INSPIRING ACTION:

THE IMPACT OF AND RECOMMENDATIONS ON INCLUDING DIAGNOSTICS IN NATIONAL ACTION PLANS

amr INDUSTRY ALLIANCE

Contents

List of Abbreviations

AIIMS – All India Institute of Medical Sciences
AMR – Antimicrobial Resistance
ASM – American Society for Microbiology
AST – Antimicrobial Susceptibility Testing
BIRAC – Biotechnology Industry Research Assistance Council
CDC – Centers for Disease Control and Prevention
CE – Clinical Engagement
CLSI – Clinical Laboratory & Standards Institute
DTC – Drug and Therapeutic Committee
ECDC – European Center for Disease Prevention and Control
EUCAST – European Committee on Antimicrobial Susceptibility Testing
GAP – Global Action Plan
GDP – Gross Domestic Product
GLASS – Global Antimicrobial Resistance and Use Surveillance System
HAI – Hospital-Acquired Infections
IACG – Interagency Coordination Group
ICMR – Indian Council of Medical Research
IDDS – Infectious Disease Detection and Surveillance
IHHN – Indus Hospital and Health Network
IPC – Infection Prevention and Control
JEE – Joint External Evaluation
LMIC – Low- or Middle-Income Country
MAAP – Mapping Antimicrobial Resistance and Antimicrobial Use Partnership
MCC – Multi-Sectoral Coordination Committee
NAP – National Action Plan
NCDC – National Center for Disease Control
NIH – National Institutes of Health
QC – Quality Control
QMS – Quality Management System
SDG – Sustainable Development Goals
SOP – Standard Operating Procedure
TrACSS - Tracking Antimicrobial Resistance (AMR) Country Self-Assessment Survey
UN – United Nations
USAID – United States Agency for International Development
WHA – World Health Assembly
WHO – World Health Organization

Introduction

In 2015, the World Health Assembly (WHA) endorsed the global action plan (GAP) on antimicrobial resistance (AMR), encouraging countries to develop national action plans (NAP) to tackle AMR. Accompanying this, the World Health Organization (WHO) Global Antimicrobial Resistance and Use Surveillance System (GLASS) launched in 2015 to encourage AMR surveillance and provide insight for the development of strategies to contain AMR. GLASS provides reporting on testing coverage and laboratory quality assurance in addition to resistance data. Annual GLASS reports began in 2017, and the most recent GLASS report was issued in 2022, summarizing data from 2020. GLASS is an important component of Global Action Plan implementation, and participation in GLASS reporting can serve as a useful indicator of national surveillance activities.

The United Nations (UN) Interagency Coordination Group (IACG) has called on Member States to accelerate the development and implementation of their NAPs within the context of the UN's Sustainable Development Goals (SDGs). This call to action focuses on the optimal use of essential high-quality, safe, effective, and affordable antibiotics. Additionally, the WHO has created an AMR Diagnostic Initiative to strengthen bacteriology and mycology diagnostic capacity, laboratory systems, and service delivery in low- and middle-income countries (LMICs).

As a result, we wished to examine the role of diagnostics in NAPs and highlight successful examples of integrating and implementing diagnostics into NAPs in LMICs to combat AMR. We conducted a review of the Global Database for Tracking Antimicrobial resistance (AMR) Country Self-Assessment Survey (TrACSS) from 2022 for countries with NAPs approved by the country's

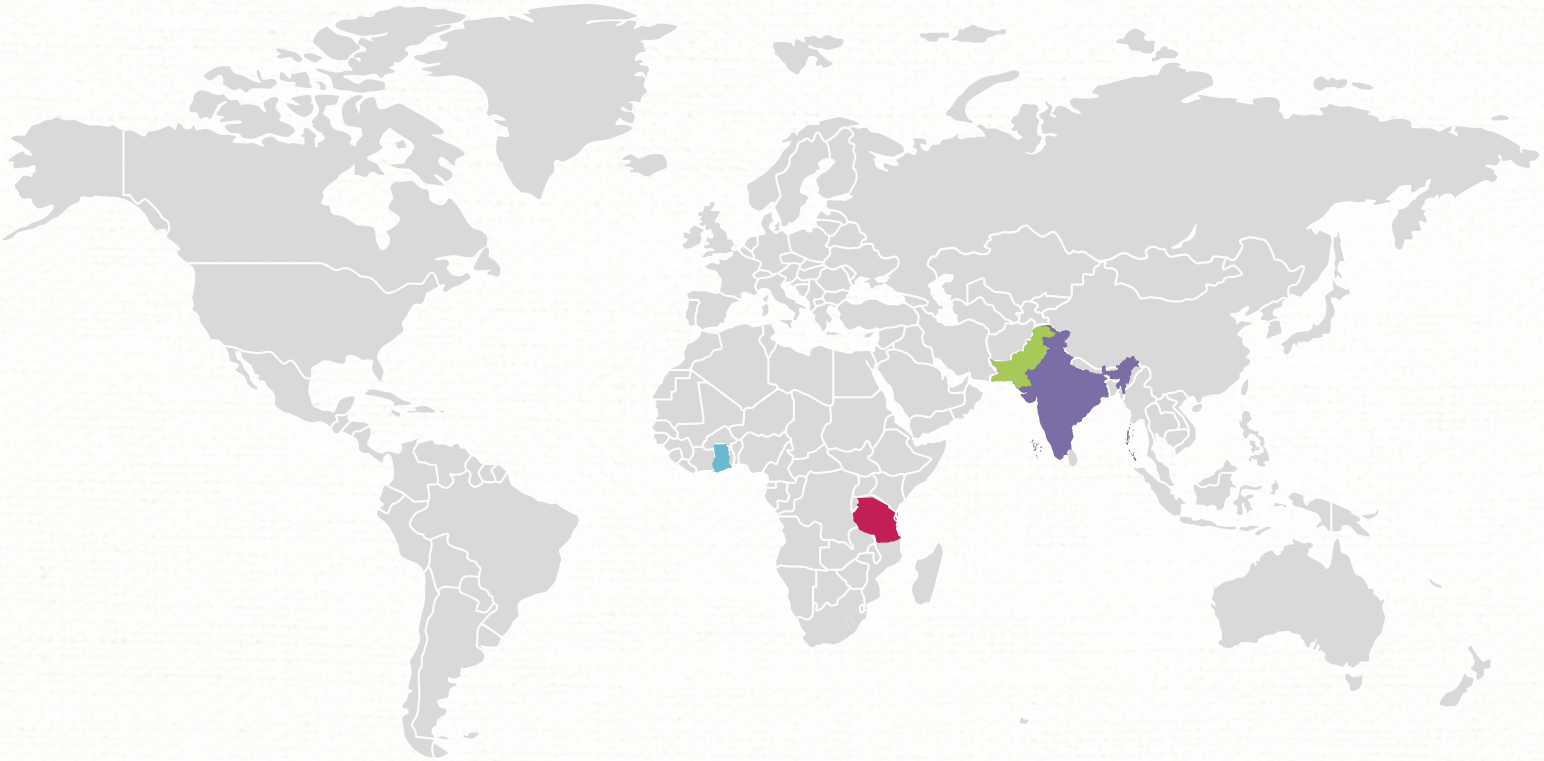
government that include operational plans, financial provisions, and monitoring and evaluation plans. The self-reported data was cross-referenced with the WHO Library of NAPs, and the Global Health Security Index. Finally, we reviewed individual NAPs for their inclusion of diagnostics, as well as their level of detail. We reached out to teams within the countries we identified for successful projects incorporating diagnostics and thus identified the included case studies. For more information about the selection process, please see the appendix.

High-Level Findings

Of the 166 country reports that were generated in 2022 TrACSS, 79 countries were identified to have country progress with development of a national action plan on AMR and to have a monitoring and evaluation plan for the national action plan.

Of those 79 countries, 34 were identified as LMICs. 32 of 34 of these countries had a published NAP to review for inclusion of diagnostics. 26 countries included diagnostics at a high level while 12 had a detailed diagnostic plan.

The folllowing case studies highlight countries who had detailed plans and impactful projects incorporating diagnostics.



Case Studies

United Republic of Tanzania

Ghana

India

Pakistan

United Republic of Tanzania

Country Background

The United Republic of Tanzania, located in Eastern Africa, borders the Indian Ocean and the countries of Burundi, Democratic Republic of the Congo, Kenya, Malawi, Mozambique, Rwanda, Uganda, and Zambia. It has a population of 65,642,682 (2023 est.).[1] Its 2022 GDP was US$76 billion and its health expenditure is 3.75% of its GDP.[2, 3] Data from the Global Research on Antimicrobial Resistance (GRAM) project in 2019 estimates the AMR burden in the United Republic of Tanzania at roughly 12,500 deaths attributed to AMR and 54,000 deaths associated with AMR in 2019.[4] Survey results from one study indicate that investing in and improving lab infrastructure in the country is an important goal; the labs that have been improved thus far in the country help to confirm correct diagnoses and prescribing practices.[5]

Country National Action Plan (NAP)

United Republic of Tanzania's current NAP,[6] which runs from 2023-2028, includes two different references to diagnostics. Firstly, diagnostics is mentioned in the context of staff training and mentorship for their use. Secondly, one of its objectives calls for sustainable investment in new diagnostic tools, medicines, and vaccines.

This plan also has a budget, monitoring and evaluation plan, list of key performance indicators, and full operational plan outlining key activities, lead implementors, and funding source.

The previous NAP,[7] which strongly influenced the case study featured in this paper, ran from 2017-2022 and included specific references to diagnostics in its activities and indicators of success: within the objective of "capacity building for designated laboratories for surveillance," training, mentorship and supportive supervision for personnel on diagnostics, and antimicrobial susceptibility testing are included as key activities. The number of personnel with skills related to diagnostics and AST and the percentage of diagnostics and reagents available for surveillance are included in the NAP as indicators of success.

Data Reporting and Practice

As of the 2021 reporting cycle, Tanzania had not yet enrolled in GLASS or begun reporting.[8] Tanzania has a system for reporting AMR data at the national level.[9]

As part of the Mapping Antimicrobial Resistance and Antimicrobial Use Partnership (MAAP) project,[10] 6,213 laboratories in Tanzania were mapped to the national laboratory network. An eligibility questionnaire was sent to 35 laboratories identified as having capacity for bacteriology testing. Of the 27 laboratories that responded to the questionnaire and had AST capacity, the majority were affiliated with the government, and 16 labs were identified for data collection. Of these, all had an experienced laboratory scientist or technologist, 93% had up-to-date records on training and competence, but only 22% had at least one qualified microbiologist. The laboratory readiness scores of the surveyed laboratories varied widely (range: 39.5-76.3%).

Tanzania's data quality score of the 72,587 valid culture records obtained from the 16 laboratories in Tanzania was 2.8 out of 4, categorized as "average," for AMR analysis. All 16 selected laboratories used CLSI standards for AST testing. Over a three-year period, susceptibility results could be collected for 13,204 positive cultures. Routine testing does not appear to be the norm in most hospitals and laboratories.

Laboratory Capacity Building in Tanzania

Established in May 2018, USAID's Infectious Disease Detection and Surveillance (IDDS) project is a five-year, US$120 million initiative that operates in more than 20 countries in Africa and Asia, including Tanzania.

Following the WHO Joint External Evaluation (JEE) conducted in February of 2016, which examined preparedness to address public health threats including AMR, Tanzania began the development of its national action plan on AMR (2017-2022), as the evaluation found Tanzania to have no capacity on three of four AMR indicators, including AMR detection, surveillance of infections caused by antimicrobial-resistant pathogens, and antimicrobial stewardship activities.[11] However, there was, and is, strong political commitment to addressing AMR, supported by leadership from the national government.[12]

Within the NAP (2017-2022) is the AMR surveillance framework, which identified 25 civilian sites in the country, which were national and regional hospitals. The IDDS program supports four laboratories, including one zonal or tertiary-level lab and three regional referral (sub-national) hospital laboratories, strengthening the capacity for bacteriology. Before implementing a project to improve capacity, the team conducted a capacity assessment that examined human resources, laboratory information systems, laboratory procedures, culturing of pathogens, sensitivity testing, storing and management of information generated, and quality issues, as well as reporting ability to the national level and GLASS.

The project implemented SOPs, training of laboratory staff, and supply chain management including consumables, which enabled AMR reporting to the national level and GLASS. The project also addressed high staff turnover rates in subnational

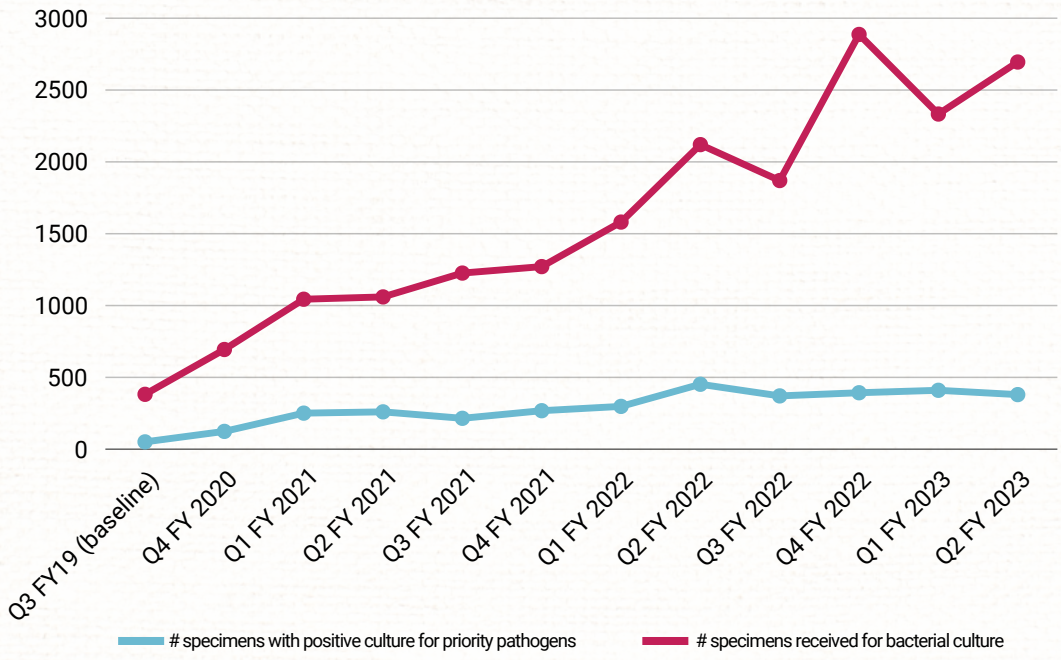
level sites through support for supervisors, mentorship programs using national staff, and data review for better data quality.

IDDS also helped to acquire laboratory supplies and commodities to support uninterrupted culture and antimicrobial susceptibility testing, and provided routine maintenance and repairs to equipment.

The NAP is instrumental to the program; it establishes the governance structures for these programs, including the Multi-Sectoral Coordination Committee (MCC, which is the national coordinating board), and stipulates the presence of the national coordination laboratory and the formation of technical working groups. The MCC was consulted in the site selection process, and the project reports to routine MCC meetings and adheres to technical guidelines from the working groups.

The project is also monitoring progress on a quarterly basis through indicators including number of specimens received, turnaround time, and rejection levels.

Number of specimens with positive culture for priority pathogens at IDDS sites and Number of specimens received for bacterial culture at IDDS sites



Major challenges remain in human resource capacity and infrastructure. Infrastructure is limited at subnational level laboratories, so additional investment is still needed. Subnational laboratories do not yet have the capabilities to support automated machines and other needed instruments, and are subject to power outages. These laboratories are also subject to supply chain management issues, as most of them are government owned and do not have a reliable source of income to ensure they have a constant supply, and thus are subject to frequent stockouts. For example, in one recent reporting period, three of the four IDDS supported labs had stock outs of reagents for culture and AST; however, only one of the laboratories had a temporary interruption of bacteriology testing services for one week.

Awareness as to the necessity of testing is also an issue, as many doctors will prescribe antibiotics empirically without further diagnostic testing to ensure empirical prescribing practices are appropriate. However, data from the IDDS program labs as well as those from the ASM engagement can improve patient management, enabling those who received antibiotic prescriptions empirically without improvement to receive diagnostic testing for more appropriate and effective treatment. In one case, a four-year-old child suffering from chronic ear discharge since birth was recommended for culture and antibiotic susceptibility testing of the discharge by a laboratory staff member participating in IDDS-supported surveillance testing. *Pseudomonas aeruginosa* was isolated, susceptible only to meropenem and levofloxacin – antibiotics that are expensive and not readily available locally. They were obtained in another city, and after a month of treatment the infection was cleared, relieving years of suffering.

The IDDS program also helped to establish the latest NAP, which runs from 2023-2028, in partnership with the Ministry of Health, Ministry of Livestock and Fisheries, and other stakeholders.

The WHO JEE in 2023 rated Tanzania a 4, meaning “demonstrated capacity,” demonstrating the significant progress Tanzania has made since initially assessing its capacity in 2016.[13]

Ghana

Country Background

Ghana, located in Western Africa, borders the Gulf of Guinea in the south and the countries Côte d'Ivoire, Togo, and Burkina Faso. It has a population of 33,846,114 (2023 est.).[14] Its 2022 GDP was US$73 billion and its health expenditure is 3.99% of its GDP.[15,16] Data from the GRAM project in 2019 estimates the AMR burden in Ghana at roughly 5,900 deaths attributed to AMR and 25,300 deaths associated with AMR in 2019.[17] In November 2018, Ghana hosted an international "Call to Action" event with global stakeholders to reaffirm commitments to fight AMR including the need for strong NAPs, cross-sectoral collaboration and coordination, increased surveillance and access, among other messages.[18] At this event, the Ghana Declaration Call to Action on Antimicrobial Resistance was signed by numerous countries and global organizations including Ghana, Thailand, UK, Wellcome Trust, World Bank, UN Foundation, among other partners.[19]

Country National Action Plan (NAP)

Ghana's NAP,[20] which ran from 2017-2021, includes diagnostics within three of its strategic objectives. Within one of the strategic objectives that calls for establishing national labs and databases for surveillance, there is a specific call to improve laboratory diagnostic services by providing additional resources. Additionally, under the objective that aims to optimize the use of antimicrobial agents, there is a sub-objective that seeks to secure rapid diagnostic testing to assist in diagnosis. Lastly, diagnostics are part of another strategic objective which aims to create a sustainable investment environment to increase new AMR interventions, specifically calling out diagnostics as a tool that requires more research and investment.

The NAP also contains an operational plan that outlines key activities, lead implementers, collaborators, and time of implementation. There is a progress indicator matrix that includes targets and progress indicators for each activity. It also has a detailed budget, including funding sources. Finally, it contains a monitoring and evaluation alongside a detailed compendium.

Data Reporting and Practice

Ghana joined GLASS in 2019 and began submitting data in 2021; however, only five sites are participating in reporting as of the 2021 data call.[21]

As part of the Mapping Antimicrobial Resistance and Antimicrobial Use Partnership (MAAP) project,[22] 4,841 laboratories in Ghana were mapped to the national laboratory network, and eligibility questionnaires identified 93 laboratories as having capacity for bacteriology testing, with the majority of survey respondents being government affiliated. Of 16 laboratories selected for study, all had an experienced laboratory scientist or technologist, with 66% of the laboratories having at least one qualified microbiologist, however, only 50% had up-to-date records on training and competence. The laboratory readiness scores of the surveyed laboratories varied widely (7.9–78.9%). The MAAP project notes that while the Fleming Fund Regional Grant was a step toward digitization, many of the laboratories surveyed are still dependent upon paper records, which may inhibit broader data reporting, including to GLASS.[23]

Ghana's data quality score of the 17,096 valid culture records obtained from the 16 laboratories was 3.1 out of 4, categorized as "good," for AMR analysis. Of 16 laboratories selected and assessed by the MAAP project, 14 laboratories used CLSI standards for AST testing and 2 reported compliances with EUCAST standards. Over a four-year period, susceptibility results could be collected for 4,394 positive cultures.

While most of the surveyed laboratories reported implementing QMS, not all of the laboratories were certified or accredited. The laboratories also did not equitably cover the country's population of over 31.1 million with low testing load, lack of routine microbiology testing and a likelihood that the AMR rates are overestimated as most tests would have been conducted on special patient categories (such as those unresponsive to first-line therapy or admitted to the intensive care unit).

Hospital-Wide Stewardship Program in Ghana

Lekma Hospital cites the NAP as the inspiration for the development of its stewardship program in Teshie, Ghana to address the burden of AMR in its patient population. The goals of the program are to create a comprehensive program to promote antimicrobial stewardship with the aim of reducing inappropriate prescribing and strengthening the capacity of healthcare professionals in data analysis, infection prevention and general AMR knowledge. To achieve these goals, the hospital implemented a multifaceted approach which included improved lab surveillance and testing as well as capacity building in its clinical staff as part of a hospital-specific action plan based on the NAP. The hospital also incorporates AMR surveillance and capacity building in its 5-year strategic plan, and as a core component of its Drug and Therapeutic Committee (DTC).

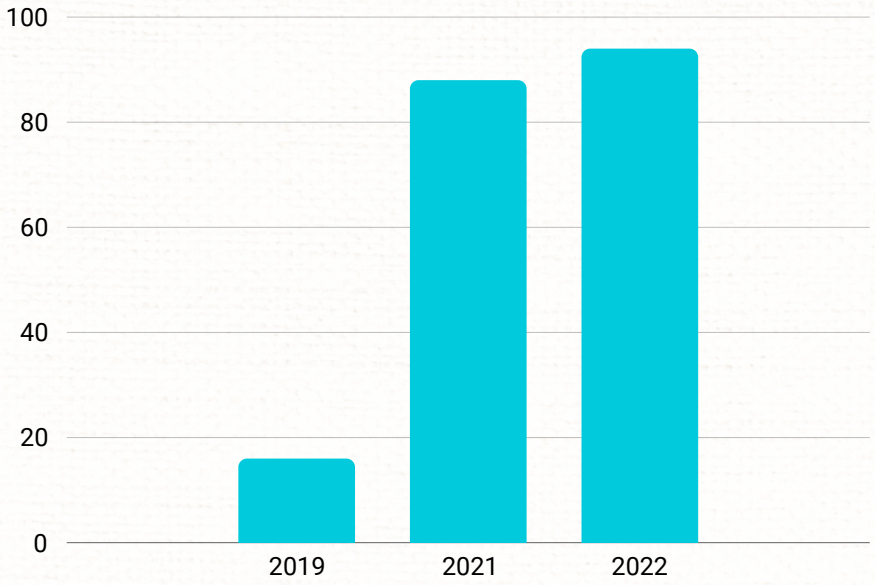
The program formed an AMR Committee which includes the Medical Superintendent of the Hospital and the Head of Pharmacy as the chairperson, and the Committee formed the hospital action plan and AMR policy based on the NAP. A core component of the program is isolate identification and susceptibility testing for clients presenting with infectious diseases. External quality assurance is built in, with isolate storage onsite and referral to a reference laboratory.

14 laboratory SOPs were developed, including blood, urine, wound, throat, high vaginal, and eye swabs or cultures, as well as biochemical testing, waste management, susceptibility testing, transport and storage of samples, and clinical data on laboratory request forms. The program trained doctors, laboratory

technicians, and pharmacists on AMR testing, data collection, prescribing practices, infection prevention and control measures. The hospital also established an AMR Committee. In addition to staff training, they created awareness week videos and held events with the public to educate them on AMR.

After implementation of their stewardship program, the hospital saw drastic changes in its prescribing practices. From 2019-2021, the hospital saw the percentage of prescriptions which matched a diagnosis rise from 16% to 93.6%. Lekma Hospital cites improved laboratory testing and increased number of cultures as key factors in why this percentage increased so dramatically over three years.

Percentage of prescriptions with stated matching diagnostics



A laboratory data collection tool has also been implemented for surveillance of resistance. Lekma Hospital also shared data collected with the Ministry of Health to inform AMR policy at the national level.

For their efforts, Lekma Hospital received the award for best-performing hospital in the Greater Accra Region, Ghana in 2021.

India

Country Background

India, located in South Asia, borders seven countries: Myanmar and Bangladesh in the east, Pakistan and Afghanistan in the northwest, and China, Nepal, and Bhutan to the north. India has a population of 1.4 billion people, making it the world's largest democracy.[24,25] Its 2022 GDP was US$3.39 trillion and its health expenditure is 2.96% of its GDP.[26,27] India not only leads the world in antibiotic use in humans, but also has one of the highest age-standardized infectious disease mortalities in South Asia.[28] Data from the GRAM project in 2019 estimates the AMR burden in India at roughly 297,000 deaths attributed to AMR and 1,042,500 deaths associated with AMR in 2019.[29] In 2015, the Indian government launched the Free Diagnostics Service Initiative, which provides public health facilities free diagnostic tests.[30]

Country National Action Plan (NAP)

India's NAP,[31] which ran from 2017-2021, highlights the need for increased investment in diagnostics. One of the strategic objectives focuses on investments for research and interventions in AMR. Within this objective, it specifically includes diagnostics as one tool that needs further research and investment. The NAP does have a monitoring and evaluation plan for each strategic objective.

In addition to the country-wide NAP, in 2018, the Indian Ministry of Health and Family Welfare and the National Center for Disease Control released guidance for developing state-level action plans, and several Indian states have their own state action plans on AMR.[32,33] All of the current state action plans include strategic objectives calling for strengthened laboratory capacities as well as investment and research into new rapid diagnostic tools.

Data Reporting and Practice

India enrolled in GLASS in 2017, and participates in two of its focused surveillance (surveillance of AMR in *Candida spp.*) and special studies (integrated global surveillance of ESBL-producing *Escherichia coli* using a "One Health approach") in addition to the standard GLASS reporting.[34] India meets all of the GLASS National AMR Surveillance System Indicators, including a national surveillance plan, national coordination center, national reference laboratory, external quality assurance of both the national reference laboratory and the local laboratories performing AST, and complies with CLSI standards for AST.[35] 91 sites report data to GLASS as of the 2021 data call.[36]

While data comparable to that available from the MAAP reports is not available for India, India does have three AMR networks collecting data from tertiary hospital settings:[37]

- Implementation of the National Programme on Containment of AMR is led by the National Center for Disease Control (NCDC) and collects data from approximately 60 tertiary hospitals. All India Institute of Medical Sciences (AIIMS) New Delhi, Centers for Disease Control and Prevention (CDC) and the Indian Council of Medical Research have collaboratively established a specific surveillance network for hospital-acquired infections (HAIs).
- A network established by the Indian Council of Medical Research (ICMR) has collected, managed, and analyzed data from 30 public tertiary hospitals and some private hospitals and labs since 2013.

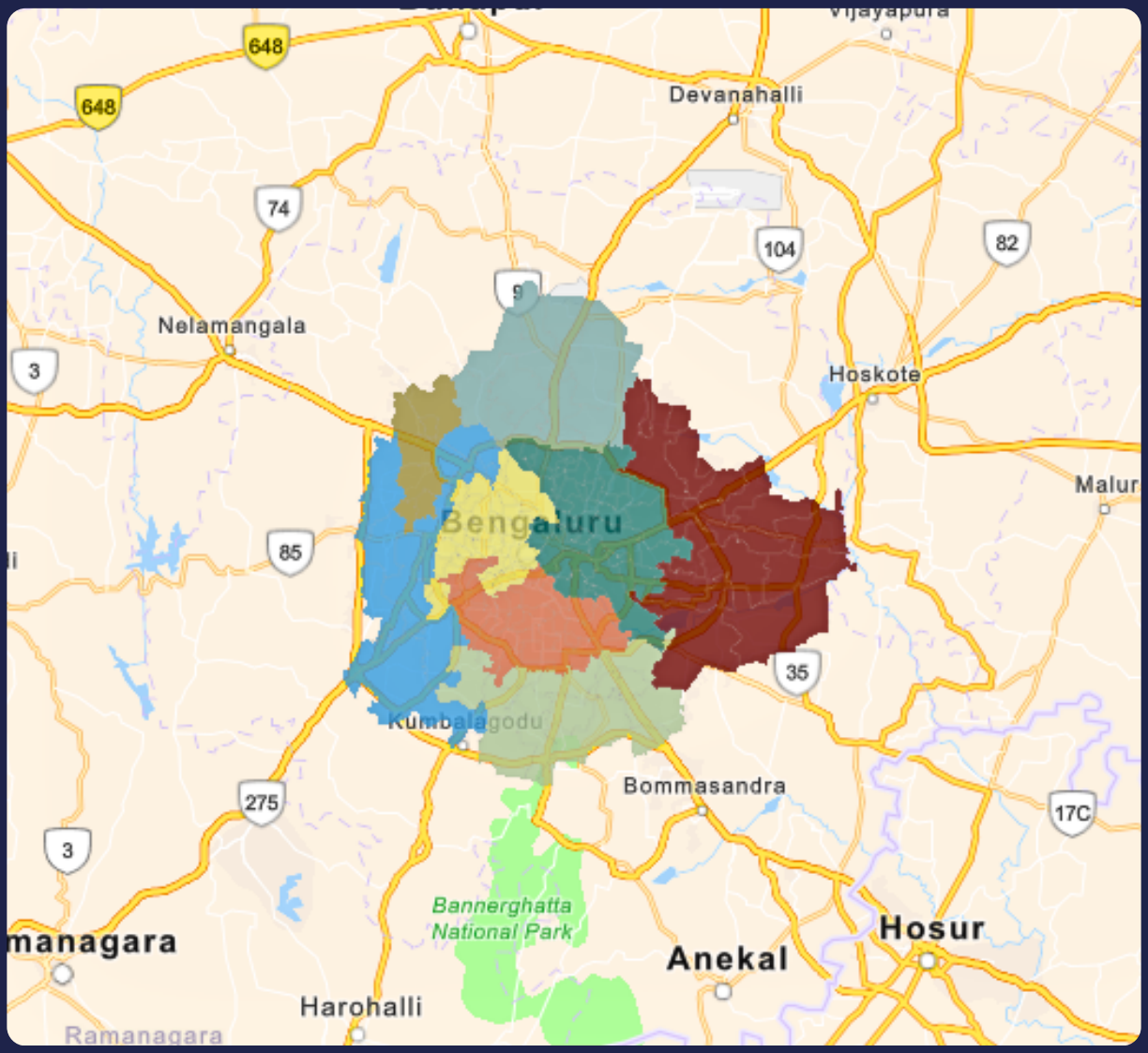
Wastewater Testing Program in India

The Precision Pandemic Health Surveillance program, conducted in 2021, monitors wastewater for AMR in Bangaluru, India. Initially begun as a program for COVID-19 monitoring, wastewater testing was expanded to monitor AMR, utilizing wastewater analysis as a surrogate for measuring community-level antibiotic resistance data, which is difficult to obtain in India. This aligns with the GLASS recommendation of complementary AMR surveillance approaches to help evaluate and inform AMR response.[38] The program itself also aligns with India's NAP, particularly in its call to "strengthen microbiology laboratories (including private sector) for antimicrobial susceptibility testing (AST) in medical labs, ensuring SOPs, quality assurance and *community data*," (Strategic Priority 2.1.1.1, emphasis added).[39] The pilot program tested wastewater from 66 open storm drain sites in city wards in eight administrative zones. The program aligned with the Ministry of Health's Antibiotic Policy and biomedical waste management guidelines, and aimed to influence local antibiotic prescription practices through AMR surveillance. This program was funded by external non-governmental Indian and foreign agencies including the Skoll Foundation, Schmidt Futures, USAID through the Precision Pandemic Health Platform, Blockchain for Impact, and Biotechnology Industry Research Assistance Council (BIRAC).

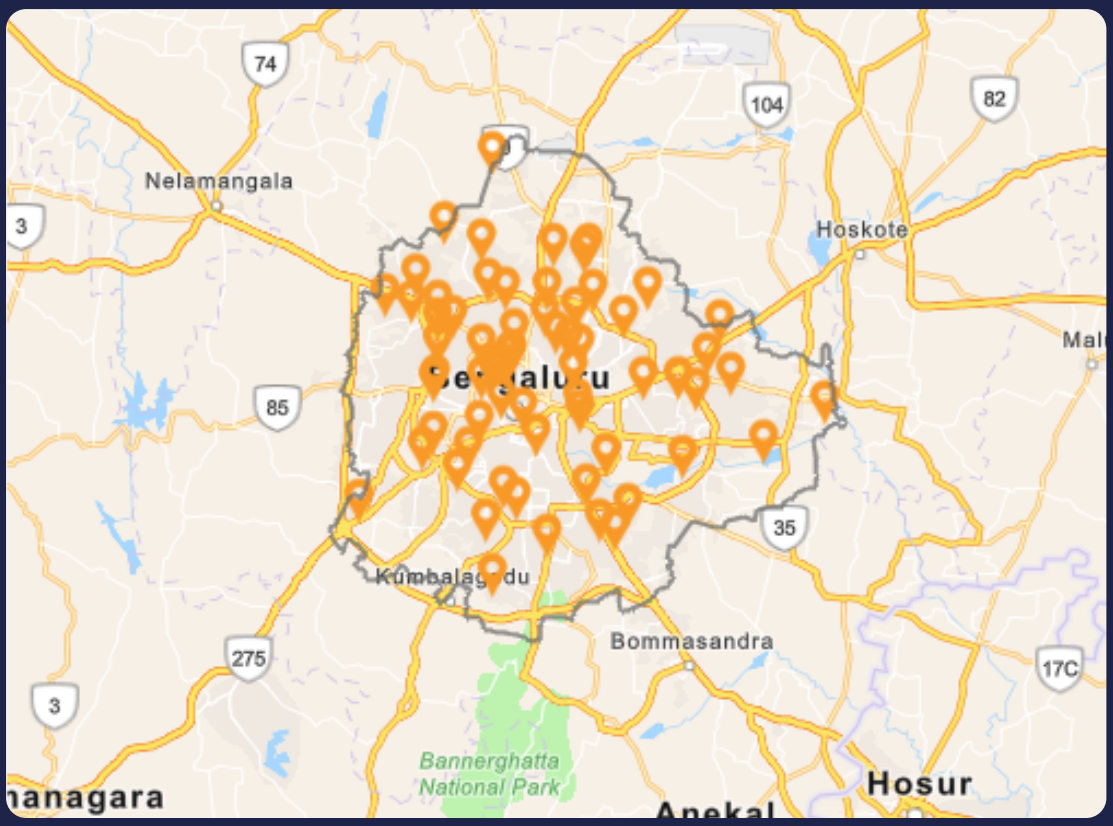
The surveillance program sought to quantify the burden of resistance against specific antibiotics in eight administrative zones of Bengaluru and create a hyperlocal, interactive AMR site map of Bengaluru showing the patterns and burden of resistance.

Precision Health Initiative: A Case Study of Bangalore City

BBMP-Zone Map



Locations of Sample Collected: Zones and Sites



Bommanahalli

- Anjanapura (196)
- Arekere (193)
- BTM layout (176)
- Hongasandra (189)

Dasarahalli

- Chokkasandra (39)
- Peenya (41)

Mahadevapura

- Basavanapura (53)
- Bellandur (150)
- Doddanekundi (85)
- Garudacharpalya (82)
- Hoodi (54)
- Horamavu (25)
- Varthur (149)
- Vignan Nagar (81)

East

- Agaram (114)
- Banaswadi (27)
- Bharathinagar (91)
- HBR layout (24)
- Kaushal Nagar (31)
- Ramaswamy Palya (62)
- S K Garden (61)
- Shanthala Nagar (111)

West

- Aramane Nagar (35)
- Chalavadi Palya (138)
- Dattatreya (77)
- Gandhinagar (94)
- Govindrajnagar (104)
- Kaveripura (103)
- Mathikere (36)
- Nandini Layout (43)
- Okalipuram (96)
- Shakarmatha (75)
- Srirama Mandir (108)
- Subhashnagar (95)

Rajarajeshwarinagar

- Doddabidarakallu (40)
- Hemmigepura (198)
- HMT (38)
- Hosakerehalli (161)
- Rajarajeshwari (160)

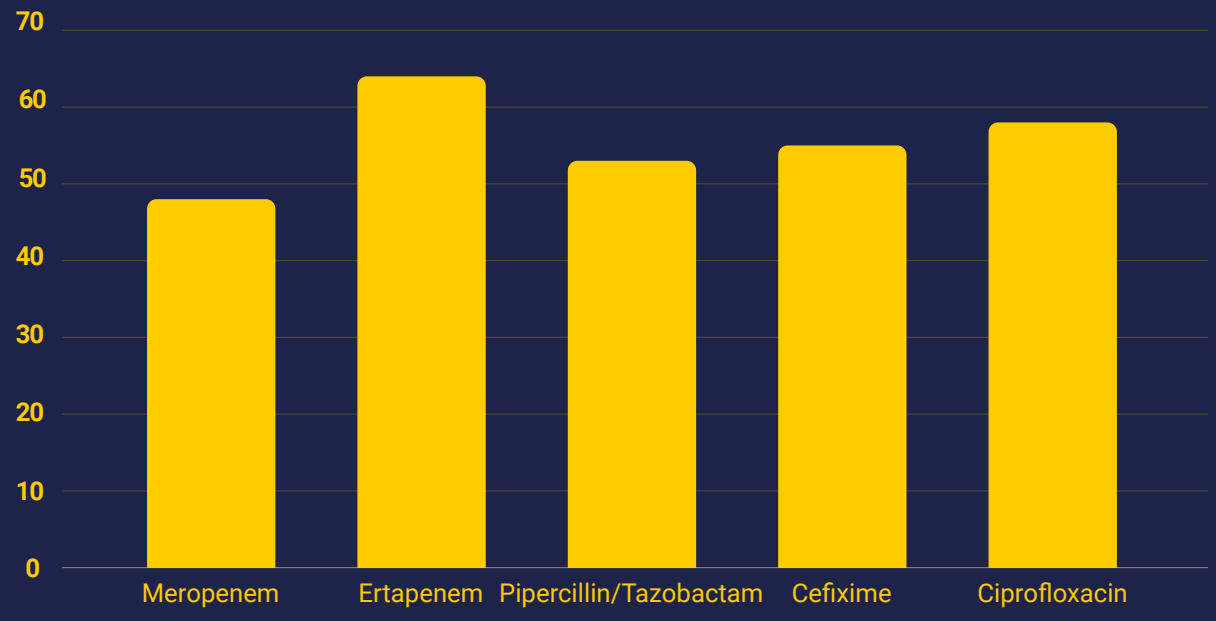
Yelahanka

- Attur (3)
- Byatarayanapura (7)
- Doddabommasandra (10)
- Nagavara (23)
- Thanisandra (6)

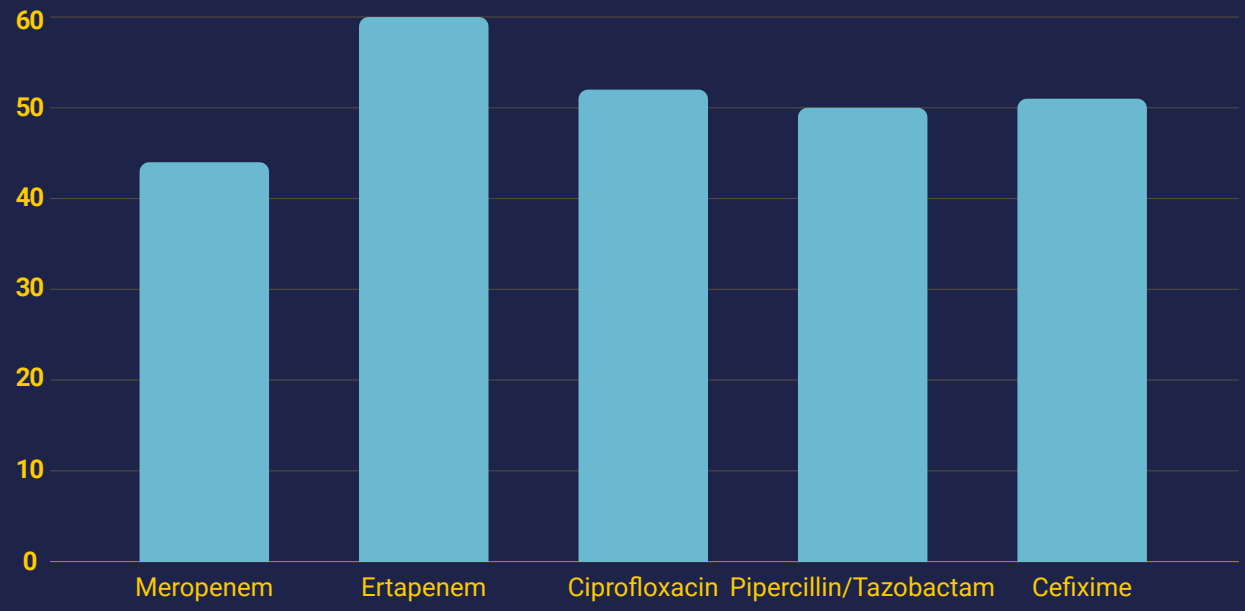
South

- Banashankari Temple (180)
- Ejipura (148)
- Girinagar (162)
- Sarakki (178)
- Siddapura (144)

% Resistance observed from the sites tested within the zone (Average of two colonies isolated per site)



% Resistance observed at site-level



To achieve this, researchers utilized a Vitek™ machine and trained personnel in appropriate collection, transportation, testing and analysis of wastewater systems. The team tested for the phenotypic patterns of Gram-negative bacteria against four key antimicrobial classes and five commonly prescribed antibiotics – ciprofloxacin (Fluoroquinolone), cefixime (3rd generation cephalosporin), piperacillin/tazobactam (TZP, beta lactam/beta lactamase inhibitor), ertapenem and meropenem (carbapenems) – among the wards of Bengaluru using wastewater surveillance. The data collected demonstrated approximately 28% of the clinically relevant Enterobacteriaceae isolates were susceptible to all five antibiotics and 12% were resistant to all five antibiotics. After implementation of the precision health study program, the data was shared with the state-level AMR government team (raw data, ArcGIS mapping and report), and highlights that 1) open drains hold a substantial number of drug-resistant bacteria, 2) wastewater can serve as a method to estimate community AMR burden and 3) there is geographical variation of patterns and burdens of AMR within the city. Coordination with the national-level bodies responsible for AMR policy is a future goal for the team.

The program underscores the necessity of continued sustainable funding and suggests a need for standardized methodologies to conduct longitudinal community-based AMR surveillance, as relying solely on national databases for antibiotic resistance trends or guidance towards prescriptions patterns may not fully capture the variations of AMR at the community level.

Pakistan

Country Background

Pakistan, located in South Asia, borders India, Iran, Afghanistan, and China. It has a population of 247,653,551 (2023 est.).[40] Its 2022 GDP was US$377 billion.[41] Its health expenditure is 2.95% of its GDP.[42] Data from the GRAM project in 2019 estimates the AMR burden in Pakistan at roughly 59,200 deaths attributed to AMR and 221,300 deaths associated with AMR in 2019.[43] Pakistan has a similarly high age-standardized infectious disease mortality to India.[44]

Country National Action Plan (NAP)

Pakistan's NAP,[45] which started in 2017, mentions diagnostics within one strategic objective. Diagnostics are directly mentioned in a call to increase sustainable investment in diagnostic tools, new medicines, and vaccines. Within this objective, there are strategic priorities, which include specific references to diagnostics. Diagnostics are to be included in research agendas and to develop effective diagnostic tools.

The NAP also contains an operational plan with timelines and a monitoring and evaluation plan.

Data Reporting and Practice

Pakistan enrolled in GLASS in 2017, and participates in two of its focused surveillance (surveillance of AMR in *Candida spp.*) and special studies (integrated global surveillance of ESBL-producing *Escherichia coli* using a "One Health

approach") in addition to the standard GLASS reporting.[46] Pakistan meets all of the GLASS National AMR Surveillance System Indicators, including a national surveillance plan, national coordination center, national reference laboratory, external quality assurance of both the national reference laboratory and the local laboratories performing AST, and complies with CLSI standards for AST.[47] 37 total sites report data to GLASS as of the 2021 data call.[48]

Pakistan established its National Surveillance System in 2019; as of May 2021, this system includes 40 surveillance sites, including 19 hospitals, one outpatient facility and 20 in/outpatient facilities.[49] However, quality diagnostic facilities are limited, including microbiological laboratory capacity and diagnostic tools.[50] Pakistan's National Institutes of Health (NIH) has had difficulty recruiting sites to participate in GLASS reporting.[51] The government of Pakistan established an intra-sectoral core committee on AMR to identify key stakeholders and experts in policymaking, assess the status of AMR, and provide policy recommendations.[52] However, reporting is still challenging, as microbiology laboratories are not currently standardized and lack quality assurance systems.[53] Existing studies have examined local prevalence, so it is difficult to obtain a national picture.[54]

Training and Lab Capacity Building in Pakistan

Located in Pakistan, the Clinical Engagement (CE) Program is managed by the UK Fleming Fund/UK Department of Health and Social Care and implemented by DAI. In Pakistan, the CE program is led by the Indus Hospital and Health Network (IHHN) and overseen by DAI Fleming Fund. The pilot program took place in six tertiary care public sector hospitals across Pakistan.

The CE program seeks to reduce the burden of AMR by identifying gaps in surveillance in multidrug resistant bacteria and enhance the capacity of sentinel sites in regard to diagnosis, data collection, and surveillance. Specifically, the program enhanced knowledge and strengthened healthcare providers' capacities to send clinical samples for cultures with appropriate information on test forms before prescription or initiation of antibiotic, collecting the right clinical data, and using an evidence-based approach to improving antimicrobial prescribing policy in addition to developing local infection prevention and control (IPC) guidelines in hospital settings.

The framework of the CE program focused on three areas: diagnostics, antibiotic use, and IPC measures. Baseline surveys were conducted in participating hospitals using the Point Prevalence Survey – Cross-Sectional methodology, which was developed by the ECDC and later modified by the WHO for low- and middle-income countries.[55] The assessment determined ceftriaxone, a third-generation cephalosporin, is the most prescribed antibiotic across the six sites; antimicrobial use is high for surgical prophylaxis and community-acquired infections; and the clinical teams in most hospitals lacked capacity to oversee and implement AMR and AMU surveillance due to poor infrastructure such as a lack of equipment as well as training and personnel.

The CE program was tailored based on the results of the survey. Training modules were implemented, including one module on sample management including methodology, protocols for ordering cultures and interpreting results, and understanding antibiograms. Seminars were held at five sentinel sites in partnership with the Medical Microbiology and Infectious Diseases Society of Pakistan and with Pakistan Biological Safety Association. The program team conducted supervisory visits and facilitation of antibiotic prescription to demonstrate protocols for the collection of samples for culture and sensitivity testing. In addition to training, direct, material support was provided to labs in the form of laboratory equipment, consumables, and infrastructure refurbishment. The program performs quarterly lab performance reviews, and highlighted the need for updating general microbiology lab SOPs, and developing and implementing internal QC procedures and specimen collection guidelines. The program also worked to develop AMR data management practices and SOPs. One lab was previously non-functional and lacked dedicated laboratory staff. The program revived the microbiology lab through the appointment of staff and lab space, preparation of refurbishment and mentorship plans, initiation of lab refurbishments, formal wet lab trainings for newly appointed staff, provision of consumables and basic equipment, and initiation of samples receipt and processing for culture and sensitivity results.

Most sites did not have AMR stewardship programs or bodies, so these were also successfully formed in three sites.

The work of the CE program in Pakistan mirrors several of the interventions mapped within the NAP, including the importance of training programs and establishing appropriate lab facilities.

Recommendations

Diagnostics form the basis of good stewardship and should be included in any NAP. While priorities set at a national level do not necessarily and immediately affect behaviors at a local level, national governments can demonstrate commitment and intent by including clear and specific goals and plans for implementation which serve as guidance for regional and local institutions. These should also include investment in the form of budget or other indication of methods of real-world implementation. Including diagnostics in NAPs is an excellent first step towards implementing policy change.

Political commitment is necessary to ensure follow-through. Without the political will to ensure plans laid out in NAPs become implemented policies, NAPs remain just documents. For NAPs to serve their intended purpose, they should contain actionable steps and plans which can serve as a guide to real-world implementation. Establishing a national committee which will oversee the implementation of the NAP, particularly one that is cross-sector and takes a "One Health" approach, is a meaningful first step towards policy and practice change. Including metrics of success within the NAP to provide a goal and a way to demonstrate progress is a best practice.

Real world experience can provide valuable lessons for success. Policy must be driven by on-the-ground data and evidence. Diagnostics can help diagnose not just specific pathogens causing infection, but are critical in establishing larger patterns of clinical practice and data collection. Cross-sector coordination is needed to ensure the insights and experience of on-the-ground programs are incorporated into future iterations of NAPs.

Leveraging engagement in non-governmental sectors is crucial to supporting implementation. Before implementing new programs, conducting stakeholder mapping can help to understand the current landscape and identify key partners for program implementation, which in many countries may include private, non-governmental laboratories, clinics, pharmacies, and other healthcare facilities. This can also include assessing best practices within the country and in similar resource settings elsewhere in the world to model successful programs and methods of implementation.

Further investment is necessary in diagnostics in LMICs to effect valuable change in good stewardship practices. A common theme across case studies is the need for sustainable investment and funding for these programs, many of which receive funding from external, international sources. While the upfront expenditure presents a challenging burden, the resulting improvement in stewardship practices will ultimately result in more sustainable healthcare systems and better health for a country's citizens. AMR is a global issue, not just a local one, and continuing investment from national governments and international sources will prove critical to reducing the burden of AMR and extending the use of existing antibiotics. Diagnostics are a critical component of appropriate use and stewardship practices, and both valuing and reimbursing diagnostics appropriately are important for the long-term sustainability of both antimicrobial treatments and of the local healthcare system.

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Appendix – Methodology

Preliminary Assessment

To identify countries to incorporate, we began by reviewing the Global Database for Tracking Antimicrobial Resistance (AMR) Country Self-Assessment Survey (TrACSS). The TrACSS survey data used was that of 2022, which is the latest available data set. We selected an initial list of countries for evaluation based on the following survey questions:

- (2.3) Country progress with development of a national action plan on AMR. Answers selected for:
  - (C) National AMR action plan approved by government and is being implemented.
  - (D) National AMR action plan has costed and budgeted operational plan and has monitoring mechanism in place.
  - (E) Financial provision for the national AMR action plan implementation is included in the national plans and budgets.

- (2.3.b) Does the country have a monitoring and evaluation plan for the national AMR action plan? Answer selected for:
  - Yes

After applying these two filters, the list of countries was filtered to only leave LMICs (lower-middle-income and lower income countries), based on the list from the World Bank.[56]

The resulting LMIC countries were:

Bangladesh	Benin	Burundi	Cabo Verde
Cambodia	Côte d'Ivoire	Democratic People's Republic of Korea	Democratic Republic of the Congo
Egypt	El Salvador	Eritrea	Eswatini
Ethiopia	Ghana	Guinea	India
Indonesia	Iran (Islamic Republic of)	Kenya	Kyrgyzstan
Liberia	Madagascar	Malawi	Mali
Mongolia	Nicaragua	Nigeria	Pakistan
Sierra Leone	Timor-Leste	Uganda	Ukraine
	United Republic of Tanzania	Zimbabwe	

NAP Confirmation

Within the established list of 34 countries, we conducted a further examination of NAPs for specific inclusion of diagnostics in the plans. Because TrACSS data is self-reported, additional outside resources were used to verify the responses. First, countries were checked to confirm existence of an NAP using the WHO Library of AMR NAPs as well as the Global Health Security Index, updated 2021.

The following countries were removed for lack of an available NAP:

- Ukraine
- Nicaragua

The countries that remained after this step were:

Bangladesh	**Benin**	**Burundi**	**Cabo Verde**	**Cambodia**
Côte d'Ivoire	**Democratic People's Republic of Korea**	**Democratic Republic of the Congo**	**Egypt**	**El Salvador**
Eritrea	**Eswatini**	**Ethiopia**	**Ghana**	**Guinea**
India	**Indonesia**	**Iran (Islamic Republic of)**	**Kenya**	**Kyrgyzstan**
Liberia	**Madagascar**	**Malawi**	**Mali**	**Mongolia**
Nigeria	**Pakistan**	**Sierra Leone**	**Timor-Leste**	**Uganda**
United Republic of Tanzania	**Zimbabwe**			

Following this, NAPs were reviewed manually for inclusion of diagnostics at a broad level. At this stage in the review, NAPs were not checked for details such as budget or monitoring and evaluation plans.

The resulting review eliminated these countries for lack of inclusion of diagnostics:

- Bangladesh
- Benin
- Burundi
- Cabo Verde
- Guinea
- Mongolia

The remaining countries specifically mention diagnostics in their NAPs and were designated for further, in-depth review to determine a final list of countries:

Cambodia	**Côte d'Ivoire**	**Democratic People's Republic of Korea**	**Democratic Republic of the Congo**
Egypt	**El Salvador**	**Eritrea**	**Eswatini**
Ethiopia	**Ghana**	**India**	**Indonesia**
Iran (Islamic Republic of)	**Kenya**	**Kyrgyzstan**	**Liberia**
Madagascar	**Malawi**	**Mali**	**Nigeria**
Pakistan	**Sierra Leone**	**Timor-Leste**	**Uganda**
	United Republic of Tanzania	**Zimbabwe**	

Final Selection Process

In selecting the final list of countries, we further assessed the NAPs for the level of inclusion of diagnostics and the level of detail of the plan overall. Some countries mentioned the need for increased diagnostics but did not provide detail as to implementation, lacking, for example, timelines, key metrics, or funding. For more robust NAPs, countries included specific mentions of investment into diagnostic tools including budgeting, specific activities and collaborations, and timelines of implementation, and other details.

Countries were selected if they included most or all of these elements to demonstrate support of the role of diagnostics in NAPs, including but not limited to specific mention of diagnostics, budget (with funding sources), timelines for key activities, and monitoring and evaluation plans. Geographic diversity was also considered in the decision-making process.

The following countries were removed from consideration during this process:

- Democratic People's Republic of Korea
- Democratic Republic of the Congo
- El Salvador
- Eritrea
- Eswatini
- Iran (Islamic Republic of)
- Kenya
- Kyrgyzstan
- Madagascar
- Mali
- Nigeria
- Sierra Leone
- Timor-Leste
- Zimbabwe

This analysis led to the final countries for evaluation, to accommodate equally strong NAPs alongside geographic variety. The final list features countries with clear integration of diagnostics into their NAPs, either as one of their main objectives or as a key component throughout. Furthermore, the plans have outlined the ways in which they will support activities, whether it be through funding, monitoring and evaluation plans, institutions tasked with implementation, or key metrics to determine if goals are being met.

The resulting countries were:

Cambodia	**Indonesia**	**Ghana**	**Malawi**	**India**	**Liberia**
Uganda	**Egypt**	**United Republic of Tanzania**	**Pakistan**	**Côte d'Ivoire**	**Ethiopia**

Lastly, countries in which ongoing armed conflict, civil unrest, or political instability were likely to render in-country project teams difficult to find or contact were removed from consideration.

The countries removed from consideration in this step were:

- Liberia
- Ethiopia

This process resulted in the final list of countries:

Cambodia	**Indonesia**	**Ghana**	**Malawi**	**India**
Uganda	**Egypt**	**United Republic of Tanzania**	**Pakistan**	**Côte d'Ivoire**

Case Study Identification

We reached out to contacts within each of these countries, requesting examples of projects incorporating diagnostics. Respondents to outreach were interviewed directly about their projects or provided additional contacts for outreach.

Selection Process Diagram

TrACCS Filtering Questions:

(2.3) Country progress with development of a national action plan on AMR.

Answers selected for:

- (C) National AMR action plan approved by government and is being implemented.
- (D) National AMR action plan has costed and budgeted operational plan and has monitoring mechanism in place.
- (E) Financial provision for the national AMR action plan implementation is included in the national plans and budgets.

(2.3.b) Does the country have a monitoring and evaluation plan for the national AMR action plan?

Answer selected for:

- Yes

Select for LMICs

Bangladesh	Benin	Burundi	Cabo Verde	Cambodia	Côte d'Ivoire	Democratic People's Republic of Korea
Democratic Republic of the Congo	Egypt	El Salvador	Eritrea	Eswatini	Ethiopia	Ghana
Guinea	India	Indonesia	Iran (Islamic Republic of)	Kenya	Kyrgystan	Liberia
Madagascar	Malawi	Mali	Mongolia	Nicaragua	Nigeria	Pakistan
Sierra Leone	Timor-Leste	Uganda	Ukraine	United Republic of Tanzania	Zimbabwe	

NAP Confirmation

Countries Removed:
Lack of Available NAP

Ukraine	Nicaragua

Bangladesh	Benin	Burundi	Cabo Verde	Cambodia	Côte d'Ivoire	Democratic People's Republic of Korea	Democratic Republic of the Congo
Egypt	El Salvador	Eritrea	Eswatini	Ethiopia	Ghana	Guinea	India
Indonesia	Iran (Islamic Republic of)	Kenya	Kyrgystan	Liberia	Madagascar	Malawi	Mali
Mongolia	Nigeria	Pakistan	Sierra Leone	Timor-Leste	Uganda	United Republic of Tanzania	Zimbabwe

Selection Process Diagram (Continued)

Filtering for Inclusion of Diagnostics (Broad)

Countries Removed: *Brief or No Mention of Diagnostics in NAPs*

Bangladesh	Benin
Burundi	Cabo Verde
Guinea	Mongolia

Cambodia	Côte d'Ivoire	Democratic People's Republic of Korea	Democratic Republic of the Congo	Egypt
El Salvador	Eritrea	Eswatini	Ethiopia	Ghana
India	Indonesia	Iran (Islamic Republic of)	Kenya	Kyrgystan
Liberia	Madagascar	Malawi	Mali	Nigeria
Pakistan	Sierra Leone	Timor-Leste	Uganda	United Republic of Tanzania
Zimbabwe				

NAP In-Depth Review

Countries Removed: *Robustness of Plan*

Democratic People's Republic of Korea	Democratic Republic of the Congo	El Salvador
Eritrea	Eswatini	Iran (Islamic Republic of)
Kenya	Kyrgystan	Madagascar
Mali	Nigeria	Sierra Leone
Timor-Leste	Zimbabwe	

Cambodia	Côte d'Ivoire	Egypt
Ethiopia	Ghana	India
Indonesia	Liberia	Malawi
Pakistan	Uganda	United Republic of Tanzania

Final Selection

Countries Removed: *Armed Conflict/Civil Unrest*

Ethiopia	Liberia

Cambodia	Côte d'Ivoire
Egypt	Ghana
India	Indonesia
Malawi	Pakistan
Uganda	United Republic of Tanzania

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ABOUT THE AMR INDUSTRY ALLIANCE

The AMR Industry Alliance is one of the largest private-sector coalitions established to provide sustainable solutions to curb antimicrobial resistance. The Alliance, comprised of 77 biotechnology, diagnostics, generics, and research-based pharmaceutical companies and 10 trade associations, facilitates collaboration, reports on the industry's contribution to the fight against AMR, and engages with external stakeholders. The Alliance seeks to contribute sustainable solutions to curb antimicrobial resistance by creating broad industry momentum and facilitating collaboration between the public and private sectors.

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