responding to incidents in their immediate aftermath will provide needed insight into what additional efforts are needed to support victims of violence given the unique challenges present in the healthcare industry.

3523

#### Innovative Approaches to Clinical Research on Placebo Effects: A Regulatory Science Perspective

Kimberly Uweh<sup>1</sup>

Georgetown - Howard Universities

OBJECTIVES/SPECIFIC AIMS: To analyze contemporary study design methods and clinical trial approaches in placebo research. METHODS/STUDY POPULATION: An analysis was conducted on the following studies: I. "Managing" the Placebo Effect: The Single-Blind Placebo Lead-in Response in Two Pain Models by RN Haden, et al. The objective of the study was to consider elements of the placebo response in the context of two pain models using a "single-blind placebo lead-in" design (SBPLI) by engaging the "placebo response" prior to randomization to active drug and placebocontrolled conditions. The methods of the study included two pilot drug trials using knee osteoarthritis (KOA) and non-radicular low back pain (LBP) subjects, SBPLI protocols were conducted. In the first study, 36 subjects with non-radicular CLBP were enrolled in a double-blind, randomized, placebo-controlled trial of hydromorphone ER. In the second study, a total of 42 subjects with chronic KOA pain were enrolled in a double-blind, randomized, placebocontrolled study of milnacipran. Gender and/or diagnosis affected placebo responses as observed in changes in patient self-reported pain, depressive and pain anxiety symptoms were examined. Additionally, the placebo response on performance-based tests (stair climbing, range of motion (ROM), sit to stand repetitions, and 6-minute treadmill distance) was evaluated. II. Randomized Placebo-Controlled Placebo Trial to Determine the Placebo Effect Size by L. Gerdesmeyer, et al. The objective of the study was to analyze the pure placebo effect on clinical, chronic pain through a blinded RCT. The methods of the study included 182 patients suffering from chronic plantar heel pain for over 6 months, who failed to respond to conservative treatments, were screened and 106 of these patients were enrolled into this study. The patients were randomly assigned to receive either a blinded placebo shockwave treatment or an unblinded placebo shockwave treatment. The primary outcome measure was the differences in percentage change of visual analogue scale (VAS) scores 6 weeks after the intervention. The secondary outcome measure was the differences in Roles and Maudsley pain score (RMS) 6 weeks after intervention. III. Open-label placebo treatment in chronic low back pain: a randomized controlled trial by C. Carvalho, et al. The objective of the study was to investigate whether placebo effects in chronic low back pain could be harnessed ethically by adding open-label placebo (OLP) treatment to treatment as usual (TAU) for 3 weeks. The methods of the study included 97 randomized participants in a 3-week randomized control trial comparing current treatment plus OLP to current treatment alone (TAU). RESULTS/ANTICIPATED RESULTS: N/a DISCUSSION/ SIGNIFICANCE OF IMPACT: The aforementioned studies provide placebo researchers with contemporary and reliable methodologies to examine placebo effects on participants. These methodologies provide scientists with clinical translational research methodology styles based on the foundation of regulatory science.

# Science and Health Policy/Ethics/Health Impacts/Outcomes Research

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### Assessing Racial Disparities in Hepatitis C Retention of Care

Austin Taylor Jones<sup>1</sup>, Dr. Lisa Moreno-Walton, MD<sup>2</sup>, Kanayo R. Okeke-Eweni<sup>2</sup>, Keanan M. McGonigle<sup>1</sup>, David H. Yang<sup>2</sup>, Morris Kim<sup>1</sup>, Jenna Miller<sup>2</sup> and Dr. Patricia Kissinger, PhD, MPH <sup>1</sup>Tulane University School of Medicine and <sup>2</sup>LSU Health Sciences Center - New Orleans

OBJECTIVES/SPECIFIC AIMS: The objective of this study is to assess differences in outcomes between African Americans (AAs) and whites along the HCV care cascade. Primary outcome was retention in the HCV care cascade, measured in two ways. For viral RNA confirmation, retention was a percentage of those having screened antibody reactive. For hepatic ultrasound, primary care, HCV specialty clinic, treatment initiation, and sustained viral load (SVR), retention was a percentage of those found chronically infected by positive RNA viral load. Secondary outcome was time to follow-up from antibody screening to each subsequent step in the care cascade. METHODS/STUDY POPULATION: A retrospective cohort study was performed. AA and white patients who tested HCV antibody reactive from March to October 2015 at the University Medical Center (UMC) Emergency Department in New Orleans, LA were included in this study. Outcomes were assessed using the HCV Continuum of Care model, delineating successive stages of care from identification to cure. RESULTS/ANTICIPATED RESULTS: A total of 728 patients screened HCV antibody reactive, including 446 AAs and 282 whites. AAs (53.5 years, SD 10.2) were disproportionately older than whites (46.7 years, SD 11.9) (p < 0.001), more likely to be insured (89.2% vs 78.7%, p<0.001), had higher rates of Medicare (28.0% vs 12.1%, p<0.001), and less frequent history of intravenous drug use (IVDU) (32.3% vs 46.1%, p<0.001). For AAs, retention in the treatment cascade was 96.2% for viral RNA confirmation, 50.9% for hepatic ultrasound, 26.8% for primary care, 35.2% for HCV specialty clinic, 14.5% for treatment initiation, and 9.6% for sustained viral response (SVR). Among whites, retention in the treatment cascade was 96.8% for viral RNA confirmation, 37.8% for hepatic ultrasound, 16.1% for primary care, 23.3% for HCV specialty clinic, 8.8% for treatment initiation, and 7.8% for SVR. AAs had a higher likelihood of receiving a hepatic ultrasound (OR=1.70; CI=1.19-2.25; p<0.005), following up with primary care (OR = 1.91, CI=1.21-3.02, p<0.005), and attending the viral hepatitis specialty clinic (OR=1.79, CI=1.20-2.68, p<0.005), as compared to their white counterparts. After adjusting for age, insurance, and history of IVDU, AAs did not have a higher likelihood of receiving a hepatic ultrasound (aOR=1.09, CI=0.995-1.19) or seeking primary care (aOR=1.05, CI=0.98-1.14). AAs had attenuated odds of attending viral hepatitis specialty clinic (aOR=1.09, CI = 1.01-1.19). There was no statistically significant difference in follow-up time in the treatment cascade for AAs versus whites. DISCUSSION/SIGNIFICANCE OF IMPACT: Race alone cannot explain differences in achievement along the care cascade. Significant differences in retention along the HCV care cascade appear to be related primarily to differences in age and insurance status. In our population, older AAs are disproportionately insured through Medicare, thereby expanding their access to health resources. Their white counterparts are younger and more uninsured, leading to decreased access to care and ability to attend HCV follow-up appointments. ED HCV screening programs are still in their infancy and have opportunities to improve their linkage to care rates. Additional interventions are needed to better connect patients screened positive in the ED to HCV specialist care, preserving equity across racial groups.

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#### Assessing the Relationship between Resilience and Pain Catastrophizing in Patient Reported Outcomes following Total Knee Replacement

Vesta Nwankwo<sup>1</sup>, William Jiranek<sup>2</sup>, Steven George<sup>2</sup> and Janet Bettger<sup>2</sup>

<sup>1</sup>Duke University and <sup>2</sup>Duke University Health System

OBJECTIVES/SPECIFIC AIMS: The aim of the present study is to explore the relationships between resilience, pain catastrophizing, and functional outcomes in pre-and post-operative TKR patients. The primary outcome is the ability of the Brief Resilience Scale (BRS) to predict function using the Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR.) and overall health on the Patient-Reported Outcome Measurement Information System Global Health (PROMIS GH). METHODS/STUDY POPULATION: Recruited patients will provide informed consent during in-person office visits. At the pre-surgery intake appointment, patients will provide demographic information and complete baseline questionnaires assessing resilience, pain catastrophizing, knee stiffness, pain, and function, and impression of overall health. In-person or electronic follow-up assessments will be administered post-surgery at 6-week, 3month, and 6-month appointments. RESULTS/ANTICIPATED RESULTS: We aim to recruit 150 patients for this study. We do not expect a difference in sociodemographic characteristics of the patient sample. P-values will be based on t-tests and correlations calculated by comparing only non-missing values. Each outcome measure will be examined at each time point and trajectories will be calculated to determine the change in each outcome over time. Using latent class growth modeling we will examine individual change over time for each outcome (BRS, PCS, PROMIS GH, and KOOS JR.), and the association of resilience and pain with change in function (KOOS, JR. total score) and overall health (PROMIS GH). DISCUSSION/SIGNIFICANCE OF IMPACT: To our knowledge, this is the only known study that will compare resilience, pain catastrophizing and longitudinal health outcomes in a single paradigm. Results will hopefully inform the design and implementation of future studies that will assess the impact of preoperative treatment of vulnerable patients. The ultimate goal is to improve functional recovery by using pre-identified psychological constructs as intervention points. Ideally, the same measures would be implemented, however, details of this plan will be established following completion of this study.

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# Association of ancestral genetic admixture and obesity at 12 months of age

Sahel Hazrati<sup>1</sup>

Inova Health System

OBJECTIVES/SPECIFIC AIMS: We intended to investigate the relationship between children's genetic admixture proportions and the incidence of obesity at 12 months of age METHODS/STUDY POPULATION: 821 twelve month old children were included and

their genetic admixture was estimated using the ancestry and kinship toolkit (AKT). Weight for Length Percentile (WFLP) at 12 months of age was categorized as  $<95^{th}$  percentile and  $\ge95^{th}$  percentile. Multiple logistic regression analysis was performed to calculate odds ratios (ORs) with 95% confidence intervals (CIs) for association of admixture proportion including EUR, AMR, AFR, EAS and SAS with WFLP categories adjusting for maternal education, birth weight, frequency of breast feeding and juice consumption RESULTS/ANTICIPATED RESULTS: 821 children were included; WFLP <95<sup>th</sup> percentile = 671 (81.7%) and WFLP  $\geq$ 95<sup>th</sup> percentile = 150 (18.3%). Crude odds ratios showed EUR admixture was protective (OR 0.45 (95% CI 0.27–0.74)) whereas AMR (OR 3.85 (95% CI 1.92 -7.70)) and AFR (OR 5.70 (95% CI 2.19 –14.85)) were positively associated with obesity. After adjusting for confounding variables, only AFR was associated with WFLP≥95<sup>th</sup> (OR 7.38 (95% CI 2.31 – 23.59)), AMR and EUR were no longer associated with WFLP≥95<sup>th</sup> DISCUSSION/SIGNIFICANCE OF IMPACT: The AFR admixture proportion remains associated with early childhood obesity after accounting for confounding variables, suggesting the ancestral genetic background may contribute to the differences seen in early childhood obesity

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### Asthma and Depression in Children: the Role of Family Structure

Magda Shaheen<sup>1</sup> and Senait Teklehaimanot <sup>1</sup>David Geffen School of Medicine at UCLA

OBJECTIVES/SPECIFIC AIMS: Our objective is to examine the relationship between depression, childhood asthma and family structure. METHODS/STUDY POPULATION: We analyzed data from The National Survey of Children's Health 2011-2012 for the variables family structure, parent's smoking, education, poverty, available emotional support, and children's age, gender, race/ethnicity, asthma, physical/mental health, access to care, and insurance. Data were analyzed using multiple logistic regression in STATA 14 (sampling and weight). RESULTS/ANTICIPATED RESULTS: Of the 95,000 participants, 3.8% had depression, 5.1% had anxiety, 8.5% had emotional, developmental, or behavioral problem, 14.6% had asthma and 19% were single-parent family. Asthmatics had higher chance for depression relative to non-asthmatics (Adjusted Odds Ratio (AOR)=1.5, 95% confidence interval (CI)=1.2-1.8), p=0.001). Those living in a single-family home had higher chance for depression than those living in 2-parents homes (AOR=2.5, 95% CI=1.9-3.2), p=0.001). Other predictors were lack of emotional support, age, poverty <100%, poor health, and smoking parent (p<0.05). DISCUSSION/ SIGNIFICANCE OF IMPACT: We concluded that depression was associated with asthma in children from poor single family who lack an emotional support. Management of asthma should include screening and management of psychosocial factors.

## **Bowel Ischemia after Continuous Flow Ventricular Assist Device Therapy: A Single Center Analysis**

Ashley Y Choi<sup>1</sup>, Jatin Anand<sup>2</sup>, Muath Bishawi<sup>2</sup>, Mani A. Daneshmand<sup>2</sup>, Jacob N. Schroder<sup>2</sup>, Suresh M. Agarwal<sup>2</sup> and Carmelo A. Milano<sup>2</sup>

<sup>1</sup>Duke University and <sup>2</sup>Duke University Hospital

OBJECTIVES/SPECIFIC AIMS: The purpose of the study was to describe patient characteristics associated with subsequent