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

Improved Access.
Improved Services.
Better Health Outcomes.

Onsite infection prevention and control mentorship at the theater at Sekou Toure Hospital (mentees are being shown IPC best practices guidelines). Photo credit: MTaPS Tanzania

MTaPS COUNTRY SUMMARY REPORT
TANZANIA (2018–2024)

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, and health technologies and products, as well as fortifying 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 system–strengthening approach that identifies and implements strategies and actions to achieve coordinated and sustainable improvements. In doing so, MTaPS ensures that local pharmaceutical systems are more responsive and resilient and will contribute to 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 Tanzania, from 2018 to 2024, MTaPS provided technical assistance (TA) to the Ministry of Health (MOH) to strengthen pharmaceutical systems and services in these areas: multisectoral coordination (MSC) on antimicrobial resistance (AMR), infection prevention and control (IPC), antimicrobial stewardship (AMS), and regulatory system strengthening, including pharmacovigilance (PV) in line with the World Health Organization's (WHO) Global Benchmarking Tool (GBT). MTaPS also played a critical role in supporting Tanzania's COVID-19 response, specifically in strengthening the adverse events following immunization (AEFI) reporting mechanisms for COVID-19 vaccines to assure safety of the mass vaccination program, as well as in mitigating transmission among health care workers (HCWs) and patients through improved IPC.

CHALLENGES

- Inefficient MSC on AMR containment
- Outdated AMS national guidelines
- Weak IPC practices at health facilities (HFs)
- Lack of health care-associated infection (HAI) surveillance systems at primary health care facilities
- Lack of AMS programs, resulting in the irrational use of antimicrobials
- Bottlenecks in the registration and importation of medicines
- Low reporting of AEFIs and adverse drug events (ADEs) by HFs, including during mass COVID-19 vaccination

PARTNERS

- AMR Multisectoral Coordinating Committee (MCC) and the AMR awareness, AMR surveillance, IPC, AMS, and monitoring and evaluation (M&E) technical working groups (TWGs)
- Amref Health Africa, Tanzania
- Association of Private Health Facilities in Tanzania (APHFTA)
- Center for Distance Education (CDE)
- Centers for Disease Control and Prevention (CDC)
- Food and Agriculture Organization (FAO)
- Medical Stores Department (MSD)
- Medipeace, Tanzania
- Ministry of Agriculture (MOA)
- MOH
- Ministry of Livestock and Fisheries (MLF)
- Muhimbili University of Health and Allied Sciences (MUHAS)
- President's Office Regional Administration and Local Government (PO-RALG)
- Extension for Community Healthcare Outcomes (Project ECHO)
- TMDA
- USAID Infectious Disease Detection and Surveillance (IDDS) Project
- WHO
- University of Dar es Salaam (UDSM)

COUNTRY CONTEXT PRIOR TO IMPLEMENTATION

Tanzania was first in Africa to undergo the WHO Joint External Evaluation (JEE) in 2016 (JEE version 1) to assess capacity to prevent, detect, and rapidly respond to public health risks. The country was classified as having developed capacity (3/5 benchmark actions) for IPC and no capacity (1/5) for AMS. In response to the 2016 JEE, Tanzania developed its first and then second National Antimicrobial Resistance Action Plans (NAP-AMR 2017–2022 and 2023–2028), which guide stakeholders on AMR prevention and containment efforts.[2,3]

The Tanzania Medicines and Medical Devices Authority (TMDA) achieved WHO GBT maturity level (ML) 3 (a stable, well-functioning regulatory system) in 2018 for medicines and vaccines (non-producing). The TMDA is aiming for ML4 (i.e., a regulatory system at an advanced level of performance and continuous improvement) and for total control and effective oversight of the medical products market. The TMDA faced various challenges, such as bottlenecks in medicines registration and importation processes that were hampering access to medicines such as antiretrovirals (ARVs) and to maternal, newborn, and child health (MNCH) products; an inadequate number of assessors to conduct complex medical product registration applications; and a lack of advanced evaluation competency.

The national pandemic response to COVID-19 was impeded by weak infrastructure and IPC practices while COVID-19 vaccine introduction was undermined by inadequate HCW knowledge on PV and numerous facilities' failures to report adverse events following immunization (AEFIs), hampering the TMDA's ability to assure safety and trust in the mass vaccination program.

STRATEGIC APPROACH

MTaPS' goal, in support of USAID's Global Health Security Agenda (GHSA) objectives on AMR, is to contribute to enhancing the capacities and raising the JEE score for MSC and AMS. MTaPS Tanzania worked to strengthen systems and practices toward AMR containment in partnership with the Government of Tanzania (GOT) and in alignment with both the NAP-AMR 2017–2022 and 2023–2028 goals. MTaPS' TA followed the One Health (OH) approach, which promotes MSC across multiple sectors and uses the JEE and the WHO Benchmarks for International Health Regulations (IHR) Capacities (2019) actions as two key tools to guide and measure progress of these efforts. With technical support from MTaPS and other partners, the country designed and implemented multifaceted interventions to strengthen MSC, improve IPC, and optimize antimicrobial use through promoting AMS, to strengthen Tanzania's AMR response.

MTaPS' strategic approach to advancing the TMDA's regulatory capacity toward ML4 involved addressing key gaps identified in the 2018 WHO GBT assessment, addressing the TMDA's priorities, and building institutional capacity to regulate the medical products market.

MTaPS also helped strengthen the country's response to COVID-19 by improving HCW and patient safety and by mitigating transmission by rapid "just-in-time" IPC capacity development, followed by compliance monitoring and supportive supervision. In addition, MTaPS strengthened all aspects of the COVID-19 vaccines PV system, including guidance development, training, supportive supervision, and VigiFlow data integration to address needs specified by the TMDA.

KEY MILESTONES

2018
- Introduction of MTaPS to stakeholders and prioritization of interventions

2019
- National IPC guidelines revised per WHO recommendations, printed, and disseminated
- Multiyear national antimicrobial consumption (AMC) survey and trend analysis

2020
- Policy guidelines for implementing AMS, and Multisectoral AMR Communication Strategy 2020–2025 adopted/ approved by the GOT

2021
- Launch of Standard Treatment Guidelines/ National Essential Medicines List of Tanzania (STG/NEMLIT) with Access, Watch, and Reserve (AWaRe) classification
- Launch of IPC M&E system and HAI surveillance system and tools, with data capture via DHIS2
- Launch of IPC e-Learning course for online training of HCWs

2022
- Review of implementation status of NAP 2017–2022 activities; development and launch of NAP-AMR 2023–2028
- Launching of IPC and AMS ECHO for remote mentorship of HCW

2023
- First country self-evaluation of progress on actions in WHO Benchmarks for IHR Capacities in areas of MSC, IPC, and AMS
- Increased AEFI reporting for COVID-19 and other vaccines achieved, ensuring the safety and effectiveness of Tanzania's mass COVID-19 vaccination campaign

2024
- IPC & AMS mentorship capacity of HFs transferred to local partners to foster ownership and sustainability

KEY RESULTS

Working in collaboration with MOH and other stakeholders, MTaPS supported Tanzania in achieving the following key results:

Global Health Security Agenda/antimicrobial resistance (GHSA/AMR)

As stated above, Tanzania received a score of level 3 (demonstrated) capacity for IPC and level 1 (no) capacity for AMS during the 2016 baseline JEE evaluation. The JEE tool version used for this evaluation did not have an MSC indicator. During its startup period, MTaPS used the WHO Benchmarks for IHR Capacities (2019) actions to conduct a situational analysis, which showed that the country at that time had partially or fully addressed 9/17 (53%) benchmark actions in MSC, 3/21 (14%) actions in IPC, and 6/24 (25%) actions in AMS. Over the life of the project, MTaPS collaborated with the GOT and other partners and provided TA to national counterparts to fully or partially address 43 of 62 (69%) benchmark actions (as of August 2023). The percentage of JEE benchmark actions accomplished by MTaPS support across MSC, IPC, and AMS in different levels (1–5) is as follows:

- On MSC: 100% of capacity level 2, 100% of actions for level 3, 100% for level 4, and 40% for level 5
- On IPC: 100% of actions for level 2, 100% for level 3, 100% for level 4, and 100% for level 5
- On AMS: 100% for level 2, 100% for level 3, 100% for level 4, and 57% for level 5 actions

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

Effective multisectoral coordination on AMR

- Strengthened the national MCC to oversee, monitor, and coordinate AMR activities across sectors.
- Second NAP-AMR 2023–2028 adopted to guide AMR prevention and containment implementation across human health, animal health, and environmental sectors.
- Developed and implemented Multisectoral AMR Communication strategy 2020–2025 to help improve OH communications, practices, and implementation between the MOH, the MALF, PO-RALG, the AMR-MCC and its five TWGs (awareness, surveillance, IPC, AMS, and M&E), and other stakeholders.
- Strengthened AMR governance structures to oversee, monitor, and support implementation of the second NAP-AMR 2023–2028. The committees, focal persons, and champions are established at the central, regional, district, and facility levels.

Infection prevention and control

- HCWs in 28 regional hospitals and 4 zonal hospitals have access to revised IPC guidelines, standards, standard operating procedures (SOPs), and onsite continuous education opportunities.
- Trained 744 HCWs on current IPC practices to help minimize the spread of infections and protect HCWs and patients. 61 health-related colleges have access to and are using the revised IPC curriculum for health-related learning institutions.
- Developed 8-module IPC e-Learning course, which was adopted by the Medical Association of Tanzania, the Tanzania Nursing and Midwifery Council, and the Pharmacy Council as an accreditation requirement for health professionals.
  - 226 HCWs completed the course from 2021 to the end of 2023.
- Developed IPC standards for HFs and integrated them into the MOH supportive supervision platform (AfyaSS). These were adopted by the MOH and health supervisors to assess compliance and provide feedback for improvement as required, while HFs are using AfyaSS for self-assessment and gap identification.
- Developed IPC M&E system with 21 IPC indicators, including HAI surveillance system (surgical site infections). This is now an integral part of the national health management information system, DHIS2, which helps HFs to report progress on IPC interventions to the MOH.
  - This institutionalized routine monitoring of facility-level IPC through standardized tools allows the MOH and facilities to pinpoint areas for IPC improvement. 117 HFs were reporting through DHIS2 by December 2023.
- Developed National IPC/AMR Communication strategy and implemented it to improve IPC practices both at HFs and the community level.
- Improved performance in core IPC components in all 10 MTaPS-supported facilities. For example, HAI surveillance has improved in the supported facilities because of development and implementation of the HAI surveillance system. Facilities started HAI surveillance after provision of necessary tools and guidelines. The 10 facilities improved HAI surveillance from 10% to 59%. The score during national baseline assessment (2020) was 2%, and during the follow-up assessment done in 2023, the score was 63%.
- Trained 108 journalists to increase their knowledge and awareness on IPC to help advocate for IPC practices and implementation at all levels.
- Project ECHO, a knowledge-sharing, telementoring model developed by the University of New Mexico, is available to use for mentorship of HCWs, specifically reaching 1,342 HCWs to improve IPC practices.[5]

Trained **744** **HCWs** on general IPC practices and **1,373 on COVID-19 IPC.**

IPC e-Learning course developed. **226** **HCWs completed the course** from 2021 to 2023.

Developed IPC M&E system. **117** HFs reporting through DHIS2 by December 2023.

Trained **108** **journalists** to increase their **knowledge and awareness on IPC** to help advocate for IPC practices and implementation at all levels.

110 participants (43 female) trained on ethical prescribing and dispensing of antimicrobial agents **to promote appropriate antimicrobial use in HFs.**

Use of antimicrobial medicines optimized

- Developed policy guidelines for implementing antimicrobial stewardship and used them to improve AMS implementation and practices.
- WHO AWaRe classification of antibiotics adapted for Tanzania and integrated into the national STG/NEMLIT and used countrywide for rational use of antibiotics. HFs, including 10 MTaPS-supported hospitals, have started to classify antibiotics per AWaRe and have documented evidence on improvements toward rational use of antibiotics.
- Developed hospital formulary template with AWaRe-classified antibiotics and piloted it in 10 MTaPS-supported hospitals; it has been disseminated and is now available nationwide. Revised hospital medicine and therapeutics committee (MTC) guidelines that are used to guide functioning of MTCs in HFs to promote and monitor rational use of antimicrobials.
- Trained 110 participants (43 female) on ethical prescribing and dispensing of antimicrobial agents to promote appropriate antimicrobial use in HFs.
- AMC trend analysis done over 6 years (2017–2019 and 2020–2022) to make AMC data available to relevant stakeholders for decision making and to improve consumption of antimicrobials following the recommended standards.[1]
- Conducted rapid situational analysis of AMS policies in both animal and human sectors; the findings were used to inform NAP-AMR 2023–2028 development.
- Developed in-service AMS curriculum and training manual and used them to train 116 HCWs to promote optimal use of antimicrobials at HFs.
  - Strengthened collaboration between AMS and surveillance team at the facility and AMS team sensitized and collected sample for culture and sensitivity; the findings from laboratory guided rational use of antibiotics, formulation of hospital formulary, and development of antibiogram.
  - Spearheaded the formation of M&E TWG that developed the M&E of AMR surveillance activities alongside MSC, surveillance, IPC, and AMS TWGs.
- Initiated AMS Project ECHO to support AMS mentorship, leading to the mentorship of 693 HCWs in AMS practices.

COVID-19 IPC

- Improved compliance with COVID-19 IPC standards among HCWs, enhancing the safety of both staff and patients during the pandemic through effective use of standardized SOPs.
  - Printed and distributed 1,900 IPC SOPs (a bundle of 27 SOPs, including hand hygiene, health care waste management, instrument processing, and preparation of chlorine) to increase access to standardized guidelines and continuous education onsite.
- Increased protection and safety for HCWs and patients across 193 HFs, achieved through targeted training and mentoring in COVID-19 response measures.
  - Trained 1,373 (733 female) HCWs in 193 HFs countrywide as part of the COVID-19 response to minimize the spread of the virus and protect HCWs and patients.
  - Mentored HCWs on use of the SOPs to improve compliance and safe provision of services.

COVID-19 vaccination

- Trained 1,022 HCWs, including 94 regional and council health management team specialists, in COVID-19 vaccine PV.
- With MTaPS' support 910 COVID-19 vaccine AEFIs (including 6 severe cases) reported to TMDA, and TMDA's follow-up response facilitated to help assure safety and trust in COVID vaccines.
- Disseminated more than 1,200 COVID-19 vaccine information, education, and

communication materials (brochures, flyers, and chart) and conducted supportive supervision in 19 regions to support compliance with TMDA reporting requirements and sustain COVID-19 response in the longer term.

- Enhanced AEFI reporting system with COVID-19 vaccine functionality to address the immediate needs of the COVID-19 vaccination program. The system was subsequently leveraged for reporting AEFI from other vaccines and ADEs, which has improved the safety of pharmaceutical services.

Pharmaceutical regulation and PV

- Strengthened safety monitoring of medicines at the National HIV program, through developing guidelines for safety monitoring of pediatric medicines and expanding the Vigilance Technical Committee (VTC), by supporting the TMDA to review the VTC's terms of reference and seconding 4 pediatric experts.
  - The VTC helped to review and monitor pediatric pharmaceutical products, which led to increased safety of the pediatric population.
  - This also led to improved safety monitoring of medicines and quality of decision making by the VTC to enhance patient outcomes and reduce the risk of adverse events.
- Enabled monitoring, review, and reporting of medicines safety issues by training 33 (16 female) qualified persons responsible for PV from various Marketing Authorization Holders.
- Increased the pool of competent PV experts at TMDA by training 51 (16 female) assessors on Periodic Safety Update Reports (PSURs) and Risk Management Plans (RMPs). These PV experts reduced the PSUR and RMP backlog and improved access to quality-assured medicines, including ARVs.
- Reduced dossier backlog from 311 to 216 (2022–2023) by training 52 (18 female) medicine evaluators on conducting medicine dossier assessments, improving access to quality-assured medicines, including ARVs.
- Improved clinical trials (CT) site compliance to good clinical practice (GCP) and National CT guidelines by training 26 (16 female) CT officers on evaluation of CT applications and 25 (13 female) CT officers on CT site inspection for GCP compliance, leading to improved participant safety and CT data integrity.
- Enhanced the technical capacity of TMDA assessors to review files, particularly through training in bioequivalence studies, followed by workshops aimed at addressing the backlog of dossiers awaiting review. This streamlined the medicine registration process, and contributed to several positive outcomes:
  - Reduced timeline for registration of medicines from 240 to 180 days.
  - Increased number of registered medicines from 5,434 (2021 baseline) to 7,458 (December 2023).[4]

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Family planning/reproductive health and MNCH

- Leveraged MNCH core funds to support the TMDA to host a Southern African Development Community joint review of MNCH medicines to facilitate registration in the region and to host
  the following:
  1. A capacity building session on regulation of MNCH medical devices for regulators from 10 African countries
  2. A study visit for 2 TMDA staff to a WHO collaborating center—Saudi Arabia Food and Drug Authority
  3. A twinning visit for 3 assessors of medical devices on the continent to the TMDA

These initiatives enhanced the TMDA's role in regional regulatory harmonization, contributing to the positioning of the Authority to become a center of regulatory excellence for medical devices.

- Developed a template, SOPs, a checklist, and formal training materials on Summary Product Characteristics (SmPCs) and Public Assessment Reports (PARs) that were used to train 25 (9 female) assessors, facilitating the TMDA to improve SmPC and PAR publications, regulatory transparency, and patient safety.

> *"As a visionary founder of the implementation of antimicrobial stewardship programs in Tanzania, MTaPS has shown unparalleled leadership and dedication in the fight against antimicrobial resistance through financial and technical support in the implementation of AMS programs from the national level to health facilities. Their pioneering efforts have not only saved lives but have also set a gold standard for innovation in health care in Tanzania, leaving a lasting legacy of progress and sustainability in the fight against antimicrobial resistance."*
>
> *Emiliana Francis*
> *National AMR coordinator*

Infection prevention and control in Tanzania: MTaPS key in developing a successful M&E system

The first national IPC M&E framework in Tanzania was established by leveraging DHIS2 for integrating IPC reporting into the national HMIS. As a result, 117 facilities report monthly and quarterly on IPC to the MOH (March 2024). The M&E system has equipped the MOH with necessary data, allowing for timely feedback. Coupled with training, HCWs are prepared for improved consistent reporting, and new capacities for peer learning allow for the exchange of information and best practices, which is crucial for sustaining IPC improvements and staying updated with global practices.

To ensure sustainability, HFs in Tanzania are taking actions such as including IPC-related M&E activities into budgets and comprehensive health operational plans. The MOH is scaling up the IPC M&E system to other HFs and conducting targeted mentorship to support continuous improvement efforts.

Onsite mentorship on how to use IPC M&E tools and report through DHIS2. Photo credit: Doris Lutkam, MTaPS Tanzania

PEER-REVIEWED PUBLICATIONS

- National Consumption of Antimicrobials in Tanzania: 2017–2019. (2020) http://doi.org/10.3389/fphar.2020.585553
- Antimicrobial use across six referral hospitals in Tanzania: a point prevalence survey. (2020) https://doi.org/10.1136/bmjopen-2020-042819
- Identifying and addressing challenges to antimicrobial use surveillance in the human health sector in low- and middle-income countries: experiences and lessons learned from Tanzania and Uganda. (2023) https://doi.org/10.1186/s13756-023-01213-3

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. MTaPS strengthened the capacity of local public, private, and civil society institutions for improved, locally led, sustainable pharmaceutical service delivery, as highlighted below:

- Governance structures are operationalized to oversee, monitor, and support AMR implementation at the national level (MCC, IPC, AMS, and M&E TWGs) and the facility level (AMS committees, IPC committees) to ensure sustainable implementation and stewardship.
- Implementation experience in the 10 MTaPS-supported hospitals is being used to promote best practices and learning by other HCWs, underscoring commitment to continuous improvement.
- Improved IPC surveillance indicators through DHIS2 with 117 facilities so far utilizing the IPC M&E system countrywide, providing a foundation for long-term monitoring and data-driven program management.
- IPC e-Learning platform established at and run by CDE; online IPC course available/accessible to all health workers.
- AMS curriculum and training package for in-service HCWs developed, accredited, and run by MUHAS in collaboration with the MOH, contributing to a sustainable workforce development framework.
- Facility uptake in independently conducting AWaRe categorization of antibiotics and using findings to inform decision making will improve rational use of antimicrobials long-term.
- Creation of a pool of regulatory experts at the TMDA to mentor new regulatory officers and maintain an adequate regulatory workforce.
- Availability of a monitored reporting system of AEFIs and ADEs from facilities to the central level (TMDA) with regular review of received AEFIs and ADEs provides a lasting mechanism in safety surveillance.

RECOMMENDATIONS

- MCC to continue building capacity of the AMR coordinating team and engage local academic institutions to sustain HCW capacity building (MUHAS for AMS course, regulatory systems training/refreshers) and IPC M&E system updates (UDSM for DHIS2).
- The MOH to support rollout of AMS/IPC programs to more HFs.
- The MOH to expand support for AMR/IPC to primary-level HFs.
- The MCC to strengthen capacity of the M&E TWG to monitor implementation of the NAP-AMR among all TWGs and stakeholders.
- TMDA to build on the achieved results to sustain the functionality of the regulatory system and aim for ML4 for medicines and continue to position as a center of regulatory excellence for medical device regulation.
- The MOH to continue supporting COVID-19 vaccine PV. Key factors are the competency of HCWs, frequent and transparent vaccine safety communication, public awareness and engagement, feedback mechanisms, wider use of electronic reporting systems, and continual improvement through mentorship and supervision.

FEATURED RESOURCES

- IPC e-Learning course National e-Platform for Health
- Technical Brief: Improving Infection Prevention and Control in Tanzania
- Technical Brief: Strengthening Antimicrobial Stewardship (AMS) in Tanzania
- Tanzania Technical Brief: Introducing the WHO Antibiotics Categorization in Tanzania
- USAID MTaPS. 2021. Improving Access to Maternal, Newborn, and Child Health Products in Low- and Middle-Income Countries: Considerations for Effective Registration Systems.
- Standard Treatment Guidelines and National Essential Medicine List 2021 (STG-NEMLIT)

Standard Treatment Guidelines and National Essential Medicine List 2021 (STG-NEMLIT)

FUTURE CONSIDERATIONS

- Increase private sector engagement, including private pharmacies, drug dispensing outlets, and private HFs, in the fight against AMR.
- Continue supporting the TMDA to maintain ML3, progress to ML4, and work toward being a WHO Listed Authority, which is globally recognized as performing at an advanced level. Furthermore, support TMDA to position itself as a regional center of excellence for medical devices regulation.
- A concentrated investment in one area, such as COVID-19 vaccine PV, can indirectly lead to improvement across broader health domains, including other product adverse event monitoring and reporting, thus creating a multiplier effect. This insight can guide future strategic planning and interventions to optimize the use of resources and maximize health outcomes.

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