Children's Healthcare of Atlanta

EMORY UNIVERSITY

2020 Pediatric Research and Career Development Symposium

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Abstracts

CLINICAL POSTERS ONLY

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Clinical Research POSTERS ONLY

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C5. Achieving Wellness After Illness for Teens (AWAIT): An App-Based Hope Intervention

Authors: Effinger, Karen E.; Williamson Lewis, Rebecca; Getachew, Betelihem; Mitra, Kuheli; Potts, Jessica; Berg, Carla; and Mertens, Ann C.

Presenting Author:	**Karen Effinger, MD, MS**; karen.effinger@emory.edu
Type:	Clinical - Poster
Poster Available:	Yes - P1
Poster Session Zoom Room Link:	Email Dr. Effinger with any questions.

BACKGROUND: Childhood cancer survivors (CCS) are at increased risk of morbidity and mortality due to treatment-related chronic conditions, which may be augmented by an unhealthy lifestyle. Hope, a positive psychological concept focused on goal-directed thinking, has been associated with engaging in health-promoting behaviors. Achieving Wellness After Illness for Teens (AWAIT) is a behavioral intervention focused on increasing hope in order to improve quality of life (QoL) and health-promoting behaviors in adolescent CCS.

OBJECTIVES: To test the feasibility and acceptability of the AWAIT intervention.

METHODS: CCS aged 13-17 years and >3 months from therapy completion were randomized 2:1 to the AWAIT intervention or attention control stratified by diagnosis and time since therapy completion (<3 years or ≥3 years). Those randomized to the 8-week AWAIT intervention received access to weekly coaching calls to discuss progress towards patient-selected goals and a mobile app with weekly video modules, practice exercises and behavioral and mood tracking. Participants completed a modified Children's Hope Scale, PedsQL v4.0 and assessments of diet and physical activity at baseline and 2 months. Intervention acceptability was measured at the end of intervention. Differences between groups were assessed using Fisher's exact and Wilcoxon Rank Sum tests. Changes within the groups were evaluated using McNemar's and paired t-tests.

RESULTS: Overall, participants (n=48) were median age 15 years, 54% male and 42% leukemia/lymphoma CCS with no differences between the groups. Twenty participants (63%) completed intervention activities in at least 7 of 8 weeks (prior to COVID19 pandemic 20/28 [71%], after pandemic 0/4 [0%]). Currently 34 participants (71%; AWAIT 21/32 [66%], Control 13/16 [81%]) have completed the 2-month evaluation. Compared to baseline, there was no change in hope or QoL in either arm. AWAIT participants decreased hours of television (p=0.08) and other screen time (p=0.03). Most participants (86%) were satisfied with the intervention; 95% would recommend it to another CCS; 76% felt the information was relevant; and 90% felt the coaching calls were helpful.

CONCLUSIONS: Implementation of the AWAIT intervention is feasible and adolescent CCS found it acceptable. Future analyses will evaluate the ideal time from completion of therapy for AWAIT participation.

Poster Presentations: C5 - C16 (In Order by Presenting Author Last Name)

C6. Cobalamin Deficiency in Children With Sickle Cell Disease: An Unanticipated Risk for Use of Nitrous Oxide Gas

Authors: Krieger, Rachel; Brown, Lou Ann; Dampier, Carlton; Harris, Frank; Manoranjithan, Shaminy; Mendis, Reshika; Cooper, Nicholas; Figueroa, Janet; and Morris, Claudia R.

Presenting Author:	**Rachel Krieger, DO**; rkriege@emory.edu
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Poster Session Zoom Room Link:	**Visit Krieger Zoom Room**

BACKGROUND: The prevalence of cobalamin (B12) deficiency in children with sickle cell disease (SCD) is unknown, however B12-deficiency has been reported in 18% of SCD-adults versus 10% in patients without SCD (Kamineni 2006). A higher frequency of B12-deficiency in SCD may be due to higher rates of hemolysis, erythrocyte turnover and folate deficiency. Nitrous oxide gas is commonly used for dental procedures and is standard therapy for sickle-related vaso-occlusive-pain in France. Recently we reported acute resolution of sickle-related priapism with nitrous therapy (Greenwald 2019). Although nitrous is generally considered safe, patients with B12-deficiency can experience serious neurologic complications, as nitrous impacts cobalamin metabolism. This study evaluates B12 status in children with SCD.

METHODS: Urine samples were prospectively collected as part of a randomized-controlled trial of parenteral arginine therapy in children with SCD requiring admission for treatment of moderate-to-severe pain. Urine methylmalonic acid (MMA) level corrected for creatinine (Cr) reflecting B12 status, was measured via mass spectrometry. B12 deficiency was defined as MMA/Cr of 2.2-5, while severe B12 deficiency was reflected by MMA/Cr>5; MMA/Cr of 1.8-2.2 were considered possibly deficient while an MMA/Cr<1.8 was defined as normal B12 status.

RESULTS: Ninety-four children with SCD and pain were enrolled. Median age was 13 years (Q1, Q3: 10, 16), 51% female, 68% Hb-SS, and 71% were on hydroxyurea (Table 1). Twenty-six percent (24/94) of patients demonstrated evidence of B12 deficiency, 25% of whom demonstrated a severe B12 deficiency (6/24). Another 7% (7/94) demonstrated possible deficiency. There were no statistically significant differences in age, gender, SCD genotype, hemoglobin levels, MCV or hydroxyurea use in those with and without B12 deficiency.

CONCLUSIONS: Approximately a quarter of children with SCD demonstrated evidence of B12-deficiency, which is higher than expected. Cobalamin deficiency is associated with a constellation of clinically relevant symptoms that may be overlooked in patients with SCD. In addition, these patients may be uniquely at risk for adverse neurological sequelae when receiving treatment with nitrous oxide gas. B12-deficiency is easily corrected with an intramuscular injection of methylcobalamin. Although further study in a larger cohort is needed, screening for B12 deficiency may be warranted in patients with SCD.

Poster Presentations: C5 - C16 (In Order by Presenting Author Last Name)

C7. Cerebral Effect of Blood Transfusion in Children with Sickle Cell Disease

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Chronic blood transfusion is the current standard therapy to reduce the risk of primary and recurrent stroke in children with sickle cell disease (SCD). Despite the beneficial effects of transfusion, it poses a long-term burden to patients and their family due to significant risks. Thus, individualized monitoring of response to transfusion may help optimize the therapy and further mitigate risk of infarctions. In this study, we present low-cost, portable and non-invasive optical techniques that can quantify tissue-level cerebral blood flow (diffuse correlation spectroscopy, DCS) and oxygenation extraction fraction (frequency-domain near infrared spectroscopy, FDNIRS) and aim to determine if FDNIRS/DCS can detect changes in cerebral hemodynamic/metabolic status that occur in response to transfusion.

To date, we have recruited six children with SCD undergoing chronic transfusion therapy at CHOA. To assess the effects of transfusion, brief (< 5 min) FDNIRS/DCS measurements were made immediately prior to the start and end of transfusion. For each FDNIRS/DCS measurement, the optical sensor was manually held over patients' forehead to acquire blood flow index (BFI) and oxygen extraction fraction (OEF). Oxygen metabolism (CMRO2) was also calculated using BFI and OEF.

One patient data was excluded due to poor data quality. Of the remaining 5 patients, OEF, BFI and CMRO2 decreased after transfusion in 4 patients by a median of -30.0%, -6.4% and -10.2% , respectively. Compared to results of a previous MRI study that quantified both OEF and CBF response to transfusion in a similarly aged cohort, our FDNIRS-measured OEF decrease is comparable. However, the DCS-measured BFI decrease is more prominent than previously reported (30% vs. 9%). Moreover, CMRO2 decreases after transfusion while MRI study has reported no difference between before and after transfusion. The enhanced sensitivity of BFI to CBF in sickle cell disease was reported in our recent study and is likely attributed to the confounding influences of hematocrit.

Our results demonstrate that hybrid optical spectroscopies are sensitive to the expected decreases of CBF and OEF after transfusion. These data suggest that optical technique may be a promising bedside tool for real-time monitoring of therapeutic efficacy, which ultimately lead to personalized monitoring.

Poster Presentations: C5 - C16 (In Order by Presenting Author Last Name)

C8. Quantifying the Difference in Risk of Adverse Events by Induction Treatment Regimen in Pediatric Acute Lymphoblastic Leukemia

Authors: West, Zachary; Castellino, Sharon; Monroe, Caitlin; Thomas, Amanda; McCracken, Courtney; and Miller, Tamara

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Poster Available:	Yes - P2
Poster Session Zoom Room Link:	**Visit Miller Zoom Room**

BACKGROUND: Despite recent advancements, children receiving induction therapy for Acute Lymphoblastic Leukemia (ALL) still experience adverse events (AEs). This study compared induction morbidity by treatment regimen (3-drug vs. 4-drug).

METHODS: This retrospective cohort included patients with B- or T-cell ALL ages 1-21 years who received induction chemotherapy at Children's Healthcare of Atlanta between January 2010 and May 2018. Manual chart abstraction identified and graded 20 clinically-relevant AEs, readmissions, and ICU admissions. Outcomes were compared across induction regimens in multivariate analyses using Cox proportional hazard ratios (HR) with 95% confidence intervals (CI).

RESULTS: Among 486 eligible patients, 378 (77.8%) experienced at least one AE during induction. Rates were comparable between therapy groups. In adjusted analyses, The adjusted risks of sepsis (HR=2.16, 95% CI: 1.11, 4.19), hypoxia (HR 2.08, 95% CI: 1.03, 4.18), hyperbilirubinemia (HR 2.48, 95% CI: 1.07, 5.74), hyperglycemia (HR 2.65, 95% CI: 1.29, 5.42), thromboembolic event (HR 4.50, 95% CI: 1.30, 15.6), and hyponatremia (HR 7.88, 95% CI: 1.26, 49.4) were significantly higher in the 4-drug group. The risk of hypertension was higher in the 3-drug group (HR 0.67, 95% CI: 0.46, 0.96). There were no differences in hospital readmission or ICU admissions rates, but patients receiving 4-drug induction had greater total number of inpatient days (12 days, interquartile range (IQR) 5-20 vs. 4 days, IQR 3-8; $p<0.0001$).

CONCLUSIONS: Patients receiving 4-drug induction therapy were more likely to experience clinically significant AEs and had significantly longer hospitalizations. This information can inform supportive care practices during ALL induction and guide patients and families.

C9. Evaluation of Changes in Use of Methadone and Benzodiazepines Following Implementation of an Analgosedation Protocol in the NICU

Authors: Ocampo, Claudia; Hamrick, Shannon; and David, Kaitlin

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Neonatal research has focused its attention on the potential long-term side effects of analgesics and sedatives on child development. New evidence points at adverse neurodevelopmental outcomes and brain injury caused by certain drugs such as benzodiazepines, ketamine and opioids. Notably, medications which act via the NMDA and GABA receptors have been shown in animal models to be implicated in affecting synapse formation as well as neuroapoptosis in developing brains, leading to worse neurocognitive outcomes later in life. This Quality Improvement project studies an analgesia/sedation protocol created with the purpose of decreasing the prevalence of neurotoxic agents used to manage pain and agitation in post-surgical patients in our NICU.

KEYWORDS: Analgosedation, NICU, dexmedetomidine, methadone, morphine, benzodiazepines

C10. Investigating the Contribution of Unique Risk and Protective Factors Associated With Health-Related Quality of Life in Newly Diagnosed Pediatric Inflammatory Bowel Disease

Authors: Reed, Bonney; Shih, Sharon; Cushman, Grace; and Kugathasan, Subra

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OBJECTIVE: Health-related quality of life (HRQOL) is typically examined from a deficit standpoint, meaning that little is known about factors associated with resilient outcomes in pediatric illness samples. The aim of the current study was to use a risk and resilience framework to investigate demographic, disease, and temperamental factors associated with child and parent-report of health-related quality of life in youth newly-diagnosed with inflammatory bowel disease (IBD).

METHODS: Participants included 54 caregivers and 56 youth ages 8 to 17 diagnosed with IBD who each completed ratings of the child's HRQOL using the IMPACT-III, a disease-specific measure. Parents rated their child's emotional reactivity, conceptualized as a risk factor, and adaptability, conceptualized as a protective factor. Disease symptoms were rated by youth, and physician global assessment of disease activity was obtained.

RESULTS: HRQOL was rated lower by children and their parents as self-reported disease symptoms and parent-rated emotional reactivity increased. Conversely, total HRQOL was higher for children with higher parent-ratings of adaptability. In multiple regression analyses, higher levels of adaptability along with male sex and lower child-reported disease symptoms were associated with higher child, $R2 = .73$, $F = 31.33$, $p < .001$, and parent-reported, $R2 = .43$, $F = 9.01$, $p < .001$, HRQOL.

CONCLUSIONS: Attention should be given to protective as well as risk factors associated with differential outcomes in HRQOL for youth newly-diagnosed with IBD. By focusing on protective factors, a strengths based approach may offer patients the opportunity to maximize HRQOL when facing a new IBD diagnosis.

Poster Presentations: C5 - C16 (In Order by Presenting Author Last Name)

C11. The Role of Pre-Extubation Caffeine on Extubation Success in Preterm Infants

Authors: Salem, Anand; and Dryer, Rebecca; and Saroha, Vivek; and Patel, Ravi

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BACKGROUND: In the neonatal intensive care unit, caffeine is commonly administered prior to planned extubation, and its use is associated with increased extubation success. Despite the broad use of caffeine, there is no established optimal time for its administration in the peri-extubation setting. This leads to some infants receiving caffeine immediately prior to planned extubation while others may receive caffeine 20 or more hours before extubation.

HYPOTHESIS: Infants who receive caffeine more proximally to extubation will demonstrate greater odds of extubation success compared to those that receive caffeine further from extubation.

METHODS: We conducted a retrospective observational cohort study at a single level III unit of very low birth weight infants born between August 2008 and July 2017. We evaluated the association between the timing of caffeine administration prior to extubation and extubation failure (defined as needing re-intubation within 1 week of extubation) using multivariable logistic regression. We specified timing of caffeine using tertiles and adjusted for confounding variables, including gestational age, weight at extubation, caffeine dose, and pH prior to extubation.

RESULTS: We evaluated 205 infants, with a mean gestational age of 26.8 weeks (SD 2.1) and a mean weight at extubation of 987 grams (SD 292). The median pre-extubation caffeine dose was 5.6 mg/kg (IQR 5.0-20.0 mg/kg). Extubation failure occurred in 67 infants (33%). There was no significant difference in extubation failure among caffeine groups, with an incidence of 32%, 37% and 29% in the 1st, 2nd and 3rd tertiles (with relation to caffeine timing prior to extubation) respectively. Gestational age at birth was the most significant factor associated with extubation failure ($P<0.001$).

CONCLUSION: Our study does not support the hypothesis that use of caffeine more proximal to extubation improves extubation success in very low birth weight infants.

C12. Racial and Socioeconomic Disparities in Non-Accidental Trauma Screening of Infants Presenting With Simple Skull Fractures

Authors: Sooknarine, Hayley; and Richer, Edward

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AIMS: 1) Evaluate NAT screening practices of young infants presenting with apparently isolated skull fractures, and 2) to identify which infants have a high level of concern for NAT.

METHODS: This was a retrospective chart review. Inclusion criteria were patients under 6 months of age presenting to 2 metropolitan Pediatric trauma centers (academic and non-academic) with simple skull fractures between January 2014 and December 2016. Patients were excluded if there was high level of concern for NAT on presentation.

The study population was divided into 2 groups: infants undergoing skeletal surveys (SS) versus not. Data analysis was performed using $\chi 2$ and odds ratio (OR) calculations.

RESULTS: 157 infants were included. 64 infants (40.8%) underwent NAT screening with skeletal survey, and 1 of these surveys showed additional fractures (1.6% of those screened). The infant with the positive SS had no history to explain the fracture.

66% of black infants were screened, 31.4% of white infants were screened, and 25% of Asian/other infants were screened ($P<0.001$). The academic hospital screened 53% of presenting infants, while the non-academic hospital screened 33% ($P<0.001$). Over 2 times more black infants were screened at the academic hospital vs. 1.33 times more were screened at the non-academic hospital ($P = 0.05$). Conversely, only 26% of white infants were screened at the non-academic hospital compared to 41.4% at the academic hospital ($P<0.001$).

87% of black infants were publicly insured versus 47.7% of white infants and 79.2% of Asian/other infants. Of the publicly insured, 29/41 black infants (70.7%) were screened versus 20/41 white infants (48.8%). 4/19 (21%) Asian/other publicly insured patients were screened. The odds ratio for being screened if publicly insured was 4.517 (CI: 2.0993 to 9.7191, $P=0.0001$). Both hospitals saw lower numbers of privately insured patients; however, a smaller proportion of privately insured patients were surveyed at the non-academic hospital (15.8%) compared to the academic hospital (27.8%) ($P<0.0001$).

CONCLUSION: There are both racial and socioeconomic disparities in screening for this injury with low specificity but potential nonetheless for physical abuse. There is a need for appropriate protocols to reduce disparities for NAT screening of patients.

C13. Impact of Gut Microbiome Changes on Hematopoietic Stem Cell Transplantation Outcomes in Children

Authors: Teherani, Mehgan; Pratte, Zoe; Banksota, Samridhi; Gulick, Dalia; Djeddar, Naima; Horan, John Gibson, Gregory; and Qayed, Muna

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BACKGROUND: In adults undergoing allogeneic hematopoietic stem cell transplantation (allo-HSCT), higher microbiome diversity results in reduced bloodstream infections (BSIs) and improved overall survival. We are investigating the use of rifaximin prophylaxis (ppx) in pediatric allo-HSCT in an ongoing trial to improve microbiome diversity and decrease BSI. Here we present our preliminary results.

METHODS: This ongoing study utilizes a prospective treatment group on rifaximin, with a retrospective control or children undergoing HCT for hematologic malignancy. The control cohort did not receive prophylactic antibiotics while the treatment cohort received rifaximin ppx through 28 days post-HSCT (D+28). BSIs caused by mucosal barrier injury and considered derived from the gut from blinded review were included. Most patients received piperacillin-tazobactam at the onset of fever. Timing of systemic antibiotics was categorized as none, early (before D0), and late (after D0). Primary outcome was death by D+180 post-HSCT. We performed 16S rRNA sequencing of weekly stool samples obtained at baseline, day 0 to D+28 and calculated the Shannon-index of diversity using QIIMEII.

RESULTS: We have enrolled 21 rifaximin patients with clinical outcomes. Twelve rifaximin patients and 61 controls were included in the microbiome analysis. Median age of the patients was 9 years (range 1-20). 41% Caucasian, 21% Hispanic, and 29% Black race.

We observed a significant drop in diversity for patients who received antibiotics early (Mean=2.7, SE=0.2) compared to late (M=3.7, SE=0.1), with highest diversity for patients who did not receive antibiotics (M=4.1, SE=0.4); p=0.0041). Death at D+180 was associated with a lower diversity at D+28 that patients who survived (M = 2.9 versus 1.73, p=0.04. 14% of the controls developed a BSI within the first 30 days post-HSCT. Early analysis of BSI in the rifaximin group shows only one gut BSI out of 21 patients.

CONCLUSIONS: We have shown a significant correlation between engraftment (D+28) microbiome diversity and 6-month overall survival. Early antibiotic exposure in our cohort was detrimental to microbiome diversity. Approaches to preserve microbiome diversity while preventing BSI are likely to improve transplant outcomes. Our ongoing trial using rifaximin ppx will provide data regarding this approach.

Poster Presentations: C5 - C16 (In Order by Presenting Author Last Name)

C14. Use of a Novel Human Milk-Based Fortifier in Term Infants With Surgical Congenital Gastrointestinal Disorders Improves Growth at Discharge

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BACKGROUND/PURPOSE: Human milk (HM) is the ideal source of nutrition for all infants, but alone is insufficient in protein and calories for infants with surgical congenital gastrointestinal disorders (S-CGD). Currently, the only option for term infants is fortification with formulas which have been associated with increased risk of necrotizing enterocolitis (NEC) in the preterm population and may contribute to the high rates of NEC in those infants with congenital gastrointestinal disorders. The purpose of this study is to demonstrate the safety and efficacy of a novel HMBF designed for term infants with S-CGD.

METHODS: This is a cohort of an ongoing multi-center, prospective, case-control, open-label comparative effectiveness trial of approximately 150 infants with qualifying surgical intestinal disorders (gastroschisis, omphalocele and intestinal atresias). Patients were fed an exclusive human milk diet of mother's own milk (MOM), and pasteurized donor human milk (PDHM, Prolacta Bioscience) fortified with a novel HMBF (PBCLN-002, Prolacta Bioscience) formulated for the term infant. The first 26 term infants enrolled in this trial were evaluated for safety and efficacy of PBCLN-002 compared to a cohort of patients fed diets containing MOM and formula. The retrospective cohort was matched based on diagnosis, sex, birthweight and gestational age.

RESULTS: Baseline characteristics were well matched between the groups. There were no adverse events in the PBCLN group and no significant effect on feeding tolerance, interruptions or maximum direct bilirubin. Infants receiving PBCLN-002 grew faster in terms of weight, length and comparative head circumference velocity; however, these were not statistically significant. Discharge weight and length were significantly higher for the PBCLN group as compared to the retrospective cohort. Adjusting for baseline using a basic analysis of covariance model, these differences remained significant for discharge weight ($p=0.02$) and discharge length ($p=0.003$).

CONCLUSIONS: In this small cohort of patients with surgical congenital gastrointestinal disorders, PBCLN-002 demonstrates safety and efficacy by increased growth at the time of discharge. The non-significant differences in daily weight gain and growth velocities between these two groups may reflect the small sample size and differences in parenteral nutrition support during the early phases of surgical recovery.

Poster Presentations: C5 - C16 (In Order by Presenting Author Last Name)

C15. Parent Psychological Distress and Chronic Pain in Pediatric Sickle Cell Disease

Authors: Woodward, Kerri; Sil, Soumitri; Johnson, Yelena; Dampier, Carlton; and Cohen, Lindsey

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INTRODUCTION: Pediatric chronic pain can be associated with increased parenting stress and poor emotional and family functioning in pediatric sickle cell disease (SCD). Parenting stress has been associated with poorer child pain-related outcomes, including increased disability and reduced quality of life. This study aimed to investigate how parenting stress, parent emotional functioning, and family functioning 1) were associated with child outcomes and 2) differed based on the chronicity of pediatric SCD pain.

METHODS: Children and adolescents with SCD (n=77; Mage=14.24, SD=2.48) and their parents were recruited from comprehensive SCD clinics; 93.5% (n=72) completed study procedures. Youth were primarily African American (93.2%), female (55.8%), with hemoglobin type HbSS (72.7%); parents were mostly female (90.9%). Youth were classified as having chronic pain if they reported ≥15 pain days/month for ≥ 6 months (n=32, 41.6%). Youth with episodic pain reported <15 pain days/month (n=40, 51.9%). Parents completed the Pediatric Inventory for Parents, Center for Epidemiological Study – Depression Scale, Patient Health Questionnaire – Generalized Anxiety Disorder, and Family Assessment Device. Youth completed the Pediatric Quality of Life Inventory – SCD and Functional Disability Inventory.

RESULTS: Parenting stress frequency, parenting stress difficulty, and parent anxiety were significantly correlated with child functional disability and quality of life (all $p<0.05$). Parents of children with chronic SCD pain reported significantly more frequent parenting stress ($p<0.01$), more difficult parenting stress ($p<0.01$), and more symptoms of anxiety ($p=0.04$) than parents of youth with episodic SCD pain. Parent depressive symptoms and family functioning did not significantly differ by pain groups ($p>0.10$).

CONCLUSIONS: Results indicate that pediatric pain chronicity in sickle cell disease is related to increased parenting stress, and increased parenting stress and anxiety are associated with worse child outcomes. Future studies are needed to evaluate potential parent-focused interventions for managing stress and anxiety in the context of chronic pediatric pain.

Poster Presentations: C5 - C16 (In Order by Presenting Author Last Name)

C16. Development and Validation of the HIV Adolescent Readiness for Transition Scale (HARTS) in South Africa

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Poster Available:	Yes - P9
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BACKGROUND: Adolescents living with perinatally-acquired HIV have low rates of viral suppression after transition to adult care. In South Africa, timing of transition to adult care is often arbitrary and occurs with little or no preparation.

MATERIALS AND METHODS: We iteratively created the HIV Adolescent Readiness for Transition Scale (HARTS) by conducting focus groups with healthcare providers (n=11), and adolescents (n=20 in 2 groups) before transition to adult care. We then administered the HARTS questionnaire to 131 adolescents to determine the psychometric properties of the questionnaire. Based on item response theory, we used generalized linear equation models with the overall score and with the individual domains. We correlated the responses to self-described transition readiness and age using liner regression. We then validated the scale by prospectively administering it to 199 different adolescents in a separate setting prior to their transition and measured viral suppression (viral load <200 copies/ml) one year after transitioning to adult clinic. We evaluated transition outcomes using multivariable logistic regression based on the continuous HARTS.

RESULTS: We identified 4 domains that were important to HIV transition readiness: disclosure, health navigation, self-advocacy, and health literacy. Fifteen of the sixteen questions were significantly associated with their domain and overall HARTS score. Positive correlations with self-described transition readiness were significant with the overall HARTS score ($p<0.0004$) and domains of health navigation ($p=0.028$), self-advocacy ($p=0.0014$), and health literacy ($p=0.0023$). Scores and domains increased with age but not significantly. In the prospective validation, the total 15 question HARTS score ranged from 2 to 56. For participants receiving first-line antiretroviral therapy, each 10-point increase in HARTS score was associated with 0.53 odds of viral failure ($p=0.001$; 95% CI 0.36 – 0.77) in our multivariable model adjusting for age at antiretroviral therapy initiation, sex, disclosure status, drug and alcohol use, peer support, and self-esteem. Age alone at time of transition was not significantly associated with viral suppression 12 months after transition to adult care.

CONCLUSION: The HARTS questionnaire is a validated scale that can be used to determine which adolescents may require additional interventions prior to transitioning to adult care to improve viral suppression.

Posters

All clinical research posters provided by abstract authors are available in the following pages. Available posters are labeled P1 - P9.

Achieving Wellness After Illness for Teens (AWAIT): An App-Based Hope Intervention

Karen E. Effinger, MD, MS;[1,2] Rebecca Williamson Lewis, MPH;[2] Betelihem Getachew, MPH;[3] Kuheli Mitra, MPH;[3] Jessica Potts, MPH;[3] Carla J. Berg, PhD, MBA, LP;[4] Ann Mertens, PhD[1,2]

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BACKGROUND

- Childhood cancer survivors (CCS) are at increased risk of morbidity and mortality due to treatment-related chronic conditions, which may be augmented by an unhealthy lifestyle.
- Hope, a positive psychological concept focused on goal-directed thinking, has been associated with engaging in health-promoting behaviors.
- Achieving Wellness After Illness for Teens (AWAIT) is a behavioral intervention focused on increasing hope in order to improve quality of life (QoL) and health-promoting behaviors in adolescent CCS.

PURPOSE

- To test the feasibility and acceptability of the AWAIT intervention in CCS.

METHODS

Patient population

- Age 13-17 years
- >3 months from completion of cancer therapy

Randomization

- 2:1 AWAIT intervention vs. attention control
- Stratified by time from therapy completion
  - Early Survivor: 3-36 months off-therapy
  - Late Survivor: >36 months off-therapy
- Stratified by tumor type
  - Leukemia/Lymphoma
  - Brain Tumor
  - Other Solid Tumor

AWAIT Intervention

- 8 weeks
- Mobile app: 8 modules with videos and practice exercises, tracking of mood and healthy lifestyle behaviors, healthy lifestyle tipsheet
- Weekly Coaching Calls to review material and apply new skills

Assessments

- Baseline, 2 months (end of intervention), 4 months
- Revised Children's Hope Scale, PedsQL v4.0, Youth Risk Behavior Surveillance System questions, Acceptability metrics

Analysis

- Fisher's exact, Wilcoxon Rank Sum tests were used to assess differences between groups.
- Paired t-tests and McNemar's tests were used to evaluate changes within groups.

Implementation of the AWAIT intervention is feasible and acceptable to adolescent survivors of childhood cancer.

Survivors receiving the AWAIT intervention showed improvement in aspects of hope specific to goal-directed thinking, increased physical activity and decreased screen time.

RESULTS

Table 1: Demographic & Treatment Characteristics by Treatment Arm

	AWAIT N=32	Control N=16	P-value
Female sex, n (%)	16 (50.0)	6 (37.5)	0.54
Age at enrollment, yrs (med, range)	15 (13-17)	15.5 (13-17)	0.78
Diagnosis, n (%)			0.92
Leukemia/Lymphoma	13 (40.6)	8 (50.0)	
Brain Tumor	6 (18.8)	3 (18.8)	
Other Solid Tumor	13 (40.6)	5 (31.3)	
Age at diagnosis, yrs (med, range)	10 (0-16)	11.5 (1-15)	0.37
Time from therapy completion			1.0
Early Survivor	16 (50.0)	8 (50.0)	
Late Survivor	16 (50.0)	8 (50.0)	

Table 2: Feasibility of the Intervention

	AWAIT N=32	Control N=16
Completion of intervention activities in at least 7 out of 8 weeks	21/32 (66%)*	N/A
Completion 2-month evaluation	21/32 (66%)	13/16 (81%)
Completion 4-month evaluation*	15/24 (63%)	12/14 (86%)

* Pre-COVID19: 20/28 (71%); Post-COVID 19 0/4 (0%)

¥4-month evaluations are still ongoing. Results based on patients who have received 4-month evaluation

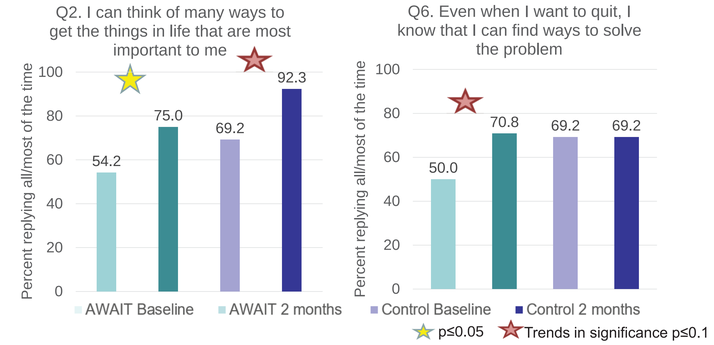
Acceptability

- 72% very/quite satisfied with AWAIT
- 92% would recommend AWAIT to another survivor
- AWAIT participants who felt components were helpful:
  88% coaching, 75% videos, 63% tracking mood, 58% tracking behaviors, 54% practice exercises

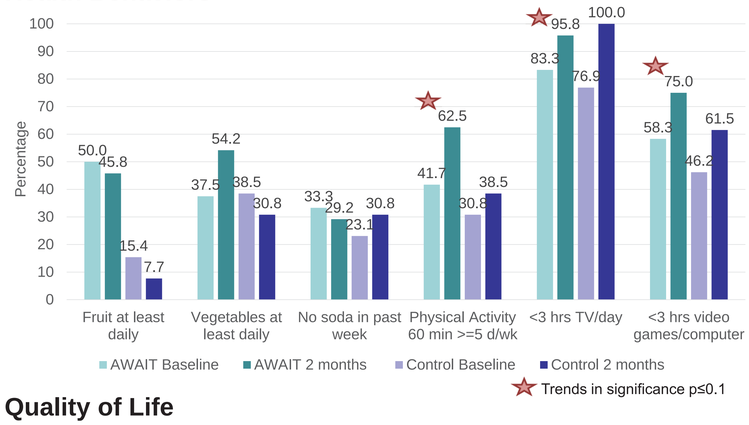
RESULTS

Hope

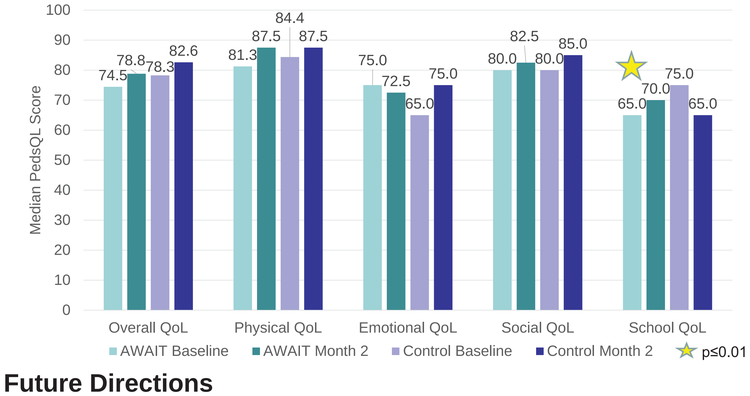
- No change in overall Hope Score (Scale 0-5) for either group (AWAIT 3.8 to 3.9, p=0.13, Control 3.6 to 3.8, p=0.28); however, changes specific in goal-directed thinking were seen.



Health Behaviors



Quality of Life



Future Directions

- We will evaluate for persistence of changes at 2 months after the end of intervention.
- We will compare intervention effectiveness in early and late survivors to determine the ideal time for AWAIT participation.

This work was funded by the Woodruff Health Sciences Synergy Award and the Aflac Pilot Grant.

Quantifying Differences in Risk of Adverse Events by Induction Treatment Regimen in Pediatric Acute Lymphoblastic Leukemia

Zachary West, MD,[1] Sharon M. Castellino, MD, MSc,[1,2] Caitlin Monroe, Ms,[2] Amanda Thomas, MS,[1] Courtney McCracken, PhD,[1] Tamara P. Miller, MD, MSCE[1,2]
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PURPOSE

- To describe the overall incidence of clinically significant adverse events (AEs), hospital readmission, and ICU admission during the first treatment course (Induction) for *de novo* pediatric Acute Lymphoblastic Leukemia (ALL).
- To compare morbidity by treatment regimen for children during Induction.
- To identify if rates of hospital readmission or ICU admission differed by treatment regimen during Induction.

BACKGROUND

- Advances in therapy for pediatric ALL have led to 5-year survival rates of up to 94%.
- Despites advances, children and adolescents experience AEs during all courses of therapy.
- AEs are identified and graded in pediatric oncology using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) system.
- Treatment regimen during induction is based on NCI risk at diagnosis:
  - NCI High Risk (HR): ≥10 years of age and/or WBC ≥50,000/uL
  - NCI Standard Risk (SR): 3-drug regimen - steroid, vincristine and asparaginase
  - NCI-HR: 4-drug regimen - steroid, vincristine, asparaginase and anthracycline
- There are no predictors of the risk of AEs during Induction.
- There are currently no evidence-based guidelines regarding length of initial hospitalization after diagnosis.

METHODS

- Retrospective cohort study of patients ages 1-21 years with B- or T-cell ALL diagnosed between 1/1/10 and 5/15/18 at Children's Healthcare of Atlanta.
- Developed *a priori* algorithms to identify and grade 20 clinically-significant AEs based on CTCAE v5 definitions.
- Performed manual chart abstraction to capture presence and highest grade of each AE during Induction, hospitalization dates and ICU admissions.
- Chart abstraction of chemotherapy administered was used to characterize Induction treatment regimen as 3-drug or 4-drug.
- Extracted demographic data from the electronic medical record.
- Risk of AEs was compared between Induction treatment regimens in unadjusted and adjusted models using Cox proportional hazard ratios (HR) with 95% CI.
  - Multivariable analyses adjusted for race, ethnicity, body mass index, sex, and central nervous system disease status at diagnosis

RESULTS

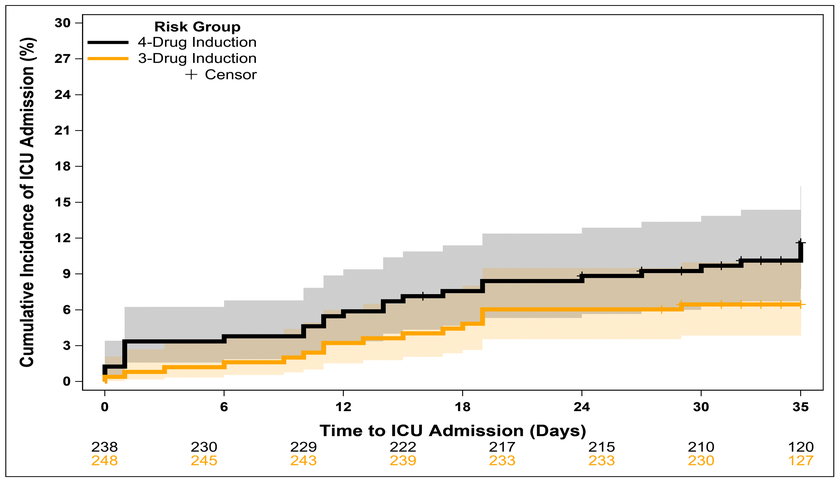
- Of 486 eligible patients, 248 received 3-drug and 238 received 4-drug induction.
  - 45% Female, 58.8% White, 22.8% Hispanic
- Overall, 77.8% (n=378) patients experienced at least one AE.
- Unadjusted risk of multiple AEs differed significantly by treatment regimen. (Table)
- Multivariable analyses:
  - 4-drug: Higher risk of sepsis, hypoxia, hyperbilirubinemia, hyperglycemia, and thromboembolic event
  - 3-drug: Higher risk of hypertension and hepatotoxicity
- Total number of inpatient days differed significantly by treatment regimen (4-drug: 12 days, 3-drug: 4 days, p<0.0001).
- There was no significant difference in rates of hospital readmission (p=0.062) or ICU admission (p=0.117, Figure) by treatment regimen.

Rates and Risks of Clinically Significant AEs by Treatment Regimen

AE	3-drug Induction n (%)	4-drug Induction n (%)	Hazard Ratio[$] (95% CI)	p-value
Fever	61 (24.6)	58 (24.8)	1.00 (0.71, 1.42)	0.991
Infection	81 (32.7)	81 (34.4)	1.05 (0.77, 1.42)	0.775
Sepsis	18 (7.26)	28 (11.8)	1.66 (0.92, 3.00)	0.091
Hypotension	18 (7.26)	26 (10.9)	1.49 (0.82, 2.72)	0.19
Hypertension	73 (29.4)	73 (30.7)	1.04 (0.77, 1.42)	0.786
Hypoxia	14 (5.65)	29 (12.2)	2.24 (1.19, 4.22)	**0.012**
ARDS	0 (0.00)	3 (1.26)	N/A	0.078
Pancreatitis	5 (2.02)	8 (3.36)	1.67 (0.55, 5.10)	0.369
ALT elevation	79 (31.8)	54 (22.7)	0.70 (0.50, 0.99)	**0.041**
AST elevation	21 (8.47)	23 (9.66)	1.15 (0.64, 2.06)	0.646
Hyperbilirubinemia	11 (4.44)	28 (11.8)	2.74 (1.36, 5.49)	**0.005**
Hyperglycemia	12 (4.84)	43 (18.1)	3.91 (2.09, 7.31)	**<0.001**
Thromboembolic Event	3 (1.21)	21 (8.82)	7.58 (2.27, 25.4)	**0.001**
Stroke	2 (0.81)	2 (0.84)	1.05 (0.15, 7.40)	0.908
Neuropathy	22 (8.87)	11 (4.62)	0.51 (0.25, 1.05)	0.066
Seizure	4 (1.61)	6 (2.52)	1.57 (0.45, 5.55)	0.481
Anaphylaxis	0 (0.00)	2 (0.84)	N/A	0.148
Hyponatremia	1 (0.40)	8 (3.36)	8.47 (10.6, 67.4)	**0.044**
Ileus	1 (0.40)	5 (2.10)	5.25 (0.62, 44.7)	0.129
Constipation	0 (0.00)	3 (1.26)	N/A	0.076
Any AE	187 (75.4)	191 (80.3)		0.199

[$] Reference group: 3-drug regimen
AEs ≥ Grade 2: fever, infection, hyperglycemia, thromboembolism; all other AEs were ≥ Grade 3

Time to First ICU Admission by Treatment Regimen



CONCLUSIONS

- Patients receiving 4-drug Induction therapy are more likely to experience clinically significant AEs.
- Patients receiving 4-drug Induction are likely to require a higher total number of hospital than those receiving 3-drug regimens.
- While the lack of difference in hospital readmission rates or ICU admissions may not support longer initial hospitalizations for patients receiving 4-drug Induction, the increased risk of severe AEs indicates strategies to reduce morbidity are needed for this group.

Funding : NCI K07CA211956 (TPM)

Use of Opioids and Benzodiazepines pre/post Analgosedation guideline in the NICU

A Quality Improvement project / Claudia Ocampo, MD; Kaitlin David, PharmD; Martha Wetzel, MSPH; Shannon Hamrick, MD

Introduction

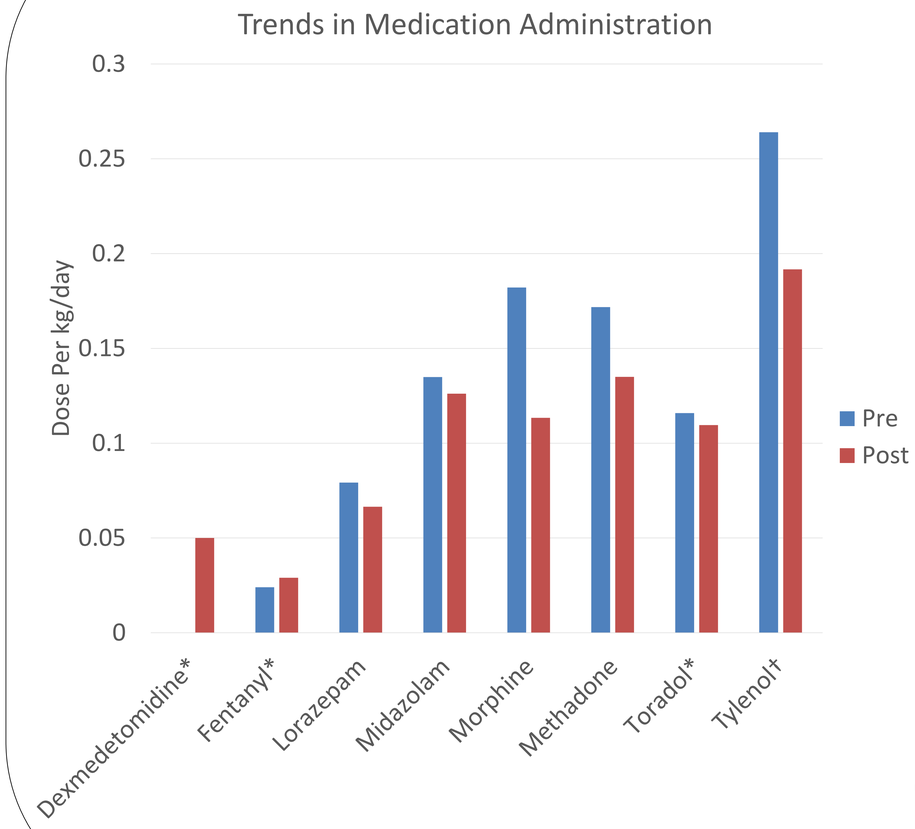
- Surgical NICU patients are frequently exposed to sedatives and analgesics, such as benzodiazepines and opioids.
- An analgosedation guideline for post-surgical patients was created with the goal of decreasing opioid and benzodiazepine use for pain management in the NICU and use of dexmedetomidine as first line agent.
- Dexmedetomidine has been shown to be neuroprotective in animal models.

Methods

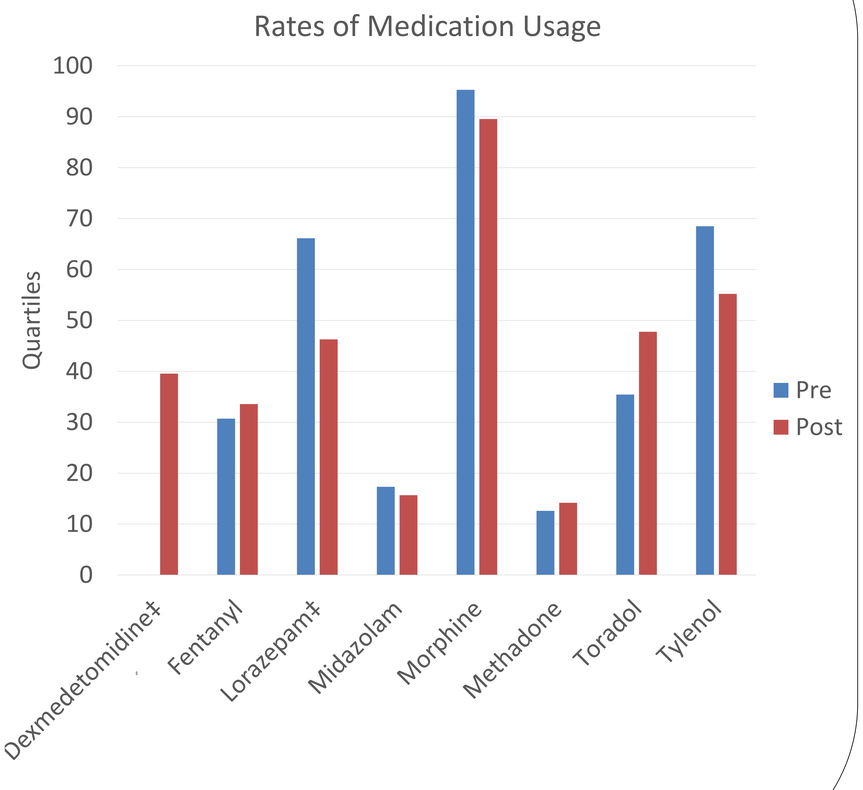
- Retrospective chart review of patients hospitalized prior to and following implementation of analgosedation guideline.
- Patients were grouped as needing light, moderate or both sedation levels according to surgical procedure or intervention.
- Exclusion criteria: did not meet hospitalization dates criteria; incomplete data; unqualifying procedure.
- Utilization of benzodiazepines, opioids, acetaminophen and ibuprofen was compared before and after implementation period.

Drugs that act at the GABA and NMDA receptors have been associated with negative effects on neuroapoptosis and synapse formation during early development in animal models.

Results



*Dose adjusted by factor of 10
†Dose adjusted by factor of 100



‡Statistically Significant

Conclusions

No statistically significant differences were observed in the doses of the medications. A higher percentage of patients received **dexmedetomidine** and toradol in the post period compared with the pre period, and a lower percentage received **lorazepam** and Tylenol. Adjustment for procedure count did not change the statistical significance of any of the outcomes.

Investigating the Contribution of Unique Risk and Protective Factors Associated with Health-related Quality of Life in Newly Diagnosed Pediatric Inflammatory Bowel Disease

Bonney Reed[1], PhD; Sharon Shih[2], MS, Grace Cushman[3], MS, and Subra Kugathasan[1], MD

[1] Emory+Children's Pediatric Institute, [2] Georgia State University, [3] University of Georgia

This research was supported by the National Center for Advancing Translational Science (NCATS) of the National Institutes of Health under Award Number UL1TR002378 and KL2TR002381 and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health under Award Number K23DK122115 awarded to the first author.

Background and Objectives

- Health-related quality of life (HRQOL) in pediatric inflammatory bowel disease (IBD) is typically examined from a deficit standpoint
- Little is known about emotional factors associated with resilient HRQOL outcomes
- Emotional reactivity and adaptability are temperamental characteristics
  - Emotional reactivity is a dispositional attribute characterized by emotional responses that are intense, peak rapidly, and/or are slow to return to baseline
  - Adaptability refers to the ability to quickly and easily adjust to changes in environment or unexpected circumstances
- Aims were to (1) characterize emotional reactivity and adaptability, and (2) use a risk and resilience framework to investigate how emotional reactivity and adaptability are related to parent and child ratings of child HRQOL in a sample of youth with newly diagnosed IBD

Experimental Methods

- Participants included 54 caregivers and 56 youth ages 8 to 17 diagnosed with IBD, recruited in clinic within 45 days of diagnosis
- Measures
  - Child HRQOL using the IMPACT-III (Otley et al., 2002), a disease-specific measure
  - Emotional Reactivity, Parent Report of Children's Reactions (Reynolds & Alfano, 2016)
  - Adaptability Subscale, BASC-2 Parent Report (Reynolds & Kamphaus, 2004)
  - Clinical disease activity, physician global assessment
    - Male participants endorsed significantly higher total HRQOL (male M = 142.84, SD = 11.84, female M = 125.71, SD = 19.65, t = -3.83, p < .001, d = 1.06)
    - Parents reported greater emotional reactivity for their female children compared to males (female M = 30.97, SD = 6.54, male M = 26.87, SD = 6.59, t = 2.25, p = .03, d = 0.62)
    - Parents on average rated their children with IBD as demonstrating typical levels of adaptability based on age and sex norms available (M = 50.27, SD = 9.99)
- Multiple linear regression analyses were conducted to examine the associations between total HRQOL and risk (emotional reactivity) and protective (adaptability) variables.

Results

Multiple regression analyses examining the effects of Demographic, Medical, and Psychosocial Variables on Child-reported and Parent-reported HRQOL

Dependent Variable and Predictors	B	SE B	β	t	F	R^2	ΔR^2
Child-reported HRQOL							
Demographics					17.14^{***}	.26	
Child Sex	13.15	2.99	$.35^{***}$	4.39^{***}			
Medical Variables					42.71^{***}	.64	.38
Disease Symptoms	-1.25	.16	$-.63^{***}$	-8.09^{***}			
Psychological Risk					34.30^{***}	.68	.05
Emotional reactivity	-.37	.23	-.14	-1.58			
Protective Factor					31.33^{***}	.73	.05
Adaptability	.43	.16	2.80^{**}	2.80^{**}			
Parent-reported HRQOL							
Demographics					7.11^{**}	.13	
Child Sex	8.17	4.25	.22	$1.92^{\dagger}$			
Medical Variables					6.44^{**}	.21	.08
Disease Symptoms	-.59	.22	-.30	-2.70^{**}			
Psychological Risk					6.82^{**}	.30	.09
Emotional reactivity	-.43	.33	-.16	-1.29			
Protective Factor					9.01^{***}	.43	.14
Adaptability	.74	.22	.40	3.35^{**}			

Note. Italicized variables are dependent variables. $^{\dagger}p < .10$, $^{*}p < .05$, $^{**}p < .01$, $^{***}p < .001$

Racial and Socioeconomic Disparities in Non-Accidental Trauma Screening

Hayley Sooknarine & Edward Richer

Background: It has been found that minority children undergo screening more frequently for non-accidental trauma (NAT). This can be the case despite controlling for expert opinion on NAT likelihood.

Aims: 1) Evaluate NAT screening practices of young infants presenting with apparently isolated skull fractures, and 2) identify which infants have a high level of concern for NAT.

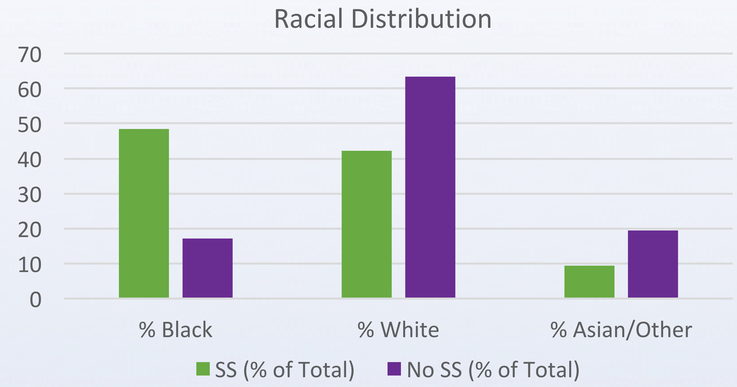
Methods: This was a retrospective chart review. Inclusion criteria were patients under 6 months of age presenting to 2 metropolitan Pediatric trauma centers (one academic and one non-academic) with simple skull fractures between January 2014 and December 2016. Patients were excluded if there was high level of concern for NAT due to history, examination findings, or additional head CT findings.

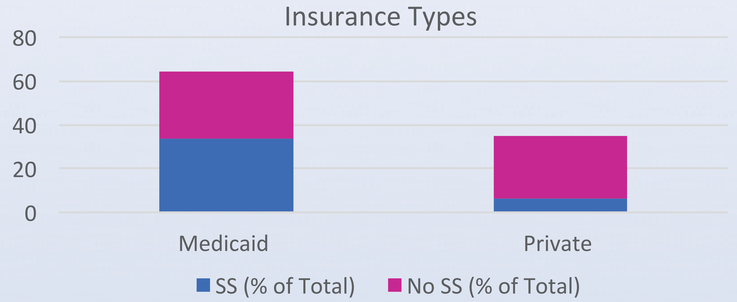
The study population was divided into 2 groups: infants undergoing skeletal surveys (SS) versus not. Demographic information was collected, and information was obtained on history of presentation and SS results. Data analysis was performed using χ^2, Fisher exact test, and odds ratio (OR) calculations.

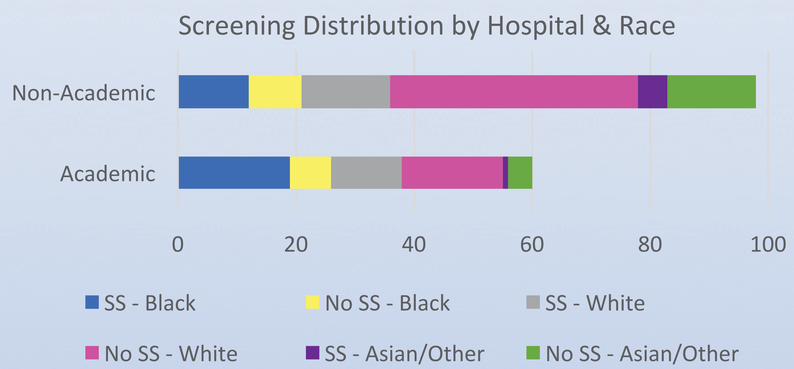
Results: 157 infants were included. 54.8% were white, 29.9% were black, and 15.3% were Asian/other. 64.3% were publicly insured and 35.7% were privately insured. It was noted that of the excluded patients, at least 2 had isolated simple skull fractures due to inflicted injury (ex. hit during parental intimate partner violence). 40.8% underwent NAT screening with skeletal survey, and 1 of these surveys showed additional fractures which increased the level of concern for NAT (1.6% of those screened). The infant with the positive SS had no history to explain the fracture.

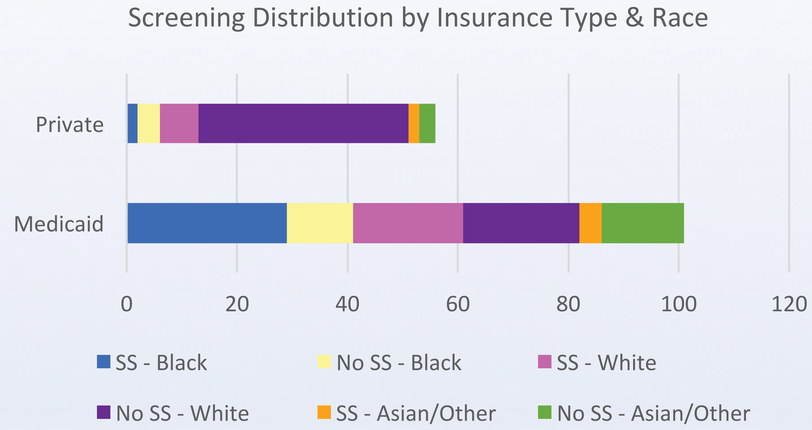
66% of black infants were screened, 31.4% of white infants were screened, and 25% of Asian/other infants were screened (P<0.001). 32.1% of Hispanic infants were screened. The academic hospital screened 53% of presenting infants, while the non-academic hospital screened 33% (P = <0.001). Both hospitals screened higher percentages of black infants compared to other races. 73.1% of black infants were screened at the academic hospital, versus 57.1% at the non-academic hospital (P = 0.05). Conversely, 26.3% of white infants were screened at the non-academic hospital compared to 41.4% at the academic hospital (P = <0.001).

87.2% of black infants were publicly insured versus 47.7% of white infants and 79.2% of Asian/other infants. 89.3% of Hispanic infants were publicly insured. Of the publicly insured, 70.7% of black infants were screened versus 48.8% of white infants and 21% of Asian/other infants (P=0.001). 36% of publicly insured Hispanics were screened.









The odds ratio for being screened if publicly insured was 4.517 (CI: 2.0993 to 9.7191, P=0.0001). Of the privately insured patients, less than 50% of patients in all races underwent skeletal surveys (2 of 6 (33.3%) black, *7 of 45 (15.6%) white*, 2 of 5 (40%) Asian, P=0.2).

Both hospitals saw lower numbers of privately insured patients; however, a smaller proportion of privately insured patients were surveyed at the non-academic hospital (6 of 38 (15.8%)) compared to the academic hospital (5 of 18 (27.8%)) (P<0.0001).

Discussion: This retrospective chart review demonstrated multiple disparities: 1) Racial disparity; 2) Socioeconomic disparity; and 3) variation in screening practices between 2 metropolitan Pediatric trauma centers (academic versus non-academic). Of the publicly insured, more black infants were screened compared to white and Asian/other infants. When comparing the 2 facilities, less privately insured patients were surveyed at the historically private facility. It was also noted that of the private patients, a smaller proportion of white infants were screened compared to black and Asian infants, although the latter groups were much smaller.

Conclusions: There were racial, socioeconomic, and center-to-center disparities in screening for simple skull fractures. These fractures have a low specificity for physical abuse but can occur due to inflicted trauma (as noted for some excluded patients in this study). When controlling for each variable (race and insurance type i.e. socioeconomic status), disparities persisted.

These findings support a need for standardized protocols, especially for injuries of lower specificity for NAT.

Impact of gut microbiome changes on hematopoietic stem cell transplantation outcomes in children.

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[1]Emory University School of Medicine, Atlanta, GA [2]Children's Healthcare of Atlanta, Atlanta, GA; [3]Department of Biological Sciences, Georgia Institute of Technology,, Atlanta, GA [4]Molecular Evolution Core, Georgia Institute of Technology, The Center for Integrative Genomics, Atlanta, GA

Background

- Higher gut microbiome diversity in adult allogeneic hematopoietic cell transplantation (HCT) recipients is associated with reduced bloodstream infections and improved overall survival.
- In single center studies, antibiotic exposure through engraftment has been linked to reduced short chain fatty acid (SCFA) producing organisms.
- We examine changes in microbiome in a cohort of pediatric patients undergoing HCT.

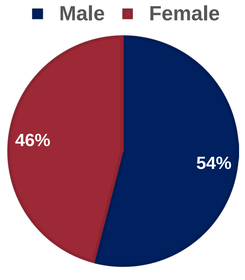
Methods

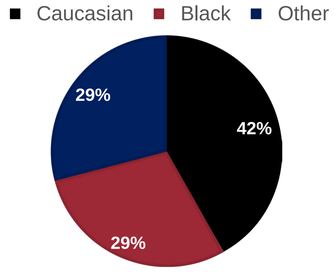
- Children (<21 years) undergoing allo-HSCT for a hematologic malignancy, using myeloablative conditioning, between 2013-2020.
- Patients were enrolled in an institutional biorepository (n=82) with a subset enrolled in an ongoing trial using rifaximin prophylaxis (n=21).
- Primary outcome: Death at 1 year post-HCT.
- Timing of systemic antibiotics for all patients: none, early (≤D0, day of graft infusion), and late (>D0).
- 16S rRNA sequencing of stool samples obtained at baseline, D0 to D+28, weekly.

Results

Clinical characteristics

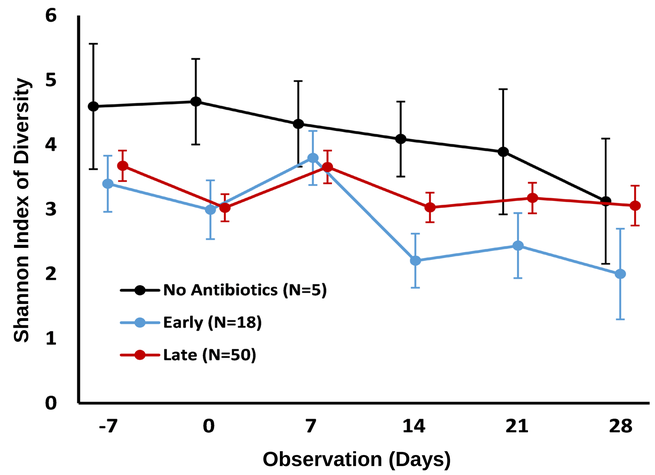
• Median age was 9 years old (range 1-20).





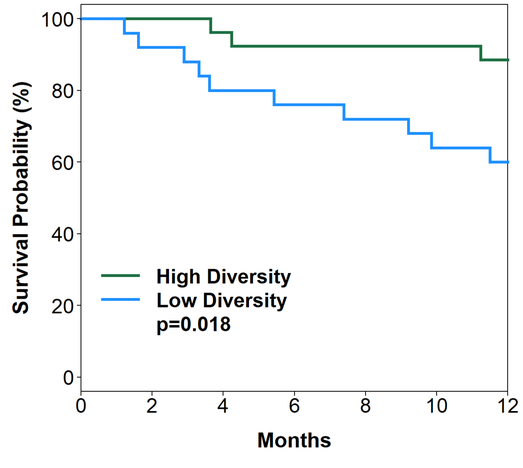
Microbiome diversity changes significantly over time

- Diversity decreased significantly for all patients in the first month post-HCT (p=0.008).
- Piperacillin-tazobactam was used empirically in 91% of patients.
- Higher diversity was seen when patients received none or late versus early antibiotics, but this was not statistically significant, p=0.23.



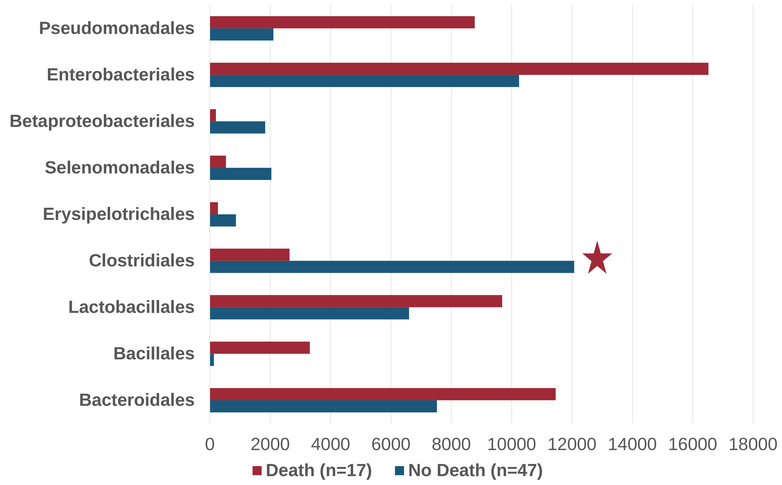
Microbiome diversity at D28 post HCT correlates with overall survival

- OS at 1 year was 88.5% for patients with high diversity (≥median) versus 60% with low diversity.



Significant depletion of Clostridiales among patients who died when compared to survivors

- There was a significant difference in absolute abundance of Clostridiales order among survivors and non-survivors (p=0.0045).
- Other observed expansion of pathogenic orders such as Pseudomonadales, Enterobacteriales, Bacillales, Bacteroidales was not statistically significant.



★ Denotes significant difference (p=0.0045) of Clostridiales order

Conclusions

- Early antibiotic exposure is detrimental to microbiome diversity.
- Microbiome diversity at engraftment is strongly correlated with survival.
- Higher quantity of SCFA producing bacteria, Clostridiales, is associated with improved survival.
- Approaches to preserve microbiome diversity, such as limiting anaerobic antibiotic exposure, may improve SCT outcomes.
- Our ongoing study will provide preliminary data on the impact of rifaximin on preserving microbiome diversity.

References:
1) Taur, Y., et. al. *CID*. 55(2012): 905-914.
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Use of a Novel Human Milk-Based Fortifier in Term Infants with Surgical Congenital Gastrointestinal Disorders Improves Growth at Discharge

Sarah M. Tweddell, MD, Maria E. Barbian, MD, Heidi E. Karpen, MD, Emory University, Children's Healthcare of Atlanta

Introduction

- Human milk (HM) is the ideal source of nutrition for all infants, but alone is insufficient in protein and calories for infants with surgical congenital gastrointestinal disorders (S-CGD) and critically ill infants.
- Currently, the only option for term infants is fortification with formulas which have been associated with increased risk of necrotizing enterocolitis (NEC) in the preterm population and may contribute to the high rates of NEC in those infants with congenital gastrointestinal disorders.
- A human milk-based fortifier (HMBF) formulated for term infants with S-CGD is needed to provide optimal nutrition.
- The purpose of this study is to demonstrate the safety and efficacy of a novel HMBF designed for term infants with S-CGD.

Methods

- Patients were fed an exclusive human milk diet consisting of mother's own milk (MOM), and pasteurized donor human milk (PDHM) fortified with a novel HMBF (PBCLN-002, Prolacta Bioscience) specifically formulated for the term infant.
- The first 26 term infants enrolled in this trial were evaluated for safety and efficacy of PBCLN-002 compared to a recent cohort of patients fed diets containing MOM and formula.
- The retrospective cohort was matched based on diagnosis, sex, birthweight and gestational age.

In patients with surgical congenital gastrointestinal disorders, a human-milk based fortifier demonstrates safety and efficacy by increased growth at the time of discharge.

Results

- There were no adverse events in the PBCLN group and no significant effect on feeding tolerance, interruptions or maximum direct bilirubin.
- Infants receiving PBCLN-002 grew faster in terms of weight and length and head circumference velocity; however, these were not statistically significant.
- Adjusting for baseline using a basic analysis of covariance model, these differences remained significant for discharge weight (p=0.02) and discharge length (p=0.003), and marginally for discharge head circumference (p=0.13).

Table 1. Infant Demographics and Baseline Characteristics.

	PBCLN (n = 26)	Control (n = 26)
Birth Weight (g)	2874 ± 468	2833 ± 564
Birth Length (cm)	47.6 ± 3.0	47.2 ± 3.1
Birth FOC (cm)	33.3 ± 1.6	32.9 ± 1.4
Female (%)	15 (57.7%)	14 (53.8%)

Birth measurements are reported in mean ± SD.

Table 2. Outcomes.

Measurements are reported as mean ± SD (median). The 95% normal-theory CI is also reported. Wilcoxon signed-rank test was run to generate the p-value.

		PBCLN (n = 26)	Control (n = 26)	p-value	95% CI (Prolacta-Control*)
Feeding Intolerance (Days)	≥ 1 0 Median ± IQR	5 21 0 ± 0	6 20 0 ± 0.25	0.69	
Feeding Interruptions (Days)	≥ 1 0 Median ± IQR	8 18 0 ± 1	5 21 0 ± 0	0.35	
Maximum direct bilirubin (mg/dL)		1.08 ± 1.12 (0.65)	0.95 ± 1.21 (0.60)	0.31	-0.45 to 0.72
Weight gain (g/day)		24.4 ± 12.6 (25.5)	19.5 ± 10.5 (22.1)	0.30	-3.0 to 12.9
Weight gain (g/kg/day: exponential)		7.2 ± 3.3 (8.0)	6.5 ± 3.8 (6.5)	0.76	-1.5 to 3.1
Discharge weight (g)		3935 ± 776 (3892)	3463 ± 1144 (3156)	0.03	-61.4 to 1005.2
Length velocity (cm/week)		0.86 ± 0.40 (0.90)	0.73 ± 0.66 (0.80)	0.44	-0.15 to 0.42
Discharge length (cm)		52.7 ± 2.4 (53)	50.3 ± 4.2 (49)	0.025	0.44 to 4.32
Head circumference velocity (cm/week)		0.50 ± 0.27 (0.55)	0.55 ± 0.28 (0.49)	0.78	-0.20 to 0.10
Discharge head circumference (cm)		36.4 ± 1.9 (36.4)	35.2 ± 2.4 (34.8)	0.052	-0.003 to 2.37

Conclusions

- In this cohort of patients with S-CGD, PBCLN-002 demonstrates safety and efficacy by increased growth at the time of discharge.
- The non-significant differences in daily weight gain and growth velocities between these two groups may reflect the small sample size and differences in parenteral nutrition support during the early phases of surgical recovery.

Parent Psychological Distress and Chronic Pain in Pediatric Sickle Cell Disease

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Background

- Chronic pain occurs in approximately 20-40% of adolescents and adults with sickle cell disease (SCD), which is correlated with decreased quality of life and physical functioning and more anxiety/depression symptoms[1-3].
- Pediatric chronic pain is associated with increased parenting distress and poor emotional and family functioning[4,5].
- Although parents' distress is an appropriate emotional response to a child's chronic medical condition, it has also been associated with poorer child outcomes, including increased disability and reduced quality of life[5,6].
- Despite studies supporting the influence of parental distress and child outcomes in medical populations, research is needed to investigate these psychosocial influences in SCD.
- This study aimed to investigate how parenting stress, parent emotional functioning, and family functioning 1) were associated with child outcomes and 2) differed based on the chronicity of pediatric SCD pain.

Hypotheses

For children and adolescents with SCD, parenting stress, parent emotional functioning (e.g., anxiety, depression), and family functioning will:

- **Be associated with child outcome.** More parenting stress, anxiety, and depression and poorer family functioning will be associated with poorer child quality of life and greater child functional disability.
- **Differ based on chronicity of child SCD pain** Parents of youth with chronic pain will experience more stress, anxiety, and depression and poorer family functioning than parents of youth with episodic pain.

Method

Participants

- 77 youth with SCD
- Ages 9-20 years; M_{age}=14.2 years (*SD*=2.5)
- 57% Female
- 93% African American, 3% Biracial, 1% Caucasian
- 75% HbSS, 13% HbSC, 9% HbSB^{+}thal, 1% HbSB^{0}thal
- 81% prescribed Hydroxyurea
- 15% receiving chronic transfusions
- 44% chronic pain, 55% episodic pain

Method (Continued)

Procedure

- Participants completed validated measures during an SCD outpatient clinic visit or at home via paper-pencil or web-based (REDCap®).

Measures

- Parent Measures
  - Pediatric Inventory for Parents[7,8]
  - Center for Epidemiological Study – Depression Scale Revised[9-13]
  - Generalized Anxiety Disorder Scale[14-17]
  - Family Assessment Device[18-22]
- Child Measures
  - Pain Characteristics: Average pain intensity (0-10), pain frequency (0-30 days/month), and pain duration[1,2]
  - Functional Disability Inventory[23-25]
  - Pediatric Quality of Life – SCD Module[26-29]

Results

Correlations Among Parent Functioning and Child Functioning

	Child Functioning	
Parent Variables	Functional Disability	Quality of Life
Parenting Stress Frequency	0.42***	-0.40***
Parenting Stress Difficulty	0.34**	-0.40***
Depressive Symptoms	0.34**	-0.26*
Anxiety Symptoms	0.26*	-0.25*
Family Functioning	0.01	-0.24*

*p<.05, **p<.01, ***p<.001

- Greater parenting stress frequency, greater parenting stress difficulty, greater parent depression, and greater parent anxiety were associated with increased child functional disability (p's<.05).
- Greater parenting stress frequency, greater parenting stress difficulty, greater parent depression, and greater parent anxiety were associated with poorer child quality of life (p's<.05).
- Poorer family functioning was associated with poorer child quality of life (p<.05).

Results (Continued)

- Parents of children with chronic pain endorsed significantly more frequent and difficult parenting stress than parents of children with episodic pain (p's<.01).
- Parents of children with chronic pain endorsed more symptoms of anxiety than parents of children with episodic pain (p=.03).
- Depressive symptoms and family functioning did not differ between parents of children with episodic versus chronic pain (p's>.05).

Mean (M) and Standard Deviation (SD) Scores on Parent Functioning for Youth with Episodic and Chronic Sickle Cell Pain

	Child Episodic Pain M (SD)	Child Chronic Pain M (SD)	t-value [95% CI]	p-value
Parenting Stress Frequency	83.88 (31.43)	121.26 (30.51)	-5.06 [-52.11, -22.65]	<.01
Parenting Stress Difficulty	73.0 (29.45)	100.61 (40.47)	-3.30 [-44.29, -10.93]	<.01
Depressive Symptoms	7.76 (6.51)	9.13 (6.27)	-0.90 [-4.42, 1.67]	.37
Anxiety Symptoms	3.51 (3.94)	6.03 (5.78)	-2.20 [-4.81, -0.23]	.03
Family functioning	1.67 (0.59)	1.50 (0.39)	-1.51 [-0.41, 0.06]	.14

Conclusions

- Pediatric pain frequency in SCD is associated with increased parenting stress.
- Additionally, increased parenting stress, anxiety, and depression and poorer family functioning are associated with poorer child outcomes (i.e., quality of life, functional disability).
- Further studies are needed to investigate parent-focused interventions to manage stress, emotional functioning, and family functioning for parents of children with chronic pain.

Poster and references are available upon request.

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Development and Validation of the HIV Adolescent Readiness for Transition Scale: HARTS

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INTRODUCTION

Background

- Approximately 320,000 perinatally-HIV infected children and adolescents are living in South Africa.
- There are no guidelines on how or when to transition adolescents from pediatric to adult care in South Africa.
- In multiple settings, adolescents living with HIV have poor retention in care and viral suppression after transitioning to adult care.

Objective

- We designed and validated the HIV Adolescent Readiness to Transition Scale (HARTS) to determine when an adolescent is ready to transition to adult care and to identify at-risk adolescents who may need further interventions prior to transition.

METHODS

HARTS Development:

Setting: Mahatma Gandhi Hospital, KwaMashu, South Africa

Inclusion criteria:

- Perinatally HIV-infected
- Receiving ART
- Fully aware of their HIV status

Focus Groups:

1. Adolescents: 20 participants between ages 15 and 24 years
2. Healthcare Providers: 11 (physicians, nurses, counselors, social workers and pharmacists)
3. The HARTS questionnaire was revised based on participant feedback using consensus.

Psychometric Properties

- 131 adolescents receiving ART completed HARTS
- Generalized linear equation models with the overall HARTS score and with the individual domains
- Correlated the responses to self-described transition readiness and age using liner regression
- Test-retest variability with 13 (10%) adolescents
- Cronbach's alpha

HARTS Validation:

Setting: Prince Mshiyeni Hospital, Umlazi, South Africa

Inclusion criteria:

- Perinatally HIV-infected
- Receiving ART
- Fully aware of their HIV status
- Prior to transition to adult clinic

Participants:

- 199 Adolescents completed HARTS prior to transition

Analysis:

- Viral suppression (<200 copies/ml) measured after 12 months in adult clinical care
- Multivariable logistic regression based on the continuous HARTS value and covariates with a p value of less than 0.2 on bivariate analysis
- Adjusted for age at ART initiation, ART regimen, sex, disclosure status, drug and alcohol use, peer support, and self-esteem

RESULTS

Development of HARTS

Table 1: Participant characteristics for HARTS development and validation

Enrollment characteristics	Scale Development (n=131)	Scale Validation (n=199)
Recruitment site	Mahatma Gandhi Memorial Hospital	Prince Mshiyeni Hospital
Median age at enrollment (years) (IQR)	13.95 (13.15 – 14.75)	13 (12 - 13)
Median age at ART initiation (years) (IQR)	7.13 (4.73 – 8.91)	8 (5 - 9)
Female n (%)	64 (49%)	98 (49%)
First-line ART regimen n (%)	111 (85%)	184 (93%)
Drug / alcohol abuse n (%)	35 (3%)	19 (10%)
Documented Disclosure n (%)		89 (45%)
Outcomes	(n=50)	
Viral suppression after transition n (%)	39/50 (78%)	112 (57%)

- For the test-retest variability the mean score on test 1 was 36.3 (SD 7.3) and 36.9 (SD 6.7) on test 2 with no statistical difference in means (p=0.69).
- Positive correlations with self-described transition readiness were significant with the overall HARTS score (p<0.0004) and domains of health navigation (p=0.028), self-advocacy (p=0.0014), and health literacy (p=0.0023). Cronbach's alpha was 0.78.

Table 2: HARTS question correlation to individual domains and overall score

HARTS Question	Disclosure Coef; p-value (95% CI)	Health Navigation Coef; p-value (95% CI)	Self Advocacy Coef; p-value (95% CI)	Health Literacy Coef; p-value (95% CI)	Overall HARTS Coef; p-value (95% CI)
HARTS 1	0.54; <0.001 (0.33 – 0.76)				0.43; <0.001 (0.26 – 0.60)
HARTS 2	0.53; <0.001 (0.33 – 0.74)				0.38; <0.001 (0.20 – 0.56)
HARTS 4	0.32; 0.005 (0.09 – 0.54)				0.26; 0.006 (0.07 – 0.44)
HARTS 5	0.01; 0.927 (-0.21 – 0.23)				0.11; 0.249 (-0.08 – 0.31)
HARTS 6		0.63; <0.001 (0.50 – 0.76)			0.61; <0.001 (0.48 – 0.75)
HARTS 7		0.29; 0.001 (0.12 – 0.47)			0.24; 0.010 (0.06 – 0.43)
HARTS 8		0.76; <0.001 (0.64 – 0.88)			0.64; <0.001 (0.48 – 0.79)
HARTS 9		0.50; <0.001 (0.34 – 0.66)			0.59; <0.001 (0.45 – 0.73)
HARTS 3			0.44; <0.001 (0.28 – 0.60)		0.51; <0.001 (0.35 – 0.66)
HARTS 10			0.45; <0.001 (0.29 – 0.60)		0.48; <0.001 (0.32 – 0.64)
HARTS 11			0.73; <0.001 0.62 – 0.85)		0.72; <0.001 (0.59 – 0.85)
HARTS 12			0.34; <0.001 (0.17 – 0.51)		0.36; <0.001 (0.18 – 0.53)
HARTS 13			0.21; 0.032 (0.02 – 0.40)		0.30; 0.001 (0.12 – 0.48)
HARTS 14				0.34; 0.001 (0.14 – 0.53)	0.26; 0.006 (0.07 – 0.44)
HARTS 15				0.55; <0.001 (0.35 – 0.75)	0.44; <0.001 (0.27 – 0.60)
HARTS 16				0.28; 0.011 (0.06 – 0.49)	0.21; 0.031 (0.02 – 0.40)

Validation

Table 3: Multivariable logistic regression for virologic failure among non-substance using adolescents on first-line ART prior to transition to adult care

Covariate	Adjusted Odds Ratio	P-value	95% CI
HARTS Score (10 point increase)	0.44	<0.001	O.29 – 0.69
Female	2.39	0.023	1.13 – 5.10
Alcohol use	4.08	0.001	1.84 – 9.04
Disclosure	0.46	0.028	0.24 – 0.95
Age at ART initiation	1.21	0.003	1.07 – 1.38

- For substance abusing participants who were on first line ART, the HARTS score was not associated with viral failure (OR 1.58; p=0.35; 95% CI 0.61 – 4.08).
- For non-substance abusing participants who were on second line ART, the HARTS score was not associated with viral failure (OR 0.93; p=0.74; 95% CI 0.64 – 1.37).
- Age at time of transition was not significantly associated with viral suppression 12 months after transition to adult care.

CONCLUSIONS

The HARTS questionnaire is a validated scale that can be used to determine which adolescents may require additional interventions prior to transitioning to adult care to improve retention in care and viral suppression. It is particularly useful for adolescents on first line ART who are not abusing drugs to predict who may not need additional services during transition from pediatric to adult care.

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