Consumer Wearable Technology for AF Screening, Detection, and Management: Bold, New, and Useful?

The Heartline Study
www.Heartline.com

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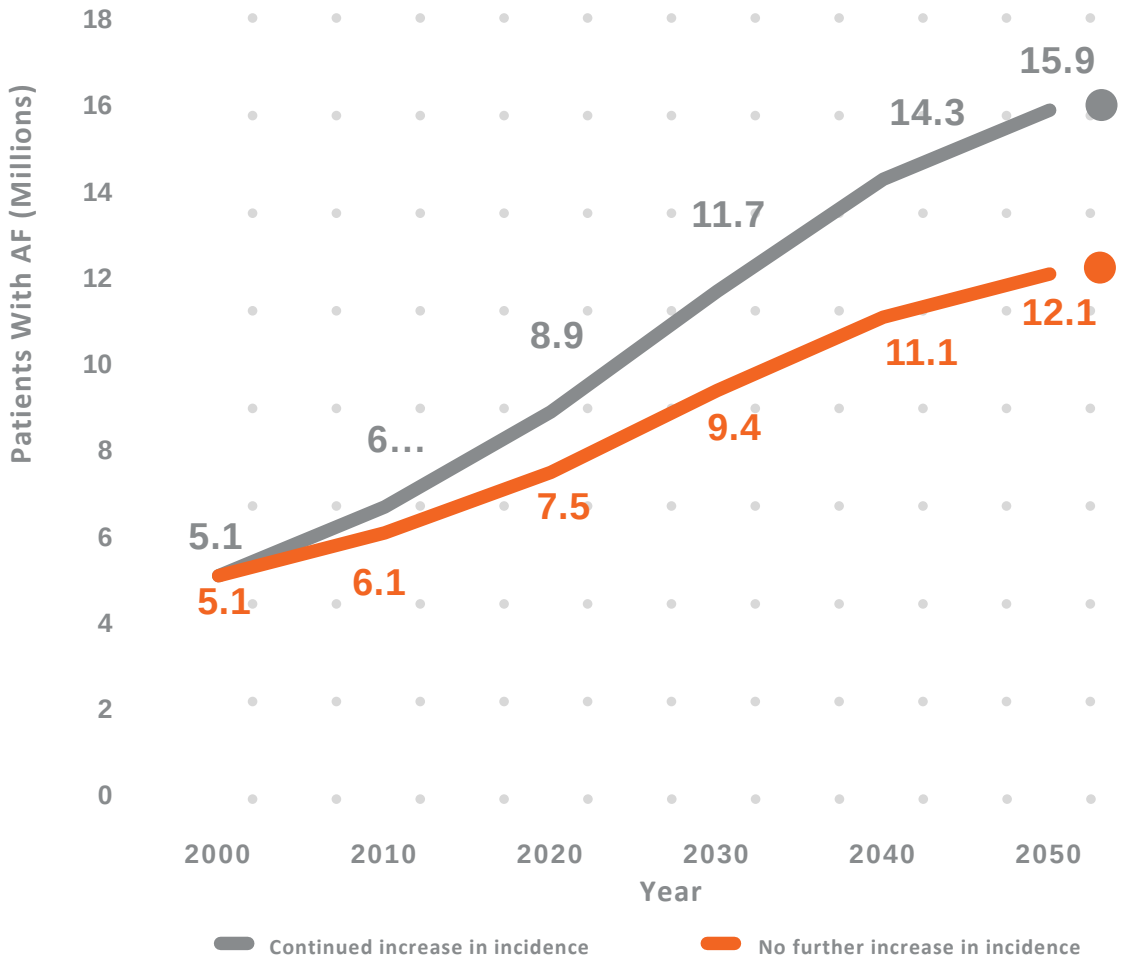
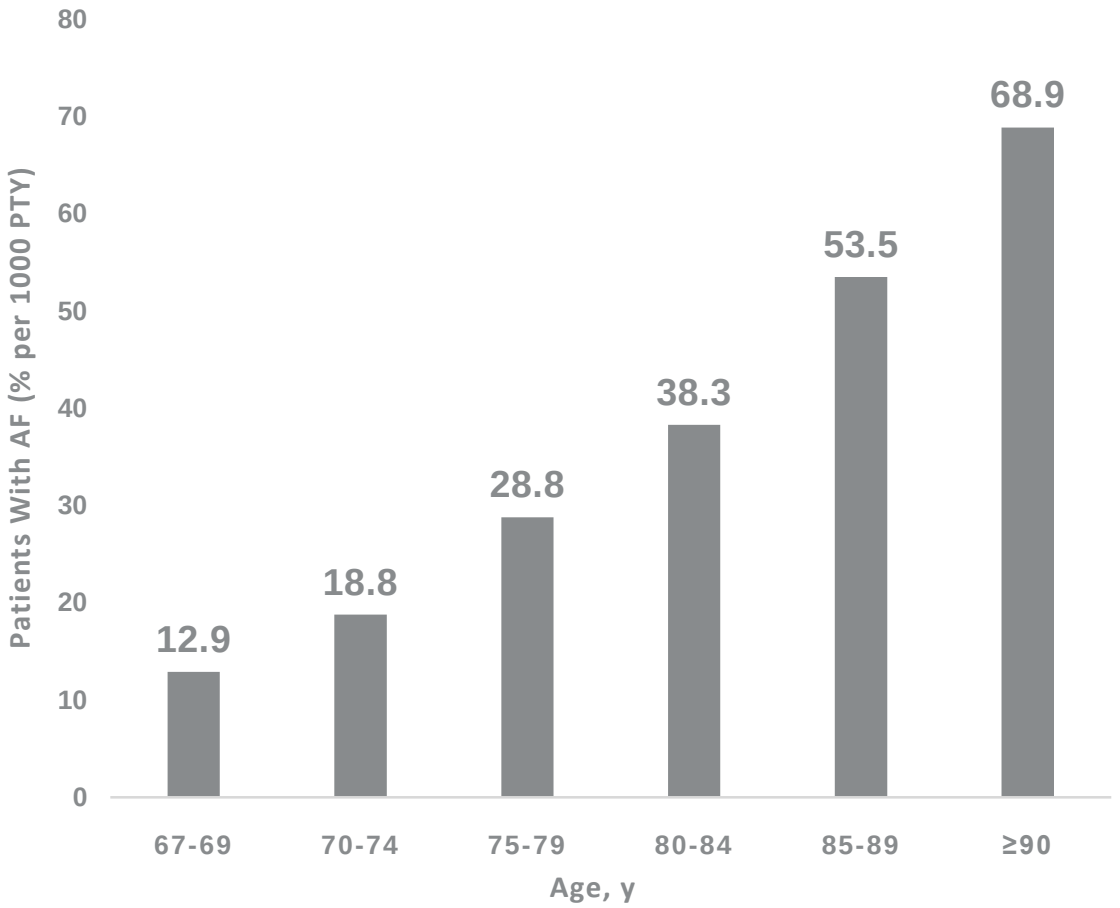
Epidemiology of AF

- Most common sustained cardiac arrhythmia observed in clinical practice
- An estimated 2.7–6.1 million people in the US have AF
  - With the aging of the population, this number is expected to increase worldwide.
- Approximately 2% of people <65 have AF, while about 9% of people >65 years have AF
- Because AF cases increase with age and women generally live longer than men, more women than men experience AF

Projected Prevalence of AF In The United States[1]



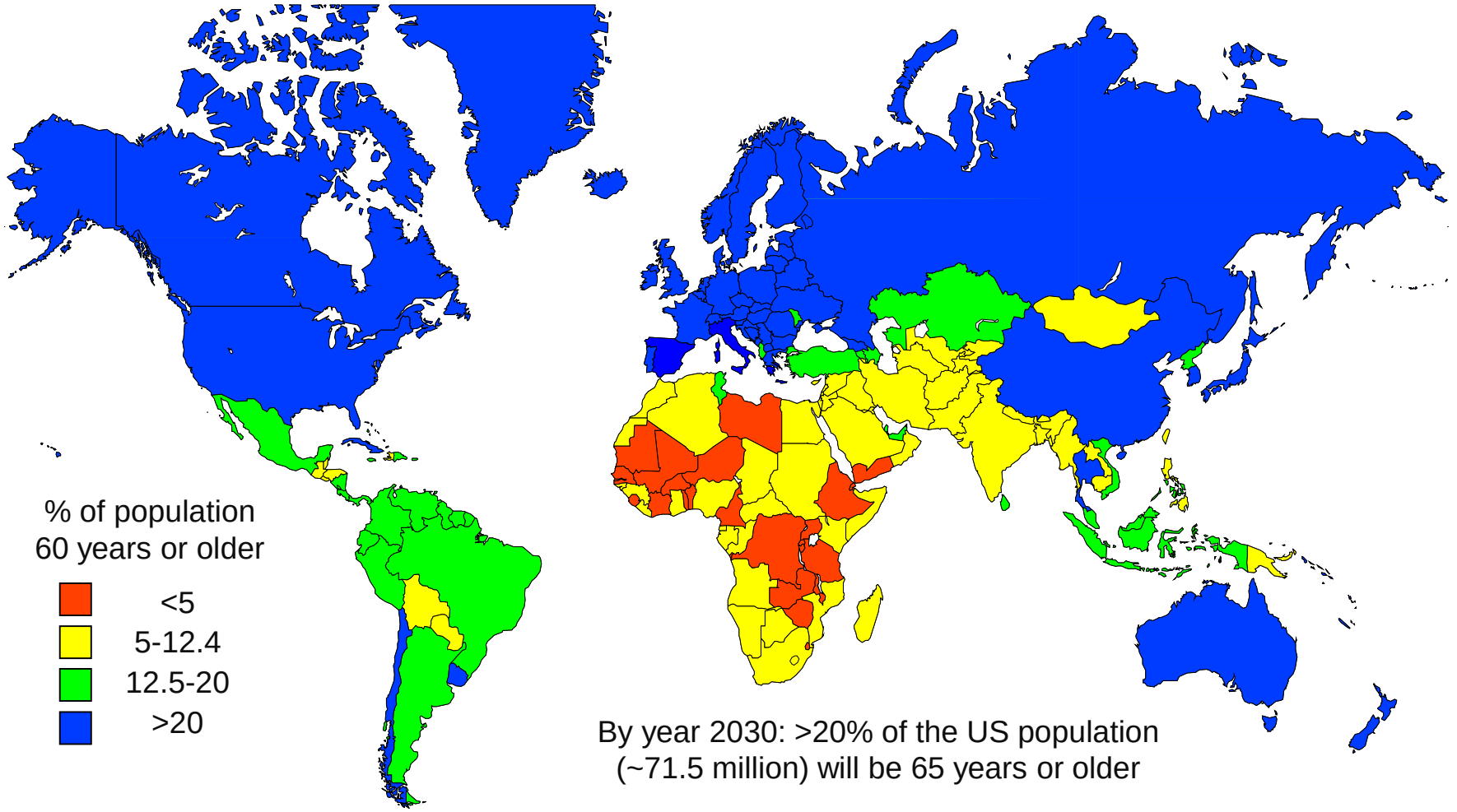
AF Prevalence Increases With Age[2]



AF=atrial fibrillation; PTY=patient-year; y=year.

1. Miyasaka Y, et al. *Circulation*. 2006;114:119-125. **2.** Piccini JP, et al. *Circ Cardiovasc Qual Outcomes*. 2012;5:85-93.

Aging and World Population 2005-2025

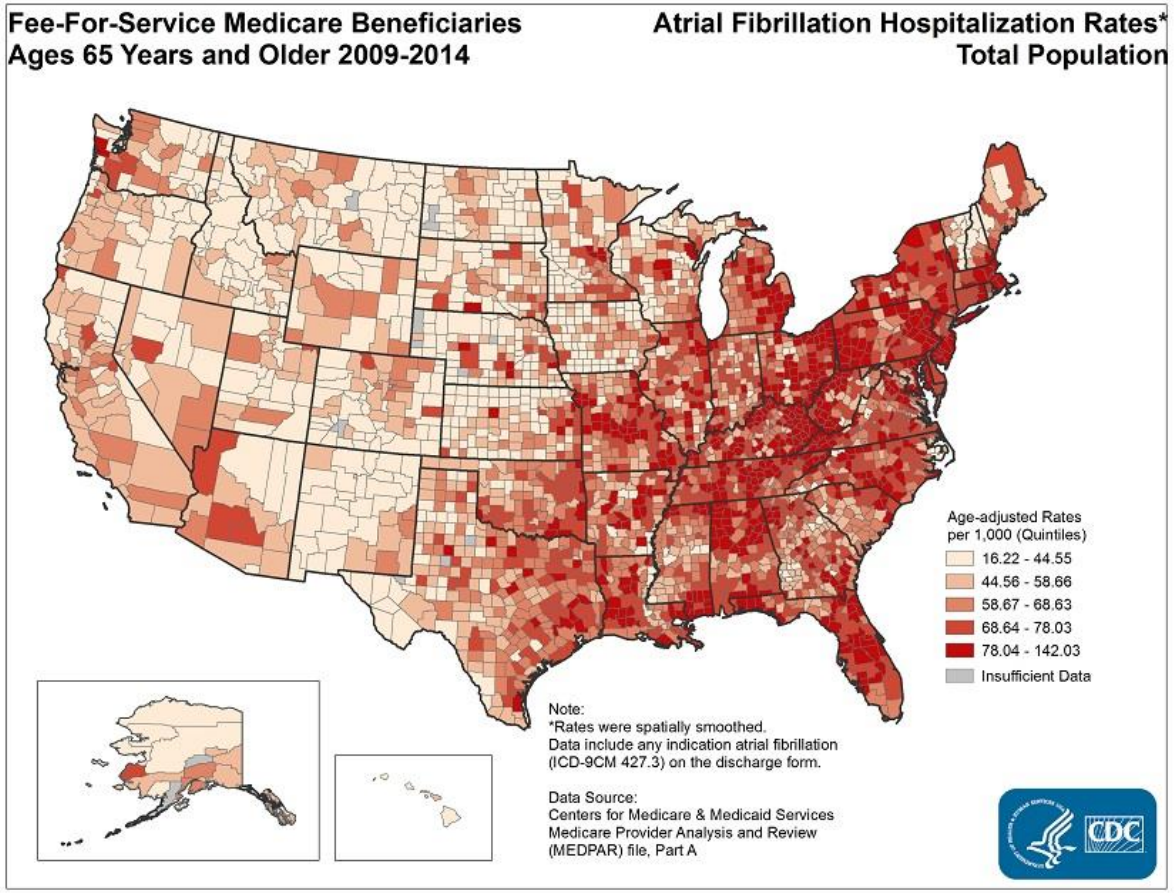


By year 2030: >20% of the US population (~71.5 million) will be 65 years or older

Jahangir A et al. *J Appl Physiol* 2007;103:2120-2128.

Mortality, Hospitalizations, and Costs of AF

- More than 750,000 hospitalizations occur each year because of AF.
- The condition contributes to an estimated 130,000 deaths each year.
  - The death rate from AF as the primary or a contributing cause of death has been rising for more than two decades.
- AF costs the US about $6 billion each year.
- Medical costs for people who have AF are about $8,705 higher per year than for people who do not have AF.



In the US, Stroke is the 5th Leading Cause of Death and Leading Cause of Disability

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AF results in a **5x greater risk** for stroke but up to 30% of AF cases go undiagnosed until life threatening complications occur

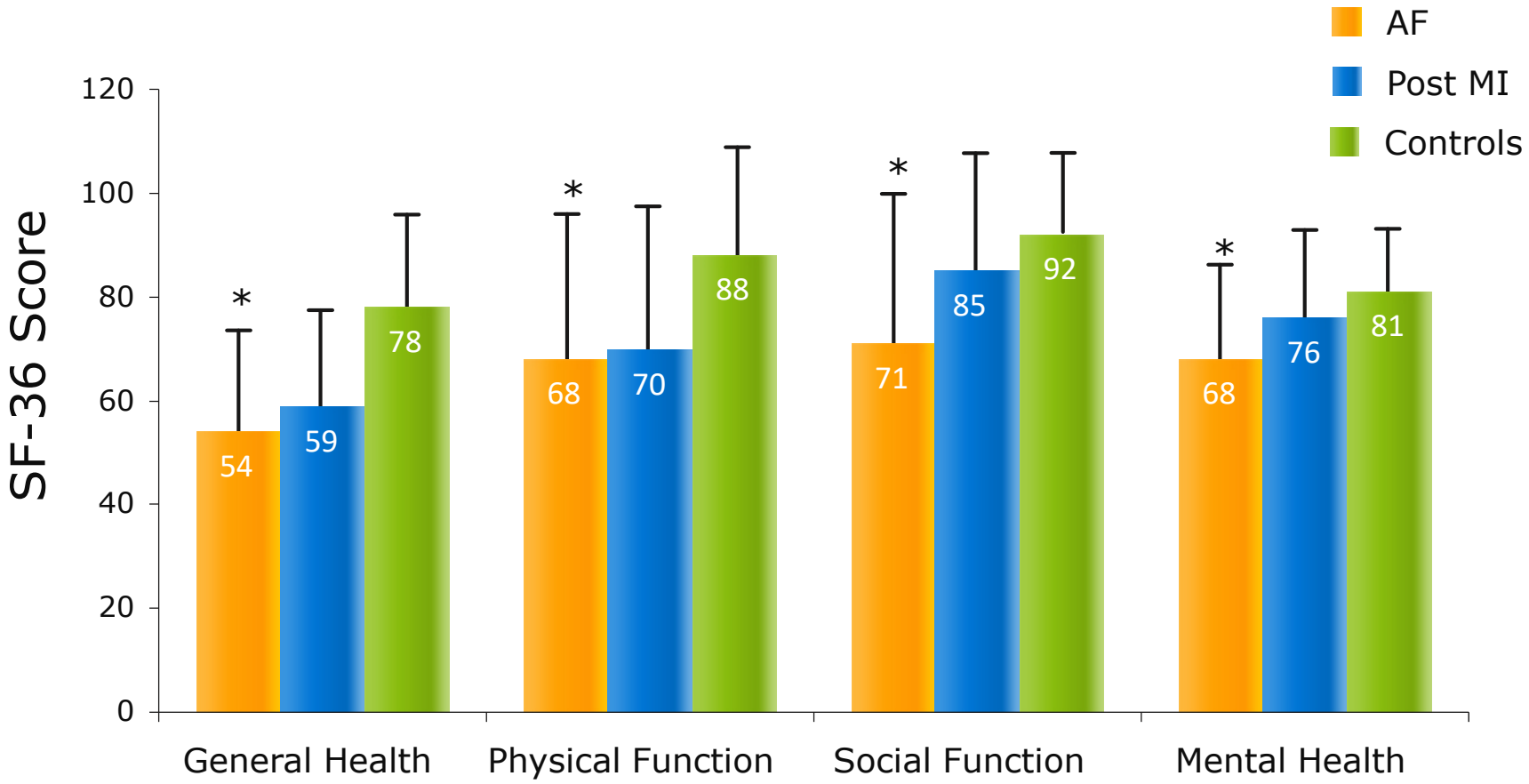
EVERY
40 SECONDS
SOMEONE HAS A STROKE

EVERY
3 MINUTES AND 45 SECONDS
SOMEONE DIES OF A STROKE

~1 IN 19 DEATHS
IS DUE TO A STROKE

Benjamin EJ, et al. *Circulation*. 2018;137:e67-e492.

AF Adversely Affects Quality of Life (QoL)



*P < .05 AF vs controls

Smart Watches for AF Detection

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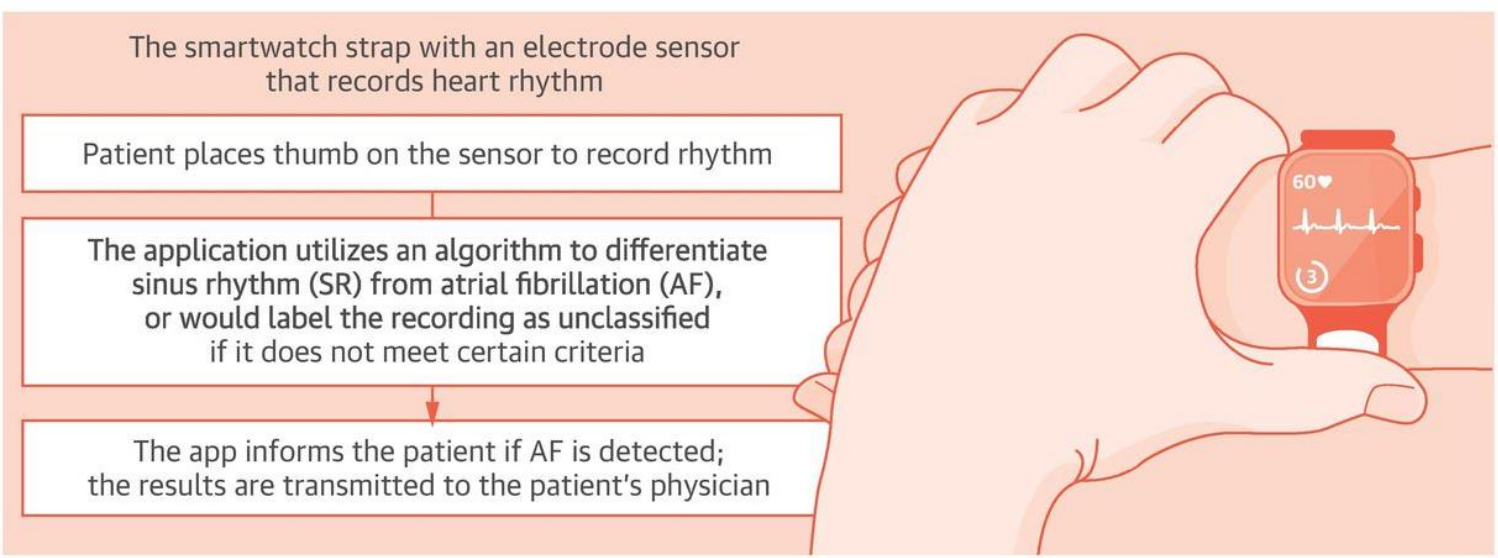

Method for interpreting the recording:	% of patients with interpretable results	Accuracy of AF diagnosis compared to 12 lead electrocardiogram
App algorithm only	66%	93% sensitivity; 84% specificity
Physician only	87%	99% sensitivity; 83% specificity
Recordings labeled as "unclassified" by the app algorithm when reviewed by physician	100%	100% sensitivity; 80% specificity

Bumgarner JM et al. *JACC* 2018;71: 2381-2388.

Apple Heart Study

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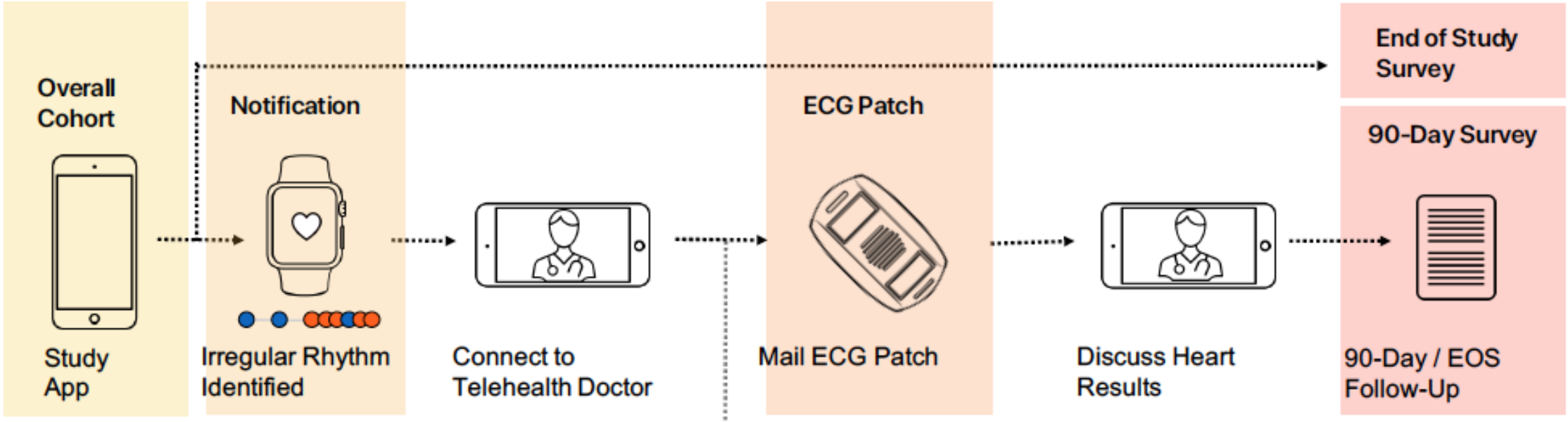

Inclusion criteria

- Age ≥ 22; U.S. Resident
- iPhone (5S or higher) + Watch (Series 1-3)

Exclusion criteria

- Atrial fibrillation or atrial flutter
- Current use of anticoagulation

Apple Heart Study

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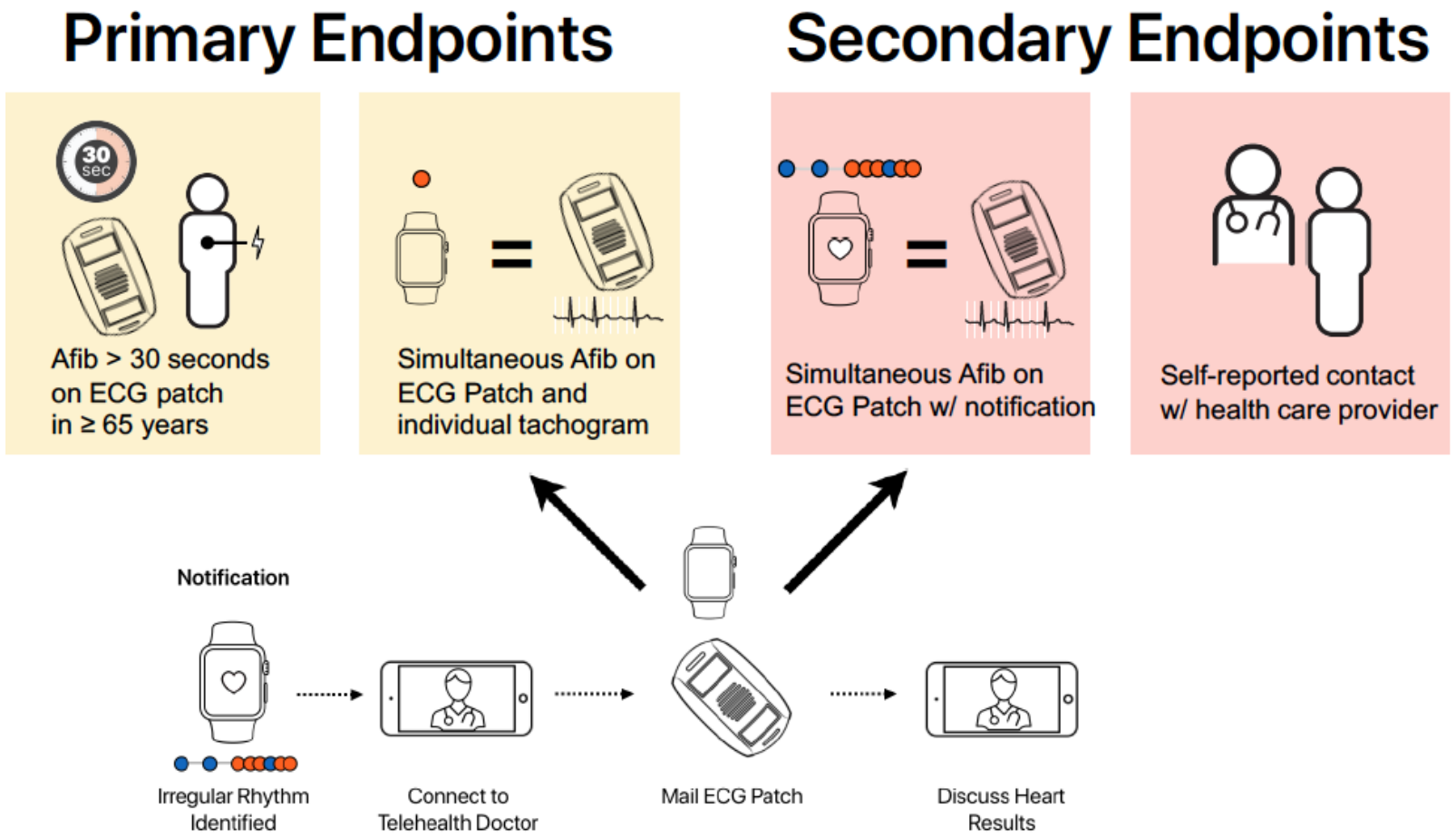

Apple Heart Study

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Study w/ Novel Virtual Design
419,297 in 8 months

Proportion Notified low
Overall: 0.52% (0.49-0.54)

ECG patch 13 days after
34% had Afib

Positive predictive value
Tachogram: 0.71 (0.69-0.74)
Notification: 0.84 (0.76-0.92)

57% Notified (surveyed)
Contacted Non-Study Provider

Exposure to the
app was safe

HEARTLINE is the Next Logical Step in a Series of Wearables Clinical Studies in AF

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1 — JULY 2018

mSToPS (mHealth Screening to Prevent Strokes) showed that a wearable patch can increase AFib detection in an asymptomatic patient population.[1]

2 — MARCH ACC* 2019

Apple Heart Study, showed the Apple Watch can identify heart rhythm irregularities with a very low false positive rate.[2]

mSToPS showed decreased hospitalization and ED visits in those patched vs. not patched.[3]

3 — Q1 2020

J&J in collaboration with Apple, launch HEARTLINE, a clinical study to determine if the Apple Watch and a heart health program can improve heart health outcomes.[4]

[1]JAMA. 2018;320(2):146-155. [2]https://professional.heart.org/professional/ScienceNews/UCM_503785_Apple-Heart-Clinical-Trial-Details.jsp.
[3]http://www.onlinejacc.org/content/73/9_Supplement_1/296. [4]www.HEARTLINE.com.

Objective 1:
Atrial Fibrillation Detection/Treatment

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INCLUSION

All participants in the study ≥65 years of age **who do not have a diagnosis of AF at study entry**

PRIMARY OBJECTIVE

Determine whether a broad health-focused engagement program* paired with the heart arrhythmia alert (PPG) and an ECG sensor via the Apple Watch® in participants ≥65 years of age with undiagnosed symptomatic or asymptomatic AF **can increase the clinically confirmed diagnosis rate of AF vs standard of care (ie, control group)**

*Health engagement program=broad heart and AF education, challenges, and electronic PRO surveys through the Apple Watch and/or iPhone® app, with rewards for their engagement with these study-related tasks

PRIMARY ENDPOINT

The number (%) of clinically confirmed diagnoses of AF at a defined timepoint with validation obtained from a claims database. Time to receiving an alert and a confirmed diagnosis from a physician will also be considered as endpoints for analysis

Key Secondary Endpoint: CV outcomes defined as MACE (stroke, MI, CV death)

Objective 2:
Anticoagulation Medication Adherence

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INCLUSION

All participants ≥65 years of age **who have a confirmed diagnosis of AF and have been on an anticoagulant for >30 days** at the time of study entry

PRIMARY OBJECTIVE

Determine if an anticoagulation adherence module,* administered via an app on the iPhone and Apple Watch, **drives better adherence to novel oral anticoagulation medication vs control**

*Anticoagulation adherence module=reminders, goal-setting, and completion of education content through the Apple Watch and/or iPhone app. There are no rewards related to the adherence module.

PRIMARY ENDPOINT

Percent days covered (PDC). The primary measure will be the use of prescription novel oral anticoagulants (NOACs) following a confirmed diagnosis of AF

Heartline Study Design

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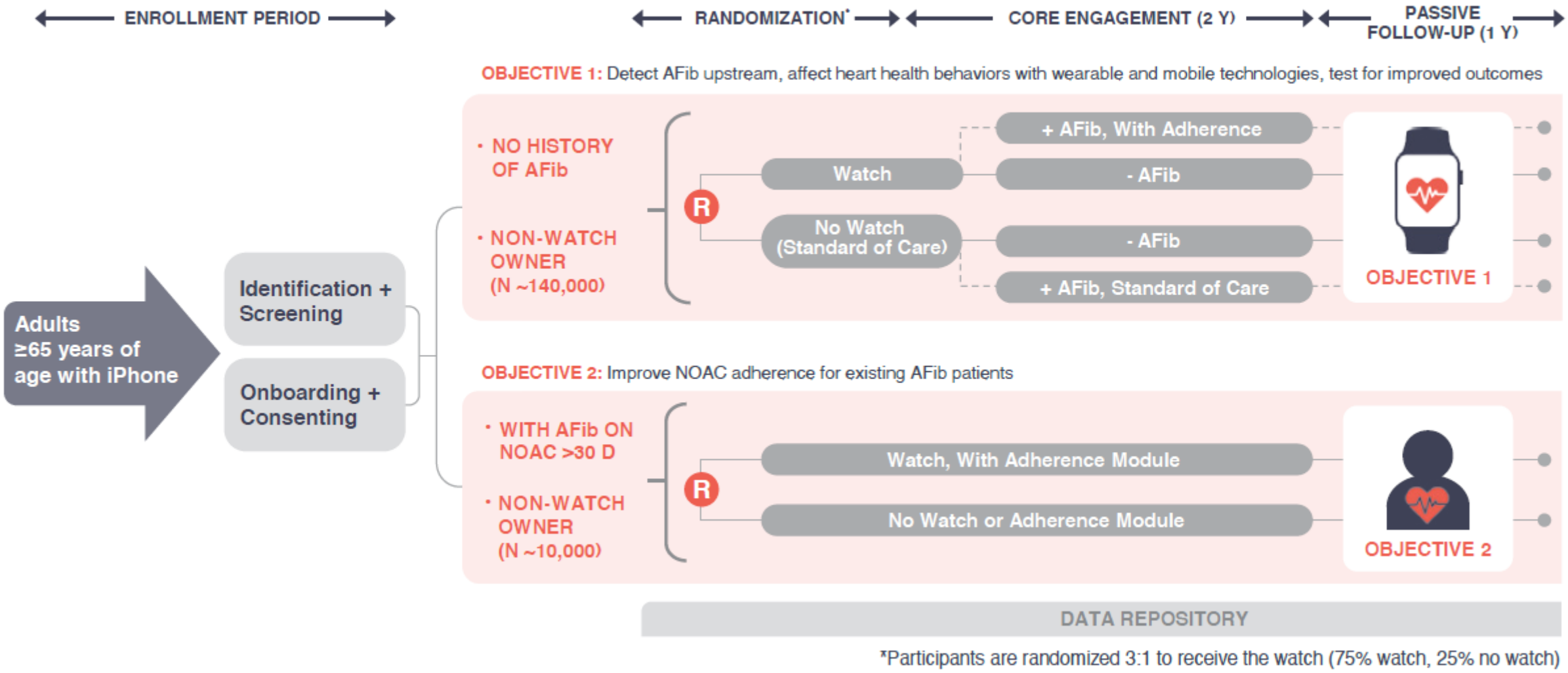

*Participants are randomized 3:1 to receive the watch (75% watch, 25% no watch)