

ANTIMICROBIALS WORKING GROUP

Innovation, Antimicrobials, and Stewardship in Today's AMR Climate: Enabling the Right Antimicrobial for the Right Patient at the Right Time for the Right Duration

The Antimicrobials Working Group (AWG), whose mission is to improve the regulatory, investment, and commercial environment for antimicrobial drug and diagnostic device development to provide doctors and patients with innovative infectious disease treatment options, is committed to partnering with all infectious disease stakeholders invested in combatting antimicrobial resistance (AMR) – including drug developers, healthcare providers, and policymakers – to deliver patient-centric stewardship programs that focus on the right antimicrobial for the right patient at the right time for the right duration to optimize clinical care outcomes.

AWG has outlined four unifying principles inherent in stewardship that are central to innovation in antimicrobial discovery and development. Our blueprint aligns with the collective strategies and recommendations of the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), and other key public health organizations.¹

Antimicrobial stewardship should aim to optimize outcomes for individual patients.

Stewardship promotes individualized treatment of patients based on their unique medical needs. Health care providers are accountable for their patients' clinical outcomes and are best suited to make individual prescribing decisions on therapy. Stewardship ensures that the best therapies are readily available when patients need them the most. In so doing, these approaches should also be aimed at optimizing appropriate antimicrobial use to decrease adverse reactions in individual patients as well as control the threat of antimicrobial resistance.

Stewardship programs: Enabling patient access to newer treatment options by identifying unmet clinical needs in the community and therefore accelerating innovation of new antimicrobials.

Recent studies have identified a significant delay in the availability in many healthcare institutions of new antimicrobials with improved efficacy and lower toxicity than many older agents – thus depriving vulnerable patients of the benefits of recently introduced therapies. In addition, many treatment guidelines lack information about newer agents developed under higher evidence standards, as well as information about emerging resistance trends and current resistance definitions or modernized approaches to breakpoint ascertainment. Stewardship experts are frequently called upon to advise medical staff, formulary committees, and policymakers about appropriate antimicrobial use, particularly for newly developed agents. Stewardship programs can ensure that regional and national antimicrobial guidelines are balanced against local epidemiology in clinical practice. Stewardship professionals should be encouraged to collaborate with drug developers to help elucidate unmet clinical needs and improve patient access to treatment options, including novel agents that help prevent complications of AMR, such as repeat hospitalizations, sepsis, and mortality.

Stewardship: Further optimizing patient care by developing pragmatic, value-based, quality-of-care metrics.

Stewardship should seek to promote clinically pragmatic, value-based and quality-of-care metrics to fully inform institutional and health system budgeting to optimize individual patient care. Hospital management should consider evaluating stewardship teams based on value and quality-of-care metrics and shift the focus beyond primarily pharmacy drug costs/budgets. Stewardship programs developed within a framework for measuring the value of a new therapy beyond its unit price will ensure appropriate patient access to new antimicrobials that may deliver improved tolerability and earlier hospital discharge, as well as prevent infectious complications from surgery and hospitalization from community-acquired and nosocomial infections.

Stewardship: Helping to refine antimicrobial reimbursement mechanisms by defining the value of novel therapies.

Diagnosis-Related Group (DRG)-based reimbursement policies incentivize the use of inexpensive therapies that are often less reliable as an empiric first-line treatment in at-risk or critically ill patients due to increasing rates of AMR – putting patients at higher risk of clinical failure. Stewardship can help implement mechanisms that value antimicrobial drug discovery and innovation through payment reforms that align reimbursement with patient outcomes (i.e. total cost of care and patient outcomes vs. pharmacy cost only).

¹ AWG reviewed the Centers for Disease Control and Prevention (CDC)'s *Core Elements of Hospital Antibiotic Stewardship Programs* and the World Health Organization (WHO)'s *Global Action Plan on Antimicrobial Resistance*, as well as stewardship positions developed by the Infectious Diseases Society of America (IDSA) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).