Conclusion. This study demonstrated no increased risk of post-operative infection in patients with a positive urinalysis or urine culture with bacteriuria prior to intervention. There was a high use of broad-spectrum antibiotics as a reflex to positive urinalyses alone highlighting an avenue for improved anti-microbial stewardship. More research is needed to guide clinicians on the role of urines and antibiotics prior to non-urgent urological procedures.

Disclosures. All authors: No reported disclosures.

1477. A Randomized 2 Phase Study of Cefepime with the Novel Extended Spectrum β-Lactamase Inhibitor Emzetabolzam in Colonized Adults with Complicated Urinary Tract Infections (cUTI) Including Acute Pyelonephritis (AP) in the MenACWY-TT and MenACWY-PS Groups

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Background. Third-generation cephalosporin (3GC)-resistant Enterobacteriaceae has been classified as critical priority pathogens. The novel extended-spectrum β-lactama- messible 3GC (ESBL) vaccine (MenACWY-TT; Nimenrix) is licensed in various countries.

Methods. Forty-five patients were enrolled in a randomized, multicenter, double-blind study of hospitalized adults with cUTI/AP. Patients received dosing regimens of FEP or FEP-EMT IV therapy q by 2 hours infusion (table) for 7 to 10 days with a follow-up. Efficacy was evaluated in a microbiological-modified intent-to-treat (gMITT) population. Safety was monitored in patients who received at least 1 dose of study drug. Clinical cure was designated as the resolution of cUTI symptoms present at study entry. Plasma and urine PK were determined from all patients.

Results. The drugs were well tolerated in each cohort, with similar adverse events and no new or unexpected safety concerns (table). Two discontinuations were due to allergic dermatitis. The microbiological- and clinical responses at test-of-cure for the combined FEP-EMT group were 83.3% (20/24) and 95.8% (23/24) compared with responses in the combined FEP group of 73.3% (11/15) and 93.3% (14/15), respectively (table). The most common baseline pathogens were Esherichia coli (66.6%) and Klebsiella pneumoniae (23.1%). 28.2% of isolates produced ESBL with eradication rates for the combined FEP-EMT group of 85.7% (6/7) and for the combined FEP group of 78.6% (6/7). FEP and EMT PK were best described by a 2-compartment linear PK model. Both agents exhibited half-lives of 2.3 hours. Creatinine clearance had a significant covariate effect on FEP and EMT, consistent with predominant renal excretion of both agents.

Conclusion. Results from this phase 2 study justify advancement to phase 3 studies to evaluate the safety and efficacy of FEP-EMT in patients with cUTI/AP.

Disclosures. All authors: No reported disclosures.

1478. Efficacy and Safety of a Booster Dose of the MenACWY-TT Vaccine Administered 10 Years After Primary Vaccination with MenACWY-TT or MenACWY-PS

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Background. The quadrivalent meningococcal ACWY polysaccharide tetanus toxoid conjugate vaccine (MenACWY-TT; Nimenrix) is licensed in various countries to prevent disease caused by meningococcal serogroups A, C, W, and Y. In a previous phase 3 study, the primary MenACWY-TT recipients with prebooster titers ≥1:8 were observed during the booster phase. Functional antibody responses elicited by MenACWY-TT persisted 10 years after primary vaccination; the booster dose was well tolerated and elicited robust immune responses.

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Table. Safety and Efficacy Outcomes in Patients with cUTI/AP in the Phase 2 Study Following Treatment with Cefepime or Cefepime-Extended Spectrum β-Lactamase

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