

Stakeholder Engagement in Clinical Research

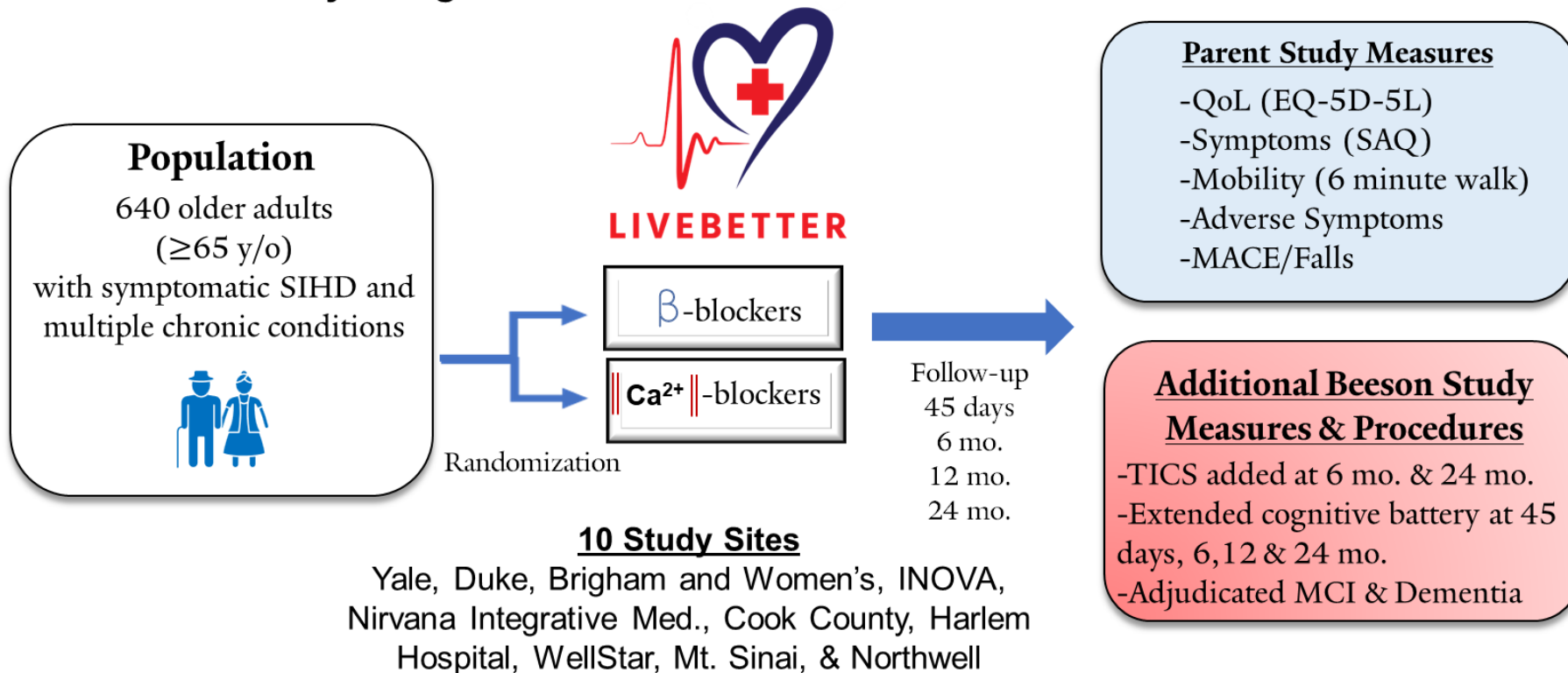
Lessons Learned From the LIVEBETTER Trial



Michael Nanna, MD, MHS

Yale SCHOOL OF MEDICINE

LIVEBETTER Study Design



Healthy Aging: Optimizing Physical and Mental Functioning Across the Aging Continuum FAQs



Meaningful Inclusion of Partners in Decision Making

Projects should use engagement structures and processes that include partners in decision making throughout all phases of the project, with consideration of the project's goals, scope and scale.

[Learn more >](#)

Engagement Resources

What is Engagement in Research?

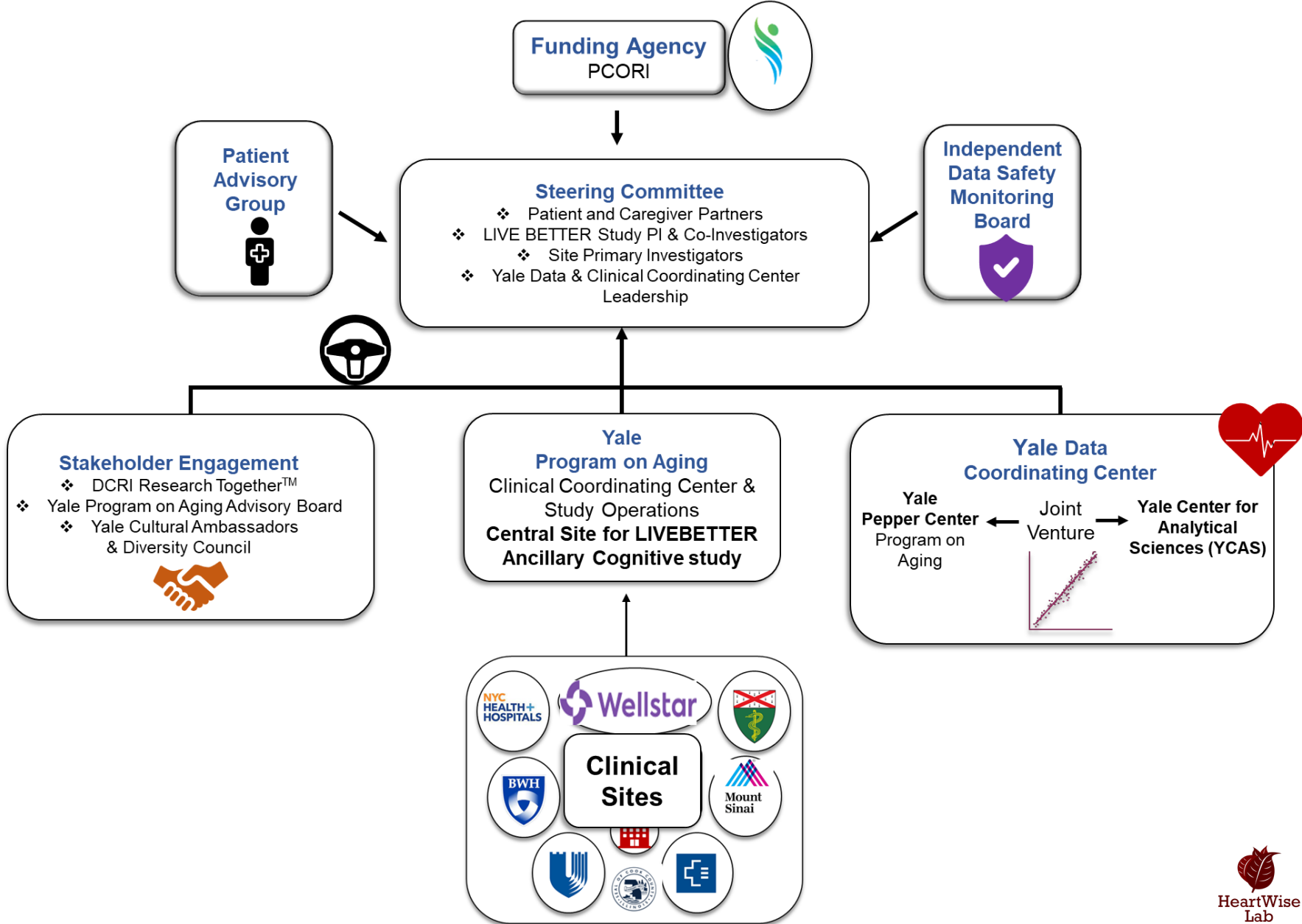
The meaningful involvement of patients, caregivers, clinicians, and other healthcare stakeholders throughout the entire research process—from planning the study, to conducting the study, and disseminating study results.

Yale Pepper Center

Community Advisory Board

Lesson # 1: Listen

Organizational Structure: LIVE BETTER





Research Together

Yale School of Medicine /

Yale Center for Clinical Investigation

Cultural Ambassadors

A Unique Community Partnership

Lesson # 2: Learn

From clinician, patient, caregiver, & community stakeholders

Stakeholder Engagement: Clinicians



Stakeholder Engagement: Patients



Hear from our Patient Stakeholders

Why I think it's important to do studies like
LIVEBETTER in older adults....

"To help in the long term for other people who suffer from the same illness that I have. Knowledge is power."

Stakeholder Engagement: Caregivers



ABOUT LIVEBETTER

The purpose of the LIVEBETTER study is to find out which type of heart medications (beta-blockers or calcium channel blockers) contributes to a better quality of life in older adults with heart disease. Quality of life includes function, symptoms, and help with day-to-day activities.

Beta-Blockers (BB) ● metoprolol
● atenolol

or

Calcium Channel Blockers (CCB) ● amlodipine
● diltiazem



LIVEBETTER TRIAL
Yale University, Cardiology &
Program on Aging
300 George St, Suite 775
New Haven, CT 06511
Toll Free: (888) 683-0865
Email: livebetter-trial@yale.edu
Website: www.livebettertrial.org

Learn about the
LIVEBETTER TRIAL
for Loved Ones of
Older Adults with Heart Disease

Based on a 2020 Report on Caregiving from the American Association of Retired Persons (AARP) and the National Alliance for Caregiving almost 20 million people in the U.S. help care for an older adult ≥ 75 years or older. A medication that improves quality of life can be important not only for older adults with heart disease but also the people that help them with day-to-day activities.



Care needs will be different for everyone and can range from helping with occasional tasks to providing around-the-clock care. If your loved one enrolled in the LIVEBETTER study and you agree to

If you want to learn more or have questions, a person from the research team can talk to you.

[SPACE FOR LOCAL CONTACT STICKER]

Coping with Stress

If your loved one has other health problems and requires a lot of day-to-day support, it can be difficult. If you are feeling stressed, remember to also take care of yourself by:

- Eating healthy foods
- Exercising or going for a walk
- Getting enough sleep
- Doing activities together

Support Resources

To find professional services that help older adults in your area:

<https://eldercare.acl.gov>

or (800) 677-1116

To learn about national and local resources to help pay for care:

<https://www.nia.nih.gov/health/paying-care>

To find other local resources like support groups, transportation, and more:

<https://www.aarp.org/caregiving/local/>



Stakeholder Engagement: Community







Lesson # 3: Be Flexible

Be willing to adapt your research plan/design/operations based on stakeholder feedback

Key Amendments Based on Feedback



Domain	Prior	New
Age Eligibility	≥75	≥65 all participants
Medication Use	Not on any BB or CCB	Current BB or CCB users eligible
Caregiver Target	320	101

An Engagement Plan for Patients and Stakeholders in Research

Engagement in PCORI-funded studies can take many forms. Effective engagement of patients and stakeholders in research requires a well-thought-out engagement plan. Thus, all applications for PCORI research funding must include an outline of how stakeholder partners will be involved in study preparation, conduct, and the dissemination of findings within its Engagement Plan.

The Engagement Plan within the research application is evaluated throughout the official merit review process to assess the patient-centeredness and engagement elements of the proposed research study. The Engagement Plan portion of an application is the conceptualization of how the research team will be responsive to PCORI's Merit Review Criteria for funding.

Following the receipt of a funding contract, awardees will submit a more robust engagement design using PCORI's Updated Engagement Plan template. As engagement generally varies with the nature of the research, we encourage applicants to propose creative engagement ideas that will meaningfully involve patients and stakeholders with a vested interest in the healthcare topic.

Engagement in Research: Not One-Size-Fits-All

Just as there is no one-size-fits-all study design, there's also no one-size-fits-all approach to research engagement. Engagement approaches and practices can—and should—vary with condition, geography, the target population, and other factors, such as the type of healthcare setting, or even the social ecosystem.

Understanding these contextual indicators is crucial to devising an effective engagement strategy in a PCORI-funded research study. Engagement is how this understanding gets generated and incorporated into the study and beyond.

Stakeholder Engagement Lessons From LIVEBETTER

- Listen early and often
- Learn from experienced stakeholders/stakeholder groups
- Be flexible to feedback