Role of Continuous Ambulatory Rhythm Monitoring

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Objectives

- Indications for continuous rhythm monitoring
- Modalities of continuous rhythm monitoring
  - Wearables: (Holter and event monitors)
  - Implantable: Loop recorders
- Challenges of continuous rhythm monitoring with loop recorders and troubleshooting
- AF monitoring capabilities for transvenous devices (pacemakers and defibrillators)
- Role of loop recorders for cryptogenic stroke
- Management of device detected atrial fibrillation

Indications for continous ambulatroy rhythm monitoring

- Symptoms:
  - Palpitation- Description varies based on arrythmia
    - PVC – strong and weak beats (rubber band analogy)
    - NSVT/atrial tach (intermittent)
    - PSVT (sustained)
  - Dizziness/lightheadedness (often reflective of slow heart rate)
  - Syncope (history is key to differentiate vasovagal vs brady or tachycardia mediated)
- Incidental EKG/telemetry findings
  - PVCs
  - AV block

1- Modalities of continuous rhythm monitoring - Wearables

- Categories:
  - 24 HOLTER MONITOR
  - 3-14 DAY HOLTER MONITOR
  - EVENT MONITOR
  - MOBILE CARDIAC TELEMETRY (MCT)
- Key features to understand differences
  - Multiple EKG patches and wires vs single chest patch
  - Can it be mailed to the patients or not?
  - Waterproof or not: Can patient take a shower with this?
  - What information is recorded?
  - Is the data transmitted wirelessly?

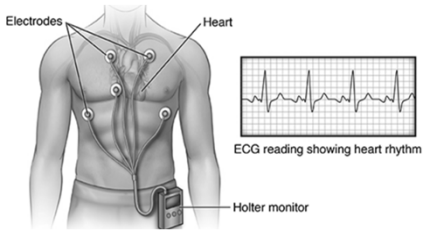
Modalities of continuous rhythm monitoring - Wearables, cont.

- Except 24 hour Holter, all other monitors can be mailed to the patient.
- All wearable monitors can be mailed back after completion of monitoring
- Monitors with single chest patch are waterproof
- Holters provide count of ventricular or atrial ectopy during period of monitoring.
- Event monitor vs MCT: Both devices records all arrythmia but MCT gives duration of arrythmia episodes as well.

Modalities of continuous rhythm monitoring - Wearables, cont.

- How to choose which one is needed?
  - Depends on indication and frequency of symptoms
  - For PVCs, PACs and to assess rate control in permanent AF, Holter should be used.
  - For assessment of infrequent symptoms, asymptomatic episodes of arrythmia or slow/rapid heart rate: MCT is preferred.
- How the information is communicated to the patient?
  - Patient is notified after arrythmia is detected
  - Ordering physician is notified
  - Completed report prepared by technician is reviewed by electrophysiologist and sent to the ordering physician

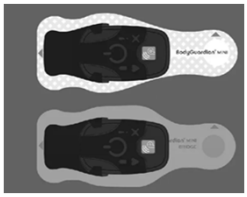
Modalities of continuous rhythm monitoring - Wearables, cont.



Key differences :

Wires vs patch

Waterproof vs not



2- Modalities of continuous rhythm monitoring - Implantable Loop- Indications

- Rare but life threatening arrythmias in patients who don't qualify for pacemaker or defibrillator
- Patients with unknown risk of life threatening arrythmias
  - Sarcoidosis, inherited conditions (Long QT, Brugada, ARVC)
- Syncope of unknown etiology
  - Diagnose life threatening arrythmias
  - Avoid unnecessary cardiac work up in patients with recurrent non-cardiogenic syncope
- Cryptogenic stroke
  - To diagnose atrial fibrillation for possible use of therapeutic anticoagulation

Nadkarni et al. Expert Rev Med Devices. 2021 Jul;18(7):587-596

Modalities of continuous rhythm monitoring - Implantable- Procedure and types

- Outpatient procedure
- Implant location
  - Males: Left parasternal at 45 degrees
  - Females: Parallel or at right angle to the sternum
- Continous monitoring- some variations among vendors
  - LINQ: (Medtronic)
  - Confirm (Abbott)
  - LuX (Boston Sci)
  - Biomonitor (Biotronik)

Korada et al. JACC Clin Electrophysiol. 2020 Sep;6(9):1185-1186
Afzal MR. JACC Clin Electrophysiol. 2020 Dec;6(14):1858-1860.

Data transmission and adjudication for implantable loop recorders

- Data recording by device:
  - Episodes fulfilling the criteria for brady or tachyarrhythmia are stored as long as the device memory is not exceeded (~ 45 to 60 minutes)
  - Older episodes are replaced by newer ones
- Data transmission to the device clinic
  - Alerts: received once a day
  - Scheduled transmissions: monthly or quarterly
- Data adjudication:
  - All episodes are reviewed by device clinic RN
  - Episodes of concern are reviewed with electrophysiologist and final report is generated

OSU protocol to improve device clinic workflow for ILR data

- Over 2000 ILRs are monitored by OSU device clinic
- ~ 10 device clinic nurses review the data on weekdays durign working hours
- OSU studies led industry wide changes in device programming for arrythmia detection
- OSU electrophysiologists led studies on
  - Optimal device location
  - Incidence of false positive
  - Resource utilization
- Indication based programming of ILR resulted in significnat reduction in incidence of false postive episodes and resource utilization for data adjudication

Afzal MR. JACC Clin Electrophysiol. 2021 Jun;7(6):745-754
Afzal MR. Heart Rhythm. 2020 Jan;17(1):75-80

Device (pacemakers and defibrillators) detected AF and risk of stroke

- Various features of devices help for diagnosis of atrial arrythmia
  - Atrial high rate: Episodes are reported after rate increases a pre-set criteria, usually > 175 BPM
  - Mode switch function: (Device stops responding to atrial events after atrial rate increases a certain threshol
- Asymptomatic AF in patients with devices and risk of stroke
  - ASSERT: **NEJM 2012:** 6 minutes of AF increases risk of stroke
  - TRENDS: **Circ A & E:** 5.5 hours AF doubles the risk of thromboembolic events

Device detected atrial fibrillation- Who should be anticoagulated?

Data from ~22,000 patients with device detected AF and NO anticoagulaiton were reviewed.

- Stroke risk with ⇧ with higher CHADS2-VAsc socre and duration of AF

Maximum Daily AF Duration		CHA_2DS_2-VASc Score			
		1 n=258 (4.1%)	2 n=731 (11.7%)	3-4 n=2294 (36.6%)	≥5 n=2981 (47.6%)
	No AF n=2628 (42.0%)	0.49% (0.12-1.94) 2 events	0.75% (0.39-1.45) 9 events	0.81% (0.54-1.23) 23 events	1.51% (1.13-2.03) 45 events
	AF 6 min–23.5 h n=1446 (23.1%)	0.00% (0) 0 events	0.53% (0.17-1.66) 3 events	0.70% (0.39-1.26) 11 events	2.07% (1.47-2.93) 32 events
	AF >23.5h n=2190 (35.0%)	0.56% (0.14-2.25) 2 events	0.86% (0.41-1.80) 7 events	0.72% (0.44-1.18) 16 events	1.60% (1.18-2.19) 40 events

Kaplan et al. J Am Heart Assoc. 2020 Dec 15;9(24):e018378
Kaplan et al. Circulation. 2019 Nov 12;140(20):1639-1646

Asymptomatic atrial fibrillation in patients with cryptogenic stroke

- AF prevalence in cryptogenic stroke:
  - EMBRACE: **NEJM 2014:** 30 sec AF in 16% of the patients with 30 day monitoring
  - CRYSTAL AF: **NEJM 2016**: 30 sec AF in 12% of the patients during 12 months of monitoring
  - Stroke AF trial: **JAMA 2021**: 30 sec AF in 12% of the patients during 12 months of monitoring

Summary

- Choice of a wearable monitoring modality depends on the indication and frequency of arrythmia
- ILRs provide the most reliable long-term rhythm monitoring
- ILR data should be reviewed carefully to assess for false positive episodes
- Indication based programming of ILR can minimize the data deluge
- Decision about anticoagulation for device detected AF is dictated by duration of AF and chad-Vasc score

Acknowledgement

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Consumer "Wearable" Rhythm Monitoring Devices

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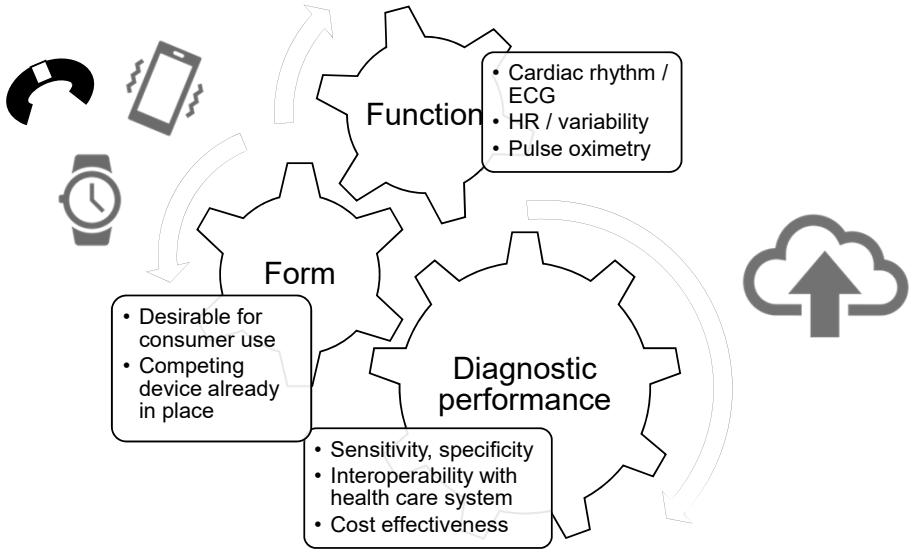
Disclosures

- No relevant competing financial interests
- Some, but not all, wearable and fitness tracking devices are FDA cleared

Introduction

- "Internet of things" now includes biometrics
- Cardiac rhythm is now easily ascertainable
- Harnessing this enormous data source for health care remains challenging

Considerations for devices



Al-Alusi MA, Ding E, McManus DD, Lubitz SA. *Curr Cardiol Rep.* 2019;21(12):158.

Device Summary

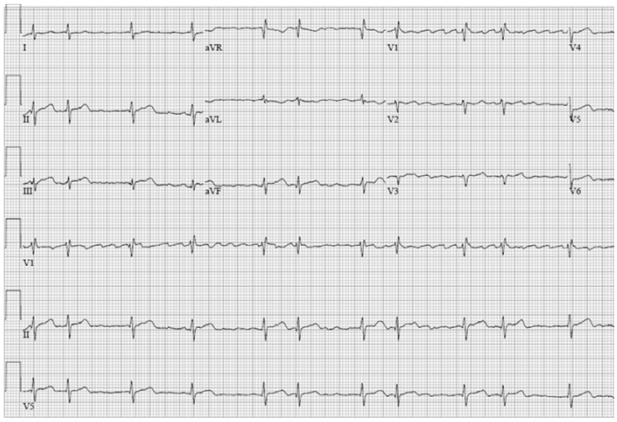
- Selected devices (*FDA cleared) capable of ECG tracings

Device	Manufacturer	Configuration	Tailored to consumers?
KardiaMobile* (1L, 6L, card)	AliveCor	Handheld device	Yes
QardioCore	Qardio Inc.	Worn device (chest band)	Yes
Hexoskin	Carre Technologies Inc.	Worn device (smart garment)	Yes
AppleWatch* (Series 4+)	Apple	Wristwatch	Yes
Fitbit* (Flex, One, Charge)	Fitbit	Wristwatch	Yes
ScanWatch	Withings	Wristwatch	Yes
Study Watch*	Verily (Alphabet Inc.)	Wristwatch	No (research)
Eko Duo	Eko Devices	Digital stethoscope	No (medical diagnostic)

Al-Alusi MA, Ding E, McManus DD, Lubitz SA. *Curr Cardiol Rep*. 2019;21(12):158.
Bayoumy K, Gaber M, Elshafeey A, et al. *Nature Reviews Cardiology*. 2021;18(8):581-599.

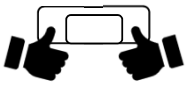
Atrial fibrillation detection

- Key questions
  - Known diagnosis?
  - Pretest probability?
  - Would diagnosis determine management?
  - Risk-benefit same for sub-clinical AF?



Isakadze N, Martin SS. *Trends Cardiovasc Med*. 2020;30(7):442-448.
Lopes RD, Alings M, Connolly SJ, et al. *Am Heart J. 2017*;189:137-145

STROKESTOP study



- Handheld, single-lead device (Zenicor II)
- Recordings 2x/day x 2 wks
- AF diagnosed ≥ 30s

- CVA/embol. intention-to-treat shown (as-treated was significant)

Randomly (1:1) selected 75 to 76-year-olds in defined geographical region

AF screening group (n=14,387) → Primary: 4456 (**HR 0.96, p=0.045**) CVA/embol.: 812 (HR 0.92, p=0.10**)**

Control group (n=14,381) → Primary: 4616 CVA/embol.: 874

- No loss of follow up in this Swedish study
- Composite primary endpoint: ischemic or hemorrhagic CVA, systemic embolism, bleeding leading to hosp., all-cause mortality

Svennberg E, Friberg L, Frykman V, et al. *Lancet (London, England).* 2021;398(10310):1498-1506.

Comparison of diagnostic accuracy: watch vs. insertable cardiac monitor (ICM)

KardiaBand** applied to patients (n=24) with **ICM in place & PAF**

SmartRhythm 2.0 (conv. neural network trained on 7500 AliveCor users)

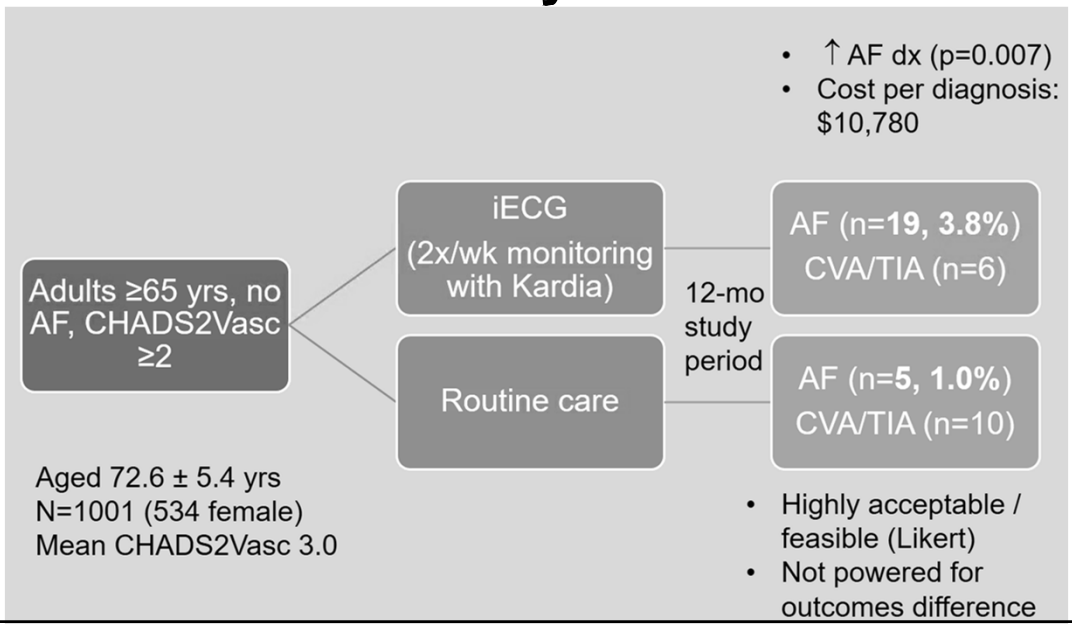
- 31,349 hrs (11.3 hrs/day) simultaneous watch-ICM data

- 82 episodes of AF ≥ 1hr
- Episode sensitivity: 97.5%
- Duration sensitivity: 97.7%

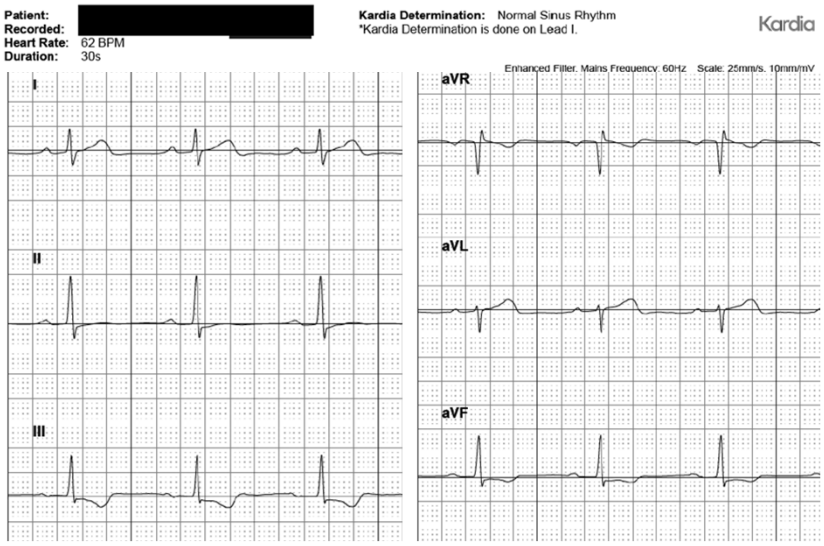
**Note that KardiaBand was an earlier iteration of the Kardia devices and is discontinued
Wasserlauf J, You C, Patel R, et al. *Circ Arrhythm Electrophysiol.* 2019;12(6):e006834.

AliveCor Kardia

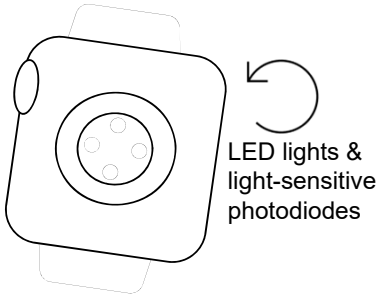
AliveCor Kardia
REHEARSE-AF study



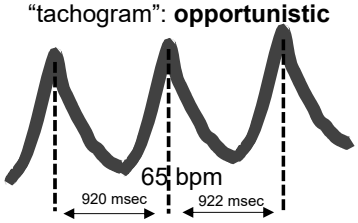
AliveCor Kardia 6L



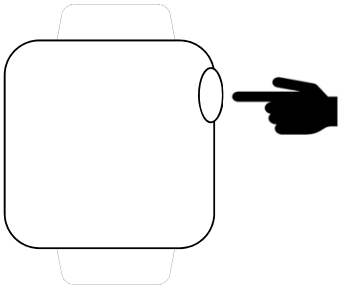
Apple Watch

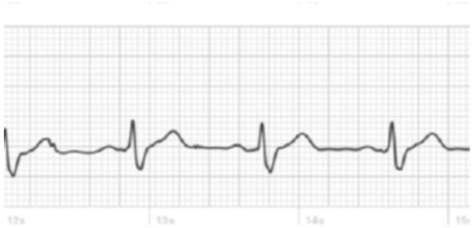


Photophlethysmographic (PPG) "tachogram": **opportunistic**



Vector between watch-worn wrist and contralateral finger: **user-initiated**





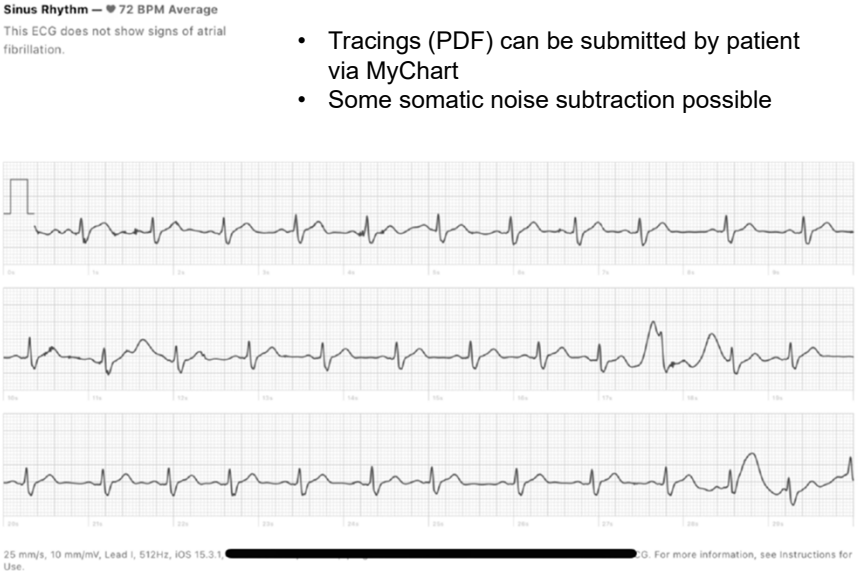
Lead I approximation

Turakhia MP, Desai M, Hedlin H, et al. *Am Heart J.* 2019;207:66-75.

Apple Watch

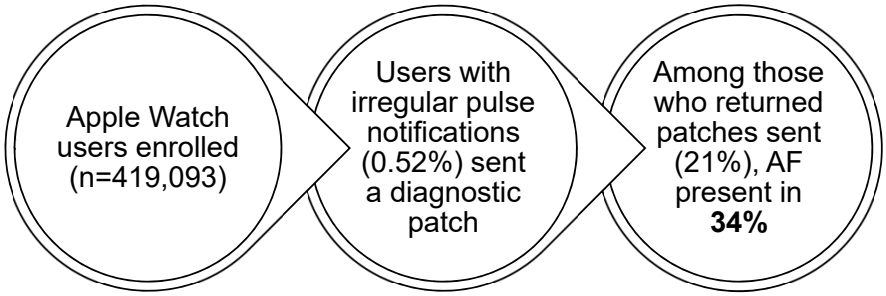
Video: Original ; Spoken Content: Karmen CL, Reisfeld MA, et al. Cardiol Rev. 2019;27(2):60-62. & Turakhia MP, Desai M, Hedlin H, et al. *Am Heart J.* 2019;207:66-75.

Apple Watch



- Tracings (PDF) can be submitted by patient via MyChart
- Some somatic noise subtraction possible

Apple Watch
Apple Heart Study



- Prospective, single arm study
- Telehealth study visits & electronic consent process

Turakhia MP, Desai M, Hedlin H, et al. *Am Heart J.* 2019;207:66-75.
Perez MV, Mahaffey KW, Hedlin H, et al. *N Engl J Med.* 2019;381(20):1909-1917.

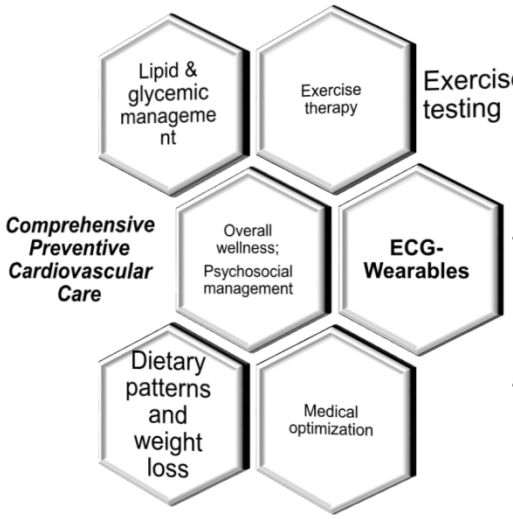
USPSTF Recommendations

Asymptomatic adults 50 years and older	**USPSTF concludes that the current evidence is <u>insufficient</u> to assess the balance of benefits and harms of screening for atrial fibrillation**	**I**

- Updates the 2018 statement
  - Inadequate evidence for **1-time** screening
- **Adequate** evidence that screening diagnoses AF > usual care
- Inadequate evidence regarding **benefits** of treatment of **screen-detected AF**

Davidson KW, Barry MJ, et al. Screening for Atrial Fibrillation: US Preventive Services Task Force Recommendation Statement. *JAMA.* 2022;327(4):360-367.

Cardiac "Tele-rehabilitation"



- **Benefits**
  - **Synchronous / asynchronous activity supervision**
  - **Rhythm tracing review**
- **Barriers**
  - **EHR integration**
  - **Digital literacy variability**
  - **Reimbursement and regulatory issues**

Taylor RS, Afzal J, Dalal HM. *Eur J Prev Cardiol*. 2021.

Stock photo was purchased from istock.com by the Ohio State Heart & Vascular Center

"ABCD" guide to wearables

	Topics	Questions	Examples
A	**Assess**: device, literature, reg. approval, price	• What data / clinical **utilities** are generated? • What **evidence** supports use?	• HR, physical activity, single-lead ECG • No RCTs yet suggest ECG-wearables improve outcomes
B	**Benefit**: patients, practice	• What potential **time**/ • convenience **savings** are possible? • Workflow / cost-effectiveness?	• Remote management of patients with AF • Potential for anticoag. initiation for primary AF
C	**Clinical** workflow integration	• Logistics of working the device into practice? • Are monitoring services **billable**?	• Telehealth care requires consent • Staff teaching / familiarity learning curve
D	**Data** rights and governance	• Who owns the rights to data ? • Can the data be used for **research**? • HIPAA	• Patient must consent to data use sharing with 3rd parties or research • Breaches possible

Bayoumy K, Gaber M, Elshafeey A, et al. *Nature Reviews Cardiology*. 2021;18(8):581-599

Conclusions

- "Wearables" are becoming ubiquitous
- Use of ECG-capable consumer devices should be approached thoughtfully
- AF detection is a special situation of particular interest

Stock photo was purchased from istock.com by the Ohio State Heart & Vascular Center

References

1. Al-Alusi MA, Ding E, McManus DD, Lubitz SA. Wearing Your Heart on Your Sleeve: the Future of Cardiac Rhythm Monitoring. *Curr Cardiol Rep.* 2019;21(12):158.
2. Bayoumy K, Gaber M, Elshafeey A, et al. Smart wearable devices in cardiovascular care: where we are and how to move forward. *Nature reviews Cardiology.* 2021;18(8):581-599.
3. Isakadze N, Martin SS. How useful is the smartwatch ECG? *Trends Cardiovasc Med.* 2020;30(7):442-448.
4. Lopes RD, Alings M, Connolly SJ, et al. Rationale and design of the Apixaban for the Reduction of Thrombo-Embolism in Patients With Device-Detected Sub-Clinical Atrial Fibrillation (ARTESiA) trial. *Am Heart J.* 2017;189:137-145.
5. Svennberg E, Friberg L, Frykman V, Al-Khalili F, Engdahl J, Rosenqvist M. Clinical outcomes in systematic screening for atrial fibrillation (STROKESTOP): a multicentre, parallel group, unmasked, randomised controlled trial. *Lancet (London, England).* 2021;398(10310):1498-1506.
6. Halcox JPJ, Wareham K, Cardew A, et al. Assessment of Remote Heart Rhythm Sampling Using the AliveCor Heart Monitor to Screen for Atrial Fibrillation: The REHEARSE-AF Study. *Circulation.* 2017;136(19):1784-1794.
7. Turakhia MP, Desai M, Hedlin H, et al. Rationale and design of a large-scale, app-based study to identify cardiac arrhythmias using a smartwatch: The Apple Heart Study. *Am Heart J.* 2019;207:66-75.
8. Karmen CL, Reisfeld MA, McIntyre MK, Timmermans R, Frishman W. The Clinical Value of Heart Rate Monitoring Using an Apple Watch. *Cardiol Rev.* 2019;27(2):60-62.
9. Perez MV, Mahaffey KW, Hedlin H, et al. Large-Scale Assessment of a Smartwatch to Identify Atrial Fibrillation. *N Engl J Med.* 2019;381(20):1909-1917.
10. Wasserlauf J, You C, Patel R, Valys A, Albert D, Passman R. Smartwatch Performance for the Detection and Quantification of Atrial Fibrillation. *Circ Arrhythm Electrophysiol.* 2019;12(6):e006834.
11. USPSTF: Davidson KW, Barry MJ, et al. Screening for Atrial Fibrillation: US Preventive Services Task Force Recommendation Statement. *JAMA.* 2022;327(4):360-367.
12. Taylor RS, Afzal J, Dalal HM. The promise and challenge of telerehabilitation in cardiac rehabilitation. *Eur J Prev Cardiol.* 2021.