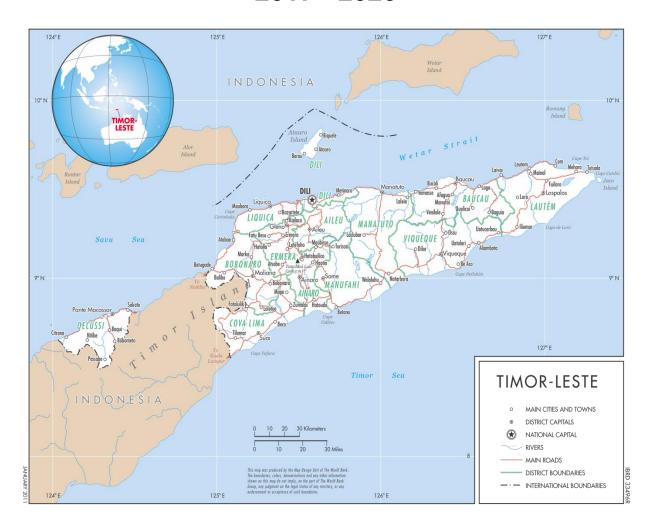
# National Action Plan on Antimicrobial Resistance: Timor-Leste

2017 - 2020



# **Ministry of Health, Timor-Leste**

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Developed by the Antimicrobial Resistance team of the Ministry of Health, Timor-Leste with technical support from WHO

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# Abbreviations and Acronym

AMA : Antimicrobial agent

API : Active Pharmaceutical Ingredient

AMR : Antimicrobial Resistance

AMSP : Antimicrobial Stewardship Program

AMU : Antimicrobial use

AMSP : AMU Surveillance Specialized Task Force

AGISAR : Advisory Group on Integrated Surveillance of Antimicrobial

Resistance

DRA : Drug Regulatory Authority

EQAS : External Quality Assessment Scheme FAO : Food and Agriculture Organization

GAP : Global Action Plan

GASP : Gonococcal Antimicrobial Surveillance Programme

GFATM : Global Fund for AIDS, TB and Malaria

HAI : Hospital Acquired Infection
IHR : International Health Regulations
IPC : Infection Prevention and Control

MS : Member States MoH : Ministry of Health

MoAF : Ministry of Agriculture & Fisheries

NAP : National Action Plan

NARCC : National Antimicrobial Resistance Control Committee

NFP : National Focal Point

NMC : National Multi-Sectoral Coordination group

NRA : National Regulatory Authority NRL : National Referral Laboratory

OTC : Over the Counter

OIE : World Organisation for Animal Health
SEARO : South-East Asia Regional Office
STG : Standard Treatment Guidelines
UNGA : United Nations General Assembly
WASH : Water, Sanitation and Hygiene

WHA : World Health Assembly
WHO : World Health Organization
WHOCC : WHO Collaborating Centre

# Executive Summary

"All Member States must develop their own, tailor made National Action Plans on Antimicrobial Resistance by May 2017, duly aligning them with the principles and approaches espoused by the Global Action Plan on AMR"

Mandate of the Global Action Plan on Antimicrobial Resistance

National Antimicrobial Resistance Control Committee

The tiny island state of Timor Leste is a mere dot on the world map. As one of the least developed nations in the world, it suffers a high burden of infectious disease. An ongoing challenge has been to effectively reach its 1.17 million population, most of whom battle tuberculosis, acute respiratory infections, diarrhoea, malaria and neonatal sepsis amongst under-five children.

Limited research data on the occurrence of resistant organisms in the nation have made it hard to estimate the exact antimicrobial resistance (AMR) scenario. In the absence of AMR surveillance efforts, a recent MEDLINE indexed publication that studied resistance profile of bacterial isolates from a Timorese sample, pointed towards the presence of resistant organisms. Nevertheless, several key steps by Government of Timor-Leste have been instrumental in paving the way for the country to join other nations in the South East Asia Region to speed up its plan on addressing the AMR crisis.

As part of these initial steps, during 2010-2015, several Regional Committee Resolutions on prevention and containment of AMR were adopted. According to one of the resolutions, combating antimicrobial resistance would require political commitment, multi-sectoral coordination, sustained investment and technical assistance.

Taking this resolve further, a Situation Analysis was undertaken in August 2016 using a tool developed by WHO SEARO based on discussions between national AMR Control Committee members, senior technical leaders of the national health authorities and veterinary sector and WHO team. It identified opportunities, challenges and implementation gaps to improve implementation of NAP AMR in ways that could meet the 68th World Health Assembly (WHA) resolution on AMR.

The indicators in the situation analysis protocol were grouped under the heads of National AMR Action Plan in line with GAP-AMR; National AMR surveillance system; Antimicrobial Stewardship and Surveillance of antimicrobial use; Infection Prevention Control in healthcare settings; Awareness raising; Research & innovation and One-Health engagement. Each of these focus areas were consistent with the five strategic objectives of the WHO GAP-AMR, namely the phases of exploration

and adoption; programme installation; initial implementation; full operation and sustainable operation.

The Situation Analysis revealed a high level of political commitment supporting AMR containment efforts as reflected in the formation of a National Multi-Sectoral Coordination (NMC) group. A number of initiatives were launched and existing ones strengthened. The government in partnership with WHO conducted national level campaigns to raise awareness on AMR targeting general population and health professionals. A national drug regulatory authority (NRA) was put into place with the National Directorate (Pharmacy and Drug), under the DG (Service Delivery) to oversee regulation and licensing, pharmacovigilance and market authorisation. Next, national medicine policies were updated while a standard treatment guideline for antibiotic prescription i.e. 'Antibiotic Guidelines' is in place. Public health system strengthening is an ongoing process while formal campaigns are consolidated or launched focusing on vaccination, sanitation and hygiene at community level.

The National Action Plan on AMR for the period 2016 – 2020 takes these efforts further, reinforcing the government's commitment to make universal healthcare and animal welfare, food security a reality. Based on implementation of the five strategic objectives, each of which has its specific sub-objectives, strategic interventions and key activities, the NAP AMR charts a new phase in Timor Leste's journey towards achieving goals related to AMR compliance.

To implement strategic objective 1 related to bridging knowledge and awareness gaps, NAP AMR will establish an evidence-based public communications programme on a national scale to improve awareness of AMR amongst general public and professionals. By 2019, the county would have carried out nationwide evidence based awareness campaigns with regular M&E.

To implement strategic objective 2 related to surveillance of AMR, steps would be taken to understand how resistance develops and spreads. This will be done by having a nationwide AMR surveillance system in place along with a national early warning system to identify early the emergence of resistance in priority pathogens and to critical antimicrobials by 2019.

To implement strategic objective 3 related to strengthening of hygiene, infection prevention and control, a national infection prevention and control programme would be implemented in compliance with IPC guidelines within healthcare settings, animal husbandry systems and fisheries and the food chain. Also, actions to decrease Hospital Acquired Infection (HAI) and associated AMR through facility based HAI surveillance programme (Human Health) would be conducted.

To implement strategic objective 4 related to optimising use of antimicrobial medicines, a national AMR containment policy would be announced along with a

series of Antimicrobial Stewardship Programmes (AMSP) and Standard Treatment Guidelines (STG) at the national scale for prudent use of antimicrobials. Moreover, mechanisms would be established to monitor antimicrobial usage on a national scale to inform interventions to reduce overuse and promote prudent use of antimicrobial substances.

To implement strategic objective 5 related to building a case for sustainable investments for new medicines, diagnostic tools/vaccines/aids that help bring down use of AMR, it is being mooted to build the human health and institutional capacity in the context of research on AMR. A strategic research agenda that is relevant to the Timorese context will be developed and implemented. This will be done, in large part, through international collaborations given the limited in country capacity.

Most of these activities will be implemented by the key actors as outlined in the proposed strategic plan that covers the period 2017-19. Following submission of the final report to the World Health Assembly, the Government of Timor-Leste will continue with its deliberations and planning process under the leadership of National Multi-Sectoral Coordination group (NMC).

# Background

## Setting the Context: From Global to National Action Plans

Antimicrobial resistance (AMR) has emerged as one of the biggest public health threats of the modern epoch. At the 68<sup>th</sup> World Health Assembly (WHA) in May 2015, a global action plan on AMR (GAP AMR) was adopted in response to the acknowledgement of this emerging crisis (1). The GAP AMR has been developed at the request of the Health Assembly in keeping with resolution WHA67.25 of May 2014, which was reflective of the global consensus that AMR was a major threat to human health.

The GAP AMR has advocated for the One Health approach to form the basis for the global response to AMR, especially in case of developing countries, which are expected to contribute to the increasing trends of antimicrobial agent (AMA) consumption and therefore, likely to be at a higher risk of emerging resistant microbes (2–4). The need for this was further stressed at the 2015 WHA through resolution WHA68.7.<sup>1</sup>

Consolidating the position of the GAP AMR, the global political will came together to further commit to the cause of containment of AMR at the United Nations General Assembly (UNGA) at the high level meeting on AMR on 21 September, 2016, in New York (5). At this meeting, global leaders committed to "taking a broad, coordinated approach to address the root causes of AMR across multiple sectors, especially in human health, animal health and agriculture" (5).

One of the overarching requirements outlined by the GAP AMR was that all Member States (MS) should develop their own, tailor made National Action Plans on AMR (NAP AMR), duly aligned with the principles and approaches espoused by the GAP AMR by May 2017.<sup>2</sup>

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<sup>&</sup>lt;sup>1</sup> Recognising that the main impact of antimicrobial resistance is on human health, but that both the contributing factors and the consequences, including economic and others, go beyond health, and that there is a need for a coherent, comprehensive and integrated approach at global, regional and national levels, in a "One Health" approach and beyond, involving different actors and sectors such as human and veterinary medicine, agriculture, finance, environment and consumers.

<sup>&</sup>lt;sup>2</sup> To have in place, by the Seventieth World Health Assembly, national action plans on antimicrobial resistance that are aligned with the global action plan on antimicrobial resistance and with standards and guidelines established by relevant intergovernmental bodies;

The process of framing a contextually-driven NAP AMR will provide a baseline understanding of the local AMR situation, along with highlighting gaps and available capacities. This will serve as valuable information, allowing different countries to customise their NAP AMR as per their local realities.

The process of framing a NAP AMR for Timor-Leste was initiated through a situation analysis, which provided details of the existing AMR situation, gaps and capacity in the local context.

## Situation Analysis and Assessment

The island nation of Timor-Leste has a population of about 1.18 million people, of which almost 70% reside in rural areas, according to the population and housing census of 2015 (6). According to the United Nations Conference on Trade and Development, Timor-Leste is one of the least developed countries in the world (7). The country has a significant burden of infectious diseases, as is evident from 87 deaths per 100,000 population due to tuberculosis in non-HIV infected people; this is more than thrice the value of neighbouring nation of Indonesia (25/100,000 population). Infectious diseases burden is also likely contributed by a modest proportion of population using improved drinking water sources (72%) and relatively low proportion using improved sanitation (41%) (8). Accounting for 11% of all deaths in 2012, tuberculosis remains the leading cause of death in the nation. Acute respiratory infections, diarrhoea, malaria and neonatal sepsis are responsible for almost 40% of deaths in under-five children (9). Child immunization coverage however has shown a promising trend (76%) indicating the focus of health system to population health early in life which is also indicated by significant improvement in life expectancy at birth and healthy life expectancy of 9.6 years and 8.9 years between 2000 and 2015 (8). Success of public health measures is also indicated by both U5 mortality and neonatal mortality declining to nearly half between 2000 and 2015 (8).

Inspite of the abovementioned evidence on different health and development indicators, there is very limited research evidence available on the occurrence of resistant organisms in the nation. The same has been highlighted in previous research efforts, and has been acknowledged by the recent situation analysis of the AMR containment efforts underway in Timor-Leste (10). There are no AMR surveillance efforts involving the nation, including the WHO global Gonococcal Antimicrobial Surveillance Programme (GASP) (11). In the only MEDLINE indexed publication that studied resistance profile of bacterial isolates from a Timorese sample, trends indicate that resistant organisms could be a problematic issue. Over half of the gram positive cocci isolated were resistant to multiple antimicrobials; resistance against oxacillin (33%), cephalexin (37%), cefotaxime (41%), ampicillin (44%) and penicillin G (44%) were common. Of the gram positive bacilli, 75% were resistant to multiple antibiotics, with resistance against tetracycline (25%),

enrofloxacin(25%), cephalexin (30%), sulfamethoxazole-trimethoprim (34%), ampicillin (40%), streptomycin (43%), penicillin G (49%) and oxacillin (73%) being common (12).

Timor-Leste has, recently, joined the countries of South East Asia Region in addressing the AMR crisis. Several Regional Committee Resolutions on prevention and containment of AMR have been adopted since 2010, and the 2015 Regional Committee resolution in Timor-Leste emphasised "that "combating antimicrobial resistance shall require political commitment, multi-sectoral coordination, sustained investment and technical assistance," and it called on Member States to put AMR as one of the top priorities on their national agendas" (13).

A situation analysis was undertaken in Timor-Leste in August 2016 using a tool developed by WHO SEARO. The specific objectives of the situation analysis were:

- To conduct the situation analysis prior to strengthening and developing the National Action Plan, aligning with Global Action Plan to determine the baseline regarding implementation and functionality in terms of sufficient qualified human resources, funding and functional structures of command and coordination of AMR program in the country;
- To identify opportunity, challenges and implementation gaps in order to improve the overall NAP implementation;
- Assist Timor-Leste to identify vulnerabilities, opportunities and needs to meet the 68th WHA resolution on AMR and prioritise the activities for AMR containment as per NAP;
- To facilitate WHO in fulfilling its commitment to report on the development, implementation, monitoring and evaluation of the NAP-AMR and to identify priority areas for WHO to support.

The situation analysis process comprised of guided discussions between the National AMR Control Committee members, senior technical leaders of the national health authorities and the veterinary sector, and WHO team. The situation analysis looked at how well developed the AMR programme was in terms of governance, policy and systems and its review focused on broad system analysis rather than assessing quality of policies and documents.

The indicators in situation analysis protocol were grouped into seven focus areas: 1. National AMR Action Plan in line with GAP-AMR; 2. National AMR surveillance system; 3. Antimicrobial Stewardship and Surveillance of antimicrobial use; 4. Infection Prevention Control in healthcare settings; 5. Awareness raising; 6. Research & innovation; and 7. One-Health engagement. These focus areas were consistent with the five strategic objectives of the WHO GAP-AMR.

Each of the focus areas was comprised of a list of sub-focus areas. Each sub-focus area was graded on five levels to show the incremental extent of AMP programme implementation. These five levels of phases are stated as follows: Phase 1: Phase of exploration and adoption; Phase 2: Phase of programme installation; Phase 3: Phase of initial implementation; Phase 4: Phase of full operation; Phase 5: Phase of sustainable operation (14).

A thematic situation analysis was conducted based on the phases in which each of the indicators were placed in. The phases reflect phases of the installation and implementation of the AMR containment program in terms of governance, policy and system. Phases 1 and 2 – relates to policy development and planning but no implementation; Phases 3-5 are related to different levels of implementation including Initial implementation; phase of full operation; and phase of sustainable operation. These phases from 3 to 5 are the strengths of the system. Sustainable operation is considered best practice and defined here as an operation that incorporate an M&E system.

Figure 1 shows the status of implementation of AMR containment programme in Timor-Leste. Green colour indicates complete implementation, yellow indicates partial implementation and red implies no implementation.

Focus area	Strategic activity	Exploration and Adoption	Programme Installation	Initial Implemention	Full Operation	Sustainable Operation
Developing or strengthening the NAP	NAP AMR developed in alignment with GAP AMR					
AMR Awareness raising	Awareness campaigns for the public					
	Education and training strategies for professionals					
AMR surveillance	National AMR surveillance					
	National laboratory					
	network strengthening Early warning system					
Rational use of antimicrobials and surveillance of antimicrobial use and sale	A national AMR containment policy for					
	control of human use of antimicrobials; AMR stewardship in the					
	community National Regulatory					
	Authority (NRA) or Drug Regulatory Authority (DRA)					
	Surveillance of antimicrobial use and sales in humans in the community					
	Regulation of finished					
	antibiotic products and active pharmaceutical ingredients (APIs)					
	Regulation of pharmacies on over the counter (OTC) sales and inappropriate sale of antibiotics					
Infection Prevention and Control and AMR stewardship programme in healthcare settings	AMR stewardship programmes in healthcare settings					
	Infection Prevention and Control programme in healthcare settings					
	National Hospital Acquired Infection and related AMR surveillance					
	Sanitation & hygiene and vaccination					
Research and Innovation	Research funding; National Policy to promote and foster innovation					
One Health Engagement	A national AMR containment policy and regulatory framework or control of animal use and their registration for use					
	National surveillance of AMR and the use and sale of antimicrobials at national levels in the veterinary sector					
	Infection Prevention and Control programme in the animal sector					
	AMR awareness generation and education in the animal sector					

Figure 1: Status of implementation of AMR containment programme/initiatives in Timor-Leste, by phase of implementation

The situation analysis in Timor-Leste revealed a high level of political commitment supporting AMR containment effort as was reflected in the formation of a National Multi-Sectoral Coordination (NMC) group with chairpersons and focal point identified. The formal endorsement of the governance mechanism is yet to take place. Government of Timor-Leste, in partnership with WHO, have conducted national level campaigns to raise awareness on AMR targeting general population and health professionals.

Currently, AMR surveillance is limited to disease control programmes such TB, HIV. National TB reference lab within the National Health Laboratory (NHL) has advanced facilities with culture, gene X and BSL 3 facilities; lab also collaborates with other WHO CCs including in Australia. TB, HIV and Malaria networks are independent and GFATM supported including their laboratory services. There is support at times to NHL.

AMR for general pathogens, however, is limited mainly due to limited availability human resources. NHL carries out all routine microbiology cultures plus sensitivity for basic set of antibiotics. NHL provides diagnostic support to National Hospital laboratory that doesn't undertake culture based microbiology. As an important public health function, NHL also tests food and water samples using rapid kits for residues and culture for *E coli* in water samples. NHL has been participating in EQAS since 2009 that is run by Pacific Paramed Training Centre (PPTC), Wellington, New Zealand. This was discontinued since last two years due to sample transportation issues. Fastidious organisms such as chlamydia, other STDs and difficult to grow organisms are tested by PCR at NHL.

In spite of a health system which is in an inception phase, Government of Timor-Leste has put in place a national drug regulatory authority (NRA), the National Directorate (Pharmacy and Drug), under the DG (Service Delivery). The NRA is responsible for regulation and licensing; pharmacovigilance and market authorization. Post licensing inspections including for retail pharmacies and OTC sales are done by Cabinet of Inspection, an independent body that reports to the Vice Minister (Health). Non regulatory functions of the NRA include planning and management of acquisition of pharmaceuticals and medicaments.

From the perspective of optimising use of antimicrobials, National medicine policies are being updated and Standard treatment guidelines for antibiotic prescription are in the final stages of drafting. In addition, regular communications are sent out by national agencies (such as National Hospital), to promote prudent use of AMAs in different health care settings.

Pilot efforts have been made in IPC in hospitals. Some of the measures include training for various target groups in basic IPC at the National Institute of Health. Quality Control department in each hospital across the system looks after IPC as

one of its component. These include water quality, general cleanliness and hand washing.

The public health system strengthening is being undertaken, efforts have maintained focus on vaccination, sanitation and hygiene at community level through formal campaigns.

Overall, most of the key elements of a containment programme are only in the policy formulation and planning phase mainly due to the fact that Timor-Leste is a young country which is in the process of institution building. Essential elements of AMR containment are yet to take off including comprehensive awareness program, surveillance of AMR and AMU including laboratory capacity, IPC and AMSP. Given limited production of animal source foods, animal health system is yet to be developed to serve public health functions.

Limited institutional capacity has also not allowed much recognition of public health research as a priority need. On its own there is no research agenda and no research is undertaken except a recent proposal that has been submitted to Cabinet of Ethics. The proposal deals with studying antibiotic susceptibility patterns in urinary isolates. Research is often undertaken to support programmatic decisions. For example, NHL has forged some research collaborations with universities, department of public health and WHO in the field of Neglected Tropical Diseases (NTDs) and Vector Borne Diseases (VBDs).

# National Action Plan on AMR (2017 – 2020)

## Goal, Objectives and Guiding Principles

The goal of the GAP AMR is: "to ensure, for as long as possible, continuity of successful treatment and prevention of infectious diseases with effective and safe medicines that are quality-assured, used in a responsible way, and accessible to all who need them."

To achieve this, the GAP-AMR has laid down five strategic objectives which form the basis for developing public health response to AMR globally. These strategic objectives are:

- **Objective 1:** Improve awareness and understanding of antimicrobial resistance through effective communication, education and training
- **Objective 2:** Strengthen the knowledge and evidence base through surveillance and research
- **Objective 3:** Reduce the incidence of infection through effective sanitation, hygiene and infection prevention measures
- **Objective 4:** Optimize the use of antimicrobial medicines in human and animal health
- **Objective 5:** Develop the economic case for sustainable investment that takes account of the needs of all countries, and increase investment in new medicines, diagnostic tools, vaccines and other interventions

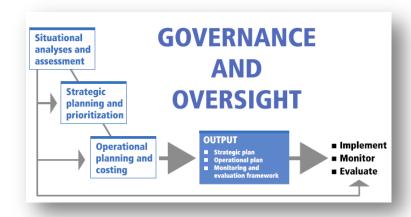
Additionally, the NAP AMR is expected to reflect the five principles based on which the GAP AMR strategies have been enunciated. These include: Whole-of-society engagement including a One Health approach, Prevention first, Access, Sustainability, and Incremental targets for implementation (15).

# **NAP Development Process**

The development of NAP followed the guidelines enshrined in WHO's "Antimicrobial resistance: A manual for developing national action plans" (16). The approach was structured around the five strategic objectives and five principles which are embodied by the GAP AMR (15).

Within the five strategic objectives of the GAP AMR, 12 key strategic interventions were included. Each of these interventions were described in terms of specific objective, with a defined set of activities to be carried out successfully to execute the strategic intervention and eventually to fulfil the strategic objective. Key M&E

indicators were defined for activities under each of the strategic interventions with the operational plan comprising of detailed planning by activity. This was developed along with the budget allotted for the respective activities.



The NAP thus consists of the Situation Analysis and

Assessment, a Strategic Plan, an Operational Plan as described in the WHO guidance manual and a Sample template (16,17).

The Situation Analysis by WHO SEARO focused on how well developed the AMR programme is in terms of governance, policy and system formed the basis for identifying gaps and strategic priorities (World Health Organization Regional Office for South-East Asia. 2016). The situation analysis was further supported by literature review including grey literature provided by country level stakeholders.

Based on the extent of implementation, each of the strategic interventions was graded on an incremental scale consisting of five phases (14). The first phase that of exploration and adoption, indicates that the process of designing an AMR containment programme has been initiated. Once the decision to implement the programme has been made, systems progress to the second phase, that of programme installation. The third phase, of initial implementation, is one of the most challenging phases for programmes in developing countries. Once the early implementation barrier is overcome and the programme is scaled up, the fourth stage – full operation – is achieved. Once the programme starts to function at the highest grade of operational efficiency, the fifth and final stage, that of sustainable operation, is attained.

Findings from the Situation Analysis helped situate the current state of NAP in the country along the incremental scale. To enable the MS to make the most progress towards implementing NAP, GAP principle of "Incremental targets for implementation" was followed with the ultimate aim of achieving phase 5 of sustained operations. Flexibility was built into the planning process including monitoring and reporting arrangements, in order to allow the country to determine priority actions that it needs to take in order to attain the five strategic objectives and

implement actions in a step-wise manner that meets both local needs and global priorities.

NAP development involved the process of participative dialogue with important stakeholders and informants. Further expansion into a detailed operational by sub activities and validation was done by country team and stakeholders. Technical support was provided by WHO Country office, WHO SEARO and the Consultant.

# Country Response

#### Governance

A national multi-sectoral governance mechanism is the pivot around which AMR-related activities can be effectively coordinated in all the relevant sectors. This will ensure a systematic and comprehensive approach However, the scope should be broad enough to address all five strategic objectives of the global action plan, prioritising activities in a step-wise approach.

The governance mechanism for Timor-Leste will comprise of a High Level National Multi-sectoral Committee (NMC), for Antimicrobial Resistance. NMC will be supported by a multi-sectoral Technical Working Group who will address the strategic objectives of GAP through specialised Task Forces on related to the five strategic objectives of GAP. Each of these will be formed and will function as per the following criteria.

# National Multisectoral Committee (NMC) for Antimicrobial resistance (AMR)

The NMC will be the implementation agency for NAP AMR and will draw its powers and mandate from Government resolutions. Being a high level committee, NMC will also provide strategic vision to AMR control efforts in Timor-Leste. The NMC will provide the platform for programme planning and implementation through a supporting structure comprising of technical working group.

The NMC is envisioned as a multi-sectoral group of political member and senior policy makers and programme managers from different ministries. Representatives of non-governmental agencies, cooperatives, civil society representatives, media, and international agencies (WHO/FAO/OIE) will be co-opted members. By way of its multi-sectoral composition, it will ensure adequate integration of AMR containment efforts into the existing health system, public health and disease-specific programmes, animal health and production food sector and other environmental initiatives.

#### Composition of NMC:

The NMC will be chaired by Vice Minister for Health and Co-Chaired by Vice Minister for Agriculture. Its membership will be as follows:

- Vice Minister for Health (Chairman)
- Vice Minister for Agriculture (Co-chair)
- DG for Health Service Delivery, MoH Secretariat (Focal Point for AMR)
- DG for Livestock and Veterinary, MoAF (Focal Point for AMR)
- DG for Agriculture, Horticulture and Extension Services, MoAF
- DG for Fisheries and Aquaculture, MoAF
- DG for Environment, MoICE (Focal Point for AMR)
- DG for State Budget and Finance, MoF
- DG for Tertiary Education, MoE
- Executive Director for National Hospital, MoH
- Executive Director for National Health Laboratory, MoH
- Executive Director for Institute of Health Science, MoH
- Coordinator, National Authority for Food Safety, Sanitation, and Economic Activity, Prime Minister's Office
- Secretary of State for Social Communication, Prime Minister's Office
- OIE
- FAO
- WHO

#### Logistics of the NMC

 The NMC will meet every six months. The NMC will have a rotatory Chairmanship between MoH and MoAF. The rotation will happen annually. The NMC Secretariat will be located in General Directorate for Health Services Delivery

#### Scope

- The NMC will address all AMR-related activities in country.
- The scope will be broad enough to address all five strategic objectives of the global action plan, prioritizing activities in a step-wise approach.

#### Roles and responsibilities of NMC:

Detailed and specific roles and responsibilities of the NARCC have been mentioned in the Strategic Plan. Broadly, it will be responsible for:

- Planning, implementation and Monitoring & evaluation of different strategic interventions and activities of NAP AMR
- Reporting implementation status to national agencies and international partners

- Constituting technical working group and commission task forces for tasks that include providing technical input for program support and NARCC decision-making
- Facilitating collaborations with internal and external agencies and organizations, especially in the field of surveillance and innovations
- Advocate for prevention and containment of AMR

#### **Appointing a National focal point**

National Directorate of Pharmaceutical and Medicine, MoH and National Directorate of Veterinary – will be the National AMR focal points responsible for coordinating AMR activities and tasks in the health, animal, aquaculture, food production and environment sectors. The responsibilities of NFP will be to:

- Build sustained partnerships and work nationally and internationally on containment of AMR;
- Identify stakeholders and facilitate formation of an inclusive NMC;
- Lead and coordinate drafting of a national action plan for containment of AMR;
- Facilitate and oversee implementation, M&E of the plan through the NMC;
- Ensure regular data collection and information sharing by instituting effective communication and coordination among all stakeholders, the members of NMC and their constituencies, sectors and disciplines;
- Coordinate national activities for establishment of AMR surveillance systems
- Report on prevalence of and trends in AMR to the global AMR surveillance system (GLASS)

## **Forming Technical Working Groups**

Technical working group (TWG) will form an integral part of the governance mechanism in Timor-Leste. It will be multi-sectoral in composition and will report to the national NMC. TWG will be formed and will be mandated with specific tasks such as providing technical input, conducting situational analyses, drafting NAPs, planning and budgeting, commissioning specialised task forces and overseeing implementation of strategic interventions and corresponding key activities under the five strategic objectives.

Each of the TWGs will be responsible for programme planning and budgeting referring to NAP on AMR while focusing on One Health and for coordinating between the different agencies and secretariats. They will assume charge for monitoring and evaluation and based on their interactions and review mechanisms come up with a set of workable recommendations. ToRs for Technical Working Group will include:

- Provide strategic direction by identifying intervention and key activities
- Conducting the AMR situational analysis

- Conducting detailed stakeholders mapping (SWOT)
- Prepare and develop the NAP AMR
- Monitor and evaluate the implementation of the NAP AMR
- Coordinate with the NMC AMR for budget allocation or any approval for AMR related issues
- Drafting technical advice and reports

The TWG will be chaired by a person nominated by the NMC. Secretariat of TWG will be located in Department of Pharmacovigilance and Medicines Control, MoH and Department of Veterinary Diagnostic Laboratory, MoAF, meet every three months; more frequently in case of extraordinary situations. The TWG will be comprised of the following members:

- National Director for Public Health, MoH
- National Director for Veterinary, MoAF
- National Director for Livestock, MoAF
- National Director for Agriculture, MoAF
- National Director for Hospital Support and Emergency, MoH
- National Director for Pharmaceutical and Medicines, MoH
- National Director of Quarantine and Biosecurity, MoAF
- National Director for Curriculum Development for tertiary institutions
- Director for Professional Development (National Health Institute)
- AMR Laboratory Surveillance Focal Point, National Health Laboratory, MoH
- Representative of Internist from National Hospital, MoH
- Head of Department of Veterinary Diagnostic Laboratory (AMR Focal Point MoAF)
- Head of Department of Pharmacovigilance and Medicines Control (Secretariat)/AMR Focal Point
- Representative from Medical Associations
- Representative from Pharmacist Associations
- Representative from Nursing Associations
- Representative from Public Health Associations
- Representative from Veterinary Associations
- OIE
- FAO
- WHO

## **Constituting Specialised Task forces**

Specialised task forces will be commissioned by the TWGs for delivering on specific tasks in the respective strategic areas. The will work under the technical guidance and supervision of respective TWG and will comprise of in-country as well as

international experts, including those from WHO/FAO/OIE. The Task forces will be tasked with functions such as evaluation of existing policies, frameworks, interventions and guidelines and the development of guidelines and standards. They will be envisioned for the implementation of the Timor Leste National Action Plan as mentioned in the Strategic Plan document.

There will be five specialised task force and the specialized task forces will comprised of the following:

- AMR Surveillance in Human and Animal Health Task Force: The Task
  Force will be composed of the following members i.e. representatives from
  National Health Laboratory, Laboratory Department at NHGV, Department of
  Diagnostic Veterinary Laboratory.
- 2. Antimicrobial Consumption (AMC) Surveillance in Human and Animal Health Task force: The Task Force will be composed of the following members i.e. representative from National Directorate for Pharmaceutical and Medicines, representative from National Directorate for Veterinary, representative from Research Department (National Institute for Health).
- 3. AMR Public Awareness Task Force: The Task Force will be composed of the following members i.e. representative from department of Health Promotion, representative from department of pharmaco-vigilance and control, representative from national health laboratory, representative from national directorate for veterinary, representative from the Ministry of Education
- 4. *Infection Prevention Control in Healthcare Task Force*: The Task Force will be composed of the following members i.e. representative from cabinet of quality assurance services, representative from quality control from NHGV and referral hospital, representative from national directorate for veterinary
- 5. Research and Innovation in Human and Animal Health Task Force: The Task Force will be composed of the following members i.e. representative from National Health Institute, representative from Faculty of Medicines and Health Science, representative from ministry of education, representative from national directorate for veterinary etc.

# Strategic Plan

The strategic plan for Timor-Leste's NAP AMR is based on implementation of five strategic objectives, each of which has its objectives, strategic interventions and key activities

## **Strategic Objective 1: AWARENESS**

The GAP AMR has identified the need to raise awareness of AMR and promote behavioural change through public communication programmes that target different audiences in human health, animal health and agricultural practices as well as a wide range of consumers related to these sectors. The GAP AMR has also focused on making AMR a core component of the professional education training, certification, continuing education and development in the health and veterinary sectors and agricultural practice. This approach is expected to foster proper understanding and awareness amongst professionals.

The Situation Analysis revealed although awareness campaigns had been carried out with technical support from WHO Country Office, these were on a limited scale for general public and few professional groups. Limited in service training of human health professionals has also been carried out.

By 2019, Timor-Leste will carry out nationwide evidence based awareness campaigns with regular M&E. The aim is also to revise curricula in undergraduate medical and veterinary, food industry and agriculture teaching and Continuous Professional Development courses. Revised curricula will be implemented on a limited scale but with regular audits. The Strategic Plan is as follows:

# Objective 1.1: To improve awareness of AMR amongst the general public and professionals

Strategic intervention 1.1 Establish an evidence-based public communications programme targeting audiences in policy making, human and animal health practice, the general public and professional on prudent use of antimicrobials

#### **KEY ACTIVITIES**

Under the technical guidance of TWG:

2017	1. The MoH and MoAF (or agencies identified by them) with support of WHO, FAO and OIE will conduct KAP Studies on a national scale on AMR, IPC, environmental relationships (environmental impacts and impact of environment laced with AMAs and AMRs on health of humans, animals and environment) to assess awareness levels and gaps in knowledge in general public, including farmers and school children
2018	<ol> <li>MoH and MoE will design evidence based communication campaigns using evidence generated that will include accurate and relevant messages targeting primary and secondary school curriculum, general public and media with support from WHO, FAO, OIE and Secretary- State Communication.</li> <li>MoH and MoAF will develop awareness material on IPC and biosecurity measures for professional groups: para-veterinarians and veterinarians, paramedical staff</li> </ol>
2017-18	<ol> <li>MoH and MoAF will identify pilot sites to implement communication campaign for antimicrobial including antibiotic awareness improvement. Limited scale roll out will be done with support from WHO, FAO and relevant NGOs</li> </ol>
2019-20	<ol> <li>Pilot campaigns will be evaluated in 2018. This will be followed by nationwide scale up and scale out of awareness campaigns in 2019 with regular monitoring, evaluation and refresher trainings and awareness campaigns</li> </ol>

### Responsible Agency

MoH, MoAF, MoE, MoICE

#### Partners and Stakeholders

WHO, FAO, OIE, NGOs, Civil Society Organizations, Media Agencies, Religious groups

#### **Illustrative Indicators**

- Evidence based communication campaigns tailored for specific target groups;
   and
- Increased awareness on AMR and related issues among general public and professionals

# Objective 1.2: Improve knowledge of AMR and related topics in professionals through professional education and training deployed at the national scale

Strategic intervention 1.2 Include AMR and related topics such as Infection Prevention Control a core component of professional education, training, certification and Development for health care providers and veterinarians including Veterinary and Livestock technicians

#### **KEY ACTIVITIES**

Under the overall supervision of TWG:

#### 2017

 The MOH and MOAF (or agencies identified by them) will conduct KAP Studies on a national scale on AMR, hygiene & IPC, environmental relationships (environmental impacts and impact of environment laced with AMAs and AMRs on health of humans, animals and environment) to assess awareness levels and gaps in knowledge in professionals (veterinarians and veterinary technicians, physicians, environmental, health, agriculture/production experts, ministry officials of relevant departments and policymakers)

2018

- MoH and MoAF, under technical guidance of Ministry of Education, will undertake revision for professional development courses by respective councils/universities (human and animal health, the food industry and agriculture). Roll out of courses will be done on a limited scale along with concurrent regular audits followed by nationwide scale up
- MoH and MoAF will conduct capacity building of health care providers and veterinarians including veterinary and livestock technicians on AMR including rational use of antibiotics during 2017-2018

#### 2019-20

4. MoH and MoE will incorporate the AMR and related topics in undergraduate and postgraduate curricula in human and animal health, the food industry and agriculture. Limited scale testing of

revised curriculum along with regular audit of courses will be conducted before planning a nationwide scale up in next phase of NAP

#### Responsible Agency

MoH, MoAF, MoE, MoICE

#### Partners and Stakeholders

WHO, FAO and OIE

#### **Illustrative Indicators**

- Revised curricula for undergraduate, postgraduate and Continuous Professional Development courses in human and animal health sectors and food industry; and
- Increased knowledge of AMR and related topics among professionals

## Strategic Objective 2: SURVEILLANCE OF AMR

The GAP AMR identifies the need to establish an evidence based surveillance for AMR in the nation and identifies the following critical information/evidence gaps:

- Descriptive epidemiology of resistant organisms as they emerge
- Understanding how resistance develops and spreads
- The ability to rapidly characterise the emergent resistant organisms
- Understanding social sciences, behavioural and other research needed for holistic fulfilment of all five strategic objectives
- Treatment and prevention of infections, especially in the low resource settings
- Basic and translational research to support the development of new treatments, diagnostic tools, vaccines and other interventions
- Alternatives to non-therapeutic uses of antimicrobial agents in the context of agriculture, aquaculture and their use in crop protection
- Economic research

The situation analysis revealed that AMR surveillance has not been established in Timor-Leste. It is in policy formulation and planning phase due mainly due to limited human resource and therefore material resources capacity in the country. Limited testing of clinical isolates is carried out at the National Health Laboratory. AMR surveillance is mainly carried out in disease control programs such TB, HIV where in collaborations.

By 2019, Timor-Leste will have a nationwide AMR surveillance system in place. Resistance profiles of priority pathogens will be reported. These efforts will be supported by quality assured national referral laboratories in human and animal health sectors and their network of surveillance laboratories. By 2019, a national early warning system will be in place to identify early the emergence of resistance in priority pathogens and to critical antimicrobials. The Plan will be rolled out as below:

# Objective 2.1: Set up a national surveillance system for antimicrobial resistance under the leadership of a National Coordinating Centre.

Strategic intervention 2.1 Establish a national coordination structure for surveillance of AMR in the MoH and the MoAF

#### **KEY ACTIVITIES**

## 2017 1. The TWG will identify a National Coordination Centre (NCC), define its mandates and terms of reference and designate a National Focal Point followed by notification by ministerial dispatch. The NCC will be located in the MoH/ National Health Laboratory (NHL) and Veterinary Diagnostic Laboratory (VDL) in the MoAF 2. Establish National AMR Surveillance Unit, within the NHL in the MoH, and National VDL in the MoAF 2018 3. Under the technical guidance of NCC and technical support from WHO, OIE and FAO, The MoH (National Laboratory and Hospital Laboratory) and MoAF (Veterinary Diagnostic Laboratory) will develop guidelines for AMR Surveillance including guidelines for data sharing (indicators, triggers, analysis plan, response plan), incorporating the critical components as outlined in guidance documents (WHO sample templates, GLASS implementation guide, AGISAR technical recommendations, OIE, Codex, etc). 2018 4. The NCC will identify priority pathogens, sample sites and pathogen-antimicrobials combinations in humans and animals, based on the country's AMR situation 5. NCC will develop a One Health AMR surveillance plan in humans, animal and food (sample selection, number of samples, sample processing, logistics) 6. NCC will assess and inventory resources for monitoring, surveillance and testing sentinel environmental sites for antimicrobial resistant organisms and antimicrobial agents 7. NCC will train surveillance staff and clinical staff in AMR surveillance and lab techniques according to GLASS standards 8. NCC will develop an integrated human and animal IT platform

for AMR surveillance reporting. WHONET platform will be implemented for AMR surveillance data entry, storage and

	transmission
2018	<ol> <li>NCC will implement a national AMR surveillance program that is representative of the country situation but with limited number of operational sites. Maliana and Baucau Municipality will be targeted in the pilot phase. Regular data of AMR along with resistance profiles of priority pathogens for human, animal and food will be made available to NCC from limited number of sites in the two target municipalities.</li> <li>Antibiotic resistant organisms in representative environments. (hospitals, animal production units, slaughterhouses, pharmaceutical manufacturing units etc.) and selected organisms in water and soil, with varying degrees of exposure to antibiotics will be mapped by NCC.</li> <li>Data will be reported, exchanged and queried through the integrated AMR surveillance IT platform; WHONET platform implemented by NCC will be utilised.</li> </ol>
2019-20	<ul> <li>12. The NCC will establish formal linkages between national AMR surveillance programme and WHO GLASS. Reporting to GLASS will commence after formal assessment of national AMR surveillance program pilots.</li> <li>13. TWG (Surveillance) will conduct a formal assessment of National AMR surveillance followed by recommendations of nationwide scale up.</li> </ul>

#### Responsible Agency

MoH, MoAF

#### Partners and Stakeholders

WHO and FAO, Department Surveillance and Epidemiology (DSE), MoH, National Health Laboratory, National Hospital, Veterinary Diagnostic Laboratory Department, MoAF

#### Illustrative Indicators

- National AMR Surveillance network with focal point; and
- Improved surveillance of priority pathogens and pathogen-antimicrobials combinations in humans, animals, environment and food industry

Objective 2.2: Build laboratory capacity under the leadership of a National Referral Laboratory (NRL) to produce high-quality microbiological data for patient and food-safety management and support surveillance activities.

Strategic intervention 2.2 Establish a quality assured national laboratory surveillance network (for AMR surveillance and action)

#### **KEY ACTIVITIES**

Under the overall technical guidance of TWG (Surveillance):

2017

- 1. The National Health Laboratory will be identified as NRL for AMR Surveillance in Timor-Leste. NHL will cater to human, animal and food sector as NRL. The NRLs will develop expertise in methods for confirming and characterising specific pathogens, performing susceptibility testing, organising quality assurance and participating in external quality assurance schemes (EQAS). NRL will subscribe to Thailand EQAS network. The NRLs will coordinate a national network of surveillance laboratories to monitor AMR in human clinical, animal and food samples. Further, environmental surveillance for AMR will be carried out as per 2.1 in human/animal health surveillance labs.
- 2. Laboratories linked with AMR surveillance sites in 2.1 will be identified by the NRLs. These surveillance laboratories will be capable of identifying target pathogens and perform susceptibility testing as per standard operating procedures (SoP) laid down by the NRLs. Alternatively, the NRLs will establish a specimen storage and transportation system for more efficient use of existing in country laboratory resources.
- 3. The NRLs, in partnership with Veterinary Lab (MoAF) will develop and share AMR surveillance standards and guidelines, including SoPs, incorporating other intergovernmental standards (OIE/WHO GLASS and AGISAR/Codex) with surveillance labs.

2018

- NRL will train surveillance staff, clinical staff, and laboratory personnel in AMR surveillance, lab techniques and data management according to international standards (WHO GLASS and AGISAR, OIE, CODEX).
- 5. Lab surveillance network in support of National AMR

surveillance network will be rolled out in limited number of sites (Maliana and Baucau Municipality will be targeted in the pilot phase).

#### 2019-20

- 6. TWG will conduct a formal assessment of National laboratory surveillance network followed by recommendations for a nationwide scale up.
- 7. NRL will expand the network into a nationwide quality assured laboratory AMR surveillance network. NRL will establish linkages with international and global surveillance and internationally relevant initiatives (like GLASS, GFN). Reporting to GLASS will commence from surveillance sites recruited and operationalised in initial phase.

#### Responsible Agency

MoH, MoAF

#### Partners and Stakeholders

WHO and FAO, Surveillance Department (MoH), National Health Laboratory, National Hospital, Diagnostic Veterinary Laboratory Department

#### Illustrative Indicators

- National laboratory surveillance network with National Reference Laboratory (NRL) and quality assured network of surveillance laboratories; and
- Laboratory surveillance of AMR strengthened

Objective 2.3: Develop a multi-centric surveillance system on the national scale to provide early warning of emerging resistance and monitoring of secular trends at national and sub-national levels.

Strategic intervention 2.3 Establish a systematic, standardized process to collect, assess and share data, maps and trends on AMR hazards; develop communication and dissemination systems to ensure coordination and information exchange; and initiate responses to warning triggers

#### **KEY ACTIVITIES**

Under the overall technical guidance of TWG and with technical support from WHO and FAO:

#### 2017-18

- 1. The NCC will identify agencies (related to agriculture, human and animal health, drug control, environmental health) to be involved in AMR hazard and risk assessment, and outline their roles and responsibilities
- The NCC will frame guidelines and national standards for systematic collection, sharing, and assessment of AMR hazard events framed in keeping with international standards (IHR/WHO/OIE/FAO); includes surveillance manual, investigation/response guidelines, case management guidelines and lab guidelines.
- 3. List and definitions of priority events (priority pathogens, specimens, and pathogen-antimicrobial combinations) will be developed in keeping with country AMR situation
- 4. The NCC will commission National Institute of Health to conduct surveys to establish baseline estimates and trends of AMR to determine and establish thresholds for alerts and action systems

#### 2019-20

- A central library or database will be established at the NCC to store AMR risk information, and make data available to government agencies, public and international community as appropriate in future.
- 6. Data transmission on AMR alerts will start flowing from initial phase AMR surveillance sites identified and recruited in 2.1. Processing of information will be initiated in real time or close to real time. This will be followed by a comprehensive analysis on AMU in the human and veterinary sector and its linkage with the resistance profiles reported in animals and humans by the laboratory based AMR surveillance programme.

#### Responsible Agency

MoH, MoAF

#### Partners and Stakeholders

WHO and FAO, Surveillance Department (MoH), National Health Laboratory, National Hospital, Diagnostic Veterinary Laboratory Department

#### **Illustrative Indicators**

- National early warning system on AMR hazards with central database on AMR risk information
- Thresholds for alerts and action applied for early identification of AMR hazards and risks

# Strategic objective 3: HYGIENE, INFECTION PREVENTION AND CONTROL

Infection prevention and control, especially in the context of hospitals, is an extremely important aspect of a strategic plan to contain AMR. This is essentially because a clinical setting represents an ecosystem of high antimicrobial usage. Within this ecosystem, exist patients, who may be immunologically impaired. These patients not only represent the population that is vulnerable to serious, lifethreatening infections, at the same time, they promote the emergence of resistance.

On the other hand, better hygiene (WASH) and Infection prevention control (IPC) represent methods to cut down on the spread of infections in ambulatory human and animal care facilities, in food production systems and in the community in general. Vaccination in humans and animals and biosecurity in food production systems are specific interventions that if implemented effectively, can result in better health outcomes and reduced risk of emergence of AMR.

The Situation Analysis of measures related to hygiene, infection prevention and control in human, animal and related sectors in Timor-Leste shows that initial efforts, though elementary in nature, have been initiated in human health sector alone in the field of infection prevention and control methods in hospital settings. Human health sector also has implemented nationwide vaccination, sanitation and hygiene campaigns. Other measures such as AMR stewardship programme in healthcare settings or ambulatory settings, in human and animal health and food production sectors and HAI are yet to be initiated.

The Strategic Plan as outlined below aims to roll out a comprehensive multi-sectoral national IPC programme on a limited scale in healthcare facilities in public and private sector and in selected food chains (farms, slaughterhouses, food processors, aquaculture etc.). Similarly, HAI surveillance will be implemented in few public and private healthcare facilities. In community settings, formal campaigns for sanitation and hygiene including biosecurity and animal husbandry practices, food handling practices and vaccination on a small scale in animal and food production sites. Human vaccination is a well-developed program that will be further consolidated and strengthened.

Objective 3.1: To establish a national infection prevention and control programme through full implementation and compliance with the IPC guidelines within healthcare settings, animal husbandry systems and fisheries and the food chain

Strategic intervention 3.1 Create a formal organizational structure to ensure proper development and use of infection prevention and control policies and strategies in health care settings, animal rearing facilities and in fisheries

#### **KEY ACTIVITIES**

2017

 The Cabinet of Quality assurance in Health in collaboration with the National Directorate of Hospital Support Services will commission a multi-sectoral task force that will evaluate existing IPC guidelines and develop a national IPC policy, mandating the creating of a National IPC Programme in healthcare facilities, animal health care facilities including use of personal protective equipment (PPE), and food production systems.

# Under the overall technical of TWG and supervision of Cabinet of Quality assurance in Health and National Directorate of Hospital Support Services:

2017-18

- 2. The multi-sectoral taskforce on IPC will develop IPC guidelines with implementation and M&E plans covering infection prevention and control in all health care settings (hospital and ambulatory) in human sector including linking it with hospital accreditation system; IPC/biosecurity in animal health facilities (hospital and ambulatory), vaccination, and biosecurity in the farm to fork chain in line with international standards set out by OIE/FAO in animal and food production sectors. Existing guidelines on patient safety, in hospital services that is implemented by Quality Control Departments will be integrated into these guidelines.
- The taskforce, in collaboration with WHO, FAO, OIE and NCC will identify target groups to be trained in IPC from different sectors (human health, animal health, food production/agriculture, environment) and at different levels (policy makers, programme managers, general people, industry leaders, farmers, etc.).

2017-18

4. MoH and MoAF, through the National Institute of Health, will coordinate capacity building at healthcare facilities and create dedicated, trained IPC teams at facilities in selected number of sites. These should also include trained biosecurity teams at large farms, slaughterhouses, food processing industries, etc.

- 5. MoH and MoAF, in collaboration with MoE, will review existing curricula of professional courses with respect to content on IPC and with support from WHO/FAO/OIE/UNFPA/UNICEF, develop training modules for incorporation into professional courses,
- 6. MoH (INS) will develop the IPC training modules for in service training for health professionals

2019-20

7. MoH and MoAF will roll out IPC programme on a limited scale, with dedicated, trained teams in place in some public healthcare facilities and private sector and in selected food chains (farms, slaughterhouses, food processors, aquaculture etc.).

TWG will conduct a formal assessment of National IPC Programme followed by recommendations of nationwide scale up in all human and animal healthcare facilities across the nation and across all food production systems.

#### Responsible Agency

MoH, MoAF, Cabinet of Quality Assurance in Health, National Directorate of Hospital support services

#### Partners and Stakeholders

WHO, FAO, UNFPA, UNICEF, Surveillance Department (MoH), National Health Laboratory, National Hospital, National Institute of Health (NIH)

#### Illustrative Indicators

- A National IPC programme for human, animal health and food industry sector is in place; and
- Proportion of human, animal, food industry facilities with functional IPC programme implemented

# Objective 3.2: Decrease Hospital Acquired Infection (HAI) and associated AMR (Human Health)

Strategic intervention 3.2 Implement a healthcare facility-based HAI surveillance system along with related AMR surveillance (human health).

#### **KEY ACTIVITIES**

2017

 The TWG will commission a multi-sectoral task force that will develop guidelines for HAI surveillance (objectives, standardised case definitions, methods of detecting infections/procedures/exposures and exposed populations, process for analysis of data, evaluation of data quality, reporting/communication lines at local level and from local to national facilities, quality assured microbiology capacity including a designated national reference laboratory, training programme, financial outlays).

2018

2. NCC for AMR surveillance will implement on pilot scale a HAI surveillance in few public and private healthcare facilities. HAI surveillance data will be reported centrally from these public and private healthcare facilities.

2019-20

3. NCC will carry out a formal assessment of HAI surveillance pilot. Data from HAI surveillance network will be integrated into National AMR surveillance network. Integrated analysis of surveillance data will form the basis for monitoring and response frameworks, including the identification of priority triggers (priority pathogens or pathogen-drug resistance combination) that will be established by NCC. HAI surveillance will be implemented on a national wide scale covering national, regional, referral, municipal and district level hospitals in public and sentinel private hospitals/chains of hospitals,

#### Responsible Agency

MoH, National Health Laboratory

#### Partners and Stakeholders

**WHO** 

- National HAI surveillance program for priority infections, procedures and exposed populations;
- Proportion of health care facilities with functional HAI surveillance programme;
   and
- Reduced HAI and associated AMR in health care facilities

### Objective 3.3: To limit the development and spread of AMR outside health settings

Strategic intervention 3.3 Promote sanitation and hygiene by social mobilisation and behavioural change activities

#### **KEY ACTIVITIES**

2017

 The TWG, in collaboration with MoE, will commission a multisectoral task force. The taskforce will review and evaluate the existing national campaigns, generate new evidence wherever necessary and modify guidelines suitably to address issue of sanitation and hygiene including, food handling practices and vaccination in humans and animals.

#### **Under the overall technical supervision of TWG:**

2018

- 2. MoH and MoAF will implement formal campaigns for sanitation and hygiene including biosecurity and animal husbandry practices, food handling practices and vaccination on a small scale in animal and food production sites.
- MoAF will strengthen vaccination programmes for preventable infections. Animal vaccination campaigns will be rolled out on limited scale with a plan for phased nationwide scale up developed; MoAF will evaluate existing vaccination programme for their effectiveness and coverage,

2018-19

 MoH and MoAF in collaboration with MoE will include sanitation and hygiene including food handling practices in the core curricula in secondary and undergraduate education for school children,

2019-20

 MoH and MoAF will carry out monitoring and concurrent evaluation of campaigns on sanitation and hygiene including biosecurity and animal husbandry practices and food handling practices to inform nationwide scale-up,

#### Responsible Agency

MoH, MoAF

#### Partners and Stakeholders

#### MoE, WHO and FAO

- Evidenced based national campaigns on water, sanitation & hygiene (WASH), food safety, and vaccination in humans and animals;
- Increased coverage of WASH related interventions and vaccination in humans, animals and food industry; and
- Reduced infections and associated AMR outside health settings

## Strategic Objective 4: OPTIMISE USE OF ANTIMICROBIAL MEDICINES

Use of antimicrobials in any form, even when rational and prudent, can precipitate resistance in target microbes. High antibiotic use may reflect over-prescription, easy access through over-the-counter sales, and more recently sales via the Internet which are widespread in many countries.

The situation analysis reveals that Timor-Leste has a functional National Regulatory Authority that is responsible for regulation and licensing; pharmacovigilance and market authorization. Post licensing inspections including for retail pharmacies and OTC sales are carried out on limited scale. However, the country lacks important instruments and systems such as a National AMR containment policy, AMR stewardship programme for control of use of antimicrobials, AMU surveillance including sales of antimicrobial agents. Animal health sector, however, lags on all of the above fronts.

Timor-Leste will establish a robust system for regulation and surveillance of use of antimicrobial agents for control of human and veterinary use of antimicrobial substances. Some of the measures taken will include a National AMR Containment and Use Policy and related regulatory frameworks, National Drug Policy, National Drug Regulatory Authority, essential medicines list and standard treatment guidelines with special reference to use of antimicrobial agents, evidence based guidelines for National Antimicrobial Stewardship Programme in human and animal health care, ambulatory and community settings as well as aquaculture and an AMU monitoring programme in humans and food animals including, residues testing in food products. All of the above systems to optimise use of antimicrobials, however, will be implemented on a limited scale during 2017-2019. Formal assessments will be carried out at the end of this period before nationwide scale up. The Strategic Plan to establish the above is as outlined below:

# Objective 4.1: Establish a national Antimicrobial Stewardship Programme on a national scale to improve and measure the appropriate use of antimicrobials

Strategic intervention 4.1 Create a national AMR containment policy for control of use of antimicrobials in humans and animals, and establish a comprehensive evidence-based formal antimicrobial stewardship programmes at the national level

#### **KEY ACTIVITIES**

The TWG will commission a task force to develop a National AMR Containment and Use Policy and related regulatory frameworks. Within this policy framework, the task force will:

2017

- Propose a formal organisational structure responsible for implementation of the National AMR containment policy.
- Formulate regulatory framework for control of human and veterinary use of antimicrobial substances, including but not limited to the phasing out of Antimicrobial Growth Promoters (AGPs) and establishment of system for certification of farm products free from antibiotic residue

2018

- 3. Revise and Update existing essential medicines list with special reference to use of antimicrobial agents. Antimicrobial agents in the EML will be considered for inclusion based on Timor-Leste's situation of current levels of AMR, availability, supply chains, financial outlays and international guidelines and standard treatment guidelines in human medicine, veterinary medicine, aquaculture and food production (including antimicrobial growth promoters; AGPs). In addition, general guidelines for antibiotic use currently being developed at National Hospital will be considered when developing EML.
- 4. STGs and clinical guidelines will be developed by the taskforce for training, supervision and supporting critical decision-making in antimicrobial use practices, in human and veterinary healthcare and fisheries and food production section
- 5. Conduct baseline surveys to assess the extent, barriers and enablers of AMSP at institutional levels
- 6. Develop comprehensive, evidence based guidelines for National AMSP for addressing the core areas (leadership commitment; accountability; drug expertise; actions to support optimal antimicrobial use; monitoring antimicrobial prescribing, use and resistance; reporting information to staff; education for clinicians) in human and animal health care, ambulatory and community

settings as well as aquaculture.

#### Under the overall supervision of TWG

2018-19

7. MoH and MoAF will implement AMR policy for control of human and veterinary use of antimicrobial substances, including the phasing out of Antimicrobial Growth Promoters (AGPs). Limited scale implementation of the national AMSP in human and animal health care and ambulatory facilities and aquaculture will be done. This will be followed by nationwide implementation.

#### Responsible Agency

MoH, MoAF

#### Partners and Stakeholders

WHO and FAO

#### Illustrative Indicators

- A national AMR containment policy for control of use of antimicrobials in humans, animals and food industry;
- Evidence-based National Antimicrobial Stewardship Programmes; and
- Proportion of human, animal health and food industry facilities with functional AMSP

## Objective 4.2: Regulate post-marketing quality of drugs to ensure access to safe and quality antibiotics

Strategic intervention 4.2 Strengthening of a competent National Medicines Regulatory Agency (NMRA) which can enforce quality standards of antimicrobial drugs (veterinary, human, and aquaculture)

#### **KEY ACTIVITIES**

2017

1. TWG will formulate the Antimicrobial Containment Policy with special reference to AMAs and AMR for Human and Animal Health Sector. The Policy will be applicable to human and animal health, aquaculture and food production sectors. The Policy will be made available in the public domain

#### Under the overall supervision of TWG:

2017

- 2. MOH will strengthen and designate National Directorate for Pharmaceutical and Medicines as the National Medicines Regulatory Authority (NMRA) with the mandate of drug control, import, manufacture, quality, distribution, pricing, market authorization, advertising, retail sales, and inspection, and to implement the relevant policies. NMRA will cover drugs used in human health. The MoAF will strengthen the National Directorate for Veterinary as National Regulatory for Veterinary Products (NRVP) for animal health, aquaculture and food production).
- NMRA will develop regulations and quality checklists for AMAs, APIs and OTC sales.
- 4. NMRA will establish a system for the coordination and collation of data on drug quality (including supply, storage, transportation) from different sources or parts of the nation; tracking and reporting suspected product quality and treatment failure. The system will be implemented by regional DRAs.

#### 2018-19

- 5. Within the regulatory frameworks laid down by NMRA, the MoH, MoA and MoF will establish an institutional network with the capacity for quality control of antimicrobial agents or APIs. Existing system of inspection by Cabinet of Health General Inspection will be reviewed for its efficiency and suitability before deciding on strengthening it or integrating into a new system. Regional Inspectorates will be set up and will be responsible for carrying out inspections in different types of pharmaceutical establishments; formal registration procedures for drugs; and legal provisions for penal sanctions for non-compliance. Relevant authorities within the regional Inspectorates will be tasked with their implementation and enforcement of regulatory provisions
- 6. Regional Inspectorates will also be responsible for strengthening the pharmaceutical supply chain, including the procurement, supply and management system in human health, animal health and aquaculture
- 2017-19
- 7. TWG will commission independent periodic surveys to estimate the extent of OTC and inappropriate sales of antibiotics and APIs and the drivers for the same and evaluate the effectiveness of OTC regulations done and corrective measures undertaken

#### 2018-20

8. During first years of NAP, drug regulation will be enforced in limited areas of Timor-Leste. Nationwide implementation of drug

#### Responsible Agency

MoH, MoAF

#### Partners and Stakeholders

National Directorate for Pharmaceutical and Medicines, Cabinet of Health General Inspection, WHO and FAO, National Directorate for Veterinary

#### Illustrative Indicators

- National Drug Policy with special reference to AMAs and AMR;
- National DRAs with appropriate mandate, TORs, and institutional network;
   and
- Number of sites (provinces, townships, districts etc.) with strengthened post marketing drug quality monitoring system

# Objective 4.3: Establish mechanisms to monitor antimicrobial usage on a national scale to inform interventions to reduce overuse and promote prudent use of antimicrobial substances

Strategic intervention 4.3 Monitoring antimicrobial use (AMU) and sales in humans, animals and fisheries; monitor trends of residues of antimicrobials in food chains to inform interventions to promote prudent use of antimicrobials

#### **KEY ACTIVITIES**

#### Under the overall technical guidance of TWG

NCC (Department of Pharmacovigilance and Control) will establish a subcommittee called AMU Surveillance Specialized Task Force (ASSTF) with appropriate mandate, TORs and Focal Point (FP) that links with NCC (Department of Pharmacovigilance

#### and Control)

#### 2018

2. The ASSTF will coordinate policies on AMU and monitoring their impact on AMR. ASSTF will design an AMU monitoring program in humans and food animals including, residues testing in food products (guidelines and standards for surveillance design, data type, reporting formats, reporting sites, sources of antimicrobial usage/sales data, list of indicators - defined daily doses or DDD, duration of therapy or DOT, sales quantity per kg of slaughtered animal, sales quantity per PCU etc.). ASSTF will also develop guidelines to implement residue testing including data sharing

#### 2019

- 3. MoH and MoAF will implement AMU surveillance and residue testing. Healthcare facilities, including in ambulatory and community settings (human and animal pharmacies etc.) and in (parts of) animal husbandry chains (e.g. farm level) will be recruited on a limited scale. For residue testing, NHL and its surveillance sites operationalised for AMR Surveillance in 2.1 will be recruited. AMU surveillance and residue testing will be conducted on limited scale by 2019. Data for the use of antimicrobial substances and sales data in humans, animals, aquaculture and food production will be available by 2019
- 4. The ASSTF will analyse AMU data in linkage with the resistance profiles reported by the laboratory based AMR surveillance programme. Actionable recommendations will be made to modify existing local STGs

#### Responsible Agency

MoH, MoAF

#### Partners and Stakeholders

National Health Laboratory, National Directorate for Pharmaceutical and Medicines, National Directorate for Veterinary, Cabinet of Health General Inspection, WHO and FAO

- AMU and residue surveillance and monitoring system; and
- AMU, AMR and residue surveillance data analysed to guide programme planning

# Strategic Objective 5: (ECONOMIC) CASE FOR SUSTAINABLE INVESTMENTS AND INCREASE INVESTMENTS IN NEW MEDICINES, DIAGNOSTIC TOOLS, VACCINES AND OTHER INTERVENTIONS TO REDUCE ANTIMICROBIAL USE

The GAP AMR posits that the economic case should reflect the need for capacity building and training in low resource settings, while developing evidence based interventions to reduce infections and combat AMR. The 2001 strategy for AMR containment could not achieve its goals; one of the reasons cited for the same is that there were economic assessments, which evaluated the cost of doing nothing versus the cost/benefits of action at the present.

The Situational Analysis in Timor-Leste indicates that public health research in general and research on AMR has not been a priority for both policy makers and research community. Limited human resource and institutional capacity are the greatest challenge as is the competing priority of building a functional health system. However, the phase of development of the health system also provide an opportunity to put in place strategic research agenda for public health research and AMR in particular to inform health system responses.

The Strategic Plan lays down a roadmap for establishing a strategic research agenda, with systematically prioritised research areas and knowledge gaps related to AMR that will feed into a national policy for research and innovation. By 2019, multi-stakeholder platform and research consortia will be established that will generate program and policy relevant evidence on and compare cost effectiveness of AMR control strategies. The strategic plan also envisions collaborations with national and international agencies, for implementation of strategic research agenda. This will be the main strategy for Timor-Leste, given its limited existing institutional capacity.

Objective 5.1: To promote sustainable investment in new medicines, diagnostic tools, vaccines and other interventions by developing a strategic research agenda and national research policy

Strategic intervention 5.1 Generate cost effectiveness and benefit evidence for reducing AMU & AMR; develop a national strategic research agenda

#### **KEY ACTIVITIES**

2017

 The TWG will commission a task force to assess the (costeffectiveness) and feasibility of existing interventions to reduce the need for antimicrobial use in health care settings, animal husbandry systems and fisheries

#### Under the overall supervision of TWG and in collaboration with MoE:

2017-18

- 2. The NCC will create an inventory of relevant networks, initiatives, institutions and experts involved in AMR research in the country/region. The NCC will assess existing research, capacities, future plans and funding sources for research and innovations through a landscape analysis.
- 3. NCC will develop a Strategic research agenda, with systematically prioritised research areas and knowledge gaps related to research and innovation in the field of AMR, and resource needs that are relevant for Timor-Leste (in terms of human resources, materials and funding). Priority research will include:
  - Research to estimate and characterize burden and risk of AMR and AMU in human, food animal production and environment sectors including prescribing behaviours as well as treatment and care-seeking, barriers and drivers for uptake of prudent antimicrobial use practices. Special focus will be on broader socioeconomic burden of antimicrobial resistance and cost effectiveness and feasibility of interventions to reduce AMR and AMU across different sectors.
  - Systems and policy research including operational research to understand and improve priority areas such as regulatory frameworks and their enforcement, stakeholder analysis, supply chains, public private partnerships, interoperability between different elements of AMR control plans and sectors, information management systems, AMR and AMU surveillance and use in health care and ambulatory settings across sectors, laboratory support.

#### 4. TWG will develop a national policy for research and innovation in AMU practices and AMR, including research into alternatives for AMU practices

#### 5. TWG (Innovation and Investment) will establish a multistakeholder platform to guide AMR research and innovation. The research platforms will develop research consortia, and establish collaboration with national and international agencies, for implementation of strategic research agenda. National University

- implementation of strategic research agenda. National University of Timor-Leste (UNTL) and private universities will be closely involved to orient them and gain their support in the field of public health research.
- 6. NCC in collaboration with academic institutions and WHO/FAO will conduct priority research on cost effectiveness and feasibility of interventions to reduce AMU and assessment of barriers and drivers for uptake of prudent antimicrobial use practices will be undertaken to immediately inform strategic interventions in other strategic objectives such as prioritisation of interventions that could reduce the need for antimicrobial use in several settings (health care, animal husbandry, aquaculture and food production)

#### Responsible Agency

MoH, MoAF, MoE, AIFAESA

#### Partners and Stakeholders

National Health Laboratory, National Directorate (Pharmacy and Drugs), INS, Cabinet of Inspection, WHO and FAO

- Research network and collaborations;
- Multi-stakeholder research initiative National Research Policy on AMAs and AMR Research:
- Strategic research agenda, with prioritised research areas, and resource needs in the field of AMAs and AMR; and
- Increased availability of peer reviewed evidence to support sustainable investments for containment of AMR

#### Way Forward

The National Action Plan for prevention and control of AMR in Timor-Leste has been prepared by stakeholders from different ministries in Timor-Leste. The Plan is a Strategic Plan with Operational details. In spite of the limited in-country institutional capacity and competing priorities of a national human and animal health system that is still in its inception phase, the Plan has emerged as a comprehensive document that describes the country's vision of AMR prevention and control.

The Plan has built upon some of the critical insights that have emerged from the Situation Analysis and a host of interviews, guided discussions and participative dialogues that have been undertaken with multi-stakeholders. The NAP AMR of Timor-Leste in its current form provides a constructive opportunity for the government to fine tune it based on its local realities and sensitivities. Most importantly, it presents an affirmative statement of goals, objectives and strategic interventions that will be deployed to achieve the objectives set out clearly in the document.

The strategic plan envisions collaborations with national and international agencies, for implementation of a strategic research agenda that will serve as a major strategy for the country, given its limited existing institutional capacity. Essential elements of AMR containment which have so far not completely taken off the ground will now see movement as comprehensive awareness programmes are conducted, surveillance of AMR and AMU including laboratory capacity, IPC and AMSP are strengthened and other public health functions are aligned to the new AMR goals.

Following submission of the final report to the World Health Assembly, the Government of Timor-Leste will continue with its deliberations and planning process under the leadership of NMC. Next, the NMC through its constituent TWG and Task Forces will draw up a detailed operational plan in addition to its budget and monitoring and evaluation plan for successful implementation of the activities. Most of these activities will be implemented by the key actors as outlined in the strategic plan that covers the period 2017-19.

The successful implementation of the NAP AMR will bring together all the critical players from the public health domain creating greater responsibility, ownership and transparency. Working closely with a more sensitized and aware population, the country will bring down its levels of AMR and going forward institutionalize mechanisms to arrest its spread.

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## **Annexure 1:** Interpretation of phase of AMR prevention and control program implementation

Phase of	What it means
Programme	
Implementation	
Phase 1	There are no programmes implemented in a systematic manner
Phase of Exploration and Adoption	in order to conduct AMR prevention and control in the country. However, the process of designing a program has been initiated, and depending on the progress made (as seen through the indicators), it may be that one or more of the following activities are being undertaken:
	<ul> <li>Identification of needs, options and resources</li> </ul>
	Identification of potential barriers to implementation     (funding, human resources, system responsiveness, etc.)
	Investing in systems to augment their readiness to deploy the programme and overcome the identified barriers in implementation
	<ul> <li>Identifying structures (both in policy making and implementation frameworks) to aid in the implementation of the programne</li> </ul>
	As the nation gets closer to the end of Phase 1, it is on the verge of implementing (at any scale, even a pilot project) an AMR surveillance programme.
Phase 2	The decision to implement a programme has been made and
Phase of Programme Installation	the initial set of activities have been undertaken in order to launch the program. These may include:
	- Capacity building
	- Resource allocation
	<ul> <li>Establishment of data transmission, security, and sharing protocols</li> </ul>
	<ul> <li>Development of process indicators, standard operation protocols and other guidelines to be adhered to by institutions participating in the programme</li> </ul>
	In course of the second phase, there is more emphasis on development of infrastructure, and allocation of resources in order to implement a programme in a defined context and then

	scale it up to the national context in the subsequent phases.
Phase 3 Phase of Initial Implementation	This is probably the most challenging phase in the stages of early implementation of any programme within the context of developing nations. In this phase, there is a need to initiate a change or an intervention, which may have patchy uptake or maybe avoided altogether.
	<ul> <li>In course of this phase, a functional model of the program is identified</li> </ul>
	- All protocols, SOPs, etc. undergo a real world challenge
	This is a very crucial phase and most programs are likely to find it difficult to come out of this phase.
Phase 4 Phase of Full	This is the process of <b>scaling up a successful model</b> of the programme that may have been trialled in the previous phase.
Operation	- The programme is part of accepted practice
	There is a nation-wide (or a large scale) adoption of the programme
	The programme is functional by generating outputs and outcomes on a regular basis (seek proof of evidence)
Phase 5 Phase of Sustainable	This is the highest grade of <b>operational efficiency of the programme</b> and indicates that the programme can have long- term survival.
Operation	<ul> <li>The programme is resilient to changes in funding volume, partner agency support, etc. external factors which were essential for installation and initial implementation of the programme.</li> </ul>
	<ul> <li>Through a functional M&amp;E mechanism, there is systematic improvement of capacity, especially in human resources and system capacity, to enable the programme to function without extensive need to invest in continued capacity building</li> </ul>