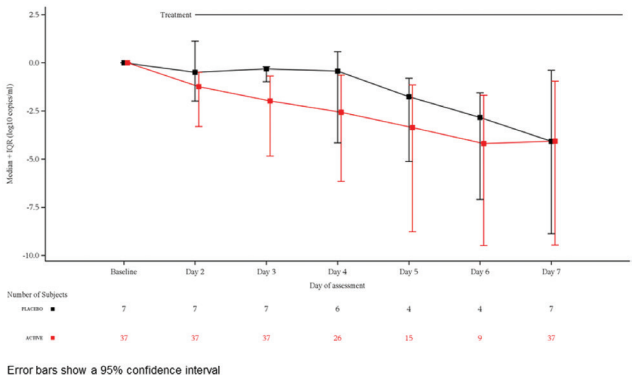
with JNJ-8678 appeared to reduce VL more rapidly than PBO (figure). Median change in VL from baseline (BL) in JNJ-8678-treated patients (combined dose groups) vs. PBO was −1.98 vs. −0.32 log_{10} copies/mL at Day 3. Mean differences in change from BL (90% CI) of JNJ-8678 (combined dose groups) vs. PBO on Days 2 and 3 were estimated −1.33 (−2.26; −0.39) and −1.62 (−2.55; −0.69) log_{10} copies/mL, respectively (general linear model, adjusted for BL VL; $P \leq 0.05$). 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



Error bars show a 95% confidence interval

Table: PK Data by Dose/Age Group

Dose	Dose (mg/kg) All $n = 4$	Age (Months)	AUC_{24} Day 7, Mean ± SD	C_{trough} 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	17,867 ± 1,747	345 ± 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
High	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

Disclosures. **F. Martinon-Torres**, Pfizer: Consultant, Consulting fee. SPMSD: Consultant, Consulting fee. GSK: Consultant, Consulting fee. **S. Rusch**, Janssen: Employee and Shareholder, Salary. **D. Huntjens**, Janssen: Employee and Shareholder, Salary. **B. Remmerie**, Janssen: Employee and Shareholder, Salary. **J. Vingerhoets**, Janssen: Employee and Shareholder, Salary. **K. McFadyen**, Janssen: Employee and Shareholder, Salary. **E. Baraldi**, Abbvie: Lectures, Speaker honorarium. Chiesi Farmaceutici: Consultant, Consulting fee. Novartis: Consultant, Consulting fee. Janssen: Consultant, Consulting fee. **M. Stevens**, Janssen: Employee and Shareholder, Salary.

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.

Figure 1: Outcomes in Ceftriaxone Non-Susceptible Pathogens

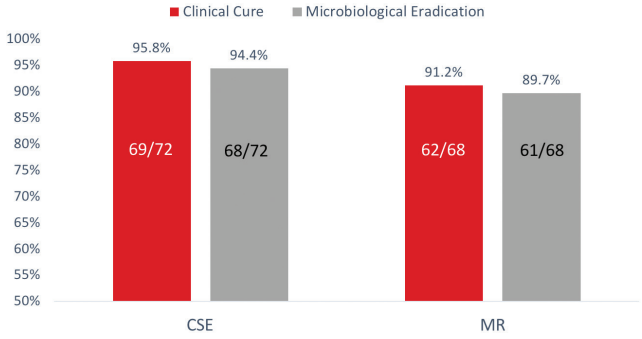


Figure 2: Outcomes in ESBL-Positive Pathogens

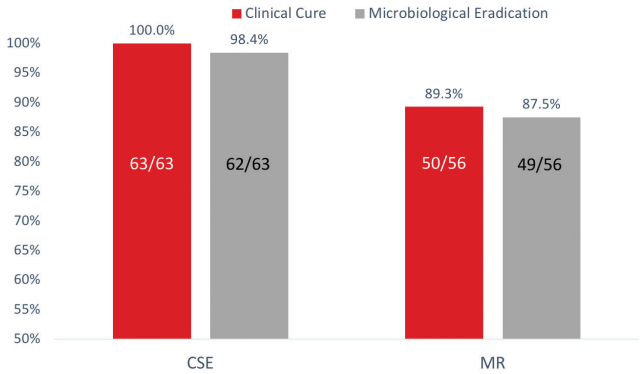
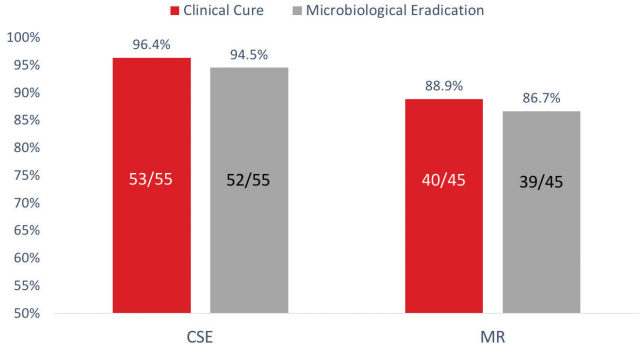


Figure 3: Outcomes in MDR Pathogens



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. Penicillin allergy is reported in 10% patients in the US Patients with penicillin allergies are treated with broader spectrum antibiotics, often leading to more antibiotic-resistant infections, including *C. difficile*, increased risk of surgical site infections, and increased healthcare costs.

Methods. After informed consent, Medical-Surgical patients with documented allergies to penicillin (P) or cephalosporins (C) were given challenge doses through a standardized 2-step protocol from June 2015 to November 2017 at our community hospital. Patients with documented IgE-mediated hypersensitivity (HSR), rash or unknown reactions were eligible. Those with anaphylaxis or Type II-IV HSR were excluded. Treating clinicians selected the antibiotic for testing guided by the protocol: 323/336 patients (96%) were challenged with C. Based on results, allergies were updated in patients' charts, noting that tolerance of cephalosporins does not preclude penicillin allergy. Charts were reviewed to determine adverse events and antibiotic narrowing, the latter adjudicated by ID specialists not directly involved in the patient's care. A cost analysis used the acquisition cost of administered antibiotics before and after testing.

Results. 336 patients (53 Medical, 283 Surgical) underwent the allergy test dose protocol: 267 with reported P allergy, 47 C allergy, 22 P+C allergy. None had a major adverse reaction. 7 patients (2%) experienced minor reactions: rash (4), throat irritation (1), urticaria (1), wheezing (1). Before testing, 321/336 were prescribed inappropriate or broad antibiotics. After challenge dose testing, the antibiotic spectrum was narrowed in 308/321 (96%). The total Pharmacy cost savings was $38,281.00 with the optimized antibiotic regimen, translating to $630 saved per patient. In Surgical patients there was a 50% cost savings.

Conclusion. Despite the frequency with which β-lactam allergies are reported, few patients had an allergy that interfered with optimal treatment when tested. This standardized protocol can be safely performed in a community hospital setting and lead to improved antibiotic choice and pharmacy cost savings.

Reference

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Disclosures. **All authors:** No reported disclosures.

1961. A Randomized Controlled Trial of the Effect of Accelerated Copper Textiles on Healthcare-Associated Infections and Multidrug-Resistant Organisms: The "Investigating Microbial Pathogen Activity of Copper Textiles" (IMPACT) Study

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Background. Healthcare-associated infections (HAIs) and multidrug-resistant organisms (MDROs) remain critically important problems. Although copper has well-described antimicrobial properties, the impact of copper-impregnated linens 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 1/12/16 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 ≥3 days and were followed prospectively for development of an HAI (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, or ceftriaxone-resistant or carbapenem-resistant Enterobacteriaceae. A patient could be included more than once for distinct ICU stays ("episodes").

Results. Among 1,021 subjects, the median age was 61 and 448 (44%) were female. Of 1,205 total episodes, 678 (56%) were in the MICU, 527 (44%) were in the SICU, 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 AutoPilotDx-Study

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Background. Differentiating between viral and bacterial etiology 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. Infection etiology 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 EVO75 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, respectively. 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 workup for febrile children and may reduce antibiotic misuse.

Disclosures. **L. Etshtein**, MeMed Diagnostics: Employee, Salary. **N. Mastboim**, MeMed Diagnostics: Employee, Salary. **A. Cohen**, MeMed Diagnostics: Employee, Salary. **E. Simon**, MeMed: Employee, Salary. **O. Boico**, MeMed Diagnostics: Employee, Salary. **L. Shani**, MeMed Diagnostics: Employee, Salary. **T. Gottlieb**, MeMed Diagnostics: Employee, Salary. **R. Navon**, MeMed Diagnostics: Employee, Salary. **K. Oved**, MeMed Diagnostics: Board Member, Employee and Shareholder, Salary. **E. Eden**, MeMed Diagnostics: Board Member, Employee and Shareholder, Salary.