USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program

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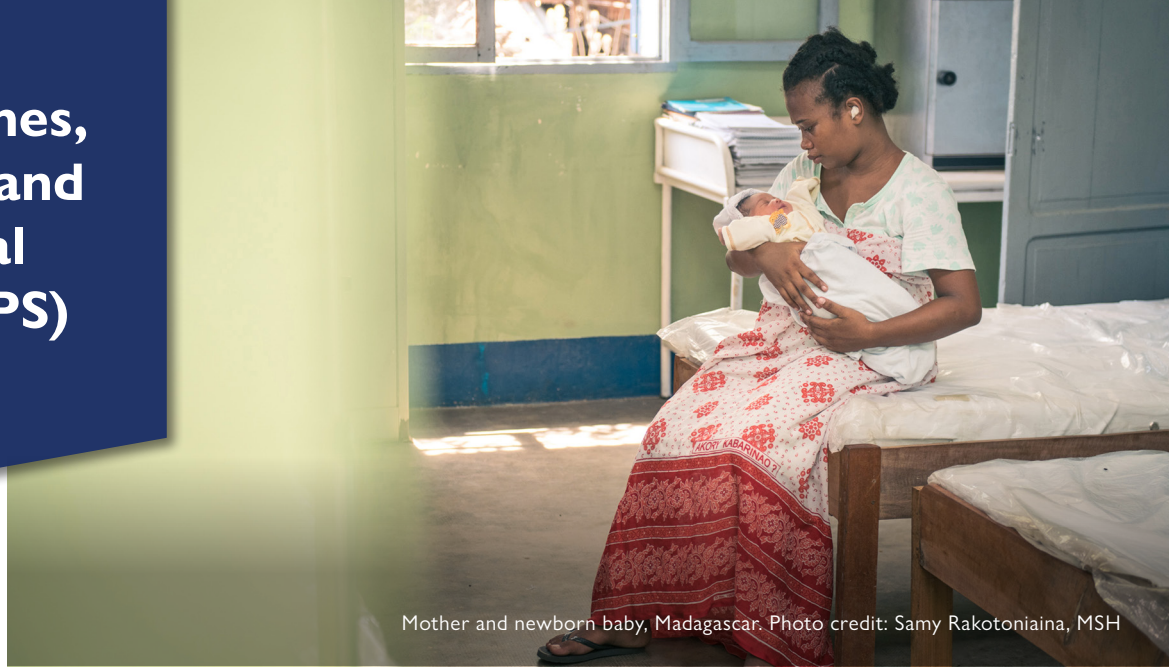

Mother and newborn baby, Madagascar. Photo credit: Samy Rakotoniaina, MSH

MATERNAL, NEWBORN, AND CHILD HEALTH (MNCH) 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 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. MTaPS employs a pharmaceutical systems strengthening (PSS) approach to identify and implement strategies and actions that achieve coordinated and sustainable improvements of a pharmaceutical system to make it more responsive and resilient for achieving better health outcomes.

The goal of the MTaPS maternal, newborn, and child health (MNCH) core-funded portfolio is to ensure the availability and appropriate use of safe, effective, and quality-assured medical products, as well as effective pharmaceutical services to ultimately reduce maternal, newborn, and child mortality by strengthening pharmaceutical systems.

CHALLENGE

Every year, more than 5 million children under age 5 and 200,000 women across the globe succumb to largely preventable causes.[1] While progress has been made in reducing maternal and child mortality rates, few countries met the 2015

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Millennium Development Goals. Achieving the more ambitious Sustainable Development Goals (SDGs) for maternal, newborn, and child mortality targets requires a systems strengthening approach. Currently, over 50 countries are off track. However, the preventive and curative measures for the major causes of maternal, newborn, and child deaths are well-established. A significant number of these deaths could be prevented with enhanced access to quality medicines and supplies, as well as skilled health care providers, for women and children.

USAID renewed its commitment to ending preventable maternal and child deaths in 2023, releasing *Preventing Child and Maternal Deaths: A Framework for Action in a Changing World, 2023-2030*, in which it set forth ambitious targets for reduced child and mortality rates and increased coverage levels of lifesaving interventions.[2] USAID's strategy is to improve the coverage, quality, and equity of health interventions that can save millions of lives. However, lifesaving MNCH medicines, equipment, and supplies are often left off country agendas, and policy and systems factors that facilitate their access are often not in place.

Inefficient regulatory processes and lack of guidelines and procedures negatively impact access to safe, efficacious, and quality-assured MNCH medical products. The slow uptake of global recommendations, procurement in insufficient quantities to reach primary care settings, and weaknesses in distribution, among other factors, result in barriers to access and appropriate use of lifesaving MNCH medicines.

Without reliable access to quality medical products—such as oxytocin for postpartum hemorrhage, antibiotics and oxygen for childhood pneumonia, and oral rehydration solution and zinc for childhood diarrhea—preventable deaths will continue.

STRATEGIC APPROACH

Achieving SDG 3 (ensure healthy lives and promote well-being for all at all ages) targets 3.1 and 3.2 for maternal, newborn, and child mortality necessitates a holistic approach that goes beyond ensuring product availability. Over the life of the project, MTaPS has specifically worked at the global, regional, and country levels, focusing on overcoming barriers that impede access to and appropriate use of safe, effective, affordable, and quality-assured MNCH medical products (medicines and medical devices) and pharmaceutical services, thereby reducing maternal, newborn, and child mortality. This is achieved through a systems approach of improving governance, strengthening human resource capacity for management of medical products, increasing the availability and use of information for decision-making, optimizing financing management of medical products, and improving pharmaceutical services and the availability of medicines, technologies, and supplies.

MTaPS' core funded MNCH portfolio highlighted the importance of MNCH medical products and services, mapping gaps and weaknesses in the pharmaceutical system, raising awareness of the barriers to their access, and providing technical assistance to reduce these barriers at the global, regional, and country levels. This was achieved through developing and disseminating global technical leadership documents, engaging in technical discussions with MNCH groups at the global level, and implementing key interventions to improve access to quality MNCH medical products in selected regions such as the Southern African Development Community (SADC) and specific countries (e.g., DRC, Nepal, and Rwanda) as an example for other countries. Specifically, the portfolio targeted interventions in civil society engagement, regulation, forecasting and supply planning, procurement, quality assurance, and adherence to lifesaving treatments such as antibiotics for pneumonia.

KEY ACHIEVEMENTS

MTaPS has a key role to provide global technical leadership in PSS for MNCH, and as such has produced a total of 14 technical documents as resources to orient partners and country stakeholders in various PSS approaches they can apply to improve MNCH outcomes.

Objective 1: Pharmaceutical-sector governance increased

Stakeholder engagement and empowerment, including civil society and consumers, increased for access to medicines, technologies, and supplies for women, newborns, and children

- Discussion paper developed on engaging civil society in social accountability to improve access to and appropriate use of safe, effective, and quality-assured MNCH medical products and services. This paper was the subject of a knowledge exchange held with the Momentum suite of projects, and other flagship USAID MNCH projects, to encourage more considered actions involving civil society to improve medicine availability and use, or even to apply to other areas of health care delivery to priority populations.
  - A primer developed on the key messages and action points in the discussion paper was shared with USAID missions and partner organizations to facilitate their application by non-governmental organizations and governments.
- The key actions highlighted in the document to engage civil society through social accountability to increase access to essential services, including medical products, include:
  - Map and analyze the **accountability ecosystem** before designing social accountability interventions
  - Diagnose the problem area's **capacities, gaps, and bottlenecks**
  - Design and implement **strategic social accountability** interventions with multiple tactics geared to the characteristics of specific accountability ecosystems and build capacity and mobilize users of services
  - Design and implement **vertically integrated** interventions that act at different levels of the health system
  - Engage and form coalitions with a broad set of stakeholders **beyond policymakers** such as journalists and health activists

Objective 2: Institutional and human resource capacity for pharmaceutical management and services, including regulation of MNCH products, strengthened

Regulatory system for registration of MNCH medical products improved

- Mapped challenges in registering MNCH medical products and status of registration of MNCH medicines in nine countries to inform interventions for support according to USAID's priorities.[3]
- Held a regional knowledge exchange with 33 regulators from 12 of 16 countries of the SADC member states and selected manufacturers of MNCH medicines, focused on the optimization of MNCH medical product registration. Emphasis was placed on addressing challenges related to regional regulatory harmonization, obstacles in MNCH medical product registration, and implementing mitigation strategies, and resulted in an advocacy document for national medicines regulatory authorities to prioritize registration of MNCH medicines.
  - The document underscores the crucial role of regulatory stakeholders and issues a call to action to prioritize registration of MNCH medicines in their countries and was shared as a resource with regulators in the SADC region and from across the continent through the African Medicines Regulatory Harmonization Initiative.

After highlighting challenges in registration of MNCH medicines in a mapping in 9 LMICs, **8 MTaPS supported countries to enhance registration procedures and the SADC** (with 16 member states) **to streamline registration of MNCH medicines**

Supported AMDF to build capacity in **regulation of MNCH medical devices** through development and dissemination of guidance in a webinar of **42 participants** from **17 African national regulatory authorities** and its use in **building capacity of 22 medical devices assessors** from **10 national regulatory authorities**

- Conducted an in-person regional special session of joint review of four maternal health medicines with the SADC/ZAZIBONA collaborative platform. The primary objectives were to facilitate their registration in individual countries within the region and enhance the technical capabilities of participating countries regarding registration of MNCH medical products.
- Supported the African Medical Devices Forum (AMDF), a subgroup of AUDA-NEPAD, to develop a resource document on specific considerations for strengthening regulation of MNCH medical devices to ensure their quality, safety, and effectiveness on the continent.
  - The resource is publicly available on AUDA-NEPAD's website and was disseminated in a virtual continental orientation held in August 2023.[4] It was also used as a resource to guide an in-person capacity building session on regulation of MNCH medical devices held in Dar es Salaam, Tanzania, in November 2023, during which 22 medical device assessors from 10 countries discussed best practices in regulating medical devices and reviewed technical files of 3 medical devices used in MNCH care.
- MTaPS supported Tanzania Medicines and Medical Devices Authority to position themselves as a potential regional center of excellence for medical devices regulation through an exchange visit of two staff to the Saudi Arabia Food and Drug Authority and through supporting them to host three medical device assessors from three African countries to build their capacity in medical devices regulation, especially for MNCH.

Objective 3: Availability and use of pharmaceutical information of MNCH medicines for decision-making increased and global learning agenda advanced

PSS global learning agenda advanced for MNCH

- MTaPS developed a microlearning seminar series that addresses the importance of PSS for women's and children's health outcomes. The series is part of the global PSS learning agenda and is included in the PSS 101 e-Learning course.[5]

Support to GFF on management of medicines

- As a result of MTaPS support, the country focal points and country teams of the Global Financing Facility (GFF) have resources (guidance documents on managing medicines and quality in procurement and webinars) on management of medicines and supplies and the importance of prioritizing a robust pharmaceutical system to support MNCH interventions. A section on medicines was included in the GFF annual report.
- MTaPS helped to resolve stock-outs in essential medicines, including those for MNCH in Liberia by supporting the Ministry of Health (MOH) and the World Bank Performance-Based Financing team in Liberia to establish a framework agreement (FA) for county procurement of specific MNCH medicines and supplies from approved wholesalers when the Central Medical Stores are unable to supply them. The FA allows counties implementing PBF to ensure availability of quality medicines and is expected to be rolled out nationwide.

Subnational procurement of MNCH medicines

Recognizing that in many countries procurement of essential medicines, including MNCH medicines, is conducted at subnational levels with potentially limited capacity to assess quality and ensure affordability, MTaPS developed a set of resources:

- Global guidance document on best practices in subnational procurement of MNCH commodities in the public sector, disseminated in December 2023 to around 120 attendees at a virtual workshop.

- Technical brief on subnational procurement practices in Liberia, Nigeria, and Tanzania, highlighting key areas to consider to ensure the quality of products procured.[6]

Objective 5: Pharmaceutical services for women, newborns, and children—including product availability and patient-centered care—improved

Availability of essential medicines, supplies, and other health technologies for MNCH improved

- MTaPS updated the 2016 document Quantification of Health Commodities: RMNCH Supplement Forecasting Consumption of Select Reproductive, Maternal, Newborn, and Child Health Medical Products. This revision was crucial, including both best practices for the quantification of reproductive MNCH (RMNCH) medical products and recent evidence—including new WHO and country-specific guidelines and data—for countries to develop a more robust forecast which directly affects product availability and the potential to save the lives of women, newborns, and children.
  - The revised RMNCH forecasting supplement, available in English and French, was disseminated through a series of webinars to more than 160 people and at least 13 country teams have used the supplement. Notably, it is referenced in the recent Global Fund (GF) guidance to countries to consider inclusion of non-malaria integrated community case management (iCCM) commodities in their GF proposals. In addition, the flow charts of assumptions from the RMNCH forecasting supplement have been integrated into the Quantification Analytics Tool developed by Global Health Supply Chain - Procurement and Supply Management (GHSC-PSM) for global use.
- To assist countries in incorporating non-malaria iCCM commodities in their GF funding requests, MTaPS developed Excel-based quantification tools adapted from the forecasting guide to facilitate estimation of needs and to help countries complete the tables for the GF funding request. MTaPS supported six countries to consider including non-malaria iCCM commodities in their GF funding request, of which three did include non-malaria commodities.

Updated RMNCH **forecasting guidance** shared with over **160 people,** through a series of webinars, has been used in more than **13 countries,** and is also routinely used by **implementing partners in their support** to country quantification exercises

Supported **6 countries** to consider **non-malaria iCCM commodities** in their **GF funding requests**

Pharmaceutical services for women and children improved

Access to and appropriate use of amoxicillin is still problematic in many countries despite the efforts of governments and partners under the UN Commission on Life-Saving Commodities.

- After a series of consultative meetings with wide stakeholder engagement, MTaPS developed a call-to-action paper addressing key bottlenecks in access to and appropriate use of amoxicillin and gentamicin, in collaboration with UNICEF, USAID, USAID GHSC-PSM, and USAID Promoting the Quality of Medicines Plus.[7]
  - The paper was disseminated at the community health worker symposium in Liberia, at the second Global Pneumonia Forum in Madrid, and at the International Maternal and Newborn Health Conference in Cape Town to drive action at the country level as part of Child Survival Action and was used in one country to stimulate dialogue and develop an action plan to improve access to amoxicillin.
- To promote adherence to correct treatment protocols for amoxicillin dispersible tablets (used for treating pneumonia in children under five and in combination with gentamicin for treating possible serious bacterial infections in newborns), MTaPS updated a set of job aids and dispensing envelopes for health care providers and caregivers, previously developed by partners under the UN Commission for Life Saving Commodities, which are available on the MTaPS and Child Health taskforce websites.

Developed a **call-to-action paper to drive action** to improve access to and **use of amoxicillin and save children's lives**—shared widely in 3 global forums, to over 10 USAID missions and participants from **23 countries, 29 organizations,** and **utilized in 1 country**

Oxygen is a key part of pneumonia management, and while there has been much investment in improving availability of medical oxygen since the COVID-19 pandemic, less focus has been on quality.

- MTaPS has developed and disseminated a technical resource document for the quality assurance of medical oxygen throughout the distribution chain, from sourcing to patient delivery. This resource will inform actions to address the identified gap and complement other operational guidance that WHO is developing.
  - The resource was virtually disseminated to over 230 people from 42 countries with panelists who are champions of oxygen from across Africa, reflecting on measures to improve quality of medical oxygen, and was also presented to participants from 62 members states and 69 partners at the WHO "National Oxygen Scale-Up Framework: Road to Oxygen Access" meeting in Dakar, Senegal.
- MTaPS supported the Rwanda Biomedical Center to review their quality assurance practices for medical oxygen management at two facilities and analyze the findings to generate a framework for improving quality assurance of medical oxygen, which was incorporated in the national strategic plan for sustainable oxygen systems.[8] Collaboration with global health organizations CHAI, PATH, and UNICEF to implement the resource in the countries they support is being explored.

Shared **new resource on quality assurance practices** for **access to medical oxygen** in a virtual workshop **with over 230 people** (mostly from LMICs) and led to **development of a quality assurance framework in Rwanda**

Key Country Achievements

- In DRC, MTaPS supported the provincial medicine technical working groups in Nord Kivu and Ituri to strengthen their stewardship roles. An MNCH subgroup was established in each province, with a special focus on MNCH health products, and resulted in more effective distribution of MNCH medicines using the national supply chain system and more effective collaboration and coordination with donors and implementing partners.
- MTaPS has also supported the engagement of civil society in DRC to improve transparency in managing health commodities, particularly with respect to MNCH and family planning/ reproductive health commodities and finances, and improved accountability in medicine management through the effective participation of the community in inventory management. The proportion of community care sites reporting data to health facilities increased from 0% in years 3 and 4 to 93% (152/164) in year 5.
- MTaPS contributed to improving quality of care and pharmaceutical services in DRC through support to the MOH to update certain MNCH treatment guidelines, adapt and adopt job aids for the management of pneumonia, and disseminate and update health workers on all the MNCH protocols in training sessions in the two provinces.
  - Health workers, as a result of the above, felt empowered to manage eclampsia cases that they rarely encounter, and the rate of correct management of pneumonia cases according to standard protocol was over 95% in both provinces per DHIS2 data at the end of 2022.[9]
- In Nepal, MTaPS conducted a mapping assessment and held a dissemination workshop to support the MOH in understanding the challenges of subnational procurement of medicines, including for MNCH.[10]
  - Key interventions such as introducing good storage and distribution practices and considering establishing a centrally negotiated framework agreement were included in annual plans and budgets at national and regional levels to improve the quality of and access to medicines procured at subnational levels.
- Supported Mozambique's regulatory authority, Autoridade Nacional Reguladora de Medicamentos, Instituto Publico (ANARME, IP), in streamlining registration of MNCH medicines aimed at improving access and efficiency of regulation by using findings and recommendations from the registration mapping:
  - Built capacity of 13 assessors from ANARME, IP in the assessment of bioequivalence studies for generic oral medicines.[11]

- Increased visibility and transparency of registration procedures through a workshop of 70 manufacturers, importers, and distributors hosted by ANARME, IP.[12]

- In Rwanda, guidelines on regulating medical gases were developed to ensure the availability of quality oxygen for the management of hypoxic newborns and children as well as cases of COVID-19, where medical oxygen is an essential part of treatment.
- MTaPS also supported the development of the terms of reference for an oxygen and respiratory care technical working group aiming to improve access to, and appropriate use of, oxygen through improved coordination among partners and stakeholders and supported the development and printing of job aids on oxygen administration for hospitals and health centers.
- MTaPS also supported the MOH in a rapid assessment of the management of medicines for postpartum hemorrhage and eclampsia, and as a result supported the development of an implementation manual for cold storage of oxytocin in Rwanda to guide health care workers in health centers and hospitals on procedures for correct storage and management to ensure quality to the point of use.

FEATURED RESOURCES

- Specific Considerations for Regulating Maternal, Newborn, and Child Health Medical Devices—Market Authorization
- A Guide to Best Practices in Subnational Procurement of MNCH Commodities in the Public Sector
- Forecasting Consumption of Select Reproductive, Maternal, Newborn, and Child Health Medical Products
- Engaging Civil Society in Social Accountability to Improve Access to and Appropriate Use of Quality Maternal, Newborn, and Child Health-Related Medical Products: A Discussion Paper
- Toolkit for Administration of Amoxicillin for Childhood Pneumonia
- Quality Assurance Practices for Medical Oxygen Systems: Technical Resource for Distribution- and Facility-Level Medical Oxygen Systems
- Maternal, Newborn, and Child Health & Pharmaceutical Systems Strengthening Microlearning Course
- Estimating Needs of Non-Malaria Commodities for Integrated Community Case Management (iCCM)
- Call to Action: Expanding Access to Medicines
- Why African countries should prioritize the registration of maternal, newborn, and child health medical products: a call to action.

FUTURE CONSIDERATIONS

- Program interventions that target access to medicines for a specific disease area benefit and contribute to improvements in system strengthening across all essential medicines. Continue to raise awareness that investing in strong pharmaceutical systems benefits MNCH outcomes and therefore universal health coverage.
- Continue to support countries to strengthen their regulatory systems—even though it is a lengthy, time-consuming process—as the broader pharmaceutical system and the safety, quality, and effectiveness of medical products is important for MNCH outcomes. Streamlined registration, for example, depends on policy, organizational, and system changes that are not quick fixes and take careful consultation and gradual progress to implement.
- As decentralization or devolution extends, subnational procurement will become more commonplace and mechanisms such as those described in the best practices guidance document need to be put in place to ensure quality and affordability of key MNCH medicines, which are primarily procured using government funds. Support countries with decentralized settings to implement best practices for subnational procurement to ensure quality and affordability of MNCH medicines, including establishing standards for storage and distribution practices.
- Engagement of civil society can be applied to management of medicines and is not just important at the grassroots level—it encompasses a variety of stakeholders at all different levels.

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