TATFAR

2016-2020

TATFAR Progress Report

Produced by the U.S. Centers for Disease Control and Prevention as Secretariat for the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR)

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Disclaimer

Transatlantic Taskforce for Antimicrobial Resistance (TATFAR)

The TATFAR Progress Report is a publication by TATFAR summarizing work from 2016-2020 to address the growing global threat of antimicrobial resistance.

At the time of publishing, the U.S. Centers for Disease Control and Prevention served as the secretariat for TATFAR, providing administrative support and maintaining the TATFAR website. The report is available online at https://www.cdc.gov/drugresistance/tatfar/links.html.

The report uses the term “antimicrobial resistance” to describe TATFAR’s focus on resistant bacteria and fungi. Sometimes the report also uses the term “antibiotic resistance” when specifically addressing antibiotic use to treat infections caused by bacteria.

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Acronyms

AAFC: Agriculture and Agri-Food Canada

AMR: Antimicrobial resistance

ARD: Advanced Research and Development

BARDA: Biomedical Advanced Research and Development Authority

CDC: U.S. Centers for Disease Control and Prevention

CFIA: Canadian Food Inspection Agency

CIHR: Canadian Institutes of Health Research

CLSI: Clinical and Laboratory Standards Institute

DHHS: U.S. Department of Health and Human Services

EC: European Commission

ECDC: European Centre for Disease Prevention and Control

EC-DG RTD: European Commission – Directorate-General for Research and Innovation

EC-DG SANTE: European Commission – Directorate-General for Health and Food Safety

EMA: European Medicines Agency

EFSA: European Food Safety Authority

EPA: U.S. Environmental Protection Agency

EU: European Union

EUCAST: European Committee on Antimicrobial Susceptibility Testing

FDA: U.S. Food and Drug Administration

GLASS: WHO's Global Antimicrobial Resistance Surveillance System

HAI: Healthcare-associated infections

HC: Health Canada

IMI: European Innovative Medicines Initiative

ISED: Innovation Science and Economic Development Canada

JPIAMR: Joint Programming Initiative on Antimicrobial Resistance

NIH: U.S. National Institutes of Health

NIPH: Norwegian Institute of Public Health

NVI: Norwegian Veterinary Institute

OGA: Office of Global Affairs

PHAC: Public Health Agency of Canada

PPS: Point prevalence survey

TATFAR: Transatlantic Taskforce for Antimicrobial Resistance

USDA: U.S. Department of Agriculture

WAAW: World Antimicrobial Awareness Week

WGS: Whole genome sequencing

WHO: World Health Organization

Foreword

TATFAR Co-Chairs, Larry Kerr (L) and John F. Ryan (R) at the 2018 in-person meeting in Atlanta, GA.

Since its inception in 2009, the Transatlantic Taskforce for Antimicrobial Resistance (TATFAR) has been an excellent forum for collaboration on antimicrobial resistance (AMR). Throughout the years, technical dialogue and information exchange has improved and advanced surveillance, prudent use of antimicrobials, research, and prevention. This work was accomplished with a One Health approach that spans human and animal health, and increasingly, the environment (e.g., water, soil).

We are closing this work period (2016-2020) in the midst of the largest public health emergency in living memory—COVID-19. While the COVID-19 pandemic has dominated the headlines, we must continue to address other well-known health threats we have been fighting for many years. Additionally, experts are concerned that the COVID-19 pandemic could undo progress made against AMR. We must strengthen our efforts to prevent bacteria and fungi from developing resistance to available drugs and from spreading between people, animals, and the environment. On AMR, TATFAR must act now.

Foreword

The next TATFAR work period (2021-2026) offers opportunities for advancing shared goals and committing to even closer collaboration to address this global, One Health threat. TATFAR will work towards strengthening communication and raising awareness, because everyone has a role to play in combating AMR. There are various activities that are essential to fight AMR, such as improving animal husbandry practices and biosecurity measures, developing vaccination and novel diagnostic tools, and promoting prudent use of antimicrobials. Personal protective behaviors like hand hygiene and covering coughs, infection prevention and control, and vaccination can also contribute to reducing infections and the need for antimicrobials in people and animals. It is important to raise awareness and to work together with human healthcare providers, veterinarians, and the agriculture/aquaculture food sector. In the next work period, TATFAR will also expand collaboration in the environment. We still have much to learn about how human health and AMR are connected to the environment, and the multiple roles that water and soil may play in spreading AMR.

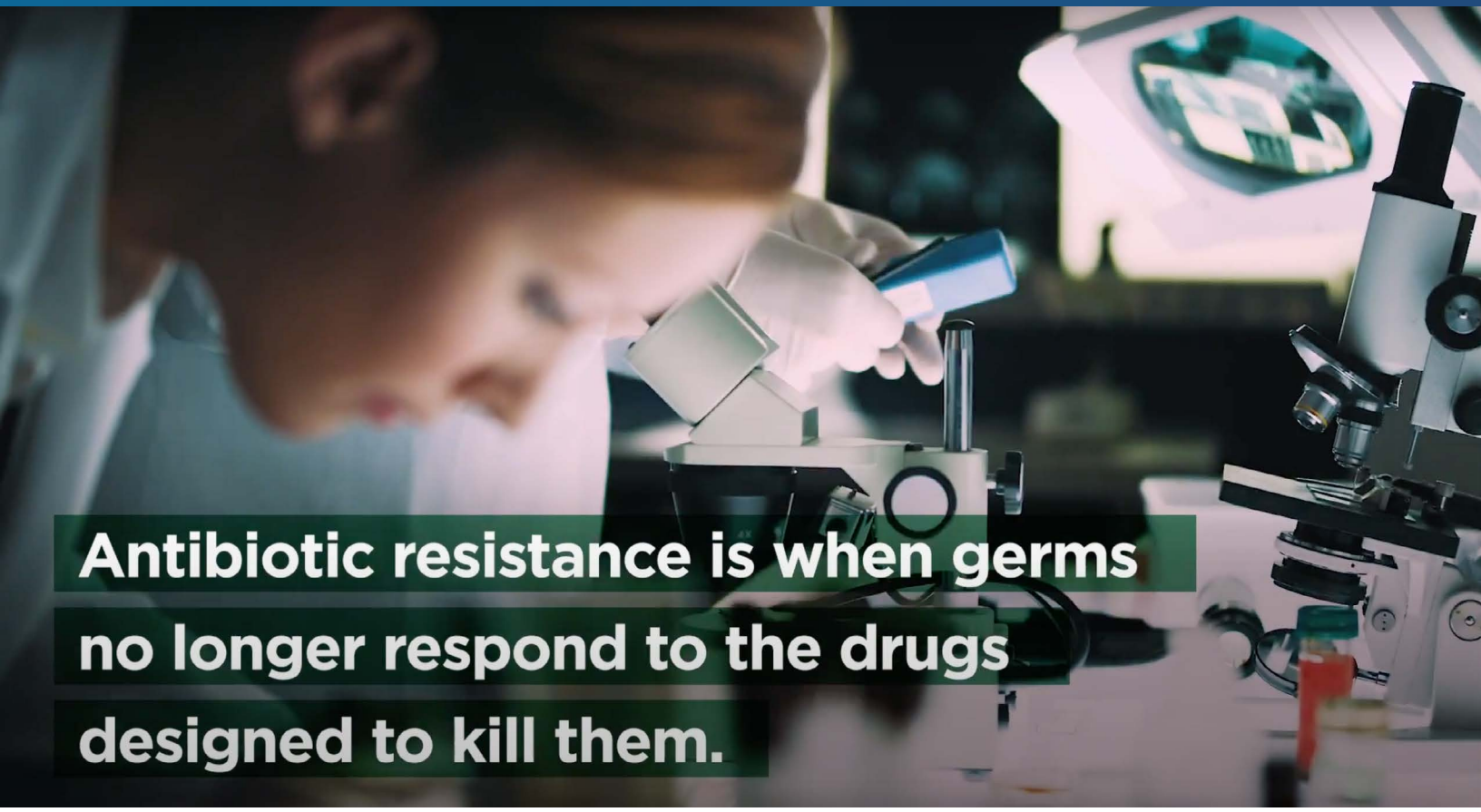
Government agencies are leading urgent and critical activities—often in partnership with other agencies, non-profit organizations, and private sector companies—to combat AMR domestically and globally. TATFAR provides opportunities for this collaboration at a technical and scientific level through increased information exchange, understanding best practices, putting international discovery into practice, and development of peer relationships. Through this work, TATFAR is instrumental in strengthening domestic and global efforts to combat AMR and is determined to take this role forward into the future.

Yours faithfully,

Larry Kerr, TATFAR Co-chair

John F. Ryan, TATFAR Co-chair

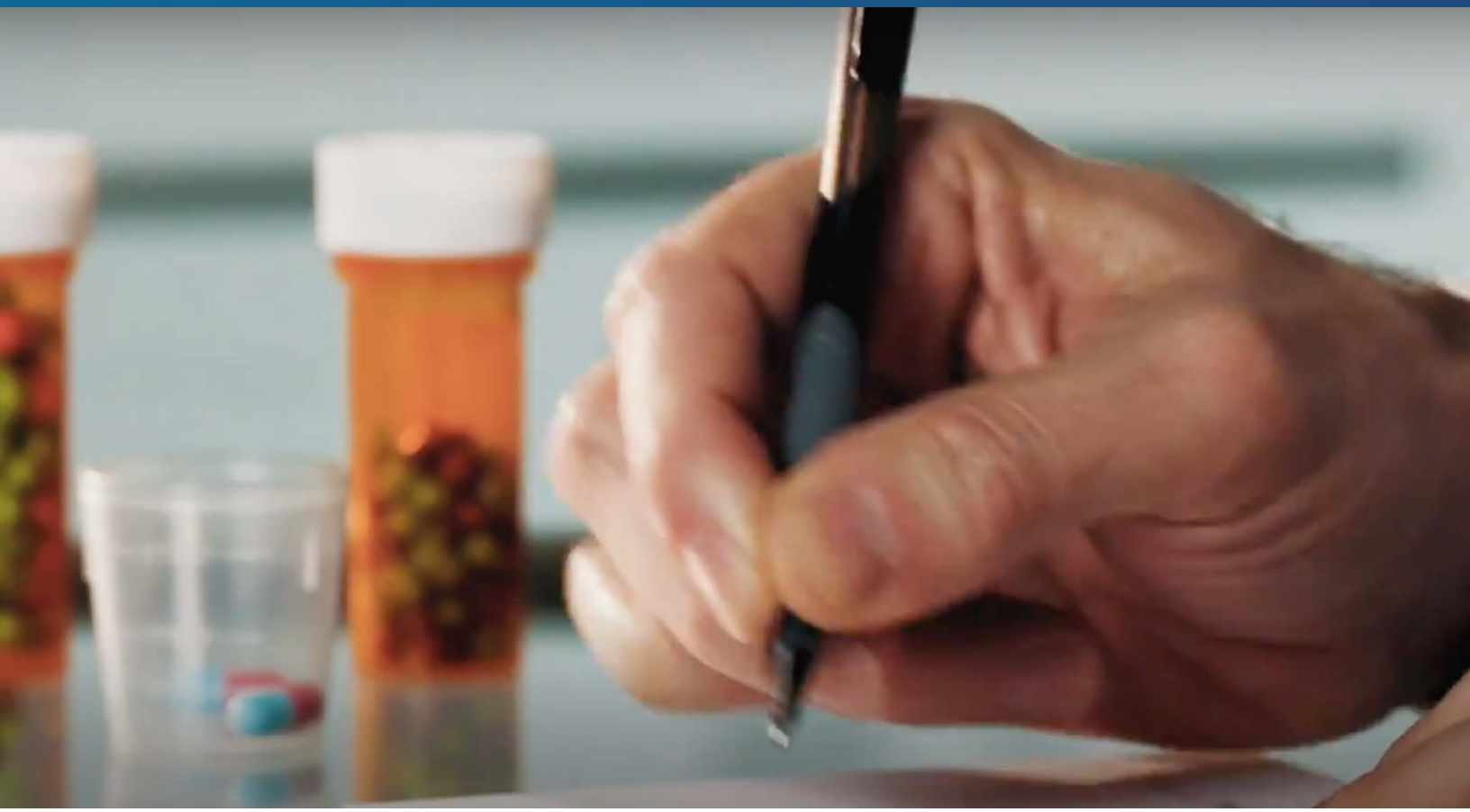
Introduction



AMR is one of the most serious global public health threats. The TATFAR partners—technical experts from government agencies in Canada, the European Union (EU), Norway, and the United States (U.S.)—are committed to the One Health approach to combat AMR by collaborating on activities to improve appropriate antimicrobial use in human health care, veterinary medicine, food animal production and plant protection, prevent antimicrobial-resistant infections, and strengthen the antimicrobial, alternatives, vaccines, and diagnostic pipeline. This report summarizes the progress and outcomes of each action during TATFAR's last implementation period (2016-2020), as well as plans for continued work for the next five-year work plan (2021-2026).

Although AMR is not a new phenomenon, the current magnitude of the problem and the speed with which new resistance phenotypes and mechanisms have emerged and spread elevates its public health significance.

Introduction



Antimicrobials can save lives and are critical tools for treating infections. However, any time antimicrobials are used—in people, animals, or crops—they can lead to unintended consequences, including contributing to the development of AMR.

AMR is considered a One Health issue that requires a holistic and multi-sectoral approach from experts across a variety of disciplines, including but not limited to physicians, veterinarians, microbiologists, epidemiologists, biologists, and public health professionals. As AMR becomes an even more urgent and serious health concern worldwide, developing new drugs alone is not sufficient to address the growing resistance problem. Microbes and pathogens will always find a way to overcome the therapeutic effect of new drugs. Infections can be stopped by preventing the spread of germs and improving infection prevention and antibiotic use in all settings.

AMR requires constant vigilance with ongoing information exchange and collaboration. Even amid the COVID-19 pandemic, task force partners continued to increase information exchange, develop peer relationships, and gain a better understanding of best approaches and practices to combat AMR.

TATFAR History and Overall Progress

TATFAR was created in 2009, during a U.S.-EU summit, where U.S. President Obama, Swedish Prime Minister, then-European Council President Reinfeldt, and European Commission President Barroso recognized the need to address the urgent threat of AMR. In May 2014, the taskforce released its first report summarizing the progress and outcomes of implementation from the 17 original activities.

Per the 2009 U.S.-EU presidential summit, the taskforce remained an EU and U.S. collaboration until October 2015, when Canada and Norway were invited to become partners. Collaboration across government agencies from Canada, EU, Norway, and the U.S. enhances synergy and communication, leading to strengthened domestic and global efforts.

While significant progress has been made, concern related to AMR continues to escalate. In October 2015, TATFAR revised its work plan and extended the collaboration for an additional five years (2016-2020). TATFAR partners jointly, as well as individually, participated in the AMR Challenge launched by the U.S. government as an effort to accelerate the fight against AMR across the globe. TATFAR endorses the AMR Challenge and will continue to work to raise awareness and support action by its partners and networks through initiatives such as the AMR Challenge to garner additional commitments and action that further progress the fight against AMR.

U.S. Secretary of Health and Human Services Alex Azar speaking at the 2018 AMR Challenge.

Working together the past five years, TATFAR member agencies have continued valuable technical engagement to address AMR in the following three key areas and associated actions.

KEY AREA 1

Appropriate therapeutic use in human and veterinary medicine

Key Area 1

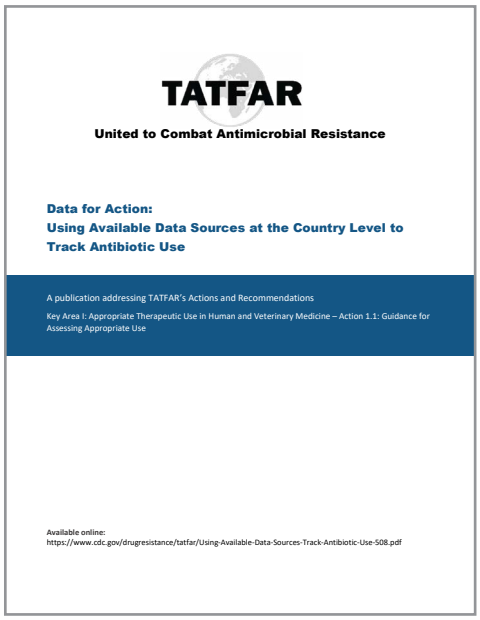
ACTION 1.1: Develop guidance for assessing appropriate antibiotic use

Implementers: CDC, ECDC, DoD, PHAC, NIPH | Lead: CDC

PROBLEM: Tracking how healthcare providers prescribe to treat their patients is a critical step to understand how antibiotics are used. With this information, experts can identify targets for interventions to improve use. Improving the way healthcare providers prescribe and use antibiotics, a practice referred to as "stewardship," can protect patients from harm and combat antibiotic resistance. However, there are many strategies and different data sources for tracking and collecting data on antibiotic use.

ACTION: TATFAR partners understand that tracking and collecting data on antibiotic use varies by country. To address this issue, TATFAR countries published an online report titled Data for Action: Using Available Data Sources at the Country Level to Track Antibiotic Use.

BOTTOM LINE: Tracking antibiotic use is a critical step to understand how antibiotics are used and to inform antibiotic reduction goals referred to in Action 1.2. The report serves as a resource for public health agencies, governments, and other stakeholders to explore examples of different data sources that can be leveraged for improving antibiotic use.



Cover of online report titled Data for Action: Using Available Data Sources at the Country Level to Track Antibiotic Use.

ACTION 1.2: Publish a review of antibiotic reduction goals in human medicine from TATFAR partner countries

Implementers: CDC, ECDC, PHAC, NIPH | Lead: ECDC

PROBLEM: Unnecessary and inappropriate use of antibiotics in human health care is a major driver for the development and spread of antibiotic resistance. Many countries are implementing measures to limit the overuse and misuse of antibiotics, for instance through the establishment of antibiotic use reduction goals. The aim of Action 1.2 was to review the existence and type of reduction goals (or so-called "targets") for antibiotic use in humans in TATFAR partner countries.

ACTION: TATFAR implementers developed a questionnaire, which was sent to the National Focal Points for Antimicrobial Consumption and the National Focal Points for Antimicrobial Resistance in 28 EU countries, Iceland, and Norway, as well as to TATFAR implementers in Canada and the U.S. Data collection took place in April and May 2017. The results include tables with detailed information on the reduction goals targets and corresponding metrics, which were compiled into an article published in July 2019 in Eurosurveillance under the title Targets for the reduction of antibiotic use in humans in the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) partner countries.

BOTTOM LINE: Out of 30 responding countries, nine had established targets to reduce inappropriate antibiotic use in humans, and 17 indicated they were working to establish such targets, often in the context of developing a national action plan against antibiotic resistance. The metrics and reported targets varied greatly between countries.

The survey did not address the methodology for selection of specific indicators and targets. The baseline situation, feasibility, and availability of resources are factors that influence the selection of targets. Though the rationale was described explicitly for a few countries, it would be useful for other countries to understand the rationale behind more of these selections. However, there is no consensus methodology for setting quantitative targets on antibiotic use in humans.

BOTTOM LINE (CONTINUED):

This TATFAR review provides detailed information on existing antibiotic use targets in TATFAR partner countries and can be a useful resource for these and other countries willing to engage in the reduction of antibiotic use in humans.

ACTION 1.3: Continue the coordination of campaigns to promote appropriate antibiotic use in human medicine

Implementers: CDC, ECDC, PHAC, NIPH | Lead: ECDC

PROBLEM: There is a need to increase awareness of prudent antibiotic use and of AMR across the world. This includes encouraging best practices around using antibiotics among the general public, healthcare workers, and policy makers to avoid the further emergence and spread of AMR. TATFAR partners acknowledge that sustaining antibiotic stewardship efforts is critical to address this threat.

ACTION: TATFAR partners collaborated with WHO and non-TATFAR countries to encourage appropriate use of antibiotic use. One example is the participation of TATFAR partners in the World Antimicrobial Awareness Week (WAAW), as well as individual country awareness weeks and the European Antibiotic Awareness Day (EAAD). TATFAR partners also completed specific national and regional activities around appropriate use of antibiotics and AMR, such as global Twitter conversations and publishing news pieces on the TATFAR website summarizing member activities (2016, 2017, 2018, 2019, 2020).

Key Area 1

BOTTOM LINE: Since 2010, TATFAR partners led and coordinated annual observances to raise awareness about prudent use of antibiotics and AMR. This collaboration served as a model for global action and continues under the WAAW, launched by WHO in November 2015.

For example, from 2016-2020, ECDC and CDC alternated at coordinating and leading a global Twitter chat, resulting in more than 4 million impressions and 66,000 engagements overall. In 2020 alone, the WAAW global Twitter chat resulted in more than 1 million impressions and 12,000 engagements, with 260 global partner participants. The Government of Canada's WAAW social media campaign reached approximately 383,000 Canadians through Facebook, Twitter and LinkedIn. CDC had more than 5,000 downloads of its Be Antibiotics Aware print materials during WAAW 2020, and more than 350 participants attended a continuing education webinar on antibiotic use in hospitals.

In 2020, **ECDC** released a video on "Antibiotic Resistance: What can you do as a healthcare specialist?," **receiving more than 1,000 views.** TATFAR partners also shared the challenges presented by AMR in connection with COVID-19. For example, with support from the Government of Canada, Choosing Wisely Canada published a toolkit addressing the management of respiratory tract infections with considerations of COVID-19 and virtual care, including when to prescribe antibiotics. **This work will continue in TATFAR's new work plan for the next five-year implementation period.**

Still from ECDC video on Antibiotic Resistance: What can you do as a healthcare specialist. The video has garnered over 1,600 views as of August 2021.

ACTION 1.4: Cooperate in the development of methodology for measuring and reporting the consumption of antimicrobials per species in veterinary medicine

Implementers: FDA, EMA, HC, PHAC, EFSA, DG SANTE, CFIA, USDA, NVI | Lead: EMA

PROBLEM: It is challenging to collect antimicrobial use data by species because the drivers of antimicrobial use differ between animal species due to different management practices, disease pressures, and animal physiology. And, although some countries have moved forward with collecting these data, best methods to calculate and report antimicrobial use measures are still under discussion. Trends in antimicrobial use over time within an animal sector can be useful indicators of success of various stewardship efforts. Measuring antimicrobial use concurrently with disease prevalence can help better identify drivers of antimicrobial use and appropriate areas for research and education.

ACTION: All TATFAR member countries sent representatives to the annual European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) Network meetings. In 2016 and 2017, a main theme was methods for surveillance of antimicrobial consumption per species. Representatives presented and discussed the development of methodology in depth. In November 2020, the key topic of this annual meeting was antimicrobial use data collection and preparations in line with requirements of Article 57 of Regulation (EU) 2019/6. FDA, OIE, and PHAC participated as observers and updated the Network on their projects and systems for antimicrobial consumption and use surveillance.

From 2016–2020, EMA organized regular teleconferences to provide a forum for communication and exchange of information between TATFAR partners. The presentations from EMA, FDA, and PHAC triggered discussions and highlighted topics to address moving forward.

Key Area 1

Canada

- In 2018, Canada commenced with the mandatory collection of annual antimicrobial sales data from importers, compounders, and manufacturers of medically important antimicrobials (those important to human medicine as outlined on List A) intended for use in animals, called the Veterinary Antimicrobial Sales Reporting (VASR) System. The VASR information complements on-going farm-level antimicrobial use data collection by the Canadian Integrated Program for Antimicrobial Resistance Surveillance and Fisheries and Oceans Canada.

European Union

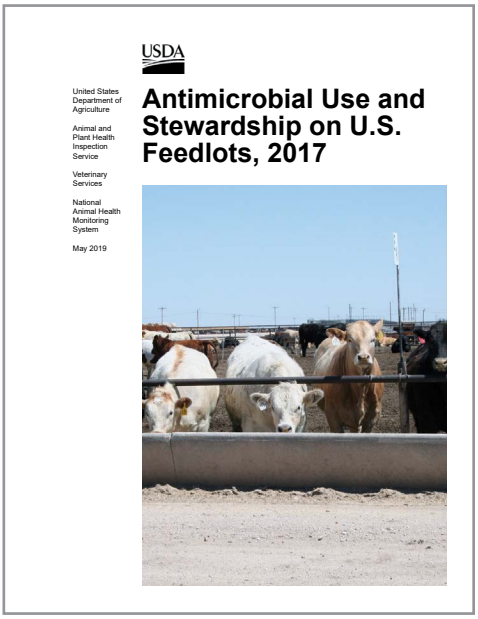
- In 2018, EMA published a guidance on methods for antimicrobial data collection by animal species at a national level, as well as on the denominator to report the data.
- In 2019, the EU adopted Regulation (EU) 2019/6 on veterinary medical products. The regulation foresees the adoption of a delegated act establishing the requirements for data collection on sales and use of antimicrobials in animals at the EU level and of an implementing act to define the format of the data to be collected by EU Member States and then transferred to EMA for analysis. Moreover, the EMA, with experts from the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) network, have started to develop a guideline on reporting antimicrobial sales and use in animals at the EU level that will provide guidance on some technical details relating to the format of the data to be collected, in line with the relating implementing act to be adopted. EMA published a concept paper setting the scope of the guideline to be developed.

Norway

- In Norway, it is mandatory to report all data on antibiotic prescribing and use for farmed fish and terrestrial animals to the Norwegian Veterinary Prescription Register. Since 2016, Norway has worked to improve the register's data in terms of quality (standardization) and reporting compliance.

United States

- Since 2016, FDA collects and reports data on the estimated sales of antimicrobials by animal species for the four major food-producing animals in the U.S. (cattle, swine, chickens, turkeys). In 2019, the FDA released the latest annual antimicrobial sales reports, titled 2019 Annual Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals.
- In 2017, FDA published a proposed method for adjusting data on antimicrobials sold or distributed for use in food-producing animals, using a biomass denominator. These adjusted estimates will provide insight into broad shifts in the amount of antimicrobials sales use in food-producing animals and give a more nuanced views of why sales fluctuate over time.
- Beginning in 2016, the FDA funded five-year pilot projects to explore methodologies for on-farm antimicrobial use data collection for cattle, swine, and poultry.
- In 2019, the USDA Animal and Plant Health Inspection Service's National Animal Health Monitoring System (NAHMS) published two reports titled Antimicrobial Use and Stewardship on U.S. Feedlots, 2017 and Antimicrobial Use and Stewardship on U.S. Swine Operations, 2017. These reports summarize the antimicrobial use practices on feedlots and swine operations in 2016, before the FDA implemented antimicrobial use policy changes on January 1, 2017.



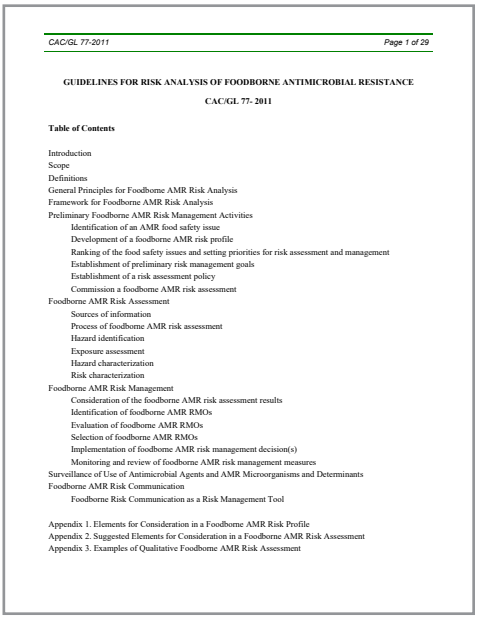
Cover of report titled Antimicrobial Use and Stewardship on U.S. Feedlots, 2017.

BOTTOM LINE: Member countries are taking action and will continue to exchange information and discuss ongoing and future activities, ultimately resulting in a review paper on methodologies for reporting antimicrobial consumption per species in veterinary medicine. **This work will continue in TATFAR's new work plan for the next five-year implementation period.** TATFAR partners will author a review paper on methodologies for reporting consumption of antimicrobials by animal species, summarizing the various methods used by TATFAR partners. This will provide external partners with insight into various methods and considerations for measuring antimicrobial consumption in animals and help inform comparisons in antimicrobial consumption between countries.

ACTION 1.5: Collaborate on implementation of the Guidelines for Risk Analysis of Food-borne Antimicrobial Resistance adopted by Codex Alimentarius Commission

Implementers: AAFC, CDC, CFIA, DG SANTE, EFSA, EMA, FDA, HC, PHAC, USDA | Lead: PHAC

PROBLEM: The Codex Guidelines for Risk Analysis of Foodborne AMR provides a framework for assessing the risk to human health from foodborne AMR and determining appropriate risk management strategies to control those risks. Due to the biological complexity of AMR, the multidisciplinary aspects of AMR within the entire food production to consumption continuum, and the need to identify appropriate risk management strategies, many countries have difficulty in implementing the Codex Guidelines.



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GUIDELINES FOR RISK ANALYSIS OF FOODBORNE ANTIMICROBIAL RESISTANCE

CAC/GL 77- 2011

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Cover of report titled Codex Guidelines for Risk Analysis of Foodborne AMR.

Key Area 1

ACTION: TATFAR partners focused on aspects related to implementing the Codex Guidelines for Risk Analysis of Foodborne AMR. They developed a table of risk profile elements to streamline future risk profiles, the time and data needed for those elements, and considerations for which elements would be required depending on the problem.

The information sharing aspect of this working group continues to be an integral component of the activities. Discussion of the latest advancements in risk analysis of foodborne AMR through presentations by partners and invited technical experts and round table updates have been valuable for sharing developments in this field.

Partners continue to discuss the best ways to share risk profile information to ensure the material is evergreen and available for all partners, noting that the information rapidly changes, and resources are required to keep materials current. Moving from a risk profile to a quantitative risk assessment, partners discussed published models, including details on the types of questions addressed by the models. The purpose is to have a ready source of options available to those conducting risk assessments. Partners also discussed including whole genome sequencing (WGS) in risk profiles and risk assessments and will continue this discussion, as it is a rapidly evolving topic.

BOTTOM LINE: The initial focus was to implement the Codex Guidelines for Risk Analysis of Foodborne AMR. Going forward, the action shifted into a platform to exchange information on risk analysis of foodborne AMR, and the action was renamed accordingly in the last year of the implementation period. To continue long-standing information sharing on approaches to risk analysis for foodborne AMR, partners will meet on a consistent basis to share ideas and expertise on how to effectively conduct risk analysis of foodborne AMR. **This work will continue in TATFAR's new work plan for the next five-year implementation period.**

ACTION 1.6: Enhance information sharing on approaches to promoting appropriate use in veterinary communities

Implementers: USDA, FDA, EMA, EFSA, DG SANTE, NVI, CFIA, HC | Lead: USDA

PROBLEM: Veterinarians play a critical role in ensuring appropriate use of antimicrobials to help combat AMR. There are various challenges to addressing appropriate use in animals and approaches to promoting appropriate use vary among TATFAR partners. TATFAR partners acknowledge that a lack of reliable data, and confusion about labeling claims and antimicrobial drug residues versus antimicrobial resistance can add to public misconception and raise potential animal health and welfare concerns.

ACTION: TATFAR partners identified defining, implementing, and promoting stewardship as key components to addressing challenges. Practices, such as measuring veterinary antibiotic use, record keeping, and employee training can help strengthen antimicrobial stewardship. Working together over the last five-year implementation period, TATFAR partners shared information around promoting antibiotic stewardship principles among veterinarians.

Canada

- Canada provided a comprehensive view of efforts to develop their Pan-Canadian Framework for Action to address AMR. The approach was a combination of regulatory efforts, increased veterinary oversight, and stakeholder engagement.
- Canada also described the Clinical and Laboratory Standards Institute (CLSI) work to help clarify interpretive criteria for improving use of susceptibility data by veterinarians, and thereby enhance clinical stewardship.

European Union

- DG SANTE established the "Better Training for Safer Food" initiative that included the promotion of prudent and responsible use of antimicrobials in animals.
- The new legislation on veterinary medicinal products and medicated feed, which was adopted in the EU in 2018 with concrete measures to fight AMR and promote prudent and responsible use of antimicrobials in animals, was presented by DG SANTE. It will apply as of 2022.
- DG SANTE also presented the overview report on measures to tackle AMR through prudent use of antimicrobials in animals published in 2019, based on various sources of information, among which was a series of fact-finding missions in EU with ECDC aiming to support the development of national policies against AMR.

Norway

- In 2017, In response to the governmental strategy against AMR (2015-2020), the Norwegian food-producing animal industry published a common action plan against AMR bacteria which focused on prevention of diseases and on prudent use of antibiotics.
- In 2017, Norway restricted the use of human antibiotic medicinal products that the Antimicrobial Advice Ad Hoc Expert Group (AMEG) of EMA advised for restriction due to the potential consequences of AMR to public health.
- Guidelines for prudent use of antibiotics in horses were published in 2019, while guidelines for the major food-producing animal species and for dogs and cats were published previously.
- In 2018, the expiration date for prescriptions of antibiotics to animals was changed from 1 year to 10 days.

Key Area 1

United States

- The USDA's Animal and Plant Health Inspection Service described on-farm antimicrobial use in two species (beef cattle and swine) and the American Veterinary Medical Association (AVMA) Committee on Antimicrobials (CoA) convened multiple species groups to develop and disseminate a common definition and Core Principles for antimicrobial stewardship for practicing veterinarians.
- The FDA finalized their five-year plan, Supporting Antimicrobial Stewardship in Veterinary Settings released in September 2018 to further stewardship and monitoring.
- The National Institute of Antimicrobial Resistance Research & Education participated in various private sector engagements to establish public-private partnerships to further stewardship.

BOTTOM LINE: Practitioners may be more likely to listen to and learn from their professional organizations, in addition to government entities. Professional organizations may play an important role in relaying information and indications given by government entities. Sector-specific guidance and science-based scenarios are most convincing for clinicians to address stewardship. Limited information regarding appropriate antimicrobial breakpoints for some species challenge stewardship efforts. TATFAR partners shared information on approaches to promote antimicrobial stewardship principles in among veterinarians. These regular exchanges of information helped inform the most impactful activities to address stewardship. **This work will continue in TATFAR's new work plan for the next five-year implementation period.**

ACTION 1.7: Cooperate to improve surveillance of AMR in food-borne bacteria through the exchange of methodology and best practices to enhance data collection and reporting

Implementers: FDA, EMA, EFSA, DG SANTE, NVI, CFIA | Lead: FDA

PROBLEM: New technological advancements in genomics, data analytics, bioinformatics, and new data sources have laid the groundwork for best practices to conduct surveillance within the One Health spectrum. However, with the increasing use of WGS techniques there is a need for more in-depth and integrated collaboration with global organizations and other countries to ensure comparisons are both easier and more meaningful.

ACTION: Starting in 2018, the group proposed to focus on surveillance, along with the four topics:

- Using next generation sequencing technologies to conduct genomic surveillance of resistance
- Best practices for conducting surveillance within the One Health paradigm
- Examples where surveillance was able to document success stories to limit or reverse resistance trends
- Sharing emergent resistances of special public health concern

EFSA and ECDC produced yearly European Summary Reports for AMR (EFSA-ECDC EUSR-AMR) on AMR in zoonotic and indicator bacteria from humans, animals, and food according to the European Legislation.

PROBLEM (CONTINUED):

Partners from the Americas and EU countries have exchanged AMR surveillance updates through a number of scientific conferences focused on food safety and genomics. TATFAR partners participated in several conferences to share information on best practices for One Health AMR surveillance. In October 2020, the US National Antimicrobial Resistance Monitoring System held a public meeting to outline U.S. efforts to develop a One Health AMR monitoring system and announce a new five-year strategic plan. The two-day conference outlined a proposed approach to surface water monitoring, the use of genomic and metagenomic methods, and plans for animal pathogen testing and data sharing. Details on this effort were presented at an ECDC conference (2021) and EURL-AMR network meetings (2019, 2020). Conference calls were held between U.S. and EU scientists to explore ways to further harmonize susceptibility testing methods and breakpoints for foodborne pathogens (2021).

BOTTOM LINE: TATFAR partners have shared important information on efforts to improve surveillance of AMR in foodborne bacteria. For many common AMR genes, TATFAR partners have demonstrated the ability of genomic information to predict clinical resistance in target bacteria, paving the way for genomics-based surveillance. TATFAR partners have shared strategies and data on approaches to environmental surveillance of the watershed and waste waters, which continue to develop. Each collaboration has helped identify barriers and successes to a One Health model of surveillance that will continue to present challenges in the future and necessitate ongoing communication and collaboration. **This work will continue in TATFAR's new work plan for the next five-year implementation period.**

ACTION 1.8: Cooperate in improving understanding of the impact on public and animal health of restricting certain uses of antimicrobial drugs in food-producing animals

Implementers: FDA, USDA, CDC, EMA, EFSA, DG SANTE, DG RTD, ECDC, CFIA, NVI

Lead: Due to limited bandwidth of TATFAR technical experts, engagement on this action was incomplete. This topical area will be addressed in TATFAR's next five-year implementation period.

PROBLEM: The relationship between antimicrobial use in food-producing animals and the development of AMR is extremely complex. In the 2016 TATFAR Report on Recommendation 18, the working group identified numerous knowledge gaps in understanding and limiting the transmission of resistant bacteria from food-producing animals to humans.

BOTTOM LINE: TATFAR partners shared important information regarding the use of antimicrobials and AMR in humans and food-producing animals. EU partner agencies adopted a joint scientific opinion on indicators to help assess partner agencies' progress of EU Member States towards reducing the use of antimicrobials and AMR in both humans and food-producing animals. Partner agencies also released various advice and guidance documents that highlight measures to fight AMR and promote responsible use of antimicrobials in animals. While surveillance results indicate some positive impact on public health, the multitude of AMR control efforts underway make it challenging to determine which interventions are most effective. **This work will continue in TATFAR's new work plan for the next five-year implementation period.**

KEY AREA 2

Prevention of drug-resistant infections

Key Area 2

ACTION 2.1: Consultation and collaboration on point-prevalence surveys of healthcare-associated infections

Implementers: CDC, ECDC, PHAC, NIPH | Lead: CDC

PROBLEM: Each TATFAR partner has developed expertise and experience in the performance of point prevalence surveys (PPSs) of healthcare-associated infections (HAIs) and in the use of PPS data to complement data received through prospective surveillance systems. Given the differences that exist in health systems and care delivery, each partner has designed their PPS to meet their own distinct public health needs and resources. However, there are also substantial domains of commonality among the partners' approaches. There is a need for TATFAR partners to not only review differences between methods used but also to identify harmonized approaches to validate PPS data, identify best practices for using and sharing PPS data, and identify additional information about HAIs that may need more attention.

ACTION: Under this area of collaboration, TATFAR partners shared ideas and further refined and harmonized selected aspects of PPS methodology. TATFAR partners compared and contrasted PPS methods used in Canada, the EU/European Economic Area, Norway, and the U.S., with a focus on surveillance definitions, data collection and management, validation, and estimation of burden of HAIs. TATFAR partners worked on three collaborative manuscripts addressing PPS methods and PPS data use for hospitals and for long-term care facilities/nursing homes. Because of delays related to the COVID-19 pandemic, the development of these manuscripts will occur in the next implementation period.

Canada

- In 2017, PHAC conducted its third PPS in large acute-care hospitals of HAIs, antibiotic-resistant organisms, and antimicrobial use. The results on HAI and antibiotic-resistant organisms were published in the Canadian Medical Association Journal in September 2019.
- In 2019, PHAC conducted its second PPS in smaller, remote, and northern Canadian acute-care hospitals of HAIs, antibiotic-resistant organisms, and antimicrobial use.
- In 2019, PHAC conducted its first PPS in long-term care facilities of antibiotic-resistant organisms and antimicrobial use, with information on exposure to hospitals.

European Union

- In 2016-2017, ECDC conducted its second PPS of HAIs, including AMR in HAIs, and antimicrobial use in European acute care hospitals.
- Also in 2016-2017, ECDC conducted its third PPS of HAIs, including AMR in HAIs, and antimicrobial use in European long-term care facilities.
- ECDC organized webinars for training of national staff (PPSs in acute care hospitals and in long-term care facilities), sending hospital feedback reports as the data came in (including the IPC indicators reported by WHO core components) and feedback on the validation results.
- Find more information on ECDC PPSs.

Norway

- NIPH has conducted point prevalence surveys of HAIs and antimicrobial use in long-term care facilities twice annually.
- NIPH has conducted point prevalence surveys of HAIs and antimicrobial use in hospitals twice annually.
- In 2017, Norway participated in the ECDC PPS of HAIs and antimicrobial use in hospitals and long-term care facilities.

United States

- Between May and September 2015, CDC worked with the Emerging Infections Program (EIP) to complete a second, full-scale PPS in hospitals focused on antimicrobial use and HAIs in hospitals.
- In 2017, CDC worked with the EIP to complete its first full-scale PPS in nursing homes focused on HAIs and antimicrobial use in nursing homes.
- Find more information on CDC PPSs.

BOTTOM LINE: AMR has become a dangerous threat to public health worldwide, making it critical for public health agencies around the world to assess and compare the prevalence of HAIs in health care in different countries. Prevalence surveys are powerful tools for understanding the global breadth and burdens of HAIs in hospitals. This TATFAR collaboration has provided valuable opportunities for exchanging information, comparing methodologies, and sharing experiences related to the importance of conducting large prevalence surveys. **This work will continue in TATFAR's new work plan for the next five-year implementation period. TATFAR partners will complete planned publications for this work.**

ACTION 2.2: Develop a common system for sharing and analyzing bacterial resistance patterns for pathogens identified as urgent and serious threats

Implementers: CDC, ECDC, DoD, PHAC, NIPH | Lead: ECDC

PROBLEM: There is a need for international standards and systems to share WGS-derived information. This would help TATFAR partners exchange standardized data in a timely way, which would support early and concerted responses to the emergence or spread of high-threat multidrug-resistant pathogens. Transnational alert systems require a degree of harmonization of WGS analytical approaches; epidemiological interpretation criteria and genomic nomenclature for clonal types, plasmid types, and resistance AMR determinants; and interconnection of databases and analytical platforms. TATFAR partners also recognize that although WGS can be a valuable addition to AMR surveillance frameworks, not all surveillance or detection data for emerging AMR is WGS-based. There will be significant limitations towards the amount of data available to share and actions taken to contain emerging threats if AMR surveillance systems are based solely on genomic data.

ACTION: Starting in 2018, TATFAR partners mapped the availability of genomic information on carbapenem-resistant Enterobacterales (CRE) across TATFAR countries. Partners also addressed bioinformatics approaches and the need for available microbiological and epidemiological information with provisional agreement on essential information, such as the sample origin and type, date of sample collection, and country. CRE were identified as a priority target to explore the feasibility, potential channels, epidemiological data, and barriers for genomic data sharing.

In October 2019, partners discussed possible approaches to exchange surveillance data on CRE at an in-person meeting in Stockholm, Sweden. Partners agreed that the current, most feasible solution was to use available platforms to exchange information, such as the TATFAR communication of critical resistance AMR threats (see Action 2.3).

ACTION (CONTINUED):

Partners explored using protected space to share data. A likely solution includes an upcoming new ECDC epidemic intelligence information system, which will be part of the new ECDC Surveillance platform (EpiPulse) launching in 2021. This platform will support the exchange of genomic data. Potential synergies with Action 1.7 (Cooperate to improve surveillance of AMR in foodborne bacteria through the exchange methodology and best practices to enhance data collection and reporting) were identified as an area of future collaboration under a One Health perspective.

BOTTOM LINE: Partners mapped current national and international AMR surveillance systems to identify gaps and unmet public health needs relevant to the use of genomic information; identified CRE as priority target pathogens of high public health international impact for a pilot data sharing system; mapped available bioinformatics data management platforms and standards for storing and analyzing genomic information relevant for AMR in CRE; and proposed a system to facilitate the exchange of information among TATFAR partners on genetic determinants and vectors of AMR patterns.

It is important to exchange genomic information for public health purposes, specifically for AMR and the continuous rapid development in this field. This will require ongoing TATFAR collaboration and close follow-up. TATFAR is well-placed to address the needs and possible solutions to facilitate the exchange and interpretation of genomic information. **This work will continue in TATFAR's new work plan for the next five-year implementation period.**

ACTION 2.3: Develop a rapid alert system for communication of new or novel AMR findings

Implementers: CDC, ECDC, DoD, PHAC, NIPH | Lead: CDC

PROBLEM: Multidrug-resistant organisms do not respect international borders. Local emergence of AMR pathogens can spread quickly and internationally. National efforts to improve early detection of new resistance would greatly improve if there was a global mechanism to communicate findings no matter where they occur in the world. TATFAR partners recognize the importance of developing a common system for sharing and analyzing bacterial resistance patterns for urgent and serious pathogens (see Action 2.1). Rapid development in this area will help facilitate better communication of data on these AMR threats across TATFAR countries.

ACTION: TATFAR partners recognize that proactive communication is extremely valuable in order to inform early detection of novel resistance trends. To help address communication around emerging and concerning AMR, TATFAR partners collaborated to improve communication between government agencies to alert one another of AMR findings of interest. TATFAR partners updated each other about new AMR findings and trends during specific and regularly scheduled calls. TATFAR partners also participated in WHO's development of the Emerging Antimicrobial Resistance Reporting component within the Global Antimicrobial Resistance Surveillance System (GLASS-EAR) to support detection, early warning, and risk assessment capacities of national AMR surveillance programs, as well as global exchange of information on emerging AMR threats.

BOTTOM LINE: Timely communication about newly detected AMR findings can influence surveillance and control strategies. TATFAR partners acknowledge the importance of early prevention of new resistance, which requires early detection. TATFAR partner agencies met on a regular basis to discuss emerging and concerning trends, which provided a fruitful platform to discuss the emergence of urgent threats, including CRE and *Candida auris*. **This work will continue in TATFAR's new work plan for the next five-year implementation period.**

ACTION 2.4: Encourage efforts to harmonize interpretive criteria for susceptibility reporting of bacterial isolates for contribution of data to the WHO Global Antimicrobial Resistance Surveillance System (GLASS)

Implementers: CDC, ECDC, PHAC, NIPH, CLSI, EUCAST | Lead: CDC

PROBLEM: Breakpoints are an integral part of microbiology laboratory practice. They are used to define susceptibility and resistance to antimicrobials. However, the lack of harmonization of breakpoints, terminology, and methods makes it challenging to compare antimicrobial surveillance data and to communicate between the medical profession, the pharmaceutical industry, and regulatory authorities.

ACTION: TATFAR partners worked with CLSI and EUCAST, international clinical breakpoint setting organizations, to harmonize breakpoints focused on bug/drug combinations. This work resulted in harmonized breakpoints for colistin and gram-negative pathogens. In addition, there are harmonized breakpoints and epidemiological cutoff values for *Neisseria gonorrhoeae*.

While there has been success, more work is needed. For example, CLSI and EUCAST should agree on a single disk diffusion test for each bug/drug combination with a focus on those that affect WHO GLASS surveillance. Agreement would avoid confusion and potential testing errors (for instance, many labs use both CLSI and EUCAST guidance and they could apply a CLSI interpretation to a EUCAST disk test or vice versa and report inaccurate results). There are also places where breakpoints differ and discussions between CLSI and EUCAST would result in a consensus recommendation for surveillance.

BOTTOM LINE: TATFAR partners worked with CLSI and EUCAST to harmonize breakpoints with the focus geared towards bug/drug combinations included in WHO GLASS. CLSI and EUCAST have made progress toward harmonization, including harmonized breakpoints for colistin and gram-negative pathogens and harmonized breakpoints and epidemiological cutoff values for *Neisseria gonorrhoeae*.

ACTION 2.5: Coordinate guidance for detection of outbreaks or concerning resistance trends and appropriate response

Implementers: CDC, ECDC, PHAC, NIPH | Lead: ECDC

PROBLEM: AMR often emerges and spreads extensively before the magnitude of the threat is realized, limiting the options for an effective public health response. Recent emerging AMR threats highlight gaps in detection, verification, and communication at a global level. Although international rapid alert systems are under development, mechanisms to ensure that information is available and assessed at a national level are not always uniformly present. These concerns indicate a need to develop guidance to support the capacity for timely detection of emerging resistance threats, verification, and dissemination of relevant information.

ACTION: Starting in 2018, Action 2.5 focused on systems and processes to timely detect AMR threats and address necessary elements at a national level. An in-person meeting was held in November 2018 in Stockholm, Sweden, with participation from CDC, PHAC, NIPH, ECDC, and experts from the TATFAR partner and EU countries.

BOTTOM LINE: To ensure the timely identification of future emerging AMR threats, there is a need for a system with the capacity to collect, integrate, and interpret data from clinical laboratories; organize and carry out microbiological and epidemiological studies; assess the magnitude of the threat; and communicate with relevant organizations and agencies and act on the data as possible. Elements of this system could include:

- Establishing surveillance of emerging AMR, especially against novel antimicrobials
- Involving clinical laboratories as the frontline for the detection and assessment of unusual susceptibility results
- Ensuring the availability of reference laboratories that are responsible for verifying and further characterizing emerging AMR

BOTTOM LINE (CONTINUED):

- Establishing an AMR network linking laboratories, infection prevention and control professionals, and public health to facilitate communication and assessment
- Developing criteria to assess emerging AMR and methods to assess AMR trends

This work will continue in TATFAR's new work plan for the next five-year implementation period. TATFAR partners will complete a final report on an approach to share and analyze resistance patters for pathogens identified as urgent or serious threats.

KEY AREA 3

Strategies for improving the pipeline of new antimicrobial drugs

Key Area 3

ACTION 3.1 & 3.2: Incentives work for antibacterial drug development

Implementers: BARDA, DG RTD, DG SANTE, HC, NIPH, ISED

Leads: BARDA (3.1) and NIPH (3.2)

PROBLEM: Although AMR levels are increasing globally, the world currently lacks the drug candidates to ensure a diverse and robust pipeline of antibacterial drugs. There are few pull incentives implemented to incentivize antibacterial therapy development. Some experts argue that this is the remaining piece that requires action to create an ecosystem of incentives to mobilize industry to re-enter antibacterial drug discovery and development.

ACTION: TATFAR partners examined the issue of economic incentives for drug development. The goal was to determine areas of global consensus and conduct an analysis to determine the incentives that promote innovations while ensuring access and appropriate use.

These groups published two articles focused on incentives. The most recent in June 2017 titled Pull Incentives for Antibacterial Drug Development: An Analysis by the Transatlantic Taskforce on Antimicrobial Resistance, which examined various pull incentives to potentially incentivize antibacterial drug development. The group also published an article in 2016 in Clinical Infectious Diseases titled, Economic Incentives for Antibacterial Drug Development: Literature Review and Considerations from the Transatlantic Taskforce on Antimicrobial Resistance. For this manuscript, TATFAR partners explored economic incentives for antibacterial drug development and provided recommendations for potential global implementation.

BOTTOM LINE: The lack of antibacterial drug candidates is a function of both scientific challenges of antibacterial drug development and the lack of profitability that currently exists in the antibiotic market, particularly when compared with other therapeutic areas. Antibiotics are unique in that the more they are used the faster resistance can develop. TATFAR partners hope collaborations under this area will help inform upcoming policy decisions regarding the development of a package of economic incentives needed to spur innovation in antibacterial drug development. **This work will continue in TATFAR's new work plan for the next five-year implementation period.**

ACTION 3.3: Foster international research and product development to address challenging problems in the management of AMR

Implementers: BARDA, DG RTD, DG SANTE, CIHR, NIPH, NIH, HC | Leads: NIH and DG RTD

PROBLEM: Basic, translational, and clinical research are critical to developing the vaccines, diagnostics, antibiotics, and non-traditional therapeutic products that are needed to mitigate AMR infections. International communication and collaboration are needed to ensure priorities are aligned and the best science is funded with the resources available.

ACTION: TATFAR partners participated in quarterly phone calls to share information on current and upcoming funding opportunities, workshops, and other activities. All implementers participated in a workshop on aligning clinical trials networks in January 2016, and the European Innovative Medicines Initiative (IMI) and two U.S. NIH-funded groups formed international collaborations as a result. These partnerships have helped facilitate enrollment in several clinical trials, and an agreement between IMI and the NIH-supported Antibacterial Resistance Leadership Group promises that additional collaborations will be established in the future. NIH and RTD gave a meet-the-experts presentation at the European Society of Clinical Microbiology and Infectious Diseases conference in 2016 to share information on funding opportunities with the scientific community.

Canada

- CIHR is a founding member of JPIAMR. CIHR also sits on the JPIAMR Management Board and Steering Committee, continues to be a top funder within this network, and leads the JPIAMR Virtual Research Institute (VRI) task with eight other member states.
- Canada is engaged in a number of international efforts in the area of AMR and has supported declarations focused on AMR and framed Canada's position at the international table of the WHO, WHA, UNGA, G7, and G20, and is developing action plans and frameworks.
- Between 2015-2016 and 2019-2020, CIHR invested $130.7 million in AMR-related research, including $26.3 million in 2019-2020 alone.
- In 2019, Health Canada launched a challenge as part of the Innovative Solutions Canada program that provided investments to support Canadian small business in the development of point of care diagnostics to combat AMR.

European Union

- The EU supports the functioning of the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR) via coordination and support actions, as well as via topping up the budget for research calls issued by JPIAMR.
- Since its launch in 2011 the IMI, a public private partnership, has invested around EUR 950 M in the development of new antimicrobials via its New Drugs for Bad Bugs and its AMR Accelerator programs (around half of that comes from the EC budget).
- The European Commission is a founding member of the global AMR R&D hub, in which it together with all other members collects and presents information on AMR R&D investments and market interventions. Since its launch in 2018 this hub aims to 1) Guide and support evidence-based decision making, 2) Enhance collaboration and coordination; and 3) Promote awareness, knowledge, and visibility.

Key Area 3

Norway

- Norway continues to invest in AMR-related research both through national funders but also through JPIAMR, Europe's IMI, and others, calculated at a NOK 537 million (€ 53 million) annual investment in 2017.
- NIPH performs leadership roles in multiple initiatives with a focus of stimulating antibiotic innovation and improving access, including DRIVE-AB and the EU Joint Action on AMR and Healthcare-Associated Infections (EU-JAMRAI).
- Norway actively engages in UN, WHO, Global AMR R&D Hub, and other fora related to all AMR-related areas.

United States

- In 2016, BARDA within the Office of the Assistant Secretary for Preparedness and Response, NIH, and the Wellcome Trust established CARB-X, an international public-private partnership focused on supporting the preclinical development of therapeutics, preventatives, and diagnostics. Funding participation has expanded since 2016 to include the Bill & Melinda Gates Foundation, GAMRIF, and the German Government Federal Ministry of Education and Research. CARB-X has received $303 million from these funders and has supported 86 antibacterial therapeutics, prevention, and diagnostics programs between 2016 and 2020. The portfolio is characterized by a high level of innovation with new classes of compounds, compounds that reach new targets, compounds with new mechanisms of action, and non-traditional approaches. Seven programs have advanced into Phase 1 clinical development with the support of CARB-X.

United States (Continued)

- BARDA has invested over $1.5 billion in antimicrobial development both through CARB-X and the Advanced Research and Development (ARD) portfolio since its inception in 2010. Between 2016 and 2020, the ARD portfolio, which is a mix of drug candidates and products in preclinical, Phase 1, Phase 2, Phase 3, and Phase 4 development, has helped bring 3 new antibacterials to market and added 11 new compounds into its pipeline bringing the portfolio to 13 partnerships developing 16 drug candidates/product candidates that address a majority of the Gram-negative and Gram-positive drug-resistant pathogens identified by the CDC as "urgent" and "serious" threats. Among the new additions to the portfolio, two are non-traditional candidates: an engineered phage cocktail carrying a CRISPR-Cas3 cassette for the treatment of recurrent urinary tract infection caused by *Escherichia coli* and a microbiome treatment for the prevention of recurrent *Clostridioides difficile* infection. The inclusion of these types of products is a new frontier for BARDA that underscores the need and potential utility of new, innovative products to overcome the increasing challenge of AMR bacteria.
- In 2019, BARDA awarded a Project BioShield contract to Paratek Pharmaceuticals to support the advanced clinical development and procurement of Omadacycline. This contract was designed to also provide funding during capital-intensive stages of commercializing a newly approved antibiotic, in particular, pediatric studies and post-marketing commitments.
- The NIH-supported Antibacterial Resistance Leadership Group, launched in 2013, has established collaborations in 19 countries and activated more than 130 clinical trial sites globally to advance a robust clinical research program addressing AMR. Studies conducted include clinical testing of new drugs to treat multidrug-resistant Gram-negative bacteria, evaluating diagnostic devices in clinical settings, and optimizing treatment regimens to reduce the emergence of resistance. In 2019, NIH renewed the program's funding, providing up to $102.5 million over 7 years.

United States (Continued)

- In September 2016, NIH and BARDA announced the Antimicrobial Resistance Diagnostic Challenge competition for $20 million and in August 2020 completed the final phase of this 5-year competition. The $19 million prize was awarded to Visby Medical, Inc. for an innovative, rapid, point-of-need diagnostic test capable of accurately and reliably detecting *Neisseria gonorrhoeae* and determining antibiotic susceptibility in under 30 minutes.

BOTTOM LINE: The work within this action remained a fruitful platform for TATFAR partners to engage in regular communication, focused collaboration among funders and the research community, facilitate research and product development opportunities, and enable clinical research. **This work will continue in TATFAR's new work plan for the next five-year implementation period.**

ACTION 3.4, 3.5, & 3.6: Regulatory approaches for antimicrobial products

Implementers: FDA, EMA, HC, NMA | Leads: EMA (3.4-3.6) and FDA (3.5-3.6)

PROBLEM: Market approval for new antimicrobial products is critical to ensure alternatives are safe. However, there are varying procedural processes between drug regulatory authorities to approve these products which makes drug development and approval both costly and tedious. Innovative regulatory and research approaches are needed to guide the development of new antimicrobial products.

ACTION: TATFAR partners recognize that these regulatory barriers pose significant challenges to combat antimicrobial resistance. TATFAR partners regularly discussed antibacterial drug development programs, clinical trial designs for studying new antibacterial drugs, emerging safety issues, and coordinated efforts on scientific meetings to facilitate antibacterial drug development among TATFAR partners. TATFAR partners also shared information and worked together to develop future public meetings to describe approaches for developing alternative approaches for treating bacterial diseases.

BOTTOM LINE: TATFAR partner meetings and exchanges under these activities have led to agreements on clinical trial recommendations that will be reflected in updated guidance documents for several different types of bacterial diseases. Through these shared experiences, TATFAR partners have allowed the opportunity to advance mutual efforts to facilitate antibacterial drug development to meet patients' needs. **This work will continue in TATFAR's new work plan for the next five-year implementation period.**

ACTION 3.7: Veterinary regulatory agencies will discuss the particular challenges related to authorization of novel veterinary therapies presented as alternatives to antimicrobials

Implementers: FDA, EMA, HC, CFIA, DG SANTE, USDA | Lead: FDA

PROBLEM: There are various challenges related to authorizing novel veterinary therapies presented as alternatives to antimicrobials. Challenges include the need to provide a framework to evaluate vaccines that are presented as reducing the need for antimicrobials; the need to define authorization requirements for novel therapies that reduce the need for antimicrobials; and, how to promote development of in vitro diagnostics that will support appropriate antimicrobial use. TATFAR partners benefit from knowledge sharing on how others are addressing these challenges and collaboration can lead to harmonized approaches to authorization of novel therapies.

ACTION: EMA and FDA discussed particular challenges for bringing to market novel veterinary therapies presented as alternatives to antimicrobials. As part of the Veterinary Implementers Informal Group, discussion at teleconferences in June and November 2017 explored possibilities for cooperation within the context of TATFAR on promoting the development and regulatory approval of alternatives to antibiotics in veterinary medicine. USDA chaired a session on alternatives to antibiotics at the TATFAR face-to-face meeting in 2018. Participants exchanged information on the approach to authorizing alternatives in their region and the initiatives already underway to promote access to market for such products while ensuring appropriate levels of quality, safety, and efficacy.

Key Area 3

BOTTOM LINE: This working group consisted of TATFAR veterinary regulatory agencies who discussed various challenges related authorization of novel veterinary therapies presented as alternatives. The group aimed to develop similar approaches and requirements to accelerate these new therapies to market. TATFAR partners also used this forum to bring the public sector bodies (academia, research organizations, and regulators) working on alternatives to antimicrobials to glean from one another on ways to rapidly promote access to market for these alternatives. **This work will continue in TATFAR's new work plan for the next five-year implementation period.**

Conclusion

TATFAR brings together technical experts from Canada, the EU, Norway, and the U.S. to collaborate and share best practices to strengthen both global and domestic efforts to combat AMR. This report summarizes the progress and outcomes of TATFAR partners from 2016-2020 to strengthen communication and cooperation in the area of AMR. Although TATFAR partners made notable progress together over the past five years, more effort is needed to accelerate the fight against AMR. TATFAR partners have agreed to continue collaborations for the next five-year implementation period, which allows partners to evaluate current work, redevelop priorities, engage new partners, and consider new areas for collaboration. New areas of collaboration will extend into the environment, modeling strategies, communications, and policy. TATFAR partners have committed to continue this critical collaboration to combat AMR.

TATFAR

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