

Zio Service for detecting cardiac arrhythmias

Medtech innovation briefing

Published: 28 March 2017

nice.org.uk/guidance/mib101

Summary

- The **technology** described in this briefing is the Zio Service. It is a remote cardiac monitoring system used for detecting cardiac arrhythmias.
- The **innovative aspects** are that this device can collect continuous cardiac monitoring data for up to 14 days through an adhesive biosensor patch (the Zio Patch). At the end of the monitoring period, the user posts the Zio Patch to the manufacturer, who produces a report for clinicians (the Zio Report). The Zio Patch is non-invasive, water resistant and has no leads or wires so people may find it easier to wear than other ambulatory monitors.
- The **intended place in therapy** would be instead of current methods of cardiac event detection, such as Holter monitoring or event recording in people suspected of having cardiac arrhythmias.
- The **main points from the evidence** summarised in this briefing are from 6 studies based outside the UK: 2 comparative studies (n=220), 2 non-comparative prospective studies (n=249) and 2 large non-comparative retrospective studies (n=149,205) on adult patients in a home setting. Of the 2 comparative studies, 1 reported that the Zio Service detected more arrhythmia events than Holter monitoring in the first 24 hours and the other reported excellent agreement between the 2 methods. Both studies found that using the Zio Service over 14 days detected more arrhythmia events than Holter monitoring over 24 hours.
- **Key uncertainties** around the evidence or technology include that there is no evidence comparing the Zio Service with other monitoring devices that have a similar monitoring period.

- The **list price** of the Zio Service is around £800 per unit (exclusive of VAT). This includes the patch, the data analysis and the report. 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.

The technology

The Zio Service (iRhythm Technologies) is designed to detect cardiac arrhythmias and is comprised of the Zio Patch, an adhesive patch with a 1-lead ambulatory electrocardiogram (ECG), and the Zio Report, a summary of the recorded data that have been analysed.

The Zio Patch is a lightweight water-resistant ECG monitor that has no external leads or wires. The patch is stuck on the person's left upper chest and can record a continuous beat-to-beat ECG for up to 14 days. Each Zio Patch is intended for single-patient use.

Wearers can carry on with their usual daily activities during monitoring. When they feel a symptom, the wearer can press a trigger button on the device that highlights the recording 45 seconds before and after the button was pressed. The wearer is also asked to keep a paper-based log in which they write down any symptomatic events that happen during the 14-day monitoring period, as well as information on what they were doing and the conditions at the time. This allows for a symptom-rhythm correlation to be included in the final report.

After the monitoring period, the wearer removes the Zio Patch and sends it to the company by Freepost through the Royal Mail. The recordings are analysed by the company, using proprietary machine-learned algorithms (Zio ECG Utilization Service System [ZEUS System]), and a report is produced. The report describes all cardiac arrhythmia events over the total wear time and the analysis by the ZEUS system, and it is reviewed by a certified cardiac technician. This Zio Report is sent electronically to the ordering clinician through iRhythm's secure web-based portal. The full ECG data can be sent to the clinician on request. Patient data are otherwise only used by the company in a de-identified form for quality reporting and system improvements.

Parts of the analysis are done in the UK and the US. The manufacturer states that transmission, processing and storage of all data complies with relevant EU and UK legislation. There are no patient identifiers in or on the Zio Patch and data cannot be accessed if the Zio Patch were to be physically intercepted. iRhythm uses security measures to prevent inappropriate access to or manipulation of the data.

Innovations

The Zio Service provides a continuous recording of ambulatory cardiac monitoring for up to 14 days. The wearer can go about their normal daily activities during monitoring, including showering or bathing because the device is water resistant.

The Zio Service can be used for a longer monitoring period than a standard Holter monitor, which can be up to 7 days but usually for 24 to 48 hours. The Zio Patch has no external leads or wires and this is intended to reduce noise artefacts in the data. It can be worn under clothing, so may be more discreet than Holter monitors, which are generally worn in a pouch around the waist or neck, or carried in a pocket.

The Zio Service uses machine-learned analytics in the form of proprietary software to create the report that is delivered to the clinician. This is intended to reduce the time needed for NHS staff to analyse the continuous monitoring data.

Current NHS pathway

The current methods of arrhythmia detection ([NHS Choices](#)) are:

- 12-lead ECG
- 24- to 48-hour or 7-day continuous ambulatory monitoring, including using Holter monitors
- long-term continuous monitoring for up to 30 days
- external loop recorders
- insertable loop recorders, which can record events for up to 3 years for arrhythmias that occur sometimes months apart.

The Holter monitor is the method most commonly used in the NHS for detecting atrial fibrillation. Holter monitors continuously record the heart rhythm using several electrode patches, which are stuck on the user's chest. These electrodes detect and record electrical signals produced by each heartbeat, and are connected by wires to a portable recording machine. The user can press a button on the front of the recording machine at specific times, such as when having symptoms, going to bed or taking medication. These points can then be easily found in the continuous monitoring data. Holter monitoring is used for 24 to 48 hours for people who have regular symptoms, or can be used for up to 7 days for people with symptoms that happen less often, such as if they only have arrhythmia every 3 to 4 days. Results are analysed by the user's clinician.

The NICE guidelines on [managing atrial fibrillation](#) and [transient loss of consciousness \('blackouts'\) in over 16s](#) recommend a 12-lead ECG for the first assessment. If further assessment of possible cardiac arrhythmia is needed, ambulatory ECG monitoring is recommended for 24 or 48 hours. The choice of monitor depends on symptoms and symptom frequency and includes Holter monitoring and external or implantable event recorders.

If the first 24- to 48-hour Holter monitor test does not give a clear diagnosis, people are referred for further investigations. This can include event recording for up to 7 days or admission to hospital for more invasive options, such as fitting an implantable loop recorder.

Estimates of the diagnostic yield for 24-hour Holter monitoring vary. [Barbeito–Caamano et al. \(2016\)](#) reported that syncope was only diagnosed in 4% of people in a cohort monitored for 24 hours. [De Asmundis et al. \(2014\)](#) reported that Holter monitoring led to a diagnosis of any arrhythmia in 1.8% of people monitored for 24 hours, whereas [Kinlay et al. \(1996\)](#) reported a diagnosis rate of 35% after 48-hour Holter monitoring.

The Zio Service would be used for monitoring over 14 days as well as, or instead of, 24- to 48-hour and 7-day Holter monitoring or event recording.

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to Zio Service:

- Bardy 7-day patch (Cardiologic)
- SEEQ MCT monitor (Medtronic)

Population, setting and intended user

The Zio Service would be used in a home setting for people with suspected cardiac arrhythmias. The device can be used for people with suspected arrhythmias and unexplained loss of consciousness. The Zio Service would be used instead of Holter monitoring or event recording when continuous monitoring needs to be extended for up to 14 days.

A clinician would prescribe monitoring with the Zio Service, most likely a cardiologist in secondary care or possibly a GP in primary care. The Zio Patch is intended to be applied to the person by the clinician, or by a cardiac physiologist or healthcare support worker in hospital, or a nurse or healthcare support worker in primary care. Occasionally, it may be applied by the person themselves if the clinician thinks that this is appropriate. After the monitoring period, the person

sends the Zio Patch by Freepost through the Royal Mail to iRhythm for data analysis and production of the report.

The manufacturer states that minimal training is needed to apply and use the Zio Patch and that full instructions are provided in the user manual. The chest area may sometimes need to be shaved before applying the device. iRhythm states that the clinician will not need additional training to interpret the Zio Report, because it is clear and complete.

Very occasionally, such as with paroxysmal atrial fibrillation, monitoring for more than 14 days may be needed because events are very intermittent. In this situation 2 patches would be worn in succession.

Costs

The manufacturer has given an example list price of £800 per unit for the Zio Service. In practice, prices will vary depending on the procurement and volume arrangements for each hospital. This single price includes the cost of the Zio Patch, the data analysis, and the clinical report for one 14-day monitoring period for a single patient. A specialist commentator provided the following costs (excluding equipment costs) for 24-hour Holter monitoring, per patient:

- monitoring and interpretation of results:
 - £95.42 without overheads (defined as staff, heating and computer use)
 - £118.60 with overheads
- monitoring and no interpretation of results:
 - £39.17 without overheads
 - £48.69 with overheads.

An example of a reusable Holter monitor is the Spacelabs LifeCard CF Holter recorder, which has a list price of £1,632.14 (NHS Supply Chain).

Resource consequences

The Zio Service is currently available in 6 NHS trusts.

The purchase price of the Zio Service may be lower than that of a Holter monitor, but the cost of 24-hour Holter monitoring per patient would be lower. Cost savings could be generated if using the Zio Service reduced the need for repeated or prolonged Holter or event monitoring. The Zio Service offers 14-day monitoring, which may improve the detection of infrequent arrhythmias compared with 24- to 48-hour or 7-day Holter monitoring. This could save any costs that could be avoided by having a correct diagnosis, including repeat hospital inpatient and outpatient admissions related to complications such as syncope, chest pain, stroke or transient ischaemic attack.

The costs of applying the Zio Patch to the patient are minimal. It is simple to use and can be removed without medical supervision. People having Holter monitoring must visit the cardiologist to return the monitor after the recording period, whereas the Zio Service is returned to iRhythm by post, which may be more convenient for people.

Regulatory information

The Zio Service was CE marked as a Class IIa device in December 2014.

A search of the Medicines and Healthcare products Regulatory Agency website revealed that no manufacturer field safety notices or medical device alerts have been issued for this technology.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Cardiac arrhythmias can develop in people of any age, but are more common in people over 60 years. Women tend to be at higher risk of certain arrhythmias, including atrioventricular nodal tachycardia, whereas men are 3 times more likely to develop atrial fibrillation at any age. However, of those people who develop atrial fibrillation, women have a much higher incidence of morbidity and mortality. Age and sex are protected characteristics under the Equality Act. People whose first language is not English or who cannot write may not be able to give written information on their symptoms while using the Zio Service.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Six studies are summarised in this briefing with a total of 149,674 participants. Two of these studies were within-subject comparative studies comparing ambulatory 14-day Zio Service monitoring with 24-hour standard care Holter monitoring (n=220), 2 were non-comparative prospective studies (n=249) and 2 were very large, non-comparative retrospective studies (n=149,205).

Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

There is limited evidence on the effectiveness of the Zio Service compared with standard care. The 2 available comparative studies do not compare Zio Service with a monitoring device that uses a similar monitoring period, instead comparing 14-day Zio Service monitoring with 24-hour Holter monitoring.

The sizes of the 2 comparative studies on Zio Service are relatively small with a total of 220 people included. Although these studies were carried out in the US, they are likely to be relevant to the current NHS care pathway because they compared Zio Service with 24-hour Holter monitoring, which is considered standard care in the NHS. The 2 very large retrospective studies are less informative because they were non-comparative and retrospective.

More studies comparing the Zio Service with ambulatory electrocardiogram (ECG) including Holter and event monitoring over 7 days or longer would be useful to determine its clinical and cost effectiveness in the NHS. Two studies, which will compare the Zio Service with standard monitoring in a UK cohort, are currently in progress.

Table 1 Summary of included studies

Barrett et al. (2014)

Study size, design and location	<p>Prospective within-subject comparison of 24-hour Holter monitoring and 14-day Zio Patch monitoring.</p> <p>Evaluation of cardiac arrhythmias in 146 adult outpatients (after loss to follow-up).</p> <p>US.</p>
Intervention and comparator	<p>The Zio Patch compared with the Holter monitor. All patients wore both devices for the first 24 hours and then continued with Zio Patch.</p>
Key outcomes	<p>During the first 24 hours of simultaneous monitoring, the Holter monitor detected statistically significantly more events than the Zio Patch. All the clinically significant arrhythmias that were undetected by the Zio Patch were later detected during prolonged monitoring with the patch.</p> <p>The Zio Patch detected statistically significantly more arrhythmia events than the Holter monitor over the total wear time.</p> <p>Participants found the Zio Patch more comfortable to wear and preferred it to the Holter monitor.</p> <p>Median wear time for the Zio Patch was 11.1 days (no reasons were given for the shorter than expected wear time).</p>
Strengths and limitations	<p>Some of the patients had pre-existing arrhythmias and were referred for reasons other than symptomatic arrhythmias.</p> <p>The manufacturer, iRhythm, partly funded the study.</p>
<p><u>Rosenberg et al. (2013)</u></p>	
Study size, design and location	<p>Prospective within-subject comparison of 24-hour Holter monitoring and 14-day Zio Patch monitoring.</p> <p>Evaluation of 74 adults with paroxysmal atrial fibrillation (after loss to follow-up).</p> <p>US.</p>
Intervention and comparator	<p>Monitoring using the Zio Patch compared with the Holter monitor. All patients had both types of monitoring.</p>

<p>Key outcomes</p>	<p>During the first 24 hours of simultaneous monitoring, there was excellent agreement between both devices for identifying AF events and AF burden.</p> <p>Because of a longer monitoring time, AF episodes were detected in statistically significantly more patients with the Zio Patch compared with the Holter monitor.</p> <p>AF events were identified in 18 more participants and the documented pattern of symptoms changed in 21 more participants using the Zio Patch than with the Holter.</p> <p>Clinical management of the condition changed as a result of the Zio Patch in 28.4% of patients.</p> <p>Less than half of the self-reported symptoms (using the button press on the Zio Patch) correlated with arrhythmia events.</p> <p>Median time to detection of first event with Zio Patch was 3.7 days, with 90% detected by day 7.</p> <p>Mean wear time for Zio Patch was 10.8 days.</p>
<p>Strengths and limitations</p>	<p>Pilot study with a relatively small sample size.</p> <p>The manufacturer, iRhythm, supported the study with a restricted research grant.</p>
<p><u>Schreiber et al. (2014)</u></p>	
<p>Study size, design and location</p>	<p>Prospective, multicentre observational study of 174 adult participants using the Zio Patch.</p> <p>US.</p>
<p>Intervention and comparator</p>	<p>The Zio Patch; no comparator.</p>
<p>Key outcomes</p>	<p>Ninety-eight arrhythmia events were detected over a median wear time of 6.9 days. Intervention duration was only 7 days.</p> <p>Of the patients who pressed the event button, 53% did not actually have an arrhythmia at the time.</p> <p>Median time-to-first event was 1.0 days.</p> <p>Median time-to-first symptomatic event was 1.5 days.</p> <p>Median time to event for some types of arrhythmia was 5.8 days.</p> <p>Overall diagnostic yield was 63.2%.</p>

<p>Strengths and limitations</p>	<p>All of the Zio Patches were returned for analysis, suggesting that all of the patients used them as advised.</p> <p>There was no statistical analysis of the data.</p> <p>Enrolment was based on clinician judgement alone because it was an observational study.</p> <p>There was no randomised comparison with standard care.</p> <p>The duration of monitoring was short compared with other studies.</p> <p>Clinical history and data on pre-existing cardiac abnormalities were lacking.</p>
<p><u>Solomon et al. (2016)</u></p>	
<p>Study size, design and location</p>	<p>Retrospective cross-sectional analysis of 122,454 adult patients using the Zio Service.</p> <p>US.</p>
<p>Intervention and comparator</p>	<p>The Zio Service; no comparator.</p>
<p>Key outcomes</p>	<p>High-risk arrhythmia events were detected in 20,685 (21.7%) records.</p> <p>For ventricular arrhythmias, only 52.5% were detected in the first 24 hours and 92.9% were identified by day 7. The trend for bradyarrhythmia results was similar.</p> <p>The differences in diagnostic yield between 2 and 7 days for both ventricular arrhythmias and bradyarrhythmias were statistically significant.</p> <p>Median time-to-first event was between 22 and 74 hours depending on type of arrhythmia.</p> <p>Mean wear time was 9.6 days.</p>
<p>Strengths and limitations</p>	<p>The sample was very large.</p> <p>There was no follow-up after the first monitoring period.</p> <p>The investigators did not have the symptomatic self-report data so could not correlate symptomatic triggers with true arrhythmias.</p> <p>A quarter of patients did not wear their devices for at least 7 days, which limited the amount of data for analysis.</p> <p>The manufacturer, iRhythm, sponsored the study.</p>
<p><u>Turakhia et al. (2013)</u></p>	

Study size, design and location	Retrospective cross-sectional study of 26,751 adult patients having monitoring using the Zio Patch. Single centre in US.
Intervention and comparator	The Zio Patch; no comparator.
Key outcomes	Single and multiple arrhythmias were detected in 16,142 (60.3%) of patients. The overall mean time taken to detect the first arrhythmia was 1.7 days, with some specific arrhythmias taking longer to detect (mean 3.4 days). Mean wear time was 7.6 days.
Strengths and limitations	The sample was large. Some parameters were not analysed statistically, for example, whether the diagnostic yields were different between early and late monitoring. Patients' clinical backgrounds differed. Some of the arrhythmias detected may not have been clinically significant because of their short duration, which could have skewed the results. The manufacturer, iRhythm, supported the study through a grant. The mean wear time was short compared with other studies, possibly because of clinicians prescribing different monitoring durations.
<u>Turakhia et al. (2015)</u>	
Study size, design and location	Single-centre prospective screening study of 75 male adult patients. US.
Intervention and comparators	The Zio Patch; no comparator.

<p>Key outcomes</p>	<p>Any arrhythmia of more than 8 beats was detected in 36 (48%) of participants; 35% of them had the first arrhythmia after 48 hours of monitoring.</p> <p>AF was detected in 4 participants, with 3 of them having their longest episode after 48 hours of monitoring.</p> <p>Over a third of participants had an arrhythmia other than AF more than 48 hours after monitoring started.</p> <p>Mean wear time was 13 days.</p>
<p>Strengths and limitations</p>	<p>Procedures were more likely to be standardised because the study was done at a single centre.</p> <p>Participants wore the device for a reasonable length of time, which increased available data.</p> <p>Used an all-male sample, which is not representative of the population as a whole and could have biased the results.</p> <p>Some parameters were not analysed statistically, for example, whether the diagnostic yields were different between early and late monitoring.</p>
<p>Abbreviation: AF, atrial fibrillation.</p>	

Recent and ongoing studies

- [NCT02031484](#) – Comparison of continuous sternal ECG patch monitors (Carnation and Zio) trial. Trial is enrolling participants by invitation only. Estimated completion date was January 2017.
- [NCT02506621](#) – ELR monitoring against permanent pacemaker in atrial fibrillation (REMAP-AF). UK-based trial but not yet open for recruitment. The manufacturer has advised that the estimated completion date is June 2017.
- [NCT02683174](#) – Diagnostic yield of an ambulatory patch monitor in unexplained emergency department syncope: a pilot study (PATCH-ED). UK-based trial currently recruiting participants. Estimated completion date is December 2017.
- Real-world heart monitoring strategy, evaluation, treatment patterns and health metrics in atrial fibrillation (RHYTHM Study). US-based trial. Estimated completion date of Aim 1 is May 2017 and Aims 2 and 3 is October 2017.

- Randomised clinical trial of early prolonged ambulatory cardiac monitoring after stroke (EPACS). UK-based trial. Results presented at the International Stroke Conference in February 2017. Enrolment completed.
- CCG trial of innovative alternative palpitation pathway. UK-based trial with the Ealing Clinical Commissioning Group. Estimated completion date is June 2017.

Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Two out of 3 specialist commentators were familiar with or had used this technology before. One stated that they were involved in an ongoing clinical trial using the device and another that it was used regularly in their private practice.

Level of innovation

Two commentators agreed that the Zio Service is very innovative. One stated that people tolerate it much better than other monitoring devices and another noted that it is beneficial for people who have transient loss of consciousness during arrhythmia because they cannot actively record symptoms as needed with some mobile apps. The third commentator stated that although it is a novel concept and design, extended monitoring for up to 7 days is readily available in the NHS and has been for many years.

One commentator stated that the Zio Patch's ease of use and waterproof design are an improvement on other traditional recorders and that the report produced is excellent with an easy-to-read layout. The commentator also recommended showing people how to apply the patch, but has previously sent patients the patch to apply themselves and they did not have any problems doing this. Another commentator stated that no training on applying the patch is needed, only on how to send it for analysis. A third believed that older people could struggle to correctly position the device, but that it is quite simple for those who have been appropriately trained.

Potential patient impact

All commentators agreed that the Zio Service could have benefits for people. One commented that the device can be applied during consultation, avoiding an extra session or outpatient appointment to have a monitor fitted. Also, there is less chance of a Zio Patch failing than a Holter monitor.

Another commentator noted that Holter monitors can be affected by motion artefacts and the leads can get damaged, which can prevent accurate monitoring. The Zio Patch is beneficial for all people because it is leadless and more robust, but also particularly for children, and for people with mental health or cognitive problems.

All 3 of the commentators noted that because the Zio Service can be used for longer than the standard 24- to 48-hour monitoring period, it can help to detect arrhythmias that occur after this period. One commentator felt that Zio Service could also be useful in quantifying atrial fibrillation burden and stratifying the risk of stroke. It is likely to prevent some people from having implantable devices that are not needed, which could reduce discomfort and infection risk.

One commentator suggested that this device could result in earlier diagnosis and another that it may reduce the number of hospital visits for patients because they can return the monitor by post. One commentator also mentioned that there is less risk of skin reactions because of fewer electrodes being attached to the patient and less repeat monitoring, which could mean that people wear it for the full monitoring period.

Potential system impact

One commentator stated that using the Zio Patch could increase the efficiency of screening patients for arrhythmias and, in theory, replace a consultation in secondary or tertiary care if the results showed that the symptoms were not serious or could be managed in primary care. But, because an external agency was producing the reports, clinicians would be unaware if data had been missed unless the full dataset was disclosed. Two commentators agreed that having the data analysed externally could free up clinical staff to be used elsewhere. A third commentator thought that the device may reduce admissions because it can easily be applied in an emergency department rather than needing to admit someone for observation. But, the report would need to be interpreted by a senior member of the clinical team, probably a consultant cardiologist, to decide future management.

All commentators agreed that minimal changes in facilities or infrastructure would be needed if the Zio Service was adopted in standard practice, with only storage of return boxes and typical IT infrastructure needed.

Two of the 3 commentators felt that it would be unlikely to generate cost savings for the NHS because the device has a significant cost for each patient. One commented that it might be cost effective in a specific subset of patients as an adjunct rather than a replacement for current methods of monitoring. The third commentator believed it could be cost effective because of

reduced need for repeat monitoring, admissions or implantable event recording devices and associated costs, but that savings would depend on the cost of the device to the NHS. One commentator pointed out that implantable loop recorders are more expensive, but offer 18 to 24 months of monitoring, which might be more cost effective for certain patients, and that it would be useful to determine their comparative effectiveness with the Zio Service in a randomised controlled trial.

General comments

One commentator noted that other similar products are available and felt that these should be considered alongside the Zio Service. Another commentator warned against clinicians recommending this kind of monitoring service unnecessarily instead of taking a full clinical history to inform decision-making. Clinicians should also be aware that extended monitoring could pick up unexplained symptoms with unknown significance and consideration is needed on how to deal with this.

Patient organisation comments

The Arrhythmia Alliance, the Atrial Fibrillation Association and the Syncope Trust And Reflex Anoxic Seizures (STARS) Charity were all asked to comment on this briefing. Their responses are summarised below.

All 3 patient organisations agreed that the Zio Service would allow people to be monitored at home because the patch is very discreet and lets wearers carry on with their normal day-to-day life. One organisation stated that during Holter monitoring, some people with syncope will not have a syncopal attack because their daily activities are limited. The added benefit of the patch being water resistant means that wearers can still exercise and shower.

The Zio Service could improve patient outcomes by capturing symptoms that may be missed during 24-hour Holter monitoring, resulting in earlier correct diagnosis. The Atrial Fibrillation Association noted that atrial fibrillation is often intermittent, and so prolonged monitoring with the Zio Service could increase the chance of capturing an event and reduce the delay in diagnosis. It could also reduce strokes related to atrial fibrillation and the misdiagnosis of epilepsy in people with unexplained loss of consciousness. In relation to children, the STARS charity commented that because the Zio Patch is small and its application is similar to putting on a plaster, children are less scared of the device than of traditional monitors.

None of the patient organisations reported negative feedback from people who had used the Zio Service. The Arrhythmia Alliance noted that wearers sometimes have to order a second patch if there are no symptoms in the first 14 days. This is beneficial because it could avoid the need for a further more invasive procedure.

All the organisations agreed that because of its ease of use and minimal training need, it is better than current methods for detecting arrhythmias. They also thought that using the Zio Service could be cost saving for the NHS because it could reduce hospital visits and long waiting times for monitoring equipment, and avoid the need for large pieces of equipment usually used to diagnose arrhythmias. All of the patient organisations would recommend the Zio Service.

Specialist commentators

- Shane Exton, Lead Cardiac Physiologist/Clinical Scientist for Non-Invasive Cardiac Diagnostics, University Hospital Wales, Cardiff and Vale University Health Board. No conflicts of interest declared.
- Dr Stephen Murray, Cardiologist, Freeman Hospital, Newcastle, The Newcastle upon Tyne Hospitals NHS Foundation Trust. No conflicts of interest declared.
- Dr Matthew Reed, Consultant in Emergency Medicine, Royal Infirmary of Edinburgh, NHS Lothian. Chief investigator on the PATCH-ED study investigating Zio Patch. iRhythm is only supplying the device and has no input on the study design, process or reporting.

Patient organisations

The following patient organisations contributed to this briefing:

- Arrhythmia Alliance
- Atrial Fibrillation Association
- Syncope Trust And Reflex Anoxic Seizures (STARS)

Development of this briefing

This briefing was developed for NICE by Cedar. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-2399-1