

The Apple Heart Study: An Appraisal



Stanford | MEDICINE

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Ohio
CHAPTER

Disclosures

- I have no actual or potential conflict of interest in relation to this program/presentation
- I will not be discussing “off-label” uses of the any medications or devices
- I *do* own and wear a series 4 Apple Watch

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Poll: Do you wear an Apple Watch?

The Apple Heart Study

- *Not yet published*
- Presented at the annual ACC Meeting at New Orleans, March 2019
- Sponsored by Apple, conducted by Stanford University w/ other US sites
- Principal Investigators : Mintu Turakhia MD MAS, Marco Perez MD



Background

- 700,000 people in the US may have previously unknown AF, w/ incremental cost burden of \$3.2B
 - High CV morbidity
- Traditional methods to detect AF
 - Physical exam for irregular pulse, resting EKG, continuous 2-14 day monitor, episodic home based monitoring : not sensitive enough
 - Implantable monitors : expensive and inconvenient

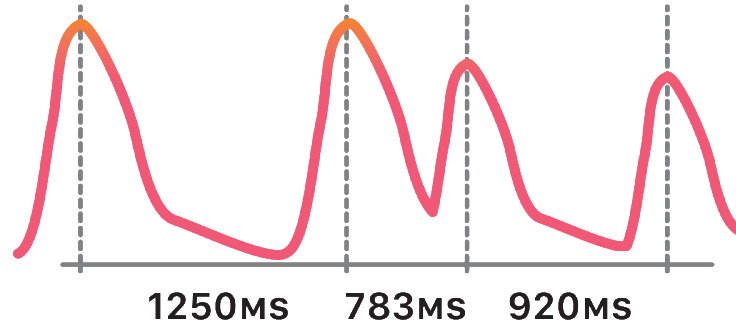




- “Wearables” measure pulse rate from the wrist using photoplethysmography (PPG), using optical sensor
- Pulse data analyzed for *irregularity and variability*
- Requires “*gold-standard*” for confirmation
- Provision for clinical evaluation needed, otherwise potential for harm

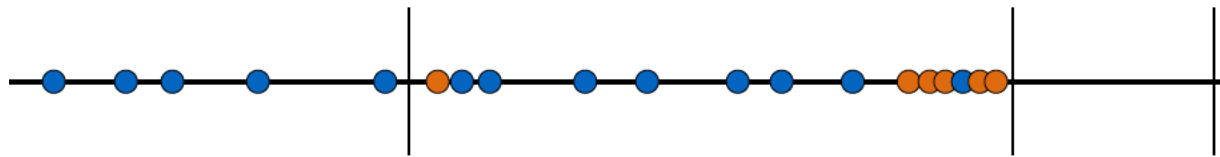


Irregular Pulse Notification Algorithm



Algorithm results

- Regular pulse
- Suggestive of Afib



Tachogram = Periodic, opportunistic measurements

5 confirmations \Rightarrow notify user



Positive triggers frequent measurements
Not confirmed \Rightarrow return to usual sampling

The algorithm does not use the watch ECG feature

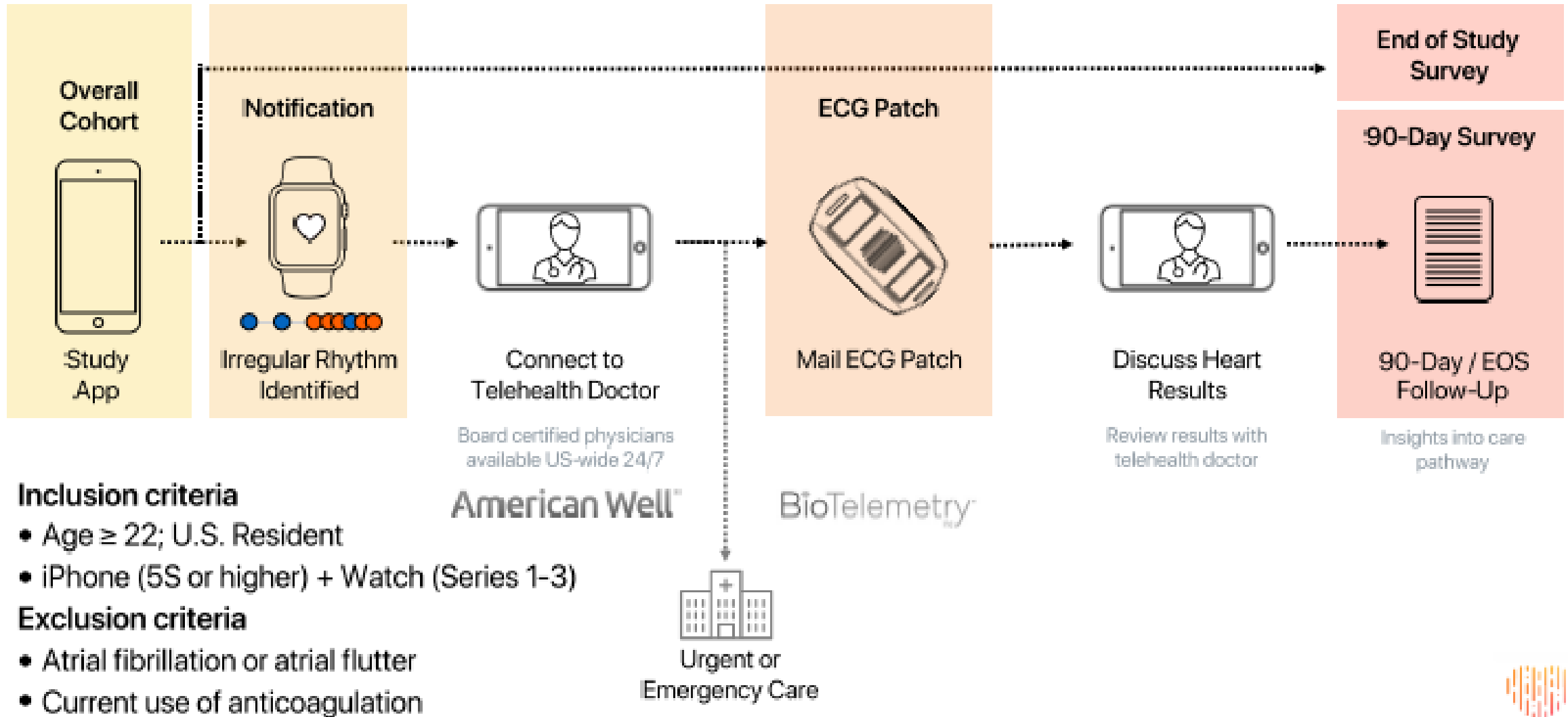
Overall Goals



To evaluate the ability of the irregular pulse notification algorithm to identify atrial fibrillation and guide subsequent evaluation

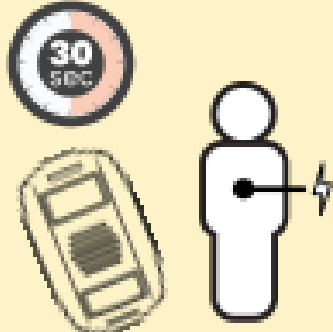
- Notification burden
- Subsequent Afib diagnosis
- Algorithm performance
- Safety
- Pragmatic and generalizable
- Scalable procedures

Prospective, Single Arm, Open Label Study

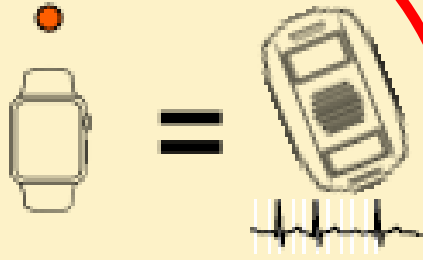


Primary Endpoints

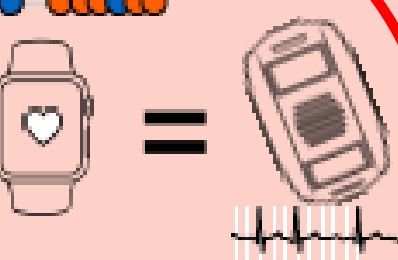
Secondary Endpoints



Afib > 30 seconds on ECG patch in ≥ 65 years



Simultaneous Afib on ECG Patch and individual tachogram



Simultaneous Afib on ECG Patch w/ notification



Self-reported contact w/ health care provider



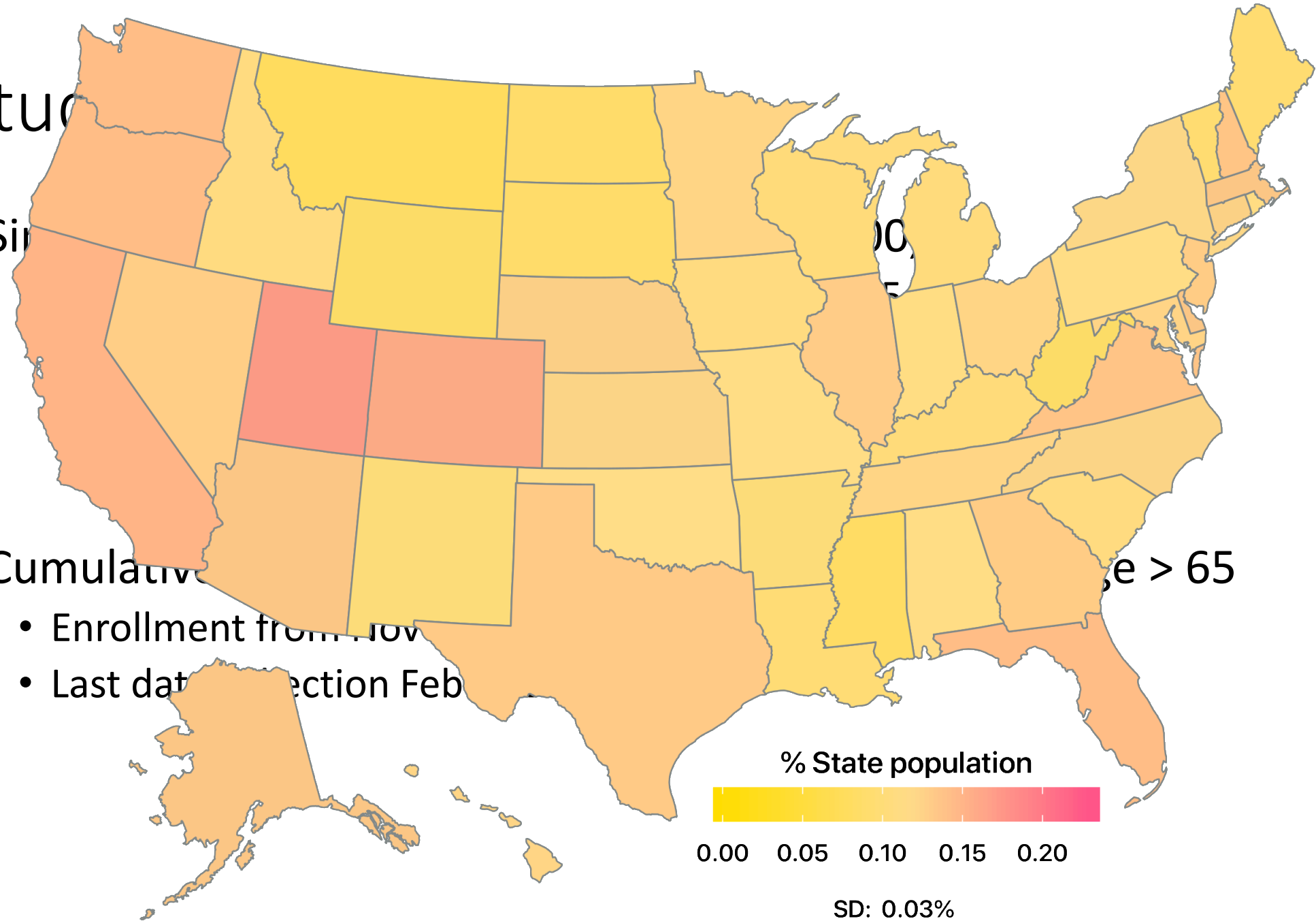
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- Cumulative

- Enrollment from Nov

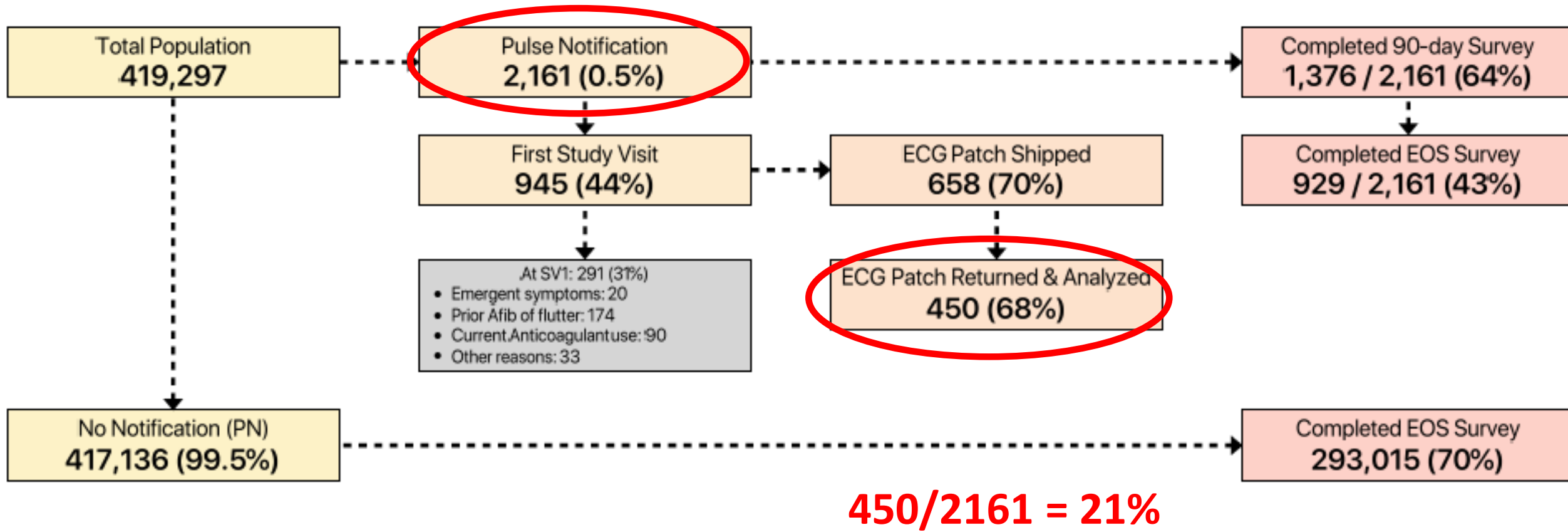
- Last date of infection Feb






0.00
0.05

Age > 65

Consort Diagram



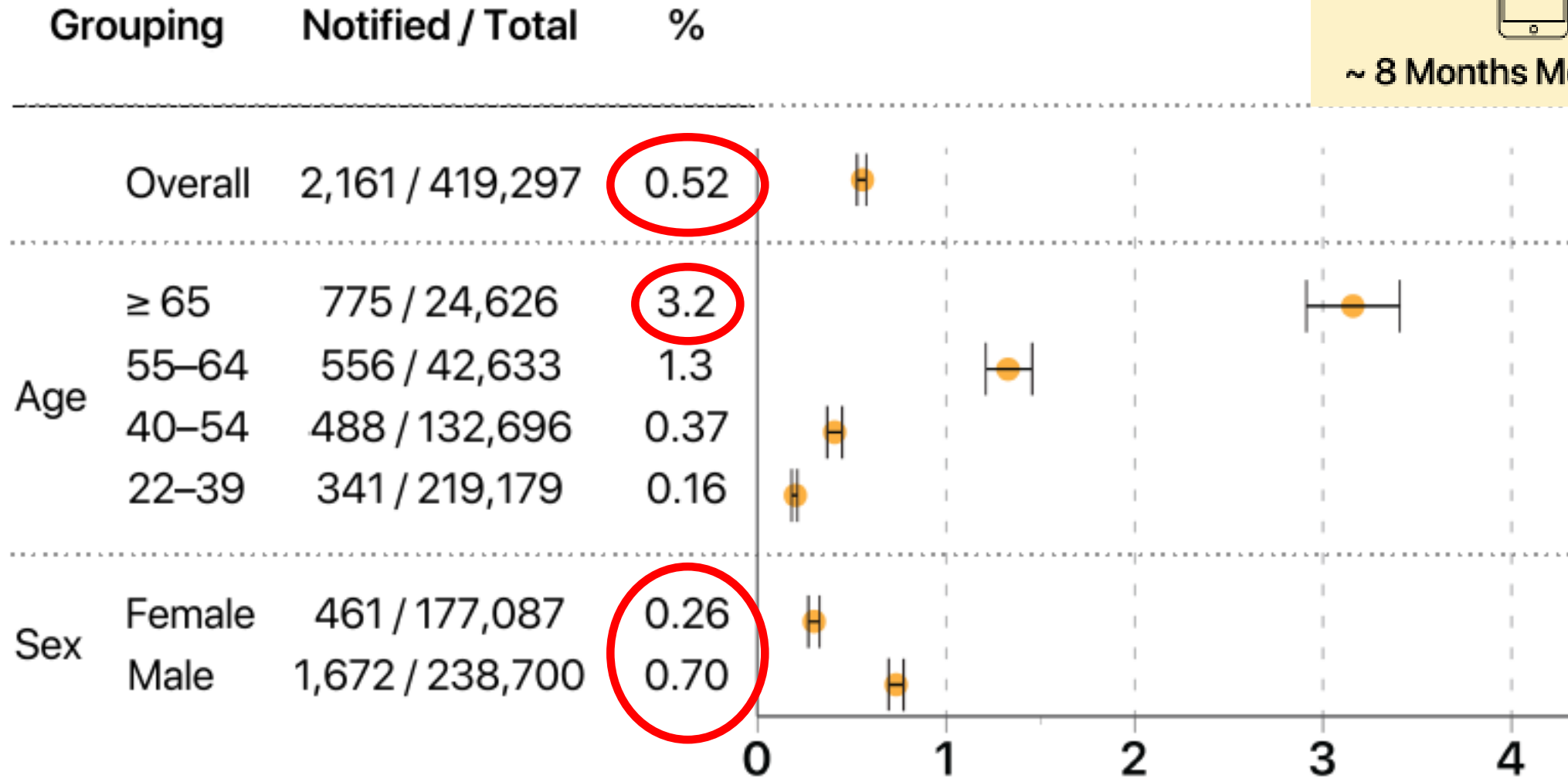
Demographics

		Overall Cohort 	Notification 	ECG Patch 
	N	419,297	2,161	450
	Female (%)	177,087 (42)	461 (21)	102 (23)
Age	Age, mean (sd)	41 (13)	57 (15)	59 (14)
	≥ 65	24,626 (6)	775 (36)	181 (40)
	55–64	42,633 (10)	556 (26)	114 (25)
	40–54	132,696 (32)	488 (23)	106 (24)
	22–39	219,179 (52)	341 (16)	49 (11)
Race	White	286,190 (68)	1,747 (81)	379 (84)
	Hispanic	48,775 (12)	104 (5)	20 (4)
	African American	32,275 (8)	106 (5)	16 (4)
	Asian	26,156 (6)	87 (4)	8 (2)
	Other Mixed Ethnicity	7,958 (2)	32 (1)	6 (1)

Initial Irregular Pulse Notifications

Overall Cohort

~ 8 Months Monitoring



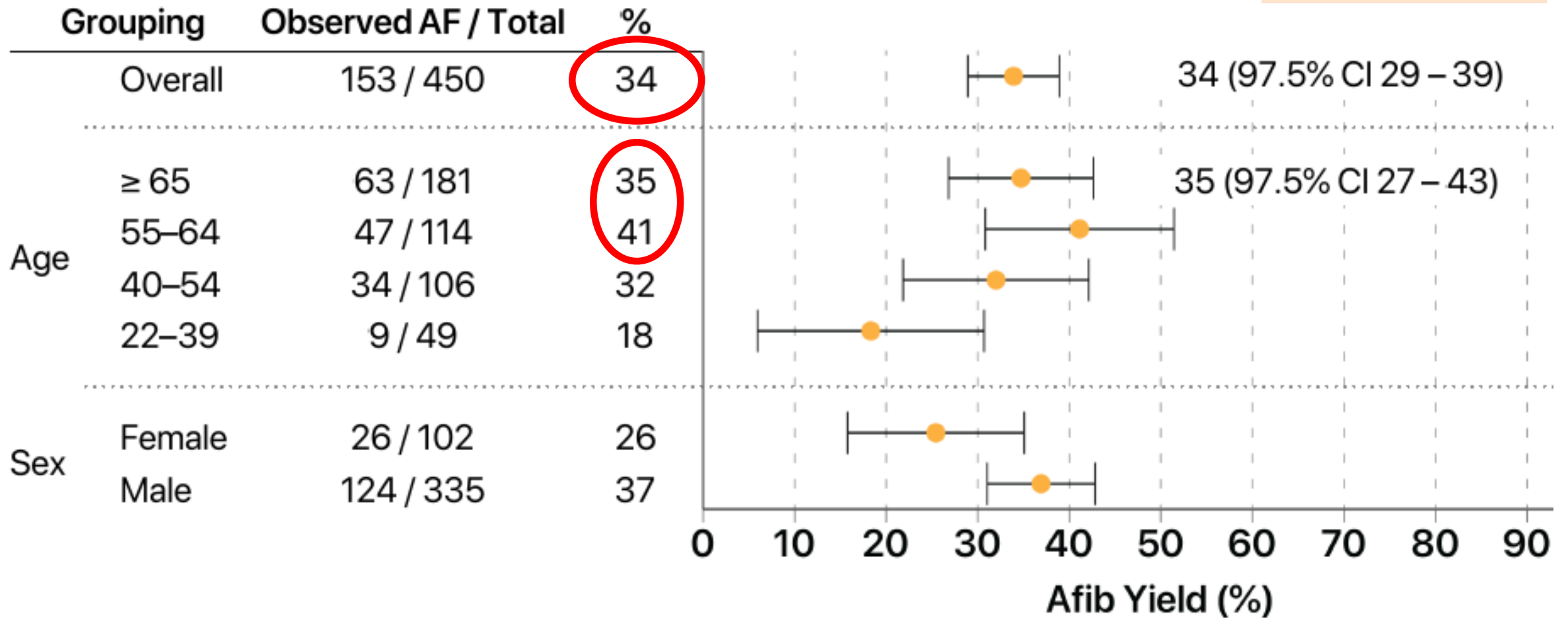
Percent of subjects notified

Atrial Fibrillation on Subsequent ECG Patch

ECG Patch 450

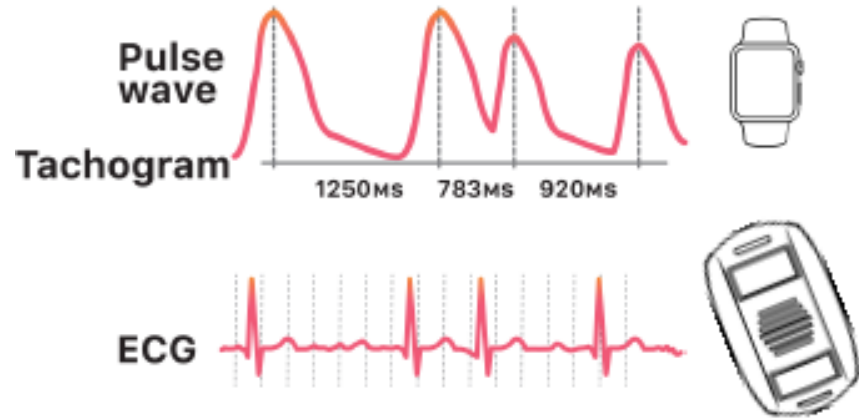


Mean time to hookup: 13 days
Mean wear time: 6.3 days

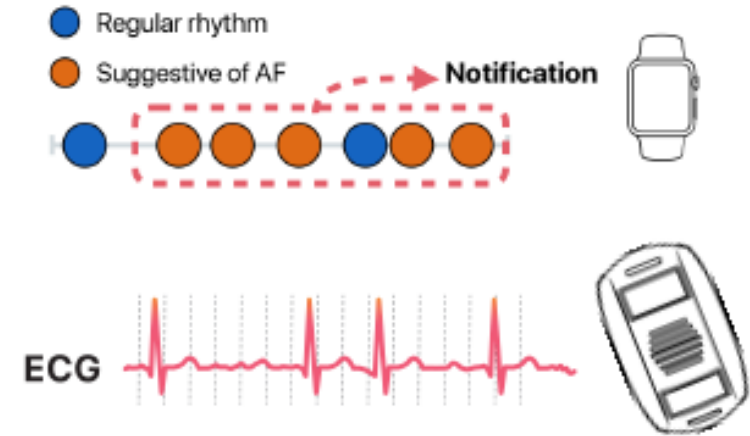


Positive Predictive Values

Irregular Tachograms



Irregular Pulse Notifications



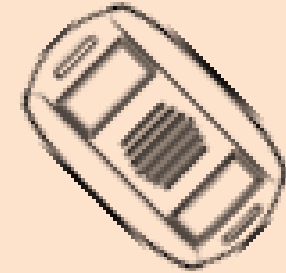
	Afib on ECG patch	Positive Tachograms	PPV (97.5% CI)
Overall	1489	2089	0.71 (0.69-0.74)
Age > 65	548	914	0.60 (0.56-0.64)

	Afib on ECG patch	Positive Notifications	PPV (95% CI)
Overall	72	86	0.84 (0.76-0.92)
Age > 65	25	32	0.78 (0.64-0.92)

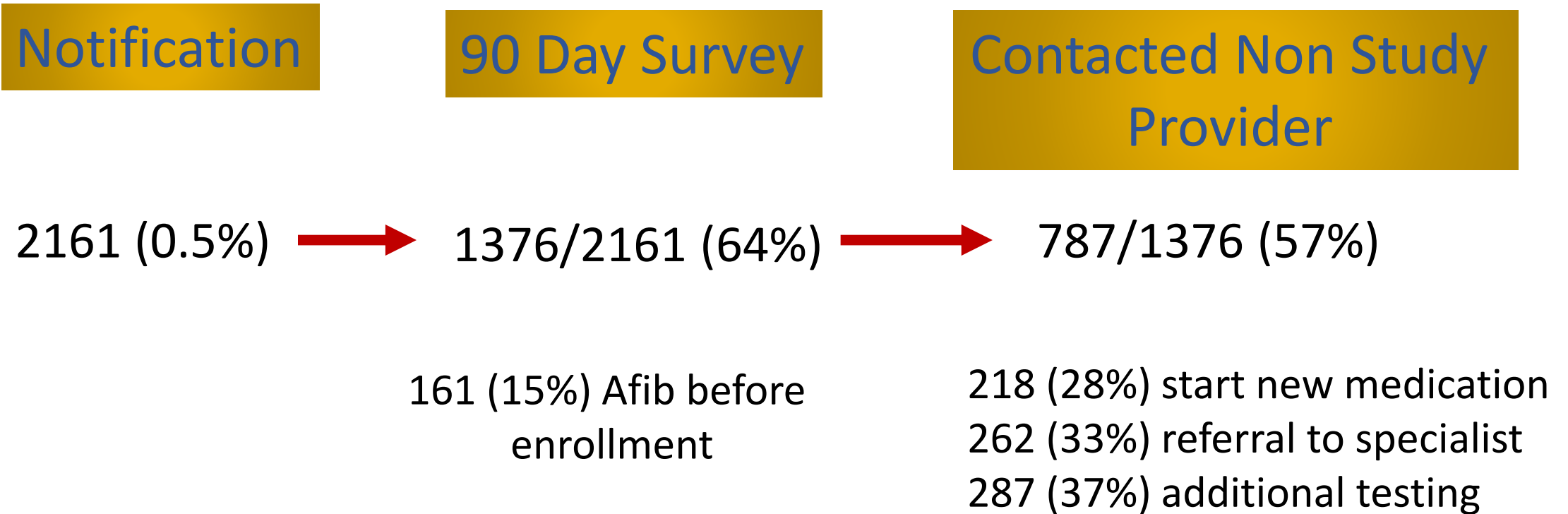
Burden of Atrial Fibrillation

- 24 hour: 25.5%
 - 6 hour: 34%
 - 1 hour: 29.4%
 - 6 min: 5.9%
 - 30 sec: 5.2%
- } 89%

ECG Patch
153/450 With AF



90 Day Survey



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Poll: In your opinion, what Positive Predictive Value is the minimal acceptable for a wearable for predicting atrial fibrillation?

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Poll: Based on the results of the Apple Heart Trial, how likely are you to recommend a similarly functioning wearable to your slightly elevated risk, worried well patient?

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Poll: Would the detection of PVCs and ST shifts (ischemia) on the ECG algorithm in addition to Afib detection change your likelihood of "prescribing" a wearable and if so, by how much?

Conclusions

- Novel virtual design
- Low notification percent (0.5%)
- ECG patch 13 days after notification – 34% had Afib
- PPV – Tachogram: 0.71, Notification: 84%
- 57% of those notified contacted Non-study provider
- Exposure to App was safe

Limitations

- Higher than anticipated drop offs after notification
- Fewer ECG patches than planned
- Virtual Study Design (large, quick, pragmatic study)
 - Relied on self-assessment of enrollment criteria, outcomes