

# Process Evaluation for Technology Enabled Atrial Fibrillation Screening after a Stroke in Scotland

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## Executive summary

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Diagnosis of Atrial Fibrillation (AF) after stroke is a national priority. AF-related strokes typically cost twice as much to manage as non-AF related strokes (Miller et al, 2005). If diagnosed with AF, further stroke can be reduced by 60% by taking medications such as anticoagulants. Because AF can be paroxysmal- that is the heart can go in and out of AF- it is not always detected during hospitalisation for stroke. If there is a reasonable suspicion that stroke may have resulted from undetected AF, guidelines recommend screening with a Holter monitor - an ambulatory electrocardiogram (ECG) applied in a hospital clinic for 72 hours.

A 'Test of Change' within one local hospital in Scotland (NHS Lanarkshire) was conducted during 2019 where a new managed service involving devices (applied to n=64 patients) were considered for AF screening that would allow for up to 14 days of continuous monitoring in the home setting. This new technology enabled service also included reporting conducted by the company providing the service as a proposed alternative to clinicians inside the NHS doing all the report reading and analysis. Clinicians and other key implementers involved in the planning, set up, delivery, and evaluation of this service innovation were interviewed throughout the project to gather qualitative data on the potential barriers and facilitators to this type of service working longer term locally for them and or potentially scaling nationally. Patient experience was also captured through interviews with a sample of patients who received the new service (8/64; 12.5%) to capture acceptability of the new device and resulting service within this NHS setting.

Findings revealed that patients found the new monitoring device acceptable. Stroke clinicians and nurses invested additional time in training (4 half days) to use the software, apply the devices and in home-visits to apply devices but also highly valued the availability of 14 days of continuous data. For further adoption of this type of service, it is critical to explore whether clinicians would adopt a system or service that produces the reports for them or whether they would prefer to have the reports generated by NHS staff (trust and control versus cost and capacity for reporting).

It is anticipated that this report will benefit policy makers in government, operational managers, clinical leads, service managers and digital and IT managers and leads and many others by providing key barriers and facilitators and therefore a realistic checklist of what must be considered in planning for implementation of new technology enabled services to monitor for intermittent AF within a care pathway.

## **Abbreviations**

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<b>AF</b>	<b>Atrial Fibrillation</b>
<b>DHI</b>	<b>Digital Health and Care Institute</b>
<b>ECG</b>	<b>Electrocardiogram</b>
<b>GSA</b>	<b>Glasgow School of Art</b>
<b>HCP</b>	<b>Health Care Professional</b>
<b>NASSS</b>	<b>Non-adoption, Abandonment, Scale-up, Spread, and Sustainability framework</b>
<b>NHS</b>	<b>National Health Service</b>
<b>MCN</b>	<b>Managed Clinical Network</b>
<b>UoS</b>	<b>University of Strathclyde</b>
<b>UX</b>	<b>User Experience</b>
<b>TIA</b>	<b>Transient Ischaemic Attack</b>

## 1 Aims and objectives

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The aim of this evaluation was to qualitatively explore the patient, clinical, and organisational experiences and acceptance of adopting and scaling a new technology enabled service for 14-day continuous monitoring in the AF screening pathway in secondary care.

The report will meet the following objectives in order to meet this aim:

- |           |  |
|-----------|--|
| CHAPTER 2 | Present the background, context and motivation for a new technology enabled pathway for AF screening after stroke.                                 |
| CHAPTER 3 | Identify and evaluate currently available home-based AF continuous screening devices and the evidence that exists around their use and acceptance. |
| CHAPTER 4 | Describe the methods used to evaluate the patient, professional and implementation experience stories with this new AF care pathway.               |
| CHAPTER 5 | Understand and map the existing AF pathway in one local context in NHS Lanarkshire.  |
| CHAPTER 6 | Understand and map a real live 'Test of Change' new technology enabled care pathway for AF screening carried out in NHS Lanarkshire.               |
| CHAPTER 7 | Report on the patient and professional acceptance and experiences of the new AF screening technology and service around it.                        |
| CHAPTER 8 | Report on the implementation experience (Process of clinical and service delivery) from the testing of the new AF screening pathway.               |
| CHAPTER 9 | Present recommendations for future work implementing new technology enabled AF screening nationally.   |

## 2 Background and Context

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### 2.1 Atrial Fibrillation

Atrial Fibrillation (AF) is a cardiac arrhythmia affecting the top sections of the heart (atria) and can lead to ischaemic stroke. As the heart is pumping irregularly, not all of the blood is being forced out of the heart and blood can collect in the atria allowing clots to form. Some factors are reported to increase the risk of clotting (e.g. older age and having a history of stroke). If any blood clots travel directly to the brain and restrict blood to the brain tissue this is known as an ischaemic stroke. AF is associated with a five-fold increase risk of stroke (The Framington Heart Study; Wolf et al, 1983). Although the severity of a stroke is dependent on the individual, AF related strokes are often more severe and may negatively impact the persons quality of life.

Prevalence of AF in the UK is estimated at 1.2 million people and it is reported that 0.5 million individuals or more may be undiagnosed with AF (Stroke Association, 2017). In Scotland the current figures are just over 96,000 (BHF, 2018). people being diagnosed with AF with up to 50,000 with AF but without a diagnosis (BHF, 2018). The cost of a single stroke is estimated to cost the NHS between £9,500 and £14,000. This is estimated to cost the NHS £2.8 billion per year (Spieler et al, 2002; Brüggjenjürgen et al, 2007). Current healthcare provisions for stroke through the NHS, private healthcare or un-paid care are estimated to cost the UK £26 billion per year (Stroke Association, 2018). As AF related strokes cost more than strokes from other causes, there is a significant financial impact of stroke on Scottish health and social care systems resources (BHF, 2018).

Frequently AF is first detected during hospitalisation for stroke or transient ischaemic attack (Stroke Association, 2017). Almost 25% of all ischaemic strokes are thought to be related to AF (Yin et al, 2017). If diagnosed with AF, further stroke can be reduced by 60% by taking medications such as anticoagulants (Lip et al, 2007). AF can be asymptomatic, and frequently is first detected at time of admission for an acute stroke. However, AF can also be paroxysmal, meaning that the heart can change between a regular normal rhythm and AF. If there is a reasonable suspicion based on the presentation of stroke and clinical signs, but the patient is in a normal heart rhythm at the time of stroke, then international guidelines recommend monitoring the patient for 72 hours to determine if paroxysmal AF is present and therefore treatment of AF with an oral anticoagulant drug is recommended.



## **2.2 Current AF screening technology**

In the first instance, a 12-lead ECG is recorded in hospital. This 12 lead ECG captures a 30 second snapshot of the electrical rhythm of the heart from different viewpoints. Patients may be monitored via telemetry during their hospital stay but because AF can be paroxysmal, it might not be present during hospitalisation. If there is a reasonable suspicion that AF is the cause of stroke, then a Holter monitor, which is an ambulatory ECG may be applied for up to 72 hours (ESC, 2016). While debate remains about the precise amount of AF that leads to stroke, it is clear that the longer patients are monitored for, the more likely it is that AF will be detected. It has been proposed therefore that longer term monitoring via newer technologies should be considered to capture potential asymptomatic AF in this population (Verma et al, 2014; January et al, 2014; Kirchhoff et al, 2016).

A cross-party inquiry examining the management of Atrial Fibrillation (AF) specifically within Scotland recently recommended investments in the use of new technologies to improve the rates of earlier AF screening (BHF, 2018). Although a wide range of AF screening devices to allow longer monitoring periods are becoming more readily available (such as handheld devices, single lead monitors and adhesive devices), some may not be appropriate to use (either for some patient populations or for some clinical contexts). It is important therefore to explore which of these might be acceptable by both patients and clinician's and also evaluate if and how these can be incorporated into the current AF screening pathways to improve AF screening, diagnosis and resulting treatment.

A scoping review of current evidence for AF screening technology is provided in Chapter 3.

A situational market review of AF technologies conducted by the DHI prior to this project (during 2018-2019) can be found in Appendix 1.

## **2.3 Improving AF screening with new Technology Enabled Care Pathways**

New technologies have shown great potential at improving the quality of health and care from the perspective of the patient, workforce and healthcare system (Health Education England, 2018). Implementation of technology within health and care has also been accepted by patients and has been reported to empower patients, improve independence and allow further care in the community. This has also allowed the provision of new roles associated with technology and reduced the cost of long-term health care (Castle-Clarke, 2018).

Technology implementation projects have often been completed poorly in large scale projects and often result from trials that are very specific to the population and/or context they are trialled in (Greenhalgh et al, 2017; Castle-Clarke, 2018). Researchers have frequently highlighted that the process of implementing technology within the NHS should be better reported, providing further details regarding the benefits and challenges of the implementation process (Castle-Clarke, 2018). As technology advances at pace it is crucial that we examine how these newly emerging devices and care delivery pathways are accepted (or not) by patients and also how they can be adopted and integrated into existing or even new clinical pathways to improve or disrupt the current status quo in order to reach better targets for screening and ultimately deliver the appropriate care in a timelier way. This will include looking at innovative managed service models and how these can be implemented and scaled up across the national health system more widely.

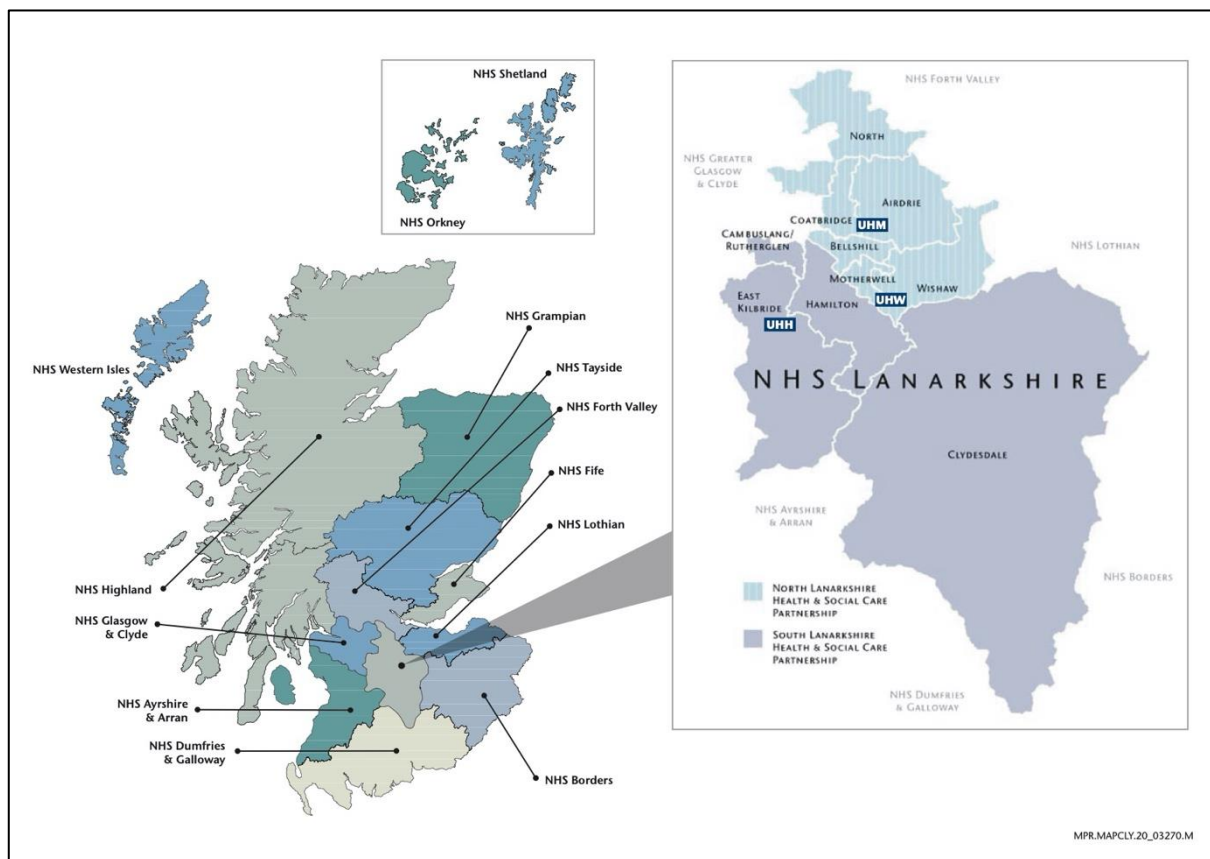
### **2.3.1 The Digital Health and Care Institute**

The Digital Health & Care Institute (DHI) is part of the Scottish Funding Council's Innovation Centre Programme, which is designed to support user and patient centred innovation in the digital health and care sector. They do this in part by fostering collaboration between universities, businesses, third sector and civic partners to adopt new innovative care pathways. By working collaboratively with a variety of experts including, academics, industry and service providers and service recipients (patients, service users and citizens) they also examine the whole process of implementation (which includes designing, developing, evaluating, and implementing) of new devices, managed services, and care pathways within the current healthcare system. They also aim to drive forward commercial and economic growth in the sector by understanding best practices and new ways of working between innovative technology companies and healthcare providers (DHI Scotland, 2018).

One of the DHIs supported national challenges focuses on examining the implementation of new Atrial Fibrillation (AF) screening service in the care of individuals who have had a stroke. DHI have previously undertaken work in partnership with Scottish Government in the screening of AF in primary care (BHF, 2015). This project builds on this work by examining the role of new AF screening technologies and pathways in secondary care.

### 2.3.2 The Context: NHS Lanarkshire

To provide a basis for national rollout of the use of new digital services to monitor AF, this study will use one implementation site as a case study. This site was NHS Lanarkshire in Scotland UK (see Figure 2.1). NHS Lanarkshire are an innovation ready service within Scotland and they currently provide stroke services for around 10% of the Scottish population (574,637 out of 5,295,403) (National Records of Scotland, 2011). It contains a representative mix of rural and urban populations. The population is served by three distinct district general hospitals, each with cardiac physiology departments that work in different ways.



**Figure 2.1. Diagram of NHS Lanarkshire sites. Used with permission, Michael Brady, Medical Illustration, NHS Lanarkshire, 07.02.2020. UHH is University Hospital Hairmyres, UHM is University Hospital Monklands and UHW is University Hospital Wishaw**

In NHS Lanarkshire they aim to conduct prolonged ECG monitoring to detect paroxysmal AF in stroke patients with (i) no known history of AF and no contraindication or definite indication for lifelong oral anticoagulation, with any of the following:

- i. History of frequent palpitation
- ii. Syncope or pre-syncope
- iii. Recent myocardial infarction
- iv. Recent cardiac surgery
- v. Cardiac failure
- vi. Ischaemic stroke/TIA affecting more than one vascular territory
- vii. A cortical ischaemic stroke/TIA with no other explanation

In NHS Lanarkshire, 72 hour tapes can be applied on all appropriate patients, however, these cannot be reported within the desired time frame. NHS Lanarkshire are ready as an organisation to innovate and saw an opportunity to improve this service with support from DHI.

### **2.3.3 The role of University of Strathclyde**

The University of Strathclyde were commissioned to conduct a qualitative process evaluation of this live implementation or 'Test of Change' in order to capture how the device and service around this were chosen, used, and accepted by both the patients receiving the device and the clinicians and health professionals involved in applying the device, reading the reports, and diagnosing AF cases (the full service pathway). Edinburgh Napier University collaborated with the University of Strathclyde to provide academic and clinical advice on screening of AF. This type of pragmatic real time evaluation is crucial in order to understand if and how this new pathway would work in practice in the longer term for NHS Lanarkshire but to also identify what the key barriers and facilitators are for the wider adoption and scaling of similar solutions nationally across other health boards in Scotland and beyond.

### 3 Scoping Review

#### What does the existing literature say about available AF screening technology?

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This scoping review aimed to identify existing AF screening technology which would be suitable for individuals who have had a stroke and review what evidence exists (and what gaps there might be) for the use of these devices in practice. We identify devices which are currently used for short periods but can be used for longer periods of time (more than 72 hours) to achieve to the recommended screening time in this population (Kirchhoff, 2016; ISD Scotland; 2017).

This scoping review therefore aimed to identify technology which:

- Can continuously monitor cardiac rhythms for more than 72 hours (essential)
- Has been used for screening for AF individuals who have had a stroke (essential)
- Has evidence of patient involvement/feedback (desired)

*Note: This review excluded implantable devices due to high cost and invasive nature of procedure.*

#### 3.1 Search Method

The database PubMed was searched on 4<sup>th</sup> Sept 2019 by one researcher SH. The full search criteria can be found in Appendix 2. Literature was restricted to English, full text and being published in the last 10 years. The resulting papers were reviewed to identify AF screening technology used in individuals who have had a stroke and to evaluate the reported usability of the technology found in the existing literature.

#### 3.2 Findings

Thirty-two pieces of literature met the outlined criteria above. An overview of the available technology that was reviewed is presented in Table 3.1. The full set of findings for this review have been presented in Table 1 in Appendix 3.

*An initial market review of devices was also conducted by DHI earlier in the project (before devices were selected and implemented in NHS Lanarkshire) and for reference this can be found in Appendix 1.*

Technology	Device Category	Device subcategory reported	Summary of type of device	Device examples in general literature	No. different devices identified in the literature review.
Technology to assess heart rate.	Non-ECG monitoring	Pulse palpation	Assessment of heart rhythm by radial pulse.	NA. Fitzmaurice et al, 2014.	N=1
		BP machine	Device measures the last 10 pulse intervals during cuff deflation and calculates the mean and SD of the time intervals.	WatchBP Home Kearley et al, 2014	N=2
Technology to assess heart rhythms.	Handheld technology	Photoplethysmography (PPG)device	Device uses light passing through skin to detect blood volume changes in the microvascular bed of tissue.	Cardio Rhythm smartphone application Tang et al. 2017.	N=0
		Smart phone + case electrode	Phone case assesses rhythm providing a single lead rhythm strip.	AliveCor Kardia Galloway et al, 2013.	N=2.
		Electrode stick	Device assesses rhythm providing a single lead rhythm strip.	MyDiagnostick Tieleman et al, 2014	N= 0
		Single lead monitoring device.	Device assesses rhythm providing a single lead rhythm strip.	Zenico-ECG Poulsen et al, 2017	N= 1.
	ECG screening (single lead)	Monitoring patch.	Patch includes electrode to assess rhythm providing a single lead rhythm strip.	Zio patch Tung et al. 2015.	N=2
		Wrist/watch recorder	Device assesses rhythm providing a single lead rhythm strip.	AliveCor Kardia Band Bumgarner et al. 2018.	N=0.
	ECG screening (multi lead)	Wearable device	Available devices include products with straps or devices in clothes.	Worn like necklace. Textile Wearable Holter (vest device) Pagola et al. 2018.	N= 1.
		Holter monitor	Currently used with NHS.	Sposato et al.,2012.	N= 26.
		ECG	Gold standard in screening	Lazzaro et al, 2012.	N= 13.
		Continuous ECG	Gold standard in screening, required in hospital stay.	Scheitz et al., 2015.	N= 4.

**Table 3.1. Table summarising different devices available in the general literature and devices identified in this literature review which provide continuous monitoring in the stroke population identified in this literature review.**

*Please note, due to the focus of the review, studies or devices that were identified in the general literature but were not identified as providing continuous monitoring were listed as n=0.*

This scoping review was intended to provide the reader context in relation to some of the other currently available devices for measuring heart rhythm and to review what potential evidence is available and acceptable for use in individuals who have had a stroke. The scoping review found that in general the available AF screening technology either used an ECG, photoplethysmography, or oscillometric assessment of regularity of heart rhythm. Studies which do not use ECG technology are not the primary focus of this scoping review, as they require further follow up if an irregular rhythm is identified. Similarly, the review of single-time point monitoring provided here is not exhaustive, as the primary focus of this work is longer term monitoring to detect paroxysmal AF.

### **Single time point monitoring studies**

One recent systematic review examined twenty four studies which identified AF using a single time point device (Lowres et al, 2019). The devices identified in the single time point systematic review included: 12 lead ECG (n=5) (one of these studies used an ECG to confirm AF identified by pulse palpation); single lead (Omron HCG-801) (n=1); single lead ECG (AliveCor) n=6; single lead ECG (MyDiagnostick) (n=1); single lead ECG (HeartCheck, CardioComm ) (n=2); Pulse palpation n=3; modified blood pressure machine (Microlife WatchBP Home A ) (n=2); single lead ECG (lead II during cardiac CT scan) (n=1) (Lowres et al, 2019). Nineteen of these twenty four studies agreed to collaborate and share the patient level data. From this collective data, it was noted that n=141,220 participants were screened across the studies, and AF was identified in n=1,539 cases.

### **Using handheld technology to assess heart rhythm**

Four studies were noted to use handheld technology which assessed heart rhythm to identify AF, specifically Zenicor Medical handheld products (Levin et al, 2014; Engdahl et al, 2013; Poulsen et al, 2017; Doliwa Sobocinski et al, 2012). All four of these studies used a combination of intermittent and continuous monitoring (using Holter monitors) for varying time periods (24 hours – 30 days). One of these studies also additionally used ECG technology to aid diagnosis of AF (Engdahl et al, 2013). Doliwa Sobocinski et al, 2012 and Levin et al, 2015 reported diagnosing AF in 17 individuals (out of 249) over a period of 30 days using an intermittent screening using a handheld device in addition to a Holter monitor. Levin et al,

2015 also provides a cost effectiveness analysis which reported the continuous monitor as being less cost effective than intermittent screening because it was more costly and had less sensitivity.

Poulsen et al, 2017 noted that 20 individuals had AF diagnosed but only ten individuals (37%) had AF recorded on both the Holter monitor and handheld ECG device. A Holter monitor can provide a continuous ECG reading, a handheld device can provide intermittent ECG readings. Engdahl et al (2013) reported that 40 (out of 848) individuals were diagnosed with AF, 10 of these diagnosed by an ECG and 30 of these by using the handheld device. Poulsen et al. 2017 reported that 22% of patients were excluded from their study due to physical or cognitive impairments which limited their ability to hold the device, and this is noted as an important consideration in individuals who have had a stroke. Poulsen et al (2017) report that when compared to the Holter monitor, the sensitivity of the thumb ECG was 59% and the specificity was 87%. Although limited information is provided about the quality of the reports, Poulsen et al (2017) noted that 13% of handheld ECGs were of poor quality and not useable, noting that this was due to the age of participants and ability to hold the device. Poulsen et al (2017) also noted that patients appeared more bothered wearing the Holter monitor compared to the intermittent screening handheld device. Engdahl et al (2013) reported that the ability to hold the device was assessed by the nurse in their study but the findings of this are not reported. As this was assessed, it could be argued that this further supports the importance of the potential limitations in individuals who have had a stroke and may have difficulty holding devices. In summary, none of the handheld devices from these studies were solely able to provide continuous monitoring, meaning that participants were required to wear more than one device. Furthermore, the suitability of handheld devices may be limited to individuals who have the cognitive and physical ability and strength to hold the device for the required length of time.

### **Single Lead Continuous Monitoring Devices**

Two studies reported the use of single lead monitoring devices (Lumikari et al. 2019; Akiyama et al, 2017). The first study, a clinical trial by Lumikari et al (2019) used a single lead device for up to four weeks and a 12 lead ECG, identifying AF in seven individuals (out of 75). Four of the seven cases identified were asymptomatic of AF. This clinical trial was the longest continuous screening period noted in this review. This study reported 18 patients had 80% of



ECG monitoring which was considered good quality. The next study considered (Akiyama et al, 2017) was a case study which used a single lead monitoring device to screen for AF for a period of 11 days. AF was noted on two separate occasions on day 5 and day 9 in this individual. The small size of the device, its application on the centre of the chest and being wireless were noted as factors which led to clearer ECG readings.

Researchers reported some poorer quality ECG. This may be due to the adhesive patch drying out as participants either did not change the patch regularly or when replacing the skin patch, the position was poor. Ability to continuously record heart rhythm, compact size and ease of the device for the patient were factors which influenced the choice of this device. However, skin irritation was reported in two individuals. Skin integrity and application of devices may therefore also be an important aspect of consideration especially in the population considered for this study. It is also important to note that two devices were reported as being damaged due to showering, so this may mean that activities of daily life may be impacted by current screening technologies.

### **Multi-Lead Monitoring Devices**

Yayehd et al, 2015 evaluated the use of a wearable three lead device, worn by patients for 21 days, identifying 2 individuals with AF out of 56. Researchers in this study note a potential limitation is the small sample size within this research study. A major benefit of this research study is the length of time the device was worn for an extended period of time (21 days).

Throughout this scoping review, a high prevalence of research studies (n=26) reported the use of multi lead devices referred to as Holter monitors. The majority of studies reported use of a Holter monitor in addition to other devices such as 12-lead ECG devices (n=8) (Arevalo-Manso et al, 2016; Thakkar and Bagarhatta, 2014; Suissa et al, 2014; Higgins et al, 2013; Yodogawa et al, 2013; Suissa et al, 2013; Lazzaro et al, 2012; Gumbinger et al, 2012) and 12-lead continuous beside monitor (n=2) (Lazzaro et al, 2012; Sposato et al, 2012). Variability of the types of Holter monitors was noted in a review completed by the Digital Health and Care Institute (2018) and this has been included with permission in Appendix 1 for reference.

In addition to a Holter monitor (six leads), one study used mobile data transmission (Policardiógrafo IP) (PoIP) software to transmit the recordings in real time to allow analysis (Sampaio et al, 2018). Researchers acknowledge the small sample size (n=52). Researchers also noted issues related to low signal strength related to 2G and 3G transmission issues

(6.8%), issues which can be expected to be reduced when using 4G technology. Patients in the control group were noted to have greater data loss, but researchers note this is due to the increased amount of freedom this group were given to move and poor reception may have impacted this.

Many of these studies did not appear to consider important factors such as patient comfort or acceptability, both of which are key components that could facilitate wider scale adoption of these technologies in larger scale screening programmes moving forward.

### **3.3 Discussion**

Paroxysmal AF can be harder to identify due to its intermittent occurrence. Hariri et al (2016) suggest that devices with continuous monitoring may increase the likelihood of capturing an episode of intermittent AF. Limitations relating to patient inconvenience and compliance are also reported with existing technology (Poulsen et al, 2017). However, a recent literature review and meta-analysis suggests newer portable devices may provide an alternative option for continuous screening for AF compared to the current use of Holter monitors (Ramkumar et al, 2018). The review by Ramkumar et al (2018) suggested that intermittent screening (of less than 20 minutes over a period of time) may provide a screening rate similar to the results of a continuous Holter monitor worn over 24 hours but highlight that due to differences in reporting between studies, the regularity at which intermittent screening occurred could not be distinguished. Furthermore, the authors acknowledged the use of such a device is best placed in those who have symptomatic AF and are compliant with using the device regularly (Ramkumar et al, 2018).

Although advancing technology provides great potential for the use of single time point devices for the general population, this may be limited in those who have reduced independence and reduced mobility or whose ability to wear or hold devices may be difficult. This difficulty does not reduce the importance of continuous monitoring in patients who have had a stroke and have a higher risk of further stroke. Therefore, identifying suitable devices which are easily applied, wearable, and have higher user acceptability may increase compliance of wearing the device and potentially the quality of the data received from the device. Most focus on suitability or usability has been placed on the quantitative assessment of the device, however a small number of studies have included the qualitative assessment

of the device. One pilot study conducted by Arevalo-Manso et al (2016) in Spain investigated the suitability of a wearable vest (textile wearable Holter) in individuals who have had a stroke (n=162). Although a small number of participants did not complete the monitoring period due to technical issues (n=8), non-compliance due to discomfort (n=8) the overall findings suggest that such a device is feasible in this population due to the user comfort (Pagola et., al 2018). Although a wide range of AF screening devices to allow longer monitoring periods are available (such as handheld devices, single lead monitors and adhesive devices), some may not be appropriate to use in some individuals. Loss of ability, loss of independence and the reliance on others for lifelong care caused by stroke may mean using some AF screening devices will be more difficult to use. For example, a hand-held device (requiring both hands to use) may not be the most suitable technology to screen for AF in a person with limb weakness as some devices require good skin contact.

Challenges associated with the use of new AF screening technology is documented throughout literature. Issues with poorly tested automatic algorithms may lead to over diagnosis and false positives, especially with other arrhythmias such as atrial tachycardia (AT) (Ramkumar et al, 2018). False positive rates may also be impacted by the large number of younger populations who are more likely to use technology devices independently and who are less likely to have AF when compared to an older generation (Singh et al, 2018; Ramkumar et al, 2018). Inconsistency between recommendations of the length of periods of AF which leads to a diagnosis may also lead to challenges for healthcare providers (Singh et al, 2018). Due to such challenges, some researchers are calling for further investigation for recommendations for the use of new AF screening technology within healthcare as available published recommendations are quickly becoming outdated as devices and monitoring advances (Singh et al, 2018; Milani and Franklin, 2017; Hivert et al., 2017).

One randomised control trial (Steinhubl et al., 2018) used a patch single lead monitor (iRhythm Zio<sup>XT</sup>) worn for up to four weeks to assess opportunistic screening implications on patient care. The findings of this RCT reported those who are at high risk of AF (such as those who have had a previous stroke/TIA) who had immediate and continuous monitoring had a higher diagnosis rate compared to those who had delayed monitoring which started four months after enrolment (Steinhubl et al., 2018). Another result of this RCT was the

increased utilisation of healthcare resources (Steinhubl et al., 2018). One potential limitation in this RCT was that it did not report the implications from the patient perspective such as technology acceptance, feasibility and device utility but rather it presented medically focused outcomes such as diagnosis rates (Steinhubl et al., 2018). Although this may not have been the main focus of this paper, other researchers have reported the Zio Patch validation or usability. For example, Rosenberg et al. (2013) reported no significant difference between the amount of AF measured when comparing the Zio patch and the 24 hour Holter monitor. They also noted that it was well tolerated by participants, this was indicated by the mean length of time worn ( $10.8 \pm 2.8$  days).

The identification of available single time point AF screening devices has been examined (Health Innovation Network South London. 2017). One report identified several single time point screening devices however, continuous monitoring was outside the scope of that review. This review identified two pilot studies completed in Australia, which evaluated used a single time point device in the general population (Lowres et al. 2014; Orchard et al, 2014). Eleven points have been identified for consideration when purchasing an AF single time point ECG screening device which can be applied to continuous monitoring devices.

1. Setting of the device use;
2. Staff involved;
3. Device health, environmental and safety requirements;
4. Device Accuracy;
5. Data security and transmission;
6. Device Memory;
7. Consumables;
8. Cost;
9. MHRA guidance;
10. ECG leads;
11. Hardware. (Health Innovation Network South London. 2017).

AF is more likely to be asymptomatic and paroxysmal in patients who have had a stroke (Sanna et al, 2014; Kirchhof et al, 2016), this highlights the importance of continuous and immediate or early screening following a stroke outlined by recent guidelines (Kirchhof et al, 2016). As already presented in Chapter 2, although AF screening in individuals who have had a stroke is reported as essential, due to limited funding and a reduction in devices (Tulloch, 2018) the application of devices is often delayed. This highlights the importance of capturing the current care pathway early within the NHS. This step is also highlighted as an initial way to implement sustainable innovation (NHS Innovation, 2018). Despite this very few studies have considered the impact of the implementation of new continuous monitoring technology within the clinical care pathway. No study to date has reviewed the full implementation process of new AF continuous screening monitoring in individuals who have had a stroke.

NHS Innovation (2018) has reported several case studies implementing technology within the current NHS care system. One case study reported the process of implementing the AliveCor Kardia device. The involvement of various healthcare professionals led to opportunistic screening in GP practices and in community pharmacies. Identified difficulties associated with using the device (such as poor readings in noisy environments) led to adapted training techniques. Furthermore, feedback from GP staff who identified additional and unnecessary workload occurred as a result led to a new care pathway for the patient being formed, reducing the time to access treatment from 12 weeks to 2 weeks. However, this study did not include patient experiences.

Technology advances in this area are also likely to continue. For example, one recent study has highlighted the potential of and recent development of a phone application (Cardio Rhythm) which has been shown to be 95% effective in identifying an irregular rhythm by measuring variations in the colour of the persons face. This removed the need of application to the skin, removing infection control concerns which may occur when using a multi-use device. The use of such a device, has the potential of allowing the identification of AF in a large group of people at one time (Freedman, 2016). Singh et al., (2018) suggest that software adaptations may allow three-dimensional ECGs allowing more sensitive screening for other cardiac problems such as ST elevation (this is where the ST segment of an ECG is abnormally high) which indicates cardiac death (ischaemia) or QT changes. Issues relating to the

compatibility of new AF screening devices to current healthcare ICT systems may require adaption. For example, some AF screening devices produce a report in PDF format which may not be able to be added to patient clinical notes or require manual review or entry to ensure adequate documentation.

### **3.4 Conclusions**

Further work is necessary to improve regulations and the quality of available devices suitable for screening in this population, improving the sensitivity, increasing patient comfort, reducing device size, improving user acceptability, whilst making costs acceptable (Murray and Krishnan, 2018).

This scoping review focused on identifying suitable continuous AF screening device(s) (>72 hours) for individuals who have had a stroke. The review highlights the need for the following:

- The use of devices which have patient involvement in development, to ensure its suitability for use in the population (e.g. the hand-held device was not suitable for all participants who had a previous stroke, due to limited physical strength or ability).
- The development of devices which have high sensitivity (to ensure accurate diagnosis).
- The need for a study which describes the implementation process of short term continuous cardiac monitoring.

## 4 Process Evaluation: Methods

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This evaluation was led by University of Strathclyde and collaboratively developed by the University of Strathclyde (UoS), NHS Lanarkshire, Edinburgh Napier University (Prof Lis Neubeck), and the DHI design team (Angela Bruce).

### 4.1 Purpose and Aim

The aims of this evaluation were to:

1. **Map and understand both the current and future AF screening care pathways in NHS Lanarkshire Scotland** (See Chapters 5 and 6)
2. **Capture Acceptance and User Experiences (UX)** from (see Chapter 7)
  - (A) citizens/patients
  - (B) healthcare professionals and
  - (C) other people involved in implementation and adoption such as friends/family/carers, technology providers, commissioners
3. **Identify Barriers and Facilitators for wider implementation and adoption** (see Chapter 8)

*Note: While the criteria of the device(s) selected was considered throughout the process of the project (outlined in Table 6.1), the purpose of this project was not to evaluate the device itself or its ability to monitor intermittent AF and diagnose it, but rather the process of implementation of innovative AF technology enabled services within NHS Lanarkshire and beyond.*

## 4.2 Data Collection

The evaluation used qualitative methods (interviews) with patients, clinicians, and other key implementers across the lifetime of the project to explore each of the stages of implementation (see Figure 4.1). Patient Interviews were conducted by telephone and all other interviews were completed either face to face or by telephone. Some of the health care professional (HCP) and implementer sessions were done as round table discussions but were also semi-structured in nature and transcribed and analysed in the same way as the interviews. The semi structured interview schedules were developed by researchers at UoS and drew upon key components of the NASSS framework (see Appendix 10).

All interviews were digitally audio-recorded. The audio recordings were transcribed by a third party (a data processing agreement was put in place for this process). The use of the professional transcriber improved the reliability of the data transcribed. Upon completion of the transcriptions, the identifiable audio files were deleted from the recording device. All focus group/interview transcripts were anonymised using un-identifiable pseudonyms. The audio-files stored on the researchers' password protected computers on secure network drives ('Strathcloud') at the UoS were deleted at the end of the research project and once all reporting to funders was concluded in 2020.

Although not the main focus, this project also captured some quantitative data for descriptive purposes (e.g. number of AF cases, devices returned, cost of reports, time to generate reports). Clinicians and or clinical researchers were asked to complete a CNR (case notes record) extraction data form developed for this project to collate the quantitative data for each individual patient. This task involved reviewing medical notes and reviewing the device report following analysis.



### 4.3 Participants

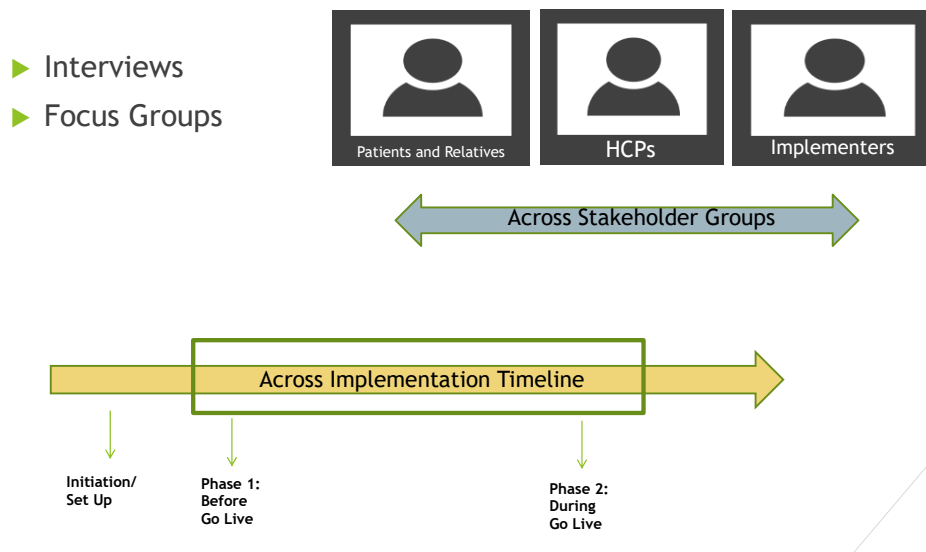
NHS Lanarkshire recruited a total of 64 patients to experience the new service for AF screening from 1<sup>st</sup> July 2019-1<sup>st</sup> October 2019. Clinical leads and AF experts (key contributors) considered that a sample size of 60 participants was appropriate and achievable within this time frame and to capture a wide range of patient experiences.

Given the findings from the scoping review presented in Chapter 3, the experience of patients was placed at high value, however, the view of health care professionals and other stakeholders involved in the pathways were of equal importance in order to better understand the perceived costs and benefits to patients, clinicians, service delivery and implementation and to identify the barriers and facilitators of new technology enabled AF services more widely. These were identified as gaps in the existing literature as outlined in Chapter 3. Table 4.1 provides an overview of the number of interview participants.

<b>Group</b>	<b>Target</b>	<b>Actual Number</b>
<b>Patients &amp; Relatives</b>	Traditional Pathway: 10  New Pathway: 10	NA (zero due to delayed start)  N=8+1
<b>HCPs</b>	N= 10-20 over duration of project	N= 12
<b>Other</b>	N= 8-10 over duration of project	N=6

**Table 4.1 Overview of numbers of Interviews**

## Methods: Data Collection



**Figure 4.1. Overview of methods across stakeholders and across timeline of implementation**

**Patient Inclusion Criteria:**

- Adults aged 18 and over;
- Able to provide informed consent;
- Receiving/received services (including anticoagulant medication) by NHS Lanarkshire;
- Are sufficiently proficient in English to be able to participate in data collection activities;
- Are able to participate in sustained conversation with research team and/or are not considered cognitively impaired;
- Have experienced Atrial Fibrillation screening services in NHS Lanarkshire i.e. they have had investigations to screen for cardiac arrhythmias such as Atrial Fibrillation (which may include wearing a portable ECG monitor).

Patients did not require a diagnosis of AF to have had experience of these services.

**Health Care Professional Inclusion Criteria:**

Given the multidisciplinary nature of stroke care, it was important to engage with a range of HCPs from NHS Lanarkshire throughout this evaluation. The following inclusion and exclusion criteria were used to screen the suitability of health care professionals for their suitability.

- Members of the stroke care team in secondary care involved in the screening of AF following a stroke and/or have experience working with those who have been diagnosed with AF following a stroke.
- Able to provide informed consent.
- Able to communicate sufficiently well in English.
- Knows of, or has experience of, the AF services whether that be a technological, personal, family, stakeholder or procurement experience of the services.

**Other**

- Knows of, or has experience of, the implementation process of the AF services whether that be a technological, stakeholder or funder experience of the implementation process.

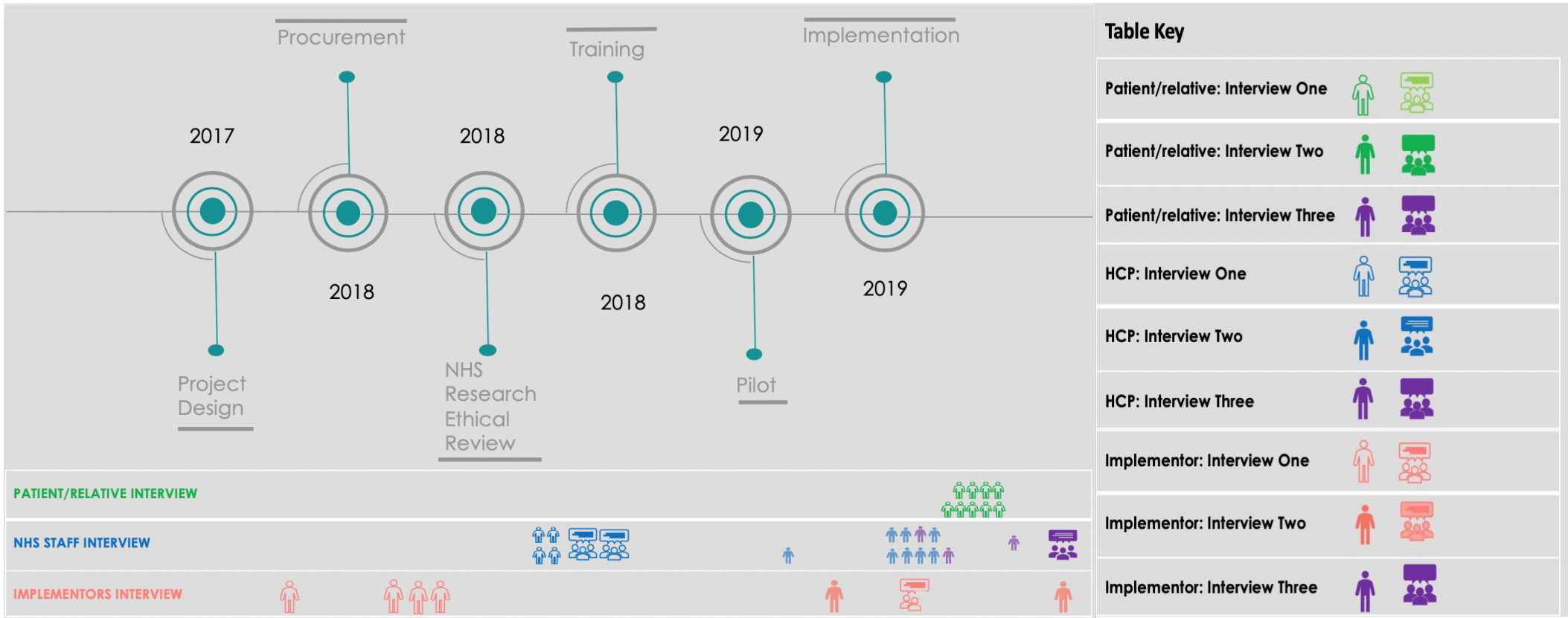
#### **4.4 Recruitment**

Convenience methods were used to recruit patients. HCPs acted as gatekeepers for all patient participants. The clinical team covers three hospital sites: University Hospital Hairmyres, University Hospital Monklands, and University Hospital Wishaw. HCPs received participant information leaflets from UoS either via post via clinical services and/or in person. Clinicians initially screened the patients' suitability for this project in accordance to the criteria outlined above. Clinicians approached the patients and provided them with the participant information leaflet. It was made clear that not participating would not affect their standard of care. Patients still received the device (as part of their routine care) even if they chose to not take part in this evaluation.

The Stroke Managed Clinical Network (MCN) team (which includes stroke specialist nurses) identified recent patients who met the inclusion criteria (n=67). For the new pathway evaluation, the Stroke MCN team identified and approached patients within the three stroke units involved. HCPs provided an overview of the project and an information leaflet. Sixty-four individuals consented to wearing the device. Two individuals refused to participate, and clinicians felt that participation would not be appropriate for one patient. The information leaflet given included UoS research teams contact details. All patients were able to contact the UoS team directly for further details of the project. If the patient preferred to be contacted by the UoS team, clinicians were required to take preliminary consent to allow initial contact from the evaluation team at UoS. This preliminary consent was to allow the patients contact details to be sent to the UoS and was not considered as participation in the first instance. Contact details were sent from the clinician to UoS research staff from an nhs.net email address to an nhs.net email address in keeping with information governance guidelines. Informed consent was obtained at the beginning of evaluation sessions by the research team (UoS/GSA) before any evaluation activities or data collection in accordance with GCP guidelines. The UoS team either discussed the project in further detail to the potential participant over the phone or in person on the hospital site. Consent to participate was either taken over the phone or in person, however consent was always obtained by the UoS team prior to participation in the evaluation interviews. Consent for telephone interviews was also taken over the phone prior to the interview, this conversation was audio recorded

and transcribed by researchers at UoS. Of those who contacted UoS, only two patients refused to participate, a total of eight patients and one relative participated in the interviews (see Appendix 6).

HCPs and other key stakeholders that were not patients were identified and approached through stakeholders and the Stroke MCN team for input throughout the evaluation. This also involved Strathclyde approaching external groups such as procurement teams, the device manufacturers, the service providers, and those involved nationally in decision making around AF services more widely.



**Figure 4.2 Overview of Interviews.** Note: Individual figures indicate the number of participants in each interview or group interview.

#### **4.5 Analysis and underlying theoretical frameworks**

Thematic analysis methods were used to analyse all of the data collected. This involves reading and becoming familiar with the data; creating a coding framework (set of codes) that describe the data (tagging quotes with these themes) and mapping and organising these into themes which are higher level labels to explain the concepts described by the coded data.

This initial process was completed by one researcher who reviewed the qualitative data and noted main themes. Several transcripts were also coded by a second researcher, following this, initial main themes identified by the two researchers were then compared. In addition to traditional and well established physical post-it-note mapping and charting methods we also used NVivo version 12 to organise and manage our transcripts and conduct the coding. This software allowed the main themes to be supported with direct written quotations from the original data, ensuring clarity throughout the analysis process with the added benefit of allowing the participants words to be presented in the final report. The evaluation drew primarily upon the Non-adoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) framework (used in Greenhalgh et al, 2017) which looks more widely at complexity and context (see Figure 4.2). This considers:

- the nature and factors of the condition
- the technology (in this project the device)
- the perceived value of the device for both the user and supplier
- those involved in adopting and using the device
- the capacity of the organisation for change and changes needed to make the intervention work
- the wider system factors such as regulations
- adaptation over time – more specifically what scope there is for future use.

(Greenhalgh et al, 2017)

The use of this framework allowed us to take a systematic approach to developing interview schedules and allowed our findings to be mapped onto key concepts which are highlighted in existing literature.

It is important to note however that we used a general thematic analysis approach where we coded the datasets and generated themes and then examined if and how they fitted (or not) to the NASSS framework. This allowed additional themes to emerge that might not fit neatly into the existing NASSS framework.

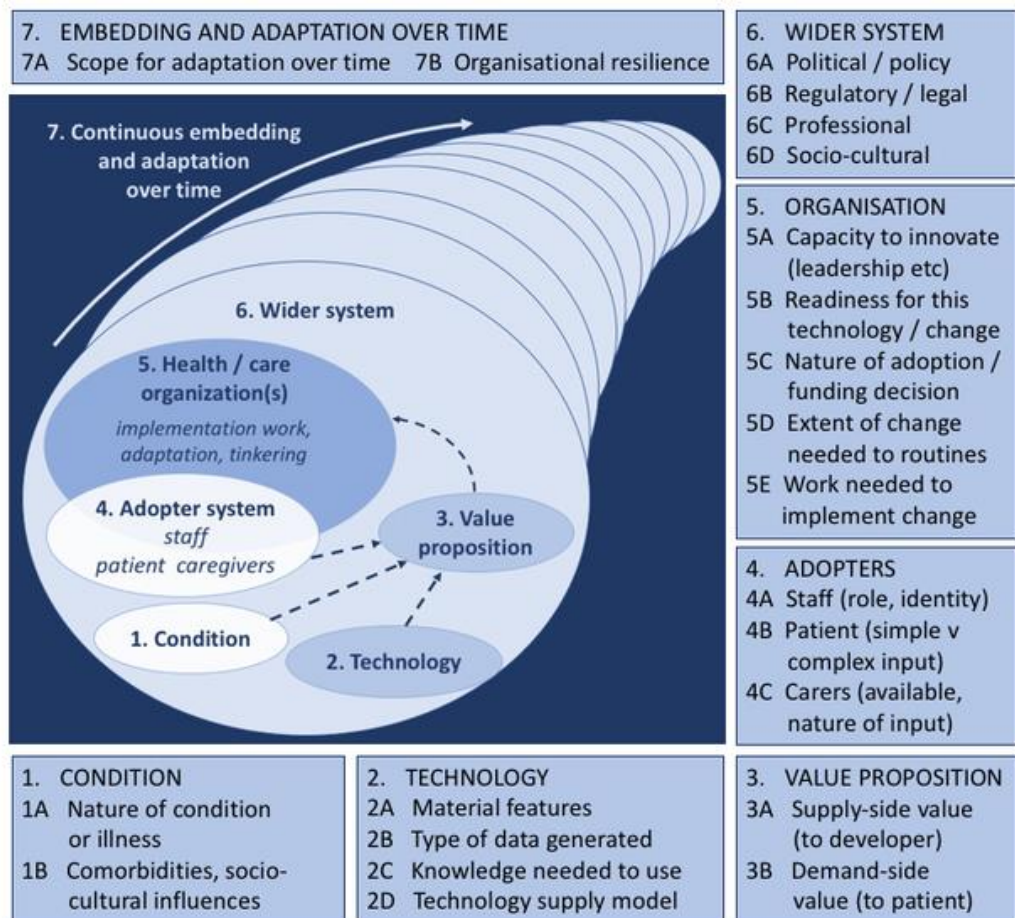


Figure 4.2: NASSS Framework (Greenhalgh et al, 2017)



#### **4.5 Ethical and Regulatory Considerations**

All personal data was treated as confidential. When participants were recruited to the study, they were allocated a unique study number by the research team for reporting purposes. During the analysis process, participants were assigned a pseudonym to further ensure they were not identifiable. Prior to the commencement of the evaluation, approval was gained from necessary regulatory bodies (NHS REC, R&D approval). In accordance of GCP guidelines, members of the UoS and GSA research team had received GCP training, research passports and disclosure Scotland clearances in place prior to any data collection activities commenced.

Stroke can affect cognitive ability in some cases and certain participants, dependent on age range and capabilities, may have found the length of time needed within some of the activities tiring or difficult. For this reason, the research team accommodated these participants by providing adequate breaks within sessions. The participants were informed that they were welcome to invite a carer or family member along to the activities if they wished for support and to facilitate their participation. The research team ensured as much as possible data collection activities were arranged at a time and place that is most convenient for the individuals involved. Additionally, participants were informed that they could leave the session or end the interview at any time and could choose to not contribute to any activities if they felt unable or uncomfortable doing so.

Participant Information Sheets (PIS) and consent forms clearly outlined how data relating to this project was collected, stored and published in accordance to General Data Protection Regulations (GDPR, 2018). The consent forms and participant information sheets contained a privacy notice to adhere to the new General Data Protection Regulation (GDPR) guidelines. To ensure the UoS research team was safeguarding personal data and appropriate safeguarding measures being adhered to. It was emphasised throughout the consent process that participation is voluntary and withdrawal from the study was permitted at any time without reason in accordance to GCP guidelines.

## 5 Mapping the Current AF screening Pathway in NHS Lanarkshire

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This section of the report describes and illustrates the existing traditional care pathway and patient journey for AF using continuous cardiac monitoring devices such as the Holter monitor in three NHS hospital sites in NHS Lanarkshire, Scotland. The resulting mapping can be seen in Figure 5.1 but please also refer to the full interactive process mapping document created by The Digital Health and Care Institute Design Team (from Glasgow School of Art (GSA)). The interactive map which captures service insights, opportunities and challenges is available at:

<https://futurehealthandwellbeing.org/atrial-fibrillation> (Bruce, 2019)

### 5.1 Methods

Qualitative methods were used to capture and understand the current AF screening pathway and to identify areas that might present challenges and opportunities for improvement.

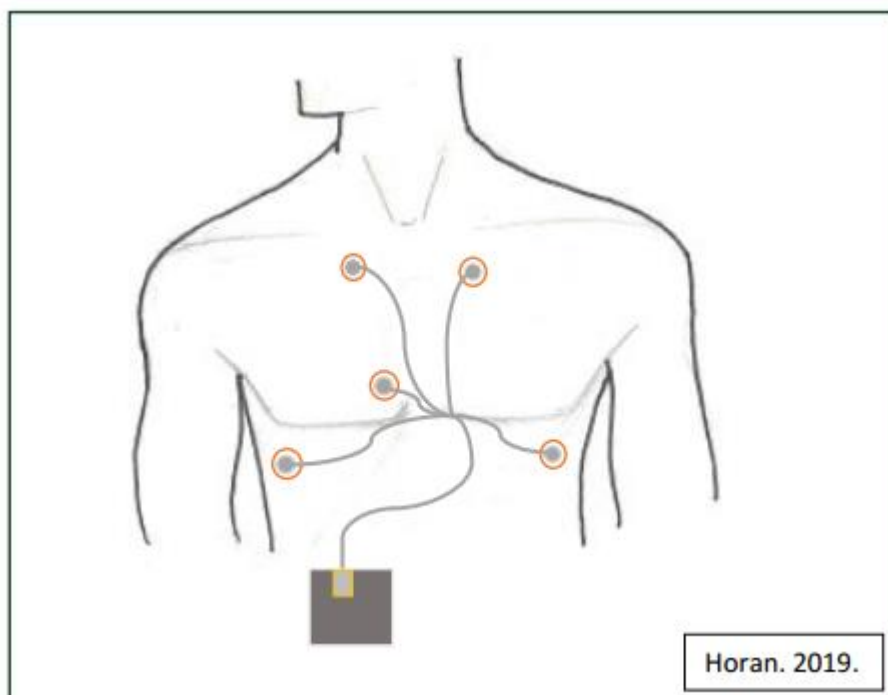
A focus group with stroke liaison nurses (n=6) and four semi-structured interviews stroke consultant (n=1), cardiologists (n=2) and cardiac physiologists (n=2) were conducted during the initiation stages of the project to understand the existing workflow and pathway. Visual mapping tools were also used by the DHI design team to guide the discussions (see Figure 5.1). These were conducted between May 2018 and July 2019 before the new device and service were adopted for this Test of Change in NHS Lanarkshire.

This data collection activity was audio recorded and transcribed by a professional transcriber for analysis and validation. Transcripts from the interviews were initially thematically analysed by GSA and UoS. Transcripts and visual outputs from the interviews and focus group were analysed using 'analysis on the wall' (Sanders and Stappers, 2012) methods in order to quickly synthesise the key insights and cluster emerging themes thematically. The findings were presented visually to show the insights, service opportunities and challenges along the patient pathway.

## 5.2 Findings

In NHS Lanarkshire, patients are required to wear a Holter monitor (see figure 5.1) for 24, 48 or 72 hours. The variation is due to inequity of access to prolonged cardiac monitoring for stroke patients across the three cardiac physiology departments. After having a stroke, a patient may attend the stroke unit via emergency services and may have their initial consultation and assessment on a ward setting. They may need to spend a period of time in a stroke unit setting for investigation +/- rehabilitation in which case a Holter device would be applied and removed in the hospital setting by the cardiac physiologist (inpatient).

It was reported during our process mapping that on some occasions, due to limited numbers of devices available, the discharge of some patients may be delayed to ensure the patient has the device fitted before they leave. Health Care Professionals (HCPs) expressed a view that patients who received a Holter monitor as an inpatient do, however, often receive their Holter monitor faster (depending on availability of devices) than those who were outpatients.



**Figure 5.1 Holter monitor (cardiac monitoring device) schematic. Used with permission, Horan 2019.**

The Holter monitoring device can also be applied on an outpatient basis (patient is sent home with device fitted). For some patients, for whom there is a high suspicion of stroke or TIA, but no severe symptoms warranting hospitalisation, they may be referred by their GP to a TIA or minor stroke clinic. This first visit will confirm the diagnosis of a stroke and will attempt to identify the underlying cause of the stroke. This referral process takes approximately three days before a patient consultation within a hospital outpatient setting. At this first visit, if no cause is identified or if AF is suspected, patients will be referred to a cardiac outpatient department for cardiac monitoring. An appointment will be arranged for the patient within 3-4 weeks. Patients are required to attend an in-person outpatient cardiac appointment, which lasts 10-15 minutes. This appointment will be with a cardiac physiologist who will prepare the patients skin (which may involve cleansing the skin and or shaving the skin), fit the 3 lead Holter monitor (which involves placing adhesive leads onto the skin and connecting the cardiac Holter monitor) and show the patients and or carer how to reapply the adhesive leads. Patients will be provided with a contact number (if there are any problems with the device) and a patient diary which allows opportunity to keep notes of cardiac symptoms. According to interviewees, this can be a very challenging appointment as often patients are unsure of the purpose of their appointment resulting in the cardiac physiologist spending extra time explaining why they have been referred for cardiac monitoring.

Although regulatory guidelines highlight the length of time of screening should be a minimum of 72 hours, the length of screening often fails to achieve this due to lack of devices and poor battery life of current devices. One clinician highlighted how outpatients may have to attend hospital once every 24 hours to have the battery changed. This inconvenience was voiced as leading both the clinician and patient to request screening for less time despite national guidelines for 72 hours of monitoring.

One main benefit of receiving a Holter monitor via the outpatient approach is the ability for patients to live their life within their normal setting (i.e. at home or other setting). Outpatients may however be required to attend a midweek hospital appointment for a minimum of three visits (one for the application, one for returning the Holter and the final for an explanation of the results). Due to the battery life of available devices patients at some sites may be required to attend the outpatient department every 24 hours to swap devices. The attendance of these appointments was reported as an inconvenience for the patient, with some patients having

to request time off work. The patient is then required to arrange the return of the device, either themselves or by a carer or relative. As devices are in short supply, if the device is not returned, the Cardiac physiologist will spend time chasing the return of the device. Delay in the patient returning the Holter monitor back to hospital or loss of device in hospital due to inappropriate return such as out of hours, resulted in additional time being wasted in chasing from hospital staff (such as the stroke liaison nurse or cardiac physiologist). Due to a reduced number of Holter monitors, this often results in other patients experiencing delays to their Holter monitor applications and therefore diagnosis.

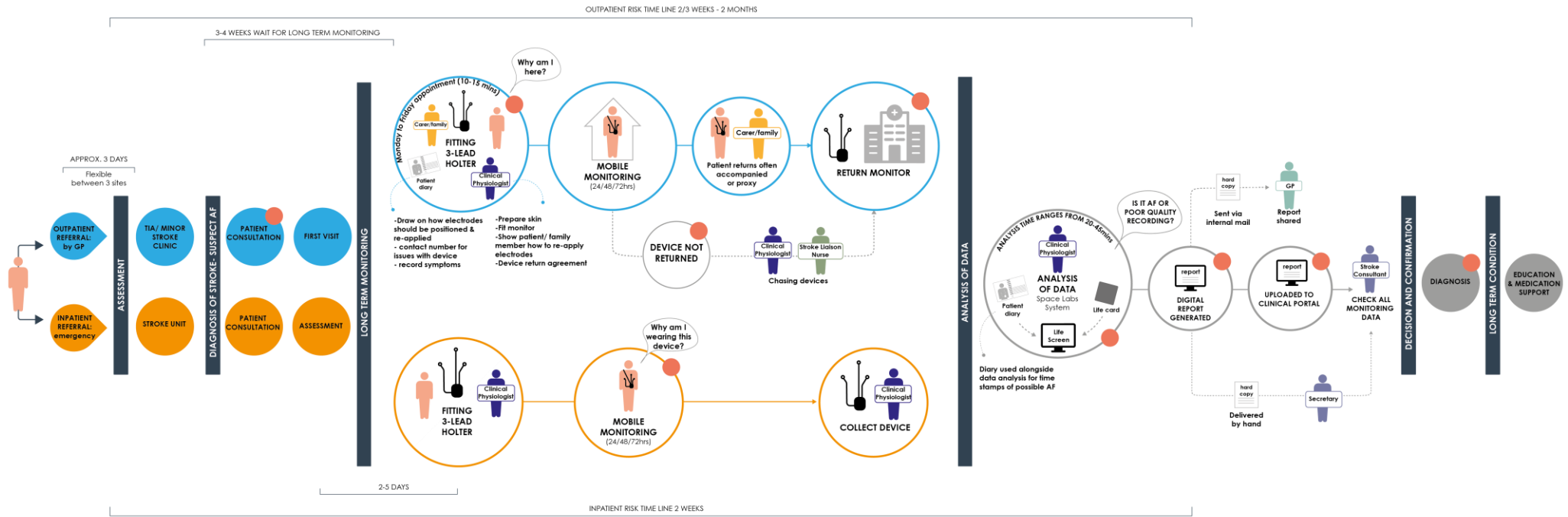
Following the return of the Holter monitor the device is docked, data uploaded, and digital report is generated and uploaded to the online system called a Clinical Portal. Senior (Band 6 and Band 7) Cardiac physiologists analyse the Holter monitor recording using a Space Labs analysis programme called Life screen. A patient diary along with a time stamped report of the output from the device is reviewed. This review process takes around 20-45 mins depending on the length of the screening time. The results of the Holter monitor are summarised into a written report. This report may be uploaded to a clinical portal or a hard copy is forwarded to relevant recipients such as the stroke clinician or GP. Either of these health professionals will then liaise with the patient to decide on the treatment pathway. In addition to this process, a hard copy of the report may be sent via internal mail to the patients General Practitioner (GP). Depending on accessibility, the digital report may also be delivered by hand to the stroke consultant by the stroke consultants secretary. Upon review of the report, a diagnosis of AF may be confirmed, and long-term management of the condition can be commenced including education, medication and support.

Some healthcare professionals highlighted that lack of staff can lead to delays in this analysis process. They also highlighted that the lack of staff and resulting high workload within this speciality has resulted in the delay of results for patients. Lack of cardiac physiologists is highlighted in recent literature (BHF, 2018) which recommends that additional funding is provided to increase HCPs in this area (Scottish Government, 2019). Problems associated with inaccessibility or lack of awareness of the computer programme to access of the report and loss of paper copies sometimes required secretaries to manually check the status of the analysis process to ensure the quality care for the patient.

It was reported that the current Holter monitor used in the screening of AF is associated with some inconvenience or discomfort for patients. For example, the bulkiness of the Holter monitor was reported as hard to disguise under normal clothing especially in clothes worn in warmer weather. This can cause some patients to feel distress and has resulted in patients having to disclose personal information relating to their screening due to relatives or friends questioning the reason for wearing such a device. It was also reported that some patients have expressed sensitivity to the patches and feeling uncomfortable as a result of wearing the device in warmer weather. The Holter Monitor should be removed when showering or bathing and reapplied when this activity of daily life was finished. This routine daily task can result in short periods of time when the continuous recording is interrupted and poor-quality recording is often experienced after reapplication.

In summary a number of challenges exist when using existing Holter monitoring. AF can sometimes have no symptoms (asymptomatic), which can mean the person is not aware of having AF. Identifying AF can therefore be difficult as AF does not always present with symptoms and episodes of AF can be intermittent. Therefore, longer screening periods may be needed to detect AF in some individuals than is currently available via the Holter monitors. The current Holter monitors require the patient to attend a hospital or clinic in person on at least two occasions to have the device fitted and removed. This can be resource intensive for the hospital staff but also inconvenient to the patient. An additional burden is that the patient cannot shower with the current Holter device on which can have a significant impact on patient experience. Finally, it was recognised that there is currently a national shortage of cardiac physiologists who undertake the device fitting and interpretation of the device data (BHF, 2018). The current mapping stage suggests that the use of alternative technology could improve the timeliness of screening and quality of screening for AF in this population.

Figure 5.1 Existing Service Model and Pathway (Bruce et al, 2019)



 SERVICE CHALLENGE

## 6 A New Technology Enabled Care Pathway for AF screening in NHS Lanarkshire

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This chapter of the report presents the new AF pathway (innovative technology enabled service) that was deployed in NHS Lanarkshire as a Test of Change during 2019. UoS along with the DHI design team (GSA) mapped the new pathway using interview data in order to highlight areas along the pathway that might introduce time or cost savings (compared to existing pathway presented in Chapter 5) if the new service was introduced, or other perceived benefits to either the clinician or the patients.

### 6.1 Procurement of new AF screening Technology in NHS Lanarkshire

Together with NHS Lanarkshire we undertook a national procurement exercise looking for commercially available products. This was done through the national procurement system with NSS (National Services Scotland) procurement for NHS Scotland to ensure that any devices (and associated services) selected would be readily available for scaling. The UoS and Napier research team, along with NHS Lanarkshire agreed a set of criteria that the device must conform to in order to be issued a Prior Identification Notice (PIN) notice for calls for bids through national procurement services to be the test of change service provider for the new AF screening technology (see Table 6.1).

Seven companies submitted bids for this project, however, only two companies met the procurement criteria and both were selected for a pilot with n=10 patients. This was decided so that different form factors and devices could be compared for acceptability and usability within the clinical context prior to full implementation and final evaluation. One of the devices selected was reported to cause serious or significant skin irritation in four out of the ten patients that the device was applied to and therefore it was decided quickly not to progress with the full evaluation of this device.

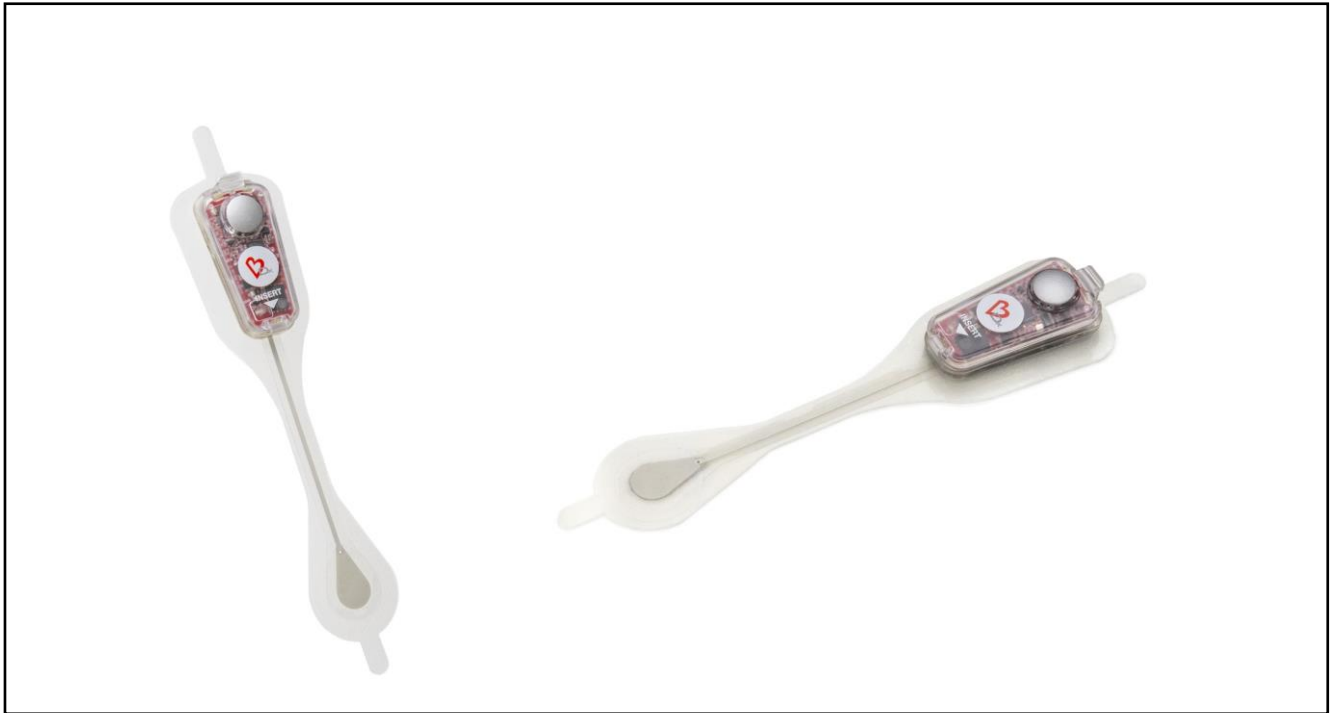
The device that was selected for the full roll out in NHS Lanarkshire was the BARDY CAM™™ by Bardy Diagnostics (<https://www.bardydx.com/>) (see Figure 6.1). The CAM is designed to be placed along the sternum—over the heart—to optimize P-wave signal capture. The idea is that the result should be improved ECG resolution, providing more information about the heart rhythm which may lead to more clinically actionable diagnoses. The distributor for this device during the GoLive for this implementation was a company called Dot Medical (<http://www.dot-medical.com/>).



The BARDY CAM™ (at the time of testing) allowed 7 days of continuous monitoring and therefore 2 devices per patient were purchased to allow for 14 days of continuous monitoring. The company also provide a managed service around this device which included (i) initial training of staff, (ii) software for uploading the data from the device, and (iii) a reporting service conducted by the company rather than the NHS. The data from the devices is used to generate event-tagged reports. These reports can be generated within the NHS context by trained staff but the company also provide a service where they have technicians and a system for generating the reports and providing these to the HCPs at an additional cost. This device was selected as a demonstrator to test how this and similar new wearable and commercially available AF monitoring devices might be adopted. This also allowed them to test how the service could benefit from moving some of the reporting to outside of the NHS.

<b>Criteria category</b>	<b>Definition/ criteria of Assessment</b>
<b>CE marking?</b>	If a device is marked with the initials CE (Conformité Européene), this ensures the device confirms to European standards of safety. Such a requirement is essential for use within the NHS and for use within the public population (GOV, 2018).
<b>Recording time.</b>	Recording time should be documented. For purposes of this study 72 hours of continuous recording time is required.
<b>Available for home use?</b>	Available to be purchased and used within the home environment. Not requiring in hospital stay.
<b>Evidence of ease of use?</b>	Evidence of feedback regarding the ease of using the device (application, charging, reapplying etc).
<b>Evidence of patient comfort?</b>	Evidence of feedback regarding the comfort of the device (specifically no evidence of skin irritation when wearing the device). Evidence of being user friendly.
<b>Specificity/ sensitivity</b>	Evidence of the ability of the device to identify AF.
<b>Single/multi-use?</b>	Evidence on whether the device is single or multipurpose use.  Both have advantages:  Single use: infection control implications reduced.  Multi use: reusable devices can be used on more than one patient  Easy to clean?
<b>Cost?</b>	Price is documented.
<b>Control of data?</b>	Documented evidence of:  Who owns the data?  What data is collected?  Where is the data sent and stored?  When is the data deleted?  How is the data transferred and reported?
<b>Battery</b>	Chargeable? Battery length?

**Table 6.1 Selection Criteria for Procurement of AF device for Test of Change in NHS Lanarkshire**



**Fig 6.1: Used with permission. BARDY CAM™ device**

## **6.2 The new AF service pathway**

In order to understand the new AF pathway incorporating the new device and 14-day outpatient monitoring being tested in NHS Lanarkshire, the new pathway was mapped with the health professionals involved in this pathway. Two seven-day BARDY CAM™ devices were provided to N=64 patients in NHS Lanarkshire to allow up to 14 days of continuous monitoring data (swapped on day 8). The first device was issued and applied to the patients during a clinical visit by the stroke nurse. The second device was applied during a second visit on day 8 (where the first device was then docked to allow uploading of the seven days of data). The data was uploaded for the second device (second seven days of monitoring) when the device was posted back by the patient to the hospital site. The BARDY CAM™ software provided a report which the lead clinician could review for diagnosis producing a total of 128 reports (64 patients with two set of seven days of data on each device). An example report produced by the company can be found in Figure 6.2.

For this roll out, a subset of the reports (28 reports) were also analysed by a subcontracted NHS cardiac physiologist. This would allow us to compare a potentially more cost-effective off-site analysis of the reports by the company and compare the analysis done (cases found and time taken) by both the

commercially available system and the off-site but NHS based cardiac physiologist. The results from this comparison are presented in Chapters 7 and 8.

Figure 6.3 shows the visual mapping for the new pathway once this device and reporting system (the service) was introduced. We focused on three main themes or strands for this analysis – Patient experience, Clinical experience, and Implementation of the new service in the NHS setting. This can be compared to Figure 3.1 to identify potential points in the pathway that have been affected by the introduction of the new service (reduced or additional time or costs for example). Please refer to Chapter 7 for the origin of these experience and implementer quotes.

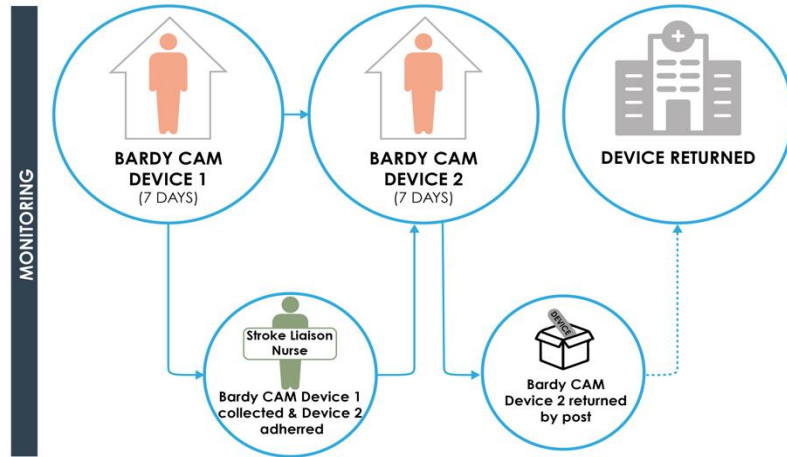
Figure 6.3 the visual mapping for the new pathway



### FUTURESTATE MAP: PATIENT EXPERIENCE

“To be honest, once the nurse came to the house and put it [on]... we had to shave a little bit of hair beside my breastbone, once it was on, I could shower no problem, it didn't interfere with my clothing... it was actually ok, no problems at all with it.” (Pt003)

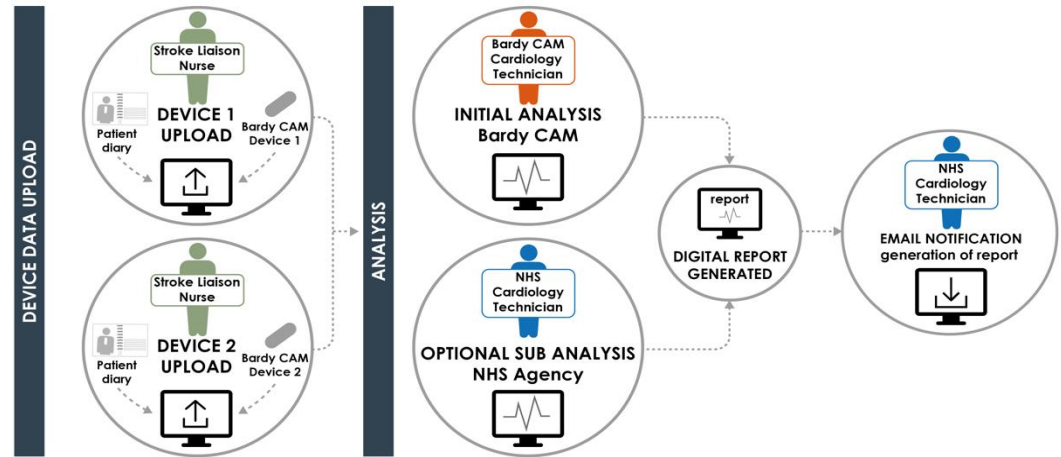
“No, no I'm just quite happy that I got the chance to use the device and it helped with my diagnosis that gave me some reassurance that I was on the mend. No overall I was 100% happy with it.” (Pt003)



“The only thing that they did say to me was, I wear underwire bras, so they had told me don't wear underwire bras with it because the wire could affect the monitor. But that was the only issue and that wasn't a problem, I just got out and got other ones.” (Pt002)

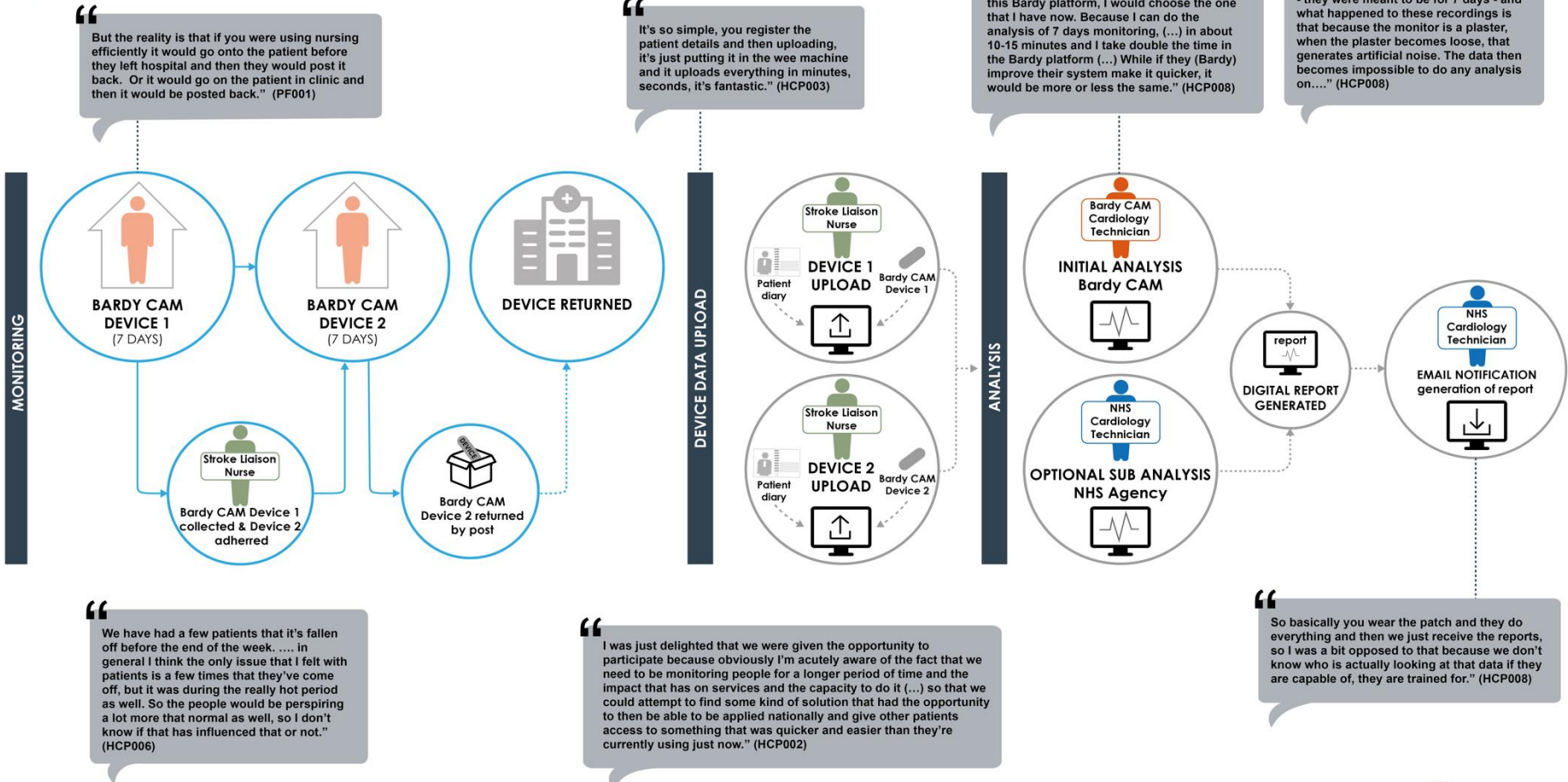
“Yeah you actually forgot you had it on, because where it was sitting it was really very comfortable, you didn't have any problems with it at all. The only thing when I was showering, I covered it in Clingfilm just so it wouldn't get wet.” (Pt002)

“It was quite comfortable. You didn't know you had it on.” (Pt007)





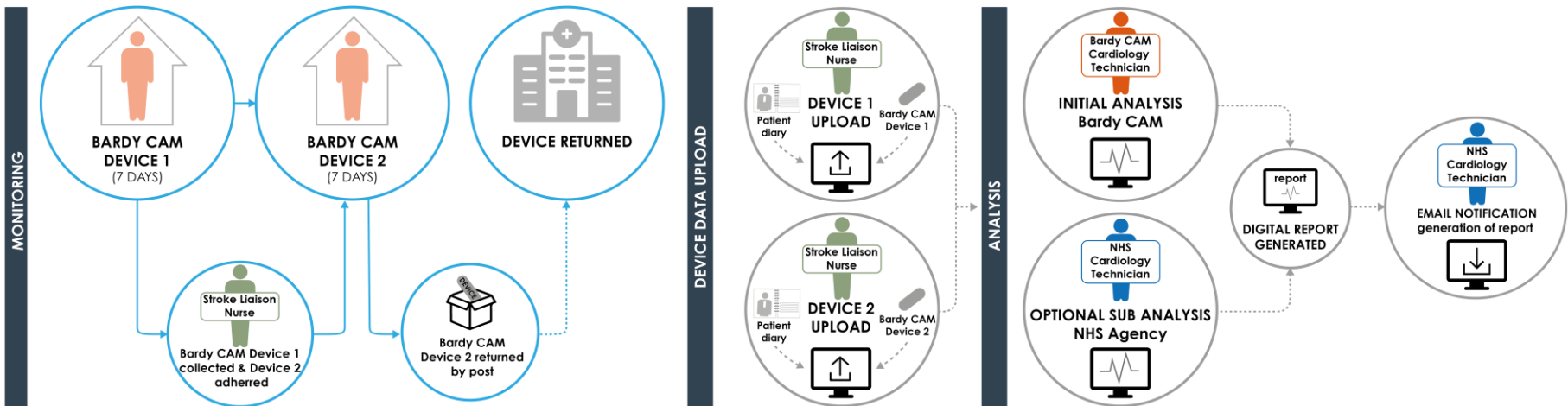
## FUTURESTATE MAP: CLINICAL PATHWAY





# FUTURESTATE MAP: IMPLEMENTATION

“ I think the big savings in the pathway are to the whole system, to the hospital system rather than to our part of the pathway. So the savings are around patient transport to attend cardiology. The cardiology department, time, the use of the Holter. The Holter from the hospital side, so it's all cardiology time savings, ambulance time, the patient's time and convenience to family members.” (PF001)



“ More recently we had a whole batch to do, so that was quite, it was full on really trying to get them all done and then getting back a week later along with putting new ones on. So that was taking an awful lot of our time because obviously our role goes on everyday as normal...” (HCP006)

“ There was quite a lot of time spent as well around IT issues and how those [health care professionals] that were training were going to upload and then interpret the data...” (FG001)

“ We couldn't put our software- we can't our hardware onto our network that hasn't been purchased by the NHS.” (PF001)



## 7 FINDINGS

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### 7.1 Summary of Quantitative Results

Sixty-four (64) participants (patients) wore the BARDY CAM™ device from July-October 2019 meaning that during this test of change NHS Lanarkshire increased the length of time of continuous AF monitoring (5-14 days [average 12.09 days]) for 64 patients. Four individuals (out of 64) had AF diagnosed (6.25%) during this time. All these individuals were commenced on a blood thinning drug as they were considered to be at a high risk of having a further stroke. Two individuals had another unknown and clinically significant heart arrhythmia diagnosed whilst wearing the BARDY CAM™ device and their treatment and care pathway changed due to this finding.

Some participants noted skin tolerance issues (n=9) which included the device falling off (n=2), one person reapplied with skin tape; skin redness (n=4) and itch (n=1) delicate skin (n=1); broken skin (n=1). The one individual who was noted to have broken skin was also noted to have an allergy to nickel, the device does not include nickel, however the skin preparation was noted to include nickel, but this was not noted until further investigation by stroke liaison nurses.

#### 7.1.1 Costs (£)




The initial outlay costs for the test of change which included the device and the service around it (the reporting done by the company) are reported here for descriptive purposes only. A full cost-benefit analysis will not be conducted here but is likely to be something that some people would look for longer term. However, throughout this chapter we have sought to capture some of the additional perceived costs and benefits to both the clinician's and patients which could potentially be used for a fuller cost benefit analysis in future work. As a cost analysis was not the purpose of this chapter, please note, additional costs related to HCP involvement (such as specialist nurse over time, additional visits, travel costs) were not recorded. See figure 7.1.

BARDY CAM™ (per device) = £117.  
 120 devices were purchased (2 devices per patient for 8 days plus 7 days) = 60 patients.  
 Devices Total Cost = £14,040.  
 Docking station: £300 (per station) (n=1).  
 Report generated by the company (including VAT) = £34 per report.  
 120 reports (60 patients) = £4,080  
 Reports secondary analysis within NHS = £2,208 (6 days' work) (Included training time, ICT set up and output 28 reports).  
**Total = £20,628**

**Figure 7.1. Overview of costs associated with project.**

## 7.2 Qualitative Findings Overview

As described in Chapter 4, interviews were conducted with a small but purposive sample of patients (n=8 Patients and n=1 relative) to capture how the patients felt after wearing the new device and experiencing the new pathway. Six (out of the 8) patient participants were male, two were female and the one relative was female. In addition, interviews were conducted throughout the project (before [n=5 implementers, n=11 HCPs] during [n=2 implementors, n=9 HCPs], and after [n=1 implementor, n=4 HCPs]) to capture expectations of the new service, experiences of the new pathway (Stroke nurses and clinicians) to identify potential barriers and facilitators to the adoption and uptake of this kind of service within an NHS setting.

	<b>Patient Experience</b>	Condition, Technology, Value.
	<b>Clinicians Experience</b>	Condition, Technology (device and reporting), Value (Accuracy and Trust).
	<b>Implementation</b>	Procurement, Planning, Participation, Training, Resources.

**Table 7.1 Overview of key themes**



### 7.3 Patient Acceptance and Experiences



Eight patients and one family member were interviewed to capture experiences of wearing the new device and the overall AF screening experience from start to finish. The important issues (themes) that emerged from the patient perspective will be presented in the following summary with supporting quotes.

#### 7.3.1 Condition (diagnosis, fear, identity)

All patients (n=8) explained their experience of their stroke and the feelings associated with their experience in relation to the condition itself. For example:

*'I had come down the stairs in the morning and I went into the kitchen and I just felt my whole body going to the floor and I couldn't move, I tried to move, I couldn't move my body at all, it was quite frightening, you know.'*(Pt006)

The physical impact of the stroke varied between participants, with one explaining her difficulty communicating to her daughter and health care professionals.

*'...they were speaking to me and I knew the answers but I just couldn't get the answer out... I was quite concerned because I kept looking at my daughter and my son and tried to tell them what it was and it really got me quite upset.'* (Pt 002)

Others described the loss of physical sensation, collapse, and the accompanied fear they experienced. One of the participants had no recollection of his stroke and relied on his relative's explanation of events as this interaction illustrates:

*(Participant 008). 'He was lying on side and I knew right away that there was something wrong. So I started to talk to him and he just made this noise and I got him out of the bed and onto the floor..... So I got him down and I put the phone on loud speaker and I dialled the ambulance and he was really out of it. The ambulance stopped at the gate and he started to come round a bit, by the time they came in I had him up'.*

*'I can't remember any of this' (Pt008, relative)*

The psychological impact of having a stroke was described by one participant:

*'My grandson brought me magazines in and I couldn't read a line, I just kept going back over and back over the reading and my grandson put the wee cards in the television. So I was sitting trying to concentrate on what was getting said on the television, because I just felt I was isolated you know, and everyone was different. But I was trying to get myself a bit of something for me, you know, I wanted to do something – I'm just trying to think how I was feeling you know. It was a harrowing time – I never had anything like that in my life if was quite unknown in my body, you know what I was going through and yet it was me that was having to go through it you know.'*(Pt006)

Two patients described attending their GP prior to their stroke and not necessarily receiving a clear diagnosis at the time which led to some additional confusion and fear. For example:

*'When I got to see the doctor and I told him about the sore head and my fingers weren't working properly and he said, "how are they now" and I said, "they're working fine now." So he lost interest in that part, he examined my ears, told me I had an ear infection, which I didn't know anything about and gave me antibiotics' (Pt009)*

As well as the physical and psychological impact of experiencing a stroke, other impacts such as housing adaptations, impact on work and loss of independence were also discussed by patients and the relative. For example:

*'He was in for two weeks basically because we had renovated the bathroom to get him home and I had to change it all because we couldn't have got him in the bathroom. So that took the time before I could get him out and it's me that said it needed done, but it was worth it'. (Relative 008) (Relative)*

*'I had to take the week off work ..... because I work up on scaffold, so I couldn't go to work, they said, "right you can't go on scaffold."' (Pt004)*

Experience regarding the NHS was voiced as being overall positive, with one participant describing his experience as; *'I got first class treatment, first class'* (Pt 005). One relative described being overall being pleased with the care, however expressed that concerns when in an emergency setting they didn't feel that they were taken seriously. Another participant expressed disappointment with the lack of communication within the hospital ward setting.

*'I think it was because of me I didn't know what I was really doing, but there was not much encouragement being brought [referring to a ward setting], only that it was the young nurse that would come over and ask things you know. But the older, the senior ones I just felt there was a lack of communication, maybe not wanting to respond to somebody with a stroke, I'm not sure. You know I felt that could really be something done, yeah.'* (Pt006)

### **7.3.2 Recruitment and Participation**

Most participants were pleased to hear about the evaluation of the device they were wearing, however one participant (a relative) had concerns that this might mean that something was wrong with their relative, this is reflected by the below quote.

*'I was a wee bit concerned that there was maybe something wrong, that he had been chosen for it, but when I spoke to the male nurse that came in, he said, "no it's for research, basically it's a research programme," I said, "yes, because if there was something wrong I would like to know about it," he said, "you would know about it"...' (Pt008) (Relative).*

After initial approach, the stroke liaison nurse contacted the patient to arrange a suitable time to visit their home. The standard and quality of explanations was considered to be good by all, no participants voiced difficulty in understanding or poor explanation from the stroke liaison nurses. Visiting at home appeared for most to be convenient and valued, this is supported by the below quote.

*'[He] hates hospitals, when we go to them it's a screaming match, but I think the fact that he came to the house and it was just us, you know it was easier. I think maybe a younger person getting it fitted would be alright in a hospital, but he took the time to explain everything out. Whereas in the hospital they usually, that's it and then you go and this is what you do and hand you a bit of paper, but he explained it right from the word go to the end of it.' (Pt 008) (Relative).*

Although most patients were happy to be recruited into this project, one HCP highlighted that one patient declined to participate due to the requirement of wearing a non-underwired bra for the duration of the project.

*'I think the benefits are obviously diagnostic getting a diagnosis, I think the disadvantages are, I think basically very individual depending on the potential participant of wearing it, I think it's their choice and I think that's probably that the main disadvantage, as particularly for female patients the fact of not being able to*

*wear an underwired bra but for myself in relation to the overview of the device it's of more value than it is non-value.'* HCP004

*'And has there been any patients that have declined to wear the device?'*

*'I've had one lady that, basically my process of introducing the device is explaining the purpose, that's it a diagnostic test, it's a unique system that's advantageous for our team to be able to apply it, have it analysed and then look at the treatment, so the whole process. And again I focus it on, the purpose of it is for the early diagnosis to reduce the risk of that individual person having another stroke. So I explained all that side of it first and then it was a lady, so I then explained to her where the device was applied and then I asked her is that an underwire bra, something that you wear on a daily basis and she said yes. I said in relation to wearing an underwire bra and the device, I explained that can be a bit of interference so to optimise the benefits we would recommend that you wear a sports bra. She had a function at the weekend and didn't want to wear it, I offered to delay applying it but for her personally and for herself image she just was not prepared to wear an underwire bra for the duration that was required, so she declined for that reason.'* (HCP004).

## **7.4 Technology**

Two BARDY CAM™ devices were applied for seven days each. One BARDY CAM™ was applied on Day 1 by the nurse in the home. Prior to its application, the skin was shaved (if required) and cleansed. On day 8, the first BARDY CAM™ device was removed, the patient had an opportunity for a shower, the skin was shaved (if needed) and cleansed and the second device was applied and worn for seven days. The second BARDY CAM™ device was removed by the patient or relative and returned directly to the hospital, either by the relative or by post.

#### **7.4.1 Application of the device by Stroke Liaison Nurse**

Both BARDY CAM™ devices were applied by the stroke liaison nurses in the homes of the participants, this is reflected by the below quote;

*'It really was quite straight forward, I had a phone call and a letter in to say when to go and at time when you leave hospital. Somebody came out and it just stick on, it took about quarter of an hour, twenty minutes all in and that was it. I had to keep it on for a week and then change it to another one which was the same.'* (Pt004).

*'The stroke nurse came in, after the first seven days she came into the hospital took the first one off and put the second one on for me, and then she come in the following week and did the same thing.'* (Pt002).

All participants interviewed stated this process worked well.

Although all patients had the device applied by a nurse, some patients expressed concern that if applying the device themselves, they may have they may have had difficulty (Pt001; Pt003) and would have required clear instructions if completing it independently (Pt001) whilst one relative suggested they would need to apply the BARDY CAM™ , as it may be too difficult for their relative. Another expressed they were happy for the support but felt able to put another device on, this is reflected by the below quote.

*'Well I was pleased that they put it on initially but I think it's a device that you could put on yourself because it's very, very simple and even taking it off it's just a matter of taking it off and just making sure that your skins alright'* (Pt003).

#### **7.4.2 Appearance of the device**

Overall feedback regarding the appearance of the device was positive, participants described the device as *'Unobtrusive'* (Pt 001); *'more than fit for purpose'* (Pt004), *'nice and neat and small and it wasn't an inconvenience to me, I thought it was ideal'* (Pt 003). *'Forgetting about it'* was a theme expressed by five participants (001; 002; 005; 007; 009), this is supported by the below quotes.

*Well it was pretty unobtrusive really, most of the time you forgot it was there' (Pt 001).*

*'I don't even know it's there dear to tell you the truth.'* (Pt 005).

*'Yeah, it was quite comfortable. You didn't know you had it on' (Pt007).*

*'It was completely painless, I didn't even notice it, even in the shower and the only time it ever became a problem was when I was drying myself, because you forget it's there.'* (Pt009).

However, one participant noted that although mostly forgetting it was there, the button placement at the front made him conscious of wearing the device at times. This is supported by the below quote.

*'Aye, as I say you forgot it was there, but again that's the only thing I would say is if you leaned against something you were conscious of especially the button being in the front'(Pt001).*

### **7.4.3 Comfort of the device**

Three participants clearly articulated there was no effect on skin. Although mainly positive feedback was captured, one participant noted a skin irritation, describing the first day wearing the BARDY CAM™ device as *'slightly itchy'*, which was considered as mainly being due to the adhesive from the device (Pt009). Discomfort and difficulties were expressed when removing the BARDY CAM™. One relative described the skin as being red after removal, this is supported by the below quote.

*'Because after it came off, I thought I'd took the skin off all of it, but I hadn't it was just a red mark where it had been sitting, but then again it would need to be like that*

*because it was underneath your clothes all the time, you know if it didn't like a plaster if would have been off in a couple of days'. (Pt008) (Relative).*

The participant related to the above relative described the process of the removal of the device as being *'sore coming off'* (Pt007), another participant described it as rather *'painful'* (Pt009), this is further supported by the below quote.

*'Aye, well the chap that did the fitting took it off, but he also had some fluid or other that he dabbed on it and actually came away not too bad. But when I did it, I had an awful time, I had to get a knife, I couldn't pull it because my skin was coming out, right and I didn't want to [cause] myself any damage, so I got a fileting knife from the kitchen and Vaseline and just slowly just sat and worked it down. It was rather painful coming off, that was the second one.'* (Pt 009).

The cause of discomfort appeared to stem from the adhesive, with some patients expressing that it was too sticky. However, one participant expressed that their second BARDY CAM™ lost its adhesiveness. This is reflected in the below quote.

*'I had to keep it on for a week and then change it to another one which was the same... it stayed on, it started to lose its stickiness after about four days, come day six, day seven, well on me anyway it had moved a bit, but it was still in place but it was definitely losing its stickiness. But other than that it was brilliant.'* (Pt004).

Other feedback focused on personal washing. One participant expressed no difficulty with personal washing, this is reflected by the below quote.

*'To be honest, once the nurse came to the house and put it [on]... we had to shave a little bit of hair beside my breastbone, once it was on, I could shower no problem, it*



*didn't interfere with my clothing, it didn't interfere with... it was actually ok, no problems at all with it.'* (Pt003).

However, one participant expressed altering her personal washing and two participants explained how they placed Clingfilm over the device before showering.

*'Well if you're getting a bath, you couldn't really get washed the way you normally did in your bath, but that didn't bother me because I knew it was something that I wanted help with. It helps yourself and the doctors and surgeons for other people, and it wasn't a bother really, I just did what I did. It didn't worry me, to help you know.'* (Pt006).

*'Yeah you actually forgot you had it on, because where it was sitting it was really very comfortable, you didn't have any problems with it at all. The only thing when I was showering I covered it in Clingfilm just so it wouldn't get wet.'* (Pt002).

To gain a clearer reading from the device, participants are requested to not wear an underwired bra whilst wearing the device. Although, some participants expressed to healthcare professionals (see HCP results) their refusal to participate due to this reason, only one participant from those interviewed expressed purchasing alternative underwear, but stated this wasn't an inconvenience, this is supported by the below quote.

*'The only thing that they did say to me was, I wear underwire bras, so they had told me don't wear underwire bras with it because the wire could affect the monitor. But that was the only issue and that wasn't a problem, I just got out and got other ones.'* (Pt002).

#### **7.4.4 Returning the device**

Most participants wore two devices over a 14-day period. The first device which was worn on day 1 until day 8, was removed and collected by the stroke liaison nurse on day 8. The second device was removed by the patient or their relative on day 14 and was posted back or returned back in person, depending on preference. Participants were provided with a stamped and addressed envelope on day 8 by the stroke liaison nurse. Most participants expressed they were able to post the second device back via post and did not verbalise any difficulty with this process. One participant expressed preference that his daughter would return the device in person (Pt005).

#### **7.4.5 Comparison with other cardiac monitoring devices**

Some participants had worn other cardiac monitoring devices in the past such as Holter monitors and so were able to draw comparisons between the two devices. One participant expressed a preference to wear the BARDY CAM™ device compared to wearing a Holter monitor, but only if the adhesive was altered, this is reflected by the below quote.

*Interviewer: 'So if you were to compare the two devices, which one do you think you would like to have again if you had to have it again?'*

*'The most recent one, if they do something with the adhesive.'* (Pt009).

This participant also stated that when wearing the Holter monitor, the showering was restricted, this reflects the importance of the ability to shower with a device, and is reflected by this quote;

*'For the three day one I stopped showering, for the seven day [Holter] one, I said, "look I'm not wearing it unless I can take a shower" (Pt009).*

Another two participants explained their experiences of wearing a Holter monitor in comparison to the BARDY CAM™ device.

*'They gave me some [adhesive patches] just in case they came off, "what if it comes off," "just put it the same place, make sure the same cable goes in," they were all colour coded anyway so it's. Again a couple of them came off, when you go for a shower and that but apart from that it was a pain compared to the one that you just stick in the middle. The difference is unbelievable because as I say that one is pretty unobtrusive, the things with all the stickers and the wires all over the place, they were just a pain.'* (Pt001).

*'I would recommend it, I would say if anybody was given an option of wearing the three prong ones or wearing this, I would take the sticky middle of your chest one every time. It's easy, it's stuck on and that's it. I would reckon if you were just doing an ordinary desk job or something you probably wouldn't have any problems with it staying on for the full seven days. I think it was me being out in the kind of work that I do that it started to lose its stickiness after the five days. Aye it was very easy to wear, the fact that you can come in and get a shower with it on and be normal was magic.'*(Pt004).

*'I think this is a better device because the other ones some of them are quite bulky and that and a lot of people don't want to wear them. But I think if you were offering this to people I'm sure they would be very willing to use it. As is say, I know I would anyway'* (Pt002)

Comfort and ease of use were important aspects of the device which were reflected from some interviews. Although, they stated they trusted the device, when asked, one participant and their relative joked that they were concerned that someone was listening or filming them. They expressed their two-and-a-half-year-old granddaughter thought wearing the device was funny, this potentially reflects lack of embarrassment of wearing the device in front of family members. The below quote may indicate a lack of trust with the device or healthcare providers.

*'I was a bit worried they were maybe filming us, [laughing] somebody's listening to us here [laughing].'* (Pt008).

*'Our granddaughter] was only two and half then, [she] was like this, what is this, and she said, "is that an eye" she used to dance in front of you, "are you watching me?" She thought it was hilarious.* (Pt007).

Cardiac physiologists commented on the form of the new AF devices:

*"I like the idea of a plaster, that would be better for the patient's comfort (they can have shower, they can run with it), much better for them."* (HCP008).

### **7.5 Perceived Value (reported by Patients)**

Although some participants expressed that their participation was to be a help to others, some expressed value to their own health if Atrial Fibrillation was identified. This is reflected in the below quotes.

*'It would be helpful because if it had recorded any faults or that, that would have been helpful at the time, but it recorded nothing untoward.* '(Pt009).

*'Well I think it's helped a lot because as I say I was able to find out exactly what it was, what was happening to me.... if I hadn't had that device on I wouldn't have had a clue of what it was. ... if you go to the doctor you maybe taking any of these things at the time and they don't know what's happening with you. I think it will be a very useful thing to have'* (Pt 002).

Having the stroke liaison nurse team as a support was reassuring to some participants, with another stating:

*'To be honest the [hospital] has been wonderful, they really have.'* (Pt008).

*'No, I can't really think of anything, I'm just so grateful for like my stroke nurses coming in, you know the girl that came in, even in [to the] ward you know it was really a place where people, nurses do help you know and it's a place – they're needed'* (Pt006).

Overall, patients considered wearing the device as a positive event, often referring to it as an experience which would be of help to others, this is supported by the below quotes.

*'Yeah, my experience of using the device, it was no problem it didn't interfere with my everyday life, yeah no problems.'* (Pt003).

*'No, no I'm just quite happy that I got the chance to use the device and it helped with my diagnosis that gave me some reassurance that I was on the mend.'* (Pt003).

*'If it's going to help anybody, I'm 100% for it.'* (Pt005).

## **Summary**

Sixty-four patients wore the BARDY CAM™ for 5-14 days (average 12.09 days) in a new managed AF screening service. Eight patients and one relative were interviewed in person or over the phone to explain their experiences of the new service and technology. Feedback from patients was also relayed from interviews with health care professionals. Patient experiences of the new screening service were overall noted to be positive. The results indicate that patients appeared to value the technology within the service, however some comfort and skin sensitivity issues were noted to impact acceptability and are recommended to be resolved. Some patients also altered aspects of their daily life (such as showering) when wearing these devices. Overall, patients appeared accepting of the new service and value its potential improvements to the NHS.

## 8 FINDINGS: Implementation

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This chapter will focus on the findings from the perspective of the health and care professionals involved (stroke team) and also those involved in the wider implementation of the complete service (e.g. from procurement, to project management, to the reporting service). Key themes emerging from the interview data will be highlighted with the support of quotes from the interviews to highlight key barriers and facilitators to the success of the roll out of the new device in NHS Lanarkshire.

*It is important to note that different individuals were involved at various time points during this implementation process, and therefore their perspective may be influenced by their role at this time.*

### 8.1 Procurement, Device Selection, and Piloting

Initial stages examining the adoption of a new AF monitoring service into the health service involved the procurement process. This involved collaborations from academics, an innovation centre and local NHS teams meeting for ‘two or three half days’ PF001 and included ‘read[ing] through all the leaflets and kind of scor[ing] them...’ (PF001).

While national guidelines should clearly inform device selection, local expertise and practices may also determine what properties and behaviours the device should and should not have. Therefore, a set of inclusion and exclusion criteria for AF device selection was established by a team consisting of 2 digital health experts from University of Strathclyde (LM and MML), an AF academic expert from Napier University (LN), and 2 clinical stroke care experts (MB and KB) from NHS Lanarkshire (Table 6.1). Further input on coordinating and facilitating the procurement process guided the PIN notification process, this was provided by a procurement expert at the National Services Scotland (NSS). It was agreed that the acceptability, usability and feasibility of these devices should be more closely assessed by both patients and

professionals during a pilot phase and within the main implementation and roll out of any selected device(s).

This collaborative partnership process was unique and essential in order to fully capture barriers and facilitators that exist even as early as identifying what devices and/or companies fulfil not only the clinical requirements but also governance requirements such as where the data is stored (data governance) as well as what devices might be acceptable nationally, and also what type of data and reporting the device and company can provide in the context of both the service delivery itself but also in terms of what data would be available for ongoing evaluation of that device and surrounding processes.

A prior information notice (PIN) was advertised online on the 27th February 2018 which commenced the first stage of procurement. Following the closing date on the 9th March 2018, members of the collaborative team (JB; MB; KB and LM) met to review and consider the applications (15th March 2018). Although no contract was formed at that time point with either of the companies, both agreed to provide initial training, and made two devices available for a trial period with no associated costs (July-Aug 2018). This initial pilot was focused on evaluating the process of using the devices (patient and clinician perspective).

Health professionals valued this opportunity to pilot devices within their work processes and with their intended patients' groups:

*'it's one of the more interesting parts of the study ... you could easily as a health board have gone out and bought [the device]'* (PM001)

Referring to one of the devices available, one HCP noted the difference between devices that are marketed more towards a consumer market and those that are still marketing to the NHS as the primary buyer.

*'their packaging, they're marketing it very well, it's very consumery, buy it off the shelf, buy it yourself, health monitor. It looks like a heart- it's a cool a bit of kit, it's got a good branding around it'* (PF003).

The training day for one of the selected companies - BARDY CAM™ (Device 1) took place in May 2018. This training day introduced the device to relevant healthcare professionals. They had the opportunity to practice applying the devices and giving the individuals further information about how the device works, how it may impact their daily activities and advice regarding returning the device. Feedback throughout this day was overall positive. University of Strathclyde (SH) and Napier University (LN) were present for this training day and informally captured qualitative feedback. Positive feedback was given to the clinician from patients and healthcare staff regarding the training and device. Prior to two interviews being led by GSA, some staff also informally provided positive feedback about the training day and device.

The product was initially piloted on a healthcare professional (n=1) and a selection of inpatients and outpatients (n=9). These volunteers wore the devices for a seven-day period. It was planned that following the return of the devices, analysis would be completed by relevant cardiac physiologists. However, difficulty setting up the software on the NHS computers delayed analysis of the device reports by these staff members. To ensure analysis reports did not delay patient treatment, this process was outsourced entirely to the company (BARDY CAM™) for the pilot to reduce the workload on cardiac physiologist.

The training of Device 2 took place on 29<sup>th</sup> August 2018 with 5 patients being fitted with the device on the same day. After a few days however, the clinicians stopped the pilot early due to several concerns from both patients and clinicians about the comfort and clinical suitability of the CE marked device (primarily due to the comfort and wear-ability of the device).

Significant skin irritation issues related to the second device that was piloted led to removal of this device from the test of change. The amount of evidence and the range of populations that have tested each device is of significant importance for the HCPs. Many new devices are marketed well but there is a lack of evidence for their use with different patient groups in a variety of contexts. It is important that evidence-based judgments can be made about the true efficacy of the device for any particular group or setting.

*'But the problem, and I think we were possibly slightly naive was, they had never put it on frail people. It had always gone on athletes etc. before, and I think that was the problem. It was a completely different cohort of patients that we're looking at, who*



*potentially didn't have the mobility or the body mass that they had been using it on before.'* (PF1)

Clinical experts decided to proceed therefore with the implementation of device one - the BARDY CAM™ device into their service.

It is likely in a market with many new emerging devices that procurement checklists will have to be updated to allow newer more innovative devices and smaller companies onto the market. This will require a step change away from larger corporations with legacy NHS contracts towards more innovative and adaptive procurement policies and practices. Not all NHS boards will be equally equipped to deal with this and therefore checklist and guidelines for procurement will be a necessity moving forward in this area.

## **8.2 Distributing, applying, and returning the devices**

### **8.2.1 Device distribution**

In the initial stages of the research project, a cardiac physiologist was planning to be involved in the application, collection, upload and analysis of the AF monitoring data. Due to the limited number of cardiac physiologists, stroke liaison nurses led in the application, collection and upload of the BARDY CAM™ devices for the test of change and analysis was outsourced to a company. Although stroke liaison nurses were not previously directly involved in the care pathway for individuals who require screening for AF, involvement in this project led to the adoption of new roles which required additional training, additional planning and additional resources (travel visits to the participants homes).

Length of time of application of the first device varied from 4 – 15 mins (with a mean application time of 6.15 mins). Length of time of the application of the second device varied between 3-15 mins (with a mean application time of 5.47 mins). Two main challenges were noted by stroke liaison nurses, the first was related to approaching the participant in the first visit and this may have impacted the length of time of this visit, which may be related to the application, this is outlined in the below quote.

*'...it just meant that the second visit lasted an hour, which is what we'd scheduled for, it could potentially last two hours. Because you would be going into the first visit and*

*then we kind of tweaked it around whether you apply the device and then do the visit or do the visit and then apply the device. Because you've got to bear in mind these people have been at their work on Tuesday, had a massive stroke, they go home two weeks later, you're going in three days later after they've come back home, a completely different person.... So any first visit is tricky, but to do that and then say, and by the way, we're going to monitor to make sure you don't have another one and I'm just about to shave your chest and put this on you, and then I'm going to tell you all the things you've got to do. That could - made it a difficult visit, extremely difficult. So that's why the length of time that it took for us, was sometimes longer than we expected, because of the complexity of the visit.' PF001*

It was anticipated patients would wear the device for 14 days. Reasons for early removal of the device included; reason unknown (n=8) (length of recording [days]; 9, 10 [n=2], 12 [n=3] 13 [n=2]) ; patient preference (n=4) (only wanted to wear one device) (length of recording [days]; 7 [n=4]); both devices fell off (patient reported high perspiration) (recording length [days]; 11); device failure (n=2) (one device did not record any data and the other snapped in half when placing the device) (length of recording [days]; 7); Patient died (n=1) (length of recording [days]; 7); bottom half of device came loose (n=1) (length of recording [days]; 11); skin issues (n=3) (length of recording [days]; 7 [n=2], 10); unnecessary (n=1) (length of recording [days]; 5) and patient going on holiday (n=1) (length of recording [days]; 6).

There were issues around workload and time needed that were introduced because of delays to the project (devices being ordered, and contracts being signed). This meant that a large number of patients were identified and lined up ready to receive devices during a period (summer). They had to then issue devices quickly over a period of time which might not reflect what would happen in routine practice where patients would be identified on a rolling basis.

*'And that was why the start was so difficult for us. But I think that's good learning for other people in that scheduling in on a dripped basis. Don't hold back and then think that you can do 20 odds in the one week, which we did. We probably didn't need to do that, we could just have staggered them, but that's just not the nature of how we do our work.' PF001*

### 8.2.2 Application of the device

Overall, the feedback relayed from patients to HCP was positive regarding the device itself, however, one HCP expressed that a few devices had fallen off early and most significantly, one patient had developed a sore whilst wearing the device. These statements are supported by the below quotes.

*'We have had a few patients that it's fallen off before the end of the week. .... in general I think the only issue that I felt with patients is a few times that they've come off, but it was during the really hot period as well. So the people would be perspiring a lot more than normal as well, so I don't know if that has influenced that or not.'* (HCP006).

*'I have had a patient who had a real sore under the actual metal part, but it transpires as I was going out the door, because I then couldn't put the second week on because you just couldn't have put it on top of that. She said that she'd been allergic to nickel but I believe that there's no nickel in it but there will be some other metal thing and she must have been allergic to it, so it was a sore, it wasn't just a rash or anything. So there's been several people with a bit of a rash but nothing that I felt that I couldn't put the Bardy on, they were happy for it to get back on for the second week. But she was one I just couldn't put back on.'*(HCP006).

*'It's been excellent, definitely there's only the one with the skin contamination I don't know what to call it, that's the only negative experience, but she actually persevered for seven days, although she was scratching the first day, she persevered...but even she couldn't give negative feedback even with the reaction. So I don't think there's been any negatives at all.'* (HCP003).

### **8.2.3 Returning Devices**

Poor parking in the NHS site car parks led to healthcare professionals having difficulty returning the devices to the appropriate hospital for upload.

*'One comment that they've made, ....to be plugged in for reading and it's really difficult getting parked here. So, in terms of practicalities, I think they're very keen for one of those docking devices on the machine, down at [their hospital site] so they can just drop it off in their local place and I think that would save quite a lot of time.'* (HCP005).

To address this issue, healthcare professionals organised a docking station at their individual hospital sites to allow the devices to be docked and data to be uploaded for analysis.

## **8.3 Data Analytics and Reporting**

One of the significant service changes using the new device was that the company offered a service where the reporting is done by their diagnostic team and software off site outside of the NHS. This could be a novel model for reporting which could save significant amounts of time for NHS staff. It was crucial therefore to examine what challenges and opportunities around the analytics and reporting service were present in the interview data with those involved.

### **8.3.1 Quality of Device Data**

In terms of data gathering the device was not perceived to necessarily be providing a better quality of data than the devices currently used by NHS Lothian or Lanarkshire. In 10% of the cases dual analysed (3 patients) (i.e. having additional analysis by the cardiac physiologist as part of the evaluation) poor quality recordings were noted. This is supported by the below statements.

*'In terms of the outcome itself -detection of AF- I don't see any difference between Bardy and the other systems.'*(HCP008).

*'I found that 10%, 3 of the 30 recordings - they were meant to be for 7 days - and what happened to these recordings is that because the monitor is a plaster, when the plaster becomes loose, that generates artificial noise. The data then becomes impossible to do any analysis on. That could be a down point as well. It could be that it wasn't fitted properly, or the patient removed it, we don't know. But that could be an issue.'* (HCP008).

Issues in some poor-quality recordings was noted by the cardiac physiologist who was involved in NHS secondary reporting included (periods of QRS under-sensing leading to inaccurate R-R plot (n=1); frequent noise from artefact (n=2, with one of these noted to only provide 50% of readable data); poor quality recordings (n=3). There is no clear reason why there was poor quality from these devices. However, potential reasons of poor-quality ECG or artefact may include poor adherence to the skin, this may be due to poor skin preparation, hair regrowth, perspiration, impact from water or loss of device adhesive, interference from having a mobile phone in close proximity, walking and moving around, wearing a bag and wearing an underwire bra. The cardiac physiologist was not concerned however about a company actually storing the patient data as long as the security measures are in place.

*'The data is fine since they have all the security in place.'* (HCP008).

### **8.3.2 Report Generation and Analysis**

Due to the national shortage of cardiac physiologists, the main analysis of the reports (n=64) was outsourced to the company supplying the device. This involved a cardiac physiologist and a cardiac consultant from within the company tagging the data-stream once uploaded from the devices and generating a report for clinicians to read (see Figure 8.1).

Bardy provides an online platform for analysing the ECG data. This platform can be used on any computer that has a connection to the internet. The platform provides the tools needed for analysing the data and compiling the reports. Using the Bardy platform it currently takes a cardiac physiologist roughly double the time to access and analyse all the required data points to generate a report compared to the existing systems used for reporting (within NHS Lothian). This was reported as being because of (i) the longer loading times for the data and (ii) not being familiar with the software.

*'If I had to choose from what I have now or this Bardy platform, I would choose the one that I have now. Because I can do the analysis of 7 days monitoring, (...) in about 10-15 minutes and I take double the time in the Bardy platform. And the reason for that it takes 1 minute some time to load ECG if you want to see a specific point and if you would like to see a few ones that takes you a few more minutes, while in the system that I have you just click and it takes you there, takes 1 second. (...) if they (Bardy) improve their system make it quicker, it would be more or less the same.'* (HCP008).

Using the current Bardy online platform the clinician has to extract the data (from the device) and put the data into another platform in order to generate the report. In other similar platforms everything is done on the same system. However, this was not considered to be a major problem.

*'In other systems the reporting and the analysis are in the same platform, so you don't go away. So in this one, you need to go on another platform that generates a window but we can still see the other (analysis) platform and then we just type everything (...) so it's something you can do (reporting) but it is a bit weird, but it works out - we can do the report, it doesn't take a huge effort to do the report'* (HCP008).

Despite the problems with loading time, the online platform for BARDY CAM™ was considered easy to use and required little training to get used to using it.

*'Because it is a new platform, .....I need to know where the buttons are but I found that that was kind of easy to start with, it is not something very complex that we need a lot of training in. Possibly because I have already a few good years of doing analysis in other systems and that allowed me possibly to learn the system quicker.'* (HCP008).

It was noted that issues related to the bespoke software needed to read the data. This led to some perceived waste of resources, as some technology had to be returned to the company early in the test of change. This issue because of NHS systems not necessarily being ready to

work with outside software and so during procurement and initial set up it is important to ensure that all software compatibility and governance issues have been addressed.

*'And there was quite a lot of time spent as well around IT issues and how those [health care professionals] that were training were going to upload and then interpret the data...'* PF001.

*'We couldn't put our software- we can't our hardware onto our network that hasn't been purchased by the NHS.'* PF001

After training and receiving relevant usernames and passwords, the stroke liaison team uploaded the device data to the online server to be analysed. Staff considered this process to be a simple one:

*'It's so simple, you register the patient details and then uploading, it's just putting it in the wee machine and it uploads everything in minutes, seconds, it's fantastic.'*  
(HCP003)

A selection of these reports (N=28) were subject to a separate secondary analysis conducted by an NHS cardiac physiologist at another hospital in Scotland. This was deemed as a necessary step in order to (i) evaluate the trust and confidence that the clinicians had in the medical device company providing the reports and (ii) to conduct a cost and time comparison for a model where the reporting would be conducted within the NHS in the future. Reports completed by the company can take up to 2 working days. An example of the reports from the company can be seen in Figure 8.1. Reports completed by the NHS cardiac physiologist took an average of 45 mins per report once received.

Major concerns related to the quality of the reporting conducted by the company's systems (for 3 patients) occurred at an early stage of analysis (for example not identifying AF, episodes of Ventricular Tachycardia) from the first ten reports. Concerns were raised immediately to the company when the stroke consultant received the device reports (these devices were not dual analysed at this point). An internal investigation was conducted immediately by the

company and the erroneous reports were due to 1. internal processes (which have since been changed) and 2. human error. The results of both device reports were reviewed by the stroke consultant. When setting up the system within the UK for this implementation, a fault occurred meaning that instead of receiving checks by 2 more junior and supervised staff members, the report was sent to the clinician immediately after the analysis by the first staff member. This issue led to some discrepancies in some initial reports. Discrepancies in early reports were highlighted to the company and consequently the quality of the reports improved, and no further reporting accuracy issues were reported. The company have now resolved this issue but this did highlight the importance of a quick feedback loop between the clinicians and the device company to quickly identify and resolve any issues that might have an impact on clinical practice. This may have contributed to clinicians expressing preferences earlier in the project for inhouse NHS analysis. However, clinicians reported that the company were very responsive to feedback in relation to acknowledging this issue and fixing the issues in a brief time period.



**Doe, Jane**

Patient ID 514608  
Date of Birth 07/12/1962 (56 years)  
Sex Female  
Indication Palpitations, Near-Syncope, Chest Pain  
Pacemaker Unknown  
Duration 6 days, 1 hour  
04:25pm 05/03/2018 to 05:37pm 05/09/2018

**Preliminary Findings**

- Predominant underlying rhythm was Normal Sinus Rhythm (NSR). Periods of Sinus Tachycardia (>100 bpm) accounted for less than 1% of the total time. Sinus Bradycardia was present.
- Paroxysmal Atrial Fibrillation (AF)/2:1 Atrial Flutter (AFL) occurred (0.3% burden), longest for 15 minutes and ranging from 124-177 bpm (avg 151 bpm).
- Ventricular Ectopic Beat(s)= 7 (<1%), 7 isolated unifocal PVCs
- Supraventricular Ectopic Beat(s)= 63182 (12%), 20152 isolated PACs/Aberrant PACs, 17001 pairs, and 2697 Atrial Tachycardia (AT) runs.
- Longest AT Run= 10 beats @ 120 bpm and Fastest AT Run= 7 beats @ 178 bpm
- Patient events correlated with PACs/Aberrant PACs or AF.
- Scanned by: PAS/JDM

**BardyDx Cardiovascular Group**

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Applied ECG Clinic

**Physician Interpretation**

**ECG Intervals**

Min HR	Max HR	Mean HR	PR	QRS	QT	QTc
40	177	59	0.17s	0.09s	0.52s	0.52s

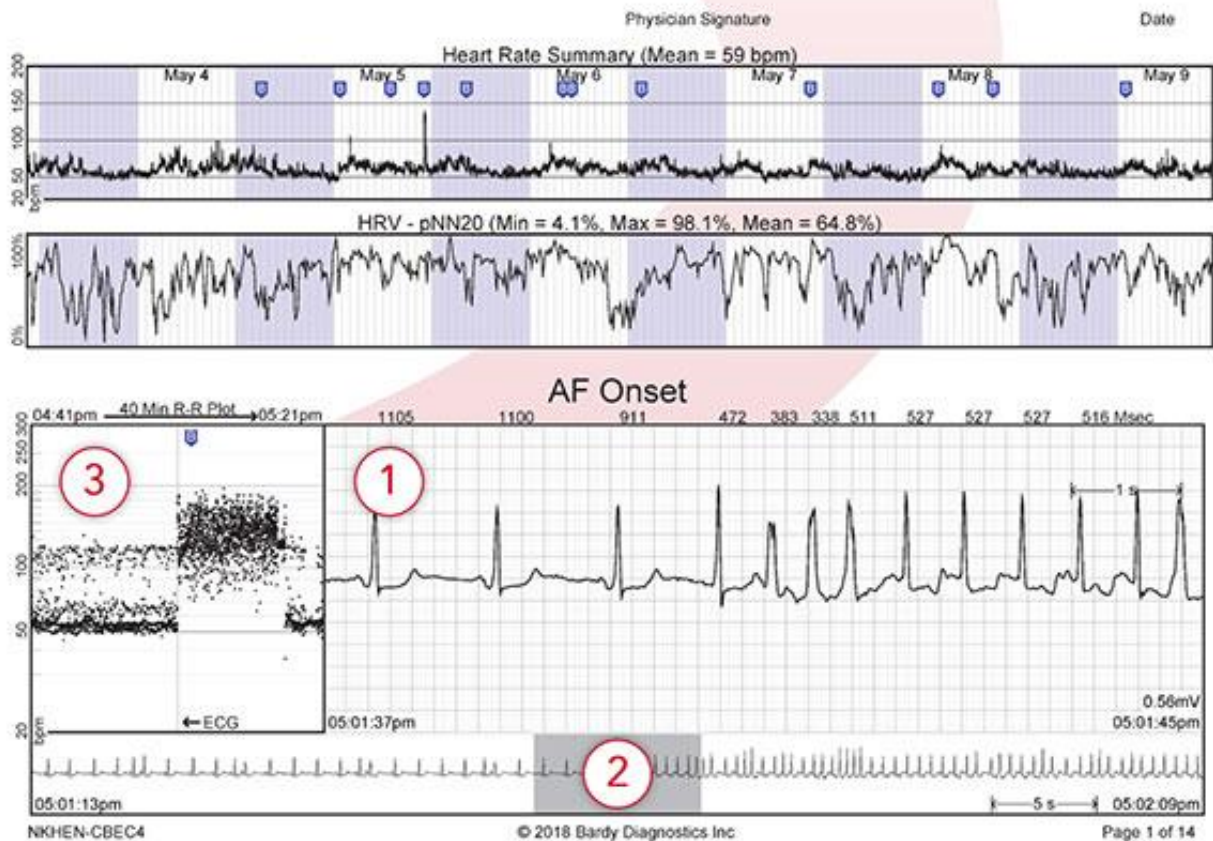


Figure 8.1. Report Produced by the Bardy Platform

### 8.3.3 Trust in the reports

The participant considered the role of the clinical expertise crucial for the robustness of the results. There was a lack of trust in a report generation process that was happening outside of the NHS where the process for this reporting and the qualifications of the staff generating these reports was unknown. Some of the comments actually referred to not knowing what level of machine analysis Vs human analysis was happening and this is something that needs to be considered carefully.

*'You can trust the person that is doing the analysis. (...) Somethings the system misses and this is understandable, they miss things because they are very complex and technical to explain, but all the systems do their own mistakes, that's why we have a trained specialist to do the analysis and identify them and do the reports. (...) We need always to see all the data, we cannot trust a computer to do it for us. (...) The system itself needs to have some sort of feature that shows us, it flags them to us (...) showing us where he thinks it could be something wrong. If the computer does that automatically its fine, but we always need to check.'* (HCP008).

Prior to reviewing the BARDY CAM™ device and creating device reports, the NHS cardiac physiologist also reflected on participation in a previous research study in which upon reflection he noted the qualifications, experience and ongoing competency of the analysis team (within any outsourced company) may be something that requires consideration in relation to the trust that is then placed in these reports.

*'So basically you wear the patch and they do everything and then we just receive the reports, so I was a bit opposed to that because we don't know who is actually looking at that data if they are capable of, they are trained for.'* (HCP008).

Following participation in this implementation process, the cardiac physiologist involved suggested the way the NHS has structured the cardiology teams is very credible and

controlled. Any outsourcing to a company does not guarantee that the results would be reliable.

*'For the good sake of our patients we cannot trust a company to do the reports and the analysis. I am a specialist and sometimes I do have doubts and I ask other consultants and they still have doubts, 'cause sometimes it is very hard to see what it happening in there... I don't like the idea someone doing the analysis and sending us back the report. How can we trust them? Who are they? I don't think that would be a good thing to do.'* (HCP008).

Another thing that required some design consideration for the outsourced reporting to be accepted by the clinicians is the American-English currently used by the Bardy reports. There are different terminologies for cardiology related topics in an American and British-English context.

*'Another thing is that this is an American company and something that I saw, yes we both speak English, but they have different terminology for cardiology e.g. we call "Supraventricular topics" they call it "premature atrial contractions" for the same thing. All the analysis I am making is in American English. They have to do an UK version of that.'* (HCP008).

#### **8.4 Perceived Costs and Benefits (Value)**

Although the perceived value (to both the patient and the stroke service) from the HCPs was overall positive, the financial and time costs associated with this project were noted by the HCPs throughout.

The stroke liaison nurses noted that the large quantity of participants who were included in a short period of time for a test of change caused additional work (for the nurses) during the test of change but also noted that this could be avoided in further roll out of the service:

*'We could just have staggered them [the issuing of devices to patients], but that's just not the nature of how we do our work'* (PF001).

There were also additional time costs associated with the actual process of managing the patient home visits to apply the devices. A stroke liaison nurse expressed:

*'This took about a day and a half to two days of your week, easily. In terms of organising visits, retrieving things that had gone missing, uploading the devices when they came back, chasing the devices from patients that had perhaps not sent them back.'* (PF001).

The stroke consultant also noted that due to anonymity with sending the data from the devices without the patients' number:

*'This led to masses of my time... looking at the reports and the system ... But actually, in the real world the consultant would take pretty much exactly what it currently takes to read, 2-3 minutes.'* (PM1)

In order to ensure recruitment rates within the time frame anticipated, the leading clinician commenced identifying individuals who may be suitable to take part in this new pathway, who were awaiting AF screening within the current pathway. It was anticipated that the project would commence late March 2019, as this period was anticipated, the manager of this site had planned accordingly, ensuring adequate staff and planning for a quieter workload period. However, due to delays the start date was later than planned, meaning staff were on annual leave and it was the busiest period of the year. It also meant that the stroke liaison nurses received a list of sixty possible individuals who could be readily recruited into this pathway when the project commenced. This significant increase in workload was a negative aspect and appeared to be reflected in the analysis of the interviews. This is reflected in the below quote.

*'I love it, I really, really do think it's an excellent service. There has to be a better way though of us putting it on, because we had 20 we had to put one in a week and if you can imagine we cover the whole of [this area]. So the geography of where people were living, we were having to travel to put that on them and do visits as well as. It was really, really very, very time consuming and our workload was horrendous. I think we*

*had arranged to do it previously maybe in March time when it was full capacity of staff and there wasn't anybody on holiday. So I think the workload had increased quite significantly, but hopefully that wouldn't be every week. So there needs to be an easier way of us to work it and I know the guidelines say that it's for two weeks however we get 72 hour holders just now so it would be good if it was just a week, a week long patch would be ideal and it would be less time consuming and easier to organise.'* (HCP001)

*'More recently we had a whole batch to do, so that was quite, it was full on really trying to get them all done and then getting back a week later along with putting new ones on. So that was taking an awful lot of our time because obviously our role goes on everyday as normal. So that was like a huge extra that we're putting in to get that done. But if it gets rolled out properly it won't be the same intensity, so therefore I don't see why it shouldn't fit in ok with us.'* (HCP006).

It should be noted however that many of these are a result of this being a pilot and many of these issues could be addressed if adopted into mainstream practice. Although these were challenges noted, Stroke Liaison nurses noted ways of overcoming these challenges.

*'But the reality is that if you were using nursing efficiently it would go onto the patient before they left hospital and then they would post it back. Or it would go on the patient in clinic and then it would be posted back.'* (PF001).

The stroke liaison nurses valued the positive impact on the patient but also note the potential financial and time savings for various departments within the service.

*'I think the big savings in the pathway are to the whole system, to the hospital system rather than to our part of the pathway. So the savings are around patient transport to attend cardiology. The cardiology department, time, the use of the Holter. The Holter from the hospital side, so it's all cardiology time savings, ambulance time, the patient's time and convenience to family members.'* (PF001)

The positive attitude of the staff and their willingness to put the patient as their priority regardless of their workload appeared to reflect a positive working environment, with staff

appearing happy to be involved. The positive attitude within this site, appeared to overcome the barriers. All HCP interviewed in this project appeared to find benefit in this project especially in relation to the patients impact on this care pathway.

*'I was involved in the background, getting a good understanding of the purpose of it, the benefit that it is to a client group, especially in relation to stroke care and stroke management. The quicker we can identify AF has been an element that could have increased that individual person's risk of stroke, so the early diagnosis means more effective and quicker establishing in their appropriate management. So I think the early diagnosis and commencing prompt treatment is that the key factors about the device.'* (HCP004).

*'I was just delighted that we were given the opportunity to participate because obviously I'm acutely aware of the fact that we need to be monitoring people for a longer period of time and the impact that has on services and the capacity to do it. So anything that was going to expedite that in any way I thought would be really useful and that's why I was keen to bring this to Lanarkshire.'* (HCP002).

Cardiac physiologists commented on the potential costs and benefits of using such a new device compared with the existing technology:

*'... it is also much more expensive than the one we have and use at the moment. (...) It doesn't matter to us which system we use to record, since it records and it's a good quality that we can analyse, doesn't matter if it's a patch or a wee monitor with 2 cables. If we get the data and we analyse the data for us it's the same.'* (HCP008).

The Stroke manager of this NHS site appeared to appreciate the value of the implementation of the project from the outset and this appeared to flow down to the staff involved in the project to increase professional readiness and buy in early on.

## 8.5 Training and Technical Support

One thing that the cardiac physiologist commented on was that the company provided the monitor and the platform was based in the USA. This created some issues specifically due to difficulties in communication. The participant explained that the time difference made it hard to contact the company, during working hours, in order to resolve technical issues. However, the support when received was very helpful.

*'Because their IT is based in America, this made things a bit difficult. (...) I had to phone at 6pm which is 9am in America to get an IT from the company so that's something that is not ideal. But apart from that, the support was good, the training was good, and they were quite helpful on what they could do in terms of if there was any issue.'* (HCP008).

With any adapted pathway (new devices and/or new processes) there are training implications. This includes training the health professionals (e.g. device application, reading reports) and also training patients on anything related to the device such as charging devices, showering, how to wear, how to fill in patient diaries etc.

*'So, there was four, there was three days of training for cardiologists and stroke nurses together. And then there was two days of training for stroke nurses and that was all with company number one'* (PF002).

During this test of change it was noted by professionals that the company provided excellent training but that this was done first with one company and then by another company when there was a change in the device distributor in the UK.

*'There was 'a lag of a year before we actually started, before we were anywhere near applying a Bardy. So, the nurses were then retrained by company number two.'* (PF001).

Although the training was found to be beneficial it was found to be time consuming for the stroke liaison nurses as they were still required to complete their usual workload.

*'[Attending training led to] pulling seven stroke nurses out of clinical time for half a day, which is significant in the wards... So, it's potentially 18 home visits that aren't being done.'* (PF001).

*'As soon Doc Medical came onboard everything just happened, because they were extremely well supported.'* (PF001).

*'Only half an hour, it didn't take too long. Just downloaded it and then plugged in the wee uploader and we could all log on, on our computers. Only that wouldn't happen in my computers, so but the rest of them could, go on their systems... But again, Dot Medical talked every person through exactly what they needed to do and then phoned them to check that everything was okay, and that they had managed their emails and everything.'* (PF001).

## **8.6 Role of Innovation Centres in Innovation within the NHS**

Although healthcare professionals were aware of the importance of screening for AF in those who have had a stroke, some barriers and facilitators may still exist which may prevent or reduce the effectiveness of the actual realisation or implementation of new technology within the NHS. The role of the facilitators of this process is to work 'with all of those agencies and making sure that communication goes between and trying to bring that collaboration together' (IP003). This role has been seen as a positive within this implementation especially at early stages.

*'so I think it's been incredibly important and it's a really interesting process and it's been fascinating to be involved in understanding the real complexity of generating change within an organisation and getting buy-in from all the different stakeholders trying to ensure we're doing something that can go forward because instead of seeing a study end you hope to be able to have impact and make that work go forward across the nation or even further.'* (IP001)



At later stages of the project, HCP involved in this implementation process suggested that to facilitate the project, key recommendations include having a local collaborator as the main form of contact would be beneficial.

*'... it's not how I've worked with other parties whenever we've tried any kind of implementation. So for example going straight to people in IT in Lanarkshire, going straight to senior managers who actually aren't involved in the process, they may well say the right or wrong thing to the [...] individual, these things should always be done through the person who's the link in that health board. Apart from anything else they understand what's happening, but they also understand the people who are involved and how to approach them and how to ensure we're getting a speedy resolution to issues that arise. So I think that there should be lessons learned from that and there should be a local collaborator highlighted and that's who all of the requests for that health board should go through.'* (HCP002)

Other key recommendations include having support and involvement in the initial set up from the local R&D department, having a realistic start date with adequate staff numbers and workload would ensure the facilitation of future work.

*'I was running about pretty much putting on six or seven in the one day and it was a bit ridiculous but I dare say we could cope better if it was maybe two, three, four a week. I think it's doable.'* (HCP001).

*'I think the main barriers were the same as the facilitators, had we had a clearer plan from the outset I think things would have been done in a much more streamlined way and those have been the main barriers for me is that we've waited until we absolutely need something to initiate it rather than having it prepared.'* (HCP002).

## **9 Conclusions: Recommendations for Wider Adoption and Scale**

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This report focused on a process evaluation of AF screening in NHS Lanarkshire. We examined patient experience (patients mostly found the device comfortable and acceptable and saw value in being able to wear the device and be monitored for 14 days continuously at home). We also closely followed clinical and service delivery experiences and reported that both senior stroke clinicians and stroke nurses involved in applying the devices highly valued the 14 days of continuous monitoring in this patient group. We revealed some remaining improvements are needed such as (i) making available a device that enables 14 days monitoring (battery life) without a switch over to a second device for the second 7 days, (ii) considering training needs and costs provided both by the commercial provider and also by NHS stroke teams and/or cardiac physiologists, (iii) tailoring the reports to the local context and (iv) creating transparent demonstrators of how the data is generated from the device and used in the reporting system (currently manually tagged by experts in the commercial company) to increase trust in the reporting process in order to realise full benefits of contracting full service to the commercial provider and (v) further considering the costs and workforce implications in NHS boards choose to generate the reports in house in the NHS.

### **9.1 Strengths and Limitations of this project**

This evaluation was innovative in that it was embedded within the entire Test of Change process from procurement through to implementation and evidence generation. This involved a collaborative partnership between one NHS board, academic partners, a commercial provider and an innovation centre. This meant implementation and evaluation were embedded throughout the project and generated evidence to support adoption of this new service within the local context. Wider adoption was also considered throughout the process evaluation and real-life experiences were captured, thereby providing usable insights for others to inform their adoption of this service (or services like it) within different clinical sites and contexts.

However, one limitation that was observed was the lack of a defined dedicated implementation or process project manager from the project outset. There were defined clinical leads, technical leads, commercial leads and evaluation leads but no one designated party specifically responsible for implementation management overall. Consequently, unexpected set up delays were encountered initially, impacting on activities associated to establishing roles and responsibilities and producing appropriate data sharing agreements. It also meant that recruitment and data collection responsibilities were ultimately shared, taking time to negotiate especially within the NHS context where it is still often unclear whether these types of evaluation require NHS ethical approval (as research) or not (as service evaluation). To ensure tasks were completed, the health care professionals and academic team took a larger role in the implementation and project set up than originally anticipated. It could be argued that this resulted in the evaluation team becoming less objective than initially planned and this may have impacted the perspective of the project. However, the resulting benefit of this is an evaluation that is much more action research based and that allowed us to capture wider planning and implementation barriers and facilitators across time from various stakeholders throughout the project. An additional benefit is that the innovation centre has now put in place a process to ensure that partnership projects are fully resourced either by itself or one of the partner organisations and that this is formalised through revised project documentation to maximise working arrangements across the partnership.

Although this approach did not allow us to systematically compare delivery of the new service to the existing one, it did allow for an innovative new service model to be tested with real patients in order to monitor how acceptable they found the new service. Of note, our approach also allowed us to capture the perceived value of the new technology enabled service to the patient (including staying at home, less hospital visits, less travel, receiving treatment more quickly, for example). We encountered some recruitment challenges, with a smaller number of patients recruited than originally planned (n=8 instead of n=20). This may have been partly due to the process of patient referral and due to a limited time for recruitment caused by delays in the project implementation itself. This may decrease the generalisability of the study results in relation to overall patient experience.

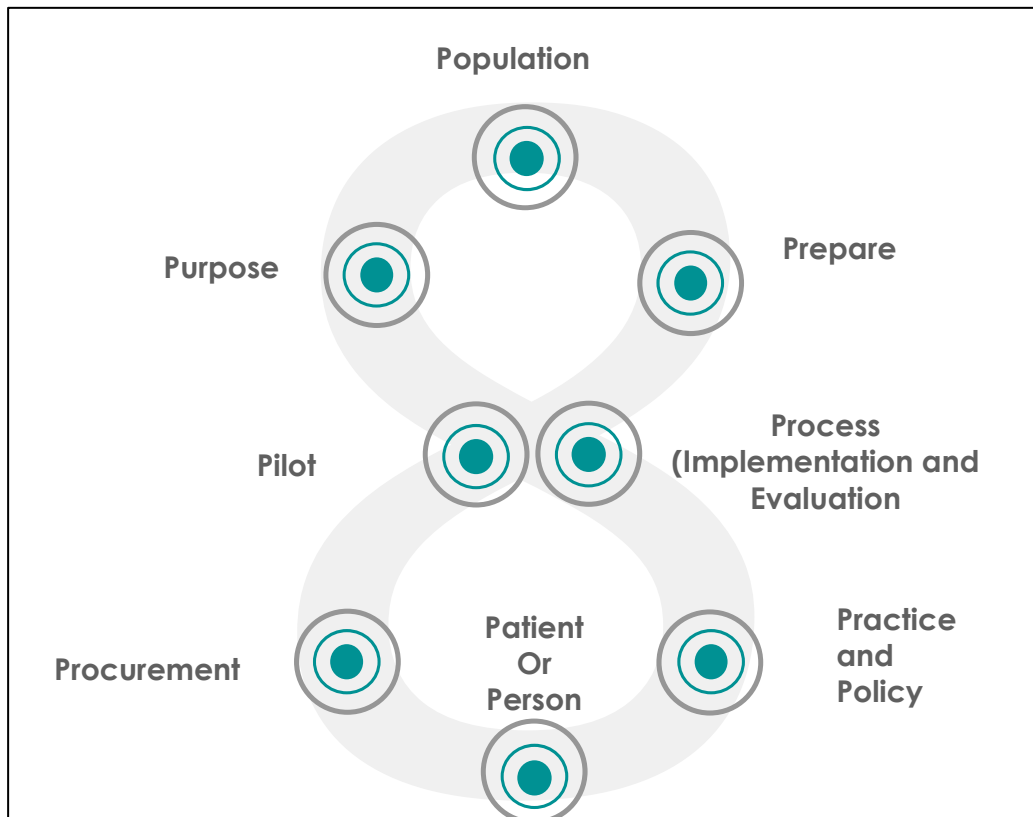
One major advantage of this study was that healthcare professionals were interviewed at various points during implementation which allowed us to capture a wide range of barriers and facilitators to the service implementation. Future service evaluation research should continue to place a strong emphasis on gathering evidence around patient experience, clinical experience, and the factors that increase readiness to implement alongside any other ongoing clinical feasibility and/or cost benefit economic studies.

This process evaluation allowed us to gain insight into how the implemented device and managed service was implemented in one particular context. These findings can now be used for this board to consider whether to adopt this device and service into routine practice or to consider alternative devices and associated digitally enabled services. In relation to the device itself, one specific limitation to note is the device deployed in this test for change was designed to have a battery lasting for 7 days. This means the true experience of collecting 14 days continuous data was not fully realised but this was unavoidable as a device with 14 days batter for continuous monitoring did not exist at the time of procurement. It did however allow clinicians and stroke nurses to gain invaluable insight into how they would make this work in practice. As the devices improve, and the reporting process is refined, it is advised that decisions are made now with regards to whether the reporting is done inhouse (within the NHS) or whether it is outsourced to a device company. If the latter approach is adopted, then the reporting would need to be tailored to the local needs and context and specific targeted information strategies focusing on increasing clinicians trust in new devices and third party reporting (and machine learning if this becomes part of the system) need to continue.

## **9.2 Recommendations**

Figure 9.1 shows a key set of interrelated implementation activities that are key to the successful adoption and scaling of new technology enabled care services. Furthermore, in order to provide generalisable and usable results from this test of change a recommendations checklist has been developed (see Table 9.1) so that the findings of this service evaluation can be readily applied to other real-life implementation studies. Some examples from this project are provided in the table but the checklist can also be used for different contexts and different sites (for example with different technologies or different

service models or populations and contexts). It is advised that in addition to these key recommendations, researchers should also continue to draw upon recent appropriate and validated theoretical frameworks in the development of their projects (for example, the NASSS framework (Greenhaugh et al, 2017).



**Figure 9.1 Figure of 8, showing the eight aspects of implementation to be considered**

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<b>P-domain</b>	<b>Description</b>
<b>Purpose</b>	The reasons for implementing the new technology enabled service. These could be to save time, reduce costs, improve patient experience, change the way or working, reduce waiting times for example.
<b>Population</b>	The intended target population (patient, service user, citizen). There may already be existing evidence for this technology being used in this population. It might be important to consider how the service might extend to other populations.
<b>Planning and Preparation</b>	The preparation that is required (both pre-implementation and during and after the implementation process). Technical infrastructure, workforce readiness, resource allocation, and issues around data collection/monitoring and governance all need to be considered.
<b>Procurement</b>	The process of procurement in health innovation is ever changing and has to adapt to keep pace with the advances in technologies (e.g. smaller companies producing devices and managed services). Embedding evaluation and implementation champions or leads in the procurement process should lead to better evidence being generated and possibly accelerated routes to market for smaller companies.
<b>Pilot</b>	Even during implementation, the role of pilots should be considered. These could be short agile user testing in context type pilots either pre-procurement (to inform procurement) or after procurement but pre roll out to minimise risks that the technology or service is not fit for purpose.
<b>Patient Experience</b>	To optimise patient or user adoption and acceptance, experience of the patient/user needs to be considered. Implementations programmes should consider how best to capture this even beyond evaluation and embedding this in the service itself.
<b>Process (implementation and evaluation)</b>	Process evaluations should continue to be conducted alongside clinical trials in order to maximise chances of adoption and scale. The feasibility and workability of a technology enabled service is likely to increasingly depend on smoothing the process of implementation alongside clinical efficacy.
<b>Practice and Policy</b>	It is critical to consider if and how practice and policy are either informing or influencing the design of the new service and how the results of any new implementations might inform future practice and policy.

**Table 9.1. Table provides a description of the main P domains for the implementation process.**

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<b>Recommendations for the Implementation of Technology Enabled Services</b>			
	<b>Recommendation</b>	<b>Checklist Question for Implementers*</b>  <i>*Implementers could be health professionals, commercial device or service providers, evaluators, decision makers.</i>	<b>Has this been completed satisfactorily? Indicate Yes/No</b>
<b>1</b>	<b>Purpose, population and Preparation</b>		
1.1	Identify the primary intended purpose of the service/intervention and clarify this with all partners.	Have you identified and clearly stated the primary intended purpose of the service/intervention and gained sign off on this with all partners?	
1.2	Identify what population is being targeted as this might affect (i) what is implemented and (ii) what the implementation and evaluation priorities are.	Have you confirmed the population that is being targeted for the implementation/intervention/service?	
1.3	Conduct a preliminary stakeholder analysis and identify and prioritise the intended primary desired outcome of each stakeholder	Have stakeholders been identified, consulted about their requirements, and involved in the evaluation design and implementation?	
1.4	Identify and agree scope of implementation and evaluation and align with business case requirements at earliest opportunity.	Has the scope of the evaluation and its alignment within the business case (evidence needed) been identified and agreed?	
1.5	Conduct a requirements analysis and identify and prioritise business needs, clinical needs, technical needs, service delivery needs, and patient acceptance/end user needs.	Have you conducted a requirements analysis and identified and prioritised business needs, clinical needs, technical needs, service delivery needs, and patient acceptance/end user needs?	
1.6	Create a data management plan and agree this with NHS and commercial partners prior to Go Live date.	Has a data management plan been agreed with NHS and commercial partners before the Go Live date?	
1.7	Create and use Data Sharing Agreements at procurement and pre-planning stages.	Has a Data Sharing agreement been created at early stages prior to procurement? Have GDPR risk assessments been completed at early stages?	
1.8	Consider whether the project is considered an NHS research project (requiring NHS ethics review) or service evaluation.	Have all partners agreed the project is considered a research project or service evaluation?	

<b>2</b>	<b>Procurement and Pilot</b>		
<b>2.1</b>	Form an innovation partnership with the NHS board, service provider, and evaluation partners from the outset.	Has an innovation partnership been formed with the NHS board and evaluation partners?	
<b>2.2</b>	If possible/required, pilot the project using a smaller number of patients/users.	Will the device/service be piloted on a small number of users prior to procurement or implementation? Has the device/service been piloted here or elsewhere?	
<b>3</b>	<b>Planning and Process</b>		
<b>3.1</b>	Identify service design, delivery, implementation, and evaluation leads and create a working group to identify roles and responsibilities.	Have service design, delivery, implementation and evaluation leads been identified? Has a working group been created? Have roles and responsibilities been outlined?	
<b>3.2</b>	Identify (and or plan to gather) evidence for patient acceptance as well as efficacy/accuracy/reliability.	Is there existing evidence for / are you collecting data that will help you generate evidence for patient acceptance?	
<b>3.3</b>	Provide project managers with change management and implementation experience.	Do the project managers have change management or implementation experience? Or is further training or support needed?	
<b>3.4</b>	Embed evaluation and implementation throughout.	Has the evaluation and implementation been embedded throughout?	
<b>3.5</b>	Develop a specific implementation strategy and plan per site – create a template for planning based on NASSS as an appendix or point people to complete the planning document by Greenhalgh et al?	Has an implementation strategy/plan been based upon a framework such as NASSS?	
<b>3.6</b>	Consider wider technical infrastructure and systems requirements early in procurement and delivery process.	Have wider technical infrastructure and system requirements been considered early in procurement and at delivery stages?	
<b>3.7</b>	Provide access to tech support throughout project – rapid resolution to any challenges encountered is key to keep momentum and adoption pathway.	Will technology support be available throughout the project? Is support available within the same time zone where the technology is being used?	



<b>4</b>	<b>Practice and Policy</b>		
<b>4.1</b>	Have a clear communication plan for clinicians / health professionals “on the ground” with expected / anticipated dates of delivery, rollout, unexpected delays etc.	Has a clear communication plan been created (with expected/anticipated dates of delivery, rollout delays etc)?	
<b>4.2</b>	Set realistic goals and track them – i.e. deploy to X sites in one go then gradually increase, or deploy to X patients then gradually increase etc.	Have realistic goals been set? Will they be tracked?	
<b>4.3</b>	Provide appropriate training at timely point pre-deployment if considered too long, from the initial training, this should be repeated.	Has appropriate training been arranged prior to deployment?	
<b>4.4</b>	Identify possible barriers at each site / locality pre-deployment and any existing barriers. Consider how local-level barriers could be translated to facilitators with appropriate activities / support.	Will/ have possible barriers been identified at local sites pre-deployment? How will facilitators overcome these barriers?	
<b>4.5</b>	Work with hospital communications / marketing team to raise awareness of the change in service from the inside and externally so people know things are changing, why they are changing and when they are changing.	Will the hospital communication/marketing team be contacted?	
<b>4.6</b>	Have key champion(s) at the deployment site to encourage others along the implementation pathway.	Have key champions been identified at the deployment site to encourage others along the implementation process?	
<b>4.7</b>	Involve R&D early and form a partnership between them and the implementation and evaluation teams.	Has a partnership been formed between the implementation and evaluation team? Will R&D been involved at early stages?	
<b>4.8</b>	Involve local IT and form a partnership between them, the tech service provider, and the implementation and evaluation teams.	Has a partnership been formed with local IT, tech service provider(s), implementation and evaluation teams?	
<b>4.9</b>	Conduct workforce planning prior to implementation (to identify roles, shifting roles and training needs)	Has workforce planning been conducted (to identify roles, shifting roles and training needs)?	
<b>4.10</b>	Create time and budget for initial and ongoing training costs	Has a time and budget been set for initial and ongoing training costs?	
<b>4.11</b>	Identify what is needed for the business case both locally and in the wider scale up environment.	Have the requirements for the business case been outlined (both locally and in the wider scale up environment)? Can these requirements be linked to National strategies?	

<b>4.12</b>	Identify audience for outputs of the implementation.	Has the audience been identified for the output of the implementation?	
<b>4.13</b>	Some implementation could be mandated by the Government to provide a higher-level structure of support for the change.	Should implementation be mandated by the Government to provide a higher-level structure of support for the change?	
<b>4.14</b>	Prioritise outcomes (clinical, cost-benefit, patient acceptance, clinical acceptance, feasibility, scalability).	Have the outcomes (clinical, cost-benefit, patient acceptance, clinical acceptance, feasibility, scalability) been prioritised?	
<b>4.15</b>	Awareness of context and identification of parts of the deployment process or activities that can be adapted to local context to best work within existing structures.	Have parts of the deployment process/activities been adapted to the local context to work within the existing structures?	
<b>4.16</b>	Monitor and evaluate implementation progress and adopt corrective actions where necessary.	Will implementation progress be monitored and evaluated? Will corrective actions be adopted where necessary?	
<b>4.17</b>	Work alongside HCP team to allow some tailoring of implementation to specific contexts – i.e. is it feasible for nursing staff to travel to every patient’s house to do the switch over or collect devices? How can this process be better streamlined to still be time efficient for patients and staff? Important for remote and rural deployments.	Can the process of implementation be amended to be more efficient depending on the site?	
<b>4.18</b>	Share successes – e.g. first patient recruited / device deployed etc	Will successes be recorded? How will they be recorded? Where and how will they be shared?	

**Table 9.2. Table outlining recommendations and checklist for implementation.**

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**If the answer was yes to any of the above items and you wish to record more detail, please do so here:**

**If the answer was no to any of the above items; please describe details:**

**Person(s) completing form, please sign and date:**

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### Appendix 1: DHI Market Review

The below has been used with permission. Reference: Digital Health and Care Institute (2018). *Ambulatory electrocardiography equipment: A market analysis of wearable technologies measuring heart output.*

#### **Ambulatory electrocardiography equipment: A market analysis of wearable technologies measuring heart output**

The aim of this document is to provide a brief overview of “Conformité Européene” (CE) marked continuous monitoring technology used in measuring cardiac output for the purposes of detecting Atrial Fibrillation (AF), specifically for patients following the onset of a stroke

In Scotland the standard and most the most cost-effective method for detecting AF is through opportunistic screening of 65+ year old patients by radial pulse checking followed as soon as practicable by a 12-lead electrocardiogram for those with an irregular pulse.

The most well-known AF monitoring technology, with built in algorithms that interpret the recorded data is AliveCor’s heart monitor and associated AliveECG app. The AliveCor Heart Monitor and AliveECG app were CE-marked to AliveCor as a Class IIa medical device in January 2015. What follows are a selection of alternative ECG monitors on the market.

#### **Zio Service iRhythm**

The Zio service received it’s CE mark as a Class IIa device in December 2014, for its continuous heart monitoring. The technology is a remote cardiac monitoring system used to detect cardiac arrhythmias. The service is comprised of the Zio patch, an adhesive patch containing a 1-lead electrocardiogram, and the Zio report, an analysed summary of the recorded data. The patch is placed on the patients left upper chest and can record up to 14 days of continuous heart monitoring data, patients are also asked to record a written log to record any symptomatic events that happen during the monitoring period. Following the monitoring period, the patient removes the oatch and posts it (via royal mail). The recordings are analysed by the company, using proprietary machine-learned algorithms, Zio ECG Utilisation Service System (ZEUS System), and a report is produced. Said report contains all cardiac

arrhythmia events over the monitoring period and is analysed by a trained cardiac technician. The report is sent electronically to the patient's clinician via iRhythm's web-based portal. The full ECG is available upon request from the clinician. Parts of the analysis occur in the UK and the USA, with all transmissions, data storage and analysis complying with all relevant EU and UK legislation.

### **Cost**

The price of the Zio Service currently stands at £800 per unit (excluding VAT). This price includes the patch, the data analysis and the report for one individual patient. In practice, the price will vary depending on the procurement and volume arrangements of individual healthcare institutions. The resource impact would be increased monitoring costs compared with 24-hour Holter monitoring, but this could be offset if Zio Patch were shown to increase early and correct diagnoses and reduce repeat monitoring and admissions.

### **Cardiologic Bardy Carnation Patch, the Carnation Ambulatory Monitor (CAM)**

The CAM is a P-wave centric ECG monitor, the CAM is a single patient use monitor that records a continuous ECG for up to 7 days. The CAM is a heart monitor can be worn discretely, in the centre of a patient's chest. The carnations P-wave centric detection is the result of combining the sensors placement over the sternum atop the atria. The CAM report is emailed to the patient's clinician, with a focus on any notable events that have occurred over the monitoring period.

### **Spyder**

The Spyder wireless ECG monitoring system is a wearable ECG sensor that monitors heart rhythm via Bluetooth enabled device. The SPYDER is attached with an adhesive pad to the patient's chest and is advertised as being inconspicuous when worn, allowing patients to behave normally whilst being monitored. The SPYDER continuously measures and transmits real time ECG signals to a computer server that is programmed to identify abnormal patterns. Clinicians can review these recordings via secure web based interface, named DoctorSpyder. All ECG data is encrypted and only authorised users will have access to ECG data, the ECG data can also be analysed and reported in the same manner as a traditional holter ECG. All detected anomalies are brought to the attention of the patient's clinician, allowing them to consider the best course of action for the patient.

## **Cost**

The Spyder ECG wireless monitor is sold by SPYDER for \$299 for the Spyder personal monitor, they also offer a bundled in Spyder personal with an android smart phone (pre-loaded with the Spyder App) for \$499.

### **SEEQ MCT monitor**

The SEEQ Mobile Cardiac Telemetry (MCT) System is comprised of a the MCT wearable sensor, the SEEQ transmitter, the Medtronic monitoring centre and the final clinical report. The SEEQ sensor is a wire-free device that provides continuous monitoring for a patient over 7.5 days, with multiple sensors allowing for up to 3 days of monitoring, the wearable sensor transmits data to the SEEQ transmitter via Bluetooth connection, automatic event transmission is performed using cellular networks and data is transmitted to the Medtronic monitoring centre. The centre provides 24/7 reviews of incoming ECG data and report generation, these are analysed by trained cardiographic technicians, the final reports are accessible 24/7 online. There are no publicly available costs for the SEEQ MCT Medtronic service.

### **Other monitors**

The Reveal LINQ became CE marked in February 2014 is an insertable cardiac monitors (ICM) produced by Medtronic, the device is around one-third the size of a AAA battery, making it more than 80 percent smaller than other ICMs. The device is part of a system that allows clinicians to continuously and wirelessly monitor a patient's heart over a three-year period, with 20 percent more data memory than its larger predecessor, the Reveal® XT. Additionally, the system provides remote monitoring through the Carelink Network, through this healthcare professionals can request notifications to alert them if their patients have had any cardiac events. The Reveal LINQ system also includes the new MyCareLink Patient Monitor, a simplified remote monitoring system with global cellular technology that transmits patients' cardiac device diagnostic data to their clinicians from nearly any location in the world. Reveal LINQ costs fluctuate between regions in Europe and further afield, however comparative analysis with previous iterations of Medtronic ICM's have shown Reveal LINQ to be more cost effective. The Reveal LINQ approximately £1,500 per device.

The **Coala** is a CE-approved Class IIa medical device system approved for home use. It's based on advanced technology that is simple and very easy to use. A wireless and cloud-based service that allows anyone, anywhere to quickly check their heart. The Coala is available in two versions; Coala sold direct to consumers and the Coala Pro offered to caregivers. Coala enables simultaneous ECG and digital heart sound recordings, with advanced, smart ECG algorithms developed in collaboration with the Karolinska Hospital and Lund Universities, providing near real time results in the Coala App. The Coala heart monitoring service is currently only available in Sweden, but can be easily adapted and licenced for other regions. The premium package in Sweden **COSTS** approximately £121 for the monitor, followed by a subscription of £28 per month.

**Mydiagnostick** is a CE marked medical device that records high-quality ECG and analyses it within 60 seconds. It is a medical grade 2a device, with a patented algorithm so it can signal for AF via red or green LED light (the red light means you should contact your clinician). The accuracy of MyDiagnostick is over 90% sensitivity and 95% specificity and the MyDiagnostick device is priced at €850.00.

The Omron HCG-801 is a CE marked compact, patient operated, handheld that is designed as a single lead electrocardiogram that records 30 seconds of ECG data. The omron Heartscan monitor costs £399.99 (exclusive of VAT), this price includes HeartScan ECG Software, and is suitable for use in all primary and secondary care environments. It offers the opportunity to effectively screen large patient populations reducing referral rates and costs.

Microlife's BP A200 AFIB device is a CE marked blood pressure monitor with stroke risk detection. The A200 AFIB is equipped with Microlife's unique AFIB technology, which makes it possible to detect atrial fibrillation while measuring blood pressure at home. The package consists of the actual monitor and its blood pressure cuff. Microlife AFIB detects AF with high accuracy (sensitivity 98%, specificity 92%) as demonstrated in multiple comparative studies with ECG, indicating that it can be used as a reliable screening test for early diagnosis. The BP A200 AFIB can be purchased for £128.78 (including VAT). Microlife also offer the **WatchBP** another blood pressure device that can detect Atrial Fibrillation with an accuracy upwards of 97%, and can be purchased for around £108. Abbott have recently debuted their CE marked smartphone compatible ICM Confirm Rx. Its companion app myMerlin serves as an integrated transmitter and symptom recorder, as well as a repository of resources for the patient. The



app encrypts wireless communications ensuring a secure and protected remote monitoring service. The device currently has a 2-year battery life. There currently is no public pricing available.

**QardioCore** is a CE marked wearable device that is paired with the Qardio heart health iOS application. Priced at £449, the device allows for continuous screening for AF. The device has been clinically validated and allows for ECG data to be shared with healthcare professionals. Qardio's QardioArm blood pressure monitor, costing £99, can also monitor for irregular heartbeat to provide a warning sign for AF.

### **Ongoing Research**

Currently there is a comparison study of continuous sternal ECG patch monitors trial, the study compares the carnation patch system with the Zio patch, as these represent the current standard for continuous recording of an ECG for extended periods. The study will encompass monitoring for AF, syncope, presyncope, palpitations and supraventricular Tachycardia, and its primary focus of the study will observe the ECG signal quality, while the secondary focus will observe device comfort. The aim of research is to confirm the clinical value of a new P-wave sensitive recording vector combined with an easy-to-use long-term cardiac rhythm monitoring patch system, the CAM System. The P-wave is a critical aspect of the electrocardiogram and a key finding for proper arrhythmia diagnosis. The CAM system is optimized for both ease of use and for maximum P-wave clarity for arrhythmia diagnosis. *Note - Since this review was completed in 2017-2018, the study findings have been published. Their findings indicate that the rhythm specificity was higher in the CAM system compared to the Zio XT patch (Rho et al, 2019).*

Another study performed in 2017 was a 'randomised clinical trial of early prolonged ambulatory cardiac monitoring after stroke; interim analysis'. The study was performed due to the fact that paroxysmal atrial fibrillation often goes undetected by the short-duration holter monitors. There is a need for a patient-friendly long-duration cardiac monitoring system for stroke patients which can be performed without significant delay from the index event and with superior yield to Holter ECG's. the study conducted randomised controlled trial of cardiac monitoring after an ischaemic stroke or TIA to increase detection of paroxysmal atrial fibrillation using a wearable water-proof adhesive cardiac monitoring patch that can be fitted immediately by the clinician early after the index event for up to 14 days or

a standard Holter ECG. The interim analysis detected PAF in 4/17 cases in the active arm and 0/16 cases in the control arm. The commonest arrhythmias detected were atrial tachyarrhythmias followed by PAF. Those in the control arm of Holter ECG's had significant delays to initiate cardiac monitoring due to scheduling delays and patient non-attendance. There were no device-attributable serious adverse events. The conclusion of the study stated that the convenience of the Zio Patch cardiac monitor substantially increased the uptake and efficiency of cardiac monitoring early after ischaemic strokes and TIA.

**Below is a list of multiple AF monitors with active licensing as medical devices. These do not all fit the specifications of the research request, but this is a clear representation of the market.**

Device Name	Manufacturer
Insertable cardiac monitors	
Reveal LINQ	Medtronic Inc.
Reveal XT	Medtronic Inc.
Reveal PLUS	Medtronic Inc.
External loop recorders	
ER920-AF Series Event Recorder	Braemar Manufacturing, LLC
ER900L-RT Event Recorder	Braemar Manufacturing, LLC
PER 900	Braemar Manufacturing, LLC
Heart 2006 Dual Channel Loop Event Recorder	Aerotel Medical Systems (1998) Ltd.
Vitaphone 1-Channel ECG Loop Recorder	Vitasystems GmbH
Vitaphone 3-Channel ECG Loop Recorder	Vitasystems GmbH
GemsTrak AF Monitor	Universal Medical Inc.
Heartrak Smart AF	Universal Medical Inc.
Cardioblue Recorder	Meditech Ltd.
CardioCall VS20	Spacelabs Healthcare Ltd.
CG-6106 Personal 1-Lead ECG Transmitter With Memory	LifeWatch Technologies Ltd.
CG-7100 Personal 12-Lead ECG Transmitter With Memory	LifeWatch Technologies Ltd
Ambulatory Holters	
Chroma RZ153c Holter	ScottCare Corporation
3 Channel Digital Holter Recorder	BIOX Instruments Co. Ltd.
Ambulatory ECG System/Holter Recorder	BIOX Instruments Co. Ltd.
DL900 Series Holter Monitor	Braemar Manufacturing, LLC
Holter ECG Model DL800	Braemar Manufacturing, LLC
SEER 1000	GE Medical Systems Information Technologies, Inc.
SEER 12 Holter Recorder	GE Medical Systems Information Technologies, Inc.
SEER Light	GE Medical Systems Information Technologies, Inc.
CardioMem CM 4000	Getemed Medizin-Und Informationstechnik Ag
CardioMem CM 3000	Getemed Medizin-Und Informationstechnik Ag
Lifecard CF Recorder	Spacelabs Healthcare Ltd.
Lifecard 12 Recorder	Spacelabs Healthcare Ltd.
Spiderview Holter	Sorin Group Italia S.R.L. (Sorin CRM)
DigiTrak XT	Philips Medical Systems
H12+ Holter Recorder	Mortara Instrument Inc.
H3+ Holter Recorder	Mortara Instrument Inc
CardioMera Recorder	Meditech Ltd.

QRS Q100/HE Digital Recorder	National Biomedical, LLC DBA QRS Diagnostic
AR12 Plus	SCHILLER AG
AR4 Plus	SCHILLER AG
FD5 Plus	SCHILLER AG
FD12 Plus	SCHILLER AG
MT-101	SCHILLER AG
External Mobile Cardiac Telemetry	
Telesentry Recorder Model TS01	ScottCare Corporation
HeartView	Aerotel Medical Systems (1998) Ltd.
AliveCor Mobile ECG	AliveCor, Inc.
Vitaphone Tele-ECG Card	Vitasystems GmbH
HeartCheck Handheld ECG Monitor	CardioComm Solutions, Inc.
HeartCheck ECG PEN	CardioComm Solutions, Inc.
Infinity M300	Draeger Medical Systems, Inc.
Telemetry Transmitter	Mortara Instrument Inc.
ECGBT2	Norav Medical
SelfCheck 1/12-Lead ECG Event Monitor	LifeWatch Technologies Ltd.



### Appendix 3: Scoping Review Findings

	Device Category	Reference	Where?	When?	Sample size	Type of Study/Methods	Devices used?	Number of devices used	AF screening?	CVA population?	Length of time?	Findings	Included to next stage? & Reason.
<b>Non-ECG monitoring &amp;</b>	Pulse palpation.	Fitzmaurice et al, 2014.	United Kingdom Multi-site (n=50).	2001-2003.	N= 425.	Randomised Controlled Trial.	Pulse palpation & ECG.	1 (ECG).	Yes.	Yes.	Seconds - Opportunistic/systematic screening.	N= 149 episodes of AF identified.	No. Not continuous monitoring (-).
<b>ECG screening (multi lead)</b>	Blood pressure machine.	Wiesel et al, 2013.	United States of America.	Not reported.	N=139.	Study.	Microlife BP monitor & Heartrak 2; Mednet Healthcare, Ewing, New Jersey).	2: BP and ECG recording .	Yes.	Yes.	Daily recording for 30 days.	2 individual s with no history of AF, had AF diagnosed .	No. Not continuous monitoring (-).
	Blood pressure machine.	Gandolfo et al, 2015.	Italy	Not reported.	N=207	Observational Study	AFib model BP3MQ1-2D (Microlife USA, Dunedin, FL)	2: BP and ECG recording .	Yes	Yes	10-minute session: 48 hours after stroke.	N=38 individual s identified with AF. Failed to diagnose n=4 individual s. Led to false identification of AF in n=2 individual s.	No. Not continuous monitoring (-).
<b>Handheld technology &amp;</b>	Single lead monitoring device &	Levin et al, 2014.	Sweden	Not Reported .	N= 249.	Study.	Zenikor-EKG; Zenicor Medical Systems AB)	2: Handheld device and	Yes	Yes	Intermittent monitoring (10 seconds; twice a day) for 30-day	Total N= 17	Yes, continuous monitoring used but

ECG screening (multi lead)	Holter monitor.						& Holter monitor (Braemar DL700 analysed by Aspect 3.81R3a; GE Health-care, Chalfont St. Giles).	Holter monitor.			period and 24-hour Holter monitor.	diagnosed . 15 with intermittent and 2 with Holter monitor.	noted not >72 hours (-).
	Single lead monitoring device & 12 lead ECG & Holter monitor	Engdahl et al, 2013.	Sweden	Not reported.	N=848	Study	Zenacor Medical Systems AB	Up to 3 devices: Handheld device and 12 lead ECG & potential of Holter monitor.	Yes	Yes	Daily 20-30 seconds of ECG for 2 weeks.	10 diagnosed with ECG. 30 diagnosed with AF using handheld monitor.	Yes. For discussion. Ability of hold was assessed by study nurse. Those who had poor signal offered opportunity to have Holter (+).
	Holter monitor and handheld device	Poulsen et al, 2017.	Denmark	2012-2015	N=100	Study	Zenacor-ECG (enicor Medical Systems AB, Stockholm, Sweden) And Holter monitor (A Lifecard CF (Del Mar Reynolds Medical, Irvine, Calif.) ).	2 devices: Holter monitor and handheld device	Yes	Yes	30 seconds twice a day: 30 days (handheld device); 5-day monitoring wearing Holter monitor.	20 identified with AF. handheld device. Only 10 of these noted with both methods.	Patient experiences relating to bother noted. Ability to hold device impacted quality of thumb holding device.

	Holter Monitor and handheld device.	Doliwa Sobocinski et al., 2012	Sweden	Not reported	N=249	Clinical Trial	Braemar DL700 analysed by Aspect 3.81R3a; GE Healthcare and Zenicor EKG*; Zenicor Medical Systems – 10 s Rhythm Recordings once in the morning and once in the evening for 30 days	Handheld device	Yes	Yes	30 days (intermittent)	AF diagnosed in n= 17 patients	Intermittent screening. May not be suitable for all in stroke population.
ECG screening (single lead) ECG screening (multi lead)	Monitoring patch & Holter monitor.	Lumikari et al. 2019	Finland	Not reported.	N=57	Clinical Trial	Bittium Faros 180° ECG  ECG machine not reported.	2 devices.  Single lead monitor & ECG.	Yes	Yes	Up to 4 weeks.	New AF detected in 12.3% (n=7) of patients. Four of which were asymptomatic.	Yes. Note. Skin irritation reported (n=2); 2 devices damaged due to shower.
ECG screening (single lead)	Monitoring patch	Akiyama et al, 2017.	Japan	2016..	N= 1	Case study	Duranta	1 device. Single lead monitor.	Yes	Yes	11 days	AF noted on 5 <sup>th</sup> and 9 <sup>th</sup> days after stroke.	Yes.
ECG screening (multi lead)	Wearable devices	Yayehd et al, 2015.	Italy	Not reported	N = 56.	Observational study.	Spider Flash	2 channel ECG device (worn like necklace)	Yes	Yes	21 days	AF identified in n=2 patients.	Yes.



ECG screening (multi lead)	Holter 24 monitors	Sampaio et al, 2018.	Brazil	Not reported.	N=52 (n=26 controls + N=26 stroke)	Clinical trial	DMS 300-8 and DMS 300-9 Analysis software: DMS CardioScan II software (DM Software Inc. Stateline, NV, USA) Transmission software: Policardiógrafo IP®, PoIP, eMaster, Belo Horizonte, MG, Brazil	1 device. Single lead monitor.	Yes	Yes	24-hour Holter.	Equal performance noted between PoIP and Holter within the first 24 hours. AF noted in n= 1 patient with holter and n= 7 patients with PoIP. (-) data transmission issues noted.	Yes. Used Holter monitor only. Potential for PoIP technology to be used with other technology.
ECG screening (single lead) & ECG screening (multi lead)	Single lead monitor and continuous ECG recorder.	Sejr et al, 2019.	Denmark	2013-2017	N= 1412	prospective cohort study	R.Test Evolution 4 (NorDiaTech, Paris, France) & Life Card CF digital ECG recorder from Spacelabs Healthcare Diagnostic Cardiology.	2 devices: Single lead monitor and continuous ECG recorder	Yes	Yes	2-day continuous recording	N=32 in ELR recordings and continuous recordings	? Automatic external loop recorder not considered appropriate as single tool for screening for AF. (-)
ECG screening (multi lead)	Holter monitor. Bedside ECG.	Ross et al, 2018.	Not reported.	2013-2014.	N= 1,153	Study	Not stated. Analysis software: Apoplex Medical	2 devices: Holter monitor.	Yes	Yes	Bedside ECG monitoring. 24 h Holter ECG	Results differed between risk of AF in those	Stroke analysis software found to be highly

							Technologies, Pirmasens, Germany)	Bedside ECG. & analysis software (stroke risk analysis, SRAclinic[ C], Apoplex Medical Technologies, Pirmasens, Germany )				with PAF and persistent. 289 identified as having a medium – high risk of AF.	sensitive at detecting risk of AF but cannot be used alone to diagnose AF.
<b>ECG screening (single lead) &amp; ECG screening (multi lead)</b>	ECG and Holter monitor	Sanak et al, 2015.	Czech Republic	2011-2014.	N=105	Study.	24-hour Holter monitor: Philips-ZyMed DigiTrack plus/DigiTrack XT (Philips, Netherlands) & 3-weeks Holter = MDT Vitaphone Loop 3100 BT (Vitaphone GmbH, Germany ECG type not stated.	3 devices. ECG and Holter monitor.	Yes.	Yes.	24-hour Holter monitor and 3 weeks Holter monitor.	N=9 PAF identified.	3 weeks screening increased screening rate.
<b>ECG screening (single lead)</b>	Holter monitor and ECG.	Arevalo-Manso et al, 2016.	Spain.	2011-2012.	N=76.	Observational study.	ECG: DASH 2500, General Electric	2 devices. ECG monitor and	Yes.	Yes.	Continuous ECG monitoring performed for 2 days.	N=20 individuals	Arrhythmia software noted to identify

& ECG screening (multi lead)							Healthcare with software; GE- EK Pro arrhythmia algorithm v.11  OR Mod. 90369, Spacelabs Healthcare, Issaquah, Washington, USA Cardiac monitor: DASH 5000, General Electric Healthcare, Milwaukee, Wisconsin, USA	Holter monitor.				Holter monitor; 24 hours.	identified with AF.	more episodes of AF compared to other equipment.
ECG screening (single lead)  & ECG screening (multi lead)	Holter & 12 lead ECG.	Thakkar and Bagarhatta 2014.	India.	Not Reported	N= 52.	Study.	24-hour Holter monitor: SCRIBE, Mortara in- struments, Inc. Milwaukee USA  12 lead ECG; not reported.	2 devices; Holter & 12 lead ECG.	Yes.	Yes.	Holter monitor; 24 hours.	N=3 individuals identified with AF.	Screening consecutive patients led to the identification of AF.	
ECG screening	Holter & 12 lead ECG.	Suissa et al, 2014.	France.	2011- 2012.	N=362.	Prospective observational study.	Infinity M300 telemetry for the conventional	2 devices: ECG and Holter.	Yes.	Yes.	Few hours in non-AF patients.	N=22 individuals	Early and continuous monitoring associated	

g (single lead) & ECG screening (multi lead)							stroke unit area. 12 lead ECG: not reported.					identified with AF.	with diagnosis of AF.
ECG screening (single lead) & ECG screening (multi lead)	Holter monitor & 12 lead ECG.	Higgins et al, 2013.	United Kingdom (Glasgow).	2010-2011.	N=100.	Randomised Controlled Trial.	Novacor R-test Evolution 3 device	2 devices: Novacor R-test Evolution 3 device & ECG.	Yes.	Yes.	24 Holter monitor and 7-day cardiac monitoring.	N= 44% PAF noted.	Yes. Continued monitoring advantageous in this population.
ECG screening (single lead) & ECG screening (multi lead)	Holter monitor & 12 lead ECG.	Yodogawa et al, 2013.	Japan.	2006-2011.	N=68.	Prospective trail,	DX-6521(Fukuda DenshiCo.Ltd.,Tokyo,Japan ECG type not reported.	2 devices.	Yes.	Yes.	24-hour Holter monitor.	7 asymptomatic patients identified as having AF.	Yes.
ECG screening (multi lead)	Holter monitor.	Gaillard et al, 2010.	Not reported.	Note reported.	N=98.	Study.	Not reported in abstract.	Not reported in abstract.	Yes.	Yes.	Post 24 hour.	N=9 individual's notes to have AF.	NB. Not able to open full article. Note: this study considered patient population after stroke whose

													Holter monitor was negative. ++
ECG screening (multi lead)	Holter monitor.	Riley et al, 2014.	USA.	Not reported.	N=1990	Study.	Transtelephonic ECG monitoring (TTM). Type not specified.	1 device; not reported	Yes.	Yes.	3-week at 6 and 12 months follow up.	N=12 with stroke had AF diagnosed .	No. Mainly focused on stroke risk after ablation.
ECG screening (multi lead)	Holter Monitor.	Grond et al, 2013.	Germany (multi centre)	2010-2011.	N= 1135	Prospective cohort study.	Holter Monitor. Lifecard CF, Spacelabs Healthcare, Issaquah, WA.	1 device: Holter monitor.	Yes.	Yes.	72 Holter ECG.	N=49 individuals diagnosed with AF with up to 72 hours of screening.	Yes. Improved screening of AF in asymptomatic patients.
ECG screening (multi lead)	Holter Monitor	Wachter et al, 2013.	Germany .		N=281.	Prospective observational trial	Not reported.	1 device.	Yes.	Yes.	7-day Holter monitor.	N=33 individuals had AF noted as a result of screening.	Yes.
ECG screening (multi lead)	Holter monitor.	Miller et al, 2013.	United States of America.	2009-2011.	N=156.	Retrospective analysis	CardioNet® (CardioNet, Conshohocken, PA, USA	1 device.	Yes.	Yes.	1-30 days of monitoring	N=27 individuals noted to have AF.	Yes. Mailed to patient. Self-adhered. Results indicated 21 days of screening needed.

ECG screening (multi lead)	Holter monitor.	Alhadramy et al, 2010.	Not stated (not, corresponding author Canada)	2005-2006.	N= 1128	Retrospective.	Not stated.	One device; Holter.	Yes.	Yes.	Not stated; Mean time 22.6 hours.	N= 39 individuals noted to have AF.	Yes. Not the focus but in the discussion, they argue and quote someone else, that if the person is screening within 72 hours after stroke, this improves screening rates.
ECG screening (multi lead)	ECG.	Deif et al, 2013.	Australia.	2011.	N= 2802	Study.	Not stated.	2 devices.	Yes.	Yes.	Single ECG recording.	N= 12	No. Not continuous.
ECG screening (single lead) & ECG screening (multi lead)	Holter monitor & 12 lead ECG.	Suissa et al, 2013.	France.	2007-2010.	N= 1166	Study.	Infinity Central Station (Dräger, Lübeck, Germany)  ECG type not specified.	2 devices.	Yes.	Yes.	24 hour monitoring.	N=96 diagnosed with AF.	Yes. Continuous monitoring whilst in hospital noted to be beneficial at diagnosing AF.

ECG screening (single lead) & ECG screening (multi lead)	Holter monitor and 12 ECG.	Gumbinger et al, 2012.	Germany	Not reported.	N= 370	Pilot study.	Infinity Delta; Draeger Medical Systems Inc., Luebeck, Germany	3 devices; Bedside monitor, ECG and Holter monitor.	Yes.	Yes.	24 hours.	N=44 individuals noted to have AF.	Yes. For discussion. Read discussion, Holter monitor noted to have no additional benefit compared to continuous monitoring ECG with intermittent analysis by trained staff.
ECG screening (single lead) & ECG screening (multi lead)	Holter monitor and bedside ECG monitoring.	Sposato et al, 2012.	Argentina	2007-2008.	N=155.	Retrospective.	Holter: Infinity telemetry system (Draeger Medical, Telford, PA. Hospital Bedside monitors: Infinity Vista XL ECG; Marquette Dash 4000 Pro (GE Health-care, Chalfont St. Giles, UK), and Eagle 4000 (GE Health-care)	2 devices.	Yes.	Yes.	Note stated; appears 3 days admission for most patients. 71% of patients diagnosed within 24hrs.	N=21 patients diagnose with AF.	Yes. Immediate and Continuous monitoring improves AF screening rates.

							multi-lead ECG patient monitors						
ECG screening (single lead) & ECG screening (multi lead)	Holter monitor; ECG and continuous ECG bedside monitoring.	Lazzaro et al, 2012.	United States of America.	2007-2008.	N=133.	Study.	Not stated.	3 devices.	Yes.	Yes.	22-24 hours of monitoring.	N=5 individuals identified to have AF.	Yes. Screening rate of AF was noted to be higher in Holter monitor than Continuous cardiac telemetry (during hospitalisation)  Note: discussion states although the length of assessment is important, the type of device used, and the expertise of the person analysing is also important.



<b>ECG screening (multi lead)</b>	Continuous 12 lead ECG.	Fernandez et al, 2014.	France.	2012.	N=187.	Study	12 lead ECG: CSM Philips IntelliVue MP50 system, 24-hour ECG monitoring	1 device: ECG.	Yes.	Yes.	24 hours.	N=19 individuals identified with AF.	Continuous screening identified AF.
<b>ECG screening (multi lead)</b>	ECG (bedside monitor)	Scheitz et al, 2015.	Not reported.	2011-2013.	N= 1228	Study.	Bedside patient monitor Philips, IntelliVue MP50	1 device: ECG.	Yes.	Yes.	2-4 days monitoring.	Unknown AF identified in n=114	(-) Bedside monitoring. Cost implications. Impact on daily activities.

## Appendix 4: Criteria for Device

- The device can be used outside of a hospital setting.
- It is easy to use.
- Device itself, and the data gathered on it, should not leave Scotland, ideally held on NHS premises and the company accesses the data from there.
- It is CE marked.
- Cost is ideally less than £400 for 14-day monitoring period.
- Data transferred to a cloud space.
- Ideally multi-use.

Criteria category	Definition/ criteria of Assessment
CE marking?	If a device is marked with the initials CE (Conformité Européene), this ensures the device conforms to European standards of safety. Such a requirement is essential for use within the NHS and for use within the public population (GOV, 2018).
Recording time.	Recording time should be documented. For purposes of this study 72 hours of continuous recording time is required.
Available for home use?	Available to be purchased and used within home environment (not requiring hospital stay)
Evidence of ease of use?	Evidence of feedback regarding the ease of using the device (application, charging, reapplying etc).
Evidence of patient comfort?	Evidence of feedback regarding the comfort of the device (specifically no evidence of skin irritation when wearing the device). Evidence of being user friendly.
Specificity/ sensitivity	Evidence of the ability of the device to identify AF.
Single/multi-use?	Evidence on whether the device is single or multipurpose use.  Single use: infection control implications reduced.  Multi use: reusable devices can be used on more than one patient; more cost effective. Easy to clean?
Cost?	Price is documented.
Control of data?	Documented evidence of:  Who owns the data?  What data is collected?  Where is the data sent and stored?  When is the data deleted?  How is the data transferred and reported?
Battery	Chargeable? Battery length?

## Appendix 5: Screening and Recruitment Procedure

### **Screening:**

Patients suitability screened by clinical team: i.e. treating consultant/stroke specialist nurses/research team (such as research nurses).

### **Information given:**

Patients given PIS and copy of consent form by ward staff/consultant/clinical specialists/ research nurses. Contact details of UoS included in PIS.

### **Referral:**

Patient given contact details of UoS and requested to contact research team or patients name and contact details will be passed onto UoS research team by clinical team via email or over the telephone (if patient provides consent to be contacted to further discuss the study).

### **UoS Initial Contact:**

UoS contacted or UoS contacts participant to discuss study over the phone/ arrange suitable time for meeting.

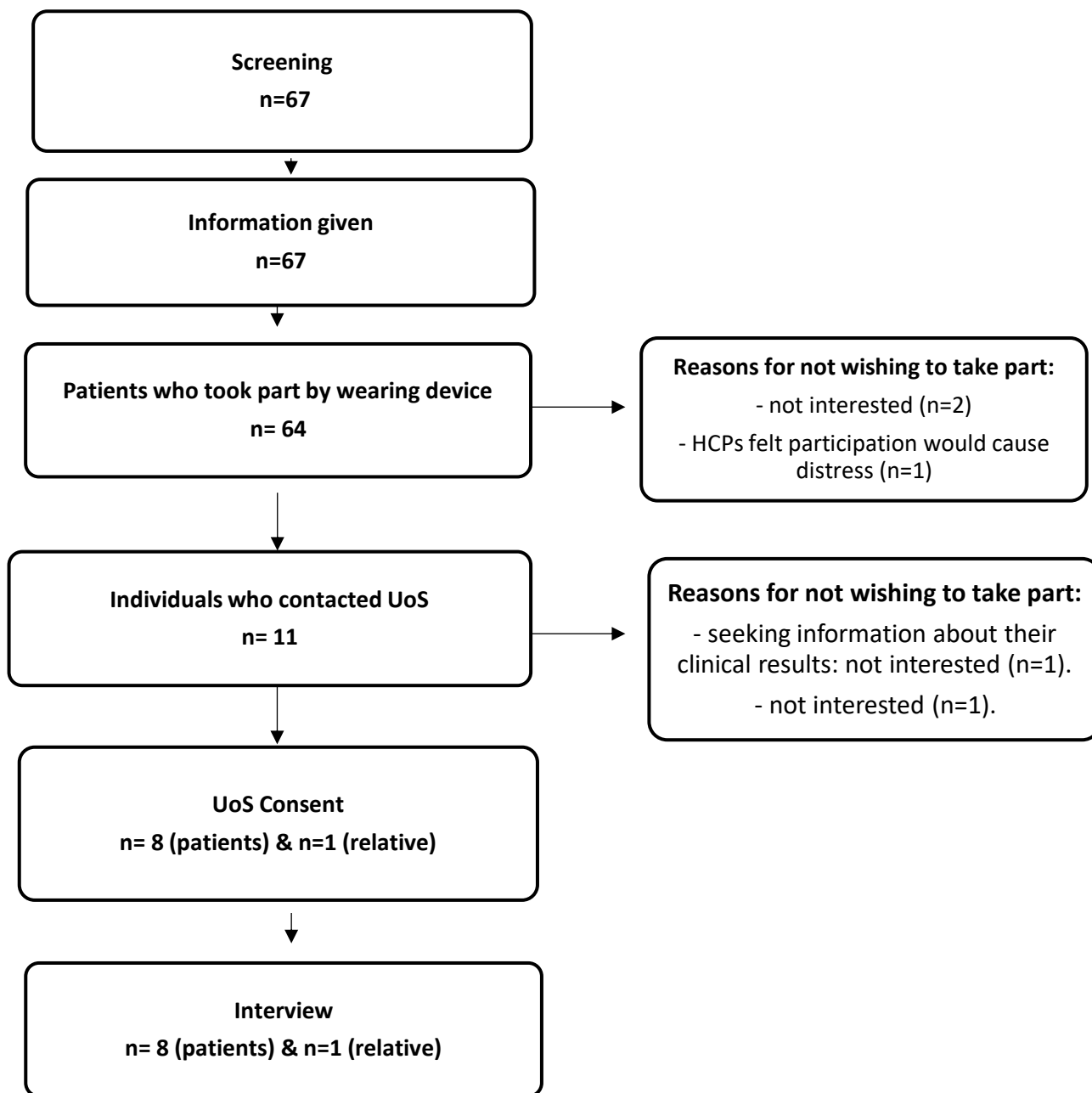
### **Consent:**

Consent to be taken by Research Assistant/ Research Associate (UoS/GSA) prior to interview. This can be completed over the phone.

### **Interview:**

Interview conducted with participant (over the phone/in person) in persons home/ hospital outpatient setting/UoS grounds/ at a time and place which is most convenient to patient. UoS team liaise with clinical team to arrange the interview to be on the same day as other appointments if possible to reduce patient burden. Completed by UoS team.

**Appendix 6: Flow chart: Screening and Recruitment Procedure**



## Appendix 7: Schedule of Procedures

Procedures	PART ONE: Current Practice (led by GSA) (Also referred to as Work Package 1) Patients with previous diagnosis of AF			PART TWO: New Device(s)/Future (led by UoS) (Also referred to as Work Packages 2-4) Patients with no previous diagnosis of AF				
	Screening	Baseline	Follow up 1 (GSA)	Screening	Baseline (Part 2)	Follow up 1 (UoS)	Follow up 2	Follow up 3
Initial approach screening	**X			**X				
Preliminary consent to contact	**			**				
Informed consent		X			X			
Demographic/ medical history		X			X			
Quantitative Data Collection: Observation of care pathway		X	X		X	(x)	(x)	(x)
Quantitative Data Collection: Survey			X			(x)	(x)	(x)
Qualitative Data Collection: Focus Group			X			(x)	(x)	(x)
Qualitative Data Collection: Interview (phone/face to face)			X			(x)	(x)	(x)
Qualitative Data Collection: Interactive Workshop			X			(x)	(x)	(x)

As outlined throughout the protocol to explore the current pathway, patients may take part in Part One or Part two. NB: There is a different inclusion and exclusion criteria applied to each part of this study.

Please note, participant may take part in data collection on one or more occasions. Research procedures which are highlighted in brackets may be performed several times during the project. The number of times any of the methods is repeated, is dependent on consent given and the participants' availability. \*\* = Activity performed by HCP

### Schedule of Procedures: Other Participants

Procedures	PART ONE: Current Practice (led by GSA) (Also referred to as Work Package 1) Observation of patients with previous diagnosis of AF			PART TWO: New Device(s)/Future (led by UoS) (Also referred to as Work Packages 2-4) Observation of patients with no previous diagnosis of AF				
	Screening	Baseline	Follow up 1 (GSA)	Screening	Baseline (Part 2)	Follow up 1 (UoS)	Follow up 2	Follow up 3
Initial approach screening	**X			**X				
Preliminary consent to contact	**			**				
Informed consent		X			X			
Demographic/ medical history		X			X			
Quantitative Data Collection: Observation of care pathway		X	X		X	(x)	(x)	(x)
Quantitative Data Collection: Survey			X			(x)	(x)	(x)
Qualitative Data Collection: Focus Group			X			(x)	(x)	(x)
Qualitative Data Collection: Interview (phone/face to face)			X			(x)	(x)	(x)
Qualitative Data Collection: Interactive Workshop			X			(x)	(x)	(x)

### Schedule of Procedures: Healthcare Professionals (HCP)

Procedures	PART ONE: Current Practice (led by GSA) (Also referred to as Work Package 1) Observation of patients with previous diagnosis of AF			PART TWO: New Device(s)/Future (led by UoS) (Also referred to as Work Packages 2-4) Observation of patients with no previous diagnosis of AF				
	Screening	Baseline	Follow up 1 (GSA)	Screening	Baseline (Part 2)	Follow up 1 (UoS)	Follow up 2	Follow up 3
Initial approach screening	X			X				
Informed consent		X			X			
Demographic/ medical history		X			X			
Quantitative Data Collection: Observation of care pathway		X	X		X	(x)	(x)	(x)
Quantitative Data Collection: Survey			X			(x)	(x)	(x)
Qualitative Data Collection: Focus Group			X			(x)	(x)	(x)
Qualitative Data Collection: Interview (phone/face to face)			X			(x)	(x)	(x)
Qualitative Data Collection: Interactive Workshop			X			(x)	(x)	(x)

**Appendix 8: Amendment History**

Study Name: \_\_\_\_\_

<b>Amendment Number</b>	<b>Protocol Version</b>	<b>Date of Amendment (submission &amp; approval)</b>	<b>Amendment Type (Major / Minor)</b>	<b>Author(s)</b>	<b>Amendment Summary</b>	<b>Justification for Amendment</b>

NB: Any protocol amendments will be submitted to the Sponsor for approval prior to submission to the REC.



## **Appendix 9: Telephone Interview Process**

*Introductions (name and role within UoS) & confirmation of suitability of time (e.g. Is now a good time to speak, or would you like me to call you back at a better time?)*

*Thank you for agreeing to take part in this interview.*

*Did you get the information leaflet about the research study from the nurse from NHS Lanarkshire? The hospital is using a different heart monitor device and the University of Strathclyde is looking at how this new service has gone. We would like to ask you some questions about how you found the heart monitor device. We would like to ask about experiences of wearing the heart monitor device. Have you been able to read the information sheet the nurse gave you? (if yes proceed) (If not, provide opportunity to ring at a different day/time or if helpful to patient, offer to read the PIS over the telephone with the patient - And then ring back for an interview a different day). Do you have any questions? (Answer questions /if no further questions proceed).*

*This conversation will be audio recorded to record our conversation. If you are happy, I am going to turn on the voice recorder.*

*(if yes, turn on voice recorder).*

*So, before we begin, I will read some statements. I will ask you to say yes or no for each statement.*

*Please tell me if you do not understand any statements.*

*Please tell me if you would like me to repeat anything.*

*We can have a break at any time. We can stop at any time.*

1. I have read and understood the information sheet
2. I have had time to think about the information and ask questions.
3. I am happy with the answers to these questions
4. I am happy to take part in 1 interview about my experiences.
5. I understand that I can stop at any time. I do not have to give a reason.
6. I understand the interview to be audio-taped and typed up.
7. I understand that research and hospital staff will be told about the study, but my name will never be used.
8. I understand that my GP will be told I am in the study.
9. I understand that quotes from the interview might be used in academic journals, reports, and conferences. I understand that my name will never be used.
10. I understand that hospital staff involved in this study might look at my medical notes. I am happy with this.
11. I am happy to take part in this study.

Can you confirm your name?  
(Turn off recorder)

Note: Start new file for audio recording for the interview.

## Appendix 10: Topic Guide

### Process Evaluation for Technology Enabled Atrial Fibrillation Detection in Secondary Care in Scotland: Topic Guide: Patients

These are the topic guides we will draw on for our qualitative research on patients' experiences of technology enabled atrial fibrillation screening in secondary care in Scotland. These questions have been split into two phases to reflect the different work packages (see below). These topic guides will influence all of our activities which include interviews (face-to-face and telephone), focus groups, workshops and surveys.

#### Work Package 1 = Current experiences and expectations

##### **1.1 Can you tell me about your stroke?**

*Potential prompts (if not mentioned throughout the discussion):*

- a) How was it diagnosed?
- b) Can you tell me about your first meeting with a clinician [this could be GP visit /specialist consultation for AF/stroke]?
- c) Did you have any treatments for this? If so, where was this?
- d) Did your stroke leave you with any limitations, please specify.

##### **1.2 Did you have investigations for any heart arrhythmias?**

If yes, can you tell us about your experience of this?

##### **1.3 What are your experiences of AF Services/appointments?**

*Potential prompts (if not mentioned throughout the discussion):*

- a. How/was your heart rate or rhythm monitored by GP or clinicians before your diagnosis?
- b. Can you describe this experience?
- c. Do you have any comments about the care?

##### **1.4 What (if any) are your thoughts or experiences of the AF screening device/monitor used in your care?**

##### **1.5 Would you like to tell us anything else about your experience that we may have missed?**

**2.1 Tell us about your experience of using the [AF device] so far?**

*Potential prompts (if not mentioned throughout the discussion):*

- a) Can you explain, how heard about this device? Who invited, you to take part and how did they do this?
- b) What has the device been like so far?

**2.2 Can you tell me about your stroke?**

*Potential prompts (if not mentioned throughout the discussion):*

- a) How was it diagnosed?
- b) Can you tell me about your first meeting with a clinician [this could be GP visit /specialist consultation for AF/stroke]?
- c) Did you have any treatments for this? If so, where was this?
- d) Did your stroke leave you with any limitations, please specify.

**2.3 Have you ever had similar screening for AF or other heart arrhythmias?**

*Potential prompts (if not mentioned throughout the discussion):*

- a) Have you used any other products to measure your rate or rhythm (to identify AF or another heart arrhythmia)?
- b) If so, can you tell me about this?

**2.4 The next questions are asking about your opinion of the introduction of this device to the service.**

*Potential prompts (if not mentioned throughout the discussion):*

- a) What do you think the purpose of the device is?
- b) How did the use of this device impact your care?
- c) Can you tell me your thoughts about the device? Why?
- d) What did you think of the way the device looked?
- e) What was the device like to wear? (Further prompt: if needed) Was it comfortable?
- f) Did you have to alter your activities/life to use this device?
- g) If it was needed, would you be happy to wear this device again, if so, why?

**2.5 What did healthcare professionals say to you about the [device or service]?**

*Potential prompts (if not mentioned throughout the discussion):*

- a) Was it all understandable?

**2.6 Do you think this device changed your treatment?**

*Potential prompts (if not mentioned throughout the discussion):*

- a) How?

**2.7 Do you think there are any benefits or disadvantages of using this device?**

*Potential prompts (if not mentioned throughout the discussion):*

- a) How would you feel if you were given the device again?

Continued...

**2.8 What do you think about using other devices, or technology in your future care to screen or diagnose AF?**

*Potential prompts (if not mentioned throughout the discussion):*

- a) Can you explain these thoughts?

*Further potential prompts (if needed) (if not mentioned throughout the discussion):*

- b) What do you think are key things that the technology should be or do to be acceptable to screen patients for AF? (Acceptability/easy to use)
- c) Do you have any thoughts about the importance of the usability of the screening device? (Further prompt: if needed) is being able to use the device yourself important?
- d) Have you any thoughts about what the device is like to wear? (Further prompt: if needed) is comfort important? (comfort)
- e) Do you have any thoughts about trusting the device? (Further prompt if needed, to screen for AF/or about the storage of data?) (trust)

**2.9 Based on your experiences, what could help make the experience better in the future?**

**3.0 Would you like to tell us anything else about your experience that we may have missed?**

## **Appendix 11: Arrangement for Lone working (UoS)**

This guidance document was developed based upon guidance provided from the University of Strathclyde (Travel and Work Off University Campus: Staff and Students, June 2013).

It is preferred that researchers will attempt to conduct data collection activities in person (at local hospitals/NHS premises) or over the telephone. If the participant is unable to attend a local healthcare facility in person and does not wish to have a telephone phone call, the interviewer will at this stage offer to conduct an interview at the interviewees' home.

If this occurs the researcher(s) will follow the below pathway.

Prior to interview the relevant line manager/ colleague will be informed of:

- location of interview (address),
- time of commencement of interview,
- anticipated time of finishing,
- contact details of interviewer,
- contact details of interviewee.

The Interviewer will contact line manager/colleague before the interview and will contact the same individual following the interview. If the interview time is anticipated to be later than originally planned, the interviewer is expected to contact the colleague / line manager to inform them of this change. If the interviewer does not contact the designated person within this planned time frame, the colleague / line manager should first attempt to contact the interviewer. If they are not successful at this, the interviewee should be contacted to speak to the interviewer. If no contact is available, this should be escalated and advice from senior colleagues should be sought. Emergency contacts (University security/police) may be required in the event no contact is able to be achieved.

Prior to a conducting a home interview, researchers should complete the relevant risk assessment in line with the University of Strathclyde Lone working policy. The individual should also complete the relevant insurance document to ensure the University is informed of out of office working.

Any concerns or events should be documented, and the Principle investigator and Sponsor informed.