A New World of Engagement
The Health eHeart Initiative

Mark J. Pletcher, MD MPH
Dept of Epidemiology and Biostatistics
University of California, San Francisco
Overview

• Health eHeart Study: Engaging research subjects
  – Rationale, goals, design
  – Highlight modular consent and co-enrollment systems
  – Recruitment and data

• Health eHeart Alliance: Engaging citizen-scientists
  – Philosophy and approach
  – Connection with PCORnet

• Engaging YOU
  – Emerging opportunities for novel, efficient research
  – A series of invitations
Health eHeart Team

- Jeff Olgin  | Study PI
- Greg Marcus | Study PI
- Debbe McCall | Alliance Patient PI
- Carol Maguire | Study PD
- Madelaine Faulkner | Alliance PD
- Geoff Tison | Alliance Co-lead
The Health eHeart Study™
Using big data to reduce heart disease
The Health eHeart Study

• **Overarching Goal:**
  – Do tech-enabled research that improves cardiovascular health

• **Approach:**
  – Collect “big data” from all-comers
  – Keep marginal costs low
  – Support ancillary studies, including RCTs
Join the study to end heart disease.

Be a part of an ambitious study to end heart disease. It only takes a few minutes to make a big difference. Anyone can join — whether you have heart disease or not.

Join the Study
Integrated devices and apps

- Background continuous data collection from smartphone sensors
- Reminders/Messaging
- Contextual alerts

- Mobility & Activity
- Screen interaction, call/text interaction
- Behavior modeling

AliveCor

iHealth
- Pulse Oximetry
- BP
- Wt/Body Comp

fitbit

Withings
Modular Consent System

• Start with “umbrella” consent to answer surveys and use data for research

• Then offer easy, short, just-in-time consent modules for each optional feature
  - Each device company
  - Medical records/HIPAA Authorization
  - Food Frequency Questionnaire
  - Ginger.io and Azumio apps
  - In-person testing, biobanking
2-Step Fitbit Consent Module

Connect your Fitbit

It's easy. Clicking the button will take you to their website to enter your Fitbit login and authorize the connection.

Once you do this, we can import the data from your Fitbit devices into your profile, and we'll use it to fight heart disease!

We'll keep your Fitbit data (private and secure), just like we do with all your study data.

Connect
Cancel
Modular Consent System

• Tech Detail: We use Oauth 2.0 – an industry standard – for authentication/“integration”

• Extremely efficient and secure
Referral and Co-Enrollment Tracking Systems

• Unique URL for each referring partner
  – Customized landing page
  – Track source of recruitment

• Add identifier for “co-enrollment” of individual participants
  – Link with data assets provided by a referring partner
  – “Mail-merge” is only requirement for partner
Example #1

https://www.health-eheartstudy.org/gored

Join **Go Red for Women** in the fight against heart disease.

Be a part of an ambitious study to end heart disease. It only takes a few minutes to make a big difference.

Anyone can join — whether you have heart disease or not.

[Join the Study](https://www.health-eheartstudy.org/gored)
Example #2

https://www.health-eheartstudy.org/?rfk=69da54e535641439234236&id=A
Referral and Co-Enrollment Tracking Systems

• Successful campaigns
  – AHA’s Go Red for Women
    • → 11,000 participants (almost all women!)

  – UCSF patients
    • 200,000 emails → 6,000 ppts (3% uptake)
    • Linkable to medical records if they consent

  – Childhood Cancer Survivors Study
    • 500 → 310 (63% uptake)
    • Linked Fitbit data to CCSS Cohort data
Referral and Co-Enrollment Tracking Systems

• An invitation for YOU:

   HeH can collect mHealth data for your study

   (No study is too small)
Small MS study that used HeH

- Fitbit steps: a marker of disability in Multiple Sclerosis

Gelfand et al. Manuscript in preparation
Recruitment

41,911 registered
32,260 consented

UCSF

Go Red
United States Geographic Distribution (Cities): Consented Participants via Google Analytics
Big Data

Self report
• 685,424 surveys completed (from n=28,289 people)
• 19,689 blood pressure measurements (from n=10,795)
• 5,585 LDL measurements (from n=7,691)
• 1,876 Food frequency questionnaires (from n=1876)

Participant-triggered device measurements
• 246,209 weights (from n=643)
• 35,145 blood pressure measurements (from n=419)
• 45,078 EKGs from AliveCor monitors (from n=406)
  – 1,089 with an Afib flag (from n=76)

Passively collected device/app measurements
• 821,787 daily step counts (from n=1709)
• 314,418 days of Ginger.io-derived movement/communication patterns (from n=2264)
• 283 hospitalizations detected from 121 hospitals (n=156)
New measurement: 6MWT by app

- Validation in patients with and without disease

Summary - Health eHeart Study

• A grand experiment in research engagement

• **Success**: efficient recruitment and collection of tech-enabled measurements

• **Challenge**: volunteers are not representative of the population

• **Primary value**: Platform to support mHealth/tech-related research
The Health eHeart Alliance
The Health eHeart Alliance

• A Patient-Powered Research Network
  – Funded by PCORI
  – A member of PCORnet

• Goal: Pioneering new ways to empower patients in improving research, care, and quality of life for heart patients.
The Health eHeart Alliance

• A “Big Tent” philosophy

Figure 1. Membership in The Health eHeart Alliance
The Alliance welcomes anyone declaring their interest in cardiovascular research, defines participation broadly, and expects different levels of engagement
The Health eHeart Alliance

- Includes Health eHeart Study participants...but also anyone else registering interest

Figure 1. Membership in The Health eHeart Alliance
The Alliance welcomes anyone declaring their interest in cardiovascular research, defines participation broadly, and expects different levels of engagement
The Health eHeart Alliance

- A Steering Committee chaired by Debbe McCall

Figure 1. Membership in The Health eHeart Alliance
The Alliance welcomes anyone declaring their interest in cardiovascular research, defines participation broadly, and expects different levels of engagement
The Health eHeart Alliance

A new Community Forum integrated with the Health eHeart Study

Welcome to the Alliance! 🎉

About the Alliance

madelaine.faulkner 😊

Here’s a welcome note from our Patient Chair of the Alliance Debbe McCall:

Welcome to the Health eHeart Alliance. Thank you for considering yourself and others in fighting heart disease. For the first time, patients and their families are part of the research process and solutions in their care. We can recommend research questions and focus. As kind and thoughtful as our healthcare providers can be, it is not the same as living with heart failure, high blood pressure, adult congenital heart disease or atrial fibrillation. We, as patients, have intimate knowledge of what it is like to live day-by-day, sometimes hour-by-hour, with our disease.

My family is likely similar to yours. My mother and her siblings had their first heart attacks before their 50th birthdays. I grew up around heart disease, diabetes, obesity and worked to avoid my genetics and family history. Unfortunately, despite multiple lifestyle changes to avoid it, atrial fibrillation reared its ugly head soon after my 50th birthday. Today, I am AF free and active in the heart disease community.

We can work together with researchers and clinicians to find answers to questions we have long asked. The Health eHeart Alliance supports the Health eHeart Study that looks long-term for the causes and treatment of heart disease involving heart patients and their family members, we can find connections and causes to what we have had to live with so that our children can lead happier and healthier lives. Thank you for being part of our community and the solution.
The Health eHeart Alliance

- A set of criteria and procedures for enlisting sponsorship of the Alliance

Health eHeart Alliance Criteria for Sponsorship of a Research Study

Research projects may benefit from formal affiliation with the Health eHeart Alliance. Our members can engage with the research team, provide detailed feedback, staff Patient Review Boards for the study, recruit patients, utilize the Health eHeart Study platform, and help disseminate study updates and results to the larger community of patients and stakeholders interested in heart health. Our network is funded by the Patient-Centered Outcomes Research Institute (PCORI) as a Patient-Powered Research Network. We are part of PCORnet, and can help outside researchers with a heart-related research project access PCORnet resources and conduct PCORnet studies.

The Health eHeart Alliance will sponsor research projects that meet the following criteria:

1. Scientifically sound cardiovascular-related research
2. At least one Health eHeart Alliance member is participating as a patient-leader in a decision-making role and getting compensated for that role
3. Accountability reporting on study progress and results back to the Health eHeart Alliance Community and the Steering Committee
4. Co-authorship for at least one Alliance patient-leader on final results paper
5. Acknowledgement of the Health eHeart Alliance in the final results paper
The Health eHeart Alliance

- A growing list of major research projects
Patient-Centered Reviews

- Example: Hypertension telehealth study - Karen Margolis

- Proposed to Alliance
- 8000 Health eHeart Study participants with HTN emailed
- 1000 clicked through to a Google Doc
- Hundreds participated in simultaneous editing and commenting (broke Google docs!)

→ Conference call and surveys for patient input, and strong Alliance support for the grant application
Patient-Powered Research
Patient-Powered Research

• Triggers of MI
• N of 1 toolkit for statin decliners → CVD risk, satisfaction
• N of 1 toolkit for paroxysmal afib → QOL
• Online support groups for newly diagnosed afib
• Qualitative study of transitions in care, role of data
• Using activity monitors to increase activity in CVD patients
• Sharing mental health issues with cardiologists
• Improving “success in life” among young stroke patients
Patient-Powered Research

- Triggers of MI
- N of 1 toolkit for statin decliners → CVD risk, satisfaction
- N of 1 toolkit for paroxysmal afib → QOL
- Online support groups for newly diagnosed afib
- Qualitative study of transitions in care, role of data
- Using activity monitors to increase activity in CVD patients
- Sharing mental health issues with cardiologists
- Improving “success in life” among young stroke patients
HeH Alliance and PCORnet

- Health eHeart Alliance is PCORnet’s cardiovascular-focused patient-powered research network

- Opportunities for research are immense
  - Engaged patients in PPRNs
  - 100 million recruitable patients with EHR data in CDRNs
  - HeH Study provides a way to engage these patients and collect PROs and mHealth data
HeH Alliance and PCORnet

• Health eHeart Alliance is PCORnet’s cardiovascular-focused patient-powered research network

• Opportunities for research are immense
  – Engaged patients in PPRNs
  – 100 million recruitable patients with EHR data in CDRNs
  – HeH Study provides a way to engage these patients and collect PROs and mHealth data

Learn more at 4pm today!
We want YOU!

Come to our 4pm PCORnet Session later today
Propose PCORnet Research and get grant application support
Call for Proposals: https://www.bit.ly/1VHmukD

Join the Study: https://www.health-eheartstudy.org/
and/or the Conversation Forum: /community

Analyze Health eHeart Study data
Use Health eHeart (or our NIH-funded white-labeled platform) to collect mHealth data for your research project
Email me, Jeff Olgin or Greg Marcus
### Volunteer bias

<table>
<thead>
<tr>
<th></th>
<th>US pop NHANES n=6,113</th>
<th>Health eHeart All n=26,982</th>
<th>eVisit done + Fitbit n=16,501</th>
<th>n=1,276</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean</td>
<td>47</td>
<td>51</td>
<td>52</td>
<td>49</td>
</tr>
<tr>
<td>% Female</td>
<td>52%</td>
<td>75%</td>
<td>74%</td>
<td>68%</td>
</tr>
<tr>
<td>% AA</td>
<td>12%</td>
<td>6%</td>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td>% College+</td>
<td>29%</td>
<td>71%</td>
<td>74%</td>
<td></td>
</tr>
</tbody>
</table>
Volunteer bias

• Similar patterns of response in other internet-based studies

Comparison of the sociodemographic characteristics of the large NutriNet-Santé e-cohort with French Census data: the issue of volunteer bias revisited

Valentina A Andreeva, ¹ Benoît Salanave, ² Katia Castetbon, ² Valérie Deschamps, ² Michel Vernay, ² Emmanuelle Kesse-Guyot, ¹ Serge Hercberg ¹,²,³

78% female, 65% post-secondary education
HeH Alliance and PCORnet

• PCORnet Cardiovascular Health Collaborative Research Group (CVH CRG)
  – Initial focus on HTN, CHF, Women with Chest Pain
    • Bluetooth BP cuffs → Better/faster BP Control?
    • Precision BP medication prescribing?
    • BP Control “Laboratory” in PCORnet?
    • EHR data → Early warning system for CHF hosp?
    • 6MWT app for CHF home self-monitoring?
    • Does atherosclerosis Rx or ACE-I help women with CP?
  – Propose your own project!
HeH Alliance and PCORnet

• PCORnet Cardiovascular Health Collaborative Research Group (CVH CRG)

– Come to 4pm session today to hear more and get engaged!
  • Travel $ and support for PCORI-style applications
  • Call for Proposals: https://www.bit.ly/1VHmukD
Health eHeart → Health ePeople

• U2C contract from NIH: Mobilizing Research
  – General platform for gathering mHealth data from research participants
  – Open up broadly to research community

  – Coming this Summer!
Pragmatic Technology-Enabled Randomized Controlled Trials

• eRCTs should be able to:
  – Approach, consent, and enroll over the internet
  – Use online surveys for self-reported data
  – Use electronic health records for finding patients and collecting health measurements and outcomes
  – Use sensors to collect and transmit real-time/real-life data, deliver novel interventions
  – Use smartphone geolocation and movement pattern data to detect hospitalization events
  – Use online social networks and forum technology to collect social data, engage ppts
Pragmatic Technology-Enabled Randomized Controlled Trials

• eRCTs should be able to:
  – Approach, consent, and enroll over the internet
  – Use online surveys for self-reported data
  – Use electronic health records for finding patients and collecting health measurements and outcomes
  – Use sensors to collect and transmit real-time/real-life data
  – Use smartphone geolocation and movement pattern data to detect hospitalization events
  – Use online social networks and forum technology to collect social data, engage ppts

Cheaper, faster, easier, better?
Specific questions from Dr. Margolis and colleagues

[What about those who do not have high blood pressure, but are always 'borderline'? Please type your suggestions here]

I think discussing diet and exercise are important, as well as other natural means of controlling high BP. I'd like to know all about fluctuations in BP levels - why is it sometimes high, sometimes low, sometimes borderline? Information helps a person stick to proper procedures to help their BP stay at optimum levels.

1. Besides seeing how much blood pressure changes in our study, what other "outcomes" should we measure that are important to you? Some examples of other outcomes might be avoiding medication side effects, avoiding interference with work or other responsibilities, or having treatments that are simple to do.

4. Knowing which treatment modality is more effective is a pretty good outcome to start with. It would also be interesting to know what kinds of patients respond better to the different modalities, i.e., do women respond to one better than men, or does the different kind of hypertension respond better, essential vs renovascular.

There should be a more accurate way to take blood pressure. One way to lower it is to lose weight. You only get improved blood pressure WHILE you're losing weight. Not a good treatment for long-term use....
Disclosures

Research infrastructure grants from PCORI and NIH supporting the Health eHeart Alliance and the Health ePeople Resource for mHealth data collection