

# The UK needs more systemic support for antibacterial innovation

**The UK has played a leading role in international efforts to address antimicrobial resistance (AMR) through science policy and diplomacy. Domestically, a new reimbursement model that better recognises the value of new antibacterial drugs is being piloted, and there is much relevant research activity. However, areas of weakness remain that limit the UK's contribution to antibacterial innovation. The UK's capabilities in this vital field need long-term support through joined-up policies and a range of indicators need to be closely monitored to track the impact of these interventions.**

## Main messages

- Expert interviews with a range of stakeholders and documentary analysis suggests that the UK needs a more coordinated approach to managing research and development (R&D) and innovation for new antibacterials.
- Key indicators are declining for vital functions needed to support the UK's role in antibacterial innovation.
- In order to ensure the UK continues to contribute new medicines to tackle AMR, government needs to adopt a systematic approach to monitoring indicators and actions to address weaknesses in the system.
- Consideration is needed around R&D funding levels and priority setting to ensure that key products are in fact advancing towards the market.

## Background

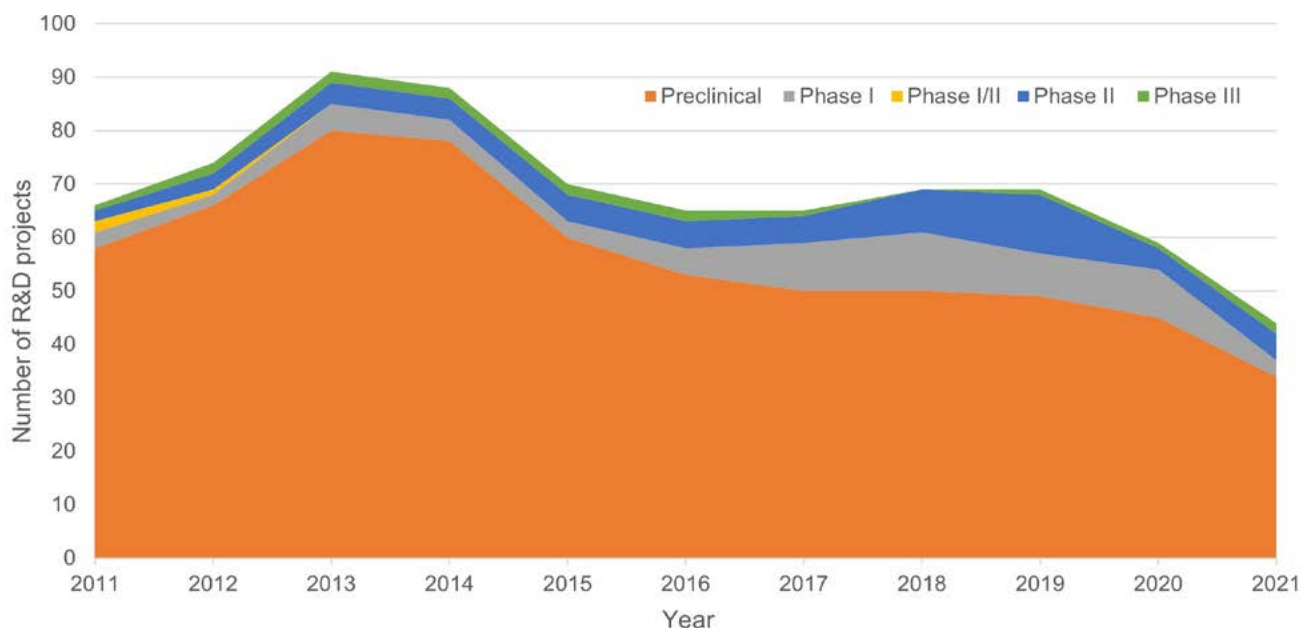
Antibiotics underpin modern medicine and save millions of lives per year globally. The UK has played an important role in highlighting the growing problem of AMR in international debates, however its contribution to the pipeline of novel antibiotics has not improved since the O'Neill review (2016). AMR is a complex, multi-generational challenge requiring us to build the foundations of a sustained response. This evidence brief highlights indicators that can help to monitor activity at the system level, providing intelligence that can inform the joined-up policies needed for this long-term effort.

## Findings

This study explores seven different aspects of antibacterial innovation in the UK, following the functional approach to innovation systems as specified by [Wieczorek & Hekkert \(2012\)](#).

Findings are reported from analysis of quantitative indicators describing UK activity, combined with insights from 37 hours of expert interviews with a range of stakeholders.

## 1 Antibacterial drug projects in the R&D pipelines of UK firms



Source: Authors' analysis of data from Pharmaprojects (Informa)

### 1 Insufficient private sector antibacterial pipeline development

The R&D pipeline of antibacterial drugs under development by UK-headquartered firms is declining, most notably at the pre-clinical end of the process. The UK's largest pharmaceutical firms have shifted away from traditional antibiotics, although new firms willing to undertake R&D activity in this field continue to emerge. Those UK firms focused mainly on antibacterials are all small or micro entities and show no net employee growth over recent years, which is concerning for future prospects in this part of the life sciences industry. At interview, a range of stakeholders overwhelmingly concluded that activity in the UK's commercial sector is insufficient. One industry figure suggested "the UK is punching well below its weight".

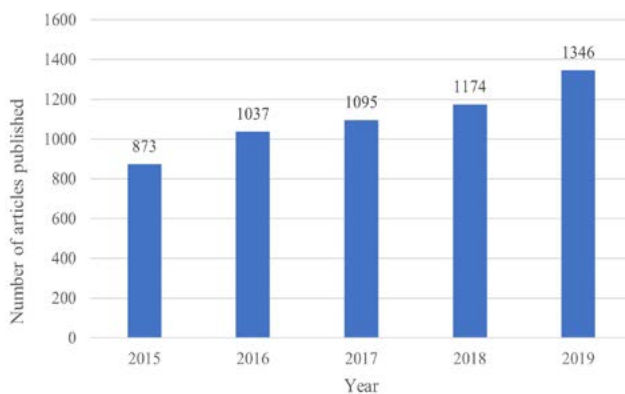
### 2 Scientific research grows while clinical studies decline

There has been steady growth in the output of scientific publications on antibacterial agents by UK researchers in recent years. Yet, in the area of clinical trials, activity has fallen by around two thirds since 2015. This fall, which pre-dates COVID-19, is reflected in activity by commercial and non-commercial trial sponsors as well as UK and non-UK based sponsors.

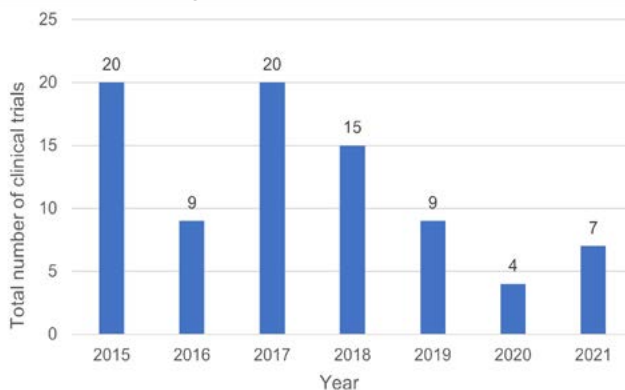
Some stakeholders suggest that UK academic research is not progressing to clinical studies due to a lack of funding for early-stage drug projects. Others highlight a lack of understanding in the academic community of the requirements of viable commercial

projects, as well as poor incentives for academics to devote their efforts to such studies. There may be a logic to conducting such studies abroad, but this raises questions about the appropriate role of the UK's clinical investigators.

### 2 Articles on antibacterial agents published by UK-based researchers

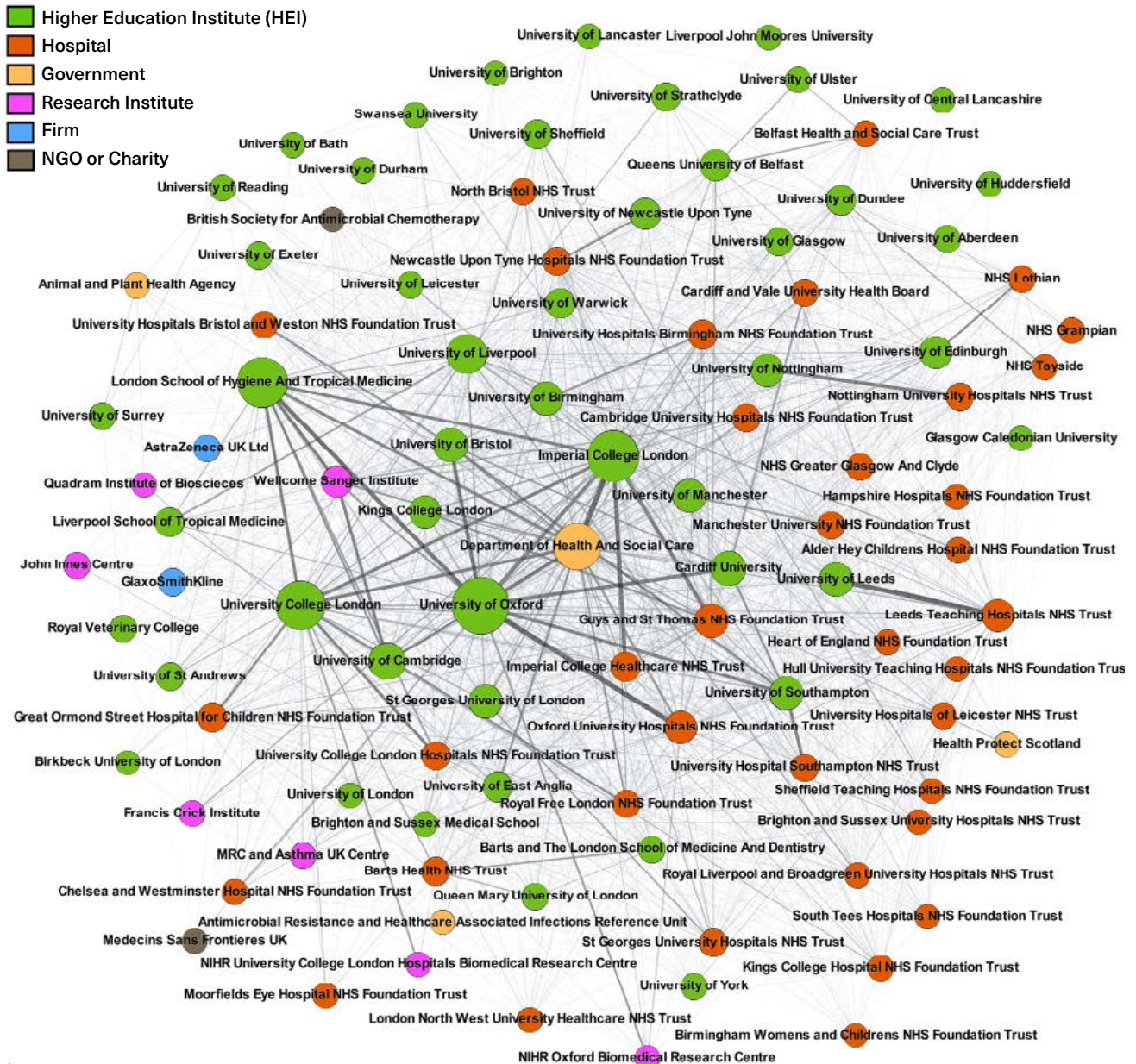


### 2 Clinical trials conducted in the UK focusing on antibacterial agents



Source: Authors' analysis of data from Web of Science/Pubmed (articles) and Trialstrove (Informa) (clinical trials)

**3 Network diagram showing co-authorship collaborations between the top-100 UK organisations publishing on the Medical Subject Headings term “antibacterial agents” (2015–2019)**



**3 Universities and hospitals are weakly linked to industry researchers**

The UK antibacterial innovation system is fragmented, with insufficient flow of knowledge and information between academia, firms, funders and clinicians. This is illustrated by mapping collaborative activity through publication, which reveals that around half of UK firms engaged in relevant R&D do not collaborate with UK scientists on the topic of antibacterial agents – and many have no co-authored scientific articles at all.

Positive developments, such as the [Infection Innovation Consortium \(iiCON\)](#) and the [Antibiotic Discovery Accelerator Network \(ABX\)](#) demonstrate how centrally-funded or grassroots initiatives can build

community and coherence, but need to be embedded within wider networks.

Dedicated funding for open-source science, academic-industry partnerships, translational research projects, and active technology transfer mechanisms may enhance knowledge diffusion, although incentives may need to be reshaped to facilitate links.

**4 Priorities need to guide R&D activity**

In the absence of clear market signals, bodies like the [National Institute for Health and Care Excellence \(NICE\)](#) and the [World Health Organization \(WHO\)](#) play important roles in indicating areas of current and future healthcare needs to those developing products.

“Drug-bug” lists at national and international levels provide a way to monitor resistance and focus research attention on priority infections. Relevant watch lists include that of the [English Surveillance Programme for Antimicrobial Utilisation and Resistance \(ESPAUR\)](#), which draws upon advice from the [UK Advisory Committee on Antimicrobial Prescribing, Resistance and Healthcare Associated Infection \(APRHAI\)](#) and the WHO list of priority pathogens. Research funders then have a role in reinforcing such research priorities, and in providing adequate support through AMR-specific programmes. These processes need to be coordinated and clear signals shared with researchers.

Currently, just over half of UK firms with active antibacterial pipelines are advancing drugs targeting priority infections designated by ESPAUR or WHO.

A more diverse range of therapeutic modalities – including vaccines and phage therapies – is developing as the UK’s largest firms move away from traditional small molecule antibiotics. At the level of the innovation system, this diversity is important and needs to be maintained, given the uncertainty of future threats and market conditions.

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## 5 Stronger market signals are needed

The UK Government has a rigorous approach to pharmaceutical price control with national expenditure capped through multi-year agreements with industry. Consequently, the UK has, for its size, a relatively small share of the global pharmaceutical market (between 2-3 per cent). Furthermore, antibacterial drug use in the National Health System (NHS) is relatively tightly controlled. The market for antibacterials is actually a patchwork of sub-markets for drugs of different types. While trends within specific sub-markets differ, overall, UK prescriptions for the major antibiotic classes have been reducing in recent years due to successful antimicrobial stewardship policies and practices. These have contributed to the UK being ranked number one in an international AMR Preparedness Index (GCOA, 2021).

This raises a paradox, as summarised by one senior clinician-researcher:

*“On one hand, we’re trying to stop people using antibiotics, and on the other hand, we’re trying to persuade drug companies to invest in making antibiotics. Why make drugs which people are trying desperately not to use?”*

(Clinician-researcher, June 2021)

Poor market prospects for antibacterial drug developers disincentivise R&D investment, even for those focusing on the much larger US market. In response to the resulting market failure, the UK’s NICE, Department of Health and Social Care and NHS recently opened a pilot scheme to reward firms that launch new drugs, through an annual fixed fee of up to £10m for up to 10 years (based on value to the NHS) - delinking financial reward from volume of prescriptions (known as the ‘subscription’ or ‘Netflix’ model). Payments for two (already developed) drugs have been agreed, but the UK’s fee will not be sufficient to stimulate new drug development on its own. For this new model to become a powerful market signal to industry, other countries will need to offer similar schemes and co-ordinate on priorities.

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## 6 Better mobilisation to bolster R&D

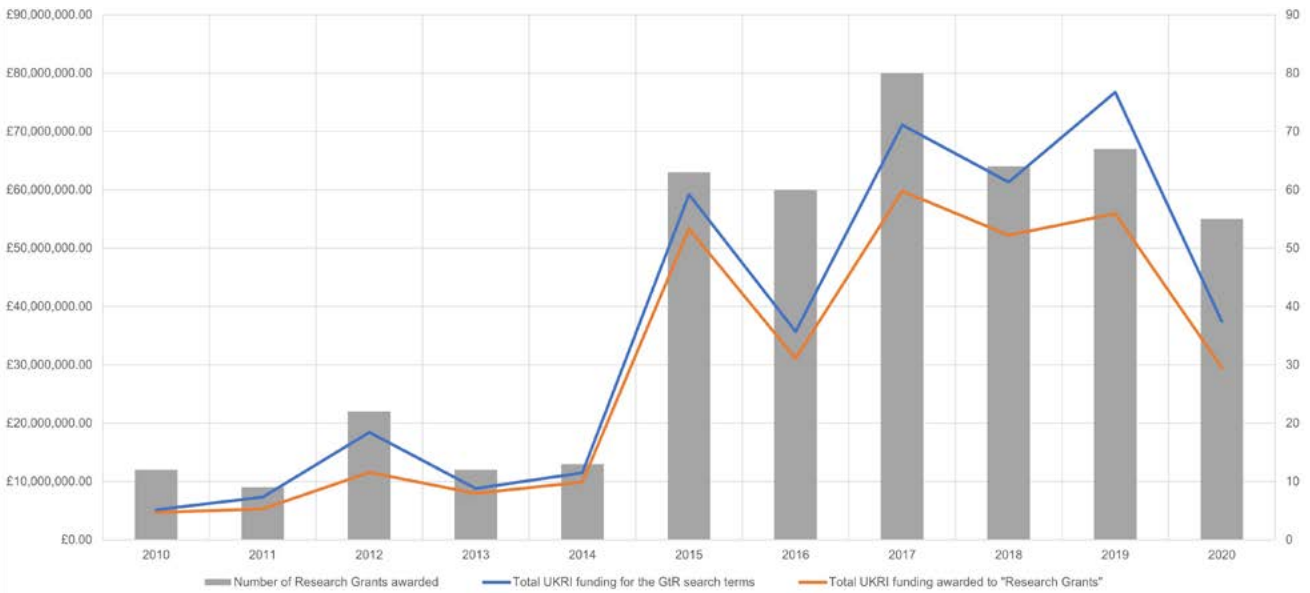
Successful innovation relies on resource mobilisation, with the allocation of funding by public and private sources being highly visible indicators of investment.

Public funding through UK research councils increased strongly in 2015 with the ‘Tackling AMR’ programme, although the programme’s scope extended far beyond drug development. Since 2015, public funding has plateaued, and no replacement for the Tackling AMR programme has been announced. Even at the funding levels seen in recent years, stakeholders suggest that high levels of competition and a lack of coordination result in problems for drug development, where continuity of funding over the long term is required. Interruptions in funding can lead to a ‘valley of death’, where projects are abandoned and new firms fail to transition from start-up.

Private investment for antibacterial drugs in the UK is insufficient. Large pharma have a declining interest in traditional antibiotics, while the emerging firms most focused on antibacterial R&D in the UK have faced declining investment over recent years. Private investment in this area has been significantly curtailed as confidence in seeing a return on investments was wiped out by the collapse of companies that brought new antibiotics to market, such as Achaogen and Malinta in the US. The emerging UK-based private firms most focused on developing antibacterials have also faced declining investment in recent years.

Internationally, BARDA, [CARB-X](#), and the [AMR Action Fund](#) may be important funding sources going forward – although these too may be insufficient given the high costs of drug R&D, the high failure rates of R&D projects (>90 per cent) and the number of firms seeking funds globally.

## 6 Total UKRI Research Grants awarded and their value



Source: Authors' analysis of Gateway to Research data

Greater mobilisation also requires new human resources, with current numbers of available microbiologist researchers and clinicians a potential concern.

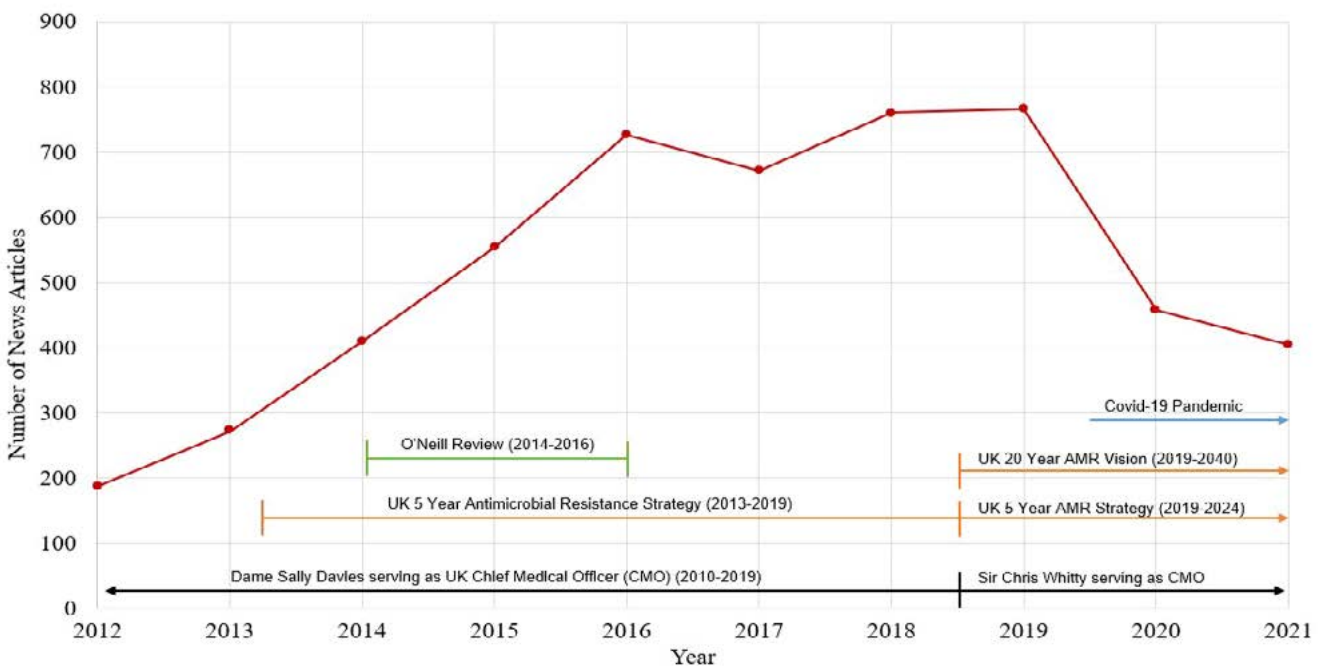
## 7 Increased advocacy for tackling AMR

The UK has played a major role internationally in promoting action to tackle AMR. Key to this work has been the high priority given to AMR by Dame Sally Davies in her term as Chief Medical Officer, and the impact of Lord O'Neill's [Review on Antimicrobial Resistance](#), commissioned by former Prime Minister David Cameron. With these individuals now out of post, the UK lacks a focused advocate for tackling AMR. The

situation has also been made considerably worse by the arrival of COVID-19, which has shifted the focus of a wide range of stakeholders, including those in research, policy, industry, and healthcare, from a long-term potential bacterial pandemic threat to the immediate viral pandemic threat. One indication of the scale of this impact is media coverage of AMR, which has declined by over 40 per cent since the arrival of COVID-19.

Between 2013 and 2020, the UK had sought to implement a joined-up strategy that placed emphasis on surveillance, reporting and stewardship, and to a lesser degree on new drug innovation. Alongside charities such as Wellcome, Antibiotic Research UK and others,

## 7 Number of media articles mentioning AMR between 2012 and 2021



Source: Authors' analysis based on data from Lexisnexis, from leading UK newspapers

the government has produced toolkits, resources, and public campaigns that have improved AMR awareness locally and internationally. The UK must continue to develop these areas (in particular learning lessons from COVID-19 with regard to infection control, public campaigns, and supporting targeted R&D). Yet the absence of specific, long-term support for antibacterial drug innovation continues to imply that drug innovation remains the preserve of the private sector, which in turn continues to receive relatively weak market signals.

## Practical implications

Faced by a multi-generational struggle against bacterial infection, the UK should track the progress of domestic antibacterial drug projects and capabilities through a broad set of indicators, to inform the development and performance of the UK's antibacterial innovation system. UK policy makers should not be content with studies of international drug pipeline progress to guide decision making on antibacterial R&D, as these do not show the UK's own contribution, or its strengths and weaknesses. Exploration of some potentially useful wider indicators, above, have identified areas of concern, such as a reduction in private investment and decline in clinical trials undertaken in the UK. However, further useful indicators could also be developed to:

- characterise and monitor scientific breakthroughs relevant to antibacterial innovation
- track the firms involved and their overall profiles, projects, patents and attendant technologies
- measure the volume of funding by commercial and non-commercial organisations
- assess human resources and their demographics
- generate data on the speed and success of clinical trials

Developing and embedding a dashboard of indicators into long-term AMR policy planning and implementation would help to inform a more systemic and coordinated approach to UK antibacterial innovation. Similar approaches could be applied in other fields (e.g., antifungals) and in other countries, where data exist,

as **BIO** appears to be doing in the US. Informed by such a dashboard, targeted and networked funding from UKRI might help to push novel antibiotics beyond the laboratory and aid the development of partnerships with the private sector to bring high-priority drugs through clinical trials. More also needs to be done to ensure that clinical needs feed back to shape R&D and deliver the most urgently needed products – including through market signals from an expanded NHS subscription model. More broadly, policies need to move beyond push and pull incentives to focus on more systemic coordination (e.g., through foresight programmes and innovation missions) and collaboration (e.g., through public-private partnerships and policies to encourage risk-sharing and access to key resources).

Whilst several organisations have defined activities under the **UK's National Action Plan** and **20 Year Vision**, coordination could be improved and it is not always clear where the responsibility for delivery or accountability lies. More visible leadership is needed, with a central individual and new coordinating body, or extended remit for an existing organisation, to address the fragmentation in the UK innovation system for antibacterials, and ensure the system is articulating effectively domestically as well as with international partners.

## Further reading

O'Neill, J. (2016) 'Tackling drug-resistant Infections globally: final report and recommendations' [https://amr-review.org/sites/default/files/160525\\_Final%20paper\\_with%20cover.pdf](https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf)

HMG (2019) 'Tackling antimicrobial resistance 2019-2024 – The UK's five-year national action plan' <https://www.gov.uk/government/publications/uk-5-year-action-plan-for-antimicrobial-resistance-2019-to-2024>

HMG (2019) 'Contained and controlled – The UK's 20-year vision for antimicrobial resistance' <https://www.gov.uk/government/publications/uk-20-year-vision-for-antimicrobial-resistance>



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