NICE National Institute for Health and Care Excellence

NICE guidance

Zio XT for detecting cardiac arrhythmias

Medical technologies guidance
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Contents

This guidance replaces MIB101.

1 Recommendations

1.1 Zio XT is recommended as an option for people with suspected cardiac arrhythmias who would benefit from ambulatory electrocardiogram (ECG) monitoring for longer than 24 hours only if NHS organisations collect information on:

- resource use associated with use of Zio XT
- longer-term clinical consequences for people who have monitoring with Zio XT (such as incidences of further stroke, transient ischaemic attack and other thromboembolisms, arrhythmia-related hospitalisations, mortality, uptake of anticoagulants or other changes in medication related to the monitoring result).

1.2 Evidence shows that Zio XT is convenient and easy to wear, with an improved diagnostic yield (a measure of how many people with cardiac arrhythmia are diagnosed) compared with standard 24-hour Holter monitoring. The technology is likely to be cost neutral or cost saving compared with 24-hour Holter monitoring, but more evidence is needed.

1.3 NHS organisations using Zio XT should make sure that the service complies with general data protection regulations (GDPR), and that informed consent covers how a person's data will be used.

Why the committee made these recommendations

Zio XT is a remote ECG monitoring service used to detect cardiac arrhythmias. The service comprises a wearable single-lead ECG device, a software algorithm that analyses the ECG data and a report for the clinician.

Clinical evidence shows that people prefer Zio XT to standard care in the NHS, which usually involves wearing a continuous ECG monitor such as a 24-hour Holter monitor. Evidence also shows that Zio XT improves patient wear time and how many people are diagnosed with cardiac arrhythmias compared with 24-hour Holter monitoring. People can wear Zio XT for up to 14 days, which makes it suitable for people with symptoms of

arrhythmia that happen more than 24 hours apart. Diagnostic accuracy evidence shows that the software algorithm performs well in recognising arrhythmias.

The effect of adopting Zio XT on costs and resource is uncertain because there is not enough evidence about resource use and the long-term consequences of using it. However, the estimates suggest that using Zio XT is likely to be cost saving or cost the same as using 24-hour Holter monitoring. So, NICE recommends Zio XT as an option for detecting cardiac arrhythmias but NHS organisations using it should collect further evidence to resolve the uncertainties.

2 The technology

Technology

2.1 Zio XT (iRhythm Technologies) is a remote cardiac monitoring service used to detect cardiac arrhythmias. It has 3 components:

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

The Zio biosensor is placed on the person's left upper chest. It can be fitted in clinic or sent directly to the person where they can fit it themselves at home. It records a continuous beat-to-beat ECG for up to 14 days. The person 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 sends it to the company by Freepost. The ECG recordings are analysed using ZEUS's algorithm, overseen by company-based accredited cardiographic technicians. A technical report including arrhythmia episodes, wear and analysis time, and patient-captured events is sent to the prescribing healthcare professional for final analysis and interpretation. There are no patient identifiers in or on the Zio biosensor, and data cannot be accessed if the Zio biosensor was to be physically intercepted.

Innovative aspects

2.2 Zio XT provides a continuous recording of ambulatory cardiac monitoring for up to 14 days. This is a longer monitoring period than continuous ECG monitors used in NHS standard care, such as a Holter monitor, which can be up to 7 days but is usually for between 24 and 48 hours.

2.3 The wearer can go about their normal daily activities during monitoring,

including showering or bathing, because the device is water resistant. Zio XT 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.

2.4 The Zio biosensor has no external leads or wires; this is intended to reduce noise artefacts in the data. Zio XT uses proprietary software to detect arrhythmic events in the ECG data and to create the report that is delivered to the healthcare professional. The intention is to reduce the time needed for NHS staff to analyse the continuous monitoring data.

Intended use

2.5 NICE's guideline on transient loss of consciousness ('blackouts') in over 16s and on managing atrial fibrillation recommend the best ways to detect arrhythmia. The NICE Pathway on heart rhythm conditions describes NICE recommendations on the care pathway for patients. NICE recommends a 12-lead ECG for the first assessment. If the ECG does not detect arrhythmia, and paroxysmal atrial fibrillation is suspected, ambulatory ECG monitoring is recommended using either Holter monitoring or cardiac event recorders, depending on symptoms and symptom frequency. In people with infrequent blackouts (less than once every 2 weeks), an implantable cardiac monitor may be offered. NICE's diagnostics guidance on implantable cardiac monitors to detect atrial fibrillation after cryptogenic stroke also recommends using an implantable cardiac monitor to detect atrial fibrillation after cryptogenic stroke, if a cardiac arrhythmic cause of stroke is still suspected after ambulatory ECG monitoring.

2.6 Zio XT provides another ambulatory ECG monitor option to current standard care (24-hour Holter monitoring or cardiac event recorder monitoring) for detecting cardiac arrhythmia in people with palpitations, fainting (syncope) and suspected cardiac arrhythmia. People can wear Zio XT for up to 14 days, which makes it suitable for people who experience symptoms of arrhythmia more than 24 hours apart. Zio XT is prescribed by a healthcare professional, most often a cardiologist or GP, in primary, secondary or tertiary care. It may also be prescribed by a stroke clinician or neurologist.

2.7 Full details on using Zio XT are in the instructions for use.

Costs

2.8 During consultation, the company revised the cost of monitoring with Zio XT from £310 to £265 per patient (excluding VAT). This figure includes the cost of the biosensor and the cost of analysing and reporting the data.

For more details, see the website for Zio XT.

3 Evidence

Clinical evidence

The clinical evidence comprises 30 published studies

3.1 The clinical evidence comprises 17 published studies, which include 169,063 people referred to ambulatory monitoring, and 13 abstracts:

- 1 UK-based randomised controlled trial (Kaura et al. 2019)
- 3 prospective within-subject comparative studies (Barrett et al. 2014, Eysenck et al. 2019, Rosenberg et al. 2013)
- 6 prospective non-comparative studies (Rho et al. 2018, Heckbert et al. 2018, Reed et al. 2018, Schreiber et al. 2014, Steinhubl et al. 2018, Turakhia et al. 2015)
- 7 retrospective non-comparative studies (Eisenberg et al. 2014, Go et al. 2018, Schultz et al. 2019, Solomon et al. 2016, Tung et al. 2015, Turakhia et al. 2013, Wineinger et al. 2019)
- 13 abstracts (Agarwal et al. 2015, Chandratheva et al. 2017, Ghosh et al. 2018, Hall et al. 2019, Keibel et al. 2015, Malhotra et al. 2018, Miller et al. 2014, Norby et al. 2018, Salazar et al. 2011, Sattar et al. 2012, Su et al. 2014, Turakhia et al. 2012, Ullal et al. 2013).

  The external assessment centre (EAC) noted that some of the non-comparative studies may have overlapping populations because the data are retrospective. For full details of the clinical evidence, see section 3 of the assessment report, which is in the supporting documents for this guidance.

Four comparative studies are considered pivotal to the decision problem

3.2 Three of the 4 comparative studies compared 14-day Zio XT with a

24-hour Holter monitor (Barrett et al. 2014, Kaura et al. 2019, Rosenberg et al. 2013) and 1 compared it with an external loop recorder (the Novacor R. Test; Eysenck et al. 2019). The size of the studies varied, with a total of 357 people, including those with a recent stroke or transient ischaemic attack, people with pacemakers or diagnosed atrial fibrillation, and people with suspected arrhythmia. The EAC considered the multicentre UK randomised controlled trial to be the highest-quality study (Kaura et al. 2019). The EAC considered the other 3 comparative studies to be of adequate quality. The EAC did not do a meta-analysis because it considered the evidence to be too heterogeneous in terms of populations, methodology, comparators, and outcomes reported.

The UK-based randomised controlled trial has a high withdrawal rate because there was a high refusal rate for the Holter monitor

3.3 The randomised controlled trial compared the diagnostic yield of 14-day Zio XT with 24-hour Holter monitoring in 116 people with stroke or transient ischaemic attack. People randomised to the Zio XT monitoring arm also had 24-hour Holter monitoring. There was a high withdrawal rate from both arms of the trial because 20% of the randomised patients refused to use the 24-hour Holter monitor. This may have biased results. According to the trial authors, the study was adequately powered for the primary outcome. An independent power analysis done by the EAC found that the randomised controlled trial was likely to be underpowered because of the high withdrawal rate. The trial is underpowered for the secondary outcomes, which included anticoagulation use and mortality.

Evidence suggests that monitoring with Zio XT increases diagnostic yield

3.4 Three studies comparing arrhythmia detection rates for Zio XT with 24-hour Holter monitoring showed an increased diagnostic yield with Zio XT over total wear time. Results from Eysenck et al. (2019) suggested that Zio XT may be more accurate in detecting the presence or absence of atrial fibrillation than the Novacor R. Test (an external event loop monitor, described as current standard practice) but less accurate than pacemaker data (described as gold standard).

Evidence suggests that patients found Zio XT acceptable and wore it for most of the scheduled days

3.5 Evidence from comparative studies suggested that most patients were happy to wear the Zio XT biosensor, with median wear time ranging from 10.8 days (Rosenberg et al. 2013) to 12.8 days (Eysenck et al. 2019) out of a scheduled 14 days. In Eysenck et al. (2019), the Zio XT biosensor was worn for longer than 3 of the other continuous cardiac monitors evaluated. In Barrett et al. (2014), 93.7% of patients found the biosensor comfortable to wear compared with 51.7% for the Holter monitor. A survey of patients from a UK cardiology clinic (Hall et al. 2019) found that Zio XT was statistically significantly preferred to Holter monitoring in terms of shape, comfort, practicality and returning method.

The diagnostic accuracy of Zio XT and the effect of the technology on clinical outcomes are uncertain from the published evidence

3.6 The diagnostic accuracy of Zio XT compared with standard care was not clearly defined in any study. Barrett et al. (2014) and Rosenberg et al. (2013) did some analysis comparing a Holter monitor and Zio XT over the same 24-hour period with different results. Rosenberg et al. (2013) reported that there was statistically significant agreement between Zio XT and the Holter monitor recordings over the same 24-hour period. However, Barrett et al. (2014) reported the Holter monitor detected 11 arrhythmia events that were not detected by Zio XT over a simultaneous 24-hour monitoring period. The authors stated that 2 were caused by Zio XT algorithm misclassification, which was then corrected, and 7 were errors made by the company's report reviewer. A technical study by Hannun et al. (2019) reported good diagnostic performance for the deep neural network used as part of Zio XT compared with a committee of cardiologists. There is no evidence to show that an increased diagnostic yield with Zio XT improves clinical outcomes. The EAC considered that, without more information about diagnostic accuracy, it is not clear if the changes to treatment reported in the studies were an appropriate response to the patient's condition. During consultation, the company submitted unpublished technical data to support diagnostic accuracy claims. This is detailed in section 3.8.

The evidence for Zio XT is broadly generalisable to NHS practice

3.7 Five studies were done in the UK and the EAC considered the evidence is generalisable to the NHS: 2 comparative studies (Kaura et al. 2019, Eysenck et al. 2018), 1 prospective non-comparative study (Reed et al. 2018), and 2 conference abstracts (Chandratheva et al. 2017, Ghosh et al. 2018). The 2 remaining comparative studies were in the US.

Evidence submitted during consultation

The company's evidence shows the ZEUS algorithm has good diagnostic accuracy per episode

3.8 During consultation, the company submitted technical data reporting the performance of Zio XT's algorithm (ZEUS) at detecting 11 arrhythmia types and sinus rhythm. Using a reference database of known clinical rhythms (over 150 examples of each), the ZEUS algorithm showed a sensitivity of over 90% and a specificity of over 95% for detecting atrial tachycardia (including atrial fibrillation and supraventricular tachycardia) from a total of over 1,400 episodes. Post-market analysis using clinical records processed by Zio XT showed a sensitivity of over 90% for detecting atrial tachycardia from a total of over 50 million episodes. Newcastle EAC reviewed the technical data provided by the company and concluded that Zio XT shows excellent agreement with cardiographic technician assessment of identified arrhythmia episodes. However, it highlighted that the analyses were done per episode and not on a per-patient basis. But it stated that, in principle, good per-episode performance should translate to good per-patient performance.

An EAC review of artificial intelligence in Zio XT raised no concerns

3.9 During consultation, KiTec EAC reviewed the artificial intelligence in Zio XT's ZEUS software. It noted that the algorithm to detect arrythmia uses a fixed deep neural network (a computational model made up of multiple processing layers) and that the training of the system is adequate. The EAC noted it had a large training dataset and that

uncommon rhythms were well represented within this dataset. The software also used an external database for validation. The EAC also reviewed the internal quality assurance process and noted that before providing a report to clinicians, the algorithm outputs are checked by the company's cardiographic technicians (certified by The Society for Cardiological Science and Technology and Cardiac Credentialing International). The percentage of electrocardiogram (ECG) traces that are quality assured by cardiographic technicians was not reported but the agreement between algorithms and cardiographic technicians was high (over 99% overall episodic sensitivity in post-market analysis).

Clinical experience from an NHS trust and a sustainability and transformation partnership does not add to the evidence base

3.10 During consultation, 1 NHS trust and 1 sustainability and transformation partnership provided feedback and results from using Zio XT. The EAC reviewed the evidence submitted but did not consider it added anything to the existing evidence base. It concluded that clear conclusions about efficacy could not be drawn from the results because there was not enough information on the patient populations.

Cost evidence

The cost evidence comprises 5 published studies

3.11 Five published studies reported the economic impact of the technology:

- a UK budget impact analysis (Kaura et al. 2019)
- a UK study reporting technology costs using data from the REMAP-AF trial (Eysenck et al. 2019)
- a prospective matched cohort study reporting healthcare resource use (Steinhubl et al. 2018)

- 2 conference abstracts (Ghosh et al. 2018, Chandratheva et al. 2017).

  Two studies reported that the technology was cost saving. Two reported it was not cost saving compared with other devices including Holter monitoring. Studies consistently reported that Zio XT is the most efficient in terms of avoiding delays between clinic and diagnosis confirmation.

The company presented 3 cost models showing that monitoring with Zio XT saves between £55 and £85 per patient over 1 year

3.12 The company created 3 de novo cost analyses comparing the 14-day Zio XT with blended strategies, based on a 24-hour Holter monitor or a cardiac event recorder, in different care pathways:

- The cardiology model (presented as a base case) considered people with symptomatic palpitations or syncope and assessed the costs associated with the diagnostic process only.
- The stroke model (presented as a base case) considered people who have had a stroke or transient ischaemic attack and assessed the costs associated with the diagnostic process only.
- The downstream stroke model was presented as a scenario analysis and extrapolated the economic consequences of the extra risk of recurrent stroke because of delayed or missed diagnosis of atrial fibrillation.

  All models had a time horizon of 1 year. Overall, the company's models showed that using Zio XT saves between £55 and £85 per patient because of reductions in repeat testing, referrals or cardiology outpatient review, and events in stroke populations. For full details of the cost evidence, see section 4 of the EAC's assessment report in the supporting documents for this guidance.

The EAC's changes to the models make monitoring with Zio XT cost incurring

3.13 The EAC revised the base-case (cardiology and stroke) models to address some potential limitations:

- the proportion of patients having repeat Holter tests after 24-hour Holter monitoring was changed to 27%
- NHS reference costs were used for Holter monitoring rather than Patient Level Information and Costing System (PLICS) data
- the cost of an outpatient appointment before discharge was included for all tests.

The EAC revised the downstream stroke model to:

- include the cost of anticoagulants (and their side effects)
- lower the estimated stroke risk
- include repeated diagnostic test costs.

The EAC considered the downstream stroke cost model the most informative. After these revisions, the EAC concluded that Zio XT is unlikely to be cost saving at the original price when compared with current practice. Zio XT became cost incurring by:

- £0.82 per patient per year in the cardiology model
- £70.81 per patient per year in the stroke model
- £20.83 per patient per year in the downstream stroke model.

Scenario analyses suggest that cost savings are influenced by the number of repeat tests and outpatient follow-up appointments

3.14 The EAC did a scenario analysis to explore the impact of repeat monitoring after a negative test. Zio XT was cost incurring when all monitoring was repeated after a negative test. When monitoring with a 24-hour Holter or a 7-day cardiac event recorder was repeated after a negative first test, but Zio XT was not repeated, the technology was cost saving. The EAC also explored the impact of excluding follow-up outpatient appointments after monitoring for some or all tests. Full descriptions of the 5 scenarios explored and results for each of these scenarios can be found in section 2 of the addendum to the EAC's assessment report in the supporting documents for this guidance.

Cost evidence submitted during consultation

A revised cost of £265 makes Zio XT cost saving or broadly cost neutral

3.15 During consultation, the company revised the cost for the technology to £265 per person. The EAC recalculated the results from the cost modelling with the lower price in the 2 most relevant scenarios, which included the following assumptions:

- no appointment needed after a negative result, and no repeated test (scenario 3)
- no appointment needed after any negative result, whether or not the test is repeated (scenario 5).

The results showed Zio XT is likely to be cost saving or cost neutral compared with standard care in the cardiology model (£59.80 less for scenario 3; £3.47 less for scenario 5 per patient per year). For the stroke model, the results were still cost incurring (£14.93 more for scenario 3; £79.47 more for scenario 5 per patient per year) but the downstream model results for the same population showed the results moved towards Zio XT being cost saving (£72.55 less for scenario 3; £33.79 more for scenario 5 per patient per year). Full results for all 5 scenarios explored can be found in section 1 of the additional economic analyses in the supporting documents for this guidance.

Increasing the probability of testing with implantable cardiac monitors does not substantially change the cost-modelling results

3.16 Additional sensitivity analysis was done to examine the effect of a potential change in the use of implantable cardiac monitors. The experts did not all agree that use of implantable cardiac monitors is likely to increase in the future. In the stroke and cardiology models, a small percentage of patients (2%) who have a negative test will go on to have implantable cardiac monitoring. Increasing the probability of testing with implantable cardiac monitors to 10% did not substantially change the

results of the Zio XT cost modelling. For full details, see the additional sensitivity analysis report and additional clinical expert advice in the supporting documents for this guidance.

Threshold analysis results for repeat tests range from 1.30 to 1.78 per person

3.17 The EAC also did a threshold analysis to assess the number of repeat tests per person in the current care arm needed to equalise the cost of Zio XT and current care. The average number of repeat tests after a negative result with either 24-hour Holter or cardiac event recorders was assumed to be 1.389 per person in the base case. Threshold analysis results ranged from 1.30 to 1.78 repeat tests per person, depending on the model and scenario evaluated. For full details, see the additional sensitivity analysis report in the supporting documents for this guidance.

4 Committee discussion

Clinical-effectiveness overview

Zio XT is an innovative technology which shows promise for ambulatory monitoring

4.1 The clinical experts who had experience of using Zio XT explained that it offers continuous monitoring over 14 days and is well accepted by patients. Experts commented on how easy it is to fit and that patients find it acceptable, adding that people are more likely to wear Zio XT for longer. The committee agreed that Zio XT is an innovative design and there is a plausible patient benefit.

The evidence shows that Zio XT can improve diagnostic yield and patient wear time

4.2 Evidence shows that Zio XT can increase patient wear time. Three of the 4 comparative studies showed improved diagnostic yield over total wear time compared with 24-hour Holter monitoring. Eysenck et al. (2019) reported a longer wear time for Zio XT compared with the R-test (a cardiac event recorder). The clinical experts agreed that it was plausible that monitoring with Zio XT could increase diagnostic yield, primarily because Zio XT is worn for 14 days, which is much longer than the Holter monitor. The clinical experts also advised that Zio XT has usability advantages for patients. It is more discreet and convenient to wear than a Holter monitor and the Zio biosensor stays on better. The committee concluded that Zio XT increases diagnostic yield for detection of cardiac arrhythmias compared with 24-hour Holter monitoring.

The committee considers Zio XT to be a diagnostic service for detecting cardiac arrhythmia

4.3 The committee questioned whether Zio XT is a diagnostic service. The

company said that the Zio XT algorithm highlights areas of concern on the electrocardiogram (ECG) trace, then a company-based cardiac physiologist reviews and confirms the arrhythmia type. A report including a sample of the ECG trace is generated for the referring healthcare professional. The company said that the technology is a decision support tool that provides a report allowing the referring healthcare professional to make a diagnosis. The company also said that full disclosure of ECG traces is available on request. The committee discussed the likely dependence of healthcare professionals on the report and queried the reliability of the data in it. The committee accepted that although Zio XT provides useful information about the number of episodes and type of arrhythmic events, the final diagnosis and treatment decision remains with the referring healthcare professional. The committee concluded that Zio XT is a diagnostic service, which provides information to clinicians to help make a diagnosis.

Zio XT has good diagnostic accuracy on a per-episode basis

4.4 The available published evidence did not provide reliable estimates of diagnostic sensitivity or specificity. Hannun et al. (2019) showed that Zio XT's ZEUS algorithm was able to classify a broad range of distinct arrhythmias and had a similar accuracy to cardiologists. However, the study was not done with the Zio Patch or in a clinical setting. Also, Zio XT's ECG recordings are captured using a single-lead biosensor while Holter monitors use 3 leads. Experts said that although 3-lead ECG recordings may be better at detecting certain types of arrhythmia, most clinical decisions can be made from 1 lead. At the draft guidance meeting the committee was concerned about the lack of detail for the diagnostic accuracy data and recommended further research. After consultation, the committee considered the technical data provided by the company and the EAC's review of this data. It agreed with the EAC's view that the Zio XT software has good per-episode performance for detecting cardiac arrhythmia and this should translate to good per-patient performance. The committee concluded that Zio XT shows good performance in recognising episodes of identified arrhythmia in ECG traces but noted that publication of future data would be valuable.

Additional information about the long-term clinical

consequences of using Zio XT would be valuable

4.5 In their evidence review the EAC queried the effect of an increased diagnostic yield on clinical consequences. It considered that further comparative evidence about how Zio XT affects clinical management of cardiac arrhythmias and patient outcomes would be helpful. The committee understood the limitations of the evidence base and agreed that more information about the long-term clinical consequences of using Zio XT would be valuable.

Other patient benefits or issues

Shaving of bodily hair is common to both Zio XT and Holter monitoring and is unlikely to restrict access for patients

4.6 Applying the Zio XT biosensor may mean body hair needs to be shaved. Some religions forbid cutting or shaving body hair. The clinical experts advised that shaving is needed for both Zio XT and Holter monitoring. They believed this would not restrict access for particular groups of people and said that, in their experience, most people agree to shave when using the Zio XT biosensor.

NHS considerations overview

Zio XT is scalable but there are concerns about its impact on NHS resources

4.7 Clinical experts highlighted that there is currently a shortage of cardiac physiologists in the NHS. They noted that more widespread adoption of Zio XT in the NHS may further affect the recruitment of cardiac physiologists if they leave the NHS to work for the service. But they also said that reducing the burden on cardiac physiologists in the NHS of analysing ECG reports should be considered a benefit of Zio XT. The company said that it has the capability to scale up its service to the UK, and that it would adapt a successful model used in the US. The company confirmed that the turnaround time for reports (4 days maximum but

usually 24 hours) would not change. The committee was reassured that Zio XT is potentially scalable across the NHS but it was less certain about the impact on the NHS cardiac physiologist workforce.

Zio XT uses anonymised patient data and appears to comply with privacy laws

4.8 The data used for developing and training the algorithm come from a database of anonymised ECG traces from patients who have previously used the service. The committee queried if patients are aware of this when they use the service and discussed considerations for the use of anonymised data in software development and training. The company explained that Zio XT meets all the relevant NHS data governance standards including the NHS Digital Toolkit and general data protection regulation (GDPR) privacy requirements. The committee noted that people give consent for their data to be used and that Zio XT appears to comply with all applicable privacy laws. The committee concluded that NHS organisations using Zio XT should make sure that the service is compliant with GDPR, and that informed consent for the investigation covers how a patient's data will be used.

Cost-modelling overview

The EAC's base case does not fully reflect clinical practice regarding outpatient appointments

4.9 In its base-case analysis, the EAC assumed that all monitoring tests would be followed up with an outpatient appointment. Clinical advice was that outpatient appointments are not usually needed after a negative result from Zio XT, and that practice varies. In scenarios in which follow-up outpatient appointments were included for standard care but not for Zio XT, Zio XT was cost saving across all 3 of the EAC's revised models. Comments and clinical expert advice received at consultation suggested that an outpatient appointment would normally only be needed after a significant positive result, regardless of the ECG monitoring device used. The committee concluded that out of the scenarios explored by the EAC, 2 scenarios best reflected current clinical practice (see section 3.15).

Zio XT may have additional benefits not captured in the cost modelling

4.10 The committee noted that the long-term clinical benefits of identifying significant arrhythmias were not captured in the stroke or cardiology models, which only evaluated diagnosis costs. The committee considered the downstream stroke model to be more informative because it took into account the benefits in terms of stroke outcomes within the first year, in addition to the cost of diagnosis. However, longer-term benefits were not included. There is no equivalent model for the cardiology patients so the longer-term benefits of earlier diagnosis in this group have not been calculated. The EAC advised that there was not enough information available to model longer-term benefits in the cardiology model. The committee concluded that there are likely to be additional benefits of using Zio XT which have not been captured in the current cost modelling.

Zio XT is likely to be cost saving or broadly cost neutral, but this is uncertain

4.11 After consultation, the EAC presented new cost-modelling results including the reduced price for Zio XT. The committee accepted that this reduction in price made Zio XT slightly cost saving compared with standard care for patients in the cardiology model (people with symptomatic palpitations or syncope). The clinical experts explained that the benefits of Zio XT in this population are likely to be realised with careful patient selection based on frequency of symptoms. The committee considered that Zio XT is most likely to be cost saving when used by patients who have symptoms more than 24 hours apart. For patients who have had ischaemic stroke or a transient ischaemic attack without current evidence of atrial fibrillation, the downstream results show Zio XT is likely to be cost neutral or cost saving. The assumptions about follow-up appointments and repeat tests affected the results significantly. Expert advice showed that there is significant variation in the resources used for monitoring. The committee accepted the limitations of the current models and concluded that Zio XT is likely to be cost saving or broadly cost neutral, but more information is needed about resource use.

Further information about resource use and the long-term consequences of Zio XT monitoring would be valuable

4.12 The committee accepted the EAC's changes to the models but considered there was still uncertainty about resource use and the long-term consequences of using Zio XT. Therefore, it was difficult to draw firm conclusions about the extent of any cost benefits. The committee noted the influence of assumptions about the need for outpatient appointments and the number of repeat tests on the cost modelling and the variation in ECG monitoring practice across the NHS. It concluded that more detailed data from sites that have used Zio XT in their ECG monitoring pathway could provide valuable information about resource use. This could inform the cost modelling and possibly some best practice guidelines for adopting Zio XT. The committee also concluded that further information on the long-term consequences of Zio XT monitoring (such as incidences of further stroke, transient ischaemic attack and other thromboembolisms, arrhythmia-related hospitalisations, mortality, uptake of anticoagulants or other changes in medication related to the monitoring result) would likely strengthen the certainty of cost benefits associated with its use.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more technical analysts (who act as technical leads for the topic), a technical adviser and a project manager.

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