



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 continuous ambulatory rhythm monitoring

- **Symptoms**
 - Palpitation- Description varies based on arrhythmia
 - 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 HOLTHER MONITOR
 - 3-14 DAY HOLTHER 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?

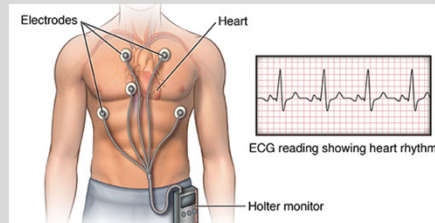
Modalities of continuous rhythm monitoring - Wearables, cont.

- 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 arrhythmia but MCT gives duration of arrhythmia episodes as well.

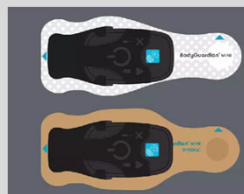
Modalities of continuous rhythm monitoring - Wearables, cont.

- 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 arrhythmia or slow/rapid heart rate: MCT is preferred.
- How the information is communicated to the patient?
 - Patient is notified after arrhythmia 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 arrhythmias in patients who don't qualify for pacemaker or defibrillator
- Patients with unknown risk of life threatening arrhythmias
 - Sarcoidosis, inherited conditions (Long QT, Brugada, ARVC)
- Syncope of unknown etiology
 - Diagnose life threatening arrhythmias
 - 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
- Continuous 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 during working hours
- OSU studies led industry wide changes in device programming for arrhythmia detection
- OSU electrophysiologists led studies on
 - Optimal device location
 - Incidence of false positive
 - Resource utilization
- Indication based programming of ILR resulted in significant reduction in incidence of false positive 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 arrhythmia
 - 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 threshold)
- 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 anticoagulation were reviewed.

- Stroke risk with ↑ with higher CHADS₂-VAsc score and duration of AF

		CHA ₂ DS ₂ -VAsc Score			
		1	2	3-4	≥5
Maximum Daily AF Duration		n=258 (4.1%)	n=731 (11.7%)	n=2294 (36.6%)	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 arrhythmia
- 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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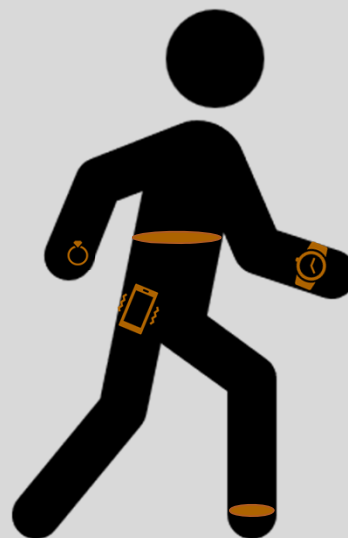


Disclosures

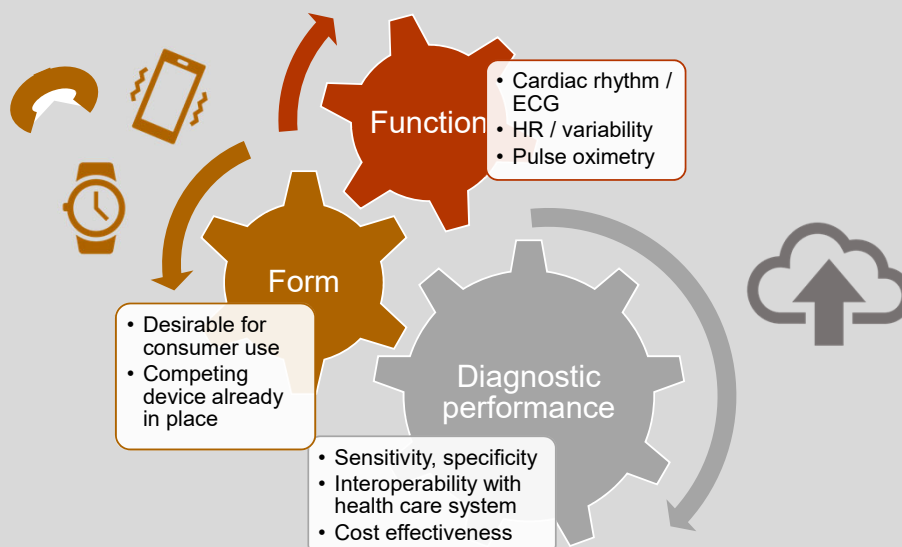
- No relevant competing financial interests
- Some, but not all, wearable and fitness tracking devices are FDA cleared

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

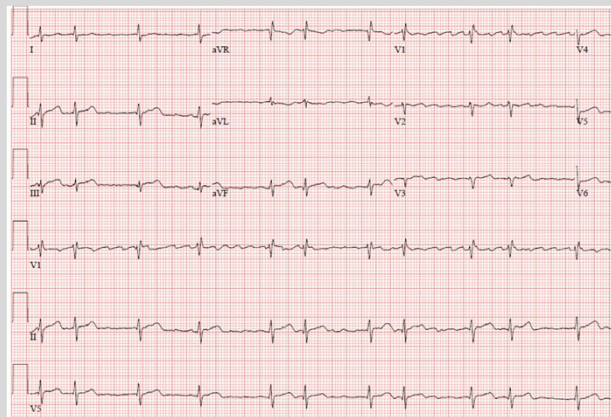
- Selected devices (*FDA cleared) capable of ECG tracings

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?



PPG ↑ ↑ ↑ ↑ ↑ ↑ ↑ ↑ ↑

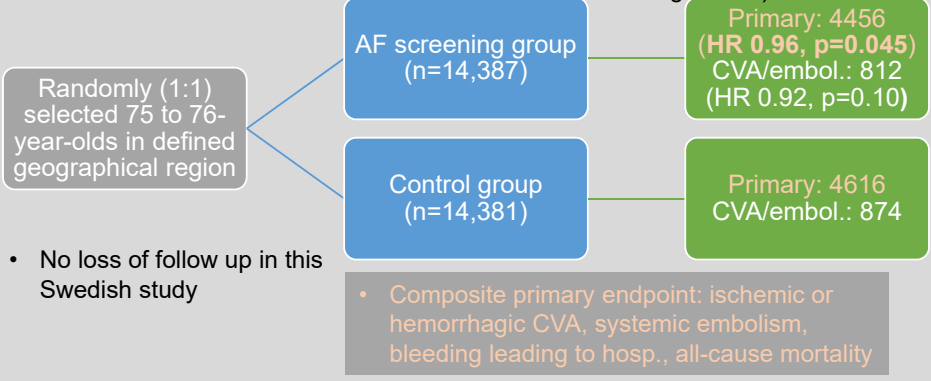
Isakadze N, Martin SS. *Trends Cardiovasc Med.* 2020;30(7):442-448.
 Lopes RD, Alings M, Connolly SJ, et al. *Am Heart J.* 2017;189:137-145

STROKESTOP study



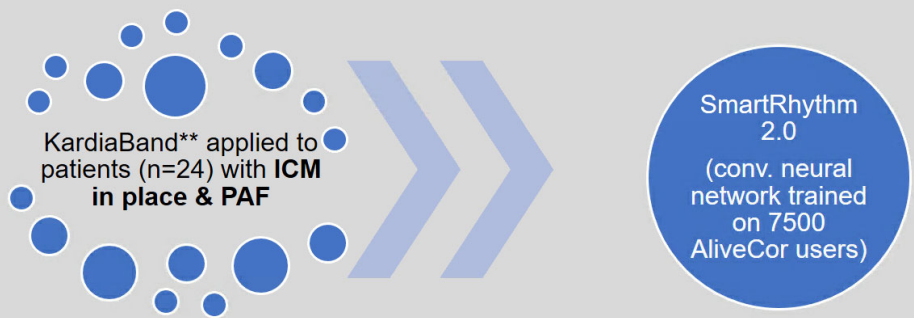
- Handheld, single-lead device (Zenikor II)
- Recordings 2x/day x 2 wks
- AF diagnosed \geq 30s

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



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)



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

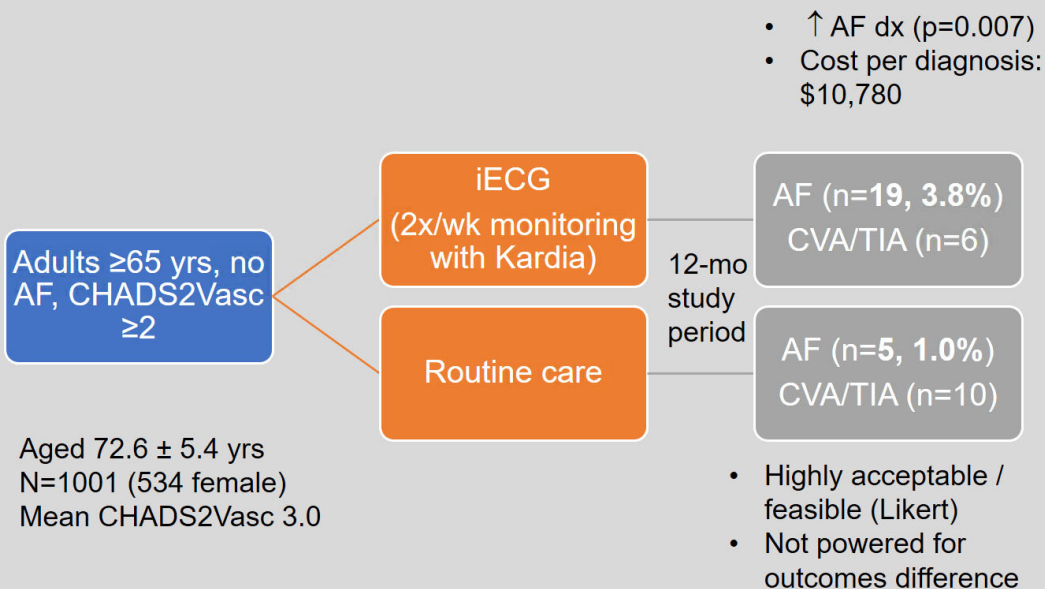
- 82 episodes of AF \geq 1hr
- Episode sensitivity: 97.5%
- Duration sensitivity: 97.7%

**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.

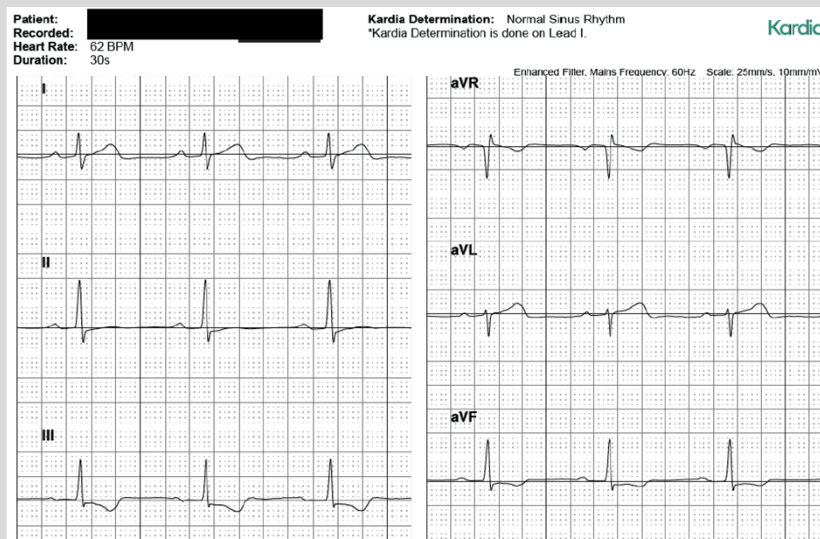
AliveCor Kardia



AliveCor Kardia REHEARSE-AF study

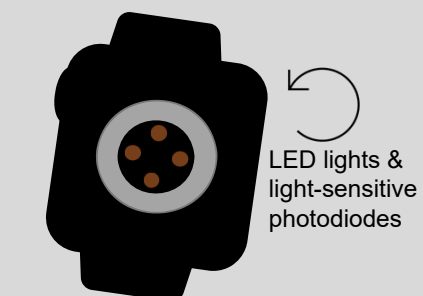


AliveCor Kardia 6L

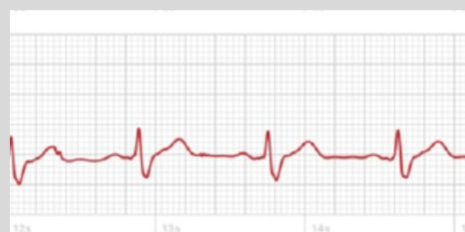
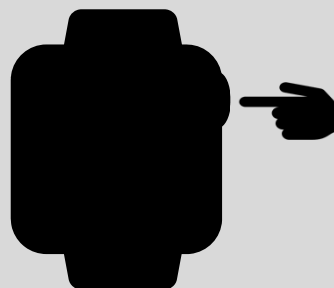
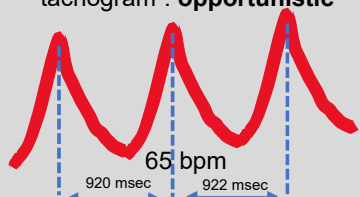


Apple Watch

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



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



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

Sinus Rhythm — ♥ 72 BPM Average

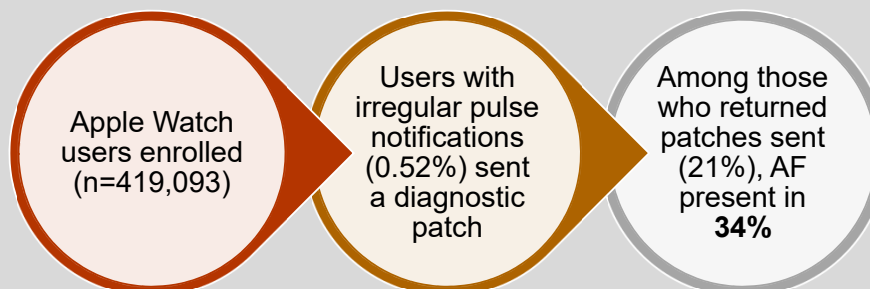
This ECG does not show signs of atrial fibrillation.

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



25 mm/s, 10 mm/mV, Lead I, 512Hz, iOS 15.3.1 © Apple. For more information, see instructions for Use.

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

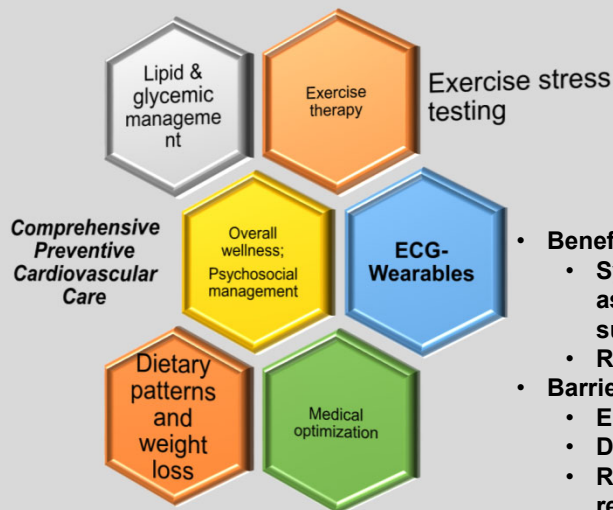
USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for atrial fibrillation



- 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	<ul style="list-style-type: none"> • What data / clinical utilities are generated? • What evidence supports use? 	<ul style="list-style-type: none"> • HR, physical activity, single-lead ECG • No RCTs yet suggest ECG-wearables improve outcomes
B	Benefit: patients, practice	<ul style="list-style-type: none"> • What potential time/ convenience savings are possible? • Workflow / cost-effectiveness? 	<ul style="list-style-type: none"> • Remote management of patients with AF • Potential for anticoag. initiation for primary AF
C	Clinical workflow integration	<ul style="list-style-type: none"> • Logistics of working the device into practice? • Are monitoring services billable? 	<ul style="list-style-type: none"> • Telehealth care requires consent • Staff teaching / familiarity learning curve
D	Data rights and governance	<ul style="list-style-type: none"> • Who owns the rights to data ? • Can the data be used for research? • HIPAA 	<ul style="list-style-type: none"> • 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

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