

Sexually-transmitted infections

Antimicrobial resistance (AMR) is a major and rapidly growing global public health threat. Responsible for more than 700,000 deaths a year, it poses a significant threat¹ to the attainment of the UN Sustainable Development Goals (SDGs), in particular SDG3, which aims to ensure healthy lives and promote wellbeing for all.²

The Global Antibiotic Research and Development Partnership (GARDP) is a not-for-profit research and development organization that addresses global public health needs by developing and delivering new or improved antibiotic treatments, while endeavouring to ensure their sustainable access.

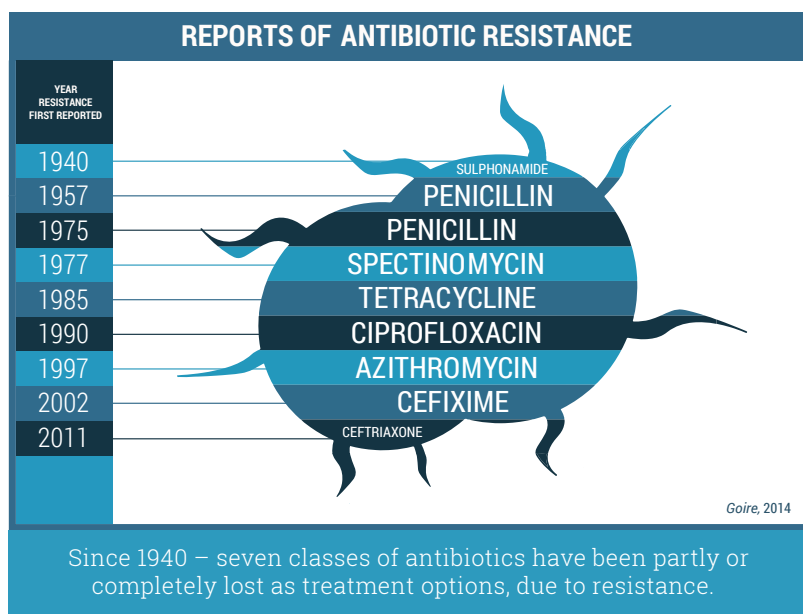
Initiated by the World Health Organization (WHO) and the Drugs for Neglected Disease *initiative* (DNDi) in May 2016, GARDP is an important element of WHO's Global Action Plan on Antimicrobial Resistance that calls for new public-private partnerships to encourage R&D of new antimicrobial agents and diagnostics. Following a successful incubation period, GARDP became an independent legal entity in 2019.

GARDP's programmes incorporate access and stewardship strategies to ensure treatments are affordable and available to all those who need them.

Partnerships are central to GARDP's model and include WHO, pharmaceutical and biotechnology companies, academia, governments, health authorities, philanthropic organisations and civil society from across the world.

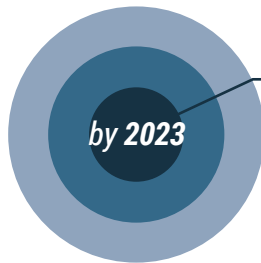
There are around 376 million new cases of sexually-transmitted infections (STIs) across the world each year. AMR is making them harder to treat. The bacteria that causes gonorrhoea is particularly prone to drug resistance, and is classed as 'high priority' for renewed antibiotic R&D by the WHO.³

There are an estimated 87 million new cases of gonorrhoea every year across the world.⁴ It is the second-most frequently reported infectious disease in the USA,⁵ and in South Africa it accounts for up to 90% of urethral discharge in men.⁶ If left untreated, gonorrhoea increases the risk of contracting and transmitting HIV, and has serious consequences for reproductive health and fertility, including ectopic pregnancies, spontaneous abortions and stillbirths. In a WHO survey of 77 countries, 97% reported recorded instances of resistance to commonly used treatment regimens and 66% to cephalosporins, the last options for monotherapy. There have also been increased cases of 'super-gonorrhoea.'



GARDP'S STI PROGRAMME

GARDP's STI programme aims to help tackle the global public health threat of drug-resistant STIs. It includes efforts to develop a new treatment for drug-resistant gonorrhoea, investigate new combinations of antibiotics to treat STIs, and ensure sustainable access strategies.



- Starting with gonorrhoea, GARDP's STI programme aims to develop and deliver at least one treatment that will most impact on public health by ensuring it meets three criteria:
 - works against drug-sensitive and drug-resistant gonorrhoea
 - is suitable for integration into international and national STI treatment guidelines
 - can address urogenital and extra-genital infections

TO DATE, GARDP HAS

- Developed a peer-reviewed R&D strategy for STIs. The strategy, published in PLOS Medicine in 2017⁷, starts with an R&D roadmap to accelerate the development of antibiotics to treat drug-resistant gonorrhoea.
- Entered, in 2017, into partnership with Entasis Therapeutics⁸ to develop zoliflodacin – a novel, first-in-class oral antibiotic. Zoliflodacin has shown high activity in a phase II clinical trial, published in the New England Journal of Medicine.⁹
- Prepared for a pivotal phase III clinical trial. Pivotal trials are designed to provide the evidence needed to approve a drug. Preparation for the phase III trial included a clinical trial to confirm a safe and effective dose of zoliflodacin. Forty-eight patients in

the US were enrolled into a phase I 'food effect' study to investigate the effect of food on a new formulation of zoliflodacin.

- Collaborated with the Foundation for Innovative New Diagnostics (FIND Dx) as it develops new tools to diagnose gonorrhoea.

LOOKING AHEAD

- The multi-site phase III pivotal clinical trial will start in the Netherlands, South Africa, Thailand and the USA in 2019. GARDP will continue to work on cost and affordability as part of the development plan. If the trial is successful, zoliflodacin will serve as a pilot case study in introducing new antibiotics into the market in a way that can assure effective stewardship and access.

"GARDP is developing new treatments on a not-for-profit basis through public-private partnerships. One new antibiotic showing promise is for drug-resistant gonorrhoea, an infection that has failed treatment with last-resort antibiotics in at least 10 countries. If it works, this partnership could be a model for how to increase access to and affordability of medicines, which is key to achieving universal health coverage."

Dr Tedros Adhanom Ghebreyesus,
WHO Director-General

A GLOBAL COLLABORATION

Partners & trial sites



The STI programme has partners and/or trial sites in

The Netherlands
South Africa
Sweden
Thailand
USA

For a full list of partners see gardp.org/partners

- 1 O'Neill, J. (Chair) Antimicrobial Resistance: [Tackling a crisis for the health and wealth of nations](#): The Review on Antimicrobial Resistance, 2016
- 2 The [2030 Agenda for Sustainable Development](#), 2015.
- 3 World Health Organization (WHO) priority pathogen World Health Organization (2017). [WHO publishes list of bacteria for which new antibiotics are urgently needed](#).
- 4 World Health Organization (WHO), [Report on globally sexually transmitted infection surveillance 2018](#)
- 5 The US Centers for Disease Control and Prevention (CDC): [Sexually Transmitted Disease Surveillance, 2017](#)
- 6 Sentinel Surveillance, STI South Africa, Communicable Disease Communique, February 2016
- 7 Alirol E, Wi TE, Bala M, Bazzo ML, et al. [Multidrug-resistant gonorrhoea: A research and development roadmap to discover new medicines](#). PLoS Med, 2017. 14(7): e1002366
- 8 GARDP briefing paper. [Tackling the rise in drug-resistant gonorrhoea, partnership to develop new drug](#). 2017
- 9 Taylor, S, Marrazzo, J, Batteiger, B et al. [Single-Dose Zoliflodacin \(ETX0914\) for Treatment of Urogenital Gonorrhoea](#), N Engl J Med 2018; 379:1835-1845