

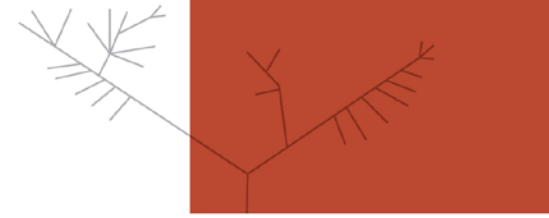


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Coordinating development of new antimicrobials and susceptibility testing methods

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Disclosures (M. Miller)



- Grant support
 - Luminex Molecular Diagnostics
 - GenMark Diagnostics
 - Hologic
- Scientific Advisory Board
 - Cepheid



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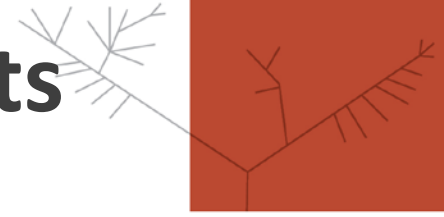
ASM and Laboratory Practices

- The **American Society for Microbiology** is the largest single life science society, composed of over 47,000 scientists and health professionals. ASM's mission is to promote and advance the microbial sciences through conferences, publications, certifications and educational opportunities.
 - Many of ASM's members are individuals responsible for directing clinical microbiology, immunology and molecular diagnostic laboratories, individuals licensed or accredited to perform such testing, industry representatives manufacturing products for use, and researchers involved in developing and evaluating the performance of new technologies.
 - The **Committee on Laboratory Practices** is concerned with issues that involve the science and technology of microbiology laboratory practice that are directly or indirectly controlled by the government, an agency of the government, or an accrediting or standard-setting private agency.



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Antimicrobial resistance efforts

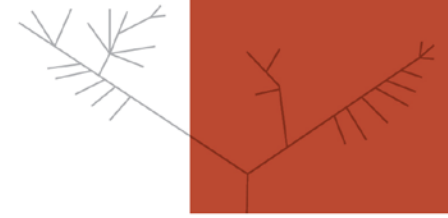


- <http://www.asm.org/index.php/issues-we-follow/98-policy/issues/2637-antimicrobial-resistance>
 - 2016
 - Participated in UN General Assembly meeting on AMR – petition, letter and representation
 - Provided recommendations to the Presidential Campaigns including AMR
 - Supported Antibiotic Incentive Amendment to the National Defense Authorization Act
 - 2015
 - Participated in the Presidential Advisory Council CARB (Combating Antibiotic-Resistant Bacteria) Working Group Meeting
 - Responded to AMR Rapid Point of Care Diagnostic Test Challenge
 - Participated in White House Antibiotic Stewardship Forum



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1. Patient care

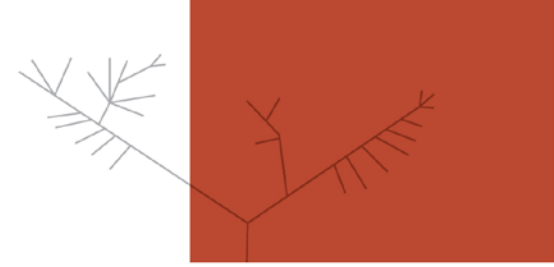


- **The significant delay between the availability of new antimicrobials and approved susceptibility methods negatively impacts patient care.**
 - Physicians are reluctant to use a new antimicrobial without susceptibility data.
 - MDROs may not be adequately treated.
 - Empiric treatment of MDROs without supporting susceptibility data is not without consequence.
 - New antimicrobials may not be effectively restricted (i.e., susceptibility required prior to use).
 - Could lead to increased antimicrobial resistance (and loss of active agents)
 - Results from a reference laboratory (*if available*) may not return in a “clinically actionable” timeframe.
 - May restrict testing to FDA approved indications.



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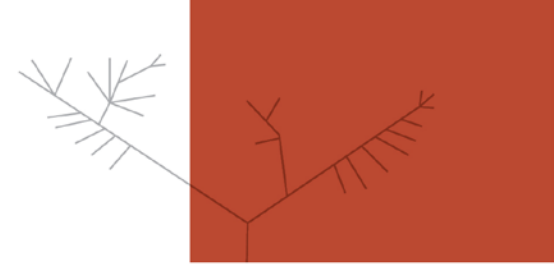
2. Research Use Only



- **Initial testing methods that are commercially available are limited to disks and agar gradient diffusion strips that are labeled for “Research Use Only.”**
 - Companies require laboratories to sign a statement that the products will not be used for clinical care.
 - May also require that the data be reported back to the company.
 - Many clinical laboratories cannot report RUO results in the patient chart without IRB approval and patient consent or waiver.
 - Some laboratories do not have this capability or the time required.
 - Clinical laboratories cannot bill for RUO tests.
 - Tests may be unreliable in performance, or provide misleading results.



3. Transparency



- **More transparency is needed between companies and clinical laboratories.**
 - Companies may revise or reformulate their RUO disks/agar gradient diffusion strips before they are FDA cleared.
 - Labs will need to re-verify test performance.
 - Disks/agar gradient diffusion strips may be provided for verification studies, but subsequent orders are often restricted or product is unavailable.



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4. Verification of new methods

- **Clinical laboratories struggle with how to verify new antimicrobial susceptibility tests when there is no reference method available to compare results.**
 - CLIA requires new test verification prior to reporting patient results and ongoing validation of accuracy.
 - Reference laboratories are needed to provide this service, but may be too expensive.
 - Some pharmaceutical companies provide reference testing, but can they accommodate all requests?
 - A designated verification panel of organisms with known susceptibility profiles is needed for verification/validation for each new drug.



5. Automated testing devices

- **A process is needed to fast track antimicrobial placement onto AST devices.**
 - An expedited process similar to Qualified Infectious Disease Products (QIDPs) under the GAIN Act is needed for adding new drugs to previously approved antimicrobial testing devices/panels.
 - Although QIDPs are being expedited, laboratories cannot perform susceptibility testing.

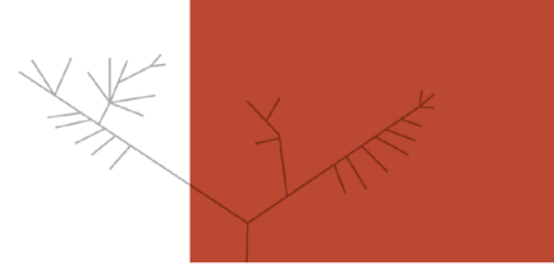


6. Co-development/FDA review

- Simultaneous development/review/approval
 - Availability of accurate susceptibility test methods should be coordinated with new drug applications.
 - *Without* delay in development or approval of new antimicrobials.



7. ASM's role



- ASM has interfaced with the FDA on numerous occasions and is committed to working together to solve this important issue for clinical laboratories.
 - Experts from our membership are willing to serve on working groups to develop and implement a solution.
 - Once a proposed solution is agreed upon, oversight by outside organizations will be important to keep the issue a priority.
 - Advocacy in collaboration with other societies and organizations.



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