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MAPPING GLOBAL AND NATIONAL *IN VITRO* DIAGNOSTICS APPROACHES TO THE QUESTION OF ANTIMICROBIAL RESISTANCE IN HUMANS AND THE GUIDING ROLE OF CBDL ON THE TOPIC

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CBDL Covering Letter

Sepsis is a common and potentially serious illness requiringemergency care. It is characterized by a set of criticalmanifestations that spread throughout the body, in responseto the progression of an infectious condition.

Antimicrobial resistance is now recognized as one of the tenmajor threats to global health. Rapid and accurate diagnosisis essential to ensure appropriate treatment, improvemonitoring, control outbreaks, and promote the rational useof antimicrobials.

Sepsis is responsible every year for at least 11 million deathsworldwide. According to data from the Institute for HealthMetrics and Evaluation (IHME) and Oxford University,approximately 58 deaths per 100,000 inhabitants wererecorded in Brazil in 2021[1]. Almeida *et al.* (2022), maintain that the average mortality rate was 22.8 deaths/100,000 inhabitants in 2010 - 2019. According to Brazil's Ministry of Health, 400,000 cases of sepsis occur in adult patients per year. Of this total, 240,000 die - 60% of total sepsis deaths.

The annual number of cases among Brazil's children is 42,000, of which 8,000 do not survive, indicating a mortality rate of 19%. According to the Latin AmericanSepsis Institute (ILAS), Brazil is among the countrieswith the highest mortality rates from sepsis, also knownas "generalized infection", which underscores the needfor greater attention to be focused on the issue,especially faster diagnosis[2].

Limited access to diagnosis is one of the greatest challenges both globally and in Brazil. In terms of antimicrobial resistance (AMR), this constraint uindermines clinical management, contributes to increased morbidity and mortality, and favors the spread of resistance, since the absence of early and accurate diagnosis of bacterial, viral, parasitic, and fungal infections prevents an effective response to outbreaks and pandemics. Resistant co-infections are also an additional risk to achieving global targets for combating HIV, tuberculosis, and malaria. Individuals infected with multiple pathogens tend to have worse clinical outcomes and present a greater risk of transmission. Thus strengthening diagnostic systems is a strategic priority for tackling AMR in order to prepare countries for future pandemics.

1. MICROBE: Measuring causes infectious and resistance outcomes for disease burden estimation [online]. IHME/University of Oxford. Available at: https://vizhub. healthdata.org/ microbe. See Chart 1. Accessed on: December 14, 2025.

2. World Sepsis Day: Brazil has a high sepsis mortality rate among developing countries [online]. Noticias. Brazil Ministry of Health, EBSH. Available at: https://www.gov.br/ ebserh/ pt-br/ hospitais-universitarios/regiao-sudeste/hu-ufjf/comunicacao/noticias/2023/World Sepsis Day - Brazil has-high-mortality-rate-due--sepsis-among-developing-countries. Accessed on: December 14, 2025.

To achieve this, it is necessary to ensure equitable access to good quality testing, improve laboratory infrastructure, and integrate diagnostic services into public health policies in line with WHO guidelines.

Expanding access to quality tests and the rational use of microbiological diagnostics are fundamental for the effective surveillance of resistance, prevention and control of the spread of multidrug-resistant bacteria, as well as for the responsible use of antibiotics and other antimicrobials, as established in the WHO Global Action Plan on AMR (WHO, 2015).

Against this background CBDL is committed to playing a leading role in compiling information on AMR diagnostics in Brazil, promoting debate on the local production of in vitro diagnostics (IVD), simplifying regulatory approaches, overcoming quality and access barriers, and encouraging research, innovation, and development in the laboratory diagnostics sector.

These actions are aligned with proposals 1, 2, and 6 of the CBDL White Paper on Laboratory Diagnostics. Proposal 1 concerns deepening understanding of the IVD sector's dynamics in the health area by providing key information to enable health managers to formulate their requirements to the market. Proposal 2 seeks to promote digital inclusion and improve IVD related health data in Brazil, while Proposal 6 outlines ways of repositioning Brazil in the IVD industry's global value chain, in order to meet health sector current and prospective demands. The mapping of global and Brazilian approaches to the question of in vitro diagnostics in relation to AMR, as well the guiding role of CBDL, mark thebeginning of this journey.

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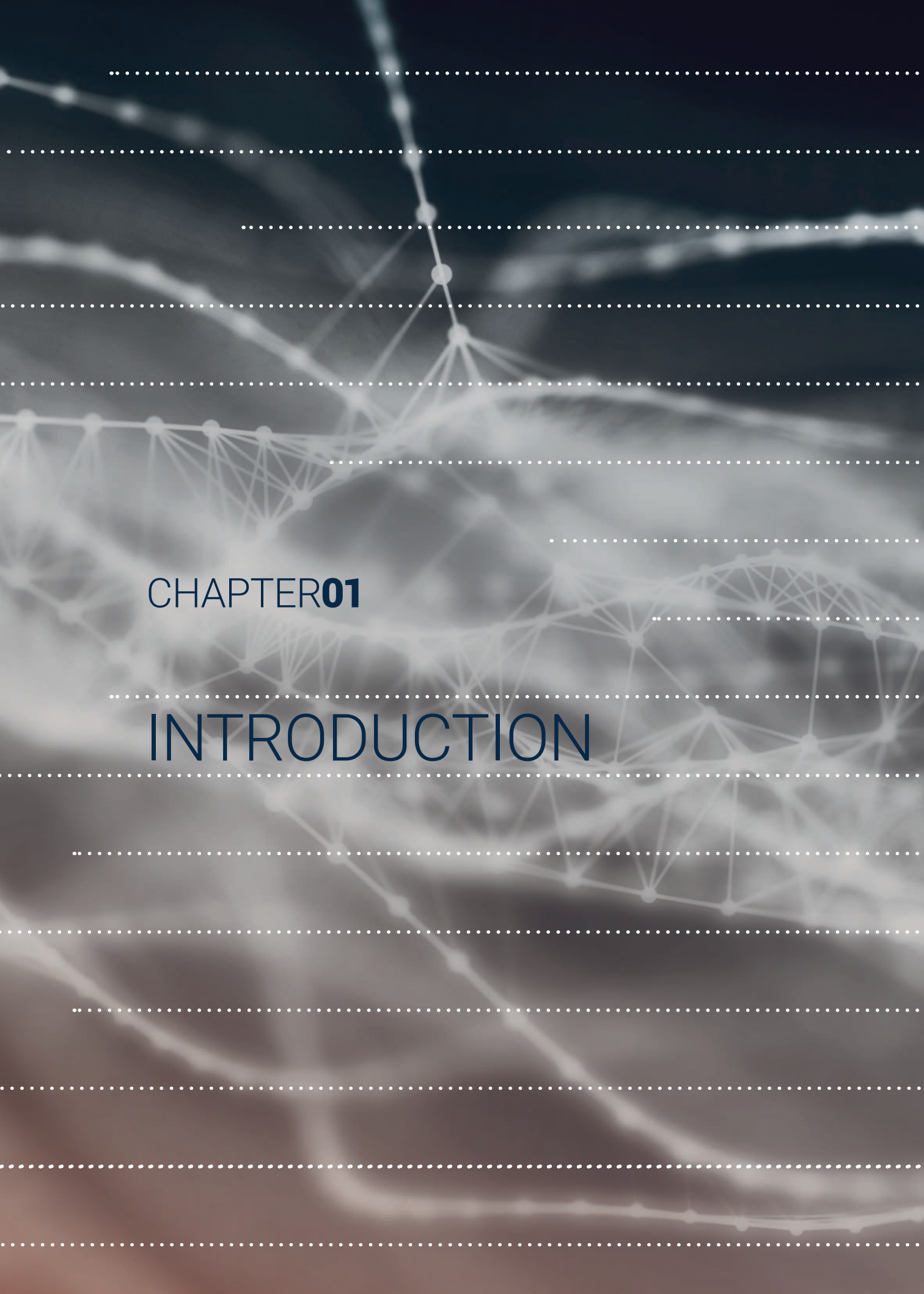


CHAPTER**01**

INTRODUCTION

Introduction

AMR refers to the ability of microorganisms such as bacteria, viruses, fungi, and parasites, to survive and multiply in the presence of antimicrobial drugs (such as antibiotics) that were previously effective against them.

This important public health issue is one of the main threats to global health. tt can lead to ineffective treatments, increased disease duration and severity of infections, and thus an increased risk of death.

AMR particularly affects low- and middle-income countries and vulnerable groups such as newborns. Bacterial and fungal co-infections worsen the situation in people with HIV, tuberculosis, and malaria, thereby increasing the risk of resistant infections and transmission to other persons (WHO, 2024).

Microbial infections are one of the main causes of morbidity and mortality in the hospital setting, especially when associated with delays in diagnosis and the initiation of appropriate treatment. Studies show that each hour of delay in administering appropriate antimicrobial therapy in patients with sepsis can result in a significant increase in mortality (7 to10% (apud Rodrigues, 2018, p. 5).

The situation is even more serious when resistant microorganisms are present. For example, bacteria such as Klebsiella pneumoniae, Acinetobacter baumannii, and Pseudomonas aeruginosa exhibit high levels of resistance, making treatment difficult.

Regarding methicillin-resistant Staphylococcus aureus (MRSA), delays of up to 48 hours in the initiation of appropriate antimicrobial therapy can double mortality in cases of severe sepsis (van Hal *et al.* 2012).

Fungal infections also present significant challenges. Species such as Candida auris and Candida glabrata infections often require precise laboratory identification, but a delay of 48 to 72 hours in delivering blood cultures can hold back the administration of appropriate antifungals and compromise patient survival. There is evidence that mortality associated with C. auris infections can range from 30% to 72% (Alvarez-Moreno *et al.*, 2023).

In immuno-compromised individuals, invasive aspergillosis is particularly lethal: each day of delay in starting antifungal treatment is associated with a 72.7% increase in mortality rates in patients with late-diagnosed invasive aspergillosis (Truda, 2023).

Finally, in patients living with HIV, late diagnosis of cryptococcal meningitis, caused by the Cryptococcus species, can increase mortality to over 50% (Pi-zani, 2015).

Although laboratory diagnostics are essential to ensure the correct choice of treatment and control of AMR, half of the world's population still lacks access to these services. The lack of high quality diagnostics contributes to increased morbidity, mortality, as well as healthcare costs. This demonstrates the need to strengthen laboratory capacity as part of the WHO Global Action Plan (WHO, 2024).

The main tests available for the microbiological diagnosis of septicemia are those of the following modalities: Culture, MALDI-TOF, multiplex PCR, Galactomannan and ÿ-D--glucan, whose main targets, principles and methods, times and degree of sensitivity of the results are found in TABLE 1.

TABLE **01**

MAIN TESTS AVAILABLE FOR THE MICROBIOLOGICAL DIAGNOSIS OF SEPTICEMIA

TEST (BIBLIOGRAPHIC REFERENCE)	MAIN TARGET	PRINCIPLE / METHOD	AVERAGE TIME FOR THE RESULT	SENSITIVITY / SPECIFICITY (APPROX.)
Blood culture (gold standard) (Evans, 2021)	Viable bacteria and fungi in the blood	Isolation and growth micro-organisms in a culture medium	48 h	65–80% / ≈100%
Culture of other fluids (Zakhour *et al.*, 2023)	Site pathogens (urine, cerebrospinal fluid, secretions)	Identification of the infection focus by culture	48 h	60–85% / high
MALDI-TOF MS (Mimica *et al.*, 2013)	Bacterial proteome of colonies	Rapid proteomic identification of bacterial colonies	1–2 h	90–99% / high
Procalcitonin (PCT) (Schuetz *et al.*, 2018)	Procalcitonin in serum (bacterial marker)	Bacterial infection marker and inflammatory response	2–4 h	75–90% / 70–85%
Interleukin-6 (IL-6) (Takahashi *et al.*, 2016)	IL-6 in serum (cytokine)	Initial pro-inflammatory cytokine	2–4 h	70–90% / 65–85%
NGS (Next Generation Sequencing) (Wilson *et al.*, 2019)	Metagenomic DNA of pathogens	Direct genomic identification of pathogens	24–72 h	80–95% / 80–95%
Multiplex syndrome panels (e.g. BioFire) (Salimnia, 2016)	Panels: multiple pathogens and resistance genes	Rapid detection of pathogens and resistance genes	1–2 h	85–98% / 85–99%

TEST (BIBLIOGRAPHIC REFERENCE)	MAIN TARGET	PRINCIPLE / METHOD	AVERAGE TIME FOR THE RESULT	SENSITIVITY / SPECIFICITY (APPROX.)
Combination of Biomarkers (PCT+IL-6+Lactate) (Liu *et al.*, 2020)	Combination of targets (PCT, IL-6, lactate)	Combination of biomarkers for diagnosis and prognosis	1–3 h	≈90% / variable
Cepheid rapid test (GeneXpert) 12 (Cordioli *et al.*, 2024)	Specific genes (MRSA, KPC, etc.) and target pathogens of the panel	Real-time PCR real automation for rapid detection of pathogens and resistance genes	1 h	92–98% / 95–99%
Staphylococcus aureus MRSA - Molecular test (Stürenburg, 2009)	mecA/mecC gene (methicillin resistance in *S. aureus*)	Specific PCR for detection of the mecA gene/ mecC of resistance to meticilina	1–2 h	95% / 98%
Galactomannan (GM) (Salzer, 2018; Paterson *et al.*, 2019)	Fungal antigen (*Aspergillus spp.*)	Immunological assay diagnostic test for the detection of galactomannan in serum or BAL	3–6 h	70–90% / 85–95%
β-D-Glucan (BDG) (Ostrosky-Zeichner, 2012)	Polysaccharid in the cell wall of fungi	Colorimetric or chemiluminescent assay for β-D-glucan in blood	2–6 h	60–80% / 70–85%

SOURCE: COMPILATION BY WEBSETORIAL AND CBDL.

Other tests such as creatinine, platelet count, lactate, and bilirubin are important aids in the clinical characterization of sepsis.

This study mapped the key actors, globally and in Brazil, involved in the question of antimicrobial resistance in humans, with a particular focus on the usefulness of *in vitro* diagnostics. The study's aim was also to understand the actions these actors promote, as well as to seek to define CBDL's role in this context, and propose specific initiatives for the organization to undertake.

Key points

- AMR is one of the major global threats to public health. It is estimated that bacterial AMR was directly responsible for 1.14 million deaths worldwide in 2021, including 194,000 children under 5 years of age, and was associated[3] with 4.71 million deaths (IHME, 2025).[4]

- The inappropriate and excessive use of antimicrobial agents in humans, animals and plants is the main driver of the development of drug-resistant 5 pathogens (WHO, 2025).[5]

- In Brazil, it is estimated that in 2021, 31,662 deaths were directly caused by AMR and another 129,826 deaths were associated with this type of resistance in that year (IHME, 2025).

- In addition to death and disability, AMR carries significant economic costs. Healthcare costs alone are increased by US$66 billion, and this value is likely to increase to US$159 billion if resistance rates follow historical trends (McDonnell et al., 2024).

3. Associated Death Estimate
Associated deaths refer to deaths of peoplewith a drug-resistant infection-that contributed to their death. The infection was implicated in the cause of death, but resistance may or may not have been a determining factor.

4. Source: IHME. Available at: https://vizhub.healthdata.org/mic robe/. Accessed on:December14,2025

5. WHO. Antimicrobial Resistance. Available at: https://www.who.int/news-room/fact-sheets/detail/antimicrobial resistance. Accessed on:December 14, 2025.

- According to Santos (2022), the average cost per hospitalization in Brazil of a patient with sepsis is as much as R$ 3,748.12, with the daily cost amounting to R$433.31

- AMR affects all countries in all regions and at all different income levels. Its outcomes are exacerbated by poverty and inequality, with low- and middle income countries being the most affected.[3]

- AMR makes complex medical procedures and treatments, such as surgery, cesarean sections, and cancer chemotherapy, much riskier to perform (WHO, 2025).[3]

- Priorities for dealing with AMR from a human health standpoint include: infection prevention; ensuring access to infection diagnostics and correct treatment; strategic information; and innovation through developing new vaccines, diagnostics, and mediciines.

- The world is facing a crisis of supply and access to antibiotics. Research and development are proving inadequate in view of increasing resistance levels. There is an pressing need to take steps to ensure equitable access to new and existing vaccines, diagnostics and medicines (WHO, 2025).[3]

CHAPTER**02**

THE ROLE OF DIAGNOSTICS IN THE CONTEXT OF ANTIMICROBIAL RESISTANCE (AMR)

The role of diagnostics in the context of antimicrobial resistance (AMR)

Antimicrobial drugs are cornerstones of modern medicine, essential for treating numerous diseases and for preventing serious complications in procedures such as chemotherapy, cesarean sections, implants, transplants, and other surgeries.The emergence and spread of resistant pathogens threaten the effectiveness of treatments and hold back progress in developing new drugs,etc.

Antimicrobial resistance (AMR) occurs when bacteria, viruses, fungi, and parasites cease to respond to commonly-used medications, such as antibiotics, antivirals, and antifungals. This phenomenon makes infections more difficult to treat, increasing the risks of aggravation, transmission, and mortality. Although antimicrobial resistance is a natural phenomenon resulting from genetic mutations and the adaptive selection of microorganisms, its emergence and spread are intensified by the excessive and inappropriate use of antimicrobials in humans, animals, and agriculture. Moreover, the horizontal transfer of resistance genes between microorganisms accelerates the spread of these determinants, making infection prevention and control increasingly challenging, especially in hospital settings, where selective pressure and patient vulnerability favor the emergence and maintenance of microorganisms.

Antibiotic resistance is on the rise globally, with high rates occurring in bacteria such as Escherichia coli and Staphylococcus aureus, compromising the treatment of common infections. The situation demands more effective surveillance systems and robust management strategies. IHME projections indicate that, if the present situation continues, AMR could cause 38.5 million deaths worldwide between 2025 and 2050 (McDonnell *et al.*, 2024).

The rise in fungal resistance, especially of species like Candida auris, is also a growing challenge, particularly in patients with comorbidities. In response to this challenge, the WHO has developed a priority list of fungi for global surveillance (See FIGURE 4).

Resistance to drugs used in the treatment of HIV, tuberculosis, and malaria erodes control of these diseases which require constant monitoring. The situation is also of concern in neglected tropical diseases such as leprosy, trypanosomiasis, leishmaniasis, and helminthiasis. The elimination of the latter in vulnerable populations is threatened by increasing resistance and the scarcity of new treatments.

Acute respiratory infections (ARIs) impose high costs on healthcare systems and economies in general, by requiring more complex and prolonged treatments, longer hospital stays, and reducing the productivity of patients and caregivers. Agricultural production and food security are also negatively affected.

Since this is a transnational threat, it follows that the response to AMR must be coordinated globally.

Different factors contribute to the spread of the dangers of AMR, including limited access to drinking water, basic sanitation and hygiene, failures in infection prevention and control, shortages of vaccines, diagnostics and effective/affordable medical drugs, low awareness of AMR and defective implementation of relevant public policies and legislation.

The priorities for addressing AMR in human health include the following:

(i) prevention of infections that may result from the inappropriate use of antimicrobial agents; (ii) ensuring universal access to rapid, accurate and quality diagnosis and appropriate treatment of infections; (iii) strategic information obtained from surveillance of AMR and the consumption and use of antimicrobial agents; and (iv) innovation through research and development of new vaccines, diagnostics and drugs.

ANTIMICROBIAL RESISTANCE IS A COMPLEX GLOBAL PROBLEM. ADDRESSING THE ISSUE SUCCESSFULLY REQUIRES CLOSE COLLABORATION BY THE HEALTH, AGRICULTURAL, EDUCATION AND R & D SECTORS, ETC.

Consequences of antimicrobial resistance

AMR has a number of consequences for the healthcare system and society in general:

- **INEFFECTIVE TREATMENTS:** Resistant infections require more complex treatments, often with more expensive medications and more serious side effects.
- **HIGHER RISK OF DEATH:** Resistant infections can be more difficult to treat, leading to longer hospital stays and higher mortality, especially in patients with compromised immune systems.
- **HEALTHCARE COSTS:** Antimicrobial resistance generates additional costs for the healthcare system, including costs for medications, hospitals, and longer treatment periods.
- **IMPACT ON FOOD PRODUCTION:** In the agriculture and livestock farming areas, antimicrobial resistance can harm food production and increase the risk of infection transmission to humans.
- **SOCIAL COSTS:** Infections or sepsis may lead to absence from work, and possible loss of quality of life after hospitalization.

The importance of diagnostics for AMR control

Diagnostics play a crucial role in combating AMR, guiding and monitoring appropriate treatment, and avoiding the unnecessary use of antibiotics.

Diagnosis helps to identify resistant bacteria, determine susceptibility to different antibiotics, and distinguish between bacterial and viral infections.

Reliable diagnostic tools help reduce the spread of AMR and are important for fast and effective treatment.

Diagnostics employ various approaches to identify antimicrobial resistance, including the following:

1. DETECTION TESTS: manual or automated, in different types of samples, are used to confirm the presence of bacterial, aerobic or anaerobic infection.The key advantage of automated systems is their ability to monitor the growth of bacterial cultures in real time, generating detailed growth graphs that can be directly integrated into Laboratory Information Systems (LIS) and management thus optimizing clinical decision-making.

2. IDENTIFICATION: There are several options currently available for bacterial identification systems, both manual and automated, some using PoC diagnostics allowing for rapid testing at the point of care (PoC), enabling quick decision-making and treatment. Some tests, such as multiplex PCR, can identify several pathogens and resistance genes simultaneously, enabling quicker diagnosis. At present there are panels that identify/differentiate multiple pathogens from a single clinical sample - a particularly important rapid diagnostic method in complex cases of bacterial infections. There are also specific panels for sepsis that allow speedier initiation of treatment. Other panels group together viruses and bacteria for respiratory infections, gastrointestinal infections, meningitis and encephalitis.

3. SUSCEPTIBILITY TESTS: involve growing and testing bacteria in the laboratory.in the presence of different antibiotics to determine which are effective (culture-based methods) - either antibiograms or antimicrobial susceptibility tests (ASTs), or phenotypic screening. The most common methods include disk diffusion, broth microdilution, and gradient tests. Molecular methods, such as PCR, identify specific genes associated with resistance. These methods however are time-consuming. Automated panels that test for resistance or susceptibility to various antimicrobial agents have recently become commercially available (BioMérieux, BD, and Beckman Coulter), and help speed up and standardize the antibiogram.

4. DISTINGUISHING BETWEEN BACTERIAL AND VIRAL INFECTIONS: Rapid diagnosis can help distinguish bacterial from viral infections, avoiding the unnecessary use of antibiotics in cases of viral infections.

5. ANTIMICROBIAL MANAGEMENT AND STEWARDSHIPS: Accelerating microbial identification allows for more robust clinical decision-making with the rational use of antimicrobials and, consequently, better clinical outcomes for the patient. Antimicrobial stewardship is a set of practices to optimize the use of antibiotics, antivirals, and antifungals, aiming to combat microbial resistance, improve patient outcomes, and ensure the long-term effectiveness of these medications. This responsible management approach involves selecting the best therapeutic option, with the correct dose and duration, as well as monitoring its administration to reduce the emergence and spread of resistant microorganisms.

6. SURVEILLANCE AND OUTBREAK DETECTION: Diagnostic data are fundamental for identifying resistance patterns, mapping emerging threats, and monitoring outbreaks.With the advance of technologies based on AI, interoperability, and predictive analytics, these capabilities are being expanded, enabling a more agile, integrated, and strategic response to antimicrobial resistance.

TABLE 2 describes the main characteristics of the tests currently available for septicemia diagnosis.

TABLE **02**

MAIN CHARACTERISTICS OF TESTS AVAILABLE FOR SEPTICEMIA DIAGNOSTICS

TEST (BIBLIOGRAPHIC REFERENCE)	KEY CHARACTERISTICS	ADVANTAGES	LIMITATIONS / CHALLENGES	RELATIVE COST $ (LOW) $$ (MEDIUM) $$$ (HIGH)
Blood culture (gold standard) (Evans, 2021)	Allows for culture and antibiogram; etiological confirmation	Allows for culture. and antibiogram; etiological confirmation	Takes long time; sensitivity reduced in case of a previous antibiotic; contamination	$$
Culture of other fluids (Zakhour *et al.*, 2023)	Identifies source and guides therapy	Identifies source and guides therapy	Collection and contamination; growth time	$$
MALDI-TOF MS (Mimica *et al.*, 2013)	Quick identification after colony; reduces diagnosis time	Quick identification after colony; reduces diagnosis time	Requires colony; cost of equipment	$$$
Procalcitonin (PCT) (Schuetz *et al.*, 2018)	Helps in decision to start/end antibiotics	Helps in decision to start/end antibiotics	Interpretation in conjunction with clinical practice; cost	$$
Interleucina-6 (IL-6) (Takahashi *et al.*, 2016)	Early onset; sensitive at the beginning of infection	Early onset; sensitive at the beginning of infection	Varies with sampling time; limited availability	$$
NGS (Next Generation Sequencing) (Wilson *et al.*, 2019)	Wide coverage of agents; identifies rare pathogens	Wide coverage of agents; identifies rare pathogens	High cost; need for bioinformatics and clinical validation	$$$$

TEST (BIBLIOGRAPHIC REFERENCE)	KEY CHARACTERISTICS	ADVANTAGES	LIMITATIONS / CHALLENGES	RELATIVE COST $ (LOW) $$ (MEDIUM) $$$ (HIGH)
Multiplex syndro panels (e.g. BioFire) (Salimnia, 2016)	Fast response time; includes genetic resistance	Fast response time; includes genetic resistance	Limited to panel targets; cost per test	$$$
Combination of Biomarkers (PCT + IL-6 + Lactate) (Liu *et al.*, 2020)	Greater diagnostic accuracy and prognostic value	Greater diagnostic accuracy and prognostic value	Standardization is necessary; cost and availability	$$$
Cepheid Rapid Test (GeneXpert) 12 (Cordioli *et al.*, 2024)	Automated; fast; includes resistance genes	Automated; fast; includes resistance genes	High cost per test; requires proprietary platform	$$$$
Staphylococcus aureus MRSA - Molecular test (Stürenburg, 2009)	Specific target; allows isolation and rapid hospital control	Specific target; allows isolation and rapid hospital control	Does not differentiate between colonization and infection; requires laboratory quality	$$$
Galactomannan (GM) (Salzer, 2018; Paterson *et al.*, 2019)	Aids in the early diagnosis of aspergillosis; monitoring of antifungal therapy	Ajuda no diagnóstico precoce de aspergilose; monitoramento de terapia antifúngica	False positives with certain antibiotics or food; variable sensitivity	$$$
β-D-Glucan (BDG) (Ostrosky-Zeichner, 2012)	Detects invasive fungi in general; useful for systemic cases of fungal infection	Fast-acting; covers multiple fungi; useful in immuno--compromised patients	False positives in blood derivatives, dialysis or antibiotics; does not specify species	$$$

SOURCE: COMPILATION BY WEBSETORIAL AND CBDL.

New diagnostic technologies are being developed, such as infrared (IR) and Raman (RS) spectroscopy, for the rapid and accurate detection of AMR, although these spectroscopic techniques are still not widely accessible. Moreover, whole-genome sequencing will provide a comprehensive view of bacterial genomes, including AMR genes. CRISPR- based diagnostics can be counted among the innovative methods for rapid detection of AMR.[6]

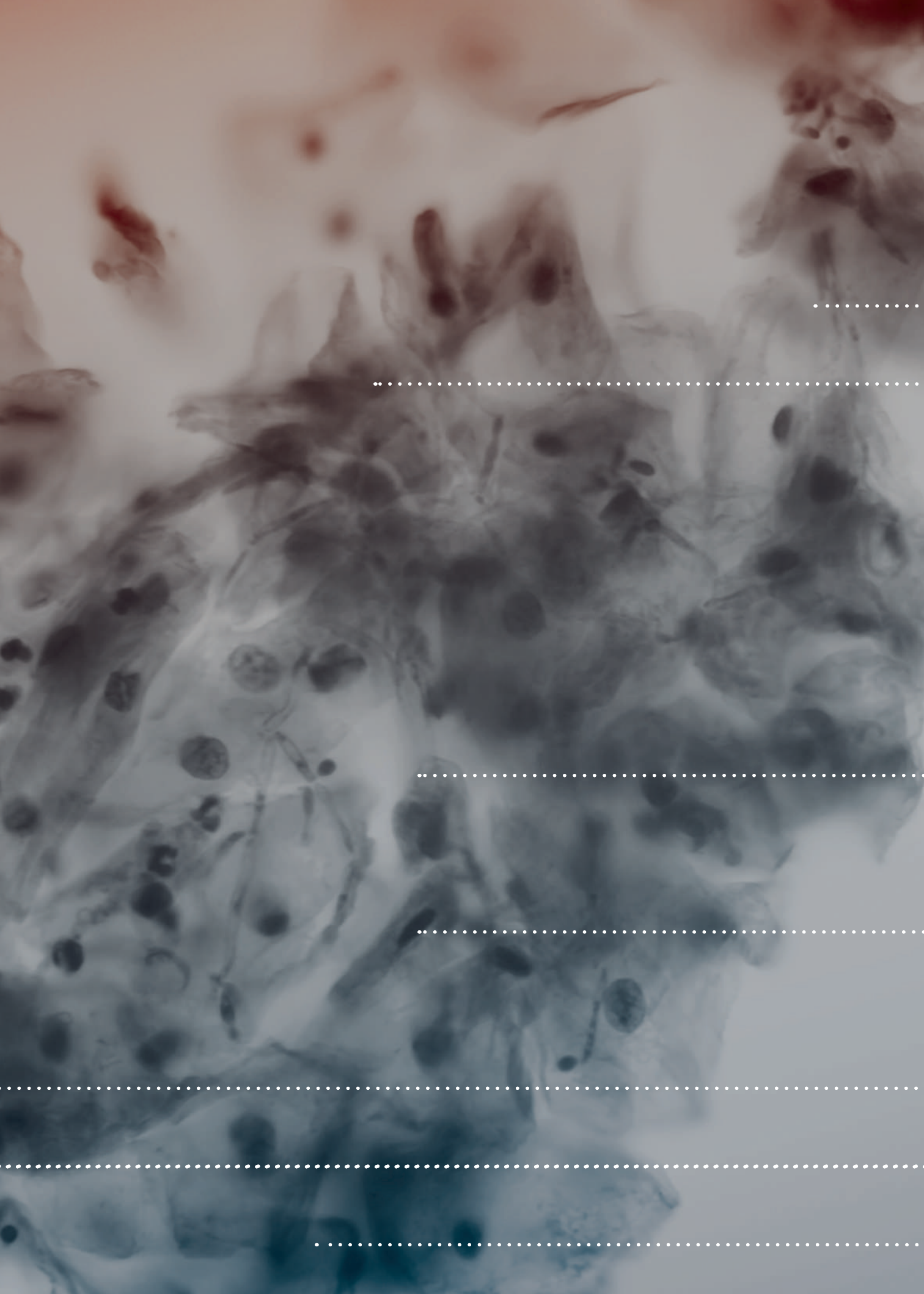
6. CRISPR, or CRISPR-Cas9, is a gene- editing technique that allows scientists to modify the DNA of organisms precisely and efficiently.

DIAGNOSTICS PLAY A CRUCIAL ROLE IN COMBATING AND MONITORING ANTIMICROBIAL RESISTANCE (AMR), GUIDING APPROPRIATE TREATMENT AND AVOIDING UNNECESSARY USE OF ANTIBIOTICS.

How to combat antimicrobial resistance?

Combating resistance in a coordinated manner depends on the action of local agents paying attention to : (i) the correct use of antimicrobials (only when necessary and under medical guidance), applying the indicated dosage for the indicated period; (ii) improved hygiene and sanitation; (iii) combating cross-contamination in hospitals and other healthcare environments, ensuring adequate disinfection and sterilization of equipment and surfaces to prevent the spread of resistant microorganisms; (iv) investment in research and development of new antimicrobial drugs, and in alternative strategies to combat infections; and (v) continuous epidemiological monitoring of antimicrobial resistance through essential data and information provided by laboratories and hospitals to identify and control the emergence of new resistant strains.

CONTINUOUS EPIDEMIOLOGICAL SURVEILLANCE OF ANTIMICROBIAL RESISTANCE, THROUGH DATA AND INFORMATION PROVIDED BY LABORATORIES AND HOSPITALS, IS ESSENTIAL TO IDENTIFY AND CONTROL THE EMERGENCE OF NEW RESISTANT STRAINS.



CHAPTER**03**

THE ROLE OF THE WHO IN COMBATING AMR

The Role of the WHO in Combating AMR

The following are the general lines of action for addressing AMR promoted by the World Health Orgaization and its members .

The 'One Health' approach[7]

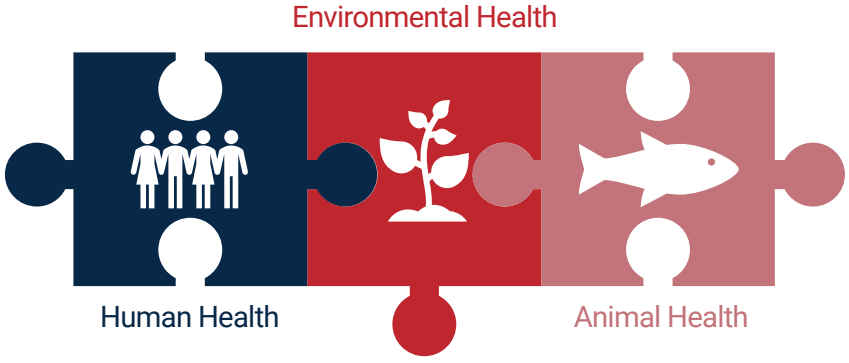
Given its complexity, AMR requires specific and integrated actions in the areas of human and animal health, food production, and environment. The 'One Health' approach is a strategy designed to unify, balance and optimize, in a sustainable way, the health of people, animals, and ecosystems. In short, this approach seeks to promote interdependence between human, animal, plant, and environmental health.

Through the 'One Health' approach, different sectors and stakeholders work collaboratively in the formulation, implementation, and monitoring of policies, programs, laws, and research aimed at preventing and controlling AMR, thus promoting better public health outcomes and durable economic benefits.

7. WHO. Home. Health topics. One Health. Available at: https://www.who.int/ health-topics/ one-health#tab=tab1. Accessed on: December 14, 2025.

FIGURE **01**

SIMPLIFIED SCHEMATIC REPRESENTATION OF THE 'ONE HEALTH' CONCEPT



SOURCE: WHO, 2025[7]

Global Action Plan (GAP) on Antimicrobial Resistance

To address AMR on a global scale, the 2015 World Health Assembly adopted the Global Action Plan (GAP)[8] n AMR for a number of countries committed to developing and implementing national action plans enshrining a multi-sectoral approach to AMR based on the 'One Health' concept.

GAP was later endorsed by important international bodies, including the UN Food and Agriculture Organization (FAO), the World Organisation for Animal Health (WOAH, formerly OIE), and the United Nations Environment Programme (UNEP).

Despite these initiatives, the capacity of low- and middle-income countries to prevent, diagnose, and treat bacterial infections and drug resistance, and provide evidence of the development of relevant policies, has been limited. In the group of countries mentioned, the incorporation of antimicrobial resistance interventions in health environments and their links with other health system capacities and priorities often go unrecognized in universal healthcare strategies or emergencies.

8. Global action plan on antimicrobial resistance. Available at: https://www.who.int/publications/i/item/9789241509763. Accessed on: December 14, 2025.

The UN Director-General explained to the 76th World Health Assembly the need to accelerate the implementation of national action plans on antimicrobial resistance, proposing the development of a WHO strategic and operational framework to address drug-resistant bacterial infections in the human health sector.

The WHO strategic priorities over years 2025-2035 for addressing drug-resistant bacterial infections in human health (2025-2035), were ratified at the 77th WHO General Assembly which issued a document issues by the Secretary General "Antimicrobial resistance: accelerating national and global responses to WHO strategic and operational priorities to address drug-resistant bacterial infections in the human health sector, 2025–2035".(WHO, 2024).

Based on the feedback received during the public consultation, the WHO developed a monitoring framework to track the implementation of actions to address AMR. This plan addressed three key areas:

1.IMPACT: Monitor and reverse the public health crisis caused by drug resistant infections in humans.

2. EXPECTED RESULTS: Reduce the emergence and spread of resistant bacterial infections,preserving the effectiveness of antibiotics for future generations.

3. STRATEGIC PRIORITIES:

- Infection prevention;
- Guaranteeing universal access to good quality, affordable diagnostics and appropriate treatment;
- Promoting the production and use of science, innovation and strategic data;
- Strengthening governance and sustainable financing.

To deal with AMR in the human health sector the GAP outlined priorities for worldwide efforts focused on various important areas: (i) robust infection prevention and control (IPC) measures; (ii) ensuring equitable access to diagnostics and treatments; (iii) close surveillance to detect emerging trends in AMR; and (iv) governance and substantial investment in R&D for creating new medical drugs, prevention tools and diagnostics..

Implementing the policies

The operational priorities related to the strategic definitions ratified at the 77th session of the World Health Assembly include:

- Implementation of the WHO core intervention package fornational action plans using a people-centered approach;
- Additional governance and financing actions at the national and global levels;
- Ongoing technical support to Member States, based on information reported to or received by the WHO.

To support the practical aspects of these policies, the WHO's Surveillance, Prevention and Control Department[9], coordinates (i) the technical aspects of work involved in surveillance and monitoring resistance and antimicrobial consumption; and (ii) the strengthening of antimicrobial resistance control capacities to monitor countries' progress in implementing their national action plans.

Monitoring is carried out based on officially reported data provided by the different countries to the Global Antimicrobial Resistance Surveillance System (GLASS) and on the annual self-assessment questionnaire on AMR by country - the *Country Self-Assessment Survey* (TrACSS).

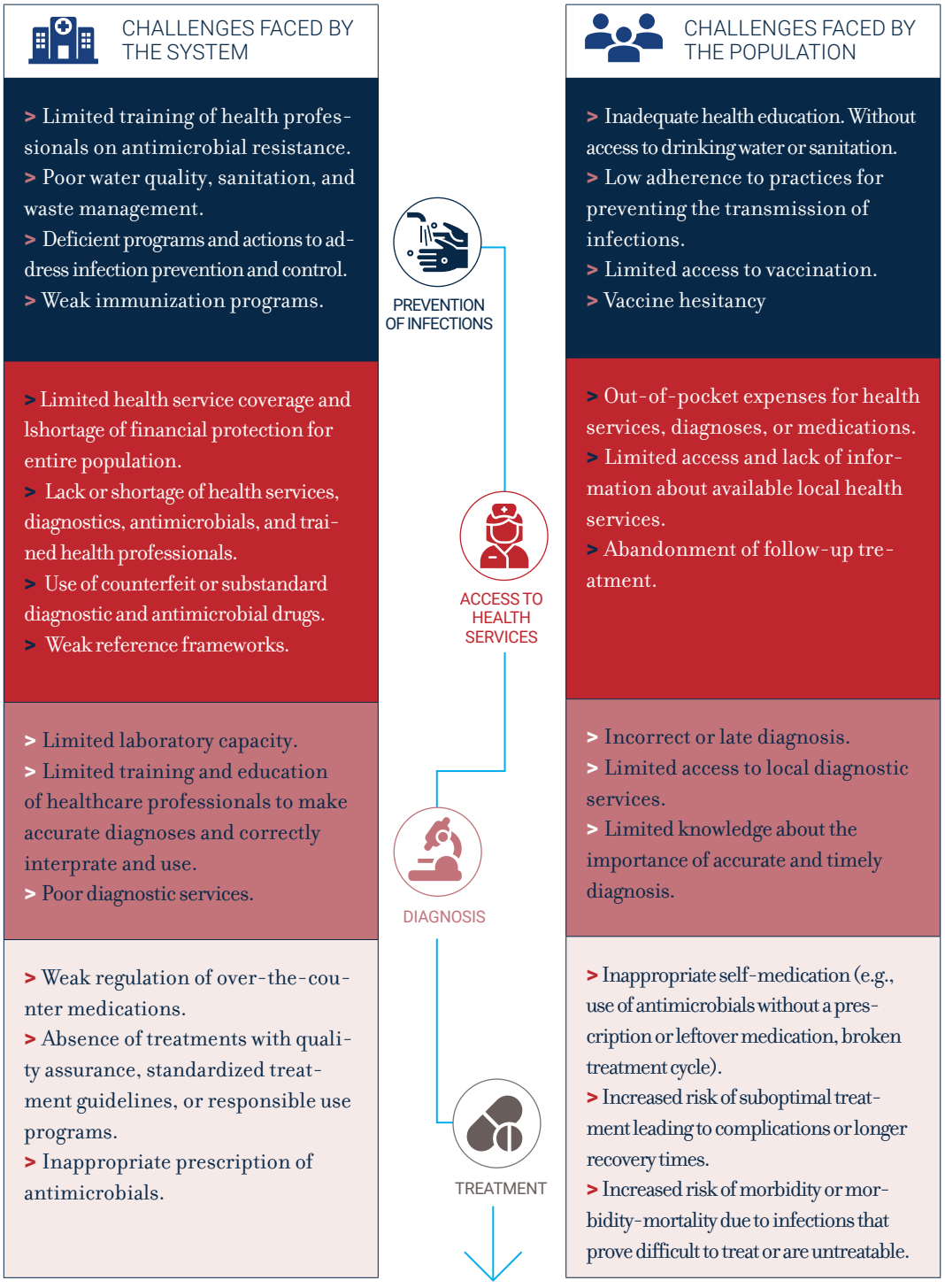
9. The Surveillance, Prevention and Control (SPC) Department. Available at: https://www.who.int/ teams/ surveillance-preven-tion-control-AMR/ national-ac-tion-plan-monitoring-evaluation/monitoring-theimplementation-of- -the-who-strategic-and-operational- -priorities-to-address- -drug-resistan-t-infections 2025-35 Accessed on December 14, 2025

The people-centered approach and the WHO core package of interventions

WHO has developed a people-centered approach to combat AMR, in light of the challenges faced by the health system and the population in general (FIGURE 2). Given these challenges WHO has defined certain intervention priorities for infection prevention, equitable access to health services and improved quality of diagnosis and treatment (TABLE 3).

FIGURE **02**

AMR-RELATED CHALLENGES TO THE HEALTHCARE SYSTEM AND INDIVIDUALS



SOURCE: WHO (2024).

The people-centered approach to addressing AMR consists of integrated actions at the national level, aligned with primary care, universal health coverage, and emergency response. This approach places people at the center of interventions, taking into account systemic and individual challenges, involving communities, health professionals, academia, the public and private sectors and civil society as a whole.

Structured around 4 programmatic pillars and supported by strategic data and effective governance, this approach serves as a guide for countries to develop or review their national action plans to combat AMR, identify gaps, and incorporate interventions in health systems (TABLE 3).

TABLE **03**

STRATEGIC PRIORITIES AND A PEOPLE-CENTERED APPROACH TO ANTIMICROBIAL RESISTANCE (WHO, 2024)

STRATEGIC PRIORITIES	PILLARS OF PEOPLE CENTERED APPROACH	MAIN INTERVENTIONS
Prevention	Prevention	> Universal access to drinking water, sanitation, hygieneand waste management > Implementation of essential components of infection prevention and control > Access to vaccines and expansion of immunization
Universal access	Access to essential health services	> Availability and accessibility of services for the diagnosis and management of antimicrobial resistance > Continuous supply of antimicrobials > Essential and quality-assured health products to combat antimicrobial resistance
	Timely and accurate diagnosis	> Laboratory quality system and diagnostic manage-ment practices to ensure clinical bacteriology (and mycology) testing
	Appropriate treatment to be of guaranteed quality	> Updated, evidence-based treatment guidelines and programs > Regulations to restrict the sale of antimicrobials withouta prescription
Strategic data, science and innovation	Data-based strategic action	> National network to monitor antimicrobial resistance, to generate quality data and guide patient care and actions on AMR > Monitor the consumption and use of antimicrobials, and guide clinical policies and actions to deal with adver-se drug reactions (ADRs) > Research and innovation in antimicrobial resistance, including behavioral and implementation sciences
Governance and financing	Basis for effective governance	> Political influence, governance, andaccountability inthe human health sector, in collaboration with other sectors > Raising awareness, educating, and adapting the approach of healthcare professionals and communities to antimicrobial resistance

Antimicrobial management and AWaRe

Antimicrobial management is a WHO strategy that guides and empowers healthcare professionals to prescribe antibiotics appropriately, with expertise based on scientific guidelines, in order to ensure drug efficacy. The WHO recommends implementing national antimicrobial management programs as an effective measure to improve treatments, reduce antimicrobial resistance, and prevent hospital-acquired infections. To support this approach, the leading health authority developed the AWaRe (Access, Watch, Reserve)[10] classification of antibiotics. This is intended to guide the rational and responsible use of antibiotics in different clinical environments.

Strategic information to inform the response to AMR

In 2015, the WHO launched GLASS [11], aimed at filling knowledge gaps Antimicrobial Resistance and Use and guiding strategies at all levels. GLASS progressively iincorporates data on adverse drug reactions (ADR) in humans, on antimicrobial use and consumption, and on information from the 'One Health' sectors, including the food chain and the environment.

The system uses a standardized approach to the collection, analysis, interpretation, and sharing of data among countries, territories, and regions, and to monitoring the quality and sample adequacy of national surveillance systems. Some WHO regions have created technical support networks to facilitate countries' adherence to GLASS.

The WHO pays special attention to supporting low- and middle--income countries,and assisting the collection and use of data for the formulation of public policies, both through GLASS and national surveys on AMR prevalence.

10. AWaRe classification of antibiotics for evaluation and monitoring of use. WHO, 2023. Available at: https://www.who.int/ publications/ i/ item/WHO-MHP-HPS--EML-2023.04. Accessed on: December 14, 2025.

11. WHO. Data/GHO/Themes/Topics. Global Antimicrobial Resistance and Use Surveillance System (GLASS). Available at:https://www.who.int/data/gho/data/themes/topics/ global-antimicrobial-resistance-sur-veillance-system-glass. Accessed on: December 14, 2025.

According to the WHO report (2024), 89 countries reported data on AMR to GLASS in 2023.

With regard to AMR diagnostic tests, according to the report "*WHO Antimicrobial Resistance Diagnostic Initiative: strategic and operational framework for strengthening bacteriology and mycology diagnostic capacity*" (WHO, 2024), the data in the GLASS system on test coverage varies widely. between low- and middle-income countries and richer countries, since access to routine bacteriological testing is often insufficient in many of the former. The quality of testing remains a concern in many contexts, including in national reference laboratories.[12]

Defining priorities for the research and development of new AMR-related drugs and diagnostic tests

The development of new antimicrobials is facing a crisis situation, with the clinical *pipeline* nearly exhausted, and major issues in accessing antibiotics (especially generics) that affect rich and poorer countries alike.

The slow pace of innovation is also a key concern. While Murray *et al*. (2022) estimated the impact of resistance on 88 combinations of pathogens and drugs, the WHO 2024 Annual Review identified only 27 antibiotics in development that target priority pathogens - with only 6 considered to be truly innovative.

To guide R&D of new antimicrobials, diagnostics and vaccines, the WHO developed its List of Priority Bacterial Pathogens in 2017, updated in 2024[13] and the List of Priority Fungal Pathogens[14] in 2022.

The 2024 List of Priority Bacterial Pathogens includes 15 families of antibiotic resistant pathogens, grouped in three risk categories - critical, high, and medium priority - calling for R&D and public health measures to be taken FIGURE 3.

12. Technical consultation on the WHO Antimicrobial Resistance Diagnostic Initiative: strategic and operational framework for strengthening bacteriology and mycology diagnostic capacity, Geneva, Switzerland, 5-7, July 2023, published in 2024.

13. WHO bacterial priority pathogens list, 2024: Bacterial pathogens of public health importance to guide research, development and strategies to prevent and control antimicrobial resistance. Available at: https://www.who.int/ publications/i/item/9789240093461. Accessed on: December 14, 2025.

14. WHO list of priority fungal pathogens to guide research, development and public health action. Available at: https://www.who.int/publications/i/item/9789240060241 Accessed on: Dec. 14, 2025.

CRITICAL GROUP

- Antibiotic-resistant bacterial pathogens pose the greatest threat to public health.
- Treatment options are extremely limited or nonexistent.
- Associated with high mortality and morbidity.
- Increasing rates of resistance with few or no promising antibiotics in development.
- Highly transmissible and difficult to prevent.
- Pathogens exhibit global resistance mechanisms and/or multidrug-resistant strains in specific regions.

HIGH RISK GROUP

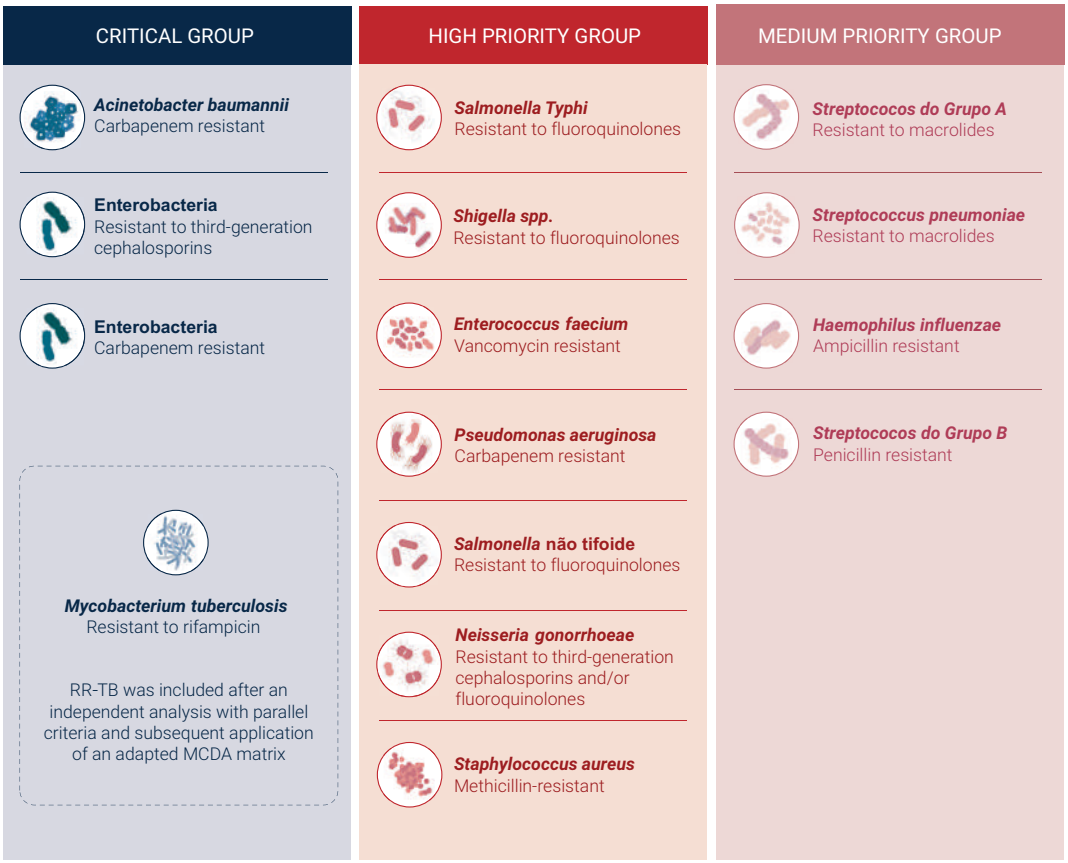
- Resistant bacterial pathogens that are very difficult to treat.
- Substantial disease burden (mortality and morbidity).
- Increasing resistance over time.
- Difficult to prevent and highly transmissible.
- Few therapeutic alternatives are being developed.
- Critical in regional or population contexts, although not a global priority.

MODERATE RISK GROUP

- Pathogens that are moderately difficult to treat.
- Moderate clinical impact (mortality and morbidity).
- Resistance trends are growing, but are controllable.
- Some challenges regarding prevention and transmissibility.
- More treatment options are under development.
- They may be relevant to specific populations or regions, although not a global priority.

FIGURE **03**

FUNGAL PATHOGENS THAT ARE A PRIORITY FOR THE DEVELOPMENT OF MEDICINES (WHO, 2024)



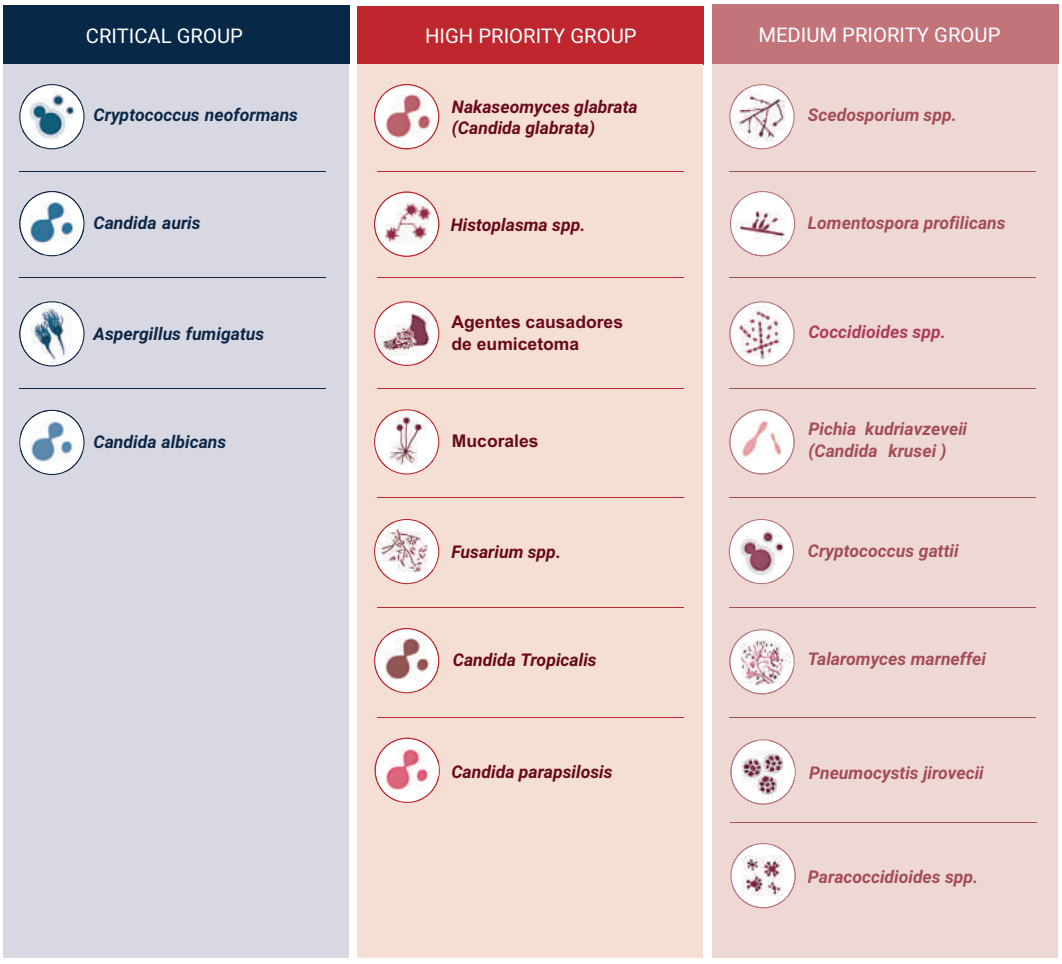
SOURCE: WHO (2024).

The WHO also collaborates with initiatives such as the Global Partnership for Antibiotic Research and Development (GARDP), the AMR Action Fund, and the Biopharmaceutical Accelerator for Combating Antibiotic- Resistant Bacteria (CARB-X), in addition to supporting governments that are testing models to encourage innovation in antimicrobials, focused especially on expanding access to diagnosis and treatment.

More investment in epidemiological and operational research is needed. In this regard, the WHO has defined 40 priority research topics on AMR in human health and, in partnership with organizations in the 'One Health' sector, has developed a joint research agenda to address the global threat.

FIGURE **04**

FUNGAL PATHOGENS THAT ARE A PRIORITY FOR THE DEVELOPMENT OF MEDICINES (WHO, 2024)



SOURCE: WHO (2024, P. 6).

The report *"Landscape of diagnostics against antibacterial resistance, gaps and priorities"* (WHO, 2019) mapped the available and developing anti-AMR diagnostics up to the year of publication, identified the gaps in the availability of these diagnostics in low- and middle-income countries, and introduced a list of research and development (R&D) priorities for diagnostics designed to address AMR in years 3 to 5.

The report maps typical installations and resources from the lowest to the highest level, covering facilities for Primary Care (Level 1), Secondary Care facilities/district hospitals (Level II), regional and provincial labo-

ratories (Level III), and national and multi-country reference laboratories (Level IV). The laboratory infrastructure and testing capabilities at each level of the public health system should play an important role in improving access to diagnostics for combating AMR.

Human skills, infrastructure, and the requirement for quality systems in clinical microbiology laboratories mean that bacterial culture, antimicrobial susceptibility testing (AST), and even molecular testing are generally only available in Tier III and Tier IV facilities, thus restricting access to testing for most patients.

According to the same report (WHO, 2019), most of the existing diagnostic and antimicrobial susceptibility testing (AST) facilities do not adequately meet the needs of primary (Level I) and secondary (Level II) healthcare units in low-and middle-income countries. This constrains referrals for testing, especially to Levels III and IV, where there are more sophisticated, well-equipped laboratories and well-trained personnel with the necessary diagnostics expertise.

The main gaps in the diagnostics area are highlighted by the WHO:

- Lack of effective point-of-care tuberculosis (TB) tests that can replace traditional smear microscopy and perform TB testing in an accessible way;
- Inability to perform simplified phenotypic bacterial identification and TSA at levels II and III, especially for bloodstream infections (BSI) such as sepsis;
- Lack of rapid and patient-centered testing for identification and TSA of multidrug-resistant Neisseria gonorrhoeae ;
- Shortage of simple and robust tests to differentiate bacterial from non-bacterial infections in primary care settings, using minimally invasive samples (blood, urine, stool, swabs);
- Lack of multiplex PCR platforms for direct detection of bacterial pathogens and TSA in whole blood, without the need for a culture, suitable for levels I and II;
- Lack of rapid diagnostic tests for blood samples, such as multiplex PCR, on simplified platforms thatcan be performed at or near the patient's point of care;

- Lack of simple and appropriate platforms for direct AST in blood, urine, feces or respiratory secretions, without the need for culture.

- As for pricing for antimicrobial agent identification and TSA, there is no harmonization of procedures and the methodologies used vary greatly from laboratory to laboratory. The available TUSS codes are too restrictive given the complexity and costs of these procedures and are limited to manual and automated antibiograms.

Sexually transmitted infections (STIs), resistance, percentages, and risk of treatment failure

Sexually transmitted infections (STIs) show increasing rates of antimicrobial resistance. This compromises the effectiveness of available treatments and increases the risk of treatment failure. An estimated 50% of Neisseria gonorrhoeae strains in some countries already show resistance to at least one first-line antibiotic, making gonorrhea, for example, one of the biggest global concerns in the STI area. Resistance is associated with treatment failure rates varying from 5% to 25%, depending on the region concerned and the regimen used.

Another critical example is syphilis, caused by Treponema pallidum, in which mutations in the 23S rRNA gene have resulted in resistance to azithromycin, especially in areas of high prevalence, with treatment failure reported in up to 12% of cases treated with macrolides.

In the case of trichomoniasis, resistance of Trichomonas vaginalis to metronidazole, the standard treatment, has been documented in 4% to 10% of infections and is associated with prolonged disease, a higher risk of transmission, and reproductive complications.

Chlamydia trachomatis, the causative agent of chlamydia, although still exhibiting low documented resistance rates, is a concern due to possibly selecting resistant strains for repeated use of doxycycline and azithromycin, which could increase the risk of treatment failure in vulnerable populations.

Given these scenarios, the spread of resistant STIs threatens the effectiveness of current therapies, increases public health costs, and raises the risk of serious complications such as infertility, vertical transmission, and HIV co-infections. Continuous monitoring of resistance and the search for new therapeutic regimens are essential to containing this situation (TABLE 4).

TABLE **04**

SEXUALLY TRANSMITTED INFECTIONS (STI), RESISTANCE, PERCENTAGES AND RISK OF THERAPEUTIC FAILURE

STI/ AGENT	ANTIBIOTICS WITH RESISTANCE DOCUMENTED	PREVALENCE/ RESISTANCE TREND (BRAZIL/GLOBAL)	RISK OF THERAPEUTIC - FAILURE (QUALITATIVE)
Gonorreia Neisseri a gonorrhoeae (Brazil, 2023; Wi *et al.*, 2017)	Ciprofloxacin, azithromycin, cefixime; increasing alert for ceftriaxone	Brazil: High and increasing resistance to ciprofloxacin; Increase for azithromycin/cefixime (SenGono surveillance). Global: Outbreaks with decreased susceptibility/ resistance to ceftriaxone reported in several countries.	Moderate-high when empirical therapy employs compromised drugs (e.g., ciprofloxacin/azidime). High in scenarios with ↓ susceptibility to ceftriaxone (requires monitoring and dose adjustment/ regimen).
Chlamydia – *Chlamydia trachomatis* (Workowski *et al.*, 2021; Unemo and Jensen, 2017)	Clinical resistance stable/low to macrolides and tetracyclines; also reports of failures not necessarily due to true AMR (persistence, reinfection, adhesion)	Global: first-line (azithromycin/doxycycline) continues to be highly effective; resistance continues. Confirmed resistance is rare and difficult to measure.	Low-moderate (failure usually linked to reinfection/adherence/ site of infection rather than proven AMR).
Mycoplasma genitalium (MG)4,5 (Barazetti *et al.*, 2023)	Macrolides (azithromycin) and fluoroquinolones (parC mutations)	Brazil (emerging data): re-reported and widespread macrolide mutations in different regions; Global: meta-analyses 35%–50% macrolide-AMR upward trend post-2016; fluoroquinolone-AMR variable.	High, because empirically treated with azithromycin without resistance test; need for NAAT-guided strategies + resistance testing, switching to moxifloxacin when indicated.
Sífilis – *Treponema pallidum* (Stamm, 2015)	Macrolides (azithromycin, erythromycin) – mutations 23S rRNA A2058G/A2059G; Penicillin G benzatina remains effective.	Global: "almost universal" AMR to macrolides in various contexts; Brazil: reports with detection of mutations in recent past sample.	High for regimens with macrolides (should be avoided); Low with benzathine penicillin (standard).

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A programmatic response to AMR in countries – National action plans against AMR

National action plans should include multi-sectoral governance mechanisms for AMR through the prioritization of activities, the development of a work plan with estimated costs, and the effective implementation of each National Plan.

To globally monitor progress in implementing AMR national action plans, signatory countries have committed to completing an annual multi-sectoral self-assessment questionnaire on AMR (TrACSS).This was launched in 2016, with the results available at: [https://www.amrcountryprogress.org/].

178 countries had developed multisectoral national action plans on antimicrobial resistance. by 2023, although only 27% reported implementing their action plans effectively. Meanwhile only 11% had budgeted enough funds to put them into practice.

The main findings of the TrACSS report on Brazil are presented in the section on national initiatives in this document.

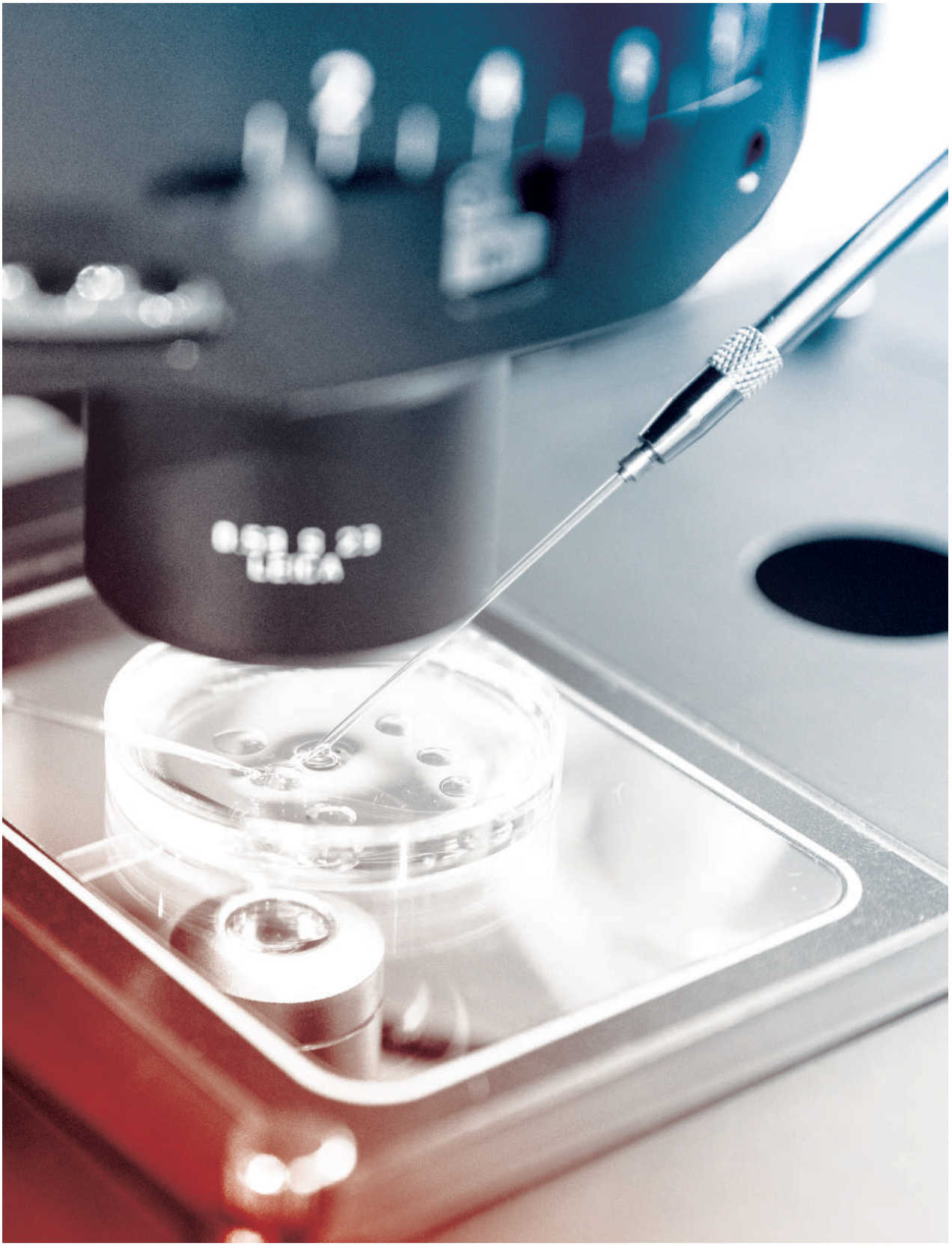
Funding for the implementation of national plans

International cooperation, external funding, and global partnerships play a key role in tackling antimicrobial resistance.

In the first round of funding from the Pandemic Fund, more than 80% of the grants approved for countries included actions aimed at combating AMR.

In February 2024, 25 countries had incorporated initiatives related to AMR into their proposals submitted to the Global Fund.

Targeted efforts – including existing and new international funding mechanisms, and innovative partnerships – are crucial to address the crisis in antibiotic access and development, as well as to meet other scientific and research demands that are viewed as a strategic priority (WHO, 2024, p. 9).



CHAPTER**04**

INTERNATIONAL BODIES THAT ALSO WORK TO CONTROL AMR, IN ADDITION TO THE WHO

International entities that also work to control AMR, in addition to WHO

Other international institutions with global reach, in addition to the WHO, have collaborated in tackling AMR. There are also various national and regional organizations engaged in this effort (chapter 6, item 6.3 of this report).

AMR Global Health Academy

Created by Drs. Rosanna Peeling (formerly of LSHTM) and Debi Boeras (formerly of the CDC) as an educational initiative to strengthen the global response to antimicrobial resistance (AMR), the academy provides a specific curriculum to support the training of AMR professionals and managers, especially in low- and middle-income countries. It is a virtual community offering healthcare professionals free access to AMR-related high-quality educational materials and informational resources. Accessible at: [https://www.globalhealthcpd. com/the-amr-global-health-academy/].

Global Health Network

This is an advisory support center for the World Health Organization focused on sharing scientific information, online education, and capacity building. It has a specific department, the Antimicrobial Resistance Knowledge Hub (https:// amr.tghn.org/), which promotes knowledge exchange and monitors advances in research on AMR globally.The resource is open and free of charge, intended for the global community of practice (CoP), bringing together researchers, healthcare professionals, and laboratory teams from different organizations involved in AMR research. The hub acts as a central point of access to relevant content, providiing tools, data, and different kinds of information to support the work of researchers and specialists worldwide. Accessible at: [https://tghn.org/].

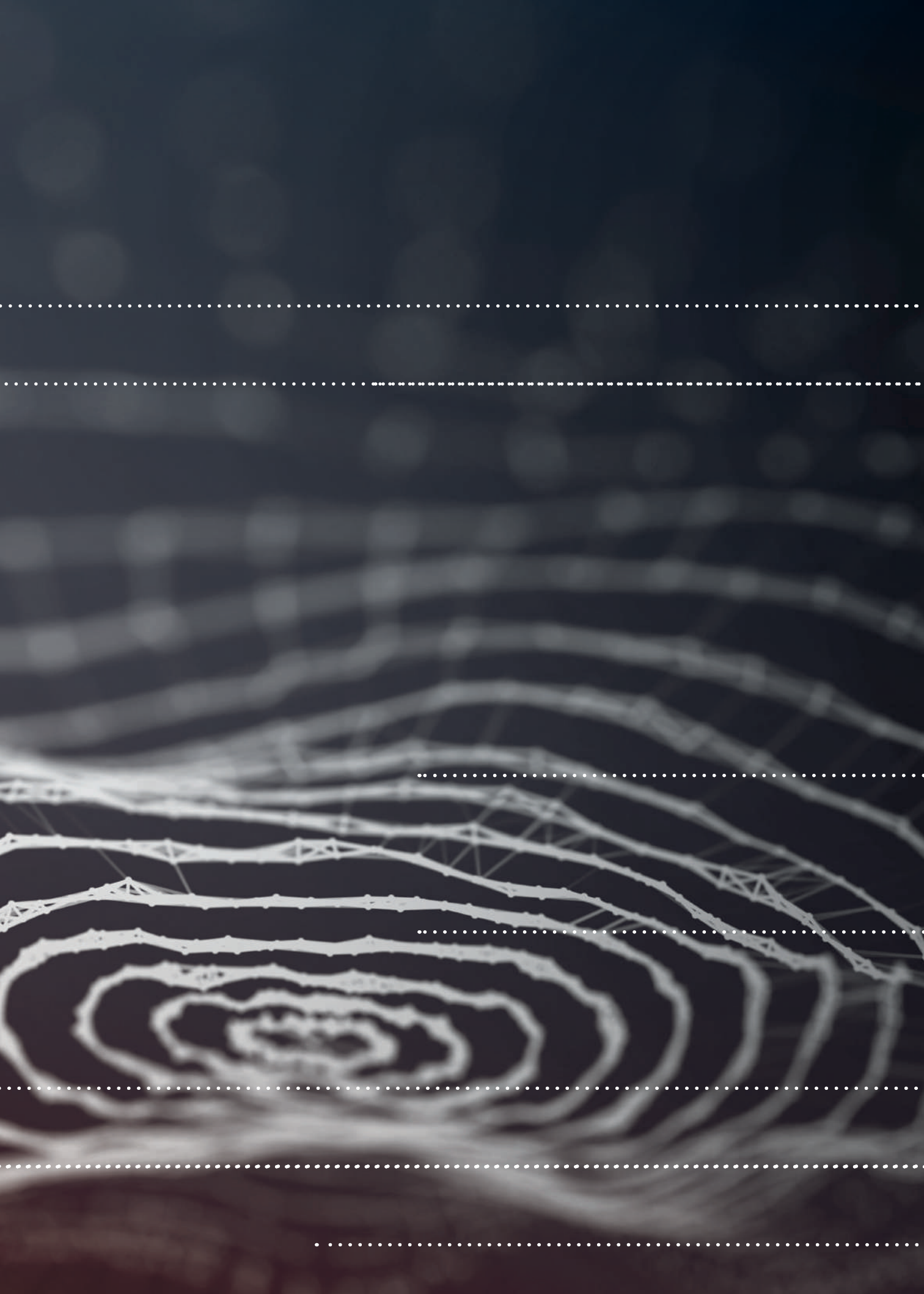
Fleming Initiative (https://www.fleminginitiative.org)

The Fleming Initiative is[15] a joint effort between the Fleming Centre, at Imperial College London and the Imperial College NHS Healthcare Trust to jointly promote solutions to antimicrobial resistance through interaction with patients, the public and policymakers. Research is based on concepts from behavioral science and public engagement. Strategies and actions, focused on the UK, aim at influencing individual conduct and policy decisions on the issue of AMR.

Centros para a Rede de Otimização AntiCenters for the Antimicrobial Optimization Network, known as CAMO-Net

CAMO-Net is a global multidisciplinary network funded by the Wellcome.org, comprised of research institutions with solid expertise in AMR. The centers are in 13 locations in 11 countries, primarily in the Global South, where the impact of AMR is more severe and disproportionate. The Net's mission is to complement and strengthen existing global programs, promoting a sustainable, equitable, and collaborative research ecosystem focused on reducing the impact of AMR and neglected infections. The initiative seeks to optimize the use of antimicrobials in humans through the generation of high- quality scientific evidence. In Brazil, the CAMO-Net center is located at the Faculty of Medicine, University of São Paulo, under the leadership of Professors Anna Levin and Silvia Costa. The Brazilian team focuses on supporting decisions on antibiotic prescribing in the community, implementing interventions in primary care in a heterogeneous urban population, as well as monitoring wastewater and asymptomatic carriers to assess impacts and trends. Accessible at:[https://camonet.org/].

15. The DxAMR project aims to improve equitable access and effective use of diagnostics for antimicrobial resistance (AMR). It is supported by the Fleming Initiative. Available at: https://dxamr.com/. Accessed on: February 2, 2026.



CHAPTER**05**

GLOBAL ACTION PLAN FOR THE LABORATORY DIAGNOSTICS AREA: TACKLING AMR AND STRENGTHENING THE BACTERIOLOGICAL AND MYCOLOGICAL DIAGNOSTIC CAPACITIES OF, AND ACCESS TO, LABORATORY SYSTEMS

Comprehensive action plan for the laboratory diagnostics system to tackle the AMR question – aimed at strengthening bacteriological and mycological diagnostic capacity of, and access to, laboratory systems

Strengthening bacteriological and mycological capacities is essential to achieving the goals of reducing the burden of major infectious diseases such as HIV, tuberculosis, and malaria by 2030.

In 2023, the WHO and Member States committed, through Resolution WHA 76.5 "Strengthening Diagnostic Capacity", to developing national strategies and global initiatives to expand access to quality diagnostics, strengthening local diagnostic capacity and expanding equitable access to effective tests.

The Initiative's main objective is to position diagnostics as a core element in the global response to Antimicrobial Resistance. It seeks to support member countries in strengthening the capacity of microbiology laboratories and promoting equitable access to quality diagnostic tests for resistant bacteria, fungi, and other pathogens, at different levels of health systems and within the community,through new technologies and testing environments, and particularly in primary care.

The initiative also aims to ensure the appropriate use of diagnostics, in order to contribute to the clinical management of patients, the rational use of antimicrobials, the prevention and control of infections, the investigation of outbreaks, and the routine monitoring of adverse drug reactions (ADRs).

The initiative seeks to tackle the challenges of conducting bacteriological and mycological tests. These challenges include underfunding, inadequate planning, limitations in standardization and quality assurance, irregular acquisitions, maintenance problems, direct costs to patients, and low confidence levels among healthcare professionals regarding laboratory results.

Addressing these challenges envisages actions to encourage local production, the simplification of regulatory approaches, overcoming quality and access barriers, and promoting research and innovation.

The group of members of the "Initiative" have already drawn up a plan with four lines of action aimed at supporting Member States to set their own achievable strategic objectives and core activities required to create an effective national system of clinical bacteriology and mycology laboratories FIGURA 5.

- **STRATEGIC AND OPERATIONAL STRUCTURE:** defines standards and provides guidelines for implementing actions aimed at strengthening bacteriology and mycology laboratory services.

- **STANDARDIZED ASSESSMENT MECHANISMS:** utilizes standardized tools to assess, monitor, and report on the capacity of bacteriology and mycology laboratories, both nationally and globally.

- **GLOBAL NETWORK OF AMR LABORATORIES:** composed of laboratories designated by the WHO to conduct bacteriological, mycological and antimicrobial susceptibility tests, operating at national, supranational and specialized levels.

- **RESEARCH AND INNOVATION:** focused on improving the accuracy, speed, and applicability of AMR diagnostic tools.

The group also suggests increasing investments in infrastructure, training, quality, and access to bacteriological and mycological testing, integrating these services into health systems in a broader and more sustainable way.

FIGURE **05**

THE FOUR BASIC COMPONENTS OF NATIONAL STRATEGIES SUGGESTED BY THE ANTIMICROBIAL RESISTANCE DIAGNOSTIC INITIATIVE

SOURCE: WHO (2024).

In line with the basic generic components FIGURA 5, the report of July 2023 "*Technical consultation on the WHO Antimicrobial Resistance Diagnostic Initiative: strategic and operational framework for strengthening bacteriology and mycology diagnostic capacity*" sets forth certain strategic objectives to be achieved in the AMR diagnostics area.

The first objective will be the strengthening of governance and resource allocation to promote bacteriological and mycological diagnostic services, recommending that bacteriological and mycological diagnostic capacities be integrated into existing health structures, with specific representative units embedded in Ministries of Health, and the designation of precise diagnostic functions at the national level, tailored to the various countries' different structures. The 2023 Report also recommends the development of a national operational plan containing estimated costs for the diagnostic services to ensure that funds and other resources are appropriately allocated. The proposed cost management strategies include joint procurement, local production, and strategic involvement by the industry.

The second goal is to provide equitable access to bacteriological and mycological diagnostic services throughout the health system. Concerned with the population's ability or willingness to present for such tests, the group has proposed the development of a list of essential diagnostic tests.

The essential list of bacteriological and mycological diagnoses needed at each level of the healthcare system will aid effective planning, resource allocation, and the standardization of care protocols.

Testing in bacteriology and mycology includes rapid and point-of-care tests, microscopy, culture, antimicrobial susceptibility testing, serology, and molecular tests.

A list of these tests aligned with the WHO List of Essential In Vitro Diagnostics should be made readily available throughout the health system. Guidelines are also required to enable countries to implement the tests systematically at the different levels of their healthcare systems.

Dr. Chad Centner, of the WHO's AMR Division, has published a roadmap to define the allocation of priority bacteriology and mycology tests across health systems, outlining parameters for different test modalities: disease-specific rapid and point-of-care tests, microscopy, culture and antimicrobial susceptibility testing, and molecular tests. The availability of tests will depend on the context in which they are used, thus the need for georeferencing. Dr. Centner points out that demographic data and population risk factors will inform testing capacity depending on the local context (WHO, 2024).

Evaluating people-centered factors raises concern about testing costs. Consideration therefore needs to focus on areas such as social welfare, including patients' out-of-pocket direct payments for treatment and whether they are willng to accept

testing at all. Ensuring equitable access must involve both the for-profit and non-profit private sectors.

The third objective refers to safeguarding high-quality bacteriological and mycological diagnostic services, including national and external quality assurance programs. The development of training programs and curricula is also necessary for tackling the challenges of retention and equitable distribution of qualified staff. Technical feasibility must be also be considered, since it is heavily dependent on suitable equipment, infrastructure, human resource capacity, and robust quality assurance. Processing criteria, access to specialized resources, adequate incubation conditions, accurate identification capabilities, and staff proficiency in performing antimicrobial susceptibility testing, play crucial roles in determining technical requirements.

The fourth objective concerns fine-tuning the use of bacteriological and mycological data and diagnostic services. The group highlighted the need to involve a wide range of national stakeholders, to include pharmacists, nursing staff, hospital administrators, physicians, and the MoH, finance and higher education representatives, to ensure the best possible use of bacteriological and mycological diagnostic services and data. The targeted use of diagnostics in patient care needs to be considered, as well as the consolidated management and effective data use at the laboratory, national, regional, and global levels. Digital and innovative technologies should be used for the interpretation of results, communication, and data analysis.

Dr. Mikashmi Kohli (of FIND) has presented a study on enhancing the diagnostic network and its application to AMR. The Lancet Commission on Diagnostics pointed to a gap in access to diagnosis. According to Kholi's paper and the WHO (2024), the population segment suffering an undiagnosed condition varies between 35% and 62%, emphasizing the crucial need for upgrades in diagnostic capabilities. Diagnostic network optimization is a geospatial analysis approach aimed at improving diagnostic networks, recommending the creation of a digital twin of a country's diagnostic network to test various hypothetical scenarios. This includes modeling customized testing strategies, evaluating trade-offs in terms of access, utilization, cost, and impact, and considering the inclusion, relocation, or replacement of existing tools.

The benefits of optimizing the diagnostic network include minimizing overall network costs, generating insights into the demand, capacity and utilization of tests, and facilitating country-led coordination for planning and implementation by partners (WHO, 2024).

The outcomes of diagnostic network optimization include visualizing and conducting gap analyses of laboratory capacity relative to demand, acquiring new devices, relocating devices, adding new laboratory shifts, and establishing new routing sys-

tems for samples. Optimization can provide a data-driven methodology to address the diagnostic disparity, ensuring that diagnostic networks are not only efficient but also tailored to the unique challenges and priorities of each country. Diagnostic network optimization can also be used to inform the allocation of diagnostics: for example, determining which hospitals among a group of hospitals with an equal number of beds should host a laboratory analysis facility targeted atr AMR detection. Countries using diagnostic network optimization should consider addressing multiple programs rather than focusing on single diseases.

CHAPTER**06**

INITIATIVES TO COMBAT AMR UNDERWAY IN BRAZIL (UP TO 2025)

Initiatives underway to combat AMR in Brazil (up to 2025)

Brazil has a long-standing Surveillance Program led by the National Health Surveillance Agency (Anvisa), which compiles data on Health Associated Infections (HAIs).

Since 2014, Anvisa has been systematically collecting and analysing data from all the hospitals with ICU beds used for HAIs, especially concerning bloodstream infections requiring the use of catheters (CRBSIs or Catheter-Related Bloodstream Infections) and their microbial resistance markers. In 2017, 72% of Brazilian hospitals provided data on laboratory-confirmed bloodstream infections.

Even with surveillance spearheaded by Anvisa, an AMR-related data gap persisted in Brazil, notwithstanding the One Health approach aimed at highlighting the need to monitor not only resistant nosocomial bacteria[16] but also the most common community isolates.

In 2016 and 2017, discussions were held to prepare Brazil's Plan for tackling AMR (PAN-BR).

16. Nosocomial bacteria, also known as hospital-acquired bacteria or healthcare-associated bacteria acquired during stays in hospitals or other health institutions.

In parallel with the development of the PAN-BR, technical documents on antimicrobial resistance were developed, such as the National Guideline for the Development of Antimicrobial Management Programs in Healthcare Services, published by Anvisa in 2017. The Brazil Management Project[17] fwas developed in 2019 to assess antimicrobial management programs in Brazilian hospitals with adult ICU beds.

In terms of coordination and planning, the Ministry of Health established in 2017 the Working Group for the Analysis of Methodologies for Sensitivity Tests used in Microbiology Laboratories (GT-TSA),[18] composed of representatives from the human and animal health sectors.

In 2018, the GT-TSA resolutions made way for key advances in the standardization of the method for interpreting antimicrobial susceptibility tests, and the implementation of a unified network for monitoring antimicrobial resistance in Brazil.

The Brazilian Global Antimicrobial Resistance Surveillance System (BR-GLASS) was installed in 2018 as a pilot project in sentinel hospitals in the state of Paraná.

Brazil's accession to GLASS in 2017

Pillonetto et al. (2021) records that Brazil joined GLASS In December 2017. From January 2018, Brazil commenced its own national antimicrobial surveillance program (BR-GLASS) aimed at understanding the impact of resistance in the country. A BR-GLASS pilot project was launched, also in 2018, in the state of Paraná.

Paraná was selected to host the pilot project due to the state's technical capacity and certain epidemiological factors, such as prior experience in controlling hospital infections, expertise in public health laboratories, an extensive health surveillance system, and a number of different dynamic hospital environments.

The GLASS Program adopts a distinct approach to Health Associated Infections - those acquired by patients during healthcare provision in hospitals, outpatient clinics, intensive care units,or other healthcare facilities that were not present or incubating in the patient before hospitalization.

17. Notícias. Anvisa. Disponível em: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2019/anvisa-e-abih-lancam-projeto-stewardship-brasil. Acesso em: 14 dez. 2025.

18. Ministério da Saúde. Portaria GM/MS n. 125, de 18 de janeiro de 2017. Brasília (DF): Diário Oficial da União. 2017. Disponível em: https://bvsms.saude.gov.br/bvs/saudelegis/gm/2017/prt0125_18_01_2017.html. Acesso em: 02 jul. 2025.

The moment of admission is used for data collection and analysis, incorporating a broader 'One Health' perspective. This approach includes obtaining information on antimicrobial resistance in isolates from both inpatients and outpatients. The program also provides for real-time monitoring of participating health services through interactive control panels.

Following the decision to join GLASS, the Brazilian Ministry of Health designated the General Coordination of Public Health Laboratories (CGLAB) of the Department of Strategic Actions in Health Surveillance (DAEVS) as the National Coordination Center for BR-GLASS and designated the Central Public Health Laboratory of Paraná (LACEN-PR) as the National Reference Laboratory (LNR) responsible for taking the BR-GLASS Program forward.

Between December 2017 and December 2018, a multidisciplinary team – composed of microbiologists, infectious disease control specialists, information technology experts, and statisticians – developed a strategic plan for the implementation of the National Antimicrobial Resistance Surveillance Program (BR-GLASS) with the objective of significantly expanding the scope of surveillance, and to analyse all possible samples and etiological agents in different healthcare settings while remaining aligned with the principles and methodologies established by the GLASS program. In July 2019, following a qualification and validation process, Brazil submitted its first consolidated data GLASS collected from three participating hospitals (Pillonetto *et al*., 2021).

The original BR-GLASS plan stipulated that the program would be gradually expanded to other states annually and be operational in 95 sentinel hospitals in at least 15 states across Brazil's five different geographic regions after five years.

Selection of analyses for data submission and compilation of BR-GLASS

The Information Technology (IT) team at BR-GLASS receives data from the Hospital Information System (HIS) in the form of compilations of tables containing key patient information. These tables exhibit patient hospital registration number, age, sex, patient origin (hospital or community), date of admission, sample collection time, type of biological sample, bacterial identification, and antimicrobial susceptibility test results (Pillonetto *et al*., 2021).

The hospital teams (infection control professionals, microbiologists, and IT specialists) in each sentinel unit are able to access an online platform via [https://gae.saude.[gov.br/], to view and analyze the data of the respective hospital. Access to the platform is restricted, requiring authentication with a unique login and password.

Only the National Coordinating Center and the National Reference Laboratory are permitted to access the consolidated data from all the participating hospitals. The program provides for the annual release of aggregated results for the benefit of public health professionals: physicians, infection control specialists, microbiologists, and hospital managers, etc. (Pillonetto *et al.*, 2021).

All the samples delivered to routine microbiology laboratories are eligible for inclusion in the program, while only positive cultures accompanied by antimicrobial susceptibility test results aree considered. The three participating institutions used automated methods to determine the minimum inhibitory concentration (MIC) of the tested antimicrobials, except in cases where such methodology was not recommended (Pillonetto *et al.*, 2021).

Infection was considered community-acquired if the sample was collected from outpatients or collected less than 48 hours after admission. Exclusion criteria: more than one isolate of the same species from the same sample within 12 months; incomplete results; and no antimicrobial susceptibility test results made available.

Selection of hospitals participating in BR Glass in 2018

Of a total of 429 hospitals in Paraná, 32 met the cutoff criteria (having more than 20 ICU beds in general (adult ICUs, neonatal ICUs, and other ICU modalities). Participation in the program required the presence of 20 ICU beds, inpatient and outpatient services, an active infection control team, and an external laboratory quality control program.

The established criteria required the presence on the team of at least one hospital epidemiologist and one clinical microbiologist. Technical capacity to execute resistance detection protocols using phenotypic and genotypic methods was also obligatory, as well as the hospital's formal membership of the Anvisa surveillance program.

Eleven of the 32 hospitals (34.4%) surveyed met the minimum requirements and scores for enrollment in the program. The program got underway in December 2018, and by October 2019, three hospitals had completed the data submission for all the 2018 isolations (Pillonetto *et al.*, 2021).

It is worth highlighting the importance of establishing public-private partnerships as a way of accelerating the application of an AMR surveillance system for the broad-scale implementation of BR-GLASS.

The Brazilian National Action Plan for the Prevention and Control of Antimicrobial 19 Resistance (PAN-BR) 2018-2022[19]

The Brazilian National Action Plan for the Prevention and Control of Antimicrobial Resistance (PAN-BR) 2018-2022 was developed in line with the objectives of the three-pronged alliance between the WHO, the UN Food and Agriculture Organizations (FAO) and the OIE, and presented in the Global Action Plan on Antimicrobial Resistance.

The overall objective of the action plan is to guarantee the capacity to treat and prevent infectious diseases with safe and effective medical drugs, ensuring quality, responsible use and accessibility to all who need them.

To tackle the challenges of control and prevention, PAN-BR brought together several key players: the Ministry of Health (MoH), Anvisa, Ministry of Agriculture, Livestock and Supply (Mapa), the Ministry of Cities (MCidades), the Ministry of Education and Culture (MEC), the Ministry of Science, Technology, Innovation and Communications (MCTIC), the Environment Ministry (MMA), the National Health Foundation (Funasa). Additional support was provided by the National Health Council (CNS) and the National Water Agency (ANA).

To strengthen the PAN-BR actions, governance structures (e.g. specific committees instituted by government decrees) were established in the entities directly involved in the topic.

In addition to the committees, joint discussions and meetings were held with the aim of developing viable priority interventions with a multidisciplinary and multisectoral approach. Tthe Strategic Plan of PAN-BR 2018-2022 embraced 14 Main Objectives, 33 Strategic Interventions, Iand 75 Activities, aligned with the 5 Strategic Objectives of the Global Action Plan. Meanwhile, other bodies and institutions went ahead to publish their own operational and monitoring plans: MAPA (Ministry of Agriculture, Livestock and Supply), ANVISA (National Health Surveillance Agency) etc,.

19 . Health. Publications. National Action Plan for the Prevention and Control of Antimicrobial Resistance within the One Health Framework: 2018-2022. Available at: https://www.gov.br/health/pt-br/topics/health-of-a-az/u/uma-so-saude/publicacoes/national-action-plan-for-prevention-and-control-of-resistance-to-antimicrobials-in-the-environment--from-one-health--2018-to-2022#:~:text=O%20PAN%2DBR%20has%20validity%20of%20five%20year%2C,Objectives%20Main, 33 Strategic Interventions and 75. Accessed on: December 14, 2025.

Following the publication of PAN-BR, changes were made regarding coordination of the human health sector.

> *In 2021, the Antimicrobial Resistance Technical Group (GTAMR) was established to coordinate the actions of the National Antimicrobial Resistance Program (PAN-BR) within the Ministry of Health, meeting on a regular 6 months basis. According to Government Ordinance 157/2021, Anvisa established a working group to develop, evaluate, and monitor the actions and activities established in the Action Plan for the Health Surveillance of Antimicrobial Resistance (PAN-VISA), which now meets every two months. No interministerial commission or technical group was identified to coordinate policies and actions in the human, animal, and environmental health sectors (Nunes Aguiar et al., 2023, p. 8).*

The National Plan 2025-2030

André Luiz de Abreu, a member of the AMR technical group of the MoH in the 2025 administration, presented on January 21, 2025 in an online seminar "Engagement and awareness in the prevention and control of antimicrobial resistance in Brazil[20] the National Action Plan to Prevent and Combat Antimicrobial Resistance 2025-2030 (2nd edition currently under review). The Plan's actions are conducted by the Antimicrobial Resistance Technical Group (GTAMR), responsible for discussing and monitoring the implementation of the National Action Plan.

In addition to monitoring and evaluating surveillance, overseeing control and protection/prevention actions against AMR, the GTAMR is charged with reviewing MoH actions concerning the revision of the PAN-BR. Although the GT-AMR is within the purview of the MoH, it may invite official bodies linked to the Ministry of Health to participate in its meetings (e.g., staff from the Federal Government, specialists in AMR issues, representatives of social movements, etc.

It is worth noting that the period of the Plan's validity extends beyond the Federal Government's current mandate.

20. Seminar. Ministry of Health. Available at: https://www.youtube.com/live/Sj9q4hddFoA. Accessed on: December 14, 2025.

The VigiRAM[21] platform

Although a new specific national plan for the Prevention and Control of Antimicrobial Resistance in Brazil has not yet been formally presented, the VigiRAM platform is an initiative dedicated to the surveillance, prevention and tackling of antimicrobial resistance in Brazil.

The initiative is funded by the United States Centers for Disease Control and Prevention (CDC/USA) and coordinated by the Oswaldo Cruz Institute (IOC/Fiocruz) Laboratory of Bacteriology Applied to One Health and Antimicrobial Resistance, the General Coordination of Public Health Laboratories of the Ministry of Health (CGLAB/MS), and the Central Public Health Laboratory of Paraná (Lacen-PR).

VigiRAM functions as a national hub, consolidating guidelines, protocols, scientific publications, training, and educational materials focused on the surveillance and prevention of AMR. The platform also supports research and innovation activities, encouraging collaboration between institutions, health professionals, and researchers in the area of expertise.

The initiative is part of the project "Strengthening a Brazilian System for Surveillance and Prevention of Antimicrobial Resistance (AMR)", funded by the CDC/USA through grant CD--C-RFA-CK21-2104, aimed at building an effective national system to monitor, prevent and combat AMR in Brazil.

The main aims of this digital platform are: to provide data and educational materials; raise awareness; improve interaction and communication; foster institutional cooperation; and support research and innovation.

There are no GLASS georeferenced data in VigiRAM (at least not publicly available). Strategic partners linked to the VigiRAM platform include the Oswaldo Cruz Institute (IOC/Fiocruz), Laboratory of Bacteriology Applied to One Health and Antimicrobial Resistance), which undertakes research, teaching, technological development, and scientific dissemination activities focused on applied bacteriology in the context of

21. The web page address is [https://vigiram.org.br/o-projeto/].

One Health, with an emphasis on antimicrobial resistance, and is also responsible for important biological collections: the Collection of Cultures of Bacteria of Hospital Origin and the Collection of Cultures of the Bacillus Genus and Correlated IOC Genera.

Carneiro and Pillonetto (2025, pp. 1-10) also detail the efforts on the prevention and control of AMR in Brazil.

Expert assessment of the current situation in Brazil

At a seminar on July 1, 2025 at the French Consulate General in Rio de Janeiro (sponsored by the BioMérieux): *"Resistance to Antibiotics in a One Health context: An agenda for the future of public health,"* clinical pathology experts reported the following challenges to be overcome in Brazil:

IMPROVE DATA EXCHANGE AND INTER-TEAM COORDINATION TO FACILITATE AMR MANAGEMENT: AMR management faces serious challenges due to data fragmentation and the lack of interoperability between systems. The absence of multiplex PCT panels (i.e., multiplex laboratory tests based on real-time PCR, used for the simultaneous detection of multiple pathogens (and, in some cases, resistance genes based on a single clinical sample) that differentiate bacterial from viral infections, and the shortage of integrated monitoring, pose an obstacle to clinical decision-making and strategic AMR management. It is essential to promote greater integration between laboratories, physicians, clinicians, communication teams, and technical trainers. The present discussion about AMR is generally confined to specialized groups, with little awareness by the population, and often even among GPs. Wide-ranging and effective awareness policies are urgently needed.

USING METRICS FOR DETECTION, MONITORING, AND IMPACT: Environmental surveillance is still in its early stages, despite its importance. Evaluating wastewater, especially hospital wastewater, to isolate pathogens, is a low-cost, high-impact public health action. Moreover, it is essential to establish and standardize metrics such as "average length of ICU stay", outcomes (including mortality), antimicrobial consumption (in Defined Daily Dose-DDD), treatment costs, productivity loss (DALYs), and cost- effectiveness studies related to adverse drug reactions (ADRs).

DEVELOPING PUBLIC POLICIES: There is an urgent need to formulate a National Plan to Combat AMR that addresses the human, animal, and environmental aspects in a comprehensive manner (the 'One Health' approach). Brazil is significantly behind in the regulation of AMR in the animal sector, in contrast to countries like

France. It is necessary to strengthen enforcement mechanisms, including the requirement for mandatory reporting of cases of microbial resistance. A policy specifically for the diagnostic sector is essential for the effective control of AMR.

IMPROVING INFRASTRUCTURE AND ACCESS TO DIAGNOSIS AND TREATMENT: Despite the absence of a coherent plan and the investment in 2024 by the Federal Government of R$84 million to expand laboratory capacity, inequality in laboratory infrastructure persists. It is essential to increase local capacity for producing inputs, in vitro products, and diagnostic services. Money saved on expensive medications and treatments (antibiotics and catheter use, etc.,) could be redirected to earlier diagnoses, with more positive impacts on public health.

6.1. ORGANIZATION OF PUBLIC LABORATORY NETWORKS AND THE MICROBIAL RESISTANCE MONITORING NETWORK IN BRAZIL

The General Coordination of Public Health Laboratories of Brazil (CGLAB) and the National System of Public Health Laboratories (SISLAB)

In Brazil, CGLAB, linked to the Ministry of Health, was established by Ordinance No. 1,419, of June 8, 2017. It is responsible for the National Network of Epidemiological Surveillance Laboratories and the National Network of Environmental Health Surveillance Laboratories, which form SISLAB (Brazil, 2017a; 2017b; 2017c; 2021).

CGLAB is linked to the Department of Strategic Coordination of Health Surveillance (DAEVS), of the Secretariat of Health and Environment Surveillance (SVSA). Its work focuses on areas that contribute to the study and resolution of key public health events, providing accurate laboratory data to enable the SVSA to make decisions and adopt appropriate measures. CGLAB is responsible for:

> coordinating, supervising, and advising the national network of epidemiological surveillance and environmental health laboratories, in order to develop technical excellence for laboratory diagnostics and support decision-making within the health surveillance system at the national and international levels. TABLE 5 (Guide, Brazil, 2021, p. 12).

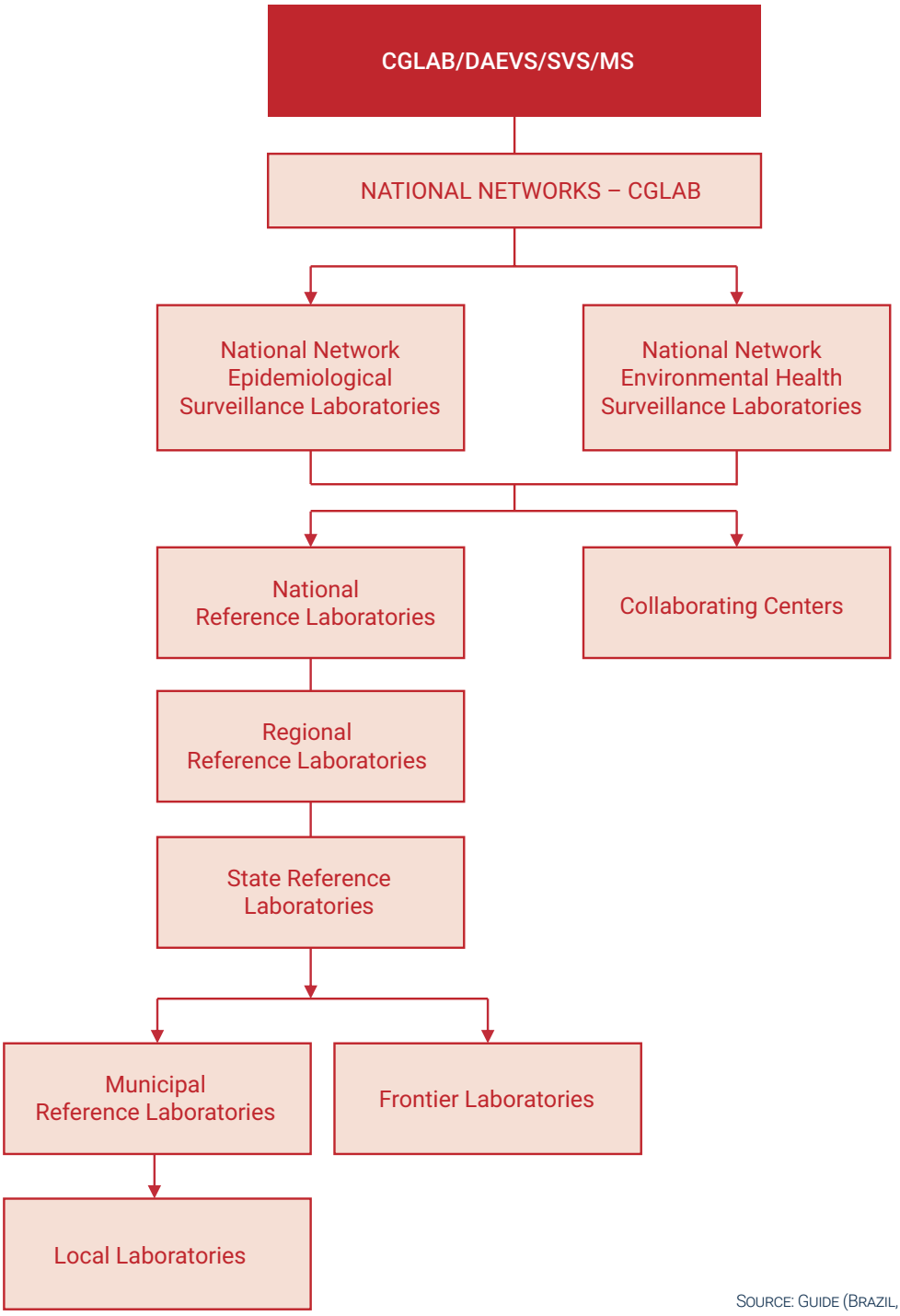
Sislab

Sislab is a system organized into sub-networks by disease or program, hierarchically structured according to degree of complexity. Established by Ordinance GM/MS No. 2,031, of September 23, 2004, Sislab is aligned with the principles of Brazil's Unified Health System (SUS).

FIGURE 6 shows the organization of CGLAB/SISLAB, and the responsibilities of the National Laboratory Networks are outlined i TABLE 5.

FIGURE **06**

FLOWCHART: LABORATORY NETWORKS COORDINATED BY CGLAB/SISLAB



SOURCE: GUIDE (BRAZIL, 2021, P. 9).

TABLE **05**

MAIN RESPONSIBILITIES OF NATIONAL LABORATORY NETWORKS

NATIONAL NETWORKS	MAIN ACTIVITIES (PROBLEMS OR PROGRAMS)
Epidemiological monitoring	• Diagnosis of diseases subject to mandatory reporting • Surveillance of communicable and non-communicable diseases • Monitoring of antimicrobial resistance • Defining the standardization of diagnostic kits to be used in the network
Environmental monitoring	• Monitoring the quality of water for human consumption • Monitoring of air and soil quality • Monitoring of physical, chemical and biological environmental factors (vectors, hosts, reservoirs and venomous animals) • Monitoring of human populations exposed to biological, chemical, and physical environmental factors
Health surveillance	• Food, medicines, cosmetics and cleaning products • Immunobiologicals and blood products • Human toxicology • Biological and non-biological contaminants in health-related products • Products, materials and equipment for use in healthcare • Surveillance at ports, airports and borders
Medical assistance	Complementary support for diagnosing diseases and other health issues

SOURCE: GUIDE (BRAZIL, 2021, P. 9).

Antimicrobial Resistance Monitoring Network in Brazil

The *Guide for Laboratory Diagnosis in Public Health – Guidelines for the National System of Public Health Laboratories* provides information on the working of Sislab, in addition to describing all the procedures involved in the stages of Laboratory Diagnosis of Compulsory Notifiable Diseases (DNC) established by Consolidated Administrative Regulation GM/MS No. 4, of September 28, 2017 (Brazil, 2017).

The Guide describes all the procedures, methodologies, and workflows that samples must follow, and the necessary measures to be taken for the preservation, proces-

sing, and ransportation, as well as aspects of laboratory biosafety that involve the pre-analytical, analytical, and post-analytical processes.

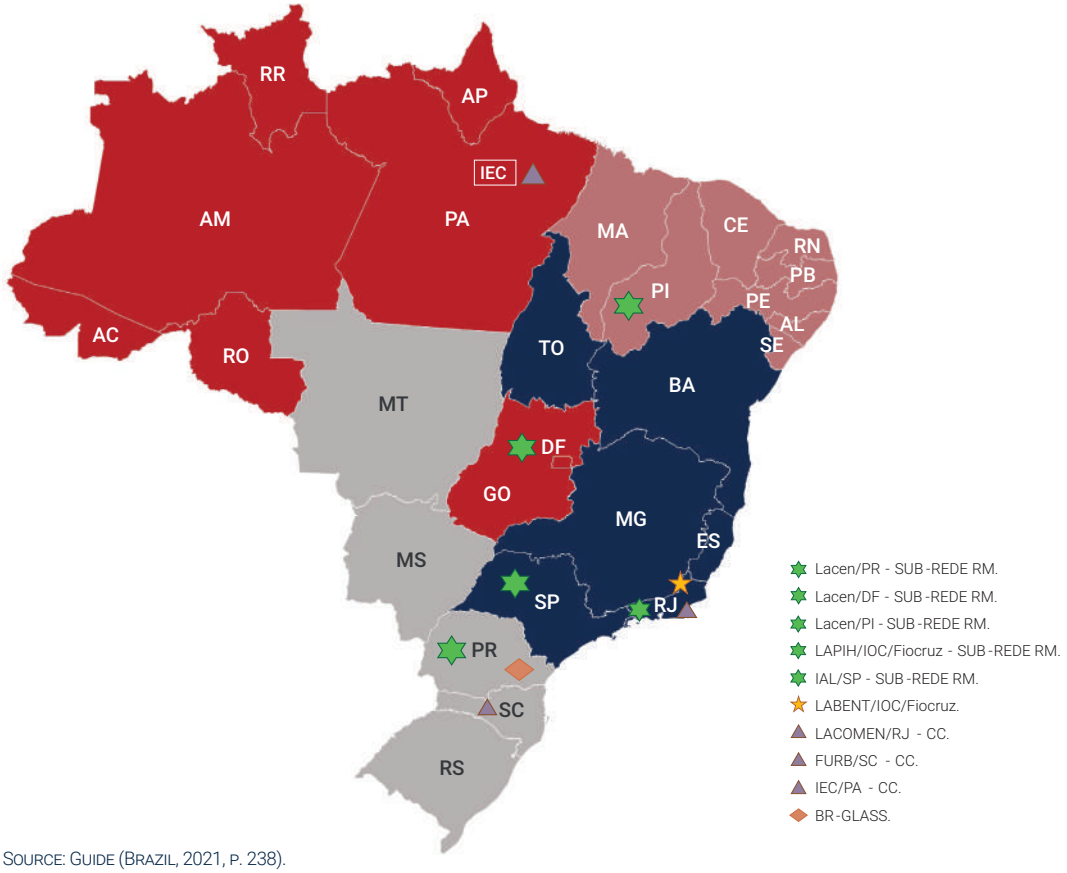
Precautions involve inter alia standardizing laboratory practices and routines to ensure technical efficiency and quality, thus directly or indirectly improving the process of combating AMR as a whole.

The Guide also cites the Reference Networks and the professionals responsible for individual health issues in the Central Public Health Laboratories (Lacen), State Reference Laboratories (LRE), National Reference Laboratories (LRN), Regional Reference Laboratories (LRR), and the Collaborating Centers (CC).

The Microbial Resistance Monitoring Network in Brazil comprises the laboratories (regional and others as shown in FIGURE 7 and TABLE 6.

FIGURE **07**

MICROBIAL RESISTANCE MONITORING NETWORK IN BRAZIL BY REGION



SOURCE: GUIDE (BRAZIL, 2021, P. 238).

TABLE **06**

MICROBIAL RESISTANCE MONITORING LABORATORIES IN BRAZIL

LABORATORY	IDENTIFICATION	SENSITIVITY TEST (TSA)	PHENOTYPIC TRIAGE FOR AMR	MOLECULAR BIOLOGY
Lacen/PR[2] – RM subnetwork, Lacen/DF – RM Subnetwork	Culture; mass spectrometry	Sensitivity test	Phenotypic screening for AMR[3]	PCR
Lacen/PI – Sub-rede RM	Culture	Sensitivity test		PCR
LAPIH/IOC/ Fiocruz[1] – Sub-rede RM; Labent/IOC/ Fiocruz	Culture; spectrometry mass	Sensitivity test	Phenotypic screening for AMR	PCR; sequencing
IAL/SP – Sub-rede RM; IEC/ PA – CC	Culture	Sensitivity test	Phenotypic screening for AMR	PCR
Lacomen/RJ[4] – CC	Culture (food samples)	Sensitivity test		PCR
Furb/SC – CC	Culture (*S. aureus*)	Sensitivity test	Phenotypic screening for AMR	PCR
Todas as UF	Culture	Sensitivity test		

SOURCE: GUIDE (BRAZIL, 2021, P. 239).

NOTES:

1. Lapih/IOC/Fiocruz performs molecular characterization of multidrug-resistant Gram-negative bacilli and Gram-positive cocci (VRE, MRSA, and VRSA) for the entire national territory, when necessary. Labent/IOC/Fiocruz is a Local Research Network (LRN) for Community Resistance to bacterial enteroinfections.
2. Lacen-PR is part of the coordination of the National Program for Surveillance and Monitoring of Antimicrobial Resistance (BR-GLASS), together with CGLAB/Daevs/SVS.
3. AMR – Antimicrobial Resistance.
4. Lacomen-RJ – Food Microbiological Control Laboratory of the School of Nutrition.

The distribution of the state LACENs (Central Public Health Laboratories) is as shown in TABLE 7, in accordance with Ordinance GM/MS No. 3,120/2013.

TABLE **07**

DISTRIBUTION OF THE LACENS (CENTRAL PUBLIC HEALTH LABORATORIES) OF THE STATES SERVED BY THE REFERENCE LACENS FOR THE ANALYTICAL SUB-NETWORK ON MICROBIAL RESISTANCE

REFERENCE LACEN FOR THE AMR SUBNETWORK	STATES SERVED
Federal District	Acre, Amapá, Amazonas, Goiás, Pará, Rondônia, Roraima.
Paraná	Mato Grosso, Mato Grosso do Sul, Rio Grande do Sul, and Santa Catarina.
Piauí	Alagoas, Ceará, Maranhão, Paraíba, Pernambuco, Rio Grande do Norte.
São Paulo	Bahia, Sergipe, Tocantins, Espírito Santo, Minas Gerais and Rio de Janeiro.
Lapih – Fiocruz	Intended to perform the analysis of samples forwarded by the Lacens (from the sub-network or from the states), when the reference laboratories of the sub-network do not have sufficient operational capacity or if the demand of the sub-network is exceeded

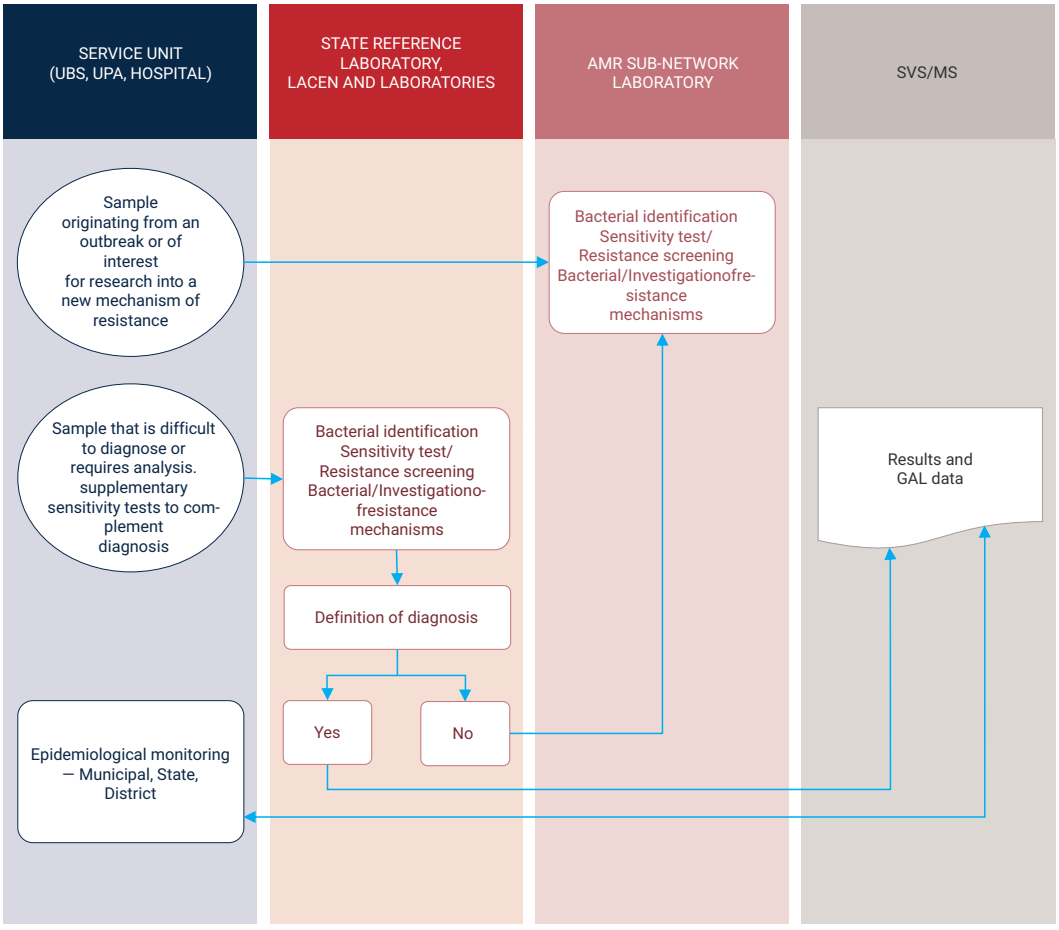
SOURCE: GUIDE (BRAZIL, 2021, P. 241).

All laboratory data in Brazil is centralized and registered in the GAL System (Laboratory Environment Management). The evaluation and analysis of this data allows for understanding the epidemiological profile of diseases, trends, and indicators that strengthen decision-making, especially during public health emergencies in Brazil.

The flow of bacterial sample collection is shown in FIGURE 8:

FIGURE **08**

LABORATORY FLOW ALGORITHM FOR THE MICROBIAL RESISTANCE MONITORING NETWORK



SOURCE: GUIDE (BRAZIL, 2021, P. 242).

The Guide (Brazil, 2021) contains other useful information, such as instructions for collecting and forwarding samples for laboratory diagnosis within the antimicrobial resistance monitoring network.

The Ministry of Health SenGono Project

Brazil is one of the member countries of a program that monitors the susceptibility of gonococcus to antimicrobials through the SenGono Project.

The Ministry of Health – through the Department of HIV, AIDS, Tuberculosis, Viral Hepatitis and Sexually Transmitted Infections of the Secretariat of Health Surveillance and Environment – monitors the sensitivity of gonococcus to antimicrobials through the SenGono (Gonococcus Sentinel) initiative, coordinated by the Laboratory of Molecular Biology, Microbiology and Serology of the Federal University of Santa Catarina (UFSC), under the responsibility of Dr. Maria Luiza Bazzo, in partnership with states, municipalities, assistance services and local laboratories.

Surveillance involves collecting and processing samples, identifying the etiological agent, gathering epidemiological data, and defining the sensitivity profile, among other analyses essential for developing the strategy.

6.2. ASSESSMENT OF BRAZIL'S APPROACH TO MONITORING THE INCIDENCE OF AMR USING WHO INDICATORS

Brazil's Performance According to the Country Self-Assessment Survey (TrACSS)[22]

In order to monitor countries' progress in implementing national action plans to combat AMR, the FAO, WHO, WOAH and UNEP jointly manage the annual country self-assessment survey entitled the Global Database for Tracking Antimicrobial Resistance (AMR) (TrACSS).

The WHO assessment is calculated by assigning points to questionnaire responses and comparing them between member states. The metrics are as follows:

- **A – NONE –** there is no formal multi-sectoral governance or coordination for AMR.
- **B – LIMITED –** multi-sectoral coordination mechanism on AMR established under government control.
- **C – DEVELOPED –** Formalized multi-sectoral coordination mechanism with technical working groups in place. The multi-sectoral working group(s) are functional, with designated ToR and responsibilities, regular meetings, activities and accountability.
- **D – DEMONSTRATED –** joint work on issues that include agreement on common objectives.
- **E – SUSTAINED –** integrated approaches used to implement the national action plan to combat AMR. Relevant data and lessons learned from all sectors were used for implementation of the action plan. Brazilian official health bodies do not submit data, and there is no information

22. Banco de dados. TracSS. Disponível em: https://new.amrcountryprogress.org/. Acesso em: 14 dez. 2025.

available for entering in the GLASS [23] databank on antibiotic consumption in Brazil.

Regarding the responses on the AMR measures taken by Brazil, the following WHO assessment addresses Brazil's performance regarding compliance with AMR control targets up to 2023 outlined in the TrACSS report, More recent data was not available at the time of preparation of this CBDL[24] study.

- According to TrACSS, Brazil's record in combating AMR is similar to that of most other member countries. Measures to combat AMR are at different stages of development:
  - **DEVELOPED (C):** vocational training and education for combating AMR in the human health sector.
  - **DEVELOPED (C):** a national action plan on AMR.
  - **LIMITED (B):** training and vocational education on AMR provided to the agricultural (animal and plant), food production, environment and security sectors.
- Regarding initiatives to combat AMR in Brazil, based on the response to TrACSS, Brazil is at a more advanced stage compared to the global average in the following areas:
  - **DEMONSTRATED (D):** awareness and understanding of the risks and response to AMR.
  - **DEVELOPED (C):** optimization of the use of antimicrobials in human health.
  - **DEMONSTRATED (D):** infection prevention and control (IPC) in human health
  - **DEVELOPED (C):** adoption of the "AWaRe" classification of antibiotics in the List of Essential Medicines

23. WHO. Country, territory or area profiles. Available at: https://worldhealthorg.shinyapps.io/glass--dashboard/_w_14663b1fa90b4ba-3872316b40c3de19/#!/cta-profiles. Accessed on: December 14, 2025.

24. TrACSS. Available at: https://www.amrcountryprogress.org/#/country--profile-view. Accessed on: December 14, 2025.

- **DEMONSTRATED (D):** national surveillance system for antimicrobial resistance (AMR) in humans.
- **DEVELOPED (C):** training and professional education on AMR in the aquatic animal health sector.
- **DEVELOPED (C):** training and professional education on RAM in the seveterinary sector.
- **DEMONSTRATED (D):** national surveillance system for antimicrobial resistance in live terrestrial animals.

- According to TrACSS, initiatives to combat AMR in Brazil are below the global average in the following sectors
  - **LIMITED (B):** national system for monitoring consumption and use of ra-National impactofantimicrobialsonhumanhealth.
  - **LIMITED (B):** biosecurity and good animal husbandry practices to reduce the use of antimicrobials and minimize the development and spread of infections. transmission of AMR in terrestrial animal production.
  - **LIMITED (B):** biosecurity and good animal husbandry practices to reduce the use of antimicrobials and minimize the development and spread of infections. AMR transmission in aquatic animal production.

According to the TrACSS questionnaire, the areas of activity to be improved are:

NEED FOR INSTITUTIONAL IMPROVEMENT

- There is no focal point or specific working group responsible for monitoring and evaluating the implementation of the national action plan against AMR.
- The country has not yet established an Integrated Antimicrobial Resistance Surveillance System.
- There is a lack of awareness-raising activities at the local and/or subnational level regarding the risks of antimicrobial resistance and actions to combat it.

LACK OF DATA

- Data for the indicators defined in the monitoring and evaluation plan of the national action plan against AMR are not collected regularly in all key sectors.
- The country lacks the technical capacity, resources, and adequate systems to collect data in all key sectors.
- The relevant data are not disaggregated by gender, geographic location, income, etc.
- The data are not analyzed and used by the AMR multi-sectoral coordination mechanism for decision-making in all relevant sectors and advocating for policy changes, the allocation of appropriate resources, etc.
- The country lacks important data on the consumption/use of antimicrobials so as to inform operational decision-making and policy changes;

GAPS IN THE CAPACITY TO PERFORM DIAGNOSTIC TESTS

Brazil has not demonstrated the capacity to perform AST (antibiotic susceptibility testing) for critically important fungi, because

- there is no mechanism to communicate the lack of reagents/consumables for the diagnosis of bacterial infections and AST in clinical bacteriology laboratories in the public health sector, since each bacteriology laboratory manages stock shortages without mandatory communication. Has the country developed a national list of essential in vitro diagnostics that includes all essential AMR diagnostics? The answer is positive: the country has a national list of essential in vitro diagnostics that includes all essential diagnostics.for AMR (see Module 10 – Detection of the Main Mechanisms of Bacterial Resistance to Antimicrobials by the Clinical Microbiology Laboratory, Brazil, 2020).

AMR DEATHS IN BRAZIL

The following observations illustrate the AMR situation in Brazil:

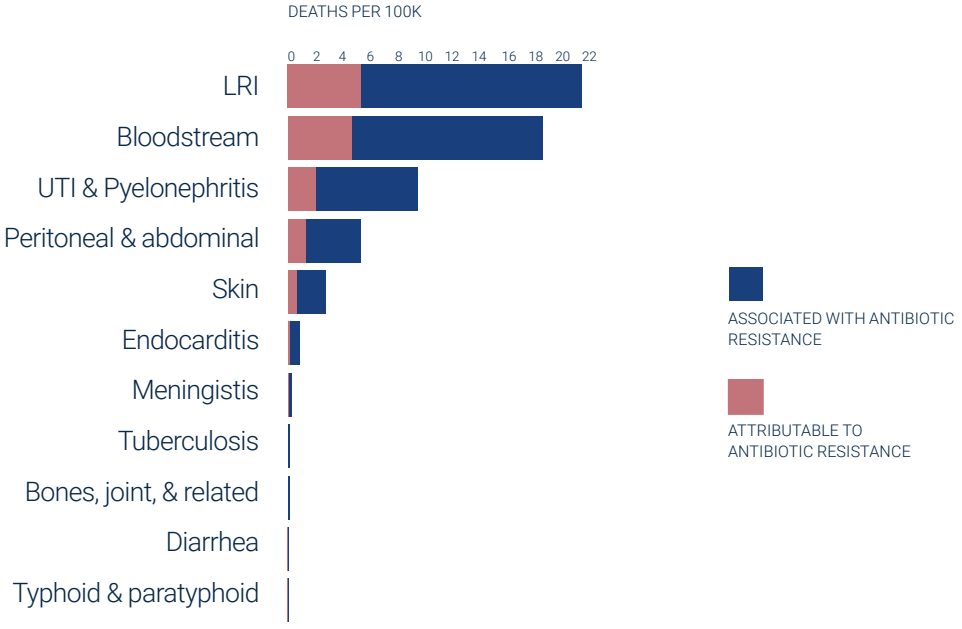
The most concise data on AMR-related deaths in Brazil were extracted from the IHME database. IHME is an independent population health research organization at the University of Washington School of Medicine (USA).

According to the IHME, in the analysis of deaths per 100,000 inhabitants associated with and attributed to bacterial AMR by type of syndrome, the most common cases are: respiratory diseases (21.35 associated deaths/100,000 and 5.22 attributed

deaths per 100,000) and, secondly, bloodstream diseases (18.58 associated deaths/100,000 and 4.53 attributed deaths per 100,000), followed by urinary tract infections (9.47 associated deaths/100,000 and 2.09 attributed deaths per 100,000), as shown in CHART 1.

CHART **01**

BRAZIL: DEATHS PER 100,000 INHABITANTS ASSOCIATED WITH AND ATTRIBUTED TO AMR SYNDROME BY TYPE, FOR ALL AGES AND GENDERS (IN 2021)

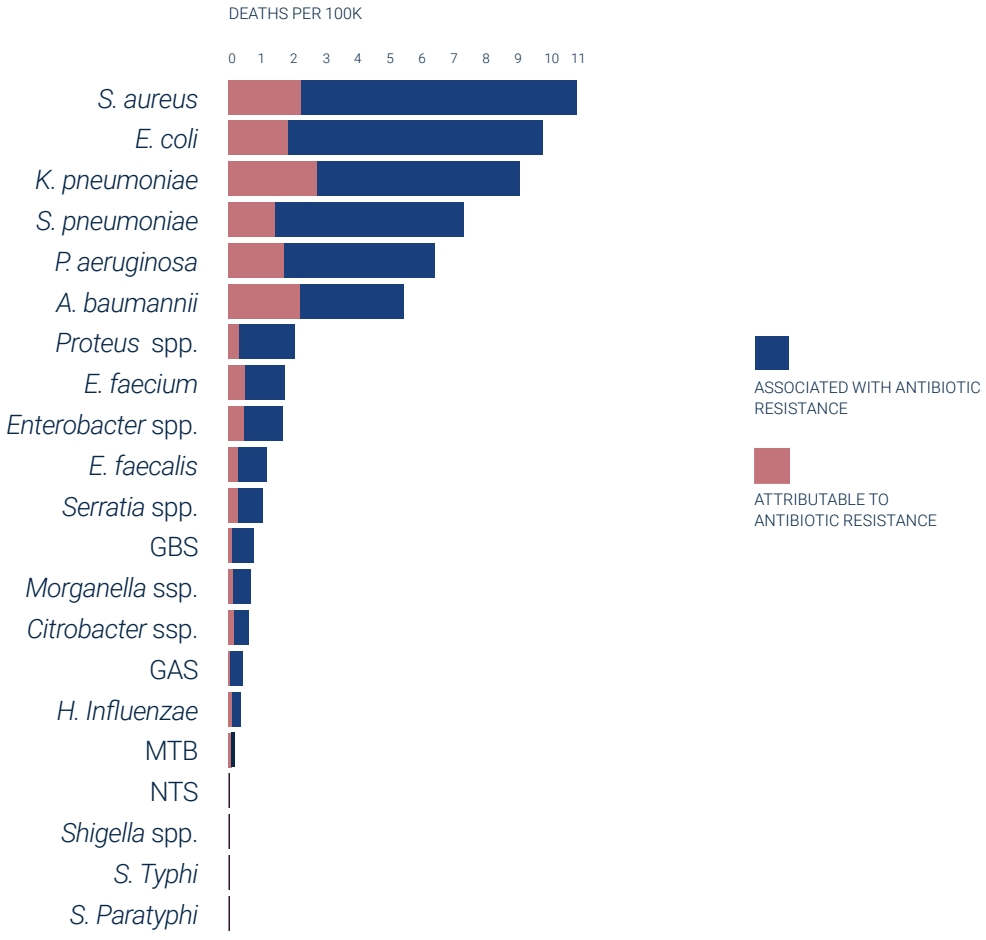


SOURCES: IHME & OXFORD UNIVERSITY.

In the analysis of deaths per 100,000 inhabitants associated with and attributed to AMR bacterial pathogen , the most common cases are: Staphylococcus aureus, Gram-positive bacteria (10.75 associated deaths/100,000 and 2.24 attributed deaths per 100,000), while the world average is 9.86 associated deaths/100,000 and 2.49 attributed deaths per 100,000; the second category of cases are related to Escherichia coli, Gram-negative bacteria (9.71 associated deaths/100,000 and 1.79 attributed deaths per 100,000), while the world average is 9.46 associated deaths/100,000 and 2.04 attributed deaths per 100,000. Klebsiella pneumoniae, a Gram-negative bacteria, takes third place (9.01 associated deaths/100,000 and 2.72 attributed deaths per 100,000), while the world average is 7.27 associated deaths/100,000 and 2.01 attributed deaths per 100,000 (CHART 2).

CHART **02**

BRAZIL: DEATHS PER 100,000 INHABITANTS ASSOCIATED WITH AND ATTRIBUTED TO AMR BACTERIAL PATHOGEN INFECTION IN ALL AGES AND ALL SEXES (IN 2021)



SOURCES: IHME & OXFORD UNIVERSITY.

6.3. PRIVATE BRAZILIAN INSTITUTIONS WORKING TO COMBAT AMR

The Latin American Sepsis Institute

ILAS is a non-profit institution founded in 2005, with four strategic objectives: (i) to deepen and disseminate knowledge about sepsis and severe infections; (ii) to develop programs to improve the quality of care for patients with sepsis and survivors, and consequently reduce their mortality and long-term effects; (iii) to coordinate clinical studies on sepsis; and (iv) to increase awareness of sepsis among ordinary people, healthcare professionals, politicians, and opinion formers. ILAS promotes actions that can reduce the impact of sepsis in terms of lives lost, long-term repercussions for survivors, and costs to the healthcare system.

ILAS collects sample data on the incidence of health issues through agreements with hospitals, with 166 hospital institutions in Brazil participating in the organization's quality program. More information available at [www.ilas.org.br].

BrCAST – Brazilian Committee for Sensitivity Testing

The Brazilian Committee on Antimicrobial Susceptibility Testing (BrCAST) is a technical committee jointly run by a group of scientific entities: the Brazilian Society of Clinical Analysis (SBAC), Brazilian Society of Infectious Diseases (SBI), the Brazilian Society of Microbiology (SBM), and the Brazilian Society of Clinical Pathology and Laboratory Medicine (SBPC/ML) Information accessible at: [https://brcast.org.br/].

BrCAST activities commenced in 2014, and in 2016 the committee was recognized as a National Committee linked to the European Committee on Antimicrobial Susceptibility Testing (EU-CAST). After publication of MoH Ordinance No. 64h, in 2018, its guidelines were officially adopted by all public and private microbiology laboratories in Brazil.

Subsequently BrCAST has worked closely with the MoH and Anvisa, focusing on standardization and quality improvement of antimicrobial susceptibility testing throughout the country, thus making a notable contribution to combating AMR.

Its main objectives include: (i) to establish and periodically review the cut-off points for the interpretation of antimicrobial susceptibility tests for clinical and epidemiological purposes, proposing their adoption by Anvisa in clinical laboratories throughout the country; (ii) to lead and promote the development, standardization and improvement of in vitro antimicrobial susceptibility tests; (iii) to coordinate actions aimed at ensuring and controlling the quality of such tests; (iv) to promote technical training and professional development to perform susceptibility tests; (v) to seek the recognition of Anvisa as an integral part of the process of defining interpretative criteria for in vitro susceptibility tests, both for current antimicrobials and for new agents to be licensed in Brazil; and (vi) to represent the country in national and international institutions involved in standardizing antimicrobial susceptibility methods; and (vi) to seek international consensus and/or harmonization with the criteria established by EUCAST and the Clinical and Laboratory Standards Institute (CLSI).

The Brazilian Association of Professionals in Infection Control and Hospital Epidemiology (ABIH)

The Brazilian Association of Professionals in Infection Control and Hospital Epidemiology (ABPCIEH) is a non-profit scientific association composed of entities in the health sector with expertise in hospital epidemiology and infection control. The institution has the following objectives: (i) to bring together, through regional associations, professionals working on infection control and epidemiology in healthcare services; and (ii) to provide scientific support to agencies interested in Epidemiology and Infection Control in Healthcare Services. More details available at: [https://www.abih.net.br/ index.php].

Brazilian Network of Nurses for Combating Antimicrobial Resistance – Rebran

The XVIII Brazilian Congress of Infection Control and Hospital Epidemiology launched the Brazilian Network of Nurses for Combating Antimicrobial Resistance (Rebran) on October 27, 2022, with the purpose of establishing a technical cooperation group among professional nurses working in the areas of antimicrobial resistance (AMR) and antimicrobial management programs (AGP).

Rebran seeks to foster scientific debate, encourage research on the topic, and contribute to the dissemination of knowledge, strengthen the engagement of nursing staff in addressing the challenges of AMR in Brazil.

CEPID – ARIES

The São Paulo Institute for Antimicrobial Resistance (ARIES) is a center of excellence dedicated to investigating the mechanisms and evolution of antimicrobial resistance (AMR), formulating public policies, and developing innovative solutions to mitigate it. It is a Research, Innovation and Dissemination Center (CEPID) of the São Paulo Research Foundation (FAPESP), which brings together researchers from five universities in São Paulo, experts from public institutions (e.g. Embrapa and CETESB), as well as representatives from other government agencies, including the Ministries of Agriculture and Health, ANVISA, and the Pan American Health Organization (PAHO).

The activities of ARIES are organized in five main areas: (i) the Socio-environmental Observatory and Data Science Center for monitoring ecosystems involved in the spread of AMR; (ii) mechanisms of acquisition and pathogenicity of antimicrobial--resistant microorganisms; (iii) development and validation of new strategies for controlling and preventing antimicrobial resistance in humans, animals and the environment; (iv) encourage innovation and entrepreneurship related to antimicrobial resistance; (v) disseminate knowledge and expertise to the wider public.

In addition to strengthening surveillance systems for the early detection of antimicrobial resistance, ARIES seeks to structure effective interventions to prevent and contain resistant infections in healthcare settings, the food production chain, and communities. [https://site.unifesp.br/ cepidaries/].

CHAPTER**07**

CONCLUDING REMARKS AND POLICY RECOMMENDATIONS

Concluding remarks and policy recommendations

A people-centered approach to tackling antimicrobial resistance (AMR) involves integrated actions at the national level, aligned with primary care, universal health coverage, and emergency response.

This approach places people at the center of interventions, and takes into account both systemic and individual challenges. It involves communities, healthcare professionals, civil society, academia, and the public and private sectors.

Structured around four programmatic pillars : (i) information; (ii) infrastructure, financing and awareness; (iii) institutional coordination; and (iv) access to diagnosis, supported by strategic information and effective governance, this approach serves as a guide for countries to develop or revise their national action plans to combat AMR, identify gaps, and incorporate interventions into health systems. Seeking a better interrelationship between public, private, and academic actions, and in light of the information assembled in this report it is proposed that CBDL could contribute by offering to guide actions in combating AMR, as outlined in TABLE 8.

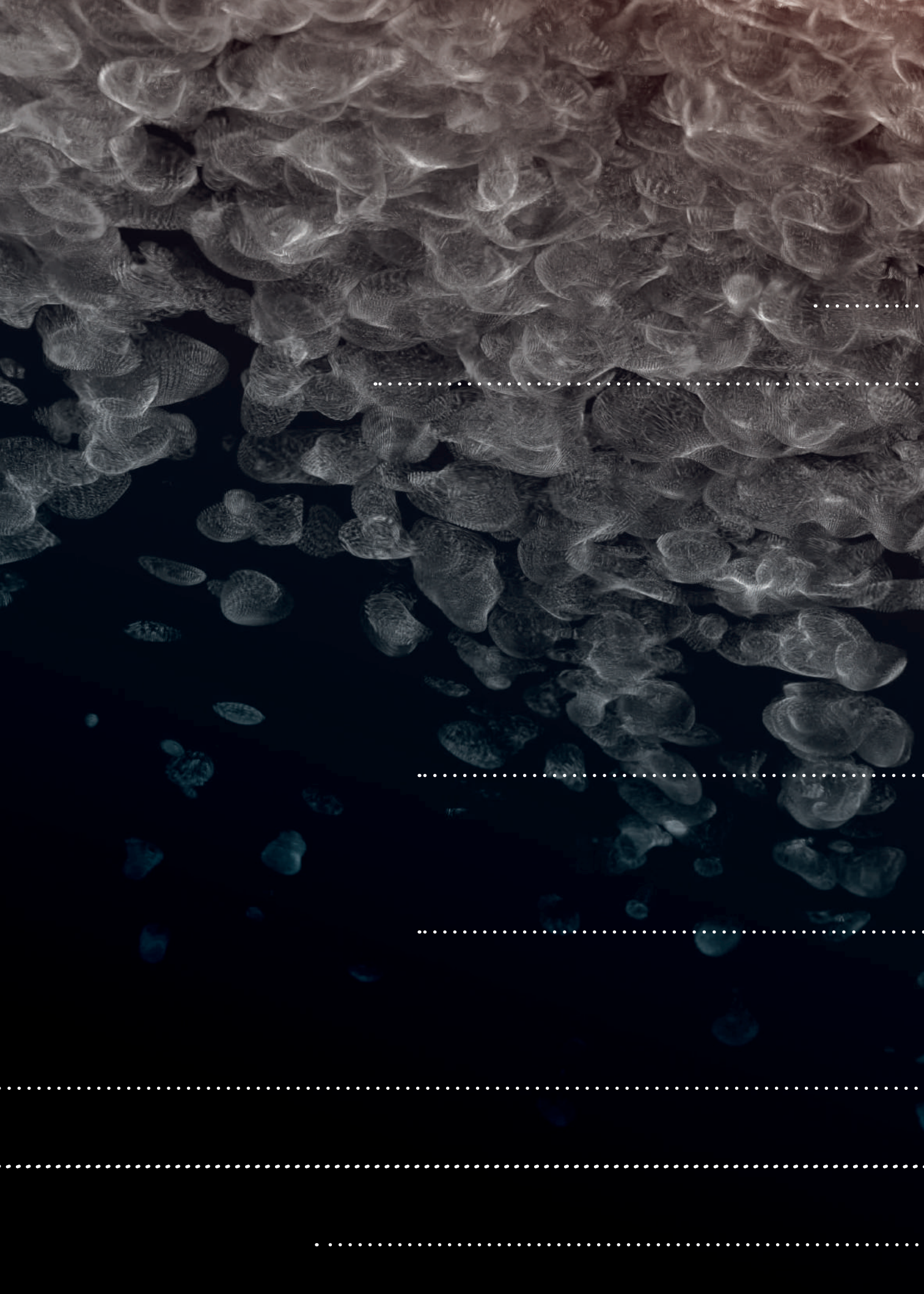
TABLE **08**

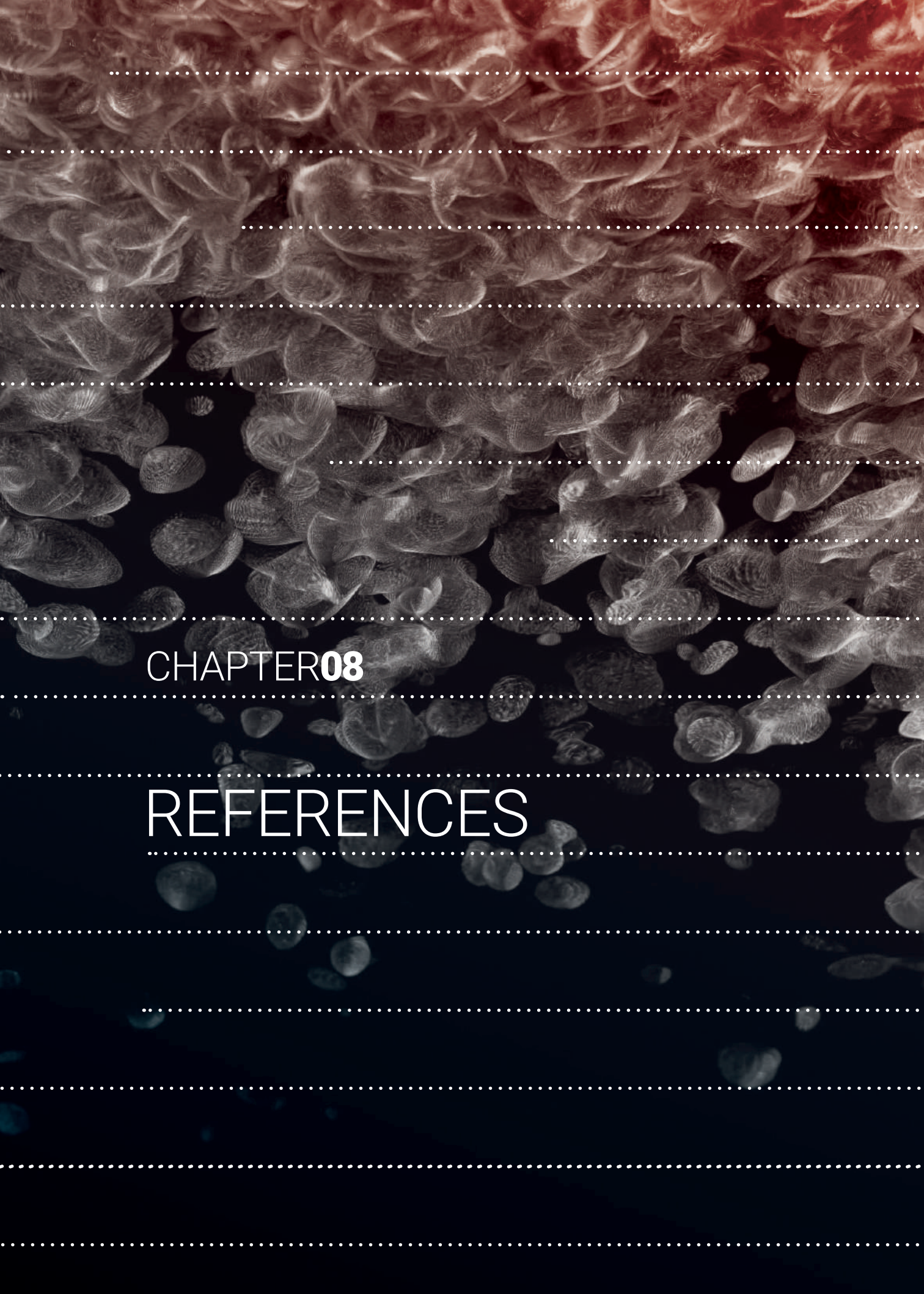
THE ROLE OF THE CBDL IN THE CONTEXT OF AMR

ACTION	JUSTIFICATION
INFORMATION	
Indicators (pp. 10-77), and WHO reports of April 2024 should be incorporated into CBDL's BI	There is insufficient data to monitor AMR
Georeferencing results of diagnostic testing for bacteria, fungi and AMR	There is insufficient data to monitor AMR
Develop directory of products for consultation–minimum list for particular care levels–I;II and ICU	Brazil does not have a minimum list of diagnostic tests for the AMR, or, if it exists, it is not widely dissemiinated
Generate data onconsumer antibiotics	Brazil has not collected samples from pharmacies and has not recorded antibiotic consumption data since 2022; there is a need to resume recording this key data
To promote a georeferenced survey of the effective use of tests for the detection, identification, and AST of bacteria and fungi through the CBDL Observatory	Identify and report on: **1.** gaps in healthcare services or outbreaks of infections caused by multidrug-resistant bacteria that require immediate action by public health managers; **2.** any unmet needs so that the Innovation Hubs in IVD can focus their R&D&I projects.
INFRASTRUCTURE, FINANCING AND AWARENESS	
To provide greater support for investments in public sanitation	The importance of universal sanitation in Brazil and waste treatment policies within the AMR environment
Identify funding sources	Fundiing sources for implementing AMR-related actions need clarifying
Support programs to raise public awareness of AMR	A program recommended by the WHO but not promoted by Brazilian public health authorities.

ACTION	JUSTIFICATION
INSTITUTIONAL COORDINATION	
CBDL can assume a leading role as a link between the private and public sectors	Poor integration of BR-GLASS with the private sector
Advance towards CBDL obtaining a seat in the "Diagnostic Initiative" and in the "Global Coalition of "Diagnostics" created at the 78th WHA	Brazil has no representatives in the WHO's AMR Diagnostic Initiative. Effective participation in the Global Diagnostics Coalition will encourage support of local and regional initiative for "Strengthening Diagnostic Capacity".
ACCESS TO DIAGNOSTICS	
Filling the gaps in diagnosis	• Lack of effective point-of-care tests for tuberculosis (TB) that can replace traditional smear microscopy and performTSA in an accessible way; • Need to provide automated platforms for IGRA detection (LTBI diagnosis), which allow for the decentralization of testing and have a high impact on the care regimen • Inability to perform simplified phenotypic bacterial identification and TSA at levels II and III, especially for bloodstream infections (BSIs), such as sepsis; • Need for emphasis on rapid tests, blood diagnostics, such as mass spectrometry and multiplex PCR; • Lack of rapid, patient-centered testing for identification and AST of multidrug-resistant *Neisseria gonorrhoeae*; • Shortage of simple and robust PoC (Point of Care) tests to differentiate bacterial from non-bacterial infections in primary care settings, using minimally invasive samples (blood, urine, stool, swabs); • Lack of multiplex PCR platforms for direct detection of bacterial pathogens and AST in whole blood, without the need for culture, suitable for levels I and II;
Essential List	There is a need to develop and update an essential diagnostic list for Brazil at the complexity levels of clinical laboratories.
Local Production and Research - Define national priorities for local production and for R&D of new diagnostic tests related to AMR.	There is no definition of national priorities for the production and R&D of new AMR-related diagnostic tests. See the 2019 document "*Landscape of diagnostics against antibacterial resistance, gaps and priorities*", available at: https://www.who.int/publications/i/item/ 10665326480

SOURCE: PREPARED BY THE AUTHORS.





CHAPTER**08**

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DIAGNÓSTICO PARA A VIDA

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