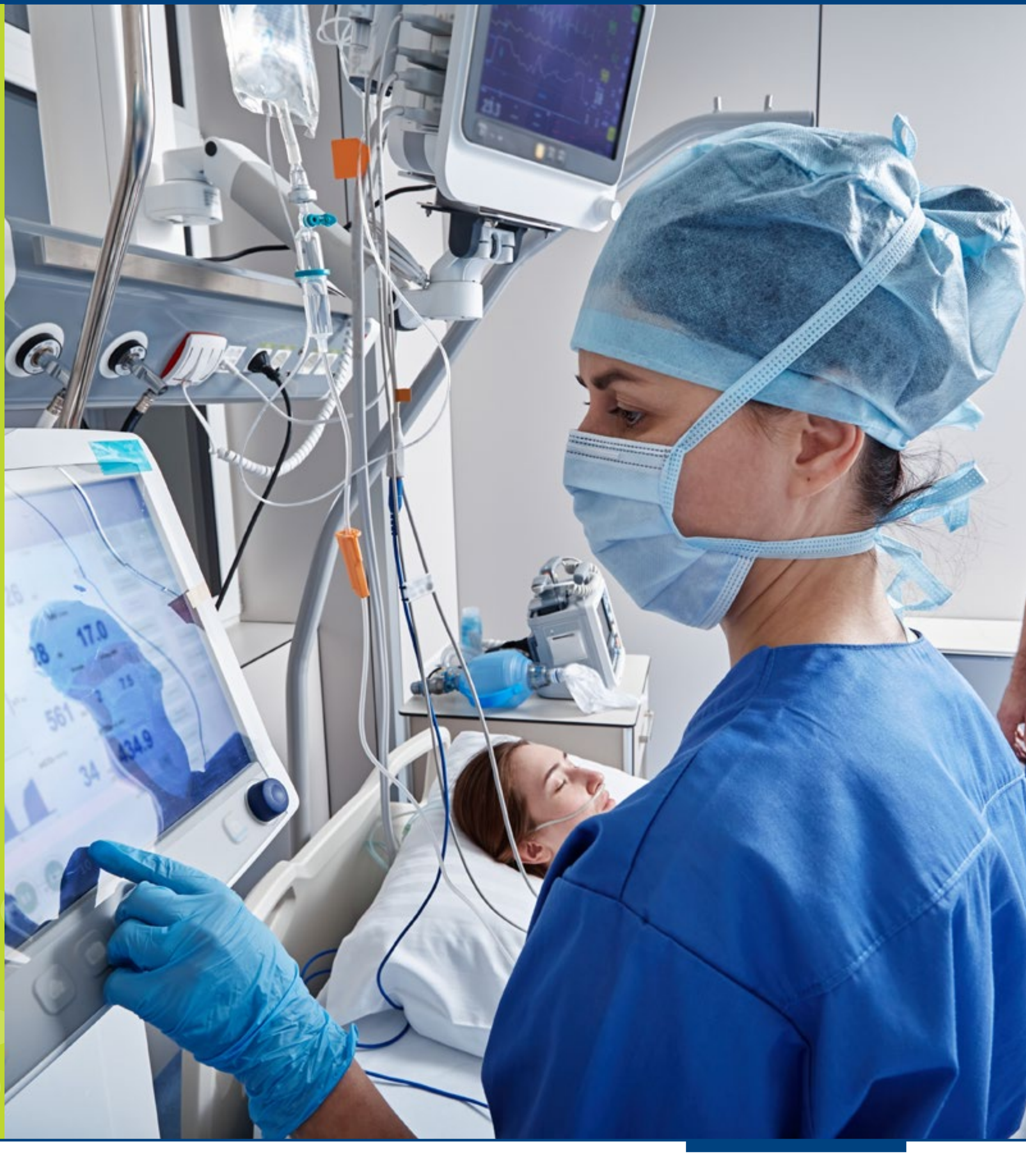
A **HANDBOOK**

THE ANTIMICROBIAL RESISTANCE CRISIS

Understanding the Scope and Impact of a Growing Threat



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PIONEERING DIAGNOSTICS

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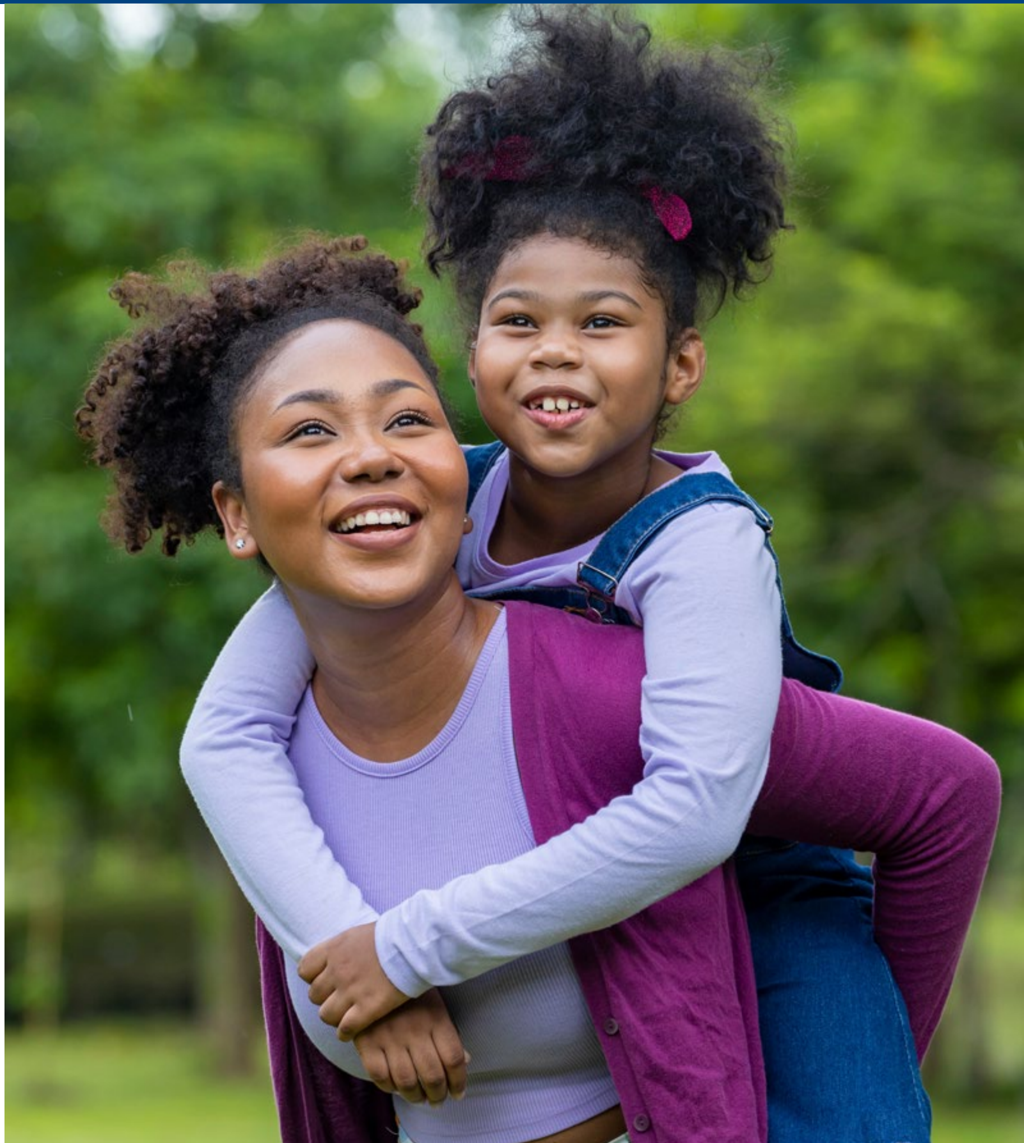


Stemming the tide of antimicrobial resistance

The world of medicine changed dramatically with the discovery of antibiotics. When antibiotics were introduced in the 1940s, infectious diseases, which had dominated the field of healthcare for centuries, became treatable and deaths preventable. Antibiotics also made other forms of fundamental medical care viable and safe, such as surgeries and chemotherapy. But today, antibiotic use is being threatened by antimicrobial resistance (AMR)—bacteria, viruses, fungi, and parasites that are difficult to defeat using available antibiotics.

Antimicrobial resistance is a global threat. It is estimated that AMR was directly responsible for 1.27 million global deaths in 2019.[1] In the US, more than 2.8 million drug-resistant infections occur each year, and more than 35,000 people die as a result. When *Clostridioides difficile* (CDI) is added, the total incidents of all resistant infections is estimated to exceed 3 million, leading to approximately 48,000 deaths.[2] In 2021, the number of ED visits with infectious or parasitic diseases was 3.8 million.[3] That same year, the number of visits to physician offices for infectious and parasitic diseases was 39.5 million.[4]

Preventing and overcoming antimicrobial resistance has become a global and national patient safety priority, touching every provider and every care setting. A multi-faceted, multidisciplinary approach has been adopted worldwide to combat the AMR crisis. Healthcare professionals across the US must become educated and active participants in this endeavor.

In this handbook, we'll provide background on the AMR crisis and focus on proven and emerging strategies that effectively address AMR challenges and complications. We'll also discuss the vital role clinical microbiologists play in advancing diagnostics to better identify and treat antimicrobial-resistant infections.

Understanding drug resistance

The science behind antimicrobial resistance

Pathogens are hardwired to protect themselves and overcome any threats to their existence. They have five built-in resistance mechanisms to:[2]

1. Develop new cell processes that avoid using the antibiotic's target.
2. Change or destroy the antibiotics with enzymes and proteins that break down the drug.
3. Restrict access by changing or limiting the entryways.
4. Change the antibiotic's target so that the drug no longer fits and does its job.
5. Get rid of antibiotics using pumps.

Not only do individual pathogens resist antimicrobials, but they can also spread their resistant DNA to other bacteria. The more we use a specific antibiotic, the more opportunity pathogens have to impose their inherent resistance mechanisms, which can make the medication ineffective on a wider scale. In some cases, antibiotics also kill helpful bacteria that protect us, giving resistant pathogens more of a chance to multiply and spread. Add to this the emergence of multidrug-resistant organisms (MDROs), bacteria that no longer respond to at least one (or more) classes of antimicrobials.

Ultimately, antimicrobials can fail to be effective against infections, which is what has led to our current AMR health crisis.

Antibiotic-resistant infections pose a serious risk for medicine today

Without effective antimicrobials to prevent or adequately treat infections, many healthcare treatments will be at risk:

Surgeries: Surgical site infections are a known risk and among the most preventable healthcare-acquired infections (HAIs). Without effective antibiotics to prevent these infections, many surgeries would not be possible.[2]

Chronic conditions: Many chronic conditions, like diabetes and asthma, put people at a higher risk for infection. Additionally, these conditions and many of the medications used to treat them can weaken the immune system, making these patients more susceptible to infections.[2]

Cancer care: People receiving chemotherapy are at a higher risk of developing infections. Roughly 650,000 people receive outpatient chemotherapy each year.[2]

Dialysis: People with advanced kidney disease receiving dialysis are more likely to contract infections. Infections are the second leading cause of death among dialysis patients.[2]

Sepsis: At least 1.7 million people develop sepsis each year.[2] Timely treatment with antibiotics is required to prevent tissue damage, organ failure, or death.

Factors contributing to the rise of antimicrobial resistance

Antibiotics are not just used to counter infections in humans. They are also used to maintain the health of animals and crops. Let's consider how AMR is impacted by the use of antibiotics for humans, animals, and the environment.

Human factors

In the US, the primary cause of AMR in humans is the inappropriate use of antimicrobials. Research shows that 30% of all antibiotics prescribed in U.S. acute-care hospitals are either unnecessary or inappropriate.[5] Statistically, about one-third of hospitalized patients[6] and more than two-thirds of critically ill patients[7] are on antimicrobial therapy at any time, so the numbers are quite significant. Add to this that roughly 20% of hospitalized patients on antibiotics experience side effects[8] and complications from antibiotics lead to an estimated 143,000 emergency department visits annually.[9]

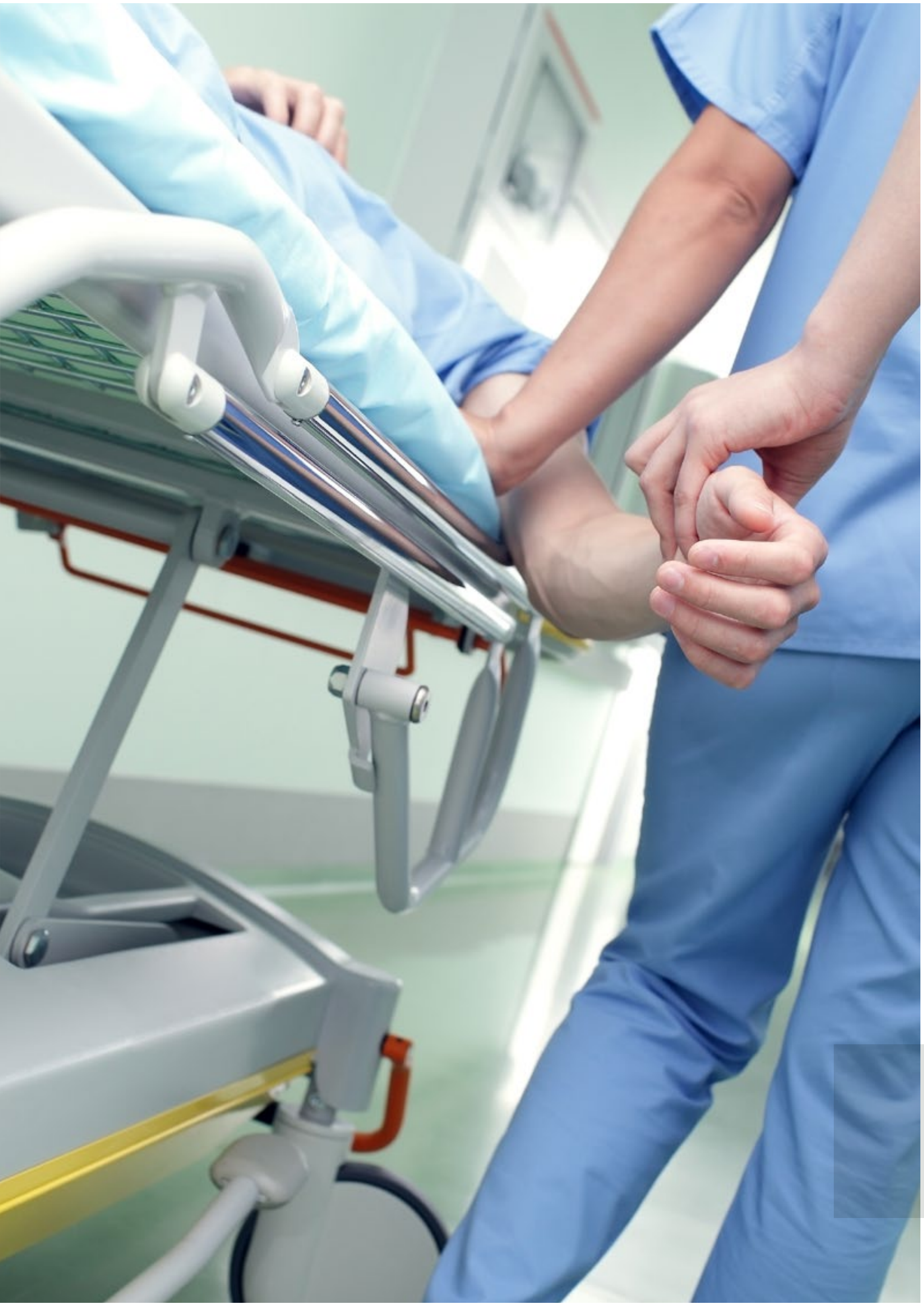
The problem doesn't just occur in acute-care settings. Each year antibiotics are prescribed in doctor's offices and emergency departments for infections that don't need them (e.g., colds and the flu) more than 47 million times.[10] That's about 28% of all antibiotics prescribed in these settings.[10]

Worldwide, antibiotic use increased by 65% between 2000 and 2015, largely associated with overconsumption among developing countries with rising incomes.[11] While the highest antibiotic consumption rate in 2000 was in the US, France, Spain, New Zealand, and Hong Kong, by 2015, the four top consumers of antibiotics were in low-middle-income countries (LMICs), such as Turkey, Tunisia, Algeria, and Romania.[11]

Antibiotic resistance also spreads easily across the globe today, thanks to the ease and affordability of travel. The CDC reports that one billion people travel across international borders each year, and 350 million travelers arrive in the US through more than 300 ports of entry.[2] A resistance threat from anywhere could spread quickly simply by people traveling across borders.

Animal and environmental factors

The increase in AMR worldwide is also caused by animal and environmental contributors. In the US, approximately 80% of all antibiotics sold were applied to food animals eat.[11] In 2010, 63,200 tons of antibiotics were used in livestock production worldwide, a much higher consumption level than in humans.[11] In the US alone, over 70% of antibiotics (by weight) are sold for livestock.[12] Antibiotics are also regularly added to animal feed and drinking water to prevent sickness.[11] Increases in AMR will make treating infections in animals more difficult and cause animal infections to be more severe.[11] This could potentially lead to decreased production of livestock and elevated prices for protein sources such as milk, eggs, and meat.[11] Antibiotics are also used in herbicides and pesticides to treat food crops and can infiltrate the soil and our water supplies, which also contributes to AMR.[13]



Impact on public health

Both healthcare-acquired infections (HAIs) and community-acquired infections contribute to the AMR crisis. Studies show that HAIs—infections that spread from patient to patient within a healthcare facility and across healthcare facilities and settings—are often the deadliest. Their spread is frequently caused by patient transfer from one location (e.g., an emergency department) to another (e.g., an intensive care unit).[2] That means that patient transfer needs to be an area of evaluation and improvement to help prevent AMR both in hospitals and the community.

Many infections that originate in the community are also drug resistant. But our public health system lacks the capacity and infrastructure to deal effectively with AMR. More resources are needed to enable data collection and sharing, the development of effective community-based interventions, and education for both public health professionals and consumers.

The economic burden of antimicrobial resistance

Not surprisingly, AMR is associated with higher healthcare expenditures. The World Bank estimates that AMR could result in $1 trillion in additional healthcare costs by 2050 and $1 trillion to $3.4 trillion in gross domestic product losses per year by 2030.[14] It also estimates that annual global GDP could decrease by about 1% by 2050, with projections for developing countries of about 5 – 7%. This all adds up to about $100 – $210 trillion in costs worldwide by 2050.[11]

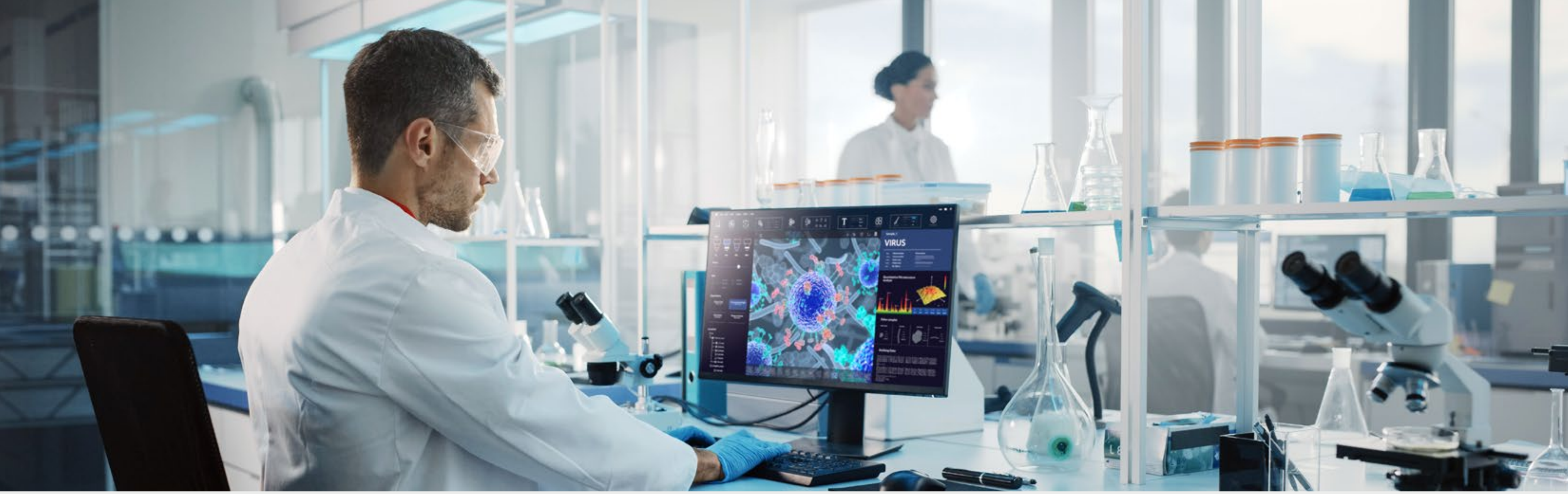
The cost to the US healthcare system of antibiotic-resistant infections is $21 billion – $34 billion each year and more than 8 million hospital days.[15] The national cost to treat infections caused by six MDROs alone is more than $4.6 billion annually.[16] One study estimated that the attributable cost for resistant infections can be as high as $29,289 per patient episode.[12]

Patient outcomes are also negatively affected by AMR:

- Hospital readmissions are 49.2% higher among patients with drug-resistant infections versus those with infections that are susceptible (treatable using antimicrobials).[12]
- Lengths of stay were higher in patients with resistant infections, with a per-patient episode of 26.4 days compared to 18.9 days among patients with susceptible infections.[12]
- Mortality rates for patients with resistant infections was 17.4%, compared to 10.5% for patients with susceptible infections.[12]

AMR doesn't just contribute to healthcare costs—it also impacts levels of productivity. The CDC estimates annual losses in productivity will cost the US $35 billion a year.[11] In low-income countries, AMR not only reduces productivity levels but also shrinks workforces because of associated sickness and premature death.[11] In fact, the World Bank projects that exports might decrease significantly by 2050 as a result of AMR in labor-intensive sectors.[11]

These impacts underscore the urgency with which we need to address antimicrobial resistance. Success has been achieved by combining antimicrobial stewardship with other proven tactics, such as infection prevention and control efforts, vaccinations, safer use of antimicrobials, and environmental controls. However, some significant obstacles remain a challenge.



Key challenges

There are many challenges to combating drug resistance, including allocating more resources, building increased capacity, and fostering deeper expertise to address AMR both in healthcare and the community. However, three specific challenges are shaping the global and national agenda.

1 Limited availability of new antimicrobials

The development of new antimicrobial treatments has dropped dramatically since the 1990s and is reaching a crisis stage today. According to the World Health Organization (WHO), there were only 27 new antibiotics for priority pathogens in clinical development in 2021, down from 31 in 2017.[17] In 2019, the Pew Charitable Trusts documented worldwide efforts to develop new antibiotics. They identified 43 antibiotics in development; four with new applications; 19 that could treat infections caused by some gram-negative bacteria; 10 that could address urgent threats from gonorrhea or *C. difficile*; and only one in four of them is a novel drug.[18] New drug development faces daunting hurdles, including lengthy pathways to approval, high costs of development, and low success rates. To address the current AMR crisis, developing a more robust pipeline of new antimicrobials must become a priority.

2 Learning curve of rapid diagnostics

Some traditional diagnostics, like growing cultures to identify infectious pathogens, can take too much time. As a result, clinicians may be forced to prescribe antimicrobials before test results are completed, which can lead to overuse and misuse of antibiotics. Rapid diagnostics offer quicker turnaround times and greater accuracy, but as new technologies, they are costlier and require training and mastery to interpret effectively. More rapid diagnostic options are under development, but they need to be mastered and integrated quickly to make inroads towards reducing AMR.

3 Emergence of multidrug-resistant pathogens

As stated earlier, MDROs are on the rise. These organisms are primarily found in hospitals and nursing homes, which may account for why they tend to occur more in the sick and the older populations.[19] Usually, MDROs develop when antimicrobials are either taken unnecessarily or for longer than needed. Treatment options for MDROs may require a complex combination and sequencing of more than one antibiotic, which can have more serious side effects. Ideally, new antibiotic drugs will target MDROs.

Challenges in Healthcare and the Community[2]

In healthcare

- Preventing the spread of pathogens, including in non-hospital settings such as long-term care facilities
- Spread of pathogens from the healthcare environment (e.g., bedrails, devices, and surfaces)
- Incomplete adoption of the containment strategy
- Inconsistent implementation of some CDC recommendations (e.g., contact precautions)
- Introduction of emerging threats outside of the United States
- Continued vigilance against serious threats like "nightmare bacteria" CRE (carbapenem-resistant Enterobacterales)

In communities

- Poor hygiene, such as not cleaning or wiping hands properly after toileting or diapering
- Spread of resistant threats in the food supply
- Improving antibiotic use worldwide
- Inconsistent use of safe sex practices
- Few vaccines to prevent infections and spread of resistant threats
- Stopping spread of germs in animals
- Understanding the role of antibiotic-resistant germs in the environment

Collaborative Interventions for Addressing AMR: A Multifaceted Approach

Several tactics have proven helpful in addressing AMR, including antimicrobial stewardship (AMS), infection prevention and control, and data sharing. AMS programs are implemented in healthcare settings to ensure that antimicrobials are applied responsibly and effectively, which is essential for battling the rise of AMR. AMS programs are now mandated by the Joint Commission and the Centers for Medicare and Medicaid Services (CMS).

By coupling AMS with aggressive infection prevention and control efforts, vaccination programs, and other useful tactics, we can potentially make serious inroads into tackling AMR and drive the best clinical outcomes related to antimicrobial use, minimize toxicity and other adverse events, reduce healthcare costs for infections, and limit the selection of antimicrobial-resistant strains.

Optimizing antibiotic use

Combating AMR has been a national patient safety priority for more than a decade. Over that time, proven strategies have surfaced that effectively reduce antimicrobial overuse and misuse.

National and hospital guidelines

In 2014, the CDC released its first set of guidelines for AMS, which were updated in 2019. Many of their interventions were adopted by the Joint Commission and CMS and offer a disciplined approach to AMS management in a variety of healthcare settings. These guidelines establish standards for structuring and implementing an AMS committee; establishing accountability; implementing data collection, tracking, and evaluation; delivering education and training; and communicating requirements, standards, and progress.[20] The national guidelines need to be combined with hospital-specific standards for diagnosing, prescribing, and treating infections. Healthcare providers must use evidence-based methods to assess their specific infection prevention and control practices, determine susceptibility testing levels, and delineate treatment pathways based on infection type and severity.

Strengthening hospital-wide commitment

CDC guidelines emphasize the importance of leadership buy-in to guarantee that AMS programs are fully integrated into hospital operations. This includes ensuring that the resources needed to effectively manage AMS, including staffing and financial resources, are designated and that the institution's commitment to AMS is continually reinforced.

Also critical to the success of AMS programs is a multidisciplinary approach. The AMS committee must include representatives from every area of the hospital that may have an impact on antimicrobial stewardship, including:

- Clinicians
- Department and program heads
- Pharmacists
- Infection prevention and control
- Nurses
- Quality improvement, patient safety, and regulatory staff
- Epidemiologists
- Information technology staff
- Microbiology lab professionals

Antimicrobial stewardship education

To be successful at AMS management, healthcare providers must ensure that everyone in the organization understands the challenges, strategies, and behaviors that lead to effective infection control and antimicrobial use. Ongoing education about AMR and AMS is vital so that each professional embraces their responsibilities toward infection prevention and control. Multiple educational formats are recommended, with regular reinforcement and updating. The education should delineate hospital-specific infection policies, convey antibiotic use patterns, highlight treatment standards and pathways, and promote adherence.

Infection prevention and control

Fundamental to the success of any AMS program are essential preventative measures, known as standard precautions, that are an integral component of infection prevention and control in acute-care settings. These evidence-based guidelines are simple, manageable steps that have been proven to prevent and limit the spread of infections. They include:[20]

- Hospital environmental hygiene, describing standard cleaning practices, the use of disinfectants, equipment cleansing and decontamination, and how to maintain safe and clean clinical environments.
- Hand hygiene, including sequence, frequency, and other protocols for hand washing, alcohol-based hand rub use, patient and visitor hand hygiene, and ongoing hand hygiene education.
- Use of personal protective equipment, including when and how to use gowns, masks, gloves, eye protection, and other respiratory protective equipment.
- Safe use and disposal of sharps.
- Urethral catheter use, including need assessment, catheter selection, insertion and removal, catheter maintenance, and interventions for reducing the risk of infections.
- Intravascular catheter use, including aseptic technique for insertion, catheter and catheter site selection, cutaneous antisepsis, catheter and site care, and catheter removal.

Strategies in Action

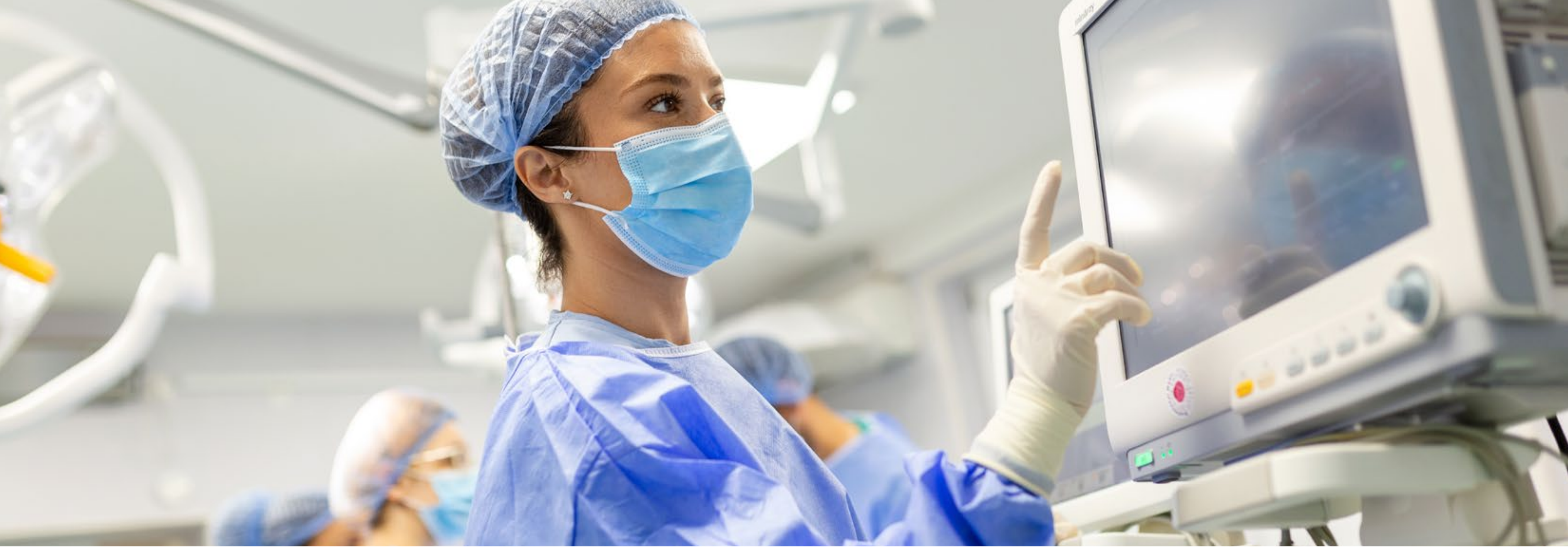
The CDC has identified five strategies each that work toward reducing AMR in healthcare and in communities:[2]

In healthcare

- Preventing device and procedure-related infections, such as from urinary catheters and central lines
- Stopping the spread of resistant pathogens within and between healthcare facilities
- Containing emerging threats through early detection and aggressive response
- Tracking and improving appropriate antimicrobial use
- Infection prevention and control in non-hospital settings, such as long-term care facilities

In communities

- Widespread use of vaccines to prevent infections and spread
- Routine tuberculosis and gonorrhea screening for at-risk groups and prompt treatment
- Using safer sex practices
- Safe food handling and preparation
- Improving antimicrobial use worldwide



Core Components for Infection Prevention and Control

The WHO has embraced a leadership role globally in addressing the challenges associated with AMR. One valuable resource is its core components for infection prevention and control, targeting healthcare leadership.[5] It focuses on preventing HAIs and reducing antimicrobial resistance at a facility and national level.

The eight components recommended emphasize:

1. **Infection prevention and control programs** should be created in all acute-care settings with dedicated and trained teams operating to prevent HAIs and enhance the appropriate use of antibiotics.
2. **National- and facility-level infection prevention and control guidelines** that are evidence-based need to be developed, disseminated, and implemented.
3. **Infection prevention and control education and training** for both those involved in infection prevention/control and all other healthcare staff should be continuous, practical, and take advantage of multiple training formats.
4. **Healthcare-associated infection surveillance** should be implemented to guide interventions for HAIs and other antimicrobial-resistant pathogens and to assist in the detection of outbreaks.
5. **Multimodal strategies for implementing infection prevention and control activities** are recommended that integrate core elements such as system changes, culture changes, and education and training.
6. **Monitoring, evaluation, and feedback** should occur regularly on a facility and national basis and be conducted in a non-punitive manner.
7. **Workload, staffing, and bed occupancy controls** on a facility level are needed to prevent overcrowding and/or understaffing, which could negatively impact the quality of care and increase disease transmission.
8. **Built environment, materials, and equipment for infection prevention and control** at the facility level should be implemented using internationally recognized standard precautions and safety standards for sanitation, water quality, and environmental health.

Data sharing and communication

A growing and evolving body of knowledge related to AMR is accumulating worldwide as a result of efforts to counter AMR locally, nationally, and globally. Data sharing and communications within healthcare settings, across the community, and on a national and international level are essential to alleviating the AMR crisis.

Within a healthcare setting

Healthcare providers need to share information across their healthcare settings about infection rates, patterns, and trends; antibiotic prescribing practices; infection prevention and control protocols; and AMS best practices.

Throughout the community

Public health officials need to collaborate with healthcare providers to gain insights into infection rates, patterns, and trends; local susceptibility levels; epidemiology; and coordinated efforts to control any outbreaks.

On a national and international level

Collaborative networks are forming on local, state, national, and international levels in which data is exchanged and best practices are identified and detailed. This effectively enables the refinement of guidelines and standards to combat AMR. One of the most notable collaborative networks is the National Antimicrobial Resistance Monitoring System (NARMS), an interagency partnership between the CDC, the Food and Drug Administration, and the US Department of Agriculture. This partnership reflects a One Health approach to AMS, which frames the AMR crisis worldwide from the perspective of the interconnectedness of humans, animals, and the environment. While One Health is emphasized in all countries, it is particularly significant in LMICs, where human, animal, and environmental conditions have fewer lines of delineation.

The lab's role in combating drug resistance

Microbiology lab professionals have become essential members of AMS committees nationally because of the unique role they play in advanced diagnostics and data trending and analysis related to infections. Clinical microbiologists offer experience and insights and are primarily responsible for:

Detection and monitoring

Microbiology labs provide reliable systems, equipment, and technologies to obtain meaningful data that can be used to detect and monitor infections, AMR, and the efficacy of different antibiotic treatment options.

Susceptibility reporting

Susceptibility reporting is used for two purposes: to guide empirical antimicrobial therapy for the treatment of common infection syndromes in individual patients, and to identify emerging infections and resistance patterns to prevent outbreaks and guide better public health. Clinical microbiologists excel in conducting these studies to assess the susceptibility of pathogens to specific antibiotics. They also provide a rationale for antibiotic formulary selection and support the detection of changes in antibiotic resistance over time.

Diagnostic stewardship

Microbiology lab professionals provide nuanced insights to help clinicians select the best method for identifying specific infections, accurately interpreting test results, and translating these findings into the best antibiotic treatment pathways.

Innovation and research

Microbiology labs are instrumental in current research to expand advanced and rapid diagnostic testing methods. Their ongoing efforts support improvements in AMR data collection and assessment and discovery of new evidence for the appropriate use of antibiotics. Microbiology labs also serve a vital role by researching novel antimicrobial compounds, which could expand the antibiotic pipeline.

In sum, long-term success at combating antimicrobial resistance will also depend upon contributions from microbiology lab professionals to increase the speed and reliability of diagnostic testing, document infection and susceptibility patterns, and provide insight into the best course of treatment for each patient, each time.

MALDI-TOF MS: A Revolutionary New Tool

Matrix-assisted laser desorption/ionization-time of flight mass spectrometry (MALDI-TOF MS) is a novel form of rapid molecular testing used to identify cultured bacterial and fungal infections. MALDI-TOF MS can produce microbiology results in up to 24 hours faster than traditional testing, and it is highly reliable.[21] MALDI-TOF MS enables the identification of AMR markers so quickly that, in some cases, the selection of an appropriate antimicrobial drug can be made before susceptibility reports are available. By reducing the time for empirical infection treatments, these rapid results contribute toward reductions in the misuse or overuse of antimicrobials.[22]

MALDI-TOF MS is currently used for the identification of infectious bacteria and fungi but holds promise as a technique that can be applied to viruses and parasitic infections as well.[21] It truly is a transformative technology that will deliver future advances in diagnostics and targeted therapies.

Case Example

At age 25, Vanessa experienced a severe car accident in Johannesburg, South Africa, that caused massive, life-threatening injuries that left her with organ damage, internal bleeding, serious fractures, and wounds that disfigured the right side of her face. It was these facial wounds that led to a serious decline in the quality of her life for more than a decade—mostly driven by antimicrobial-resistant infections.

Over the next 10 years, Vanessa underwent a series of facial reconstruction surgeries. Shortly after receiving a facial prosthetic, she felt fluid draining out of her face. An emergency procedure to clean the infected prosthetic only made the situation worse. Vanessa fought an endless battle against one antimicrobial infection after another. As time passed, the infections caused much of her face to deteriorate, making it impossible for her to wear her prosthetic eye.

None of the antibiotics her doctors prescribed could clear the infection.

Finally, clinical pathologists tested the facial prosthetic and discovered the presence of Methicillin-resistant *Staphylococcus aureus* (MRSA). Using this insight, her medical team adjusted their prescribing practices to target her specific infection.

She then underwent a second surgery to repair the disfigurement. Unfortunately, another infection appeared. A course of rotating antibiotics was then used and, three months later, her face finally began to heal. But the impact on her self-image and confidence was profound. It would take years until she felt like she could go out in public without covering her face to avoid unwanted attention.

Vanessa's story serves as a cautionary tale. In complex cases like this, where multiple infections occur requiring multiple and repeated antimicrobial treatments, early detection is critical. Antimicrobial treatment pathways for MRSA have advanced considerably since Vanessa's case, but there is still much to learn and improve.

Conquering antimicrobial resistance: from global priority to your priority

Stopping the spread of antimicrobial resistance demands aggressive action worldwide to prevent infections in the first place, slow the development of resistance through improved antibiotic use, and stop the spread of resistance when it does occur. Efforts over the past decade have shown that the disciplined, multidisciplinary approach that characterizes antimicrobial stewardship can drive measurable improvements. Infection prevention and control, vaccinations, and environmental interventions also contribute to tackling AMR. But success depends on:

- A relentless commitment to action from healthcare leadership
- High levels of engagement by a wide variety of healthcare clinicians and professionals
- Data collection and sharing on a local, national, and international basis
- Continuous creation and refinement of evidence-based best practices
- Collaboration between healthcare providers and public health officials
- Extensive education and training within healthcare, across the community, and among the public
- Timely development of novel diagnostic tools and new antibiotic options

Each and every healthcare professional, whether patient-facing or not, must accept responsibility to understand and act upon the strategies identified to help your healthcare organization, your community, your nation, and the world change the path and impact of AMR.

bioMérieux offers informative resources to provide you with more information about AMR, AMS, and advanced diagnostics. See the resources section for more.

Resources

For webinars, guides, and other educational resources about AMR and AMS

Visit Page

www.biomerieux.com/us/en/educational-support/antimicrobial-resistance-stewardship.html.

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Our diagnostic solutions bring high medical value testing to healthcare professionals, providing them with the most relevant and reliable information, as quickly as possible, to support treatment decisions and better patient care.

bioMérieux's mission entails a commitment to support medical education, by promoting access to diagnostic knowledge for as many people as possible. Focusing on the medical value of diagnostics, our collection of educational booklets aims to raise awareness of the essential role that diagnostics test results play in healthcare decisions.

Other educational booklets are available. Consult your local bioMérieux representative or visit biomerieux.com/en/education/educational-booklets

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