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

Framingham Heart Study (N=5070)

- 2-year age-adjusted incidence of stroke/1000
  - With AF: 48
  - Without AF: 10
  - Risk ratio = 4.8
  - p < 0.001

Impact of AF

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

Framingham Heart Study (N=5070)

*Severe disability was defined as a score of ≤40 in the modified BI of activities of daily life.

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**

November 2009, London
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
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

Source: Public Health England 2015
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.

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**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>
<thead>
<tr>
<th>Table 2</th>
<th>New cases of atrial fibrillation (AF) by trial arm identified in case notes 12 months after baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>Patients</td>
</tr>
<tr>
<td>Control</td>
<td>4936</td>
</tr>
<tr>
<td>Intervention:</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>9866</td>
</tr>
<tr>
<td>Opportunistic*</td>
<td>4933</td>
</tr>
<tr>
<td>Systematic*</td>
<td>4933</td>
</tr>
</tbody>
</table>

*Subsets of total intervention population.

Guideline Recommendation

Recommandation for screening of AF

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>I</td>
<td>B</td>
<td>14, 15</td>
</tr>
</tbody>
</table>
# Recommendations for screening for atrial fibrillation

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opportunistic screening for AF is recommended by pulse taking or ECG rhythm strip in patients &gt;65 years of age.</td>
<td>I</td>
<td>B</td>
<td>130, 134, 155</td>
</tr>
<tr>
<td>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.</td>
<td>I</td>
<td>B</td>
<td>27, 127</td>
</tr>
<tr>
<td>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.</td>
<td>I</td>
<td>B</td>
<td>141, 156</td>
</tr>
<tr>
<td>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.</td>
<td>IIa</td>
<td>B</td>
<td>18, 128</td>
</tr>
<tr>
<td>Systematic ECG screening may be considered to detect AF in patients aged &gt;75 years, or those at high stroke risk.</td>
<td>IIb</td>
<td>B</td>
<td>130, 135, 157</td>
</tr>
</tbody>
</table>
European Primary Care Cardiovascular Society (EPCCS) consensus guidance on stroke prevention in atrial fibrillation (SPAF) in primary care

FD Richard Hobbs¹, Clare J Taylor², Geert Jan Geersing³, Frans H Rutten³ and Judith R Brouwer⁴, 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.
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

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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
Evidence – National Guidance

AliveCor Heart Monitor and AliveECG app for detecting atrial fibrillation

Medtech innovation briefing
Published: 5 August 2015
nice.org.uk/guidance/mlb35

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

AF prevalence range: 5.7% to 25.4%

Pooled data results

<table>
<thead>
<tr>
<th>Method</th>
<th>Pooled Sensitivity (95% CI)</th>
<th>Pooled Specificity (95% CI)</th>
<th>Positive Likelihood Ratio (95% CI)</th>
<th>Negative Likelihood Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse Palpation (6 studies)</td>
<td>0.92 (0.85-0.96)</td>
<td>0.82 (0.76-0.88)</td>
<td>5.2 (3.8-7.2)</td>
<td>0.1 (0.05-0.18)</td>
</tr>
<tr>
<td>Blood Pressure Monitors (6 studies)</td>
<td>0.98 (0.92-1.00)</td>
<td>0.92 (0.88-0.95)</td>
<td>12.1 (8.2-17.8)</td>
<td>0.02 (0.00-0.09)</td>
</tr>
<tr>
<td>Non-12 Lead ECG (10 studies)</td>
<td>0.91 (0.86-0.94)</td>
<td>0.95 (0.92-0.97)</td>
<td>20.1 (12-33)</td>
<td>0.09 (0.06-0.14)</td>
</tr>
<tr>
<td>Smart phone applications (3 studies)</td>
<td>0.97 (0.95-0.99)</td>
<td>0.95 (0.88-0.98)</td>
<td>19 (8-45)</td>
<td>0.03 (0.01-0.05)</td>
</tr>
<tr>
<td>Device</td>
<td>Setting</td>
<td>Country</td>
<td>Screening process</td>
<td>Number of participant screened</td>
</tr>
<tr>
<td>---------------------</td>
<td>----------------------------------------------</td>
<td>--------------</td>
<td>-----------------------------------------------------------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>AliveCor</td>
<td>Community Pharmacy</td>
<td>Australia</td>
<td>Single time point screening, with single lead ECG</td>
<td>966</td>
</tr>
<tr>
<td>AliveCor</td>
<td>Community pharmacy</td>
<td>New Zealand</td>
<td>Single time point screening, with single lead ECG</td>
<td>121</td>
</tr>
<tr>
<td>Microlife WatchBP Office</td>
<td>Community pharmacy</td>
<td>Italy</td>
<td>Single time point screening, using at least two of three measurements to detected AF</td>
<td>220</td>
</tr>
<tr>
<td>MyDiagnostic</td>
<td>Primary care (Influenza vaccination)</td>
<td>Netherlands</td>
<td>Single time point screening, with single lead ECG</td>
<td>3269</td>
</tr>
<tr>
<td>Omeron Heartscan HCG-801</td>
<td>Primary care screening programme 'Week of heart rhythm'</td>
<td>Belgium</td>
<td>Single time point screening, with single lead ECG</td>
<td>13,564 of whom 10,758 were ≥ 40 years</td>
</tr>
<tr>
<td>RhythmKiosk (Cardiocity ltd)</td>
<td>Primacy care (GP surgery)</td>
<td>UK</td>
<td>Single time point screening, with single lead ECG</td>
<td>To date 25,547</td>
</tr>
<tr>
<td>Zenicor</td>
<td>Patients Home</td>
<td>Sweden</td>
<td>Intermittent ECG screening for 2 weeks</td>
<td>7173</td>
</tr>
<tr>
<td>Zenicor</td>
<td>Patients Home</td>
<td>Sweden</td>
<td>Intermittent ECG screening for 2 weeks</td>
<td>403</td>
</tr>
</tbody>
</table>
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

**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](#).

**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**

80 – 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 to 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 9.35cm

**Weight**

Not specified

**List price**

£82.50 (+VAT)

**Supplied accessories**

Attachment plate with adhesive

**Warranty**

1 year [www.alivecor.com](http://www.alivecor.com)

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### MyDiagnostic

**Model description**

ECG event recorder

**User manual**

[MyDiagnostic Device Manual.pdf](#)

**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 memory 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 2000mAh 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.mydiagnostic.com/home-en
THANK YOU FOR YOUR ATTENTION!