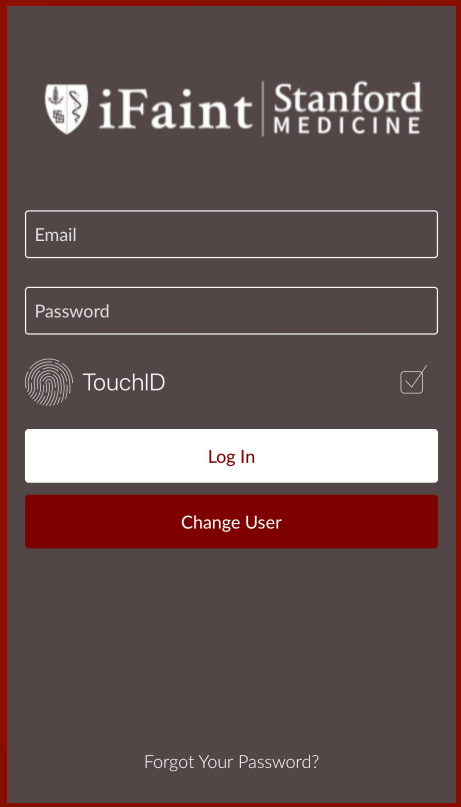
iFaint Research App

Smartphones and Wearables to Improve Research, Diagnosis and Care



James Quinn MD MS

Professor Department of Emergency Medicine

Vice Chair of Institutional Review Board

Stanford University

Disclosures

- Member of Scientific Advisory Board of "iRhythm Technologies Inc."

iRhythm

STANFORD biodesign

Outline

- Review syncope and state of research
- Big Data/Personalized Medicine - iFaint App
- Discuss general app development issues
  - Build, HealthKit integration
  - Data use and security
- Demonstrate the App

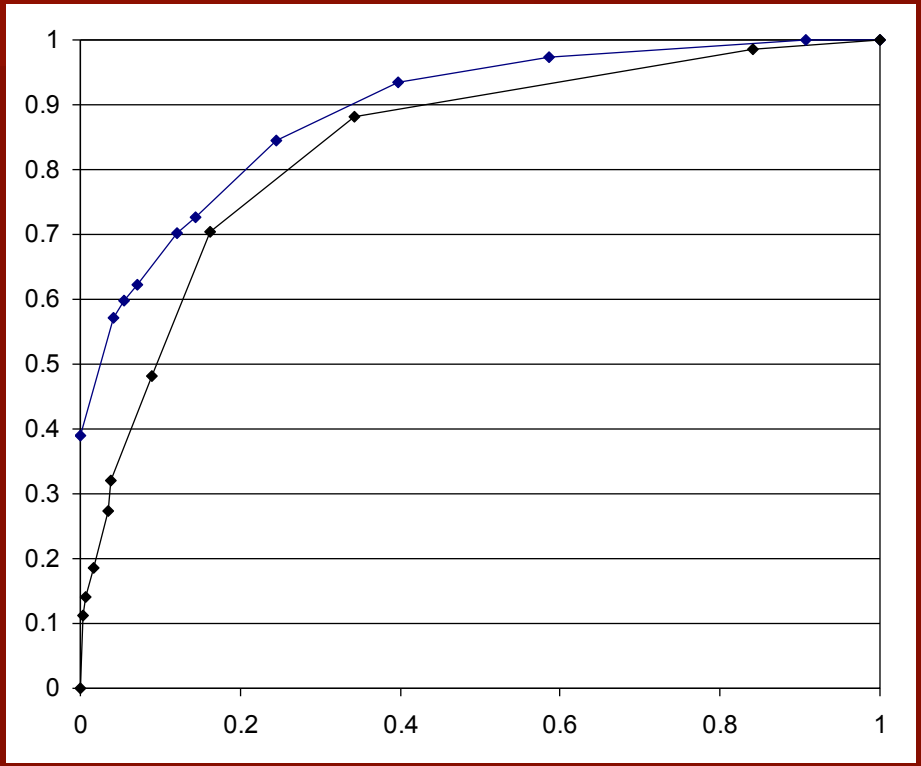
The Syncope Dilemma

- Very Common
- Presentation can be dramatic
- Most causes are benign
- The value of hospitalization is debatable
- Tremendous variation on how patients are managed

"Syncope is just like being dead but you wake up"

Need For Risk Stratification

- Physician judgment is good; they just don't trust it
- US physicians admit 30% of low risk patients
- Great potential for risk stratification
- Numerous Risk Tools/ Scores



Physician Judgment 0.89 (95% CI 0.85 – 0.93)

Physician Admission Behavior 0.83 (95% CI 0.81 – 0.85)

Prognosis: One Year Risk

Kapoor

- Syncope is associated with increase risk of death and cardiovascular morbidity at one year
- Syncope itself is not an independent risk factor for increased overall mortality, cardiac mortality.
- Underlying heart disease is a risk factor for mortality regardless of whether the patient has syncope or not

- **ECG** abnormalities and existing structural heart disease as predicted by **CHF** was most valuable
- **Age <45** was low risk

NEJM 1983, Ann Emerg Med 1997, Arch Intern Med 1999

Prognosis: One Year Risk

Colivicchi

- **EKG** abnormalities
- History of cardiovascular disease (**CHF**)
- Lack of Prodrome
- **Age > 65**

- Predicted death at one year

European Heart Journal 2003

San Francisco Syncope Rule

- Attempt to risk stratify patients into high and low risk
- Considered 50 clinical variables
- Prospectively derived and validated

1) **Abnormal ECG or rhythm**
2) **Complaint of SOB**
3) **History of CHF**
4) **Hct < 30**
5) **SBP < 90**

- Predicted patients at risk for 7 day outcomes
- Predicts syncope related death
- Could reduce admissions by 10%

Arrhythmia Risk Score

- Small convenience cohort of ED patients with unknown cause of syncope to determine risk of arrhythmia
- Underwent aggressive EP testing
- All arrhythmias could be predicted by an abnormal **EKG**, History of **CHF** and **age > 65**

STePS (Short Term Prognosis of Syncope 10 days)

- ECG
- Concomitant Trauma
- No warning symptoms
- Male

Long Term risk (1 year)

Age > 65, structural heart disease, history of arrhythmia, hx of CVA or associated neoplasm

J Am Coll Cardiol 2008

ROSE

(**R**isk **S**tratification **o**f **S**yncope in **E**mergency Department)

- ECG
- BNP (Heart Disease Marker)
- Occult Blood
- O2 sat < 94%
- hemoglobin < or =90 g/l

Reed, J Am Coll Cardiol 2010

Canadian Risk Score

- ECG
- History of Cardiac Disease
- Predisposition the vasovagal Syncope
- BP abnormalities <90, >180

Venk, 2016 CMAJ

Simple Risk Stratification Score

- ECG Abnormalities
- Previous Heart Disease
- Previous Syncope

- Only looked at cardiac outcomes

Gomes, J Interv Card Electrophysiol 2016

Summary

- **ECG**/rhythm abnormalities, a history of **Heart Disease** are high risk criteria
- Patients with vasovagal syncope are low risk

(as long as we can agree who they are?)

- "Sudden cardiac related death"

-It is what we are worried about

-It is rare and we need lots of patients to study it as an outcome

The International Workshops on Syncope Emergency Department/First Assessment

Gargnano 2013

Palermo 2017

SYNERGI

Priorities for Emergency Department Syncope Research.

Sun BC[1], Costantino G[2], Barbic F[3], Bossi I[4], Casazza G[5], Dipaola F[3], McDermott D[6], Quinn J[7], Reed M[8], Sheldon RS[9], Solbiati M[5], Thiruganasambandamoorthy V[10], Krahn AD[11], Beach D[12], Bodemer N[13], Brignole M[14], Casagranda I[15], Duca P[5], Falavigna G[16], Ippoliti R[17], Montano N[2], Olshansky B[18], Raj SR[19], Ruwald MH[20], Shen WK[21], Stiell I[10], Ungar A[22], van Dijk JG[23], van Dijk N[24], Wieling W[24], Furlan R[3].

Ann Emerg Med. 2014 Jun 2

Next Steps in Syncope Management

- Standardized ED management (ECG/ monitoring)
- Improved Clinical Decision Support
- Personalize Risk Determination
- Shared Patient Decision Making
- Evaluating new technology with improved outcome measures

Standardized Care versus Personalized Medicine

"It is better to do it the same than to do it right"

Intermountain Healthcare

"Precision Health and Personalized Medicine is the Future"

Lloyd Minor, Dean of Stanford University School of Medicine

"I want to be treated like all patients who are just like me"

This is not unique and in healthcare may not be wrong

General vs Personalized Risk

Traditional Risk Stratification

- Classic Odds/Risk Ratio
- Multiplicative Properties
- Not dependent on the incidence in population
- Generalizable if developed in generalizable population
- Require Pre-test probability (Gestalt)
- Reasonable sized cohorts

Personalized Risk Stratification

- No “Gestalt”
- Based on actual outcomes from people with closely matched characteristics
- Better shared decision-making
- Requires large cohorts with precise variables and outcomes

iFaint App
Personalized Risk

- Potential to develop a large cost effective cohort
- Collect variables and outcomes of interest
- Validate risk factors
- Consider new ones (HR, HRV, activity)
- Use the large dataset accumulated over years to determine personal risk

App Considerations

- Easy to use
- Least Burdensome
- Added value/motivation - Dashboard
- Real/eligible users

– Is data accurate and generalizable

– iOS/android variability, absent wearables

- HealthKit update IRN, ECG

- Data management, Security, Privacy and Ethical Considerations

Data Security, Privacy, Ethics

New medical research platform for IRB, institutions and countries

-3rd party vendors with expertise

-Leverage security and access to platforms – HealthKit through consent

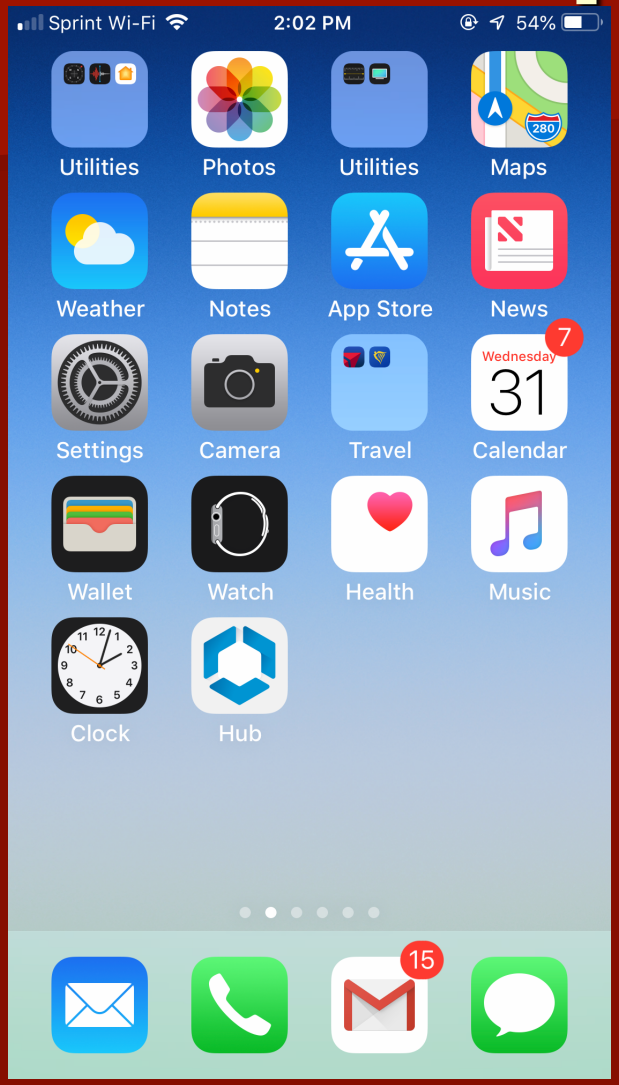
-Experience from others at Stanford – CDH

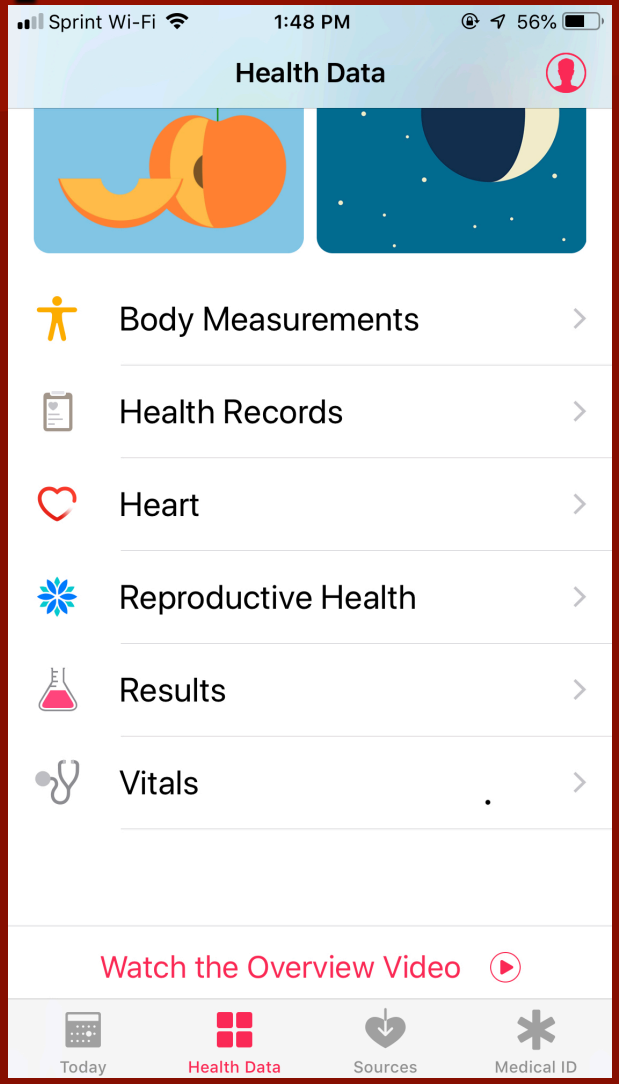
"Apple Heart Study", "MyHeart Counts"

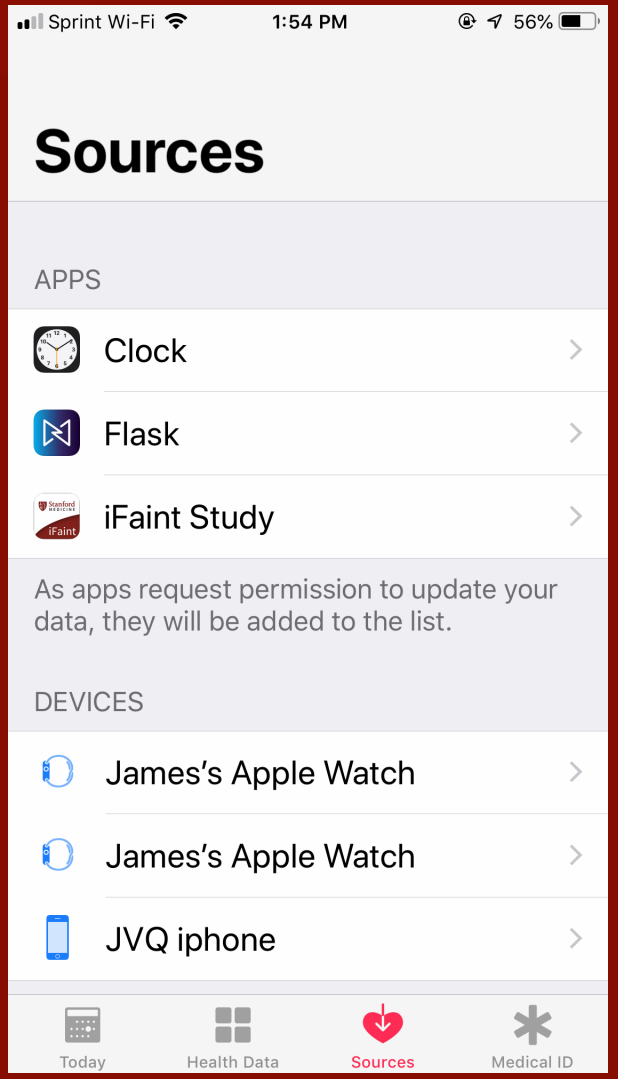
-Changing rules – new EU guidance

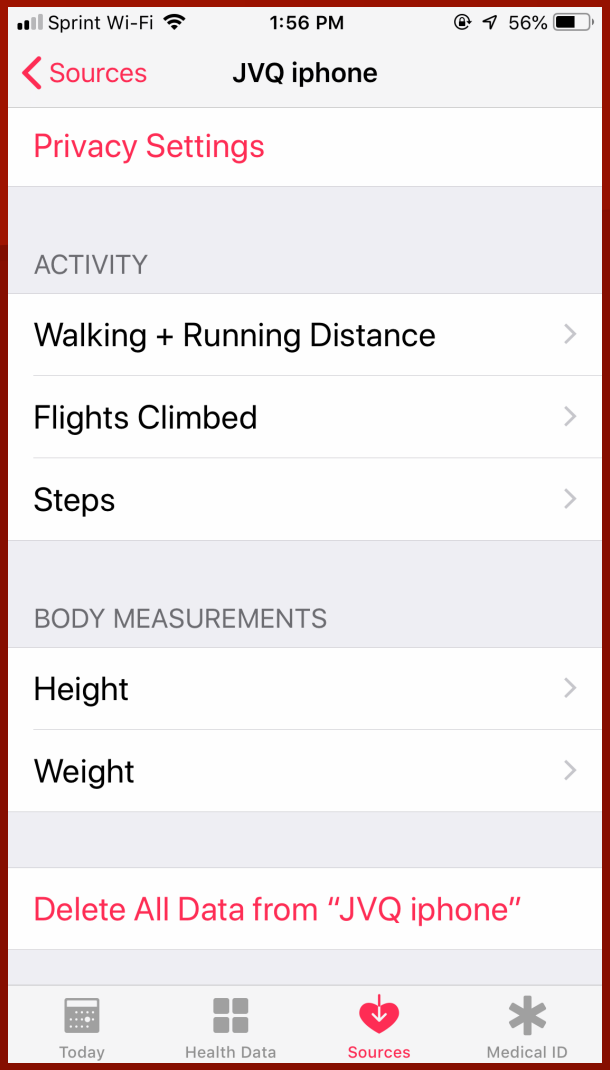
-Roll out and testing

Apple HealthKit





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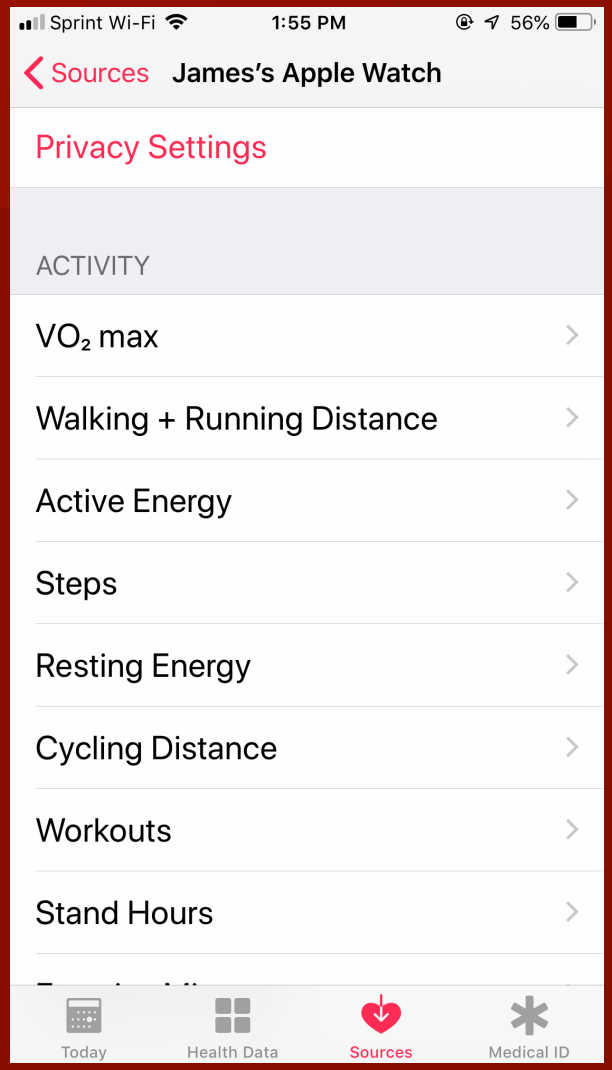
1:56 PM
56%
Sources
JVQ iphone
Privacy Settings
ACTIVITY
Walking + Running Distance
Flights Climbed
Steps
BODY MEASUREMENTS
Height
Weight
Delete All Data from "JVQ iphone"
Today
Health Data
Sources
Medical ID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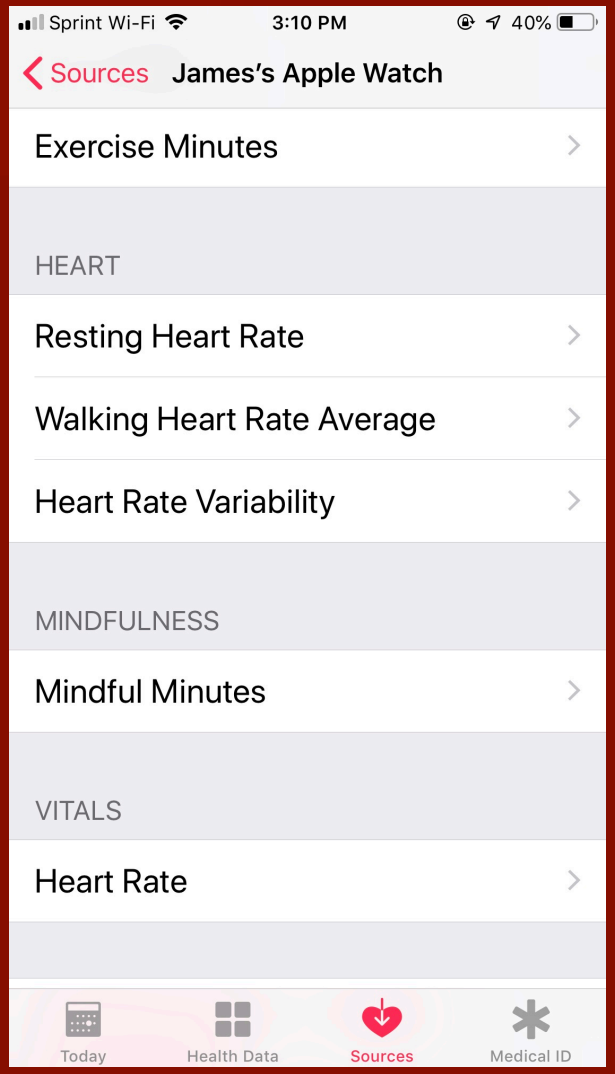
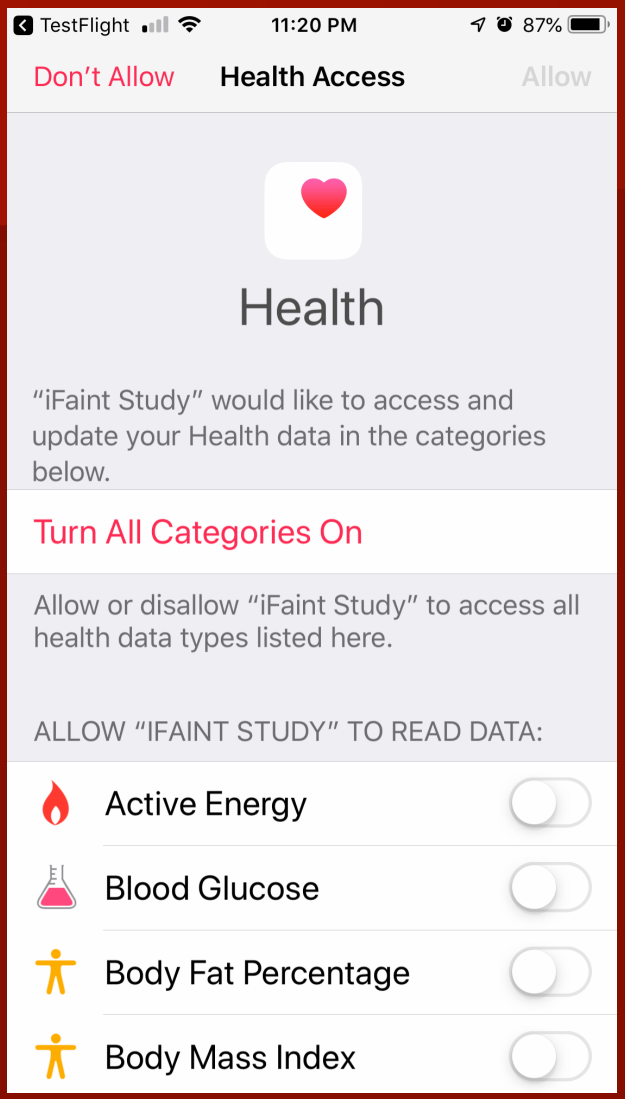
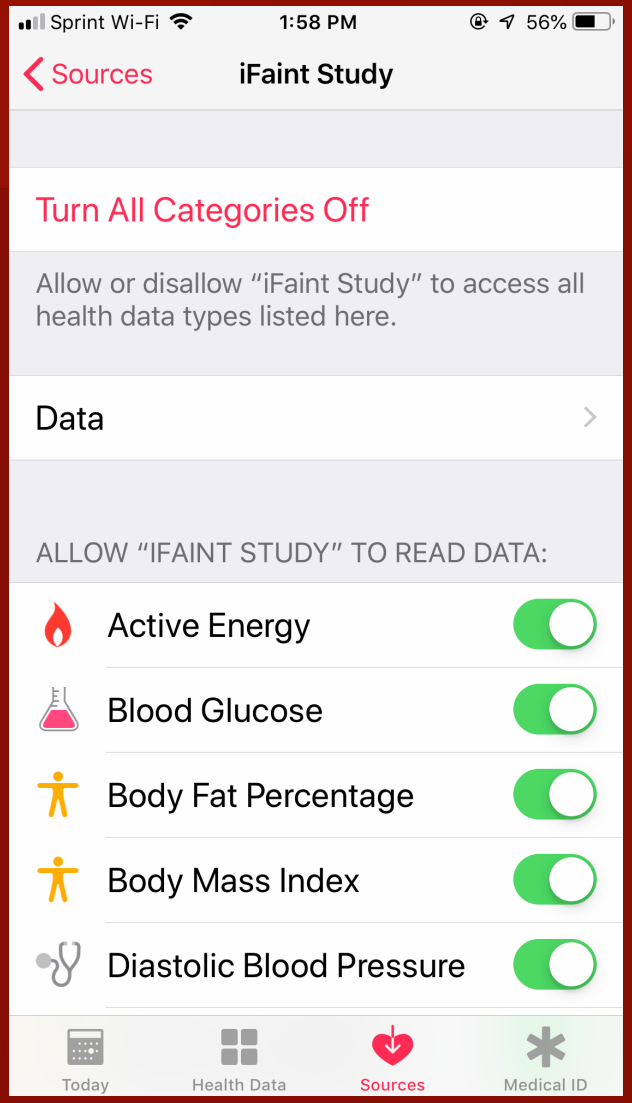
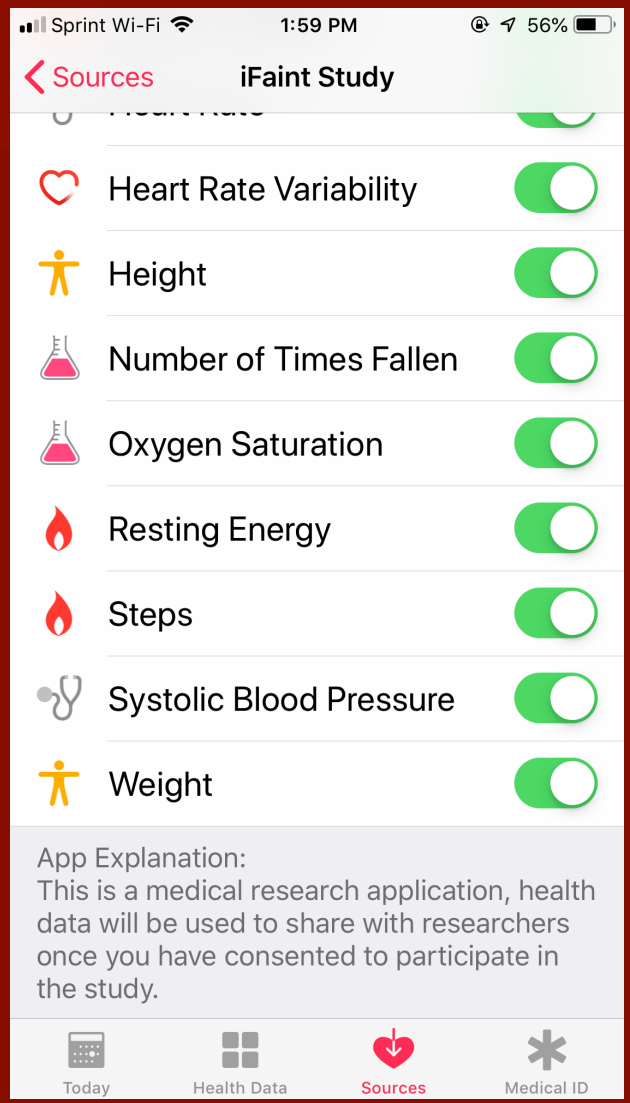
Sources
James's Apple Watch
Privacy Settings
ACTIVITY
VO2 max
Walking + Running Distance
Active Energy
Steps
Resting Energy
Cycling Distance
Workouts
Stand Hours
Today
Health Data
Sources
Medical ID

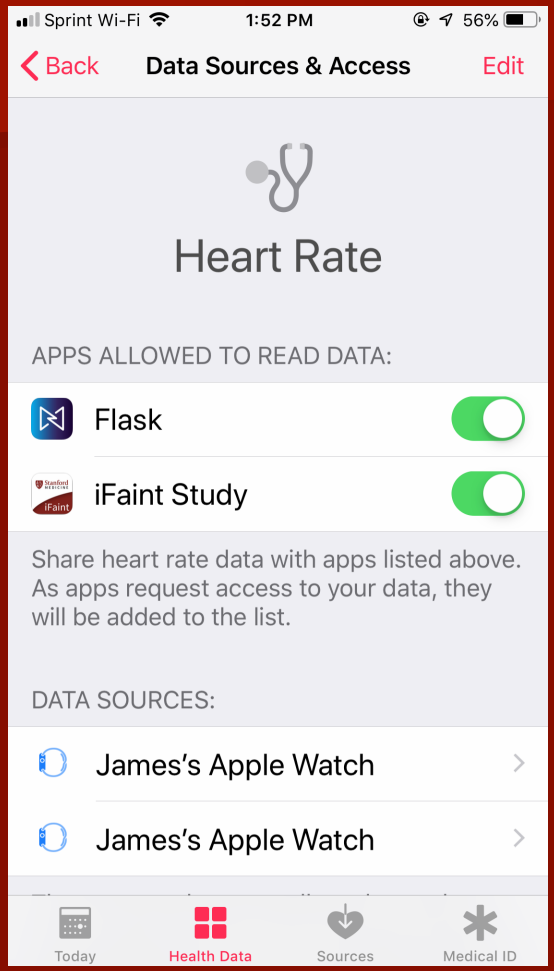

Sprint Wi-Fi
3:10 PM
40%
Sources
James's Apple Watch
Exercise Minutes
HEART
Resting Heart Rate
Walking Heart Rate Average
Heart Rate Variability
MINDFULNESS
Mindful Minutes
VITALS
Heart Rate
Today
Health Data
Sources
Medical ID

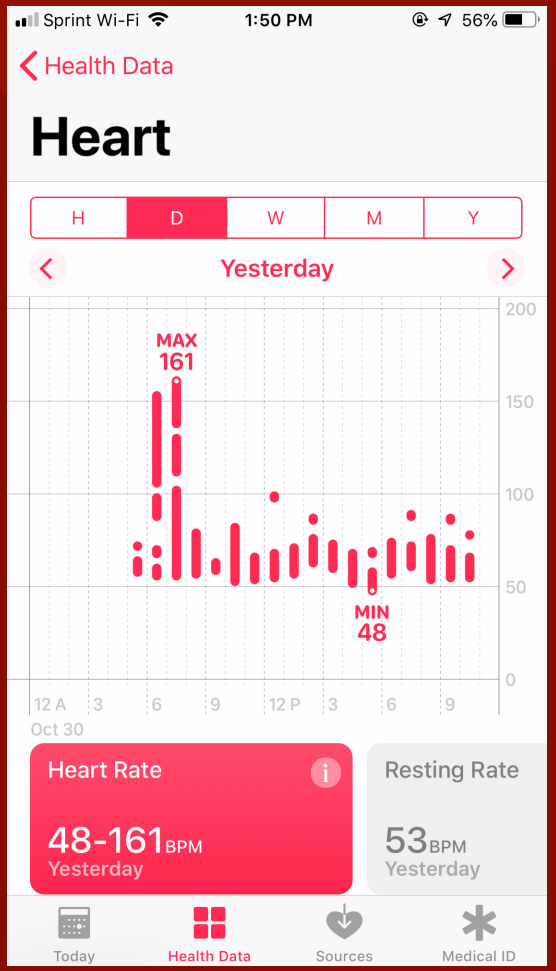

TestFlight
11:20 PM
87%
Don't Allow
Health Access
Allow
Health
"iFaint Study" would like to access and update your Health data in the categories below.
Turn All Categories On
Allow or disallow "iFaint Study" to access all health data types listed here.
ALLOW "IFAINT STUDY" TO READ DATA:
Active Energy
Blood Glucose
Body Fat Percentage
Body Mass Index

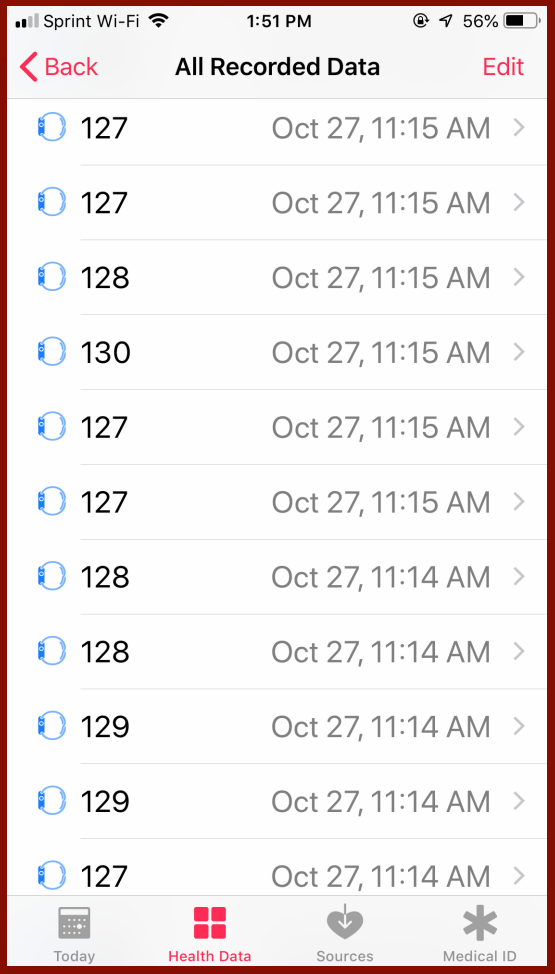

Sprint Wi-Fi
1:58 PM
56%
Sources
iFaint Study
Turn All Categories Off
Allow or disallow "iFaint Study" to access all health data types listed here.
Data
ALLOW "IFAINT STUDY" TO READ DATA:
Active Energy
Blood Glucose
Body Fat Percentage
Body Mass Index
Diastolic Blood Pressure
Today
Health Data
Sources
Medical ID


Sprint Wi-Fi
1:59 PM
56%
Sources
iFaint Study
Heart Rate Variability
Height
Number of Times Fallen
Oxygen Saturation
Resting Energy
Steps
Systolic Blood Pressure
Weight
App Explanation:
This is a medical research application, health data will be used to share with researchers once you have consented to participate in the study.
Today
Health Data
Sources
Medical ID

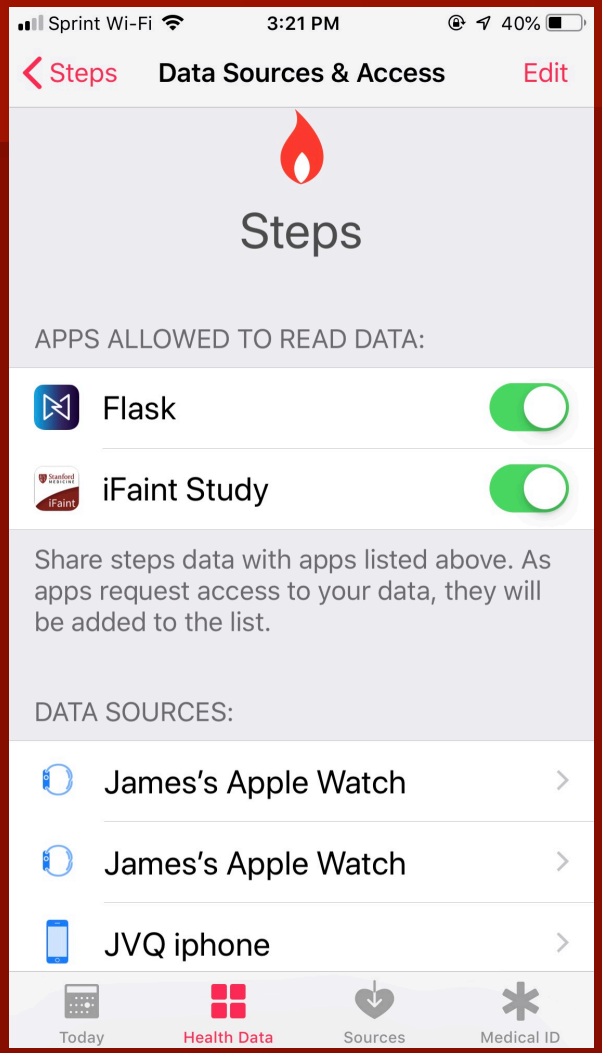
Data Detail – Heart Rate

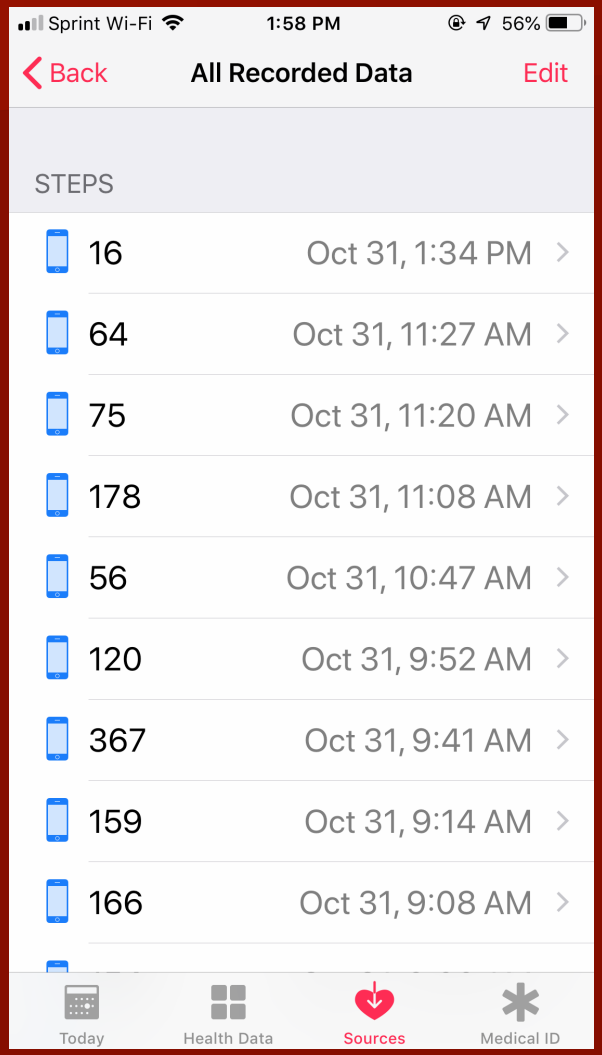


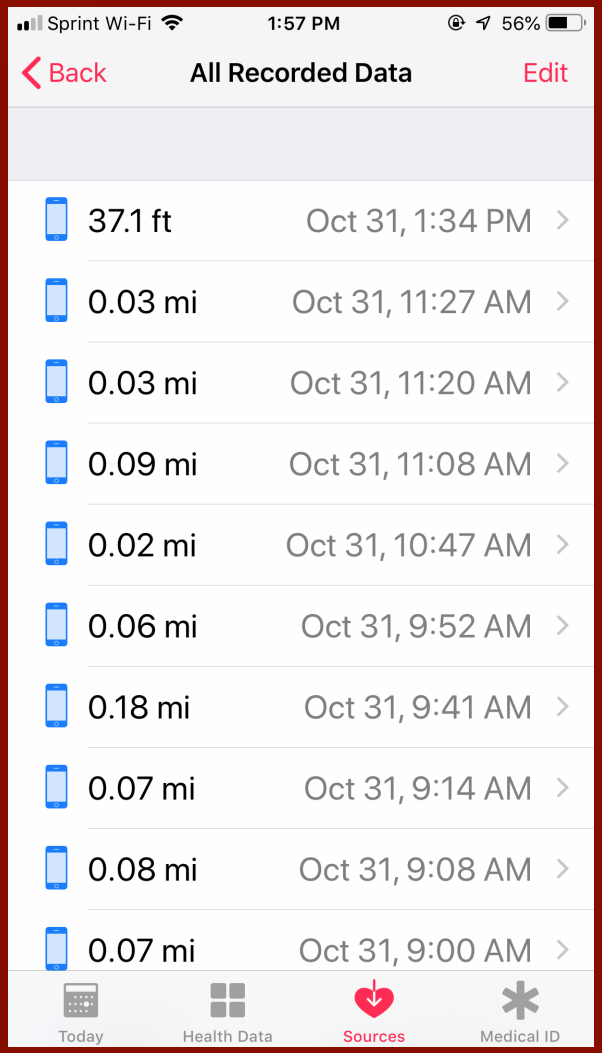




Data Detail - Steps







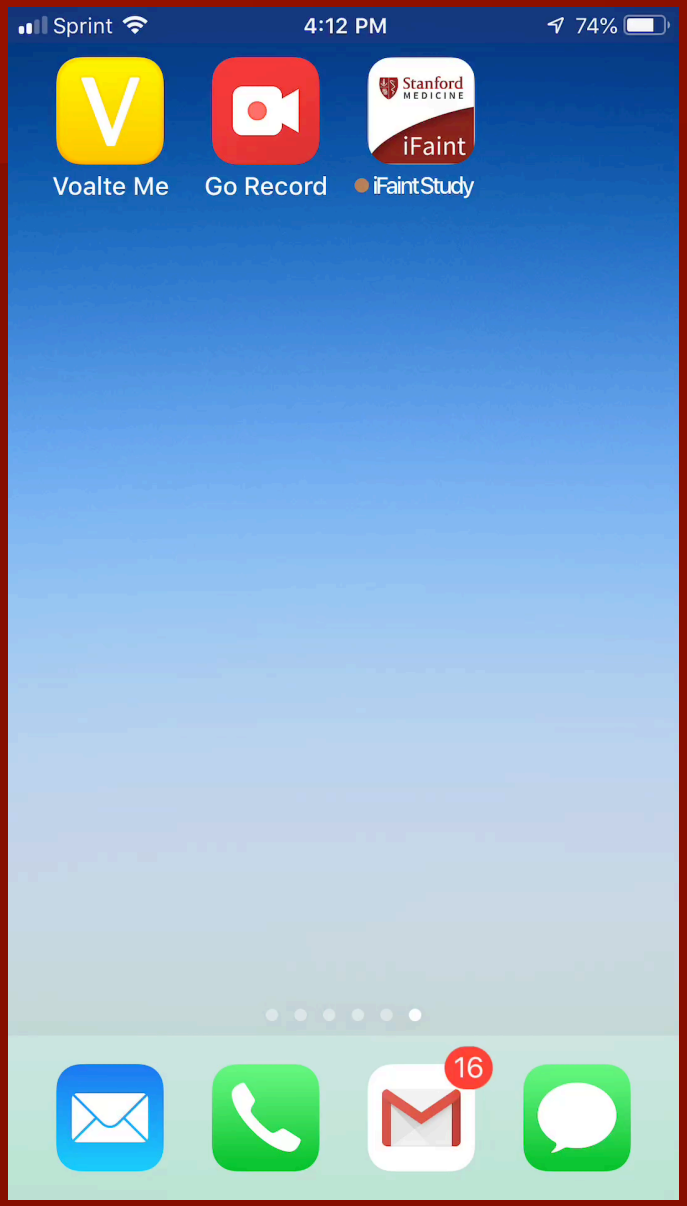
iFaint App - Dashboard

- Risk factors and outcomes from surveys
- Integrates new variables and potential risk factors from HealthKit Data
- Displays in patient dashboard

iFaint App Geo-Locator

- Weekly pop up for 4 weeks, after new events and once at 6 months
- Update health information
- Complete outcome survey
- Geo-locator for hospital visits > 2 hour

iFaint Video Demo



Questions??

http://med.stanford.edu/ifaint.html