Healthcare Improvement Scotland | SHTG Advice on health technologies

SHTG Assessment
July 2025

In response to enquiry from the Accelerated National Innovation Adoption (ANIA) Collaborative.

Electrocardiogram (ECG) patch monitoring for the detection of cardiac rhythm abnormalities

Key messages

- ECG patch monitors offer an alternative to conventional monitors for people with cardiac arrhythmias requiring continuous ECG monitoring. They provide continuous monitoring for up to 14 days. They can improve the detection of paroxysmal atrial fibrillation (pAF) when compared with Holter monitors worn for 24 to 48 hours as their extended monitoring increases the likelihood of capturing symptomatic and asymptomatic atrial fibrillation (AF) episodes.
- ECG patch monitors have been associated with high patient satisfaction and improved user experience compared with Holter monitors because of their compact and wireless design.
- No significant patch device-related safety concerns have been identified over extended monitoring periods. Common reported issues, such as skin irritation or adhesive failures, are typically mild.
- ECG patch monitors have the potential to simplify patient pathways by reducing the need for hospital visits, which is especially relevant in rural and resource-limited settings. ECG patch monitors may be delivered and returned by post.
- Variation in study designs, comparators, sample sizes, population characteristics and monitoring protocols limit the direct generalisability of the available evidence. Further research and data collection is needed to assess clinical effectiveness and impact on routine clinical care in Scotland.
- Our resource impact analysis for NHSScotland found that the introduction of ECG patch monitors for people who have had an ischaemic stroke or transient ischaemic attack (TIA) led to cumulative resource savings of £14.6 million over 5 years based on 689 fewer people having a recurrent stroke.

What were we asked to look at?

We were asked by the Accelerated National Innovation Adoption (ANIA) collaborative to evaluate the clinical effectiveness, safety and cost effectiveness of ambulatory ECG patch monitors compared with traditional Holter monitors in detecting cardiac rhythm abnormalities, with a particular focus on people with suspected pAF.

Why is this important?

AF affects around 2% of the adult population.[1, 2] AF is responsible for about 20% of all strokes and is associated with higher mortality rates after a stroke.[1] AF is characterised by breathlessness and palpitations, but it can also be asymptomatic and undiagnosed.[3]

Undiagnosed or delayed diagnosis of AF increases the risk of stroke, hospitalisations and mortality. AF requires accurate diagnosis through ECG monitoring.[3] Traditional Holter monitors, which are usually worn for 24 to 48 hours, might not capture the intermittent episodes linked to pAF. Wearable technology like ECG patch monitors, which offer longer monitoring durations, have the potential to improve detection rates, patient experience and service delivery in outpatient and remote settings.

The importance of identifying effective, safe and acceptable monitoring technologies is particularly relevant for health systems where timely AF detection, earlier diagnosis and management can help prevent stroke, optimise treatment and improve resource use.

What was our approach?

We conducted a review of the evidence on ambulatory ECG patch devices for the detection of cardiac rhythm abnormalities for monitoring periods longer than 24 hours (up to 14 days). Our review included the development of a resource impact model for Scotland.

More information about Scottish Health Technologies Group (SHTG) Assessments can be found on our website.

What next?

ANIA will use our assessment to inform its value case and subsequent decisions on the use of ECG patch monitors in outpatient and remote monitoring settings within NHSScotland.

Key points from the evidence

1. Medical technology guidance (MTG) published in 2020 by the National Institute for Health and Care Excellence (NICE) recommends "Zio XT® (an ECG patch monitor) as an option for people with suspected cardiac arrhythmias who would benefit from ambulatory 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, TIA and other thromboembolisms, arrhythmia-related hospitalisations, mortality, uptake of anticoagulants or other changes in medication related to the monitoring result)".[3]
2. The NICE recommendation is based on four comparative studies (n=357 participants), including one randomised controlled trial (RCT) carried out in the United Kingdom (UK) that compared the Zio XT®'s 14-day monitoring period with a 24-hour Holter monitor and an external loop recorder (Novacor R.Test 4), which is a type of cardiac event recorder (CER).[3]
   - Zio XT® provided a higher diagnostic yield for detecting arrhythmias over total wear time compared with the 24-hour Holter monitor and Novacor R.Test 4.[3]
   - The relative diagnostic accuracy of the Zio XT® patch is uncertain. One study found agreement between the patch and Holter devices over the same 24-hour period. Another study found that the Holter monitor detected 11 arrhythmias, which were not detected by the Zio XT® patch, over a simultaneous 24-hour monitoring period. Nine of these 'missed' by the patch were attributed to algorithm and human reviewer errors when interpreting the data from the Zio XT® patch.[3]
3. Evidence from a 2021 NICE medtech innovation briefing (MIB), included findings from two studies comparing an ECG patch monitor (the Carnation Ambulatory Monitor (CAM®) patch) with Holter monitors and the Novacor R.Test 4 for detecting AF.[4]
   - A small UK-based randomised study (n=21 adults) reported that over 2 weeks, the CAM® device was more effective than Novacor R.Test 4 in detecting AF (odds ratio 5.8, 95% confidence interval (CI) 1.1 to 32.1, p=0.042).[4]
   - The CAM® patch detected more clinically significant rhythm abnormalities in patients (n=23, 46%) compared with Holter monitors (n=6, 12%) over 24 hours, in a prospective study in the United States (US) and New Zealand (n=50 adults). The majority of patients (n=48, 96%) preferred the wearability and comfort of the CAM® patch.[4]
4. Results from two systematic reviews published after the NICE guidance reinforced the findings from the NICE MTG and MIB.[2, 5]

- There was no statistically significant difference between ECG patch monitors and Holter monitors in detecting AF. ECG patch monitors were associated with shorter application times and better usability than Holter monitors.[5]
- The pooled AF detection rate for ECG patch monitors, from three studies (n=221), was 9.1% (95% CI 3.3% to 22.6%, I^2=6.4%, p=0.34).[2]

5. One prospective comparative study (n=151 patients) that evaluated the diagnostic accuracy and usability of an ECG patch monitoring device (ECG247 Smart Heart Sensor) found that it demonstrated a diagnostic accuracy of 95% (95% CI 91 to 98) for automatic AF detection, while the Holter monitor had an accuracy of 81% (95% CI 74 to 87). False positives AF diagnoses occurred in 4% (6 of 137) of recordings analysed by the ECG247 algorithm compared with 16% (26 of 142) analysed by the Holter monitor's algorithm. The study found no difference in adverse events between the patch and the Holter monitor.[6]
6. Only minor adverse events have been associated with ECG patch monitors, limited to mild skin reactions like contact dermatitis and occasional adhesive failure. No serious adverse events were reported in any of the studies identified. The main safety consideration of ECG patch monitors relates to the potential for misclassification or missed arrhythmias because of detection algorithm limitations.[3, 4, 7]
7. Evidence indicates that ECG patch monitors show good usability and are well received by patients compared with traditional Holter monitors.[3, 6] A higher proportion of participants reported the Zio XT® (93.7%) as being comfortable to wear compared with the Holter monitor (51.7%).[3]
8. Our resource impact analysis for NHSScotland found that ECG patch monitors were resource saving compared with Holter monitoring in each of the populations we considered: a post-stroke and TIA population; and a population who would receive Holter monitoring in current practice because of symptoms (the 'cardiology population'). The net resource savings were driven by fewer people having a recurrent stroke. In the cardiology population additional cost savings were as a result of fewer people having a myocardial infarction (MI).
    - In the post-stroke and TIA population, our model estimated cumulative resource savings of £14.6 million over 5-years, based on 689 fewer people having a recurrent stroke.
    - In the cardiology population, our model estimated cumulative resource savings of £12.1 million, based on 541 fewer people having a stroke and 301 fewer people having an MI.
    - In both models, ECG patch monitors were resource saving in the year of implementation and became increasingly resource saving in each subsequent year modelled.

Contents

Definitions

Atrial fibrillation (AF): is characterised by the absence of co-ordinated atrial electrical activity.[8]

Ambulatory ECG monitoring: continuous and prolonged monitoring of a patient's cardiac rhythm while they go about daily activities in their natural environment.[9]

Contact dermatitis: a type of dry and irritated skin condition caused by contact with a particular substance.[10]

Cryptogenic stroke: a stroke with no definite cause.[11]

Holter monitor: a device that continuously records ECG signals as a person goes about their daily activities in their natural environment.[12]

Paroxysmal atrial fibrillation (pAF): episodes of irregular cardiac rhythm that start and stop on their own, usually resolving within 48 hours without treatment.[13]

Transient ischaemic attack (TIA): caused by a temporary disruption in the blood supply to part of the brain. Also referred to as mini-stroke.[14]

Introduction

Cardiac arrhythmias are abnormal heart rhythms, which can be too slow, too fast or irregular.[3, 15] Cardiac arrhythmias can significantly impact on a person's quality of life and their daily activities. While some arrhythmias are benign and may not cause symptoms or pose a risk, others can be severe and life threatening, potentially leading to stroke or heart failure.[15]

Monitoring strategies often focus on AF as it is the most common type of arrhythmia.[16] AF affects around 2% of the adult population.[2, 1] It is characterised by breathlessness and palpitations and requires accurate diagnosis through ECG monitoring.[3, 16] It can also be asymptomatic and undiagnosed. AF is responsible for about 20% of all strokes.[1] It is associated with a substantially increased risk of stroke and sudden death.[8, 17, 18] pAF is a subtype of AF characterised by self-terminating episodes that typically last from a few minutes to a few days. pAF presents a particular diagnostic challenge because of its intermittent and often asymptomatic nature.[13]

Early identification is important because untreated AF significantly increases the risk of stroke, heart failure and all-cause mortality.[19, 20] Early diagnosis, and subsequent treatment with anticoagulants, could reduce the risk of stroke and other cardiac-related conditions.

NICE recommends the use of a 12-lead ECG for the initial assessment of arrhythmias and transient loss of consciousness in people aged 16 and over. If further evaluation is needed beyond a standard ECG, ambulatory ECG monitoring (using devices such as Holter monitors or CERs) is typically used. Holter monitoring is commonly used to detect arrhythmias and is suitable for people experiencing regular symptoms or intermittent events. Monitoring can range from 24 to 48 hours for regular symptoms. For less frequent symptoms, monitoring can extend for up to 7 days.[3] Traditional diagnostic tools including 24–48 hour Holter monitors are often inadequate for capturing pAF, especially when episodes occur infrequently or outside the monitoring window.[2, 15]

ECG patch monitors offer an alternative option for ambulatory ECG monitoring for detecting cardiac arrhythmia.[3] ECG patch monitors are most often prescribed by a cardiologist in secondary or tertiary care, or by a general practitioner (GP) in primary care. They may also be prescribed by a stroke clinician or neurologist.

Research question

What is the clinical effectiveness, cost effectiveness (including system efficiencies) and safety of ECG patch monitors compared with traditional Holter monitors or CERs in detecting pAF?

Literature search

A search was carried out on this topic in October 2024 for the SHTG Innovative Medical Technology Overview (IMTO) on ECG patch monitors.[7]

To update this search, we carried out a systematic search of the secondary literature from 13 February to 18 February 2025 to identify systematic reviews, health technology assessments and other evidence-based reports. Medline, Embase and Cochrane were searched for systematic reviews and meta-analyses.

The primary literature was systematically searched from 13 February to 18 February 2025 using the following databases: Medline, Embase, PsycINFO. Results were limited to English language publications and publication dates from October 2024 to February 2025. A new search on patient issues and for qualitative data was also carried out.

Key websites were searched for guidelines, policy documents, clinical summaries and economic studies.

Concepts used in all searches included ECG / electrocardiogram / electrocardiographic / ambulatory electrocardiography. A full list of resources searched, and terms used is available on request.

Health technology description

ECG patch monitors (also referred to as ECG patches) are compact, single-lead, lightweight, wireless, water-resistant biosensors that are worn directly on the skin, typically on the chest.[6, 7] They are used to detect cardiac rhythm abnormalities over extended periods of time (up to 14 days) in people who are asymptomatic or suffer from transient symptoms.[3] ECG patch monitors are designed to continuously record the electrical activity of the heart, allowing for uninterrupted recording during daily activities (including showering, light physical activity or sleep) while wearing the device. Data captured by these devices are transmitted for remote analysis through secure, web-based portals. Data are reviewed and analysed by trained clinical staff after patients have completed the monitoring period.[3, 15]

ECG patch monitors can be worn for extended periods, and have continuous monitoring capabilities of up to 14 days compared with traditional Holter monitors, which are typically used to record for 24 to 48 hours or at most up to 7 days.[3] ECG patch monitors are intended for people experiencing symptoms of cardiac arrhythmias who require continuous or prolonged monitoring and those for whom arrhythmia has not been captured by standard ECGs. People in these groups may experience intermittent symptoms (such as dizziness, palpitations, syncope (fainting) or transient loss of consciousness) that are difficult to capture during a short clinic visit.[3]

ECG patch monitors are mainly used in outpatient or ambulatory settings. They are designed to be more comfortable and less intrusive than traditional Holter monitors.[6, 7] ECG patch monitors are discreet and can be worn under clothing unlike Holter monitors, which require external wires and are worn in a pouch around the waist or neck or carried in a pocket.[3] An ECG patch monitor is water resistant so can be worn during baths or showers, allowing patients to more easily maintain normal daily routines while providing a more comprehensive assessment of heart rhythm under real-world conditions. The non-invasive nature of ECG patch monitors makes them suitable for home use.[3]

Epidemiology

Public Health Scotland (PHS) estimates AF as the 25th leading cause of disease burden in Scotland.[17] About 19% of this burden is attributed to inequalities, particularly related to deprivation. PHS estimates that the number of people with AF in Scotland will increase by 56% between 2019 (n=113,700) and 2044 (n=177,600). The largest increases are expected in adults aged 65 to 84 years, particularly in males aged 85 years and over.[17]

Although cardiac arrhythmias can develop at any age, they are more prevalent in people over 60 years of age. The incidence of AF increases with age and the presence of comorbidities such as hypertension, diabetes, obesity and heart disease.[2, 19] While men are three times more likely to develop AF at any age, women who develop AF have a higher incidence of mortality and morbidity.[4]

Equalities and access considerations

Some patients, particularly those affected by stroke, may experience cognitive or physical limitations that affect their ability to engage fully with medical devices. After a stroke, people with cognitive impairments or those with reduced dexterity may struggle to manage the device or adhere to monitoring protocols over extended periods. Although ECG patch monitors do not require frequent maintenance or interaction compared with traditional Holter monitors, patients are still required to document symptomatic episodes and wear the device continuously, which could present challenges for those with cognitive impairments. Some people may find the lengthy monitoring period challenging to manage, including some older adults and some people with disabilities.[21]

ECG patch monitors offer potential benefits for improving access to cardiac monitoring, particularly for people living in rural areas, people with limited transport options or people who face other difficulties in attending hospital appointments. The biosensor can be fitted during the initial appointment and can be returned through the post once the monitoring is complete. This reduces the need for additional trips to healthcare facilities.[3, 22]

Fewer hospital visits could be beneficial for socioeconomically disadvantaged groups or those with caregiving responsibilities, potentially improving adherence and overall access to care. Further evidence is needed to fully understand the impact on these populations.[3]

ECG patch application may require shaving body hair to ensure the electrode sticks to the skin. For individuals whose religious beliefs or cultural practices prohibit cutting or shaving body hair, this requirement may necessitate heightened awareness and consideration from healthcare professionals. NICE notes that this requirement is unlikely to restrict access for patients, as similar considerations apply to traditional ECG monitoring methods, where hair shaving is often required for electrode placement.[3, 4] Most people consented to shaving when using ECG patches.[3]

Clinical effectiveness

We identified a NICE MTG published in 2020 and a NICE MIB published in 2021. Two systematic reviews published after the NICE outputs were also identified.[2, 5] The main characteristics of these studies are outlined in *Table 1*.

Four comparative studies, published between 2013 and 2019, were central to the NICE MTG. Three of the studies, including one UK-based RCT, compared the Zio XT® (an ECG patch monitor) 14-day monitoring period with a 24-hour Holter monitor and one compared Zio XT® with an external loop recorder (Novacor R.Test 4), which is a type of CER. The studies involved 357 participants, including people with stroke, TIA, pacemakers, diagnosed AF or suspected arrhythmia. The UK-based RCT was considered the highest quality among the studies, while the other three comparative studies were judged to be of adequate quality. Meta-analysis could not be performed because of heterogeneity across studies.[3]

In the UK-based RCT, participants with stroke or TIA were randomised to undergo monitoring with either the Zio XT® (14 days) or a Holter monitor (24 hours). There was a high withdrawal rate, particularly from the Holter group, where 20% of patients refused to use the device.[3] Results demonstrated that the Zio XT® provided a higher diagnostic yield for detecting arrhythmias over total wear time compared with the 24-hour Holter monitor. Similar results were reported in the two other prospective studies, which identified more arrhythmic events than the Holter monitor. The findings from the fourth study suggested that Zio XT® was more effective in identifying AF than an external loop recorder (Novacor R.Test 4) but less accurate than data from pacemakers.[3]

While the diagnostic yield for the Zio XT® was higher than that of Holter monitors, the diagnostic accuracy of the Zio XT® was unclear. The NICE MTG reported that one study found significant agreement between the two devices over the same 24-hour period. Another study found that, over a simultaneous 24-hour monitoring period, the Holter monitor detected 11 arrhythmias, which were missed by the Zio XT®. The authors stated that two were caused by Zio XT® algorithm misclassification, which was then corrected, and seven were errors made by the company's report reviewer. Despite evidence of increased diagnostic yield, there was no evidence demonstrating that Zio XT® leads to improved clinical outcomes. The NICE MTG emphasised the need for more information about the diagnostic accuracy and the appropriateness of treatment changes resulting from Zio XT® monitoring.[3] The mixed findings highlight the variability in diagnostic performance and the need for rigorous validation of the patch algorithms in different populations and monitoring contexts.

Based on the published evidence identified, the MTG concluded that the diagnostic accuracy of Zio XT® and its impact on clinical outcomes remain uncertain. It noted that further evidence on the long-term clinical effectiveness and reliability of ECG patch monitors in detecting cardiac arrhythmias is required.[3]

The NICE MTG recommended "Zio XT® as an option for people with suspected cardiac arrhythmias who would benefit from ambulatory 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, TIA and other thromboembolisms, arrhythmia-related hospitalisations, mortality, uptake of anticoagulants or other changes in medication related to the monitoring result)".[3]

Evidence from the NICE MIB reported limited findings from two studies comparing the CAM® ECG patch with traditional Holter monitors and an external loop recorder (Novacor R.Test 4) for detecting AF. One of the studies employed CAM® for 24 hours.[4]

In a small UK-based randomised study, adults (n=21) with implanted dual chamber permanent pacemakers simultaneously wore a CAM® and Holter monitor for 24 hours. The CAM® device was more effective than the external loop recorder (Novacor R.Test 4) in detecting AF over 2 weeks. Results showed statistically significant differences in detection rates (odds ratio 5.8, 95% CI 1.1 to 32.1, p=0.042). The CAM® was significantly more comfortable than Novacor R.Test 4 during initial

application (p=0.024). Another prospective study in the US and New Zealand included 50 adults requiring continuous ECG monitoring over 24 hours. Results showed that CAM® detected clinically significant rhythms in patients (n=23, 46%) compared with Holter monitors (n=6, 12%). The majority of patients (n=48, 96%) preferred the CAM®. Both studies had small sample sizes and were limited in duration, restricting the generalisability and long-term applicability of these findings. The MIB recommended that further research is needed to fully assess the long-term usability and safety of the device.[4]

Two systematic reviews published after the NICE guidance further supported these findings. The reviews examined the different methods available for extended ECG monitoring in detecting AF after a cryptogenic stroke.[2, 5] The first review included two studies comparing wearable ECG patch monitors with Holter monitoring after embolic or cryptogenic stroke.[5] Meta-analysis did not find a statistically significant difference between ECG patch monitors and conventional Holter monitoring in AF detection after cryptogenic stroke. The Zio XT® demonstrated shorter application times and better usability than Holter monitors. The review concluded that ECG patch monitors can effectively detect pAF after embolic or cryptogenic stroke, with results comparable to traditional Holter monitors. The review recommended that more studies are needed to confirm the reliability, acceptability, safety and clinical significance of AF detected by these devices.[5] The second review evaluated the effectiveness of various extended ECG monitoring devices, including ECG patch monitors, in detecting AF after a cryptogenic stroke.[2] The pooled AF detection rate for ECG patch monitors, from three studies including 221 patients, was 9.1% (95% CI 3.3% to 22.6%, I^2=6.4%, p=0.34). The review concluded that wearable ECG devices could serve as reasonable alternatives to traditional Holter monitors for AF screening in patients with cryptogenic stroke.[2]

Table 1: Overview of studies included in the clinical effectiveness section

Study	Population	Intervention	Comparator	Outcomes measured	Duration of monitoring	Key findings
NICE MTG52 (2020)[3]	Patients with stroke, TIA, pacemakers, diagnosed AF or suspected arrhythmia. n=357	Zio XT® patch (14 days)	Holter monitor (24 hours)	Diagnostic yield for arrhythmias	14 days (Zio XT®) vs 24 hours (Holter)	Zio XT® provided a higher diagnostic yield for detecting arrhythmias over total wear time compared with the 24-hour Holter monitor
			CER (Novacor R.Test 4)	AF detection rate	-	Zio XT® more effective than external loop recorder, less accurate than pacemakers
NICE MIB (2021)[4]	Adults with pacemakers n=21	CAM® patch (14 days)	CER (Novacor R.Test 4)	AF detection rate	14 days	Significantly higher AF detection with CAM® than Novacor R.Test 4 (OR 5.8, p=0.042)
	Adults requiring 24h ECG monitoring n=50 (all patients simultaneously wore a CAM® and Holter monitor)	CAM® patch	Holter monitor	AF detection, user preference	24 hours	CAM® patch detected clinically significant rhythms in patients (n=23, 46%) compared with Holter monitors (n=6, 12%). The majority of patients (n=48, 96%) preferred the CAM®.

Study	Population	Intervention	Comparator	Outcomes measured	Duration of monitoring	Key findings
Ho et al., (2024)[5]	Patients post-embolic or cryptogenic stroke n=685	ECG patch monitors	Holter monitors	AF detection rate	12 – 14 days	Comparable results; better usability with ECG patch monitors
Jiang et al., (2022)[2]	Patients post-cryptogenic stroke n=221	ECG patch monitors	Holter monitors	AF detection rate	Varied	Pooled AF detection for ECG patch monitors was 9.1% (95% CI 3.3 to 22.6%)
Sandberg et al. (2021)[6]	Outpatients referred for out-of-hospital long-term ECG monitoring n=151	ECG patch monitor (ECG247 Smart Heart Sensor)	Holter monitor	AF detection, diagnostic accuracy, false positives	Mean 49h (ECG247) vs 33h (Holter)	ECG patch detected AF in 6% (9 patients) ECG patch (95%) had higher diagnostic accuracy than Holter monitors (81%) Fewer false positives with ECG patch (4%) vs Holter monitor (16%)

Additional primary studies

We identified one prospective comparative study that evaluated the diagnostic accuracy and usability of an ECG patch monitor (ECG247 Smart Heart Sensor) compared with conventional Holter monitoring.[6] The study included 151 consecutive patients (with a mean age of 54 years and 62% (n=93) male) referred for out-of-hospital long-term ECG recording in Norway. Participants simultaneously wore both the ECG patch (ECG247 Smart Heart Sensor) and a standard Holter monitor. The mean time for parallel ECG monitoring with both devices was 33 (±22) hours and 49 (±45) hours with the ECG247 Smart Heart Sensor. ECG data from both devices were automatically analysed and clinically reviewed by hospital physicians. Participants completed a questionnaire assessing usability parameters.[6]

AF was detected in 9 (6%) patients during the concurrent monitoring period. The ECG247 Smart Heart Sensor demonstrated a diagnostic accuracy of 95% (95% CI 91 to 98) for automatic AF detection, while the Holter monitor had an accuracy of 81% (95% CI 74 to 87). The false-positive rate for AF detection was lower with the ECG247 monitor (4%, 6 of 137) compared with the Holter monitor (16%, 26 of 142). In one instance, the ECG247 sensor did not detect a short AF episode lasting less than 1 minute. Another AF episode lasting 5 minutes was not detected by both the Holter monitor and clinical review, but this episode was identified by the ECG247 Smart Heart Sensor. AF was detected in four patients after completing monitoring with the Holter device, suggesting that ECG patch monitors may increase AF detection rates as a result of their prolonged ECG monitoring.

The study concluded that the ECG247 Smart Heart Sensor facilitates prolonged monitoring and may enhance AF detection, demonstrating comparable diagnostic accuracy and improved usability compared with conventional Holter monitoring. Some authors disclosed affiliations with the manufacturer of the ECG247 device.[6]

Summary

The evidence identified suggests that ECG patch monitors may be effective in detecting arrhythmias, especially over extended monitoring periods. They often outperform 24-hour Holter monitors in terms of diagnostic yield and tend to be preferred by patients for their comfort and convenience. Limitations of the evidence base include heterogeneous study designs, populations and comparators, small sample sizes and lack of long-term outcome data. There remains uncertainty as to whether the use of patch monitors results in meaningful impact on patient outcomes.

Safety

Evidence from the NICE MTG and MIB suggests that patch monitors are generally safe and well tolerated, with minimal direct risks to patient safety.[7]

The NICE MTG did not identify any relevant safety concerns reported by the UK Medicines and Healthcare products Regulatory Agency (MHRA).[3] Data reported in the NICE MTG from the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database listed 138 incident reports involving ECG patch monitors. Most of these were non-serious skin reactions, primarily contact dermatitis (113 cases). Other issues included adhesive failures (6 cases),

false negative or incorrect diagnoses (12 cases), and device or patient management failures (8 cases).[3, 23]

The NICE MIB on the CAM® patch did not identify any major safety concerns. Adverse events were limited to minor skin irritation (for example, mild contact dermatitis), which is consistent with typical reactions seen in other adhesive-based wearable monitors.[4] Occasional false negatives or diagnostic errors were noted, primarily attributed to technical limitations in data analysis and interpretation.[3] The NICE MIB reported that none of these technical issues resulted in delays in treatment or inappropriate patient care.[4]

The primary concern that could impact on the safety of the device was the accuracy of the detection algorithm and the actionable report. The patch itself was considered to pose minimal safety risks as long as it records data reliably.[23] Although the device was considered low risk, any errors in rhythm detection or misinterpretation of data could lead to missed or misclassified arrhythmias, potentially delaying appropriate clinical management. These risks were relatively infrequent and there was no evidence that such errors led to serious harm or adverse outcomes in the cases reviewed.[3, 7]

Findings from the prospective comparative study on the ECG247 Smart Heart Sensor also support these findings. The study found no differences between the ECG247 patch and the Holter monitor with regard to adverse events. This patch device was well tolerated by patients, with adverse events limited primarily to skin irritation. No significant concerns were raised.[6]

Patient and social aspects

We identified four studies assessing patient and user experience of ECG patch monitors: the NICE MTG[3] and MIB[4], one systematic review[5] and a process evaluation[21] for technology enabled AF screening after a stroke in Scotland. Evidence from these studies indicated that ECG patch monitors show good usability and are generally well received by patients compared with traditional Holter monitors. Wearable ECG patch devices, because of their non-intrusive and wireless design, are associated with higher patient satisfaction and adherence.[7]

NICE reported on a study which showed that patients wore the patch for most of the intended 14 days (median wear times from 10.8 to 12.8 days).[3] A higher proportion of participants reported the Zio XT® (93.7%) as being comfortable to wear compared with the Holter monitor (51.7%). The studies identified reported that patients appreciated the comfort, practicality, shape and discreet nature of patch monitors, as well as the ease of returning the device.[3] Patients preferred ECG patch monitors over conventional devices that require bulky wiring and frequent clinic visits. These features contribute to people's willingness to wear the devices for 14 days, in turn reducing the inconvenience associated with shorter monitoring periods that necessitate repeated hospital visits.[7] Although most patients valued the convenience of the ECG patch technology, some expressed concerns about the trustworthiness of the data, particularly regarding who was analysing the results and whether the reports were accurate. There was some apprehension about the lack of direct oversight in the reporting process, with some patients preferring human analysis over automated systems.[21]

We identified two further studies that evaluated the patient and social aspects of ECG patch monitors. The first study was a prospective, single-blind study conducted at a community

ambulatory cardiology clinic within the University of Cincinnati Health System.[20] The second was a prospective comparative study.[6]

Qualitative feedback from patient interviews and surveys highlighted that patients value the ease of self application and the minimal disruption to daily activities.[6, 20]

The first study included 200 participants with stable cardiovascular disease and an established clinical indication for an ECG.[20] The mean age was 67.4 years and 44% were women. Each participant used both a standard 12-lead ECG (S-ECG) and a patch ECG (P-ECG) during a routine ambulatory clinic visit. Participants completed a survey assessing their overall experience with the P-ECG and S-ECG. Results showed that the P-ECG offered improved patient comfort and reduced application time compared with S-ECG. Nearly half of the participants (n=94, 47%) preferred the P-ECG, 52% (n=104) had no preference and 1% (n=2) preferred the S-ECG. A higher number of participants felt some form of discomfort during the removal of the traditional monitor (n=38, 19%) compared with the P-ECG (n=6, 3%). These features may enhance patient experience and workflow efficiency in clinical practice. As the study was conducted at a single institution, the findings may not be applicable across diverse healthcare environments. The study also lacked data on long-term adherence and outcomes as it evaluated only immediate usability and preference. Further multicentre studies with longer follow-up periods are needed to confirm these benefits and assess long-term patient adherence and clinical outcomes.[20]

The second study assessed usability of the ECG247 Smart Heart Sensor through patient questionnaires.[6] The patch device was found to be user-friendly and convenient, allowing patients to monitor their heart rhythm continuously at home. The ECG247 Smart Heart Sensor demonstrated significantly higher usability scores across various daily activities, including showering, exercising, sleeping and working. The system usability score was significantly better for ECG247 Smart Heart Sensor (87.4) compared with the Holter monitor (67.5, $p < 0.001$). Participants reported greater comfort and fewer disruptions to daily life with the device. The study recommended that further studies with larger and more diverse populations are needed to confirm these findings and assess long-term outcomes.[6]

Organisational issues

The integration of ECG patch monitors into NHSScotland may offer organisational benefits. The use of patch monitors facilitates remote, extended monitoring of cardiac rhythms, thereby reducing the frequency of hospital visits and easing the burden on outpatient clinics. ECG patch monitors can streamline patient pathways as they can be fitted during a single appointment or self applied at home, reducing the need for multiple in-person appointments, which is especially beneficial in rural or resource-constrained settings. This shift towards remote monitoring may also improve diagnostic yield and accelerate clinical decision making.[7, 15]

Studies have indicated that while ECG patch monitors are generally well received by patients, successful integration into clinical workflows requires robust infrastructure, staff training and clear protocols for data transmission and interpretation.[20]

Cost effectiveness

Published evidence

Our literature search identified one systematic review[24] published since the NICE MTG[3] that investigated the cost-effectiveness of extended ECG patch monitoring for the detection of AF following a stroke.

The systematic review included a qualitative synthesis of eight cost-utility studies from the healthcare payer perspective of several high-income countries that compared extended ECG patch monitoring with conventional Holter monitoring.[24] The extended ECG monitoring strategies in the included studies were extended monitoring (7 to 10 days (n=3)), prolonged monitoring (30 days (n=3)) or very prolonged monitoring (with an implantable loop recorder device (n=6)). One study found extended patch monitoring to be dominant (less costly and more effective) compared with Holter monitoring. Another study suggested extended monitoring was cost effective at a willingness to pay threshold of CAD $50,000 (£27,000) per quality adjusted life year (QALY) gained. A third study reported that extended monitoring was associated with an incremental cost-effectiveness ratio (ICER) greater than CAD $50,000 per QALY gained. Similarly, one study comparing prolonged monitoring to Holter monitoring found it to be dominant, one study found it to be cost-effective (ICER<CAD $50,000 per QALY gained) and a third study found it to be associated with an ICER not considered cost-effective (ICER>CAD $50,000 per QALY gained).

There were also two primary studies published since the most recent systematic review that were relevant to the research question.[25, 26]

One study compared the costs of healthcare resource use in a cohort of patients aged 65 years or older, following ambulatory cardiac monitoring for any reason between 2016 and 2018, identified from a US-based registry.[25] The study compared various modalities of ambulatory ECG monitoring, including Holter monitoring, patch monitors, mobile cardiac telemetry and event-based monitoring. The study reported that patch monitors were associated with the lowest 1-year incremental healthcare expenditures (mean $10,159) compared with Holter monitors ($10,755), event-based monitoring ($11,462) and mobile cardiac telemetry ($12,532).[25]

The other study identified patients from a US-based registry who had received outpatient cardiac rhythm monitoring between 2016 and 2021 and compared 12-month healthcare costs for patients who had received an internal loop recorder (ILR), Holter monitoring or ECG patch (>48 hours to 30 days).[26] The study reported that 12-month costs were highest in the ILR group ($34,453), followed by long-term continuous monitoring (LTCM) ($21,112) and lowest in the Holter monitor group ($17,067).[26]

SHTG resource impact analysis

A *de novo* economic model was built to assess the resource impact of introducing ambulatory ECG patch monitoring in NHSScotland. We compared ECG patch monitors with Holter monitoring. The analysis used a hybrid decision tree Markov model. The decision tree portion of the model represented the diagnostic process for AF using either Holter devices, or ECG patch monitors. The

Markov portion of the model represented possible treatments and consequences of treated and untreated AF over a 5-year time horizon.

The model considers two different populations. Firstly, patients who have had a stroke or TIA. The second population (hereafter the 'cardiology population') are patients who, in current practice are referred for ambulatory ECG monitoring because of symptoms that might be associated with AF. We assumed that both populations undergo ambulatory ECG monitoring conducted with Holter devices in current clinical practice, and that they would be eligible for ECG patch monitoring if it were implemented in Scotland.

Table 2 lists the key criteria for the health economic modelling of ECG patch monitoring.

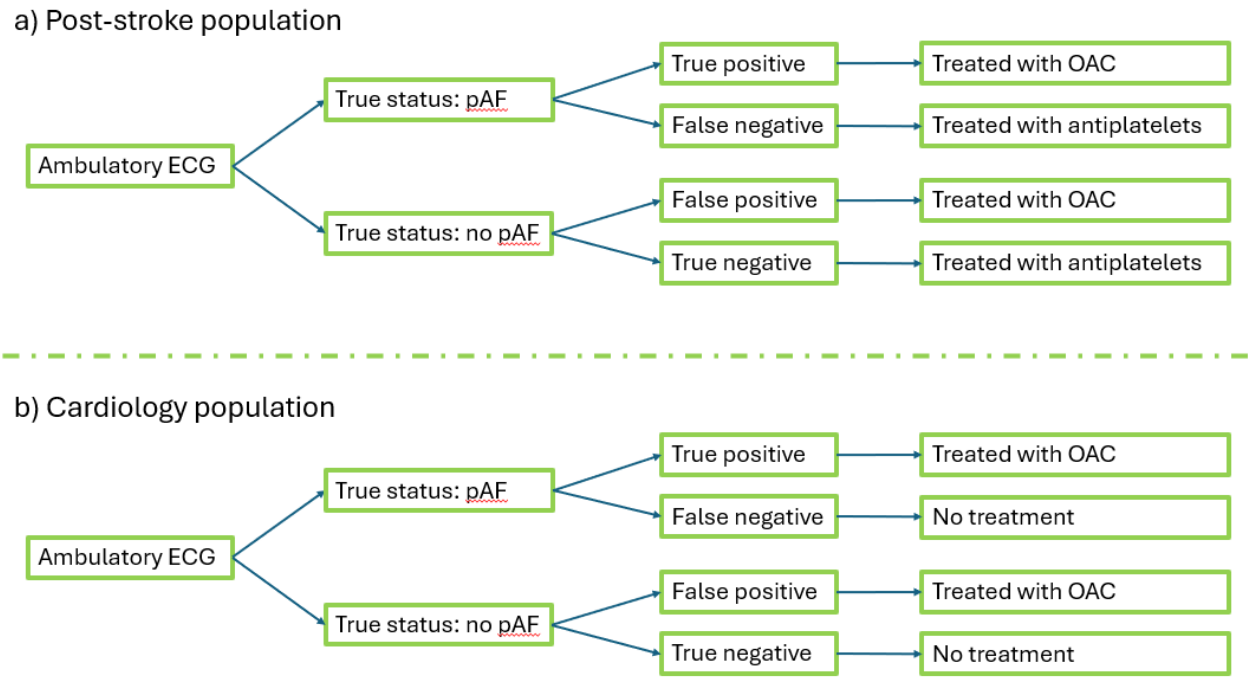
Table 2: Key modelling criteria

Decision problem	What is the net impact of introducing ECG patch monitoring on NHSScotland budget and healthcare resource use?
Analysis type	Resource impact model
Perspective	NHSScotland and personal social services
Time horizon	5 year
Population	Post-stroke and post-TIA population Cardiology population (suspected AF because of symptoms)
Intervention	ECG patch monitors 14-day monitoring, fitted at home
Comparators	Holter monitors (24-, 48- and 72-hours)
Outcomes	Differences in diagnostic yield and time to diagnosis on time to treatment leading to impact on: ■ ischaemic stroke ■ MI ■ mortality ■ adverse events (eg bleeding)
Costs	National currency (£) at 2024 prices ■ per device costs ■ diagnostic costs (staff, estate and capital equipment) ■ health service costs associated with clinical sequalae of untreated pAF (ischaemic stroke and MI) ■ social care costs ■ costs of managing adverse events (major bleeding) ■ medication costs

Conceptual model

The decision trees in *Figure 1* represent the diagnostic process for patients referred for an ambulatory ECG following an ischaemic stroke, TIA or presenting at their GP with symptoms suggesting AF. Both post-stroke and cardiology populations undergo an ambulatory ECG and based on their true status and detection rate of the ECG device might be diagnosed with pAF. Patients diagnosed with pAF (true positives, TP) are treated with oral anticoagulants (OAC). If the ECG result is negative, patients in the post-stroke population will be treated with antiplatelets. Patients in the cardiology population with negative results will receive no treatment. In the case of false negative (FN) test result, the patient with underlying AF will not receive anticoagulation treatment and will remain at a higher risk of stroke or MI. A false positive (FP) result means that patients without AF (and therefore with no increased risk of stroke and MI) will be started on treatment unnecessarily. Patients in the cardiology population without AF and with negative test result (true negatives, TN) leave the model.

Figure 1: Model of the paroxysmal AF diagnostic process for (a) post-stroke population and (b) cardiology population



The Markov component of the model shown in *Figure 2* represents the longer-term consequences of the results of the diagnostic test for patients who remained in the model after the diagnosis. The model includes health states for two clinical sequelae of AF, which are ischaemic strokes and MI, plus serious adverse events related to treatment with oral anticoagulants and antiplatelet medication, which are major bleeds including intracranial haemorrhage (ICH) and haemorrhagic stroke. The ischaemic and haemorrhagic stroke health states are divided into three severity levels (mild, moderate, and severe) according to the resulting level of disability following the event, measured with modified Rankin Scale (mRS).[29] All these events could be fatal. The non-fatal events generate higher costs in the first year following the event and a lower cost in subsequent years, therefore all these events have different states for the first and subsequent years.

Figure 2: State transition model following the diagnosis of pAF

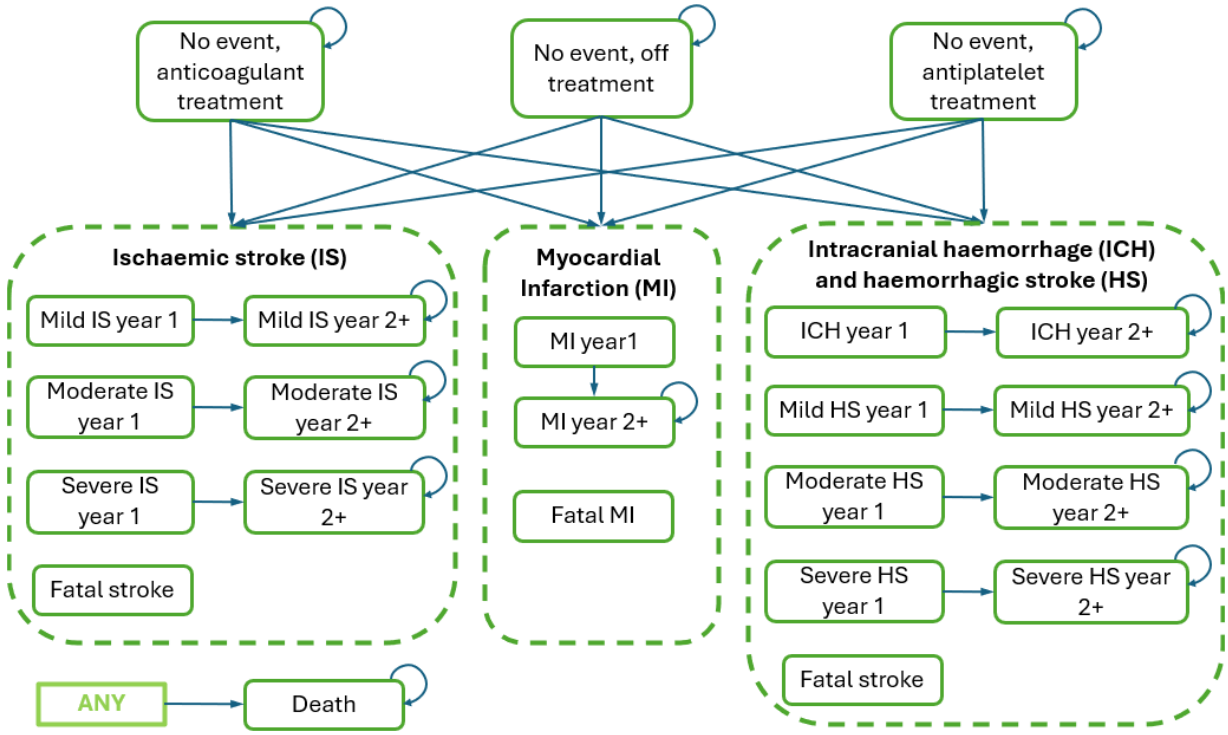


Table 3. Model assumptions

Assumption	Reason
Patients who experience a clinical event (stroke, bleed or MI) in the model are assumed to remain in the respective health state for the remainder of the model time horizon and face no further stroke or bleeding risks.	This is a simplifying assumption to minimise the number of transition probabilities required to populate the model which would increase complexity and uncertainty.
Patients in the post-stroke population are assumed to be treated with antiplatelet therapy until AF is detected. If AF is detected, then they are assumed to commence anticoagulation therapy.	To reflect treatment effect in terms of risk of stroke, MI and bleed and costs associated with treatments.
Patients in the symptomatic model (cardiology population) are assumed to be on no relevant treatment unless pAF is detected.	
Repeat Holter monitoring is not included in the base case analysis.	Time to repeat Holter and the proportion of patients who receive a repeat Holter is unclear in Scottish clinical practice.
Risk for ischaemic stroke and MI for patients with paroxysmal AF is assumed to be equal to that of general AF population.	Limited data for patients with undiagnosed AF. Similar assumption in the literature for paroxysmal AF event probabilities.

Eligible population

Post-stroke and post-TIA population

The population considered eligible for monitoring with ambulatory ECG patches following an ischaemic stroke each year in the model was the proportion of all patients in Scotland who have had an ischaemic stroke or TIA who remain at suspicion of undetected AF and, in current practice, are recommended to have ambulatory ECG monitoring. The annual number of patients receiving Holter monitoring following a stroke or TIA in current Scottish clinical practice is unknown as these data are not reported nationally.

Clinical experts consulted by SHTG considered that the proportion of patients eligible for ambulatory monitoring following an ischaemic stroke or TIA were all those for whom AF was not detected during their initial inpatient admission following their stroke and their stroke was not severely disabling or fatal (F. Ahmed, Cardiology Cons. personal communication, 28 March 2025). We applied the proportion of ischaemic strokes from the literature that were not severely disabling and where AF was not detected during the initial inpatient stay to the annual numbers of people who had an ischaemic stroke in national data reported by the Scottish Stroke Improvement Programme (SSIP).[27] A proportion of people who had a TIA that were eligible for the prolonged ambulatory ECG monitoring (80%) were also included according to expert opinion and data published by PHS (*Table 4*).[28]

Table 4: Eligible population post-stroke and TIA

Parameter	Value	Source
Annual number of ischaemic strokes	9,182	SSIP 2024[27]
Proportion of strokes that are severely disabling	10%	Diamantopoulos 2016[29]
Proportion of people with ischaemic stroke where AF is detected in current practice	30.1%	Ciminata 2020[30]
Annual number of TIA	3,442	PHS[28]
Proportion of people with TIA eligible for prolonged ambulatory ECG monitoring	80%	Clinical expert opinion
Total annual number of people eligible for prolonged ECG monitoring following a stroke or TIA per year	8,254	Calculated

Cardiology population

An additional population eligible for ambulatory ECG patch monitors are patients who currently receive Holter monitoring for cardiology symptoms. The Centre for Sustainable Delivery (CfSD) provided an estimate of the overall annual number of Holter monitor tests conducted, which was provided to them by individual health boards (54,659 per year). We subtracted the estimated number of Holter monitor procedures for patients following an ischaemic stroke or TIA. We subtracted a further 10% of the remaining number to account for paediatric patients, as estimated

by health boards consulted by CfSD. This resulted in an estimated 41,765 patients per year eligible for ambulatory ECG monitoring because of cardiology symptoms.

ECG patch and Holter monitor detection rates

Post-stroke and post-TIA population

Detection rates of paroxysmal AF with ECG patch and Holter monitoring in the post-stroke population used in the model are shown in *Table 5*. The detection rate of paroxysmal AF in the post-stroke population with ECG patch monitors was from the only UK-based randomised study that compared short-term Holter monitoring to 14-day ECG patch monitoring.[31] Short-term monitoring in the randomised study was 24-hour Holter monitoring, which is shorter than the monitoring duration for this group of patients in Scottish clinical practice, according to experts consulted by SHTG.

As the detection rate over 24 hours may underestimate the detection of AF in this patient group in Scottish clinical practice, the detection rate with Holter monitoring in the model was assumed to be equal to that reported by a non-UK prospective cohort study using 72-hour Holter monitoring in unselected patients after a stroke or TIA.[32]

Table 5: Post-stroke and post-TIA population ECG patch and Holter monitor paroxysmal AF detection rates

Parameter	Value	Source
72-hour Holter monitor detection rate	4.3%	Grond 2013[32]
14-day ECG patch detection rate	16.1%	Kaura 2019[31]

Cardiology population

Detection rates of paroxysmal AF with ECG patch and Holter monitoring in the cardiology population used in the model are shown in *Table 6*. No study reported paroxysmal AF detection rates using ECG patch monitors in a population representative of patients who would be referred for ambulatory ECG monitoring using Holter monitors in current Scottish practice. One study reported the rate of paroxysmal AF detected in a UK population, which included referral for symptoms and follow up after a stroke using 7-day Holter monitoring and disaggregated the results by presenting reason for monitoring.[33] We used the detection rate at 7 days in patients presenting with symptoms from this study as the detection rate for ECG patch monitors assuming that the difference in rates of paroxysmal AF detection between ECG patch monitors and Holter devices is because of duration of monitoring only.

No studies were available that reported 24-, 48- or 72-hour Holter detection rates in this population. We assumed the same detection rate for Holter monitoring in the cardiology population as that applied in the stroke/TIA population in the model.

Table 6: Cardiology population ECG patch and Holter monitor paroxysmal AF detection rates

Parameter	Value	Source
Holter monitor detection rate	4.3%	Grond 2013[32]
7-day ECG patch detection rate	8.6%	Jawad-Ul-Qamar 2020[33]

Treatment following detection of AF

If patients in the model were found to have AF, then they were assumed to commence treatment with an anticoagulant which was either warfarin (4%) or a direct oral anticoagulant (DOAC) (96%). This reflected prescribing practices observed in an analysis of anticoagulation prescriptions by drug in Scotland for the financial year 2023 provided to us by PHS (E. Bates, Senior Information Analyst, PHS, personal communication, 15 May 2025). Patients in the post-stroke or post-TIA population and cardiology populations were assumed to be treated with antiplatelet therapy or no treatment, respectively, if AF was not detected.

Risk of recurrent stroke – post-stroke and post-TIA population

The risk of recurrent stroke for patients with AF that is undetected, detected and on treatment with warfarin, detected and on treatment with a DOAC, and no paroxysmal AF, was from an economic evaluation of ILRs for the detection of AF in patients who had a prior stroke or TIA (*Table 7*).[29]

Table 7: Annual rate of recurrent stroke by AF and treatment status, post-stroke population

Parameter	Annual rate	Source
Risk of recurrent stroke without AF	5.28%	Diamantopoulos 2016[29]
Risk of recurrent stroke with AF on antiplatelet therapy	7.85%	
Risk of recurrent stroke with AF on warfarin	3.1%	
Risk of recurrent stroke with AF on DOAC	3.19%	

Patients in the post-stroke population with undetected AF are assumed to remain on antiplatelet therapy. Studies we identified found no statistically significant difference for rate of MI in patients with AF who were treated with an antiplatelet compared with anticoagulants.[34]

Risk of stroke – cardiology population

Table 8 shows the risk of stroke and MI for patients in the cardiology population with AF but not on treatment and with AF treated with oral anticoagulant.

Table 8: Annual rate of stroke by AF and treatment status, cardiology population

Parameter	Annual rate	Source
Risk of stroke with AF not on treatment	3.4%	Gage 2004[35]
Risk of stroke with AF on anticoagulant	1.2%	Gage 2004,[35] adjusted using hazard ratio (HR) from Sterne 2017[34]
Risk of MI with AF not on treatment	1.2%	Soliman 2014[36]
Risk of MI with AF on anticoagulant	0.01%	Soliman 2014,[36] adjusted using HR from Sterne 2017[34]

Data for the risk of stroke with AF and not on treatment in the cardiology population were from the same source as in the economic evaluation of ILRs for the detection of AF in patients who had a prior stroke, however they were not adjusted for prior stroke.[35] Patients diagnosed with AF in the cardiology model were assumed to have a $CHADS_2$ score of between 1 and 2, based on international guidelines, and were representative of patients in the study that provided detection rates, as most with AF detected were prescribed oral anticoagulants.

Patients in the cardiology population with untreated AF were also at increased risk of MI. Risk of MI was based on the association observed in a US-based prospective cohort study.[36]

The treatment effect of oral anticoagulants on the risk of stroke (HR 0.369) was applied to the baseline risks for these events, resulting in a hazard ratio 0.0079 for MI in patients with AF treated with an anticoagulant. These data were from a meta-analysis that reported no statistically significant difference between risk of stroke or MI in patients treated with warfarin compared to direct oral anticoagulants.[34]

Rates of bleeding by treatment

Types of bleeds included in the model were ICH, of which a proportion were haemorrhagic stroke. Patients not treated with an oral anticoagulant assumed the general population risk of a bleeding event. Patients treated with an oral anticoagulant were at an increased risk of bleeding at rates depending on whether they were treated with warfarin or a DOAC. Probability of bleeds were from the economic evaluation of ILRs[29] and a trial comparing antiplatelet therapies for patients with stroke (*Table 9*).[37]

Table 9: Annual rates of ICH by treatment

Parameter	Value	Source
ICH no treatment	0.05%	Diamantopoulos 2016[29]
ICH warfarin	11.9%	
ICH DOAC	0.5%	
Risk of bleed on antiplatelet	0.14%	PRoFESS trial[37]

Distribution of stroke and bleed severity

The proportion of ICH that were haemorrhagic stroke, their distribution of severity and the distribution of ischaemic stroke severity were from the economic evaluation of ILRs (*Table 10*).[29]

Table 10: Proportions of stroke and bleed severity

Parameter	Value	Source
Ischaemic strokes that are mild	42%	Diamantopoulos 2016[29]
Ischaemic strokes that are moderate	26%	
Ischaemic strokes that are major	10%	
Ischaemic strokes that are fatal	22%	
ICH that are haemorrhagic stroke	59.7%	
Haemorrhagic strokes that are mild	28%	
Haemorrhagic strokes that are moderate	23%	
Haemorrhagic strokes that are major	12%	
Haemorrhagic strokes that are fatal	37%	

Mortality

The approach to estimating mortality in the model was similar to the approach taken by Diamantopoulos and colleagues[29] and data for post-stroke mortality were from the same study. General population mortality was applied to patients in the no event health state for patients in the cardiology population based on Scottish lifetables adjusted for the proportion of deaths as a result of cerebrovascular disease. Mortality in the no event health state in the post-stroke population was adjusted to account for these patients having experienced a prior cerebrovascular event. Additional mortality risk was included for patients in the post-stroke health states according to the severity of the stroke and for patients who had an MI.[38]

Technology costs

The cost of ECG patch monitors was estimated using the most recent publicly available cost from a poster presentation[39] and was for the Zio XT device. The cost used in the analysis was £199 per patient, which was for 14 days of monitoring including analysis.

The cost of Holter monitoring was estimated using the same approach as that taken by NICE in their appraisal of the Zio XT device.[3] This approach assumed that the NHS cost data for *EY51Z:*

Electrocardiogram monitoring and stress testing within the cardiology services speciality was the most suitable source of cost data for Holter monitoring plus an additional cost for hardware and maintenance. We used the most recent published NHS Cost Collection data from 2022/23[40] (£156) and uprated the hardware and maintenance cost reported in the NICE appraisal[3] to 2024 prices (£34). This resulted in an estimated Holter monitor cost of £190 per patient.

The per patient Holter monitor cost is assumed to include the cost of staff time for device fitting, removal and reporting. We have reported staff time saved which could be expected with the introduction of ECG patch monitors, according to the staff time associated with Holter monitors as estimated by Scottish clinical experts (C. Vaughan, Clinical Lead Cardiac Physiologist, Queen Elizabeth Hospital, NHS Greater Glasgow and Clyde. Personal Communication 1 May 2025) (*Table 11*).

Table 11: Staff time for Holter monitoring

Parameter	Value	Source
Band 3 fitting (5 minutes) and removing device (5 minutes) per Holter monitor test	10 minutes	Expert opinion
Proportion of patients monitored with a 24-hour Holter, cardiology population	20%	
Proportion of patients monitored with a 48-hour Holter, cardiology population	20%	
Proportion of patients monitored with a 72-hour Holter, cardiology population	60%	
Proportion of patients monitored with a 24-hour Holter, post-stroke population	0%	
Proportion of patients monitored with a 48-hour Holter, post-stroke population	10%	
Proportion of patients monitored with a 72-hour Holter, post-stroke population	90%	
Average Band 6 cardiac physiologist reporting time per Holter monitor test – cardiology population	27 minutes	30 minutes per 24- and 48-hour tape and 45 minutes per 72-hour tape, calculated using distribution of monitoring time
Average Band 6 cardiac physiologist reporting time per Holter monitor test – post-stroke population	44 minutes	

Healthcare resource use costs

Costs were included for follow-up appointments, which varied by test result and population (*Table 12*). In the post-stroke population, patients were followed up at a consultant-led outpatient appointment regardless of the outcome of the test. In the cardiology population, patients with AF detected on ambulatory ECG were followed up at a consultant-led outpatient appointment and those with a negative result were followed up in primary care. Costs associated with referral were

not included as these were thought to remain constant across the intervention and comparator arms of the model. This was consistent with the approach taken in the NICE appraisal of the Zio XT patch monitor.[3]

Table 12: Healthcare resource use costs associated with follow up after a test

Parameter	Value	Source
Follow-up appointment, all post-stroke population and positive test cardiology population	£230	Outpatient consultant-led, PSSRU 2024[41]
Follow-up appointment, negative test cardiology population	£45	GP appointment, PSSRU 2024[41]

Medication costs

Medication costs were included for anticoagulants and antiplatelet medications (*Table 13*). The cost of warfarin was from a UK cost-effectiveness analysis comparing DOACs to warfarin for the prevention of stroke in people with AF[42] and uprated to 2024 prices. This source included the purchase cost of warfarin and additional healthcare resource use costs associated with warfarin therapy (international normalised ratio (INR) monitoring and dose adjustments). The costs of DOACs were assumed to be equal to the purchase cost of apixaban 5 mg tablets twice per day. Apixaban was the most frequently prescribed DOAC according to the analysis of anticoagulation prescriptions by drug in Scotland for the financial year 2023 provided to us by PHS (E. Bates, Senior Information Analyst, PHS, personal communication, 15 May 2025). The cost of dual antiplatelet therapy was from the British National Formulary (BNF).[43]

Table 13: Annualised medication costs

Parameter	Value	Source
Warfarin	£518	Thom 2019[42]
DOAC (assumed apixaban)	£37.82	BNF[43]
Dual clopidogrel 75 mg/dayand aspirin 75 mg/day	£23	

Health state costs

Health state costs (*Table 14*) covered NHS and social care costs associated with the acute and long-term management of stroke, ICH and MI. Costs following a stroke were according to the severity of stroke and whether the patient had a prior stroke before entering the model. Health state costs in the first year and subsequent years after an ischaemic stroke were based on a Sentinel Stroke National Audit Programme (SSNAP) health economic report.[44] Ongoing costs for health and social care because of disability following a haemorrhagic stroke were assumed to be equal to ischaemic strokes with a corresponding level of disability. The costs of haemorrhagic stroke in the first year

were from a study based on the Oxford Vascular study that collected healthcare resource use following a stroke in patients with AF.[45]

Patients in the post-stroke population incurred ongoing health state costs in the no event health state associated with their prior stroke. Costs associated with mild stroke were also higher in this group because of the prior event. These costs were reweighted for the proportion of patients in the post-stroke population who had a prior TIA and who did not incur costs for a prior stroke.

Costs associated with treating MI and its ongoing care costs were from a UK-based retrospective cohort study investigating the economic burden of cardiovascular events.[46]

Table 14: Health state costs

Parameter	Value		Source
	Post-stroke population	Cardiology population	
No event	£5,759	0	SSNAP[44]
Mild ischaemic stroke first year	£24,926	£21,168	
Mild ischaemic stroke subsequent years	£11,227	£9,166	
Moderate ischaemic stroke first year	£34,906		
Moderate ischaemic stroke subsequent years	£13,549		
Severe ischaemic stroke first year	£44,627		
Severe ischaemic stroke subsequent years	£17,393		
ICH that is not haemorrhagic stroke (HS)	£3,419		Luengo-Fernandez 2013[45]
Mild HS first year	£13,402		
Moderate HS first year	£34,432		
Major HS first year	£58,243		
Mild HS subsequent years	£11,227	£9,166	Equal to post ischaemic stroke according to disability following stroke
Moderate HS subsequent years	£13,549		
Major HS subsequent years	£17,393		
MI first year	£5,681		Danese 2016[46]
MI subsequent year	£1,225		

Travel distance and costs

A previously published SHTG recommendation included an analysis of average travel distance for a diagnostic procedure in Scotland, the proportion of patients eligible for reimbursed travel costs and the average travel claim. We assumed that these data were generalisable to patients travelling to collect and return Holter monitors and uprated the average travel claim to 2024 prices (*Table 15*).

Table 15: Travel distances and costs

Parameter	Value	Source
Average patient travel distance for an outpatient diagnostic procedure NHS Scotland	16 miles	SHTG 2020
Average patient travel distance to collect/return Holter monitor	32 miles	Calculated
Proportion of patients eligible for reimbursed travel costs	2.97%	SHTG 2020
Average travel claim	£12	SHTG 2020, uprated to 2024 prices

Results

Post-stroke and post-TIA population

The base case results from our cohort resource impact analysis in the post-stroke and post-TIA population are presented in *Table 16*. The results indicate that ECG patch monitors are associated with a resource saving of £5.1 million over 5 years compared with Holter monitoring for a single cohort of patients. ECG patch monitors were cost saving in year 1 compared with Holter monitoring, with a resource saving of £800,000. Each year, from year 2 onwards, ECG patch monitors are increasingly resource saving compared with Holter monitoring with resource savings of £1.2 million in year 5.

Table 16: Base case cohort resource analysis results for NHSScotland years 1 – 5, post-stroke and post-TIA population

ECG monitoring strategy	Annual costs (£m)					Total (£m)
	Year 1	Year 2	Year 3	Year 4	Year 5	
Holter	62.3	59.6	60.1	60.3	60.2	302.5
ECG patches	61.5	58.6	59.0	59.2	59.1	297.4
Net change	-0.8	-1.0	-1.1	-1.1	-1.2	-5.1

The resource savings associated with ECG patch monitoring in the post-stroke population are driven by a reduction in the number of people who have a stroke. Savings include resources such as staff and hospital resources (for example MRI and CT scanners) and these resources are likely to be fixed

over the short term; staff are likely to still be employed with the NHS and hospital equipment is still likely to be used. The proportion of the savings that may be cash releasing over a shorter time is unknown.

The resource impact analysis results for the post-stroke and post-TIA population were disaggregated to explore the distribution of resource cost impact across cost domains included in the analysis (*Table 17*). ECG patch monitors were associated with resource savings of £9.1 million that were attributable to prevented stroke. These cost savings were partially offset by increases in costs associated with the diagnostic procedure (£100,000), medication (£3 million) and costs attributable to an increase in bleeding events (£600,000).

Table 17: Disaggregated cohort resource analysis results, post-stroke and post-TIA population

Item	Cost (£m)		
	Holter	ECG patches	Net
Diagnostic procedure	1.6	1.6	0.1
Follow-up appointments	1.9	1.9	-
Medication	180.2	183.5	3.3
Stroke	118.2	109.1	-9.1
Bleed	0.6	1.2	0.6
Total	**302.5**	**297.4**	**-5.1**

We also estimated the cumulative net resource, clinical outcome, patient travel and staff time impact of introducing ECG patch monitors for people who had a stroke or TIA over a 5-year period (*Table 18*). This was based on a new cohort of patients entering the model each year and assumed a constant rate of stroke and TIA in Scotland over the 5-year period. These results estimate a net resource saving of £14.6 million associated with the introduction of ECG patch monitors. The model found that the number of recurrent strokes were lower in people who had ambulatory ECG patch monitors. The number of strokes prevented in the first year was 54. The number of strokes prevented increased over the 5-year period because people continued to remain at risk over time and new people became eligible for the test in each subsequent year. The cumulative number of strokes prevented over 5 years was 689 with the ECG patch monitor strategy.

Other clinical outcomes estimated by the model included the impact on bleeding events and deaths. Introducing ECG patch monitors was associated with 319 fewer deaths over 5 years as a result of lower stroke-related mortality in the ECG patches arm of the model compared with the Holter monitoring strategy. There were 133 more bleeding events in the ECG patches arm. An increase in bleeding events was observed in the ECG patches arm of the model because of a higher number of patients being treated with an oral anticoagulant (OAC) for detected AF.

The introduction of ECG patch monitors was also associated with a reduction in distance travelled by patients to collect and return Holter monitor devices. The model estimates that each year patients

would collectively travel 264,000 miles less with ECG patch monitors than if tested with Holter monitors. Over 5 years this equated to 1.3 million miles of travel saved.

Staff time saved with ECG patch monitoring compared with Holter monitoring was estimated to be 0.7 whole time equivalent (WTE) and 3.1 WTE NHS Agenda for Change staff time at Band 3 and Band 6, respectively. Band 3 staff time was for fitting and removing Holter devices; Band 6 staff time was for cardiac physiologists reading and reporting Holter monitor tapes.

Table 18: 5-year cumulative annual cohort net resource, clinical outcome, patient travel and staff time impact results for ECG patch monitoring versus Holter monitoring, post-stroke and post-TIA population

Year	Stroke	Bleeding events	Deaths	Resource impact (£m)	Travel (000 miles)	Band 3 staff time (WTE)	Band 6 staff time (WTE)
1	-54	9	-10	-0.8	-264	-0.7	-3.1
2	-101	18	-29	-1.8	-264	-0.7	-3.1
3	-143	27	-56	-2.9	-264	-0.7	-3.1
4	-180	35	-91	-4.0	-264	-0.7	-3.1
5	-212	43	-134	-5.1	-264	-0.7	-3.1
Total	-689	133	-319	-14.6	-1,320	-3.6	-15.7

Cardiology population

The base case results from our cohort resource impact analysis in the cardiology population are presented in *Table 19*. The results indicate that ECG patch monitors are associated with a resource saving of £5.2 million over 5 years for a single cohort of patients. ECG patch monitors were cost saving in year 1 compared with Holter monitoring, with a resource saving of £70,000. Each year, from year 2 onwards, ECG patch monitors are increasingly cost saving with resource savings of £1.6 million in year 5.

Table 19: Base case resource analysis results for NHSScotland years 1 – 5, cardiology population

ECG monitoring strategy	Annual costs (£)					Total (£m)
	Year 1	Year 2	Year 3	Year 4	Year 5	
Holter	48.2	46.0	57.2	67.9	78.0	297.3
ECG patches	48.2	45.1	56.0	66.5	76.4	292.1
Net change	-0.07	-1.0	-1.2	-1.4	-1.6	-5.2

The resource savings associated with ECG patch monitors in the cardiology population are driven by a reduction in the number of people who have a stroke. Savings include resources such as staff and hospital resources (for example MRI and CT scanners) and these resources are likely to be fixed over the short term; staff are likely to still be employed with the NHS and hospital equipment is still likely to be used. The proportion of the savings that may be cash releasing over a shorter time is unknown.

The cohort resource impact analysis results for the cardiology population were disaggregated to explore the distribution of resource cost impact across cost domains included in the analysis (*Table 20*). ECG patch monitors were associated with resource savings of £6.5 million that were attributable to prevented stroke. A further £800,000 in resource savings were attributable to prevented MIs. These cost savings were partially offset by increases in costs associated with the diagnostic procedure (£400,000), medication (£500,000) and costs attributable to an increase in bleeding events (£1 million).

Table 20: Disaggregated cohort resource analysis results, cardiology population

Item	Cost (£m) Holter	ECG patches	Net
Diagnostic procedure	7.9	8.3	0.4
Follow-up appointments	2.2	2.5	0.3
Medication	0.5	1.0	0.5
Stroke	262.7	256.2	-6.5
MI	18.0	17.2	-0.8
Bleed	2.2	3.1	1.0
Total	297.3	292.1	-5.2

We also estimated the cumulative net resource, clinical outcome, patient travel and staff time impact of introducing ECG patch monitors for people who were eligible for ambulatory ECG because of symptoms that could be AF (*Table 21*). This was based on a new cohort of patients entering the model each year and assumed a constant rate of people eligible for ambulatory ECG in Scotland over the 5-year period. These results estimate a net resource saving of £12.1 million associated with the introduction of ECG patch monitors. The model found that the number of recurrent strokes were lower in people who had ambulatory ECG patch monitors. The number of strokes prevented in the first year was 39. The number of strokes prevented increased over the 5-year period because people continued to remain at risk over time and new people became eligible for the test in each subsequent year. The cumulative number of strokes prevented over 5 years was 541 with the ECG patch monitor strategy.

Other clinical outcomes estimated by the model included the impact on bleeding events and deaths. Introducing ECG patch monitors was associated with 161 fewer deaths over 5 years because of lower stroke-related mortality in the ECG patches arm of the model compared with the Holter monitoring strategy. There were 237 more bleeding events in the ECG monitoring arm. An increase in bleeding events was observed in the ECG patches arm of the model because of a higher number of patients being treated with an OAC for detected AF.

The introduction of ECG patch monitors in the cardiology population was also associated with a reduction in distance travelled by patients to collect and return Holter monitor devices. The model estimates that each year patients would collectively travel 1.3 million miles less with ECG patch

monitors than if tested with Holter monitors. Over 5 years this equated to 6.7 million miles of travel saved.

Staff time saved with ECG patch monitoring compared with Holter monitoring, if introduced for people eligible for ambulatory ECG monitoring because of symptoms, was estimated to be equivalent to 3.6 WTE and 15.9 WTE NHS Agenda for Change staff time at Band 3 and Band 6, respectively.

Table 21: 5-year annual cohort net resource, clinical, travel and staff time impact results for ECG patch monitoring versus Holter monitoring, cardiology population

Year	Stroke (n)	MI (n)	Bleeding events (n)	Deaths (n)	Resource impact (£m)	Travel (000 miles)	Band 3 staff time (WTE)	Band 6 staff time (WTE)
1	-39	-21	16	-5	-0.07	-1,337	-3.6	-15.9
2	-76	-42	32	-15	-1.0	-1,337	-3.6	-15.9
3	-110	-61	48	-28	-2.2	-1,337	-3.6	-15.9
4	-143	-80	63	-46	-3.6	-1,337	-3.6	-15.9
5	-173	-97	78	-67	-5.2	-1,337	-3.6	-15.9
Total	-541	-301	237	-161	-12.1	-6,682	-18.1	-80

Sensitivity analysis

One-way sensitivity analysis

We conducted one-way sensitivity analysis (OWSA) to explore uncertainty around the cost of, and AF detection rates with, ECG patch monitors and Holter monitors. Detection rates were varied by increasing or decreasing by 20%, whereas technology costs were varied by 25% and 50%. The results of the OWSA are shown in *Table 22* and *Table 23* for the post-stroke and post-TIA population and cardiology populations, respectively. In all the analyses ECG patch monitors remained cost saving.

Table 22: OWSA – post-stroke and post-TIA population

Parameter (% variation from base case)	5-year pathway cost (£million)		Net change (£million)	Change from base case
	Holter	ECG patches		
Holter detection rate (+20%)	£302.4	£297.4	-£5.0	-2.5%
Holter detection rate (-20%)	£302.6	£297.4	-£5.3	+2.5%
ECG patch detection rate (+20%)	£302.5	£296.4	-£6.1	+19.5%
ECG patch detection rate (-20%)	£302.5	£298.4	-£4.1	-19.5%
Holter cost (+25%)	£302.9	£297.4	-£5.5	+8%
Holter cost (+50%)	£303.3	£297.4	-£5.9	+15.5%
Holter cost (-25%)	£302.1	£297.4	-£4.8	-7.5%
Holter cost (-50%)	£301.7	£297.4	-£4.4	-15.5%
ECG patch cost (+25%)	£302.5	£297.8	-£4.7	-8%
ECG patch cost (+50%)	£302.5	£298.2	-£4.3	-16%
ECG patch cost (-25%)	£302.5	£297.0	-£5.6	+8%
ECG patch cost (-50%)	£302.5	£296.5	-£6.0	+16%

Table 23: OWSA – cardiology population

Parameter (% variation from base case)	5-year pathway cost (£million)		Net change (£million)	Change from base case
	Holter	ECG patches		
Holter detection rate (+20%)	£296.4	£292.1	-£4.3	-18.5%
Holter detection rate (-20%)	£298.3	£292.1	-£6.2	+18.5%
ECG patch detection rate (+20%)	£297.3	£290.2	-£7.1	+37%
ECG patch detection rate (-20%)	£297.3	£294.0	-£3.3	-37%
Holter cost (+25%)	£299.3	£292.1	-£7.2	+38%
Holter cost (+50%)	£301.3	£292.1	-£9.2	+76%
Holter cost (-25%)	£295.3	£292.1	-£3.3	-38%
Holter cost (-50%)	£293.3	£292.1	-£1.2	-76%
ECG patch cost (+25%)	£297.3	£294.2	-£3.1	-40%
ECG patch cost (+50%)	£297.3	£296.3	-£1.1	-80%
ECG patch cost (-25%)	£297.3	£290.0	-£7.3	+40%
ECG patch cost (-50%)	£297.3	£287.9	-£9.4	+80%

In the post-stroke and post-TIA population, the OWSA showed that the resource impact results were most sensitive to changes in the ECG patch detection rate (+/-20%) followed by where technology costs were varied by 50%. The magnitude of resource cost savings was more sensitive to varying the parameters included in the OWSA for the cardiology population. In the cardiology population the results were most sensitive to varying technology costs by 50%.

Scenario analysis

We conducted two scenario analyses to explore selecting alternative sources for key parameters in each population.

The first scenario (*Table 24*) considered a different size of post-stroke and post-TIA population. For this scenario we assumed that in the post-stroke population only patients with non-lacunar cryptogenic stroke, or embolic stroke of undetermined source (ESUS), would be eligible for ambulatory ECG monitoring in practice. The proportion of ischaemic strokes that were ESUS was from a systematic review of studies that reported average frequency of ESUS amongst ischaemic stroke patients.[47] The number of patients eligible for ambulatory ECG monitoring following a TIA was held equal to our base case. The resulting population size was 4,315 (compared with 8,254 in base case), with 63.8% having had a TIA. The magnitude of net resource cost savings was 28% lower than in our base case analysis.

Table 24: Alternative population size for post-stroke and post-TIA population

Scenario	5-year pathway cost (£million)		Net change (£million)	Change from base case
	Holter	ECG patches		
Post-stroke and post-TIA population N=4,315, TIA=63.8%	£148.7	£145.0	-£3.7	-28%

The second scenario analysis (*Table 25*) considered an alternative source for the AF detection rate for ECG patch monitoring in the cardiology population. For this scenario we used the results of a study that reported AF detection rates with 14-day continuous Holter ECG monitoring.[48] This study reported that AF was detected in 14% (compared with 8.6% in the base case) of patients monitored for this duration. This is a more optimistic detection rate than in our base case analysis, though the generalisability of these data to the population modelled is more uncertain as 47% of study participants had a history of stroke. This scenario yielded an increase of 116% in net resource cost savings compared to our base case analysis.

Table 25: Alternative ECG patch monitoring detection rate – cardiology population

Scenario	5-year pathway cost (£million)		Net change (£million)	Change from base case (%)
	Holter	ECG patches		
Cardiology population ECG patch monitoring detection rate 14%	£297.3	£286.1	-£11.3	+116%

Limitations

Our analysis was subject to some limitations. These included:

- The size of the eligible population following a stroke or TIA was uncertain because of an absence of ambulatory ECG monitoring data reporting for this group in Scottish clinical practice. We relied on published data for the overall annual number of people who have an ischaemic stroke in Scotland[27] and calculated the number of those eligible according to reasons for exclusion according to expert opinion. We explored an alternative approach to estimating the eligible population for ECG patch monitoring following an ischaemic stroke or TIA in a scenario analysis. In this scenario ECG patch monitors remained cost saving compared with Holter monitors, though with a smaller eligible population the magnitude of cost saving was lower.
- No data were available to inform the number of people who receive ambulatory ECG monitoring in Scottish clinical practice because of symptoms (the cardiology population in our model). The size of the cardiology population was based on estimates provided by individual health boards to CfSD.
- The Holter monitor AF detection rate in the post-stroke and post-TIA population was from a different study than the one used for ECG patch monitoring in this subgroup.[31] Holter monitoring in this study was for 24-hours whereas we were advised that Holter monitoring following a stroke or TIA in Scottish clinical practice is predominantly for 72-hours. A Holter detection rate reported in a study that reported AF detection patients who had 72-hour monitoring following a stroke or a TIA was chosen for the analysis.[32]
- Evidence of effectiveness of ECG patch monitors for detecting AF was not available for a population representative of patients in the cardiology population. The AF detection rate for ECG patch monitors in this subgroup was from a UK-based study that reported AF yield using 7-day Holter monitoring in the most representative population available in the literature.[33] We held the detection rate of AF with conventional Holter monitoring equal to the post-stroke and post-TIA population. Our estimation of the magnitude of cost savings in the cardiology population may be conservative. The detection rate in the ECG patch arm of the

model may be an underestimation of the detection rate if these patients receive longer monitoring of over 14-days, and the detection rate in the Holter arm may be an overestimation. A scenario analysis that used higher AF detection rates for ECG patch monitors in the cardiology population resulted in a large increase in the resource cost savings estimated by our analysis.

- We did not model the events (ischaemic strokes, myocardial infarctions, and mortality) within the waiting times for the ambulatory ECG. This is particularly important for the post-stroke population, as the risk of a subsequent ischaemic stroke is highest shortly after the first stroke. This could underestimate the cost savings associated with shorter time to diagnosis with ECG patch monitors.
- The fatal events (strokes, MIs, and ICHs) did not generate costs. This was caused by the difficulty in separating the cost data of the fatal events from the non-fatal ones. By excluding these costs, the overall costs of mortality may have been underestimated in the model.
- The technology costs for Holter monitoring and ECG patch monitors were uncertain. Holter monitor costs were based on NHS Cost Collection data, which included other modes of ECG monitoring (such as stress tests and 12-lead ECG), which may mean that the per patient costs for Holter monitoring are different in practice. The per patient cost of ECG patch monitors was based on the most recent publicly available prices, however discounted prices may be available to NHSScotland based on order volume size. We varied the price of each technology in OWSA and in all analyses ECG patch monitors remained cost saving compared with Holter monitoring. The results of our analysis were most sensitive to changes to the cost of either technology in the cardiology population.

Conclusion

Evidence indicates that ECG patch monitors offer a promising alternative to traditional Holter monitors in detecting cardiac rhythm abnormalities, particularly pAF. Their extended monitoring durations of up to 14 days increases the likelihood of capturing intermittent arrhythmic events that can be missed by Holter monitors worn for 24 to 48 hours. Comparatively high patient satisfaction and usability ratings in studies demonstrate that patch monitors not only enhance diagnostic yield but are also generally safe and exhibit high patient acceptance because of their comfort and convenience. These findings suggest that ECG patch monitors can play a role in early detection and management of pAF, potentially reducing the risk of stroke and other adverse outcomes.

The current evidence base is limited by several factors. Many studies have small sample sizes or evaluate the devices over shorter monitoring periods than their full 14-day potential. This may underestimate their benefits. Additionally, heterogeneity in study design, patient populations and outcome measures limit the generalisability of the findings. Safety profiles appear favourable, with only minor adverse events reported. However, further research is needed to fully evaluate long-term safety, including issues related to skin integrity and device durability.

While ECG patch monitors demonstrate promising clinical effectiveness and patient acceptability, larger well-designed studies are required to confirm these findings and to evaluate their impacts in real-world settings.

The results of our resource impact analysis for Scotland found that implementing ECG patch monitoring for people who have had an ischaemic stroke or TIA, or present with symptoms that might be AF, is likely to be resource saving over 5 years.

Identified research gaps

While the available studies provide emerging evidence that ECG patch monitors improve the detection of AF compared with traditional Holter monitors, several research gaps remain. Larger controlled trials are needed that directly compare the diagnostic yield and clinical outcomes of ECG patch monitors with traditional Holter monitors.

Although studies report high patient satisfaction and increased comfort with patch devices, there remains a paucity of qualitative data exploring patient experiences over extended wear periods.[6, 19] Their safety profile, especially regarding their long-term impact and device durability, is not comprehensively explored.

Organisational issues such as workflow integration and resource allocation are also underexplored.[22]

Acknowledgements

Healthcare Improvement Scotland development team

- Mr James Chappell, Senior Health Economist
- Dr Anna Donten, Health Economist
- Ms Hilda Emengo, Lead Author/Health Services Researcher
- Ms Joanna Kelly, Health Services Researcher
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Peer reviewers

We would like to thank the following individuals who took part in the peer review and provided comments on the draft document.

- Dr Faheem Ahmad, Consultant Cardiologist and Cardiology Innovation Lead (West of Scotland Hub)
- Dr Anthony Byrne, Consultant Stroke Physician, NHS Forth Valley
- Dr Ross Campbell, Senior Clinical Lecturer in Cardiology and Honorary Consultant Cardiologist
- Professor Jesse Dawson, Professor of Stroke Medicine, University of Glasgow
- Mr Peter Kerr, Advanced Nurse Practitioner, NHS Greater Glasgow and Clyde
- Mr Austin Willett, CEO, Different Strokes

We would also like to thank members of the SHTG Evidence Review Team and SHTG Council who provided comments on the draft document.

Declarations of interest from all reviewers are published alongside the review on our website. Reviewers had no role in authorship or editorial control and the views expressed are those of Healthcare Improvement Scotland.

Published July 2025

Suggested citation: Emengo H, Chappell J, Donten A, Kelly J, Miller C, Nicol T. (2025). Electrocardiogram (ECG) patch monitors for the detection of cardiac rhythm abnormalities. ECG Patch Monitors

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Appendix 1: abbreviations

AF	atrial fibrillation
ANIA	Accelerated National Innovation Adoption
BNF	British National Formulary
CAD	Canadian
CAM	Carnation Ambulatory Monitor
CER	cardiac event recorder
CfSD	Centre for Sustainable Delivery
CI	confidence interval
DOAC	direct oral anticoagulant
ECG	electrocardiogram
ESUS	embolic stroke of undetermined source
FDA	Food and Drug Administration
FN	false negative
FP	false positive
GP	general practitioner
HR	hazard ratio
HS	haemorrhagic stroke
ICER	incremental cost-effectiveness ratio
ICH	intracranial haemorrhage
ILR	internal loop recorder
IMTO	Innovative Medical Technology Overview
INR	international normalised ratio
LTCM	long-term continuous monitoring
MAUDE	Manufacturer and User Facility Device Experience
MHRA	Medicines & Healthcare products Regulatory Agency
MI	myocardial infarction
MIB	medtech innovation briefing
mRS	modified Rankin Scale

MTG	medical technology guidance
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OAC	oral anticoagulant
OWSA	one-way sensitivity analysis
pAF	paroxysmal atrial fibrillation
P-ECG	patch ECG
PHS	Public Health Scotland
PSSRU	Personal Social Services Research Unit
QALY	quality adjusted life years
RCT	randomised controlled trial
S-ECG	standard 12-lead ECG
SHTG	Scottish Health Technologies Group
SSIP	Scottish Stroke Improvement Programme
SSNAP	Sentinel Stroke National Audit Programme
TIA	transient ischaemic attack
TN	true negatives
TP	true positives
UK	United Kingdom
US	United States
WTE	whole time equivalent