NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Assessment Programme

Algorithm-based remote monitoring of heart failure risk data in people with cardiac implantable electronic devices

Final scope

May 2023

1 Introduction

The TriageHF Plus is manufactured by Medtronic. The topic selection oversight panel selected and routed the TriageHF Plus for guidance development by the Diagnostics Assessment Programme based on a NICE medtech innovation briefing on the TriageHF Plus for remote monitoring of heart failure risk in people with cardiac implantable electronic devices published in May 2022. The scope of this diagnostics assessment will focus on the use of algorithm-based remote monitoring technologies which passively monitor heart metrics and raise an alert of signs of heart failure as well as worsening heart failure to health professionals.

The final scope was informed by discussions at the scoping workshop held on 3 May 2023 and assessment sub-group meeting held on 17 May 2023. A glossary of terms is provided in appendix A.

2 Description of the technologies

This section describes the properties of the diagnostic technologies based on information provided to NICE by manufacturers and experts, and information available in the public domain. NICE has not carried out an independent evaluation of this description.

2.1 Purpose of the medical technologies

Cardiac implantable electronic devices (CIED) are recommended as treatment options for specific people who have or are at high risk of heart failure. These devices include some pacemakers, implantable cardiac defibrillators (ICDs) or cardiac resynchronization therapy (CRT) devices. Monitoring is recommended for people who have CIEDs. As a minimum, monitoring currently includes a clinical assessment, a review of medication, and renal function assessments (see section 3.3). The frequency of the reviews varies according to the person's condition. Clinical experts highlighted that there is a lot of variation in current standard of care, and sometimes reviews are only triggered if worsening symptoms are reported by the person with the CIED.

Algorithm-based remote monitoring systems capable of identifying new onset acute heart failure or worsening signs of heart failure (decompensation) captured by CIEDs, could help clinicians identify people who need a review. When used within a monitoring pathway alongside standard care, passive monitoring of data from CIEDs could enable earlier identification of people at risk of acute heart failure or worsening heart failure and ensure earlier access to interventions. This could help to prevent symptoms occurring or worsening, reducing cardiac events, improving health outcomes and resulting in fewer hospitalisations. Remote monitoring could also reduce the number of unnecessary follow-up appointments or face-to-face reviews, freeing up NHS resources, and travel, stress and anxiety for people with CIEDs.

2.2 Product properties

Remote monitoring systems for implanted cardiac devices are only compatible with specific devices manufactured by the same company. The technologies suggested for the assessment are systems that remotely monitor physiological parameters measured by an implanted cardiac device, and generate an alert to notify healthcare professionals when heart failure metrics worsen. All technologies are intended for use with a single person with an implanted device, none are reprogrammable for use with another person. All systems require an internet connection for clinicians to access their relevant data management platforms. The essential criteria identified for technologies to be included in the final scope are listed below:

- intended for use in people with an implanted cardiac device
- available in the UK
- holds a CE-mark

The identified technologies are summarised in table 1.

Table 1 Product properties

Algorithm-based remote monitoring system	Manufacturer	Components	Compatible CIEDs
CorVue and Merlin.net Patient Care Network	Abbott Medical	• CorVue algorithm (integrated within CIED) • Transmitter mobile app (myMerlinPulse) or remote monitoring unit (Merlin@Home) if app-based smartphone transmitter not used • Management system (Merlin.net PCN platform)	Abbott devices: Gallant Single Chamber ICD, Gallant Dual Chamber ICD, Gallant HF, Quadra Allure MP CRT-P Pacemaker, Quadra Assura MP CRT-D, Ellipse Single, Chamber ICD, Ellipse Dual Chamber ICD, Fortify Assura Single Chamber ICD, Fortify Assura Dual Chamber ICD, Unify Assura CRT-D, Assurity Dual Chamber PPM, Assurity Single Chamber PPM
HeartInsight and BIOTRONIK Home Monitoring	Biotronik	• Management system (BIOTRONIK Home Monitoring Service Centre) • HeartInsight algorithm (integrated within management system) • Transmitter (CardioMessenger) • Optional BIOTRONIK mobile app	BIOTRONIK heart devices: Acticor/Rivacor, Ilivia Neo/Intica Neo, Ilivia/Intica /Inlexa -5 and -7 series ICD DX/DC and CRT-D
HeartLogic and LATITUDE NXT Heart Failure	Boston Scientific	• Transmitter (LATITUDE) • HeartLogic algorithm (integrated within the CIED) • LATITUDE NXT Patient Management system	Boston Scientific devices: Perciva, Momentum EL, Resonate EL, Vigilant EL, and CRT-Ds: Resonate X4, Vigilant

Management system		• Optional MyLATITUDE mobile app	X4, Momentum X4 and Momentum
TriageHF and CareLink remote monitoring (TriageHF Plus)	Medtronic	• TriageHF risk algorithm (integrated within CIED) • CareLink monitoring platform • Optional MyCareLink heart mobile app	Medtronic CIEDs with OptiVol measurement capability

CIED: cardiac implantable electronic device, App: application,

2.2.1 CorVue and Merlin.net patient care network - Abbott Medical

The CorVue algorithm and Merlin.net patient care network (PCN) platform are intended for the remote monitoring of early signs of heart failure in people who have compatible implanted devices. The CorVue algorithm is integrated with the implanted device and has Active Implantable Medical Devices (AIMD) classification.

The CorVue algorithm collects intrathoracic impedance (ITI) data from the implanted device and transmits to the Merlin.net PCN platform via the mobile app (myMerlinPulse) using Bluetooth technology and an internet or mobile network connection to generate an alert. Alternatively, a remote monitoring unit (Merlin@Home) connected via wifi, 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.

The CorVue algorithm automatically calculates the mean daily impedance (from 12 measurements taken daily) and collects reference impedance data based on the previous 12-14 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. Any medical condition that causes ITI to decrease (for example, a chest infection) may create a false positive. CorVue is suitable for people who have a CIED and congestive heart failure with ventricular dyssynchrony.

2.2.2 HeartInsight and BIOTRONIK Home Monitoring system - Biotronik

The BIOTRONIK Home Monitoring system (HMSC) and HeartInsight algorithm are intended for the prediction of worsening heart failure in people with chronic heart failure who have compatible implantable devices. It is indicated for heart failure patients with NYHA Class II or III. The HeartInsight algorithm is integrated within the HMSC and has a Class III CE-mark.

The system includes a handheld CardioMessenger transmitter device which transmits data daily from the implanted cardiac device to the BIOTRONIK HMSC via a mobile phone network. The BIOTRONIK HMSC receives and analyses the data using the integrated HeartInsight algorithm to identify people with a higher risk of decompensation and predict heart failure hospitalisations.

The HeartInsight algorithm combines 7 parameters into 1 composite score (calculated daily): atrial burden, heart rate variability, mean heart rate, heart rate at rest, general activity, thoracic impedance, and premature ventricular contractions, with an optional additional baseline rate parameter. HeartInsight triggers an alert to healthcare professionals (via text message and/or email) once the threshold is exceeded for three consecutive values (days), indicating higher risk of worsening heart failure. The system is set to raise an alert to health 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 website platform.

Following an alert, the person is automatically sent a Heart Failure Screening Questionnaire (HFQ) via the BIOTRONIK Patient App to report any relevant behaviours and symptoms. The BIOTRONIK Patient App is an optional tool to use as an electronic symptom diary or self-monitoring device information. The app is free of charge and can be downloaded to the person’s smartphone.

There are no known contraindications with its use, however HeartInsight is not recommended in patients without or with a deactivated atrial lead and permanent atrial fibrillation. It is also not recommended in patients with insufficient mobile network coverage or the inability to use BIOTRONIK Home Monitoring.

2.2.3 HeartLogic and LATITUDE NXT Heart Failure Management system - Boston Scientific

The HeartLogic algorithm and LATITUDE NXT Heart Failure Management system are intended for remote monitoring of worsening of heart failure in people who have a compatible implanted devices. The HeartLogic algorithm is integrated within the implanted device and has a Class III implantable CE-mark.

The LATITUDE NXT Heart Failure Management system includes a wireless LATITUDE transmitter and optional weighing scales and a blood pressure monitor. The LATITUDE NXT system is further described in the NICE Medtech innovation briefing MIB67, published in 2016. HeartLogic is currently in use in 13 NHS Trusts.

Measurements including heart sounds, thoracic impedance, respiration, heart rate and activity are collected by the implanted device, which the HeartLogic algorithm combines into 1 composite index that indicates decompensation. The data is transferred from the CIED to the LATITUDE NXT patient management system via the LATITUDE transmitter. The system has daily data transfers to the clinical team. The transmitter can use a mobile phone connection, an internet connection or a landline connection to relay the data. The system is configured to send an alert to health professional when the index is over a set threshold (customisable by the clinician). Health professionals need to log on to the LATITUDE NXT website to receive alerts. Secondary notification of alerts may be through email or text message.

2.2.4 TriageHF and CareLink remote monitoring (Triage HF Plus) - Medtronic

TriageHF Plus is intended for remote monitoring and managing the increased risk of heart failure or worsening heart failure in people with Medtronic compatible CIED devices. The TriageHF algorithm is integrated within the implanted device and has Active Implantable Medical Devices (AIMD) classification, Annex 2 (4).

TriageHF is an alert-based algorithm that is hosted on the Medtronic CareLink network platform for collaborative patient management between clinical teams. 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 by patients if they perceive symptoms, automatically based on TriageHF algorithm alert triggers, or through a 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) 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 TriageHF algorithm uses physiological parameters measured by the CIED (compatible Medtronic devices that monitor the OptiVol Fluid Status [thoracic impedance over time]) to create a hospitalisation risk score. The following parameters factor into the algorithm: atrial tachycardia (AT) or atrial fibrillation (AF) burden, ventricular rate during AT or AF, 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.

The CareLink network sends an alert for people who have high risk score so that they are contacted for a telephone consultation with a heart failure nurse. A set of standardised questions are used to distinguish between worsening heart failure and other issues. Healthcare professionals can also be notified of alerts via text messaging or email. The manual states that there are no known contraindications for the use of TriageHF Plus. The TriageHF Plus care pathway is currently in use in 12 NHS Trusts, of which over 80% already have the CareLink platform installed.

3 Target conditions

3.1 Heart failure

Heart failure is a clinical syndrome caused by any structural or functional cardiac disorder that impairs the heart's ability to function efficiently and 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). The European Society of Cardiology (ESC) guidelines for the diagnosis and treatment of acute and chronic heart failure highlight that atrial fibrillation and heart failure frequently coexist, and they can cause or exacerbate each other.

Heart failure may present as acute or chronic, depending on whether a person has an established diagnosis of heart failure and speed of symptom onset. Acute heart failure may be the first occurrence of heart failure in people without a heart failure diagnosis (new onset) or, more frequently, be in people with a chronic heart failure diagnosis who experience sudden deterioration in heart function and worsening of symptoms, which is known as acute decompensated heart failure.

The British Heart Foundation website explains that heart failure can be grouped into different categories depending on the strength of the heart, that is, the left ventricular ejection fraction (LVEF), which is the amount of blood squeezed out of the main chamber of the heart with every beat. Depending on the percentage ejection fraction (where 50% or greater is considered normal), heart failure may be classed as the following:

- HFpEF - heart failure with preserved ejection fraction (over 50%)
- HFmrEF - heart failure with mildly reduced ejection fraction (between 40% and 49%)
- HFrEF – heart failure with reduced ejection fraction (below 40%)

Heart failure may also be grouped by symptom severity and limitation of physical activity according to the New York Heart Association (NYHA) functional classification of heart failure, ranging from class I (no limitations) to class IV (inability to carry out any physical activity without discomfort and symptoms which may be present at rest).

Heart failure mainly affects people over the age of 65, with an average age of diagnosis of 77, and risk increases significantly with age. Around 1 in 35 people aged 65–74 years have heart failure, which increases to 1 in 15 of people aged 75–

84 years, and to just over 1 in 7 people of those aged 85 years and above (NICE 2018).

Around 920,000 people in the UK were living with heart failure in 2018 with an estimated 200,000 new diagnoses each year (NHS England 2022). The incidence of heart failure in the UK is 140 per 100,000 men and 120 per 100,000 women (NICE TA314). The prevalence of heart failure is increasing over time because of population ageing and a rise in the prevalence of associated comorbidities.

Heart failure has a poor prognosis - estimates of 1-year mortality vary, but a long term registry of people with heart failure found a mortality rate of 23.6% for people with acute heart failure and 6.4% for those with chronic heart failure across Europe (Crespo-Lairo, 2016). A UK-based population study conducted between 2000 and 2017 found that patients diagnosed with heart failure had a 1 year survival rate of 81%, 5-year survival of 48% and 10-year survival of 26% (Taylor, 2019).

Heart failure accounts for a total of 1 million inpatient bed days – 2% of all NHS inpatient bed-days – and 5% of all emergency medical admissions to hospital. The figures from NHS Hospital Episode Statistics indicate that there were 98,884 hospital admissions for heart failure in 2021/22 compared with 86,474 in 2018/19. This is at significant cost to the NHS – a 2016 All Party Parliamentary Group report on heart failure found that the condition costs the NHS around £2 billion per year, or approximately 2% of the total NHS budget (All-Party Parliamentary Group report published in 2016).

3.2 Diagnostic and care pathway

3.2.1 Diagnosis, assessment and management of acute heart failure

Acute heart failure can present as acute decompensation of chronic heart failure or as new-onset heart failure. For the diagnosis, assessment and monitoring of acute heart failure, the NICE guidelines for acute heart failure recommend taking a clinical history, performing a clinical examination and doing testing in line with NICE guidelines for diagnosis and management of chronic heart failure in adults. Testing for serum natriuretic peptide levels should be offered to people who are suspected to have acute heart failure. People with raised peptide levels should be offered a

transthoracic Doppler 2D echocardiography within 48 hours of admission to establish the presence or absence of cardiac abnormalities.

3.2.2 Assessing and monitoring chronic heart failure

The NICE guidelines for diagnosis and management of chronic heart failure in adults recommend that monitoring of people with chronic heart failure should include a clinical assessment of functional capacity, fluid status, cardiac rhythm (minimum of examining the pulse), cognitive status and nutritional status, a review of medication, and an assessment of renal function. Clinical experts highlighted that in practice a combination of the ESC guidelines and the NICE guidelines are followed in the NHS. The ESC guidelines add that heart failure management may involve in person service models or home-based telemonitoring, and that the COVID-19 pandemic has highlighted some of the potential advantage of the latter. While care is usually followed up by heart failure clinics, suitable patients may be followed up by community heart failure nurses or a GP with a special interest in heart failure. Clinical experts emphasised that there is no standard heart failure service model and current practice is highly varied.

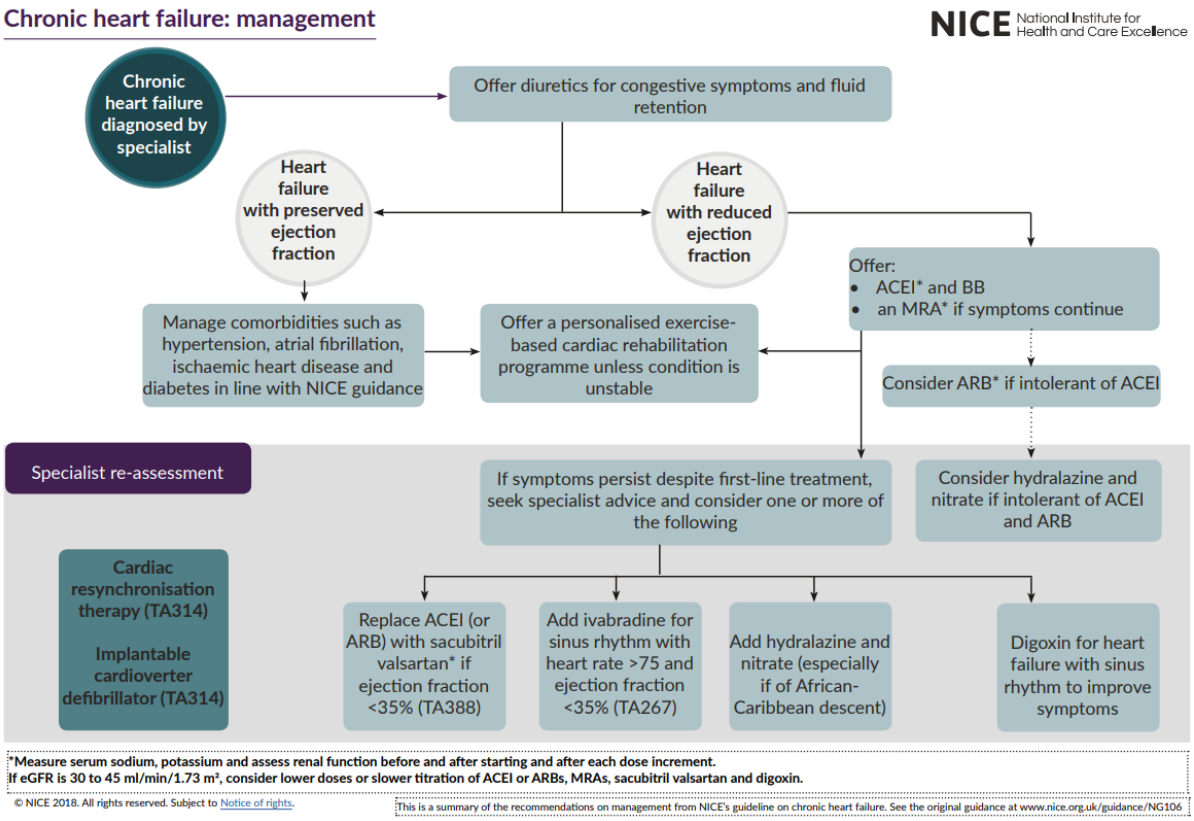
People should have additional monitoring if they have comorbidities, are taking co-prescribed medications or if their condition has deteriorated since their last review. The frequency of monitoring is dependent on the clinical status and stability of the person's condition. For people whose condition is unstable monitoring may be offered as frequently as every few days, up to every 2 weeks. NICE guidelines for diagnosis and management of chronic heart failure in adults recommend 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 whilst some people with a stable condition may not have a review at all. Early follow up visits are recommended at 1 to 2 weeks following hospital discharge to assess signs of congestion and drug tolerance. Levels of serum natriuretic peptide may be monitored as a surrogate biomarker for heart failure in people under 75 who have heart failure with reduced ejection fraction and an estimated glomerular filtration rate above 60 ml per minute per 1.73 m^2.

Signs of heart failure can also be monitored using CIEDs, some of which may also deliver a therapeutic intervention (such as pacemakers, implantable cardioverter defibrillators (ICDs), and cardiac resynchronisation therapy (CRT) devices), whilst others only monitor metrics over time.

3.2.3 Treatments for chronic heart failure

NICE guidelines for diagnosis and management of chronic heart failure in adults recommend the use of pharmacological treatments including routine use of diuretics for the relief of congestive symptoms, amiodarone and anticoagulants. People with heart failure should also be offered a personalised, exercise-based cardiac rehabilitation programme if their condition is stable and they are able.

Figure 1 NICE guidelines on chronic heart failure management



In the case of heart failure with reduced ejection fraction, the NICE guidelines for diagnosis and management of chronic heart failure in adults recommend that an angiotensin-converting enzyme (ACE) inhibitor, or angiotensin II receptor blockers (ARBs) licensed for heart failure if the person is intolerant to ACE inhibitors, should

be offered as a first line treatment in combination with a beta-blocker licensed for heart failure.

If people are continuing to experience symptoms, mineralocorticoid receptor antagonists (MRAs) may be used in addition to first line therapies. The ESC guidelines also recommend the use of sodium-glucose cotransporter-2 (SGLT2) inhibitors as a first line therapy in people with reduced ejection fraction. The NICE technology appraisal guidance on Dapagliflozin for treating chronic heart failure with reduced ejection fraction also supports the use of an SGLT2 inhibitor in these people, as an add-on to optimised standard care with:

- angiotensin-converting enzyme (ACE) inhibitors or angiotensin-2 receptor blockers (ARBs), with beta blockers, and, if tolerated, mineralocorticoid receptor antagonists (MRAs), or
- sacubitril valsartan, with beta blockers, and, if tolerated, MRAs.

The ESC guidelines states that intravenous iron supplementation with ferric carboxymaltose should be considered in symptomatic people with heart failure who have recently been hospitalised for heart failure, who have left ventricular ejection fraction below 50% and an iron deficiency to reduce the risk of heart failure hospitalisation.

A person should be referred to a specialist multidisciplinary heart failure team (where available) or cardiology service for specialist treatment if a person has:

- Severe heart failure (NYHA class IV).
- Heart failure that does not respond to treatment in primary care or can no longer be managed in the home setting.
- Heart failure resulting from valvular heart disease.
- Left ventricular ejection fraction of 35% or less.
- A NT pro-BNP level above 2000 ng/L (236 pmol/L). These people should be referred urgently for specialist assessment and transthoracic echocardiography within 2 weeks.

- A NT pro-BNP level between 400 and 2000 ng/L (47–236 pmol/L). These people should be referred to have specialist assessment and transthoracic echocardiography within 6 weeks.

Specialist pharmacological treatments for heart failure with reduced ejection fraction may include ivabradine, sacubitril valsartan, hydralazine in combination with nitrate and digoxin.

In people with both reduced ejection fraction and chronic kidney disease, lower doses of pharmacological treatments being offered should be considered. Specialist referral for transplantation should be considered for heart failure patients with severe refractory symptoms or refractory cardiogenic shock. People suitable for transplantation may also be offered a left ventricular assist device (LVAD) to support pumping of blood around the body either while waiting for a suitable transplant to become available or as a permanent intervention.

3.2.4 Devices for heart failure

As the condition becomes more severe, cardiac function and symptoms may no longer be controlled by pharmacological treatment alone. The NICE Technology appraisal TA314 recommends the use of implantable cardioverter defibrillators (ICDs), cardiac resynchronisation therapy (CRT) with defibrillator (CRT-D) or CRT with pacing (CRT-P) as treatment options for people with heart failure or people at risk of heart failure (people with previous serious ventricular arrhythmia). People with heart failure include those who have left ventricular dysfunction with a left ventricular ejection fraction of 35% or less (according to NYHA functional class, QRS duration and presence of left bundle branch block (LBBB) (see table 2)).

Table 2 Recommended cardiac implantable electronic devices for people with different symptoms and QRS intervals where LVEF is 35% or less

	NYHA classification of symptoms			
QRS interval	**I**	**II**	**III**	**IV**
<120 milliseconds	**ICD if there is a high risk of sudden cardiac death**			**ICD and CRT not clinically indicated**
120–149 milliseconds without LBBB	ICD	ICD	ICD	CRT-P
120–149 milliseconds with LBBB	ICD	CRT-D	CRT-P or CRT-D	CRT-P
≥150 milliseconds with or without LBBB	CRT-D	CRT-D	CRT-P or CRT-D	CRT-P

NYHA: New York heart association, ICD: Implantable cardiac device, CRT-P: Cardiac resynchronisation therapy with pacing, CRT-D: Cardiac resynchronisation therapy with defibrillation, LBBB: Left bundle branch block

A clinical expert highlighted that in some cases, people with heart failure with preserved ejection fraction would have been implanted with a pacemaker for traditional pacing (usually programmed to pace the heart only) indications.

3.2.5 Follow up of people with CIEDs

Clinical experts explained that people at risk of heart failure or worsening heart failure who have a CIED are usually managed in multiple clinics. For example, a heart failure clinic manages the medication review, and a cardiac physiologist led clinic manages the follow up of the CIED. The extent to which these services overlap varies between centres.

The British Heart Rhythm Society's (BHRS) clinical standards and guidelines for the follow up of CIEDs for cardiac rhythm management state that managing heart failure is a multidisciplinary process, and recommends that monitoring includes a regular technical review of device function, monitoring of symptoms, and management of

new and changing conditions. The guidelines also state that clear local protocols should be in place for suspected worsening heart failure.

The BHRS standards also state that although current practice includes periodic follow up, alert-based remote follow up should be considered as standard care for CIED patients, including those with pacemakers, and annual in-person follow up is not mandated for all CIED patients. However, device follow up may also include in person evaluation and can differ according to clinic policies, the capabilities and maintenance needs of the CIED, and patient needs or preferences. A clinical expert commented that most newer devices allow for remote monitoring, but older devices may require the patient to attend an in-person appointment so that data collected from the device may be downloaded.

3.2.6 Treatment for acute heart failure

The NICE guidelines for diagnosis and management of acute heart failure in adults recommend that people requiring immediate treatment for acute heart failure should be offered intravenous diuretic therapy, which should be started using a bolus or infusion strategy.

In cases where people have potentially reversible cardiogenic shock, inotropes or vasopressors may also be recommended if given in a cardiac care unit or high dependency unit or an alternative setting where at least level 2 care can be provided.

People with acute onset heart failure may also require ventilation. If a person has cardiogenic pulmonary oedema with severe dyspnoea and acidaemia consider starting non-invasive ventilation without delay, while invasive ventilation may be appropriate where heart failure is leading to or is complicated by either respiratory failure or reduced consciousness or physical exhaustion.

3.3 Patient issues and preferences

Heart failure is a long-term condition with no cure. People with the condition have many symptoms including breathlessness, fatigue and oedema which may make it difficult for them to attend hospital appointments. There is often anxiety associated with having the condition and this can impact on an individual's daily activities.

Experts highlighted that some technologies in the assessment could produce false-positive alerts, and this could lead to unnecessary contact with healthcare specialists, leading to increased patient anxiety. Alternatively, remote monitoring could reduce anxiety because people with CIEDs know that their condition is being closely monitored. This could provide reassurance when an individual's condition is stable and provide early warning signs when their condition worsens enabling them to modify lifestyle behaviours.

Objective monitoring of physiological metrics could help people who are unable to advocate for themselves, for example people with cognitive impairment who are less likely to recognise or describe their symptoms. Clinicians highlighted that the technologies could also help monitor the condition of people who are less likely to engage with the healthcare system.

Patient experts explained that having access to objective monitoring of data could also give people with CIEDs or their carers the confidence to request a clinical review appointment, especially if there are communication barriers.

Remote monitoring systems could predict the signs, symptoms and behaviours associated with worsening heart failure. This may enable earlier and more appropriate intervention potentially reducing hospital admissions and improving outcomes and quality of life. In addition, avoiding hospital admissions could reduce hospital acquired infections. Remote monitoring could reduce the number of face-to-face appointments and the potential stress and travel costs associated with these appointments.

4 Comparator

The current standard of care for monitoring heart failure for people who have CIEDs is periodic reviews of device function with a cardiac physiologist or cardiologist, and ad-hoc reviews of symptoms with a GP, specialist nurse, cardiologist or a heart failure team. The number and timing of the reviews varies depending on patient symptoms. Clinical experts explained that reviews can be over the telephone or in-person, and that they are most commonly triggered by self-reporting of worsening symptoms from the person with the CIED. The organisation of heart failure

monitoring pathways varies in practice between different trusts, and even between different hospitals.

5 Scope of the assessment

Table 3 Scope of the assessment

Decision question	Does algorithm-based remote monitoring of heart failure risk data in people with cardiac implantable electronic devices (CIEDs) represent a clinical and cost-effective use of NHS resources?
Populations	1. People who have a CIED and do not have a diagnosis of chronic heart failure but are at high risk of new onset acute heart failure If data allows, sub-analyses on the following subgroups should be included. People who: a) have a CRT-P device b) have a CRT-D device c) have an ICD device d) have a pacemaker device 2. People who have a CIED and have a diagnosis of chronic heart failure If data allows, sub-analyses on the following subgroups should be included. People who: a) have a CRT-P device b) have a CRT-D device c) have an ICD device d) have a pacemaker device e) have a diagnosis of heart failure New York Heart Association (NYHA) class I and II, or III and IV (at study recruitment) f) have a prior heart failure hospitalisation or urgent care visit within the last 12-months
Interventions	Algorithm-based remote monitoring systems for heart failure risk data in people with CIEDs (including Implantable cardioverter defibrillators [ICD] and Cardiac Resynchronization Therapy [CRT] devices): • CorVue and Merlin.net patient care network (Abbott Medical)

	• HeartInsight and BIOTRONIK home monitoring system (Biotronik) • HeartLogic and Latitude NXT heart failure management system (Boston Scientific) • TriageHF and CareLink remote monitoring (Triage HF Plus; Medtronic)
Comparator	Standard care for monitoring heart failure risk in people with CIEDs (see section 4)
Healthcare setting	Secondary care
Outcomes: intermediate measures	Intermediate measures for consideration may include: • Prognostic accuracy (including the number of false positive alerts) • Changes to clinical management (including non-pharmacological treatment and medications) • Time between an alert and a heart failure event • Alert response rates (including time between an alert, clinical review and change in clinical management) • Number of heart failure and all-cause hospitalisations • Number of emergency or urgent care visits • Length of hospital stay • Rate of software errors (including failed data transmissions) • Number of monitoring reviews (remote and face-to-face)
Outcomes: clinical	Clinical outcomes for consideration may include: • Rate of heart failure events • Rate and category of atrial fibrillation (subclinical, paroxysmal or persistent/permanent) • Morbidity (including adverse events from treatments) • Changes in NYHA classification of symptoms • Mortality (cardiac and all-cause mortality)
Outcomes: patient-reported	Patient-reported outcomes for consideration may include: • Health-related quality of life • Patient reported outcome measures such as satisfaction, anxiety and stress • Adherence to treatments (as agreed between the prescriber and the person taking the medication)

Outcomes: costs	Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include: • Costs of software and any downstream services necessary for using the device • Cost of care (including routine reviews, additional reviews and any further tests, treatment and hospitalisations [number and length] of stays, including those associated with adverse events) • Cost of staff time (including reviews, time spent reviewing data and time spent responding to the alerts) and any associated training
Measuring cost-effectiveness	The cost-effectiveness of interventions should be expressed in terms of incremental cost per quality-adjusted life year.
Time horizon	The time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.

6 Other issues for consideration

6.1 Sustainability

Use of remote monitoring systems could reduce the number of unnecessary hospital appointments, reducing travel for people with heart failure and reducing carbon emissions.

7 Potential 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.

The following potential equality issues are related to the condition:

- Heart failure can have a substantial and long-term adverse effect on a person's ability to carry out normal day to day activities. Therefore, people with the condition may be covered under the disability provision of the Equality Act (2010).

- Heart failure is more common in men, people who are over 65 years old and those in lower socio-economic groups.

The following potential equality issues are related to use of remote monitoring systems:

- Clinicians commented that people with heart failure who are no longer able to drive to hospital appointments may additionally benefit from remote monitoring.
- Access to technologies for remote monitoring may be restricted in some populations due to internet or smart phone requirements. This may mean that people in rural or lower socio-economic areas could be less able to adopt remote monitoring as they may not have access to a home Wi-Fi connection or a smartphone.
- NICE guidance on chronic heart failure (NG106) highlights that serum natriuretic peptide levels can be reduced in people who are obese, have an African or African–Caribbean family background, or people having treatment with diuretics, angiotensin-converting enzyme (ACE) inhibitors, beta-blockers, angiotensin II receptor blockers (ARBs) or mineralocorticoid receptor antagonists (MRAs). The guidance recommends that measuring serum natriuretic peptide should be considered as part of a treatment optimisation protocol only in a specialist care setting for specific people. Technologies may offer an added benefit to people for whom testing for the natriuretic peptide surrogate biomarker may not be well suited. Clinical experts highlighted that in practice these tests are rarely used.
- People with cognitive or physical impairment may require a carer to assist with using the transmitter hardware for these technologies.
- Wider availability of remote monitoring may also allow greater access to care for people who are less able to attend in-person appointments (due to costs associated with travel, poor public transport, time taken from work, physical impairments or anxiety).

8 Potential implementation issues

8.1 Restricted access

Clinical experts highlighted that eligibility for the new technology will vary between people, because of compatibility issues with older devices. They also noted that some technologies require access to the internet or mobile networks (such as 4G), which may restrict access for some people who live in rural areas. Appropriate IT infrastructure and phone services also need to be in place for both clinicians and people with CIEDs.

8.2 Capacity constraints

Experts have highlighted that chronic understaffing of heart failure services and recent increases in the number of heart failure patients may make implementation difficult. Experts have highlighted that this may create issues in terms of capacity such as responding to alerts and managing streams of data.

8.3 Informed consent

Patient and clinical experts highlighted that it is important to have informed consent from people using the technology as they need to understand what they are getting. This could improve uptake of the technology.

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Appendix A Glossary of terms

Arrythmia

Arrhythmias, also known as cardiac arrhythmias, heart arrhythmias, or dysrhythmias, are irregularities in the heartbeat, including when it is too fast or too slow.

Cardiac implantable electronic devices

Cardiac implantable electronic devices (CIEDs) are used to manage slow and fast heart rates, and in the treatment of selected patients with heart failure. CIEDs are usually implanted under the skin, with 1 to 3 leads threaded down a vein to connect to the heart. Types of CIED include permanent pacemakers, implantable cardioverter defibrillators, and cardiac resynchronisation therapy (CRT) devices.

Cardiac resynchronisation therapy

Cardiac resynchronisation therapy (CRT) is a treatment used to help the heart pump more effectively. It is recommended for some patients with poor ventricular function (when the heart is not pumping as well as it should). A CRT pacemaker (CRT-P) is used to treat heart failure when the two sides of the heart lose their coordination and become less efficient at pumping blood around the body. A CRT defibrillator (CRT-D) does the same as a CRT-P but has additional defibrillation therapy to correct abnormal heart rhythms.

Heart failure

Heart failure means that the heart is unable to pump blood around the body properly. It usually happens because the heart has become too weak or stiff.

Heart failure decompensation

Heart failure decompensation is the rapid worsening of symptoms and/or signs of heart failure that warrants immediate medical intervention. It typically includes difficulty breathing (dyspnoea), leg or feet swelling, and fatigue.

Implantable cardioverter defibrillator

An implantable cardioverter defibrillator (ICD) is a device implanted in the chest to detect and control irregular heart rhythms by sending electric shocks to the heart.

Pacemaker

A pacemaker sends electrical pulses to the heart to control the pace at which it beats. It consists of a pulse generator, which has a battery and a tiny computer circuit, and 1 or more wires known as pacing leads, which attach to the heart.

QRS

The QRS complex is the time taken for complex is the combination of 3 of the graphical deflections seen on a typical electrocardiogram. It reflects the depolarization of the right and left ventricles of the heart and contraction of the large ventricular muscles.