NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

KardiaMobile for detecting atrial fibrillation

1 Technology

1.1 Description of the technology

KardiaMobile (AliveCor) is a portable electrocardiogram (ECG) recorder. It works with a compatible mobile device (such as a smartphone or tablet,) running the Kardia app, which is intended to be used for analysing the ECG recording and sending it to a healthcare professional for interpretation.

KardiaMobile is available as a single-lead or as a 6-lead (KardiaMobile 6L) ECG recorder. The single-lead version has 2 electrodes on the top surface; 2 fingers from the left hand are placed onto 1 electrode and 2 fingers from the right hand are placed onto the other electrode. KardiaMobile 6L has 3 electrodes; 2 electrodes on the top surface (for 2 fingers from each hand), and one on the bottom which is placed on the left leg. The device is small and is designed to be used anywhere that is convenient.

People must keep their arms still and must keep touching the electrodes for at least 30 seconds for a complete reading to be taken. The app has an option for either single-lead or 6-lead ECG reading. The company recommends that recordings are taken daily at random, or whenever symptoms are experienced that may be atrial fibrillation (AF). There is no restriction on the number of times the device should be used. Healthcare professionals may advise people on the frequency and length of use.

Internet access is not needed when taking the reading. While taking a reading, the ECG recoding is sent wirelessly to the mobile device, where it can be viewed using the Kardia app. The app works on devices running Apple or Android operating systems (a full list is available on the compatibility

section of the company's website). It shows the ECG trace, a measure of heart rate, and it uses an artificial intelligence led algorithm to classify the traces as:

- normal
- possible AF
- tachycardia
- bradycardia
- sinus rhythm with premature ventricular contractions (PVCs)
- sinus rhythm with supraventricular ectopy (SVE)
- sinus rhythm with wide QRS or
- unclassified.

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 to be shared with healthcare professionals. Patient data can be added to the recording in accordance with information governance and the general data protection regulations (GDPR). When the device has a Wi-Fi or mobile connection, the recording automatically synchronises with a secure encrypted cloud server (this can be turned off manually from the device). An option (additional fee) for healthcare professionals is the KardiaPro software, which allows remote monitoring of users and generation of reports.

KardiaMobile is not intended for use in children and must not be used in adults with cardiac pacemakers, implantable cardioverter-defibrillators or other implanted electronic devices. The company states that the ECG recorded by KardiaMobile is used to help diagnose heart rhythm disturbances but is not intended to be used to diagnose other cardiac conditions. The interpretations should be reviewed by a medical professional and used to support clinical decision-making.

The average lifespan of the single-lead and 6-lead devices is 2 years. The technology has previously been known as AliveCor Heart Monitor and AliveCor Mobile ECG. A smartwatch band, KardiaBand, has been discontinued and is not included in the scope of this evaluation.

1.2 Relevant diseases and conditions

KardiaMobile is designed for use in adults to detect abnormal heart rhythms (cardiac arrythmia) via single time point testing or longer term monitoring to support clinical decision-making. This guidance focuses on the use of KardiaMobile for detecting atrial fibrillation by ECG monitoring. NICE diagnostics guidance (DG35, 2019) assessed on the use of lead-I ECG devices (including KardiaMobile) for detecting symptomatic atrial fibrillation using single time point testing in primary care. Therefore, single time point detection of atrial fibrillation is not included in the scope of this evaluation.

Cardiac arrythmias are experienced by more than 2 million people a year in the UK. The term covers a number of conditions in which the heartbeat is irregular, too fast or too slow. Common types of arrhythmia are atrial fibrillation, supraventricular tachycardia, bradycardia, heart block and ventricular fibrillation (NHS, 2018).

Atrial fibrillation is the most common sustained cardiac arrhythmia. It has been estimated that 1.4 million people in England have atrial fibrillation, equating to 2.5% of the population. The likelihood of atrial fibrillation increases with age. The prevalence of atrial fibrillation is higher in men than in women (2.9% compared with 2.0%). People with atrial fibrillation may present with breathlessness, heart palpitations and dizziness or temporary loss of consciousness. The frequency and severity of symptoms varies from person to person and symptoms of a person can also fluctuate widely over time. These changes can be monitored via ECG. Atrial fibrillation can also be asymptomatic. It is estimated that around 425,000 people in England have undiagnosed and untreated atrial fibrillation (Public Health England, 2017).

Atrial fibrillation is associated with an increased risk of thrombo-embolic complications including stroke as well as the need for hospitalisation, and death. 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).

1.3 Current management

In clinical practice, an electrocardiogram (ECG) is commonly used to diagnose an arrhythmia. An ECG is done in a general practice or hospital setting and records heart rhythm over a short period of time. If the ECG doesn't reveal an abnormality at that moment in time, the person's heart rhythm may need monitoring for a longer period of time. This may involve wearing a small portable ECG recording device for 24 hours or longer. This is often known as a Holter monitor or ambulatory ECG monitoring. Alternatively, cardiac event recorders may be used in patients with occasional symptoms. These are either a portable device to record the heart rhythm at the time of symptoms using a device that is worn strapped to a person's body and may require electrodes to be stuck to the skin, or a device that is implanted under the skin.

NICE's guidelines on managing atrial fibrillation and transient loss of consciousness ('blackouts') in over 16s provide recommendations on current methods of arrhythmia detection.

The NICE guideline on managing atrial fibrillation recommends performing manual pulse palpation to assess for the presence of an irregular pulse in people presenting with any of the following:

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

It is recommended that an ECG be performed in all people, whether symptomatic or not, in whom atrial fibrillation is suspected because an irregular pulse has been detected. Arrhythmias may be missed by a 12-lead ECG in people with paroxysmal AF (that is, intermittent AF) because of the occasional nature of the arrhythmic episodes. If arrhythmia is not detected on the initial 12-lead ECG and further assessment of suspected paroxysmal atrial

fibrillation is needed then ambulatory ECG monitoring is recommended. The choice of monitor used depends on the nature and frequency of symptoms.

The guideline recommends the following:

- use a 24-hour ambulatory ECG monitor (such as a Holter monitor) in people with suspected asymptomatic episodes or symptomatic episodes less than 24 hours apart
- use an event recorder ECG (which can be external or implantable) in people with symptomatic episodes more than 24 hours apart

For people with transient loss of consciousness (TLoC) and a suspected cardiac arrhythmia (including AF), the NICE guideline on transient loss of consciousness ('blackouts') recommends offering an ambulatory ECG. The type of device should be chosen on the basis of the patient's history and frequency of TLoC. Holter monitoring (up to 48 hours if necessary) is recommended in people who have TLoC at least several times a week. In those with TLoC every 1 to 2 weeks an external event recorder should be offered. An implantable event recorder should be offered to people with infrequent TLoC (less than once every 2 weeks).

The company states that KardiaMobile is intended to replace or enhance the current care pathway for detecting atrial fibrillation in patients with symptoms such as palpitations and TLoC but that the device can also be used to assess the adequacy of treatment for AF when this has been offered. KardiaMobile would be used for a monitoring period predetermined by a physician in place of current methods of cardiac event detection, such as Holter monitoring or event recording in people suspected of having atrial fibrillation. The use of KardiaMobile would be recommended by a clinician, most often a cardiologist or GP, in primary, secondary or tertiary care.

1.4 Regulatory status

The KardiaMobile single-lead heart monitor and Kardia app received a CE mark in January 2018 as a class IIa medical device for recording single-lead ECG for identifying ECG rhythms. KardiaMobile 6L heart monitor received a

CE mark in August 2019 as a class IIa medical device for recording six leads ECG for identifying ECG rhythms.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Improved identification of people with atrial fibrillation, potentially leading to a reduction in the occurrence of clinical sequelae of atrial fibrillation such as stroke and heart failure.
- Improved diagnostic accuracy and efficiency in detecting atrial fibrillation in symptomatic and asymptomatic patients.
- Improved diagnostic yield, minimising the number of repeat tests needed to confirm or rule out atrial fibrillation.
- Earlier diagnosis and potential initiation of treatment to control atrial fibrillation or prevent the occurrence of clinical sequelae of atrial fibrillation such as stroke and heart failure.
- Ease of use with minimal disruption to patients' daily activities leading to improved patient compliance and data collection.

The benefits to the healthcare system claimed by the company are:

- Reduction in costs and resources that could be avoided through earlier diagnosis and treatment of atrial fibrillation, such as repeat hospital admissions related to the clinical sequelae of atrial fibrillation, such as stroke or heart failure.
- Avoiding unnecessary referral to secondary care.
- Ease of implementation; minimal changes in facilities or infrastructure needed when KardiaMobile adopted in standard practice, including in rural areas.
- Reduction in health service resource use such as staff in the ambulatory ECG monitoring pathway, due to reduced in-clinic analysis of ECG recordings and reduced outpatient appointments.

2 Decision problem

Population	Adults (18 years or older) with known or suspected atrial fibrillation who are referred for ambulatory ECG monitoring by a clinician in primary, secondary or tertiary care.
Intervention	The KardiaMobile system: KardiaMobile hardware (single-lead or 6 lead ECG monitor) and KardiaMobile app. Single time point detection of atrial fibrillation is not included in the scope of this evaluation. The analysis should explore the impact of using the technology algorithm for trace classification, or interpretation of the ECG trace for detecting atrial fibrillation.
Comparator(s)	Current pathway for atrial fibrillation detection, which includes ECG (a 12-lead ECG, performed and interpreted by a trained healthcare professional, is the reference standard for assessing diagnostic accuracy) and ambulatory monitoring (Holter and/or event monitoring).
Outcomes	The outcome measures to consider include: System outcomes • Diagnostic yield and accuracy (sensitivity and specificity) • Atrial fibrillation burden, including the number of symptomatic and asymptomatic atrial fibrillation events detected during the recording period, and the time spent in atrial fibrillation • Time to detect first or recurrent atrial fibrillation events • Time to diagnosis or rule out of atrial fibrillation • Time to initiation of treatment (control symptoms and/or preventing the risk of future events) • Rate of test failure • Data transfer failure • Rate of fail to classify • Rate of secondary care referral • Total number of hospital outpatient appointments for investigation • Hospital admission • Number of outpatient visits and staff time for undertaking and analysing diagnostic tests • Number of visits to GP or urgent care • Number of further tests needs in addition to KardiaMobile • Morbidity (including stroke, thromboembolism, heart failure, and complications associated with preventative treatment) • Mortality Patient outcomes: • Ease of use (for patients and healthcare professionals), including training requirements • Device acceptability and patient satisfaction

	• Health-related quality of life • Device-related adverse events	
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	• Adults referred for ambulatory ECG monitoring, who are symptomatic or asymptomatic • Adults referred for ambulatory ECG monitoring in primary care • Adults referred for ambulatory ECG monitoring in secondary care	
Special considerations, including those related to equality	KardiaMobile is not approved for use in children and must not be used in adults with cardiac pacemakers, implantable cardioverter-defibrillators or other implanted electronic devices. The device may not be suitable for people who cannot remain still or have problems holding the device; for example, people with tremor may have difficulty with recording an accurate trace. People are not able to use the device if they do not have a compatible smart device to access the KardiaMobile app. Age and disability are protected characteristics under the Equality Act. Full details of contraindications are listed the instructions for use for KardiaMobile.	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
	Cardiac arrhythmias can develop in people of any age but are more common in people over 60 years. The lifetime risk of developing atrial fibrillation is similar for both men and women, although it is slightly higher in men. Age and sex are protected characteristics under the Equality Act. People whose first language is not included in the app or who cannot read may not be able to communicate recorded information on their symptoms while using the KardiaMobile system. The app is	

	available in the following languages including English, German, Dutch, Spanish, French, Italian, Norwegian (Bokmål), Chinese (simplified or traditional), and Korean.

3 Related NICE guidance

Published

- Zio XT for detecting cardiac arrhythmias (2020) NICE medical technology guideline MTG 52.
- Lead-I ECG devices for detecting symptomatic atrial fibrillation using single time point testing in primary care (2019) NICE diagnostics guidance DG35.
- Atrial fibrillation: management (2014) NICE clinical guideline CG 180.
- WatchBP Home A for opportunistically detecting atrial fibrillation during diagnosis and monitoring of hypertension (2013) NICE medical technology guidance MTG 13.
- Transient loss of consciousness ('blackouts') in over 16s (2010) NICE clinical guidance CG 109. Last updated in 2014.

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- Academy for healthcare science
- British Association for Nursing Cardiovascular Care
- British Cardiovascular Society
- British Heart Rhythm Society
- Royal College of Emergency Medicine
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Physicians
- Society for Cardiological Science and Technology

4.2 Patient

NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Arrhythmia Alliance
- Atrial Fibrillation Association
- Blood pressure UK
- British Cardiac Patients Association (BCPA)
- British Heart Foundation
- Cardiovascular Care Partnership
- Children's Heart Federation
- Down's Heart Group
- Heart Rhythm Alliance
- Heart UK
- Heart Valve voice
- Pumping Marvellous