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The Cruel Mystery

LUPUSTM

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Diversifying Clinical Trials: Challenges and Opportunities

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Objectives

- Describe importance of diversity in clinical trials
- Explain disparities in systemic lupus erythematosus
- Outline patient, provider and systems/ policy related challenges to diversifying clinical trials
- Offer solutions for addressing barriers to diverse patient population participation in clinical trials
- Highlight work that Lupus Foundation of America is doing in the clinical trials space

Importance of Diversity in Clinical Trials



- Well designed clinical trials are inclusive and representative of the population living the disease.
- A representative population allows for results that are generalizable to the population.
 - Promotes equitable outcomes and social justice
- Data from representative trials also accounts for variations in social/medical experiences, environment and responses to medications that could potentially inform realworld, clinical utility and guidelines.
 - This information could ultimately address health disparities

Disparities in Systemic Lupus Erythematosus

- Lupus impacts 300,000-1.5 million Americans, 90% of whom are women [1,2].
- Black/African American, Asian, and Hispanic make up 70% of prevalent lupus cases in the US [2].
- Lupus is a top 10 cause of death in Black/African American and Hispanic women ages 15-44 [3].

Disparities in Systemic Lupus Erythematosus

- Black/African American, Hispanic and Asian women living with lupus generally have a higher burden of disease (including LN), lower quality of life and more economic consequences.
- High disease activity and poverty predicted higher mortality in Black and Hispanic patients with lupus [4].

Disparities in Systemic Lupus Erythematosus

- Black/African American women with lupus die up to 20 years earlier than non-Hispanic white women with lupus [5,6].
- Death in Hispanic and Asian women with lupus is 4X higher than expected in the general population [5].

Lupus Clinical Trials

- There are roughly 400 sites throughout the US that conduct lupus clinical trials.
- Black African Americans make up 43% of the lupus population but only 14% of all clinical trial participants while Hispanics make up roughly 16% of all lupus clinical trial participants. [7].

Diversification of Lupus Clinical Trials

Patient-related Challenges

- Challenges with access to care dovetail those with access to trials
- Patient-physician communication/relationship
 - Mistrust, lack of respect, concordance
- Transportation
 - Location of trial too far from patient's residential area
- Childcare/Elder care
- Job Inflexibility

Diversification of Lupus Clinical Trials

Patient-related Challenges

- Lack of knowledge and low health literacy
- Misconceptions and personal attitudes
- Exclusion
 - Physician doesn't present opportunity
 - Patient doesn't meet inclusion/exclusion criteria
- Compensation too low

Diversification of Lupus Clinical Trials

Physician-related Challenges

- Lack of knowledge about the basic fundamentals of clinical trials
- Lack of understanding of the importance of diversity in clinical trials
 - Inclusion of diverse populations in trials can address health disparities
- Poor patient-physician relationships
- Insufficient knowledge on how to provide culturally congruent education/care to patients from diverse backgrounds or patients with a low level of health literacy
 - Lack of training on explaining complex concepts to patients
- Implicit bias and presumptions about patients

Diversification of Lupus Clinical Trials

System and Policy-related challenges

- Centralized trials
- Lack of focus on patient preference/patient centric approaches to trials
- Lack of federally required action plans for inclusion of diverse populations in clinical trials in pharmaceutical companies and accountability for implementing those plans

Diversification of Lupus Clinical Trials

Patient-focused solutions

- Patient/family clinical trial education delivered by members of clinical/non clinical workforce
 - Nurses/Pharmacists
 - CHWs/Patient Navigators
 - Peer to Peer Education
- Clinical trial design accounts for negative social determinants of health
 - Virtual/community-based trial design
 - Visits on weekends/after hours
- Inclusion of patients in all phases of clinical trial design
 - Allows industry to understand patient preference (mode of delivery, medication frequency, etc.)
- Compensate patients adequately for time and reimburse for travel/childcare/time off work

Diversification of Lupus Clinical Trials

Provider-focused solutions

- Engage in patient/physician shared decision making
 - Improves patient/physician communication; increases patient satisfaction; can reduce cost and improve medication taking behaviors
- Educate clinical/nonclinical members of the healthcare workforce about clinical trials and the importance of diversity in clinical trials
 - Nurses/Pharmacists
 - CHWs/Patient Navigators
 - Peer to Peer Education
- Educate physicians/nurses about how to communicate with patients from diverse backgrounds and take into consideration the implications of negative social determinants of health on barriers to participation
- Improve overall delivery of high-quality care

Diversification of Lupus Clinical Trials

Policy-focused solutions

- Enforce FDA guidance on diversity action plans for clinical trial enrollment
- Implementation of decentralized trials
- Incentives for training diverse clinical trialists who historically have not been involved in clinical trials
- FDA should require industry to engage patient advocacy organizations to better understand overall patient preference and support programs that capture preference from underrepresented populations
 - Patients from diverse backgrounds
 - Most vulnerable populations
 - Patients in rural/underserved areas
 - Pediatric populations

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Initiatives Focused on Increasing Diversity in Trials

- FDA listening sessions and PFDD
 - assisted FDA with [series of listening sessions](#) in 2021 that were focused on diversity in lupus trials to better understand why people do/don't participate in trials
- Worked with Congress to encourage OMH
 - to develop diversity action plans for trials but also provide funding to support implementing those plans (IMPACT+).

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Initiatives Focused on Increasing Diversity in Trials

- Initiative for Promoting Diversity in Clinical Trials (IMPACT and IMPACT+) funded by the Office of Minority Health
 - Faith-based education program on clinical trials
 - Nurse patient education program
 - Lupus Research Action Network Peer-to-Peer education program
 - Patient Navigator education program
- Research Accelerated by You
 - Patient and caregiver registry
 - Provides insights on demographics, geographic location, patient preference for medication use
 - Patients participate in PFDD activities with FDA/pharma

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