NICE National Institute for Health and Care Excellence

NICE guidance

Heart failure algorithms for remote monitoring in people with cardiac implantable electronic devices

HealthTech guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

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Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces MIB298 and DG61.

1 Recommendations

Use as an option

For people with heart failure

1.1 Use HeartLogic and TriageHF as options for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have heart failure. They should be used as part of a specialist multidisciplinary heart failure service with alerts reviewed and acted on by specialist healthcare professionals.

Can only be used in research

For people with heart failure

1.2 More research is needed on HeartInsight for algorithm-based remote monitoring in people with CIEDs who have heart failure, before it can be routinely used in the NHS.

For people at risk of developing heart failure

1.3 More research is needed on HeartInsight, HeartLogic and TriageHF for algorithm-based remote monitoring in people with CIEDs who are at risk of developing heart failure, before they can be routinely used in the NHS.

More research

1.4 More research for the technologies in sections 1.2 and 1.3 is needed in the populations outlined. This research is needed on:

- prognostic accuracy
- rates of false positives or unexplained alerts
- hospitalisation rates
- heart-failure-related mortality rates
- rates of emergency department or primary care visits
- patient-reported outcomes.

1.5 Access to the technologies in sections 1.2 and 1.3 in the populations outlined should be through company, research or non-core NHS funding, and clinical or financial risks should be appropriately managed.

Do not use

1.6 CorVue should not be used for algorithm-based remote monitoring in people with CIEDs who have or are at risk of developing heart failure.

Why the committee made these recommendations

Algorithm-based remote monitoring automatically detects the early signs of worsening heart failure and sends an alert to the healthcare professional. People who have or are at risk of developing heart failure can be offered CIEDs as part of heart failure therapy. Algorithm-based remote monitoring may be activated in a person's CIED.

Evidence for HeartLogic and TriageHF shows that they can detect the signs of worsening heart failure that could lead to hospitalisation or an unscheduled clinic visit (referred to as heart failure events). Evidence shows that CIEDs used with HeartLogic or TriageHF reduce hospitalisations compared with CIEDs used with remote monitoring only. Collection of

registry data is recommended for these algorithms to confirm the extent of the benefit seen in the studies.

It is uncertain whether the HeartInsight algorithm can detect early signs of worsening heart failure. There is also no evidence to show how well CIEDs that use HeartInsight reduce heart failure events. HeartInsight may be better at predicting worsening heart failure and reducing hospitalisations than CIEDs without algorithms, so more research is recommended.

More research is also recommended for HeartInsight, HeartLogic and TriageHF in people at risk of developing heart failure because there is very limited evidence in this population.

CorVue collects only intrathoracic impedance data, while the other algorithms monitor additional factors. Clinical trial evidence suggests that CorVue fails to detect some signs of worsening heart failure and has a high rate of false-positive alerts (alerts that are not followed by a heart failure event). So CorVue is not recommended for use in the NHS.

2 Heart failure algorithms

Clinical need and practice

2.1 Heart failure is a clinical syndrome caused by any structural or functional cardiac disorder that impairs the heart's ability to efficiently pump blood around the body. The most common symptoms of heart failure are breathlessness, fatigue and oedema. Conditions that can cause heart failure include:

- coronary heart disease
- high blood pressure
- heart rhythm or valve abnormalities and
- conditions affecting the heart muscle (cardiomyopathies and myocarditis).

Around 920,000 people in the UK were living with heart failure in 2018 with an estimated 200,000 new diagnoses each year. Heart failure mainly affects people over 65, with an average age at diagnosis of 77.

2.2 Cardiac implantable electronic devices (CIEDs) are recommended as treatment options for some people who have or are at high risk of heart failure. The different types of CIEDs are pacemakers, implantable cardioverter defibrillators, and cardiac resynchronisation therapy devices.

2.3 Remote monitoring is the ability for a CIED to communicate wirelessly with a remote monitoring system. People who have CIEDs must be followed up by hospitals for regular technical reviews of how their device is working. They may also have scheduled appointments, during which the clinical events recorded by the device are monitored. There is a lot of variation in clinical practice and the frequency of these follow-up visits varies according to the person's condition. NICE's guideline on diagnosis and management of chronic heart failure in adults recommends that reviews are offered every 6 months for people whose condition is stable, but clinical experts highlighted that in practice most people would have a review annually. Sometimes clinical reviews are only triggered if the person with

the CIED reports worsening symptoms.

2.4 Some CIEDs have algorithm-based remote monitoring incorporated in the device. Heart failure algorithms analyse and collate different clinical data recorded by the device to detect gradual worsening of heart failure. The system can send alerts to healthcare professionals to prompt a review of the stored data. This enables proactive investigation into the cause of the suspected decompensation, potentially before the person even feels symptomatic. This could ensure that people have appropriate treatment as early as possible, reducing the number of unnecessary hospital visits.

The interventions

There are 4 heart failure algorithms that were identified as relevant for inclusion in this assessment. Each algorithm is only compatible with specific CIEDs manufactured by the same company that makes the algorithm.

CorVue (Abbott Medical)

2.5 The CorVue algorithm works with the Merlin.net Patient Care Network (PCN) platform, and is intended for remotely monitoring for the early signs of heart failure in people who have compatible CIEDs. The CorVue algorithm collects intrathoracic impedance data from the CIED and transmits it to the Merlin.net PCN platform via the mobile app (myMerlinPulse). It does this using Bluetooth and an internet or mobile network connection to generate an alert. Or, instead of using the app-based smartphone transmitter, the company can provide a remote monitoring unit (Merlin@Home) that connects via Wi-Fi, mobile or landline connection. Healthcare professionals can view the data transmitted by the device on the Merlin.net PCN platform. Access to Merlin.net and the mobile transmitter is provided as part of the CIED, and the CorVue algorithm comes free of charge with the CIED devices.

2.6 The CorVue algorithm automatically calculates the mean daily impedance (from 12 daily measurements). It also collects reference impedance data based on the previous 12 to 14 days, which changes continuously based on new impedance readings. If a consistent drop of daily impedance values is detected (13 or

14 consecutive days in congestion) then a congestive event is reported and detected during device check-up. Patient alerts can be activated via remote monitoring if the person wishes.

HeartInsight (Biotronik)

2.7 HeartInsight is a predictive algorithm designed to monitor for early signs of worsening heart failure in people with compatible CIEDs. The algorithm works with the BIOTRONIK Home Monitoring system. The HeartInsight algorithm combines the following 7 parameters into 1 composite score (calculated daily):

- atrial burden
- heart rate variability
- general activity
- thoracic impedance
- heart rate
- heart rate at rest and
- premature ventricular contractions.

2.8 HeartInsight triggers an alert to healthcare professionals (via text message, email or both) once the prespecified threshold is exceeded for 3 consecutive transmissions (normally 3 consecutive days), indicating higher risk of worsening heart failure. The threshold is customisable. Upon receipt of an alert, a healthcare professional logs on to the Home Monitoring Service Centre website to review and assess the alert.

2.9 The system includes the handheld CardioMessenger device, which transmits data automatically and daily from the CIED to the BIOTRONIK Home Monitoring system via a mobile phone network. Access to HeartInsight has a one-off cost of £450 per person. Standard Home Monitoring is a separate cost.

HeartLogic (Boston Scientific)

2.10 HeartLogic is a diagnostic algorithm designed to monitor for early signs of worsening heart failure in people with compatible CIEDs. It works with the Latitude NXT Patient Management System. Measurements including heart sounds, thoracic impedance, respiration, heart rate and activity are collected by the implanted device. The HeartLogic algorithm then combines these into 1 composite index that indicates decompensation. Boston Scientific's HeartLogic and Latitude NXT Patient Management System work together to provide advanced monitoring and management capabilities for people with heart failure who have CIEDs. The system has daily data transfers to the clinical team. The transmitter can use a mobile phone connection or an internet connection to relay the data. The system is configured to send an alert to a healthcare professional when the index is over a set threshold (customisable by a healthcare professional). Healthcare professionals need to log on to the LATITUDE NXT website to receive alerts. Secondary notification of alerts may be through email or text message. Access to HeartLogic has a one-off cost of £3,650 per person, but discounts may be offered based on purchase volume.

TriageHF (Medtronic)

2.11 TriageHF is an alert-based algorithm used with CareLink remote monitoring. It is a monitoring system for identifying and managing an increased risk of heart failure or worsening heart failure in people with CIEDs. When TriageHF is used within a structured heart failure clinical care pathway it is called TriageHF Plus. TriageHF is hosted on the Medtronic CareLink network for collaborative management of heart failure between clinical teams. The algorithm monitors the following parameters:

- atrial tachycardia
- atrial fibrillation burden
- ventricular rate during atrial tachycardia or atrial fibrillation
- OptiVol fluid index (which tracks changes in thoracic impedance over time)
- general activity

- night ventricular rate
- heart rate variability
- percent of ventricular pacing
- treated ventricular tachycardia or ventricular fibrillation and
- defibrillator shocks.

CareLink uses a plug-in monitor or a smartphone app for transmitting data. Using a mobile or landline connection, data is transmitted from the CIED to the CareLink network where it can be accessed by healthcare professionals. Data can be transmitted:

- manually, if a person notices symptoms
- automatically, based on TriageHF algorithm alert triggers, or
- by scheduled transmission, based on a predefined date to replace a routine check.

For each day the data is transmitted, the TriageHF algorithm generates a daily risk status of a heart failure event occurring in the next 30 days (low, medium or high risk). This is based on the maximum daily risk status for the previous 30 days. A heart failure management report is generated on the daily risk status. The CareLink network sends an alert for people who have high-risk score so that they can be contacted for a telephone consultation. Access to TriageHF and CareLink remote monitoring has a yearly cost of £100 per person.

The comparator

Conventional remote monitoring of heart failure in people with CIEDs

2.12 Standard care for monitoring heart failure in people who have CIEDs is periodic

reviews of device function with a cardiac physiologist or cardiologist. A person will also have ad hoc reviews of symptoms with a GP, specialist nurse, cardiologist or a heart failure team. The number and timing of the reviews varies in practice depending on the person's symptoms (see section 2.3). The organisation of heart failure monitoring pathways varies in practice between different trusts, and even between different hospitals.

3 Committee discussion

The diagnostics advisory committee looked at evidence on algorithm-based remote monitoring of heart failure in people with cardiac implantable electronic devices (CIEDs). Evidence was considered from several sources, including an external assessment report and an overview of that report. Full details are in the project documents for this guidance.

Patient considerations

3.1 Wider availability of algorithm-based remote monitoring may allow greater access to care for people who are less able to attend in-person appointments (because of costs associated with travel, poor public transport, time taken from work, physical impairments, or anxiety). An alert may be followed by an initial telephone call to determine whether in-person follow up is needed. This could reduce the number of unnecessary in-person clinic visits.

3.2 The patient expert explained that CIEDs provide a sense of security to people because they know that their condition is being managed. With conventional remote monitoring, an unscheduled review would only be triggered if the person reports worsening symptoms. Algorithm-based remote monitoring provides reassurance to people because they know that alerts are transmitted automatically and reviewed by a healthcare professional, potentially before they experience symptoms. This could prevent people being admitted to hospital and improve their quality of life. But the committee acknowledged that, for some people, false-positive alerts (when an alert is triggered but there are no signs of decompensation) may cause unnecessary anxiety. The committee recommended more research on people's experiences with having heart failure algorithms activated on their CIEDs.

Clinical effectiveness

Prognostic accuracy

3.3 The committee noted that the heart failure algorithms needed to be considered independently of each other because they are each unique and have different alert rates and levels of accuracy. Each of the heart failure algorithms collects different data types to monitor decompensation or predict a person's risk status. The committee noted that CorVue collects only intrathoracic impedance data, while the other algorithms monitor additional factors (see sections 2.5 to 2.11). The committee noted that the prognostic accuracy of CorVue may be affected by the collection of only 1 data type.

3.4 For the heart failure event endpoint defined by the Framingham Heart Study, CorVue had a sensitivity of 68%. For endpoints related to hospitalisation, clinic visits and changes to treatment, sensitivity ranged from 20% to 61.9%. This suggests that people who are experiencing decompensation may not have an alert triggered using CorVue. Clinical experts noted that heart failure algorithms should have a high sensitivity. This is to ensure that people with early signs of a heart failure event can be identified, assessed and have treatment if necessary, and so people are not missed. False positives were also considered to be high in all studies reporting this outcome. All studies were also assessed by the external assessment group (EAG) as being at a high risk of bias, with a key concern being the analysis methods. The committee concluded that CorVue cannot accurately predict heart failure events.

3.5 Evidence from a single published study suggested that, at the nominal threshold of 4.5, HeartInsight had 65.5% sensitivity and 86.7% specificity for the endpoint of first post-implant heart failure hospitalisation. For the endpoint of heart failure hospitalisation, outpatient intravenous intervention or death, HeartInsight had 54.8% sensitivity and 86.5% specificity. The positive predictive value was reported as 7.7%, indicating that there is a high probability that an alert is a false positive. This study was also assessed by the EAG as being at a high risk of bias, with a key concern being the analysis methods. The committee concluded that it is uncertain whether HeartInsight can accurately predict heart failure events.

3.6 Using the study endpoint of worsening heart failure, HeartLogic showed

sensitivity ranging from 70% to 100%, and specificity ranging from 61% to 93%. False positives and unexplained alert rates were generally low in 6 studies. Statistically significant associations were observed between being in alert and hospitalisations, length of hospital stay, rate of heart failure events and rate of emergency care visits. All studies reporting prognostic accuracy data for HeartLogic were assessed by the EAG as being at a high risk of bias with the analysis methods being a key concern. The committee also considered data from a study that was published after the EAG's review was complete. Singh et al. (2024) evaluated HeartLogic in 1,458 people. For the endpoint of detecting heart failure events, HeartLogic demonstrated sensitivity of 74.5% and false-positive rate of 1.48 alerts per patient-year. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that HeartLogic can predict heart failure events.

3.7 Using the study endpoint of worsening heart failure in people with a 'high-risk' status, TriageHF demonstrated sensitivity ranging from 87.9% to 98.6% and specificity ranging from 59.4% to 63.4%. The false-positive rate was reported in 1 study and was considered to be low. Most studies reporting prognostic accuracy data were assessed by the EAG as being at a high or unclear risk of bias. A key concern was the analysis methods, and some of the studies were only available as abstracts that contained limited information. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that TriageHF can predict heart failure events.

False-positive or unexplained alerts

3.8 The committee noted that heart failure algorithms are intended to be used to support review of heart failure data by healthcare professionals, and should not be used in isolation to make treatment decisions. This is because events other than heart failure decompensation can sometimes trigger an alert. For example, viral respiratory illnesses can increase a person's intrathoracic impedance, which could cause an alert to be triggered even if the person has no decompensation. In a study this would be classed as a false-positive alert. The committee noted that these alerts and the follow up with a person would still be valuable because a non-heart-failure clinical event may still require intervention.

3.9 Some studies reported high rates of false-positive alerts. But the committee noted that all alerts would be reviewed alongside other clinical information and discussed with the person before a treatment decision is made. So the committee considered that unnecessary treatment arising from false-positive alerts is unlikely and so harms from over treatment when using heart failure algorithms are expected to be low.

3.10 The committee discussed the impact that the number of false positives could have on service burden. Specialist committee members indicated that this burden is low in their experience, because initial interaction following an alert is usually via phone call rather than in-person. The committee concluded that more research should be done on the rate of false-positive alerts.

Intermediate and clinical outcomes

CorVue

3.11 Shapiro et al. (2017) showed a statistically significant reduction in hospitalisations for people using the CorVue algorithm. But, this study was assessed by the EAG as being at a substantial risk of confounding because the comparator was people with no implanted device having home care. So the reduction in hospitalisations reported in the study could be because of the CIED rather than the CorVue algorithm. The committee concluded that it is uncertain whether use of CorVue can reduce hospitalisations.

HeartInsight

3.12 No evidence was identified that compared the HeartInsight algorithm with no algorithm use.

HeartLogic

3.13 Evidence suggests that using the HeartLogic algorithm instead of conventional remote monitoring, provides statistically significant reductions in:

- hospitalisations
- the rate of heart failure events
- the length of hospital stays and
- emergency or urgent care visits.

The 2 key comparative studies that were used in cost-effectiveness modelling both had small sample sizes; Treskes et al. (2021) included 68 people and Feijen et al. (2023) included 161 people. This raised concerns regarding the statistical power of these studies to detect the effects of heart failure algorithms. These studies were also assessed by the EAG as being at serious risk of bias. The committee concluded that while there are concerns regarding the quality of the comparative evidence for HeartLogic, it is likely that HeartLogic can reduce heart failure events compared with no algorithm use.

TriageHF

3.14 For TriageHF, comparative evidence was limited to 1 study, Ahmed et al. (2024). This is a real-world, UK study of 758 people. This study reported a statistically significant reduction in hospitalisation with TriageHF compared with no algorithm use. Ahmed et al. was assessed by the EAG as being at a critical risk of bias because of risks of confounding and selection bias. The committee concluded that while there are concerns regarding the quality of the comparative evidence from Ahmed et al., it is likely that TriageHF can reduce heart failure events compared with no algorithm use.

Failure rates

3.15 CIEDs may fail to transmit data if there are technical problems or connectivity issues, including internet problems, or if they are out of range of the transmission device. The committee noted that failure rates in the studies appear to be high, but it is difficult to separate transmission failure due to technical issues from transmission failure due to connectivity issues. If data transmission is missed,

each algorithm has built-in retry mechanisms that will attempt transmission again. Healthcare professionals will be notified if a person's data transmission is missed for a number of weeks. The companies commented that they pay stringent attention to device failures and always follow up on these. High failure rates reported in Debski et al. (2020) have been addressed by ensuring that devices are correctly programmed and that local protocols are in place. The committee concluded that they have no concerns regarding transmission failure, because systems are in place to manage and resolve this.

Cost effectiveness

A pairwise analysis approach was used

3.16 A pairwise analysis approach was taken to estimating cost effectiveness. This was because of the lack of data comparing algorithms and because the comparator for each algorithm is a brand-specific CIED that is not using the heart failure algorithm. The EAG explained that the comparator costs differ for each pairwise analysis because different data sources were used to derive model inputs. For HeartLogic and TriageHF, evidence on hospitalisation rates was available, so different rates were used for these 2 interventions and their comparators. Because of the lack of evidence for CorVue and HeartInsight, no difference in hospitalisation was assumed between these heart failure algorithms and their comparators. The hospitalisation rate for these 2 algorithms and their comparators was assumed to be an average of the rates used for HeartLogic and TriageHF.

Model structure

3.17 The EAG used comparative hospitalisation data to model the impact of heart failure algorithms rather than using prognostic accuracy data and a linked evidence approach. False-positive alerts were indirectly captured in the model for HeartLogic and TriageHF because study results on the number of unscheduled visits would be impacted by false-positive alerts. For CorVue and HeartInsight, no published data was available on unscheduled visits, so it was assumed that there

was no difference in the number of unscheduled visits between these heart failure algorithms and their comparators. This may underestimate the impact that false-positive alerts have on the cost-effectiveness estimates for CorVue and HeartInsight.

Probabilistic sensitivity analysis

3.18 The EAG's economic model showed that HeartLogic and TriageHF were more effective and less costly than standard care. The first probabilistic sensitivity analysis used probability distributions around mortality and intervention costs. This analysis showed that the probability of HeartLogic being cost effective was 81% at a threshold of £20,000 per quality-adjusted life year (QALY) gained and 73% at a threshold of £30,000 per QALY gained. The probability of TriageHF being cost effective was 85% at a threshold of £20,000 per QALY gained and 76% at a threshold of £30,000 per QALY gained. The committee noted that intervention costs would not be higher than the list price and so uncertainty around intervention cost should not be included in the probabilistic sensitivity analysis. The committee acknowledged the importance of considering the uncertainty around mortality rates, but noted limitations with how this uncertainty had been modelled. So, an additional probabilistic sensitivity analysis that excluded uncertainty around intervention costs and mortality was done. This analysis showed that both HeartLogic and TriageHF have a 100% probability of being cost effective at thresholds of £20,000 and £30,000 per QALY gained.

Cost-effectiveness estimates are driven by hospitalisation rates

3.19 There was no comparative evidence on hospitalisations for CorVue or HeartInsight that was considered suitable for inclusion in the EAG's economic model. A conservative deterministic base-case model assumption was made of no difference in hospitalisations between CorVue and HeartInsight and their comparators. The results of this deterministic model showed CorVue and HeartInsight to be more costly than standard care and equally as effective. Threshold analysis showed that only a small reduction in hospitalisations would make these heart failure algorithms cost effective.

3.20 The EAG's model used published hospitalisation rates for HeartLogic and TriageHF. For HeartLogic, the hospitalisation incidence rate ratio of 0.28 was calculated from Treskes et al. (2021), which indicates a 72% lower rate of hospitalisations in the intervention group. For TriageHF, the hospitalisation incidence rate ratio of 0.42 was taken from Ahmed et al. (2024), which indicates a 58% lower rate of hospitalisations in the intervention group. These inputs resulted in the technologies being dominant (less costly and more effective than standard care) in the deterministic model base case. The committee noted that post hoc or subgroup analyses from these publications show that reductions in hospitalisations were smaller in some subgroups than in the overall study populations. For example, an analysis by Ahmed et al. that was limited to data collected before the onset of the COVID-19 in the UK, gave a hospitalisation incidence rate ratio of 0.69, indicating a 31% lower rate of hospitalisations in the intervention group. The committee also recalled the concerns regarding the quality of the comparative evidence for HeartLogic (see section 3.13) and TriageHF (see section 3.14) and noted that the risk of confounding may impact the reliability of the results from these studies. But, only small reductions in hospitalisations are needed for HeartLogic and TriageHF to be cost effective in the EAG's model. So the committee concluded that HeartLogic and TriageHF are likely to be cost-effective uses of NHS resources.

Potential uncaptured benefits

3.21 There was a lack of evidence for the impact of heart failure algorithms on heart-failure-related mortality rates and health-related quality of life. In the EAG's deterministic base-case model, conservative assumptions were made that there is no difference in heart-failure-related mortality rates between heart failure algorithms and their comparators. The committee noted that if there was an improvement in mortality or if health-related quality of life is greater when using heart failure algorithms, then there would be gains in QALYs. These potential benefits could not be captured in the model because of the lack of evidence.

Modelling of scheduled visits

3.22 The base case modelled 2 scheduled visits per year, in the intervention and

comparator arms. In clinical practice, people who have stable heart failure would likely only have 1 scheduled visit per year. Other people may also only have 1 visit because of capacity issues. The EAG modelled 2 additional different scenarios for the intervention arms: no scheduled follow-up visits per year and 1 scheduled follow-up visit per year. These scenario analyses did not impact the direction of the model results.

Modelling of unscheduled visits

3.23 In the EAG's base-case model it was assumed that all alerts are reviewed and followed by an unscheduled, in-person follow-up visit. In practice, alerts may be followed by an initial remote interaction (such as a phone call) to determine whether an in-person visit is necessary. Scenarios were modelled in which it was assumed that 25% and 50% of alerts initially require non-face-to-face follow up. The committee agreed that the base-case scenario and scenario analyses were reasonable. Scenarios were also done in which the base-case number of interactions in the intervention arm was doubled and quadrupled. The committee agreed that this assumption was reasonable. This was because the overall number of interactions is likely to be increased in the heart failure algorithm arm because of healthcare professionals reviewing alerts and following up with people remotely or in-person. Unscheduled emergency visits to an emergency department or primary care settings were not modelled. The committee noted that the number of emergency visits is expected to be lower for people with heart failure algorithms because alerts are intended to be triggered before the person experiences symptoms.

More data is needed on people without a diagnosis of heart failure

3.24 There was very limited evidence in people who have a CIED and do not have a diagnosis of heart failure but are at high risk of new onset acute heart failure. One study for TriageHF reported that a proportion of people in the cohort did not have a prior diagnosis of heart failure. But results were not reported separately for each population and so could not be used by the EAG to model the population of people at risk of heart failure. The committee agreed that data is needed on the

prognostic accuracy and clinical impact of using heart failure algorithms in this population.

Collection of registry data

3.25 The committee noted that the evidence available for HeartLogic and TriageHF suggests that they can accurately detect the signs of worsening heart failure that could lead to hospitalisation or an unscheduled clinic event. The evidence also suggests that HeartLogic and TriageHF can reduce the number of heart failure events compared with conventional remote monitoring. But there are some concerns about the quality of the evidence for these algorithms and the size of the effects that could be seen.

3.26 To confirm the extent of the benefit seen in the studies, companies should work with the NHS to collect registry data for HeartLogic and TriageHF on:

- hospitalisation rates
- heart-failure-related mortality rates
- rates of emergency department or primary care visits
- patient-reported outcomes.

Equalities

Heart failure algorithms could reduce inequalities

3.27 Algorithm-based remote monitoring systems are ideally positioned to reduce inequalities in access to healthcare. The committee heard that many people, particularly those from ethnic minority groups and lower socioeconomic backgrounds, do not seek medical assistance until they need to attend emergency services. Heart failure algorithms could benefit these people, because signs of decompensation would be detected and healthcare professionals automatically alerted, before the person needs to seek emergency

assistance. For this reason, people who are unable to advocate for themselves or who have less awareness of their symptoms would also benefit from heart failure algorithms. Algorithm-based remote monitoring could also benefit people who are less mobile or people who live in remote areas. This is because following an alert, initial follow up may be a phone call to determine if an in-person follow up is necessary. This will reduce the need for unnecessary travel to hospital appointments.

Digital inclusion

3.28 Apart from the technologies that can use a landline to send data, access to technologies for remote monitoring may be restricted in some populations because of internet requirements. This may mean that older people, people from lower socioeconomic groups and people in rural areas could be less able to use algorithm-based remote monitoring because they do not have access to a Wi-Fi connection. The committee noted that the technology is incorporated into the person's CIED and does not need the person to engage directly with the technology themselves.

People may feel confined to their home to ensure their data is transmitted

3.29 All of the algorithms can transmit data using Wi-Fi, and some using a landline connection. If people are not in range of a connection, their data will not be transmitted until they are in range. This may cause anxiety for some people when leaving their home, because they do not want to risk transmission of an important alert being missed or delayed.

Ensuring equitable access to heart failure algorithms

3.30 The committee discussed that for heart failure algorithms to be used effectively in clinical practice, they should be used as part of a multidisciplinary specialist heart failure service and specialist staff should be available to review and action alerts. Protocols should also be in place to ensure heart failure is properly

managed and alerts are responded to in a timely manner. At present, the way centres manage heart failure and respond to alerts can vary. This could mean that some centres are unable to implement heart failure algorithms into their services, which could lead to inequity of access across the country. Specialist committee members indicated that directives and initiatives are in place to steer heart failure services in the right direction for providing equitable access. Protocols should detail how heart failure alerts fit within the clinical pathway and how they should be responded to.

4 Implementation

NICE intends to develop tools, in association with relevant stakeholders, to help organisations put this guidance into practice.

In addition NICE will support this guidance through a range of activities to promote the recommendations for further research. NICE will also incorporate the recommendations for research in sections 1.2 to 1.4 into its guidance research recommendations database and highlight these recommendations to public research bodies.

5 Diagnostics advisory committee members and NICE project team

Committee members

This topic was considered by the diagnostics advisory committee, which is a standing advisory committee of NICE.

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

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

Additional specialist committee members took part in the discussions for this topic:

Specialist committee members

Alastair Gray
Consultant cardiologist, Southern Health and Social Care Trust

Alison Seed
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Andy Smith
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Rushabh Shah
GP partner and GP with extended roles in cardiology, Radford Medical Practice

NICE project team

Each diagnostics evaluation is assigned to a team consisting of a technical analyst (who acts as the topic lead), a technical adviser and a project manager.

Sophie Harrison
Topic lead

Frances Nixon
Technical adviser

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Update information

Minor changes since publication

December 2025: Diagnostics guidance 61 has been migrated to HealthTech guidance 730. The recommendations and accompanying content remain unchanged.

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