

# Guideline on Antimicrobial Consumption (AMC) Surveillance in Bangladesh

Version. 01

Effective Date: July, 2022



Directorate General of Drug Administration Mohakhali, Dhaka-1212 Bnagladesh, Ministry of Health and Family Welfare, Bangladesh.

# **Table of Content**

Abbreviations
Introduction
Global Response
Bangladesh Context
Antimicrobial Consumption (AMC) Surveillance National Action Plan
AMC Surveillance in Context of Bangladesh
Methodology
National AMC/U task force
Data Collection
Validation
Data Management
Reporting
Reporting to GLASS-AMC platform
Data dissemination and converting data to regulatory/policy decisions
Conclusion
Definitions
Annexes

# Abbreviations

Directorate General of Drug Administration
Standard Operating Procedure
World Health Organization.
Defined Daily Doses
The Anatomical Therapeutic Chemical code
Drug Utilization 75
Access. Watch. Reserve.
Antimicrobial Consumption.
Antimicrobial Use.
Global Antimicrobial Resistance and Use Surveillance System.
DDD per 1000 inhabitants per day

## Introduction

Antimicrobial resistance (AMR) is a global health and development threat. It requires urgent multisectoral action in order to achieve the Sustainable Development Goals (SDGs). WHO has declared that AMR is one of the top 10 global public health threats facing humanity. 'Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis,' The Lancet, 2022 published that every year 1.27 million people died on AMR. From this study it was found that five regions including all four regions of sub-Saharan Africa and south Asia had all-age death rates associated with bacterial AMR higher than 75 per 100000:.



Surveillance is an essential tool to inform policies and infection prevention and control responses. Surveillance and monitoring are widely acknowledged as critical components of the response to antimicrobial resistance (AMR) and are one of the five strategic priorities of the Global Action Plan (GAP) on AMR. Through surveillance, countries can detect the emergence of AMR and collect the data on AMR prevalence and antimicrobial use (AMU) necessary to guide patient treatment, identify populations at risk, inform policy development and assess the impact of interventions.

## Role of Surveillance data on Antimicrobial Consumption:

> Data on antimicrobial consumption provide an important basis for countries to better understand the patterns and amount of antimicrobials used at the national level, which can inform policies, regulations and interventions to optimize the use of antimicrobials.

> This surveillance shows the great variation in quantity and type of antimicrobials consumed between the included countries. While the observed variation may be due to the selection and coverage of data sources, it also reflects an actual difference in antimicrobial use.

> The use of antimicrobials appears to be very high in some parts of the world, suggesting their overuse, whereas it is low in others, which may indicate limited access to these life-saving medicines.

Findings from this report confirm the need to take action to ensure that antimicrobials are used appropriately, such as enforcing prescription-only policies and implementing antimicrobial stewardship programmes.

Sovernments and the international community should also ensure equitable access to antimicrobials, for example through strengthening of regulatory frameworks, procurement and supply chains.

> The process of implementing national surveillance of antimicrobial consumption has prompted countries to review national regulations, procurement and supply chains of medicines as a starting point to strengthen overall pharmaceutical systems.

> Reporting and sharing data on antimicrobial consumption both nationally and internationally is an essential element of surveillance and provides important information in the global fight against antimicrobial resistance.

### **Global Response to Antimicrobial Resistance**

The WHO global action plan on antimicrobial resistance (GAP) adopted in the World Health Assembly requested the all countries to formulate National Actional Plan (NAP) on AMR according to the GAP and outlined he strategic objectives to be achieved (*WHO*, 2015). The researcher and policy makers around the globe considered this issue a major threat to humanity and therefore United Nations General Assembly acknowledged the importance of collective initiative to promote sensible use of antimicrobials (*UN*, 2016). Irrational use of antimicrobials was identified long before and number of interventions attempted to improve their use. Though World Health Organization (WHO) has taken initiative long before, very little progress has been achieved so far (*WHO*, 2001). In spite of scarcity of information on microbial sensitivity pattern, couple of studies have been carried out to explore the situation of Antimicrobial Resistance in Bangladesh as well as to identify the effective intervention (*Rahman and Huda*, 2014; Sultana and Rahman, 2017; GARP-BWG, 2018; Mahboob and Rahman, 2019).

The Global Framework for Development & Stewardship to Combat AMR, developed by WHO, OIE and FAO, provided guidance for global and national strategies with a focus on the appropriate use of antimicrobials in the context of One Health (*WHO*, *FAO and OIE*, 2017).

WHO updated its Model List of Essential Medicines in 2017 and grouped antibiotics into Access, Watch and Reserve (AWaRe) categories based on treatment profile and potential for development of resistance (*WHO*, 2017; Sharland et al., 2018). The upgradation is expected to ensure availability of appropriate antimicrobials whenever needed and thereby increase appropriateness of prescribing. Rational use may in turn reduce the possibility of development of resistance and may help to conserve the last-resort antimicrobials at the time of actual need.

## **Bangladesh Context**

Bangladesh has formulated the strategic document titled "National Strategy for Antimicrobial Resistance Containment in Bangladesh 2011-2016", which outlines tiered monitoring frameworks incorporating different important stakeholders from human and animal health sector (MoHFW, 2015[a]).

## **Road map of National Action Plan of ARC**

The Ministry of Health and Family Welfare (MoHFW) also developed and endorsed a National Action Plan, which identified the key areas and specific activities to be undertaken (MoHFW, 2017[a]). Later on, a detail document titled "Road map of National Action Plan of ARC" was also formulated that clearly outlined the activities along with the responsible government players and their expected role (MoHFW, 2017[b]).

In the Roadmap, under the heading of "4.2. Monitor use of Antimicrobials", the statement has been mentioned as "4.2.3. Estimation of consumption of antimicrobials both in human and animal health sector". The Directorate General of Drug Administration (DGDA) is the responsible authority for estimating the consumption of antimicrobials.

In recent National Strategy and National Action Plan for Antimicrobial Resistance Containment in Bangladesh (2021-2026) section 3.3.3 DGDA is responsible to establish a system for the national surveillance of antimicrobial consumption (AMC) in human health;

## Formation of the Task Force to Monitor AMC/AMU Surveillance in Bangladesh

In 2017 Directorate General of Drug Administration formed the "Task Force to Monitor Antimicrobial Consumption in Bangladesh". The main responsibilities of this Task Force was: Approval of the methodology to study antimicrobial consumption in Bangladesh with appropriate modification of the WHO Methodology. A series of meeting has been conducted to develop the methodology to conduct AMC surveillance in Bangladesh. In 2021 Ministry of Health and Family Welfare reformed the "Task Force to Monitor Antimicrobial Consumption and Antimicrobial Use Surveillance in Bangladesh".

## AMC Surveillance in Context of Bangladesh

Back in 2017, World Health Organization (WHO), Bangladesh Country Office initiated capacity building to collect antimicrobial consumption data according to the WHO methodology for surveillance of antimicrobial consumption. WHO provided training of two focal persons by WHO/HQ, training of a wider group of professionals at DGDA.

In 2017, during the pilot phase attempts were made to adopt the global methodology in accordance with the perspective or context of Bangladesh. That modification was placed and accepted by the Task Force to Monitor Antimicrobial Consumption in Bangladesh.

In order to implement these activities in a scientific way and to keep objectivity, WHO provided support to DGDA in collaboration with Bangabandhu Sheikh Mujib Medical University to establish a National Antimicrobial Monitoring System.

Since 2016, in Bangladesh, WHO, DGHS, DGDA, FAO, DG DLS and BSMMU are participating World Awareness Antibiotics Week in order to build awareness among the concerned people regarding issues related to AMR. In addition, civil society initiatives (Bangladesh AMR Response Alliance (BARA), online social forum for medical profession 'Platform' and different professional organizations also organized and participated in number of awareness campaign and scientific seminars. These activities has attracted , immense interest amnog key persons of the Ministry of Health and Family Welfare (MoHFW) and Ministry of Livestock and Fisheries (MoLF).

In 2021 with the funding and technical support of Fleming Fund Fellowship, a SOP was developed to conduct the Antimicrobial Consumption Surveillance. With the help of mentorship from Statens Serum Institut, Denmark and Fleming Fund AMC/U surveillance Fellow conducted the Antimicrobial Consumption Surveillance for the year 2019 and 2020.

The Ministry of Health and Family Welfare nominated DGDA as the National Centre for AMC surveillance of Bangladesh and also nominated the National and alternate National focal for AMC surveillance reporting to WHO GLASS-AMC platform. As a continuation of these activities, this guideline for AMC surveillance in Bangladesh has been developed.

## National center for Antimicrobial Consumption (AMC) Surveillance

Directorate General of Drug Administration (DGDA) will play the role as the National center for Antimicrobial Consumption (AMC) Surveillance in Bangladesh based on official nomination of Ministry of Health and Family Welfare (Annex-1). The nominated National focal and an alternate National Focal will coordinate the overall surveillance activities including GLASS-AMC data reporting, the collaboration with World Health Organization and other relevant Developments partners as relevant. Ultimately the "AMR Cell" of DGDA will involve to conduct the Antimicrobial Consumption (AMC) Surveillance every year.

## ToR of "Task Force to Monitor AMC/AMU Surveillance in Bangladesh"

- 1. Approval of the methodology to study antimicrobial consumption and antimicrobial use in Bangladesh with appropriate modification of the WHO/OIE Methodology.
- 2. Periodic review and approval of the National Antimicrobial Consumption and Antimicrobial Use survey activity & report.
- Monitor and evaluate the implementation status of the National Antimicrobial Consumption and Antimicrobial Use surveillance.
   Formation of sub-committee/ working committee to work closely with special priorities on Antimicrobial Containment issues.

## ToR of AMR Cell of DGDA

- 1. To conduct AMC/U surveillance in Bangladesh.
- 2. Implementation of National Action Plan and Strategic Plan of AMR (DGDA part).
- 3. Coordinate and implement AMR Awareness.
- 4. On behalf of DGDA this cell will work on AMR related activities.

## **Relevant Stakeholders:**

The registered manufacturers of antimicrobial drugs in Bangladesh, the importers and the Government agencies who are involve in donation receive (antimicrobial drugs) are the main key stakeholders.

## Timeline for the data submission and report generation:

Every year in January DGDA will issue an official letter to the antimicrobial drug manufacturer to submit the distribution data of last year within 30th January. The report will be generated within April. The reporting frequency and timeline can be changed with prior permission from the "Task Force to Monitor AMC/AMU Surveillance in Bangladesh".



## **Methodological Perspectives**

The Directorate General of Drug Administration, as national regulatory authority, is responsible ensuring the quality, safety and efficacy of medical products in Bangladesh. In Bangladesh, as per the Drugs (Control) Ordinance, 1982 section 5 (1) " No medicine of any kind shall be manufactured for sale or be imported, distributed or sold unless it is registered with the licencing authority." For setting up a surveillance system on antimicrobial consumption and for standardized data collection at the national context, DGDA will follow the following WHO's guidance documents as common technical basis-

- 1. WHO methodology for a global programme on surveillance of antimicrobial consumption.
- 2. GLASS Methodology for surveillance of national antimicrobial consumption
- 3. GLASS Manual on the management of antimicrobial consumption data

## ATC/DDD System

## ATC Classification system

The Anatomical Therapeutic Chemical (ATC) classification system is the most commonly used method for aggregation of medicines data and allows flexibility in reporting by medicine or groups of medicines. In this system, the active substances are divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.

Level 1.	indicates the anatomical main group and consists of one letter		
	indicates the unatomical main group and consists of one letter.		
	There are 14 main groups. The group most relevant to work on		
	antimicrobials is group J Anti-infectives for systemic use. However, there are some examples of antimicrobials classified in other main groups, e.g. antibiotics used as intestinal anti-infectives are in ATC main group A		
	Alimentary tract and metabolism, while some oral and rectal anti-		
	protozoal agents are in ATC main group P Anti-parasitic products,		
	insectides and repellants.		
Level 2:	pharmacological/therapeutic subgroups, e.g. J01 is Antibacterials for		
	systemic use, J02 Antimycotics and J04 Antimycobacterials.		

Level 3:	chemical/pharmacological subgroups, e.g. J01C is Beta-lactam
	antibacterials, penicillins
Level 4:	pharmacological subgroup, e.g. J01CA is Penicillins with extended
	spectrum
Level 5:	chemical substance, e.g. J01CA01 is ampicillin and J01CA04 is
	amoxicillin.

## **Measurement Units : Defined Daily Dose (DDD)**

The most commonly used measurement statistic is the number of Defined Daily Doses (DDDs). The Defined Daily Dose (DDD) is the assumed average maintenance dose per day for a medicine used for its main indication in adults. A DDD is only assigned for drugs that already have an ATC code. The DDD, however, is only a technical unit of use and does not necessarily reflect the recommended or average prescribed dose.

The DDDs for the anti-infectives are as a main rule based on the use in infections of moderate severity. However, some anti-infectives are only used in severe infections and their DDDs are assigned accordingly. There are no separate DDDs for children which makes the DDD estimates for paediatric formulations more difficult to interpret.

The numbers of DDDs is calculated as follows:

Number of DDDs = Total grams used/DDD value in grams

Where the total grams of the medicine used is determined by summing the amounts of active ingredient across the various formulations (different strengths of tablets or capsules, syrup formulations, injections etc.) and pack sizes.

The numbers of DDDs provides a measure of extent of use, however for comparative purposes these data are usually adjusted for population size or population group, depending on the medicines of interest and the level of data disaggregation that is possible.

For most antimicrobials, the DDDs/1000 inhabitants/day (DID) will be calculated for the total population including all age and gender groups (if applicable). The possible to stratification of the national estimates are age group, gender, sectors (community and hospital, public and private).

## Antimicrobials included in monitoring

Based on the WHO surveillance program, DGDA focuses only on antimicrobials for systemic use excluding the Topical Antimicrobials.

The core set of antimicrobials that are included in the National AMC surveillance in Bangladesh are:

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

In consideration of optimal list of Antimicrobials available in Bangladesh, National AMC surveillance will include the registered molecules of the following categories -

Antifungals	J02
Antimycotics	D01BA
Antivirals	J05
Antimycobacterials for treatment of tuberculosis	J04A
Antimalarials	P01B

## Different level of health care Sector

National AMC surveillance center as well as AMR cell of DGDA will explore the mechanism of stratifying the National level data based on WHO recommended the health care sector (Public & Private) and two health care level (hospital & Community).

LEVEL / SECTOR	PUBLIC	PRIVATE	GLOBAL
Community			
Hospital			
Total			

## Combinations of health care sectors and levels

## Data Source of AMC surveillance

As per GLASS Methodology for surveillance of national antimicrobial consumption Guideline potential sources of information on AMC Information on the AMC can be obtained from five levels of the value chain of medicines as shown in Fig. 3.

The levels are:

- procurement and supply
- distribution
- prescribing
- dispensing
- patient use.

There are several potential sources of information on AMC at each level:

- procurement and supply level
  - import data (using data from customs records and declaration forms)
  - production records of domestic manufacturers (excluding any exports of products)





## The framework for estimating consumption in the Context of Bangladesh

- > The General estimate of the national Antimicrobial Consumption in Bangladesh are-
- Sale in the Domestic Market + Import (finished product) + DonationTherefore, only the sale in the domestic market and antimicrobials distributed through different programs are consumed by the inhabitants of the country. For convenience and accuracy, the quantity of pharmaceutical products leaving the factory to be distributed within the country for domestic consumption will be collected. If there is no import or no donation of the Antimicrobial Products then the value zero "o" will be incorporated.
- > Finally, the proxy estimate of the National Consumption in Bangladesh is-

Products leaving the factory for distribution in the Domestic Market + Import (finished product) + Donation

## **Data Collection**

According to the WHO- "GLASS Methodology for surveillance of national antimicrobial consumption", the general elements of data collection for AMC are-

Antimicrobial consumption data	<ul> <li>Product level data</li> <li>Consumed packages at product level (aggregated packages)</li> <li>May be stratified by health care levels and sectors</li> </ul>
Denominator data	<ul> <li>Population under surveillance to which data apply</li> <li>May be stratified by health care sectors</li> </ul>
Contextual information related to antimicrobial consumption	<ul> <li>Data source information; for example, national reference data (total) or health care sector (community or hospital)</li> <li>Which antimicrobials are included in surveillance</li> <li>Specific exclusions of health care institutions (e.g. nursing homes, day care centres, psychiatric facilities and private sector)</li> </ul>

## Steps by step the data collection Procedures

Step-1: Updating the Antimicrobial products in prescribed excel format

- For the collection of AMC surveillance data, DGDA-AMR cell will update the product list and the manufacturer list every year based on the relevant data of AM products. (Until web-based AMC data reporting system developed)
- The distribution data for AMC surveillance will be updated at the product level (proprietary and generic products) and comprise information on the active substance(s) of the product, route of administration, strength per unit, number of units per package and total number of packages consumed.
- Data collection will be facilitated by means of a standard Excel template with functions to calculate volume and consumption for each product.
- Appropriate coding (ATC5) at WHO AMC template will also be populated and/or updated based on Product ID.

Step-2: Communication with the stakeholders

- DGDA will issue an official letter to the manufacturers & relevant stakeholders to provide the antimicrobial distribution data (or donation or import if any). (Annexure -2: Letter Format of AMC Surveillance).
- Export data will not be collected. The antimicrobials available only for veterinary use will only be included when it is necessary.
- DGDA will provide an Excel sheet for each manufacturer/stakeholders to provide the data. This EXCEL sheet will be formulated/updated by using DGDA website database (Annexure-3: Template of Data Collection (in EXCEL sheet) for AMC Surveillance).
- In case of development of Web based AMC data reporting system, the communication with the stakeholders will be facilitated by the IT system.
- Proper monitoring and overall coordination of data collection will be conducted by the AMR cell in collaboration with WHO.

**Step-3:** Preliminary validation and re-communication (if required)

The received data will be thoroughly evaluated for ensuring the harmonized "quantity based on unit" provided by the stakeholder/manufacturer.

- In case of any confusion arise during checking, AMR cell will communicate with the concerned stakeholder to confirm/correct the data or triangulate with other sources of data like IQVIA.
- > The collection of relevant contextual information will also be ensured.

Step-4: Compilation of data and populating WHO AMC template

> The Compiled data will be populated to the latest WHO AMC template.

## **Template for Data Collection**

The WHO AMC Excel template has multiple worksheets for entering:

- data for the main ATC groups and health care sectors and levels per year
- population per year
- consumption data at product level including:
- the list of products
- the consumed number of packages per year, and the health care sectors and levels.

1. Macro	These are embedded routines to assist in data checking and export.
2. Data Availability	for each category of medicine (A07AA, D01BA, J01, J02, J04, J05, P01AB, N04BB) indicate whether the data represent the total, community or hospital consumption
3. Product Data	the key worksheet for data. A separate guidance document is available to provide step-by-step advice on completing this worksheet.
4. Population Data	for each category of medicine (A07AA, D01BA, J01, J02, J04, J05, P01AB, N04BB) indicate population to which the given consumption data apply
5. ATC	list of medicines being monitored, with ATC code and ATC level.
6. DDD	the DDD assigned by the WHO Collaborating Centre with units of measurement (gram, mg, MU)

## Structure of template

7. DDD combination	provides a list of combination medicines that have an approved DDD or
	approved 'unit dose' measurement
8. Conversion	a table of conversion factors from MU to grams (See Annex 4)
9. Units	a description of the units used (See Annex 5)
10. Salts	the specification of salts is only required for hexamine (hippurate or
	mandelate) and where erythromycin data relate to the ethylsuccinate
	salt.
11. RoAs	routes of administration (oral, parenteral, rectal, inhalation powder,
	inhalation solution). (See Annex 6)

## Variables

Variables for antimicrobial medicines register

DGDA has a database of registered drugs in their website (www.dgda.gov.bd) which are publically available. Using this database a list of antimicrobial drugs can be created. The following product-level variables are being used to conduct this AMC surveillance.

Table 2: Product-level data variables for the antimicrobial register

Variable name	Content
COUNTRY	Based on ISO 3166 alpha-3 country codes
PRODUCT_ID	Unique identifier of the medicinal product
	package (MPP).
LABEL	Medicinal product package label
PACKSIZE	Size of the package
PACKSIZE_UNIT	Pack size unit of measurement
PAEDIATRICS_PRODUCT *	Is it a paediatric medicine product
FORM*	Pharmaceutical formulation type
ROUTE_ADMIN	Route of administration
STRENGTH	Quantity of the main ingredient of each
	item
STRENGTH_UNIT	Unit measurement of strength
INBASQ	Basic ingredient quantity

Variable name	Content
INBASQ_UNIT	Unit measurement of the basic ingredient
	quantity
ATC5	WHO ATC code at substance level
	(ATC5-level)
SALT *	Salt of the active substance (hexamine,
	erythromycin only)
COMBINATION	The WHO CC has defined DDD for
	combined products
PRODUCT_NAME *	Medicinal product name
INGREDIENTS *	Ingredient name: e.g. amoxicillin and
	enzyme inhibitor.
PRODUCT_ORIGIN *	The product can be import, donation or
	locally produced.
MANUFACTURER_COUNTRY	The country of the manufacturer of the
	product.
MANUFACTURER *	Name of manufacturer
GENERIC*	Is the product a generic?
CONV_FACTOR (macro)	Transform strength expressed in IU into
	G.
WHO_DDD (macro)	The DDD defined by the WHO CC for the
	ATC code
WHO_DDD_UNIT (macro)	Unit measurement of the WHO DDD
	(MG, G, IU, MU, UD)
DPP (macro)	DDD Per Package

Incorporation of data into WHO\_AMC\_Template\_latest version:

Steps involved in entering data into WHO\_AMC\_Template

- $\checkmark$  Enter the product information
- $\checkmark$  Enter the population information
- ✓ Enter the information about availability of data collected and reported

- ✓ Run the Macros to validate entered data and calculate DDD
- $\checkmark$  Run the Macros to export data into the required format for GLASS submission

Population Data- Denominator data:

ISO Country code (Alpha-3 Code): BGD

Year:

Sector: GLO

Total Population: UN population data will be collected from the following website: https://population.un.org/wpp/Download/Standard/Population/

## **Product Data:**

- ✓ Mandatory data will be required to be inserted (blue color cells), Like: COUNTRY, PRODUCT\_ID, LABEL, PACKSIZE, PACKSIZE\_UNIT, ROUTE\_ADMIN, STRENGTH, STRENGTH\_UNIT, INBASQ, INBASQ\_UNIT, ATC5, SALT, COMBINATION
- ✓ Optional data will be used to collect/gather additional information e.g. generics, marketing authorization holder, country of origin, etc.

Validation of data: Correction of red color indicated data to be done as possible

The details of GLASS-AMC Excel template have been attached in Annex- 6

## **Reporting metrics:**

The standard reporting metric for national estimates is DDDs/1000inhabitants/day (DID). The data collection template requires entry of numbers of packages for each product included in the register. These packages may be summed to give a total number of packages consumed. This will provide a crude estimate of the number of courses of treatment with antimicrobials used per year and is based on the assumption that one package = one course of treatment. This measure needs to be interpreted carefully. In some settings, a package of oral medicine will represent a course of treatment. In other settings, patients may buy small numbers of tablets or capsules or dispensing is from large containers of the medicine, in which case a package will have very little meaning. A package is not likely to be a good guide to a course of treatment with an injectable antimicrobial.

## Data Analysis using the exported AMC Excel files

The export excel file from WHO AMC template will be used for further analysis of DDDs/DIDs. The "GLASS Manual on the management of antimicrobial consumption data" will be followed for step-by-step analysis of the AMC data.

Absolute or relative consumption can be presented as- DDD per 1000 inhabitants per day in total and by:

- by pharmacological subgroup
- by route of administration (mainly oral and parenteral)
- by AWaRe categories (Access, Watch and Reserve)
- by generation
- by geographical region
- by sector (hospital/community, private/public)
- o list of most frequently used substances (comprising 75% or 90% of total consumption)

## **Report Generation:**

The macros of the WHO AMC Template will check the validity of the entered data and finally the consumption data will be exported as Defined Daily Doses (DDD) per 1000 inhabitants per day. The Final report will consist the following results:

a) Total Consumption of Antimicrobials.

Antimicrobial consumption will be expressed in Defined Daily Doses (DDD) per 1000 inhabitants per day.



Output example: National antimicrobial consumption in Bangladesh, 2019-2020

## b) Detail of the Total Consumption of Antimicrobials:

The list of selected antimicrobials, consumption of which will be studied (in alphabetic order), ATC Code and their corresponding consumption will be expressed in DDD/1000 inhabitants per day during the study period.



## c) DID by AWaRe categories.

For an example:



## d) DID by pharmacological subgroup.

For an example:



## c) DID by route of administration (mainly oral and parenteral).

For an example:

Antimicrobial Drugs	DU 75% (Oral)		DU 75% (Parenteral)	
	2020	2019	2020	2019
azithromycin	7.09	6.18		
ceftriaxone			0.31	0.40
cefixime	3.06	3.59		
metronidazole	2.70	2.20	0.039	0.042
doxycycline	2.15	1.73		
ciprofloxacin	1.60	1.84		
cefuroxime		1.45		
flucloxacillin	1.50	1.41		
amoxicillin	1.41			

f) DID of Other Antimicrobials not Mentioned in AWaRe Categorization.

	Consumption of Antimicrobials (DDD			
	per 1000 inhabitants per Day)			
AWaRe Category	2019	2020		
Access	9.08	10.24		
Watch	15.40	14.90		
Reserve	0.06	0.06		
Others	0.21	0.18		

For an example:

- g) DID by sector or geographical region (if required)
- h) List of most consumed or Drug Utilization 75%/90% (DU75 / DU90)
- i) Pattern of Consumption of Antimicrobials by generation

For an example:



j) Any other analysis report as appropriate.

## **Dissemination of data**

Every year AMR cell of DGDA will conduct the AMC surveillance and place the report to the taskforce to monitor AMC/AMU Bangladesh. (Annexure-5: Office order of "AMR Cell" of DGDA).

An expert committee will analyze/evaluate this data. This committee will evaluate the trend of antimicrobial consumption patterns compared with AMR data (collected from IEDCR) and will recommend for decision/policy making. The recommendation of this expert committee will be presented in the Taskforce to monitor AMC/AMU Bangladesh. The Taskforce will finally recommend further required action.

After approval and recommendation of the Taskforce the following action will be taken:

(a) Regulatory action/decision of policy making will be taken by DGDA/DGHS/CDC/IEDCR. On the basis of this recommendation if any regulatory action will be taken that will be presented in the next Task Force meeting. The Concerned department/Ministry will monitor the activity.

(b) The national focal person of AMC surveillance/ the alternet national focal person of AMC surveillance will report to GLASS AMC and publish at national and international level.

(c)The summary report will be published/ reported to GLASS AMC through the GLASS-AMC National Focal or Alternet National Focal.

## Conclusion

Tracking antibiotic consumption within a country is an important component of the national action plan of AMR of Bangladesh. It allows for informed decisions on where to focus efforts to reduce unnecessary use and can assist evaluation of initiatives. Information on antibiotic consumption at the national level is valuable when formulating policies, developing formulary controls, or making decisions on prescribing guidelines or guidelines for prudent use in animals. Consumption data is further useful for benchmarking purposes and comparison between countries/regions/hospitals/farms. So as a National center for AMC surveillance, DGDA will continue the Antimicrobial Consumption Surveillance every year.

## References

- 1. GLASS methodology for surveillance of national antimicrobial consumption.
- 2. Antimicrobial Resistance in the Western Pacific Region: A Review of Surveillance and Health Systems Response.
- 3. GLASS guide for national surveillance systems for monitoring antimicrobial consumption in hospitals.
- 4. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis
- 5. Surveillance and monitoring forantimicrobial use and resistance- IACG discussion paper.
- 6. WHO Report on Surveillance of Antibiotic Consumption: 2016 2018 Early implementation.
- 7. GLASS Manual on the management of antimicrobial consumption data.



## Definition

## Antimicrobials:

Antimicrobials – including antibiotics, antivirals, antifungals and antiparasitics – are medicines used to prevent and treat infections in humans, animals and plants.

## Antimicrobial Resistance (AMR):

Antimicrobial Resistance (AMR) occurs when bacteria, viruses, fungi and parasites change over time and no longer respond to medicines making infections harder to treat and increasing the risk of disease spread, severe illness and death.

As a result of drug resistance, antibiotics and other antimicrobial medicines become ineffective and infections become increasingly difficult or impossible to treat.

## Antimicrobial stewardship

The use of co-ordinated interventions to improve and measure the use of antimicrobials by promoting optimal drug regimen, dose, duration and route are key components of a multi-faceted approach to prevent antimicrobial resistance and limit selection of resistant pathogens.

## AWaRe Classification:

The AWaRe Classification of antibiotics was developed in 2017 by the WHO Expert Committee on Selection and Use of Essential Medicines as a tool to support antibiotic stewardship efforts at local, national and global levels. The AWaRe Classification classifies Antibiotics into three groups, Access, Watch and Reserve, taking into account the impact of different antibiotics and antibiotic classes on antimicrobial resistance, to emphasize the importance of their appropriate use.

## **Broad-spectrum antibiotics**

These are effective against a wide range of bacteria. For example, meropenem is a broad-spectrum antibacterial.

## Carbapenems

Carbapenems are broad-spectrum antibiotics, often used as the last line of treatment for hard to treat human infections caused by Gram-negative bacteria.

## Carbapenemases

These are enzymes produced by bacteria which destroy carbapenems and other beta-lactam antibiotics.

## Cephalosporins

Types of broad-spectrum antibiotics.

## **Cephalosporins – third-generation**

Cephalosporins like cefotaxime and cefixime are particularly active against Gram-negative bacteria.

## Generic (name)

The accepted or official nonproprietary name (not a chemical formula or a brand) by which a medicine is identified.

## Gram-negative bacteria

Those bacteria that do not retain crystal violet dye in the Gram-staining procedure. They can cause many types of infection and include E. coli and Pseudomonas aeruginosa.

## Gram-positive bacteria

These are bacteria that are stained dark blue or violet in the Gram-staining procedure. They include Staphylococcus aureus and Clostridium difficile.

## Multi-drug resistant

Resistance to two or more antibiotics from different classes.

## 'One-Health' approach

Describes a coordinated, collaborative, multi-disciplinary and cross-sectoral work at local, national, and global levels to attain optimal health for people, animals and the environment.

## Pathogen

An infectious agent (bug or germ), a microorganism such as a virus, bacterium, or fungus that causes disease in its host.

## **Consumption data**

Consumption data refer to estimates derived from aggregated data sources such as import or wholesaler data where there is no information available on the patients who are receiving the medicines or why the antimicrobials are being used. These data sources provide a proxy estimate of use of antimicrobials.

Consumption data may be presented as total consumption for a country or may be disaggregated by setting (community or hospital; public or private sectors).

## Antimicrobial use data

Antimicrobial use data refer to estimates derived from patient-level data. These data may allow disaggregation of data based on patient characteristics (gender, age), or indication for which the medicine is being used. Depending on the source of information, it may be possible to determine the patients' symptoms, physician diagnoses and medications ordered. This will facilitate assessment of clinical practice against agreed protocols and treatment guidelines.

## **AMC Surveillance:**

AMC data are estimates derived from aggregated data sources (ranging from macro-level, such as imports, distribution and sales, to micro-level, such as data on prescriptions, dispensing and insurance). Consumption indicates the types and quantities of antimicrobials used in a specific setting over a specific period.

In order to obtain a thorough and comprehensive picture of antimicrobial resistance and to be able to identify areas in which actions are needed, surveillance data are essential. This includes data on antimicrobial resistance and also antimicrobial consumption. Surveillance systems should provide data that can be easily compared, exchanged or used locally, nationally and globally.

#### Annexure-1



Government of the People's Republic of Bangladesh Ministry of Health and Family Welfare Health Services Division Drug Administration-1 Section ...www.hsd.gov.bd



Record Number: 45.00.0000.182.82.001.21.48 Date: 2/2/2022

Recipients: Dr. Bardan Jung Rana, WHO Representative World Health Organization, Country Office for Bangladesh

SubjecNomination of the National Focal Point and Alternative National Focal point for WHO Global Antimicrobial Resistance Surveillance System (GLASS-AMC) reporting.

Ref: 1. WHO South-East Asia memo no- D7/48/1, dated: 10 June, 2019 2. DGDA memo no: DGDA/AMR/2020/90, dated: 27/01/2022.

As per the above mentioned subject, we are happy to know that WHO inviting Bangladesh to enroll in the antimicrobial consumption component of WHO Global Antimicrobial Resistance Surveillance System (GLASS-AMC).

02. In response to the letter of WHO South-East Asia memo no- D7/48/1, date: 10 June, 2019 I am nominating below persons as GLASS-AMC National Focal Point and Alternate National Focal Point as per instruction.

#### National Center for AMC surveillance:

Name of Institution: Directorate General of Drug Administration Address: Aushadh Vaban, Mohakhali, Dhaka-1212. Institutional E-mail: dgda.gov@gmail.com Institution phone: +880222280803

National Focal Point(s) for AMC Surveillance:

#### • National Focal Point:

- Surname: Salahuddin First Name: Md Title: Mr.
- Position: Director (cc)
- Institution: Directorate General of Drug Administration
- E-mail: salahuddin733@yahoo.com
- Telephone: Work: N/A Mobile: +8801711242493
- Alternate National Focal Point:
  - Surname: Yesmin First Name: S. M. Sabrina Title: Ms.
  - Position: Assistant Director
  - Institution: Directorate General of Drug Administration
  - E-mail: sabrinayesmin22@gmail.com
  - Telephone: Work: N/A Mobile: +8801722903474

03. We hope that Bangladesh will work together with WHO regarding capacity building, access to implementation tools and surveillance of Antimicrobial Consumption at National level.

Attachment: Annex-'A'

Yours faithfully,

#### (URTIN)

2-2-2022 Muhammad Mustafizur Rahman Assistant Secretary Phone: 9545462 (Office) Email: drugad 1@hsd.gov.bd

Record Number:

45.00.0000.182.82.001.21.48/1(6)

Date: 2/2/2022

Copy for kind information and necessary action (Not according to seniority): 1) Director General, Directorate General of Drug Administration, Mohakhali, Dhaka.

 Additional Secretary (Drug Administration), Health Service Division, Dhaka.
 PS to Senior Secretary, Health Services Division, Ministry of Health and Family Welfare, Dhaka.

 4) Systems Analyst, Computer Cell, Ministry of Health and Family Welfare, Dhaka (with a request to upload this notification on the Ministry's website)
 5) Dr. Mohamed Ramzy Ismail, Technical Officer-EDM, WHO Country Office for Bangladesh, House: 1/A, Road-8, Gulshan-1, Dhaka.
 6) Office Copy.

#### (UCTOR)

<sup>2-2-2022</sup> Muhammad Mustafizur Rahman Assistant Secretary

## **Annexure-2** Letter Format of AMC Surveillance.

### Government of the People's Republic of Bangladesh Directorate General of Drug Administration Aushodh Vaban Mohakhali, Dhaka-1212, Bangladesh

Memo No: DGDA/AMR-1/2020/

.....

Date:

To: M/S.....

#### Subject: To provide distribution statement of antibiotic for Antimicrobial Consumption Surveillance (AMC) for the Year ......

According to the above subject this is to inform you that Antimicrobial use is one of the main drivers of antimicrobial resistance (AMR); hence, surveillance and optimal use of antimicrobial medicines are among the key strategies to combat AMR. There is an urgent need for mechanisms to monitor antimicrobial consumption (AMC).

In this regard you are requested to submit your antibiotic locally distribution (excluding export data) statement (for the Year ......) as per the provided XL-sheet to your e-mail.

Please send the antibiotic distribution statement within ..... to the following e-mail:

.....

<u>Attachments:</u> 1. XL-sheet (send by e-mail). 2. Product List,

> Signature Director General Directorate General of Drug Administration Cont: 02222280803 e-mail: dgda.gov@gmail.com Date: .....

Memo No: DGDA/AMR-1/2020/ Attention:

- 1. Chairperson, the task force to monitor AMC/AMU Bangladesh.
- 2. Focal/ Alternet focal of AMC surveillance in Bangladesh.
- 2. Technical Officer-Essential Drugs and Medicines, WHO, Bangladesh country office.
- 3. Others (if required).

Director General Directorate General of Drug Administration

## Annexure-3 Template of Data Collection (in EXCEL sheet) for AMC Surveillance

The template of data collection (in EXCEL sheet) for AMC Surveillance will be contained the following variables:

Name of the Manufacturer
Production Unit (if any)
Brand Name
Generic Name
DAR
Strength
Dosage Description
Route of admin
Pack Size
Pack Size (unit)
Year Jan-Jun (pcs) Jul-Dec (pcs)





## Annexure-5 Office order of "AMR Cell" of DGDA

