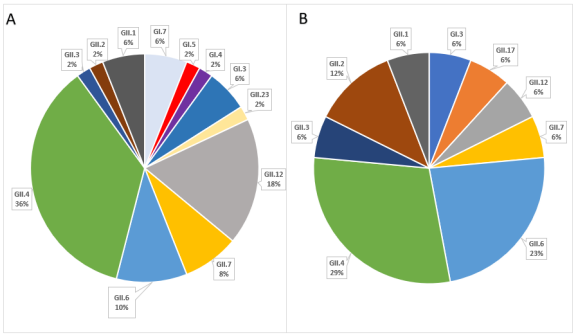
Table 3 -Laboratory Profile of Patients with Acute and Chronic Diarrhea.

Lab Parameter	Acute diarrhea (n=97)	Chronic diarrhea (n=35)	Total (n=132)	p-value
WBC K/uL, median (range)	6 (0-39.6)	4 (0.3-35.5)	5 (0-39.6)	0.038
ANC K/uL, median (range)	3.2 (0-22.8)	2.3 (0-9.6)	2.9 (0-22.8)	0.049
ANC < 500/mm^3	16 (16)	8 (23)	24 (18)	0.403
ALC K/uL, median (range)	0.8 (0-40.6)	0.7 (0-24)	0.8 (0-40.6)	0.418
ALC < 1000/mm^3	55 (57)	23 (66)	78 (59)	0.353
IgG < 400 mg/dL	9/41 (22)	14/21 (67)	23/62 (37)	0.001
Prior IVIG	17 (18)	9 (26)	26 (20)	0.296
IgA < 85 mg/dL	19/32 (59)	10/12 (83)	29/44 (66)	0.171
Serum albumin mg/dL, median (range)	3.7 (1.7-5.2)	3.2 (0.2-4.5)	3.6 (0.2-5.2)	0.002
Serum creatinine mg/dL, median (range)	0.8 (0.1-8)	0.8 (0.3-4.2)	0.8 (0.1-8)	0.853

Abbreviations – WBC, white blood cell count; ANC, absolute neutrophil count; ALC, absolute lymphocyte count; IgG, immunoglobulin G; IVIG, intravenous immunoglobulin; IgA, immunoglobulin A.

Figure 1 - Genotypic diversity in patients with acute (panel A) and chronic diarrhea (panel B)



Patients with chronic diarrhea (n=17) had a higher genotypic diversity compared to those with acute diarrhea (n=50) (Simpsons reciprocal diversity index 5.65 vs 5.18). About 50% of samples in both groups could not be genotyped.

Conclusion. In patients with cancer, CD from NoV is associated with severe immunosuppression, is refractory to therapy and can be caused by a variety of NoV genotypes/genogroups.

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701. An Open-label Phase 2a Study of Ibezapolstat, a Unique Gram-positive Selective Spectrum (GPSS) Antibiotic, for Patients with *Clostridioides difficile* Infection

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for the Ibezapolstat Study Group

Session: P-33. Enteric Infection

Background. Ibezapolstat, a DNA polymerase IIIC inhibitor, currently in Phase 2 clinical development for treatment of *C. difficile* infection (CDI). Its unique mechanism of action targets low G+C content Gram-positive bacteria primarily Firmicutes including *C. difficile*. Phase I healthy volunteer results demonstrated a favorable microbiome profile suggestive of an anti-recurrence effect. The purpose of this study was to report clinical outcomes, pharmacokinetics, and microbiome changes from this Phase 2a clinical study and to continue to test for anti-recurrence microbiome properties.

Methods. Ibezapolstat 450 mg was given twice daily for 10 days to patients with mild-moderate CDI defined as diarrhea plus a positive *C. difficile* toxin test. Test of cure was evaluated at day 12 and sustained clinical cure at day 38. Stool samples were evaluated for *C. difficile* cultures and microbiome changes.

Results. Ten subjects (female: 50%) aged 50 ±15 years were enrolled. All ten subjects experienced a clinical cure by the test of cure visit at day 12 and all 10 subjects experienced a sustained clinical cure at the day 38 visit. Ibezapolstat was well tolerated with 1 adverse event (nausea) probably related to drug. Ibezapolstat systemic exposure was minimal with no plasma level reaching 1 ug/mL any time during therapy. Ibezapolstat colonic concentrations averaged 400 ug/g stool at day 3 and greater than 1,000 ug/g by day 10 of dosing. Six of the seven available baseline stool samples grew toxigenic *C. difficile* of various ribotypes including RT078-226 and RT014-020 (Ibezapolstat MIC range: 0.25-1 ug/mL). Follow-up cultures were no growth starting from day 3 stool cultures. Microbiome changes included overgrowth of Actinobacteria and/or Firmicute phylum species while on therapy.

Conclusion. Favorable clinical efficacy and safety results were observed in ibezapolstat patients with CDI including 100% clinical cure and sustained clinical cure. These results begin to validate our approach to ibezapolstat development in that the favorable microbiome effects seen in healthy Phase 1 volunteers may be predictive of beneficial patient outcomes, including low rates of recurrence. These results support the continued clinical development of ibezapolstat.

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702. Risk Factors for Acute Gastroenteritis Among Patients Hospitalized in 5 Veterans Affairs Medical Centers, 2016–19

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Session: P-33. Enteric Infection

Background. In the United States, an estimated 179 million acute gastroenteritis (AGE) episodes occur each year. Identifying factors contributing to AGE susceptibility and severity is important to address the high disease burden of AGE among adults. The primary objective of this analysis was to identify risk factors for all-cause AGE, norovirus-associated AGE and severe AGE among hospitalized adults.

Methods. We analyzed data from 1029 inpatient AGE cases and 624 non-AGE controls enrolled prospectively from December 1, 2016 – November 30, 2019 from 5 Veterans Affairs Medical Centers (Atlanta, Bronx, Houston, Los Angeles, Palo Alto). Standardized patient interviews and medical chart abstractions were conducted to collect demographics, exposure history, and underlying medical conditions. Stool samples from participants were tested for 22 pathogens using the BioFire Gastrointestinal Panel. Severity of AGE was determined using a 20-point modified Vesikari score (MVS) and severe AGE was defined as a MVS score of ≥ 11. Multivariate logistic regression was performed to assess associations between potential risk factors and outcomes.

Results. Of the total AGE cases, 551 (54%) had severe AGE; 44 (4%) were norovirus positive. Risk factors for all-cause AGE vs. non-AGE controls included household contact with a person with AGE in the past 7 days (aOR=2.9, 95% CI:1.3-6.7), severe renal disease (aOR=3.1, 95% CI:1.8-5.2), human immunodeficiency virus (HIV) (aOR=3.9, 95% CI:1.8-8.5), and immunosuppressive therapy (aOR=5.6, 95% CI:2.7-11.7). Factors associated with norovirus positivity by univariate analysis were contact with a person with AGE outside (OR=4.4, 95% CI:1.6-12.0) and within (OR=5.0, 95% CI:2.2-11.5) the household in the past 7 days. Detection of any viral pathogen (aOR=4.0, 95% CI:1.7-9.5) was a risk factor for severe AGE.

Conclusion. Our findings suggest that inpatients with HIV or severe renal disease, on immunosuppressive therapy, or in contact with a person with AGE within household are at higher risk for all-cause AGE. Patients with these medical conditions should be monitored for AGE related hospitalizations and may benefit from targeted AGE prevention messaging.

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703. Peritoneal Coccidioidomycosis in a Pediatric Patient: An Extremely Rare Presentation and Literature Review

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Session: P-33. Enteric Infection

Background. Chronic peritonitis is an unusual manifestation of coccidiomycosis (CM) that is challenging to diagnose and manage due to its propensity for relapse. It is even more unusual to diagnose peritoneal CM in the pediatric population, with only two other cases reported in the literature.

Methods. We present the case of a previously healthy 5-year-old Filipino female in Florida who was diagnosed with peritoneal CM. After months of unintentional weight loss and worsening abdominal distention, she presented to medical care. Imaging revealed significant abdominal ascites and nodularities throughout the peritoneum. The peritoneal fluid demonstrated a lymphocytic pleocytosis and infectious workup was benign. CA125 levels were elevated, but peritoneal adenosine deaminase was within normal limits. A biopsy of the affected tissue revealed diffuse granulomas surrounding spherules that were positive on GMS and PAS staining, concerning for CM. Exposure history revealed that she was raised in California and moved to Florida one year prior to presentation. Complement fixation titers were significantly elevated at ≥ 1:512 and immunodiffusion titers were positive. A Coccidioides PCR was sent from the tissue to the Mayo clinic and was positive, and fungal cultures from the tissue grew *C. immitis/posadasii.* Immunologic workup was reassuring. She was started on oral Fluconazole with rapid resolution of her symptoms.