Personalized Treatments for Depressive Symptoms in Patients with Advanced Heart Failure
Overview

PART 1: How PCORI approaches research and stakeholder engagement

PART 2: How our study fits into the PCORI framework
Part 1: PCORI
About PCORI’s Research

- Key Features of PCORI’s Funded Research
  - Compares at least two alternate healthcare options
  - Focuses on outcomes that are meaningful to patients
  - Engaged patients and other stakeholders at every stage

![Chart showing research projects by area and most studied conditions and priority populations](chart_image.png)

**BY THE NUMBERS**

Research Projects By Area

- **METHODOLOGY**
  - $133 Million (6%)

- **INFRASTRUCTURE**
  - Including PCORnet
  - $377 Million (16%)

- **CER**
  - $1.9 Billion (78%)

**Most Studied Conditions**

- Mental/Behavioral Health: 121
- Cancer: 86
- Neurological Disorders: 74
- Cardiovascular Diseases: 69
- Multiple/Comorbid Chronic Conditions: 58

**Most Studied Priority Populations**

- Racial/Ethnic Minorities: 301
- Low Socioeconomic Status: 200
- Women: 154
- Older Adults: 137
- Individuals with Multiple Chronic Conditions: 112

*Number of projects (out of a total of 459). A project may study more than one condition or priority population.*
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.
Stakeholders: Who are they?

- Individuals who have experience living with, caring for, advocating for, and/or treating those with a condition.
“The Science of Engagement”

• How specifically is engagement influencing the course of our studies, our portfolio, and the individuals who take part in the work?

• If patient and stakeholder engagement changes the course of studies, how did that happen? How can that be replicated? How can it be sustained?

• How do we demonstrate the value of patient and stakeholder engagement in research?
Part 2: Our Study
Our Stakeholders

• Who you are:
  • Jamie Kay
  • Sharon Dunas
  • John Harold
  • Garrett Shaw
  • Michael Roy
  • Rodney Samaan
  • Garo Harmandayan
  • Ken Wells
  • Jeanne Miranda
  • Mike Ong
Stakeholder impact on study design
Patient Partners

- A member who has been struggling with depression speaks publicly about the importance of treating depression
- Previously: Two heart failure patients who struggled with depression who decided to remain anonymous and not participate in a formal advisory board

<table>
<thead>
<tr>
<th>Goals</th>
<th>Input Provided</th>
<th>How it Shaped Our Design</th>
</tr>
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</table>
| • Represent and advocate for the interests of patients enrolled in the study, from the perspective of the patient. | • It is important to examine the impact of psychotherapy in the treatment of depression in HF  
  • It is important to know which intervention will improve Morbidity and Mortality. | • Created the behavioral activation psychotherapy comparative arm.  
  • Added Morbidity indicators such as ED visits, readmissions, total days in the hospital, and Mortality. |
## Caregiver Partners

- A member a is caregiver for her husband who has advanced heart failure
- Previously: A member who is a caregiver for his two adult children suffering from depression

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<th>Represent and advocate for the interests of caregivers enrolled in the study.</th>
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| Input Provided | • It is important to measure the impact on caregivers.  
• It is hard for HF patients to attend therapy in person. |
| How it Shaped Our Design | • Added caregiver burden measure after informed consent.  
• Added the use of Smart Phone/iPad/Tablet/Telephone. |
Community Organization Partners

- Includes representatives from NAMI, Life Adjustment Team, Clearview programs
- Previously: A member from Painted Brain, which creates lasting community-based solutions to mental health challenges and the impact of social injustice through arts, advocacy, and enterprise.

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<th>• Represent and advocate for the interests of caregivers enrolled in the study, from the perspective of the caregiver.</th>
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<td>Input Provided</td>
<td>• It is important to emphasize functional outcomes, not just depressive symptoms.</td>
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<tr>
<td>How it Shaped Our Design</td>
<td>• Added physical, mental, and heart-failure-specific health-related quality of life to outcomes.</td>
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Physician Partners

- An American College of Cardiology past president, a Cardiologist who specializes in preventative cardiology who is also an underserved community Chief Medical Officer, and a Supportive Care Physician at Cedars-Sinai
- Previously: A primary care provider, and a cardiac ICU director

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<th>Goals</th>
<th>Weigh in as clinicians to challenges and opportunities in delivering care to a patient population suffering from heart failure and depression.</th>
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<td>PCPs often have questions about antidepressants and find it hard to keep track of patients’ progress.</td>
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<tr>
<td>How it Shaped Our Design</td>
<td>Implement the Collaborative Care (CC) model, which provides psychiatry support to the PCP through the help of a care manager.</td>
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Decisions We have Made during the “Conducting the Study” phase with stakeholder input

• Having our BA Therapy supervisor, Dr. Robert Chernoff, supervise some BA sessions directly, which was translated into the decision to have Dr. Chernoff participate in sessions sporadically, with patient permission. [September Advisory Board Meeting]

• Allow participants to switch social workers in their respective treatment arms (or assess participants’ relationship with their assigned social worker if they’ve expressed a desire to end treatment) [December Advisory Board Meeting]

• Refining the language we use to address patients who might be good candidates to participate in the study. [January Advisory Board Meeting]

• Work closely with participants to be as transparent as possible with participants about what we share with caregivers. [January Advisory Board Meeting]

• Collect information about any additional therapies our participants engage in post recruitment (for example, if a participant in the MEDS arm desires psychotherapy outside the study). [October Advisory Board Meeting]

• Have social workers focus exclusively on delivering BA Therapy or Care Management so as to reduce possible contamination in our results. [November Advisory Board Meeting]
Future directions: Dissemination

- Move away from traditional models of dissemination and think more creatively about how to get information in the hands of those who need it.
- Identifying partner organizations for dissemination, to ensure meaningful and direct connections with end-users.
- Planning and participating in dissemination efforts.
- Identifying opportunities to present or share information about the study, even as it is in progress.
We will be distributing an online survey after this meeting to gather more information about your experience as a stakeholder.
Thank you for all your contributions!