

AliveCor Heart Monitor and AliveECG app (Kardia Mobile) for detecting atrial fibrillation

Medtech innovation briefing

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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.

The AliveCor Heart Monitor was rebranded as Kardia Mobile in October 2016. AliveCor Heart Monitor and Kardia Mobile are functionally identical.

Product summary and likely place in therapy	Effectiveness and safety
<ul style="list-style-type: none">• The AliveCor Heart Monitor is a pocket-sized electrocardiogram (ECG) recorder that is used with a mobile device app (application).• It detects paroxysmal atrial fibrillation and can be used by people with intermittent palpitations to help determine the cause of their symptoms.• The system would be used in any setting in place of existing portable ECG recorders. It is particularly designed to be used by people during their normal activities.	<ul style="list-style-type: none">• Two studies reported sensitivity higher than 85% and specificity higher than 90% for the AliveCor Heart Monitor and the AliveECG app, in detecting atrial fibrillation.• Two further studies of a clinician's ability to interpret AliveCor Heart Monitor readings reported sensitivity and specificity rates higher than 90%.• A user preference survey reported that most users preferred the AliveCor Heart Monitor to traditional transtelephonic monitors.

<p>Technical and patient factors</p> <ul style="list-style-type: none"> • The monitor contains 2 electrodes. It can be connected to the back of a smartphone or tablet using an adhesive attachment plate or used within range of a mobile device, to allow it to communicate wirelessly (using proprietary high frequency sound transmission) with the AliveECG app. The user places 2 fingers from each hand on the monitor for 30 seconds to take an ECG recording. • The AliveECG app analyses the ECG and alerts the user if AF is detected. The data held in the app is synchronised to the company's encrypted server and can be accessed by a healthcare professional using either a web-based application or an emailed report. • The AliveECG app is available for Apple and Android operating systems. • Minimal training is needed to enable people to make ECG readings at any time. 	<p>Cost and resource use</p> <ul style="list-style-type: none"> • An AliveCor Heart Monitor unit costs £62.49, excluding VAT. The AliveECG app and the Provider Dashboard are free of charge. • A health economic evaluation of community-based screening in Australia reported that the AliveCor system was cost effective in detecting AF and preventing stroke, with an ICER of £2799 when compared with standard diagnostic assessment for AF, which included consultation with a GP and a specialist, and a 12-lead ECG.
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Introduction

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia. It is described as an irregular heart rhythm that is often abnormally fast (World Heart Federation 2015). The NICE commissioning guide on [anticoagulation therapy](#) stated that the prevalence of AF in England in 2011 was likely to be close to 2.0%, which equated to about 835,000 people living with AF. Although AF can affect adults of any age, prevalence in the population increases as people get older. A UK study of 6286 adults found the prevalence ranged from 0.2% in people aged between 45 and 54, to 14.0% in people aged over 85 years (Davis et al. 2012). The prevalence of AF is reported to be greater in men. For example, in the Rotterdam study the overall prevalence in men was 6.0%, compared with 5.1% for women, and prevalence across all assessed age groups was also higher in men (Heeringa et al. 2006).

AF can cause morbidity and mortality, either directly or due to AF being a major risk factor for stroke (Wolf et al. 1991). Davis et al. (2012) found that people with AF had a higher prevalence of heart failure, myocardial infarction, hypertension, angina and diabetes. AF is associated with a 5-fold increase in the risk of stroke (Wolf et al. 1991). Each year AF accounts for between 25,000 and 35,000 strokes in the UK (Allaby 2014). The risk of stroke can be reduced if suitable treatment is given after diagnosis of AF. For example, it has been shown that adjusted-dose warfarin can reduce the risk of stroke by 62% (Hart et al. 1999).

The Framingham Heart Study enrolled 5209 people aged 28 to 62 to investigate the consequences of cardiovascular disease. To assess the impact of AF, Benjamin and colleagues analysed 40 years of follow-up data from the study. After adjusting the mortality risk to account for pre-existing cardiovascular conditions, the risk of death in people of all ages with AF was 50% greater in men and 90% greater in women, compared with those without AF (Benjamin et al. 1998).

AF can be classified into different categories, according to the frequency and duration of the cardiac arrhythmia:

- Paroxysmal AF is an arrhythmia that occurs occasionally and then stops. Episodes can last from minutes to days before the heart spontaneously returns to normal rhythm.
- Persistent AF lasts for longer than 7 days and does not resolve without treatment. Normal rhythm can be achieved with medication, electric shock treatment or ablation.
- Permanent AF causes people to be in AF at all times. Normal heart rhythm cannot be maintained even with medication, electrical shock treatment or ablation (NHS Choices 2013; Camm et al. 2010).

AF may have non-specific symptoms or no symptoms at all. It is often only diagnosed following serious complications including stroke, thromboembolism and heart failure. The NICE guideline on [atrial fibrillation](#) states that opportunistic screening of people at high risk of AF can detect the condition before serious complications develop. Risk factors for AF include:

- high blood pressure
- atherosclerosis
- asthma
- pneumonia
- diabetes (NHS Choices 2013).

Case finding in high risk populations through the use of an electrocardiogram (ECG) recording can help to identify people with undetected AF. Single time-point screening using pulse palpitation or ECG in people aged 65 years and over, found that 1.4% of people tested had previously undiagnosed AF, and 67% of these people were at high risk of stroke (Lowres et al. 2013).

Taking repeat ECG recordings continuously over a 24-hour period or recording events over several days can increase the probability of detecting an arrhythmia. This can be achieved using portable ECG recorders, and different types of recorder are available.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of health care professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

The AliveCor Heart Monitor and AliveECG app (application) were CE-marked to AliveCor as a Class IIa medical device in January 2015.

Description

The AliveCor Heart Monitor provides a portable electrocardiogram (ECG) recorder. The monitor works with a compatible mobile device (such as a smartphone or tablet) running the AliveECG app, which can be used to analyse the ECG recording and send it to a healthcare professional for interpretation. The healthcare professional accesses this information through the Provider Dashboard software.

The AliveCor Heart Monitor is a pocket-sized rectangular device containing 2 electrodes. It is either attached directly via an adhesive attachment plate to a mobile device, or must be within 30 cm of the mobile device during operation. The AliveCor Heart Monitor can be removed from the plate when not in use, with the plate remaining attached to the mobile device.

The mobile device must be a standard internet-enabled mobile phone or tablet, onto which the AliveECG app must be downloaded. The AliveCor Heart Monitor and AliveECG app are compatible with devices running Apple or Android operating systems (a full list is available on the

manufacturer's website). The manufacturer states they are planning to expand to other operating systems, including Windows.

To record an ECG, the user places 2 or more fingers from the left hand onto 1 of the AliveCor Heart Monitor electrodes and 2 or more fingers from the right hand onto the other electrode. The user keeps contact with the electrodes for at least 30 seconds to ensure that a complete reading is taken, while keeping their arms still because arm movement may interfere with the ECG reading. The manufacturer recommends that the recordings are taken daily, or whenever AF symptoms are experienced. A user may also be given specific advice by their physician on how often to use the device.

After the AliveCor Heart Monitor has taken a reading, it is sent wirelessly by a patented high frequency sound transmission to the mobile device, where it can be viewed using the AliveECG app. The app stores and analyses data from the AliveCor Heart Monitor. It displays the ECG trace, which includes a measure of heart rate, and the in-built software notifies the patient if their reading is normal or if AF has been detected due to an irregularity in the reading. Patient information, such as name and NHS number, can also be added to the recording. If or when the device has a suitable Wi-Fi or mobile connection, the recording will automatically synchronise with the secure encrypted AliveCor cloud server. The user can also send the recording directly to a relevant healthcare professional, such as a GP, to be read using the Provider Dashboard, which is a web-based application run from any standard PC. To access all AliveCor services, the healthcare professional and their patient must each have an AliveCor account. The healthcare professional can then email their patient to link their accounts through the secure Provider Dashboard. The AliveECG app can also be used to email the recording, or create a PDF version that can be printed.

The AliveCor Heart Monitor is not recommended for use in children, or in adults with cardiac pacemakers or other implanted electronic devices.

Setting and intended user

The AliveCor Heart Monitor and AliveECG app is intended for use by adults at risk of AF, to detect abnormal heart rhythms. It is particularly suitable for people with suspected paroxysmal AF, which can go undetected using standard 12-lead ECG recording due to the intermittent nature of the arrhythmia. Because the AliveCor Heart Monitor is portable, readings can be taken at any time of the day while the user goes about their normal activities. This increases the probability of an arrhythmic episode being detected and recorded. As a portable device, it can be used in any setting but is particularly designed for home use by people.

The manufacturer states that ECG recordings should be reviewed by a physician. Therefore the AliveECG app should not be used by patients to diagnose AF.

The AliveCor Heart Monitor can also be used to evaluate heart rate and rhythm in people with congestive heart failure; however, this is beyond the scope of this briefing.

Current NHS options

The NICE guideline on [atrial fibrillation](#) recommends that people with suspected AF have manual pulse palpation to detect any irregular pulse.

AF is commonly suspected in people with any of the following symptoms:

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

The NICE guideline recommends that when an irregular pulse is detected, an ECG should be done regardless of whether the patient has symptoms. Arrhythmias may be missed by conventional 12-lead ECG in people with paroxysmal AF because of the occasional nature of the arrhythmic episodes.

The NICE guideline on [atrial fibrillation](#) defines 2 categories of portable recorders. An ambulatory ECG monitor is a device that can continuously record cardiac electrical activity. This category includes both Holter-monitors and implanted recorders. An event ECG recorder is a device that records particular events, either automatically by a software programme, or manually by the user. People with suspected paroxysmal AF should use a 24-hour ambulatory ECG monitor, if symptomatic episodes are less than 24 hours apart. For those with episodes more than 24 hours apart, an event ECG recorder should be used.

Screening for AF in asymptomatic people who are at risk, and aged 65 years or over, is not recommended by the National Screening Committee (NSC 2014), nor is it listed as a recommendation in the NICE guideline.

An irregular pulse may be identified using the [WatchBP Home A for opportunistically detecting atrial fibrillation during diagnosis and monitoring of hypertension](#), a device recommended by NICE for use in primary care.

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to the AliveCor Heart Monitor and AliveECG app:

- Dicare m1CC colour portable ECG recorder (Dimetek)
- MD100A ECG reader (Choice Medical)
- MD100E ECG reader (Choice Medical)
- HCG-801 ECG reader (Omron).

Costs and use of the technology

The AliveCor system consists of an AliveCor Heart Monitor and the AliveECG app. The AliveCor Heart Monitor costs £62.49, excluding VAT, for a single unit. For orders of 50 units or more, the price reduces to £50 each, excluding VAT. The AliveECG app is available as a free download from the Apple App Store or from Google Play, and the web-based Provider Dashboard is free to use. There will also be a small cost to the NHS for a healthcare professional's time to review an ECG reading generated by the AliveCor system.

To use the AliveCor Heart Monitor, users must have a compatible mobile device. AliveCor does not provide internet-enabled mobile phones or tablets for use with the AliveCor system.

People can be trained to use the AliveCor system during a brief appointment with a suitably trained professional, often a healthcare assistant. Instructions for use are also contained in the user manual.

Maintenance consists of cleaning the AliveCor Heart Monitor with an alcohol-based sanitiser before each use. When the monitor is no longer needed by a person, it can be used by someone else. The manufacturer states that the monitor has no expected lifespan. The 3 volt battery in the monitor should be replaced when needed, generally every 6 to 12 months.

The NICE support for commissioning for [transient loss of consciousness](#) estimated the cost of a standard 12-lead ECG, in which a practice nurse applies the test and a GP reviews the results, to be £36.33 with the cost of an ambulatory ECG as £170 (NICE 2014).

Likely place in therapy

The AliveCor Heart Monitor enables portable event-monitoring of the electrical activity of the heart and could therefore be used by people during normal activities, while under the care of a primary or secondary healthcare professional, as an alternative to existing portable ECG devices.

Specialist commentator comments

Two commentators stated that the AliveCor Heart Monitor is a useful screening tool for the detection of symptomatic AF. Both highlighted the practicality and ease of use of the device. One of these specialists also remarked that it may be used to detect both paroxysmal and persistent AF in people who are asymptomatic, and advocated the use of the AliveCor Heart Monitor in people with intermittent palpitations to determine the cause of their symptoms. The underlying cause of these symptoms may not always be AF, and a correct diagnosis is important for making treatment decisions. One specialist commentator noted that the available evidence suggested that the AliveCor system is both practical and cost effective, and given the importance of early AF detection in preventing strokes, the system could contribute to improved stroke prevention in the NHS.

One specialist commentator noted that using the AliveCor Heart Monitor is unlikely to cause an increase in, but may decrease, the number of ECGs that need to be interpreted by physicians following manual pulse palpitation. Similarly, a second commentator thought that the AliveCor Heart Monitor would not increase the number of ECGs for interpretation, because it would simply replace other monitoring devices, particularly 7-day ambulatory ECGs. This commentator believed that use of the AliveCor Heart Monitor needed similar amounts of healthcare assistant time as ambulatory ECGs. However, it may increase overall productivity because of a greater probability of arrhythmias being detected.

One commentator stated that it is unlikely that the NHS would provide a mobile device for use with the AliveCor Heart Monitor. This expert also reflected that paroxysmal AF may occur only once or twice a year and so a loaned AliveCor Heart Monitor could be offered to targeted groups of people. A second expert noted that in their experience most people provide their own mobile device to use with the AliveCor Heart Monitor, but it may be possible for the NHS to provide mobile devices, with a strict returns policy. However, they also stated that organising this would have its challenges and may be impractical.

Equality considerations

NICE is committed to promoting equality and eliminating unlawful discrimination. In producing guidance, NICE aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

The level of manual dexterity needed to record an ECG on the AliveCor Heart Monitor may exclude some people with disabilities from using the device. The AliveCor Heart Monitor is not intended for use in children. Some people at higher risk of AF may not be familiar with how to use a compatible mobile phone or tablet; in particular, adoption may be low amongst older people, reflecting the lower rates of mobile device usage in this group. The prevalence of AF increases in older age and is greater in men. However, the risk of death from AF is slightly higher in women. Disability, age and sex are protected characteristics under the Equality Act (2010).

Patient and carer perspective

A spokesperson acting on behalf of both the Arrhythmia Alliance and the Atrial Fibrillation Association, 2 separate charities with an interest in the detection of AF, gave the following patient perspectives:

- The patient groups have distributed 1500 AliveCor Heart Monitors to people of all ages, all of whom have provided positive feedback. The feedback included incidents when the AliveCor system had helped to capture an episode of AF, leading to a diagnosis; and an instance when the user's symptoms had been confirmed as anxiety rather than AF.
- One person out of the 1500 returned their AliveCor Heart Monitor because they felt they were checking their heart rate too often and worrying about the results.
- The spokesperson commented on the suitability of the AliveCor system for older people. They noted that many older people are regular users of mobile technology and, contrary to some expectations; older people have given positive feedback about using the AliveCor system.
- The patient groups have also used the AliveCor system in a public engagement campaign, taking it into schools, shopping centres, GP surgeries and pharmacies. At one event, of

480 people monitored using the AliveCor, 26% of recordings showed a previously undetected arrhythmia and 5% were advised to see their doctor urgently.

- They reported that the benefit of the AliveCor system is that it is relatively inexpensive and can be used anywhere, at any time. The ECG recording can be saved, emailed or printed to show to the user's doctor. The recordings can also be annotated to record information, such as symptoms, medication, and activity immediately before recording, giving a clear history for the doctor to review.

The spokesperson concluded that the AliveCor Monitor was easy for people of all ages to use, and felt that it could save money for the NHS when compared with the cost of ECG recordings made in NHS clinics. They believed that the AliveCor system would help to capture episodes of AF outside of the clinic, enabling earlier diagnosis that could reduce the number of AF-associated strokes.

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website revealed no manufacturer Field Safety Notices or Medical Device Alerts for this device. No reports of adverse events were identified from a search of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE).

Clinical evidence

Of 9 studies identified, 3 were excluded due to small sample sizes (10 or fewer individuals) and 2 did not report relevant outcomes. The remaining 4 papers are summarised in this briefing.

Lau et al. (2013) carried out a diagnostic accuracy evaluation of the AliveCor Heart Monitor, compared with a standard 12-lead ECG. Two groups of people aged over 65 were recruited into this study from an Australian treatment centre; firstly a group of 109 people, and secondly a group of 204 people. All of the people in both groups of the study were assessed firstly with a 12-lead ECG, followed by an AliveCor Heart Monitor reading within 6 hours.

For the first group of people, ECG readings recorded using the AliveCor Heart Monitor were stored in the mobile device, before being interpreted by 2 cardiologists blinded to the 12-lead ECG results. The AliveCor Heart Monitor ECG readings were also interpreted by automated software (a

prototype version of the AliveECG app). The 12-lead ECG readings were independently interpreted by a third cardiologist, to confirm the results. Using this data, the automated software was improved to achieve better diagnostic accuracy.

The second group of people were analysed in the same way, using 12-lead ECG followed by AliveCor Heart Monitor ECG. However, for this group the AliveCor Heart Monitor readings were interpreted with the improved automated software, and this updated software was also applied retrospectively to the readings from the first group.

The improved automated software is the basis for the diagnostic element of the current AliveECG app. Before the commercial launch, the software was recoded so that it could operate on all compatible mobile phones and tablets.

One cardiologist, interpreting the AliveCor Heart Monitor readings, made an accurate diagnosis in 93.6% (102/109; 95% confidence interval [CI] 87.2–97.4%) of cases for the first group. The second cardiologist made an accurate diagnosis in 95.4% (104/109; 95% CI 89.6–98.5%) of cases. The results of similar analyses were not provided for the second group. The original automated software had an overall accuracy of 93.6% (102/109; 95% CI 87.2–97.4%). This increased with the updated software to 97.2% (106/109; 95% CI 92.2–99.4%) in the first group, and 97.1% (198/204; 95% CI 93.7–98.9%) in the second. Full study outline and results are reported in [table 1](#).

Lowres et al. (2014) conducted a community-based, opportunistic screening programme of 1000 people aged 65 years and over, using the AliveCor Heart Monitor to detect AF. The study was set in 10 pharmacies in Sydney, Australia. Diagnoses were based on a cardiologist's interpretation of the AliveCor Heart Monitor ECG recordings. In a subsequent analysis, the AliveECG app was used to retrospectively interpret the original AliveCor Heart Monitor readings to identify AF. The 2 different sets of results were then compared. The cardiologist found the AliveCor Heart Monitor readings sufficient to diagnose 97.5% of people (975/1000), although probable diagnoses were provided for the remaining 2.5% of people (25/1000) based on noise-reduced AliveCor Heart Monitor readings and 12-lead ECGs where available. Following the analysis of 996 readings, excluding 4 people with pacemakers, the AliveECG app had 98.5% sensitivity (67/68; 95% CI 92.1%–100%) and 91.4% specificity (849/929; 95% CI 89.4–93.1%), using the cardiologists' diagnosis from the AliveCor Heart Monitor reading as the reference case. Full study outline and results are reported in [table 2](#).

Haberman et al. (2015) measured the accuracy of the AliveCor Heart Monitor in detecting major cardiac abnormalities, including AF, for 3 groups of people; athletes (n=123), young healthy individuals (n =128) and cardiology clinic patients (n= 130). The mean ages across these groups

were 19 for the athletes, 25 for the young healthy adults and 59 for the cardiac patients; with an overall mean age of 35 years. All people were assessed with a 12-lead ECG and the AliveCor Heart Monitor, which were used in immediate succession. In this study, the AliveECG app was not used to diagnose AF, but simply to store readings for clinical interpretation. For this process, 2 electrophysiologists collaboratively interpreted both the 12-lead ECG and the AliveCor Heart Monitor readings for all groups, with the 12-lead ECG diagnosis serving as the reference standard. For all groups combined, the electrophysiologists' interpretation of the AliveCor Heart Monitor reading had a sensitivity of 94.4% (17/18; 95% CI 72.7%–99.9%) and a specificity of 99.4% (361/363; 95% CI 98.0%–99.9%). Full study outline and results are reported in [table 3](#).

Tarakji et al. (2015) used the AliveCor Heart Monitor as a monitoring device in people following a cardiac ablation. This study recruited 55 people with a mean age of 60 years, who had the procedure at a US clinic, and were then discharged. They were given both an AliveCor Heart Monitor and a traditional transtelephonic monitor (TTM), and were asked to use them simultaneously when they had symptoms at home. A TTM is an event recorder used for monitoring heart rhythm outside of hospital. These readings are transmitted to a clinician by connecting the device to a telephone line. As in the Haberman et al. (2015) study, the AliveECG app was not used to diagnose AF, but to store ECG readings, which were then emailed to the electrophysiologists for interpretation. The group was divided between 2 electrophysiologists, each of whom independently interpreted both the AliveCor Heart Monitor and the TTM readings for their subgroup, with the TTM readings used as the reference standard. The electrophysiologists' interpretations of the AliveCor Heart Monitor readings had 100% sensitivity (46/46; 95% CI 92.3%–100%) and 97.0% specificity (328/338; 95% CI 94.6%–98.5%), with a Kappa statistic of 0.82 (when AF and atrial flutter were considered to be a single disease state). When asked about their preferences, 92% of the monitored users in the study preferred the AliveCor Heart Monitor to the TTM. The electrophysiologists responsible for interpreting the device readings reported that of the 55 readings, 12.7% (7) AliveCor Heart Monitor recordings were more easily interpreted than TTM recordings; 72.7% (40) of the AliveCor Heart Monitor recordings were as easily interpreted as the TTM recordings; and 14.6% (8) AliveCor Heart Monitor recordings were less easily interpreted than the TTM recordings. Full study outline and results are reported in [table 4](#).

Recent and ongoing studies

Twenty-three recent, ongoing or in-development trials on the use of the AliveCor Heart Monitor in the assessment of AF and arrhythmias were identified in the preparation of this briefing. Four of these were listed on the clinicaltrials.gov website:

- [Validation of an iPhone-based event recorder for arrhythmia detection \(NCT02005172\)](#). The expected primary completion date for the study was January 2015, although it listed as being in progress in May 2015.
- [Can patients with atrial fibrillation read their own rhythm recording using a novel wireless ECG recording system? iRead Study \(NCT02214069\)](#). The expected primary completion date for the study was August 2014, although it was listed as being in progress in May 2015.
- [Using an iPhone ECG to monitor the QT interval on dofetilide and sotalol patients \(NCT02241252\)](#). The expected primary completion date for the study was May 2015.
- [Hong Kong outpatient AF screening using single-lead ECG device \(NCT02409654\)](#). The estimated primary completion date for the study is March 2017.

Eight of the remaining studies are set in the UK and 11 in the USA. Research questions are on the diagnostic accuracy of the AliveCor Heart Monitor (n=8), its use in screening (n=6), use in paediatrics (n=3) and the monitoring of medication (n=2). One additional study was identified that is assessing the use of the AliveCor Heart Monitor in heart failure detection.

Costs and resource consequences

The AliveCor Heart Monitor could be used in primary care as an alternative to other portable ECGs recorders to detect paroxysmal AF. There are several different portable ECGs available to the NHS. These devices, and the number of people in England who were monitored using the device in 2013-14 following an outpatient appointment, are listed below (Health & Social Care Information Centre 2015):

- ECG loop recorder – 63 people
- 24-hour ambulatory ECG – 80,264 people
- 48-hour ambulatory ECG – 2863 people
- Holter extended ECG – 7186 people
- Cardiomemo ECG monitor – 4973 people.

It is expected that the purpose of portable ECG monitoring in a large proportion of these people was to detect paroxysmal AF. Therefore, the AliveCor Heart Monitor and AliveECG app may be suitable for a large number of people.

Given that the mean cost of ambulatory ECG monitoring is £170, the adoption of the AliveCor may produce savings to the NHS. Savings will occur if the AliveCor Heart Monitor is cheaper than current portable devices, and if it requires less staff time. There is anecdotal evidence to suggest that the adoption of the AliveCor system may lead to fewer GP appointments, because people will feel reassured by the results generated by the AliveECG app. Alternatively, because any AF diagnosis needs to be confirmed with a 12-lead ECG, the total cost for undertaking 12-lead ECGs may increase if the AliveCor system increases the rate of detection for paroxysmal AF.

If the AliveCor system leads to the earlier detection of AF, it will impact on resource use, in particular an increase in the number of treatments (such as warfarin) being given to prevent stroke. This increase is expected to be partly offset by lowering the incidence of stroke, and associated treatment costs. The NICE costing report for [atrial fibrillation](#), estimated that the net cost of implementing the NICE guidance on AF would be £88,000 per 100,000 of population.

Health economic evaluation

Lowres et al. (2014) evaluated the cost effectiveness of using the AliveECG app to diagnose AF in an Australian population screening programme. This study assumed AF prevalence to be 4.4% and AF incidence to be 1.4% in a population aged 65 years or over. The study assumed costs of £9.35 per AliveECG screen and £118 for a standard diagnostic assessment for AF, including a GP consultation, specialist consultation and then a 12-lead ECG reading. From an Australian healthcare perspective, the incremental cost-effectiveness ratio (ICER) per quality-adjusted life year (QALY) gained was £2799 (95% confidence interval £754 to £6280). Sensitivity analysis produced a range of £1448 to £7742. The full study outline and results are reported in [table 2](#). (All costs were converted into pounds sterling from Australian dollars, using 2014 purchasing power parities [Organisation for Economic Co-operation and Development 2015]).

Strengths and limitations of the evidence

Findings from the evaluation of the 4 studies using the QUADAS-2 tool are reported in table 5.

Table 5 Summary of QUADAS-2 results for diagnostic evaluation papers

	Lau et al. (2013)	Lowres et al. (2014)	Haberman et al. (2015)	Tarakji et al. (2015)
Domain 1: Patient selection				
Risk of bias	Unknown	No	Unknown	No

Concern over match to review question	Yes	Yes	Yes	Yes
Domain 2: Index test				
Risk of bias	Unclear	Unclear	Unclear	No
Concern over match to review question	No	No	No	No
Domain 3: Reference standard				
Risk of bias	Unclear	Yes	Yes	Yes
Concern over match to review question	No	Yes	No	Yes
Domain 4: Flow and timing				
Risk of bias	Yes	Yes	No	No

In the study by Lau et al. (2013), reporting of the study population characteristics and recruitment method was limited, and so it was difficult to assess bias and generalisability to the NHS setting. The study used the AliveCor Heart Monitor and an early version of the AliveECG app, which was subsequently recoded for use on a wider range of mobile devices. Recoding of the app may have affected the sensitivity and specificity of the app, but this effect has not been assessed. The study did use an appropriate reference test and the cardiologists were blinded to the 12-lead results before interpreting the AliveCor readings. However, it also had an interval between the 12-lead ECG and the AliveCor Heart Monitor reading of up to 6 hours, giving rise to the possibility of change in heart rhythm during the intervening period.

Lowres et al. (2014) carried out a diagnostic accuracy study of the AliveCor Heart Monitor, with readings retrospectively interpreted using the AliveECG app to indicate the presence of AF, and a cost-effectiveness analysis of their use in an opportunistic screening programme. Recruitment procedures and patient characteristics in the diagnostic study were well reported and a suitable reference test of a 12-lead ECG was used, but only for patients who tested positive with the AliveCor Heart Monitor. The main weakness was the mean time of 16.6 days between the use of AliveCor and the reference test, giving rise to the possibility of a change in a person's condition in the meantime. Patients did not have access to the full AliveECG app during the study; instead it was used to interpret the readings retrospectively. Therefore, patients could not use the heart monitor and app together, as they would in clinical practice.

For the cost-effectiveness analysis (Lowres et al. 2014), the Australian costs may not be generalisable to the NHS. The sensitivity analysis is limited, so it is difficult to establish how much uncertainty exists around the results. Furthermore, a full economic evaluation should have compared the use of the AliveCor Heart Monitor with all possible comparators, including manual pulse palpation as a screening option.

In the Haberman et al. (2015) study, the recruitment process and the characteristics of those recruited were not reported in sufficient detail to rule out the possibility of bias. The population recruited to this study may not match those who would be tested in clinical practice in the UK, because it included athletes and healthy young people as well as cardiology clinic patients. Therefore, it is uncertain if aspects of the analysis can be generalised to an NHS setting. It is also unclear whether the cardiologists interpreted the readings from the 2 technologies independently from each other or not, introducing the risk of interpretation bias. Strengths of this study include that an appropriate reference test was used, and that there was no time delay between the 12-lead ECG and the AliveCor Heart Monitor ECG assessments. However, the study used the AliveECG app to record the AliveCor Heart Monitor ECG, and not to interpret the ECG readings. This means that the results may not be generalisable to how the device would be used in practice. The authors noted that positioning of the body between the 2 readings may influence results.

The major strength of the Tarakji et al. (2015) study is that patients were able to use the AliveCor Heart Monitor multiple times in a community setting. This may better represent how the device could be used in clinical practice in UK, although use of the device in people who have had cardiac ablation may not. Patient characteristics were well reported, the timing of tests was adequate, clinicians were blinded and there was a valid reference test.

All 4 papers used the Kappa statistic to measure the agreement in diagnoses between the AliveCor Heart Monitor and the comparator test. Given the binomial nature of the test, the McNemar's statistic may be a more appropriate measure. Insufficient information was presented in all 4 of the papers for researchers to calculate this independently.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

- [Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers \(the CoaguChek XS system and the INRatio2 PT/INR monitor\)](#) (2014)
NICE diagnostics guidance 14

- [Atrial fibrillation: the management of atrial fibrillation](#) (2014) NICE guideline CG180. Date for review: September 2016
- [Apixaban for preventing stroke and systemic embolism in people with nonvalvular atrial fibrillation](#) (2013) NICE technology appraisal guidance 275
- [WatchBP Home A for opportunistically detecting atrial fibrillation during diagnosis and monitoring of hypertension](#) (2013) NICE medical technology guidance 13
- [Rivaroxaban for the prevention of stroke and systemic embolism in people with atrial fibrillation](#) (2012) NICE technology appraisal guidance 256
- [Dabigatran etexilate for the prevention of stroke and systemic embolism in atrial fibrillation](#) (2012) NICE technology appraisal guidance 249
- [Dronedarone for the treatment of non-permanent atrial fibrillation](#) (2010) NICE technology appraisal guidance 197

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Search strategy and evidence selection

Search strategy

The search strategy was designed to identify evidence on the clinical and cost effectiveness of the AliveCor Heart Monitor and AliveECG app.

The strategy was devised using a combination of subject indexing terms and free text search terms in the title, abstract and keyword heading word fields. The search terms were identified through discussion within the research team, scanning background literature, browsing database thesauri and use of the PubMed [PubReMiner](#) tool. The strategy reflected the nature of the MIB assessments as rapid evidence reviews.

The search comprised two concepts:

- 1) ECG
- 2) mobile phone / mobile tablet device / mobile application.

The mobile phone / mobile tablet / mobile application terms included terms for the named devices and operating systems that are currently indicated as supporting use of the AliveCor Heart Monitor (lines 20–22 in the MEDLINE strategy). Eight additional search lines (search lines 31–38 in the MEDLINE strategy) included terms for brand and manufacturer names (AliveCor, AliveECG), pre-combined terms (iECG), known study names (iTransmit, search-AF, GP-search), terms for mobile ECGs, and highly focused title-only searches on mobile devices and rhythms. These additional lines were used as stand-alone searches and were designed to capture any records that may have been missed by the two concept approach.

The strategy excluded non-English language publications. Animal studies were also excluded using a standard algorithm. No additional filters for study design were applied. Results were limited to studies published from 2008. This date reflected the year in which development of the device first began (AliveCor 2012).

The final MEDLINE strategy was peer-reviewed by an independent information specialist. The MEDLINE strategy was translated appropriately for the other databases searched. The PubMed search was limited to records that were not fully indexed on MEDLINE. Conference-related records were excluded from the Embase search.

The following databases were searched:

- Cochrane Central Register of Controlled Trials (Cochrane Library, Wiley)
- Cochrane Database of Systematic Reviews (Cochrane Library, Wiley)
- Database of Abstracts of Reviews of Effects (Cochrane Library, Wiley)
- Embase (Ovid SP)
- Health Technology Assessment Database (Cochrane Library, Wiley)
- MEDLINE and MEDLINE in Process (Ovid SP)
- NHS Economic Evaluation Database (Cochrane Library, Wiley)
- [PubMed](#).

Evidence selection

A total of 1033 records were retrieved from the literature search. After de-duplication, 642 records remained. The title and abstracts of all 642 records were screened independently by 2 reviewers, in order to exclude any that did not meet the exclusion criteria adopted for the review. The following exclusion criteria were used:

- conference abstracts
- non-English language studies
- review protocols
- sample sizes of fewer than 10 patients (for example case reports)
- articles of poor relevance against the search terms
- studies undertaken before 2008
- paediatric studies.

Disagreements between the 2 reviewers were resolved through discussion. This first sift excluded 627 papers. Full records were retrieved for the remaining 15 papers, and a second sift was carried out by the same reviewers, against the following inclusion criteria:

- use of the AliveCor Heart Monitor
- patients with suspected atrial fibrillation
- comparative studies.

Papers that failed these inclusion criteria, or the previous exclusion criteria, were excluded. Again, disagreements between the 2 reviewers were resolved through discussion. Eleven papers were excluded for not assessing the AliveCor Heart Monitor (n=6), testing too few individuals (n=3) and not reporting appropriate outcomes (n=2).

All papers were assessed for methodological quality using the checklists provided within the NICE guidelines manual: [appendices B-I](#).

Appendix

Contents

Data tables

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Table 1 Overview of Lau et al. (2013) study

Study component	Description
Objectives/hypotheses	To assess the accuracy of an iPhone ECG (using the AliveCor Heart Monitor), compared with a 12-lead ECG interpreted by a cardiologist, as a diagnostic screening tool to detect AF.

<p>Study design</p>	<p>Diagnostic accuracy evaluation. The AliveCor Heart Monitor reading was taken within 6 hours of the 12-lead ECG. The AliveCor Heart Monitor reading for the first group of people (n=109) was interpreted by 2 cardiologists and a software programme (a developmental model of the AliveECG app). After analysis of these results, the software was updated and the new version was used to report readings for the second group of people in the study (n=204).</p> <p>The updated software was used to build diagnostic functionality into the AliveECG app, but not before being recoded to work on compatible mobiles and tablets.</p> <p>The 12-lead ECG formed the reference test and was interpreted by a third cardiologist.</p>
<p>Setting</p>	<p>AliveCor Heart Monitor reading and 12-lead ECG conducted within an Australian clinical setting.</p>
<p>Inclusion/exclusion criteria</p>	<p>Patients recruited from a single centre: 39 people in Group 1 and 48 in Group 2 had a diagnosis of AF at entry.</p>
<p>Primary outcomes</p>	<p>Sensitivity, specificity, Kappa statistic and overall accuracy of AliveCor Heart Monitor.</p>
<p>Statistical methods</p>	<p>Not disclosed.</p>
<p>Patients included</p>	<p>2 groups were recruited sequentially. Results from Group 1 (n=109) were used to assess and update the software. The results from Group 2 (n=204) were used only to assess the diagnostic accuracy of updated software.</p>

<p>Results</p>	<p>Outcome of 12-lead ECG treated as definitive diagnosis, and used to define sensitivity and specificity of the AliveCor Heart Monitor.</p> <p>Learning set (n=109)</p> <p>Original software</p> <ul style="list-style-type: none"> • Sensitivity: 87.2% (34/39; 95% CI 72.6%–95.7%) • Specificity: 97.1% (68/70; 95% CI 90.1%–99.7%) • Overall accuracy: 93.6% (102/109; 95% CI 87.2%–97.4%) • Kappa (agreement with 12-lead ECG): 0.86. <p>Updated software</p> <ul style="list-style-type: none"> • Sensitivity: 100% (39/39; 95% CI 91.0%–100%) • Specificity: 95.7% (67/70; 95% CI 88.0%–99.1%) • Overall accuracy: 97.3% (106/109; 95% CI 92.2%–99.4%) • Kappa (agreement with 12-lead ECG): 0.94. <p>Cardiologist A</p> <ul style="list-style-type: none"> • Sensitivity: 100% (39/39; 95% CI 91.0%–100%) • Specificity: 90.0% (63/70; 95% CI 80.5%–95.9%) • Overall accuracy: 93.6% (102/109; 95% CI 87.2%–97.4%) • Kappa (agreement with 12-lead ECG): 0.87. <p>Cardiologist B</p> <ul style="list-style-type: none"> • Sensitivity: 94.9% (37/39; 95% CI 82.7%–99.4%) • Specificity: 94.3% (66/70; 95% CI 86.0%–98.4%) • Overall accuracy: 95.4% (104/109; 95% CI 89.6%–98.5%) • Kappa (agreement with 12-lead ECG): 0.88. <p>Validation set (n=204)</p> <p>Updated software</p>
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	<ul style="list-style-type: none"> • Sensitivity: 97.9% (47/48; 95% CI 80.9%–99.9%) • Specificity: 96.8% (151/156; 95% CI 92.7%–98.9%) • Overall accuracy: 97.1% (198/204; 95% CI 93.7%–98.9%) • Kappa (agreement with 12-lead ECG): 0.92.
Conclusions	The authors concluded that the AliveCor Heart Monitor and the AliveECG app have high diagnostic accuracy and are useful for community screening for AF.
Abbreviations: AF, atrial fibrillation; CI, confidence interval; ECG, electrocardiogram; n, number of patients; NR, not reported.	

Table 2 Overview of Lowres et al. (2014) study

Study component	Description
Objectives/ hypotheses	Assess the feasibility and cost effectiveness of community-based AF screening using the AliveCor Heart Monitor and the AliveECG app.
Study design	Observational study of 1000 people, mean age 76 years and cost-utility analysis comparing the AliveCor System in a screening programme with no screening. The cost utility analysis used a hypothetical strategy not matched by the data collection method where people are given a provisional diagnosis by the AliveECG app. Those with suspected AF are referred on to a cardiologist for further testing. This analysis projected costs and benefits over a 10 year period.
Setting	Screening intervention to detect AF, based in 10 Australian pharmacies between June 2012 and January 2013: ECGs done under supervision of trained pharmacists.
Inclusion/ exclusion criteria	All individuals aged 65 years and over entering participating pharmacies were eligible for inclusion.
Primary outcomes	Cost effectiveness of AF screening using the AliveCor system, sensitivity and specificity of the AliveCor Heart Monitor with the AliveECG app used to indicate AF and societal prevalence of AF.

Statistical methods	Summary statistics and decision tree economic model. Monte Carlo simulation adopted, selecting age and gender-specific incidence rates from log-normal distributions to generate the 95% CIs.
Patients included	Analysis conducted on 1000 pharmacy users. 1051 individuals recruited with 51 exclusions due to withdrawal of consent (n=2), duplicate recruitment (n=3), incorrect age (n=42) and incomplete screening (n=4).
Results	<p>Cost effectiveness</p> <p>Base-case analysis reported an ICER of £2799 (95% CI £745–£6280). Two-way sensitivity analyses altered treatment adherence rates, costs and QALY gain per stroke avoided. ICERs ranged from £1448 (95% CI £27–£3867) to £7742 (95% CI £4371–£13,471). (All costs were converted into pounds sterling from Australian dollars, using 2014 purchasing power parities [OECD 2015]).</p> <p>Sensitivity and specificity of the AliveECG app with cardiologist's interpretation of the AliveCor reading as the reference test</p> <p>Sensitivity: 98.5% (67/68; 95% CI 92.1%–100.0%)</p> <p>Specificity: 91.4% (849/929; 95% CI 89.4%–93.1%)</p> <p>Prevalence based upon cardiologist's interpretation of the AliveCor readings</p> <p>Prevalence of AF identified by screening was 6.7% (67/1000; 95% CI 5.2%–8.4%). Newly identified AF was found in 15 people (1.5%; 95% CI 0.8%–2.5%). Of these, 10 people had no prior history of AF, and 5 had an unknown recurrence of AF \geq3 years after cardioversion.</p>
Conclusions	The authors concluded that pharmacy-based screening for AF using the AliveCor system in individuals over 65 years is feasible and cost effective.
Abbreviations: AF, atrial fibrillation; CI, confidence interval; ECG, electrocardiogram; ICER, incremental cost-effectiveness ratio; OECD, Organisation for Economic Co-operation and Development; QALY, quality-adjusted life year.	

Table 3 Overview of Haberman et al. (2015) study

Study component	Description
Objectives/hypotheses	To compare the accuracy of the AliveCor Heart Monitor with 12-lead ECG in assessing ECG intervals, heart rate and heart rhythm.

Study design	Diagnostic accuracy evaluation and user satisfaction survey.
Setting	Individuals enrolled between August and December 2012 from a US college campus and cardiology treatment centre. 12-lead ECG was done immediately after the completion of the AliveCor Heart Monitor reading. All ECGs were collected within a clinical setting supervised by the study investigators.
Inclusion/exclusion criteria	Assessment conducted within 3 separate populations: student athletes, healthy young adults and cardiology clinic patients. Cardiology patients were recruited from patients pre-scheduled for a 12-lead ECG.
Primary outcomes	Sensitivity and specificity of the AliveCor for AF or flutter.
Statistical methods	2×2 contingency tables were used to calculate sensitivity and specificity for each abnormality and Kappa plots were constructed. Post participation surveys were compared using a Chi-square test.
Patients included	Student athletes, n=123 Healthy young adults, n=128 Cardiology clinic patients, n=130.

<p>Results</p>	<p>Sensitivity and specificity of detection of AF or atrial flutter</p> <p>Based upon comparison of the AliveCor Heart Monitor with 12-lead ECG reading, which was considered fully accurate.</p> <ul style="list-style-type: none"> • Athletes: sensitivity – N/A (0/0); specificity – 99.2% (122/123; 95% CI 95.6%–100.0%); Kappa – N/A. • Healthy young adults: sensitivity – N/A (0/0); specificity – 100% (128/128; 95% CI 97.2%–100.0%); Kappa – N/A. • Cardiology patients: sensitivity – 94.4% (17/18; 95% CI 72.7%–99.9%); specificity – 99.1% (111/112, 95.1%–100.0%); Kappa – 0.94. • Total: sensitivity – 94.4% (17/18; 95% CI 72.7%–99.9%); specificity – 99.4% (361/363; 95% CI 98.0%–99.9%); Kappa – 0.91. <p>User satisfaction (selected items)</p> <p>Results presented in diagrammatic format only, so figures are rounded to nearest 5%. All statements were positively worded. The post participation survey was completed by student athletes and healthy young adults only.</p> <p>Level of agreement with selected statements:</p> <ul style="list-style-type: none"> • I had no problems with the smartphone ECG: 95% • The smartphone ECG was more comfortable: 70% • The smart phone ECG was faster: 75% • I prefer the smartphone ECG: 75%.
<p>Conclusions</p>	<p>The authors concluded that the AliveCor Heart Monitor accurately detects atrial rate, conduction intervals and common arrhythmias such as AF, and can be used for large scale screening.</p>
<p>Abbreviations: AF, atrial fibrillation; AV block, atrioventricular block; ECG; electrocardiogram; n, number of patients; N/A, not applicable.</p>	

Table 4 Overview of Tarakji et al. (2015) study

Study component	Description
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Objectives/ hypotheses	Compare the accuracy and usability of the AliveCor Heart Monitor with traditional transtelephonic monitors (TTM), to monitor individuals after an ablation procedure for AF.
Study design	Diagnostic accuracy evaluation, comparison of quality of readings and user satisfaction survey. For a comparison of the quality of monitor readings, the electrophysiologists responsible for interpreting the device readings were asked to comment on their quality compared to the TTM readings.
Setting	55 people recruited from a single US treatment centre after cardiac ablation were monitored for 3 months using the AliveCor Heart Monitor and TTM in a non-clinical setting. User satisfaction survey conducted 3–4 months after ablation procedure. Enrolment took place between July and November 2013.
Inclusion/ exclusion criteria	All of the people in the study had had an ablation procedure for AF. Inclusion criteria were ownership of an iPhone, age 18 to 75 years, history of paroxysmal or persistent AF and willingness to use the AliveCor Heart Monitor. People were excluded if they were unable or unwilling to use an iPhone or lived outside the USA.
Primary outcomes	<ul style="list-style-type: none"> • Sensitivity and specificity of the AliveCor Heart Monitor reading interpreted by electrophysiologists using TTMs as a reference test. • Level of agreement between the AliveCor Heart Monitor and TTMs. • Patient satisfaction with the AliveCor Heart Monitor. • Electrophysiologists' assessment of quality of the AliveCor Heart Monitor readings compared with TTMs.
Statistical methods	Power calculation carried out to determine a sample size to detect a sensitivity of at least 90% with the AliveCor Heart Monitor. The Kappa statistic of >0.8 was excellent agreement. TTM was assumed to have 100% sensitivity and specificity.
Patients included	Final analysis done on 384 simultaneous readings from 55 people. Although 60 people enrolled, 5 did not complete the study due to overseas travel (n=1), change of phone (n=1) and consent withdrawn (n=3). Five readings were excluded because of non-interpretability, 4 from the AliveCor Heart Monitor and 1 from TTM.

<p>Results</p>	<p>Diagnostic accuracy</p> <p>AF and flutter treated as a single condition:</p> <ul style="list-style-type: none"> • sensitivity: 100% (46/46; 95% CI 92.3%–100%) • specificity: 97.0% (328/338; 95% CI 94.6%–98.6%) • agreement between the AliveCor Heart Monitor and TTM: Kappa = 0.82. <p>User satisfaction(selected items)</p> <ul style="list-style-type: none"> • How easy was it to use each device? <ul style="list-style-type: none"> - Very easy: TTM 47%; AliveCor 80% - Moderately easy: TTM 35%; AliveCor 18% - Difficult: TTM 18%; AliveCor 2%. • How often did you have access to each monitor when you had symptoms and needed to transmit a recording? <ul style="list-style-type: none"> - Every time: TTM 45%; AliveCor 84% - Sometimes: TTM 40%; AliveCor 11% - Not at all: TTM 15%; AliveCor: 5%. • Which device would you prefer to use in the future? <ul style="list-style-type: none"> - TTM 8%; AliveCor 92%. <p>Electrophysiologists' interpretations of quality of readings</p> <ul style="list-style-type: none"> • 72.7% (40/55) were rated of equal quality • 14.6% (8/55) rated TTM readings of higher quality • 12.7% (7/55) rated the AliveCor Heart Monitor readings of higher quality.
<p>Conclusions</p>	<p>The AliveCor Heart Monitor could be a useful monitoring tool, with high sensitivity, specificity and user satisfaction. Authors noted concerns about data security, resourcing, insurance coverage and incorporating readings into medical records.</p>

Abbreviations: AF, atrial fibrillation; CI, confidence interval; ECG, electrocardiogram; TTM, traditional transtelephonic monitors

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

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Declarations of interest

No relevant interests declared.

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