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National Action Plan for Containment of Antimicrobial Resistance

2017-2022

Maldives Food and Drug Authority



Ministry of Health

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Abbreviations and Acronyms

AGISAR	:	Advisory Group on Integrated Surveillance of Antimicrobial Resistance	
AGP	:	Antimicrobial Growth Promoter	
AMA	:	Antimicrobial Agent	
AMR	:	Antimicrobial Resistance	
AMSP	:	Antimicrobial Stewardship Programme	
AMU	:	Antimicrobial Use	
APAC	:	Asia Pacific	
API	:	Active Pharmaceutical Ingredient	
ARO	:	Antimicrobial Resistant Organism	
ASCU	:	AMR Surveillance Coordination Unit	
AST	:	Antibiotic Susceptibility Testing	
AUSC	:	AMU Surveillance Committee	
CME	:	Continuing Medical Education	
DG	:	Director General	
DRA	:	Drug Regulatory Authority	
EML	:	Essential Medicines List	
EQAS	:	External Quality Assessment Scheme	
FAO	:	Food and Agriculture Organization	
FHS	:	Faculty of Health Sciences	
FoS	:	Faculty of Science	
GAP	:	Global Action Plan	
GASP	:	Gonococcal Antimicrobial Surveillance Programme	
GDP	:	Gross Domestic Product	
GFN	:	Global Foodborne Infections Network	
GLASS	:	Global Antimicrobial Resistance Surveillance System	
GMP	:	Good Manufacturing Practices	
HAI	:	Hospital Acquired Infection	
HCF	:	Health Care Facility	
HICC	:	Hospital Infection Control Committee	

HPAI	: Highly Pathogenic Avian Influenza
ICC	: Infection Control Committee
IGMH	: Indira Gandhi Medical Memorial Hospital
IHR	: International Health Regulation
IPC	: Infection Prevention and Control
KAP	: Knowledge Attitude Practices
M&E	: Monitoring and Evaluation
MCG	: Multi-sectoral Coordination Group
MDA	: Maldives Dentists Association
MDR	: Multi Drug Resistant
MMC	: Maldives Medical Association
MNA	: Maldives Nurses Association
MNU	: Maldives National University
MoFA	: Ministry of Fisheries and Agriculture
MoH	: Ministry of Health
MoE	: Ministry of Education
MS	: Member State
NABH	: National Accreditation Board for Hospitals and Healthcare Providers
NACC	: National AMR Coordinating Centre
NAP	: National Action Plan
NDRA	: National Drug Regulatory Authority
NFP	: National Focal Point
NHL	: National Health Laboratory
NMSC	: National Multi-Sectoral Steering Committee
NRA	: National Regulatory Authority
NRL	: National Referral Laboratory
OIE	: World Organisation for Animal Health, Organisation mondiale de la santé animale
OTC	: Over the Counter
PCU	: Population Correction Unit
QARD	: Quality Assurance and Regulation Division
R&D	: Research and Development
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STG	:	Standard Treatment Guideline
STO	:	State Trading Organization
TWG	:	Technical Working Group
UNFPA	:	United Nations Population Fund
UNGA	:	United Nations General Assembly
UNICEF	:	United Nations International Children's Emergency Fund
WaSH	:	Water, Sanitation and Hygiene
WHA	:	World Health Assembly
WHO CC	:	WHO Collaborating Centre
WHO SEARO	:	World Health Organization Southeast Asia Regional Office

Foreword

I am honoured to share the first national action plan for the containment of antimicrobial resistance (AMR) in the Maldives. Despite limited resources and geographical challenges in reaching the entire population, Maldives was among the first nations to embrace the global action plan on AMR in 2015 at the 68th World Health Assembly.

To address this global health crisis nationally, a National committee on AMR was commissioned in early 2016. Further to this, a situation analysis was conducted in 2016 to fully comprehend the current AMR status of the country and inform the development of the national action plan. The findings of the situation analysis provide a snapshot of the areas that require strengthening to successfully tackle antimicrobial resistance in the country.

The National Action Plan on Antimicrobial Resistance (NAP AMR) five key strategic objectives identified through the situation analysis. These five objectives focus on improving public knowledge and awareness on AMR; development of a sustainable surveillance system on the emergence and spread of resistance; enforcing infection prevention and control within healthcare settings, food production as well as within the community; rational use of antimicrobials through antimicrobial stewardship programmes, standard treatment guidelines and stronger regulatory control; develop evidence based and cost effective AMR control measures through research activities. Within these focus areas, specific objectives that define interventions and activities to accomplish the goals of NAP through the period of 2017 to 2022.

Addressing antimicrobial resistance in Maldives is a top priority of the government and I believe NAP AMR will be the roadmap to foster coordinated nationwide efforts to combat AMR in the country. With the implementation of this plan, I hope that the emergence of resistance can be lowered and by the end 2022 and Maldives remains a GAP AMR compliant, role model country in the SEAR region.

Abdulla Nazim Ibrahim

Minister of Health

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Foreword:

Antimicrobial resistance is one of the biggest threats to global health, food security, and development today. It can affect anyone, of any age, in any country. Though antibiotic resistance may occur naturally but misuse of antibiotics in humans and animals coupled with poor infection prevention and control is accelerating the process as it is rising to dangerously high levels in all parts of the world. New resistance mechanisms are emerging and spreading globally, threatening our ability to treat common infectious diseases.

In line with WHA and RC resolution, it is appreciable to note that Ministry of Health accorded high priority to AMR containment and designated the Maldives Food and Drug Authority (MFDA) as National AMR focal agency and also established a multiministerial and multi sectoral AMR committee to provide oversight to AMR work.

Facilitating technical assistance, WHO country office supported the Situation Analysis in 2016 using the tool developed by South East Asia Regional Office which identified development of National Action Plan (NAP) to address Antimicrobial Resistance as one of the key priority activities. I would also like to acknowledge the multisectoral and multi stakeholder consultative and participatory processes undertaken for developing National Action Plan (NAP) which is also aligned to Global Action Plan.

I believe the NAP outlines in sufficient details the strategic approaches and activities such as advocacy for policy formulation on antibiotic use, building capacities through curriculum development for in and pre-service public health and nursing courses and raising awareness amongst providers and people on the use and misuse of antibiotics as some of the examples. The NAP will be used as strategic tool to prepare and respond to some the challenges by strengthening the health system while addressing issues related to animal welfare and food security and keeping focus on ensuring quality services. It goes without saying that steps need to be taken at all levels of society to reduce the impact and limit the spread of resistance.

WHO Country Office for Maldives considers it a matter of great privilege for extending technical support to the Ministry of Health for development of National Action Plan. As a trusted and reliable partner, I assure continued support of WHO in implementing and monitoring this plan in the coming years.

Derotins

Dr Arvind Mathur WHO Representative to Maldives

Executive Summary

Maldives has made significant strides in the area of infectious disease prevention and control. This is exemplified by elimination of malaria from Maldives in 2015 and successes in TB control. In addition, Maldives is a front runner in infectious disease prevention through successful water, sanitation, hygiene and vaccination campaigns and coverage.

However, given the limited evidence that exists with respect to the occurrence of resistant organisms in the nation, it is hard to estimate the exact antimicrobial resistance (AMR) scenario. Also, it becomes difficult to compare the current situation with other countries in the region. Moreover, limited evidence exists on the trends of use of antimicrobial agents (AMA) in Maldives. Although, recent prescription audits have indicated overuse of antibiotics, especially for common conditions such as flu, cough and fever.

Meanwhile, several key steps have been taken by the Government of Maldives that have been instrumental in paving the way for the country to join other nations in the South East Asia Region (SEAR) to speed up its plan on addressing the AMR crisis. Combating AMR would therefore require the highest political commitment in addition to, strong multi-sectoral coordination, sustained investment and technical assistance.

A Situation Analysis was undertaken in August 2016 using a tool developed by WHO SEARO based on discussions between National Multi-sectoral AMR Coordination Committee members, senior technical leaders of the national health authorities and the veterinary sector and the WHO team. It identified opportunities, challenges and implementation gaps to improve implementation of National Action Plan on Anti-Microbial Resistance (NAP AMR) in ways that can meet the 68th World Health Assembly (WHA) resolution on AMR.

The indicators in the Situation Analysis protocol were grouped under the heads of the 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. They were further analysed along the five phases of programme implementation, namely exploration and adoption; programme installation; initial implementation; full operation and sustainable operation.

Key findings from the Situation Analysis revealed a fair amount of commitment among the political and technical leadership of the country. It was also found that they supported AMR containment efforts, evidenced through the formation of a National Multi-sectoral AMR Coordination Committee. A fully functional national drug regulatory authority had been set up to oversee regulation and licensing, pharmacovigilance and market authorisation. These efforts clearly stood out as strong elements that had potential to be leveraged as building blocks of an effective NAP AMR. Similarly, Water, Sanitation and Hygiene (WaSH) related initiatives in human health along with high vaccination coverage were found to be significant infection control mechanisms within community settings. Finally, limited infection control

initiatives in healthcare institutions were seen as opportunities to leverage for instituting effective AMR containment measures in Maldives.

The Situation Analysis threw light on initiatives that are being taken to develop and draft national standards and guidelines, such as the national drug policies, updated essential medicines lists and standard treatment guidelines, including for antibiotic prescription.

Traditionally, lack of animal populations and commercial orientation of food animal production systems based on terrestrial animals has led to limited development and capacity of veterinary health services. Accordingly, majority of the food consumed in Maldives is imported into the country. Recently, the Government of Maldives laid emphasis on diversification into poultry and goat farming as well as aquaculture with the objective of attaining greater food security. This calls for greater attention to the problem of AMR and antimicrobial use (AMU) in veterinary sector. As of now, the animal health sector in general lags behind in AMR containment efforts.

The National Action Plan on AMR for the period 2017 - 2022 takes the current 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 objectives, strategic interventions and key activities, the NAP AMR charts a new phase in Maldives' 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 the year 2022, the country would have carried out nationwide evidence-based awareness campaigns with regular monitoring and evaluation (M&E). Further, necessary revision and pilot scale implementation of curricular revisions for professional groups to improve knowledge among them would also have been undertaken by 2022.

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 establishing a nationwide AMR surveillance system along with a national early warning system to identify early the emergence of resistance in priority pathogens and to critical antimicrobials by 2022.

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 Infection Prevention and Control (IPC) guidelines within healthcare settings, and in the emerging animal husbandry systems and food production systems including aquaculture. Also, actions to decrease Hospital Associated Infection (HAI) and associated AMR through facility based HAI surveillance programme (Human Health) would be conducted. Hygiene and sanitation related campaigns in community settings are strength in human health sector. This will be consolidated and lessons passed on to the animal sector including emerging food production systems. 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 measures on Antimicrobial Stewardship Programmes (AMSP) and Standard Treatment Guidelines (STG) at the national scale to promote 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. Regulatory structures will be strengthened with special emphasis on import control.

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 institutional capacity in the context of research on AMR. A strategic research agenda that is relevant to the Maldives context will be developed and implemented. This will be done in large part, through leveraging existing capacity, building additional capacity as well as developing international collaborations.

Most of these activities will be implemented by the key actors as outlined in the proposed strategic plan that covers the period 2017-22. Following submission of the final report to the World Health Assembly (WHA), the Government of Maldives will continue with its deliberations and planning process under the leadership of a National Multi-Sectoral Steering Committee (NMSC).

Background

Setting the Context: From Global to National Action Plans

One of the biggest concerns in the public health domain today relates to antimicrobial resistance (AMR). Governments across the globe are striving to estimate the crisis in their nation states and the kind of impact it is having on both human and animal life. At the 68th World Health Assembly (WHA) in May 2015, a global action plan on AMR (GAP AMR) was adopted in response to the acknowledgment of this emerging crisis (1). The GAP AMR has therefore 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 indeed a serious 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 the case of developing countries, which are expected to contribute to the increasing trends of antimicrobial agent (AMA) consumption and therefore, likely to be at higher risk of emerging resistant microbes (2–4). The need for this was further stressed at the 2015 WHA through resolution WHA68.7.

Consolidating the position of the GAP AMR, the global political will come 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. 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 customize their NAP AMR as per their local realities. Prior to embarking on conducting the Situation Analysis for Maldives, an effort was made to understand its unique geographical location as also the quality and reach of its public health system and the burden of infectious disease. The island nation of Maldives has a population of about 364,000 people, of which almost 65% reside in rural areas, according to the population and housing census of 2015(6). The Maldivian nation is made up of 1192 coral islands in the Indian Ocean. These islands are made up of 26 natural atolls spreading approximately 860 km long and 480 km wide. The Maldivian Exclusive Economic Zone covers about 90000 km2. Land area is estimated to cover only about 300 km2 and some 80% of the total landmass lie a mere one meter above mean sea level. The North-East monsoon from December to February and the South-West monsoon from May to September is the main characteristic of the humid tropical climate of Maldives (7).

The health system in Maldives is characterized by dominant expatriate health workforce, limited institutional capacity and total import based medical supplies including AMAs. Yet, with total health expenditure as the share of GDP being 13.7%, Maldives is a front runner in improved health outcomes in SEA region. This is exemplified by 99% Relative inequality P a g e 10 | 63 score for reproductive, maternal, newborn and child health intervention coverage, which is highest in the region, and >60% UHC coverage index of essential health services.

In the area of infectious diseases prevention and control, Maldives has made significant strides. The DPT3 coverage in the country is nearly (8). 99% of the population uses improved drinking water sources and 98% population uses improved sanitation (8). Malaria was declared eliminated from Maldives in 2015 (9). Maldives reports the lowest incidence rate of all forms of TB (53/100,00 population per year) and mortality due to TB (5.4/100,000 population per year) in SEA region. MDR-TB incidence in Maldives is also among the lowest in the region. However, in case of general bacterial pathogens, no data on antimicrobial resistance or prevalence is available in the country and hence the impact of the situation is not evaluated, even though it is commonly accepted that there is resistance among the microbial population (10)

Situation Analysis and Assessment

The process of framing a NAP AMR for Maldives was initiated through a Situation Analysis, which provided details of the existing AMR situation, gaps and capacity in the local context.

Antimicrobial resistance and use in human health sector

While TB prevention and control, including multi-drug resistant tuberculosis (MDR-TB), is a success story in Maldives, in the absence of AMR surveillance and evidence, the same cannot be said about AMR in general pathogens. In an update to WHO, limited data on AMR from Indira Gandhi Memorial Hospital (IGMH) Lab information system from 2007 to 2009, reportedly indicated rising trend of AMR in common pathogens. Three organisms (Escherichia coli, Staphylococcus aureus, and Klebsiella species) commonly isolated were selected along with the antibiotics tested for them. Over 70% is resistance to Ampicillin and Amoxicillin in all organisms. Amikacin showed less than 3% resistance to E.coli and Klebsiella. The resistance of Klebsiella to all antibiotics was found to be much more compared to that of E.coli(11). In another update to WHO, similar findings emerged from IGMH data. Ampicillin resistance has increased over the years, but co-amoxiclav and Amikacin still have a good sensitivity. Commonly isolated organisms include Escherichia coli, Staph aureus, and Pseudomonas sp. The methicillin-resistant

Staphylococcus aureus (MRSA) isolation has been very low, with only one or two cases being reported each year (12). These data are however too unstructured and limited to make any comparison or inference on the overall situation of AMR in Maldives.

Limited evidence also exists on the trends of use of AMAs in Maldives. In 2011, a prescription audit was undertaken to evaluate the prescription and consumption patterns of antibiotics. The result showed that 40% of prescriptions contained an antibiotic and 22% is prescribed for flu, cough, and fever. The most frequent antibiotic prescribed was Augmentin. It was recommended that prescription audits, together with data on communicable disease surveillance and import of antibiotics to the country could form the basis for the development of an intensive antimicrobial resistance and use surveillance in the country.

Subsequently, the country undertook further prescription audit for antibiotic use, and developed media campaigns, audio spots and video spots as well as pamphlets, leaflets and posters and disseminated to the public, prescribers, and pharmacists.

AMR and AMU in animals and livestock sector

Livestock sector

Maldives is a country without cows or buffalo. However, goat and poultry production are two growing economic activities for outlying island communities. Goats are in demand for cultural events while eggs are popular throughout the country and especially among the 100 plus high-end resort islands. Animal production is limited to small scale rearing of chicken and goats in the backyards. Chicken farming in cages contained free-range and backyard poultry is practiced widely throughout the country. Most of the households own about 6-8 chicken. For chicken farming, feeding materials are imported and production costs are high. In 2010, Food and Agriculture Organization (FAO) in collaboration with the United Nations Development Programme (UNDP) provided support to develop poultry production in two islands. The success of this activity has resulted in a government plan to expand egg production to a number of other islands because it generates income for the people while reducing the country's dependency on imported eggs (7,13).

The demand for goats exceeds supply. The shortage of available land limits the expansion of goat production, although feed can be supplied from materials available in roadside live fences, the undercover of forest lands and lands cultivated with perennial crops. There is also a potential for supplying goat milk and cottage cheese production. Goat milk is a traditional drink which is considered to be nutritious and would be a good option for responding to the poor nutrition of children of schooling ages (7,13,14).

Fisheries and aquaculture

The Maldivian economy has for centuries been entirely dependent on fisheries and other marine products and fishing and related marine activities continue to employ a significant proportion of the population. Resultantly, the government gives priority to the development of the fisheries sector, which at present contributes over 15% of its gross domestic product (GDP). About 30% of the country's workforce is engaged in the fisheries sector which is the second most important sector after tourism. Given its vast marine resources, aquaculture has a limited role to play in the fisheries sector and therefore the use of AMAs for production. However, little evidence exists on the use of AMAs in the post-harvest phase.

Government efforts to attain greater food security

Maldives currently imports over 90% of its food supplies from abroad and is dependent on forces that are beyond its control. Not surprisingly, one of the main goals of the Government is to reduce its dependence on imported foods by at least 10% during the current government's administration. This will increase food security which is a direct consequence of increased food production. Some of the initiatives that will help to achieve this objective are by promoting and providing direct assistance to the efforts of farmers with a view to

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attaining a high level of diversified food production (15). Such efforts to increase food production, especially in the meat and poultry sector is likely to increase the use of antibiotics, as is the case in other settings. This will in turn call for regulation and surveillance of AMR and AMU in the livestock and fisheries sectors.

Situation analysis of AMR containment efforts in Maldives

A Situation Analysis was undertaken in Maldives in August 2016, using a tool developed by WHO SEARO. Specific objectives 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 opportunities, challenges and implementation gaps in order to improve the overall NAP implementation;
- To assist Maldives in identifying vulnerabilities, opportunities and needs to meet the 68th WHA resolution on AMR and prioritising 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 Coordination Committee members, senior technical leaders of national health authorities and veterinary sector, and WHO team. It looked at how well developed the AMR program was in terms of governance, policy, and systems. The review focused on broad system-wide analysis rather than assessing the quality of policies and documents.

The indicators in the 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 above mentioned focus areas comprised of a list of sub-focus areas and each subfocus area were graded on five levels to show the incremental extent of AMR programme implementation. These five levels of phases included 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 (16) (Figure 1) (Annexure 1).

For purpose of clarity and in-depth understanding, a theme-based Situation Analysis process was undertaken, based on the phases in which each of the indicators were placed in. Each of



the phases reflected phases of installation and implementation of the AMR containment

programme 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; the phase of full operation; and phase of sustainable operation. It was found that phases 3 to 5 were the backbone or strength of the system. Sustainable operation is considered best practice and defined here as an operation that incorporates the M&E system.

Figure 1: Phases of programme implementation

Figure 1 shows the status of implementation of AMR containment program in Maldives. Green color indicates complete implementation; yellow indicates partial implementation and red implies no implementation. Following were the findings from the Government of Maldives-WHO Situational Analysis:

National AMR Action Plan in line with GAP-AMR

Maldives have started initial work for developing a National Action Plan for AMR containment. A national multi-sectoral AMR coordination committee has been announced with the Director General of Maldives Food and Drug Authority (MFDA) identified as the National Focal Point. Further, governance mechanisms to implement plans under different strategic objectives and interventions will be developed as part of the NAP AMR.

Awareness raising

The Situation Analysis in Maldives revealed that awareness campaigns on AMR have only recently been initiated. With the support of WHO Country Office, the MFDA coordinated a series of awareness activities during the AMR awareness week in 2015 and 2016. This was done by mainly targeting the general public including schools, but also reaching out to the executive committee of Minister of Health, clinicians in public and private hospitals, nurses, pharmacists, allied health professionals and government officials in health and other sectors. Awareness in livestock and fisheries sector including farmers is yet to be planned and conducted.

Maldives's health system is characterized by a substantial presence of expatriate doctors. In the absence of medical schools in the country, doctors of Maldivian origin are trained outside of the country. This does not provide an opportunity for curricular level interventions but leaves a scope for continuous professional development related to AMR and related issues. Similarly, in the absence of veterinary schools and veterinarians, there are only opportunities

for continuing education in the veterinary sector. MFDA has recently collaborated with Ministry of Education (MoE) and Maldives National University (MNU) to submit Terms of Reference to WHO Country Office for technical support for curriculum development on AMR and related issues for grades 1-12 in schools as well as professional groups (nurses, allied health professionals, lab technologists). Under Ministry of Education, the National Institute of Education (NIE) and MNU/FHS are responsible for curriculum development for schools and health services in humans respectively.

National AMR surveillance system

An AMR surveillance system that captures standardized epidemiological, clinical and laboratory data on AMR has not been set up in Maldives. In the public sector, clinical diagnostic services are provided through a four-tiered system of the tertiary hospital (IGMH), regional hospitals, Atoll Hospitals (Levels 1-3) and Health Centres (Level 3-1). Bacterial culture and sensitivity testing are carried out in IGMH and all Regional and Atoll Hospitals in Maldives. At peripheral levels, clinical samples could be sent to hospitals for antibiotic susceptibility testing (AST), through clinical sample transport mechanisms. IGMH additionally carries out blood and CSF culture and sensitivity. Bacterial culture and sensitivity facility is also available at ADK Hospital, a private tertiary care hospital.

A system of internal quality control and standardized testing is however practiced at IGMH. IGMH has also started participating in Thailand External Quality Assessment Scheme (EQAS) for SEAR and along with ADK Hospital has recently reached out to CMC Vellore EQAS Program. A recently conducted training on standardized bacterial culture and sensitivity testing and WHONET software have identified several gaps in internal quality control at different levels of facilities carrying out bacterial culture and sensitivity.

Data is maintained mostly in paper-based format hospital laboratories without any system of reporting to the higher level or feedback to lower level. Data comprises of isolates and their AST results without any epidemiological information. A national referral laboratory for AMR surveillance is yet to be identified.

In the absence of systematic data collection and analysis of AMR trends, an early warning system for emerging trends drug resistance trends is not operational in Maldives. The Situation Analysis revealed some anecdotal evidence of hospital-level analysis on a case-to-case basis following identification of unusual resistance patterns or in the event of a hospital outbreak.

A National Health Laboratory, Male' under the MFDA undertakes food testing for imported food products, water samples, and pharmaceuticals. The National Health Laboratory (NHL), Male' is equipped with sophisticated equipment such as High-Pressure Liquid Chromatography (HPLC) for residue testing. Testing for antibiotic residues in imported food and quality of imported antibiotics is however limited and ad hoc.

Epidemiological surveillance of communicable diseases, apart from vertical disease control programs, is carried out by Health protection Agency (HPA) of Ministry of Health (MoH). Close to 18 notifiable diseases are reported daily from all healthcare facilities through a web-

based reporting system. Laboratory support is sought on a case-to-case basis but the surveillance system is not adapted to capture AMR data. There is no linkage of HPAs Communicable Diseases surveillance with surveillance of HAIs.

Antimicrobial Stewardship, drug regulation and surveillance of antimicrobial use

Medicines including AMAs used in Maldives are imported with no local production; major sources being India, Sri Lanka, Pakistan and Malaysia. Import, distribution and sale including over-the-counter (OTC) sales are regulated by MFDA, a fully functional and strong national drug regulatory authority. The MFDA is also responsible for the regulation of food imports and exports. National Health Laboratory (NHL) of the MFDA is responsible for providing laboratory support for chemical and microbiological standards testing. However, limited human and technical capacity exists at NHL for testing the quality of imported medicines and food at the points of entry, although a system for post-marketing surveillance system is in place under MFDA for both imported medicines and food. Inspection of OTC sales by MFDA is carried out systematically and regularly 1-2 times a year covering all public and private pharmacies in the country. Inspections are carried out through its own system and in collaboration with Public Health Units of MoH in smaller and difficult to reach islands. Recently approved Health Services Bill 2016 though its Medicines Chapter has resulted in a major shift in the regulatory powers of MFDA wherein the Authority has been empowered with penal powers in case of violation. A recent survey of OTC sales of prescription only medicines including AMAs conducted by MFDA in 2015 revealed 25% pharmacies violating the regulatory provisions (personal communication from MFDA) and indicates presence of irrational use and violation in spite of a rigorous monitoring system.

STO which is an autonomous and the main agency that procures medicines including AMAs and through its nationwide network of distribution system, it provides medicines to hospitals and pharmacies under its network. At least one pharmacy is operational in each of the islands. The private importers are significant operators in the medicines market in Maldives. Approved drug lists for human and animal medicines, has both registered and pre-authorised medicines in the lists, and is characterised by relaxed criteria for import permission. Import criteria such as good manufacturing practices (GMP) certification, is further relaxed as in the case of 'critical' situations such as supply shortages and stock out situations. Limited size of the Maldivian market does not allow the MFDA to negotiate with manufacturers and enforce mandatory criteria for registration of unregistered drugs in the approved list. Consolidation and bulk purchase by STO has recently been proposed as one of the mechanisms to enforce compliance.

The AMSP as an important strategy for monitoring and improving the use of AMAs in different health care settings is yet to be introduced in Maldives's health sector. Notably, the National STG is in the process of being drafted by the MoH. Currently, the treatment guidelines, including use of AMAs, is guided by empirical evidence and adapted by local physicians and surgeons in hospitals. Local STGs are seldom guided by local AMR surveillance data.

Surveillance for AMU is not operationalized in Maldives. Import data provides an opportunity to monitor their use through sales data which is mostly not analysed. Similarly, surveillance for use in hospital and ambulatory care settings has not been operationalized. A recent proposal by the Quality Assurance and Regulation Division recommends a review of at least one month's antibiotics prescription on acute respiratory tract infections and viral fevers from healthcare facilities that can be conducted twice a year. The objective is to understand the nature and extent of AMU by facilities and departments and provide feedback as well as report to insurance agencies when processing claims.

Infection Prevention Control in healthcare settings

Infection control and patient safety policy were introduced in healthcare settings by MoH some years ago. Infection control committees (ICC) and teams are in place under the policy with infection control guidelines. However, except for limited activities related to education and training in hand hygiene, standard precautions and additional (transmission related) precautions, there is the limited activity of ICCs. The quality of microbiology laboratory testing is not assured except the recent subscription of IGMH to Thailand EQAS. No analysis of hospital-associated infections data, AMR surveillance and AMU data is conducted to prevent infections and improve AMAs. Recently, safe disposal of hospital waste has been disrupted in both public and private health care facilities. Resource constraints including human resource constraints and lack of standards and guidelines are often cited as the reasons for IPC programs not being implemented to their fullest potential. As part of its effort to achieve National Accreditation Board for Hospitals and Healthcare Providers (NABH) Accreditation, ADK Hospital - the largest private hospital in the country is in the process of setting up an Infection Control and AMSP at the facility level. Some of the features in place include infection control committee, infection control guidelines, surveillance for HAIs, AMR surveillance, feedback to clinicians on AMR trends. Prescription audits and surveillance of use are yet to be established as the standard component.

The recently drafted National Health Care Quality Standards by the Quality Assurance and Regulation Division of MoH will be published in April 2017. The Standards will include a list of 625 criteria that cover different quality aspects of health care delivery in acute care facilities throughout the country. The list includes criteria for licensing as well as voluntary accreditation and includes laboratory standards, infection control, and patient safety as an essential domain. Standards for AST, however, have not been included in the list.

Research & innovation

In spite of modest institutional capacity, public health research in general and AMR research specifically has not caught the attention of the research community as it is reflected in limited peer-reviewed publication base from Maldives. Even opportunistic research in clinical settings to fulfil mandatory academic requirements is not conducted, as health care facilities are not academic institutions. No international collaborations have been established on AMR or related research. Maldives has a National Health Research Committee (NHRC) that

reviews proposals for health research in the country. However, a strategic research agenda and priorities for health research in Maldives are yet to be identified.

One-Health engagement

Maldives has traditionally lacked animal populations and commercial orientation of food animal production systems based on terrestrial animals. The focus of agriculture sector has predominantly been on fisheries (wild fish). This has led to limited development and capacity of veterinary health services. Recent diversification into poultry and goat farming as well as aquaculture have raised the possibility of AMU and AMR and need for strengthening efforts in that sector.

The animal health sector in general lags further behind in AMR containment efforts. AMR containment policy, AMR surveillance, AMSP and awareness programs have not been initiated. Guidelines have been developed on poultry production, goat farming, biosecurity and hygiene related interventions. However, in the absence of animal extension services guidelines are not adequately disseminated and practiced. There are veterinarians or paraveterinarians or capacity building opportunities through university system in Maldives. Ministry of Fisheries and Agriculture (MoFA) is dependent on NHL for testing of food, especially for residues.

One of the major constraints in controlling AMU in a veterinary sector has been the absence of regulatory control of veterinary sector on licensing, regulating and controlling AMAs. The veterinary sector is only mandated to recommend AMAs for the approved drug list requisitioned by animal production units. The regulatory control by MFDA at MoH lacks effectiveness at the field level.

Overall, AMR containment efforts in Maldives are in the phase of exploration and adoption in different focus areas with initial implementation in awareness and hygiene/sanitation; drug regulation is in process of achieving full operation (Figure 2).

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 in humans					
	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 2: Status of implementation of AMR containment programme/initiatives in Maldives, by phase of implementation

National Action Plan on AMR (2016 – 2020)

Goal, Objectives and Guiding Principles

The process of developing the NAP-AMR for Maldives was initiated by first spelling out the goal of the GAP AMR. At all times, effort was made to: "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 laid down five strategic objectives which form the basis for developing public health response to AMR globally and to Maldives in particular. 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: Optimise 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 (17).

NAP Development Process

The development of NAP has followed the guidelines enshrined in WHO's "Antimicrobial resistance: A manual for developing national action plans" (18). The approach is structured around the five strategic objectives and five principles which are embodied by the GAP AMR (17).

Within the five strategic objectives of the GAP AMR, 12 specific objectives have been included. Each of these specific objectives has been described in terms of a Strategic Intervention, with a defined set of key activities to be carried out successfully to execute the strategic intervention and eventually to fulfil the strategic objective. Key Monitoring & Evaluation (M&E) indicators have been listed for activities under each of the strategic interventions with the operational plan comprising of broad planning by activity. Detailed planning along with the budget allotted for the respective activities will be done in due course by national stakeholders.

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 (18,19).

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The Situation Analysis by WHO SEARO focused on how well developed the AMR programme is in terms of governance, policy and systems formed the basis for identifying gaps and strategic priorities. It was further supported by a 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 comprising of five phases adapted from the Indicator Standards Assessment Tool developed by UNAIDS (16). 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, which is 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. It is only after the programme starts to function at the highest grade of operational efficiency, that the fifth and final stage 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 Maldives to make maximum progress towards implementing NAP, the 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 to implement actions in a step-wise manner that meets both local needs and global priorities.

The development of NAP entailed a process of participative dialogue with important stakeholders and informants. Technical support was provided by WHO Country office, WHO SEARO and the Consultant. Its further, expansion into a detailed operational plan by sub-activities and validation will be done by country teams and stakeholders.

Country Response

The country response for Maldives will be mounted based on a well-appointed governance mechanism. Each of its aspects have been detailed with clearly assigned roles and responsibilities in the following section.

Governance

Having a national multi-sectoral governance mechanism will serve as the central intervention around which all the AMR-related activities can be effectively coordinated in each of 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 Maldives will comprise of a High Level National Multi-Sectoral Steering Committee (NMSC), for Antibiotic Resistances. The NMSC will be supported by a National AMR Coordinating Committee (NACC) and multi-sectoral Technical Sub Committees (TSC) who will address the strategic objectives of GAP through specialised Task Forces related to the five strategic objectives of GAP. Each of these will be formed and will function as per the following structure.

National Multi-Sectoral Steering Committee (NMSC) for Antibiotic Resistance

The NMSC will provide the necessary political commitment and support for national AMR containment efforts in Maldives and to the international global health community. Given the ultimate goal of AMR containment efforts that are geared to improve human health outcomes, the NMSC will be formed under the leadership of MoH with Minister of Health as the Chairperson.

Composition of NMSC

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

- Minister for Health (Chairman)
- Minister for Fisheries & Agriculture (Co-chair)
- Minister of Education
- Minister of Environment and Energy
- Minister of Finance and Treasury

Logistics of the NMSC

The NMSC will meet bi-annually when it will be appraised of AMR control efforts in the country. NMSC will provide necessary political support to avail financial and human resource for any course modifications and programme implementation.

National AMR Coordinating Committee (NACC)

The NACC will be the implementation agency for NAP AMR and will draw its powers and mandate from Presidential Decree while NMSC will provide strategic vision to AMR control efforts. The NACC will provide the platform for programme planning and implementation through a supporting structure comprising of technical working groups for individual strategic objectives.

The NACC is envisioned as a multi-sectoral group of senior programme managers from different ministries with adequate representation of non-governmental agencies, cooperatives, civil society representatives, media, international agencies (WHO/FAO/OIE). 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 food production sector and other environmental initiatives.

The chair and vice chair will be appointed by the Minister of Health, and its Secretariat will be in MFDA. Its membership will be drawn from the:

- Ministry for Health (MFDA, HPA)
- Ministry for Fisheries & Agriculture
- Ministry of Education
- Ministry of Commerce
- Ministry of Finance
- Ministry of Information and Broadcasting
- Professional associations
- International organizations (WHO/FAO/...)
- Others.

Logistics of the NACC

The NACC will meet regularly. The NACC will have a rotatory Chairmanship between MoH and MoFA. The rotation will happen annually.

Roles and responsibilities of NACC:

Roles and responsibilities of the NACC 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 NMSC, national agencies and international partners
- Constitute technical working groups for tasks that include providing technical input for program support and decision-making
- Facilitate collaborations with internal and external agencies and organizations in the field of surveillance and innovations
- Advocate for prevention and containment of AMR

Appointing a National Focal Point

Director General(DG) of MFDA will be the National AMR focal point responsible for coordinating AMR activities and tasks in the health, animal, fisheries, 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 NACC;
- Lead and coordinate drafting of a national action plan for containment of AMR;
- Facilitate and oversee implementation, M&E of the plan through the NACC;
- Ensure regular data collection and information sharing by instituting effective communication and coordination among all stakeholders, the members of NACC 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 Sub Committees

Technical Sub Committees (TSC) will form an integral part of the governance mechanism in Maldives. These will be multi-sectoral in composition and will report to the NACC. They will be formed *as a priori*ty 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.

The proposed thematic TSCs that will be formed include:

- 1. Awareness
- 2. Surveillance
- 3. Infection Prevention and Control and Hygiene
- 4. Optimizing Antimicrobial Use
- 5. Research and Innovation

Each of the TSCs 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 secretariat. They will assume charge for monitoring and evaluation and based on their interactions and review mechanisms come up with a set of workable recommendations.

The 5 TSCs will be mandated by the NACC and will report to their Chairpersons and to the National Focal Point of the NACC. The organisational structure, composition, locus of coordination centre and general terms of reference are listed below. Specific jobs of individual TSCs have been detailed in the Strategic Plan document

General Terms of references of Technical Sub Committee

Technical Sub Committee (TSC) will be multi-sectoral in composition and will report to the NACC. In their respective strategic objective, the TSC will:

- Provide strategic direction by identifying intervention and key activities
- Conduct situational analyses
- Draft detailed sub activity level NAP
- Plan and budget for different activities
- Monitor and evaluate implementation of strategic interventions and corresponding key activities
- Provide technical input
- Commission specialised task forces

Constituting Specialised Task forces

Specialised task forces will be commissioned by the TSCs for delivering on specific tasks in the respective strategic areas. The task forces will work under technical guidance and supervision of respective TSC 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 Maldives National Action Plan as mentioned in the Strategic Plan document.

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Figure 2: NAP Governance Structure in Maldives, 2017-2022

Strategic Plan

While developing the NAP-AMR for Maldives, a strategic plan has been formulated, keeping in mind its geographical aspects as also its public health and other socio-cultural and economic status. The NAP AMR has been based on the 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 as 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 in Maldives revealed that awareness campaigns on AMR have recently been initiated with the support of WHO Country Office. Awareness campaigns that are led by MFDA target different groups including general public and professionals in health sector. Awareness in livestock and fisheries sector including farmers is yet to be planned and conducted.

Initial planning is also underway to introduce curricular interventions in schools and allied health services. Continuous professional education for in service professionals in health sector are also being proposed and technical support sought. MoFA is yet to plan similar curricular/continuous professional education level interventions.

By 2022, Maldives will carry out nationwide evidence-based awareness campaigns with regular M&E. The aim is also to develop/revise curricula in schools, nurses, allied health and veterinary services, 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 professionals on prudent use of antimicrobials

KEY ACTIVITIES

Under the technical guidance of TSC (Awareness):

Year	Activity	Description of Activity
2017	Conduct KAP Studies on	A task force will conduct KAP Studies on a national scale on AMR, AMU, environmental relationships to
	AMR, AMU ,(human and	assess awareness levels and gaps in knowledge in different target groups. Priority target groups will include
	animal) environmental	school students and teachers, general public, policy makers, clinicians, pharmacists, nursing staff, farmers
	relationships in different	in poultry/goat/aquaculture farming, pet owners and pet shop owners
	target groups	
2018	Design evidence based	MoH and MoFA, in collaboration with MoE, will design evidence based communication campaigns using
	communication campaigns	evidence generated that will include accurate and relevant messages targeting priority groups (school
	with accurate and relevant	students and teachers, general public, policy makers, clinicians, pharmacists, nursing staff, farmers in
	messages targeting priority	poultry/goat/aquaculture farming, pet owners and pet shop owners). Awareness campaigns conducted
	groups	recently by MFDA on AMR and AMU will be reviewed for suitability for inclusion in overall
		communication strategy
2017-18	Roll out communication	MoH and MoFA will identify pilot sites to implement communication campaign for antibiotic awareness
	campaigns on AMR	improvement. Limited scale roll out will be done with support from WHO, FAO and relevant NGOs
2019	Incorporate AMR and	AMR and related topics will be incorporated in grade 1-12 school curricula. Limited scale testing of revised
	related topics in school	curriculum along with regular audit of courses will be conducted before planning a nationwide scale up by
	curricula	2022

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Evaluate communication	Pilot campaigns will be evaluated in 2019. This will be followed by nationwide scale up and scale out of
campaigns followed by	awareness campaigns in 2019 with regular monitoring and evaluation
nationwide	
implementation	

Responsible Agency

MoH (MFDA, HPA), MoFA, MoE (NIE, School health)

Partners and Stakeholders

WHO, FAO, OIE, State Trading Organization (STO), Maldives Medical Association, Dentists Association, Nurses Association, Private Hospital's Association, Fisheries Association, Pharmacy Association, PSM, Broadcasting Commission, Media council, NGO's

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 national scale

Strategic intervention 1.2 Include AMR and related topics such as Infection Prevention Control as a core component of professional education, training, certification and development for health care providers in human and animal health and food production industry including aquaculture

KEY ACTIVITIES

Under the overall supervision of TSC (Awareness):

Year	Activity	Description of Activity
2017-18	Conduct KAP Studies to	Task Force commissioned in 1.1 will conduct KAP Studies on a national scale to assess
	assess gaps in knowledge on	awareness levels and gaps in knowledge in professional groups on AMR, AMU, hygiene & IPC,
	AMR, hygiene & IPC,	environmental relationships. Priority professional groups will include: clinicians, pharmacists,
	environmental relationships	nursing staff, medical laboratory technicians, health assistants, public health & primary health
	in professional groups	care professionals, ministry officials of relevant departments and policymakers
2019-20	Revise and roll out	MFDA and MoFA Counterpart, under technical guidance of MoE, and in collaboration with
	professional development	WHO Country Office will undertake revision for professional development courses (human
	courses of human and animal	health, animal health, aquaculture and food industry). Proposals submitted by MFDA and MoE
	health, the food industry and	will be reviewed for their suitability for new curricular strategies. Roll out of courses will be
	agriculture sectors to include	done on a limited scale along with concurrent regular audits followed by nationwide scale up.
	topics on AMR and related	
	issues	
2020-22	Revise undergraduate and	AMR and related topics will be incorporated in undergraduate and postgraduate curricula
	postgraduate curricula in	including in allied health courses (pharmacists, nursing staff, medical laboratory technicians,
	human and animal health,	health assistants, public health & primary health care professionals). Limited scale testing of
l	numan and annual neatur,	neatur assistants, public neatur & primary neatur care professionals). Linned scale testing o

Food industry and	revised curriculum along with regular audit of courses will be conducted before planning a
Agriculture sector to include	nationwide scale up in next phase of NAP
topics on AMR and related	
issues	

Responsible Agency

MoH (MFDA, HPA), MoFA, MoE (NIE, School health), MNU (Faculty of Health Sciences and Faculty of Science)

Partners and Stakeholders

WHO, FAO, OIE, NGOs, Maldives Medical Association (MMA), Maldives Dentists Association (MDA), Maldives Nurses Association (MNA)

Illustrative Indicators

- Revised curricula for undergraduate, postgraduate and Continuous Professional Development courses in human and animal health 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 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 several elements of systematic AMR surveillance are not in place in different sectors such as surveillance standards/guidelines, laboratory standards, systematic data collection and analysis including electronic reporting, recording and linkage with HAI surveillance. Human health sector is ahead with an institutional level bacterial AST and initial efforts to put quality assurance system in selected laboratories performing AMR testing. However, animal health sector has no AMR surveillance in the emerging food animal production systems of poultry, goat farms and aquaculture.

By 2022, Maldives will consolidate its strengths in AMR surveillance and develop a high quality AMR surveillance system on a limited scale that will integrate AMR surveillance in laboratories, hospitals, AMU and surveillance in animal sectors. Sentinel environmental surveillance in high risk settings will be established. By 2022, a national early warning system will be in place to identify early, the emergence of resistance in priority pathogens and to critical antimicrobials. Nationwide expansion will be planned at the end of this phase of NAP in 2022. The Plan will be rolled out as below:

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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

KEY ACTIVITIES

Year	Activity	Description of Activity
2017	Establish AMR Surveillance Coordination Unit, define mandates, terms of reference and identify a focal point	The TSC (Surveillance), TSC (IPC) and TSC (AMU) will jointly identify an AMR Surveillance Coordination Unit (ASCU), define its mandates and terms of reference followed by notification by ministerial decree. The ASCU will be located in the MFDA.
2017-18	Develop a One Health AMR guidelines and plan for surveillance in humans, animal and food industry based on international standards and guidelines	 The ASCU, with technical support from WHO, OIE and FAO, 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 Alimentarius, etc.) ASCU will develop a One Health AMR surveillance plan in human health care settings and food animal production sector including aquaculture (sample selection, number of samples, sample processing, logistics)with identification of surveillance sites
2017-18	Enlist priority pathogens and antimicrobials for surveillance in human, animal and food industry	The ASCU will identify priority pathogens, sample sites and pathogen-antimicrobials combinations in humans and food animal production systems, based on the country's AMR situation
	Assess and inventory of resources for sentinel environmental surveillance Conduct trainings on AMR	 ASCU, in collaboration with Environment Protection Agency (EPA) and MoEE, will assess and inventory resources for monitoring, surveillance and testing sentinel environmental sites for antimicrobial resistant organisms and antimicrobial agents ASCU will be responsible for training of surveillance staff and clinical staff in AMR

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	surveillance for surveillance staff	surveillance and lab techniques according to GLASS standards
	Develop an integrated human and animal IT platform for AMR surveillance reporting	Under the technical guidance of ASCU, MoH will develop an integrated information system to ensure interoperability between AMR surveillance and hospital infection surveillance in different HCFs. WHONET platform will be implemented for epidemiological and laboratory AMR surveillance data entry, storage and transmission in human clinical and food testing labs
2019-22	Implement National AMR Surveillance Program including sentinel environmental surveillance of antimicrobial resistance organisms and antimicrobial residues	ASCU will implement a national AMR surveillance program that is representative but with limited number of operational sites. IGMH, Regional Hospitals and Atoll Hospitals with existing Bacterial AST facility will be targeted in the pilot phase. Additionally, ADK Hospital from private sector will be included as a surveillance site. For animal surveillance selected poultry commercial, goat farms and aquaculture farms will be recruited and specimens submitted to NHL. One tertiary hospital, 1 commercial poultry production unit, 1 hospital waste dumping island will be recruited as sentinel sites for environmental surveillance. Regular data of AMR along with resistance profiles of priority pathogens for humans, animals, aquaculture and environmental sites will be made available to ASCU from these, limited number of sites. Integrated information system will be integral to the AMR surveillance pilot
2021-22	Establish formal linkage of National AMR Surveillance Programme and WHO GLASS	The ASCU 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
	Conduct formal assessment of National AMR Surveillance Program	TSC (Surveillance) will conduct a formal assessment of National AMR surveillance followed by recommendations of nationwide scale up

MoH (MFDA, HPA), MoFA, MoEE (EPA)

Partners and Stakeholders

WHO, FAO, OIE

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 TSC (Surveillance):

Year	Activity	Description of Activity
2017	Identify National Reference	The Microbiology Laboratory at IGMH will be identified as National Reference Laboratory
	Laboratory (NRL) for	(NRL) for AMR Surveillance in Maldives. IGMH will cater human clinical samples. MFDA's
	AMR Surveillance in	National Health Laboratory will support IGMH in testing of food samples, samples from food
	Maldives with expertise in	animal production systems, animal feeds, and environmental samples for presence of
	methods for confirming and	antimicrobial resistant organisms (AROs) and antibiotic residues as part of the overall
	characterising specific	surveillance of AMR & AMU. The IGMH will develop expertise in methods for confirming and
	pathogens, performing	characterising specific pathogens, performing susceptibility testing, organising quality assurance
	susceptibility testing,	and participating in external quality assurance schemes (EQAS). IGMH will continue to

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	organising quality	participate in Thailand EQAS network for a regular EQAS participation in addition to additiona
	assurance and participating	efforts to subscribe to CMC Vellore EQAS program. The IGMH in collaboration with QAD and
	in external quality	MFDA will coordinate a national network of surveillance laboratories to monitor AMR in human
	assurance schemes (EQAS)	clinical, animal, food and environmental samples.
		A laboratory designated to cater animal samples is needed.
	Identify participating	Laboratories linked with AMR surveillance sites in 2.1 (7) will be identified by IGMH. Thes
	laboratories of National	surveillance laboratories will be capable of identifying target pathogens and perform
	AMR Surveillance	susceptibility testing as per standard operating procedures (SoP) laid down by IGMH
	Network that are capable of	
	identifying target	
	pathogens and perform	
	susceptibility testing	
	Develop AMR surveillance	The IGMH, in partnership with NHL will develop and share AMR surveillance standards and
	standards and guidelines,	guidelines, including SoPs, incorporating other intergovernmental standards (OIE/WHO GLAS
	incorporating	and AGISAR/Codex) with surveillance labs
	intergovernmental	
	standards	
2018	Train surveillance staff,	IGMH and NHL will train surveillance staff, clinical staff, and laboratory personnel in AMI
	clinical staff, and	surveillance, lab techniques and data management according to international standards (WH
	laboratory personnel in	GLASS and AGISAR, OIE, Codex Alimentarius)
	AMR surveillance, lab	
	techniques and data	
	management	
2018-19	Roll out National AMR	Lab surveillance network in support of National AMR surveillance network will be rolled out i
	Laboratory Surveillance	limited number of sites (Sites identified in 2.1 (7) will be targeted in the pilot phase)
	network	
2022	Conduct a formal	TSC (Surveillance) will conduct a formal assessment of National AMR surveillance networ
	assessment of National	followed by recommendations for a nationwide scale up
L		Page 38 63

 AMR Labora	atory	
Surveillance network		
Establish linkage	with	IGMH will expand the network into a nationwide quality assured laboratory AMR surveillance
international and gl	lobal	network. IGMH will establish linkages with international and global surveillance and
surveillance	and	internationally relevant initiatives (like GLASS, GFN). Reporting to GLASS will commence from
internationally rele	evant	surveillance sites, recruited and operationalized in initial phase
initiatives		

MoH (MFDA, NHL), IGMH, MoFA, MoEE (EPA), Health Facilities under MoH

Partners and Stakeholders

WHO, FAO, OIE, private Hospitals and clinics

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 TSC (Surveillance) and with technical support from WHO and FAO:

Year	Activity	Description of Activity
2017-19	Establish a network of agencies for AMR hazard and risk assessment	The ASCU will identify agencies (related to human and animal health, aquaculture, drug control, environmental health) to be involved in AMR hazard and risk assessment, outline their roles and responsibilities
	Develop and disseminate guidelines and national standards for systematic collection, sharing, and assessment of AMR hazard events	The ASCU 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
	Enlist priority pathogens and AMAs for AMR hazard risk assessment	Lists and definitions of priority events (priority pathogens, specimens, and pathogen- antimicrobial combinations) will be developed in keeping with country's AMR situation
	Conduct surveys to establish baseline estimates and trends of AMR to determine risks and establish thresholds for alerts and action systems	The MFDA will collaborate with MoH, IGMH, QAD and HPA to conduct surveys to establish baseline estimates and trends of AMR to determine risks and establish thresholds for alerts and action systems
2020-21	Establish a central library or database on AMR risk information	A central library or database will be established at the ASCU to store AMR risk information, and make data available to government agencies, public and international community as appropriate in future
2021-22	Conduct and communicate comprehensive real time analysis of AMR hazards in the human, animal, food industry and environment	Data transmission on AMR alerts will start flowing from initial phase AMR surveillance sites identified and recruited in 2.1 (7). 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 animal sector and its linkage with the resistance profiles reported in animals and humans by the laboratory based in AMR surveillance programme

MoH (MFDA, NHL), IGMH, MoFA, Ministry of Environment (EPA), Health Facilities under MoH, MoEE

Partners and Stakeholders

WHO, FAO, OIE, private Hospitals and clinics

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 (Ipc)

Infection prevention and control, especially in the context of hospitals, is an important aspect of a strategic plan to contain AMR since clinical settings represent an ecosystem of high antimicrobial usage. Within this ecosystem exists patients, who may be immunologically impaired. These patients not only represent the population that is vulnerable to serious life-threatening infections and at the same time, they promote the emergence of resistance.

On the other hand, better hygiene (WaSH) and Infection prevention control 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 Maldives reveals frameworks that have been developed. However, in the absence of standardised guidelines, awareness, training and resources, the quality and scale of implementation has been less than optimal. Health Care Quality Standards are platforms that could be capitalised. Other measures such as AMR stewardship programme in healthcare settings or ambulatory settings, in human and animal health and food production sectors and HAI surveillance 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, private sector and in selected food animal production sector (poultry, goat farms, aquaculture). 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 and food handling practices on a small scale in animal and food animal production sites. Human vaccination programs are well-developed programs that will be further consolidated and animal vaccination 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, fisheries and the food chain

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

KEY ACTIVITIES

Year	Activity	Description of Activity
2017-18	Evaluate existing IPC, and Biosecurity guidelines	TSC (IPC) in collaboration with TSC (Surveillance) and TSC (AMU) will commission a multi-sectoral task force that will evaluate existing IPC, Hygiene, IPC and Biosecurity components of food production systems. Existing guidelines and programmes (such as the Health Care Quality Standards) on patient safety in human hospital services will be reviewed for their strengths and weaknesses including resource constraints and technical capacity. The Task Force will develop a national IPC policy, mandating the creation and harmonization of National IPC Programmes in healthcare facilities and food production systems (poultry, goat farms, aquaculture)
Under th	he overall technical supervision of TSC	<i>(IPC):</i>
2017-18	Develop IPC guidelines with implementation for infection prevention and control in all health care settings (hospital and ambulatory) in human sector; IPC/biosecurity in animal health facilities (hospital and ambulatory), vaccination, and biosecurity in the farm to fork	The 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 food animal production facilities, vaccination, and biosecurity in the farm to fork chain in line with international standards set out by OIE/FAO. Existing guidelines and program will be reviewed before integration into national guidelines

	chain	
	Identify target groups to be trained in IPC from different sectors and at different levels	The Task Force, in collaboration with WHO, FAO, OIE and ASCU will identify target groups to be trained in IPC from different sectors (human health, food production, environment) and at different levels (policy makers, programme managers, industry leaders, farmers, etc.)
	Train target groups in different sectors in IPC	TSC (IPC) through MFDA and Quality Assurance and Regulation Division (QARD), will coordinate capacity building at healthcare facilities to create dedicated, trained IPC teams at facilities in selected number of sites including large private hospitals. MFDA and MoFA will conduct training of biosecurity teams to implement and supervise food animal production units
	Roll out IPC program in human health, animal health and food industry	TSC (IPC) through MoH and MoFA will roll out IPC programme on a limited scale, with dedicated trained teams placed in some public healthcare facilities, private sector and in selected food chains
2019-20	Review existing professional curricula for content on IPC and develop training modules for their incorporation into professional courses	QAD and MoFA, in collaboration with MoE, will review existing curricula of professional courses with respect to content on IPC and develop training modules for incorporation into professional courses
2022	Assess National IPC Programme and recommend Nationwide scale up in human, animal healthcare facilities, food production systems.	TSC 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.

MoH (MFDA, NHL, QAD), IGMH, MoFA, MoEE (EPA), Health Facilities under MoH, MoE (School health programme)

Partners and Stakeholders

ADK Hospital, MMA, MDA, MNA, Livestock/ Fisheries Producers' Associations, WHO, FAO

Illustrative Indicators

- A National IPC programme for human, animal health and food industry sector; 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

Year	Activity	Description of Activity
2017-18	Develop guidelines for	The TSC (IPC) will commission a multi-sectoral task force that will, as part of Hospital IPC
	Hospital Associated	Guidelines, develop guidelines for HAI surveillance (objectives, standardised case definitions,
	Infection (HAI)	methods of detecting infections/procedures/exposures and exposed populations, process for analysis
	Surveillance	of data, evaluation of data quality, reporting/communication lines at local level and from local to
		national facilities, quality assured microbiology capacity, training programme, financial outlays).
2019-22	Implement a pilot scale	ASCU will implement on pilot scale a HAI surveillance in select public and private healthcare
	on HAI surveillance in	facilities. HAI surveillance data will be reported centrally from these public and private healthcare
	select public and private	facilities
	healthcare facilities	
2022	Integrate HAI	ASCU will carry out a formal assessment of HAI surveillance pilot. Data from HAI surveillance
	surveillance network into	network will be integrated into National AMR surveillance network as outlines in 2.1 (7). Integrated
	National AMR	analysis of surveillance data will form the basis for monitoring and response frameworks, including
	surveillance network;	the identification of priority triggers (priority pathogens or pathogen-drug resistance combination) that

Conduct formal	will be established by ASCU. HAI surveillance will be implemented on a nationwide scale covering
assessment of HAI	tertiary, regional, Atoll hospitals, health centres in public and sentinel private hospitals
Surveillance network for	
nationwide scale-up	

MoH (MFDA, NHL), IGMH, MoFA, MoEE (EPA), Health Facilities under MoH

Partners and Stakeholders

ADK Hospital, MMA, MDA, MNA, WHO

Illustrative Indicators

- 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

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

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

Year Activity

Description of Activity

2017	Review and evaluate the existing national campaigns on water, sanitation & hygiene (WaSH), food safety, and vaccination in humans and animals	The TSC (IPC), in collaboration with MoE, will commission a multi-sectoral task force. The taskforce will review and evaluate the existing national campaigns, generate new evidence wherever necessary, modify guidelines suitably to address issue of sanitation and hygiene including, food handling practices, vaccination in humans and animals
2018	Implement formal campaigns for sanitation and hygiene in human, animal, food animal production sectors	MoH and MoFA will implement formal campaigns for sanitation and hygiene, vaccination and food handling practices among general public; biosecurity and vaccination on a small scale in food animal production sites
	Evaluate existing vaccination programme in human and animal sectors for their effectiveness and coverage	MoFA will strengthen immunization programmes for preventable infections; MoH and MoFA will evaluate existing vaccination programme for their effectiveness and coverage
2018- 19	Review and revise undergraduate and post graduate curricula to include course content related to water, sanitation, hygiene and food handling practices	MoH and MoFA in collaboration with MoE will include sanitation and hygiene including food handling practices in the core curricula in secondary and undergraduate education for school and college students
2019	Evaluate campaigns on hygiene and sanitation	MoH and MoFA will carry out monitoring ,concurrent evaluation of campaigns on sanitation and hygiene to inform nationwide scale-up

MoH (MFDA), IGMH, MoFA, MoEE (EPA), Health Facilities under MoH, MoE (School health programme)

Partners and Stakeholders

ADK Hospital, MMA, MDA, MNA, Livestock/ Fisheries Producers' Associations, WHO, FAO, OIE, UNFPA, UNICEF

Illustrative Indicators

- Evidenced based national campaigns on water, sanitation & hygiene (WaSH), food safety, vaccination in humans and animals;
- Increased coverage of WaSH related interventions, 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 Maldives has a fully functional National Regulatory Authority that is responsible for regulation and licensing; drug import and pharmacovigilance. Post licensing inspections including for retail pharmacies and OTC sales are carried out on national scale regularly. However, limited human and technical resources as well as the complex challenges of import based system of procurement limit the effectiveness of regulatory activities. Import of AMAs used in food animal production sector including aquaculture is covered by the regulatory framework. The country lacks important instruments and systems such as a National AMR containment policy, AMU surveillance including surveillance of sales of antimicrobial agents. Animal health sector lags on all of the above fronts and is also constrained by lack of regulatory powers.

Maldives will establish a robust system for regulation and surveillance of use of antimicrobial agents for control of use of antimicrobial substances in human, animal and food production sectors. Some of the measures taken will include an empowered National Drug Regulatory Authority, import frameworks favourable to regulatory requirements, National AMR Containment and Use Policy and related regulatory frameworks, standard treatment guidelines with special reference to use of antimicrobial agents, National Antimicrobial Stewardship Programme and AMU monitoring programme in human and food animal production systems, ambulatory and community settings and 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 2017-2022. 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 use of antimicrobials in humans and animals, and implement a comprehensive evidence-based formal antimicrobial stewardship programmes at the national level

KEY ACTIVITIES

The TSC (AMU) in collaboration with TSC (Surveillance) and TSC (IPC) will commission a task force to develop a National AMR Containment, Use Policy and related regulatory frameworks. Within this policy framework, the task force will:

Year	Activity	Description of Activity
2017-19	Develop a national AMR containment policy and organizational framework within the charter of the Policy	Develop a national AMR containment policy and propose a formal organisational structure responsible for implementation of the National AMR containment policy. The Policy will mandate provisions for the five strategic objectives enshrined in GAP and NAP AMR for Maldives
	Formulate a regulatory framework for control of antimicrobial substances in human, animal sectors and food industry	MFDA in consultation with stakeholders will develop an essential medicine lists with special reference to the use of antimicrobial agents. Antimicrobial agents in the EML will be considered for inclusion based on Maldives's situation of current levels of AMR, availability, supply chains, financial outlays, international guidelines and standard treatment guidelines in human medicine, veterinary medicine and aquaculture (including antimicrobial growth promoters; AGPs). Existing EML to be reviewed in light of the National AMR Containment Policy
	Develop standard treatment guidelines (STGs) for antimicrobial use in human and animal healthcare and food industry	STGs (including antimicrobials) will be developed by the taskforce for training, supervision and supporting critical decision-making in antimicrobial use practices, in human and veterinary healthcare and food production. Existing efforts of Quality Assurance and Regulation Division will be reviewed for informing STGs for AMAs

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	Conduct surveys to characterize institutional Antimicrobial Stewardship Programmes (AMSP)	Conduct baseline surveys to assess the extent, barriers and enablers of AMSP at institutional levels
	Develop evidence based guidelines for a National AMSPDevelop comprehensive, evidence based guidelines for a National Antimicrobial Ster Programme (AMSP) with the aim of improving and measuring the appropriate antimicrobials in human , animal health care, ambulatory and community settings a aquaculture.	
Under the	e overall supervision of TSC (AMU)	
2018-22	ImplementAMRcontainmentpolicyforcontrolofhumanveterinaryuseofantimicrobialsubstancesinhumanandanimalhealthcare,ambulatoryandcommunitysettingsandfoodindustrysettings	MFDA, QAD and MoFA will implement AMR policy for control of human and veterinary use of antimicrobial substances, including the preventing introduction/phasing out of AGPs. Limited scale implementation of the national AMSP in human health settings, ambulatory, community settings and food animal production systems will be done. This will be accompanied by monitoring and concurrent evaluation followed by nationwide implementation in the next phase of NAP

IGMH, ADK, MoH (MFDA, QAD) & MoFA

Partners and Stakeholders

WHO, FAO, OIE, Maldives Medical Association, Maldives Nurses Association, Pharmacy Association, NGOs

Illustrative Indicators

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- A national AMR containment policy to control the 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 Regulatory Authority (NRA) which can enforce quality standards of antimicrobial drugs (veterinary, human, and food production sectors)

KEY ACTIVITIES

Under the overall supervision of TSC (AMU):

Year	Activity	Description of Activity
2017	Formulate a National Drug	MFDA in collaboration with a suitable counterpart in MoFA will review the National
	Policy with special reference	Medicine Policy, Medicine Chapter of Health Services act 2015, relevant regulations, with
	to AMAs and AMR	special reference to AMAs and AMR. The Policy will be applicable to human, animal health,
	applicable to human, animal	aquaculture and food production sectors.
	health, and food industry	Introduce legislation and regulations on AMAs for veterinary use.
2017-	Strengthen existing National	MoH will further strengthen MFDA in serving its mandates of drug control, import, quality,
<i>19</i>	Drug Regulatory Authority	distribution, pricing, market authorization, advertising, retail sales, inspection, and to
	and establish additional	implement the relevant regulations. Human resource and technical capacity of National
	regulatory frameworks	Health Laboratory of MFDA will be strengthened to establish systematic surveillance of
		quality of imported drugs and food at points of entry as well as post marketing surveillance of
		drugs and food. MFDA will cover drugs used in human health , extend similar regulatory
		framework to import medicines for animal health, aquaculture and food production
	Establish import	Bulk procurement system of drugs including AMAs through the STO will be established to
	procurement systems	ensure import frameworks favourable for regulatory compliance

	favourable to regulatory compliance	
	Establish a system for the coordination and collation of data on drug quality	NDRAs 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 designated regional institutions. Special attention will be given to international border areas known for illegal import of drugs
2017- 22	Establish and implement an institutional network with the capacity for quality control and enforcement of regulatory provisions for antimicrobial agents or APIs	Within the regulatory frameworks laid down by MFDA, the MoH will review and strengthen the existing institutional network/system of inspection, 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. System strengthening will include building capacity of Public Health Units that support MFDA and are responsible for selected drug regulatory functions such as supply chain, inspection of pharmacies for OTC sales in peripheral parts of the country. Human resources will be adequately provisioned for effective monitoring and enforcement
	Conduct independent periodic surveys to estimate the extent of OTC and inappropriate sales of antibiotics and APIs	MFDA in collaboration with QAD, HPA and MoFA counterparts will continue to conduct independent periodic surveys to estimate the extent of OTC ,inappropriate sales of antibiotics and the drivers for the same and evaluate the effectiveness of OTC regulations done and corrective measures undertaken. Monitoring &evaluation of AMA sale in veterinary sector

MoH (MFDA) & MoFA health Facilities (PHUs)

Partners and Stakeholders

WHO, FAO, OIE, HPA, QAD, STO

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 (islands, atolls and locations.) with strengthened post marketing and 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 TSC (AMU), TSC (Surveillance) and TSC (IPC):

Year	Activity	Description of Activity
2017	Establish AMU Surveillance	ASCU will establish a subcommittee called AMU Surveillance Committee (AUSC) with
	coordination structure	appropriate mandate, TORs and Focal Point (FP) that links with ASCU
2018	Design an AMU and residue monitoring program in humans, animals and food industry; develop guidelines to implement residue testing	The AUSC will coordinate policies on AMU and monitoring their impact on AMR. AUSC will design an AMU monitoring program in humans and food animal production systems 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). AMU monitoring will include monitoring of sales data in humans as well as animals (sales quantity per kg of slaughtered animal, sales quantity per PCU etc.). Quantity and quality of AMU in different settings will be assessed through point prevalence surveys by QAD, HPA and MFDA. Longitudinal surveillance will be planned in the next phase of NAP
		In collaboration with NHL, AUSC will also develop guidelines to implement residue testing

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		including data sharing
2019-22	Implement AMU	AUSC will implement AMU surveillance and residue testing, Healthcare facilities, including
	surveillance and residue	in ambulatory, community settings and parts of food animal production systems will be
	testing	recruited on a limited scale. For residue testing, surveillance sites operationalized for AMR
		Surveillance in 2.1 (7) will be recruited. AMU surveillance and residue testing will be
		conducted on limited scale by 2022. Data for the use of antimicrobial substances and sales
		data in humans, animals, and food production sectors will be available by 2020
	Conduct integrated analysis	The AUSC will analyse AMU data in linkage with the resistance profiles reported by the
	of AMU, AMR and residue	AMR surveillance programme. Actionable recommendations will be made to modify existing
	surveillance data to guide	local STGs
	programme planning	

MoH (MFDA, QAD, HPA), MoFA, IGMG, MoEE

Partners and Stakeholders

Ministry of economic development, WHO, FAO, OIE

Illustrative Indicators

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

Year Activity

Description of Activity

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 was absence of economic assessments, which evaluated the cost of doing nothing versus the cost/benefits of action at the present.

The Situational Analysis in Maldives indicates that research on AMR has not been a priority for both policy makers and research community. Limited evidence exists on the nature and extent of AMR as a public health threat and drivers of AMR and AMU. This calls for policy and program relevant research to support planning and implementation of public health interventions. The phase of development of the health system provides 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 2022, 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 envision collaborations with national and international agencies, for implementation of strategic research agenda. This will be one of the key strategies for Maldives, given its existing nature of AMR threat and limited 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

Under the overall supervision of TSC (Research):

2017- 18	Create an inventory of relevant networks, initiatives, institutions and experts involved in AMR research	In collaboration with National Medical Research Committee (NMRC), Faculty of Health Sciences (FHS) and Faculty of Science (FoS) at MNU will create an inventory of relevant networks, initiatives, institutions and experts involved in AMR research across human and animal health sectors in Maldives. The NMRC will assess existing research, capacities, future plans and funding sources for research and innovations through a landscape analysis
	Develop a Strategic research agenda, with systematically prioritised research areas and knowledge gaps in the field of AMR	FHS & FoS 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 Maldives (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. Priority research to support implementation of NAP will include human resources for implementation
2017- 18	Develop a National AMR Research Policy	TSC (Research) will develop a national policy for research and innovation, based on the research agenda

2018- 19	Establish a multi-stakeholder platform to guide AMR research and innovation	TSC (Research) will establish a multi-stakeholder platform to guide AMR research and innovation. The research platforms will develop research collaboration between national agencies and with international partners, for implementation of strategic research agenda
2020- 22	Document and disseminate to different stakeholders, evidence on AMR and related issues for policy and programme intervention	TSC (Research) will make evidence available through research databases, peer reviewed publications, policy briefs, policy advocacy dialogues to inform national, local policies and strategic interventions in different strategic objectives to reduce the need for antimicrobial in several settings (health care, animal husbandry, aquaculture and food production)

MoH (NMRC), MoE (FHS, FoS) & MoFA, Ministry of Environment (EPA)

Partners and Stakeholders

IGMH, National Health Laboratory, HPA, Villa College, WHO, FAO, OIE

Illustrative Indicators

- Research network and collaborations;
- Multi-stakeholder research initiative National Research Policy on AMAs and AMR Research;
- Strategic research agenda, with prioritised research areas, 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 Maldives covers the period 2017-2022. It factors in the expert view of stakeholders from different ministries to come up with a Strategic Plan, outlining a set of operational details. The Plan takes into account both strengths and limitations that are unique to Maldives and consolidates them before formulating a vision of AMR prevention and control. It builds on the government's concern to make universal healthcare available to all and to simultaneously ensure animal welfare and food security across the length and breadth of the country.

The Plan draws from valuable insights that emerged from a Situation Analysis that was conducted along with one-on-one interviews, guided discussions and participative dialogues that were undertaken with multiple stakeholders from the government, civil society, NGOs and others. Technical support was provided by WHO Country office, WHO SEARO and an independent Consultant.

The NAP AMR of Maldives in its existing form provides a constructive opportunity for the government to fine tune it based on its local realities and sensitivities. Further, 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 or roadmap outlines collaborations with national and international agencies, for implementation of a strategic research agenda that has potential to serve as a major strategy for the country. Undoubtedly, it will use both evidence to guide programme planning and action. 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 Maldives will continue with its deliberations and planning process under the leadership of NMSC. Next, the NMSC through its constituent NACC, TSCs and Task Forces will draw up a detailed operational plan in addition to its budget, 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 2017-22.

The successful implementation of the NAP AMR within a stipulated time frame is estimated to bring together all the critical players from the human and animal health and related domains on a common platform. This will inevitably create greater responsibility, ownership and transparency. Working closely with a more sensitized and aware population, Maldives, like other countries in the region, is expected to bring down its levels of AMR. In the months to come it will also institutionalize some of its mechanisms to better manage and arrest the spread of AMR.

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Annexures

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

Phase of Programme Implementation	What it means	
Phase 1 Phase of Exploration and Adoption	conduct AMR prevention and control in the country. However, the proce of designing a program has been initiated, and depending on the progre made (as seen through the indicators), it may be that one or more of the	
	- Identification of needs, options and resources	
	- 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	
	- Identifying structures (both in policy making and implementation frameworks) to aid in the implementation of the programme	
	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 Phase of Programme	The decision to implement a programme has been made and the initial set of activities have been undertaken in order to launch the program. These may include:	
Installation	- Capacity building	
	- Resource allocation	
	- Establishment of data transmission, security, and sharing protocols	
	- Development of process indicators, standard operation protocols and other guidelines to be adhered to by institutions participating in the programme	
	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	This is probably the most challenging phase in the stages of early implementation of any programme within the context of developing	

Implementation	nations. In this phase, there is a need to initiate a change or an intervention, which may have patchy uptake or maybe avoided altogether.	
	- In course of this phase, a functional model of the program is identified	
	- 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	This is the process of scaling up a successful model of the programme that may have been trialled in the previous phase.	
Phase of Full		
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	This is the highest grade of operational efficiency of the programme and	
Phase of indicates that the programme can have long-term survival.		
Sustainable Operation	- 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.	
	- Through a functional M&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	

Endorsed by: Hussain Rasheed State Minister Date: 16th May 2017