

PACCARB

Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

Meeting Summary

**Twelfth Public Meeting of the
Presidential Advisory Council on
Combating Antibiotic-Resistant Bacteria
April 8, 2019
Teleconference: Noon to 1:15 p.m.**

Meeting Proceedings

Welcome

Martin Blaser, M.D., Chair, and Lonnie J. King, D.V.M., M.S., M.P.A., ACVPM, Vice Chair

Dr. Blaser called the meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) to order at 12:02 p.m. and welcomed the participants. The goal of this meeting was to discuss a recommendation proposed by the Council's Immediate Action Subcommittee, because an important incentive for helping sustain antibiotic stewardship programs in hospitals might not be realized if no action is taken by June of this year (see Appendix A). Sara E. Cosgrove, M.D., M.S., spearheaded the Subcommittee's effort to develop a letter and recommendation to bring the issue to the attention of the Secretary of the Department of Health and Human Services (HHS).

Overview, Rules of Engagement, and Roll Call

Jomana F. Musmar, Ph.D., M.S., Designated Federal Officer, National Vaccine Program Office, HHS

Dr. Musmar described the Council's charter and gave an overview of the agenda. She explained the rules governing the Council under the Federal Advisory Committee Act and conflict-of-interest guidelines and called the roll. (See Appendix B for the list of participants.)

Immediate Action Subcommittee Report: Overview, Discussion, and Vote

Sara E. Cosgrove, M.D., M.S., PACCARB Voting Member

Overview

The Subcommittee called for the immediate finalization of a proposed rule by the Centers for Medicare & Medicaid Services (CMS) establishing a condition of participation (CoP) that would require antibiotic stewardship programs in hospitals. The proposed rule will not go into effect unless it is finalized by CMS by the June 2019 deadline. The Subcommittee agreed that the CoP will ensure the kind of organized, actionable, mandatory approach to antibiotic stewardship that must occur to reduce antibiotic overuse and the associated emergence and spread of resistant organisms. Ultimately, antibiotic stewardship programs will optimize the safety of all patients receiving antibiotics and other patients in the hospital setting, said Dr. Cosgrove.

Dr. Cosgrove described the benefits of having a CMS CoP as twofold:

1. A CoP creates a clear expectation from the U.S. Government (USG) that antibiotic stewardship programs are desired and valuable to combat antibiotic resistance and demonstrates USG leadership nationally and internationally.
2. A CoP ensures that programs are required, regardless of the type of hospital or the type of body that accredits it.

Dr. Cosgrove observed that The Joint Commission currently requires antibiotic stewardship programs in acute care hospitals, which is commendable, but those requirements can be withdrawn at any time. A CoP would require enduring antibiotic stewardship programs across all acute care hospitals, including critical access hospitals.

Discussion

Dr. Blaser said antibiotic stewardship has never been more important, and the CoP is a vital tool the USG can use to combat antibiotic-resistant bacteria.

Aileen M. Marty, M.D., FACP, suggested Dr. Cosgrove clarify the cost-effectiveness of antibiotic stewardship programs. Dr. Cosgrove said that, at the simplest level, it is generally acknowledged that antibiotics are overused. Using them more rationally should decrease overuse and associated expenditures. Furthermore, patients face many consequences as a result of overuse, such as side effects that include *Clostridioides difficile* infection, organ dysfunction (e.g., kidney and liver), and skin reactions. Extended courses of antibiotics require extended hospitalization. Tightening up use at the individual patient level to ensure that only needed antibiotics are prescribed and that they are prescribed in the appropriate way will reduce side effects and help patients get out of the hospital sooner, which also would reduce the cost of medical care, Dr. Cosgrove concluded.

Vote

Council members voted unanimously in favor of the proposed recommendation that CMS finalize the CoP requiring hospitals to have antibiotic stewardship programs.

Dr. Musmar will send the recommendation to the Secretary. If the Secretary chooses to accept the recommendation, it will be included in a decision memorandum that is sent to the President.

Dr. Blaser thanked the Council members for participating. He noted that antibiotic stewardship is an important issue around which PACCARB can make a difference.

Acknowledgement of Submitted Public Comments

Jomana F. Musmar, M.S., Ph.D., Designated Federal Officer, National Vaccine Program Office, HHS

Dr. Musmar noted that written comments were received from the following:

- Bruce Quinn, M.D., Ph.D., Bruce Quinn & Associates
- Bruce Quinn, M.D., Ph.D., Thermo Fisher Scientific
- Anonymous member of the public “Jean”
- Susan Van Meter, Brad Spring, and Phi D. Vu, AdvaMedDx

Final Comments and Adjournment

Martin Blaser, M.D., Chair, and Lonnie J. King, D.V.M., M.S., M.P.A., ACVPM, Vice Chair

Dr. Blaser announced the next public PACCARB meeting will take place in McLean, VA, July 10–11, 2019. At that meeting, the Council will vote on a draft report, prepared at the request of the Secretary, on priorities for the next generation of the *National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020–2025*.

The National Vaccine Program Office (NVPO) is accepting nominations for PACCARB voting members and liaisons. More information is available on the [PACCARB website](#).

Dr. King thanked the members for enacting the important recommendation for antibiotic stewardship programs. Dr. Musmar thanked the staff for organizing the meeting. The meeting adjourned at 12:20 p.m.

Appendix A: Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria Recommendation to the Secretary



Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

DRAFT – DO NOT DISTRIBUTE

XX, XX, 2019

The Honorable Alex M. Azar II
Secretary, Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Azar,

On behalf of the Presidential Advisory Council on Combating Antibiotic Resistant Bacteria (PACCARB), we bring to your attention a critical issue that, if not immediately addressed, would undermine the collective U.S. government effort in combating antibiotic resistance (AR). There is a critical need for mandatory, not voluntary, implementation of Antibiotic Stewardship Programs (ASPs) in our nation's hospitals to curtail the over-prescription of antibiotics--a lead cause in the rise in antibiotic-resistance. **We urge the immediate finalization of the proposed Centers for Medicare and Medicaid Services (CMS) conditions of participation (CoP) rule, in advance of the upcoming June 2019 deadline. This rule requires the adoption of Antibiotic Stewardship Programs in hospitals, especially critical access hospitals (CAHs), to help reduce the daunting overtreatment of patients with unnecessary broad-spectrum antibiotics, and thereby, improve the care of patients receiving the appropriate antibiotics.**

Antibiotic resistance continues to be a major public health threat that leads to lives lost and impose a disproportionate burden on our entire health system with costs up to \$2.2 billion annually; without important action, we anticipate that number to rise.¹ Antibiotic Stewardship Programs have been demonstrated to be effective in reducing the inappropriate prescribing practices that contribute to AR, to patient harm, and to increased healthcare costs.²

As previously recommended in the PACCARB's 2018 Report, *Key Strategies to Enhance Infection Prevention and Antibiotic Stewardship*, the members urged the finalization of the current proposed CMS CoP rule and recommended the incorporation of the CDC's Core Elements of Hospital ASPs as guidelines to support implementation.^{3,4} The PACCARB believes that requiring hospitals and CAHs to develop and implement ASPs will have a direct, positive, and immediate impact on antibiotic prescribing practices, thus aiding in the fight against AR and preserving of our nation's health in the face of this increasing public health threat.

Sincerely,

Martin J. Blaser, M.D.
Chair

Lonnie J. King, D.V.M., M.S.
Vice Chair

¹ Thorpe, Kenneth, J., Peter, and Kerion Johnston. "Antibiotic-Resistant Infection Treatment Costs have Doubled since 2002, Now Exceeding \$2 Billion Annually." *Health Affairs*. 37(4): 2018. <https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1153>

² Strecher, Edwards, et al. Impact of Implementing Antibiotic Stewardship Programs in 15 Small Hospitals: a Cluster-Randomized Intervention. *Clinical Infectious Diseases* 67(4): 2018. <https://doi.org/10.1093/cid/civ155>

³ PACCARB. "Key Strategies to Enhance Infection Prevention and Antibiotic Stewardship: Report with Recommendations for Human and Animal Health." HHS OASH. Report (2018). <https://www.hhs.gov/sites/default/files/final-ips-report-10-03-2018.pdf>

⁴ Centers for Disease Control and Prevention. "Implementation of Antibiotic Stewardship Core Elements at Small and Critical Access Hospitals." <https://www.cdc.gov/antibiotic-use/healthcare/implementation/core-elements.html>

Appendix B: Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) Members

April 9, 2019

PACCARB Voting Members Present

Martin J. Blaser, M.D., Chair
Lonnie J. King, D.V.M., M.S., M.P.A., ACVPM, Vice Chair
Michael D. Apley, D.V.M., Ph.D., DACVCP
Helen W. Boucher, M.D., FIDSA, FACP
Angela Caliendo, M.D., Ph.D., FIDSA
Sara E. Cosgrove, M.D., M.S.
Paula J. Fedorka Cray, Ph.D.
Christine Ginocchio, Ph.D., MT
Locke Karriker, D.V.M., M.S.
Kent E. Kester, M.D., FACP, FIDSA, FASTMH
Aileen M. Marty, M.D., FACP
Robert A. Weinstein, M.D.
David White, M.S., Ph.D.

Organizational Liaisons Present

American Nurses Association

Elaine Larson, Ph.D., RN

Association for Public Health Laboratories

Denise M. Toney, Ph.D.

National Turkey Federation

Alice L. Johnson, D.V.M.

North American Meat Institute

Tiffany Lee, D.V.M., Ph.D., M.S.

Pew Charitable Trusts

Kathryn L. Talkington

Ex Officios Present

U.S. Department of Health and Human Services

Michael Craig, M.P.P. (for Rima Khabbaz, M.D.), National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention

Dennis M. Dixon, Ph.D., National Institute of Allergy and Infectious Diseases, National Institutes of Health

Lynn Filpi, Ph.D. (for Lawrence Kerr, Ph.D.), Office of Pandemics and Emerging Threats, Office of Global Affairs

Chris Houchens, Ph.D., Biomedical Advanced Research and Development Authority

Daniel W. Sigelman, J.D., Senior Advisor, Office of Public Health Strategy and Analysis, Office of the Commissioner, Food and Drug Administration

U. S. Department of Agriculture

Emilio Esteban, D.V.M., M.B.A., M.P.V.M., Ph.D., Food Safety and Inspection Service
Chelsey Shively (for Sarah Tomlinson, D.V.M.), Animal and Plant Health Inspection Service

U.S. Department of Defense

Paige Waterman, M.D., FACP, FIDSA, COL, Walter Reed Army Institute of Research,

Designated Federal Officer

Jomana F. Musmar, M.S., Ph.D., Advisory Council Committee Manager, Office of the Assistant Secretary for Health, Department of Health and Human Services

Advisory Council Staff

Ayah O. Wali, M.P.H., Committee Management Officer, Office of the Assistant Secretary for Health, Department of Health and Human Services

Sarah McClelland, M.P.H., ORISE Fellow, Office of the Assistant Secretary for Health, Department of Health and Human Services

Mark Kazmierczak, Ph.D., Consultant, Gryphon Scientific

Glossary of Abbreviations

| | |
|---------|--|
| CMS | Centers for Medicare and Medicaid Services |
| CoP | condition of participation |
| HHS | U.S. Department of Health and Human Services |
| PACCARB | Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria |
| USG | United States Government |