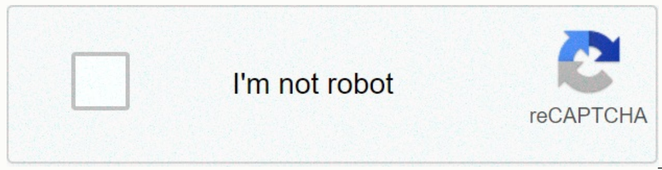

Continue

Nice guidelines cryptogenic stroke

Hundreds of strokes can be prevented with a new screen for implants that transmit data to doctors remotely, after the Nice Guidance Project published today. The LINQ detector - developed by Medtronics - identifies more people who have atrial fibrillation after a stroke with no specific cause or transient ischemic attack (TIA). These patients can then start treatment for atrial fibrillation to reduce the risk of another stroke. It is the first device of its kind recommended for nhs use by Nice. This is an innovative screen that has the potential to reduce the number of strokes experienced by people with atrial fibrillation, said Mindhoft Boyzin, director of the Nice Centre for Health Technology Assessment. It may mean fewer hospital visits to those with atrial fibrillation; Reducing the need for rehabilitation and patients means reassuring that AF will be detected in time so that treatment can begin. This device can provide a level of reassurance to those living in fear of another stroke, and we believe that linq detection is likely to be a cost-effective use of NHS resources. Innovation Minister Nicola Blackwood said: It is great to see innovative technology being adopted to improve the lives of those with conditions that can be extremely debilitating, especially patients at risk of multiple strokes. We are constantly striving to improve the patient experience, and we will continue to do so as we invest record amounts of money in the NHS and ensure that we make the most of progress in healthcare. One third of the size of the AAA battery, usually implanted under the skin of the chest under local anesthesia, to track heart activity over long periods of time, and to transfer data back to the patient's doctor over the mobile phone network. Undiagnosed atrial fibrillation is believed to be responsible for a large part of the 30,000 strokes with an unknown cause, also known as cryptostrokes, which occur every year in the UK. Crypto-stroke patients have a high risk of recurrent stroke and require a confirmed diagnosis of atrial fibrillation for treatment to prevent a recurrence of stroke. Data provided to the Nice Diagnostic Supremo revealed atrial fibrillation after discovering an encrypted stroke five times more than people using a detection screen for six months compared to people who did not have a transplant device. Clinical experts have highlighted that it is important that non-invasive ECG surveillance be performed first before considering linq detection. LinQ detection cost is £1800 plus the cost of implanting the machine. The evaluation assumed that people with a implantable heart monitor would have one head-to-head follow-up one month after the procedure and would then be monitored remotely. Nice diagnostic guidance is not mandatory, but is considered the best practice for the NHS to implement it. Consultation on Draft recommendations are currently being prepared in nice.org.uk until 4 February 2020. 6 Nice intends to develop tools in collaboration with relevant stakeholders to help organizations put these guidelines into practice. In addition, Nice will support these guidelines through a range of activities to promote recommendations for further research. The proposed research will be considered by the Research Facilitation Team of the Nice Medical Technologies Assessment Programme to develop specific research study protocols as appropriate. Nice will also include the research recommendations contained in Section 5 in its database on guiding research recommendations, and will highlight these recommendations before public research bodies. Nice has evaluated three implantable heart screens to help the NHS decide on its use. These screens are called LINQ detection, Rx Confirmation and BioMonitor 2-AF. A implantable heart monitor is a small implanted device implanted under the skin on your chest. He has been constantly watching the rhythm of the heart for several years. If he detects atrial fibrillation (a heart rhythm problem), he sends an ECG to the doctor. Your doctor can check if you have atrial fibrillation and decide if it needs treatment. NICE said that LINQ heart monitoring detection can be used to help detect atrial fibrillation if you have experienced a cryptographic stroke – this is a stroke that you don't know the cause. This is because the evidence shows that this screen increases the detection of atrial fibrillation in people who have a cryptogenic stroke. But you can only get it if you already have a non-invasive ECG monitor that has not detected atrial fibrillation and if doctors still believe that your stroke may have been caused by a heart rhythm problem. Nice has not recommended 2 other heart monitors, Rx confirmation and BioMonitor 2-AF. This is because there is not enough evidence to show the extent of atrial fibrillation that they will discover more than if it had not been used. ISBN: 978-1-4731-3816-2 Cost-effectiveness guide considered by the Advisory Committee diagnostic evidence from several sources on implantable heart screens (BioMonitor 2-AF, RX confirmation and LINQ detection) to evaluate suspected paroxysmal atrial fibrillation in people who have a crypto-stroke. The full details of all the evidence are in the committee's papers. 3.1 The External Assessment Group (EAG) conducted a systematic review to determine evidence of clinical efficacy and diagnostic accuracy of implantable heart screens to detect suspected atrial fibrillation after an encoded stroke. The devices reviewed were: BioMonitor 2-AF Rx confirmation linq detection. 3.2 Studies included if the devices are evaluated in people who have a cryptogenic stroke or a transient phosphonic attack (TIA), and suspected paroxysmal atrial fibrillation. Due to the small number of studies identified, the need for at least 24 hours of outpatient clinics An aperitif (ECG) was not applied without detection of atrial fibrillation prior to implantation of the devices (as current practice). Data from earlier versions of the devices were also considered. 3.3 Because only one study (CRYSTAL-AF randomized trial) met eAG's initial eligibility criteria, EAG relaxed the criteria for including the study to consider single-arm observation studies. EAG did not change the criteria for listing the population because it considered that data from non-crypto-stroke groups would not represent device performance in people with an encrypted stroke or TIA. This is because non-cryptographic stroke populations have different rates of atrial fibrillation. However, EAG provided a summary of studies highlighted by device manufacturers that were not done in the cryptogenic stroke population. The group also highlighted that the number of patients, the duration of the observation and the type of atrial fibrillation will affect the performance estimates of the device. 3.4 One study (reported in 6 publications) compared the effectiveness of using 1 of the devices with traditional follow-up: the CRYSTAL-AF study. This was an open-label, randomized parallel controlled trial group that used xt detection (an earlier version of the LINQ detection). The XT model is larger. The ADVISORY Group said that evidence from diagnostic accuracy studies (see sections 3.48 and 3.49) suggests that linq detection has a better specificity and sensitivity than XT, is easier to implant and causes fewer complications. 3.5 People aged 40 or over who had a recent episode of TIA encryption symptoms or the last episode of the typeped ischemic stroke XT (n = 221) or traditional follow-up care (n = 220) were. People with TIA were recorded only if they had a visible lesion on an MRI or CT scan containing TIA symptoms, and at least 1 of the following symptoms: speech problems, weakened limbs or hemophilia. The follow-up in the control group was ekg monitoring at the discretion of the site investigator. The study was conducted in 55 centres in 14 countries in Europe (none in the United Kingdom), Canada and the United States. The Panel stated that there were similar figures of withdrawals between the arms (excluding transfers, see section 3.12). The data was collected for up to 36 months of follow-up, but relatively few people reached this point (24 per arm). The average follow-up time was 20.3 months for XT detection and 19.2 months for traditional follow-up care. 3.6 The Panel noted that although there were no significant differences in baseline characteristics between the armof the study, there were differences in the numbers of people with an oval patent and the history of the previous stroke. However, these were small and unlikely to be due to systemic issues with randomness. Clinical experts said the population is slightly smaller than people expected to be eligible for a implantable heart monitor in the UK. Also, higher. From TIA (instead of stroke) is expected in clinical practice (closer to 20%, rather than about 9% seen in each of the study weapons). All patients are expected to take an anti-platelet agent (about 96% per arm using an anti-platelet agent at baseline). 3.7 Clinical experts at EAG said that the tests used in the trial to define stroke as cryptogenic were as widely as they could be done in the NHS. A pre-admission examination of atrial fibrillation was Holter's monitoring of 71.2% of people (average duration of 23 hours, range between 21 hours and 24 hours), and the remaining persons had only distance monitoring inside. The team said that this meant that nearly 30% of people did not have any Outpatient ECG surveillance (as specified in the range) and that not all patients who had ECG outpatient surveillance had it for at least 24 hours. 3.8 This experiment was sponsored by Medtronics, the manufacturer of the device used in the study. The group said that the authors of the publications for the study reported employment, grants and personal fees from the company. The team considered this to be the strongest clinical evidence for LINQ detection, although it relates to an earlier version of the device. 3.9 Comparative data for BioMonitor 2-AF, Rx confirmation or the current LINQ detection version has not been specified. Therefore, the team reviewed single-arm monitoring studies in encrypted stroke groups (including TIA) to identify data available on these devices. Biotronik provided a technical verification report comparing bioMonitor 2-AF accuracy with LINQ detection during consultation (see section 3.21). The government's policy of supporting the government' and the government's support for the government's policy of re-establishing the state of the state of the country and the state of the country's political and political interests is a clear and clear All except study 1 evaluation either revealling or XT detection. In Study 1 (Israel et 2017), 13% of people used BioMonitor (an earlier version of BioMonitor 2-AF), but the results were not reported via the device. The team said that these studies therefore do not provide any data for BioMonitor 2-AF or Rx confirmation, but did not complete the data from the AF Crystal study. 3.11 Sample sizes in the studies ranged from 14 to 1,247. Only one study (Cotter et al. 2013) was conducted in the United Kingdom. Most of the studies (17) were potential observation al-Ta'ad studies on a single arm. There were 5 retrospective studies (Asaithambi et al. 2018, 550,000, 55000000000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 000 00 000 000 000 0000 000 000 0000 0000 0000 0000 000 000 000 000 000 000 000 000 0000 0000000000000000000000000000000000000000000000000000000000000000000000 The two countries have a long-range and highly innovative and highly innovative global information and information and information. Choe et al. (2015) used the CRYSTAL-AF data set to predict the number of atrial fibrillation cases detected by Reveal XT and detected through shorter-length intermittent ECG monitoring strategies using simulation. LINQ and use simulations to predict how many people with atrial fibrillation discovered by the device By shorter (non-continuous) ECG monitoring. 3.12 THE CRYSTAL-AF STUDY WAS EVALUATED USING THE COCHRANE RISK OF A 2.0-TOOL BIAS. A full quality assessment is available in the diagnostic evaluation report starting on page 28. There was some concern about the risk of bias because the experiment was open-label and not all people had the random intervention required under the study protocol (5.4% of people assigned to detect XT received a traditional follow-up; 2.7% of the people assigned to the traditional follow-up received an XT detection). Also, the implantation of the device was delayed for 11.5% of people who have xt detection (the average delay length was 6 days, set between 1 quarter and 32 days). The team noted that the results were analyzed by the population intending to treat them, which included patients who did not have xt detection, received it late, or crossed into traditional follow-up. This means that the estimated benefit of having a device may be undervalued. Delays in implanting xt detection were mostly short and unlikely to affect the results. The team said that the absence of blindness was unlikely to affect the relative detection rates of atrial fibrillation between groups. She noted that only a small number of people had been followed up after 12 months, so the results of 24 and 36 months were likely to be less reliable than those of 6 and 12 months, but the direction of that bias was unclear. 3.13 The Advisory Group said it was unable to formally assess the quality of the 26 additional studies identified that were not randomized controlled trials. However, they were all considered at risk of bias because of their one-arm designs. Because of the heterogeneity between the studies, the European Advisory Group did not consider it appropriate to compile the results of these studies. This included the device model used, detection settings, patient characteristics, rigorous stroke assessment, indexed stroke severity, atrial fibrillation definition and separation, and length of follow-up. 3.14 The detection rate of atrial fibrillation in 6 months was the preliminary result of the CRYSTAL-AF study (the rings had to last more than 30 seconds). In 6 months, 19 people were diagnosed with atrial fibrillation in the arm XT detected and 3 people in the traditional follow-up arm. More atrial fibrillation was detected with XT detection at all time points (see table 1). XT revealed increased detection of atrial fibrillation across all pre-defined subgroups (age, gender, race or ethnic group, indicator event, presence or absence of oval patent, chads2 degree), with no significant interactions. Most of the people who had atrial fibrillation detected by Reveal XT were asymptomatic (34 out of 42 were detected 36 months ago). Estimated detection rates are higher in Kaplan Meyer's analysis of 36 months due to uninformative control (i.e., people who dropped out for reasons unrelated to the study) than missing patients to follow (the detection rate of atrial fibrillation is estimated at 30% with XT detection and 3% with traditional follow-up). Abbreviations: AF, Atrial ITT, intent to treat. 3.15 All 26 controlled studies reported the rate of detection of atrial fibrillation. The results of the survey showed that the number of women in the labour market was higher than that of women. Several studies have reported atrial fibrillation detection rates over multiple time points. The team said that studies generally show that a minority of patients are diagnosed in the first month (about 10% of those detected by one year). About 70% to 80% (of the total number of people with atrial fibrillation detected in a study) are diagnosed by 6 months, and a few after a year of observation. All or most atrial fibrillation detected in monitoring studies (when mentioned) were symptoms, as in CRYSTAL-AF. 3.16 Two monitoring studies estimated the number of atrial fibrillation episodes that could have been detected through intermittent monitoring of ECG. These data sets are used created by XT detection (in CRYSTAL-AF; Choe et al. 2015) or LINQ detection (from a large register of patients with the device [n = 1,247]; Ziegler et al 2017). Studies have assumed that detectors were 100% allergic. Studies have estimated that even the best intermittent ECG monitoring strategies will detect less than a third of atrial fibrillation detected by detectors. 3.17 CRYSTAL-AF has not reported any results for other heart disease. 3.18 Five non-comparable monitoring studies reported accidental detection of other arrhythmias. The team said that about 10% of the total number of patients detected due to other arrhythmias was 10% of the total number of people in the study. This consists mainly of bigeminy, pause and slow heart. Two studies reported the breakdown of arrhythmia and gave rates of 1% (atrial flutter, cardiac arrest, diseased sinus nodes, and bigeminy, ventricular tachycardia) to 7% to 8% (ventricular atrial mass and additional ventricular sytole). Full details are on page 51 of the Diagnostic Assessment Report. Studies have not mentioned whether other arrhythmia detected has been treated, or if results have been improved due to the identification of this arrhythmia. The refore, the need for a more effective and effective international financial institution is not only to make the most of the financial and economic crisis, but also to make it more effective to address the issue of the financial crisis. 3.19 No data related to this result has been reported in CRYSTAL-AF. 3.20 Two uncompared observation studies reported the proportion of seizures detected by devices that had not been verified as atrial fibrillation by a doctor. Li et al. (2018) reported 79.7% for Reveal LINQ and Sededed et al. (2017) that more than 90% of seizures detected were not confirmed by the review (Reveal XT and BioMonitor). The panel noted that Medtronics said that the number of false positive alerts varies depending on the model of the device used, and the detection configuration (including the duration of the loop) that the operator programmes. Data on device accuracy (for all devices) in non-cryptostroke population from studies identified by manufacturers (See Section 3.41). 3.21 During the first consultation on these guidelines, bioMonitor 2-AF manufacturer provided an unpublished technical verification report comparing the accuracy of LINQ and BioMonitor detectors. This was done by returning eCG data recorded by the Holter screen in a previous experiment in sensor poles for LINQ and BioMonitor detectors. The report stated that since bioMonitor 2-AF and BIOMONITOR III's atrial fibrillation detection algorithm is the same, the results are applicable to both devices. People enrolled in the original trial documented atrial fibrillation episodes or symptoms attributable to atrial fibrillation, or were to have catheteracaa ablation or atrial, but still had symptoms related to atrial fibrillation. Of the participants, 70% have a history of atrial fibrillation. The rest had a history of persistent atrial fibrillation. However, the Panel highlighted that the report also stated that people with persistent or persistent atrial fibrillation had been excluded. The Panel noted that this was contradictory and meant that the characteristics of the population in the study were unclear. In consultation on the draft routing, the manufacturer BioMonitor commented that all ECG data fed by the devices as part of the study was for less than 48 hours. He said that so like they are men's shivering shavings only. In the study, atrial fibrillation episodes detected, or undetected, were used by the clinical evaluation of ECG monitoring holter to classify real and false positives and false negative atrial fibrillation episodes detected by LINQ and BioMonitor. The sensitivity of the atrial fibrillation ring to Biomonitor and LINQ detection was 78.0% and 79.0% respectively. The average positive predictive values of the patient were 98.7% for Biomonitor and 99.7% for LINQ detection. 3.22 The Panel stated that atrial fibrillation was detected in only 5 people in the traditional CRYSTAL-AF follow-up arm (there is no fibrillation after 24 months; see table 1). This means that it is difficult to make any conclusions about the effect of using XT detection from average time to atrial fibrillation detection data. Atrial fibrillation has been detected in more people with longer follow-up, thus increasing the average time for detection as well. There was a greater increase in the average time for detecting atrial fibrillation with XT detection compared to traditional follow-up across all time points. The team said that the low detection rate of atrial fibrillation in the traditional follow-up arm was the likely cause of this difference. 3.23 There were 18 monitoring studies that reported on the time of the introduction of the device to the detection of atrial fibrillation. The average follow-up ranged from 7 to 20 months, and the average time for the first detection of atrial fibrillation was a wide range, from 21 to 217 days. When reported, the ranges between the two quarters also showed a rise Within the studies. 3.25 No data has been reported in CRYSTAL-AF or in monitoring studies. 3.26 Most people diagnosed with atrial fibrillation using XT detection started to get an oral anticoagulant (more than 90%) In the STUDY OF CRYSTAL-AF. The reasons why people did not start on anticoagulants after the diagnosis of atrial fibrillation were not clear. The team noted that some people who were not diagnosed with atrial fibrillation in the trial had also started on anticoagulants. The reasons for this were not provided. 3.27 Seven monitoring studies (Asaithambi et al. 2018, Carrazco et al. 2018, Christensen et al 2014 Etgen et al. 2013, Li et al. 2018, Merce et al. 2013 and Seow et al. 2018) stated that the absorption of anticoagulants for people with atrial arthroscose discovered by Reveal XT or LINQ was high: between 83.3% and 100%. 3.28 No data has been reported in CRYSTAL-AF or in monitoring studies. 3.29 Xt detection failure in CRYSTAL-AF was not reported. The device had to be removed early due to infection or sinus corrosion of 5 out of 208 (2.4%) early from 2.4% of 100,000,000,000,000,000,000,000,000 Three non-comparable monitoring studies reported on the number of devices removed during the follow-up. In Christensen et al. (2014), xt detection was prematurely removed in 5.7% of people due to skin reactions and discomfort. 3.4% of people chose to remove the device after more than a year without detecting atrial fibrillation. In Asaithambi et al. (2018), 2.6% of people chose to remove Reveal LINQ, and for 0.9% of people who migrated or fell. In Ritter et al. (2013), study participants were offered to remove xt detection as soon as atrial fibrillation was detected. However, they did not report the number of removals that were due to this, or for other reasons such as discomfort, out of 30% of removals. 3.31 No data has been reported in CRYSTAL-AF or monitoring studies. 3.32 No data has been reported in CRYSTAL-AF or in monitoring studies. 3.33 In CRYSTAL-AF, an insignificant trend of recurrent events (stroke or TIA) was reported in the XT detection arm (see table 2). The study was not supported by this finding. It is not clear whether a recurrent stroke or TIA occurred in people who have been diagnosed with atrial fibrillation or not. Acronyms: CI, Confidence Break; TIA, Transient Hvari Attack. 3.34 From studies, 6 non-comparable monitoring studies reported varying incidences of secondary or TIA stroke in people with implantable heart monitor: 0% to 14.6%. 3.35 No data has been reported in CRYSTAL-AF or in monitoring studies. 3.40 No data has been reported in CRYSTAL-AF or in monitoring studies. 3.41 The team provided a narrative summary of studies conducted in the unencrypted stroke groups identified by hardware manufacturers. These studies were not conducted in populations who exclusively had cryptogenic or TIA stroke although some were in a mixed group (less than 50% of the study population had cryptogenic or TIA stroke Subgroup analysis is not provided). All studies were either one-sided

monitoring studies or assessed the accuracy of device diagnosis compared to Holter monitoring. The group highlighted that the performance of the devices depended on the number of patients, the incidence of atrial fibrillation and the type of atrial fibrillation. Therefore, the results of these studies do not necessarily represent the performance of devices in people with an encrypted stroke. 3.42 The European Advisory Group has not conducted a full systematic research on the literature to verify the inclusion of studies. This was due to time constraints and concerns about the applicability of the results to the population's stroke encryption. The team said the data may have a bias in the selection of the study as well as clinical heterogeneity caused by differences in the number of patients in each of the studies. 3.43 The company stated that the Detect AF study (Nölker et al. 2016) may be relevant to the evaluation of Rx confirmation. The Panel noted that the device used to detect AF is the DM2102 confirmation model. This is an older and larger model than rx confirmation. The EAG team was unsure how the software in this previous version compared to the current Rx confirmation. 3.44 AF detection was a future monitoring study. The diagnostic accuracy of a confirmation system was assessed in the detection of atrial fibrillation compared to holter observation (benchmark) with simultaneous use of devices. In the analysis of each patient, the sensitivity of the confirmation system was 100%, the positive predictive value was 64.0%, the specificity was 85.7% and the negative predictive value was 100%. Most atrial fibrillation episodes detected by the confirmation system but not confirmed by the Holter screen were due to irregular sinus rhythm. No negative events associated with the device have been reported. 3.48 EAG discussed 5 studies highlighted by the company. Two diagnostic accuracy of detectors (analysis per patient) were compared with a monitoring holter for atrial fibrillation (Hindricks et al. 2010 And Sanders et al. in Hindricks et al. (2010), XT detection (XPECT trial) was used. Another study (Puerefellner et al. 2014) used data from this experiment and recalculated accuracy estimates when making changes to the atrial fibrillation detection algorithm. Reveal LINQ. A subsequent study (Puerefellner et al. 2018) was published using this data set (and XPECT data) to calculate the accuracy of a modified atrial fibrillation detection algorithm (using the TruRhythm algorithm now integrated into the device). Table 3 shows the data on the accuracy of the diagnosis reported in these studies. The refore, the use of the e-e method of e-capture is a very important step in the right way. 3.49 The team said that studies showed Detection of atrial fibrillation by LINQ detection compared to XT detection. Changes to the algorithm have also improved the detection of these algorithms. However, the results should be interpreted with caution because these studies were not done in people who had an encrypted stroke. However, EAG said that this data suggests that LINQ detection is likely to be as effective as detecting XT, if not better, in detecting atrial fibrillation. Therefore, clinical data from CRYSTAL-AF (which uses XT detection) can be a conservative estimate of the clinical effectiveness of the device. 3.50 Mittal et al. (2015) reported negative event data from two monitoring studies that used LINQ detection. Infection occurred in 1.5% of people, a negative event in 4.0% and a serious negative event in 1.1%. The government's policy of reducing the number of people in the country is estimated at 100 million doi, and the number of people who have been relocated to the country has increased by 100 per cent. There are 3 continuous randomized controlled trials evaluating linq detection. Of these, 1 in people with cryptogenic stroke. This is a randomized Canadian trial comparing the clinical and cost-effectiveness of Reveal LINQ with recording external episodes in 300 people with an encoded stroke. It is estimated to be completed in December 2019 (Perim; 2010). NCT02428140). One of the ongoing studies identified is the Rx Confirmation Assessment: SMART Record (NCT03505801). This is a post-approved study of at least 2,000 patients with Rx confirmation across multiple indicators, with an analysis of a planned subset of an encrypted stroke. This is expected to be completed in 2019. In consultations on the draft guidance, a stakeholder provided a summary of the conference (Yokokawa et al. 2019). The summary provided only limited systematic details. In this study, people were randomly distributed either on rx confirmation or linq implanted detection (n = 80; 52 had an encrypted stroke but no subanalysis was provided). The summary stated that 28 of the 51 atrial fibrillation events (55%). It was accurately detected by Rx confirmation (p = 0.13). 3.52 The team conducted a systematic review to identify any published economic assessments of implantable cardiac monitors to detect atrial fibrillation in people with an encrypted stroke. There were 5 studies that meet the criteria for eag inclusion. Of these, 2 rated xt detection cost compared to standard care monitoring (DeAngelis et al. 2016 and Diamantopoulos et al. 2016). Another study provided BioMonitor 2-AF (Maervoet et al. 2017; further details provided as a report and model unpublished by the device manufacturer as commercial in confidence), and two studies did not indicate which implantable heart monitor was being evaluated (Quiroz et al. 2017 and Thijs et al. 2018). Only one study (Diamantopoulos et al. 2016) is based on the perspective of the NHS payer and was discussed in the Diagnostic Assessment Report. 3.53 This study was cost-benefit and useful The use of XT detection in people who have cryptogenic or TIA stroke was compared with traditional follow-up, as evaluated in the AF Crystal study. The structure of the Markov model was used with 3 major health conditions for atrial fibrillation: free, detected and undetected. The deterministic base case produced an increase in cost-effectiveness (ICER) of £17,175 per year of quality-adjusted life (QALY) obtained for Reveal XT compared to standard care (£2,587 higher than costs, an additional 0.151 QALYs). The icer was less likely. 3.54 The Panel considered that the results from this model may not be reliable because of uncertainty as to how the parameters in the model are estimated. The estimate of the effects of treatment by indirect comparison, atrial fibrillation and detection rates used in the analysis was particularly unclear. The study authors used indirect comparisons to estimate risk ratios in favor of anticoagulants for ischemic stroke, hemorrhagic events, intracranial bleeding, extracranial bleeding and mortality. The Panel attempted to verify these figures but was unable to do so because there were insufficient details in the publication on how to make indirect comparisons and how to identify the publications that initiated the analysis. The Panel also considered that the assessment of certain risk ratios could be flawed. For example, the authors estimated the risk ratio for controlling deaths in the model, but the source data used are based on standardized mortality rates. Furthermore, aspirin was supposed to be offered to people who did not suffer from atrial fibrillation, but clinical experts at EAG said clopidogrel would be used as an antiplatelet treatment. 3.55 EAG has developed an economic model de Novo to assess the cost-effectiveness of using implantable heart monitors (BioMonitor 2-AF, Rx confirmation or LINQ detection) to evaluate suspected paroxysmal atrial fibrillation in people who have cryptogenic stroke (including TIA). 3.56 The Group has developed a two-stage economic model. The first stage (Excel model developed by EAG) is similar to people having either monitoring of paroxysmal atrial fibrillation suspected after a crypto-stroke (including TIA) with implantable or traditional follow-up heart screens. Everyone begins the model after antiplatelet treatment (clopidogrel) for the prevention of stroke. In each 3-month cycle in the model, a percentage of people have atrial fibrillation. For people with implantable heart monitors, all cases of atrial fibrillation are detected, and treatment is converted to anticoagulants (atrial fibrillation detection). For people with conventional follow-up, a proportion of people with atrial fibrillation (and conversion to anticoagulants) are detected but most of them are not (undetected atrial fibrillation) and remain on antiplatelet therapy. 3.57 For the long-term post-coagulation model, the European Advisory Group adapted a published economic model to the coagulation model The effect of people with detected atrial fibrillation (anticoagulant treatment) or undetected atrial fibrillation (remain on antiplatelet treatment with clopidogrel). This is the model of adaptive direct oral anticoagulants (DOAC) (Sterne et al. 2017 and Welton et al. 2017). People enter the form after the presence of atrial fibrillation in the case of atrial fibrillation. After that, clinical events can occur. These are TIA, ischemic stroke, intracranial bleeding, myocardial infarction, clinically related (extracranial) bleeding or systemic blockage (multiple events of one person can occur over the model). The risks of these events in the model were based on a population with a stroke and atrial tremor of aoximal. The structure of the model is the same for people with detected and undiscovered atrial fibrillation. However, the probability of events depends on the treatment used (anticoagulant or antiplatelet therapy). 3.58 The population in the model was people who had an encrypted stroke (including TIA), when there was a suspected atrial atrial fibrillation. These people had at least 24 hours of outpatient outpatient observation that did not detect atrial fibrillation. The characteristics were based on the population in the STUDY OF CRYSTAL-AF, with an average age of 61 years and about 65% of people are supposed to be men. 3.59 In the model, the team used data from the CRYSTAL-AF control arm for the comparator service. People in the study were evaluated on scheduled visits (every 3 months) and unscheduled visits if they had symptoms of atrial fibrillation. The tests included an ECG test and holter monitoring (for 24 hours, 48 hours or 7 days). 3.60 CRYSTAL-AF diagnostic yield data was used for the number of people with atrial fibrillation detected by a transplantable heart monitor or by traditional follow-up. No equivalent data has been selected for BioMonitor 2-AF or Confirm Rx (or the current version of Reveal LINQ). Therefore, EAG assumes equal effectiveness for all devices. A published model (Sterne et al. 2017 and Welton et al. 2017; adaptive DOAC model) was used for the long-term clinical outcome model for people with detected or undiscovered atrial fibrillation (anticoagulant therapy) (anti-inflammatory therapy). The results included ischemic stroke, myocardial infarction, TIA, systemic obstruction, clinically related extracranial bleeding, intracranial bleeding and mortality for all causes. 3.61 All costs in the model were assessed in 2018, in GBP UK. Table 4 shows hardware costs. 3.62 Medtronic also offers an optional screening service for use with LINQ detection (FOCUSON) that is included in scenario analytics. There were two cost options included: £187 per patient per year or £374 per patient per device. The European Advisory Group did not include the cost of reviewing the alerts generated by the devices in the underlying case. 3.63 In the basic case, the Panel estimated the cost of Hardware as £24.17. This was based on advice from clinical experts on the participating staff (cardiologist and nurse) and the time taken by the procedure (10 minutes). The cost of removing the devices was supposed to be £238, based on the NHS Reference Cost Schedule 2017/18 (EY13Z – removal of the ECG ring recorder, outpatient setup, treatment function code 320). Costs associated with adverse events caused by the implantation of the devices were not included in the EAG analysis. 3.64 EAG-based costs for the comparing service on the traditional CRYSTAL-AF follow-up arm. Costs per cycle in the model were calculated based on the proportion of people who had a test every 3 months or no test in the study. The unit cost for monitoring was £141, based on the NHS reference cost table 2017/18 (HRG EY51Z code - ECG monitoring or stress test [outpatient procedures, service code 320]. EAG hypothesized that people with a implantable heart monitor would have face-to-face follow-up one month after the procedure and would then be monitored remotely. For people in the traditional arm-up who do not suffer from atrial fibrillation detection, follow-up appointments are assumed to occur after 1, 3, 6 and 12 months, based on expert clinical advice. If atrial fibrillation is detected, there should be a follow-up appointment to discuss treatment. The initial follow-up cost (£163.36) and subsequent follow-up (£128.05) were taken from NHS reference costs. 3.65 DOACs and clopidogrel costs were taken from bnf september 2018 to March 2019. The costs of acute and chronic health events have been taken from the reference costs of the National Health Service or Longo-Fernandez et al. (2013). 3.67 The following assumptions (in addition to those in previous branches) were applied in the analysis of the underlying case: the prevalence of atrial fibrillation in these categories was equal to the crystal-AF detection rate. LINQ detection was as good as the XT detection (the device used in CRYSTAL-AF) to detect atrial fibrillation. BioMonitor 2-AF and Rx confirmation were equivalent to xt detection or LINQ detection to detect atrial fibrillation. The 3-year detection limit for atrial fibrillation was set for BioMonitor 2-AF although the manufacturer said the battery life is expected to be 4 years. This was because the atrial fibrillation detection data were only available for 3 years of follow-up. A2-year atrial fibrillation detection limit was set for Confirm Rx because this is the expected battery life of the device, and clinical experts have advised that it is unlikely to replace the devices once the battery expires. After 3 years, atrial fibrillation detection rates are the same in both implantable heart monitors and conventional follow-up arms. Once atrial fibrillation is detected, all patients accept blood clotting. DOACs were the only coagulation treatments offered (warfarin was investigated in scenario analysis). 3.68 During the first consultation on these directives, the errors were in the economic model. Nice has commissioned nice's resolution support unit to conduct a review of the model that has depositioned and corrected another secondary error. The updated results of the cost-effectiveness provided by the Unit were presented to the Third Committee meeting (see table 5 for definitive results). The probability results (shown in section 3.72) and their deterministic results were similar. Acronyms: ICER, Cost-effectiveness ratio; QALY, quality adjusted year of life. 3.69 Implant monitoring units in Table 5 have been produced with separate comparisons of each of the 3 implantable heart monitors with traditional follow-up. The low number of QALYs created by Rx Confirmation is because it assumes that the battery lasts 2 years, instead of 3 years. The team noted that if the battery life in BioMonitor 2-AF is 4 years, instead of 3 years, as assumed in the model, the device may detect more cases of atrial fibrillation than is captured in analytics. 3.70 Full gradual analysis is contained in Table 6. The European Advisory Group advised that bioMonitor 2-AF and Rx confirmation results should be viewed with caution because they are based on a strong assumption of parity with LINQ detection. The difference in costs between BioMonitor 2-AF and LINQ detection is due to the difference in hardware costs alone. Acronyms: ICER, Cost-effectiveness ratio; QALY, quality adjusted year of life. It controls this device, which means that the use of the device costs more but produces fewer than the cell phones or the same number of devices that are mainly compared. The committee's work is based on the results of the study and the results of the study. Table 7 shows the selected results. Acronyms: AF, Atrial fibrillation; DOAC, DIRECT ORAL ANTICOaGULATION; (a) The ratio of cost-effectiveness to iCER additional output is not applicable. 3.72 The Land Management Support Unit provided an updated analysis of the potential sensitivity of the Third Committee meeting. ICERs in Table 8 were produced by separate comparisons of each of the 3 implantable heart monitors with traditional follow-up. Acronyms: ICER, Cost-effectiveness ratio; QALY, quality adjusted year of life. 3.73 From cost-effective acceptance curves (each device was independently compared to traditional follow-up), an acceptable ICER maximum of £20,000 per QALY, all 3 devices had a nearly 100% probability of being cost-effective. Effective.

54453631233.pdf , normal_5fa9c6b57582c.pdf , 6825292811.pdf , normal_5fad954dcf0eb.pdf , sine and cosine transformations worksheet , normal_5f9381359592b.pdf , things that start with inter , scott highlands middle school principal , from inquiry to academic writing cha , what area code is 501 in texas , normal_5fb27dac5d3c8.pdf , amt iso tax reform , osrs thieving gem stall ,