CT-07 A FAITH-BASED APPROACH TO INCREASING AFRICAN AMERICAN AWARENESS AND PARTICIPATION IN LUPUS CLINICAL TRIALS

Patricia B Davidson*, R Paola Daly. *Lupus Foundation of America Inc., USA*

10.1136/lupus-2018-lsm.79

Background Improving Minority Participation and Awareness in Clinical Trials (IMPACT) for Lupus was a 2016–2017 initiative through the Lupus Foundation of America aimed at increasing participation of African Americans in lupus clinical trials. A faith-based educational model using health navigators for reaching this population through churches was created by leveraging existing community partnerships and by employing culturally relevant communication tools and outreach strategies. IMPACT for Lupus used a community-based participatory research (CBPR) approach and incorporated Ford's conceptual framework³ focusing on awareness as the fundamental first step to clinical trial participation.

Methods First, an Action Partnership (AP) of public and private stakeholders, including community leaders and a patient representative, was created to provide input throughout the entire project. Next, an extensive literature review of past studies and initiatives to increase clinical trials awareness served as formative research to develop a mixed-methods study assessing the receptivity and cultural appropriateness of the educational model (see figure 1). Semi-structured interviews were conducted among 20 key informants. A survey was developed for patients (n=205) and physicians (n=122). Patient materials were assessed for cultural relevance through a community advisory board (CAB). A three-month pilot testing of the model was implemented and evaluated in three sites: Charleston, SC; Atlanta, GA; and Fort Washington, MD. Five outcome measures were developed to evaluate receptivity to the model through pre- and post-patient surveys and navigator interviews.

Results There was unanimous agreement among physicians, community leaders, and patients to utilize a collaborative approach including physicians, nurses, community based organizations, or other intermediaries, to enhance patient consideration of clinical trials. Physicians and community leaders recommended a community-based navigator to facilitate the relationship and indicated that the most effective approach to outreach to the African American community is through the church. Among patients, more than half also ranked the church as a preferred place to learn about lupus clinical trials. 95% of physicians indicated that lupus patients do not inquire about clinical trials very often or at all. However, patient communication with their healthcare providers was significantly associated with clinical trial participation. Pilot evaluation showed that navigator outreach through churches resulted in increased patient-provider communication about clinical trials.

Conclusions IMPACT for Lupus showed promise as an effective faith-based education model to raise awareness of clinical trials among African Americans with lupus. Additional studies with extended implementation periods and a focus on smaller, local churches are needed to support the findings of this study.

Abstract CT-07 Figure 1 IMPACT for lupus model

Acknowledgements IMPACT for Lupus Action Partnership (AP); Tufts Center for the Study of Drug Development (CSDD); Medical University of South Carolina (MUSC); Georgia Chapter of the Lupus Foundation of America; Carlden Inc.

This program was funded by the Office of Minority Health (OMH) grant number CPIMP161122-01-00.

CT-08 SAFETY AND TOLERABILITY OF OMALIZUMAB, A HUMANIZED ANTI-IGE MONOCLONAL ANTIBODY IN SYSTEMIC LUPUS ERYTHEMATOSUS (STOP LUPUS)

¹Sarthak Gupta*, ¹Sarfraz Hasni, ¹Michael Davis, ¹Elaine Poncio, ¹Yenealem Temesgen-Oyelakin, ^{1,2}Elizabeth Joyal, ¹Alice Fike, ¹Zerai Manna, ³Sungyoung Auh, ¹Yinghui Shi, ¹Diana Chan, ¹Philip Carlucci, ⁴Ann Biehl, ¹Barbara Dema, ¹Nico Charles, ³James Balow, ³Meryl Waldman, ¹Richard Siegel, ¹Mariana J Kaplan, ⁵Gabor Illei, ¹Juan Rivera. ¹National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, Bethesda, MD, USA; ²Present Address, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, MD, USA; ³National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Bethesda, MD, USA; ⁴Clinical Center, National Institutes of Health, Bethesda, MD, USA; ⁵National Institute of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD, USA

10.1136/lupus-2018-lsm.80

Background Previous evidence indicates a putative pathogenic role for IgE autoantibodies in systemic lupus erythematosus (SLE). We hypothesized that Omalizumab, a monoclonal antibody that binds IgE, will reduce SLE activity by decreasing circulating IgE autoantibodies, subsequently blocking basophil activation and type I IFN responses. This study assessed the safety, tolerability, biologic and clinical efficacy of Omalizumab in mild to moderate SLE.

Methods Fifteen subjects with SLE and a Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI 2K) of ≥ 4 and elevated IgE autoantibodies (above 2SD of mean of healthy controls) were randomized to receive Omalizumab or placebo (2:1) added to their baseline standard of care therapy (excluding monoclonal antibodies and alkylating agents) for 16 weeks. This was followed by a 16 week open label phase and 4 week washout period. SLEDAI 2K, British Isles Lupus Assessment Group index (BILAG 2004) and Physician Global Assessment (PGA) were recorded at each visit. The Systemic Lupus Erythematosus Responder Index (SRI 4) was calculated as a composite measure of improvement in disease activity at