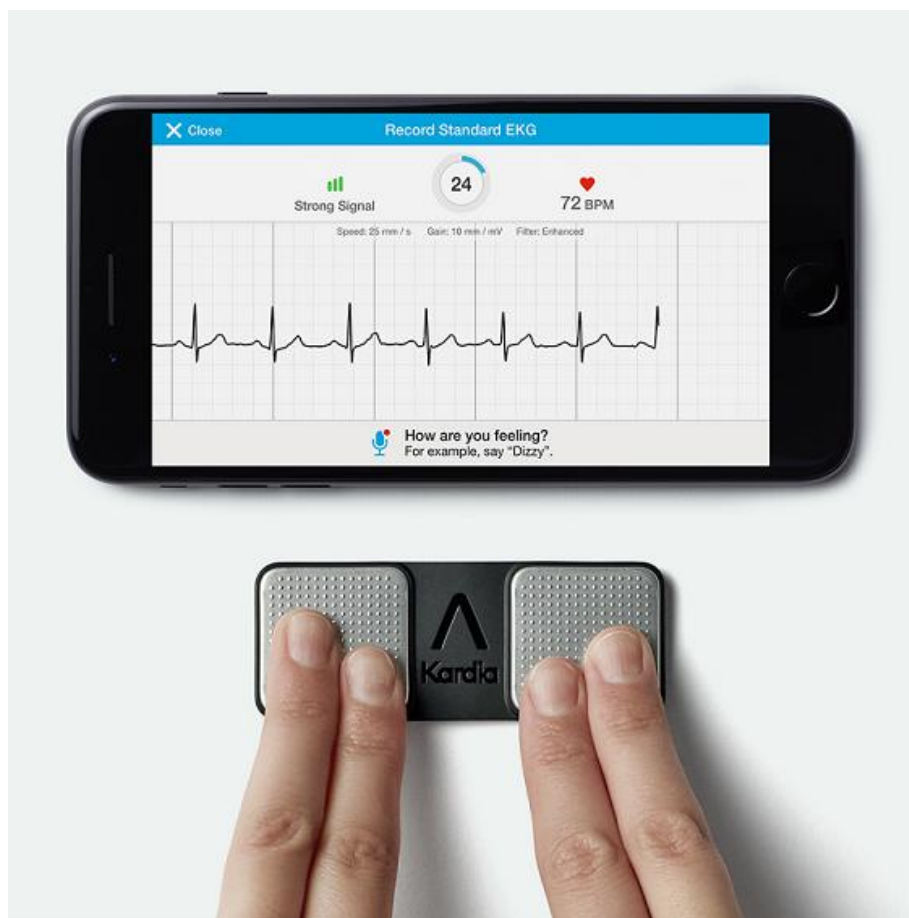


Implementation Toolkit

AliveCor's Kardia™



Introduction

NHS England's Innovation and Technology Tariff (ITT) went live on 1 April 2017. This new Tariff was introduced to incentivise the adoption and spread of transformational innovation in the NHS. The first two-year ITT runs from 2017 to 2019, with six themed product types identified as being suitable for at-scale introduction in the NHS and likely to result in great benefits for patients.

Four innovations on the NHS Innovation Accelerator (NIA) - an NHS England initiative supported by England's 15 Academic Health Science Networks (AHSNs) - meet the required theme specifications of the ITT.

These are: myCOPD, the Non-Injectable Arterial Connector (NIC), PneuX Prevention System, and Episcissors-60. Under the ITT, the first three innovations are funded under a zero cost model. Providers order the innovations directly from the supplier at no cost and NHS England reimburses the supplier directly. Episcissors-60 can be ordered via NHS Supply Chain, with providers reimbursed based on use.

In parallel, but separately from the ITT, NHS England is centrally funding the purchase of mobile ECG technology. A further NIA innovation, AliveCor's Kardia, meets the stringent specification of this technology, which will be available and managed via the AHSN Network.

The NIA has produced Implementation Toolkits for Episcissors-60, myCOPD, the Non-Injectable Arterial Connector (NIC), PneuX Prevention System, and AliveCor's Kardia. These toolkits detail how the innovations provide solutions to key challenges within our healthcare system; impact and outcomes, including cost savings, patient benefit and organisational advantage; an evidence summary and supporting testimonials; plus an overview of how to procure each innovation, including payment/price detail.

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Introducing the NHS Innovation Accelerator (NIA)

The NHS Innovation Accelerator (NIA) is an NHS England Initiative delivered in partnership with the Country's 15 Academic Health Science Networks (AHSNs), hosted by UCLPartners. It supports delivery of the *Five Year Forward View* by accelerating uptake of high impact innovations for patient, population and NHS staff benefit, and providing real time practical insights on spread to inform national strategy.

Fellows supported by the NIA all share a set of values and passion for scaling evidence-based innovation to benefit a wider population, with a commitment to share their learnings. Some impressive results have been achieved by the NIA Fellows in their first 20 months since July 2015, with 469 additional NHS commissioners and providers now using NIA innovations; £28.6m in external funds secured; 14 awards won; 51 jobs created; and ten innovations selling internationally. In addition, impact data is already available at adopter sites which demonstrates earlier intervention, reductions in complications and emergency admissions, alongside cost savings.

The NIA hosts 25 Fellows representing 26 innovations aimed at: activating people to self-manage; earlier intervention; long term conditions management and improving safety. The next NIA call, to be launched in June 2017, will select innovations that address the population challenges prioritised within the 44 Sustainability and Transformation Partnerships (STPs).

For more information about the NIA, email NIA@uclpartners.com

An overview of the Innovation and Technology Tariff (ITT)

The Innovation and Technology Tariff (ITT) has been introduced to incentivise the adoption and spread of transformational innovation in the NHS.

Introducing new innovative products to the NHS can often be hampered by the need for multiple local price negotiations. The ITT aims to remove this need, while guaranteeing that local NHS organisations will be reimbursed for the costs of purchasing an ITT-approved product type. At the same time, the ITT allows NHS England to optimise its purchasing power and negotiate national 'bulk buy' price discounts wherever possible on behalf of the whole NHS.

The first two-year ITT runs from 2017 to 2019. This first Tariff has been developed as a pathfinder, with six themed product types identified as being suitable for at-scale introduction in the NHS, and likely to result in great benefits for patients.

The ITT themes are:

- Guided mediolateral episiotomy to minimise the risk of obstetric anal sphincter injury
- Arterial connecting systems to reduce bacterial contamination and the accidental administration of medication
- Pneumonia prevention systems which are designed to stop ventilator-associated pneumonia
- Web-based applications for the self-management of chronic obstructive pulmonary disease
- Frozen Faecal microbiota transplantation (FMT) for recurrent Clostridium difficile infection rates
- Management of Benign prostatic hyperplasia as a day case

The ITT operates under a zero cost model for four of the six themes, which allows providers to order ITT innovations without the need for multiple financial transactions. The zero cost model has been established to minimise the number of transactions and create a more efficient system to administer across the NHS. Both the 'guided mediolateral episiotomy to minimise the risk of obstetric anal sphincter injury' and 'the Management of Benign prostatic hyperplasia as a day case' operate under separate arrangements.

Mobile ECG Technology

In parallel, but separately from the tariff, NHS England is centrally funding the purchase of mobile ECG technology to improve diagnosis of atrial fibrillation (AF). Taking repeat ECG recordings continuously over a 24-hour period or recording events over several days can increase the probability of detecting an arrhythmia, but needs small, portable ECG machines to be practical. The availability of this technology will be managed through the Academic Health Science Networks (AHSNs).

The NHS England Innovation and Technology Tariff 2017-2019 Technical Notes is available to download at: www.england.nhs.uk/resources/pay-syst/development/tech-tariff-17-19-technical-notes/

Introducing AliveCor's Kardia Mobile ECG

Challenge/problem identified

According to the National Cardiovascular Health Intelligence Network (NCVIN, 2016) co-ordinated by Public Health England, the estimated prevalence gap for people aged 64/+ with atrial fibrillation (AF) not yet diagnosed is 420,498. Left undetected and untreated, this presents a risk of over 12,600 AF-related strokes per year in England.

Early detection and monitoring can pave the way for better treatment for people with atrial fibrillation; avoidance of the illness, disability and premature death associated with AF-related strokes, and major healthcare savings. Conservatively, an AF-related stroke costs the NHS £12,228 (NICE CG 180) in the first year.

Solution

AliveCor's Kardia Mobile Electrocardiogram (ECG) device is a mobile heart monitor that allows individuals to detect, monitor, and manage heart arrhythmias with automatic analysis. AliveCor's Kardia captures ECG recordings of the heart using FDA-cleared machine algorithms in just 30 seconds, anytime and anywhere, providing instant feedback.

From a strip that can be optionally attached to the back of most Apple and Android devices, the device captures an ECG recording and detects atrial fibrillation simply by pressing two fingers from each hand on the device. The app-based service also allows its user to share the data with their doctor for analysis and diagnosis. The rhythm strip is produced as a PDF for diagnosis, sharing and storage into the electronic health record. The European Society of Cardiology, August 2016 AF guidelines state that a rhythm strip is sufficient to diagnose AF¹.

In addition to ECG recordings, the device can be used to capture shortness of breath, heart palpitations, dietary habits, sleep and exercise patterns.

Based on the number of published, peer-reviewed clinical studies using Kardia Mobile, Kardia is the most clinically-validated mobile ECG available.

Selected for the NIA in July 2015, it is currently being used in over 38 NHS organisations including GP practices and acute trusts across all 15 Academic Health Science Networks, enabling the recording of two million ECGs across the UK. This includes a trial within Care City NHS Test Bed in north east London, where the device is being used within community pharmacies to screen people over 65 years old.

The AliveCor Heart Monitor and AliveECG app (application) were CE-marked to AliveCor as a Class IIa medical device in January 2015 (NICE Medtech innovation briefing [MIB35]).

Impact and outcomes

Key statistics

- 835,000 people in England are currently living with AF
- An AF-related stroke costs the NHS £12,228 (NICE CG 180) in the first year
- AF can affect adults of any age but prevalence increases from 0.2% in people aged 45-54, to 14% in people aged over 85
- 90% of strokes can be prevented when symptoms are caught early enough to take proactive measures
- AliveCor's Kardia is being used in over 38 NHS organisations, including GP practices and acute trusts across all 15 Academic Health Science Networks (AHSNs)
- AliveCor's Kardia has recorded over two million ECGs in England, Scotland and Wales.

Testimonials

"I love my AliveCor and can't praise it highly enough, it's so quick and easy to use and always close to hand. Since having my AliveCor I feel in control and very reassured, before I had my device it was so hard trying to explain to medical staff how I felt and what was happening when I was having an atrial fibrillation episode."

Patient

"I found the AliveCor Mobile ECG very useful to illustrate the exact natures of my AF as it had not been recorded by any ECG taken at a hospital or surgery."

Patient

How to procure AliveCor's Kardia Mobile ECG

AliveCor's Kardia Mobile ECG will be made available as part of a centrally funded seventh theme - 'Identification and measurement of atrial fibrillation through mobile ECG technology' - in parallel, but separately from the Innovation and Technology Tariff.

The below is detailed within The NHS England Innovation and Technology Tariff 2017-2019 Technical Notes, available to download at:

www.england.nhs.uk/resources/pay-syst/development/tech-tariff-17-19-technical-notes/

Current status

This technology theme is not part of the ITT. Instead, NHS England is working with England's 15 Academic Health Science Networks (AHSNs) to procure mobile ECG technologies based on local CCG needs.

Further details on this will be released in due course. In the meantime, email england.innovation@nhs.net for further information.

Additional information

NICE has produced the following guidance on the management of Atrial Fibrillation: www.nice.org.uk/guidance/CG180/chapter/introduction

Evidence summary

- **Automated atrial fibrillation algorithm accuracy:** Kardia Mobile's automated algorithm for atrial fibrillation has a high sensitivity of 98% and a high specificity of 97%².
- **Atrial fibrillation screening:** Study which screened over 13,000 Hong Kong citizens for AF discovered newly diagnosed AF in 0.8%. Conclusion: Kardia Mobile can be used for community-wide AF screening by non-medical volunteers³.
- **Atrial fibrillation screening:** Study screened around 1,000 patients aged over 65 in Sydney, Australia. New AF was discovered in 0.8%. The sensitivity and specificity of the automated algorithm for detecting AF was 95% and 99% respectively. Conclusion: Kardia Mobile can be used to screen for AF at the time of influenza vaccination by primary care nurses⁴.
- **Atrial fibrillation screening:** Study screened 1,000 pharmacy customers ages over 65. Newly identified AF was found in 1.5%. Conclusions: Kardia Mobile can be used by pharmacists to screen for AF in pharmacy customers; screening for AF using Kardia Mobile is cost-effective⁵.
- **Atrial fibrillation screening:** Study screened 9,000 patients aged over 65 in Hong Kong attending medical clinics. Newly identified AF was found in 1.5%, and an additional 1.2% was detected in those screened on multiple occasions. Conclusions: Kardia Mobile can be used for mass AF screening of patients in medical clinics; repeated AF screening with Kardia Mobile increases diagnostic yield⁶.
- **Evaluation of palpitations:** 32-person study evaluating the diagnostic yield of Kardia Mobile versus a 14-day event monitor, with the use of both devices simultaneously, found that: Kardia Mobile is non-inferior to use of a 14-day event monitor for diagnosis of symptomatic arrhythmias, including AF; Kardia Mobile is associated with better patient compliance than a traditional event monitor; patients are more likely to use Kardia Mobile than a traditional event monitor in social or work situations⁷.
- **Evaluation of palpitations:** 20-person UK study evaluated patients with palpitations using simultaneous Holter and Kardia Mobile monitoring, found that: Kardia Mobile used over 12 weeks has greater diagnostic yield for arrhythmias than a seven-day Holter monitor (45% vs. 10% of patients); the number of uninterpretable Kardia Mobile ECGs over a 12-week period is low (4%); provider workload for Kardia Mobile (12 weeks) versus Holter (7 days) is comparable (43 vs. 39 minutes)⁸.
- **Atrial Fibrillation monitoring:** Study evaluating self-monitoring for recurrent post-operative AF in 42 participants, for four weeks after cardiac surgery, found that: Kardia Mobile is a non-invasive, inexpensive, convenient, and feasible way to monitor for recurrent AF after cardiac surgery; Kardia Mobile empowers patients by giving them the ability to monitor their heart rate and rhythm, and providing feedback on the presence or absence of AF⁹.
- **Atrial Fibrillation monitoring:** During a study which evaluated 55 patients with AF after they underwent ablation, the patients recorded their rhythm using Kardia Mobile and a traditional transtelephonic monitor (TTM) whenever they had symptoms, or at least one a week, for three to four months following ablation. Of the 389 simultaneous recordings with Kardia Mobile and TTM, there was excellent agreement (K statistic 0.82). Conclusion: Kardia

Mobile is an alternative method to transtelephonic monitoring for evaluation of recurrent AF after AF ablation¹⁰.

- **Patient compliance and preference:** Kardia Mobile is preferred by the majority of patients (92%) over traditional transtelephonic monitoring; patients find Kardia Mobile easy to use compared with traditional transtelephonic monitoring; Kardia Mobile is preferred by patients over traditional transtelephonic monitoring because it is easy to access, patients can see what they record, and patients feel like active participants in their care¹⁰.
- **Patient compliance and preference:** Kardia Mobile is associated with better patient compliance than a traditional event monitor (94% vs. 58%)⁷.
- **Patient compliance and preference:** Kardia Mobile is easier to use than a traditional event monitor; patients are more likely to use Kardia Mobile than a traditional event monitor in social or work situations (81% vs. 33%)⁷.
- **Patient compliance and preference:** Patients prefer Kardia Mobile over Holter monitoring because it is less intrusive, and because it is accessible and easy to use, and with them for a longer period of time⁸.

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Useful links

- Identifying the early signs of Atrial Fibrillation, Healthy Communities, Healthy People news programme, New NHS Alliance Action Summit:
<https://www.youtube.com/watch?v=qEaME6C6bw4>
- Kardia General Practice user guide:
http://wmahsn.org/news/2016/07/22/Guide_to_innovate_ECG_device_now_available
- Meet Kardia Mobile, AliveCor Inc. YouTube channel: www.youtube.com/alivecor
- Clinical research testing accuracy, screening, and monitoring abilities of AliveCor's Kardia Mobile ECG: <https://www.alivecor.com/research/>
- NICE Medtech innovation briefing [MIB35]:
<https://www.nice.org.uk/advice/MIB35/chapter/Technology-overview#costs-and-use-of-the-technology>

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