

# RECOMMENDATIONS

OCTOBER 2021 • COMBATING ANTIMICROBIAL RESISTANCE AND PROTECTING  
THE MIRACLE OF MODERN MEDICINE

**Recommendation 4-1:** The National Library of Medicine (NLM) should establish an open-source, unified antimicrobial resistance database that integrates raw phenotypic data from national and international efforts. This database should support automatic importation from hospitals, laboratories, and surveillance networks and linking to genotypic data when available. NLM should engage the Centers for Disease Control and Prevention, the U.S. Department of Agriculture, and other relevant stakeholders to determine the necessary data elements and confidentiality procedures.

**Recommendation 4-2:** The Environmental Protection Agency should provide guidance and funding to states for testing point source discharge at wastewater treatment plants for antimicrobial resistance traits and integrating these data with other surveillance networks.

**Recommendation 5-1:** The Centers for Medicare & Medicaid Services should require nursing homes, long-term acute care hospitals, and dialysis centers to have antimicrobial stewardship programs and include that information on the Care Compare website. These programs should, at a minimum, designate key staff, a system for preauthorization of restricted antimicrobials, and a process for regular review of all antimicrobial prescriptions.

**Recommendation 5-2:** The Food and Drug Administration's Center for Veterinary Medicine should establish a process and clear metrics to facilitate better tracking of antimicrobial consumption in animals. This information would support the design and implementation of stewardship programs.

**Recommendation 5-3:** The Food and Drug Administration's Center for Veterinary Medicine should convene an advisory committee to coordinate development of antimicrobial susceptibility test breakpoints in animals and identify priority animal, drug, and pathogen combinations. When necessary, the Center for Veterinary Medicine would fund the research needed to develop the priority breakpoints.

**Recommendation 5-4:** The Department of Health and Human Services agencies, including the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Centers for Medicare & Medicaid Services, and the Patient-Centered Outcomes Research Institute should support outcomes research in diagnostic testing to drive an iterative process of guidelines development and to influence reimbursement for diagnostic testing.

**Recommendation 5-5:** The National Institutes of Health and the Centers for Disease Control and Prevention should provide supplemental research funding to track antimicrobial use and antimicrobial resistance in immunization trials and large cohort studies to measure the indirect benefits vaccines provide and to provide evidence to enhance vaccine deployment as a tool to mitigate antimicrobial resistance.

**Recommendation 6-1:** A Department of Health and Human Services (HHS) interagency committee should establish well-targeted, objective criteria to identify novel antimicrobials with high potential for filling a critical, unmet need. HHS should then support trials to establish the additional clinical benefit and optimal use of these drugs.

**Recommendation 6-2:** To reduce regulatory hurdles in bringing automated susceptibility tests to market, the Food and Drug Administration should coordinate the review of new antimicrobials with the review of their automated susceptibility tests and work with the Clinical Laboratories Standards Institute to issue and update breakpoints for microbe–drug combinations.

**Recommendation 6-3:** Congress should make automated susceptibility test manufacturers eligible for tax incentives to bring new automated susceptibility tests to market.

**Recommendation 6-4:** The Centers for Disease Control and Prevention (CDC) should expand the capacity of the Antibiotic Resistance Laboratory Network by offering expedited, expanded susceptibility testing of all broad-spectrum antibiotics via certain CLIA–certified laboratories.<sup>1</sup> The CDC should also promote this service to clinical laboratories.

**Recommendation 6-5:** The Department of Health and Human Services should establish a public–private partnership similar to ACTIV for antimicrobial resistance, bringing together the Biomedical Advanced Research and Development Authority, the National Institutes of Health, the U.S. Department of Agriculture, the Environmental Protection Agency, and the Department of Defense and interested academic, industry, and nonprofit organizations. The partnership would have working groups on diagnostics, alternatives to antibiotics, and prevention, with a goal of supporting a diversified and balanced portfolio of tools to reduce antimicrobial resistance using a One Health approach.

**Recommendation 7-1:** Congress should direct the Government Accountability Office (GAO) to conduct biennial evaluations of federal agencies’ progress toward meeting the goals of the 2020–2025 *National Action Plan for Combating Antibiotic-Resistant Bacteria* to ensure objective assessment of agencies’ activities. Congress and the GAO should consider ways to use their evaluations to direct course corrections when necessary.

**Recommendation 8-1:** Congress should expand the United States global engagement on antimicrobial resistance by (1) strengthening surveillance of resistant pathogens both by supporting existing, multilateral surveillance systems and by expanding U.S. agencies’ international surveillance programs; (2) reducing need for antimicrobials by broadening agencies’ work on infection prevention and antimicrobial stewardship in humans and animals; and (3) ensuring sustained leadership and critical evaluation by creating a Global Coordinator for Antimicrobial Resistance similar to the Global AIDS Coordinator.

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<sup>1</sup> The Clinical Laboratory Improvement Amendments (CLIA) regulate testing and are required for laboratories handling human samples.

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