Wessex Academic Health Science Network

NHS

Independent Evaluation of the AHSN Network mobile ECG roll-out programme

Full Report:

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EVALUATION TEAM

Andrew Liles, Strategic Advisor, Wessex Academic Health Science Network

Philippa Darnton, Associate Director - Insight, Wessex Academic Health Science Network

Dr Andrew Sibley, Programme Manager, Wessex Academic Health Science Network

Sarah Harraway, Senior Programme Manager, Wessex Academic Health Science Network

Philippa Moran, Senior Programme Manager, Wessex Academic Health Science Network

Joe Sladen, Associate Director Strategic Programmes, Wessex Academic Health Science Network

Tim Benson, Director, R-Outcomes Ltd

CORRESPONDENCE

Philippa Darnton, Associate Director - Insight

Wessex Academic Health Science Network,

Innovation Centre, 2 Venture Road, Southampton Science Park, SO16 7NP

DISCLAIMER

This report presents the findings of an independent evaluation of the AHSN Network mobile ECG devices rollout programme. The findings of this independent evaluation are those of the evaluation team and do not necessarily represent the views of the AHSN Network.

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We would like to thank the AHSN rollout leads, deployment locations, and mobile ECG device users for their participation and support in this evaluation.

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EXECUTIVE SUMMARY

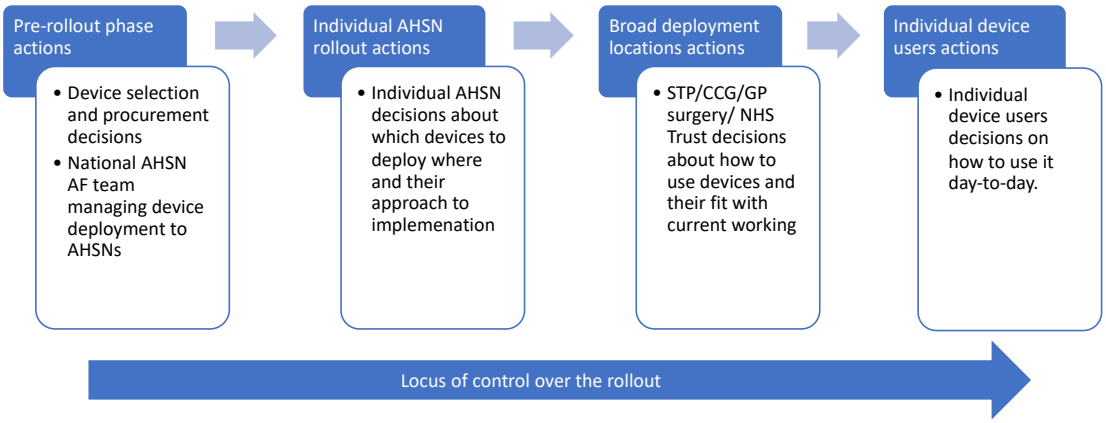
OVERVIEW OF THE MOBILE ECG ROLLOUT PROGRAMME

The national roll out of mobile ECG devices by Academic Health Science Networks (AHSNs) was born out of a system-wide procurement initiative to promote the uptake of a digital technology (mobile ECG). This was a novel approach to facilitate innovation adoption which prompted the AHSN Network to commission an independent evaluation of the roll out, at AHSN level, to understand its effectiveness, and in particular what can be learned about: the environments in which the devices are most effective, what characterises an effective implementation package, the impact on the market place, patients (through AF detection) and providers; and the health economic aspects of this type of programme.

The programme origins are described as Simon Stevens' speech at the NHS Confederation Conference in June 2016, when he held up a KardiaMobile device as an example of an innovation that should be spread. Shortly afterwards, NHS England identified £500,000 to purchase and make available a large number of Kardia mobile-ECG devices to be rolled out, and through the influence of the AHSN commercial directors the procurement was extended to include five mobile-ECG devices.

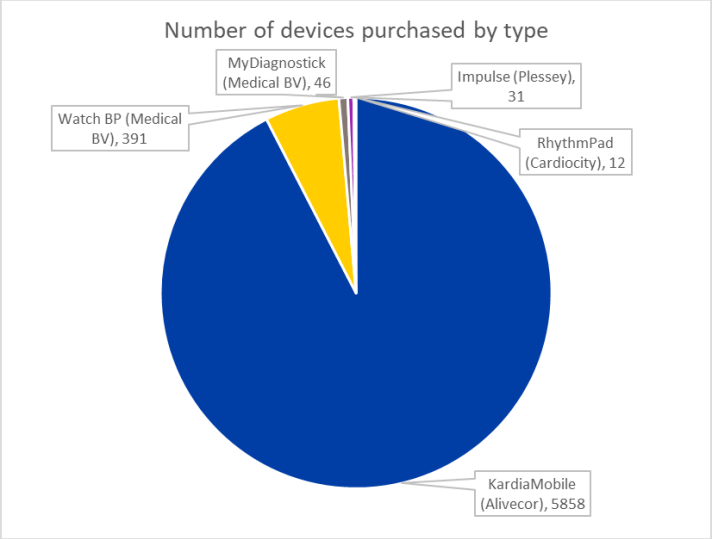
The AHSN Network had an established AF programme and in early 2017 were asked by NHS England to lead on rolling-out these devices in each of their 15 AHSN regions.

The following figure describes how the programme progressed, from NHS England and the national shaping and planning of the programme; to the work by individual AHSNs to plan their roll-outs and engage local organisations and support device users; to the organisations within which the devices were used (CCG's, General Practice, Trusts etc.) to the individual staff and volunteers that used the devices to take readings.



A common theme of the evaluation was the impact of the decisions made during the pre-rollout phase and in particular, the extended time frame between AHSNs approaching their local CCGs and Trusts to get their expressions of interest in Spring 2017 and when the devices began to arrive in January 2018. There were two main contributions to this delay 1) one company raised several Data Protection Act concerns with NHS England that took time to resolve and 2) protracted negotiations for the KardiaMobile devices after the procurement team were engaged in May 2017. As well, The AHSN Network AF Steering Group was in place only from August 2017 and an early task was to develop methods for data collection on device usage.

In March/ April 2017 the AHSN Network AF team sent each AHSN details of their indicative budget and of the 5 devices that had been selected for inclusion in the programme. They were asked to decide how many of each device they would want procured for them to distribute. KardiaMobile devices accounted for 92% of the selected devices.



The scale of the programme was large and complicated, with 6,338 devices procured for roll out across 15 AHSN areas, in multiple deployment environments and engaging thousands of device users. The following table describes the distribution and utilisation of the mobile-ECG devices in each AHSN:

AHSN	Devices procured	Devices distributed	% of procured devices distributed	Average readings per registered device	No. and % of readings that detected possible AF
East Midlands	535	287	54%	12	221/ 9%
Eastern	503	503	100%	28	393/ 6%
Health Innovation Manchester	340	340	100%	19	151/ 7%
Health Innovation Network	413	413	100%	39	535/ 5%
Imperial College Health Partners	275	219	80%	26	139/ 5%
Innovation Agency	382	282	74%	7	101/ 7%
Kent, Surrey and Sussex	556	556	100%	30	742/ 10%
North East and North Cumbria	370	374	101%	54	1175/ 6%
Oxford	222	202	91%	13	75/ 14%
South West	248	250	101%	72	459/ 6%
UCLPartners	670	536	80%	12	231/ 6%
Wessex	350	310	89%	23	311/ 10%
West Midlands	589	586	99%	26	288/ 8%
West of England	285	223	78%	16	111/ 9%
Yorkshire and Humber	600	515	86%	23	612/ 9%
TOTAL	**6,338**	**5,596**	**88%**	**26**	

Note: Device distribution covers all devices; utilisation data is only for the registered KardiaMobile devices.

Although there was national co-ordination by the AHSN Network of some aspects of the roll-out, there were variations in uptake between individual AHSNs. This table shows that:

- 12% (742) of the devices procured weren't distributed by AHSNs
- Device distribution varied from 54% to 101%.
- Average readings per device varied from 12 to 72
- Possible AF detection rates varied from 5% to 14%

The evaluation evidence helps to explain how local circumstances (environments) and approaches to implementation contributed to device uptake, and consequently AF detection. They also provide learning points for future digital innovation implementation programmes.

THE EVALUATION METHODOLOGY

The evaluation used a mixed methods concurrent triangulation design to simultaneously collect quantitative data, qualitative data and synthesise findings to address the six evaluation questions.

In order to understand the experience of the programme at AHSN level and the impact on providers, it was agreed that the qualitative fieldwork would focus on the AHSN roll out teams and the device users. Data was collected through interviews or focus groups with 57 AHSN roll out leads and 125 device users and these captured evidence about the environmental and implementation themes.

622 users completed on-line surveys measuring four domains relating to the adoption of digital innovation: **digital confidence** (digital literacy and confidence to use digital products), **innovation readiness** (how much they are open to and up to date with new ideas, and whether their organisation is receptive to and has innovation capabilities), **innovation adoption** (how they found the process of adopting mobile ECG devices to make them work in practice) and **product rating** (usefulness, ease of use, support and satisfaction).

In addition, interviews were undertaken with the five device suppliers and five AHSN Commercial Directors to inform an assessment of whether the programme stimulated the market in this area. The perspectives of four national programme leads were also collected.

The quantitative analysis included automated and manually collected data on device utilisation and AF detection taken over a 14 month period (January 2018- March 2019).

To understand the **environments** in which the devices were rolled out and the **implementation approaches** taken by rollout leads, themes identified in the qualitative fieldwork were combined with quantitative data sources for each AHSN. The combined position of these findings generated and explained **typologies** for each AHSN.

There were a number of **serious issues with the quantitative data collection** throughout the programme which caveat the results of this evaluation. Use of the KardiaMobile devices required their registration with their supplier AliveCor, but only 56% of them were registered, meaning that no data was available to the analysis for unregistered devices. The quarterly manual data collection by AHSNs of the other four devices was often incomplete. The qualitative interviews identified a tendency for device users to repeat a test when they got a 'possible AF' reading, which would overstate the number of possible AF detections. Other issues are set out in the full report.

WHAT WE LEARNT ABOUT WHERE THESE DEVICES WERE DEPLOYED AND THE EXPERIENCE OF THOSE USING THEM

This table summarises the settings within which the devices were used:

Setting	No. of users	Ave readings per user	Possible AF Detection %
General Practice	1,201	38	6.9%
Domiciliary	166	41	5.9%
Community based clinics	111	34	6.3%
Acute Hospital	73	58	7.1%
Community Pharmacy	51	64	6.0%
Other	91	45	8.2%
Not recorded	395	44	7.1%
Total	**2,088**	**38**	**6.8%**

General Practice was by far the most common setting (58%).

Utilisation of the devices (average readings per user) was highest in Community Pharmacies.

This table summarises the data on who used the devices:

Occupational group	No. of users	Ave readings per user	Possible AF Detection %
Doctors	759	36	6.8%
Health Care Assistants	417	42	5.9%
Registered Nurses	161	38	9.9%
Pharmacist	93	57	6.1%
Admin, Clerical and management	48	57	6.5%
Other	260	16	8.3%
Not recorded	395	46	6.5%
Total	**2,133**	**38**	**6.8%**

Doctors were the largest group of users (36%) followed by Health Care Assistants (20%). Detection rates were similar across user groups and settings. Registered nurses were the highest, though this may be a factor of their subjects' demography – older and symptomatic.

622 users completed surveys covering the four measures of innovation adoption. Their digital confidence was generally high as was their innovation readiness (open to and receptive to new ideas). Their satisfaction rating of the mobile ECG device they used was mostly positive, particularly its ease of use, but was lower for being able to get help if needed. They were least positive about their experience of the process of adopting the ECG devices.

Doctors' scores were less positive across the board, particularly their experience of the adoption process and of being able to access help. Their satisfaction with the devices was lower and they were more likely to stop using the device early. However, the evaluation found a lot of evidence that these devices can be effectively used by many other staff groups, such as Health Care Assistants.

There were large differences between the perceptions of users depending upon how much they reported using their device. Two-thirds of the respondents used their device less than 25 times. While their digital confidence is similar to the higher use group, they reported lower innovation readiness, a much poorer experience of the adoption process and much lower product satisfaction. Doctors were the biggest group to stop before 25 readings (77%) and the smallest were the Health Care Assistants (55%).

Some doctors raised concerns about the impact of device use on an already stretched workload by generating additional tasks such as checking traces or confirmatory 12-lead testing. Conversely, others recognised that their use could avoid unnecessary 12-lead testing.

Whilst most devices were deployed in a general practice setting and used by doctors, the ability of a wide range of occupational groups to use the devices (e.g. health care assistants, pharmacy technicians, social prescribers) enabled them to be used in settings not usually visited by primary care e.g. football matches, park run, and supermarkets. A range of positive impacts, including raising awareness of AF and wider health issues, were reported to staff by patients.

WHAT WE LEARNT ABOUT THE ENVIRONMENTAL CONTEXT IN WHICH AHSNS IMPLEMENTED THEIR ROLL-OUT

The qualitative fieldwork identified a number of important **common environmental themes** that impacted on the roll-out programmes in each AHSN. The programmes were large and complicated, involving many commissioner and provider organisations, and hundreds of device users, many of whom had no prior relationship with their AHSN.

A number of common themes described high levels of ambiguity with the practical deployment of the devices. All of the focus groups/interviews revealed mixed views on the clinical application and advantage of the devices. Some clinicians were happy to use the devices together with their clinical judgement to make decisions. Others wanted more information on the relative value of the device compared to manual pulse checks. There was ambiguity over whether these lead-I devices were a replacement for 12-lead assessments and how these devices should fit in with the wider local AF pathway.

We found high levels of ambiguity arose despite the provision of implementation guidance by the AHSN Network roll-out team at the start of the roll out in January 2018 that sought to resolve or reduce this. This may reflect the wider debate about who may benefit from AF screening. People reported that this guidance did not always filter down, or failed to be understood, or agreed upon, or followed by deployment locations.

The evaluation sought to understand **key environmental themes that varied between AHSNs** and the impact this could have on the effectiveness of their roll-out programmes. Five were identified:

1. Clinical leadership support	The degree to which the AHSNs were working with deployment locations with clinical leadership available and engaged. Limited clinical leadership support, often due to an absence of appropriate personnel, was present in AHSNs with poorer device utilisation.
2. Relationships with deployment locations	The reported level of engagement and relationship quality with deployment locations. AHSNs with positive existing relationships and/or able to generate positive relationships with deployment locations during the rollout reported better device utilisation.
3. Burden of local information governance	The extent to which additional Information Governance (IG) approvals were required at the local level, despite many IG issues being addressed in a supporting document by the AHSN Network AF programme team. AHSNs working with deployment locations with additional, often unexpected, IG requests and processes experienced rollout delays and poorer device utilisation.
4. Readiness to integrate into AF pathway	The degree to which deployment locations were ready and/or willing to integrate ECG devices into existing AF pathways. Deployment locations that did integrate, often re-organise, their AF pathway had better device utilisation. Deployment locations with limited interest in pathway integration reported more ambiguity about how to use the device and had poorer device utilisation.
5. Technological readiness and willingness of deployment locations	The reported level of technological readiness and willingness in deployment locations. Those with poor readiness (e.g. poor internet access, not willing to use personal smartphones with KardiaMobile, no access to NHS.email accounts) had poorer device utilisation.

Evidence about these qualitative themes in each AHSN was synthesised with the quantitative data on device utilisation and the user innovation survey results to identify **five typologies** – describing different types of environment at AHSN regional level. AHSNs with the best levels of utilisation were typified by strong clinical leadership in the deployment locations, strong relationships and engagement with deployment locations, and structures in place which enabled the roll out (low burden of local IG, readiness to integrate the devices into the AF pathway and good technological readiness). Conversely, those with the lowest levels of utilisation were typified by relatively light engagement with deployment locations and structures which hindered the roll out. These are described in the full report.

WHAT WE LEARNT ABOUT AHSN APPROACHES TO IMPLEMENTATION

Each AHSN decided where they were going to deploy the devices by inviting expressions of interest form their local organisations about the type of devices, number of devices and preferred locations.

The qualitative fieldwork identified a number of important **common implementation themes** that impacted on the roll-out programmes in each AHSN. A very strong theme was the impact of the **extended timescales** between AHSNs engaging and seeking expressions of interest from their local organisations in March/April 2017 and the devices beginning to arrive in January 2018. This was due to the length of time it took to procure the devices and to establish the information governance compliance of the programme, including written complaints and a Freedom of Information request about whether the programme was compliant with the Data

Protection Act. AHSNs described how the communication around these delays was not always clear and how it led to some disengagement and withdrawal by users.

All AHSN roll-out leads shared the view they were under-resourced to manage such a wide-ranging roll-out. The view was that more devices could have been deployed and better utilised if more roll-out staff were available. The AHSN Network AF Steering Group recognised that the starting points across AHSNs were different, some were more interested in the programme than others and some were more flexible in how they staffed and supported the programme.

The KardiaMobile devices require a smartphone or tablet to run the associated app. The decision was taken to not include these in the programme, but to rely on people using their personal devices or NHS provided devices (many of which did not meet the required technical specification). Many staff were unwilling to use their personal device for work purposes and this was reported as a key brake on the roll-out and utilisation of devices.

The evaluation sought to understand **key implementation themes that varied between AHSNs** and the impact this could have on the effectiveness of their roll-out programmes. Five were identified:

1. Rollout responsibility	The degree to which the AHSN retained or delegated responsibility for the rollout as the programme progressed and devices were deployed in CCGs, Trusts and practices. Delegation was associated with poorer device utilisation.
2. General approach to support for deployment locations	The level and style of support provided by the AHSN, including face to face support, remote distance support, and/or flexible or fixed support. Face-to-face support was associated with better device utilisation.
3. Training and device registration approach	The level of and style of support for training and device registration as key elements of AHSN rollout work. This theme highlighted to what degree AHSNs undertook flexible, tailored and numerous training/registration opportunities to support device users. AHSNs undertaking the latter were associated with better device utilisation.
4. Device distribution and management	The degree to which devices were carefully managed and if necessary, recalled to be redistributed. AHSNs who retained devices until training and registration was complete and recalled unused devices to redistribute were associated with better device utilisation.
5. Clarity of expectations around device use	The level to which AHSN rollout leads organised plans, documentation, and introductory meetings with deployment locations to create clear expectations about device use with deployment locations. AHSNs promoting clear expectations were associated with better device utilisation.

Evidence about these qualitative themes in each AHSN was synthesised with the quantitative data on device utilisation and the user innovation survey results to identify **four typologies** – describing different types of implementation approaches. Those with the best levels of utilisation were typified by a 'fully managed' approach, while those who delegated management to the deployment locations had the lowest levels of utilisation. These are described in the full report.

THE IMPACT ON PATIENTS

The quantitative data collected by AHSNs between January 2018 and March 2019 for the registered KardiaMobile devices showed that 81,933 readings were taken and that 5,586 possible cases of AF were detected.

The national AHSN Network AF programme aims to prevent 4,000 strokes by the end of 2019/20. It has identified a set of evidenced assumptions to model the impact of improvements and innovations, such as the improved detection of possible AF by the mobile ECG devices rolled out by this programme.

The following table sets out these assumptions and what they infer could be the impact on patient outcomes from this programme:

National AF Programme Assumption	Potential impact
Possible AF detections by mobile-ECG devices in this roll-out programme	5,586
Confirmed AF 94.4% of those detected by a KardiaMobile device will have a confirmed diagnosis of AF following a test with a 12 lead ECG device (the true positive rate). [4 13]	5,273
Requiring treatment 84.2 % of these patients will need and receive anticoagulant treatment [14]	4,440
Receiving treatment 84% of patients with AF with a record of a CHAD2D2-VASc score of 2 or more are treated with anticoagulation drug therapy [15]	3,731
Potential strokes avoided 5% of patients presenting with an acute ischemic stroke have AF. [16]	**187**

However, the full report describes five important issues that mean that **the 'real' number of strokes avoided by this programme could be significantly different**. An issue that would point to it potentially being higher than 187 is that the 5,586 recorded possible AF detections recorded by the programme only covers 56% of the distributed devices - it excludes the unregistered KardiaMobile devices and the four other devices for which data on possible AF detection was incomplete. Conversely, an issue that would point to it potentially being less than 187 is that when AF is detected by a mobile device, some users told us that they run the test again to be sure, double counting the number of detections.

While the serious issues with the utilisation data have not made it possible to be precise with the modelled number of potential strokes avoided, it is clear that the quantum is a small contribution to the overall AF programme aim of preventing 4,000 strokes.

Nonetheless, each stroke avoided has a significant impact on someone's life, their family and society. Furthermore, the avoidance of stroke has an economic impact. The average cost of health and social care for patients suffering a stroke in the first five years is estimated to be £46,039 [17]. If 187 strokes were avoided by this programme that could save £8 million over 5 years. If the experience and lessons from this programme led to improved utilisation of the devices then this could be even more positive. It is likely that a business case for mobile ECG devices that included sufficient implementation costs and good utilisation of the devices could be compelling.

THE IMPACT ON THE MARKET

The aim of this programme was to test whether a system wide procurement initiative improves the uptake of innovative technology and stimulates the market in primary and community settings.

The evaluation did not find evidence to indicate that the programme has resulted in more suppliers or devices. 92% of the devices procured by the programme (based on the decisions made by each AHSN) were KardiaMobile, and their company, AliveCor, report continued growth in the UK market that this programme has contributed to. Three of the other companies described dissatisfaction with the programme and felt it was a lost opportunity. They did not feel that the AHSNs understood how their devices differed and that theirs were designed for multiple user settings (e.g. GP surgery) rather than individual use (e.g. KardiaMobile) which

is why they cost more. They were frustrated that the programme could have done more to stimulate the market for smaller suppliers with earlier discussions about its aims.

The suppliers described growing competition and product development in the market for people to buy their own devices to monitor their own health – a different market to the one for health services that this programme focussed on. New technology is focussing on wearable patch technology, the best known example being Apple's watch.

The procurement team also felt that more could have been done to stimulate the market if they had been involved sooner and before the five devices had been selected. This could have included supplier workshops that enabled clinicians and AHSNs to try and compare the devices before selecting those to include and procure.

The suppliers described a common concern that there is a particular challenge with the adoption of their devices in General Practice, where people are busy and reluctant to take on extra work and require resource or payment to adopt something new. This is a large market with around 4,400 GPs in around 7,000 practices. The recent NICE report on single lead ECG devices[6] concluded that more research is needed to support their routine use in primary care. Suppliers will need consider how they can support this by supporting data collection and interpretation.

The delivery of more than 1200 devices to general practice can be seen as a success of this programme and an opportunity for the suppliers. However, among users of the devices, doctors were the staff group with the lowest satisfaction and were the most likely to abandon use of the devices early (before 25 uses). Effective use of the devices was seen in other staff groups, such as health care assistants and pharmacists.

WHAT WERE THE KEY LESSONS OF THIS PROGRAMME?

This novel approach of a national system-wide procurement to promote the uptake of a digital innovation led to a large and complicated roll-out programme for the AHSN Network and its constituent 15 AHSNs. The extended time frame for decisions before roll-out, variation in how AHSNs implemented the roll out, differences in their local adoption environments and the different perceptions of device users contributed to the levels of device uptake and utilisation. Overall device users were least positive about their experience of the adoption process, and more positive about their receptiveness to innovation, digital confidence and satisfaction with the technology. Sustained use was not seen in two thirds of users. The evidence provides some lessons for those involved in other large scale roll out programmes of this nature.

1. The perceptions of staff towards innovation offer some insights into those staff groups most likely to be ready to adopt innovation of this kind. Although doctors were the largest user group, other staff groups (including non-clinical staff) were more positive about the innovation and its adoption.
2. While general practice was the most common setting, the devices were demonstrated to have impact in a range of settings that present more choices for adoption and spread. Novel settings (e.g. non-clinical public settings), not normally visited by primary care, may provide opportunities for roll out.
3. Roll out programmes need to mitigate against early abandonment of the innovation. Around two thirds of respondents were low users (<25) and had lower perceptions of the programme overall. Doctors were most likely to abandon use early compared with other staff groups.
4. People engagement and structural enablers, and their underpinning concepts identified in this evaluation, are key to success. An understanding of these environmental characteristics would enable some mitigation of predictable barriers.

5. Planning to address ambiguities, and relational work to see through those plans, is likely to be important in preparing for adoption.
6. The extent to which the rollout is actively managed is a critical factor in explaining implementation success.
7. Collecting utilisation information from the devices was difficult and incomplete. The suppliers have an important role in improving their support to this and this expectation should be included in programme planning. Manual data collection done by device users does not work.
8. Involvement of procurement before device selection can help stimulate the market and bring suppliers and users together to understand the differences between devices – as well as meet the lead times for procuring the devices.
9. Central guidance on Information Governance for digital devices would likely reduce duplication of effort at deployment locations and facilitate faster adoption.

1. INTRODUCTION

1.1. OVERVIEW OF THE MOBILE ECG ROLLOUT PROGRAMME

The rollout of mobile ECG devices by the Academic Health Science Network programme was established to test if an intervention in the health care market place (mobile-ECG devices) could stimulate innovation and improve modifiable health risks at scale; and reduce demand on secondary care.

AF is a national priority in England because:

- Nearly 1.4 million people have AF – it is the most common type of irregular heart rhythm
- However, 400,000 people are unaware they have it, as not all experience the symptoms
- People with AF are 5-6 times more likely to suffer a stroke – and AF is responsible for 1 in 5 of all strokes
- AF related strokes are more severe and more likely to be fatal

Once diagnosed, effective management of AF and optimal anticoagulation can significantly reduce the risk of AF-related stroke. The wider AHSN Network AF programme[1] aims to spread and adopt best practice across England in order to:

- **Detect** AF in more people and earlier
- **Protect** more people with increased rates of anticoagulant therapy where clinically indicated
- **Perfect** and optimise the anticoagulation therapy in people with newly diagnosed AF

The aim of the whole AF programme is that by the end of 2019/20:

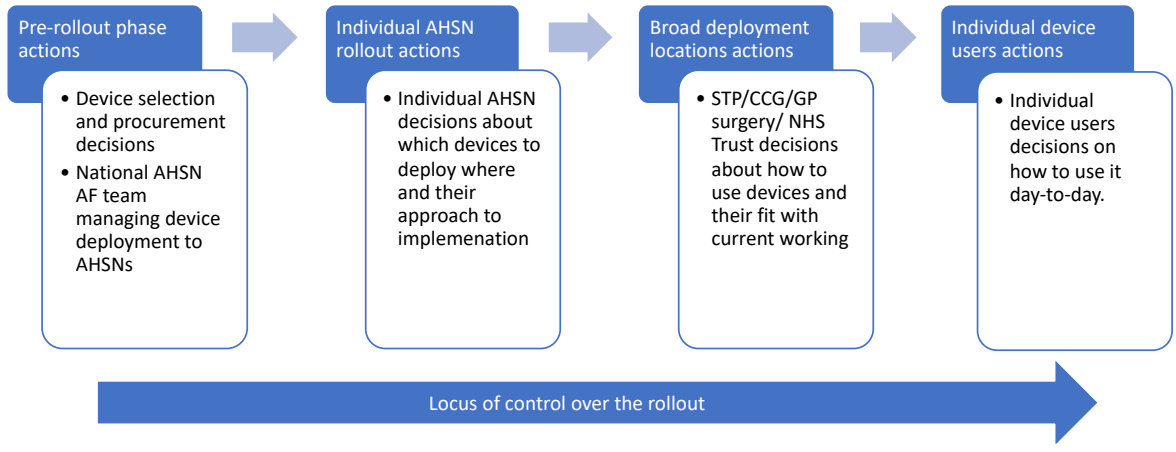
- **134,000 more people with AF are detected**
- **Preventing over 4,000 strokes**
- **Saving over 1,000 lives**
- **Representing cost savings of over £84 million in the NHS and over £100 million in social care**

This evaluation is limited to the deployment and utilisation of mobile ECG devices, which is one element of the 'Detect' component of the wider AF programme.

Programme overview and national programme timeline

The rollout programme progressed through four phases of decision making and activity, starting with the key national decisions that established it in Autumn 2016 to Summer 2017, to implementation planning by the 15 AHSNs in the second half of 2017, to the arrival and deployment of devices in local organisations in 2018 and their use on a daily basis by staff. This is described in the following figure:

Figure 1: Overview of the four phases of the rollout programme



[1] https://www.ahsnnetwork.com/about-academic-health-science-networks/national-programmes-priorities/atrial-fibrillation

As the programme progressed, the degree of control over the success of the rollout shifted. This evaluation aimed to cover all four phases of activity, not just the actions of the 15 AHSNs in the second phase of the programme. The following table sets out the key milestones from a national programme perspective, covering the first two phases in figure 1. The prolonged timescales between AHSNs consulting on and selecting devices and their arrival in January 2018 is a common theme in this evaluation.

Table 1: Key milestones in pre-rollout phase (see figure 1)

June 2016	Simon Stevens' speech at NHS Confederation Conference holds up an AliveCor KardiaMobile ECG device as an example of an innovation that should spread. This is welcomed by AHSNs, some of whom had been using a range of technologies to test for AF.
Autumn 2016	AliveCor apply to the Innovation Technology Tariff (ITT) programme to support spread of KardiaMobile in the NHS. In November, the ITT panel took the decision to develop a theme which considered multiple technologies supported by £500K investment. NHS England receive a number of letters from Cardiocity Ltd making the case for a range of mobile ECG devices, not just KardiaMobile.
Feb – May 17	NHS England and AHSNs develop a specification for the mobile ECG devices that will be made available from the fund. AHSNs pool knowledge on the mobile ECG market and consult with stakeholders – to identify 5 products that will be made available from the national funding. AHSNs were asked to engage local stakeholders to understand what opportunities there may be to use each type of device in different clinical setting in accordance with the specification. AHSNs are sent details of their indicative budget and the 5 devices and are asked to decide how many of each device they would want bought for them to distribute. AliveCor KardiaMobile devices account for approximately 90% of selected devices.
May 17	Procurement of the 5 devices commences – led by Lancashire Care NHS Foundation Trust (who host the Innovation Agency AHSN) in late May. Initial steps are taken to identify supply options for each of the five devices, with four being deemed to be low value purchases while the fifth was a significant transaction which required compliance with the Public Contract Regulations. Discussions begin with the four companies with small numbers of devices selected by AHSNs to begin discussions about price.
Jun – Aug 17	Approach to procuring the large number of KardiaMobile devices is developed. The value exceeds Official Journal of the European Union (OJEU) limits, but the devices are on two national Frameworks – G.Cloud (Crown Commercial Services) which includes the supplier (AliveCor) and NHS Supply Chain which includes a distributor, Technomed. National AHSN Network Programme Manager and Clinical Advisor appointed.
Sept – Oct 17	Contract variation agreed by NHSE to cover the delivery of the programme by the AHSN Network (the agreement is between Lancashire Care NHS Foundation Trust (acting for North West Coast AHSN) and NHS Commissioning Board). Lancashire Care then set up separate arrangements with each AHSN to manage local roll out of the devices. Procurement assessment of the two options for purchasing the KardiaMobile devices and negotiation with the two potential companies – AliveCor and Technomed. Technomed offer a lower price and are the preferred supplier.
Nov – Dec 17	Problems arise in the commercial relationship between AliveCor and Technomed that threatens Technomed's ability to deliver. AliveCor change the commercial model of their smartphone app to a subscription one which requires further negotiation to maintain the ability to access a basic app at the same unit price. –AHSN Network are not made aware of the changes until after the app has gone live and need to re-write their guidance on usage procedures for the AHSNs. . AliveCor are selected as the supplier of the KardiaMobile devices following further discussions on the reporting requirements and a final concession on price from AliveCor to bring price in line with Technomed.
Sept 2017	Complaint from Cardiocity Ltd, to Simon Stevens raising concerns that the use of AliveCor risks breaching the Data Protection Act.

Nov 2017	Reply from NHS England reporting that they are happy that the AHSN Network systems and guidance for the AliveCor devices be used in guest mode means that personal identifiable data is neither entered nor stored.
Dec 2017 January 2018	Further email from Cardiocity Ltd, asking for further clarification about NHS England's stance that it believes the arrangements for using AliveCor devices in guest mode doesn't breach the Data Protection Act. Letter from NHS England to each of the points raised and setting out their opinion that the Act is not being breached. First devices arrive at AHSNs. National rollout team issue 37-page guidance document to AHSNs that includes metrics and data collection, information governance and roles and responsibilities. Cardiocity Ltd continue to raise concerns through 2018 including a Freedom of Information request in May 2018 to all AHSNs, CCGs and Trusts involved in the programme. Further legal advice in August 2018 confirms the programme is compliant. Agreements are finalised between Lancashire Care NHS Foundation Trust and each AHSN for the transfer of responsibility for the devices (March 2018).

Diagnosing Atrial Fibrillation

Atrial Fibrillation is a type of arrhythmia that causes an irregular or abnormally fast heart rate. It is the most common arrhythmia and has a higher incidence in older people.

Symptoms of AF include feeling dizzy, being short of breath, feeling tired, having chest discomfort and heart palpitations – although around one third of people have no symptoms. AF can be classified as permanent (present all the time), persistent (episodes lasting longer than 7 days) and paroxysmal (intermittent episodes usually lasting less than 2 days). All three forms of AF carry the same risk of stroke.

The traditional way of detecting AF is identifying an irregular pulse rhythm using manual pulse-palpation. AF is then either confirmed or excluded using a 12-lead ECG in primary or secondary care, interpreted by a trained healthcare professional.

Single time-point case finding is a strategy of detection by checking a pulse or heart rhythm during a routine consultation with a health worker. A range of studies have identified opportunistic screening of people for AF using single time-point case finding is the more effective way of improving the diagnosis of AF.[1] [2] Lowres et al found that the number of people that needed to be screened to detect one case of undiagnosed AF in the general population is 100 and in those aged 65 or older is 71.[3]

The aim of the mobile-ECG devices rolled out in this programme was to support opportunistic screening of undiagnosed AF in a range of settings. They were to be used at a single time-point (rather than repeatedly over time) and provide an alternative to manual pulse palpation, providing an option for those settings that may not have considered pulse-palpation previously. People detected by these devices as possibly having AF still require their diagnosis to be confirmed by a 12-lead ECG interpreted by a trained healthcare professional.

The devices available for detecting possible AF

A range of devices can detect AF. A review of these by the Health Innovation Network[4] divides them into three broad types and the five devices selected for this programme are shown in bold:

1. Automated Blood Pressure sphygmomanometers

Some automated blood pressure sphygmomanometers have a built-in AF algorithm to analyse any irregularity of the pulse rate and apply a threshold for detecting AF. **WatchBP Home A** (Microlife

Health Management Ltd) is the only monitor to have a medical technology appraisal recommendation from NICE for opportunistic detection of AF during the diagnosis and monitoring of hypertension.[5]

2. Handheld ECG monitors

Many of these devices have electrodes that can be activated by placing thumbs, fingers or palms on the device. Many have built in AF algorithms for auto-analysis to instantly inform the user of the outcome or the ECG can be transmitted for interpretation by a telemedicine service. Three of the devices included in this rollout programme are in this category – **MyDiagnostick** (Medical B.V); **RhythmPad GP** (Cardiocity Ltd); and **imPulse** (Plessey Semiconductors Ltd).

3. Mobile ECG recorder and apps

Advances in design and technology are allowing the adaption of non-healthcare equipment (smartphones/tablets etc.) to become medical devices. **KardiaMobile** (AliveCor, Inc) wirelessly connects electrode attachments to a smartphone to digitally capture an ECG. The associated **KardiaMobile app** has a built-in AF detection algorithm that provides an instant interpretation and ECGs can be transmitted to a secure server and be read by a telemedicine service. The AliveCor company were successfully selected in 2015/16 for the NHS Innovation Accelerator programme.

Further details of the 5 products included in this rollout programme are included in Appendix 1.

Devices procured and distributed by this rollout programme

The following number of devices were procured by this rollout programme and sent to AHSNs for distribution:

Table 2: Total number of devices procured and distributed by AHSN (all types of devices)

AHSN	Devices procured	Devices distributed	% of procured devices distributed
East Midlands	535	287	54%
Eastern	503	503	100%
Health Innovation Manchester	340	340	100%
Health Innovation Network	413	413	100%
Imperial College Health Partners	275	219	80%
Innovation Agency	382	282	74%
Kent, Surrey and Sussex	556	556	100%
North East and North Cumbria	370	374	101%
Oxford	222	202	91%
South West	248	250	101%
UCLPartners	670	536	80%
Wessex	350	310	89%
West Midlands	589	586	99%
West of England	285	223	78%
Yorkshire and Humber	600	515	86%
TOTAL	**6,338**	**5,596**	**88%**

Note: Scores of more than 100% are due to multiple registrations of devices and/or the redistribution of devices during the programme.

The following table shows the number of devices delivered to AHSNs – 92% were KardiaMobile. The devices selected by each AHSN were informed by the preferences of their local stakeholders.

Table 3. Range and numbers of devices selected by AHSNs and their unit price.

Device	No. delivered	No. of AHSNs	Unit price[a]
KardiaMobile (AliveCor)	5,858	15	£61[b]
Watch BP (Medical BV)	391	6	£54 + £15[c]
MyDiagnostick (Medical B.V)	46	2	£652
Impulse (Plessey)	31	2	£220
RhythmPad (Cardiocity)	12	3	£850
Total	**6,338**		

(a) The unit price negotiated for this programme
(b) For the KardiaMobile device and app, but not the smartphone or tablet it runs on
(c) Watch BP unit price was £54 and the programme also bought L/XL cuffs at unit price of £15

1.2 THE AIM OF THE INDEPENDENT EVALUATION OF THE PROJECT

The evaluation of the roll out of mobile ECG devices was commissioned by the Innovation Agency (North West Coast AHSN hosted by Lancashire Care NHS Foundation Trust), on behalf of the AHSN Network. Wessex AHSN evaluation team were selected through invitation to tender to provide an independent evaluation of how well the programme had met its overarching evaluation question:

"Can a system-wide procurement initiative improve the uptake of innovative technology (mobile ECG) and stimulate the market in primary and community settings, to better identify AF?"

To support the above, the independent evaluation was asked to answer six questions:

1. **What environments are the devices most effective in?**
2. **What features of the implementation packages are most effective? What defines successful implementation?**
3. **What impact has the programme had on the market place?**
4. **What impact has the programme had on patient outcomes?**
5. **What health economic aspects has the programme achieved?**
6. **What is the impact on providers?**

The focus of this evaluation was the programme to purchase and rollout approximately 6,300 mobile ECG devices across the NHS by 15 AHSNs. Importantly, **this was not an evaluation of the effectiveness of the devices themselves.** NICE has recently published their findings on the evidence of the effectiveness of the devices in primary care with symptoms of AF which are summarised in section 6.[6]

1.3 EVALUATION METHODS USED

This evaluation used a mixed methods concurrent triangulation design[7] to simultaneously collect quantitative data, qualitative data and synthesise findings to answer the six evaluation questions. Different levels of synthesis were enacted depending on the evaluation question. Questions 1 (the Environment) and 2 (the Implementation) synthesised multiple sources of data in order to develop

typologies*[2]' of the environments experienced during the rollout and of implementation to describe the decisions and actions taken by AHSNs.

Qualitative methods

Site visits were offered to all 15 AHSNs for the purpose of understanding peoples' experiences of using devices in their context, the positives, the challenges, the facilitators, perceived impacts and lessons learnt. 11 of the 15 AHSNs were able to accommodate a site visit, which included a focus group at each AHSN site led by a qualitative researcher from the evaluation team with participants from the AHSN rollout team and a range of device users. These groups were supplemented with semi-structured one to one interviews with the local rollout team. In the four AHSNs that weren't able to arrange a visit, views were gathered and recorded through telephone interviews. In total across the 15 AHSNs, 125 device users participated in the qualitative field work, including 38 GPs, 20 nurses and 14 senior managers. A breakdown of participation by AHSN is included in Appendix 3. Across the 15 AHSNs, 57 AHSN rollout staff were interviewed for this evaluation. Three AHSN Network AF programme leads were also interviewed.

The aims and content of the focus groups and semi-structured interviews were informed by the framework for evaluating Nonadoption, Abandonment and Challenges to the Scale-Up, Spread and Sustainability of Health and Care Technologies (NASSS*[3])[8] and Normalisation Process Theory (NPT*[4])[9] to ensure appropriate implementation topics were covered. The focus groups and semi-structured interviews were designed to address, along with other data collection methods, evaluation questions 1, 2, 4 and 6.

Prior to typology generation to address evaluation questions 1 and 2, the focus groups/interviews with device users and interviews with AF rollout staff were analysed using a recognised process of thematic analysis[10] to identify themes*[5] from these data sources. The goal of the analysis was a table of well-defined and described themes after data saturation*[6] was reached. The various themes identified are organised under the relevant evaluation question in this report.

Questions 1 and 2 were also informed by the collection of timelines to depict the implementation journeys at each AHSN. These identified the issues that affected the rollout at AHSN level. Three examples are included in Appendix 7. To understand the impact on the marketplace (evaluation question 3), semi-structured interviews were undertaken with five AHSN Commercial Directors who had been involved in developing this programme, the procurement manager, and the senior representatives of the five device suppliers.

Quantitative data collection

The AHSN Network AF programme team agreed a set of metrics to be regularly collected and submitted by the AHSNs, and this was included in their programme guidance. The metrics were:

i. Number of devices deployed
ii. Description of settings into which devices have been deployed
iii. Sustained use of devices (number of devices in use at 1,3,6,12 months)
iv. Number of people screened using all devices
v. Number of people with 'possible AF' (and where possible, unclassified/unreadable outcomes)

[2] * See Glossary for further explanation of this term
[3] * See Glossary for further explanation of this term
[4] * See Glossary for further explanation of this term
[5] * See Glossary for further explanation of this term
[6] * See Glossary for further explanation of this term

The aim was to register the KardiaMobile devices with AliveCor who would then collect metrics ii. to v. AHSNs would need to manually collect metric i. for all devices and all of the metrics for the other devices.

The evaluation team produced a monthly quantitative report that was circulated to all of the AHSNs.

A number of serious issues were apparent with the quantitative data collection through the programme:

i) All KardiaMobile users should have registered their device against an individual account, and it is likely that devices were registered to multiple users. In addition, there was some confusion over the serial numbers for devices, which may have meant one device was registered under two different serial numbers. 2900 different serial numbers were registered by 3417 users. If only one serial number per device were registered this means only half of purchased devices were registered. It may be that these devices were used, but no data for this was available. It is likely that there is an additional number of patients with possible AF detected by the programme, which cannot be quantified.

ii) The evaluation team discovered an error in Alivecor's recording of activity that meant all of the 2018 data had to be re-provided and re-analysed.

iii) The registration and activity databases were not linked as originally planned due to contracting/procurement issues. Additionally, devices could not be registered effectively by serial number due to issues in the distribution from AliveCor's UK distributor (Oury Clarke). This meant it was not possible to analyse users and device use together. Additionally, usage data was collected at user level rather than at device level, which caused data counting issues.

iv) The quarterly manual data collection for the other types of devices was often late, incomplete and inconsistent. Therefore, data about the number and type of readings made on these devices was not sufficiently robust to include in the analysis.

v) It was originally intended that AliveCor would hold a record of serial numbers of KardiaMobile devices issued to each AHSN to allow tracking of individual devices and to prevent devices not purchased by the fund from being registered. Unfortunately, this didn't happen, impacting the ability to accurately track the devices and their usage.

vi) For KardiaMobile usage, only the care setting in which the registered user usually worked was recorded – not the care setting in which the device was necessarily used. This meant that usage in unusual settings (eg at football grounds) could not be analysed.

An additional issue reported to the evaluation team is that when a 'possible AF' reading is given, the user may repeat the test, which could overstate the number of detections of possible AF.

The evaluation team has done a lot of work to make the quantitative data as accurate as possible, but it is important that these serious limitations are considered.

A summary of the quantitative data is included in Appendix 2.

R-Outcomes

R-Outcomes provide a wide-range of self-reported outcome measures, including a set that support innovation evaluation[11]:

- The **Digital Confidence Score** self-rates users' digital literacy and confidence to use digital products, with dimensions of familiarity, social pressure, support and digital self-efficacy.
- The **Innovation Readiness Score** rates how much users are open to and up to date with new ideas, and whether their organisation is receptive to and has innovation capabilities.
- The **Innovation Adoption Score***[7] rates how staff found the process of adopting mobile ECG devices to make them work in practice; whether the original vision was followed, whether there was planning in advance, whether staff worked together and whether they reflected on how best to keep it working. It is based on Normalisation Process Theory (NPT).

[7] * See Glossary for further explanation of this term

- The **Product Rating Score** provides a user assessment of a digital product in terms of usefulness, ease of use, support and satisfaction.

Each measure has four questions, with four possible responses. Further details of these measures are included in Appendix 5.

622 users submitted self-reported measures online, from the staff groups in the following table:

Table 4: R-Outcomes responses by staff group

Staff group (as stated by users when registering their device)	Number of users by staff group	Response rate
Medical	283	37%
Healthcare Assistant	105	25%
Nurse or midwife	80	50%
Pharmacist	42	45%
Admin & Clerical, Management	39	81%
Other[8]	73	28%
Total	**622**	

The number of user responses by AHSN ranged from 10 (in Oxford) to 88 (in Kent, Surrey and Sussex). The full set of responses and scores for each AHSN is included in Appendix 6. Scores are presented out of 100 and the higher the score the better.

The R-Outcomes scores contributed to the development of the typologies for the Environment (question 1) and Implementation packages (question 2) and in understanding the staff perspective of the impact on providers (question 6).

Typology development

Developing typologies – an organised system of types based on the available evidence – is often used to bring together a range of data sources, particularly when attempting to draw inferences from both quantitative and qualitative findings about the same phenomenon[12].

To understand the environments in which the devices were rolled out and the implementation approaches taken by rollout leads, themes identified in the qualitative fieldwork were combined with quantitative data sources for each AHSN. A synthesis grid was created to map all the findings at the individual AHSN level. Only qualitative themes that varied between AHSNs were included in typology generation. The themes that varied were considered 'characteristics' of either the environments or the implementation approaches, whereby some were reported as strong and some weak in each AHSN.

For the development of environment typologies, the environment-related qualitative themes that varied were mapped against several utilisation metrics and R-Outcomes domains 'Digital Confidence' and 'Innovation Readiness'. The combined position of these findings generated and explained the typologies assigned to each AHSN.

For the development of implementation approach typologies, the implementation-related qualitative themes that varied were mapped against several utilisation metrics and R-Outcomes domain 'Adoption Process'. The combined position of these findings generated and explained the typologies assigned to each AHSN.

To ensure robustness of the typologies, the individual data sources were checked for accuracy and the typology development process was undertaken by the whole evaluation team and continued until consensus was reached.

There are some important caveats to the development of typologies at AHSN level as follows.

[8] Includes paramedics (9); physiotherapists (2); podiatrists (8); public health (6); social care (2)

Focus group and interview participant numbers were lower than specified at many AHSNs. Whilst the evaluation team aimed to recruit up to 20 device users per AHSN to ensure a good sample from each AHSN (consistent with other similar qualitative investigations), recruitment relied on the support from each AHSN roll out lead who found that some health professionals were unable to commit time to the evaluation. This led to a high overall number of recruited device users (n=125) and thus enabled the development of the 'common themes' from a very strong base of views, but participant numbers for some AHSNs were 10 or under.

Focusing on the number of staff alone would be simplistic as many focus group participants were champions for their practice/unit/service and shared the combined views of many staff with whom they worked. This issue, combined with the experience of the qualitative investigator to judge data saturation, and the numbers of staff recruited provided a reasonable degree of confidence to the evaluation team that the qualitative findings at the AHSN level were trustworthy.

Whilst more participants at the AHSN level would have been welcome, the typologies were drawn from a range of qualitative and quantitative findings, so this limitation was lesser than if the typologies were developed solely on the device user focus group/interview findings.

The typologies were based on a sample of the deployment locations participating in the roll out in each AHSN. This made them contextual to the participating deployment locations and not a statement about all deployment locations (e.g. CCG, Trusts, General Practice) within any given AHSN. However, they can be considered indicative of some of the deployment locations with which the programme engaged. Importantly, they provide broader learning about device roll-out and implementation and characterise the complicated nature of the roll out programme.

2. WHAT ENVIRONMENTS ARE THE DEVICES MOST EFFECTIVE IN?

2.1 INTRODUCTION

This section provides an understanding of the environmental factors and themes that impacted on the rollout of the devices in the 15 AHSNs. It begins by describing the qualitative findings of the **common environmental themes** experienced by all AHSNs during their rollouts; a mixture of issues that would be present in any programme of this nature and those that resulted from the design and evolution of this programme. It then describes a set of **environment typologies** based on a synthesis of the qualitative and quantitative findings; to describe five different types of environments within which the AHSNs were rolling-out their devices. Key findings are summarised at the end of the section.

2.2 COMMON ENVIRONMENTAL THEMES THAT IMPACTED THE ROLL OUT

During the qualitative fieldwork, 125 device users and 57 AHSN staff across all 15 AHSNs described their experience of the rollout through focus groups and interviews. A thematic analysis of these views highlighted 5 environmental issues common to all AHSNs. These issues were always present in the background as AHSNs and device users attempted to use devices in their environmental settings. A range of other issues that varied between different AHSNs and contexts are discussed in section 2.3.

Table 5: Environment-related common themes from qualitative fieldwork

	Environment-related common themes across all AHSNs
1	Wide range of preferences and decisions about adoption
2	Adopter support for use of devices is vital
3	Logistical ambiguity about device use
4	Clinical ambiguity about device use
5	Ambiguity of fit with AF pathways

Environment theme 1: Wide range of preferences and decisions about adoption

Rollout staff in the 15 AHSNs engaged and worked with a wide range of clinical and non-clinical deployment locations. They also worked across wide geographic and health care boundaries and this presented challenges to overcome in terms of working with decision makers at many levels to operationalise the use of the devices. More than two thousand health care staff were involved in the organisation of this work and were recipients of devices from the AHSNs, some with no prior relationship with or understanding of AHSNs. Relationships were required at STP/ICS, CCG, General Practice and Trust levels, as well as with voluntary agencies. Device users made clear that hundreds, if not thousands, of individual decisions were made about how, when and why the devices would be used in each of the individual contexts.

> *"There are a lot of people involved in this rollout and a lot of decisions being made up and down the line. To get this rollout going we had to navigate all sorts of thinking…some CCGs we're working with are paying locally commissioned services to do 12-lead assessments, some are not, some are saying they'll use KardiaMobile and stop doing 12-lead assessments, some aren't, some practices don't have 12-lead kits so they said there's no point having an KardiaMobile to spot more AF…as you can see it's a mixed bag of CCG and practice decisions we had to deal with."*
>
> Source: AHSN local roll out lead

Environment theme 2: Adopter support for use of devices vital

A key facilitator in the various rollout locations was enthusiasm for med-tech devices to improve health care. Generally, AHSNs benefitted from good engagement at the device-user level as they could see the potential benefits of using the ECG devices rolled out. Importantly, as described in the next section of this report, the logistical challenges would far outweigh this facilitator and affect the rollout. Nearly all device users from the 15 focus groups reported their and patients' views of the device being 'immediately liked' and 'technologically intriguing', 'having instant interest potential', and 'at public health related events could generate large groups of people around a table being tested'.

> *"We've had a good range of interest for KardiaMobile from clinicians, most have said it's an interesting bit of kit on face value, its portable, easy to use and seems to do the job intended."*
>
> Source: AHSN local roll out lead

> *"A well-known and respected Consultant Cardiologist supported the rollout as an adviser and sense-checker for how and when to rollout. Their credibility has been a major facilitator of GP engagement in our area."*
>
> Source: AHSN local roll out lead

Environment theme 3: Logistical ambiguity about device use

During the rollout, almost all device users highlighted some level of ambiguity about how and when to use the devices in practice. This was a function of many AHSNs giving a large amount of control to deployment locations 'to fit it into their work as they see fit'. Whilst this could be considered a form of rollout co-production, it led to confusion in most environments and considerable reliance on staff willing to 'just run with it'. The AHSN Network Programme Team suggested that AHSNs should work with local teams to understand current pathways and to identify settings with likely capacity to include device use. Suggestions included 'high throughput' situations like flu clinics and other settings in which

"We wanted to try it [KardiaMobile] in flu clinics but then decided not to in case it affected the number of flu jabs we could offer in a day. I know other places have used it in waiting rooms and in flu clinics but it's been hard to know how and when, or which member of practice staff should use the device. There hasn't been that kind of detailed support available." Source: Practice nurse device user

people at higher risk of AF might attend, but clinicians did not always view these as appropriate (see Appendix 4 for a range of environments described in the qualitative fieldwork). The AHSN Network programme team did provide guidance to local AHSN leads but it was reported this information did not always filter down, or failed to be understood, or agreed upon, or followed by deployment locations.

"In the early days our expression of interest form to CCGs didn't ask them to specify how and when they would use the [KardiaMobile] devices and roll them out. After a few months of non-engagement and the devices not being used, we realised that was a mistake and changed our forms to ask for that detail of new rollout sites." Source: AHSN roll out lead

Environment theme 4: Clinical ambiguity about device use

This debate was highlighted by clinicians in all AHSNs and clinicians sought clarification about the relative value of device use compared to manual pulse checks. Views were mixed, some positive and some negative, about the value of Lead-I ECG devices. Some clinicians were happy to use the devices combined with clinical judgment to make clinical decisions. Some were not and wanted more sensitivity data on the device. Some clinicians, including GPs, reported they did not feel confident in their own AF knowledge to make decisions from the use of a Lead-I ECG device. Many questioned whether the Lead-I ECG devices were a replacement for 12-lead assessments, whether they could detect Atrial Flutter, and whether they were valuable to detect paroxysmal AF. The AHSN Network AF programme team did provide guidance to local AHSN leads (including guidance on how each of the devices handled issues such as background noise to support local decisions about which device was most appropriate for their situation) but it was reported this information did not always filter down, or failed to be understood, or agreed upon, or followed by deployment locations.

Furthermore, most clinicians questioned whether the diagnostic potential was strong enough to validate its use. Many clinicians reported a problem of 'unclassified' findings using the KardiaMobile device. This left clinicians no option but to retest or abandon its use during the clinical encounter. Unclassified results were considered not only frustrating but also diminished the perceived value of the device in busy time-pressured practice settings. Interestingly, many clinicians 'experimented' with the device and made their own decisions about whether to continue its use based on their personal experimentation process. In that sense, an unofficial clinical real-world validation was ongoing during the rollout.

"I had a patient whose KardiaMobile test indicated things were 'normal', as in it wasn't AF, but as someone who is used to looking at ECGs I could see it was a type of arrythmia and something was not right. Sure enough after the 12-lead assessment they were diagnosed with AF and anti-coagulated."

"If it's really noisy in the clinic or there is electronic interference of some sort then I get unclassified readings, which is frustrating particularly as we have to do the test again or give up in a busy clinic. The other problem with unclassified findings is I can look at them and still move forward but my Health Care Assistant using the device can't." Source: GP device user

Environment theme 5: Ambiguity of fit with AF pathways

Almost all device users reported challenges, in one form or another, in fitting the device use into existing AF pathways. Guidance was provided from the AHSN Network Programme Team, but some issues required a local response from AHSN roll out staff. In most cases, no integration was achieved, and device testing was done ad hoc. A key perception was the ambiguity about how mobile-ECG devices' testing fits with the more diagnostically definitive 12-lead assessment. This presented challenges in other parts of the system, such as staff receiving more 12-lead assessment requests and uncertainty about how to deal with referrals/signposting from non-clinicians using devices in the voluntary sector/football grounds/community groups, and in contexts where AF pathways were underdeveloped. Importantly, a few AHSNs in a few deployment contexts did attempt to organise device use into existing AF pathways, but this was time consuming and generally only raised more questions about wider AF pathway work. Almost all device users and AHSN staff said that not formally integrating the device into existing AF pathways was a missed opportunity in the rollout.

"Some CCGs refused to participate in the rollout because they felt their AF pathways weren't mature enough to introduce another step [KardiaMobile]…and some CCGs didn't think KardiaMobile fit with their existing arrythmia/AF plans…it's down to each practice and CCG to decide in the end and we've been at the mercy of their existing plans when it came to this rollout."

Source: AHSN roll out lead

"I'll be honest with you; we've had to limit the amount of KardiaMobile testing we've done here. Having tested hundreds of people we generated 50 new 12-lead assessments and that was a lot of work for our practice staff to absorb within a reasonable timeframe, in terms of testing patients in a timely way. There's been a bit of an assumption that GPs have the capacity to absorb that extra work…I also heard from colleagues that some CCGs have quotas for 12-lead assessments and may not pay for any extra done over that quota. This has led to other colleagues limiting their KardiaMobile testing."

Source: GP device user

Furthermore, some clinicians reported the post-test work from KardiaMobile use had increased, but others reported 12-lead assessments had been avoided due to the use of KardiaMobile. What clinicians did agree upon was confusion about how to manage post-test work. This issue was left to deployment contexts to organise and did lead to the management of KardiaMobile testing in order to manage the post-test burden of work.

2.3 ENVIRONMENT TYPOLOGIES THAT DISTINGUISH THE AHSNS

A range of qualitative and quantitative findings were synthesised to generate *environment typologies.**[9] These sought to provide an organised system of types, to explain and group the characteristics witnessed in each AHSN into a digestible analysis. These aim to describe the different environments that AHSNs were rollout the devices in.

Five environment-related qualitative themes that *varied between AHSNs* were identified from focus groups and interviews with device users and AHSN rollout staff and these could be further summarised into 'people engagement' and 'structural enablement.'

[9] * See Glossary for further explanation of this term

Table 6: The environment-related qualitative themes that varied between AHSNs

Themes	Description
People engagement themes	
1. Clinical leadership support	The degree to which the AHSNs were working with deployment locations with clinical leadership available and engaged. Limited clinical leadership support, often due to an absence of appropriate personnel, was present in AHSNs with poorer device utilisation.
2. Relationships with deployment locations	The reported level of engagement and relationship quality with deployment locations. AHSNs with positive existing relationships and/or able to generate positive relationships with deployment locations during the rollout reported better device utilisation.
Structural enablement themes	
3. Burden of local information governance	The extent to which Information Governance (IG) requirements were required at the local level, despite many IG issues being addressed in a supporting document by the AHSN Network AF programme team. AHSNs working with deployment locations with additional, often unexpected, IG requests and processes experienced rollout delays and poorer device utilisation.
4. Readiness to integrate into AF pathway	The degree to which deployment locations were ready and/or willing to integrate ECG devices into existing AF pathways. Deployment locations that did integrate, often re-organise, their AF pathway had better device utilisation. Deployment locations with limited interest in pathway integration reported more ambiguity about how to use the device and had poorer device utilisation.
5. Technological readiness and willingness of deployment locations	The reported level of technological readiness and willingness in deployment locations. Those with poor readiness (e.g. poor internet access, not willing to use personal smartphones with KardiaMobile, no access to NHS.email accounts) had poorer device utilisation.

A process of **synthesis** brought together the reported position of each AHSN in relation to the five themes (some good, some moderate, some poor), with the quantitative data available on device utilisation (see Appendix 2 for device utilisation data) and the R-Outcomes scores on the 'Digital Confidence' and 'Innovation Readiness' domains. This synthesis identified **5 environment typologies**:

Table 7: AHSNs by environment typologies

Typology	AHSN
Fully Engaged & Enabling Structures	North East and North Cumbria South West
Moderately Engaged People & Partially Enabling Structures	Health Innovation Network Kent Surrey Sussex Imperial College Health Partners Yorkshire and Humber
Fully Engaged People & Partially Enabled Structures	Eastern
Moderately Engaged People & Hindering Structures	Wessex East Midlands Innovation Agency Health Innovation Manchester West Midlands
Lightly Engaged People & Hindering Structures	West of England UCLPartners Oxford

Environment typology 1: Fully Engaged & Enabling Structures

This typology was characterised by a positive position on environment-related qualitative themes, positive digital confidence findings, positive innovation readiness findings, and good utilisation of the devices within their control. The environments in North East and North Cumbria and South West AHSNs fit this typology.

Good utilisation of devices can be explained by full people engagement and enabling structures in which the devices were deployed. Full people engagement was clear from high digital confidence scores and a positive position on the themes of good clinical leadership support and good relationships with collaborating CCG/STPs/deployment locations. Devices were predominately deployed into and benefited from enabling structures, whereby there were no/limited additional Information Governance (IG) processes to enact and most CCGs were ready to integrate device use into existing AF pathways. This typology also had strong technological readiness and willingness to use the devices.

The R-Outcome scores for users' digital confidence and innovation readiness were higher in these AHSNs[10]:

Table 8: environment scores for AHSNs in this typology

AHSN	Digital confidence	Innovation readiness	% of procured devices distributed	% of distributed devices registered	Avg. readings per device registered
North East and North Cumbria	87.4	80.9	101%	102%	54
South West	81.6	76.9	102%	53%	72
Average of all AHSNs	81.2	77.5	89%	57%	26

Note: Utilisation data is for KardiaMobile devices only. Scores of more than 100% are due to multiple registrations of devices and/or the redistribution of devices during the programme.

This typology described the most effective position to deploy devices within, with strong people and structures to support the rollout.

"We already had quite an active AF work programme in our area and this supported the rollout a lot. Our [AHSN] relationships with local CCGs was very strong…we had worked with them before on AF…some of our team sat on CVD committees in the CCG and attended local pharmacy committees…we had access to a locally well respected clinical champion who was instrumental in convincing GPs to participate and provided clinical leadership throughout, particularly at the start when we had to build coherence around the rollout so everyone knew what was going on."

Source: AHSN local roll out lead

Environment typology 2: Moderately Engaged People & Partially Enabling Structures

This typology was characterised by mixed views on the five environment-related qualitative themes, moderate digital confidence findings, moderate innovation readiness findings, and moderate utilisation of the devices within their control. The environments in the Health Innovation Network, Kent, Surrey and Sussex, Imperial College Health Partners and Yorkshire and Humber AHSNs were found to fit this typology.

Moderate utilisation of devices can be explained by moderate people engagement and partially enabling structures in which the devices were deployed. Moderate people engagement was clear from

[10] Details of these scores can be found at appendix 5 and the complete scores at appendix 6

moderate digital confidence scores and mixed views on themes of clinical leadership support and on relationships with deployment locations.

Devices were predominately deployed into environments partially ready to support the devices, characterised by the need for additional IG processes prior to device use which caused delays, the need to spend more time than expected planning how device use would fit into existing AF work, and with a mixed picture of technological readiness across deployment locations.

"We've had a difficult time engaging with some of our CCGs and practices, I know they have capacity issues and that's fine, but just getting an email response was difficult and frustrating during this rollout."

Source: AHSN local roll out lead

The R-Outcome scores for users' digital confidence and innovation readiness were mostly moderate in these AHSNs:

Table 9: environment scores for AHSNs in this typology

AHSN	Digital confidence	Innovation readiness	% of procured devices distributed	% of distributed devices registered	Avg. readings per device registered
Health Innovation Network	81.8	78.6	100%	86%	39
Kent, Surrey and Sussex	79.0	72.7	100%	46%	30
Imperial College Health Partners	77.8	76.2	80%	57%	26
Yorkshire and Humber	77.1	78.9	80%	74%	23
Average of all AHSNs	81.2	77.5	89%	57%	26

Note: Utilisation data is for KardiaMobile devices only.

"We put a lot of effort into one STP area but rolling it out to the other STPs has been really slow…people and personalities have driven the engagement levels in each area and that's been frustrating…in one STP area we engaged at that level and they weren't interested. There wasn't any support to move forward and contact GPs. They also wanted us to pay the GPs and we couldn't do that…another thing was we haven't always had the strongest links with the CCG clinical leads, so we tried to target that but it wasn't always successful…and I don't think we and the STPs and CCGs really thought about the 'box of work' this rollout would involve for GPs before we started." Source: AHSN local roll out lead

Environment typology 3: Fully Engaged People & Partially Enabled Structures

This typology was characterised by a largely positive position on the qualitative themes, positive digital confidence findings, moderate innovation readiness findings, and moderate utilisation of the devices within their control. The environment in Eastern AHSN was found to fit this typology.

Moderate utilisation of devices can be explained by full people engagement but only partially enabling structures in which the devices were deployed. Full people engagement was clear from high digital confidence scores and positive positions on the themes of clinical leadership support and relationships with deployment locations. However, devices deployed were subject to additional IG processes despite AHSN Network AF programme team guidance to support this issue and only some of the CCGs were ready to integrate device use into existing AF pathways. In this typology, there was some evidence to suggest a moderate to good level of technological readiness and willingness to use the devices.

The R-Outcome scores for users' digital confidence and innovation readiness were higher in this AHSN:

Table 10: environment scores for AHSNs in this typology

AHSN	Digital confidence	Innovation readiness	% of procured devices distributed	% of distributed devices registered	Avg. readings per device registered
Eastern	82.4	79.4	100%	50%	28
Average of all AHSNs	81.2	77.5	89%	57%	26

Note: Utilisation data is for KardiaMobile devices only.

"Some individual GPs applied directly to us [AHSN] for [KardiaMobile] devices and were early adopters and often purchased tablets to use with KardiaMobile and implement the devices…their clinical leadership was vital to making it a success in those practices. Also, the practice managers were driving a lot of operational change and central to supporting this digital innovation."

Source: AHSN local roll out lead

"Quite a few practices had concerns about using their own smartphone or tablets to use KardiaMobile. We couldn't get around this in some areas and didn't get the devices deployed."

Source: AHSN local roll out lead

"Several of our CCGs raised additional information governance concerns and insisted they discuss the rollout with their local IG committees…their questions centred on the detail in the national AF team document about IG, additional information about KardiaMobile certificates of use, and the NHS Digital Bring Your Own Device policy…all these issues led to delays to some degree."

Source: AHSN local roll out lead

Environment typology 4: Moderately Engaged People & Hindering Structures

This typology was characterised by mixed views on the qualitative themes, moderate innovation readiness findings but high digital confidence findings, and moderate to poor utilisation of the devices within their control. The environments in Wessex, East Midlands, Innovation Agency, Health Innovation Manchester and the West Midlands AHSNs were found to fit this typology.

Moderate to poor utilisation of devices can be explained by moderate people engagement and hindering structures in which the devices were deployed. Moderate people engagement was clear from mixed views on the existence of good clinical leadership support and good relationships with deployment locations. Devices deployed were subject to significant additional IG processes despite guidance from the AHSN Network AF programme team to support this issue and there was limited interest from CCGs to integrate device use into existing AF pathways. Moderate to poor technological readiness and willingness to use the devices affected the rollout of devices in deployment locations.

The R-Outcome scores for users' digital confidence and innovation readiness were high:

Table 11: environment scores for AHSNs in this typology:

AHSN	Digital confidence	Innovation readiness	% of procured devices distributed	% of distributed devices registered	Avg. readings per device registered
Wessex	80.8	78.3	89%	42%	23
East Midlands	81.8	79.4	54%	76%	12
Innovation Agency	81.6	80.2	85%	73%	7
Health Innovation Manchester	81.4	79.9	100%	31%	19
West Midlands	83.9	79.5	100%	24%	26
Average of all AHSNs	81.2	77.5	89%	57%	26

Environment typology 5: Lightly Engaged People & Hindering Structures

"We had mixed relationships with CCGs and at practice level before and during this rollout, it was difficult to get those relationships organised due to the resources we had at the AHSN…also until you get those [relationships] sorted out it's very difficult to get people to answer your emails and get going with training, registration, faulty device issues, supporting queries about devices and rollout processes…we were waiting for practices to make decisions about what they want to do quite a lot. This led to a lot of unused [KardiaMobile] devices and delays. Because of the relationship problems we couldn't get much leadership support in CCGs and at practice level…we had feedback that about 30% of practices stated KardiaMobile just wasn't working in their context and we think it was due to our relationships situation." Source: AHSN local roll out lead

This typology was characterised by largely negative positions on the five qualitative environment themes, moderate digital confidence findings, moderate to poor innovation readiness findings, and moderate to poor utilisation of the devices within their control. The environments in the West of England, UCLPartners and Oxford AHSNs were found to fit this typology.

Moderate to poor utilisation of devices can be explained by poor people engagement and hindering structures in which the devices were deployed. Poor people engagement was clear from moderate digital confidence scores and largely negative views on the clinical leadership support and relationships between AHSN leads and the deployment locations. Devices deployed were subject to significant additional IG processes despite guidance from the AHSN Network AF programme team to support this issue and there was limited interest from CCGs to integrate device use into existing AF pathways. Poor technological readiness and willingness to use the devices significantly affected the rollout of devices in deployment locations.

The R-Outcome scores for users' digital confidence and innovation readiness were generally lower in these AHSNs. Importantly, typology development does not mean AHSNs fit perfectly into each typology, as seen below with the Digital Confidence scores for UCLPartners. However, considering the negative position of the qualitative themes, Innovation Readiness data and device utilisation data, it was apparent UCLPartners fit this typology more so than another typology.

Table 12: environment scores for AHSNs in this typology

AHSN	Digital confidence	Innovation readiness	% of procured devices distributed	% of distributed devices registered	Avg. readings per device registered
West of England	78.2	72.5	78%	34%	16
UCLPartners	82.9	75.9	80%	64%	12
Oxford	73.3	65.8	84%	51%	13
Average of all AHSNs	81.2	77.5	89%	57%	26

Note: Utilisation data is for KardiaMobile devices only.

"We had substantial problems with some CCGs as some didn't want KardiaMobile as they saw issues with information governance coming and wanted to wait until that had been sorted out…this delayed or stopped the rollout in those CCGs. Also, one CCG has a history of non-engagement with our AHSN which is frustrating for everyone…[also] clusters of practices wanted different devices and that process had to be worked through. There were lots of issues to think about, some practices didn't want to use their own smartphones and mergers between CCGs created delays in the rollout. In one CCG, the IT [Information Technology] support was organised by the local CSU [Commissioning Support Unit] but this just created another step in the process of the rollout and led to delays." Source: AHSN local roll out lead

2.4 ENVIRONMENTS KEY FINDINGS

This evaluation found evidence of a common set of environment issues that impacted upon all of the AHSNs' roll-out programmes. There was ambiguity about where the devices should be used, their clinical advantage over current methods and their alignment with the wider AF diagnostic and treatment pathway.

It is also clear that there is large variation in the success of the 15 roll-out programmes in terms of their distribution and utilisation of the 6,338 devices:

- % of devices distributed to users ranged from 54% to 100%
- % of devices registered by their users ranged from 31% to 100%
- Average readings per device ranged from 7 to 72

There is evidence that important environmental factors contributed to this variation. In particular the level of people engagement (clinical leadership and relationships) and the enabling structures (local information governance processes, integration with the wider AF pathway and technological readiness). Five typologies have been identified to help further understand the impact of different environments across the 15 AHSNs.

Highest device utilisation was seen in AHSNs with evidence of fully engaged people (strong clinical leadership and strong relationships with deployment locations) and enabling structures (low burden of local IG., good AF pathway readiness and good technological readiness). Conversely, those with evidence of lightly engaged people and hindering structures had the lowest device utilisation.

Findings about the physical environments of users and the experiences of different staff groups are presented in section 7.

3 WHAT FEATURES OF THE IMPLEMENTATION PACKAGES ARE MOST EFFECTIVE? WHAT DEFINES SUCCESSFUL IMPLEMENTATION?

3.1 INTRODUCTION

This section provides an understanding of the implementation approaches taken at AHSN level and some common barriers to implementation. Key findings are summarised at the end of this section.

The national programme team adopted a co-production approach to the rollout. Each AHSN decided how they were going to deploy the devices by inviting expressions of interest (EOI) from their local organisations about the type of devices, number of devices and preferred contexts. Whilst the EOI approach was common, AHSNs varied in when they did this, in the speed at which AHSN leads could act and in specifics such as obtaining device usage plans or setting up of Memoranda of Understanding. Environmental factors also contributed to the success of implementation, in particular the levels of engagement and readiness for change at the adopting sites (see section 2).

As described in the four identified phases of the rollout (Figure 1), the actions of AHSN local rollout leads were affected by decisions that preceded their involvement and decisions taken by the local deployment contexts – they were not operating in a vacuum.

3.2 IMPLEMENTATION THEMES COMMON TO ALL AHSNS

During the qualitative fieldwork, 125 device users and 57 AHSN staff across all 15 AHSN described their experience of the rollout through focus groups and interviews. A thematic analysis of these views highlighted four key implementation issues common to all AHSNs.

In the opinion of most participants, it is reasonable to conclude these issues significantly reduced the distribution and utilisation of devices. The learning points described below offer opportunities to improve future rollout activity. Four common implementation related themes were identified:

1. **Pace of implementation is crucial**
2. **Operationalising device rollout is resource intensive**
3. **Avoid assumptions about staff personal device use**
4. **Ensure that data collection on device utilisation is robust**

The themes described below illustrate how each AHSN responded to these challenges in different ways.

Implementation theme 1: Pace of implementation is crucial

All local AHSN rollout leads reported they experienced significant delays during the pre-rollout phase – between introduction of the programme in approximately February 2017 and the devices being procured and delivered to individual AHSNs in approximately January 2018. Having engaged local CCGs and other deployment locations to begin the rollout process, delays in device arrival led to some disengagement, some withdrawal from the rollout, and some CCGs proceeding to purchase devices independently of the programme. The time taken to obtain IG assurance and related documentation from the AHSN Community of Practice Group, and to agree a joint approach to metrics collection were perceived to have most impact on the rollout timelines. In most cases, the Freedom of Information request received by the AHSNs, CCGs and Trusts team also halted rollout activities. It was strongly felt by local rollout leads that good communication was important to effectively manage the impact of delays. Despite regular communications from the AHSN Network AF programme team (6 weekly webex, quarterly Community of Practice events, fortnightly email updates, Dropbox for sharing documents and NHS Futures page) and regular contacts between rollout leads and the programme team, most rollout leads described an 'ebb and flow' style to the communication and pressure to roll out the devices as quickly as possible. AHSNs responded differently to these circumstances. Some distributed the devices at pace with limited support to device users while others took a slower more managed approach, foreseeing logistical challenges and avoiding tensions with deployment locations. This latter approach yielded better device utilisation.

> *"The long wait for the KardiaMobile devices was very frustrating for us. Having been told about it and thinking through how we'd use them in practice, it was 5 months before we got to use one in anger. Our senior GPs had gone lukewarm on the topic by that time and needed considerable nudging to come around to using them again."*
>
> Source: general practice device user

> *"The delays caused a problem for the rollout, the IG issues were being thrown around, and people [deployment locations] had been waiting a long time for their devices. A lot of fizz about the idea had gone out them [staff]…they'd applied for devices many months before, some for 6 months, and nothing had happened…the bottom fell out of it unfortunately."* Source: AHSN local roll out lead

"It was difficult and tense sometimes, we were under a lot of pressure to get the devices into practices but having to wait for things like guidance on IG and then encountering lots of issues to overcome in the practices like the registration problems… we would often hear nothing about the rollout guidance, plans and advice and then have a deluge of information land on our desks…this made planning the rollout difficult, particularly with limited resources" Source: general practice device user

The AHSN Network AF Programme Team were also interviewed about their experience of managing the programme and highlighted a range of issues similar to the procurement challenges identified in section 4.4 of this report. For example, this national lead highlighted procurement challenges, legal arrangements for device ownership and the Freedom of Information request as reasons for the delay in device distribution to local AHSNs:

"We were happy to take the lead in the procurement and thought it would be fairly straightforward, however, we had a range of challenges to overcome…our procurement team [linked to NHS Trust] had to follow NHS rules and regulations and it turned out, for example, it was cheaper to buy the devices through Technomed rather than KardiaMobile direct…this created a huge amount of problems between KardiaMobile and us and subsequently delays. The lesson was to try and make sure we get the right price, but we need a procurement expert to do this kind of device procurement and rollout. There was also the issue of whether we owned the devices and we had to ask each AHSN to sign a contract…which took months to organise…to say they would take ownership so we wouldn't end up with hundreds of GPs from around the country asking us [procuring AHSN] for support with the devices. We also had to deal with a Freedom of Information request which delayed our work…and AHSNs do not have dedicated Information Governance experts and there were plenty of issues to sort out there too like personal phone use, the need for NHS.net email addresses and taking time to speak to the Caldicott guardian…but I think if we'd taken a model whereby 15 AHSNs procured their own devices it would have got really messy." Source: AHSN Network AF programme team member

Implementation theme 2: Operationalising device rollout is resource intensive

An important learning point, common to all AHSNs, was not to underestimate the resources required to deliver the rollout effectively. All local rollout leads shared the view they were under-resourced to manage such a wide-ranging rollout. In some cases, only one member of staff or a combination of part-time staff to the equivalent of 1 FTE (full time equivalent), was employed to distribute hundreds of devices, conduct device training, support registration of the devices for monitoring and evaluation, manage queries, and feedback data to deployment sites. Several AHSNs recognised this challenge early and acquired funding from pharmaceutical or other sources to pay for staffing to support the rollout activities. In the views of many, it was reasonable to conclude more devices would have been deployed and better utilised if more rollout staff were available. Similarly, ensuring that there is enough resource and time for good communication between the AHSN Network AF Programme Team, AHSN teams and users was important. Implementation work typically relies on a few key people – champions, opinion formers and early adopters – and it is important that there are enough of these key resources as well.

"I think our start point of stimulating the market led to limited resources in place for this programme, just a programme lead role actually working part-time on it…as we got further into our discussions with the national team we quickly realised this was a much larger job than previously realised…we hired a dedicated rollout staff member to distribute the devices, manage the administration of devices and conduct the training face to face but even that didn't mean she got to all the device locations or spoke to every device user. That's hundreds of people and she's only one person." Source: AHSN local roll out lead

"We were desperately under-resourced to deal with all the implementation work. One solution might have been to deliver the devices to CCG partners and practices directly to avoid our involvement in that part…but I know that would need a lot of planning too…it was the physical need to wait for device arrival, store hundreds of them, re-package them, get the tailored support plans in place and get the devices to practices by hand…that literally took months for me to do alone." Source: AHSN local roll out lead

The AHSN Network AF Programme Team acknowledged resources was a locally managed issue and highlighted the start point for each AHSN was not equal, for example:

"We liaised with each AHSN about how many devices they wanted, that part was straightforward…and we encouraged each AHSN to develop implementation plans but their plans varied in their depth based on the resources in that AHSN, by that I mean the intellectual resources and awareness of implementation knowledge as well as physical staff available…also, some AHSNs got on board with the AF rollout but some weren't as interested and maybe that was because it wasn't part of their individual business plans. Some just didn't want to know and maybe that affected their resourcing plans…some flexed their staffing to manage this national priority more than others. Source: National AF team member

Implementation theme 3: Avoid assumptions about staff personal device use

The requirement for KardiaMobile to be delivered through a smartphone/tablet proved a significant barrier to device utilisation. NHSE funding only covered the purchase of the devices themselves and therefore the programme had to rely on the "bring your own devices" legislation from NHS Digital to engage staff in personal device use. Many staff were unwilling to do so. Concerns about patients dropping smartphones and the blurring of work/home life boundaries were reported by device users at all of the focus groups. Only one AHSN, East Midlands, took the decision to purchase these for some practices to avoid practices withdrawing from the rollout.

Implementation theme 4: Ensure that data collection on device utilisation is robust

All AHSN rollout leads highlighted the significant challenge of ensuring that devices were accurately registered to enable monitoring and evaluation of device use. Problems associated with registration were identified mid-way through the rollout and included not responding to emails from AHSN rollout leads, not having time to register, not wishing to register, registering the device with the incorrect serial number (due to there being two possible numbers on each device and despite guidance in the registration portal). The reported impact of these issues was some disengagement from adopting staff and organisations as they were not able to receive monitoring data from the AHSN rollout leads. Monitoring data was managed centrally by the AHSN Network AF programme team due to arrangements with KardiaMobile and to minimise the data handling burden for each AHSN, but it was perceived that this affected the timeliness of access to device monitoring data at the local level.

"We had to get the devices to practices quickly due to delays receiving them…this led to registrations not being done because we didn't have time to train or help staff register. This led to a lot of non-use of devices and them sitting in desk drawers."

Source: AHSN local roll out lead

There were many references to data limitations. These have been summarised in section 1.3.

Future rollouts will wish to ensure that the collection of monitoring data is robust, and that there are planned activities with deployment locations to ensure that staff receive feedback on device use sufficient to make a judgement on whether it's working for them.

"We feel the local AHSN leads didn't stress the importance of device registration and data collection for the evaluation…it should have been straightforward, staff go onto the website and answer half a dozen questions…and they [device users] should have been told they were being given an expensive bit of kit and its only 10mins of your life to register. Some AHSN leads got on top of that and had 100% registration, but [for] most AHSNs it was a major problem and we weren't able to know how the devices have been used. We wrote training slides for local AHSN leads and device users to use but I don't think they made it to the stakeholders." Source: National AF team member

The AHSN Network AF Programme Team highlighted they were aware of the potential for the registration issue to affect the evaluation but passing on guidance alone was not in itself a guarantee of device registration.

3.3 IMPLEMENTATION TYPOLOGIES

A range of qualitative and quantitative findings were synthesised to generate *implementation typologies**[11]. These sought to provide an organised system of types, to explain and group the characteristics witnessed in each AHSN into a digestible analysis. The implementation typologies seek to describe the different management approaches taken by AHSNs. They include the degree and nature of delegation, clarity and communication of expectations, the level and style of support and training that was provided and how devices were issued and subsequently managed (e.g. recalled if not used).

Five implementation-related qualitative themes that *varied between AHSNs* were identified from focus groups and interviews with device users and AHSN rollout staff:

Table 11: The implementation-related qualitative themes that varied between AHSNs

Implementation themes that varied between AHSNs	Description
1. Rollout responsibility	The degree to which the AHSN retained or delegated responsibility for the rollout as the programme progressed and devices were deployed in CCGs, Trusts and practices. Delegation was associated with poorer device utilisation.
2. General approach to support for deployment locations	The level and style of support provided by the AHSN, including face to face support, remote distance support, and/or flexible or fixed support. Face-to-face support was associated with better device utilisation.
3. Training and device registration approach	The level of and style of support for training and device registration as key elements of AHSN rollout work. This theme highlighted to what degree AHSNs undertook flexible, tailored and numerous training/registration opportunities to support device users. AHSNs undertaking the latter were associated with better device utilisation.
4. Device distribution and management	The degree to which devices were carefully managed and if necessary, recalled to be redistributed. AHSNs who retained devices until training and registration was complete and recalled devices to redistribute were associated with better device utilisation.
5. Clarity of expectations around device use	The level to which AHSN rollout leads organised plans, documentation, and introductory meetings with deployment locations to create clear expectations about device use with deployment locations. AHSNs promoting clear expectations were associated with better device utilisation.

[11] * See Glossary for further explanation of this term

A process of **synthesis** brought together the reported position of each AHSN in relation to these five themes (some good, some moderate, some poor), with the quantitative data available on utilisation (see Appendix 2) and the R-Outcomes scores on the 'Innovation Adoption' domain. This synthesis identified **four implementation typologies**:

Table 12: AHSNs by implementation typology

Typology	AHSN
1. Fully managed rollout	Health Innovation Network North East and North Cumbria South West Yorkshire and Humber
2. Moderately managed rollout	Eastern Imperial College Health Partners Kent, Surrey and Sussex Wessex
3. Lightly managed rollout	Health Innovation Manchester Innovation Agency Oxford West of England West Midlands
4. Delegated management rollout	East Midlands UCLPartners

Implementation typology 1: Fully managed rollout

This typology was characterised by a positive position on all five implementation qualitative themes, good utilisation of the devices within their control and with more positive Innovation Adoption scores. The implementation approaches of the Health Innovation Network, North East and North Cumbria, South West and Yorkshire and Humber AHSN were found to fit this typology.

These AHSNs maintained rollout responsibility themselves rather than delegating this to CCGs and deployment locations. They recognised that CCGs probably didn't have the resource to do this and wanted to maintain control of the rollout of devices over time, rather than all at once. Training and registration support were flexible and tailored and general support to users was delivered face to face. Device distribution and management was closely controlled by the AHSN, including ensuring users had been registered and trained before receiving a device. They promoted clear expectations about device use, often supplementing the guidance from the AHSN Network programme team. They maintained a close watch on devices not being used and would recall and redistribute them.

These AHSNs had the best utilisation of their devices and their device users gave more positive responses to the Innovation Adoption measure:

Table 13: implementation scores for AHSNs in this typology

AHSN	% Devices distributed to users	% Devices registered	Avg. readings per registered device	R-O Innovation Adoption Score
Health Innovation Network	100%	86%	39	68.2
North East and North Cumbria	101%	102%	54	77.8
South West	102%	53%	72	66.7
Yorkshire and Humber	80%	74%	23	62.4
Average of all AHSNs	89%	57%	26	65.1

Note: Utilisation data is for KardiaMobile devices only. Scores of more than 100% will either be due to multiple registrations of devices and/or the redistribution of devices during the programme.

"I tried to make the implementation as slick as possible. I went to practices and joined their business meetings to make sure I saw all the relevant people. The GPs, practice manager, and senior nurses are always at those meetings…I held back giving the devices out until staff had registered and been trained, that meant it was slower but they were clear about how to use the device, had time to think through how they were going to use it, and I had less problems later on." Source: AHSN Local roll out lead

Implementation typology 2: Moderately managed rollout

This typology was characterised by a mixed position on the five implementation qualitative themes above and was associated with moderate utilisation of the devices within their control and generally moderate Innovation Adoption findings. The implementation approaches of Eastern, Imperial College Health Partners, Kent, Surrey and Sussex and Wessex AHSNs were found to fit this typology.

In two AHSNs (Wessex and Eastern) rollout responsibility was maintained by them and they did not delegate it to CCGs or deployment locations. They offered flexible and tailored training to deployment locations. In the other two (Kent, Surrey and Sussex and Imperial College Health Partners), some delegation was given to deployment locations and they provided moderately flexible training, largely due to the challenge of spreading their devices over many CCGs/deployment locations. In all four, a mix of general support (face to face and distance support) was offered and several moved from distance to face to face support as device usage failed to increase over time. All four had a moderate level of device management, with only an occasional recall of devices if they were not being used. All four promoted clear expectations on the use of their devices which suggested they planned to develop good understanding of the purpose and activities of the rollout and device use with deployment locations.

These AHSNs had moderate utilisation of their devices and their users gave generally moderate responses to the Innovation Adoption measure:

Table 14: implementation scores for AHSNs in this typology

AHSN	% devices distributed to users	% devices registered	Avg. readings per registered device	R-O Innovation Adoption Score
Eastern	100%	50%	28	65.6
Imperial College Health Partners	80%	47%	26	73.3
Kent, Surrey and Sussex	100%	46%	30	60.5
Wessex	89%	42%	23	65.5
Average of all AHSNs	89%	57%	26	65.1

Note: Utilisation data is for KardiaMobile devices only.

"The paperwork around using the KardiaMobile device was overwhelming…it's a simple device but not simple to manage due to the paperwork requirements to get it rolled out. We tried to offer training in all our CCG locations but we're talking double figures in numbers of CCGs and dozens of individual practices…so a lot of communication was done at distance. We tried training practice managers so they could tell their clinicians about it but the messages just got lost in translation somehow, we didn't get devices registered and it stalled the rollout." Source: AHSN Local roll out lead

Implementation typology 3: Lightly managed rollout

This typology was characterised by a moderate to poor position on all five implementation qualitative themes, and associated with poor utilisation of the devices within their control and moderate to poor Innovation Adoption findings. The implementation approaches of the Health Innovation Manchester, the Innovation Agency, Oxford, West of England and West Midlands AHSNs were found to fit this typology.

In these AHSNs a lot of rollout responsibility was given to deployment locations, largely due to resource limitations but also due to preferences that CCGs would be better placed to manage distribution to collaborating practices. These AHSNs' general approach to support was largely distance-based but a few rollout leads did change to face to face support and training when device usage was found to be poor. For the same reasons, moderate to limited training and registration opportunities were available for device users although that did improve over time, device distribution was largely postal to device users and these were lightly managed once distributed. Limited attempts to recall and redistribute devices were undertaken. Limited clarity of expectations and plans for device use were highlighted in four of the five AHSNs, largely due to either limited AHSN resources for the rollout, , a broad remit of distribution across dozens of CCGs, and attempts to provide a geographically even spread when a clustered/targeted approach may have been more appropriate. Despite the AHSN Network producing written guidance on how to implement the devices, AHSN local rollout leads also felt that there was a lack of training support that contributed to AHSNs adopting different approaches to implementation.

These AHSNs had poor utilisation of their devices and their users gave generally moderate to poor responses to the Innovation Adoption measure:

Table 15: implementation scores for AHSNs in this typology

AHSN	% Devices distributed to users	% Devices registered	Avg. readings per registered device	R-O Innovation Adoption Score
Health Innovation Manchester	100%	31%	19	60.8
The Innovation Agency	85%	73%	7	63.5
Oxford	84%	51%	13	41.7
West of England	78%	34%	16	59.2
West Midlands	100%	24%	26	66.9
Average of all AHSNs	89%	57%	26	65.1

Note: Utilisation data is for KardiaMobile devices only.

"We didn't provide a structured training session and provided all our information at distance; this was just the reality we were in with only one person staffed to do this work. We did, perhaps naively, assume the devices [KardiaMobile] weren't that hard to use, so didn't think we needed training sessions. We did change that plan once we realised no-one had registered or was using the devices." Source: AHSN Local roll out lead

Implementation typology 4: Delegated management rollout

This typology was characterised by a poor position on all five implementation qualitative themes, and associated with poor utilisation of the devices within their control and moderate Innovation Adoption findings. The implementation approaches of East Midlands and UCLPartners and were found to fit this typology.

In these AHSNs, the vast majority of rollout responsibility was given to deployment locations. This was a decision explicitly made at AHSN level and driven by AHSN resource concerns, the belief that CCGs would be better placed to communicate and distribute devices, and indications that CCGs insisted on their involvement as gatekeepers to working with their practices. This led to not really knowing what was happening in each of the deployment locations, in terms of who had the devices and what they were doing with them. The poor utilisation can also be explained by a largely distance support approach, with occasional face to face support. Very limited training events/opportunities were offered, devices were distributed by posting them to users, and these were not managed once distributed due to not knowing which health professionals were in possession of them.

These AHSNs had poor utilisation of their devices and their users gave moderate responses to the Innovation Adoption measure:

Table 16: implementation scores for AHSNs in this typology

AHSN	% Devices distributed to users	% Devices dist'd registered	Avg. readings per registered device	R-O Innovation Adoption Score
East Midlands	54%	76%	12	64.6
UCLPartners	80%	64%	12	62.5
Average of all AHSNs	89%	57%	26	65.1

Note: Utilisation data is for KardiaMobile devices only.

"We took the decision, based on AHSN resources and a large patch, just to engage with CCGs and not to engage with practices directly. We posted the first few hundred devices to the CCG leads and also asked KardiaMobile to post some directly too. We didn't provide any support documents at that time as they weren't ready and lots of things were still to be debated by the national AF team. I know this wasn't the ideal way to do this now as our device use has been poor but we were under lots of pressure to get going…the CCGs did what they could but they have their own resources issues too. Our main problem though was not knowing where the devices were…so we couldn't intervene to sort out any problems." Source: AHSN Local roll out lead

3.4 IMPLEMENTATION KEY FINDINGS

This evaluation found evidence that all AHSN implementation plans were negatively affected by the protracted national timescales for delivery of the programme during much of 2017 and up to Spring 2018, and it was commonly felt that more resource and that improved communication between all stakeholders (AHSN Network AF programme team and local rollout leads, and local leads and device users) would have facilitated rollout of the devices. An assumption about personal use of smartphones/tablets for KardiaMobile, coupled with logistical complexities of staff using their own smartphones, reduced device utilisation. Problems associated with registration and data collection affected the availability, breadth and accuracy of the utilisation data received.

It is also clear that there is large variation in the success of the 15 roll-out programmes in terms of their distribution and utilisation of the 6,338 devices:

- % of devices distributed to users ranged from 54% to 100%
- % of devices registered by their users ranged from 31% to 100%
- Average readings per device ranged from 7 to 72

There is evidence that important differences in the implementation approaches taken by the 15 AHSNs contributed to this variation. These include the degree and nature of delegation of responsibilities, clarity and communication of expectations, the level and style of support and training that was provided and how devices were issued/recalled. Four typologies have been identified to help further understand the impact of different implementation packages across the 15 AHSNs.

AHSNs found to be in the 'fully managed' typology had the highest levels of utilisation, while those who delegated management to the deployment locations had the lowest levels of utilisation.

Overall, these findings would suggest that the utilisation of devices in this roll-out programme could have been higher if the common implementation issues were addressed and the variation between AHSNs was reduced.

4 WHAT IMPACT HAS THE PROGRAMME HAD ON THE MARKET PLACE?

4.1 INTRODUCTION

This section describes the impacts the programme had on the market place, based upon the views of five AHSN Commercial Directors involved in the design of the programme, the five device suppliers and the procurement manager. It looks at the impact on the market from a supply side, demand side and procurement perspective.

The following table describes the number and range of devices and their unit price.

Table 17. Range and numbers of devices selected by AHSNs and their unit price.

Device	Number delivered	Number of AHSNs	Unit price[a]
KardiaMobile (AliveCor)	5,858	15	£61[b]
Watch BP (Medical BV)	391	6	£54 + £15[c]
MyDiagnostick (Medical B.V)	46	2	£652
Impulse (Plessey)	31	2	£220
RhythmPad (Cardiocity)	12	3	£850
Total	6,338		

(a) The unit price negotiated for this programme

(b) For the KardiaMobile device and app, but not the smartphone or tablet it runs on

(c) Watch BP unit price was £54 and the programme also bought L/XL cuffs at unit price of £15

4.2 SUPPLY ISSUES

Perspectives of AHSN Commercial Directors

The AHSN Commercial Directors described a range of impacts the programme had on the supply of mobile ECG devices. A number of them focused on the design of the programme in early 2017 and were pleased that NHS England's approach moved from an intention to purchase KardiaMobile only to offering a range of devices. Some felt that current national programmes can get 'hung up' on particular products rather than specifications and they supported the development of a mobile ECG specification for this rollout programme.

They weren't sure that the programme had set out to stimulate the market and that what this meant in practice hadn't been defined. Its real focus had been to buy the devices and to get the benefit of their use. All of them expressed concerns about the impact of delays in the programme during 2017 – from asking AHSNs to select their devices in May and the first of these not arriving until January 2018 (documented in table 1).

All of them were acutely aware that despite the change of intent from NHSE from buying only KardiaMobile devices to offering a choice of five – that 92% of the devices selected by AHSNs were KardiaMobile Mobiles. Some felt uncomfortable that the market leader had been made stronger and that it would make it harder for new entrants to join this market – others felt that this was the market in action and recognised the relative benefits of the KardiaMobile devices.

Perspectives of Device Suppliers

The three suppliers selected to provide small volumes of devices, described dissatisfaction with the programme and felt it was a lost opportunity. They felt that the chance to supply a large number of devices and to price that accordingly wasn't explained to them and they could have lowered their price for a larger order. They didn't feel the AHSNs understood the difference between their devices and KardiaMobile, as theirs were designed for a multiple user setting (e.g. GP surgery) rather than personal

use which drives their build costs. They were frustrated that the programme could have done more to stimulate the market for smaller suppliers with earlier discussions about its aims.

Microlife have been focusing on selling their device to GPs, pharmacies and hospitals through device distributors in the UK – promoting the benefit of the NICE technical guidance for opportunistic screening during diagnosis and management of hypertension. This programme hasn't changed their market. It has been helpful to have more exposure but the 391 devices are a very small proportion of their business and their device is about more than detecting AF.

AliveCor are a US business that launched their device in the UK in 2013. In 2015 their VP for Sales Business Development was successful in his application to be a National Innovation Accelerator Fellow and in 2017 they received this large order from the NHS. In the US, KardiaMobile is marketed as a low cost consumer device sold direct to the public. The NHS is a different kind of market and it has been important that they are seen as clinically and scientifically valid, not a gadget. They were most affected by the delays in the programme. They expanded their UK team to meet increased demand from this programme, but this happened 6 months later than they expected. They were able to deal with this, but felt that smaller companies or start-ups would find this much harder.

The suppliers described growing competition in the field of mobile ECG technology, particularly in the market focusing on the public monitoring their own health:

- At the European Society of Cardiology Congress in August 2018, there were around 15 companies displaying new wearable patch technologies
- Apple have developed an ECG app for their watch that they say identifies signs of AF – this is similar to another AliveCor product, the KardiaMobile Band
- There are a number of similar ECG monitoring devices on Amazon priced competitively – though many of these don't have an AF algorithm or a CE mark like the devices in this programme

What was less clear was whether the health service market (practices, pharmacies and hospitals) is different to the one for individuals choosing to buy their own device. AliveCor have focused on the personal market and the other four companies in this rollout have focused on the health service market. The qualitative findings from the staff device user focus groups described in section 7 didn't find a preference from NHS users for these four devices over KardiaMobile.

4.3 DEMAND ISSUES

Perspectives of AHSN Commercial Directors

There was wide agreement this programme had been a positive way for AHSNs to link with commissioners, providers and clinicians – particularly GPs – to explore and trial a technological innovation. It enabled a different approach to supporting spread and adoption – making the device a gift, supporting with training and building a relationship. This evaluation also found good and innovative examples in secondary care, mental health and the voluntary sector.

There was a counter view, that this approach ran the risk of developing a dependency culture and that people or organisations may think that someone else is going to source innovations for them.

Perspectives of Device Suppliers

Unsurprisingly, the companies selected to provide small number of devices did not think there had been an impact on demand. Medical B.V (391 Watch BP's) also hadn't noticed an impact on demand.

AliveCor reported encouraging levels of adoption generally in the UK and that this programme had played an important part in the awareness of and trust in their device. A number of AHSNs have bought additional devices to those procured through this programme. They are selling 6-7000 devices per month in the UK.

The suppliers' perception indicated it was generally easier to introduce these devices in secondary care than General Practice. There was a concern there was a particular challenge with GPs who are very busy, reluctant to take on extra work and require resource or payment to adopt. The recent NICE report on single lead ECG devices[6] concluded that more research is needed to support their routine use in primary care. Suppliers will need consider how they can support this by supporting data collection and interpretation.

This is a large market, with around 44,000 GPs in around 7,000 practices. 1,201 of the 2,088 devices in this rollout programme were delivered to General Practice which provided an important opportunity to the suppliers.

4.4 PROCUREMENT ISSUES

The procurement of the devices was led by Lancashire Care NHS Foundation Trust, who host the Innovation Agency AHSN. They became involved in the programme in late May 2017 and the AHSN Network AF Programme Team were complementary about the value they added.

The five devices were selected using the specification, the review by the Health Innovation Network [4] and the pooled knowledge of the AHSNs of the market. It isn't clear how this final list of 5 were agreed. There were other products that met the specification.

The procurement teams view was that it would have been better to involve their expertise at an earlier stage. By the time they got involved the five devices to be included had been agreed and AHSNs had selected the ones they wanted to rollout and indicative numbers. Earlier procurement options could have included supplier workshops that enabled clinicians and AHSNs to try and compare the devices and this could have helped stimulate the market. The smaller suppliers felt strongly that the differences between the relative strengths of products in different settings were not properly understood and that price became the main factor rather than value for money.

With the devices and their numbers already agreed, the procurement team described their task as primarily being about buying the devices in a way that met legal requirements and was at the best price. Four of the devices were deemed to be low value purchases below tender thresholds and the job was to work with them to agree a price, which the procurement team undertook.

Purchasing the KardiaMobile devices was the main procurement work because its value meant that it was a significant transaction that required compliance with the Public Contract Regulations and exceeded OJEU limits. There were two supplier frameworks that could be used to purchase the devices. AliveCor were on the G.Cloud framework and Technomed, a specialist cardiology diagnostic product distributor, could supply them through the NHS Supply Chain framework. The two options were assessed. Technomed offered the lower price and was the preferred supplier at the end of October 2017. However, at this point, two challenges emerged that risked the purchase of the KardiaMobile devices:

i) Problems arose in the commercial relationship between AliveCor and Technomed that threatened Technomed's ability to deliver the devices. AliveCor had anticipated that it would be supplying these devices and had prepared for this. However, their price per unit was higher than the NHS had expected. The result was the preferred supplier switched to AliveCor, at a re-negotiated price.

ii) AliveCor changed their international commercial model for their smartphone app from being free to requiring a subscription that would increase costs considerably. This also had to be negotiated back to a more basic app that would be free.

The negotiations with AliveCor concluded in December 2017.

The final 'hurdle' was the need to develop a legal agreement to transfer responsibility for the devices from Lancashire Care NHS Foundation Trust to the 15 AHSNs. Developing this and getting it signed by all of the AHSNs took place between December 2017 and March 2018.

4.5 MARKET IMPACT KEY FINDINGS

This evaluation didn't find evidence to indicate that the programme has resulted in more suppliers or devices. Whilst it has contributed to AliveCor's growth in the UK, the companies selected to provide a small number of devices are concerned that the programme has reduced competition.

The market that appears to be developing and where there is a lot of international product development is for individuals to buy their own device to monitor their own health. This is a different market to that of health services which this programme sought to stimulate.

The delivery of 1,201 devices to general practice may be seen as a success and an opportunity for the suppliers. However, suppliers perceived that introducing these devices to GPs is challenging, due to their time pressures, reluctance to take on extra work and required resource or payment to adopt.

Doctors' perceptions of the rollout programme were much lower than the other staff groups, their satisfaction with the devices was a bit lower (figure 4); and doctors were more likely to stop using the device before they have performed 25 readings (figure 5). Nevertheless, this evaluation found a lot of evidence that these devices can be effectively used by many other staff groups, such as healthcare assistants and pharmacists.

Suppliers have an important role in will need consider how they can support this by supporting data collection and interpretation of the utilisation of their devices. This programme has demonstrated that manual data collection does not work.

There were many issues in what proved to be a difficult and protracted procurement of the mobile ECG devices. The key lesson is that the procurement team should be involved as early as possible and before devices are selected.

5 WHAT IMPACT HAS THE PROGRAMME HAD ON PATIENT OUTCOMES?

5.1 INTRODUCTION

This section provides an understanding of the impact of the programme on patient outcomes. It includes findings about the settings in which patients were tested, the number of possible cases of AF detected. It uses the national AHSN Network assumptions to model what the potential impact on avoided strokes could have been, though there are some important caveats to this. The views of patients, as reported by staff, are also described (the evaluation brief didn't include collecting evidence directly from patients). Key findings are summarised at the end of this section.

5.2 QUANTITATIVE FINDINGS

The quantitative data collected by AHSNs between January 2018 and March 2019 for KardiaMobile devices showed that:

- 2,088 staff have undertaken:
- 81,933 readings, which have detected:
- 5,586 possible cases of AF

The data received for the use of other mobile ECG devices (which was captured manually by the AHSNs) was not sufficiently robust and therefore could not be included in this analysis. Data limitations are described in section 1.2. Appendix 2 includes the reported recordings and AF detections for the other devices (6141 readings with 131 possible AF detections – 2.1%)

The following table shows the KardiaMobile data by the main settings that the registered users categorised themselves as working in:

Table 18: Setting summary quantitative analysis

Setting	No. of users	No. of readings	Avg. readings per user	Possible AF Detections	AF Detection %
General Practice	1,201	45,999	38	3,178	6.9%
Community based clinics	111	3,828	34	240	6.3%
Domiciliary	166	6,777	41	398	5.9%
Community Pharmacy	51	3,273	64	198	6.0%
Acute Hospital	73	4,241	58	300	7.1%
Other	91	413	45	34	8.2%
Not recorded	395	17,402	44	1,238	7.1%
Total	**2,088**	**81,933**	**38**	**5,586**	**6.8%**

The national AHSN Network AF programme aims to prevent 4,000 strokes by the end of 2019/20 (described at 1.1). It has identified a set of evidenced assumptions to model the impact of improvements and innovations, such as the improved detection of possible AF by the mobile ECG devices rolled-out by this programme. The following table sets out these assumptions and what they infer could be the impact on patient outcomes from this programme:

Table 19: National AF programme outcome assumptions

National AF Programme Assumption	Potential impact of the mobile ECG roll-out
Possible AF detections by mobile-ECG devices in this roll-out programme	5,586
Confirmed AF 94.4% of those detected by a KardiaMobile device will have a confirmed diagnosis of AF following a test with a 12 lead ECG device (the true positive rate). [4] [13]	5,273
Requiring treatment 84.2 % of these patients will need anticoagulant treatment [14]	4,440
Receiving treatment 84% of patients with AF with a record of a CHAD2D2-VASc score of 2 or more are treated with anticoagulation drug therapy [15]	3,731
Potential strokes avoided 5% of patients presenting with an acute ischemic stroke have previously undiagnosed AF. [16]	**187**

These national modelling assumptions are helpful in indicating the potential contribution of this roll-out programme to the national AF programme described at 1.1 and its aim of preventing 4,000 strokes.

However, there are a number of important issues that mean that the 'real' number of strokes avoided by this programme could be significantly different.

These are:

1. The 5,586 possible AF detections only relate to the 56% of registered KardiaMobile devices that were registered and had their utilisation collected. The other devices would also have detected possible AF.
2. Some AF detections via this rollout programme may have been detected anyway, via existing pathways, so should not be attributed to this programme.
3. When AF is detected via a mobile device it is possible that the test may be run again on the same individual to confirm the results leading to double counting and an inflated number of AF detections. This was confirmed in our focus groups with device users.
4. Some patients identified by mobile ECG devices in non-healthcare settings may never get through to a formal diagnosis and therefore may not receive treatment.
5. Not all strokes can be avoided by identification and treatment. Treatment reduces the risk of stroke but does not eliminate it entirely.
6. Other assumptions and methodologies could be used which may provide a different estimate of the number of strokes avoided.

5.3 QUALITATIVE FINDINGS

Other insights into the impacts of the programme on patients were gathered from device users in the focus groups and interviews and are described below in seven themes. It should be noted that staff views will be influenced by their own experience of using the devices and in particular the themes reported in section 3 on implementation. The majority of the feedback related to the KardiaMobile devices. Comments about MyDiagnostik and WatchBP were also received and are included at the end of this section.

Patient theme 1: High Acceptability

Patients had fed back to a wide range of professionals how much they liked KardiaMobile. In particular, they appreciated the technological innovation of the device and its quick and easy testing experience.

"Patients really like it [KardiaMobile], they want to be tested, seriously it's brilliant…they love the gadgetry of it and its ability to tell them instantly what their heart rate situation is. It's easy to use and very loved by patients. I was using it in a practice waiting room recently and patients didn't want to leave until they were tested…letting them know it'll only take 30 seconds and they'll see the visual traces was a good way to engage them."

Source: Nurse practitioner

Patient theme 2: Raised Awareness

The majority of device users highlighted how patients appreciated the increased awareness of AF and its link with stroke risk. The outcome of this was that several patients found to be at risk of AF, some in almost every AHSN, bought their own KardiaMobile to self-manage their situation and potentially to test their relatives and friends.

"It's been great at raising awareness of strokes and AF with patients and they've welcomed the heads up too. I always introduce the device with stroke risk information and that always gets their attention. With that and the technological nature of the device, it's easy to convince patients to do a quick test…in our area we've done this sort of health promotion in lots of places, including

"I've conducted some KardiaMobile tests to help to put patients' minds at ease about their heart rate. Usually after a manual pulse check…but it's the PDF of the trace that helps to convince them. They can see it with their own eyes and think ok I'm fine. It's definitely helped reassure some patients with palpitations who [were] frequently calling their GP." Source: practice nurse

Patient theme 3: Managing Anxiety

A large number of device users indicated KadiaMobile testing can ease anxiety about heart rate related conditions in those with concerns.

Patient theme 4: Flexibility

In some AHSNs, practices preferred to use KardiaMobile to assess paroxysmal AF over a longer timeframe rather than take the single visit short assessment approach seen in many device deployment contexts. This flexibility was welcomed by patients and some AF was identified this way.

"As a practice, we had to think about how this [would] work for us…we decided the best situation was for patients to take the KardiaMobile home and monitor their heart rate for us for the paroxysmal AF patients…we already have a 12-lead device in the practice so our GPs felt giving the KardiaMobile to patients was the best use of the device and staff time. So, when a patient was identified for KardiaMobile testing they would be sent down to me [practice manager]…if they were considered reliable, had their own smartphone, and known to have a good level techy knowledge so they would be able to use the app and KardiaMobile. I had a chat with them, asked them to sign a form to guarantee the return of the KardiaMobile after 6 weeks. We used a shared email address, our practice email address, in the app for all the patients so they could email us traces and we could monitor them. We knew this whole approach wasn't part of the original plan from the AHSN but we considered this the best way forward from a clinical point of view. We've only been doing this for a few months…we've given KardiaMobile out to the 5 patients in total and after the monitoring they did have confirmed AF." Source: practice nurse

Patient theme 5: Preventing unnecessary 12 lead tests

Almost all device users across all AHSNs reported patients had avoided unnecessary 12-lead assessments. This was an important positive patient impact, as well as it being a clear system benefit. As many health professionals agreed, patients living with long-term conditions is a lot of work and avoiding unnecessary investigations and visits to see professionals was universally welcomed by patients.

"In the district general hospital, they operate community clinics and have hubs in primary care centres. From there they have locality teams of specialist nurses who go out into the community. Previously, these cardiology nurses go out to patients' homes and end up doing a manual pulse check and then, if needed, go back to the hub to pick up the 12-lead kit and test the patient in a second visit. Now they have KardiaMobile, they are avoided a lot of back and forward getting the 12-lead kit and doing unnecessary test. Multiplied across the various professionals in the locality teams, it saved a large amount of time for them and made the service much more efficient." Source: Community Cardiology services

"We don't have a 12-lead kit in the practice so have to send patients off for that when we have our suspicions about AF…using KardiaMobile we've saved lots of those 12-lead tests and that's been a real positive for us and them." Source: GP

Patient theme 6: Unexpected identification of AF

"I had a patient come into the clinic who was complaining of being breathless and I knew had COPD, so I thought it was their COPD playing up, but I used the device [KardiaMobile] and saw their heart rate was very low and that is why they were so breathless…it gave me enough of a reading to know it wasn't sinus rhythm so I told the GP I was blue-lighting the patient and off they went." Source: paramedic practitioner

Many device users highlighted the patient benefit of identifying potential AF with KardiaMobile unexpectedly. Case finding for the benefit of the patient was an important theme health professionals wished to convey in the focus groups.

Patient theme 7: Identifying undiagnosed conditions

"A 53-year-old lady attended the practice for a non-AF issue…had a KardiaMobile check anyway based on the GP's concerns at the time…the GP was concerned she had a left bundle branch block so was sent for a 12-lead ECG. From that starting point the GP later found out she had hypertrophy which led to an echo and she was diagnosed with mild heart failure. This lady wouldn't have normally fell into any natural screening process due to her relatively young age. So, it was a combination of the new promotion AF work and GPs examination that led to this early diagnosis of heart failure." Source: practice nurse

A wide range of device users wished to highlight how KardiaMobile could play a part to support the identification of undiagnosed heart conditions. This was clearly perceived as a benefit for patients and the example below highlights how KardiaMobile played its part in clinical investigations.

Patient theme 8: Promoting wider health conversations

Device users were aware that through AF testing they were undertaking prevention work. They often highlighted in the focus groups how the KardiaMobile testing started other beneficial conversations with patients that further supported their general prevention work.

"The KardiaMobile device test can spark other conversations about their health. I've had discussions about patients weight management and COPD as well as their potential AF and AF referral I'd just made for them." Source: GP

Overall, KardiaMobile was positively perceived by patients, as reported by device users, and a range of patient benefits were described. However, there were some caveats to this, the most important of which was KardiaMobile was not suitable for all patients encountered. KardiaMobile could not be used with patients with hand tremor, dementia, extreme frailty, and Parkinson's disease. In these cases, a manual pulse check was clinically preferable.

"They are more expensive than KardiaMobile but the fire service staff have really taken to them…they've been used a lot by the firemen as they've visited people's homes for fire checks. They said they're easier to use than the other devices we offered them and happier with what to do next and what it means. There isn't the uncertainty about what to do, which you can get with KardiaMobile and the unclassified readings issue I've had before." Source: AHSN local roll out lead

Limited feedback about **MyDiagnostick** was received. The only patient impact theme from that feedback was related to the success it's had in the fire service context. Several AHSNs promoted the use of this device with the fire service and they undertook its use during their home fire risk assessment visits.

"There have been a number of positives of using MyDiagnostick in the fire service and thus for patients too…it's a good device for non-medical people like us…it's much easier to use than the other devices we were shown. We have over 200 people in our fire service area involved in this work…we're using operational fire fighters and other support staff during home fire risk assessments. We've been really happy to get involved in more work linked to home fire risk assessments as this has driven down our fire incidents over the last 15 years…we know upstream prevention work, like AF testing as part of home risk assessment can mean less work for us and fewer dangerous situations for vulnerable elderly patients. We see MyDiagnostick as a great way to make every contact count." Source: Fire Service Manager

WatchBP: Mixed feedback about WatchBP was received. The only patient impact themes from that feedback were related to patients' (positive and negative) satisfaction with the device and getting better access to hard to reach patients.

"Patients liked the device as a gadget …once the patient has been tested we immediately referred onward." Source:GP

"We had too many unclassified findings using KardiaMobile so switched to WatchBP and it worked better. It got us into places we wouldn't have got into, such as with people with drug/alcohol issues and homeless people. You can't expect all relevant people with potential AF to visit their GP, you have to get out and find them any way you can. You have to get out there and meet the people." Source: Healthwatch device user

"As a team, we didn't like WatchBP as much as KardiaMobile as it requires 3 tests of blood pressure in a row to do it and that was too much for elderly frail patients. Also, the cuff has been often too tight on patients, I've heard that a lot from patients and my colleagues too." Source: GP

No feedback was received about **Cardiocity** or **imPulse**.

5.4 PATIENT OUTCOMES KEY FINDINGS

This evaluation found that 81,933 readings were taken and 5,586 possible cases of AF detected. Using the national AHSN Network AF programme assumptions for preventing strokes, it is possible to model that this could potentially have avoided 187 strokes. **However**, this evaluation found a number of issues that caveat this finding, not least the accuracy of the quantitative utilisation data.

A range of positive impacts from use of KardiaMobile were perceived by patients, as reported by staff device users. Patients were said to have high acceptability for the device, testing helped to raise awareness of AF and wider health issues, helped to manage anxiety about heart conditions, was flexible and was reported to have prevented unnecessary 12-lead assessments. Device use supported the opportunistic identification of undiagnosed heart conditions in some circumstances.

Limited findings were available on the other devices deployed. MyDiagnostick was taken up by Fire Services in several AHSN areas with positive feedback. This device was preferred over KardiaMobile due to its ease of use for non-clinicians.

Considering the range of environmental challenges faced by the AHSNs and the variation in implementation approaches (described in sections 2 and 3) it is reasonable to conclude that while the programme has delivered positive patient outcomes, there was potential for these to be greater. The number of detections and strokes avoided could have been higher.

6 WHAT HEALTH ECONOMIC ASPECTS HAS THE PROGRAMME ACHIEVED?

6.1 INTRODUCTION

This section draws on the evidence from this evaluation, and the recent evidence review by NICE (May 2019), to contribute to an economic appraisal of this rollout programme. It considers the aspects of the programme that should be understood in developing a business case for future, or similar, rollouts of medical technologies such as this: costs, productivity and outcomes.

6.2 NICE REVIEW AND COST EFFECTIVENESS

In May 2019, NICE published its findings and guidance for devices used to record and analyse single time point lead-I ECG devices for people in primary care with symptoms of AF and an irregular pulse.[6] This is a different population than for this rollout, which was directed towards opportunistically testing people who were asymptomatic.

NICE evaluated four mobile-ECG devices, including three that were part of the AHSN rollout programme – KardiaMobile, imPulse and MyDiagnostick. The external assessment group's (EAG) systematic review of evidence of diagnostic accuracy and clinical effectiveness, didn't identify any studies for people in primary care with signs of AF and irregular pulse. They extended their review to people who did not present with signs and symptoms, which aligns with the population targeted by this rollout programme. KardiaMobile had the most studies, though there was insufficient data to formally assess differences between diagnostic accuracy across the devices.

The EAG highlighted 2 recently published economic evaluations (Welton et al. 2017 and Jacobs et al. 2018)[6] that suggested that lead-I ECG devices may represent a cost effective use of resources for systematic, opportunistic screening of people aged 65 years and over during a routine GP appointment (paragraph 4.24).

The EAG developed a de novo economic model designed to evaluate the cost effectiveness of the devices for people presenting in primary care with signs and symptoms. The model compared the effect of using the mobile-ECG device with manual pulse palpation, covering a diagnostic phase and post-diagnostic phase (covering 30 years from diagnosis of AF). It took account of the diagnostic accuracy of the mobile-ECG devices, mortality and cerebrovascular events for people with AF, with and without treatment and treatment costs. The model calculated Quality Adjusted Life Year (QALY) and Incremental Cost Effectiveness Ratio (ICER) for the standard pathway (manual pulse) and each of the four devices. The model found that KardiaMobile dominated – '*that is, KardiaMobile cost less but*

produced more quality-adjusted life years' (paragraph 4.43). KardiaMobile's incremental cost-effectiveness was comparable with the standard pathway.

The committee concluded that although there is plausible potential for the lead-I ECG devices to be cost effective when used for single time point testing in primary care (for people with signs and symptoms of atrial fibrillation with an irregular pulse), there was insufficient evidence at present to determine if the predicted benefits of using the devices would be realised in practice. (paragraph 5.11). They recommended further research into how AF detection compared with the standard pathway and the impact on 12-lead investigations to diagnose AF.

6.3 INFORMING THE BUSINESS CASE FOR MOBILE ECG DEVICES IN THE NHS

The AHSN Network AF programme team asked the evaluation team to consider how the evidence gathered could inform how the NHS develops the business case for technology like the mobile-ECG devices. Put another way, if the case for £500,000 investment in mobile-ECG devices were being made now, what would it need to include?

Costs of the devices and associated implementation costs

The advice from the programme's Procurement Team was that they should be involved early, and before the final set of devices are selected. They would be able to stimulate the market and bring suppliers and users together to understand the differences between devices, as well as get a good price per unit.

This programme found that there are other costs that need to be clarified before purchase, including whether there are software or subscription costs, which is the commercial model that KardiaMobile had switched to and had to be re-negotiated. Additional hardware costs also need to be identified. The KardiaMobile devices require a smartphone or tablet to run on and NHSE did not include funding for personal devices in their budget for this programme. There was feedback from the focus groups that some staff were reluctant to use their own personal devices, and this limited the rate of adoption.

The programme didn't include depreciation costs, presumably because the devices were a one-off purchase as a trial. If the devices are expected to be replaced at the end of their useful life, then depreciation costs should be included in the business case. The companies with more expensive devices in this rollout programme believed that this was partly due to them being designed and built for greater and longer use than KardiaMobile.

The programme didn't include additional training and implementation costs – AHSNs were asked to prioritise this rollout as part of their overall work programme. There is also a need to quantify impacts on the whole AF pathway, in particular on the expected number of 12-lead ECG tests and the resource and timescales for delivering these set out.

Utilisation/productivity

Setting out the expected utilisation of the devices is an important part of the business case. In overall terms, this programme did not perform as well as was probably expected when the £500,000 budget was identified:

- 88% of the devices (all types) were distributed to users (AHSN range from 54% to 100%), with 742 not reported as being distributed for use
- On average, users used KardiaMobile devices to take readings 23 times (AHSN range from 6 to 65). (Due to data limitations it is not possible to calculate this for the other device types)

This evaluation has found variation in the degree of management of the programme (see implementation typologies in section 3) – with evidence that AHSNs taking a 'fully managed' approach

achieving higher levels of device utilisation than those with 'moderate' or 'lightly' managed rollouts. The R-Outcome product rating from staff who didn't maintain their use of the device was lowest in their view that they could get help if they need it (figure 4).

The business case should demonstrate that enough training, implementation and support resource and planning is in place to give assurance that the devices will be well utilised and deliver their expected benefits.

There are also choices about which staff should have the use of these devices included in their roles. This evaluation doesn't answer that but does give some interesting insights. The largest staff group using the devices in this rollout were doctors (759 of 2,133). Their AF detection rates were not higher than other staff groups (6.8% table 18), but there was qualitative evidence that doctors are able to interpret the ECG (not rely on the AF algorithm) and make informed patient pathway decisions. However, there was also qualitative evidence that some GPs struggled to find time to use the device. Health Care Assistants were the second largest staff group (417 of 2,133) and while their AF detection rate was a bit lower than doctors (5.9%) their utilisation of the device was higher (table 18). Using the R-Outcomes analysis of staff who used the devices but gave up using their device before they'd done 25 readings (table 4) - this was highest in doctors (77%) and lowest in Health Care Assistants (55%).

Outcomes/ benefits

As this evaluation has highlighted, data collection on this scale and for this type of implementation programme is complex and must overcome a number of challenges. The business case should be clear on how user and activity data will be accurately collected. This should not rely on manual data collection. The ability to account for double counting when 'possible AF' readings are repeated should be developed.

Return on investment

With accurate costs and utilisation data; and an agreed evidenced assumption (such as those set out in 5.2) on the impact of improved detection, it would be possible to calculate an expected return on investment (ROI).

The average cost of health and social care for patients suffering a stroke in the first five years is estimated to be £46,039. [17]

This evaluation hasn't been able to calculate a ROI for this programme. As described in 1.3 and 5.2, there are too many too many issues with the accuracy of the utilisation data; and as described above, the full costs of the roll-out programme aren't known.

However, to understand the quantum of potential ROI for a programme like this, if 187 strokes (see 5.2) were really avoided this could save £8 million of health and social care costs over 5 years. It is likely that a business case that included sufficient implementation costs and good utilisation of the devices could be compelling.

6.4 HEALTH ECONOMICS KEY FINDINGS

The evaluation has identified a number of considerations that should inform a future business case for the rollout of these devices or similar medical technologies. These include a full understanding of the costs involved (including any additional hardware, depreciation costs and other implementation costs), robust collection of activity data to overcome quality limitations and an agreed set of assumptions for modelling the health and economic outcomes of possible AF detection.

With the average cost of health and social care for patients suffering stroke in the first five years estimated to be £46,039, it is likely that a compelling potential return on investment could be identified if the case was made that these devices increase the rate of AF detection and avoid strokes.

7 WHAT IS THE IMPACT ON PROVIDERS?

7.1 INTRODUCTION

This section describes how more than 2,000 staff have responded to the opportunity to adopt a new digital diagnostic device into their working lives. The analysis includes device use by occupational groups and primary work setting, and an exploration of staff perceptions of the devices, their readiness for innovation and their experience of the adoption process are presented. Key findings and what this may mean for providers wanting to adopt new medical technology in their services are included at the end of the section.

7.2 OCCUPATIONAL GROUPS AND SETTINGS

Examples of how specific individual contexts used the devices, from the qualitative fieldwork, are provided in Appendix 4.

The KardiaMobile registration information recorded users' occupational group and their primary work setting and their activity is summarised in the following two tables:

Table 20: Occupational group summary quantitative analysis

Occupational group	No. of users	No. of readings	Ave readings per user	Possible AF Detections	Possible AF Detection %
Doctors	759	27,606	36	1,888	6.8%
Health Care Assistants	417	17,559	42	1,044	5.9%
Registered Nurses	161	6,195	38	613	9.9%
Pharmacist	93	5,368	57	325	6.1%
Admin, Clerical and management	48	2,753	57	180	6.5%
Other	260	4,147	16	346	8.3%
Not recorded	395	18,305	46	1,190	6.5%
Total	**2,133**	**81,933**	**38**	**5,586**	**6.8%**

Table 21: Registration setting summary quantitative analysis

Setting	No. of users	No. of readings	Ave readings per user	Possible AF Detections	Possible AF Detection %
General Practice	1,201	45,999	38	3,178	6.9%

Community based clinics	111	3,828	34	240	6.3%
Domiciliary	166	6,777	41	398	5.9%
Community Pharmacy	51	3,273	64	198	6.0%
Acute Hospital	73	4,241	58	300	7.1%
Other	91	413	45	34	8.2%
Not recorded	395	17,402	44	1,238	7.1%
Total	**2,088**	**81,933**	**38**	**5,586**	**6.8%**

From this quantitative data we can see that:

- Doctors were the largest group of users (36%) followed by Health Care Assistants (20%)
- General Practice was by far the most common setting (58%), though if the device was used outside of the Practice this wasn't recorded
- There was a wide range of the number of times different occupational groups and settings used the device (34 to 57). Utilisation was highest in Community Pharmacy settings.
- AF detection rates were similar across groups and settings. Registered Nurses were the highest (9.9%) – and this may be a factor of the demographic nature of the people they tested (e.g. older, symptomatic)

7.3 STAFF PERCEPTIONS OF THE DEVICES AND THE PROGRAMAME

622 users completed the R-Outcomes survey to measure how they feel about:

- Their **Digital Confidence –** measuring users' digital literacy and confidence to use digital products, with dimensions of familiarity, social pressure, support and digital self-efficacy
- The **Innovation Readiness -** measuring how much users are open to and up to date with new ideas, and whether their organisation is receptive to and has innovation capabilities.
- The **Innovation Adoption -** measuring how staff experienced the process of adopting mobile ECG devices to make them work in practice; whether the original vision was followed, whether there was planning in advance, whether staff worked together and whether they reflected on how best to keep it working.
- The **Product Rating -** assesses the mobile ECG device they used in terms of usefulness, ease of use, support and satisfaction.

Further details of these measures and their questions are included in appendix 5.

Table 22: R-Outcomes response rates by staff group

Staff group (as stated by users when registering their device)	**No. of users by staff group**	**Response rate**
Medical	283	37%
Healthcare Assistant	105	25%
Nurse or midwife	80	50%
Pharmacist	42	45%
Admin & Clerical, Management	39	81%
Other[12]	73	28%
Total	**622**	

The following figure shows the results for **all 622 users**. It shows the scores out of 100 for four measures summarised above and the four questions that comprise them. The higher the score the better – and as a guide:

[12] Includes paramedics (9); physiotherapists (2); podiatrists (8); public health (6); social care (2)

- 80+ scores are recognised to be high and positive/ good
- 60 - 80 are moderate
- <60 is low

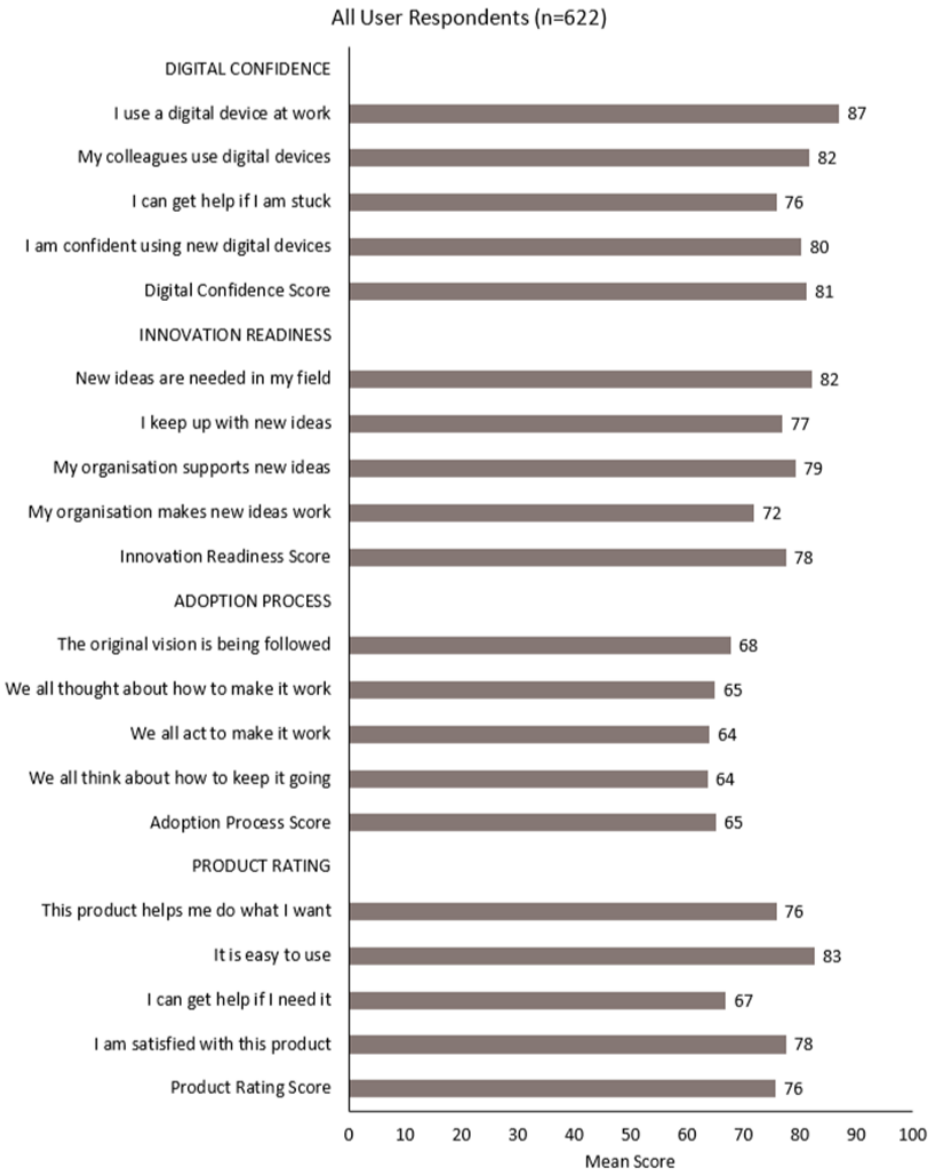


Figure 3: R-Outcomes mean scores for all user respondents

The scores for Digital Confidence for the users of the mobile ECG devices are generally good. Their lowest rating was for being able to get help if they are stuck. Although some AHSNs were working in environments with staff with low scores, it appears Digital Confidence was less of a problem overall compared to other R-Outcomes domains.

Users responses to their and their organisation's readiness to innovate are moderately positive. They felt strongly that new ideas are needed in their field and also that their organisation supports new ideas. They were less positive about how well their organisation makes new ideas work. These findings are similar to the all-AHSN position on Digital Confidence.

The adoption process for mobile-ECG rollout received the lowest responses. Based on NPT, this domain aims to measure the degree to which the rollout programme was implemented and embedded in practice. The evaluation assumed that users were likely to be responding to their experience in the three phases in figure 1 on page 3 covering their AHSN, local organisation and own day to day actions. The overall all-AHSN position maps well to the wide range of implementation challenges highlighted previously in the report. Many AHSNs took ineffective implementation approaches and this has been confirmed by device users' responses on this domain.

Users were mostly positive about their experience of using the mobile-ECG devices – particularly their ease of use. Once again, being able to get help was the lowest score. This finding maps well to the qualitative fieldwork and highlights that device acceptability was always relatively high, but the main problems with this rollout were environmental support by deployment locations and implementation decisions made by AHSNs.

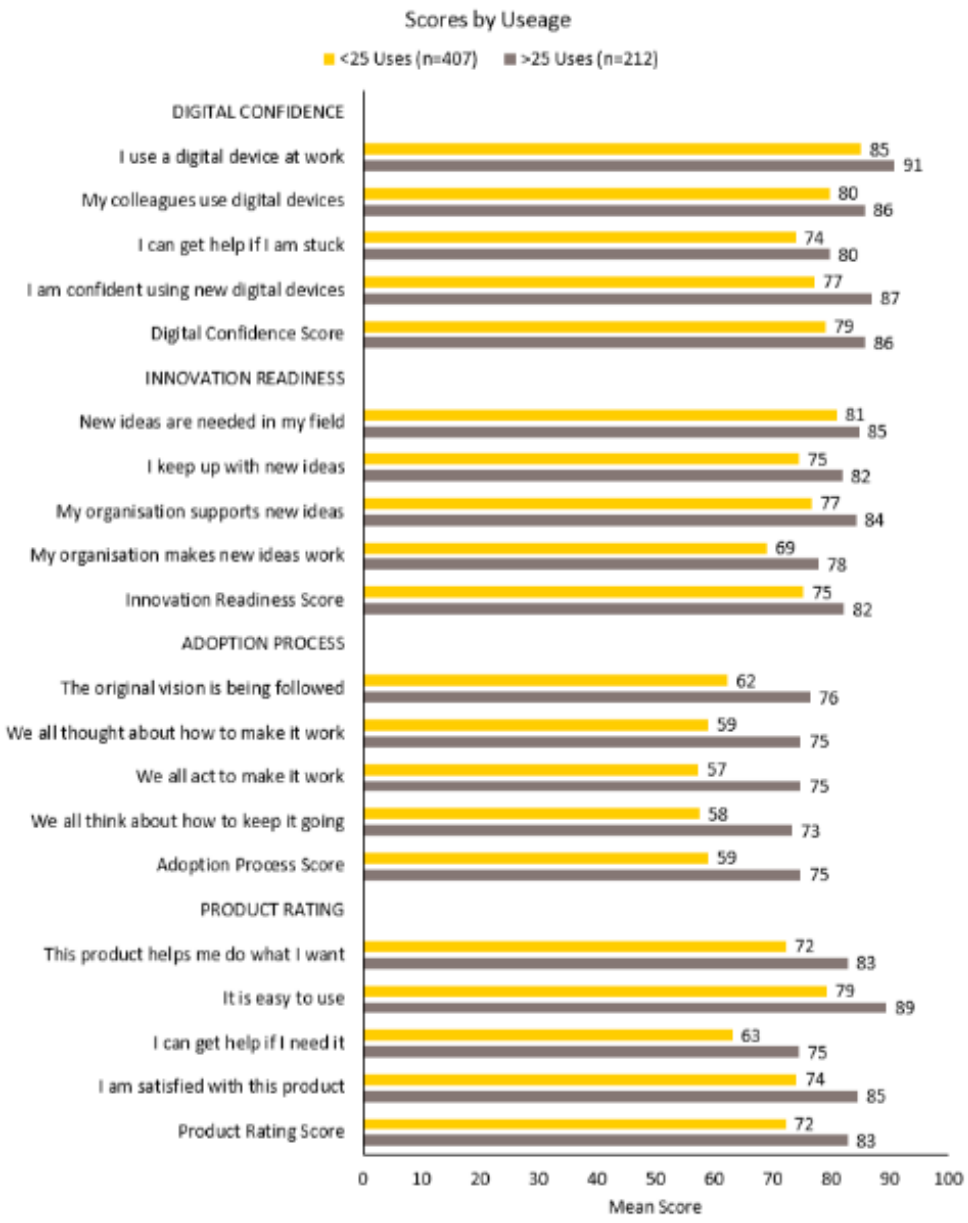


Figure 4: Comparing high and low users' perceptions

High users – people who use the device at least 25 times were more positive about the devices and the programme. We don't know if they used the devices a lot because they like them – or they like them because they've used them a lot. But this could be evidence that rollout programmes need to give emphasis on supporting people to not give up early. Doctors were the biggest group to stop before 25 readings (77%) and lowest were the Health Care Assistants (55%).

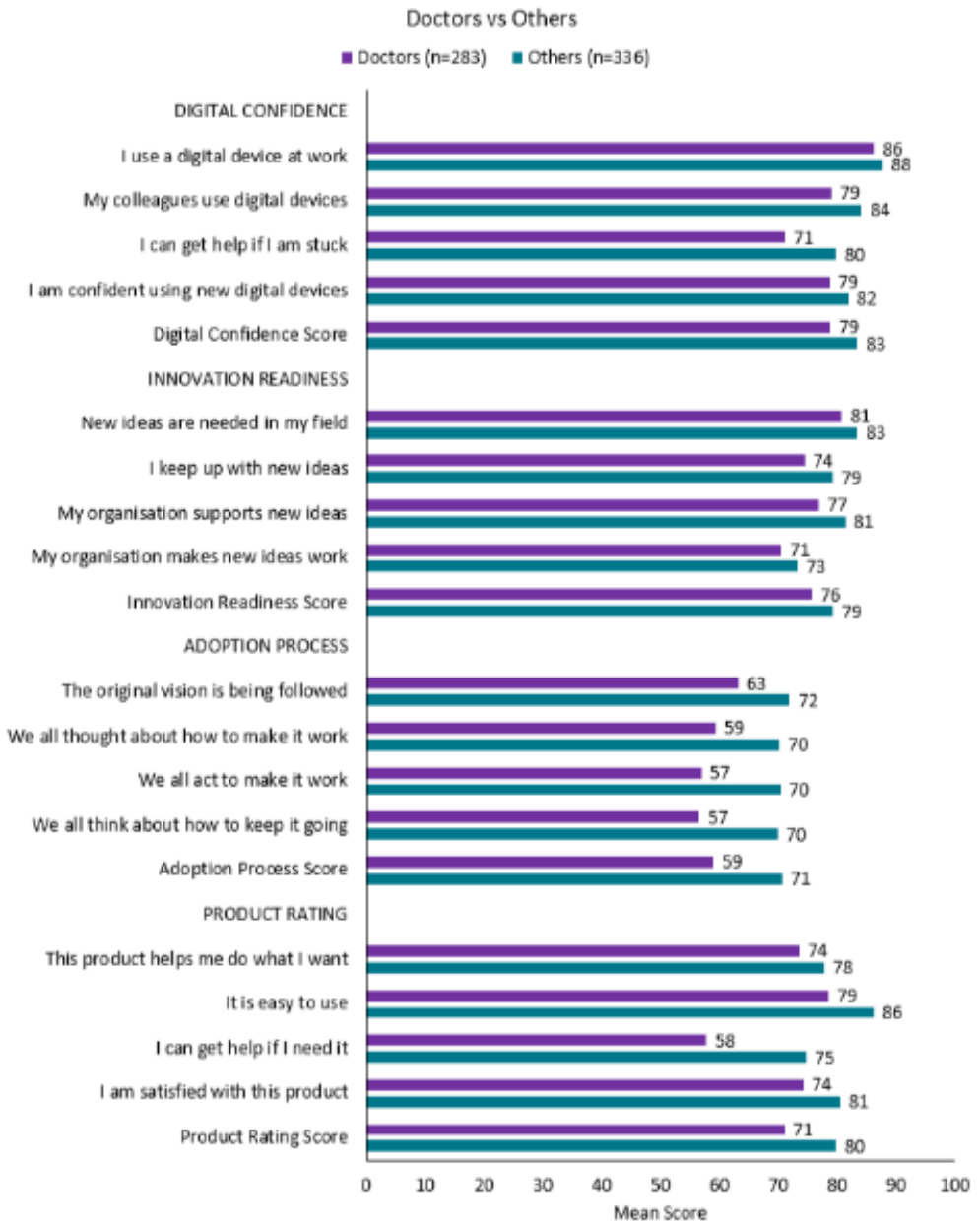


Figure 5: Comparing how Doctors compare with other staff groups

Doctors were the largest single occupational group and are important opinion formers around the local rollout of new technology. Overall, their perceptions were lower than users in other staff groups. This was particularly the case about their perception of the adoption process and whether they were able to get help and how well they felt the rollout programme was implemented.

7.4 QUALITATIVE FINDINGS ON IMPACT ON PROVIDERS

A number of themes for providers were identified in the focus groups and interviews with device users. Many of these build on the themes identified in section 2 describing the Environment (including ambiguity about how and where the devices should be used and fitted into the AF pathway) and in section 3 describing Implementation (including training, support and communications from the AHSN rollout teams).

The following seven themes relate to the KardiaMobile devices. Comments received about other devices are included at the end of this section.

Provider theme 1: Mixed reviews from GPs about KardiaMobile

In addition to some ambiguity about clinical use described in section 2, GPs reported mixed views about KardiaMobile. Many GPs reported they liked the device as it was quick and easy, but many had serious concerns about its wider impact on generating extra work and how it fit within existing AF work/pathways. Also, many GPs did not agree they should be using their personal smartphone or tablet to pair with KardiaMobile.

"Generally, my partners and I are positive toward AF detection and using their [KardiaMobile] devices. But I do have concerns about extra work, the extra 12-lead ECG testing, we are very stretched as it is." Source: GP

However, interestingly, many nurses provided the opposing view:

"I heard they [GPs] have concerns about extra 12-lead tests but surely it must be better to do them rather than pick up the pieces after someone has had a stroke." Source: Practice Nurse

"I know many GPs were frustrated by the decision of AHSNs to let them work out how to use the devices in their context. We really needed more support to understand how it might best fit with our work. It was the absence of this that led to many of my colleagues disengaging from using the device [KardiaMobile]."

Source: GP

Also, part of the explanation of GPs' mixed reviews was also placed on the AHSNs for not providing enough guidance of how and when to use the device in real world settings.

An important positive reported by GP device users was the value they placed in KardiaMobile PDF traces.

"I've found the PDF trace really helpful, particularly when done by a non-clinician colleague…it's allowed to me to see the evidence so to speak and not have to rely on a verbal report of information about the manual pulse check etc." Source: GP

Provider theme 2: KardiaMobile easy to operate

In sharp contrast to the logistical challenges of when and how to use KardiaMobile seen in previous sections, many clinicians valued the portable, lightweight, ease of use nature of KardiaMobile. Using the device was straight forward but understanding its value in the wider sense was less clear.

"Our non-clinicians can use KardiaMobile as it's easy to use, but they're not always sure what to do with unclassified findings or any ambiguities. Also, some of my GP colleagues highlighted it creates other tasks, like checking the traces or whatever the HCA has found." Source: GP

Provider theme 3: Non-clinicians can use KardiaMobile

An important provider impact was the perceived ability of non-clinicians to use the devices. A wide range of non-clinicians used KardiaMobile in practices and community settings. This has been an important success from the KardiaMobile rollout.

"It really doesn't need to be a pharmacist or nurse doing the AF screening…it makes sense to have health care assistants and pharmacy technicians to do them…this means the work of GPs and pharmacists aren't caught up with this extra work. I don't see why our colleagues who support us cannot do this testing." Source: GP

"We use social prescribers and health activities teams in our area…that came from a Public Health England consultant we knew and that has worked really well. We did a face-to-face training session…their engagement is high and number of KardiaMobile checks is really high. They signpost people onto GPs if they get possible AF readings." Source: AF local roll out lead

Many non-clinicians took KardiaMobile to public places like football matches, park run, community groups, supermarkets and other voluntary sector locations. Many were very successful in obtaining a high number of AF tests. However, there were caveats to this, as best described by the example below.

"To engage with the people in public, we need a hook. We started with BMI [Body Mass Index] checks in supermarkets and added the KardiaMobile testing to that and that worked really well. We started using it on any adults who were interested but later limited it to people over 65 years old, as we were worried we were generating too much activity for local GPs. Also, we got a lot of unclassified results through, which we think was because of the noise interference in public places. Also, testing in public can lead to some tricky conversations and we could have done with more training on that from the AHSN…we had a few distressed people when we recommended they see their GP after we used the device.." Source: Non clinician device user

Provider theme 4: Increased proactive case finding of possible AF

It was clear that professionals were involved in, and welcomed the ability to, pro-actively case find possible AF in several ad hoc ways.

"I was asked to see a lady for other reasons, in her own home, did her observations for the other reasons and also did a manual pulse check. It was a bit high, so I used the KardiaMobile. She was very elderly, in her 90s, so I had to gain her trust a bit and explain about the device so she wouldn't worry. She had a bit of arthritis in her hands so I was mindful of that and asked if it was ok for her to press as hard as she could to make sure we got a reading…we got the reading and I sent her for a 12-lead assessment and contacted the GP. It turned out the lady did have AF so was put on medication, so that was a good result." Source: Practice nurse with pro-active community nurse

"I've been using it for a couple of months now in a primary care context and it gives you enough information to help your decision making. I'm aware its designed to detect AF but we've used it for more than that…because we're clinicians who can read ECGs, we can tell if someone is bradycardic or tachycardic, and we can diagnose and arrange further investigations from there. It's an added value which

"We were doing a talk about stroke prevention in the community and demonstrating the KardiaMobile device as part of the talk…we tested a person attending and they were a possible AF so we referred them into outpatients for more investigations." Source: stroke consultant

Provider theme 5: Pharmacist incentivisation for AF testing

An impact on providers has been to raise the issue of incentivisation for using KardiaMobile in pharmacy settings. The issue of incentivisation did not lead to many other professionals reducing or

stopping their KardiaMobile screening. But some pharmacists, across many AHSNs, did disengage or stop once it became clear they would be unlikely to receive any incentive.

"There's the pharmacy integration fund and over the last few years pharmacists have been working in general practice, urgent care and care homes…we screen patients whilst doing medication reviews, which also included care home medication reviews. Also, I had a few colleagues take KardiaMobile to a couple of pharmacy conferences, screened some colleagues and found possible AF. So, it has a really good ad hoc testing ability which is really liked by my pharmacy colleagues. I suppose the issue for us is the incentivisation for AF screening and the Medication Use Reviews we do. At the moment, we get paid £28 for each MUR done by the CCG, managed through PharmOutcomes and we know its [KardiaMobile testing] more work inside that MUR consultation so we were wondering why we didn't get paid to do AF screening…I'd hear from other pharmacists colleagues in London they were being paid an extra £1.50 to do the AF screening…and also got another amount if AF was confirmed…with KardiaMobile so that's added to our confusion and left us wondering whether we should or could be paid for AF screening." Source: clinical pharmacist in general practice

Provider theme 6: Perceptions of practices improved

An interesting impact for providers, namely general practices, was the perception that patients had increased their satisfaction with practices' work due to the KardiaMobile testing. This was surprisingly more common than anticipated and may be part of the technological/gadgetry value patients placed on mobile ECG devices.

"I've had feedback from patients saying they thought we were doing a more thorough assessment [from using KardiaMobile] than they'd had before." Source: Diabetes clinic nurse

Provider theme 7: Avoided 12-lead tests at local hospitals

"We've been using it as part of our new patient assessments and they really liked it as 'an extra check'…and they said they feel like the practice is on the ball." Source: GP

"There are several GPs practices in my area using KardiaMobile who don't have 12-lead assessment machines, so they refer those tests to the hospital. With the KardiaMobile I can test the patient and write to the GP indicating they have a normal rhythm and avoid some trouble for patients and clinicians." Source: GP device user

As well as the patients benefitting from avoided 12-lead tests, device users benefitted from reduced work in this area.

MyDiagnostick: Very limited feedback about MyDiagnostick was received. The only provider impact feedback was related to its success in the fire service context. Several AHSNs promoted the use of this device with the fire service and they undertook its use during their home fire risk assessment visits. It was considered very easy to use for non-clinicians (fire service staff) but they also highlighted an important process issue when using it.

"It doesn't show you the reading, you have to download it, and then include it in the patient record. The process isn't ideal, there's no integration with another device like a smartphone. There isn't a screen on it, so you have to remember what order you've done the test in, so when you get back to your office you know which test is linked to which patient you've seen that day." Source: Fire service device user device user

Cardiocity: Very limited feedback about Cardiocity was received. The only provider impact feedback was related to set up issues and use in practice, as outlined below.

"We have been trialling the use the devices [Cardiocity] in our diabetic clinics, training our HCAs to do the information gathering before seeing the nurse for the more complex bits. We have been training Health Care Assistants to use Cardiocity. Using the device has been easy, but we've had reason to question the quality of ECG trace data, particularly an unexpectedly high false-positive rate for AF, we found 5 of 35 tested. We didn't seem to get a nice trace between the P-waves and the T-waves, we got a lot of jiggling around which we believe may be from electrical interference from other devices. We tried turning off devices but of course you need a PC turned on to make Cardiocity work. We contacted the supplier but never received any feedback from them. All this led to us to feel less confident using it and reducing its use in practice." Source: GP

"It needs software to use it…we had no help from CSU or others to use the software or use Cardiocity on GPs computers, in order to upload the information required. We contacted the suppliers but didn't receive a reply and

No user feedback was received on the **WatchBP** and **imPulse** devices.

7.5 PROVIDER IMPACTS KEY FINDINGS

2,133 staff used these devices and their experience provides important evidence for providers wanting to adopt new medical technology in their services.

Doctors were the largest single group of device users and general practice the most common setting. However, other staff (pharmacists and admin, clerical and management staff) had a higher average use per device. Furthermore, doctors were also the group most likely to stop using devices before completing 25 uses suggesting that, despite the focus of the rollout on this group, they were not the most optimal or receptive context in which to deploy devices. These quantitative findings were confirmed by their mixed perceptions about KardiaMobile.

Device utilisation was highest in community pharmacy settings, although lack of financial incentivisation led to some staff discontinuing use. AF detection rates were similar across groups and settings, but registered nurses were the highest (9.9%) which may be due to factors associated with their patient cohort.

Self-reported outcomes by device users of their 'Digital Confidence' was generally high and less of an issue for the rollout compared to 'Innovation Adoption' (which was generally low). The overall position on Innovation Adoption maps well to the wide range of implementation challenges found by the evaluation.

Device users were mostly positive about their experience of using the mobile-ECG devices – particularly their ease of use. This finding maps well to the patient views of high acceptability described in section 6.

From a provider perspective, this evaluation has found evidence that a large and varied group of staff are ready to innovate and digitally confident. There are choices about which staff groups to engage and this may not necessarily be the Doctors. The quality of the adoption/ implementation process is important if staff are to sustain their use of the devices – with evidence that staff feel more positive about the innovation when they keep using it.

8 CONCLUSIONS

This was a large and ambitious programme, rolling out innovative medical technology to more than 2,000 users in hundreds of organisations across 15 AHSNs. It was an innovative approach to supporting adoption of new technology across the NHS, aimed to stimulate the market for mobile ECG devices and make a positive contribution to the national priority programme for Atrial Fibrillation.

The independent evaluation was asked to provide evidence in response to six questions about the rollout of mobile ECG device for the detection of AF. In total 6,338 of devices were procured, with 5,596 distributed to users. KardiaMobile devices accounted for 92% of the devices selected by the AHSNs and procured by the programme.

Between January 2018 and March 2019, over 2,000 staff undertook almost 82,000 readings and detected more than 5,500 possible cases of AF. Data was collected on utilisation, deployment contexts, implementation approaches and experience of using the devices, including the collection of over 600 self-reported outcomes surveys, interviews and focus groups with 125 device users and 57 rollout staff across the 15 AHSN areas. In addition, three national programme leads, five AHSN commercial Directors, the procurement lead for the rollout and representatives from the five device suppliers were interviewed. The findings were synthesised to address six evaluation questions and are summarised here.

One of the key findings in this report is the large variation in the success of the 15 roll-out programmes in terms of their distribution and utilisation of the 6,338 devices:

- % of devices distributed to users ranged from 54% to 100%
- % of devices registered by their users ranged from 31% to 100%
- Average readings per device ranged from 7 to 72

A focus of this evaluation has been seeking to understand the reasons for this variation. It should be noted that all conclusions are subject to the limitations of the quantitative data, as described in section 1.2.

8.1 What environments are the devices most effective in?

Section 2 describes how the contexts of each deployment environment were important in explaining the extent of device use and possible detection of AF.

Across the AHSNs, the rollout programmes were affected by several issues that were common to all environments. There was ambiguity about where the devices should be used, their clinical advantage over current methods and their alignment with the wider AF diagnostic and treatment pathway.

Differences between the environments led to the identification of **five typologies** which characterise the relationships between people engagement (clinical leadership and relationships), enabling structures (local information governance processes, integration with the wider AF pathway and technological readiness) and the level of device utilisation. Highest device utilisation was seen in AHSNs with evidence of fully engaged people (strong clinical leadership and strong relationships with deployment locations) and enabling structures (low burden of local IG, good AF pathway readiness and good technological readiness). Conversely, those with evidence of lightly engaged people and hindering structures had the lowest device utilisation.

8.2 What features of the implementation packages are most effective? What defines successful implementation?

Section 3 explores the different ways in which AHSNs managed the rollout of the devices and offers further understanding of the factors which influenced device use and possible detection of AF.

Some common themes beset all AHSNs. All plans were negatively affected by the protracted national timescales for delivery of the programme during much of 2017 and up to Spring 2018, and it was commonly felt that more resource and better communication would have facilitated a better rollout. An assumption about personal use of smartphones/tablets for KardiaMobile, coupled with logistical complexities of staff using their own smartphones, reduced device utilisation. Problems associated with registration and data collection affected the availability, breadth and accuracy of the utilisation data received.

There is also evidence that important differences in the implementation approaches taken by the 15 AHSNs contributed to the variation in success. **Four typologies** were identified to describe the different implementation packages across the 15 AHSNs. These characterise the degree and nature of delegation, clarity and communication of expectations, the level and style of support and training that was provided and how devices were issued/recalled. AHSNs found to be in the 'fully managed' typology had the highest levels of utilisation, while those who 'delegated' management to the deployment locations had the lowest levels of utilisation.

Overall, these findings would suggest that the utilisation of devices in this programme could have been higher if the common implementation issues were addressed and the variation between AHSNs reduced.

8.3 What impact has the programme had on the market place?

Section 4 explores the extent to which the programme aim of 'stimulating the market' was addressed.

There was no evidence to indicate that the programme has resulted in more suppliers or devices. Whilst it has contributed to AliveCor's growth in the UK, the companies selected to provide a small number of devices are concerned that the programme has reduced competition. The market that appears to be developing and where there is a lot of international product development is for individuals to buy their own device to monitor their own health. This is a different market to that of health services which this programme sought to stimulate.

The delivery of 1,201 devices to general practice may be seen as a success and an opportunity for the suppliers. However, suppliers perceived that introducing these devices to GPs is challenging, due to their time pressures, reluctance to take on extra work and required resource or payment to adopt. Furthermore, Doctors' perceptions of the rollout programme were much lower than the other staff groups, their satisfaction with the devices was a bit lower (figure 4); and doctors were more likely to stop using the device before they have performed 25 readings (figure 5). Nevertheless, this evaluation found a lot of evidence that these devices can be effectively used by many other staff groups, such as healthcare assistants.

This programme has struggled to collect data on the utilisation of the devices. Suppliers have an important role in supporting this. NICE have recommended that more research is needed on their routine use in primary care and this requires more accurate utilisation information than was available for this programme. Manual data collection was shown to not work.

8.4 What impact has the programme had on patient outcomes?

Section 5 describes the settings within which 5,586 possible cases of AF were detected by this programme. Using the national AHSN Network AF programme assumptions for preventing strokes, it is possible to model that this could potentially have avoided 187 strokes. **However**, this evaluation found a number of issues that caveat this finding, not least the accuracy of the quantitative utilisation data.

A range of positive impacts from use of KardiaMobile were perceived by patients, as reported by staff device users. Patients were said to have high acceptability for the device, testing helped to raise awareness of AF and wider health issues, helped to manage anxiety about heart conditions, was flexible and was reported to have prevented unnecessary 12-lead assessments. Device use supported the

opportunistic identification of undiagnosed heart conditions in some circumstances. Limited findings were available on the other devices deployed, though MyDiagnostick was used by the Fire Service in a number of AHSNs with positive feedback.

Considering the range of environmental challenges faced by the AHSNs and the variation in implementation approaches (described in sections 2 and 3) it is reasonable to conclude that while the programme has delivered positive patient outcomes, there was potential for these to be greater. It should be noted that data about unregistered KardiaMobile device usage was not available and it is likely that there is an additional number of patients with possible AF detected, but unfortunately this cannot be quantified.

8.5 What health economic aspects has the programme achieved?

Whilst insufficient data was available to calculate a Return on Investment for the rollout programme, section 6 identified a number of considerations that should inform a future business case for the rollout of these devices or similar medical technologies. These include a full understanding of the costs involved (including any additional hardware, depreciation costs and other implementation costs), robust collection of activity data to overcome quality limitations and an agreed set of assumptions for modelling the health and economic outcomes of possible AF detection. With the average cost of health and social care for patients suffering a stroke in the first five years estimated to be £46,039 [17] it is likely that if the case is made that these devices increase the rate of AF detection and avoid strokes, that a positive business case could be made.

8.6 What is the impact on providers?

Providers will be interested in the experience of the 2,133 staff that used these devices and how this might inform how they plan and support the adoption of new medical technology in their services.

Doctors were the largest single group of device users and general practice the most common setting. However, other staff (pharmacists and admin, clerical and management staff) had a higher average use per device. Furthermore, doctors were also the group most likely to stop using devices before completing 25 uses suggesting that, despite the focus of the rollout on this group, they were not the most optimal or receptive context in which to deploy devices. These quantitative findings were confirmed by their mixed perceptions about KardiaMobile.

From a provider perspective, this evaluation has found evidence that a large and varied group of staff are ready to innovate and digitally confident. There are choices about which staff groups to engage and this may not necessarily be the Doctors. The quality of the adoption/ implementation process is important if staff are to sustain their use of the devices – with evidence that staff feel more positive about the innovation when they keep using it.

8.7 Final observations and lessons for the future

Overall, the evidence for a system-wide procurement as a means to improve the uptake of innovative technology is mixed. Whilst a large number of devices were distributed (5596), and acceptability was high, overall distribution was lower than planned at only 88%. Only approximately half of KardiaMobile devices were registered, with an average of 27 uses per device.

The deployment of devices by a centralised process with NHS endorsement, and avoidance of multiple procurement decisions, appealed to many device users and likely supported the uptake in the early stages of the rollout. However, it was clear that there were missed opportunities with the procurement exercise that may have helped to stimulate the market for these devices.

In the later stages of the rollout, when individual AHSNs facilitated their local rollouts, a number of environmental and implementation challenges were identified. The characteristics that accompanied high device use were fully engaged people (strong clinical leadership and strong relationships with

deployment locations), enabling structures (low burden of local IG, good AF pathway readiness and good technological readiness) and fully managed (not delegated) rollout.

It is likely that uptake can also be explained by looking at the combination of environmental and implementation positions. For example, UCLPartners and East Midlands both took the decision to delegate the rollout and were simultaneously attempting to work in environments with hindering structures and lightly/moderately engaged device users. The combination of these factors is likely to explain their lower utilisation findings. In further support of this conclusion, North East North Cumbria and South West AHSNs undertook the 'fully managed' implementation approach and also benefitted from engaged device users and enabling structures. They had relatively good utilisation of devices.

The evidence provides some lessons for those involved in other large scale roll out programmes of this nature.

The perceptions of staff towards innovation offer some insights into those staff groups most likely to be ready to adopt innovation of this kind. Although doctors were the largest user group, other staff groups (including non-clinical staff) were more positive about the innovation and its adoption.

1. While general practice was the most common setting, the devices were demonstrated to have impact in a range of settings that present more choices for adoption and spread. Novel settings (e.g. non-clinical public settings), not normally visited by primary care, may provide opportunities for roll out.
2. Roll out programmes need to mitigate against early abandonment of the innovation. Around two thirds of respondents were low users (<25) and had lower perceptions of the programme overall. Doctors were most likely to abandon use early compared with other staff groups.
3. People engagement and structural enablers, and their underpinning concepts identified in this evaluation, are key to success. An understanding of these environmental characteristics would enable some mitigation of predictable barriers.
4. Planning to address ambiguities, and relational work to see through those plans, is likely to be important in preparing for adoption.
5. The extent to which the rollout is actively managed is a critical factor in explaining implementation success.
6. Collecting utilisation information from the devices was difficult and incomplete. The suppliers have an important role in improving their support to this and this expectation should be included in programme planning. Manual data collection done by device users does not work.
7. Involvement of procurement before device selection can help stimulate the market and bring suppliers and users together to understand the differences between devices – as well as meet the lead times for procuring the devices.
8. Central guidance on Information Governance for digital devices would likely reduce duplication of effort at deployment locations and facilitate faster adoption.

This novel approach of a national system-wide procurement to promote the uptake of a digital innovation led to a large and complicated roll-out programme for the AHSN Network and its constituent 15 AHSNs. It has clearly delivered benefits to many patients and staff. More importantly, it has generated a greater understanding of the factors which can affect the adoption of such technologies and of how the NHS can improve the effectiveness of nationally planned and regionally delivered roll-out programmes.

GLOSSARY

Term	Definition
Data Saturation	'Data saturation' refers to the quality and quantity of information in the qualitative findings. Investigators usually define data saturation as the point, after conducting a thematic analysis, when 'no new information or themes are observed in the data'.
Environment Typology	An organised system of types, to explain and group the characteristics of the environments in which the devices were deployed
Implementation Typology	An organised system of types, to explain and group the characteristics of the implementation approaches used by each AHSN
Innovation Adoption Score	An important aspect of top-down innovation dissemination is the way it is done (process). NPT was developed by May and others to help understand the dynamics of implementation of complex interventions in healthcare.[1] It helps explain how new methods and processes become routinely embedded in their contexts, based on four mechanisms: 1. Coherence of the original vision 2. Cognitive participation and planning 3. Collective action to make it work 4. Reflexive monitoring to make it better. NPT focuses on the work that people do at each stage. NPT has been used successfully alongside R-Outcomes in several evaluations of new models of care. Traditionally, NPT was used by trained interviewers with staff collecting qualitative (narrative) answers to 16 questions (NoMAD).[2] Working with NPT practitioners, we looked at the feasibility of creating a staff-reported module related to NPT to help evaluate specific innovations, consistent with R-Outcomes look and feel. This is shown in figure 3. This uses an agree/disagree structure, with four items asked of staff about their experience of adopting mobile ECG devices: • Is the original vision being followed? (coherence) • Did staff plan in advance how to make it work? (cognitive participation) • Are all staff working together to make it work? (collective action) • Does everyone reflect on how best to keep it working? (reflexive monitoring). 1. May C, Finch T . Implementing, embedding, and integrating practices: an outline of normalization process theory. Sociology 2009; 43: 535–54 2. Finch TL , Rapley T , Girling M , et al . Improving the normalization of complex interventions: measure development based on normalization process theory (NoMAD): study protocol. Implement Sci 2013; 8 (1): 43
NASSS	The framework for Nonadoption, Abandonment and Challenges to the Scale-Up, Spread and Sustainability of Health and Care Technologies (NASSS) was developed as many promising technological innovations in health and social care are characterized by nonadoption or abandonment by individuals or by failed attempts to scale up locally, spread distantly, or sustain the innovation long term at the organization or system level. The NASSS is an evidence-based, theory-informed, and pragmatic framework to help predict and evaluate the success of a technology-supported health intervention. For further information, see: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5688245/
NPT	Normalisation Process Theory is a toolkit to understand the dynamics of implementing, embedding, and integrating new technology or complex intervention. It helps disassemble the human processes that are at work when we encounter a new set of practices and enact new work. The theory is based on four main concepts, engaging in sense-making work, engaging in relationship work, engaging in processes to do the work, engaging in reflective/monitoring work. Each of these types of work support each other and are considered important for successful implementation. For further information, see: http://www.normalizationprocess.org/
Theme	Themes are patterns of shared meaning across participants involved in qualitative investigation, characterised by a central concept, that are important in understanding a phenomenon. In this case ECG device rollout. In this report, some of the themes were common to all AHSNs and reported separately from the themes that varied (were present / partially present / not present) across the AHSNs. Themes that varied across AHSNs were used in the development of the environment typologies and implementation typologies.
Typology	An organised system of types, to explain and group particular characteristics observed in each AHSN into a digestible analysis

APPENDICES

Appendix 1 – details of the 5 devices available through this programme[13]

KardiaMobile ECG & KardiaMobile app (AliveCor, Inc.) *(Multiple suppliers:, MS instruments, Technomed Group, NHS supplies Chain, G Cloud)*	
	
Model description	AliveCor's KardiaMobile Mobile ECG is a single-channel cardiac event monitor. It consists of a device and app that enables the user to record, share and review ECG trace(s). The device can attach to the back of most iOS (iPhone, iPod and iPAD) and android devices which are required to generate the ECG rhythm trace and display the results
User manual	Click here to view, Quick Start and Full Manuals https://www.AliveCor.com/en/quickstart/
	Click here to view AliveCor user guide
Patient connection	Single-lead ECG event recorder with integrated two electrodes within the rectangular device that can be attached directly to a mobile device or be within 30cm of the mobile device during operation Voice to text for simultaneous symptom capture and annotation during recording
Heart rate range	30 – 300 beats per minute
Display	ECG transmitted wirelessly to the KardiaMobile app. In addition to a full rhythm trace, a message is displayed as: Atrial fibrillation ("AFib"), Normal, unreadable recording. For traces that are not normal, AF or had no interference detected will display message "unclassified"
Memory type	Software application, uses smartphone/tablet and EU compliant encrypted cloud
Recording capacity	Software application can store 1000s of recording on a smart phone or tablet. These are accessible through authorised cloud based provider dashboard
Data transfer	Share, print or email a PDF of the rhythm trace on the smartphone, download PDF from eu.AliveCor.com Optional: Cardiac Physiologist report returned in-app within 24 hours for £5 incl. VAT per recording
Printing	E-mail as a PDF, print or upload from device. Individuals and Healthcare workers can also access the recordings through login at eu.AliveCor.com
Power	3V CR2016 Coin Cell
Battery lifespan	Minimum 200 hours operating time, 12 months typical use
Physical Size (LxWxH)	8.2 cm x 3.2cm x 0.35cm
Weight	Not specified
List price	£82.50 (+VAT)
Supplied accessories (Batteries & user manual assumed)	Attachment plate with adhesive
Warranty	1 year
	www.AliveCor.com

[13] These summaries were produced as part of the Health Innovation Network review of devices – apart from the one for Impulse, which wasn't included so has been compiled for this report.

MyDiagnostick (MyDiagnostick Medical B.V) (Multiple *Suppliers: Cardiologic Ltd, TechnoMed, or direct)*	
	
Model description	ECG event recorder
User manual	MyDiagnostickDevice Manual.pdf
Patient connection	Single lead, integrated two electrodes within the device that has a shape of a stick
Heart rate range	Not specified
Display	Device has indicator that will turn green for normal cardiac rhythm and red in case of AF
Memory type	It consists of an internal priority storage scheme
Recording capacity	Up to 140 x 60 to 70 seconds ECG recordings. Note: Device will overwrite oldest recordings in the following order: a) Recordings during which an error has occurred b) Recordings with no AF detection c) Recordings with AF detection
Data transfer	USB connection to computer to download a recorded file
Printing	ECG recordings can be retrieved from device using appropriate MyDiagnostic software
Battery type	2 x NiMH 1.2V 2000 mAh rechargeable (via USB connector)
Battery lifespan	Minimum 500 recordings at 60 to 70 s or 2 months regular use if the device while measuring 3 to 5 times per day
Physical Size (Length x diameter)	260 x 22mm
Weight	180g
List price	£650 (excluding VAT and Carriage)
Supplied accessories (Batteries & user manual assumed)	USB cable, additional information obtainable from website.
Warranty	2 years. The warranty only applies to failures that are the result of manufacturing faults and/or material defects.
	https://www.mydiagnostick.com/home-en

RhythmPad (Cardiocity Ltd)		
		
Model description	ECG detection tool that is suitable for continuous operation	
User manual	Click here to view user guide	
Patient Connection	1 or 6 channel, integrated electrodes within the device.	
Heart rate range	Not specified	
Display	Utilises a Windows PC or Tablet screen to display either the full lead 1 or 6 lead ECG. Uses the PC or Tablet screen as data entry to take in patient details, shows patient video of how to place hands on pad to take reading.	
Memory type	Utilise the processing of a Windows based PC or Tablet PC running windows 7 or later.	
Recording capacity	Software suite records all readings onto PC or Tablet Hard Drive. All readings are stored as PDF and are time stamped. This allows for readings to be moved into Electronic Patient Records through third party tools such as DocMan. Software suite also allows for readings to be emailed to nominated email address or printed out A4 to any networked Windows Printer. Software suite can be configured to connect to Cardiocity's cloud and arrange for automatic interpretation of ECG recording strip via Cardiocity's online Electrophysiology review service. All cloud connectivity was designed in conjunction with Information Commissioners Office to ensure compliance with Data Protection Act. **It is the responsibility of the user to ensure that they are operating the RhythmPadGP product in accordance to their local data protection policy**	
Data transfer	Wired through USB 2.0 port	
Printing	Export the data in PDF or PNG form to any third party system.	
Power	USB 5.0vDC supplied from Windows PC or Tablet	
Dimensions (RhythmPad):	135 x 80.6 x 44.8 mm	
Weight (RhythmPad):	165g	
List price	RhythmPadGP (running on your own PC) £1099 RhythmPadGP-Portable (Supplied in portable conference folder with Tablet PC) £1699 RhythmPadGP Kiosk £2500 RhythmPad Analysis Service £3/day Optional: Third Electrode – to enable 6 lead readings £200	
Supplied accessories (Batteries & user manual assumed)	Supplied with Instructions for Use, USB cable. Manual is available for download as is full software suite	
Warranty	1 year	
Instruction selection mode	English, Italian, French, German, Spanish, Russian, Portuguese and Polish	
Website	www.cardiocity.com	

Watch BP Home A (Microlife Health Management Ltd) (Multiple suppliers: Oncall medical supplies, Mortara Dolby, Intermedical)	
	
Model description	A modified oscillometric BP machine that flashes when it detects Atrial Fibrillation (AF) during automatic BP measurement. Device can be used either in: a) 'Diagnostic' mode (For 7 day scheduling with average morning, evening and overall BP readings tabulating in easy to read format) or b) 'Usual mode' (single measurement taken at any time). AF is detected in all readings of triple measurement in 'usual' mode or all four readings of one day in 'diagnostic mode to confirm AF
User manual	Click here to view user manual
Measuring procedure	Oscillometric, corresponding to Korotkoff
Measurement range: **Blood pressure** **Pulse**	 30 – 280mmHg 40 – 200 beats per minute
Display	Displays blood pressure measurement (SBP and DBP values), Pulse indicator (AFIB or Normal) and pulse rate
Memory type	Results are stored in an internal memory and can be downloaded to a removable memory device for clinician's evaluation
Recording capacity	250 measurements in usual mode
Data transfer	PC connectivity – transmits BP measurement data to any PC via USB connectivity
Power	4 x 1.5 V Batteries: size AA (Main adaptor: DC 6V, 600mA (optional))
Battery lifespan	Not specified
Dimensions	150 x 100 x 50 mm
Weight	385g (including batteries)
List price	£100
Supplied accessories (Batteries & user manual assumed)	Supplied with medium (22 - 32cm) size cuff. Other cuffs in Small (17 - 22cm) and Large (32 - 42cm) size are available to purchase separately
Warranty	5 years
	www.watchbp.co.uk

Impulse (Plessey Semi-Conductors Ltd)	
	
Model description	Impulse lead-I ECG monitor
User manual	Not available
Measuring procedure	Single lead, integrated thumb electrodes
Heart rate range	Not available
Display	ECG transmitted using Bluetooth to a smart phone or computer and displays the ECG combined with the heart rate
Memory type	Not available
Recording capacity	Not available
Data transfer	Bluetooth signal to smart phone or computer
Power	600 mAh 3.6v LifePo rechargeable battery (not replaceable)
Battery lifespan	6 hours
Dimensions	124x90x40mm
Weight	150g
List price	c. £220
Supplied accessories (Batteries & user manual assumed)	
Warranty	1 year
Website	www.plesseysemiconductors.com

Appendix 2 – summary quantitative data

AHSN	Devices procured	Devices distributed	Devices registered	% of procured devices distributed	% of distributed devices registered	Avg readings per device registered	Avg readings per user	Users per resgisted device	% of final users registered in first 6 months
East Midlands	535	287	219	54%	76%	12	9	12	38%
Eastern	503	503	253	100%	50%	28	23	28	38%
Health Innovation Manchester	340	340	107	100%	31%	19	17	19	46%
Health Innovation Network	313	313	268	100%	86%	39	29	39	51%
Imperial College Partners	275	219	104	80%	47%	26	22	26	44%
Innovation Agency	300	254	186	85%	73%	7	6	7	35%
Kent, Surrey & Sussex	556	556	253	100%	46%	30	25	30	52%
North East North Cumbria	370	374	382	101%	102%	54	50	54	23%
Oxford	95	80	41	84%	51%	13	12	13	70%
South West	196	199	105	102%	53%	72	65	72	51%
UCL Partners	670	536	342	80%	64%	12	9	12	24%
Wessex	350	310	131	89%	42%	23	20	23	22%
West Midlands	570	570	136	100%	24%	26	24	26	66%
West of England	285	223	76	78%	34%	16	15	16	41%
Yorkshire and Humber	500	400	297	80%	74%	23	22	23	31%
TOTAL	**5858**	**5164**	**2900**						

Notes:

This data is for KardiaMobile devices only

The final column is used as a measure for the speed of implementation – how many of the users were registered in the first 6 months

Some devices were moved between AHSNs late in the programme, which is reflected in the devices distributed column, but not the devices procured column.

	WatchBP			My diagnostick			Plessey			Cardiocity RhythmPad		
AHSN	Devices Procured	Devices distributed	Percentage of all devices distributed	Devices Procured	Devices distributed	Percentage of all devices distributed	Devices Procured	Devices distributed	Percentage of all devices distributed	Devices Procured	Devices distributed	Percentage of all devices distributed
East Midlands												
Eastern												
Health InnovationNetwork	100	100	100%									
Health InnovationManchester												
Imperial College Partners												
Innovation Agency	19	18	95%	35	7	20%	28	3	11%			
KSS												
NENC												
Oxford	119	119	100%							8	3	38%
South West	50	49	98%							2	2	100%
UCL Partners												
Wessex												
West Midlands	3	3	100%	11	9	82%	3	2	67%	2	2	100%
WoE												
Yorkshire and Humber	100	115	115%									
TOTAL	**391**	**404**	**103%**	**46**	**16**	**35%**	**31**	**5**	**16%**	**12**	**7**	**58%**

Notes:

This data is for all other types of devices and was captured manually by each AHSN. There are discrepancies – for example the number of reported WatchBP devices distributed in Y&H is more than the number they reported as procured.

These devices were not registered in the same way as KardiaMobile devices.

AHSN	Pre April 2018	Q1 2018/2019	Q2 2018/2019	Q3 2018/2019	Q4 2018/2019
HIN	0/189	12/880	16/916	8/825	21/854
Innovation Agency	0/0	0/0	0/34	9/288	2/556
Oxford	0/0	0/0	5/31	0/0	0/0
SW	0/26	9/225	25/829	16/437	0/0
West Mids	0/0	4/27	1/16	3/8	2/9
Yorkshire and Humber	0/0	0/0	0/0	0/0	0/0

Notes:

This table shows the AF detection rates and total recordings by AHSN for WatchBP, My Diagnostick, Plessey and Cardiocity RhythmPad devices. This data was recorded manually by the AHSNs.

Appendix 3 – participation in qualitative evaluation

AHSN	GP	Assistant & Associate practitioner	Nurse	Practice m'ger	Psychiatrist	Commissioner	Improvement/ Transformation Manager	Podiatrist	Emergency care practitioner / paramedic	Pharmacist	Non-clinical staff / HCA / Vol sector / Fire service	Totals
Eastern	2		3	1		1			2		1	**10**
HIN	1	1	2				3	2				**9**
East Midlands	5			1			1			1		**8**
ICHP	4					1	1			1	1	**8**
Oxford	6								2			**8**
Manchester	1		2			2	2				1	**8**
Y&H	3	1	2								1	**7**
West Midlands	3		3		1	1				1		**9**
Wessex	4		2				3		1			**10**
South West			5				2			2		**9**
West of England	3		1								1	**5**
Inn' Agency	2										6	**8**
NENC	1	1	1	2			3			1		**9**
UCLPartners	1					5	2					**8**
KSS	2		4							1	2	**9**
Totals	**38**	**3**	**25**	**4**	**1**	**10**	**17**	**2**	**5**	**7**	**13**	**125**

Appendix 4 – Examples of specific environments described in the qualitative fieldwork

Feedback on how devices were used in different contexts depended on the professionals attending the focus groups/telephone interviews, therefore a completely representative range of contexts could not be ascertained. However, the examples below provide important insight into how KardiaMobile devices were used in a range of locations and its potential value.

Clinical pharmacists in general practice: "Since I've had an AliveCor I've done 114 tests and 8 cases of AF and onto anti-coagulation. I've found them really easy to use but I do get the unclassified issue now and then

which is frustrating. I've used it during medication reviews for people with hypertension and they tend to be older people. I use AliveCor fairly routinely and do a manual pulse check as well…I have 15mins appointments and I keep one of the devices with me all the time but I know the GPs in my practice are often messaging around asking where one is so they can use it with a patient. If we had more that would be helpful for our practice." (Clinical pharmacist)

Community pharmacy: "AliveCor testing is unpaid in our area so that has been a major barrier for community pharmacists who are very commercially driven. Most of the people we approached were private businesses. We met the local pharmacy committees in the area to promote the use of AliveCor but had mixed results from that. We did a lot of training with them but that didn't seem to matter, it's always been about the funding issue and AliveCor device use has been low with this group because of that." (AHSN local rollout lead)

Practice nurse with proactive community focus: "I was asked to see a lady for other reasons, in her own home, did her observations for the other reasons and also did a manual pulse check. It was a bit high, so I used the AliveCor. She was very elderly, in her 90s, so I had to gain her trust a bit and explain about the device so she wouldn't worry. She had a bit of arthritis in her hands so I was mindful of that and asked if it was ok for her to press as hard as she could to make sure we got a reading…we got the reading and I sent her for a 12-lead assessment and contacted the GP. It turned out the lady did have AF so was put on medication, so that was a good result." (Pro-active nurse)

Flu clinic (positive): "We had a flu clinic and I was testing as many people as they came through the door…I tested 189 people that day, it was pretty full on, and 9 people were obviously in AF so I referred them immediately. Six people I called back for a 12-lead ECG, of which 2 had normal ECGs, 2 had a different type of arrythmia and 2 had AF." (GP)

"We decided to test it on our over 55-year olds in our flu clinics…we offered it as an extra thing and the patients were really keen and it only took two minutes each. I [GP] just sat at a table in the waiting room and asked if people were willing to be tested as they came in and left...I did it for 2.5 hours…we were keen to do it and lucky that our practice is fully staffed and able to do it so that's important to mention. I did 228 tests and that led to 50 possible AF findings using AliveCor and they were all brought back for a 12-lead assessment…8 people haven't had their 12-lead yet as the flu clinic was only last week, but we know already there are 4 with confirmed AF diagnoses and now on medication." (GP)

Flu clinic (negative): "Our GP Partners discussed using AliveCor in flu clinics, but we decided not to in the end. To be honest, we were worried about the extra work we would generate, not only on the day and potentially do less flu jabs, but after the AF testing. Also, we were concerned we may affect relationships we have with our local hospital and cardiology consultants as some of the work would ultimately be heading in their direction. In our area, I don't think our AF detection and management pathway is mature enough to handle more work currently, but we are looking into it." (GP)

Non-clinician using devices at public venues: (e.g. community centres, football grounds, festivals) "We did the AliveCor training before starting to use the device. We provide a letter with information about AF and why we are testing. Once tested we ask the patients to contact their GP and go from there. We've also contacted the patients about 2 to 3 weeks later to see if they followed up on contacting their GP." (Non-clinician device user)

Community cardiology services: "In the district general hospital they operate community clinics and have hubs in primary care centres. From there they have locality teams of specialist nurses who go out into the community. Previously, these cardiology nurses go out to patients' homes and end up doing a manual pulse check and then, if needed, go back to the hub to pick up the 12-lead kit and test the patient in a second visit. Now they have AliveCor, they have avoided a lot of back and forward getting the 12-lead kit and doing unnecessary testing. Multiple tests have been avoided across the various professionals in the locality teams,

it's saved a large amount of time for them and made the service much more efficient." (Community cardiology services)

Community rapid response team: "For us they've been invaluable…it's a very easy device to use…we visit patients in their homes to potentially avoid a hospital admission and we now use the device to detect AF. If we detect possible AF, we set up the onward referral. We have time to do this sort of thing and we're interested in preventative work, so it has fitted in with our work seamlessly…the only thing stopping us can be poor phone signal." (Community nurse)

Memory service: "I'm using AliveCor about twice a day…in our clinic we don't have an ECG machine, the main hospital deal with these, so with AliveCor I can decide if I need to send them for a full ECG, so that helps avoid unnecessary 12-leads assessments and couple of weeks delay for patients. Also, as we're part of a Mental Health Trust we don't have to pay the hospital to do the 12-lead ECGs, so there is a financial benefit there too. My normal role is to diagnose memory problems and prescribe medications as needed…before, if I thought I needed to do a 12-lead assessment that would have postponed my dementia prescribing decisions. I've liked being able to find out if they definitely need a 12-lead test and when they don't." (Consultant)

Podiatry and Diabetes clinics: "It's been great…the patients we see in diabetes clinics are at risk of complications like strokes and heart disease, so it's a good use of our time to test them for AF…I tend to use it on first assessment with diabetes patients and use AliveCor about 5-10 times a week. Patients can be surprised by the request but because it's so fast, only 30 seconds to do the trace, they don't mind and understand why. One patient was like this and after using AliveCor I did refer her to her GP for the full ECG test and later she was diagnosed with AF and prescribed anti-coagulants. The patient later told me she was really glad we'd done the AliveCor test."

TIA / Stroke clinic: "We use it with 2 or 3 patients a week, particularly to help identify high risk patients, who we will probably want to send for a 3-day 24hour tape heart rate assessment…using AliveCor first helps us be sure that patient definitely needs to be monitored over 3 days. (Consultant)

"From a suspicion of AF in a high risk individual, using AliveCor I can potentially avoid unnecessary tests like the 24-hour tape tests which may have shown nothing in the end, and I can get an echocardiogram done instead and focus on other diagnostic issues. We're still working to understand how best to use AliveCor, but I think it's the way forward to be honest." (Consultant)

"We've got an inpatient and outpatient stroke service and we wanted to know what would work best. We've mostly been using it outpatients, as the inpatients are really appropriate for several reasons…like patients who have extensive physically disability from stroke, those that aren't cognitively well enough to participate in the test, or working out which staff would do the AliveCor tests on the wards and allocate man-hours for that." (Consultant)

"We had 20 AliveCor devices provided to us…based on what we knew about the patients…who were physically and cognitively stable but needed their heart rate monitoring, we've lent about 20 outpatients patients the AliveCor for 20 days, helped them install the app on their smartphone, asked them to do readings 5 times per day. We asked patients to email the PDF traces to me or one of the consultants and we would decide if we wanted to call them into outpatients for more investigation…several of these, sorry I can't remember how many exactly, were confirmed AF and brought back for discussions about next steps." (Consultant)

Stroke specialist nurse in the community: "It's worked really well for me using it with people I see in the community. But with the GPs, one problem I've found is some of the local GPs don't take on board the AliveCor findings without AF being flagged whilst the patient was still in hospital after their stroke. So those GPs will wait for more information from rhythm strips from the hospital teams before taking the AliveCor test seriously. We also had an issue with the Trust and the iPads we were using, they didn't think they had the

relevant security levels, but this was confusing because there isn't any patient identifiable information in the app on the iPad to use AliveCor. Despite this, it's still a good idea as I have more time with patients in the community so can get into this sort of preventative work, so I test everyone I see and that's been good and generated some possible AF readings." (Stroke specialist nurse)

Paramedic: "I've used AliveCor for about 4 months…about 5 times a week…I use the device and email myself the trace and add a copy into the patient's notes. I find it useful to see if there is AF, but also any ectopics or any changes like wider QRS's before I contact other paramedics or the ambulance service to collect the patient. I've used it during home visits and out and about myself…for the ambulance crews, they already have 12-lead devices with them so there aren't needed there…I've used it as a precursor to further investigations." (Paramedic)

Paramedic practitioner: "I've been using it for a couple of months now in a primary care context and it gives you enough information to help your decision making. I'm aware its designed to detect AF but we've used it for more than that…because we're clinicians who can read ECGs, we can tell if someone is bradycardic or tachycardic, and we can diagnose and arrange further investigations from there. It's an added value which has been a good thing for us." (Paramedic practitioner)

With people with suspected slow, fast or irregular heart rate I use the AliveCor to get the 30 second rhythm strip, upload the trace PDF onto EMIS, the GP software, so everyone can see it. Depending on what we'll find we'll onward refer them, maybe for a 12-lead or into secondary care. (Wessex)

Older adult psychiatry: "Our Trust was involved with the AHSN so the [AHSN rollout lead] contacted me to see if I was interested…and it seemed like AliveCor would fit well into the dementia diagnosis work that I primarily do. Once someone has a diagnosis I start to think about prescribing medication and quite often it's important for me to know if someone has brachycardia or arrhythmias…it saves me unnecessary contact with GPs to do ECG traces and rhythm strips and then wait for the replies. Screening isn't usually part of my service so it's nice to be involved in that kind of work with these people over 65 years old…it's definitely led to faster decision making and stop delayed access to medication." (Consultant)

Pre-operative assessment clinic: "It's worked in the pre-operative clinic context…large numbers of patients are seen in this setting. Patients can be in this setting for a while and it's an opportunity to screen for AF. AliveCor are now incorporated patient wide throughout pre-operative assessment and we'd saved quite a few unnecessary 12-lead tests and delays for patients." (Nurse practitioner)

Use of AliveCor by patients at home: "As a practice, we had to think about how this work for us…we decided the best situation was for patients to take the AliveCor home and monitor their heart rate for us for the paroxysmal AF patients…we already have a 12-lead device in the practice so our GPs felt giving the AliveCor to patients was the best use of the device and staff time. So, when a patient was identified for AliveCor testing they would be sent down to me [practice manager]…if they were considered reliable, had their own smartphone, and known to have a good level techy knowledge so they would be able to use the app and AliveCor. I had a chat with them, asked them to sign a form to guarantee the return of the AliveCor after 6 weeks. We used a shared email address, our practice email address, in the app for all the patients so they could email us traces and we could monitor them. We knew this whole approach wasn't part of the original plan from the AHSN but we considered this the best way forward from a clinical point of view. We've only been doing this for a few months…we've given AliveCor out to the 5 patients in total and after the monitoring they did have confirmed AF." (Practice manager)

Appendix 5 – The R-Outcomes measures used in the evaluation

R-Outcomes have developed a set of person-reported innovation measures, which are used in this study. The measures that have been used are:

Digital Confidence rates users' digital literacy and confidence to use digital products, with dimensions of familiarity, social pressure, support and digital self-efficacy.

Innovation Readiness measures user perceptions of how much they are open to and up-to-date with new ideas, and whether their organisations are receptive to and capable of innovation. It is based on Rogers' classification of innovativeness (innovator, early adopter, early majority, late majority and laggard).[2]

Product Rating assesses a digital product in terms of usefulness, ease of use, support and satisfaction.

Innovation Adoption rates the adoption process in terms of coherence and reflective thought before, during and after implementation. It is based on May's Normalisation Process Theory (NPT).[3]

These measures share a common look and feel, with 4 items and 4 responses each. Each item is scored on a scale from 0 (disagree) to 3 (strongly agree). For reporting the scores are converted to a scale from 0 (all disagree) to 100 (all strongly agree). A high score is always good. A summary score may also be calculated as the sum of the four items. This is also reported on a 0–100 scale.

These were the surveys received by the device users in this programme:

Digital Confidence	Strongly agree	Agree	Neutral	Disagree
I use a digital device at work				
My colleagues use digital devices				
I can get help if I am stuck				
I am confident using new digital devices				
Innovation Readiness	Strongly agree	Agree	Neutral	Disagree
New ideas are needed in my field				
I keep up with new ideas				
My organisation supports new ideas				
My organisation makes new ideas work				
Product Rating	Strongly agree	Agree	Neutral	Disagree
This product helps me do what I want				
It is easy to use				
I can get help if I need it				
I am satisfied with this product				
Innovation Adoption	Strongly agree	Agree	Neutral	Disagree
The original vision is being followed				
We all thought about how to make it work				
We all act to make it work				
We all think about how to keep it going				

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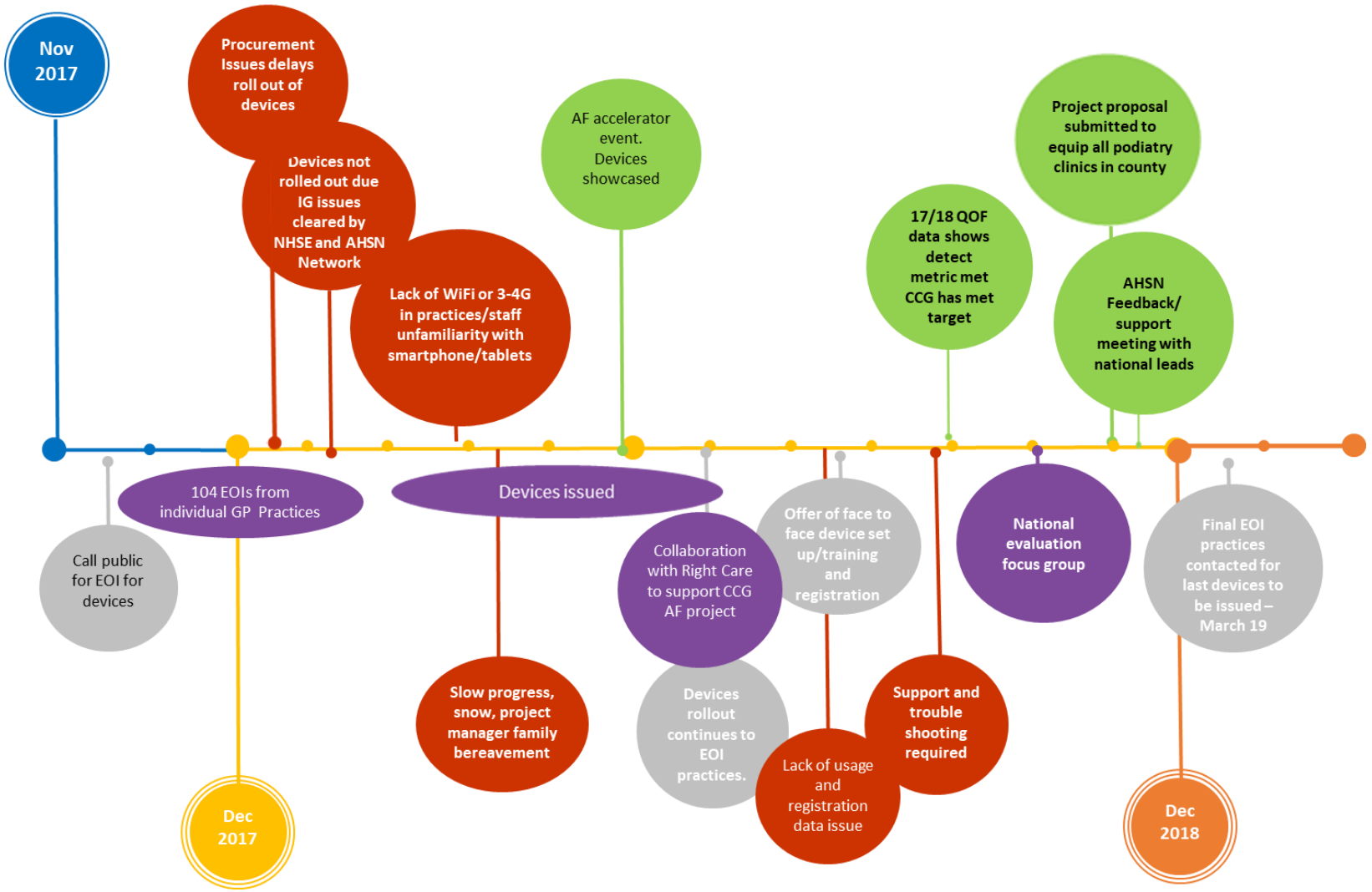
Appendix 6 – R-Outcomes scores by AHSN

AHSN	EM	East	HI (Man)	HIN	Imperial	IA (NWC)	KSS	NENC	Oxford	SW	UCLP	Wessex	WM	WE	Y&H	Overall
n	40	60	17	73	14	21	88	43	10	60	34	43	43	13	60	619
DIGITAL CONFIDENCE																
I use a digital device at work	89.2	90.6	82.4	86.3	88.1	82.5	86.7	89.9	76.7	84.4	92.2	88.4	88.4	82.1	83.9	87.0
My colleagues use digital devices	84.1	83.1	84.3	79.8	74.4	85.0	80.1	88.4	76.7	80.7	83.9	79.8	82.2	79.5	80.0	81.7
I can get help if I am stuck	74.6	74.7	74.5	74.2	69.2	76.2	71.2	86.0	70.0	81.0	79.8	72.1	82.1	79.5	71.7	75.8
I am confident using new digital devices	79.4	81.4	84.3	86.9	79.5	82.5	78.0	85.3	70.0	80.2	75.8	82.9	82.9	71.8	72.8	80.3
DCS summary score	81.8	82.4	81.4	81.8	77.8	81.6	79.0	87.4	73.3	81.6	82.9	80.8	83.9	78.2	77.1	81.2
INNOVATION READINESS																
New ideas are needed in my field	82.9	87.2	80.4	85.0	81.0	85.7	79.2	78.9	70.0	77.2	85.3	84.9	85.3	72.7	81.7	82.1
I keep up with new ideas	75.6	81.4	82.4	77.9	73.8	79.4	74.6	82.9	70.0	74.4	75.0	79.4	76.7	72.7	73.3	76.9
My organisation supports new ideas	84.1	75.6	80.4	80.3	78.6	84.1	72.7	82.9	66.7	80.6	77.8	79.1	82.2	75.0	83.3	79.2
My organisation makes new ideas work	74.8	73.3	76.5	71.4	71.4	71.7	64.4	78.9	56.7	75.3	65.7	69.8	73.6	69.7	77.2	71.9
Innovativeness summary score	79.4	79.4	79.9	78.6	76.2	80.2	72.7	80.9	65.8	76.9	75.9	78.3	79.5	72.5	78.9	77.5
PRODUCT RATING																
This product helps me do what I want	77.0	73.3	76.5	70.4	71.4	81.0	73.9	83.7	73.3	74.7	81.8	78.6	78.3	63.9	76.7	75.8
It is easy to use	84.9	82.2	90.2	83.6	78.6	87.3	75.4	91.5	63.3	84.2	85.3	81.0	83.7	75.0	83.3	82.6
I can get help if I need it	65.0	63.9	76.5	65.7	66.7	68.3	61.7	85.3	46.7	73.1	63.6	61.1	65.9	66.7	67.8	66.9
I am satisfied with this product	81.7	73.3	87.5	74.6	82.1	84.1	72.0	81.4	63.3	78.2	83.8	78.6	81.0	63.6	79.4	77.5
Product rating summary score	77.2	73.2	82.7	73.6	74.7	80.2	70.7	85.5	61.7	77.5	78.6	74.8	77.2	67.3	76.8	75.7
INNOVATION ADOPTION																
The original vision is being followed	63.9	64.6	60.0	70.0	76.7	60.4	67.6	80.0	47.6	66.7	66.7	68.5	70.4	60.0	68.3	67.7
We all thought about how to make it work	61.1	68.0	60.0	68.3	76.7	66.7	58.9	77.8	38.1	66.7	57.7	66.7	68.5	63.6	61.8	65.0
We all act to make it work	66.7	62.6	63.3	66.7	70.0	66.7	59.8	76.7	42.9	65.9	62.8	63.0	64.8	56.7	61.0	64.0
We all think about how to keep it going	66.7	67.4	60.0	67.8	70.0	60.4	55.6	76.7	38.1	67.5	62.8	63.9	63.9	56.7	58.5	63.6
Innovation adoption summary score	64.6	65.6	60.8	68.2	73.3	63.5	60.5	77.8	41.7	66.7	62.5	65.5	66.9	59.2	62.4	65.1
Overall mean score	75.7	75.2	76.2	75.6	75.5	76.4	70.7	82.9	60.6	75.7	75.0	74.9	76.9	69.3	73.8	74.9

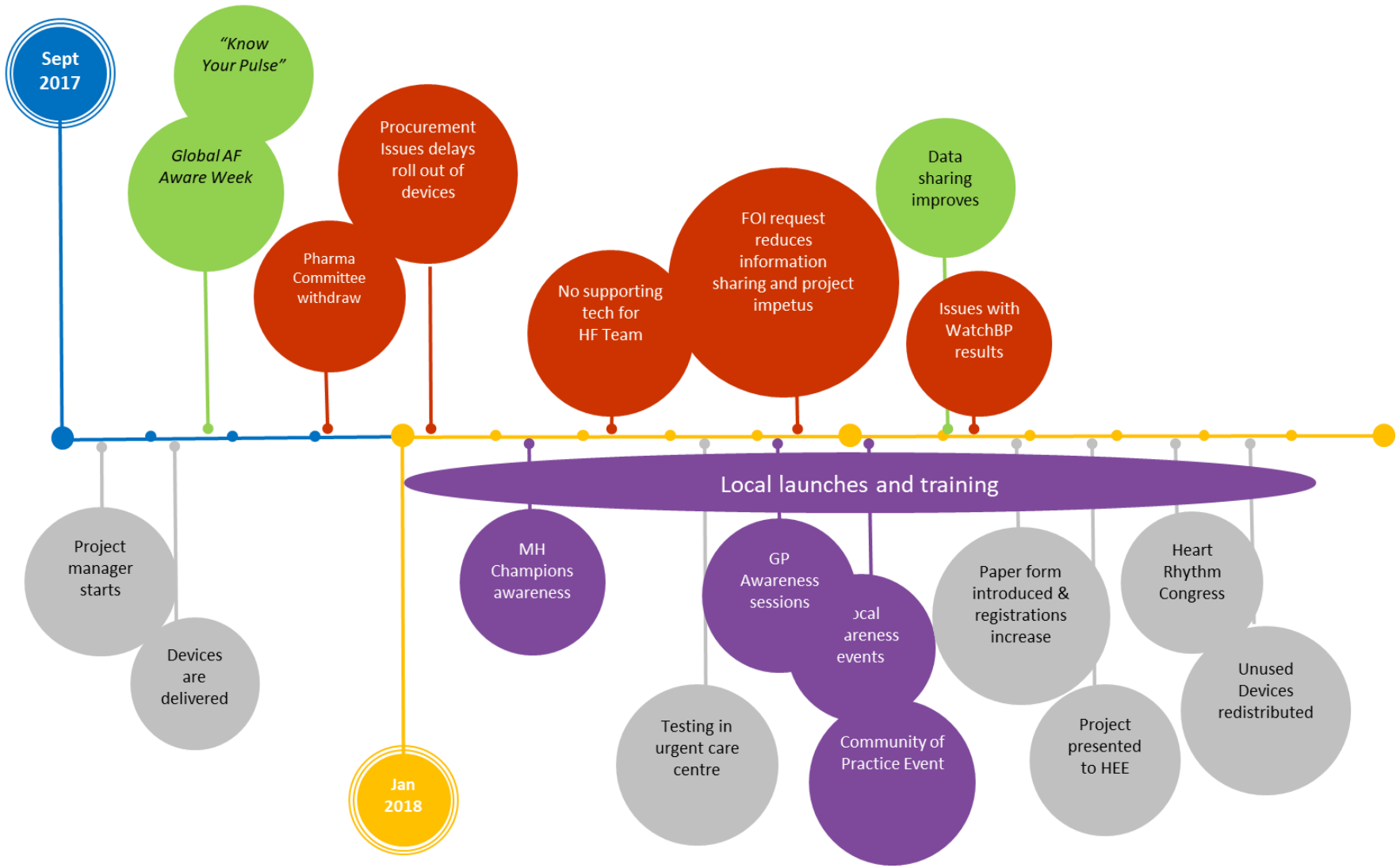
R-Outcomes are scored out of 100 - the higher the score, the more positive the response from the individual to the four questions making up each measure. Scores over 80 are positive/ good; 60-80 are moderate; and under 60 are low

Appendix 7 – 3 examples of the timeline infographics compiled for each AHSN

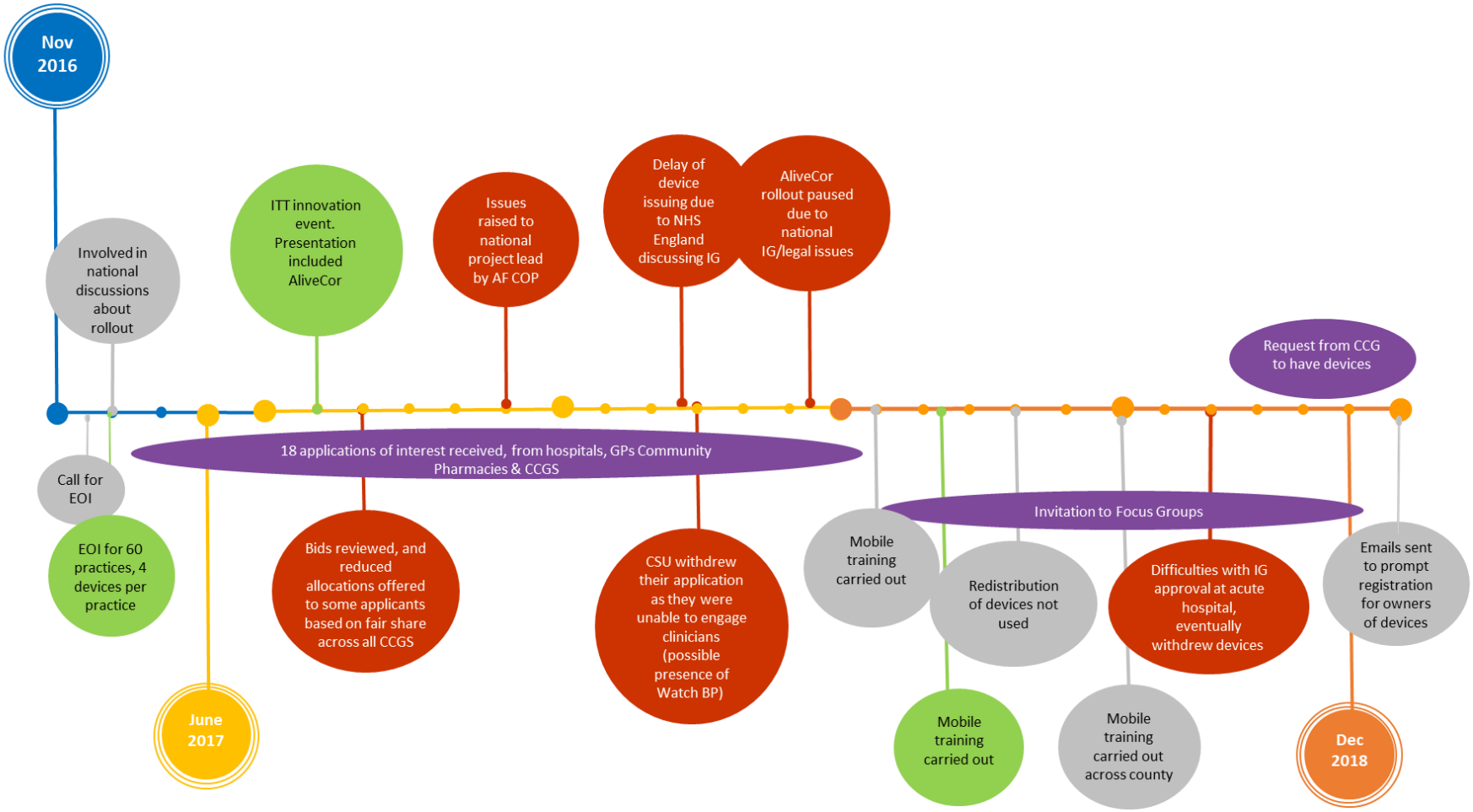
AHSN 1 — timeline of rollout of mobile ECG devices



AHSN 2— timeline of rollout of mobile ECG devices



AHSN 3 — timeline of rollout of mobile ECG devices



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