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VIEWPOINTS

A Nonprofit Drug Development Model Is Part of the Antimicrobial Resistance (AMR) Solution

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Antibiotics underpin modern medicine and are critical for pandemic preparedness. Push funding has revitalized the preclinical antimicrobial resistance (AMR) pipeline and government funding via CARB-X and BARDA, as well as private sector–led investment via the AMR Action Fund, will help several new antibiotics obtain regulatory approval. Nevertheless, revenues generated by new antibiotics are not considered sufficiently profitable by commercial developers to address unmet need. The question remains: Who could viably fund development and secure global equitable access for new antibiotics? Public health need should be the primary driver for antibiotic development. Improved prioritization and government oversight by funders who allocate public resources are a needed first step. In this framework, nonprofit research and development organizations, with support from public funders, and unconstrained by commercial profitability requirements are well positioned to work with public and private actors to viably provide new antibiotics to all in need.

Keywords. nonprofit; AMR; research and development.

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) global pandemic has demonstrated the failure to prepare for a global public health emergency and its consequences [1]. Coronavirus disease 2019 (COVID-19) has led to unprecedented public spending, rapid marshalling of scientific and medical expertise through international collaboration, and accelerated development of vaccines, diagnostics, and treatments. The response to the long-standing threat of drug-resistant bacterial infections due to antimicrobial resistance (AMR) is weaker and receives less global funding. One lesson of the SARS-CoV-2 pandemic is that unlocking global collaboration and public investment after a threat is a global crisis is unacceptable.

SARS-CoV-2 and AMR are parallel and interacting emergencies [2]. Like SARS-COV-2, drug-resistant infections spread rapidly worldwide through international travel, migration, and supply chains. Effective antibiotics are a foundation of health systems. Future viral pandemics carry a significant risk of hospitalization and secondary bacterial infections, so health systems will require timely access to antibiotics.

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Unlike the SARS-CoV-2 virus, which required bold efforts to identify medical interventions, there are promising solutions available in the antibiotic pipeline. The risk of failure in the clinical development of antibiotics is low compared with treatments for other therapeutic areas [3]. Yet, in April 2021, the World Health Organization (WHO) warned in its latest "Antibacterial Pipeline Report" that the pipeline was insufficient to counter rising drug resistance, including serious threats posed by carbapenem-resistant gram-negative bacteria.

WHY IS THERE A STRUGGLE TO FUND AND FINANCE THE DEVELOPMENT OF NEW TREATMENTS FOR BACTERIAL INFECTIONS?

First, funding may not be aligned to address the most critical public health needs [4]. Significant additional funding is needed throughout the pipeline, from early discovery research to keep populating the preclinical pipeline [5] to clinical development and postapproval activities. Hundreds of millions of dollars have been invested in national programs and global collaborative efforts such as CARB-X [6], particularly by the governments of the United States, Germany, and the United Kingdom, and the Wellcome Trust. Others, such as the Novo Foundation REPAIR Impact fund [7], have become important funders of preclinical research and early clinical trials. Upfront "push" funding has helped potential new treatments enter the pipeline. In 2020, the $1 billion AMR Action Fund sponsored by a consortium of multinational pharmaceutical companies, the WHO, and the European Investment Bank was announced [8]. It will invest in smaller biotech companies that are developing treatments targeting existing health priorities [9]. Yet, as

the fund acknowledges, it only aims to support development of between 2 and 4 therapeutics and will be insufficient [10].

Second, existing push and pull incentives, while critically important to maintain industry engagement, may be inadequate to sustain private research and development fulfilling public health needs. In most therapeutic areas, smaller companies developing new compounds are either acquired by or license an investigational compound to a larger pharmaceutical company, at the latest after first proof of efficacy in humans (phase 2a). In contrast, in the antibiotic market, small companies often rely upon public funding to conduct and complete clinical studies and drug licensure. Large pharmaceutical companies do not generally deem such drugs as attractive for investment or acquisition compared with more promising commercial opportunities.

Despite support from government agencies such as the Biomedical Advanced Research and Development Authority (BARDA) [11], smaller companies have gone bankrupt, even after a drug has been approved for human use. The most cited example is former US biotech company Achaogen, which developed the aminoglycoside plazomicin. Not only did Achaogen declare bankruptcy, but Cipla (an Indian generics company) that acquired plazomicin withdrew its application for marketing authorization to the European Medicines Agency (EMA) due to pharmacoeconomic reasons [12].

Third, even though the burden of drug-resistant infections in low- and middle-income countries (LMICs), where most of the world's population resides, is far higher than in high-income countries, these countries are not commercially attractive markets. There is little to no profitability to market medicines in challenging or complex contexts with low purchasing power. The United States is the world's largest pharmaceutical market, but even when coupled with new initiatives such as the AMR Action Fund, it may be insufficient to address the broader challenges for global access [10]. This unmet need does not encourage private companies to develop new antibiotics. Thus, policymakers cannot rely purely on market-driven solutions. Progress has been made towards developing appropriate pull incentives that improve the commercial viability of antibiotics, including the Pasteur Act under consideration in the United States [13] and different antibiotic reimbursement schemes currently being piloted in several European countries [14].

Fourth, each new antibiotic may be clinically important but of therapeutic benefit for few patients and so a small and potentially unattractive commercial market may be further limited by good antimicrobial stewardship. Developing new treatments for drug-resistant infections addressing AMR is not the same as addressing infections caused by tuberculosis (TB), SARS-CoV-2, or human immunodeficiency virus (HIV). Unlike these single-pathogen infections, antibiotics are rarely effective against all bacterial species, let alone all drug-resistant strains. Furthermore, there are many different drug-resistant bacteria, and each causes infections in different body sites, so new antibiotics must be effective against different pathogens infecting these areas (eg, lungs, bladder, or bloodstream); it can be challenging to get drugs at clinically effective concentrations at all body sites. Finally, antibiotics need to be available for use in many different populations (eg, neonates and infants, as well as elderly or immunocompromised individuals) and healthcare settings. The need for numerous new therapeutic options further exacerbates insufficient commercial interest.

Finally, even if economic incentives, the commercial market, or private funding could address the gaps in the pipeline, such measures may not safeguard access. The SARS-CoV-2 pandemic has highlighted the importance and difficulties of securing equitable access to health tools. Access to antibiotics is already a major challenge in LMICs [15]. Economic incentives (eg, guarantees to purchase a drug by a specific country) are insufficient, although needed. All countries must be able to purchase antibiotics and ensure that an approved antibiotic is available and accessible to all in need. While there is a need for more push and pull incentives to reinvigorate the R&D pipeline, other interventions are required to facilitate effective and responsible global access.

REVITALIZING ANTIBIOTIC RESEARCH AND DEVELOPMENT WHILE ENSURING ACCESS

To accelerate the development of treatments and to secure an optimum public return on public funding, the public sector should exert leadership to identify and set priorities for drug development and ensure timely access. This includes prioritizing clinical development according to public health priorities identified by WHO while acknowledging country-by-country differences. This is increasingly possible due to collection of surveillance data from the WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS) surveillance program on the prevalence of drug-resistant bacteria and attributable mortality [16]. An additional metric could be the use of global burden of disease figures. Hughes et al [17] have developed 2 new measures: the Empiric Coverage Index (ECI) and the Empiric Options Index (EOI). These could also inform policymakers and funders and contribute to priority setting by identifying gaps that need addressing due to drug resistance and/or lack of a therapeutic option.

Several public-private partnerships and public and private funding mechanisms have been established (eg, [18, 19]), including the funding mechanisms of the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), BARDA, CARB-X, REPAIR Impact Fund, the AMR Action Fund, and EU IMI The New Drugs for Bad Bugs. Yet, such funding models may be insufficient. There is also a need for entities that harness such funding to co-develop and introduce new antibiotics.

Table 1. What a Nonprofit With Its Partners Can Contribute to Address the Global Crisis of Antimicrobial Resistance

The Issue	Area of Intervention	Desired Outcome	Why a Nonprofit?
Meeting global public health needs	• Addressing public health priorities via an objective and long-term approach • Targeted PPPs, harness best of public and private sector • Conduct R&D in different, challenging geographies	• Ensure new treatments address public health needs and not just based on regulatory endpoints or commercial viability	• Focus on populations and geographies from a public health perspective • Mission requires a long-term commitment • Less risk averse to explore a potential product
Best use of public money and ensuring a public return on public money	• Explore and invest in high-risk, but high societal value projects • Expand LMIC access (licensing, registration, guidelines, support stewardship, supply)	• Deliver "most needed" treatments • Bring novel interventions to the most affected patients in geographies with little or no market potential	• Collaborative approach • Projects with little or no initial commercial value but fulfilling a public health need • Local and multilateral approaches for R&D and access
Ensuring equity and strengthening global R&D infrastructure	• R&D and network strengthening for populations with high burden and need (eg, neonates) • Set up and support global networks and collaborations especially in high-burden countries	• Address underserved areas • Deliver clinical trial data from networks including countries with a high burden of drug-resistant infections • Strengthen research capacity in areas with a high AMR burden	• Work on multiple projects with regional partners • Perceived as a "neutral," trusted partner by the public and private sectors • Motivation and capacity to mobilize resources to foster R&D infrastructure

Abbreviations: AMR, antimicrobial resistance; LMIC, low- and middle-income country; PPP, public-private partnership.

Hybrid R&D models [18] have been suggested. This includes the establishment of a limited for-profit/public benefit corporation [20] or a fully public/academic organization [21]. Both models have potential benefits and drawbacks. A limited for-profit/public benefit corporation can integrate social and environmental objectives into its business planning and decision making and can access different funding sources, including social impact investors, sovereign investment funds, and program investment arms of foundations [22]. Yet, it is still a profit-making enterprise. Given the current challenges faced by for-profit companies, it remains unclear whether the latter can generate a sufficient return on investment to attract capital to self-sustain operations. The need to generate profit can skew priority setting to those drugs that may generate greater revenues. It is also unclear whether such an organization would operate differently compared with a large generic manufacturer. Conversely, it may also deter the participation of other private sector entities.

An R&D approach solely within the public sector may lack sufficient funding and expertise, particularly in clinical development; does not address how to access privately held drugs; and may struggle with manufacturing and distribution. It could also undermine instead of complement small and medium-sized for-profit companies. The challenge is to harness public and private sector expertise and resources [23].

Nonprofit collaborative R&D organizations can help meet this challenge. Since 2010, nonprofit developers have developed and introduced 66 new health technologies for priority public health needs, reaching more than 2.4 billion people worldwide (including vulnerable populations) and include new treatments for TB and neglected tropical diseases (NTDs) [24]. As with AMR, even though TB and NTDs are urgent public health priorities for many countries, there are insufficient commercial returns to sustain private R&D investment. The successes of nonprofit collaborative R&D organizations should encourage those vested in revitalizing the antibiotic pipeline. Nonprofit collaborative approaches, which are the basis of organizations like the Global Antibiotic Research and Development Partnership (GARDP) [25], could be a basis for sustained investment and action. GARDP, an independent foundation founded by the WHO and Drugs for Neglected Diseases initiative in 2016, is a nonprofit developer of treatments for drug-resistant infections. GARDP focuses on global public health needs defined by the WHO priority pathogen list, on unmet needs, and those of priority populations unlikely to be tackled by other actors. GARDP aims to deliver 5 new treatments focusing on sexually transmitted infections, sepsis in neonates and infants, and drug-resistant infections in hospitalized adults and children. There are several features of the nonprofit model, including the GARDP model, well suited to addressing AMR. These are listed in the Table 1 and below.

Meeting Global Public Health Needs

R&D decisions should be guided by global public health need. Nonprofit developers, unlike commercial entities, can set priorities and make decisions closely aligned to medical necessity and public health need and do not need to focus on achieving the greatest commercial return. This includes decisions about which products to develop and the populations and geographies to serve. Nonprofit developers can prioritize development of products for certain populations (eg, pediatric) not seen as

sufficiently profitable for commercial development. Although there may be a risk of prioritizing a project due to a conflict of interest (eg, a project leader or a funder is committed to a specific program), such risks are addressed through a nonprofit's governance mechanisms (independent scientific advisory committee and board) and scrutiny from governments, civil society, and industry. Nonprofit developers can also meet clinical needs by developing global public health–driven disease area strategies that will inform the requirements of specific interventions including antibiotic treatments. Specific target product profiles (TPPs) [26] aligned with disease area strategies can be developed that are "public interest" focused (for which third parties set out the characteristics of an appropriate product adapted and priced fairly for all health settings).

A nonprofit developer is therefore well suited to identify and address an unmet need or gap, and not what may earn the most revenue. One proposal to improve the targeting of antibiotic incentives in the United States was establishment of a Developing Antibiotics for Resistant Targets (DART) Board [27]. This board would include clinical experts, patient advocates, and representatives from government, industry, and nonprofit organizations, to develop and regularly update a dynamic list that restricts the bacterial species for which public drug development funding can be provided. The list would focus on serious and life-threatening infections caused by drug-resistant bacteria, as well as advantageous treatment modalities such as oral antibiotics. This approach could be applied globally.

Best Use of Public Money

With the primary objective of developing affordable and accessible drugs, nonprofit developers can overcome a fragmented R&D ecosystem via pooled funding from public, private, and philanthropic donors and through partnerships. Nonprofit entities can also act as a "safe harbor" for public funding. A nonprofit entity that secures public funding for a new antibiotic will not have commercial prerogatives that supersede a commitment of long-term availability of an approved drug. This can be enshrined in a nonprofit's policies and practices, the access commitments it may be required to adopt in exchange for funding, and through license agreements that a nonprofit developer signs with public or private entities. In contrast, nearly all SARS-CoV-2 vaccines, despite substantial public funding, have not assured equitable global access according to need.

Nonprofit developers employ a flexible collaborative approach with transparent governance, allowing partnerships with healthcare organizations, academia, and industry, thereby drawing upon knowledge and scientific expertise. A networked approach is equally possible in a space with little initial commercial value. Development within a partnership can be publicly led (eg, GARDP), especially where incentives are inadequate or development is intended to focus upon specific populations and geographies that are unlikely to attract private sector investment, private-led, or a combination. The use of public-private partnership models by a nonprofit developer can have a public health objective and outcome even if companies within such a partnership remain focused on shareholder returns.

Nonprofit developers can employ higher-risk approaches that are not commercially interesting and that few other R&D-based companies would tackle. A nonprofit developer selects projects based on what best aligns with its mission, the scientific promise of the project, and whether the outcomes can be affordable and accessible for target populations, not future profitability.

Strengthening Global R&D Infrastructure to Address Emerging Threats While Ensuring Equity

Ensuring that certain countries and communities are not excluded from clinical development is critical to ensuring equity and access. Nonprofit developers can focus on carrying out clinical trials in key geographies with the highest burden of infection by the drug-resistant target pathogen(s). Such trials or geographies may pose commercial challenges to companies. Global partnerships and networks can improve the ability to undertake clinical trials in countries with a high burden of drug-resistant infections [19]. This includes phase 3 studies in populations and for indications for which there is a clinical need for the new drug, including in LMICs. GARDP is investing in clinical trial networks with a focus on South Africa and India and populations such as neonates and infants (with the Penta Foundation). The Wellcome Trust is launching an Asian clinical trial network [28].

Ensuring Availability and Appropriate Use

New antibiotics are often not used appropriately or are unavailable due to challenges with supply, affordability, or because there is insufficient evidence and guidance for its use for certain drug-resistant infections or populations. Evidence to guide appropriate use should be generated through pre-registration and post-registration studies; the latter includes phase IV clinical trials, pharmacovigilance, resistance surveillance, and observational studies. Nonprofit developers can play a key role in sponsoring such studies and bringing together public and private sector stakeholders to execute them.

Use of new antibiotics by clinicians is often off-label and non–evidence-based, thereby compromising antibiotic stewardship. There is also prolonged lack of access to new drugs for high-risk and high-burden populations [29, 30]. A regulatory agency requires a single phase 3 clinical trial that is recognized as providing an adequate safety and efficacy database. For a drug with efficacy for drug-resistant infections and for which there are limited treatment options (eg, anti–multidrug-resistant gram-negative bacterial activity), typically such trials are in patients with complicated urinary tract infections [31]. Sometimes trials are conducted in sites with clinical research experience but without consideration of drug-resistance prevalence or burden of

disease. This results in delays in generating evidence needed to treat those serious bacterial infections in populations impacted by AMR (eg, nosocomial pneumonia, bloodstream infection/sepsis). These delays are magnified in resource-constrained countries where the burden of drug-resistant infections can be high.

Nonprofit developers support (eg, with industry [32, 33]) or sponsor pre-regulatory and post-regulatory studies to ensure availability and appropriate use. Pursuit of additional indications and clinical evidence will be closely aligned to a nonprofit developer's own organizational priorities and mandate to address unmet need. A nonprofit developer can collect postapproval data to evaluate a drug's value, utility, and safety.

Integrating solutions to access and stewardship should be a core element of the development process. This ensures new antibiotics reach those who require them without exacerbating AMR [19]. Notably, in LMICs, nonprofit developers can work with both public and private partners to ensure introduction and sustained availability of drugs by leveraging local actors to manage and distribute a product responsibly and affordably, and contribute to the design of appropriate reimbursement models, such as subscription models. Partnerships and appropriate reimbursement models are critical because there are significant funding and human resource requirements associated with maintaining a product on the market. These include registration-related costs, maintaining the supply chain, and development of additional indications and formulations.

The Importance of Public Sector Input and Oversight

There are likely to be different public-private partnership models employed by nonprofit developers. The main driver for developing new treatments for drug-resistant infections should be public health need. This requires governments and foundations to deploy their resources to ensure needs-driven R&D and access. Entities like GARDP, which are largely publicly funded, do this through joint R&D projects with oversight of the decision making, direct sponsorship of trials, in-licensing of compounds, and direct interventions that facilitate access. This approach may encourage governments to subsequently augment incentives for public and private R&D actors, including appropriate pull incentives, as governments will have a sense of ownership and responsibility for the technologies developed.

CONCLUSIONS

The June 2021 G7 Health Ministers' Declaration highlighted the necessity of tackling AMR, and AMR has been a topic of concern at the G20 [34]. Although there are ongoing challenges to ensuring equitable access during the global response to the SARS-CoV-2 pandemic, the pandemic response also illustrates that the public and private sector can work together in a flexible and nimble manner. Nonprofit developers can bring public and private partners together to tackle the AMR crisis and deliver treatments to those who need them sustainably and equitably.

Notes

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