NICE advice

KardiaMobile for the ambulatory detection of atrial fibrillation

Medtech innovation briefing
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This advice replaces MIB35.

Summary

- The **technology** described in this briefing is the KardiaMobile heart monitor and Kardia app (AliveCor) used for identifying atrial fibrillation (AF).
- The **innovative aspect** is its simple mode of action. Two fingers from each hand are placed on the KardiaMobile heart monitor to record an electrocardiogram (ECG). This is transmitted wirelessly to the Kardia app (using high frequency sound waves), which analyses and displays the ECG trace.
- The intended **place in therapy** would be as an alternative to existing portable ECG devices for detection of AF.

- The **main points from the evidence** summarised in this briefing are from 11 studies (2 randomised controlled trials, 1 pilot [case-control] study, 1 feasibility study and 7 diagnostic accuracy studies) including a total of 1,218 adult patients. The comparative evidence shows that KardiaMobile can detect more cardiac arrhythmias and can do so faster than standard care. Diagnostic accuracy studies (using different reference standards) show that KardiaMobile's sensitivity ranged between 77.0% and 96.6% and specificity ranged between 76.0% and 99.1% in the detection of cardiac arrhythmia.

- **Key uncertainties** are that the evidence base for KardiaMobile involves different populations, in different settings and in different clinical scenarios. Also, the automated arrhythmia detection algorithm gave inconclusive results in between 0.8% and 27.6% of KardiaMobile ECGs.

- The **cost** of KardiaMobile heart monitor is £82.50 per unit (excluding VAT). The Kardia app is free of charge. An optional extra KardiaCare membership is £9.99 per month or £99 per year. The **resource impact** would be in addition to current care (confirmation of arrhythmia is by 12-lead ECG).

The technology

KardiaMobile heart monitor (AliveCor) is a portable single-lead electrocardiogram (ECG) recorder. The monitor works with a compatible mobile device (such as a smartphone or tablet) running the Kardia app, which analyses the ECG recording and sends it to a healthcare professional for interpretation.

KardiaMobile 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. The user must keep their arms still and must keep touching the electrodes for at least 30 seconds for a complete reading to be taken. The company recommends that recordings are taken daily, or whenever atrial fibrillation (AF) symptoms are experienced. A user may also be given specific advice by their physician on how often to use the device and in-app reminders can be set.

The KardiaMobile monitor must be within 30 cm of the mobile device during use and can be attached to the mobile device using an adhesive attachment plate, if preferred. KardiaMobile can be removed from the attachment plate between uses, and the plate remains attached to the mobile device. The mobile device is a standard internet-enabled mobile phone or tablet with the Kardia app installed. However, internet access is not needed when taking the reading. The app saves and analyses data from the monitor, and works on devices running Apple or Android operating systems

(a full list is available on the compatibility section of the company's website).

While KardiaMobile is taking a reading, it is sent wirelessly (using high frequency sound waves) to the mobile device, where it can be viewed in the Kardia app. It shows the ECG trace, a measure of heart rate, and classification of the rhythm as normal sinus rhythm, AF, bradycardia, tachycardia or unclassified (reading errors or unclassified rhythms). Patient information, such as name and NHS number, 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. Storage can be turned off manually from the device (to support GDPR). The free Kardia app includes: unlimited ECG readings, storage of ECGs on phone and ability to share by email, as well as tracking of weight and blood pressure. KardiaCare membership (additional fee) offers additional services: ECG review by a clinician every 90 days, monthly heart health report, automatic ECG sharing with family or caregivers, medication tracking, and cloud storage and security to allow recordings to be accessed on any device. The company states that readings taken by the monitor should be reviewed by a medical professional for clinical decision making.

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.

Two variants of the device include: KardiaMobile 6L (6-lead alternative, with 3 electrodes) and KardiaBand (smartwatch band, which is no longer available), both are outside the scope of this briefing.

Innovations

The company claims that KardiaMobile is portable and easy to use, allowing users to record the electrical activity of the heart at any time, and to view, save and share the reading with healthcare professionals to allow faster detection and diagnosis of AF.

A number of similar devices have been identified (see National Institute for Health's Health Technology Assessment, 2020): imPulse (Plessey), MyDiagnostick (MyDiagnostick Medical), Zenicor-ECG (Zenicor Medical Systems), Apple Watch Series 5 (Apple Inc.), and Zio XT (iRhythm UK).

Current care pathway

There is no national screening programme for AF. Most pathways are developed locally.

NICE's guideline on atrial fibrillation recommends that people with suspected AF have manual pulse palpation to detect an irregular pulse. If an irregular pulse is detected, an ECG should be done whether or not the patient has symptoms.

The current methods of arrhythmia detection are:

- 12-lead ECG
- continuous ambulatory monitoring, including using Holter monitors for 24 hours or longer
- external loop recorders (for occasional symptoms)
- implantable loop recorders (for infrequent symptoms).

The following NICE publications have been identified as relevant to this care pathway:

- NICE's diagnostics guidance on lead-I ECG devices for detecting symptomatic atrial fibrillation using single time point testing in primary care, which includes KardiaMobile.
- NICE's medical technologies guidance on WatchBP Home A for opportunistically detecting atrial fibrillation during diagnosis and monitoring of hypertension.

The European Society of Cardiology also published guidelines for the diagnosis and management of atrial fibrillation in 2020.

Population, setting and intended user

The KardiaMobile heart monitor and Kardia app is intended for adults to detect abnormal heart rhythms. It can be used for screening for AF, but this is out of scope for this briefing, which focuses on those with symptoms or known AF. For example, it can be used in patients with existing AF (to determine AF burden), in patients after treatment (to investigate AF recurrence), and in patients with unclear palpitations (investigation). It is particularly suitable for people with suspected paroxysmal AF, which might not be detected using a standard 12-lead ECG if the person is not in arrhythmia at the time of recording. Because the KardiaMobile heart monitor is portable, readings can be taken at home, or in any other setting, and at any time of the day. This increases the diagnostic yield of an arrhythmic episode being detected and recorded.

The device is contraindicated for use in patients with pacemakers, implantable cardiac devices, or other implanted electronic devices. The device is not intended for paediatric use because it has not been tested.

The company states that ECG recordings should be reviewed by a clinician. Therefore, the Kardia app should not be used by patients to diagnose their own AF.

The KardiaMobile heart monitor can also be used to evaluate heart rate and rhythm in people with congestive heart failure, but this is beyond the scope of this briefing.

Costs

Technology costs

The 4th generation KardiaMobile heart monitor is £82.50, excluding VAT. The only maintenance needed is a CR2016 battery, which the company recommends is replaced annually. The Kardia app is needed to use the device and is free of charge but must be installed on an internet-enabled compatible mobile device. Optional extras for the patient include: a protective carry case (£20.83 excluding VAT), phone clip (£10.00 excluding VAT) and KardiaCare membership (£9.99 per month or £99 per year). An optional extra for healthcare professionals is the KardiaPro software, which allows remote monitoring of Kardia users and generation of reports (the cost of KardiaPro software is based on the number of connections needed per institution).

Costs of standard care

The average NHS cost of ECG monitoring or stress testing (across all hospital settings: inpatient, day-case, outpatient, directly accessed diagnostic services) is £102 (NHS Reference Costs 2018/19).

Resource consequences

It is not possible to identify all NHS trusts using the device, because there are many procurement options (direct, online, resellers). However, the company provided a list of 92 hospitals and trusts across the UK known to be using the device.

Use of KardiaMobile may reduce the number of referrals for 12-lead ECG but may also lead to increased detection of AF, which will impact on resource use. It will increase the number of treatments (such as warfarin) being given to prevent ischaemic stroke, which is expected to lower the incidence of ischaemic stroke and its associated treatment costs. The average cost of NHS and Personal Social Services care in the first year after an intracerebral haemorrhage stroke was £24,297 and £20,121 after an ischaemic stroke.

Regulatory information

The KardiaMobile heart monitor and Kardia app were CE-marked as a Class IIa medical device in January 2018.

Equality considerations

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

Some people with disabilities or with conditions affecting manual dexterity may not be able to record an electrocardiogram on the KardiaMobile device. The KardiaMobile is not intended for use in children and is contraindicated in people with implantable electronic devices (including pacemakers and implantable cardioverter defibrillator). Prevalence of atrial fibrillation (AF) increases with age and is greater in men, but the risk of death from AF is slightly higher in women. Disability, age and sex are protected characteristics under the Equality Act (2010).

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Evidence from 11 studies and 1,218 patients are summarised in this briefing, including 2 randomised controlled trials (RCTs), 1 pilot (case-control) study, 1 cohort feasibility study and 7 diagnostic accuracy studies (comparators included 12-lead electrocardiogram [ECG], external loop recorder, transtelephonic monitor, and comparison of automated algorithm in arrhythmia detection versus clinical interpretation of KardiaMobile acquired ECG). Three of the diagnostic accuracy studies were done after atrial fibrillation (AF) therapy in a monitoring setting.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The pilot case-control study and 2 RCTs all found that KardiaMobile resulted in more cardiac arrhythmias being detected than standard care. One RCT (set in the UK) also reported that time to diagnosis was quicker and cost of diagnosis was lower with KardiaMobile.

Across the 4 diagnostic studies that compared KardiaMobile with 12-lead ECG (gold standard), including a total of 328 patients, the sensitivity ranged between 77.0% and 96.6% and specificity ranged between 76.0% and 99.1%.

Across the included studies, the automated arrhythmia detection algorithm considered between 15.0% and 27.6% of KardiaMobile ECGs to be unclassified, and between 0.8% and 4.0% unreadable.

Patients in 5 studies reported that KardiaMobile was easy to use.

Reported issues included: lack of access to a compatible smartphone, lack of network connectivity (which may affect those who live in rural areas), not enough manual dexterity to work the device (which may exclude older people and those with certain medical conditions), and KardiaMobile being of limited use in short-lived palpitations (where symptoms may stop before recording on KardiaMobile device).

While all 7 diagnostic accuracy studies were in scope, only the largest and most relevant studies were included in the narrative review below (4 studies omitted from narrative review: Koshy et al. 2018; Narasimha et al. 2018; Tarakji et al. 2015; Haberman et al. 2015).

Reed et al (2019)

Study size, design and location

An RCT in adults aged 16 and over (n=243), presenting to 10 UK hospital emergency departments, with palpitations or pre-syncope and whose underlying ECG rhythm was still undiagnosed after assessment.

Intervention and comparator

Intervention: ECG recorded and analysed using KardiaMobile during palpitations or presyncope, plus standard care (n=126, of which 124 were available for analysis).

Comparator: Standard care only (n=117, of which 116 were available for analysis).

Key outcomes

Statistically significantly more patients had symptomatic cardiac arrhythmias detected at 90 days in the intervention arm (n=11) than in the control arm (n=1, p=0.006). Mean time to symptomatic cardiac arrhythmia detection was reduced from 48.0 days in the control arm, to 9.9 days in the intervention arm (p=0.004). Serious outcomes at 90 days (including all-cause death and major adverse cardiac events) were 11 in the intervention arm and 2 in the control arm. Treatment was planned or ongoing in 12 patients in the intervention arm and 6 patients in the control arm. Cost per symptomatic rhythm diagnosis was £474 in the intervention arm, and £1,395 in the control arm. Eighty out of 92 (87.0%) patients found KardiaMobile easy to use.

Strengths and limitations

This was a large, multicentre study done in the UK. The study used a central ECG reading service that may not be generalisable across the NHS. As well as AF, symptomatic cardiac arrhythmia detection included supraventricular tachycardia, sinus bradycardia and atrial flutter, which are out of scope of this briefing.

Goldenthal et al. (2019)

Study size, design and location

An RCT in adults aged 18 and over (n=238), having catheter radiofrequency ablation or direct current cardioversion in a cardiac electrophysiology clinic in the US. All had a history of documented AF and at least 1 AF risk factor (sedentary lifestyle, obesity, hypertension, smoking, and diabetes).

Intervention and comparator

Intervention: ECG recorded and analysed using KardiaMobile once per day, plus when symptoms happened (n=115).

Comparator: Standard care (n=123, follow up not obtained in 5 patients).

Key outcomes

At 6 months, 58 patients (50.4%) in the intervention arm had a recurrence of AF or atrial flutter, compared with 49 patients (41.5%) in the control arm. Multivariate Cox modelling showed the

likelihood of recurrence detection was greater (p=0.024) in the intervention arm. All-cause hospitalisations and emergency room visits did not differ significantly between arms.

Strengths and limitations

Almost 98% of patients (233/238) were followed for 6 months. This was a single centre study in a non-UK setting. There was a potential for selection bias because of the narrow inclusion criteria (population with a high AF burden), and undefined criteria for ablation or cardioversion. Arrhythmia detection also included atrial flutter, and patients in the intervention arm were sent 3 motivational messages per week, which may have influenced outcomes.

Hickey et al. (2017)

Study size, design and location

A pilot case-control study in adults aged 21 and over (n=46) attending routine visits to cardiac electrophysiology clinics and cardiac ambulatory care in the US. All had documented history of AF, cases had normal sinus rhythm restored by cardioversion, ablation or medical management, and controls were age- and gender-matched patients having usual cardiac medical care.

Intervention and comparator

Intervention: ECG recorded and analysed using KardiaMobile once per day, plus when symptoms happened (n=23).

Comparator: Standard care (n=23).

Key outcomes

Over the 6-month follow-up period, AF or atrial flutter was detected in 14 patients in the intervention arm (61%), compared with 7 patients in the control arm (30%). Cox proportional hazard model analysis confirmed the likelihood of recurrence was greater in the intervention group (p=0.04). For patients with quality-of-life assessments (SF-36V2) at baseline and 6 months (n=13), significant improvements were seen in the 'physical functioning', 'role physical', 'vitality', and 'mental health' domains. The rate of all-cause hospitalisation did not differ between arms, and there were no deaths during follow up.

Strengths and limitations

This was a small non-randomised sample in a non-UK setting, in a population with high AF burden.

Arrhythmia detection also included atrial flutter, and patients in the intervention arm were sent educational messages, which may have influenced outcomes.

Lowres et al. (2016)

Study size, design and location

A cross-sectional cohort–feasibility study in adults aged 18 and over (n=42), who had transient AF after cardiac surgery at a tertiary teaching hospital and private hospital in Australia. All had no history of AF before admission and stable sinus rhythm was achieved before discharge.

Intervention and comparator

Intervention: ECG recorded and analysed using KardiaMobile 4 times per day, plus when symptoms happened, and completion of a symptom diary.

Comparator: Unclear, but assumed to be interpretation of the KardiaMobile ECG by a clinician.

Key outcomes

A total of 3,481 ECGs were collected, with 146 (4%) non-diagnostic because of hand tremor, or poor mobile reception. KardiaMobile had sensitivity of 94.6% and specificity of 92.9%. AF recurrence was detected in 10 patients (23.8%) within 17 days of discharge, and 95% of patients found it easy to use.

Strengths and limitations

This was a non-UK study partly done in a private setting, so may not be generalisable to the NHS. Authors acknowledge that hand tremors influenced the quality of the ECG recordings. Follow up was limited across the cohort to a range of 9 to 46 days.

Selder et al. (2019)

Study size, design and location

This was a diagnostic accuracy study in patients (n=233) presenting to a private outpatient cardiology clinic in the Netherlands, with paroxysmal AF, palpitations of unknown origin or near-collapse. Patients were included in a remote monitoring program for heart rhythms at the discretion of cardiologists and submitted KardiaMobile ECGs.

Intervention and comparator

Index test (intervention): ECG recorded and analysed using KardiaMobile when symptoms happened.

Reference standard (comparator): ECG recorded using KardiaMobile when symptoms happened, and analysed by the study team.

Key outcomes

A total of 5,982 ECGs were collected, with a median of 28 per patient per year. KardiaMobile failed to classify 19%, and 8% could not be interpreted by the clinical team. KardiaMobile had sensitivity of 92% and specificity of 95% at detecting AF (compared with cardiologist interpretation).

Strengths and limitations

Sample size was large compared with other studies. Authors acknowledge potential selection bias because of retrospective design and inclusion criteria, and that lack of 12-lead ECG as comparator may have resulted in overestimation of specificity for KardiaMobile.

William et al. (2018)

Study size, design and location

Diagnostic accuracy study (n=52) in patients aged between 35 and 85 years admitted to a single US centre to start having anti-arrhythmic drugs, with a history of paroxysmal or persistent AF.

Intervention and comparator

Index test (intervention): ECG recorded using KardiaMobile and analysed by electrophysiologists, 2 hours after each of 6 drug doses.

Reference standard (comparator): 12-lead ECG analysed by electrophysiologists, 2 hours after each of 6 drug doses.

Cardioversion was applied if AF remained after 4 doses.

Key outcomes

A total of 225 simultaneous KardiaMobile and 12-lead ECGs were recorded. KardiaMobile could

not classify 62 (27.6%) of its own ECGs, and interpreting clinicians could not classify 9 KardiaMobile ECGs and 2 12-lead ECGs. KardiaMobile had 96.6% sensitivity and 94.1% specificity in the detection of AF, compared with 12-lead ECG. Also compared with 12-lead ECG, clinician interpretation of KardiaMobile ECGs had 100% sensitivity and 89.2% specificity. KardiaMobile had 92.4% sensitivity and 97.8% specificity compared with clinician interpretation of KardiaMobile ECGs. KardiaMobile missed 28.8% of AF cases detected on 12-lead ECG, and 91.3% of these cases had not been classified. Most patients (93.6%) found the device easy to use, and AF diagnosis-related anxiety reduced in 59.6%. Of those responding, 63.8% preferred continued use of KardiaMobile for AF detection.

Strengths and limitations

Authors acknowledge that quality of KardiaMobile ECG recordings may vary in an ambulatory setting, and that algorithm performance may vary in those with lower AF burden. Generalisability may be limited by small sample size and narrow inclusion criteria.

Williams et al. (2015)

Study size, design and location

This was a diagnostic accuracy study in patients (n=95) attending a cardiology outpatient clinic in the UK for a routine appointment. Patients were either known to have AF or known not to have AF but having 12-lead ECG for other reasons.

Intervention and comparator

Index test (intervention): ECG recorded using KardiaMobile and analysed by a cardiac physiologist and special interest GP.

Reference standard (comparator): 12-lead ECG analysed by a cardiac physiologist and special interest GP.

Key outcomes

The cardiac physiologist detected AF using the KardiaMobile ECGs with 90% sensitivity and 86% specificity. The special interest GP detected AF with 93% sensitivity and 76% specificity. In the population likely to be tested, the negative predictive value is almost 100%, and authors suggest KardiaMobile is used to rule out AF, with positive results confirmed by 12-lead ECG.

Strengths and limitations

KardiaMobile was used only to record ECGs, and not to analyse them.

Sustainability

No sustainability claims have been made by the company and there are no published data.

Recent and ongoing studies

Sixteen ongoing studies were identified:

- Atrial fibrillation health literacy and information technology trial in rural PA countries (AFibLITT_R) (NCT04076020). Study type: Randomised parallel assignment (n=264). Study completion date: August 2023. Country: US
- Atrial fibrillation health literacy and information technology trial in Pittsburg (AFibLITT) (NCT04075994). Study type: Randomised parallel assignment (n=240). Study completion: March 2024. Country: US
- Smartphone electrocardiogram for recording atrial fibrillation after a cerebral ischemic event (SMART-AF) (NCT04332718). Study type: Randomised parallel assignment (n=233). Study completion date: March 2021. Country: Malaysia
- Early diagnosis of atrial fibrillation in the wait-time prior to seeing a cardiologist (CATCH-AF) (NCT04302311). Study type: Randomised parallel assignment to KardiaMobile or Holter monitor (n=220). Study completion date: July 2022. Country: Canada
- Evaluation of ambulatory monitoring of patients after high-risk acute coronary syndrome using two different systems: Biomonitor-2 and Kardia Mobile (Monitor-ACS) (NCT03940066). Study type: Randomised parallel assignment to KardiaMobile or no intervention (n=150). Study completion date: December 2021. Country: Spain
- Better outcomes for anticoagulation treatment through observation of atrial rhythm (BOAT OAR) (NCT03515083). Study type: Randomised parallel assignment (n=100). Study completion date: July 2020. Country: US
- Kardia – A smartphone-based care model for outpatient cardiac rehabilitation (NCT03415841). Study type. Randomised parallel assignment (n=100). Study completion date: March 2020. Country: Singapore

- AFib clinic of the future using KardiaPro platform for chronic care of patients with AF after ablation procedure (AliveCor) (NCT03557034). Study type: Randomised parallel assignment (n=100). Study completion date: December 2020. Country: US
- Detraining on atrial fibrillation (DAF) (NCT03642886). Study type: Randomised parallel assignment (n=73). Study completion date: April 2020. Country: Canada
- Renal nerve denervation after pulmonary vein isolation for persistent atrial fibrillation (NCT03246568). Study type: Randomised parallel assignment (n=40). Study completion date: June 2020. Country: Hong Kong
- Implementing digital health in a learning health system (ASE-INNOVATE) (NCT03713333). Study type: Randomised sequential assignment (n=500). Study completion date: October 2019
- Validation of a Smartphone-based recorder for detection of cardiac arrhythmias (NCT03996954). Study type: Non-randomised (n=400). Study completion date: October 2020. Country: UK
- Health eHeart BEAT-AFib – Health eHeart biomarkers of early atrial transformation in atrial fibrillation (NCT04404465). Study type: Observational cohort (n=3,000). Study start date: June 2020. Study completion date: June 2040. Country: US
- Evaluation of the safety and clinical utility of handheld ECG technology in psychiatry (NCT04227418). Study type: Observational cohort (n=1500). Study completion date: August 2021. Country: UK
- Atrial fibrillation research in Catalonia (AFRICAT) (NCT03188484). Study type: Observational patient registry (n=500). Study completion date: October 2019. Country: Spain
- Validation of a novel smartphone-based method for heart rhythm monitoring in the home environment (NCT04300270). Study type: Observational cohort (n=480). Study completion date: December 2021. Country: Sweden

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 6 experts were familiar with this technology; 4 had used the technology within their clinical

practice and 2 had been involved in implementing spread and adoption of the technology across the North East and North Cumbria in primary care, secondary care and community settings.

Level of innovation

All 6 experts described the technology as innovative. One stated that it had already changed clinical pathways for those with suspected arrhythmia, and another stated that it had potential to change standard of care. Another suggested it could be used in novel settings, outside of healthcare.

Potential patient impact

Four experts stated that the technology would help increased detection of AF, with 2 highlighting quicker time to diagnosis. Three experts commented on the ease of use of the device, 2 stated the device offers reassurance to patients with palpitations and 1 stated the technology was patient orientated, enabling high correlation between recorded symptoms and captured data. The experts could see the benefits of the technology across a variety of patient groups and settings. Four experts stated that the elderly, frail and those with limited dexterity may find it challenging to use this technology. Two of these described instead placing the device on the sternum to obtain a reading (this location is not mentioned in the instructions for use of the device). Four experts suggested this technology could be more reliable than other methods because it could be used in a number of settings and at any time, including when symptoms happen. All experts stated that this technology had the potential to change standard care in some way (earlier diagnosis, quicker intervention, fewer hospital visits and referrals, fewer strokes) improving both patient outcomes and patient satisfaction.

Potential system impact

Four experts stated that the technology would reduce hospital resource use (fewer hospital visits, referrals, investigations). Four experts referred to existing use in primary care and felt that use in community settings would increase. One expert stated that the technology had the potential to direct management to a primary care setting, and 2 experts stated that the technology would allow remote consultations (which are increasing because of COVID-19). Two experts also felt it was ideal for use in care homes, and for home visits, and 2 experts had used the device on patients who were unable to attend for a 12-lead ECG. One expert highlighted that KardiaMobile would lead to more efficient working, 1 stating that the device could be implemented by a range of staff, another commenting on how use of the device would lead to expansion of professional roles (for example, training). Two experts highlighted that reviewing the device output needs no additional staff or

skills than interpreting outputs from the standard care 12-lead ECG. All experts agreed that use of the technology could reduce overall healthcare costs compared with standard care, and 3 referred to costs associated with reduction in stroke admissions. Two experts highlighted that KardiaMobile can detect other cardiac abnormalities, not just AF, and therefore has wider benefits. All experts agreed that the device would be in addition to standard care, but 4 experts stated that there was potential for the device to replace standard care in some settings and patient groups, and 1 suggested it could replace standard care in the next 5 years. One expert highlighted that the device would not directly replace 12-lead ECG for confirmation of arrhythmia because the instructions for use state that KardiaMobile interpretations should be reviewed by a medical professional for clinical decision making.

General comments

Three experts highlighted potential confidentiality issues if using a personal phone with a patient in the clinic or community (where patient identifiers should not be assigned to the reading). One expert raised infection control as a potential issue, and the need to clean the device between uses. Four experts highlighted that a compatible smart device was needed to use KardiaMobile and 1 added that this could exclude some users. Two experts highlighted that training would improve widespread implementation of the technology and reduce variation in use across the NHS. However, experts initial cost and the inability to bulk buy devices may be barriers to implementation. The company has since stated that it is possible to bulk buy the device.

One expert stated that the detection algorithm could be improved to reduce unclassified ECGs, and to be less sensitive to artefact. The company claims that a software update in 2019 reduces the number of 'unclassified' readings. However, there is no published evidence to show an improvement in efficacy since this software update.

Patient organisation comments

Key benefits for patients identified by patient organisation(s) are ease of use, speed and accuracy of the device.

The patient organisation commented that patients who have atrial fibrillation (AF) are often anxious, stressed, exhausted, breathless, have heart pounding and are scared. The technology can provide reassurance by confirming if symptoms are because of an arrhythmia or a panic attack. Patients can share evidence with doctors and carers or family members to make sure their symptoms are managed appropriately. Without this evidence, patients can be left feeling alone and isolated.

Patient subgroups who could particularly benefit from the technology include symptomatic patients who have yet to be diagnosed, and those who have paroxysmal AF (which is hard to detect on a standard 12-lead electrocardiogram or Holter monitor).

The technology has no side effects and does not need any extra travel. There may be practical difficulties if patients do not know how to download and use the app. AF tends to affect older people with other comorbidities, so patients may have multiple health conditions. People with certain physical disabilities (such as those who are unable to use their hands) or a cognitive impairment that affects their ability to understand how to use the technology would need help from a carer.

Cost was highlighted as a potential barrier to access. The device may be provided by the healthcare professional or purchased privately. The organisation noted that compared with long waits and travel to and from hospital or GP appointments (and appointments cancelled or postponed because of COVID-19), the technology is proven to be cost efficient with the same or similar outcomes. In some cases, outcomes are better because the patient can keep the monitor for longer and capture intermittent spells of AF if needed. Patients prefer this technology to having electrodes on their skin for 7 to 14 days and having to travel back and forth to hospital.

The patient organisation thought that there was an urgent need for guidance on the technology and highlighted that evidence in the European Heart Journal from Denmark that there was a 47% reduction in AF detection in March and April 2020 compared with March and April 2019 because of the COVID-19 pandemic. This may have led to an increase in AF-related strokes. Having KardiaMobile readily available across the NHS and in pharmacies would: make sure patients can capture their irregular heart rhythms; allow collection of the evidence to show their doctors AF; protect against AF-related stroke with anticoagulation therapy; help patients to access appropriate treatments to manage the symptoms and correct arrhythmia.

Expert commentators

The following clinicians contributed to this briefing (all declarations have been considered by NICE):

- Dr Muhammad Yassir Javaid, GP and cardiovascular lead, Danes Camp Surgery and Nene CCG. Did not declare any interests.

- Dr Shouvik Haldar, consultant cardiologist and electrophysiologist, Royal Brompton and Harefield NHS Trust. Declarations include chair of education at the British Cardiovascular Society, and executive committee member at the Arrhythmia Alliance.
- Kate Mackay, AF programme manager, Academic Health Science Network for the North East and North Cumbria. Declarations included senior partner in MuMac Consultancy, working within AHSN NENC and receive payment from NHS England, work as Honorary Senior Lecturer within University of Bradford.
- Nikki Holdsworth, project lead and regional coordinator, Academic Health Science Network for the North East and North Cumbria. Did not declare any interests.
- Kevin McGibbon, arrhythmia clinical nurse specialist, University Hospital of North Midlands. Declarations included use of the device for a current pilot study, previous use for screening.
- Shona Holding, cardiovascular advanced nurse practitioner, Affinity Care. Did not declare any interests.

Representatives from the following patient organisations contributed to this briefing:

- AF Association
- Arrhythmia Alliance

Development of this briefing

This briefing was developed for NICE by Newcastle External Assessment Centre. NICE's interim process and methods statement for the production of medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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