NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Assessment Programme

Lead-I electrocardiogram (ECG) devices for detecting atrial fibrillation using single-time point testing in primary care

Final scope

March 2018

1 Introduction

The medical technologies advisory committee identified lead-I electrocardiogram (ECG) devices for detecting atrial fibrillation as potentially suitable for evaluation by the diagnostics assessment programme on the basis of a briefing note. This assessment will include lead-I ECG devices which incorporate an automated algorithm to interpret the captured trace, and focuses on their use as a single-time point test for people presenting to primary care with signs and symptoms of atrial fibrillation. The National Screening Committee is responsible for recommendations relating to systematic population screening for atrial fibrillation. The use of lead-I ECG devices in patients who do not have signs or symptoms which may indicate underlying atrial fibrillation is therefore outside the scope of this assessment.

The final scope was informed by discussions at the scoping workshop held on 22 January 2018 and the assessment subgroup meeting held on 7 February 2018.

A glossary of terms and a list of abbreviations are provided in appendices A and B.

2 Description of the technologies

This section describes the properties of the following technologies based on information provided to NICE by companies and experts. NICE has not carried out an independent evaluation of these descriptions.

2.1 Purpose of the medical technology

Lead-I electrocardiogram (ECG) devices are hand held devices which can be used in primary care to aid the detection of atrial fibrillation in people

presenting with signs or symptoms of the condition. The devices include touch electrodes, internal storage for ECG recordings and automated software which can interpret the ECG trace, giving an indication of whether atrial fibrillation is present, and allow data to be transferred to a local or remote computer for further analysis by a healthcare professional if necessary. It is claimed that using lead-I ECG devices can improve detection of atrial fibrillation. This may lead to earlier identification of people who are at risk of having a stroke and who will benefit from treatment with anticoagulants. The use of lead-I ECG devices may also allow ECGs to be quickly recorded when atrial fibrillation is suspected. This would help to identify people with intermittent (paroxysmal) atrial fibrillation, which may have stopped before a 12-lead ECG can be done.

2.2 Product properties

Several lead-I ECG devices that can be used by healthcare professionals in primary care to detect atrial fibrillation, and that are available to NHS, have been identified. Lead-I ECG devices can also be used by people at home for self-testing and longer-term monitoring when paroxysmal atrial fibrillation is suspected, but this indication is outside of the scope for this assessment which focuses on single-time point testing done in primary care.

Devices have been selected for inclusion if they have built-in software, or software that can be loaded onto a computer, which can analyse ECG traces and assess whether atrial fibrillation is potentially present.

2.2.1 imPulse (Plessey Semiconductors Ltd)

The imPulse is a CE marked lead-I ECG device which is provided with downloadable software for data analysis (imPulse Viewer) and also a cable for charging the device. ECG readings are taken by holding the device in both hands and placing each thumb on a separate sensor on the device for a pre-set length of time (from 30 seconds to 10 minutes). To operate, the device requires the associated software to be installed on a nearby PC or tablet. Data is transferred to hardware hosting the analytical software using Bluetooth, with the recorded ECG trace being displayed in real-time.

Once the recording has finished, the generated ECG trace can be saved in the imPulse viewer. Previously recorded readings can also be loaded into this viewer and ECG traces can be saved as a PDF. The software has an atrial fibrillation algorithm which analyses the reading and states whether atrial fibrillation is unlikely, possible or probable. In the event of a ‘possible’ or ‘probable’ result, the company recommend that the individual should undergo further investigation, and that the algorithm should not be used for a definitive

clinical diagnosis of atrial fibrillation. The company state that data from the device is not currently uploaded to centralised or online storage.

The company state that the device is for use in people aged 18 years and over. There have been no previous versions of the imPulse device.

2.2.2. Kardia Mobile (AliveCor Ltd)

The Kardia Mobile is a CE marked lead-I ECG device which works with the Kardia app to record and interpret ECGs. In addition to the Kardia Mobile device and app (which is free to download), a compatible Android or Apple smartphone or tablet is required.

Two fingers from each hand are placed on the Kardia Mobile device to record an ECG, which is sent wirelessly to the device hosting the Kardia app. The default length of recording is 30 seconds, however this can be extended up to 5 minutes. The measured ECG trace is then automatically transmitted as an anonymous file to a server within the European Union for storage as an encrypted file.

The app uses an algorithm to classify measured ECG traces as either (i) normal, (ii) possible AFib detected, or (iii) unclassified. The instructions for use state that the Kardia app assesses for atrial fibrillation only, and the device will not necessarily detect other cardiac arrhythmias. Any detected non-atrial fibrillation arrhythmias, including sinus tachycardia, are labelled as unclassified. The company state that any ECG labelled as ‘possible AFib’ or ‘unclassified’ should be reviewed by a cardiologist or qualified clinician. ECG traces measured by the device can be sent from a smartphone or tablet by email as a PDF attachment and stored in a patient’s records.

The company state that the internal hardware of the device has not changed since release. The first version of the Kardia app did not have automatic diagnostic functionality. The atrial fibrillation algorithm was added to the app from January 2015 and the normal sinus rhythm algorithm was added from March 2015. The Kardia Mobile has previously been available as the AliveCor Heart Monitor.

The device is not intended for use for paediatric patients, people with a pacemaker or implantable defibrillator because the diagnostic algorithms have not been tested or optimised for use in these groups.

2.2.3. MyDiagnostick (MyDiagnostick Medical B.V.)

The MyDiagnostick is a CE marked handheld lead-I ECG device which can produce and interpret an ECG recording. An ECG recording is generated by

holding metal handles at each end of the device, which act as electrodes, for 1 minute. The device activates automatically when gripped by a person, and deactivates automatically when released. A light on the device will turn green if no AF is detected, or red if AF is detected. If an error occurs during the reading the device produces both an audible warning and a visible warning from the light on the device. Up to 140 ECG recordings can be recorded on the device before it starts to overwrite previous recordings.

The MyDiagnostick can be connected to a computer via a USB connection to download the generated ECG trace for review and storage using free software that can be downloaded from the MyDiagnostick website. The company state that the device automatically interprets ECGs, but that a clinical professional should examine the ECG trace to confirm the diagnosis. The company state that data from the device is not currently uploaded to centralised or online storage.

The device's battery charges when connected to a USB power source. The instructions for use advise that the battery life is expected to be 5 to 10 years with 'intensive use'. The company state that since the release of the device in 2012 there have been no technical or software changes.

2.2.4. RhythmPad GP (Cardiocity)

The RhythmPad GP is a CE marked lead-I ECG device which is provided with software for data analysis. Lead-I ECG readings are taken by placing the palms of both hands on the surface of the device for 30 seconds after first being cleaned with an alcohol gel. Alternative configurations can be used if a person is unable to place their hands flat on the device, for example if they have arthritis. The software needs to be installed on a device running Windows XP or a later version and which has a USB port. Data is transferred directly to a computer using the USB connection for storage on the device's hard drive in PDF format. The instructions for use state that the device should not be used for people under the age of 10 years.

The software includes an algorithm that can determine if a person is in sinus rhythm or atrial fibrillation, or has bradycardia, tachycardia, sinus arrhythmia, premature ventricular contractions or right bundle branch block. The recorded ECG trace is also available for further analysis by a healthcare professional. The company state that data from the device is not currently uploaded to centralised or online storage.

A third electrode can also be purchased for use with the device, allowing it to record a 6-lead ECG. The company suggest that if atrial fibrillation is detected by the device in lead-I mode, then a 6 lead ECG using this third electrode can

be used for further confirmation. However, this additional functionality is outside the scope of this assessment, which focuses on lead-I ECG devices. The company also recommend that a 12 lead ECG is used to confirm a case of atrial fibrillation detected by the RhythmPad GP device.

The company state that the device hardware has not changed since the first released version. The current software version is V17.07 with a new version for GPs being released in 2018; the only planned change to the software being a new interface.

2.2.5. Zenicor-ECG (Zenicor Medical Systems AB)

The Zenicor-ECG is a CE marked system with 2 components: a lead-I ECG device (Zenicor-EKG 2) and an online system for analysis and storage (Zenicor-EKG Backend System version 3.2). The online system is not installed on the healthcare practice's computer, rather the device transmits data to a remote server within the European Union which can be accessed using a web browser without prior installation of software, and requires a user licence. ECG readings are taken by placing both thumbs on the device for 30 seconds. The instructions for use state that the electrodes in the Zenicor EKG-2 should be replaced after every 500 measurements. The device is powered by 3 alkaline batteries which the company state are expected to last for at least 200 measurements and transmissions.

Once a measurement is made using the Zenicor-EKG 2 device, the ECG measurement can be transferred from the device (using a built-in mobile network modem) to a Zenicor server in Sweden. Here the ECG is analysed using the Zenicor-EKG Backend System, which includes an automated algorithm. This can categorise an ECG into one of 12 groups corresponding to potential arrhythmias; 1 of which includes atrial fibrillation. The algorithm will also report if the recorded ECG cannot be analysed. The company state that a clinician needs to manually interpret the ECG trace generated by the Zenicor-ECG in order to make a final diagnosis of atrial fibrillation.

Clinicians can view the analysis using the Zenicor Doctor System user interface which they can access using a web browser. The measured ECG trace is also available via this interface, and can be downloaded or printed as a PDF report. The system can either be used in a mode to take multiple ECGs from a single person (when used for self-testing) or for 'one time ECGs' which allows ECGs taken by the same device to be assigned to different patients on the system. The company state that the ECG is available via the web-interface about 4 to 5 seconds after the ECG has been transmitted from the device.

The company state that the Zenicor EKG-2 does not store, contain or transmit any patient identifiable information. ECGs are sent via the built-in mobile network modem to the Zenicor server labelled with the device's identity number. Communication between the Zenicor server and a web browser accessing it are encrypted.

The Zenicor-EKG2 was launched in 2010 as a successor to the Zenicor-EKG. The company state that both are lead-I ECG devices and the main difference is the technology used to transfer data to the Zenicor server.

3 Target condition

3.1 Atrial fibrillation

Atrial fibrillation is a type of arrhythmia which causes an irregular or abnormally fast heart rate. It is the most common arrhythmia and it has a greater incidence in older people.

Data recorded for the Quality and Outcomes Framework (QOF) 2016/17 gives an estimated prevalence of diagnosed atrial fibrillation of 1.8%. However because many people with atrial fibrillation are asymptomatic, this will be an underestimate of the real prevalence of the condition. Public Health England has estimated that 1.4 million people in England have atrial fibrillation (2.5% of the population), with 80.5% in people aged over 65 (Public Health England, 2017). Men have about a 1.5 times greater risk of developing AF than women (2.9% compared with 2.0%). This report also estimates that 425,000 people in England have undiagnosed and untreated atrial fibrillation.

When a person experiences atrial fibrillation, it causes the upper chambers of the heart (the atria) to beat irregularly which makes the heart less effective at moving blood into the ventricles. This can cause clots to form in the blood which may subsequently cause a stroke. The European Society of Cardiology Guidelines for the management of atrial fibrillation state that untreated atrial fibrillation is associated with a 5 fold increased risk of stroke and a 3-fold increased risk of heart failure (European Society of Cardiology, 2012). Atrial fibrillation-related stroke is also potentially more severe than non-atrial fibrillation-related stroke and has been associated with increased mortality (Lin et al. 1996). Early detection of atrial fibrillation allows adoption of preventative treatment; for example oral anticoagulants to reduce the risk of stroke.

The abnormal electrical impulses in the heart muscle which cause atrial fibrillation can be persistent, permanent or intermittent. This causes the 3 types of atrial fibrillation:

- Permanent atrial fibrillation: atrial fibrillation present all the time.
- Persistent atrial fibrillation: episodes last longer than 7 days (if left untreated)
- Paroxysmal atrial fibrillation: intermittent episodes which usually last less than 2 days and stop without treatment.

Symptoms which suggest that someone may have atrial fibrillation include feeling dizzy, being short of breath, feeling tired and having heart palpitations. Atrial fibrillation can also be asymptomatic.

Atrial flutter is a further type of cardiac arrhythmia, with similar symptoms to atrial fibrillation. In atrial flutter, the atria beat regularly (unlike in atrial fibrillation) but faster than usual and more often than the ventricles. People with atrial flutter can also have atrial fibrillation.

3.2 Diagnostic and care pathway

The NICE guideline on atrial fibrillation provides recommendations on diagnosis and management of the condition. An update of this guideline is planned.

The European Society of Cardiology have also published guidelines on the management of atrial fibrillation (2016).

3.2.1. Diagnostic pathway

The NICE guideline on atrial fibrillation recommends that manual pulse palpation should be used to assess for the presence of an irregular pulse that may indicate underlying atrial fibrillation in people presenting with any of the following:

- breathlessness/dyspnoea
- palpitations
- syncope/dizziness
- chest discomfort
- stroke/transient ischaemic attack.

Clinical experts commented that people presenting with a stroke or transient ischaemic attack would have ECG testing for atrial fibrillation in secondary care, and are outside of the scope of an assessment focussing on primary care

The NICE atrial fibrillation guideline also recommends performing an ECG in all people, whether symptomatic or not, in whom atrial fibrillation is suspected because an irregular pulse has been detected.

Clinical experts commented that in current practice a 12-lead ECG, which can be carried out in primary or secondary care, interpreted by a trained healthcare professional would be used to confirm atrial fibrillation that is suspected on the basis of manual pulse palpation before treatment is started. Clinical experts also advised that a 12-lead ECG is important for people diagnosed with atrial fibrillation to identify any additional abnormalities, such as left ventricular hypertrophy, which need to be considered when deciding on further treatment.

For people with suspected paroxysmal atrial fibrillation (that is, intermittent atrial fibrillation) which is subsequently not detected by standard ECG recording, the NICE atrial fibrillation guideline recommends using:

- a 24 hour ambulatory ECG monitor for people with suspected asymptomatic episodes or symptomatic episodes less than 24 hours apart, or
- an event recorder ECG in those with symptomatic episodes more than 24 hours apart.

For people diagnosed with atrial fibrillation, the NICE guideline also includes recommendations on the subsequent use of echocardiography (transthoracic or transoesophageal) to assess heart structure and inform management of the condition.

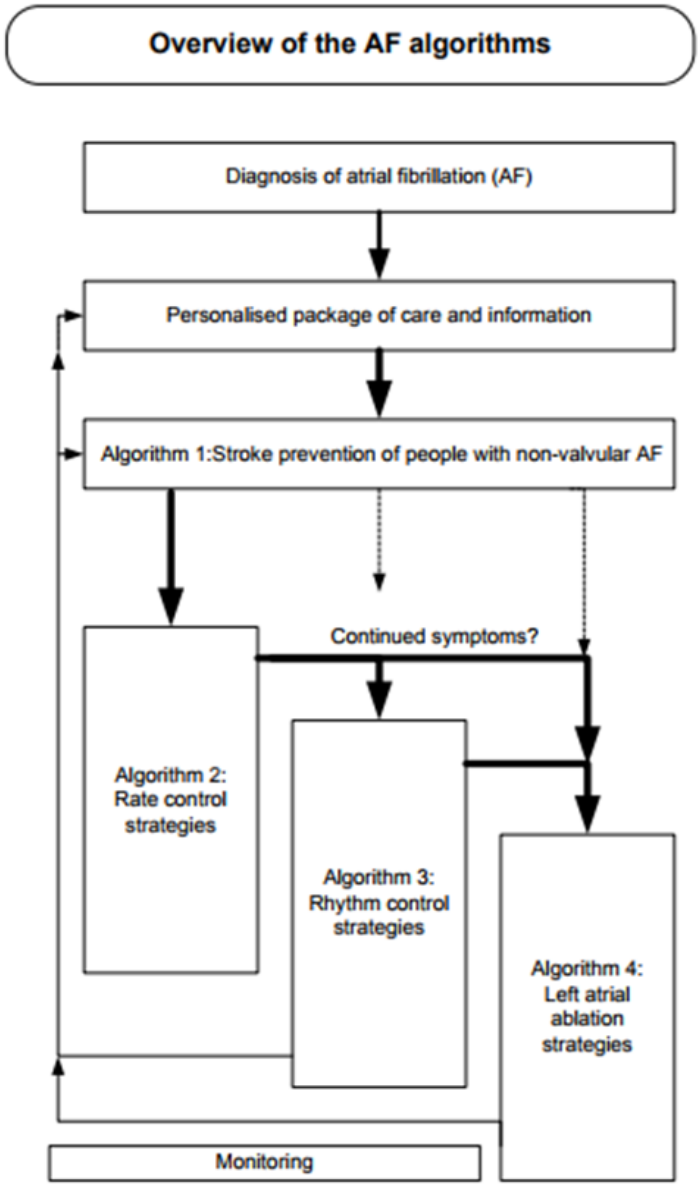
Lead-I ECGs

Clinical experts advised that lead-I ECGs would be used in the diagnostic pathway for people with signs and symptoms of atrial fibrillation after manual pulse palpation has revealed an irregular pulse. Where atrial fibrillation is detected by a lead-I ECG, anticoagulation treatment would initially be started with a non-vitamin K antagonist therapy until further assessment has been done. A 12-lead ECG would subsequently be used to identify any additional abnormalities, such as left ventricular hypertrophy, which need to be considered when deciding on further treatment. If no atrial fibrillation is detected by 12-lead ECG (but has been by an earlier lead-I ECG), this suggests paroxysmal atrial fibrillation.

3.2.2. Care pathway

The NICE guideline on atrial fibrillation has recommendations for the care of people diagnosed with atrial fibrillation, which are summarised into algorithms for the diagnosis and management of the condition. An overview of the treatment pathway is provided in figure 1, and explained in more detail below.

Figure 1 Overview of atrial fibrillation algorithms from NICE guideline on atrial fibrillation



Stoke prevention (algorithm 1)

Recommendations include how to assess stroke and bleeding risk using the CHA_2DS_2VASc and HAS-BLED scores, and the use of interventions to prevent stroke (apixaban, dabigatran etexilate, rivaroxaban or a vitamin K antagonist). NICE technology appraisal guidance has been produced on apixaban (TA275), dabigatran etexilate (TA249) and rivaroxaban (TA256). In addition, a further anticoagulant is now available and has been assessed by NICE in TA guidance 355 (edoxaban for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation).

A recently published study (Loo et al. 2017) has reported increased prescription of novel oral anticoagulants (such as dabigatran, rivaroxaban and apixaban) in primary care in the UK and falling use of vitamin-K antagonists.

NICE diagnostics guidance on self-monitoring coagulation status using point of care coagulometers recommends the use of coagulometers for patients to self-monitor their coagulation status when on long-term vitamin K antagonist therapy.

Rate and rhythm control strategies (algorithms 2 and 3)

Recommendations include interventions to offer as part of a rate control strategy (beta-blockers, calcium channel blocker, digoxin) or rhythm control strategy (pharmacological and/or electrical rhythm control).

Left atrial ablation strategies (algorithm 4)

Recommendations on the use of left atrial ablation and pace and ablate strategies

3.3. Patient issues and preferences

It is not anticipated that there will be any substantial difference to patients in terms of the length of time needed for testing if lead-I ECG devices are adopted in place of manual pulse palpation. Some people may be more reassured by use of technology to assess for atrial fibrillation (giving them more confidence in results) and that an ECG can be recorded quickly, whilst others may prefer not to use the devices. For example, some people may not be able to use the devices unaided if they are being tested for atrial fibrillation because they have had a stroke and have reduced movement in their arms. In addition, any improvement in test accuracy will have patient benefits. Earlier recognition of atrial fibrillation and adoption of preventative measures will reduce the occurrence of related morbidities such as stroke.

Patients may also need to give consent for data measured by the device to be submitted to a company's server for the included devices which have this functionality.

4. Comparator

The comparator for this assessment is a 12-lead ECG, used to assess for atrial fibrillation after an irregular pulse has been detected by manual pulse palpation. An irregular pulse on manual pulse palpation is not thought to be sufficient for initiation of anticoagulation therapy and so in this diagnostic pathway patients are not treated until a 12-lead ECG confirms atrial fibrillation.

Clinical experts commented that there can be delays in arranging 12-lead ECGs after an irregular pulse is detected, which can delay diagnosis of atrial fibrillation, or potentially miss paroxysmal atrial fibrillation altogether because the initial examination did not include an ECG recording, unlike the lead-I ECG diagnostic pathway. The length of this delay will vary and is dependent on local arrangements for doing 12-lead ECGs; for example, if this can be carried out in primary care or if a referral to secondary care is needed. The length of this delay in the comparator pathway is likely to impact on the benefits associated with the lead-I ECG devices.

5. Scope of the assessment

Table 1 Scope of the assessment

Decision question	Does the use of lead-I ECG devices to detect atrial fibrillation in people presenting to primary care with signs or symptoms of the condition and who have an irregular pulse represent a cost-effective use of NHS resources?
Populations	People with signs or symptoms that may indicate underlying atrial fibrillation and in who manual pulse palpation suggests atrial fibrillation. Signs and symptoms of atrial fibrillation include: • breathlessness/dyspnoea • palpitations • syncope/dizziness • chest discomfort (see section 3.2.1) If data permits, the following subgroup may be considered: • People who are unable to use the device electrodes as recommended by the companies (for example, people with movement disorders)
Interventions	A single lead-I ECG carried out by a healthcare professional using one of the following technologies, with initiation of anticoagulation therapy for people with a positive result: • imPulse • Kardia Mobile • MyDiagnostick • RhythmPad GP • Zenicor-ECG The analysis should explore the impact of using a device's algorithm, or interpretation of the lead-I ECG trace by a

	suitably qualified healthcare professional, on the diagnostic accuracy of the lead-I devices.
Comparator	Manual pulse palpation followed by a 12-lead ECG in primary or secondary care prior to initiation of anticoagulation therapy. 12-lead ECG, performed and interpreted by a trained healthcare professional, will be the reference standard for assessing diagnostic accuracy
Healthcare setting	Primary care
Outcomes	Intermediate measures for consideration may include: • Diagnostic accuracy • Time to ECG diagnosis of atrial fibrillation • Time to initiation of preventative treatment (such as interventions to prevent stroke) • Concordance between lead-I ECG devices • Test failure rate • Time to complete testing and store produced ECG trace • Ease of use of devices (for patients and healthcare professionals), including training requirements • Impact of test results on clinical decision making • Number of 12-lead ECGs carried out • Diagnostic yield (number of atrial fibrillation diagnoses)
	Clinical outcomes for consideration may include: • Mortality • Morbidity (including stroke, other thromboembolisms and heart failure, and any complications arising from preventative treatment, such as adverse effects of anti-arrhythmic, rate control or anticoagulation treatment)
	Patient-reported outcomes for consideration may include: • Health-related quality of life • Acceptability of the devices
	Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include: • Costs related to assessment of people with signs or symptoms of atrial fibrillation (including staff time to carry out tests and interpret results) • Costs related to use of the lead-I ECG devices (including maintenance, software installation, training and consumable costs)

	• Treatment for conditions related to atrial fibrillation (such as stroke and heart failure), including emergency presentations as a result of delayed diagnoses, and preventive treatment costs (including medication used for stroke prevention and rate/rhythm control strategies) • 12-lead ECG measurement and interpretation costs • Costs related to assessment of people who are diagnosed with atrial fibrillation (such as echocardiography) • Costs related to further assessment required for people with suspected paroxysmal atrial fibrillation (such as ambulatory ECG monitors or event recorders)
	The cost-effectiveness of interventions should be expressed in terms of incremental cost per quality-adjusted life year.
Time horizon	The time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.

6. Other issues for consideration

Studies assessing lead-I ECGs often focus on diagnostic accuracy rather than longer term clinical outcomes resulting from use of the devices. A linked-evidence modelling approach may therefore need to be used for this assessment.

Lead-I ECG devices can produce both an automatic-assessment of the likelihood of atrial fibrillation and an ECG trace. Whether a lead-I ECG device has given a positive result for potential atrial fibrillation may vary between studies; for example, being determined entirely by the automatic diagnostic function of the device or a healthcare professional's interpretation of an ECG trace, or taking into account both. Device accuracy may therefore vary between studies depending on how device outputs are used and the experience of the healthcare professionals interpreting the device. In clinical practice, the relative importance of the automatic-assessment function of the devices may vary depending on the expertise of the healthcare professional. For example, a GP with a Special Interest in cardiology may just use the lead-I ECG trace, whereas practitioners with less experience in interpreting ECGs may be more reliant on the automatic diagnostic function of the devices.

Several published studies have assessed the accuracy of lead-I ECG devices used at a single-time point to detect atrial fibrillation in an asymptomatic population; for example, opportunistic testing for people who attend primary

care for flu vaccinations (Jacobs et al. 2016). The severity of atrial fibrillation may differ between people who do and do not have symptoms; therefore diagnostic accuracy estimates of devices tested in an asymptomatic population may not accurately represent the accuracy of the devices in a symptomatic population (which is the focus of this assessment). Clinical experts commented that diagnostic accuracy estimates done in asymptomatic populations may be useful for this assessment, particularly if there is a lack of studies in symptomatic populations.

The timing of index tests and the reference standard may be a significant source of bias in diagnostic accuracy studies assessing atrial fibrillation because if there is a delay between tests, cases of paroxysmal atrial fibrillation detected by the first test may stop. Differences between studies in the time between index and reference standard tests may therefore affect accuracy estimates. Further, use of the devices may increase diagnosis of paroxysmal atrial fibrillation. There are uncertainties about the comparative risk of stroke for people with persistent and paroxysmal atrial fibrillation (see, for example Steinberg et al. 2015) and consequently therefore the level of risk reduction attributable to preventative treatment between these groups.

In addition to generic patient reported outcome measures (PROMs), such as the EQ-5D, several condition-specific PROMs have been developed to measure the quality of life of people with atrial fibrillation. While these tools may be more sensitive to capture the effects of atrial fibrillation on quality of life, several deficiencies in available instruments for assessing disease-specific quality of life in patients with atrial fibrillation have been reported (Kotecha et al. 2016). Clinical experts commented that there is considerable variation between the results of the different atrial-fibrillation specific PROMs, and that many of the tools have not been validated.

Any updates made to devices, in terms of hardware or analytical software, can affect diagnostic accuracy for atrial fibrillation. For example, changes over time in the reported sensitivity and specificity estimates of the AliveCor ECG (a previous version of the Kardia Mobile) have been attributed to an intentional change in the diagnostic algorithm to increase the specificity of the device (Freedman, 2016). Studies reporting data obtained using earlier versions of the devices may therefore not give an accurate indication of the current version’s accuracy.

Some lead-I ECG devices can also be used to produce 6-lead ECGs, through use of additional electrodes. Clinical experts advised that this additional function is unlikely to be used in practice.

Digital apps proposed to be adopted by the NHS are subject to a technical assessment process which is under development. NICE intends to carry out a relevant technical assessment of the app functionality of the lead-I ECG devices in the scope of this evaluation.

7. Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Men have a higher risk of developing atrial fibrillation than women. In addition, the incidence of atrial fibrillation increases with age. It has also been reported that women with atrial fibrillation experience worse symptoms than men, and have a higher risk of stroke and death (Ko et al. 2017). The incidence of atrial fibrillation has been reported as lower for people of south Asian or Caribbean family origin (Amponsah, et al. 2013). These potential equalities issues are related to the condition and are unlikely to be impacted on by the use of the technology.

The devices may not be suitable for use in people with upper limb amputations or missing fingers. In addition, some people may need assistance in holding the devices in the required way to obtain a reading; for example, people who have had a stroke or who have arthritis in their hands may not be able to grip a device unaided. The accuracy of readings taken using the devices may be adversely affected if a person has a tremor or a skin condition. Some of the devices are not intended for use in people with a pacemaker or implantable defibrillator.

8 Potential implementation issues

Lead-I ECG interpretation and training

Skills in interpreting lead-I ECG traces to identify potential atrial fibrillation will vary across primary care and concerns about the ability of healthcare practitioners to interpret results may be a barrier to adoption. Devices included in this assessment have associated software which analyse the generated ECG traces and provide an indication of whether atrial fibrillation is potentially present which may help to overcome this adoption barrier.

Procurement and commissioning

Any cost savings generated by use of the devices is likely to occur in secondary care (for example, reduced hospitalisation for strokes prevented by earlier recognition of atrial fibrillation) rather than primary care where the

devices are purchased. Clinical experts have suggested that there would be greater success in securing funding for the devices if there is a local initiative that the device would support; for example, to reduce strokes or reduce low risk referrals to secondary care cardiology.

Clinical experts have also suggested that healthcare professionals will need immediate access to the devices when required. When procuring the devices it will therefore be necessary to consider how many healthcare professionals will need access to them.

Device usability

Any difficulties in converting generated ECG traces into a format suitable for a person's records (for example, a PDF file) and transferring this to the necessary system for storage may deter healthcare professionals from routinely using the devices. The availability of additional technology required to use the devices, such as devices with Bluetooth connectivity and available Wi-Fi signal, could also act as barriers to adoption of the devices.

Information governance and IT

The ability to save and send information could be a risk to data protection and information governance if not done correctly. If clinicians and managers have a concern that using the devices could pose a risk to data protection and information governance, this could act as a barrier to adoption. Companies have stated that they have appropriate systems in place to ensure the devices and software are compliant with the relevant policies and law; however organisations seeking to adopt these technologies will need appropriate governance in place, with the flexibility to update as regulations and legislation change.

9. Authors

Thomas Walker
Topic Lead

Rebecca Albrow
Technical Adviser

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Appendix A Glossary of terms

Cardiac arrhythmia
An abnormality of the heart's rhythm; which can beat too slowly, too quickly or irregularly.

Electrocardiogram (ECG)
A test to monitor the heart's rhythm and electrical activity using sensors applied to the skin (see NHS Choices for more detail).

Heart palpitations
Heart beats that are suddenly more noticeable, and which can feel like the heart is pounding, fluttering or beating irregularly (see NHS Choices for more detail)

Lead-I ECG
The term "lead" in electrocardiography refers to the 12 different vectors along which the heart's depolarisation is measured. Each of these leads represents the electrical potential difference between 2 points. Lead-I is the voltage between the (positive) left arm electrode and right arm (negative) electrode. Handheld Lead-I ECG devices use thumb and finger contacts with simple touch electrodes, rather than adhesive electrodes attached to the skin needed for 12-lead ECGs.

Appendix B Abbreviations

ECG
Electrocardiogram

PROMs
Patient reported outcome measures

TA
Technology appraisal

Appendix C References

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