



# CIDRAP Antimicrobial Stewardship Project (ASP)

Quarterly Policy Update: July 2019

A continuation of our series on current policy issues regarding antimicrobial stewardship and the threat of antimicrobial resistance (AMR), this update provides a broad overview of recent policy changes, initiatives, and new findings that have impact on policy decisions. We welcome your feedback on any of the issues addressed in this series. If you have comments or suggestions, please share your thoughts with CIDRAP's ASP project team via Twitter at [@CIDRAP\\_ASP](https://twitter.com/CIDRAP_ASP) or email at [asp-cid@umn.edu](mailto:asp-cid@umn.edu).



## Achaogen bankruptcy raises worry over antibiotic pipeline

Achaogen, a biopharmaceutical company that researches and develops new antibacterial agents to address multi-drug resistant infections, [announced in April](#) that it is filing for bankruptcy. Achaogen's antibiotic plazomicin was approved by the US Food and Drug Administration in June 2018 for the treatment of complicated urinary tract infections, and launched in the United States in July 2018. Plazomicin was seen as an important option for treatment of carbapenem-resistant Enterobacteriaceae infections, which are among the most difficult bacterial infections to treat. The company also had other antibacterial products in its pipeline, but was not making enough profit to stay afloat.

Achaogen was among the few companies working on new antibiotics, and its bankruptcy has raised more concerns regarding the feasibility of bringing a new antibiotic to market. Achaogen received financial "push" incentives from the US National Institutes of Health, the US Biomedical Advanced Research and Development Authority (BARDA), and the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) to get the company through the early stages of antibiotic development. Some advocates say that "pull" incentives are also needed to ensure that new antibiotics will be profitable.

## More commentary on antibiotic research and development

In the *Financial Times*, Jeremy Farrar, OBE, MBBS, DPhil, [reflects on the need](#) to address systemic global problems in the demand for and supply of new antibiotics.

On *Stat*, Thomas B. Cueni, MS, [describes the need](#) for partnerships between government and industry that will spur progress on the development of new antibiotics.

On *The Hill*, Allan Coukell, BSc Pharm, and Helen Boucher, MD, [outline a proposed US approach](#) to pull incentives for antibiotic research and development.

On **Stat**, Kevin Outterson, JD, and Helen W. Boucher, MD, [discuss issues](#) and potential solutions concerning the connections between antibiotic development, drug-resistant infections, and Medicare reimbursement for antibiotic use in the US.

On **Stat**, Meghana Keshavan [describes multidisciplinary perspectives](#) on incentives for antibiotic research and development presented during a panel at the Milken Institute Global Conference.

In **Bloomberg**, Robert Langreth [discusses the current state](#) of pharmaceutical companies' investment in antibiotic manufacture, along

with options for incentives to encourage antibiotic research and development in the US.

In **Wired**, Maryn McKenna, MSJ, [discusses proposals](#) to shift antibiotic research and development into the purview of governments and nonprofits.

For the **American Council on Science and Health**, David Shlaes, MD, PhD, [discusses factors](#) affecting the participation of pharmaceutical and biotechnology companies in antibiotic research and development, with particular attention to the potential of mergers.

## International Stewardship News

The **United Nations Interagency Coordination Group on Antimicrobial Resistance** [released a report](#) calling for immediate and united action on AMR, recommending the prioritization of national action plans, stronger One Health regulatory systems, improved investment in antimicrobial research and development, and an urgent phase-out of medically important antimicrobials as growth promoters in agriculture.

The report warns that, if no action is taken to address AMR, global deaths from drug-resistant infections could rise to 10 million a year by 2050, and the economic impact could be similar to the 2008 financial crisis.

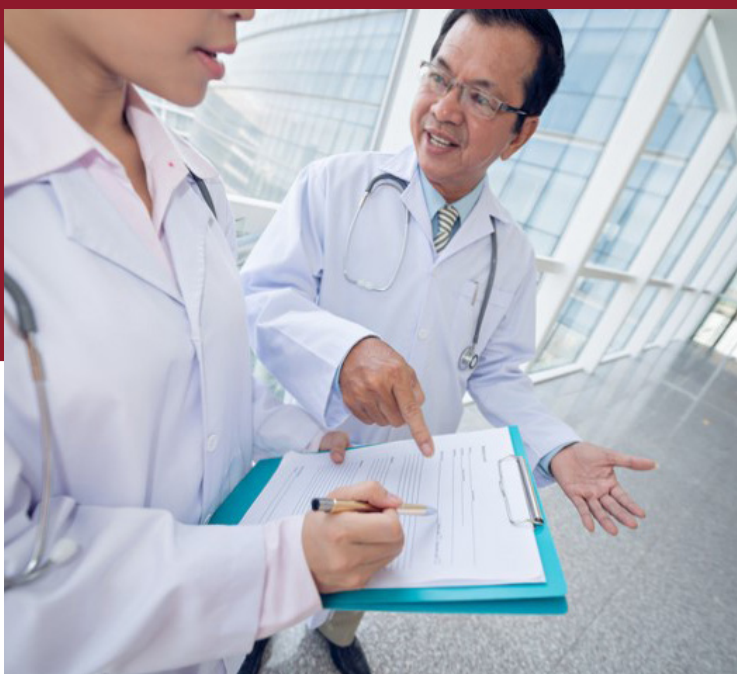


While more than 100 countries to date have developed national plans to combat AMR, implementation of those plans has been slow. And for many low-income nations, inadequate and under-resourced healthcare facilities, combined with a lack of political awareness and commitment, present barriers to implementation.

The **Food and Agriculture Organization**, the **World Organisation for Animal Health**, and the **World Health Organization** [announced the formation](#) of the AMR Multi-Partner Trust Fund, a dedicated funding mechanism that allows partners to devote resources to accelerate global action against antimicrobial resistance.

## Experts urge approval of hospital antibiotic stewardship requirement

In April, members of the Presidential Advisory Council on Combating Antibiotic Resistant Bacteria (PACCARB) [urged the US Department of Health and Human Services](#) to finalize a policy that would make antibiotic stewardship mandatory in US hospitals. The rule would require all hospitals that take part in Centers for Medicare and Medicaid Services (CMS) programs to adopt infection and prevention control and stewardship programs. Leaders of PACCARB warned that the \$2.2 billion annual burden that drug-resistant infections place on the US healthcare system will likely rise if no action is taken.



The **US Joint Commission** [announced](#) that, effective Jan 1, 2020, five new antimicrobial stewardship performance requirements will be applicable to Joint Commission-accredited ambulatory healthcare organizations that routinely prescribe antimicrobials.

A new poll from the **Kaiser Family Foundation** [found that the US public](#) is aware of antibiotic resistance, but gaps in understanding still remain. The poll was designed to gauge the public's experience with and knowledge of antibiotic resistance, and assess how the issue measures up against other health threats, such as the opioid crisis and measles outbreaks.

Just over half of the US adults polled ranked antibiotic overuse as a major problem, and just under half said they haven't taken antibiotics as prescribed.

## Guidelines

### UK releases guidance on surgical-site infection prevention

The UK National Institute for Health and Care Excellence [released guidance](#) on antibiotic use for surgical-site infection prevention and management in adults and children.

### Joint clinical guidelines for recurrent UTIs in women

The American Urological Association, the Canadian Urological Association, and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction [issued a guideline](#) for the diagnosis and treatment of uncomplicated recurrent urinary tract infections in women, with a focus on antimicrobial stewardship.

## Reports

### JPIAMR Roadmap of Actions 2019-2024

The Joint Programming Initiative on Antimicrobial Resistance (JPIAMR) published the [JPIAMR Roadmap of Actions 2019-2024](#), which is intended to guide future joint transnational actions of the JPIAMR as well as to serve as an information resource for other strategic initiatives to support coordination and synergistic actions.

### CDDEP issues report on barriers to accessing antibiotics

The Center for Disease Dynamics, Economics & Policy (CDDEP) [released a report](#) on the public health implications of barriers to accessing antibiotics, especially in low- and middle-income countries.

### Northern Ireland launches 5-year One Health national action plan

Northern Ireland's Department of Health, Food Standards Agency, and Department of Agriculture, Environment and Rural Affairs launched a five-year [One Health national action plan](#) to address antimicrobial resistance.

### Annual Swedish Veterinary Antimicrobial Resistance Monitoring

The Public Health Agency of Sweden and the Swedish National Veterinary Institute released the annual [Swedish Veterinary Antimicrobial Resistance Monitoring](#) (Swedres-Svarm) report on 2018 data.

## Partnerships

### New VALUE-Dx consortium formed to address AMR

The University of Antwerp, bioMérieux, and the Wellcome Trust [announced VALUE-Dx](#), an Innovative Medicines Initiative consortium project, which will bring together six in-vitro diagnostics companies and 20 non-industry partners to address AMR in acute respiratory tract infections acquired in community care settings.

### New collaboration to strengthen stewardship initiatives in Tanzania

The American Society for Microbiology, in collaboration with the Fleming Fund, [will partner](#) with the Southern Africa Centre for Infectious

Disease Surveillance and Africare to strengthen AMR surveillance and One Health antimicrobial stewardship initiatives in Tanzania.

### AMR data-collection initiative in 12 African countries

The Fleming Fund [announced](#) the Mapping Antimicrobial Resistance and Antimicrobial Use Partnership, an AMR data-collection initiative across 12 African countries that will also digitize and analyze previously unusable paper-based data.



## Launch of International Network for AMR Social Science

The Global Strategy Lab [announced](#) the launch of the International Network for AMR Social Science (INAMRSS), which comprises many founding research centers, including CIDRAP.

## Product supply agreement to manufacture essential antibiotics

Civica Rx and Xellia Pharmaceuticals [announced](#) that they have signed a product supply agreement under which Xellia will manufacture essential antibiotics, including vancomycin and daptomycin, for Civica's member health systems.

## Agriculture

### Antimicrobial use in aquaculture

In Forbes, Maisie Ganzler [discusses barriers](#) to and options for reducing antimicrobial use in land-based, coastal, and deep-water aquaculture and describes labeling practices that may help consumers and large purchasers understand antibiotic use in seafood.

### Potential effects of bactericide use on orange and grapefruit trees

In the *New York Times*, Andrew Jacobs [outlines the ramifications](#) of the US Environmental Protection Agency's decision to approve two bactericides for use on orange and grapefruit trees, with attention to the decision's potential effects on human health and on the livelihoods of citrus farmers.

### Investors push restaurant chains to cut antibiotics in meat supply

The Farm Animal Investment Risk and Return coalition [released a report](#) suggesting that the world's largest fast food and casual dining companies are beginning to phase out routine antibiotic use in livestock, poultry, and seafood supply chains. Of the 20 companies included in the report, 17 now have publicly available policies.

### Effects of a reduction in veterinary antibiotic sales in the Netherlands

Wageningen Economic Research [released a report](#) finding that a 63% reduction of veterinary antibiotic sales in the Netherlands from 2009 to 2017 was not associated with negative effects on production or economic results for poultry farmers.

### Antibiotic use in UK pig operations continues to fall

The UK Agriculture and Horticulture Development Board [announced](#) that antibiotic use in UK pig operations has dropped for the third consecutive year, falling by 16% from 2017 to 2018 and putting farms on track to meet the 2020 industry target. Figures were collected using the electronic medicine book (eMB), an antibiotic reporting website for pig producers.

### British Veterinary Association publishes statement on responsible antimicrobial use in food-producing animals

The British Veterinary Association [published a position statement](#) on responsible antimicrobial use in food-producing animals that consolidates and expands on existing policies and proposes 15 overarching recommendations on responsible antimicrobial stewardship for veterinarians, farmers, and government.

### Communications campaign by drug manufacturer appears to urge farmers to give antibiotics to healthy pigs

In the *New York Times*, Danny Hakim and Matt Richtel, MS, [discuss a recent communications campaign](#) by a livestock drug manufacturer that appeared to urge farmers to give antibiotics to healthy pigs, providing an in-depth look at the context of US industrial farming, promotion of and profit from veterinary medicines, and adherence to global guidelines and regulations regarding animal antibiotic use.

### Constraints to rapid diagnostics in LMICs

A post from ReAct [considers constraints](#) to the implementation of rapid diagnostics in low- and middle-income settings, including the availability and technical capacity of clinical laboratories, training for skilled staff, and the ability to invest financially in tools that are cheap, simple to use, and do not require laboratories or a stable power supply.

### Changes to US performance measures may improve antimicrobial prescribing

In an analysis for the Pew Charitable Trusts, David Hyun, MD, and Rachel Zetts, MPH, [discuss proposed changes](#) to the US National Committee for Quality Assurance Health Effectiveness Data and Information Set performance measures, which may improve the ability to assess antimicrobial prescribing, particularly in outpatient settings and for pediatric populations.

### Research needs to address AMR

In *Nature*, Holly Else, MSc, interviews Sally Davies, DBE, MBChB, MSc, about the [research needed](#) to address AMR in the areas of therapeutics and diagnostics, the role of the environment, and behavioral aspects of AMR.

### Government involvement and leadership in health system stewardship

ReAct highlights [recommendations](#) for government involvement and leadership in health system antimicrobial stewardship from a letter written by Anthony So, MD, MPA, and Otto Cars, MD, PhD, to the United Nations Member States.

### Benefits of building diagnostic testing capacity in pharmacies

In *Forbes*, Madhukar Pai, MD, PhD, [discusses the benefits](#) that may be afforded by building diagnostic testing capacity in pharmacies, especially in low- and middle-income countries, including the possibility that offering tests might reduce the number of antibiotics sold without prescriptions or indications.

### Potential incentives for development of products to fight AMR

On EURACTIV, Kasey Baiter and Sarantis Michalopoulos, MA, [interview](#) Nathalie Moll, director-general of the European Federation of Pharmaceutical Industries and Associations, about the potential for European legislation to offer incentives for the development of products that fight AMR.

### Global governance mechanism to stop misuse of antibiotics

Chatham House [published an expert comment](#) from David Heymann, MD, and Emma Ross, MSc, regarding implementation of a global governance mechanism that includes a handful of priority measures to stop the misuse and overuse of antibiotics to which all countries can commit and implement in unison.

### Experts: Policies to cut antibiotic use need more scrutiny

In *PLOS Medicine*, researchers [concluded](#) that government policies designed to reduce the use of antimicrobials need more rigorous evaluation. The studies evaluated by the researchers described policies used by governments to limit antimicrobial use, but few used rigorous enough methods to confidently assess the policies' effectiveness.