Aldrich (2), neuroblastoma (2) and 1 osteopetrosis and 1 medulloblastoma. Norovirus was detected by RNA RT-PCR test of stool performed by Focus Diagnostics, Cypress, Ca. The dose of Nitazoxanide was 100 mg po BID for ages 1 to 4 years, 200 mg po BID for age 4 to 11 years, and 500 mg po BID for greater than 11 years.

1 pt, 33 months post allo HSCT with normal immune studies was not treated as symptoms resolved prior to test result. All other pts clinically responded with improvements in diarrhea, nausea, and abdominal pain in 2-4 days (median 2 days). 3 pts were pre-HSCT on chemo/immunotherapy and 11 were 17 days to 34 months after HSCT. All the treated pts were on immune suppression or chemotherapy. 9 allo HSCT pts were on immunosuppression and 5 of these had GVHD at onset of symptoms. Immune suppression included tacrolimus/solumedrol (3), cellcept/solumedrol (2) plus infliximab (1), tacrolimus (1), cyclosporine (1), tacrolimus/cellcept (1). 3 pts were receiving immunotherapy (1), or chemotherapy for solid tumors (2) prior to planned HSCT. 1 pt was 10 months post auto HSCT. Clearance of stool virus was variable. 2/3 pts treated prior to HSCT became negative on stool study within 5-14 days of treatment (1 unknown duration). Among pts treated after HSCT 4/9 had persistent viral shedding, 2 received drug until death (1 adenovirus, 1 CHF) both were treated greater than 2 months, 3 with GVHD still shed virus after 6 months of treatment, and 4 are off therapy and remain negative for norovirus RNA. 1 auto HSCT pt stopped viral shedding 2 months post starting Nitazoxanide. 2 HSCT pts with clinical resolution but persistent viral shedding stopped treatment and had clinical symptoms return. These pts responded to restarting therapy within 2 days but continue to shed virus. UGI endoscopy/colonoscopy were performed in 5 pts at the time of infection, all showed inflammation/edema but no GVHD was seen on histology. Peripheral blood CD4 counts among those with persistent viral shedding ranged from <50-445/ul and for those that cleared virus 143-1222/ul.

Nitazoxanide is effective therapy for norovirus gastroenteritis in immune compromised patients. Therapy needs to be continued until stool RNA studies become negative.

359

Safety and Feasibility of Administering Lactobacillus Plantarum to Children Undergoing Myeloablative Hematopoietic Cell Transplantation (HCT)

Michael L. Nieder [1], *Elena J. Ladas* [2], *Monica Bhatia* [3], *Michael Gates* [4], *Frances Hamblin* [5], *Aleksandra Petrovic* [6], *Lu Chen* [7], *Eric Sandler* [8]. [1] *Blood and Marrow Transplantation, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL;* [2] *Division of Pediatric Hematology/Oncology/Stem Cell Transplant, Columbia University, New York, NY;* [3] *Division of Pediatric Hematology, Oncology, and Stem Cell Transplantation, Department of Pediatrics, Columbia University, New York, NY;* [4] *Pediatric Hematology/Oncology/BMT Research, All Children's Hospital Johns Hopkins Medicine, St. Petersburg, FL;* [5] *All Children's Hospital Johns Hopkins Medicine, St. Petersburg, FL;* [6] *Blood and Marrow Transplant, All Children's Hospital Johns Hopkins Medicine, St. Petersburg, FL;* [7] *Preventive Medicine, Children's Oncology Group Statistical Data Center and University of Southern California, Monrovia, CA;* [8] *Nemours Children's Clinic, Jacksonville, FL*

Myeloablative regimens are associated with prolonged periods of cachexia/anorexia, nausea/vomiting, mucositis, and compromised gut integrity (CGI). Studies suggest that CGI could increase the risk of developing acute Graft versus Host Disease (aGVHD). Preserving gastrointestinal integrity may decrease the risk of aGVHD which occurs in approximately 35% of children undergoing allogeneic HCT. Probiotics (nutritional supplements that contain viable microorganisms and confer a benefit to the host) have emerged as a possible therapeutic agent in preserving gut integrity. Animal studies have found that administration of probiotics reduced the incidence of aGVHD when compared to placebo. Clinical trials in children with HIV infections and adults receiving organ transplants have found probiotics to reduce morbidity and mortality. Prior to our Pilot Trial, probiotics had not been investigated in the HCT setting. This pilot study evaluated the safety and feasibility of probiotics administered to children undergoing allogeneic HCT. Patients received once daily supplementation with *L.plantarum* 299v (1 x10^7 CFU/kg/day) beginning on Day − 7 and continued until Day + 14. Thirty-one patients who were undergoing myeloablative allogeneic HCT were enrolled. One patient was not evaluated for safety because only one dose was given and the patient withdrew from the study. Safety: Of 30 evaluable patients, there were no cases of *Lactobacillus plantarum* bacteremia (0% (0/30) with 95% exact binomial CI (0%, 12%)). Feasibility: Of the 31 eligible patients, only one (#12) received < 50% of the dose. Therefore, 97% of the eligible patients (30/31), 95% CI (83%-100%), received at least 50% of the probiotic dose. Clostridium difficile infections were noted in 20% of the patients by Day + 100. Non-lactobacillus bacteremia was noted in 23% of evaluable patients. Three patients died before Day + 100, but no deaths were associated with lactobacillus administration. Stage 1-3 acute gastrointestinal aGVHD was noted in 22% of patients who survived to Day + 100. The overall incidence of Grades II-III GVHD was 26%. No patients had Grade 4 GVHD. Lactobacillus plantarum can safely and feasibly be administered to children undergoing myeloablative HCT.

	Evaluable Patients (N=30)
Age at enrollment (years)	
Mean(SD)	7.7 (4.7)
Median (range)	6.9 (2.2-17.3)
Age at enrollment (years)	
2-3.99	10 (33%)
4 or older	20 (67%)
Stem Cell Source	
Cord blood	5 (16%)
Marrow	21 (70%)
Marrow and cord blood	1 (3%)
PBSC	3 (10%)
Stage of Acute GI GVHD for patients alive through Day 100	
0	21 (78%)
1	2 (7%)
2	1 (4%)
3	3 (11%)
Overall Grade of Acute GVHD for patients alive through Day 100	
0	20 (74%)
2	4 (15%)
3	3 (11%)

360

Clostridium Difficile Infection in Patients Undergoing Hematopoietic Cell Transplantation. Results from the Transplantation Group at the Catholic University Hospital in Santiago, Chile

Javier Pilcante, Patricio Rojas, Daniel Ernst, Mauricio Sarmiento, Mauricio Ocqueteau, Pablo Bertin, Maria Jose Garcia, Maria Alejandra Rodriguez, Veronica Jara, ***Pablo A. Ramirez.***