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

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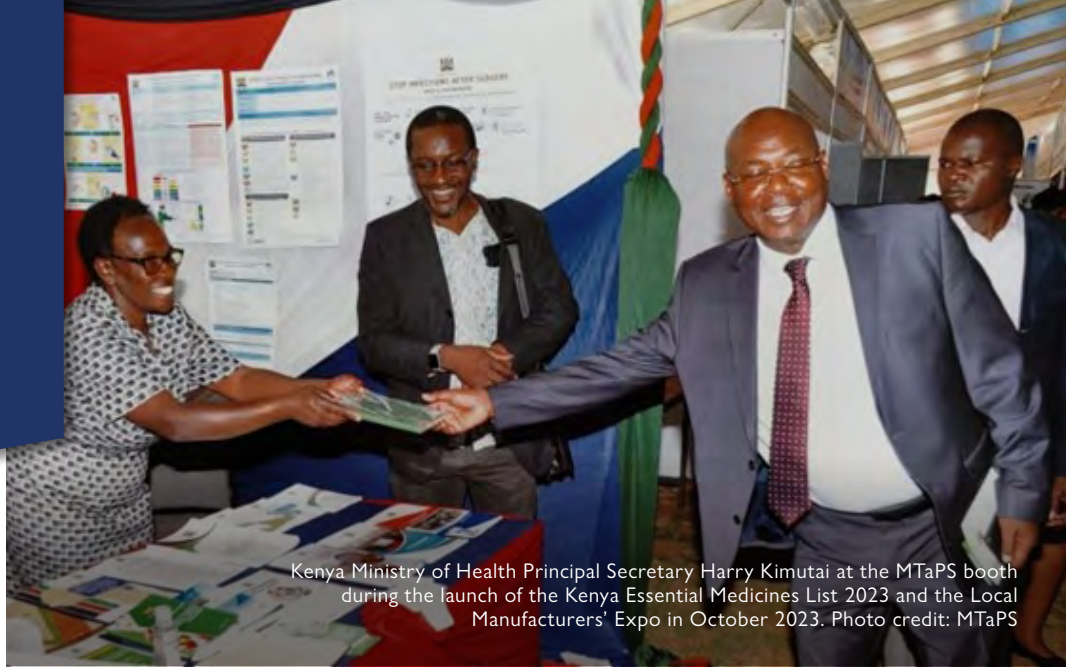

Kenya Ministry of Health Principal Secretary Harry Kimutai at the MTaPS booth during the launch of the Kenya Essential Medicines List 2023 and the Local Manufacturers' Expo in October 2023. Photo credit: MTaPS

MTaPS COUNTRY SUMMARY REPORT
KENYA (2019–2024)

About USAID MTaPS

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

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

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INTRODUCTION

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

MTaPS employs a pharmaceutical systems–strengthening approach to identify and implement strategies and actions that achieve coordinated and sustainable improvements of a pharmaceutical system to make it more responsive and resilient for achieving better health outcomes. The MTaPS approach emphasizes locally led development, country ownership, and self-reliance to support countries on the pathway to sustainability.

At the country level, the MTaPS approach is adapted to the specific context, national health system–strengthening strategies, and USAID's vision and support. In Kenya, from 2019 to 2024, MTaPS provided technical assistance to the Ministry of Health (MOH) and selected counties to strengthen pharmaceutical systems and services, including in the areas of multisectoral coordination (MSC) for antimicrobial resistance (AMR), infection prevention and control (IPC), optimizing the use of antimicrobials through antimicrobial

CHALLENGES

Kenya

- Weak coordination of AMR activities at both the national and county levels
- Lack of an M&E framework for AMR activities
- Lack of AMS policy, framework, or program in human health and animal health sectors
- Inappropriate antimicrobial use in both human health and animal health sectors
- Limited capacity for implementation of IPC interventions at all levels
- Weak monitoring, feedback, and support system for compliance with IPC guidelines and standards
- Limited HCW COVID-19 IPC capacity and guideline compliance
- Lack of an electronic AEFI reporting system and vaccine safety training
- Lack of skills and competencies for effective regulatory oversight of local vaccine manufacturing

IGAD and EAC Regions

- Low technical capacity of the regional secretariats and member states
- Weak governance structures for regulatory work
- Lack of collaborative mechanisms and commitment among the member states
- Differences in maturity levels and structures at regional and country levels
- Weak PV systems at cross-border areas
- Noncompliance with good regulatory standards and requirements among local manufacturers

stewardship (AMS), and regulatory systems strengthening, including pharmacovigilance (PV) in line with the World Health Organization's (WHO) Global Benchmarking Tool (GBT). MTaPS also supported Kenya's COVID-19 preparedness and response, specifically in mitigating transmission among health care workers (HCWs) and non-health workers, such as teachers, religious leaders, and support staff, through IPC and in strengthening the adverse events following immunization (AEFI) reporting mechanisms for COVID-19 vaccines to assure safety of the mass vaccination program.

COUNTRY CONTEXT

AMR is a priority in Kenya following findings from One Health ministries, departments, agencies, and stakeholders. The 2017 WHO-led Joint External Evaluation (JEE) of the International Health Regulations (IHR) demonstrated gaps in core capacities for the country to prevent, detect, and respond to public health emergencies.[1] AMS scored 2 (limited capacity), due to lacking an AMS policy, framework, plan, and human health and animal health sector programs. IPC scored 3 (developed capacity), due to weak monitoring and limited compliance with IPC guidelines and standards. MSC was not evaluated in this version of the JEE, but major weaknesses include limited coordination of AMR activities and absence of a monitoring and evaluation (M&E) framework.

The national response to COVID-19 was impeded by inadequate IPC capacity among HCWs, fragmented support and uncoordinated partners, lack of educational materials, and inadequate IPC supplies.

In 2022, Kenya was rated at maturity level (ML) 1 by WHO using the GBT. WHO and the Pharmacy and Poisons Board (PPB) put together institutional development plans across different regulatory functions to be implemented, aiming for ML3 (stable, well-functioning regulatory system), which is required for supporting local vaccine manufacturing. Between 2019 and 2022, MTaPS sought to align Intergovernmental Authority on Development (IGAD) and the East African Community (EAC) with the African Medicines Regulatory Harmonization agenda, the IGAD and EAC Medicines Regulatory Harmonization agenda, and USAID Kenya and East Africa priorities on integrated support for areas such as tuberculosis, HIV, maternal and child health, and family planning/reproductive health.

STRATEGIC APPROACH

MTaPS focused on strengthening existing core governance structures for MSC (National Antimicrobial Stewardship Interagency Committee [NASIC] and County Antimicrobial Stewardship Interagency Committees [CASICs]), AMS, and IPC through structured design and systematic implementation of key activities at the national, county, and health facility levels. MTaPS leveraged the existing systems, infrastructures, and expertise to widen scope and ensure sustainability of interventions. Additionally, MTaPS collaborated with various partners to conduct joint planning, co-implementation, co-monitoring/review, documentation, and reporting of activities. MTaPS supported county- and facility-level implementation of medicines and therapeutics committees (MTCs), AMS, IPC, occupational safety and health (OSH), and water, sanitation, and hygiene (WASH) activities through a continuous quality improvement (CQI) approach for sustainable capacity.

COVID-19 response assistance was aligned with international evidence-based guidelines, including those from WHO and the US Centers for Disease Control and Prevention. Utilizing a participatory stakeholder collaboration approach, MTaPS supported development of tools,

job aids, standard operating procedures (SOPs), and e-Learning materials; delivery of refresher training; periodic compliance evaluations; and development of electronic reporting and data analysis platforms for sustainable health system strengthening, to ensure preparedness for future emergencies beyond the COVID-19 pandemic.

In IGAD and EAC, MTaPS focused on developing and executing joint activity implementation plans to promote partnership and capacity building of the IGAD/EAC secretariats and PV experts. MTaPS identified areas of synergy and collaboration between bilateral and regional partners to advance the journey to self-reliance. MTaPS undertook a baseline assessment of the PV systems in IGAD to help design targeted interventions. Furthermore, MTaPS undertook an assessment in IGAD and EAC to ascertain local manufacturers' compliance with good regulatory requirements and standards and to address identified and prioritized gaps/needs.

KEY MILESTONES

2019
- Kenya Essential Medicines List (KEML) 2019 revised to incorporate Access, Watch, and Reserve (AWaRe) categorization
- First National AMS guidelines published

2020
- In-service IPC and AMS continuing professional development (CPD)–accredited courses launched
- COVID-19 IPC compliance monitoring initiated in 33 counties

2021
- First National Action Plan on AMR (NAP-AMR) M&E Framework and the national IPC M&E Framework launched
- COVID-19 vaccine supply chain microplan developed and disseminated to all 47 counties for resource management and preventing stockouts

2022
- National AMS in-service curriculum and training materials launched and finalized by the MOH
- Mobile app and USSD code for reporting AEFIs, adverse drug reactions, substandard and falsified products, medication errors, and safety concerns from blood products and medical devices launched to accelerate investigation and response

2023
- NAP-AMR 2023–2027, KEML 2023, and national IPC and Health Care Waste Management (HCWM) guidelines finalized and launched
- First Kenya National Medicines Formulary (KNMF) (2023) and National Guidelines on Healthcare-Associated Infections Surveillance (2023) published

2024
- A mobile app for uploading and accessing key AMR documents developed for use by HCWs. This app is yet to be launched
- Revised Murang'a, Kilifi, Nairobi, and Kiambu County IPC Advisory Committee (CIPCAC) work plans launched for implementation
- Revised Murang'a and Kilifi CASIC work plans for implementation
- Developed Nairobi and Kiambu CASIC work plans (first editions)

PARTNERS

- Christian Health Association of Kenya (CHAK)
- County governments
- EAC secretariat
- Federation of East African Pharmaceutical Manufacturers
- Food and Agriculture Organization (FAO)
- IGAD secretariat
- Kenya Association of Pharmaceutical Manufacturers
- Kenya Conference of Catholic Bishops (KCCB)
- Kenya Health Federation (KHF)
- Kenya Medical Research Institute (KEMRI)
- PPB
- Ministry of Agriculture, Livestock and Development
- Ministry of Environment and Climate Change
- MOH
- Ministry of Mining and Blue Economy
- National Environment Management Authority
- National Nurses Association Kenya
- Pharmaceutical Society of Kenya (PSK)
- ReACT Africa
- Supreme Council of Kenya Muslims (SUPKEM)
- United Nations Environmental Program
- University of Nairobi (UoN)
- USAID Infection Disease Detection and Surveillance (IDDS)
- WHO
- World Organization of Animal Health (WOAH)
- Youth Empowerment and Development Network

KEY RESULTS

As stated above, Kenya received a score of level 3 (developed) and 2 (limited) capacity for IPC and AMS, respectively, during the baseline JEE conducted in March 2017. The version of the JEE tool used for this evaluation did not have an MSC indicator. During its startup period, MTaPS used the WHO Benchmarks for IHR Capacities tool (2019) to conduct a situational analysis, which showed that the country at that time had partially addressed 8/17 (47%) benchmark actions in MSC, 6/21 (29%) actions in IPC, and 2/24 (8%) actions in AMS. Over the life of the project, MTaPS collaborated with and provided technical assistance to national counterparts and selected counties to fully or partially address benchmark actions as follows (as of September 2023):

- On MSC: 100% of actions for capacity level 2, 100% for level 3, 100% for level 4, and 60% for level 5
- On IPC: 100% of actions for level 2, 83% for level 3, 80% for level 4, and 40% for level 5
- On AMS: 100% for level 2, 100% for level 3, and 29% for level 4, and 0% for level 5 actions

With national stakeholders' ongoing commitment and efforts, complemented by collaboration and support from MTaPS and other implementing partners, Kenya has demonstrated progress toward level 4 (demonstrated) capacity in MSC, level 3 (developed) capacity in IPC, and level 4 in AMS.

Effective Multisectoral Coordination on AMR

- NASIC capacity for coordinating and managing the implementation of the NAP-AMR at the national and county levels improved. Through provision of mentorship and technical guidance the NASIC has strengthened its governance and ensured provision of policy direction for AMR containment at the county and national levels.
- Six CASICs were established in Nyeri, Kisumu, Murang'a, Kilifi, Nairobi, and Kiambu counties that oversee AMR-related activities at the county level.
  - The six CASICs have costed work plans, aligned to the NAP-AMR, that guide resource mobilization and the county's AMR containment efforts.
- Kenya now has a full set of policies, guidance, advocacy, and performance-monitoring documents, such as the NAP-AMR, NAP-AMR M&E framework, CASIC orientation package, AMR bulletins, and AMS and IPC policies and guidelines, all required for successful containment of AMR.
- Annual commemoration of World AMR Awareness Week (WAAW) at the national and county levels, since 2019, raising awareness on AMR. National and county levels include WAAW activities in their annual work plans.

Infection Prevention and Control

- Improved dissemination of core IPC documents to counties and health facilities, including an IPC M&E framework, SOPs, IPC-related guidelines, and an IPC strategic plan, helping the country to achieve the 8 WHO IPC core components.
- IPC human resource capacity strengthened through implementation of in-service training programs and implementation of CPD licensure–linked IPC curriculum through health professional associations across the country, training more than 7,000 HCWs.
- IPC governance structures established and operationalized in 13 counties and in 22 health facilities, through costed CIPCAC work plans/facility IPC work plans in line with the national IPC policy. The 22 facilities had improved performance in core IPC components.
- Institutionalization of the IPC CQI approach in the implementation of IPC programs in 22 health facilities generated data used for decision making on IPC interventions.
- Incorporation of related program components (i.e., OSH, WASH, and quality of care) into IPC created synergy in human resource constrained establishments.

IPC governance structures established and operationalized in

13 **counties**

and

22 **health facilities**

More than

7,000

health care workers trained on IPC in-services courses and

4,000

health care workers trained on AMS in-services courses

Use of Antimicrobial Medicines Optimized

- The National Medicines and Therapeutics Committee was inaugurated, with the focus-facility MTCs institutionalized to facilitate and coordinate AMS activities.
- The core policy and guidance documents required for AMS implementation are now available, including the national AMS guidelines; two editions of the KEML incorporating AWaRe categorization of antibiotics; the first KNMF; and AMS-related SOPs, job aids, and information, education, and communication (IEC) materials.
- In-service AMS course is now available for CPD implementation through health professional associations. This has seen the training of more than 4,000 HCWs on AMS by MTaPS to improve service delivery.
- HCWs entering the workforce are equipped to implement AMS as a result of a pre-service curriculum that was implemented through an MTaPS and UoN collaboration. To date, over 80 pharmacy students have been trained.
- Improvements in antimicrobial medicines prescribing or use observed in 24 health facilities and 2 community pharmacies, with documented evidence of improvement available. The health facilities have adopted and implemented AMS activities using CQI action plans to ensure sustainability of the program even after MTaPS support.

COVID-19

- COVID-19 training packages and IEC materials were implemented, which bridged the gap that existed in the country to train HCWs (including morticians and staff working in special units and prisons) and to raise countrywide awareness on COVID-19.
- Trained 5,099 workers, including trainers of trainers (TOTs), in 33 counties on COVID-19 topics related to IPC, HCWM , and WASH to promote compliance with IPC practices. These trainers were used by MTaPS and various partners to cascade training of HCWs and for supervision in their respective counties.
- PPB's Emergency Use and Compassionate Use guidelines assisted in expediting market authorization of COVID-19 vaccines, critical for rapid deployment and effective COVID-19 pandemic response.
- Gaps in COVID-19 vaccine deployment, related to resource allocation, vaccine storage, distribution, administration, HCW training, and patient communication, were identified and addressed, thanks to MOH-led facility assessments in 10 counties.
- HCWs equipped with essential knowledge and tools through the development of a MOH training package and SOPs/job aids for the administration and logistics of COVID-19 vaccines, which improved efficiency and safety of the vaccine rollout during the pandemic.
- Under MOH ownership, supply chain microplan developed and implemented in counties to quantify COVID-19 vaccine needs, optimize vaccine distribution, and ensure adequate supply for response.
- Under the PPB and MOH initiative, development of a mobile application and a short messaging service for reporting AEFIs related to COVID-19, other vaccines, and health products significantly improved the monitoring of vaccine safety and enabled prompt response to adverse events during the pandemic.
    - The cumulative adverse event reports received at PPB increased from 16,452 in 2020 to 27,121 at end of 2023, a 65% increase over a 3-year period. The reported AEFIs increased from an annual total of 861 (405 male, 456 female) in 2021 to 3,251 (905 male, 2,342 female, 4 unknown) in 2023.
- MOH job aids and IEC materials promoted COVID-19 vaccine uptake among youth, clergy, expectant women, and health workers, which increased awareness and acceptance of the vaccine and contributed to increased vaccination coverage across these key demographic groups.

5,099
health care workers
trained on COVID-19–related IPC

3,462 **COVID-19 AEFI reports**
submitted to country monitoring system as of June 2024

More than **200** **health workers** trained on PV

Regulatory Systems Strengthening

- PPB's increased regulatory capacity, with 25 staff recruited as a result of MTaPS-supported comprehensive competency mapping, improved regulatory oversight of local manufacturing and ensured strict adherence to safety and efficacy standards.
- PPB's updated SOPs across various regulatory functions, aimed at meeting ML3 certification requirements and achieving compliance with international standards, enhanced regulatory effectiveness and alignment with global best practices.
- Detection, assessment, understanding, and prevention of adverse events improved through PPB's development of key PV documents, such as a strategic plan for active surveillance, an M&E framework, and key performance indicators, ultimately assuring patient safety.
- National capacity to manage drug and vaccine safety and the efficacy of future vaccine manufacturing and deployment significantly improved through PPB's training of more than 200 HCWs on PV.
- Data sharing and analysis capabilities, critical for real-time monitoring of drug and vaccine safety and prompt response to assure patient safety and effective program management, significantly improved through PPB's enhancement of the PV electronic reporting system (PVERS) and mobile PVERS' integration with the Kenya Health Information System.
- Standards of safety and efficacy in clinical research raised ensuring reliable and valid outcomes, due to PPB's training of 30 HCWs from various clinical trial (CT) sites.
  - PPB staff capacity to ensure rigorous oversight and adherence to international research standards improved, thanks to the training of 25 PPB staff on CT protocol evaluation and CT site inspection.
- Enhanced coordination and support for regional PV activities achieved through capacity building and establishment and operationalization of PV governance structures in collaboration with IGAD and EAC secretariats.

Preventing COVID-19 Transmission in Kenyan Prisons

When the Ministry of Health confirmed Kenya's first COVID-19 patient in March 2020, there was fear, panic, and disbelief among HCWs and the community at large. As the COVID-19 positivity rate increased, so did the unique clinical and public health challenges in health care settings. Health care facilities in prisons were no exception, facing a plethora of challenges exacerbated by crowded living conditions.

To contain the spread of COVID-19 in selected prisons across 13 counties, MTaPS prioritized capacity building of HCWs to enable implementation of risk mitigation techniques, such as hand hygiene, mask wearing, and waste management, through a layered approach including institutional strengthening of the prisons themselves and training of 364 HCWs across 13 counties. Posters and job aids were distributed during the training sessions. Furthermore, as part of the COVID-19 IPC trainings, the HCWs developed action plans to guide implementation of prioritized post-training interventions in their respective prisons.

Hand washing station for inmates installed at one of the prisons. Photo credit: MTaPS Kenya

"USAID MTaPS came in and their main objective was to strengthen our medicines and therapeutic committee and establish antimicrobial stewardship committees. So far, the successes that I've seen include the guidance provided to show us what we can do and how we can realize our low-hanging fruits. The biggest success I've seen is doing surveys and studies with our data, so we know where we are at and use our data to make interventions and inform decisions. In addition, I now get to mentor others and see them realize their inner strengths. Knowing they can make a change with what they have. So, that I enjoy best is teaching and mentoring others and just seeing change growing."

Dr. Aisha Mongi
Kilifi County AMS focal person

PATHWAY TO SUSTAINABILITY

MTaPS provides technical guidance and supports countries in establishing strategic direction and development of critical capacities on a pathway to sustainable and resilient pharmaceutical systems. Through its activities in country, MTaPS strengthened the capacity of local governments and organizations (public, private, and civil society) for improved, locally led, and more sustainable pharmaceutical service delivery, as highlighted below:

- Costed NAP-AMR and M&E framework in place that allows for mobilization of resources for sustainable implementation of AMR containment efforts.
- Established national and county MSC mechanisms for AMR which are now fully functional at the national level and in selected counties. These collaborate with One Health stakeholders and AMR partners, such as FAO, WHO, WOAH, and USAID IDDS. Participated in joint planning and implementation of various government-led AMR activities that have drawn support from various One Health stakeholders, ensuring country ownership and promoting the path to sustainability.
- Institutionalization of MTaPS-supported interventions, such as implementation of tools, training packages, policies, guidelines, job aids, and SOPs, within the existing structures, mechanisms, and procedures, allows for continuity of implementation of the NAP-AMR and strengthening of IPC and AMS programs.
- MTaPS worked through the MOH and health professional associations, developing champions, TOTs, and mentors to rapidly implement activities and build sustainable human resource capacity. These champions, TOTs, and mentors are already embedded within the MOH at the national and county levels and continue to be utilized by the MOH and other implementing partners for ongoing support to various activities using the cascade-training approach.
- Functional sustainable county IPC governance structures were established to effectively manage and coordinate IPC programs across 13 counties.
- MTaPS established sustainable CASIC and AMS programs in 6 counties and their respective focus health facilities to contain AMR and promote AMS.
- MTaPS developed a replicable approach and tools that supported the rapid strengthening of PV capacities within the cross-border areas; HCWs within the IGAD region were equipped with safety-monitoring skills and knowledge for enhanced PV awareness and safety reporting.
- Existence of PV governance structures in both EAC and IGAD ensures continuity of the work within the region, e.g., through the PV expert working groups and the costed IGAD work plan.

RECOMMENDATIONS

- NASIC and CASICs to integrate AMR interventions across other One Health programs (such as zoonotic diseases and food safety) to support the expansion of AMR containment efforts.
- Establishment of One Health Mechanism or Steering Committee at national and county levels to coordinate One Health Agenda and activities to minimize duplication, optimize use of resources, and enhance accountability.

FEATURED RESOURCES

- Strengthening Multisectoral Coordination to Contain Antimicrobial Resistance (AMR) in Kenya
- Effective and Sustainable Governance Structures for Combating Antimicrobial Resistance at Health Facilities in Kenya
- Kenya Essential Medicine List 2023
- Kenya National Medicines Formulary 2023
- Kenya National Antimicrobial Stewardship Guidelines 2019
- Kenya National Policy on Infection Prevention and Control for Health Care Services 2021
- Kenya National Strategic Plan on Infection Prevention and Control for Health Care Services 2021–2025
- National Infection, Prevention and Control Monitoring and Evaluation Framework 2021–2025
- Kenya National Action Plan on Prevention and Containment of AMR 2023–2027
- National Action Plan on Prevention and Containment of AMR Monitoring and Evaluation Framework 2023–2027

PEER-REVIEWED PUBLICATIONS

- Joshi et al. Moving from assessments to implementation: promising practices for strengthening multisectoral antimicrobial resistance containment capacity. One Health Outlook. 2023;5(article 7).
- Joshi et al. Strengthening multisectoral coordination on antimicrobial resistance: a landscape analysis of efforts in 11 countries. J of Pharm Policy and Pract. 2021;14(article 27).

- MOH and the county governments to make a budgetary line item available for AMR activities at all levels of government (including the national, county, and facility levels).
- MOH to include MTaPS-developed AMR-related training curriculums into existing platforms, such as open-source learning management systems, including Moodle, the MOH e-Learning academy, or another platform in use by health training institutions in Kenya. This is to ensure scale-up of training of HCWs using the comprehensive IPC and AMS training packages.
- MOH and county governments should incorporate compliance monitoring for HCWs and health facilities in IPC and AMS programs through regular supportive supervision to assess/monitor CQI plans.
- The continued funding of the regional secretariat teams at IGAD and EAC by member/partner counties and donors is essential for spurring regulatory harmonization activities planned in the region.
- Implementation of systemic approaches to PV reporting systems by all stakeholders should be maintained to ensure that AEFI reporting and other required reporting happens without a need to develop parallel systems.
- Ongoing leveraging of existing IPC systems and structures should be promoted among all stakeholders due to the limited resources currently available for strengthening AMR activities. COVID-19 support was beneficial, as it contributed to strengthening IPC systems and structures.

FUTURE CONSIDERATIONS

- Scale up IPC, MSC, and AMS interventions to more counties and health facilities.
- Work more closely with with the private and faith-based sectors to sustain implementation of IPC, MSC, and AMS interventions.
- Support improved supply chain performance to ensure the uninterrupted flow of health commodities to service delivery points and patients/clients, including during public health emergencies or unanticipated shocks to the health system.
- Slow the development and spread of AMR and strengthen pandemic preparedness and response through advocating for sustained domestic funding for IPC and AMS programs.
- For stronger pandemic preparedness, it is essential to develop robust vaccine PV systems as well as market authorization processes to ensure vaccine safety and efficacy, continuous safety monitoring to detect and assess adverse events, and comprehensive post-marketing surveillance to track vaccine performance in real-world conditions.
- Improve patient safety through strong PV systems.
- Support strengthening the pharmaceutical regulatory bodies along WHO GBT standards, including the implementation of relevant electronic platforms, to increase their capacity for rapid product authorization, surveillance, and ongoing quality control.

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1. Joint External Evaluation of IHR Core Capacities of the Republic of Kenya Mission Report, 27 February to 3 March 2017. https://extranet.who.int/sph/sites/default/files/document-library/document/JEE%20Report%20Kenya%202017.pdf

RECOMMENDED CITATION

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