions, soil types and variety of other environmental factors. If antimicrobials in the environment are not efficiently degraded, the residues may contribute in development of antimicrobial resistant in microbial populations [54]. Studies on antibiotic residues in the environment have been conducted mostly in high-income countries and relatively little is known of the situation in developing countries.

In aquaculture, there is a variable extent of resistance of up to 70% and the resistance observed was mainly due to environmental contamination. The origins of the pathogens were anthropogenic through human and animal wastes and urine with resistant genes for drugs and their residues. This contributes to emergence of resistance bacteria in aquaculture. In areas where integrated aquaculture is implemented the challenge may be more evident. Prominent genes encoding resistance to tetracycline, trimethoprim, amoxicillin, streptomycin, chloramphenicol, and erythromycin were identified in integrated fish farming systems [47]. Strength, weakness, opportunities and challenges facing management of VMU of anti-microbial are shown in details in Table 6

Table 6: Strengths, Weakness, Opportunity and Challenges (SWOC) Analysis

STRENGTHS
Existence of legislation for regulation of quality, safety and efficacy of antimicrobial agents (Acts, Regulations and Guidelines)
Existence of regulatory bodies for medical products and professional conduct (TFDA, TBS, VCT, Department of Veterinary Services, Department of Preventive Services, Plant Health Services and other departments)
Systems in place for quality control of antimicrobial agents and supply chain
Existence of policy guidelines for management and optimal use of antimicrobial agents
Political will, supportive government policies and structure.
Establishment of multi-disciplinary structure for antimicrobial stewardship and existence of OH strategic Plan, National Action Plan for Public Health Security (NAPHS) and AMR National Action Plan (NAP).
Existence of infrastructure (Laboratories and human resource skills) to monitor bacterial resistance and antimicrobial residue patterns
Existence of interested professional bodies, associations and civil Societies in the country
Training of clinicians, veterinarians and other professionals on improving antibiotic prescription in the human health, food and agriculture sectors.
WEAKNESS
Absence of a formal and specific regulatory framework for preservation of new antimicrobials
Weak enforcement of laws and professional ethics that govern management and use of antimicrobial agents in public health, animal health, agriculture and environment
Inadequate policies providing for governance of antimicrobial agents in food, agriculture and environment sectors.
Improper handling and storage of antimicrobials leading to sub-effectiveness of these drugs.
Inadequate access to data on antimicrobial use and resistance from primary to tertiary level.
Lack of a system for control of prescriptions including post prescriptions review.
Absence of national veterinary formulary
Absence of national disease treatment/ protocol in food and agriculture sectors
Absence of health insurance schemes in food and agriculture sectors
Poor coordination among stakeholders in antimicrobial use.
OPPORTUNITIES
Existence of professional bodies and associations
The growing bodies of stakeholders (donors, International Partners and agencies) interested in AMR
The growing bodies of AMR network at regional and global levels
Existence of internationally accepted Tools/data sharing systems for AMR/AMU monitoring/surveillance (GLASS, ATLASS, WHONET)
CHALLENGES
Wide spread and uncontrollable use of antimicrobial agents in the society
Dispensing of antimicrobial agents done by non-professional individuals
Erosion of ethical conduct by professionals.
Mushrooming of unregistered premises that stock and sale medicines including antimicrobial agents in food and agriculture sectors

4.2 GOAL AND OBJECTIVES

4.2.1 GOAL

The goal is to contribute to combating and reducing the burden of antimicrobial resistant bacteria in food, agriculture and the environment in the URT through effective monitoring of pathogens and antimicrobial sensitivity testing. The end desire is to enhance the prudent use of antimicrobials through communication of outcomes to the public with an ultimate aim of preserving valuable antimicrobials.

4.2.2 STRATEGIC OBJECTIVES

i. Establish profiles of priority resistant pathogens against antimicrobial agents and monitor AMU and AMR in the food producing animals and their products to inform control interventions

ii. Establish AMR baseline data from wastewaters, soil and other water sources in the environment

iii. Generate AMR data, from animals, food, crops and environment for policy, control and future research guidance

iv. Develop an early warning notification system for emergence of novel resistant strains/ pathogens and aid in rapid identification and control of outbreaks

4.3 SURVEILLANCE METHODS

AMR Surveillance shall intend to collect, analyze and interpret AMR data for early detection of resistant strains and sharing of necessary information for appropriate action. Different surveillance methods will be employed in this surveillance plan in order to obtain relevant and reliable AMR data to allow interventions to reduce antimicrobial resistance burden in the food and agriculture sectors to be implemented in the country.

Depending on the type of information required and availability of resources, both passive and active surveillance types will be implemented in order to track infections and resistant strains. It is also expected that both clinical and microbiological AMR data will be captured and analyzed in order to have valid and accurate AMR data. The surveillance methods in this framework will mainly focus on AMR and antimicrobial usage for the purpose of monitoring the trend of antimicrobial use in the food and agriculture sectors depending on circumstances.

Surveillance of antimicrobial resistance or monitoring of prevalence of resistant bacteria of animal, food, environmental and human origin at regular intervals will be undertaken aimed at limiting the spread of antimicrobial resistance and optimizing the choice and use of antimicrobials.

4.3.1 TARGET PRODUCTION SYSTEMS FOR FOOD AND AGRICULTURE

AMR surveillance will target the broad sectors of interest, types, roles or end user and production environments in which terrestrial and aquatic animals, plants would be found (Table 8).

Table 7: Classification groups of terrestrial and aquatic animals and plants population for consideration within surveillance

Production system	Environment	Animal/ Plant type	Major commodities (source of samples)
Extensive and intensive ruminant production	Grazing (pastoral and agro-pastoral), feedlots	Cattle, goats, sheep	Meat, milk, manure
	Pasture based and semi/zero-grazing	Cattle (graded/ improved)	Milk, meat and manure
Commercial, semi intensive and extensive Poultry production	cages, poultry houses and backyard	Indigenous (chicken, ducks, guinea fowls), broilers and layers	Meat, eggs, manure
Extensive(free range) and intensive pig production	Pig houses and backyard	Local and Improved breeds of pigs	Meat, manure
Companions animals (Stray and housed)	houses and backyard	Dogs, cats	Faecal
Aquaculture and mariculture	Cages, Recirculation Aquaculture System, pond and Happas	Finfish and Crustaceans	Freshwater and marine foods
Intensive and extensive crop production	farm land	Vegetables, Fruit trees, Sunflower, cashew-nuts	Fresh fruits and vegetables
Honey production	Bee hives	Bee	Honey
Processed/ semi processed food/ environment	Processing plants, transportation and storage facilities	Meat, milk, fish, canned food	Swabs, wall, effluent, workers

4.3.2 TARGET BACTERIA FOR AMR SURVEILLANCE

Bacteria have coexisted with humans, animals and plants for millennia and many are essential to life, while others coexist without causing harm. Some may exist as part of the 'normal flora' of a human or animal in good health, but can cause disease when introduced to "normally" sterile parts of the body, such as when the host's immune system is compromised and in cases of septicemia.

There are varieties of bacteria that can be considered in the context of food, agriculture and environment health. In order for a bacterium to be considered sufficient enough for inclusion as an indicator pathogen for surveillance, they should be representative, of high incidence/ prevalence, have zoonotic potential, cause food-borne illnesses and of relatively high pathogenicity. In addition, such organism should have the potential to develop or is known to have developed antimicrobial resistance that is of concern to human, animal, crop and environmental health. These are E. coli. Enterococcus spp, Salmonella spp, Streptococcus, Staphylococcus aureus and Pseudomonas aeruginosa.

4.3.3 TARGET ANTIMICROBIAL AGENTS

For the purpose of this surveillance, selection of antimicrobials of interest was based on expert opinion and available literatures regarding their availability, accessibility to farmers, spectrum and efficacy, and misuse or abuse. Others include related classes of antimicrobial of public health importance [5]

Table 8: Antimicrobials Targeted for Surveillance

	Classes	Principal use in humans	Principal use in animals
1	Tetracyclines (Chlortetracycline, oxytetracycline, tetracycline, doxycycline)	Used for treatment of infections of the urinary tract, respiratory tract, and the intestines and are also used in the treatment of chlamydia, especially in patients allergic to □-lactams and macrolides	Major broad-spectrum primary agent for systemic infections in animals
2	Cephalosporins	Treatment of infections in penicillin allergic patients. Prophylaxis in orthopaedic and other surgery and respiratory infections	Intramammary treatment of mastitis due to staphylococci and streptococci in dairy cattle/ intrauterine treatment for metritis in cattle
3	Aminoglycosides (Gentamycin and Neomycin)	Topical agent for skin infection and gut suppression	Primary agent for enteric infections in livestock (oral form); broad spectrum primary agent for a range of systemic infections in livestock. Primary agent for *E. coli* and *Salmonella* infections in calves, pigs and broilers
4	Sulfonamides (Trimethoprim/ sulphonamide, Sulfadiazine, Sulfadoxine)		Primary agents for broad-spectrum infections in livestock, horses and dogs including enteritis and pneumonia (oral and injectable), Oral sulfonamides (without Trimethoprim) are also used for coccidiosis in poultry and aquatic Used for treating and preventing powdery mildew in cashew-nuts
5	Macrolides (Erythromycin, and Azithromycin, Tylosin)	Treatment of minor Gram-positive, *Chlamydia* and *Mycoplasma* infections.	Livestock for respiratory infections and other serious systemic infections including mastitis. Respiratory disease in broilers

*(Source: modified from surveillance and reporting of AMR and AMU in animals and Agriculture in Australia, 2014)

4.4 SURVEILLANCE CATEGORIES

Based on World Organization for Animal Health (OIE) Terrestrial Animal Health Code' (OIE, 2013c) and 'OIE Aquatic Animal Health Code' (OIE, 2013b), AMR surveillance should help to answer the following key questions:

a. How do you sample?
b. Which sample origin/animal species?
c. Which bacterial species?
d. Which antibiotics are tested?
e. How do you interpret the data?

Furthermore, a code identifies the monitoring of AMR in terrestrial and aquatic animals to be necessary in order to:

a. establish baseline data on the prevalence of antimicrobial resistant microorganisms and determinants;
b. assess and determine the trends and sources of antimicrobial resistance in bacteria;
c. detect the emergence of new antimicrobial resistance mechanisms;
d. provide the data necessary for conducting risk analyses as relevant to animal and human health;
e. provide a basis for policy recommendations for animal and human health;
f. provide information for evaluating and guiding antimicrobial prescribing practices and for prudent use recommendations; and
g. Explore the potential relationship between antimicrobial resistance in aquatic animal microorganisms and the use of antimicrobial agents.

Methods/ Types of AMR surveillance will vary according to situation, and this may include needs and resources availability among others. There will be a well- coordinated three types of surveillance; passive, active and participatory AMR surveillance (figure 3).

4.4.1 PASSIVE SURVEILLANCE

Passive surveillance system will target collecting data and samples that have been submitted to diagnostic laboratories for clinical purposes during routine activities. Diagnostic laboratories involved are zonal centers, wildlife and academic/research institution and private laboratories where appropriate. Electronic based system will be used to capture data.

4.4.2 ACTIVE SURVEILLANCE

Active surveillance will be planned to target gathering information to guide prudent use of antimicrobials. Longitudinal, cross sectional or purposive surveillance will be used to establish changes in trends over time of resistance prevalence and the emergence of resistant priority pathogens. Surveillance sites will be selected based on the identified production systems and priority species as indicated in table 8.

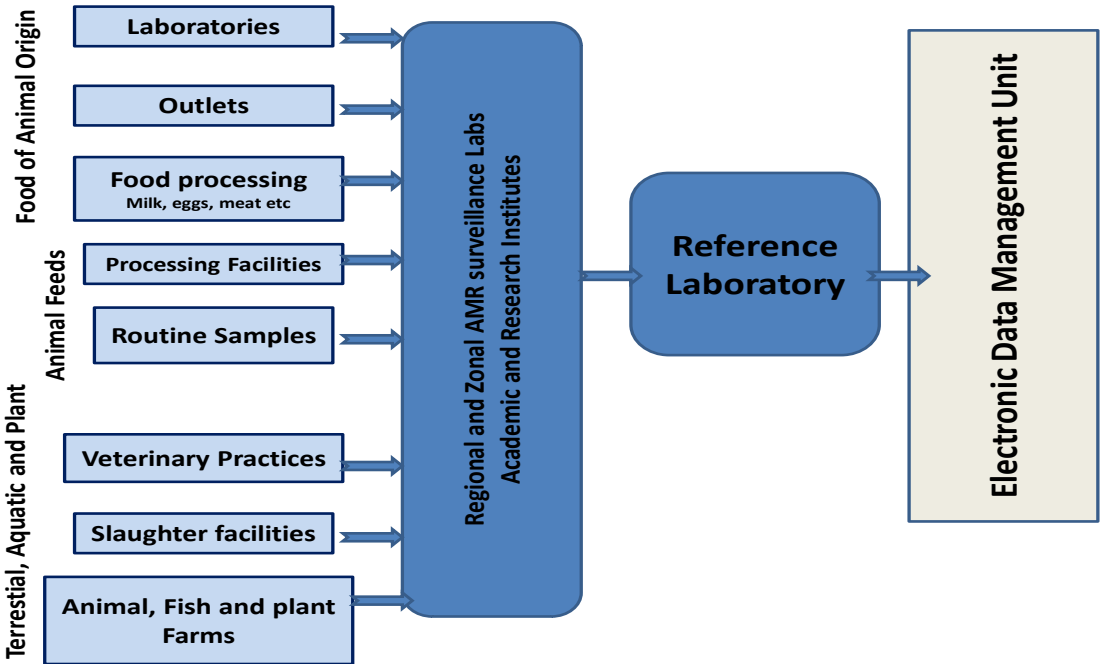

Figure 3: Flow chart of AMR coordination and the surveillance

4.4.3 PARTICIPATORY BASED SURVEILLANCE

This is the application of Participatory Rural Appraisal (PRA) methods for the collection of epidemiological information to inform decision-making and action where by this method can be used in AMR surveillance at public and community level. The information to be captured during Participatory Surveillance will include knowledge, attitude, practices and perceptions on AMR and AMU.

Tools to be used in the Participatory Surveillance will include Focus Group Discussion (FGD), semi-structured questionnaire, check list, scoring, ranking, proportional piling and matrix scoring to characterize consumer and suppliers perceived relative preferences and risk factors (drivers) for AMU and AMR.

4.5 SAMPLING PROTOCOL

Sampling protocol describes sampling purpose, design and operating procedure.

4.5.1 PURPOSE

The purpose of this surveillance protocol is to describe sampling design, type of data to be collected, procedures for collecting, handling, transportation and storage of samples (quality specimen) for AMR laboratory analysis so as to ensure reliable laboratory test results as well as laboratory analyses.

4.5.2 USERS AND RESPONSIBILITY

This protocol is intended to be used by all institutions/parties participating in AMR surveillance in Tanzania. It is the responsibility of the sample collectors and analyst to follow this procedure while collecting and handling samples from field to laboratories. Laboratory personnel should ensure that samples submitted meet the sample acceptance criteria for the laboratory testing.

4.5.3 SAMPLING DESIGN

Longitudinal, cross sectional or purposive surveillance design will be used to establish changes in trends over time of resistance prevalence and the emergence of resistant of priority pathogens.

4.5.4 SAMPLE SIZE

The sample size will vary depending on survey methodology to be employed, level of precision, animal species, and type of samples to be collected. For large animals sample size is calculated with the expected minimum disease prevalence of 1% and 95% level of confidence, the population being considered infinite in each sampling location. The sample size will be calculated using the standard formula for estimation of proportion: $n = z^2 \times P (1 - P) / d^2$, Where: n = the required sample size; P = estimated prevalence = 0.01; z = level of confidence as 1.96 and d = Desired precision level = 0.05. Sample size in Poultry and eggs is calculated as a Function of Population Size and Minimum Probability of Detection as shown in (Table 10)

Table 7: Sample size estimation at predefined level of precision level

		Number of birds in flock				
95% CI		#50	#100	#500	#100	#10,000
Estimated Prevalence	1%	48	96	225	258	29
	5%	31	45	56	59	59
	10%	22	25	28	29	29
99% CI						
Estimated Prevalence	1%	50	99	300	68	448
	5%	39	59	83	86	90
	10%	29	36	42	43	44

CI = Confidence Interval, # =Number: Adopted from: USDA, APHIS, VS, NVSL, Ames, Iowa 50010 – World Reference Lab.

4.5.5 INDIVIDUAL STUDY SAMPLE SIZE ESTIMATION

Surveillance standards for antimicrobial resistance adopted from the WHO will be used to guide sample size collection (Table 11). This standardized guide provides the relationship between sample numbers, and the sensitivity of a surveillance system to detect increases in resistance. For example, if a sample size of 200 yields a resistance rate of 5 per cent to a particular antibiotic, the resistance level measured in a second sample of the same size would need to rise above 11 per cent before it can be stated that the level of resistance in the population has increased. However, the sensitivity of the system can be improved by increasing the number of samples. To avoid effect of non-random distribution (clustering) of resistance isolates and recognizing the fact that resistance is randomly distributed throughout the population of isolates (assumption of statistical independence), the sample size requirement will need to be valid and much higher.

Table 10: Estimated sample size needed for documenting increasing AMR frequencies

Resistance detected in original sample (%)	Level of Resistance that would indicate significant increase in AMR frequency (%)				
	Sample size(100)	Sample size(200)	Sample size(300)	Sample size(400)	Sample size(500)
2	9	7	5	4	3
5	14	11	9	8	7
10	21	17	15	14	12
25	39	35	32	31	28
50	65	60	58	56	52

Source: (World Health Organization, 2002)

4.5.6 ENVIRONMENTAL SAMPLING

For environmental (soil, water and plants) samples, abstract transect can be used to determine the sampling frame and subset of sample population to be considered and the locations. The sample size shall be determined using randomization to select predetermined numbers as shall be informed by anecdotal evidence in the absence of adequate data on sample population. The active sampling shall be quarterly from selected sites

4.6 LABORATORY STANDARDS

Table 11: Minimum requirements for laboratory participation as a surveillance site in the AMR Surveillance System

Capacity	Minimum Requirements
Technical laboratory skills	· Identify priority organisms and perform AST in accordance with WHO or CLSI standards · Perform AST by using disc diffusion, semi-automated, or manual testing for minimum inhibitory concentration and gradient diffusion
Quality control	· Utilize a CVL-approved QC system · Maintain QC data records for potential review by CVL
External quality assurance	· Participate in a recognized EQA program · Achieve acceptable performance reviews on periodic EQA dispatches
Data management	· Make commitment to collect and report good-quality data in accordance with reporting timelines · Employ staff trained in collecting, analyzing and reporting epidemiological, clinical and laboratory data · Dedicate time for staff member(s) to regularly input, analyze, and report data
Site and Laboratory Staff	· Willingness to participate · Adequate physical infrastructure and equipment · Adequate existing human resources · Microbiology expertise among laboratory staff · Information Systems

To avoid challenges associated with results variability and in order for AMR data to be broadly comparable, laboratory methods must be standardized and harmonized, and AMR data be reported quantitatively.

4.6.1 SAMPLE SUBMISSION AND CODING

All samples submitted to the laboratory for AMR Surveillance should be accompanied by a completed sample submission form where information regarding Sample (animal/fish spp, breed, animal/fish Identification, age, sex and collection date), farming system, location and owner and indicated (see information on submission form). On the other hand for food and feed samples: information contained in the form will include location, premise, sampling date, owner of the premise, food type, date of manufacturing, manufacturer and storage condition. For environmental samples: location, premise, sampling date, premise neighboring activities, and sample type information should be included.

4.6.2 SAMPLE COLLECTION

Types of samples to be collected in relation to priority organisms are indicated in the table 12 and 13. Standard procedures for sample collection, preservation, transportation and storage should be adhered

Table 8: Samples from Animals

Priority organisms for screening	Type of Samples
Salmonella spp	Swabs eg. Surface, Faecal sample GIT, etc
Staphylococcus spp	Swab samples from food producing animals (Faecal, nasal, choanal, cloacal and septic wound)
E. coli	Faecal sample, GIT swabs, body swab, water
Enterococcus spp	Faecal sample
Campylobacter spp	Faecal sample

Table 9: Food Crop and Environmental Samples

Priority organisms	Type of Samples
Streptococcus spp	· Milk from cows with mastitis · Tissue samples, Plant tissue · Water sample
Staphylococcus spp	· Milk from cows with mastitis · Eggs, Plant tissue · Tissue samples, Plant tissue · Water sample
Salmonella spp	· Eggs, Plant tissue · Water sample
E. coli	· Eggs, Plant tissue · Water sample

4.6.3 LABORATORY TESTING STANDARDS

All AMR testing should follow approved Tanzania Standards. During laboratory analysis for detection and isolation of particular bacteria, respective tests method should be used. Tanzania Standards methods will be given first preference. Where the Tanzania Standards are not available ISO standards will be opted. To determine the susceptibility of the isolate, ISO 20776 shall be used. There shall be specific SOPs for each priority pathogen identification namely: *Salmonella, E. coli, Staphylococcus aureus*, *Aeronomonas, Enterococcus and Klebsiella.* Antimicrobial Susceptibility Testing (AST) will be performed for the following antimicrobial groups namely: - Tetracycline, Penicillin, Sulfonamides, Cephalosporins, Aminoglycosides and Macrolides.

Quantitative results (disc diffusion, zone diameters or minimum inhibitory concentration values) will be performed in accordance to CLSI standards. The confirmation of isolates should be done using recommended techniques such as serotyping (salmonella spp), Polymerase Chain Reaction (*E.coli* and *S.aureus*) and E kits specific for ESBL Chromogenic media and other biochemical tests. For some species it will be necessary to identify pathogen to the type level (e.g. serotypes)

4.6.4 ANTIMICROBIAL SUSCEPTIBILITY TESTING

Antimicrobial susceptibility testing for priority pathogens shall be carried out in line with Clinical Laboratory Standards Institute (CLSI) guidelines, using the disc diffusion method. The laboratories shall document whether isolates are susceptible (S), intermediate (I) or resistant (R) according to clinical breakpoints defined by CLSI together with the zone sizes (mm) to allow for retrospective adjustment if new breakpoints are set. As the laboratory performance becomes acceptable, minimum inhibitory concentrations (MICs) may be determined by broth dilution (manual or automated) or gradient diffusion tests such as E-Tests. MIC values shall be recorded. These shall happen after reviewing with the labs that will be part of this surveillance system to see if this is feasible. When a new drug is introduced into clinical practice, laboratories will routinely test susceptibility to the drug in order to identify emerging resistance. Laboratory staff will be trained to recognize unusual or unexpected findings in routine samples. They will also be instructed to inform CVL when this happens and if needed request technical assistance

4.6.5 LABORATORY SUPPLIES, REAGENTS AND EQUIPMENT

Bacteriological media and reagents to be used in isolation, characterization and susceptibility testing should be as per respective test method standards and described in the respective SOPs.

When selective media used is not described in the standards manufactures instruction shall be incorporated in SOP, operations of the equipment in the entire testing sequence should be described in the equipment operation SOP but the test condition will be as per respective test methods (Standard) or SOP. The laboratory involved in the implementation of this plan should ensure availability of all necessary supplies.

4.6.6 QUALITY ASSURANCE

To assure the quality of results, the laboratory shall ensure the availability of competent technical personnel, implementation of Quality Management System (QMS), participation in intra and inter laboratory comparison testing. Internal and external quality audit and implementation of the non-conformance identified during audit should be part and parcel of each participating laboratory. Standards reference materials for each priority pathogens will be made available at all laboratory testing to minimize user errors and incorrect identifications. Each test kit should have a set of positive and negative controls that are to be included in each test run. QC data sheets and summaries of corrective action shall be retained for documentation.

- These will be reviewed and checked periodically by the CVL.
- Supervisory review shall be performed for out-of-range QC results and laboratories shall document corrective action that was taken on all QC failures.

4.6.6.1 INTERNAL QUALITY CONTROL

Inter-laboratory Comparison test panel will be prepared and supervised by CVL to cover for IQC. It should cover all steps of each diagnostic test from the collection of specimen to the transmission of the results, as well as media production and maintenance of equipment. IQC testing should be performed regularly with each laboratory determining the frequency depending on the load of specimens it receives for antimicrobial susceptibility testing. Ideally, each batch of AST should be accompanied by an IQC. Laboratory equipment should be assessed on a regular basis to ensure maintenance and quality.

The use of reference bacterial strains as recommended by CLSI standard guidelines will contribute to the monitoring of the accuracy of the results. If the results for the control strain are accurate, i.e. all antimicrobial agents are in the control range, the procedure is assumed to be accurate and so AST may be performed on significant isolates. If the zones produced by the QC strains are out of the expected ranges, the technical personnel should try to determine the possible sources of the error and should troubleshoot the causes. If additional assistance is needed the sites will request assistance if they are unable to resolve the error on their own from CVL. IQC must be performed prior to initiating AST on the isolates. The control strains for the laboratories will be purchased from the American Type Culture Collection (ATCC) and the National Collection of Type Cultures (NCTC).

In retesting and rechecking IQC, positive isolate (including few negative) from each surveillance sites will be send to CVL for rechecking, and feedback will be provided for corrective action. In addition, during onsite evaluation visit, stored isolated will be picked randomly and retested for QA. For sustainability of ILC program during surveillance period, capacity need will be built at CVL to ensure consistent supply of panel materials to participating laboratories. At the beginning of the surveillance, ILC will be conducted twice a year, retesting of isolates at CVL from surveillance site will be performed quarterly. On site visit evaluation retesting will depend on the number of visits to the surveillance sites.

4.6.6.2 EXTERNAL QUALITY ASSURANCE (EQA)

CVL will be participating into Proficiency testing (PT), re-testing (rechecking) and on-site evaluation organized by international and reference lab for AMR to cover for EQA. PT results must be reported according to instructions and submitted within required deadlines to agency implementing EQA, which provides feedback and allows comparison with results from other laboratories. CVL may conduct yearly and whenever possible twice per year in EQA and QC performance.

4.6.7 ISOLATE REPOSITORY

All banked cultures should have a repository at National reference AMR laboratories (CVL). Once a month, surveillance sample collection sites will send AMR priority isolates to the national reference laboratory for isolate repository. Prior to and during transport, isolates will be stored, in accordance with SOPs at -20°C or -80°C. The repositories will be equipped with ultra-low freezers, generator and a robust electronic specimen tracking system with bar-coding to allow for retrieval of bacterial isolates overseen by a freezer manager. This resource will be a key asset in promoting nationally relevant research as it will house isolates and sources in the AMR surveillance network. Once a quarter, every 10% isolate found to have a priority AMR organism sent for repositories will undergo confirmatory testing. CVL will investigate any discrepant results for correction.

4.7 DATA MANAGEMENT AND INFORMATION SHARING

Social, Field and laboratory data collected via surveillance will be handled and managed centrally at designated appropriate competent authorities. Screening analysis will be performed to generate information to inform level of resistance per microbial agents, resistant pathogen and likely risk areas along the broad chain of microbial agent's distribution for consumption among different stakeholders. A principal element of AMR surveillance systems is the detection and demonstration of significant differences in proportion of resistant isolates from year to year and significant trends over periods of three or more years.

Data analysis software will be done by using Laboratory Information Management System (LIMS) and other electronic software (e.g. Epicollect). They shall be used for flexible exploration and reporting of antimicrobial resistance. Data and any other information recorded in the LIMS will be used for generation of respective reports for implementation or subsequent intervention. Sharing of the information will be done depending on the requirements. Some of the stakeholders in the implementation of the plan will be linked directly to LIMS. National Reference Laboratory will host and manage the database server.

4.8 ANTIMICROBIAL USE SURVEILLANCE

Monitoring of bacteria and Antibiotic residue from products of animal origin intended for human consumption collected at different steps of the food chain, including processing, packing and retailing, will be part of surveillance of antimicrobial use (AMU).

Monitoring of AMU involves collection of quantitative information by animal species, antimicrobial agent or class of agent, user (i.e. farmers) perception (access, storage, use, and handling), type of use, including therapeutic and non-therapeutic, and route of administration. The collection and analysis of such information is intended to support planning and risk analysis, and to address the problem systematically. Publication of these data will promote transparency and allow interested parties to assess trends and contribute to risk assessment and risk communication. World Health Organization recommends the following steps and factors to be considered in monitoring antimicrobial usage.

i. Describe the system of distribution of antimicrobial agents in the country and identify sales points outside the mainstream regulatory system, for example, internet sales, import of medicated animal feeds and movement of antimicrobial agents across borders
ii. Identify the antimicrobial agents in commercial circulation.
iii. Identify potential points of data collection
iv. Assess what each data source represents
v. Set parameters for precision and completeness of the surveillance system

4.8.1 SOURCE OF DATA FOR AMU

It is expected that the source of data for AMU will include but not limited to customs, import and export data, manufacturing and sales data. Others include from veterinary medicinal product registration authorities, wholesalers, retailers, pharmacists, veterinarians, feed stores, feed mills and pharmaceutical industry associations. Various tools including comprehensive designed data collection form to fill in data, registries will be used at defined periodic intervals.

4.8.2 DATA COLLECTION PROCEDURES

To be able to monitor use of antimicrobial agents different data types and collection procedures will be employed as described below;

i. Collect appropriate information of the pharmaceutical manufacturers and the regulatory authority (TFDA), targeting types of drugs, importers, volumes, labelling and packaging and distribution channels.
ii. Non-conventional sources including Internet sales data related to antimicrobial agents could be collected where available
iii. Collect information from the end-user (veterinarians and food animal producers) Collection, storage and processing of data from end-use sources should be carefully designed, well managed and have the capability to produce accurate and targeted information.

4.8.3 TYPES OF DATA TO BE COLLECTED

i. Quantity of the active ingredient of the antimicrobial (s) used in food-producing animals per year.
ii. Estimate of total usage: i.e. sales data, prescribing data, manufacturing data, clients, drugs usage records(type, amount, sources, storage, administration), import and export data or any combination of these

iii. Information on dosage regimens (dose, dosing interval and duration of the treatment) and route of administration are elements to include when estimating antimicrobial usage in food-producing animals.

iv. Total number of food-producing animals by species, type of production and their weight in kilograms for food production per year; and

v. Types of drugs, importers, volumes, labelling and packaging and distribution channels

vi. Disposal of expired products? Responsible authorities? From government, private, institution?

4.9 MONITORING AND EVALUATION OF AMR SURVEILLANCE

Monitoring and evaluation are dedicated to the assessment of overall performance of the AMR Surveillance system. Monitoring and evaluation of the AMR Surveillance System in the food, agriculture and environment sectors will begin in 2018. Prior to that time, an evaluation team will be identified (local and external evaluator), with representation from the NMCC, Universities, development partners and some participating laboratories to evaluate the capacity of the existing laboratories in the food, agriculture and environment sectors.

Performance Indicators

Indicators
a. Proportion (%) of Institutions incorporated the AMR surveillance into their work plans.
b. Proportion (%) of targeted resistant pathogens profiles established annually.
c. Proportion (%) of surveillance sites covered in AMR surveillance annually.
d. Proportion (%) of surveillance reports generated and shared quarterly, bi-annually and annually.
e. Number of sites participating in ILC and EQA
f. Number of policy documents developed
g. Proportion (%) of early warning notifications resulted from emergency of novel resistant pathogen

CHAPTER FIVE

ROLES AND RESPONSIBILITIES

5.1 NATIONAL MULTISECTORAL COORDINATING COMMITTEE

The country has developed organizational structures for AMR surveillance with defined terms of reference. The National Multi-sectoral Coordinating Committee (MCC) on AMR is the central National steering body to oversee and coordinate all AMR related activities in all sectors. The AMR action plan operations shall be managed and implemented by different ministries and institutions but monitored through the MCC under the chairmanship of the Chief Medical Officer.

The role of MCC is to advice, receive and approve surveillance plan and reports after being pre reviewed and recommended by AMR TWG responsible for surveillance and Research. Additional roles of MCC is oversee, coordinate and evaluate all AMR surveillance related activities in the food and agriculture sectors in the country; mobilize the needed resources and convene or organize scientific meetings, seminars and serve as national scientific platform for AMR surveillance in the food, agriculture and environment sectors

The MCC has the National AMR Secretariat (with national AMR focal persons for the human and animal sectors) with responsibility among others to coordinate national activities for establishment of AMR surveillance system and report on the prevalence and trends in AMR to GLASS.

5.2 NATIONAL AMR SURVEILLANCE TECHNICAL WORKING GROUP

The technical working group for AMR Knowledge, Surveillance, Research and sustainable investments shall provide technical support during implementation of AMR surveillance as per the NAP. The TWG is comprised of relevant technical specialties including experts from infectious diseases, microbiology, epidemiology, laboratory, animal health, infection prevention and control, pharmaceuticals. It is mandated with specific tasks including:

- Support the development of a national surveillance system for antimicrobial resistance
- Monitor the collection and reporting of data on use of antimicrobial agents in human and animal health and agriculture so that trends can be monitored and the impact of action plans assessed.
- Oversee and support implementation of public health research agenda on antimicrobial resistance, including: research to promote responsible use of antimicrobial medicines; defining improved practices for preventing infection in human and animal health and agricultural practice; and encouraging development of novel diagnostic tools and antimicrobial medicines

5.3 INTERNATIONAL STAKEHOLDERS

- Support in building laboratory capacity to identifying and report AMR organisms
- Provide technical (e.g. trainings, mentorship, assessments) and material (e.g. reagents, equipment) support towards implementation of AMR surveillance
- In consultation with the MCC, include the country AMR data in global reporting of AMR burden

5.4 SPECIFIC ROLES AND RESPONSIBILITIES IN THE HUMAN SECTOR

5.4.1 AMR SURVEILLANCE SUB-TECHNICAL WORKING GROUP

- Providing technical input and support to NHLQATC
- Planning human public health strategic priorities for AMR surveillance
- Working close with NHLQATC on ensuring AMR surveillance is conducted
- To assist NHLQATC for quantification of equipment, reagents and supplies
- Reviewing and scrutinizing AMR data before submission to AMR TWG and Ministry of Health, Community development, Gender, Elderly and Children.

5.4.2 NATIONAL REFERENCE LABORATORY

National Health Laboratory Quality Assurance and Training Centre (NHLQATC) is designated as the National Reference Laboratory (NRL) and this will include AMR. The roles and responsibilities of NRL include: -

- To provide guidance and technical support in AST and quality management to surveillance network laboratories
- To provide a reference service for core organism/antimicrobial combinations as a minimum, for borderline isolates or isolates with unexpected or unusual resistance profiles
- To confirm unusual or new resistance patterns before they are reported to the relevant national authority
- To participate in EQA through appropriate international schemes
- To liaise with the MCC in standardizing and verifying microbiological results
- Receiving and managing surveillance data from all participating laboratories
- To provide EQA across sentinel site laboratories and providing feedback
- To assist sentinel site laboratories to procure equipment, reagents and supplies
- To conduct or support research studies on AMR in collaboration with MCC and share findings with national and international stakeholders.
- To maintain a bio-repository for bacterial isolates

5.4.3 DATA MANAGER / IT SPECIALIST

- Assist surveillance site laboratories in data management setup, training, and troubleshooting
    - Ensure electronic laboratory data base software is installed at sites
    - Train on data entry, transmission, and manipulation (e.g. how to compile AST results and antibiograms)
    - Assist sites with troubleshooting electronic database
- Provide sites with guidance on how to create internal hospital aggregated reports
- Maintain the national AMR surveillance database

- Ensure sites send raw, line-listed data monthly
- Work with AMR surveillance sites to enforce data quality standards and proper data collection policies and procedures
- Review AMR data and ensure that data reported meets AMR surveillance system requirements
- Perform data cleaning and de-duplication prior to compilation of national AMR data and long-term storage
- Maintain data back-ups
- Perform data analyses and prepare annual regional and national AMR reports
- Conduct periodic data verification visits which will compare source data and system data
- Conduct periodic evaluation of data from facilities

5.4.4 LOGISTICS AND PROCUREMENT PERSONNEL

- To coordinate procurement of supplies and reagents and ensure a sustainable supply chain system for the laboratories participating in the AMR surveillance system
- Coordinate distribution of standardized reagents and supplies across participating laboratories.
- Maintain a list of quality supplies and suppliers
- Manage stocks to prevent interruptions in testing and increase accountability for items procured
- Ensure that the sites request their annual supply needs
- Negotiate service contracts across county and reference laboratories

5.4.5 AMR SURVEILLANCE SITES (HOSPITALS/CLINICS AND LABORATORIES)

5.4.5.1 HOSPITAL ADMINISTRATION

- Ensure that there are adequate staff and physical infrastructure in place to perform surveillance activities
- Assign a clinical focal person, with a commitment to AMR
- Ensure clinicians have appropriate containers and specimen collection materials
- Provide staff with specimen collection SOPs and laboratory requisition forms
- Ensure frequent communication between the clinical focal personnel and laboratory
- Provide MCC with annually updated estimates of hospital and population data
- Review and disseminate surveillance reports at the facility level.
- Establish hospital AMR Committee consisting of clinicians, laboratory technologists, pharmacists and IPC nurses to meets quarterly

5.4.5.2 HOSPITAL AMR COMMITTEE

Each participating site shall have an AMR site committee; their members will be selected from hospital therapeutic committee which includes relevant representatives, for example: site coordinator, hospital administrator, data manager, laboratory manager, clinical microbiologist, physician, pediatrician, infection control manager, pharmacist and public health specialist. The role of the Hospital AMR Committee, led by the site coordinator, includes:

- Working with the national technical team to facilitate a situational analysis of current capacity and sustainability at the site
- Planning strategic priorities at the site
- Liaise between hospital clinical and laboratory teams
- Convene quarterly to discuss how to address challenges associated with specimen collection, specimen transport, results, reporting
- Provide feedback on system and individual performance to the members of the surveillance system at the hospital
- Review reports and make recommendations to the hospital administration
- Share data and recommendations with additional committees and staff members
- Ensure specimens are collected according to the SOPs
- Ensure QC measures and regular audit for all AMR surveillance processes
- Work with the national technical team to establish internal QA assessment, progressing to EQA assessment
- Ensure effective lines of communication are in place for feedback of AMR results to clinicians and feedback of summarized AMR data to stakeholders (administration, clinical, IPC, laboratory and data staff)

5.4.5.3 CLINICIANS (DOCTORS, CLINICAL OFFICERS AND NURSES)

- Request the necessary laboratory tests based on the symptomatic and clinical diagnosis
- Submit and transport priority specimens per approved specimen collection SOP
- Complete laboratory requisition forms [Appendix II] consistently and correctly with the required clinical data

5.4.5.4 LABORATORY TECHNOLOGISTS

- Identify the pathogen accurately and perform the AST according to the SOP
- Return routine culture results to the requesting hospital/clinicians in a timely manner
- Track and keep records of rate of specimen rejection and rates of contamination
- Maintain proficiency testing standards and conduct root cause analysis and correction when failure occurs
- Manage inventory of all necessary reagents
- Adhere to and keep records of proper equipment maintenance

5.4.5.5 LABORATORY MANAGER

- Assign a laboratory focal person, with a commitment to AMR
- Liaise between hospital clinical and laboratory teams
- Ensure adherence to SOPs in the bacteriology laboratory
- Review all positive culture results prior to returning to hospitals/ordering clinicians
- Review and approve monthly submissions of AMR data to NRL
- Perform supervisory review for out-of-range QC results and document corrective action that was taken on all QC failures
- Review EQA results and conduct root cause analysis and correction when failure occurs
- Share hospital antibiogram with the relevant clinical departments and hospital committees
- Ensure appropriate inventory management of all necessary reagents and supplies such that isolation, identification, and AST of priority pathogens can be conducted at all times.
- Quantify and forecast annual laboratory supply needs
- Ensure equipment are in good working order, schedule maintenance and repairs, and replace equipment when needed
- Manage major microbiology equipment service contracts for laboratory

5.4.5.6 LABORATORY FOCAL PERSON FOR AMR

This shall be typically a laboratory technologist trained on electronic laboratory database eg. WHONET

Input data into electronic AMR database e.g. WHONET

- Submit line-listed data monthly to NHQATC
- Send identified AMR priory pathogen isolates to the NHQATC as outlined in SOPs
- With assistance from NHLQATC data manager use electronic AMR database e.g. WHONET to produce antibiogram for hospital
- Train new staff on AMR surveillance system, data reporting, and AMR specific SOPs when necessary

5.5 SPECIFIC ROLES AND RESPONSIBILITIES IN THE FOOD, AGRICULTURE AND ENVIRONMENT SECTORS

5.5.1 AMR SUB-TWG FOR THE FOOD, AGRICULTURE AND ENVIRONMENT SECTORS

There shall be a sector specific TWG on AMR surveillance in the food, agriculture and environment sectors. Members of this AMR sub-TWG will comprise relevant technical experts from TFDA, VPO- environment division, PMO-One Health Coordination desk, MLF (livestock and aquaculture) Animal (terrestrial/aquatic) health, TVLA and Ministry of Agriculture (plant health division). It may also constitute experts from NEMC, academic and research institution like SUA and FAO country office based AMR focal point. Role and responsibilities of the sub- AMR TWG shall include:

- Reporting to NAP TWG (Surveillance and Research) on the progress and the implementation of the AMR surveillance plan in the food, agriculture and environment
- Operationalizing the National AMR surveillance plan in the food and agriculture and environment sectors;
- Providing technical input, conducting situational analyses in these sectors;
- Preparing annual work plans in the food, agriculture and environment as per National AMR Action Plan;
- Reporting to NMCC
- Providing updates on ongoing activities and provide technical advice to the NMCC
- Prepare annual AMR surveillance work plan in the food, agriculture and environment
- Map AMR surveillance activities in the food and agriculture and environment sectors;
- Prepare budget for AMR surveillance
- Prepare consolidate report for AMR surveillance in the food, agriculture and environment sectors.

5.5.2 NATIONAL REFERENCE LABORATORY

The roles and responsibilities of CVL will include the following:-

- To provide technical support and guidance in AST testing and quality management to surveillance network laboratories
- To provide bio-repository service for core organism/antimicrobial combinations as a minimum, for borderline isolates or isolates with unexpected or unusual resistance profiles;
- Host and manage AMR surveillance database and share AMR information to the stakeholders
- To confirm/characterize unusual or new resistance patterns before they are reported to the relevant national authority
- To participate in external quality assurance through appropriate international schemes
- To liaise with the MCC in standardizing and verifying microbiological results;
- To provide external quality assurance across sentinel site laboratories and providing feedback
- To assist sentinel site laboratories to procure equipment, reagents and supplies
- To conduct or support research studies on AMR in collaboration with MCC and share findings with national and international stakeholders.

Note: Operation of AMR surveillance framework for food, agriculture and environment sectors shall be managed and implemented through the MLF under the Tanzania Veterinary Laboratory Agency (TVLA).

5.5.3 SURVEILLANCE SITES AND OTHER COLLECTION SITES

- Receive/collect samples/specimen and perform AST as per protocol
- Transportation of samples/ pathogen isolates to the NRL for confirmation
- Perform initial /descriptive AMR data analysis
- Share AMR data with National Reference Laboratory for confirmation and analysis
- Ensure that there are adequate staff and physical infrastructure in place to perform surveillance activities
- Assign a clinical focal person, with a commitment to AMR
- Ensure clinicians have appropriate containers and specimen collection materials
- Provide staff with specimen collection SOPs and laboratory requisition forms
- Ensure frequent communication between the AMR focal personnel and laboratory
- Provide CVL with annually updated estimates of samples collected and population data
- Review and disseminate surveillance reports at the facility level
- Establish center AMR Committee consisting of Veterinarians, laboratory technologists, and field officers to meets quarterly

5.5.4 FARMERS ASSOCIATIONS AND AMR SURVEILLANCE NETWORK

- Facilitate availability of AMR surveillance data
- Facilitate dissemination of feedback information
- Holders of AMR surveillance data – for policy and control advice
- Obligatory mandate – sharing AMR data with RECs, AU-IBAR and OIE
- Provide policy and future research direction for AMR
- Facilitate importation/ exportation(paper work, logistics) of material/ supplies related to AMR

CHAPTER SIX

LEGAL FRAMEWORK AND RESOURCE MOBILIZATION

6.1 LEGAL FRAMEWORK

The implementation of the AMR Surveillance Framework requires a strong and sound managerial capability of ensuring an optimal coordination. A legislative framework must be strengthened in order to enforce implementation of the Framework. This Antimicrobial Resistance surveillance framework is fully aligned with the National Action Plan on AMR (2017-2022) and provisions for its regulation exists in different policies and legislations governing food, agriculture and environment sectors. These policies and legislations but not exhaustive include:

i. National Health Policy, 2007 (Current in review)
ii. National Livestock Policy of 2006
iii. The Animal Disease Act No. 17 of 2003
iv. The Veterinary Act No. 16 of 2003
v. Tanzania Food, Drugs and Cosmetics Act No. 1 of 2003
vi. Fisheries Act No. 20 of 2003
vii. Tanzania Plant Protection Act of 1997
viii. Tanzania Pesticides and Research Institute Act No. of 1979
ix. The National Environment Management Act No. of 1983.

Other plans/ strategies that are closely linked to this include Tanzania Development Vision 2025 (Vision 2025), One Health Strategic Plan 2015 -2020, Health Policy 2007, Livestock Development Strategic Plan (2010-2015) and Tanzania Action Plan for Health Security (2017-2012). Furthermore, the framework is closely linked with other existing treaties and agreements addressing AMR at regional and global levels. These include: The East African Community Sanitary and Phytosanitary, FAO, OIE, WTO and WHO protocols/plans prescribing prudent use of antimicrobials specifically WHO Global AMR Action and the FAO Action Plan on AMR (2016-2020).

6.2 RESOURCE MOBILIZATION

The costs of AMR surveillance are high, and involve considerable resources. Financial resources to implement AMR surveillance activities in the country will come from both external and domestic sources. It is expected that the Government of the united Republic of Tanzania through the respective ministries will allocate funds to implement and sustain AMR surveillance activities in the country.

Private Institutions and other interested private, domestic and international stakeholders/ partners with capacity to finance AMR surveillance activities in the country. International organizations such as FAO, WHO, OIE, WB, UNDP through global, continental, regional and country programmes may be potential sources of funding for AMR surveillance activities in Tanzania. Other Global partners like Mott McDonald, The Fleming Fund, GARP, ReAct, Bilateral partners such as USAID, DFID and OHCEA can also provide financial support to implement AMR activities in Tanzania.

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APPENDIX

APPENDIX I: LIST OF EXPERTS WHO PARTICIPATED IN THE DEVELOPMENT OF THE NATIONAL AMR SURVEILLANCE FRAMEWORK

S/N	NAME	POSITION/ PROFESSION	ORGANIZATION
1.	Dr Mtebe Majigo	Microbiologist	MUHAS
2.	Dr. Charles Masambu	Assistant Director Diagnostics	MoHCDGEC
3.	Prof. Stephen Mshana	Department of Microbiology	CUHAS
4.	Dr. Joseph Masambu	Principal Veterinary Research Officer	Tanzania Veterinary Laboratory Agency
5.	Dr. Rogath Kishimba	Field epidemiologist	MoHCDGEC
6.	Ms. Siana Mapunjo	AMR Focal Point	MoHCDGEC
7.	Optatus Maleo	Laboratory Scientist	CDC
8.	Dr. Bachana Rubegwa	National AMR Coordinator/One Health Epidemiologist	Food and Agriculture Organization of the UN
9.	Dr. Anthony A. Nsojo	Clinical Microbiologist Lab Manager	Mbeya Zonal Referral Hospital
10.	Dr. Tumain Nagu	Infectious Disease Specialist	MUHAS
11.	Dr. Mabula Kasubi	Microbiologist	MNH
12.	Mr. Victor Mchunguzi	Lab Scientist	NHLQATC
13.	Dr. Joel Manyahi	Microbiologist	MUHAS
14.	Mr. Salum Said Alli	Lab Scientist	Mnazi Mmoja Hospital-Zanzibar
15.	Dr. Emmanuel Swai	Veterinary Epidemiologist	Ministry of Livestock and Fisheries
16.	Dr. Zachariah Makondo	Centrol Vet Laboratory - Manager	Tanzania Veterinary Laboratory Agency
17.	Dr. Nyambura Moremi	Microbiologist	CUHAS
18.	Dr. Gibonce Kayuni	AMR Focal Point	Ministry of Livestock and Fisheries
19.	Dr. Justin Assenga	Veterinary Epidemiologist	One Health Coordination Desk Prime Minister's Office
20.	Dr.Sero Hassan Luwongo	Pharmacologist/Principal Veterinary Officer	Ministry of Livestock and Fisheries
21.	Dr.Hamis Nikuli	Principal Veterinary Officer	Ministry of Livestock and Fisheries
22.	Dr. Deusdedit Tinuga	Veterinary Epidemiologist	Ministry of Livestock and Fisheries
23.	Dr.Adelard Mtenga	Head of Food Safety Department	Tanzania Food and Drugs Authority
24.	Prof.Amandus Muhairwa	Head, Department of Medicine and Public Health	Sokoine University of Agriculture
25.	Mr Joseph Tarimo	Food Safety expert	Tanzania Bureau of Standards

26.	Ms. Kimambo	Environmental Expert	Vice President's Office
27.	Dr.Khadija Noor Omary	Head, Central Veterinary Laboratory	Ministry of Agriculture, Natural Resources, Livestock and Fisheries, Zanzibar
28.	Prof.Fasina Folorunso	Country Team Leader	Food and Agriculture Organization of the UN
29.	Dr.Niwael J. Mtui - Malamsha	Veterinary Epidemiologist	Food and Agriculture Organization of the UN
30.	Dr. Raphael Sallu	National Laboratory Expert	Food and Agriculture Organization of the UN

APPENDIX II: ROAD MAP FOR ROLL-OUT OF THE TANZANIA ANTIMICROBIAL RESISTANCE SURVEILLANCE SYSTEM

	2017		2018				2019				2020			
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
AMR Strategic Planning														
AMR Strategic Surveillance Plan ratified														
Phase I lab														
Prep for surveillance activities														
Surveillance activities														
First (6-month) surveillance evaluation														
First AMR report														
phase II lab														
Prep for surveillance activities														
Surveillance activities														
Second surveillance evaluation														
Second AMR report														
Phase III laboratory														
Prep for surveillance activities														
Surveillance activities														
Third AMR report														

APPENDIX III: LABORATORY REQUISITION FORM

Hospital / Facility: _____

Ordering Physician: _____ Telephone: _____

Patient Name: _____

Patient Medical Record Number: _____

Date of Birth *(dd/mm/yyyy)*: _____/_____/_____

Gender: ☐ Male ☐ Female

In-Patient Ward / Department: _____ ☐ Out-Patient

Date of Admission *(dd/mm/yyyy)*: _____/_____/_____ ☐ Out-Patient

Specimen Type: ☐ Blood ☐ Sputum
☐ Urine ☐ CSF
☐ Stool ☐ Other: _____
☐ Wound

Specimen Collection Date *(dd/mm/yyyy)*: _____/_____/_____ Time: _____AM/PM

Specimen Collected By: _____

- TO BE FILLED OUT BY LABORATORY - - - - - - - - - - - - - -

Specimen Receive Date *(dd/mm/yyyy)*: _____/ _____/ _____ Time: _____AM/PM

Specimen Received By: _____

Specimen accession number: _____

Notes: _____
_____
_____
_____
_____

APPENDIX IV: PAPER-BASED REPORTING FORM

Laboratory Facility Name: _____

Corresponding Hospital (if applicable):_____

#	Patient Medical Record Number	Date of Birth (or Age)	Gender (F/M)	Inpatient / Outpatient (IP/ OP)	Patient Ward (inpatient only)	Admission Date (inpatients only)	Date of Specimen Collection	Specimen Type	Gram Stain	Pathogen Identified		Amikacin	Ampicillin	Etc.
1											Zone Diameter			
											Interpretation (S, I, R)			
2											Zone Diameter			
											Interpretation (S, I, R)			

APPENDIX V: ANTIBIOTICS TO BE TESTED FOR EACH PRIORITY ORGANISM FOR FOOD, AGRICULTURE AND ENVIRONMENT

Priority pathogens	Antimicrobial	*E.coli*	*S. aureus*	*Pseudomonas*	*Klebsiella*	*Salmonella*	*Shigella spp*	*S. pneumoniae*	*Acinetobacter*
Sulfonamides/ trimethoprim	Cotrimoxazole	X		X	X			X	
Fluoroquinolones	Ciprofloxacin/ levofloxacin	X		X	X	X	X		
3" cephalosporins	Ceftriaxone / Cefotaxime	X			X	X	X	X	
	Ceftazidime	X			X				
4" cephalosporins	Cefepime	X			X				
Carbapenems	Imipenem/ Meropenem	X			X	X		X	X
Polymxins	Colistin	X			X				X
Penicillins	Oxacillin							X	
	Penicillin G							X	
	Ampicillin	X		X					
Penicillinase stable beta lactams	Cefoxitin / Oxacillin Amoxicillin clavulanic		X					X	
Macrolides	Azithromycin						X	X	
Aminocyclitols	Spectinomycin								
Aminoglycosides	Gentamicin							X	X
	Amikacin								X
Tetracyclines	Tigecycline /minocycline			X					X

APPENDIX VI: FOOD, AGRICULTURE AND ENVIRONMENTAL SAMPLE COLLECTION AND SUBMISSION FORM

ZONE		REGION	
DISTRICT		WORK STATION	
VILLAGE/SITE			

GRID REFERENCE:

LATITUDE	LONGITUDE

IDENTIFICATION

	YES		NO	

DATE OF SAMPLING	SPECIES	SOURCE/TYPE OF SAMPLES (TICK)									
		Meat	Blood	Milk	Eggs	Feacal	Manure	Fruits	Fish	Water	Vegetables
		Additional Information:									

PRODUCTION SYSTEM		Sample Packaging Info	Sample Storage Condition	
TYPE	TICK		TYPE	TICK
			Ice	
Red meat production			2-8 C	
Dairy production			-20 C	
Poultry production			-80 C	
Pork production		(Describe packaging of samples)	Liquid Nitrogen	
Companions animals			Room Temperature	
Aquaculture				
Horticulture				
Processed / semi processed food				

Laboratory test requested	

Note: Provide any information on treatment (livestock) or cultural practices (crops) .....
.....
.....

Full Name:..... Signature.....Title:.....