West of England Academic Health Science Network

Final report on the implementation and proof of value evaluation of a cardiac patch technology in a hospital setting

June 2023

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Affiliations

[1]West of England Academic Health Science Network, [2]Unity Insights, [3]North Bristol NHS Trust, [4]iRhythm Technologies Ltd.

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Assurance rating

*This report can be used for context and background information	
**This report can help inform decision making, when considered with other information	✓
***This report is the best available evidence to date	

Disclaimer

This final report presents the findings of an analytic evaluation of the ZIO by iRhythm device and service. The findings are those of the West of England AHSN and do not necessarily represent the views of iRhythm Limited.

Declaration of Interest Statement

The West of England AHSN supports innovators to bring their innovations to the NHS. This may, where appropriate, include supporting evaluation delivery to our member organisations, and innovations we have supported. Whilst these evaluations are independently conducted, for transparency we disclose our dual role where applicable. In this report we note the dual role of the West of England AHSN to facilitate and evaluate ZIO by iRhythm.

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Executive summary

Background

The West of England Academic Health Science Network (AHSN) has been working with North Bristol NHS Trust (NBT) to assess the benefits for patients and staff of a cardiac monitoring solution that is seen as a technological advancement from traditional electrocardiogram (ECG) Holter monitoring systems, and focusing on supporting pathway transformation. Using a real-world evaluation approach to better understand the impacts of the project, this report shares the findings from the project implementation and ambulatory evaluation within NBT's cardiology pathway.

Clinical context

Cardiac arrhythmias are any abnormality of the heart's rhythm such as a slow, fast, or irregular heartbeat. Over 1.2 million people in the UK have an atrial fibrillation (AF) diagnosis, the most common type of cardiac arrhythmia with an estimated 500,000 more people who are undiagnosed. AF is linked to health complications and has been shown to independently increase the risk of death. Early and appropriate identification and treatment reduces mortality and morbidity and is linked to better outcomes.

The Holter monitor is the predominant form of ambulatory ECG monitoring in the UK and is initially fitted by a healthcare professional in a clinical setting. Holter systems have several drawbacks including trips to healthcare facilities for fitting, feeling bulky during wearing and the need for removal while washing.

Adhesive single lead devices have been emerging over the last 20 years as an improved method of ECG remote monitoring. These patch technologies have been shown to outperform Holter monitors in diagnosing cardiac arrhythmias. ZIO® by iRhythm (Zio) is an example of a continuous ambulatory monitoring patch technology used to detect cardiac arrhythmias. The service provided by iRhythm Technologies Limited (iRhythm) means Zio monitors can be posted directly to and from the patient without the requirement for outpatient hospital visits. This is designed to take pressure off cardiac physiology services and improve patient experience.

Innovation deployment

In March 2021, the cardiology and stroke departments at the Trust utilised Artificial Intelligence (AI) in Health and Care Award funding to purchase the Zio patch technologies. As part of this work, significant pathway transformation took place throughout 2021 to create and refine a remote pathway incorporating the Zio Service.

Evaluation overview

The evaluation was a single-centre, retrospective cohort evaluation and compared four months of data from a cohort of participants from the cardiology pathway prescribed Holter devices pre-Covid (January – April 2019) with four months of data from a cohort of patients prescribed Zio patches post-Covid (January – April 2022). Self-reported data from patients using the Zio patch from both the cardiology and stroke pathways at NBT was analysed to ascertain the patient experience during the study period, as well as an NHS staff experience survey.

Objectives

The primary outcome was to ascertain the extent to which implementing this type of technology (Zio) in the cardiology pathway at the hospital demonstrated increased efficacy (diagnostic rate) and efficiencies (in particular, staff utilisation) in comparison to routine use of the existing Holter monitors in the setting.

The secondary objective was to identify additional advantages or disadvantages highlighted by implementing this type of technology at the hospital and to understand the experience of staff and patients.

Methods

As this was a retrospective, observational evaluation with routine outpatient data from NBT, the evaluation collected four months of data from a cohort of patients wearing Holter devices and this was compared with a four-month cohort of patients wearing Zio patches. At the time of the evaluation, Zio was the standard of care at the NHS site participating in this project and care received by patients involved in this study was not affected.

For this real-world evaluation, the project team worked with stakeholders to develop a logic model and identified outcomes were tested in the analysis as part of the programme theory.

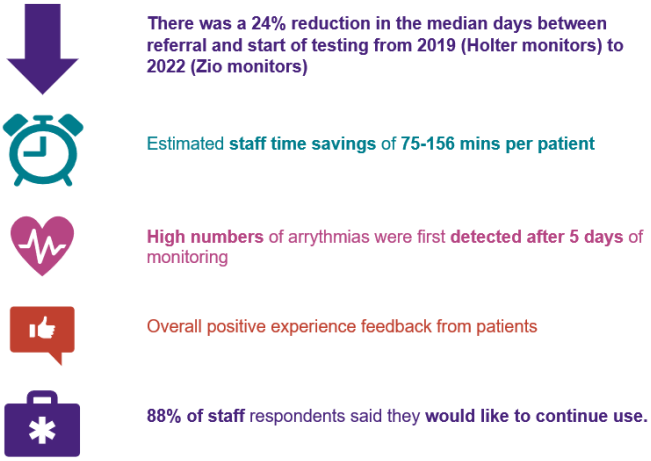
All data shared between the iRhythm, NBT and the West of England AHSN was anonymised and processed in line with GDPR guidance. Evaluation oversight has been provided through the project steering group, led by the West of England AHSN. The study was registered for service evaluation approval with the Quality Assurance & Clinical Audit Department at North Bristol NHS Trust

Findings

Evaluation of the implementation of the Zio device has demonstrated improved system efficiencies in the cardiology pathway at NBT by increasing the number of patients completing the diagnostic pathway, and a decrease in waiting list times.

Findings highlighted:

- An increase of 32% in referrals from 2019 to 2022.
- An increase in numbers of extended monitoring devices fitted from 2019 to 2022.
- A decrease in waiting list times.
- Reduced footfall of patients in the hospital, which was of particular benefit during the pandemic.
- Reduction in estimated staff time requirements in the Zio pathway by approximately two-thirds.



Cardiac physiologists were identified as the most impacted staff group in the Zio pathway, with an estimated 75-156 minutes saved per patient. This saved time means that cardiac physiologist capacity is likely to be released and could be utilised in alternative areas of the clinical service.

The evaluation has shown that Zio is particularly acceptable to patients. It is generally easy to use, well tolerated and comfortable. Staff also found Zio to be generally acceptable.

Limitations

Findings should be applied with caution due to the limited quantities of respondents to both the staff and patient surveys.

The voluntary nature of the survey may have led to stronger responses overall with those that felt either very positively or very negatively being more inclined to participate. In this evaluation, we did not collect data to measure how/if the Zio device would impact on healthcare inequalities affecting patients.

Conclusion

Evaluation of the implementation of the Zio device has demonstrated improved system efficiencies in the cardiology pathway at NBT and was found to be particularly acceptable to patients. It is generally easy to use, well tolerated and comfortable. Staff also found Zio to be generally acceptable.

Waiting times for monitoring have reduced, high numbers of arrhythmias were identified after the five-day monitoring period traditionally carried out by Holter monitors, and feedback from staff and patients was overall positive.

This information can be used, alongside the existing evidence base and other solutions available on the market, to inform decisions about future deployment of this type of technology. Alternative suppliers of patch technologies exist, with varying service models and supporting evidence/ accreditation, and any decisions to deploy should be subject to the procurement policies of the relevant organisation and should be company agnostic.

Next steps

In conducting this evaluation, several other areas of interest were highlighted:

(i) Environmental sustainability was noted on the staff survey due to the nature of Zio being a single-use device. However, the manufacturer states that 90% of the device is recycled or re-used. There are likely to be environmental benefits due to reduction in the number of hospital visits. Evaluation of this impact would be a useful focus of future projects.

(ii) Potential for the device being lost in the post (or unreturned to iRhythm by the patient) was also highlighted, as several devices failed to be returned. However, this can be balanced against the failure rate of Holter monitors due to patients not attending their appointments. Overall, the failure rate of the Zio device was not worse than that of Holter monitors.

(iii) There were comments from a small number of staff who felt the Zio reports were too long and difficult to understand. This may be an area in which iRhythm could conduct future follow-up to better understand or explore those opportunities which aid ongoing improvements.

Project background

During 2022-23 the West of England Academic Health Science Network (AHSN) worked with North Bristol NHS Trust (NBT) to assess the benefits for patients and staff of a cardiac monitoring solution that is seen as a technological advancement from traditional electrocardiogram (ECG) Holter monitoring systems.

In April 2021, digital healthcare company iRhythm Technologies Ltd was awarded funding from the Artificial Intelligence (AI) in Health and Care Award to trial its Zio product across multiple NHS hospital sites, including NBT's cardiology and stroke services.

The AHSN collaborated with NBT on a 'proof of value' project, which has focused on supporting and assessing the impact of pathway transformation. Using a real-world evaluation approach to better understand the impacts of the project, this report shares the findings from the evaluation within NBT's cardiology pathway.

Context

The NHS Long Term Plan aims to prevent 150,000 heart attacks, strokes, and cases of vascular dementia over the next 10 years. The plan is to do this by improving the detection and treatment of high-risk conditions that increase CVD risk.

Cardiac arrhythmias are any abnormality of the heart's rhythm such as a slow, fast, or irregular heartbeat[1]. Over 1.2 million people in the UK have an atrial fibrillation (AF) diagnosis, the most common type of cardiac arrhythmia, with an estimated 500,000 more people who are undiagnosed[2]. AF is linked to health complications such as heart failure, embolisms, and stroke, and has been shown to independently increase the risk of death[3]. Early and appropriate identification and treatment reduces mortality and morbidity and is linked to better outcomes[4,5].

Cardiac arrhythmias are diagnosed primarily through electrocardiogram (ECG) monitoring[1]. The Holter monitor, first introduced in the late 1940s, is the predominant form of extended ECG monitoring in the UK[4]. Holters are multi-lead monitors worn by a patient over a period of 24 hours, 48 hours, or 5 days[5]. The monitor is initially fitted by a healthcare professional in a clinical setting and is worn around the patient's neck with leads attached to specific points of their chest for the specified amount of time before being returned to the hospital.

Holter systems have several drawbacks. Firstly, patients must make several trips to a healthcare facility to have the device fitted and to return the device. This can be difficult for patients as transportation may be unavailable, costly, or time consuming. Some populations may be disproportionally affected by this, which may increase health inequalities. Some evidence for this can be seen by the higher numbers of patients that "did not attend" (DNA) in populations with higher levels of deprivation (data from BNSSG (Bristol, North Somerset, and South Gloucestershire) Outpatient DNA rates dashboard, January 2023). Additionally, Holter monitors are bulky and can interfere with daily activities such as attending the workplace and other activities of living. The device also must be removed and replaced during washing, which has been shown to negatively impact patient compliance[5,6].

Extended monitoring periods (over 24 hours) with high levels of patient compliance are recommended to increase the diagnostic yield of cardiac arrhythmias[4,7]. However, Holter device limitations mean that the monitoring periods are limited to a maximum of five days and often fail to detect arrhythmia events, especially in cases where the events are infrequent or asymptomatic[5]. Inconclusive results necessitate re-testing, which is inconvenient for the patient, and inefficient and costly for the NHS.

Waiting times for Holter devices are significant due to the high referral rates, the need for re-testing and the need to organise multiple hospital visits. Staff shortages in cardiac physiology and cardiologist roles, worsened by the Covid-19 pandemic[8], also increase patient waiting times as cardiac physiologists currently have the time-consuming role of extracting and analysing the data from the Holter monitors. Longer waiting times can result in delays in diagnosis, which carry the potential of increased risk of negative health impacts for patients and the potential for additional longer-term costs for the NHS. Furthermore, Covid-19 has impacted the service as fewer patients are able or prepared to visit healthcare settings, especially those from more vulnerable population groups[9]. Covid-19 has led to a shift to a "digital first" delivery of healthcare, which is less compatible with the use of the traditional Holter system[10].

Patch technology

Adhesive single lead devices that can be worn for longer periods of time (up to 30 days), known as "patch technologies/devices", have been emerging over the last 20 years as an improved method of ECG remote monitoring[7]. These patch technologies have been shown to outperform Holter monitors in diagnosing cardiac arrhythmias, and it has been suggested that this is due to the longer window for recording and the less obtrusive design resulting in improvements to patient compliance[4,11].

Intervention

Zio® by iRhythm (Zio) is an example of a continuous ambulatory monitoring patch technology and service, used to detect cardiac arrhythmias. There are other solutions available on the market, but Zio was selected independently by North Bristol Trust via the AI awards funding and is the example utilised within this pilot.

It has three components:

1. Zio biosensor: a wearable single-lead ambulatory ECG
2. ZEUS: a proprietary algorithm, regulated software platform and online portal that stores, analyses, and sorts the ECG data to generate a report of the findings Zio technical report
3. A clinically actionable summary of the recorded ECG data.

The Zio biosensor is placed on the person's left upper chest. It can be posted directly to the patient to be independently fitted at home. There is also an option for the device to be fitted in clinic for patients who need more support. It records a continuous beat-to-beat ECG for up to 14 days and can be worn 24/7, including while washing. The patient can also press a button to register when they feel symptoms (patient-captured events). Each Zio biosensor is intended for single-patient use. After the monitoring period is completed, the wearer removes the biosensor and returns it to the company using a Freepost packet. The ECG recordings are analysed using a proprietary algorithm (by iRhythm Technologies), overseen by UK-based accredited Cardiac Physiologists and Associate Practitioners, employed by the company. A technical report including arrhythmia episodes, wear and analysis time, and patient-captured events is sent to the prescribing healthcare professional within four working days for final analysis and interpretation. The company recycles over 90% of the Zio biosensor once returned.

NICE published Medical Technologies Guidance [MTG52] relating to the Zio device in December 2020 with a recommendation that NHS organisations using it should collect further evidence in relation to resource use and longer-term clinical consequences.

Zio in North Bristol Trust (NBT) Cardiology

In March 2021, the cardiology and stroke departments at North Bristol Trust (NBT) utilised AI in Health and Care Award funding to purchase devices from iRhythm Ltd, to support service delivery. As part of this work significant pathway transformation took place throughout 2021 to create and refine a remote pathway incorporating the Zio service, which has been in place since January 2022 (see Appendix A for side-by-side comparison of service pathways).

At the time of the project, the remote pathway utilised by NBT involved the Trust posting the devices to patients. It is noted that following an update to iRhythm's product licence in 2023 the company are now able to deliver a direct to patient model.

The use of the Zio devices within the stroke pathway at NBT is being separately evaluated as part of the AI in Health and Care Award by the King's Technology Evaluation Centre (KiTEC), with the publication of results expected in Summer 2023.

The West of England AHSN proof of value project

Through the use of real-world evaluation this proof of value project sought to support NBT to retrospectively analyse the data collected over a three-month period since the implementation of the remote pathway in January 2022 to evaluate whether there is a compelling local business case for using this or an equivalent competitor technology in the cardiac monitoring pathway going forwards.

Evaluation overview

The evaluation was a single-centre, retrospective cohort evaluation that looked at the implementation of the Zio device in the cardiology pathway within one hospital trust. The evaluation compared four months of data from a cohort of participants prescribed Holter devices pre-Covid (January – April 2019) with four months of data from a cohort of patients prescribed Zio patches post-Covid (January – April 2022) in the Cardiology pathway at North Bristol NHS Trust (NBT). Although there is a time gap between the two real-world data sets, it was felt that the pre-Covid data selected most closely to Zio deployment represented the real-world usage of Holter devices for a comparison with post-Zio implementation data.

Additionally, self-reported data from patients using the Zio patch, from both the cardiology and stroke pathways at NBT, was analysed to ascertain the patient experience during the study period, as well as an NHS staff experience survey. This evaluation uses real-world data, and as such, there will not be exact matches between the two patient cohorts.

Evaluation objectives

Primary objective

The primary outcome was to ascertain the extent to which implementing this type of technology (Zio) in the cardiology pathway at the hospital demonstrated increased efficacy and efficiencies in comparison to routine use of the existing Holter monitors in the setting. Outcomes considered included:

i. reduction in number of patients on waiting lists
ii. reduction in the number of face-to-face appointments within the pathway
iii. increased number of patients moving through the service
iv. released staff capacity
v. reduced need for repeat testing

Secondary objective

The secondary objective was to identify additional advantages or disadvantages highlighted by implementing this type of technology (Zio) in the cardiology pathway at the hospital and to understand the experience of staff and patients.

Data collection

This evaluation used hospital real-world data on Holter activity pre (cohort one) and post-Covid (cohort two). Primary data used in the analysis included:

i. number of requests for monitoring
ii. number of patients on waiting list
iii. time to test
iv. tests performed.

Zio data (post-covid) collected by iRhythm was used for comparison with routinely collected Holter activity data. Secondary data was collected by iRhythm and the hospital site. This data included:

i. Hospital staff survey - designed by the West of England AHSN to explore acceptability of implementing Zio
ii. Patient Reported Experience Measures (PREMs) – collected by Zio for patient experience and acceptability
iii. Number and type of arrhythmias found.

Methods

As this was a retrospective, observational evaluation that observed outpatients at North Bristol NHS Trust (NBT), the evaluation collected four months of data from a cohort of patients wearing Holter devices and this was compared with a four-month cohort of patients wearing Zio patches.

At the time of the evaluation, the use of the Zio service was the standard of care at the NHS site participating in this study but may not be the standard of care across the NHS. The standard of care received by patients involved in this study was not affected by their participation in the study.

Study governance

A data protection impact assessment (DPIA) was carried out and approved by the participating organisations. The study was registered for service evaluation approval with the Quality Assurance & Clinical Audit Department at North Bristol NHS Trust. All data shared between iRhythm, NBT and the West of England AHSN was anonymised and processed in line with GDPR guidance. Evaluation oversight has been provided through the project steering group led by the West of England AHSN.

Statistical analysis

Each of the data sources were analysed separately, which allowed for comparative analysis between the cohorts. As an observational real-world evaluation, a pilot was not required, and the data was collected retrospectively. The analysis style of the quantitative data was descriptive so trends and potential relationships could be identified.

The qualitative analysis style was thematic and centred around the questions posed. Primary analysis was carried out by the analyst from the West of England AHSN Evaluation & Insight team and was then quality assured by a senior analyst. All analysis was performed using Microsoft Excel.

Findings

Cohort information: descriptive data about the patient group

There were 472 patients fitted with the Holter devices (for extended monitoring, not 24 hours) in 2019, in comparison to 500 patients fitted with the Zio extended monitoring device in 2022 (table 1).

Data received from iRhythm indicated that in 2022 there were 455 patients who had returned their device and whose results were recorded. This highlights 45 patients (9%) did not return the device once it had been despatched, and this is discussed later in the report (see section 3 [ii]).

There were 172 patients who completed the patient survey. This was real-world data from iRhythm and contained PREMs for both stroke and cardiology pathway patients at NBT. Patients could not be stratified by their clinical pathway, and therefore the data presented in this report contains both pathway cohorts and is not specific to just cardiology patients. However, it was felt that the nature of the PREMs data remained representative of the aims of this evaluation to document patient experience of Zio, and data have therefore been included in full. There were 12 responses from the staff survey.

Table 1: Number of patients identified in each data sources

Description	Data source	Time period	Patients
Patients fitted with an extended monitoring device	NBT	January – March 2019	472
Recorded patients fitted with a Zio extended monitoring device	iRhythm	January – March 2022	455
Recorded patients fitted with a Zio extended monitoring device	NBT	January – March 2022	500
Patients who filled out the Zio survey (PREMs)	iRhythm	March – August 2022	177
All responses to the staff survey	NBT	December 2022	12

**PREMs data was completed by both Cardiology and Stroke patients*

The characteristic data of the 2019 cohort one was unknown, however the characteristic data from cohort two (patients who were prescribed Zio) are shown in figure 1. Looking further into this cohort, the age breakdown of 65+ accounted for over 50% of patients and followed by 46–64-year-olds at 27%. The gender breakdown of the 2022 cohort two comprised of more females than males (figure 2).

***Figure 1**. Age breakdown of Zio patients*

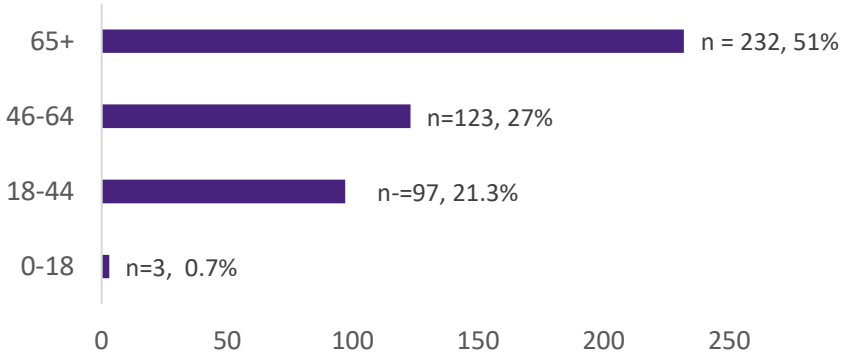
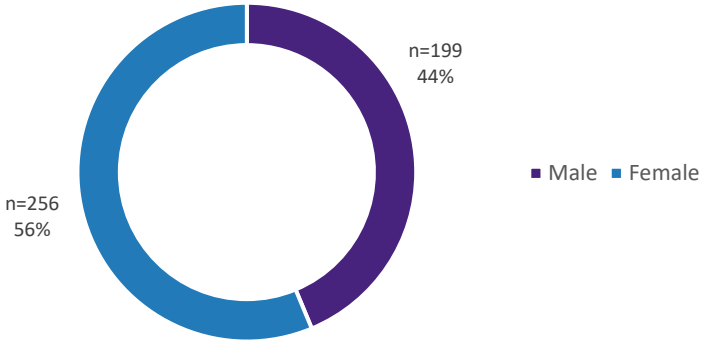
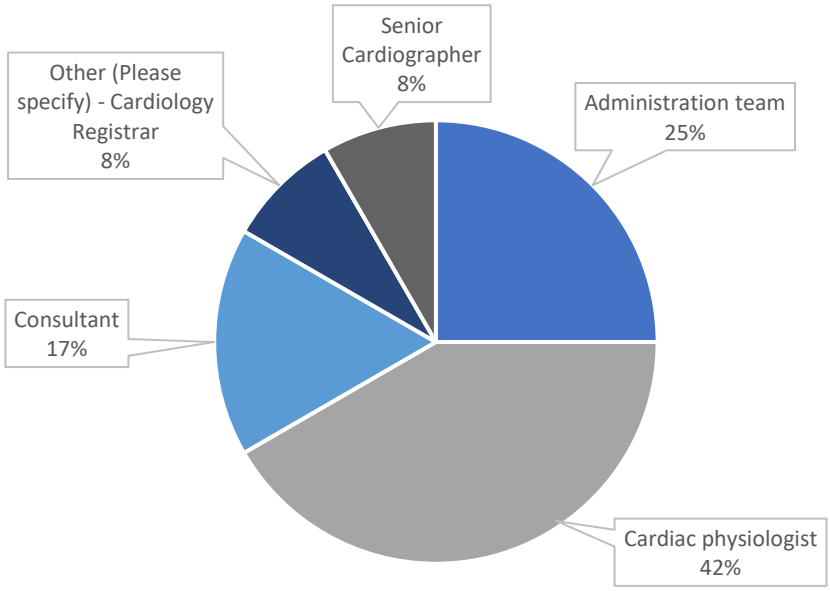


Figure 2. *Gender breakdown of ZIO by iRhythm patients*



The occupation breakdown of the staff survey is identified in figure 3 with cardiac physiologists making up 42% of the responses.

Figure 3. *Staff group survey*



Programme theory describes a variety of ways of developing a model that links programme inputs and activities to a chain of intended outputs and observed outcomes, and then uses the model to guide evaluation. For this real-world evaluation, the project team worked with stakeholders to develop a logic model (see Appendix B), and these outcomes were tested in the analysis as part of the programme theory. The following sections now report on these outcomes, where the sufficient real-world data was available to allow for appropriate testing.

1.0 Analysis of the predicted short-term programme outcomes

(i) Has a reduction of waiting list times led to increased access for patients?

The data shows there have been a number of changes in service outcomes. Analysis has shown:

- An increase of 32% in referrals from 2019 to 2022 (figure 4).
- An increase in numbers of extended monitoring devices fitted from 2019 to 2022.
- There was a decrease in waiting list times (table 2).
- A 24% decrease in the median number of days from referral to fitting of an extended monitoring device between 2019 and 2022.

Looking more closely at the data, the boxplot (figure 5) shows the ranges of number of days from referral to being fitted in 2019 and 2022. The data from 2019 shows there was a wider spread of outliers, including waiting time for one patient that was 349 days (the reason for this is unknown). The data in 2022 also shows outliers, however the median number of days is still less than 2019.

Figure 4. *Number of extended monitoring devices requested and fitted.*

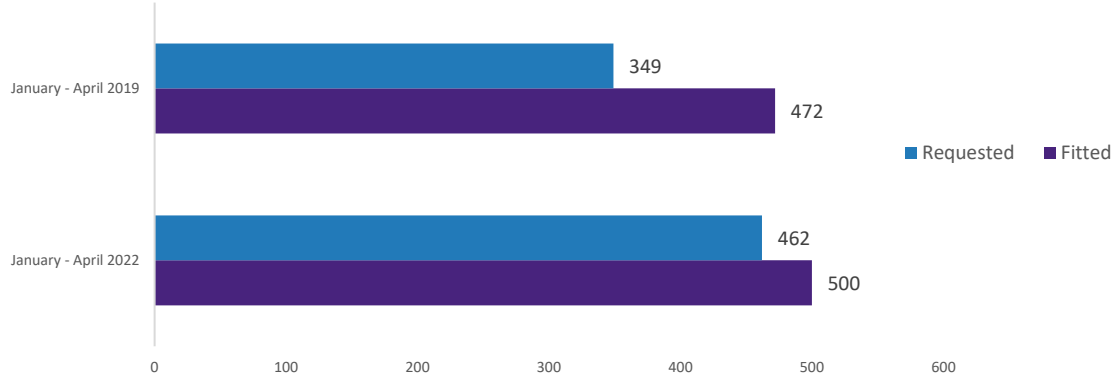
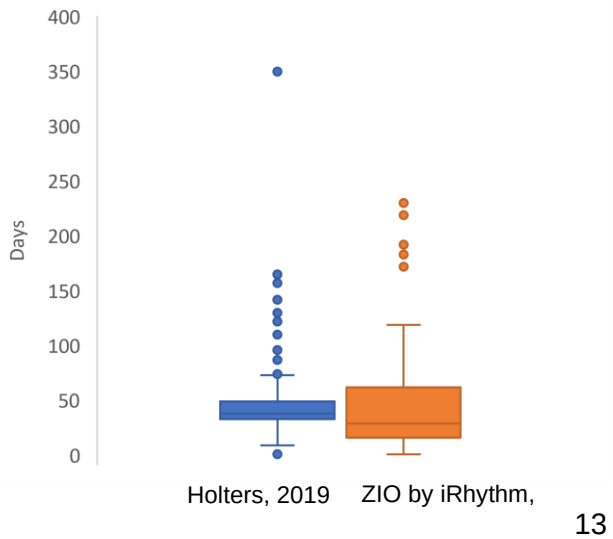


Table 2. *Median days from requests to testing*

	2019	2022
	Median (days) from request to testing*	
24 hour device (Holters)	30	40
Extended monitoring device (Holters v Zio XT)	37	28

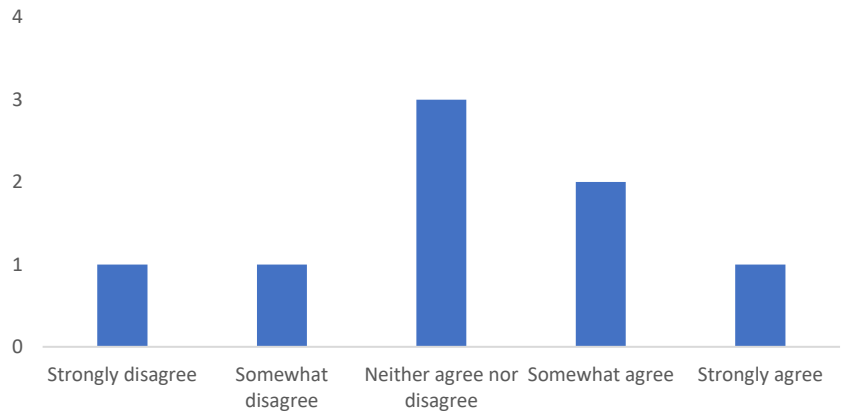
**Median is used in this analysis as median is the most informative measure of tendency when there may be a wide range of data points*

Figure 5. *Waiting times for extended monitoring*



On the staff survey, the staff were asked to rate the statement, '*our waiting times for extended monitoring have reduced*.' Staff survey results show that staff perceptions varied about whether they believed waiting times had decreased even though the data shows the waiting times have decreased by 24% (figure 6). Some staff members expressed that it had reduced the waiting list times, however some views expressed about this statement can be attributed to waiting times building up again as a result in delays in gaining funding for more devices after the initial implementation.

Figure 6. *Staff survey results for perceived waiting times*



"Much easier to reduce waiting list size due to patients not needing to attend appointments/return physical monitor. However, supply/funding issues have led to large delays and an extended waiting list." – Staff survey respondent

"With the end of trial occurring before planned we now have an extensive waiting list of patients awaiting Zio that needs to be validated for who a Holter would be suitable for." – Staff survey respondent

(ii) Has there been a release in staff capacity?

It is estimated that staff time requirements in the Zio pathway were reduced by approximately two thirds.

Cardiac physiologists were identified as the most impacted staff group in the Zio pathway, with an estimated 75-156 minutes saved per patient. This saved time means that cardiac physiologist capacity is likely to be released and could be utilised in alternative areas of the clinical service.

We were unable to measure exact release in staff capacity, however table 3 illustrates the cardiac physiology monitoring staff capacity comparing cohort one and two data. It suggests less time was taken in the 2022 pathway and a movement of staff capacity to other clinical areas. This estimated activity data was sourced from the cardiac service at NBT. Further information is available Appendix B outlining a comparison of the cardiology pathway pre and post implementation of Zio.

Table 3. *Physiology monitoring staff capacity comparison**

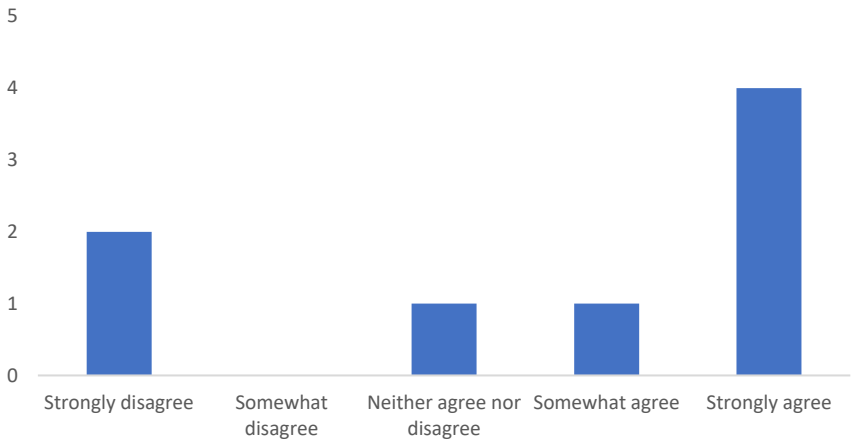
Role (NHS Band)	January – April 2019	January – April 2022
B2 Admin (outpatient)	25 mins	10 mins
B2 Admin (cardiology resource)	1-2 mins	1 – 2 mins
Clinical fellow SPR	30 mins	-
B3 Senior Cardiographer	50 mins	30 mins *(+20 mins for patients who want clinical support fitting the device)*
B6 Cardiac Physiologist	60-90 mins (for 5-day tapes) *Time given for urgent findings same as in the Zio pathway*	- *Only time given for urgent findings = same as 2019*
B8a Cardiac Physiologist	-	*(+30 mins if patches have not been activated)**
Total	**167 – 197 mins**	**41 – 92 mins**

*requiring additional contact time with patient by team to encourage activation

Source: data collection and analysis were conducted by the West of England AHSN project team

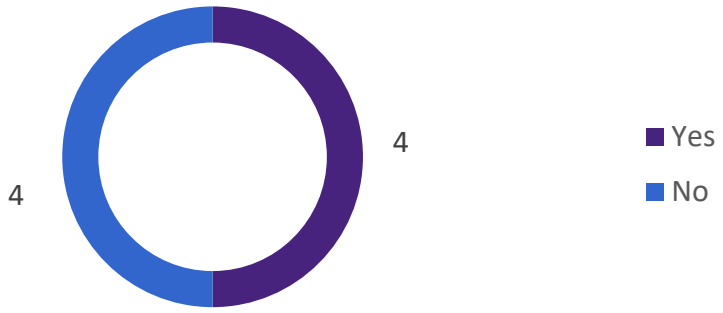
On the staff survey, respondents were asked to rate the statement, 'the use of Zio has saved me time in my role' (figure 7). Feedback to this question was mixed, and there were no additional free text answers from any respondents to provide further understanding of responses given.

Figure 7*. Staff survey results: The use of ZIO by iRhythm has saved me time in*



The staff were asked to answer the question, '*have you experienced any difficulties in implementing Zio in the cardiac physiology department*?' Generally, the response to how Zio impacted the pathway was positive. There were a few comments that mention it taking the pressure off physiologists but increasing the workload of cardiologists and administration staff. However, the survey results (figure 8) from the cardiologists and administration staff were generally positive indicating it has fitted well into the pathway aside from any implementation difficulties reported in the staff survey, such as increasing the administration workload.

Figure 8. *Staff survey results: Have you experienced difficulties implementing Zio in the cardiac physiology department?*



"It has taken the pressure off physiologists to analyse but has massively increased cardiographers workload with the admin side" – Staff survey respondent

"Through covid it was perfect as it massively reduced the amount of patients through the hospital while still monitoring them and providing them care" – Staff survey respondent

"There has been of feedback on the administration trail and how that has increased compared to the Holters. It has but find the admin trail high - Drs and GPs constantly contacting us re many queries etc re the Zio etc" – Staff survey respondent

(iii) Has there been evidence of improved staff acceptability?

Staff acceptability of Zio was investigated through a series of questions on staff views on diagnostic reporting, perceived changes to waiting times, and job satisfaction.

Staff were asked to rate the statement, *'the diagnostic reports are clear and easy to understand.'* Feedback from the respondents has been generally positive and agreed the reports were clear and easy to read:

"I found them clearly laid out with all of the potential most significant findings on the front - if these were missing it was clear the patient had not had one of these events while wearing it - which made it quick and easy to answer most questions in the request." – Staff survey respondent

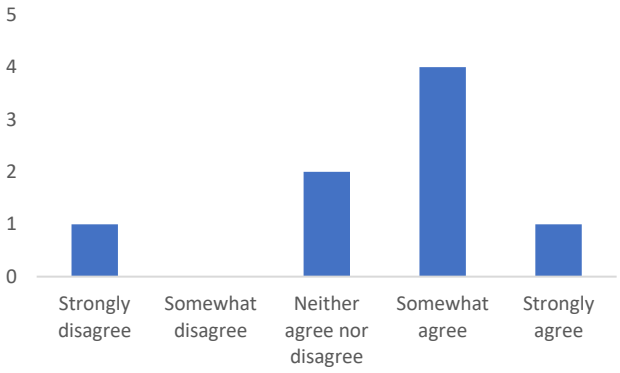
However, there was some mixed feedback about the Zio reports (figure 9). One respondent strongly disagreed with this statement and noted the length of the reports:

"Automated report contains a long list of findings most of which are seen in otherwise healthy patients. The abnormality described is often minor (variation of normal) The report is not useful and the ECG tracings need to be reviewed." – Staff survey respondent

It was of note that when staff were asked answer the question, *'do you want to continue using Zio?*', 88% of respondents showed strong support for the device, and only one out of the eight respondents to this question did not want to continue to use the device; their reasoning was attributed to cost and environmental reasons:

"There are better alternatives which are cheaper and more environmentally friendly" – Staff survey respondent

Figure 9. *Staff survey results when asked if the diagnostic reports are clear and easy to read.*



In relation to staff acceptability, there was some administrative concern around there not being a system able to record if a patient has received the device.

"Creates additional administrative work as it isn't clear whether a patient has worn the monitor or not, and results in calling patients to find out if they received the monitor, wore it and/or returned it. Also, the process for booking is slightly complicated due to auto generated letters - needs specific letters created for the Zio pathway. However, overall saves patient footfall and generally a shorter wait time." – Staff survey respondent

(iv) Has the evidence shown a reduction in face-to-face outpatient appointments?

The data shows there was a reduction in face-to-face appointments in the hospital. In the 2019 pathway (cohort one data /Holters), every patient was fitted with a device in hospital. When looking at 2022 (cohort two data / Zio), there were no patients routinely fitted with the Zio device in hospital settings. Patients were able to request an appointment for extra support in fitting the device, although the data relating to the numbers who requested this was not available. It was suggested by the respondents that the number of patients requiring extra support was minimal.

Comments from the staff survey suggested that some patients struggled with fitting the device to themselves and appointments were made for the device to be fitted in the hospital:

"Some patients found it confusing to attach the Zio in the first place meaning they had to come into clinic for it (very few overall) and some found they didn't stick for long or irritated their skin so removed them after a few days." – Staff survey respondent

Whilst we did not set out to show a benefit in terms of carbon impact and travel costs to the patient, there will have been an indirect benefit by the nature of Zio not requiring a hospital appointment to be fitted. This may be an area of interest for any future impact analysis.

(v) Is there a reduction of repeat testing (short/med)?

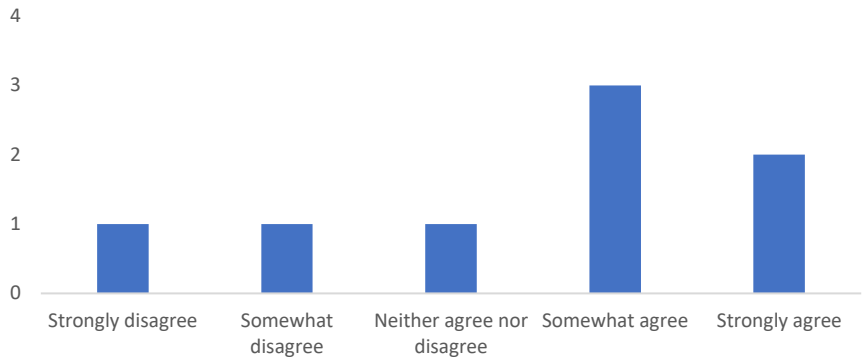
Data was not available to measure this outcome, and therefore was out of scope for this evaluation.

(vi) Has an increased number of patients moved through the pathway within a specified time period?

The staff were asked on the survey to rate the statement, '*Using Zio has improved the overall diagnostic pathway at the hospital*'. The feedback was mixed but more respondents agreed that the Zio device fitted well into the pathway (figure 10):

" Zio has integrated well into the pathways at the [the hospital], essentially just replacing the current method of extended ambulatory ECG monitoring." – Staff survey respondent

Figure 10. *Staff survey results regarding improved the overall diagnostic pathway at the hospital.*



Feedback was recorded from staff about maintenance of stock with regards to orders being slow to arrive and the waiting list left over after the initial implementation period ended. However, as previously highlighted, issues around re-procurement was the main cause of negative feedback from staff, such as maintaining stock and slow delivery times:

"Difficulties in maintaining stock - orders could be slow to arrive and some with parts missing i.e., patient information leaflets. This led to delays in sending them out and reports returning etc." – Staff survey respondent

(vii) Has there been an increased diagnostic yield?

Previous research comparing Holters and Zio[13] found that using a Zio monitor had a greater diagnostic yield and detected more events than a Holter monitor. Therefore the aim of this real-world evaluation was not to replicate this existing evidence.

The number of different arrhythmias found during the 2022 (Zio) data can be identified. Table 4 highlights the different types and number of those arrhythmias detected.

Table 4*. Number of rhythms detected (n=455).*

Title	Number	Percentage
Sinus rhythm	332	73%
Supraventricular tachycardia found	67	15%
Supraventricular ectopic (SVE) couplet found	60	13%
Atrial fibrillation associated with patient event	32	7%
Supraventricular ectopic (SVE) triplet found	26	6%
Ventricular couplet found	16	4%

Title	Number	Percentage
Ventricular tachycardia found	7	2%
Trigeminy found	6	1%
Ventricular triplet found	5	1%
Ventricular fibrillation found	0	0%

An important feature of patch technology is the ability for longer monitoring periods. Extended monitoring using Holters was only possible up to five days compared to a maximum of 14-days for a Zio device. Therefore, analysis was conducted to ascertain how many arrhythmias were found after the initial five-days of monitoring and therefore are likely to have not been detected during the testing five-day period using a Holter monitor (Table 5).

Table 5. Number of arrhythmias detected after five days (n=455)

Arrhythmia	Found post 5 days	Percentage found post 5 days
Paroxysmal atrial fibrillation	21	84%
Pause Greater than or equal to 3 seconds	17	77%
Supraventricular tachycardia greater than or equal to 30 seconds	21	72%
Ventricular tachycardia greater than or equal to 8 Beats	32	71%
Atrioventricular Block (2nd Degree Mobitz II or 3rd Degree)	5	71%

Previously published literature also demonstrates that longer-term continuous ambulatory ECG monitoring, including Zio, provides detection of potentially clinically relevant arrhythmic events[5,14]. It is likely that in the previous pathway (2019) patients who had an arrhythmia event outside of the five days of Holter monitoring would have required a repeat test. NBT confirmed this would have required them being re-referred to the Cardiology service, thus taking more time and resources, and increasing the risk of an adverse event in the meantime.

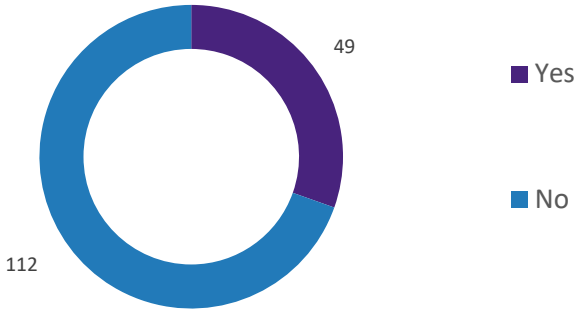
Comparative data for the diagnostic yield associated with using Holter devices was not available as this would have involved manual analysis of Holter reports and was therefore outside the scope of this evaluation.

Our data shows that Zio was introduced effectively into the clinical pathway at NBT to achieve the benefits of improved diagnostic capability for arrhythmias (along with others identified in our programme theories).

(viii) Has there been improved patient experience/ acceptability?

In the PREMs data, 49 patients had worn a cardiovascular device previously. Of those who had worn a monitor previously, the majority of people felt the experience was much better than their previous experiences of wearable devices (figure 11).

Figure 11. *Number of patients who had worn a monitor previously.*

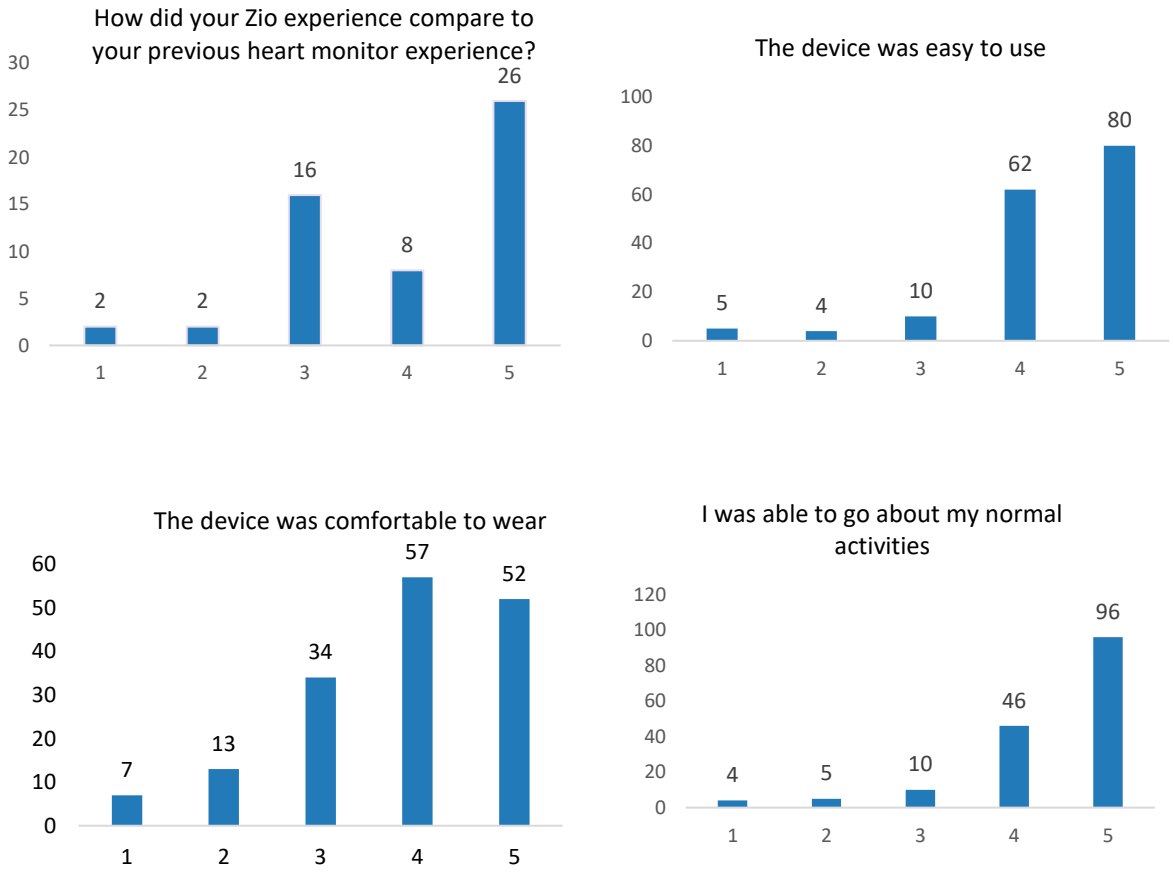


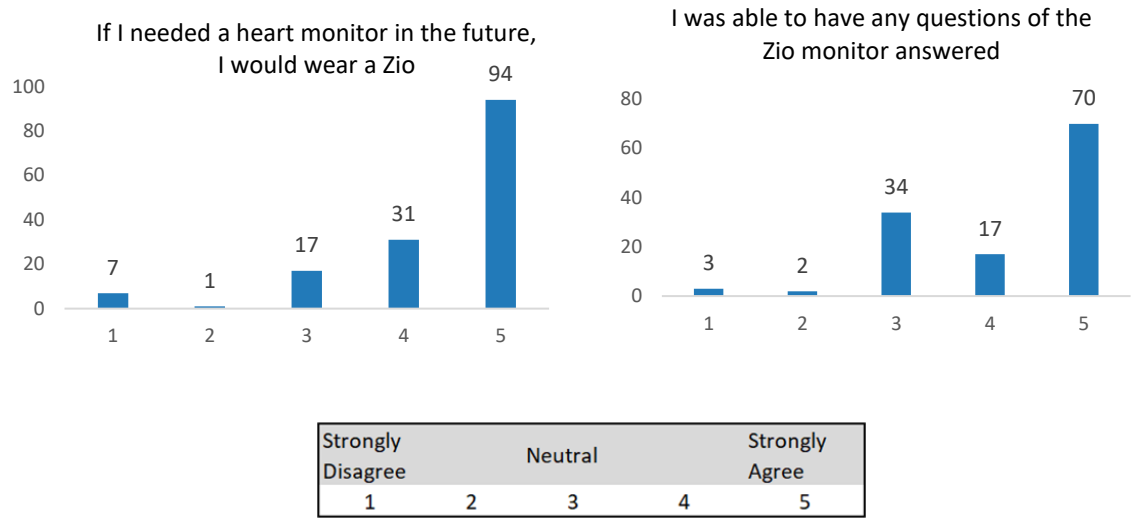
Feedback from patients was overall positive (table 6 and figure 12) with the average of all the questions three or more (neutral or better). Five out of six questions were rated at four or more out of five.

Table 6. *Average results from patient experience.*

Easy to use	Comfortable	Normal activities	Help & support	Wear Zio again?	Is Zio better?
4.3	3.8	4.4	4.2	4.3	4.0

Figure 12. *Patient experience of wearing the device.*

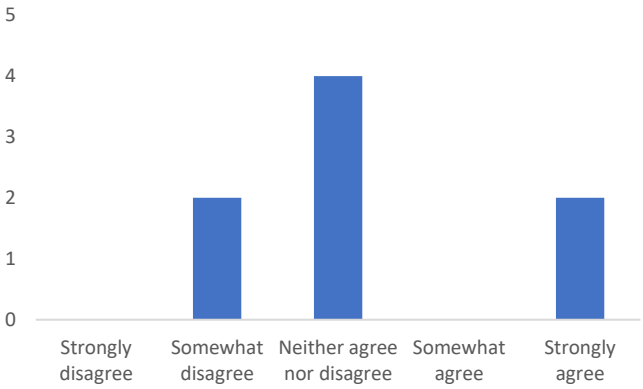




Further data from the staff survey shows staff were asked to rate the statement, '*Zio has a lower failure rate than Holter monitoring'*. However '*failure rate*' was not defined in the survey, which impacts the validity of the reported data. Data shown below (figure 13) is 'staff perception of failure rate'. Generally, the feedback was neutral, with staff outliers on both spectrums of level of agreement. Some staff noted the potential for the Zio device getting lost in the post or people unable to use it (we are unable to report or evidence through the data available why this may be):

"Many elderly patients either struggled with or weren't confident in applying the Zio to themselves, so still had to come in and have the device applied for them." – Staff survey respondent

Figure 13. *Perceived failure rate of device by staff.*



2.0 Analysis of the medium-term outcomes identified in the programme logic model

Data was not available to measure this programme outcome, and therefore was out of scope for this evaluation.

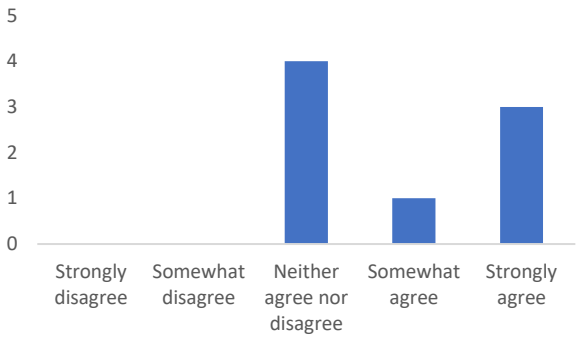
3.0 Analysis of the long-term outcomes identified in the programme logic model

Some long-term outcomes from the logic model could not be measured, therefore the evaluation reports on those where data supported further analysis.

(i) Was there a reduction in staff skill usage (ECG analysis) leading to deskilling workforce and possible impact on job satisfaction?

Staff were asked to rate the statement, '*I feel my professional skills are still being applied and valued while using the Zio technology*' and the response to this was generally positive (figure 14).

Figure 14. *Staff views when asked if their professional skills are still being applied.*



(ii) Identifying waste within resource use (DNA & did not receive/use device data)

Cohort one data (Holters, 2019) highlighted 76 (16%) people who did not attend their appointment (DNA data). Zio is not an appointment-based service, therefore there it was not possible to report on system efficiencies that relate to patients who do not attend outpatient appointments, as there is no comparable data between the two cohorts. Therefore the '*failure rate'* for Zio is at least no worse than the DNA rate for Holter monitors.

However, we do also identify that in cohort two data (Zio, 2022) 45 (9%) people either did not use their device or did not receive the device (this category is collated so we cannot break it down). This was also noted in the staff survey as a concern:

"We seem to have had quite a few Zio which have disappeared in the post which has caused failure, as well as a few which have come unstuck." – Staff survey respondent

The costs associated with the Zio device, at the time of evaluation was estimated at £155 per device. For this period the total cost of devices deployed amounts to £6,975. Whilst we cannot compare DNA data with '*device not received/used*' data, it might be useful to describe the costs associated with each group in future work, even if this is not a direct comparison.

Evaluation limitations

As the staff and patient survey sample contains a limited number of respondents, findings must be applied with caution. The voluntary nature of the survey may have led to stronger responses overall, for example those that felt either very positively or very negatively may have been more inclined to participate.

We received qualitative feedback from staff as part of the survey. However, we did not receive any qualitative feedback from patients as part of the reported PREMs, and this was from combined cardiology and stroke patient data direct from the company. Future evaluation may look to investigate this aspect further, such as patient feedback on instructions for use.

In this evaluation, we were unable to comment on any impact of the Zio device on healthcare inequalities. Further evaluations specifically looking at this information may be needed to understand these impacts and expand on the programme theories associated with them.

As we were unable to compare the numbers of arrhythmias detected between the two patient cohorts, we cannot evidence if the Zio device increased diagnostic yield, and this outcome is already evidenced in the existing published literature.

Conclusion

Evaluation of the implementation of the Zio device has demonstrated improved system efficiencies in the cardiology pathway at NBT by increasing the number of patients completing the diagnostic pathway, and a decrease in waiting list times. The data shows a 24% decrease in the median number of days from referral to fitting of the Zio extended monitoring device between 2019 and 2022. There was also reduced footfall of patients in the hospital, which was of particular benefit during the pandemic.

An important feature of patch technology is the ability for longer monitoring periods. The evaluation showed a high percentage of arrhythmias were found after five-days of monitoring.

An arrhythmia event outside of the five days of Holter monitoring would have required a repeat test, indicating a re-referral to the cardiology service, which suggests additional time and resources would be required.

There is an estimated reduction in the staff time requirements in the Zio pathway by approximately two thirds. Cardiac physiologists are identified as the most impacted staff group in the Zio pathway, and the time saved suggests staff capacity is likely to be released and could be utilised in alternative areas of the clinical service.

The evaluation has shown that Zio was particularly acceptable to patients. It was generally easy to use, well tolerated and comfortable. Staff also found Zio to be generally acceptable. In conducting this evaluation, several other areas of interest were highlighted:

(i) Environmental sustainability was noted on the staff survey due to the nature of Zio being a single-use device. However, the manufacturer states that 90% of the device is recycled or re-used. There are likely to be environmental benefits due to reduction in the number of hospital visits. Evaluation of this impact would be a useful focus of future projects.

(ii) Potential for the device being lost in the post (or unreturned to iRhythm by the patient) was also highlighted, as several devices failed to be returned. However, this can be balanced against the failure rate of Holter monitors due to patients not attending their appointments. Overall, the failure rate of the Zio device was not worse than that of Holter monitors.

(iii) There were comments from a small number of staff who felt the Zio reports were too long and difficult to understand. This may be an area in which iRhythm could conduct future follow-up to better understand or explore those opportunities which aid ongoing improvements..

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Appendix A: The ZIO by iRhythm Project Logic Model

Situation: Demonstrate whether there is value of implementing ZioXT for NBT and patients (including resource use, patient experience, cost)

Inputs	Outputs		Outcomes -- Impact		
	Activities	*Reach*	*Short*	*Medium*	*Long*
1. Data from the Cardiology department from Jan 2022 onwards (business intelligence team) 2. Ratio of patients receiving standard 24/48hr monitoring vs Zio continuous monitoring (business intelligence team) 3. Patient experience data (iRhythm survey) 4. iRhythm data (inc. service reviews) 5. Sample the data, including patient notes 6. Staff surveys/ interviews (new data would need to be generated)	1. NBT implement ZIO by iRhythm device in cardiology pathway from Jan 2022 (via NHSx AI Award funding)	1. Cardiology clinical staff 2. Cardiology admin staff 3. Medicines business intelligence team 4. iRhythm team members 5. Patients requiring extended ambulatory monitoring	1. Reduction of waiting lists and maintenance of waiting times leading to increased access for patients 2. Release of staff capacity 3. Reduction in face-to-face outpatient appointments 4. Reduction of repeat testing (short/med)? 5. Increased number of patients moving through the pathway within a specified time period 6. Increased diagnostic yield 7. Improved patient experience/ acceptability 8. Improved staff acceptability	1. Increased advice and guidance requests from primary to secondary care 2. Patients receiving earlier intervention following quicker diagnosis 3. Reduction in patients requiring emergency/ secondary care	1. Redeployment of staff leading to improved efficiency in other areas of work 2. Shift in the setting of care, follow-up is primary care led rather than secondary care 3. Wider patient impacts e.g. faster returns to work and less overall sick time 4. Reduction in staff skill usage (ECG analysis) leading to deskilling workforce and possible impact on job satisfaction 5. Providing security of service with current staffing resources

Assumptions

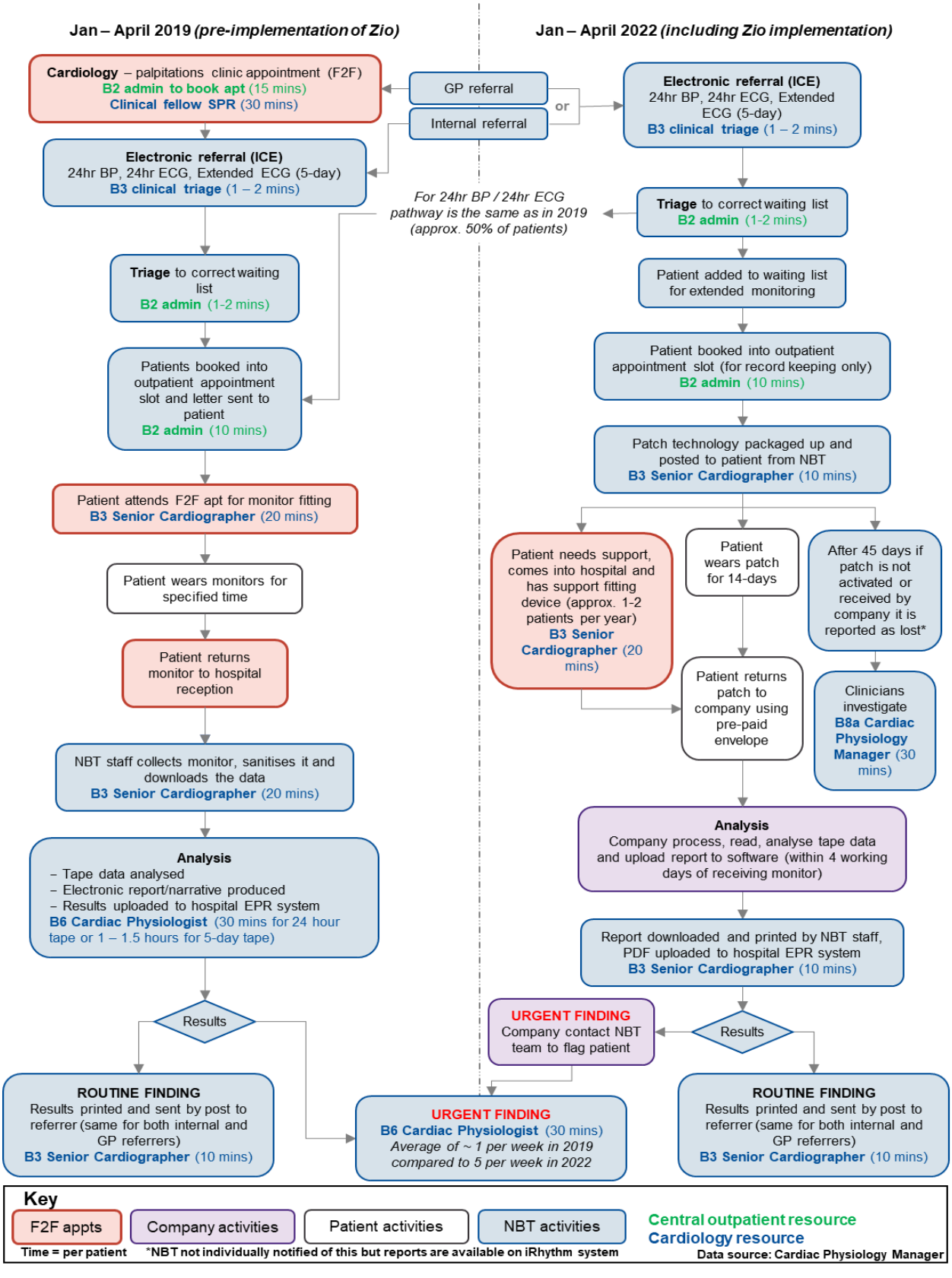
- Any resources released will be redeployed within the cardiac physiology service.
- Additional data from the Stroke pathway can be utilized for a business case if necessary.
- There is a clear way to baseline the NBT service without it being skewed due to the Covid-19 pandemic.

External Factors

- GPs may require additional information/support provided via advice and guidance.

V1.1 13/09/2022

Appendix B: Side by side comparison of Cardiology pathway pre- and post- Zio implementation



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