What can we learn from COVID-19 to advance antibiotic R&D?

Dr Manica Balasegaram Executive Director GARDP GARDP

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Could the next pandemic be caused by a drug-resistant infection?

Learning from COVID-19 to Tackle Antibiotic Resistance

https://gardp.org/news-resources/learning-covid19-antibioticresistance/

COVID-19 and drug-resistant infections



- Drug-resistant infections have some commonalities with fast-moving pandemics like COVID-19 for 3 reasons:
- **Reason 1:** Drug-resistant infections are a silent pandemic.
- **Reason 2:** Timely access to appropriate antibiotics will be an important component of preparedness and response to future viral pandemics .
- Reason 3: Antibiotic prescriptions increase substantially during a viral pandemic as early evidence during COVID-19 has shown.

COVID-19 lessons learned

5 early lessons of the COVID-19 pandemic:

Lesson 1: Investments in preparedness are necessary, and costeffective for a pandemic, including research and development of new treatments and vaccines.

Lesson 2: Collaboration and international coordination are critical to address a pandemic.

Lessons 3: Medical countermeasures have not been available because traditional market incentives are neither sufficient nor appropriate to ensure their timely development on a global scale.

Lesson 4: Equitable and affordable access to medical countermeasures is an essential element of a comprehensive and effective pandemic response.

Lesson 5: Inequitable access to medical countermeasures can undermine the trust many countries have in the 'international system'.



How do we prevent the next health emergency?



- Investments in pandemic preparedness & antibiotic R&D are needed now more than ever to prevent future infectious disease outbreaks.
- Antibiotics are a critical tool in pandemic preparedness – investing in AMR tools is a good investment to prevent and address future pandemics.
- But unlike COVID-19, the pathogens responsible for bacterial infections are well identified and targeted action can be taken now to avert another health emergency tomorrow.

Recommendations for governments

The impact of the COVID-19 pandemic, along with its lessons, presents a turning point to improve the response to pandemics, particularly the silent pandemic of drug-resistant infections.

We recommend 5 concrete measures that would strengthen domestic and global responses to AMR:

- 1. Recognise and urgently address the silent pandemic of drug-resistant infections.
- 2. Invest in the development of medical countermeasures as a critical element of pandemic preparedness.



Recommendations for governments



- 3. Ensure that access to diagnostics, treatments and vaccines for all is a cornerstone of pandemic preparedness and response.
- 4. Expand global cooperation across geographies and sectors and within a One Health framework.
- 5. Ensure low- and middle-income countries are equal partners in a comprehensive global response. Solutions that have been pioneered by such countries should be recognised and integrated into pandemic preparedness and response.

Antibiotic development has not kept pace

Half of all antibiotics used today were discovered between the **1950s and 1970s.** Since then, drug discovery and development has become more complex, time-consuming and expensive. In the past 20 years, no new antibiotic class against Gram-negative bacteria has been approved.



Overuse and misuse of antibiotics has accelerated resistance

Bacteria can change naturally in response to medicines, developing the ability to defeat drugs, but the overuse and misuse of antibiotics has accelerated this process.

Between 2000 and 2015, global consumption of antibiotics increased by **65%** The number of antibiotics prescribed unnecessarily 1 in 5 in the U.K. 1 in 3 in the U.S.

Why is there a crisis?

Antibiotics: a high investment for public health but with no market return

Expected net present value in US\$ million (range)

- The R&D is scientifically challenging as novelty in new drugs is relatively rare
- A blockbuster model is not sustainable for antibiotic R&D
- Antibiotic R&D is not an attractive investment; many in the private sector have difficulties raising capital and have left the field



GARDP's vision: All infections are treatable for everyone, everywhere





Our mission

GARDP brings together the public and private sectors to develop new treatments for bacterial infections. We ensure responsible and sustainable access, addressing the public health impact of antibiotic resistance.

Our focus

Bacteria on the WHO priority pathogen list Diseases and populations disproportionally affected by drug resistance Late-stage clinical development and access

Our approach

INVEST IN LIVES IMPROVED & SAVED

GARDP is developing new and improved treatments for priority drug-resistant infections that cause hundreds of thousands of deaths every year.

INNOVATIVE PARTNERSHIPS

In four years, GARDP has formed more than 50 partnerships in 20 countries, built a solid base of knowledge and expertise, and created research programmes to deliver new treatments.

DELIVERING IMPACT

Through collaborations, GARDP has evaluated 100 substances for antibacterial activity, resulting in six drug candidates for infections that pose the greatest threat to health.

GARDP's commitment 2020-2025

What will GARDP develop treatments for?

- Serious bacterial infections in hospitalized people
- Drug-resistant infections in children
- Neonatal sepsis in newborns
- Sexually transmitted infections

WHO priority pathogen list for which there is a critical and high need for new antibiotics.

How will GARDP accomplish its ambition?

• Focus on developing new and improved treatments in late-stage clinical development and ensuring responsible and sustainable access.

€500 million to accelerate development and delivery of 5 new treatments that address urgent public health needs by 2025

Achievements to date

Serious Partnered with **Venatorx Pharmaceuticals** to develop a new drug candidate, cefepime-taniborbactam, for serious bacterial • infections in hospitalized adults, including those for which there are limited treatment options bacterial infections Children's Completed one of the largest global studies on newborns with sepsis (over 3,000 babies enrolled). Results will inform empiric trial that will evaluate combination treatments for neonatal sepsis (a leading cause of death among babies). antibiotics Completed a safety evaluation of an existing antibiotic (fosfomycin) for use in babies to treat drug-resistant infections, including neonatal sepsis Sexually transmitted Partnered with Entasis Therapeutics to develop a first-in-class treatment for gonorrhoea ٠ infections Global phase III trial recruiting patients in most sites in US, the NL, after a Covid-19 pause, South Africa & Thailand ٠ **Discovery &** exploratory Screened >65'000 compounds and evaluated more than 100 new and 'recovered' chemical entities as part of our discovery and research exploratory research programme to boost antibiotic R&D **Scientific** Launched REVIVE, an online knowledge sharing platform on antimicrobial R&D and secured attendance of over 5,700 participants at ٠ 32 webinars led by experts in the field affairs Launched Antimicrobial R&D Encyclopaedia ٠

Value of a not-for-profit model

The issue	Area of intervention	Desired outcome	Why a not-for-profit?
Meeting global public health needs	Objective and long-term public health portfolio approach Targeted PPPs, ensuring return on public investment	Ensuring new treatments are available long term	Can take a long term 'big picture' approach, not tied to any product
Best use of public money	Explore and invest in high-risk projects; rescue 'abandoned' projects (safe harbour)	Deliver 'most needed' treatments for Public Health	Less risk averse; take on projects with no commercial value; do research in nontraditional setting
Ensuring availability and appropriate use	Obtain key indication approval; generate more real-world data	Good stewardship of new antibiotics; minimise off-label use; enhance public health value of portfolio	Invest in areas of low commercial, high public health return; Less reluctance to conduct studies that may 'diminish' product
Ensuring equity, meeting specific challenges	R&D in populations with high burden & need, e.g. neonates	Addressing underserved areas	Address areas seen as too challenging (and with little commercial return)
Addressing emerging threats	Global Access: Conduct R&D in different, sometimes challenging geographies and link with licensing, registration, guidelines, stewardship, supply	Accelerate access including in high burden areas; enhance appropriate use	Companies will focus on territories with commercial return; NFP can take local and multilateral approaches for R&D and global access
Infrastructure for global R&D projects	Set up and support global networks and collaborations	Set up trial networks; strengthen research capacity	Working long term with regional partners



