

**HF Collaboratory: Representative Populations Working Group Q2 Call
June 25th, 2020**

Group Members Present:

Orly Vardeny (Chair, Univ. of Minnesota)
Muthiah Vaduganathan (Chair, Brigham and Women's)
Chris O'Connor (Inova)
Mona Fiuzat (Duke/FDA)
Mitch Psotka (Inova)
Mariell Jessup (AHA)
Phil Adamson (Abbott)
Melvin Echols (Morehouse)
Lawton Cooper (NIH)
Fred Senatore (FDA, CDER)
Eric Leifer (NIH)
Laura Williams (Patient Representative)
Lauren Cooper (Inova)
Ersilia DeFilippis (Fellow, Columbia)
Martin Mendoza (HHS)

Guests:

Wayne Batchelor (Inova)

Group Members Not Present:

JoAnn Lindenfeld (Chair, Vanderbilt)
Dalane Kitzman (Wake Forest)
Clyde Yancy (Northwestern)
John Godwin (Patient Representative)
Piper Dankworth (Patient Representative)

Staff

Heather Applegate
Nicole Fauteux

Dr. O'Connor opened meeting with brief recap of chairs' June 10 call to discuss updating the working groups' objectives.

Dr. Vaduganathan discussed the need to reconfigure activities to focus on race and issues surrounding race. He then briefly outlined the following potential projects and requested input from the group.

- Scientific statement on inclusion of under-represented cohorts to highlight inequities in trials
- Develop database of sites; Identify sites with a track record of successfully enrolling patients of diverse backgrounds in clinical trials
- Diversifying investigators: include FIT/early career of diverse backgrounds in HFC activities

Overall, the group agreed with the three potential projects and felt that the time is right to pursue. Below is a snapshot of each discussion with action items.

Scientific Statement

The group whether they should have a single statement on inclusion – focus on all groups – or one at a time. The group agreed to have a single statement.

From discussion,

- The health impact of excluding underrepresentation in trials - point to solutions and consequences
- Emphasize barriers to participation
- Is there better uptake of studied therapies among underrepresented populations in real-world settings when these groups are appropriately represented in clinical trials?
- Overcoming prior authorization and other financial and social barriers to access may be additional factors that limit uptake in underrepresented populations
- Will enhanced representation lead to better clinical care and reduction in disparities?

Site Database

The group discussed the need to be more deliberate with about site selection to get underrepresented populations included. The NIH mandates targets for their trials – have they met these targets?

Three key factors were addressed:

1. US vs Outside the US – US 14% of enrollees are black; OUS 1% of enrollees are black;
2. Site locations predicted minority enrollment, e.g. Southeast more blacks; Southwest more Hispanics
3. A level of trust is needed in the community to ensure underrepresented enrollment

Diversifying Investigators

The group discussed the need to invest in FIT/early career from diverse backgrounds that need clinical trials training. Potential activities: the HFC can include in future meetings/projects and HFC/HFSA can develop workshops.

Action Items

1) Consider Invited State of the Art called “Systemic Racial Bias in HF Clinical Trials” for JACC: Heart Failure. To include new data from below; Include discussion pertaining to racism and how it systemically biases HF research and clinical care.

2) Differential Uptake of Therapies by Racial and Ethnic Groups

- a) GWTG-HF or other national registry: Evaluate changes in background therapies of hospitalized patients with HF in the US. **Muthu** to speak with Ask Gregg Fonarow
- b) US nationwide data: **Mariell** to speak ask Greg Roth (IHME) regarding opportunities to explore in Global Burden of Disease (GBD)
- c) Abbott Databases: Did sites with greater racial/ethnic variation in CardioMEMS program have greater uptake of CardioMEMS? **Phil Adamson** to explore.

3) Identify US Sites that have Been Successful with Diverse Enrollment

- a) NIH-sponsored trials: **Lawton** and **Melvin** to evaluate HF trials and if site-based information could be shared
- b) FDA databases: **Fred** will check if they have this from FDA databases, and if they could share it
- c) HFSA Research Network: Partner with HFSA to get site demographics in HFSA Research Network. Outreach to sites with under-represented investigators, help with resources (partner w/ HFSA), get them included in Research Network (**Melvin**).

Perhaps invite Greg Folz (contractor with HFSA research network, who does site training and resource development) along with John Barnes to join next call. (**Mona** and **Chris** to arrange).

d) Dr. Batchelor just completed a paper looking at characteristics of sites that have been successful at enrolling diverse patients. (Mona, Chris and JoAnn are co-authors.) Will get the data from that paper.

4) Support Underrepresented Investigators:

- Partner with HFSA and research network to identify needs and next steps (asked Melvin to help with this)

- Industry willing to support this initiative. HFSA can apply for grants to support the workshop.

- Identify under-represented trainees and invite to our meetings, conferences (**Orly** to ask Mariell and Clyde to help us get a list)

5) Letter to Congress to Authorize FDA to Enforce NIH Mandates: The decision was made to draft a LETTER TO CONGRESS to authorize FDA to enforce NIH mandates for inclusion in trials.

- Develop draft (**Silia**)

- Look into background on NIH thresholds and how they were set (**Lawton**)

- There are existing incentives built into pediatric therapeutic programs; **Fred** to investigate the groundwork needed to establish those incentives

- We will ask for partners with societies – HFSA, ACC, AHA. We can utilize their contacts in advocacy to get the letter to the right place, possible Martin from HHS can help us with where to send it.

Select PLATINUM Diversity References:

<https://pubmed.ncbi.nlm.nih.gov/29049508/>

<https://pubmed.ncbi.nlm.nih.gov/30998393/>