



CONNECT-HF

Partnering to improve cardiac care

Connect-HF

Duke Clinical Research Institute

Disclosures

- I have no financial disclosures.



CONNECT-HF

Partnering to improve cardiac care

Study Purpose

CONNECT-HF: Care Optimization through patient and hospital Engagement Clinical Trial for Heart Failure

A large-scale, pragmatic, cluster-randomized trial to evaluate 2 heart failure quality-improvement initiatives, compared with usual care, with the goal of driving evidence into practice and improving patient outcomes



CONNECT-HF

Partnering to improve cardiac care

Expanding Choices & Decisions in Heart Failure

1989

- Digoxin
- Diuretics
- Vasodilators

Today

- ACE inhibitors/ARBs
- Beta-blockers
- Aldosterone antagonists
- ARB/Neprilysin Inhibitor
- Hydralazine/Nitrates
- Ivabradine
- ICD and CRT
- Mechanical circulatory support
- CardioMEMS
- Disease management
- Palliative care



Connecting the Challenge with “WIFM” in Care Transitions: *Poor Communication for Symptom and Medication Management*

- **Key Contributors**

- Payment models do not cover post discharge care
- Discharge education is inadequate in 50-70% cases
- **Communication is not bi-directional**

- **Quality Metrics at Discharge are Poor**

- Medication reconciliation – National Quality Forum, CMS
- Skill-based patient education – The Joint Commission
- Communication at discharge – AHRQ, CMS-HCAHPS/CAHPS
- Engagement at follow-up – CMS-Meaningful Use

- **Result**

- Readmission is high → 20% in HF at 30 days
- Costs are high → \$32 billion/year

Anderson, et.al., 2013, 2014; Mueller, et al., 2012; Gheorghide, et al., 2013;
Bailey SC, et.al., 2013.



CONNECT-HF

Partnering to improve cardiac care

Study Objectives

- Primary objective is to assess the effect of 2 QI initiatives compared with usual care on HF outcomes and HF quality metrics at 1 year after discharge for participants with acute HF and reduced ejection fraction
 - 2 Co-primary endpoints:
 - 1) time to first HF rehospitalization or death within 12 months after discharge
 - 2) improvement in an opportunity-based composite score for adherence to quality metrics for HF



Study Objectives

- Secondary objectives are to examine the effect of 2 QI interventions compared with usual care, on the following:
 - Per-opportunity adherence rate for site-level HF discharge quality measures
 - Participant-level healthcare expenditures
- Exploratory objectives of this trial are to examine the effect of 2 QI initiatives compared with usual care on the following:
 - Participant-reported medication adherence
 - Change in KCCQ and EQ-5D



Hospital Eligibility

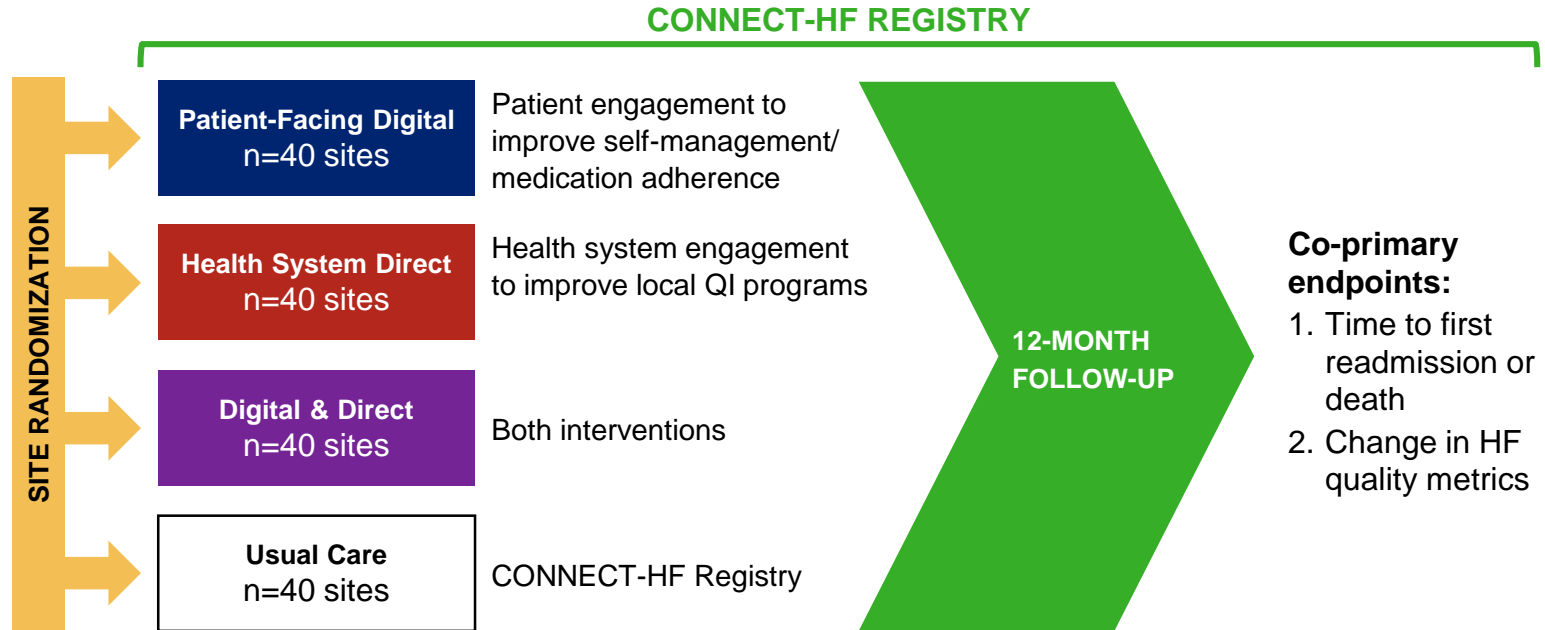
Hospitals eligible for inclusion in this trial must fulfill the following criteria:

- Treat ≥ 50 patients for acute or chronic HF annually
- Have the capacity to be randomized to a system-based QI intervention



CONNECT-HF Study Design

160 US Sites and 8000 patients



CONNECT-HF

Partnering to improve cardiac care

Patient Eligibility

Inclusion

- Age \geq 18 years
- Primary reason for hospitalization is acute on chronic HF
- LVEF \leq 40% on last local measurement
- Planned discharge to home or other care facility where patients manage medications

Exclusion

- Prior heart transplant or current/planned LVAD
- Chronic kidney disease requiring dialysis
- Life expectancy of less than 1 year due to other illness
- Are unable to utilize mobile applications or participate in longitudinal follow-up



CONNECT-HF Study Assessments

Baseline

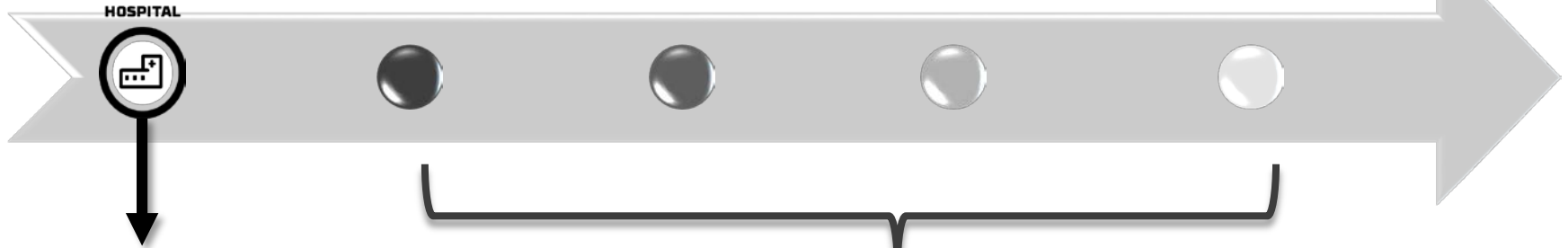
Visit

6 Week

3 Month

6 Month

12 Month



- Patient demographic and baseline characteristics, physical exam, lab assessments, 12-lead ECG
- Kansas City Cardiomyopathy Questionnaire
- EuroQOL Five Dimensions Questionnaire (EQ-5D)
- Onboarding of CONNECT-HF mobile apps

DCRI Call Center

- Medication Adherence
- Quality of Life Assessments
- Outcomes



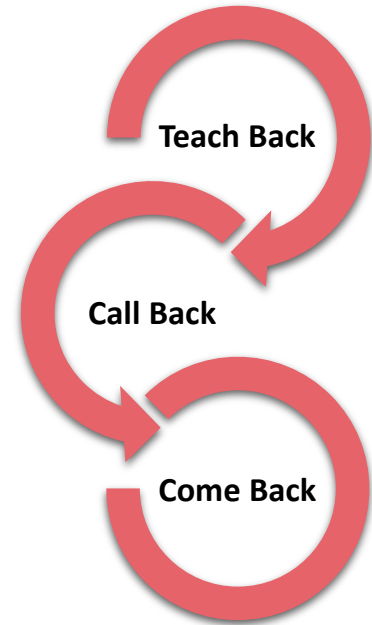
CONNECT-HF

Partnering to improve cardiac care

Health System Direct Engagement

A health system direct engagement strategy that will involve

- Site visits
- Ongoing mentoring from experienced teams
- Health systems and hospitals designing local quality improvement plans

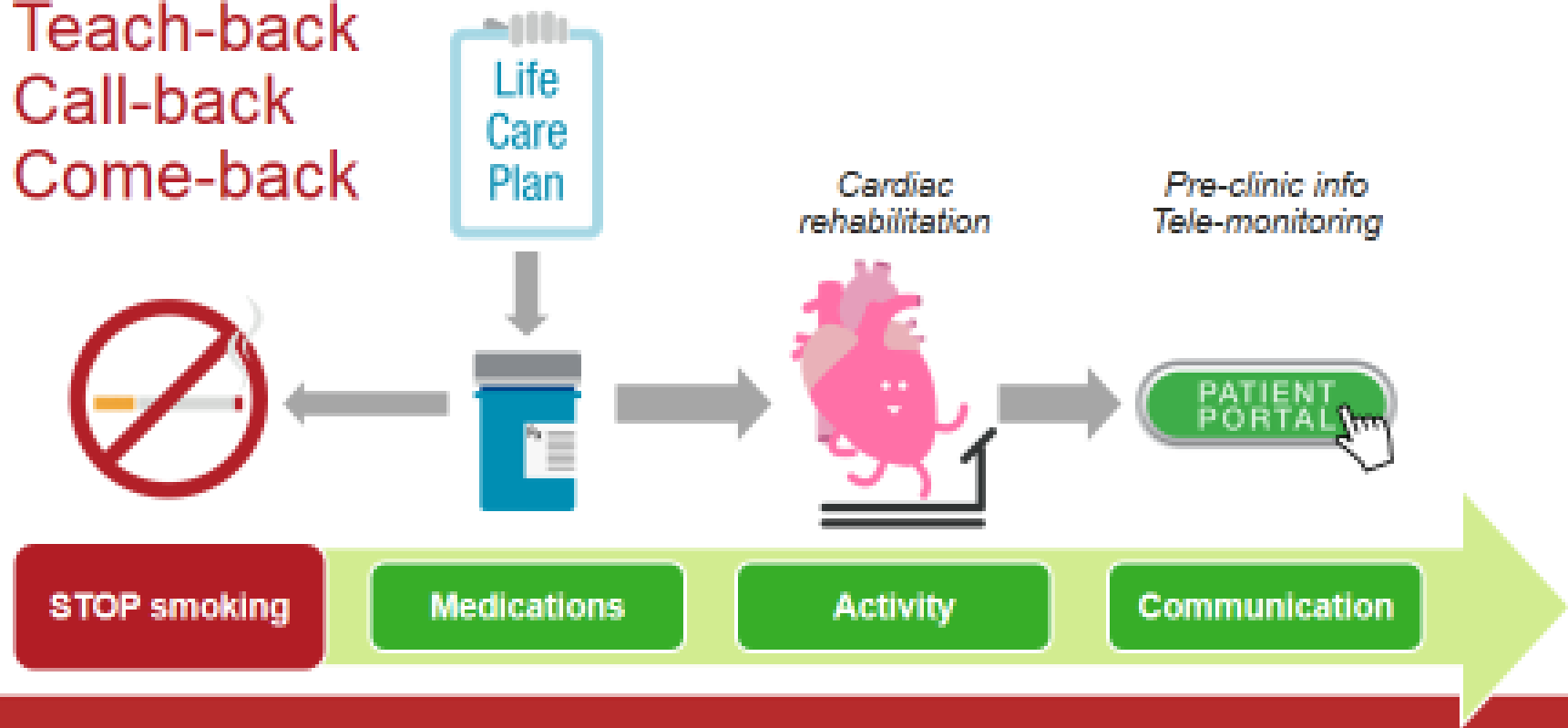


CONNECT-HF

Partnering to improve cardiac care

Core components in Direct CONNECT-HF:

Teach-back
Call-back
Come-back



CONNECT-HF

Partnering to improve cardiac care



CONNECT-HF

Partnering to improve cardiac care

Connect-HF

Duke Clinical Research Institute