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

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FISCAL YEAR 2020 ANNUAL REPORT AND QUARTER 4 (JULY-SEPTEMBER 2020) REPORT



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# **PROJECT OVERVIEW**

Program Name:		USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program						
Reporting Period:		Fiscal year (FY) 2020 and FY20 Quarter 4 (July-September 2020)						
Activity Start Date and End	d Date:	September 20, 2018–September 19, 2023						
Name of Prime Implement	ting Partner:	Management Sciences for Health						
Contract Number:		7200AA18C00074						
	Core Partners:	Boston University, FHI360, Overseas Strategic Consulting, Results for Development, International Law Institute-Africa Centre for Legal Excellence, NEPAD						
MT DC D	Global Expert Partners:	Brandeis University, Celsian Consulting, Deloitte USA, Duke- National University of Singapore, El Instituto de Evaluacion Technologica en Salud, IC Consultants, MedSource, IQVIA, University of Washington						
MTaPS Partners:	Capacity Resource Partners:	African Health Economics and Policy Association, Ecumenical Pharmaceutical Network, U3 SystemsWork, University of Ibadan, African Collaborating Centre for Pharmacovigilance and Surveillance, Kilimanjaro School of Pharmacy, Muhimbili University, Pharmaceutical Systems Africa						
	Collaborators:	International Pharmaceutical Federation, Howard University, University of Notre Dame, WHO, World Bank						

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USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703.524.6575

Fax: 703.524.7898 Email: mtaps@msh.org

## **ACRONYMS AND ABBREVIATIONS**

ABHR alcohol-based hand rub
ADR adverse drug reaction

ADRAC Adverse Drug Reaction Advisory Committee aDSM active drug safety monitoring and management

AIDS acquired immunodeficiency syndrome

AMR antimicrobial resistance

AMRH African Medicines Regulatory Harmonization

AMS antimicrobial stewardship

ARTI acute respiratory tract infection

ARV antiretroviral

ASEAN Association of Southeast Asian Nations
ATC Anatomical Therapeutic Chemical
AWaRe access, watch and reserve (WHO)
BCC behavior change communication

CDC Communicable Disease Control (Bangladesh)
CDC US Centers for Disease Control and Prevention

CIAPOL Ivorian Anti-Pollution Center
CLA collaborative learning and adapting

COI conflict of interest

COR contracting officer representative
CPD continuous professional development
CQI continuous quality improvement
CRO Oceanography Research Center

CSO civil society organization
CTD common technical document

CUK University of Kinshasa Teaching Hospital

D10 10ème Direction

DAMS Drug Administration Management System (Nepal)

DDA Department of Drug Administration

DDD defined daily dose

DDL Development Data Library

DEC Development Experience Clearinghouse
DFRS Directorate of Training and Health Research
DGDA General Directorate of Drug Administration

DGFP Directorate General of Family Planning (Bangladesh)

DGHS General Directorate of Hospital Services

DGOGSS General Directorate for the Organization of Health Care

DGS General Directorate of Health

DMAP Data Management and Analytics Platform

DMHP Directorate of Hospital and Proximity Medicine

DOH Department of Health

DPM Directorate of Pharmacy and Medicine

DPS division provinciale de la santé

DQSHH Directorate of Hospital Quality, Security, and Hygiene

DRA Drug Regulatory Authority

DRC Democratic Republic of the Congo

DSFGS Direction pour de la Santé de la Famille et Groupe Specifique (DRC)

DSV Directorate of Veterinary Services

DT dispersible tablet

DTC drug and therapeutics committee

DTG dolutegravir

EAC East African Community

eAMS electronic asset management system

ECOWAS Economic Community of West African States

EDT electronic dispensing tool

eLMIS electronic logistics management information system

EML essential medicines list

EMP essential medicines and health products (WHO)

EWG Expert Working Group

FAO Food and Agriculture Organization
FDA US Food and Drug Administration

FP family planning FY fiscal year

GBT Global Benchmarking Tool (WHO)

GFF Global Financing Facility

GHSA Global Health Security Agenda
GMP Good Manufacturing Practices

GRevP Good Review Practices

HCAI healthcare-associated infection

HIPC hygiene and infection prevention and control

HIV human immunodeficiency virus HTA health technology assessment

HZ health zone

ICC infection control committee

IDDS Infectious Diseases Detection and Surveillance Program

IGAD Intergovernmental Authority on Development

IHR International Health Regulation

ILI-ACLE International Law Institute-African Center for Legal Excellence

IPC infection prevention and control

IPCAF Infection Prevention and Control Assessment Framework

IPCAF Infection Prevention and Control Assessment Framework (WHO)

IPCAT2 IPC assessment tool

IPRA Ivorian Pharmaceutical Regulatory Authority

JAG joint action groups

JEE joint external evaluation (of International Health Regulations [2005] core capacities)

KEML Kenya Essential Medicines List

KM knowledge management

KMITS Knowledge Management and Information Technology Service

LANADA National Laboratory for the Support of Agricultural Development

LDP+ Leadership Development Program Plus

LGU local government unit

LMICs low- and middle-income countries

LMIS logistics management information system

M&E monitoring and evaluation

MAAIF Ministry of Agriculture, Animal Industry, and Fisheries

MCC Multisectoral Coordination Committee
MCCH Maternal Child and Community Health
MCG Multisectoral Coordination Group

MCH maternal and child health
MDG Millennium Development Goal

MDR multidrug resistant

MEL monitoring, evaluation, and learning

MESRS Ministry of Higher Education and Scientific Research
MINADER Ministry of Agriculture and Rural Development
MIRAH Ministry of Animal and Fisheries Resources

MNCH maternal, neonatal, and child health

MOH Ministry of Health

MOHCDGEC Ministry of Health, Community Development, Gender, Elderly and Children

MOHFW Ministry of Health and Family Welfare
MOHP Ministry of Health and Population
MOU memorandum of understanding
MSC multisectoral coordination

MSH Management Sciences for Health
MSHP Ministry of Health and Public Hygiene

MSR medical surgical requisites

MTC medicines and therapeutics committee

MTC Multisectoral Technical Committee (Côte d'Ivoire)
MUHAS Muhimbili University of Health and Allied Sciences

NAMRAC National Antimicrobial Resistance and Containment Advisory Committee (Ethiopia)

NAMRsC National Antimicrobial Resistance (AMR) Sub-Committee

NAP National Action Plan

NC-AMR National Commission on Antimicrobial Resistance
NCAT National Committee for Antibiotic Treatment (Senegal)

NDA National Drug Authority

NEPAD New Partnership for Africa's Development

NGO nongovernmental organization

NMTC National Medicines and Therapeutics Committee

NTP national tuberculosis program

OH One Health

OHP One Health Platform

OIE World Organization for Animal Health

ORMICI Observatory on Antimicrobial Resistance in Cote d'Ivoire

OSC Overseas Strategic Consulting

PD Pharmacy Department

PEPFAR US President's Emergency Plan for AIDS Relief

PLMC Procurement and Logistics Management Cell (Bangladesh)
PMED Pharmaceuticals and Medical Equipment Directorate (Ethiopia)

PMIS pharmaceutical management information system
PNAM National Medicines Supply Program (DRC)

PNDAP National Program for the Development of Pharmaceutical Activity

POPCOM Commission on Population (Philippines)
PPB Pharmacy and Poisons Board (Kenya)

PQM+ Promoting the Quality of Medicines Plus Program
PSCM procurement and supply chain management

PSCMT Procurement and Supply Chain Management Team (Philippines)

PSM procurement and supply management PSS pharmaceutical systems strengthening

PV pharmacovigilance

PViMS pharmacovigilance monitoring system

PY program year

QMS quality management system

RCORE regional center of regulatory excellence

RH reproductive health

RHSC Reproductive Health Supplies Coalition

RMNCH reproductive, maternal, newborn, and child health

RSS regulatory systems strengthening

SADC Southern African Development Community

SCMP Supply Chain Management Portal
SEARN Southeast Asia Regulatory Network
SEARO WHO regional offices for South-East Asia

SIAPS Systems for Improved Access to Pharmaceuticals and Services

SOW scope of work

SPRINT Scaling Pneumonia Response Innovations

STG standard treatment guideline

TB tuberculosis

TIMCI Tools for Integrated Management of Childhood Illnesses

TLD tenofovir/lamivudine/dolutegravir

TOR terms of reference training of trainers

TTC Technical Thematic Committee

TWG technical working group
UHC universal health coverage

UN United Nations

UNCoLSC UN Commission on Life-Saving Commodities
UNDP United Nations Development Programme
USAID US Agency for International Development

VEML Veterinary Essential Medicines List

WASH water, sanitation and hygiene WHO World Health Organization

#### INTRODUCTION

#### **PURPOSE**

Funded by the US Agency for International Development (USAID) and implemented by a team led by Management Sciences for Health (MSH), the purpose of the five-year MTaPS Program (2018–2023) is to provide pharmaceutical system strengthening assistance for sustained improvements in health system performance and to advance USAID's goals of preventing child and maternal deaths, controlling the HIV/AIDS epidemic, and combatting infectious disease threats, as well as expanding essential health coverage.

#### **GOAL**

The goal the MTaPS Program is to help low- and middle-income countries strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines, vaccines, and other health technologies and pharmaceutical services.

#### MTAPS Approach to Strengthening Pharmaceutical Systems

USAID awarded the MTaPS Program to enable low- and middle-income countries to strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines, vaccines, and other health technologies and pharmaceutical services. In this context, "access" refers specifically to affordability, acceptability (or satisfaction), geographical accessibility, availability, and equity (the extent to which pharmaceutical systems deal fairly with population subgroups differentiated along various parameters). "Use" refers to prescribing, dispensing (or sale or supply to the user), and consumption (or end use).

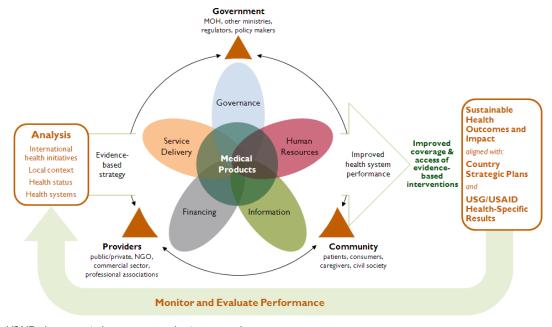


Figure 1. USAID pharmaceutical systems strengthening approach

The program's theory of change is based on USAID's Vision for Pharmaceutical Systems Strengthening (PSS), which posits six functions of health systems that must be strengthened to achieve sustained and equitable access to essential, high-quality services: human resources, health finance, health governance, health information, medical products/vaccines/technologies, and service delivery. MTaPS has adopted this framework to the pharmaceutical sector as per figure 1, which illustrates a comprehensive set of dynamic relationships among a health system's functions with an overarching focus on the role medical products are expected to play in improving health system performance.

#### **ABOUT THIS REPORT**

This report presents a summary of achievements by portfolio for fiscal year 2020 and highlights from MTaPS' performance for fiscal year 2020, quarter 4 (July-September 2020). It summarizes program performance and key challenges and is organized by core funding, objective, and country.

Implementation of planned activities this quarter continued to be impacted by the COVID-19 pandemic. Some activities have been delayed or postponed due to the general slowdown of activities and restrictions on gatherings/movement, as well as the limited availability of the staff.

 $^{\text{I}} \text{ US Agency for International Development. USAID's vision for health systems strengthening, 2015-2019. Available at: \\ \text{https://www.usaid.gov/sites/default/files/documents/1864/HSS-Vision.pdf.}$ 

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### MTAPS RESPONDING TO THE COVID-19 PANDEMIC

Early in 2020, MTaPS received additional funding from USAID to respond to the COVID 19 pandemic in 13 countries (Bangladesh, Burkina Faso, Cameroon, Côte d'Ivoire, Ethiopia, Jordan, Kenya, Mali, Mozambique, the Philippines, Senegal, Tanzania, and Uganda). COVID-19 activities build off the program's existing platforms and best practices. In these countries, the program assists government stakeholders and implementing partners in strategic planning around the COVID-19 response for infection prevention control and emergency supply management.

Activities under each technical area are broadly categorized through the following:

- Adapting WHO and national guidance and standard operating procedures for COVID-19
- Developing IPC guidance for healthcare workers, health facility workers, patients, family
   members, caregivers, and visitors
- Assessments of COVID-19 capacity at the national, regional, sub-regional, and facility level
- Training on newly adapted guidance and standard operating procedures
- Disseminating materials (i.e., guidelines, job aids, etc.)
- Assessing and monitoring compliance to policies and guidelines
- Supporting general program management

Table I highlights some the results as of September 30, 2020; for additional information, <u>refer to monthly progress reports</u> on MTaPS COVID-19 activities.

Table I. Cumulative MTaPS COVID-19 indicators

#	INDICATOR	CUMULATIVE (AS OF SEPTEMBER 30, 2020)
1	# of MTaPS-supported health facilities whose staff received COVID-19-related IPC training:*	3,103
l.a	# of facilities trained in IPC for COVID-19	2,679
I.b	# of facilities trained in emergency supply chain management	642
1.c	# of facilities trained in health care waste management (HCWM)	2,287
2	# of health workers who received COVID-19-related training	38,686
2.a	female	22,175
2.b	male	16,295
2.c	sex unknown	216
3	% of MTaPS-supported facilities in compliance with IPC COVID-	48%
	19 guidelines/SOPs	(665/1,376)
4	% of MTaPS-supported facilities that report stock data for IPC	96%
	commodities with required frequency	(694/726)

<sup>\*</sup> Because some health facilities received training in more than one technical area, indicator I and sub-indicators Ia, Ib, and I.c are counted separately to prevent double counting.

# PROGRESS BY CORE-FUNDED PORTFOLIO

### **GLOBAL HEALTH SECURITY AGENDA**

# **SUMMARY OF ACTIVITIES THIS YEAR (FY20)**

Beginning in March 2020, the effect of COVID-19 started spreading through all MTaPS Global Health Security Agenda (GHSA) countries with lockdowns, curfews, restrictions on gatherings, and limited availability of government counterparts who were tied up with the national response. As a result, depending on the country, activities slowed due to postponed and cancelled meetings; objectives related to multisectoral coordination (MSC) were particularly affected. However, after the first months, MTaPS teams, most of whom started teleworking, were creative in using remote solutions and focusing on activities that they could accomplish with minimum interaction with outside stakeholders. As a result, with some unavoidable delays and postponements, MTaPS continued to make good progress even during the pandemic.

**Tracking performance**. During the reporting period, the GHSA indicators and performance indicator reference sheets were finalized with USAID input and approved. The MTaPS monitoring, evaluation, and learning approach ensures that MTaPS (HQ and country teams), USAID, and other stakeholders have access to timely, accurate information to monitor program performance and make appropriate

decisions, as well as the ability to evaluate outcomes toward longer-term program goals. The indicators will be used to monitor GHSA country program outcomes, identify gaps in activities, and inform and adapt existing approaches and will be major components of reporting and learning. The program will use the MTaPS analytics platform as its data management system to simplify routine and ad hoc reporting. MTaPS collects data quarterly, bi-annually, or annually as appropriate for each indicator and uploads the data into the MTaPS analytics platform. MTaPS also ensures that indicators are disaggregated as needed to correctly reflect the results of the activities.

Table 2 and Figures 2-4 below provide detail on how well each country made progress on the pathway to attaining a higher Joint External Evaluation (JEE) capacity score in the three focus areas of MSC, infection prevention and control (IPC), and antimicrobial stewardship (AMS) based on their completion of the WHO benchmark actions. These tables and figures reflect only MTaPS-supported achievements.

GHSA-SUPPORTED COUNTRIES:

Bangladesh
Burkina Faso
Cameroon
Côte d'Ivoire
DRC
Ethiopia
Kenya
Mali
Senegal
Tanzania
Uganda

Benchmarks actions		Country									
Completed/supported	BD	BF	CM	CI	CD	ET	KE	ML	SN	TZ	UG
Infection prevention and control											
Limited Capacity – 02 (5 actions)	40%		40%	100%	20%	60%	80%	60%	60%	40%	80%
Developed Capacity – 03 (6 actions)	0%		33%	33%	17%	83%	33%	33%	50%	67%	83%
Demonstrated Capacity – 04 (5 actions)	0%		0%	0%	0%	0%	0%	0%	0%	40%	0%
Antimicrobial stewardship											
Limited Capacity – 02 (4 actions)	0%	50%	50%	75%	75%	0%	50%	75%	50%	50%	0%
Developed Capacity – 03 (6 actions)	17%	33%	0%	0%	50%	50%	50%	17%	17%	33%	33%
Demonstrated Capacity – 04 (7 actions)	0%	0%	0%	0%	0%	14%	0%	0%	0%	0%	0%
Sustainable Capacity – 05 (7 actions)	0%	0%	0%	0%	0%	0%	0%	0%	0%	14%	0%
	Multi	isecto	oral co	ordin	ation	on Al	ИR				
Limited Capacity – 02 (4 actions)	25%	50%	25%	50%	75%	75%	0%	0%	75%	25%	50%
Developed Capacity – 03 (4 actions)	25%	50%	50%	75%	50%	75%	0%	100%	50%	50%	50%
Demonstrated Capacity – 04 (4 actions)	25%	0%	25%	50%	25%	50%	75%	0%	50%	25%	25%

Table 2. Percentage of WHO Benchmark Actions Completed in IPC, AMS, and MSC with MTaPS Support for each JEE Capacity Level

# P.3.1 Effective MSC on AMR

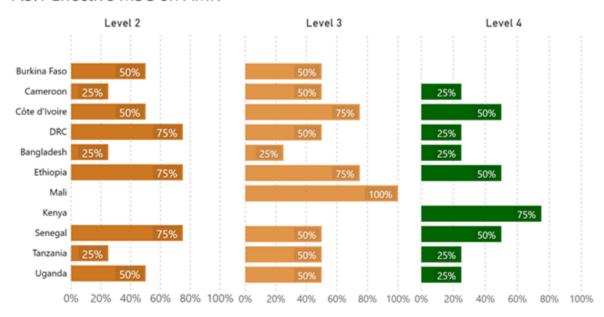


Figure 2. Percentage of WHO benchmark actions on MSC/AMR completed with MTaPS support for each JEE capacity level

# P.3.3 Infection prevention and control proportion

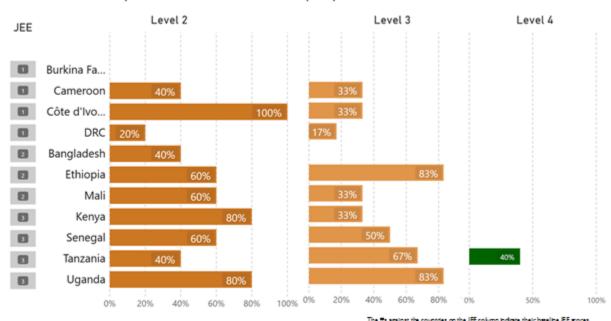


Figure 3. Percentage of WHO benchmark actions on IPC completed with MTaPS support for each JEE capacity level

# P.3.4 Antimicrobial stewardship activities proportion

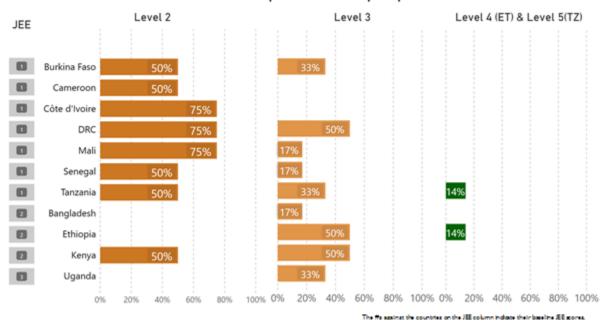


Figure 4. Percentage of WHO benchmark actions on AMS completed with MTaPS support for each JEE capacity level

The baseline data collection process, which began in Q1 of FY2 (Oct–Dec 2019), was completed in Q2 (Jan–Mar 2020) in all MTaPS GHSA countries. MTaPS collected data via record review, key informant interviews, surveys, and facility assessments. The baseline assessed both long-term outcome indicators and routinely collected quarterly indicators. These baseline values will be used to set targets, plan activities, and monitor performance over the life of the project.

**Standardized country resources**. During the reporting year, MTaPS finalized four technical miniguides with process checklists to help countries plan, jump start, and implement activities that are common to all MTaPS GHSA countries. These guidance documents provide a standard and step-wise approach to the implementation process, a list of major steps, and available resources, all of which countries can adapt for their own implementation plans. These documents are serving as a quality assurance mechanism and simplifying the work by basing it on a standardized process that can potentially generate ample opportunities for cross-learning and South-South collaboration across countries. The four guides relate to:

- IPC assessment
- Continuous quality improvement (CQI) for IPC
- Pre-/in-service training and eLearning
- Implementing facility-level AMS programs

In total, MTaPS has finalized and distributed <u>seven mini-guides</u> to its GHSA countries, which include the above four and three others that were developed during the previous year relating to MSC on antimicrobial resistance (AMR); AWaRe (Access, Watch, Reserve) categorization of antibiotics; and assessment of AMS policies/regulation.

Training and learning. To fill an identified gap, MTaPS developed a generic three-day AMS training course for health facility workers that countries can adapt for their own contexts. The two primary documents that MTaPS used as resources are the WHO's Antimicrobial stewardship programmes in health-care facilities in low- and middle-income countries: a WHO practical toolkit countries<sup>2</sup> and the US Centers for Disease Control and Prevention's (CDC) Core Elements of Human Antibiotic Stewardship Programs in Resource-Limited Settings.<sup>3</sup> The course is divided into five modules covering AMR and its global/country impact, AWaRe classification, quantity and quality of antibiotic use, implementing AMS interventions in a health care facility, and developing a health facility AMS action plan. In addition, course participants produce a SWOT analysis and an action plan for AMS interventions for their facilities. The course was translated into Portuguese and piloted in Mozambique with field-support funds, thus leveraging the GHSA/AMR work.

The recognition and use of eLearning is growing, and the current COVID-19 pandemic has further highlighted the importance of such digital modes of teaching-learning. MTaPS supported five GHSA countries to upload IPC eLearning courses to local platforms by working with MTaPS-oriented local eLearning teams (Cameroon, Mali, Senegal, Tanzania) and adapt IPC curricula to eLearning course formats (Cameroon, Côte d'Ivoire, Mali, Senegal, Tanzania).

Through the MTaPS predecessor program, MSH developed two courses on AMR (Part 1 and Part 2) for USAID's Global Health eLearning platform, which were widely used. The courses were published in 2015 and 2016. Substantial developments have occurred in this area since that time, and an update was

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<sup>&</sup>lt;sup>2</sup> World Health Organization. (2019). Antimicrobial stewardship programmes in health-care facilities in low- and middle-income countries: a WHO practical toolkit. World Health Organization. https://apps.who.int/iris/handle/10665/329404.

<sup>&</sup>lt;sup>3</sup> CDC. The Core Elements of Human Antibiotic Stewardship Programs in Resource -Limited Settings: National and Hospital Levels. Atlanta, GA: US Department of Health and Human Services, CDC; 2018. Available at: https://www.cdc.gov/antibiotic-use/healthcare/implementation.html

needed. MTaPS is revising the courses, with a draft of Part I complete. The revision reflects the salient developments in the last four or five years and incorporates GHSA perspectives and actions on AMR.

**Building advocacy**. Various MTaPS teams helped organize and participated in countries' events during World Antibiotic Awareness Week (November 18–24, 2019). For example, MTaPS/Ethiopia sponsored a multisectoral panel discussion on translating the national action plan into practice. MTaPS-oriented journalists also contributed AMR messages in the media related to the event; MTaPS/Kenya presented at an AMR symposium, while MTaPS/Tanzania brought together approximately 700 health workers, university students, and members of the public to attend an AMR symposium organized by the Tanzania Pharmaceutical Students' Association, at which an MTaPS senior technical advisor was a panelist. MTaPS supported the Uganda Ministry of Health (MOH) to disseminate the national IPC survey findings during the national AMR conference attended by more than 500 people working in AMR. MTaPS Burkina Faso helped organize and participated in a multisectoral conference on AMR.

Improving IPC and AMS practices. In 11 countries, MTaPS provides direct support to 86 health facilities to strengthen IPC (77 facilities) and AMS (75 facilities) practices (as of September 2020); about a quarter of those facilities are in the private sector. In 64 facilities, MTaPS is strengthening both areas, which is more cost-efficient and produces synergy.

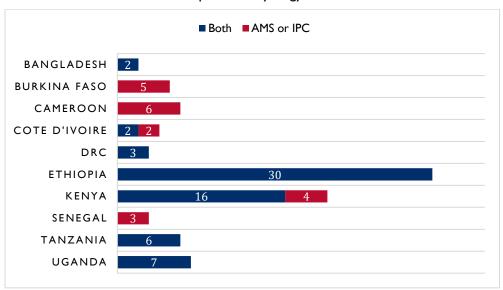


Figure 5. Number of health facilities supported by MTaPS for GHSA/AMR activities

Table 3 shows the percentage and number of MTaPS facilities that have put functioning IPC committees in place over the year, disaggregated by quarter during the reporting year. The table also includes the baseline values for comparison.

Table 3. Percentage and Number of Health Facilities with Functional IPC Committees

Country	Baseline	PY2Q1	PY2Q2	PY2Q3	PY2Q4
Cameroon	0	0	0	0	83.3% (5/6)
Côte d'Ivoire	0% (0/4)	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)
Ethiopia	96.7% (29/30)	100% (30/30)	100% (30/30)	100% (30/30)	100% (30/30)
Kenya	0% (0/16)	100% (16/16)	100% (16/16)	100% (16/16)	100% (16/16)
Senegal	0% (0/3)	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Tanzania	0% (0/6)	16.7% (1/6)	16.7% (1/6)	83.3% (5/6)	100% (6/6)
Uganda	0% (0/7)	0% (0/7)	100% (7/7)	100% (7/7)	100% (7/7)

MTaPS promotes the integration of CQI approaches so that facilities can identify, address, and monitor areas that need improvement in IPC practices. Figure 6 illustrates the number of MTaPS-supported facilities that have incorporated CQI over the year.

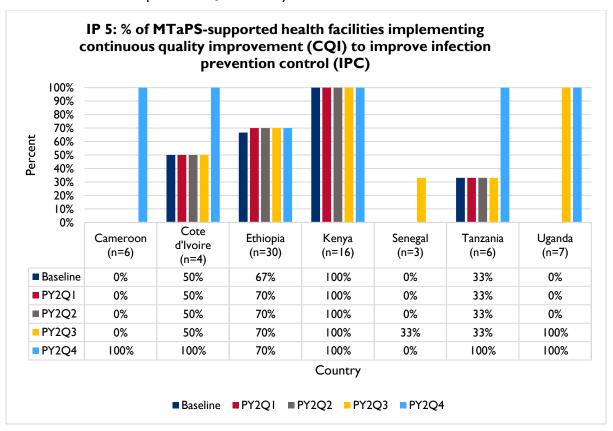


Figure 6. Percentage of MTaPS-supported health facilities using CQI to improve IPC practices

Table 4 provides information on country progress with conducting AMS assessments of policies, guidelines, and regulations in the human and animal sectors.

**Table 4. AMS Country Assessment Status** 

COUNTRY	ASSESSMEN	DEPORT	
COUNTRY	HUMAN SECTOR	ANIMAL SECTOR	REPORT
Burkina Faso	Completed	Completed	Final (both sectors)
Cameroon	Completed	Completed	Report validated and finalized (both sectors)
Côte d'Ivoire	Completed	Completed	Report validated and finalized (both sectors)
DRC	Policy assessment completed; rapid use and consumption assessment started	N/A	Report drafted for policy assessment
Mali	Completed	Completed	Report drafted (both sectors)

**Collaboration with other partners.** In addition to our partnerships with every country's government agencies on health and agriculture/fisheries/husbandry, MTaPS has worked with the following organizations through September 2020.

Table 5. MTaPS collaboration with multisectoral organizations

PARTNER CATEGORY	ORGANIZATION
International/regional agencies	WHO; WHO Afro; UN Food and Agriculture Organization (FAO) Emergency Center for Transboundary Animal Diseases (ECTAD); World Organisation for Animal Health; UNICEF; CDC; Africa CDC; DRC Red Cross; Croix Rouge Internationale (Cameroon)
Donors/development and implementing partners	PATH; Sanitation for Health; HRH 2030 Project; Action; Neema; Renforcement du Système de Santé plus; Infectious Disease Detection and Surveillance (IDDS); Global Health Supply Chain-Procurement and Supply Management; Metabiota; Intrahealth; Momentum 2 A; Farmer-to-Farmer; Regional Disease Surveillance Systems Enhancement Phase III; Jhpiego; Deloitte; Fleming Fund; MTaPS program partners University of Washington and Overseas Development Consulting
Professional associations	Tanzania Pharmaceutical Students Association; Kenya Veterinary Association; National Nurses Association of Kenya; Pharmaceutical Society of Kenya; Kenya Medical Association; Association of Kenya Medical Laboratory Scientific Officers; Kenya Association of Clinical Pathologists
Academic/research institutions	Infectious Diseases Institute (Uganda); International Training and Education Center for Health (Kenya); Makerere University; University of Nairobi; Catholic University of Health; Allied Sciences-Bugando; St. John's University and Muhimbili University in Tanzania; Addis Ababa University; local training institutions
Commercial-sector	Biomerieux
Civil society/other nongovernmental organizations	Ecumenical Pharmaceutical Network/Action on Antibiotic Resistance; Infection Prevention Network, Kenya; THET Uganda, Reseau d'Acces aux Medicaments Essentiels (Burkina Faso)

The following tables provide country-level detail on collaboration with FAO, WHO, CDC, and IDDS as of September 2020.

Table 6. Examples of MTaPS collaboration with FAO, WHO, CDC, and IDDS September 2020

COUNTRY	FAO COLLABORATION
Multiple	Work together on One Health committees
Bangladesh	Collaborate in joint meetings and to develop standard treatment guidelines (STGs)
Burkina Faso	<ul> <li>Work together within the AMR Commission</li> <li>Collaborate on developing a national plan to strengthen AMS in the animal sector</li> </ul>
Cameroon	Collaborate on drafting national AMR operational plan
DRC	Conduct joint field support visits to selected veterinary clinics
Ethiopia	<ul> <li>Celebrate World Antibiotics Awareness Week and AMR Day at national level</li> <li>Conduct the fourth Tripartite AMR Country Self-assessment Survey (TrACSS)</li> </ul>
Kenya	<ul> <li>Develop NAP-AMR monitoring and evaluation plan</li> <li>Collaborate on World Antibiotic Awareness Week activities</li> <li>Support activities of the National Antimicrobial Stewardship Interagency Committee (NASIC).</li> </ul>
Mali	<ul> <li>Collaborate in MSC/AMR activities and IPC activities in the animal health sector (ECTAD)</li> <li>Provide input on rapid assessment of AMS policies and supply chain management</li> </ul>
Senegal	Collaborate with FAO/ECTAD to draft AMR action plan, concept note for tripartite funding, and national AMS plan
Tanzania	<ul> <li>Engage FAO experts to provided technical input on the design and content of the AMS policy guidelines</li> </ul>
Uganda	<ul> <li>Collaborate on essential medicines list for veterinary use; guidelines for antimicrobial use in animal sector; and AMR communication strategy, including the animal sector</li> </ul>
	WHO COLLABORATION
Multiple	Work together on One Health committees
Bangladesh	Collaborate in joint MSC meetings and for IPC, STGs, and other AMS activities
Burkina Faso	Collaborate on essential medicines list revision/dissemination and IPC activities
Cameroon	<ul> <li>Collaborate on IPC assessment and development of IPC training package</li> <li>Draft AMR operational plan</li> </ul>
Côte d'Ivoire	<ul> <li>Collaborate on IPC training of trainers</li> <li>Collaborate on conducting the national-level IPC assessment</li> <li>Implement an IPC emergency operations plan based on the national COVID-19 emergency plan</li> </ul>
DRC	<ul> <li>Provide technical support to DRC to conduct TrACSS 2019–2020</li> <li>Help revise DTC training and implementation materials</li> <li>Design an AMS rapid assessment of antibiotic use and consumption and developed terms of reference for the study (Geneva and Brazzaville)</li> <li>Organize a virtual training session on the AWaRe categorization methods and processes for members of the drug regulatory authority</li> </ul>
Ethiopia	<ul> <li>Collaborate on essential medicines list revision/dissemination</li> <li>Celebrate World Antibiotics Awareness Week and AMR Day at national level</li> <li>Conduct the fourth TrACSS</li> </ul>
Mali	Coordinate AMR work plan activities

Senegal	<ul> <li>Support conduct of IPCAT2 assessment</li> <li>Collaborate in MSC/AMR and AMS activities</li> </ul>
Tanzania	<ul> <li>Work together to develop AMS guidelines/policies, including implementation plans</li> <li>Organize a workshop to classify antibiotics into AWaRe groups and develop an implementation strategy</li> <li>Collaborate on IPC activities</li> </ul>
Uganda	Collaborate on update of IPC guidelines
	CDC COLLABORATION
Multiple	Work together on One Health committees
Bangladesh	Develop national guidelines on IPC for health care providers
Cameroon	Collaborate with CDC Metabiota on the AMR operational plan
Côte d'Ivoire	<ul> <li>Collaborate on conducting the national-level IPC assessment</li> <li>Validate IPC training materials</li> </ul>
Ethiopia	Attend World Antibiotics Awareness Week panel discussion on AMR
Kenya	Develop national IPC training resources
Senegal	<ul> <li>Collaborate with CDC/PATH's GHSA Project on MSC/AMR, IPC, and AMS activities</li> </ul>
	IDDS COLLABORATION
Multiple	<ul> <li>Work together on One Health committees and meet to determine areas of overlap and potential collaboration</li> </ul>
Cameroon	<ul> <li>Collaborate on the AMR operational plan</li> <li>Co-organize a five-day workshop with 42 participants to prioritize 2020 activities</li> </ul>
Ethiopia	<ul> <li>Coordinate AMS implementation activities at Black Lion Hospital</li> <li>Collaborate on IPC activities</li> </ul>

#### **EFFECTIVE MULTISECTORAL COORDINATION ON AMR**

During the last year, in all 11 target countries, MTaPS helped establish and/or facilitate MSC meetings with representation from organizations involved in the countries' One Health activities. Support included developing terms of reference and designing MSC body organizational structures and implementation plans for the national action plans on antimicrobial resistance (NAP-AMR). MTaPS also helped establish and/or guide IPC and AMS technical working groups (TWGs) to prioritize, plan, and review specific activities and, in some countries, to develop national IPC or AMS action plans (Cameroon, Côte d'Ivoire, DRC, Ethiopia Kenya, Mali, Tanzania, and Uganda) The focus of these meetings was often to update stakeholders on the status of implementing the NAP-AMR.

Strengthening MSC governance structures and functions. MTaPS/Bangladesh facilitated the development of the monitoring and evaluation (M&E) framework for the country's NAP-AMR. MTaPS/Kenya also supported stakeholder meetings to review the draft M&E framework for the national AMR action plan, incorporate feedback, and revise it. MTaPS contributed to drafting the ministerial order that defines the roles, composition, and functioning of the One Health Steering Technical Committee, the One Health Technical Secretariat, the One Health Technical Commissions, and the ministerial focal points in Burkina Faso. DRC and Kenya completed and maintained national AMR stakeholder maps. MTaPS/Côte d'Ivoire supported the AMR-TWG to develop a NAP-AMR governance handbook and the national AMR policy document to disseminate to multisectoral ministries.

MTaPS helped conduct the tripartite AMR country self-assessment survey 2019–2020 in **DRC** and **Ethiopia**. In **Ethiopia** and **Senegal**, MTaPS provided support to develop a national concept note for the tripartite One Health AMR Multi-Partner Trust Fund, which was finalized and submitted. In

Tanzania, MTaPS helped finalize the policy guidelines on implementing the country's AMS program and a multisectoral AMR communication strategy. The policy guidelines were approved by the Multisectoral Coordination Committee in February 2020 and will guide stakeholders who are implementing AMS-related activities. The Uganda team worked to develop and operationalize an online information exchange platform for stakeholders in the human, animal, and environmental sectors to support implementation of AMS and IPC activities under the NAP-AMR. Data on the platform includes TWG objectives, terms of reference, composition, meeting schedules and minutes, reference documents, tools, and research information. The platform was built within the existing MOH infrastructure, is hosted on the MOH server, and will be linked with other data platforms. During the year, MTaPS/Ethiopia provided technical support to the MOH's Pharmaceuticals and Medical Equipment Directorate to develop and finalize a three-tiered structure for the national AMR governance and coordination platform—the National Antimicrobial Resistance and Containment Advisory Committee. The platform consists of a national interministerial committee at the top, followed by the national AMR advisory committee, which oversees six multisectoral TWGs including IPC and AMS. MTaPS was heavily involved with helping those two TWGs get established and operational.

**Promoting AMR advocacy and communication**. MTaPS/**Tanzania** helped finalize a multisectoral AMR communication strategy. In **Burkina Faso**, MTaPS collaborated with the Ministry of Environment, Green Economy, and Climate Change to organize a national training workshop for members of parliament who sit on the Commission on Rural Development, Economy, and Climate Change. The workshop focused on raising AMR awareness and the key role that the parliament can play in enacting laws and regulations to combat AMR. In **Côte d'Ivoire** MTaPS supported the AMR-TWG to develop an advocacy document to accompany the NAP-AMR.

#### INFECTION PREVENTION AND CONTROL IMPROVED AND FUNCTIONAL

With the COVID-19 pandemic appearing and escalating during this program year, IPC activities in our II GHSA countries have taken on a sense of urgency. During this time, MTaPS facilitated the development or review of national guidelines on IPC in Bangladesh, Cameroon, Kenya, Senegal, Uganda, Tanzania, Mali, and Côte d'Ivoire, with the last two also including the animal sector. During the reporting period, MTaPS also worked with country counterparts to conduct IPC national assessments using IPCAT2 (Ethiopia, Mali, Côte d'Ivoire) and IPC facility assessments using IPCAF (Bangladesh, Côte d'Ivoire, Ethiopia, Senegal, Tanzania); 25 veterinary clinics and farms in Mali also underwent an IPC and hygiene assessment. IPC training packages were developed in Cameroon, Kenya, Mali, Senegal, and Côte d'Ivoire (including the animal sector). As part of support to targeted health facilities, MTaPS teams worked with facility staff to establish or strengthen IPC committees and/or help those committees develop action plans (Cameroon, Côte d'Ivoire, DRC [in collaboration with the DRC Red Cross], Kenya, Senegal, Tanzania, Uganda); moreover, CQI mechanisms for facility IPC practices have been introduced in Cameroon, Côte d'Ivoire, Ethiopia, Kenya, Senegal, Tanzania, and Uganda.

Developing and implementing IPC policy and guidance documents. MTaPS/Kenya supported the review of the National Infection Prevention and Control Policy and the National IPC Strategic Plan for health care services to update them according to current global IPC principles and standards. The team worked with the MOH Clinical Services Directorate to develop a draft national IPC plan for Ethiopia using IPCAT2 results; MTaPS also supported the Ethiopian MOH to launch newly revised national IPC guidelines, which was a televised event, and an IPC monitoring and evaluation tool for health facilities to track implementation.

**Developing individual and local capacities.** To determine human resource capacity gaps in IPC and AMS in **Cameroon**, MTaPS used a variety of methods such as site visits, focus group discussions, and phone interviews to identify gaps and develop national capacity-building plans for AMS and IPC. Also in Cameroon, with help from an MTaPS capacity-building expert, MTaPS conducted a five-day workshop to

train 10 health experts on how to design curricula adapted for adult learning. Senegal is also adapting IPC training to an eLearning platform with MTaPS' help, and with the Directorate of Hospital Quality, Security and Hygiene, MTaPS is supporting the development of videos of hand hygiene, bio cleaning, and waste management practices to add to the IPC eLearning platform. Tanzania converted eight IPC training modules to an eLearning format. In **Côte d'Ivoire**, MTaPS collaborated with human and veterinary MOH directorates during five workshops to convert IPC training materials to a competency-based training package adapted for eLearning. MTaPS/**Kenya** collaborated with the National Nurses Association of Kenya, the MOH, and a task force comprising key medical professional associations to develop a continuing professional development- and re-licensure-linked in-service IPC training curriculum outline, PowerPoint modules, and an implementation strategy for delivery through professional associations. To date, 393 health care workers have been trained and awarded continuing professional development (CPD) credits. Similar work is ongoing with the Pharmaceutical Society of Kenya to advance AMS curricula for CPD.

Assessing IPC programs at national and facility levels and developing responsive action plans. MTaPS supported the AMR-TWG to conduct a rapid assessment of hygiene and IPC conditions in 10 veterinary clinics, 8 slaughterhouses, and 33 poultry farms throughout Côte d'Ivoire using tools adapted from IPCAT2 and IPCAF. The overall results showed: average IPC levels in veterinary practices surveyed-basic level; average level of biosecurity in slaughterhouses surveyed-basic level; and average level of biosecurity in poultry farms surveyed-intermediate level. In Ethiopia, the team re-assessed IPC practices in four hospitals using IPCAF to measure progress after interventions. All four hospitals showed improvement in their IPCAF scores and two progressed to the next level, one from inadequate to the higher end of the score for basic level and another from basic to intermediate level. MTaPS Kenya made follow-up visits to 16 target facilities to assess whether IPC standards were being met and activities performed according to action plans and to provide mentoring on areas of improvement. As a result of IPC interventions, in all 16 facilities, IPC committees have been established; hand hygiene facilities (i.e., soap and hand washing sinks) are now available; and waste disposal and segregation practices have improved. Likewise, in Tanzania, after IPCAF baseline assessments at six hospitals between October 2019 and January 2020, follow-up assessments were conducted in May 2020. All hospitals improved their scores, and the results indicate the success of MTaPS-supported interventions aimed at using mentorship to integrate IPC into the practices of every cadre and unit in hand hygiene; budgeting for and use of IPC supplies, including personal protective equipment; health care waste management; and using multimodal strategies to implement IPC interventions. In addition, to establish water, sanitation, and hygiene (WASH) improvement needs, MTaPS led a WASH assessment at four of the six supported hospitals. MTaPS oriented staff responsible for WASH and IPC at three hospitals on the WASH guidelines and reviewed the assessment results with them, which had significant impact. Facilities began to take action immediately, especially on things that did not require resources. For example, Temeke Regional Referral Hospital installed elbow-driven handwashing sinks and repurposed unused equipment. As part of the MOH's plan for building the capacity to produce alcohol-based handrub (ABHR) locally in Ethiopia, MTaPS helped develop, print, and distribute 4,000 sets of standard operating procedures to regional health bureaus and 400 hospitals. Initially, nine hospitals began production, but within a few months, the process expanded substantially—147 health facilities are now producing and using ABHR. Several zonal offices of regional health bureaus are producing and distributing ABHR to the community to use as hand sanitizer to help fight COVID-19.

From April to June 2020 in **Mali**, MTaPS collaborated with the National Directorate of Veterinary Services and the AMR Secretariat to conduct a nationwide rapid assessment of hygiene and IPC in the animal health sector. Data collectors interviewed 38 informants from 13 veterinary clinics and 12 farms in six geographic areas. Results showed that IPC practices in the animal health sector scored at the basic level of 287 out of 600. Recommendations related to disease control and prevention, infrastructure,

training, and funding were developed as a result, and the findings will contribute to IPC guidelines for the animal health sector.

#### **USE OF ANTIMICROBIAL MEDICINES OPTIMIZED**

Several MTaPS teams have noted that the AMS concept is a new one in their countries. Therefore, stakeholders in the government often need to be oriented to lay the groundwork for AMS activities. In seven countries, MTaPS facilitated the development or review of national guidelines or action plans on AMS—Burkina Faso, DRC, Senegal, Tanzania, Cameroon, Côte d'Ivoire, and Mali. The last three also included work on animal sector guidance documents. Teams conducted AMS national situational analyses of policies, guidelines, and legislation in DRC, Burkina Faso, Cameroon, Mali, Senegal, and Côte d'Ivoire, with the last five also including assessments of the animal sector. MTaPS also helped conduct facility-level AMS assessments in Bangladesh and Ethiopia and supported the development of training packages in DRC, Côte d'Ivoire, and Ethiopia. Target facilities were supported to establish or strengthen facility drug and therapeutics committees (DTCs), and those committees were assisted to develop action plans (Burkina Faso, Ethiopia, Kenya, Mali, Uganda, Côte d'Ivoire, and DRC, whose team also introduced the CQI approach to improve practices). A major priority for GHSA countries has been for MTaPS to assist with updating or developing essential medicines lists and/or STGs to reflect the WHO AWaRe classification of antimicrobials. MTaPS supported that process in —Burkina Faso, Kenya, DRC, Ethiopia, Senegal, Tanzania, and Mali; Uganda also developed its first-ever essential medicines list for veterinary use, and MTaPS supported the first-ever national guidelines for using antibiotics in the animal sector in Burkina Faso.

# Developing and implementing AMS policy and guidance documents.

During the year, MTaPS/**Uganda** conducted virtual regional meetings to get stakeholder feedback, and after approval from the Ministry of Agriculture, Animal Industries, and Fisheries (MAAIF), helped MAAIF finalize five documents that contribute to AMR control in the animal sector with MTaPS support—the Uganda Veterinary Essential Medicines List 2020–2025 and four sets of guidelines for infection prevention and appropriate antimicrobial use in animal sector for pig, goat and sheep, fish, and cattle farming.

Assessing AMS policies and practices. MTaPS/Mali's rapid assessment of stewardship policies and regulations and of antimicrobial supply

"Colleagues from MAAIF and other sectors join me in thanking USAID/MTaPS for taking leadership in the development of these key policy documents. For long we have struggled with the use of antibiotics and availability of medicines and control of their access in the agricultural sector. With the EVML and guidelines on infection prevention and use of antimicrobials developed, we now have a basis for implementing the changes that we have always wanted to implement. We need to go out and support the farmers and district teams to disseminate and roll out these guidelines."

- Dr. Anna Rose Ademun, Chief Veterinary Officer and Commissioner, Animal Health, MAAIF.

chain management in the human and animal health sectors found structural and organizational weaknesses, lack of an antimicrobial regulatory framework, lack of comprehensive treatment guidelines for infectious diseases, lack of a framework to monitor compliance with the national essential drug list, and inadequate reports of adverse medicine events. For veterinary medicine, the assessment revealed the lack of a regulatory framework and regulations on use and inadequate adherence to regulations or standardized therapeutic protocols; in addition, due to unrestrained and often illegal competition, ineffective, outdated, and even dangerous products are on the market. On the animal health side, MTaPS/DRC worked with the drug regulatory authority and the AMR-TWG to conduct multisectoral field support visits to animal clinics and farms to learn more about the use of antimicrobials in the animal

and environmental sectors, identify bottlenecks that hinder appropriate use, and provide recommendations. Findings included uncontrolled use of antimicrobials, a lack of understanding of AMR by most of the actors, no legal provisions to coordinate the management and the use of antimicrobials among sectors, and an undefined supply chain.

Developing individual and local capacities. In Tanzania, the team conducted multimodal assessments to develop IPC/AMS capacity building plans, finding a lack of knowledge from country leadership to the community level due to a dearth of AMR awareness programs in the country; consequently, MTaPS adapted the generic AMS training material that MTaPS headquarters had developed to suit the Tanzanian context and used the adapted materials to train 27 newly appointed National Medicines and Therapeutic Committee members to build their capacity on how to coordinate and oversee Tanzania's AMR/AMS-related activities. To characterize antimicrobial consumption and use in Tanzania, MTaPS worked with the Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC) to conduct two studies: a facility-based use study based on the WHO's point prevalence survey tool and a national medicine consumption study based on data from the Medical Stores Department, Tanzania Medicines & Medical Devices Authority, and pharmaceutical manufacturers. MTaPS and the MOHCDGEC will use the findings from the point prevalence survey on antibiotic use to provide supportive feedback to selected health facilities where AMS interventions will be implemented. Working with MOHCDGEC staff, MTaPS has built their capacity to conduct such surveys routinely and compare performance against other countries. MTaPS/Kenya worked with the University of Nairobi School of Pharmacy to conduct a preservice AMS training needs assessment that contributed to the development of AMS curriculum and course content for undergraduate and graduate students. MTaPS is working with country counterparts to develop capacity in conducting studies to help characterize antimicrobial use. For example, in Ethiopia, MTaPS provided technical assistance to St. Peter Specialized Hospital to conduct a drug use evaluation on ceftriaxone, which showed that ceftriaxone use was inappropriate for the clinical condition in 75% of patients. MTaPS worked with AMS teams in two hospitals in Kenya to conduct prescription audits to determine outpatient prescribing practices.

"We are really thankful to MTaPS/Tanzania, and the consultants from OSC. They did a great job in capturing our ideas and thoughts and they came up with a very comprehensive document, we are really grateful."

- Dr. Sero Luwongo, Chair of the Awareness and Education TWG of the Multisectoral Coordination Committee in Tanzania Increasing awareness of AMR. In accordance with Tanzania's NAP-AMR, MTaPS worked with stakeholders and partner Overseas Strategic Consulting to develop and disseminate a national communication strategy for AMR to guide the design and implementation of coordinated, enduring, and behaviorally focused communications activities. The strategy describes the messages and channels that will be most effective in influencing the audiences to adopt desired behavior change. To increase

AMR awareness in **Uganda's** animal sector, MTaPS supported consultative meetings between the MAAIF and other partners working in the agricultural and animal sectors, including the FAO, to identify audiences for AMS messaging, ranging from the Veterinary Medicines Regulatory Authority to livestock farmers and media, and the best methods to reach each group. One of the messages developed is "Adhere to the recommended dosage when using antimicrobials," which is targeted to farmers. MTaPS/**Ethiopia** worked over the year to increase public knowledge and behavior change regarding the AMR threat. The team prepared a behavioral change communication strategy for AMR prevention and an AMR training course for journalists and communication professionals that covered AMR issues in human and animal health and the environment. The strategy provides guidance to stakeholders on

strategic approaches and coordination mechanisms to improve the effectiveness of community awareness and educational interventions. This includes using role model stories about real people and how they achieved healthy behavior changes. MTaPS partnered with the MOH and civil society organizations to build capacity in journalists and civil society organizations. For example, MTaPS trained and supported the Ethiopian Youth and Women Federations to sensitize the public on AMR during their primary work promoting hygiene and maternal and child health in their communities. After training 29 volunteers from the Addis Ababa chapter, the volunteers developed AMR action. The 21 trained female volunteers, with technical support from MTaPS, conducted educational sessions on rational use of antimicrobials for 520 female members of the Addis Ababa Women Federation.

# **SUMMARY OF ACTIVITIES THIS QUARTER (FY20Q4)**

COVID-19's effect on all of MTaPS' GHSA countries continued this quarter; however, the teams adapted well, and activities mostly continued with some delays or postponements. Compared with last quarter, when MSC was particularly affected, MSC meetings and collaborations continued using virtual means. MTaPS activities also pivoted to working with health facilities to strengthen their IPC structures and practices—often through a COVID-19 lens. For example, the importance of eLearning intensified along with the pandemic, and a standard 10-module online course was developed for Francophone countries. The USAID MTaPS eLearning Courses on IPC can be accessed at <a href="https://leadernet.org/infection-prevention-control-courses/">https://leadernet.org/infection-prevention-control-courses/</a>. (For progress on MTaPS COVID-19 activities, click here.)

MTaPS completed the outline for the Global Health eLearning course on AMR (Part I) and began work on the course revision and on developing a similar outline for Part 2 of the course.

Collaboration with multisectoral international and national organizations continued during the quarter. MTaPS collaborated with United Nations organizations in many of our GHSA countries; for example, building local capacity in assessing antimicrobial consumption in DRC—WHO staff from Geneva and Brazzaville; organizing a workshop to develop a costed One Health work plan for Nyeri county, Kenya—the FAO; and drafting a national AMS plan in Côte d'Ivoire—World Organization for Animal Health. MTaPS continued to engage with other USAID and donor implementing partners, particularly the USAID Infectious Disease Detection and Surveillance program, including collaborating to organize the MSC quarterly meeting in DRC, develop a One Health work plan in Kenya, and share project updates at AMR partner meetings in Tanzania.

# **COUNTRY PROGRESS FOR FY20Q4**

The focus of the MTaPS approach and implementation framework is to help countries make progress on the pathway to the next level of joint external evaluation (JEE) capacity in MSC, IPC, and AMS. Table 7 highlights the areas in which MTaPS supported this quarter. In addition, MTaPS is supporting the COVID-19 response in some countries.

Table 7. GHSA activities supported this quarter by MTaPS

	GHSA-funded country											
GHSA Result Area	Activity	Bangladesh	Burkina Faso	Cameroon	Cote d'Ivoire	DRC	Ethiopia	Kenya	Mali	Senegal	Tanzania	Uganda
Effective Multisectoral	Strengthening MSC governance structures and functions	Х				X		X				
Coordination on AMR	Holding multisectoral meetings	Х			Х	X		X		X	X	X
Infection	Strengthening governance structures for IPC at the facility level			Х								
Prevention Control	Assessing IPC programs at national and/or facility levels and/or developing responsive action plans	X		X	х		X		X		X	
Improved and Functional	Developing and implementing IPC policy and/or guidance documents			Х	Х		Х	Х				
	Developing individual and local capacities				Х			Х		Х		Х
Use of Antimicrobial Medicines Optimized	Developing and implementing AMS policy and guidance documents	Х	Х	Х		X	X	X			X	Х
	Assessing AMS policies and practices	Х		Х		Х						
	Developing individual and local capacities		Х		Х	Χ	Х	X	X	X		
- Cpaninzea	Increasing awareness of AMR						X	X			Х	X

#### **EFFECTIVE MULTISECTORAL COORDINATION ON AMR**

To implement a NAP-AMR, MSC is paramount, but it requires strong country governance structures with clear roles and mandates—and often the creation of new structures, depending on the country. The COVID-19 pandemic slowed MSC progress in some countries, such as Mali, while virtual meetings and forums continued in other countries as detailed below.

MSC highlights in two important areas are as follows.

**Strengthening MSC governance structures and functions.** MTaPS/**Bangladesh** and **Kenya** facilitated the development of M&E frameworks for their countries' NAP-AMR. The frameworks will help both countries track NAP-AMR implementation status and make informed decisions. MTaPS/**DRC** helped IPC, AMS, and AMR surveillance sub-committees draft action plans using SWOT, Fishbone, and 5-WHY analyses to identify, analyze, and prioritize actions for the plans.

Holding multisectoral meetings. MTaPS/Bangladesh, in collaboration with the Center for Disease Control/Directorate General for Health Services (CDC/DGHS), organized another stakeholder workshop to discuss NAP-AMR implementation status. In Côte d'Ivoire, MTaPS supported both the Multisectoral Technical Committee (MTC) 5 and the IPC TWG MTC 4 to conduct virtual meetings to track NAP-AMR progress; all 20 activities planned by MTC 4 were implemented with financial support from USAID through MTaPS. In DRC, MTaPS supported the drug regulatory authority and the national commission on AMR to organize a multisectoral quarterly meeting with participation from the civil society health coordination group and the USAID Infection Disease Detection and Surveillance project.

The **Kenya** team participated in and supported a number of multisectoral meetings in Q4, including the national AMS TWG meeting and Nyeri county Antimicrobial Stewardship Interagency Committee meeting to discuss work plans; a five-day workshop in September in collaboration with Nyeri county and FAO officials to further develop the county's One Health costed work plan; the national IPC committee to review the 2015 national IPC policy and strategic plan for health care settings; and Nyeri County IPC Advisory Committee and Kisumu County Health Management Team meetings to discuss IPC performance in MTaPS-supported facilities. In Senegal, MTaPS contributed to two meetings of the AMR working group, which produced the technical validation of the AMS situational analysis and the objectives of the national AMS plan. MTaPS/Tanzania worked with the MOHCDGEC and other AMR partners to organize two important multisectoral forums: one in which AMR partners shared progress and challenges and potential collaboration and the other being the Multisectoral Coordination Committee meeting where participants received updates from three TWGs. MTaPS completed the development of an information and documentation exchange platform and user guide for the National Antimicrobial Resistance Sub-Committee in **Uganda**. MTaPS is supporting the sub-committee to transfer the platform to the MOH website for long-term hosting. MTaPS supported the National AMR Advisory Committee's 37th regular (virtual) meeting in August to discuss STGs, the national AMR strategy revisions, and the AMR advisory committee plan.

#### INFECTION PREVENTION AND CONTROL IMPROVED AND FUNCTIONAL

Strengthening governance structures for IPC at the facility level. MTaPS/Cameroon supported the establishment of IPC committees in six MTaPS-supported health facilities and trained 60 committee members in leadership and management of an IPC program.

Assessing IPC programs at national and facility levels and developing responsive action plans. In Bangladesh, MTaPS conducted a baseline IPC assessment at Comilla Medical College Hospital and Munshiganj District Hospital using the WHO IPCAF tool. The score for Comilla Medical College Hospital was 273.5, which puts it at the basic level, and the score for Munshiganj District Hospital was 507.5, which corresponds to advanced level. Figure 7 shows scores for the individual components.

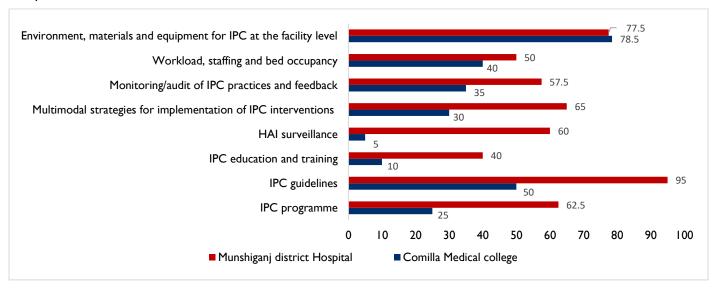


Figure 7. IPCAF core component scores for two hospitals in Bangladesh

MTaPS provided technical assistance to new IPC committees at six health facilities in **Cameroon** to draft their IPC action plans using the results of the IPCAF assessment. Some IPC committees have already begun meeting to follow up on the activities in their plans. The **Côte d'Ivoire** team supported

the AMR-TWG, MTC 4, and experts from the Directorate of Veterinary Services to validate the final report of the hygiene and IPC rapid assessment in animal health facilities at a virtual meeting in July; participants also came from the Ministry of Animal and Fisheries Resources and the Association of Private Veterinarians. MTaPS/**Mali** collaborated with the national MSC committee and National Directorate of Veterinary Services to use the results of the rapid hygiene and IPC assessment to develop IPC guidelines and an action plan for the animal health sector. A consultant also collected additional data at two slaughterhouses to inform the guidelines. In **Tanzania**, MTaPS conducted WASH assessments in four MTaPS-supported health facilities using a national assessment tool. Major gaps included intermittent water supply; poorly maintained sanitation systems; malfunctioning sinks and showers; and a lack of resources for maintenance, planning, or management. After reviewing the results with hospital staff, facilities began to take action, especially on things that did not require resources. For example, Temeke Regional Referral Hospital installed elbow-driven handwashing sinks and repurposed unused equipment.

In **Ethiopia**, MTaPS used the IPCAF to assess four hospitals whose baseline assessments had been done in October 2019 to see the results of MTaPS' technical support (table 8).

Table 8. Result of IPC implementation assessment before and after MTaPS support

NAME OF REFERRAL HOSPITAL	BASELINE (	OCTOBER 2019)	AFTER TECHNICAL SUPPORT FROM MTAPS (AUGUST 2020)		
	IPCAF score (out of 800)	Classification of IPC practice	IPCAF score (out of 800)	Classification of IPC practice	
AaBET Hospital	183.5	Inadequate	382.5	Basic	
Hawassa University Hospital	452.5	Intermediate	565	Intermediate	
Felege Hiwot Hospital	385	Basic	527.5	Intermediate	
Debre Berhan Hospital	410	Intermediate	500	Intermediate	

Specifically, the following major improvements were observed in the hospitals:

- IPC programs were established with clearly defined objectives
- IPC committees were established with doctors and nurses as members
- Dedicated and full-time IPC focal persons are assigned to lead IPC activities
- IPC guidelines were made available on hand hygiene, standard precautions, transmission-based precautions, disinfection and sterilization, prevention of surgical site infection, catheter-associated urinary tract infections, central line-associated bloodstream infections, and outbreak management and preparedness
- Hospitals adopted the WHO multimodal strategy for implementing IPC interventions.

**Developing and implementing IPC policy and guidance documents.** The **Kenya** team provided technical and financial support to update and validate the national IPC policy and strategic plan for health care settings to align with global IPC practices during workshops in July, August, and September. MTaPS supported the Ministry of Public Health in **Cameroon** to organize a five-day workshop to finalize and

validate the national IPC guidelines in August. Staff from WHO participated to ensure that the IPC guidelines align with WHO recommendations. In **Côte d'Ivoire**, MTaPS helped the AMR-TWG organize three multisectoral workshops to validate IPC guidelines for the animal sector and the IPC plan for animal health using findings from the rapid assessment that MTaPS supported and review and update the IPC plan for human health based on IPCAF and IPCAT results. MTaPS/**Ethiopia** provided technical and financial support to the MOH to revise the national IPC guidelines. It also helped develop and finalize the national IPC program and practice-monitoring tool in collaboration with the MOH and Addis Ababa City Administration Health Bureau.

**Developing individual and local capacities.** This quarter, MTaPS helped train 178 people in IPC, including trainers who will cascade the training in their countries. Cumulatively, 1,539 people have been trained on IPC. MTaPS supported **Côte d'Ivoire's** AMR-TWG, in collaboration with MTC 4 and experts from the Directorate of Veterinary Services, to organize a five-day training of trainers workshop on IPC for the animal health sector in August. The 10 master trainers are ready to conduct onsite IPC trainings of animal health care providers; a similar workshop was held for 25 Directorate of Veterinary Services and Ministry of Animal and Fisheries staff. On the human health side, MTaPS collaborated with the AMR-TWG and MTC 4 to train 24 people, including 20 health care providers, from the Bouake University Teaching Hospital. In **Kenya**, MTaPS continued its work with the National Nurses Association of Kenya to advance the IPC CPD course to be delivered through the professional association: the purpose of one meeting was to share findings of the IPC CPD training needs assessment, and participants at two other workshops developed and reviewed the first draft of the IPC CPD curriculum outline, implementation strategy, and course content.

MTaPS continued to work with county IPC advisory committees in Nyeri and Kisumu to virtually mentor IPC teams and follow up on their activities at 16 target health facilities. MTaPS held virtual health talks in September on patient safety targeting health care workers and IPC and AMS committee members in the 16 facilities. The virtual health talks were attended by more than 50 participants, including national and county government officials and the head of the head of the Division for Occupational Safety and Health. MTaPS/Senegal supported the technical review and validation of IPC training modules during a workshop in August and also supported IPC training sessions for 30 health care workers at a hospital in Tivaouane. MTaPS' support to the three targeted hospitals to implement their action plans resulted in functional IPC committees, implementation of CQI and the use of standardized monitoring tools to improve IPC, better hand hygiene compliance, and improved performance in core IPC components. Additionally, the incidence rate of health care associated infections at the MTaPS-supported private faith-based hospital declined to 1% (30/2,296) from January to June 2020. MTaPS also continued progress to deploy an eLearning course by conducting virtual sessions for Ministry of Health and Social Welfare staff to manage the Moodle platform and institutionalize the eCourse. MTaPS/Uganda conducted supportive supervision visits at target health facilities, which helped facilities link to the national logistics team to obtain additional IPC supplies; in addition, each ward has IPC mentors and a reporting system has been set up, including COVID-19 surveillance data for health care workers. As part of DTC interventions in DRC, MTaPS provided refresher training to IPC committees and health care workers in the three target hospitals with a focus on COVID-19.

#### **USE OF ANTIMICROBIAL MEDICINES OPTIMIZED**

**Developing and implementing AMS policy and guidance documents.** With the national AMS regulatory framework for both the human and animal health sectors almost final, MTaPS/**Burkina Faso** organized a two-day workshop with stakeholders from the public and private sectors and professional associations to finalize the draft national guidelines for the use of antimicrobials in the animal sector. Since July, MTaPS/**DRC** has been working with microbiologists and other experts to collect data on the local epidemiology and profile of AMR in targeted hospitals and laboratories and using the data to



Essential Medicines Adviser at WHO Tanzania Ms. Rose Shija doing a presentation on AWaRe categorization of antibiotics process during the first workshop for classification of antibiotics registered in Tanzania into AWaRe classes. Photo credit: Richard Valimba, STA MTaPS

categorize antimicrobials on the DRC essential medicines list into the AWaRe groups. The revised list was reviewed by stakeholders in August and is being finalized. In Ethiopia, MTaPS provided technical and financial support for the revision of the STGs for general hospitals, which are out for technical review. MTaPS/Tanzania organized two stakeholder workshops during the quarter to revise and finalize Tanzania's STGs and national essential medicines list with AWaRe classification and develop a strategy for incorporating the classification into policy and action. The revised drafts are under review.

MTaPS helped complete the draft of a

national essential veterinary medicines list and guidelines on IPC and use of antimicrobials to strengthen AMS in the agricultural sector—a ground-breaking activity in animal health in **Uganda**. The **Kenya** MOH launched its revised essential medicines list and national AMS guidelines in an event in July attended by more than 300 participants from various sectors and counties. MTaPS collaborated with the AMS-TWG and National Medicines and Therapeutics Committee in Kenya to develop a complementary dissemination, implementation, and training package for the AMS guidelines that will be used to build capacity of health care workers. MTaPS provided technical support to the Kenya Pharmacy and Poisons Board to review the draft guidelines for scheduling and rescheduling health products and technologies to align them with the new AWaRe categorization. The scheduling guidelines will restrict the use of certain medicines, including antimicrobials. During the quarter, MTaPS worked with the Bangladesh CDC/DGHS to conduct the first meeting in the process of developing STGs for infectious diseases. In Cameroon, MTaPS helped the MOH and Ministry of Animal Husbandry draft an integrated national AMS action plan based on results from the two sectoral situational analyses. MTaPS helped the newly formed AMS-TWG in Côte d'Ivoire organize a multisectoral workshop to update the AMS policy and plan and develop an AMS plan and national guidelines for health care settings using results from a previously conducted rapid assessment. The National AMS Plan 2021-2025 and the documents for health care settings were validated in July. In September, MTaPS supported a workshop for the AMR-TWG to review and finalize all of the documents. Using the results of rapid AMS assessments in the human and animal sectors in DRC, MTaPS helped the drug regulatory authority draft a situational analysis that also included the plant sector to form the basis of a three-year AMS plan. Priorities are promotion and monitoring of appropriate antimicrobial use, fighting illicit sales, and managing consumption data. MTaPS helped technical officers in Uganda's National Drug Authority present the draft framework for monitoring the use of antimicrobials to senior management.

Assessing AMS policies and practices. MTaPS conducted a rapid AMS baseline assessment in its two target hospitals in **Bangladesh**—Comilla Medical College Hospital and Munshiganj District Hospital—using simple checklists from the quality improvement secretariat at the DGHS, WHO, and other sources. Comilla Medical College Hospital showed better overall readiness to conduct AMS, with two of the six core components (AMS actions and monitoring and surveillance) reaching scores above 90% and another two (leadership and reporting and feedback) reaching above 65%. On the other hand, Munshigani District Hospital's readiness scores for all six components are below 40%, and two (leadership and reporting and feedback) scored zero. MTaPS will use the results to work with the hospitals to increase their readiness to implement AMS programs. MTaPS supported the Ministry of Livestock and Animal Husbandry in Cameroon to conduct a rapid assessment of the policies and regulations regarding antimicrobial use in the animal sector. In a three-day workshop, multisectoral experts reviewed and validated the rapid assessments from both the human and animal sectors. During this quarter, MTaPS/DRC supported the drug regulatory authority and national committee on AMR to conduct multisectoral field visits to animal clinics and agricultural institutions, including two veterinary clinics, one phytosanitary center, and one environmental laboratory for vectors analysis and control. The aim of these visits was to learn more about the use of antimicrobials in the animal and environmental sectors and provide recommendations. Findings included little awareness regarding AMR, no legal provisions to coordinate the management and use of antimicrobials among sectors, an undefined supply chain, and uncontrolled use of antimicrobials. MTaPS also validated rapid AMS assessments in the human and animal sectors, which had determined that existing policies and regulations do not promote appropriate medicine use in either sector. MTaPS then mapped stakeholders involved with antimicrobial management revealing that while most MOH partners (e.g., Global Fund, World Bank, UNICEF, WHO, USAID) procure and manage large quantities of antimicrobials, none are involved in AMR or use of antimicrobials except for USAID, WHO, and the World Organisation for Animal Health. In addition, in collaboration with WHO Geneva and Brazzaville, MTaPS supported the drug regulatory authority to assess the consumption of antimicrobials using the anatomical therapeutic chemical/defined daily dose methodology. The sources of data included regional distribution centers, the drug regulatory authority, central procurement units, and private suppliers. Data collectors and clerks received a three-day training by WHO in August. The assessment will be conducted annually and reported to the WHO Global Antimicrobial Surveillance System.

Developing individual and local capacities. Over the course of the reporting period, MTaPS helped train 174 people, including many DTC members, on AMS topics. In Burkina Faso, MTaPS worked with the Directorate of Hospital Pharmacy to establish DTCs in five health care facilities, including developing terms of reference and budgets. MTaPS/Côte d'Ivoire used a previous DTC capacity assessment to help the AMR-TWG develop and validate DTC training design and materials over the course of several workshops. The first DTC trainings took place in September at the Bouake and Cocody University Teaching Hospitals for 21 and 19 DTC members, respectively. A facilitator from the MSH-led Leadership Development Plus (LDP+) program led the AMS action plan session using LDP+ tools. In DRC, MTaPS continued to support the MOH to establish and strengthen DTCs in selected health facilities, and three hospitals were chosen as pilots. After baseline antimicrobial use studies, MTaPS trained 80 DTC members on AMS using newly updated DTC training materials. The DTC members used the baseline information to draft situational analyses for their hospitals and developed AMS action plans. A preservice AMS curriculum for the University of Nairobi School of Pharmacy in Kenya was finalized this quarter after undergoing external review by AMS experts in academia, policy, health systems strengthening, and hospital pharmacy practice. Classes with postgraduate students will begin next quarter; in addition, the AMS curriculum for CPD was finalized and a plan for implementation through professional associations was developed, with the National Nurses Association of Kenya and the Pharmaceutical Society of Kenya hosting their first webinars in September 2020. MTaPS Kenya's support to 16 target facilities in Nyeri and Kisumu counties in AMS this quarter included Medicines and Therapeutics Committee/AMS training for 38 health care workers in Kisumu as well as continued

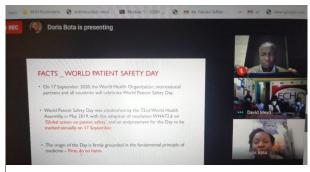
mentoring and follow up with AMS and Medicines and Therapeutics Committee teams to implement their AMS action plans. In Othaya Referral Hospital in Nyeri county, MTaPS worked with the AMS team to develop and issue guidelines to clinicians on antibiotic use in pneumonia, pharyngitis, otitis media, and surgical prophylaxis to enhance prescribing of antimicrobials. The team also conducted prescription audits to determine outpatient prescribing practices. WHO recommends that no more than 20.0%—26.8% of encounters in a typical outpatient setting include an antibiotic prescription.

The results of the audits at Othaya are shown in table 9. Although there has been a steady decline in antimicrobial use for children, more attention is required to meet the target range.

Table 9: Proportion of antibiotics prescribed in Othaya Referral Hospital, Nyeri county, January-June 2020

PRESCRIPTIONS	JAN	FEB	MARCH	APRIL	MAY	JUNE
Adults	N=3,014	N=2,794	N=2,711	N=2,665	N=2,657	N=2,282
	40.11%	25.30%	29.83%	23.71%	18.59%	20.03%
Pediatrics	N=455	N=510	N=445	N/A	N/A	N/A
	73.18%	65.29%	54.38%			

At St. Elizabeth Hospital in Kisumu, the AMS team conducted prescription audits covering April and May prescriptions from the outpatient department. In April, 35% of 103 patient encounters included an antibiotic, while in May, 40% of 105 encounters did. In addition, the team conducted an assessment of polypharmacy (more than the average of two medicines recommended by WHO) from March to May. Of 125 encounters in March, 18% of prescriptions included polypharmacy, as did 13% of 103 prescriptions in April and 35% of 105 prescriptions in May. The AMS team noted that clinicians at the hospital lacked experience with the Kenyan guidelines on antibiotic prescribing; therefore, the team is sharing results with prescribers, investigating contributing factors, and generating approaches to improve antibiotic prescribing. At Outspan Hospital in Nyeri, the AMS team investigated adherence to AWaRe guidelines in prescribing. They noted that culture and sensitivity tests were being ordered before prescribing Reserve antibiotics but that in some cases, the antibiotics were being prescribed, dispensed, and administered before the results were even released from the laboratory. MTaPS offered technical input into the review of Kenyatta National Hospital's AMS policy and prescribing guidelines. MTaPS also offered technical and financial support in the second review of the hospital's medicines formulary in September 2020. At Gertrude's Children's Hospital, MTaPS worked with the AMS committee to review the hospital's AMS policies, guidelines, and STGs for infections.



MTaPS participation during a health talk at Nyakach County Hospital. Photo credit: Collins Jaguga

MTaPS provided technical assistance to St. Peter Specialized Hospital in **Ethiopia** to conduct a drug use evaluation on ceftriaxone. The evaluation was a retrospective review of patient charts to identify patients who received ceftriaxone during hospitalization in the internal medicine ward from March 2019 to March 2020. The preliminary findings showed that in 75% of patients, ceftriaxone use was inappropriate for the clinical condition; in addition; the practice of culture and sensitivity testing before initiation and changing antibiotics was very poor. MTaPS trained 16 health professionals from nine MTaPS-supported hospitals in September

on the AWaRe categorization and on how to implement AMS interventions. Participants practiced using the prescription audit and feedback tool using case scenarios.

MTaPS/**Kenya** participated in two workshops organized by Africa One Health University Network—one to validate a mapping of One Health partners and a training needs assessment for frontline workers and the other to review the AMR curriculum for in-service training on AMS for human, animal, and environmental health professionals. MTaPS was a member of the planning team that organized a weeklong series of events for the 2nd World Patient Safety Day on September 17, 2020. The planning team was responsible for setting the agenda, budgeting, and logistics for the week's activities. The events had more than 600 participants. MTaPS conducted a webinar on patient safety organized by the Nyeri county health department with more than 100 officials attending and virtual health talks for more than 50 health care workers, IPC and AMS committee members, and county health officials in our two target counties.

MTaPS/Mali helped organize a workshop in July to develop draft STGs for common infectious diseases with government staff and doctors and pharmacists from several health facilities. MTaPS also recruited two consultants to develop the national AMS plan for the animal and human health sectors, which was co-led by Directorate of Pharmacy and Medicine and Directorate of Veterinary Services directors. The draft is under review. During the quarter, MTaPS collaborated with the national Multisectoral Coordination Committee, Directorate of Pharmacy and Medicine, and the Agence Nationale d'Evaluation des Hôpitaux to establish DTCs by facilitating the validation of DTC terms of reference; selecting DTC members in five hospitals (national, regional, and district); and developing eight DTC training modules. During this quarter in Senegal, MTaPS continued collaborating with a consulting firm, which provided the first results of the rapid situational analysis of antimicrobial use, legislation, and control in the human, animal, and environmental health sectors. In July, MTaPS supported a validation workshop for the report sponsored by the One Health Permanent Secretariat and attended by representatives from the government agencies for human, animal, and environmental health as well as the private sector. In September, the MTaPS subcontractor submitted the draft implementation plan of the national AMS plan, which is under review. In Ethiopia, the team supported the Pharmaceuticals and Medical Equipment Directorate/MOH to conduct a validation workshop to finalize the training course and materials on AMR for health care professionals, which was followed by a pilot test of the course.

Increasing awareness of AMR. MTaPS/Kenya provided technical support as a member of the panel of judges in a hackathon organized by Africa One Health University Network on "One Health Application Development Challenge" for university students. The winning team developed an application that is intended to be used by community health volunteers to educate the public on zoonotic diseases. MTaPS/Ethiopia collaborated with the MOH to develop a training course on AMR for journalists and communication professionals to raise awareness on AMR issues and on how to frame AMR messages for the public. In Uganda, the communication strategy and messages about AMR targeting the agricultural sector that the team helped develop were approved by the Ministry of Agriculture, Animal Industry and Fisheries. MTaPS/Tanzania supported the MOHCDGEC by printing 7,000 copies of the AMR Communication Strategy, which had been developed previously.

#### MATERNAL, NEWBORN, AND CHILD HEALTH

Preventing child and maternal deaths requires treatment with safe, effective, and quality-assured medicines and pharmaceutical services. The MTaPS maternal, newborn, and child health (MNCH) portfolio contributes to achieving Sustainable Development Goal 3: Ensure healthy lives and promote well-being for all at all ages and prevent child and maternal deaths by increasing global awareness of the barriers to access to essential maternal and child health (MCH) medicines and supplies and by providing technical assistance to reduce these barriers at both the global and country levels. The goal of the MTaPS/MNCH portfolio is to ensure availability and appropriate use of safe, effective, and quality-assured medical products and effective pharmaceutical services to reduce maternal, newborn, and child mortality by strengthening pharmaceutical systems.

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

In program year 2, MTaPS continued to support strengthening of pharmaceutical systems to improve MNCH outcomes through:

- Mapping country registration processes and how they pertain to MNCH medical products
- Documenting strategies to ensure quality of medicines when procured at a subnational level
- Supporting global learning on pharmaceutical systems strengthening for MNCH through the development of three microlearning videos
- Strengthening the respiratory ecosystem through mapping partner support and the guidance on the technical package for oxygen therapy

During this program year, MTaPS has updated the reproductive, maternal, newborn, and child health (RMNCH) forecasting supplement developed under the UN Commission on Life-Saving Commodities (UNCoLSC), based on comments from reviewers from partner organizations, USAID, and UNICEF and discussions with technical experts at WHO. This update includes recent recommendations from WHO on the management of post-partum hemorrhage as well as a new section on antihypertensives in pregnancy. The final draft will be validated with country quantification teams in a follow-on activity to inform the finalization of the document prior to wider dissemination. The inclusive consultative process of updating the supplement ensured buy-in of many partners and will, as a result, increase the use of the guide by country teams to quantify RMNCH commodities, which are often underutilized or scaled up and for which consumption methods for forecasting cannot be applied.

During this second year of the program, MTaPS finalized the full set of job aids and dispensing envelopes to promote adherence to amoxicillin dispersible tablets (DT) for treatment of childhood pneumonia. These tools had initially been developed by partners under the UNCoLSC, and although studies had been conducted to validate them, the tools were never finalized or disseminated. MTaPS took the recommendations from those studies and applied them to finalize the tools in English, French, and Spanish for amoxicillin DT for all age bands of the WHO treatment protocol and also for amoxicillin suspension. The tools are available in DEC in both pdf and editable formats so that country teams can print and use or adapt as needed before using. MTaPS has disseminated the tools directly to two projects working with pneumonia treatment (Tools for Integrated Management of Childhood Illnesses [TIMCI], implemented by PATH and funded by UNITAID, and the Scaling Pneumonia Response Innovations [SPRINT] Project, implemented by UNICEF) and will also disseminate them through the Every Breath Counts coalition. Many factors can affect adherence to amoxicillin DT for childhood pneumonia, but some barriers to adherence can be addressed by job aids and dispensing envelopes as part of a strategy to improve adherence. While the tools only consider the treatment of pneumonia, amoxicillin DT is also used to treat possible serious bacterial infection in newborns and severe acute malnutrition; however, it was important to disseminate the pneumonia version of the tools and improve the use of amoxicillin for children with pneumonia and hopefully at some point in the future adapt them to include other indications.

#### **QUARTER PROGRESS FOR FY20Q4**

#### **OBJECTIVE 1: PHARMACEUTICAL-SECTOR GOVERNANCE STRENGTHENED**

Contributing to the MTaPS sub-objective to increase stakeholder engagement and empowerment to improve access to and appropriate use of safe, effective, affordable, quality-assured medicines, technologies, and supplies for women and children, MTaPS has started work on a rapid literature review on civil society engagement interventions with, or that hold promise for the inclusion of, a component on availability, affordability, and appropriate use of quality medical products, with a particular focus on MNCH products. This review will document relevant social accountability and other experiences, best practices, tools, and approaches that engage civil society to strengthen social accountability for improved access to and appropriate use of quality medicines for women and children.

## OBJECTIVE 2: INSTITUTIONAL AND HUMAN RESOURCE CAPACITY FOR PHARMACEUTICAL MANAGEMENT AND SERVICES, INCLUDING REGULATION OF MNCH PRODUCTS

MTaPS continues to support countries to ensure the quality of MNCH medical products by strengthening the product registration systems and improving procurement practices at sub-national levels.

#### Activity 2.1.1: Review of registration of MNCH commodities

MTaPS conducted a mapping exercise to identify barriers and bottlenecks in registration of MNCH medical products in nine countries (Bangladesh, DRC, Mali, Mozambique, Nepal, Rwanda, Senegal, Tanzania, and Uganda) approved by USAID missions to engage in this activity. During this quarter, all reports documenting the registration processes and bottlenecks for MNCH medicines and medical devices and highlighting key issues that national medicine regulatory authorities should consider to further improve the process, were completed and are at different stages of external and internal review.

MTaPS engaged with 13 pharmaceutical manufacturers to discuss their perspectives on registration of MNCH medicines and the barriers they encounter to registering quality MNCH products in low- and middle-income countries (LMICs). MTaPS is consolidating the findings to document in a technical brief, together with the findings of the country registration mapping. Considerations for improving the registration process will help inform regulatory authorities and other policy makers of strategies to eliminate the identified barriers and bottlenecks to increase access to MNCH medical products.

#### Activity 2.1.2: Document quality assurance in local procurement

This activity will document best practices to ensure quality of medicines when they are procured subnationally, which is often the case for MNCH medicines in LMICs, using examples from Tanzania and Nigeria. During this quarter, data were collected by two consultants from key contacts in the selected states and regions, virtually in Nigeria and both virtually and through some site visits in Tanzania. The best practices and lessons learned are being documented in a technical brief.

## OBJECTIVE 3: AVAILABILITY AND USE OF PHARMACEUTICAL INFORMATION OF MNCH MEDICINES FOR DECISION MAKING INCREASED AND GLOBAL LEARNING AGENDA ADVANCED

#### 3.2.2: Global learning on pharmaceutical systems for MNCH

As part of the global learning agenda on pharmaceutical systems for MNCH, MTaPS is developing a series of microlearning4 seminars to raise awareness and promote understanding of why strengthening the pharmaceutical system is important for women's and children's health outcomes. These microlearning videos are a complement to the MTaPS e-learning and face-to-face PSS 101 courses. During this quarter, MTaPS finalized the beta version of all three videos. The first video is a general introduction to pharmaceutical systems strengthening; the second is on regulatory systems and their importance for improving access to safe, effective, and quality-assured medical products and improving MNCH outcomes; and the third is on financing pharmaceuticals and medical products for MNCH outcomes. After review by USAID, the final versions are being completed and will be finalized early in quarter 1 of year 3.

## OBJECTIVE 5: PHARMACEUTICAL SERVICES FOR WOMEN AND CHILDREN, INCLUDING PRODUCT AVAILABILITY AND PATIENT-CENTERED CARE, IMPROVED

## Activity 5.1.1: Revise the reproductive, maternal, newborn and child health (RMNCH) quantification guide

Quantification practices have a direct effect on product availability. MTaPS has been further revising the RMNCH forecasting supplement developed under UNCoLSC this quarter and integrating final comments from reviewers at USAID and UNICEF and technical input from WHO. A revised final draft has been completed and will be copyedited prior to a collaborative validation exercise with the USAID/Global Health Supply Chain Procurement Supply Management project in some countries to inform a final version of the guide as a follow-on activity.

#### Activity 5.2.1: Improve adherence to amoxicillin DT for childhood pneumonia

Many factors can affect adherence to amoxicillin DT for childhood pneumonia. Some of the barriers to adherence can be addressed by job aids and dispensing envelopes as part of a strategy to improve adherence.

MTaPS completed the updating of the job aids and dispensing envelopes developed in 2015 by partners under UNCoLSC by incorporating minor edits from the validation studies conducted at that time. A final package of all the tools for all age bands and for amoxicillin suspension are available for dissemination in English, French, and Spanish, as pdf for printing and as editable files for adaptation prior to printing as needed.

#### Activity 5.2.2: Define respiratory package

During this quarter, MTaPS submitted to USAID the mapping of partner support in the respiratory ecosystem, which showed what is being done by whom and where to strengthen systems to ensure appropriate oxygen administration. This mapping highlights the partners supporting the respiratory ecosystem at the global and country levels and components of the system that are not as well addressed, such as regulation.

<sup>&</sup>lt;sup>4</sup> This process entails turning complex technical content into smaller bite-size or shorter nuggets of content that are more easily digestible by using learning tactics in a manner that makes sense, saves time, and engages learners.

MTaPS completed a comparison of guidance on the technical packages of medical devices and their technical specifications for the respiratory ecosystem to highlight discrepancies in these packages for administering oxygen therapy.

These documents will be completed in quarter 1 of year 3, after receiving feedback from USAID.

ACTIVITIES FOR NEXT QUARTER		
ACTIVITY AND DESCRIPTION	DATE	
1.3.1 Strengthen civil society engagement to increase access to and appropriate use of safe, effective, quality-assured MNCH medicines, technologies and supplies and pharmaceutical services (Year 2 activity)	December 2020	
The rapid literature review on civil society engagement interventions that include a component on availability, affordability, and appropriate use of quality medical products, with a particular focus on MNCH products, will be completed.		
2.1.1: Review of registration of MNCH commodities	December 2020	
Country reports will be finalized, approved by USAID, and shared with national medicines regulatory authorities and country missions. The technical brief will be completed.		
2.1.2: Document quality assurance in local procurement	December 2020	
A technical brief on best practices of sub-national procurement will be developed.		
3.2.2: Global learning on pharmaceutical systems for MNCH	November 2020	
The microlearning videos on the impact of pharmaceutical systems strengthening on MNCH will be disseminated and made available on LeaderNet.		
5.1.1: Revise RMNCH quantification guide	November 2020	
The forecasting guide will be copyedited and made available for the validation exercise.		
5.2.2: Define respiratory package	October 2020	
The mapping of the global landscape of implementation and support on the respiratory ecosystem and the comparison of technical packages for oxygen therapy will be finalized.		

#### OFFICE OF HEALTH SYSTEMS, CROSS BUREAU FUNDING

Activities in this portfolio allow MTaPS to demonstrate and advance technical leadership in pharmaceutical systems strengthening (PSS), in line with the overall program goal and objectives.

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

In program year 2, MTaPS embarked on advancing PSS research and the global learning agenda and undertook other activities that helped to demonstrate technical leadership in regulatory systems strengthening at the regional level, health technology assessments (HTA), and pharmaceutical expenditure tracking.

The program advanced the global learning agenda by:

- Continuing to develop PSS Insight
- Collaborating with the World Health Organization (WHO) on measuring access to medicines and PSS
- Convening the Pharmaceutical Systems Strengthening Technical Advisory Group (PSS TAG)
- Developing the PSS 101 course
- · Developing and implementing a multiyear research plan
- Creating a learning exchange on the Joint Learning Network (JLN)

At the start of FY20, PSS Insight contained 117 indicators and was intended for use as a global-level tool for monitoring pharmaceutical systems strengthening across countries and over time. As the purpose of the tool evolved to focus increasingly on use by national-level policy and decisionmakers for internal pharmaceutical systems monitoring, it became clear that the tool was too large to be practically implemented at this level. As a result, MTaPS worked with core partner Boston University School of Public Health (BUSPH) to reconfigure the tool, reducing the number of indicators from 117 to 38, and proposed a method for benchmarking progress that can be readily deployed at the national level. MTaPS also initiated collaboration with WHO on the development of its proposed Access Global Benchmarking Tool (GBT), with the goal of integrating it with PSS Insight.

The e-learning and face-to-face PSS 101 course is a key deliverable for the Cross Bureau portfolio. MTaPS developed and launched the face-to-face course and made significant progress in developing the e-learning version of the course. The course will increase USAID staff's understanding of the basic principles of PSS, including how addressing pharmaceutical management problems contributes to advancing universal health coverage (UHC); combating antimicrobial resistance (AMR), HIV and AIDS, malaria, and TB; and promoting maternal and child health.

MTaPS worked with BUSPH to develop a concept for a learning exchange entitled *Medicines in UHC* on the JLN platform. MTaPS participated in JLN's biennial meeting where the program introduced the concept and facilitated a mini-scoping session with participants to hone the specific topic for the exchange. Based on the discussions, MTaPS proposed that the learning exchange focus specifically on medicines pricing strategies, which was the area of strongest interest among participants. MTaPS and BUSPH worked with the JLN team to obtain approval for the exchange from the JLN steering committee and recruit participants. The program convened a learning exchange on pricing strategies for medical products consisting of three virtual sessions between July and September 2020, averaging 22 participants per session. MTaPS engaged with participants from 17 countries directly involved in or responsible for national health insurance schemes and strategic and operational decisions relating to procurement and distribution of medicines. The exchange represents the first medicines-specific technical initiative on the JLN platform and lays the foundation for other technical initiatives, such as a community of practice for PSS.

MTaPS developed a multiyear research plan that aims to document and analyze the processes and results of the program's PSS interventions and understand the factors that facilitate or hinder success. The primary aim of the research plan is to contribute to the PSS evidence base, thereby providing a deeper understanding of PSS and facilitating informed decisions on the use of scarce resources at the national, regional, and global levels. The secondary aim is to use the generated evidence in MTaPS' networking and collaboration efforts to help shape the global health discourse and norm-setting activities with respect to medicines in health systems. The sum effect will be to help shape and advance the PSS global learning agenda.

In line with its research plan, MTaPS started developing its publication pipeline by using Cross Bureau funds to draft six manuscripts for peer review, with two of those published, three under review, and one being finalized. A commentary entitled <a href="Integrating Pharmaceutical Systems Strengthening in the Current Global Health Scenario: Three 'Uncomfortable Truths'</a>, co-authored with members of the PSS TAG, was published in June 2020 in the <a href="Journal of Pharmaceutical Policy and Practice">Journal of Pharmaceutical Policy and Practice</a>. Another manuscript by MTaPS on the WHO GBT for evaluation of national regulatory systems, entitled The <a href="WHO Global Benchmarking Tool: Game Changer for Strengthening National Regulatory Capacity">WHO Global Benchmarking Tool: Game Changer for Strengthening National Regulatory Capacity</a>, was published in <a href="BMJ Global Health">BMJ Global Health</a> in August 2020.

MTaPS launched a brown bag series entitled *Pharmaceutical Systems in Practice*. The series provides a collegial environment for MTaPS staff and partners to share lessons and discuss questions and challenges emerging from program implementation. The first brown bag was in February, and there have been four subsequent sessions. Through the five sessions, MTaPS staff and partners have shared experiences from implementing an electronic asset management system in Bangladesh, designing a multisectoral AMR strategy in Tanzania, providing a stepwise approach for advancing and institutionalizing HTA, and supporting multisectoral coordination on AMR in Kenya and Uganda. Attendance averaged 85 participants representing MTaPS staff and partners, MSH staff, and the USAID/COR team.

In the area of regulatory systems strengthening, MTaPS collaborated with the African Union Development Agency New Partnership for African Development (AUDA-NEPAD) to support convergence and harmonization of medical products regulation in Africa. MTaPS facilitated the development of institutional capacity for regulatory systems through the validation of the monitoring and evaluation tool for Regional Centers of Regulatory Excellence (RCOREs) under the African Medicines Regulatory Harmonization Initiative. The program has since used the tool to conduct a baseline assessment of RCOREs' performance, which will inform RCOREs of their current status and form the baseline for routine monitoring and evaluation of their performance. The program is also working to develop a web-based platform for improving pharmacovigilance (PV) systems in the Economic Community of West African States (ECOWAS) region. The platform will collate regional data and information on findings on the PV function from the WHO GBT for evaluation of national regulatory systems and aggregate data on adverse drug reactions (ADRs). The platform will enable member states in the region to exchange information and share experiences and will serve as a one-stop portal at the national and regional levels for monitoring the status of PV systems in Africa.

MTaPS developed a roadmap for HTA institutionalization in low- and middle-income countries (LMICs) to provide a stepwise approach for advancing and institutionalizing HTA, including agenda setting, policy formulation, potential options for implementation, and impact evaluation. The team developed the roadmap through an extensive systematic literature review and peer review process to capture lessons from the global experience in introducing and applying HTA. MTaPS leveraged funds from both Asia Bureau and Cross Bureau to complete this activity. Lessons learned will help other LMICs in their journey of advancing HTA. It will also help identify opportunities for future engagement and capacity building in the region with respect to HTA. The program will be implementing the roadmap in Year 3.

The program collaborated with LaunchDSI, funded by the Bill & Melinda Gates Foundation, to conduct a case study in Tanzania on the engagement of retail drug outlets by the National Health Insurance Fund

(NHIF) in the national benefits program. The case study characterizes barriers and facilitators related to incorporating retail drug outlets into national prepayment schemes and provides insights that countries can use when designing initiatives to include retail outlets in their health insurance schemes. The resulting manuscript is one of the three under peer review.

As part of its collaboration with the USAID Local Health System Sustainability (LHSS) Project to improve the availability and quality of pharmaceutical expenditure data, MTaPS initiated the process for conducting field work in Burkina Faso to understand and document the data availability challenges faced by stakeholders who have to make decisions about pharmaceutical spending in country, obtain existing pharmaceutical expenditure data from stakeholders, and determine how the data can be aligned with the System of Health Accounts 2011 framework. MTaPS will continue this activity in Year 3.

The program also worked to identify gaps in integration of infection prevention and control (IPC)/water, sanitation, and hygiene (WASH) critical conditions into the quality of care (QOC) and quality improvement (QI) tools and processes. Adapting a methodology from the USAID/Maternal and Child Survival Program gap analysis,<sup>5</sup> MTaPS reviewed documents related to QOC/QI in the Bangladesh health system, with an emphasis on maternal, newborn, and child health (MNCH). The review examined the critical conditions and the break-out of sub-conditions by document, a ranking of the conditions that were most prevalent across documents, and a summary of instances of IPC/WASH references that apply specifically to MNCH topics in the Bangladesh QOC documents. Ultimately, this analysis will feed into identifying how IPC/WASH adherence in MNCH services can be strengthened through QOC/QI approaches.

Together, these activities allowed the program to contribute to advancing the following program sub-objectives:

- 1.2: Evidence-based medicines policies, laws, regulations, guidelines, norms, and standards improved and enforced
- 2.4: Medicines regulatory capacity strengthened, including through regional regulatory harmonization
- 3.2: Information on pharmaceutical systems available and used
- 3.3: Pharmaceutical systems strengthening research and global learning agenda advanced
- 4.1: Financial barriers to access to medicines reduced
- 4.3: Efficiency of pharmaceutical resource allocation and use increased
- 5.3: Patient safety and therapeutic effectiveness ensured
- 5.4: Antimicrobial resistance containment supported

More broadly, the portfolio activities have helped advance the program's technical leadership in PSS and contribute to Office of Health Systems' generation of new knowledge in the PSS domain.

5 MCSP. 2019. Tools for Improving Quality of Care for Mothers and Newborns. A Review and Gap Analysis of Critical Environmental Conditions. USAID Maternal and Child Survival Program. Available at https://www.mcsprogram.org/resource/tools-for-improving-quality-of-care-for-mothers-and-newborns-a-review-and-gap-analysis-of-critical-environmental-conditions/

#### **QUARTER PROGRESS FOR FY20Q4**

#### **ACTIVITY I: REFINE/VALIDATE PSS INSIGHT IN USAID MTAPS-SUPPORTED COUNTRIES**

MTaPS drafted the technical report for the indicator reduction, which is undergoing internal review prior to finalization early next quarter.

#### **ACTIVITY 2: ENHANCE THE GLOBAL PHARMACEUTICAL SYSTEMS LEARNING AGENDA**

During this quarter, MTaPS completed and uploaded six (1, 2, 3, 4, 6, 8) of the eight PSS e-learning modules onto MSH LeaderNet platform for wider public consumption. The development of these modules was done through a collaborative process involving the USAID/COR team and other USAID experts. MTaPS has also refined and submitted module 7 to USAID for review and feedback. Based on the feedback provided by the USAID/COR team, MTaPS continued to refine the information systems module (5). Concurrently, MTaPS submitted a proposal to the GHeL team to adapt the e-learning course to its platform to further expand the reach of the PSS e-learning program.

With approval from the JLN steering group, MTaPS convened a learning exchange on pricing strategies for medical products. Working with BUSPH, MTaPS hosted three virtual sessions facilitating cross-country exchange of knowledge and experiences on strategies for making valid price comparisons, negotiating prices for single-source products, and identifying best practices for assessing the effects of pricing policies. Participants represented 17 countries. Attendance averaged 22 participants and ranged from 18 to 29 over the three sessions. The typical participant was a government official directly involved in or responsible for national health insurance schemes and strategic and operational decisions relating to procurement and distribution of medicines.

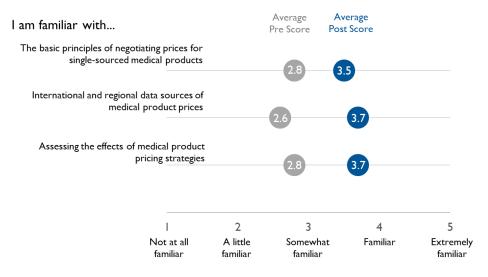


Figure 8. Shift in knowledge among learning exchange participants who responded to the post-assessment survey.

Among the participants who responded to the post-survey, there was a notable increase in knowledge of the topics covered (figure 8). Further, 93% (14/15) reported sharing new information from the learning exchange with coworkers or others at their job, and 67% (10/15) reported using information from the exchange in their daily work. For example, some respondents reported using the price data resources shared and insights gathered from the discussion on negotiation skills to push for greater price transparency as part of their national COVID-19 response and to inform drafting of new guidelines for price negotiation. All 15 survey respondents noted they had benefited in some way from

participating in the learning exchange and expressed interest in participating in future JLN learning initiatives on PSS. MTaPS developed a reference document for the participants, highlighting some of the key learnings from the exchange and summarizing common pricing strategies, the key factors influencing price negotiations, and key considerations for monitoring and evaluating the effects of pricing strategies. The reference document also provided a list of pricing data resources.

With respect to research and publications, MTaPS' commentary on the GBT entitled *The WHO Global Benchmarking Tool: Game Changer for Strengthening National Regulatory Capacity* was published in *BMJ Global Health* in August. The program also drafted a manuscript on generating political will for regulatory systems strengthening and submitted it for peer review.

MTaPS drafted an abstract on the reconfiguration of the supply chain to balance equity and emergency response during the COVID-19 pandemic in the Philippines. The team submitted the abstract for consideration as an oral presentation at the 13th Global Health Supply Chain Virtual Summit, scheduled for November 17–19, 2020. MTaPS is awaiting a response on the submission.

The program also continued with its *Pharmaceutical Systems in Practice* series. MTaPS/Uganda shared the team's experience supporting the Zoonotic Disease Coordination Center and the National One Health Technical Working Group in implementing Uganda's national action plan on AMR. The presentation demonstrated how the MTaPS/Uganda teams' support is strengthening multisectoral coordination on AMR and building the country's capacity to control AMR. Eighty-seven staff, representing MSH staff, MTaPS partners, and the USAID/COR team, attended the virtual brown bag. The program also presented on health technology assessments (HTAs), providing an overview of the policy actions needed to successfully implement HTAs and discussing the MTaPS-developed guide, *A Roadmap for Systematic Priority Setting and Health Technology Assessment (HTA)*. The event had 103 participants from MSH, MTaPS, and USAID.

# ACTIVITY 3: IN COLLABORATION WITH CORE PARTNER NEPAD, SUPPORT THE AMRH INITIATIVE TO INCREASE INSTITUTIONAL AND HUMAN RESOURCE CAPACITY FOR PHARMACEUTICAL REGULATORY SYSTEMS IN AFRICA

MTaPS finalized the report on data and information collected from the 11 selected RCOREs using the validated RCOREs monitoring and evaluation (M&E) tool. The report is currently undergoing editorial review before submission to USAID and AUDA-NEPAD for onward dissemination among the RCOREs. The findings from the baseline evaluation reveal the progress achieved by some RCOREs, including:

- Development of 26 curricula related to regulatory systems strengthening
- Capacity building for 361 pharmaceutical and medical personnel across Africa to improve the technical capacity of pharmaceutical regulators on the continent
- The Kenyan RCORE has conducted PV and post-marketing surveillance sensitizations (training lasting less than two days) to more than 4,000 health care workers in 2019 and 2020
- Eight staff members from the RCOREs are pursuing PhDs, which speaks to progress on one stated goal of the program—to impede the "brain drain" of technical and regulatory expertise either to the private sector or out of the continent. This improved capacity goes to improve the functioning of national medicines regulatory authorities.
- The RCORE experts have worked to provide technical assistance to other non-RCORE regulatory authorities. For example, the Ghana FDA assisted Guinea in the review of the treatment protocol for Ebola in West Africa.

The evaluation also revealed several challenges, including the lack of adequate and consistent sources of funding. There are limited numbers of publications from the RCOREs to inform the global community about their achievements. Further, some RCOREs are not doing enough to promote awareness about their RCORE designations through their own websites or other media. The Ghana FDA and the

Medicines Control Authority of Zimbabwe are the only RCOREs that have dedicated areas on their websites that are regularly reviewed to discuss and publicize RCORE activities.

As part of the evaluation, MTaPS proposed options for AUDA-NEPAD to consider in addressing the identified challenges and improve the performance of the RCOREs to deliver advancements in regulatory systems strengthening and increase expertise in medicines regulation on the continent, including:

- AUDA-NEPAD should implement an M&E system on a regular basis to capture the performance of RCOREs over time.
- AUDA-NEPAD should assist RCOREs in their fundraising activities by linking the RCOREs with possible funders and by promoting RCORE designation activities to possible funders.
- RCOREs need to publish their work as a resource for non-RCORE institutions.

Activity 3.3: Participate in collaborative meetings of NEPAD, AMRH steering committee, technical working groups of Regulatory Capacity Building and Pharmacovigilance and the Biennial Scientific Conference on Regulation of Medical Products (SCoMRA) and African Medicines Regulators Conference (AMRCO)

MTaPS worked with AUDA-NEPAD to improve the Medicine Regulatory Harmonization (MRH) Program management guidance tool. The tool is aimed at assisting Regional Economic Communities (RECs), such as the ECOWAS, Intergovernmental Authority on Development, and Southern African Development Community, to implement medicines regulatory harmonization programs in a more effective, efficient, and sustainable manner. MTaPS worked with AUDA-NEPAD to develop and administer an online survey to the RECs and pharmaceutical industry to obtain information on the achievements, challenges, and constraints. MTaPS will work with a consultant to incorporate the findings of the survey into the document and provide more insights on the successes and challenges of implementing medicines regulatory harmonization program in RECs.

MTaPS participated in virtual meetings with AUDA-NEPAD to discuss the ongoing and potential support to harmonize medicines regulation in Africa. Due to the demand for quality medical devices for use in the prevention, diagnosis, and treatment of COVID-19, MTaPS had interactions with the African Medical Devices Forum (AMDF) to determine the priority areas for support. AMDF shared the 2020 work plan with MTaPS. Based on the priority areas under the scope of work and the AMDF work plan, MTaPS developed a concept note for funding consideration by USAID in subsequent cycles. The concept note elaborates on harmonization of medicines registration systems in Africa through the AMRH initiative.

## ACTIVITY 5: DEVELOP A ROADMAP FOR HEALTH TECHNOLOGIES ASSESSMENTS (HTA) INSTITUTIONALIZATION FOR LMICS

MTaPS finalized the HTA core document after receiving feedback from 12 expert reviewers and USAID. The team copyedited and developed an e-book of the document, A Roadmap for Systematic Priority Setting and Health Technology Assessment (HTA): A Practical Guide for Policy Action in Low- And Middle-Income Countries. Global announcements and social media campaign are under way to create awareness and generate interest in the roadmap among target stakeholders. These stakeholders include country policy makers and HTA practitioners, global HTA experts, and other partners. MTaPS also finalized plans for a webinar, scheduled for October 8, 2020, to formally launch the roadmap and disseminate it to the public. The launch will include an interactive panel discussion on the tools provided in the different chapters of the roadmap, country experiences, lessons learned, and future opportunities in HTA. Global experts from LMICs in Asia, Eastern Europe, Latin America, and Sub-Saharan Africa will participate in the panel.

# ACTIVITY 6: EXAMINE OPPORTUNITIES FOR AND BARRIERS TO THE USE OF DRUG SELLERS IN INCREASING ACCESS TO MEDICINES AND OTHER HEALTH TECHNOLOGIES IN LOW- AND MIDDLE-INCOME COUNTRIES IN SUPPORT OF UNIVERSAL HEALTH COVERAGE (UHC) OBJECTIVES

Sustainable access to safe, effective, quality pharmaceutical products, health technologies, and related services is a critical component in efforts to achieve UHC. Because the private sector provides a large proportion of health care services and products in LMICs, interest is growing in how the private sector can contribute to UHC goals—particularly as countries are designing and implementing different types of health insurance schemes to meet those goals. Under this activity, MTaPS collaborated with MSH's LaunchDSI project, funded by the Gates Foundation, to leverage our 15+ years of experience working with the accredited drug dispensing outlet (ADDO) program in Tanzania and our work in promoting medicines benefits in countries' health insurance schemes to develop a case study to show how the Tanzania NHIF has successfully incorporated retail drug outlets into its national benefits program. The case study supports MTaPS' objectives related to developing private-sector capacity to support pharmaceutical operations, engaging with national insurance schemes to improve access to medicines, and advancing the global learning agenda on the intersection of retail outlets and national prepayment schemes.

The case study objectives were to:

- Characterize barriers and facilitators to incorporating retail drug outlets into national prepayment schemes
- · Add evidence on national health insurance coverage of products from retail drug outlets
- Inform countries that are designing pharmaceutical benefits for insurance schemes

Two primary sources of data formed the basis for this case study: semi-structured in-person or phone interviews with key informants and government documents related to the country's prepayment schemes. After reviewing the literature, MTaPS and LaunchDSI worked with Tanzania consultants to design a study protocol, including identifying key informants and drafting semi-structured interview guides. The LaunchDSI research associate traveled to Tanzania in December 2019 to finalize the study tools and conduct interviews. MTaPS interviewed 10 representatives of the NHIF, district government, Pharmacy Council, and President's Office of Regional Administration and Local Government. MTaPS also interviewed 15 owners and dispensers from seven pharmacies and five ADDOs. Topics covered included level of knowledge of the NHIF in the community; NHIF administration (e.g., claims, terms); availability of medicines in the public sector; specific issues with ADDOs; and challenges and improvements to linkage between NHIF and the outlets.

Our results showed that important enablers for NHIF/retail outlet engagement include widespread awareness of the NHIF in the community, NHIF's straightforward certification process, and its reimbursement speed. All of the retail respondents felt that the NHIF helps their business and their clients to some degree. As for barriers, retailers thought that the NHIF needed to provide more information to them and to its members, particularly regarding coverage changes. Some retailers and government officials thought that the product reimbursement prices were below market and not adjusted often enough, and pharmacy respondents were unhappy about claim rejections for what they felt were insignificant issues. All interviewees agreed that one of the biggest problems is poor prescribing practices in public health facilities. They reiterated that prescribers need more supervision to improve their practices, particularly to ensure adherence to standard treatment guidelines, which the NHIF requires for approving a claim.

Working with our Tanzanian colleagues, MTaPS analyzed the data and drafted our deliverable—an article that was submitted to the *Journal of Pharmaceutical Policy and Practice* in July 2020. It is under review.

## ACTIVITY 7: SUPPORT WHO-LED CONSULTATIONS ON IDENTIFYING ENABLERS AND PREDICTORS OF ACCESS TO MEDICINES

MTaPS and WHO's Access to Medicines and Health Products Division have agreed to collaborate to define the concept for the development of an Access GBT. The purpose of the tool is to enable countries to benchmark the performance of a set of pharmaceutical system functions and provide the basis for the development of an improvement plan for the national pharmaceutical system. Considerations for MTaPS include how to make the best use of the work that already exists and to ensure the alignment of concepts and measures to enable integration of PSS Insight with its quantitative measures for access to medicines and PSS. In this reporting period, MTaPS and BUSPH reviewed and provided written feedback on WHO's draft scoping document for the Access GBT and met with WHO to discuss the comments and the way forward. Given the current involvement of the staff of WHO's Access to Medicines and Health Products Division in the COVID-19 responses, MTaPS and WHO agreed that MTaPS will take the lead on developing the Access GBT concept paper. The concept note was drafted and is now pending internal review by WHO's Access to Medicines and Health Products Division and the MTaPS senior management team. The paper, developed by MTaPS and BUSPH, discusses the importance and relevance of a benchmarking tool; reflects on prior efforts to measure pharmaceutical system performance and lessons learned from the development of other tools; sets out options for the vision and purpose of the tool; and proposes steps in the development process, timeline, and benchmarks.

## ACTIVITY 8: SUPPORT AFRICAN REGIONAL HARMONIZATION EFFORTS FOR PHARMACOVIGILANCE

Building on the discussions with and consensus among the 15 member countries of ECOWAS in collaboration with West Africa Health Organization (WAHO), MTaPS worked to coordinate the various stakeholders to reach agreement on several issues, including:

- A regional approach for monitoring countries' PV performance on the GBT is desirable as it will provide a means to support countries to improve their PV functions.
- Many countries within the region have very weak PV systems that need to be supported to attain an acceptable level of performance on the GBT.
- Countries are willing to contribute data to the platform, but there is need to define the type of data that will be required from countries.
- Data confidentiality issues need to be addressed before countries can share their data.
- A survey should be done to get a sense of possible data elements that countries would be willing to share to guide further implementation.
- The proposed community of practice should have at least one representative from each member country.

MTaPS collaborated with WAHO to conduct a survey of the 15 member countries to define and fine tune the data elements that countries are willing and able to contribute to the platform. The results show that all responding countries (12/15) are willing to share data and information related to some aspects of their GBT assessment. Furthermore, countries indicated interest in sharing aggregated data on PV indicators, such as number of ADR reports received within a given period and number of serious ADR reports received disaggregated by gender, age, and system organ class. Other reports include number of signals detected and evaluated by countries; number of safety reports (periodic safety update reports, periodic benefit—risk evaluation reports); and risk management plans assessed. Countries also indicated a willingness to develop a community of practice to facilitate collaborative sharing of information and learning to enhance PV capacity within the region. Based on the survey, MTaPS developed a report of the key data elements that should be captured on the platform and shared examples of how such data could be presented on the platform. MTaPS learned that WAHO is already

at an advanced stage in the development of a web portal to support regulatory activities within the region, including PV. MTaPS and WAHO therefore agreed that MTaPS will piggyback on the existing portal to launch the PV platform.

## ACTIVITY 9: LHSS AND MTAPS COLLABORATION ON INCREASING ACCURACY OF PHARMACEUTICAL EXPENDITURES

Building on SIAPS' work on tracking pharmaceutical spending, MTaPS and LHSS conducted a desk review of existing Health Accounts data to understand how pharmaceutical expenditures have been tracked to date. This review documents existing gaps in measuring and reporting pharmaceutical expenditure data. This will inform how the Health Accounts methodology can be customized and enhanced. It will also help determine how guidance can be improved to fill the identified gaps and produce higher quality and more detailed data on pharmaceutical expenditure. LHSS developed a draft outline of the guidance and policy questions, which MTaPS reviewed. The policy questions' goals are to understand the policy priorities around pharmaceutical spending, the decision that policy actors face that pharmaceutical spending data could help answer, and the type of data policy actors are interested in when it comes to pharmaceutical spending.

MTaPS and LHSS started the exploratory study implementation in Burkina Faso. The public supply system in Burkina Faso is mainly organized around the Centrale d'Achat des Médicaments Essentiels Génériques (CAMEG). CAMEG supplies private pharmacies and pharmacies in private health facilities with and without agreement. The private supply system is run by wholesale distributors who supply mainly private pharmacies but also public and private health facilities. The levels of the supply chain are the central level, represented by CAMEG, private wholesale distributors, and the depots of some health programs at the central level; the regional level, represented by the regional agencies of CAMEG and private wholesalers; and the decentralize level, represented by the district depot, private pharmacies, and hospitals depots, as well as nongovernmental organization depots.

The two projects started to work with the Burkina Faso national health accounts team and a consultant to identify all data sources for pharmaceutical spending in Burkina Faso, including the private sector and donors. Due to the exploratory nature of the activity and the COVID-19 pandemic, data collection is limited to secondary sources in each health district or hospital. MTaPS developed a list of potential stakeholders the consultant will contact for data, including the regional pharmacy depots and regional pharmacists; CAMEG; districts; and health programs depots (e.g., TB, HIV, malaria). Data collection has encountered some difficulties and delays due to administrative procedures in Burkina Faso. The USAID country office has sent a notification letter to the Ministry of Health. and pending a response from the Ministry, MTaPS will begin data collection.

## ACTIVITY 10: IDENTIFY GAPS IN INTEGRATION OF IPC/WASH CRITICAL CONDITIONS INTO THE QUALITY OF CARE AND QUALITY IMPROVEMENT TOOLS AND PROCESSES

The objective of this activity is to identify gaps in integration of IPC/WASH critical conditions into the QOC and QI tools and processes with a focus on Bangladesh. With the help of our MTaPS team in Bangladesh, the program identified and reviewed 19 documents related to QOC/QI in the Bangladesh health system, with an emphasis on MNCH documents, adapting a methodology from the USAID/Maternal and Child Survival Program gap analysis.<sup>6</sup> To better characterize how IPC/WASH is integrated into these QI documents, MTaPS bolstered the analysis to include IPC conditions that go beyond just the supplies included in the original analysis by using the WHO core components on IPC as

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<sup>6</sup> USAID/Maternal and Child Survival Program. 2019. Tools for Improving Quality of Care for Mothers and Newborns: A Review and Gap Analysis of Critical Environmental Conditions. Washington DC: MCSP.

a basis for developing five additional conditions that were particularly applicable to the Bangladesh context:

- National and facility IPC guidelines (core component 2)
- IPC education and training (core component 3)
- Health care-associated infection surveillance (core component 4)
- Monitoring, evaluation, and feedback of IPC practices (core component 6)

Our review examined the critical conditions and the break-out of sub-conditions by document, a ranking of the conditions that were the most prevalent across documents, and a summary of instances of IPC/WASH references that apply specifically to MNCH topics in the Bangladesh QOC documents.

Based on the review, our impression is that the Ministry of Health and Social Welfare's Quality Improvement Secretariat has produced a substantial number of policy and guidance documents on using QOC and QI methods to increase the quality of health services in Bangladesh; however, MTaPS was unable to find any indication of how the documents relate to each other or how they should be implemented. For example, a few of the checklists note that they are annexes, but it is unclear which documents are annexes. In addition, many of the documents include guidance on IPC and WASH topics, but that guidance was not consistent across and sometimes within documents. MTaPS noted that many overlapped with each other, particularly the checklists and standard operating procedures.

The program also reached out to MTaPS country staff to provide national strategies and plans that may be available in these areas, and received documents from Burkina Faso, Ethiopia, Côte d'Ivoire, DRC, Rwanda, Senegal, Tanzania, and Uganda. MTaPS will apply the WASH/IPC critical conditions analysis to these key QOC/QI and MNCH documents from other MTaPS countries to provide some country-level comparison to help contextualize the findings from Bangladesh. In addition, our plans to conduct interviews of key stakeholders from the Bangladesh health system have been put on hold by that country's intense focus on the COVID-19 response. Ultimately, these analyses will feed into identifying how IPC/WASH adherence in MNCH services can be strengthened through QOC/QI approaches, which supports MTaPS' objective to improve patient-centered care.

ACTIVITIE	S FOR NEXT QUARTER	
ACTIVITY	DESCRIPTION	DATES (2020)
I	Finalize the technical report	October
2.3	Work with the LeaderNet team to deploy the uploaded modules  Continue to follow up on the GHeL proposal	October–December
3	MTaPS team to work with consultant to finalize review and restructuring of the MRH program management guidance and incorporate achievements and challenges from RECs and the pharmaceutical industry in medicines regulatory harmonization	October
5	Host a webinar to launch the roadmap	October
7	Revise the draft concept note based on comments from WHO's Access to Medicines and Health Products Division and the MTaPS senior management team and solicit feedback through WHO from WHO regional offices and other departments, USAID, and other selected stakeholders  Assist WHO to identify experts, implementers, and stakeholders that can serve	October–December
	on a network of experts to guide Access GBT development	
8	Share and meet with PV representatives of the 15 ECOWAS countries to present the report of the survey and the identified data elements to obtain their approval and commitment to share data on the platform	October
	Hold meetings with the PV and IMS expert working groups and WAHO IT team to agree on key aspects to operationalize the platform	October–November
	Meet with WHO Geneva team to share the data elements for the platform and discuss the possibilities for harvesting data from existing WHO platforms, such as VigiBase and GBT Sharepoint	November
	Specify specifications and technical requirements of web-based platform and community of practice with ECOWAS IMS TWG	December

Finalize the data collection in Burkina Faso, complete the data mapping, and

collaborate with the LHSS project to develop a policy brief

October-December

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#### **CROSS-CUTTING ACTIVITIES**

#### **GENDER ACTIVITIES**

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

In the Philippines, during this reporting period, MTaPS finalized a gender analysis that I) identified key gender issues, inequalities, constraints and opportunities in family planning (FP) product selection, sex-specific adverse effects of TB medicines, and gender- and age-specific barriers for accessing commodities and pharmaceutical services related to TB and FP programs in the Philippines; 2) is built on and leveraged by other USAID gender analyses currently being developed; 3) builds buy-in from DOH as a key MTaPS partner; and 4) offered insights and recommendations for gender action plan and gender integration into the MTaPS Philippines strategies and work plans. Gender norms and the imbalance in power dynamics between men and women are often reflected within health systems and institutions, especially concerning access to pharmaceutical services and the doctor-patient relationship. In contrast, sex differences and/or biological factors play a role in how medications are metabolized and/or eliminated, which manifests in adverse drug events (ADEs), adverse drug reactions (ADRs) and AMR. The ability to identify and address gender constraints and sex differences in pharmaceutical services is an important element in the design of appropriate and sustainable programs that support equitable access to pharmaceutical services.

The analysis commenced during FY19 and the report was finalized in FY20. Following rounds of revisions and validation and the development of a draft gender action plan, the report was submitted to USAID by the MTaPS/Philippines team and is pending final approval by the Mission.

The key recommendations for accessing commodities and pharmaceutical services for TB and commodity and product selection for FP are the following:

- Sex-disaggregated data collected must be analyzed and reported to ensure that interruption of TB
  treatment does not disproportionately affect one sex over another to ensure gender equity for PSM
  decision making for FP products and commodities.
- Sex-disaggregated medicine utilization data collected in PViMS must be analyzed and reported to
  ensure gender equity in PSM decision making, including systematic forecasting and supply planning and
  efficient procurement of pharmaceuticals.
- Data must be analyzed to ensure that FP stock-outs do not disproportionately affect one sex over another, products stocked do not have a high rate of ADE reporting, and the cost of products is prioritized at the expense of FP clients.<sup>7</sup>

The capacity of the GAD focal point system should be strengthened. The focal point system has identified the need for gender sensitivity training for SCM staff as part of its gender mainstreaming in the human resource capacity development plan.

The national pharmacovigilance coordinator should establish a pregnancy register and report current and cumulative results. All women who are identified as having received TB medications while pregnant should be followed up for the outcome of the pregnancy and health of the fetus/infant and the mother.

<sup>&</sup>lt;sup>7</sup> Management Sciences for Health. 2018. Rapid diagnostic report: procurement, supply chain management and pharmacovigilance in the Philippines (DRAFT)

- The DOH should integrate gender concerns into all relevant policy documents to ensure that gender indicators and sex-disaggregated data are mandated, including their analysis and use for TB treatment policy and programming and use for FP programming.
- A committee should address FP ADEs and ADRs by analyzing data using a gender perspective and report current and cumulative results to develop policy to ensure that FP products are being utilized without harm and per choice/preference.

In addition, gender recommendations were added to address AMR and gender considerations during pandemics/emergencies.

Development of the analysis was led by Overseas Strategic Consulting, Ltd., a core MTaPS partner, in close collaboration with the MTaPS Philippines and US teams.

### PROGRESS TOWARD OBJECTIVES

## OBJECTIVE I: PHARMACEUTICAL-SECTOR GOVERNANCE STRENGTHENED

Promoting transparency and accountability is a prerequisite for improving access to essential medicines and strengthening health systems to achieve universal health coverage (UHC).8 Poor governance in pharmaceutical systems can reduce access to pharmaceutical products, inflate medicine prices, and waste scarce health system resources.9 Governance plays a critical role in minimizing opportunities for corruption and mitigating other system inefficiencies. It also shapes the ability of the health system to respond to challenges. This section highlights selected areas of work on MTaPS governance activities in this reporting period.

For more detail on MTaPS' AMR activities and GHSA, refer to the GHSA section and Objective 5/AMR activities in this report.

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

#### STRENGTHENING PROCUREMENT AND SUPPLY CHAIN GOVERNANCE IN THE PHILIPPINES

MTaPS is providing technical assistance to the **Philippines** Department of Health (DOH) to increase its capacity to plan, implement, and sustain an integrated and well-functioning supply chain that will ensure adequate availability of health commodities and support the government's commitment to UHC. A key component of the technical assistance focuses on strengthening the capacity of the DOH's procurement and supply chain management team (PSCMT) to effectively fulfill its redefined stewardship role. In parallel, MTaPS is working to bolster oversight and accountability for PSCM at the regional level. MTaPS activities aim to support the Philippines in transitioning from a centralized model with fragmented PSCM functions to a decentralized and integrated system and increasing transparency, accountability, and efficiency of the PSCM system nationwide.

<sup>8</sup> Wirtz VJ, Hogerzeil HV, Gray AL et al. 2017. Essential medicines for universal health coverage. The Lancet 389(10067), 403–476.

<sup>9</sup> WHO. 2013. Good Governance in the Pharmaceutical Sector. Geneva: World Health Organization. Available at: http://www.who.int/medicines/areas/governance/EMP\_brochure.pdf?ua=1

MTaPS' technical assistance in governance to GHSAsupported countries in year 2 has resulted in:

- 3 countries established national platforms for governance and coordination of national AMR responses
- Burkina Faso
- · Côte d'Ivoire
- Ethiopia
- 8 countries developed or updated TOR for groups that provide leadership, coordination, management, and technical implementation of AMS and/or IPC activities
- Burkina Faso
- Cameroon
- Côte d'Ivoire
- Democratic Republic of Congo (DRC)
- Ethiopia
- Kenya
- Mali
- Tanzania
- 4 countries developed or updated important policy guidelines to guide AMS and/or IPC for the human sector
- •Côte d'Ivoire
- Cameroon
- Kenya
- Mali
- 3 developed key guidelines for the animal and/or agricultural sectors
- Burkina Faso
- Mali
- Uganda
- 6 countries integrated the AWaRe classification into national EMLs:
- Burkina Faso
- •DRC
- Ethiopia
- Kenya
- Mali
- Tanzania
- 5 countries integrated AWaRe classification into STGs:
- Burkina Faso
- Ethiopia
- Mali
- Senegal
- Tanzania
- 6 countries carried out a desk review and gap analysis of documents governing the use of antibiotics in both the human and animal sectors and used the studies to develop action plans
- Burkina Faso
- Cameroon
- Côte d'Ivoire
- •DRC
- Mali
- Senegal

In year 2, MTaPS supported the DOH PSCMT in completing an exercise to refocus its role from operational management of PSCM and articulating its redefined role for leadership, policy guidance, and capacity-building support to LGUs in a strategic commitment document. With assistance from MTaPS, the PSCMT developed a roadmap for improving PSCM processes and integration into local health systems, documentation that sets out its stewardship roles, and a performance management system for monitoring PSCM functions and service delivery. A recent exercise bought together PSCMT and key stakeholders from various DOH bureaus, the national regulatory authority, and other implementing partners to analyze current PSCM processes, ascertain challenges related to product registration, and identify steps to address them. At the regional level, MTaPS advocated for and supported the Central Visayas region in forming a regional governance mechanism for PSCM and pharmacovigilance (PV) within the regional health development center and helped the center develop an action plan for integrating PSCM and PV governance and performance management at the regional level. This work can serve as a model for integrating PSCM and PV governance into regional health development centers in other regions and clarifying their role in these areas within the devolved health system.

IMPROVING THE ENABLING LEGAL AND REGULATORY FRAMEWORK FOR NATIONAL MEDICINES REGULATORY AUTHORITIES IN NEPAL, MOZAMBIQUE, AND RWANDA

As part of ongoing efforts to ensure that an adequate legal and regulatory framework is in place that provides for the establishment and/or effective operation of a national medicine regulatory authority (NMRA), in year 2, MTaPS supported the development of a

zero draft of the new drug law in **Nepal** and five regulations, three guidelines and one list of over-the-counter or non-prescription medicines in **Mozambique**. In **Rwanda**, two regulations and three guidelines were drafted/reviewed and five regulations, eight guidelines, and three lists of authorized medicines and cosmetics were validated with assistance from MTaPS.

- MTaPS' partner, the International Law Institute-African Center for Legal Excellence (ILI-ACLE) conducted a gap analysis of Nepal's legal and regulatory framework and prepared a zero draft of the drug law for feedback. The zero draft law will serve as a resource document and reference for drafting Nepal's new drug law and identifying regulations and codes that need updating. MTaPS is also assisting the Department of Drug Administration (DDA) to map all the different rules, regulations, codes, and guidance to provide an overview of the documents, their scope, and their relation to one another and to the existing Drug Act. MTaPS is also helping the DDA translate the codes and guidelines only available in Nepali to English for uploading onto DDA's website.
- In **Mozambique**, the regulations and guidelines for medicine registration, regulatory inspections, licensing of pharmaceutical establishments, PV, and pharmacy practice were drafted with support from MTaPS to enable further implementation of the country's 2017 Law on Medicines, Vaccines, and Other Biological Products for Human Use and address important gaps identified in the 2018 WHO Global Benchmarking Tool (GBT) assessment.
- MTaPS provided technical support to the Rwanda Food and Drug Authority (FDA) to draft, review, and/or validate regulations and guidelines for registration, premises licensing, control of manufacture of medical products, and Rwanda FDA service fees, among others. In addition to addressing critical regulatory gaps, the new regulations and guidelines also provide for fast-tracking registration for prioritized categories of medicines, such as antiretroviral medicines, and recognition of fast-track collaborative assessments with WHO and national regulatory authorities within the East African Community. Another important achievement in Rwanda is MTaPS' collaboration with the MOH, Rwanda FDA, and the National Pharmacy Council to develop pharmaceutical service standards for accreditation to complement the well-established clinical care standards. Approved by the Rwanda minister of health in July 2020, the standards and plan that guides implementation of the standards are important tools for providing improved pharmaceutical services at hospitals and pharmacies in the public and private sectors.

#### ENGAGING JOURNALISTS AND CIVIL SOCIETY ORGANIZATIONS IN ETHIOPIA'S AMR RESPONSE

MTaPS has been working with the MOH to increase the engagement and build the capacity of journalists and communication professionals to support **Ethiopia's** national response to prevent and contain AMR. At the beginning of year 2, more than 50 professionals from public and private electronic media in Ethiopia attended a one-day AMR sensitization workshop organized by MTaPS in collaboration with the country's MOH. As a result of the workshop, the media more actively participated in World Antibiotic Awareness Week. Then, in line the multisectoral behavior change communication strategy developed by MTaPS, the program collaborated with the MOH in developing an AMR training course for journalists and communication professionals working in the public and private sectors.

MTaPS also supported capacity building of civil society organizations (CSO) and community organizations in AMR prevention and containment. At the beginning of the year, MTaPS organized and facilitated a 3-day training for 21 female and 8 male volunteers from the Ethiopian Youth and Women Federations. The 29 participants developed action plans for follow-on work in the community as part of the training, which aimed to increase their knowledge on AMR and approaches for raising awareness in their communities, where they already work to promote better sanitation, hygiene, and maternal and child health care. Then, with support from MTaPS, the trained female volunteers conducted educational sessions on the rational use of antimicrobials for 520 members of the Addis Ababa Women's Federation.

#### **QUARTER PROGRESS FOR FY20Q4**

#### TRANSPARENCY AND ACCOUNTABILITY OF COUNTRY PHARMACEUTICAL SYSTEMS IMPROVED

In North Kivu and Ituri provinces in eastern **DRC**, MTaPS is providing technical assistance to strengthen the capacity of provincial health divisions (division provinciale de la santé [DPS]) to better steward the pharmaceutical system at the provincial level. As a first step, MTaPS is assisting the DPS in improving the function of provincial TWGs on medicines, which have an important role to play in coordinating development partners and managing and overseeing the provision and distribution of life-saving MNCH and other essential medical products and mitigating issues, such as expiries, that waste scarce health system resources. In this reporting period, MTaPS supported the DPS in North Kivu and Ituri provinces to convene meetings of the TWGs on medicines and to develop TOR for MNCH sub-groups. The program also helped prepare a road map for building the capacity of MNCH sub-groups to provide technical advice to help the DPS make informed decisions regarding operational activities related to the management of MNCH medical products, including data collection and reporting, quantification and supply planning, distribution and rational use.

As reported under year 2 highlights, in the **Philippines**, MTaPS is providing technical assistance to bolster the capacity of the DOH's PSCMT to effectively fulfill its redefined role of stewardship, policy making, capacity building of LGUs, oversight of PSCM performance, and providing shared services to support the transition from a centralized model with fragmented PSCM functions to a decentralized and integrated system. In this reporting period, MTaPS supported the DOH in conducting a mapping exercise that brought together PSCMT and key stakeholders from various DOH bureaus, the national regulatory authority, and other implementing partners to analyze current PSCM processes, ascertain challenges related to product registration, and identify steps to address them. MTaPS also helped the DOH in developing a performance management system for monitoring PSCM functions and service delivery. Additionally, in the Central Visayas region, MTaPS supported the regional health development center and the newly established PSCM-PV committee in developing an action plan for integrating PSCM and PV governance and performance management at the regional level.

In **Nepal**, MTaPS is assisting the DDA and the Ministry of Health and Population (MOHP) in reviewing options and proposing a new organizational structure for the DDA that best supports its functional responsibilities in the newly decentralized system, as well as its transition to a single autonomous body that will be responsible for regulating both medical products and food. MTaPS partner Celsian finalized a comparative analysis of the organizational structure of national regulatory authorities in other countries, and MTaPS presented the findings, which included a compilation of the advantages and disadvantages of including food as a responsibility of a national medicine regulatory agency, to DDA. Based on this analysis, Celsian then developed a report that proposed different organogram structures for the new FDA. MTaPS shared the report with the DDA to inform its discussion with the MOHP on different organogram options for the new FDA.

With **Asia Bureau** funding, MTaPS is partnering with WHO Geneva, WHO SEARO, and the WHO Collaborating Center for Governance, Transparency, and Accountability in the Pharmaceutical Sector in Toronto to develop a how-to manual on managing conflicts of interest (COIs) within public pharmaceutical sector committees. In this reporting period, the protocol for the study that MTaPS and WHO SEARO are conducting as a first step toward developing the manual was finalized this quarter and submitted by WHO SEARO for ethical clearance/exemption, and the online search component initiated. The study will identify what COI management policies are in place in the Asian region/subregion, explore if and how policies are implemented, particularly in low-resource countries, collect copies of what exists, and solicit information on key challenges and examples of good practices.

## EVIDENCE-BASED MEDICINES POLICIES, LAWS, REGULATIONS, GUIDELINES, NORMS, AND STANDARDS IMPROVED AND ENFORCED

National pharmaceutical policies and legislation promote equitable and sustainable access to safe and efficacious medicines of assured quality. MTaPS worked with countries to develop, update, review, and establish national policies for medical products and legislation for regulation of medicines and other health products using best practice standards and guidelines by international organizations, such as WHO. Support was also provided to develop and review guidelines required to provide direction and clarity on the statutory requirements for compliance by users, such as manufacturers, wholesalers, and importers.

As reported under year 2 highlights, MTaPS, in partnership with ILI-ACLE, finalized the assessment and gap analysis of **Nepal's** legal and regulatory framework and drafted a zero draft of the drug law for feedback. The zero draft law will serve as a resource document for drafting Nepal's new drug law. However, one challenge is the very tight deadline set by MOHP to complete the drafting of the new law, including stakeholder consultations, which may hinder a thorough discussion of the zero draft.

In Mozambique and Rwanda, MTaPS is providing technical assistance to develop, review and validate regulations that support the newly enacted medicines acts in these countries and operationalize the new national medicine regulatory authorities established by these acts. In this reporting period, MTaPS assisted Mozambique's National Directorate of Pharmacy in reviewing and updating a regulation on PV to clarify the roles and responsibilities and coordinate various entities involved in PV monitoring and reporting, among other updates. Technical assistance was also provided to draft the guidelines for labelling and package leaflets for pharmaceutical products to provide clarity as specified in the medicine registration regulation. MTaPS provided technical support to Rwanda FDA for the development of two guidelines, one for technology transfer of pharmaceutical products and a draft guideline for the quality audit of medical device manufacturers. MTaPS also supported development of a quality management manual that will guide implementation of Rwanda FDA's quality management system (QMS) and 14 QMS documents, including SOPs.

In **DRC**, MTaPS supported the national medicine regulatory authority to update the online Directory of Registered Medicines, which is used by customs officers and pharmacist inspectors at the regional level to track and confiscate all unregistered products, including MNCH products. The updated version will be made available online in November, and printed copies will also be sent to provincial officers.

MTaPS collaborated with the Promoting Quality of Medicines Plus (PQM+) program to assist the Directorate General of Drug Administration (DGDA) in **Bangladesh** in establishing a mechanism for preparing and disseminating a list of manufacturers of personal protective equipment that DGDA has identified as eligible for emergency use authorization to support the country's COVID-19 response. MTaPS prepared the initial list, which has now been shared with DGDA for review.

With the assistance of MTaPS, the **Philippines** DOH updated the draft administrative order that provides for multi-year framework agreement and pooled procurement mechanisms, which will strengthen procurement practices and address some key constraints associated with fiscal year-bound procurements.

As part of GHSA-funded activities to strengthen AMS, MTaPS helped **Burkina Faso**, **Cameroon**, **Côte d'Ivoire**, **DRC**, **Mali**, and **Senegal** used the findings from their rapid situational analyses of antimicrobial policies and regulations in the human and the animal sectors (conducted in the previous reporting period) to draft AMS national action plans and national strategies; in Côte d'Ivoire, they were also used to draft national AMS guidelines for health care settings and to revise the national AMS policy. **Kenya** launched AMS guidelines for health care settings that were developed and validated with support from MTaPS, and Burkina Faso finalized national guidelines for using antimicrobials in the animal sector. As a result of MTaPS assistance, the AWaRe classification was incorporated into the revision of **DRC** 

and **Kenya's** national essential medicines lists and **Ethiopia's** revision of the standard treatment guidelines. Also, in this reporting period, **Cameroon** finalized and validated the national IPC guidelines, **Kenya** finalized the national IPC policy, and **Mali** finalized IPC guidelines and an action plan for the animal sector.

For more detail on MTaPS' AMR activities and GHSA, refer to the GHSA section and Objective 5/AMR activities in this report.

## STAKEHOLDER ENGAGEMENT AND EMPOWERMENT, INCLUDING CIVIL SOCIETY AND CONSUMERS INCREASED

Recognizing the importance of effective stakeholder engagement in formulating laws and regulations, MTaPS included a component on managing stakeholder consultations in the four-day capacity-building course for **Mozambique's** legal team and technical regulatory personnel. The training included information and practical examples on how to undertake a stakeholder consultation. The knowledge will be used to implement stakeholder consultations for all pending draft regulations, before they are considered for approval. This exercise is planned for next quarter PY 21.

In **Ethiopia**, MTaPS developed the first draft of a multi-sectoral behavior change communication strategy for AMR prevention and containment. The strategy identifies target audiences, key messages for different audiences, and message delivery modalities, including through the media. A notable benchmark in this quarter was the development of an AMR training course for journalists and communication professionals working in both the public and private sectors. The course materials, which have now been reviewed by the MOH, cover the burden and causes of AMR, its national and global consequences, strategies to tackle AMR, the role of mass media in AMR prevention, and the principles of framing AMR messages to raise public awareness. Also, **Tanzania** helped disseminate the AMR communication strategy to help them effectively coordinate stakeholders' efforts in conveying appropriate messages that promote containing the spread of AMR. MTaPS' partner OSC supported development of the strategy through a process that included early stakeholder involvement and multisectoral participation during the design.

In **DRC**, the civil society health coordination group participated in the multisectoral coordination quarterly meeting organized by the National Commission on Antimicrobial Resistance and contributed to analyzing AMS and IPC issues and identifying priority actions to address key problems. In **Burkina Faso**, civil society was invited by the minister of animal resources and fisheries to select representatives for the One Health platform. Also, stakeholders from the private sector (private veterinarians, pharmacists, and clinicians) and representatives of the National Council of Veterinarians and the Association of Private Veterinarians joined public sector stakeholders for a two-day workshop to finalize Burkina Faso's draft national regulatory framework for AMS for the animal sector.

# OBJECTIVE 2: INSTITUTIONAL AND HUMAN RESOURCE CAPACITY FOR PHARMACEUTICAL MANAGEMENT AND SERVICES INCREASED, INCLUDING REGULATION OF MEDICAL PRODUCTS

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

## DEVELOPING INDIVIDUAL AND LOCAL CAPACITY TO SUPPORT THE GLOBAL HEALTH SECURITY AGENDA

MTaPS assisted II countries in planning and implementing a variety of innovative GHSA-related capacity building and training activities, ranging from curriculum design/reform and e-learning course development to in-service training-of-trainer (TOT) workshops. These activities collectively contributed to strengthening the capacity of the health workforce in **Bangladesh**, **Burkina Faso**, **Cameroon**, **Côte d'Ivoire**, **DRC**, **Ethiopia**, **Kenya**, **Mali**, **Mozambique**, **Senegal**, and **Tanzania** and equipped them with knowledge and skills to prevent health care-associated infections and support institutionalizing IPC/AMS practices. Selected areas of GHSA-related work and key achievements in the second year of the program are highlighted below.

- E-learning platform installation and management: As part of critical first steps for strengthening the capacity of countries to host and manage e-learning platforms, MTaPS supported Burkina Faso, Côte d'Ivoire, Cameroon, and Mali in identifying and selecting suitable e-learning platforms for their IPC/AMS e-learning programs. This process involved conducting a rapid digital assessment to determine technology gaps and e-learning capacity-building needs. Once the host institutions were selected, MTaPS, in collaboration with the Empower School of Health, provided a series of virtual capacity-building trainings to e-learning platform administrators to enhance their technical skills in virtual platforms and course management. Subsequently, the trained e-learning teams were able to independently install Moodle platforms (in countries that did not have one) and then upload the IPC e-learning courses developed with support from MTaPS.
- Capacity building and e-learning plans: In Tanzania, MTaPS supported the Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC) to develop an e-learning and capacity-building plan, which sets out steps for designing and deploying e-learning pre-service and in-service programs to strengthen the capacity of health care professionals and promote good IPC/AMS practices throughout the country (from national and district to lower-level facilities). The plan also sets out recommendations for strengthening the capacity of IPC/AMS e-learning facilitators, including their facilitation skills through various digital platforms.
- IPC e-learning program course designs: MTaPS produced a comprehensive IPC e-learning course in French for use in Burkina Faso, Cameroon, Côte d'Ivoire, and Mali. The e-learning course consists of 10 highly interactive modules and an introductory video that can be deployed either synchronously or asynchronously. In parallel, MTaPS developed an eight-module country-specific course in IPC for Tanzania and a two-module course for Senegal. These courses are currently available on each country's local e-learning platforms.
- Curricula and competency-based trainings: MTaPS supported counterparts in 10 GHSA-funded countries to develop IPC and/or AMS-specific training packages, which have been adapted for delivery through e-learning platforms for both in-service and pre-service training. Each country's curriculum comprises an instructor guide, participant manual, PowerPoint slides, baseline data collection tools, and job aids. MTaPS collaborated with Côte d'Ivoire's AMR-TWG to deliver a series of workshops to orient counterparts on applying the curriculum. To date, these 10 countries have provided competency-based training to 745 (429 males, 316 females) medical officers, clinical officers,

nurses, laboratory scientists, public health officers, surveillance officers, pharmacists, and county health managers. In addition, a comprehensive DTC curriculum was designed and produced in French for Burkina Faso, Côte d'Ivoire, and DRC. The curriculum was designed based on adult learning principles and emphasized 12 competency areas. The process involved first revising the national IPC/AMS guidelines and subsequently developing the competency-based curricula based on these guidelines and related SOPs.

- Pool of master trainers: To further strengthen local institutional capacity, MTaPS helped to organize and conduct TOT workshops and create pools of master trainers to support both AMS and IPC training activities. This has helped institutionalize IPC/AMS training program implementation and management competencies in Bangladesh, Burkina Faso, Cameroon, Côte d'Ivoire, Ethiopia, Kenya, Mali, Mozambique, and Tanzania. Creating pools of master trainers enabled a more rapid, but cost-effective, scale-up of onsite IPC/AMS training in facilities through a cascaded approach. Senegal, for example, now has a pool of 16 IPC master trainers (plus 4 private hospital staff) who, soon after they participated in MTaPS-led TOTs, went on to independently train 98 IPC champions.
- Mentoring support: As a follow-up to training activities delivered by MTaPS-trained master
  trainers, MTaPS teams conducted supportive supervision and mentoring activities jointly with local
  counterparts. For example, in Tanzania, IPC mentoring and coaching support was provided to 180
  health care workers in 6 MTaPS-supported hospitals to follow up on implementation of their IPC
  action plans. The team utilized the standards-based management and recognition quality
  improvement approach for IPC practices in health facilities.

By applying blended (mix of traditional and e-learning) approaches, MTaPS country teams were able to support countries to quickly design, implement, monitor, and evaluate capacity-building activities to transfer IPC and AMS skills to health workers and committees, such as DTCs. They were also able to establish e-learning platforms to provide ongoing training through distance learning. MTaPS teams provided virtual TOT sessions to 146 master e-learning trainers in Burkina Faso, Kenya, Mali, Senegal, and Tanzania and introduced them to distance learning platforms, such as Moodle and WebEx. These sessions also equipped trainers with e-learning facilitation skills and, with the advent of COVID-19, enabled them to pivot to virtual modes whenever face-to-face trainings were no longer feasible. These systems also provided a springboard for swift adaptation of IPC training materials to support COVID-19 responses.

#### **DEVELOPING THE WORKFORCE IN THE PHILIPPINES**

MTaPS assisted the DOH in conducting a workforce assessment and develop a draft workforce capacity development plan as part of efforts to strengthen and institutionalize PSCM and PV systems. The assessment findings will inform creation of a workforce development plan that sets out the required number and distribution of PSCM and PV staff positions, their roles, and needed skill sets. The plan also provides recommendations for addressing identified gaps and professionalizing the PSCM and PV workforce to ensure uninterrupted access to pharmaceutical services and safeguard patient safety.

## IMPROVING CAPACITY OF PRIVATE SECTOR ORGANIZATIONS TO SUPPORT PHARMACEUTICAL OPERATIONS

In **Rwanda**, the pharmaceutical services standards for accreditation developed to complement the well-established clinical care standards were approved by the Rwanda minister of health in July 2020. The standards developed (through MTaPS collaboration with the MOH, Rwanda FDA, and the National Pharmacy Council) and plan that guides implementation of the standards represent an important benchmark toward improving the quality of pharmaceutical services at private hospital and community pharmacies as well as at pharmacies in public sector health facilities.

In **Kenya**, MTaPS collaborated with the Pharmaceutical Society of Kenya and representatives of various health professional associations to develop a continuing professional development and relicensure-linked in-service AMS course that the associations will deliver to their members working in both public and private sectors beginning in year 3. MTaPS also worked with a task force of professional associations to develop and review curricula and draft modules for a continuing professional development and relicensure IPC course.

## STRENGTHENING MEDICINES REGULATORY CAPACITY, INCLUDING THROUGH REGIONAL REGULATORY HARMONIZATION

In year 2, MTaPS provided technical assistance to five countries (Bangladesh, Mozambique, Nepal, Philippines, Rwanda) and four regional economic communities (EAC, ECOWAS, IGAD, SADC) to strengthen their institutional and individual capacity to improve functionality of their regulatory systems. This work included supporting countries to establish or improve the legal framework for carrying out regulatory activities, notably in Nepal, Mozambique, and Rwanda where MTaPS helped develop, review, or validate various regulations and guidelines (see Objective I, Evidence-Based Medicines Policies, Laws, Regulations, Guidelines, Norms, and Standards Improved and Enforced, for more details). With support from MTaPS, DNF in Mozambique and the Rwanda FDA reviewed and updated their five-year strategic plans for strengthening their institutional capacity to effectively regulate medicines and health technologies. A key component of MTaPS institutional capacity-building involves helping national medicine regulatory authorities (NMRAs) establish functional quality management systems (QMS), and progress toward this end began in Mozambique, Rwanda, and Nepal with the situational analysis, development of quality manuals, and capacity building for regulatory personnel on various aspects of QMS.

MTaPS provided technical assistance to countries in Africa and Asia to streamline and improve their registration systems through capacity building by imparting principles of Good Review Practices (GRevPs) and improvements in the regulatory framework. Some planned activities for quarters 2 and 3 were delayed because of the lock-down in many countries because of the global COVID-19 pandemic. However, MTaPS provided remote support to all program-supported countries, including conducting numerous online capacity-building sessions, and was able to continue implementing many planned activities during this time. In Mozambique, for instance, MTaPS organized a number of virtual capacity-building workshops on QMS and PViMS for staff of the DNF, HIV program, and health facilities. Also, in the Philippines, the team facilitated many PViMS orientation sessions virtually for staff of the pharmaceutical department, FDA, and other stakeholders. In Rwanda, MTaPS drafted relevant regulations and guidelines remotely that support the regulatory framework for the nascent NMRA for in-country review. In Nepal, the team, in collaboration with WHO counterparts, validated the documents submitted by the DDA virtually in lieu of a planned, in-person, interim GBT assessment.

MTaPS worked with several continental and regional organizations to support convergence and the road to harmonization of medical product regulation in PV, regulatory inspections, and regulatory information management system. MTaPS offered technical assistance to validate and use the regional centers of regulatory excellence (RCOREs) monitoring and evaluation tool to measure the performance of 11 designated centers and provide baseline information on the status of the institutions and organizations providing capacity development in medicine regulation.

#### **QUARTER PROGRESS FOR FY20Q4**

## INSTITUTIONALIZATION OF PROVEN, INNOVATIVE APPROACHES TO BUILDING HUMAN RESOURCE CAPACITY

#### Workforce Planning and Development

In this reporting period, MTaPS collaborated with the **Philippines** DOH to complete the workforce capacity development plan. The purpose of the plan is to institutionalize PSCM and PV systems. Key components of the plan include measures to create and fill the required number and distribution of PSCM and PV staff positions, as well as recommendations for improving services related to PSCM and PV to ensure uninterrupted access to medical products and safeguard patient safety.

#### **Curricula and Training Materials**

Building on accomplishments from last quarter, MTaPS supported **Kenya's** University of Nairobi/School of Pharmacy to finalize the AMS curriculum for pre-service training. The purpose of the pre-service curriculum is to sensitize and educate all future health care providers in AMS prior to their entering the professional workforce. The curriculum covers several key technical competencies, including planning and establishing an AMS program at a health facility, IPC, diagnostic stewardship and surveillance, leadership, governance, ethics, and communication. The course will be implemented next quarter for first-year pharmacy postgraduate students for the first time.

MTaPS continues to support the Directorate of Hospital Quality, Security, and Hygiene (DQSHH) in **Senegal** to ramp up the capacity of health facilities to implement IPC programs. During this quarter, the IPC training modules developed in the previous reporting period were reviewed and validated through a three-day workshop supported by MTaPS. The training modules are expected to help standardize the provision and quality of IPC trainings for additional health facilities that are enrolled in the coming year.

MTaPS is helping **Burkina Faso, Côte d'Ivoire,** and **DRC**, to establish DTCs, develop training materials, and capacitate DTC members. In DRC and Côte d'Ivoire, MTaPS teams collaborated with counterparts to finalize the training materials development process begun last quarter. Ten of the eleven planned modules were drafted, reviewed, and validated. The draft modules were shared with Burkina Faso and DRC to adapt to their local context. Both DRC and Côte d'Ivoire have now completed the adaption of the validated DTC modules to comprehensive in-service training packages through curriculum design workshops. Each country's curriculum comprises an instructor guide, participant manual, PowerPoint slides, baseline data collection tools, and job aids. The program collaborated with the Côte d'Ivoire's AMR-TWG to deliver a series of workshops to orient counterparts on the application of the curriculum. In DRC, 80 appointed DTC committee members were trained using the materials. In addition to acquiring curriculum design skills, participants received training on how to conduct continuous quality improvement processes. MTaPS will focus on assisting local counterparts in developing action plans in the next quarter and will also support the AMR-TWG in monitoring implementation of these plans.

#### **E-Learning Platforms and Course Materials**

During the previous reporting period, MTaPS collaborated with staff from the MOHs in Burkina Faso, Mali, Senegal, and Tanzania to establish e-learning programs to mitigate IPC challenges and increase IPC capacity. In this quarter, the program's efforts focused on finalizing the e-learning courses, preparing local platforms, and training teams responsible for managing these platforms. MTaPS supported **Tanzania** in producing five IPC e-learning modules, which, together with the three modules developed in the previous quarter, will provide a comprehensive e-learning package for in-service training for health care workers. In addition, MTaPS helped finalize the design of 3 IPC modules for **Senegal** and 10 IPC generic e-learning modules for **Burkina Faso** (as a cost share with the group of MTaPS

francophone countries). The courses consist of a short introductory video along with highly interactive modules with regular quizzes to check the learners' understanding of the content. To further institutionalize Senegal and Burkina Faso's e-learning activities, MTaPS helped provide virtual training and capacity-building sessions to their local e-learning teams. Given the highly technical content of the sessions, they were delivered in three parts to incrementally equip participants with the necessary competencies to sustainably manage their respective e-learning programs. Twenty-three IT specialists and e-learning platform administrators in the two countries were trained on how to use the different functionalities of their Moodle platforms to upload e-learning courses, enroll users into courses, monitor users' performance, and produce course reports. Each session lasted two hours with a gap of one week in between to give participants time to practice what they had been taught. At the end of these sessions, participants were able to independently upload the IPC e-learning courses onto their Moodle platforms. MTaPS has started providing training on effective e-learning training facilitation skills using the newly customized modules and hope to complete this in the next quarter.

#### Supportive Supervision and Mentoring

As a follow on to a water, sanitation, and hygiene (WASH) assessment and orientation on the new WASH guidelines, MTaPS Tanzania provided mentoring support to 18 health care workers from 4 MTaPS-supported health facilities. The mentorship emphasized availability, maintenance and use of handwashing facilities, minimum water storage requirements and treatment, and waste management and standards for sanitation facilities in health care settings, all of which help facilities provide a conducive environment for IPC.

#### STRONGER CAPACITY OF GOVERNMENT TO MANAGE PHARMACEUTICAL SYSTEMS

#### **Competency-Based Training Activities**

In **Bangladesh**, MTaPS is supporting the National Tuberculosis Control Program (NTP) to roll out e-TB Manager nationwide. In this reporting period, MTaPS supported organizing and implementing a series of capacity-building sessions for managers, supervisors, and users on how to use the e-TB Manager system to improve the accuracy and timely availability of individual TB patient information for monitoring and actions. The program also rolled out its electronic Asset Management System (eAMS) to 15 more district-level hospitals. The purpose of the eAMS is to monitor the status of medical equipment at all district-level hospitals and make evidence-based decisions to reduce waste of resources and develop better plans for procurement. As part of this initiative, 57 participants were trained on eAMS.

Following development of IPC curricula and establishment of IPC committees, MTaPS supported the organization and implementation of capacity building and training activities for IPC committee members in Cameroon, Côte d'Ivoire, DRC, and Senegal. In DRC, the program conducted refresher trainings on IPC standard precautions for 94 health care workers (50 females, 44 males). Similarly, MTaPS Cameroon, in collaboration with the MOH, trained 60 (10 members per health facility) IPC champions from 6 MTaPS-supported health facilities to equip them with IPC program leadership and management skills. At the end of the training, participants were able to draft their facility IPC action plans, which some have already begun implementing. As a next step, MTaPS will collaborate with counterparts in post-training follow-up, supportive supervisory visits, and mentorship to these committees to improve their effectiveness. MTaPS supported Côte d'Ivoire's IPC TWGs and experts from the Directorate of Veterinary Services to train 16 animal health care providers. The training focused on equipping participants with effective training and facilitation skills and ensuring they are ready to independently conduct onsite trainings. A pool of 10 IPC master trainers was created (as a result of the 5-day TOT workshop) who can support facility-level training for the animal health sector. MTaPS also helped Côte d'Ivoire's AMR-TWG with planning and conducting three sets of competency-based training workshops for frontline health care workers in the four selected intervention facilities. In

partnership with the DQSHH, MTaPS Senegal trained 30 health care workers (20 females, 10 males) using the IPC modules, also validated in this reporting period.

#### Institutional Capacity Building

Well-functioning pharmaceutical systems depend on national departments of pharmacy, procurement agencies, contracting, accreditation, and other national and sub-national government departments and managers that have enough capacity to steward, manage, and coordinate stakeholders and effect positive change within the pharmaceutical sector.

In the **Philippines**, MTaPS is providing technical assistance to strengthen the capacity of the DOH's PSCMT to effectively fulfill its redefined role of stewardship, policy making, capacity building of local government units, oversight of PSCM performance, and provision of shared services to support the transition from a centralized model with fragmented PSCM functions to a decentralized and integrated system. In this reporting period, the DOH conducted a mapping exercise with support from MTaPS that brought together PSCMT and key stakeholders from various DOH bureaus, the national regulatory authority, and other implementing partners to analyze current PSCM processes, ascertain challenges related to product registration, and identify steps to address them. MTaPS also helped the DOH develop a performance management system for monitoring PSCM functions and service delivery.

In North Kivu and Ituri provinces in eastern **DRC**, MTaPS is assisting the provincial TWGs on medicines in improving their capacity to lead collaborative efforts with development partners and manage and oversee the provision and distribution of lifesaving MNCH and other essential medical products. In this reporting period, MTaPS supported the provincial health divisions (division provinciale de la santé [DPS]) in North Kivu and Ituri provinces to convene meetings of the TWGs on medicines and develop TOR for MNCH sub-groups. The program also helped develop a road map for building the capacity of MNCH sub-groups to provide technical advice to help the DPS make informed decisions on operational activities related to the management of MNCH medical products and the coordination of partners.

MTaPS is assisting **Nepal's** DDA and the Ministry of Health and Population (MOHP) in developing a new organizational structure for the DDA that best supports its functional responsibilities and its role in stewardship, coordination, and oversight as the country transitions to a federated system and the NMRA transitions to a single autonomous body that will be responsible for regulating both medical products and food. A comparative analysis of the organizational structure of NMRAs in other countries was finalized by MTaPS' partner Celsian, and MTaPS presented the findings to DDA, which included a compilation of advantages and disadvantages of including food as a responsibility of an NMRA. Celsian also developed a report that proposes different organogram structures for the new FDA; MTaPS shared the report with the DDA to inform its discussion with the MOHP on different organogram options for the new agency.

## IMPROVED CAPACITY OF PRIVATE-SECTOR ORGANIZATIONS TO SUPPORT PHARMACEUTICAL OPERATIONS

MTaPS collaborated with the **Rwandan** MOH, Rwanda FDA, and National Pharmacy Council to develop standards for pharmaceutical services and performance assessment tools that will be used to accredit private hospital and community pharmacies as well as pharmacies in public sector hospitals and health facilities as part of a comprehensive quality assurance framework for measuring, evaluating, and improving the quality of health services in the country. The standards address pharmaceutical care practices and safety of medicines in health care systems, including reporting ADRs and suspected pharmaceutical quality-related concerns to relevant clinical governance committees and to the Rwanda FDA. In this reporting period, the standards and a plan for their implementation were approved by the Rwanda minister of health.

As part of GHSA-funded efforts to support **Kenya** in optimizing the use of antimicrobial medicines and improve IPC, MTaPS collaborated with the Pharmaceutical Society of Kenya and representatives of various health professional associations to finalize a continuing professional development and relicensure-linked in-service AMS course that the associations will deliver to their members working in both public and private sectors, beginning in year 3. MTaPS also worked with a task force of professional associations to analyze the findings of a needs assessment for a continuing professional development and relicensure-linked in-service course on IPC and supported a workshop to develop the first draft of the curriculum outline, implementation strategy, and course content.

## STRONGER MEDICINES REGULATORY CAPACITY, INCLUDING THROUGH REGIONAL REGULATORY HARMONIZATION

## Enhancing the functional capacity of NMRAs through pharmaceutical regulatory system strengthening

MTaPS sustained its support to countries by completing ongoing activities, including reviewing DDA QMS documents, developing a basic QMS training package in **Nepal**, and reviewing or finalizing draft documents, such as the report for streamlining registration of MNCH products in **Bangladesh** and the PV regulation and quality manual in **Mozambique**. Other activities included drafting regulations for technology transfer in **Rwanda**, training Rwanda FDA senior management on QMS, and finalizing the report on PV workforce development assessment and related implementation plan in the **Philippines**. These activities have contributed to strengthening the institutional and individual capacity of the NMRA in the different countries.

Technical assistance was provided to NMRAs to strengthen their regulatory systems and attain the status of a functional regulatory system, which is maturity level 3 according to the WHO GBT version 6. In this reporting period, MTaPS supported various regulatory system strengthening areas, including improving the legal framework for regulatory systems, QMS, product registration systems, PV systems, provision of quality pharmaceutical services to patients, and information for regulatory decision making. Highlights of the support provided during the quarter in these areas are provided below. For more detail on MTaPS' PV activities, refer to objective 5/PV activities in this report.

#### Capacity to manage key functions of the regulatory system

MTaPS provided support to NMRAs' overall strategic planning for strengthening regulatory systems by working with the **Rwanda** FDA to review and finalize the institution's five-year strategic plan (2020-2025). To ensure alignment with country priorities, all products regulated by the authority were incorporated within the scope of the strategic plan, including food safety, cosmetics, and veterinary medicines. Implementation of the strategic plan is anticipated to start in January 2021. In **Bangladesh**, MTaPS provided technical support to translate the NMRAs's strategic plan (2017-2021) into an action plan for 2020. Noting NMRAs' efforts to align their priorities with their countries' context and changes in policy, MTaPS worked with NMRAs in **Mozambique** and **Nepal** to plan for support and resources to refine the strategic plans commencing in 2021. In Mozambique, MTaPS reviewed the draft strategic plan and provided comments on areas for improvement to DNF for consideration. Further support will be provided in year 3 to refine and finalize the plan. In Nepal, MTaPS worked with DDA and partners, such as WHO and Promoting the Quality of Medicines Plus (PQM+) program, to plan for the meeting to finalize verification of the DDA's GBT assessment report in FY21 Q1, which will inform development of DDA's institutional development plan and five-year strategic plan.

To determine the gaps in medical product registration, MTaPS undertook an evaluation of the barriers and bottlenecks to registration of MNCH medical products in **Bangladesh**, **DRC**, **Mali**, **Mozambique**, **Nepal**, **Rwanda**, **Senegal**, **Tanzania**, and **Uganda**. Findings reveal inadequate capacity to perform assessments of advanced and complex products, such as biologicals and vaccines.

MTaPS addressed this gap in Rwanda and Mozambique by providing technical assistance to equip medicine regulatory assessors with the necessary skills and knowledge (for more detail, see product registration systems improvements below and MNCH portfolio).

MTaPS assisted four countries in strengthening use of electronic information technology for more efficient and transparent medicine regulatory processes. Information management system solutions speed up delivery of services and provide transparent processes with assurance of quality services. In Bangladesh, MTaPS assisted the DGDA in reviewing the online process for ADR reporting and organized a workshop where limitations of the current manual and online systems for ADR reporting were reviewed and potential solutions presented to stakeholders for their input. In Mozambique, MTaPS has been supporting the DNF in improving the functionality and use of the medicine registration tool Pharmadex. Building on the work in the previous reporting period, MTaPS and DNF conducted user acceptance testing of the import module of Pharmadex and worked on getting a cloud hosting solution for the online version of Pharmadex. The medicines import module will allow applicants to request import authorization online and print import authorization documents. MTaPS also submitted an official letter to the DNF management on a data use agreement that would allow deployment of the internet-ready version of Pharmadex on the internet server (cloud); the letter and non-disclosure agreement are awaiting DNF's signature. MTaPS developed system requirement specifications for the premises licensing module of Pharmadex based on guidance provided by DNF, which will form the foundation for future development of the premises licensing module. The program also developed two additional functionalities (import of non-medicines and import of non-registered products for emergency situations) for the import module of Pharmadex. Additionally, MTaPS, in collaboration with Columbus Consulting, facilitated a two-day training for system administrators that will provide IT support to users of the tool at the health facility and central levels and troubleshoot any problems with the tool.

In **Nepal**, a comparative assessment of the current information management system (DAMS) of DDA and Pharmadex concluded that it was more feasible and cost-effective to deploy Pharmadex than upgrade DAMS; MTaPS made a presentation on Pharmadex to DDA, which generated strong interest in Pharmadex. DDA decided to run both Pharmadex and DAMS in parallel for six months after which a decision will be made whether to phase out DAMS and transition to Pharmadex. MTaPS is currently drafting the system requirement specifications to implement Pharmadex's registration module. MTaPS finalized and shared with the DDA the TOR for updating the DDA website by a local IT company (CMS Design) to make the website more dynamic and add a repository for updated information on its regulatory processes. Additionally, MTaPS drafted hardware and software requirements to support the DDA MIS infrastructure and is also supporting DDA in developing an online portal for managing information on imported products.

MTaPS is supporting the **Philippines** in introducing PViMS to support implementation of active TB drug-safety monitoring and management (aDSM). In this reporting period, MTaPS facilitated a second orientation on PViMS version 2 to a larger group of stakeholders, including the PD, NTP, FDA, Lung Center of the Philippines research group, and selected TB providers/partners engaged in a series of test runs of PViMS version 2. MTaPS will continue to support the Department of Health's Knowledge Management and Information Technology Service (KMITS), PD, FDA, and NTP in rolling out PViMS to all sentinel sites and develop their capacity to sustain the use of PViMS for implementation of aDSM.

#### Establishing a QMS to improve regulatory system capacity

To develop NMRA institutional capacity, MTaPS is supporting countries in implementing QMS in accordance with ISO standard 9001:2015 and WHO guidelines. In **Mozambique**, MTaPS worked with the DNF to finalize the quality manual that will guide QMS implementation. MTaPS also worked with the DNF to develop the TOR for capacity building DNF internal auditors to equip them with the knowledge and skills to assess the compliance of DNF's process and activities with ISO standards. In **Nepal**, MTaPS participated in remote validation of the DDA's regulatory status, including QMS implementation based

on documents submitted to the WHO after the GBT self-assessment. The findings indicate that although DDA has made progress in some indicators, it generally remains at level I maturity. MTaPS will continue to support DDA in strengthening its regulatory system. MTaPS' partner Celsian prepared a basic training package on QMS for the staff of DDA and the National Medicines Laboratory in preparation for an intensive training scheduled for October 2020. The MTaPS team conducted a gap analysis of the **Rwanda** FDA QMS and developed recommendations for improvement and addressing identified gaps. The team also supported development of a quality management manual and several guidelines and SOPs to guide implementation of QMS. MTaPS also trained the senior management of Rwanda FDA on QMS awareness and implementation.

#### Product registration systems improvements

To protect public health, NMRAs must establish strong registration systems to ensure the quality, safety, and efficacy of medicines and other medical products before marketing authorization. MTaPS provided technical assistance in several countries in Africa and Asia to improve their medicine registration systems. In **Mozambique**, MTaPS, together with DNF, conducted a 2-day workshop to train 12 DNF regulators on GRevPs for registering medical products. The course improved the knowledge and raised awareness of DNF medicine registration personnel on GRevPs and provided skills to improve medical product dossier evaluation, project management, and strategic communication for internal and external clients. DNF agreed to work with MTaPS to develop a guideline on GRevPs based on WHO model guidance to assist the authority in streamlining their medicine registration processes.

MTaPS provided technical assistance to conduct capacity-building workshops in assessment of medical products dossiers for 55 assessors from **Rwanda** FDA. Conducted through virtual platforms, the sessions aimed to equip the assessors with knowledge and skills to perform scientific evaluations of medicines, medical devices, and medicated cosmetics. Participants were also provided with information on GRevPs and applying them in the context of the Rwandan pharmaceutical market. MTaPS also supported the Rwanda FDA in signing up for the WHO collaborative registration process to facilitate product registration and improve access to life-saving medicines.

In the **Philippines**, MTaPS conducted a process mapping exercise involving key stakeholders from various bureaus of the DOH, FDA, and implementing partners. This exercise enabled them to thoroughly analyze current PSCM processes, identify immediate registration process optimization opportunities and challenges, and define options to address those challenges to ensure continued access to health products at all levels of care. Additionally, MTaPS conducted an analysis to identify TB medicines that need to be registered and gaps in the current registration system. Based on this analysis, MTaPS developed a technical document that sets out the current registration process, identified bottlenecks, and made recommendations for DOH and FDA to improve efficiency of registration in prioritized health program medicines. Moving forward, MTaPS will assist the FDA in optimizing their overall registration process while prioritizing registration of identified essential medicines needed by DOH's public health programs to support continued availability of these medical products.

To identify major barriers and bottlenecks in registering MNCH essential medicines, MTaPS has been surveying medicine registration processes in nine countries in Africa and Asia. During this reporting period, MTaPS compiled survey reports, including identified barriers and options for addressing them for consideration by country NMRAs and USAID. Findings revealed that there is no special consideration of registration of MNCH medicines in any of the countries surveyed. To improve access, NMRAs could consider adding essential MNCH medicines to the list of prioritized medicines for registration among other solutions. Refer to MNCH portfolio for further details.

## Improving pharmaceutical services by enhancing pharmaceutical standards and workforce capacity for pharmacy and clinical staff

In **Rwanda**, the minister of health approved the draft implementation plan and tools for operationalizing the standards for pharmaceutical services and pharmacy accreditation. MTaPS is currently printing the document for distribution to facilitate implementation.

#### Improving the legal framework and establishing collaborative enforcement mechanisms

The MTaPS team supported the Rwanda FDA in developing three guidelines related to GRevPs, technology transfer for pharmaceutical products, and quality audit of medical device manufacturers. In **Mozambique**, as part of efforts to transform the DNF into a semi-autonomous authority, MTaPS worked with them to review the PV regulation, in accordance with good legislative practices. Also, capacity-building sessions were conducted to improve knowledge on developing regulations and guidelines and implementing good regulatory practices. In **Bangladesh**, MTaPS, in coordination with PQM+, supported the DGDA in developing a mechanism for preparing and uploading the list of personal protective equipment (PPE) manufacturers in the country. MTaPS also prepared a list of DGDA-recommended PPE manufacturers eligible to have a no objection certificate and shared with DGDA.

Refer to Objective I, <u>Evidence-Based Medicines Policies</u>, <u>Laws</u>, <u>Regulations</u>, <u>Guidelines</u>, <u>Norms</u>, <u>and Standards Improved and Enforced</u>, for more details.

#### Advancing regional regulatory harmonization efforts

Harmonization of medical product regulation yields benefits to both NMRAs and end users by creating efficiency gains and ensuring access to quality-assured medicines. There are various stages in harmonizing medical product regulation that countries or regions could apply to foster use of similar standards. These entail exchange of information and work sharing before eventually signing more legally binding agreements to attain mutual recognition and harmonization. MTaPS worked with several continental and regional organizations to support convergence and the road to harmonization of medical product regulation in PV, regulatory inspections, and regulatory information management systems.

To support local manufacturers in **IGAD/EAC** regions to improve compliance with regional and national pharmaceutical regulatory standards and requirements, MTaPS is assessing the local pharmaceutical industry to examine their capacities to adhere to good regulatory practices. The inception report was finalized, and assessment tools developed, and the consultant is now consolidating the findings into a report with plans to disseminate the findings, sensitize stakeholders, and develop improvement plans for enhancing regulatory compliance in FY21. MTaPS also offered a capacity-building course on PV for cross-border and facility focal persons in IGAD member states. The course was offered jointly with IGAD-PV experts and to equip participants with skills to conduct PV baseline assessment systems by using the indicator-based PV assessment and monitoring tool.

To harmonize PV processes and tools in the **EAC** region, MTaPS worked with the EAC lead NMRA in PV (Pharmacy and Poisons Board of Kenya) to develop a draft harmonized PV curriculum and training modules and draft harmonized SOPs to support implementing the draft PV compendium. The EAC harmonized PV compendium and SOPs will also be adapted for IGAD and will be available for use in EAC and IGAD countries as well as cross-border areas. The harmonized PV curriculum will be used for TOTs who will then train in-country health care providers with a dedicated focus on cross-border areas to promote safety monitoring.

To improve efficiency and accountability in delivering pharmaceutical regulatory services, NMRAs have embarked on digitalizing regulatory functions by using varied approaches. However, the data needs and suitability for digitalization varies across the different regulatory decisions associated with each regulatory function. In this reporting period, MTaPS developed a plan for gaining consensus on common standards for regulatory MIS and applying them to the current software used in MTaPS-supported

countries and other LMICs. The plan is to provide a guidance document that countries can use to streamline their regulatory MIS or when considering digitalizing their processes.

Interaction with key networks **SEARN** and **SEARO** yielded an opportunity for MTaPS to support strengthening regulatory standards and requirements in the Asian region. MTaPS provided preliminary technical assistance to contribute to the design and delivery of an online course on current Good Manufacturing Practices for pharmaceutical manufacturers in India as a pilot in the first phase, in collaboration with WHO and JSS University (India). The plan is to roll out the course to other SEARN member states in 2021. MTaPS commented on the concept note for delivery of the online course and held preliminary meetings with SEARN, SEARO, JSS, USAID India, USAID Asia Bureau, USAID COR, and PQM+ to prepare for designing the course and providing technical experts that will contribute to implementation.

# OBJECTIVE 3: AVAILABILITY AND USE OF PHARMACEUTICAL INFORMATION FOR DECISION MAKING INCREASED AND GLOBAL LEARNING AGENDA ADVANCED

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

Over the course of FY2020, USAID-MTaPS has continued to support the selection, design, implementation, and scale-up of information systems that allocate and distribute pharmaceutical products to patients and facilities and collect, analyze, and disseminate information on the use and safety of these products for decision makers.

In **Bangladesh** this year, the countrywide rollout plan for the electronic Asset Management System (eAMS) was finalized in the first quarter and culminated in the final training for district-level hospital staff this quarter—all district-level hospitals in the country are now implementing eAMS to track the location and operational status of medical equipment and to manage equipment repairs. The eAMS connects the Central Medical Store Depot, which procures and delivers equipment, with health facilities, which enter asset information, update operating status, and request repairs from the National Electro-Medical Equipment Maintenance Workshop, which receives and acts on maintenance requests or approves third-party repairs. Before implementing eAMS, all hospitals are required to create a master registry of all assets and upload the registry to the eAMS. These assets are then cross-referenced with the national table of organization and equipment, which is a national guideline for planning and standardizing medical equipment at health facilities.

This process provides important information to stakeholders even before eAMS is fully implemented at a health facility; for example, the presence of non-standardized or unapproved equipment or a large proportion of defunct equipment can signal possible issues in selecting and procuring assets, product quality issues, poor maintenance practices, or lack of local repair capacity. Medical equipment, as defined for inclusion in the eAMS, has a value of at least 30,000 Bangladeshi taka (approximately USD 360) and is expected to have a lifespan of over 2 years. It is essential that these high-value assets remain operational for as long as possible to avoid waste and maintain service delivery to patients. Once health facilities implement eAMS, they register new assets as they enter service and make requests for maintenance or repair. The National Electro-Medical Equipment Maintenance Workshop views repair requests through a national dashboard and either performs the requested services, provides approval certificates for local repair services, or declares that the equipment may not be repaired. The Central Medical Store Depot procures and delivers assets based on needs identified through the dashboard, which can highlight where equipment may be lacking or over-concentrated. Warehousing this information in eAMS and providing real-time access to it for critical decision makers and stakeholders should expedite repairs, increase the operational lifetimes of medical equipment, and direct medical assets to where they are needed most.

Information systems for PV and product safety reporting were implemented and expanded this year through the PV Monitoring System (PViMS) tool in the **Philippines**, **Mozambique**, and **Rwanda**. All three countries had implemented PViMS to some extent prior to FY2020 but scaled up its use and began using the tool for more evidence-based decision making over the course of the year. In the **Philippines**, system improvements were made to address identified issues with data entry and management, and the tool was rolled out in more facilities in MTaPS-supported regions to expand the network of sentinel sites for detecting issues of product quality and patient safety. The use of PViMS in the Philippines was reinforced with Administrative Order No. 2020-0025 by the Department of Health issued this year, which specifies that PViMS is the tool that will be used nationwide to collect and disseminate data and reports on PV issues.

In **Mozambique**, PViMS was introduced as part of the active surveillance system, enacted this year, to standardize data collection, entry, management, and analysis of safety data generated by PV initiatives.

This year, PViMS was adapted to the Mozambique context, and piloted using program-provided tablets at 10 health facilities. Through master TOTs, USAID-MTaPS in Mozambique expanded use of PViMS to a further nine health facilities and completed two training sessions with national-level staff at the drug regulatory agency (DNF) and the HIV program to manage data, troubleshoot, perform data analysis, and provide IT assistance to facility-level PViMS users. In **Rwanda**, the FDA began entering data captured in other formats into PViMS, starting with data on the Ebola vaccination program. In collating all the vaccine program's data together from all sources, a clear picture of the scope of the program and any patient safety issues can emerge. Information on first- and second-dose administration, adverse events following immunization (AEFI), pregnancy after vaccination, and follow-up of AEFI were recorded in PViMS. This provides valuable information on the safety of the vaccine program and the functioning of the active surveillance system itself. PViMS is a cornerstone of the Rwanda FDA's active surveillance strategy, the goal of which is to use PViMS at all levels of the health system for all medicine safety data reporting and analysis.

This program year, MTaPS supported medicines registration in **Nepal** and **Mozambique** through the use of Pharmadex, a web-based tool that streamlines the medicines registration process, increasing the efficiency of ensuring access to quality-assured medical products. In **Nepal**, the national medicines regulatory authority, the Department of Drug Administration (DDA), approved transitioning its current medicines registration system to Pharmadex, following an options analysis conducted by the program. The two systems will be co-implemented for six months, after which Pharmadex will be solely used. This transition will continue in to program year 3, with MTaPS providing continued technical assistance. Pharmadex is already in use in **Mozambique** and during the second program year, MTaPS customized an importation module and finalized the licensing module, allowing applicants to submit applications online, rather than in-person. These improvements create efficiencies for both the regulatory authority, pharmaceutical producers seeking product registration, and entities applying for licenses to sell or dispense medical products.

### QUARTER PROGRESS FOR FY20Q4

### INTEROPERABILITY OF PHARMACEUTICAL MANAGEMENT INFORMATION SYSTEMS THAT LINK PATIENTS AND PRODUCTS

This quarter, USAID-MTaPS worked to further develop and implement information systems across pharmaceutical systems to promote product quality, availability, and safety. In **Bangladesh**, MTaPS worked with other international aid organizations to scale up electronic logistics management information systems (eLMIS) for priority MNCH commodities. This quarter, 138 new health facilities were added to the eLMIS to improve stock management and availability of these commodities. Also, in **Bangladesh** this quarter, training was completed for district hospital-level users on the eAMS. This system tracks the location and operating status of medical equipment at district hospitals, which enables decision makers to better allocate these resources and make evidence-based procurement and repair decisions.

Several countries are working to establish and expand systems to ensure proper regulation of pharmaceutical products. This quarter, **Mozambique** continued to scale up Pharmadex, an electronic tool for pharmaceutical product regulation. When the system was first implemented, it only included capabilities for managing the product registration function of the Mozambique medicine regulatory authority, the DNF. System requirement specifications are now developed to include the modules for licensing premises and product importation. Work continued this quarter to fully operationalize Pharmadex using cloud-based solutions to enable pharmaceutical companies to submit applications online for marketing authorization. This capability should improve the speed and transparency of the

product registration process, in turn, promoting timely access to quality-assured pharmaceutical products in Mozambique.

Similarly, **Nepal** has been working to strengthen the electronic regulatory capabilities of the Nepalese medicine regulatory authority, the Department of Drug Administration (DDA). This quarter, MTaPS performed an options analysis to determine the optimal electronic regulatory system for implementation in Nepal. Based on funding availability and desired functionality, the DDA decided to co-implement Pharmadex and the current information system, the Drug Administration Management System (DAMS), for a six-month period, with improvements recommended during the options analysis. Following this period, DDA will determine the most appropriate information system for implementation moving forward. This collaborative process promotes ownership of the regulatory information system by the DDA and will help make an evidence-based decision to optimize the management of regulatory information in Nepal, even after the MTaPS program concludes.

### INCREASED AND BETTER USE OF INFORMATION ON PHARMACEUTICAL SYSTEMS FOR DECISION MAKING

USAID-MTaPS has been working to sustainably improve the use of information to support evidence-based decision-making processes for pharmaceutical systems. In the area of stock monitoring and product availability, MTaPS/Nepal worked this quarter to integrate stock status reporting of pharmaceutical products from importers with the weekly DDA report to facilitate effective decision making on supply forecasting and procurement alongside other regulatory processes. In the Philippines this quarter, a planned procurement and implementation of an eLMIS was put on hold due to the ongoing COVID-19 pandemic. MTaPS developed an interim stock monitoring system that uses consumption and inventory data to support informed allocation and distribution decision making to promote product availability throughout the Philippines' health system. To mitigate transportation challenges caused by the pandemic, the MTaPS team also compiled a list of logistics providers at central and local levels to provide alternative distribution channels for essential medical products during the pandemic. These systems are intended to keep the supply chain functioning and provide timely information for decision makers, as needs and conditions evolve during the pandemic and beyond.

The PViMS tool is active in **Mozambique**, **Rwanda**, and the **Philippines**, and is generating adverse event reports to promote patient safety. In **Mozambique** this quarter, staff members from the DNF and national HIV program were trained on how to use PViMS for data analysis, so that adverse event reports can be more effectively used to identify product quality or safety issues that may require corrective action. This quarter, MTaPS in **Rwanda** conducted training for members of DTCs at health facilities on how and when to report suspected adverse events. As a result of the training, 26 adverse event reports and 45 reports of poor product quality were submitted to the Rwanda FDA, demonstrating that capacity-building activities on the use of PViMS and other PV reporting mechanisms have a direct impact on the availability of information that impacts patient safety.

### ADVANCEMENTS IN PHARMACEUTICAL SYSTEMS STRENGTHENING RESEARCH AND THE GLOBAL LEARNING AGENDA

Please refer to Cross Bureau, activity 2 for a full description of progress on this activity.

## OBJECTIVE 4: PHARMACEUTICAL-SECTOR FINANCING, INCLUDING RESOURCE ALLOCATION AND USE, OPTIMIZED

### **HIGHLIGHTS FOR PROGRAM YEAR 2 (FY20)**

### **EVIDENCE-BASED MEDICINE STRATEGIES AND PHARMACEUTICAL BENEFIT PROGRAMS DEVELOPED**

MTaPS is providing global thought leadership on building health systems capacity for health technology assessment (HTA). In addition to supporting decision making in health care and promoting appropriate resource allocation, HTA enables credibility, transparency, and accountability in health care decisions related to pharmaceutical benefit development and medicine coverage.

In year 2, MTaPS finalized the HTA road map core document entitled A Roadmap for Systematic Priority Setting and Health Technology Assessment (HTA): A Practical Guide for Policy Action in Low- and Middle-Income Countries. The online launch is targeted at a wide range of experts from Asia, Latin America, and Africa and will take place next quarter. MTaPS has started developing an addendum to the road map specifically targeted at HTA development in Asia.

MTaPS/**Philippines** continued to support the national Department of Health (DOH) in operationalizing HTA with specific inputs on pharmaceutical pricing. Based on cost-effectiveness and cost-benefit analysis, the selection of health technologies will serve as inputs for additional price negotiation by the central price negotiation body.

As part of the global learning agenda, in year 2, MTaPS finalized content for three supplementary videos, the third of which was on financing MNCH products. Under **Cross Bureau**, MTaPS and with the Joint Learning Network held a learning exchange event on pricing strategies for medical products. The objective was to facilitate exchange of knowledge, experiences, and best practices on price comparisons, negotiations, and pricing policies. The event had participants from 17 countries, with an average of 22 participants for the three-sessions. Following the learning exchange, MTaPS drafted a reference document that include key learnings from the event, along with pricing data resources.

Also, in year 2, the MTaPS/**Asia Bureau** developed a guidance brief on defining pharmaceutical benefits. Designing a health benefits package (HBP) is a necessary step for countries as they work toward achieving universal health coverage (UHC).<sup>10</sup> An HBP is the set of health services and medical products that a particular set of beneficiaries is entitled to receive that provides specified financial protection; it is funded by the government or another coverage arrangement. As a sub of the HBP, the pharmaceutical benefit package<sup>11</sup> (PBP) is a list of covered medicines that should be carefully selected and, where possible, costed to ensure that funders are apprised of the budget impact of the PBP. In addition to enhancing financial protection for households, a well-defined PBP can ensure that the country's resources are spent on cost-effective, highly valued medical products and help expand coverage to otherwise underserved populations and provide explicit entitlements for all beneficiaries. In year 2, MTaPS/Asia Bureau finalized its mapping and analysis of pharmaceutical benefit coverage in 12 Asian countries and produced a brief on key steps for defining PBPs.

<sup>&</sup>lt;sup>10</sup> Greß S, Niebuhr D, Rothgang H, Wasem J. (2005). Criteria and procedures for determining benefit packages in health care: A comparative perspective. Health policy, 73(1), 78-91.

<sup>&</sup>lt;sup>11</sup> Rankin J, Gremillion M, Eghan K. (2015). Management of Medicines Benefit Programs in Low-Income Settings: Adapting Approaches from High-Income Settings.

#### THE EFFICIENCY OF PHARMACEUTICAL RESOURCE ALLOCATION AND USE INCREASED

As countries work at improving access to much-needed pharmaceuticals, understanding how available funds for pharmaceuticals are expended is a critical step to sustainability. Policymakers need to understand data sources and implement processes to easily obtain data on pharma spending. In year 2, based on initial work done under SIAPS to develop a guide to tracking pharmaceutical expenditures in LMICs, MTaPS, in collaboration with the LHSS Project, conducted additional desk reviews of existing health accounts data to understand how pharmaceutical expenditures have been tracked to date. This review identifies existing gaps in measuring and reporting pharmaceutical expenditure data. This activity will inform how health accounts methodology can be customized and enhanced. It will also help determine how guidance can be improved to fill identified gaps and produce higher quality and more detailed pharmaceutical expenditure data. MTaPS, in collaboration with LHSS, started in Burkina Faso to identify all the data sources for pharmaceutical spending in that country. It is expected that the results of this work will lead to the development of a guideline and methodology on how to adapt the national health account methodology for routine pharmaceutical expenditure tracking.

MTaPS/**Cameroon** conducted a costing exercise on the country's One Health platform operational, monitoring, and evaluation plans. MTaPS/Bangladesh's plans to review, update, and cost the medical and surgical list within the public sector was canceled due to COVID-19.

To facilitate strategic planning and enable better pharmaceutical financing decision making, MTaPS developed a guidance document to build countries' capacity to cost PBPs using the One Health Tool. During year 2, MTaPS completed a review of 41 costing tools and 58 costing studies in and outside the Asia region to determine which would be the most appropriate in estimating expenditures for drug benefits, leading to the selection of the One Health Tool. Avenir Health developed the One Health Tool for high-level financing and diagnostic-specific services. It can be used for either bottom-up or top-down costing exercises. The comprehensive guidance document will support pharmaceutical system managers in assessing pharmaceutical coverage costs and assist them in securing adequate funding to meet population needs.

#### MOBILIZATION OF ADDITIONAL AND SUSTAINABLE RESOURCES INCREASED

In year 2, MTaPS/**Bangladesh** assisted the National TB Program in preparing concept notes for funding through the Global Fund for 2020-2023.

### **QUARTER PROGRESS FOR FY20Q4**

### **EVIDENCE-BASED MEDICINE STRATEGIES AND PHARMACEUTICAL BENEFIT PROGRAMS DEVELOPED**

During Q4, MTaPS finalized the HTA core roadmap document A Roadmap for Systematic Priority Setting and Health Technology Assessment (HTA): A Practical Guide for Policy Action in Low- And Middle-Income Countries. MTaPS announced the global launch of the roadmap through a series of social media campaigns and blogs to create awareness and generate interest among target stakeholders, e.g., country policymakers and HTA practitioners, global HTA experts, and other partners. MTaPS also initiated the development of an addendum to the core roadmap document focused on Asia.

Being cognizant of the varied stages of HTA advancement across LMICs, the addendum will provide updates on progress made, recent experiences, and practical considerations for various settings in the region. The addendum draft is currently being reviewed internally and is planned to be finalized in the next quarter.

MTaPS/Asia Bureau finalized two reports on costing pharmaceutical benefits. The reports identified the One Health Tool as a recommended tool for costing pharmaceutical benefits. MTaPS reviewed 41 existing tools for costing PBPs using criteria that included whether the tool is electronic, allows for customization and flexibility in treatment guidelines for diseases to reflect the local context, and enables forecasting and projections. The reports also provided tailored guidance for country stakeholders to use the One Health Tool for PBP costing. With this guidance, stakeholders will be better able to 1) use the One Health Tool to derive coverage targets, costing, and impact information; 2) estimate the cost of a PBP; 3) assess the needed government contribution and the fiscal gap to afford the overall drugs needed in the country; and 4) facilitate discussions regarding priority setting for drugs within each disease area, as well as adjustments to pharmaceutical benefits for each disease, intervention, or health condition. As a result, countries will manage and allocate funds more efficiently and ultimately ensure sustainable access to safe, effective, quality-assured, and affordable essential medicines and pharmaceutical services.

To effectively manage pharmaceutical expenditures, health systems need to understand and manage the prices and quantities of pharmaceuticals consumed within their systems. To promote transparency in pricing through a regional pricing database, MTaPS researched pricing policies and techniques used in Asian countries. A consultant on pharmaceutical pricing policies with deep knowledge of the region was engaged to produce a summary paper documenting pricing policies within the Asian region. The consultant reviewed supply-side policies, including internal and external reference pricing, generic caps, cost-plus pricing, tendering, among others, and demand-side policies, including generic prescribing, (mandatory) generic substitution, prescribing protocol, and electronic prescribing monitoring tools from 11 countries. In addition to highlighting what policies and strategies each of the 11 countries rely on, the paper identifies focus areas in existing country approaches to pricing where technical assistance might help. The report will help countries understand how other countries within the region approach pharmaceutical pricing and approaches to improving pricing transparency. The consultant has submitted a first draft of the report, which is currently under review by MTaPS.

#### THE EFFICIENCY OF PHARMACEUTICAL RESOURCE ALLOCATION AND USE INCREASED

Containing rising pharmaceutical expenditures remains a key strategic focus of many health systems. The quantity of commodities procured or consumed and the prices impact total pharmaceutical expenditures. To enhance efficiency in resource allocation and use for pharmaceuticals, in Q4, MTaPS/**Philippines**, supported DOH in updating the draft administrative order for framework agreement and pooled procurement mechanisms to strengthen strategic procurement practices. MTaPS also supported the country's strategic efforts to contain prices by providing technical inputs to the formation and operationalization of the National Price Negotiation Board's central price negotiation functions.

#### MOBILIZATION FOR ADDITIONAL FUNDING AND SUSTAINABLE RESOURCES INCREASED

MTaPS/**Philippines** supported the DOH in identifying funding gaps, following a three-year quantification of FP, general TB commodities, and the newly approved TB combination drug regimen (rifapentine plus isoniazid). In addition, MTaPS supported the Philippine National TB Program to provide strategic insights to the government on the financial implications for transitioning PSCM activities from the Global Fund to government funding. The funding analysis and its implication for the transition will aid government decisions for timely allocation of funding to prevent interruption of much-needed TB services.

# OBJECTIVE 5: PHARMACEUTICAL SERVICES, INCLUDING PRODUCT AVAILABILITY AND PATIENT-CENTERED CARE TO ACHIEVE DESIRED HEALTH OUTCOMES, IMPROVED

### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

#### **IMPROVED AVAILABILITY OF PHARMACEUTICAL PRODUCTS**

In **Bangladesh**, the highlights for MTaPS year 2 to ensure increased availability of essential medicines and other health technologies were the countrywide implementation of inventory management systems, review of medical surgical requisites (MSRs), active functioning of the Procurement and Logistics Management Cell (PLMC), completion of the electronic Asset Management System (eAMS) in all district hospitals, and implementation of e-TB Manager. The details of these key achievements and their outcomes are highlighted as follows:

- Countrywide introduction of a standard inventory management system within the Directorate General of Health Services (DGHS) was completed, which made the recording and reporting system uniform and ultimately will contribute to minimize stock disruptions in the country.
- More than 2,000 MSR items were reviewed and updated to improve procurement efficiency of health facilities under the DGHS (part of the Ministry of Health and Family Welfare [MOHFW]).
- The PLMC was functional as an oversight body for procurement and supply management for the MOHFW.
- Introduction of the eAMS was completed in all district hospitals for more efficient resource planning, allocation, and utilization to improve patient-centered care nationwide.
- Individual TB patient recording and reporting system (e-TB Manager) was implemented in 665 sites
  with more than 550,000 TB patients reported in the system to ensure that updated information on
  TB treatment and outcomes are properly recorded, analyzed, and used for critical decision making.

In the same period, in year 2, highlights from MTaPS/Philippines were:

- The support provided to the central DOH PSCMT to align its role with UHC to go from being an
  operator of supply chain to be a steward, a leader in PSCM and to provide policy guidance and
  capacity building to LGUs.
- A PSCM workforce assessment was conducted to determine the necessary skill sets, staffing, and motivation in professionalizing the supply chain workforce.
- Introduction of an interim tool that uses consumption and stock data for allocation and distribution
  decisions, despite the cancelation of end-to-end eLMIS procurement due to COVID-19. The interim
  tool helped avoid stock-outs and overstocks and ultimately ensured availability of products at all
  levels of health care in the Philippines.
- Compilation of alternative logistics service providers into a directory at the central and local
  government levels to ensure continued access to essential commodities by Filipinos during the
  pandemic.
- The integration of FP commodity warehouses, which were previously managed discretely by DOH
  and the Commission on Population (POPCOM). The integration allowed efficient use of available
  warehouses and harmonized the management of FP commodities at the regional level.

#### PHARMACEUTICAL SERVICES AND PATIENT-CENTERED CARE

Over the previous year, MTaPS/Jordan's activities were strengthened the national AMR steering committee and its technical subcommittees to operationalize the national action plan on AMR through

multisector coordination and to pilot an AMS program at two leading hospitals in Amman, so the experience can be scaled up to other hospitals countrywide. For the first activity, MTaPS conducted a thorough stakeholder mapping and analysis of the AMR/AMS initiatives in Jordan and identified the primary challenges and opportunities to implement the activity. However, after COVID-19 hit the country, MTaPS could not continue working with its main counterpart, the MOH Communicable Diseases Directorate, because of their priority to the pandemic response. The second activity was also disrupted because of shifting health care system priorities and pandemic-related curfews, and moreover, the selected hospitals were designated as COVID-19 treatment centers, so planned AMS activities were postponed to FY21. MTaPS managed to continue supporting the MOH National AMS Committee focal point to develop critical technical documents through discussions with hospitals, which paved the way for AMS program implementation when feasible. These activities will improve antibiotic prescriptions and consumption practices at the hospitals and help contain the spread of AMR.

Despite the changing priorities at MOH and the increasing demand for MTaPS support to the COVID-19 response, the team maintained strong working relations with MOH counterparts to sustain AMR work during these difficult times. MTaPS turned challenges into opportunities by linking COVID-19 and AMR/AMS activities, and the MOH expressed its appreciation for MTaPS' commitment during the pandemic.

In **Mozambique**, during the year, the MTaPS team provided technical support to the Hospital Pharmacy Department to adapt in-service AMS training materials for health care workers for the country context. MTaPS conducted a training of trainers to provide the MOH staff (Hospital Pharmacy Department and National Directorate of Medical Assistance) with the capacity to cascade health workers' training and supported the training of 31 health providers (12 female and 19 male) from 7 provincial hospitals and 3 general hospitals in Maputo City. MTaPS helped each provincial hospital develop its own AMR action plan by systematically reviewing the current situation and processes, identifying critical problems, and prioritizing mitigation actions using available resources. MTaPS supported the Hospital Pharmacy Department in receiving, reviewing, and documenting the hospitals' monthly reports on AMS implementation and to follow up with the facilities.

### **QUARTER PROGRESS FOR FY20Q4**

### **INCREASED AVAILABILITY OF ESSENTIAL MEDICINES AND OTHER HEALTH TECHNOLOGIES**

Ensuring the availability of safe, effective, quality assured, and affordable medicines and health technologies is critical for effective health outcomes. It also requires sustainable demand planning; efficient and coordinated procurement systems; optimized warehousing, inventory management, and delivery systems; and reliable data for decisions supported by local institutional and individual capacity.

In this quarter, MTaPS/Bangladesh supported the PLMC, which is the overseeing governance body for procurement activities. MTaPS facilitated a virtual meeting led by MOHFW officials to discuss procurement and other supply chain issues, such as timely online submission of procurement plans, active utilization of the SCMP, and continuing to develop the capacity of MOHFW officials and directorates on efficient procurement activities. Following the meeting, MTaPS facilitated a workshop on online submission of procurement plans for 2020-2021 through the SCMP (a web-based procurement and supply chain management portal); procurement decision makers attended the workshop. MTaPS, in collaboration with the MOHFW IT cell, demonstrated online submission steps and processes that enable timely and efficient procurement to acquire essential health commodities during the COVID-19 pandemic. To sustain this initiative, this capacity building has been made mandatory for newly recruited personnel to ensure the functioning and sustainability of efficient procurement at MOHFW. A second training on procurement was organized by MOHFW and conducted by the Engineering Staff College of Bangladesh under the agreement with USAID MTaPS.

In the **Philippines**, the recently enacted UHC law provided local governments with the responsibility and financial accountability to implement health system functions. To align these changes, MTaPS provided technical assistance to the DOH PSCMT to redefine its role from being an operator of PSCM to providing leadership, stewardship, and capacity-building roles to LGUs. MTaPS supported the development of a roadmap to facilitate integration of PSCM into the local health system. The role clarification and roadmap will help DOH focus on providing policy direction and harmonizing system development and implementation across all LGUs. Besides, the focus on building capacity at the local government level will ensure efficient supply chain service delivery close to the people who seek the service. MTaPS also continues to strengthen its partnership with the leadership of the PSCMT to enhance their capacity and enable their confidence and willingness to take a stewardship role on the PSCM cycle from product selection to service delivery at each level of the system. To support effective implementation of this initiative, MTaPS supported DOH by developing a performance management system anchored on the governance roles of the PSCMT with the realignment of DOH's roles to the UHC law. The performance management system not only allows the DOH to measure and monitor implementation but also to take a more proactive role to effectively provide PSCM oversight, policy direction, and capacity building to LGUs. To cascade PSCM governance to the regional level, MTaPS supported the formation of a PSCM-PV committee at the Central Visayas (region) Center for Health Development and the development of a regional action plan as part of implementing the UHC law.

In the **Philippines**, to professionalize the PSCM workforce, MTaPS, in collaboration with DOH, assessed the PSCM workforce's needs to determine appropriate skill sets, supply chain organization structure, and staffing. Based on the findings, the workforce development plan is being drafted. When approved and implemented, it will provide a path to hire and place the right workforce with the right competency for effective and efficient PSCM and provide improved supply chain services to the people.

In **Bangladesh**, MTaPS facilitated the merging and harmonization of the MOHFW's newly developed human resource (HR) document with the standard list of equipment recently updated and supported the drafting of the table of organization and equipment to be used by DGHS and MOHFW. Completion of the harmonization process and vetting is expected the next quarter. Once vetted, the document will serve as a reference for targeted HR capacity building and better planning of asset acquisition, avoiding duplication, unnecessary procurement, and wastage of public funds.

Also, in **Bangladesh**, MTaPS, through the regional technical advisors, collaborated with DGHS in scaling up the introduction of a manual, standard inventory management system in the remaining 19 districts. Blended virtual and face-to-face training strategies were used for DGHS officials in these districts on how to use inventory tools; 183 persons (95% male) were trained on using the tools, along with some basic logistics management concepts. This activity marked the completion of countrywide rollout training in all 64 districts. The manual, standard inventory management system laid the foundation to further develop a dedicated eLMIS for DGHS, similar to the Directorate General of Family Planning (DGFP). In the DGFP system, it was observed that there was a less than 1% stock-out rate for contraceptives at service delivery points maintained throughout the year. MTaPS is continuously supporting data analysis as well as informing the DGFP for their evidence-based decisions.

In addition, MTaPS/**Bangladesh** supported DGFP in reopening the remodeled Barishal regional warehouse by developing an action plan on how to operationalize the warehouse and how to implement it, including a timeline. On August 25, 2020, the new warehouse was inaugurated virtually by Mr. Md. Ali Noor, Honorable Secretary, Health Education and Family Welfare Division. The remodeled warehouse will contribute to optimal use of warehouse space and good storage practices for FP, reproductive health commodities and other essentials. It will also help alleviate the overburden of three nearby warehouses and significantly reduce transportation costs during distribution.

In **Philippines**, MTaPS supported the DOH and POPCOM in consolidating subnational-level FP commodity management by consolidating POPCOM warehouses and regional offices into the FP

commodity supply chain network. MTaPS also supported POPCOM in developing logistics and supply chain management guidelines and facilitated a training workshop on inventory and warehouse management for DOH and POPCOM supply and logistics personnel. This initiative avoided redundancies and maximized utilization of existing warehouses for managing commodities. Furthermore, MTaPS/**Philippines** facilitated the use of an interim distribution tool for FP commodities. The tool was codeveloped by MTaPS and the national FP program to support regional FP supply chain coordinators to ensure rational commodity distribution decisions. The guidelines, tool, and training will help DOH and POPCOM better manage regional storage and distribution of FP commodities, which will, in turn, reduce the logistics burden of the DOH and free up limited space in DOH warehouses.

Although MTaPS/**Philippines** supported the DOH in developing high-level system requirements and facilitate resource mobilization, such as funding to procure an off-the-shelf eLMIS, the procurement failed twice because of a procurement policy bottleneck and later canceled because of COVID-19 and consequent redirection of resources to pandemic control. In the advent of this situation, MTaPS supported DOH in exploring feasible options and drafted a multi-year eLMIS procurement and implementation plan with cost. When the multi-year phased approach options are approved, DOH will benefit from long-term (maximum three years) engagement of eLMIS solution providers without forfeiting resources allocated in a single fiscal year.

In **Bangladesh**, MTaPS supported completion of eAMS rollout by training 15 more district hospitals. The completion and effective implementation of eAMS in all district hospitals helps decision makers monitor the status of medical equipment nationwide to ensure efficient utilization of resources to provide improved patient care. In addition, MTaPS collaborated with USAID MaMoni Maternal and Newborn Care Strengthening Project of Save the Children to scale up DGHS eLMIS for MNCH commodity tracking and improved stock management.

In FY19, MTaPS/Philippines supported the DOH in conducting a three-year quantification of FP and TB commodities, which informed three-year commodity quantity, budget requirements, and identification of resource gaps. In FY20, MTaPS continued the support to revise the forecast based on the previous result and new information for TB and FP commodities to help procurement planning and funding gap identification. MTaPS also supported the National TB Program (NTP) in quantifying the newly recommended three-month weekly rifapentine-plus-isoniazid regimen for programmatic preventive therapy of latent TB infection. Furthermore, MTaPS supported the NTP in developing a plan for financing the transition of second-line anti-TB medicines from the Global Fund to the Government of Philippines. The transition plan includes financing for HR, who are managing the supply chain.

### **IMPROVED PATIENT SAFETY AND THERAPEUTIC EFFECTIVENESS**

MTaPS/**Bangladesh** assisted the Directorate General of Drug Administration (DGDA) in conducting a workshop on improving online reporting and monitoring of adverse drug events. Stakeholders from the technical sub-committee, Adverse Drug Reaction Advisory Committee (ADRAC), and the pharmaceutical industry attended the workshop. A draft guidance document was presented at the workshop on how to improve patient safety. In preparation for the national scaling up of the PV program, MTaPS supported the DGDA in organizing workshops for stakeholders to create awareness and scale up implementation of PV activities in pharmacies and hospitals. With support from MTaPS, DGDA staff have started uploading the backlog of adverse drug reaction data to the WHO Vigiflow database.

Throughout PY2, MTaPS/**Mozambique** supported the DNF and the national HIV program in implementing an active surveillance activity for monitoring HIV patients on the tenofovir + lamivudine + dolutegravir regimen. As of August 2020, 1,936 patients were enrolled in the cohort in the 9 participating health facilities with about 1,500 patient records entered into the electronic PV monitoring system (PViMS). In light of the COVID-19 pandemic, MTaPS continued to support the DNF, HIV

program, and provincial focal points to conduct virtual supportive supervisory phone calls to participating sites. The supervisory calls help monitor adherence to the protocol at the sites and to check quality and consistency of collected data. In Q4, MTaPS facilitated two training events focused on equipping national-level staff (i.e., DNF and the national HIV program) in data analysis and DNF's System Administration on data management, IT assistance to PViMS users, and troubleshooting the tool. MTaPS is currently supporting the DNF and HIV program to clean the data in PViMS in preparation for data analysis.

To strengthen the reporting and safety monitoring of medicines, this year MTaPS/**Rwanda**, in collaboration with the University of Rwanda, provided technical support to the MOH, Rwanda FDA, and RBC/HIV Division to develop the following documents: framework for active surveillance of the new dolutegravir (DTG)-based ARV regimens, draft protocol for active surveillance of DTG-based regimens, a costed multiyear national PV plan aligned with the Rwanda FDA institutional development plan. The draft national PV plan is under review by the Rwanda FDA. To further strengthen the capacity of health care providers in PV, MTaPS worked with the Rwanda FDA to develop the course content for a PV elearning module; 8 of 12 mini modules have been drafted and are under review for approval prior to further formatting and uploading onto MOH's e-learning platform.

MTaPS supported the Rwanda FDA in establishing and activating PViMS, which is currently available for use by Rwanda FDA and its stakeholders. The user manual for PViMS is being adapted. Activation of PViMS will ensure that Rwanda FDA has firsthand access to adverse drug reaction and poor-quality information and can provide timely feedback to reporters to improve pharmaceutical services. Data on Ebola vaccination has been entered into PViMS already. It is envisioned that all medicine safety data and reporting will be done through PViMS, all hospitals will report through PViMS, and the Rwanda FDA will analyze the data. A total of 39 severe adverse events have been reported with the Ebola vaccinations to date, of which 5 cases involving weakness, vomiting, post-vaccination fever and convulsion, and gastroenteritis may be related to the vaccine. A total of 181 pregnancies were reported after the first dose of the vaccine. Details of the reports are contained in the country report.

During quarter 2, MTaPS/**Philippines** assisted the DOH in conducting a workforce needs assessment to determine the number of staff positions, roles, and skill sets required to ensure the functioning of the PSCM and PV systems in the country. Following the assessment, a PSCM and PV workforce development plan was drafted this quarter to help DOH stakeholders address workforce development needs. MTaPS plans to present the workforce assessment report and plan to DOH in October 2020 to help inform the DOH's HR master plan. This will help DOH take necessary measures to create and fill the required positions and professionalize their workforce to address current HR gaps and improve procurement and supply chain management and pharmaceutical services.

In the Philippines, use of PViMS was reinforced with the issuance of the Administrative Order No. 2020-0025, which mandates implementation of the active drug safety monitoring (aDSM) framework. During this quarter, MTaPS facilitated an orientation to test run version 2 of PViMS. The orientation included participants from the Pharmaceutical Division (PD), NTP, FDA, Lung Center of the Philippines research group, and selected TB providers/partners. Moving forward, MTaPS will continue to support DOH's Knowledge Management and Information Technology Service, PD, FDA, and NTP in rolling out PViMS to all identified sentinel sites and develop their capacity to sustain the use of PViMS for implementing aDSM and, ultimately, ensure the safety of medicines.

To build the **East African Community (EAC)** and the **Intergovernmental Authority on Development (IGAD)** secretariats' capacity to coordinate regional PV activities, MTaPS participated in various consultation meetings on the medicine regulatory harmonization agenda. During this quarter, MTaPS assisted EAC in developing and finalizing the harmonized EAC PV SOPs to guide EAC PV's compendium implementation. Jointly with IGAD, MTaPS has continued to discuss and guide countries' plans for conducting baseline assessments of PV systems and activities in the IGAD region. Particularly,

MTaPS assisted in training focal persons in IGAD member states to conduct PV baseline assessments using the indicator-based PV assessment and monitoring tool. From July to September 2020, 81 PV focal staff were trained in Ethiopia, Kenya, Somalia, and Uganda.

Furthermore, MTaPS has worked with lead NMRAs, the Kenya Pharmacy and Poisons Board, and EAC partner states to promote ownership and ensure sustained capacity building for EAC-PV experts. In this effort, MTaPS assisted EAC in developing critical regional PV documents, including a roadmap for developing a harmonized EAC-PV curriculum, an assessment tool for developing EAC SOPs for implementing the EAC harmonized PV compendium/guidelines and harmonized PV curriculum and training modules.

### BETTER CONTAINMENT OF ANTIMICROBIAL RESISTANCE AND INFECTION PREVENTION AND CONTROL

MTaPS continued supporting the **Jordan** MOH's National AMS Committee in finalizing technical documents needed to establish an AMS program at designated MOH hospitals (i.e., TOR for the hospital AMS committees, AMS program core-elements checklist, and AMS program implementation plans). The MTaPS team, accompanied by the AMS committee focal point, met with the members of the hospital AMS committees to discuss next steps to implement AMS programs at their hospitals. The MOH assigned a focal point at each hospital to liaise with the MTaPS program, and the MTaPS team worked with them to analyze their hospital situations and identify gaps, strengths, and areas for improvement using the checklist. Inputs were integrated into the documents, which were approved by the national AMR steering committee's AMS technical subcommittee and will be disseminated to selected hospitals in the next quarter.

In this quarter, MTaPS in **Mozambique** continued to help the Hospital Pharmacy Department receive, review, and document hospitals' monthly reports on AMS implementation and to follow up with staff. In addition, a draft implementation status report on AMS activities in the selected health facilities is being developed, including AMR capacity building and development and follow-up of health facility AMS action plans. The report's recommendations will allow health care workers in the target facilities to implement AMS interventions as part of the WHO's multi-pronged technical approach.

#### SUPPORT TO COUNTRIES' ACHIEVEMENT OF GLOBAL HEALTH SECURITY AGENDA OBJECTIVES

In addition to AMR-related activities under Objective 5, MTaPS supports GHSA/AMR activities in Bangladesh, Burkina Faso, Cameroon, Côte d'Ivoire, DRC, Ethiopia, Kenya, Mali, Senegal, Tanzania, and Uganda, focusing on promoting AMS, infection prevention coordination, and multisectoral coordination. For more details GHSA portfolio progress, refer to the GHSA section of this report.

### PROGRESS BY REGIONAL BUREAU PORTFOLIO

### **ASIA REGIONAL BUREAU**

### **HIGHLIGHTS FROM PROGRAM YEAR 2**

#### COMPLETING THE HEALTH TECHNOLOGY ASSESSMENT ROADMAP

MTaPS completed the Health Technology Assessment (HTA) roadmap, which will be launched in October 2020. The launch aims to generate additional feedback and discussion with Asian low- and middle-income countries (LMICs) for implementation of activities in Year 3. In addition, an Asia-focused addendum of the core roadmap was created and is currently under internal review. It depicts the progress of HTA in Asia and provides contextualized information that will help in creating targeted and robust plans for HTA implementation support in Asian countries. As a result, it is expected that explicit priority setting will enable countries to make the best use of limited resources based on the best available evidence while maximizing health benefits and increasingly looking at HTA as a policy solution to reach universal health coverage.

#### **DEFINING AND COSTING PHARMACEUTICAL BENEFITS PACKAGES IN ASIAN COUNTRIES**

MTaPS analyzed Asian countries' current pharmaceutical benefits packages and developed guidance for countries seeking to define a pharmaceutical benefits package. The landscape analysis found that most countries in the region define some form of pharmaceutical benefits coverage for their populations but largely rely on normative drug lists and implicit rationing; few countries use explicitly defined pharmaceutical benefits packages that identify and quantify the use of drugs by beneficiary populations, create legal entitlements to that package, or outline financing arrangements for the included drugs. The guidance that MTaPS developed on how to define pharmaceutical benefits packages will enable countries to move toward more explicit entitlements to drug coverage, improving value for money for purchasers and financial coverage for consumers.

MTaPS also reviewed available tools for costing pharmaceutical benefits packages and prepared detailed guidance for using the OneHealth Tool to do so. In its review, MTaPS compared tools used in Asian countries and elsewhere to forecast total spending on pharmaceutical benefits coverage. Several tools are available to conduct actuarial studies with detailed costing, project health benefit package costs, and build coverage scenarios, especially in LMICs in the region. After appraising these tools, MTaPS recommended using the OneHealth Tool to support pharmaceutical package costing and forecasting, because the tool has ongoing support from a global community of programmers; it is more robust and user friendly than many other costing tools, especially for pharmaceuticals; and it provides a unified framework for integrated planning as well as a modular instrument for program-specific and sector-wide applications. The detailed guidance document will support pharmaceutical system planners to conduct robust, comparable estimates of the costs of pharmaceutical coverage in their contexts that can be adapted and replicated over time and help to ensure that adequate financial resources for this coverage are allocated to meet population needs.

#### MAPPING KEY ENTITIES IN PHARMACEUTICAL REGULATORY SYSTEMS STRENGTHENING

To gain knowledge about opportunities for collaboration with key players in the region and priority areas of support, MTaPS undertook a mapping exercise to identify key entities (i.e., initiatives, networks, stakeholders) at the regional and sub-regional levels that are supporting or working in pharmaceutical

regulatory systems strengthening, including pharmacovigilance (PV), in Asia. Through this exercise, MTaPS identified six key entities that aim to strengthen different pharmaceutical regulatory functions/areas, such as product registration, PV and post-marketing control; and regulatory inspection. These include the Asian Pharmacoepidemiology Network, Association of Southeast Asian Nations (ASEAN), the WHO collaborative registration procedure (CRP), the Southeast Asia Regulatory Network (SEARN), and the WHO regional offices for South-East Asia (SEARO) and the Western Pacific Regional Office.

MTaPS had several engagements with two major networks—ASEAN and SEARN/SEARO—throughout the year involving participation in conferences, virtual meetings, and presentation of concept notes that culminated in opportunities for providing technical assistance in improving regulatory systems in the Asia region. MTaPS provided technical assistance to the design and development of an online Good Manufacturing Practice (GMP) course for pharmaceutical manufacturers as a pilot, which will be rolled out to other member states of SEARN. Increasing the knowledge and practical application of current GMP among pharmaceutical manufacturers and regulators will contribute to improvements in the quality of medicines used in the Asia region and beyond.

### **QUARTER PROGRESS FOR FY20Q4**

OBJECTIVE I: CAPACITY TO CONDUCT AND USE HEALTH TECHNOLOGY ASSESSMENT TO SUPPORT THE INSTITUTIONALIZATION OF TRANSPARENT AND EVIDENCE-BASED DECISION MAKING IN ASIA REGIONAL COUNTRIES STRENGTHENED

### Activity 1.1.1: Adapt and pilot a roadmap for HTA implementation in three Asia regional countries

Roadmap Launch and Dissemination

After finalizing the MTaPS HTA core roadmap document this quarter, the first area of focus for next quarter is to prepare for dissemination and a formal launch. The MTaPS technical developed the final electronic document: A Roadmap for Systematic Priority Setting and Health Technology Assessment (HTA): A Practical Guide for Policy Action in Low- and Middle-Income Countries. Global announcements and a social media campaign are under way to create awareness and generate interest in the roadmap among target stakeholders (e.g., country policy makers, HTA practitioners, global HTA experts). Blogs have been published on the MTaPS and MSH websites to introduce the roadmap to a global audience, accompanied by communications to HTA network mailing groups, contributors, regional experts in various countries in the region, and other members of the global HTA community. The core roadmap document has already generated significant interest and positive feedback from stakeholders. Key informant interviews for the contextualization of the roadmap (please see the next section for additional information) have also provided positive feedback. Tools provided in the document help countries benchmark progress and provide useful references and a stepwise approach for specific components of HTA advancement, including setting the agenda, formulating policy, potential options for implementation, and evaluating impact.

A webinar to formally launch the roadmap and make it publicly available has been scheduled for the next quarter. During the launch, MTaPS and global HTA experts will share the stepwise approach to HTA institutionalization presented in the roadmap. The launch includes an interactive panel discussion on the tools provided in the different chapters of the roadmap, country experiences, lessons learned, and future opportunities in HTA. Global experts from LMICs in Asia, Eastern Europe, Latin America, and Sub-Saharan Africa will participate in the panel. Throughout the launch/webinar, time has been allocated for questions and answers from participants, especially LMIC stakeholders interested in scaling up HTA. LMIC country policy makers and HTA practitioners, global HTA experts, development partners, other

implementing partners focused on HTA, WHO experts, and members of the global HTA community have been invited to attend the webinar.

### Contextualization of the HTA Roadmap

The second area of focus for this quarter has been on contextualization of the roadmap for Asia. The MTaPS team is finalizing an addendum to the core roadmap document focused on Asia. A Balanced Scorecard framework based on recent research on important factors for HTA institutionalization has been used for the contextualization and depicting the progress of HTA in Asian countries. Eight countries—China, India, Indonesia, Malaysia, South Korea, Thailand, Philippines, and Vietnam—at different stages of HTA implementation and different health system contexts have been scored on their progress on the conducive factors identified in the research paper. Additional desk research of recently published literature was conducted for the analysis. This is being supplemented by key informant interviews with HTA experts and practitioners from the region. MTaPS has conducted three interviews with experts from China, Indonesia, and Taiwan. Given the variability in HTA advancement across countries in the region, the addendum will provide updates on progress made, recent experiences, and practical considerations from various settings in the region. A draft of the addendum is under internal review and planned to be finalized in the next quarter.

## OBJECTIVE 2: CAPACITY TO DEFINE AND COST EVIDENCE-BASED PHARMACEUTICAL COVERAGE AND PROMOTE SHARING OF PHARMACEUTICAL PRICES TO IMPROVE VALUE IN PURCHASING IN THE ASIA REGIONAL COUNTRIES STRENGTHENED

### Activity 2.1.1: Support the development of national processes for defining pharmaceutical benefits package

This program year, MTaPS activities included analyses of countries' current pharmaceutical benefits packages, development of guidance and best practices for countries seeking to define a pharmaceutical benefits package, review of available tools for costing pharmaceutical benefits packages, and guidance on the process to cost a pharmaceutical benefits package.

The first analysis outlines four major ways in which the analyzed countries define service and pharmaceutical benefits under their different coverage arrangements. These modalities include using an essential medicines list (EML) to define pharmaceutical procurement/distribution, defining drug benefits as any drug medically indicated for included services, having a de facto explicit pharmaceutical benefits package based on a national formulary/EML, and defining an explicit pharmaceutical benefits package. The majority of coverage arrangements employed the first three modalities, while relatively few arrangements used explicitly defined pharmaceutical benefits packages that identify and quantify the use of drugs by beneficiary populations, create legal entitlements to that package, and outline financing arrangements for the included drugs. The landscape analysis was completed in quarter 3.

MTaPS also developed a brief summarizing a high-level, six-step process for articulating pharmaceutical benefits coverage. The process builds on a framework developed by Glassman et al., and highlights examples from the Asia region, including Thailand's HTA process, Indonesia's national formulary, and PhilHealth's "Z benefits" package. The brief was finalized in quarter 4 and is undergoing final internal review.

<sup>&</sup>lt;sup>12</sup> Sarocha Chootipongchaivat, Nattha Tritasavit, Luz A, et al. Conducive factors to the development of Health Technology Assessment in Asia. 2017.

### Activity 2.1.2: Build capacity for costing pharmaceutical benefits coverage

To further build the evidence base for defining and costing pharmaceutical benefits packages to inform pharmaceutical policy making, MTaPS completed a related pair of reports on the topic of costing pharmaceutical benefits. The first report included a review of tools for costing pharmaceutical benefits packages. The report analyzed a set of criteria including whether a tool is electronic, allows for customization and flexibility in treatment guidelines for diseases to reflect the local context, and enables forecasting and projections. The report identified the OneHealth Tool as the most suitable to conduct pharmaceutical benefits package costing.

The second report built on the first and provided tailored guidance for country stakeholders to use the OneHealth Tool for pharmaceutical benefit package costing. With this guidance, stakeholders will be better able to use the OneHealth Tool to derive coverage targets and costing and impact information; estimate the cost of a pharmaceutical benefit package; assess the needed government contribution and the fiscal gap to afford the overall drugs needed in the country; and facilitate discussions regarding priority setting for drugs within each disease area, as well as adjustments to pharmaceutical benefits for each disease, intervention, or health condition. As a result, countries will be able to manage and allocate funds more efficiently and ultimately ensure sustainable access to safe, effective, quality-assured, and affordable essential medicines and pharmaceutical services.

### Activity 2.2.1: Promote transparency in pricing through development of regional pricing database

MTaPS conducted research on pricing policies and techniques used within Asia region countries. An expert consultant on pharmaceutical pricing policies with deep knowledge of the region was engaged to produce a draft. The consultant reviewed supply-side policies, including internal and external reference pricing, generic caps, cost-plus pricing, and tendering and demand-side policies, including generic prescribing; (mandatory) generic substitution; prescribing protocols; and electronic prescribing monitoring tools from 11 countries: Bangladesh, Cambodia, India, Indonesia, Kyrgyz Republic, Myanmar, Nepal, Philippines, Sri Lanka, Timor-Leste, and Vietnam.

All of the 11 countries reviewed use tendering, and most use another strategy as well. The region is slowly moving away from free pricing that allows the manufacturer/importer to set the price based on competition and market status—the only countries where a pure free pricing approach is still taking place are Timor-Leste, Myanmar, Nepal, and Cambodia. Vietnam employs six strategies (the most of any country). Six countries rely on internal or external reference pricing, with Vietnam using both.

Demand-side interventions, or provider policies, are just beginning to develop in Asian countries. As the payer and universal health coverage concepts are being developed, demand-side policies tend to become more complex, particularly if supply-side pricing policies are weak. All countries were found to rely on treatment guidelines and generic prescribing, with some also enforcing generic substitution and prescribing protocols. In addition to highlighting the policies and strategies that each of the 11 countries relies on, the report identifies focus areas in existing country approaches to pricing where technical assistance might be helpful. The report will help countries understand the ways in which other countries within the region approach pharmaceutical pricing and approaches to improving transparency in pricing. The consultant has submitted a first draft of the report, which is currently under review by MTaPS.

### Activity 2.3.1: Support development of a standardized process for pharmaceutical expenditure tracking in the Asia region

After holding a conference call in last quarter with partners from the USAID/Indonesian Mission and the USAID Indonesia Health Financing Activity (HFA) program to discuss pharmaceutical expenditure tracking and how Indonesia's data systems may support such tracking in the future, there was consensus to postpone an initial webinar to ensure thorough understanding of country stakeholders' needs and to further identify stakeholders to be involved in the webinar. In quarter 4, given that government stakeholder availability is still limited due to COVID-19 and that refinements to the pharmaceutical

expenditure tracking methodology are ongoing, it was agreed to conduct the webinar early in the next project year. This will also align with the development of an expected Indonesia Mission buy-in.

### OBJECTIVE 3: MEDICINES REGULATORY CAPACITY AND PHARMACEUTICAL-SECTOR GOVERNANCE IN ASIA REGIONAL COUNTRIES STRENGTHENED

Activity 3.1.1: Support regional and sub-regional collaboration and advocacy to advance pharmacovigilance for new essential medicines/Activity 3.1.2: Explore opportunities for supporting regional and sub-regional initiatives and collaboration to strengthen regulatory systems in Asia regional countries

In program year 2, Asia Bureau work plan activities 3.1.1 and 3.1.2 were performed jointly and are reported jointly.

Based on the mapping findings and interactions with stakeholders, three key areas for collaboration were prioritized and recommended as the most feasible to focus MTaPS support and effort toward strengthening regulatory systems in the region in the coming years, as follows.

- I) Supporting harmonization initiatives to assist networks and countries in SEARN, ASEAN, and the Asia region in adopting uniform guidelines for registration and PV
- 2) Supporting SEARN and other countries in the region to participate in the WHO CRP so that they can optimize their regulatory resources
- 3) Establishing north-south collaboration between key academic/research institutions, including the Regional Centre of Regulatory Excellence (RCORE)—Duke NUS, the WHO Collaborative Centre for Pharmacovigilance in Public Health Programs and Regulatory Services for SEARN and ASEAN countries, and the University of Washington in growing the workforce capacity for PV in the region.

Through several interactions and meetings with key players in the Asia region, MTaPS prioritized dialogue with SEARN, SEARO, and ASEAN, leading to seizing openings for collaboration to strengthen medicines regulatory systems in the region. Key interactions included participation in virtual meetings and strategic engagement with the networks, aided by USAID and the US Government Department of Commerce.

Positive and continual engagement with ASEAN and SEARN led to the development of concept notes for consideration by the networks in partnership with the Promoting the Quality of Medicines Plus (PQM+) program.

MTaPS and PQM+ submitted a combined concept note to the ASEAN Consultative Committee on Standards and Quality through the US Department of Commerce outlining details and specific regulatory system strengthening areas that both programs could support through the ASEAN Pharmaceutical Product Working Group (PPWG) independently or jointly based on the key priority areas mentioned above. A response on the specific area to support regulatory system convergence in ASEAN is expected in November 2020.

The engagement with SEARN yielded an opportunity to provide technical assistance and contribute toward the design and delivery of an online course on current GMP for pharmaceutical manufacturers in India as a pilot in the first phase in collaboration with WHO-JSS University India. The plan is to roll out the course to other SEARN member states in 2021.

During the last quarter of the year, MTaPS held preliminary meetings with SEARN, SEARO, JSS University India, USAID India, USAID Asia Bureau, USAID COR, and PQM+ to prepare for the design of the course and provision of technical experts to contribute toward its implementation. MTaPS also provided comments to the concept note on development of the current online GMP course.

### Activity 3.2.1: Develop a how-to manual on managing conflict of interest

The protocol for the baseline study that MTaPS and WHO SEARO are conducting as a first step toward developing the manual was finalized this quarter and submitted by WHO SEARO for ethical clearance/exemption. The baseline study will identify what conflict of interest (COI) management policies are in place in the Asian region/subregion; explore if and how policies are implemented, particularly in low-resource countries; and collect copies of what exists and examples of good practices. MTaPS reviewed the terms of reference of the consultant, and WHO SEARO contracted a consultant who is a researcher at the University of Toronto and has carried out several studies in the area of COI disclosure and management in health systems to conduct the study. The key informant interview guide, recruitment emails, consent forms, and coding manual for reviewing COI policies and practices were developed and submitted with the study protocol to the WHO SEARO Research Review Committee and to the University of Toronto Human Research Ethics Board. The consultant has begun the online search and scan of relevant websites to determine which public pharmaceutical committees and agencies of interest are operating in the countries and to identify and collect policies and documentation guiding their management of and reporting on COIs and mitigation actions. WHO SEARO began contacting ministries of health to inform them about the study and to request their assistance in validating the findings of the online search and for approval to contact key informants to solicit information on challenges in identifying and managing COIs in the committees of interest and examples of lessons learned and good practices. The key informant interviews will begin once ethical approvals have been received. MTaPS anticipates longer than usual timelines for obtaining country responses to the survey because of staff engagement in managing the COVID-19 response.

The objectives of the literature review to identify model guidance, policies, and procedures on managing COI in the pharmaceutical sector that can be applied or adapted for the Asia region were agreed on among partners, including the WHO Collaborating Center for Governance, Transparency, and Accountability in the Pharmaceutical Sector in Toronto, which is taking the lead on conducting the search.

ACTIVITIES FOR NEXT QUARTER	
ACTIVITY AND DESCRIPTION	DATE
Activity 1.1.1: Adapt and pilot a roadmap for HTA implementation in three Asia regional countries	Oct. 2020
<ul> <li>HTA Roadmap launch event</li> <li>External draft of Asia focused addendum</li> </ul>	Oct. 2020
<ul> <li>2.1.1: Support development of national processes for defining pharmaceutical benefits package</li> <li>Disseminate report on pharmaceutical benefits mapping</li> <li>Disseminate brief on defining pharmaceutical benefits packages</li> </ul>	OctDec. 2020
<ul> <li>2.1.2: Establish guidance for estimating financial outlays for pharmaceutical benefits packages in Asia regional countries</li> <li>Disseminate two reports</li> </ul>	Oct.–Dec. 2020
<ul> <li>2.2.1: Promote transparency in pricing policies through development of regional pricing database</li> <li>Finalize and disseminate the short report</li> </ul>	Oct.–Dec. 2020
2.3.1: Strengthen capacity for pharmaceutical expenditure tracking in the Asia region     Develop and revise a concept note for the pharmaceutical expenditure tracking webinar and agree on timing for the webinar in consultation with Indonesian stakeholders and HFA	OctDec. 2020
Activity 3.1.1: Support SEARO/SEARN in capacity building for Indian pharmaceutical manufactures in cGMP as a pilot  MTaPS technical resource persons to provide technical assistance in the design and delivery of the course content for capacity building in cGMP in collaboration with WHO-JSS University and in partnership with PQM+	OctDec. 2020
Activity 3.1.2: Engagement with ASEAN  • Present key priority areas of support and collaboration to the PPWG	Nov. 2020
Activity 3.2.1: Complete the online search of country websites, conduct the survey and key informant interviews, and draft a report of study findings; develop literature search strategy; conduct the search; and analysis and write up search findings.	OctDec. 2020

## INTERGOVERNMENTAL AUTHORITY ON DEVELOPMENT (IGAD) AND EAST AFRICAN COMMUNITY (EAC)

### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

### DEVELOPMENT, CAPACITY BUILDING, AND APPLICATION OF **IGAD** HARMONIZED **PV** INDICATOR-BASED ASSESSMENT AND MONITORING TOOLS

The USAID MTaPS Program, in collaboration with Intergovernmental Authority on Development (IGAD) Secretariat, builds capacity of the IGAD Pharmacovigilance (PV) Expert Working Group (EWG) comprised of PV champions drawn from the IGAD member states of Djibouti, Ethiopia, Kenya, Somalia, South Sudan, Sudan, and Uganda. The systemic capacity-building started in mid-March 2020 and has focused on:

- Equipping experts with skills on core principles of PV for safety monitoring and how to conduct PV system assessment using harmonized PV indicator-based assessment and monitoring tools
- Reviewing the terms of reference for the IGAD PV-EWG and developing a comprehensive IGAD PV work plan for 2020
- Developing country plans for baseline assessment of the PV system in each of the
  member states; these country plans entail training in-country teams by the IGAD PVEWG members on the core principles of PV, data collection, entry, and report writing

### IGAD countries

Djibouti Eritrea Ethiopia Kenya Somalia South Sudan Sudan Uganda

### EAC countries

Burundi Kenya Rwanda South Sudan Tanzania Uganda

**Results:** To date, Kenya, Somalia, Ethiopia, and Uganda have trained in-country teams, undertaken data collection, and written draft reports. Baseline data collection was done in selected IGAD cross-border sites, other health facilities, public health programs, marketing authorization holders, and national regulatory authorities. Preliminary findings show that IGAD countries are at different levels regarding the status of their PV systems with clear gaps for safety monitoring at cross-border sites.

### **QUARTER PROGRESS FOR FY20Q4**

#### **OBJECTIVE 1: IMPROVE PHARMACEUTICAL SECTOR GOVERNANCE**

### IGAD 1.1.1: Assist IGAD in establishing and operationalizing governance structures for PV

During the past quarter, the USAID MTaPS program held several meetings with IGAD and EAC Secretariat to review the joint work plans on PV and status of implementation. To build the capacity of IGAD and EAC secretariats for safety monitoring for self-reliance, MTaPS works very closely with IGAD and EAC secretariats and respective focal persons on the medicine regulatory harmonization agenda. Jointly with IGAD, MTaPS continuously discussed and guided implementation of baseline assessment of PV systems and PV activities in the IGAD region. Post-award of the IGAD implementation letter, MTaPS met with the IGAD Secretariat to co-create and align the two work plans to ensure streamlined implementation of activities.

On the EAC front, MTaPS continued to discuss and strategize on the development and finalization of harmonized EAC PV SOPs to guide implementation of the EAC PV compendium and harmonized PV curriculum for training EAC and IGAD countries and cross-border sites. This continuous consultation serves to build capacity of EAC and IGAD secretariats for coordinating regional PV activities.

In August 2020, MTaPS participated in the fourth meeting of the heads of national medicine regulatory authorities (NMRAs). The meeting was attended by the heads of NMRAs or their senior designate officers; their respective medicine regulatory harmonization initiative focal persons from all IGAD

member states (with the exception of the Ethiopia); health experts from the IGAD Secretariat from the Health and Social Development Division; the African Union Development Agency-New Partnership for Africa's Development (NEPAD); World Bank; and the World Health Organization (WHO). The meeting reviewed progress in implementing IGAD-supported medicine regulatory harmonization activities.

MTaPS also participated in an EAC meeting focusing on implementing a Regional Pharmaceutical Manufacturing Plan of Action, which highlighted progress and prevailing challenges for local production, including the impact of COVID-19.

### EAC I.I.I: Implement the EAC harmonized PV manual and tools to monitor safety and quality of registered medical products and health technologies

USAID MTaPS provided technical assistance to the EAC Secretariat and the EAC EWG on PV on the following:

- Development of a guidance document, a roadmap for developing the harmonized EAC-PV curriculum through scoping and analyzing existing PV training materials in the EAC region and comparing with the WHO-PV curriculum and other recognized PV training packages
- Development and finalization of a structured assessment tool for developing EAC SOPs for implementing EAC harmonized PV compendium/guidelines: This assessment tool was used to determine the status of implementing the PV compendium and the availability of SOPs in EAC partner states. The information collected from the tool guided the allocation of SOPs to be developed by each EAC partner state.
- Development of a draft harmonized PV curriculum and training modules, which will be further discussed in quarter 1 of year 2021
- Development of draft harmonized SOPs to support implementing the PV compendium, which will be finalized

The process of developing the above documents was EAC-led, with MTaPS closely working with the lead NMRA, the Kenya Pharmacy and Poisons Board (PPB), and EAC partner states to promote ownership and ensure sustained capacity building for EAC-PV experts. This approach is also key for subsequent implementation in EAC countries and across EAC border sites to promote safety monitoring.

### OBJECTIVE 2: STRENGTHEN INSTITUTIONAL AND HUMAN RESOURCE CAPACITY TO MANAGE PHARMACEUTICAL SYSTEMS

### EAC 2.1.1: Build capacity of national medical regulatory authorities in EAC to analyze and use PV data for regulatory decision making

No activities were planned or held this quarter.

### IGAD 2.1.2: Support post-marketing surveillance and PV activities along IGAD cross-border points to promote patient safety

USAID MTaPS held several meetings with the IGAD Secretariat and EWG on PV from IGAD member states (with exception of Eritrea) to review progress on executing baseline assessment trainings, data collection, and report writing in view of COVID-19. PV champions from member states agreed to review their plans for activities and incorporate new ways of training and implementing the baseline assessment in light of COVID-19. MTaPS, IGAD Secretariat, and member states adopted a virtual approach to implementing the baseline assessment by using focal persons from identified border sites and other health facilities who would be trained and equipped to collect and transmit data to the national PV experts for consolidation and report writing. However, some members states with unique country situations (internet, staffing, knowledge gaps, weak PV system), e.g., Djibouti, were encouraged

to devise other ways to ensure the activity is implemented, including, where possible, moving to border areas to collect data. The baseline assessment will inform subsequent activities at cross-border areas as identified from the report, and hence, the reasons focal persons from border areas were trained to participate in the data collection as a way of building their knowledge, skills, interest, and capacity on PV. Throughout the quarter, MTaPS provided ongoing mentorship to PV experts on data collection and report writing.

### IGAD/EAC 2.1.3: Support local manufacturers in IGAD/EAC regions to better comply with regional and national pharmaceutical regulatory standards and requirements

During the quarter, MTaPS continued to undertake an assessment of the local pharmaceutical industry to examine their capacities to adhere to good regulatory practices to ensure sustained availability of critical essential medicines in line with international standards. An inception report was finalized, and assessment tools developed for the exercise. Currently, the consultant is consolidating the findings into a report with plans to disseminate the findings, sensitize stakeholders, and develop improvement plans for enhancing regulatory compliance in quarter 1.

### OBJECTIVE 3: STRENGTHEN SYSTEMS FOR PROVIDING PATIENT-CENTERED PHARMACEUTICAL CARE AND SERVICES

### IGAD/EAC 3.1.1: Strengthen and harmonize PV processes and tools in IGAD and EAC regions and support uptake by border sites and regional stakeholders

During the quarter and jointly with IGAD-PV experts, MTaPS provided technical support in training of PV cross-border and facility focal persons in IGAD member states to conduct PV baseline assessments systems using the Indicator-based PV assessment and monitoring tool as follows:

- Kenya trained 25 and Somalia 17 focal PV persons in July 2020. Subsequently, baseline data collection
  was done.
- Ethiopia and Uganda trained on PV and the baseline assessment of PV in September 2020; 33 participants were trained, 16 in Uganda and 17 in Ethiopia.
- In Uganda, MTaPS further supported in-country training of six participants from Tororo cross border health facilities in late September 2020 on using and applying the indicator-based PV assessment and monitoring tool to promote patient safety.
- Baseline assessment plans are advanced for Djibouti with plans for the World Bank to support Sudan and South Sudan, which are not supported by USAID.

USAID MTaPS held several meetings with the EAC lead NMRA in PV (PPB-Kenya) to offer technical support to develop draft documents for discussion with other EAC-PV experts as a way of building their leadership role in PV within the EAC medicine regulatory agenda.

As reported under EAC 1.1.1, MTaPS supported the EAC in harmonizing PV processes and tools through technical support for developing draft harmonized:

- Curriculum and training modules that will be further discussed in quarter 1 of year 2021
- SOPs to support implementation of the PV compendium.

The EAC harmonized PV compendium and SOPs will be adapted for IGAD to be used in EAC and IGAD countries and cross-border areas. The harmonized PV curriculum will be used for training of trainers (TOTs) in IGAD and EAC countries who will further train more in-country health care providers, with a dedicated focus on cross-border areas to promote safety monitoring.

### IGAD/EAC 3.2.1: Support IGAD and EAC AMR containment initiatives (in years 2 and 3)

No activities were planned or held during the quarter.

### **ACTIVITIES FOR NEXT QUARTER**

ACTIVITY AND DESCRIPTION	DATE
IGAD PV baseline assessment report writing and dissemination:	Oct. – Dec. 2020
Review and compile country reports on the baseline assessment and disseminate to inform country and cross-border facility improvement plans	
Finalization EAC and IGAD PV training curriculum and package:	Oct. – Dec. 2020
Develop a harmonized EAC and IGAD PV training curriculum and package for training border sites in both IGAD and EAC	
Training PV-TOTs and champions at country level and border sites:	Nov. – Dec. 2020
Training of PV TOTs from countries, including border sites	
IGAD cross border: Stakeholder sensitization on importance of PV (Moyale, Mandera, Amudat/West Pokot, Turkana-Moroto):	Oct. – Dec. 2020
Sensitization meeting with IGAD cross-border stakeholders	
IGAD cross-border health facilities (public and private) trained on PV: Moyale, Mandera, Amudat/West Pokot, Turkana-Moroto:	Nov. – Dec. 2020
Training of IGAD border facilities	

### PROGRESS BY COUNTRY

### **BANGLADESH**

For progress on MTaPS/Bangladesh's COVID-19 activities, click here.

### MISSION-FUNDED ACTIVITIES

### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

- Countrywide introduction of a standard inventory management system within the Directorate General of Health Services (DGHS) was completed, which made the recording and reporting system uniform and ultimately will contribute to minimizing stock disruptions in the country.
- More than 2,000 medical and surgical requisites (MSR) items were reviewed and updated to improve procurement efficiency of the health facilities under the DGHS of the Ministry of Health and Family Welfare (MOHFW).
- The Procurement and Logistics Management Cell (PLMC) is now functional as an oversight body for procurement and supply management of the MOHFW.
- The introduction of the electronic Asset Management System (eAMS) was completed in all district hospitals for more efficient resource planning, allocation, and utilization to improve patient-centered care nationwide.
- The individual TB patient recording and reporting system (e-TB Manager) was implemented in 665 sites with more than 550,000 TB patients reported in the system to ensure that updated information on TB treatment and outcomes is properly recorded, analyzed, and used for critical decision making.
- Lessons learned: Timely development of a contingency plan once the COVID-19 pandemic hit the country was critical to mitigate the constraints and challenges of project implementation and ensure that Year 2 activities were completed by September 2020 as planned. Introduction of virtual events (i.e., meeting and workshops) was instrumental to complete the activities rather postpone to next year or cancel the activity during any emergency situation, such as the COVID-19 pandemic.

### **QUARTER PROGRESS FOR FY20Q4**

#### **OBJECTIVE 1: PROCUREMENT AND SUPPLY CHAIN SYSTEMS IMPROVED AND MODERNIZED**

MTaPS provided support to organize a virtual meeting of the PLMC led by the Additional Secretary (Dev), Health Service Division (HSD), MOHFW, to discuss the procurement and supply chain functions of the MOHFW. It was decided to perform timely online submission of procurement plans, including revitalization of the functionalities of the Supply Chain Management Portal (SCMP), and develop capacity of relevant officials of the MOHFW and its directorates on efficient procurement activities. As a follow up to this meeting, a workshop attended by the respective Line Directors; the Secretary, HSD, MOHFW; and the Director General (DG) of the DGHS was held on online submission of procurement plans under different operational plans of the MOHFW and its directorates for 2020–2021 through the SCMP. During the workshop, MTaPS delivered a technical presentation, and a practical demonstration of the online submission process was carried out by the programmer of the MOHFW IT cell. This activity will reduce the lead time of procurement planning and contribute to timely acquisition and availability of health commodities. A second training on procurement was organized by the MOHFW and conducted by the Engineering Staff College of Bangladesh under the agreement with MTaPS. This capacity building is

mandatory for newly recruited personnel to ensure the functioning and sustainability of an efficient procurement system for the MOHFW.

MTaPS facilitated the merging and harmonization of the newly developed human resource document of the MOHFW with the recently updated standard list of equipment and supported the drafting of the Table of Organization and Equipment (TOE) to be used by the DGHS and MOHFW. Completion of the harmonization process and vetting is expected in the next quarter. Once vetted, the document will serve as a reference for better planning of asset acquisition to avoid duplication, unnecessary procurement, and wastage of public funds.

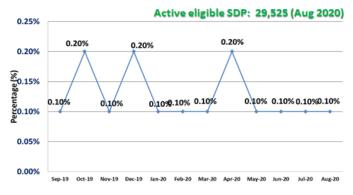
The list and specification of MSR drafted last quarter has been discussed in small groups of various disciplines to develop a final draft. Next steps are the finalization of the document and vetting by the respective body of the MOHFW. Considering the comprehensiveness of the document and the bureaucratic process of the government, the activity may extend into next quarter. The document will support efficiency in the procurement process, ensure acquisition of quality products for better pharmaceutical service delivery, and ultimately save lives. Moreover, the reviewed list and specification will be used for assigning a rate (price) of the items and as the reference document for the financial resource allocation activity planned in FY21.

MTaPS regional technical advisors worked closely with the DGHS in scaling-up the introduction of a manual standard inventory management system in the remaining 19 districts in Year 2. MTaPS facilitated capacity building activities for DGHS officials in these districts and enhanced their knowledge and skill through blended virtual and physical training on how to use inventory tools. A total of 183 persons (95% male) were trained on the use of the tools and on basic logistics management concepts. By concluding this activity, the countrywide roll-out has been completed in all 64 districts. The DGHS now has its own standard and uniform inventory management system at all levels of health facilities countrywide from which it can generate accurate logistics report and maintain a uniform record keeping system. The inventory tools are:

- Inventory Control Register
- Issue Voucher
- Indent & Issue Voucher for hospitals
- Indent & Issue Voucher for stores
- Bin Card

The manual standard inventory management system will contribute to developing a dedicated electronic logistics management information system (eLMIS) for the DGHS similarly to the Directorate General of Family Planning (DGFP) eLMIS supported by MTaPS. The DGFP system showed a stock-out rate of less than 1% for contraceptives at the service delivery point (SDP) level throughout the year (figure 9). MTaPS is continuously supporting data analysis to inform DGFP decisions.

#### Trend of SDP stock-out of any FP method (National status- 64 Districts) Period: September 2019 to August 2020



Source: <a href="https://scmpbd.org/index.php/sdp-report/stock-out-of-any-method">https://scmpbd.org/index.php/sdp-report/stock-out-of-any-method</a>; Dt: 10 Sep 2020

Figure 9: Trend of SDP stock-out of any FP method

MTaPS provided technical assistance to the DGFP to re-open the remodeled Barishal Regional Warehouse. MTaPS developed the action plan, including how to operationalize the warehouse, and the implementation process and timeline. On August 25, 2020, the new warehouse was inaugurated by Mr. Md. Ali Noor, Honorable Secretary, Health Education and Family Welfare Division, MOHFW, through a virtual session. Re-opening of this warehouse will contribute to properly storing family planning and reproductive health commodities and other essential medicines allocated for the region. It will also help to alleviate the burden of three nearby warehouses and significantly reduce transportation costs. MTaPS will continue to assist and

enhance the knowledge and skills of DGFP officials of that warehouse for smooth operation and maintenance of good warehousing practices.

MTaPS regional technical advisers attended TB quarterly monitoring meetings in three districts during this quarter to discuss how the program can ensure isoniazid preventive therapy to childhood TB patients, increase new case notification, and improve performance of health workers on data entry and TB medicine stock status monitoring using e-TB Manager. Information sharing by MTaPS technical staff helps local-level managers make evidence-based decisions on program development and implementation.

### **OBJECTIVE 2: PHARMACEUTICAL REGULATORY SYSTEMS STRENGTHENED**

MTaPS assisted the Directorate General of Drug Administration (DGDA) in conducting a workshop to identify areas for improvement in online reporting and monitoring of adverse drug events (ADEs) involving its stakeholders from the technical sub-committee, Adverse Drug Reaction Advisory Committee, and pharmaceutical industry. Shortcomings in the existing manual and online systems were identified, and a draft document on how to improve patient safety was presented, including options for a mobile application-based digital system for reporting and monitoring of ADEs.

MTaPS facilitated workshops for the DGDA and its stakeholders on awareness and scale up of pharmacovigilance (PV) in pharmacies and hospital settings. Participants were selected based on the poor reporting of ADEs to the DGDA and included new stakeholders from Dhaka and Chattogram divisions to be included in the existing DGDA list in preparation for national scale up of the PV program. The workshop discussed the importance of PV, the interventions needed to implement a PV system at the facility level, experience already gained by the facilities, and the commitment of stakeholders in implementing the PV system. These activities will increase the number of ADE reports submitted and enable more efficient actions to address them.

MTaPS facilitated DGDA officials uploading backlog adverse drug reaction information to the WHO Vigiflow database, which made them more comfortable with the system, procedures, and exact information required to populate the fields. This approach will bring sustainability in maintaining the Vigiflow system and ownership by the DGDA.

MTaPS facilitated review by the DGDA of the survey report prepared in Q3 on the registration systems of maternal, neonatal, and child health (MNCH) products in Bangladesh. The review focused on the legal

basis, process, staffing, and expertise and the cost involved in the registration process. The report is under editorial review and it will be later shared with USAID and the DGDA with a set of recommendations regarding the barriers and bottlenecks identified in the registration system. It will help to optimize and streamline registration and availability of not only MNCH products but also other critical medicines and medical devices in the country.

As instructed by the USAID Mission, MTaPS and the PQM+ Program created a mechanism for the list preparation and uploading it to the DGDA website for manufacturers of personal protective equipment (PPE) in consultation with the DGDA functional lead. Many PPE manufacturers' information was not centrally controlled and collected by DGDA officials. MTaPS also prepared a list of DGDA-recommended PPE manufacturers eligible to have no objection certificate and shared it with the DGDA. This process will ensure sharing of uniform information about PPE manufacturers to all concerned authorities and contribute to good governance of the regulatory sector in Bangladesh.

#### **OBJECTIVE 3: SYSTEMS FOR EVIDENCE-BASED DECISION MAKING INSTITUTIONALIZED**

As part of the countrywide roll out of e-TB Manager, MTaPS, in collaboration with the National Tuberculosis Control Program (NTP), organized a series of capacity building sessions for managers, supervisors, and e-TB Manager users at Khulna and Chattogram divisions, including new doctors at the NTP, to develop skills for program organizers and training for users from all TB reporting centers of those divisions. Due to its comprehensiveness, the activity may continue in the next quarter. These activities will improve the accuracy and timely availability of individual TB patient information for monitoring and action as well as will contribute to better patient management and improved treatment outcomes.

The eAMS was developed and implemented to improve medical equipment tracking in government hospitals and increase the availability of functional equipment. MTaPS completed training on the eAMS to roll it out in 15 district-level hospitals in this quarter, reaching 49 hospitals in Year 2. Fifty-seven participants attended the four-day of training, which concluded the eAMS roll-out plan for this level of hospitals. Once the system is effectively implemented, national-level decision makers can monitor the status of medical equipment at all district-level hospitals and make evidence-based decisions to reduce the wastage of resources and help develop better plans for procurement with existing resources, ultimately improving patient care.



Participants practicing how to use e-TB Manager system. Photo Credit: Mr. A.K.M Sirajuddin (MTaPS)

MTaPS collaborated with the USAID MaMoni Maternal and Newborn Care Strengthening Project (MaMoni) of Save the Children to scale up the DGHS eLMIS for MNCH commodities. MTaPS provided technical support to MaMoni to bring 138 new health facilities under DGHS eLMIS coverage. With these new facilities, the DGHS eLMIS now covers 4,171 health facilities for improved stock management, ultimately ensuring increased availability of critical products to the population.

### OBJECTIVE 4: PHARMACEUTICAL SERVICES THAT PROMOTE APPROPRIATE MEDICINES USE AND ANTIMICROBIAL RESISTANCE CONTAINMENT IMPROVED



Participants at the sharing and planning workshop on national level IPC assessment report. Photo Credit: Md. Selim (MTaPS

MTaPS assisted the Communicable Disease Control (CDC) directorate of the DGHS to conduct a baseline assessment for national-level infection, prevention, and control (IPC) using the WHO 2017 IPC Assessment Tool 2 (IPCAT2). The draft assessment report was completed by MTaPS, the CDC, and the DGHS. It was shared with stakeholders through a planning workshop where findings were validated, and an implementation plan was drafted by participants.

The report is expected to be finalized soon. The assessment has identified existing strengths, weaknesses, and opportunities of the national IPC program and recommended feasible actions to strengthen the IPC situation of Bangladesh, which will also contribute to improving antimicrobial resistance (AMR) containment in the country.

### **OBJECTIVE 5: PHARMACEUTICAL FINANCIAL RESOURCE ALLOCATION AND USE OPTIMIZED**

No progress as the activity is dependent on support from international experts and due to the COVID-19 pandemic, travel is not allowed.

### **ACTIVITIES FOR NEXT QUARTER**

ACTIVITY AND DESCRIPTION	DATE
Activity I.I.I: Work with DGHS to develop a standardized price list of medical and surgical requisites (MSR) in line with updated specifications - Initiate to develop a standard price list of MSR through local consultant	December 2020
Activity 1.1.2: Update the Price Guide of medical equipment and align it with the revised Table of Organization and Equipment (TOE) - Initiate update to price guide of medical equipment through local consultant	December 2020
Activity I.2.3: Assist NTP to assess the peripheral TB storage system and develop an integration plan - Assessment of the peripheral TB storage system	December 2020
Activity 2.1.2: MTaPS will work with DGDA in collaboration with Better Health in Bangladesh (BHB) to develop an electronic pharmacy inspection and licensing system (ePILS) - MTaPS will collaborate with BHB project to start developing ePILS	December 2020
Activity 2.2.1: Work with DGDA to address relevant GBT IDPs (e.g., development of investigation and risk-based management procedures for PV activities) and continue to support ongoing PV activities - Meeting will be organized with DGDA to address relevant GBT IDPs	December 2020
Activity 3.1.1: Collaborate with different USAID partners and other development partners to scale up DGHS eLMIS for MNCH commodities in selected districts - In collaboration with USAID implementing partners and other development partners, DGHS eLMIS will be further scaled up	December 2020
Activity 3.1.2: Assist National Tuberculosis Control Program (NTP) to roll out e-TB Manager to Dhaka Division - Preparation (site selection, participant selection, material development) for capacity building of NTP staff as part of roll out	December 2020
Activity 3.2.2: Enhance and integrate the existing electronic Logistics Management Information Systems for DGHS and conduct a user acceptance test (UAT) on TB logistics - An IT vendor will be engaged and start working on it	December 2020

#### **GHSA-FUNDED ACTIVITIES**

### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

- The M&E framework on National Action Plan (NAP) on AMR (2017–2022) was developed.
- The joint stakeholder workshop was organized in collaboration with CDC/DGHS with active participation of more than 15 organizations, institutes, and departments contributing to the One Health approach.
- Lessons learned: Stakeholder concernment and buy-in and effective communication by MTaPS can establish functional multisectoral coordination and organize a successful virtual workshop despite limitations imposed by the COVID-19 pandemic.

### **QUARTER PROGRESS FOR FY20Q4**

#### RESULT AREA I: EFFECTIVE MULTISECTORAL COORDINATION ON AMR

MTaPS, in collaboration with the CDC/DGHS, organized a joint stakeholder follow up workshop on the implementation status of the NAP on AMR with active participation of both government and development partners on the AMR containment portfolio. The forum emphasized the revitalization of the National Technical Committee (NTC) and One Health platform and recommended the development of standard treatment guidelines on infectious diseases. Periodic coordination, updates, and sharing on AMR containment issues was also suggested for progressing the activities as per the NAP. Regular joint stakeholder meetings allow multisectoral involvement through the One Health approach, which is critical to visualize the overall improvement of AMR containment.

MTaPS, in collaboration with the CDC/DGHS and in consultation with other stakeholders, facilitated the development of the M&E framework on the NAP on AMR (2017–2022). This framework will help the CDC/DGHS collect information on indicators that will ultimately demonstrate the implementation status of the NAP on AMR and support the decision making process.

### **RESULT AREA 2: INFECTION PREVENTION AND CONTROL**

MTaPS selected two health facilities to implement GHSA interventions—tertiary-level Cumilla Medical College Hospital and secondary-level Munshiganj District Hospital.

With the leadership of the CDC/DGHS, MTaPS facilitated a baseline assessment on IPC status at Cumilla Medical College Hospital and Munshiganj District Hospital using the WHO IPC Assessment Framework tool. The assessment report developed by the consultant with support from MTaPS advisors at the country level and at the MSH home office followed the standard procedures of data collection, cleaning, and analysis. Findings and recommendations will be used to strengthen the IPC activities and core components in the participating facilities; prevent nosocomial transmission to health care workers, patients, and visitors; and ultimately reduce the spread of infectious diseases in the country.

### **RESULT AREA 3: USE OF ANTIMICROBIAL MEDICINES OPTIMIZED**

A rapid baseline assessment on antimicrobial stewardship (AMS) status was completed in Cumilla Medical College Hospital and Munshiganj District Hospital using simple AMS-related checklists from the quality improvement secretariat (QIS)/DGHS, WHO, and other sources. The assessment report developed by a consultant with support of MTaPS advisors at the country level and the MSH home office followed the standard procedures of data collection, cleaning, and analysis. Based on the recommendations and findings, AMS practices will be strengthened in participating facilities and ultimately improve rational use of antibiotics at different levels of care.

In collaboration with the CDC/DGHS, MTaPS initiated the development of the standard treatment guideline (STG) on infectious diseases, which will be followed by development of a STG app adopting the concepts and practice of available content. This assignment involved a consultant who is coordinating the process with continued guidance from CDC/DGHS and MTaPS advisors.

ACTIVITIES FOR NEXT QUARTER	
ACTIVITY AND DESCRIPTION	DATE
I.I.I: Continue strengthening national level multisectoral coordination mechanisms to facilitate operationalization of the National Action Plan on AMR and its roadmap - Meeting of NTC on AMR	December 2020
2.2.1: Develop training materials based on the hospital IPC manual and other guidelines and checklists issued by QIS/MOHFW and train health care workers using those materials - Development of training materials based on the hospital IPC manual	December 2020
2.5.1: Continue to strengthen IPC activities in the two participating facilities and scale up similar initiatives in two new facilities - Start background work to strengthen IPC activities in the two participating facilities	December 2020

### **BURKINA FASO**

For progress on MTaPS/Burkina Faso's COVID-19 activities, click here.

### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

In March 2020, the COVID-19 outbreak spread to Burkina Faso and has seriously affected the implementation of MTaPS. Despite the disruptions, the MTaPS Burkina Faso team has strived to continue implementing program activities in collaboration with country stakeholders. MTaPS Burkina Faso carried out many activities in FY20, several of which are highlighted below.

On February 18, 2020, MTaPS collaborated with the Ministry of Environment, Green Economy, and Climate Change to organize a national training workshop for members of Burkina Faso's parliament who sit on the Commission on Rural Development, Economy, and Climate Change (CRDECC). The workshop focused on raising awareness on AMR and the key role that the trainees can play in enacting laws and regulations to combat AMR. Mr. Tini Bonzi, the chairman of the CRDECC, committed to establishing a coordination group within Parliament to address AMR, which will contribute to achieving the country's goals in the fight against AMR with the support of MTaPS.

MTaPS has supported the operationalization of the One Health Platform (OHP). MTaPS contributed to drafting the ministerial order that defines the roles, composition, and functioning of the One Health Steering Technical Committee, Technical Secretariat, Technical Commissions, and the respective ministerial focal points. The ministerial order was endorsed and signed on June 30, 2020, by all ministers involved in the OHP. MTaPS also contributed to developing a roadmap of the OHP. The activities highlighted within the roadmap are planned to be carried out within a timeframe of one year, during which time the platform will be fully operationalized.

During FY20, MTaPS collaborated with the Ministry of Animal Resources and Fisheries to produce Burkina Faso's first guidelines for the rational use of antimicrobials in the animal sector. The process included iterative exchanges in drafting and finalizing the document through a two-day workshop with stakeholders, including animal sector stakeholders from the public and private sectors and civil society. The validated document will become a national reference document for practitioners in the animal sector.

In addition, MTaPS contributed to the review and integration of AWaRe classification into the essential medicines list (EML) and the standard treatment guidelines (STGs) for rationalizing the use of antimicrobials to control infections through workshops organized by the Ministry of Health with the financial contribution of the World Health Organization (WHO). These national documents will contribute to higher Joint External Evaluation (JEE) scores for the country.

The MTaPS team conducted a rapid assessment of stewardship policies, tools, and activities in the field to identify the gaps and challenges that perpetuate poor antibiotic use practices. MTaPS and relevant counterparts reviewed and agreed on the assessment tool and conducted a desk review of laws, decrees, policy documents, and regulations for human and animal sectors. The stewardship assessment was an opportunity to review the policies and regulations governing the use of antimicrobials in both sectors to identify potential gaps and prepare the country to develop its national AMS plan. A report presenting the gaps and challenges to be addressed has been developed and reviewed and is in the process of being finalized.

MTaPS used the findings of the AMS rapid assessment to develop the national AMS regulatory framework, considering both the human and animal health sectors. The framework addresses the following goals:

- Improving patient outcomes, including reducing infection rates, surgical site infection rates, morbidity, and mortality
- Improving patient safety and minimizing unintended consequences of antimicrobial use (i.e., reducing antimicrobial consumption without increasing mortality or infection-related readmissions)
- Reducing AMR through appropriate use of antimicrobials

MTaPS also supported the MOH in organizing a one-day sensitization workshop for hospital directors general on establishing and maintaining functional Drugs and Therapeutics Committees (DTCs). The meeting was held on June 24, 2020, in Ouagadougou and brought together 17 directors general of health care facilities, the directors of hospital pharmacies, and health officers to provide greater information on the process. During this meeting, participants were sensitized on the importance of establishing and running a DTC and on how to establish, maintain, and use a DTC. The next step is to use the information from the workshop to move forward in establishing DTCs in the represented health care facilities.

### **QUARTER PROGRESS FOR FY20Q4**

### **RESULTS AREA I: EFFECTIVE MULTISECTORAL COORDINATION ON AMR**

### Activity 1.1.1: Provide support to the AMR Technical Thematic Committee (TTC) to improve its organizational, governance, and practical management capacities

During this quarter, MTaPS contributed to drafting a technical note and letter for the Minister of Animal Resources and Fisheries to invite civil society to select its representatives for the OHP. He also contributed to amending the terms of reference for a meeting of the OHP with the ministers and the prime minister to present the OHP roadmap of activities to be implemented within one year.

### Activity 3.1.1: Provide technical support to the AMR-TTC and stakeholders to develop a national plan to strengthen AMS in the human and animal health sectors

The developed national AMS regulatory framework for both the human and animal health sectors has been reviewed and is ready to be shared with national counterparts for finalizing. MTaPS is in the process of developing an AMS plan that will be shared electronically with local counterparts at the relevant ministries for review and finalizing.

On July 9-10, 2020, MTaPS organized a two-day workshop involving stakeholders from the public (Ministry of Animal Resources and Fisheries) and private (private veterinarians, pharmacists, and clinicians) sectors and from civil society (National Council of Veterinarians, Association of Private Veterinarians) to finalize the draft national guidelines for using antimicrobials in the animal sector. Following the workshop, MTaPS worked with the Direction Générale des Services Vétérinaires to integrate all recommendations and suggestions to improve and finalize the national guidelines. The final draft is now available for validation.

#### **RESULTS AREA 3: USE OF ANTIMICROBIAL MEDICINES OPTIMIZED**

### Activity 3.5.1: Support implementation of guidelines and policies at the peripheral level

Establishing DTCs is critical for optimizing the use of antimicrobial medicines. Work during this quarter has focused on establishing DTCs within five health care facilities. Terms of reference and budgets have been developed, and the process of setting up DTCs is ongoing. These activities are carried out with the support of the Directorate of Hospital Pharmacy. In collaboration with the Ministry of Health, MTaPS has also developed terms of reference for DTC trainings.

### ACTIVITIES FOR NEXT QUARTER

ACTIVITY AND DESCRIPTION	DATE
Activity 3.1.1: Provide technical support to AMR-TTC and stakeholders to develop a national plan to strengthen AMS in the human and animal health sectors	Oct – Nov 2020
<ul> <li>Organize a one-day workshop to validate the national guidelines for using antimicrobials in the animal sector</li> <li>Develop a national AMS plan that includes both human and animal sectors</li> <li>In collaboration with National Drug Regulatory Agency/Centre de Documentation et d'Information sur le Médicament, print copies of the EML and organize three two-day workshops to disseminate the EML</li> </ul>	
Activity 3.5.1: Support implementation of guidelines and policies at the peripheral level	Oct – Dec 2020
<ul> <li>Develop a plan to establish and strengthen DTCs in health care facilities</li> <li>Using the tools above, establish and build the capacity of DTCs in five facilities (including at least one national teaching hospital, one regional hospital, and one reference center) to oversee implementation of AMS interventions</li> <li>Support the Direction Générale des Statistiques Sectorielles and AMR-TTC to conduct a joint four-day induction workshop on using the above tools for selected staff (facility champions) from all five targeted facilities</li> <li>Organize two-day onsite technical assistance at each facility to establish the facility DTC and organize training and sensitization activities at the facility level</li> <li>Establish a central-level DTC oversight structure to regularly review self-assessment data from facilities and provide ongoing support and coaching and periodic onsite mentoring visits</li> </ul>	

### **CAMEROON**

For progress on MTaPS/Cameroon's COVID-19 activities, click here.

### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

MTaPS supported the establishment of IPC and AMS technical working groups (TWGs) with their terms of reference. Even though these TWGs are in the process of being formalized (with a ministerial service note), MTaPS has supported the organization of routine meetings of the TWGs and the technical secretariat to monitor and coordinate implementation of AMR activities.

In its quest to improve IPC practices in Cameroon, MTaPS supported the MOH in developing and validating the national IPC guidelines, developing IPC training curricula, training master trainers, and establishing IPC committees in six pilot health facilities. MTaPS supported the organization of two five-day workshops that brought together 20 experts from relevant MOH departments and key partners, such as WHO, to draft, finalize, and validate the national IPC guidelines. In the process of establishing the IPC committees, MTaPS supported the MOH in developing terms of reference for the committees, advocated for the committees to be formalized via service notes by facility leadership, and organized onsite trainings of 61 committee members in 6 pilot health facilities. MTaPS provided technical assistance to the committees to evaluate IPC practices in their various health facilities, the results of which informed the development of action plans. Five of these six (with the exception of Bonassama district hospital) committees have been organizing meetings to monitor implementation of activities to improve IPC in their health facilities. These activities have positioned MTaPS as the lead in the area of IPC, and national counterparts and partners, including the WHO, have been advocating for MTaPS to scale up its activities and provide technical assistance in IPC (IPC evaluation and trainings). These activities are particularly valuable and timely, given the prevailing COVID-19 pandemic.

Another notable achievement of MTaPS in FY20 was supporting the MOH and the Ministry of Animal Husbandry in developing and validating an integrated AMS national action plan. MTaPS conducted a situational analysis of policies and regulations on antimicrobial use in both the human and animal sectors. The AMS situational analysis report was reviewed and validated by experts from both sectors during a three-day workshop organized by MTaPS. Building on the situational analysis, MTaPS drafted an integrated national AMS plan, which was reviewed and finalized during a five-day workshop bringing together experts from the MOH and Ministry of Animal Husbandry. The document will be validated during a three-day workshop scheduled for October 7-9 with experts from both sectors.

### **QUARTER PROGRESS FOR FY20Q4**

Implementation of planned activities during this quarter was impacted by COVID-19. Because of the general slowdown of activities, lockdowns, and restrictions on gatherings, as well as the limited availability of national stakeholders (most of whom were involved with the national response team), MTaPS Cameroon developed a contingency plan. This plan outlined the anticipated impact of the pandemic on progress in implementing the GHSA work plan and proposed mitigation actions. In line with the contingency plan, the following activities were carried out during this quarter.

### **RESULT AREA 2: INFECTION PREVENTION AND CONTROL**

### Activity 2.1.1: Support the development, validation, and dissemination of IPC guidelines for the human sector

To strengthen the governance of IPC, MTaPS supported the MOH in organizing a five-day workshop to finalize and validate the national IPC guidelines. This workshop took place in Douala, August 24-28,

2020, and was organized in two phases. The first three days brought together 10 participants from various departments of the MOH, University of Douala, and one hygiene resource person to finalize the draft document. During the last two days, six additional high-ranking staff from the MOH and reference hospitals joined the 10 initial participants to review and validate the guidelines. Staff from WHO participated in the workshop to ensure that the guidelines align with WHO recommendations for IPC. The next steps consist of printing and disseminating the guidelines at the various levels of the health system (during the Y3 period) to facilitate improvement of IPC practices by all health care workers.

### Activity 2.2.1: Develop a national training package and strengthen master trainers' capacity to plan and carry out cascaded competency-based training

Following the development of IPC curricula adapted for adult learning and the training of master trainers on IPC, MTaPS supported establishment of IPC committees, as well as the onsite training of their members in six MTaPS-supported health facilities. Altogether, 60 staff (10 per health facility) were trained in leadership and management of an IPC program in health facilities. During the IPC committee trainings, MTaPS provided technical assistance to the health facilities to draft their IPC action plans, following assessment of IPC practices by using the WHO recommended tool (IPCAF). Some of the IPC committees have already begun meeting to follow up on the implementation of activities in their work plans. As a next step, MTaPS plans to support the monitoring and evaluation of these committees to improve their effectiveness.

#### **RESULT AREA 3: USE OF ANTIMICROBIAL MEDICINES OPTIMIZED**

## Activity 3.1.1: Provide technical support to the AMR Multisectoral Coordination Committee and stakeholders to develop a national plan to strengthen AMS in the human and animal health sectors

Prior to supporting the government to develop a national AMS plan, MTaPS supported the MOH in carrying out a situational analysis of policies and regulations on using antibiotics in the human sector, and supported the Ministry of Livestock and Animal Husbandry to conduct the same analysis for the animal sector. MTaPS supported the organization of a 3-day workshop bringing together 22 experts (11 from each sector) to review and validate the situational analysis reports from both sectors.

Following the validation of the above-mentioned reports, MTaPS supported the MOH and Ministry of Animal Husbandry to draft an integrated AMS national action plan. MTaPS subsequently supported the organization of a 5-day workshop of 20 participants (10 from each sector) to review and finalize the draft plan. As the next step, MTaPS plans to organize a 3-day workshop of 25 participants from both sectors to validate the AMS national action plan October 7-9, 2020.

ACTIVITIES FOR NEXT QUARTER	
ACTIVITY AND DESCRIPTION	DATE
Support the IPC and AMS TWGs in organizing monthly coordination meetings	Oct. 2020
Support the TS of the AMR-MSC in organizing quarterly coordination meeting	Nov. 2020
Validate and adopt the AMS national action plan: support a three-day validation workshop and an adoption meeting.	Oct. 2020
Support establishment of IPC committees in six additional health facilities	Nov. 2020
Put in place and train DTCs in six selected health facilities and develop tools to build DTC capacity	Oct.–Nov. 2020

### **CÔTE D'IVOIRE**

For progress on MTaPS/Côte d'Ivoire's COVID-19 activities, click here.

### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

The Ivorian government created a national One Health Platform in April 2019 to institutionalize a national multisectoral coordination (MSC) mechanism to address public health threats, including antimicrobial resistance (AMR). A technical working group (TWG) on AMR was established and is connected to the One Health Platform through a national coordinating body called the Multisectoral Coordination Group on AMR. MTaPS supported the AMR-TWG to establish the Multisectoral Coordination Group (MCG), which is a key governance body for AMR governance structures in the human, environmental, and animal health sectors; 25 participants attended the workshop to validate the list of members.

MTaPS facilitated a multisectoral workshop that produced two important guiding documents: an AMR national policy and a governance manual for AMR containment. The AMR policy lists the various government entities on human and animal health, agriculture, and the environment that are tasked with improving prevention, detection, and surveillance of AMR and describes their roles and responsibilities for a coordinated response across sectors. Recommendations for additional support include a unified multidisciplinary and multisectoral information sharing mechanism, an AMR communication plan, and an information-sharing platform.

MTaPS supported the country, in collaboration with the General Directorate of Health (DGS), Directorate of Hospital and Proximity Medicine (DMHP); Directorate of Public Hygiene, Health, and the Environment; World Health Organization (WHO); USAID; and the Centers for Disease Control (CDC), to assess the infection prevention and control (IPC) national program using the WHO IPCAT2 and to conduct IPCAF assessments in two health facilities. The findings from these assessments were used to target areas that needed to be strengthened in the national program and helped the country set priorities at the national level in updating the national IPC plan for the human health sector. MTaPS also supported an IPC assessment in the animal health sector and helped develop an IPC plan and guidelines. In addition, MTaPS supported the AMR-TWG in establishing/strengthening IPC committees in two hospitals and two animal health facilities. MTaPS also provided support to the AMR-TWG, in collaboration with the DGS, DMHP, Directorate of Training and Health Research (DFRS), and Directorate of Veterinary Services (DSV), for developing/revising and validating IPC training modules taking into account the WHO IPC action package and supporting the training of 12 human health trainers and 10 animal health trainers, as well as on-site trainings for 60 health workers from 4 health facilities. MTaPS supported the AMR-TWG in converting validated IPC training materials to a competency-based training package adapted for e-learning. These modules are being used by all partners supporting IPC work, including the IPC COVID-19 response.

MTaPS supported the AMR-TWG in assessing AMS policies, regulatory framework, and antimicrobial use using a multisectoral approach. MTaPS also supported the AMR-TWG in conducting an assessment of antimicrobial use and regulations in animal health; conducting an evaluation of antimicrobial dispensing in both the human and animal health sectors; and using reports to provide baseline information on the regulatory framework and use of antimicrobials to guide development of AMS plans, policies and guidelines. MTaPS also supported the AMR-TWG in developing a tool to assess the functionality of DTCs and conduct AMS practices in two hospitals. These documents were used to develop and validate training materials. MTaPS supported the AMR-TWG to train 40 DTC members in two university teaching hospitals through a competency-based training, using the developed modules.

#### **QUARTER PROGRESS FOR FY20Q4**

Following the first COVID-19 cases in Côte d'Ivoire on March 11, 2020, the government implemented social distancing measures to control the spread of the pandemic. As a result, in-person activities of the AMR-MCG were suspended. On June 3, 2020, the AMR-MCG decided to resume activities in the field.

#### **RESULT AREA I: EFFECTIVE MULTISECTORAL COORDINATION ON AMR**

#### Activity 1.1.2: Strengthen the AMR secretariat

Support the National Institute of Public Hygiene (INHP) and the National AMR Secretariat in establishing and building capacity within the AMR, IPC, and AMS technical sub-working groups

On July 7, 2020, MTaPS supported the AMR-TWG in organizing a meeting of the AMS-TWG. Ten (six females and four males) participants attended the Multisectoral Technical Committee (MTC) 5's online meeting to review progress on implementing MTC 5 activities, representing the AMR National Secretariat-Observatory on Antimicrobial Resistance in Cote d'Ivoire (ORMICI), Teaching Hospitals of Treichville, National Laboratory for the Support of Agricultural Development (LANADA), Oceanography Research Center (CRO), World Organization for Animal Health (OIE), Pasteur Institute of Côte d'Ivoire, National Program for the Development of Pharmaceutical Activity (PNDAP), Ivorian Anti-Pollution Center (CIAPOL), professional associations, and the Ivorian Pharmaceutical Regulatory Authority (IPRA). A presentation highlighting progress made so far on activity implementation, ongoing activities, and on-track activities was made. The overall implementation rate of the AMS-TWG work plan has improved over time.

MTaPS provided support to the IPC TWG (MTC 4) to organize a meeting to review activities implemented from June 1, 2019, to September 30, 2020. This meeting was held online on September 30, 2020, and was attended by 12 people, including the deputy general director of health in charge of public hygiene, members of MTC 4 from both the human and animal health sectors, and MTaPS. From the meeting, participants learned that all 20 activities planned by MTC 4 were implemented with financial support from USAID through MTaPS. All participants expressed their satisfaction with and commitment to those results that will contribute to the country's progressing on JEE scores.

#### **RESULT AREA 2: INFECTION PREVENTION AND CONTROL**

#### Activity 2.1.1: Developing a national action plan for IPC in human and animal health sectors

Support the AMR Secretariat in conducting a rapid assessment of hygiene and IPC (HIPC) conditions in animal and human health

MTaPS supported the AMR-TWG, in collaboration with MTC 4 and experts from the DSV, in validating the final report of the rapid assessment of HIPC conditions in animal health. This was done through a one-day meeting held via WebEx on July 7, 2020, that was attended by 10 people (I female and 9 males), including members of the AMR Secretariat, MTC 4, experts from the DSV and Ministry of Animal and Fisheries Resources (MIRAH), and the Association of Private Veterinarians of Cote d'Ivoire.

Support the AMR Secretariat and DSV in developing a national plan to implement IPC guidelines to control infection transmissions associated with health care activities in the human domain and to develop guidelines on IPC in the animal domain, including an implementation plan

Following the validation of the final report of the rapid assessment of HIPC conditions in animal health, MTaPS supported the AMR-TWG in organizing a three-day workshop at Hôtel La Prunelle de Jacqueville July 13-15, 2020, to validate the IPC guidelines for the animal health sector, based on the draft developed by MTaPS. The workshop was attended by 24 people (3 females and 21 males), including experts from the World Organization for Animal Health (OIE), the Ministry of Health and Public

Hygiene (MSHP), MIRAH, the Ministry of Higher Education and Scientific Research (MESRS), the Ministry of Agriculture and Rural Development (MINADER), private entities working in the animal health sector, AMR-TWG, MTC 4, and MTaPS.

After the validation of the IPC guidelines for the animal health sector, MTaPS supported the AMR-TWG in organizing a three-day workshop from July 27-29, 2020, to validate the IPC plan for animal health. MTaPS developed a draft plan using the rapid assessment findings, IPC guidelines, and updated IPC plan. The workshop was attended by 22 people (4 females and 18 males), including experts from the OIE, MSHP, MIRAH, MESRS, MINADER, private structures working in the animal health sector, AMR-TWG, MTC 4, and MTaPS.

MTaPS also supported the AMR-TWG in organizing a three-day workshop from July 20-22, 2020, to review and update the IPC plan in the human health sector, taking into account the findings of the IPCAF assessment conducted in Bouake and Cocody university hospitals and the IPCAT assessment. The workshop was attended by 20 people (5 females and 15 males), including experts from the MSHP, MIRAH, MESRS, MINADER, AMR-TWG, MTC 4, and MTaPS.

## Activity 2.5.2: Strengthen capacity of health care providers to implement IPC and AMS standards

Support building a pool of national IPC facilitators in the human and animal health sectors

MTaPS supported the AMR-TWG, in collaboration with MTC 4 and experts from the DSV, in organizing a five-day training of trainers' workshop on IPC for the animal health sector August 10-14, 2020, in Dabou. This workshop was attended by 16 people (3 females and 13 males), consisting of 10 learner-trainers from the DSV and the MIRAH Regional Directorate of Bouake, 4 trainers, and 2 supervisors; 10 master trainers (2 females and 8 males) were trained on IPC and are ready to conduct onsite trainings of animal health care providers.

Support competency-based training of frontline health care workers in the four selected intervention facilities

MTaPS supported the AMR-TWG, in collaboration with MTC 4, in organizing a three-day training workshop in IPC for health care providers of the Cocody University Teaching Hospital August 12-14, 2020, in Dabou. This workshop was attended by 23 people (9 females and 14 males), consisting of 20 participants from the Cocody University Teaching Hospital and 3 master trainers for the human health sector; 20 health care providers (9 females and 11 males) were trained in IPC.

MTaPS supported the AMR-TWG, in collaboration with MTC 4, in organizing a three-day training workshop on IPC for health care providers from the Bouake University Teaching Hospital August 25-27, 2020, in Bouake. This workshop was attended by 24 people (8 females and 16 males), consisting of 20 participants from the Bouake University Teaching Hospital, 3 master trainers for the human health sector, and I supervisor; 20 health care providers (13 females and 7 males) were trained in IPC.

MTaPS supported the AMR-TWG, in collaboration with MTC 4 and experts from the DSV, in organizing a three-day training workshop in IPC for the animal health sector August 25-27, 2020, in Jacqueville. This workshop was attended by 25 people (4 females and 21 males), consisting of 20 participants from the DSV and the MIRAH Regional Directorate of Bouake, 3 master trainers from the animal health sector, and 2 supervisors; 20 animal health care providers (4 females and 16 males) were trained in IPC.

#### **RESULT AREA 3: USE OF ANTIMICROBIAL MEDICINES OPTIMIZED**

MTaPS supported the AMR-TWG in establishing an AMS multisectoral committee in May 2019. The committee is coordinating stewardship activities through bimonthly meetings and activities on the ground. During the past quarter, MTaPS helped the AMS-TWG implement the following activities.

Activity 3.1.1: Improve the rational use of antimicrobials in the human and animal health sectors

Support the AMR Secretariat in developing/updating a policy and plan for infectious diseases in the human and animal health sectors that covers national and facility levels

MTaPS helped the AMR-TWG in conducting a rapid assessment of AMS policies, regulatory framework, and antimicrobial use. The rapid assessment report was validated during the previous quarter. An AMS policy and guidelines were developed and validated.

Support the AMR-TWG in using the results of the AMS situational analysis and WHO-led assessment tool on the use of antimicrobials to draft a national AMS plan in the human and animal health sectors that covers national and facility levels

Following the validation of the rapid assessment, MTaPS supported the AMR-TWG in using the results of the rapid assessment to draft national AMS guidelines for health care settings and revise the national AMS policy and plan through a workshop in Jacqueville, June 29-July 2, 2020. This meeting brought together 20 participants (8 females and 12 males) from the AMR Secretariat-ORMICI, LANADA, CRO, OIE, PNDAP, Pasteur Institute of Côte d'Ivoire, CIAPOL, health professional associations, DMHP, IPRA, and DSV. The objectives of this workshop were to (1) review supporting documents for drafting the guidelines and revising the policy and national antimicrobial stewardship plan; (2) review the working document provided for each deliverable; (3) provide feedback to help finalize the drafts; (4) format each document; (5) validate the national AMS plan; and (6) validate the next steps.

On July 3, 2020, MTaPS supported the AMR-TWG in validating the newly updated National AMS Plan 2021-2025 during a workshop that took place in Jacqueville with 28 participants (9 females and 19 males) from ORMICI, LANADA, CRO, OIE, Pasteur Institute of Cote d'Ivoire, PNDAP, DMHP, CIAPOL, health professional associations, and IPRA.

Support the AMR Secretariat to validate both the national AMS policy and plan covering human and animal health sectors

MTaPS supported the AMR-TWG in validating the National AMS Plan 2021-2025 on July 3, 2020, in Jacqueville with 28 participants (9 females and 19 males). Following the workshop, MTaPS helped finalize the plan. This entailed supporting the AMR-TWG in organizing a workshop in Jacqueville July 15-17, 2020, with 17 participants (8 females and 9 males) from ORMICI, LANADA, CRO, OIE, Pasteur Institute of Cote d'Ivoire, PNDAP, DMHP, CIAPOL, health professional associations, and IPRA. During this meeting, the operational plan was reviewed to identify organizations responsible for each action, list the deliverables, and determine timelines.

Another workshop was held July 23-25, 2020, in Dabou with 20 participants (6 females and 14 males) from the human, animal, environmental, and agricultural sectors to validate the draft national AMS policy and stewardship guidelines for health care settings. Participants were divided into two groups to review the drafts during the first two days, before a final plenary session on the last day to validate the AMS documents. The next step includes having the AMS-TWG review the deliverables (AMS rapid assessment report, policy, plan, and guidelines) before printing.

To this end, MTaPS has supported the AMR-TWG in organizing a workshop to review the rapid assessment of AMS policies, stewardship activities, regulatory framework report, and the national AMS plan, policy, and guidelines. This workshop took place September 17-18, 2020, in Dabou with 12 participants (6 females and 6 males) from ORMICI, LANADA, CRO, OIE, Pasteur Institute of Cote d'Ivoire, PNDAP, and CIAPOL. The deliverables were finalized after integrating the comments and input of attendees.

#### Activity 3.5.1: Establishing and/or strengthening the capacities of members of DTCs

Support the AMR Secretariat in establishing and/or strengthening the capacities of DTC members to implement policies and standards to promote AMS

MTaPS, in collaboration with MTC 5, previously supported the AMR-TWG in assessing the functionality and capacity of DTCs in two teaching hospitals (CHU Bouake on December 9-10, 2019, and CHU Cocody-Abidjan, December 12-13, 2019). Representatives from the DPML; MTC 5 (represented by the Service of Infectious and Tropical Diseases of Treichville); the Leadership, Management, and Governance Project (the other MSH project in Cote d'Ivoire); and the AMR-TWG visited the two hospitals to evaluate the functionality of the DTCs and collect baseline data for MTaPS. The assessment focused on the organization and operation of the committees, activities carried out, regulatory framework and policies, monitoring antimicrobial prescribing and dispensing, assessment of drugs before selection and inclusion in the formulary, pharmacovigilance, and studies done on drug safety and efficacy.

The evaluation revealed the need to build capacity in several areas, including supporting DTCs in developing and implementing TORs and training DTC members to leverage their capacities to implement AMS activities. This requires the development of training materials, as no such materials on AMS activities have been developed by the country. MTaPS supported the AMR-TWG in developing and validating training materials for the selected DTCs. Several workshops were organized to achieve this goal.

On August 3-6, 2020, MTaPS supported the AMR-TWG in organizing a workshop to review and validate the draft modules developed by the AMS-TWG members. A total of 18 participants attended the workshop (7 females and 11 males) from the AMR National Secretariat-ORMICI, LANADA, CRO, OIE, Pasteur Institute of Cote d'Ivoire, PNDAP, CIAPOL, DMHP, and IPRA. The draft slide deck was validated after integrating the comments and input of attendees.

MTaPS also developed and validated two modules for the animal health sector:

- Overview of pharmacovigilance
- Pharmacovigilance regulatory framework in the animal health sector

Six additional modules will be developed and validated later for the animal health sector.

MTaPS supported the AMR-TWG in organizing a workshop on August 17-21, 2020, in Jacqueville with stakeholders to develop the macro and micro designs of the modules to train DTCs.

After this workshop, the newly developed macro and micro designs were validated in a two-day workshop held in Abidjan September 1-2, 2020; 14 participants attended this workshop (8 females and 6 males). During the same workshop, pre-test, post test questions, and the training workshop evaluation grid were developed and validated by the AMS-TWG. This workshop was also an opportunity for the AMS-TWG to plan the trainings of DTC members in the two pilot sites (the university teaching hospitals of Cocody and Bouake). The next steps will consist of organizing trainings in both health facilities.

The training of DTC at the university teaching hospital in Bouake took place September 22-25, 2020; 21 members (7 females and 14 males) of the local DTC were trained during 18 sessions. A key point for this workshop is the contribution of a local Leadership Development Program Plus (LDP+) facilitator to reinforce the DTC's capacity in the continuous quality improvement process. The LDP+ facilitator led the AMS action plan session by using the LDP+ tools. As a next step, MTaPS, in coordination with the local LPD+ facilitator, will monitor the development and implementation of a three-month action plan to revitalize the committee.

Training the DTC at the university teaching hospital in Cocody took place September 30-October 2, 2020; 19 health care professionals from the University of Cocody attended the workshop (11 females and 7 males); 14 sessions were held over the 3 days to reinforce the capacities of the DTC. A key point of this workshop will be the development of an action plan facilitated by one of MSH's LDP+ senior technical advisors. The trained health care professionals were equipped to start implementing AMS activities in their respective health facilities.

In conclusion, despite the challenges related to the COVID-19 pandemic, the activities planned in the FY20 work plan have been implemented. Members of the Secretariat-RAM-ORMICI and the IPC and AMS TWGs have shown commitment and taken all the necessary initiatives to enable the activities to proceed.

#### ACTIVITIES FOR NEXT QUARTER

ACTIVITY AND DESCRIPTION	DATES
Activity 1.1.1: Support the AMR-TWG in reviewing plans and progress on implementing the NAP-AMR, with a view to defining priorities for 2021-2025 and where the impact of resistance would be greatest	Nov.–Dec. 2020
<ul> <li>Support the AMR-TWG in undertaking a situation analysis to identify major risks for developing and transmitting AMR</li> <li>Hold a three-day workshop with the participation of high-level decision makers</li> </ul>	
from the various sectors to review the progress made in implementing the NAP-AMR 2019-2020	
<ul> <li>Support the AMR-TWG in drafting an updated version of the NAP-AMR 2021-2025</li> <li>Organize a five-day workshop to revise the NAP-AMR</li> </ul>	
Activity 1.1.3: Strengthening functionality of the MCG by organizing effective coordination through regular meetings of the AMR-TWG	OctNov. 2020
<ul> <li>Support the INHP and National AMR Secretariat in establishing and building capacity within the AMR, IPC, and AMS technical working sub-groups</li> </ul>	
Assisting 2.1.1. Company the AMP TM/C in accessing the IPC annual control and facilities	Nov. 2020
Activity 2.1.1: Support the AMR-TWG in assessing the IPC program at the national and facility evels	1407. 2020
<ul> <li>Support the AMR-TWG in conducting a baseline assessment on HIPC using the WHO</li> </ul>	1401. 2020
evels	1107. 2020
<ul> <li>Support the AMR-TWG in conducting a baseline assessment on HIPC using the WHO IPCAF</li> <li>Site visits in eight additional health facilities to conduct IPC baseline</li> </ul>	Dec. 2020
Support the AMR-TWG in conducting a baseline assessment on HIPC using the WHO IPCAF     Site visits in eight additional health facilities to conduct IPC baseline assessments by using IPCAF  Activity 2.5.1: Strengthen functionality of IPC committees in the human health sector and the	

#### **ACTIVITIES FOR NEXT QUARTER**

#### **ACTIVITY AND DESCRIPTION**

**DATES** 

Activity 3.1.1: Support the AMR TWG to improve the national EML using the WHO antibiotic AWaRe categorization

Oct.-Nov. 2020

- Support the AMR-TWG to update the national EML using the WHO antibiotic AWaRe categorization antimicrobial use and regulation in the human and animal sectors
  - Hold a preliminary, one-day stakeholders meeting attended by the National Therapeutic Commission members, the Ivorian Pharmaceutical Regulatory Authority (IPRA), and the DAPL, in preparation for the antibiotic categorization workshop
- Support the AMR-TWG in updating the national EML by using the WHO antibiotic AWaRe categorization
  - Through the Directorate of Pharmaceutical Medicines and Laboratories, organize a two-day workshop to categorize the antimicrobials

Activity 3.1.3: Support the AMR-TWG to establish SOPs and tools for monitoring antimicrobial use in humans and animals

Oct. 2020

- Conduct a national-level assessment of systems to monitor antimicrobial use by using a multisectoral approach
  - Hold a stakeholders meeting to develop and validate TOR for recruiting two consultants to assess systems to monitor antimicrobial use
  - $\circ$  Hold a one-day meeting of the AMR-TWG for recruiting two consultants

#### **DEMOCRATIC REPUBLIC OF CONGO**

#### **GLOBAL HEALTH SECURITY AGENDA ACTIVITIES**

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

The joint external evaluation (JEE) conducted in March 2018 in DRC revealed that the country needs to put in place mechanisms to raise its scores on all four JEE antimicrobial resistance (AMR) indicators, including antimicrobial stewardship (AMS) and infection prevention and control (IPC), to meet the priorities of the Global Health Security Agenda (GHSA). Since the JEE, DRC has made significant progress in implementing JEE's recommendations for containing AMR. With MTaPS' support, key milestones were achieved during FY20 in multisectoral coordination (MSC) and AMS.

Although IPC-specific interventions were not part of this work plan, a few IPC interventions, such as establishing IPC committees and training IPC members on using IPC guidelines, were conducted in the three MTaPS-supported facilities.

During the work plan period, MTaPS supported the National Commission on Antimicrobial Resistance (NC-AMR) in establishing three sub-committees: AMS, IPC, and AMR detection and surveillance sub-committees. The NC-AMR revised its terms of reference to include the scopes of the three newly established sub-committees and developed their terms of reference. Additionally, MTaPS supported the NC-AMR in holding four quarterly multisectoral meetings with stakeholders from the human, animal, and agriculture sectors; WHO; FAO; the One Health Platform; and Breakthrough Action.

To ensure strong coordination and operationalization of the sub-committees' activities, a three-day workshop was organized in August 2020 to develop their 12-month action plans. MTaPS also supported the NC-AMR in organizing multisectoral field visits, which took place in July 2020 at animal clinics and agropastoral institutions in Kinshasa province. Four institutions were visited, including two veterinary clinics, one phytosanitary center, and one environmental laboratory for analysis and control of vectors. The aim of these visits was to learn more about the use of antimicrobials in the animal and environmental sectors, identify bottlenecks that hinder the appropriate use of antimicrobials, and provide appropriate recommendations.

MTaPS, in collaboration with the NC-AMR, supported the Drug and Regulation Authority (DRA) by conducting a rapid assessment of AMS policies and regulations governing the use and management of antimicrobials in the human and animal sectors. MTaPS also supported the DRA in mapping stakeholders involved in the management of antimicrobials and the fight against AMR and rapidly assessing the consumption of antimicrobials by using the Anatomical Therapeutic Chemical (ATC) classification system and defined daily dose (DDD) as a measuring unit. MTaPS conducted the latter in collaboration with WHO. The findings from these assessments reveal that, in general, existing policies and regulations governing the use and management of medicines do not promote the rational use of antimicrobials in the human and animal sectors; most of the MOH partners, such as Global Fund, World Bank, UNICEF, WHO, EU, etc., procure and manage large quantities of antimicrobials, do not promote the appropriate use of these antimicrobials, and are not involved in the fight against AMR.

MTaPS supported the DRA in using the findings from the above-mentioned rapid assessments to develop a three-year AMS action plan and identify priority issues for optimizing antimicrobial use.

MTaPS, in collaboration with WHO and the World Bank, supported the DRA in revising the national essential medicines list (NEML) in consideration of access, watch, and reserve (AWaRe) categorization. This activity was conducted in two phases. The first phase consisted of classifying the antimicrobials into AWaRe groups, and the second phase consisted of revising the 2018 NEML according to the AWaRe categorization list produced in the first phase. In addition to AWaRe categorization of antimicrobials, a

number of new products were included in the revised 2020 NEML, such as bleomycin (an anticancer) and carbetocin (a prophylactic uterotonic and newer analogue of oxytocin that is effective in reducing postpartum hemorrhage [PPH] with a greater biological effect and longer half-life).

MTaPS also supported the General Directorate for the Organization of Health Care (DGOGSS) and the DRA in establishing and strengthening drugs and therapeutics committees (DTCs) at the University of Kinshasa Teaching Hospital (CUK), which is a national pre- and post-graduate training institution, and Monkole and Saint Joseph hospitals, which are among the best health institutions in the country. All three facilities are expected to play a leading role in AMR containment in DRC.

Prior to training DTC members, MTaPS conducted process sensitization meetings on AMR, followed by a baseline study. In addition, MTaPS developed and updated training tools, including the DTC manual, DTC training modules (PowerPoint slides), facilitator guide, participant manual, and baseline data collection tools.

In addition to AMS activities, MTaPS DRC also conducted IPC activities as part of DTC interventions. MTaPS, in collaboration with DGOGSS, facilitated a three-day IPC refresher training in each facility June 13-25, 2020; 94 heath care workers (50 females and 44 males) were trained on IPC standard precautions.

#### **Lessons Learned**

- Ensuring regular meetings with multisectoral representation (human, animal, and
  agriculture/environmental sectors) is essential as it provides a platform to discuss and share
  experiences and to coordinate and build trust among stakeholders, which is key to an AMR
  containment coordinated effort.
- A greater understanding of the AMR threat makes stakeholders (including partners, health institutions, and government counterparts) enthusiastic and receptive to the AMR issue and helps facilitate stakeholders' buy-in and eagerness to tackle and address the issue.

#### **QUARTER PROGRESS FOR FY20Q4**

#### **RESULT AREA I: EFFECTIVE MSC ON AMR**

## Activity 1.1.1: Provide technical support to the AMR technical working group to improve IPC and AMS coordination

During this quarter, from July 8 to 13, MTaPS supported the DRA and the NC-AMR in conducting multisectoral field support visits to animal clinics and agropastoral institutions in Kinshasa province.

The field team visited four institutions: two veterinary clinics, one phytosanitary center, and one environmental laboratory for the analysis and control of vectors. The aim of these visits was to learn more about using antimicrobials in the animal and environmental sectors, identify bottlenecks that hinder the appropriate use of antimicrobials, and provide appropriate recommendations. The findings from these visits include:

- Lack of awareness at most of the sites visited about the problem of AMR
- No legal provisions/arrangements to coordinate the management and the use of antimicrobials between different sectors
- Undefined supply chain
- Uncontrolled use of antimicrobials

Following the field visits, the supervisory team gave a brief overview on AMR and recommendations to health providers to promote the appropriate use of antimicrobials.

From August 17 to 21, 2020, MTaPS supported the DRA and the NC-AMR in organizing the last MSC quarterly meeting for this fiscal year, with the participation of the civil society health coordination group and the USAID Infection Disease Detection and Surveillance project. The meeting focused on the findings from the latest multisectoral field visits that took place in July 2020, presenting the summary report on the rapid assessment of AMS policies and regulations that govern the management of antimicrobials and the rapid assessment of antimicrobial use and consumption. Moreover, meeting participants conducted a thorough analysis of issues on AMS and IPC in DRC using the SWOT analysis model to identify issues or problems undermining implementation of AMR interventions. Participants used the fishbone and 5-why models to identify the root causes and drafted the action plans of the three sub-committees (i.e., IPC, AMS, and AMR detection and surveillance), including priority actions meant to address these problems.

#### **RESULT AREA 3: USE OF ANTIMICROBIAL MEDICINES OPTIMIZED**

#### Activity 3.1.1: Support the drafting of a national strategy or plan to strengthen AMS

Conduct a rapid assessment of AMS policies and regulations governing management of antimicrobials

MTaPS completed the quality review of the assessment reports on AMS policies and regulations governing the use and management of antimicrobials in the human and animal sectors, as well as the mapping of all stakeholders involved in managing antimicrobials and the fight against AMR. The findings from the assessments reveal that existing policies and regulations do not promote the rational use of antimicrobials in the human or animal sector. The mapping of stakeholders involved in managing antimicrobials also reveals that, although MOH partners, such Global Fund, World Bank, UNICEF, WHO, USAID, EU, etc., procure and manage large quantities of antimicrobials, only USAID, WHO, and OIE are involved in promoting the appropriate use of those antimicrobials and in combating AMR.

In collaboration with WHO, conduct a rapid assessment of antimicrobial use and consumption in the human health sector

MTaPS supported DRA in conducting a rapid assessment on antimicrobial consumption using the ATC classification system and DDD as a measuring unit.

The WHO technical teams from Geneva and Brazzaville facilitated the preparation phase of the assessment. During the meeting, the WHO team presented the assessment methodology to participants, including data collection and analysis tools. Then, MTaPS and WHO teams developed the terms of reference for the assessment and identified data sources. They include the regional distribution centers, DRA, central procurement units (Bureau de Coordination des Achats de la FEDECAME). Private import suppliers' investigators, data collectors, and data clerks were also selected. The WHO technical team provided a three-day training on data collection and data analysis tools August 7-11, 2020. The workshop included participants from Kinshasa, Nord Kivu, and Haut-Katanga provinces, which are the main entry points for medicines and related supplies in DRC.

The ATC/DDD methodology facilitated the presentation and comparison of drug consumption statistics at the international, national, and regional levels despite differences in nomenclature (both branded and generic), packing sizes, pricing, and customary dosages. The point of this ATC/DDD survey model is to ensure that antimicrobial consumption data are collected on an annual basis and reported through the Global Antimicrobial Surveillance System, which is a platform for sharing global data on AMR worldwide. The data generated will help to inform decision making, strategies, and advocacy.

Drafting the national AMS plan

MTaPS supported DRA in using the findings from the above-mentioned rapid assessments (activities 3.1 and 3.2) to develop a three-year AMS action plan. During the workshop, participants identified priority issues for optimizing antimicrobial use in the DRC after carrying out a holistic situational analysis of the

use and management of antimicrobials in three health sectors (human, animal, and agriculture). The situational analysis was carried out using the information obtained and observations made from the rapid assessment of policies and regulations governing the use and management of antimicrobials, as well as from the one on antimicrobial consumption in the human and animal sectors in DRC. In addition to the two surveys, participants fleshed out the situational analysis using the SWOT analysis model. This made it possible to identify the crucial issues on the use and management of antimicrobials in the DRC. Next, the root causes of these problems were identified using the fishbone and 5-why methods, and priority actions were identified to stem the root causes of the problems identified.

Subsequently, four following areas of intervention have been defined: 1) promoting appropriate use and management of antimicrobials; 2) strengthening the fight against the illicit sale of antimicrobials; 3) organizing the monitoring of the rational use of antimicrobials in human and animal health; and 4) managing antimicrobial consumption data. The AMS action plan has been finalized and is undergoing the last steps of technical review before submission.

#### Activity 3.1.2: Integrate the WHO AWaRe classification into the revised EML

MTaPS, in collaboration with WHO and PDSS/World Bank project, supported the DRA in revising the NEML and integrate the WHO AWaRe classification. The activity took place in two phases. MTaPS technically and financially supported the first phase that consisted of classifying the antimicrobials into AWaRe groups. The AWaRe task force, composed of various experts including microbiologists, pharmacologists, and clinicians, analyzed the infectious diseases data collected in various selected hospitals and laboratories in Kinshasa, Lubumbashi, Bukavu, Goma, Kisangani, Kisantu, and Bunia and defined the AMR profile that helped guide the AWaRe categorization of antimicrobials in these three groups. Some of the antimicrobials listed in the WHO AWaRe model were not part of the DRC NEML, although most of them were already abundantly used, especially in the private sector. They are phosphomycin, clarithromycin, ceftazidime-avibactam, cefuroxime, piperacillin-tazobactam, colistin, and plasomycin. These antimicrobials were therefore included in the DRC AWaRe list.

The PDSS/World Bank project financially supported the second phase of the activity, i.e. the revision of the NEML. The revision exercise consisted of reviewing the 2018 NEML while considering the DRC AWaRe list obtained from the AWaRe categorization exercise. On August 25, the AWaRe task force presented the first draft of the DRC AWaRe categorization to all stakeholders, including NC-AMR members, MOH specific programs (HIV, TB, MNCH, and Malaria), and other related experts. The classification exercise was done using the findings from the data analysis and the WHO AWaRe categorization model.

In addition to the AWaRe list of antimicrobials, the group of experts added a number of new products in the revised 2020 NEML, such as carbetocin, a prophylactic uterotonic and newer analogue of oxytocin which is effective in reducing PPH and has a greater biological effect and longer half-life. It is also more heat-stable than oxytocin, which is of crucial importance to resource-limited settings such as DRC.

The first draft of the NEML that includes the AWaRe classification was produced and shared with the technical team for review. The validation session is scheduled to take place October 13-15. The AWaRe classification narrative report has also been shared for technical review.

### Activity 3.5.1 Establish/strengthen DTCs to oversee implementation of AMS and IPC interventions

MTaPS supported the DGOGSS and DRA in establishing and strengthening a DTC at CUK and the Monkole and Saint Joseph hospitals. All three hospitals are among the best health institutions of the country and are expected to also play a leading role in AMR containment efforts.

The DTC establishment process started with AMR sensitization meetings in the three health institutions. MTaPS introduced the DTC concept and its role in AMR containment efforts to the multidisciplinary clinical teams of the three selected health institutions. Around 200 health care workers participated in these AMR sensitization meetings held on February 21, 2020 (CUK), March 5, 2020 (Saint Joseph), and March 9, 2020 (Monkole). Discussion topics included USAID support for combatting AMR through MTaPS, the antibiotic discovery gap and growth of AMR, and the role of DTCs in overseeing AMS and IPC interventions at the health-facility level.

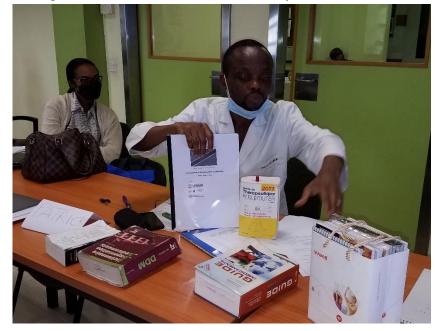


DTC Training at CUK: Participants and members of DTC received the certificate of attendance. Photo credit: MTaPS

Prior to the baseline assessment and training of DTC members, MTaPS developed and updated the training tools including the DTC manual, DTC training modules (PowerPoint slides), facilitator guide, participant manual, and the baseline data collection tools. Then, MTaPS supported the facilities to collect baseline data using INRUD technical indicators. The INRUD process and impact indicators help monitor the effectiveness and impact of DTC interventions on the appropriate use of medicines in general as well as the optimization of the use and management of antimicrobials at health facility level. The baseline

assessments also help identify the medicine use issues/problems related to prescribing and dispensing behaviors, which can help the hospital management teams and health care workers make a case for and facilitate buy-in of the DTC approach. The baseline study was followed by a training on DTCs and AMS for 80 appointed DTC members.

The last step consisted of the development of a DTC action plan. To this end, each DTC conducted a situational analysis regarding medicine use and management and AMR in their respective facilities. The situational analysis was conducted using the findings



Analysis of data on the INRUD indicators at Monkole Hospital. Photo credit: MTaPS

from the baseline assessments and the SWOT analysis model to identify issues or problems undermining the implementation of AMR interventions for AMS and IPC.

ACTIVITIES FOR NEXT QUARTER	
ACTIVITY AND DESCRIPTION	DATE
Finalize data analysis and compile the technical report of the rapid assessment on the consumption of antimicrobials in DRC	October 15, 2020
Finalize the revision of the EML, including AWaRe categorization	October 15, 2020

#### MATERNAL, NEWBORN, AND CHILD HEALTH ACTIVITIES

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

The MTaPS MNCH DRC work plan was approved in early July 2020 and aims to support the Divisions Provinciales de la Santé (DPS) in Nord Kivu and Ituri provinces to improve maternal, newborn, and child health (MNCH) by strengthening and improving the management and provision of MNCH-related commodities in 10 selected health zones (HZs) for 166 health facilities.



MNCH protocols and job aids reception in Ituri. Photo credit: Jérémie Fikiri

MTaPS began work plan implementation in collaboration with the DPS in Nord Kivu and Ituri. This phase began with the selection of the I0 HZs to be supported in the two provinces (five in Nord Kivu and five in Ituri). HZ selection criteria consisted of:

- Security and geographical accessibility
- Presence of other partner(s) supporting MNCH (providing MNCH commodities)
- Existence of community care sites

The HZs supported in Nord Kivu province are Goma, Karisimbi, Rwanguba, Nyiragongo, and Kirotshe, consisting of 86 health facilities. In

Ituri province, the project is implemented in Bunia, Rwampara, Nizi, Lita, and Gethy HZs, covering 80 health facilities.

During FY20 (July, August, and September 2020), four activities were selected and identified as high-priority interventions, including updating and disseminating the register of authorized medicines, dissemination of MNCH protocols and job aids, training health providers on using paper-based data collection and reporting tools, and improving the functioning of the provincial technical working group (TWG) on medicines.

#### **UPDATING THE REGISTERED MEDICINES DIRECTORY**

MTaPS supported the Drug Regulatory Authority (DRA) in conducting an MNCH product registration survey to identify challenges, bottlenecks, and barriers in the registration process; propose and recommend solutions and strategies to eliminate or reduce those barriers; and improve the registration process for MNCH commodities.

MTaPS also supported the DRA in finalizing the review and updating of the Registered Medicines Directory. The directory will be used by pharmacist inspectors and customs officers to track and confiscate all unregistered products, including those for MNCH. By November 2020, an electronic copy of the updated directory will be available online and the printed copies disseminated in provinces (DPS and customs officers).

MTaPS supported the DPS in Nord Kivu and Ituri provinces to conduct meetings of provincial medicine TWGs on August 14 in Bunia and August 20 in Goma. These meetings were opportunities for MTaPS to highlight MNCH commodity-related issues (e.g., stock-outs of MNCH products while the same products are expiring at regional distribution centers) as important topics to be discussed at quarterly medicine TWG meetings. Meeting participants created MNCH sub-groups, their terms of reference, and a roadmap.

MTaPS is working to improve the use of paper-based LMIS and data entry into the DHIS 2/InfoMED platform at the HZ level. MTaPS, in collaboration with the CORDAID/Global Fund project, trained 36 members of DPS and HZs in Nord Kivu and Ituri on using InfoMED. The trainings started on September 25, 2020, and are expected to be completed by October 19. In addition, MTaPS is supporting DPS in organizing a separate three-day training workshop on using paper-based tools for data collection and reporting in Nord Kivu and Ituri, in collaboration with the Global Fund and the National Medicines Supply Program (PNAM).

MTaPS, in collaboration with the MNCH Directorate (D10) and the reproductive health (RH) programs at the provincial level, disseminated 16 protocols and job aids in 86 MTaPS-supported health facilities. The protocols/guidelines cover chlorhexidine 7.1%, oxytocin, magnesium sulfate, amoxicillin dispersible tablets, dexamethasone, misoprostol 200 µg, calcium gluconate, MNCH community interventions, treatment of diarrheal diseases, female condoms, treatment of acute respiratory tract infections (ARTI), Maternal Death Monitoring Tool, partogram, child health record, integrated MNCH interventions in the DRC, health service standards for adolescents and youth, and MNCH guidelines in the context of COVID-19. Disseminating the protocols will



Disseminating MNCH protocols and job aids in Nord Kivu Photo credit: Jérémie Fikiri

improve the offer of MNCH services and promote good care practices to reduce maternal and child mortality in both provinces.

#### **QUARTER PROGRESS FOR FY20Q4**

#### **OBJECTIVE 1: PHARMACEUTICAL SECTOR GOVERNANCE STRENGTHENED**

## Activity 1.1.1. Assist DPM in strengthening medicine registration procedures and update the directory of market-authorized products

MTaPS provided financial and technical support to the DRA to finalize the review and updating of the Registered Medicines Directory. A 15-day meeting was conducted to collect and record 2019 and 2020 marketing authorization-related data for the directory.

#### Activity 1.1.2. Improve the functioning of provincial TWGs on medicines in Nord Kivu and Ituri

To enhance the coordination among partners in Nord Kivu and Ituri and as a first step to strengthen DPS' capacity to better steward the pharmaceutical system at the provincial level, MTaPS supported the DPS in organizing meetings of the provincial medicine TWGs in Bunia and Goma in August to highlight MNCH product-related issues. During the respective meetings, participants:

- Created MNCH sub-groups within the provincial medicine TWGs and drafted their TOR
- Made recommendations to the regional distribution center to reallocate/redistribute MNCH
  commodities that are close to expiring to other HZs and facilities to prevent expiration; a quick
  medicine stock-taking was conducted to estimate the value of all medicine items at risk of expiry
- Redistributed a significant number of family kits procured by UNICEF to HZs (including those outside UNICEF intervention areas) to prevent expiries

Then, MTaPS, in collaboration with EU/PRODSS, Global Fund/SANRU, UNICEF, and other USAID implementing partners, supported the DPS in developing roadmaps for MNCH commodity management in Ituri and Nord Kivu provinces to synergize efforts and rationalize the use of resources.

## OBJECTIVE 3: AVAILABILITY AND USE OF PHARMACEUTICAL INFORMATION FOR DECISION MAKING INCREASED, AND GLOBAL LEARNING AGENDA ADVANCED

## Activity 3.2.1. Assist DPS and HZs to strengthen the paper-based data collection system to improve availability, quality, visibility, and use of logistics data

MTaPS, in collaboration with the Global Fund and PNAM, supported the DPS in organizing a three-day training workshop on the use of paper-based tools for data collection and reporting in Nord Kivu and Ituri. This workshop brought together 36 participants (16 DPS technical advisors and 20 HZ members), including 7 women. The workshop was an opportunity to build the capacity of the DPS and HZ management teams to monitor logistics data collection and reporting activities at health facilities, coach staff as needed, and work with DPS and HZ members staff to take appropriate action to address data collection and reporting-related issues.

Following the training, MTaPS will work with DPS and HZ teams to facilitate the data entry and recording of MNCH commodities in DHIS 2 data analysis and visualization through the InfoMED platform. This follow-on activity will be done in collaboration with the Global Fund.

## OBJECTIVE 5: PHARMACEUTICAL SERVICES, INCLUDING PRODUCT AVAILABILITY AND PATIENT-CENTERED CARE TO ACHIEVE DESIRED HEALTH OUTCOMES, IMPROVED

Activity 5.2.1. Support DPS in strengthening MNCH health care capability by disseminating updated MNCH treatment protocols and related job aids to health facilities and training health care providers on their appropriate use

The MOH has developed several MNCH treatment protocols and job aids. However, these important documents/tools are not always available at the point of service. During this quarter, MTaPS worked with the MNCH Directorate (D10) and RH programs at the provincial level to disseminate the MNCH protocols and job aids in MTaPS-supported health facilities. Specifically, MTaPS:

- Organized preparatory meetings at the national and provincial levels
- Facilitated a briefing at the central level on the methodology for disseminating protocols
- Facilitated the shipping of MNCH treatment protocols and related job aids to provinces
- Organized joint field visits with the MOH Direction pour de la Santé de la Famille et Groupe Specifique/10ème Direction (DSFGS)/D10 and RH program) to Goma and Bunia to disseminate protocols and job aids to DPS and HZs members
  - O During the visits, a three-day training/orientation was conducted on using the treatment protocols and job aids prior to their dissemination to health facilities.
  - A total of 30 HZ team members and 10 DPS staff, including the provincial MNCH program and medicine TWG members in Goma and Bunia, attended the training/orientation.

ACTIVITIES FOR NEXT QUARTER	
ACTIVITY AND DESCRIPTION	DATE
Enhance the role of CODESAs and CACs in medicine management at the health center and community levels	Dec. 2020
Support DPS in strengthening technical and managerial capacities of health facility staff in pharmaceutical management	Nov. 2020
Assist DPS, inspectors, and customs officers in accessing and using the updated list of registered products for inspections and import control	Dec. 2020
Assist DPS in establishing and increasing the technical capacity of provincial medicine quantification committees	Dec. 2020
Improve the availability of commodities needed for iCCM and treating women and children in selected HZs	Dec. 2020

#### **ETHIOPIA**

For progress on MTaPS/Ethiopia's COVID-19 activities, click here.

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

#### Antimicrobial resistance governance

During the year, MTaPS provided technical support to the Pharmaceuticals and Medical Equipment Directorate (PMED) of the Ministry of Health (MOH) to develop and finalize the three-tier structure of the national antimicrobial resistance (AMR) governance and coordination platform. The platform consists of a national interministerial committee at the top, followed by the National AMR Advisory Committee, which provides oversight to six multisectoral technical working groups (TWGs). The six TWGs are organized under the following thematic areas: education and awareness; infection prevention and control (IPC) and hygiene; surveillance and research; antimicrobial stewardship (AMS); resource mobilization for AMR; and regulatory and pharmacovigilance.

From the outset, MTaPS recognized that the Ethiopian AMR program lacked a strong coordinating body. Moreover, the IPC component of the National Action Plan for AMR was not adequately elaborated. MTaPS held several meetings with MOH officials about the need to establish a strong AMR unit that could coordinate both AMR and AMR-related IPC activities. In addition to this, MTaPS produced and submitted to PMED/MOH a concept note on the proposed set-up of the unit. In parallel, MTaPS started building the capacity of PMED/MOH by assigning a senior technical advisor to prepare the unit's action plan and facilitate its implementation with technical and financial support from MTaPS.

As the result of MTaPS' strategy recognizing the need for a functional AMR coordinating unit with good leadership (governance), the National Antimicrobial Resistance and Containment Advisory Committee (NAMRAC), which comprises several institutions with a stake in AMR and IPC, was established. MTaPS is a member of the IPC TWG and serves as its secretary. MTaPS provided technical support in reviewing the draft terms of reference for the TWGs. The TWGs provide guidance in developing annual operational and strategic plans and programmatic focus areas, in addition to providing information on monitoring and evaluation of IPC interventions.

#### **Infection Prevention and Control Activities**

MTaPS provided technical and financial support to the MOH to develop standard operating procedures (SOPs) for alcohol-based hand rub (ABHR) production in health facilities. Even in countries with a developed health infrastructure, current scientific literature favors the use of ABHR over hand washing in health facilities. The main reason for this recommendation is that only about 40% of health care workers comply with handwashing guidance.

Having taken note of the difficulties faced by many health facilities to implement hand hygiene, which is one of the major interventions in infection control, MTaPS collaborated with the MOH to improve hand hygiene practice by making ABHR widely available. Handwashing was not being implemented in health facilities due to poor infrastructure, including interruptions in water supply, soap shortages, and overworked staff who say they have no time for handwashing. This intervention brings a local solution to sustain improved hand hygiene practice as a measure to prevent the spread of health care-associated infections. Following the preparation of the SOPs, orientation trainings were organized for target health facilities. MTaPS printed 4,000 copies of the SOP for ABHR and took responsibility for distributing it to 400 hospitals around the country. The need for the ABHR SOP has significantly increased since the onset of COVID-19, and many regional health bureaus have started to produce ABHR and distribute it to the public as hand sanitizer.

MTaPS provided technical and financial support to the MOH to develop a national IPC program implementation monitoring and evaluation tool for health facilities. The tool, which was designed to address IPC program implementation, is based on WHO guidelines on the eight core components of an IPC program at the health facility level. It is adapted from the Infection Prevention and Control Assessment Framework (IPCAF) tool, and the recommended IPC practices are based on the revised national IPC guidelines. The MOH, regional health bureaus, and other USAID implementing partners will use the tool to regularly monitor implementation of IPC activities at health facilities. The lack of such a tool had prevented assessment of the outcome of IPC efforts in the past.

#### Changing behavior around antimicrobial resistance

MTaPS took the initiative to prepare a multisectoral behavioral change communication (BCC) strategy for AMR prevention and AMR training course for journalists and communications professionals. The preparation of these documents was evidence based and drew largely from the global experience. The One Health approach covering pertinent AMR issues in human and animal health and the environment was considered during the development of the BCC strategy and training course for journalists. The BCC strategy provides guidance to stakeholders on strategic approaches and coordination mechanisms that will improve both the effectiveness and the efficiency of community awareness and educational interventions. Bringing awareness to the public should go beyond a knowledge deficit approach and engage stakeholders directly. This includes using role model stories about real people and how they achieved healthy behavior changes.

Recognizing the importance of effective communication to educate the public to change behavior and social norms for preventing AMR, MTaPS, in partnership with the MOH, civil society organizations (CSOs), and community organizations, implemented capacity building activities for journalists and CSOs. MTaPS trained and supported the Ethiopian Youth and Women Federations to sensitize the public on AMR during their work promoting hygiene and maternal and child health in their communities. Twentynine volunteers (21 female and 8 male) from the Addis Ababa Youth and Women Federation trained for this purpose. The main objective of the training was to capacitate youth and women volunteers on AMR so they could create awareness among the community where they are already engaged in promoting sanitation, hygiene, and maternal and child health. After the training, participants developed action plans for AMR work in their communities. With technical support from MTaPS, the trained female volunteers conducted educational sessions on rational use of antimicrobials for 520 female members of the Addis Ababa Women Federation.

#### Revising the national essential medicines list

MTaPS supported the revision of the national essential medicines list (EML), last updated in 2014, in line with the WHO recommendation to categorize antibiotics into access, watch, and reserve (AWaRe) groups to improve prescribing and use of antimicrobials. This is the first time in Ethiopia that antibiotics have been listed according to the AWaRe categorization. MTaPS provided technical assistance as a member of one of the core groups that reviewed the list of anti-infective medicines and supported the entire process, both technically and financially. In addition, MTaPS supported the MOH to revise the national standard treatment guidelines (STGs), which also included the AWaRe categorization of antibiotics. The Ethiopian government had developed and issued STGs tailored for health facilities at different levels of the three-tier system: referral/specialized hospitals, general hospitals, and health centers. Except for the first edition of the STG developed in 2004, USAID-funded programs implemented by MSH in Ethiopia have taken the lead in revising document. The STG was last revised in 2014. To keep up with changing health trends and evidence-based best practices, regular updating of STGs is of paramount importance. The incorporation of the AWaRe categorization will guide prescribers to promote appropriate use of antibiotics based on current knowledge of trends in AMR in Ethiopia and globally.

#### **QUARTER PROGRESS FOR FY20Q4**

#### RESULT AREA I: EFFECTIVE MULTISECTORAL COORDINATION ON AMR

## Activity 1.1.2: Support PMED to organize effective multisectoral coordination through regular meetings of AMR stakeholders, including animal health and environmental protection

MTaPS supported the national AMR secretariat at PMED/MOH to conduct NAMRAC's 37th regular virtual meeting on August 7, 2020. Thirty-one advisory committee members, invited guests from stakeholder organizations, and consultants attended the meeting. The main agenda items of the meeting were the status of the STG revision, a progress report of the Dire Dawa AMR Advisory Committee, an update on the draft AMR advisory committee plan for 2013 Ethiopian Calendar, and an update on the national AMR strategy revision.

Valuable comments regarding revision of the STG, the work of the AMR advisory committee, and the national AMR strategy and action plan revision have been forwarded to the AMR secretariat. The session provided an opportunity to both the national and the regional advisory committee to discuss performance, challenges, and support needed to strengthen AMR prevention and containment efforts in the regions.

#### **RESULT AREA 2: INFECTION PREVENTION AND CONTROL**

#### Activity 2.3.2: Monitor IPC improvement in selected health care facilities using IPCAF

MTaPS conducted IPC implementation assessments in four targeted hospitals using the IPCAF tool to identify gaps. The four targeted referral hospitals (AaBET Hospital, Felege Hiwot Hospital, Debre Berhan Hospital, and Hawassa University Hospital) were randomly selected from three regions of the country (Addis Ababa, Amhara, and Hawassa). The purpose of this assessment was to evaluate the status of IPC implementation and the contribution of MTaPS in improving IPC by comparing the findings with baseline data. Accordingly, the selected facilities conducted assessments using the IPCAF tool and shared the findings with MTaPS. The results of the IPC implementation assessment are shown in table 10.

Table 10. Result of IPC implementation assessment before and after MTaPS support

NAME OF	BASELINE (OCTOBER 2019)		AFTER TECHNICAL SUPPORT FROM MTAPS (AUGUST 2020)	
REFERRAL HOSPITAL	IPCAF score (out of 800)	Classification of IPC practice	IPCAF score (out of 800)	Classification of IPC practice
AaBET Hospital	183.5	Inadequate	382.5	Basic
Hawassa University Hospital	452.5	Intermediate	565	Intermediate
Felege Hiwot Hospital	385	Basic	527.5	Intermediate
Debre Berhan Hospital	410	Intermediate	500	Intermediate

All four hospitals showed improvement in their IPCAF score; one hospital progressed from inadequate to the higher end of the score for basic level, while another progressed from basic to intermediate because of MTaPS' support. The two remaining two hospitals (Hawassa University Hospital and Debre Berhan Hospital), which did not progress in their IPC level, showed IPC score improvements of 24.9% and 21.9%, respectively, due to support from MTaPS. The following major improvements were observed in the hospitals:

- IPC program was established with clearly defined objectives
- IPC committees were established in the hospitals where doctors and nurses are members of the committees
- Dedicated and full time IPC focal persons are assigned in the hospitals to lead IPC activities
- IPC guidelines on hand hygiene, standard precautions, transmission-based precautions, disinfection
  and sterilization, prevention of surgical site infection, catheter-associated urinary tract infections,
  central line-associated bloodstream infections, and outbreak management and preparedness were
  made available in the hospitals
- Hospitals have adopted the WHO multimodal strategy for implementation of IPC interventions.

Ethiopia's score according to JEE Core Capacities evaluation (2016) for IPC was 2 out of 5. The progress shown by the four hospitals is indicative of the effectiveness of MTaPS' technical assistance and will contribute to raise the country's JEE score on IPC from 2 to 3.

MTaPS provided technical and financial support to the MOH to revise the national IPC guidelines. It also supported development of the national IPC program and practice monitoring tool in close collaboration with the MOH and Addis Ababa City Administration Health Bureau. The tool is now completed and shared with the MOH for use.

#### **RESULT AREA 3: USE OF ANTIMICROBIAL MEDICINES OPTIMIZED**

## Activity 3.1.1a: Support updating of standard treatment guidelines (STGs) to reflect AWaRe categorizations of antibiotics and promote their appropriate use

MTaPS provided technical and financial support for the revision of the STGs. The first draft of the STGs for general hospitals was developed by a group of consultants hired by MTaPS and distributed for technical review and comments. The revision incorporated WHO's AWaRe categorization of antibiotics to support the implementation of AMS programs. Development of STGs for primary hospitals and health centers will follow once the outline and contents of the STGs for general hospitals approved.

## Activity 3.2.1: Build the capacity of journalists and civil society groups (including the Ethiopian Pharmaceutical Association) to raise awareness of AMR initiatives and issues

During this quarter, MTaPS developed the first draft of a multisectoral BCC strategy document for AMR prevention and containment. MTaPS worked closely with the consultant it hired for this purpose by reviewing the outline of the BCC strategy, interview guides, and reports of the literature review and formative assessment. The BCC strategy provides guidance on priority behaviors that need to be changed to prevent and contain AMR; it also addresses important issues such as identifying target audiences, key messages for each target audience, message delivery modalities, roles of stakeholders, and approaches in measuring outcomes of BCC interventions.

MTaPS supported PMED/MOH to develop a training course on AMR for health care professionals, which includes a participant manual and PowerPoint slides. In addition to working as a member of the task force that developed the training materials, MTaPS supported the validation and course development workshops in May and September 2020. Eight professionals (all male) drawn from the MOH, St. Peter Specialized Hospital, MTaPS, and USAID GHSC-PSM participated in the workshops.

Following this, a pilot test of the training course was held September 5–9, 2020, to evaluate the practicality of the proposed training modality and allotted time.

MTaPS collaborated with the MOH to develop a training course on AMR for journalists and communication professionals, which serves as a guide to build the capacity of journalists and communication professionals working both in the private and public sectors. MTaPS solicited the services of a local consulting firm to prepare the training course and provided technical assistance by reviewing the outline and contents of the training course. Furthermore, MTaPS and MOH technical staff undertook technical review of the training course. The course content covers the burden and causes of AMR, its national and global consequences, strategies to tackle AMR, the role of mass media in AMR prevention, principles of framing AMR messages, and the significance of creating public awareness.

#### Activity 3.5.1: Support AMS implementation in health facilities

MTaPS provided technical assistance to St. Peter Specialized Hospital to conduct a drug use evaluation (DUE) on ceftriaxone. The DUE was a retrospective review of patient charts to identify patients who received ceftriaxone during hospitalization in the internal medicine ward from March 2019 to March 2020. The preliminary findings showed that in 75% of patients, ceftriaxone was inappropriately used for the clinical condition. In addition, the practice of culture and sensitivity testing before initiation and changing of antibiotics was very poor. This baseline information will serve to guide the implementation of AMS interventions to improve appropriate antimicrobial use through a continuous quality improvement approach.

MTaPS collaborated with the MOH in conducting training on AMS focusing on the AWaRe categorization of antibiotics for 16 health professionals (13 male and 3 female) drawn from nine MTaPS-supported hospitals in Addis Ababa September 5–9, 2020. Participants of the training were physicians, pharmacists, lab technologists, and nurses. The main objective of this training was to build the knowledge and skill of health care professionals to implement AMS interventions at their hospitals as per the recommendation of the national practical guide on AMS. Participants practiced using the audit and feedback tool using two hypothetical case scenarios. The AWaRe categorization for antibiotics and actions required to implement it at health facilities were discussed during the training.

ACTIVITIES FOR NEXT QUARTER	
ACTIVITY AND DESCRIPTION	DATE
Conduct mentorship support to one hospital in Addis Ababa to implement AMS programs	Oct.–Dec. 2020
Promote STGs and AMR BCC strategy	Nov.–Dec. 2020
Analyze and write up the Knowledge, Attitude, and Practice assessment on AMR among members of the Addis Ababa women federation	Oct.–Nov. 2020
Conduct antibiotic (ceftriaxone) use evaluation at St. Peter Hospital	OctNov. 2020
Provide TA to World Antimicrobial Awareness week (WAAW)	Nov. 2020
Support revision of the 3rd national AMR strategy and plan of action with monitoring and evaluation framework	Oct.–Dec. 2020
Conduct IPC evaluation assessment using IPCAF in three MTaPS-supported hospitals (two public and one private)	Oct.–Dec. 2020
Provide training on home-based isolation and care to 100 health professionals from Addis Ababa	Oct.–Dec. 2020

#### **JORDAN**

For progress on MTaPS/Jordan's COVID-19 activities, click here.

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

MTaPS/Jordan started with two main activities: to strengthen the National Steering Committee and its Technical Subcommittees to support the operationalization of the National Action Plan on Antimicrobial Resistance (AMR) through multisector coordination and to pilot an antimicrobial stewardship (AMS) program at two leading hospitals in Amman so the experience could be replicated and scaled up to other hospitals countrywide.

For the first activity, MTaPS conducted a thorough stakeholder mapping and analysis of the AMR/AMS initiatives in Jordan and identified the main challenges and opportunities for project implementation. However, after COVID-19 hit the country, MTaPS could not continue working with our main counterpart, the Ministry of Health (MOH) Communicable Diseases Directorate, as it gave maximum priority to the pandemic response.

For the second activity, MTaPS could not start the planned operationalization of AMS programs at the selected hospitals due to shifting health care system priorities and partial and complete curfews as a consequence of COVID-19. Moreover, the selected hospitals were designated as COVID-19 treatment centers, so planned AMS activities were postponed to FY21. MTaPS continued to support the MOH National AMS Committee focal point to develop critical technical documents through discussions with hospitals, paving the road for the full AMS program implementation once feasible. These activities will improve antibiotic prescriptions and consumption practices at the hospitals and contribute to containing the spread of AMR across the country.

Despite changing priorities at the MOH and countrywide and the increasing demand for MTaPS support to the COVID-19 response, the MTaPS team maintained strong working relations with MOH counterparts, realizing the importance of sustaining the AMR work even during these difficult times. MTaPS managed to turn challenges into opportunities by linking the COVID-19 and AMS activities. The MOH expressed its appreciation for MTaPS' commitment during the pandemic.

#### **QUARTER PROGRESS FOR FY20Q4**

#### OBJECTIVE 5: PHARMACEUTICAL SERVICES, INCLUDING PRODUCT AVAILABILITY AND PATIENT-CENTERED CARE, TO ACHIEVE HEALTH OUTCOMES IMPROVED

MTaPS continued providing support to the MOH Central AMS Committee to finalize technical documents needed to establish an AMS program at the designated MOH hospitals (i.e., terms of reference for the Hospital AMS Committee, AMS program core elements checklist, and AMS program implementation plan). The MTaPS team, accompanied by the AMS Committee focal point, conducted meetings with the members of the Hospital AMS Committees to discuss the technical documents and next steps to implement an AMS program at their hospitals. The MOH assigned a focal point for MTaPS at each hospital, and the MTaPS team worked with them to analyze their hospital situations and identify gaps, strengths, and areas for improvement using the provided checklist. Input received was integrated into the documents before finalization. These documents were approved by the AMS Technical Subcommittee of the National AMR Steering Committee and will be disseminated to selected hospitals in the next quarter.

# ACTIVITIES FOR NEXT QUARTER ACTIVITY AND DESCRIPTION DATE Provide required capacity building for concerned staff at the selected hospitals Oct.—Dec. 2020 Start implementation of the AMS programs at the selected hospitals Oct.—Dec. 2020

#### **KENYA**

For progress on MTaPS/Kenya's COVID-19 activities, click here.

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

#### Kenya Essential Medicines List with Access, Watch, and Reserve Categorization of Antibiotics

MTaPS, in collaboration with the National Medicines and Therapeutics Committee (NMTC), the Kenya Essential Medicines List (KEML) technical working group (TWG), and other stakeholders, offered technical and financial support in revising the 2016 KEML. The KEML has a careful selection of a limited range of essential medicines targeting the priority health care needs of Kenyans, including treatment of the common infectious diseases in Kenya. This results in better quality of care and better medicines management, including improved quality and more cost-effective use of health resources.

In addition, antibiotics in the KEML were categorized according to the access, watch, and reserve (AWaRe) classes as recommended by the World Health Organization (WHO). The AWaRe categorization classifies antibiotics into three groups based on the potential to induce and propagate resistance. The 2019 KEML, which includes the AWaRe classification of antibiotics, was validated by various health care specialists and approved by the Chief Administrative Secretary (Deputy Minister) and Cabinet Secretary (Minister), Ministry of Health (MOH). This revised edition was officially launched by the Chief Administrative Secretary on July 22, 2020, at an event attended by more than 300 stakeholders. A national dissemination and implementation plan for the AWaRe categorization of antibiotics will be developed pending final review and ratification by the NMTC in quarter 1 (Q1) of Year 3 (Y3).

The AWaRe categorization will promote appropriate antimicrobial use and progression to Joint External Evaluation (JEE) capacity level 2.

#### National Antimicrobial Stewardship Guidelines for Health Care Settings in Kenya

MTaPS, in collaboration with the National Antimicrobial Stewardship Interagency Committee's (NASIC) antimicrobial stewardship (AMS) TWG and other stakeholders, offered technical and financial support in developing the national AMS guidelines for health care settings in Kenya. The purpose of the guidelines was to give direction to health care workers (HCWs) on how to establish and run AMS programs in health care settings and the community at large.

Once developed, the guidelines underwent external validation by AMS experts and were ratified by the top three senior MOH officials—the Director General for Health, Chief Administrative Secretary, and Cabinet Secretary. The guidelines were officially launched on July 22, 2020, by Dr. Rashid Aman, Chief Administrative Secretary. In addition, a dissemination, implementation, and training package was developed that will be validated, approved, and disseminated in Y3.

The national AMS guidelines will serve as a framework to promote and facilitate implementation of good AMS practices in health care facilities (HCFs) and support progress on the pathway toward JEE capacity level 3 on optimizing antimicrobial use.

## National Antimicrobial Stewardship Committee's Technical Working Groups for Infection Prevention and Control and Antimicrobial Stewardship

MTaPS offered technical and financial support in the review of the TWGs' terms of references and developing their annual work plans. The terms of reference were aligned to the national action plan (NAP) on prevention and containment of antimicrobial resistance (AMR) as well as the annual work plans that prioritized actions for implementation during the year. Functional infection prevention and

control (IPC) and AMR TWGs will help coordinate activities for the effective implementation of AMR and IPC programs.

#### Infection Prevention and Control Continuing Professional Development Course

MTaPS, in collaboration with the National Nurses Association of Kenya (NNAK), MOH, and a taskforce committee comprising medical professional associations, developed a continuing professional development (CPD)- and re-licensure-linked in-service IPC training package (curriculum and PowerPoint slides) for delivery through professional associations. The content of the training package was informed by the results of a training needs assessment. The development process included piloting and validation of the training content to assess the feasibility and applicability of the curriculum in real time and incorporating input from stakeholders to strengthen the course content. A CPD implementation strategy that runs well into Y3 was also developed.

So far, four trainings targeting 393 HCWs drawn from the NNAK, Association of Kenya Medical Laboratory Scientific Officers (AKMLSO), Kenya Society of Physiotherapists (KSP), and Kenya Clinical Officer Association (KCOA) have been conducted, with the attendees awarded CPD points. The other professional associations involved in this activity were the Pharmaceutical Society of Kenya (PSK), Kenya Society of Physiotherapy, Kenya Pharmaceutical Association (KPA), AKMLSO, KCOA, Kenya Medical Association (KMA), and Nursing Council of Kenya (NCK). The professional development course will help improve both public- and private-sector HCW competencies in IPC and contribute to maintaining JEE level 3 for indicator P.3.3 and meeting actions in WHO's benchmark 3.3 on IPC practices (level 3) related to capacity building of HCWs on IPC practices.

## Building Capacity of Health Care Workers in Antimicrobial Stewardship at Pre- and In-Service Levels

MTaPS, in collaboration with the University of Nairobi School of Pharmacy (UON/SOP), developed a pre-service AMS curriculum. The content of the curriculum was informed by the results of a training needs assessment. Several meetings were held to develop the course content, and the curriculum underwent external review by AMS experts in academia, policy, health systems strengthening, and hospital pharmacy practice. The curriculum includes an introduction to AMS; components, core elements, and monitoring and evaluation (M&E) for AMS programs; actions and effective interventions to support AMS; potential pitfalls and mitigation; planning and establishing an AMS program at a health facility; IPC; diagnostic stewardship and surveillance; and leadership, governance, ethics, and communication. The AMS curriculum aims to develop competent and practice-ready health care professionals before graduation and internship. The course is set to be administered to first-year pharmacy postgraduate students beginning in October 2020.

In parallel, MTaPS, in collaboration with the PSK, MOH, and representatives of health professional associations, developed a CPD- and re-licensure-linked AMS training package (curriculum and PowerPoint slides) for delivery through health professional associations. A training needs assessment informed the content of the training package, which was peer reviewed by AMS experts including clinical pharmacists, pharmacologists, medical officers, a nurse, health care managers, infectious diseases specialists, laboratory scientists, and pharmacists. The other professional associations that were involved in this activity were the AKMLSO, KMA, NNAK, KPA, and Kenya Association of Clinical Pathologists. Since AMS is not a core component of professional education, training, or certification in either human health or agricultural courses in Kenya, this course aims to provide participants with the right knowledge, skills, and attitude on appropriate handling of antimicrobials in health care settings and the community. Implementation of the AMS CPD program has commenced and will continue well into Y3.

Improved in-country capacity to support practices to ensure appropriate use of antimicrobials in HCFs helps meet JEE level 3 for indicator P.3.4 and progress toward meeting action items listed in the capacity levels of WHO's benchmark 3.4 on optimizing use of antimicrobials.

#### QUARTER PROGRESS FOR FY20Q4 (JULY 1-SEPTEMBER 30)

## RESULT AREA I: EFFECTIVE MULTISECTORAL COORDINATION ON ANTIMICROBIAL RESISTANCE

Activity 1.1.1: Strengthen the capacity of the national antimicrobial stewardship interagency committee (NASIC) as a leadership, governance, and oversight body for One Health implementation in Kenya

MTaPS coordinated the development of the M&E framework for the NAP on prevention and containment of AMR. A virtual meeting with 10 animal-, agricultural-, and environmental-sector representatives (5 male and 5 female) was held on July 6, 2020, to review the draft M&E framework. On July 16, 2020, MTaPS, in collaboration with the AMR secretariat and human health sector stakeholders, held a virtual meeting to review the draft M&E framework. Work is ongoing to finalize and incorporate an implementation plan for the M&E framework to guide activities, aiming for completion next quarter.

MTaPS provided technical and financial support in the review and finalization of the national IPC policy and strategic plan for health care settings during a two-day workshop on July 2–3, 2020. Sixteen members (6 male and 10 female) of the IPC TWG drawn from hospitals, parastatal organizations, the MOH, and implementing partners attended and contributed to the



documents' review. Internal and external validation meetings were held on August 3 and September 7, 2020, respectively, where the documents were updated with current global IPC practices and standards. The meetings were attended by representatives from national and county governments, private hospitals, and implementing partners.

The finalized AMS guidelines for health care settings in Kenya were officially launched by Dr. Rashid Aman, Chief Administrative Secretary, MOH, on July 22, 2020. The event was attended by more 300 participants from various sectors and counties. A dissemination, implementation, and training package were developed that will be validated, approved, and disseminated in Y3.

MTaPS attended and participated in NASIC's AMS TWG meeting on September 10, 2020. The meeting focused on reviewing progress of the 2019/2020 work plan. During the meeting, it was agreed that activities for the work plan would be extended to cover the 2020/2021 program year.

Other multisectoral coordination-related activities conducted during the quarter are summarized below:

- The mapping matrix for AMR-related stakeholders was updated in the period under review.
- MTaPS participated in the Nyeri County Antimicrobial Stewardship Interagency Committee (CASIC) virtual meeting on August 18, 2020. The meeting was a co-creation activity to review the preliminary 2020/2021 work plan. In attendance were representatives from the human health and animal health sectors, MOH, and Division of Patient and Health Worker Safety (DPHWS). During the meeting, MTaPS gave a presentation on its work on establishing AMS programs in the county and offered technical input in the review process of the CASIC's work plan.
- MTaPS, in collaboration with the County Government of Nyeri and the Food and Agriculture
  Organization of the United Nations (FAO), held a five-day workshop September 21–25, 2020, to
  develop a comprehensive One Health costed CASIC work plan for 2020–2022. The workshop was
  attended by 30 participants (10 female and 20 male), including the County Executive Committee

- Member (CECM) for Health; CECM for Agriculture, Livestock, and Fisheries; Acting Chief Officer cum County Director, Environment, Natural Resources, and Sanitation; Deputy Country Team Leader cum National Coordinator for AMR Programme, FAO Emergency Centre for Transboundary Animal Diseases (ECTAD); and IDDS and MTaPS representatives.
- MTaPS provided technical assistance and financial supported during two quarterly National Infection Prevention Control and Advisory Committee (NIPCAC) meetings on September 30, 2019, and May 18, 2020. NIPCAC has the IPC mandate at the national level and the authority to revise or make recommendations for revising the national IPC guidelines for health care services in Kenya, which should be subjected to review every four years. The NIPCAC, which comprises the MOH and implementing and development partners, should also ensure that health care providers obtain appropriate IPC training. During the meetings, recommendations were made to review the 2015 national IPC policy and strategic plan for health care settings in Kenya. MTaPS provided technical assisitance and financial support during the quarterly County IPC Advisory Committee (CIPCAC) meeting in Nyeri county on November 12, 2019, and the County Health Management Team meeting in Kisumu county on May 29, 2020, during which IPC issues, including findings of the IPC baseline assessments, support supervisions, and performance of IPC activities in MTaPS-supported facilities, were discussed.

#### **RESULT AREA 2: INFECTION PREVENTION AND CONTROL**

## Activity 2.2.1: Provide technical assistance to develop a continuing professional development (CPD)- and re-licensure-linked in-service IPC training course for delivery through professional associations

MTaPS analyzed and disseminated the findings of the IPC CPD training needs assessment to the MOH DPHWS on July 30, 2020, during a virtual meeting with eight attendees. The TWG spearheading the development of the IPC CPD course met on August 4, 2020, with 19 participants (10 male and 9 female) from professional associations, training institutions, and referral hospitals. The NNAK took the lead in the process by hosting the course with collaboration from other professional associations to foster inter-professional learning as part of the journey to self-reliance.

MTaPS, in collaboration with the NNAK, held a three-day TWG workshop August 4–6, 2020, to develop the first draft of the IPC CPD curriculum outline, implementation strategy, and course content. The meeting was attended by 21 participants (11 female and 10 male) from the KMA, KCOA, AKMLSO, KSP, NNAK, NCK, Clinical Officers Council, and MOH.

MTaPS, in collaboration with the NNAK and partnering health professional associations, offered technical and financial support in the review of the draft IPC CPD curriculum and training modules at a workshop September 8–9, 2020.



Education committee during a workshop to develop the IPC CPD course content.

Photo credit: Doris Bota.)

#### Activity 2.5.1: Support county, sub-county, and facility-level IPC activities

MTaPS, in collaboration with the CIPCAC, continued to offer mentorship to IPC teams in HCFs in Nyeri and Kisumu counties in the implementation of their IPC action plans. The target facilities continued to implement IPC interventions through a structured approach led by HCF-based champions. Follow-ups were done through virtual platforms.

MTaPS held virtual health talks on September 17 and 22, 2020, focusing on patient safety targeting HCWs and IPC and AMS committee members in 16 of its supported HCFs in Nyeri and Kisumu counties. The virtual health talks were attended by more than 50 participants, including the CECM for Health (Nyeri County), County Directors for Health (Nyeri and Kisumu counties), Head of the Division for Occupational Safety and Health (OSH), and a representative from the DPHWS. OSH is a component of a typical HCF IPC program.

#### **RESULT AREA 3: USE OF ANTIMICROBIAL MEDICINES OPTIMIZED**

## Activity 3.1.1: Development and implementation of national antimicrobial stewardship guidelines

MTaPS, in collaboration with representatives of the NASIC AMS TWG and the NMTC, provided technical and financial support in a workshop held August 11–14, 2020, to develop the national AMS guidelines dissemination, implementation, and training package. Nine participants (2 male and 7 female) attended the workshop. The AMS resources will be validated, approved, and disseminated in Y3. The training package will be used by the MOH to develop the capacity of HCWs countrywide to establish AMS programs in HCFs.

# Activity 3.1.2: Support to revise the Kenya Essential Medicines List and classify essential medicines list antibiotics into access, watch, and reserve categories

The revised KEML was officially launched by Dr. Rashid Aman, Chief Administrative Secretary, MOH, on July 22, 2020. The event was attended by more than 300 participants from various sectors and counties. A dissemination and implementation plan for the AWaRe categorization of antibiotics will be developed, pending review and ratification, by the NMTC at a workshop scheduled October 15–16, 2020.

MTaPS provided technical support to the Pharmacy and Poisons Board to review the draft guidelines for scheduling and rescheduling health products and technologies in Kenya. The document aims to schedule



and restrict the use of certain medicines, including antimicrobials, and to align them with the AWaRe categorization of antibiotics as outlined in the 2019 KEML. This will promote appropriate use and curb resistance to existing antibiotics. This is an ongoing activity that will be finalized in Y3.

## Activity 3.2.1: Support the University of Nairobi/School of Pharmacy (UON/SOP) to reform the preservice curriculum to integrate AMS-related topics of practical importance

Development of the preservice AMS curriculum was finalized this quarter after undergoing external review by AMS experts in academia, policy, health systems strengthening, and hospital pharmacy practice. The curriculum's modules cover an introduction to AMS; components of AMS programs; core elements for AMS programs; actions and effective interventions to support AMS; AMS potential pitfalls and mitigation; M&E of AMS programs; planning and establishing an AMS program at an HCF; IPC; diagnostic stewardship and surveillance; and leadership, governance, ethics, and communication. Implementation of the curriculum is to begin in October 2020 with postgraduate pharmacy students at the UON and continue into Y3.

## Activity 3.2.2: Technical assistance to develop a continuing professional development and relicensure-linked in-service AMS training course for delivery through professional associations

Development of the in-service AMS curriculum was finalized during this quarter. A plan for implementing the curriculum through professional associations was developed, with the NNAK and PSK hosting their first webinars on September 28 and 29, 2020, respectively.

#### Activity 3.5.1: Support to county, sub-county, and facility-level AMS activities

MTaPS and the Kisumu County Government held phase 2 of the Medicines and Therapeutics Committees (MTCs) and AMS programs for HCF teams. This MTC/AMS training took place July 1–2, 2020. Thirty-eight HCWs (17 female and 21 male) from nine HCFs attended the training. The training focused on identifying problems with medicines use, structures for HCF AMS programs, planning AMS programs in HCFs, and performing AMS interventions in HCFs.

MTaPS, in collaboration with county AMS focal persons, continued to offer mentorship to AMS and MTC teams in HCFs in Nyeri and Kisumu counties in the implementation of their AMS/MTC action plans. The target facilities continued to implement various AMS interventions through a structured approach led by HCF-based champions. Follow-ups were done through virtual platforms. AMS and MTC teams were requested to submit monthly reports highlighting activities accomplished each month.

Highlights of AMS/MTC activities reported during the quarter are provided below.

#### Nyeri county

Othaya Referral Hospital, Nyeri County

With regards to AMS, the process of AWaRe categorization of essential antibiotics dispensed from the hospital is ongoing. In terms of adoption of preauthorization of Watch and Reserve antibiotics, the AMS committee considered existing preauthorization forms and resolved to come up with a facility-specific form considering the medical staff cadres in the hospital. The AMS team developed and issued guidelines to clinicians on antibiotic use in pneumonia, pharyngitis, otitis media, and surgical prophylaxis to enhance prescribing of antimicrobials.

Retrospective audits for prescriptions were conducted between January and June 2020 to determine the extent of antibiotic prescribing in the outpatient setting. Inappropriate prescribing of antibiotics is known to result in AMR, increase cost of care, and increase the risk of adverse events. WHO recommends that the percentage of encounters where an antibiotic is prescribed in the typical outpatient setting should be between 20.0% and 26.8%. <sup>13</sup> The results of the audits are shown in table 9.

Table 9: Proportion of antibiotics prescribed in Othaya Referral Hospital, Nyeri county, January-June 2020

PRESCRIPTIONS	JAN	FEB	MARCH	APRIL	MAY	JUNE
Adula	N=3,014	N=2,794	N=2,711	N=2,665	N=2,657	N=2,282
Adults	40.11%	25.30%	29.83%	23.71%	18.59%	20.03%
Dadiania	N=455	N=510	N=445	N/A	N/A	N/A
Pediatrics	73.18%	65.29%	54.38%			

From the data obtained from the analysis, the AMS team noted that the average for the three months (January–March) was 31.75% for adults and 64.28% for pediatrics, making the average for the hospital 48%. Although there was a steady decline in antimicrobial use for pediatrics in the hospital, even more of a decline is required to ensure that the desired target range is achieved.

The hospital's MTC recommended having carbonated and duplicated prescription books to facilitate retrospective audits of prescriptions. The MTC also resolved to have a facility medicines formulary but agreed that this would be developed progressively with reference to the national essential medicines formulary list. The policy on regulation of medical representatives was disseminated to prescribers, and monitoring is to be done regularly to assess adherence. The committee also resolved to provide treatment guidelines in departments that do not have copies and to provide each department with medication error reporting forms.

#### St. Elizabeth Hospital, Chiga, Kisumu County

The AMS team resolved that since the hospital lacked the necessary infrastructure to carry out culture and sensitivity tests for antibiotics, it should collaborate with Jaramogi Oginga Odinga Teaching and Referral Hospital to send samples for culture and sensitivity testing where feasible.

Retrospective audits for prescriptions were conducted for April and May 2020 to determine the extent of antibiotic prescribing in the outpatient setting. The results of the audits are shown in table 10.

<sup>&</sup>lt;sup>13</sup> The development of standard values for the WHO drug use prescribing indicators. Available at http://archives.who.int/icium/icium/997/posters/1a2\_txt.html

Table 10: Proportion of antibiotics prescribed in St. Elizabeth Chiga Hospital, Kisumu county, April-May 2020

PRESCRIPTIONS	APRIL 2020	MAY 2020
FRESCRIFTIONS	N=103	N=105
Antibiotic	35%	40%
No antibiotic	65%	68%

The proportion of antibiotics prescribed exceeded WHO's recommendation that the percentage of encounters where an antibiotic is prescribed in the typical outpatient setting be between 20.0% and 26.8%. Sharing of results with prescribers and generating approaches to improve prescribing of antibiotics is under way. The AMS team noted that it was a challenge to determine irrational antibiotic prescribing due to limited clinical experience on the Kenyan guidelines on antibiotic prescribing.

The facility MTC conducted retrospective audits for prescriptions for March, April, and May 2020 to determine the extent of polypharmacy. Polypharmacy is a medication use problem where prescribers prescribe three or more medicines to treat the most trivial conditions for the sake of satisfying a patient's need to receive medicines or a pharmaceutical seller's need for profit. Polypharmacy increases the cost of health care for the patient as well as the government and can result in adverse drug reactions due to drug—drug interactions. WHO recommends an average of two medicines per patient encounter in the outpatient setting. The results of the audits are shown in Table 11.

Table 11: Analysis of prescriptions by polypharmacy in St. Elizabeth Chiga Hospital, Kisumu county, March-May 2020

PRESCRIPTIONS	MARCH 2020 APRIL 2020		MAY 2020
PRESCRIPTIONS	N=125	N=103	N=105
Polypharmacy	18%	13%	35%
Non-polypharmacy	82%	87%	65%

Between 13% and 35% of prescriptions over the three months displayed polypharmacy. The MTC plans on sharing the results with prescribers and holding a sensitization session to determine contributing factors, root causes, and mitigation measures.

Outspan Hospital, Nyeri County

The AMS team commenced implementation of the AWaRe categorization of antibiotics in the hospital. One major challenge encountered was the strategy that needs to be adopted to ensure that prescribers adhere to the prescribing guidelines. It was noted that Reserve antibiotics were being prescribed after culture and sensitivity results were out but, in some instances, antibiotics were being prescribed, dispensed, and administered even before the results were released from the laboratory.

#### Nairobi county

2020.

Kenyatta National Hospital, Nairobi county

MTaPS offered technical input into the review of this teaching and referral hospital's AMS policy and prescribing guidelines. MTaPS also offered technical and financial support in the second review of the hospital's medicines formulary September 16–17, 2020. The formulary is a tool that the hospital's MTC uses to guide appropriate use of medicines in the hospital. The formulary is undergoing final review and should be finalized by end of September 2020.

Gertrude's Children's Hospital, Nairobi county

MTaPS offered technical assistance to the hospital's AMS committee to review the hospital's AMS policies, guidelines, and standard treatment guidelines for infections.

below:

MTaPS participated in and provided technical

MTaPS also took part in the activities summarized



Participants at the workshop to review Kenyatta National Hospital's 2nd edition of its medicines formulary. Photo credit: Collins Jaguga, USAID

- support as a member of the panel of judges in a hackathon organized by Africa One Health University Network (AFROHUN), formerly One Health Central and Eastern Africa, on the One Health Application Development Challenge for university students. This activity was undertaken as part of the One Health Workforce Next Gen Project, implemented by a University of California Davis-led consortium with funding and support from USAID. Eight multidisciplinary students were challenged to leverage technology and develop a solution that can be used by frontline workers in responding to public health challenges using a One Health approach. The winning team developed an application that was intended to be used by community health volunteers to educate the public on zoonotic diseases August 31-September 2,
- MTaPS attended and participated in a workshop on September 14, 2020, organized by AFROHUN to validate findings following the completion of a mapping of strategic One Health partners and a training needs assessment for frontline workers to chart a way forward for future engagement. In another workshop September 21–25, 2020, MTaPS and AFROHUN offered technical input toward review of an AMR curriculum for in-service training on AMR stewardship for human, animal, and environmental health professionals in Kenya.
- MTaPS provided technical and financial assistance to the MOH Directorate of Standards, Quality Assurance, Policy, and Regulation to organize a celebration of World Patient Safety Day on September 17, 2020. The theme for this year's event was "Health Workers Safety: A Priority for Patient Safety" and was mainly informed by the COVID-19 pandemic. MTaPS provided a monument and the MTaPS/Kenya Country Project Director gave opening remarks in a virtual commemoration attended by more than 600 participants. MTaPS held virtual health talks September 17 and 22, 2020, focusing on patient safety targeting HCWs and IPC and AMS committee members in 16 of its supported HCFs in Nyeri and Kisumu counties. The virtual health talks were attended by more than 50 participants, including the CECM for Health (Nyeri County), County Directors for Health (Nyeri and Kisumu counties), Head of Division for OSH, and a representative from the DPHWS.

#### ACTIVITIES FOR NEXT QUARTER

ACTIVITIES FOR NEXT QUARTER	
ACTIVITY AND DESCRIPTION	DATES
Activity 1.1.1: NASIC'S IPC and AMS Technical Working Groups	Oct.–Dec. 2020
<ul> <li>Participation in monthly AMS TWG meetings to offer technical advice in the implementation of the team's work plan</li> <li>Review of national AMS guidelines dissemination, implementation, and training package</li> <li>Participation in monthly IPC TWG meetings to offer technical advice in the implementation of the team's work plan</li> <li>Finalization of M&amp;E framework, including costing and implementation plan</li> </ul>	
Activity 2.2.1: Technical assistance to develop a continuing professional development (CPD)- and re-licensure-linked in-service IPC training course for delivery through professional associations	Oct.–Dec. 2020
<ul> <li>Application of updated IPC/CPD materials in target CPD sessions</li> <li>E-learning course development and piloting</li> </ul>	
Activity 2.5.1: Support to county, sub-county, and facility-level IPC activities	Oct.–Dec. 2020
Technical supportive supervision and mentorship in the implementation of county and health facility IPC interventions (Nyeri and Kisumu counties)	
Activity 3.1.1: Support the development and implementation of national antimicrobial stewardship guidelines	Oct.–Dec. 2020
<ul> <li>Final review, validation, and implementation of the AMS guidelines dissemination, implementation, and training package</li> </ul>	
Activity 3.1.2: Support revision of KEML and classify EML antibiotics into AWaRe categories	Oct.–Dec. 2020
Review, validate, and implement the AWaRe dissemination and implementation plan	
Activity 3.2.1: Support UON/SOP to reform preservice curriculum to integrate AMS-related topics of practical importance	Oct.–Dec. 2020
Implementation of the preservice AMS curriculum among pharmacy postgraduate students at UON/SOP	
Activity 3.2.2: Provide technical assistance to develop a CPD- and re-licensure-linked in-service AMS course for delivery through professional associations	Oct.–Dec. 2020
Application of AMS CPD resources in target CPD sessions	
Activity 3.5.1: Support to county, sub-county, and facility-level AMS activities	Oct.–Dec. 2020
Technical supportive supervision and mentorship in the implementation of county and health-facility AMS interventions (Nyeri and Kisumu counties)	

#### **MALI**

For progress on MTaPS/Mali's COVID-19 activities, click here.

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

This year was marked by the start of the COVID-19 pandemic, which has greatly impacted the implementation of planned activities. In particular, the quarterly meetings of the National Multisectoral Coordination Group (GCMN) and its two technical working groups (TWGs) have been affected, as most members are deeply involved in the COVID-19 response. However, MTaPS has continued to work with the GCMN through small working groups from the infection prevention and control (IPC) and antimicrobial stewardship (AMS) TWGs. MTaPS provided support to launch the GCMN, which included organizing workshops to develop its terms of reference (TOR). The launch of GCMN activities enabled working groups to hold four meetings, produce reports, and act on recommendations. The MTaPS team also participated in the meetings of the One Health Platform. During one of the meetings, the MTaPS team presented its project to all stakeholders. As deliverables, the validated TOR for the multisectoral group and IPC and AMS TWGs and meeting reports are available.

MTaPS supported the GCMN and General Health Directorate (DGS) to revise IPC guidelines for the human sector. MTaPS also provided technical support to organize a competency-based workshop to build the skills of the GCMN (including the DGS) on the design and delivery of innovative capacitybuilding approaches to IPC training for 30 participants from the human and animal health sectors. Participants produced a competency-based curriculum consisting of a facilitator guide, a participant manual based on IPC guidelines, PowerPoint slides covering 20 sessions, and job aids. The abovementioned documents are elements of the training toolkit. In the context of COVID-19, MTaPS, the GCMN, and the IPC/COVID-19 subcommittee adapted the toolkit to train trainers and health care providers. The training toolkit serves as reference material for IPC in Mali. In addition, MTaPS, in collaboration with EMPOWER, developed 10 IPC e-learning modules; installed the Moodle platform at three local institutions (DGS, Institut National de Formation des Sciences en Santé-INFSS, and Faculty of Medicine); and trained their respective IT staff to use and manage the platform. The installation of the three Moodle platforms was done with multisectoral engagement, notably with stakeholders from the human, animal, agricultural, and environmental sectors. This approach contributes to strengthening communication and raising awareness among stakeholders on the issue of antimicrobial resistance (AMR).

MTaPS/Mali collaborated with the National Directorate of Veterinary Services (DNVS) and the AMR Secretariat to conduct a nationwide rapid assessment of hygiene and IPC in the animal health sector. The results showed that IPC practices in the animal health sector were at the basic level (with a score of 287; basic range: 151–300). The scores for four key components—environment, buildings, materials, and equipment; education and training; monitoring and evaluation; and IPC program—were weaker than the other two components evaluated, which were animal disease prevention and control guidelines and strategies for implementing interventions. The assessment results informed the development of IPC guidelines and an action plan for the animal health sector to support the DNSV.

Regarding AMS, MTaPS supported a rapid assessment of stewardship policies and regulations and supply chain management of antimicrobials in the human and animal health sectors. The findings were validated with stakeholders from the different sectors. The report is available, and the results informed the development of AMS action plans for the human and animal health sectors.

MTaPS, under AMS TWG leadership through the Directorate of Pharmacy and Medicine (DPM), worked with local stakeholders to collect service statistics on infectious diseases treated at the facility level for the past five years and other documents to inform the development of standard treatment guidelines

(STGs) for infectious diseases, as well as to group essential medicines list antibiotics into the AWaRe categories. It was through MTaPS that the AMS group first heard of AWaRe. During the orientation workshop, it was revealed that colistin is used as a first-line drug in the animal sector despite its classification in the WHO reserve category. Participants raised concerns about the abuse of antibiotics in both the animal health sector and health facilities. The representative of the National Insurance Fund of Mali declared, "I have goose bumps when I see all the damage that antimicrobial resistance causes, and I believe that the implementation of the AWaRe concept will certainly make it possible to have more adequate use of antibiotics and to reduce the cost of prescriptions since these products represent more than 50% of prescription costs." The country adopted AWaRe, and the implementation process is ongoing. Three of I I steps were completed, and the remaining steps of this activity will continue in Year 3.

MTaPS, in collaboration with the DPM team and the AMS TWG of the GCMN, conducted facility visits to the five selected sites in January 2020 to discuss the establishment of Drug and Therapeutics Committees (DTCs) and the assessment of AMS activities using the WHO tool. The visits revealed that the five sites did not have DTCs, nor were there guidelines for setting up DTCs. TOR and training materials based on national guidelines and protocols need to be developed.

#### **QUARTER PROGRESS FOR FY20Q4**

#### RESULT AREA I: EFFECTIVE MULTISECTORAL COORDINATION ON AMR

No activity took place this quarter, as all coordination activities were focused on COVID-19.

#### **RESULT AREA 2: INFECTION PREVENTION AND CONTROL**

#### Activity 2.1.1: Strengthen IPC programming at the central and peripheral levels

During this quarter, MTaPS collaborated with the DNSV and the GCMN to develop IPC guidelines and an action plan for the animal health sector to support the DNSV. The results of the rapid assessment of hygiene and IPC in the animal health sector were used during this process. An animal health sector expert validated the methodology developed by a consultant. To collect complementary data, the consultant carried out site visits to two slaughterhouses (Baguineda and Kanadjiguila). The developed IPC guidelines and plan were shared with the DNSV, and the validation workshop is scheduled for September 30–October 2, 2020.

#### **RESULT AREA 3: USE OF ANTIMICROBIAL MEDICINES OPTIMIZED**

#### Activity 3.1.1: Strengthen AMS

During this quarter, MTaPS worked with stakeholders to develop STGs for infectious diseases, which was done under AMS TWG leadership through the DPM. The results of the rapid assessment of stewardship policies and regulations and supply chain management of antimicrobials in the human and animal health sectors were used to develop the AMS action plan. The work was done by two consultants from the animal and human health sectors whose methodology was validated by experts from both the agriculture and environment sectors. This activity was co-led by the DPM and DNSV directors. The draft version has been reviewed by HQ and will be validated in October 2020.

#### Activity 3.5.1: Support the DPM to establish the DTCs in the five selected sites

During this quarter, MTaPS, in collaboration with the GCMN, DPM, and Agence Nationale d'Evaluation des Hôpitaux (ANEH), facilitated the:

Validation of the TOR for DTCs

- Selection and formal nomination of DTC members in national hospitals (Point G and Luxembourg), regional hospitals (Nianakoro Fomba de Segou and Hospital of Sikasso), and the district hospital of Koutiala
- Development of eight DTC modules and data collection tools
- Establishment of facility DTCs to improve practices around antimicrobial prescribing, dispensing, and use by ensuring adherence to related guidelines and by disseminating educational materials to aid compliance with medication instructions



Participants in a working session to develop and update DTC training modules. Photo credit: Ousmane Traore, STA, MTaPS

#### **ACTIVITIES FOR NEXT QUARTER**

ACTIVITY AND DESCRIPTION	Date
Activity 2.1.1: Strengthen IPC programming at the central and peripheral levels - Develop national guidelines for IPC in animal health: Validation workshop	Oct. 2
Activity 3.1.1: Strengthen AMS - Develop the national action plan for AMS and develop AMS guidelines in the human sector	Oct. 8
Activity 1.1.1: Provide technical and operational support to the National Multisectoral Coordination Group (GCMN) and its two subcommittees (IPC and AMS)	Oct.– Dec.
Activity 2.1.1: Support the GCMN-RAM and DNSV to print and disseminate IPC guidelines for the animal sector	Nov.
Activity 2.5.1: Support the GCMN and DGSHP to implement IPC programming at new health facilities	Nov.–Dec.
Activity 2.5.2: Support the GCMN and DGSHP to monitor the implementation of IPC practices at health facilities	Oct.–Dec.
Activity 2.5.3: Strengthen institutional capacity building for local training institutions to manage elearning on IPC and AMS for both pre- and in-service health care workers	Dec.
Activity 3.5.1: Support the GCMN, DPM, and ANEH to establish DTCs in 13 new sites	Nov.–Dec.

#### **MOZAMBIQUE**

For progress on MTaPS/Mozambique's COVID-19 activities, click here.

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

During Program Year 2, MTaPS provided support and technical assistance to establish the regulatory framework for control of medical products on the market in Mozambique. Reference was made to the observations and findings in the assessment report of the legal and regulatory framework conducted in Year I. Overall, the MTaPS team supported the National Directorate of Pharmacy (DNF) to draft five regulations and guidelines for medicines registration, regulatory inspections, licensing of pharmaceutical establishments, pharmacovigilance (PV), and pharmacy practice for further administration of Law I2/2017 and with reference to the gaps identified in the 2018 World Health Organization (WHO) Global Benchmarking Tool (GBT) assessment. In addition, MTaPS provided technical assistance to develop guidelines for medicines registration specifically focusing on labeling of medicines and package leaflets.

Capacity development for regulation of medical products is critical to ensure effective regulatory services in a country and ensure access to quality assured, safe, and efficacious medical products. MTaPS provided technical assistance to build capacity of DNF personnel using impact-driven approaches and methodologies. During the last two quarters of Year 2, MTaPS provided two capacity building courses in the regulatory area on development of regulations and orientation on stakeholder engagement and on principles and application of Good Review Practices for medicines registration. The courses enriched the DNF legal and registration teams with practical skills and knowledge to fully understand and implement Good Regulatory Practices and Good Review Practices, which will contribute to a more successful professional, efficient, and transparent approach in their regulatory practices and facilitate the provision of safe, effective, and quality medicines to the Mozambican population.

During Q2, MTaPS developed Pharmadex's medicine importation module to allow applicants to request import authorization online and print import authorization documents. During Q3, the DNF recognized that the developed module meets the requirements specified in the DNF import standard operating procedure (SOP) but requested that more functionalities be added to the import module. Therefore, in Q4, MTaPS finalized the development of additional functionalities, including import of nonmedicines and import of nonregistered products for emergency situations. Pharmadex's medicine importation module will reduce the DNF's paperwork and workload to produce statistical reports.

In Q4, MTaPS developed and finalized system requirements specifications for the premises licensing module of Pharmadex based on SOPs and information collected from the DNF. The system requirements specifications document is the foundation for development of the premises licensing module in Pharmadex, which will provide functionalities to allow applicants to submit online applications for licensing authorization of premises and improve customer service and efficiency as applicants will no longer be required to travel to the DNF.

A functional Quality Management System (QMS) increases legitimacy, prevents mistakes, reduces costs, and has a positive impact on regulatory outputs. MTaPS, in partnership with Celsian, supported the DNF to establish a QMS for the medicines regulatory authority as required for attainment of maturity level 3 in the WHO GBT and ISO 9001:2015 certification. Also, in partnership with Celsian, MTaPS worked with the DNF to review the quality policy and initiate development of a quality manual for effective management of regulatory activities leading to accreditation. The support entailed providing capacity building sessions to DNF management and operational technical personnel to create awareness about QMS, share knowledge on risk management, and perform a situational analysis of the DNF QMS. Implementing a QMS will enable the DNF comply with international standards with well-defined and controlled procedures that promote transparency and accountability in specified regulatory functions.

To establish an active surveillance system for monitoring HIV patients on the tenofovir + lamivudine + dolutegravir (TLD) regimen, during Q2 MTaPS supported the DNF and the national HIV program to train 14 provincial focal persons from seven provinces and 72 health care workers, while 368 health care workers from nine participating health facilities (HFs) were sensitized on the protocol for active surveillance of TLD and proper data collection. In March, the MTaPS team supported the HIV program in conjunction with the DNF and HF staff to follow-up enrolled patients to ensure they complete all scheduled follow-up visits and that clinical staff document all follow-up visits even if the patient did not have any adverse events. A total of 1,936 patients were enrolled into the cohort in the nine participating HFs as of August 2020. During Q3 and Q4, onsite support supervisory visits were not possible due to the COVID-19 situation. MTaPS supported the DNF and HIV program to conduct virtual central-level supportive supervision through phone calls to participating sites and ensure monthly support supervisory calls to participating sites by provincial focal points. Based on the information collected in the supervision calls, MTaPS produced a follow-up call report that contains key findings on implementation from the different facilities, key implementation challenges, mitigation measures, recommendations, and next steps for proper implementation of the protocol based on each facility's situation. The supervisory calls allowed the team to monitor the sites to ensure adherence to the protocol and support quality and consistency of the process, including data collection.

Following the implementation of the active surveillance system to ensure proper collection, entry, management, and analysis of safety data generated from the activity, during Q2, MTaPS, in conjunction with Columbus Consulting, adapted the Pharmacovigilance Information Management System (PViMS) to the Mozambique context and procured and configured tablets to be used in 10 HFs for data entry into PViMS. In Q3, MTaPS and Columbus Consulting trained DNF and national HIV program staff as PViMS master trainers, supported the training of 34 health workers from nine HFs on PViMS data entry, deployed PViMS for data collection in the selected HFs, and supported the data synchronization process from the HF to the central level. In Q4, MTaPS further facilitated two trainings to equip national-level DNF and national HIV program staff on data analysis using PViMS and to equip the DNF system administration team on data management, troubleshooting the tool, and providing IT assistance to PViMS users.

In Q1, the MTaPS team provided technical support to the Hospital Pharmacy Department (DFH) to adapt in-service antimicrobial stewardship (AMS) training materials for health care workers to the country context. In Q2, MTaPS conducted a training of trainers (ToT) to provide Ministry of Health (MOH) staff (DHF and National Directorate of Medical Assistance) with the capacity to facilitate health worker training and supported the training of 31 health providers (12 female and 19 male) from seven provincial hospitals and three general hospitals in Maputo City. MTaPS supported each provincial hospital to develop its own antimicrobial resistance action plan by applying a systematic approach to review the current situation and processes, identify critical problems, and prioritize key mitigation actions using available resources. MTaPS is supporting the DFH to receive, review and document monthly reports from HFs on AMS implementation.

#### **QUARTER PROGRESS FOR FY20Q4**

#### **OBJECTIVE 1: PHARMACEUTICAL-SECTOR GOVERNANCE STRENGTHENED**

### I.I.I. Support the MOH in Mozambique to operationalize new legislation for establishing ANARME, a semi-autonomous regulatory authority

Transforming the National Directorate of Pharmacy (DNF) into a new semi-autonomous authority, Autoridade Nacional Reguladora de Medicamentos de Moçambique (ANARME), according to Law 12/2017 of September 8, 2017, on Medicines, Vaccines, and Biological Products requires establishment of regulations for control of medical products on the market in Mozambique. As part of its ongoing

efforts to establish regulations for all key regulatory functions to achieve this requirement, in Q4 MTaPS, in conjunction with an independent consultant, worked to review the DNF regulation on PV in accordance with good legislative practices, WHO GBT recommendations, and the overarching medicines law. The updated draft regulation on PV provides clear roles, responsibilities, and coordination of different entities involved in monitoring and reporting medicine adverse events. The previous decree specified a complicated notification system for adverse drug reactions by providing a long list of entities that appeared to be tasked with receiving notifications, without a comprehensive structure that clearly defines the relationship to the National Centre of Pharmacovigilance. The updated regulation will remove the overlap and establish a workable enforcement structure.

Using a strategic approach for sustainability and knowledge transfer, MTaPS conducted a four-day capacity building course on development of regulations and orientation on stakeholder engagement for DNF personnel. The course involved 20 participants (16 female and 4 male).

Participants included the DNF legal team, which is directly involved in the elaboration of regulations, resolutions, decrees, and guidelines, and key technical regulatory personnel. The training offered knowledge and practical illustrations on good regulatory practices and standards of regulation content, the process of drafting a regulation, and how to undertake stakeholder consultation.

Besides the guidance on stakeholder orientation, the course provided the DNF with practical skills and hands-on experience for the development, analysis, interpretation and discussion of regulations as well as tools to fully understand pharmaceutical regulation, legal argumentation, and enforcement. This course will contribute to greater professionalism at the DNF and a more conscious practice of the components of rationality while addressing legal tasks presented in the regulation of medicines and other health products in compliance with Good Regulatory Practices to guarantee safe, effective, and quality medicines to the Mozambican population.

To foster capacity development for DNF personnel in medical products registration, MTaPS conducted a two-day capacity building course on principles and application of Good Review Practices for medicines registration. The course was aimed at providing knowledge and information on international guidance and application of Good Review Practices for registration of medical products at the DNF.



Photo caption: National Pharmacy Directorate working group during the training in Good Review Practices. Photo credit: Eunice Dias Seni, MTaPS Mozambique

The course involved 12 DNF participants (10 female and 2 male), including medical products registration personnel directly involved in product assessment and clinical trials personnel. The training offered knowledge and practical illustrations on principles of Good Review Practices and conducting and managing the review process.

The course improved the knowledge and awareness of DNF medicines registration personnel on Good Review Practices and provided skills to improve medical product dossier evaluation, strategic communication for internal and external clients, and project management in relation to medical product dossier assessment.

The achievements made in this quarter will contribute to effective pharmaceutical governance and a

robust legal framework so that the medicine regulatory authority can ensure increased availability of and access to safe, efficacious, and quality-assured medicines.

# OBJECTIVE 2: INSTITUTIONAL AND HUMAN RESOURCE CAPACITY FOR PHARMACEUTICAL MANAGEMENT AND SERVICES INCREASED, INCLUDING REGULATION OF MEDICAL PRODUCTS

### 2.1.1 Strengthen use of electronic information technology solutions for efficient and transparent medicine regulatory processes

With support from MTaPS, Link Informatica, an IT services company, is providing essential limited support to the DNF to ensure continued functionality of Pharmadex for medicine registration and PViMS, including maintaining the DNF servers and a computer network, providing technical support, and ensuring that DNF IT systems are running smoothly.

During this quarter, MTaPS developed system requirements specifications for the premises licensing module of Pharmadex based on SOPs and information collected from the DNF. The system requirements specifications document has content covering the overview of the licensing process, software functions, data and software security, environment, future development and extensions, documentation requirements, performance indicators, implementation schedule, and acceptance criteria. The system requirements specifications document is the foundation for future development of the premises licensing module in Pharmadex, which will provide functionalities to allow applicants to submit online applications for licensing authorization of premises and improve customer service and efficiency as applicants will no longer be required to submit applications physically at the DNF.

During the last quarter, MTaPS conducted a user acceptance test with the DNF to get approval on the import module of Pharmadex. The DNF recognized that the developed module meets with the requirements specified in the DNF import SOP but requested that more functionalities be added to the import module. As a result, during this quarter, MTaPS developed two additional functionalities for import of nonmedicines and import of nonregistered products for emergency situations. Pharmadex's medicine importation module will allow applicants to request import authorization online and print import authorization documents, which will reduce the DNF's paperwork and workload to produce statistical reports.

During this quarter, MTaPS continued working with DNF counterparts to get approval from the DNF on cloud-based solutions to make the online version of Pharmadex fully functional. In the last quarter, MTaPS met with the DNF senior leadership team to explain the advantages of the proposed solution and the sustainability plan. As a result, during this quarter, MTaPS submitted an official letter to DNF senior leadership to facilitate a data use agreement to allow deployment of the internet-ready version of Pharmadex on the internet server (cloud). The letter indicated the IT service provider responsible for hosting the data, how data will be protected, and where data will be stored. MTaPS also prepared a nondisclosure agreement to prevent the unauthorized disclosure of confidential PViMS and Pharmadex information by Management Sciences for Health (MSH), its employees, contractors, agents, or assignees that is to be signed by MSH and the DNF. The letter and nondisclosure agreement were shared with the DNF and are pending signatures. Cloud hosting will offer the DNF advantages in terms of solution performance, lower internet costs, and higher data security—conditions that make this solution the most compatible with the current state of the infrastructure and internet at the DNF.

With the deployment of this new version of Pharmadex, pharmaceutical companies can submit applications for marketing authorization of medicines online. This enhancement is intended to improve speed, transparency, and quality of the medicine registration process; reduce the clerical workload; and improve customer service and efficiency, thereby easing access to quality-assured, safe, and effective medicines for the population of Mozambique.

### 2.1.2 Support DNF to develop a QMS leading to ISO 9001:2015 accreditation (Activity Continuing from FY19)

During Q4, MTaPS worked with the DNF to finalize the draft quality manual to reflect the desired QMS at the national regulatory authority in accordance with the reference guidance from the ISO 9001 standard; the WHO GBT; and DNF governance documents, including Law 12/2017. The quality manual establishes and defines the QMS that the DNF has adopted and entrenched, which complies with ISO 9001:2015 and is in line with the DNF's own objectives and requirements. This is achieved by defining responsibilities and authority levels; managing process inputs, controls, and outputs to ensure that the desired results are achieved; and managing the interfaces among interrelated processes to ensure system effectiveness is maintained, thereby reducing potential risk.

One of the requirements for implementation of a QMS is to ensure that an internal auditing system and compliance are in place. MTaPS worked with the DNF to develop the terms of reference for a capacity building course in internal auditing for DNF auditors. The course is aimed at equipping DNF personnel with internal auditing skills to assess compliance of the various regulatory services and activities to the ISO standards with the objective of attaining effective regulatory services and customer satisfaction. MTaPS plans to help the DNF and conduct the capacity building session in October 2020.

### OBJECTIVE 3: STRENGTHEN SYSTEMS FOR PROVIDING PATIENT-CENTERED PHARMACEUTICAL CARE AND SERVICES

### 3.1.1 Provide technical assistance to establish an active surveillance system for newly introduced medicines in HIV and TB programs

During this quarter, MTaPS supported the DNF and HIV program to conduct central-level support supervisory calls and to ensure monthly supportive supervision of participating HFs by provincial focal points. Based on information collected during the supervisory calls, MTaPS produced a follow-up call report that contains:

- Key findings on implementation from HFs, including Mavalane, Machava II, Ndlavela, Macia, Carmelo, Marrere, Namacurra, Gondola, and Cuamba
- Key Implementation challenges reported by the facilities
- Mitigation measures for proper implementation of the protocol based on clinical situation
- Recommendations and next steps, responsible parties, and deadlines

Key recommendations for improving the process include:

- Prescreening of patients at the facility reception to identify those eligible to be enrolled in the active PV surveillance system
- Adequate planning for data entry into PViMS
- On-the-job training for clinicians on how to correctly complete forms
- Completing form B for all patients being followed up by phone calls even if there were no adverse events
- Making monthly follow-up calls to patients who did not come to the HF for follow-up
- Placing the identification (MAS in Portuguese) code on the master file and the patient card to easily identify patients on the monitoring program

Supervisory calls allowed the team to monitor the sites to ensure adherence to the protocol and support quality and consistency of the process, including data collection.

During this quarter, the MTaPS team continued to support the HIV program, in conjunction with DNF and HF staff, to follow up enrolled patients to ensure they complete all scheduled follow-up visits and that clinical staff document any adverse events. A total of 1,936 patients were enrolled into the cohort in the nine participating HFs as of August 2020 (table 12).

Table 12: Patients enrolled since start of active surveillance system

HEALTH FACILITY	MONTH ENROLLMENT COMMENCED	NO. OF ENROLLED PATIENTS AS OF AUGUST 2020 (FORM A)	NO. OF PATIENTS WITH FOLLOW UP VISIT (FORM B)	NUMBER OF PATIENTS WITH A PREGNANCY OUTCOME (FORM C)
Carmelo	March	220	70	0
Gondola	March	210	160	8
Namacurra	March	165	13	0
Marrere	March	326	116	0
Macia	April	230	26	0
Cuamba	April	120	0	0
Mavalane	April	265	2	0
Machava II	April	250	41	0
Ndlavela	May	150	10	3
Total		1,936	438	П

### 3.1.2 Adapt the Pharmacovigilance Monitoring System (PViMS) to the Mozambique context and train DNF staff and data collectors on its use

Following implementation of the active surveillance system and to ensure that the collected data are analyzed by the DNF and utilized for regulatory and clinical decision making, MTaPS, with support from Columbus Consulting, facilitated a three-day ToT to equip the national-level team of DNF and HIV program staff on use of PViMS for data analysis.

The training was conducted online because of the restrictions in movement due to the COVID-19 lockdown using synchronous learning with video and audio conferencing for communication between facilitators in South Africa and Nigeria and trainees in Mozambique. The training comprised didactic sessions, demo sessions, and practical exercises.

During the training, seven professionals (three female and four male) were trained on use of PViMS for data analysis, including:

- Collection of longitudinal clinical data for all patients with a focus on complete medication history and list of adverse events experienced
- PV analysis on all adverse drug events, including medicine coding, setting of terminology, and medication causality
- Signal detection, data trends, and reporting results
- Reporting on clinical data collected and analysis conducted

The trainees included one investigator (DNF), two co-investigators (DNF and HIV), two system administrators (DNF), and two DNF PV technicians.

MTaPS, with support from Columbus Consulting, also facilitated a two-day system administrator training to equip the DNF system administration team to provide IT support to PViMS users at the HF and central levels and to troubleshoot potential problems with the tool.

The training was conducted online due to COVID-19-related restrictions in movement using synchronous learning with video and audio conferencing for communication among facilitators in South Africa and Nigeria and trainees in Mozambique. Two professionals from the DNF and two from Link Informatica were trained on:

- Audit trail
- User configuration
- System configuration

- Reference data
- Work configuration
- Information and reporting

### 3.2.1 Strengthen Drugs and Therapeutics Committees (DTCs) to promote appropriate use of medicines and AMS

During this quarter, MTaPS continued to support the DFH to receive, review, and document monthly reports from HFs on AMS implementation. In addition, a draft implementation status report on AMS activities in selected HFs is being developed that will provide a description of the implementation process, including capacity building on antimicrobial resistance and development and follow up of HF AMS action plans. The report will provide conclusions and recommendations that will allow health care workers to implement AMS interventions in prioritized HFs as part of the multipronged technical approach.

#### **ACTIVITIES FOR NEXT QUARTER**

#### ACTIVITY AND DESCRIPTION

**DATE (2020)** 

Activity I.I.I Support the MOH in Mozambique to operationalize new legislation for establishing ANARME, a semi-autonomous regulatory authority

October– November

October-

December

- Continue to draft guidelines agreed with DNF for licensing and registration
- Review SOPs for licensing and registration in line with Pharmadex
- Conducting virtual remote stakeholder consultation in agreement with DNF

Activity 2.1.1 Strengthen use of electronic information technology solutions for efficient and transparent medicine regulatory processes

IT support company for Pharmadex:

Supervise services delivered to DNF

Implement new version of Pharmadex:

- Obtain agreement with DNF to deploy new online version of Pharmadex using cloud solution
- Test new version of Pharmadex using cloud solution
- Conduct training on the online version:
- Deploy new version of Pharmadex using cloud solution
- Compare cloud solution performance/new Pharmadex server and document results

Implement import module of Pharmadex:

- Develop the new functionalities requested by the DNF to be added to the import module
- Conduct import module ToT and other user acceptance testing for version 2 (online version) to approve the requested functionalities

Activity 2.1.2 Support DNF to develop a QMS leading to ISO 9001:2015 accreditation (activity continuing from FY19)

Finalize the QMS manual:

- Complete information according to Southern African Development Community requirements Organize and conduct an internal audit (IA) training for DNF staff:
  - Develop course content and training materials to build capacity
  - Organize logistics for conducting virtual learning sessions
  - Conduct the training

Perform IA desk review:

October-December

- Collect desk review requirements
- Plan desk review
- Conduct desk review

Perform gap analysis:

- Collect gap analysis requirements
- Plan gap analysis
- Conduct gap analysis

#### **ACTIVITIES FOR NEXT QUARTER**

#### **ACTIVITY AND DESCRIPTION DATE (2020)** Activity 3.1.1 Provide technical assistance to establish an active surveillance system for newly introduced medicines in HIV and TB programs Continue enrollment and follow up of enrolled patients on dolutegravir (DTG) October-December Support monthly support supervision of participating sites by provincial focal points Support DNF and HIV program to provide central-level supportive supervision and monitoring of the sites to ensure adherence to protocol Support periodic coordination and review meeting Activity 3.1.2 Adapt the Pharmacovigilance Monitoring System (PViMS) to the Mozambique context and train DNF staff and data collectors on its use October-Review the PViMS manual December Support periodic data cleaning and analysis Support use of data for clinical and regulatory decision making Activity 3.2.1 Strengthen Drugs and Therapeutics Committees (DTCs) to promote appropriate use of medicines and AMS AMS action plans Continue to review and document AMS action plans developed by the seven HFs during the October-AMS training December Health facility reports Continue to support the DFH on the report template, and receive, review, and document monthly reports from HFs on AMS implementation Produce report on implementation

Finalize the report on implementation of agreed-upon AMS activities

#### **NEPAL**

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY19–20)**

MTaPS activities have continued but have been hampered by the inability to organize meetings and broad stakeholder consultations due to COVID-19. For example, the zero draft of the new drug law and the reorganization options finalized in September are awaiting broader stakeholder consultation. The technical legislative gap analysis and the zero draft law will facilitate the Department of Drug Administration's (DDA) draft of a new medicines product law that is expected to be ready to submit to the Ministry of Health and Population (MOHP) in October. All existing regulations, codes, and guidelines have been translated into English, and based on the mapping of these documents, a priority list for updating them to align with the new law can be agreed to and updates can start next quarter.

The final comparative analysis of selected countries' drug regulatory authorities' organizational structures formed the basis for proposing different options for the DDA's new organizational structure. After being presented to the DDA, the options are being discussed and should be ready for wider consultation at the end October.

The quality management system (QMS) technical gap analysis was used to draft the QMS manual, which will include standard operating procedures (SOPs) for all DDA functions; however, finalizing the manual is on hold until targeted training sessions are conducted to increase the DDA staff's QMS capacity. Training sessions are scheduled for the beginning of October, and two more are expected by the end of October.

The planned virtual meeting between the DDA, the World Health Organization (WHO), MTaPS, and Promoting the Quality of Medicines Plus (PQM+) to discuss verification of the DDA's Global Benchmarking Tool (GBT) maturity level has again been postponed until the end of October. The GBT report will inform the development of the DDA's institutional development plan (IDP) and the five-year strategic plan.

Following the options analysis for the DDA's regulatory management information system (MIS), the DDA decided to transition to the Pharmadex system, and the SQL source code for the existing Drug Administration Management System's (DAMS) MIS was transitioned to MTaPS at the end of September. MTaPS drafted the system requirement specifications, which should be finalized by the end of October after discussions with the DDA. With MTaPS now having the SQL source code and with the finalized system requirement specifications, the installation of Pharmadex, which initially will run in parallel with DAMS, can begin.

Following USAID's feedback on the performance indicator reference sheets and performance indicator tracking table, MTaPS submitted the final monitoring, evaluation, and learning (MEL) plan at the end of September. Recruitment of three technical staff members and one administrative staff member as per the approved 2020/21 work plan has started. MTaPS held monthly update and progress meetings with PQM+, the USAID Mission, and the DDA in July, August, and September, and four-corner update meetings were held at the end of July and the end of September.

#### QUARTER PROGRESS FOR FY20Q4

#### **OBJECTIVE I: PHARMACEUTICAL-SECTOR GOVERNANCE STRENGTHENED**

MTaPS partner Celsian finalized and submitted to the DDA a report on the comparative analysis of the autonomy, scope, and structure of national medicines regulatory agencies from selected countries. Based on the comparative analysis, Celsian submitted another report that proposes different

organogram options for the FDA. MTaPS reviewed the report and has begun its discussion with the DDA to finalize it for wider consultation in October 2020.

Based on the feedback received from the DDA, National Medicine Laboratory, and PQM+, MTaPS completed the technical report on the pharmaceutical legal and regulatory framework and gaps in Nepal. The report will be widely circulated in early October 2020. Following consultation with the DDA, National Medicine Laboratory, MTaPS, and PQM+ in the previous quarter, MTaPS partner International Law Institute-African Center for Legal Excellence prepared and submitted a zero draft of the drug law for feedback. The zero draft, which addresses gaps identified in the technical report, is expected to be finalized in October 2020. The zero draft law should act as a resource document for the DDA to draw up the new Nepal medicines law and to map regulations and codes that need updating. However, at the end of September the MOHP set a challenging timeline to finish drafting the new law, and as a result of this new deadline, the zero draft law will likely not be discussed fully or finalized in time to serve as an absolute and complete resource document for the drug law amendment.

MTaPS supported the DDA to translate the final four existing codes and guidelines from Nepali to English<sup>14</sup> to be uploaded to the DDA website. The upload is still pending and may be delayed until an external consulting firm updates the website with MTaPS' support.

MTaPS is also assisting the DDA to map current regulations, codes, and guidelines as mentioned above, which should be completed and agreed to in the next quarter. The mapping and the new draft law will guide the revision of these documents in the next quarter.

### OBJECTIVE 2: INSTITUTIONAL AND HUMAN RESOURCE CAPACITY TO REGULATE MEDICINES, FAMILY PLANNING COMMODITIES, AND HEALTH TECHNOLOGIES INCREASED

MTaPS assisted in the drafting of the WHO GBT verification report in June and submitted it with plans for discussion and finalization in a meeting with participants from WHO Geneva, WHO South-East Asia Region, WHO Nepal, the Director General DDA, PQM+, and MTaPS. However, due to other pressing issues at the DDA, the meeting was postponed to next quarter. The verification report found that the DDA's progress was limited to a few indicators, and its overall maturity level was unchanged at I. The aim is for MTaPS to help the DDA reach maturity level 2 before the end of 2021 in addition to supporting the DDA's reorganization and possible transition to an FDA. In collaboration with the technical working group led by the DDA, MTaPS will detail activities needed to reach level 2 that need to be included in the IDP.

MTaPS recognized the need to build the capacity of DDA staff to understand QMS principles and interpret the ISO 9001: 2015 requirements correctly. Therefore, MTaPS consulted with USAID and expanded the initial capacity building plans to include intensive training for five QMS focal persons and members of a quality assurance technical working group in October. After the training, the DDA will be better able to contribute to finalizing the draft QMS manual and SOPs. In addition, MTaPS partner Celsian has prepared a basic training package on QMS for DDA and National Medicines Laboratory staff in October.

### OBJECTIVE 3: AVAILABILITY AND USE OF PHARMACEUTICAL INFORMATION FOR DECISION MAKING INCREASED AND GLOBAL LEARNING AGENDA ADVANCED

MTaPS has been providing technical assistance to the DDA to strengthen its electronic regulatory MIS by mapping the DDA's divisional workflows and aligning them with the current and expansion needs of

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<sup>&</sup>lt;sup>14</sup> Drugs Sales and Distribution Codes, 2015; Health Technology Product & Equipment Directive 2074 (2017); Hospital Pharmacy Service Guideline, 2072 (2015); Special Permission Guidance 2074 (2017)

the existing IT solutions to be able to select the most suitable one. MTaPS carried out an MIS and IT infrastructure options analysis of usability and user satisfaction with the current MIS—DAMS. The study included interviews with DDA management and staff at the central and provincial levels, DAMS developers, and local manufacturers. DAMS and other regulatory MIS were compared. Although regulatory agencies have similar roles and responsibilities, the best match for Nepal was Pharmadex after considering accessibility, experience, use in other countries, status as an off-the-shelf solution, requirements for system maintenance and updates, annual fees, access to source code and the possibility of tailoring to the country context, applicability to a mature drug regulation authority, and Nepal's future needs. The study showed that DAMS has issues related to overall speed and user interface, few standard reports, insufficient capacity to attach documents and generate customized reports, suboptimal communication functions for clients and the DDA, and a slow search engine. The study also investigated the platforms' hardware, software, networking, and information sharing aspects as the DDA has no file server or archive systems for information management, information sharing, or backup and recovery.

Following the presentation on Pharmadex, the DDA and MTaPS met at the end of August, where there seemed to be strong support to transition to Pharmadex. However, because funding was available to strengthen DAMS, the DDA decided to implement improvements identified in the MTaPS comparative study. Subsequently, the DDA decided to run both MIS—Pharmadex and DAMS—in parallel for six months and then either phase out or transition to Pharmadex. DDA provided DAMS's SQL source code to import DAMS backup data into Pharmadex and to be able to visualize information in reports.

In the interim period, MTaPS will focus on adapting Pharmadex to the Nepal context and as per the requirements set to the new system and getting the registration module up and running.

MTaPS will finish drafting the detailed system requirement specifications needed to implement the Pharmadex registration module in October 2020. MTaPS is supporting the DDA to update its website, and terms of reference were finalized and shared with the DDA in September. The website will be made dynamic and have updated information available in an online repository in October.

MTaPS drafted hardware and software requirements and specifications for the IT infrastructure of the DDA MIS, including local area network configuration; platform design for information sharing and backup; and terms of reference for the update of the DDA website with the local IT contractor, CMS Design. MTaPS is in the process of procuring a local file server for the DDA to share information on an intranet and store DAMS, the DDA website, and DDA information as backup and recovery.

The DDA requested MTaPS' support during the 2019–2020 Nepali fiscal year to start developing a new online portal to track stock information on medical products from importers. MTaPS has been providing regular support to the DDA to track and report on the stock status of essential medicines using data visualization. Weekly reporting started in April 2020. MTaPS requested access from the MOHP to the electronic logistics management information system reporting module. After getting access, MTaPS will integrate national- and provincial-level stock status into the DDA weekly report to facilitate effective decision making.

#### ACTIVITIES FOR NEXT QUARTER

ACTIVITIES FOR NEXT QUARTER	
ACTIVITY AND DESCRIPTION	DATE
Assist DDA in organizational restructuring     Revise structure for DDA/FDA central and provincial levels     Support DDA/FDA to develop terms of reference for coordination and oversight structure	October–December
<ul> <li>Update drug law, regulations, rules, and guidelines</li> <li>Finalize draft zero of the new drug law</li> <li>Organize remote consultations on legal revision of the drug law and regulation</li> <li>Access and update regulations, rules, and guidelines needed to implement the revised drug law</li> <li>Translate current rules and codes into English and make them available on the DDA website in English and Nepali</li> </ul>	October November October–December October–December
Develop a five-year strategic plan for strengthening functionality of medicines regulation  • Assist the DDA in developing a five-year strategic plan based on the IDP  • Support drafting and implementation of the DDA year I strategic plan	October–December
Strengthen regulatory systems for medical products registration and good distribution and good pharmacy practices (GXP)  • Strengthen, develop, and update guidelines for drug registration and provide capacity building sessions on good review practices for DDA master assessors  • Update DDA regulations to incorporate good dispensing practices compliance and revise and implement good dispensing practices guidelines for effective medicines quality assurance	Ongoing
Assist DDA in developing a QMS     Develop a draft DDA quality manual, including marketing authorization, licensing of premises, and inspections processes     Create awareness among key decision makers and build QMS capacity among implementers through virtual training	October–December
Develop system requirements specifications for selected regulatory modules of an integrated electronic MIS  • Develop requirements and technical specifications for select modules of a future regulatory MIS  • Provide technical support for monitoring essential medicines' stock status at manufacturers and importers	September–October Ongoing
Assist the DDA to select an MIS solution and if needed, outsource the design and development of a system and initiate software development with an IT company	Ongoing
Explore strategies to strengthen GXP and medicines management in government and private-sector health facilities and pharmacies  • Engage and orient private-sector pharmacies and wholesalers on new GXP requirements  • Design and implement problem analysis of medicines management in public sector facilities	December

#### THE PHILIPPINES

For progress on MTaPS/Philippines COVID-19 activities, click here.

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

MTaPS supported the Department of Health (DOH) in redefining its role from operational management of procurement and supply chain to providing leadership, policies, guidance, and capacity building support to local government units (LGUs), in line with the changes associated with further devolution of health system functions and implementation of the universal health coverage (UHC) law. MTaPS assessed procurement and supply chain management (PSCM) and pharmacovigilance (PV) workforce needs to determine necessary positions, structures, and skill sets required to perform these redefined roles. A planned procurement and deployment of an electronic logistic management information system (eLMIS) was cancelled by the DOH due to COVID-19. Therefore, MTaPS introduced an interim tool that uses consumption and stock data for evidence-based allocation and distribution decisions to avoid stock-outs and overstock and ultimately ensure availability of products at all levels of health care in the Philippines. To address transportation challenges that arose from the COVID-19 situation, MTaPS compiled a directory of alternative logistics service providers at the central and local government levels to ensure continued access to essential commodities by Filipinos during the pandemic.

The planned PSCM system design was postponed due to COVID-19. However, MTaPS continued working with the DOH and the Commission on Population (POPCOM) to set up a subnational-segmented supply chain management (SCM) system for family planning (FP) commodities by integrating POPCOM warehouses and regional offices into the FP commodities supply chain network to ensure efficient supply and sustainable availability of products at service delivery points. MTaPS continues to provide support on data analysis, forecasting, and early warning for TB and FP commodities; identify facilities with potential stock-outs or overstock; and provide evidence-based recommendations to minimize stock disruptions, optimize procurement planning, and identify funding gaps.

MTaPS supported the National TB Program (NTP) to implement an active drug safety monitoring (aDSM) framework, build capacity on active PV, and upgrade the PharmacoVigilance Monitoring System (PViMS). MTaPS provided support to analyze gaps in the current registration system in the Philippines and identified a list of TB medicines that need to be registered in the country as a formative step for product registration to meet the prerequisite for ensuring uninterrupted availability of commodities for essential treatment of TB.

In Year 3, MTaPS will further build on its gains from Year 2 implementation to support the DOH in consolidating its central stewardship role, pursuing workforce development initiatives, planning and implementing an eLMIS, establishing framework agreements and pooled procurement mechanisms, addressing gaps in product registration process, and institutionalizing an active PV system to reduce the gaps between the current practices and desired performance in PSCM and patient safety.

#### **QUARTER PROGRESS FOR FY20Q4**

#### **OBJECTIVE 1: PHARMACEUTICAL-SECTOR GOVERNANCE STRENGTHENED**

#### Strengthening the PSCM Governance Mechanism

In line with the changes associated with the devolution of health system functions and implementation of UHC law in the Philippines, MTaPS supported the DOH in redefining its role toward the path from operational management of procurement and supply chain to providing leadership, policy guidance, and capacity building support to LGUs as articulated in the Procurement and Supply Chain Management Team's (PSCMT) strategic commitment document to increase the efficiency of the whole supply chain

nationwide. In this process, MTaPS supported the PSCMT in developing a roadmap to improve processes for PSCM and to facilitate integration of PSCM into local health systems. Furthermore, MTaPS supported documentation of summary stewardship roles of the PSCMT, in line with the implementation of UHC and system devolution.

MTaPS continued to strengthen its partnership with the leadership of the PSCMT to enhance its capacity and enable its confidence and willingness to take on a stewardship role and full leadership of the PSCM cycle, including product selection, quantification, procurement, warehousing, distribution, and rational use of commodities from the central to the rural health unit level. MTaPS conducted a process mapping exercise attended by key stakeholders from various bureaus of the DOH, Food and Drug Administration (FDA), and other implementing partners. This collaborative exercise enabled partners and MTaPS to thoroughly analyze the current PSCM processes, identify immediate registration process optimization opportunities and challenges, and define options to address those challenges and ensure continued access to health products at all levels of care in the Philippines.

MTaPS supported the DOH in developing a performance management system to ensure that PSCM services are delivered and performance is measured, monitored, and managed. This system is anchored on the proposed governance roles of the PSCMT in conjunction with the strategic realignment of the DOH's commitments to and goals for the UHC law.

MTaPS continued strengthening PSCM governance at the regional level. In the Central Visayas region, MTaPS actively advocated for and supported the formation of a PSCM-PV Committee at the Central Visayas Center for Health Development (CVCHD). MTaPS also supported the CVCHD in developing a PSCM-PV regional action plan as part of a UHC law implementation initiative by the Central Visayas region. This regional PSCM-PV plan sets an advanced example of integrating PSCM and PV governance at the regional level and clarifies the envisioned role of the regional health development center (CHD) in the context of devolved health systems and UHC law implementation to ensure uninterrupted availability and safe use of health commodities at all levels under a CHD.

Strengthening the PSCM governance and performance management will allow the DOH to take a more proactive role to effectively provide PSCM technical leadership, oversight, policy direction, and capacity building to LGUs.

### OBJECTIVE 2: INSTITUTIONAL AND HUMAN RESOURCE CAPACITY FOR PHARMACEUTICAL MANAGEMENT AND SERVICES INCREASED, INCLUDING REGULATION OF MEDICAL PRODUCTS

#### **PSCM** and **PV** Workforce Assessment

MTaPS assessed PSCM and PV workforce needs to determine necessary positions, structures, and skill sets required to perform redefined roles. A PSCM and PV workforce development plan has been developed based on the findings to help DOH stakeholders address workforce development needs and inform the redesign of the PSCM system and functionality of the PV system. MTaPS will present the PSMC and PV workforce assessment report and workforce development plan to the DOH in October 2020 to help DOH leadership make informed decisions and to integrate the PSMC and PV workforce development plan into the human resources master plan for the DOH. This will help the DOH take measures to create and fill in necessary positions and professionalize the workforce to address human resources gaps in the PSCM and PV systems and ensure improved services related to PSCM and pharmaceutical services.

### OBJECTIVE 3: AVAILABILITY AND USE OF PHARMACEUTICAL INFORMATION FOR DECISION MAKING INCREASED AND GLOBAL LEARNING AGENDA ADVANCED

#### Harnessing a Roadmap for an Electronic Logistic Management Information System

MTaPS supported the DOH to develop high-level system requirements and resources such as funding and to launch the bidding process twice to procure an off-the-shelf eLMIS, which failed due to challenges related to bottlenecks in the procurement process and disruptions caused by COVID-19. Consequently, the procurement was cancelled due to redirection of resources toward the COVID-19 pandemic response. MTaPS captured the lessons learned, explored feasible options for the DOH, and prepared a draft multiyear, phased project implementation plan with costing for eLMIS procurement, deployment, and maintenance.

The options analysis indicated that the DOH may benefit from exploring alternative ways of acquiring a standard eLMIS and planning for multiyear implementation of the end-to-end eLMIS project. In Year 3, MTaPS will support the DOH to undertake an assessment of existing DOH systems (i.e., contraceptive logistic management information system, online malaria information system, integrated TB information system, pharmaceutical management information system, COVID-19 supply management tracking system); potential license-free standard eLMIS software applications (e.g., Open LMIS, mSupply, RxSolution); and the requirements identified in the DOH-approved terms of reference and capabilities evaluation criteria. Results of the assessment will help to finalize the multiyear implementation plan and associated costs of different options and also help the DOH make an informed decision on selecting and implementing the appropriate eLMIS solution to improve commodities tracking, minimize stock disruptions, and ensure availability of products at all levels of the supply chain.

MTaPS also continues to provide support to forecast TB and FP commodities, identify facilities with potential stock-outs and overstock, provide evidence-based recommendations to minimize stock disruptions, and ultimately ensure continued access to these critical products by Filipinos.

### OBJECTIVE 4: PHARMACEUTICAL-SECTOR FINANCING, INCLUDING RESOURCE ALLOCATION AND USE, OPTIMIZED

#### Strategic Purchasing

MTaPS supported the DOH to update the draft administrative order for a framework agreement (FA) and pooled procurement mechanism (PPM) to strengthen strategic procurement practices. MTaPS also conducted a market scan to identify alternative logistics service providers and suppliers of commodities during the COVID-19 pandemic. A directory of alternative logistics service providers and suppliers was developed and shared with the DOH and LGUs to help identify alternative sourcing and ensure continued availability of essential commodities during the pandemic. At the central level, MTaPS provided input on the formation and operationalization of central price negotiation functions by taking part in the technical working group for the National Price Negotiation Board. Moving forward, MTaPS will continue to support the DOH Central Office and Philippines Pharmaceutical Procurement Inc. (PPPI) in setting up and implementing FAs and PPMs for TB and FP program commodities and LGUs to overcome the bottlenecks associated with current annual appropriation-based procurement practices and to pave the way for ensuring access to essential health commodities for TB and FP services.

### OBJECTIVE 5: PHARMACEUTICAL SERVICES, INCLUDING PRODUCT AVAILABILITY AND PATIENT-CENTERED CARE TO ACHIEVE DESIRED HEALTH OUTCOMES, IMPROVED

#### **Designing a Family Planning Commodity Management Process**

MTaPS continued working with the DOH and POPCOM to consolidate a subnational-level SCM system for FP commodities by bringing POPCOM warehouses and regional offices into the FP commodity supply chain network. MTaPS supported the DOH and POPCOM to reach an agreement to utilize warehouses owned by POPCOM for FP commodity management. MTaPS also supported POPCOM in developing logistics and supply chain management guidelines and facilitated a training workshop for DOH and POPCOM supply and logistics personnel on inventory and warehouse management. This initiative avoided redundancies and maximized utilization of existing warehouses for the management of FP commodities.

MTaPS also supported the DOH's National Family Planning Program in the use of an Interim Distribution Tool for Family Planning commodities. The tool was co-developed by MTaPS and the national FP Program to support regional coordinators and regional pharmacists to ensure rational commodities distribution decisions. This Excel-based calculation tool utilizes logistics data generated through existing DOH systems and calculates the commodity resupply needs for health facilities in an automated and evidence-based way. Through this tool, FP coordinators are able to determine if there is sufficient stock to last until the next order and adjust allocation plans accordingly to avoid stock-outs and expiry. The guidelines, tool, and training will help the DOH and POPCOM better manage regional storage and distribution of FP commodities, which will in turn reduce the logistics burden of the DOH and free up limited space in DOH warehouses.

#### **Conducting National Quantification for TB and FP Commodities**

MTaPS supported the DOH to conduct a three-year quantification of FP and TB commodities, which resulted in an informed three-year commodity quantity, budget requirements, and identification of resource gaps. Quantification of TB and FP commodities was updated during FY20 to help procurement planning and identification of funding gaps.

MTaPS supported the NTP for the quantification of the newly recommended three-month weekly rifapentine plus isoniazid regimen for programmatic preventive therapy of latent TB infection. MTaPS also supported the NTP in the development of a transition plan for second-line TB medicines to switch the funding support for PSCM activities for these commodities from the Global Fund to government funding sources. The PSCM transition plan provided comprehensive options with justifications for planning and managing the transition, including human resource and financial implications of the whole process to ensure a smooth transition of functions and funding sources without interrupting essential services.

#### Registration of Prioritized Health Program Medicines

MTaPS conducted an analysis to identify TB medicines that need to be registered in the Philippines and gaps in the current registration system. Based on the analysis, MTaPS developed a technical document on the registration of prioritized health program medicines. The document analyzed the current registration process, identified bottlenecks, and mapped out a plan to improve the efficiency of the registration process of prioritized health program medicines. Moving forward, MTaPS will assist the FDA in optimizing its overall registration process, while prioritizing registration of identified essential medicines needed by the DOH's public health programs to ensure continued availability of these medical products to the population.

#### Pharmacovigilance and PViMS

Use of PViMS was reinforced with the issuance of Administrative Order No. 2020-0025 by the DOH, wherein PViMS has been identified as the information management system to be primarily used to capture and analyze aDSM reports. In Year 2, MTaPS supported the DOH's efforts to establish an aDSM framework, provide capacity building on aDSM, and upgrade PViMS. MTaPS worked with the DOH's KMITS in updating PViMS to address data entry and management challenges. In collaboration with the Pharmaceutical Division (PD), MTaPS facilitated an orientation on the key PViMS updates and new software features. MTaPS facilitated a second orientation on PViMS version 2 to a larger audience, including the PD, NTP, FDA, Lung Center of the Philippines research group, and selected TB providers/partners who were engaged in a series of test runs of PViMS version 2.

Moving forward, MTaPS will continue to support KMITS, PD, FDA, and NTP in rolling out PViMS to all identified sentinel sites and develop their capacity to sustain the use of PViMS for the implementation of aDSM and ultimately ensure the safety of medicines for the population of the Philippines.

ACTIVITIES FOR NEXT QUARTER	
ACTIVITY AND DESCRIPTION	DATE
Activity 1.1.1: Strengthen the stewardship role of the PSCMT to set up centrally integrated PSCM functions with decentralized implementation (Support integration of Drug Supply Management unit of NTP into PSCMT)	Dec 2020
Activity 1.2.1: Support the DOH to implement a PSCM and PV workforce development plan for institutional capacity building (Identify and offer e-learning modules through DOH Academy)	Dec 2020
Activity 1.3.1: Conduct an assessment and support the DOH to develop a roadmap and implementation plan for an end-to-end eLMIS	Dec 2020
Activity 1.4.1. Support the DOH and LGUs to conduct procurements through FA and PPM for FP and TB commodities (Support PS and PPPI to complete the bidding process for FA and PPM)	Dec 2020
Activity 2.4.1. Support the DOH in rolling out PViMS for active PV	Dec 2020
Activity 3.3. Support the DOH and hospitals to strengthen practices related to health care waste management (HCWM) and emergency supply chain (Offer and promote e-learning modules on HCWM and SCM)	Dec 2020

#### **RWANDA**

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

Supporting Rwanda FDA to establish solid regulatory framework for regulation of medical products and adapting international mechanisms for reliance in registration of medicines

To strengthen the Rwanda Food and Drug Authority's (FDA) medicines regulatory capacity, including pharmaceuticals used in HIV/AIDS; maternal, newborn, and child health (MNCH); and family planning (FP)/reproductive health (RH) programs, MTaPS worked with the Rwanda FDA to draft, review, and validate key guidance documents for good governance of the pharmaceutical sector. The regulations on suitability of premises dealing with pharmaceutical products and those governing registration and general conditions of sale of pharmaceutical products were reviewed. Five regulations, eight guidelines, and three authorized lists of medicines and cosmetics were validated.

MTaPS also worked with the Rwanda FDA to develop a draft five-year strategic plan and draft documentation toward establishing the Quality Management System (QMS) as the authority works toward attaining ISO 9001:2015 certification, such as a quality manual with SOPs for key regulatory functions, including medicine registration, inspection, licensing, and enforcement.

After establishment, the Rwanda FDA did not have adequate and qualified human resources to help in executing the mandate, and it recruited new personnel and determined there was need to build capacity of new assessors to effectively perform registration activities to ascertain product quality, efficacy, and safety. MTaPS supported the Rwanda FDA to build the capacity of registration personnel involved in medical product dossier evaluation and assessment via a virtual capacity building workshop organized for 55 staff (33 male and 22 female). The six trainers who delivered the workshop were based in Uganda, Kenya, Tanzania, and the US.

Acknowledging the benefits of the WHO collaborative registration procedure (CRP), MTaPS introduced and informed the Rwanda FDA about the existence of the mechanism and encouraged the authority to apply to WHO by linking the Rwanda FDA team to the WHO focal person, which resulted in endorsement of a WHO CRP agreement between the Rwanda FDA and WHO on February 18, 2020. Since the CRP agreement became effective, 10 applicants have submitted their expression of interest to apply for marketing authorization of their products to the Rwanda FDA using the mechanism. As a result, 10 medicines, including HIV and malaria products, are under evaluation. The signing of the WHO CRP by the Rwanda FDA has helped in supporting implementation of the MTaPS objective of improving access to quality, safe, and efficacious medical products in Rwanda by improving efficiency in medicines registration utilizing a fast tracking and ensured pathway through CRP implementation.

The lesson learned is that access to quality, safe, and efficacious medicines can be achieved using global approaches such as the CRP mechanism and capacity building of regulators while applying regulatory techniques that have been proven effective globally. MTaPS will support the Rwanda FDA to increase awareness among its stakeholders about the benefit of the WHO CRP so that more products can be registered through this mechanism to access the Rwandan market.

### Empower health care providers and Rwanda FDA personnel to monitor medicines safety and strengthen pharmacovigilance

MTaPS supported the Rwanda FDA to develop a costed national pharmacovigilance (PV) implementation plan, which is under review by the Rwanda FDA before approval by stakeholders. The plan is an important document that provides clear steps and required resources to support and guide the implementation of medicines safety monitoring and PV activities.

Further, for safety monitoring of medical products and strengthening of PV activities, an electronic online reporting tool, PViMS, has been set up at the Rwanda FDA. This tool will ensure that medicines safety monitoring reports are quickly received and analyzed and that feedback to clients, patients, and health facilities is disseminated in a timely manner.

Based on the need to establish capacity in medicines safety monitoring and reporting, the Rwanda FDA, with support from MTaPS, organized a Drug and Therapeutics Committee (DTC) training workshop on PV and medicines safety for new Rwanda FDA staff and health care service providers from public and private health facilities. The course included content on what and when to report. The trainees included 15 doctors, 9 nurses, and 14 pharmacists, all of whom are members of DTCs in public and private hospitals (24 male and 14 female).

As a result of the training, the Rwanda FDA received 26 adverse drug reaction (ADR) reports (2 HIV cases, 11 malaria treatment cases, 8 for warfarin/rivaroxaban [including 5 fatalities], and 5 on essential medicines). In addition, it received 45 reports on poor quality, of which 2 were MNCH (oxytocin and magnesium sulphate), 6 on batches of warfarin, 34 on essential medicines, and 3 on hand sanitizers. The materials used in the training are being used in the development of a PV e-learning course that will lead to sustainability of PV capacity building.

A lesson learned from the process was that reporting of medicines safety issues directly increased with capacity building of health care providers, as reporting from health facilities increased after the training. With the planned introduction of a PV e-learning course, the number of trained health care providers will increase, which is anticipated to lead to an increase in the number of ADR reports received by the Rwanda FDA. With use of PViMS, it will be easy for the Rwanda FDA and other users to share and report on medicines safety issues for appropriate decisions to be made in time. MTaPS will continue supporting the Rwanda FDA and its stakeholders to continue with the implementation of PViMS and the costed PV plan.

#### Pharmaceutical services standards for accreditation

MTaPS supported the Ministry of Health (MOH) to develop the pharmaceutical services standards for accreditation and an implementation plan, which were approved and signed by the Rwanda Minister of Health in July 2020. The pharmaceutical services standards, together with other hospital and primary health care standards, will be used by hospital and community pharmacies to improve provision of pharmaceutical services and enhance overall health care service provision. The standards are currently being printed. MTaPS will work with the MOH and its stakeholders disseminate and implement the standards.

#### **QUARTER PROGRESS FOR FY20Q4**

#### **OBJECTIVE I: IMPROVE PHARMACEUTICAL-SECTOR GOVERNANCE**

### I.I.I: Strengthen the capacity of Rwanda FDA in regulating pharmaceuticals used in HIV/AIDS, MNCH, and FP/RH programs (Activity continuing from FYI9)

After instituting the Medicines Act, the Rwanda FDA required accompanying regulations and guidelines to effectively control the safety, quality, and efficacy of medicines and other health products on the market. During Q4 of Program Year 2, MTaPS continued to support the Rwanda FDA to develop/review regulations and guidelines. In this regard, MTaPS provided technical support in the drafting, review, and validation of the following documents for the Rwanda FDA:

I) MTaPS is currently supporting and working with the Rwanda FDA to finalize the institution's five-year strategic plan (2020–2025). To ensure alignment with country priorities, MTaPS agreed with

the Rwanda FDA to incorporate food safety, cosmetics, and veterinary medicine components. It is expected to be ready for implementation by January 2021.

- 2) Development of the following guidelines:
- Guideline for technology transfer of pharmaceutical products has been submitted to the Rwanda FDA for final review
- Draft guidelines for quality audit of medical device manufacture
- 3) Development of the QMS:
- A gap analysis of the Rwanda FDA QMS was undertaken, and a report with recommendations for implementation is available
- Supported development of Rwanda FDA quality management manual, which will be used to guide implementation of the OMS
- Supported development of several QMS guidelines and SOPs:
- Medicines registration process flow

MTaPS also supported the Rwanda FDA to conduct QMS awareness and implementation requirements training to top Rwanda FDA management on September 11, 2020.

As a next step, MTaPS will support the Rwanda FDA to conduct a stakeholder validation workshop to validate the documents for approval and implementation.

### I.I.2: Streamline registration of essential medicines and medical devices, including those used in MNCH and FP programs

The Government of Rwanda established a national regulatory authority of medical products—the Rwanda FDA—in 2018 by Law N° 003/2018 of 09/02/2018 with a clear mandate to protect public health by regulating human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, and tobacco and tobacco products and by conducting clinical trials.

One of the key regulatory functions of the Rwanda FDA is medicines registration/marketing authorization, which contributes to ensuring quality of pharmaceutical products through assessment of manufacturers' product dossiers and registration. Dossiers are assessed and approved or rejected based on scientific information and evidence to increase access to quality, efficacious, and safe medical products for prevention and control of diseases of public health concern. In some cases, additional information may be required to be submitted to the authority to further clarify issues arising from the preliminary evaluations conducted by assessors.

After establishment, the Rwanda FDA did not have adequate and qualified human resources to help in executing the mandate, and it recruited new personnel to increase its human resource capacity to deliver the required regulatory services. The Rwanda FDA realized the need to build capacity of new assessors to effectively perform registration activities to ascertain product quality, efficacy, and safety. Based on the needs, the authority thus requested technical support from MTaPS to assist in strengthening the capacity of registration personnel involved in medical product dossier evaluation and assessment. A virtual capacity building workshop was organized for 55 staff (33 male and 22 female) led by six trainers based in Uganda, Kenya, Tanzania, and the US. The workshop was organized to ascertain the pre- and post-training knowledge participants on the subject matter. At the end of the training, 64% of participants understood the content as opposed to 44.1% before the training.

At the end of the training, participants were given an opportunity to evaluate the course on a scale of I – 5 (strongly agree to strongly disagree). The overall appreciation of training was 93%, or 4.65 out of 5.

The capacity building of medicines assessors in medicines assessment, evaluation, and registration is aligned to the MTaPS goal of supporting and strengthening the medicines regulatory system in Rwanda

through the Rwanda FDA. This will ensure availability and accessibility to quality, safe, and efficacious medicines in the country.

The training, although virtual and not in person, successfully delivered capacity building interventions. The main constraints of using information technology are the requirement to be connected via the internet with strong bandwidth and reliability throughout the session and participants either being in one location using one electronic screen or having individual devices to access the sessions.

As the Rwanda FDA is a newly established medicines regulatory agency and in line with WHO Global Benchmarking Tool recommendations, developing a guideline on good review practices and validating the regulation and guideline on medical devices were required to streamline the registration functions. MTaPS supported the Rwanda FDA to sign the WHO CRP agreement. MTaPS supported the Rwanda FDA to develop the following documents:

- Guideline on good review practices
- · Report on validation of the regulation and the guideline on medical devices

### 1.2.1: Enhance the capacity of pharmacy and clinical staff on managing the transition of patients to tenofovir, lamivudine, and dolutegravir (TLD) at ART sites

As part of the medicines regulatory systems strengthening support to Rwanda, which includes medicines safety monitoring, MTaPS is providing technical support to strengthen PV systems, starting with health care service delivery points, the Rwanda FDA, and other health programs in the country.

During Year 2, MTaPS and the Rwanda Biomedical Center (RBC) identified 10 high-volume health facilities to be supported to transition patients on the tenofovir, lamivudine, efavirenz (TLE) antiretroviral therapy (ART) to TLD, which is the preferred first-line regimen.

During this quarter, MTaPS collected data related to transitioning of clients from TLE to TLD in the 10 high-volume facilities. Collectively, the facilities have 26,125 patients on ART, 88.3% of whom are eligible to transition to dolutegravir (DTG). Of those eligible, 56% have been successfully transitioned.

The current status of the TLD rollout in the 10 health facilities indicates good progress in two health facilities where 100% of clients have been transitioned to TLD, while four have above 70% patient transition, three above 50%, and one at 40%.

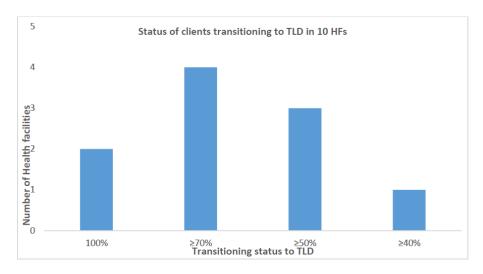


Figure 10: Status of clients transitioning to TLD at 10 health facilities

#### **OBJECTIVE 2: STRENGTHEN GOVERNMENT CAPACITY TO MANAGE PHARMACEUTICAL SYSTEMS**

### 2.1.1: Strengthen site-level tools for tracking and reporting patients receiving three- and six-month MMD of ARVs

According to the available data from the 10 high-volume facilities, 67% of ART clients are stable and enrolled on three-month multi-month dispensing (MMD).

In Q4, MTaPS worked with the RBC/HIV Division to conduct a survey in the 10 health facilities covering their prescribers and dispensers and the clients at the clinics through exit interviews, as well as the RBC Director of HIV Care & Treatment. The overall expected outcome of the assessment is to provide information that will improve the implementation of MMD and reporting of ADRs from patients on ART by understanding the preferences of clients for three- or six-month MMD. It will also help to identify the benefits and challenges to MMD from the perspective of patients and care providers and enable the HIV program to determine the current status of MMD rollout, including bottlenecks, and to make recommendations.

The report of the assessment is under review and is expected to be finalized before the end of October. Taking into consideration the preliminary findings, 96 clients (32%) wanted to remain on 3MMD while 199 (66%) are willing to be upgraded to 6MMD, which they associate with benefits such as fewer visits to the health facility, reduced transport costs, and fewer absences from work.

### OBJECTIVE 3: STRENGTHEN SYSTEMS FOR PROVIDING PATIENT-CENTERED PHARMACEUTICAL CARE AND SERVICES

# 3.1.1: Strengthen delivery of high-quality, patient-centered pharmaceutical care through the development of pharmacy service standards aligned with Rwanda's health care quality and accreditation system

With ongoing support from MTaPS to the MOH and its stakeholders to improve the quality of health care services in health facilities through the implementation of pharmaceutical services, pharmacy accreditation standards were developed. The standards and the implementation plan and tools for operationalizing the standards were approved by the Minister of Health in July and are currently being printed.

The standards are expected to have a positive impact on the way pharmaceutical services have been managed and preserved in both public and private health care facilities. MTaPS will support and continue working with the MOH to disseminate and implement the standards.

MTaPS also supported the drafting of terms of reference and job descriptions for pharmacy service, which will be shared with the MOH for consideration, review, and approval.

MTaPS started drafting the pharmacy services quality manual but was challenged by the fact that it was targeting the Pharmacy Unit, which in the new public service structure released in August 2020 has only one staff person overseeing pharmaceutical-sector policy and oversight coordination. This new arrangement makes it difficult to pursue establishment of the Pharmacy Unit. Aspects of pharmacy services quality are also addressed in the MOH's Citizen Service Charter.

### 3.1.2: Improve quality and use of medicines for pre-eclampsia, eclampsia, and postpartum hemorrhage

During this quarter, MTaPS worked with the MOH and the RBC/Maternal Child and Community Health (MCCH) Division to determine strategies to improve the quality of medicines used in the management of maternal health conditions, particularly pre-eclampsia, eclampsia, and postpartum hemorrhage. The

work feeds in the country's vision of significantly reducing maternal and child mortality based on the Sustainable Development Goal targets.

At the request and guidance of the mission, the situation analysis on the status of management and storage of oxytocin was not conducted, due in part to the COVID-19 pandemic and in part because it was felt enough was known about the current situation. Working with the MOH and the RBC/MCCH Division, several guidelines, tools, and documents shared by the RBC/MCCH Division are being reviewed by MTaPS, and a draft set of guidelines for the storage and management of oxytocin is being developed for the RBC/MCCH Division and other stakeholders to review and adapt. The draft will be shared with the MOH for discussion and revision early next quarter. The guidelines will help improve management and storage of oxytocin in health facilities and all health service delivery points and the efficacy of oxytocin products.

### 3.1.3: Improve access to and administration of oxygen to hypoxic newborns and children with pneumonia

MTaPS is working with the MOH to improve access to and administration of oxygen in health facilities, beginning with identification of the existing gaps.

In 2017, the MOH, with technical support from the Clinton Health Access Initiative (CHAI), conducted a situational analysis and developed a proposed action plan. Last quarter, MTaPS conducted a rapid desk review of the availability and use of oxygen, equipment, and medical devices, which is currently being finalized. The MOH is conducting a nationwide inventory assessment with support from CHAI. With both of these inputs expected to be completed early in the next quarter, MTaPS will support the MOH Clinical Services Department and the RBC to update and revise a comprehensive oxygen roadmap. This will be the first key activity of the oxygen coordination mechanism, whose establishment MTaPS is discussing with the MOH. This mechanism will provide a forum for coordinating activities related to oxygen within the MOH and with donors and implementing partners and ensure that all actions are in accordance with the MOH's vision. MTaPS will support the clinical services director to play the convening role for that committee and to establish a rolling agenda, terms of reference, and action plan.

The MOH has expressed interest in MTaPS' support to develop the policy framework on the use and management of oxygen, guidelines and SOPs to guide use and management of oxygen, and capacity building of biomedical engineers on production and supply chain management of oxygen and clinicians on the administration of oxygen.

Based on the assessment findings and the actions to be defined in the roadmap, MTaPS will support the MOH and other stakeholders in the development of the policy framework, guidelines, and SOPs on the use and management of oxygen in the coming year.

#### 3.1.4: Support management of medicines at community level

MTaPS is working with the MOH and the RBC/MCCH Division to review and address gaps in the management of health commodities by community health workers (CHWs). MTaPS and the MCCH team are reviewing the tools and guidelines utilized by CHWs undertaking community-based health care provision to identify any gaps that require interventions and plan how to implement recommendations. A meeting of District Health Management Team representatives and health center staff responsible for CHWs is being planned to further clarify the gaps and define the content of mini lessons on resupply and management of medicines at the community level. The District Health Management Teams will be supported via refresher training. This activity will commence next quarter.

### 3.2.1: Support establishment of a system for active surveillance of the new DTG-based regimen and strengthen the existing spontaneous reporting system (Activity continuing from FY19)

Active surveillance is a key function of a strong PV system as part of medicines regulatory requirements. MTaPS is providing technical support to both the Rwanda FDA and the RBC/HIV Division to establish a system for active safety monitoring and reporting of adverse events related to TLD.

The Rwanda FDA is mandated to regulate and monitor medical product safety. To strengthen the reporting and safety monitoring of medicines, this year MTaPS worked with the MOH, Rwanda FDA, RBC/HIV Division, and University of Rwanda to provide technical support to develop the following deliverables that will facilitate implementation of active safety surveillance of patients taking DTG-based regimens:

- A framework for active surveillance of the new DTG-based antiretroviral (ARV) regimens. The draft framework is currently with the RBC for final formatting.
- A protocol for active surveillance of DTG-based regimens. The draft active surveillance protocol is being reviewed by the RBC.
- A costed multiyear national PV plan aligned to the Rwanda FDA Institutional Development Plan. The draft national PV plan is under review by the Rwanda FDA.

To further build and strengthen the capacity of health care providers in PV, MTaPS worked with the Rwanda FDA and stakeholders to develop the course content for a PV e-learning course. MTaPS and the Rwanda FDA are jointly developing the course to ensure ownership and sustainability. Eight of the 12 mini modules have been drafted and are under review for approval prior to further formatting and uploading onto the MOH's e-learning platform.

In recent years, the Government of Rwanda has dedicated resources for automating most services in the country to improve service delivery and pivot to e-governance. Based on the desire to ensure data security and rapid information exchange, especially on medicines safety surveillance, MTaPS has been supporting the Rwanda FDA to establish an online medicines safety reporting system to improve electronic medicines safety reporting, make it easy to detect any medicines safety and quality issues and help in rapid decision making by management.

MTaPS supported the Rwanda FDA to establish and activate PViMS, which is currently available for use by the Rwanda FDA and its stakeholders. The user manual for the PViMS module is being adapted. The activation of PViMS will ensure that the Rwanda FDA accesses firsthand ADR reports and information on poor quality medicines and provides timely feedback to reporters to improve pharmaceutical services.

The Rwanda FDA started entering data captured in other formats into PViMS, starting with data on the Ebola vaccination. Eventually it is envisioned that all medicines safety data and reporting will be in PViMS, all hospitals will report through PViMS, and the Rwanda FDA will conduct analyses of the data.

In Q2, with MTaPS support, the Rwanda FDA conducted a three-day training for 48 health care providers (36 male and 12 female) in PV and patient safety and as a result, reports on ADR and Ebola vaccination were submitted by health facilities to the Rwanda FDA.

Table 13. ADRs and poor-quality medicines reported to Rwanda FDA (cumulative for Q3, Q4)

ADR reports (26 total)	Reports on poor quality (45 total)	Comments
2 - HIV on DTG+3TC+TDF  II - malarial treatment cases  8 - warfarin/rivaroxaban including 5 fatal  5 - cases on essential medicines	<ul><li>2 - MNCH (oxytocin and magnesium sulphate)</li><li>6 batches of Warfarin</li><li>34 essential medicines</li><li>3 hand sanitizers</li></ul>	The products were recalled, and quality issues included: - Mislabeling -Discoloring of tablets -Microbial contamination

For MNCH products, oxytocin being reported as a poor quality product relates to mislabeling. The manufacturer never indicated storage conditions in terms of temperature on the secondary packaging material. Magnesium sulphate was also mislabeled and appeared damaged as per reports from health facilities.

Additionally, MTaPS is supporting the Rwanda FDA to develop information, education, and communication materials to increase awareness among health care providers and the public on the need to detect, document, and report all suspected ADRs and other drug-related problems to the Rwanda FDA. A strategy for developing and disseminating the materials has been developed as has draft content for some of the materials, such as stickers and posters, which are currently under review.

#### **ACTIVITIES FOR NEXT QUARTER**

ACTIVITY AND DESCRIPTION	DATE
Finalize development of Rwanda FDA draft five-year strategic plan	December 2020
Finalize guidelines for quality audit of medical device manufacturers	October 2020
Conduct training of DTC members and providers at the 10 selected facilities on medicines safety and reporting to increase capacity and strengthen the role of DTC members to support TLD transitioning at selected health facilities	November 2020
Develop guidelines and tools for better storage and management of oxytocin	November 2020
Update MOH oxygen roadmap	December 2020
Develop training materials on oxygen management and avail as e-learning draft materials on the MOH e-learning platform	December 2020
Updated tools and job aids for CHWs	December 2020
Facilitate hosting of PV e-learning module	November 2020
Complete technical report on ADRs for patients using ARVs and other medicines in Rwanda	December 2020
Facilitate approval of protocol, training materials, SOPs, and job aids for active surveillance of HIV medicines	November 2020

#### **SENEGAL**

For progress on MTaPS/Senegal's COVID-19 activities, click here.

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

MTaPS provided financial and/or technical contributions to four multisectoral meetings of the AMR working group. These meetings were organized under the aegis of the One Health (OH) Permanent Secretariat. These meetings contributed to:

- Revitalizing the OH platform, which became largely inactive following dissolution of the Office of the Prime Minister within the Government of Senegal, through financial and technical support to organize the first technical meetings
- Reinstating the AMR working group as a subset of the newly created TWG PREVENTION
- Finalizing the AMR annual action plan for 2020
- Developing the national concept note for the tripartite (FAO-OIM-OIE) OH AMR funding
- Validating the rapid situation analysis of the regulations, control, and use of antimicrobials in the human, animal, and agricultural health sectors and the strategic axes and objectives that the MTaPS subcontractor (Cabinet IP3 Conseil) used in developing the first draft of the national AMS plan

MTaPS supported the Directorate of Hospital Quality, Security, and Hygiene (DQSHH)/MOH to revitalize three pilot hospitals' infection control committees (ICCs) by helping them implement their action plans, which were developed during a participatory initial baseline assessment conducted using WHO's Infection Prevention and Control Assessment Framework (IPCAF). Even though the implementation of the improvement action plans was slowed by the government's focus on the COVID-19 response, the ICCs of the three pilot hospitals were revitalized and are applying continued quality improvement (CQI) and multimodal approaches to improve IPC. As a result, the Tivaouane level I hospital improved its capacity level from inadequate (100/800) to intermediate (500/800). In the level 2 hospital (FBO/private) in Thiès, the capacity level improved from intermediate (500/800) to advanced (688/800), and the incidence rate of health care-acquired infections (HCAIs) in MTaPS-supported health facilities has improved, declining by 16% (2.38 in 2018 and 2.06 in 2019). Furthermore, during January-June 2020, when MTaPS' support for the implementation of hospitals' action plans intensified, the HCAI incidence rate was 1% (30/2296).

MTaPS worked with Cabinet IP3 Conseil to support a validation workshop for reports, organized under the aegis of the OH Permanent Secretariat. In addition to the government departments for the human, animal, and environmental health sectors, the private sector participated in the workshop, which concluded by determining next steps. These include providing the AMR TWG with the final version of the consolidated report and the proposed strategic axes and objectives of the national AMS plan. The AMR TWG validated these documents on September 2, 2020, under the aegis of the OH Permanent Secretariat.

MTaPS also worked with Cabinet IP3 Conseil to provide financial and technical support to the AMR TWG to validate the rapid situation analysis report of the regulations, control, and use of antimicrobials in the human, animal and agricultural health sectors and the strategic axes and objectives of the national AMS plan. On September 18, 2020, Cabinet IP3 Conseil shared the first draft of the national AMS plan with MTaPS and the Directorate of Pharmacy and Medicines (DPM) for their initial review. The validation workshop of the national AMS plan will be organized in October 2020.

MTaPS provided support to the National Committee for Antibiotic Treatment (NCAT) to organize several technical meetings to update the antibiotic policy and standard treatment guidelines (STGs) that were developed in 2010 but never used. MTaPS used the opportunity to provide a technical orientation

to NCAT's four TWGs<sup>15</sup> on the WHO's AWaRe categorization of antibiotics, which the NCAT adopted. The validation workshop of the antibiotic policy and STGs, which include AWaRe categorization, was initially planned for March 2020 but has not yet taken place because of the lack of availability of NCAT leadership because of COVID-19 constraints. Once validated, MTaPS will support the use of and compliance with the antibiotic treatment policy and STGs by health facilities targeted in year 3.

Overall, the government's focus on the COVID-19 response and related restrictions contributed greatly to slowing down implementation of work plan activities during the three last quarters of PY20. However, MTaPS COVID-19 funding was an opportunity to demonstrate alignment with the government's priorities and to successfully advocate for implementing GHSA activities that are critical to strengthening the health system and improving its resilience.

OH leadership has been critical for effective implementation of multisectoral activities, particularly those related to the development of the national AMS plan. Implementation of these activities had slowed under DPM/MOH leadership because of competing priorities with the COVID-19 pandemic.

The cross-fertilization between francophone countries has been beneficial and includes sharing experiences at monthly meetings and technical documents. Senegal benefitted from a set of 10 generic IPC e-learning modules funded jointly by three other francophone countries. The MOH stressed that these e-learning modules will be prioritized for all IPC trainings of health care providers. As a result, more resources will be allocated to supervision and monitoring field visits to ensure increased compliance with IPC guidelines.

#### **QUARTER PROGRESS FOR FY20Q4**

#### **RESULT AREA I: EFFECTIVE MULTI SECTORAL COORDINATION ON AMR**

### Strengthen the functionality of the OH Permanent Secretariat and its AMR TWG by supporting effective coordination through regular meetings

The OH platform became largely inactive following dissolution of the Office of the Prime Minister. During previous quarters, MTaPS contributed to revitalizing the OH platform through financial and technical support to organize its first technical meetings.

During this quarter, MTaPS contributed to two additional technical meetings of the AMR working group, which were organized under the aegis of the OH Permanent Secretariat. The outcomes from these meetings included technical validation of the rapid situation analysis of the regulations, control, and use of antimicrobials in the human, animal, and agricultural health sectors, as well as the strategic axes and objectives of the national AMS plan.

The above achievements contributed to the following results:

- Four AMR-related in-country meetings or activities conducted with multisectoral participation
- Females represented 36% (71/200) of participants in meetings or other events organized by the multisectoral body on AMR
- Three operational documents related to the national action plan on AMR implementation were developed with MTaPS' support, including the finalized AMR annual action plan for 2020; the validated rapid situation analysis of the regulations, control, and use of antimicrobials in the human,

<sup>&</sup>lt;sup>15</sup> Antibiotic therapy policy; antibiotic therapy for community infections of adults and children; antibiotic therapy of HCAIs; and antibiotic prophylaxis

- animal, and agricultural health sectors; and the validated strategic axes and objectives of the national AMS plan development
- The multisectoral coordination actions of WHO's benchmark 3.3 for IHR capacities were completed as follows: 75% (3/4) of level 2 actions, 50% (2/4) of level 3 actions, and 50% (2/4) of level 4 actions

#### **RESULT AREA 2: INFECTION PREVENTION AND CONTROL**

#### Activity 2.3: Strengthen the capacity of health facilities for implementing IPC programs

During this quarter, amid the ongoing COVID-19 pandemic, DQSHH/MOH scheduled a series of IPC trainings for selected trainers in all 14 regions of Senegal. MTaPS supported the technical review and validation of IPC training modules during a workshop held August 3-5, 2020. The DQSHH will use the training modules to conduct quality and standardized sessions in a series of upcoming trainings for any additional health facilities that will be enrolled in year 3.

From August 18 to 27, MTaPS supported two training sessions at the level I hospital Mame Abdou Aziz Sy of Tivaouane for 30 health care workers (20 females and 10 males). The trainings focused on IPC core components, emphasizing waste management practices and using personal protective equipment in the context of COVID-19. Participants were also provided with information on the multimodal strategic approach and the CQI approach, as well as on how to apply these approaches during implementation of the IPC action plan.

MTaPS' support to the implementation of the three targeted hospitals' action plans during FY20 contributed to the following results:

- All three MTaPS-supported facilities improved their performance in core IPC components (IP8 indicator).
- All three of MTaPS-supported health facilities are implementing CQI to improve IPC.
- All three MTaPS-supported health facilities have functional IPC committees.
- All three MTaPS-supported health facilities have improved hand hygiene compliance.
- The incidence rate of HCAIs in MTaPS-supported health facilities has improved in the level 2 hospital (FBO/private), declining by 16%. For January-June 2020, the HCAI incidence rate was 1% (30/2296).
- MTaPS-supported health facilities that are using standardized tool(s) for monitoring IPC and informing programmatic improvement (100% in PY20 Q1, PY20 Q2 and PY20 Q4; 68% in PY20 Q3).
   In Q3, the level I hospital's ICC was not able to conduct IPC monitoring meetings and other MTaPS-supported capacity-building activities, due to a surge of COVID-19 cases in the hospital.

#### **RESULT AREA 3: USE OF ANTIMICROBIAL MEDICINES OPTIMIZED**

### Activity 3: Provide technical support to formulate a national AMS plan and improve prescribing adherence to treatment guidelines

During the previous quarter, MTaPS used the TOR for AMS plan development from MTaPS Côte d'Ivoire and worked to update them with a small group from the AMR TWG, under the leadership of the DPM. MTaPS used the finalized TOR during the process of selecting and subcontracting with Cabinet IP3 Conseil to conduct a rapid situational analysis and use its findings to develop a national AMS plan in the human, animal, and environmental health sectors.

During this quarter, MTaPS continued collaborating with Cabinet IP3 Conseil, which provided the first version of the results of the rapid situational analysis of antimicrobial use, legislation, and control in the human, animal, and environmental health sectors. Cabinet IP3 Conseil provided the primary results in two reports, one on antimicrobial legislation and control and the second on antimicrobial use. On July 24, MTaPS supported a validation workshop of the reports under the aegis of the OH Permanent Secretariat. In addition to the government departments for the human, animal, and environmental health

sectors, the private sector participated in the workshop, which concluded by determining next steps that include providing the AMR TWG with the final version of the consolidated report and the proposed strategic axes and objectives of the national AMS plan. The AMR TWG validated these documents on September 2, 2020, under the aegis of the OH Permanent Secretariat.

On September 18, Cabinet IP3 Conseil submitted the first draft of the proposed national AMS plan for review by MTaPS and DPM. MTaPS will complete its internal review of the draft AMS plan before the technical validation workshop to ensure that its feedback will be considered in an improved second draft that will be reviewed and validated by the AMR working group.

The MTaPS Senegal team continued working with the NCAT and advocating for organizing the validation workshop for the policy and STGs, which includes AWaRe categorization, that was initially planned for March 2020. Once validated, MTaPS will support the use of and compliance with the antibiotic treatment policy and STGs by health facilities targeted in year 3. The validation workshop is still postponed, as key leadership of the NCAT are heavily engaged in COVID-19 emergency response, in addition to the outbreak response measures and restrictions put in place by the government.

The above achievements contributed to the completion of 75% (3/4) of AMS level 2 actions of WHO's benchmark 3.3 for IHR capacities as follows:

- Undertake an assessment of stewardship policies and activities, including the regulatory framework and supply chain management of antimicrobials, using a multisectoral approach
- Assess existing monitoring of antimicrobial use and consumption
- Develop a draft national AMS plan or strategy and national legislation that regulates use, availability, and quality of antimicrobials

### Activity 4: Incorporation of IPC and AMS topics as components of safe, effective, and quality care in leadership and management training modules for policy and decision makers

During last quarter, MTaPS helped Senegal's MOH produce a country-specific e-learning course consisting of three modules and a short introductory video. The e-learning course focuses on IPC standard precautions and hand hygiene with regular quizzes to check the learners' understanding of the content. As a follow-on activity, MTaPS assisted MOH with preparing the MOH e-learning teams (DQSHH, in-service training department, and the IT/Technology Unit) to deploy the e-learning program. During this quarter, MTaPS, jointly with Empower, organized and conducted highly interactive virtual sessions to equip them with the necessary competencies to sustainably manage MOH e-learning programs. The sessions took place on September 16 and 23, 2020, and covered 13 technical topics focused on the basics of the Moodle platform, an open source software package designed to help users and educators create quality online courses and manage learner outcomes. In addition to site management, participants were also taught how to upload e-learning courses, enroll users into courses, monitor users' performance, and produce course reports. Each session lasted two hours with a gap of one week in between to give participants time to practice what they were taught. At the end of these sessions, participants were able to independently upload the e-learning course produced with MTaPS support in the previous quarter on their Moodle platform. Leveraging MOH's existing Moodle e-learning platform in this manner is the logical solution to mitigate IPC challenges, as it will help institutionalize elearning and capacity-building efforts in Senegal. A third training session will be organized specifically on effective e-learning training facilitation skills using the newly customized modules.

In addition, MTaPS will provide the MOH with the set of 10 IPC generic e-learning modules developed with the group of MTaPS francophone countries. They will complement the existing modules without additional costs.

#### ACTIVITIES FOR NEXT QUARTER

ACTIVITY AND DESCRIPTION	DATE
Support AMR TWG meeting under the aegis of OH Permanent Secretariat	November 2020
Support the IPC joint lessons learned workshop of the three pilot hospitals	October 2020
Support the validation workshop and dissemination of the proposed national AMS plan	Oct. – Dec. 2020
Support the validation workshop and dissemination of the policy and STGs on antibiotic therapy	Oct. – Dec. 2020
Support the design of capacity-building interventions to translate the AMS plan into routine practice	November 2020

#### **TANZANIA**

For progress on MTaPS/Tanzania's COVID-19 activities, click here.

#### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

MTaPS worked collaboratively with the Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC) and its core partner Overseas Strategic Consulting (OSC) to develop the multisectoral antimicrobial resistance (AMR) communication strategy. The purpose of the strategy is to coordinate efforts of stakeholders implementing activities addressing AMR-related issues to align with the priorities of the National Action Plan (NAP) on AMR. The strategy has been developed to inform and guide decision making surrounding the design and implementation of coordinated, systematic, enduring, and behaviorally focused communications activities for improving appropriate use of antimicrobial agents in the country. Early stakeholder involvement and multisectoral participation during the design process was key for the government's buy-in for the AMR Communication Strategy document. A community that is aware of and informed about AMR is more likely to engage in and support infection prevention and control (IPC) and antimicrobial stewardship (AMS) activities at the community level, thus promoting the rational use of antimicrobial agents. The achievement contributes toward attaining Joint External Evaluation (JEE) capacity level 3.

Another notable achievement is the technical assistance extended to the MOHCDGEC for active dissemination of the updated IPC guidelines. Two modalities were used for this dissemination. The first was a formal one-week training conducted in four regions (Dar es Salaam, Mwanza, Kigoma, and Songwe) that reached 350 health care workers. The second modality involved carrying out IPC guidelines compliance supportive supervision visits to six supported facilities in six regions, through which 180 health care workers were reached.

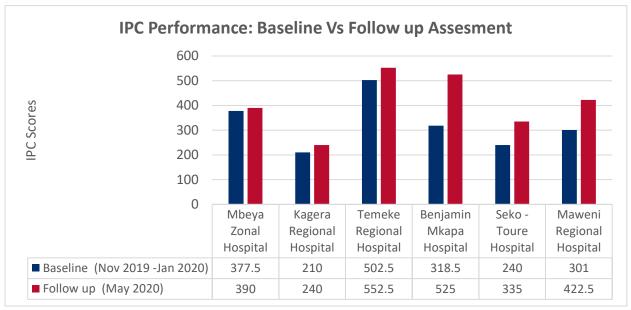


Figure 11: IPCAF results in six MTaPS-supported health facilities

The third achievement was the significant improvement achieved in World Health Organization (WHO) Infection Prevention and Control Assessment Framework (IPCAF) scores from the baseline, which was seen in all six MTaPS-supported facilities during a follow-up assessment (Figure 11). Specifically, two health facilities (Benjamin Mkapa Hospital and Maweni Regional Referral Hospital) moved from basic to intermediate level in their WHO IPCAF score. This achievement was a result of consistent capacity

building and technical assistance in IPC provided to health care workers in these facilities. MTaPS, in close collaboration with the MOHCDGEC, provided formal IPC training and routine mentorship and supportive supervision visits to the facilities using the continuous quality improvement approach to attain and sustain desired changes. This contributed to more health facilities and health care personnel adhering to the IPC guidelines, which is a condition for progressing from IEE capacity level 3 to 4.

#### **QUARTER PROGRESS FOR FY20 Q4**

#### **RESULT AREA I: EFFECTIVE MULTISECTORAL COORDINATION ON AMR**

#### Activity 1.1.1: Enhance multisectoral coordination to improve AMR containment

MTaPS worked with the MOHCDGEC and other key AMR partners to organize two important forums as part of the strategy to enhance multisectoral coordination on AMR. The first forum was the partners coordination meeting, which brought together collaborators working on AMR to share their project progress and challenges. Participants brainstormed issues about AMR data management; suggested monthly partner meeting to discuss AMR progress; and discussed how projects can implement mentorship programs, supportive supervision, and other trainings. The meeting also identified areas of collaboration to avoid overlap or duplication of activities in partners' future work plans. The meeting was attended by representatives from the National Health Laboratory Quality Assurance and Training Centre, Infectious Diseases Detection and Surveillance (IDDS) project, Ministry of Livestock and Fisheries, and MTaPS. Secondly, MTaPS supported the coordination of the Multisectoral Coordination Committee meeting (MCC). Participants received updates from the AMR Awareness, Surveillance, IPC, and AMS Technical Working Groups and progress reports on project implementation from MTaPS, IDDS, and other projects supporting the MOHCDGEC in AMR containment.

Element	вмн	MZRH	TRRH	KRRH	Overall N=4
Availability adequate reserve of water at least 80- 100 Lts/P/D	٧	٧	٧	٧	100%
Periodic water quality analysis	Х	Х	Х	Х	0%
Cleaning schedule of the reserve tanks as per guideline	Х	Х	Х	Х	0%
Water tanks cleaned periodically	٧	Х	Х	Х	25%
Water treatment at facility level	٧	Х	Х	Х	25%
Alternative source (s) of water	X	Х	X	Х	0%

Table 2: Water Supply Assessment

Activity 5.2.1: Complement WASH and waste management initiatives through collaboration with MOH, national stakeholders, and collaborators

MTaPS conducted water, sanitation and hygiene (WASH) assessments in four MTaPS-supported health facilities. Selected assessment results are shown in Table 2 – Table 4 and in Figure 12. The major gaps observed on WASH in health care can be divided into technical, infrastructure, and deficient resources capacity. Under technical infrastructure, challenges include

intermittent water supply; poorly maintained sanitation systems; malfunctioning sinks and showers; and deficiency of sanitary facilities for special groups (the elderly, children, and those with impaired mobility). Under resources capacity, the identified gaps were inadequate resources (financial and personnel) for operation, maintenance, planning, and management; inadequate monitoring; and lack of guidelines for WASH in health care facilities. WASH infrastructure and services are essential to allow health care workers to implement appropriate IPC practices.

MTaPS conducted an orientation on the new WASH guidelines and provided mentorship to 18 health care workers from the four MTaPSsupported health facilities. The mentorship emphasized availability, maintenance, and use of handwashing facilities; minimum water storage and treatment requirements; and waste management and standards of sanitation facilities in health care settings, all of which help facilities have a supportive environment for IPC. This activity contributes to progress on the pathway toward JEE capacity level 4. In addition, progress will be enabled by implementing the recommended actions in benchmark 3.3 on IPC in WHO's 2019 International Health Regulations (IHR) capacities benchmarking tool.

## RESULT AREA 3: USE OF ANTIMICROBIAL MEDICINES OPTIMIZED

No activities were held this quarter for activities 1.3.3, 2.3.1, and 3.3.1.

# Activity 1.3.1: Support the development of AMS policies and guidelines, including action plans and implementation plans, in collaboration with WHO

MTaPS is supporting the printing of 15,000 copies of the Multisectoral AMS Policy Guidelines. MTaPS had earlier provided technical assistance and support in the development, drafting, and finalization of the document. This policy guidelines document is important for guidance on implementation of AMS activities at the national level and in the supported facilities. Completion of this activity will help Tanzania make progress on the pathway toward JEE capacity level 2 in indicator P.3.4, antimicrobial stewardship activities.

Element					
	вмн	MZRH	TRRH	KRRH	Overall
Connection to sewer	٧	٧	٧	Х	75%
Adequate Toilets at OPD	٧	٧	٧	٧	100%
Toilets for people with disability at OPD	٧	٧	Х	٧	75%
Availability of toilets for Staff at OPD	٧	٧	٧	٧	100%
Availability of toilet for staff in Wards	٧	٧	٧	٧	100%
Availability of Menstrual hygiene management facility in female wards	Х	Х	Х	Х	0%

**Table 3: Sanitation Assessment** 

Element					
	вмн	MZRH	TRRH	KRRH	Overall
Functional hand washing point at OPD	٧	٧	Х	٧	75%
Appropriate tap at the HWF	٧	٧	Х	X	50%
Availability of soap at HWF in OPD	٧	٧	Х	٧	75%
Availability of soap at HWF in Wards	٧	٧	٧	٧	100%
Availability of hand driers/paper towel in consultation rooms	Х	Х	Х	٧	25%

Table 4: Hygiene Assessment

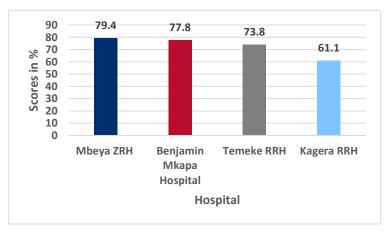


Figure 12: Overall ranking of four hospitals based on national WASH criteria

### Activity 1.3.2: Assist with classifying EML antibiotics into AWaRe (Access, Watch, Reserve) categories per WHO guidance

MTaPS supported Tanzania to use the WHO AWaRe categorization as a model list to classify the antibiotics registered for use in the country into Access, Watch, and Reserve categories according to WHO recommendations based on epidemiological data on resistance and sensitivity. The list will serve as an integral part of the newly revised Standard Treatment Guidelines (STGs) and National Essential Medicines List (EML).

The AWaRe classification is an important and basic tool in restricting antibiotic use in clinical settings and the community as a whole, especially those antibiotics with higher potential for creating AMR. The appropriate classification of EML antibiotics into AWaRe categories is one of the global and country-specific strategies for combating AMR and promoting rational use of antimicrobials.

Two workshops were organized during the classification process. Experts from health research institutions (Kilimanjaro Christian Research Institute and National Institute of Medical Research); medical universities (Muhimbili University of Health and Allied Sciences [MUHAS] and Kilimanjaro Christian Medical University College); national tertiary hospitals; members of the National Medicines and Therapeutics Committee (NMTC), and representatives from the President's Office-Regional Administration and Local Government and National Reference Laboratory participated in the first workshop. The workshop outcome was a draft of the list of antibiotics classified into AWaRe groups as per the country's identified list of infectious diseases and syndromes.

The second workshop built upon the work done in the first workshop, whereby doctors from different medical specialties were invited from institutions including MUHAS; regional referral hospitals; the NMTC; and national hospitals (KCMC Hospital, Mbeya Zonal Referral Hospital, Bugando Hospital, Tumbi Hospital) as well as MOHCDGEC representatives from Pharmaceutical Services Unit and Curative Department. The workshop finalized the AWaRe categorization of antibiotics as per the country's list of infectious diseases and syndromes and integrated the AWaRe antibiotics into the STGs and National EML, which is being reviewed. A strategy for operationalizing the AWaRe antibiotics into policy and action was also developed that will assist in implementing and monitoring AMS activities at the national and facility levels.

Appropriate classification of antibiotics in the EML will facilitate the tailored control/regulation of antibiotics according to the risk or propensity toward abuse/misuse and resistance development. This activity helps promote appropriate antimicrobial use and progression toward JEE capacity level 2. In addition, this progress will be enabled by implementing the recommended actions in benchmark 3.4 on optimal use of antimicrobials in WHO's 2019 IHR capacities benchmarking tool.

# Activity 5.3.1: Promote community awareness and preparedness through Information Education Communication/Behavior Change Communication (BCC) activities on IPC/AMS for patients and the public

MTaPS supported the MOHCDGEC with printing 7,000 copies of the AMR Communication Strategy. MTaPS had earlier worked collaboratively with the MOHCDGEC and OSC to develop the multisectoral communication strategy to help the country coordinate stakeholders to implement activities addressing AMR-related issues to align requirements of the NAP on AMR. The availability of the multisectoral AMR Communication Strategy will help Tanzania effectively coordinate stakeholder efforts in conveying appropriate messages promoting containment of the spread of AMR in the country. This contributes toward attaining JEE capacity level 3 in indicator P.3.4, antimicrobial stewardship activities.

ACTIVITIES FOR NEXT QUARTER	
ACTIVITY AND DESCRIPTION	DATE
Review plans and progress through regular meetings of the MCC (MTaPS will organize targeted MCC meetings to evaluate activity implementation progress and troubleshoot challenges.)	Oct. 2020
Support active implementation of the approved national IPC guidelines (MTaPS will support the MOHCDGEC to actively implement the approved national IPC guidelines in the priority regions and collaborate with partners to secure their contributions.)	Oct. 2020
Strengthen institutional capacity building to local training institutions to manage e-learning on IPC for both pre- and in-service health care workers (MTaPS will continue working with the MOHCDGEC to strengthen institutional capacity of local training institutions to provide quality e-learning on IPC for both pre- and in-service learners.)	Nov. 2020
Develop a system for M&E of IPC program in health facilities (MTaPS will support M&E system design and development, customizing data elements and data sets into the Health Management Information System.)	Dec. 2020
Continue promoting a self-improvement culture through local teams that use continuous quality improvement methodologies for IPC (MTaPS will actively revitalize the quality improvement teams and IPC sub-committee to implement quality improvement in health care facilities.)	Oct. – Dec. 2020
Support development of hospital antimicrobial formulary and other related AMS policies (MTaPS will support health care facilities to develop their own hospital formulary that can ensure appropriate prescribing, dispensing, and use of medicines.)	Dec. 2020

#### **UGANDA**

For progress on MTaPS/Uganda's COVID-19 activities, click here.

### **HIGHLIGHTS FROM PROGRAM YEAR 2 (FY20)**

Development of the Veterinary EML and guidelines on infection control and use of antimicrobials in the agricultural sector

MTaPS engaged the National Drug Authority (NDA); the Ministry of Agriculture, Animal Industry, and Fisheries (MAAIF); the National Antimicrobial Resistance (AMR) Sub-Committee (NAMRsC); and Makerere University to develop the Uganda Veterinary Essential Medicines List (VEML) and develop guidelines on infection prevention and use of antimicrobials in the agricultural sector.

MTaPS worked collaboratively with all involved stakeholders to plan the activity and develop a roadmap for completion, promoted country ownership and cooperation in the development of the VEML and guidelines. The planning process culminated in an inception meeting between MTaPS and the MAAIF, where an agreement was reached on the format of the documents. The final documents to be developed were the VEML and guidelines on infection prevention and use of antimicrobials for the five leading agriculture production systems in Uganda—cattle farming, poultry farming, goat and sheep farming, fish farming, and pig farming.

A literature review was conducted for all documents, and the documents were drafted. The first drafts of the documents were then presented to the MAAIF, NDA, and other stakeholders for input and review. During this one-day meeting, stakeholders provided input on the process of development of the documents. All comments were captured and review of the documents undertaken. Copies of the documents and revisions were the shared with the MAAIF technical team for concurrence. Regional stakeholder meetings were conducted for input by veterinary practitioners, farmers, and district teams. After capturing input from the regional consultative meetings, the documents were shared with the MAAIF for review. This was the followed by another national consultative meeting attended by the NDA, MAAIF, Makerere University, and other stakeholders. Due to COVID-19, this meeting was held online. In this meeting, the progress on activity implementation was presented to the team for input and concurrence. The input from stakeholders was captured by the MAAIF for review. The MAAIF provided final technical input, and the technical team approved the versions of the reports as final. MTaPS followed this up by organizing a national validation meeting. Stakeholders in the agricultural sector were invited to attend this meeting for input and validation. This was an online meeting due to COVID-19 restrictions on meetings. Attendees at this meeting resolved that the documents were validated and recommended technical and political approval by the MAAIF. MTaPS provided editorial review of the documents and forwarded the final version to the MAAIF for signing.

These documents help MTaPS control AMR by reducing the gap between animal health and human health for antimicrobial stewardship (AMS). The activity also contributes to JEE-2 P.3.4 capacity 2 for AMR.

Key lessons learned include the need for early engagement of all stakeholders starting with activity inception to help overcome political and technical bottlenecks. The technical review of these documents was conducted online due to COVID-19 restrictions. This demonstrates that technology can be successfully used to implement MTaPS activities and hold meetings while achieving deliverables.

#### Development of key messages on AMR in the agricultural sector

MTaPS worked the MAAIF and the NAMRsC to develop key messages aimed at increasing AMR awareness in the agricultural sector.

Initiation activities included a series of meetings with the MAAIF Department of Animal Health and NAMRsC to plan the activity and develop timelines. It was agreed that the MAAIF would take the technical lead role. The NAMRsC would be given regular updates. MTaPS developed AMR stickers, posters, factsheets, website content, an MAAIF press release on AMR in the livestock sub-sector, and an MAAIF AMR policy brief. Stakeholder meetings were held for review of the messages, which were subsequently validated and approved by the MAAIF.

MTaPS result areas for Uganda include multisectoral coordination for AMR, infection prevention and control (IPC), and AMS. All of these areas are directly and indirectly impacted by AMR awareness. The messages are targeting members of the public, farmers, veterinary drug users, animal health professionals, and veterinary practitioners. Increased awareness about AMR in the animal sector offers an opportunity for all AMR-related activities to benchmark on this knowledge to advance successful AMR implementation in Uganda by gaining buy-in and public acceptance quickly.

It was key to engage stakeholders early, especially the MAAIF and NAMRsC. These engagements gained us significant buy-in for the upcoming activities. The stakeholders were very cooperative whenever called upon. In addition, this activity was a timely one as the sector badly needed it. It is prudent to identify sector needs and priorities and focus on funding them.

#### Development of a platform for information and document exchange for the National AMR Sub-Committee

MTaPS engaged the Ministry of Health (MOH), MAAIF, and NAMRsC to develop a platform for information and document exchange for the NAMRsC. The platform is aimed at increasing multisectoral collaboration for the Global Health Security Agenda, particularly AMR containment.

The NAMRsC is a One Health body that is overseeing the implementation of the National Action Plan for AMR. The sub-committee works through five technical working committees (TWCs), including IPC and AMS. The platform is a three-in-one platform for the NAMRsC and the IPC and AMS TWCs. The platform has current guidelines on best practices, details of meetings, a meeting and activity scheduler, research papers, terms of reference, membership, and general information about these three committees. This works as a one-stop center for information on the detailed activities of AMR implementation in Uganda.

MTaPS engaged the MOH Department of Pharmaceutical Services and National Medicines, NAMRsC, and MAAIF Department of Animal Health in a series of meetings aimed at planning and envisioning milestones for the platform. It was agreed that the NAMRsC would take the lead and make decisions during the development of the platform. A layout of the platform was developed and presented to the NAMRsC, which provided input and recommendations. Further engagements were made with the NAMRsC chairperson since the entire sub-committee could not hold meetings due to COVID-19. In June 2020, an IT specialist was brought on board to populate the platform and build it to completion. In September 2020, the updated site was presented to the NAMRsC chairperson; upon approval, procedures to transfer the site to the MOH server were initiated. Meetings with the Department of Health Informatics were held, and approval was granted to transfer the site to the MOH server.

The platform offers an opportunity for better collaboration of the NAMRsC. A key challenge for multisector coordination has been the lack of a clear collaboration platform for both data and information sharing given the siloed nature of work in the key line ministries that comprise the One Health Platform and the NAMRsC. By completing this activity, MTaPS has supported the Government of Uganda contribute to the completion of the following WHO benchmark for P. 3.1: Organize effective coordination through regular meetings.

The key lessons learned include assessing the need for the activity before it is planned. This bought us buy-in from all stakeholders, as the need for the platform was appreciated by everyone. Another lesson

learned was the need for early engagement of stakeholders right from the beginning. The COVID-19 pandemic restricted NAMRsC meetings, making it harder to work with a bigger group.

### **QUARTER PROGRESS FOR FY2 Q3**

#### RESULT AREA I: EFFECTIVE MULTISECTORAL COORDINATION ON AMR

# Activity 1.1.1: Work with Ugandan National AMR Sub-Committee (NAMRsC) to set up IPC and AMS technical working committees

MTaPS has completed the development of an information and documentation exchange platform for the NAMRsC. A user guide has also been developed and submitted to the MOH IT Department. The platform has been approved by the NAMRsC. MTaPS is supporting the NAMRsC to transfer the platform to the MOH website for long-term hosting.

#### **RESULT AREA 2: INFECTION PREVENTION AND CONTROL**

# Activity 2.5.1: Identify gaps in IPC implementation at select referral hospitals and implement action plans

MTaPS conducted supportive supervision to supported health facilities to strengthen IPC. The supervision was part of the COVID-19 IPC support to health facilities that is being provided by MTaPS and implemented through a national mentorship program. Through the supportive supervision visits, the health facilities have been linked to the national logistics team to obtain additional supplies for IPC. IPC mentors based at each ward have been identified, and a system for routine reporting of data for both case management and health care worker COVID-19 surveillance has been created. There is the potential to harness work done during COVID-19 to build partnerships for roll out of IPC work at lower-level health facilities. This could be achieved by working with PEPFAR-funded district partners to implement the MTaPS-developed curriculum on IPC and AMS. Additionally, data collection tools developed by MTaPS could be rolled out at a larger scale through these collaborations, leading to wider impact of the work done by MTaPS.

#### **RESULT AREA 3: USE OF ANTIMICROBIAL MEDICINES OPTIMIZED**

# Activity 3.1.1: Work with National Drug Authority and Ministry of Agriculture, Animal Industry, and Fisheries (MAAIF) to update the EML for veterinary use and develop guidelines on the use of antimicrobials in the animal sector

MTaPS has completed the development of the VEML and guidelines for infection prevention and use of antimicrobials in the agricultural sector and submitted the documents to the MAAIF for approval.

# Activity 3.3.1: Work with the National Drug Authority (NDA) to establish the data and information platform for national-level activities aimed at monitoring the use of antimicrobials

MTaPS supported NDA technical officers to present the draft framework for monitoring the use of antimicrobials to senior management. MTaPS will follow up with the NDA on its review and adoption.

#### Activity 3.5.1: Increase antimicrobial resistance (AMR) awareness in the animal sector

MTaPS developed messages about AMR in the agricultural sector and they have been technically reviewed by the MAAIF. Once finalized, the messages will be submitted to the MAAIF for printing. The use of these messages will help to increase awareness of AMR in the animal health sector and advance the country's JEE-2 capacity 2 on benchmark P.3.1.

# **ACTIVITIES FOR NEXT QUARTER**

ACTIVITY AND DESCRIPTION	DATE
Initiate the use of the developed information exchange platform: MTaPS will work with the NAMRsC and the IPC and AMS optimal access and use TWCs to demonstrate the use of the information exchange platform for decision making.	Dec. 2020
Print copies of the Veterinary EML and guidelines for later dissemination: MTaPS will undertake the printing of the VEML and guidelines according to the specifications of the MAAIF	Nov. 2020
Conduct supportive supervision: Supportive supervision of IPC work being done at MTaPS-supported health facilities	Dec. 2020
Print messages on AMR awareness in the animal sector: MTaPS will undertake the printing of the developed AMR awareness messages according to the specifications of the MAAIF	Nov. 2020
Supportive supervision for the Medicines and Therapeutics Committee (MTC) and AMS teams: Conduct support supervision to monitor progress on facility improvement plans	Dec. 2020
Support NAMRsC meeting: Support the quarterly NAMRsC meeting of the One Health Platform	Dec. 2020
Support AMS TWC meeting: Support the quarterly AMS TWC meeting	Dec. 2020
Support IPC TWC meeting: Support the quarterly IPC TWC meeting	Dec. 2020
Support facility-based IPC and AMS committee meetings: Support two monthly IPC and MTC/AMS committee meetings	Dec. 2020
Finalize the draft for the framework for measuring the consumption of antimicrobials at the national level: Support the NDA to review and adopt the framework for data monitoring	Dec. 2020

# MONITORING, EVALUATION, AND LEARNING

#### MONITORING AND EVALUATION

#### Baseline Report

The global baseline report, including 16 individual country baseline reports, was reviewed by the contracting officer representative (COR) team and revised by the Monitoring, Evaluation, and Learning (MEL) team during the last quarter. The MEL team also conducted an after-action review to reflect on the lessons learned from the design and implementation of the MTaPS baseline assessment. Four key lessons were documented to inform future MTaPS assessments: (1) allocate sufficient time (over 2 months) to obtain approvals from local institutional review boards to collect data on facility- and patient-level indicators, (2) involve technical staff at various stages of the baseline assessment, particularly during the design stage, to a greater degree, (3) finalize indicators and their PIRS before collecting data, and (4) establish and adhere to the assessment protocol to ensure uniform application of methods across countries.

#### Gender Indicator Development

A technical review of indicators conducted in Q3 identified some gaps in the indicator definitions, including the insufficient selection of all necessary indicators for measuring activities included in the countries' work plans. The review also revealed that more indicators were needed for measuring MTaPS gender activities. Following review and consultations with the gender advisor from Overseas Strategic Consulting (OSC) and MTaPS' senior management team, two additional indicators were identified for monitoring gender results for the MTaPS program:

- # of pharmaceutical sector-related policies, legislation, regulations, or operational documents with gender-inclusive language that are developed or updated with technical assistance from MTaPS
- # of gender-related technical guidance documents and other capacity-building products produced by MTaPS

The MEL team continued to finalize PIRS for the gender indicators. The revised indicators and their PIRS will be shared with the COR team and included in countries' MEL plans during Q1 of project year 3.

#### Sentinel Sites Concept

The MEL team continued developing the concept note for establishing sentinel sites for extensive monitoring and detailed reporting on selected, key MTaPS activities. The purpose of monitoring sentinel sites is to better understand the approaches' effectiveness of select MTaPS interventions that are not captured by the standard MTaPS indicators. During the reporting period, the MEL team collaborated with the technical team to select specific activities that MTaPS implements that would be well suited for the sentinel site concept. The draft concept note was reviewed internally with the senior management team. The final draft will be shared with the COR team for feedback.

#### Support for Country MEL Plans and Work Plans

The draft template for country MEL plans was reviewed by the senior management team and the COR team in Q4. After incorporating feedback and finalizing the template, the MEL team began rolling out the new template for use by MTaPS country programs. Technical support was provided to Rwanda, Tanzania, Kenya, Uganda, Ethiopia, Bangladesh, Nepal, Philippines, and Mozambique to develop MEL plans using the new template. In project year 3, the MTaPS headquarters and regional MEL teams will support all other MTaPS countries in revising or developing their MEL plans using the newly developed template.

During Q4, the MEL team also supported country teams with their project year 3 work plans. The MEL team supported the technical and project management staff to identify appropriate indicators for each activity and to ensure that MEL activities were included in each work plan.

### Monthly M&E Sessions for Country Teams

In Q4, the MEL team began facilitating monthly meetings with all country teams. The meetings are an opportunity for country teams to receive MEL-related training and guidance and for country teams to share experiences and review progress regarding implementation of MEL activities. Three monthly meetings held during the reporting period focused on training countries to use SurveyCTO for data entry, developing and implementing MEL plans, and planning for annual reporting. Country teams were oriented on knowledge management (KM) and learning plan development, practical application of lessons learned, technical documentation, success story development, standardized templates for presentations and reports, compliance with submissions to the USAID Development Experience Clearinghouse (DEC) and MTaPS Institutional Memory, and how to access and use KM resources available for staff. Future monthly sessions will focus on country teams sharing experiences regarding implementation of KM, best practices, and capturing and documenting lessons learned.

#### **Programing of MTaPS Indicators into SurveyCTO**

The MEL team completed programming the MTaPS SurveyCTO system for reporting on MTaPS indicators. A list of health facilities with corresponding locations, types, and tiers was programmed into the SurveyCTO server. The MEL team added data collectors, data reviewers, and monitors to SurveyCTO and ensured the data collected are automatically synced to spreadsheets for further analysis.

A SurveyCTO user guide was developed to support field office data reporting, and SurveyCTO training was provided to country team staff to ensure efficient data entry. The MEL team rolled out the incountry review and approval process for data entered in SurveyCTO. All countries are now using the system to report data on their indicators.

#### **Data Entry and Verification SOP**

The MEL team began drafting an SOP for data entry and verification during Q4. The purpose of the SOP is to provide country teams with comprehensive and standardized guidance for entering and validating MTaPS performance data using the MTaPS Data Management and Analytics Platform (DMAP), which consists of SurveyCTO and PowerBI. The SOP includes a guide describing a step-by-step process for entering data into the SurveyCTO server and a data review and verification approach. The SOP guides supervisors' review and approval of entered data, data flow, and data export from SurveyCTO as comma separated values (Excel). The SOP also includes information about compliance with the US government open data policy and procedures for submitting data to the Development Data Library (DDL). The MEL team will finalize the SOP and roll it out for implementation by country programs in Q1 of project year 3.

#### COVID-19 Monthly Reports

The MEL team prepared progress reports based on MTaPS country teams' reporting and documentation of COVID-19-related implementation and lessons learned. PowerBI was used to generate the COVID-19 indicator dashboard for July, August, and September. The monthly reports include data on health workers who have received training on COVID-19 and the amount of COVID-19-related infection prevention and control (IPC) training conducted in health facilities. During Q4, three reports were created: a one-page summary report by each country, an all-country combined summary report, and country-specific detailed reports.

#### Miscellaneous Monitoring and Evaluation Support

During Q4, the MEL team also supported USAID with the review, testing, and feedback on the COVID-19 Pillar 2 reporting system (Excel-based). Technical support was also provided to USAID with the development of indicators for the interagency IPC.

#### **KNOWLEDGE MANAGEMENT**

#### Knowledge Management Guidance

In Q4, MTaPS drafted the following guidance documents, which will be finalized and rolled out in the next quarter.

Guide for Integrating CLA Practices in MTaPS Activities

The purpose of the collaborative learning and adapting (CLA) guide is to help MTaPS staff identify and integrate CLA practices into the program and foster a strong learning organization capable of managing adaptively. It supports MTaPS staff in deliberately thinking of the approach to CLA that might be best tailored to program context and identifying CLA components that could be built upon and strengthened. During the next quarter, the CLA guide will be translated into French and rolled out to country teams. To operationalize CLA, country teams will be oriented on how to integrate CLA practices within country programs. Specifically, country teams will be given ongoing support to capture and document best practices and lessons learned, plan and conduct virtual pause and reflect sessions to answer learning questions and use the outputs to adapt activities.

#### Peer-Reviewed Publications Guidance

MTaPS developed draft guidance for staff seeking to publish articles in peer-reviewed publications. The guidance provides a broad overview of the writing process, specifically, guidelines for determining the type of article to write, considerations for choosing a journal and submitting the article, criteria for determining authorship, and links to resources for staff seeking to publish in peer-reviewed publications. In Q1 of project year 3, MTaPS will finalize and roll out the guidance in English and French.

#### Standard Requirements for Deliverables

MTaPS developed draft standard requirements for deliverables identified in the MTaPS contract and annual work plans. This document describes the standard requirements and process for developing MTaPS' contract and annual work plan deliverables, including technical reports, fact sheets, presentations, success stories, guidelines, SOPs, job aids, technical highlights, technical briefs, case studies, videos, communication materials, training materials, recorded trainings, websites, etc. In the next quarter, MTaPS will finalize and roll out the standard requirements to all staff, partners, and consultants.

#### Guidance on Open Data Compliance and Submission

MTaPS developed draft guidance for compliance with the open data policy requirements and the process for data submission to USAID's DDL. The guidance includes a standardized process for data clearance (within MTaPS), external data clearance (by the host country government and USAID Mission as required), COR approval/clearance, and data submission to the DDL. The guidance includes information on types of data to submit, where and how to submit the data, and when data access can be shared and reused. Also included is a data compliance checklist for staff responsible for data compliance and submission. This guidance will be incorporated into the data entry and verification SOP being developed by the MEL team in the next quarter.

### Support to Country Programs for KM and Learning Plan Development

In the last quarter, MTaPS developed a KM and learning plan template for country MEL plans and standardized language on KM and learning activities for annual work plans. Once the template and standardized language were finalized after incorporating internal feedback, they were shared with country teams. During Q4, technical support was provided to country teams to develop KM and learning plans and integrate them into country MEL plans. Technical support was provided to country programs to integrate KM and learning activities within the MEL section of project year 3 country work plans.

#### Rapid KM Assessment

MTaPS rolled out a questionnaire in Q4 to assess country teams' understanding and adherence to processes that ensure KM standardization across the program. All MTaPS-supported countries completed the assessment. The findings were used to orient country teams about KM at the monthly MEL team meetings held in July, August, and September on existing KM processes and available resources, including:

- Standardized KM plan template for country programs, with clearly defined activities, outputs, and implementation timeframe
- Standardized learning plan for country programs to ensure alignment with the global learning agenda
- Coordinating M&E, communication, and KM functions within the country program
- Process for gathering technical knowledge from outside the country program for internal use through targeted literature searches and literature reviews provided by KM teams
- Mechanisms, such as brown bags, for knowledge sharing and exchange with technical staff in other MTaPS-supported countries and home office staff
- System and process for capturing, documenting, sharing, and applying lessons learned from project implementation experience
- Designating a point of contact within the country program team for submitting narratives to the MTaPS lessons learned collection
- Use and application of lessons learned in future work planning and implementation
- Standards developed by MTaPS for technical documentation, including a process, timeframe, and descriptions of key content elements to be included in technical products, such as highlights and briefs
- Guidelines and process for developing articles and manuscripts for peer-reviewed publications
- Process and template for developing and submitting quality success stories for quarterly/annual reporting
- Guidance on filing program documents on the local access network (the M drive), including folder and sub-folder structures, descriptions of folders, filing governance, and management responsibility
- Guidance and process for submitting deliverables to the USAID DEC and MSH/MTaPS institutional memory database

A quick reference sheet with descriptions of KM process and guidance documents and links to available resources was developed to help countries readily access them. In the next quarter, targeted training will be provided to country teams on how to conduct and facilitate pause and reflect meetings and afteraction reviews. Country teams will be oriented on developing peer-reviewed publications and collaborating, learning, and adapting.

#### **Knowledge-Sharing Events**

In Q4, MTaPS organized two brown bag presentation as part of the program's *Pharmaceutical Systems in Practice* series, focused on health technology assessments (HTAs) and AMR work in Uganda. MTaPS held a webinar for USAID staff on pharmacovigilance (PV) and organized a panel discussion on accelerating access to quality medical products during COVID-19 and beyond.

#### Health Technology Assessments in Practice

As part of the MTaPS' *Pharmaceutical Systems in Practice* series, held on July 17, 2020, MTaPS gave a presentation on how the program is advancing HTA use in LMICs. Health systems face the challenge of managing and allocating limited resources. More countries are using HTA processes to determine the value of health technology (e.g., drugs, medical devices, diagnostic tests, and medical procedures) at different points in its lifecycle to better inform coverage, reimbursement, quality, and pricing decisions. HTA is thus a valuable component of decision making to promote an efficient, equitable, and high-quality health system.

#### Multisectoral AMR Approach in Uganda

At a knowledge-sharing brown bag for MTaPS staff and partners, held on September 29, 2020, MTaPS Uganda shared their experiences, challenges, and lessons learned in controlling AMR. They supported the Zoonotic Disease Coordination Center and the National One Health Technical Working Group in implementing Uganda's national action plan for AMR.

Mitigating Medical Product Risks and Building Trust, How Pharmacovigilance Systems Serve during Pandemics and Beyond

MTaPS hosted a webinar for USAID staff worldwide on August 12, 2020 as part of the program's pharmaceutical systems strengthening webinar series for USAID that presented on the why, what, and how of PV and on MTaPS' work that supports strengthening PV systems in LMICs during and post COVID-19, which is pivotal to better health outcomes and higher performing health systems. Webinar presenters included global, regional, and country experts.

Seizing the moment: Providing faster access to quality medical products during COVID-19 and beyond

On September 17, 2020, MTaPS and partner Deloitte spoke at a virtual expert panel hosted by MTaPS. The discussion focused on accelerating access to quality medical products during COVID-19 and beyond. The speakers outlined the clear and urgent need for strong pharmaceutical systems and explored novel approaches emerging from the COVID-19 response. These approaches can be leveraged to efficiently and effectively respond to the pandemic while accelerating universal health coverage progress.

#### **LEARNING ACTIVITIES**

In Q4, MTaPS advanced the global learning agenda by:

- Developing six of eight modules of the PSS 101 e-learning course to increase USAID staff's
  understanding of the basic principles of PSS, including how addressing pharmaceutical management
  problems contribute to advancing universal health coverage; combating AMR, HIV and AIDS, malaria,
  and TB; and promoting maternal and child health
- Continuing to refine PSS Insight, working with partner Boston University School of Public Health to reconfigure the tool, reducing the number of indicators from 117 to 38, and proposing a method for benchmarking progress at the national level
- Initiating collaboration with WHO on the development of its proposed Access GBT, with the goal of integrating it with PSS Insight
- Convening three virtual learning exchange sessions on the Joint Learning Network on medicine
  pricing strategies between July and September 2020, engaging with participants from 17 countries
  directly involved in or responsible for national health insurance schemes, and procuring and
  distributing medicines
- Publishing two peer-reviewed articles a commentary, <u>Integrating Pharmaceutical Systems Strengthening</u>
   in the <u>Current Global Health Scenario</u>: <u>Three 'Uncomfortable Truths'</u>, was published in June 2020 in the
   Journal of Pharmaceutical Policy and Practice and an articles, entitled The <u>WHO Global Benchmarking Tool</u>:

<u>Game Changer for Strengthening National Regulatory Capacity</u>, was published in BMJ Global Health in August 2020.

- Collaborating with LaunchDSI on a case study on the engagement of retail drug outlets by the National Health Insurance Fund in Tanzania's national benefits program and developing a manuscript, which is currently under peer-review
- Drafting a manuscript on generating political will for regulatory systems strengthening and submitting it for peer review
- Submitting an abstract for consideration as an oral presentation at the 13th Global Health Supply Chain Virtual Summit, scheduled for November 17-19, 2020, on reconfiguring the supply chain to balance equity and emergency response during COVID-19 in the Philippines
- Completing development of a roadmap for institutionalizing HTA and planning the launch of the roadmap in early October

Details on these activities can be found in the Cross-Bureau section of this report.

#### **LESSONS LEARNED AND ADAPTATIONS**

When lockdowns and work-from-home directives went into effect in supported countries, MTaPS leveraged remote collaboration software to ensure that staff could work from home efficiently without pause in activities by using WebEx and Google Meet. In the face of restrictions on in-person meetings, MTaPS country teams held virtual meetings and oriented partners and clients on adopting them. MTaPS also used online surveys to gather expert input instead of in-person workshops. When face-to-face training events could not take place as planned, MTaPS country teams converted them into virtual events, where reliable information and communications technology existed while making concessions for in-person training activities only when safe and necessary. MTaPS embraced online learning approaches, converting training packages into e-learning modules, and leveraging e-learning platforms, such as Moodle, for hosting e-learning courses.

Developing and implementing COVID-19 mitigation plans enabled MTaPS country programs to make timely programmatic decisions, adjust work plans, and engage partners in modifying activities in response to the pandemic.

#### Lessons Learned from Technical Implementation

In Q4, MTaPS country teams systematically documented lessons learned and best practices from implementing PSS and GHSA activities during the pandemic. These lessons and best practices are summarized below.

Building the capacity of hospitals and health facilities to develop locally available, standard IPC solutions is vital for responding to outbreaks, such as COVID-19. In Ethiopia, the production of alcohol-based hand rub (ABHR) at local hospitals has increased Ethiopia's resources of ABHR and facilitated improved hand hygiene practices. ABHR-producing facilities across all corners of Ethiopia have created a chance for nearby health facilities and the local public to have affordable and reliable access to standardized ABHR. As part of its IPC-related work, MTaPS provided technical and financial support to the IPC Technical Working Group (TWG) for the development of an SOP for ABHR production at the facility level. The MOH launched the SOP for ABHR production in January 2020 and trained selected pharmacists in hospitals, including the University of Gondar and Tikur Anbessa hospitals, to increase ABHR production capacity. The development of the SOP for ABHR production and its launch and the initiation of capacity building across health facilities and health care professions was timely—over 140 hospitals in Ethiopia produced ABHR in response to the COVID outbreak.

Linking the action plan with appropriate ongoing initiatives of the government increased acceptability of MTaPS initiatives and thus the feasibility of implementation. The MTaPS Jordan team managed to turn challenges into opportunities by staying adaptive and linking COVID-19 and action plan on AMR/AMS

activities. MTaPS Jordan was tasked with two major activities: (1) strengthening the National Steering Committee and its technical subcommittees to support operationalization of the national AMR committee through multisector coordination and (2) pilot-testing the AMS program at two leading hospitals in Amman. In the beginning, MTaPS Jordan conducted a thorough stakeholder mapping and analysis of AMR/AMS initiatives and identified the main challenges and opportunities for project implementation. Following the outbreak of COVID-19, MTaPS could not continue working with the MOH Communicable Diseases Directorate, the main counterpart. In addition, MTaPS Jordan could not start the planned operationalization of AMS programs at the selected hospitals due to shifting health care system priorities and countrywide curfew due to COVID-19. MTaPS directed its support to the MOH National Action Committee, assisting them with preparations for the full AMS program implementation, once feasible.

Multiple initiatives for PSCM and PV strengthening that were implemented by the MTaPS Kenya team were challenged with the abrupt changes in the context of the health care system (such as the shift of PSCM roles from a national level to the local level) and COVID-19. The MTaPS team discussed these shifts internally to see if their technical approaches for activities were still valid and continued to work closely with DOH and partners to ensure that activities were aligned with DOH's priorities. Further monitoring of the situation at the national DOH level was also critical to see if other shifts in priorities were occurring.

Addressing the rising threat of AMR requires a multisectoral approach referred to as One Health where MTaPS helps strengthen multisectoral coordination for AMR containment. The leadership of One Health is critical for effective implementation of multisectoral activities in MTaPS-supported GHSA countries, particularly developing the national AMS plan in Senegal, which had slowed under DPM/MOH leadership due to competing priorities with the COVID-19 pandemic. Moving forward, MTaPS Senegal will ensure that multisectoral activities in its work plan are implemented in coordination with and through the AMR TWG, under the guidance of One Health leadership. In Burkina Faso, the MTaPS team realized the importance of the One Health platform (OHP) and the need to push the Technical Secretariat to fully operationalize the OHP, which is key to implementing multisectoral stakeholder coordination. To support operationalization of the OHP, MTaPS contributed to drafting the ministerial order that defines the roles, composition, and functioning of the One Health Steering Technical Committee, Technical Secretariat, and technical commissions and contributed to developing a roadmap for the OHP.

Collaborating with professional health associations and councils to determine IPC training needs and codesigning and implementing training are key in building the capacity of health care workers through inservice IPC continuous professional development (CPD)-linked courses. The MTaPS Kenya team collaborated with health professional associations (National Nurses Association of Kenya [NNAK], Kenya Clinical Officer Associations [KCOA], Association of Kenya Medical Laboratory Scientific Officers [AKMLSO], Kenya Society for Physiotherapists [KSP], Kenya Pharmaceuticals Association, Kenya Medical Association, and Pharmaceutical Society of Kenya) to develop an IPC CQI-linked in-service course. Collaboration between the associations led to the development of the training curriculum and modules that were implemented through NNAK, KCOA, AKMLSO, and KSP.

Linking in-service courses to CPD credits and re-licensing in Kenya incentivizes health care professionals to attend training and apply acquired skills in their practice. A total of 339 members from health professional associations, including NNAK, KCOA, AKMLSO, and KSP, attended the AMS CPD training webinars organized by MTaPS Kenya. A training needs assessment informed course content, which was extensively peer reviewed by AMS experts, including clinical pharmacists, pharmacologists, medical officers, a nurse, health care managers, infectious diseases specialists, laboratory scientists, and pharmacists. Since AMS is not a core component of professional education, training, or certification in both human and agricultural courses in Kenya, this training course aims to provide participants with the

right knowledge, skills, and attitude on appropriate handling of antimicrobials in health care settings and the community.

Ongoing communication and close coordination with stakeholders are critical for managing activities affected by transitions in host-country government structures. In May, the president of Nepal announced that the Department of Drug Administration (DDA) would transition to an autonomous Food and Drug Administration (FDA), which affected the majority of MTaPS Nepal's activities, specifically amendment of the drug law, reorganization of the DDA, and implementation of the quality management system (QMS). After the president's announcement, it was unclear whether Nepal's Department of Food Technology and Quality Control, under the Ministry of Agriculture and Livestock Development (which regulates food in the country), would merge with DDA or whether the DDA would take on only select food combined-medicine products, such as nutraceuticals. In preparation for the shift, MTaPS compared the organizational structures of other countries' FDAs and MTaPS-supported neighboring countries and compiled the advantages and disadvantages of including food as a responsibility of a national medicine regulatory agency. The MTaPS Nepal team shared the report with the DDA to inform its discussion with the MOHP on the topic. If the new FDA oversees all aspects of food, a separate act focusing on food will be required. Overall, clear and consistent communication through virtual conference calls, including the monthly meetings with the DDA, USAID Mission, and the Promoting the Quality of Medicines Plus (PQM+) program, allowed the MTaPS Nepal team to adjust plans and provide instrumental support to DDA's transition to an FDA.

A best practice, no matter how good it is, must be put into context and understood by the client before it can be implemented successfully. In Nepal, MTaPS planned to work with the DDA to develop a QMS with the goal of ISO 9001: 2015 certification. The country team faced a challenge in that the concept of ISO certification was not familiar to the Government of Nepal, since only commercial and manufacturing companies in the country use ISO certifications as a marketing tool. MTaPS had already begun investing resources to amend the drug law, regulations, codes, and guidelines, working toward the goal of certification of ISO 9001: 2015. The MTaPS Nepal team discussed with DDA staff the principles and benefits of the QMS and shared a draft of the quality manual for feedback based on the DDA's experience with inspecting manufacturing sites for compliance with WHO good manufacturing practices. To increase DDA staff awareness of QMS principles and build their capacity to interpret the requirements of ISO 9001: 2015, MTaPS is organizing training for DDA staff, developing SOPs, and conducting effective gap analyses and quality audits.

Virtual participation in online meeting/event platforms can be impacted by participants' lack of knowledge about the use of such platforms, as observed in MTaPS Bangladesh. Once MTaPS Bangladesh conducted an orientation for the online meeting platforms, participation increased, and online meetings and workshops started and ended on time. Building in time for orientation of participants to virtual meeting platforms is therefore crucial to the success of these events.

To gain knowledge about opportunities for collaboration with key players in Asia and priority areas of support, MTaPS undertook a mapping exercise to identify key entities (i.e., initiatives, networks, and stakeholders) at regional and sub-regional levels that are supporting or working in pharmaceutical regulatory systems strengthening, including PV. Through this exercise, MTaPS identified six key entities that aim to strengthen different pharmaceutical regulatory functions/areas, such as product registration; PV and post-marketing control; and regulatory inspection. These include the Asian Pharmacoepidemiology Network, Association of Southeast Asian Nations (ASEAN), the WHO collaborative registration procedure, the Southeast Asia Regulatory Network (SEARN), the WHO regional offices for South-East Asia (SEARO), and the Western Pacific. MTaPS subsequently engaged with two selected major networks, ASEAN and SEARN/SEARO, that culminated in opportunities for providing technical assistance to improve regulatory systems in Asia. Through its engagement with SEARN, MTaPS provided technical assistance to the design and development of an online Good

Manufacturing Practice (GMP) course for pharmaceutical manufacturers as a pilot, which will later be rolled out to other member states of SEARN. Increasing the knowledge and practical application of current GMP among pharmaceutical manufacturers and regulators will improve the quality of medicines used in Asia and beyond.

ACTIVITIES FOR NEXT QUARTER	
ACTIVITY AND DESCRIPTION	DATE
Support all country teams to finalize MEL plans	Nov. 2020
Complete and roll out data entry and verification SOP	Oct. 2020
Finalize revisions of standard MTaPS indicators for project year 3	Nov. 2020
Review SurveyCTO data entry to include any changes to year 3 country indicator mapping	Nov. 2020
Complete and roll out DMAP	Nov. 2020
Roll out Peer-Reviewed Publications Guidance	Oct. 2020
Orient country teams on how to pause and reflect	Oct. 2020
Hold webinar for USAID staff	Nov. 2020
Roll out Standard Requirements for Deliverables	Nov. 2020
Roll out CLA Guide and orient country teams	Dec. 2020

### **ANNEX I: SUCCESS STORIES**

# CÔTE D'IVOIRE LAUNCHES FIRST-EVER AMS MULTISECTORAL PLAN TO COMBAT AMR

In Côte d'Ivoire, uncontrolled use of antibiotics for human and animal health is encouraging the spread of antimicrobial resistance (AMR) and the rise of health care-acquired infections. These include high rates of resistance for the bacteria Enterobacteriaceae, which is responsible for E. coli and salmonella, as well as germs that can lead to staph infections, pneumonia, and urinary tract infections, according to data from the Institut Pasteur in Côte d'Ivoire.

MTaPS supported the country's AMR Technical Working Group in setting up its first-ever national Multisectoral Technical Committee on Antimicrobial Stewardship (AMS). It aims to optimize antimicrobial management in the human, animal, and environmental sectors in accordance with the World Health Organization's One Health approach.

Louis Ketremindie, veterinarian and vice chair of the new committee, said, "If we do nothing about the uncontrolled use of antimicrobials for human and animal health, this inappropriate use will lead to levels of resistance that...could reduce treatment options for patients and also negatively impact our country's health care system."

Representatives from the ministries of health, agriculture, animal resources, and the environment conducted a situational analysis of antimicrobial management and, based on the results, defined a new national AMS policy and a 2021–2025 multisectoral action plan.

The team also developed guidelines for AMS in health care facilities. Training for health workers has begun and is ongoing, which should improve the rational use of antimicrobials and quality of care in Côte d'Ivoire and will promote better health outcomes for patients with diseases that require medicines at risk for resistance.

The next step will be using these tools as a basis for developing training materials to build the capacity of Drug and Therapeutics Committees and health care workers in AMS. The National Antimicrobial Stewardship Action Plan will guide AMS activities implementation in the human, animal, agricultural, and

environmental sectors.

"Implementing antimicrobial management guidelines in health care facilities should enable prescribers and providers to better navigate the choice of antimicrobials in treatment to improve the cure rate of infectious diseases."

-Louis Ketremindie

The national focal point on AMR from the Ministry of Higher Education, Professor Nathalie Guessennd, said the collaboration was a first for the country and reflected shared goals and commitment. "A few years ago, no one could have imagined that all these sectors could work together," she said.



Participants presenting at the AMS Guidelines Validation workshop on July 25, 2020. (Photo credit: Hérodias Ahimon, Senior Technical Advisor, MTaPS Côte d'Ivoire)

# ESTABLISHING PHARMACOVIGILANCE FOR A NEW HIV DRUG IN MOZAMBIQUE

Active monitoring of patients for medicine safety is an important part of pharmacovigilance (PV), particularly when a new medicine is introduced into the health system. PV serves as an early warning system to detect potential adverse effects that may not have been picked up during clinical trials. Thus, it plays a critical role in enhancing patient safety, maintaining people's confidence in the health system, and ensuring a well-functioning pharmaceutical sector as part of quality health care.

MTaPS helped the National Directorate of Pharmacy (DNF) in Mozambique establish an active surveillance system to assess the safety of a new dolutegravir (DTG)-based highly active antiretroviral regimen—tenofovir/lamivudine/dolutegravir (TLD)—which was introduced in the country to treat HIV patients, including pregnant women. The concern for pregnant women stems from earlier indications of neural tube defect in babies born to women taking the medicine and the fact that women are disproportionately affected by HIV in Mozambique. Women make up 60% of the estimated 2 million



Pharmacovigilance focal person introducing data into PViMS at the facility level. Photo credit: Eunice Dias

people living with the disease in the country, according to <u>UNAIDS</u>. The World Health Organization has recommended that continued surveillance be implemented for the drug.<sup>16</sup>

When the national HIV program introduced the new DTG-based regimen for HIV in 2018, the DNF, which is the government body responsible for monitoring the effects of medicines, had only a spontaneous PV reporting system in place that relied on health care providers to report the occurrence of adverse drug reactions (ADRs) in patients when they felt the need—a method that severely limits safety data collection.

MTaPS is working with Mozambique's national HIV program and the DNF to actively monitor adverse events from TLD in nine facilities across the country. Establishing the active surveillance system involved setting up the infrastructure and introducing an information system for data collection and reporting.

### Setting up the active surveillance infrastructure

The collaboration began in 2019 with the development of a framework and an implementation plan for active surveillance. As a first step, MTaPS worked with the DNF's PV and national HIV program teams to develop the active surveillance protocol for patients on the DTG-based regimen and obtain approval from the Ministry of Health's ethics committee to implement a safety surveillance system. Prior to enrolling patients in the active monitoring activity, a three-day training oriented 72 health care workers from the participating health facilities and provincial focal persons on the protocol. Onsite training at the facilities helped sensitize staff and secure their cooperation.

MTaPS helped the DNF and HIV program with developing standard operating procedures and providing support supervisory visits to implementing facilities to establish a practice of following up with enrolled patients to document ADRs, which is key to ensuring the success of the PV system. The supervision

<sup>&</sup>lt;sup>16</sup> World Health Organization. 2019. Update of recommendations on first- and second-line antiretroviral regimens. Geneva, Switzerland: World Health Organization; 2019 (WHO/CDS/HIV/19.15). Licence: CC BY-NC-SA 3.0 IGO.

procedures were adapted to virtual monitoring and phone support in response to the COVID-19 pandemic.

As of September 2020, more than 2,237 patients have been enrolled in the cohort in the nine health facilities, with approximately 715 having recorded at least one follow up visit.

#### Introducing an information system for real-time monitoring and reporting

An effective surveillance system must have a mechanism for timely recording and analysis of generated data. MTaPS is supporting the DNF to adapt the pharmacovigilance monitoring system (PViMS), a web-

based tool developed by MTaPS' predecessor, the USAID-funded SIAPS program, for monitoring medicine safety. A data capture approach has been agreed upon for health facility focal points, and tablets have been procured for data entry for the participating health facilities. The comprehensive reporting from PViMS on not only ADRs but also patient information, such as medication history and follow-up visits, has streamlined data management and active surveillance of TLD.

MTaPS trained focal persons for HIV and PV at the provincial level and the health facilities and the PV staff of the DNF on the use of PViMS, while a system administration team was trained in August 2020 to administer the tool at the central level. The records of about 1,500 enrolled patients have been entered into PViMS. So far, data on approximately 5 adverse events and 11 pregnancy outcomes have been recorded in PViMS.

"Previously, Mozambique had not implemented an active surveillance system needed to identify signals and determine risk factors for adverse events in patients and relate this with a medicine, in real time. The support fron MTaPS will serve the dual purpose of establishing a system for active surveillance and providing an electronic tool to support timely signal generation in pharmacovigilance."

- Dr. Jamal Mario, Head of the Pharmacovigilance Department at the DNF

The findings from the active surveillance for TLD will help the DNF and national HIV program make informed clinical and regulatory decisions related to the use of TLD and support information sharing with the global community to understand the medicine's risk-benefit profile.

The active surveillance work in Mozambique is being carried out in collaboration with MTaPS global expert partner the University of Washington and is funded through <u>USAID's PEPFAR program</u>.

# SUSTAINABLE CAPACITY BUILDING OF HEALTH WORKERS FOR COVID-19 RESPONSE IN THE PHILIPPINES

The COVID-19 pandemic compounded the challenges for the already strained health system in the Philippines. The country's Department of Health (DOH) is responsible to ensure that emergency services keep up with the changing situation, to protect people's health, and to keep the health system functioning during a crisis. But as the country went into lockdown in March to contain the pandemic, a tougher demand fell on the DOH: how to quickly train the frontline health workers to respond to the pandemic while in quarantine to prevent the spread and at the same time, keeping themselves safe so they can continue providing healthcare to the people.

The Philippine government launched a multisectoral response to the crisis; it mobilized its Interagency Task Force on Emerging Infectious Diseases, co-chaired by the Department of Health (DOH), which presented its National Action Plan on COVID-19 to contain the spread of the disease. MTaPS supported the DOH in its response by rapidly developing and implementing an innovative e-training hub to equip health care workers with the necessary skills in critical response areas. Launched on April 8, the virtual registration and training hub started out with offering a real-time course on infection prevention and control (IPC) and added two more news courses in health care waste management, and emergency

supply chain management, all tailored to COVID-19. MTaPS worked closely with the DOH, the World Health Organization (WHO) and UNICEF in the development of the training materials to ensure accurate and up-to-date information.

"Since the beginning of this pandemic, my role has become much more challenging in the area of infection control and disease surveillance; on top of monitoring COVID-19, we are also monitoring the resurgence of polio, dengue, and leptospirosis," shares Gerald Piñon, Infection Control Nurse and Disease Surveillance Officer of Ospital ng Imus, who attended all training modules provided by MTaPS.

Like Piñon, over 14,000 health workers across the 17 regions of the country received virtual



Gerald Pinon, IPC Nurse of Ospital ng Imus, attendee of MTaPS virtual training on IPC, HCWM, and SCM for COVID-19 Response. (Photo credit: Mr. Gerald Pinon – MTaPS/Philippines)

training in critical COVID-19 skills from the convenience of their homes and workplaces. MTaPS also conducted monitoring and assessment visits to 35 health facilities in the National Capital Region and Regions 3 and 4A. The visits aimed to further assist these select public and private hospitals to complement the online training as they continue to deal with COVID-19 cases.

"We look at this adversity as an opportunity – there will be times when we will have a shortage of supplies, like PPEs (personal protective equipment), but we have to be proactive and innovative in dealing with the situation. Being empowered to know what to do in these times is crucial," says Piñon, commenting on the trainings he received.

As the country continues to battle the pandemic, MTaPS converted the training modules into e-learning modules and handed them over to the DOH for integration with DOH Academy's e-learning platform, developed through the USAID HRH2030 program. The modules, made accessible on the e-learning platform, are available to wider audiences in the medical field for free and also, provide credits to health care professionals as part of their continuing professional accreditation. By leveraging the available technology, MTaPS contributed to sustainably enhancing the capacity of the Philippine health system and USAID's commitment to investing in people, technologies and resources for impact.

# NEW TOOLS LAY FOUNDATION TO IMPROVE ANTIBIOTICS USE IN THE ANIMAL SECTOR IN UGANDA

Antibiotics are essential drugs for both human and animal health. The symbiotic relationship shared between humans, animals, and the environment requires a multisectoral, transdisciplinary approach to control the growing crisis of antimicrobial resistance (AMR), which is enshrined in the One Health approach. However, this shared responsibility of protecting antimicrobials is currently not equally applied by all sectors. In 2017, the WHO's Joint External Evaluation (JEE) in Uganda revealed gaps in the capacity for appropriate use and stewardship of antimicrobials, with the human health capacity rated as higher for the appropriate use of antimicrobials compared to the animal health sector – a situation that is not unique to Uganda. According to the World Organisation for Animal Health (OIE), over 110 countries—mainly low and middle income—do not yet have relevant legislation regulating the

importation, manufacture, distribution, and use of veterinary products, including antimicrobials, with many countries having no legislation for veterinary products at all.

The development of regulations, policies, and laws to regulate antimicrobial use is a critical step toward the control of AMR and has been recommended by both the OIE and WHO benchmarks. In Uganda, while the Essential Medicines List (EML) for human health has been developed and revised over five times, an Essential Veterinary Medicines List (EVML) has never been initiated.



Dr. Dominic Mundrugo-Ogo Lali of MTaPS during a consultative activity with a veterinary drug seller (Photo credit: Dr Reuben Kiggundu – MTaPS/Uganda)

#### Breaking new ground

MTaPS helped facilitate the prioritization and development of the VEML and guidelines on infection prevention and use of antimicrobials in Uganda, convening and coordinating the process across all the stakeholders, including the Ministry of Agriculture, Animal Industry and Fisheries (MAAIF); the National Drug Authority; Makerere University; and the National AMR sub-Committee. These developments are key to laying a foundation for antimicrobial stewardship in the agricultural sector. The newly developed and validated guidelines on infection control and use of antimicrobials in the animal health sector cover all the leading animal production systems in Uganda, i.e., fish, poultry, sheep and goat, cattle and piggery.

The development of the EVML and guidelines on use of antimicrobials was a ground-breaking venture for the agriculture sector. The success was an outcome of close to a year-long participatory process – from consultations to consolidation of inputs and validation by all the national stakeholders (Figure 13). The aim of the EVML is to guide policy and regulation on importation of essential medicines into the country and took into consideration current national and global recommendations by the tripartite collaboration of OIE, WHO and the UN's Food and Agriculture Organization on the use of

antimicrobial in the agricultural sector. The guidelines for infection control and antimicrobial use will guide farmers on biosecurity on the farm, appropriate antimicrobial use, and safety of animals, thus increasing their agricultural productivity.

The EVML and the infection prevention guidelines will together regulate access to essential antibiotics, ensuring animal health and welfare while reducing their misuse. They also lay the foundation for cross-sectoral collaboration to implement Uganda's AMR National Action Plan, thus advancing the global health security agenda.

"Colleagues from the Ministry and other sectors join me in thanking USAID MTaPS for taking leadership in the development of this key policy document. For long we have struggled with the use of antibiotics and availability of medicines and control of their access in the agricultural sector. We now have a basis for implementing the changes."

- Dr. Anna Rose Ademun, Chief Veterinary Officer and Commissioner, Animal Health, MAAIF

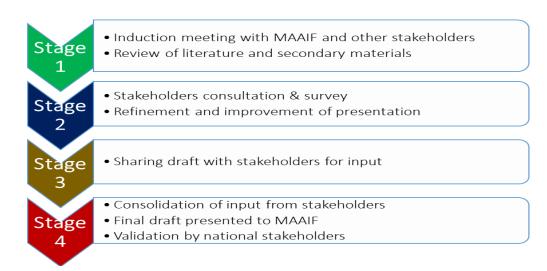


Figure 13: Process of development of the VEML and guidelines on infection control and use of antimicrobials in animal sector

# **ANNEX 2. MTAPS INDICATOR TRACKING TABLE**

## **Annex Table 1: MTaPS Performance Indicator Tracking Table**

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 Result	FY20Q2 Result	FY20Q3 Result	FY20Q4 Result	FY20 Cumulative Result
_	e 1: Pharmaceutical-Sector								
Sub-Obj	ective 1.1: Transparency and	Accountability	of Country Pharm	naceutical System	s Improved				1
MT 1.1.1	# of entities that have clarified roles and responsibilities in pharmaceutical systems and made information publicly available with MTaPS support	Annually	0	3			3		3
	Bangladesh		0	2			2		2
	Nepal		0	0			0		0
	Rwanda		0	1			1		
Sub-Obj	ective 1.2: Evidence-Based N	/ledicines Polici	es, Laws, Regulation	ons, Guidelines, N	Norms, and Stand	dards Improved	and Enforced		
MT 1.2.1	# of pharmaceutical sector-related policy, legislation, regulation, or operational documents developed or updated with technical assistance from MTaPS	Annually	0	4		·	28		28
1.2.1	Bangladesh		0	1			2		2
	Mozambique		0	1		Data no	ot available		Data not available
	Nepal		0	1			0		
	Rwanda		0	1		26			
MT 1.2.2	# of pharmaceutical regulatory enforcement mechanisms established	Semi- annually	0	3	C	0			
	Bangladesh		0	1	O	)		0	0

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target		0Q1 sult		20Q2 esult	FY20 Res		FY20Q4 Result	FY20 Cumulative Result	
	Mozambique		0	1		(	0		0			0	
	Rwanda		0	1		(	0				0	0	
MT 1.2.3	% of established pharmaceutical regulatory enforcement mechanisms that are functional	Semi- annually	0	100% (15/15)		0% (	(0/0)			47%	(7/15)	47% (7/15)	
1.2.5	Bangladesh	amidany	0	0% (0/0)		0% (	(0/0)			0%	(0/0)	0% (0/0)	
	Mozambique		0	100% (9/9)		0% (	(0/0)			22%	22% (2/9)		
	Rwanda		0	100% (6/6)	0% (0/0) 83% (5/6)						<sup>6</sup> (5/6)	83% (5/6)	
Objective 2: Institutional and Human Resource Capacity for Pharmaceutical Management and Services Increased, Including Regulation of Medical Products											ts		
Sub-Objective 2.1: Innovative and Proven Approaches for Human Resource Capacity Building Institutionalized													
MT 2.1.2	# of MTaPS-supported health professional training curricula developed or revised to address pharmaceutical management topics	Semi- annually	0	2	2 2			2			2	4	
	Bangladesh		0	2		2	2				2	4	
Sub-Obj	ective 2.2: Capacity of Gover	nment to Mana	ge Pharmaceutica	al Systems Streng	thened								
	# of persons trained in pharmaceutical management		0	1200	<b>F</b> 174	<b>M</b> 417	<b>F</b> 67	<b>M</b> 347	<b>F</b> 37	M 28	40	1,110	
MT	Bangladesh		0	1000	F	M	F	М	F	М	0	961	
2.2.2	Dangidaesii	Quarterly	<u> </u>	1000	174	417	55	315	0	0	0	301	
	Mozambique		0	100	F	<u>M</u>	F	M	F 27	M 20	40	105	
		<u> </u>			0 <b>F</b>	0 <b>M</b>	0 <b>F</b>	0 <b>M</b>	37 <b>F</b>	28 <b>M</b>			
	Rwanda		0	100	0	0	12	32	0	0	0	44	
MT 2.2.3	# of e-learning courses developed with MTaPS assistance	Annually	0	1	0		0		0	-	1	1	
	Cross Bureau		0	1	(	)		0	0		1	1	

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 FY20Q2 Result Result		FY20Q3 Result		FY20Q4 Result	FY20 Cumulative Result		
	# of people successfully				F	М	F	M	F	M		
	completing MTaPS- developed e-learning courses		0	50	0	0	0	0	37	28	Data not available	71
MT	Bangladesh	Quarterly	0	0	F	М	F	М	F	M	Data not	0
2.2.4	Bungradesn	Quarterly	Ŭ	Ŭ	0	0	0	0	0	0	available	
	Mozambique		0	50	F	M	F	M	F	M	Data not	65
	,				0	0	0	0	37	28	available	
	Rwanda		0	0	F	M	F	M	F	M	Data not	0
<u> </u>					0	0	0	0	0	0	available	
Objective 3: Availability and Use of Pharmaceutical Information for Decision Making Increased and Global Learning Agenda Advanced  Sub-Objective 3.1: Pharmaceutical Management Information Systems that Are Interoperable and Link Patients and Products Effectively Implemented												
Sub-Obj		lanagement Inf	ormation Systems	that Are Interop	perable a	nd Link	Patient	s and Pro	oducts Ef	fectively	y Implemented	
MT 3.1.1	# and % MTaPS- supported health facilities that have implemented pharmaceutical management information system (PMIS) to document specific components of the pharmaceutical system for analysis and reporting	Semi- annually	64% (1126/ 1767)	88% (5572/ 6342)		84% (53	15/6332	2)			419/6342)	85% (5419/6342)
	Bangladesh		90% (104/115)	95% (4446/4680)		92% (42	93/4680	0)			293/4680)	92% (4293/4680)
	Mozambique		62% (1022 /1652)	67% (1116/1652)	62% (1022/1652)				116/1652)	67% (1116/1652)		
	Rwanda		0% (0/0)	100% (10/10)	0% (0/0)					100%	(10/10)	100% (10/10)
MT	# and % of MTaPS- supported health facilities using interoperable PMIS	Semi-	61% (70/ 115)	95%	89% (3827/4291) 82% (5039/6154)					82% (5039/6154)		

87%

(3923/4502)

87% (3923/4502)

annually

61% (70/

115)

95%

(4277/4502)

89% (3827/4291)

using interoperable PMIS

3.1.2

tools

Bangladesh

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 Result	FY20Q2 Result	FY20Q3 Result	FY20Q4 Result	FY20 Cumulative Result
	Mozambique		0% (0/0)	95% (1569/ 1652)	0% (	0/0)	68% (11	68% (1116/1652)	
MT 3.1.3	# of countries that have a functional early warning system linking clinical and stock data	Annually	1	2			1		1
	Bangladesh		1	1			1		1
	Mozambique		0	1			0		0
Sub-Obj	ective 3.2: Information on Pl	harmaceutical S	ystems Available	and Used					
MT 3.2.1	# and % of MTaPS- supported health facilities that complete and submit an LMIS report on time for the most recent reporting period	Quarterly	74.3% (84/115)				89% (4053/4542)	92% (4293/4680)	92% (4293/4680)
	Bangladesh		74.3%	95%	98%	92% (4,184/	89%	92%	92%
Sub-Ohi	ective 3.3: Pharmaceutical S	vstams Strangth	(84/115)	(4446/4680)	(500/509)	4,545)	(4053/4542)	(4293/4680)	(4293/4680)
305-003	# of PSS technical	ysterns strengti	lennig Kesearen a	ila Global Leariil	is Ascilua Auvai	iceu			
MT 3.3.2	documents authored by MTaPS	Semi- annually		4	C	)		5	5
	Cross Bureau		0	4	C	)		5	5
MT 3.3.2	# of activities to engage with stakeholders to advance the PSS global learning agenda			5	5	1	1	4	11
	Cross Bureau	Quarterly	0	5	5	1	0	3	9
Objectiv	e 4: Pharmaceutical-Sector I					_			-
	ective 4.2: Evidence-Based N					nd Implemented	<u> </u>		
MT 4.2.1	# of pharmacy benefits programs introduced or improved into health sector	Annually	0	1	•	1			

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 Result	FY20Q2 Result	FY20Q3 Result	FY20Q4 Result	FY20 Cumulative Result			
	Bangladesh		0	1	1		1		1		1	
MT 4.2.3	# of strategic plans developed or updated to address pharmaceutical costs and financing	Semi- annually	0	2	2		0		2			
	Bangladesh		0	2	2	<u> </u>		0	2			
Objectiv	e 5: Pharmaceutical Services	, Including Prod	duct Availability a	nd Patient-Cente	red Care, to Achi	eve Health Outo	omes Improved					
Sub-Objective 5.1: Increased availability of essential medicines and other health technologies												
	% of tracer products stocked according to plan											
	Bangladesh		Male Condom:100% (27851/27851)	Male Condom:100%	Male Condom:1 (27851/27851)	.00%	Data not availa	Male Condom:100% (27851/27851)				
MT		Semi-	Oral Pills: 99% (27878/27886)	Oral Pills: 100%	Oral Pills: 99% (	27878/27886)	Data not availa	Oral Pills: 99% (27878/27886)				
5.1.2		annually	Injectables: 99% (27394/27405)	Injectables: 100%	Injectables: 99% (27394/27405)	6	Data not availa	Injectables: 99% (27394/27405)				
			IUD: 99% (5203/5212)	IUD: 100%	IUD: 99% (5203	/5212)	Data not availa	<i>IUD:</i> 99% (5203/5212)				
			Implant: 99% (801/813)	Implant: 100%	Implant: 99% (8	01/813)	Data not availa	ble	Implant: 99% (801/813)			
Sub-Obj	ective 5.3: Patient Safety and	d Therapeutic E	ffectiveness Ensur	ed								
MT	% of MTaPS-supported health facilities that have implemented medicines safety activities		31% (31/100)	100% (120/120)	31% (31/100)	53% (35/66)	34% (28/83) 10% (12/120)		10% (12/120)			
5.3.1	Bangladesh	Quarterly	31% (31/100)	100% (100/100)	31% (31/100)	Data not available	14% (7/50)	3% (3/100)	3% (3/100)			
	Mozambique		0% (0/0)	100% (10/10)		90% (9/10)	90% (9/10)	90% (9/10)				
	Rwanda		0% (0/0)	100% (10/10)	0% (0/0)	46% (26/56)	52% (12/23)	0% (0/10)				
MT 5.3.2	% of adverse drug events (ADEs) reported and	Semi- annually		90%	68% (9	5/139)	0% (	0/301)	0% (0/301)			

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 Result	FY20Q2 Result	FY20Q3 Result	FY20Q4 Result	FY20 Cumulative Result	
	reviewed in MTaPS- supported health facilities									
	Bangladesh		68% (95/139)	90%	68% (9	5/139)	0% (	0/301)	0% (0/301)	
Sub-Obj	ective 5.4: Antimicrobial Res	istance Contain	ment Supported	,						
MT 5.4.2	% of MTaPS-supported health facilities implementing locally identified and prioritized core elements of infection prevention and control activities	Semi- annually	0% (0/0)	100% (7/7)	0% (0/0)		100% (7/7)		100% (7/7)	
	Bangladesh		0% (0/0)	0% (0/0)	0% (	0/0)	0%	0% (0/0)		
	Mozambique		0% (0/0)	100% (7/7)	0% (	0/0)	1009	100% (7/7)		
MT 5.4.3	# of AMR-related in- country meetings or activities conducted with multisectoral participation	Quarterly	0	8	1	2	12	15	28	
	Bangladesh		0	4	1	0	0	1	2	
	Mozambique		0	4	0	2	12	14	26	
MTaPS 0	Global Health Security Agend	da (GHSA) Indica	itors							
Result A	rea 1: Effective multisectora	l coordination o	on AMR							
GH IO	# and % of MTaPS countries that have developed and/or implemented policies for prescription of access-, watch- or reserve-class of antibiotics according to AWaRe categorization	Annually	10% (1/10) 100% (10/10) 67% (4/6)				67% (4/6) Data not			
	Burkina Faso		0	1		Data no	Data not available			

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 Result	FY20Q2 Result	FY20Q3 Result	FY20Q4 Result	FY20 Cumulative Result			
	Cameroon		0	1		Data no	ot available		Data not available			
	Côte d'Ivoire		0	1			0		0			
	DRC		0	1		1						
	Ethiopia		0	1		0						
	Kenya		0	1		Data no	ot available		Data not available			
	Mali		0	1			1		1			
	Senegal		1	1		1 1						
	Tanzania		0	1			1					
	Uganda		0	1		Data not available						
	# and % of MTaPS countries that have implemented WHO AWaRe categories		0% (0/7)	100% (7/7)		29% (2/7)						
	Burkina Faso		0	1			0		0			
GH IO	Cameroon	Annually	0	1			0		0			
2	DRC	Annually	0	1			1		1			
	Ethiopia		0	1			0		0			
	Mali		0	1			0		0			
	Senegal		0	1			0		0			
	Tanzania		0	1			1		1			
MSC 1	# of AMR-related in- country meetings or activities conducted with multisectoral participation	Quarterly	0	48	33 24 15 51				123			
	Bangladesh		0	4	0 1 1 1				3			
	Burkina Faso		0	4	1	1	0	0	2			
	Cameroon		0	4	3	1	1	0	5			

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 Result	FY20Q2 Result	FY20Q3 Result	FY20Q4 Result	FY20 Cumulative Result
	Côte d'Ivoire		0	4	4	7	4	20	35
	DRC		0	4	0	0	0	6	6
	Ethiopia		0	4	0	0	0	1	1
	Jordan		0	4	0	0	0	0	0
	Кепуа		0	4	14	7	2	15	38
	Mali		0	4	7	1	4	4	16
	Senegal		0	4	0	2	0	2	4
	Tanzania		0	4	1	1	0	2	4
	Uganda		0	4	3	3	3	0	9
	# and % of female participants in meetings or other events organized by the multisectoral body on AMR		35% (81/233)	50%	35% (25	56/725)	42% (5	86/1410)	42% (586/1410)
	Bangladesh		29%(24/84)	50%	Data not	available	29%(24/84)		29%(24/84)
	Burkina Faso		18% (3/17)	50%	22% (	6/27)	Data not available		22% (6/27)
MSC 2	Cameroon	Semi- annually	50% (2/4)	50%	39% (3	9/101)	0% (0/0)		0% (0/0)
	Côte d'Ivoire	a,	38% (21/55)	50%	38% (2	21/55)	38%	(21/55)	38% (21/55)
	DRC		34% (14/41)	50%	35% (3	31/88)	36% (	45/124)	36% (45/124)
	Ethiopia		24% (7/31)	50%	17% (1	.6/93)	Data no	t available	17% (16/93)
	Kenya		66% (28/44)	50%	54% (6	6/123)	43% (4	96/1147)	43% (496/1147)
	Mali		15% (3/20)	50%	16% (2	0/124)		(0/0)	0% (0/0)
	Senegal		58% (54/93)	50%	58% (5	54/93)	0%	(0/0)	0% (0/0)
	Tanzania		14% (3/21)	50%	14% (	3/21)	Data no	t available	14% (3/21)
MSC 3	# policies, legislation, regulation, operational documents related to national action plan on AMR implementation	Annually	0	10			25		25

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 Result	FY20Q2 Result	FY20Q3 Result	FY20Q4 Result	FY20 Cumulative Result			
	developed, improved or updated with MTaPS support											
	Burkina Faso		0	1			0		0			
	Cameroon		0	1			1		1			
	DRC		0	1			3		3			
	Ethiopia		0	1			4		4			
	Jordan		0	1			5		5			
	Кепуа		0	1		3						
	Mali		0 1 8						8			
	Senegal	0 1 1 1 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1						1				
	Tanzania		0	1		1						
	Uganda		0	1		0						
	# of multisectoral bodies that have developed a national monitoring framework with MTaPS technical assistance		0	3		2						
	Bangladesh		0	1			1		1			
	Burkina Faso		0	0			0		0			
	Cameroon		0	0			0		0			
1466.4	Côte d'Ivoire		0	0			0		0			
MSC 4	DRC	Annually	0	0			0		0			
	Ethiopia		0	0			0		0			
	Jordan		0	0			0		0			
	Kenya		0	1			1		1			
	Mali		0	0			0					
	Senegal		0	0		0						
	Tanzania		0	1			0		0			
	Uganda	_	0	0			0		0			

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target			FY20Q2 Result		FY2 Res	0Q3 sult	FY20Q4 Result	FY20 Cumulative Result															
	# of persons trained in AMR topics		0	300	<b>F</b> 10	<b>M</b> 30	<b>F</b> 54	<b>M</b> 94	<b>F</b> 0	<b>M</b> 0	126	314															
MSC 5	Côte d'Ivoire	Quarterly	0	100	<b>F</b> 0	<b>M</b> 0	<b>F</b> 4	<b>M</b> 20	<b>F</b> 0	<b>M</b> 0	110	134															
IVISC 5	Ethiopia	Quarterly	0	100	<b>F</b> 10	<b>M</b> 30	<b>F</b> 47	<b>M</b> 47	<b>F</b> 0	<b>M</b> 0	16	150															
	Mali		0	100	<b>F</b> 0	<b>M</b>	<b>F</b> 3	<b>M</b> 27	<b>F</b> 0	<b>M</b> 0	0	30															
MSC 6	# of e-learning courses or m-mentoring platforms related to AMR developed, adapted or made available to health workforce in the reporting period	Annually								2																	
	Côte d'Ivoire		0	0					1			1															
	Ethiopia	]					-		-	-	-	-	,	-			-	0	0					0			0
	Mali		0	5					1			1															
Result A	rea 2: Infection Prevention a	and Control Imp	roved and Function	nal																							
IP 1	# of updated policies, legislation, regulations, or operational documents for improving infection prevention and control (IPC) in the reporting period	Annually	0	4					9			9															
	Cameroon		0	1					0			0															
	Côte d'Ivoire		0	1					7			7															
	Mali		0	1					1			1															
	Tanzania		0	1				ı	1	1	T	1															
10.3	# of persons trained in IPC	Outside I	0	300	<b>F</b> 175	M 131	<b>F</b> 91	<b>M</b> 66	<b>F</b> 163	<b>M</b> 119	454	1,199															
IP 2	Bangladesh	Quarterly	0	0	<b>F</b> 0	<b>M</b> 0	<b>F</b> 0	<b>M</b> 0	<b>F</b> 0	<b>M</b> 0	0	0															
	Cameroon		0	100	F	M	F	M	F	M	61	86															

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target		FY20Q1 Result		FY20Q2 Result		Result Res			FY20Q4 Result	FY20 Cumulative Result
							0	0	5	10				
	Kenya		0	100	<b>F</b> 40	<b>M</b> 26	<b>F</b> 50	<b>M</b> 46	<b>F</b> 58	<b>M</b> 29	393 (unknown gender)	642		
	Tanzania		0	100	<b>F</b> 130	<b>M</b>	<b>F</b> 41	<b>M</b> 20	<b>F</b> 100	<b>M</b> 80	0	471		
IP 3	# and % of MTaPS- supported health facilities that are using standardized tool(s) for monitoring IPC and informing programmatic improvement	Quarterly	13% (5/40)			62% (24/39)								
	Bangladesh		0% (0/0)	0% (0/0)	0%	(0/0)	0%	(0/0)	0% (	0/0)	0% (0/0)	0% (0/0)		
	Ethiopia		0% (0/30)	50% (15/30)	0% (	0/30)	50% (	16/30)	50% (	16/30)	50% (15/30)	50% (15/30)		
	Senegal		100% (3/3)	100% (3/3)	100%	ه (3/3)	100%	6 (3/3)	66%	(2/3)	100% (3/3)	100% (3/3)		
	Tanzania		33% (2/6)	100% (6/6)	33%	(2/6)	100%	6 (6/6)	100%	(6/6)	100% (6/6)	100% (6/6)		
	# of MTaPS countries with improved performance in core IPC components at national level from baseline to follow up		0	9					4			4		
	Bangladesh		0	1					0			0		
	Cameroon		0	1					0			0		
IP 4	Côte d'Ivoire	Annually	0	1					1			1		
	Ethiopia		0	1					1			1		
	Кепуа		0	1					1			1		
	Mali		0	1		·	,		0			0		
	Senegal		0	1					1			1		
	Tanzania		0	1					0			0		
	Uganda		0	1					0			0		

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 Result	FY20Q2 Result	FY20Q3 Result	FY20Q4 Result	FY20 Cumulative Result
	# and % of MTaPS- supported health facilities implementing continuous quality improvement (CQI) to improve IPC		58% (43/74)	100% (72/72)	58% (43/74)	58% (43/74)	76% (55/72)	89% (64/72)	89% (64/72)
	Cameroon		0% (0/6)	100% (6/6)	0% (0/6)	0% (0/6)	0% (0/6)	100% (6/6)	100% (6/6)
IP 5	Côte d'Ivoire	Quarterly	50% (2/4)	100% (4/4)	50% (2/4)	50% (2/4)	50% (2/4)	100% (4/4)	100% (4/4)
	Ethiopia		66.7% (20/30)	100% (21/30	70% (21/30)	70% (21/30)	70% (21/30)	70% (21/30)	70% (21/30)
	Kenya		100% (16/16)	100% (16/16)	100% (16/16)	100% (16/16)	100% (16/16)	100% (16/16)	100% (16/16)
	Mali		0% (0/5)	100% (5/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)
	Senegal		0% (0/3)	100% (3/3)	0% (0/3)	0% (0/3)	33% (1/3)	0%(0/3)	0%(0/3)
	Tanzania	_	33% (2/6)	100% (6/6)	33% (2/6)	33% (2/6)	100% (6/6)	100% (6/6)	100% (6/6)
	Uganda		0% (0/7)	100% (7/7)	0% (0/7)	0% (0/7)	100% (7/7)	100% (7/7)	100% (7/7)
	# and % of MTaPS- supported health facilities with functional IPC committees		63% (45/72)	TBD	72% (52/72)	80% (58/72)	92% (65/71)	99% (70/71)	99% (70/71)
	Cameroon		0% (0/0)	TBD	0% (0/0)	0% (0/6)	0% (0/6)	83% (5/6)	83% (5/6)
	Côte d'Ivoire		100% (4/4)	TBD	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)
IP 6	Ethiopia	Quarterly	96.7% (29/30)	TBD	70% (21/30)	90% (27/30)	100% (30/30)	100% (30/30)	100% (30/30)
	Кепуа		0% (0/16)	16	100% (16/16)	100% (16/16)	100% (16/16)	100% (16/16)	100% (16/16)
	Mali		0% (0/5)	TBD	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)
	Senegal		100% (3/3)	TBD	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
	Tanzania		17% (1/6)	TBD	17% (1/6)	17% (1/6)	83% (5/6)	100% (6/6)	100% (6/6)
	Uganda		100% (7/7)	TBD	100% (7/7)	100% (7/7)	100% (7/7)	100% (7/7)	100% (7/7)
IP 7	# and % of MTaPS- supported health facilities with improved hand hygiene compliance	Annually	0% (0/0)	100% (41/41)		88%	(36/41)		88% (36/41)
	Bangladesh		0% (0/0)	0% (0/0)		0%	(0/0)		0% (0/0)

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 Result	FY20Q2 Result	FY20Q3 Result	FY20Q4 Result	FY20 Cumulative Result		
	Cameroon		0% (0/0)	0% (0/0)	'	0%	(0/0)	•	0% (0/0)		
	Côte d'Ivoire		0% (0/0)	100% (4/4)		1009	% (4/4)		100% (4/4)		
	Kenya		0% (0/0)	100% (16/16)		100%		100% (16/16)			
	Mali		0% (0/0)	100% (5/5)		0%		0% (0/5)			
	Senegal		0%(0/0)	100% (3/3)		100% (3/3)					
	Tanzania		0% (0/0)	100 % (6/6)		100		100 % (6/6)			
	Uganda		0% (0/0)	100% (7/7)		100% (7/7) 72% (26/36)					
	# and % of MTaPS supported facilities with improved performance in core IPC components		0% (0/0)	100% (36/36)							
	Bangladesh		0% (0/0)	100% (2/2)		50%	6 (1/2)		50% (1/2)		
	Cameroon		0% (0/0)	0% (0/0)		0%	(0/0)		0% (0/0)		
IP8	Côte d'Ivoire	Annually	0% (0/0)	100% (4/4)		0%	(0/4)		0% (0/4)		
	Kenya		0% (0/0)	100% (16/16)		100%	(16/16)		100% (16/16)		
	Mali		0% (0/0)	100% (5/5)		0%	(0/5)		0% (0/5)		
	Senegal		0% (0/0)	100% (3/3)		1009	% (3/3)		100% (3/3)		
	Tanzania		0% (0/0)	100% (6/6)		1009	% (6/6)		100% (6/6)		
	Uganda		0% (0/0)	0% (0/0)		0%	(0/0)		0% (0/0)		
Result A	rea 3: Use of anti-microbial	medicines is op	timized								
	# of countries that have updated policies, regulation or legislation to foster AMS		0	7		7					
	Burkina Faso		0	0			0		0		
AS 1	Cameroon	Annually	0	0			0		0		
	Côte d'Ivoire		0	1			1		1		
	DRC		0	1			1		1		
	Ethiopia		0	1			1		1		
	Kenya		0	1			1		1		

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target		20Q1 esult		20Q2 esult		Y20Q3 Result	FY20Q4 Result	FY20 Cumulative Result
	Mali		0	1					1			1
	Senegal		0	0					0			0
	Tanzania		0	1					1			1
	Uganda		0	1					1			1
AS 2	# and % of health facilities' MTC/AMS committees or other relevant groups that implemented AMS improvement plans and/or monitoring framework in the reporting period	Quarterly	6% (1/16)	100% (33/33)	66% (	(19/29)	74% (	(23/31)	949	% (31/33)	76% (25/33)	76% (25/33)
	Jordan		0% (0/0)	100% (2/2)	0%	(0/0)	0%	(0/2)	0	% (0/2)	0% (0/2)	0% (0/2)
	Кепуа		6% (1/16)	100% (18/18)	100%	(16/16)	100%	(16/16)	100	% (18/18)	100% (18/18)	100% (18/18)
	Tanzania		0% (0/6)	100% (6/6)	0%	(0/6)	0%	(0/6)	10	0% (6/6)	0% (0/6)	0% (0/6)
	Uganda		43% (3/7)	100% (7/7)	43%	(3/7)	100%	% (7/7)	10	0% (7/7)	100% (7/7)	100% (7/7)
	# of persons trained in		0	400	F	M	F	M	F	M	122	436
	AMS topics				49	50	31	23	91	70		
	Bangladesh		0	0	<b>F</b>	<b>M</b> 0	<b>F</b>	<b>M</b> 0	<b>F</b>	<b>M</b> 0	0	0
	Bungiacon			100	F	M	F	M	F	M		
AS 3	Côte d'Ivoire	Quarterly	0	100	0	0	0	0	0	0	0	0
A3 3		Quarterly	0	100	F	M	F	M	F	M	0	165
	Kenya			49	50	20	7	21	18	-		
	Tanzania		0	100	<b>F</b> 0	<b>M</b> 0	<b>F</b> 11	<b>M</b> 16	<b>F</b> 50	<b>M</b> 37	87	201
	Uganda		0	100	<b>F</b> 0	<b>M</b> 0	<b>F</b> 0	<b>M</b> 0	<b>F</b> 20	<b>M</b> 15	35	70
AS 4	# and % of MTaPS- supported health facilities implementing	Quarterly	36% (25/70)	100% (86/86)	36% (	(25/70)	42%(	34/81)	38%	6 (39/102)	100% (36/36)	100% (36/36)

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 Result	FY20Q2 Result	FY20Q3 Result	FY20Q4 Result	FY20 Cumulative Result
	continuous quality improvement (CQI) to improve AMS in the reporting period								
	Burkina Faso		0% (0/0)	100% (5/5)	0% (0/0)	100% (4/4)	100% (5/5)	100% (5/5)	100% (5/5)
	Cameroon		0% (0/0)	100% (6/6)	0% (0/0)	0% (0/6)	0% (0/6)	0% (0/6)	0% (0/6)
	Côte d'Ivoire		0% (0/0)	100% (2/2)	0% (0/0)	0% (0/0)	0% (0/0)	100% (2/2)	100% (2/2)
	DRC		0% (0/0)	100% (3/3)	0% (0/0)	100% (1/1)	100% (3/3)	100% (3/3)	100% (3/3)
	Ethiopia		3% (1/31)	100% (31/31)	3% (1/31)	13% (4/31)	Data not available	Data not available	Data not available
	Kenya		100% (18/18)	100% (18/18)	100% (18/18)	100% (18/18)	100% (18/18)	100% (18/18)	100% (18/18)
	Mali		0% (0/5)	100% (5/5)	0% (0/5)	0% (0/5)	0% (0/5)	Data not available	Data not available
	Senegal		0% (0/3)	100% (3/3)	0% (0/3)	0% (0/3)	0% (0/3)	Data not available	Data not available
	Tanzania		0% (0/6)	100% (6/6)	0% (0/6)	0% (0/6)	100% (6/6)	100% (6/6)	100% (6/6)
	Uganda		86% (6/7)	100% (7/7)	86% (6/7)	100% (7/7)	100% (7/7)	100% (7/7)	100% (7/7)
	# / (%) of MTaPS- supported health facilities that have documented evidence of improvement in antimicrobial medicines prescribing and/or use		0% (0/0)	100% (27/27)		38%	(27/71)		38% (27/71)
46.5	Bangladesh	A	0% (0/0)	0% (0/0)		0%	(0/0)		0% (0/0)
AS 5	Burkina Faso	Annually	0% (0/0)	TBD		Data no	t available		Data not available
	Cameroon		0% (0/0)	0% (0/0)		0%	(0/0)		0% (0/0)
	Côte d'Ivoire		0% (0/0)	0% (0/0)		0%	(0/0)		0% (0/0)
	DRC		0% (0/0)	100% (3/3)		1009	% (3/3)		100% (3/3)
	Ethiopia		0% (0/0)	0% (0/0)		0%	(0/30)		0% (0/30)
	Jordan		0% (0/0)	0% (0/0)		0%	(0/2)		0% (0/2)

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 Result	FY20Q2 Result	FY20Q3 Result	FY20Q4 Result	FY20 Cumulative Result
	Kenya		0% (0/0)	100% (18/18)		100%	(18/18)		100% (18/18)
	Mali		0% (0/0)	0% (0/0)			0% (0/5)		
	Senegal		0% (0/0)	0% (0/0)		0%	5 (0/0)		0% (0/0)
	Tanzania		0% (0/0)	100% (6/6)		100		100% (6/6)	
	Uganda	0% (0/0) 0% (0/0) 0% (0/7)							0% (0/7)
Jordan C	Custom Indicators								
JD 2	% of MTaPS-supported facilities that develop, adopt, and implement AMS-related services standards	Quarterly	0	100% (2/2)	0% (0/0)	0% (0/2)	100% (2/2)	0% (0/2)	0% (0/2)
Philippin	nes Custom Indicators								
	% of service delivery points with stock out of FP, TB and HIV-AIDS tracer commodities								
	First line TB meds (4 FDC)		0% (0/0)	95%	0% (0/0)	69% (1386/2016)	30% (472/1552)		30% (472/1552)
	TB Pediatric Med (4FDC)		0% (0/0)	95%	0% (0/0)	100% (155/155)	97% (856/883)		97% (856/883)
	TB Preventive Treatment (for children)		0% (0/0)	95%	0% (0/0)	100% (518/518)	65% (645/987)		65% (645/987)
PP 1	TB Second Line Drug (Levofloxacin 500mg)	Quarterly	0% (0/0)	95%	0% (0/0)	75% (149/199)	53% (105/199)	Q4 data are not	53% (105/199)
	TB Second Line Drug (Moxifloxacin 400mg)		0% (0/0)	95%	0% (0/0)	95% (190/199)	5% (9/199)	available for this indicator	5% (9/199)
	TB Second Line Drug (Linezolid 600mg)		0% (0/0)	95%	0% (0/0)	83% (165/199)	12% (24/199)		12% (24/199)
	TB Second Line Drug (Bedaquiline)		0% (0/0)	95%	0% (0/0)	83% (164/199)	13% (25/199)		13% (25/199)
	GeneXpert Cartridges		0% (0/0)	95%			3% (13/395)		3% (13/395)
	FP Injectable		0% (0/0)	95%	0% (0/0)	44% (713/ 1631)	12% (218/1775)		12% (218/1775)

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 Result	FY20Q2 Result	FY20Q3 Result	FY20Q4 Result	FY20 Cumulative Result
	FP Implant		0% (0/0)	95%	0% (0/0)	89% (875/984)	55% (717/1316)		55% (717/1316)
	FP Oral COC		0% (0/0)	95%	0% (0/0)	42% (693/ 1633)	8% (143/1798)		8% (143/1798)
	FP Oral POP		0% (0/0)	95%	0% (0/0)	83% (923/ 1118)	31% (507/1630)		31% (507/1630)
	IUD		0% (0/0)	95%	0% (0/0)	50% (477/962)	29% (454/1566)		29% (454/1566)
	Male condom		0% (0/0)	95%	0% (0/0)	52% (825/ 1578)	21% (358/1743)		21% (358/1743)
PP4	% of MTaPS policy support initiatives for which implementation is on track	Annually	0% (0/6)	50% (3/6)		50%	% (3/6)		50% (3/6)
PP 5	% of PSCM workforce in the public sector (DOH and LGUs) certified in Supply Chain Management	Quarterly	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
PP 6	% of USG supported sites using eLMIS for procurement and supply chain management	Quarterly	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
PP 11	% of storage facilities inspected in the USG supported sites that met minimum requirements for good storage practice for TB, FP and HIV-AIDS tracer products	Quarterly	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/66)	0% (0/66)
PP 12	Average client satisfaction score for pharmaceutical services related to TB, FP and HIV- AIDS programs in the	Annually	0% (0/0)	0% (0/0)		0%	5 (0/0)		0% (0/0)

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 Result	FY20Q2 Result	FY20Q3 Result	FY20Q4 Result	FY20 Cumulative Result
	sample USG supported sites								
PP 13	% of LGUs in USG supported sites that has implemented patient centered policies and strategies to improve patient safety and rational use of TB, FP and HIV-AIDS commodities	Annually	0% (0/0)	0% (0/0)			0% (0/0)		
PP 14	% of PSCM and PV health workers who received inservice training using non-traditional learning platforms for continuous professional development (CPD) on PSCM and PV	Quarterly	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
PP 15	% of selected facilities using PViMS for active surveillance of TB commodities	Quarterly	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)	0% (0/0)
PP 16	Number of joint success stories produced	Annually	0	0% (0/0)			0		0
PP 17	Number of synergized approaches for supply chain management, human resources for health, and engagements with private sector and local government units	Annually	0	0% (0/0)	0		0		
PP 18	Number of local entities capacitated to ensure continuous provision of SC and PV trainings and capacity	Annually	0	0% (0/0)	0		0		

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 Result	FY20Q2 Result	FY20Q3 Result	FY20Q4 Result	FY20 Cumulative Result
PP 19	% of initially MTaPS/Philippines- supported entities carrying out supply chain management related functions without external technical assistance	Annually	0% (0/0)	0% (0/0)		0%	o (0/0)		0% (0/0)
PP 20	% of USG supported LGUs (PHOs and CHOs) that are adopting and implementing activities on gender in PSCM and PV	Annually	0% (0/0)	0% (0/0)	0% (0/0) 0% (0			0% (0/0)	
PP 21	% of USG supported entities that are adopting and implementing activities on climate risk management (such as medical waste management and supply chain resilience during disaster)	Annually	0%	0% (0/0)		0%	· (0/0)		0% (0/0)
MTaPS N	Aulti-Country Custom Indica	tors							
MCC 1	% of MTaPS-supported health facilities with activities that support locally identified and prioritized elements of antimicrobial stewardship	Semi- annually	100% (7/7)	100% (7/7)	100% (7/7)			100% (7/7)	
	Mozambique		100% (7/7)	100% (7/7)	/7) 100% (7/7) 100% (7/7)			% (7/7)	100% (7/7)
MCC 2	# MTaPS-supported NMRAS demonstrating	Annually	0	2			2		

Code	Performance Indicator	Reporting Frequency	Baseline Value	FY20 Target	FY20Q1 Result	FY20Q2 Result	FY20Q3 Result	FY20Q4 Result	FY20 Cumulative Result
	improved capacity in medicine regulation								
	Mozambique		0	1			1		1
	Rwanda		0	1			1		
MCC 4	% of health facilities (HF) that implemented non-PMIS web-based/electronic or mobile technology to document, analyze, and/or report on specific components of the pharmaceutical system, including logistic and patient data	Semi- annually	53% (26/56)	75%	53% (2	26/56)	46.4%	46.4% (13/28)	
	Mozambique		0% (0/0)	0% (0/0)	0% (	0/0)	0% (0/0)	0% (0/0)	
	Mozambique Rwanda		53% (26/56)	75%	53% (2	26/56)	46.4%	46.4% (13/28)	

Annex Table 2: Indicator JC1: Percentage of WHO international Health Regulation (IHR) benchmark actions completed with MTaPS support for each level of JEE capacity (IPC, AMS, and multi-sectoral collaboration) for FY20

WHO	IEE consolitu					MTaPS-	supported	country				
Benchmark	JEE capacity level	Bangla- desh	Burkina Faso	Came- roon	Côte d'Ivoire	DRC	Ethiopia	Kenya	Mali	Senegal	Tanza- nia	Uganda
	Limited Capacity - 02	25% (1/4)	50% (2/4)	25% (1/4)	50% (2/4)	75% (3/4)	75% (3/4)	0% (0/4)	0% (0/4)	75% (3/4)	25% (1/4)	50% (2/4)
P.3.1 Effective MSC	Developed Capacity - 03	25% (1/4)	50% (2/4)	50% (2/4)	75% (3/4)	50% (2/4)	75% (3/4)	0% (0/4)	100% (4/4)	50% (2/4)	50% (2/4)	50% (2/4)
on AMR	Demonstrated Capacity - 04	25% (1/4)	0% (0/4)	25% (1/4)	50% (2/4)	25% (1/4)	50% (2/4)	75% (3/4)	0% (0/4)	50% (2/4)	25% (1/4)	25% (1/4)
	Sustainable Capacity - 05	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	14% (1/7)	0% (0/5)
	Limited Capacity - 02	40% (2/5)	0% (0/5)	0% (0/5)	100% (5/5)	20% (1/5)	60% (3/5)	80% (4/5)	60% (3/5)	80% (4/5)	40% (2/5)	80% (4/5)
P.3.3 Infection	Developed Capacity - 03	0% (0/6)	0% (0/6)	33% (2/6)	33% (2/6)	17% (1/6)	83% (5/6)	33% (2/6)	33% (2/6)	50% (3/6)	33% (2/6)	83% (5/6)
prevention and control	Demonstrated Capacity - 04	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	40% (2/5)	0% (0/5)
	Sustainable Capacity - 05	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)
P.3.4 Optimize use of antimicrobial	Limited Capacity - 02	0% (0/4)	50% (2/4)	0% (0/4)	75% (3/4)	75% (3/4)	0% (0/4)	50% (2/4)	75% (3/4)	50% (2/4)	50% (2/4)	0% (0/4)
medicines in human and	Developed Capacity - 03	0% (0/6)	33% (2/6)	0% (0/6)	0% (0/6)	50% (3/6)	50% (3/6)	50% (3/6)	17% (1/6)	17% (1/6)	33% (2/6)	33% (2/6)
animal health and	Demonstrated Capacity - 04	0% (0/7)	0% (0/7)	0% (0/7)	0% (0/7)	0% (0/7)	14% (1/7)	0% (0/7)	0% (0/7)	0% (0/7)	0% (0/7)	0% (0/7)
agriculture	Sustainable Capacity - 05	0% (0/7)	0% (0/7)	0% (0/7)	0% (0/7)	0% (0/7)	0% (0/7)	0% (0/7)	0% (0/7)	0% (0/7)	14% (1/7)	0% (0/7)