with JNJ-8678 appeared to reduce VL more rapidly than PBO (figure). Median change in VL from baseline (BL) in JNJ-8678-treated patients (combined dose groups) vs. PBO was −1.98 vs. −0.32 log₈ copies/mL at Day 3. Mean differences in change from BL (90% CI) of JNJ-8678 (combined dose groups) vs. PBO on Days 2 and 3 were estimated −1.33 (−2.26; −0.39) and −1.62 (−2.55; −0.69) log₈ copies/mL, respectively (general linear model, adjusted for BL VL: P < 0.05). There was a clear separation between JNJ-8678 and PBO, but no evident exposure–response relationship. JNJ-8678 was generally well tolerated with no new safety signals compared with adults and no dose relationship with AEs or lab abnormalities were observed.

**Conclusion.** This dataset in RSV-infected infants showed a clear trend for an early antiviral effect of JNJ-8678, which was similar across dose groups. JNJ-8678 treatment was generally well tolerated.

**Fig Median change from BL VL over 7 days of treatment in RSV-infected infants**

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**Table: PK Data by Dose/Age Group**

| Dose  | Dose (mg/kg) | Age (Months) | AUC₀→₇ Day 7 Mean ± SD | C₈₀→₇ Day 7 Mean ± SD |
|-------|-------------|--------------|------------------------|-----------------------|
| Low   | 1           | 1–3          | 5,121 ± 471            | 87 ± 16               |
|       | 1.5         | 3–6          | 6,236 ± 578            | 83 ± 18               |
|       | 2           | 6–24         | 5,631 ± 605            | 39 ± 14               |
| Mid   | 3           | 1–3          | 17,067 ± 1,247         | 349 ± 64              |
|       | 4.5         | 3–6          | 21,965 ± 2,147         | 346 ± 73              |
|       | 6           | 6–24         | 19,693 ± 2,213         | 170 ± 60              |
|       | Intermediate| 8            | 6–24                   | 27,454 ± 3,108        | 256 ± 88              |
|       | 5           | 1–3          | 32,478 ± 3,194         | 675 ± 120             |
|       | 6           | 3–6          | 30,722 ± 3,015         | 510 ± 105             |
|       | 9           | 6–24         | 31,445 ± 3,565         | 303 ± 103             |

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1959. Ceftriaxone-Sulbactam-EDTA (CSE) vs. Meropenem (MR) in PLEA (a Phase 3, Randomized, Double-Blind Trial): Outcomes in Patients Infected With Ceftriaxone Non-Susceptible, Extended-Spectrum β-Lactamase and Multi-Drug-resistant Pathogens at Baseline

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**Background.** CSE, a novel combination of Ceftriaxone, Sulbactam and Disodium EDTA (Class 1 Antibiotic Resistance Breaker), is being developed for the treatment of patients with serious Gram-negative infections and has completed a Phase-3 clinical trial (NCT03477422) for treatment of complicated urinary tract infections (cUTI), including acute pyelonephritis (AP). It restores and enhances the in vitro activity of Ceftriaxone against various β-lactamases (BLs), including enzyme families that belong to Ambler class A (TEM, SHV, CTX-M), class B (NDM, VIM, IMP), class C (some variants of AmpC), and class D (OXA extended spectrum BLs (ESBLs)). This analysis was performed to assess the clinical and microbiological outcomes in patients infected with Ceftriaxone non-susceptible (C-NS), MDR and ESBL-producing Gram-negative pathogens at baseline.

**Methods.** Patients were randomized 1:1 to receive either CSE (1g Ceftriaxone/500 mg Sulbactam/37 mg EDTA) every 12 hours or Meropenem (MR) 1 g every 8 hours as 30 minutes IV infusion for 5–14 days. Oral step-down therapy was not allowed. Biological specimens were analyzed, and resistant pathogens identified. MDR was defined as resistance to at least three categories of antimicrobials. Identification of pathogens and antibiotic susceptibility testing were performed and interpreted according to Clinical and Laboratory Standards Institute methodologies. Combined Disc Diffusion Test was used to detect ESBL production in pathogens.

**Results.** Of 230 randomized patients, 143 (62.2%) were included in m-MITT (72/74 (97.3%) in CSE and 68/69 (98.6%) in MR groups had C-NS pathogens; 63/74 (85.1%) in CSE and 56/69 (81.2%) in MR groups had ESBL-producing pathogens; 55/74 (74.3%) in CSE and 45/69 (65.2%) in MR group had MDR pathogens. Mean duration of IV therapy was 7 days. The clinical cure and microbiological eradication rates for CSE and MR at the test of cure (TOC) visit in C-NS, ESBL and MDR pathogens is shown in Figures 1, 2, and 3, respectively.

**Conclusion.** At TOC, clinical cure and microbiological eradication rates were higher for CSE as compared with MR across all three analyses sets. Overall, CSE was effective in the treatment of patients with cUTI and AP caused by resistant Gram-negative pathogens.
Disclosures. M. A. Mir, Venus Medicine Research Centre: Employee, Salary. S. Chaudhary, Venus Medicine Research Centre: Employee and Shareholder, Salary. M. Chaudhary, Venus Medicine Research Centre: Board Member and Shareholder, Salary. G. Shiekh, Venus Medicine Research Centre: Employee, Salary.

1960. Antibiotic Challenge Dose Testing Improves Patient Care and Lowers Costs in a Community Hospital: A 2-Year Prospective Study
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Background. Healthcare-associated infections (HAIs) and multidrug-resistant organisms (MDROs) in healthcare settings remains a major problem. In 2011, although copper has well-documented antimicrobial properties, the impact of copper-impregnated linen on HAIs and MDROs in healthcare settings remains undefined.

Methods. This study was conducted in a 24-bed medical ICU and a 24-bed surgical ICU from 1/2/12 to 7/31/16. Six beds in each ICU were randomized to CottonX™ accelerated copper linens (flat sheet, fitted sheet, pillow cover, gown) (Argaman Technologies Ltd.) and 18 beds to regular linens. Patients were enrolled if they were in the ICU for ≥23 days and were followed prospectively for development of an HAII (including C. difficile infection) and/or MDRO from ICU day 3 through 2 days after ICU discharge. MDROs were defined as a new clinical culture (i.e., no culture with the same organism in the prior year) with methicillin-resistant Staphylococcus aureus, vancomycin-resistant enterococci, carbapenem-resistant cephalosporin-resistant or carbapenem-resistant Enterobacteriaceae. A patient could be included more than once for distinct ICU stay.

Results. Among 1,021 subjects, the median age was 61 and 448 (44%) were female. 120 total episodes, 678 (56%) were in the ICU, 527 (44%) were in the ICU, and 351 (29%) were randomized to copper rooms. There were no significant differences between study groups with regard to demographics, comorbidities, indwelling devices, or antibiotic use. The overall rate (per 1,000 patient-days) of the composite outcome (HAI or MDRO) was 11.66 and 15.44 in copper and non-copper episodes, respectively, [incidence rate ratio (IRR) = 0.76 (95% CI, 0.46, 1.19); P = 0.22]. Rates of HAIs were 10.26 and 10.41 for copper and non-copper episodes, respectively [IRR (95% CI) = 0.99 (0.57, 1.64); P = 0.97]. Rates of MDROs were 3.73 and 6.51 for copper and non-copper episodes, respectively [IRR (95% CI) = 0.57 (0.23, 1.26); P = 0.15]. Results were consistent when stratified by type of ICU.

Conclusion. While not statistically significant, there was a nearly 50% lower rate of MDRO infection and colonization with use of CottonX™ accelerated copper linens, possibly in part due to decreases in environmental contamination. Future work should further explore the role of copper linens in reducing MDROs.

Disclosures. D. Pegues, DaVita / Total Renal Care: Consultant, Consulting fee.

1962. TRAIL Level and ImmunoXpert™ Score Complement Molecular Viral Detection in the Classification of Febrile Children: An Interim Analysis From the AutoPilot-Dx Study
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Background. Differentiating between viral and bacterial infection is essential in order to enable the adequate use of antibiotics. Previous studies showed that TNF-related apoptosis induced ligand (TRAIL) can serve as a useful biomarker for distinguishing between bacterial and viral infections when combined with IP-10 and CRP (ImmunoXpert™). Here we evaluate the potential of a new proteomic fingerprints in children with suspected viral and bacterial infections that had a confirmed viral detection.

Methods. In the prospective multinational multicenter study “AutoPilot-Dx” (NCT03052088) we aim to validate the diagnostic accuracy of the ImmunoXpert™ test. Detection was assigned by majority adjudication of three experts based on comprehensive clinical and laboratory investigation. Viruses were detected using multiplex-PCR applied to nasopharyngeal swabs (Allplex™, Seegene). We performed an interim analysis of the first 134 febrile children recruited that had both PCR viral detection and etiology determination. TRAIL, IP-10, CRP and ImmunoXpert™ values were measured via a Tecan EV075 ELISA platform.

Results. Bacterial diagnoses were assigned by the experts to 29%, 29% and 25% of patients with adenovirus (ADV), rhinovirus (RV), and respiratory syncytial virus (RSV) detection. Children with a viral infection including ADV, RSV, and RV had significantly lower ImmunoXpert™ scores as compared with children with a bacterial infection. Notably, TRAIL levels were markedly increased in viral infections as compared with bacterial infection, irrespective of the detected virus.

Conclusion. Classification of viral infections correlated significantly with elevated TRAIL levels and low ImmunoXpert™ scores. The differential expression of TRAIL in response to viral vs. bacterial infections can complement molecular viral detection, appears useful in the diagnostic workaround for febrile children and may reduce antibiotic misuse.

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