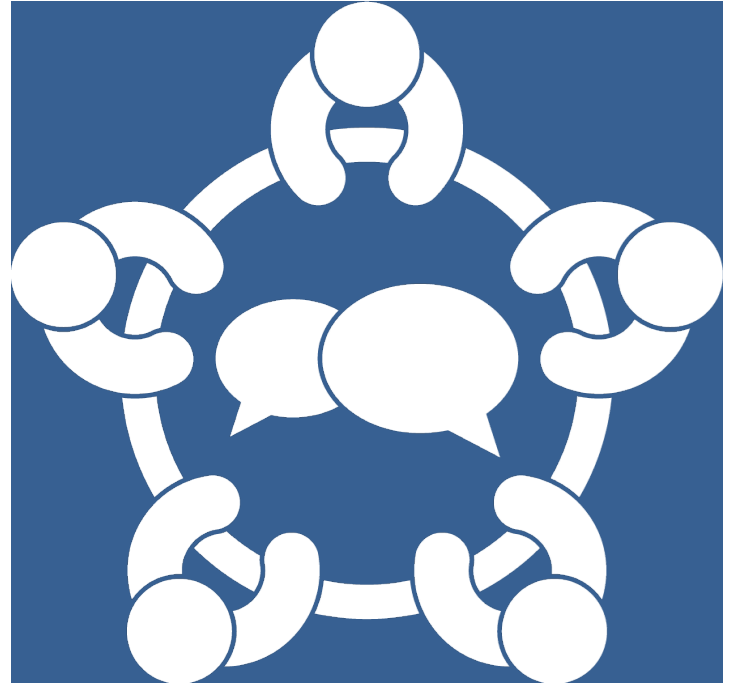


Pandemic Preparedness Working Group Report Out



One Health and Pandemic Preparedness



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201
April 13, 2022

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
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Dear Dr. Blaser:

I would like to thank you for your continued leadership of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB). Your recent public meeting on global efforts to fight antimicrobial resistance (AMR) and incorporating AMR into pandemic preparedness was an insightful session that emphasized the importance of approaching the issue of AMR from a variety of perspectives. As we move forward, it is critical that we continue to broaden the ways in which we address AMR.

The U.S. has consistently recognized the necessity of addressing AMR as a component of pandemic preparedness. The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (Public Law No. 116-22) strengthens systems to prepare for significant threats such as AMR. Likewise, preventing naturally occurring infectious diseases, including from antimicrobial-resistant pathogens, is included among the goals in our National Biodefense Strategy and corresponding Implementation Plan. The President's national security memorandum from January 21, 2021, directs a strengthening of health security and pandemic preparedness policies and procedures to improve our response to emerging infectious threats, including resistant pathogens. While we are fortunate that our National Action Plan on Combating Antibiotic Resistant Bacteria truly encompasses a whole of government approach to addressing AMR, we need to further ensure that AMR is also consistently highlighted in all of our current pandemic preparedness and response policies and activities.

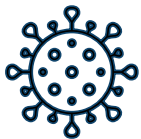
Therefore, I hereby request that the PACCARB consider how the U.S. may leverage our existing pandemic preparedness frameworks to strengthen our defense against antimicrobial-resistant pathogens in response to a potential future, large-scale disease event. The Council should examine how existing pandemic preparedness policies may be augmented to address AMR, and whether additional policies or programs may be needed to be best prepared for a large-scale outbreak of a resistant pathogen. Please ensure a One Health approach to this task, identifying lessons learned from the human, animal, and environmental health domains that can be applied

- Tasked by the Secretary of HHS to critically evaluate our pandemic preparedness policies in spring of 2022
- Evaluating pandemic preparedness from a One Health perspective
- Pandemic Preparedness Working Group

PACCARB

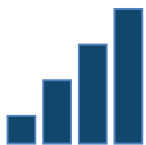
Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

Overview of the Outbreak Scenario



Highly transmissible, novel re-assortant influenza A strain

- Origin unknown



Impacting both human and swine populations

- Hospitals over capacity
- Decline in husbandry and swine health due to depleted workforce



Significant mortality from resistant secondary infections

- Pathogens associated with ventilator-associated pneumonia (VAP) and community acquired pneumonia (CAP)

*** MOCK SCENARIO ***

PACCARB

Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

Major Themes from September 2022

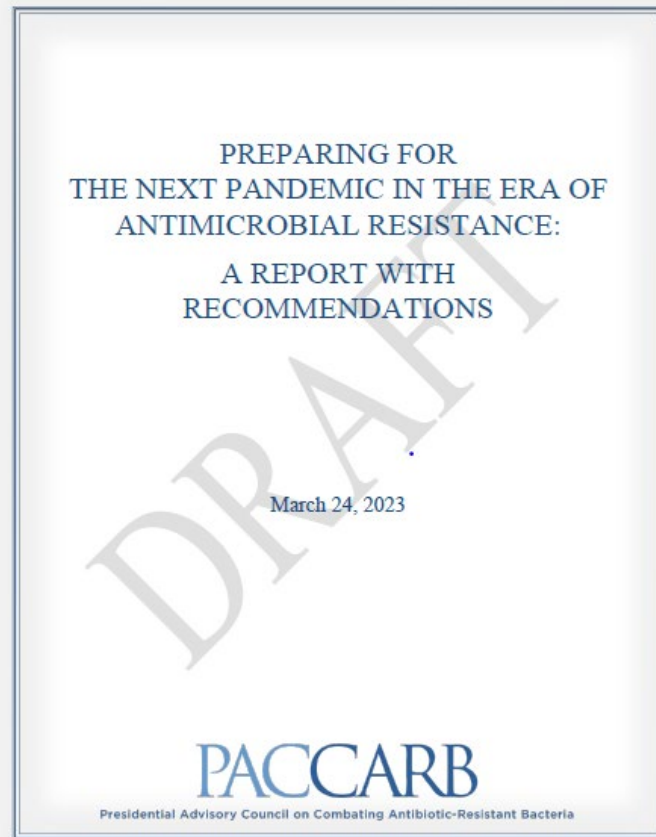
1. Steady-state operations need investment
2. Flexibility is key to rapidly scale-up in an emergency event
3. A One Health approach is crucial

Major Themes from January 2023

1. Marginalized and vulnerable populations must be included in pandemic preparedness prior to a PHE.
2. Communication strategies need to be flexible and developed as part of a preparedness plan.
3. Transparency is critical.

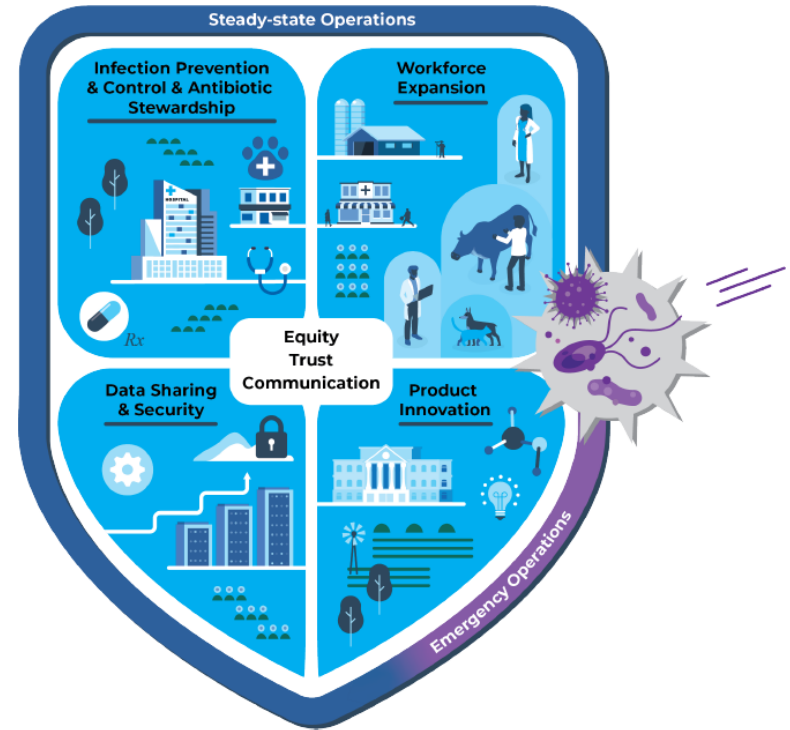
The Report

- PPWG developed a report with recommendations
- Input from:
 - Working group meetings
 - Public meetings



Report Structure

- AMR must be included in all pandemic preparedness policies
- Health equity and inclusion must drive all preparedness policy
- Preparedness starts now, before the next pandemic



Report Recommendations

Equity, Trust, and Communication Recommendations

Recommendation 1: Prioritize social, structural, and behavioral interventions that build trust in public health guidance and increase uptake of both pharmaceutical and non-pharmaceutical interventions in steady-state and during a PHE.

Recommendation 2: Include marginalized and vulnerable communities during the development, implementation, and communication of all pandemic preparedness policies.

Infection Prevention and Control and Antimicrobial Stewardship Recommendations

Specific Needs for Steady-State Operations

Recommendation 3: Include infection prevention and control and antimicrobial stewardship as core capabilities and goals in pandemic preparedness policies including through dissemination of existing and updated guidelines.

No related AP3 goal
NBS Goal 3.1.4

Specific Needs for Emergency Operations

Recommendation 4: Create a mechanism for rapid guideline development for appropriate antimicrobial use in response to an emerging AMR pathogen and to maintain antimicrobial stewardship during an emergency.

No related AP3 goal
NBS Goal 3.1.4

Report Recommendations

Workforce Expansion Recommendations

Specific Needs for Steady-State Operations

Recommendation 5: Bolster the workforce by expanding recruitment and support of infection preventionists and infectious diseases specialists and engaging a broader set of providers in human and animal healthcare.

AP3 Goal 6.1
NBS Goals 3.1.1 and 3.1.4

Specific Needs for Emergency Operations

Recommendation 6: Develop pathways that would allow for qualified practitioners in other One Health domains to provide support to human healthcare during a PHE.

AP3 Goal 6.1
NBS Goal 3.1.4

Recommendation 7: Build capacity for both human and animal diagnostic laboratory networks to meet emergency surge testing demands.

AP3 Goal 6.1
NBS Goal 3.1.1

Data Sharing and Security Recommendations

Specific Needs for Steady-State Operations

Recommendation 8: Invest in global capacity for AMR pathogen surveillance and early detection of novel AMR pathogens.

Recommendation 9: Expand and diversify sectors participating in domestic AMR surveillance efforts to include outpatient clinical settings, independent/clinical laboratories, wildlife, companion animals, wastewater, and others.

AP3 Goal 4
NBS Goals 1.1.1 and 2.2.5

Recommendation 10: Modernize existing surveillance databases for One Health interoperability to accommodate data input from different human, animal, and environmental health sources, as well as variables that capture social determinants of health.

AP3 Goal 6.2
NBS Goal 1.1.1

Recommendation 11: Invest in improved data privacy and security to encourage more private entities to contribute data, including AMR data, to federal data management systems used in public health, agricultural, and environmental sectors.

AP3 Goal 6.2
NBS Goal 1.1.1

Report Recommendations

Medical Countermeasures and Product Innovation Recommendations

Specific Needs for Steady-State Operations

Recommendation 12: Develop novel antimicrobials, vaccines, diagnostics, and threat-agnostic platform technologies focused on resistant bacterial and fungal pathogens, which are material threats likely to arise during a PHE.

AP3 Goals 2, 9.1, and 11.1
NBS Goals 3.2.3 and 3.5

Specific Needs for Emergency Operations

Recommendation 13: In anticipation of a PHE, establish flexible, response-ready clinical trial networks that include outpatient settings and vulnerable populations, such as pediatrics, and that can easily adapt in an emergency to determine the safety and efficacy of novel countermeasures.

AP3 Goal 11.2
NBS Goal 4.1.4

Recommendation 14: Develop accelerated regulatory approval pathways to assess novel, unique, or nontraditional technologies or products and ensure sufficient funding and procedures are in place to support and maintain the FDA review process during a PHE.

AP3 Goals 11.1 and 11.3
NBS Goals 3.2, 3.4, and 3.5.2

Deliberation and Vote

