

Protect Your Patients and Staff

With Cepheid's comprehensive portfolio of on-demand products

→ Tools to Help Control
**Antimicrobial Resistance and
Healthcare Associated Infections (HAIs)**
From Your Institution

CE IVD In Vitro Diagnostic Medical Device

 **Cepheid**[®]
A better way.



Threat of Antimicrobial Resistance (AMR)^{1,2}

Microorganisms are continually evolving to resist the treatments that are available.

AMR is:

- One of the biggest threats to global health, food security, and development today
- Accelerated by the misuse and overuse of antibiotics, as well as poor infection prevention and control
- Spreading globally and new resistance mechanisms are emerging, threatening our ability to treat common infectious diseases

AMR leads to longer hospital stays, increased mortality and higher medical costs.

Healthcare-Associated Infections (HAIs): A True Burden

HAIs are infections that a patient acquires when receiving healthcare or during a stay in a healthcare institution.³ HAIs can:

- Prolong treatment time for patients
- Increase healthcare costs
- Lead to multiple adverse events, including the potential for prolonged disability and death

1 Antibiotic resistance: WHO Fact sheet Updated November 2017, <http://www.who.int/mediacentre/factsheets/antibiotic-resistance/en/>

2 AMR: a major European and Global challenge, European commission 2017, https://ec.europa.eu/health/amr/sites/amr/files/amr_factsheet_en.pdf

3 MedTech Europe. Healthcare-Associated Infections. brochure; may 2017. <http://www.medtecheurope.org/node/1013>

4 WHO: Antimicrobial Resistance Global Report on Surveillance 2014 slide set, http://www.who.int/antimicrobial-resistance/publications/AMR_report_Web_slide_set.pdf?ua=1

5 AMR: a major European and Global challenge, European commission 2017, https://ec.europa.eu/health/amr/sites/amr/files/amr_factsheet_en.pdf

6 ECDC. Strategies for disease-specific Programmes 2010-2013. 2010 Jul.

7 ECDC. Summary: Point prevalence survey of healthcare-associated infections and antimicrobial use in European hospitals 2011-2012. 2013 Jul 2.

8 CDC. Antibiotic Resistance Threats in the United States, 2013. 2013 Sep 16. Accessed Nov 2014. <http://www.cdc.gov/drugresistance/threat-report-2013/>

The Facts



2.5 Million

The annual **extra hospital days** in the European Union (EU)⁴



€1.5 Million

Extra healthcare costs and productivity losses in the EU per year due to AMR^{4,5}



25,000

deaths per year in the EU are caused by AMR^{4,5}



37,000

Every year, approximately 37,000 deaths are **caused directly by HAIs**⁶



4 Million

The annual number of patients in the EU with **at least one HAI** is estimated at 4 million⁶



1 in 18

The number of patients on any given day in European hospitals affected by **at least one HAI**⁷



People at High-Risk⁸

- Cancer chemotherapy patients
- Patients undergoing complex surgery
- Those with immune mediated diseases
- Those undergoing dialysis for end-stage renal disease
- Organ and bone marrow transplant patients



Threat Level of AMR Pathogens¹

Other pathogens like viruses can contribute to the AMR threat. Influenza virus is one of them: **30 percent** of the Flu patients who were treated during the 2012-2013 influenza season may have been prescribed unnecessary antibiotics instead of antiviral therapy.⁷

1 CDC. Antibiotic Resistance Threats In The United States, 2013. Accessed Nov 2014. www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf

2 Köck R, et al. Methicillin-resistant *Staphylococcus aureus* (MRSA): burden of disease and control challenges in Europe. *Euro Surveill*. 2010 Oct 14;14(41).

3 Barbut F, et al. *Clostridium difficile* infection in Europe. Accessed Nov 2014. <http://www.multivu.com/assets/60637/documents/60637-CDI-HCP-Report-original.pdf>

4 ECDC. *Clostridium difficile* infection. Accessed Nov 25 2014. http://www.ecdc.europa.eu/en/healthtopics/Healthcare-associated_infections/clostridium_difficile_infection/pages/index.aspx

5 Gerding DN, et al. Measures to Control and Prevent *Clostridium difficile* Infection. *Clin Infect Dis*. 2008 Jan 15;46 Suppl 1:S43-9.

6 ECDC report, Tuberculosis surveillance and monitoring in Europe 2017

7 Havers , et al Use of Influenza Antiviral Agents by Ambulatory Care Clinicians During the 2012-2013 Influenza Season, *Clin Infect Dis* 2014 Sept;59(6):774-82

8 Global Tuberculosis Report 2017 World Health Organization, http://www.who.int/tb/publications/global_report/gtbr2017_executive_summary.pdf?ua=1

Clostridium difficile

Causes life-threatening diarrhea¹

- These infections mostly occur in people who have had both recent medical care and antibiotics
- *C. difficile* infections often occur in hospitalized or recently hospitalized patients

Carbapenem-resistant Enterobacteriaceae (CRE)

Has become resistant to all or nearly all available antibiotics¹

- Untreatable and hard-to-treat infections from CRE bacteria are on the rise among patients in medical facilities
- Almost half of hospital patients who get bloodstream infections from CRE bacteria die from the infection

Methicillin-resistant *Staphylococcus aureus* (MRSA)

Leading cause of HAIs¹

- MRSA causes a range of illnesses, from skin and wound infections to pneumonia and bloodstream infections that can cause sepsis and death

Vancomycin-Resistant Enterococci (VRE)

Has few or no treatment options¹

- Enterococci cause a range of illnesses, mostly among patients receiving healthcare, including bloodstream infections, surgical site infections, and urinary tract infections

Drug-resistant Tuberculosis (TB)

Frequent causes of death worldwide⁸


- In most cases, TB is treatable with conventional first-line drug regimens
- Drug-resistant TB is more challenging to treat — Treatment courses are much longer and less effective than for drug-sensitive TB. For Multi-Drug (MDR) and Extensively Drug-Resistant (XDR) TB patients only few less effective and very expensive treatment options left

URGENT


Statistics


 **172,000** *C. difficile* cases estimated annually in Europe³

 **3 Billion €** per year for additional hospital care costs³

 **5,000–15,000 €** per case⁴

Statistics¹

 **9,000** healthcare-associated infections are caused by CRE each year, in the USA

 **600+** deaths per year in the USA are caused by the two most common types of CRE

Threat Level

- *C. difficile* spreads rapidly because it is naturally resistant to many drugs used to treat other infections¹ and it is resistant to many disinfectants because it forms spores⁵
- In 2000, a more virulent strain of the bacteria emerged. This strain is resistant to fluoroquinolone antibiotics, which are commonly used to treat other infections¹
- This virulent strain has spread throughout North America and Europe, infecting and killing more people wherever it spreads¹

Threat Level¹

- Some Enterobacteriaceae are resistant to nearly all antibiotics, including carbapenems, which are often considered the antibiotics of last resort

SERIOUS

Statistics²

 **150,000** patients per year affected by MRSA in the European Union


 **380M €** per year for additional in-hospital costs


Statistics¹


 **66,000** *Enterococcus* infections per year in USA

 **20,000** of those infections are vancomycin-resistant

Statistics⁶

 **323,000** new TB cases in Europe in 2015

 **32,000** Drug-resistant TB cases were reported in Europe in 2015

 **16,022** Died from TB in Europe in 2015

Threat Level¹

- MRSA infections can be very serious
- The number of infections is among the highest of all antibiotic-resistant threats
- Resistance to methicillin and related antibiotics and resistance to cephalosporins are of concern

Threat Level¹

- Enterococci often cause infections among very sick patients in hospitals and other healthcare-settings.
- Some Enterococci are resistant to vancomycin, an antibiotic of last resort, leaving few or no treatment options.

Threat Level⁸

- The major factors driving TB drug resistance are incomplete or wrong treatment, as well as missed detection of drug-resistant bacilli in the early stages of diagnosis
- Health care providers can help prevent drug-resistant TB by using a faster detection of drug-resistant TB cases which greatly improves initiation of appropriate treatment as well as ensuring patients compliance



Fighting Back Against AMR and HAIs

The over-use of antibiotics is the single most important factor contributing to antibiotic resistance around the world.

Antibiotics are among the most commonly prescribed drugs used in human medicine. However, up to 50% of all the antibiotics prescribed for people are not needed or are not effective as prescribed.¹

There are four core actions that will help fight antibiotic resistance:



1 Preventing the spread



2 Tracking resistant bacteria



3 Improving antibiotic prescribing and stewardship



4 Developing advanced diagnostics and new antibiotics

Rapid Diagnostics to Stop Unnecessary Use of Antibiotics²

All antibiotic prescriptions will need to be informed by up-to-date surveillance information and a rapid diagnostic test wherever one exists. Rich countries should make it mandatory by 2020.

The information garnered from rapid diagnostics, might allow doctors to improve treatment and infection control to such an extent that this places negative selective pressure on resistance pathogens, thus reducing resistance in older drugs.





Preventing Infections and the Spread of Resistance

Cepheid Solution: GeneXpert® System's full range of microbiology tests for fast screening and diagnosis helps improve antibiotic prescribing and use in both outpatient and inpatient settings. By identifying infections quickly and accurately, the overuse of antibiotics can be reduced.

With Xpert® tests you get results within 45 to 80 minutes

Xpert® MRSA products

Xpert® MRSA NxG—70 minutes to result for active surveillance testing

Xpert® SA Nasal Complete—71 minutes to result for pre-surgical testing

Xpert® MRSA/SA BC—66 minutes to result for detection of MRSA and SA in positive blood culture bottles

Xpert® MRSA/SA SSTI—66 minutes to result for MRSA and SA in skin and soft tissue infections

Xpert® products

Xpert® C. difficile BT—47 minutes to result for improved infection control and therapy

Xpert® Carba-R—48 minutes to result for detection of carbapenemase genes for improved infection control

Xpert® vanA/vanB—45 minutes to results for VRE for improved infection control

Xpert® MTB/RIF Ultra—80 minutes to results for the detection of *Mycobacterium tuberculosis* and rifampicin resistance simultaneously

Xpert® Xpress Flu/RSV—in as soon as 20 minutes* to results for the near patient testing of Flu A, Flu B and RSV for improved infection control and therapy

Tracking Resistant Bacteria

Cepheid Solution: Cepheid® C360 enables to monitor trends for a variety infections, including *C. difficile*, MRSA, CRE, VRE, TB and Flu in real time.

Monitoring and reporting of local, national, and international trends of the prevalence of critical infections and antibiotic resistance may be possible among physicians and public health officials. This can help them to understand the emergence and spread of key infectious diseases.

Cepheid C360* securely collects and aggregates, in dashboard format, real-time information from any GeneXpert System to enhance productivity and performance.

This program is an integrated disease surveillance solution to detect infectious disease trends through a single web-portal.

Currently, available for English speaking countries only.



Why Fast and Accurate Results are Important

- They minimize follow-up visits by optimizing treatment early
- They support better clinical decisions improving patient outcomes¹
- They reduce the number of surgical site infections by using targeted decolonisation strategies²
- They improve antibiotic stewardship and reduce pharmacy cost²
- They improve implementation of infection prevention policies³
- They provide results that are easy to interpret and can be used for a cost effective patient management⁴



With Xpert® *C. difficile* BT you can

- Improve antibiotic stewardship
- Start contact precautions and effective treatment earlier
- Help to prevent outbreaks



With Xpert® MRSA products you can

- Manage the use of contact precautions for colonized patients more judiciously
- Prescribe targeted antibiotic therapies



With Xpert® Carba-R you can

- Identify and isolate positive patients
- Implement infection control protocols that can prevent outbreaks in your institution



With Xpert® MTB/RIF Ultra you can

- Have fast identification of infectious patients
- Guide the decision making process for an early initiation of appropriate treatment
- Have fast and accurate detection of drug-resistance in mixed infections



With Xpert® *vanA/vanB* you can

- Identify and isolate positive patients
- Implement infection control protocols that can prevent outbreaks in your institution



With Xpert® Xpress Flu/RSV you can

- Empower healthcare providers with infection control and patient management information
- Support improved antibiotic and antiviral stewardship

1 Bauer K. A. et al. An Antimicrobial Stewardship Program's Impact with Rapid PCR MRSA/ *S. aureus* Blood Culture Test in Patients with *S. aureus* Bacteremia. *Clinical Infectious Diseases* 2010; 51(9):1074–1080

2 Humphreys H. et al. *S. aureus* and surgical site infections: benefits of screening and decolonization before surgery. *Journal of Hospital Infection*. 2016.06.011.

3 Birgand G. et al. Rapid detection of glycopeptide-resistant enterococci: impact on decision-making and costs. *Antimicrobial Resistance and Infection Control* 2013, 2:30

4 Casari E. et al. Reducing rates of *C. difficile* infection by switching to a stand-alone NAAT with clear sampling criteria. *Antimicrobial Resistance and Infection Control* (2018) 7:40



GeneXpert® I



GeneXpert® II



GeneXpert® IV



GeneXpert® XVI

Simple Implementation into Institution Workflows

Three easy steps

As simple as 1, 2, 3 – Hands-On Time < 1 minute

1

Obtain specimen



2

Transfer sample to cartridge



3

Insert cartridge and start test






GeneXpert® Infinity System

GeneXpert® System

Cepheid's GeneXpert family of systems have set a new standard in workflow flexibility, 24/7 testing accuracy, and user-friendly design.

The GeneXpert System offers a complete menu of tests on a single platform. Available in a one, two, four, 16, 48, or 80-module configuration, all systems use Cepheid's proven GeneXpert module. Testing can be done on-demand — there is no need to wait and batch samples as each module can run a separate test.



The Most Extensive Molecular Diagnostics Menu Available

CE-IVD Xpert® Test Menu

Healthcare- Associated Infections

Xpert® MRSA NxG
Xpert® SA Nasal Complete
Xpert® MRSA/SA BC
Xpert® MRSA/SA SSTI
Xpert® *C. difficile* BT
Xpert® *vanA/vanB*
Xpert® Carba-R
Xpert® Norovirus

Critical Infectious Diseases

Xpert® **Xpress** Strep A
Xpert® Flu
Xpert® **Xpress** Flu/RSV
Xpert® MTB/RIF Ultra
Xpert® MTB/RIF
Xpert® EV
Xpert® Ebola

Women's & Sexual Health

Xpert® CT/NG
Xpert® CT
Xpert® TV
Xpert® HPV
Xpert® GBS

Virology

Xpert® HCV Viral Load
Xpert® HIV-1 Qual
Xpert® HIV-1 Viral Load

Oncology & Genetics

Xpert® Bladder Cancer Detection
Xpert® Bladder Cancer Monitor
Xpert® Breast Cancer STRAT4
Xpert® BCR-ABL Ultra
Xpert® FII & FV

 In Vitro Diagnostic Medical Device

May not be available in all countries.

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