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639. Short Course Therapy for Urinary Tract Infections (SCOUT) in Children
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Session: P-24. Clinical Trials

Background: The AAP recommends 7 to 14-days of antimicrobials for the treatment of urinary tract infections (UTIs), one of the most common bacterial infections of childhood. However, most physicians routinely prescribe at least 10 days of therapy. Prior observational studies suggest that courses shorter than 10 days might be effective.

Methods: The primary objective was to determine if halting antimicrobial therapy in children who improved clinically after 5 days of therapy (short course therapy) results in a similar failure rate as children who continue antimicrobials for an additional 5 days (standard course therapy).

This was a multi-center, randomized, double-blind, placebo-controlled non-inferiority clinical trial of children ages 2 to 10 years with UTI. Subjects treated with 1 of 5 antibiotics (trimethoprim-sulfamethoxazole, amoxicillin-clavulanate, cefixime, cefdinir or cephalixin) were eligible. Children were stratified by presence or absence of fever and were enrolled if they had clinical improvement before Day 5 of treatment. The a priori equivalence interval was set at 0.05 for a one-sided analysis. The primary outcome was development of a symptomatic UTI defined as the presence of symptoms, pyuria, and a positive urine culture. The Intent-to-Treat population included children who took at least one dose of study medication.

Results: A total of 693 children were randomized, 345 to short course and 348 to standard course. Median age was 4 years old (IQR; 2-6), 652 (96.3%) were female and 255 were febrile (37%). Treatment success rate was 322/336 (96%) for short course and 326/328 (99%) for standard course. The 95% upper CI limit for the difference was 0.054. Treatment failure was not related to age group, fever at presentation, antibiotic type, or study site. There were no significant differences between groups in the rates of adverse events, recurrent infection, clinical symptoms that may have been related to UTI, or emergent antibiotic resistance.

Conclusion: In children aged 2 months to 10 years with UTI, halting antimicrobial therapy in children who had exhibited clinical improvement after 5 days and continuing for an additional 5 days both resulted in high success rates. However, short course was inferior to treatment for 10 days.

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640. Analytical Validation of the BioFire Bone and Joint Infection (BJI) Panel for the Identification of Bacteria, Yeast, and Antimicrobial Resistance Genes from Synovial Fluid

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Session: P-25. Diagnostics: Bacteriology/mycobacteriology

Background: The BioFire Bone and Joint Infection (BJI) Panel is a sample-to-answer test for the qualitative detection of nearly 40 different bacteria, yeast, and antimicrobial resistance (AMR) genes in synovial fluid (SF). The panel aims to improve on current culture-based diagnostics, particularly for detection of anaerobes (e.g. *Finegoldia magna*, *Kingella kingae*, *Cutibacterium*, *Anaerococcus* and *Peptoniphilus* species, and others) in about an hour. Analytical performance of the panel (Limit of Detection (LoD), analytical reactivity and specificity, interference, reproducibility), and specimen storage conditions are described.

Methods: LoD for each analyte was estimated from serial dilutions and confirmed at the lowest titer with $\geq 95\%$ detection. A collection of >350 isolates representing genetic and geographic diversity of analytes was tested near LoD to assess analytical reactivity, and more than 420 near-neighbor, commensal, pathogenic, or environmental off-panel species were evaluated for assay specificity. Reproducibility was evaluated in a multi-laboratory multi-variable study, and the impact of storage and potentially interfering substances on the accuracy of test results was also assessed. Testing was performed with Investigational Use Only kits.

Results: The confirmed LoD for bacteria and yeast ranged from 100 - 10,000 CFU/mL. Sequence analysis and testing demonstrated clinically appropriate specificity and reactivity with a variety of isolates and different AMR gene types. Accurate and reproducible organism and AMR gene detection was observed with repeated testing of samples over several days (99.9% agreement with the expected results), and detection was not affected by potentially interfering substances nor by refrigerated sample storage.

Conclusion: The BioFire BJI Panel is a robust, accurate, and easy-to-use multiplex PCR test capable of detecting many aerobic and anaerobic bacteria, yeast, and AMR genes in synovial fluid specimens. Rapid and reliable molecular detection of possible BJI pathogens may advance the diagnosis and effective management of bone and joint infections.

Note: This panel has not been evaluated by the FDA or other regulatory agencies for diagnostic use.

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641. Carriage and Genetics of Haemophilus influenzae Serotype A (Hia) in Alaska, 2018

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Session: P-25. Diagnostics: Bacteriology/mycobacteriology

Background: *Haemophilus influenzae* serotype a (Hia) is an important cause of infection among Alaska Native children. In 2018, 4 invasive Hia cases (iHia) occurred in an Alaska community. Our response aimed to prevent more iHia and evaluate Hia carriage in the community. Whole genome sequencing (WGS) was performed to compare Hia from iHia patients across Alaska in 2018, and from healthy outbreak community members.

Methods: We collected oropharyngeal (OP) samples from outbreak community members. Children aged < 10 years and people in close contact with cases (contacts) were offered rifampin prophylaxis. A second set of OP samples was collected 8 weeks later. Isolates from iHia from across the state were collected as part of the state surveillance. Hia was detected by PCR and culture, then characterized by antimicrobial susceptibility and WGS.

Results: At baseline, contacts had a higher prevalence of Hia carriage than non-contacts (4/27(14.8%) vs 7/364(1.9%), p=0.0043). Eight weeks after rifampin prophylaxis, carriage prevalence did not significantly change among contacts (5/42(11.9%) to 6/25(24%), p=0.18) or non-contacts (7/368(1.9%) to 2/114(1.8%), p=0.47). Phylogenetic analysis of 19 iHia isolates and 15 isolates from healthy outbreak community members, revealed two major clades that differed by an average of 300 core single nucleotide polymorphisms (SNPs). Invasive and carriage isolates from the outbreak community were clustered in one clade, along with 3 non-outbreak iHia isolates. Isolates from this community differed from each other by an average of 1.2 core SNPs. Comparative genomics did not reveal any genetic mutations that distinguished carriage from invasive isolates. Three (20%) community isolates were rifampin-resistant and had a previously unreported mutation in the *rpoB* gene.

Conclusion: We found Hia carriage prevalence was highest among persons in contact with iHia cases. Long-term community carriage was not affected by rifampin prophylaxis, possibly due to staggered prophylaxis. In the outbreak community, Hia isolates from carriers were nearly genetically identical to iHia isolates. Overall, iHia isolates from Alaska in 2018 were genetically similar. The mutation conferring rifampin resistance is concerning, as rifampin is used to prophylax contacts of iHia cases.

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