

## GLOBAL CHALLENGES

### SERIOUS BACTERIAL INFECTIONS

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## INFECTIONS ARE BECOMING MORE DIFFICULT TO TREAT

Serious bacterial infections (SBIs) are a major cause of death for people in hospitals and other healthcare settings. Claiming 7.7 million lives each year, they are one of the world's biggest killers today<sup>1</sup>. If not treated promptly and appropriately, SBIs can go on to cause severe illness and life-threatening complications, such as organ failure or sepsis.

Over the last century, antibiotics have provided a critical means of protecting people from SBIs and in so doing, have increased life expectancy by an incredible 23 years<sup>2</sup>. However, the rise and spread of drug-resistant infections now threatens to reverse these gains. Growing resistance to antibiotics, including those kept as a last resort (such as carbapenems), is already leaving clinicians with increasingly limited treatment options. Without urgent action, research suggests that deaths caused by drug-resistant bacteria could rise sharply, by more than 70% globally by 2050<sup>3</sup>.

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## THE RISE AND SPREAD OF GRAM-NEGATIVE INFECTIONS

One reason for this sudden shift is the proliferation of difficult-to-treat Gram-negative bacteria, which are a leading cause of hospital-acquired infections. These pathogens pass between people or via objects, and can also form tough biofilms on medical equipment, like ventilators and catheters. This enables them to become entrenched in healthcare settings and makes it difficult to prevent their spread.

As the pharmaceutical industry has steadily retreated from antibiotic research and development (R&D), innovation has failed to keep pace with the circulation of these dangerous drug-resistant bacteria. This is expected to fuel a sharp rise in SBIs, with Gram-negative infections making up a growing proportion of AMR-related deaths.

Many of these challenges could be prevented through the development of new antibiotics, and by ensuring they reach the people who need them<sup>3</sup>. Yet even when antibiotics have been developed, access remains a major challenge - particularly in low- and middle-income countries (LMICs). Recent research by GARDP suggests that in some countries, fewer than 1 in 15 people with a SBI caused by carbapenem-resistant bacteria currently receive the right treatment that would protect their health.

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## GARDP'S FOCUS ON THE MOST DIFFICULT TO TREAT INFECTIONS

Evidence indicates that more than 11 million deaths could be prevented by 2050 through the development of new antibiotics targeting Gram-negative bacteria, and a further 50 million through broader access to essential antibiotics<sup>3</sup>. GARDP's unique public-private partnership model is designed to

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1. GBD 2019 Antimicrobial Resistance Collaborators, 2022. Global mortality associated with 33 bacterial pathogens in 2019: a systematic analysis for the Global Burden of Disease Study 2019.
  2. Hutchings, M., Truman, A.W. and Wilkinson, B. Antibiotics: past, present and future. *Curr Opin Microbiol*. 2019 Oct;51:72-80
  3. GBD 2021 Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance 1990–2021: a systematic analysis with forecasts to 2050. *Lancet* 2024; 404: 1199–226



do precisely that. By prioritizing public health impact and focusing on affordability and access within high-burden countries, GARDP develops and supports access to treatments that target World Health Organization (WHO) priority pathogens – hard-to-treat infections that pose the greatest threat to public health.

Through its dedicated programme for SBIs, GARDP works with partners to accelerate the development of innovative new treatments while also expanding access to existing ones, including new combinations of medicines, in adults and children.

By partnering with the Japanese pharmaceutical firm Shionogi as well as the Clinton Health Access Initiative and Orchid Pharma, GARDP is accelerating access to **cefiderocol**, a Reserve antibiotic approved to treat complicated urinary tract infections as well as hospital- and ventilator-associated pneumonia caused by Gram-negative bacteria in adults. As of 2021, cefiderocol is the only recently authorized antibiotic agent with activity against all three groups of Gram-negative bacteria on WHO’s critical priority pathogen list.

Aiming to make it accessible in up to 146 countries, GARDP is co-developing a novel, broad-spectrum antibiotic - **BWC0977** – with Bugworks Research Inc., in both intravenous and oral formulations. Laboratory studies show promising activity against several multidrug-resistant bacteria that commonly cause life-threatening SBIs.

In addition to this, GARDP is exploring ways to repurpose older antibiotics for new use. This includes exploratory work on **apramycin**, an older veterinary antibiotic, as well as a new treatment regimen for a group of bacteria called extended-spectrum beta-lactamase-producing Enterobacterales. These are a significant public health problem and a major killer, particularly in LMICs. In particular, it is evaluating the effectiveness of existing treatments used in combination to treat neonatal sepsis – which is important since newborns are especially vulnerable to severe life-threatening infections.

## SEPSIS

SBIs can lead to life-threatening complications, such as sepsis. This can occur when an infection triggers an extreme response from the body’s immune system, causing damage to tissues and resulting in multi-organ failure. Sepsis is one of the world’s biggest killers that is responsible for 1 in 5 deaths worldwide.

Drug resistance is a major factor shaping treatment success, and contributes significantly to hospital mortality. This highlights the need for timely effective antibiotics not only to prevent sepsis, but also to manage it when it occurs.

GARDP is working to reduce these threats by developing and improving access to treatments that target multidrug-resistant SBIs, including for children, who make up roughly half all sepsis cases. In particular, it is evaluating the effectiveness of existing treatments used in combination to treat neonatal sepsis – which is important since newborns are especially vulnerable to severe life-threatening infections.

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## WHO Bacterial Priority Pathogens List, 2024 update

