ARLG Update
Antibacterial Resistance Leadership Group

To prioritize, design, and execute clinical research that will reduce the public health threat of antibacterial resistance

ARLG Update

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For more information about the ARLG, its leaders, or its current projects, please visit **arlg.org**

Meet our Committees

Pharmacokinetics Special Emphasis Panel

Chair: Thomas Lodise


Dr. Thomas Lodise

The organizational structure of the ARLG features Scientific Subcommittees devoted to four priority areas: Gram-negative bacterial Infections, Antimicrobial Stewardship and Infection Prevention, Gram-positive bacterial Infections, and Diagnostics and Devices plus three Special Emphasis Panels (SEPs) (Special Populations, Pediatrics, and Pharmacokinetics) and a Mentoring Core. The key functions of Subcommittees and SEPs are reviewing proposals, assigning scientific merit scores, and serving as a resource in prioritizing the scientific agenda. The goal of the pharmacokinetics SEP is to identify pharmacologic strategies that optimize the utility of existing antibacterials by enhancing efficacy, reducing toxicity, and/or minimizing emergence of resistance identified by the CDC, FDA, and NIH as one of the priorities to combat antibacterial resistance. There is tremendous potential for reducing antibacterial pressure by developing regimens that are both effective and minimize emergence of resistance.

Committee Member	Institution
Thomas Lodise (Chair)	Albany College of Pharmacy and Health Sciences
David Andes	University of Wisconsin School of Medicine and Public Health
Michael Cohen-Wolkowiez	Duke University
Michael Neely	University of Southern California
Manjunath Pai	Albany College of Pharmacy and Health Sciences
Susan Rosenkranz	Harvard University
Brian Tsuji	University of Buffalo
David Nicolau	Hartford Hospital Center for Anti-Infective Research and Development
Joseph Rybak	Wayne State University

PROOF
Antibacterial Resistance Leadership Group

ARLG Project Spotlight

PROOF

Phase I Study to Evaluate Pharmacokinetics, Pharmacodynamics and Safety/Tolerability of Two Dosing Regimens of Oral Fosfomycin Tromethamine in Healthy Adult Participants (PROOF)

Principal Investigator: Keith Rodvold, PharmD


Dr. Keith Rodvold

Treatment of cUTI in 2015 is challenging for a number of reasons including the potential risk of resistant gram-negative bacteria (e.g., ESBL-producing E. coli and Klebsiella pneumoniae). Fosfomycin tromethamine is currently approved by the U.S. FDA and is considered first-line for the treatment of uncomplicated cystitis as a one-time oral dose of 3 grams. In addition to this indication, fosfomycin is frequently utilized in the clinical arena for the treatment of complicated urinary tract infections and prostatitis, amongst other disease states.

The primary objectives of this project are 1) to assess the safety and tolerability of two different dosing regimens of oral fosfomycin tromethamine in healthy adults; and 2) to evaluate the steady-state pharmacokinetics and pharmacodynamics of the two different oral dosing regimens. To accomplish this PROOF is designed as a randomized, two-way crossover trial involving up to 24 randomized participants with an anticipated drop-out rate no higher than 25% to give a total of 18 evaluable healthy adult participants.

2015 Awards and Achievements

John Bartlett, MD
4th C. Everett Koop Public Health Leadership Award

Robert Bonomo, MD
Harrington Scholar-Innovators Award 2015

Scott Evans
Mosteller Statistician of the Year 2015

Robert Bonomo, MD
Nominated to serve as the chair for the Infectious Disease Society of America (IDSA) Committee for Practice Guidelines for the Diagnosis and Management of Complicated Intra-abdominal Infections in Adults and Children. 2015

Robert A. Bonomo, MD
Nomination by the IDSA for membership on the Patient-Centered Outcomes Research Institute (PCORI) Advisory Panel on Assessment of Prevention, Diagnosis, and Treatment Options. 2015

Publications Update

Banerjee R,Teng C, Cunningham S, Ihde S, Steckelberg J, Moriarty JP, Shah ND, Mandrekar J, Patel R **Randomized Trial of Rapid Multiplex Polymerase Chain Reaction-Based Blood Culture Identification and Susceptibility Testing.** Clin Infect Dis. 2015 Oct 1;61(7):1071-80. doi: 10.1093/cid/civ447. Epub 2015 Jul 20. PubMed ID: 26197846 PMCID: PMC4560903.

Bergin SP, Thaden J, Ericson JE, Cross H, Messina J, Clark RH, Fowler V, Benjamin DK, Hornik CP, Smith PB **Neonatal Escherichia coli Bloodstream Infections: Clinical Outcomes and Impact of Initial Antibiotic Therapy.** Pediatr Infect Dis J. 2015 Sep;34(9):933-936. PubMed ID: 26065862 PMCID: PMC4581845.

Evans SR, Rubin D, Follman D, Penello G, Huskins WC, Powers J, Schoenfeld D, Chuang-Stein C, Fowler V, Lautenbach E, Chambers HF **Desirability of Outcome Ranking (DOOR) and Response Adjusted for Days of Antibiotic Risk (RADAR).** Clin Infect Dis. 2015 Sep 1;61(5):800-6. PubMed ID: 26113652 PMCID: PMC4542892.

Uno H, Wittes J, Fu H, Solomon SD, Claggett B, Tian L, Cai T, Pfeffer MA, Evans SR, Wei LJ **Alternatives to Hazard Ratios for Comparing the Efficacy or Safety of Therapies in Noninferiority Studies.** Ann Intern Med. 2015 Jul 21;163(2):127-34. PubMed ID: 26054047 PMCID: PMC4510023.

Ando Y, Hamasaki T, Evans SR, Asakura K, Sugimoto T, Sozu T, Ohno Y **Sample size considerations in clinical trials when comparing two interventions using multiple co-primary binary relative risk contrasts.** Stat Biopharm Res. 2015 Jun 24;7(2):81-94. PubMed ID: 26167243 PMCID: PMC4497828.

Messina JA, Fowler VG Jr, Corey GR **Oritavancin for Acute Bacterial Skin and Skin Structure Infections.** Expert Opin Pharmacother. 2015 May;16(7):1091-8. PubMed ID: 25803197 PMCID: PMC4580226.

Tamma PD, Han JH, Rock C, Harris AD, Lautenbach E, Hsu AJ, Avdic E, Cosgrove SE; for the Antibacterial Resistance Leadership Group **Carbapenem Therapy is Associated with Improved Survival Compared With Piperacillin-Tazobactam for Patients With Extended-Spectrum β-Lactamase Bacteremia.** Clin Infect Dis. 2015 May 1;60(9):1319-25. doi: 10.1093/cid/civ003. Epub 2015 Jan 13. PubMed ID: 25586681 PMCID: PMC4462658.

Tugal D, Lynch M, Hujer AM, Rudin S, Perez F, Bonomo RA **Multi-Drug-Resistant Klebsiella pneumoniae Pancreatitis: A New Challenge in a Serious Surgical Infection.** Surg Infect (Larchmt). 2015 Apr;16(2):188-93. PubMed ID: 24850293 PMCID: PMC4394169.

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