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GAP ASSESSMENT ON AMR POLICY AND INSTITUTIONAL FRAMEWORK AMONG COMPETENT AUTHORITIES

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Gap Assessment on AMR policy and institutional framework among competent authorities

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Review existing policies, strategies, laws and capacity building initiatives leading current efforts in antimicrobial resistance related to the livestock sector, including veterinary drug registration

Authored by UNIDO's LDDP Team:

Dr. Valeria Bortolaia - International Expert, Antimicrobial Resistance (AMR) Dr. Md. Giasuddin - National Antimicrobial Resistance (AMR) Surveillance Expert Dr. Md. Nure Alam Siddiky - National Antimicrobial Resistance (AMR) Expert Dr. Md. Ainul Haque - National Project Coordinator Dr. Md. Mehedi Hossain - National Inspection Expert Dr. S. M. Rajiur Rahman - National Livestock and Dairy Expert Prof. Samuel Godefroy - Senior Expert in Food Safety Regulatory Sciences and Policies

Report submitted by

Project Manager

UNIDO LDDP Project

Report submitted to

Project Director

Livestock and Dairy Development Project

Department of Livestock Services

Ministry of Fisheries and Livestock

Bangladesh

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List of abbreviations

ADRM	Adverse Drug Reaction Monitoring
AHCAB	Animal Health Companies Association of Bangladesh
AMC	Antimicrobial Consumption
AMR	Antimicrobial Resistance
AMU	Antimicrobial Use
API	Active Pharmaceutical Ingredient
ARAC	Antimicrobial Resistance Action Centre
AST	Antimicrobial Susceptibility Testing
BARC	Bangladesh Agricultural Research Council
BAU	Bangladesh Agricultural University
BFSA	Bangladesh Food Safety Authority
BLRI	Bangladesh Livestock Research Institute
BSTI	Bangladesh Standards and Testing Institution
BVC	Bangladesh Veterinary Council
CDIL	Central Disease Investigation Laboratory
CLSI	Clinical and Laboratory Standards Institute
CVASU	Chattogram Veterinary and Animal Sciences University
DCC	Drug Control Committee
DGDA	Directorate General of Drug Administration
DGHS	Directorate General of Health Services
DLS	Department of Livestock Services
DOF	Department of Fisheries
EQA	External Quality Assurance
EUCAST	European Committee on Antimicrobial Susceptibility Testing
FAO	Food and Agriculture Organization of the United Nations
FDIL	Field Disease Investigation Laboratory
IEDCR	Institute of Epidemiology, Disease Control and Research
LDDP	Livestock and Dairy Development Project
LRI	Livestock Research Institute
MIC	Minimum Inhibitory Concentration
МоА	Ministry of Agriculture
MoE	Ministry of Education
MoFL	Ministry of Fisheries and Livestock
MoHFW	Ministry of Health and Family Welfare
MRL	Maximum Residue Limit

NCL	National Control Laboratory
NGS	Next-Generation Sequencing
OHS	One Health Secretariat
отс	Over The Counter
WGS	Whole Genome Sequencing
WHO	World Health Organisation
WOAH	World Organisation for Animal Health

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EXECUTIVE SUMMARY

In the framework of the Livestock and Dairy Development Project (LDDP), UNIDO is contributing to the specific objective of improving the food safety system for the protection of public health systems along the livestock value chains. This document has been developed within the framework of the activities of output 2: AMR surveillance and risk mitigation program as well as surveillance and monitoring of microbial chemical and residual hazards. Under the direct supervision of Dr. Gabor Molnar, UNIDO Project Manager, with the support of Laura Natalia Fernández Cedi, project coordinator at UNIDO, experts Dr. Valeria Bortolaia – international expert on AMR surveillance, Dr. Md. Giasuddin – national expert on AMR surveillance, and Dr. Md. Nure Alam Siddiky – national AMR expert, have identified the gaps and potential solutions for the management of AMU and AMR in livestock and food of animal origin in Bangladesh.

The emergence of antimicrobial resistance (AMR) is a major global public health issue that jeopardises the efficacy of antimicrobials to cure infections in humans and animals, thereby threatening health, welfare and productivity. Several reports show that infections by antimicrobial-resistant pathogens in humans may be linked to antimicrobial use (AMU) and AMR in food-producing animals. The extensive overuse, misuse of antimicrobials, and poor infection prevention and control in veterinary settings favors the spread of AMR in livestock, which is a risk for contamination of food by AMR bacteria and foodborne transfer of AMR to humans. Furthermore, AMR bacteria of animal origin may spread to humans also via direct contact with production animals. Robust AMU and AMR data are important to monitor the progress and efficacy of interventions aiming to reduce AMU and AMR in the livestock sector. Strengthening the regulatory aspect of antimicrobial stewardship (AMS) in veterinary domain is a very important strategic focus for curbing the AMR in Bangladesh. The aim of this study is to review current policies, regulations, roles, responsibilities, legal prerogatives, and capacities and to identify gaps for the management of AMU and AMR in livestock and food of animal origin in Bangladesh. Data collection was conducted from both primary and secondary sources. The following materials were taken into consideration for this gap assessment:

- Published materials, such as existing policies, legislations, guidelines and regulations on AMU and AMR by the different competent authorities (DGHS, DGDA and DLS);
- Data collected through an online questionnaire on AMR and AMU in the livestock sector and food of animal origin in Bangladesh (Annexure 1);
- Data collected through an online questionnaire to assess the AMR surveillance capacities and strength of the laboratories in the animal health sector of Bangladesh (Annexure 2);
- The outcome of two roundtable stakeholder discussions on AMU and AMR surveillance and monitoring in the livestock sector and food of animal origin held during the 2nd UNIDO technical mission on food safety and AMR surveillance of food of animal origin;
- The outcome of key informant interviews (KII) and focus group discussions (FGD) held with high-level governmental officials, industry representatives, and development and international agencies in Bangladesh.

Overall, the study identified that regulation of AMU and AMR is complex and requires further coordinated efforts by different Authorities and Institutions. Various policies, legislations, regulations and guidelines are in place that can address mostly AMU to some extent but none can address AMR in livestock. The study critically reviewed and identified the gaps in the following policies, legislation and guidelines:

Policies, plans and guidelines:

- National Action Plan on Antimicrobial Resistance Containment in Bangladesh (2017-2022),
- Multisectoral AMR surveillance strategies,
- National Livestock Development Policy, 2007,
- National Livestock Extension Policy, 2013,
- National guideline on the pharmacovigilance system in Bangladesh,
- National Drug Policy, 2016;

Regulations, acts and ordinances:

- Regulations on sale of antimicrobials,
- Regulations for continued availability of good quality antimicrobials,
- Bangladesh Food Safety Act, 2013,
- Animal Diseases Act, 2005
- Fish Feed and Animal Feed Act, 2010,
- Bangladesh Veterinary Council Act, 2019.

By legislative mandate, the Directorate General of Drug Administration (DGDA) is responsible to register locally produced and imported antimicrobials and to control locally produced and imported antimicrobials' active raw materials, sales and distribution. It is found that the Directorate General of Health Services (DGHS) is the nodal agency to develop and coordinate policies pertaining to National Action Plan (NAP) of AMR containment with One Health approach. Furthermore, DGDA is the principal authority to develop and implement regulations and guidelines for the responsible use of antimicrobials in both human and animal health sectors. DGDA has time befitting act and regulations related to antimicrobial stewardship (AMS), but enforcement is very weak particularly due to poor coordination with DLS, and inadequate human resources in relation both to geographic and to population coverage.

A clear gap is represented by limited availability of guidelines for AMU for different livestock species/disease combinations. Also, a regulatory framework to incentivise the use of alternative to antimicrobials is lacking and efforts to fill in this gap should be initiated. A severe gap is represented by the fact that no legislation or regulation addresses AMR directly

and comprehensively. This gap should be filled in by giving clear institutional mandate and government funding to DLS to design and perform AMR surveillance activities at national level.

DLS has designated three laboratories for AMR surveillance, including Central Disease Investigation Laboratory (CDIL) in Dhaka and two Field Disease Investigation Laboratories (FDILs). With the support of the Fleming Fund, these laboratories are undergoing consistent upgrade of facilities, purchase of advanced equipment, training of personnel and drafting of SOPs for nationwide AMR surveillance. Also the Bangladesh Livestock Research Institute (BLRI) has a state-of-the-art laboratory for AMR research. Based on a questionnaire, it was found that public veterinary microbiology laboratories have the capacity to collect various types of specimens from different sources and animal species, but these sampling activities are carried out in connection to specific projects that have different purposes and are scattered in space and time, and fail to convey information on the AMR situation in livestock at country level. Thus, there is an urgent need to establish sampling schemes that are coordinated across the different public veterinary microbiology laboratories for sustainable, nationwide AMR surveillance in livestock.

With the support of LDDP, DLS has arranged several training courses on awareness regarding rational AMU and the impact of AMR in livestock. Most field veterinarians received this training. However, most veterinarians who work in the private sector are not offered these training opportunities. Different research institutions like BLRI, BARC, IEDCR, icddr,b also organise AMU and AMR training programmes for the professionals. In addition, development partners, i.e. Food and Agriculture Organization of the United Nations (FAO), Fleming Fund, US-CDC and other partners also offer hands-on training on AMR surveillance in the context of different projects. Overall, the findings clearly showed the need for designing, implementing and securing stable funding for AMU and AMR training of different professional figures linked to animal health.

Based on the situation analysis and needs identification, a set of recommendations to be used for developing a policy paper for an integrated AMU and AMR surveillance and monitoring framework in the livestock sector in Bangladesh has been identified as follows:

- Recommendations on enhancement of Legislation and Regulations and Institutional Responsibilities
 - Provision of regular AMU and AMR surveillance should be included in the legislation
 - The use of alternatives to antimicrobials (biosecurity, vaccine, probiotics, prebiotics, etc.) should be regulated and enforced
 - Roles and responsibilities for assessing compliance with new and also with existing legislation on all aspects of AMU and AMR should be clearly assigned to DLS and DGDA, and overlap of responsibilities should be avoided. In particular, it is critical to ensure adequate
 - \cdot Control that sales of antimicrobials are done only based on prescription by a veterinarian
 - · Control that only registered veterinarians prescribe antimicrobials

- Provision of penalty/ punishment for antibiotic users without prescription of a registered veterinarians
- · Control that only pharmacists monitor the sale of antimicrobials
- \cdot Verify compliance with withdrawal times and MRLs
- National policies and standard treatment guidelines (STG) for proper AMU in livestock should be developed keeping into consideration the national AMR patterns
- Adequate personnel resources, laboratory capacity and funding should be secured for:
 - Collecting and analysing AMU data
 - Carrying out sampling, antimicrobial susceptibility testing and data management for national AMR surveillance
 - Verifying compliance with AMU and AMR legislation
- Committees involving veterinary specialists/professionals should be formed to overcome any crisis regarding drug approval and other antimicrobial drug issues
- ✓ Recommendations on Surveillance and Monitoring
 - Sampling, testing methods and data management for AMR surveillance in livestock and food should be harmonized at national level
 - A dedicated system to collect, analyze and disseminate quantitative AMU data should be set up
 - A dedicated system to collect, analyze and disseminate AMR surveillance data should be set up
 - Coordination for AMU and AMR data sharing should be initiated among antimicrobial manufacturers, APIs manufacturers, drug sellers, DLS, BLRI, DGHS, DGDA, DG fisheries, and also private farm/companies
- ✓ Recommendations on Enhanced Governance
 - A clear framework to ensure usability of AMU and AMR data for policy action should be developed and regularly assessed
 - Awareness of the detrimental effects of improper AMU and spread of AMR should be continuously raised among veterinarians, pharmacists, all livestock sector operators and the general public through awareness campaigns and training courses

Advocacy about the importance of containment of AMR with the planners and policymakers

BACKGROUND

Antimicrobial resistance (AMR) is a recognised threat to human and animal health globally as it jeopardises the efficacy of antimicrobials used for treatment of bacterial infections. The occurrence of antimicrobial-resistant bacteria in animal and meat poses a risk to humans as such bacteria may transfer to humans via direct contact with animals and/or by ingestion of contaminated food. Once they have reached the human gut, antimicrobial-resistant bacteria of animal origin may be implicated in infection and/or transfer AMR genes to other bacteria causing infection. The extent of this zoonotic risk has not been fully elucidated to date. Nonetheless, as infections by antimicrobial-resistant bacteria have been associated with increased morbidity and mortality in humans, reduction of occurrence of antimicrobialresistant bacteria in animals and food is a widely supported veterinary public health measure, which has constituted the background for important policy and legislation in several countries worldwide. A few examples are the ban or phasing out of the use of growth promoters that was effective in at least 70% of the 160 WOAH Member Countries reporting quantitative data on antimicrobials used in animals in 2017-2019 (WOAH, 2021), and a mandate of a harmonized antimicrobial resistance monitoring programme in the European Union (Commission Implementing Decision 2020/1729/EU).

The animal health sector of Bangladesh is highly vulnerable for the abuse, misuse and overuse of the antimicrobials due to higher intensification of animal farming, small holding animal enterprises, weak regulatory enforcement of rational use of antimicrobials, and inadequate monitoring and surveillance of AMU and AMR, etc. Bangladesh has made many policies, regulations and guidelines for the antimicrobial stewardship. The enforcement of these regulations and guidelines are not adequate due to poor institutional capacities and poor coordination mechanisms among the regularity authorities. The important regulations are drug act, 1940, drug control ordinance, 1982, fish feed and animal feed act, 2010, etc. The medicine supply chain in Bangladesh, based on data from the DGDA dashboard, is complex. Overall, for products, there are 43,529 registered drugs from 761 manufacturers distributed through 120,871 retail outlets in the country. In terms of players, for allopathic drugs alone, there are 118,519 wholesale and retail outlets as of March 2020.

The National Action Plan on Antimicrobial Resistance Containment in Bangladesh (2017-2022) and the National AMR Surveillance Strategy of Bangladesh (2020-2025) constitute two important steps in this direction, although progress of implementation has been constrained by the shortage of trained workforce and financial resources, as well as the COVID-19 pandemic (Ahmed et al., 2022).

These data clearly show that resistance to several antimicrobials including critically important antimicrobials for human and animal health is widespread in different bacterial species from food-producing animals in Bangladesh. Therefore, there is an urgent need to establish nationwide AMU and AMR surveillance to obtain data that are critical to inform policy actions for effective control of AMR in livestock and food thereof in Bangladesh.

PURPOSES

The purposes of the study are to identify the lacuna, laps and gaps within the existing policies, legislations and regulations to support AMU and AMR stewardship in the animal health.

OBJECTIVES

The aim of this study is to review current policies, regulations, roles, responsibilities, and capacities and to identify gaps for the management of AMU and AMR in animal in Bangladesh. Furthermore, this work aims at providing recommendations underpinning an updated policy direction enabling an integrated AMU and AMR surveillance and monitoring framework, focusing on possible synergies.

This initiative supports one of the key deliverables of the Livestock and Dairy Development Project (LDDP) – Package 75, implemented by the United Nations Industrial Development Organisation (UNIDO), on AMR surveillance, risk mitigation and monitoring of microbial and chemical hazards.

METHODS

This gap analysis study related to key functions that need to be fulfilled in relation with AMU and AMR Management including Integrated Surveillance by competent authorities and stakeholders in Bangladesh was carried out based on the following guidance:

- The guidance proposed through the WHO Global Action Plan on Antimicrobial Resistance (2015)
- CXC 61-2005 The Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance Revised in 2021
- CXG94-2021, The Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance
- Codex Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL 77- 2011
- The WHO Guidance on Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach: Guidance from the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR)
- The OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials,

developed in November 2016

- OIE Standards, Guidelines and Resolution on Antimicrobial Resistance and the Use of Antimicrobial Agents
- The Landscape Analysis of Tools to Address Antimicrobial Resistance, issued by the World Bank in May 2021
- The FAO The Methodology to Analyze AMR-relevant Legislation in the Food and Agriculture Sector Guidance Document for Regulators
- The FAO Assessment Tool for Laboratories and AMR Surveillance Systems (FAO-ATLASS)
- The National Action Plan for Antimicrobial Resistance (AMR) Containment in Bangladesh 2017-22
- The National Antimicrobial Resistance (AMR) Surveillance Strategy of Bangladesh 2020-2025
- Guideline on Antimicrobial Consumption Surveillance in Bangladesh (Draft, July, 2022)
- Guidelines for Collection, Analysis and Reporting of Farm-Level Antimicrobial Use in the Scope of Antimicrobial Stewardship.

Data were collected using published material and through activities organised within this project, including:

- An online questionnaire "UNIDO-LDDP Questionnaire on AMR and AMU in the livestock sector and food of animal origin in Bangladesh", that was completed by 16 respondents representing the main stakeholders for AMU and AMR surveillance in livestock in Bangladesh (Appendix 1).
- An online questionnaire "UNIDO-LDDP Questionnaire to assess the AMR surveillance capacities and strength of the laboratories in the animal health sector of Bangladesh", that was completed by 15 respondents representing DLS, BLRI and academic institutes laboratory across the country (Appendix 2)
- The Technical Workshop on Food Safety and AMR Surveillance of food of animal origin held on 28-30 March 2022
- Online workshop on Antimicrobial Resistance (AMR) in Livestock Sector in Bangladesh
- One to one consultation of National and International UNIDO Experts with DLS, DGDA, IEDCR, BSTI, BFSA and different other stakeholders.

Importantly, the available information was reviewed by National Experts and complemented with their own long-standing expertise in AMU and AMR surveillance in livestock in Bangladesh.

KEY FINDINGS AND IDENTIFIED GAPS

Institutional and Legislative and Regulatory Assessment

Regulation of AMU and AMR surveillance is complex and requires coordinated efforts by different Authorities and Institutions. In Bangladesh, various legislations, regulations and guidelines encompass different aspects related mainly to AMU and to a lesser extent to AMR in livestock. Policy/ legislation/ regulation, regulatory agency along with main points related to AMU and AMR are summarized in in Table 1.

Table 1. Legislations, regulations and guidelines related to AMU and AMR in livestock in Bangladesh

Policy/ Legislation/ Regulation*	Area/ Regulatory Agency	Main points related to AMU/AMR
Policy/ Legislation/ Regulation* National Action Plan on Antimicrobial Resistance Containment in Bangladesh (2017-2022) https://rr-asia. woah.org/ en/projects/	Area/ Regulatory Agency Multi-sectoral (Human and Animal) AMR and AMU/DGDA, DLS	 Main points related to AMU/AMR The following directives are found in AMR national action plan that enables to contain AMU and AMR in animal health: Develop and update STGs and list of essential antimicrobials for animal health; Ensure availability of antimicrobials according to STGs; Implement the policies and regulations of animal health, including animal disease act, 2005; fish feed and animal feed Act, 2010; national livestock policy, 2007; national poultry development policy, 2008, and international regulations in use of AMs in animals; Strengthen the DGDA veterinary cell; Restrict the use of antimicrobials in animal by traditional healers and non-veterinarians; Establish one or more national reference microbiology laboratories for AMR surveillance in animal health; Ensure good laboratory practices; Ensure maintenance of the withdrawal period of antimicrobials used in animal health to prevent residual effect in human health;
antimicrobial- resistance/ members-nap/)		 Ensure enforcement to control irrational and non- therapeutic/ sub-therapeutic (e.g. growth promoter) use of antimicrobials in the livestock; Ensuring good manufacturing practice (GMP) of
		antimicrobials in animal health;
		 Promote operational research for enabling good practices; Development of national antibiotic policy in animal
		health;
		 Estimation of consumption of antimicrobials in animal health sector;
		• Establish AMR surveillance system in animal health sector.

Policy/ Legislation/ Regulation*	Area/ Regulatory Agency	Main points related to AMU/AMR
National Action Plan on Antimicrobial Resistance Containment in Bangladesh (2017-2022) https://rr-asia. woah.org/ en/projects/ antimicrobial- resistance/ members-nap/)	Multi-sectoral (Human and Animal) AMR and AMU/DGDA, DLS	N.B: Though there is a very important directives are found in AMR national action plan, but in reality, the implementations are not satisfactory may be due to poor institutional capacities, funding scarcities, lack of technical competencies, shortage of skilled human resources, poor collaboration and coordination with national and international partners.
Drug Act, 1940 (http://bdlaws. minlaw.gov.bd/ act-188.html)	AMU (Human and Animal)/ DGDA	 The drug act, 1940 has been enacted in the British regime to regulate the import, export, manufacture, distribution and sale of drugs including antimicrobials. The main features of the drug act, 1940 are (i) guidelines for the import and export of drugs, and (ii) manufacture, sales and distribution of drugs. The important milestones related to AMS found in the drug act, 1940 are: There is a prohibition of manufacture and sale of drugs which is not a standard quality and misbrand License is required before importation of any drugs including antimicrobials require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label of drugs; Every manufacturer must approve their promotional materials from the competent authority prior to distribution; Every manufacture must take marketing authorization from the competent authority. The drug act, 1940 are mostly covered human health aspect as it is very back dated act. It is suggested to update the drug act with incorporation of matters related to rational use of antimicrobials. N.B: The Cabinet has given final approval to the draft Drug Act-2022, which provides life imprisonment for manufacturing adulterated and fake medicines. The draft law was approved in the regular meeting of the Cabinet presided over by Prime Minister Sheikh Hasina.

Policy/ Legislation/ Regulation*	Area/ Regulatory Agency	Main points related to AMU/AMR
	AMU (Human and Animal)/ DGDA	The National Drug Policy 2016 updates the National Drug Ordinance from 1982 and 2005. The National Drug Policy 2016 includes well-defined directives for drug registration , production , marketing , distribution , storage , sale , use , import , export and quality control . Furthermore, the National Drug Policy 2016 encompasses regulatory aspects of the national regulatory body, the
		DGDA. Of note, antimicrobials (referred to as antibiotics in the National Drug Policy 2016) by referring to the need for hospitals to develop guidelines for use of antibiotics and to form committees to ensure rational antibiotic use, and there is no mention of AMR.
		Directives of particular importance for the livestock sector are:
National Drug		 Stringent adherence to the WHO-recommended GMP guidelines in drug production and quality control must be ensured by the pharmaceutical sector;
Policy, 2016 (https://dgda.		 Each locally produced or imported drug must be registered by the licensing authority (DGDA) based on the recommendation of Drug Control Committee (DCC);
		 Sale of drugs other than OTC drugs is prohibited without the prescription of a registered physician, and DGDA has the mandate to verify compliance with this;
		 Prescription and dispensing systems must be regularly monitored by DGDA to ensure rational use of drugs;
		 Pharmacovigilance and adverse drug reactions;
		 Manufacturing, sale and distribution of fake, adulterated, harmful, un-registered, counterfeit, misbranded and substandard drugs and medical devices must be forbidden and exemplary punishment bestowed upon people responsible for such offences;
		 DGDA has the mandate to regulate all sorts of advertisements and promotion of drugs in public media and prevent unethical marketing and multi-level marketing of all recognized system of drugs to ensure safe, rational and effective use;
		 Accessibility to drugs at affordable price that is fixed by transparent and rational methods. The government from time to time is to continue the process of drug pricing / re-pricing of enlisted drugs;

Policy/ Legislation/ Regulation*	Area/ Regulatory Agency	Main points related to AMU/AMR
National Drug Policy, 2016 (https://dgda. portal.gov.bd)	AMU (Human and Animal)/ DGDA	 As per the check list prepared by DGDA, the drug manufacturing companies will conduct internal audit at periodic intervals. DGDA will update the checklist on regular basis; Inspectors of the DGDA will be trained regularly on GMP guidelines and pertinent issues. Initiatives for training both at home and abroad will be undertaken and will arrange funding for the training courses; Training in the areas of veterinary drug registration, manufacturing, storage, distribution, sale, import, export and quality control should be provided to DGDA personnel by the veterinary specialist to enhance the skill of the personnel engaged in aforementioned areas; Concepts regarding GMP, quality assurance, drug-related legislation, National Drug Policy, rational use of drugs, essential drugs and pharmaceutical marketing practices will be included in veterinary pharmacology courses; National Control Laboratory (NCL) will play the role of central laboratory for drug testing and analysis. Initiatives will be taken to achieve WHO accreditation for NCL enriched with modern facilities, apposite machineries and skilled human resources; The list of essential veterinary drug will be prepared and published having opinion of the veterinary specialists, and the list will be updated accordingly. The production and distribution of the essential drugs for veterinary medicine will be prepared and published on the basis of the opinion of veterinary specialists; For drugs used in treatment of livestock and fish, indications of use have to be specified on the label, literature, and packaging of drugs, and drugs that are used in livestock will be discouraged from being used in fish; All recognized system of medicine manufacturing factories must have waste disposal management system for public health protection and prevention of environmental pollution.

Policy/ Legislation/ Regulation*	Area/ Regulatory Agency	Main points related to AMU/AMR
Regulations on sale of antimicro- bials (<u>https://dgda.</u> portal.gov.bd); (<u>https://www.</u> <u>thedailystar.net/</u> <u>city/take-steps-</u> <u>to-stop-sale-of-</u> <u>antibiotics-with-</u> <u>out-prescrip-</u> <u>tions-1734625</u>)	AMU (Human and Animal)/ DGDA	 As per National Drug Policy 2016, there is a provision of regulations for sale of antimicrobials: The sale of antibiotics is prohibited without the prescription of a registered physician; Selling of antibiotics without a prescription is a criminal offense and the penalty is Tk. 20,000; The High Court (HC) division of Bangladesh directed the Government to take necessary steps to stop sale of antibiotics without registered doctors' prescriptions (25th April, 2019, High Court Directives); The High Court (HC) division of Bangladesh directed the Government to take necessary steps to stop sale of antibiotics without registered veterinarians' prescriptions (25th April, 2019, High Court Directives);
Regulations for continued availability of good quality antimicrobials (<u>https://dgda.</u> <u>portal.gov.</u> <u>bd</u> ; <u>Untitled</u> (dgdagov.info))	AMU (Human and Animal)/ DGDA	 As per National Drug Policy 2016, there is a provision of regulations for continued availability of quality antimicrobials for human and animals: The DGDA examines the quality of antimicrobials at the National Control Laboratory (NCL); The NCL has issued a comprehensive Quality Manual that undergoes periodic revisions (7 revisions has been done in the period 2016-2021) and is aligned with internationally recognized ISO 17025:2017 and WHO standards. The Quality Manual describes the Quality System and the procedures to assess quality, efficacy, potency and toxicity of any drugs, vaccines and biological products produced or imported in the country; DGDA has two central NCLs in Dhaka and Chittagong and eight minilabs nationwide.
National Guide- line on the Phar- macovigilance System in Ban- gladesh (<u>https://</u> <u>dgda.portal.gov.</u> <u>bd</u> ; <u>17-100_Fi-</u> <u>nal-draft_Na-</u> <u>tional-Guide-</u> <u>lines-on-Pharma-</u> <u>covigilance-Sys-</u> <u>tems-in-Bangla-</u> <u>desh_FINAL.pdf</u> (<u>siapsprogram.</u> <u>org</u>))	AMU (Human and Animal)/ DGDA	 As per National Drug Policy 2016, a comprehensive pharmacovigilance system has been established. The Adverse Drug Reaction Monitoring (ADRM) Cell has been established within the DGDA with the purpose to: Monitor drug safety, effectiveness and quality through passive and active surveillance of adverse effects; Assess the safety, quality, efficacy and risk of drugs; Disseminate information on safety and appropriate use of drugs to the animal health; Ensure the quality and safety of marketed drugs for animal consumption. AMR is mentioned in the guideline on pharmacovigilance as one of the possible causes of therapeutic ineffectiveness.

Policy/ Legislation/ Regulation*	Area/ Regulatory Agency	Main points related to AMU/AMR
		The Bangladesh Food Safety Act 2013 makes provisions for the establishment of an efficient and effective authority (Bangladesh Food Safety Authority, BFSA) and for regulating, through coordination, the activities relating to food production, import, processing, stock, supply, marketing and sales, so as to ensure the rights toward access to safe food through appropriate application of scientific process. The following points of the Act are of particular relevance in the AMU/AMR and food safety perspective:
		Chapter II, article 13:
		• The BFSA is in charge to:
Bangladesh Food Safety Act, 2013 (<u>https://dgda.</u> portal.gov.bd);	Drug residues in food/BFSA	 Provide the concerned authority or organization with necessary support in updating or upgrading the permissible limit at its highest safety level of veterinary drug residues, antibiotics, etc. as determined by any other authority or organization under the existing laws, and monitor implementation thereof;
		• Determine, through exercise of scientific methods, permissible limit of veterinary drug residues, antibiotics, etc. where the permissible limit is not determined under any existing law.
		• <u>Chapter V, article 30:</u>
		 It is prohibited to use or include in food or food ingredients veterinary drug residues, antibiotic or growth promoter residues, active ingredients of drugs, microbes or parasites in excess to the maximum residue limit (MRL) prescribed by regulations or by any other law for the time being in force;
		 It is prohibited to store, market and sell food or food ingredient containing drug residues in excess to the MRL.
		<u>Chapter IX, article 58</u> :
		Punishment for the violation of article 30 of the Act: to use, store, market or sell food or food ingredient containing drug residues in excess to the MRL is punishable with imprisonment for a period not exceeding three years but not less than one year, or a fine not exceeding Tk. six lac but not less than Tk. three lac, or with both.

Policy/ Legislation/ Regulation*	Area/ Regulatory Agency	Main points related to AMU/AMR
National Livestock Extension Policy, 2013 (Draft)	AMU and Drug residues (Animal)/ DLS	 The National Livestock Extension Policy 2013 touches upon AMU and drug residue issues only marginally, in the section for "Emerging livestock development issues", as follows: Drug residues in food products of animal origin is a major food safety concern of present time, and effective control should be implemented following OIE (WOAH) guidelines; AMU is strictly regulated in organic farming and bio- rational-based management systems should be disseminated in the farms to ensure productivity and products' safety and quality.
Fish Feed and Animal Feed Act, 2010 (http://www. dls.gov.bd/site/ page/7ebc9c9e- cfaa-4995-b184- 9d9928d75710//\$- fei/M)	AMU (Animal)/ DLS	 The Fish Feed and Animal Feed Act 2010 regulated various aspects related to processing, quality control, import, export, marketing, sale, distribution and transportation of fish feed and animal feed. AMU-related aspects can be found in: Article 14, that bans the use of antibiotics, growth hormones, insecticides etc. in fish feed and animal feed; Article 20, that states that violation of this law is punishable with imprisonment of one year or a fine up to Tk. 50,000, or both.

Policy/ Legislation/ Regulation*	Area/ Regulatory Agency	Main points related to AMU/AMR
National Livestock Development Policy, 2007 (http://old.dls. gov.bd/files/ Livestock_Policy_ Final.pdf)	AMU (Animal)/ DLS	 The National Livestock Development Policy 2007 touches upon AMU only marginally, in the "Poultry development" and "Veterinary services and animal health" sections, by stating the following: The use of antibiotics in feeds is thought to be common and a cause of public health concern; No registration is required for feed additives such as toxins binder, antibiotics, and vitamin/mineral premixes, animal protein, many of which are potentially detrimental to human health. However, there is regulatory control by DLS on import, storage and marketing of such items; Most of the drugs traders and shop keepers have no formal training on drug handling, transportation, storing and dispensing, and readily sell drugs such as antibiotics, hormones, and sedatives across the counter without prescription. Furthermore, in the Policy framework for "Veterinary Services and Animal Health", it is specified that: An autonomous Quality Control Agency would be established to ensure quality of veterinary drugs, vaccines, feeds, feed ingredients and breeding tools and materials; The Veterinary Cell" of DGDA should be strengthened for facilitating decision making on veterinary drug registration and approval in Bangladesh. Animal Health Companies Association of Bangladesh (AHCAB) and related trade association would be included in the committee to represent the private sector.

Policy/ Legislation/ Regulation*	Area/ Regulatory Agency	Main points related to AMU/AMR
Veterinary Council Act 2019 (http://bvc.gov. bd/sites/default/ files/files/bvc. portal.gov.bd/ law/57aec277_ ade6_4f56_abd- f_9f2e2d329fe6/ BVC-Act-2019. pdf)	AMU (Animal)/ DLS	 This act makes provision for the regulation, control and registration of veterinary practitioners and paraveterinarians, and for control of the quality of veterinary education, profession, services, development, extension and research. Veterinary medicine and surgery should be practised only by registered veterinary practitioners. It also includes the constitution of a Bangladesh Veterinary Council (BVC) that, among other tasks, reviews and approves applications for registration of veterinary practitioners. The Veterinary Council is formed by: Director General, DLS; Director General, DGDA; Representative of MoFL, not less than Joint Secretary; One senior veterinarian nominated by DLS; The Dean of the Faculty of Veterinary Sciences of BAU; Two Deans from additional Faculties of Veterinary Sciences of other universities selected by government; One member of the legal profession nominated by the Attorney General, not less than Deputy Attorney General; One member of the Bangladesh Veterinary Association; Two registered veterinary practitioners nominated by the government, one will be female; One registered veterinary practitioners from each of the Administrative Divisions elected in prescribed rule; Registrar, BVC, who will be the member-secretary of the committee.

From the snapshot of legislations and regulations provided above, it is evident that several aspects of AMU are encompassed by various policies and regulations, whereas legislations and regulations regarding AMR are very limited.

By legislative mandate, the DGDA is responsible to **register** locally produced and imported antimicrobials (online 'new product registration' procedure PharmaDex) and to **control** locally produced and imported antimicrobials' active raw materials, sales and distribution.

For the approval of antimicrobials to use in livestock, DGDA has a technical committee with only one DLS representative that evaluates safety, efficacy and usefulness of locally manufactured and imported antimicrobials. Furthermore, DGDA has a dedicated team including veterinarians to inspect any premises wherein any drug is being manufactured, including the plant and process of manufacture, the means employed for standardising and testing the drugs and all related records and registers. In its assessments, the technical committee also takes into account the aware classification of antimicrobials by the WHO Expert Committee as well as AMR issues as published in the literature. With recommendations by the technical committee, the list of antimicrobials is then sent to the Drug Control Committee for final approval.

For control of quality of antimicrobials, the DGDA has two central National Control Laboratories (NCLs) in Dhaka and Chattogram with eight minilabs nationwide for control of quality of antimicrobials. Capacity for nationwide quality control of drugs is currently still limited, but there are initiatives to establish new laboratories and to train personnel.

The DGDA is also performing **pharmacovigilance** activities which, however, rely on mostly donor funding. As the pharmacovigilance database is a potentially valuable tool for the surveillance of AMR, establishing a stable, governmental budget for DGDA to perform pharmacovigilance and encouraging the reporting of suspected AMR-related adverse events could be valuable to generate AMR signals for antimicrobial stewardship programmes.

Antimicrobials cannot be used in fish and animal feed according to the Fish Feed and Animal Feed Act 2010. DLS tests antimicrobials in imported feed ingredients to some extent. Ready feed is tested sporadically.

Despite AMU being quite comprehensively addressed in the legislation, there are reported issues with **compliance** with the legislation due to lack of personnel and facilities for control, and also lack of awareness of the consequences of inappropriate AMU among sector operators. Thus, for example, even if the legislation clearly states that antimicrobials for livestock should be sold only with a prescription by a registered veterinarian, and there is a penalty for not complying with this rule, it is reported that drug shop operators, field dealers and other non-authorized personnel often encourage farmers to use antimicrobials. Of note, the malpractice of selling antimicrobials without prescription is also reported in human medicine in Bangladesh (Nizame et al., 2021). An additional example of lack of compliance with the existing legislation is given by the fact that the law prohibits the use of sub-therapeutic doses of antimicrobials in feed, however this law is anecdotally circumvented in small-scale commercial broiler farms (Al Masud et al., 2020), which is again a consequence of i) the lack of awareness among farmers of the detrimental effects of inappropriate AMU and ii) limited access to alternatives to antimicrobials.

This lack of compliance is also further bolstered by the multiplication of authorities and jurisdictions with a mandate to contribute to the oversight on veterinary substances used in conjunction with the production of animal derived foods. Overlapping responsibilities of standard setting, compliance verification and enforcement e.g., between DLS, BFSA, BSTI and DGDA, in the use of veterinary substances, lead to complex bureaucracies that are conducive to poor compliance.

Nonetheless, efforts are currently underway to address some of the challenges. The DGDA, with endorsement by the Government, is taking several **initiatives to limit inappropriate AMU**, including some very recent ones:

• Change of the packaging of antibiotics and use of a red mark on strips to facilitate the

identification of antimicrobials for both humans and animals;

- Penalty (monetary fine) for OTC sale of drugs that require prescription;
- Ban on the use of colistin sulfate and some brand of ceftriaxone and levofloxacin in livestock;
- Publication of standards for the establishment and operation of model pharmacies and model medicine shops to ensure safety and welfare of customers (DGDA, 2016);
- Publication of a Guideline on Antimicrobial Consumption (AMC) Surveillance in Bangladesh (DGDA, 2022).

Although legislations and regulations in the country address AMU quite comprehensively, it is clear that there is a **need to strengthen the veterinary cell of DGDA** by providing manpower, adequate laboratory facilities, commanding and administration power and financial resource flow, so that it can fulfill its mandate sustainably.

Furthermore, a clear gap is represented by **limited availability of guidelines for AMU for livestock** species/disease combinations. When available, these guidelines are project-based and donor-driven, and there are no regulations/policies to enforce AMU guidelines. Also, a **regulatory framework to incentivise the use of alternative to antimicrobials is lacking** and efforts to fill in this gap should be initiated.

A severe gap is represented by the fact that **no or limited legislation or regulation addresses AMR** directly and comprehensively. This gap should be filled in by giving clear institutional mandate and government funding to DLS to design and perform AMR surveillance activities at national level.

To effectively address AMR surveillance in livestock and food of animal origin, the legislation should clearly identify

- 1. The roles and responsibilities of the Authority and Institutions in charge to design and perform activities within the AMR surveillance framework
- 2. The sampling framework (including target livestock species and production categories, target bacterial species, sampling frequency, sampling design and sample size), and
- 3. Nation-wide harmonised antimicrobial susceptibility testing methods including which bacterial species/antimicrobial combinations should be tested and which criteria should be used to interpret results. Furthermore, a framework for quality control of the surveillance data as well as for reporting, dissemination and use of AMR surveillance data to inform AMU policies should also be included in the guidelines aiming at tackling AMR in livestock.

Finally, it should be emphasised that the legislation covers aspects related to **residues of antimicrobials** in food for human consumption. Currently, both BSTI and BFSA have the mandate to support the competent Authority by providing updates on MRLs set by other organizations and/or by establishing MRLs using scientific methods, whereas DGDA has the mandate to set the withdrawal period. Furthermore, BFSA has the mandate to perform surveillance of antimicrobial residues in food for human consumption and, to this purpose, BFSA can seek technical laboratory support from DLS, BLRI and other relevant laboratories with the capacity to detect and quantify antimicrobial residues. As in the literature there is ample evidence that food of animal origin including meat, eggs and milk in Bangladesh contains antimicrobial residues above the MRLs (Rahman et al., 2021 and therein cited references), it is clear that actions to ensure compliance with MRLs are urgently needed. Such actions should, at a minimum, include: i) revision of the current institutional mandates to avoid overlap of responsibilities both in setting and in controlling permissible levels of drug residues, ii) increase in the capacity to perform control activities, and iii) creation of awareness of the detrimental health effects of drug residues in food among sector operators.

SURVEILLANCE

Antimicrobial Use (AMU)

Antimicrobial use (AMU) is a recognised risk factor for the spread of antimicrobial resistance (AMR) and, at least for selected bacterial species/antimicrobial combinations, there is ample evidence showing that AMU in livestock selects for AMR in bacteria in animals and also in humans (JIACRA III, 2021). Spread of AMR is considered a public health threat as it jeopardises the effectiveness of antimicrobials in treating bacterial infections. As antimicrobials are precious resources to protect human and veterinary health, it is critical to ensure that AMU in livestock is done appropriately following rigorous antimicrobial stewardship principles to limit the spread of AMR. The World Organisation for Animal Health (WOAH) published Standards, Guidelines and Resolution on antimicrobial resistance and the use of antimicrobial agents (WOAH, 2015), in which roles and responsibilities of various actors involved with antimicrobials and AMU are thoroughly described. Briefly, the above-mentioned WOAH publication describes responsibilities of competent authorities regarding marketing authorisation, quality control, assessment of therapeutic efficacy and potential to select for AMR, establishment of acceptable daily intake (ADI), MRL and withdrawal periods in food-producing animal, post-marketing AMR surveillance and control of advertising. The current status of implementation of these AMU aspects in legislations and regulations in Bangladesh has been presented elsewhere in this report (see paragraph "Institutional and Legislative and Regulatory Assessment").

Furthermore, the above-mentioned WOAH publication reports the responsibilities of veterinarians and livestock producers when using antimicrobials. In the light of these recommendations by WOAH, current AMU practices as well as current initiatives for AMU data management in livestock in Bangladesh are presented in the following paragraphs.

AMR Surveillance

Regarding AMR, there are several evidences of the occurrence of AMR in bacteria from animals in

Bangladesh, with particular focus on bacterial species that are known to be able to transfer from animals to humans.

Status of AMR Resistance Pattern in the Livestock Sector

In Escherichia coli isolated from livestock and poultry, high occurrence of resistance to tetracycline (72-100%), oxytetracycline (78-93%), sulfamethoxazole-trimethoprim (51-88%), ampicillin (89.5-100%), amoxicillin (92-95%), streptomycin (19-70%), ciprofloxacin (50%), chloramphenicol (43-50%), gentamicin (8-28%), enrofloxacin (55%) and norfloxacin (50%) has been observed (Bag et al., 2021; Ievy et al., 2020; Sobur et al., 2019; Parvin et al., 2020; Rahman et al., 2020; Amin et al., 2020). Similarly, the AST result of Salmonella spp. recovered from poultry revealed high occurrence of resistance to ciprofloxacin (70-88%), ampicillin (66-75%), tetracycline (77-84%), gentamicin (33-68%), nalidixic acid (22-60%) and streptomycin (44-77%), whereas low occurrence of resistance (5-8%) was observed for chloramphenicol, azithromycin, imipenem, amikacin and sulfamethoxazole-trimethoprim (Siddiky et al., 2021). Among Grampositive bacteria, the AST result of Streptococcus spp. from livestock and poultry showed high occurrence of resistance to streptomycin (70-100%), amoxicillin (30-100%), and ampicillin (60-100%) (Amin et al., 2020), whereas AST result of Staphylococcus spp. revealed high occurrence of resistance to penicillin (82-100%), amoxicillin (42-100%), ampicillin (97%), streptomycin (70--100%), oxytetracycline (74-78%), ciprofloxacin (17-50%), sulfamethoxazoletrimethoprim (30%), gentamicin (18%) cefixime (73.9%), cloxacillin (82.6%) and oxacillin (56-98%) (Jahan et al., 2015; Parvin et al., 2021; Hoque et al., 2018).

Antimicrobial Stewardship

Antimicrobial stewardship is central to efforts to ensure access to effective antimicrobials (Dyar et al., 2017). Unfortunately, current practices in AMU, as obtained from a BARC study report and from answers to the "UNIDO-LDDP Questionnaire on AMR and AMU in the livestock sector and food of animal origin in Bangladesh", appear to be based more on personal experience than on solid antimicrobial stewardship principles. Respondents stated that a large variety of antimicrobials are commonly used in livestock, namely penicillin, ampicillin, amoxicillin, cloaxcillin, ceftriaxone, tetracycline, doxycycline, colistin, sulfamethoxazole-trimethoprim, gentamicin, erythromycin ciprofloxacin, streptomycin, levofloxacin, enrofloxacin and neomycin, a number of which are now supposed to be reserved for human health. The length of treatment varies between 3-5 days and 3-7 days according to different respondents.

Furthermore, respondents reported that poultry receive antimicrobials for nearly their entire whole life cycle, cattle sometimes, and sheep and goats occasionally. Antimicrobials are administered mainly orally through drinking water to poultry, and orally and parenterally to cattle, sheep and goat. According to different respondents, withdrawal period is not maintained.

These answers clearly indicate the urgent need of guidelines for AMU based on livestock species/disease combinations for veterinarians and for farmers. Although no such guidelines are available at present, there are two ongoing initiatives that started to address this gap. DLS is developing guidelines for AMU in commercial chickens built upon collected PCU data with the support of Fleming Fund Country Grant to Bangladesh and also FAO Emergency Centre for Transboundary Animal Diseases (ECTAD) has developed some guidelines for the treatments of poultry diseases. Of note, the ECTAD guidelines have been prepared based on the experiences of poultry practitioners rather than information on AMR occurrence, and are only available to those

who received training from ECTAD.

As consumption of antimicrobials is reportedly higher in poultry compared to other livestock species in Bangladesh, it is reasonable that guidelines for AMU in poultry are being developed first. However, development of guidelines for AMU in other livestock species should be urgently initiated too. Importantly, guidelines should be made widely available to sector operators.

The use of alternatives to antimicrobials represents an important way to reduce the use of antimicrobials in livestock. Current status regarding use of alternatives to antimicrobials is reported in Table 2.

Alternative to antimicrobials	Status of implementation			
Vaccines and biologics	Several vaccines are used in Bangladesh. For example:			
	 Avian influenza, gumboro, ranikhet, bronchitis, salmonella, coryza, cholera, duck plague and fowl pox, among others, for poultry; Anthrax, hemorrhagic septicemia, foot and mouth disease (FMD), PPR and black quarter, among others, for ruminants 			
	Commercial farmers (poultry, cattle, sheep and goat) vaccinate their animals regularly. On the contrary, small holding farmers vaccinate their animals only occasionally. Most of the poultry vaccines are imported from abroad whereas vaccines for livestock are mainly pro- duced locally, with the exception of FMD vaccine. It is also imported in addition to local production. Local production and supply of vac- cines are not sufficient enough to meet the local demand.			
Pre/probiotics	Used in large scale corporate commercial poultry farms to a small extent. Otherwise, most of the commercial farms are not familiar/reluctant to use of pre/probiotics.			
Biosecurity	Only few leading commercial large scale farms including parent stock, layer, broiler, dairy and beef fattening have good farm biosecu- rity. Small scale commercial farms (poultry and dairy) have big gaps in conceptual, structural and practical biosecurity measures. Small holding and scavenging farms have no biosecurity at all.			
Fencing	Large scale corporate farms have proper fencing. Most of the mid- scale poultry farms are located nearby the residence and they have single fence very close to the poultry and livestock sheds			
Good hygiene practices and farm waste management	Not properly followed at medium and small-scale farms.			
Veterinary advice	Availability of veterinary advice is as follows:			
	 One veterinarian at each Upazila Veterinary Hospital. Veterinary para-professional service is supposed to be available in each of 4500 unions. Private veterinary services for most of the commercial farms. 			

Table 2. Status of implementation of alternatives to antimicrobials in livestock in Bangladesh

From the information above, it is clear that the use of alternatives to antimicrobials especially in small and mid-scale farms must be improved. To this purpose, it is urgently needed to increase the capacity of veterinary services by hiring personnel at Upazila level.

Data management

There are different ways to measure AMU in livestock species (Sanders et al., 2020; Sanders et al., 2021). These methods can be grouped in two main categories, i.e. collection of sales data and collection of consumption data. The methods also differ for stratification of data, as collection can be done at national, farm, herd and/or animal level (ESVAC, 2013). Each method of data collection has its own advantages and disadvantages, however in most situation the choice of the method is mainly dependent on the type of data that are available.

The type of AMU data available in Bangladesh is summarised in Table 3. Of note, veterinarians do not have the responsibility nor the obligation to keep AMU data.

Institution	AMU data
DGDA	DGDA has information on yearly production and import for all finished antimicrobials and active pharmaceutical ingredients (APIs), as DGDA is required to approve all the pro-forma invoices.
DLS	DLS can collect AMU data at national level through the Bangladesh Animal Health Intel- ligence System (BAHIS), a web-based interface accessible by veterinarians from primary health care settings (Upazila Veterinary Hospital). AMU information that can be uploaded to BAHIS includes epidemiological information (patient ID, animal species, breed, herd number, besides owner information such as name, geographical location and phone number) and pharmacological information (name of antimicrobial, route and frequency of administration, and purpose and length of treatment). None of the fields on the online form to be completed with AMU information is mandatory. Thus, at present, only qualita- tive information about the antimicrobials used in veterinary hospitals and poultry farms is uploaded to BAHIS and there is no possibility to collect quantitative information. Recently the unit has taken a special initiative to collect quantitative data. From the information recorded in BAHIS, it is possible to retrieve that first-generation cephalosporin are used as first choice followed by aminopenicillin and quinolones in mammals, whereas quinolones followed by aminopenicillin and tetracycline are most frequently used in poultry farms.
icddr,b	icddr,b has information on antimicrobials used per animal species per year. They also con- duct several AMU and AMR investigations in human and animal sectors.

Table 3. AMU data available in Bangladesh

Although it is evident that efforts should be made to develop and implement a system for nation-wide collection of quantitative AMU data in livestock, an encouraging aspect is represented by existing collaborations regarding AMU data collection between antimicrobial manufacturers, APIs manufacturers, drug sellers, DGDA, DLS, Directorate General of Health Services (DGHS) and DG fisheries, and also private companies might share AMU data on demand.

This collaboration should be further enhanced and SOPs for collection, analysis and dissemination of AMU data should be developed.

Finally, it is worth mentioning that BFSA is conducting a small research with the funding of

the Orange Knowledge Program (OKP) project. Under this project, milk samples are being collected from Sirajganj, Pabna, Munshiganj and Savar and analyzed for antimicrobial residues. As reportedly withdrawal times are not observed in several cases in Bangladesh, a framework for monitoring antimicrobial residues in food products is urgently needed but assessment of current regulatory framework and capacity for monitoring antimicrobial residues is beyond the scope of this report.

Antimicrobial Resistance (AMR)

Prevention and control of AMR in livestock and food thereof at national level require

- 1. A clear legislative and regulatory mandate to identify and coordinate the role and responsibilities of relevant stakeholders (epidemiological units, microbiology laboratories, livestock and food sector operators, etc.).
- 2. Setting of harmonised sampling, laboratory and data management procedures.
- 3. Anetwork of laboratories with adequate capacity for AMR testing and reporting, and
- 4. Infrastructure and capacity to analyze and disseminate data. Data should then be used by policy makers to design actions to prevent spread of AMR.

The lack of clear legislations and regulations to address AMR surveillance in livestock in the country has been discussed elsewhere in this report. In the following paragraphs, the current sampling, laboratory and data management capacity as well as gaps in AMR surveillance in livestock in Bangladesh are summarised. This information is at the basis for the recommendations listed in the Recommendation section.

Public Institutions and Coordinating Bodies Involved in AMR Surveillance in Livestock

In Bangladesh, there are several public institutions and coordinating bodies conducting activities related to AMR surveillance in livestock, including sampling, microbiological testing and/or data management. These are:

 Department of Livestock Services (DLS). DLS is an organisation of the Ministry of Fisheries and Livestock (MoFL) with roles and responsibilities in the coordination and performance of AMR surveillance activities at national level, including sampling, microbiological testing and data management. At present, DLS has no regular revenue budget for AMR surveillance and is conducting AMR surveillance activities with financial and technical support of FAO and Fleming Fund. Furthermore, DLS is developing an AMR surveillance strategy with the support of the World Bank-funded project "Livestock and Dairy Development Project". AMR has yet to be institutionalised within the DLS organogram, which implies that no human resources specifically dedicated to AMR surveillance are available at the moment. The Central Disease Investigation Laboratory (CDIL) under DLS (Figure 1) has recently been appointed by the MoFL as the National Reference Laboratory for AMR surveillance in livestock.



Figure 1: DLS organisational structure to coordinate and conduct national AMR surveillance in the animal health sector

- Bangladesh Livestock Research Institute (BLRI). BLRI is a national livestock research organisation under the MoFL. BLRI has established a state-of-the-art laboratory for AMR research activities, which has a limited capacity of surveillance. BLRI is involved in i) AMR research activities, with the capacity to perform sampling, microbiological analyses and data management, and ii) reference AMR surveillance activities, with the mandate to characterise the isolates referred by laboratories performing primary level studies (see laboratory paragraph). BLRI has its own funds primarily to perform research activities. BLRI does not have a dedicated budget to perform reference AMR activities, which are therefore carried out based on projects or overseas funds. Currently, BLRI has regular manpower to perform the laboratory activities. BLRI is closely working with the Department of Fisheries (DOF) and the human health sector (IEDCR) for AMR surveillance. BLRI has recently been appointed by the MoFL as the National Reference Laboratory for AMR research in livestock.
- Veterinary Schools and other Science Universities under the Ministry of Education have Departments of Microbiology, Pathology and Public Health performing different projects on AMR in livestock with the assistance of Government of Bangladesh, Bangladesh Academy of Science (BAS), Krishi Gobeshona Foundation (KGF), National Agricultural Technology Project

(NATP) and development partners like FAO, Fleming Fund, USAID and World Bank. These projects involve all aspects of AMR surveillance (i.e. sampling, microbiological testing and/ or data management with some extent of molecular characterisation) but are mainly performed for research purposes in the context of post-graduate degrees and are not representative of the national situation. The Veterinary Universities and schools in Bangladesh are: Chattogram Veterinary and Animal Sciences University (CVASU), Bangladesh Agricultural University (BAU), Sylhet Agricultural University (SAU), Hajee Mohammad Danesh Science and Technology University (HSTU), Patuakhali Science and Technology University (PSTU), Rajshahi University (RU), Sher-e Bangla Agricultural university (SAU), Bangabandhu Sheikh Mujibur Rahman Agricultural University (BSMRAU), Bangabandhu Sheikh Mujibur Rahman Agricultural University, Sirajgonj Government Veterinary College, Jhenaidah Government Veterinary College, Khulna Agricultural University and Gono Bishwabibyalay.



Figure 2. National AMR Survellance and Data Sharing Platform/ Network in Animal Health Sectors

- Bangladesh Agricultural Research Council (BARC) is an organisation under the Ministry
 of Agriculture. It has the responsibility to strengthen the national agricultural research
 capability through planning and integration of resources. BARC is a coordinating authority
 that, in cooperation with several ministries, can engage various institutions leading to
 generation of national-level data. Recently, the livestock division of BARC has completed a
 coordinated AMR surveillance project on "Determination of Antimicrobial Resistance and
 Residues in Livestock and Poultry Food Products and Feed in Bangladesh". The project was
 implemented by BLRI and six Veterinary Schools (BAU, CVASU, SAU, PSTU, HSTU, RU).
- One Health Secretariat (OHS) is a governmental National One Health coordination mechanism to perform coordination and ensuring collaboration of relevant sectors for joint surveillance, joint outbreak investigations and advocacy with support from National One Health Platforms. It is an agency operated by seconded officers from Public Health, Animal Health and Environmental Health/ Wildlife sectors. OHS is located at the Institute of Epidemiology, Disease Control and Research (IEDCR), which is the Sectoral AMR Surveillance

Coordination Center for human health and also the National Reference Laboratory for AMR surveillance in bacteria from humans in Bangladesh. At present, OHS activities related to AMR surveillance in livestock are mainly limited to organisation of webinars on public health-related issues.

From the descriptions above, which are summarised in Figure 2 and Table 4, it appears that there are various institutions and organisations under different Ministries with capability to coordinate and/or conduct AMR surveillance activities in livestock. However, 13 out of 14 institutions/laboratories reported lack of regular funding for AMR surveillance activities, which are financed by various sources included government project-based funding, revenue funding and donors. The scarcity of funding as well as the diversity of the financing sources imply that AMR surveillance activities are mainly carried out in selected geographical regions and have different goals (Table 5). Efforts should be made to i) clearly define roles and responsibilities of each institution and organisation to build synergies and avoid overlaps, and ii) secure adequate funding, with the goal of establishing a nationwide AMR surveillance in bacteria in livestock (see Recommendations section).

Table 4. Overview of AMR surveillance components and geographical coverage by the various public institutions and bodies coordinating and/or conducting AMR surveillance in livestock in Bangladesh

Institution	Ministry	AMR surveillance component				
		National-level coordination	Sampling	Microbiological analysis	Data management	Research
DLS	MoFL	Yes	Yes	Yes	Yes	Yes
BLRI	MoFL	No	Yes	Yes	Yes	Yes
University Department	MoE	No	Yes	Yes	Yes	Yes
BARC	MoA	Yes	No	No	No	No
OHS	MoHFW	Yes	No	No	Planned	No

Sampling activities for AMR surveillance in Bangladesh are linked to specific projects. A list of organisations and the sampling activities coordinated, either currently or within the last year (2021), is presented in Table 5 to convey information on the actual sampling capacity for AMR surveillance.

Table 5. Recently completed and ongoing AMR surveillance activities by public institutions in Bangladesh

Organisations	Context of AMR surveillance activity	Funding	
DLS	AMR surveillance in live bird markets in	FAO	
	Dhaka City corporation.	Fleming Fund	
	Capacity building and field surveillance.		
BLRI	AMR surveillance in live bird markets, wet markets, poultry farms and environments mostly in Dhaka division. Antimicrobial residue surveillance in food of animal origin.	Government and donor (US-CDC, World Bank, ILRI, Cefas UK) funding, Fleming Fund	

Organisations	Context of AMR surveillance activity	Funding	
BARC	AMR and antimicrobial residue surveillance in livestock and poultry value chain in 33 districts under eight administrative divisions of Bangladesh.	World Bank (NATP) and IFAD joint funding	
Academic institutionsAMR and antimicrobial residue(Veterinary Schools and other universities)surveillance in livestock, poultry and animal-origin food in selected districts a farm, live bird market, and wet market level.		National/international research funding	

Information on current capacity for sampling for AMR surveillance was also gathered through the questionnaires directed to the public veterinary microbiology laboratories. From the obtained answers, it appears that sampling is done from various sources (Figure 3), animal species (Figure 4), and specimens (Figure 5), with the majority of laboratories performing AMR surveillance activities in chickens (including broilers, layers, Sonali and native chickens) using cloacal swabs collected at live bird markets. The number of samples collected for AMR surveillance yearly in the different laboratories ranged from 5 to > 2,000 samples, and half of the laboratories did not provide such information. Furthermore, the time of storage of samples (in refrigerated conditions) from collection to start of analysis varied in the different laboratories from six hours to seven days. The information gathered shows that the public veterinary microbiology laboratories have the capacity to collect various types of specimens from different sources and animal species, but these sampling activities are carried out in connection to specific projects that have different purposes and are scattered in space and time, and fail to convey information on the AMR situation in livestock at country level. Thus, there is an urgent need to establish sampling schemes that are coordinated across the different public veterinary microbiology laboratories for sustainable, nationwide AMR surveillance in livestock. As currently not all personnel involved in sampling for AMR surveillance has been trained for such activities, specific training should be provided to ensure harmonisation of sampling procedures.



Figure 3. Sample sources for AMR surveillance activities. The y-axis represents the number of laboratories



Figure 4. Animal species sampled for AMR surveillance activities. The y-axis represents the number of laboratories



Figure 5. Specimens collected for AMR surveillance activities. The y-axis represents the number of laboratories

Although there are no sampling activities for nationwide AMR surveillance in livestock ongoing in the country, a sampling plan for active, nationwide AMR surveillance in animal and aquatic health sectors of Bangladesh has been issued with the support of the Fleming Fund Country Grant. This sampling plan is comprehensive and clearly defines:

- Objectives of AMR surveillance, and planning and preparation steps to prepare for the AMR surveillance (Chapter 1);
- Target populations, laboratories, surveillance areas, bacteria and antimicrobials (Chapter 2);
- Sampling plan and sampling frame (Chapter 3).

There is current capacity in the public veterinary microbiology laboratories in the country to access the target livestock populations (broiler, layer, spent-hen, Sonali and Deshi chickens

for poultry, and cattle, sheep and goats for ruminants) and to isolate the target bacteria (Escherichia coli, Salmonella sp., Enterococcus sp., and Campylobacter sp. for poultry, and Escherichia coli, Salmonella sp., Pasteurella multocida, Staphylococcus aureus and Streptococcus sp. for ruminants) However, there is a need to expand the capacity to be able to collect and process the large number of samples included in the sampling plan.

Laboratory capability and capacity for AMR surveillance in livestock

DLS has one Central Disease Investigation Laboratory (CDIL) in Dhaka and ten Field Disease Investigation Laboratories (FDIL) covering major regions of the country. Furthermore, DLS has facilities for collection and short-time storage of samples in 64 district hospitals. DLS has also recently established a QC laboratory (QC lab) which has ISO 17025:2017 and ISO 9001:2015 accreditation, and is the first DLS laboratory holding accreditation according to international standards. The QC lab of DLS has testing facilities for livestock feed, additives, biologics as well as livestock products. The DLS laboratories currently performing AMR surveillance in livestock are the CDIL and two FDILs (Table 6). With the support of Fleming Fund, these laboratories are undergoing consistent upgrade of facilities, purchase of state-of-the-art equipment, training of personnel and drafting of SOPs for nationwide AMR surveillance. In addition, FDILs of Manikganj and Sirajganj has increased their capacity for performing antimicrobial sensitivity testing.

BLRI has a central laboratory in Savar, Dhaka and five regional laboratories. In all these laboratories, there is availability of personnel and SOPs for sample collection and processing, and of facilities for sample storage. The regional laboratories can perform some primary diagnosis, whereas further phenotypic and molecular analysis are performed at the central laboratory. The BLRI laboratory in Savar, Dhaka has BSL-2 classification.

There are some public and private academic institutions that have microbiology laboratory facilities and can be involved in activities related to AMR surveillance in livestock if coordination and financial support are provided.

Other laboratories in the country for AMR surveillance in bacteria from species other than livestock species are: i) the Quality Control Laboratory (QCL) in the Department of Fisheries, that is working as the sentinel laboratory for the Aquatic Health (AqH) sector, ii) BLRI, that works also as special National Reference Laboratory (NRL) for AMR in AqH sector and provides support to QCL; iii) IEDCR, that is hosting the NRL for AMR in the Human Health sector and works closely with nine microbiology laboratories of the medical colleges. Iv) icddr,b laboratory conducts AMU and AMR surveillance for both human and animal health sectors.

Table 6. Overview of public laboratories performing antimicrobial susceptibility testing (AST) of bacteria from livestock by phenotypic and/or genotypic methods in Bangladesh

Name of the laboratory	Organization/ Institute	Focal person and contact details	AST methods	Testing scope (environment, public health, livestock, aquaculture)	ISO 17025 Accreditation (Yes/No)
Reference Laboratories Antimicrobial Resistance Action Centre	Bangladesh Livestock Research Institute (BLRI); Savar, Dhaka	Dr. Mohammed Abdus Samad, PSO and Head, Animal Health Research Division, email: samad_blri@ yahoo.co.nz	DD, MIC, PCR, VITEK2, NGS	Livestock, and aquaculture	No
Reference laboratories Central Disease Investigation Laboratory (CDIL),	Department of Livestock Services (DLS)	Dr. Golam Azam Chowdhury, PSO, CDIL, DLS Email: ga.tulu@yahoo. com	DD, PCR and NGS (Illumina for short-read sequencing)	Livestock	No
Sentinel laboratories Field Disease Investigation Laboratory (FDIL) Feni	Department of Livestock Services (DLS)	Dr. Sajedul Hayat, Scientific Officer and Lab In-charge E mail: sajed.vet@gmail.com	DD	Livestock	No
Sentinel laboratories Field Disease Investigation Laboratory (FDIL) Jaipurhat	Department of Livestock Services (DLS)	Dr. Mamunur Rashid Lab In-charge Email: psofdiljoypur@ gmail.com	DD	Livestock	No
Sentinel laboratories Poultry Research and Training Centre (PRTC)	Chattogram Veterinary and Animal Sciences University (CVASU); Chattogram	Dr. Himel Barua, Professor and Director, Poultry Research and Training Centre (PRTC), CVASU Call+8801715297642 Email: himel.barua@ gmail.com	DD, MIC, PCR	Livestock, and aquaculture	No
Sentinel laboratories Quality Control Laboratory (QCL)	Department of Fisheries (DoF);	Manik Mia, Quality Assurance Manager, FIQCL, DoF Email: manikfiqc. govt@yahoo.com	DD	Aquaculture	Yes

DD, disk diffusion; MIC, Minimum Inhibitory Concentration; NGS, next-generation sequencing; PCR, polymerase chain reaction
Detailed information on current activities and technical capacity for AMR surveillance in livestock was gathered through the questionnaire directed to the public veterinary microbiology laboratories.

Respondents reported that their laboratories performed active AMR surveillance (n=7), passive AMR surveillance (n=2) or both (n=5), but only in six laboratories the AMR surveillance activities were linked to a national surveillance strategy. Furthermore, only two laboratories reported using nationally harmonised SOPs for AMR surveillance from sample collection to AST, whereas five laboratories had their own SOPs, three laboratories used SOPs that were shared among a subset of laboratories, three additional laboratories had no SOPs, and one did not reply.

More than half of the public veterinary microbiology laboratories in the country appears to have the capacity to isolate and identify the species relevant for AMR surveillance in livestock (Figure 6) using mainly conventional culture methods and PCR and, limited to CDIL and BLRI, VITEK 2.



Figure 6. Bacteria genera and species that can be isolated and identified in the public veterinary microbiology laboratories in Bangladesh. The y-axis represents the number of laboratories.

All laboratories reported to have the capacity to perform AST by disk diffusion and nearly half of these laboratories could also perform Minimum Inhibitory Concentration (MIC) determination (Figure 7). More than half of the laboratories reported to have the possibility to perform PCR for detection of AMR genes. Finally, CDIL and BLRI laboratories also reported to have the capacity to perform AST by VITEK2 and Next-Generation Sequencing (NGS). While the capacity to perform different AST methods appears to be good, the situation regarding interpretation of AST results appears to be heterogeneous. Half of the laboratories reported using CLSI guidelines, five laboratories reported using CLSI and EUCAST guidelines, and two laboratories reported using other non-specified guidelines. As comparability of results across laboratories is critical to establish effective a national AMR surveillance programme in livestock, improvements are needed to reach harmonisation of interpretation of AST results among laboratories.



Figure 7. Capacity for antimicrobial susceptibility testing methods available at the public veterinary microbiology laboratories in Bangladesh. The y-axis represents the number of laboratories.

Furthermore, improvements are needed regarding assessment of the quality of the AST results produced. Indeed, there are notable differences in the procedures followed by the different laboratories to verify the quality of purchased reagents with most laboratories relying on direct procurement from local vendors and chemical shops, and only one laboratory performing quality testing in house. Four laboratories reported to participate regularly to External Quality Assurance (EQA) schemes provided by APHA, FAO or Fleming Fund (EQ Asia), however, to the Authors' knowledge, only two laboratories are routinely participating in EQA schemes. Regular participation to recognised EQA schemes should be mandatory for all laboratories performing AMR surveillance activities.

Only five laboratories reported facilitating continuous education or other professional development activities for their employees on a regular basis, whereas continuous professional development was irregular and mainly depending on availability of funds in the remaining laboratories. As continuous professional development is important to retain skilled employees, it is critical to ensure stable funding for these activities.

Data management capability and capacity for AMR surveillance in livestock

To date, there have been different types of analysis and reporting of AMR surveillance data from livestock in Bangladesh by BLRI, DLS, academic institutions and icddr,b, which have established their own protocols, mainly using Microsoft Excel. Such initiatives are generally linked to programmes by individual institutions and do not cover the entire country. Indeed, only four out of 15 laboratories replying the "UNIDO-LDDP Questionnaire to assess the AMR surveillance capacities and strength of the laboratories in the animal health sector of Bangladesh" reported to upload results on a national surveillance platform (the Bangladesh Animal Health Intelligence System, BAHIS - see below). Most of the laboratories (n=10) performing AMR surveillance reported to disseminate the results via articles in peer-reviewed journals and via workshops, and a limited number of laboratories (n=3) reported to issue newsletters.

Initiatives to implement nationwide management of AMR data, including AMR data collection, analysis, reporting and/or dissemination, are:

 The Bangladesh Animal Health Intelligence System (BAHIS), which is an electronic information system to ensure timely reporting from the field as well as analysis of the received data, that will help to control and prevent animal diseases. Recently, DLS has planned to include a module for uploading AMR data to BAHIS and has formed an AMR sectoral working group including all relevant stakeholders directly involved with AMR surveillance and data management. The working group developed a standard template to report AMR data and designated the focal person with rights to access BAHIS and upload such data from each relevant institution (Table 7). Currently, AMR data from livestock that can be recorded in BAHIS are based on AMR pathogens and interpretation of antimicrobial susceptibility test results, i.e. susceptible/ intermediate/ resistant (S/I/R) categorisation and not raw data.

SI. No.	Name and Affiliation	Telephone	E-mail
1.	Director (Admin), DLS	01324288801	directoradmin@dls.gov.bd
2.	Dr. Md. Nazmul Hoque, DD, Animal Health, DLS	01712639622	<u>ddhealthdls@gmail.com</u>
3.	Dr. Golam Azam, Tulu, PSO, CDIL	01937661280	<u>ga.tulu@yahoo.com</u>
4.	Dr. TABM Muzaffar Goni Osmani, Deputy Director, Epidemiology Unit, DLS	01914862579	drmosmani@yahoo.com
5.	Dr. Mohammad Rafiqul Islam, CSO (Livestock), BARC	01716350628	mrislam 210@hotmail.com
6.	Dr. Mohammed Abdus Samad, Head, AHRD, BLRI	01717047877	samad_blri@yahoo.co.nz
7.	Professor Dr. Md. Taohidul Islam, Bangladesh Agricultural University (BAU)	01912910338	taohid.bau@gmail.com
8.	Professor Dr. Mohammad Ali Zinnah, Associate Prof, Microbiology and Public Health, Bangabandhu Sheikh Mujibur Rahman Agricultural University (BSMRAU)	01714485456	Zinnah05@gmail.com
9.	Professor Dr. KBM Saiful Islam, Sher-e- Bangla Agricultural University (SAU)	01711120108	vetkbm@yahoo.com
10.	Professor Dr. K. M. Mozaffor Hossain, Department of Veterinary and Animal Sciences, Rajshaji University (RU)	01716451593	mozaffor03@yahoo.com
11.	Professor Dr. Md. Khaled Hossain, Hajee Mohammad Danesh Science and Technology University (HSTU)	01706877533	khossainhstu@gmail.com
12.	Professor Dr. ATM Mahbub-E-Elahi, Sylhet Agricultural University (SAU), Sylhet	01711301042	atm.mahbub.elahi@gmail.com
13.	Professor Dr. Md. Alamgir Hossain, Chattogram Veterinary and Animal Sciences University (CVASU)	01716955987	Hossainalamgir54@yahoo.com
14.	Professor Dr. AKM Mostafa Anower, Patuakhali Science and Technology University (PSTU)	0171106946	anower@pstu.ac.bd
15.	Dr. Huzzat Ullah, Sirajgonj Government Veterinary College	01917629745	huzzat.lri@gmail.com

Table 7. Focal persons for AMR sectoral working groups in the livestock sector

SI. No.	Name and Affiliation	Telephone	E-mail
16.	Dr. Md. Mamun Shah, Jhenaidah Government Veterinary College	01717197365	drmamunshah@gmail.com
17.	Khulna Agricultural University (KU), Khulna	TBD	TBD
18.	Representative, Gono University, Savar	TBD	drparvejbd@gmail.com

• The One Health Event Based Surveillance (EBS) enhancement and Data visualisation dashboard project by the OHS at IECDR is a system designed to integrate information from i) Local health care services manager (Upazila or District mangers) with authorisation to enter data; ii) Emails, social media; iii) Mobile apps, SMS, WhatsApp; iv) Public web reporting for animal health; v) Environmental information; vi) Rumor management; and vii) e-Print Media and electronic media reporting. Information is then shared with the Epidemiological Units of the respective sectors (Human, Animal and Environmental Health) for verification, and validated data are made publicly available via a dashboard, and shared with relevant authorities to transform data into action. An overview of the system is provided in Figure 8. This approach has the great strength to be truly integrated and include all aspects of data management for AMR surveillance. However, only AMR surveillance data related to humans are currently in the system.



IEDCR: Institute of Epidemiology, Diseases Control & Research BFD: Bangladesh Forest Department DGHS: Directorate General Health Services

DLS: Department of Livestocks

CCF: Chief Conservator of Forest

IHR: International Health Regulation (2005)

OIE: World Organization for Animal Health MoHFW: Ministry of Health & Family Welfare MoFL: Ministry of Fisheries & Livestock MoEF: Ministry of Environment, Forest & Climate Change WHO: World Health Organization GOB: Government of Bangladesh EIOS: Epidemic Intelligence from Open Sources

Figure 8. Information flow of the One Health surveillance system platform (Source: One Health Event Based Surveillance (EBS) | IEDCR)

Currently, there is no framework to use AMR surveillance data to inform policy. This is a key issue that needs to be put at the forefront of any integrated AMR surveillance intervention. A framework and mechanisms for the use of data to inform policy directions should be urgently developed.

Awareness and Education

The first strategic objective of the WHO Global Action Plan on AMR is to improve awareness and understanding of AMR through effective communication, education and training (WHO, 2015).

The animal health sector in Bangladesh has celebrated the World Antimicrobial Awareness Week (WAAW) every year in November since few years' back. For these festive celebrations, the animal health sector organises colorful rallies involving the central, divisional, district and upazila livestock departments across the country, and produces different types of promotional materials (posters, festoon, banners) to inform the public. Probably, no evaluation of these and other awareness campaigns has been performed. However, a recent study on knowledge, attitude, and practices on AMU and AMR among commercial poultry farmers, which was based on a questionnaire sent to 420 randomly selected farmers from seven randomly selected districts, has shown that quite a relevant proportion of poultry farmers adopted incorrect practices of AMU including, among others, seeking antimicrobials from drug sellers and feed sellers or by themselves rather than registered veterinarians (30-40 % of interviewed farmers reported such practice, Figure 9) and using antimicrobials as growth promoters (43.3 % of interviewed farmers reported such practice) despite a legislative ban (Hassan et al., 2021). This clearly shows the need of designing targeted educational and awareness activities to increase the knowledge on AMR and improve AMU practices of farmers (see Recommendations section).



Figure 9. Seeking of antimicrobials by poultry farmers in Bangladesh (modified from Hassan et al., 2021)

Formal training and educational activities to the various professional figures involved in handling of antimicrobials, including veterinary students, veterinary practitioners, pharmacist, practitioners, and sector operators like feed manufacturers and farmers, is a cornerstone to ensure proper understanding of AMR and correct use of antimicrobials.

An overview of the training opportunities currently available for the different professional figures is provided below.

Veterinary students

There are no specialised courses on AMU and AMR in the curriculum of the veterinary schools in Bangladesh, but there are few-hour lectures within the pharmacology and bacteriology courses. There is a One Health Institute under the Chattogram Veterinary and Animal Sciences University (CVASU) that offers a Master in Public Health (MPH), which has an optional AMR course.

Veterinary practitioners - Continuous Professional Development on AMR

The animal health sector organises different types of stakeholder meetings, consultations, seminars and webinars on AMU and AMR for professional development of the state veterinarians.

The Livestock and Dairy Development Project (LDDP) has organised a 5-day training on "Antimicrobial Resistance in Animal Health" for veterinarians and livestock officers of DLS since

2019. The course curriculum is very comprehensive and consists of theoretical lectures on AMU (AWaRe classification of antimicrobials, antimicrobial stewardship policies and strategies, etc.) and AMR (general concepts of AMR, common drivers of AMR, AMR surveillance policies and strategies at national level, laboratory surveillance of AMR, phenotypic and genotypic characterisation of AMR, AMR intervention in livestock farming, etc.). A total of 30 participants are enrolled in each course iteration and, to date, around 2,000 veterinarians have been trained with the support of the LDDP project. Organisation of this course depends on available funding and, at present, there is no permanent schedule.

Also the Bangladesh Agricultural Research Council (BARC) has organised 5-day training programmes on AMR for field veterinarian, researcher and academic professionals in different regions of the country. BARC has provided five of these courses with 30 participants per course in 2020-2021.

DLS has arranged training courses on awareness regarding rational AMU. Most DLS field veterinarians received this training, while project veterinarians are currently being trained. However, most veterinarians work in the private sector and are therefore not included in this training programme.

Different academic institutions and research institutes like BLRI, IEDCR, icddr,b also organise AMU and AMR training programmes for professionals.

The development partners, i.e. Food and Agriculture Organization of the United Nations (FAO), Fleming fund country grant, US-CDC and others also offers hands-on training on AMR surveillance in the context of different projects.

Private companies also have awareness programmes for veterinarians (there are > 1,000 veterinarians working in private animal health companies) about the negative impact of inappropriate AMU and availability of alternatives to antimicrobials.

Pharmacy students/ Pharmacy practitioners/Drug sellers

There is no training on AMU and AMR offered to pharmacy students, pharmacy practitioners and veterinary drug sellers.

Training of sector operators (feed manufacturers, farmers, etc.)

There are limited opportunities, which are mainly linked to private companies' initiatives, to participate in AMU and AMR training by the feed manufacturers and farmers.

Overall, these findings clearly show the need for designing, implementing and securing stable funding for AMU and AMR training of different professional figures linked to animal health (see Recommendations section).

GOVERNANCE

There are three core governance structures that have been formed to address AMR containment at national level encompassing public health, animal health and environment in Bangladesh, as specified in the National AMR Surveillance Strategy of Bangladesh 2020-2025. These are

the National Steering Committee (NSC), the National Technical Committee (NTC), and the Core Working Group (CWG).

The purpose of the NSC is to oversee and coordinate policy decisions for activities related to AMR in all sectors in accordance with AMR-related public health goals.

The purpose of the NTC is to review the approach and initiatives for combating AMR and make recommendations on technical issues.

The CWG shall provide technical and operational inputs to the designated national coordinating centre for AMR, i.e. Communicable Disease Control to develop and implement the National Action Plan on AMR.

The terms of reference (ToR) and membership structure of NSC, NTC and CWG are presented in Appendix 3.

Furthermore, there are a Sectoral Working Groups (SWG) with the following ToR:

- 1. Each SWG will work as a forum of the surveillance sites, laboratory networks, and reference laboratories within the sector;
- 2. Work experiences, surveillance findings, aid issues will be shared within the SWG to facilitate joint learning and problem-solving;
- 3. The SWG will report on progress and challenges faced to the CWG and the NTC;
- 4. The SWG, along with the appropriate NRL of the sector, will ensure high safety and quality standards through established protocols for laboratory quality and participation in a national quality assurance programme;
- 5. SWG members will participate in supportive supervisory visits to the sentinel sites (each site should be visited at an interval of every two months);
- 6. SWG will convene monthly meetings and prepare quarterly progress reports for submission to CWG/NTC.

The membership structure of the SWG for animal health is the following:

Chairperson: Director (Admin), Department of Livestock Services

Members:

1. Deputy Director (HRD), Department of Livestock Services

- 2. Principal Scientific Officer (PSO), CDIL, Department of Livestock Services
- 3. Head, Epi Unit, Department of Livestock Services
- 4. Chief Scientific Officer (CSO), Livestock Division, Bangladesh Agricultural Research Council
- 5. Head, Animal Health Research Division, Bangladesh Livestock Research Institute
- 6. Country Team Lead, FAO, ECTAD, Bangladesh
- 7. Country Team Lead, Fleming Fund Grant, Bangladesh
- 8. Professor, Department of Medicine, Bangladesh Agricultural University
- 9. Professor, Microbiology and Public Health, Bangabandhu Sheikh Mujibur Rahman Agricultural University
- 10. Professor, Department of Medicine, Sher-e-Bangla Agricultural University
- 11. Professor, Department of Veterinary and Animal Sciences, Rajshaji University
- 12. Professor, Department of Microbiology, Hajee Mohammad Danesh Science and Technology University
- 13. Professor, Department of Microbiology, Sylhet Agricultural University
- 14. Professor, Department of Pathology, Chattogram Veterinary and Animal Sciences University
- 15. Professor, Department of Microbiology and Public Health, Patuakhali Science and Technology University
- 16. Representative, Sirajganj Government Veterinary College
- 17. Representative, Jhenaidah Government Veterinary College
- 18. Representative, Khulna Agricultural University

19. Representative, Faculty of Veterinary and Animal Sciences, Gono Bishwabidyalay The committee is headed by Director Admin, which is not a dedicated veterinary position. Deputy Director Animal Health is highly involved with AMU and AMR related activities but the position is not included in the committee.

Overall, while the establishment of a governance structure to contain AMR in Bangladesh has its great merit, it is noticeable that NSC, NTC and CWG have very senior representation. On the one hand, this supports a high level of awareness. On the other hand, it may be difficult for these committees to be operational and result-oriented. A simplification of the governance would likely facilitate for it to become more supportive of coordination and integration of interventions, as well as to enable for translating research and surveillance findings into policy and measures applied on the ground.

RECOMMENDATIONS

Based on the situation analysis presented in this report, needs and recommendations that should be used for developing an integrated AMU and AMR surveillance and monitoring (and management) framework in livestock were identified as follows:

- Recommendations on enhancement of Legislation and Regulations and Institutional Responsibilities
 - Sampling and analysis frameworks for AMU and AMR surveillance should be included in the legislation;
 - The use of alternatives to antimicrobials should be regulated and enforced;
 - Roles and responsibilities for assessing compliance with new and also with existing legislation on all aspects of AMU and AMR should be clearly assigned, and overlap of responsibilities should be avoided. In particular, it is critical to ensure adequate support to:
 - Control that sales of antimicrobials is done only based on prescription by a veterinarian.
 - · Control that only registered veterinarians prescribe antimicrobials.
 - · Control that only pharmacists monitor the sale of antimicrobials.
 - Verify compliance with withdrawal times and MRLs.
 - National policies and standard treatment guidelines (STG) for proper AMU in livestock should be developed keeping into consideration the national AMR patterns.
 - Adequate personnel resources, laboratory capacity and funding should be secured for:
 - Collecting and analysing AMU data.
 - Carrying out sampling, antimicrobial susceptibility testing and data management for national AMR surveillance.
 - Verifying compliance with AMU and AMR legislation.
 - Committees involving veterinary specialists/professionals should be formed to overcome any crisis regarding drug approval and other antimicrobial drug issues.
- Recommendations on Surveillance and Monitoring

- Sampling, testing methods and data management for AMR surveillance in livestock and food should be harmonized at national level.
- A dedicated system to collect, analyze and disseminate quantitative AMU data should be set up.
- A dedicated system to collect, analyze and disseminate AMR surveillance data should be set up.
- Coordination for AMU and AMR data sharing should be initiated among antimicrobial manufacturers, APIs manufacturers, drug sellers, DLS, BLRI, DGHS, DGDA, DG fisheries, and also private farm/companies.
- ✓ Recommendations on Enhanced Governance
 - A clear framework to ensure usability of AMU and AMR data for policy action should be developed and regularly assessed.
 - Ensure quality of antimicrobials during manufacturing and marketing.
 - Enforcement of compliance on ban of antimicrobial agents in animal feed.
 - Awareness of the detrimental effects of improper AMU and spread of AMR should be continuously raised among veterinarians, pharmacists, all livestock sector operators and the general public through awareness campaigns and training courses.

These recommendations are described in further details in Table 8.

Table 8. Needs and recommendations for building an integrated AMU and AMR surveillance system in livestock in Bangladesh

Context	Needs	Recommendations	Responsibility
Legislation and regulations	Translation of all directives of the National Drug Policy 2016 into regulations, and monitoring of compliance Development of a regulatory framework for AMU in livestock Development of a regulatory framework for AMR surveillance Development of a regulatory framework for use of alternatives to antimicrobials	 Roles and responsibilities for assessing compliance with legislation should be clearly assigned in particular regarding: Control that sales of antimicrobials are done only based on prescription by a veterinarian. Control that only registered veterinarians prescribe antimicrobials. Control that only 'true' pharmacists monitor sales of antimicrobials. Control of compliance with withdrawal times and MRLs. Prescription of antimicrobials by the informal prescribers must be prohibited. There should be provision of penalty for prescribing antimicrobials other than registered veterinarian. A regulatory framework to verify compliance with AMU guidelines should be developed and implemented. AMU and AMR surveillance must be included in the legislation. The use of alternatives to antimicrobials should be regulated and enforced. The veterinary cell of DGDA needs to have access to sustained governmental financing to increase staff and upgrade facilities to fulfill its mandate regarding AMU (registration, quality control, post-market surveillance, production, import etc.). 	DGDA and DLS

Context	Needs	Recommendations	Responsibility
Veterinary Antimicrobial stewardship	Proportionate inclusion of relevant veterinary specialists/ professionals in drug approval and other antimicrobial drug issues	Formation of committees involving veterinary specialists/professionals to overcome crisis and problems regarding drug approval and other antimicrobial drug issues. Development of veterinary antimicrobials stewardship policies and guidelines.	DGDA, DLS, Veterinary Academia
Guidelines for AMU based on livestock species/ disease combinations	Clear recommendations on when and how antimicrobials should be used and which antimicrobials should be used must be developed at least for veterinarians and for farmers, and ideally for all operators handling antimicrobials for livestock in the country. Such guidelines should be tailored according to the different livestock species and disease combinations	National policies and standard treatment guidelines (STG) for proper AMU should be developed for veterinarians keeping into consideration the national AMR patterns. Farmer-awareness is also to be addressed. A working group including practicing veterinarians, microbiologists, and pharmacist from all regions in the country should be set up to design, reach consensus and periodically assess such guidelines	DLS and Veterinary Academia
Alternatives to antimicrobials	The development and use of alternatives to antimicrobials should be incentivised	The use of alternatives to antimicrobials especially in small and medium scale farms can importantly contribute to diminish AMU in livestock. Alongside, research on alternative to antimicrobials should be promoted.	DLS, BLRI
AMU data collection	Dedicated system to collect, analyse and disseminate quantitative AMU data	AMU data are critical to design proper antimicrobial stewardship measures. Collection of representative, quantitative AMU national data should be planned and implemented	DLS, DGDA, BFSA, BLRI, icddr,b
AMU and AMR data sharing	Overcome limitation and lack of coordination among stakeholders to share AMU and AMR data	Initiate coordination for AMU and AMR data sharing among antimicrobial manufacturers, APIs manufacturers, drug sellers, DLS, BLRI, DGHS, DGDA, DG fisheries, and also private farm/companies. Finally, AMU and AMR data should be shared with WOAH/WHO/ international agency to reach out global database.	DLS, BLRI, DGHS, DGDA, DG Fisheries, Antimicrobial manufacturers, APIs manufacturers, Drug sellers, Private farm/ companies

Context	Needs	Recommendations	Responsibility
Institutions involved in AMR surveillance in livestock	Improved clarity regarding roles and responsibilities of the different institutions and bodies coordinating and conducting AMR surveillance activities in livestock	The terms of reference of different institutions involved in AMR surveillance should be clearly defined to avoid overlaps and ensure good communication flow.	MoFL, DLS, BLRI, BARC, icddr,b and Academia
Budgeting	Dedicated budget for AMR surveillance activities of DLS	DLS needs to have access to sustained governmental financing to increase staff and upgrade facilities to fulfill its mandate regarding AMR.	MoFL/ DLS
Sampling and AST for national AMR surveillance in livestock	Adequate skilled personnel resources and laboratory capacity to enable collection and processing of samples for national AMR surveillance in livestock	Currently, DLS does not have enough personnel resources, laboratory capacity and funding at CDIL and FDILs to carry out sampling and AST for national AMR surveillance. However, there are additional laboratories at academic institutions with capacity to collect different specimens from different sources. Furthermore, sample collection for AMR surveillance could be carried out while collecting samples for other food safety-related programmes. By leveraging on these existing capacities and enrolling additional laboratories with AST capacity by securing adequate funding and harmonised protocols, it would be possible to initiate a national AMR surveillance programme in livestock in Bangladesh. AMR surveillance should be carried out on a regular basis. AMR surveillance capacities should be created gradually to all FDILs and DVH.	DLS

Context	Needs	Recommendations	Responsibility
		The sampling plan provided by Fleming Fund could be revised to identify possible synergies with ongoing sampling activities and identify possibilities to lower the number of samples to be collected and use the same sample for different analyses.	
		should be provided to relevant personnel to ensure harmonisation of sampling procedures.	
		SOPs for sample processing, bacterial isolation and AST should be harmonised across laboratories and clear indications regarding international standards to be followed (EUCAST or CLSI) should be given.	
SOPs from	Harmonisation of methods across laboratories performing sampling, AST and data management for national AMR surveillance in livestock and food thereof	A SOP for reporting data to BAHIS should be implemented.	
sampling to Data		SOPs should be distributed to all relevant stakeholders.	DLS, DGHS, DGDA, BLRI, BFSA
management		Harmonised SOPs should be adopted to all laboratories in the network from sampling to data management.	
		A plan for performing audits and periodic SOP revisions should be drafted, implemented and evaluated.	
		Procedures for procurements of good-quality reagents should be harmonised across the laboratories performing national AMR surveillance in livestock, possibly with the support of the government.	
		Regular participation to recognised EQA schemes should be mandatory for all laboratories performing AMR surveillance activities.	
		Regular funding should be dedicated to continuous professional development for retaining employees.	
Data management	Establish a framework to use AMU and AMR surveillance data to inform policy and build awareness among veterinary practitioners, regulators, pharmacists and the general public	A clear system to ensure usability of AMU and AMR data for policy action should be designed and regularly assessed.	DLS, DGHS, DGDA

Context	Needs	Recommendations	Responsibility
	Continuous training of veterinary practitioners Motivation of planners and policy makers	Stable funding for AMU and AMR courses to train relevant DLS personnel and veterinary practitioners should be secured. Training veterinarians about use of alternatives to antimicrobials should also be set in place Advocacy programs with planners and policy makers	DLS, BLRI, BVC
	Training and education of veterinary students	Specific training and courses on AMU and AMR should be introduced in the veterinary academic and in-service training curriculum.	DLS, Academia, BVC
	Training of pharmacy students	Specific training on AMU and AMR should be introduced in the pharmacy academic and in-service training curriculum.	Academia, BVC and Bangladesh Pharmacy Council
	Training of pharmacy practitioners and drug sellers	Continuous information campaigns targeting pharmacists and drug sellers should be designed, and AMU and AMR concept should become part of the "Accredited drug dispenser" training curriculum.	DGDA, Bangladesh Pharmacy Council, DLS
Awareness and Advocacy on AMR	Training of sector operators	Animal dealers and feed producers should attend mandatory AMU and AMR courses, and also learn about use of alternatives to antimicrobials.	DLS
	Improved awareness campaigns targeting farmers	Digital communication methods for the rapid and widespread communication of AMR. awareness materials to rural communities in Bangladesh should be explored. There is much capacity for digital dissemination of AMR materials in Bangladesh since, in recent years, the Bangladesh Government has invested in creating an extensive and rapidly growing 4 G internet network: in December 2019 there were over 99 million internet subscribers (60% of the population), 94 million (57% of the population) of which accessed the internet through a mobile phone. Mobile internet usage is growing rapidly, with an average of 10 million new users per year between December 2016 and December 2019. Reference: <u>Thornber et al.,</u> <u>2019. Alongside, poster, leaflets, and</u> <u>brochures can be distributed to the</u> farmers for awareness raising.	DLS

Context	Needs	Recommendations	Responsibility
	Develop awareness and understanding of AMR by effective communication and education to the public	Print and electronic media can be used for raising awareness and understanding to the public.	DLS and BFSA

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List of Appendices

- Appendix 1 Answers to the online questionnaire "UNIDO-LDDP Questionnaire on AMR and AMU in the livestock sector and food of animal origin in Bangladesh" (Please note that this document is readable only in the online version of the report)
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- Appendix 3 Terms of Reference and Membership of the three core governance structures that have been formed to address AMR containment at national level in Bangladesh

Appendix 1: UNIDO-LDDP Questionnaire on AMR and AMU in the Livestock Sector and Food of Animal Origin in Bangladesh

Your name

Your position

Your contact details

Your organization

- 1.1. What are your organizations roles and responsibilities in the context of oversight on antimicrobial approval for use in food-producing animals? What are the policy and risk management requirements and/or practices associated with such reviews and approvals (application of Codex risk analysis criteria, exclusion of therapeutic of important human significance) followed by your organization?
- 1.2. In the context of antimicrobial stewardship, are there guidelines for veterinarians on how to use antimicrobials for different livestock species and diseases? Are there guidelines on antimicrobial use for farmers (including awareness to prevent and mitigate fraud) are these guidelines enforceable through any regulatory requirements? Are there any strategies in place to limit AMU and incentivize alternatives to antimicrobials? Do you/ your organization participate in writing these guidelines/strategies and monitoring compliance?
- 1.3. Do you/your organization have defined roles and responsibilities in relation to collection/ analysis/ reporting/ dissemination of information related to AMU? If yes, is this done at national, regional and/or local level? If no, what are the obstacles?
- 1.4. Do you have defined roles and responsibilities regarding use of AMU data to inform policy development? If yes, is this done at national, regional and/or local level? If no, what are the obstacles?
- 1.5. Do you collaborate with other stakeholders regarding any of the topic areas for AMU mentioned above? If yes, could you share with us who they are? If no, what prevents collaboration?
- 1.6. What are the conditions of sale/ oversight (under supervision from veterinary professional, etc.)?
- 1.7. How much antimicrobials are sold (per animal species, per year)?
- 1.8. How much antimicrobials are used (per animal species, per year)?
- 1.9. What types of antimicrobials are being sold (per animal species, per year)?
- 1.10 Available information on AMU: What are the types of antimicrobials used (per animal species, per year)?

- 1.11 Available information on AMU: What is the number of animals treated with antibiotics?
- 1.12 Available information on AMU: What is the length of the treatment?
- 1.13 Available information on AMU: Compliance with posology (administration route, duration of treatment)
- 1.14 Available information on AMU: Compliance with withdrawal period
- 1.15 Prudent AMU: Please list the applied vaccines
- 1.16 Prudent AMU: Do you know about any biosecurity issues?
- 1.17 Prudent AMU: Are you aware of any Good Hygiene Practice?
- 1.18 Prudent AMU: Is there any fencing applied on the relevant farms?
- 1.19 Prudent AMU: Are pre/pro-biotics used and if yes how?
- 1.20 Prudent AMU: Are veterinary advice available?
- 1.21 AMU data management: Please explain the data recording process.
- 1.22 AMU data management: What is the data collection process?
- 1.23 AMU data management: How is the data entered?
- 1.24 AMU data management: What is the data analysis process?
- 1.25 AMU data management: What is the data reporting process?
- 1.26 What AMU data is used to inform policies?
- 2.1 What are your/your organization roles and responsibilities in the design and implementation of a sampling strategy for AMR surveillance? Is the sampling strategy designed for implementation at national, regional or local level?
- 2.2 In the context of capacity for sample collection for AMR surveillance, how many DLS officers are collecting samples for AMR surveillance in livestock, poultry and food thereof, and in which geographical areas of the country? Do you have defined protocols on sampling techniques and are there trainings thereon? If yes, please share those. If the entire country is not covered in the sampling plan for AMR surveillance, what are the reason for it? Do you foresee any possibility to align the AMR sampling part with other ongoing initiatives in the food safety area?
- 2.3. What are your/your organization roles and responsibilities in the context of AMR data management? Is there a national/regional/local strategy regarding data collection, analysis, reporting and dissemination? Do you have any digitalized system or it is paper-based? If it is computer-based, could you elaborate on the data entry process and what

software is being used? Could you share with us a sample table based on which the data might be aggregated and analyzed?

- 2.4. To what extent are AMR surveillance data used to inform policy? What are the feedback mechanisms, science and policy advisory structures that are available to support the reliance on data / evidence in AMR management decision-making?
- 2.5. What are your/your organization roles and responsibilities in the context of laboratory capacity for analyses of samples for AMR surveillance in livestock animals and food thereof (e.g. contribution to SOP writing, monitoring of compliance with SOPs, training of laboratory personnel, etc.)? Do you follow any documented antimicrobial susceptibility testing method which could be shared?
- 2.6. Do you collaborate with other stakeholders or are you part of any national platforms regarding any of the topic areas for AMR mentioned above? If yes, could you share with us who they are? If no, what prevents collaboration?
- 2.7. Sample collection for AMR surveillance: What are the target animal categories/food items?
- 2.8. Sample collection for AMR surveillance: What types of samples (faeces, caecal content, etc. for food of animal origin: national/imported) are being collected?
- 2.9. Sample collection for AMR surveillance: What are the target bacterial species?
- 2.10 Sample collection for AMR surveillance: Where samples are collected (Farms/markets/ slaughterhouses/etc.) All country/specific geographical regions? Please specify
- 2.11 Sample collection for AMR surveillance: When are the samples collected (season)?
- 2.12 Sample collection for AMR surveillance: What is the sample size?
- 2.13 Sample collection for AMR surveillance: Who collects the sample?
- 2.14 Sample collection for AMR surveillance: Are all personnel trained on the AMR sample collection?
- 2.15 Sample collection for AMR surveillance: How samples are stored before testing? Are there any SOPs?
- 2.16 Sample collection for AMR surveillance: What is the maximum time allowed between sample collection and sample analysis?
- 2.17 Sample collection for AMR surveillance: Are there SOPs for sampling, storing and sending the samples to the laboratory? If yes please describe. If not please leave empty.
- 2.18 Laboratory capacity for AMR surveillance: What is the current laboratory capacity for analysing samples for AMR surveillance in livestock, poultry and food thereof? Is there a capacity to analyse samples representative of national production of livestock, poultry and food thereof?

2.19 Laboratory capacity for AMR surveillance: List the laboratories having AMR testing capacity

in your organization and at what extent.

- 2.20 Laboratory capacity for AMR surveillance: Do these laboratories have access to good quality reagents?
- 2.21 Laboratory capacity for AMR surveillance: Do they obtain reagents from regular source or from project aid?
- 2.22 Laboratory capacity for AMR surveillance: Do these laboratories have the possibility to store samples and bacterial isolates in appropriate conditions?

2.23 Laboratory capacity for AMR surveillance: Are methods for bacterial isolation, species identification and antimicrobial susceptibility testing harmonized across the laboratories?

- 2.24 Laboratory capacity for AMR surveillance: Do the laboratories have an internal Quality Management System and/or accreditation according to ISO 20776-1:2019 (Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices: Broth micro-dilution reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases) or other national accreditation scheme? If yes please specify.
- 2.25 Laboratory capacity for AMR surveillance: Do the laboratories participate to External Quality Assurance schemes?
- 2.26 Laboratory capacity for AMR surveillance: Do laboratory personnel have access to continuous education or other development activities?
- 2.27 Laboratory capacity for AMR surveillance: Is there an established laboratory network for harmonized methods, reporting and data sharing?
- 2.28 Laboratory capacity for AMR surveillance: Are AMR surveillance data used to inform policies, treatment guidance, etc.?

Appendix 2: UNIDO-LDDP Questionnaire to assess the AMR surveillance capacities and strength of the laboratories in the animal health sector

capacities and strength of the laboratories in the animal health sector of Bangladesh

The survey is intended to better understand the AMR surveillance capacity and strength of the leading laboratories across the animal health sector of Bangladesh. The United Nations Industrial Development Organization (UNIDO) appreciates your support and cooperation in completing this survey which will be used to analyse the national capacity and competency in relation to AMR surveillance in the animal health sector. Kindly complete the online survey on or before 5nd June 2022. The survey is being conducted with the following objectives:

- To assess the capacity and potentiality of the laboratories to perform AMR surveillance in animal health sectors;
- To identify the gaps among the national AMR surveillance laboratories in animal health sectors;

If you have any queries or clarifications regarding this survey, please feel free to contact Nure Alam Siddiky (<u>nasiddiky.saarc@gmail.com</u>), National AMR Surveillance Expert, UNIDO

A. Respondent's Details

- Q.1. Name of the institution:
- Q.2: Name of the department (If applicable):
- Q.3: Full name of the respondent:
- Q.4: Designation/position:
- Q.5: Affiliation:
- Q.6: Email address:
- Q.7: Cell number:

B. AMR surveillance capacity and strength of the laboratories

Q.8: Does your laboratory perform AMR surveillance?

A. Yes

B.No

Q.9: What type of surveillance do you conduct?

- A. Active surveillance
- B. Passive surveillance

C. Both

Q.10: Is your AMR surveillance linked to a national surveillance strategy?

A. Yes

B. No

Q.11: What type of SOP is used in your laboratory for AMR surveillance (sample collection to sensitivity testing?

- A. Own developed SOP
- B. National harmonized SPO
- C. Shared SOP from other laboratory
- D. No standard SOP
- E. Others (specify)

Q.12: What are the sample sources for AMR surveillance?

- A. Animal farms
- B. Live bird market
- C. Wet market
- D. Super shops
- E. Slaughtering point
- F. Environment
- G. Above all
- H. Others (specify)

Q.13: What kind of sample do you collect for AMR surveillance?

- A. Cecal sample
- B. Cloacal swab
- C. Rectal swab
- D. Fresh feces
- E. Meat

F. Milk

G. Egg

H. Soil

I. Water

J. Others (specify)

Q.14: How many samples do you tentatively collect each year for AMR surveillance?

Α.

Q.15: What type of AMR pathogen can be isolated and identified in the laboratory?

- A. E. coli
- B. Salmonella
- C. Streptococcus
- D. Staphylococcus
- E. Campylobacter
- F. Shigella
- G. Enterococcus
- H. Others (specify)

Q.16: How do you confirm the isolation and identification of AMR pathogens?

- A. Conventional culture method
- B. PCR
- C. Vitek-2
- D. MALDI-TOF
- E. Others (specify)

Q.17: What types of antimicrobial susceptibility testing facilities are available in yourLaboratory?

- A. Disk diffusion
- B. Minimum inhibitory concentration (Agar dilution/ broth dilution)

- C. MIC by Vitek-2
- D. PCR for genotypic resistance detection
- E. Sequencing
- F. Others (specify)

Q.18: What type of standard do you use to interpret antimicrobial sensitivity?

- A. CLSI
- B. EUCAST
- C. Both
- D. Others (specify)

Q.19: Does your laboratory participate in external quality assurance/ proficiency testing?

- A. Yes
- B. No

Q.20: If yes to Q.19, who provide panel for external quality assurance?

A. -----

Q.21: If yes to Q.19, how frequent do you participate in proficiency testing?

- A. 3-6 month
- B. 6-12 Month
- C. More than 1 year
- D. Irregular

Q.22: How do you confirm quality reagents in your laboratory?

- A. Direct procurement from sole distributor
- B. Uncompromised with quality brands
- C. Quality testing before receive from the vendor
- D. Direct procurement from local vendor
- E. Direct procurement from chemical shop

F. Other (specify)

Q.23: What kind of facility do you have to store samples and bacterial isolates in appropriate conditions?

- A. Refrigeration (2-8°C)
- B. Refrigeration (-20°C)
- C. Refrigeration (-80°C)
- D. No refrigerator
- E. Other (specify)

Q.24: Does laboratory personnel have access to continuous education or other professional development activities?

- A. Regular
- **B.** Sometimes
- C. Never
- D. Depends on funds

Q.25: Did you share your AMR surveillance data with national surveillance platform?

- A. Yes
- B. No

Q.26: How did you make publicly your AMR surveillance findings?

- A. Publication in peer reviewed journal
- B. Newsletter
- C. Dissemination Workshop
- D. Hoisting to BAHIS platform
- E. Others (specify)

Q.27: What are the sources of funding for your surveillance program?

- A. Govt. project based funding
- B. Govt. revenue funding

- B. Donor funding
- C. Other (specify)

Q.28: Did you face scarcity of funding for regular AMR surveillance?

A. Yes

- B. No
- C. Other (specify)

Appendix 3: Terms of Reference and Membership of the three core governance structures of AMR

National Steering Committee (NSC)

Terms of reference

- 1. The National Steering Committee (NSC) will be responsible for approving the National Strategy and Action Plans and any other guidance on antimicrobial resistance control that have a wide range of policy implications, based on the recommendations provided by National Technical Committee (NTC);
- The NSC will supervise and guide activities of the NTC and will review the annual report on the progress of the National Antimicrobial Resistance Control (NARC) Programme submitted by NTC;
- 3. The NSC will review the advocacy and policy recommendations by NTC based on generated AMR surveillance data and take necessary actions based on the evidence;
- 4. The NSC will review the proposed budget for activities outlined in Action Plans and recommend what the concerned line ministries to include in their respective budgets;
- 5. The NSC will meet every at least once in every six months and at shorter intervals when required;

Membership structure

The NSC currently has the following membership structure:

- Chairperson: Honourable Minister, Ministry of Health and Family Welfare
- **Co-chairperson:** Honourable Minister, Ministry Fisheries and Livestock
- Member-Secretary: Secretary, Ministry of Health and Family Welfare
- Members (not according to the warrant of precedence):
 - 1. Attorney General of Bangladesh
 - 2. Director-General, Directorate General of Health Services
 - 3. Director-General, Directorate General of Drug Administration
 - 4. Director-General, Directorate General of Armed Forces Medical Services
 - 5. Director-General, Department of Livestock Services (DLS)
 - 6. Director-General, Department of Fisheries

- 7. Director-General, Department of Environment
- 8. Director-General, Press Institute of Bangladesh
- 9. Principal Information Officer, Press Information Department
- 10. Director-3/Representative, Prime Minister Office
- 11. Director General, Bangladesh Livestock Research Institute (BLRI)
- 12. Director / PSO (Quality control), Directorate General Fisheries
- 13. Country Representative, World Health Organization (WHO)
- 14. Country Representative, Food and Agriculture Organization (FAO)
- 15. Country Representative, UNICEF
- 16. Country Representative, United Kingdom Department for International Development (DFID)
- 17. Executive Director, International Centre for Diarrheal Disease & Research (icddr,b)
- 18. President/Secretary General, Bangladesh Medical Association
- 19. President/Secretary, Bangladesh Veterinary Association
- 20. President/Secretary, Bangladesh Association of Pharmaceutical Industries
- 21. President/Secretary, Bangladesh Bar Council
- 22. President/Secretary, Consumers Association of Bangladesh (CAB)

National Technical Committee

Terms of reference

- 1. Act as a technical advisory body to the National Steering Committee on the Antimicrobial Resistance Control (NARC) Programme;
- 2. Develop the Strategy, Action Plans, and Guidelines for the Prevention and Control of Antimicrobial Resistance and other policy documents for submission to the NSC for final approval;
- 3. Periodically review the above-mentioned policy documents and submit to NSC for necessary decisions;
- 4. Prepare budgets for the different activities outlined in the Action Plan;
- 5. Monitor and evaluate the implementation of the NARC programme and submit an annual

report on progress to the NSC;

- 6. Make work plan based on feedback from the Core Working Group (CWG) and different Sectoral Working Groups;
- 7. Meet at least quarterly, and additionally, if the situation requires;

Membership structure

- Chairperson: Director General of Health Services
- Co-chairperson: Additional Director General (Admin) of Health Services
- Member-Secretary: Director (Disease Control), DGHS and National Focal Point, NARC Programme
- Members (not according to a warrant of precedence):
 - 1. Director (Quality Control, P. marketing, Surveillance & C. Drug Testing Lab), DGDA
 - 2. Director (Veterinary), Directorate General of Drug Administration
 - 3. Director (Hospitals), Directorate General of Health Services (DGHS)
 - 4. Director, Institute of Epidemiology, Disease Control, and Research (IEDCR)
 - 5. Director, Institute of Public Health (IPH)
 - 6. Representative from Director General of Armed Forces Medical Services
 - 7. Director, Livestock Research Institute (LRI), Department of Livestock Services (DLS)
 - 8. Director, Quality control, Directorate General Fisheries
 - 9. Professor of Microbiology, Bangabandhu Sheikh Mujib Medical University
 - 10. Professor of Pharmacology, Bangabandhu Sheikh Mujib Medical University
 - 11. Head of the Department of Microbiology, Dhaka Medical College
 - 12. Head of the Department of Pharmacology, Dhaka Medical College
 - 13. President/Secretary, Bangladesh Society of Medicine
 - 14. President/Secretary, Bangladesh Association of Physicians
 - 15. President/Secretary, Bangladesh Society of Surgeons
 - 16. President/Secretary, Bangladesh Paediatric Association

- 17. President/Secretary, Obstructive and Gynaecological Society of Bangladesh
- 18. President/Secretary, Bangladesh Pharmacological Society
- 19. President/Secretary, Bangladesh Society of Medical Microbiologists
- 20. President/Secretary, Bangladesh Pharmaceutical Society
- 21. President/Secretary, Bangladesh Pharmacy Council
- 22. President/Secretary, Bangladesh Veterinary Association
- 23. Representative from the World Health Organization (WHO)
- 24. Representative from the Food and Agriculture Organization (FAO)
- 25. Representative from International Centre for Diarrheal Disease & Research (icddr,b)
- 26. Prof. M. A. Faiz, Prof. of Medicine and Former Director-General of DGHS
- 27. Prof. Quazi Tarikul Islam, Ex Prof. of Medicine, Popular Medical College
- 28. Prof. J U Ashraful Hoq, Professor of Microbiology
- 29. Prof. Md. Zahurul Hoque, Former Director, Drug Administration
- 30. Dean, Faculty of Pharmacy, University of Dhaka
- 31. Dr. Salauddin Khan, Former Director-General, DLS
- 32. Coordinator, Core Working Group

Core Working Group

Terms of reference

The Core Working Group (CWG) is a smaller group of technical experts, typically representatives from the relevant sectors involved in AMR surveillance. The main functions of the CWG include:

- 1. Develop draft policy documents, including guidelines and strategic action plans, in response to NTC requests;
- 2. Monitor and evaluate of implementation of different components of the National Action Plan;
- 3. Prepare and submit to NTC a quarterly report on the status of the National AMR Control Programme;
- 4. Act as the coordinating body, liaising among sectoral working groups and with national reference laboratories, the National Coordination Centre, and the One Health Secretariat;

- 5. Support and monitor the activities of the surveillance network and laboratories within it to ensure the quality of AMR surveillance data generation, reporting, analysis, and sharing at all levels;
- 6. Meet at least monthly and more often, if required;
- 7. Provide secretarial support to the NTC;

Membership structure

- Chief Coordinator: Director (Disease Control), DGHS & National Focal Point
- Coordinator: One Designated Officer of CDC, Directorate General of Health Services (DGHS)
- Members:
 - 1. Prof. of Pharmacology, Bangabandhu Sheikh Mujib Medical University (BSMMU) / Competent representative
 - 2. Head, Dept. of Virology, Institute of Epidemiology, Disease Control, and Research
 - 3. PSO, Dept. of Microbiology, Institute of Epidemiology, Disease Control, and Research
 - 4. Deputy Director, Drug Administration
 - 5. DPM/ Representative from Hospital Management Service, DGHS
 - 6. DPM, Emerging & Re-emerging Diseases, CDC, DGHS
 - 7. Head, Epidemiology wing, Department of Livestock Services (DLS)
 - 8. Associate Professor of Medicine
 - 9. Lecturer, Dept. of Microbiology, Dhaka Medical College
 - 10. Associate Professor of Microbiology, BSMMU/Representative
 - 11. NPO (Epid), WHO/ Representative
 - 12. Representative from Dept. of Environment
 - 13. Regional Consultant, Bangladesh Livestock Research Institute (BLRI), DLS
 - 14. Asst. Scientist, Microbiology Lab., International Centre for Diarrheal Disease and Research(icddr,b)
 - 15. Lab personnel from FAO Food Safety Lab.




+43 1 26026-0

www.unido.org

🔀 unido@unido.org



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