

USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTAPS) PROGRAM

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A pharmacist at a Duka La Dawa Muhimu pharmacy, Tanzania, Photo credit: Michael Paydos

Introducing the WHO Antibiotics Categorization in Tanzania

Technical Brief | May 2023 | Tanzania

Using the WHO AWaRe Categorization as a Tool for Optimizing Antimicrobial Use

Background

Misuse and overuse of antimicrobial medicines drive the development of drug-resistant microbes. As drug resistance spreads, common infections increasingly require longer and more costly treatment—if they can be treated at all. Controlling antimicrobial resistance (AMR) is especially difficult in low- and middle-income countries, where antibiotics are more likely to be dispensed without prescription and the lab resources to test for drug susceptibility are more limited.

The US Agency for International Development (USAID) is working to address the threat of AMR in low- and middle-income countries through the Global Health Security Agenda (GHSA), an international effort which brings together more than 70 countries and

nongovernmental partners to collectively achieve the vision of a world safe and secure from global health threats posed by infectious diseases. The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2025) is a key implementer in USAID’s support for the GHSA vision. To help achieve this vision, since 2019, MTaPS has supported Tanzania in implementing consolidated multisectoral (One Health) coordination, strengthened infection prevention and control (IPC) practices, and optimized use of antimicrobials to prevent and contain AMR.

Problem Statement

A situational analysis conducted by the Global Antimicrobial Resistance Partnership (GARP) in 2015 highlighted significant overuse and misuse of antimicrobials in Tanzania. This is due in part to rampant inappropriate prescription of antibiotics, often without establishment of an infection needing antibiotics.¹ A study of antimicrobial use in Tanzania from 2017–2019 using the World Health Organization (WHO) defined daily dose (DDD) methodology revealed overall consumption of 80 DDD/1,000 population/day (D), which is significantly higher than the rates in the EU (18.4 DDD/1,000/D; 2018), Japan (14.1 DDD/1,000/D; 2004–2016), and China (9.1 DDD/1,000/D; 2017).² Although the country's standard treatment guidelines (STG) and National Essential Medicines List (NEMLIT) had guidance in place for categorization of antibiotics to help regulate their use, the categories were based on the levels of health facilities and did not align with WHO guidance. Since the classification was not based on epidemiological data and resistance and sensitivity of prevalent germs to antibiotics—locally or in neighboring countries—it had posed a challenge to clinicians who prescribe antibiotics without clear evidence of their effectiveness relative to local sensitivity data.

Technical Approach

Developed by the WHO in 2017 as a simple approach to enhance antimicrobial stewardship (AMS), the Access, Watch, and Reserve (AWaRe) categorization classifies antibiotics included in a country's essential medicines list (EML) into three categories. The Access category consists of antibiotics of choice for each of the 25 most common infections—these drugs should be always available for prescription, affordable, and of assured quality and are expected to account for at least 60% of antibiotics consumed in the country. The Watch category includes most of the “highest-priority, critically important antimicrobials” for human and veterinary use and are recommended only for specific, limited

indications. Reserve antibiotics should only be used as a last resort for selected serious situations.

Stakeholder Engagement

In supporting the development and implementation of the AWaRe categorization of antibiotics, MTaPS collaborates with the WHO, PATH, the Food and Agriculture Organization of the United Nations (FAO), the Ministry of Health (MOH) and its Pharmaceuticals Services Unit (PSU), the Antimicrobial Stewardship (AMS) Technical Working Group (TWG) under the National AMR Multisectoral Coordinating Committee (MCC), the National Medicines and Therapeutic Committee (NMTC), and the 10 health care facilities supported by MTaPS.

Intervention

In helping Tanzania to optimize the use of antimicrobial medicines, MTaPS worked in close collaboration with the AMS TWG to support the MOH to curb AMR through the introduction of the AWaRe categorization. To do so, MTaPS supported establishment of the foundation for introduction of the AWaRe categorization of antibiotics, development of an AWaRe categorization for Tanzania, integration of the AWaRe categorization into the STG/NEMLIT, and training on and dissemination of STG/NEMLIT in selected health facilities.

Establishing National-Level AMS Governance Structures to Support AMS, including AWaRe Implementation

MTaPS supported the MOH and other key partners in strengthening the National AMR Multisectoral Coordinating Committee as a national-level governance body for AMR. The National Committee includes IPC and AMS TWGs. The AMS TWG serves as the national partner for all AMS activities, including developing AWaRe categories, integrating them into key AMS documents, and facilitating AWaRe implementation at the facility level. MTaPS supported the development of the terms of reference for the IPC TWG, supported

¹ GARP–Tanzania working group. 2015. Situation analysis and recommendations; antibiotic use and resistance in Tanzania.

² Mbwas Romuald, Mapunjo Siana, Wittenauer Rachel, et al. National Consumption of Antimicrobials in Tanzania: 2017–2019. *Frontiers in Pharmacology*, Volume 11, 2020. <https://www.frontiersin.org/articles/10.3389/fphar.2020.585553>. DOI=10.3389/fphar.2020.585553.

regular quarterly meetings of IPC and AMS TWGs as well as MCC meetings, advocated for change of leadership of the AMS TWG and for more sectors to be included in the membership e.g. environmental, aquatic and the private sector. The multisectoral AMS policy guidelines were also developed to guide oversight of AMS implementation in all sectors by the MCC.

Generating Local Evidence to Support and Inform AMS/AWaRe

MTaPS supported point prevalence surveys (PPS) using the WHO methodology at six supported facilities. The PPS was used to collect information on prescribing practices of antibiotics and other information relevant to treatment and management of infectious diseases in hospitalization units, and supported Tanzania's first national antimicrobial consumption analysis (2017–2019) using the WHO anatomical therapeutic chemical classification/defined daily dose (ATC/DDD) method.

Developing AWaRe Categories

A five-day workshop in August 2020 brought together representatives of the MOH, the President's Office–Regional Administration and Local Government (PORALG), the NMTC, and health care facilities to develop the AWaRe categorization for Tanzania. The WHO and the PSU presented detailed information on the AWaRe categorization and STG/NEMLIT. Participants took part in a virtual capacity-building session on AWaRe led by the WHO. Following the steps outlined in the “Technical guide to implementing the World Health Organization's AWaRe antibiotic classification in MTAps Program countries,” MTAps supported participants in analyzing the country's epidemiological profile. Using data from the PPS and antimicrobial consumption analysis, participants identified prevalent infectious disease syndromes, sensitivity profiles of causal microbes to antibiotics, and availability of commonly used antibiotics (in the WHO Access category).

Participants then developed an AWaRe categorization for Tanzania using the above analysis. The group set criteria for each of the three categories (Access, Watch, and Reserve) based on WHO guidance and country considerations. Using WHO AWaRe classification

document, the WHO Model List of Essential Medicines, WHO report on the Selection and Use of Essential Medicines, and country data for guidance, participants grouped all the antibiotics on the NEMLIT into the three categories. The group provided justification for any antibiotics which were included in the Tanzania NEMLIT but not in the model WHO EML and those which the group decided to categorize in an AWaRe category that differed from that in the WHO model classification.

MTaPS supported the MOH in further refining the categorization and brought partners back together in a second workshop to finalize and validate the document. Thereafter, MTAps provided technical support to the MOH to revise the national STG and NEMLIT in accordance with the AWaRe categorization. MTAps also provided support to the medical therapeutic committees (MTCs) to oversee and monitor antibiotic use to ensure adherence to guidelines.

Fostering Adherence to the AWaRe Categorization Guidelines in Health Facilities

MTaPS supported the MOH and the AMS TWG in implementing the AWaRe categorization in selected health facilities as follows:

- Facilitated the launch and dissemination of the updated STGs and NEMLIT to all health facilities in the country in both electronic format and hard copy.
- Helped revitalize the hospital-based MTCs in the 10 supported facilities. This was done by engaging MTC members and training them on ethical dispensing and prescribing as well as on the development of hospital formularies and proper use of the STG/NEMLIT.
- Helped establish AMS subcommittees under the MTCs to serve as the facility-level partners for AWaRe implementation.
- Supported capacity building and mentoring on AWaRe/STG/NEMLIT through the following activities:
 - Orientation for health workers in 10 hospitals on AWaRe/STG/NEMLIT, training



AMS assessors review drug procurement against STG/NEMLIT protocol and AWARe categorization of antibiotics at Maweni Regional Referral Hospital (Kigoma Region), June 2022. Photo credit: Fundi Mabula, Maweni Hospital

approximately 11 health care workers from each facility on AWARe categorizations and use of the STG/NEMLIT to guide prescription practices.

- Joint supportive supervision visits to each of the 10 hospitals with MOH and technical experts, followed by monthly remote mentoring sessions with the 10 facilities.
- Training for MTCs in MTaPS-supported facilities on continuous quality improvement (CQI) in the context of STG/NEMLIT, and supported MTCs in using the CQI tools for STG/NEMLIT implementation.
- A meeting of the 10 hospitals to discuss and share experiences on AMS implementation based on their planned AMS activities, along with challenges, mitigation, and way forward.
- Supported development of a hospital formulary template and distributed it to all hospitals, accompanied by an MOH directive—for which MTaPS had advocated—calling for all tertiary-level hospitals to develop their individual hospital formularies before the end of the 2021–22 financial year.

- Assisted the MOH in developing an AMS monitoring framework (which includes AWARe) and adapting this framework to align with the WHO AMS Practical Toolkit.³

Results and Achievements

“Restriction of some antibiotics as per AWARe and as per the NHIF catalogue has reduced overuse of antibiotics; for example, cefixime tablets pack of 10: in 2019, 5,390 were used; [in] 2020, 2,000 [were used], [and in] 2021, 450.”

—Davance Leonard, Pharmacist, Mbeya Zonal Hospital

With commitment and leadership from the MOH and support from MTaPS, the AWARe categorization was developed and integrated into the national STGs and NEMLIT. These documents were distributed to all facilities, and the 10 MTaPS-supported hospitals have all drafted their own hospital formularies based on the AWARe categorization. Furthermore, the other 31 tertiary-level hospitals in the country have begun the process of developing their own formularies. More health care workers continue to be sensitized to AMR

³ WHO. 2019. Antimicrobial stewardship programs in health-care facilities in low- and middle-income countries: A WHO practical toolkit. ISBN 978-92-4-151548-1. Available from: <https://apps.who.int/iris/bitstream/handle/10665/329404/9789241515481-eng.pdf>

issues and have internalized the reasoning behind the AWARe categories. In MTaPS-supported facilities, pharmacists increasingly refuse to dispense antibiotics in the Watch and Reserve categories without appropriate backup documentation from the prescribing physician. For example, in prescription audits carried out in 2021 and 2022, Sekou Toure Hospital, a public tertiary care facility, demonstrated improved adherence to AWARe categorization (figure 1).

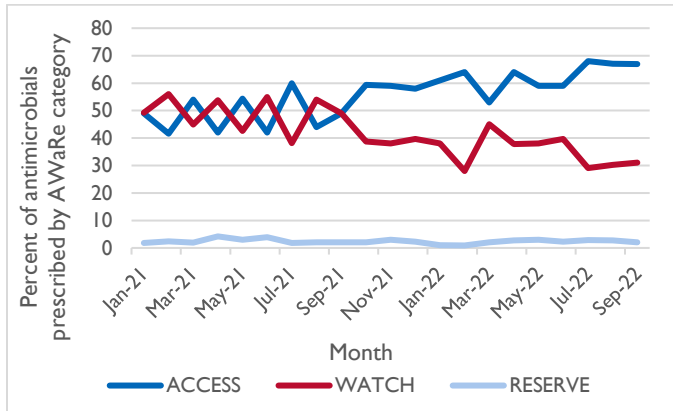


Figure 1. Sekou Toure Regional Referral Hospital, prescription audit 2021–2022

Some of the secondary and tertiary level facilities developed antibiograms within the AWARe categorization to pinpoint susceptibility of particular microorganisms to different antimicrobials.

Lessons Learned

Dedicated governance structures enhance uptake of new approaches. MTaPS struggled in its initial attempts to introduce activities to optimize the use of antimicrobial medicines before strong AMR/AMS governance structures were in place. By the time MTaPS began its collaboration with the MOH on AWARe, the multisectoral coordination committee on AMR was in place. MTaPS was able to work with the MCC to establish the National Antimicrobial Stewardship (AMS) TWG, which then took on the role of promoting AWARe categorization throughout the country.

Using local data increases acceptability and ownership. At the national level, antibiotics sensitivity testing results presented by the AMS TWG were key to informing the grouping of medications into the AWARe categories. At the facility level, the PPS methodology-

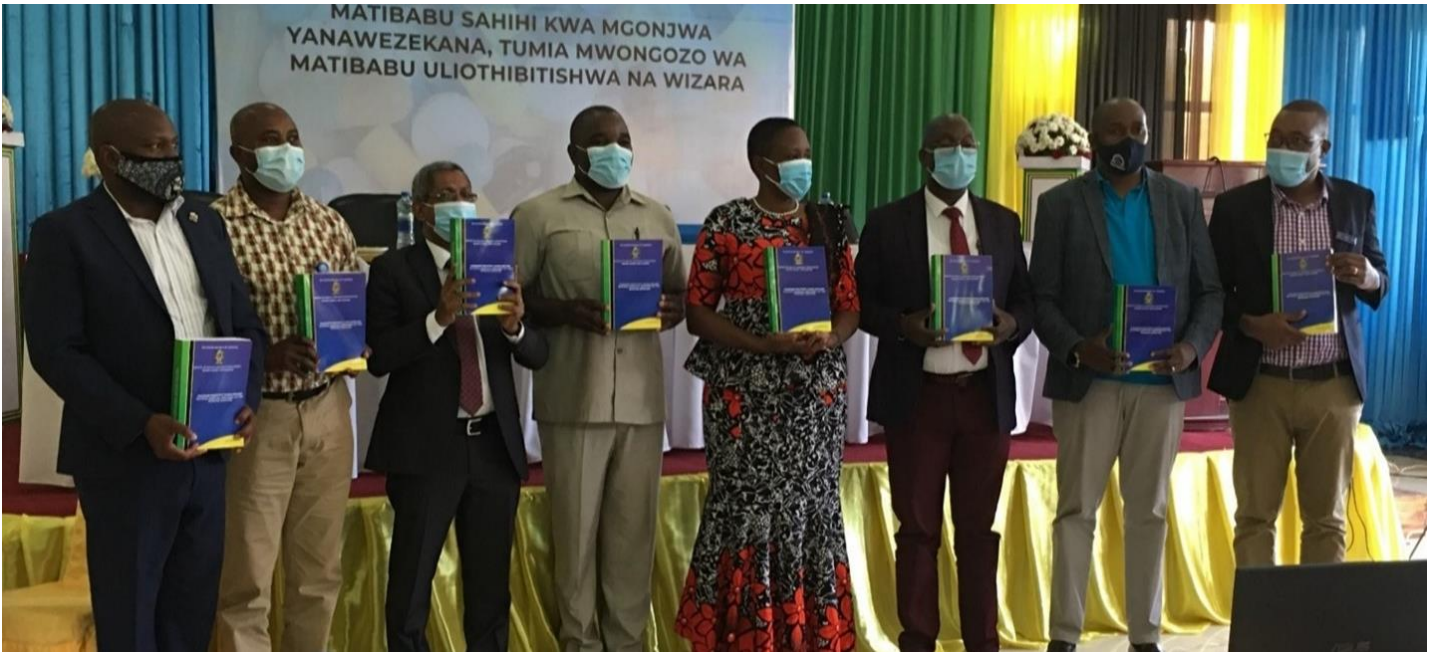
based antimicrobial use studies supported by MTaPS in six hospitals demonstrated to the facilities the rampant and inappropriate use of antibiotics and played an important role in convincing health care workers of the importance of adherence to the STGs/AWARe categorization.

“We are really thankful to the MTaPS project for providing technical and financial support for the activity on AWARe categorization of antibiotics. We specifically appreciate the technical support extended to us because our knowledge on the subject was limited, and we would have never been able to kick start and implement this activity without their support.”

—Ms. Siana Mapunjo, AMR focal person from the Ministry of Health

Developing the AWARe categories in line with availability and accessibility of antibiotics in the country facilitates implementation. All antibiotics included in the Access category must be accessible, i.e., authorized for use, in the country and available based on the country’s current supply chain. The Access category should include first- and second-choice antibiotics for common conditions. The Watch category needs to include easy-access antibiotics that can be used as alternatives if the first- and second-choice antibiotics fail. The Reserve category should include antibiotics used to treat syndromes only in very special cases, including more expensive antibiotics, newer-generation antibiotics, and the most toxic classes that require close monitoring through pharmacovigilance during treatment. In practice, this meant that the Tanzania NEMLIT included 54 antibiotics, while the WHO model EML has 39 antibiotics; after discussion and justification based on data, Tanzania placed seven antibiotics in a different AWARe category than that in the WHO global AWARe classification.

Timing the AWARe categorization to coincide with the national schedule for the revision of AMS documents (NEMLIT and STG) enables easy integration of the categories into these documents. If AWARe categorization is undertaken as the country is going through a standard revision of their EML or STG, AWARe can be integrated into the



MOH officials, WHO representative, and heads of hospitals participate in the launch of the revised STG/NEMLIT on June 25, 2021. Photo Credit: Stephano Simba, MTaPS

document through the revision process. If the national EML or STG has recently been revised without AWARe groupings, AWARe categorization guidance can be circulated separately as an addendum. In the case of Tanzania, the national STG was already scheduled for revision immediately after the AWARe categorization was carried out, and AWARe was integrated simultaneously into both the STG and the NEMLIT (EML).

An organized facility-level AMS program fosters implementation of AWARe categorization. In Tanzania, MTaPS provided technical assistance to health facilities to develop and implement a CQI approach within the MTCs in its supported health facilities. This helped ensure that providers followed the STG/NEMLIT.

Embedding new programs into existing structures helps them take root. Any program including AWARe needs to be entrenched in and implemented through the existing structures and through national documents to foster sustainable compliance. In Tanzania, the National Health Insurance Fund (NHIF) reimburses providers only for services provided in accordance with the STGs. By embedding the AWARe categorization into the national STGs, MTaPS helped ensure AWARe rollout to facilities countrywide.

“A key component. . . was that the National Health Insurance Fund [pays based on] the standard treatment guidelines. . . you cannot be reimbursed if you go outside this treatment guideline, if your prescription is not in the standard treatment guidelines. So, this forces people at the health facility to make sure that they are adhering to the STG and by doing that they have to adhere also to the AWARe categorization.”

—Talhiya Yahya, Senior Technical Advisor, MTaPS Tanzania

Careful selection of partner facilities contributes to implementation success and sustainability. MTaPS chose regional-level or referral hospitals which have human resources, laboratories, etc., to implement AMS activities. Lower-level facilities that lack this basic capacity might not have been able to succeed fully. This was important in demonstrating the potential for success of AWARe implementation. Approaches can and should be scaled up for further rollout of AMS activities to other facilities, including ones that may lack these resources. These approaches may include involving the ministry responsible for primary health care facilities—PORALG—in the national AMR governance structures and in trainings on AMS, establishing primary AMS committees in the primary health facilities, and adapting

the guidelines to be relevant to the primary health care level.

Pathway to Sustainability

With MTaPS' support, Tanzania has adapted and adopted the AWARe categorization and is implementing AWARe as part of its multipronged strategy to contain AMR. MTaPS provided Tanzania partners with AWARe tools and competencies by introducing the AWARe concept, training stakeholders at both the national and facility level, and supporting development of an AWARe categorization tailored to the country situation. Thanks to the support of key national leadership, Tanzania's AWARe categorization is integrated into the country's STGs and NEMLIT. Embedding the AWARe categorization in the STGs—which the NHIF uses to determine provider payment—means that health care facilities need to align their prescribing practices with the AWARe categorizations. Facilities have demonstrated ownership of AWARe approaches, even developing their own methodology to track AWARe adherence at the facility level. By launching its facility-level AWARe activities in region-level hospitals/referral hospitals, which have adequate resources to implement AMS activities, MTaPS established successful, sustainable models of AWARe implementation that can be adapted and rolled out to additional facilities. Further institutionalization of AWARe across all facilities will require mobilizing domestic financing, codifying clear roles and responsibilities for implementation and monitoring, and continued building of technical capacity at the facility level.

Conclusions

With MTaPS' support, Tanzania has made significant strides in introducing AWARe for optimizing use of antimicrobial medicines toward improved containment of AMR. Over the remainder of program implementation, MTaPS will help the country solidify these gains through further training for health workers to build their capacity in AMS and through facilitating targeted studies to generate further data to support active implementation of AMS at the facility level. To facilitate rollout of AWARe to all health facilities in the country, the government of Tanzania needs to undertake some longer-term actions. Some of these actions include infrastructure strengthening, to ensure

that all facilities have access to labs for susceptibility testing; establishment of a robust monitoring system for antibiotics in the AWARe categories; integration of AWARe into pre-service and continuing medical education; and development of an AWARe information package that the government can use to disseminate AWARe to facilities. Furthermore, AWARe will need to be introduced in private health facilities and in the animal health sector.

References

- Africa CDC. Extension for Community Healthcare Outcomes (ECHO). <https://africacdc.org/programme/public-health-information-systems/extension-for-community-healthcare-outcomes-echo> (accessed on January 23, 2023).
- Alombah F, Ndinda K, Fikiri J, Yahya T, et al. Integration of the WHO Antibiotics AWARe Categorization in National Antimicrobial Stewardship Programs: Experiences from MTaPS-Supported Countries (presentation). MTaPS. November 7, 2022. <https://www.mtapsprogram.org/our-resources/integration-of-the-who-antibiotics-aware-categorization-in-national-antimicrobial-stewardship-programs-experiences-from-mtaps-supported-countries/>.
- Global Antibiotic Resistance Partnership—Tanzania Working Group. 2015. Situation Analysis and Recommendations: Antibiotic Use and Resistance in Tanzania. Washington, DC and New Delhi: Center for Disease Dynamics, Economics & Policy. https://onehealthtrust.org/wp-content/uploads/2017/08/garp-tanzania_sa.pdf.
- MTaPS. A Technical Guide to Implementing the World Health Organization's AWARe Antibiotic Classification in MTaPS Program Countries. https://www.mtapsprogram.org/wp-content/uploads/2021/03/USAID-MTaPS_Implementing-WHO-AWARe-Classification.pdf.

MTaPS. A Technical Guide to Implementing Facility-Level Antimicrobial Stewardship Programs in MTAps Program Countries. <https://www.mtapsprogram.org/wp-content/uploads/2021/03/USAID-MTaPS-Mini-guide-for-facility-AMS-program.pdf>.

MTaPS. New Findings from Tanzania's 3-year National Antimicrobial Consumption Analysis. November 5, 2020. <https://www.mtapsprogram.org/our-resources/new-findings-from-tanzanias-3-year-national-antimicrobial-consumption-analysis>.

MTaPS. Tanzania Implements AWaRe Classification to Improve the Use of Antibiotics by Clinicians. May 25, 2021. <https://www.mtapsprogram.org/news-blog/tanzania-implements-aware-classification-to-improve-the-use-of-antibiotics-by-clinicians/>.

World Health Organization. Access, Watch, Reserve (AWaRe) classification of antibiotics for evaluation and monitoring of use, 2021. Geneva: World Health Organization; 2021 (WHO/MHP/HPS/NEMLIT/2021.04). License: CC BY-NC-SA 3.0 IGO. <https://www.who.int/publications/i/item/2021-aware-classification>.

Mbwasi R, Mapunjo S, Wittenauer R, Valimba R, et al. National Consumption of Antimicrobials in Tanzania: 2017–2019. *Front Pharmacol*. 2020 Oct 30. Volume 11. <https://doi.org/10.3389/fphar.2020.585553>.



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The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2025) enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to better health outcomes and higher-performing health systems. The program is implemented by a consortium of global and local partners, led by Management Sciences for Health (MSH), a global health nonprofit.

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