



NHS Innovation Accelerator

Economic Impact Evaluation Case Study: AliveCor Kardia Mobile

1. BACKGROUND

The AliveCor Kardia Mobile ECG (Kardia Mobile) is a portable single-channel cardiac event recorder that can be used in conjunction with a compatible mobile device and the free Kardia app, to record and transmit electrocardiograms (ECG).¹ The device attaches to the back of a mobile phone and is held in the hands, taking an ECG recording in 30 seconds. It produces a single-lead rhythm strip which is considered sufficient for the diagnosis of AF.²

Kardia Mobile can be used to help diagnose patients with a suspected arrhythmia, such as atrial fibrillation (AF), in a primary care setting. It is designed for health professionals to use in clinical practice and may be given or lent to patients, enabling them to monitor their heart rhythm at home or in a diverse range of community settings. The process for diagnosis of AF can be lengthy and prevalence data suggest that there are many undiagnosed cases in England. Kardia Mobile provides an alternative approach to the typical AF diagnosis pathway, helping to guide the appropriate use of diagnostic tests and cardiology referrals, thereby reducing avoidable healthcare utilisation. Earlier detection and management of AF can reduce subsequent cardiovascular events and for those with a diagnosed arrhythmia it can also help to reduce anxiety and prevent unnecessary healthcare utilisation such as attendance at the Emergency Department.

The aim of participating in the NIA programme was to increase the spread and availability of this handheld ECG device in general practice. The use of Kardia Mobile has increased considerably in the last 18 months, with 10,000 units sold in the UK and 1,911,283 ECGs being recorded in Great Britain, compared to approximately 300,000 18 months ago.³ It is now being used across 40 different NHS locations and by approximately 20% of the CCGs in England.⁴

¹ NICE 2015. *Medtech Innovation Briefing. The AliveCor Heart Monitor and AliveECG App (Kardia Mobile) for the detection of atrial fibrillation.*

² Freedman B et al. *White paper: Screening for atrial fibrillation: A report of the AF-SCREEN International Collaboration* Download from <http://circ.ahajournals.org/>. May 2017.

³ White F. *NIA economic analysis framework: AliveCor's Kardia.* March 2017.

⁴ NIA Fellow. 17 May 2017.

This case study focuses on the potential return on investment of replacing a ‘typical AF diagnostic pathway’ with a Kardia Mobile pathway, for the purposes of diagnosing AF. The analysis was developed in spring 2017 and was based on the information and evidence available at the time.

The limitations of the analysis are as follows:

- The analysis does not include the diagnostic performance of the Kardia Mobile compared to other tests in use by GPs e.g. pulse check. There is however, good evidence for the sensitivity and specificity of the ECG algorithm used by Kardia Mobile;^{5 6}
- The information on the ‘typical AF diagnostic pathway’ includes assumptions and may not be typical in all locations;
- The analysis does not include the value of patient benefits accrued from reduced anxiety and avoided cardiovascular events.

2. INPUT COSTS

The Kardia Mobile innovation was developed in the USA, with a total of \$45m being put into the AliveCor company by investors. The cost relating specifically to the development of Kardia Mobile was not available at the time of writing.

In April 2017, the retail price for one Kardia Mobile device was £99 including VAT, with an expected life of over five years. The Kardia app is free of charge. The proposed input costs for a diagnostic pathway using Kardia Mobile are listed in Table 2.1.

Table 2.1: Input costs for Kardia Mobile pathway

Inputs	Description	Cost
Equipment	Cost AliveCor Kardia mobile: unit cost - £99 including VAT (expected life 5+ years)	£99
Healthcare appointment	GP appointments x 2 @ £36 each, based on 9.22 minute appointment ⁷	£72
Software	Kardia app to review and record ECGs	No charge
Staff	Additional time taken in consultation to show the patient how to use the device	Not applicable (see assumptions)
Total		£171

3. OUTCOME METRICS

The ‘typical’ pathway for diagnosis of AF will vary from one CCG area to another, depending on the existence of services such as direct access to ECG tests in secondary care, community cardiology services and cardiology e-consultation. The pathway costed as the counterfactual scenario in this case study is an updated version of an economic case provided by the Fellow.⁸ From this it is evident that the potential for resource savings comes from reduction in appointments in primary care,

⁵ Saxon LA. *Ubiquitous wireless ECG recording: a powerful tool that physicians should embrace.* doi: 10.1111/jce.12097.

⁶ Lau KL et al. iPhone ECG application for community screening to detect silent atrial fibrillation: A novel technology to prevent stroke. *International Journal of Cardiology* 165 (2013) 193-212.

⁷ PSSRU. *Unit Costs of Health & Social Care* 2016.

⁸ UCL Partners. *AliveCor's Kardia mobile ECG: Economic Case.* August 2016.

secondary care and also avoided diagnostic tests for those with symptoms. The outcome metrics for a 'typical AF diagnostic pathway' have been valued as in Table 3.1. The number of these appointments and tests has been varied in the sensitivity analysis. Information on the steps in a 'typical AF diagnostic pathway' was provided by the NIA Fellow.

The improved detection and management of AF has the potential to bring both patient benefit and savings to the NHS and social care by reducing incidence of AF complications such as stroke. From the information available is not possible to estimate the numbers of strokes prevented as a result of using Kardia Mobile in England. However, as an indication of costs that may be avoided for one patient, the 10 year management cost of undiagnosed AF is estimated to be £5,842.⁹ The cost of an admission for stroke is £3,723.¹⁰

For cases of diagnosed AF, there will be further costs incurred in the pathway over the following years. AF management costs over 10 years are estimated to be £5,544.47,¹¹ so increasing detection of AF will itself incur some healthcare costs, albeit slightly less than the 10 year cost of undiagnosed AF. There may however, be intangible benefits of Kardia Mobile for patients diagnosed with AF, as it provides a means of patients monitoring their condition at home, thereby reducing anxiety and potentially improving quality of life.

Table 3.1: Impacts, outcome metrics and values for a 'typical AF diagnostic pathway'

Impact	Outcome metric	Proxy value
Avoided healthcare appointments	GP appointments x 2 @ £36 each, based on 9.22 minute appointment ¹²	£72
	First cardiology outpatient appointment x 1 £230 ¹³	£230
	Follow-up cardiology outpatient appointment x 2 @ £148 ¹⁴	£296
Avoided cardiology investigations	ECG diagnostic x 1 @ £52 ¹⁵	£52
	24 hour ECG x 1 @ £163 ¹⁶	£163
	7 day ECG x 2 @ £163 ¹⁷	£326
Total		£1,139

It should be noted that diagnostic tests will generate some false positive and false negative results. In the case of a false positive, an unnecessary ECG may be undertaken, incurring additional cost in order to establish that the patient does not have an arrhythmia. In the case of a false negative, potential harm could arise to a patient who remains undiagnosed. Lau et al reported high sensitivity, specificity and accuracy of the algorithm,¹⁸ although comparable data with the typical AF pathway/pulse check was not available for this analysis.

⁹ Source: Willits et al. (2012) available from: <https://www.nice.org.uk/guidance/MTG13/documents/watchbp-home-a-for-diagnosing-and-monitoring-hypertension-and-detecting-atrial-fibrillation-eac-additional-analysis-cost-impact-in-primary-care2>. Cost inflated to 2014-15 prices = £5,842.

¹⁰ Weighted average of 2015/16 NHS Reference Cost for non-elective stroke admission (Currency code AA22).

¹¹ 10 year management cost (including treatment with warfarin and complications that may arise - bleeding/stroke). Source = Willits et al. (2012) available from: <https://www.nice.org.uk/guidance/MTG13/documents/watchbp-home-a-for-diagnosing-and-monitoring-hypertension-and-detecting-atrial-fibrillation-eac-additional-analysis-cost-impact-in-primary-care2>. Inflated to 2014-15 prices = £5,544.47

¹² PSSRU. *Unit Costs of Health & Social Care* 2016.

¹³ NHS *Payment By Results Tariff, 2016/17*.

¹⁴ Ibid.

¹⁵ NHS *Reference Costs 2015/16*.

¹⁶ NHS *Payment By Results Tariff, 2016/17*.

¹⁷ Ibid.

¹⁸ Lau KL et al. iPhone ECG application for community screening to detect silent atrial fibrillation: A novel technology to prevent stroke. *International Journal of Cardiology* 165 (2013) 193-212.

4. ECONOMIC ANALYSIS

The information available enables a simple return on investment calculation to be performed, based on the input costs of using the Kardia mobile pathway and the value of the benefits accrued by not using the 'typical AF diagnostic pathway'.

A number of assumptions are necessary for the purpose of undertaking a base case analysis, as follows:

- The 'typical AF diagnostic pathway' is as described in the Kardia Mobile economic case. This involves two GP appointments, a 24-hour ECG, referral and follow-up out-patient cardiology appointments in secondary care and two 7-day ECG tests(s). The number of appointments and tests varied in the sensitivity analysis;
- The Kardia Mobile pathway does not require a follow-up 12-lead ECG, 24 or 7 day ECG to confirm the AF diagnosis. This is reliant upon the ability of the clinician using the device to interpret the ECG rhythm strip, then trusting the output from the device and being willing to follow an alternative diagnostic pathway;
- One Kardia Mobile is used per patient. This is a conservative assumption, as it is more likely that the device would be returned and used with another patient, hence reducing the cost per patient. Furthermore, if the device was used in a clinical setting, it is likely that one device will be used with several patients;
- There is no additional staff time (and cost) for showing the patient how to use the device as (in theory) pulse checks are performed, take the equivalent time and can be superseded by the use of Kardia Mobile;
- All out-patient appointments other than the first appointment are follow-up appointments;
- The patients requiring an implantable loop recorder for diagnosis would most likely require referral to secondary care and would not be those patients who can be managed solely by primary care. The number of these patients is expected to be low and hence they are not included in the typical pathway for the purposes of this case study.

Based on the above assumptions and using the stated input costs and outcome values, the financial impact of Kardia Mobile per patient being investigated for suspected AF is as follows:

Table 4.1: Financial impact of Kardia Mobile per patient investigated for AF

Item	Value
Cost of the Kardia Mobile pathway per patient investigated for AF	£171
Total value of the outcome metrics per patient investigated for AF	£1,139
Financial impact: net benefit/(deficit) per patient	£968
Return on investment in Year 1	666%

The analysis shows Kardia Mobile to give a positive return on investment and be cost saving on a per patient basis from an NHS perspective, based on the pathway described and the assumptions stated.

The use of Kardia Mobile in a typical Clinical Commissioning Group area therefore has the potential to achieve savings, if implemented at scale, by avoiding diagnostics and referrals to secondary care. For example, if 250 patients per year follow the Kardia pathway rather than the 'typical AF diagnostic pathway', the value of the savings would be £242,000 per year, rising to approximately £1,210,000 over a period of five years.

4.1 Sensitivity Analysis

The assumptions made in the analysis can be varied to allow for over or under estimation of the impacts and costs, or variations in the typical care pathway. The following scenarios have been tested to observe the effect on the financial impact and return on investment:

- Number of patients per year: if the number of patients following the Kardia Mobile pathway rather than the typical AF diagnostic pathway was 100 per year, the value of savings would be £96,800 per year, and £484,000 over five years;
- Number of patients per device: if one device was used in a GP consulting room, with 100 patients in a year (approximately twice a week), the cost reduces to £1 per patient and the ROI would be 1,560%, generating a net benefit of £106,601 per year;
- Number of diagnostic tests in the typical pathway: if the number of 7-day ECGs tests and associated cardiology out-patient appointments is reduced to one each, the ROI decreases to 484%;
- Proportion of patients in the typical pathway requiring all the tests described: if only 50% of the patients in a typical AF diagnostic pathway require all of the tests described in the Kardia economic case, the ROI reduces to 333% and the net benefit per patient in the Kardia pathway reduces to £399.

4. IMPACT ON EMPLOYMENT

The AliveCor Ltd company has increased staffing in England from one to two whole time equivalents (WTEs), in the last year, plus approximately two WTEs from other England service providers:

- You Business Voice, Yorkshire, Call Centre Service provider;
- Technomed ECG reporting service provider;
- Oury Clark Accountancy.

AliveCor Ltd also has its international logistics based in the UK (Core Fulfilment Ltd) serving Europe, the Middle East and Asia.

5. CONCLUSION

The analysis undertaken concludes that Kardia Mobile is a cost saving innovation, showing estimated net benefit of £968 per patient investigated and potential ROI from an NHS perspective of 666%, based on the assumptions stated. There are also intangible patient benefits of reduced anxiety and the potential for avoided cardiovascular events, which have not been costed in this analysis.

The ability to achieve this return is supported by audit data from two CCGs using Kardia Mobile in primary care. One CCG audit found that 70% of patients being investigated for symptoms of possible AF were subsequently managed in primary care, without onward referral. A second CCG found that 84% of patients being investigated for symptoms of possible AF avoided referral to hospital following an ECG with Kardia Mobile, saving an estimated £8,085 in three months.¹⁹

As stated in the assumptions, the return on investment is dependent on the clinician trusting the output from the device and not referring patients for a confirmation ECG. It is also dependent on the assumptions made about the usual care pathway, which contains a number of diagnostic tests and healthcare appointments. Sensitivity analysis shows that the return on investment is lower, but still positive, when the proportion of patients requiring all of these tests in the usual care pathway is reduced.

Further research into the effectiveness and cost per diagnosis of Kardia Mobile is currently underway.²⁰ An NIHR study will include, amongst other outcome measures, the financial cost per diagnosis of symptomatic rhythm using the smart phone based event recorder versus standard care, and also the composite 90 day serious outcome.

The use of Kardia Mobile in primary care has increased significantly following involvement in the NIA programme, with an estimated 20% of CCGs now using it. Although it is not possible to estimate the number of ECGs and avoided referrals resulting from this growth in activity, this analysis gives an indication of the potential for avoided healthcare utilisation if implemented at scale.

As previously mentioned, there are some limitations within the analysis, relating to the diagnostic performance of Kardia Mobile and the omission of the value of patient benefits. Any assumptions have been clearly stated.

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¹⁹ NIA Fellow. 17 May 2017

²⁰ NIHR. The IPED (Investigations of Palpitations in the ED) Study. UK Clinical Trials Gateway [Accessed on 24 April at: <https://ukctg.nihr.ac.uk/trials/trial-details/trial-details?trialNumber=NCT02783898>].