Going Macro on Micro

Microbiology in Motion: Navigating Challenges, Embracing Automation

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Introduction

In the ever-changing field of microbiology, the transition from laboratory bench to patient care and from managing data to identifying pathogens is incredibly dynamic. We wanted to explore the fascinating landscape of microbiology in motion, where challenges meet innovation and automation propels us forward.

Antimicrobial Resistance (AMR) poses a significant global challenge that demands immediate attention. It not only jeopardises our ability to treat common infections but also threatens the very foundation of modern medicine. The stakes have never been higher.

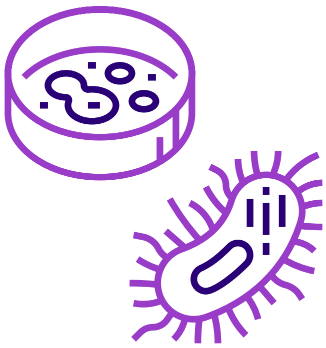
In an era defined by the convergence of science, technology, and patient care, "MICROBIOLOGY IN MOTION" serves as a guiding principle. It implies our commitment to staying in step with the changing landscape of microbiology, embracing innovation, and most importantly, ensuring that we never lose sight of the challenges that shape our path.

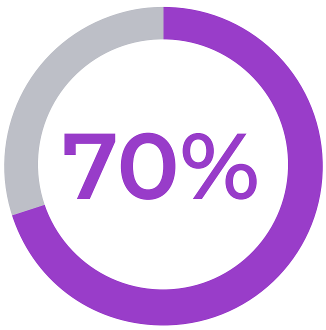
We invite you to join us on a journey where we navigate the intricacies of AMR surveillance, discover the power of research data management, and address the persistent laboratory workforce challenges that shape the course of this discipline.

We explore the vital importance of interoperability and the revolutionising impact of automation in antibiotic susceptibility testing, all of which contribute to the dynamic nature of microbiology.

Together, we will explore how this discipline is not merely a static science but one that is ever in motion, continually pushing boundaries, and forging a path toward a healthier future.

Automation for Antibiotic Susceptibility Testing





Of all healthcare decisions impacting diagnosis or treatment involve laboratory testing

Global increase in laboratory testing volumes

The changing landscape of antibiotic susceptibility testing

Antibiotic susceptibility testing is a crucial laboratory technique designed to evaluate the effectiveness of antibiotics against specific pathogens.[1] The primary goal is to determine the susceptibility or resistance of microorganisms to various antimicrobial agents. This process involves exposing the isolated pathogen to different antibiotics and observing the response, typically by measuring the extent of growth inhibition.[2]

Clinical microbiology has undergone significant development in response to changing clinical needs, with laboratories adapting to the growing demand for testing.[3] Approximately 70% of all healthcare decisions impacting diagnosis or treatment involve laboratory testing.[4] Notably, global laboratory testing volumes are growing at a rate of 10–15% annually.[5]

This surge is attributed, in part, to the demands of infection control, particularly the intensified screening for various resistant organisms such as methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant *Enterococcus* spp, and carbapenemase-resistant *Enterobacteriaceae*.

Moreover, expectations for laboratory services from both physicians and patients have undergone a transformation and rapid time to identification within the laboratory is a growing priority.[6] Patients often anticipate swift reporting of results from presentation to diagnosis and discharge.

A diverse range of samples collected from various physiological sources undergoes laboratory analysis, including cerebrospinal fluid, blood, “sterile” body fluids, tissues, pus, and urine. In this process, clinical microbiologists leverage their expertise to construct differential diagnoses and offer guidance on the necessary testing protocols.

Skilled laboratory scientists play a crucial role in selecting growth media, inoculating and incubating specimens, and analysing complex data.

The conventional methods employed in reaching definitive laboratory diagnoses often involve time-consuming processes, leading to the widespread use of empiric broad-spectrum antimicrobial therapy to stabilise patients. While the intent is to administer agents effective against unidentified pathogens, this approach can promote antimicrobial resistance.[7,8] Treatment is typically adjusted to a narrower spectrum of antimicrobials once laboratory results become available, emphasising the importance of timely and accurate diagnostic information in guiding effective treatment.

So, traditional methods of pathogen identification and antibiotic susceptibility testing, often time-consuming and resource-intensive, pose challenges in meeting the demands of modern healthcare. As the need for rapid responses to infectious threats becomes more critical, there arises a necessity for innovative approaches that can keep pace with the dynamic nature of microbiology.

Automation for susceptibility testing

"Automation is the technology by which a process or procedure is performed without human assistance."[9]

Automation has become an integral part of nearly every business sector, including medical laboratories.[10] In the laboratory context, automation implies any transition from manual work to machine-assisted processes. In this broad sense, all machines in the laboratory can be considered a form of automation. However, a more current use of the term "automation" applies to machines that execute more extensive workflows, such as automated determination of minimal inhibitory concentration (MIC).

Automated systems have already been implemented in microbiology laboratories to automate processes such as the identification of growth on plated specimens, the subculture of colonies of interest, and inoculation for organism identification and susceptibility testing.

Advantages of automation

There are several potential advantages to automation, including reduction in operational costs, enhanced standardisation of processing and testing, increased throughput capability, a higher number of isolated colonies per plate, simultaneous management of various specimen types, decreased turnaround times, and improved specimen traceability.[5,11]

Furthermore, automation can play a pivotal role in taking over various manual activities, such as specimen sorting, loading, centrifugation, aliquoting, and sealing, minimising variations among individuals and samples.[12] This allows laboratory staff to perform other responsibilities that leverage their skills and knowledge.[13] **This shift in task distribution has the potential to enhance overall efficiency and the quality of laboratory operations.**

Importantly, standardisation due to automation systems reduces the risk of human errors, particularly those arising in the pre-analytical phase.[14] Pre-analytical errors account for up to 70% of all errors made in laboratory diagnostics, many of which happen during manual tasks and storage.[15] For instance, automated robotic workstations effectively reduce errors in sorting, labelling, and aliquoting specimens, thereby enhancing the integrity of samples throughout the processing steps.[16]

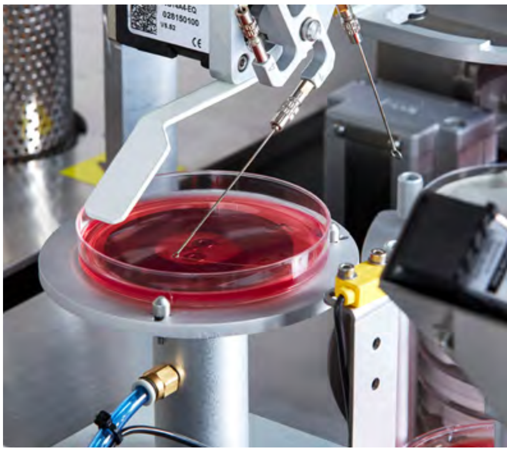
The DxM Autoplak System is a cutting-edge automated inoculation system designed to process a variety of liquid-based microbiology specimens. Its capabilities extend beyond solid media inoculation, including the processing of liquid culture media and glass slides for subsequent staining.

The DxM Autoplak 6100 Advanced System has showcased reliable and accurate inoculation capabilities across diverse media and streaking patterns.[17] With its adaptability, minimal hands-on time, and seamless integration into routine workflows, this automated inoculation system presents a promising solution for laboratories seeking increased efficiency without compromising precision.

Overall, partially or completely automating many manual tasks can improve standardisation, organisation, efficiency, and the overall quality of the testing process. While the initial investment cost may be substantial, long-term returns in terms of improved processes and quality can be expected.[18]

Increase productivity

Automate processes



Improve efficiency

Barriers to implementation

However, the implementation of automation in clinical microbiology, a traditionally manual and labour-intensive field, poses some challenges. Importantly, the implementation of laboratory automation is a substantial financial investment that requires a comprehensive reorganisation of the laboratory. There is a distinction between what is technically feasible and what can be effectively organised within the laboratory's operational framework.

The decision to automate involves careful consideration of both the technical capabilities and the organisational structure, ensuring that the chosen automation processes align with the practical realities and goals of the laboratory.

Another barrier to consider are the feelings of laboratory staff. Many workers may consider the implementation of automated systems as a threat to their employment.[19] Additionally, the perception that machines cannot exercise the critical decision-making skills necessary for processing microbiology specimens has persisted. As a result, some workers may not be fully embracing automation in their laboratory.

Therefore, the success of automation projects depends on effectively managing staff involvement and addressing their concerns. Open communication, training programs, and a supportive environment can play pivotal roles in earning staff acceptance and collaboration during the implementation of automation projects.

The future

The success of automation hinges on its flexibility in design, its acknowledgement of the human element, and its ability to adapt to the challenges posed by specimen diversity. Flexibility recognises that a one-size-fits-all approach is impractical—automated systems should be tailored to a laboratory's available space and potential future growth. Embracing the human element involves directing microbiology technologists to the most complex tasks, such as selecting colonies for further analysis, while delegating more routine tasks, like plating, to instruments operated by less trained individuals.

It is essential to recognise that automation does not eliminate decision-making for microbiology laboratory staff but rather facilitates decision-making and eliminates redundant activities.

Looking ahead, the integration of automation in antibiotic susceptibility testing continues to shape the future of microbiology. The interaction between human expertise and automated tools not only advances diagnostic processes but also opens avenues for novel discoveries.

Research Data Management in Microbiology

The roles of microbiology labs range from identifying a causative pathogen of an infection to detecting global disease outbreaks. However, these procedures and the data produced in microbiology labs are becoming increasingly complex.[20] The surge of information generated from experiments, sequencing, and analyses presents both a treasure trove of potential knowledge and a formidable challenge.

Proper data management

Proper data management is essential for organising the wealth of information generated in microbiology labs. Proper data management practices, including documentation of experimental procedures and raw data, contribute to the credibility of microbiological studies. Additionally, accessible and well-documented data sets allow other researchers to validate findings, fostering a culture of collaboration and knowledge sharing. Implementation of modern data management systems can improve the workflow, efficiency and reliability of microbiology testing and reporting.[20] **Ultimately, better data management facilitates better patient care.**

Why does research data management matter?

The sheer volume and intricacy of microbiology data pose significant challenges—traditional methods of data management struggle to keep pace with the influx of information. Managing this immense volume of information requires robust infrastructure and advanced data storage solutions.

One of the key challenges for microbiology data management is the explosion of information. This concept describes the release of a large amount of data with deep medical context due to the evolution of more microbiology fields and the switch from group-level data to person-specific data and collection[21] There is an exponential accumulation of routine data in microbiology labs, including bacteriology data and MALDI-TOF mass spectra. We already produce gigabytes of data every day that are stored for the purpose of quality control, accreditation, legal, and research purposes.[21] Due to this, it will soon become difficult for a human to keep a clear view and connect all the incoming pieces of information and data.[22] **Current methods for curating research materials and data should be revisited and updated.**

Inadequate systems may lead to data loss, corruption, or inefficiencies, hindering scientific progress and potentially compromising research outcomes. The risk of data loss or inefficiency in microbiology is not solely technical but extends to the potential loss of valuable insights and scientific discoveries. Unstructured data management may result in the misinterpretation of results, hindering reproducibility and the advancement of knowledge.

The MicroScan system is capable of performing identification and Antimicrobial Susceptibility Testing (AST). It uses LabPro software to interface with the laboratory information management software (LIS), enabling the bidirectional sharing of information between the two. LabPro can retrieve patient information and test results from the LIS for manually performed tests as well as collect results from automated tests performed by the MicroScan system. Furthermore, LabPro's AlertEX automates the detection of atypical results and guides staff on appropriate action, based on institutional procedures.

Automation and research data management

As the volume and complexity of microbiological data continue to grow, automation emerges as a key tool, streamlining data collection, storage, and analysis.

Automated systems offer several advantages:

Enhance quality of data
Automation reduces the risk of human error in data entry and processing, enhancing the overall quality and consistency of research data.

Analyse large datasets
Automated tools can swiftly analyse large datasets, identifying patterns and correlations that may be challenging for manual analysis.

Scale data processes
Automation allows for the efficient scaling of data management processes to accommodate the increasing volume of data generated in microbiological research.

Safeguard sensitive information
Automated systems can be designed with robust security features, helping researchers adhere to data protection regulations and safeguard sensitive information.

Integrate data seamlessly
Microbiology often involves the integration of diverse data types, such as genomics, transcriptomics, and metabolomics. Automation facilitates a more seamless integration of these different types of data.

Surveillance and Tracking of Antimicrobial Resistance

Antimicrobial Resistance (AMR) is a multifaceted global crisis, challenging the very foundations of modern medicine. The use patterns of antimicrobials and emergence locations of resistance genes vary globally. These differences have resulted in the uneven dissemination of resistance genes across global microbial populations, contributing to higher rates of treatment failure in certain regions.[23] **It is a must to monitor and anticipate the spread of these resistance patterns to proactively prevent, treat, and curb further dissemination.**

By 2050, AMR could cause 1 death every 3 seconds.

WORLDWIDE
10 Million
deaths per year

IN EUROPE
390,000
deaths per year

IN AFRICA
4.1 Million
deaths per year

IN ASIA
4.7 Million
deaths per year

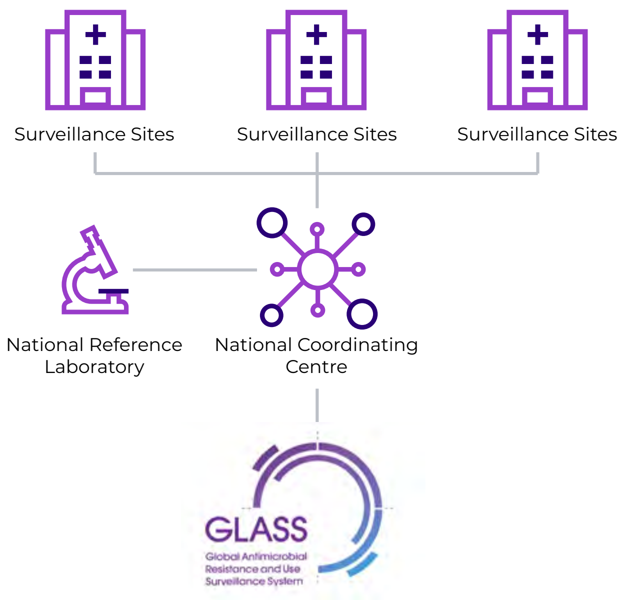
Source: Reference nr. 31

Importance of surveillance

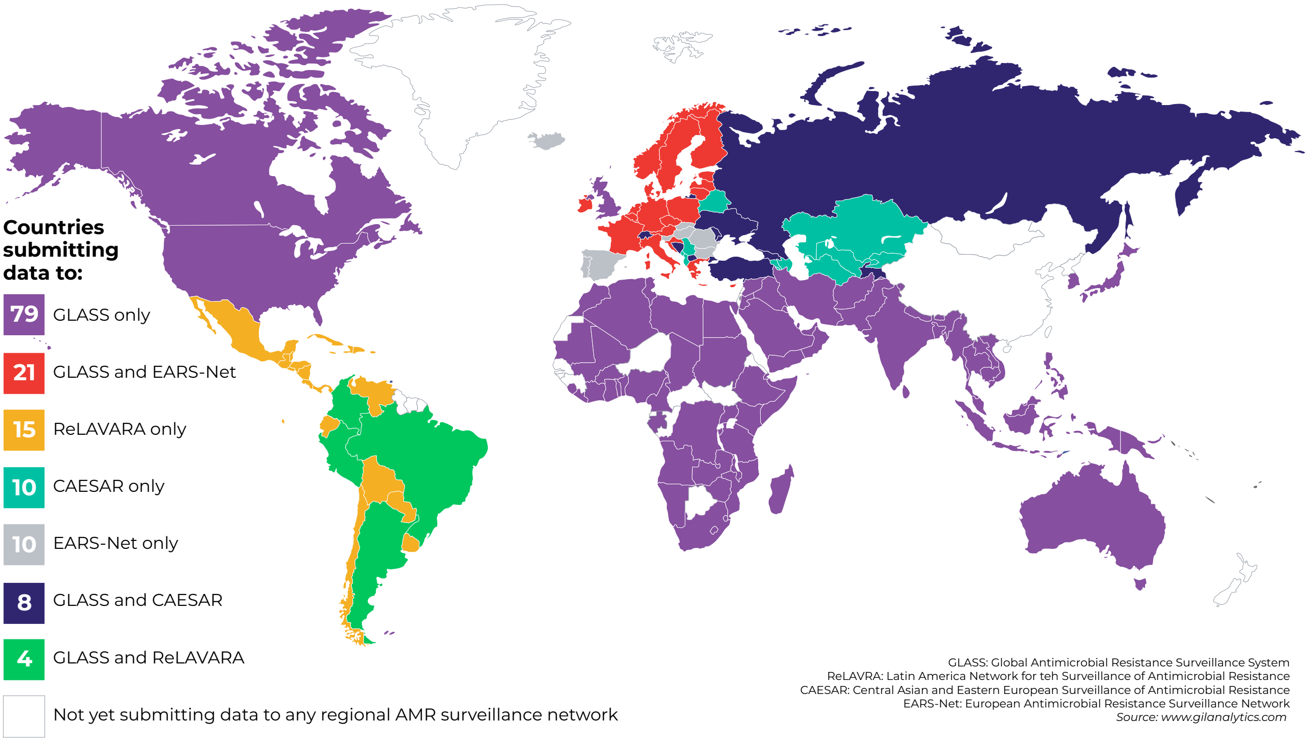
The first layer of defence against AMR is vigilant surveillance, playing a pivotal role in understanding, tracking, and mitigating the spread of resistant pathogens.[24] Surveillance helps identify patterns of resistance, enabling healthcare professionals to anticipate and respond to emerging threats.[25] For instance, the World Health Organization has launched the **Global Antimicrobial Resistance Surveillance System (GLASS)**, introducing a defined protocol for collecting data on AMR for specific high-priority pathogens and resistance phenotypes.[26]

By monitoring the effectiveness of existing treatments, authorities can adjust guidelines for antimicrobial use and develop targeted public health interventions to slow the spread of resistance. It is essential to monitor antimicrobial resistance actively for effective antimicrobial stewardship, ensuring appropriate antimicrobial use that optimises patients' clinical outcomes while minimising unintended effects of treatments.[27]

The One Health surveillance[28] approach integrates monitoring data about antimicrobial resistance in humans, animals, and the environment to enhance our understanding of the epidemiology of antimicrobial resistance.[29]



Global AMR Surveillance Networks (2021)



GLASS: Global Antimicrobial Resistance Surveillance System
ReLAVRA: Latin America Network for teh Surveillance of Antimicrobial Resistance
CAESAR: Central Asian and Eastern European Surveillance of Antimicrobial Resistance
EARS-Net: European Antimicrobial Resistance Surveillance Network
Source: www.gilanalytics.com

Improving AMR surveillance

The threat of AMR cannot be mitigated without improving surveillance systems worldwide. The challenges of AMR surveillance are as dynamic as the microbes it seeks to track.

Currently, no single surveillance system is able to achieve all the goals of monitoring AMR.

Moreover, there is a high heterogeneity of data collection and reporting between laboratories, which makes it difficult to quantify and follow AMR worldwide.[30,31] Particularly, surveillance systems are often absent in low- and middle-income countries. We need to ensure that surveillance strategies are not static but evolve to meet the ever-changing landscape of microbial threats.

Each microbiology laboratory stores years of data on microbe identities and AMR in patients. Paper logbooks are often used in many facilities to store results and are therefore unavailable to support data analysis and data sharing.[32] These files contain valuable information about the shifts in microbial populations that contribute to the development of AMR. Unfortunately, they are often not used or shared, despite their potential to shed light on the ongoing progression of AMR. As the scale and complexity of surveillance increase, automation emerges as a powerful tool.[32]

Automated systems can process vast amounts of data at unprecedented speeds, identifying patterns and trends that may elude human observation. Automated analysis can track and report the spread of resistant microbes in local and global communities. Real-time automated data collection also allows for a proactive rather than a reactive approach, empowering the healthcare system to stay one step ahead of evolving microbial threats.[32] Moreover, the development of automated linkage of routine surveillance data with other databases would provide large integrated datasets outlining the burden of AMR in different communities and settings.[25]

In the context of One Health surveillance, we need to improve surveillance systems for AMR among animals and in the food chain, as well as connect them to human surveillance systems. In addition to monitoring AMR trends, agreements on key pathogens in humans and animals need to be continuously updated based on these trends.

Laboratory Workforce Challenges —Navigating the Human Element

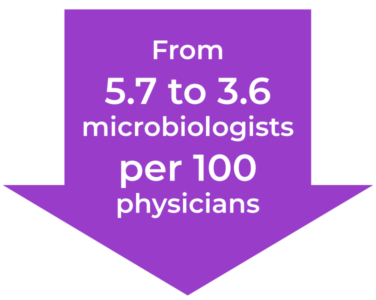
The field of microbiology currently offers more opportunities than ever before.[33] Despite the significant progress made in microbiology over the past two centuries, there is still a vast amount of biological information that can be discovered through exploring the microbial world. **Advances at the microscopic level are crucial to healthcare advancements, and skilled professionals in laboratories are the backbone of progress.**[33] Microbiology laboratory professionals are required to perform high-complexity assays and quality control, operate microbiology instrumentation, troubleshoot problems, and interpret results.

Current state of the workforce

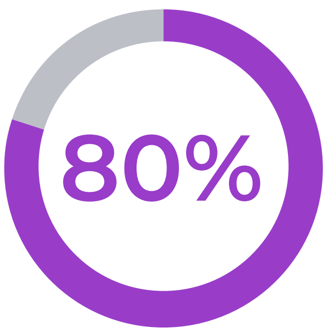
Of course, the field is not without its challenges, and perhaps one of the most pressing issues is the shortage of qualified and experienced laboratory professionals.[34] Data from the Royal College of Physicians Workforce Survey reveals a concerning trend between 2009 and 2019, indicating a decline in the number of microbiologists both in absolute numbers and in relation to the number of hospital physicians.[35] Specifically, the ratio decreased from 5.7 microbiologists per 100 physicians to 3.6 during this period.[35]

In 2021, a subcommittee within the American Society of Microbiology (ASM) collected data from ASM members involved in clinical microbiology laboratories. This survey confirmed that laboratories continue to experience significant staff shortages. More than 80% of participants indicated the presence of at least one open vacancy, with over a third reporting between 3 and 5 vacant positions. A notable 3.3% of laboratories were grappling with more than ten vacancies each.

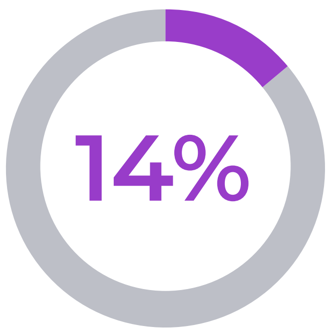
This staffing challenge was persistent across diverse institutions, encompassing large reference laboratories, academic medical centres, and private community hospitals. In the United Kingdom, a recent survey in cellular pathology reported a 14% vacancy rate.[35] These findings underscore the critical challenges faced by microbiology departments and related services, pointing to a significant and growing gap in the workforce.



Decline of the ratio between 2009 and 2019



Laboratories with the presence of at least one open vacancy



Vacancy rate in the United Kingdom for cellular pathology

The issue of the staff shortage is further complicated by changing demographics—in many countries, a large part of the microbiology workforce will retire in the next 10-15 years.[34] By 2025, the anticipated rates of staff-level retirements were recorded by the American Society for Clinical Pathology at 14.5% overall, 12.8% in microbiology, and a notably high 30.9% for microbiology supervisors.[36]

The impending retirement of many microbiology lab staff could manifest in three key ways: a surge in healthcare demand, a substantial loss of experienced professionals, and an aggravation of the shortage in the field of laboratory professionals.

A slight improvement in staff vacancy rates at microbiology laboratories has been seen recently (10.6% in 2018 and 6.9% in 2020), although, this is insufficient to replace the expected staff-level retirement.[36]

The number of newcomers to fill these vacancies is inadequate, and the number of medical laboratory staff being trained is declining.[37]

Factors influencing staff shortage

A number of factors influence the current workforce crisis in microbiology laboratories:

- Unfair compensation
- Job dissatisfaction
- Inadequate training programs
- Lack of awareness of career options in microbiology laboratories.[38]

Job satisfaction correlates with the amount of work, acknowledgement, and salary. In numerous organisations, staff shortages require the existing workforce to handle the equivalent workload of a fully staffed laboratory.[38] Staff frequently find themselves working overtime and double shifts, managing tasks with minimal crews, all while still being held to the same turnaround time expectations.

Moreover, the field of clinical laboratory work is often overlooked, rendering it a hidden profession.[38] Lab personnel are frequently not acknowledged by the general public, leading to limited awareness of their pivotal role and responsibilities in collecting and processing patient specimens. This situation can result in fatigue and burnout.

Consequences of staff shortage

This shortage poses a significant threat to the timely and accurate analysis of samples, hindering our ability to respond swiftly to emerging microbial threats. When there are lapses in staffing and training, the likelihood of errors rises, potentially adversely affecting the range and quality of diagnostic services provided. For example, a strong correlation has been observed between staffing numbers and testing volumes.[39]

Other ramifications of this shortage include delays in the diagnosis of illnesses, incompleteness in test results, and possible setbacks in treatment. Without a sufficient number of laboratory personnel to conduct tests, the entire community stands to suffer. Urgent attention and proactive measures are needed to address these critical issues and secure the future of the medical laboratory profession.

Addressing workforce challenges

One promising avenue for addressing workforce challenges lies in automation technologies.[20,40] Robotic sample handling, automated culture systems, and other innovative solutions are stepping in to augment the capabilities of human professionals. There is presently limited empirical evidence on the impact of automation on the efficiency of microbiology laboratories. Nevertheless, there is a prevailing sense of optimism within the microbiology community that automation will significantly influence patient care and laboratory work, as automation in microbiology continues to advance and gain broader acceptance.

A recent motion-capture study shed light on areas where automation could enhance daily efficiency.[41] For instance, manual inoculation and plate transfer between benchtops and incubators were found to occupy 33% and 10% of a laboratorian's time, respectively. The integration of automated workflows is expected to further reduce hands-on time for tasks such as antimicrobial susceptibility testing, MALDI-TOF mass spectrometry for organism identification, and culture interpretation, collectively accounting for an additional 40% of laboratorian's time. However, quantifying the isolated effect of automation on efficiency proves to be a challenging task.

In the coming years, traditional laboratory tasks such as manual culture plate reading and microscopy might become obsolete.[21] However, new aspects of laboratory work will emerge for microbiologists and laboratory staff. The growing demand for microbiological digital data also offers laboratory staff the opportunity to become more involved in patient assessments rather than acting as service providers.[42] This will include complex tasks such as data handling and analysis for diagnostics, research, and development.

The future of the microbiology workforce lies in harmonising the strengths of human expertise with the efficiency of automated systems.

In addition to reducing the burden of routine tasks, collaboration between skilled professionals and automation technologies facilitates more innovative and high-impact research.

Beyond automation

It is important to note that while automation can alleviate some staffing issues, the current staffing needs of laboratories still need to be met. There are some key ways of addressing this.[38,43,44]

- **Invest in training programmes**
  It is necessary to invest in training programs for potential laboratorians to increase the pool of graduates with the skills needed in clinical microbiology. Training would also benefit existing microbiology laboratory staff and provide them career advancement and professional development opportunities.

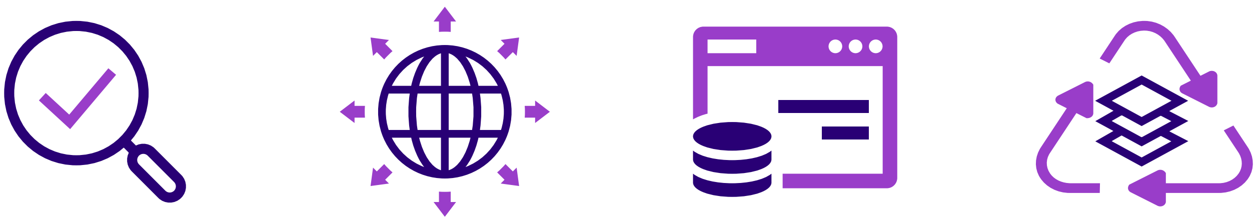
- **Increase awareness of career options in microbiology laboratories**
  Increasing awareness of career options in microbiology laboratories is essential for broadening the pool of individuals who could be trained and educated in this field. Many potential candidates may not be aware of the career opportunities available within microbiology. Educational institutions, professional organisations, and industry leaders can collaborate to create targeted outreach programs, workshops, and informational sessions that highlight the exciting opportunities and advancements in microbiology-related careers.[45] Additionally, showcasing real-world success stories of professionals who have thrived in microbiology roles can serve as a powerful motivator.

- **Ensure equitable wages**
  The compensation for microbiology laboratory professionals is often lower than other health professionals with similar educational requirements.[39] This could be one of the key reasons for the low retention of microbiology laboratory staff and needs to be addressed on a local and national level. For instance, governmental support, signing bonuses, and benefits could address this salary gap.

Interoperability Challenges

The increasing burden of AMR calls for a more coordinated and interconnected approach across different countries and different datasets. The current practice of utilising diverse data structures and local codes across institutions poses a challenge to seamless data exchange and integration. Data harmonisation that precedes the merging and joint analysis of data involves a time-consuming process of aligning disparate structures and codes.[46]

Moreover, harmonising data through mappings from proprietary codes to standard codes is inherently error-prone and often results in lower data quality. Ideally, standard codes should be incorporated into primary clinical record systems either directly or indirectly, following the **FAIR principles**—ensuring data remains findable, accessible, interoperable, and reusable.[47]



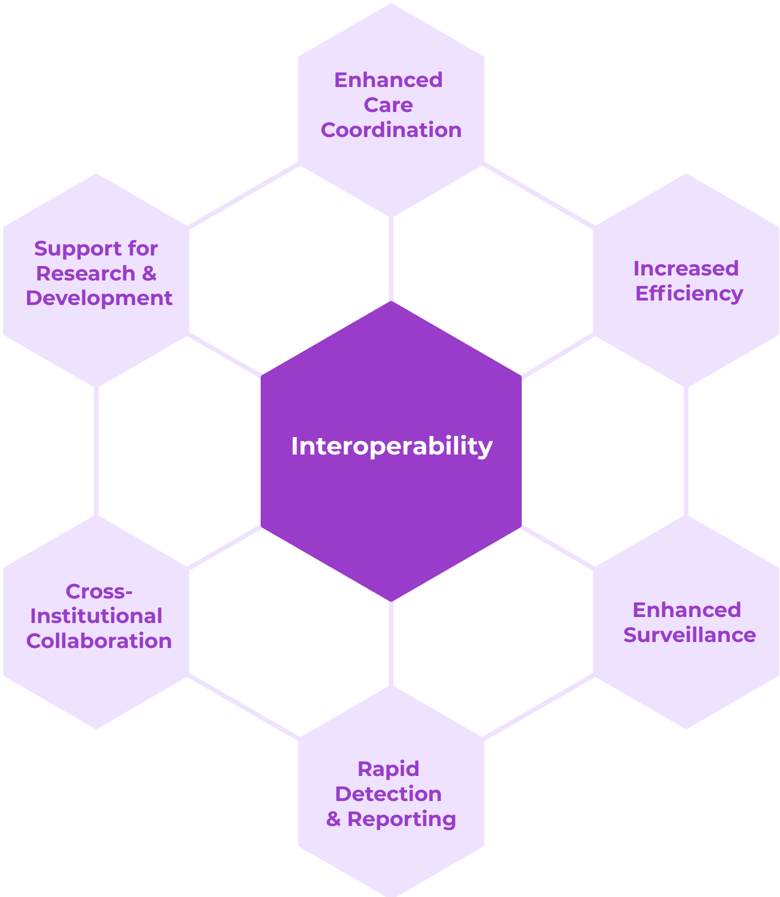
FINDABLE	**ACCESSIBLE**	**INTEROPERABLE**	**REUSABLE**
Date has rich metadata and unique identifier.	Data can be easily downloaded or used by employing standard protocols.	Metadata use an accessible and standard language.	Data is well-described and provides clear usage of licences.
F	**A**	**I**	**R**

The need for interoperability

As microbiology contributes crucial data to the broader healthcare ecosystem, the need for seamless interoperability becomes paramount. The ultimate goal of interoperability in microbiology data is to establish a universally accepted format that can be adopted across different institutions, accompanied by a common international terminology. This aims to enhance interoperability by providing a standardised framework in place of, or in conjunction with, local codes.

The collaborative effort to integrate data systems ensures that insights gained from microbiological analyses seamlessly flow into comprehensive patient records, enhancing clinical decision-making.

Benefits of Interoperability in Microbiology



Enhanced Care Coordination

Interoperability enables the integration of microbiological data with clinical and epidemiological information. This supports healthcare professionals and public health officials in making well-informed decisions regarding patient treatment, infection control measures, and public health interventions.

Increased Efficiency

Interoperable systems streamline workflows and eliminate redundant data entry. This increased efficiency not only saves time for laboratory professionals but also reduces operational costs associated with manual processes.

Enhanced Surveillance

Interoperability allows for the seamless exchange of microbiological data across different laboratories, healthcare facilities, and public health agencies. This comprehensive data sharing enhances the surveillance of AMR patterns, enabling a more accurate understanding of the prevalence and spread of resistant strains.

Rapid Detection & Reporting

Interoperable systems facilitate the rapid detection of antimicrobial resistance. Automated data exchange and real-time reporting enable timely identification of resistant pathogens, allowing for swift intervention and containment measures.

Cross-Institutional Collaboration

Interoperability fosters collaboration among different healthcare institutions and laboratories. This collaborative approach enhances the collective ability to respond to AMR challenges by sharing best practices, treatment outcomes, and resistance profiles.

Support for Research & Development

Interoperable systems support research efforts by providing access to a broader range of microbiological data. This facilitates the identification of emerging resistance patterns, aiding in the development of new antimicrobial agents and strategies.

Data silos

The increasing volume of data collection in the field of AMR raises concerns about potential data silos due to differences in methods for data description, analysis, storage, and access. Isolated data systems, often referred to as data silos, present a formidable challenge within microbiology. In healthcare, data silos often arise from functionalities that historically did not necessitate extensive data sharing. These silos hinder the seamless exchange of information between different components of the healthcare system, impeding the flow of critical data and compromising the efficiency of patient care.

Breaking down data silos in healthcare necessitates a concerted effort from all stakeholders, including healthcare organisations, technology vendors, policymakers, and regulatory bodies.

Some key strategies to promote healthcare include:

- Advocate for the adoption of standardised data formats and terminologies to ensure compatibility and seamless data exchange across systems.
- Implement interoperability frameworks to establish standard protocols for data exchange.
- Establish robust frameworks for data-sharing policies, privacy regulations, and security measures to ensure responsible and secure data exchange.
- Invest in interoperable health IT solutions that enable seamless integration with existing systems.

Data safety

Unlike other industries, healthcare data present unique challenges due to the sensitive nature of patient care. In the pursuit of interoperability, safeguarding patient data remains a top priority.

Sensitive healthcare data should only be transferred if anonymised and encoded.[48,49] Given the potential severity of consequences, with over 70% of recent hospital data breaches involving sensitive demographic or financial information that could lead to identity theft,[50] robust data safety measures are imperative.

Interconnected datasets

Today, laboratories have to access several computer programmes to collect information from various sources. In the “Research Data Management” section we also touched on the concept of the data explosion—the release of a large amount of data with deep medical context.

Laboratory specialists, lab technicians, physicians, and information technology experts will clearly be challenged to handle this rapidly approaching information wave.

Digital tools will be needed to efficiently facilitate the raw-data-to-knowledge process.[51] New communication and visualisation strategies will be important and the interface between laboratory and clinics has to evolve and adapt. For instance, dashboards can summarize the most critical clinical information and help to communicate complex data.[52,53]

Additionally, healthcare data must be standardised and annotated with internationally recognised definitions. Ontologies help to structure data in such a way by using a common vocabulary and allowing the determination of relations of variables within a data model.[54,55]

As an example, antibiotic susceptibility testing may be performed with various technical methods providing different sensitivities, error margins, and interpretation guidelines of breakpoints—the ontology term allows the specific description of the method in a machine-readable format and helps to compare results across different datasets. Various ontologies exist for clinical, laboratory and microbiological data such as the WHO’s International Classification of Diseases (ICD).

An underestimated challenge is the maintenance and curation of interconnected databases. As an example, with every annually updated antibiotic resistance interpretation by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) or Clinical and Laboratory Standards Institute (CLSI), antibiotic breakpoints may change and comparability across years is jeopardised.[56]

Comparing only the categorical trends, without further knowledge of the version used, harbours the risk of false interpretations. Therefore, changes in databases must be well documented and tracked, otherwise, temporal trends cannot be reliably analysed. A way around extensive versioning may be the storage of raw data—for example, storage of minimal inhibitory concentrations, which could be re-used using different breakpoints.

Middleware

The growing demand for advanced laboratory instrumentation, automation, and electronic reporting underscores the need for improved software solutions to effectively collect, display, and integrate data. Middleware has emerged to meet this demand. Middleware serves not only to connect legacy systems with newer ones but also facilitates data exchange and the management of complex data. Moreover, middleware solutions play a role in unifying microbiology results into a centralized and user-friendly system, addressing the limitations of traditional LIS.

The implementation of middleware not only promotes laboratory automation but also contributes to increased productivity, streamlined workflows, and standardised processes, all while minimizing the potential for human errors.

This interconnected landscape ensures that insights gained from microbial analyses contribute seamlessly to the broader healthcare narrative, propelling the field into an era where collaboration, innovation, and patient-centric care define the new standard.

Benefits of Microbiology Middleware

1 **Enhanced Efficiency**
Middleware automates and streamlines laboratory workflows, reducing manual intervention and saving time.

2 **Improved Data Management**
Middleware standardises data from different instruments into a common format, making it easier to manage and analyse.

3 **Seamless Instrument Integration**
Middleware acts as a bridge, allowing for the integration of various instruments with the laboratory information system (LIS).

4 **Comprehensive Reporting**
Microbiology middleware provides robust reporting capabilities, allowing laboratories to generate customised reports, track sample status, and monitor instrument performance.

5 **Improved Quality Control**
Middleware enables laboratories to implement and monitor quality ontrol measures more effectively.

6 **Regulatory Compliance**
Middleware helps laboratories meet regulatory requirements by providing traceability, audit trails, and data management features.

7 **Flexibility and Scalability**
Middleware can integrate with new instruments and adapt to changing laboratory workflows, ensuring seamless operation even as the laboratory expands or upgrades its equipment.

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