

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.

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### 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 placebo-controlled 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, placebo-controlled 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>  
<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