Review of devices for early AF detection

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PAN London AF Improvement programme

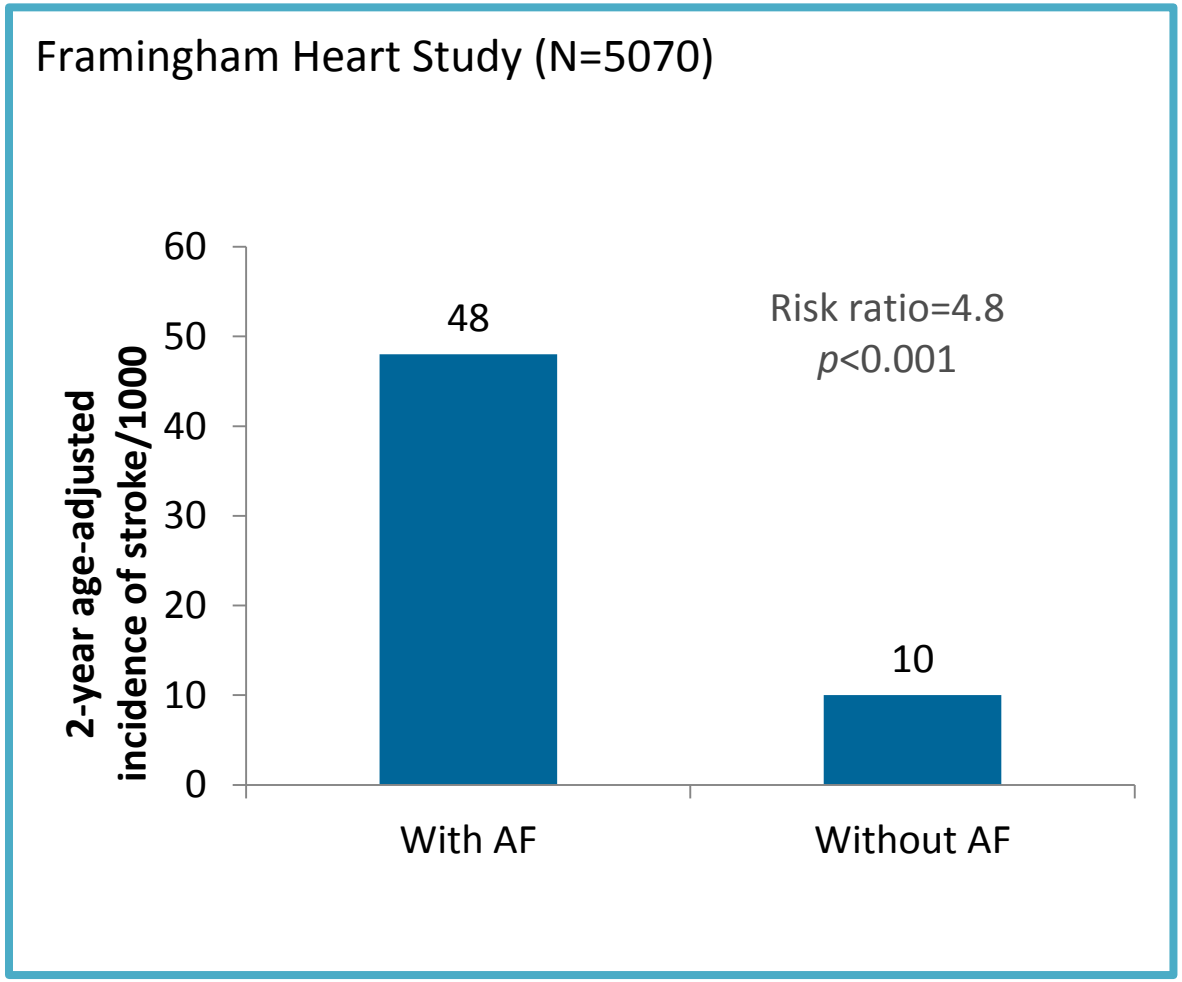
Aims:

- To prevent AF-related stroke and associated mortality through better identification and management of people with atrial fibrillation

- Increasing anticoagulation of untreated high risk AF patients
- Improving the quality of anticoagulation
- Increasing the detection of undiagnosed AF in high risk patients

Introduction

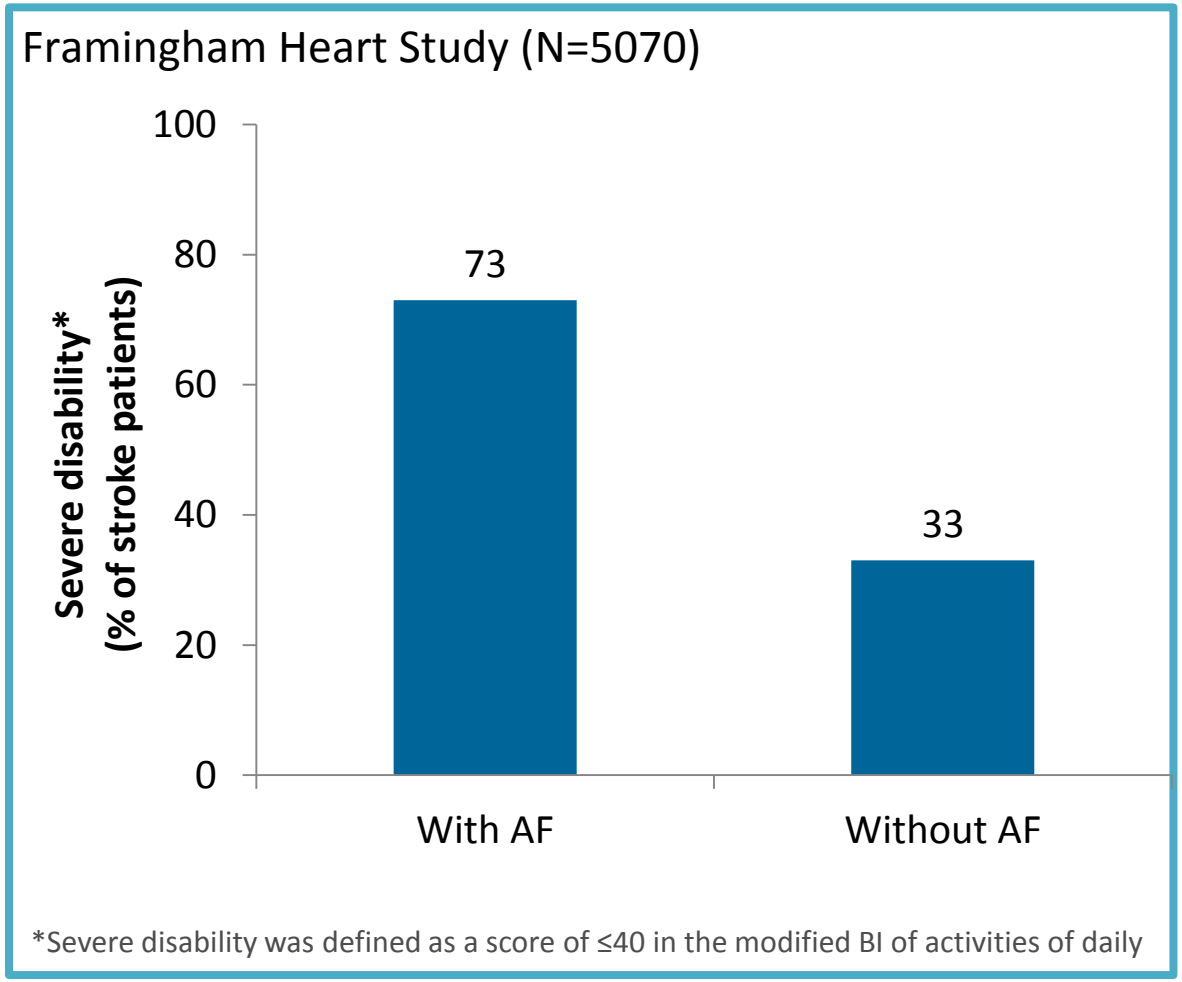
- Atrial Fibrillation (AF) is the most common cardiac arrhythmia encountered in clinical practice
- Characterized by an irregularity in pulse rhythm
- Approximately five-fold increase risk of ischaemic stroke



Wolf PA *et al. Stroke* 1991;22:983

Impact of AF

- AF strokes are typically more severe than strokes without AF, with higher mortality and greater disability



HJ *et al. Stroke* 1996;27:1760

Impact of AF

- AF strokes are typically more severe than strokes without AF, with higher mortality and greater disability
- Impose a major economic burden
- Treatment with an oral anticoagulant medication reduces the risk of stroke in patients with AF by two thirds

Office of Health Economics (2009):

- 5.7 million days in hospital beds (over £1.8 billion)
- Non-bed inpatient costs: £124 million
- Outpatient costs: £205 million

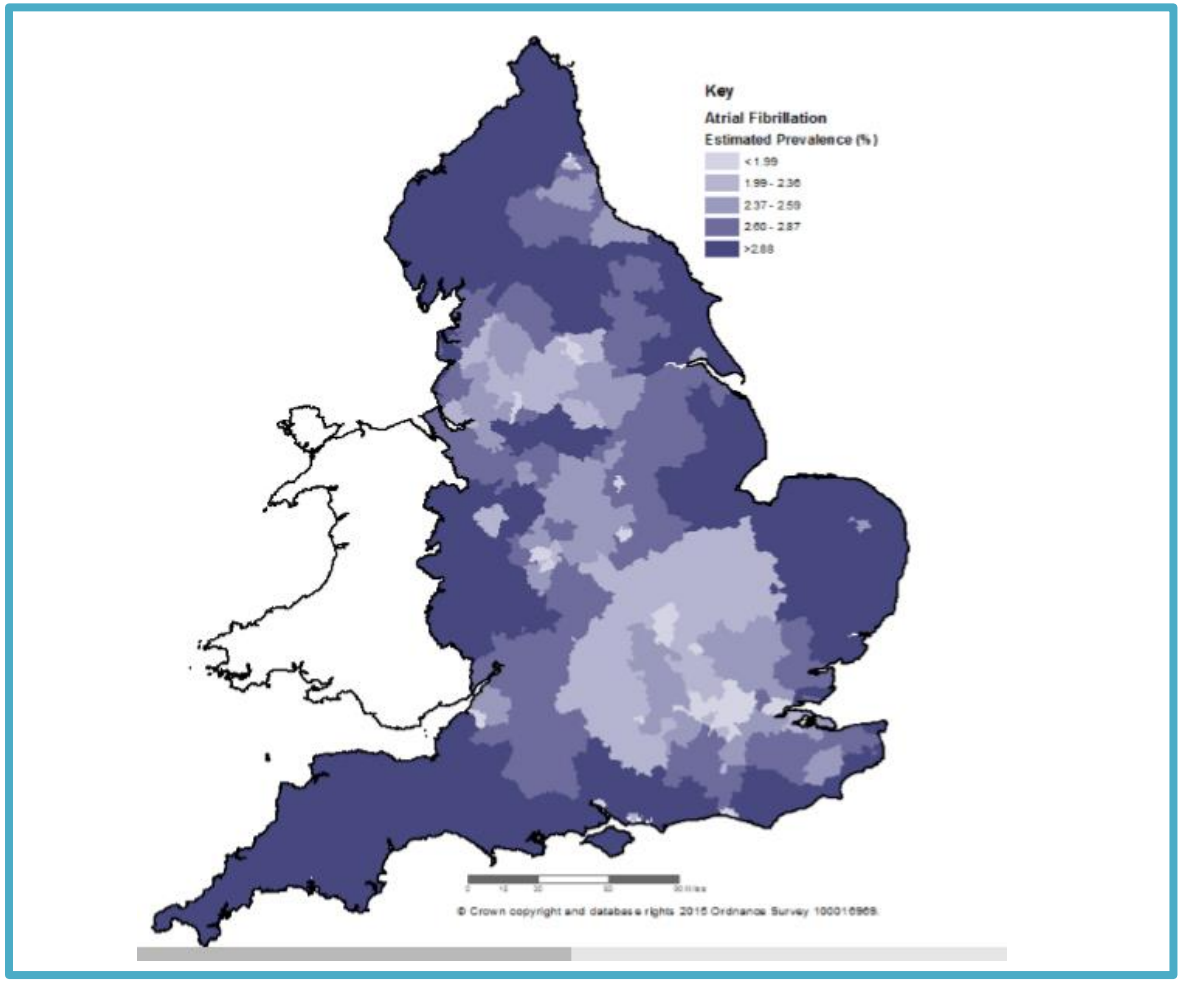
Total direct cost to the NHS:

£2.2 billion annually

The Office of Health Economics: Estimating the direct costs of atrial fibrillation to the NHS in the constituent countries of the UK and at SHA level in England, 2008. November 2009, London

Prevalence

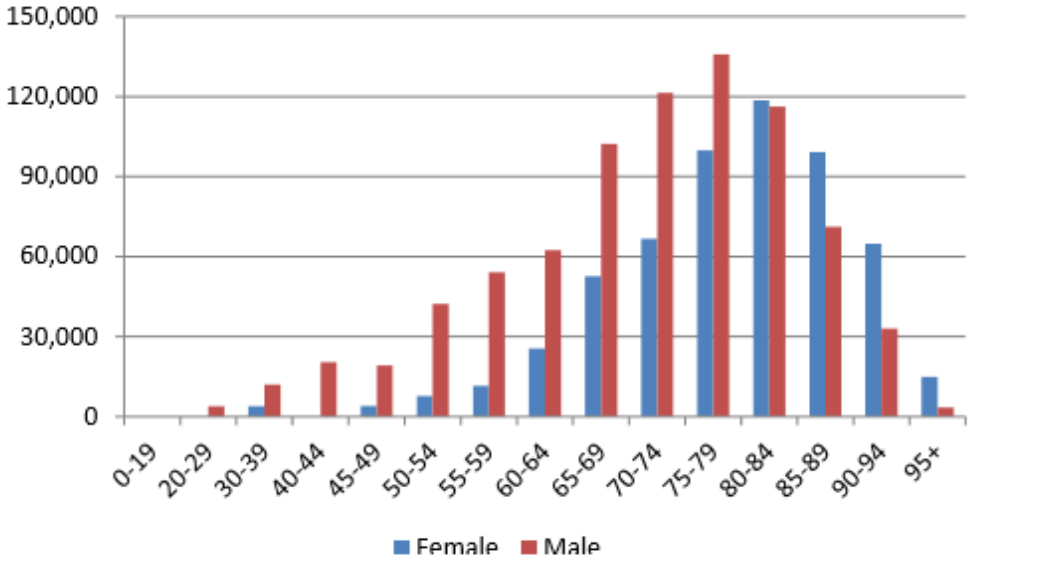
- 1.4 million people in England are estimated to have AF (2.4% of adult population)
- At Clinical Commissioning Group (CCG) level, AF prevalence ranges 1.0% to 3.8%



Source: QoF 2013/2014; NCVIN 2015

Prevalence

- 1.4 million people in England are estimated to have AF (2.4% of adult population)
- At Clinical Commissioning Group (CCG) level, AF prevalence ranges 1.0% to 3.8%
- Prevalence:
  - Increases with age
  - Higher in males than females
- Estimates will double by 2050

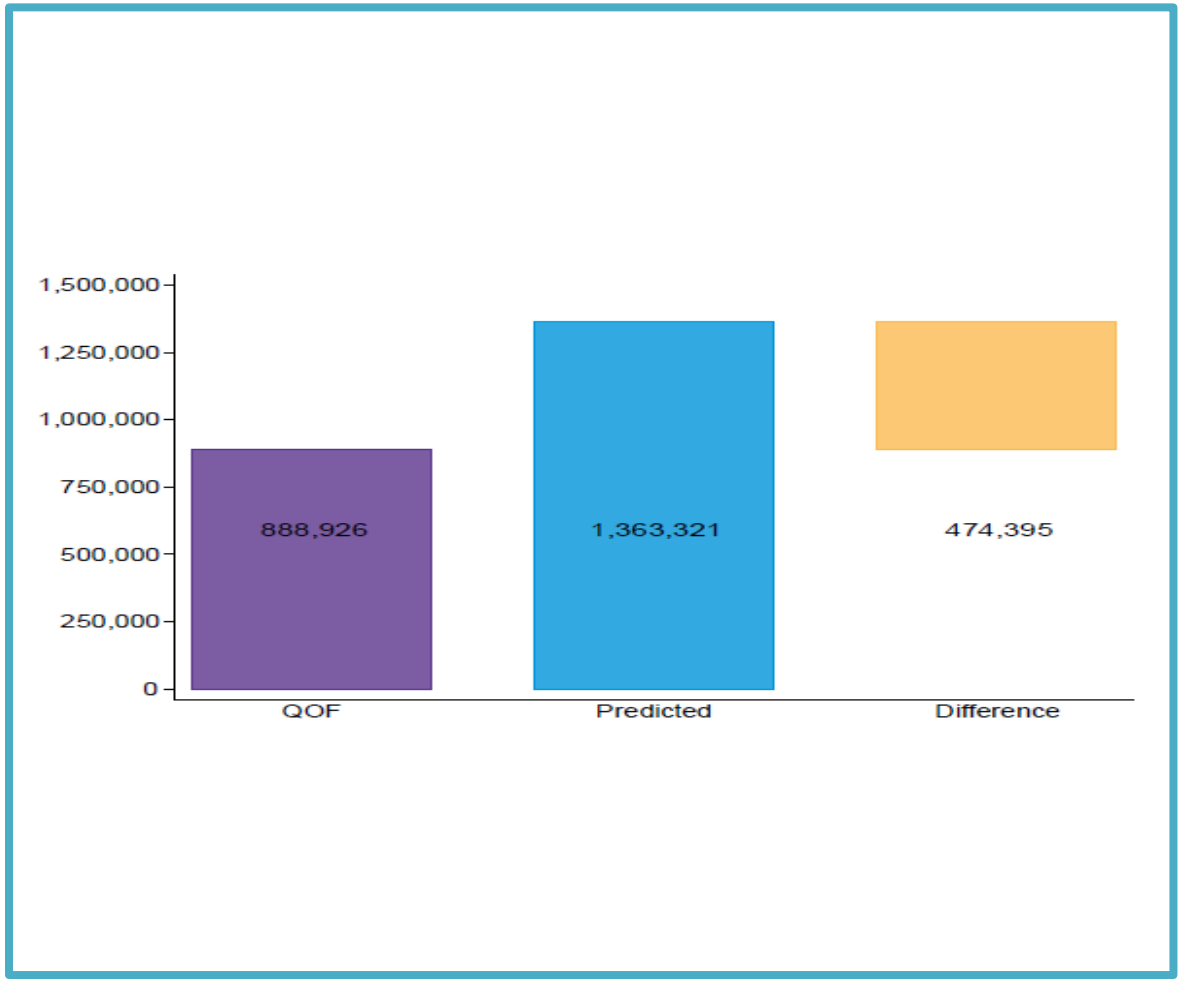


Summary of estimated atrial fibrillation prevalence in England, 2014

Source: Public Health England 2015

Prevalence

- 1.4 million people in England are estimated to have AF (2.4% of adult population)
  - 1.6% diagnosed AF
  - 0.8% undiagnosed AF
- A significant proportion of AF patients are asymptomatic, making detection challenging.



Source: QoF 2013/2014; NCVIN 2015

Screening for AF

Recommendation

9. It is recommended that the current policy is retained but that the statement is expanded to:

   Screening for atrial fibrillation in the over 65 year old population is not recommended as it is uncertain that screening will do more good than harm to people identified during screening for AF.

10. This is because:

- The treatment and care for people with AF is not optimal
- Better evidence is needed about whether AF detected at screening carries the same long term risk of stroke as AF found in the context of other conditions
- The test needs to be improved and standardised.

UK National Screening Committee

18 June 2014

Screening for Atrial Fibrillation in the over 65s

Purpose

1. The purpose of this paper is to provide background on the item addressing screening for atrial fibrillation (AF) in the over 65s.

Current policy

2. The current policy is that screening for atrial fibrillation should not be offered.

The SAFE Study

- People ≥ 65 years
- Opportunistic pulse palpation

Table 2 | New cases of atrial fibrillation (AF) by trial arm identified in case notes 12 months after baseline

Group	Patients	Baseline AF	Missing notes	Denominator	Newly identified cases	New case detection %
Control	4936	389	34	4513	47	1.04
Intervention:						
Total	9866	679	50	9137	149	1.63
Opportunistic*	4933	340	18	4575	75	1.64
Systematic*	4933	339	32	4562	74	1.62

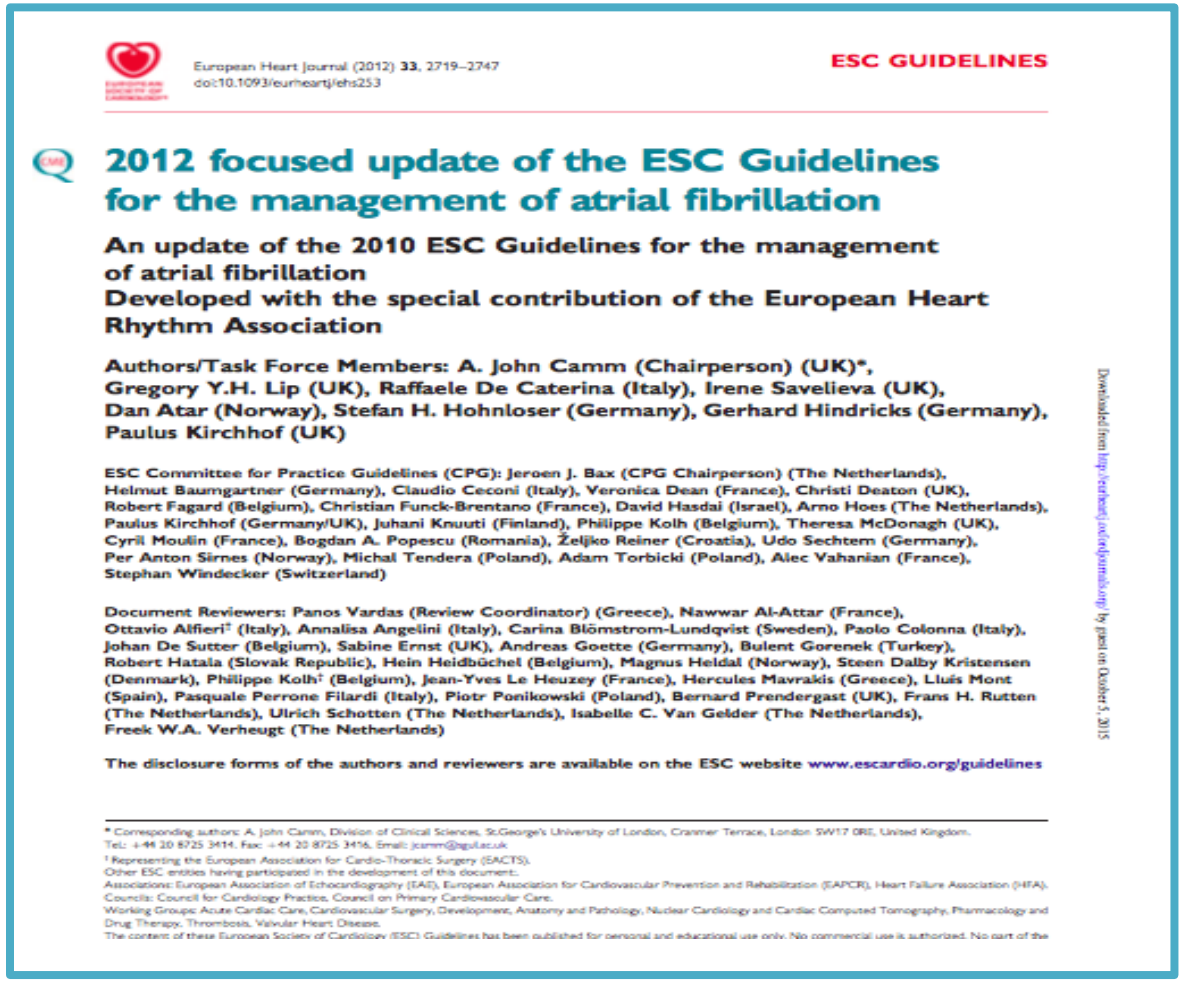
*Subsets of total intervention population.

Fitzmaurice, D. A et al. *BMJ* 2007;335:383

Guideline Recommendation

Recommendation for screening of AF

Recommendations	Class[a]	Level[b]	Ref[c]
Opportunistic screening for AF in patients ≥65 years of age using pulse-taking followed by an ECG is recommended to allow timely detection of AF.	I	B	14, 15



European Heart Journal (2012) 33, 2719–2747
doi:10.1093/eurheartj/ehs253

ESC GUIDELINES

2012 focused update of the ESC Guidelines for the management of atrial fibrillation

An update of the 2010 ESC Guidelines for the management of atrial fibrillation
Developed with the special contribution of the European Heart Rhythm Association

Authors/Task Force Members: A. John Camm (Chairperson) (UK)*, Gregory Y.H. Lip (UK), Raffaele De Caterina (Italy), Irene Savelieva (UK), Dan Atar (Norway), Stefan H. Hohnloser (Germany), Gerhard Hindricks (Germany), Paulus Kirchhof (UK)

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The disclosure forms of the authors and reviewers are available on the ESC website www.escardio.org/guidelines

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‡ Representing the European Association for Cardio-Thoracic Surgery (EACTS).
Other ESC entities having participated in the development of this document:
Associations: European Association of Echocardiography (EAE), European Association for Cardiovascular Prevention and Rehabilitation (EAPCR), Heart Failure Association (HFA).
Councils: Council for Cardiology Practice, Council on Primary Cardiovascular Care.
Working Groups: Acute Cardiac Care, Cardiovascular Surgery, Development, Anatomy and Pathology, Nuclear Cardiology and Cardiac Computed Tomography, Pharmacology and Drug Therapy, Thrombosis, Valvular Heart Disease.

Recommendations for screening for atrial fibrillation

Recommendations	Class[a]	Level[b]	Ref[c]
Opportunistic screening for AF is recommended by pulse taking or ECG rhythm strip in patients >65 years of age.	I	B	130, 134, 155
In patients with TIA or ischaemic stroke, screening for AF is recommended by short-term ECG recording followed by continuous ECG monitoring for at least 72 hours.	I	B	27, 127
It is recommended to interrogate pacemakers and ICDs on a regular basis for atrial high rate episodes (AHRE). Patients with AHRE should undergo further ECG monitoring to document AF before initiating AF therapy.	I	B	141, 156
In stroke patients, additional ECG monitoring by long-term non-invasive ECG monitors or implanted loop recorders should be considered to document silent atrial fibrillation.	IIa	B	18, 128
Systematic ECG screening may be considered to detect AF in patients aged >75 years, or those at high stroke risk.	IIb	B	130, 135, 157

Health Innovation Network South London

IMPERIAL COLLEGE HEALTH PARTNERS

NHS London Strategic Clinical Networks

UCLPartners Academic Health Science Partnership

European Heart Journal Advance Access published August 27, 2016

European Heart Journal
doi:10.1093/eurheartj/ehw210

ESC GUIDELINES

2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS

The Task Force for the management of atrial fibrillation of the European Society of Cardiology (ESC)

Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC

Endorsed by the European Stroke Organisation (ESO)

Authors/Task Force Members: Paulus Kirchhof* (Chairperson) (UK/Germany) Stefano Benussi*[1] (Co-Chairperson) (Switzerland), Dipak Kotecha (UK), Anders Ahlsson[1] (Sweden), Dan Atar (Norway), Barbara Casadei (UK), Manuel Castella[1] (Spain), Hans-Christoph Diener[2] (Germany), Hein Heidbuchel (Belgium), Jeroen Hendriks (The Netherlands), Gerhard Hindricks (Germany), Antonis S. Manolis (Greece), Jonas Oldgren (Sweden), Bogdan Alexandru Popescu (Romania), Ulrich Schotten (The Netherlands), Bart Van Putte[1] (The Netherlands), and Panagiotis Vardas (Greece)

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Clinical practice

European Journal of Preventive Cardiology

European Primary Care Cardiovascular Society (EPCCS) consensus guidance on stroke prevention in atrial fibrillation (SPAF) in primary care

FD Richard Hobbs[1], Clare J Taylor[2], Geert Jan Geersing[3], Frans H Rutten[3] and Judith R Brouwer[4], on behalf of the European Primary Care Cardiovascular Society (EPCCS) SPAF working group

Alternative approach

- Modified sphygmomanometers or other devices using single-lead ECG registrations to detect an irregular pulse may be used instead of pulse palpation, but only where they have been subject to independent validation with a 12-lead ECG.
- If not enough expertise is available in the primary care setting to confidently read a 12-lead ECG, it should be reviewed by a specialist. 12-lead ECG may also provide other useful information on cardiac functioning.

National Clinical Guideline Centre

Atrial Fibrillation

Atrial fibrillation: the management of atrial fibrillation

Clinical guideline

Methods, evidence and recommendations

June 2014

5.2.4 Recommendation

2. Perform an electrocardiogram (ECG) in all people, whether symptomatic or not, in whom atrial fibrillation is suspected because an irregular pulse has been detected. [2006]

Commissioned by the National Institute for Health and Care Excellence

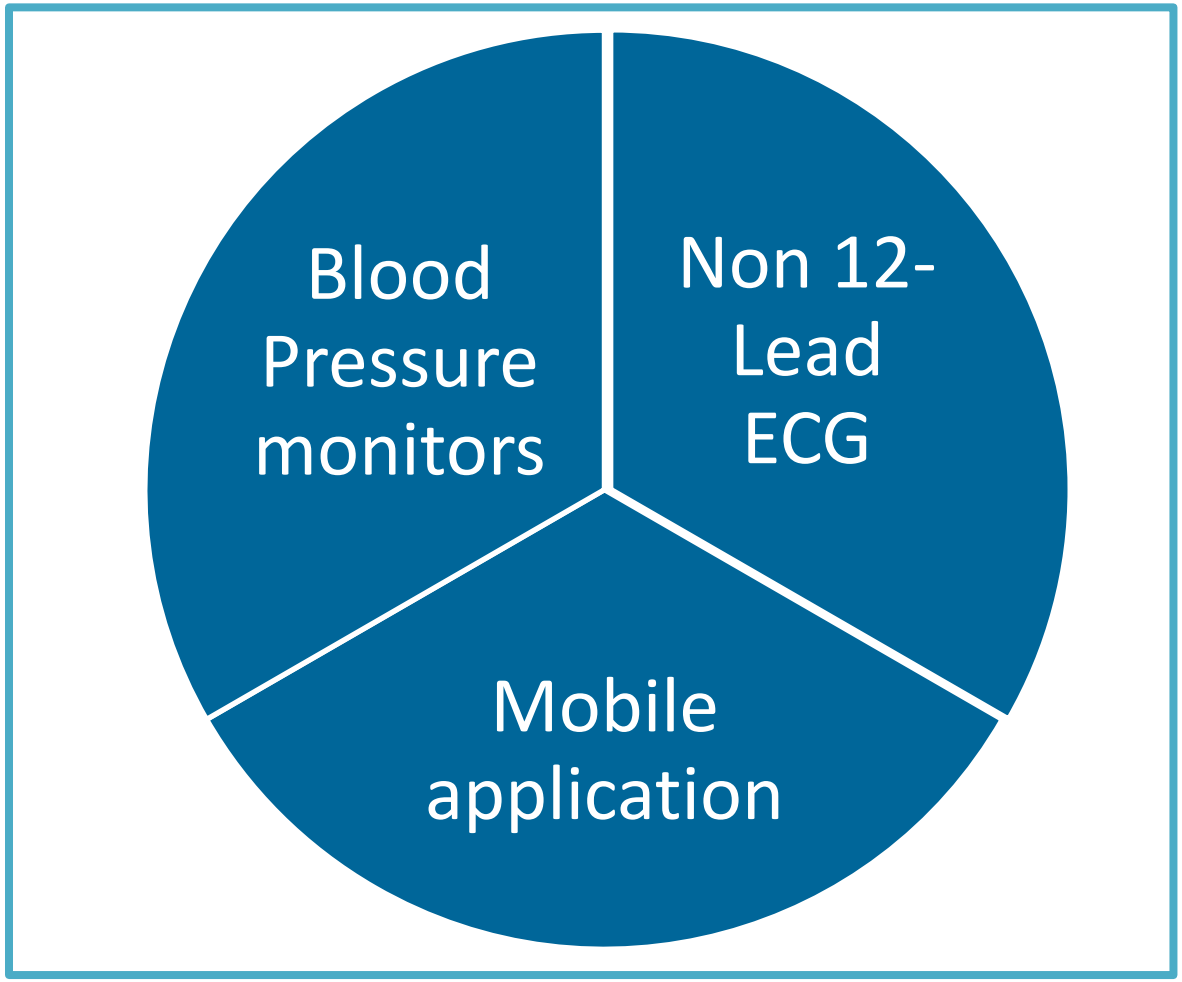
NICE National Clinical Guideline Centre, 18 June 2014;
Camm AJ *et al*. *Eur Heart J* 2012;33:2719

Pulse Palpation

- Simple screening technique for AF
- Sensitivity 87% and specificity 81%
- Not routinely performed in clinical practice

Devices to detect AF

- Enhance Detection of AF in community settings
- Reduce the cost of ‘unnecessary’ 12 lead ECGs
- Quick and easy to use
- Affordable
- Different types of device



DETECT: Finding more AF - Devices

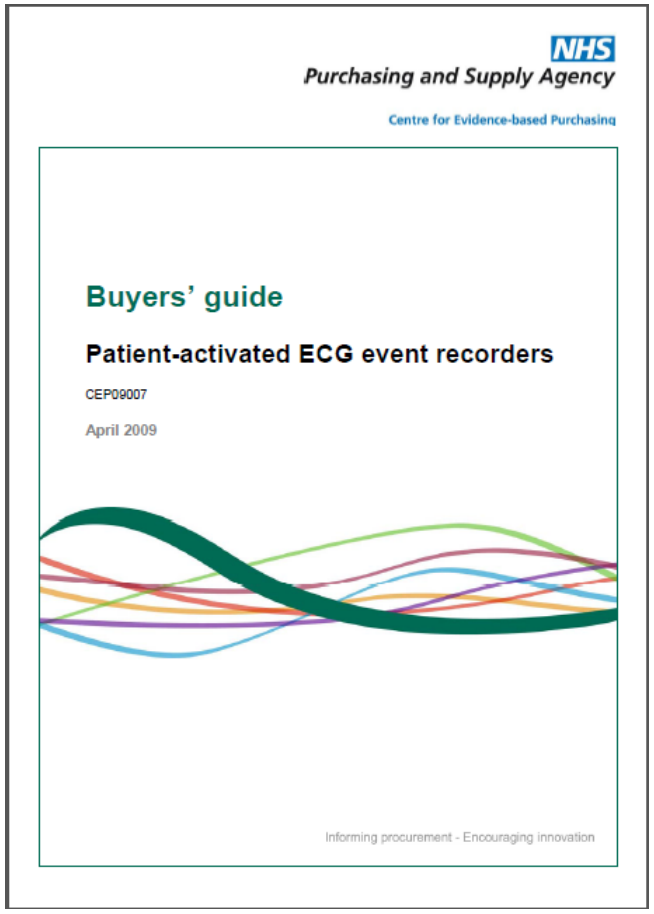
Blood Pressure monitors

Non 12-Lead ECG

Mobile application

Devices to detect AF

- Different AF detection devices
  - Current guidelines
  - NHS reports
  - Medical literature search ((MEDLINE, EMBASE, CINAHL, Global Health, The Health Management Information Consortium and Cochrane Library)
  - Food and Drug Administration (FDA)
  - Medicines and Healthcare Product Regulatory Agency (MHRA)
  - companies and/ or their websites



Devices to detect AF

- Different AF detection devices
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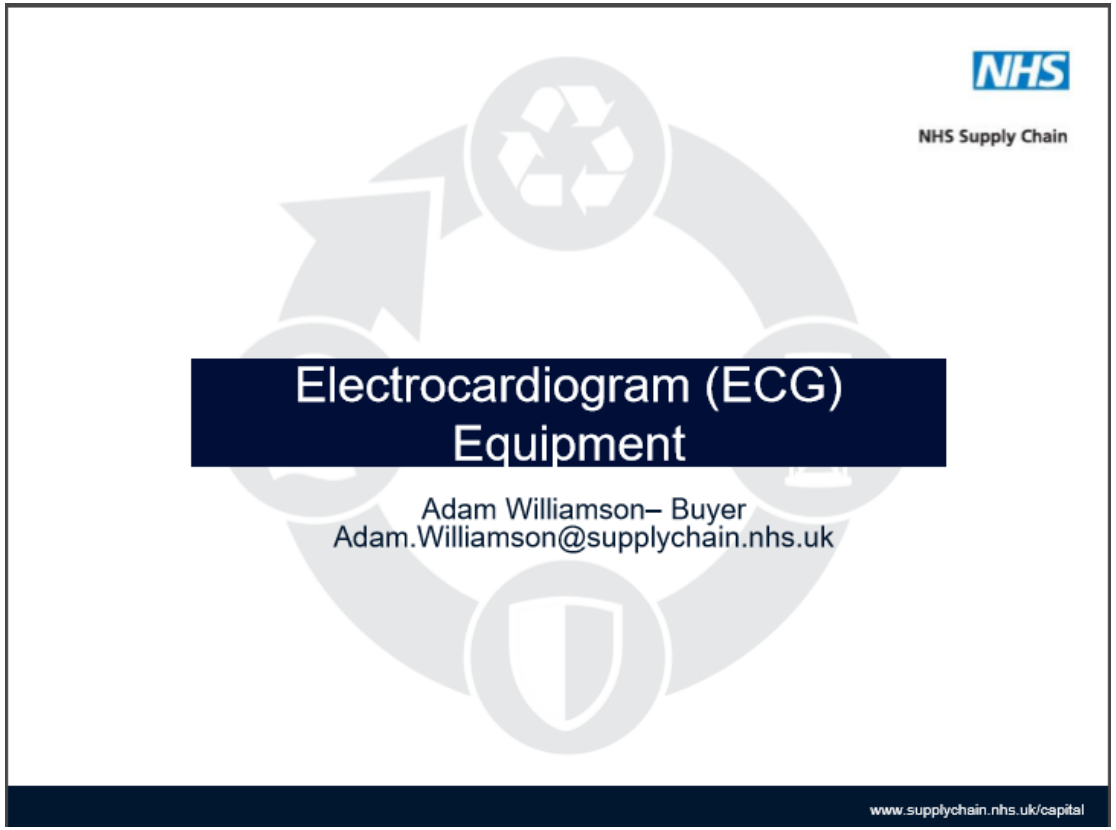


Blood pressure monitors

1. ‘AF detectors’

Built-in algorithm that analyses the irregularity of pulse rate and apply a threshold to detect AF during BP measurements

2. ‘Arrhythmia detectors’

Built-in algorithm that signals heart beat varies by more than 25% from the average during BP measurement. Detects irregular heart beat.

Handheld ECGs

1. ‘Continuous’ monitor
   - Record ECG over 24 hours to several days
   - Holter monitors and implantable devices

2. ‘Event’ monitor
   - Allow intermittent recording
   - Activated by placing the thumbs, fingers or palms on the device

Mobile application

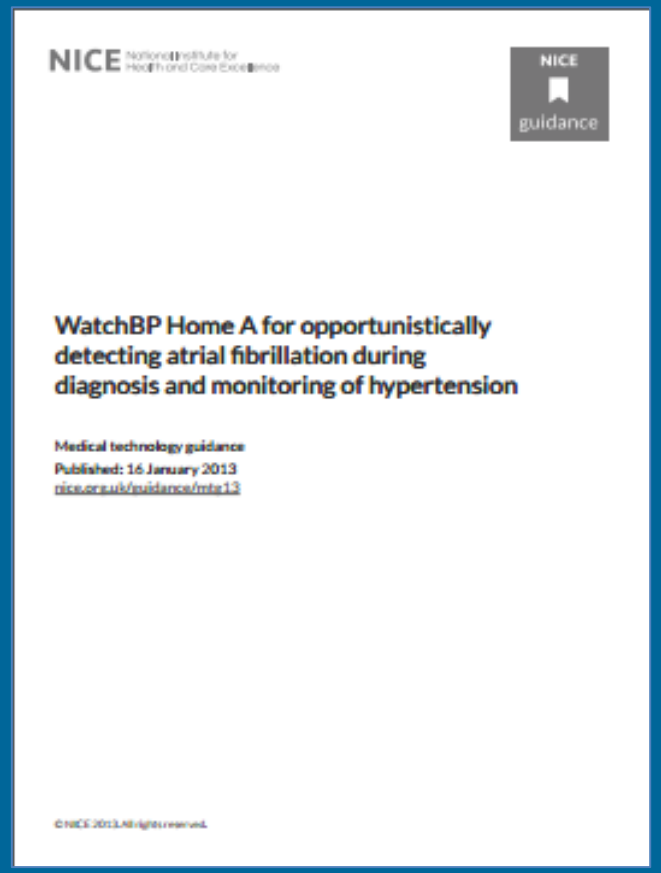
1. ‘Smart phone apps’

Determine heart rate using in-built camera and analyse the regularity of the pulse waves to detect AF or sinus rhythm

2. Electrodes connect mobile device

Transmit, record , auto-analyse and view an ECG recording using a dedicated app

Evidence – National Guidance


NICE National Institute for Health and Care Excellence

NICE guidance

WatchBP Home A for opportunistically detecting atrial fibrillation during diagnosis and monitoring of hypertension

Medical technology guidance
Published: 16 January 2013
nice.org.uk/guidance/mtg13

Evidence – National Guidance

NICE National Institute for Health and Care Excellence

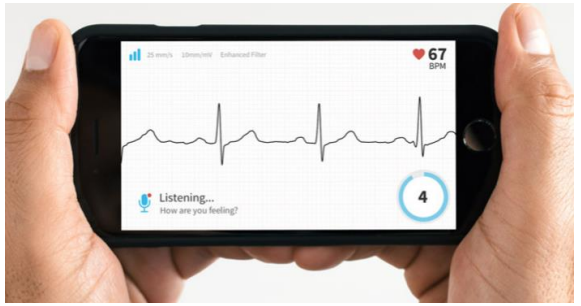
NICE advice

AliveCor Heart Monitor and AliveECG app for detecting atrial fibrillation

Medtech innovation briefing
Published: 5 August 2015
nice.org.uk/guidance/mib35

Summary

The AliveCor Heart Monitor and AliveECG app are, respectively, a pocket-sized ECG recorder and a mobile device application for analysis and communication of the results. Two fingers from each hand are placed on the AliveCor Heart Monitor to record an ECG, which is transmitted wirelessly to the AliveECG app. The aim of the device is to identify paroxysmal atrial fibrillation (AF). Two clinical studies reported that the AliveCor Heart Monitor and the AliveECG app have sensitivity above 85% and specificity above 90% in identifying AF. An AliveCor Heart Monitor unit costs £62.49, excluding VAT; the AliveECG app is free of charge. An Australian study found that opportunistic, community-based screening for undiagnosed AF, using the AliveCor Heart Monitor and the AliveECG app, was cost effective.



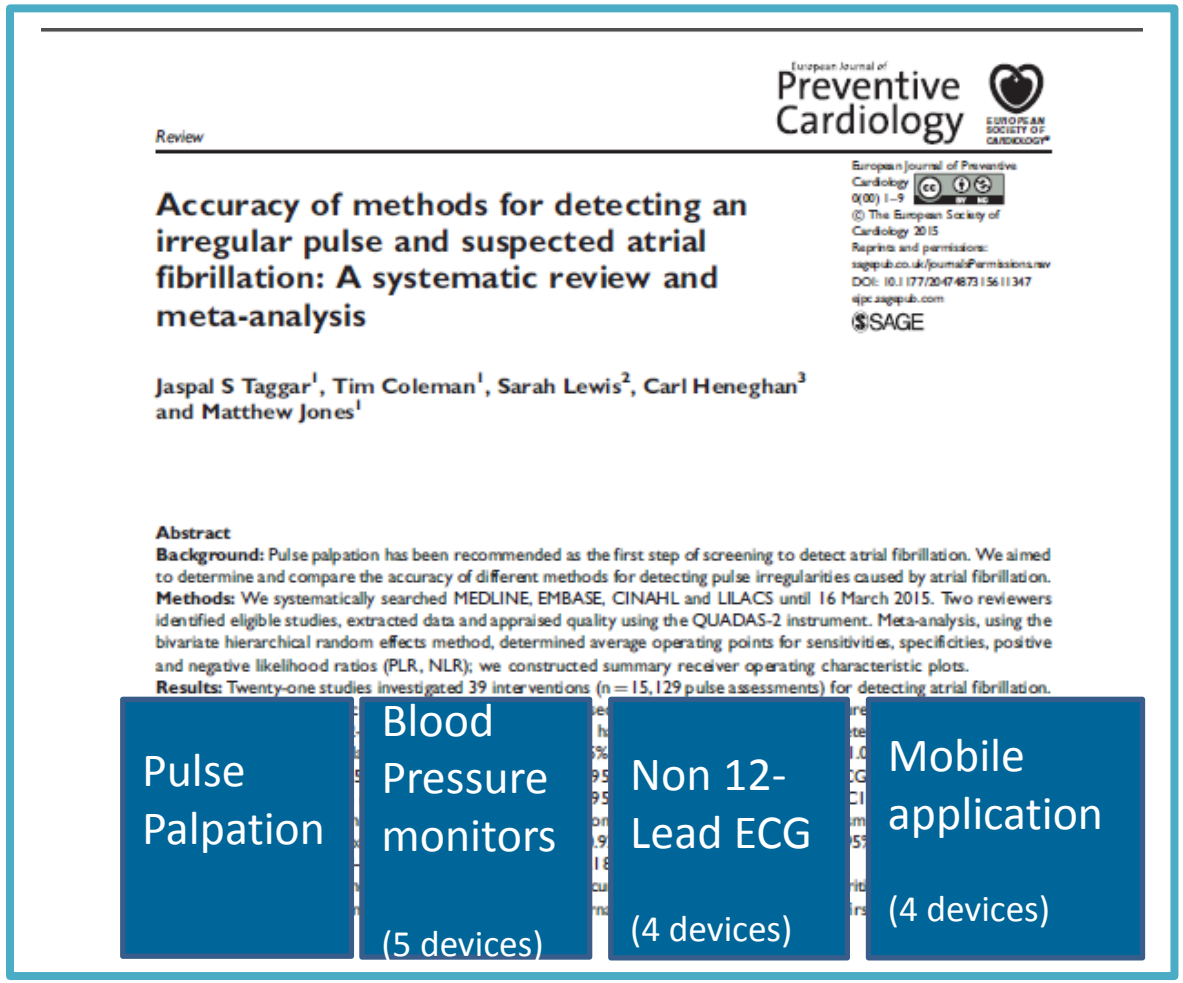
Evidence – Systematic Review & meta-analysis

21 studies

21 studies

- 2 Randomised Control Trials
- 7 Case control studies
- 2 Cohorts
- 10 Cross-sectional studies

AF prevalence range: 5.7% to 25.4%



European Journal of Preventive Cardiology

Review

Accuracy of methods for detecting an irregular pulse and suspected atrial fibrillation: A systematic review and meta-analysis

Jaspal S Taggar[1], Tim Coleman[1], Sarah Lewis[2], Carl Heneghan[3] and Matthew Jones[1]

European Journal of Preventive Cardiology 0(00) 1–9
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DOI: 10.1177/2047487315611347
ejpc.sagepub.com
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Abstract

Background: Pulse palpation has been recommended as the first step of screening to detect atrial fibrillation. We aimed to determine and compare the accuracy of different methods for detecting pulse irregularities caused by atrial fibrillation.

Methods: We systematically searched MEDLINE, EMBASE, CINAHL and LILACS until 16 March 2015. Two reviewers identified eligible studies, extracted data and appraised quality using the QUADAS-2 instrument. Meta-analysis, using the bivariate hierarchical random effects method, determined average operating points for sensitivities, specificities, positive and negative likelihood ratios (PLR, NLR); we constructed summary receiver operating characteristic plots.

Results: Twenty-one studies investigated 39 interventions (n = 15,129 pulse assessments) for detecting atrial fibrillation.

Pulse Palpation

Blood Pressure monitors (5 devices)

Non 12-Lead ECG (4 devices)

Mobile application (4 devices)

Taggar JS *et al.* Euro J Prev Cardiol. 2015:1-9

Pooled data results

	Pooled Sensitivity (95% CI)	Pooled Specificity (95% CI)	Positive Likelihood Ratio (95% CI)	Negative Likelihood Ratio (95% CI)
Pulse Palpation (6 studies)	0.92 (0.85-0.96)	0.82 (0.76-0.88)	5.2 (3.8-7.2)	0.1 (0.05-0.18)
Blood Pressure Monitors (6 studies)	0.98 (0.92-1.00)	0.92 (0.88-0.95)	12.1 (8.2-17.8)	0.02 (0.00-0.09)
Non-12 Lead ECG (10 studies)	0.91 (0.86-0.94)	0.95 (0.92-0.97)	20.1 (12-33)	0.09 (0.06-0.14)
Smart phone applications (3 studies)	0.97(0.95-0.99)	0.95 (0.88-0.98)	19 (8-45)	0.03 (0.01-0.05)

Device	Setting	Country	Screening process	Number of participant screened	Age (years)	History AF	New detected AF	Reference
AliveCor	Community Pharmacy	Australia	Single time point screening,with single lead ECG	966	≥65	9% (87/966)	1.6% (15/966)	Lowers 2014
AliveCor	Community pharmacy	New Zealand	Single time point screening,with single lead ECG	121	≥55	17% (20/17)	1.7% (2/121)	Walker 2014
Microlife WatchBP Office	Community pharmacy	Italy	Single time point screening, using at least two of three measurements to detected AF	220	>18	Not specified	1.8% (4/220)	Omboni 2016
MyDiagnostic	Primary care (Influenza vaccination)	Netherlands	Single time point screening,with single lead ECG	3269	69.4±8.9	2.6% (84/3269)	1.1% (37/3269)	Kaasenbrood 2015
Omeron Heartscan HCG-801	Primary care screening programme 'Week of heart rhythm'	Belgium	Single time point screening,with single lead ECG	13,564 of whom 10,758 were ≥ 40 years	59±11	7.2% (771/10,758)	2% (228/10,758)	Claes 2012
RhythmKiosk (Cardiocity ltd)	Primacy care (GP surgery)	UK	Single time point screening,with single lead ECG	To date 25,547	Not specified	Not specified	0.32% (81/25,547)	Not published as still on-going. The safe-2-screen programme
Zenicor	Patients Home	Sweden	Intermittent ECG screening for 2 weeks	7173	75-76	9.2% (666/7173)	3% (218/7173)	Svennberg 2015
Zenicor	Patients Home	Sweden	Intermittent ECG screening for 2 weeks.	403	75-76	9.6% (81/848)	7.4% (30/403)	Engdahl 2013

When choosing a device - consider

1. Accuracy of device (sensitivity & specificity)
2. Features of device
    1. ECG electrode connectivity
    2. Data storage and/or transmission
    3. Data interpretation (inbuilt algorithm, telemedicine service)
    4. Consumables
3. Information Governance
4. Patient consent
5. Infection Control
6. Setting for screening
7. Staff
8. Training
9. AF pathway

AliveCor Kardia ECG & AliveECG app (AliveCor, inc) *(Multiple suppliers: PMS instruments, Technomed Group, NHS supplies Chain)*	
	
Model description	AliveCor Mobile ECG is a single-channel cardiac event monitor. It consists of a device and app that enables to record and review ECG trace. The device attaches to the back of most iOS (iPhone, iPod and iPAD) and android devices
User manual	Click here to view Quick Instruction guide
	Click here to view AliveCor user guide
Patient connection	Single-lead ECG event recorder with integrated 2 electrodes within the rectangular device that can be attached directly to a mobile device or be within 30cm of the mobile device during operation
Heart rate range	30 – 300 beats per minute
Display	ECG transmitted wirelessly to the ALIVE ECG app. In addition to the trace a display a message: Atrial fibrillation, Normal, unreadable recording. For traces that are not normal, AF or had no interference detected will display message "unclassified"
Memory type	Software application
Recording capacity	Software application can store 1000s of recording on a smart phone or tablet. These are accessible through authorised cloud based provider dashboard
Data transfer	Email a PDF, print to upload ECG from device
Printing	e-mail as a PDF, print or upload from device Healthcare professionals can also access the results through a provider dashboard software
Power	3V CR2016 Coin Cell
Battery lifespan	Minimum 200 hours operating time, 12 months typical use
Physical size (LxWxH)	8.2 cm x 3.2cm x 0.35cm
Weight	Not specified
List price	£82.50 (+VAT)
Supplied accessories (Batteries & user manual assumed)	Attachment plate with adhesive
Warranty	1 year
	www.alivecor.com

MyDiagnostic (MyDiagnostic Medical B.V) *(Suppliers: Cardiologic Ltd)*	
	
Model description	ECG event recorder
User manual	MyDiagnosticDevice ManualLpdf
Patient connection	Single lead, integrated, 2 electrodes within the device that has a shape of a stick
Heart rate range	Not specified
Display	Device has indicator that will turn green for normal cardiac rhythm and red in case of AF
Memory type	It consists of an internal, priority storage scheme
Recording capacity	Up to 140 x 60 to 70 seconds ECG recordings. Note: Device will overwrite oldest recordings in the following order: a) Recordings during which an error has occurred b) Recordings with no AF detection c) Recordings with AF detection
Data transfer	USB connect to computer
Printing	ECG recordings can be retrieved from device using appropriate MyDiagnostic software
Battery type	2 x NiMH 1.2V 2000 mAh rechargeable (via USB connector)
Battery lifespan	Minimum 500 recordings at 60 to 70 s or 2 months regular use if the device while measuring 3 to 5 times per day
Physical size (Length x diameter)	260 x 22mm
Weight	180g
List price	£650 (excluding VAT and Carriage)
Supplied accessories (Batteries & user manual assumed)	None
Warranty	2 years. The warranty only applies to failures that are the result of manufacturing faults and/or material defects.
	https://www.mydiagnostick.com/home-en

THANK YOU FOR YOUR ATTENTION!