

DGDA-AMR BULLETIN

November 2022 | Issue-1

Directorate General of Drug Administration



Mr. Zahid Maleque MP
Minister
Ministry of Health and
Family Welfare

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AMR has turned into a major global health issue. Community awareness on AMR, continuous AMR surveillance encompassing human health, animal health and environment, IPC systems of the hospitals and animal farms need to be strengthened. Political will is very crucial in combating this complex issue of AMR.



Dr. Md. Anwar Hossain Howlader
Secretary
Health Services Division
Ministry of Health and
Family Welfare

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The main reasons for AMR are - poor infection control in hospitals and clinics, irrational use of antimicrobial drugs in human and veterinary, lack of people's awareness regarding AMR. So, we need to strengthen the health system, increase our testing capacity and community awareness. To control AMR, dose-based antibiotic packaging can be considered.



Major General Mohammad Yousuf
Director General
Directorate General of Drug
Administration

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AMR is increasing not only because of the irrational use of antimicrobials in humans but also in animals. We have established the Antimicrobial Consumption Surveillance in Bangladesh. We have taken policy decisions to increase public awareness and reduce self medication. Every antibiotic package will be incorporated with a "red identification mark".



Her Excellency Sheikh Hasina, Honourable Prime Minister of Bangladesh

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.

22 September, 2022, the Global Leaders Group co-chair, Her Excellency Sheikh Hasina Prime Minister of Bangladesh said, "Urgent action is required to stop the spread of antimicrobial resistance. Without action, we face a future where we will be unable to treat infections in humans, animals and plants. We must work together to protect our medicines". Mr. Zahid Maleque, MP, Honourable Minister, Ministry of Health and Family Welfare, Bangladesh was also present in the meeting.

source: [https://www.who.int/news/item/22-09-2022-the-global-leaders-group-host-side-event-at-un-general-assembly-on-antimicrobial-resistance-\(amr\)](https://www.who.int/news/item/22-09-2022-the-global-leaders-group-host-side-event-at-un-general-assembly-on-antimicrobial-resistance-(amr))

The Global Leaders Group hosted side event at UN General Assembly on AMR



Directorate General of Drug Administration (DGDA) is the National Regulatory Authority of Medical Products in Bangladesh. DGDA regulates the human and veterinary medicines in Bangladesh. DGDA is the National focal of Antimicrobial Consumption (AMC) and Antimicrobial Use (AMU) surveillance in Bangladesh. As a regulatory authority to combat AMR DGDA focuses on Regulation, Surveillance, Awareness, Monitoring, Post Marketing Surveillance and Pharmacovigilance.

Third Global High-Level Ministerial Conference on Antimicrobial Resistance

H.E. Mr. Zahid Maleque, MP, Hon'ble Minister for Health and Family Welfare led a Bangladesh delegation to Third Global High-Level Ministerial Conference on Antimicrobial Resistance held in Muscat on 24-25 November 2022. The conference agreed the Muscat Ministerial Manifesto, which sets out the three global targets:

- Reduce the total amount of antimicrobials used in agrifood systems by at least 30-50% by 2030, galvanizing national and global efforts.
- Preserve critically important antimicrobials for human medicine, ending the use of medically important antimicrobials for growth promotion in animals.
- Ensure 'Access' group antibiotics (a category of antibiotics that are affordable, safe and have a low AMR risk) represent at least 60% of overall antibiotic consumption in humans by 2030.

DGDA has already taken some initiatives of these agenda, Like:

- (a) Directorate General of Drug Administration has banned the following antimicrobial drugs in veterinary use due to importance in human treatment.

7. 23 combination of Access Group:

SL No	Generic Name
1.	Amoxicillin 1.25 gm + Cloxacillin 1.25 gm/vial Injection
2.	Amoxicillin Trihydrate 10% + Bromhexine Hydrochloride 2% + Vitamin A 500000 IU/KG Powder
3.	Doxycycline 1 gm + Oxytetracycline 2 gm Powder



Third Global High-level Ministerial Conference on Antimicrobial Resistance (AMR)

1. All dosage form of Colistin,
2. Fosfomycin,
3. All combination of Ciprofloxacin,
4. Azithromycin,
5. Amoxicillin Trihydrate+Bromhexine Hydrochloride+Vitamin A,
6. Amoxicillin Trihydrate + Cyproheptadine Hydrochloride + Guaiphenes + Lysozyme Hydrochloride + Vitamin A,

SL No	Generic Name
4.	Doxycycline 1 gm + Oxytetracycline 2 gm/100 gm Powder
5.	Doxycycline 10% + Neomycin Sulphate 10% Powder
6.	Doxycycline 10% + Oxytetracycline 20% Powder
7.	Doxycycline 10% + Tylosin 20% Powder
8.	Doxycycline 100 mg + Trimethoprim 100 mg/gm Powder
9.	Doxycycline 100 mg + Tylosin 200 mg Sachet
10.	Doxycycline 150 mg + Neomycin Sulphate 150 mg/gm Powder
11.	Doxycycline 20 gm + Tylosin 23 gm/100 gm Powder
12.	Doxycycline Hydrochloride 10% + Gentamicin 10% Powder
13.	Gentamicin 2.5% + Neomycin Sulphate 20% Powder
14.	Gentamicin 3 gm + Sulphadimidine 12.5 gm + Trimethoprim 2.5 gm/100 ml Injection
15.	Neomycin Sulphate 5% + Procaine Penicillin 8.3333% Ointment
16.	Oxyclozanide 1.4 gm + Tetracycline Hydrochloride 2 gm Bolus
17.	Procaine Benzylpenicillin 4 Lac IU + Streptomycin 500 mg/vial Injection
18.	Streptomycin 250 mg + Sulfadiazine 1.583 gm + Sulfadimidine 1.583 gm + Sulfapyridine 1.583 gm Bolus
19.	Streptomycin 250 mg + Sulphadiazine 1.583 gm + Sulphadimidine 1.583 gm + Sulphapyridine 1.583 gm Bolus
20.	Streptomycin 313 mg + Sulfadiazine 1.583 gm + Sulfadimidine 1.583 gm + Sulfapyridine 1.583 gm Bolus
21.	Sulfaclozine 300 mg + Vitamin K 20 mg/gm Powder
22.	Sulphachloropyridazine Sodium 100 mg + Trimethoprim 20 mg + Vitamin K .8 mg/gm Powder
23.	Amoxicillin Trihydrate 5% + Cyproheptadine Hydrochloride 1% + Guaiphenesin 3.5% + Lysozyme Hydrochloride 1% + Vitamin A 2500% Powder

8. 05 combination of WATCH Group:

SL No	Generic Name
1.	Ciprofloxacin 20 gm + Trimethoprim 50 gm Sachet
2.	Erythromycin 50 mg + Sulphadimethoxine Sodium 125 mg + Trimethoprim 25 mg/ml Injection
3.	Guaiphenesin 1.8% + Roxithromycin 1% + Tylosin 1% Powder
4.	Kanamycin 10000 IU/gm + Rofaxanide 2% Powder
5.	Loperamide 1 gm + Norfloxacin 25 gm + Trimethoprim 25 gm + Zinc Oxide 20 gm/KG Oral Powder

(b) Surveillance

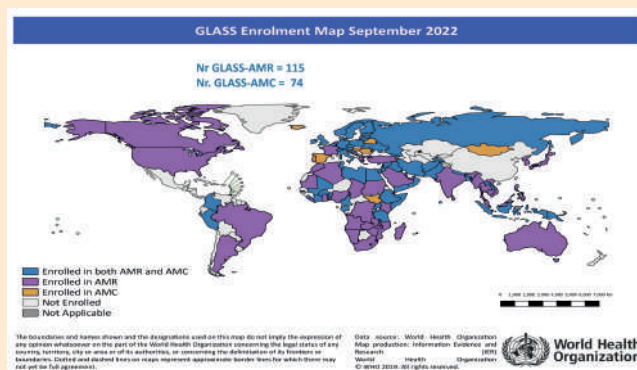
The National Centre for Antimicrobial Consumption (AMC) surveillance in Bangladesh:

As the National Centre for Antimicrobial Consumption (AMC) surveillance in Bangladesh, DGDA is conducting the Antimicrobial Consumption (AMC) surveillance from 2015 to 2021. DGDA has been enrolled in the WHO-GLASS AMC platform in 2022.

Utilization of National AMC surveillance data:

1. Provides the standard national consumption pattern of Antimicrobials which can be compared nationally, regionally and globally.
2. Data on antimicrobial consumption provide an important basis for countries to better understand the patterns and amount of antibiotics used at the national level, which can inform policies, regulations, and interventions to optimize the use of antibiotics.
3. Provides comparison of consumption in different level of ATC groups, AWaRe class or dosage form. It enables identifying the intervention areas to align the standard level of consumption per thousand population based on the National Action Plan and Global target percentage of consumption.
4. AMC surveillance data compared with lab surveillance data enables policy makers to identify the intervention areas of health system to ensure antimicrobial stewardship and implementation of standard treatment guidelines at all levels of health facilities.
5. AMC data can also indicate the pattern of use/overuse/under use of antimicrobials which indicates the over access/limited access to the lifesaving antimicrobials and provides an insight of necessary requirement to enforce prescription-only policy.
6. AMC surveillance data enables policy makers to intervene into the Essential medicines selection process for public procurement system.
7. With the Drug utilization data, policy makers can identify the highly consumed antimicrobials that are contributing 75% of total national consumption and can provide the policy decisions to increase/reduce the consumption. Also provides a sign of choice of antimicrobials by physicians and can be compared with other factors of AMR for the formulation of intervention/policy decision for the containment of AMR.

From the AMC surveillance report it is observed that the antimicrobial drug consumption trend is increasing in Bangladesh.



The highest consumed (Drug Utilization 75%) antimicrobial drugs in oral formulation are (AMC surveillance report-2020):

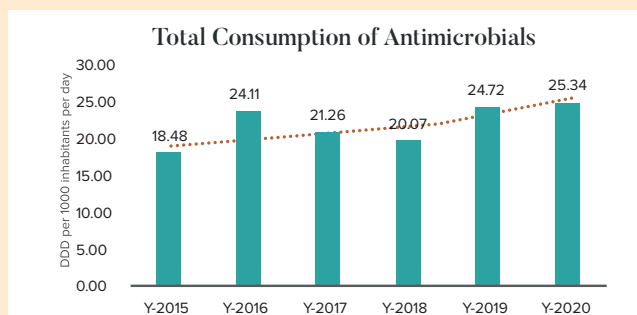
- Azithromycin - Watch Category
- Cefixime - Watch Category
- Ciprofloxacin - Watch Category
- Flucloxacillin - Access Category
- Amoxicillin - Access Category
- Metronidazole - Access Category
- Doxycycline - Access Category

Drug Utilization 75% for parenteral formulation are (AMC surveillance report-2020):

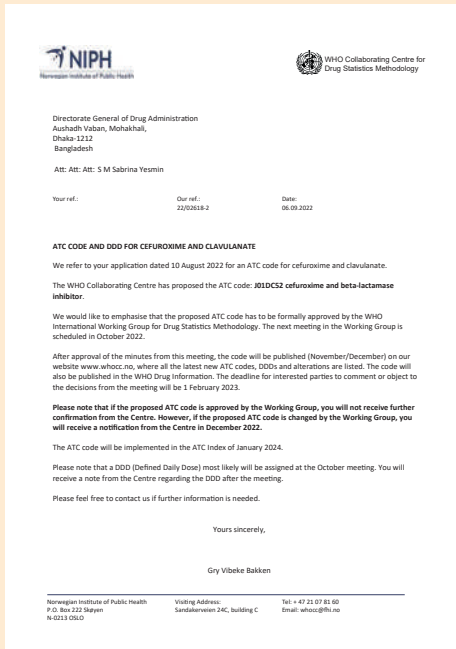
- Ceftriaxone - Watch Category
- Metronidazole - Access Category

In Bangladesh, WATCH category antimicrobial consumption is higher than the ACCESS category. From the AMC surveillance report 2015-2020, consumption of ACCESS category antimicrobial drugs is 38 to 42% in Bangladesh.

From the Drug Utilization 75% data it has been noticed that one of the main reasons for high WATCH category antibiotics consumption is the higher consumption of Azithromycin, Cefixime, Ciprofloxacin in oral dosage form and Ceftriaxone in parenteral dosage form.



- (c) There are some AMs drugs which do not have ATC code and DDD. Like: Cefuroxime and Clavulanate (beta-lactamase inhibitors) (combination). So DGDA has applied to the WHO Collaborating Centre for Drug Statistics Methodology (WHOC) for ATC code and DDD of Cefuroxime and Clavulanate (beta-lactamase inhibitors)



(combination). In the latest meeting of the WHO International Working Group for Drug Statistics Methodology held in October, 2022 has decided a temporary ATC code (J01DC52) and temporary DDDs (0.5 g) for cefuroxime and beta-lactamase inhibitors.

- (d) DGDA is trying to establish the Antimicrobial Use surveillance in hospitals and Antimicrobial Consumption Surveillance in veterinary use in Bangladesh.

On 14 September, 2022 DGDA conducted a consultative meeting to establish AMU surveillance in Bangladesh supported by Fleming Fund.



Consultative meeting to establish AMU surveillance in Bangladesh

Awareness

From January to August, 2022 DGDA has conducted



Distribution of advocacy materials

794 advocacy workshops all over the country.



Advocacy workshop in Lama Bandarban

Post Marketing Surveillance

To ensure the quality of antimicrobial drugs DGDA conducted the post marketing surveillance. DGDA has established 08 (eight) minilab in 08 (eight) divisions for primary identification of falsified/ substandard medicine.

After primary identification the sample is sent to the National Control Laboratory, DGDA for detailed test and analysis.

The taskforce to monitor AMC/AMU in Bangladesh

The meeting of the taskforce to monitor AMC/AMU in Bangladesh was held on 12 June, 2022. The taskforce recommended the following issues:

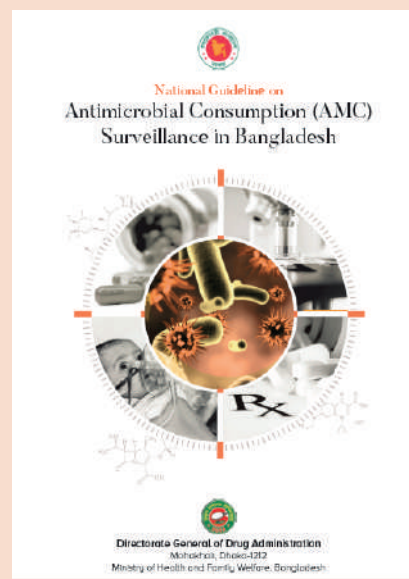
1. We need some action to reduce the consumption of antimicrobial drugs in Bangladesh.
2. Antimicrobial Use surveillance needs to be established in this country.
3. Need to conduct Antimicrobial Consumption Surveillance for veterinary.
4. Essential medicine list needs to be updated.
5. Need mass awareness program for the antibiotic packaging “red label” campaign and after the implementation an impact analysis is required.



Meeting of the taskforce to monitor AMC/AMU Bangladesh

In this taskforce meeting the National Guideline on Antimicrobial Consumption Surveillance in Bangladesh has been approved. This guideline was developed under the Fleming Fund Fellowship program and the technical support from WHO.

This guideline has been approved by the Ministry of Health and Family Welfare and has been published in the Gazette.



National Guideline on Antimicrobial Consumption (AMC) Surveillance in Bangladesh has been added at WHO international website in the below link:

<https://www.who.int/bangladesh/about-us/publications-1>

Evidence to Policy Decision

To curb the antimicrobial resistance, the National Centre for Antimicrobial Consumption Surveillance of the Directorate General of Drug Administration (DGDA) conducted the surveillance since 2015. One of the findings reported that the national consumption of antimicrobial drugs in Bangladesh is increasing and highlighted some irrational use, such as the use of Watch category antibiotics consumption is higher than the Access category.

In collaboration with WHO Bangladesh, DGDA (through Fleming Fund Fellowship program for AMC/AMU surveillance funded by Mott MacDonald) conducted a baseline survey on the level of awareness about antimicrobials and their impacts on self-medication in 8 divisions of Bangladesh on November and December 2021. Among the 427 pharmacy retailers that were surveyed, identified as having the poor knowledge of antimicrobial drugs, which resulted in the acts of dispensing antibiotics without prescription from registered physicians.

Further, DGDA (through Fleming Fund Fellowship program for AMC/AMU surveillance funded by Mott MacDonald) and WHO Bangladesh conducted key informant interviews on rapid situation analysis of present labelling of antibiotics in Bangladesh and preferences of label change patterns for incorporation of identification marks on antimicrobial products.



DGDA presented the findings of these two studies in a meeting with the members of Bangladesh Association of Pharmaceutical Industries and they have agreed to incorporate a red identification mark with the text “Antibiotic” and the message “Do not use without prescription of registered physician” in every packaging materials of antibiotics. This decision has also been endorsed by the 253rd meeting of the Drug Control Committee.

On 04 October 2022 in a coordination meeting on AMR, the Honorable Health Minister of Bangladesh said to the media “Antibiotic packaging will be red in color for easy identification. At the same time, there is a law to prevent arbitrary use of antibiotics”.



Baseline survey on level of awareness about antimicrobials & AMR and its impacts on self medication in Bangladesh



Meeting with Bangladesh Association of Pharmaceutical Industries (BAPI)



DCC 253 rd Meeting

Monitoring from the Ministry of Health and Family Welfare, Bangladesh

A meeting was convened under the chairmanship of honourable Health Minister, MOHFW Mr. Zahid Maleque, MP to prevent the arbitrary use of antibiotics in humans and animals for health protection on 04 October, 2022. Many issues have been discussed in this meeting. Like: Prohibit sale of antimicrobial drugs without a prescription

by law and take strict enforcement measures, a comprehensive policy on prescription, purchase and use of antibiotics should be formulated, need to stop any kind of aggressive policy of antibiotic sales and marketing by pharmaceutical companies, public awareness should be created widely etc.



AMR meeting in the Ministry of Health and Family Welfare



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