

CROSS BUREAU SUMMARY REPORT

About USAID MTaPS

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

Learn more at https://www.mtapsprogram.org/

INTRODUCTION

The USAID MTaPS program enables low- and middle-income countries (LMICs) to strengthen their pharmaceutical systems, which are critical for ensuring access to and appropriate use of safe, effective, quality-assured, affordable medicines, vaccines, health technologies and products, and related pharmaceutical services to improve health. MTaPS' objectives are to (1) strengthen pharmaceutical-sector governance; (2) increase institutional and human resource capacity for pharmaceutical management and services, including regulation of medical products; (3) increase availability and use of pharmaceutical information for decision making and advance the global learning agenda; (4) optimize pharmaceutical-sector financing, including resource allocation and use; and (5) improve pharmaceutical services, including product availability and patient-centered care, to achieve desired health outcomes.

USAID Office of Health Systems (OHS) works across the Bureau for Global Health's programs and is responsible for technical leadership and direction in health system strengthening, enabling countries to address complex health challenges and protect against extreme poverty. MTaPS uses OHS Cross Bureau funds to identify innovative strategies and tools to advance USAID's technical leadership in pharmaceutical systems strengthening (PSS) and improve equitable access to and appropriate use of medical products and pharmaceutical services.

CHALLENGE

Sustainably ensuring equitable access to and appropriate use of safe, effective, quality-assured, affordable medical products and pharmaceutical services requires strong, resilient pharmaceutical systems. MTaPS implemented Cross Bureau activities at the global level to develop technical leadership resources to guide global and national stakeholders in their efforts to sustainably strengthen pharmaceutical systems. With Cross Bureau activities, MTaPS supported OHS' technical leadership role in setting USAID's direction in health systems strengthening.



STRATEGIC APPROACH

Through the Cross Bureau portfolio, MTaPS works to develop evidence-based approaches and tools and identify best practices in PSS, which contribute to addressing emerging health problems. MTaPS collaborates with regional and global stakeholders to shape the norms and discourse on pharmaceutical systems and to coordinate efforts at identifying and promoting best practices. The resources, tools, and best practices developed by this effort are intended to be adopted and applied at the regional and/or country level in LMICs. Ultimately, Cross Bureau activities demonstrate and advance technical leadership in PSS, in line with the overall program goal and five technical objectives.

KEY RESULTS



Pharmaceutical-sector governance strengthened

- Study conducted, including case studies of Côte d'Ivoire, Kenya, and Nepal, to define the landscape of national pharmaceutical services units to inform the development of guidelines on the structure, mandate, role, and responsibilities of these units. These guidelines will help strengthen the units' capacity to serve as effective stewards of national pharmaceutical systems.
- Monitoring and evaluation tool validated and finalized for the performance of African Medicines Regulatory Harmonization (AMRH) Regional Centers of Regulatory Excellence, which has allowed these centers to monitor their performance.
- Advocacy undertaken, contributing to the creation of the African Medicines Agency (AMA) for improved regulation of medical products in Africa.

Institutional and human resource capacity for pharmaceutical management and services increased, including regulation of medical products

Through its continued engagement with the African Union Development Agency's New Partnership for Africa's Development (AUDA-NEPAD), MTaPS contributed to the strengthening of medical product regulation on the African continent. Key achievements include the following:

- Minimum common standards developed for regulatory information management systems for adoption in LMICs; advocacy brief and guidance for a pathway to digitalization developed to help promote the standards and encourage national regulatory authorities (NRAs) to adopt them. By adopting these standards, NRAs will be able to streamline workflows and regulatory processes, ensure uniform data capture, and enable data exchange within and among NRAs and other stakeholders who support regulatory convergence and harmonization efforts.
- Reliance framework developed and implemented in collaboration with the AMRH secretariat and the Gates Foundation. The framework between the East African Community and Intergovernmental Authority on Development regional economic regions will facilitate regulatory reliance between the two regions and is expected to ultimately form part of the AMA operationalization efforts.

Availability and use of pharmaceutical information for decision making increased and global learning agenda advanced

MTaPS advanced the global PSS learning agenda through several efforts, as follows:

- PSS Insight v2.0 developed. This indicator-based monitoring tool measures progress in strengthening components of national pharmaceutical systems when implemented over time. The tool relies on validated indicators and existing data collection mechanisms, hence providing governments with a low-cost tool to support their journey to more resilient pharmaceutical systems.
- PSS 101 course designed and rolled out. This one-module course on the basic principles of PSS, including how addressing pharmaceutical system problems helps advance universal health coverage;

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on medical products pricing
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Virtual East Africa and Southeast Asia regional workshops were held with 160 and 60 participants, respectively, increasing local institutions' understanding of available MTaPS PSS resources and how to best use these products in their working context.



As of June 2024, there have been over **77,000** unique views across the 24 papers.

combat antimicrobial resistance, HIV/AIDS, malaria, and TB; and promote maternal and child health. The course is available via USAID University and the Global Health Learning Platform (GHeL). As of July 2024, 112 USAID staff and 1,577 global participants have earned certificates through USAID and the GHeL, respectively.

- Good Governance course revised and made available on the GHeL. A total of 1,028 participants earned course certificates between October 2022 and July 2024.
- PSS skills building conducted through two peer-to-peer learning exchanges, three regional workshops, and four workshops at global conferences.
 - Learning exchanges resulted in engagement with 29 participants from 17 countries on medical product pricing strategies and with 36 participants from 16 countries on prevention and management of conflicts of interest in national pharmaceutical systems.
 - Virtual East Africa and Southeast Asia regional workshops with 160 and 60
 participants, respectively, increasing local institutions' understanding of available MTaPS
 PSS resources and how to best use these products in their working context.
 - Regional workshop targeting Francophone Africa contributed to over 180 representatives from local organizations learning about PSS resources and increased potential for their adoption in Francophone countries.
- Over 170 global conference abstracts submitted as of June 2024 and 24 peer-reviewed journal articles published, demonstrating technical leadership in various areas of PSS. As of June 2024, there have been over 77,000 unique views across 24 publications.

Pharmaceutical-sector financing, including resource allocation and use, optimized

Health technology assessment (HTA) is a "multidisciplinary process that aims to determine the value of a health technology and to inform guidance on how these technologies can be used in health systems around the world" [1]. MTaPS demonstrated technical leadership in HTA through several accomplishments, including the following:

- Practical Guide for Systematic Priority Setting and HTA Introduction in LMICs developed and launched. The policy and guideline document serves as a roadmap that provides a stepwise approach for HTA implementation.
- Evidence-based framework for the institutionalization of HTA in Ethiopia developed with MTaPS support. This led to a business plan canvas tool for HTA advancement and a published paper on HTA institutionalization in Ethiopia [2].
- Approach for tracking pharmaceutical expenditure using the Systems for Health Accounts 2011 framework developed in collaboration with the USAID Local Health Systems Sustainability project. The approach has since been used in both Benin and Burkina Faso to improve the accuracy of estimating pharmaceutical expenditure tracking.



Pharmaceutical services, including product availability and patient-centered care, to achieve health outcomes improved

- Web-based platform for improving pharmacovigilance (PV) systems in the region developed and launched in collaboration with the West African Health Organization (WAHO) and the 15 Economic Community of West African States (ECOWAS) member states.
- The platform will allow member states to share PV data, support the strengthening of PV systems in the region, and improve the safety of pharmaceutical services. The successful launch of the platform and its handover to ECOWAS countries and WAHO took place in April 2022.
- Set of behavioral nudges developed in collaboration with Deloitte. MTaPS tested the effectiveness of the nudges in reducing the frequency of antibiotic prescribing among a sample of clinicians in MTaPS-supported facilities in Uganda. The study will provide critical insight into the feasibility of using behavioral nudges as one strategy for antimicrobial resistance containment in LMIC settings.



PEER-REVIEWED PUBLICATIONS

- Embrey M, Mbwasi R, Shekalaghe E, et al. National Health Insurance Fund's relationship to retail drug outlets: a Tanzania case study. J Pharm Policy Pract. 2021;14:21. Available at: https://doi.org/10.1186/s40545-021-00303-0.
- Guzman J, Hafner T, Maiga LA, et al. COVID-19 vaccines pricing policy options for low-income and middle-income countries. BMJ Global Health. 2021;6:e005347. Available at: http://dx.doi.org/10.1136/bmjgh-2021-005347.
- Guzman J, O'Connell E, Kikule K, et al. The WHO Global Benchmarking Tool: a game changer for strengthening national regulatory capacity. BMJ Global Health. 2020;5:e003181. Available at: https://gh.bmj.com/content/5/8/e003181.
- Hafner T, Banda M, Kohler J, et al. Integrating pharmaceutical systems strengthening in the current global health scenario: three 'uncomfortable truths.' J Pharm Policy Pract. 2020;13:38. Available at: https://doi.org/10.1186/s40545-020-00242-2.
- Joshi MP, Alombah F, Konduri N, et al. Moving from assessments to implementation: promising practices for strengthening multisectoral antimicrobial resistance containment capacity. One Health Outlook. 2023;5(1):7. Available at: https://doi.org/10.1186/s42522-023-00081-6.
- Joshi MP, Hafner T, Twesigye G, et al. Strengthening multisectoral coordination on antimicrobial resistance: a landscape analysis of efforts in 11 countries. J Pharm Policy Pract. 2021;14:27. Available at: https://doi.org/10.1186/s40545-021-00309-8.
- Suharlim C, Kumar R, Salim J et al. Exploring facilitators and barriers to introducing health technology assessment: a systematic review. Int J Technol Assess Health Care. 2022;38(1):E5. Available at: https://dx.doi.org/10.1017/ S0266462321000623.
- Twesigye G, Hafner T, Guzman J. Making the investment case for national regulatory authorities. J Pharm Policy Pract. 2021;14:16. Available at: https://doi.org/10.1186/s40545-021-00299-7.



Strengthening multisectoral coordination on antimicrobial resistance: a landscape analysis of efforts in 11 countries.

Joshi MP, Hafner T, Twesigye G, et al. J Pharm Policy Pract. 2021:14:27.

Available at:

https://joppp.biomedcentral. com/articles/10.1186/s40545-021-00309-8

FUTURE CONSIDERATIONS

- Support advancement of the PSS learning agenda, with continued focus on access and appropriate use as outcomes of the pharmaceutical system, with clarity on the linkages and distinctions between supply chain management and PSS.
- The PSS Insight tool and its indicators should be incorporated into national pharmaceutical structures and documents (i.e., monitoring and evaluation plans, strategic plans, key performance indicators) and be explicitly linked to pharmaceutical system decision-making processes and implemented regularly.
- Foster the establishment of national units tasked with coordinating across pharmaceutical system stakeholders and empowered to collect and manage data that may not be routinely shared outside each reporting agency. This will facilitate adoption of the PSS Insight tool.
- Invest in capacity development for pharmaceutical system data collection, analysis, and use (with existing indicators and tools). This can help reinforce the cycle of data demand and use to ensure that system-level data are available and being actively used to inform decision making. It will also help ensure the adoption and sustainability of existing tools.
- Engagement with various stakeholders throughout the life of the program has demonstrated the need to continue clarifying the concepts of pharmaceutical systems and PSS to ensure that supply chain management is situated in the context of strong pharmaceutical systems.
- Harmonization of medical product regulations takes time, so it is important to work with willing partners and regional networks that can serve as champions and help to sustain efforts beyond the life of the program.



FEATURED RESOURCES

Tools

- PSS Insight v2.0 (https://www. mtapsprogram.org/our-resources/ pss-insight-v2-0-a-frameworkand-indicators-for-measuringpharmaceutical-systemsstrengthening/)
- Pharmadex/OpenRIMS (<u>https://www.openrims.org/</u>)

E-learning courses

- PSS 101 (https://www.globalhealthlearning.org/course/
 pharmaceutical-systems-strengthening-101)
- Good Governance (https://www. globalhealthlearning.org/course/ good-governance-managementmedicines)

Other resources

- Approaches and tools for strengthening pharmaceutical systems (https://www.mtapsprogram. org/our-resources/approachesand-tools-for-strengtheningpharmaceutical-systems/; https:// www.mtapsprogram.org/ news-blog/approches-et-outilspour-renforcer-les-systemespharmaceutiques/)
- A roadmap for systematic priority setting and health technology assessment (https://www. mtapsprogram.org/our-resources/ a-roadmap-for-systemic-prioritysetting-and-health-technologyassessment-hta-2/)
- Pharmaceutical expenditure tracking in Benin (https://www.mtapsprogram.org/our-resources/policy-brief-pharmaceutical-expenditure-tracking-in-benin-2020-data/) and Burkina Faso (https://www.mtapsprogram.org/our-resources/policy-brief-pharmaceutical-expenditure-tracking-in-burkina-faso-2018-data/)
- Adopting minimum common standards for regulatory information management systems (https://www.mtapsprogram.org/ our-resources/adopting-minimumcommon-standards-for-regulatoryinformation-management-systems/)
- Advancing equitable access to quality pharmacy services in the private sector through retail drug outlets (https://www.mtapsprogram.org/news-blog/usaid-mtaps-webinar-series-retail-drug-outlets-in-lmics-unlocking-their-potential-for-equitable-access-to-quality-healthcare-services/)

Good Governance in the Management of Medicines



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- 1. WHO. Health technology assessment. Available at: https://www.who.int/health-topics/health-technology-assessment#tab=tab 1.
- 2. Erku D, Walker D, Caruso AA, et al. Institutionalizing health technology assessment in Ethiopia: seizing the window of opportunity. Int J Technol Assess Health Care. 2023;39(1):e49. Available at: https://doi.org/10.1017/S0266462323000454.

RECOMMENDED CITATION

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