Orientation to Statement of Task

NASEM Committee on Long-Term Medical and Economic Effects of Antimicrobial Resistance

Meeting #1, September 23, 2020

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Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

National Institute of Allergy and Infectious Diseases

Outline

- Impetus for study
- Key background information
- Opportunities to add value
- Q&A

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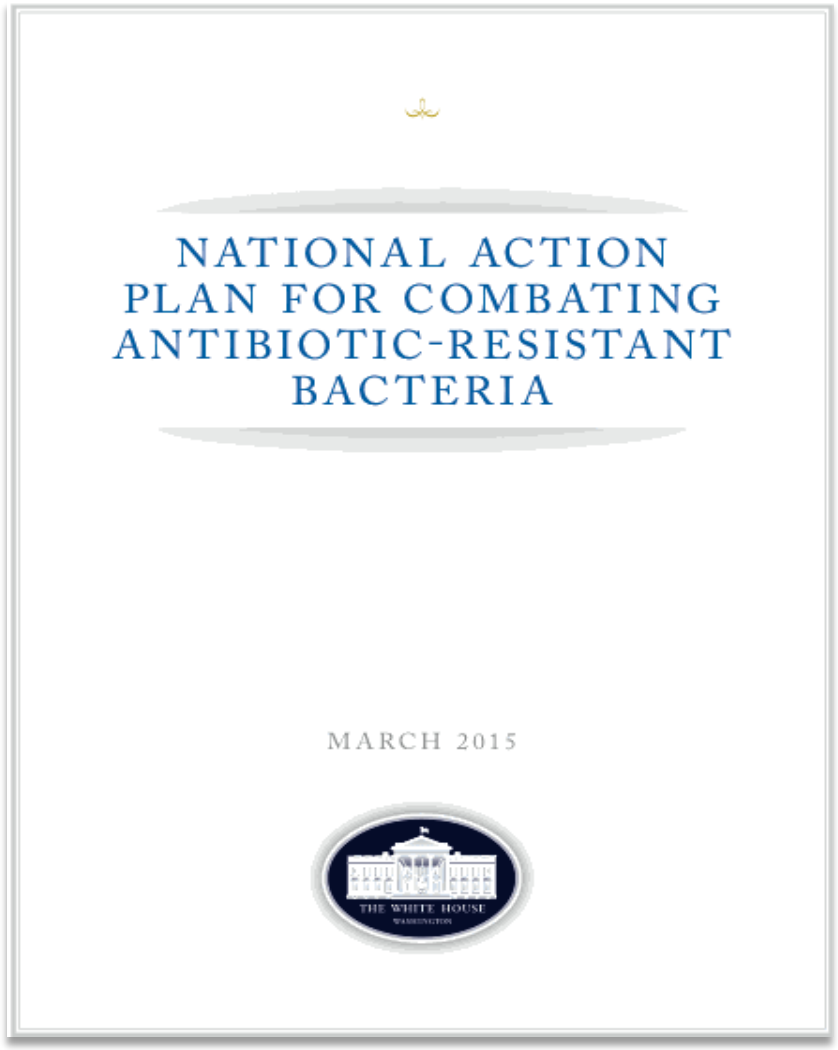
Impetus for Study: NIAID FY20 Appropriation Bill

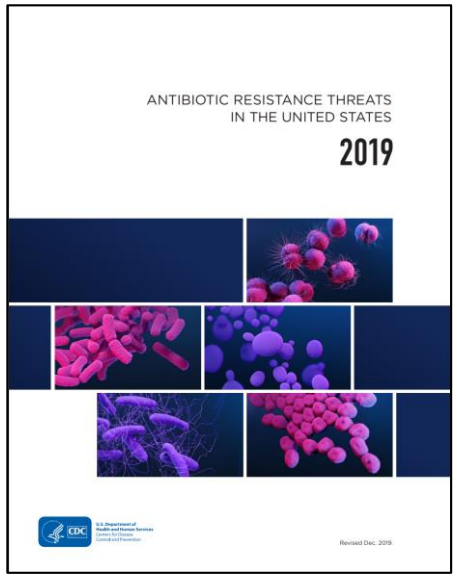
…fund a NASEM study to examine/quantify the long-term medical & economic impacts of AMR in the U.S.

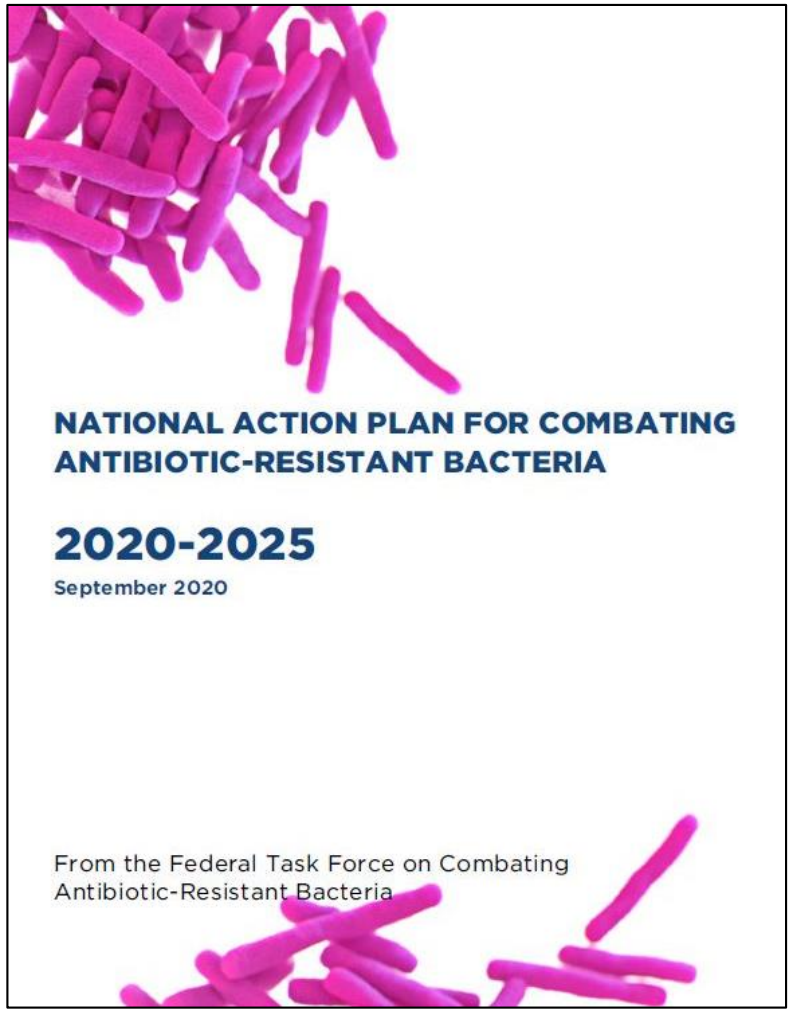
- examine progress on the U.S. National Strategy/Action Plan for Combating Antibiotic-Resistant Bacteria (NIH, CDC, FDA, ASPR, USDA, and USAID)
- make recommendations to address any gaps in
  - research and development of therapeutics and diagnostics
  - efforts to move new products to market
  - animal and human surveillance
  - prevention efforts
  - international coordination and collaboration
  - any other recommendations NASEM finds relevant to stopping the spread of AMR

Key Background Information



CARB Progress Reports





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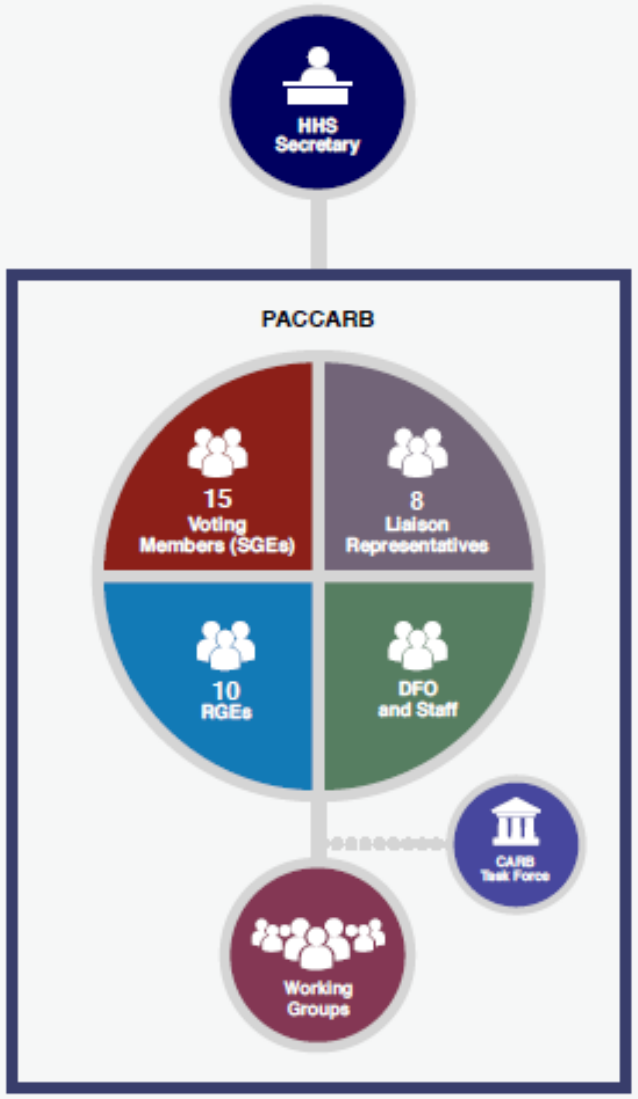
PACCARB Reports and Recommendations



Between 2016 – 2019 PACCARB has produced four Recommendations Reports:

1. Initial Assessments of the National Action Plan for Combatting Antibiotic-Resistant Bacteria (2016)
2. Recommendations for Incentivizing the Development of Vaccines, Diagnostics, and Therapeutics to Combat Antibiotic Resistance (2017)
3. Key Strategies to Enhance Infection Prevention and Antibiotic Stewardship: Report with Recommendations for Human and Animal Health (2018)
4. Priorities for the National Action Plan on Combating Antibiotic-Resistant Bacteria: 2020 – 2025 (2019)

A One Health approach is emphasized and utilized for all activities.

All archived meeting summaries, videos, presentations, and council reports are available at: hhs.gov/oash/carb | Email: CARB@hhs.gov.

GAO Report

United States Government Accountability Office

GAO

Report to Congressional Requesters

March 2020

ANTIBIOTIC RESISTANCE

Additional Federal Actions Needed to Better Determine Magnitude and Reduce Impact

https://www.gao.gov/assets/710/705578.pdf

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Pew Antibiotic Resistance Project

ANTIBIOTIC INNOVATION

Share

The history of antibiotics is cyclical: Drugs are developed, but bacterial evolution can soon render them ineffective in treating infections. Antibiotic resistance is fueled by the injudicious use of existing drugs and compounded by a failure to develop novel new ones. Today there are not enough drugs in development to meet current and anticipated patient needs, with many major pharmaceutical companies limiting or stopping their investments in antibiotic innovation.

Pew works to develop and promote policies that will support the development of new antibiotics to ensure a healthy nation today and in the future.

ARTICLE September 21, 2018

The Shared Platform for Antibiotic Research and Knowledge (SPARK)

Tracking the Pipeline of Antibiotics in Development

Economic Incentives Needed to Fix the Broken Antibiotic Market

FOCUS AREAS

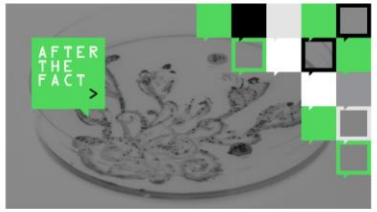
- Antibiotic Use in Food Animals
- Antibiotic Use in Human Health Care

RELATED EXPERTS

Kasia O'Neill Murray
Project Director
Antibiotic Resistance Project

Kathy Talkington
Director
Health Programs

Wes Kim
Senior Officer
Antibiotic Resistance Project



PODCAST August 10, 2018

The Fight Against Antibiotic Resistance

PEW

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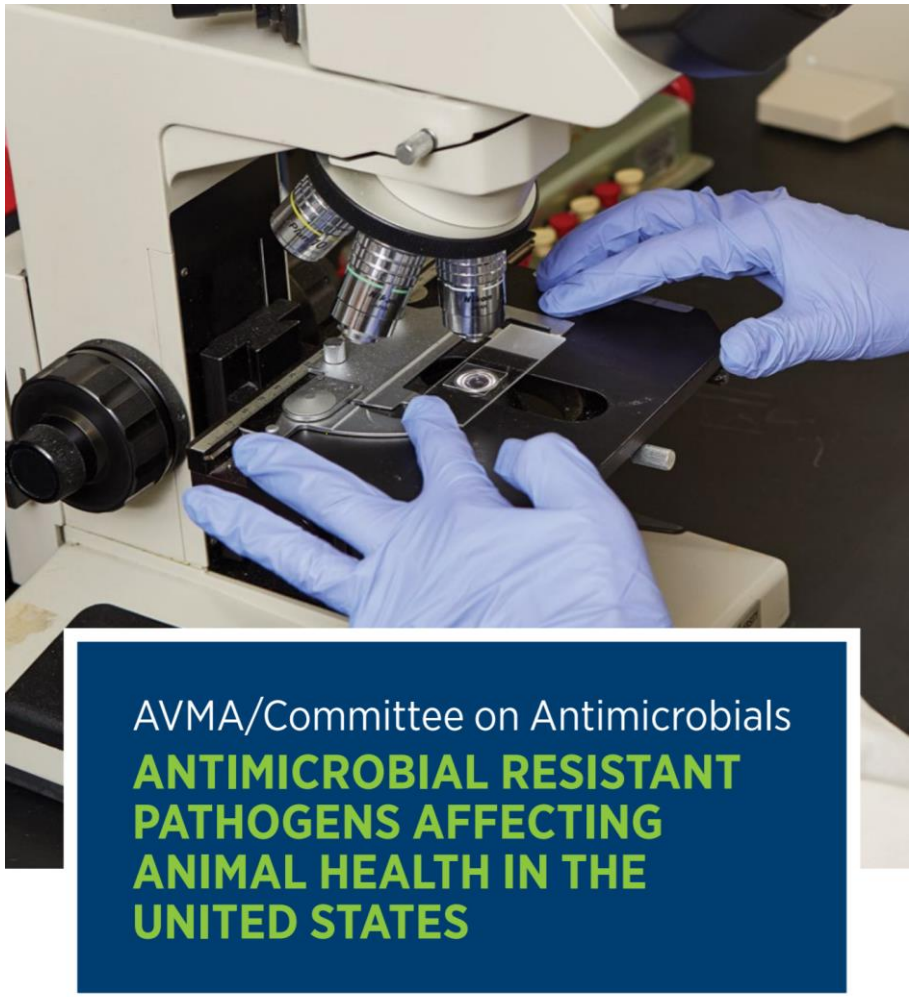
AVMA Report



AVMA launches inaugural report describing antimicrobial resistance in animals

FOR MORE INFORMATION
Mark Rosati
Phone: 847-313-9597
Cell: 847-313-9597
FOR IMMEDIATE RELEASE: 08/25/2020

Report will be a key resource for veterinarians in the fight to protect animal, human and environmental health against threat of antimicrobial resistance

AVMA American Veterinary Medical Association

NIH National Institute of Allergy and Infectious Diseases

TATFAR

Transatlantic Taskforce on Antimicrobial Resistance

TATFAR

EXPERTS UNITE ACROSS BORDERS TO IMPROVE ANTIBIOTIC USE IN HUMANS AND ANIMALS, PREVENT INFECTIONS AND THEIR SPREAD, AND STRENGTHEN THE DRUG PIPELINE.

TATFAR was created in 2009 to address the urgent threat of antimicrobial resistance (AMR). Collaboration across government agencies from Canada, EU, Norway, and U.S. enhances synergy and communication, leading to strengthened domestic and global efforts.

Key Focus Areas

Improve antibiotic use in humans and animals

Prevent infections and their spread

Strengthen the drug pipeline

Success

- Created unique collaboration between government agencies to achieve common goals.
- Provided experience and examples to help create successful AMR policies.
- Enabled coordination of research and development of new pharmaceuticals, new diagnostic tests, and clinical trials.
- Supported drug development programs collaboratively to meet EU and U.S. regulatory requirements more efficiently.
- Published papers summarizing economic incentives for antibacterial drug development.

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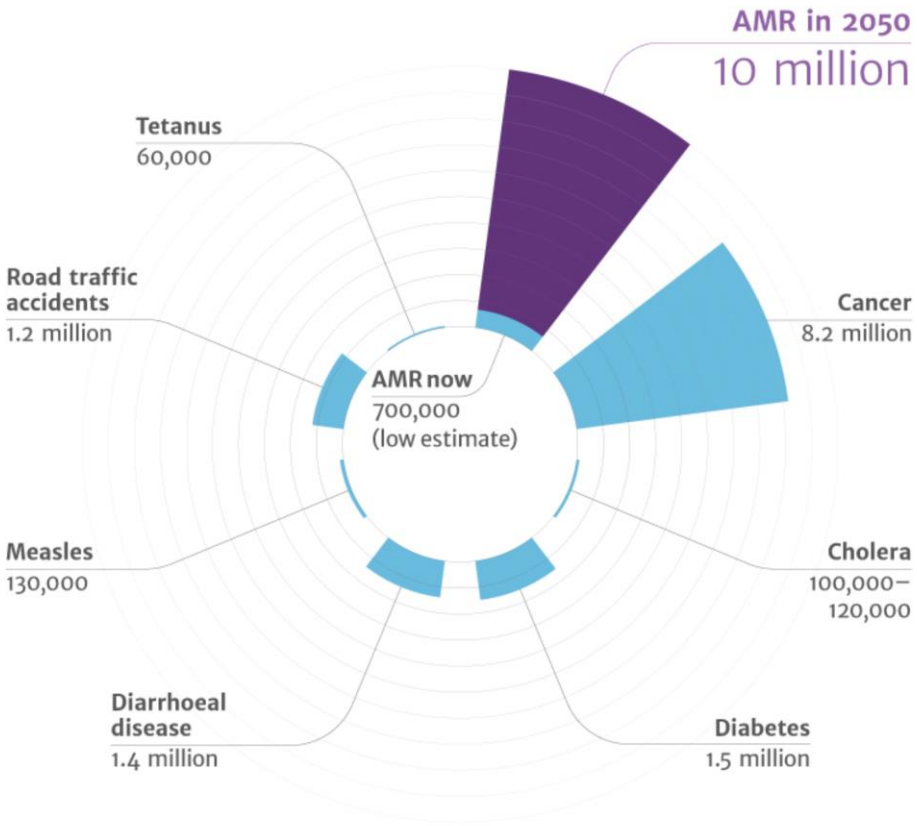
UK AMR Review 2014-2016



9 publications https://amr-review.org/Publications.html

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WHO

World Health Organization

2017

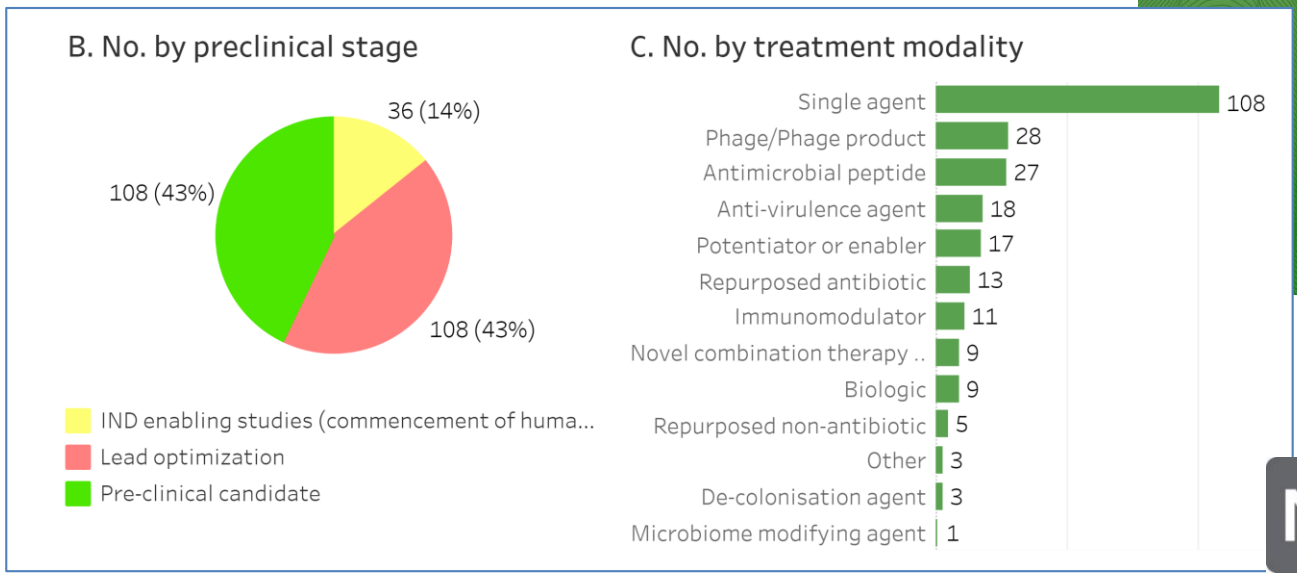
WHO PRIORITY PATHOGENS LIST FOR R&D OF NEW ANTIBIOTICS

Priority 1: CRITICAL#

Acinetobacter baumannii, carbapenem-resistant

Pseudomonas aeruginosa, carbapenem-resistant

Enterobacteriaceae*, carbapenem-resistant, 3rd generation cephalosporin-resistant



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FAO/OIE

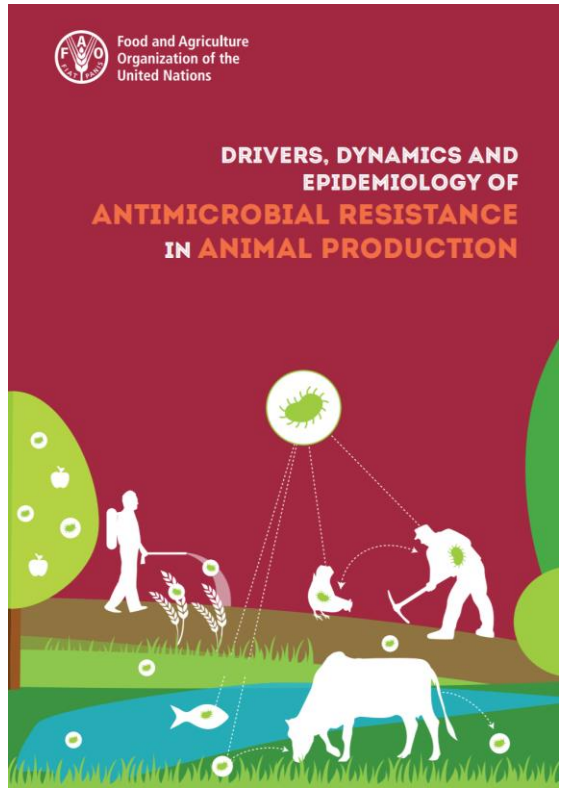
WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

Criteria used for categorisation

List of antimicrobial agents

2018

OIE LIST OF ANTIMICROBIAL AGENTS OF VETERINARY IMPORTANCE



2016

CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

Google Custom Search

support 2020

Food and Agriculture Organization of the United Nations

World Health Organization

CAC/GL 77-2011 Page 1 of 29

GUIDELINES FOR RISK ANALYSIS OF FOODBORNE ANTIMICROBIAL RESISTANCE

CAC/GL 77- 2011

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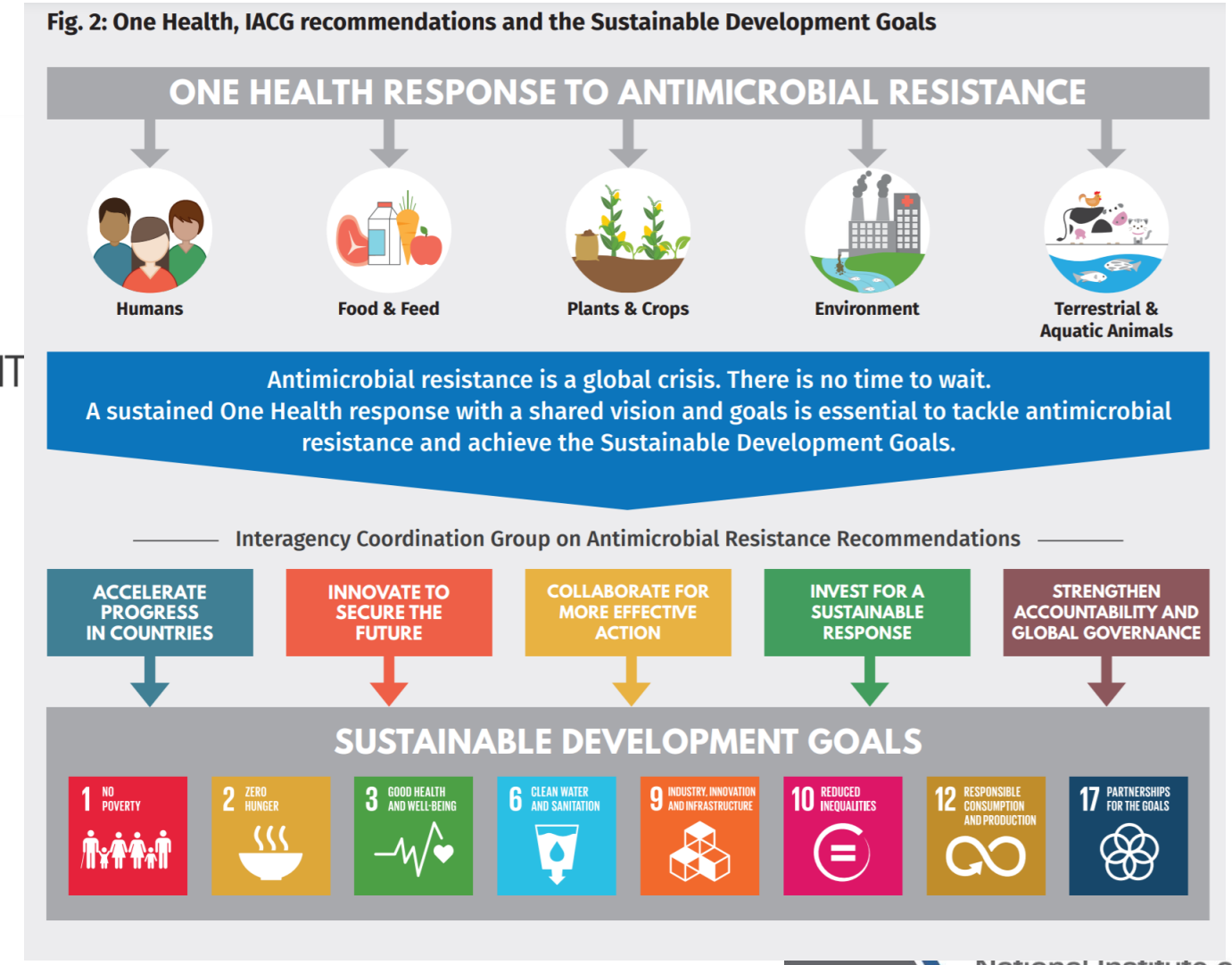
UN Interagency Coordination Group (IACG) on AMR

NO TIME TO WAIT:
SECURING THE FUTURE FROM DRUG-RESISTANT INFECTIONS

REPORT TO THE SECRETARY-GENERAL OF THE UNITED NATIONS

APRIL 2019

Fig. 2: One Health, IACG recommendations and the Sustainable Development Goals



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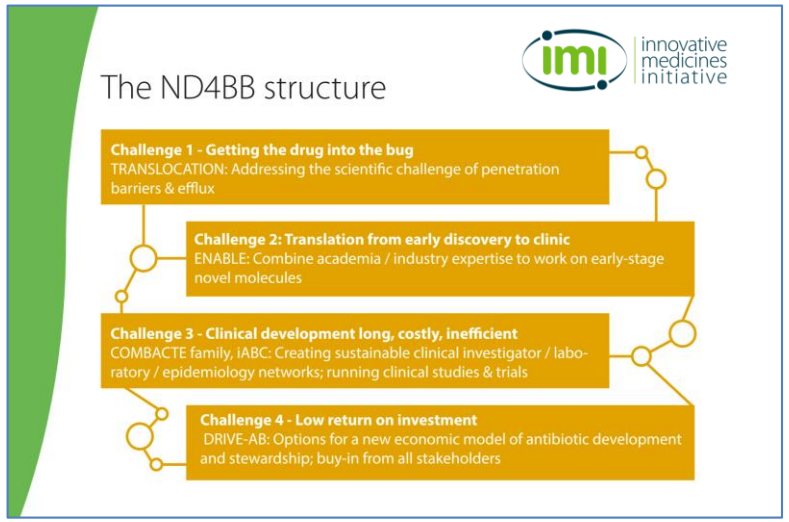
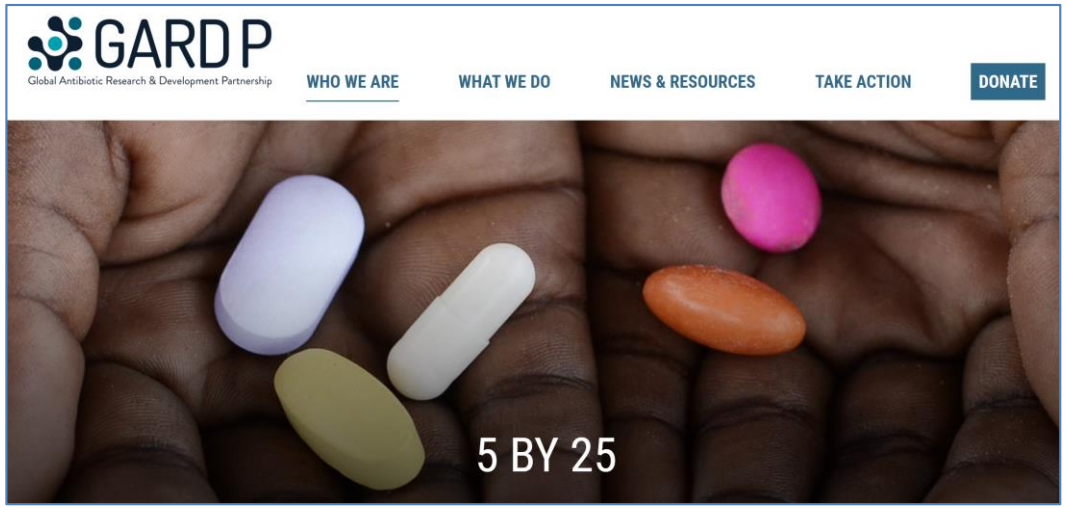
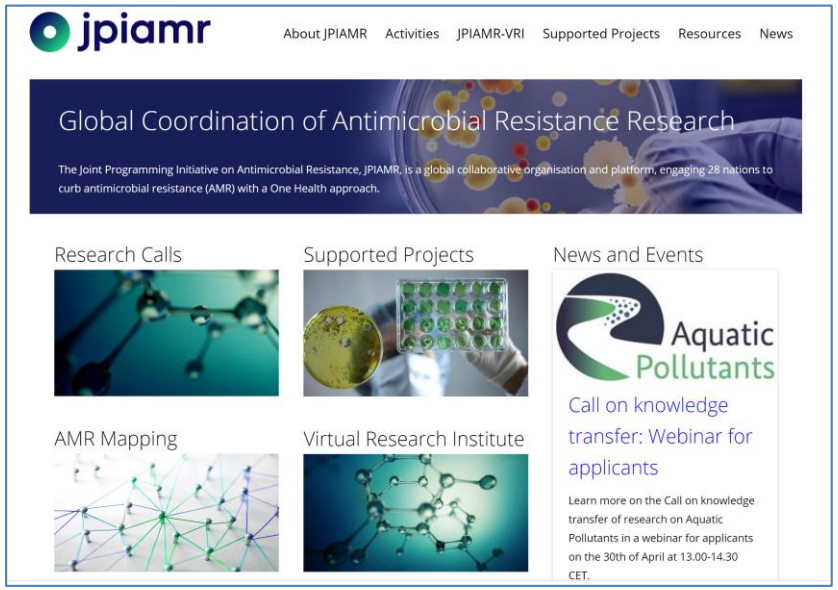
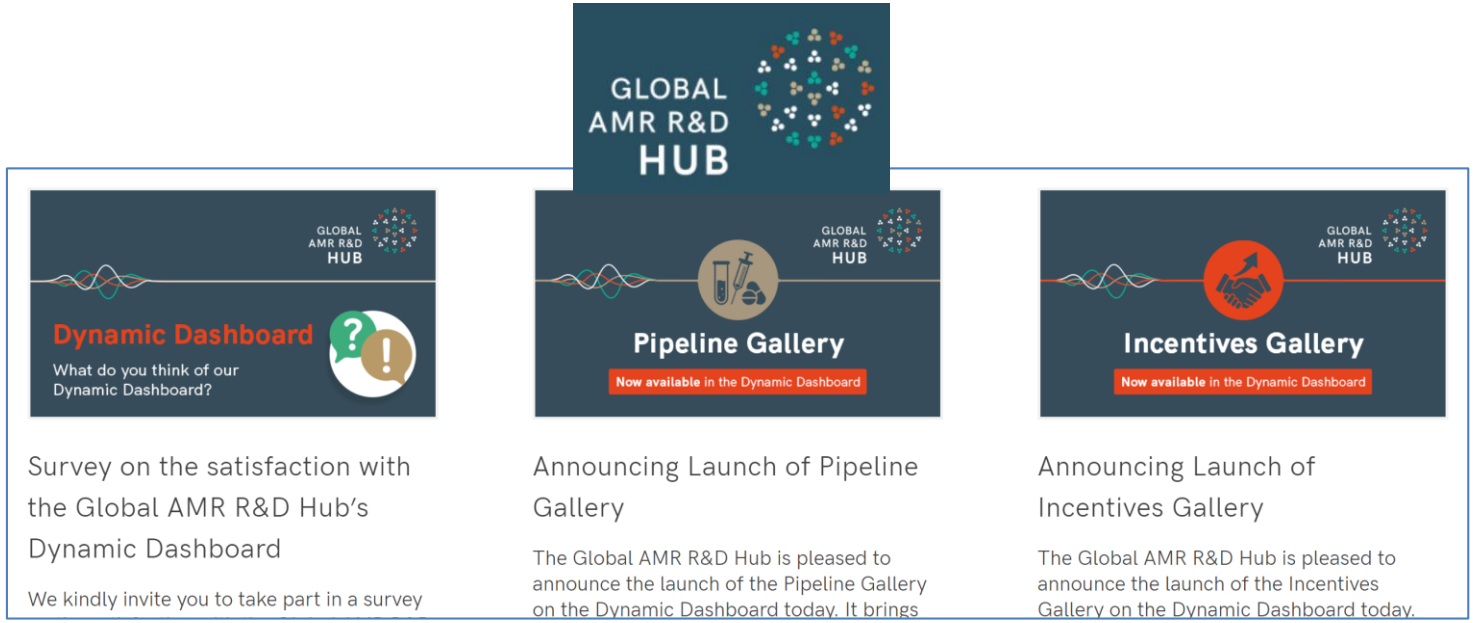
Global Research Funding and Coordination



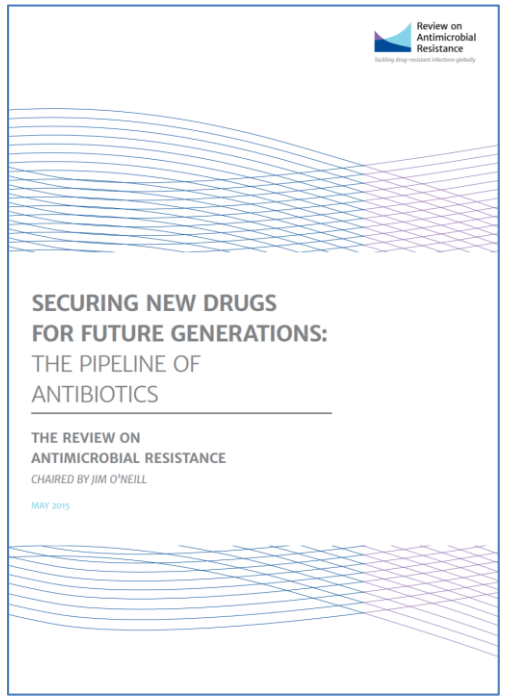




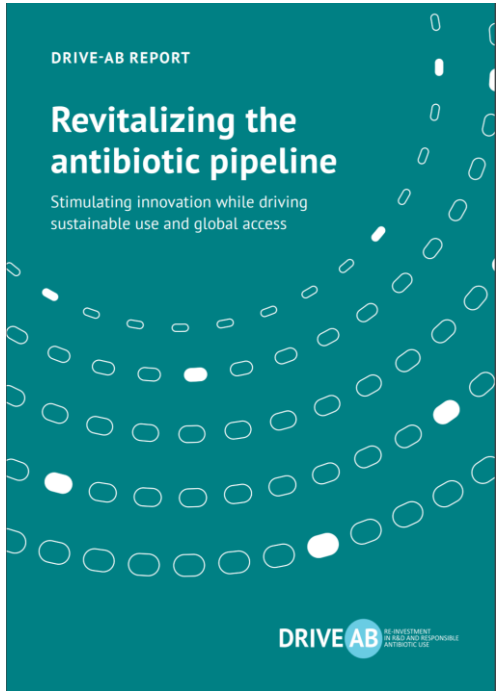


Economic Incentives for Drug Development

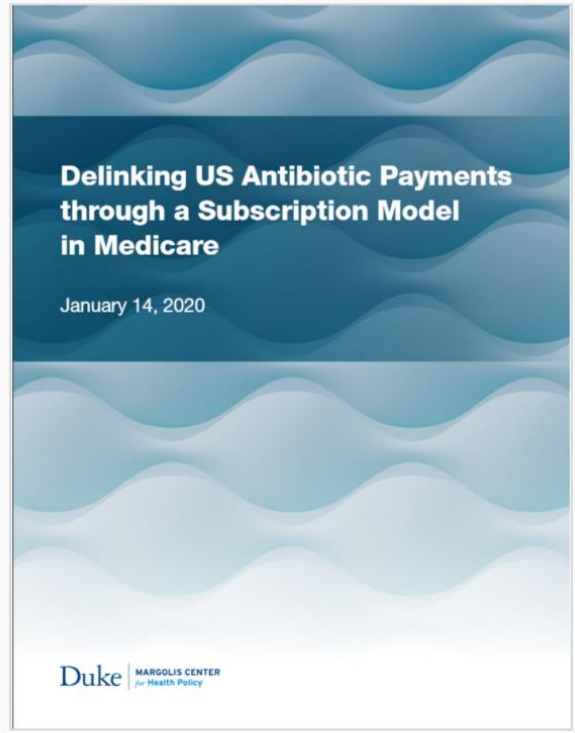
UK AMR Review



DRIVE AB 2018



Duke Margolis Center



Volume 65, Issue 8
15 October 2017

Pull Incentives for Antibacterial Drug Development: An Analysis by the Transatlantic Task Force on Antimicrobial Resistance FREE

Christine Årdal, John-Arne Røttingen, Aleksandra Opalska, Arjon J Van Hengel, Joseph Larsen

Clinical Infectious Diseases, Volume 65, Issue 8, 15 October 2017, Pages 1378–1382, https://doi.org/10.1093/cid/cix526

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Opportunities to add value (1/2)

- advising on an effective strategy to scale up global detection of resistant infections and infection prevention and control efforts – especially outside of the U.S. and Europe;
- assessing the impact of new incentives for antibiotic development (BARDA's project Bioshield, 2019 CMS IPPS) on the health of the antibiotic pipeline;
- exploring methodological innovations to improve projections of the burden of AMR and its economic impacts, with an eye toward informing the development of incentives for antimicrobial products;
- exploring ways to develop, benchmark, and track rigorous quantitative measures of the impact of various strategies to mitigate AMR, with a focus on relevant, timely, and actionable measures;

Opportunities to add value (2/2)

- helping to assess and quantify the risk to human health from environmental sources and reservoirs of antibiotic resistant pathogens and genes;
- assessing methodologies for evaluating how interventions in agriculture impact public health and how to improve them;
- assessing methodologies for evaluating the impacts of interventions in agricultural settings on animal health and welfare and how to improve them;
- assessing the need for and advise on key diseases and antibiotics for which animal-specific antimicrobial susceptibility testing breakpoints are needed; and
- assessing the need for and explore how to incentivize and promote cooperative relationships between industry and professional societies to prioritize test development of new diagnostics for use in veterinary settings, especially animal-side diagnostics that allow precise selection of antibiotics.