NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

DIAGNOSTICS ASSESSMENT PROGRAMME

Draft guidance

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

The National Institute for Health and Care Excellence (NICE) is producing guidance on using algorithm-based remote monitoring of heart failure data in people with cardiac implantable electronic devices in the NHS in England. The diagnostics advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from registered stakeholders, healthcare professionals and the public. This document should be read along with the evidence (the external assessment report and the external assessment report addendum).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound, and a suitable basis for guidance to the NHS?

Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the recommendations may need changing to meet these aims. In particular, please tell us if the recommendations:

- could have a different effect on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology
- could have any adverse effect on people with a particular disability or disabilities.

Please provide any relevant information or data you have about such effects and how they could be avoided or reduced.

Note that this document is not NICE's final guidance on algorithm-based remote monitoring of heart failure data in people with cardiac implantable electronic devices. The recommendations in section 1 may change after consultation.

After consultation, the committee will meet again to consider the evidence, this document and comments from the consultation. After considering the comments, the committee will prepare its final recommendations, which will be the basis for NICE's guidance on the use of the technology in the NHS in England.

For further details, see NICE health technology evaluations: the manual.

Key dates:

Closing date for comments: 4 June 2024

Second diagnostics advisory committee meeting: 19 June 2024

1 Recommendations

Can only be used in research

1.1 More research is needed on 3 technologies for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have or are at risk of developing heart failure, before they can be routinely used in the NHS. The technologies are:

- HeartInsight
- HeartLogic
- TriageHF.

1.2 Access to the technology should be through company, research or non-core NHS funding, and clinical or financial risks should be appropriately managed.

1.3 This recommendation is not intended to affect monitoring with HeartInsight, HeartLogic or TriageHF that was started in the NHS before this draft guidance was published. People using these algorithms outside this recommendation may continue until they and their healthcare professional consider it appropriate to stop.

More research

1.4 More 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.

Should not be used

1.5 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

People who have or are at risk of developing heart failure can be offered CIEDs, which healthcare professionals can use to remotely monitor the person's heart function. CIEDs can also be used with algorithm-based remote monitoring, which automatically detects the early signs of worsening heart failure and sends an alert to a healthcare professional.

Evidence from accuracy studies for HeartLogic and TriageHF suggests that they may be able to predict the signs of worsening heart failure that could lead to hospitalisation or an unscheduled clinic visit (referred to as heart failure events). But this is uncertain because the studies have a high risk of bias (producing uncertain results because of the study's design) because of small numbers of people in the studies or a lack of controlling for other factors that could affect the results. There is also a lot of variation in the accuracy results. There are some concerns about risk of bias with the evidence showing how well CIEDs used with HeartLogic or TriageHF reduce heart failure events compared with CIEDs used with remote monitoring only. The key comparative study for HeartLogic has problems with the analysis and small participant numbers, and the key comparative study for TriageHF is unpublished and has some information missing on how the study was done.

Evidence for the HeartInsight algorithm suggests that it may fail to predict some early signs of worsening heart failure. But this is uncertain because the evidence comes from a single trial in a small number of people. There is also no evidence to show how well CIEDs that use HeartInsight reduce heart failure events compared with those that are only used with remote monitoring.

Because of the uncertainties in the evidence, HeartLogic, TriageHF and HeartInsight cannot be recommended for routine use in the NHS. But, they may be better at

predicting worsening heart failure and reducing hospitalisations than CIEDs without algorithms, so more research is recommended.

Clinical trial evidence suggests that CorVue fails to predict 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 Predictive 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 the age of 65, with an average age of 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. CIEDs may also be used to monitor symptoms. 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 be reviewed 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 receive 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.

CorVue and Merlin.net patient care network (Abbott Medical)

2.5 The CorVue algorithm and Merlin.net patient care network (PCN) platform are 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 technology and an internet or mobile network connection

to generate an alert. Or a remote monitoring unit (Merlin@Home), connected via Wi-Fi, mobile or landline connection, can be provided by the company instead of using the app-based smartphone transmitter. Healthcare professionals can view the data transmitted by the algorithm and 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 measurements taken daily). 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 and BIOTRONIK home monitoring system (Biotronik)

2.7 The BIOTRONIK Home Monitoring system and HeartInsight algorithm are intended for monitoring cardiac function in people who have compatible CIEDs. 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, with an optional additional baseline rate parameter.

HeartInsight triggers an alert to healthcare professionals (via text message, email or both) once the threshold is exceeded for 3 consecutive days, indicating higher risk of worsening heart failure.

2.8 The system includes the handheld CardioMessenger device, which transmits data from the implanted cardiac device to the BIOTRONIK home monitoring system via a mobile phone network. The system has an integrated HeartInsight algorithm to identify people with a higher risk of decompensation and predict heart failure hospitalisations. Access to HeartInsight and BIOTRONIK Home Monitoring has a one-off cost of £450 per person.

2.9 The system is set to raise an alert to healthcare professionals according to customised parameters and the reports use a traffic-light system for prioritising alerts. Information collected by HeartInsight can be accessed and reviewed by healthcare professionals on the BIOTRONIK HMSC web platform.

HeartLogic and Latitude NXT patient management system (Boston Scientific)

2.10 HeartLogic is a diagnostic algorithm designed to monitor people with compatible CIEDs for early signs of worsening heart failure. 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 and LATITUDE NXT Heart Failure Management System has a one-off cost of £3,650 per person, but discounts may be offered based on purchase volume.

TriageHF and CareLink remote monitoring (TriageHF Plus; Medtronic).

2.11 TriageHF Plus is a monitoring system for identifying and managing an increased risk of heart failure or worsening heart failure in people with CIEDs. TriageHF is an alert-based algorithm that is hosted on the Medtronic CareLink network platform for collaborative patient management between clinical teams. The following parameters factor into the algorithm:

- 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 patient 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 data 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 The patient expert explained that CIEDs provide a sense of security in knowing 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 may provide further reassurance to people because they know that alerts are transmitted automatically and reviewed by a healthcare professional, potentially before they experience symptoms. But, false-positive alerts (when an alert is triggered but there are no signs of decompensation) could cause people unnecessary anxiety. The committee recommended more research on people's experiences with having heart failure algorithms activated on their CIEDs.

Clinical effectiveness

Prognostic accuracy

3.2 The committee noted that the heart failure algorithms needed to be considered independently of each other because they are each unique, leading to different alert rates and different 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.

3.3 Prognostic accuracy studies for CorVue reported low to adequate sensitivity (range = 20% to 68%). 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 so that people with early signs of a heart failure event can be identified, assessed and treated if necessary and so people are not

missed. False positives were also considered to be high in all studies reporting this outcome and all studies were assessed as having a high risk of bias because of small numbers of people included. The committee concluded that CorVue cannot accurately predict heart failure events.

3.4 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 assessed as having a high risk of bias because of concerns about missing data and confounding. The committee concluded that it is uncertain whether HeartInsight can accurately predict heart failure events.

3.5 The studies reporting prognostic accuracy data for HeartLogic show adequate to high sensitivity (range = 66% to 100%) and specificity (range = 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 as having a high risk of bias because of a lack of robust analysis, and small number of people in the studies. The committee concluded that while there is a stronger evidence base for the prognostic accuracy of HeartLogic than some of the other heart failure algorithms, it is uncertain whether HeartLogic can accurately predict heart failure events.

3.6 For TriageHF, sensitivity (range = 37.4% to 87.9%) and specificity (range = 44.4% to 90.2%) showed considerable variability. The committee noted that some of this variability was due to differences in the timeframes of the reporting and different outcome measures used to determine the

prognostic accuracy. The false-positive rate was reported in 1 study and was considered to be low. All studies reporting prognostic accuracy data have a high risk of bias, for reasons including missing information and a lack of controlling for confounding factors in the statistical analysis. Specifically, age, sex, New York Heart Association Functional classification, smoking status and other comorbidities. The committee concluded that while there is a stronger evidence base for the prognostic accuracy of TriageHF than some of the other heart failure algorithms, it is uncertain whether TriageHF can accurately predict heart failure events.

False-positive alerts

3.7 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. Some studies reported high rates of false-positive alert. 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. But, false positive alerts may cause people unnecessary anxiety (see section 3.1). The committee concluded that more research should be done on the rate of false positive alerts.

Intermediate and clinical outcomes

3.8 Some studies compared CIEDs that use heart failure algorithms with CIEDs that do not, to assess whether heart failure algorithms reduce heart failure events.

CorVue

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

HeartInsight

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

HeartLogic

3.11 There was evidence to suggest a statistically significant reduction in hospitalisations, heart failure events, length of hospital stay and emergency or urgent care visits with the HeartLogic algorithm compared with conventional remote monitoring. Many of the studies reporting comparative evidence were assessed as having a serious or critical risk of bias. This was caused by a lack of robust analysis to control for confounding and small participant numbers. The committee concluded that while evidence for HeartLogic is promising, it is uncertain whether using HeartLogic can reduce heart failure events compared with no algorithm use.

TriageHF

3.12 For TriageHF, comparative evidence was limited to 1 study (Ahmed et al., unpublished), which was unpublished at the time of the review. This study reported a statistically significant reduced rate of hospitalisation with use of the TriageHF compared with no algorithm use. But the study was assessed as having a critical risk of bias because of missing information,

including whether propensity score matching was successful, and the majority of hospitalisations being unrelated to heart failure or cardiovascular disease. The committee concluded that the comparative evidence for TriageHF was limited and it is uncertain whether use of TriageHF can reduce heart failure events compared with no algorithm use.

Failure rates

3.13 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 in-built 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, as systems are in place to manage and resolve this.

Cost effectiveness

A pairwise analysis approach was used

3.14 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 external assessment group (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

3.15 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

3.16 The EAG's economic model showed that HeartLogic and TriageHF were more effective and less costly than standard care. Probabilistic sensitivity 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 uncertainty around intervention costs and mortality were included in the probabilistic sensitivity analysis, and it would like to see an analysis done where these inputs are fixed.

Cost-effectiveness estimates are driven by hospitalisation rates

3.17 The studies providing comparative hospitalisation data for HeartLogic (Treskes et al. 2021) and TriageHF (Ahmed et al., unpublished) included 68 people and 758 people respectively. The committee considered these sample sizes to be small relative to the number of people living with, or at risk of, heart failure. So the committee raised concerns regarding the statistical power of these studies to detect the effects of heart failure algorithms. The key study for TriageHF (Ahmed et al., unpublished) was an unpublished manuscript at the time that the EAG reviewed it. The committee noted that Ahmed et al. (unpublished) and Treskes (2021) are not randomised studies. The committee concluded that there are concerns about using data from these studies to inform model inputs, and so the cost-effectiveness estimates are uncertain. The committee would like to see data from high quality controlled studies that are statistically powered to detect the effects of heart failure algorithms compared with no algorithm use.

3.18 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 base-case model assumption was made of no difference in hospitalisations between CorVue and HeartInsight and their comparators. In the base-case model, CorVue and HeartInsight were more costly than standard care and were equally as effective. Threshold analysis showed that only a small reduction in hospitalisations would make these heart failure algorithms cost-effective.

Potential uncaptured benefits

3.19 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 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 quality-adjusted life years. These potential benefits could not be captured in the model because of the lack of evidence.

Modelling of scheduled visits

3.20 The base case modelled 2 scheduled visits per year, in both the intervention and comparator arm. 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: 0 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

3.21 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.

3.22 Additionally, scenarios have been conducted in which the base-case number of interactions in the intervention arm is doubled and quadrupled. The committee agreed that this assumption is reasonable, because the overall number of interactions is likely to be increased in the heart failure algorithm arm due to clinicians 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 as alerts are intended to be triggered even before the person experiences symptoms.

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

3.23 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.

Equalities

Reduced need for in-person appointments

3.24 Wider availability of 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).

Digital exclusion

3.25 Apart from the technologies that can use a landline to send data, access to technologies for remote monitoring may be restricted in some populations due to internet or smart phone requirements. This may mean that older people and people in rural areas or areas that are more deprived could be less able to use algorithm-based remote monitoring because they do not have access to a Wi-Fi connection or smartphone.

Heart failure algorithms should be used as part of a clear pathway

3.26 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. The committee discussed that for heart failure algorithms to be used effectively in clinical practice, adequate staffing and protocols should be in place to ensure heart failure is properly managed and alerts are responded to in a timely manner. Protocols should detail how heart failure alerts fit within the clinical pathway and how they should be responded to.

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

3.27 All of the algorithms can transmit data using Wi-Fi, and some using a landline connection. If people are not within range of connectivity, their data will not be transmitted until they are back within 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 access to non-English speakers

3.28 The committee considered whether use of heart failure algorithms and downstream management of heart failure would be accessible to people who do not have English as a first language. For these people, translators can be available during in-person appointments. Alerts may be followed by an initial remote interaction (such as a phone call), which may cause accessibility issues if a translator is not available.

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 research recommendations in section 4 into its guidance research recommendations database and highlight these recommendations to public research bodies.

5 Review

NICE will regularly monitor its published technology guidance to check for any new evidence or information that could affect the recommendations. Guidance will not have a fixed review date.

Brian Shine

Chair, diagnostics advisory committee

May 2024

6 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

Consultant cardiologist, Lancashire Cardiac Centre, Blackpool Victoria Hospital

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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

Toni Gasse

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ISBN: