The CardioHealth Alliance: A Collaboration to Improve Care

Ken Mahaffey, MD

Stanford Center for Clinical Research, Stanford School of Medicine

Nishant Shah, MD

Duke Clinical Research Institute, Duke University School of Medicine

Neha Pagidipati, MD, MPH

Duke Clinical Research Institute, Duke University School of Medicine

CardioHealth Alliance

Focus

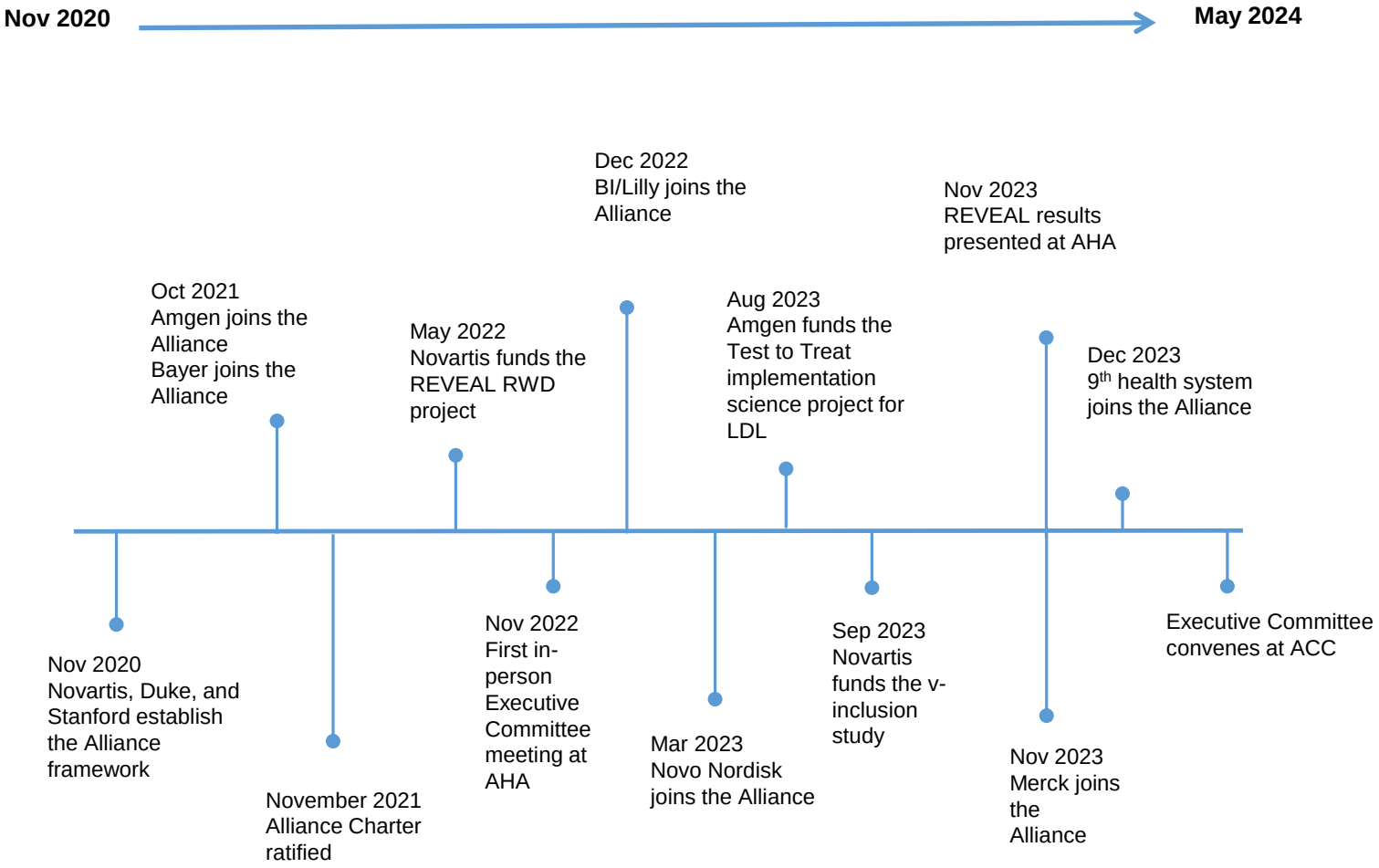
Establish a health system Alliance with engaged clinicians, data scientists, healthcare leaders to develop new care-pathways and real-world data to action platform …

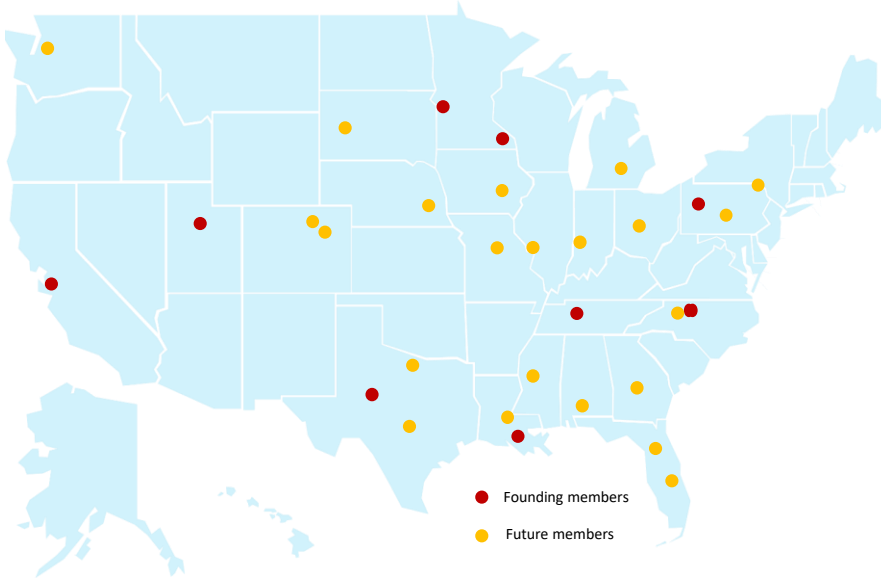
- Cardiovascular disease
- Renal disease
- Metabolic disease

And in so doing, position the consortium to:

- Establish a reusable real-world data platform to rapidly answer clinical questions
- Shorten implementation of evidence into practice
- Generate real-world evidence to inform stakeholders
- Establish an alliance to address value of care through policy

The CardioHealth Alliance





Duke	Amgen
Allina	Bayer
BSW	BI/Lilly
Essentia	Merck
Intermountain	Novartis
Ochsner	Novo Nordisk
Stanford	
UPMC	
Vanderbilt	

CardioHealth Alliance

The Alliance's four pillars include:

CardioHealth Alliance

Use real-world data to inform real-world care

Scale and optimize best practices

Develop and test new pathways and practices

Continuously address value of care through effective policy

A Solution for Learning, Scalability, and Sustainability

CardioHealth Alliance

- The Alliance will:
  - Be a reusable real-world data platform that can answer myriad clinical and implementation questions
  - Be an implementation science *learning lab*
    - Test multiple interventions simultaneously and rapidly iterate to find what works
    - Can be utilized across therapeutic areas
  - Be a *dissemination platform*
    - Rapidly translate successful interventions to sustainable programs across the country

  - **Shorten implementation of evidence into wide-spread practice**

Alliance Research Projects

- Collaborative project development
  - Review project concepts for approval (vote)
  - Review project leadership plans for approval (vote)

Funded Alliance projects to date

- **REVEAL (Novartis)**
- **Test to Treat (Amgen)**
- **V-Inclusion (Novartis)**
- **REAL-CKD Implementation (BI/Lilly and Bayer)**

REVEAL

Real-world Exploration in ASCVD of Evidence-Based Management of Atherogenic Lipoproteins

REVEAL Aims: LDL

Chronic ASCVD Population:

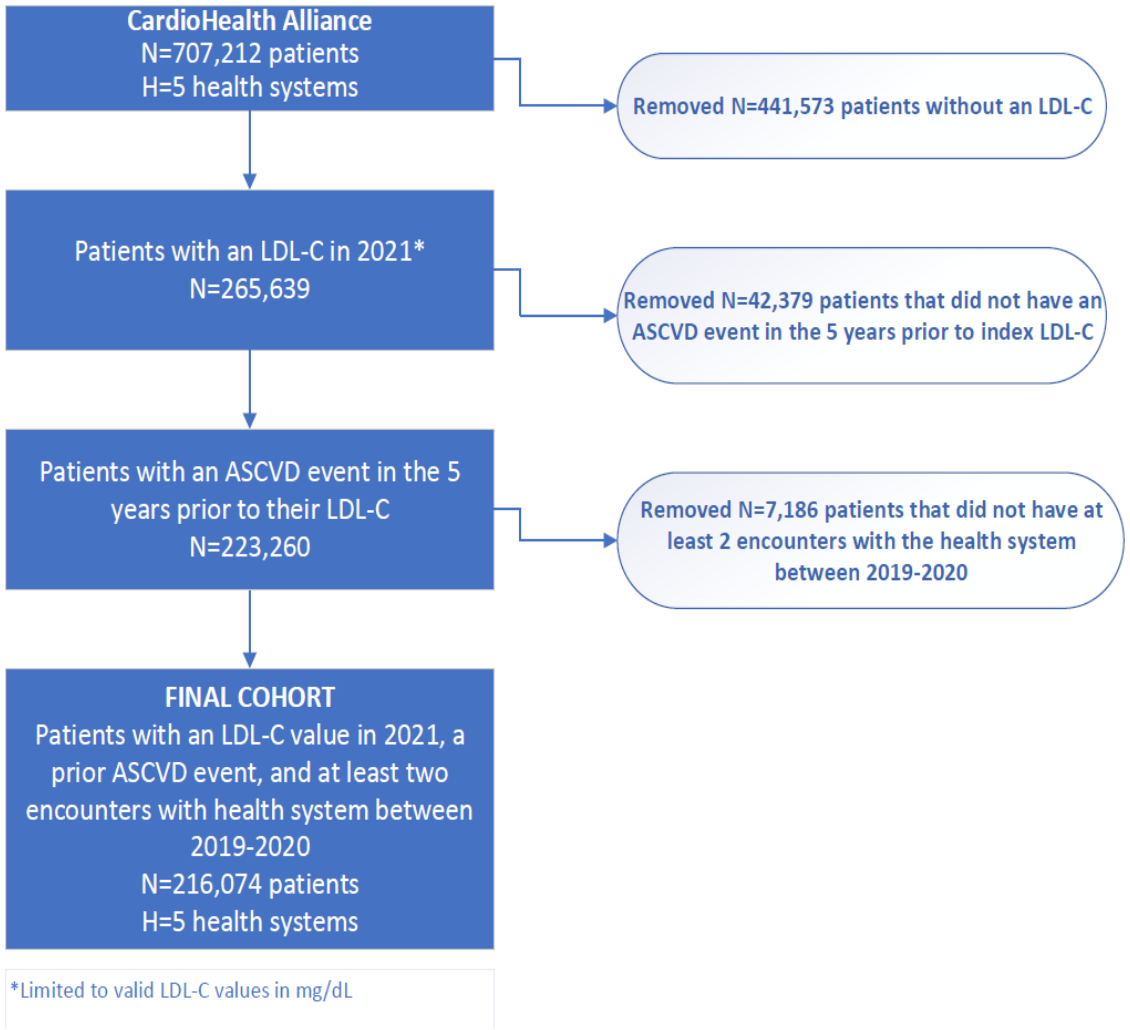
- Aim 1a. Describe the proportion of patients with ASCVD who achieve vs. do not achieve guideline-recommended LDL-C goals
- Aim 1b. Describe factors associated with achieving LDL-C goals in patients with ASCVD
- Aim 1c. Describe patterns of lipid lowering therapy (LLTs) prescriptions before and after LDL-C test by LDL-C level

REVEAL Aims: LP(a)

Chronic ASCVD Population:

- Aim 2a. Determine the proportion (and descriptive characteristics) of patients with ASCVD who undergo any Lp(a) test during the study period
- Aim 2b. Describe factors associated with undergoing Lp(a) testing in patients with ASCVD
- Aim 2c. Describe the LLTs utilization within 6 months prior to and after Lp(a) test and by Lp(a) levels

LDL Cohort


CardioHealth Alliance
N=707,212 patients
H=5 health systems
Removed N=441,573 patients without an LDL-C
Patients with an LDL-C in 2021*
N=265,639
Removed N=42,379 patients that did not have an ASCVD event in the 5 years prior to index LDL-C
Patients with an ASCVD event in the 5 years prior to their LDL-C
N=223,260
Removed N=7,186 patients that did not have at least 2 encounters with the health system between 2019-2020
FINAL COHORT
Patients with an LDL-C value in 2021, a prior ASCVD event, and at least two encounters with health system between 2019-2020
N=216,074 patients
H=5 health systems
*Limited to valid LDL-C values in mg/dL

LDL Cohort Results

- Among 216,074 ASCVD participants, only 86,188 (40%) had LDL-C <70 mg/dL

- Compared with participants with uncontrolled LDL-C (≥70mg/dL), those with LDL-C <70 mg/dL tended to be male (64.9% vs 49.1%), White (87.3% vs 83.9%), had coronary artery disease (83.5% vs 73.0%), heart failure (29.1% vs 21.3%), diabetes (48.2% vs 34.1%), and atrial fibrillation (26.1% vs 19.3%).

Factors associated with NOT achieving target LDL-C

Several factors were associated not achieving target:

Female sex (RR 1.13 [95% CI 1.12-1.14] p <0.001)

Black race (1.15 [1.14-1.16] p <0.001)

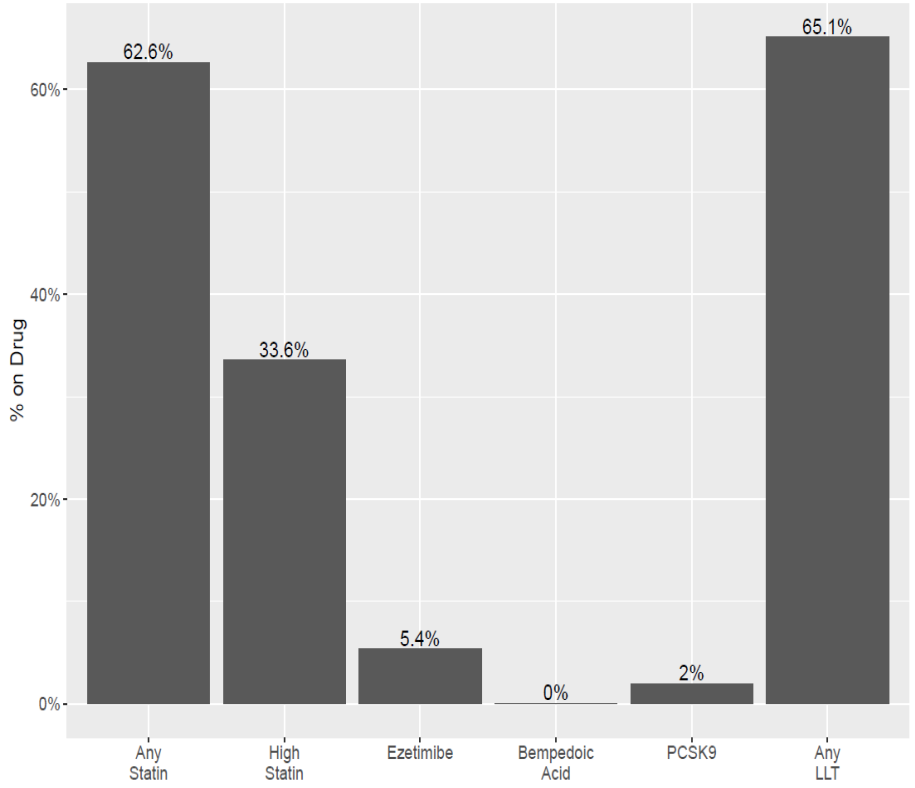
Hispanic ethnicity (1.04 [1.01-1.06] p=0.007)

Prior Lp(a) testing was associated with reaching LDL-C target (0.87 [0.82-0.92], p<0.001)

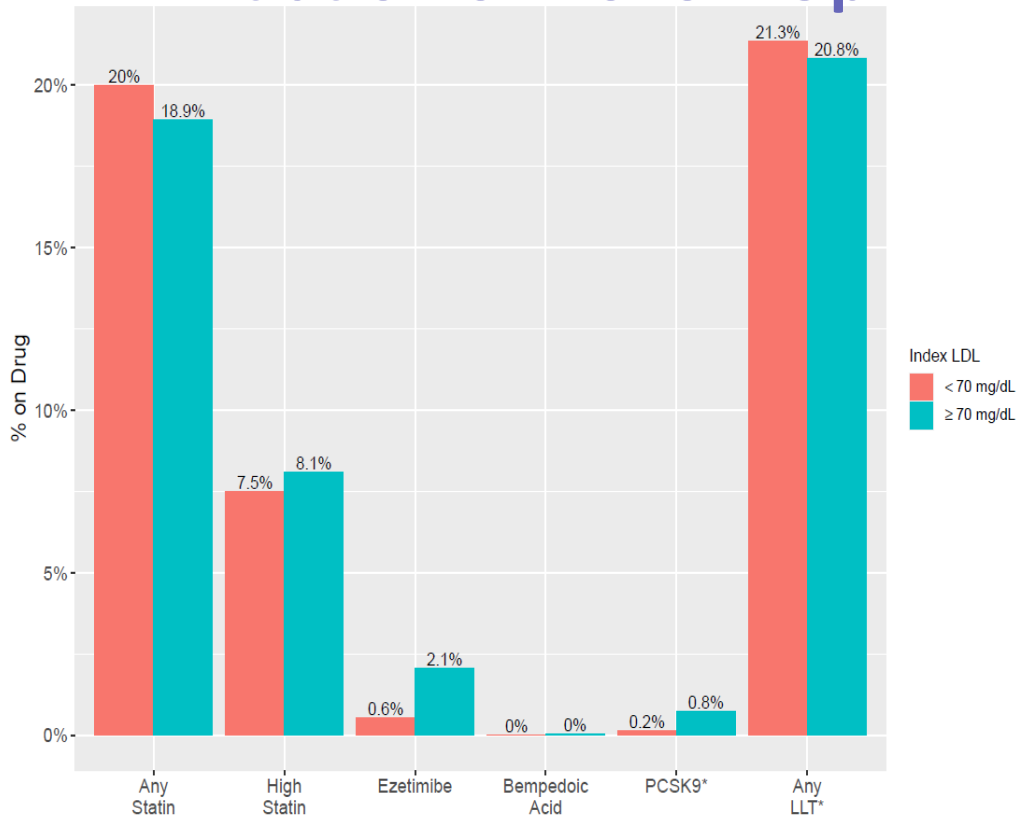
Initiation of LLT

CardioHealth Alliance

LLT at Index LDL-C



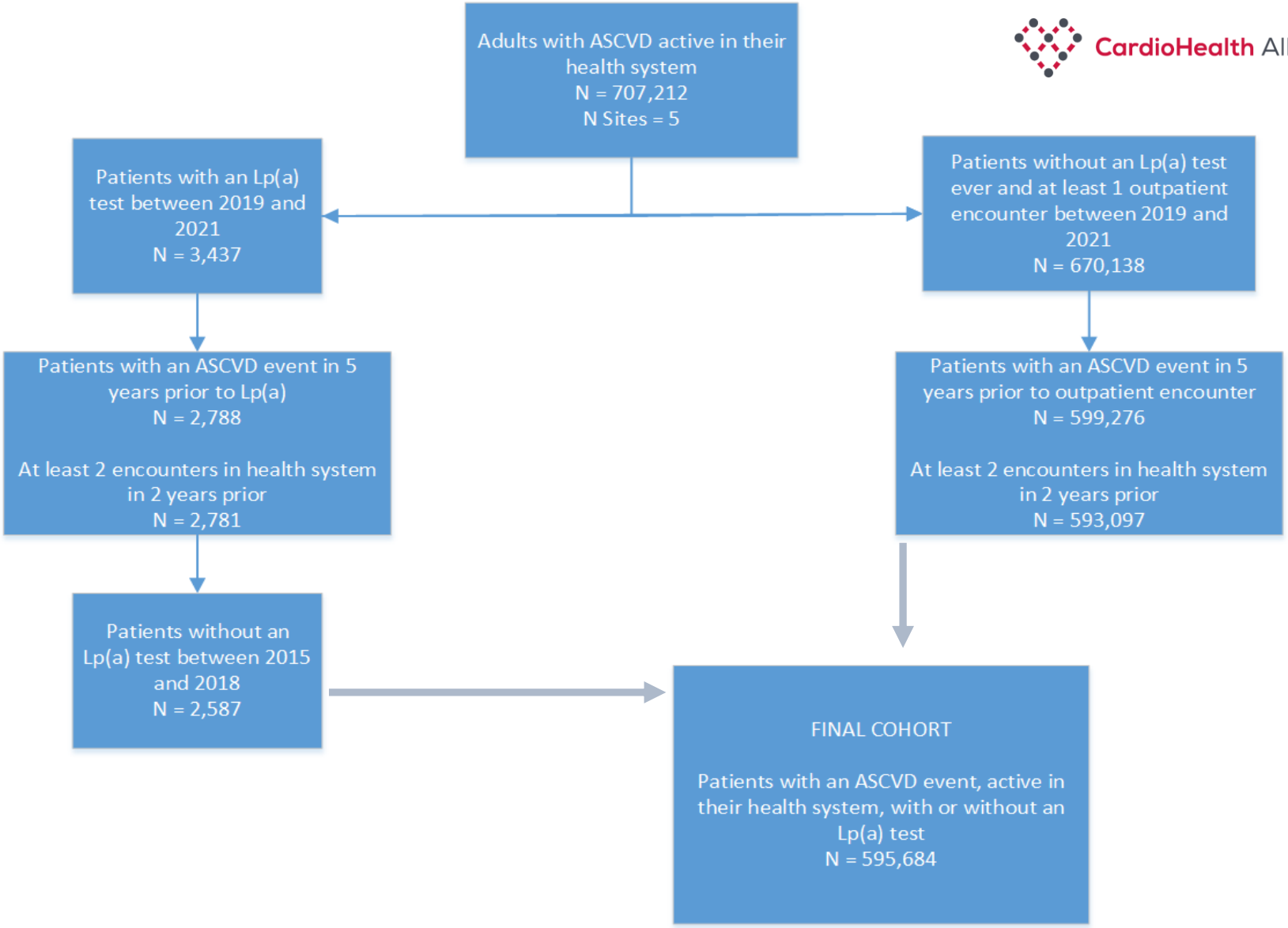
LLT Initiation on Follow Up



Among those with LDL-C ≥70 mg/dL not on lipid lowering therapy (LLT) at baseline (n=53,957 [41%]), only 20% were initiated on any LLT within 6 months of the elevated LDL-C value

CardioHealth Alliance

Lp(a) Cohort



CardioHealth Alliance

CardioHealth Alliance

Lp(a) Cohort Results

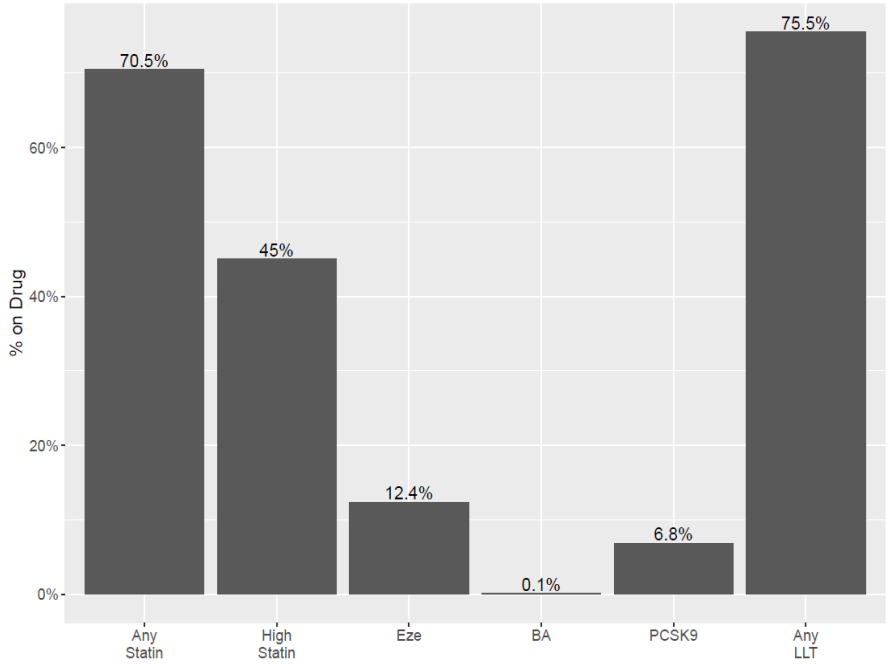
- Among 595,684 ASCVD participants, only 2,588 (0.4%) were tested for Lp(a)

- In adjusted multivariable models, those who were older, Black, or Hispanic were less likely to have Lp(a) testing, while those with familial hypercholesterolemia, ischemic stroke/TIA, PAD, prior LLT, or LDL-C ≥130mg/dL were more likely to be tested for Lp(a)

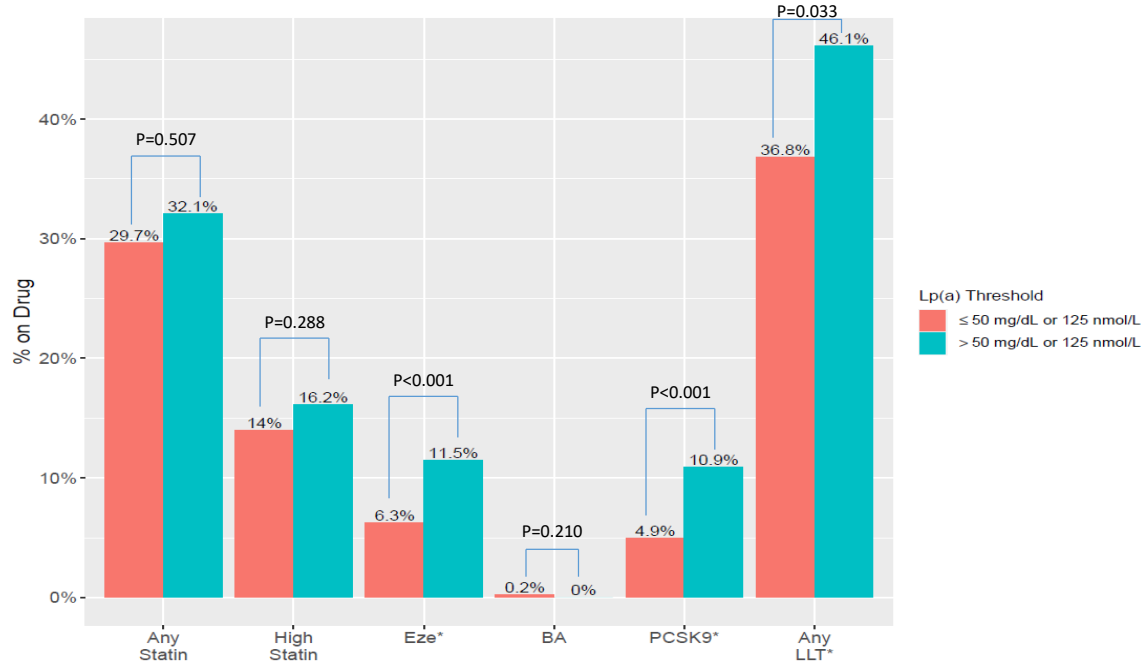
Initiation of LLT

CardioHealth Alliance

LLT At The Time Of Lp(a) Test



LLT At The Time Of Lp(a) Test



Those with elevated Lp(a) (>50mg/dL or >125 nmol/L) were more likely to initiate any LLT (43.9% vs 34.6%, p=0.03), particularly PCSK9i (10.9% vs 4.8%, p<0.01) and ezetimibe (11.5% vs 5.9%, p <0.01) compared to those without elevated Lp(a). Statin initiation remained similar between those with and without elevated Lp(a) (32.1% vs 29.5%, p=0.47).

CardioHealth Alliance

Conclusions

- Within five large U.S. health systems, only 40% of ASCVD patients achieved target LDL-C of <70 mg/dL
- Patients who were female, Black, and/or Hispanic were particularly unlikely to achieve target, highlighting significant disparities
- Additionally, Lp(a) testing in ASCVD patients is infrequent, and also with evidence of disparities by race, age, and ethnicity
- Having elevated Lp(a) was associated with higher initiation of non-statin LLT. However, overall initiation of any LLT after an elevated Lp(a) test was low

Test 2 Treat

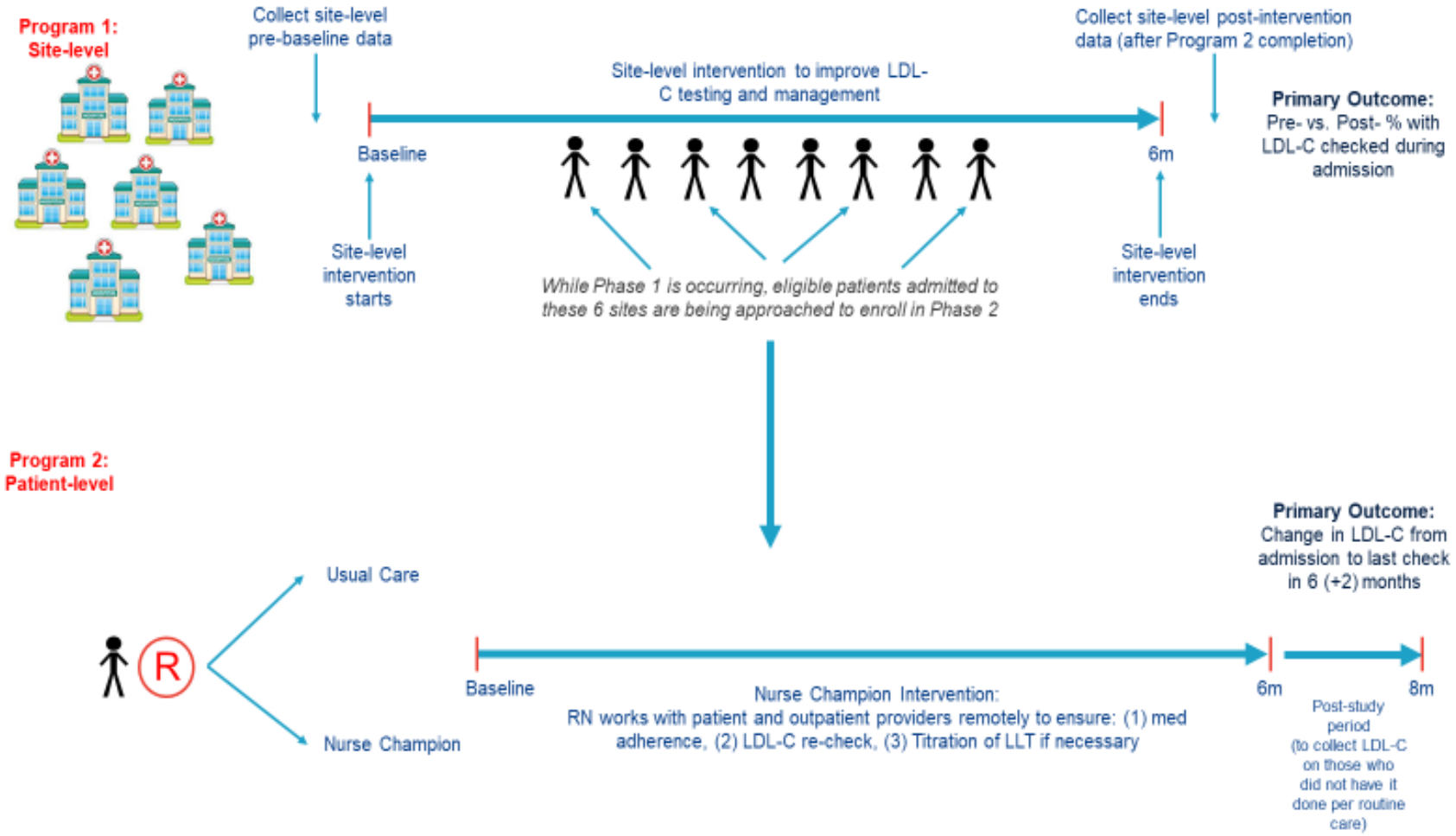
A **CARDIOHEALTH ALLIANCE** PROJECT,
PARTNERING TO IMPROVE CARE.

CardioHealth Alliance

Overview

- Test 2 Treat is an implementation science project aimed at improving LDL-C management after an ASCVD event by improving coordination of care between inpatient and outpatient teams, with the goal of preventing downstream morbidity and mortality in this high-risk population.
- Two “Programs” make up the project
  - Program 1 (Inpatient, Hospital-level intervention)
  - Program 2 (Outpatient, Patient-level intervention)

Overview


Program 1:
Site-level
Collect site-level pre-baseline data
Site-level intervention to improve LDL-C testing and management
Collect site-level post-intervention data (after Program 2 completion)
Primary Outcome:
Pre- vs. Post- % with LDL-C checked during admission
Baseline
6m
Site-level intervention starts
Site-level intervention ends
While Phase 1 is occurring, eligible patients admitted to these 6 sites are being approached to enroll in Phase 2
Program 2:
Patient-level
Primary Outcome:
Change in LDL-C from admission to last check in 6 (+2) months
R
Usual Care
Nurse Champion
Baseline
Nurse Champion Intervention:
RN works with patient and outpatient providers remotely to ensure: (1) med adherence, (2) LDL-C re-check, (3) Titration of LLT if necessary
6m
8m
Post-study period
(to collect LDL-C on those who did not have it done per routine care)

Program 1 Intervention

- Baseline assessment
- Development of pathways to address barriers (e.g. admission order sets; discharge note templates; pharmacist review of LLT plans before discharge, etc)
- Clinician education with provision of guidelines, “summary sheets” with lipid management algorithms
- Monthly review of inpatient data

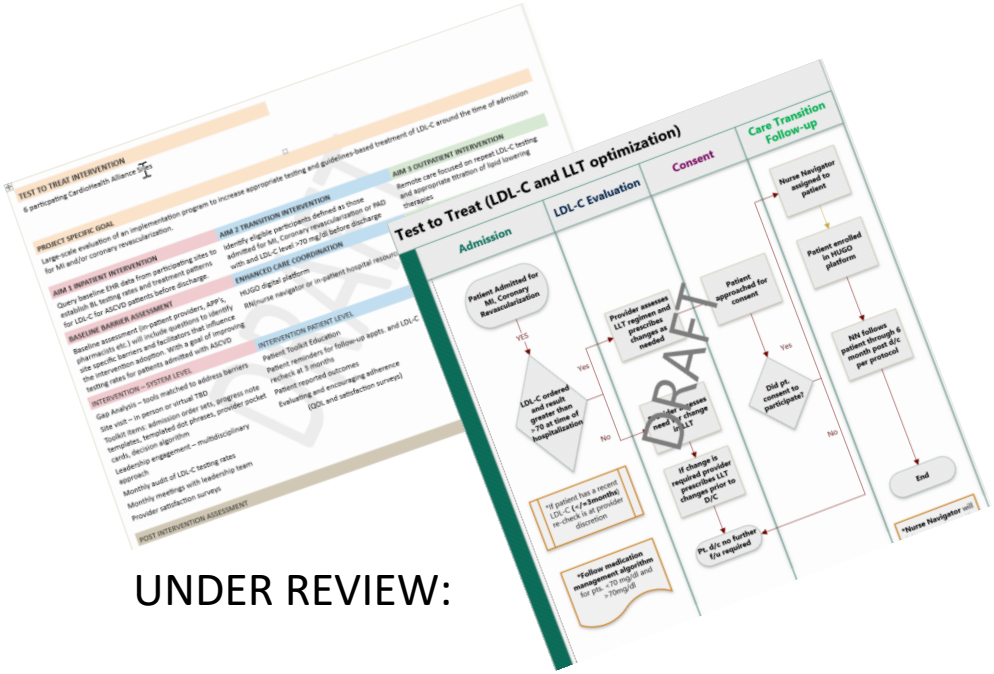
Program 2 Intervention

Nurse champion to help navigate inpatient-to-outpatient transition:

- Explain LDL-C goals before discharge, importance of meds
- Confirm access and adherence to meds
- Ensure follow-up LDL-C testing, outpatient follow-up
- Facilitate communication with outpatient team

*RN will not be responsible for prescriptions

Intervention Components



UNDER REVIEW:

Intervention Outline
Initial Patient Intake Algorithm

IN PROGRESS:

BL Assessment Survey (Health System)
Medication Management Algorithm
Nurse Navigator Algorithm
Provider toolkit
Patient toolkit (including HUGO platform)
CRF’s and PRO’s

Stakeholder Engagement

- Patient Stakeholders Identified
  - 1hr meeting before we enroll our first patient to solicit patient stakeholder feedback to ensure our study objectives align with a patient-centered approach.
  - 1hr meeting to discuss patient stakeholder feedback on the Test 2 Treat patient-facing materials.
  - 1hr meeting to present lay-summaries prior to dissemination

CardioHealth Alliance