BRIDGING THE GAP: IMPROVING ANTIMICROBIAL ACCESS AND USE ACROSS ONE HEALTH

A REPORT WITH RECOMMENDATIONS

June 2021

PACCARB

Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

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EXECUTIVE SUMMARY

The COVID-19 pandemic has transitioned more of people's interactions with their medical and veterinary prescribers to virtual platforms to facilitate healthcare access. Among animal and human health domains, antimicrobial prescribing practices are known to differ by treatment setting, medical specialty, and by animal species. As such, there has been expressed concern by the antimicrobial resistance (AMR) community that the increased use of virtual care may exacerbate inappropriate antimicrobial prescribing and possibly result in greater antimicrobial access inequities.[1] Furthermore, prescribing practices and antimicrobial use in animal healthcare versus agricultural settings, including crops, vary and are impacted by numerous known and unknown factors. Therefore, it is critical that antimicrobial stewardship practices be further researched, promoted, and in some instances, standardized across the One Health spectrum whenever such a framework is utilized to combat AMR. This process should include evidence-based guidance from the appropriate subject matter expertise to ensure equitable antimicrobial access and use in all settings to mitigate the ongoing issue of AMR.

Historically, the impact of antimicrobial use on animal and environmental health has largely been understood within the context of its direct effect on human health, and environmental and crop experts have often been excluded from these discussions. To truly embody a One Health approach to combating AMR, there must be an understanding that human, animal, plant (particularly crop), and environmental health are inextricably linked to elucidate how the health of one sector can affect the health of the others.[2] For example, to understand the impact on human health, the effect of antimicrobial use in all domains must be considered and prioritized based on risk, particularly in terms of antifungal azole use. To this end, it is particularly important that the critical expertise within these domains be consistently included in all One Health and AMR-related dialogues. By identifying the research gaps needed to portray the correlation among all domains, further steps can be taken to ensure that the appropriate interventions for improved stewardship practices are better applied to human, animal, crop, and environmental health.

In October 2020, the Assistant Secretary for Health, Admiral Brett P. Giroir, M.D., on behalf of the Secretary of Health and Human Services, Alex M. Azar, II, tasked the Presidential Advisory Council on Combating Antibiotic Resistant Bacteria (PACCARB) to provide input into how health disparities and inequities relate to how antimicrobials are accessed and used and to provide guidance on how stewardship can be encouraged in virtual modalities of care across the One Health spectrum. To accomplish this task, the PACCARB established a working group (WG) composed of council members and federal official subject matter experts (SMEs) in human, animal, and environmental domains. The WG collected and discussed information from experts in health disparities and virtual modalities of care to identify their effects on AMR.

The findings presented in this WG report align with many of the priorities set out by the current administration as it relates to both COVID-19 and future public health threats. As described in the Executive Order written on January 21, 2021 and the letter to Dr. Eric S. Lander, the President's

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[1] The AMR community referenced includes opinions expressed by the panelists and presenters invited to working group sessions, public meetings, and the sentiments made by PACCARB members.

[2] Robinson, T.P., Bu, D.P., Carrique-Mas, J., Fèvre, E.M., Gilbert, M., Grace, D., Hay, S.I., Jiwakanon, J., Kakkar, M., Kariuki, S., Laxminarayan, R., Lubroth, J., Magnusson, U., Thi Ngoc, P., Van Boeckel, T.P., & Woolhouse, M.E.J. (2016). Antibiotic resistance is the quintessential One Health issue. *Trans R Soc Trop Med Hyg, 110*, 377-380.

Science Advisor and the Director of the Office of Science and Technology Policy, the current administration has prioritized creating a stronger public health infrastructure to help prevent, detect, and effectively respond to future biological threats, including AMR.[3,4] This includes a focus on One Health and interagency coordination, as noted in the National Security Memorandum from January 21, 2021 and the National COVID-19 Strategy Plan.[5,6] Since its creation, the PACCARB too has prioritized a strong public health infrastructure with an emphasis on One Health, which can be seen throughout their recommendations.[7,8,9,10] These four documents also place a high priority on health equity, which is reflected in this report and is considered a vital component of PACCARB activities as it relates to the overall dimensions of One Health.

Another area of priority identified by the PACCARB has been the need to institute critical incentives for the development of much needed, new antimicrobials to combat AMR, which can be accomplished by the passage of two pieces of legislation: the Pioneering Antimicrobial Subscriptions To End Upsurging Resistance Act of 2020 (PASTEUR Act) and the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms Act of 2019 (DISARM Act).[11,12] The PACCARB supports passage of both complementary Acts as crucial components to continue the fight against the silent tsunami of AMR that remains a priority during the current COVID-19 pandemic.

It is imperative to note that the scope of this report has been narrowed to focus on antimicrobial stewardship within the virtual care landscape, which includes both telehealth services connected to established outpatient practices and direct-to-consumer (DTC) telemedicine.[13] However, the PACCARB

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[3] President J R Biden. (2021, January 21). Executive Order on Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats. Retrieved from https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/executive-order-ensuring-a-data-driven-response-to-covid-19-and-future-high-consequence-public-health-threats/

[4] President J.R Biden. (2021, January 20). A Letter to Dr. Eric S. Lander, the President's Science Advisor and nominee as Director of the Office of Science and Technology Policy. Retrieved from https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/20/a-letter-to-dr-eric-s-lander-the-presidents-science-advisor-and-nominee-as-director-of-the-office-of-science-and-technology-policy/.

[5] President J. R. Biden. (2021, January 21). National Security Memorandum on United States Global Leadership to Strengthen the International COVID-19 Response and to Advance Global Health Security and Biological Preparedness. Retrieved from https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/21/national-security-directive-united-states-global-leadership-to-strengthen-the-international-covid-19-response-and-to-advance-global-health-security-and-biological-preparedness/.

[6] President JR Biden. (2021, January 21). National Strategy for the COVID- 19 Response and Pandemic Preparedness. Retrieved from https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf

[7] Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2019). *Priorities for the National Action Plan on Combating Antibiotic-Resistant Bacteria: 2020-2025 A report with recommendations*. Retrieved from https://www.hhs.gov/ash/advisory-committees/paccarb/reports-and-recommendations/index.html.

[8] Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2018). *Key strategies to enhance infection prevention and antibiotic stewardship report with recommendations for human and animal health*. Retrieved from https://www.hhs.gov/ash/advisory-committees/paccarb/reports-and-recommendations/index.html.

[9] Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2017). *Recommendations for incentivizing the development of vaccines, diagnostics, and therapeutics to combat antibiotic-resistance*. Retrieved from https://www.hhs.gov/ash/advisory-committees/paccarb/reports-and-recommendations/index.html.

[10] Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2016). *Initial assessments of the National Action Plan for Combating Antibiotic-Resistant Bacteria*. Retrieved from https://www.hhs.gov/ash/advisory-committees/paccarb/reports-and-recommendations/index.html.

[11] The Pioneering Antimicrobial Subscriptions To End Upsurging Resistance Act of 2020, H.R.8920, 116th Cong. (2020). Retrieved from https://www.congress.gov/bill/116th-congress/house-bill/8920.

[12] Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms Act of 2019, H.R.4100, 116th Cong. (2019). Retrieved from https://www.congress.gov/bill/116th-congress/senate-bill/1712.

[13] In this report, telehealth is defined as two-way, real time interactive communication between the patient and the physician or practitioner at a distant site, such as a patient's established medical home, that includes audio and/or video equipment. Direct-to-Consumer (DTC) telemedicine is defined as a subset of virtual care where the visit is initiated by the client/patient with no intermediary clinician, with the visit taking place completely online.

strongly recommends a continued commitment to improving antimicrobial prescribing practices within all outpatient and urgent care settings. Prior to the COVID-19 pandemic, patients diagnosed with an acute respiratory infection at an urgent care center were approximately three times more likely to be prescribed antibiotics than patients at a retail clinic or physician office, and nearly twice as likely as patients in an emergency department.[14] Another study found that nurse practitioners, physician assistants, and family practitioners were three times more likely than pediatricians to prescribe antibiotics to children with acute respiratory infections.[15] Despite a sustained focus on these systems of care delivery, uptake of antimicrobial stewardship practices has been slow, the progress has been stagnant, and educational interventions for the prescribers in these settings are still needed. In recognition of the continued need to improve antimicrobial prescribing within the outpatient setting, the PACCARB reiterates previously published recommendations that remain relevant and actionable in addressing this persistent gap. Specifically, see the PACCARB reports on Key Strategies to Enhance Infection Prevention and Antibiotic Stewardship and Priorities for the National Action Plan on Combating Antibiotic-Resistant Bacteria: 2020 – 2025.[16,17]

Recommendations

The WG identified seven high-level recommendations affecting differences in access, prescribing, and use of antimicrobials across the One Health spectrum. The first four recommendations aim to identify gaps in research areas surrounding antimicrobial use across the One Health spectrum, including disparities in antimicrobial prescribing and stewardship in crop settings. The three remaining recommendations propose ways to increase antimicrobial stewardship in virtual care settings for both human and animal domains by adapting best practices already in place within traditional care settings, while also recognizing the ways in which progress on the proposed research gaps can further these stewardship efforts. In addition, many of the recommendations put forth in this report should be applied to outpatient and urgent care settings, where appropriate, as progress must continue in these domains to combat AMR. All seven high-level recommendations are presented in Figure 1. Detailed explanations of each recommendation, including sub-recommendations, are presented in the body of the report.

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[14]Palms, D. L., Hicks, L. A., Bartoces, M., Hersh, A. L., Zetts, R., Hyun, D. Y., & Fleming-Dutra, K. E. (2018). Comparison of antibiotic prescribing in retail clinics, urgent care centers, emergency departments, and traditional ambulatory care settings in the United States. *JAMA Internal Medicine, 178*(9), 1267-1269.

[15] Agiro, A., Gautam, S., Wall, E., Hackell, J., Helm, M., Barron, J., Zaoutis, T., Fleming-Dutra, K. E., Hicks, L. A., & Rosenberg, A. (2018). Variation in outpatient antibiotic dispensing for respiratory infections in children by clinician specialty and treatment setting. *The Pediatric Infectious Disease Journal, 37*(12), 1248-1254.

[16] Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2018). Key Strategies to Enhance Infection Prevention and Antibiotic Stewardship: A report with recommendations for human and animal health. Retrieved from: https://www.hhs.gov/ash/advisory-committees/paccarb/reports-and-recommendations/index.html.

[17] Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2019). *Priorities for the National Action Plan on Combating Antibiotic-Resistant Bacteria: 2020-2025 A report with recommendations*. Retrieved from https://www.hhs.gov/ash/advisory-committees/paccarb/reports-and-recommendations/index.html.

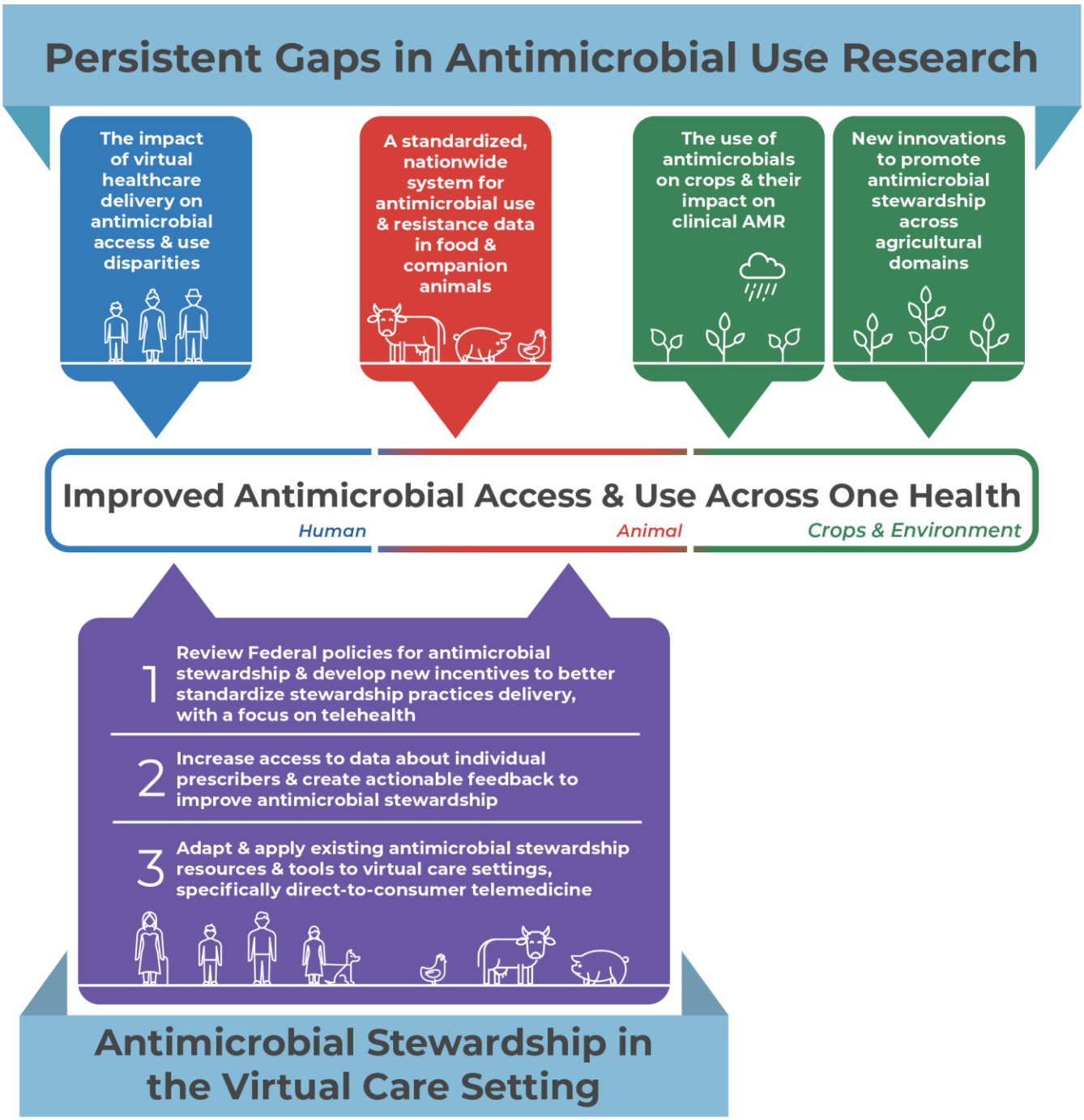

Figure 1: Summary recommendations from the PACCARB for improving antimicrobial access and use across One Health. Please see the report for the full recommendations.

INTRODUCTION

The rise of antimicrobial-resistant bacteria is a serious threat to public health. The Centers for Disease Control and Prevention (CDC) estimate that at least 2.8 million people contract an antibiotic-resistant infection annually, resulting in more than 35,000 deaths.[18] However, the nation has made significant progress towards addressing the issue of antimicrobial resistance (AMR) since the inception of the Presidential Advisory Council on Combating Antibiotic Resistant Bacteria (PACCARB) in 2014. Notably, the Federal Government renewed its commitment to combatting AMR and recognized the key role of the PACCARB in the fight, by codifying it into legislation through the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019. The PACCARB's federal partners on the Combating Antibiotic-Resistant Bacteria (CARB) Task Force also released an update to the National Action Plan for Combating Antibiotic-Resistant Bacteria (National Action Plan) in October 2020.[19] The 2020-2025 National Action Plan builds upon the first plan released in 2015 by accelerating the federal response to AMR through an expanded focus on infection prevention and control and antimicrobial use. The recommendations below address these factors and are commensurate with the existing objectives and goals included in the National Action Plan.[20]

At the agency level, the CDC updated their Core Elements of Hospital Antibiotic Stewardship Programs in 2019.[21] This document outlines the key components associated with successful antimicrobial stewardship programs, with updates based on new research over the past five years. According to the 2019 update to the CDC's Antibiotic Resistance Threats in the United States Report, dedicated antimicrobial stewardship and infection control efforts have reduced deaths from antibiotic-resistant infections in the U.S. by 18 percent overall.[22] The expansion of the Centers for Medicaid & Medicare Services (CMS) requirements for their Conditions of Participation is another example of an AMR prevention effort. This expansion now requires critical access hospitals and long-term care facilities to implement robust infection prevention and antibiotic stewardship programs to receive reimbursement from CMS.[23] In 2019, the Agency for Healthcare Research and Quality (AHRQ) released the Toolkit to Improve Antibiotic Use in Acute Care Hospitals, developed in the AHRQ Safety Program for Improving Antibiotic Use.[24] This program demonstrated a significant reduction in days of antibiotic therapy and *Clostridioides difficile* infections in a one-year cohort of 400 hospitals.

On the animal health side, the Food and Drug Administration (FDA) updated their Veterinary Feed Directive (VFD) in 2015. Most importantly, the VFD requires medically important antimicrobials used

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[18] Centers for Disease Control and Prevention. (2020, July 20). *Antibiotic/antimicrobial resistance.* Retrieved from https://www.cdc.gov/drugresistance/index.html.
[19] Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2019). *Priorities for the National Action Plan on Combating Antibiotic-Resistant Bacteria: 2020-2025 A report with recommendations*. Retrieved from https://www.hhs.gov/ash/advisory-committees/paccarb/reports-and-recommendations/index.html.
[20] Ibid.
[21] Centers for Disease Control and Prevention. (2019). The Core Elements of Hospital Antibiotic Stewardship Programs: 2019. Retrieved from https://www.cdc.gov/antibiotic-use/healthcare/pdfs/hospital-core-elements-H.pdf.
[22] Centers for Disease Control and Prevention. (2019, December). *Antibiotic resistance threats in the United States, 2019*. Retrieved from https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf.
[23] Washington State Hospital Association. (2019, October 4). *CMS finalizes the conditions of participation rule: Antibiotic stewardship programs required for hospitals*. Retrieved from https://www.wsha.org/articles/cms-finalizes-the-conditions-of-participation-rule-antibiotic-stewardship-programs-required-for-hospitals/.
[24] Agency for Healthcare Research and Quality. (2021). *Antibiotic stewardship toolkits*. Retrieved from https://www.ahrq.gov/antibiotic-use/index.html.

in the feed or water of food-producing animals to be under the oversight of a veterinarian licensed in the state where the animals reside.[25] Finally, in 2021, the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), a key partner of the PACCARB, released a Stewardship & Access Plan (SAP) Development Guide.[26] The SAP Development Guide offers grant recipients direction on meeting the SAP requirements, providing companies a new benchmark for incorporating antimicrobial stewardship principles into their activities and drug development. Despite the great gains made in efforts to enforce antimicrobial stewardship practices to combat AMR nationwide, many efforts may have been disrupted by the COVID-19 pandemic.

In recognition of these disruptions and the continued work that must be done to prevent AMR, the Assistant Secretary for Health, Admiral Brett P. Giroir, M.D., on behalf of the Secretary of Health and Human Services, Alex M. Azar, II, tasked the PACCARB to provide input on two important issues related to AMR – the first on addressing AMR through inter-professional education,[27] and the second on exploring variations in antimicrobial access and use in human, animal, and environmental health (see Appendix I for the Task Letter). This report reflects the PACCARB recommendations for the second task: understanding the access and appropriate use of antimicrobials across a One Health spectrum.

WG Approach and Process

To accomplish its assigned task, the PACCARB established a working group (WG) composed of council members and federal official subject matter experts (SMEs) in human, animal, crop, and environmental domains. This report presents the Antibiotic Access and Use (AA&U) WG's findings on the critical issues related to differences in perceptions and usage of antimicrobials among various populations, how virtual care delivery affects those differences, and the factors that may be affecting antimicrobial use among various animal care and crop agriculture settings. Each section of the report describes the issues and gaps identified regarding best practices and implementation, and the recommendations developed to address them.

The AA&U WG held a series of virtual meetings hosting federal and non-federal SMEs to explore the issues related to the WG's mission statement and goals. As part of their investigation, they also received input at the PACCARB's 16th Public Meeting, held on February 10-11, 2021. This meeting included two days of panel presentations with a range of participants from the One Health domains, with the first day focused on antimicrobial access and use. A draft of this report with recommendations was presented to the full PACCARB at the June 29-30, 2021 public meeting for further evaluation and discussion; the final version was approved unanimously for transmittal to the Secretary for Health.

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[25]U.S. Food and Drug Administration. (2021, February 11). *Veterinary feed directive final rule and next steps* [FDA fact sheet]. Retrieved from https://www.fda.gov/animal-veterinary/development-approval-process/fact-sheet-veterinary-feed-directive-final-rule-and-next-steps.

[26] Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator. (2021). *Stewardship & access plan (SAP) development guide*. Retrieved from https://carb-x.org/about/stewardship-and-access/.

[27] Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2021). *Advancing interprofessional education and practice to combat antimicrobial resistance*. Retrieved from https://www.hhs.gov/ash/advisory-committees/paccarb/reports-and-recommendations/index.html.

ORGANIZATION OF THE REPORT

The recommendations put forth in this report are divided into two topics of interest: persistent gaps in antimicrobial-use research and stewardship, and prescribing practices in the virtual health landscape. Each section contains a brief introduction to the key topics discussed followed by overarching recommendations which address these topics. Each recommendation includes one or more sub-recommendations with suggestions for federal agencies and other stakeholder organizations that could lead or support the effort.

In this report, a concerted effort was made to integrate recommendations across both human and animal health as the two domains share many of the same challenges and concerns, particularly when it comes to virtual care delivery. The first section, The Unknown: Persistent Gaps in Antimicrobial-Use Research, is split into subsections focusing on key research gaps in human health, crop health, and animal health domains. It is important to acknowledge that while crop and environmental experts were included in the development of these recommendations, the PACCARB recognizes a need for more input and expertise from plant health (especially crop health), and other authorities about environmental antimicrobial use and exposure to ensure their concerns and ideas are fully integrated into every One Health framework utilized by the AMR community.

In the second section, Antimicrobial Stewardship in the Virtual Care Setting, the recommendations apply both to telehealth services connected to established outpatient practices and direct-to-consumer (DTC) telemedicine. However, the mechanisms used to influence antimicrobial stewardship differ between the two settings, which is reflected in the recommendations. As the impact of antimicrobial use has largely been considered within the context of its effect on human health, the recommendations are meant to speak to both animal health and human health stakeholders to better address AMR's impact on animal health and welfare. Furthermore, the recommendations continue to promote stewardship within the human health sector by building upon best practices and tailoring them to meet the new demands, challenges, and opportunities within a virtual care setting. In recognition of the changing healthcare landscape, a table of key definitions has been included below to facilitate a common vernacular and ease of understanding across all recommendations.

KEY DEFINTIONS

Care Delivery: *an organization of people, institutions, and resources to deliver services to meet the health needs of a target population.*[28]

Outpatient Care: *medical consultations, procedures, or tests that can be done in a medical center without an overnight stay.*[29,30]

Virtual Care: *any interaction between patients and/or members of their circle of care, occurring remotely, using any forms of communication or information technologies, with the aim of facilitating or maximizing the quality and effectiveness of patient care. This includes the exchange of all types of information, from laboratory data to advice and ideas.*[31]

Telehealth: *two-way, real time interactive communication between the patient and the physician or practitioner at a distant site, such as a patient's established medical home, that includes audio and/or video equipment.*[32]

Direct-to-Consumer (DTC) Telemedicine: *a subset of virtual care where the visit is initiated by the client/patient with no intermediary clinician, with the visit taking place completely online.*[33]

Retail Clinics: *health clinics located mostly in drugstores, supermarkets, "big box" stores, and other large retail chain settings, and staffed by a nurse practitioner or a physician assistant.*[34]

Urgent Care Center: *a walk-in clinic focused on the delivery of medical or veterinary care outside of a traditional hospital-based or freestanding emergency department.*[35]

Veterinarian-Client-Patient-Relationship (VCPR): *the basis for interaction between veterinarians, their clients, and their patients, established in-person. Under the VCPR the veterinarian has assumed the responsibility for making clinical judgments regarding the health of the patient and the client has agreed to follow the veterinarian's instructions*.[36,37]

The recommendations in this report also reflect upon the current administration's priorities, as laid out in several executive orders and federal reports. As the nation moves toward a post-pandemic world, it is key to focus on building a stronger public health infrastructure that can tackle future challenges, including AMR. This includes a greater emphasis on One Health, understanding how humans, animals, plants (particularly crops), and the environment interact with one another and influence the rise or decline of AMR. It is the hope of the PACCARB that the recommendations put forth in this report, in concert with their previous reports, will continue to support these efforts and provide new insights and ideas as we face an evolving environment during the COVID-19 pandemic.

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[28] Piña, I. L., Cohen, P. D., Larson, D. B., Marion, L. N., Sills, M. R., Solberg, L. I., & Zerzan, J. (2015). A framework for describing health care delivery organizations and systems. *American Journal of Public Health, 105*(4), 670-679.
[29] Cigna. (2020, May 27). *Outpatient services.* Retrieved from https://www.cigna.com/individuals-families/health-wellness/hw/medical-topics/outpatient-services-ty7319.
[30] Definitive Healthcare. (2021). *Outpatient care*. Retrieved from https://www.definitivehc.com/resources/glossary/outpatient-care
[31] Jamieson, T., Wallace, R., Armstrong, K., Agarwal, P., Griffin, B., Wong, I., & Bhatia, S. (2015). *Virtual care: A framework for a patient-centric system*. Women's College Hospital Institute for Health Systems Solutions and Virtual Care (WIHV). Retrieved from https://www.womenscollegehospital.ca/assets/pdf/wihv/WIHV_VirtualHealthSymposium.pdf
[32] Medicaid.gov (n.d.) *Telemedicine.* Retrieved from https://www.medicaid.gov/medicaid/benefits/telemedicine/index.html
[33] Bollmeier, S. G., Stevenson, E., Finnegan, P., & Griggs, S. K. (2020). Direct to consumer telemedicine: Is healthcare from home best? *Missouri Medicine, 117*(4), 303-309.
[34] Association of State and Territorial Health Officials. (2011, March). *Defining the safety net: Retail clinics* [Fact sheet]. Retrieved from http://www.astho.org/programs/access/primary-care/safety-net-fact-sheets/materials/retail-clinics-fact-sheet/.
[35] American College of Emergency Physicians. (2016, October). *Urgent care centers.* Retrieved from https://www.acep.org/patient-care/policy-statements/urgent-care-centers/.
[36] American Veterinary Medical Association. (n.d.). *The veterinarian-client-patient relationship (VCPR).* Retrieved from https://www.avma.org/resources-tools/pet-owners/petcare/veterinarian-client-patient-relationship-vcpr.
[37] Extralabel Drug Use in Animals Definitions, 21 C.F.R. § 530.3 (2020).

THE UNKNOWN: PERSISTENT GAPS IN ANTIMICROBIAL USE RESEARCH

Prior to the COVID-19 pandemic, there were known research gaps across the One Health spectrum, including disparities in antimicrobial prescribing and use among certain populations, an absence of crop and environmental expert engagement on the issue of AMR, and a lack of knowledge of the true impact of AMR on food and companion animals. As our health systems evolve to meet the growing challenges of a post-pandemic world, it is imperative that these gaps in understanding are prioritized and addressed to ensure a more equitable system of care for humans, animals, and crops.

Recommendations: Examining Disparities in Human Antimicrobial Use

Data are lacking on antimicrobial access and equity within all care settings, and there is not a complete understanding of the issues and challenges being introduced by different models of outpatient care, especially virtual care, on existing disparities within the healthcare system.[38] Video visits and electronic communication with healthcare prescribers require enabled devices, internet access, and digital literacy, three factors that may not be readily available to all. Studies demonstrating the inequities of virtual ambulatory care during the COVID-19 pandemic suggest that vulnerable populations such as Black, Latinx, Asian, non-native English speakers, low-income individuals, and older adults may face technology barriers, as these groups were shown to use video in virtual visits less frequently than other populations.[39] In addition, geographic disparities exist in outpatient antimicrobial use, with the Southern region showing prescribing rates more than two times higher than the Northeast and West regions.[40] These geographic differences are likely tied to many factors, including socioeconomics, the number of clinics and prescribers per capita, overall patient health, and differences in prescribing norms and patient demand.[41,42,43] More data are needed to fully understand these disparities in antimicrobial prescribing, how these disparities affect vulnerable populations, and the impact of virtual healthcare delivery systems on antimicrobial access and use.

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[38] Goyal, M. K., Johnson, T. J., Chamberlain, J. M., Casper, T. C., Simmons, T., Alessandrini, E. A., Bajaj, L., Grundmeier, R. W., Gerber, J. S., Lorch, S. A., & Alpern, E. R. (2017). Racial and ethnic differences in antibiotic use for viral illness in emergency departments. *Pediatrics*, *140*(4).

[39] Eberly, L. A., Kallan, M. J., Julien, H. M., Haynes, N., Khatana, S. A. M., Nathan, A. S., Snider, C., Chokshi, N. P., Eneanya, N. D., Takvorian, S. U., Anastos-Wallen, R., Chaiyachati, K., Ambrose, M., O'Quinn, R., Seigerman, M., Goldberg, L. R., Leri, D., Choi, K., Gitelman, Y., Kolansky, D. M., Cappola, T. P., Ferrari, V. A., Hanson, C. W., Deleener, M. E., & Adusumalli, S. (2020). Patient characteristics associated with telemedicine access for primary and specialty ambulatory care during the COVID-19 pandemic. *JAMA Network Open*, *3*(12), e2031640.

[40] Hicks, L. A., Bartoces, M. G., Roberts, R. M., Suda, K. J., Hunkler, R. J., Taylor, T. H., Jr., & Schrag, S. J. (2015). US outpatient antibiotic prescribing variation according to geography, patient population, and provider specialty in 2011. *Clinical Infectious Diseases*, *60*(9), 1308-1316.

[41] Blaser, M. J., Melby, M. K., Lock, M., & Nichter, M. (2021). Accounting for variation in and overuse of antibiotics among humans. *BioEssays*, *43*(2), e2000163.

[42] Klein, E. Y., Makowsky, M., Orlando, M., Hatna, E., Braykov, N. P., & Laxminarayan, R. (2015). Influence of provider and urgent care density across different socioeconomic strata on outpatient antibiotic prescribing in the USA. *Journal of Antimicrobial Chemotherapy*, *70*(5), 1580-1587.

[43] Kissler, S. M., Klevens, R. M., Barnett, M. L., & Grad, Y. H. (2021). Childhood respiratory outpatient visits correlate with socioeconomic status and drive geographic patterns in antibiotic prescribing. *The Journal of Infectious Diseases*.

Recommendation 1: Increase funding of research investigating the impact of virtual healthcare delivery on existing and new health disparities related to antimicrobial use.

Recommendation 1.1: Incentivize or develop a pilot program to collect nationwide administrative and clinical baseline data on human antimicrobial prescribing within virtual care delivery settings. Data should then be collected on a continuing basis and build upon existing research efforts to better understand how antimicrobial prescribing may vary by modality, region, race/ethnicity, socioeconomic status, and other characteristics often associated with health disparities. Collected data should include information on how virtual care platforms gather and store patient information.

Suggested federal agency to support effort: CDC

Recommendation 1.2: While existing research focuses on the drivers that influence antimicrobial prescribing behavior, including the role of socioeconomic factors, geography, and racial/ethnic differences (e.g., AHRQ's Healthcare Cost and Utilization Project),[44] additional qualitative and quantitative research is needed on:

- How these drivers impact prescribing in virtual care.
- How these drivers play out at the individual patient and provider level and what can be done to change prescribing behaviors.
- Whether disparities in human antimicrobial prescribing minimize unnecessary prescriptions, or if these disparities reflect missed diagnoses of infections which warrant treatment.
- The differences in prescribing practices among human medical specialties and the underlying drivers of these differences.
- The impact of current prescribing guidelines on medical practice, including the effect on prescribing behaviors, and on economic costs.

Suggested federal agencies to support effort: AHRQ, CDC, National Institutes of Health (NIH)

[44] Agency for Healthcare Research and Quality. (2021, March). *Healthcare Cost and Utilization Project (HCUP)*. Retrieved from https://www.ahrq.gov/data/hcup/index.html.

Recommendations: Emphasizing the Inclusion of Crop Health in All AMR Discussions

Pesticides in the U.S. 101

Pesticide law defines a "pesticide" (with certain minor exceptions) as: any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest; any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant; or any nitrogen stabilizer.[45] Antimicrobials are therefore defined as pesticides when used to treat bacterial and fungal diseases in crops.

The Environmental Protection Agency (EPA) regulates pesticides under the statutory authority of the Federal Insecticide, Fungicide, and Rodenticide Act. The registration requirements for antimicrobial pesticides differ somewhat from those of other pesticides. Like all pesticides, antimicrobial pesticides must be assessed for their effects on human and ecological health, environmental fate and effects, and benefits. In addition, EPA requires special tests to ensure efficacy and information about the potential for resistance from the proposed use of any antimicrobial pesticide.[46] Since antimicrobial use in crops may impact human and animal health, the EPA frequently consults with its federal partners (primarily the CDC, FDA, and the U.S. Department of Agriculture) during the registration process for antimicrobial pesticides.[47]

Despite the widespread acknowledgement of the benefits of a One Health perspective, experts in plant (especially crop) and environmental spheres have often not been included in discussions related to AMR. It is important to include experts from these sectors as many of the antimicrobial use practices and AMR mitigation techniques used differ among sectors, particularly in comparison to human disease management. Furthermore, as azoles are currently the most common antimicrobial class used to control fungal infections in both animals and crops, concerns about potential links to human illness have been raised. Potential risks to human health need to be assessed, as azole-resistant *Aspergillus fumigatus* infections in the clinical setting can result in mortality rates upwards of 50 percent to 80 percent.[48,49,50]

Antimicrobial use practices in crops are necessarily different from those in human and animal health, with a wide array of challenges that make disease prevention and treatment a formidable challenge. For example, while humans and animals are often given antimicrobials after an infection has been diagnosed, antimicrobials are generally only applied to crops preventatively, at pre-bloom or at bloom.[51]

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[45] United States Environmental Protection Agency. (2018, April 2). *What is a pesticide?* Retrieved from https://www.epa.gov/minimum-risk-pesticides/what-pesticide.
[46] United States Environmental Protection Agency. (2020, September 2). *Antimicrobial pesticides.* Retrieved from https://www.epa.gov/pesticides/antimicrobial-pesticides
[47] Jennings, S. [Environmental Protection Agency]. (2021, February 11). *Regulating Antibiotic Use on Crops* [PowerPoint]. Virtual PACCARB Public Meeting.
[48] As presented by Dr. Melanie Ivey at the 16th PACCARB Public Meeting on February 10, 2021. Dr. Ivy also comment that "…over the past four years tandem repeat duplications associated with environmental isolates have been reported in clinical isolates and azole resistance in clinical isolates of *A. fumigatus* has been directly linked to the intensive use of azole fungicides in agriculture."
[49] Brown, G. D., Denning, D. W., Gow, N. A., Levitz, S. M., Netea, M. G., & White, T. C. (2012). Hidden killers: Human fungal infections. *Science Translational Medicine, 4*(165), 165rv113.
[50] Chowdhary, A., Kathuria, S., Xu, J., & Meis, J. F. (2013). Emergence of azole-resistant aspergillus fumigatus strains due to agricultural azole use creates an increasing threat to human health. *PLOS Pathogens, 9*(10), e1003633. 3
[51] Whetsone, H.M. (2014, June 6). *The pressure is on: New ruling will end antibiotic use in organic fruit production*. Michigan State University. Retrieved from https://www.canr.msu.edu/news/the_pressure_is_on.

Additionally, growers use different metrics for antimicrobial treatment than those used in human and animal medicine, such as timed application of pesticides during environmental conditions that may be conducive to the development of disease.[52] Therefore, it is imperative that these expert perspectives be included in the decision-making process to help elucidate how responsible use of antimicrobials in crops can be better understood.

Traditionally, in crops, the impact of antimicrobial use on AMR has largely been considered within the context of its effect on human health, and many questions remain about the impact of these pesticides on human clinical outcomes. However, the use of antibiotics and antifungals in crops is often vital to a successful harvest, as there are currently limited alternatives to address disease and healthy crops are crucial to the global food supply.[53,54] Regardless, it is important to note that the overuse and misuse of antimicrobials is unacceptable in any situation. Utilization of alternatives, as appropriate, a focus on good agricultural practices, and promoting stewardship programs in the context of integrated pest management approaches must be supported whenever indicated.

Therefore, additional research, including risk-based assessments, should be funded to explore the impact of antimicrobial runoff on the environment, how the use of antibiotic and antifungal pesticides in crops impacts human health, and its potential impact on promoting AMR. Additionally, alternative technologies to address crop diseases, particularly resistant ones, should be further assessed, and those that are scientifically determined to be efficacious and affordable should be developed.

Recommendation 2: Increase understanding among human and animal health professionals about the use of antimicrobials on crops and within other agricultural domains and their impact on clinical AMR.[55]

Recommendation 2.1: Add more crop and other agricultural experts to AMR-focused organizations and create standard definitions for key terminology to use across crop, environmental, human, and animal health, to foster consistent understanding across disciplines.

Suggested federal agencies to support effort: CDC, EPA, FDA, NIH, U.S. Department of Agriculture (USDA)

Recommendation 2.2: Fund critical research to address data gaps for risk assessments to better understand how antibiotic and antifungal pesticides interact with the environment, such as how they degrade or persist, the types of byproducts produced during degradation, the role of runoff, and how their use impacts the One Health domains. Risk/benefit analyses of alternative methods that could promote long-term benefits should also be conducted.

Suggested federal agencies to support effort: CDC, EPA, FDA, USDA

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[52] Pan, M., & Chu, L. M. (2017). Fate of antibiotics in soil and their uptake by edible crops. *Science of the Total Environment, 599-600*, 500-512.
[53] Stockwell, V. O., & Duffy, B. (2012). Use of antibiotics in plant agriculture. *Revue Scientifique et Technique (International Office of Epizootics), 31*(1), 199-210.
[54] Brauer, V. S., Rezende, C. P., Pessoni, A. M., De Paula, R. G., Rangappa, K. S., Nayaka, S. C., Gupta, V. K., & Almeida, F. (2019). Antifungal agents in agriculture: Friends and foes of public health. *Biomolecules, 9*(10).
[55] This recommendation aligns with Recommendations 3 and 5 from the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria's *Advancing interprofessional education and practice to combat antimicrobial resistance* (2021). Retrieved from https://www.hhs.gov/ash/advisory-committees/paccarb/reports-and-recommendations/index.html.

Recommendation 3: Increase funding to support research and development of new innovations to promote antimicrobial stewardship efforts in several agricultural crop domains.

Recommendation 3.1: Incentivize the uptake of new and existing innovations to better predict infection, increase precision of the application of antibiotic and antifungal pesticides, and map AMR within the environment. Examples of current innovations that should be further promoted and researched include:

- CRISPR technology used in tandem with Geographic Information System (GIS) mapping to sequence and track the spread of specific resistant strains in the environment.
- Incorporating disease resistance in fruit trees and tree nuts with the goal of eventually generating crops that will not need antimicrobials.
- Risk reduction techniques such as the targeted application of pesticides, case-by-case resistance mitigation, and the use of extension and disease forecasting tools.
- Promoting the implementation of an integrated pest management approach through Cooperative Extension in the responsible use of antibiotic and antifungal pesticides.

Suggested federal agencies to support effort: EPA, FDA, USDA
Proposed organizations for collaboration: Professional societies

Recommendation 3.2: Support the development of new antimicrobial pesticides to address increasing bacterial and fungal pressure in crops, including emerging diseases and those newly introduced into the U.S. For bacterial infections, there are currently only three active antibiotic ingredients available for use and a limited number of scenarios for which they are approved on crops. This lack of antibiotic diversity may promote AMR and limit grower capacity to treat novel resistant microbes. The availability of additional treatment options may allow for the less frequent use of the same pesticides, potentially limiting their impact on promoting increased AMR in the environment.[56]

Suggested federal agencies to support effort: CDC, EPA, FDA, NIH, USDA

Recommendations: Standardizing and Incentivizing the Reporting of Antimicrobial Use and AMR Data in Animals

A One Health approach to AMR necessitates understanding the impact of veterinary antimicrobial use on animal health as a primary outcome.[57] As in crops, the use of antimicrobials in companion and food animals is often viewed through the lens of its impact on human medicine. This means that animal health practitioners have regularly taken on the burden of strict antimicrobial guidelines that benefit human health outcomes, possibly at the expense of animal welfare. Therefore, more information is needed on the clinical impact of AMR on companion and food animals to create more appropriate

[56] van Duijn, P. J., Verbrugghe, W., Jorens, P. G., Spöhr, F., Schedler, D., Deja, M., Rothbart, A., Annane, D., Lawrence, C., Nguyen Van, J. C., Misset, B., Jereb, M., Seme, K., Šifrer, F., Tomiç, V., Estevez, F., Carneiro, J., Harbarth, S., Eijkemans, M. J. C., & Bonten, M. (2018). The effects of antibiotic cycling and mixing on antibiotic resistance in intensive care units: A cluster-randomised crossover trial. *The Lancet Infectious Diseases, 18*(4), 401-409.
[57] Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2021). *Advancing interprofessional education and practice to combat antimicrobial resistance*. Retrieved from https://www.hhs.gov/ash/advisory-committees/paccarb/reports-and-recommendations/index.html.

guidelines and better-informed decisions regarding antimicrobial use and AMR across a One Health spectrum.[58] To accomplish this, the Federal Government must build trust with food animal producers and their veterinarians, and support and strengthen existing local relationships with agricultural communities to foster the sharing of personal and proprietary data while providing adequate privacy protections.

Recommendation 4: Support and encourage a standardized nationwide system for the collection of data on antimicrobial use and AMR in food and companion animals.

Recommendation 4.1: Fund a national system with incentives for participation (see Recommendation 4.2), governed by state and local commodity groups, for the voluntary reporting of antimicrobial use and resistance data by veterinarians, veterinary hospitals, and food animal producers.[59]

The data collected should include standardized and specific metrics aimed at providing sufficient information for appropriate analysis and feedback to encourage the adoption of antimicrobial reporting procedures. Feedback should include information on any economic benefit that could result from reduced disease incidence and, therefore, lower antimicrobial use requirements. To ensure data collection is sustainable and unbiased, standard definitions of appropriate data metrics and diagnostic codes must be established for each practice segment by universities and professional associations, such as the American Veterinary Medical Association. Record systems should be designed to support this data capture in a uniform manner with minimal additional effort to prescribers, such as by ensuring interoperability and a consistent data structure.[60]

This funding should also establish a central data repository, possibly at the university or industry association level, that would be responsible for generating reports and sharing comparative data on antimicrobial use and its related drivers in a confidential format. Collected data could also lead to discussions and investigations of outcomes of the most highly used therapies. The involvement of private industry and veterinary diagnostic laboratories will be pivotal to the success of any national antimicrobial use data collection effort.

This nationwide system and data collection effort will enable the creation of a vital infrastructure that will ultimately support antimicrobial stewardship efforts that are considerate of the existing motivations and impediments for veterinarians and food animal producers.

Suggested federal agencies to support effort: FDA, USDA
Proposed organizations for collaboration: veterinary professional associations, state and local departments of agriculture, university agriculture departments, colleges of veterinary medicine, producer organizations

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[58] American Veterinary Medical Association. (2020). *Antimicrobial resistant pathogens affecting animal health in the United States [Committee on Antimicrobials Report]*. Retrieved from https://www.avma.org/resources-tools/one-health/antimicrobial-use-and-antimicrobial-resistance/antimicrobial-resistant-pathogens-affecting-animal-health.

[59] This recommendation aligns with a goal of the National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025 (see Goal 2; Priority 1); Federal Task Force on Combating Antibiotic-Resistant Bacteria. (2020, October). *National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025*. Retrieved from https://aspe.hhs.gov/pdf-report/carb-plan-2020-2025

[60] This recommendation aligns with Goal 1, Priority 2 from the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2019). Priorities for the National Action Plan on Combating Antibiotic-Resistant Bacteria: 2020-2025 A report with recommendations. Retrieved from https://www.hhs.gov/ash/advisory-committees/paccarb/reports-and-recommendations/index.html.

Recommendation 4.2: Conduct a risk/benefit analysis that is focused by commodity group and producer segment to understand the competitive value gained by data standardization and collection. Based on this information, the governing state and local commodity groups of the supported nationwide data system should develop incentives to encourage participation in the proposed data collection effort. For example, confidential benchmarking reports that provide information on how producers compare to other producers, or when possible given proprietary concerns, sharing generalized interventions and strategies that successfully reduce the need for antimicrobial use.

Suggested federal agencies to support effort: FDA, USDA
Proposed organizations for collaboration: veterinary professional associations, state and local departments of agriculture, university agriculture departments, colleges of veterinary medicine, producer organizations

ANTIMICROBIAL STEWARDSHIP IN THE VIRTUAL CARE SETTING

The research gaps addressed in the previous section are meant to support and continue the activities and recommendations in this section, as key components in the fight against AMR. As indicated, stewardship and prescribing practices have been fundamentally impacted by the COVID-19 pandemic in ways that are still not fully understood. Prior to the COVID-19 pandemic, antimicrobial prescribing practices differed by treatment setting and prescriber type within human and animal health spheres. In veterinary medicine, this is further stratified when comparing prescribing practices between companion and food animals. In companion animals, antimicrobials are most often used to treat infections in individual animals, similar to human healthcare, while in food animals, antimicrobials are more commonly used to prevent, control, or treat infections among animals in affected groups (e.g., herds, flocks).[61] The variabilities in prescribing practices in both human and animal care remain an area for targeted improvement, particularly during their transition to virtual care settings. In this section, virtual care includes both telehealth services connected to established outpatient practices and DTC telemedicine. As previously noted, the mechanisms used to influence antimicrobial stewardship and the drivers behind prescribing variations may differ between the two settings.

While the reasons behind these variabilities within the context of virtual care are not fully understood, potential driving factors in both human and veterinary medicine could include market competition, risk avoidance, customer satisfaction, and a breakdown of the prescriber-client/patient relationship; these are known behavioral influencers within traditional care settings and may, therefore, play a role in the virtual care setting.[62,63] Virtual practitioners may be more uncertain of a patient's diagnosis or about a patient's ability to receive follow-up care due to the lack of in-person contact. This uncertainty could lead to overprescribing as a means to mitigate the risk of a missed diagnosis. For example, a 2020 study found that 86 percent of telephone prescriptions from a direct-to-consumer care provider were for broad-spectrum agents compared to 56 percent of prescriptions made during in-person physician visits.[64,65,66] In food animal medicine, prescribing decisions may also be tied to production economics, in which the cost of administering antimicrobials is evaluated relative to potential production losses and welfare impacts due to disease and the costs of alternative approaches.

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[61] Tang, K. L., Caffrey, N. P., Nóbrega, D. B., Cork, S. C., Ronksley, P. E., Barkema, H. W., Polachek, A. J., Ganshorn, H., Sharma, N., Kellner, J. D., & Ghali, W. A. (2017). Restricting the use of antibiotics in food-producing animals and its associations with antibiotic resistance in food-producing animals and human beings: A systematic review and meta-analysis. *The Lancet Planetary Health, 1*(8), e316-e327.

[62] Martinez, K. A., Rood, M., Jhangiani, N., Kou, L., Boissy, A., & Rothberg, M. B. (2018). Association between antibiotic prescribing for respiratory tract infections and patient satisfaction in direct-to-consumer telemedicine. *JAMA Internal Medicine, 178*(11), 1558-1560.

[63] Servia-Dopazo, M., Taracido-Trunk, M., & Figueiras, A. (2021). Non-clinical factors determining the prescription of antibiotics by veterinarians: A systematic review. *Antibiotics (Basel), 10*(2).

[64] Zetts, R. M., Stoesz, A., Smith, B. A., & Hyun, D. Y. (2018). Outpatient antibiotic use and the need for increased antibiotic stewardship efforts. *Pediatrics, 141*(6).

[65] Uscher-Pines, L., & Mehrotra, A. (2014). Analysis of Teladoc use seems to indicate expanded access to care for patients without prior connection to a provider. *Health Affairs (Millwood), 33*(2), 258-264.

[66] Blaser, M. J., Melby, M. K., Lock, M., & Nichter, M. (2021). Accounting for variation in and overuse of antibiotics among humans. *BioEssays, 43*(2).

To accommodate the social restrictions imposed by the pandemic, the United States Government has relaxed some requirements to further facilitate prescriber/client communication virtually. For food production animals, various elements of telehealth have long been used informally to counteract veterinarian shortages in rural areas; however, new allowances have temporarily been made at the federal level for establishing a Veterinarian-Client-Patient-Relationship (VCPR) remotely to facilitate additional access.[67,68] In addition, changes have been made in payment policies for human telehealth services with Medicaid, temporarily expanding reimbursement for the types of services allowed and specialties covered.[69] These two changes have transitioned many prescribers' interactions with clients across human and animal settings from in-person to virtual spaces. Based on these vast changes, and the continued pressure to prescribe, it is critical that antimicrobial stewardship practices be promoted in virtual care settings to advance progress already made within traditional human and animal care settings, as these may serve as the status quo even in a post-pandemic world.

Recommendations

Recommendation 5: Collate, review, and evaluate current federal policies, regulations, and requirements for antimicrobial stewardship and develop new incentives to better standardize stewardship practices across different modalities of care delivery, with a focus on telehealth.

Due to the COVID-19 pandemic, telehealth service requirements and reimbursement policies have been relaxed to accommodate virtual modalities of care delivery, but these policies are temporary and inconsistent from state to state.[70,71] As innovation and technology advance to facilitate interaction in medical and veterinary spaces, it is important to develop policies that would standardize stewardship across all disciplines and platforms for uniformity and consistency. Standardizing these requirements and regulations may also help to improve prescribing variations by holding all prescribers accountable to the same goals.

Recommendation 5.1: As a mechanism to encourage standardization and widespread adoption of antimicrobial stewardship, additional funding should be allocated to the CDC to expand support for state and local health departments to implement programs and hire trained staff (e.g., infectious disease and infection control specialists) to track and provide feedback antimicrobial use data to outpatient prescribers as part of their applications for grant funding via the Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases, Antibiotic Resistance Solutions Initiative Programs, and other funding mechanisms.

Additional funds should be allocated to specifically investigate concerns of misaligned incentives, antimicrobial advertising, and priming through the virtual care experience. Particular attention should be

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[67] U.S. Department of Agriculture. *Veterinary services shortage situations map.* Retrieved from https://nifa.usda.gov/vmlrp-map.
[68] U.S. Food and Drug Administration. (2020, March 24). *Coronavirus (COVID-19) update: FDA helps facilitate veterinary telemedicine during pandemic* [FDA news release]. Retrieved from https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-helps-facilitate-veterinary-telemedicine-during-pandemic.
[69] Center for Connected Health Policy. (2020, September 15). *Telehealth coverage policies in the time of COVID-19.* Retrieved from https://www.cchpca.org/resources/covid-19-telehealth-coverage-policies.
[70] Ibid.
[71] U.S. Food and Drug Administration. (2020, March 24). *Coronavirus (COVID-19) update: FDA helps facilitate veterinary telemedicine during pandemic* [FDA news release]. Retrieved from https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-helps-facilitate-veterinary-telemedicine-during-pandemic.

given to platforms that can diagnose, prescribe, and dispense antimicrobials to address any potential conflicts of interest.

Suggested federal agency to support effort: CDC
Proposed organization(s) for collaboration: medical professional societies, large health systems, other professional associations, payers

Recommendation 5.2: CMS should develop an external, non-federal task force that will review the effectiveness of current incentives and develop a recommended list of new ones to encourage additional data reporting for all outpatient settings, including telehealth. This task force should review:

- Current regulations, standards, and guidelines that could be adapted to specifically address concerns regarding the standard of care given through telehealth platforms.
- Regulations and billing incentives that can be adapted to encourage the tracking and sharing of prescription data (use, location, demographics). This prescription data could also be incorporated into the feedback mechanism suggested in Recommendation 6.1.
- Expansion of antimicrobial use quality measures and training into the Medicare Merit-based Incentive Payment System program and the Core Measures Set and requiring the mandatory reporting of current and new antimicrobial use measures.

Suggested federal agency to support effort: CMS

Recommendation 5.3: The FDA should review and provide additional guidance on the VCPR requirements to better incorporate a virtual care framework and ensure standardization across different modalities of care. For example, defining whether a VCPR can be established via telemedicine and follow-up requirements for procedures that must be done in-person. These requirements should also encourage harmonization of telemedicine within existing medical databases and other technical platforms used in veterinary medicine. Adoption of more advanced, easy-to-use web-based platforms into veterinary care settings through regulatory and billing incentives should also be encouraged.

Suggested federal agency to support effort: FDA

Recommendation 6: Increase access to data about individual prescribers and create actionable feedback to improve antimicrobial stewardship.

Clinician and veterinarian performance, as it relates to antimicrobial stewardship, is still inconsistently evaluated across prescriber types in various human and animal healthcare delivery settings, including virtual health. Feedback, such as prescribing frequency compared to peers, allows for quality improvement and the reinforcement of best practices.[72,73,74]

[72] Milani, R. V., Wilt, J. K., Entwisle, J., Hand, J., Cazabon, P., & Bohan, J. G. (2019). Reducing inappropriate outpatient antibiotic prescribing: Normative comparison using unblinded provider reports. *BMJ Open Quality*, *8*(1).
[73] Linder, J. A., Meeker, D., Fox, C. R., Friedberg, M. W., Persell, S. D., Goldstein, N. J., & Doctor, J. N. (2017). Effects of behavioral interventions on inappropriate antibiotic prescribing in primary care 12 months after stopping interventions. *JAMA*, *318*(14), 1391-1392.
[74] Gerber, J. S., Prasad, P. A., Fiks, A. G., Localio, A. R., Bell, L. M., Keren, R., & Zaoutis, T. E. (2014). Durability of benefits of an outpatient antimicrobial stewardship intervention after discontinuation of audit and feedback. *JAMA*, *312*(23), 2569-2570.

Recommendation 6.1: Payers, large health systems, state and local health departments, and other stakeholders that have infrastructure and data to provide prescriber-level data should provide consistent and ongoing feedback of physician performance for antimicrobial prescribing in the virtual care setting as compared to the average for their prescriber type. Additional funding should also be provided to expand existing efforts at the federal level to provide prescriber-level data to states that could feed into this proposed system.

The focus of this feedback should be on improving stewardship by giving prescribers more actionable information, paired with tools that support more appropriate prescribing, such as:

- Non-antimicrobial treatments that can be offered to patients and clients
- Training on how to communicate with patients, family members, and clients about antimicrobials and their potential long-term health risks
- Clinical decision support software within electronic health records to support point-of-care decision making

As part of a proposed standardized and automated feedback system, payers, health systems, and state and local health departments should build upon the federal efforts from Recommendation 5 and work to align the consistent antimicrobial stewardship requirements needed for physician feedback based on existing best practices. Lastly, market-based incentives should be built into this system to increase buy-in and ensure consistent adherence among prescribers for this proposed feedback process.

Suggested federal agencies to support effort: CDC, CMS
Proposed organization(s) for collaboration: Medical professional societies, large health systems, other professional associations, payers, state health departments

Recommendation 6.2: For veterinary practitioners, implementation of a feedback system could similarly help to reduce variability in antimicrobial prescribing and promote more standardized stewardship practices for both companion and food animals. However, the first barrier for implementing a feedback system in this domain is obtaining meaningful, appropriate, and actionable data, including diagnostic codes and antimicrobial use information. This can only be accomplished within an economically viable and sustainable infrastructure, which cannot be ignored or delayed. This issue is directly addressed above in Recommendation 3 of this report.

Suggested federal agencies to support effort: FDA, USDA

Recommendation 6.3: Allocate grants and other resources to support research validating the proposed feedback process and to assess its effect on adherence to antimicrobial stewardship practices among human and animal prescribers. This should include research on how best to present feedback information, whether at the provider or practice level, and the frequency with which information should be presented. Ongoing systematic reviews, including spot checks of data quality and integrity, are a key component of feedback mechanisms and should be used to ensure that the data gathered is accurate and comparable across prescriber types and modalities of care.

Suggested federal agencies to support effort: CDC, CMS, FDA, USDA

Proposed organization(s) for collaboration: veterinary professional associations, other professional associations, colleges of veterinary medicine, medical professional societies, large health systems, other professional associations, payers, state health departments

Recommendation 7: Adapt and apply existing antimicrobial stewardship resources and tools to virtual care settings, specifically direct-to-consumer telemedicine.

Great gains have been made in antimicrobial stewardship in traditional care settings and retail clinics, however, new opportunities and challenges have arisen within the DTC telemedicine landscape. Existing antimicrobial stewardship interventions should therefore be adapted and expanded for DTC telemedicine practitioners across both human and animal domains. A key component of these recommendations is engagement with the companies providing DTC telemedicine and virtual care services, along with individual prescribers.

Recommendation 7.1: Characterize antimicrobial use in DTC telemedicine, including by gathering appropriate and actionable data on the type of prescribers and their prescribing practices within DTC telemedicine delivery to provide more meaningful information for those practitioners. This includes engaging with prominent DTC companies to research the impact of the user experience and market-based incentives on the pressure to prescribe. In addition, public-private partnerships can be leveraged to highlight new and ongoing stewardship efforts within DTC telemedicine and to improve marketing on appropriate antimicrobial use within these systems of care.

Suggested federal agencies to support effort: CDC, FDA, NIH, USDA

Recommendation 7.2: Adapt and tailor existing educational and communication tools to better support antimicrobial stewardship and appropriate prescribing behaviors among the wide variety of prescribers within the DTC telemedicine landscape.

Professional societies, who are mandated to educate and advocate for their members, should work closely with accrediting organizations, prescribers, payers, and other partners to develop prescriber-specific continuing education (CE) courses on antimicrobial prescribing practices that take into consideration the unique challenges presented in a DTC telemedicine model.[75] This can include trainings designed for "medical virtualists" – those specializing in providing virtual care - and guidance on combating the pressure to prescribe. Training accountability requirements should also be developed for this new "specialty."

[75] This recommendation aligns with a goal of the National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025 (see Goal 1; Objective 2); Federal Task Force on Combating Antibiotic-Resistant Bacteria. (2020, October). *National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025.* Retrieved from https://aspe.hhs.gov/pdf-report/carb-plan-2020-2025.

In addition, all educational efforts and CE courses should include clear outcome measures to further inform new and more effective guidelines, as well as best practices (e.g., improved treatment decisions, better patient engagement, stewardship targets, etc.).[76] The primary driver of educational and guideline content should be an understanding of needs and challenges at the prescriber level. [77]

Suggested federal agencies to support effort: CDC, FDA
Proposed organizations for collaboration: medical professional societies, other professional associations

Recommendation 7.3: Fund the creation of tools that help streamline the development of protocols and antimicrobial use decision-making processes for veterinary practitioners that could be used in various care settings, including virtual care.

There is a need for more user-friendly and timely evidence-based protocols for antimicrobial selection and use in veterinary medicine, including real-time updates to clinical guidance for common conditions in both food and companion animals, such as:

- Developing and maintaining point-of-care, species-specific support tools to inform antimicrobial prescribing decisions. This should include funding at the university level to develop and perform continuous surveillance of scientific literature and regulatory data to create an actionable, relevant menu of antimicrobial treatment protocol options and clinical guidance for veterinarians. These tools, which will need to be species-specific, should be integrated into new and existing virtual health platforms to assist veterinarians at the point-of-care.
- Providing funding to support veterinarians in training on-farm personnel on how to apply the newly developed protocols in the field as this is typically not reimbursed.

Suggested federal agencies to support effort: FDA, USDA
Proposed organizations for collaboration: veterinary professional associations

[76] Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2021). *Advancing interprofessional education and practice to combat antimicrobial resistance*. Retrieved from https://www.hhs.gov/ash/advisory-committees/paccarb/reports-and-recommendations/index.html.
[77] This recommendation aligns with Recommendations 3, 5, and 6 from the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria's *Advancing interprofessional education and practice to combat antimicrobial resistance* (2021). Retrieved from https://www.hhs.gov/ash/advisory-committees/paccarb/reports-and-recommendations/index.html.

CONCLUSIONS

This report has presented recommendations on behalf of the PACCARB, developed by the Antibiotic Access & Use Working Group in response to the Task Letter (Annex I). The mission of this WG was to better understand the challenges of access to and the appropriate use of antimicrobials across the One Health spectrum. The recommendations put forth focus on two main areas: major research gaps that need to be addressed to further antimicrobial stewardship efforts nationwide and to promote an equitable system of care for humans, animals, and the environment; and the effect of virtual care on access to antimicrobials, antimicrobial use, and AMR. Since PACCARB's inception in 2014, many accomplishments have been made in combating AMR. The recommendations in this report aim to keep this momentum while considering the latest issues and concerns, particularly within the context of the COVID-19 pandemic, and as a result, the rise of virtual care delivery and novel issues in health equity.

The COVID-19 pandemic has increased the use of alternate modalities of human and animal care delivery, such as virtual care. Within virtual care, the AMR community has expressed concerns that existing and newly emerging inequities in access to care, including those concerning antimicrobial prescribing, may be further exacerbated. On the human side, this includes racial/ethnic and geographical disparities in antimicrobial access and use, while on the animal side this includes prescribing differences between companion and food animal medicine. Furthermore, an increase in the use of virtual care could exacerbate known variations in antimicrobial prescribing practices as providers may be less certain of diagnoses without an in-person clinical examination. The recommendations put forth in this report aim to address these concerns as well as investigate many other emerging challenges to antimicrobial stewardship efforts presented within this new care environment.

Within animal health, one issue worth noting is that producers, farmers, and the agricultural community may not fully appreciate the value and importance of antimicrobial stewardship and the potential threat of AMR on their businesses. To promote the recommendations presented in this report and further the fight against AMR within animal health, it is vital that trust in the federal process of decision making is improved among producers, veterinarians, and other animal health professionals. The recommendations in this report aim to build upon past successes and foster future relationships between the local farming communities and federal policy makers to strengthen the foundation between these two groups, upon which further antimicrobial stewardship efforts can be built.

In the environmental domains, discussions about AMR must strive further include crop and environmental experts to ensure proper implementation of a One Health framework. The use of antibiotic and antifungal pesticides has been identified by experts as an area of concern due to their possible impacts on human and animal health, highlighting the need to include environmental experts in these discussions. Therefore, it is imperative that all future AMR discussions consider how the use of antibiotic and antifungal pesticides may directly affect AMR in the environment as its own issue. The recommendations presented in this report aim to address this shortcoming and increase antimicrobial stewardship efforts in the various agricultural domains.

Ultimately it is the PACCARB's hope that the recommendations presented here, along with the noted action steps and identified agencies and stakeholders, provide a framework for a successful path forward to combat AMR.

ANNEX I – TASK LETTER FROM THE SECRETARY

October 16, 2020

Martin J. Blaser, MD
Henry Rutgers Chair of the Human Microbiome Professor of Medicine and Microbiology – RWJMS
Director, Center for Advanced Biotechnology and Medicine Rutgers University
679 Hoes Lane West, Room 106A Piscataway, NJ 08854

Lonnie J. King, DVM, MS, MPA, DACVPM
Professor and Dean Emeritus Ohio State University
LJK Veterinary Advisors, LLC 1023 Holt's Ferry
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Dear Drs. Blaser and King:

On behalf of the Secretary of Health and Human Services, Alex M. Azar, II, I would like to thank you for your continued leadership of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The Advisory Council continues to inform and lead discussion of the most pressing issues facing us as we battle the threat of antibiotic resistance. The COVID-19 pandemic poses new challenges in this fight, and I thank you and the Advisory Council for gathering and presenting the most current information available on the intersection of antibiotic resistance and COVID-19 at your recent public meeting in September, 2020. The presentations and discussions helped raise awareness of the issues that have emerged and may still arise as we address two concurrent public health crises. As we continue our fight against antibiotic resistance during this pandemic, your expertise is once again needed to provide input on two important issues.

Task#1 – Inter-professional Education on Antimicrobial Resistance (AMR)

Education and training of our healthcare professionals is an essential component of our fight against antibiotic resistance. We must continually evaluate the effectiveness of our professional education system and incorporate modern curricula and training regimens for human health, veterinary and agricultural settings. Inter-professional education is one such strategy that deserves our attention; it occurs when two or more professions (for example, students, residents and health workers) learn with, about and from each other to enable effective collaboration and improve health outcomes.[1] Inter-professional education has the potential to lead to better implementation of infection prevention and control strategies, as well as more appropriate use of and reduced need for antibiotics, including both antibacterial and antifungal agents, in healthcare and agricultural settings.

I would like the Advisory Council to explore the status of professional education opportunities and availability, and the extent to which they incorporate inter-professional components in human, veterinary and agricultural disciplines as they relate to antibiotic stewardship and infection prevention and control.

> **Deliverable Requested by Sept 2021:** A report on the status of inter-professional education for antibiotic stewardship and infection prevention with an assessment of the extent to which a common curriculum across professions exists, and identification of opportunities for improvement. Your investigation should explore curricula for frontline healthcare workers, animal care providers and agricultural extension agents, as well as administrators and others who make purchasing decisions so that all aspects of healthcare, animal care and agricultural provisions are considered holistically. As part of your findings, please provide observations and recommendations as to whether and how U.S. educational institutions, federal agencies, training programs and specialty boards can strengthen national and state board certification and continuing education of medical and veterinary professionals.

Task #2 – Variations in Access, Prescribing and Use of Antibiotics

Appropriate use of antibiotics across One Health depends on several factors. For human health, the availability and quality of healthcare, level of knowledge among patients, and many socioeconomic factors play a key role. We know that health disparities exist among different populations in many aspects of healthcare, including those demonstrated in the current COVID- 19 outbreak. As our healthcare system evolves, new and alternate models for providing patient treatment are arising to facilitate access to healthcare, such as telehealth, walk-in retail clinics and urgent care centers. As these models become more ubiquitous, it is important to assess both the opportunities and challenges they may provide for improving antibiotic stewardship, and how they may affect currently observed disparities in antibiotic prescribing.

Additionally, given the broad variety of species and animal care settings in the veterinary sector, there are numerous factors that can impact how antibiotics and antifungals are used. Differences in how antibiotics are prescribed among veterinary settings and the different agricultural commodities may vary and should be further explored.

Therefore, I would like the Advisory Council to provide an overview of the existing variations in the prescribing, access, and use of antibiotics and antifungals (as appropriate) across the One Health spectrum (medical, veterinary, and agricultural settings), and identify any knowledge gaps that are observed. Please explore how these factors may be impacted by the availability of health resources, education level and access to appropriate information and training.

> **Deliverable Requested by Sept 2021:** A two-part report addressing human and animal health, respectively. One part should address health disparities and inequities related to how antibiotics are accessed and used. This report should include an investigation into differences in perception and usage of antibiotics among minority groups and other historically disadvantaged populations. Your findings should explore and incorporate the role that new modalities of outpatient care, such as medical telehealth options and retail walk-in clinics, may play in alleviating or deepening disparities or inequities, and the opportunities and challenges they may present in advancing antibiotic stewardship efforts.

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[1] World Health Organization. (2010). Framework for action on interprofessional education and collaborative practice. World Health Organization. https://apps.who.int/iris/handle/10665/70185

For the other part of your report, please consider the current differences among various animal care and plant agriculture settings, and the factors that may be affecting antibiotic use. It should include a discussion of how to encourage stewardship and mitigate any variances in antibiotic prescribing and use in these diverse settings and modalities.

Please form two new working groups to address these two tasks, and host two public meetings to gain stakeholder feedback to inform your reports. Thank you again for your continued dedication and I look forward to learning about your proceedings in the coming months.

Sincerely yours,

Brett P. Giroir, M.D.
ADM, USPHS
Assistant Secretary for Health

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ANNEX IV – ACRONYMS AND ABBREVIATIONS

AA&U	Antibiotic access and use
AHRQ	Agency for Healthcare Research and Quality
AMR	Antimicrobial resistance
CARB	Combating Antibiotic-Resistant Bacteria
CARB-X	Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator
CDC	Centers for Disease Control and Prevention
CE	Continuing education
CMS	Centers for Medicare and Medicaid Services
COVID-19	Coronavirus disease of 2019
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
DISARM	Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms Act of 2019
DTC	Direct-to-consumer
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
GIS	Geographic Information System
NIH	National Institutes of Health
PACCARB	Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria
PASTEUR	Pioneering Antimicrobial Subscriptions To End Upsurging Resistance Act of 2020
SAP	Stewardship & Access Plan
SME	Subject matter expert
USDA	United States Department of Agriculture
VCPR	Veterinarian-client-patient relationship
VFD	Veterinary Feed Directives
WG	Working group