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Algorithm-based remote monitoring of heart failure risk data in people with cardiac implantable electronic devices: a systematic review and cost-effectiveness analysis

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Extended Research Article

Algorithm-based remote monitoring of heart failure risk data in people with cardiac implantable electronic devices: a systematic review and cost-effectiveness analysis

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This article

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Abstract

Background: 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. Function can also be monitored using cardiac implantable electronic devices, some of which may also deliver a therapeutic benefit (e.g. pacemakers), while others only monitor metrics over time.

Implantable devices can include algorithms that aim to predict the occurrence of a heart failure event. They are intended to be used alongside clinical judgement and make treatment decisions.

Objectives: To determine the clinical and cost-effectiveness of the four remote monitoring algorithms (CorVue, HeartInsight, HeartLogic and TriageHF) for detecting heart failure in people with cardiac implantable electronic devices.

Methods: We performed systematic reviews of clinical, cost-effectiveness, quality of life and cost outcomes. We searched MEDLINE and other sources of published and unpublished literature, including manufacturers' websites and Clinical Trials Registries between June and August 2023. For the clinical effectiveness review, study selection was completed by two independent reviewers at both title and abstract, and full-text screening stages. Data extraction and study quality appraisal were completed by a single reviewer and checked for accuracy by a second. Due to heterogeneity, no statistical analyses were performed, and a narrative synthesis was reported.

A de novo two-state Markov model (with alive and dead states) was used to estimate the cost-effectiveness of algorithm-based remote monitoring of heart failure risk data in people with cardiac implantable electronic devices over a lifetime.

Results: There was reasonable evidence to suggest HeartLogic and TriageHF can accurately predict heart failure events. CorVue's prognostic accuracy is less clear due to high heterogeneity in findings between studies. There was only a single published HeartInsight study, which suggested similar accuracy to the other algorithms.

Cost-effectiveness estimates could only be produced for HeartLogic and TriageHF, which were less costly and more effective compared to the respective cardiac implantable electronic device without the algorithms. For all technologies, only a small reduction in hospitalisation rates were required for them to be cost-effective.

Limitations: The evidence for each algorithm was limited in terms of comparative evidence. Additionally, available evidence was often of low quality. The comparative outcome evidence for economic model was very limited.

Conclusions: There was a lack of comparative evidence across all technologies included in the scope. Evidence for HeartLogic and TriageHF suggests that they may have acceptable prognostic accuracy for predicting heart failure events. However, further evidence is required to confirm these results. Specifically, further comparative evidence (e.g. randomised controlled trials) is required to show the benefit of the algorithms compared to standard practice in intermediate and clinical outcomes. For example, some studies suggested high false positive rates and low sensitivity. Only a single published study was identified for HeartInsight, therefore there are insufficient data to draw conclusions on prognostic accuracy and the benefits on clinical and intermediate outcomes. It is likely remote monitoring systems for CorVue, HeartInsight, HeartLogic and TriageHF would be cost-effective were they to result in fewer hospitalisations in heart failure patients; however, in general, this may apply to any device lowering the hospital visit. In addition, any potential benefits of reduced hospitalisation need to be carefully balanced with chances of overtreatment resulting from alerts.

Future work: Prospective studies on effectiveness of remote monitoring as well as consideration of patient voice and preferences would facilitate a more complete evaluation of technology benefits.

Study registration: This study is registered as PROSPERO CRD42023447089.

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Glossary

Cost-effectiveness analysis An economic analysis that converts effects into health terms and describes the costs for additional health gain.

Economic modelling A theoretical construct that allows the comparison of the costs and outcomes of alternative healthcare interventions.

Incremental cost-effectiveness ratio The difference in the mean costs of two interventions divided by the difference in the mean outcomes in the population of interest.

Markov model An analytical framework that is commonly used to conduct economic evaluation of interventions and particularly suitable to model mutually exclusive health states and disease progression over time.

Sensitivity Proportion of people with the condition of interest who have a positive test result.

Specificity Proportion of people without the condition of interest who have a negative test result.

True negative Correct negative test result – number of non-diseased persons with a negative test result.

True positive Correct positive test result – number of diseased persons with a positive test result.

False negative Incorrect negative test result – number of diseased persons with a negative test result.

False positive Incorrect positive test result – number of non-diseased persons with a positive test result.

Area under the curve Area under a receiver operator characteristic curve (for assessing diagnostic accuracy).

List of abbreviations

6MWT	6-minute walk test	IRR	incidence rate ratio
AAD	antiarrhythmic drug	ITI	intrathoracic impedance
ACE	angiotensin-converting enzyme	IVI	intravenous intervention
A2RB	angiotensin 2 receptor blocker	LOS	length of stay
ACE I	angiotensin-converting enzyme inhibitor	LVAD	left ventricular assist device
AF	atrial fibrillation	LVEF	left ventricular ejection fraction
A2RB	angiotensin 2 receptor blocker	MLWHF	Minnesota Living With Heart Failure Questionnaire
ARNI	angiotensin receptor/neprilysin inhibitor	MORE-CARE	MONitoring Resynchronization dEVICES and CARdiac patiEnts
AIMD	Active Implantable Medical Device	MRA	mineralocorticoid receptor antagonist
AT	atrial tachycardia	NICE	National Institute for Health and Care Excellence
AUC	area under the curve	NPV	negative predictive value
BHRS	British Heart Rhythm Society	NT-pro-BNP	N-terminal pro-B-type natriuretic peptide
BMI	body mass index	NYHA	New York Heart Association
CEAC	cost-effectiveness acceptability curve	PCN	Patient Care Network
CI	confidence interval	PPM	permanent pacemaker
CFU	conventional follow-up	PPV	positive predictive value
CIED	cardiac implantable electronic device	PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
COPD	chronic obstructive pulmonary disease	PROBAST	Prediction model Risk Of Bias Assessment Tool
CRD	Centre for Reviews and Dissemination	PSA	probabilistic sensitivity analysis
CRM	cardiac remote monitoring	PSS	Personal Social Services
CRT	cardiac resynchronisation therapy	QALY	quality-adjusted life-year
CRT-D	cardiac resynchronisation therapy with defibrillator	RCT	randomised controlled trial
CRT-P	cardiac resynchronisation therapy with pacemaker	RIW	Resource Intensity Weight
EAG	Evidence Assessment Group	RMS	remote monitoring services
ECG	electrocardiogram	ROBINS-I	Risk Of Bias In Non-randomized Studies – of Interventions
ESC	European Society of Cardiology	SD	standard deviation
FU	follow-up	SoC	standard of care
GEE	generalised estimating equation	VF	ventricular fibrillation
GP	general practitioner	VT	ventricular tachycardia
HF	heart failure	WTP	willingness to pay
HFrEF	HF with reduced ejection fraction		
HR	hazard ratio		
ICD	implantable cardioverter defibrillator		
ICER	incremental cost-effectiveness ratio		
IQR	interquartile range		

Note

This manuscript is based on the Technology Assessment Report produced for NICE. The full report contained a considerable number of data that were deemed confidential. The full report was used by the Appraisal Committee at NICE in their deliberations. The full report with each piece of confidential data removed and replaced by the statement 'confidential information (or data) removed' is available on the NICE website: www.nice.org.uk.

The present monograph presents as full a version of the report as is possible while retaining readability, but some sections, sentences, tables and figures have been removed. Readers should bear in mind that the discussion, conclusions and implications for practice and research are based on all the data considered in the original full NICE report.

Plain language summary

Developments can help hospital staff track heart failure in patients. CorVue, HeartInsight, HeartLogic and TriageHF are such devices. Researchers checked if these technologies work well, improve patient health and are worth the cost.

We looked for studies from medical databases and company websites. We used this information to see how well each technology predicts heart failure, to see if they may help patients live better.

HeartLogic and TriageHF showed good results. Both of them may detect heart failure, but more research is needed to be sure. TriageHF results were varied. CorVue's results were unclear, because the results across studies were very different. HeartInsight only had one study, and it was not clear how good it was.

HeartLogic and TriageHF might help to identify heart failure early and reduce the risk of death. CorVue and HeartInsight did not have enough good information to understand if they could help patients. Only one study looked at how TriageHF affects quality of life.

The economic analysis looked at whether these technologies provide good value for the money. There is not much evidence yet, but these devices could be cost-effective if they lower hospital visits compared to regular care.

Scientific summary

Background

Heart failure (HF) 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 HF are breathlessness, fatigue and oedema. Conditions that can cause HF 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 HF in 2018, with an estimated 200,000 new diagnoses each year. HF 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 HF, which increases to 1 in 15 of people aged 75–84 years, and to just over 1 in 7 people of those aged above 85 years.

The National Institute for Health and Care Excellence (NICE) guidelines for diagnosis and management of chronic HF in adults recommend that monitoring of people with chronic HF 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. The European Society of Cardiology (ESC) guidelines for the diagnosis and treatment of acute and chronic HF add that HF management may involve in-person service models or home-based telemonitoring, and that the COVID-19 pandemic has highlighted some of the potential advantages of the latter. While care is usually followed up by HF clinics, suitable patients may be followed up by community HF nurses or a general practitioner (GP) with a special interest in HF – a clinical expert commented that there is no standard HF service model.

Patients who have cardiac implantable electronic devices (CIEDs) due to HF or who are at risk of HF may have a remote monitoring system incorporated in the device. The remote monitoring system includes a predictive algorithm for HF. The system can send alerts, and/or the stored data can be reviewed. There is additional cost to access and use the remote monitoring system. The decision question is whether the algorithm-based remote monitoring of HF risk data in people with CIEDs represent a clinical and cost-effective use of NHS resources and should be recommended for use.

Four relevant remote monitoring algorithms were identified for consideration:

- CorVue algorithm with integrated CIED [Abbott Laboratories (Abbott Park, IL, USA)]
- HeartInsight algorithm with integrated CIED (BIOTRONIK, Berlin, Germany)
- HeartLogic algorithm with integrated CIED (Boston Scientific, Marlborough, MA, USA)
- TriageHF algorithm with integrated CIED [Medtronic plc (Medtronic plc, Dublin, Ireland)].

Objectives

To determine the clinical and cost-effectiveness of the four remote monitoring algorithms for detecting HF in people with CIEDs.

Methods

Systematic review

The systematic review was conducted following the general principles recommended by the Centre for Reviews and Dissemination (CRD) guidance.

A comprehensive range of databases and sources of grey literature were searched for the identification of studies relating to the use of algorithm-based remote monitoring of HF risk data in people with CorVue, HeartInsight, HeartLogic or TriageHF CIEDs. The bibliographic databases searched were MEDLINE and EMBASE (via Ovid), the Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO), the Cochrane Database of Systematic Reviews (CDSR) and the Cochrane Central Register of Controlled Trials (CCRCT) (via the Cochrane Library) and the Database of Abstracts of Reviews of Effects (DARE) (via the CRD). International CTIRs, such as the US ClinicalTrials.gov; EudraCT; the World Health Organization's International Clinical Trials Registry Platform (ICTRP); and ScanMedicine, a multinational open access clinical trial database, were searched for the identification of ongoing clinical trials. Additionally, we searched for health technology assessment (HTA) reports in the international HTA database (INAHTA) and for protocols of systematic reviews in International Prospective Register of Systematic Reviews (PROSPERO) and International Platform of Registered Systematic Review and Meta-analysis Protocols (INPLASY), both international registers of systematic reviews. Finally, we searched for pre-print manuscripts in medRxiv, a pre-print server for health sciences. We performed backwards and forwards citation chaining to identify potentially relevant studies cited or citing the included studies. Company submission documents and company websites were also searched for additional relevant studies.

Data extraction of the study characteristics and outcome data was done by one reviewer and checked by another reviewer. The risk of bias was assessed using Risk Of Bias In Non-randomized Studies – of Interventions (ROBINS-I), whereby clinical outcomes were reported in non-randomised intervention studies; and Prediction model Risk Of Bias Assessment Tool (PROBAST), whereby prognostic outcomes, including sensitivity and specificity, were reported. The Cochrane risk of bias tool was not used because none of the included studies were randomised controlled trials (RCTs).

Due to diversity across the studies, meta-analysis was not performed, and the evidence was synthesised narratively and in tabular format.

Economic review

A broad search for cost-effectiveness studies was undertaken in the following sources: MEDLINE and EMBASE (Ovid), CDSR and CCRCT (the Cochrane Library), CRD, DARE and HTA database and NHS Economic Evaluation Database (NHS EED), the international HTA database and NIHR Journals Library. Whenever appropriate to the database, we used a validated Scottish Intercollegiate Guidelines Network (SIGN) search filter for the identification of cost-effectiveness studies.

Additionally, in August 2023, we performed focused searches for resource utilisation, quality-adjusted life-year (QALY) and utility values to populate the economic model. We searched MEDLINE and EMBASE via Ovid and used two validated economic filters for cost-of-illness studies and quality-of-life studies. We also searched specialist sources such as Cost-effectiveness Analysis Registry (CEA Registry), Research Papers in Economics (RePEC) and SchARRHUD (School of Health and Related Research Health Utilities Database at the University of Sheffield).

Economic modelling

A de novo two-state Markov model (with alive and dead states) was used to estimate the cost-effectiveness of algorithm-based remote monitoring of HF risk data in people with CIEDs. The model structure captured the key costs and outcomes associated with cardiac remote monitoring (CRM). Patients in the alive state experienced a number of hospitalisations per year, made a number of clinic visits (scheduled and unscheduled) and were at risk of dying. CorVue, HeartInsight, HeartLogic and TriageHF were modelled separately, and outcome differences for one device were not assumed to apply to another device. QALYs gained was the measure of benefit for the economic evaluation.

Results

Clinical effectiveness

Eighty-one reports comprising 42 studies of clinical effectiveness were included in the systematic review. Eight studies evaluated CorVue, 1 published study evaluated HeartInsight, 19 studies evaluated HeartLogic and 14 studies evaluated

TriageHF. Of the included studies, the great majority were single-arm cohort designs (retrospective and prospective). No RCTs were identified, and five studies provided some comparative data (CorVue; $n = 1$, HeartLogic; $n = 3$, TriageHF; $n = 1$).

The greatest amount of evidence for prognostic accuracy was identified in studies assessing the TriageHF algorithm ($n = 10$). Of these, the area under the curve (AUC) was reported in three studies assessing worsening HF (AUC = 0.75), mortality (AUC = 0.61) and hospital admissions (AUC = 0.81). Sensitivity for high risk status for HF-related events (e.g. hospitalisations) showed great variability (range = 37.4 to 87.9%). Specificity also varied (range = 44.4–90.2%). A similar amount of evidence was identified for prognostic accuracy outcomes evaluating HeartLogic ($n = 8$). Validation studies for HeartLogic to predict HF events (hospitalisations and clinical visits) reported sensitivity as adequate to high (range = 66–100%); similarly, specificity was adequate to high (range = 61–93%). False positive rates were generally low in the seven studies reporting this outcome; conversely, one study reported a high false positive rate (26 of 38 alerts). In comparison to HeartLogic and TriageHF, there was limited evidence for CorVue ($n = 5$) and HeartInsight ($n = 1$) overall and for prognostic outcomes. The CorVue algorithm demonstrated inadequate sensitivity for HF events, defined as hospitalisations (range = 20–68%). Specificity was only reported in two studies at 70% and 77%. The low predictive accuracy was also accompanied by a high false positive rate. The one published study for HeartInsight algorithm had 65.5% sensitivity and 86.7% specificity for first postimplant HF hospitalisations. Additionally, 54.8% sensitivity and 86.5% specificity for HF hospitalisation, outpatient intravenous intervention (IVI) or death. False positive rates were low.

Reported clinical outcomes included HF events, mortality and adverse events (morbidity). Twelve studies reported HF events for three algorithms (HeartLogic, $n = 7$; CorVue $n = 3$, TriageHF $n = 2$). Only one of these studies was comparative, with data showing less HF events when the HeartLogic algorithm was utilised. For non-comparative evidence using HeartLogic, there was evidence that when IN alert compared to OUT of alert related to increased risk of HF events occurring. Similarly, TriageHF showed an increased risk of HF events when in high or medium risk status. No comparative evidence was generated for CorVue, and only numerical data were presented. No evidence was identified for HeartInsight. There was limited evidence for HF-related deaths. Three HeartLogic studies demonstrated an increased risk of death when IN alert compared to OUT of alert. One study assessing differences between unplanned HF hospitalisations and medical admissions for TriageHF reported more deaths occurring during HF hospitalisations. Only two studies reported adverse events (HeartInsight $n = 1$, HeartLogic $n = 1$).

For the patient-reported outcome measures, one single prospective cohort evaluating the TriageHF algorithm provided outcomes for health-related quality of life by using the 6-minute walk test (6MWT) and Minnesota Living With Heart Failure Questionnaire (MLWHF). There was a decrease in walking distance at 8 months follow-up and no statistically significant change in the MLWHF from baseline to follow up at 8 months.

Cost-effectiveness

There was no comparative evidence on hospitalisation, mortality and follow-up visits or length of stay (LOS) for CorVue or HeartInsight. CorVue and HeartInsight were cost-increasing when a conservative assumption of no difference in hospitalisation, mortality, follow-up visits (scheduled/unscheduled) was made. Threshold analysis for these two devices showed that even a very small reduction in the incidence rate of hospitalisation would make them cost-effective.

HeartLogic had some evidence on LOS, and hospitalisation rates and the cost-effectiveness estimates showed it to be dominant (i.e. less costly and more effective than the comparator). TriageHF also had some evidence on hospitalisation rates, and was also dominant. The studies supplying the hospitalisation and LOS evidence were either at serious or critical risk of bias due to confounding.

Due to the high cost of hospitalisation, the remote monitoring services (RMS) devices for these technologies only need to reduce the hospitalisation rates by small percentage for them to become cost-effective. The lack of hospitalisation outcome evidence for CorVue or HeartInsight means it is not possible to produce cost-effectiveness estimates for these technologies. The cost-effectiveness estimates of HeartLogic and TriageHF are based on evidence that is at risk of bias. There was also limited evidence on healthcare contact outcomes.

Discussion

The majority of the evidence base for all algorithms is derived from single cohort (prospective and retrospective) studies and provide mixed results. Only five included studies reported comparative evidence.

The available evidence for the HeartLogic algorithm showed adequate to high sensitivity and specificity for the prediction of HF events (i.e. hospitalisations). False positive rates were low.

TriageHF accuracy measures varied substantially between low and high sensitivity and specificity. False positive rates were only reported in one study and were relatively low.

Evidence for the accuracy of CorVue showed low sensitivity, and specificity was generally not reported. False positive rates were high in most studies.

One study evaluating the clinical effectiveness of HeartInsight was identified. It was a development and validation study and reported adequate sensitivity and specificity for HF events. False positive rates were moderate in this single study. No comparative evidence was identified for the use of HeartInsight.

There was a paucity of data for some of the outcomes listed in the protocol, including patient-reported outcome measures for health-related quality of life and satisfaction and adherence to treatment. In addition, mortality and adverse events were not widely reported. Lastly, there was limited reporting for the software failure rate.

The assumptions around parameters may not be applicable to all populations or subgroup and may not reflect real-world experience. Limited device-specific comparative evidence on outcomes mean that the cost-effectiveness findings in this report need to be interpreted with caution. Further research and comparative evidence on effectiveness might be needed to confirm cost-effectiveness.

Conclusions

The evidence for HeartLogic and TriageHF showed a potential to be of use in clinical practice; however, there are important uncertainties due to a lack of comparative evidence. HeartLogic had the highest and most consistent accuracy measures (i.e. sensitivity of $\geq 70\%$); the data suggest that being IN alert is linked to greater risk of HF events; however, these estimates were generally derived from composite outcomes (e.g. hospitalisations and outpatient visits). TriageHF showed similar accuracy, but with further degree of variation, for detecting such HF events when in a high risk status; however, these estimates were more commonly reported from single end-point studies. HeartInsight reported comparable accuracy to HeartLogic and TriageHF (sensitivity of 65%); however, this was only based on one published study, therefore it is uncertain whether further studies will replicate these findings. CorVue prognostic accuracy data varied substantially (i.e. sensitivity reported to be as low as 20%). For all technologies, most studies were judged to be at high risk of bias, which reduces certainty about the evidence.

All remote monitoring algorithms only needed to reduce hospitalisations by a small amount for them to be cost-effective given the evidence on incremental healthcare visits use compared to no remote monitoring algorithm. Better quality and adequately powered evidence on both hospitalisations and healthcare contacts (visits, calls), which also records time spent reviewing remote monitoring data, would help inform the cost-effectiveness of the remote monitoring algorithms.

Suggested priorities for further research

Further studies on the effectiveness of remote monitoring should be prospectively designed and compare outcomes for people with a CIED and remote monitoring algorithm to people with a CIED with no remote monitoring algorithm.

In addition, inclusion of relevant patient-reported outcome measures, and patient involvement to capture the patient voice and preferences, would facilitate a more complete evaluation of the technologies' benefits.

Study registration

This study is registered as PROSPERO CRD42023447089.

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Chapter 1 Background and definition of decision problem

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 HF are breathlessness, fatigue and oedema. Conditions that can cause HF include coronary heart disease, high blood pressure, heart rhythm or valve abnormalities and conditions affecting the heart muscle (cardiomyopathies and myocarditis). The ESC guidelines for the diagnosis and treatment of acute and chronic HF highlight that atrial fibrillation (AF) and HF frequently coexist, and they can cause or exacerbate each other.¹

Heart failure may present as acute or chronic, depending on whether a person has an established diagnosis of HF and speed of symptom onset. People with chronic HF may experience sudden deterioration in heart function and worsening of symptoms, which is known as acute decompensated HF.

The British Heart Foundation website² explains that HF 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 of ejection fraction (whereby 50% or greater is considered normal), HF may be classed as the following:²

- HFpEF – HF with a preserved ejection fraction (> 50%)
- HFmrEF – HF with a mildly reduced ejection fraction (40–49%)
- HFrEF – HF with reduced ejection fraction (< 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 HF, 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 HF, which increases to 1 in 15 of people aged 75–84 years, and to just over 1 in 7 people aged above 85 years.³

Around 920,000 people in the UK were living with HF in 2018, with an estimated 200,000 new diagnoses each year.⁴ The incidence of HF in the UK is 140 per 100,000 men and 120 per 100,000 women.⁵ The prevalence of HF 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 HF found a mortality rate of 23.6% for people with acute HF and 6.4% for those with chronic HF across Europe.⁶ A UK-based population study conducted between 2000 and 2017 found that patients diagnosed with HF had a 1-year survival rate of 75.9%, 5-year survival of 45.5% and 10-year survival of 24.5%.

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 HF in 2021/22 compared with 86,474 in 2018/19.^{7,8}

This is at significant cost to the NHS – a 2016 All-Party Parliamentary Group (APPG) report on HF found that the condition costs the NHS around £2 billion per year, or approximately 2% of the total NHS budget.⁹

Patients who have cardiac implantable electronic devices (CIEDs) due to HF or who are at risk of HF may have a remote monitoring system incorporated in the device. The remote monitoring system includes a predictive algorithm for HF. The system can send alerts, and/or the stored data can be reviewed. There is an additional cost to access and utilise the remote monitoring system. The decision question is whether the algorithm-based remote monitoring of HF risk data in people with CIEDs represent a clinical and cost-effective use of NHS resources and should be recommended for use.

Description of current practice

Monitoring heart failure patients

The NICE guidelines for diagnosis and management of chronic HF in adults recommend that monitoring of people with chronic HF 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.³ The ESC guidelines for the diagnosis and treatment of acute and chronic HF add that HF management may involve in-person service models or home-based telemonitoring, and that the COVID-19 pandemic has highlighted some of the potential advantages of the latter.¹ While care is usually followed up by HF clinics, suitable patients may be followed up by community HF nurses or a GP with a special interest in HF – a clinical expert commented that there is no standard HF service model.

People should have additional monitoring if they have comorbidities, are taking coprescribed 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. Reviews are offered every 6 months for people whose condition is stable. Early follow-up visits are recommended at 1–2 weeks following hospital discharge to assess signs of congestion and drug tolerance. Levels of N-terminal pro-B-type natriuretic peptide (NT-pro-BNP) may be monitored as a surrogate biomarker for HF in people under 75 who have HFrEF and an estimated glomerular filtration rate above 60 ml per minute per 1.73 m².

Clinical experts highlighted that in practice a combination of the ESC guidelines and the NICE guidelines are followed in the NHS. The ESC guidelines for the diagnosis and treatment of acute and chronic HF recommend that an electrocardiogram (ECG) should be done annually to detect prolonged QRS duration, so that conduction disturbances and AF may be recognised and to identify people with prolonged QRS duration who may become candidates for cardiac resynchronisation therapy (CRT).¹ Repeat ECGs are also advised if there has been a deterioration in clinical status, and 36 months after optimisation of standard therapies for HFrEF.

Symptoms can also be monitored using CIEDs, some of which may also deliver a therapeutic benefit [such as pacemakers, implantable cardioverter defibrillators (ICDs) and CRT devices], while others only monitor metrics over time.

Pressure sensors placed in the pulmonary artery that work in combination with an external monitor may also be used to wirelessly monitor symptoms of HF. NICE's interventional procedures guidance states that the evidence on efficacy and safety of percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic HF is sufficient to support standard arrangements for use.¹⁰

Implantable loop recorders which are placed under the skin are capable of continuous monitoring of heart rate and rhythm and last around three years, with data checked at regular intervals by a clinician. 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. The British Heart Rhythm Society's (BHRS) clinical standards and guidelines for the follow-up of CIEDs for cardiac rhythm management states that most modern implantable pulse generators are also equipped with algorithms that provide reliable pacing threshold management.¹¹

Follow-up of people with cardiac implantable electronic devices

Clinical experts explained that people at risk of HF or worsening HF who have a CIED are usually managed in multiple clinics. For example, a HF 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 BHRS clinical standards and guidelines for the follow-up of CIEDs for cardiac rhythm management state that managing HF 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 HF.¹¹

The BHRS standards also state that 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.

Treatment of chronic heart failure

The NICE guidelines for diagnosis and management of chronic HF in adults is summarised in [Figure 1](#). The NICE guidelines recommend the use of pharmacological treatments, including routine use of 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 HF 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

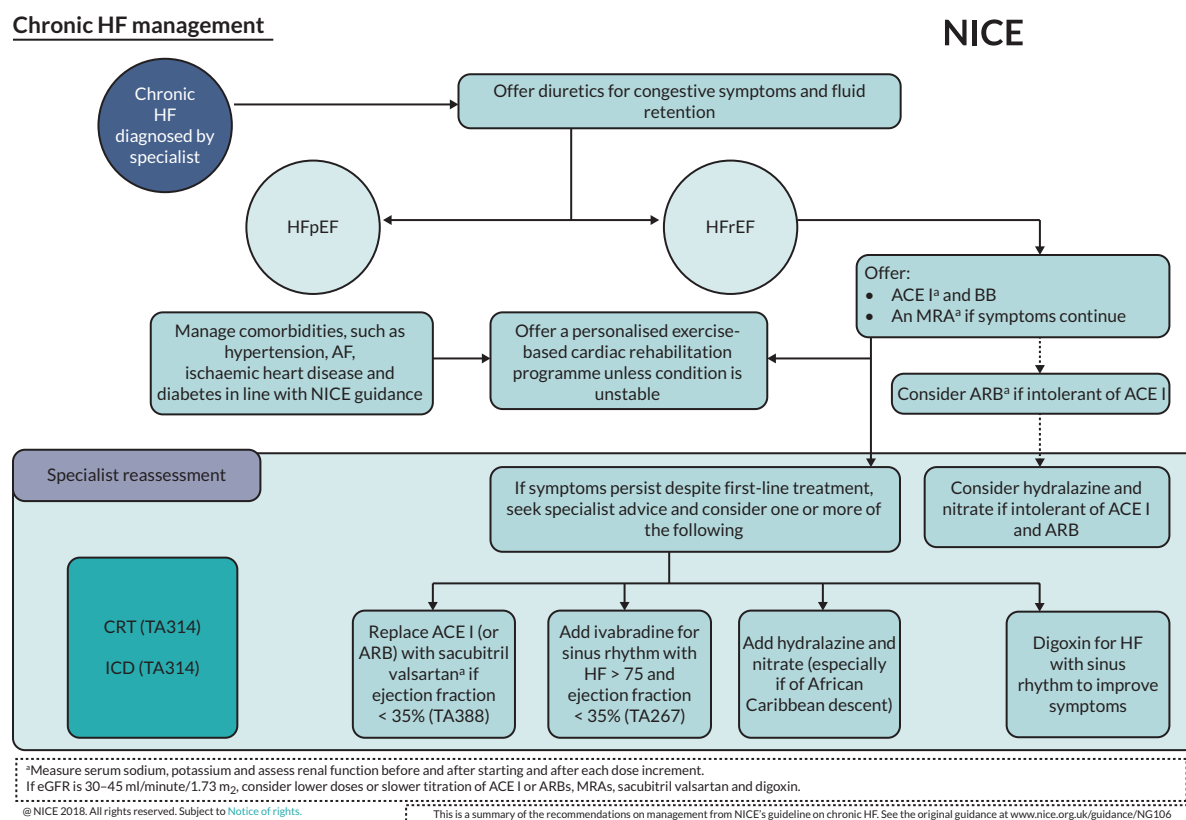


FIGURE 1 The NICE guidelines on chronic heart failure management.³ ARB, angiotensin receptor blocker; ACE-I, angiotensin-converting enzyme inhibitor; eGFR, estimated glomerular filtration rate; MRA, mineralocorticoid receptor antagonist.

be appropriate where HF is leading to or is complicated by either respiratory failure or reduced consciousness or physical exhaustion.

In the case of HFrEF, the NICE guidelines for diagnosis and management of chronic HF in adults recommend that an angiotensin-converting enzyme inhibitor (ACE I), or angiotensin 2 receptor blockers (A2RBs) licensed for HF if the person is intolerant to ACE inhibitors, should be offered as a first-line treatment in combination with a beta-blocker licensed for HF.³ 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.³ The NICE technology appraisal guidance on dapagliflozin for treating chronic HFrEF also supports the use of an SGLT2 inhibitor in these people,¹² as an add-on to optimised standard care with:

- ACE I or A2RBs, with beta-blockers, and, if tolerated, 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 HF who have recently been hospitalised for HF, who have LVEF below 50% and an iron deficiency to reduce the risk of HF hospitalisation.¹

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

- Severe HF (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.
- An 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.
- An 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 HFrEF 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 HF 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.

Treatment for acute heart failure

Acute HF can present as acute decompensation of chronic HF in addition to new-onset HF in people without known cardiac dysfunction. The NICE guidelines for diagnosis and management of acute HF in adults recommend that people requiring immediate treatment for acute HF should be offered intravenous diuretic therapy, which should be started using a bolus or infusion strategy.¹³

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 HF 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 HF is leading to or is complicated by either respiratory failure or reduced consciousness or physical exhaustion.

TABLE 1 Recommended CIEDs for people with different symptoms and QRS intervals where LVEF is 35% or less

QRS interval	NYHA classification of symptoms			
	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

CRT-D, cardiac resynchronisation therapy with defibrillator; CRT-P, cardiac resynchronisation therapy with pacemaker; ICD, implantable cardioverter defibrillator; LBBB, left bundle branch block; NYHA, New York Heart Association.

Devices and surgical procedures 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 ICDs, cardiac resynchronisation therapy with defibrillator (CRT-D) or cardiac resynchronisation therapy with pacemaker (CRT-P) as treatment options for people with HF who have left ventricular dysfunction with a LVEF of 35% or less depending on NYHA functional classification, QRS duration and presence of left bundle branch block (LBBB) (Table 1).⁵

Description of the technologies under assessment

This assessment evaluated remote monitoring systems, consisting of data collection, HF predictive algorithms, and the software and data management platforms to send, receive, store and present data and alerts for implanted cardiac devices. These remote monitoring systems are only compatible with specific devices manufactured by the same company. The CIED remotely monitors physiological parameters measured by an implanted cardiac device. The predictive algorithm determines whether an alert should be sent to healthcare professionals via the remote monitoring system software and data management platform when HF metrics worsen. All the technologies are intended for use within a single person with an implanted device; none are reprogrammable for use with another person. All require an internet connection to access their relevant data management platforms.

Every CIED has its own remote monitoring system with its own unique HF predictive algorithm for sending alerts. Where possible, outcomes for patients utilising the remote monitoring system were compared to patients without the remote monitoring system for each CIED. Remote monitoring systems were not compared with each other as that would require additional assumptions about equivalent effectiveness of the CIEDs or evaluation of the relative effectiveness of the CIEDs, which is beyond the scope of this report. The CIEDs would also need to be considered for use in the same population.

Four CIEDs (Table 2) and their remote monitoring systems were assessed. These CIEDs were considered in the NICE scope because they are:

- intended for use in people with an implanted cardiac device
- available in the UK
- hold a CE-mark
- therapeutic, not just monitoring.

HeartInsight and BIOTRONIK Home Monitoring

The BIOTRONIK Home Monitoring system (HMSC) and HeartInsight algorithm are intended for monitoring cardiac function in people who have implanted BIOTRONIK pacemakers, ICDs or CRT devices. It is indicated for HF patients with NYHA class II or III. The HeartInsight algorithm is integrated within the HMSC and has a class III CE-mark.

TABLE 2 Product properties

Algorithm-based remote monitoring system	Manufacturer	Components	Compatible CIEDs
CorVue and Merlin.net Patient Care Network (PCN)	Abbott Laboratories (Abbott Park, IL, USA)	- 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 (HMSC)] - 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 Patient Management System	Boston Scientific	- LATITUDE Communicator HeartLogic algorithm (integrated within the CIED) - LATITUDE NXT Patient Management System - Optional MyLATITUDE mobile app	Boston Scientific devices: Perciva, Momentum EL, Resonate EL, Vigilant EL, and CRT-Ds: Resonate X4, Vigilant 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

The system includes the handheld CardioMessenger device, which transmits data from the implanted cardiac device to the BIOTRONIK HMSC via a mobile phone network. The system has an integrated HeartInsight algorithm to identify people with a higher risk of decompensation and predict HF hospitalisations.

The HeartInsight algorithm combines seven parameters into one 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 and/or e-mail) once the threshold is exceeded for three consecutive values (days), indicating higher risk of worsening HF. 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 (HFSQ) 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 a lead capable of atrial sensing, with a deactivated atrial lead or with permanent AF. It is also not recommended in patients with insufficient mobile network coverage or the inability to use BIOTRONIK Home Monitoring.

HeartLogic and LATITUDE NXT Patient Management system

The HeartLogic algorithm and LATITUDE NXT HF Patient Management system (Boston Scientific) is intended for remote monitoring of HF in people who have compatible implanted devices. The HeartLogic algorithm is integrated within the implanted device and has a class III implantable CE-mark.

It is intended to be used alongside in-person or remote clinical evaluations. The HeartLogic device has an integrated HeartLogic algorithm which automatically analyses measurements. In addition to the implanted device, the LATITUDE NXT Patient Management System includes a wireless LATITUDE Communicator and optional weighing scales and a blood pressure monitor. The LATITUDE NXT system is further described in the NICE Medtech innovation briefing MIB67.¹⁴ 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 one composite index that indicates decompensation. The data are transferred to the LATITUDE NXT Patient Management System via the LATITUDE Communicator. The system has daily data transfers to the clinical team. The Communicator can use a mobile phone connection or an internet connection to relay the data. The system is configured to send an alert to a 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 e-mail or text message.

TriageHF and CareLink remote monitoring (TriageHF Plus)

TriageHF Plus is a monitoring system for identifying and managing an increased risk of HF or worsening HF in people with CIEDs. The TriageHF algorithm is integrated within the implanted device and has Active Implantable Medical Devices (AIMD) classification.

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 are 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 are transmitted, the TriageHF algorithm generates a daily risk status of a HF 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 HF management report is generated on the daily risk status.

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 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 (VT) or ventricular fibrillation (VF), 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 HF nurse. A set of standardised questions are used to distinguish between worsening HF and other issues. Healthcare professionals can also be notified of alerts via text messaging or e-mail. 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.

CorVue and Merlin.net patient care network

The CorVue algorithm and Merlin.net PCN platform are intended for the remote monitoring of early signs of HF 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 (e.g. a chest infection) may create a false positive. CorVue is suitable for people who have a CIED and congestive HF with ventricular dyssynchrony.

Population and relevant subgroups

The two populations, and their subgroups included in the NICE scope are listed below:

1. People who have a CIED and do not have a diagnosis of chronic HF but are at high risk of new-onset acute HF.

If data allowed, analyses on the following subgroups were 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 allowed, analyses on the following subgroups were 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 NYHA class I and II HF, or III and IV (at study recruitment)
- f. have a prior HF hospitalisation or urgent care visit within the last 12 months.

Comparators

The current standard of care for monitoring HF risk 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 HF team. Clinicians explained that reviews can be over the telephone or in-person, and that they are most commonly triggered by self-reporting of symptoms from the person with the CIED. The number and timing of the reviews varies in practice 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 HF monitoring pathways varies in practice between different trusts, and even between different hospitals.

For each of the technologies under assessment reported in *Description of the technologies under assessment*, the comparator is the current standard of care for monitoring HF risk described above with the same CIED associated with the technology.

Care pathways

Cardiac implantable electronic devices are recommended as treatment options for specific people who have or are at high risk of HF. These devices include pacemakers, implantable cardioverter defibrillators (ICDs) or 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. The frequency of the reviews varies according to the person's condition. Clinical experts highlighted that currently reviews are commonly triggered by worsening symptoms reported by the person with the CIED.

Remote monitoring systems capable of identifying new-onset acute HF or worsening signs of HF (decompensation) using measurements captured by CIEDs could help clinicians identify people who need a review. When used within a monitoring pathway alongside standard care, earlier identification of people at risk of new-onset acute HF or worsening signs of HF (decompensation) could 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.

Outcomes

Four key types of outcomes were considered: firstly, intermediate measures of prognostic accuracy and usage of the equipment; secondly, clinical outcomes concerned with mortality and morbidity (including adverse events from treatments); thirdly, patient-reported outcomes, such as health-related quality of life; fourthly, the cost-effectiveness of the intervention.

Intermediate outcomes

Technology performance, time, clinical management and resource outcomes were included as intermediate outcomes:

- 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 HF event
- alert response rates (including time between an alert, clinical review and change in clinical management)
- number of HF and all cause hospitalisations
- number of emergency or urgent care visits
- length of hospital stay
- software failure rate (including failed data transmissions)
- number of monitoring reviews (remote and face to face).

Clinical outcomes

Clinically defined health-related events and states were included as clinical outcomes:

- rate of HF events
- rate and category of AF (subclinical, paroxysmal or persistent/permanent)
- morbidity (including adverse events from treatments)
- changes in NYHA classification of symptoms
- mortality (cardiac and all-cause mortality)

Patient-reported outcomes

Eligible outcomes that may be reported by patients include:

- health-related quality of life
- patient-reported outcome measures such as satisfaction, anxiety and stress
- patient's adherence to treatment (as agreed between the prescriber and the person taking the medication).

Cost-effectiveness outcomes

Cost-effectiveness outcomes include cost-consequences, cost-effectiveness, cost-utility and cost-benefit outcomes.

Aims and objectives

The aim of the project is to determine the clinical and cost-effectiveness of remote monitoring devices for identifying new-onset acute HF or worsening signs of HF in people with CIEDs of the four technologies described in *Description of the technologies under assessment*.

The objectives are listed in the following text.

Clinical effectiveness

- To perform a systematic review, narrative synthesis and, if feasible, a meta-analysis of the prognostic accuracy of the four remote monitoring systems.
- To perform a systematic review, narrative synthesis and, if feasible, a meta-analysis of the clinical impact, such as morbidity and mortality, of the remote monitoring systems.
- To perform a systematic review and narrative synthesis of patient and physician opinions on the value and ease-of-use of the remote monitoring systems.

Cost-effectiveness

- To conduct a systematic review of existing economic evaluation studies of the remote monitoring systems for identifying new-onset acute HF or worsening signs of HF in people with CIEDs.
- To develop an in-house decision model to estimate the cost-effectiveness of remote monitoring systems for identifying new-onset acute HF or worsening signs of HF in people with CIEDs.

Chapter 2 Assessment of clinical effectiveness

This report contains reference to confidential information provided as part of the NICE appraisal process. This information has been removed from the report and the results, discussions and conclusions of the report do not include the confidential information. These sections are clearly marked in the report.

Methods for reviewing clinical effectiveness

A systematic review of the clinical effectiveness of the included interventions was conducted following the general principles recommended by the CRD guidance.¹⁵ We utilised Chapter 6 of the *Cochrane Handbook* for searching and selecting studies of diagnostic accuracy studies.¹⁶

Search strategies

Comprehensive searches of published and unpublished literature were undertaken to identify all completed and ongoing studies relating to the use of algorithm-based remote monitoring of HF risk data in people with CorVue, HeartInsight, HeartLogic or TriageHF CIEDs. Searches were designed following published guidance on how to search for medical devices¹⁷ and included a combination of key and text words and controlled vocabulary search terms whenever supported by the database. An Information Specialist (HO'K) designed the search strategy in Ovid MEDLINE in collaboration with the lead Information Specialist (SG) and the rest of the team. The strategy consisted of title, abstract and key word search terms describing the interventions in scope (e.g. name of implantable device) and intended purpose or health condition. To maximise sensitivity, all known development names and device codes (FDA approved device codes) were used and combined with the Boolean operator 'OR'. The algorithm-based components of the interventions were searched separately in title, abstract and key word fields. Manufacturers' names indexed in specialist database fields designed to capture these data were also included. Algorithm and manufacturers' search strings were subsequently combined with the Boolean operator 'OR' and then combined with 'AND' with strings that described the intended purpose of the algorithm (e.g. Monitor or triage), and strings that focus on the health condition or subject of this appraisal (e.g. heart failure). The final search strategy approach consisted of the following concepts:

[(implantable device names) OR (algorithm names AND Purpose AND Condition)]

Date, language and study design limits were not applied. The final MEDLINE strategy was adapted for use in all resources searched. The searches were carried out between 14 and 20 of June 2023. The bibliographic databases and grey literature sources searched are reported in [Table 3](#). Database results were downloaded into reference manager software EndNote 20 (Clarivate Analytics, US) for de-duplication. Supplementary search methods (e.g. backwards and forwards citation chasing) were used to identify potentially relevant studies cited or citing the included studies and in six reviews.^{18–22} Company submission documents and company websites were also searched for additional relevant studies.

Search strategies are reported in [Appendix 1](#).

TABLE 3 Databases searched

Source name	Platform/URL
MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions	Ovid
EMBASE	Ovid
CINAHL	EBSCO
Cochrane Database of Systematic Reviews (CDSR)	Cochrane Library available at https://cochranelibrary.com/cdsr/reviews

continued

TABLE 3 Databases searched (*continued*)

Source name	Platform/URL
Cochrane Central Register of Controlled Trials (CCRCT)	Cochrane Library available at https://cochranelibrary.com/central
Database of Abstracts of Reviews of Effects (DARE) ^a	Centre for Reviews and Dissemination (CRD) available at https://crd.york.ac.uk/CRDWeb/
PROSPERO (International Prospective Register of Systematic Reviews)	National Institute for Health and Care Research (NIHR) available at https://crd.york.ac.uk/PROSPERO/
INAHTA (the international HTA database)	The International Network of Agencies for Health Technology Assessment available at https://database.inahta.org/
NIHR Journals Library	National Institute for Health and Care Research (NIHR) journals library available at https://journalslibrary.nihr.ac.uk/#/
INPLASY	International Platform of Registered Systematic Review and Meta-analysis Protocols available at https://inplasy.com/
ClinicalTrials.gov	National Library of Medicine (US National Institute for Health) clinical research studies online database available at https://clinicaltrials.gov/
EudraCT	European Union Drug Regulating Authorities Clinical Trials Database available at https://clinicaltrialsregister.eu/ctr-search/search/
ICTRP	International Clinical Trials Registry Platform (World Health Organization) available at https://trialsearch.who.int/Default.aspx
ScanMedicine	NIHR Innovation Observatory open access clinical trial database available at https://scanmedicine.com/
medRxiv	Pre-print server for health sciences available at https://medrxiv.org/

^a Content updated until 2015.

Eligibility criteria

Population

People who have one of the CIEDs listed in [Table 2](#) and do not have a diagnosis of chronic HF but are at high risk of new-onset acute HF; and people who have a CIED and have a diagnosis of chronic HF.

Interventions

Algorithm-based remote monitoring systems for HF risk data in people with CIEDs (including ICD and CRT devices):

- CorVue and Merlin.net PCN (Abbott Laboratories)
- HeartInsight and BIOTRONIK Home Monitoring system (BIOTRONIK)
- HeartLogic and LATITUDE NXT Patient Management System (Boston Scientific)
- TriageHF and CareLink remote monitoring (TriageHF Plus; Medtronic).

Comparators

The comparator is standard care. The current standard of care for monitoring HF for people who have CIEDs is without use of remote monitoring. It includes 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 HF team. The number and timing of the reviews varies depending on patient symptoms. The organisation of HF monitoring pathways varies in practice between different trusts, and even between different hospitals. For prognostic accuracy studies a reference standard will be implemented. This may vary between the studies and the definition of the reference standard will be extracted from the individual included studies.

Outcomes

[Table 4.](#)

TABLE 4 Outcomes eligible for inclusion

Outcome type	Outcome(s) assessed
Intermediate	• 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 HF event • Alert response rates (including time between an alert, clinical review and change in clinical management) • Number of HF and all cause hospitalisations • Number of emergency or urgent care visits • Length of hospital stay • Software failure rate (including failed data transmissions) • Number of monitoring reviews (remote and face to face)
Clinical	• Rate of HF events • Rate and category of AF (subclinical, paroxysmal or persistent/permanent) • Morbidity (including adverse events from treatments) • Changes in NYHA classification of symptoms • Mortality (cardiac and all-cause mortality)
Patient-reported	• Health-related quality of life • Patient-reported outcome measures such as satisfaction, anxiety and stress • Patient's adherence to treatment (as agreed between the prescriber and the person taking the medication)

Study designs

We will consider all study designs that provide relevant outcome data as listed in [Table 4](#).

Study selection

The deduplicated citations in Endnote were exported to Rayyan, an online tool used to speed up the review process for title and abstract screening.²³ Ten per cent of the records were piloted independently by two reviewers to assess initial agreement. Once complete, the same two independent reviewers assessed the remaining titles and abstracts (RK and NO'C). Full texts of any records that were deemed to be relevant at title and abstract were obtained. The two reviewers then independently screened these records (RK and NO'C). At all stages of the study selection process, disagreements were resolved through discussion.

Data extraction

We created and piloted a data extraction form, using four randomly chosen included studies. This allowed for the data extraction form to be refined and ensure its suitability. The data of the included studies were extracted by one reviewer using the standardised form and checked for accuracy by a second reviewer. Any discrepancies were resolved by discussion. Information extracted included the study design, methodology, intervention characteristics, patient baseline characteristics, and outcome measures. Studies with multiple publications were grouped, and the most recent full-text publication chosen as the primary record, relevant outcome data were extracted from all grouped records, where the same outcome data were reported in multiple publications, the most up-to-date or complete report was used.

Quality assessment

The quality of prognostic/diagnostic test accuracy studies was assessed using the PROBAST.^{24,25}

Non-randomised studies were assessed using the ROBINS-I tool.²⁶ Many of the included studies were single cohort designs (prospective and retrospective); that is, there was no comparative group. As such, any signalling questions attaining to the comparisons between two groups were not considered for these study designs. As no RCT evidence was identified for inclusion, we did not use the Cochrane risk of bias tool.²⁷ Risk of bias was assessed by a single reviewer and checked by a second reviewer.

Method of data synthesis

The results of data extraction are presented in structured tables and as a narrative summary. A statistical synthesis using meta-analysis was proposed in the protocol. However, due to the diversity in conduct and outcomes reported, it was judged inappropriate to combine any studies in meta-analysis.

Chapter 3 Clinical effectiveness review results

General summary of evidence

The literature searches of bibliographic databases and registers identified 2699 references. Of those, 662 were duplicates and were removed. After screening of titles and abstracts, 512 were considered potentially relevant and the full-text articles were obtained. Eighty-one reports comprising 42 studies were ultimately included and 431 references excluded. Six of the included studies were identified from additional searching (company submission and websites).²⁸⁻³³ Eighty-six supporting references were submitted by the four companies. The full study selection process is illustrated in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram in [Figure 2](#). The 431 studies excluded at full-text stage are listed in [Appendix 4, Table 41](#) along with their reasons for exclusion.

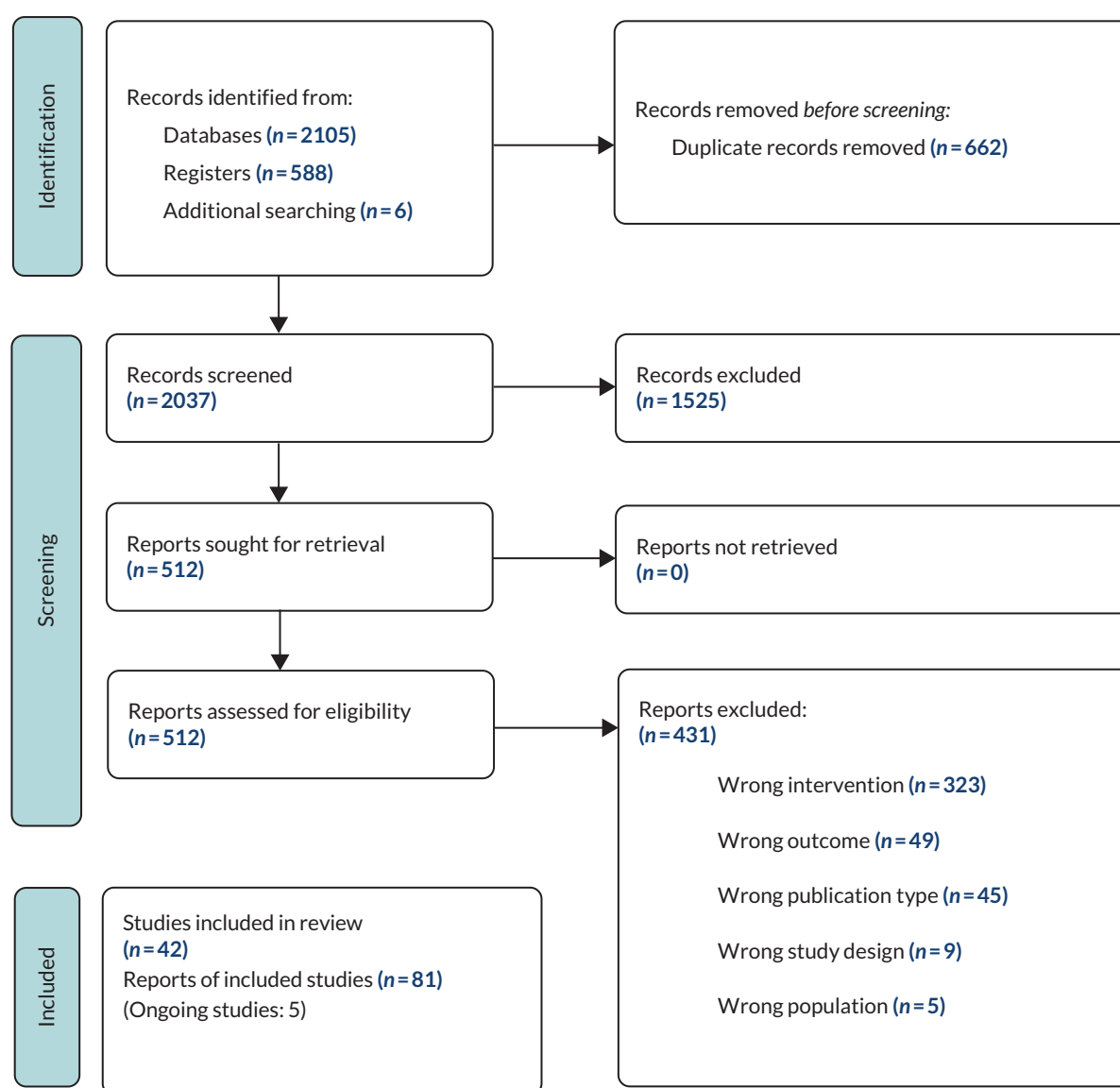


FIGURE 2 The PRISMA flow diagram of the study selection process for clinical effectiveness review.

Overview of the included studies

Five studies have been placed in awaiting classification ([Appendix 5, Table 42](#)). Forty-two studies met the eligibility criteria and have results which are synthesised in this systematic review. The study characteristics of the 42 included studies are given in [Appendix 6, Tables 43–46](#). In summary, 1 study was identified for the HeartInsight algorithm (BIOTRONIK), 8 for the CorVue algorithm (Abbott Laboratories), 14 for TriageHF (Medtronic) and lastly, 19 for HeartLogic (Boston Scientific). One study for CorVue was comparative,³⁴ three studies for HeartLogic were comparative,^{35–37} and one study for TriageHF was comparative.²⁸ The one identified HeartInsight study was conducted in Italy and Spain. Where stated, most studies for CorVue were carried out in the USA, most studies evaluating TriageHF were conducted in the UK, studies of HeartLogic were mostly conducted in Italy followed by the USA. Overall, eight studies were conducted in the UK, six for TriageHF and two for HeartLogic.

Of the 42 included studies, 26 were reported as being prospective cohorts, 10 were retrospective cohorts, 4 were described as cohorts and 2 as development and validation studies using data sets from observational and RCTs. There were no RCTs included and comparative evidence was limited to five studies.^{28,34–37}

Summary of study designs and outcomes

Outcomes provide evidence on the prognostic performance of an algorithm and association with clinical outcomes, comparative effectiveness of an algorithm, and implementation characteristics of an algorithm. Observational, single cohort study designs may provide evidence on prognostic performance, association with clinical outcomes and implementation characteristics. A single cohort study that reports the relative risk of hospitalisation IN or OUT of alert may be considered to have some predictive value. Comparative study designs (before-and-after or concurrent controlled studies) may provide evidence on comparative effectiveness and implementation characteristics. Especially, poor-quality studies providing evidence on comparative outcomes include single cohort studies that are treated as before-and-after studies where the baseline measure is considered an outcome measure in the absence of the intervention and retrospective medical chart reviews of CorVue compared to standard care.

Broad definitions of HF events used to determine the prognostic accuracy of the algorithms included combinations of changes to clinical management, hospitalisations and, to a lesser extent, mortality. Comparative outcomes could have included mortality, hospitalisations, changes to clinical management and length of hospital stay and patient-reported outcomes; but no comparative evidence was reported for mortality and patient-reported outcomes. Implementation characteristics may include alert response rates, software failure rate and number of monitoring reviews.

Outcomes are reported under the following sections:

- prognostic and association outcomes
- comparative outcomes
- implementation outcomes.

All the outcomes listed in the NICE scope and DA protocol are included in each of these sections as appropriate. All of the protocol outcomes (see [Outcomes](#)) were categorised into one of three groups: intermediate outcomes (diagnostic accuracy and predictive values), intermediate outcomes (other), and clinical outcomes. [Table 4](#) provides a more detailed description of the outcome domains assessed within the three categories.

[Table 5](#) categorises outcomes at the broadest level (prognostic, comparative, implementation). Outcome domain and quality of reporting varied within and across technologies.

TABLE 5 Categorisation of outcomes at the broadest level (prognostic, comparative effectiveness, implementation)

Research outcome type and study design	Intervention, clinical, patient outcome type	Scope/protocol outcomes
Prognostic accuracy and associations (single cohort study)	Intermediate- accuracy	False-positives, unexplained alert rates
	Intermediate- other	Not applicable
	Clinical	Changes to clinical management, hospitalisations, rate of HF events and mortality (cardiac and all-cause), HF events
	Patient-reported	Not applicable
Comparative (before-and-after study, controlled concurrent study, poor-quality single cohort study)	Intermediate- accuracy	Not applicable
	Intermediate- other	Not applicable
	Clinical	HF events, hospitalisations, mortality
	Patient-reported	Quality of life
Implementation (single cohort, before-and-after or controlled concurrent study)	Intermediate- accuracy	Not applicable
	Intermediate- other	Changes to clinical management, time between alert and HF event, alert response rates, number of emergency or urgent care visits, software failure rates, adverse events, number of monitoring reviews
	Clinical	Adverse events
	Patient-reported	Quality of life

Study quality

All studies that reported prognostic outcomes, including sensitivity and specificity, underwent risk of bias assessments at the study level using PROBAST. All non-randomised studies reporting clinical outcomes relevant to the PICO underwent risk of bias assessment at the study level using ROBINS-I. If a study reported both prognostic and clinical outcomes, they were appraised using both PROBAST and ROBINS-I. No studies were appraised using risk of bias because none of the included studies were RCTs. For prognostic outcomes, most eligible studies were external validations of previously developed predictive algorithms. Therefore, quality assessments were mainly conducted on validation studies, as data on the development of these algorithms were not available.

Risk of bias assessments for CorVue

Six external validation studies reported prognostic outcomes ([Table 6](#)).^{24,25,29,38–42} These were all assessed as being of high risk of bias. Of particular concern was the conduct or poor reporting of the analysis methods (e.g. small sample sizes and limited numbers of participants who experienced the outcome).

Five studies evaluating the CorVue algorithm reported relevant clinical outcomes and underwent risk of bias assessment using ROBINS-I²⁶ ([Table 7](#)). All studies were considered to be at serious or critical risk of bias due to the inherent limitations associated with confounding in cohort study designs, particularly retrospective designs.^{34,42–44}

Shapiro *et al.*³⁴ was the only CorVue study that included comparative data from patients who did not have the CorVue algorithm. The comparator was based on a retrospective medical chart review at substantial risk of confounding.

Risk of bias assessments for HeartInsight

One prospective cohort evaluated the prognostic accuracy in the development (sensitivity, specificity) and validation [sensitivity, specificity, negative predictive value (NPV) and positive predictive value (PPV)] of HeartInsight. This study was judged to be at high risk of bias due to concerns around the conduct or reporting in the analysis (such as missing data and the statistical analysis) ([Table 8](#)). There were no concerns about the applicability of the participants, predictors and outcomes to our research question ([Table 8](#)).

TABLE 6 PROBAST risk of bias and applicability assessment summary for CorVue studies

Study	Study design	Risk of Bias				Applicability			Overall	
		1. Parti- pants	2. Pred- ictors	3. Out- come	4. Anal- ysis	1. Parti- pants	2. Predic- tors	3. Out- come	Risk of bias	Applica- bility
Benezet Mazuecos, 2016	Cohort	?	+	?	-	+	+	+	-	+
Binkley, 2012	Cohort	-	-	-	-	-	+	+	-	+
Forleo, 2013	Cohort	+	?	+	-	-	?	+	-	+
Palfy, 2015	Cohort	?	?	?	?	+	+	+	-	+
Palfy, 2018	Cohort	+	+	?	-	+	+	+	-	+
Wakabayashi, 2021	Cohort	-	?	-	-	-	?	+	-	+

Key

+	Low risk of bias/concern
-	High risk of bias/concern
?	Unclear risk of bias/concern

TABLE 7 ROBINS-I risk of bias assessment summary for CorVue studies

Study Author, year	Study design	D1	D2	D3	D4	D5	D6	D7	Overall
Benezet Mazuecos, 2016	Cohort								Serious
Forleo, 2013	Prospective cohort								Serious
Santini, 2012	Cohort								Serious
Shapiro, 2017	Cohort with external comparator								Critical
Wakabayashi, 2021	Retrospective cohort								Critical

D1: Bias due to confounding

D2: Bias due to selection of participants

D3: Bias in classification of interventions

D4: Bias due to deviation from intended interventions

D5: Bias due to missing data

D6: Bias in measurement of outcomes

D7: Bias in selection of the reported result

Key

	Low risk of bias
	Moderate risk of bias
	Serious risk of bias
	Critical risk of bias
	No information

TABLE 8 PROBAST risk of bias and applicability assessment summary for HeartInsight

Study Author, Year	Study design	Risk of bias				Applicability			Overall	
		1. Partici- pants	2. Predic- tors	3. Outcome	4. Analysis	1. Participants	2. Predictors	3. Outcome	Risk of bias	Applicability
D'Onofrio, 2022	Prospective cohort	+	+	+	-	+	+	+	-	+

Key

+	Low risk of bias/concern
-	High risk of bias/concern
?	Unclear risk of bias/concern

TABLE 9 ROBINS-I risk of bias assessment for HeartInsight

Study Author, year	Study design	D1	D2	D3	D4	D5	D6	D7	Overall
D'Onofrio, 2022	Prospective cohort								Serious

D1: Bias due to confounding
D2: Bias due to selection of participants
D3: Bias in classification of interventions
D4: Bias due to deviation from intended interventions
D5: Bias due to missing data
D6: Bias in measurement of outcomes
D7: Bias in selection of the reported result

Key

	Low risk of bias
	Moderate risk of bias
	Serious risk of bias
	Critical risk of bias
	No information

Important concerns about missing data in the D'Onofrio *et al.* study were identified, which led to an overall risk of bias rating of serious concerns.⁴⁵ In addition, moderate concerns about confounding were also identified ([Table 9](#)).

Risk of bias assessments for HeartLogic

There was judged to be high risk of bias associated with the analysis methods used in all eligible studies evaluating prognostic accuracy outcomes for HeartLogic. These issues can be attributed to a lack of robust analysis, and small number of included participants with the outcome. There were no concerns regarding the applicability of the primary studies to our review question ([Table 10](#)).

Five of the studies which included clinical outcomes were at critical risk of bias, and caution should be given when interpreting the findings because the studies are too problematic to draw inferences with any degree of reliability ([Table 11](#)).^{35,46–50} The critical risk of bias for all studies, including Chang *et al.*, a retrospective cohort with comparative data, can be explained by a lack of robust analysis to attempt to control for confounding and small participant numbers. The only other studies to include comparative data for HeartLogic, a propensity matched cohort by Feijen *et al.* and a pre-post study by Treskes *et al.*, was at serious risk of bias due to classification of interventions and problems with uncontrolled confounding, respectively. Gardner *et al.*, a post hoc analysis from a prospective cohort, was the only study to be considered as low risk of bias in all seven domains.

TABLE 10 PROBAST risk of bias and applicability assessment summary for HeartLogic

Study Author, Year	Study design	Risk of Bias				Applicability			Overall	
		1.Partici- pants	2. Predic- tors	3. Out- come	4. Anal- ysis	1.Partici- pants	2. Predic- tors	3. Out- come	Risk of bias	Applica- bility
Boehmer, 2017	Prospective cohort	+	+	+	-	+	+	+	-	+
De Juan Baguda, 2022 (phase 1)	Retrospective cohort	+	?	?	-	+	?	+	-	+
De Juan Baguda, 2022 (phase 2 and 3)	Prospective cohort	+	?	?	-	+	?	+	-	+
De Ruvo, 2019	Prospective cohort	-	?	?	-	+	?	+	-	+
Henry, 2022	Retrospective cohort	+	?	+	-	+	?	+	-	+
Santobuono, 2023	Prospective cohort	?	?	+	-	+	?	+	-	+
Treskes, 2021	Retrospective pre-post study design	+	+	+	-	+	+	+	-	+
Vigdor, 2020	Prospective cohort	?	?	+	-	+	?	+	-	+
Wariar, 2023	Retrospective cohort	?	?	?	-	+	?	+	-	+

Key

+	Low risk of bias/concern
-	High risk of bias/concern
?	Unclear risk of bias/concern

TABLE 11 ROBINS-I risk of bias assessments for HeartLogic

Study Author, year	Study design	D1	D2	D3	D4	D5	D6	D7	Overall
Calo, 2021	Prospective cohort								Moderate
Chang, 2020	Retrospective cohort with external comparator								Critical
De Juan Baguda, 2022 (phase 1)	Retrospective cohort								Serious
De Juan Baguda, 2022 (phase 2/3)	Prospective cohort								Serious
D'Onofrio 2023	Prospective cohort								serious
Ebrille, 2021	Prospective cohort								Critical
Feijen, 2023	Retrospective cohort (propensity matched)								Serious
Gardner, 2018	Prospective cohort (secondary analysis)								low
Guerra, 2022	Prospective cohort								Moderate
Henry, 2022	Retrospective cohort								Critical
Hernandez, 2022	Prospective cohort								Serious
Lerman, 2023	Retrospective cohort								Critical
Pecora, 2020	Prospective cohort								Serious
Perez Serrano, 2019	Prospective cohort								Critical

continued

TABLE 11 ROBINS-I risk of bias assessments for HeartLogic (continued)

Study Author, year	Study design	D1	D2	D3	D4	D5	D6	D7	Overall
Santini, 2020	Prospective cohort								Serious
Santobuono, 2023	Prospective cohort								Moderate
Treskes, 2021	Retrospective pre-post study design								Serious
Vigdor, 2020	Prospective cohort								Serious

D1: Bias due to confounding

D2: Bias due to selection of participants

D3: Bias in classification of interventions

D4: Bias due to deviation from intended interventions

D5: Bias due to missing data

D6: Bias in measurement of outcomes

D7: Bias in selection of the reported result

Key

	Low risk of bias
	Moderate risk of bias
	Serious risk of bias
	Critical risk of bias
	No information

Risk of bias assessments for TriageHF

The overall risk of bias and applicability is unclear for three of the studies assessed because they were abstracts and contained limited information (Table 12).⁵¹⁻⁵³

TABLE 12 PROBAST risk of bias and applicability assessment summary for TriageHF

Study Author, Year	Study design	Risk of bias				Applicability			Overall	
		1. Partici- pants	2. Predic- tors	3. Out- come	4. Anal- ysis	1. Partici- pants	2. Predic- tors	3. Out- come	Risk of bias	Applicability
Ahmed, 2020	Cohort	+	+	-	-	-	+	-	High	High
Ahmed 2022	Cohort	+	+	-	-	-	+	+	High	High
Bachtiger, 2021	Prospective cohort	?	?	?	?	+	?	?	Unclear	Unclear
Burri, 2018	Cohort (secondary analysis)	+	+	+	?	+	+	+	Unclear	Low
Cardoso, 2021	Prospective cohort	?	?	+	?	?	?	+	Unclear	Unclear
Cowie, 2013	Validation and development study - observational and randomised	+	+	+	?	+	+	+	Unclear	Low
Gula, 2014	Validation study - using data from RCT	+	+	+	+	-	+	-	Low	High
Koehler, 2019	Cohort	+	?	+	?	?	?	+	Unclear	Unclear

TABLE 12 PROBAST risk of bias and applicability assessment summary for TriageHF (continued)

Study	Study design	Risk of bias				Applicability			Overall	
Author, Year		1. Participants	2. Predictors	3. Outcome	4. Analysis	1. Participants	2. Predictors	3. Outcome	Risk of bias	Applicability
Okumura, 2020	Prospective cohort	+	+	–	–	+	+	+	High	Low
Sammot-Powell, 2022	Prospective cohort	+	+	+	–	+	+	+	High	Low
Zile, 2020	Retrospective cohort	+	+	–	–	+	+	+	High	Low

Key

+	Low risk of bias/concern
–	High risk of bias/concern
?	Unclear risk of bias/concern

Ahmed *et al.*, the only study to provide comparative data for TriageHF, is at critical risk of bias due to missing information, including whether propensity score matching was successful and the majority of hospitalisations being unrelated to HF or cardiovascular disease (Table 13). In addition, three other studies are at critical risk of bias due to issues with confounding and four are at serious risk of bias because of confounding or the poor reporting of data. No studies that were assessed using ROBINS-I were at low risk of bias.

TABLE 13 ROBINS-I risk of bias assessment summary for TriageHF

Study Author, year	Study design	D1	D2	D3	D4	D5	D6	D7	Overall
Ahmed (AiC)	Prospective cohort with comparator	Critical	Unclear	Low	Unclear	Unclear	Low	Unclear	Critical
Burri, 2018	Cohort (secondary analysis)	Critical	Critical	Unclear	Unclear	Unclear	Unclear	Unclear	Critical
Debski, 2021	Prospective cohort	Unclear	Unclear	Low	Unclear	Unclear	Unclear	Unclear	No information
Garner, 2022	Prospective cohort	Critical	Low	Low	Low	Low	Unclear	Low	Critical
Virani, 2018	Prospective cohort	Critical	Low	Low	Low	Unclear	Unclear	Unclear	Critical
Zile, 2020	Retrospective cohort	Unclear	Unclear	Unclear	Low	Unclear	Unclear	Unclear	Serious
Zile, 2021	Prospective cohort	Unclear	Unclear	Low	Unclear	Unclear	Low	Unclear	Serious

D1: Bias due to confounding

D2: Bias due to selection of participants

D3: Bias in classification of interventions

D4: Bias due to deviation from intended interventions

D5: Bias due to missing data

D6: Bias in measurement of outcomes

D7: Bias in selection of the reported result

Key

Low risk of bias
Moderate risk of bias
Serious risk of bias
Critical risk of bias
No information

Prognostic accuracy and association outcomes

Prognostic accuracy

This section reports the development of algorithm analytics to determine alerts, and prognostic accuracy defined as sensitivity and specificity. All measures of predictive accuracy associated with algorithm alerts (sensitivity, specificity, rate ratios, hazard ratios (HRs), relative risks, odds ratios and percentages of clinical outcomes) for specific outcomes are reported in subsequent sections for each outcome definition.

Results for the accuracy of the algorithms were available in 24 studies: HeartLogic $n = 8$, CorVue $n = 5$, TriageHF $n = 10$, and HeartInsight $n = 1$.

HeartInsight was developed and externally validated using data from the selection of potential predictors of worsening HF (SELENE-HF) study.⁴⁵ The algorithm was developed using both CRT-D and ICD devices. An index was developed using remote monitoring variables (Table 14) to develop a linear combination of the variables after numerical processing. In this study, index levels of 3.5, 4.0, and 4.5 were assessed.⁴⁵ In the development cohort, a unitary increase of the index value was associated with an OR of 2.73 (95% CI 1.98 to 3.78; $p < 0.001$) for the first postimplant worsening HF hospitalisation.⁴⁵ The results suggested that the nominal threshold of 4.5 had the potential to identify worsening HF-related to hospitalisations (see Table 14).⁴⁵

HeartLogic was developed and externally validated using data from the evaluation of multisensory data in HF patients with implanted devices (MultiSENSE) study.⁵⁶ The algorithm was developed using only CRT-D devices. An index was developed using remote monitoring variables (see Table 14), from which a nominal threshold was developed (i.e. ≥ 16). If this threshold was crossed the algorithm was deemed to be IN alert, if not the patient was classified as OUT of alert.⁵⁶

TABLE 14 Algorithm components and alert threshold for CorVue, HeartInsight, HeartLogic and TriageHF

Algorithm components and threshold for alerts			
CorVue	HeartInsight	HeartLogic	TriageHF ⁵⁴ (CRT-D, ICD-DR, ICD-VR, CRT-P and DR-IPG)
1. Intrathoracic impedance (ITI) ^{a,b}	1. Atrial burden 2. Heart rate variability 3. General activity 4. Thoracic impedance 5. Heart rate 6. Heart rate at rest 7. Premature ventricular contractions 8. Baseline rate parameter Seattle Heart Failure Model (SHFM) (optional)	1. Heart sounds (S1 and S3) 2. Thoracic impedance 3. Respiratory rate and tidal volume 4. Nocturnal heart rate 5. Activity level	1. OptiVol 2. Patient activity 3. AT/AF burden ^c 4. Ventricular rate during AT/AF ^c 5. % Ventricular pacing ^d 6. Shocks ^e 7. Treated VT/VF ^e 8. Night ventricular rate 9. Heart rate variability
12 measurements are taken daily (every 2 hours) and compared to a reference impedance (mean impedance of previous 12–14 days). If the mean daily impedance is less than the reference impedance for 13–14 consecutive days (ICD and CRT-D, respectively) an alert is triggered	Transmissions were calculated daily; HF scores equal to or greater than the nominal threshold of 4.5 triggered an alert. Following an alert, the threshold was reduced to a recovery threshold of 3.5. When a HF score dropped below 3.5 the alert was cancelled	Alerts are triggered when the index exceeds the nominal threshold of 16 and moves into an 'alert-state'. Alerts continue until the index falls below the threshold of 6 and moves to an 'out-of-alert state'	HF risk is calculated based on the parameters measured from previous 30 days the risk status is calculated into low (< 0.054), medium ($0.054–0.20$) and high risk (≥ 0.20) of HF ⁵⁵

CRT-D, cardiac resynchronisation therapy with defibrillator; ICD-DR, implantable cardioverter defibrillator dual chamber; ICD-VR, implantable cardioverter defibrillator single chamber.

a ITI measured as a multi-vector between right ventricular ring to can and right ventricular coil to can for ICD devices.⁴⁰

b ITI measured as a multi-vector left ventricular ring to can and right ventricular coil to can for CRT-D devices.

c Not applicable for ICD-VRs.

d Not applicable for ICD-DR, ICD-VR and DR-implantable pulse generator (IPG).

e Not applicable for CRT-P (cardiac resynchronisation therapy with pacemaker) and DR-IPG devices.

The nominal threshold was suggested to be effective at predicting HF events (see [Table 14](#)).⁵⁶ One study assessed the accuracy of the HeartLogic algorithm in a management strategy, where they applied the nominal threshold of ≥ 16 and also a threshold of ≥ 20 .⁵⁷

The feasibility of using the CorVue algorithm, which uses impedance measures derived from a number of vector combinations (see [Table 14](#)), was assessed using a retrospective cohort, showing low sensitivity with patients implanted with CRT-Ds ([Table 15](#)).²⁹ Similar results were reported when assessing HF events in other retrospective cohorts (see [Table 15](#)) (Forleo 2013; Wakabayashi 2021).^{38,42} Further cohort studies reported a much lower sensitivity ($< 30\%$) and suggested the use of the CorVue algorithm could provide misleading information (see [Table 15](#)).^{40,43}

TriageHF was developed and externally validated using data collected in a number of trials (development: OFISSER,⁵⁸ Italian Clinical Service Project,⁵⁹ and CONNECT;⁶⁰ validation: PARTNERS-HF,⁶¹ Fluid Accumulation Status Trial (FAST),⁶² PRECEDE-HF⁶³ and SENSE-HF⁶⁴).³⁰ The algorithm includes multiple parameters (see [Table 14](#)) with the aim of developing a risk score for the identification of patients at higher risk of HF. Patients with a high risk score were identified as being 10 times more likely to have a HF hospitalisation in the next 30 days (HR 10, 95% CI 6.4 to 15.7; $p < 0.001$) compared to the low risk group. Results were similar when adjusted for the presence of HF hospitalisation in the last 30 days (HR 8.2, 95% CI 5.1 to 13.1; $p < 0.001$).³⁰ The TriageHF risk score was also reported to have acceptable discriminatory ability when assessing worsening HF, compared to clinical diagnosis alone or alongside an acute medical problem (see [Table 15](#)).⁶⁵ In contrast, data from the MOnitoring Resynchronization dEVICES and CARdiac patiEnts (MORE-CARE) study were utilised to assess the impact of a high risk score from the TriageHF algorithm with sensitivity reported $< 40\%$ for 30-day HF hospitalisations, cardiovascular hospitalisations and non-HF-related cardiovascular hospitalisations (see [Table 15](#)).^{33,66} Sensitivity was also low for all cause, cardiovascular and HF hospitalisations in a prospective cohort (see [Table 15](#)).⁶⁷ Similar results were observed in a prospective analysis of patients in high risk compared to medium and low risk categories. However, when combining high and medium risk, compared to low risk, sensitivity was improved (see [Table 15](#)).⁶⁸

One study assessed the accuracy of TriageHF and reported calibration, comparing TriageHF with an updated version (this model was not considered in this review as we were only concerned with the current TriageHF model).⁶⁹ However, the original version of TriageHF showed reasonable calibration (calibration in the large 0.15, 95% CI -0.74 to 2.09 ; slope 1.08, 95% CI 0.57 to 2.07), but its discriminatory ability of predicting HF-related mortality was low (see [Table 15](#)).⁶⁹

False-positive rates

Results of false positives tests were reported in 15 studies, HeartLogic $n = 7$, CorVue $n = 7$, TriageHF $n = 2$, and HeartInsight $n = 1$ ([Table 16](#)). The false positive rate is the most important statistic. The percentage of alerts that are false is less useful because it provides less information on the burden on the health system. The Evidence Assessment Group (EAG) has not calculated the percentage of alerts that were false to focus attention on false positive rates.

HeartInsight

The study reporting the accuracy of HeartInsight defined the false positive alert as an alert that was not followed by the primary or secondary study end point (see [Table 16](#)).⁴⁵

CorVue

One CorVue study defined a false positive as an alert after which no HF event occurred within 14 days.³⁸ Another defined a false positive as an alert that began more than 30 days before a clinical event was classified.²⁹ One study did not define a time period for false positives and merely stated that a false positive occurred if an alert was detected without subsequent clinical event.⁴⁰ Three studies did not explicitly define a false positive.^{42,43,75}

HeartLogic

Two HeartLogic studies defined the false positive rate as the ratio of the total number of alerts that were not true positive alerts over the total usable follow-up duration.^{56,72} One study defined a false positive as three consecutive remote evaluations (at 2, 6 and 10 weeks after the initial alert) with consistently fewer than two symptoms or signs of HF at each evaluation, an ongoing alert was disregarded.^{19,36} Similarly, Treskes *et al.* defined a false positive as occurring

TABLE 15 Studies reporting predictive accuracy measures

Author (year)	Study design (n)	Intervention	Study end point	AUC (95% CI)	Sensitivity (95% CI; %)	Specificity (95% CI; %)	PPV (95% CI; %)	NPV (95% CI; %)
Boehmer (2017) ⁵⁶	Prospective cohort (overall n = 900 ^a ; validation n = 400) ^b	HeartLogic	HF events of hospitalisations and clinic visits with change to treatment with primary cause of HF worsening	NR	70.0 (55.4 to 82.1)	85.7	11.3	99.98
De Juan Baguda (2022) ⁷⁰	Phase 1 (n = 101) and 2 (n = 94) are retrospective cohorts Phase 3 (n = 267) is a prospective cohort	HeartLogic	HF events of hospitalisations and clinic visits with change to treatment with primary cause of HF worsening	NA	Phase 1 = 100 Phase 2 and 3 = 98	Phase 1 = 93 Phase 2 and 3 = 90	Phase 1 = 18 Phase 2 and 3 = 29	Phase 1 = 100 Phase 2 and 3 = 99.9
Vigdor (2020) ⁵⁷	Prospective cohort (n = 80)	HeartLogic	HF events of unscheduled visits or HF hospitalisations within 6-weeks of initial alert This study assessed the standard threshold of ≥ 16 and an alternative threshold of ≥ 20	NA	Threshold ≥ 16 = 92 ≥ 20 = 69	Threshold ≥ 16 = 61 ≥ 20 = 90	Threshold ≥ 16 = 32 ≥ 20 = 56	Threshold ≥ 16 = 98 ≥ 20 = 94
De Ruvo (2019) ⁷¹	Prospective cohort (n = 101)	HeartLogic	hospitalisations and unplanned office visits	NA	100	NR	58	NR
Binkley (2012) ²⁹	Retrospective cohort (n = 61 ^a)	CorVue	HF events of hospitalisations and clinic visits with change to treatment with primary cause of HF worsening	NA	61.9	NR	40.6	NR
Forleo (2013) ³⁸	Prospective cohort (n = 80)	CorVue	HF events of HF hospitalisations requiring treatment changes and HF hospitalisations alone	NA	HF events = 61.5 (46 to 75) HF hospitalisations = 53.8 (29 to 77)	NR	HF events = 42.9 (31 to 56) HF hospitalisations = 17.9 (9 to 33)	
Benezet Mazuecos (2016) ⁴³	Cohort, unclear (n = 70)	CorVue	HF events of hospitalisations and clinic visits with change to treatment with primary cause of HF worsening and unplanned office visits	NR	20	77	5	94
Palfy (2018) ⁴⁰	Prospective cohort (n = 53)	CorVue	HF events of hospitalisations and clinic visits with change to treatment with primary cause of HF worsening	NR	24	70	6	93

Author (year)	Study design (n)	Intervention	Study end point	AUC (95% CI)	Sensitivity (95% CI; %)	Specificity (95% CI; %)	PPV (95% CI; %)	NPV (95% CI; %)
Burri (2018) ³³	Retrospective analysis of a single study (n = 722)	TriageHF	Cardiovascular or HF or non-HF-related hospitalisations	NR	All values are for high risk status Cardiovascular hospitalisations = 25.5 (18.8 to 33.6) HF hospitalisations = 37.4 (26.5 to 49.8) Non-HF cardiovascular hospitalisations = 15.4 (9.2 to 24.7)	All values are for high risk status Cardiovascular hospitalisations = 90.2 (88.6 to 91.5) HF hospitalisations = 90.1 (88.6 to 91.5) Non-HF cardiovascular hospitalisations = 89.9 (88.3 to 91.3)	All values are for high risk status Cardiovascular hospitalisations = 5.8 (3.9 to 8.5) HF hospitalisations = 4.1 (2.5 to 6.7) Non-HF cardiovascular hospitalisations = 1.7 (0.9 to 3.0)	All values are for high risk status Cardiovascular hospitalisations = 98.0 (97.5 to 98.4) HF hospitalisations = 99.1 (98.7 to 99.4) Non-HF cardiovascular hospitalisations = 98.9 (98.5 to 99.2)
Okumura (2020) ⁶⁸	Prospective cohort (n = 315)	TriageHF	HF hospitalisations requiring treatment changes	NR	High vs. Medium + low = 31.5 High + Medium vs. low = 78.7	High vs. Medium + low: 89.0 High + Medium vs. low: 44.4	High vs. Medium + low: 4.1 High + Medium vs. low: 2.1	High vs. Medium + low: 98.8 High + Medium vs. low: 99.3
Sammut-Powell (2022) ⁶⁷	Prospective cohort (n = 435)	TriageHF	All cause or cardiovascular or HF-related hospitalisations	NR	For high risk All cause hospitalisation = 37.3 Cardiovascular hospitalisation = 39.3 HF hospitalisations = 62.5	For high risk All cause hospitalisation = 86.2 Cardiovascular hospitalisation = 85.7 HF hospitalisations = 85.6	NR	For non-high risk All cause hospitalisation = 97.5 Cardiovascular hospitalisation = 99.1 HF hospitalisations = 99.7
D'Onofrio (2022) ⁴⁵	Prospective cohort (overall n = 918 ^a ; validation n = 461) ^b	HeartInsight	Secondary: any HF hospitalisation, outpatient IVI or death	Secondary end point NR	3.5 = 64.5 (51.3 to 76.2) 4.0 = 59.7 (46.4 to 71.9) 4.5 = 54.8 (41.7 to 67.5)	3.5 = 75.3 (75.2 to 75.4) 4.0 = 82.0 (81.9 to 82.2) 4.5 = 86.5 (86.4 to 86.6)	3.5 to 4.5 = 5.3 to 7.7	3.5 to 4.5 = 96.6 to 96.7
Koehler (2019) ⁵³	Retrospective analysis of registry data (n = 13 122)	TriageHF	HF hospitalisation, outpatient IVI, or death	NR	High risk = 41	High risk = 86	NR	NR
Santobuono (2023) ⁷²	Prospective cohort (n = 568)	HeartLogic	Hospitalisation or death	NA	Hospitalisation alone 66 (52 to 78) Hospitalisation or death 67 (57 to 75)	NR	NR	NR

continued

TABLE 15 Studies reporting predictive accuracy measures (continued)

Author (year)	Study design (n)	Intervention	Study end point	AUC (95% CI)	Sensitivity (95% CI; %)	Specificity (95% CI; %)	PPV (95% CI; %)	NPV (95% CI; %)
Treskes (2021) ³⁷	Retrospective pre-post analysis (n = 68)	HeartLogic	Hospital admission	NA	90 (77 to 97)	89 (79 to 95)	NR	NR
Cowie (2013) ³⁰	Retrospective analysis of seven studies (overall n = 2231, development n = 921, validation n = 1310)	TriageHF	Hospital admission	NR	Low/medium risk score (5%) = 82.8 Medium/high risk score (20%) = 46 Risk score 10% = 68.7	Low/medium risk score (5%) = 45.8 Medium/high risk score (20%) = 90.2 Risk score 10% = 71.6	NR	NR
Cardoso (2020) ⁵²	Prospective cohort (n = 94)	TriageHF	Hospital admission	0.812	NR	NR	NR	NR
D'Onofrio (2022) ⁴⁵	Prospective cohort (overall n = 918; validation n = 378) ^b	HeartInsight	Primary: First post implant worsening HF hospitalisation	Primary end point NR	3.5 = 72.4 (52.8 to 87.3) 4.0 = 65.5 (45.7 to 82.1) 4.5 = 65.5 (45.7 to 82.1)	3.5 = 75.8 (75.6 to 75.9) 4.0 = 82.4 (82.3 to 82.5) 4.5 = 86.7 (86.6 to 86.8)	NR	NR
Bachtiger (2021) ⁵¹	Prospective cohort (n = 72)	TriageHF	Worsening HF	NR	High risk = 87.9 (77.0 to 99.0)	High risk = 59.4 (50.0 to 69.0)	High risk = 40.3	High risk = 94.0
Ahmed (2020) ⁶⁵	Prospective cohort (n = 231)	TriageHF	Worsening HF (undefined)	0.75 (0.69 to 0.80)	High risk = 98.6 (92.5 to 100)	High risk = 63.4 (55.2 to 71.9)	NR	NR
Wakabayashi (2021) ⁴²	Retrospective cohort (n = 49)	CorVue	HF event defined by the Framingham Heart Study	NR	68 (48 to 84)	NR	21 (13 to 30)	NR
Ahmed (2022) ⁶⁹	Prospective cohort (n = 439)	TriageHF	Mortality	0.61 (0.56 to 0.66)	NR	NR	NR	NR

Author (year)	Study design (n)	Intervention	Study end point	AUC (95% CI)	Sensitivity (95% CI; %)	Specificity (95% CI; %)	PPV (95% CI; %)	NPV (95% CI; %)
Zile (2020) ⁷³	Retrospective cohort (monthly downloads n = 22 901; alert triggered n = 21,356; daily downloads n = unclear)	TriageHF	HF events (undefined)	NR	Monthly downloads high risk score = 39 Monthly downloads medium risk score = 85 Alert triggered high risk score = 47 Daily downloads high risk score = 51 Daily downloads medium risk score = 93	Monthly downloads high risk score = 89 Monthly downloads medium risk score = 44 Alert triggered high risk score = NR Daily downloads high risk score = NR Daily downloads medium risk score = NR	NR	NR
Henry (2022) ⁴⁷	Retrospective cohort (n = NR)	HeartLogic	HF events (undefined)	NA	70	NR	NR	NR
Wariar (2023) ⁷⁴	Retrospective cohort (n = 1567)	HeartLogic	HF events (undefined)	NA	82 (78.1 to 85.5)	NR	NR	NR

HF, heart failure; IVI, intravenous intervention; NA, not applicable; NR, not reported.

a Denotes number analysed.

b Denotes that the study reported development and validation cohorts but only the validation is reported in the table.

Note

Studies are grouped by outcomes: hospitalisation, clinic visits and changes to treatment; hospitalisation or death; hospital admission alone; worsening HF; mortality alone; and HF events (undefined); with solid black lines showing the end of each outcome group; if threshold is not reported the nominal threshold was used: see [Table 14](#)

TABLE 16 Evidence for the outcome of number of false positives and false positive rates for the algorithms

Author (year)	Study design (n)	Intervention	Number of false positives	False positive rate
Santini (2012) ⁷⁵	Cohort, unclear (n = 38)	CorVue	10 of 23 alerts in 16 patients	NR
Benezet Mazuecos (2016) ⁴³	Cohort, unclear (n = 70)	CorVue	99 of 104 alerts in 40 patients	NR
Forleo (2013) ³⁸	Prospective cohort (n = 80)	CorVue	23 patients with 32 episodes	0.6 alerts per patient year (32 episodes/53.477 patient years)
Binkley (2012) ²⁹	Retrospective cohort (n = 61 ^a)	CorVue	19 of 32 alerts	0.63 (SD: 0.1) alerts per patient year
Palfy (2015) ⁴¹	Cohort, unclear (n = 65)	CorVue	78 of 83 alerts in 32 patients	NR
Palfy (2018) ⁴⁰	Prospective cohort (n = 53)	CorVue	99 of 105 alerts	NR
Wakabayashi (2021) ⁴²	Retrospective cohort (n = 49)	CorVue	76 of 96 alerts	NR
Boehmer (2017) ⁵⁶	Prospective cohort (overall n = 900 ^a , development n = 500, validation n = 400)	HeartLogic	Development = NR Validation = NR	False positive rate ^b Development = NR Validation = 1.56 (95% CI 1.41 to 1.77)
Vigdor (2020) ⁵⁷	Prospective cohort (n = 80)	HeartLogic	26 of 38 patients experienced at least 1 false positive alert	NR
Wariar (2023) ⁷⁴	Retrospective cohort (n = 1567)	HeartLogic	NR	False positive rate ^b = 1.401 (95% CI 1.332 to 1.475)
Santobuono (2023) ⁷²	Prospective cohort (n = 568)	HeartLogic	NR	False positive rate ^b reported by study end point Cardiovascular hospitalisation = 0.99 (95% CI 0.93 to 1.05) Cardiovascular hospitalisation or death = 0.94 (95% CI: 0.89 to 0.99)
De Juan Baguda (2022) ⁷⁰	Phase 1 (n = 101) and 2 (n = 94) are retrospective cohorts Phase 3 (n = 267) is a prospective cohort	HeartLogic	Phase 1 = NR Phase 2 and 3 = NR	Phase 1 = 0.39 alerts per patient year Phase 2 and 3 = 0.64 alerts per patient year
Feijen (2023) ^{19,36}	Propensity matched retrospective cohort (n = 161)	HeartLogic	33 of 130 alerts	NR
Treskes (2021) ³⁷	Retrospective pre-post analysis (n = 68)	HeartLogic Remote monitoring pre-activation	8 of 51 alerts	NR
Garner (2022) ³¹	Prospective cohort (n = 749)	TriageHF	68 of 376 alerts	NR
Zile (2020) ⁷³	Retrospective cohort (monthly downloads n = 22 901; alert triggered n = 21,356; daily downloads n = unclear)	TriageHF		High risk status = 0.48 per patient year

TABLE 16 Evidence for the outcome of number of false positives and false positive rates for the algorithms (*continued*)

Author (year)	Study design (n)	Intervention	Number of false positives	False positive rate
D'Onofrio (2022) ⁴⁵	Prospective cohort (overall n = 918, development n = 457, validation n = 461)	HeartInsight	Development = NR Validation = NR	False positive rate per patient year reported by study end point and varying thresholds Development = NR Validation [per patient year (95% CI)] First post implant HF hospitalisation Threshold 3.5 = 1.07 (1.00 to 1.13) Threshold 4.0 = 0.86 (0.80 to 0.92) Threshold 4.5 = 0.69 (0.64 to 0.74) Any HF hospitalisation, outpatient IV, or death related to HF Threshold 3.5 = 1.05 (0.99 to 1.12) Threshold 4.0 = 0.85 (0.79 to 0.91) Threshold 4.5 = 0.67 (0.62 to 0.73)

CI, confidence interval; NR, not reported.

a Denotes number analysed.

b Denotes false positive rate was defined as the ratio of the total number of alerts that were not true-positive alerts over the total usable follow-up duration.

after three remote evaluations with no or less than two symptoms or signs of HF per evaluation, where the alert was then disregarded.³⁷ One study defined false positive alerts as unexplained alerts plus explained alerts.⁷⁰

TriageHF

One TriageHF study included here did not explicitly report false positives but the false positives were calculated based on the number of high risk alerts that did not require any further intervention.³¹ The other reported false positives (also termed unexplained detections) per patient year.⁷³

Unexplained alert rates

Unexplained alerts were reported in 10 studies: HeartLogic n = 7, CorVue n = 2, TriageHF n = 0, HeartInsight n = 1 (Table 17).

HeartInsight

HeartInsight unexplained alerts were defined as a false positive alert that was not followed by an adverse event.⁴⁵

HeartLogic

For HeartLogic, there were numerous interpretations of an unexplained alert. Henry *et al.* (2022)⁴⁷ defined the unexplained alert rate as the number of alerts per patient-year not followed by a HF event within 2 months. Boehmer *et al.* (2017)⁵⁶ reported that an unexplained alert was recorded when there was no HF event, including HF admissions with a secondary cause of HF or oral HF therapy in an outpatient setting, as well as events that did not meet data availability criteria or occurred within 45 days of device conversion. Treskes *et al.* (2021) used a similar definition to Boehmer *et al.* (2017). An unexplained alert was recorded when there was no HF event, including HF admissions with a secondary cause of HF or oral HF therapy in an outpatient setting, as well as events that did not meet data availability criteria or occurred within 45 days of device conversion.³⁷ Feijen *et al.* (2023)³⁶ defined the unexplained alert rate as the number of alerts that could not be explained by worsening HF per patient year. De Juan Baguda *et al.* (2022)⁷⁰ reported that an unexplained alert was recorded when there was no HF decompensation or no relevant clinical conditions were identified (e.g. dietary or medication indiscretion) that could produce HF decompensation. One HeartLogic study reported 105 alerts of 242 were not followed by HF therapy changes as they were deemed nonactionable, unexplained, or associated with non-HF-related conditions.⁷⁶

TABLE 17 Evidence for studies reporting unexplained alert rates for the algorithms

Author (year)	Study design (n)	Intervention	Number of unexplained alerts	Unexplained alert rate
D'Onofrio (2022) ⁴⁵	Prospective cohort (overall n = 918, development n = 457, validation n = 461)	HeartInsight	NR	Unexplained alert rate per patient year reported by study end point and varying thresholds Development = NR Validation (per patient year [95% CI]) First post implant HF hospitalisation Threshold 3.5 = 0.99 (0.93 to 1.05) Threshold 4.0 = 0.79 (0.74 to 0.85) Threshold 4.5 = 0.63 (0.58 to 0.68) Any HF hospitalisation, outpatient IV, or death related to HF Threshold 3.5 = 0.98 (0.92 to 1.05) Threshold 4.0 = 0.79 (0.73 to 0.85) Threshold 4.5 = 0.63 (0.58 to 0.68)
Treskes (2021) ³⁷	Retrospective pre-post analysis (n = 68)	HeartLogic	9 of 51 alerts	0.16 per patient year
Henry (2022) ⁴⁷	Retrospective cohort (n = NR)	HeartLogic	NR	0.7 per patient year
Boehmer (2017) ⁵⁶	Prospective cohort (overall n = 900 ^a , development n = 500, validation n = 400)	HeartLogic	NR	Development = 1.33 per patient year Validation = 1.47 per patient year
Perez Serrano (2019) ⁵⁰	Prospective cohort (n = 18)	HeartLogic	2 of 11 alerts	NR
De Juan Baguda (2022) ⁷⁰	Phase 1 (n = 101) and 2 (n = 94) are retrospective cohorts Phase 3 (n = 267) is a prospective cohort	HeartLogic	Phase 1 = 53 of 73 alerts Phase 2/3 = 120 of 277 alerts	Phase 1 = 0.52 per patient year Phase 2/3 = 0.39 per patient year
Santini (2020) ⁴⁴	Prospective cohort (n = 104)	HeartLogic	29 of 100 alerts	NR
De Ruvo (2019) ⁷¹	Prospective cohort (n = 101)	HeartLogic	NR	0.41 per patient year
Treskes (2021) ³⁷	Retrospective pre-post analysis (n = 68)	HeartLogic Remote monitoring pre-activation	9 of 51 alerts	0.16 per patient year
Feijen (2023) ³⁶	Propensity matched retrospective cohort (n = 161)	HeartLogic Conventional remote monitoring	NR	0.2 per patient year
Forleo (2013) ³⁸	Prospective cohort (n = 80)	CorVue	32 of 56 alerts	NR
Santini (2012) ⁷⁵	Cohort, unclear (n = 38)	CorVue	10 of 23 alerts	NR
NR, not reported. a Denotes number analysed.				

CorVue

For CorVue, unexplained alerts were defined in varying ways. Forleo *et al.* (2013)³⁸ unexplained detections occurred when congestion alert was not followed by a HF event within 2 weeks. Another study did not specifically state unexplained events, however, reported alerts were patients were asymptomatic without any sign of HF.⁷⁵

TriageHF

No studies reported unexplained alert rates for the TriageHF algorithm. One study used the terms false positives and as unexplained detections interchangeably, the evidence for this can be seen in the previous section.⁷³

Changes to clinical management

Changes to treatment were reported in 16 studies, HeartLogic $n = 12$, CorVue $n = 2$, TriageHF $n = 5$, and HeartInsight $n = 0$ (Table 18).

TABLE 18 Evidence from studies reporting changes to treatment

Author (year)	Study design (n)	Intervention	Alerts leading to change in treatment	Treatments changed
Hernandez (2022) ⁴⁸	Prospective cohort (n = 191)	HeartLogic	434 of 585 alerts 1777 of the 3290 weekly re-alerts until the HeartLogic index recovered below the nominal alert threshold	Diuretics = 1590 beta-blockers = 185 MRA = 132 ARNI = 124 ACE/ARBs = 108 Vasodilators = 69
Vigdor (2020) ⁵⁷	Prospective cohort (n = 80)	HeartLogic	12 of 38 alerts	Diuretic adjustments
Perez Serrano (2019) ⁵⁰	Prospective cohort (n = 18)	HeartLogic	5 of 11 alerts	NR
Pecora (2020) ⁷⁷	Prospective cohort (n = 104)	HeartLogic	43 of 100 alerts 11 of 1284 monthly remote follow-ups	NR
Ebrille (2021) ⁴⁶	Prospective cohort (n = 54)	HeartLogic	5 of 9 alerts Note: 3 of the events occurred due to inappropriate discontinuation of HF therapy	Diuretic dosage increase = 4 Electrical cardioversion (new-onset AF) = 1
De Juan Baguda (2022) ⁷⁰	Phase 1 (n = 101) and 2 (n = 94) are retrospective cohorts Phase 3 (n = 267) is a prospective cohort	HeartLogic	Phase 1 = NR Phase 2 = 12 of 44 alerts Phase 3 = 91 of 233 alerts	Phase 2 Diuretics or other drugs = 11 Change to device programming = 1 Patient education = 1 Phase 3 Diuretics or other drugs = 75 Change to device programming = 13 Patient education = 6 Cardioversion = 4 CPAP = 2 AVN ablation = 1
Santini (2020) ⁴⁴	Prospective cohort (n = 104)	HeartLogic	43 of 100 alerts	Diuretic dosage increase or other drug adjustment Device reprogramming/revision Cardioversion Patient education
Guerra (2022) ⁷⁶	Prospective cohort (n = 229)	HeartLogic	137 of 242 alerts	Diuretic dosage/switch to bioavailable diuretic = 56 Mixed interventions (n = 81) Diuretic changes = 26 Non-diuretic medicinal changes = 50 Patient education = 25 Device reprogramming and/or cardioversion = 7
De Ruvo (2019) ⁷¹	Prospective cohort (n = 101)	HeartLogic	26 of 44 alert, associated with worsening HF and/or influenced clinical decisions for changes to management	NR

continued

TABLE 18 Evidence from studies reporting changes to treatment (*continued*)

Author (year)	Study design (n)	Intervention	Alerts leading to change in treatment	Treatments changed
Calo (2021) ⁸⁰	Prospective cohort (n = 366)	HeartLogic	117 of 273 alerts	Most frequent actions taken were: Diuretic dosage increase = 77 Other drug adjustment = 40 Patient education = 7 Device reprogramming = 3
Santini (2012) ⁷⁵	Cohort, unclear (n = 38)	CorVue	13 of 23 alerts	Diuretics = 13
Benezet-Mazuecos (2016) ⁴³	Cohort, unclear (n = 70)	CorVue	5 of 104 alerts	Diuretics = 2 (3 hospitalisations)
Garner (2022) ³¹	Prospective cohort (n = 749)	TriageHF	72 of 376 high risk alerts	Referral to service Cardiology for review = 47 GP for further action = 21 Palliative care = 4
Virani (2018) ⁵⁵	Prospective cohort (n = 100)	TriageHF	High risk alerts = 13 of 24 Medium risk alerts = 24 of 31	High risk alert Medication changes = 4 Medium risk alert Medication changes = 12
Virani (2016) ⁷⁸	Prospective cohort (n = 100)	TriageHF	NR	Change in risk score [Mean (SD)] Non-MRA Baseline = 1.59 (1.29) Exit = 1.19 (0.87) Difference = -0.39 (1.51), <i>p</i> = 0.03 MRA Baseline = 1.99 (2.39) Exit = 1.49 (1.31) Difference = -0.49 (2.21), <i>p</i> = 0.60
Zile (2021) ⁷⁹	Prospective cohort (n = 66)	TriageHF	26 of 49 alerts	PRN, 22 were completed and 19 led to impedance recovery
Ahmed (unpublished) ²⁸	Retrospective single-arm with time-matched standard care controls (n overall = 758, intervention = 443, control = 315)	TriageHF Control: TriageHF Compatible devices but were not capable of performing automated transmissions	77 of 196 alerts	High risk alert led to the following number of clinical actions Diuretics = 31 GDMT = 19 Investigations = 18 Advice (daily lifestyle/long-term management) = 35 Referral to specialist = 11 Referral to primary care team < 5

AF, atrial fibrillation; AVN, atrioventricular node; CPAP, continuous positive airway pressure; GDMT, guideline-directed medical therapy; HF, heart failure; MRA, mineralocorticoid receptor antagonist; NR, not reported; PRN, diuretic up-titration.

Changes to clinical management associated with worsening HF was used to define prognostic accuracy (sensitivity and specificity) in a few studies.

If a change in clinical management closely follows an alert and the subsequent clinic visit, then earlier appropriate treatment could be attributed to the alert. The percentage of alerts that result in immediate treatment change has predictive value. This requires the study to report that clinical changes met this criterion. The proximity of clinical management changes to the start of the IN alert period was not clearly reported in any study that reported percentage statistics.

If patients stay in alert for significant periods of time and change in clinical management could occur at any time during the IN alert period then earlier appropriate treatment can no longer be attributed to the alert. In this case, the relative rate of change in clinical management IN versus OUT of alert has the most predictive value (the frequency of occurrence IN alert vs. frequency of occurrence OUT of alert). No studies reported a relative rate of change in clinical management IN versus OUT of alert, consequently the information reported below only provides direction of effect (whether alerts tend towards an increase in change in clinical management).

HeartLogic

The majority of the evidence was derived from single cohort studies evaluating outcomes IN alert versus OUT of alert. Hernandez *et al.* (2022) reported increased changes in treatment for the first 12 months of the study when IN alert compared to OUT of alert for the HeartLogic algorithm. Additionally, when IN alert, 74% of cases led to medication changes (see [Table 18](#)).⁴⁸ Pecora *et al.* (2020) compared the changes of treatment occurring in a single prospective cohort (i.e. repeated measures) following monthly remote follow-ups (OUT of alert) to those occurring when IN alert with the HeartLogic algorithm.⁷⁷ They found a significant increase in changes to treatment related to actionable HF events when IN alert compared to OUT of alert (at scheduled follow-ups) ($p < 0.001$). A similar result was observed when comparing actionable alerts from HeartLogic (43%) to treatment actions from scheduled, monthly remote monitoring of data (1%), suggesting HeartLogic alerts lead to more actionable events (alerts resulting in active clinical actions to manage the HF condition; $p < 0.001$).⁴⁴

CorVue

Changes to treatment were identified as part of a composite outcome in four studies assessing prognostic accuracy (see [Table 18](#)).^{29,38,42,43} However, no association data were reported in these studies, with two studies reporting the number of treatments changed only when in alert (see [Table 18](#)).^{43,75}

TriageHF

HF hospitalisations requiring treatment changes was a study end point in one prognostic accuracy study,⁶⁸ no further composite study end points were identified with this outcome (see [Table 18](#)). One study assessing TriageHF compared the impact of the algorithm on MRAs treatment. Specifically, the authors aimed to assess the correlation between TriageHF burden with patients' medical management. Since prescription of MRA is a marker of advanced disease, the TriageHF score was assessed in those with and without MRA use.⁷⁸ The majority of patients (69%) remained in the same medication group at study entry and exit. After an 8-month follow-up period there was a statistically significant reduction in the risk score for non-MRA users ($p = 0.03$), but not in MRA users ($p = 0.6$). The difference between the groups at baseline ($p = 0.68$) and study exit ($p = 0.51$) were not statistically different. Additionally, there was no statistically significant difference in the mean difference between the two groups ($p = 0.33$). The authors suggest the lack of a statistically significant reduction in the risk score of patients is linked to advanced HF in MRA-treated patients, which are more difficult to impact even with optimal care (see [Table 18](#)).⁷⁸

One study reported the number of medication changes in medium and high risk alerts, without providing statistical analysis.⁵⁵ One study reported the number of medication changes in alerts.⁷⁹ Another study reported number of referrals to other services when in high risk status.³¹ Another reported changes to medication, guideline directed medical therapy, investigations, advice, and referrals.²⁸

HeartInsight

No evidence was identified for this outcome for this technology.

Hospitalisations

The prognostic accuracy was reported in 4 studies for hospitalisations as a singular end point, and 12 reported it as a composite outcome, usually with clinic visits or similar. Results for prognostic accuracy of hospitalisations were reported in 16 studies: HeartLogic = 5, CorVue = 4, TriageHF = 6, HeartInsight = 1. Association results were reported for hospitalisations of HF and all cause in 7 studies: HeartLogic $n = 2$, CorVue $n = 0$, TriageHF $n = 5$, and HeartInsight $n = 0$ ([Table 19](#)).

HeartLogic

One study assessed hospital admissions as a singular end point, reporting good sensitivity (90%).³⁷ The four other studies included similar study end points, with variations of hospitalisations and clinic visits. In the development study, the sensitivity reduced from 89% to 70% when validated at the nominal threshold (≥ 16) (see [Table 15](#)).⁵⁶ This sensitivity level was generally maintained in the three other studies (range = 66% to 100%). One study assessed the accuracy of the HeartLogic algorithm in a management strategy, where they applied the nominal threshold of ≥ 16 and also a threshold of ≥ 20 .⁵⁷ The results suggested increasing the threshold to ≥ 20 improved specificity while maintaining acceptable sensitivity (see [Table 15](#)).⁵⁷

Two studies reported increased risk of hospitalisation when IN alert compared to OUT of alert (see [Table 19](#)). However, one of these studies is a composite outcome of hospitalisation or death and does not provide data individually.⁸⁰

One of these studies reported higher hospitalisation rates when IN alert compared to OUT of alert (see [Table 19](#)).⁷² Experiencing at least 1 HeartLogic alert, after correction for chronic kidney disease and AF at implantation, was linked to an increased risk of cardiovascular hospitalisation (HR 3.44, 95% CI 1.22 to 9.76; $p = 0.021$), as was time IN alert $\geq 20\%$ (HR 4.14, 95% CI 2.20 to 7.79; $p < 0.001$).⁷²

De Juan Baguda *et al.* (2022) included three phases, phases 1 and 2 were retrospective, and phase 3 was prospective.⁷⁰ Phase 1 reported a HeartLogic IN alert event rate for hospitalisation of 1.23 per patient years. No hospitalisations occurred outside of an alert in phase 1, and only one alert occurred outside of an alert in phase 2 and 3 (combined).

Another study assessed hospitalisations in patients with LVADs, observing lower index value than the recommended threshold (i.e. ≥ 16) 48 hours prior to HF-related hospitalisation (mean = 12). However, the index value was higher 48 hours prior to non-HF-related hospitalisations (mean = 18.6).⁴⁹

TriageHF

Two studies reported hospital admission as the study end point and assessed prognostic accuracy.^{30,52} One of these studies reported an AUC of 0.8, suggesting good prognostic ability.⁵² Two studies reported prognostic accuracy for the study end point of cardiovascular or HF-related hospitalisations,^{33,67} and one reported a study end-point hospitalisation requiring treatment changes.⁶⁸ The final study reported a composite study end point of hospitalisation, outpatient IVI or death.⁵³ Across the outcomes there was a variation in sensitivity when in high risk status (range = 25% to 82%; see [Table 15](#)).

In single group studies for TriageHF, which compared high and medium risk to low risk status, there was a statistically significant increased risk for HF, cardiovascular, and non-HF cardiovascular-related hospitalisation when in a high risk status, compared to low risk status (see [Table 19](#)).^{30,32,33,68} Using a generalised estimating equation (GEE), within each risk status group (i.e. repeated measures), to estimate the risk of HF-related hospitalisation, the study reported statistically significant risk in the high risk group (GEE 4.07, 95% CI 2.82 to 5.84) and in the medium risk group (GEE 1.57, 95% CI 1.09 to 2.26), but not in the low risk group (GEE 0.73, 95% CI 0.45 to 1.17).⁶⁸ There was also evidence that an increased number of high risk alerts was associated with an increased likelihood of HF-related hospitalisation for the TriageHF algorithm.³¹ Gula *et al.* (2014) also reported similar risks for CRT-D (medium risk group = 3.3, 95% CI 2.0 to 5.4; high risk group = 11.3, 95% CI 6.5 to 19.7) and ICD (medium risk = 2.3, 95% CI 1.2 to 4.6; high risk = 9.6, 95% CI 4.6 to 19.7) devices for HF-related hospitalisations.³²

CorVue

Four study end points were reported assessing the prognostic accuracy of CorVue, with a variation of hospitalisations and clinic visits with changes to treatment (see [Table 15](#)).^{29,38,40,43} Sensitivity varied to a high degree (20-61.9%), indicating inadequate prognostic accuracy.

No studies reported measures of association for this algorithm; however, three studies did report a low number of alerts led to hospitalisations (9 of 20 alerts;⁴¹ 6 of 105 alerts;⁴⁰ and 5 of 104⁴³).

HeartInsight

One published study assessed prognostic accuracy for HeartInsight. The primary end point was for the first post implant hospitalisation due to worsening HF. The secondary end point was a composite outcome of hospitalisation, outpatient IVI or death. In the development cohort, a unitary increase of the index value was associated with an OR of 2.73 (95% CI 1.98 to 3.78; $p < 0.001$) for the first postimplant worsening HF hospitalisation.⁴⁵ The results suggested that the nominal threshold of 4.5 had the potential to identify worsening HF-related to hospitalisations (see [Table 15](#)).⁴⁵ The number of hospitalisations was reported, but no further association data were available.

TABLE 19 Evidence for studies reporting the number of hospitalisations and the association between algorithm alert status from all causes

Author (year)	Study design (n)	Intervention	Hospitalisations (n)	Other
Santobuono (2023) ⁷²	Prospective cohort (n = 568)	HeartLogic	IN alert = 35 OUT of alert = 18	Event rates IN alert = 0.23 (95% CI 0.16 to 0.32) Out of alert = 0.02 (95% CI 0.01 to 0.03) IRR = 12.98 (95% CI 7.16 to 24.35)
Calo (2021) ⁸⁰	Prospective cohort (n = 366)	HeartLogic	13 patients died of other causes	Event rate of hospitalisation or death = 0.12 per patient year (44 events in 27 patients) 35 alerts were associated with HeartLogic in alert state (0.92 per patient year), 9 events occurred while out of alert (0.03 per patient year)
Burri (2018) ³³	Retrospective analysis of a single study (n = 722)	TriageHF	Cardiovascular-related 191 patients with 288 cardiovascular-related hospitalisations in 268 different months (2.2% per month) HF-related 89 patients with 142 HF-related hospitalisation in 135 different months (1.1% per month) Non-HF-related 146 non-HF-related hospitalisation in 137 different months (1.1% per month); number of patients NR	Relative risk (95% CI); low risk reference group Cardiovascular-related Medium risk = 1.8 (1.3 to 1.5), $p < 0.001$ High risk = 4.5 (3.1 to 6.6), $p < 0.001$ HF-related Medium risk = 1.5 (1.0 to 2.5), $p = 0.065$ High risk = 6.3 (3.9 to 10.2), $p < 0.001$ Non-HF-related Medium risk = 2.3 (1.5 to 3.5), $p < 0.001$ High risk = 3.5 (2.0 to 6.0), $p < 0.001$
Cowie (2013) ³⁰	Retrospective analysis of seven studies (overall n = 2231, development n = 921, validation n = 1310) ⁵	TriageHF	HF-related; hospitalisations/evaluations (%) Development Low risk = 15/4525 (0.3) Medium risk = 47/4018 (41) High risk = 29/1247 (13) Validation Low risk = 28/4838 (0.6) Medium risk = 60/4717 (1.3) High risk = 75/1100 (6.8)	HR (95% CI); low risk reference group Development Medium risk = 3.7 (2.0 to 6.7), $p < 0.001$ High risk = 6.2 (3.1 to 12.3), $p < 0.001$ Validation Medium risk = 2.1 (1.3 to 3.4), $p = 0.001$ High risk = 10.0 (6.4 to 15.7), $p < 0.001$
Garner (2022) ³¹	Prospective cohort (n = 749)	TriageHF	Overall = 76 Unplanned = 53 HF = 24 Medical admission = 29	Patients with > 3 high risk alerts likelihood of HF hospitalisation HR = 2.5 (95% CI 1.1 to 5.6), $p = 0.03$
Gula (2014) ³²	Retrospective analysis of a single study (n = 1224)	TriageHF	Overall = 258 (0.68% per month) Low risk = 33 (0.21% per month) Medium risk = 123 (0.66% per month) High risk = 102 (2.61% per month)	Relative risk (95% CI); low risk reference group Medium risk = 2.9 (2.0 to 4.4) High risk = 10.7 (6.9 to 16.6)
Okumura (2020) ⁶⁸	Prospective cohort (n = 315)	TriageHF	HF-related Low risk = 19 of 239 patients Medium risk = 42 of 268 patients High risk = 28 of 161 patients	Relative risk (95% CI); low risk reference group Medium risk = 2.18 (1.23 to 3.85) High risk = 5.78 (3.34 to 10.01)

CI, confidence interval; HF, heart failure; IRR, incidence rate ratio; IV, intravenous; NA, not applicable; NR, not reported.

Rate of heart failure events

Association data for rate of HF events were reported in 12 studies: HeartLogic $n = 2$, CorVue $n = 0$, TriageHF $n = 1$, and HeartInsight $n = 0$ (Table 20). All studies considered varying HF events (e.g. hospitalisations), with HF being a generic term to encompass numerous outcomes. In three studies a HF event was not explicitly defined (see Table 15).^{37,73,74} Here we report studies which provide association data of the occurrence of HF events.

HeartLogic

Evidence from the studies suggests an increased risk of a HF event when IN alert versus OUT of alert (see Table 20).^{80,81} For example, one of the studies reported an increased HR when IN alert for a HF event, which remained statistically significant when adjusted for chronic kidney disease and history of AF (see Table 20).⁸⁰ The same study also identified a decreased rate of events when an alert was followed by a clinical action (HR 0.37, 95% CI 0.14 to 0.99), with similar results if analyses was conducted from day 7 post clinical action (HR 0.34, 95% CI 0.12 to 0.96).

Two studies reported the number of people who had a HF event, but did not perform statistical analyses. One study reported a single HF event, which occurred OUT of alert.⁵⁷ Another reported that three of ten HF events occurred OUT of alert.⁴⁷

CorVue

No studies for CorVue reported association data for this outcome. However, one study states 20 HF developments occurred while in alert (of 96); however, the study also reported that there were a total of 28 HF development episodes with 19 of these related to an alert.⁴² The reason for the two values is unclear.

TriageHF

The singular study identified for this outcome reported increased odds of HF when in medium and high risk status compared to low risk (see Table 20).⁷³

HeartInsight

No studies for HeartInsight reported on this outcome.

TABLE 20 Evidence for studies reporting rate of HF events

Author (year)	Study design (n)	Intervention	Heart failure events	Other statistics
Gardner (2018) ⁸¹	Secondary analysis of a prospective cohort (n = 900)	HeartLogic	145 HF events from 88 patients ^a	IN alert = 0.8 events per patient year OUT of alert = 0.08 events per patient year Event ratio = 10.6 Average event rate = 0.2 per patient year IN alert event rate ratio = 7.05 (95% CI 4.69 to 10.61), $p < 0.001$ IN alert event rate ratio adjusted = 4.78 (95% CI 2.94 to 7.75), $p < 0.001$
Calo (2021) ⁸⁰	Prospective cohort (n = 366)	HeartLogic	273 alerts in 150 patients (up to 6 times per patient)	Alerts = 0.76 per patient year IN vs. OUT of alert event rates HR = 30.63 (95% CI 13.04 to 71.95) Adjusted HR ^b = 24.53 (95% CI 8.55 to 70.38)
Zile (2020) ⁷³	Retrospective cohort (monthly downloads n = 22 901; alert triggered n = 21,356; daily downloads n = unclear)	TriageHF	30-day risk of HF events Monthly downloads 2 102 had an event Low risk = 0.25% Medium risk = 0.70% High risk = 2.23% Alert-triggered downloads 1 812 patients 2853 events	Odds ratio (95% CI) Medium vs. low risk = 2.8 (2.5 to 3.2), $p < 0.001$ High vs. medium risk = 9.2 (8.1 to 10.3), $p < 0.001$

CI, confidence interval; HF, heart failure; HR, hazard ratio; NA, not applicable.

^a Number analysed.

^b Adjusted for chronic kidney disease and history of AF.

Mortality

Heart failure-related mortality

Heart failure events leading to death were reported in 4 studies: HeartLogic $n = 3$, Coruve $n = 0$, TriageHF $n = 1$, and HeartInsight $n = 0$ (Table 21).

HeartLogic

Three prospective cohorts reported increased hazard for HF-related mortality when IN compared to OUT of alert.^{45,72,80}

TriageHF

One study reported the prognostic accuracy of TriageHF for the study end point of mortality. This prospective cohort showed an inadequate AUC (i.e. < 0.7) for the prediction of mortality (see Table 15).

One study assessed TriageHF as a prognostic factor, specifically the number of alerts (> 3). While there was a statistically significant relationship between high risk alerts (> 3) and hospitalisation (HR = 2.5, see Table 21), the algorithm was not a statistically significant predictor of mortality (see Table 21).³¹

CorVue

No studies for CorVue reported on this outcome.

HeartInsight

No studies for HeartInsight reported on this outcome.

TABLE 21 Evidence for studies reporting the number of deaths related to HF

Author (year)	Study design (n)	Intervention	Number of deaths	Other statistics
D'Onofrio (2023) ⁴⁵	Prospective cohort (n = 568)	HeartLogic	33	HR ^a At least one alert = 6.07 (95% CI 6.19 to 12.97), $p = 0.004$ $\geq 20\%$ time in alert = 5.59 (95% CI 2.51 to 12.44), $p < 0.001$
Calo (2021) ⁸⁰	Prospective cohort (n = 366)	HeartLogic	8	IN alert vs. Out alert HR ^b = 11.45 (95% CI 5.55 to 23.60), $p < 0.001$
Santobuono (2023) ⁷²	Prospective cohort (n = 568)	HeartLogic	IN alert = 37 OUT of alert = 18	Cardiovascular hospitalisations or death IN alert ER = 0.48 (95% CI 0.37 to 0.60) OUT of alert ER = 0.04 (95% CI 0.03 to 0.05) IRR = 13.35 (95% CI 8.83 to 20.51) HR = 1.92 (95% CI 1.05 to 3.51), $p = 0.036$
Garner (2022) ³¹	Prospective cohort (n = 749)	TriageHF	Unplanned hospital admission Overall = 10 HF admission = 7 Medical admission = 3	Unadjusted HR (95% CI) for mortality in patients with high risk alerts Number of high-risk alerts > 3 alerts = 0.94 (0.4 to 2.2) HF admission = 2.12 (0.6 to 7.2) Unplanned admissions = 0.76 (0.3 to 2.5) Rockwood clinical frailty score (> 6) = 3.26 (1.5 to 7.3) Charlson Comorbidity Score (> 6) = 2.64 (1.2 to 5.7)

CI, confidence interval; ER, event ratio; HR, hazard ratio; IRR, incidence rate ratio; NA, not applicable.

a Adjusted for age, ischemic cardiomyopathy, chronic kidney disease, AF on implantation and HeartLogic IN alert.

b Adjusted for HeartLogic alert, chronic kidney disease, and AF history.

All-cause-related mortality

All-cause events leading to death were reported in 4 studies: HeartLogic $n = 2$, CorVue $n = 0$, TriageHF $n = 2$, and HeartInsight $n = 0$ (Table 22).

HeartLogic

One study evaluated the predictive ability of the HeartLogic algorithm to predict deaths.⁴⁵ They reported 55 deaths, with 46 of these experiencing one or more alerts during follow-up. There was an increased risk of death for those IN alert compared to OUT of alert (see Table 22). Additionally, an increased risk of death was present for having at least one HeartLogic alert and time IN alert ($\geq 20\%$, see Table 22).⁴⁵

TriageHF

A study assessing TriageHF showed greater likelihood of death when at high risk compared to not being in high risk (see Table 22).⁶⁹ Similar results were observed another TriageHF study reporting high and medium risk status was associated with significantly higher hazard of all-cause mortality.⁷³

CorVue

No studies for CorVue reported on this outcome.

HeartInsight

No studies for HeartInsight reported on this outcome.

TABLE 22 Evidence for studies reporting the number of deaths from all causes

Author (year)	Study design (n)	Intervention	Number of deaths	Other statistics
D'Onofrio (2023) ⁴⁵	Prospective cohort (n = 568)	HeartLogic	55	IN vs. OUT of alert 0.25 (95% CI 0.17 to 0.34) vs. 0.02 (95% CI 0.01 to 0.03) per patient years, $p < 0.001$ At least one HeartLogic alert HR = 2.08 (95% CI 1.16 to 3.73), $p = 0.039$ Time IN alert $\geq 20\%$ HR = 4.07 (95% CI 2.19 to 7.54), $p < 0.001$ Time to death after start of IN and OUT of alert HR = 11.00 (95% CI 6.19 to 19.48), $p < 0.001$
Calo (2021) ⁸⁰	Prospective cohort (n = 366)	HeartLogic	13 patients died of other causes	Event rate of hospitalisation or death = 0.12 per patient year (44 events in 27 patients) 35 alerts were associated with HeartLogic in alert state (0.92 per patient year), 9 events occurred while out of alert (0.03 per patient year)
Ahmed (2022) ⁶⁹	Prospective cohort (n = 439)	TriageHF	Overall = 60 Cardiovascular = 35 Respiratory disease = 7 Cancer = 6 Renal failure < 5 Falls < 5 Diabetes < 5 Dementia < 5 Missing = 6	High risk vs. not high risk OR 3.07, 95% CI 1.57 to 6.58, $p = 0.002$
Zile (2020) ⁷³	Retrospective cohort (n = 22 542)	TriageHF	Overall = 2489 Low risk = 14% Medium risk = 20% High risk = 38% Note: unclear what percentage represents	Adjusted HR (95% CI) ^a High vs. low risk = 3.5 (2.8 to 4.3), $p < 0.001$ Medium vs. low risk = 1.8 (1.4 to 2.2), $p < 0.001$

CI, confidence interval; CV, cardiovascular; HR, hazard ratio; NR, not reported.

a Number included in analysis; adjusted for age, gender, clinical history, hypertension, myocardial infarction, coronary artery disease, HF, AF, vascular disease, chronic kidney disease, and stroke, transient ischaemic attack.

Summary of prognostic performance

Meta-analysis of the available accuracy data was not completed due to a number of reasons. Many studies did not sufficiently report the data (e.g. only sensitivity was reported and a 2×2 contingency table could not be calculated from available data). Furthermore, there was variation in the definitions of study end points which would make validity of comparisons challenging, even within technologies. Finally, the risk of bias in many studies was high, meaning the quality of the evidence is low and may not produce accurate results.

TriageHF

The greatest amount of prognostic accuracy evidence was identified in studies assessing the TriageHF algorithm ($n = 10$). Of these, the AUC was reported in three studies assessing worsening HF (AUC = 0.75),⁶⁵ mortality (AUC = 0.61),⁶⁹ and hospital admissions (AUC = 0.81).⁵² Sensitivity for high risk status for HF-related events (e.g. hospitalisations) showed great variability (range = 37.4% to 87.9%). Specificity also varied (range = 44.4% to 90.2%). False positive rates were reported with the consideration of duration of follow-up (i.e. patient years).^{29,38,45,56,72–74}

Evidence of associations between being in an algorithm-defined high risk status, compared to a low risk status, suggested a higher risk of hospitalisation ($n = 5$), HF events ($n = 1$), and mortality from all causes ($n = 2$). The HR of hospitalisation ranged from 6 to 11 and was consistently statistically significant, when compared to low risk status of the algorithm.^{30–33,68} The single study for HF events suggested a high HR when in high risk status compared to low risk status (HR = 9.2).⁷³ Mortality from all causes was at a statistically significantly greater risk when in high risk status compared to low (HR = 3.5)⁷³ and compared to not high risk (i.e. medium and low risk: HR = 3.07).⁶⁹ Mortality from HF was only available in a single study, which only assessed the number of high-risk alerts (> 3 alerts).³¹ While this study was linked to an increased risk of hospitalisation with increasing number of alerts, death was not statistically significantly associated with number of alerts (HR 0.94, 95% CI 0.4 to 2.2).³¹

HeartLogic

A similar amount of prognostic accuracy evidence was identified assessing the HeartLogic algorithm ($n = 8$). In the original development and validation study for HeartLogic, the development sensitivity was 82% and this dropped to 70% in the validation cohort for the prediction of HF events of hospitalisation and clinic visits.⁵⁶ In further validation studies, which generally assessed HF hospitalisation events, sensitivity was adequate to high (range = 66% to 100%) as was specificity (range = 61% to 93%). False positives were reported in seven studies and generally showed low false positive rates. One study reported that 26 of 38 patients who had at least one alert had a false positive alert.⁵⁷

There was evidence that being IN alert, compared to OUT of alert, suggested a higher risk of hospitalisations ($n = 2$), HF events ($n = 2$) and mortality from HF ($n = 3$) or all causes ($n = 2$). The hospitalisation IRR suggested a statistically significant increased rate of hospitalisations when IN alert compared to OUT of alert (IRR = 12.98).⁷² An adjusted (for chronic kidney disease and history of AF) HR for HF events was reported, suggesting a high risk of such an event occurring when IN alert versus OUT of alert (HR = 24.53).⁸⁰ Mortality from HF was statistically significantly associated with being IN alert compared to OUT of alert in two studies (HR range = 2 to 11).^{72,80} One other study reported a statistically significant association for mortality from HF and from all causes was statistically significantly associated with having at least one HeartLogic alert (HF HR = 6.07; all-cause HR = 2.08), more time in alert (HF HR = 5.59; all-cause HR = 4.07), and was more likely to occur when IN alert versus OUT of alert (0.25 vs. 0.02 per patient years).⁴⁵

CorVue

Less evidence for prognostic accuracy was identified for the CorVue algorithm ($n = 5$). The CorVue algorithm showed inadequate sensitivity for HF events, generally HF hospitalisations (range = 20 to 68%). While specificity was only reported in two studies at 70%⁴⁰ and 77%.⁴³ Additionally, false positive rates were high in the seven studies reporting the number of false alerts (percentage range of false alerts = 43 to 95%).^{29,38,40–43,75}

No association data were available for hospitalisation; however, three studies did report low rates of hospitalisations following an alert.^{40,41,43} No further association data were reported for the other outcomes.

HeartInsight

A single published study was identified for HeartInsight. At the nominal threshold of 4.5, the algorithm had 65.5% sensitivity and 86.7% specificity for first postimplant HF hospitalisations. Additionally, it had 54.8% sensitivity and 86.5% specificity for HF hospitalisation, outpatient IVI or death. An AUC was only reported for HF hospitalisations in the development cohort (AUC = 0.89). For HeartInsight false positive rates were calculated as the number of false positive alerts (not followed by either the primary or secondary study end point) per patient year: nominal threshold of 4.5 were < 0.7 for both study end points.⁴⁵

In the development cohort, a unitary increase of the index value was associated with an OR of 2.73 (95% CI 1.98 to 3.78; *p* < 0.001) for the first postimplant worsening HF hospitalisation. No further data of associations were available for any outcome.⁴⁵

Comparative outcome results

Rate of heart failure events

One comparative study was identified for this outcome, which assessed the HeartLogic algorithm.

HeartLogic

The propensity-matched controlled study did show a statistically significant difference in HF events, with less events occurring in the HeartLogic intervention group compared to those without the algorithm (Table 23).³⁶

CorVue

No comparative evidence reporting on this outcome.

TriageHF

No comparative evidence reporting on this outcome.

HeartInsight

No comparative evidence reporting on this outcome.

Rate and category of atrial fibrillation

No evidence was identified for this outcome.

Changes in New York Heart Association classification of symptoms

No evidence was identified for this outcome.

Hospitalisation

HeartLogic

One comparative study for HeartLogic utilised a propensity-matched retrospective cohort design.³⁶ This study reported a non-statistically significant difference between the number of patients being admitted to hospital, when comparing those with and without the HeartLogic algorithm (Table 24).³⁶ One single cohort study did compare pre to post activation of the HeartLogic algorithm, reporting statistically significant reductions in HF-related hospitalisation

TABLE 23 Comparative evidence for studies reporting rate of HF events

Author (year)	Study design (n)	Intervention/control	Heart failure events
Feijen (2023) ³⁶	Propensity matched retrospective cohort (n = 161)	HeartLogic Conventional remote monitoring	Worsening HF median (IQR) Control group = 2 (0–4) HeartLogic = 1 (0–3) Less worsening HF for HeartLogic group (<i>p</i> = 0.004)

TABLE 24 Comparative evidence for studies reporting the number of hospitalisations from all causes

Author (year)	Study design (n)	Intervention/control	Hospitalisations (n)	Between-group differences for hospitalisation
Treskes (2021) ³⁷	Retrospective pre-post analysis (n = 68)	HeartLogic Remote monitoring pre-activation	HF-related Pre-activation of HeartLogic = 27 Post-activation of HeartLogic = 7	Reduction in HF-related hospitalisations for HeartLogic group vs. those without the algorithm ($p = 0.005$) Hospitalisation per patient years (SD) Pre-activation = 0.39 (0.08) Post-activation = 0.11 (0.04) reduction in hospitalisation per patient years for HeartLogic group ($p = 0.003$)
Feijen (2023) ³⁶	Propensity matched retrospective cohort (n = 161)	HeartLogic Conventional remote monitoring	HF-related Control = 17 Intervention = 8	Intervention vs. control, $p = 0.096$
Chang (2020) ³⁵	Retrospective cohort with external control (Intervention = 40; control = 100) and pre-post activation	HeartLogic Remote monitoring	Pre device implantation Intervention = 17 of 40 patients Control = 33 of 100 patients Post device implantation Intervention = 4 of 40 patients Control = 17 of 100 patients	Between groups statistical comparisons Pre device implantation, $p = 0.33$ Post device implantation, $p = 0.35$
Shapiro (2017) ³⁴	Retrospective medical chart review of CorVue device compared to standard protocol (n = 120)	CorVue No implanted device but receiving home health care	Intervention = 0 of 60 patients Control = 14 of 60 patients	Intervention vs. control: $X^2 = 15.849$, $p < 0.001$
Ahmed (unpublished) ²⁸	Retrospective single-arm with time-matched standard care controls (n overall = 758, intervention = 443, control = 315)	TriageHF TriageHF Compatible devices but were not capable of performing automated transmissions	Confidential information has been removed	Reduced risk of at least one hospitalisation for the TriageHF group compared with controls (IRR 0.42, 95% CI 0.23 to 0.76)

HF, heart failure; IRR, incidence rate ratio; SD, standard deviation.

once the algorithm was turned on (see [Table 24](#)).³⁷ One retrospective study compared pre-post activation of HeartLogic within a cohort and to an external cohort, reporting less hospitalisation post activation in the HeartLogic group. However, statistical analysis showed no statistically significant difference (see [Table 24](#)). Hernandez reports a rate of HF hospitalisation during the study as 67% lower [rate ratio (95% CI): 0.33 (0.23 to 0.47)] compared to the pre-study 12-month HF hospitalisation rate.⁸²

CorVue

A retrospective medical chart review, which included a control group, showed that those with a CorVue enabled device were less likely to be hospitalised compared to those without a device (see [Table 24](#)).³⁴

TriageHF

Comparative evidence using the TriageHF algorithm was available from a single study, which suggested a reduced IRR when comparing those with a TriageHF capable device to those with devices that were TriageHF capable but did not send automatic transmissions (see [Table 24](#)).²⁸

HeartInsight

No comparative evidence was identified for this outcome assessing HeartInsight.

Length of hospital stay

Only two studies reported length of hospital stay, both of which assessed the impact of the HeartLogic algorithm.^{36,37} One study included a control group³⁶ and the other was a single cohort compared pre and post activation.³⁷

HeartLogic

The length of hospital stay was reported as being significantly longer for those without a HeartLogic algorithm (median number of days = 8, IQR: 5–12) compared to those with a device (median number of days = 5, IQR: 2–7; $p = 0.025$).³⁶ Similar results for the HeartLogic algorithm were reported for number of days in hospital pre-activation (mean = 16, SD = 14) compared to post activation (mean = 7, SD = 5), although this was not statistically significant ($p = 0.079$).³⁷

CorVue

No studies for CorVue reported on this outcome.

HeartInsight

No studies for HeartInsight reported on this outcome.

TriageHF

No studies for TriageHF reported on this outcome.

Mortality

No comparative evidence was identified for this outcome for any of the technologies.

Health-related quality of life

No comparative evidence was identified for any technology on this outcome. One prospective cohort did assess quality of life outcomes at baseline and study exit, which is reported here.⁵⁵

TriageHF

A single prospective cohort study ($n = 100$) which assessed the TriageHF algorithm provided evidence for health-related quality of life via the 6MWT ($n = 60$) and the MLWHF ($n = 88$).⁵⁵ Walking distance for the 6MWT was reported to decrease from baseline (mean = 323, SD = 115 minutes) to end of follow-up at 8 months (mean = 295, SD = 116), which was statistically significant ($p = 0.01$). No statistically significant differences between baseline (mean = 32.8, SD = 21) and end of follow-up at 8 months (mean = 30.0, SD = 21.6) for the MLWHF was found ($p = 0.19$). However, a decrease in the overall score for the MLWHF is deemed as an improvement.⁵⁵

CorVue

No studies for CorVue reported on this outcome.

HeartLogic

No studies for HeartLogic reported on this outcome.

HeartInsight

No studies for HeartInsight reported on this outcome.

Patient experience

No evidence was identified for any technology on this outcome.

Summary of comparative outcomes

For each algorithm there was a lack of comparative evidence. HeartLogic was identified as providing the most comparative evidence ($n = 3$). TriageHF and CorVue each had a single comparative study. However, one study for TriageHF assessing quality of life was included as a comparative study in this section as it compared baseline to study exit. No comparative evidence was identified for the HeartInsight algorithm. Due to the lack of comparative data for each algorithm, it is difficult to make any conclusions about how effective they are compared to standard care. All studies were rated as serious or critical with the risk of bias tool (ROBINS-I).

TriageHF

Hospitalisations were reported to be at a reduced risk for those with a TriageHF device compared to those with TriageHF capable devices but were not performing automated transmissions (IRR = 0.42).²⁸

TriageHF was the only algorithm to have evidence for quality of life. One study assessed the 6MWT and MLWHF. The results showed statistically significant decrease in the 6MWT at baseline and study exit. This implies a negative impact between baseline and study exit as the length walked was significantly less. However, a non-statistical reduction in the MLWHF was reported, which is considered important as a decrease in the score is deemed as an improvement.⁵⁵

No comparative data for any other outcomes were identified for this algorithm.

HeartLogic

Rate of HF events was reported in a single propensity-matched controlled study, which reported less worsening HF in those with a HeartLogic device than those without ($p = 0.004$).³⁶

Hospitalisations were shown to be statistically reduced in one retrospective pre-post study when a patient had a HeartLogic enabled device compared to having conventional remote monitoring.³⁷ Two other comparative studies showed numerical trends towards a reduction in hospitalisations when having a HeartLogic device compared to conventional remote monitoring, but the differences were not statistically significant.^{35,36} Similar results were observed for the length of hospital stay outcome; one study reported a statistically significant ($p = 0.025$) reduction in time in hospital for those with a HeartLogic device compared to those without a HeartLogic device (5 vs. 8 days, respectively).³⁶ While another study reported pre-activation length of hospital stay was longer than post-activation hospital stay (16 vs. 7 days, respectively), but this was not statistically significant ($p = 0.079$).³⁷

CorVue

Hospitalisations were statistically significantly reduced in those with a CorVue enabled device compared to those with no implanted device receiving standard home care.³⁴

No comparative data for any other outcomes were identified for this algorithm.

HeartInsight

No comparative evidence was identified for any outcome for this algorithm. We therefore cannot draw any conclusions regarding its efficacy in comparison to other modes of clinical follow-up.

Implementation outcome results

Interventions following an alert

HeartLogic

Guerrera *et al.* (2022) reported a quicker decrease of the IN alert state when decongestive treatments were administered in the first two weeks, compared to no decongestive treatments in the first four weeks of alert. Similarly, multivariate analysis showed that a higher algorithm index value when IN alert with the HeartLogic algorithm (OR 1.11, 95% CI 1.02 to 1.20) and late intervention (OR 5.11, 1.09 to 24.48) were significantly associated with the need for further treatment to resolve the alert.⁷⁶ One study also reported the time to treatment, with 56 decongestive treatment adjustments being made within 2 weeks of the first alert (early action average time from alert to intervention mean = 5 days, SD = 4 days). There were also 26 late actions for treatment (mean = 40 days, SD = 27 days).⁷⁶

TriageHF

No studies assessing TriageHF were identified for this outcome.

CorVue

No studies assessing CorVue were identified for this outcome.

HeartInsight

No studies assessing HeartInsight were identified for this outcome.

Time between an alert and a heart failure event

HeartLogic

Four single cohort studies assessing the HeartLogic algorithm reported time between an alert and an event occurring.^{46,49,71,80} The median time between crossing the alert threshold and a HF clinical event in one study was 11 (IQR: 2–19) days.⁴⁶ Another reported the median number of days for an early warning of hospitalisation (median = 38 days) and clinical visits (median = 12 days).⁷¹ One study reported the median time between an alert onset to an HF event was 29 (IQR: 4–83) days.⁸⁰ Another study reported the median number of days from the first sensor alert to first hospitalisation was 145 (IQR: –1 to 380) for all causes, 63 (IQR: –26 to 229) for HF-related, and 240 (147 to 497) for non-HF-related.⁶ Another study reported an average time of 20 days from alert to hospitalisation.⁷⁰

TriageHF

One single cohort study assessing the TriageHF algorithm reported time between the last transmitted risk status alert and death.⁶⁹ The median time from the high risk status to death was 111 (IQR: 57–226) days.⁶⁹ The time between last maximum recorded risk and death was 233 (IQR: 91–390) days.⁶⁹

CorVue

No studies for CorVue reported on this outcome.

TABLE 25 Non-comparative evidence for studies reporting alert response rates and time in alert

Author (year)	Study design (n)	Intervention	Alert response rates	Time in alert (days)
Gardner (2018) ⁸¹	Secondary analysis of a prospective cohort (n = 900)	HeartLogic	NR	IN alert mean = 37.8 (median = 30) OUT of alert mean = 145.2 (median = 88)
Feijen (2023) ³⁶	Propensity matched retrospective cohort (n = 161)	HeartLogic	NR	Mean (SD) = 36 (9)
Calo (2021) ⁸⁰	Prospective cohort (n = 366)	HeartLogic	NR	Median (IQR) = 42 (24–61) Overall time IN alert = 38 patient years
Guerra (2022) ⁷⁶	Prospective cohort (n = 229)	HeartLogic	NR	Median (IQR) = 42 (25–60) Overall time IN alert = 33 patient years
Santini (2020) ⁴⁴	Prospective cohort (n = 53)	HeartLogic	NR	15% of total observation period was spent IN alert
De Juan Baguda (2022) ⁷⁰	Phase 1 (n = 101) and 2 (n = 94) are retrospective cohorts Phase 3 (n = 267) is a prospective cohort	HeartLogic	NR	11% of follow-up period spent IN alert
Pecora (2020) ⁷⁷	Prospective cohort (n = 104)	HeartLogic	NR	Alert to review Mean (SD) = 14 (8) days 14% of observed period IN alert
Hernandez (2022) ⁴⁸	Prospective cohort (n = 191)	HeartLogic	NR	Mean = 36 Median = 27 17% of follow-up time related to IN alert state
Feijen (2023) ³⁶	Propensity matched retrospective cohort (n = 161)	HeartLogic Conventional remote monitoring	NR	Mean (SD) = 36 (9)

TABLE 25 Non-comparative evidence for studies reporting alert response rates and time in alert (*continued*)

Author (year)	Study design (n)	Intervention	Alert response rates	Time in alert (days)
Garner (2022) ³¹	Prospective cohort (n = 749)	TriageHF	Response to 367 high risk alerts Telephone contact = 303 No intervention required = 128	NR
Debski (2020) ⁸³	Prospective registry (n = 132)	TriageHF	Number of high risk alerts = 398 During high risk episode = 38% After high risk episode = 62%	Median delay for transmission when receiving after the delay = 10 (IQR: 15) days
D'Onofrio (2022) ⁴⁵	Prospective cohort (overall n = 918, development n = 457, validation n = 461)	HeartInsight	NR	Development Median = NR Validation Median = 42 days

IQR, interquartile range; NR, not reported; SD, standard deviation.

HeartInsight

No studies for HeartInsight reported on this outcome.

Alert response rates

The alert response or time in alert was reported in 11 studies: HeartLogic n = 8, CorVue n = 0, TriageHF n = 2, and HeartInsight n = 1 ([Table 25](#)).

HeartLogic

Mean and median duration spent IN alert varied slightly between study (36 to 42 days).^{48,76,80,81} One study reported an average of 14 days from alert to review.^{70,77} Finally, one study reported the mean time spent IN alert was 36 days (see [Table 25](#)).³⁶

TriageHF

One study reported the number of responses required during a high risk status.³¹ Another reported the number of high risk episodes during the event and after (see [Table 25](#)).⁸³

HeartInsight

Time in alert was reported for the validation cohort only (median = 42 days; see [Table 25](#)).⁴⁵

CorVue

No studies for CorVue reported on this outcome.

Number of emergency or urgent care visits

The number of emergency or urgent care visits was reported in 11 studies: HeartLogic n = 6, CorVue n = 3, TriageHF n = 2, and HeartInsight n = 0 ([Tables 26](#) and [27](#)).

Non-comparative evidence

HeartLogic

Four of the six studies for HeartLogic were single cohort study designs. These studies reported the number of emergency or urgent care visits.

CorVue

The three studies for CorVue were all single cohort studies (see [Table 26](#)).

TriageHF

Non-comparative evidence Two studies for TriageHF were single cohort studies (see [Table 26](#)).

TABLE 26 Non-comparative evidence from studies reporting number of emergency and urgent care visits

Author (year)	Study design (n)	Intervention	Emergency and urgent care visits (n)	Other
Pecora (2020) ⁷⁷	Prospective cohort (n = 104)	HeartLogic	17 of 100 alerts required in-office visits	Overall 282 scheduled and 56 unscheduled in-office visits were performed during follow-up
De Juan Baguda (2022) ⁷⁰	Phase 1 (n = 101) and 2 (n = 94) are retrospective cohorts Phase 3 (n = 267) is a prospective cohort	HeartLogic	Unscheduled consultations (in-person or telephone) Phase 1 = 3 of 73 alerts Phase 2/3 = 46 of 277 alerts	NA
Boehmer (2017) ⁵⁶	Prospective cohort (overall n = 900 ^a , development n = 500, validation n = 400)	HeartLogic	Outpatient visits Development = 132 Validation = 60	NA
Santini (2020) ⁴⁴	Prospective cohort (n = 104)	HeartLogic	In-office examinations Unscheduled = 56 Scheduled = 282	NA
Palfy (2015) ⁴¹	Cohort, unclear (n = 65)	CorVue	11 of 20 episodes in 14 patients led to emergency room/ambulatory treatment modification	NA
Palfy (2018) ⁴⁰	Prospective cohort (n = 53)	CorVue	13 of 25 episodes in 18 patients led to emergency room/ambulatory treatment modification	NA
Benezet Mazuecos (2016) ⁴³	Cohort, unclear (n = 70)	CorVue	13 of 25 episodes in 16 patients led to emergency room/ambulatory treatment modification	NA
Virani (2018) ⁵⁵	Prospective cohort (n = 100)	TriageHF	Medium risk = 2 High risk = 0	NA
Debski (2020) ⁸³	Prospective registry (n = 132)	TriageHF	Unscheduled alerts ^b = 44% Care alerts ^b = 32%	NA

NA, not applicable.

a Denotes number analysed.

b Denotes information is undefined.

TABLE 27 Comparative evidence from studies reporting number of emergency and urgent care visits

Author (year)	Study design (n)	Intervention/Control	Emergency and urgent care visits (n)	Other
Treskes (2021) ³⁷	Retrospective pre-post analysis (n = 68)	HeartLogic Remote monitoring pre-activation	Pre- vs. post-activation of HeartLogic 1-day clinic visits Pre-activation = 32 Post-activation = 42 Proportion of patients with 1 day clinic visit Pre-activation = 24 Post-activation = 19 Ambulatory visits Pre-activation = 132 Post-activation = 117	1-day clinic visits p = 0.732 Ambulatory visits p = 0.757 Proportion of patients with 1 day clinic visit p = 0.461
Feijen (2023) ³⁶	Propensity matched retrospective cohort (n = 161)	HeartLogic Conventional remote monitoring	Clinic visits for increasing diuretics, median (IQR) Control = 2 (0–3) HeartLogic = 1 (0–2)	Difference between groups, p = 0.0001

HeartInsight

No studies for HeartInsight reported on this outcome.

Comparative evidence**HeartLogic**

One study was comparative and compared pre and post activation of the HeartLogic algorithm, observing no statistically significant differences between clinic or ambulatory visits (see [Table 27](#)).³⁷ The one controlled comparative study showed a statistically significant increase in clinic visits for diuretics post-activation.³⁶

CorVue

No comparative evidence for this outcome.

TriageHF

No comparative evidence for this outcome.

HeartInsight

No comparative evidence for this outcome.

Software failure rate**HeartInsight**

HeartInsight observed 39 of 918 patients, in a single cohort, had connection issues for home monitoring remote transmissions as they could not establish sufficient GSM (Global System for Mobile communication) coverage. The median remote monitoring rate was 91.3% of days (IQR = 83.5–95.8%) in the development cohort and 90.8% (IQR = 83.1–95.5%) in the validation cohort.⁴⁵

HeartLogic

A single study reported reasons for ungenerated alerts using the HeartLogic algorithm.⁴⁸ Delays or ungenerated alerts were reportedly caused by the home communicator not being powered or could not send data, or the patient was out of range, or alert threshold was adjusted from nominal. Of the total 3290 weekly alerts, 2934 (89%) were communicated to the sites (median delivery time < 1 day, Q3 < 1 day, max 129 days), 2894 (88%) were documented as received by sites.⁴⁸

CorVue

No studies for CorVue reported on this outcome.

TriageHF

All evidence for TriageHF was derived from a single group for this outcome. It was reported that if a patient fails to record a transmission within a 425-day window, data were lost.⁶⁹ In one study they reported 36 patients had 45 episodes over 65 days that were not transmitted.⁶⁹ Another reported 130 (33%) episodes were not transmitted within 30 days from the final day of a high risk status.⁸³

Number of monitoring reviews**TriageHF**

One study utilising the TriageHF algorithm reported remote monitoring with comanagement (i.e. HF specialist alerted). One-third of transmissions (368 alerts) were sent to comanagement.⁸³ One comparative study for TriageHF did report the average minutes per week call time (hospital 1 : 13.5 minutes; hospital 2 : 12.9 minutes; hospital 3 : 18.2 minutes) and workload (hospital 1 : 25.3 minutes; hospital 2 : 24.2 minutes; 46.9 minutes) associated with using the TriageHF plus care pathway.²⁸

HeartLogic

One study reported that of 273 alerts 204 did not require extra in-office visits and were managed remotely. OF the 69 in-office visits, 42 were scheduled examinations that were previously planned (within 7 days of the alert). The median

number of phone contacts per alert period was 1 (IQR: 1–2).⁸⁰ De Juan Baguda *et al.* reported most alerts were managed remotely. Patient phone contacts during phase 2 was 35 (0.65 contacts per patient year) and during phase 3 was 287 (1.12 contacts per patient year).⁸⁴

HeartInsight

No studies for HeartInsight reported on this outcome.

CorVue

No studies for CorVue reported on this outcome.

Adverse events

No other morbidity outcomes were identified; therefore we only focus on the available data for adverse events.

Non-comparative evidence

HeartInsight

The single published study assessing HeartInsight did report the number of HF-related adverse events in the development group; however, these were not directly linked to the use of the algorithm and are therefore not presented.⁴⁵

HeartLogic

A single cohort study for HeartLogic study reported 691 overall adverse events, with 50 related to HeartLogic. Five of 301 severe adverse events occurred in 4 of 157 patients with alerts (0.015 per patient year) and were classified as abnormal lab values, renal insufficiency/failure HF ($n = 2$), dizziness-HF, and syncope-HF.⁴⁸

CorVue

No studies for CorVue reported on this outcome.

TriageHF

No studies for TriageHF reported on this outcome.

Comparative evidence

There was no comparative evidence reported on this outcome for any technology.

Summary of implementation outcomes

There is a lack of evidence for a number of outcomes, with many of these outcomes being supported by a single study for some algorithms and no evidence for other algorithms. Due to this, it is difficult for the EAG to make conclusive remarks regarding the implementation of the algorithms in clinical practice. The majority of evidence was available for the HeartLogic algorithm. The majority of studies were rated as high risk of bias.

TriageHF

Software failure may occur where the patient is unable to send an alert. After 425 days, data were lost and cannot be assessed.⁶⁹ One study found that 33% of episodes were not transmitted.⁸³ Implementation regarding the number of monitoring reviews was reported in two studies. One of these studies reported the average workload in minutes for using the TriageHF plus care pathway.²⁸ No conclusions can be drawn based on the available data.

HeartLogic

There was evidence to suggest that being at a higher IN alert value and the amount of time IN alert was associated with further treatment needs to resolve the alert.⁷⁶ The median time between an alert and HF event varied between 11 and 63 days.^{6,46,71,80} This may provide evidence that if an IN alert status is triggered, quick actions could reduce HF events but if left unattended they may progress and require further treatment adaptations.

Comparative evidence reported a reduction in clinic visits when utilising the HeartLogic algorithm compared to a conventional remote monitoring group.³⁶ However, a pre-post analysis showed no statistically significant changes in 1-day clinic or ambulatory visits.³⁷ Therefore, we cannot draw any conclusions on the impact of the HeartLogic algorithms effect on clinic visits.

There is a potential for an issue with software failure, where the alerts are not generated or are delayed due to varying factors (e.g. home communicator not being powered or could not send data, or the patient was out of range, or alert threshold was adjusted from nominal).⁴⁸ One study found that 11% of weekly alerts were not received by sites.⁴⁸

Adverse events associated with using the HeartLogic algorithm were reported in one study. Rates were relatively low with 50 of 691 adverse events being associated with HeartLogic.⁴⁸

The evidence retrieved for HeartLogic for implementation is varied and sparse.

CorVue

Three studies reported the number of alerts leading to clinic visits.^{40,41,43} No further data are reported for any outcome. No conclusions can be drawn based on the available data.

HeartInsight

The single published study identified for HeartInsight reported a potential for software failure if there were connection issues for home monitoring transmissions (e.g. there was not sufficient GSM coverage).⁴⁵ No numerical data are reported for this outcome. No conclusions can be drawn based on the available data.

Chapter 4 Assessment of existing cost-effectiveness evidence

This section provides a summary of the systematic review of studies evaluating the cost-effectiveness of remote monitoring algorithms (Heartlogic, HeartInsight, CorVue and TriageHF) compared to usual in-person clinic visits. This section includes search methods, study selection, data extraction process, quality assessment and summary of results. See [Company submissions](#) for a brief description of company economic evaluation evidence submitted before 27 October 2023.

Methodology of the cost-effectiveness review

The purpose of this systematic review of published economic evaluations studies was:

- to inform the conceptualisation and development of our de novo economic model
- to review existing economic evaluation studies of remote monitoring systems identifying new-onset acute HF or worsening signs of HF in people with CIEDs.

By reviewing the documents provided by companies manufacturing these devices, it was anticipated that there would be a lack of relevant economic evidence for the above-mentioned monitoring devices. Therefore, to inform the development, our decision-analytic model, a broader review of cost-effectiveness studies, including all remote monitoring devices, was undertaken.

Searches

Following the same approach taken for the clinical effectiveness searches, between 14 and 20 of June 2023, we undertook a comprehensive search of the economic and cost-effectiveness literature. [Table 28](#) presents a summary of the sources searched. We used a validated search filter to identify cost-effectiveness studies.⁸⁵ Search strategies are reported in [Appendix 2](#).

Selection process

All the citations retrieved were screened based on the title and abstract by two reviewers (SH, NB) using EndNote. Two EndNote files were then merged to see discrepancies. The result was discussed between two reviewers and a final list of 33 papers were selected for full-text review. Full texts of any records that were agreed to be relevant were obtained and those citations without full text were excluded. The two reviewers then independently reviewed the full texts and disagreements were resolved through discussions.

Data extraction

A data extraction form was developed by reviewers based on the economic evaluation requirements recommended by the CHEERS checklist.⁸⁶ The included studies were extracted by one reviewer (SH) using the standardised form and it was then checked by a second reviewer (NB) for accuracy. Information extracted included the PICO (Population, Intervention, Comparator and Outcome) as well as type of economic evaluation, modelling, costing approach, outcome valuation, discount rate, price year and currency.

Quality assessment

A total of 19 economic evaluation studies were summarised of which five studies employed Markov model which suits our modelling practice. Therefore, we undertook a quality appraisal of these five studies employing CHEERS checklist.⁸⁶ A summary of this quality assessment can be found in [Table 29](#). Furthermore, 12 of 19 studies were trial-based economic evaluations of remote monitoring systems of which only one study [Treskes 2021] was found eligible comparing the clinical and economic impacts of an algorithm-based RMS in a group of patients before and after RMS activation.³⁷

TABLE 28 Databases searched for cost-effectiveness studies

Source name	Platform/URL
MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review and Other Non-Indexed Citations, Daily and Versions	Ovid
EMBASE	Ovid
Cochrane Database of Systematic Reviews (CDSR)	Cochrane Library available at https://cochranelibrary.com/cdsr/reviews
Cochrane Central Register of Controlled Trials (CCRCT)	Cochrane Library available at: https://cochranelibrary.com/central
Database of Abstracts of Reviews of Effects (DARE) ^a	Centre for Reviews and Dissemination available at https://crd.york.ac.uk/CRDWeb/
HTA Database ^b	Centre for Reviews and Dissemination available at https://crd.york.ac.uk/CRDWeb/
The NHS Economic Evaluation Database (NHS EED) ^a	Centre for Reviews and Dissemination available at https://crd.york.ac.uk/CRDWeb/
INAHTA (the international HTA database)	The International Network of Agencies for Health Technology Assessment available at https://database.inahta.org/
NIHR Journals Library	National Institute for Health and Care Research (NIHR) journals library available at https://journalslibrary.nihr.ac.uk/#/

a Content updated until 2015.

b Content updated until 2018.

Results of the cost-effectiveness review for remote monitoring systems

A PRISMA diagram of studies identified in the systematic review is presented in [Figure 3](#). The initial search identified a total of 224 citations of which 190 were screened after removing duplicated one. A total of 33 studies were identified as potentially relevant from their titles and/or abstracts. Following the full-text review, 10 studies were found eligible in terms of PICO criteria. Nine eligible studies were also added from the hand searching. Of 19 studies included, 13 were trial-based economic evaluations, metanalysis or survival studies which neither have implications for our modelling purposes nor for the review of economic evaluation of algorithm-based RMS technologies. Therefore, we just included five Markov model studies and one economic evaluation study of one of the technologies in the scope of this study which are summarised below. It should be noted that none of the studies with a Markov model mentioned the name of the device used for remote monitoring except the Burri *et al.* (2013)⁸⁷ study which assessed the BIOTRONIK technology. BIOTRONIK is one of the technologies included in our protocol although the non-algorithm-based version of it was used in this study. The Treskes 2021 study was also the economic evaluation of the HeartLogic™ algorithm which is included in our protocol.

Burri *et al.* (2013) was a 'Cost-consequence analysis of daily continuous remote monitoring of implantable cardiac defibrillator and resynchronisation devices in the UK' study employing a deterministic four-state (well, post stroke, post ADHF and death) Markov cohort model.⁸⁷ Clinical and cost data were identified through a systematic review of literature. Most of the event data were taken from (RCTs) for HM transmitter (CardioMessenger II, BIOTRONIK) synthesised using meta-analysis, where required. All costs were UK specific. Data specific for ICD and CRT-D patients or for gender were weighted, based on the number of procedures performed in the UK or the gender split in the UK population. Key findings of this study include:

- HM transmitter was predicted to be cost neutral at about £11,500 per patient in both treatment arms from the UK NHS perspective, with all initial and ongoing costs of remote monitoring included. Based on the univariate sensitivity analysis, remote monitoring was found cost-saving in the base case and 6 other scenarios.
- Fewer inappropriate shocks (–51%) reduced the need for replacing devices for battery exhaustion (–7%), and the number of FU visits was predicted to be halved by using HM.

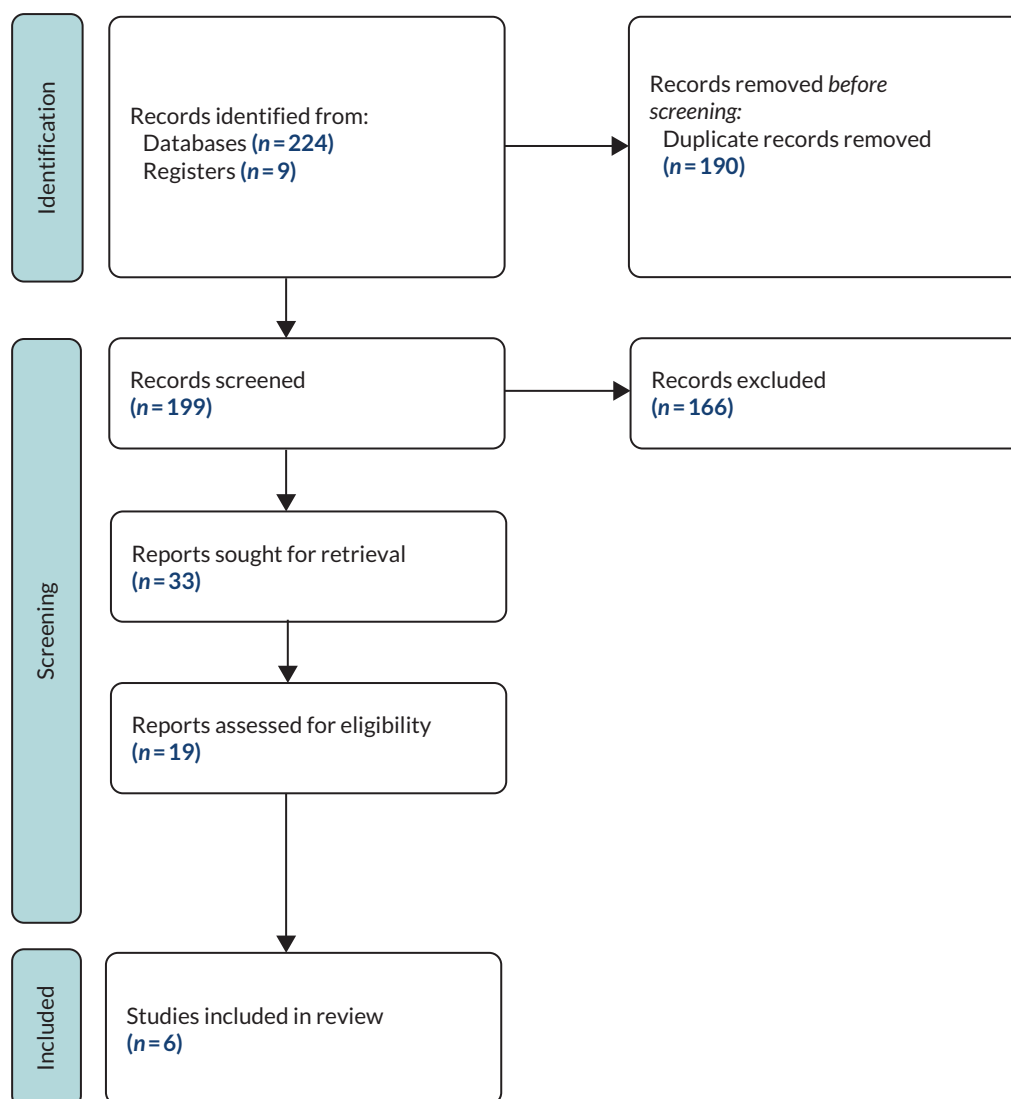


FIGURE 3 Flow diagram of the study selection process for the cost-effectiveness review.

Chew *et al.* (2022) study investigated the clinical and economic outcomes associated with remote monitoring for CIEDs using a population-based cohort study in Canada.⁸⁸ A two state, alive-dead Markov model was employed. Outcomes included life-years (LY) based on all-cause mortality, and QALYs, and total costs. Utilities for the CIED cohort were derived from a cross-sectional survey administered to a sample of CIED patients in Alberta using the EuroQOL-5D tool. Costs for inpatient hospitalisation, outpatient hospital visits, and emergency room visits were calculated based on top-down methods using the Resource Intensity Weight (RIW) and the Cost of a Standard Hospital Stay (CSHS). Key finding include:

- Over the base-case time horizon of 5 years, patients following an RM strategy accrued 3.640 QALY for a total cost of \$40,314 (£32,165.77) (exchange rate of 1 USD = 0.80 GBP, as of 26 December 2024), while patients following an in-clinic strategy accrued 3.637 QALY for a total cost of \$52,508 (£41,895.13) (exchange rate of 1 USD = 0.80 GBP, as of 26 December 2024).
- Although QALY gains were found to be similar for each strategy, RM was associated with incremental cost savings over a 5-year period compared with in-clinic visits alone [\$12,195 (£9,730.16) (exchange rate of 1 USD = 0.80 GBP, as of 26 December 2024) per person], indicating that RM technology was associated with similar patient outcomes and cost savings from healthcare perspective.

- Based on the sensitivity analysis, the differences in hospitalisation rates and inpatient costs were the primary driver of cost savings in the model. In a scenario that excluded hospitalisation costs from the model, there were no longer cost savings associated with the RM group.

Kawakami *et al.* (2023) was cost-effectiveness analysis of remote monitoring after pacemaker implantation for bradycardia in Japan.⁸⁹ They developed a six states Markov model incorporating QALY and cost data. The health states included 'Post-pacemaker implantation (PMI)', 'AF without OAC', 'AF with OAC', 'Post-stroke', 'Device trouble', and 'Dead'. The health outcome information was obtained from literature by searching the words 'utility' and 'quality of life', in conjunction with the health states. Key findings:

- It was found that RM was more effective but more costly than conventional follow-up (CFU) for all CHADS2 [CHADS is a scoring system to assess the risk of stroke in patients. It stands for (c) congestive heart failure, (h) hypertension, (a) age, (d) diabetes, and previous history of (s) stroke] scores, and higher CHADS2 scores were associated with higher costs and lower QALYs.
- Based on the results of probabilistic sensitivity analysis (PSA), RM did not show clear cost-effectiveness for patients with a CHADS2 score of 2. However, for CHADS2 scores of 4 and 6 RM was found to be a cost-effective option compared with CFU at willingness to pay (WTP) thresholds > 3,500,000 JPY and > 1,500,000 JPY, respectively.

It should be noted that only direct medical cost and long-term care costs were taken into account and social costs and patient incurred ones were not included.

Sequiera *et al.* (2020) investigated cost-effectiveness of remote monitoring of implantable cardioverter defibrillators in France.⁹⁰ It was a meta-analysis and an integrated economic model derived from RCTs. A Markov multi-state model with 1-month cycle was employed, in which each patient existed in one of three mutually exclusive states: 1 – stable outpatient, 2 – CV hospitalisation, or 3 – dead. Key findings:

RM resulted in cost-savings of €4142 per patient over a 5-year time horizon, with a QALY gain of 0.29. The incremental cost-effectiveness ratio (ICER) was €14,136/QALY, in favour of RM from French healthcare system perspective. PSA confirmed that the RM strategy was dominant over SC in 70% of cases.

- RM resulted in cost-savings of €4142 per patient over a 5-year time horizon, with a QALY gain of 0.29. The ICER was €14,136/QALY, in favour of RM from French healthcare system perspective.

Health Quality Ontario (2018) conducted a health technology assessment to compare Remote Monitoring of ICD, CRT and permanent pacemakers (PPMs) with clinic visits.⁹¹ A four-state (stable arrhythmia, post hospitalised non-stroke, post stroke and death) Markov model was developed that followed patients during the maintenance phase (3 months after successful implantation). The two model populations were: (1) ICD and CRT-D recipients with HF and (2) pacemaker recipients with arrhythmia.

Health utility estimates for ICD and CRT-D recipients were derived from literature which all used the EQ-5D5L/3L questionnaires. Utility studies used for the pacemaker recipients (Model 2) employed non-preference-based measures (SF-36 questionnaire, MLWHF). All the costs were specific to Canadian healthcare system mostly obtained from the Ontario Health Insurance Schedule and administrative data.

Treskes *et al.* (2021) evaluated the 'clinical and economic impact of HeartLogic compared with standard care in heart failure patients'.³⁷ The data were obtained from a multicentre non-blinded single-arm 1-year trial. They compared the rate of HF events in 68 patients who completed the follow-up period before and after activation of monitoring algorithm. They also measured the associated costs pre and post activation of monitoring algorithm in one centre, including 30 patients.

- Number of patients hospitalised because of HF event declined from 21 (pre-activation) to 7 (post activation) ($P = 0.005$), and the hospitalisation LOS reduced from average 16 to 7 days ($P = 0.079$).
- There was a substantial drop in average total costs per patient including and excluding deceased patients, respectively (–€9958 and –€8286). The difference mainly comes from the hospitalisation cost (€9972 and €8523) while the ambulatory cost was not found to be significantly different.

Key findings:

- Treskes 2021 was the only study which compared the economic benefits of an algorithm-based RMS (HeartLogic) technology included in the scope of this study before and after the activation of this system. Although they found a significant drop in average total costs, it should be noted that the sample size was rather small, and data were obtained only from one medical centre.
- The other five studies which employed a Markov model have not used an algorithm-based RMS technology. The study results therefore do not apply to the technologies investigated in this DA, but the study details are useful to inform the development of a model.
- For ICD and CRT-D recipients, remote monitoring plus in-clinic follow-up strategy was more costly [incremental value of \$4354 (£3473.97) (exchange rate of 1 USD = 0.80 GBP, as of 26 December 2024) per person] and more effective, providing higher QALYs (incremental value of 0.19), compared to in-clinic follow-up alone.
- Among pacemaker recipients, remote monitoring plus in-clinic follow-up strategy was less costly [with an incremental saving of \$2370 (£1890.98) (exchange rate of 1 USD = 0.80 GBP, as of 26 December 2024) per person] and more effective (with an incremental value of 0.12 QALYs) than with in-clinic follow-up alone.
- It was estimated that publicly funding remote monitoring could result in cost savings of \$14 million (£11.3 million) (exchange rate of 1 USD = 0.80 GBP, as of 26 December 2024) over the first 5 years.
- Based on the one-way sensitivity analyses, the most sensitive variables were the transition probabilities for emergency visits and hospitalisations as the main drivers of cost. Furthermore, in the deterministic sensitivity analysis, the payment for remote interrogation were changed from a 0% reduction to a 100% reduction, compared to a clinic visit. Among ICD and CRT-D recipients, the simulated ICERs remained cost-effective under commonly used thresholds.

Quality assessment of the studies

Based on the assessment of the included studies (Table 29) using the CHEERS checklist, all the 6 studies included the population, comparator, and interventions as compatible with our protocol. Economic evaluation perspective taken for all studies were healthcare system and time horizon considered in the model were 5 to 10 years. Treskes 2021 compared 12 months before and 12 months after the activation of the algorithm-based RMS.³⁷ The only study which discussed the generalisability issue is Health Quality Ontario HTA.⁹¹

Methodology of the review of studies evaluating resource use and utility of remote monitoring systems in Heart Failure**Searches**

Additionally, we performed focused searches for resource utilisation, QALY and utility values to populate the economic model. We searched MEDLINE and EMBASE via Ovid and used two validated economic filters for cost-of-illness studies and quality-of-life studies.^{92,93} We also searched specialist sources such as CEA Registry (available at <https://cevr.tuftsmedicalcenter.org/databases/cea-registry>), RePEC (available at <http://repec.org/>) and SchARRHUD (the health utilities database from the School of Health and Related Research at The University of Sheffield, available at <https://scharrhud.org/>).

Selection process

Title and abstract of all the citations were screened by two reviewers (SH, NB) using EndNote. The result was discussed between two reviewers and a final list of 12 papers was selected for full-text review. Papers were reviewed and summarised by one reviewer (SH) and seven papers were finally included, of which four papers included cost parameters and three included utility values.

Data extraction

The included studies were summarised by one reviewer (SH) using a form developed by reviewers. Information extracted included the different categories of costing, country, currency, utility values, instruments used and QALY estimates.

TABLE 29 Summary of quality assessment of the included studies

Item	Burri 2013 ⁸⁷	Chew 2022 ⁸⁸	Kawakami 2023 ⁸⁹	Sequeira 2020 ⁹⁰	Ontario HTA 2018 ⁹¹	Treskes 2021 ³⁷
Title	Page 1	Page 1	Page 1	Page 1	Page 1	Page 1
Title	Cost-consequence analysis of daily continuous remote monitoring of implantable cardiac defibrillator and resynchronisation devices in the UK	Clinical and Economic Outcomes Associated with Remote Monitoring for CIEDs: A Population-Based Analysis	A cost-effectiveness analysis of remote monitoring after pacemaker implantation for bradycardia in Japan	Cost-effectiveness of remote monitoring of ICDs in France: a meta-analysis and an integrated economic model derived from RCTs	Remote monitoring of ICDs, CRT and permanent pacemakers: an HTA	Clinical and economic impact of HeartLogic compared with standard care in HF patients
Abstract	Page 1	Page 1 -2	Page 1	Page 1	Page 3-4	Page 1
Abstract	Structured with aims, method, results and conclusion	Structured with aims, method, results and conclusion	Structured with aims, method, results and conclusion	Structured with aims, method, results and conclusion	Structured with aims, method, results and conclusion	Structured with aims, methods and results, and conclusion
Introduction	Page 2	Page 2	Page 2	Page 2	Page 13	Page 1-2
Background & objectives	Background, study objectives and policy implications reported	Background and study objectives reported	Background and study objectives reported	Background and study objectives reported.	Background, study objectives and policy implications reported	Background and study objectives reported
Methods	Pages 2-4	Pages 2-4	Pages 3-8	Page 3-7	Page 64	Page 2-5
Health economic analysis plan	NO	NO	NO	NO	Not a separate HEAP as this is a comprehensive HTA report	NO
Study population	ICD and CRT-D patients	Adults with ICD or CRT-D	elderly Japanese patients with pacemakers for bradycardia	ICD patients	ICD patients	> 18 years of age patients with HF and an ICD featuring the HeartLogic multisensor algorithm
Setting and location	UK	Alberta, Canada	Japan	France	Canada	Belgium, Netherlands and Switzerland
Comparators	Remote monitoring and Routine follow-up visits	Remote monitoring and Routine follow-up visits	RM follow-up relative to that of conventional in-office follow-up (CFU)	RM and standard care	Remote monitoring + clinic visits vs. clinic visits only	Pre-activation and post-activation within each patient
Perspective	UK National Health Service perspective	Canadian public health system payer	Healthcare provider	Healthcare system	Ontario Ministry of Health and Long-term Care	Belgian healthcare perspective
Time horizon	10 years	5 years	10 years	5 years	5 years	12 months before activation and 12 months after activation
Discount rate	3.5%	1.5%	2%	NO	1.5%	Not applicable

continued

TABLE 29 Summary of quality assessment of the included studies (*continued*)

Item	Burri 2013 ⁸⁷	Chew 2022 ⁸⁸	Kawakami 2023 ⁸⁹	Sequeira 2020 ⁹⁰	Ontario HTA 2018 ⁹¹	Treskes 2021 ³⁷
Title	Page 1	Page 1	Page 1	Page 1	Page 1	Page 1
Selection of outcomes	Twelve consequences were examined in the model	The primary end point was all-cause mortality. Secondary end points included time to first hospitalisation for a cardiovascular (CV) cause, cumulative incidence of CV hospitalisation, hospital LOS, cumulative incidence of emergency department visits, cumulative incidence of outpatient physician visits	QALYs	CV hospitalisation Death Utilities	Mortality Healthcare use Health-related quality of life	Primary end point was decompensated HF Secondary outcomes were the number of patients hospitalised for decompensated HF, the mean number of HF hospital admission per patient, mean LOS in days In addition, the total number of 1-day clinic visits, mean number of 1 day clinic visits per patient, and the number of patients with 1 day clinic visit was evaluated
Measurement of outcomes	Page 1	Page 2	Page 4	Page 7–8	Mortality, pages 73–75 Utility, page 80	Page 3
Valuation of outcomes	NA	NA	Page 4	NA	Mortality, pages 73–75 Utility, page 80	NA
Measurement and valuation of resources and costs	NO	Top-down methods using the RIW	Direct medical costs for the therapies, as well as costs for long-term disability care were included (page 3)	Pages 7–8	Pages 83–85	Page 3
Currency, price date, and conversion	GBP Page 3	Costs were valued in 2019 Canadian dollars using the Consumer Price Index for Goods and Services, if required	JPY	Euro – Price year Unknown	CAN \$ – Price year 2017	Euro- Price year unknown
Rationale and description of model	Page 2	Page 3	Page 2	Pages 6–7	Page 68	Not applicable as this a before after study
Analytics and assumptions	Page 3	Page 3	Page 2	NO	Page 67	Page 5
Characterising heterogeneity	NO	NO	NO	NO	NO	NO
Characterising distributional effects	NO	NO	NO	NO	NO	NO

Item	Burri 2013 ⁸⁷	Chew 2022 ⁸⁸	Kawakami 2023 ⁸⁹	Sequeira 2020 ⁹⁰	Ontario HTA 2018 ⁹¹	Treskes 2021 ³⁷
Title	Page 1	Page 1	Page 1	Page 1	Page 1	Page 1
Characterising uncertainty	Page 4	Page 4	Page 5	Page 7	Page 87–88	Page 5; interquartile range and standard deviations used to present results
Approach to engagement with patients and others affected by the study	NO	NO	NO	NO	NO	NO
Results	Page 4	Pages 4–5	Pages 5–8	Pages 8–9	Page 89	Pages 5–7
Study parameters	Page 4	Page 4		Page 9, table 3	Tables 35 and 36	Pages 6–7
Summary of main results	Page 4	Page 5	NO	Page 8, CEA paragraph	Page 89, reference case analysis	Tables 4 and 5, page 8
Effect of uncertainty	Page 4	Page 5	Page 4	Page 10, Figure 4 – PSA	Page 93	NO
Effect of engagement with patients and others affected by the study	NO	NO	NO	NO	NO	NO
Discussion	Pages 4–6	Pages 5–7	Page 8	Page 9	Page 95	Pages 7–9
Study findings, limitations, generalisability, and current knowledge	No generalisability	All included expect generalisability	No generalisability reported	No generalisability	All Included: page 89 and 94	All included, except generalisability
Other relevant information	Page 7	Page 8	Page 9	Page 11	NO	Page 9
Source of funding	This work was supported by BIOTRONIK. H.B was supported in part by a grant from la Tour Foundation for Cardiovascular Research.	This study was funded by Alberta Innovates Health Solutions Collaborative Research and Innovations Opportunities and by the Partnership for Research and Innovation in the Health System Grants, Government of Alberta	This research was supported by JSPS KAKENHI [grant number 22K17327]	NO external funding	–	Boston Scientific Corporation (reference number: ISRRM11793)
Conflict of interest	Page 7	Page 8	Page 9	Page 10	–	Page 10

Results of the targeted review of studies evaluating resource use and utility of remote monitoring systems in heart failure

The utility values from three papers are reported in [Table 30](#).

TABLE 30 Summary of utility values identified in the review

Citation	Utility SC (Mean, SD)		Utility RM		QALY SC	QALY RM
	Baseline	16 months	Baseline	16 months		
EVOLVO Study: ⁹⁴ Cost-Utility Analysis of the EVOLVO Study on Remote Monitoring for Heart Failure Patients with Implantable Defibrillators: RCT	0.737 (0.234)	0.711 (0.305)	0.793 (0.179)	0.754 (0.275)	0.966 (0.231)	1.032 (0.177)
PREDICT Study: ⁹⁵ Outcomes and costs of remote patient monitoring among patients with implanted cardioverter defibrillators: An economic model based on the PREDICT RM database	–	–	–	–	5.65	6.29
TARIFF study: ⁹⁶ Economic analysis of remote monitoring of CIEDs: Results of the Health Economics Evaluation Registry for Remote Follow-up (TARIFF) study	Baseline	12 months	Baseline	12 months	QALY SC	QALY RM
	0.86 ± 0.18	0.85 ± 0.18	0.87 ± 0.13	0.87 ± 0.16	0.85 ± 0.17	0.87 ± 0.13

Summaries of four papers which estimated and compared the costs of using remote monitoring versus standard care practice in different countries are provided below.

Hein Heidbuchel *et al.* undertook a study in five European countries, including UK, to evaluate net financial impact of using remote monitoring on providers (taking national reimbursement into account) and costs.⁹⁷ The price year in this study was 2013 and all costs were reported in Euro. The study was from payer perspective, so the unit costs were based on diagnosis-related groups tariffs, national or regional fee-for-service tariffs or public general hospital tariffs.

Key results:

Resource use for remote monitoring were clearly different from the standard care group (all these results are statistically meaningful):

- less FU visits (3.79 + 1.67 vs. 5.53 + 2.32)
- small increase of unscheduled visits (0.95 + 1.50 vs. 0.62 + 1.25)
- more non-office-based contacts (1.95 + 3.29 vs. 1.01 + 2.64)
- more internet sessions (11.02 + 15.28 vs. 0.06 + 0.31) and more in-clinic discussions (1.84 + 4.20 vs. 1.28 + 2.92).

There found to be numerically fewer hospitalisations (0.67 + 1.18 vs. 0.85 + 1.43) and shorter length of stay (6.31 + 15.5 vs. 8.26 + 18.6), although not statistically significant.

Josep A. Ladapo *et al.* investigated health care utilisation and expenditures associated with remote monitoring in ICD patients in USA assessing current direct costs of 1-year ICD follow-up based on RM compared with conventional quarterly in-hospital follow-ups employing a linear regression model.⁹⁸

Key results:

- They reported on inpatient admission, inpatient admission through ED, outpatient office/ED visits.

- Across almost all three subgroups (ICD, CRT-D and PPM) before and after matching, there were found to be fewer/same admissions and visits for RM group. Only outpatient office visits for ICD and CRT-D patients were slightly higher (12.18 vs. 11.99 and 13.68 vs. 13.57 respectively) for RM group after matching.
- Remotely monitored patients with ICDs experienced fewer emergency department visits resulting in discharge ($p = 0.050$).
- Remote monitoring was associated with lower health care expenditures in office visits among patients with PPMs ($p = 0.025$) and CRT-Ds ($p = 0.006$) and lower total inpatient and outpatient expenditures in patients with ICDs.

Laurence Gue'don-Moreau *et al.* investigated costs of remote monitoring versus ambulatory follow-ups of ICD patients in the randomised ECOST study in France from French health insurance system perspective. The use of RM was found to be cost saving.⁹⁹

Key results:

- Over a follow-up of 27 months, the mean non-hospital costs per patient-year were €1695 + 1131 in the RM, versus €1952 + 1023 in the control group ($P = 0.04$), a €257 difference mainly due to device management.
- The hospitalisation costs per patient-year were €2829 + 6382 and €3549 + 9714 in the RM and control groups, respectively ($P = 0.46$). Adding the ICD to the non-hospital costs, the savings were €494 ($P = 0.005$) or, when the monitoring system was included, €315 ($P = 0.05$) per patient-year.

Piotr Buchta *et al.* undertook a study to assess the impact on costs for the healthcare system of RM in patients with ICD or CRT-D in Poland over three years' follow-up. The perspective taken were National Healthcare system; therefore, they used payer costs based on diagnosis-related groups and public general hospital tariffs.¹⁰⁰

Key results:

- The reduction in the costs of treatment for National Health Care in the RM group was 33.5% (median value, $p < 0.001$) over three years' follow-up period. In patients with implanted CRT-D, the reduction reached 42.7% ($p = 0.011$) while it was 31.3% in ICD patients ($p = 0.007$).
- There was no significant reduction in the median hospitalisation costs in the three-year follow-up in the RM group despite a 25% drop in the mean value.
- The costs of outpatient visits were slightly higher in the RM group although it was not found to be statistically significant.

Conclusions of the assessment of existing cost-effectiveness evidence

A systematic review was conducted to obtain cost-effectiveness evidence for the algorithms included in this study and to retrieve studies to inform our model as well as compare the results with our model results at the end. There was only one study that was included that evaluated the cost-effectiveness of a remote monitoring algorithm.³⁷ Most studies reported in this section were studies employing Markov models regardless of technologies they used for the purpose of informing our *de novo* model, including structure, outcomes, model cycles and parameters.⁸⁷⁻⁹¹

To obtain resource use and utility values of using remote monitoring algorithms compared to standard care, we conducted a focused review of the literature. Among the studies retrieved, three of them reported on utility values and QALY estimates of using remote monitoring in two treatment arms with 12-16 months follow-up.⁹⁴⁻⁹⁶ As for resource utilisation, no UK-specific study was identified. Four studies conducted in different countries were reported, which used modelling techniques with longer follow-up periods of ICD patients who were being remotely monitored.⁹⁷⁻¹⁰⁰ This allows the estimates to be more generalisable rather than using a single centre trial-based study with short follow-up period.

Outcome event data, resource use and utility data were used to inform the parameters in our economic model. It should be noted that unit cost of each resource were obtained from UK national databases such as NHS reference cost schedule.¹⁰¹

Chapter 5 Company submissions

Overview

Medtronic submitted a cost-effectiveness model in Excel and a report for this technology assessment on the TriageHF algorithm in late October 2023.¹⁰² An abstract related to the TriageHF Plus clinical study underpinning the evidence submission was included in the systematic review Ahmed *et al.*²⁸ Further details regarding the clinical study were included in the evidence submission.

A cost-utility analysis comparing TriageHF Plus with standard of care (SoC) HF monitoring was included. Two populations were defined in analyses: (a) all people (aged 18 years or older) with a TriageHF compatible ICD or CRT who had a prior diagnosis of HF, (b) the trial population of TriageHF Plus [(confidential information has been removed) had a prior diagnosis of HF]. Subgroups were defined by CIED: ICD, CRT-P, CRT-D.

The economic decision model was a two-state (dead and alive) Markov model. The time horizon was lifetime. The Study was conducted from the perspective of the English and Welsh NHS and Personal Social Services (PSS). Costs and benefits were discounted at an annual rate of 3.5%.

Outcomes

Hospitalisations

The rate of hospitalisations, follow-up consultations and mortality were included in the model.

For the comparator, the annual rate of hospitalisations was estimated as the number of events divided by the number of person-years. The average number of hospitalisations per person-year (confidential information has been removed) for the comparator was obtained from the company submission.¹⁰² There were (confidential information has been removed) events over (confidential information has been removed) person-years. This was obtained from the TriageHF Plus study. The results have not yet been published. The IRR was estimated using a Poisson Generalised Linear Mixed Model (GLMM) with log link. The mean IRR was 0.42 (95% CI 0.23 to 0.76; $p = 0.004$, SE = 0.3).¹⁰² The average number of hospitalisations per person-year was therefore calculated to be (confidential information has been removed) in the model for TriageHF. The rate was converted to a monthly probability in the model. The EAG thinks that an average rate or Poisson distribution probability calculations are appropriate methods. In each case, the annual value is divided by 12 to derive the monthly value. However, the practical difference is small in this case and not a cause for concern.

Analysis sets from TriageHF Plus specific to the defined populations were used to estimate hospitalisations.

Because the study overlapped with the Covid pandemic, a total analysis set and pre-COVID analysis sets were defined. The total analysis set was used in the base-case analysis.

Follow-up visits

For the algorithm-based remote monitoring system, the contacts with the healthcare system other than those related to alerts were assumed to be the same as for the CIED without the algorithm-based remote monitoring system. Healthcare contacts included GP visits, A&E visits, consultant visits and others. The number of tests associated with these visits were also assumed to be the same.

For patients with an alert, (confidential information has been removed) had an initial consultation, and (confidential information has been removed) had a second consultation. Tests and treatment were also costed for these.

Mortality

There was insufficient evidence to evaluate the HR of mortality, so it was assumed that there was no difference in mortality rates. Survival analysis was conducted using a standard selection of parametric survival models.¹⁰³ and the log-normal parametric model was selected due to the most appropriate external validity based on a study by Taylor *et al.*¹⁰⁴ Survival rates were 81% at 1 year, 48% at 5 years and 26% at 10 years.

Health utilities

General population utilities were assigned to patients alive, and an annual hospitalisation utility decrement was applied.

Results

The company conducted deterministic analysis and PSA. Based on the PSA results, the average ICER was –£610,120 per QALY gained for all patients across the total study analysis set in TriageHF Plus. TriageHF results in a reduction of costs of approximately (confidential information has been removed) per person and an increase in QALYs of (confidential information has been removed). Therefore, TriageHF was dominant and cost-effective compared to SoC.

The deterministic incremental cost and QALY outcome also sits close to the middle of the PSA iterations, reducing the uncertainty associated with the deterministic model results.

The probability of TriageHF being cost-effective compared to SoC across multiple WTP thresholds was represented using a CEAC. TriageHF is 99.5% more likely to be cost-effective than SoC at every WTP threshold per QALY gained.

It should be noted that hospitalisation costs found to be the main driver of the cost-utility outcomes. This happens because of a (confidential information has been removed) reduction in hospitalisation costs as the lifetime number of hospitalisation events decreases from (confidential information has been removed) per person in the SoC arm to (confidential information has been removed) in the TriageHF arm.

The company conducted threshold analysis to find the value of the IRR at which TriageHF was no longer dominant. The breakeven value was (confidential information has been removed).

Discussion

The company adopted the same model structure that the EAG adopted. The following assumptions were made regarding outcomes: equal mortality rates for intervention and comparator; alert-related follow-up visits were additional to the SoC healthcare contacts for TriageHF; there was no difference in LOS between the intervention and comparator. Consequently, it was assumed that there would be no benefit for TriageHF associated with these outcomes.

The clinical study that underpinned this evidence submission was found to have a critical risk of confounding and information was missing for several categories (see [Risk-of-bias assessments for TriageHF](#), [Table 13](#)). The bias would need to be considerable for the IRR estimate to be > 0.91 , the point at which TriageHF is no longer dominant, instead of the study estimate of 0.42 (95% CI 0.23 to 0.76; $p = 0.004$, SE = 0.3).

Chapter 6 Independent economic assessment- Newcastle model

Overview

A de novo decision analytic model was developed to estimate the cost-effectiveness of algorithm-based remote monitoring of HF risk data in people with CIEDs. The model structure is designed to capture the key costs and outcomes associated with CRM. The conceptualisation, development and parameterisation of the economic model was informed by the economic modelling studies of remote monitoring devices described in [Results of the cost-effectiveness review for remote monitoring systems](#). A cohort Markov model was developed with alive and dead states. The model structure captured the key costs and outcomes associated with CRM. Patients in the Alive state experienced a number of hospitalisations per year, made a number of clinic visits (scheduled and unscheduled) and were at risk of dying. Mortality rates, risk of hospitalisation, clinic visits (scheduled and unscheduled) are independently modelled, which may differ by technology. LOS per hospitalisation may also differ by technology.

Each device is modelled separately. Evidence on the outcome differences for one device are not assumed to apply to another device. Where there is evidence on the difference in outcomes with and without CRM, the cost-effectiveness of CRM is estimated. Where there is no evidence on an outcome difference, either no difference in an outcome is assumed or different scenarios are modelled. These scenarios are more or less conservative with respect to CRM. Where there is evidence on the relative risk of hospitalisation, cost-effectiveness estimates are produced for the relevant scenarios. If CRM is not cost-effective in a conservative scenario, then threshold analysis is conducted on those outcomes to identify the effectiveness required for the technology to be cost-effective at cost-effectiveness thresholds recommended by NICE.¹⁰⁵

Costs are expressed in UK £ sterling (2021/22) and evaluated from the perspective of the NHS and PSS. In line with the NICE reference case,¹⁰⁵ both costs and outcomes were discounted at a 3.5% annual discount rate. The costs and outcomes were evaluated over a lifetime horizon. The model was built in Microsoft Excel. Probabilistic analysis was conducted where appropriate, using appropriate probability distributions for the model parameters where these could be fitted, and monte carlo simulation,¹⁰⁶ is used to capture uncertainty in input parameters and overall cost-effectiveness results. Scenario analyses are conducted to explore the robustness of the results to changes in input parameters.

The decision problem, the model structure and overview of key assumptions along with the data sources of model input parameters are outlined in the sections below.

Decision problem and population

The decision problem the economic model seeks to address is whether algorithm-based remote monitoring of HF risk data in people with CIEDs (CorVue, HeartInsight, HeartLogic and TriageHF) is cost-effective.¹⁰⁷

Population

The patient population considered in the model are those implanted with the named CIEDs listed above in [Health utilities](#), have previous experience of HF or at risk of new-onset HF and are > 18 years of age.

Intervention strategies/comparator

The interventions assessed were the algorithm-based remote monitoring systems for CIEDs which are capable of identifying new-onset or worsening signs of HF. Remote monitoring of data from cardiac implantable remote monitoring devices in people at risk of HF, when used alongside standard care, could enable early identification of HF risk and ensure early access to treatments. Early treatments could ultimately improve health outcomes and reduce costs of

unnecessary health care resource utilisation. Remote monitoring systems for any CIED are only compatible with the specific devices, therefore the economic evaluation compared remote monitoring system for each implanted device with no remote monitoring system for that specific device.

The economic evaluation considered the following algorithm-based remote monitoring systems as outlined in the final scope by NICE:¹⁰⁸

- i. CorVue and Merlin.net PCN
- ii. HeartInsight and BIOTRONIK Home Monitoring
- iii. HeartLogic and LATITUDE NXT Patient Management System TriageHF and CareLink remote monitoring (TriageHF Plus).

Model structure

A decision analytic model, informed by previous economic modelling studies of remote monitoring devices in HF, was developed to estimate the costs and health outcomes (QALYs) associated with algorithm-based remote monitoring of HF risk data in people with cardiac implantable devices compared to those without remote monitoring. The economic evaluation utilised a Markov model with two states: Alive and Dead ([Figure 4](#)). The Markov model design with estimates of clinical outcomes was selected over a model with prognostic and clinical outcomes linked to the prognostic outcomes because of the variation in definitions of prognostic outcomes and the anticipated difficulty of finding evidence on clinical outcomes linked to the prognostic outcomes.

Quality-adjusted life-years gained was the primary measure of benefit in the economic evaluation. Mortality, hospitalisation, follow-up visits and LOS in the hospital were inputs to the model. The Markov model took a lifetime horizon in the base-case. Monthly cycles were used and at each monthly cycle, the hypothetical cohort of patients remained in the state 'Alive' or transitioned to the state 'Dead' (absorbing state) according to the probability of death assigned for each monthly cycle. In each cycle, the patients who were alive experienced an average number of monthly hospitalisations, follow-up visits, and days in hospital. Each patient then accrued lifetime QALYs and health-care costs according to the model state they were in.

Outcome parameters

Mortality

No comparative evidence (intervention vs. comparator) for mortality was available for the devices assessed in this study.¹⁰⁹ Therefore, considering the absence of evidence, mortality rates for patients with CIEDs were assumed to be the same with and without RMS.

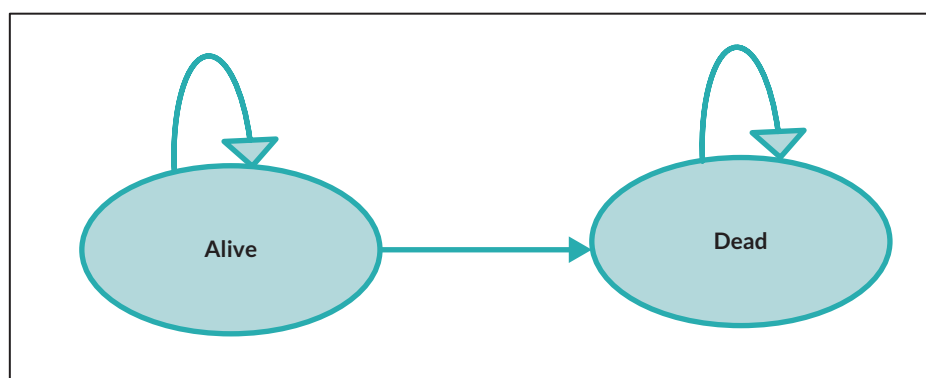


FIGURE 4 Schematic outline of the Markov model.

Findings from an analysis of Implantable cardio-verter defibrillator (ICD) and CRT implantation in England from April 2011 to March 2013 by Bottle *et al.* 2021 using the national hospital administrative database showed a 5-year survival of 64% and 58% after ICD and CRT implantation, respectively.¹¹⁰ Another study which assessed the long-term survival after pacemaker implantation in patients with severe and/or symptomatic bradycardia showed a similar (65.5%) 5-year survival.¹¹¹ We utilised the 64% 5-year survival estimate. This is equivalent to mortality of 36% over 5 years. Five-year mortality used in the base-case analysis is summarised in [Appendix 8, Table 48](#). This is used to derive a mortality rate and then monthly probabilities of dying in the decision model using an exponential distribution. The survival curve used in the EAG model is compared against that used in the Medtronic model in [Figure 5](#). The survival curve used in the Medtronic model was used in scenario analysis.

Hospitalisation

For TriageHF, the average number of hospitalisations per person-year (confidential information has been removed) for the comparator was obtained from the company submission.¹⁰² There were (confidential information has been removed) events over (confidential information has been removed) person-years. This was obtained from the TriageHF Plus study. The results have not yet been published. This study was assessed at critical risk of bias due to confounding (see [Table 13](#)).

The IRR was estimated using a Poisson Generalised Linear Mixed Model (GLMM) with log link. The mean IRR was 0.42 (95% CI 0.23 to 0.76; $p = 0.004$, SE = 0.3).¹⁰² The average number of hospitalisations per person-year was therefore calculated to be (confidential information has been removed) in the model.

For HeartLogic, the average number of hospitalisations per person-year (0.39, SD = 0.08) for the comparator was obtained from Treskes *et al.* included in the systematic review.³⁷ This study was assessed at serious risk of bias due to confounding (see [Table 11](#)).

The average number of hospitalisations per person-year for the HeartLogic group was reported to be 0.11, SD = 0.04. The incidence rate ratio derived by the EAG from these numbers is 0.282.

No evidence for the average number of hospitalisations per person-year was reported for CorVue or HeartInsight. For the comparator, the average number of hospitalisations per person-year was assumed to be the average of the rates for TriageHF and HeartLogic (confidential information has been removed). Threshold analysis was required for the IRR for these two CIEDs (see [Analysis scenarios](#) for a description).

The hospitalisation rates and the IRRs used in the models are summarised in [Table 31](#).

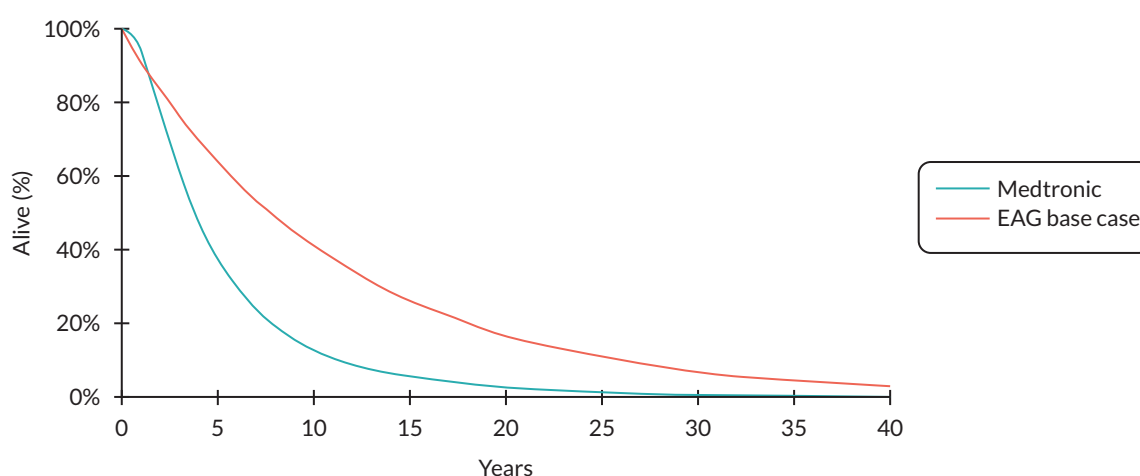


FIGURE 5 Survival curves used in the EAG model and Medtronic model.

TABLE 31 Rates of hospitalisation

RMS	Average number of hospitalisations per person-year		Source
	Comparator	Intervention	
CorVue and Merlin.net PCN	Confidential information has been removed (Assumed average of HeartLogic and TriageHF)	No evidence (threshold analysis)	
HeartInsight and BIOTRONIK Home Monitoring	Confidential information has been removed (Assumed average of HeartLogic and TriageHF)	No evidence (threshold analysis)	
HeartLogic and LATITUDE NXT Patient Management System	0.39 in a year (used in base case)	0.11 in a year (rate ratio = 0.11/0.39 i.e. 0.282) (used in base case)	³⁷
	17% in a year	10% in a year	³⁵
TriageHF and CareLink remote monitoring (TriageHF Plus)	Confidential information has been removed	Incidence rate ratio of 0.42 [95% CI (confidential information has been removed)] is used in the model to indicate (confidential information has been removed) lower rate of hospitalisations in the intervention group. Average number of hospitalisations calculated was 0.24 per person per year.	TriageHF company submission. ¹⁰²

Alerts and follow-up visits

Follow-up visits without algorithm-base remote monitoring

In the NICE scope for this Diagnostic Assessment, 'clinical experts emphasised that there is no standard HF service model and current practice is highly varied'. A combination of the ESC guidelines and the NICE guidelines are likely used.^{1,3} The ESC guidelines recommend follow-up at intervals no longer than 6 months.¹ The NICE guidelines for diagnosis and management of chronic HF in adults recommend that reviews are offered every 6 months for people whose condition is stable.³ In the scope, the clinical experts also 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'.¹ Unstable cases have more frequent follow-up frequencies.

No evidence was identified in the systematic review on follow-up visits without CRM. Pan-European data in Heidbuchel *et al.* identified in the focused review (see [Results of the targeted review of studies evaluating resource use and utility of remote monitoring systems in heart failure](#)) reported two scheduled follow-up visits per year in the CIED without remote monitoring group.⁹⁷ Since this seemed consistent with the guidelines, this was used in the base case for the CIED without remote monitoring in every case. Heidbuchel *et al.* also reported 0.62 unscheduled visits over 2 years (or 0.31 over 1 year) for the control group.⁹⁷

The Medtronic company model costed other background costs such as GP visits for their economic model. They also assumed that those costs were the same for both the CIED with remote monitoring and the CIED without remote monitoring. It is assumed here that other background costs would be the same for both groups, and have been excluded for simplicity.

Alerts and follow-up visits with algorithm-based remote monitoring

Two NICE clinical experts responded to a question on the follow-up visit schedule associated with the use of a CIED remote monitoring system. One replied that the alerts produced by the remote monitoring system would be supplementary to the existing follow-up schedule, while another replied that it was intended to replace the existing system. To recognise different possible uses of the technology, three different scenarios were modelled: zero scheduled follow-up visits per year, one scheduled follow-up visit per year, and two scheduled follow-up visits per year. In the two scheduled follow-up visits per year scenario, the number of scheduled follow-up visits is the same in both the remote monitoring group and the non-remote monitoring group.

Unscheduled visits were modelled as the number of alerts of people who are high risk. All alerts are reviewed (see [Implementation costs](#) for the cost estimate), but it is assumed that only high-risk cases have a follow-up visit. Three scenarios were modelled: the same number of unscheduled visits as for the comparator, two times the number of comparator unscheduled visits, and 4 times the number of comparator unscheduled visits.

For TriageHF, 196 high-risk alerts (transmissions) were received over (confidential information has been removed) patient-years of follow-up.¹⁰² This is an annual alert rate of (confidential information has been removed). In the TriageHF company model, (confidential information has been removed) of patients had an initial consultation, and (confidential information has been removed) of patients had a second consultation.¹⁰² In the model, this is modelled as 100% of high risk alerts have 1 in-office consultation. There was no evidence for unscheduled visits for the control group. Two scenarios were modelled: two times the unscheduled follow-up visits per year in the intervention, and four times the unscheduled follow-up visits per year in the intervention.

For HeartLogic, an annual alert rate estimate of 0.71 was obtained from Santobuno *et al.* 2023.⁷² No control evidence was provided. In the base case, it was assumed, the same as for TriageHF, that (confidential information has been removed) of alerts and had an initial consultation, and (confidential information has been removed) of alerts had a second consultation (100% of alerts have one in-office consultation). In a scenario analysis, it was assumed that 50% of alerts have one in-office consultation, and 25% have a phone call review. Two further scenarios were modelled: two times the unscheduled follow-up visits per year for the intervention group, and four times the unscheduled follow-up visits per year in the intervention.

The scheduled and unscheduled follow-up visits used in the EAG model are summarised in [Table 32](#).

Length of stay

No evidence was identified for a difference in LOS for any of the devices (with and without CRM), except for HeartLogic. Consequently, in the base case, a fixed cost was assumed for every hospitalisation. Clinical studies and economic models of related to, but not, the technologies included in this technology appraisal have included differences in average LOS for the remote monitoring compared to no remote monitoring. For the purpose of sensitivity analysis, the difference in days of LOS was included in the model.

Evidence for average LOS in the hospital for both the intervention and comparator were taken from the literature (see [Implementation costs](#)). Where evidence was not available, assumptions were made. The evidence used in the EAG model is summarised in [Table 33](#).

TABLE 32 Follow-up visits

RMS	Average follow-up visits per year	
	Comparator	Intervention
CorVue and Merlin.net PCN	Scheduled: 2 Unscheduled: 0.31	Scheduled: 0, 1, 2 Unscheduled (alerts): 0.31, 0.62, 1.24
HeartInsight and BIOTRONIK Home Monitoring	Scheduled: 2 Unscheduled: 0.31	Scheduled: 0, 1, 2 Unscheduled (alerts): 0.31, 0.62, 1.24
HeartLogic and Latitude NXT Patient Management System	Scheduled: 2 Unscheduled: 0.31	Scheduled: 0, 1, 2 Unscheduled (alerts): 0.71, 1.42, 2.84
TriageHF and CareLink remote monitoring (TriageHF Plus)	Scheduled: 2 Unscheduled: 0.31	Scheduled: 0, 1, 2 (confidential information has been removed)
Note Scheduled: 0,1,2: 0 visits, 1 visit, and 2 visits per year were modelled as different scenarios.		

TABLE 33 Length of stay in hospital

RMS	Length of stay		Source
	Comparator	Intervention	
CorVue and Merlin.net PCN	No evidence (fixed cost of a hospitalisation episode used in base case)	No evidence (fixed cost of a hospitalisation episode used in base case)	
HeartInsight and BIOTRONIK Home Monitoring	No evidence (fixed cost of a hospitalisation episode used in base case)	No evidence (fixed cost of a hospitalisation episode used in base case)	
HeartLogic and LATITUDE NXT Patient Management System	16 days per hospitalisation event (used in base case)	7 days per hospitalisation event (used in base case)	³⁷
	8 days (IQR:5–12) per hospitalisation event	5 days (IQR: 2–7) per hospitalisation event	³⁶
TriageHF and CareLink remote monitoring (TriageHF Plus)	No evidence (fixed cost of a hospitalisation episode used in base case)	No evidence (fixed cost of a hospitalisation episode used in base case)	

Adverse events

No adverse events were considered in the model because none of the studies in the systematic review reported any adverse events directly linked to the use of the remote monitoring systems for each of the CIEDs.

Health-related quality of life

The targeted literature review (see [Results of the targeted review of studies evaluating resource use and utility of remote monitoring systems in heart failure](#)) informed the utility estimates for being alive with HF or at risk of HF and with one of the CIEDs considered in the economic evaluation [CorVue:⁹⁶ comparator (0.85 ± 0.18), intervention (0.87 ± 0.16), and TriageHF:⁹⁴ comparator ($0.711;0.305$), intervention ($0.754;0.275$)]. In addition to this, the UK population-based utility estimates for HF patients reported in a recent systematic literature review ranged from 0.52 (SD 0.26) to 0.696 (SD 0.26).¹¹² However, these mean utilities reported for HF were not time dependent and also would be higher than the mean utilities in the UK general population, something not reflecting the HF population in the UK setting. Therefore, to ensure that the utility estimates for HF population do not exceed that of the general population, we utilised the approach taken in a company submission for TriageHF.¹⁰²

HF population utilities in subgroups of NYHA class (see [Appendix 8, Table 49](#)) were obtained from Griffiths *et al.*¹¹³ The EAG made the assumption that the mean utility for the undiagnosed subgroup was the same as for the NYHA class 1 subgroup. The UK general population utility 0.84^{114,115} was subtracted from the HF population utilities in subgroups of NYHA class (see [Appendix 8, Table 49](#)) to derive the utility decrement for HF population in each NYHA class (see [Appendix 8, Table 50](#)). The percentage of patients in each NYHA class was obtained from the Medtronic submission,¹⁰⁰ and this was used to calculate the weighted average utility decrement for a patient with HF (see [Appendix 8, Table 50](#)). In addition, a separate utility decrement for a hospitalisation event was calculated. Utility decrements for hospitalisation by NYHA class were also obtained from Griffiths *et al.*¹¹³ These were multiplied by the same patient distribution across NYHA class percentages from the Medtronic submission¹⁰⁰ to derive the weighted average utility decrement for hospitalisation (see [Appendix 8, Table 51](#)). HF utility decrements were applied to HF population alive at each model cycle; however, the hospitalisation decrement was only applied to the proportion hospitalised in each cycle.

Costs

The resource use and costs considered in the model were remote monitoring system costs along with any implementation costs (e.g. Training costs and device maintenance costs), hospitalisation, LOS in the hospital, and follow-ups for patients with (intervention) and without remote monitoring systems (comparator).

Estimating absolute utility decrements for both HF and hospitalisations could result in lower QALY gains from the intervention. A scenario analysis, where the relative utility decrements (instead of absolute values) was undertaken to assess the impact on QALYs of the approach taken in estimating the utility decrement from HF and hospitalisations. In this case, the utility decrement is described as a percentage of the general population age-related utility.

Remote monitoring system costs

The remote monitoring system costs were variable because of the heterogeneity in devices and any other associated maintenance costs for these devices. The costs of the remote monitoring devices considered the following components:

- i. costs of the remote monitoring device for each patient
- ii. any maintenance/consumable costs of the remote monitoring systems.

These costs of remote monitoring systems to the NHS were based on company responses to the NICE request for information. The costs of remote monitoring system for each CIED considered in the model are reported in [Appendix 8, Table 52](#).

Implementation costs

Time for staff training and responding an alert are presented in [Appendix 8, Table 53](#). The implementation costs considered in the economic model were the staff training time costs and cost of staff time needed to respond/review remote monitoring system alerts. These implementation costs reported in [Appendix 8, Table 54](#) were based on company responses to the NICE request for information on training time and time spent actioning an alert. There was heterogeneity in the implementation cost for each CIED considered in the model. The unit costs for staff time were taken from secondary source.¹¹⁶

Hospitalisation

To ensure consistency across models of each device, the same unit cost estimate of hospitalisation was used for the comparator in each model. The unit cost estimate of each hospitalisation was £3758.18. This was based on the weighted average of the costs for the Healthcare Resource Group (HRG) 'Heart Failure or Shock' (EB03A-EB03E) based on the Non-Elective Inpatient-Long Stay data obtained from NHS reference costs.¹⁰¹ Weighted average of the costs (£666.43) for the HRG 'Heart Failure or Shock' (EB03A-EB03E) based on the Non-Elective Inpatient-Short Stay data obtained from NHS reference costs¹⁰¹ was used in the scenario analysis.

Where there was no evidence for a difference in LOS of a hospitalisation, the average LOS for a hospitalisation was assumed to be the same for both CRM and no CRM; the unit cost estimate of each hospitalisation was £3758.18 for both CRM and no CRM. Where there was evidence for a difference in LOS between CRM and no CRM, the cost of a day in hospital was multiplied by the difference in days and this was added or subtracted from £3758.18 to determine the cost of hospitalisation for the intervention. See [Length of stay](#) for the cost estimate of 1 day in hospital.

Length of stay

Where there was no evidence for a difference in LOS of a hospitalisation, the average LOS for a hospitalisation was assumed to be the same for both CRM and no CRM. The cost assigned for a hospitalisation was the average cost of hospitalisation (see [Hospitalisation](#)).

Where there was evidence for a difference in LOS, the cost of an extra day in hospital was multiplied by the difference in days and this was subtracted from the comparator cost of hospitalisation. The cost of an extra day in hospital was £290, listed in the 2022/23 national tariff workbook (Annex A) – updated for national insurance changes.¹¹⁷

Follow-up visits

The unit cost estimate of a follow-up visit was £169. This was based on an Outpatient attendance for Cardiology services (both consultant led and non-consultant led) (Service code: 320) from the NHS reference costs.¹⁰¹ It was assumed that both the scheduled and unscheduled follow-up visits would have same unit costs. For the scenario

analyses, where non-face-to-face follow-up contacts are modelled, the costs was £97.44 and was based on non-admitted, non-face-to-face attendance follow-up (non-consultant led), for cardiology services (service code:WF01C) from the NHS reference costs.¹⁰¹

Analysis

Analysis scenarios

The cost-effectiveness of each implantable device with an algorithm-based remote monitoring system compared to the same device without the remote monitoring system was evaluated. Four technologies were included in the scope. The analyses undertaken varied by technology according to the availability of comparative evidence on outcomes.

Subgroup analyses were only undertaken if there were relevant comparative outcome estimates, and differences in the estimates were likely to significantly affect the cost-effectiveness results.

The ICER is calculated as

$$ICER = \frac{C_I - C_C}{Q_I - Q_C},$$

where C_I is the total cost associated with the intervention, C_C is the total cost associated with the comparator, Q_I is the total QALYs associated with the intervention, and Q_C is the total QALYs associated with the comparator.

If the $ICER < \text{threshold}$, then the technology is considered cost-effective at that threshold. The cost-effectiveness thresholds recommended in the NICE guidance are used in this report: £20,000/QALY, and £30,000/QALY.

Comparative evidence was sought for hospitalisation rates, follow-up visits, mortality and LOS. Based on the clinical studies included in the systematic review and the studies included in the systematic review of cost-effectiveness studies, hospitalisation was selected as the most important outcome. This was followed by follow-up visits, then mortality, and finally LOS. This hierarchy was set to define the model scenarios and analyses undertaken. For example, if comparative evidence on hospitalisation and follow-up visits were available for a technology, but no evidence on mortality or LOS, then no difference in mortality and LOS could be assumed and a cost-effectiveness analysis conducted.

If there was no evidence on follow-up visits, nine different scenarios of the numbers of scheduled and scheduled visits for the intervention were defined (see [Follow-up visits](#)). Given that two scheduled follow-up visits were assumed for Standard Care, either 2, 1 or 0 scheduled visits per year were assumed for the intervention. This was done to allow for different scenarios regarding the degree to which the technology displaced current monitoring practice. Given the lack of evidence on unscheduled visits, the unscheduled visits for the intervention were assumed to be either the same as in current practice, twice as many or four times as many. This meant that threshold analysis could be conducted on the incidence rate ratio of hospitalisation for scenarios defined for the other outcomes of interest. In the base-case scenario, the number of yearly scheduled and unscheduled visits were assumed to be the same for RMS and SoC. The other combinations of scheduled and unscheduled visits were secondary scenarios.

Threshold analysis involves increasing or decreasing the value of a parameter until the cost-effectiveness threshold is crossed or a technology changes from being dominant to non-dominant or vice-versa. This is often done when a technology is not cost-effective using the base-case value. Suppose, for example, there is no evidence on any of the outcomes, we may assume that there is no difference in mortality or in LOS and we define scenarios for scheduled and unscheduled follow-up visits. We also assume that there is no difference in rate of hospitalisation. The ICER of the technology is *greater* than £20,000/QALY in a couple of scenarios. In this situation we could conduct threshold analysis on the IRR of hospitalisation. We reduce the IRR (which means that the rate of hospitalisation of the intervention reduces) until the ICER of the technology becomes *lower* than £20,000/QALY. This value of IRR at which the £20,000/QALY threshold is crossed is the minimum effectiveness required of the intervention for it to be cost-effective at that threshold.

Threshold analysis can also be done where there is an effectiveness estimate and the technology is cost-effective, but due to concerns about the risk of bias or generalisability associated with the effectiveness estimate the size of effectiveness is reduced until the technology is no longer cost-effective.

The device-specific analyses conducted at the baseline is summarised in [Table 34](#).

Deterministic analyses were conducted for the scenarios which included the most conservative assumptions or estimates for the RMS technology. If the RMS technology was cost-effective in this scenario, then it would be even more cost-effective in other scenarios, and deterministic analyses were not conducted for those scenarios in that situation.

Probabilistic sensitivity analysis involves simultaneously sampling from parameter distributions that have been specified in the model to reflect uncertainty in the parameter estimate. For the PSAs conducted here, 1000 iterations were run,

TABLE 34 Summary of the base-case analyses conducted

RMS	Evidence	Analyses
CorVue and Merlin.net PCN	No evidence on any outcome	Base-case scenario assumed: no difference in mortality, LOS SoC scheduled visits = 2 SoC unscheduled visits = 0.31 RMS scheduled visits = 2 RMS unscheduled visits = 0.31 Secondary scenarios: other combinations of scheduled visits (0, 1, 2) and unscheduled (alerts) visits (0.31, 0.62, 1.24) for RMS Threshold analysis conducted on IRR of hospitalisation if technology not cost saving assuming IRR = 1 Tertiary scenarios for other parameters (see Tertiary scenario analyses)
HeartInsight and BIOTRONIK Home Monitoring	No evidence on any outcome	Base-case scenario assumed: no difference in mortality, LOS SoC scheduled visits = 2 SoC unscheduled visits = 0.31 RMS scheduled visits = 2 RMS unscheduled visits = 0.31 Secondary scenarios: other combinations of scheduled visits (0, 1, 2) and unscheduled (alerts) visits (0.31, 0.62, 1.24) for RMS Threshold analysis conducted on IRR of hospitalisation if technology not cost saving assuming IRR = 1 Tertiary scenarios for other parameters (see Tertiary scenario analyses)
HeartLogic and LATITUDE NXT Heart Failure Management System	Evidence on rate of hospitalisation and unscheduled visits	Base-case scenarios assumed: no difference in mortality, LOS SoC scheduled visits = 2 SoC unscheduled visits = 0.31 RMS scheduled visits = 2 RMS unscheduled visits = 0.71. Secondary scenarios: RMS scheduled visits (0, 1) and Unscheduled (alerts) visits (1.42, 2.84) for RMS Cost-effectiveness analysis conducted for base-case and secondary scenarios using comparative evidence for IRR of hospitalisation and IRR of unscheduled visits Tertiary scenarios for other parameters (see Tertiary scenario analyses)
TriageHF and CareLink remote monitoring (TriageHF Plus)	Evidence on rate of hospitalisation and unscheduled visits	Base-case scenarios assumed: no difference in mortality, LOS SoC scheduled visits = 2 SoC unscheduled visits = 0.31 RMS scheduled visits = 2 (confidential information has been removed) Secondary scenarios: RMS scheduled visits (0,1) and unscheduled (alerts) visits (confidential information has been removed) for RMS Cost-effectiveness analysis conducted for base-case and secondary scenarios using comparative evidence for IRR of hospitalisation and IRR of unscheduled visits Tertiary scenarios for other parameters (see Tertiary scenario analyses)

resulting in 1000 estimates of incremental cost, incremental effectiveness and cost-effectiveness. PSA was run when there was evidence of effectiveness. PSA was not run when a threshold analysis was conducted.

Incremental costs, incremental QALYs and ICER, along with other intermediate outcomes (e.g. mortality, LOS, hospitalisation and follow-up), were estimated and reported in tables. The 1000 estimates of incremental cost and incremental effectiveness for each PSA were presented as a cost-effectiveness scatter plot. The probability that a technology was cost-effective was calculated from the PSAs across a range of cost-effectiveness thresholds, and the results presented as a cost-effectiveness acceptability curve (CEAC). In addition, scenario analyses were conducted to explore the significance of different parameter values on the cost-effectiveness results.

The base-case parameters and their associated assumptions along with their sources are presented in [Table 35](#).

TABLE 35 Base-case parameters and assumptions

Parameter	Values	Source/assumptions	Probabilistic model
Age	60	Assumed	NA
Proportion of male	72.2%	¹⁰² assumed same across devices	NA
Discount rate – costs	3.5%	In line with NICE guidance	NA
Discount rate-benefits	3.5%	Same as above	NA
Utility			
HF utility decrement	–0.107	¹⁰² assumed same across devices	NA
Hospitalisation utility decrement	–0.070	Same as above	NA
Costs			
Per patient cost of the RMS –CorVue	£0	One-off; company provided information	Yes
Per Patient cost of the RMS –HeartInsight	£450	One-off, company provided information	Yes
Per Patient Cost of the RMS –HeartLogic	Confidential information has been removed	One-off, company provided information	Yes
Per Patient Cost of the RMS –TriageHF	£8.33	Per month, company provided information	Yes
Per Patient cost of RMS maintenance/consumables – All devices	£0	No additional costs of maintenance/consumables- company provided information	NA
Training cost of cardiac physiologist nurse – CorVue	£26.50	One-off, estimated as a product of time spent in training (company provided information) and per min cost of specialist nurse	Yes
Training cost of cardiac physiologist nurse – HeartInsight	£53	One-off, estimated as a product of time spent in training (company provided information) and per min cost of specialist nurse	Yes
Training cost of cardiac physiologist nurse – HeartLogic	£53	One off, estimated as a product of time spent in training (company provided information) and per min cost of specialist nurse	Yes
Training cost of cardiac physiologist nurse – TriageHF	£53	One off, estimated as a product of time spent in training (company provided information) and per min cost of specialist nurse	Yes

TABLE 35 Base-case parameters and assumptions (continued)

Parameter	Values	Source/assumptions	Probabilistic model
Per patient cost of alert monitoring time spent – CorVue	£0.11	Per month, estimated as a product of cost of time spent actioning an alert (company provided information) and alert per month. The alerts per month were assumed to be equal to the unscheduled visits	No
Per patient cost of alert monitoring time spent – HeartInsight	£0.69	Per month, estimated as a product of cost of time spent actioning an alert (company provided information) and alert per month. The alerts per month were assumed to be equal to the unscheduled visits	No
Per patient cost of alert monitoring time spent – HeartLogic	£1.31	Per month, estimated as a product of cost of time spent actioning an alert (company provided information) and alert per month per patient (derived from 0.71 alerts per patient per year provided by company; assumed same across devices)	No
Per patient cost of alert monitoring time spent – TriageHF	Confidential information has been removed	Per month, estimated as a product of cost of time spent actioning an alert (company submission document) and alert per month per patient [derived from (confidential information has been removed) alerts per patient per year provided by company; assumed same across devices]	No
Cost per hospitalisation – all devices	£3758.18	Weighted average of the costs for the HRG 'Heart Failure or Shock' (EB03A-EB03E) based on the Non-Elective Inpatient- Long Stay ¹⁰¹	Yes
Cost per follow-up visit – all devices	£169	NHS Reference costs- costs of Outpatient attendance for Cardiology services (both consultant led and non-consultant led) (Service code: 320) ¹⁰¹	Yes
Cost per specialist nurse/cardiac physiologist per hour – all devices	£53	Cost of hospital-based Band 6 Physiologist: £53 per hour. ¹¹⁶	Yes
Cost per day in hospital – all devices	£290	Cost per day in the hospital ^{101,117}	
Hospitalisation			
Hospitalisation rate per month (Comparator) – CorVue	0.0404	Derived as an average of comparator hospitalisation in HeartLogic and TriageHF	No
Hospitalisation rate per month (Comparator) – HeartInsight	0.0404	Derived as an average of comparator hospitalisation in HeartLogic and TriageHF	No
Hospitalisation rate per month (Comparator) – HeartLogic	0.033	³⁷	No
Hospitalisation rate per month (Comparator) – TriageHF	Confidential information has been removed	Confidential information has been removed	No
Hospitalisation Rate Ratio (RR) – CorVue	1	No difference between intervention and comparator assumed	Yes
Hospitalisation rate ratio (RR) – HeartInsight	1	No difference between intervention and comparator assumed	Yes
Hospitalisation rate ratio (RR) – HeartLogic	0.282	³⁷	Yes
Hospitalisation rate ratio (RR) – TriageHF	0.42	¹⁰²	Yes
Follow-up – scheduled			
Scheduled follow-up visits per month (Comparator and Intervention) – all devices	0.17	Derived from assumed two visits per year; ⁹⁷ equal visits considered in the intervention and comparator	Yes

continued

TABLE 35 Base-case parameters and assumptions (*continued*)

Parameter	Values	Source/assumptions	Probabilistic model
Follow-up – unscheduled			
Unscheduled follow-up visits (Comparator) – all devices	0.026	⁹⁷ Monthly estimates derived from 0.31 follow-up visits per year (0.31/12)	Yes
Unscheduled follow-up visits (Intervention) – CorVue and HeartInsight	0.026	Assumed no difference between the comparator and intervention	Yes
Unscheduled follow-up visits (Intervention) – HeartLogic	0.0592	⁷² Assumed equal to 0.71 alerts per year (0.0592 per month)	Yes
Unscheduled follow-up visits (Intervention) – TriageHF	confidential information has been removed	¹⁰² monthly estimates derived from (confidential information has been removed) follow-up visits per year	Yes
LOS in hospital			
LOS days per hospitalisation (Comparator) – all devices	16	³⁷ No evidence available for devices other than HeartLogic; assumed same as HeartLogic for all devices	Yes
LOS days per hospitalisation (Intervention) – CorVue, HeartInsight and TriageHF	16	No evidence available; assumed no difference to the comparator	Yes
LOS days per hospitalisation (Intervention) – HeartLogic	7	³⁷	Yes
Mortality			
All devices – hazard ratio (HR)	1	¹¹⁰ Comparator mortality percentage at 5 years = 0.36 was used to derive monthly probability as 0.00741	Yes

Subgroup analysis

The model also considered a number of subgroups of patients. The evidence for these subgroups were not available at the time the model was developed; however, the model provides a flexibility to make changes (or add new) to the model parameters as and when they become available for each subgroup in the future. The subgroups outlined in the protocol and considered in the model are:¹⁰⁷

- i. People who have a CIED and do not have a diagnosis of HF but are at risk of new-onset acute HF:
 - a. have a CRT-P device
 - b. have a CRT-D device
 - c. have an ICD device
 - d. have a pacemaker device.
- ii. People who have a CIED and have a diagnosis of chronic HF:
 - 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 NYHA class I and II HF
 - f. have a diagnosis of NYHA class III and IV HF
 - g. have a prior HF hospitalisation or urgent care visit within the last 12 months.

TABLE 36 Details of the parameters considered for scenario analyses

Scenario	Parameter	Base-case	RMS	Scenario analysis
1.	LOS in hospital intervention – HeartLogic	7	All	16 (assumed same as comparator)
2.	Cost per hospitalisation – all devices	£3758.18	All	£666.43
3.	Cost of nurse/physiologist time per hour – all devices	£53	All	£58
4.	Survival rates	Survival based on fixed monthly mortality rate of 0.00741	All	Survival based on Medtronic company submission model
5.	IRR hospitalisation	0.282	HeartLogic	0.641 (Assumed half-way between the base-case value and 1)
6.	IRR hospitalisation	0.42	TriageHF	0.71 (Assumed half-way between the base-case value and 1)
7.	Alert monitoring time – CorVue	5 minutes	CorVue	10 minutes
8.	Alert monitoring time – HeartInsight	30 minutes	HeartInsight	60 minutes
9.	Alert monitoring time – HeartLogic	20 minutes	HeartLogic	40 minutes
10.	Alert monitoring time – TriageHF	30 minutes	TriageHF	60 minutes
11.	Excluding uncertainty in mortality in the PSA	10% uncertainty was modelled in the PSA	HeartLogic and TriageHF	No uncertainty in the the mortality estimates was modelled in the PSA.
12.	Calculating utility decrement as relative values instead of absolute differences	Absolute utility decrements were used for HF and hospitalisation in the model	All	Relative utility decrements were used for HF and hospitalisation in the model.
13.	Assuming only 50% of the alerts in the intervention group require in-office follow-up visits and 25% of the alerts only require are non-face-to-face contacts	Assumed that all alerts would lead to face-to-face follow-up visit	CorVue, HeartInsigh, HeartLogic	Assumed only 50% of the alerts would lead to a face-to-face visit, and 25% of the alerts would have non-face-to-face contact with the health worker. The cost of non-face-to-face contact was assumed £97.44 (the cost of non-consultant led cardiology service (WF01C), non-admitted face-to-face attendance follow-up) ¹⁰¹

Tertiary scenario analyses

In addition to the base-case scenario and secondary scenarios defined in *Analysis scenarios*, a few tertiary scenario analyses were undertaken to test the robustness of the base-case results to key uncertainties in the model. The EAG acknowledges the difference in survival estimates used in the EAG model and the Medtronic company submission model (Figure 5). Therefore, the EAG conducted a scenario analysis of the results using the survival analysis from the Medtronic model into the EAG model. Considering the potential biases in the evidence for hospitalisation rates for HeartLogic and TriageHF, the EAG also conducted a scenario analysis of increasing the IRR of hospitalisation halfway between 1 and the IRR used in the base case. Details of base case and variations made in the scenario analyses are presented in Table 36.

Model validation

The model was developed in Microsoft Excel by NB and validated by two other health economists (SR and SH). Internal validation involved varying model input parameters and assessing whether the model results were sensitive and logical.

Model results

The economic evaluation consisted of base-case analysis (both deterministic and probabilistic) and few scenario analyses. The economic evaluation was conducted for each of the four RMS strategies, that is CorVue, HeartInsight, HeartLogic and TriageHF.

Base-case scenario and secondary scenario results

Deterministic base-case findings are presented in [Table 37](#) and the costs breakdown are presented in [Table 38](#).

There was no hospitalisation outcome evidence for CorVue and HeartInsight. For the base-case scenario assuming no difference in hospitalisations, RMS for CorVue and HeartInsight were cost-increasing because of the cost of the RMS technology and reviewing alerts. In the scenarios where unscheduled follow-up visits in the intervention group were doubled or quadrupled, RMS for CorVue and HeartInsight remained cost-increasing. However, when scheduled follow-up visits in the intervention were assumed as 1 or 0 per year (i.e. lower than two visits assumed for the comparator), the RMS intervention was cost saving for CorVue and HeartInsight.

TABLE 37 Deterministic cost-effectiveness results of the base-case analysis

Items	CorVue		HeartInsight		HeartLogic		TriageHF	
	I	C	I	C	I	C	I	C
Total								
Costs (£)	17855	17848	18415	17848	Confidential information has been removed		17748	20712
QALYs	5.83	5.83	5.83	5.83	5.84	5.83	5.84	5.82
Cumulative hospitalisations per person	5.28	5.28	5.28	5.28	1.20	4.25	2.65	6.31
Cumulative days in hospital	84.48	84.48	84.48	84.48	8.38	67.96	42.42	101
Cumulative Follow-up_1 ^a	22.22	22.22	22.22	22.22	22.22	22.22	22.22	22.22
Cumulative Follow-up_2 ^b	3.40	3.40	3.40	3.40	7.74	3.40	4.70	3.40
Proportion died after 40 years	0.97	0.97	0.97	0.97	0.97	0.97	0.97	0.97
Incremental (intervention vs. comparator)								
Costs (£)	37		568		Confidential information has been removed		-9048	
QALYs	0		0		0.01		0.01	
Cumulative hospitalisations per person	0		0		-3.05		-3.66	
Cumulative days in hospital	0		0		-59.58		-59	
Cumulative Follow-up_1 ^a	0		0		0		0	
Cumulative Follow-up_2 ^b	0		0		4.34		1.31	
Proportion died after 40 years	0		0		0		0	
ICER	Cost-increasing		Cost-increasing		Dominant		Dominant	

C, comparator; I, intervention.

^a Follow-up_1: scheduled visits.

^b Follow-up_2: unscheduled visits.

TABLE 38 Cost breakdown in the base-case cost-effectiveness analysis

Costs (£)	CorVue		HeartInsight		HeartLogic		TriageHF	
	I	C	I	C	I	C	I	C
Total								
RMS	26.40	0	501.14	0	Confidential information has been removed	0	857	0
Monitoring alert	11.08	0	66.49	0	126.15	0	92	0
Cumulative days in hospital	14651	14651	14651	14651	1795	14552	7357	17516
Cumulative Follow-up_1 ^a	2772	2772	2772	2772	2772	2772	2772	2772
Cumulative Follow-up_2 ^b	4244	424	424	424	965	424	587	424
Incremental costs (£) (intervention vs. comparator)								
RMS	26.40		501.14		Confidential information has been removed		857	
Monitoring alert	11.08		66.49		126.15		92	
Cumulative days in hospital	0		0		-12,757		-10,159	
Cumulative Follow-up_1 ^a	0		0		0		0	
Cumulative Follow-up_2 ^b	0		0		541		163	
Incremental total costs (£)	37		568		Confidential information has been removed		-9048	
C, comparator; I, intervention. a Follow-up_1: scheduled visits. b Follow-up_2: unscheduled visits.								

For the base-case scenarios for CorVue and HeartInsight, threshold analysis showed that an IRR of hospitalisation below 0.99 and 0.96 respectively would make RMS of these devices dominant (i.e. less costly, more effective). For the scenario where the unscheduled follow-up visits were quadrupled for CorVue and HeartInsight, threshold analysis showed that an IRR of hospitalisation below 0.91 and 0.87 respectively would make RMS of these device devices dominant.

There was hospitalisation outcome evidence for HeartLogic and TriageHF. In the base-case analyses both HeartLogic and TriageHF were dominant (i.e. less costly, more effective). HeartLogic and TriageHF both remain dominant if the scheduled follow-up visits are 1 or 0 per year for RMS and will be more cost-saving as long as the reduction in the number of scheduled visits is greater than additional unscheduled visits. In the scenarios where unscheduled follow-up visits in the intervention group per year were doubled or quadrupled the RMS for HeartLogic and TriageHF remained dominant.

The PSA estimates for HeartLogic and TriageHF ([Table 39](#)) were similar to the deterministic estimates, where RMS for HeartLogic and TriageHF were both dominant (i.e. less costly and more effective compared to standard care). The CEAC ([Figure 6](#)) shows that the probability cost-effectiveness for HeartLogic RMS at WTP value of £20,000 was 88% whereas at £30,000 the probability cost-effectiveness was 77%. The probability of cost-effectiveness for TriageHF RMS at WTP values of £20,000 and £30,000 were respectively 85% and 76% ([Figure 7](#)). These results observed in CEACs are also reflected in the cost-effectiveness scatterplots (see [Appendix 8](#), [Figures 8](#) and [9](#)).

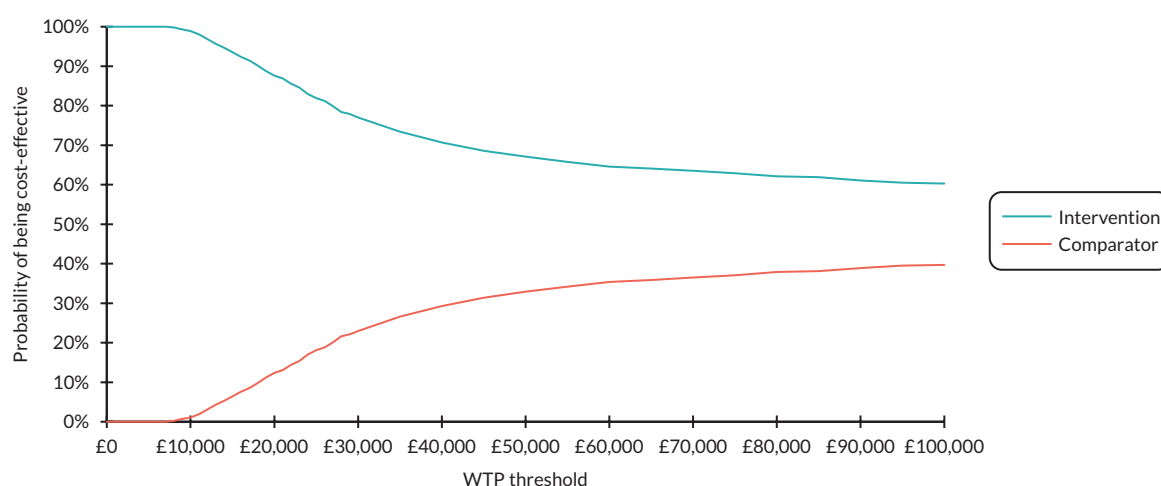
One-way sensitivity analyses

The EAG could not conduct a one-way sensitivity analysis for base-case results because it was not feasible to derive an ICER when the results were either cost saving, cost-increasing or dominant.

TABLE 39 Probabilistic cost-effectiveness results of the base-case analysis

Items	HeartLogic		TriageHF	
	I	C	I	C
Total				
Costs (£)	Confidential information has been removed	17,955	11,674	20,857
QALYs	5.85	5.83	5.84	5.82
Cumulative hospitalisations per person	1.20	4.28	2.66	6.37
Cumulative days in hospital	8.35	68.25	42.18	101.31
Cumulative Follow-up_1 ^a	22.33	22.21	22.29	22.17
Cumulative Follow-up_2 ^b	7.76	3.40	4.72	3.41
Proportion died after 40 years	0.97	0.97	0.97	0.97
Incremental (intervention vs. comparator)				
Costs (£)	Confidential information has been removed		-9183	
QALYs	0.02		0.02	
Cumulative hospitalisations per person	-3.08		-3.71	
Cumulative days in hospital	-60		-59	
Cumulative Follow-up_1 ^a	0		0	
Cumulative Follow-up_2 ^b	4.39		1.31	
Proportion died after 40 years	0		0	
ICER	Dominant		Dominant	

C, comparator; I, intervention.
a Follow-up_1: scheduled visits.
b Follow-up_2: unscheduled visits.

**FIGURE 6** Cost-effectiveness acceptability curve – HeartLogic.

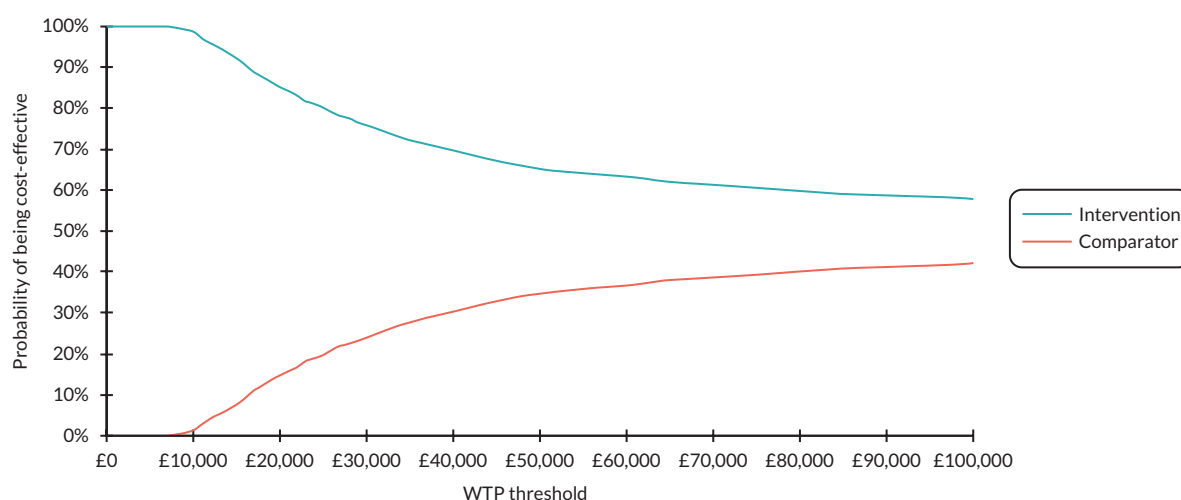


FIGURE 7 Cost-effectiveness acceptability curve – TriageHF.

Subgroup analyses

There was only evidence on hospitalisation IRR for ICT, CRT-P and CRT-D for TriageHF, which was in the company submission. The IRR of hospitalisation for TriageHF varied from (confidential information has been removed) to (confidential information has been removed). These differences will have no effect on the cost-effectiveness results for TriageHF.

There was no evidence on hospitalisation IRR for patients with a CIED without a diagnosis of chronic HF. (confidential information has been removed) of the population of TriageHF Plus had a prior diagnosis of HF.

Tertiary scenario analyses

The EAG conducted a variety of tertiary scenario analyses.

Scenario A included no difference in LOS between intervention and comparator for HeartLogic (LOS for the intervention was assumed same as comparator in the base case). Additional scenario analyses for HeartLogic and TriageHF involved increasing the IRR of hospitalisation (scenario F), and using survival data from Medtronic company submitted model for all RMS devices (scenario E), doubling the base-case alert monitoring time spent by nurse (scenario G), lower costs of hospitalisation (scenario B) and higher costs of staff time (scenario C).

Scenario analyses results are presented in [Table 40](#). The results are similar to the ones observed in the base-case analyses for all devices. When no difference in the LOS between the intervention and comparator was assumed for HeartLogic, then the RMS was dominant. The use of Medtronic submitted survival data did not change the cost-effectiveness of the devices – the results were generally similar to the base case. In addition, not modelling uncertainty in the mortality parameter in the PSA did not change the results for HeartLogic and TriageHF; however, the probability of cost-effectiveness was 100% at WTP values of £20k and £30k for both the devices. Increasing the IRR of hospitalisation halfway between the base-case value and 1, did not change the dominance of RMS observed in the base case. Changing the approach of estimating the utility decrements did not change the study conclusions; however, the QALYs gains from the interventions were higher for HeartLogic and TriageHF when relative utility decrements were used in the model. Assuming only 50% of the alerts in the intervention group would require in-office follow-up visits and 25% of the alerts would only require non-face-to-face contacts, did change Corvue from being ‘cost-increasing’ in the base case to ‘cost saving’, while there was no change in the study conclusions for HeartInsight and HeartLogic.

TABLE 40 Scenario analyses cost-effectiveness results

Label	Scenario	Device-cost-effectiveness			
		CorVue	HeartInsight	HeartLogic	TriageHF
A	LOS in the intervention equal to that of comparator in the base case	–	–	Dominant	–
B	Lower hospitalisation costs (£666.43)	Cost-increasing (threshold analysis shows that IRR hospitalisation < 0.98 will have cost-effective RMS)	Cost-increasing (threshold analysis shows that IRR hospitalisation < 0.808 will have cost-effective RMS)	Dominant	Dominant
C	Higher costs of staff time (£58 per hour)	Cost-increasing (threshold analysis shows that IRR hospitalisation < 0.99 will have cost-effective RMS)	Cost-increasing (threshold analysis shows that IRR hospitalisation < 0.96 will have cost-effective RMS)	Dominant	Dominant
D	LOS in the intervention equal to the comparator	–	–	Dominant	–
E	Medtronic Survival rates	Cost-increasing (threshold analysis shows that IRR hospitalisation < 0.99 will have cost-effective RMS)	Cost-increasing (threshold analysis shows that IRR hospitalisation < 0.93 will have cost-effective RMS)	Dominant	Dominant
F	Increased IRR hospitalisation halfway between the base-case value and 1	–	–	Dominant	Dominant
G	Doubled Alert monitoring time	Cost-increasing (threshold analysis shows that IRR hospitalisation < 0.99 will have cost-effective RMS)	Cost-increasing (threshold analysis shows that IRR hospitalisation < 0.95 will have cost-effective RMS)	Dominant	Dominant
H	Excluding uncertainty in Mortality in the PSA	–	–	Dominant (the probability of cost-effectiveness was 100% at WTP value of £20k and £30k; however, in the base case the probability was 88% at £20k, and 77% at £30K WTP value)	Dominant (the probability of cost-effectiveness was 100% at WTP value of £20k and £30k; however in the base case the probability was 85% at £20k, and 76% at £30k WTP value)
I	Caclulating utility decrement as relative values instead of absolute differences	Cost-increasing	Cost-increasing	Dominant (QALYs gained 0.02 which is higher than 0.01 observed in the base-case analysis)	Dominant (QALYs gained 0.02 which is higher than 0.01 observed in the base-case analysis)
J	Assuming only 50% of the alerts in the intervention group require follow-up visits and 25% of the alerts only require non-face-to-face contacts	Cost saving	Cost-increasing	Dominant	–

Summary of the economic analysis

The EAG utilised a de novo two state Markov model (with Alive and Dead states) to estimate the cost-effectiveness of algorithm-based remote monitoring of HF risk data in people with CIEDs. CorVue, HeartInsight, HeartLogic and TriageHF were modelled separately and outcome differences for one device were not assumed to apply to another device. The model structure captured the key costs and outcomes associated with RMS given the available evidence. There may be other benefits associated with the use of algorithms that are not included in the model, but there was limited quality evidence for the benefits included in the model. Mortality rates, risk of hospitalisation, clinic visits (scheduled and unscheduled) and LOS per hospitalisation were independently modelled. QALYs gained was the primary outcome for economic evaluation.

There was no comparative evidence on hospitalisation, mortality and follow-up visits or LOS for CorVue or HeartInsight. CorVue and HeartInsight were cost-increasing when a conservative assumption of no difference in hospitalisation, mortality, follow-up visits (scheduled/unscheduled) was made. Threshold analysis for these two devices showed that even a very small reduction in the IRR of hospitalisation would make them cost-effective.

HeartLogic had some evidence on LOS, and hospitalisation rates and the cost-effectiveness estimates showed it to be dominant (i.e. less costly and more effective than the comparator). TriageHF also had some evidence on hospitalisation rates, and was also dominant. The studies supplying the hospitalisation and LOS evidence were either at serious or critical risk of bias due to confounding.

Due to the high cost of hospitalisation, the RMS devices for these technologies only need to reduce the hospitalisation rates by small percentage for them to become cost-effective. The lack of hospitalisation outcome evidence for CorVue or HeartInsight means it is not possible to produce cost-effectiveness estimates for these technologies. The cost-effectiveness estimates of HeartLogic and TriageHF are based on evidence that is at risk of bias.

Chapter 7 Discussion

Statement of principal findings

Clinical effectiveness

Overall, the EAG considers the evidence were limited for all the algorithms. Most evidence for algorithms were derived from single cohorts (prospective and retrospective studies) that lacked a comparator group.

HeartLogic was associated with adequate to high sensitivity and specificity for the prediction of HF events (i.e. hospitalisations). False positive rates for HeartLogic were also low. Only three comparative studies were identified for HeartLogic,³⁵⁻³⁷ with the majority of the evidence derived from single cohort studies that compare IN and OUT of alert status (i.e. high vs. low risk categories based on the algorithm). Two of the comparative studies also utilised single cohorts, assessing pre and post algorithm activation. There is evidence for an association of greater risk between being IN alert compared to OUT of alert of HF events (e.g. hospitalisations). Compared to no algorithm, there was a mix of statistically significant and non-significant results, however, there was a numerical trend towards reductions in HF events (e.g. hospitalisations) when using HeartLogic.

There was substantial heterogeneity in TriageHF prognostic accuracy measures, estimates of sensitivity and specificity varied widely between studies. False positive rates were only reported in one study and were relatively low. Only a single study for TriageHF was comparative, providing real-world data on hospitalisations in a UK setting. However, this study was rated at critical risk of bias using ROBINS-I.²⁸ The remaining evidence was single cohort studies comparing risk status (high, medium and low). There is evidence for an increased risk of HF events when in high risk status compared to low risk status (e.g. hospitalisations). The lack of comparative data means we cannot draw conclusions on TriageHF use compared to standard care (i.e. no algorithm). It is worth noting that a number of studies evaluating TriageHF were undertaken in a UK setting ($n = 5$).

Evidence for the accuracy of CorVue showed low sensitivity, while specificity was not generally reported. False positive rates were high in most studies. There was one comparative study, a retrospective medical chart review of hospitalisations.³⁴ The remaining evidence was all single cohort studies, which generally compared alert to no alert. There was a lack of association data regarding the risk of an HF event. There was some evidence to suggest low hospitalisation rates when in high risk alert. However, some comparative evidence suggests a potential to reduce hospitalisations in those using CorVue compared to no device with standard home care.³⁴

For HeartInsight only one published study was identified, which was the development and validation study and showed adequate sensitivity and specificity for HF events. False positive rates were moderate in this single study. No comparative evidence was identified for the use of HeartInsight. There was a lack of evidence for the HeartInsight algorithm, as we only identified one study. This study did find a significant association with increasing risk score and HF-related hospitalisation.⁴⁵ No comparative evidence was available. The EAG do note that HeartInsight is the only monitoring system that provides daily transmissions, whereas the other technologies occur less frequently. This could have implications for missing data.

Cost-effectiveness

There was no hospitalisation, mortality, follow-up visits or LOS outcome evidence for the RMS for CorVue or HeartInsight. Consequently, no estimate of the cost-effectiveness of CorVue or HeartInsight could be produced. Making the assumptions of no difference in hospitalisation, mortality, scheduled/unscheduled follow-up visits, and LOS, both CorVue or HeartInsight would be cost-increasing due to the cost of the technology and the cost of reviewing alerts produced by the RMS. Given the much larger cost of a hospitalisation compared to other costs, the technologies only need to reduce the rate of hospitalisation by a very small amount (1-4%) for them to become cost-effective.

There was some evidence on hospitalisation, follow-up visits or LOS outcomes for the RMS for HeartLogic and TriageHF. This evidence was at risk of bias due to confounding. Making the assumption of no difference in mortality

and scheduled follow-up visits, HeartLogic and TriageHF were dominant (i.e. they were cost-saving as well as reducing hospitalisations). Threshold analysis showed that HeartLogic and TriageHF only needed to reduce hospitalisations by a few percent in order for them to be dominant.

For HeartLogic and TriageHF, the outcome evidence was mostly based on patients with a CIED who had had a diagnosis of HF. Consequently, the cost-effectiveness estimates are applicable to that subgroup. There was clinical evidence for different CIEDs in evidence submission by Medtronic. The variation in effectiveness estimates was very small across the CIEDs and the same cost-effectiveness results for all CIEDs apply to each individual CIED.

Strengths and limitations

Strengths

This is the first complete systematic review of HeartLogic, TriageHF, CorVue and HeartInsight. The review utilised extensive database and grey literature searches to identify all published evidence on the included technologies. Additionally, all included studies and previous reviews (narrative and systematic) were citation chained to identify any further literature. We also assessed their risk of bias and undertook a thorough narrative synthesis of the results. As such, this is the first review of these technologies.

The economic evaluation was based on outcome evidence identified from a systematic review of the literature and a company evidence submission. The economic decision model structure was the same as analyses in the literature and the Medtronic evidence submission. Hospitalisation, mortality and follow-up visits were directly included in the model.

Limitations

During the review process we completed single data extraction and quality appraisal assessments, rather than in duplicate. However, this is mitigated by the checking for accuracy of both assessments by a second reviewer.

Cost-effectiveness estimates could only be produced for HeartLogic and TriageHF as there was outcome evidence for those technologies only. No cost-effectiveness estimate could be produced for patients who had not had a diagnosis of HF. There was only evidence for hospitalisations and follow-up visits, and these were at high risk of bias due to confounding. The outcomes included in the model were limited by the evidence available, and there was limited evidence for the outcomes included.

Limitations of the evidence stem from the type of evidence available. The majority of the evidence was derived from single cohort studies that did not distinguish between having and not having the algorithm. While this does provide data from a real-world standpoint (e.g. correct categorisation of patients and risk associated with an HF event such as hospitalisation), there is a lack of evidence for how the algorithms perform compared to no algorithm (i.e. standard remote monitoring). Furthermore, many studies did not include adjusted analyses, which could inflate the reported effectiveness of the algorithm.

Most clinical studies identified in the systematic review were at serious or critical risk of bias. Many of the studies were at serious or critical risk of bias due to a lack of controlling for confounding factors in the statistical analysis. Specifically, age, sex, NYHA classification, smoking status and other comorbidities were largely uncontrolled for in the majority of studies. In addition, the inherent risk of bias due to the retrospective and single-arm design of many studies are likely to lead to an overestimation of the findings.

For study end points, there was a degree of variation between studies as to what constituted a HF event. Additionally, in some cases composite outcomes were utilised (e.g. HF hospitalisation, clinic visit or death). Future studies should look to adequately power their analyses to assess the end points individually, rather than using composite outcomes. There is also an issue with a lack of statistical comparisons within studies, with simple numerical changes generally reported. In addition, concerns at quality appraisal were linked to statistical analysis shortcomings. For example, the lack of consideration for confounding factors, which should be considered in future research.

The evidence for HeartLogic appears to have higher accuracy than the other algorithms, but it is still hampered by a lack of comparative data, with only two studies presenting a control condition. Of the three studies which included some comparative data for clinical outcomes, two are considered at serious risk of bias,^{36,37} and one at critical risk of bias.³⁵ The majority of remaining cohorts were at critical or serious risk of bias mostly due to unaddressed issues with confounding. Four cohorts were at moderate or low risk of bias.^{72,76,80,81} All studies reporting prognostic outcomes were at overall high risk of bias but there were no concerns with their applicability to this review.

The evidence for TriageHF suggest it has varying accuracy and is, like HeartLogic, hampered by an overall lack of comparative data between people with and without the algorithm. The one study reporting comparative data is at critical risk of bias; using the clinical outcome results in a meta-analysis is not recommended. Many studies were abstracts, lacking in information and are subsequently of unclear risk of bias.⁵¹⁻⁵³

The evidence for CorVue suggests the accuracy of the algorithm is generally low and produces high false positive alerts, which would be a concern from a clinical point of view. Increased false positives could increase the burden for clinical staff. All studies reporting prognostic accuracy outcomes are at high risk of bias, although there are no concerns regarding their applicability to this review. All studies reporting clinical outcomes were at serious or critical risk of bias. Shapiro *et al.*³⁴ includes limited comparative evidence and is at critical risk of bias, current recommendations are to avoid using data from studies at critical risk of bias in meta-analysis and to interpret studies at serious risk of bias with caution.

The evidence for HeartInsight suggests the accuracy of the algorithm is moderate but is yet to be further validated in external studies. The lack of evidence for this algorithm, both single cohort and comparative data, means that the EAG cannot provide any recommendations on its potential use in clinical practice. However, the one published study did provide similar prognostic accuracy measures to the other algorithms, as evidence by the crossover of CIs. D'Onofrio, *et al.*,⁴⁵ is at high risk of bias as assessed using PROBAST, there are no concerns regarding the applicability of the study to this review question. In addition, the study is at serious risk of bias when applying ROBINS-I because of issues with confounding, the reported clinical outcome results should be interpreted with caution.

The EAG also note that two of the algorithms (HeartLogic and HeartInsight) are currently not available on all CIEDs. They are available on ICD and CRT-D devices, while TriageHF and CorVue are also available on CRT-P devices. Currently, only CRT-P devices are recommended for those with NYHA class IV HF.⁵

Evidence gaps

The EAG have identified several gaps across the varying outcomes.

For intermediate outcomes there was a lack of evidence for several outcomes. There was no evidence for the number of monitoring reviews. Software failure rate was not commonly reported; this is potentially a key variable for RMS and future research should report this detail. Length of hospital stay also had minimal evidence; however, there was a greater evidence base for number of hospitalisations.

For clinical outcomes there was no evidence for changes in NYHA classification of symptoms or rate and category of AF. There was also minimal evidence for the rate of HFs, with only HeartLogic and CorVue reporting data for this outcome. The number of adverse events was only reported in two studies (one HeartInsight and one HeartLogic). Finally, the effect of having the algorithms on HF and all-cause mortality was seldom reported. To address these shortcomings future studies should aim to address these outcomes in greater depth. While there is a lack of evidence for mortality, the EAG is aware of an ongoing trial using the HeartLogic algorithm with the primary outcome to assess mortality between those with and without the algorithm.

There was very little evidence in the way of patient-reported outcomes. Only one single prospective cohort study included some health-related quality of life outcomes (6MWT and MLWHF). No further evidence was identified. Additionally, there was no evidence of patient experience with the algorithms. Future research should endeavor to

include patient involvement in studies. This is especially important where false positive alerts are produced, as such alerts could cause great anxiety to the individual.

For all algorithms it is also imperative that further comparative evidence is provided to show the efficacy of the algorithms compared to no algorithm (e.g. remote monitoring without algorithm). While an RCT would be the gold standard for such comparative data, further retrospective and prospective studies which are non-randomised would also be beneficial to assess each algorithm compared to no algorithm.

Equality, diversity and inclusion

The EAG obtained the views of the Diagnostic Assessment Specialist Committee members during the review process. In addition, the research question and subsequent eligibility criteria did not exclude any patient characteristics based on demographic or socio-economic factors, all individuals with HF and CIED implanted were eligible for inclusion. It is important to consider digital inequalities in this setting, as not all potential patients may have the correct access to the technologies required to support such a device.

Patient and public involvement

No patient and public involvement activity was conducted as a part of this research.

Chapter 8 Conclusions

Implications for service provision

The EAG considers there was promising evidence for HeartLogic and TriageHF. However, there is substantial uncertainty regarding the impact of these algorithms on intermediate and clinical outcomes. Further evidence generation using comparative study designs will potentially reduce this uncertainty. HeartLogic was consistently associated with the highest and most consistent accuracy measures, with data also suggesting that when IN alert state the patient is at greater risk of a HF event (e.g. hospitalisation or death). However, the majority of the studies assessing predictive accuracy for HeartLogic utilised a composite outcome, which broadened their study end point and may have increased the accuracy of the algorithm. Being in a high-risk status when patients used TriageHF also appeared to be linked to such events, although there was less evidence for some outcomes (e.g. mortality). Additionally, the majority of predictive accuracy evidence from TriageHF utilised a single (i.e. not a composite) outcome. Therefore, evidence suggests that using these two algorithms could potentially identify those at greater risk of an impending HF event, which would allow for effective and timely clinical response. However, since no study has directly compared any of the algorithms included in the scope, any conclusions are subject to uncertainty.

The EAG only identified one study of interest for HeartInsight. Therefore, we consider it too early to draw conclusions on the potential usefulness of this algorithm for clinical practice. However, the reported accuracy measures suggest it could provide similar accuracy to HeartLogic and TriageHF; although the sensitivity was < 70%. However, we did not perform any meta-analytical techniques and therefore, these quantifications are based on numerical trends only and should be interpreted with caution.

The EAG consider CorVue evidence to be more heterogenous and due to this, we cannot draw firm conclusions on the accuracy and efficacy of the algorithm in clinical practice, based on the literature available. Like the other algorithms assessed, there is a lack of comparative data. However, there is also literature reporting high false positive rates and also a low sensitivity (i.e. ~20%). However, sensitivity in some studies was also reported to be similar to the other three algorithms (i.e. > 60%).

When assessing the quality of the studies from the evidence base, across all algorithms, there were several studies that were reported as at high risk of bias. This makes the reliability of the evidence uncertain and should be considered when assessing the clinical usefulness of all the technologies.

All remote monitoring algorithms only needed to reduce hospitalisations by a small amount for them to be cost-effective given the evidence on incremental healthcare visits use compared to no remote monitoring algorithm. Better quality and adequately powered evidence on both hospitalisations and healthcare contacts (visits, calls), which also records time spent reviewing remote monitoring data, would help inform the cost-effectiveness of the remote monitoring algorithms.

Suggested research priorities

The primary research priority should be to conduct further studies into the clinical impact and usefulness of the remote monitoring algorithms. There should be a particular focus on comparative evidence, as all devices were lacking in this area. HeartInsight should focus on expanding their evidence base as there is currently too little evidence to make a judgement on its clinical effectiveness. Ideally, RCT evidence comparing the devices to standard clinical management without the use of remote monitoring or remote monitoring without the algorithm should be conducted. Cluster RCTs (clustered by centre or clinic) and quasi-randomised trials would also be valuable evidence. Further non-randomised evidence would be valuable to further support the implementation of the algorithms into practice, although great care in the design needs to be taken so they are not at high risk of bias.

Currently, there is a lack of evidence for the following outcomes and these should be key considerations for future research:

- intermediate outcomes, including the number of monitoring reviews required, length of hospital stay (ideally between those with and without the algorithm), and time between an alert and HF event
- clinical outcomes, including adverse events, morbidity, rate and category of AF, changes in NYHA classification of symptoms, and HF mortality
- patient-reported outcomes, including quality of life and patient experience.

More comparative evidence (e.g. comparing those with and without the algorithm) should be conducted for the majority of the outcomes (with the exception being prognostic accuracy studies).

All of these trials should examine whether clinical benefits vary according to key patient subgroups, such as symptom severity, NYHA classification or without a diagnosis of chronic HF. Studies should consider how the inclusion of these algorithms affects current remote monitoring practices. The implementation of algorithms may vary in practice and study designs should reflect the likely (or recommended) monitoring schedule in practice alongside the use of remote monitoring. The monitoring schedule may affect clinical outcomes and it will affect the cost-effectiveness of remote monitoring algorithms due to the associated healthcare cost with monitoring. In addition, the implementation of algorithms may result in overtreatment, and any potential benefits of reduced hospitalisation need to be carefully balanced and explored further.

The EAG considers collecting further prognostic accuracy evidence as a lower priority for HeartLogic and TriageHF, but would still be useful in providing further information. CorVue and HeartInsight do require further prognostic accuracy evidence. CorVue due to the observed heterogeneity in the measures. HeartInsight due to only identifying a single study. Future studies should also adequately power their studies as to not include composite outcomes.

Should evidence become available in the future, a more complex economic model capturing disease severity and exploring the potential benefit of RMS in mitigating disease progression or the potential differences in cost-effectiveness in more or less severe subgroups would be helpful.

Additional information

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Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at <https://doi.org/10.3310/PPOH2916>

Primary conflicts of interest: None declared.

Data-sharing statement

Requests for access to data should be addressed to the corresponding author.

Ethics statement

No ethics approval was required because this was a secondary research project.

Information governance statement

Newcastle University is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, Newcastle University is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here <https://www.ncl.ac.uk/research/research-governance/ethics/#:~:text=If%20you%20are%20not%20satisfied,%40ncl.ac.uk>.

DAR Amendments

Changes to the original report

The original EAG report was submitted to NICE on 8 February 2023. Since that submission changes have been made to respond to correct errors.

The changes are summarised in the table below.

Location in report	Edit made
Throughout	Minor grammatical and format changes
Tables 15–17 and 25	D'Onofrio name corrected to D'Onofrio
Tables 15–17 and 25 and (Appendix 7 , Table 47)	D'Onofrio (2022), reference number 45, number of participants corrected from 744 to 918
Table 15	Omitted a study by Wakabayashi <i>et al.</i> (2021), this has been added
Table 16 and False-positive rates	Corrected reference for Feijen 2023, originally reference 19, corrected to reference 36
In Limitations	Added the following text to highlight the lack of confounding consideration in the analyses: 'Most clinical studies identified in the systematic review were at serious or critical risk of bias. Many of the studies were at serious or critical risk of bias due to a lack of controlling for confounding factors in the statistical analysis. Specifically, age, sex, NYHA classification, smoking status and other co-morbidities were largely uncontrolled for in the majority of studies. In addition, the inherent risk of bias due to the retrospective and single-arm design of many studies are likely to lead to an overestimation of the findings' Added text to state crossover of values with HeartInsight and other algorithms: 'However, the one published study did provide similar prognostic accuracy measures to the other algorithms, as evidence by the crossover of confidence intervals' Added text to identify that TriageHF and CorVue are the only algorithms that can be used in CRT-P CIEDs: 'The EAG also note that two of the algorithms (HeartLogic and HeartInsight) are currently not available on all CIEDs. They are available on ICD and CRT-D devices, while TriageHF and CorVue are also available on CRT-P devices. Currently, only CRT-P devices are recommended for those with NYHA class IV HF'
In Health-related quality of life	The text has been updated to describe the utility calculations; and the references in the tables, and the footnotes have been updated
Table 9	Date of reference (D'Onofrio) changed from 2020 to 2022
Table 11	ROBINS-I assessment for D'Onofrio (2023) has been added to Table 11
Table 10	Capitalised the c in cohort in Table 10
Table 15	Corrected a typo changed vistists to visits

Location in report	Edit made
Clinical effectiveness	Included a sentence to highlight that TriageHF had a number of UK based studies: 'It is worth noting that a number of studies evaluating TriageHF were undertaken in a UK setting ($n = 5$)' Adjusted phrasing around one comparative study based on company feedback: (confidential information has been removed)
False-positive rates and Table 16	Data added for false positive rates from one study (Zile 2020) for TriageHF algorithm
Unexplained alert rates	Added text to state one study for TriageHF used the terms false positive and unexplained detections interchangeably and that the evidence is in <i>False positive rates</i>
Changes to clinical management and Table 18	Included information from unpublished study (Ahmed AiC) Added data from Calo 2021 (HeartLogic)
Software failure rate	Included median remote monitoring rates percentages information for HeartInsight algorithm
Clinical effectiveness	Highlighted in the discussion that HeartInsight is the only system to provide daily reports: 'The EAG do note that HeartInsight is the only monitoring system that provides daily transmissions, whereas the other technologies occur less frequently. This could have implications for missing data'
Rate of heart failure events	Added text relevant to rate of heart failure events. Evidence for decreased rate of further events if clinical action was undertaken: 'The same study also identified a decreased rate of events when an alert was followed by a clinical action (HR 0.37, 95% CI 0.14 to 0.99), with similar results if analyses was conducted from day 7 post clinical action (HR 0.34, 95% CI 0.12 to 0.96)'
Time between an alert and a heart failure event	Moved information from <i>Alert response rates</i> to here as it fits the definition better: 'Another study reported an average time of 20 days from alert to hospitalisation'
Table 14	Updated wording for HeartLogic algorithm components
Quality assessment and Results of the cost-effectiveness review for remote monitoring systems, Figure 3, Table 29	To add information from Treskes <i>et al.</i> 2021 and summarise the findings, including reporting quality assessment
Conclusions of the assessment of existing cost-effectiveness evidence	Text edited to make the text clear
Intervention strategies/comparator and later sections	Updated the Algorithm name for HeartLogic
Mortality	Edited text to remove McGee <i>et al.</i> 2022, incorrect reference reported in stakeholder comments
Alerts and follow-up visits . Alerts and follow-up visits with algorithm-based remote monitoring	Edited text to clarify the follow-up visits
Health-related quality of life , and Tables 35–37	Edited text and Table footnotes to clarify the utility calculations and references
Costs	Added text to state additional scenario analysis on the utility decrement calculations to reflect stakeholder comments
Follow-up visits	Added further information on the costs used in the additional scenario modelled
Table 36	Added details for additional scenarios modelled.
Tertiary scenario analyses and Table 40	Added text to summarise the results from additional scenario analyses modelled
Summary of the economic analysis	Added further text
General summary of evidence	Records identified changed from 2700 to 2699
Risk of bias assessments for CorVue	Number of CorVue studies changed from five to six
Risk of bias assessments for CorVue, Table 6	PROBAST results for Benezet-Mazuecos (2016) added
Risk of bias assessments for HeartLogic, Table 11	ROBINS-I results for D'Onofrio (2023) added

Location in report	Edit made
Risk of bias assessments for TriageHF, Table 12	PROBAST results for Ahmed (2020) added
Risk of bias assessments for TriageHF, Table 12	PROBAST results for Ahmed (2022) added
Hospitalisation	The text was added to the report following comments from the developers of HeartLogic. 'Hernandez reports a rate of HF hospitalisation during the study as 67% lower [rate ratio (95% CI) 0.33 (0.23 to 0.47)] compared to the pre-study 12-month HF hospitalisation rate. ⁸² '

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Appendix 1 Clinical effectiveness searches

MEDLINE

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions 1946–19 June 2023

Via: <https://ovidsp.dc1.ovid.com/ovid-new-a/ovidweb.cgi>

Date range searched: Inception to 19 June 2023

Date of search: 20 June 2023

Records retrieved: 385

1. (Triage?HF* or "Triage HF" or CareLink Network* or MyCareLink* or "my care link" or "00763000351656").ti,ab,kw,kf.
2. (Latitude* NXT or Mylatitude* or "my latitude" or HeartLogic* or "heart logic" or "00802526562105" or "00802526573408" or "00802526584107" or "00802526590306" or "00802526592102" or "00802526613876").ti,ab,kf,kw.
3. (biotronik home monitor* or CardioMessenger* or "cardio messenger" or HeartInsight* or "heart insight" or "04035479139360" or "04035479159115" or "04035479177768").ti,ab,kw,kf.
4. (CorVue* or mymerlinimpact or "my merlin impact" or "merlin@home" or "merlin @ home" or "merlin at home" or "merlin.net").ti,ab,kw,kf.
5. or/1-4
6. Optivol.ti,ab,kw,kf.
7. viva.ti,ab,kw,kf.
8. acticor.ti,ab,kw,kf.
9. rivacor.ti,ab,kw,kf.
10. ilivia.ti,ab,kw,kf.
11. intica.ti,ab,kw,kf.
12. inlexa.ti,ab,kw,kf.
13. resonate.ti,ab,kw,kf.
14. vigilant.ti,ab,kw,kf.
15. momentum.ti,ab,kw,kf.
16. perciva.ti,ab,kw,kf.
17. gallant.ti,ab,kw,kf.
18. quadra.ti,ab,kw,kf.
19. ellipse.ti,ab,kw,kf.
20. assura.ti,ab,kw,kf.
21. assurity.ti,ab,kw,kf.
22. (biotronik or medtronic or "boston scientific" or abbott).ab,in,go,ci.
23. or/6-22
24. (algorithm* adj2 (monitor* or triag*)).ti,ab,kw,kf.
25. (remot* adj2 (monitor* or triag*)).ti,ab,kw,kf.
26. or/24-25
27. exp arrhythmias, cardiac/ or heart defects, congenital/ or exp heart failure/ or heart valve diseases/ or heart disease risk factors/
28. (heart adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kf,kw.
29. (cardiac adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kf,kw.
30. (atrial adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kf,kw.

31. (ventricular adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kf,kw.
32. Defibrillators, Implantable/
33. or/27-32
34. 23 and 26 and 33
35. 5 or 34

EMBASE

EMBASE 1974–14 June 2023

Via: <https://ovidsp.dc1.ovid.com/ovid-new-a/ovidweb.cgi>

Date range searched: Inception to 19 June 2023

Date of search: 20th June 2023

Records retrieved: 1146

1. (Triage?HF* or "Triage HF" or CareLink Network* or MyCareLink* or "my care link" or "00763000351656").ti,ab,kw.
2. (Latitude* NXT or Mylatitude* or "my latitude" or HeartLogic* or "heart logic" or "00802526562105" or "00802526573408" or "00802526584107" or "00802526590306" or "00802526592102" or "00802526613876").ti,ab,kw.
3. (biotronic home monitor* or CardioMessenger* or "cardio messenger" or HeartInsight* or "heart insight" or "04035479139360" or "04035479159115" or "04035479177768").ti,ab,kw.
4. (CorVue* or mymerlinimpact or "my merlin impact" or "merlin@home" or "merlin @ home" or "merlin at home" or "merlin.net").ti,ab,kw.
5. or/1-4
6. Optivol.ti,ab,kw.
7. viva.ti,ab,kw.
8. acticor.ti,ab,kw.
9. rivacor.ti,ab,kw.
10. ilivia.ti,ab,kw.
11. intica.ti,ab,kw.
12. inlexa.ti,ab,kw.
13. resonate.ti,ab,kw.
14. vigilant.ti,ab,kw.
15. momentum.ti,ab,kw.
16. perciva.ti,ab,kw.
17. gallant.ti,ab,kw.
18. quadra.ti,ab,kw.
19. ellipse.ti,ab,kw.
20. assura.ti,ab,kw.
21. assurity.ti,ab,kw.
22. (biotronic or medtronic or "boston scientific" or abbott).ab,mf,my,mv,dm,dv,in,tn,go,so,dc,de,ct.
23. or/6-22
24. (algorithm* adj2 (monitor* or triag*)).ti,ab,kw.
25. (remot* adj2 (monitor* or triag*)).ti,ab,kw.
26. or/24-25
27. exp heart arrhythmia/ or congenital heart malformation/ or exp heart failure/ or valvular heart diseases/ or heart disease risk factor/
28. (heart adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kw.
29. (cardiac adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kw.

30. (atrial adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kw.
31. (ventricular adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kw.
32. implantable cardioverter defibrillator/
33. or/27-32
34. 23 and 26 and 33
35. 5 or 34

CINAHL

Via: <https://search.ebscohost.com/Login.aspx>

Date range searched: Inception to June 2023

Date of search: 20 June 2023

Records retrieved: 129

- | | |
|-----|--|
| S40 | S5 OR S39 |
| S39 | S24 AND S27 AND S38 |
| S38 | S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 |
| S37 | (MH "Defibrillators, Implantable") |
| S36 | TI (ventricular N2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*)) OR AB (ventricular N2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*)) OR SU (ventricular N2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*)) |
| S35 | TI (atrial N2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*)) OR AB (atrial N2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*)) OR SU (atrial N2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*)) |
| S34 | TI (cardiac N2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*)) OR AB (cardiac N2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*)) OR SU (cardiac N2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*)) |
| S33 | TI (heart N2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*)) OR AB (heart N2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*)) OR SU (heart N2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*)) |
| S32 | (MH "Heart Diseases/RF") |
| S31 | (MH "Heart Valve Diseases") |
| S30 | (MH "Heart Failure+") |
| S29 | (MH "Heart Defects, Congenital") |
| S28 | (MH "Arrhythmia+") |
| S27 | S25 OR S26 |
| S26 | TI (remot* N2 (monitor* OR triag*)) OR AB (remot* N2 (monitor* OR triag*)) OR SU (remot* N2 (monitor* OR triag*)) |
| S25 | TI (algorithm* N2 (monitor* OR triag*)) OR AB (algorithm* N2 (monitor* OR triag*)) OR SU (algorithm* N2 (monitor* OR triag*)) |
| S24 | S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 |
| S23 | TI (biotronic OR medtronic OR "boston scientific" OR abbott) OR AB (biotronic OR medtronic OR "boston scientific" OR abbott) OR SU (biotronic OR medtronic OR "boston scientific" OR abbott) |
| S22 | TI assurity OR AB assurity OR SU assurity |

S21	Tl assura OR AB assura OR SU assura
S20	Tl ellipse OR AB ellipse OR SU ellipse
S19	Tl quadra OR AB quadra OR SU quadra
S18	Tl gallant OR AB gallant OR SU gallant
S17	Tl perciva OR AB perciva OR SU perciva
S16	Tl momentum OR AB momentum OR SU momentum
S15	Tl vigilant OR AB vigilant OR SU vigilant
S14	Tl resonate OR AB resonate OR SU resonate
S13	Tl inlexa OR AB inlexa OR SU inlexa
S12	Tl intica OR AB intica OR SU intica
S11	Tl intica OR AB intica OR SU intica
S10	Tl ilivia OR AB ilivia OR SU ilivia
S9	Tl rivacor OR AU rivacor OR SU rivacor
S8	Tl acticor OR AB acticor OR SU acticor
S7	Tl viva OR AB viva OR SU viva
S6	Tl Optivol OR AB Optivol OR SU Optivol
S5	S1 OR S2 OR S3 OR S4
S4	Tl (CORVue* OR mymerlinimpact OR "my merlin impact" OR "merlin@home" OR "merlin @ home" OR "merlin at home" OR "merlin.net") OR AB (CORVue* OR mymerlinimpact OR "my merlin impact" OR "merlin@home" OR "merlin @ home" OR "merlin at home" OR "merlin.net") OR SU (CORVue* OR mymerlinimpact OR "my merlin impact" OR "merlin@home" OR "merlin @ home" OR "merlin at home" OR "merlin.net")
S3	Tl (biotronik home monitor* OR CardioMessenger* OR "cardio messenger" OR HeartInsight* OR "heart insight" OR "04035479139360" OR "04035479159115" OR "04035479177768") OR AB (biotronik home monitor* OR CardioMessenger* OR "cardio messenger" OR HeartInsight* OR "heart insight" OR "04035479139360" OR "04035479159115" OR "04035479177768") OR SU (biotronik home monitor* OR CardioMessenger* OR "cardio messenger" OR HeartInsight* OR "heart insight" OR "04035479139360" OR "04035479159115" OR "04035479177768")
S2	Tl (Latitude* NXT OR Mylatitude* OR "my latitude" OR HeartLogic* OR "heart logic" OR "00802526562105" OR "00802526573408" OR "00802526584107" OR "00802526590306" OR "00802526592102" OR "00802526613876") OR AB (Latitude* NXT OR Mylatitude* OR "my latitude" OR HeartLogic* OR "heart logic" OR "00802526562105" OR "00802526573408" OR "00802526584107" OR "00802526590306" OR "00802526592102" OR "00802526613876") OR SU (Latitude* NXT OR Mylatitude* OR "my latitude" OR HeartLogic* OR "heart logic" OR "00802526562105" OR "00802526573408" OR "00802526584107" OR "00802526590306" OR "00802526592102" OR "00802526613876")
S1	Tl (Triage#HF* OR "Triage HF" OR CareLink NetwORk* OR MyCareLink* OR "my care link" OR "00763000351656") OR AB (Triage#HF* OR "Triage HF" OR CareLink NetwORk* OR MyCareLink* OR "my care link" OR "00763000351656") OR SU (Triage#HF* OR "Triage HF" OR CareLink NetwORk* OR MyCareLink* OR "my care link" OR "00763000351656")

Cochrane Library

Cochrane (CCRCT, CDSR)

Via: <https://cochranelibrary.com/advanced-search>

Date range searched: Inception to June 2023

Date of search: 20 June 2023

Records retrieved: 100

#1 (Triage?HF* or "Triage HF" or CareLink Network* or MyCareLink* or "my care link" or "00763000351656"):ti,ab,kw

- #2 (Latitude* NXT or Mylatitude* or "my latitude" or HeartLogic* or "heart logic" or "00802526562105" or "00802526573408" or "00802526584107" or "00802526590306" or "00802526592102" or "00802526613876"):ti,ab,kw
- #3 (biotronic home monitor* or CardioMessenger* or "cardio messenger" or HeartInsight* or "heart insight" or "04035479139360" or "04035479159115" or "04035479177768"):ti,ab,kw
- #4 (CorVue* or mymerlinimpact or "my merlin impact" or "merlin@home" or "merlin @ home" or "merlin at home" or "merlin.net"):ti,ab,kw
- #5 ^{23-#4}
- #6 (Optivol):ti,ab,kw
- #7 (viva):ti,ab,kw
- #8 (acticor):ti,ab,kw
- #9 (rivacor):ti,ab,kw
- #10 (ilivia):ti,ab,kw
- #11 (intica):ti,ab,kw
- #12 (inlexa):ti,ab,kw
- #13 (resonate):ti,ab,kw
- #14 (vigilant):ti,ab,kw
- #15 (momentum):ti,ab,kw
- #16 (perciva):ti,ab,kw
- #17 (gallant):ti,ab,kw
- #18 (quadra):ti,ab,kw
- #19 (ellipse):ti,ab,kw
- #20 (assura):ti,ab,kw
- #21 (assurity):ti,ab,kw
- #22 (biotronic or medtronic or "boston scientific" or abbott):ti,ab,kw
- #23 {OR #6-#22}
- #24 (algorithm* NEAR/2 (monitor* or triag*)):ti,ab,kw
- #25 (remot* NEAR/2 (monitor* or triag*)):ti,ab,kw
- #26 ^{48-#25}
- #27 MeSH descriptor: [Arrhythmias, Cardiac] explode all trees
- #28 MeSH descriptor: [Heart Defects, Congenital] this term only
- #29 MeSH descriptor: [Heart Failure] explode all trees
- #30 MeSH descriptor: [Heart Valve Diseases] this term only
- #31 MeSH descriptor: [Heart Disease Risk Factors] this term only
- #32 (heart NEAR/2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)):ti,ab,kw
- #33 (cardiac NEAR/2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)):ti,ab,kw
- #34 (atrial NEAR/2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)):ti,ab,kw
- #35 (ventricular NEAR/2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)):ti,ab,kw
- #36 MeSH descriptor: [Defibrillators, Implantable] this term only
- #37 ^{44-#36}
- #38 #23 AND #26 AND #37
- #39 #5 OR #38

Centre for Reviews and Dissemination (PROSPERO, DARE)

Via: <https://crd.york.ac.uk/PROSPERO/> & <https://crd.york.ac.uk/CRDWeb/>

Date range searched: Inception to June 2023 (PROSPERO)/ 2015(DARE – date of discontinuation)

Date of search: 20 June 2023

Records retrieved: 2

- 1 (TriageHF* OR "Triage HF" OR CareLink NetwORk* OR MyCareLink* OR "my care link" OR "00763000351656")
- 2 (Latitude* NXT OR Mylatitute* OR "my latitude" OR HeartLogic* OR "heart logic" OR "00802526562105"
- OR "00802526573408" OR "00802526584107" OR "00802526590306" OR "00802526592102" OR
- "00802526613876")
- 3 (biotronik home monitOR* OR CardioMessenger* OR "cardio messenger" OR HeartInsight* OR "heart insight" OR
- "04035479139360" OR "04035479159115" OR "04035479177768")
- 4 (CORVue* OR mymerlinimpact OR "my merlin impact" OR "merlin@home" OR "merlin @ home" OR "merlin at
- home" OR "merlin.net")
- 5 #1 OR #2 OR #3 OR #4
- 6 (Optivol)
- 7 (viva)
- 8 (acticor)
- 9 (ravikor)
- 10 (ilivia)
- 11 (intica)
- 12 (inlexa)
- 13 (resonate)
- 14 (vigilant)
- 15 (momentum)
- 16 (perciva)
- 17 (gallant)
- 18 (quadra)
- 19 (ellipse)
- 20 (assura)
- 21 (assurity)
- 22 (biotronik OR medtronic OR "boston scientific" OR abbott)
- 23 #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR
- #20 OR #21 OR #22
- 24 (algorithm* NEAR2 (monitor* OR triag*))
- 25 (remot* NEAR2 (monitor* OR triag*))
- 26 #24 OR #25
- 27 MeSH DESCRIPTOR Arrhythmias, Cardiac EXPLODE ALL TREES
- 28 MeSH DESCRIPTOR Heart Defects, Congenital
- 29 MeSH DESCRIPTOR Heart Failure EXPLODE ALL TREES
- 30 MeSH DESCRIPTOR Heart Valve Diseases
- 31 MeSH DESCRIPTOR Heart Disease Risk Factors
- 32 (heart NEAR2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*))
- 33 (cardiac NEAR2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*))
- 34 (atrial NEAR2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*))
- 35 (ventricular NEAR2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*))
- 36 MeSH DESCRIPTOR Defibrillators, Implantable
- 37 #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36
- 38 #23 AND #26 AND #37
- 39 #5 OR #3

INAHTA

Via: <https://database.inahta.org/>

Date range searched: Inception to June 2023

Date of search: 20 June 2023

Records retrieved: 5

(((((ventricular) AND (failure*) OR (defect*) OR (disease*) OR (arrhythm*) OR (fibrillat*) OR (monitor*)) OR ((atrial) AND (failure*) OR (defect*) OR (disease*) OR (arrhythm*) OR (fibrillat*) OR (monitor*)) OR ((cardiac) AND (failure*) OR (defect*) OR (disease*) OR (arrhythm*) OR (fibrillat*) OR (monitor*)) OR ((heart) AND (failure*) OR (defect*) OR (disease*) OR (arrhythm*) OR (fibrillat*) OR (monitor*)) OR ("Heart Disease Risk Factors" [mh]) OR ("Heart Valve Diseases" [mh]) OR ("Heart Failure" [mhe]) OR ("Heart Defects, Congenital" [mh]) OR ("Arrhythmias, Cardiac" [mhe])) AND (((remot*) AND ((monitor*) OR (triag*))) OR ((algorithm*) AND ((monitor*) OR (triag*)))) AND (((biotronic) OR (medtronic) OR ("boston scientific") OR (abbott)) OR ((optivol) OR (viva) OR (acticor) OR (rivacor) OR (ilivia) OR (intica) OR (inlexa) OR (resonate) OR (vigilant) OR (momentum) OR (perciva) OR (gallant) OR (quadra) OR (ellipse) OR (assura) OR (assurity)))) OR (((CORVue*) OR (mymerlinimpact) OR ("my merlin impact") OR ("merlin@home") OR ("merlin @ home") OR ("merlin at home") OR ("merlin.net")) OR (((biotronic home monitor*) OR (CardioMessenger*) OR ("cardio messenger") OR (HeartInsight*) OR ("heart insight") OR ("04035479139360") OR ("04035479159115") OR ("04035479177768")))) OR (((Latitude* NXT) OR (Mylatitute*) OR ("my latitude") OR (HeartLogic*) OR ("heart logic") OR ("00802526562105") OR ("00802526573408") OR ("00802526584107") OR ("00802526590306") OR ("00802526592102") OR ("00802526613876")))) OR ((TriageHF*) OR ("Triage HF") OR (Triage-HF*) OR ((CareLink Network*) OR (MyCareLink*) OR ("my care link") OR ("00763000351656"))))

NIHR Journals Library

Via: <https://journalslibrary.nihr.ac.uk/#/>

Date range searched: Inception to June 2023

Date of search: 20 June 2023

Records retrieved: 4

"remote monitoring"

"heart monitoring"

"cardiac monitoring"

Cardiac AND remote AND monitoring

Cardiac AND monitoring

Heart AND monitoring

INPLASY

Via: <https://inplasy.com/>

Date range searched: Inception to June 2023

Date of search: 20 June 2023

Records retrieved: 1

"remote monitoring"

“heart monitoring”

“cardiac monitoring”

ClinicalTrials.gov

Via: <https://clinicaltrials.gov/>

Date range searched: Inception to June 2023

Date of search: 20 June 2023

Records retrieved: 224

Condition: cardiac events + *other terms:* remote monitoring

Condition: cardiac disease + *other terms:* remote monitoring

Condition: heart failure + *other terms:* remote monitoring

TriageHF

Latitude NXT

HeartLogic

HeartInsight

CardioMessenger

CorVue

EudraCT

Via: <https://clinicaltrialsregister.eu/ctr-search/search/>

Date range searched: Inception to June 2023

Date of search: 20 June 2023

Records retrieved: 1

Cardiac AND “remote monitoring”

Heart AND “remote monitoring”

TriageHF

Latitude NXT

HeartLogic

HeartInsight

CardioMessenger

CorVue

ICTRP

Via: <https://trialsearch.who.int/Default.aspx>

Date range searched: Inception to June 2023

Date of search: 20 June 2023

Records retrieved: 103

Cardiac AND “remote monitoring”

Heart AND “remote monitoring”

TriageHF

Latitude NXT

HeartLogic

HeartInsight

CardioMessenger

CorVue

ScanMedicine

Via: <https://scanmedicine.com/>

Date range searched: Inception to June 2023

Date of search: 20 June 2023

Records retrieved: 260

Cardiac AND “remote monitoring”

Heart AND “remote monitoring”

TriageHF

Latitude NXT

HeartLogic

HeartInsight

CardioMessenger

CorVue

medRxiv

Via: <https://medrxiv.org/>

Date range searched: Inception to June 2023

Date of search: 20 June 2023

Records retrieved: 333

Cardiac AND remote AND monitoring

TriageHF

Latitude AND NXT

HeartLogic

HeartInsight

CardioMessenger

CorVue

Appendix 2 Economic evaluation searches

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions 1946–14 June 2023

Via: <https://ovidsp.dc1.ovid.com/ovid-new-a/ovidweb.cgi>

Date range searched: Inception to 14 June 2023

Date of search: 15 June 2023

Records retrieved: 25

1. (Triage?HF* or "Triage HF" or CareLink Network* or MyCareLink* or "my care link" or "00763000351656").ti,ab,kw,kf.
2. (Latitude* NXT or Mylatitude* or "my latitude" or HeartLogic* or "heart logic" or "00802526562105" or "00802526573408" or "00802526584107" or "00802526590306" or "00802526592102" or "00802526613876").ti,ab,kf,kw.
3. (biotronik home monitor* or CardioMessenger* or "cardio messenger" or HeartInsight* or "heart insight" or "04035479139360" or "04035479159115" or "04035479177768").ti,ab,kw,kf.
4. (CorVue* or mymerlinimpact or "my merlin impact" or "merlin@home" or "merlin @ home" or "merlin at home" or "merlin.net").ti,ab,kw,kf.
5. or/1-4
6. Optivol.ti,ab,kw,kf.
7. viva.ti,ab,kw,kf.
8. acticor.ti,ab,kw,kf.
9. rivacor.ti,ab,kw,kf.
10. ilivia.ti,ab,kw,kf.
11. intica.ti,ab,kw,kf.
12. inlexa.ti,ab,kw,kf.
13. resonate.ti,ab,kw,kf.
14. vigilant.ti,ab,kw,kf.
15. momentum.ti,ab,kw,kf.
16. perciva.ti,ab,kw,kf.
17. gallant.ti,ab,kw,kf.
18. quadra.ti,ab,kw,kf.
19. ellipse.ti,ab,kw,kf.
20. assura.ti,ab,kw,kf.
21. assurity.ti,ab,kw,kf.
22. (biotronik or medtronic or "boston scientific" or abbott).ab,in,go,ci.
23. or/6-22
24. (algorithm* adj2 (monitor* or triag*)).ti,ab,kw,kf.
25. (remot* adj2 (monitor* or triag*)).ti,ab,kw,kf.
26. or/24-25
27. exp arrhythmias, cardiac/ or heart defects, congenital/ or exp heart failure/ or heart valve diseases/ or heart disease risk factors/
28. (heart adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kf,kw.
29. (cardiac adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kf,kw.
30. (atrial adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kf,kw.
31. (ventricular adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kf,kw.
32. Defibrillators, Implantable/

33. or/27-32
34. 23 and 26 and 33
35. 5 or 34

Combined with the following filter using 'AND'

1. Economics/
2. "Costs and Cost Analysis"/
3. "Cost Allocation"/
4. Cost-Benefit Analysis/
5. "Cost Control"/
6. "Cost Savings"/
7. "Cost of Illness"/
8. "Cost Sharing"/
9. "Deductibles and Coinsurance"/
10. Medical Savings Accounts/
11. Health Care Costs/
12. Direct Service Costs/
13. Drug Costs/
14. Employer Health Costs/
15. Hospital Costs/
16. Health Expenditures/
17. Capital Expenditures/
18. "Value of Life"/
19. exp Economics, Hospital/
20. exp Economics, Medical/
21. Economics, Nursing/
22. Economics, Pharmaceutical/
23. exp "Fees and Charges"/
24. exp Budgets/
25. (low adj cost).mp.
26. (high adj cost).mp.
27. (health?care adj cost\$).mp.
28. (fiscal or funding or financial or finance).tw.
29. (cost adj estimate\$).mp.
30. (cost adj variable).mp.
31. (unit adj cost\$).mp.
32. (economic\$ or pharmacoeconomic\$ or price\$ or pricing).tw.
33. or/1-32

EMBASE 1974–14 June 2023

Via: <https://ovidsp.dc1.ovid.com/ovid-new-a/ovidweb.cgi>

Date range searched: Inception to 14 June 2023

Date of search: 15 June 2023

Records retrieved: 90

1. (Triage?HF* or "Triage HF" or CareLink Network* or MyCareLink* or "my care link" or "00763000351656").ti,ab,kw.

2. (Latitude* NXT or Mylatitude* or "my latitude" or HeartLogic* or "heart logic" or "00802526562105" or "00802526573408" or "00802526584107" or "00802526590306" or "00802526592102" or "00802526613876").ti,ab,kw.
3. (biotronik home monitor* or CardioMessenger* or "cardio messenger" or HeartInsight* or "heart insight" or "04035479139360" or "04035479159115" or "04035479177768").ti,ab,kw.
4. (CorVue* or mymerlinimpact or "my merlin impact" or "merlin@home" or "merlin @ home" or "merlin at home" or "merlin.net").ti,ab,kw.
5. or/1-4
6. Optivol.ti,ab,kw.
7. viva.ti,ab,kw.
8. acticor.ti,ab,kw.
9. rivacor.ti,ab,kw.
10. ilivia.ti,ab,kw.
11. intica.ti,ab,kw.
12. inlexa.ti,ab,kw.
13. resonate.ti,ab,kw.
14. vigilant.ti,ab,kw.
15. momentum.ti,ab,kw.
16. perciva.ti,ab,kw.
17. gallant.ti,ab,kw.
18. quadra.ti,ab,kw.
19. ellipse.ti,ab,kw.
20. assura.ti,ab,kw.
21. assurity.ti,ab,kw.
22. (biotronik or medtronic or "boston scientific" or abbott).ab,mf,my,mv,dm,dv,in,tn,go,so,dc,de,ct.
23. or/6-22
24. (algorithm* adj2 (monitor* or triag*)).ti,ab,kw.
25. (remot* adj2 (monitor* or triag*)).ti,ab,kw.
26. or/24-25
27. exp heart arrhythmia/ or congenital heart malformation/ or exp heart failure/ or valvular heart diseases/ or heart disease risk factor/
28. (heart adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kw.
29. (cardiac adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kw.
30. (atrial adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kw.
31. (ventricular adj2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)).ti,ab,kw.
32. implantable cardioverter defibrillator/
33. or/27-32
34. 23 and 26 and 33
35. 5 or 34

Combined with the following filter using 'AND'

1. socioeconomics/
2. "cost benefit analysis"/
3. "cost effectiveness analysis"/
4. "cost of illness"/
5. "cost control"/
6. economic aspect/
7. financial management/
8. "health care cost"/
9. health care financing/
10. health economics/

11. "hospital cost"/
12. (fiscal or financial or finance or funding).tw.
13. "cost minimization analysis"/
14. (cost adj estimate\$).mp.
15. (cost adj variable\$).mp.
16. (unit adj cost\$).mp.
17. or/1-16

Cochrane (CCRCT, CDSR)

Via: <https://cochranelibrary.com/advanced-search>

Date range searched: Inception to June 2023

Date of search: 15 June 2023

Records retrieved: 100

- #1 (Triage?HF* or "Triage HF" or CareLink Network* or MyCareLink* or "my care link" or "00763000351656"):ti,ab,kw
- #2 (Latitude* NXT or Mylatitude* or "my latitude" or HeartLogic* or "heart logic" or "00802526562105" or "00802526573408" or "00802526584107" or "00802526590306" or "00802526592102" or "00802526613876"):ti,ab,kw
- #3 (biotronic home monitor* or CardioMessenger* or "cardio messenger" or HeartInsight* or "heart insight" or "04035479139360" or "04035479159115" or "04035479177768"):ti,ab,kw
- #4 (CorVue* or mymerlinimpact or "my merlin impact" or "merlin@home" or "merlin @ home" or "merlin at home" or "merlin.net"):ti,ab,kw
- #5 {OR #1-#4}
- #6 (Optivol):ti,ab,kw
- #7 (viva):ti,ab,kw
- #8 (acticor):ti,ab,kw
- #9 (rivacor):ti,ab,kw
- #10 (ilivia):ti,ab,kw
- #11 (intica):ti,ab,kw
- #12 (inlexa):ti,ab,kw
- #13 (resonate):ti,ab,kw
- #14 (vigilant):ti,ab,kw
- #15 (momentum):ti,ab,kw
- #16 (perciva):ti,ab,kw
- #17 (gallant):ti,ab,kw
- #18 (quadra):ti,ab,kw
- #19 (ellipse):ti,ab,kw
- #20 (assura):ti,ab,kw
- #21 (assurity):ti,ab,kw
- #22 (biotronic or medtronic or "boston scientific" or abbott):ti,ab,kw
- #23 {OR #6-#22}
- #24 (algorithm* NEAR/2 (monitor* or triag*)):ti,ab,kw
- #25 (remot* NEAR/2 (monitor* or triag*)):ti,ab,kw
- #26 {OR #24-#25}
- #27 MeSH descriptor: [Arrhythmias, Cardiac] explode all trees
- #28 MeSH descriptor: [Heart Defects, Congenital] this term only
- #29 MeSH descriptor: [Heart Failure] explode all trees
- #30 MeSH descriptor: [Heart Valve Diseases] this term only

#31 MeSH descriptor: [Heart Disease Risk Factors] this term only
 #32 (heart NEAR/2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)):ti,ab,kw
 #33 (cardiac NEAR/2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)):ti,ab,kw
 #34 (atrial NEAR/2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)):ti,ab,kw
 #35 (ventricular NEAR/2 (failure* or defect* or disease* or arrhythm* or fibrillat* or monitor*)):ti,ab,kw
 #36 MeSH descriptor: [Defibrillators, Implantable] this term only
 #37 {OR #27-#36}
 #38 #23 AND #26 AND #37
 #39 #5 OR #38

Centre for Reviews and Dissemination (NHS-EED, DARE, HTA)

Via: <https://crd.york.ac.uk/CRDWeb/>

Date range searched: Inception to 2015 (date of discontinuation)

Date of search: 15 June 2023

Records retrieved: 0

- 1 (TriageHF* OR "Triage HF" OR CareLink NetwoRK* OR MyCareLink* OR "my care link" OR "00763000351656")
- 2 (Latitude* NXT OR Mylatitude* OR "my latitude" OR HeartLogic* OR "heart logic" OR "00802526562105" OR "00802526573408" OR "00802526584107" OR "00802526590306" OR "00802526592102" OR "00802526613876")
- 3 (biotronic home monitor* OR CardioMessenger* OR "cardio messenger" OR HeartInsight* OR "heart insight" OR "04035479139360" OR "04035479159115" OR "04035479177768")
- 4 (CORVue* OR mymerlinimpact OR "my merlin impact" OR "merlin@home" OR "merlin @ home" OR "merlin at home" OR "merlin.net")
- 5 #1 OR #2 OR #3 OR #4
- 6 (Optivol)
- 7 (viva)
- 8 (acticor)
- 9 (ravacor)
- 10 (ilivia)
- 11 (intica)
- 12 (inlexa)
- 13 (resonate)
- 14 (vigilant)
- 15 (momentum)
- 16 (perciva)
- 17 (gallant)
- 18 (quadra)
- 19 (ellipse)
- 20 (assura)
- 21 (assurity)
- 22 (biotronic OR medtronic OR "boston scientific" OR abbott)
- 23 #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22
- 24 (algorithm* NEAR2 (monitor* OR triag*))
- 25 (remot* NEAR2 (monitor* OR triag*))
- 26 #24 OR #25
- 27 MeSH DESCRIPTOR Arrhythmias, Cardiac EXPLODE ALL TREES

- 28 MeSH DESCRIPTOR Heart Defects, Congenital
- 29 MeSH DESCRIPTOR Heart Failure EXPLODE ALL TREES
- 30 MeSH DESCRIPTOR Heart Valve Diseases
- 31 MeSH DESCRIPTOR Heart Disease Risk Factors
- 32 (heart NEAR2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*))
- 33 (cardiac NEAR2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*))
- 34 (atrial NEAR2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*))
- 35 (ventricular NEAR2 (failure* OR defect* OR disease* OR arrhythm* OR fibrillat* OR monitor*))
- 36 MeSH DESCRIPTOR Defibrillators, Implantable
- 37 #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36
- 38 #23 AND #26 AND #37
- 39 #5 OR #3

INAHTA

Via: <https://database.inahta.org/>

Date range searched: Inception to June 2023

Date of search: 15 June 2023

Records retrieved: 5

(((((ventricular) AND (failure*) OR (defect*) OR (disease*) OR (arrhythm*) OR (fibrillat*) OR (monitor*)) OR ((atrial) AND (failure*) OR (defect*) OR (disease*) OR (arrhythm*) OR (fibrillat*) OR (monitor*)) OR ((cardiac) AND (failure*) OR (defect*) OR (disease*) OR (arrhythm*) OR (fibrillat*) OR (monitor*)) OR ((heart) AND (failure*) OR (defect*) OR (disease*) OR (arrhythm*) OR (fibrillat*) OR (monitor*)) OR ("Heart Disease Risk Factors" [mh]) OR ("Heart Valve Diseases" [mh]) OR ("Heart Failure" [mhe]) OR ("Heart Defects, Congenital" [mh]) OR ("Arrhythmias, Cardiac" [mhe])) AND (((remot*) AND ((monitor*) OR (triag*))) OR ((algorithm*) AND ((monitor*) OR (triag*)))) AND (((biotronic) OR (medtronic) OR ("boston scientific") OR (abbott)) OR ((optivol) OR (viva) OR (acticor) OR (rivacor) OR (ilivia) OR (intica) OR (inlexa) OR (resonate) OR (vigilant) OR (momentum) OR (perciva) OR (gallant) OR (quadra) OR (ellipse) OR (assura) OR (assurity)))) OR (((CORVue*) OR (mymerlinimpact) OR ("my merlin impact") OR ("merlin@home") OR ("merlin @ home") OR ("merlin at home") OR ("merlin.net")) OR (((biotronic home monitor*) OR (CardioMessenger*) OR ("cardio messenger") OR (HeartInsight*) OR ("heart insight") OR ("04035479139360") OR ("04035479159115") OR ("04035479177768")) OR (((Latitude* NXT) OR (Mylatitude*) OR ("my latitude") OR (HeartLogic*) OR ("heart logic") OR ("00802526562105") OR ("00802526573408") OR ("00802526584107") OR ("00802526590306") OR ("00802526592102") OR ("00802526613876")) OR ((TriageHF*) OR ("Triage HF") OR (Triage-HF*) OR ((CareLink Network*) OR (MyCareLink*) OR ("my care link") OR ("00763000351656"))))

NIHR Journals Library

Via: <https://journalslibrary.nihr.ac.uk/#/>

Date range searched: Inception to June 2023

Date of search: 15 June 2023

Records retrieved: 4

"remote monitoring"

“heart monitoring”

“cardiac monitoring”

Cardiac AND remote AND monitoring

Cardiac AND monitoring

Heart AND monitoring

Appendix 3 Focused searches

Focused economic searches were run as above (clinical effectiveness searches) with the addition of the economic filters detailed below.

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions

Via: <https://ovidsp.dc1.ovid.com/ovid-new-a/ovidweb.cgi>

Date range searched: Inception to 6 August 2023

Date of search: 7 August 2023

Records retrieved: 16

1. (cost? adj2 (illness or disease or sickness)).tw.
2. (burden? adj2 (illness or disease? or condition? or economic*)).tw.
3. ("quality-adjusted life years" or "quality adjusted life years" or QALY?).tw.
4. Quality-adjusted life years/
5. "cost of illness"/
6. Health expenditures/
7. (out-of-pocket adj2 (payment? or expenditure? or cost? or spending or expense?)).tw.
8. (expenditure? adj3 (health or direct or indirect)).tw.
9. ((adjusted or quality-adjusted) adj2 year?).tw.
10. or/1-9
1. quality-adjusted life years/
2. sickness impact profile/
3. (quality adj2 (wellbeing or well-being)).ti,ab.
4. sickness impact profile.ti,ab.
5. disability adjusted life.ti,ab.
6. (qal* or qtime* or qwb* or daly*).ti,ab.
7. (euroqol* or eq5d* or eq 5d*).ti,ab.
8. (qol* or hql* or hqol* or h qol* or hrqol* or hr qol*).ti,ab.
9. (health utility* or utility score* or disutilit*).ti,ab.
10. (hui or hui1 or hui2 or hui3).ti,ab.
11. health* year* equivalent*.ti,ab.
12. (hye or hyes).ti,ab.
13. rosser.ti,ab.
14. (willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab.
15. (sf36 or sf 36 or short form 36 or shortform 36 or shortform36).ti,ab.
16. (sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab.
17. (sf12 or sf 12 or short form 12 or shortform 12 or shortform12).ti,ab.
18. (sf8 or sf 8 or short form 8 or shortform 8 or shortform8).ti,ab.
19. (sf6 or sf 6 or short form 6 or shortform 6 or shortform6).ti,ab.
20. or/1-19

EMBASE

Via: <https://ovidsp.dc1.ovid.com/ovid-new-a/ovidweb.cgi>

Date range searched: Inception to 6 August 2023

Date of search: 7 August 2023

Records retrieved: 88

1. (cost? adj2 (illness or disease or sickness)).tw.
2. (burden? adj2 (illness or disease? or condition? or economic*)).tw.
3. ("quality-adjusted life years" or "quality adjusted life years" or QALY?).tw.
4. Quality-adjusted life years/
5. "cost of illness"/
6. Exp "health care cost"/
7. (out-of-pocket adj2 (payment? or expenditure? or cost? or spending or expense?)).tw.
8. (expenditure? adj3 (health or direct or indirect)).tw.
9. ((adjusted or quality-adjusted) adj2 year?).tw.
10. or/1-9
1. quality adjusted life year/
2. "quality of life index"/
3. short form 12/ or short form 20/ or short form 36/ or short form 8/
4. sickness impact profile/
5. (quality adj2 (wellbeing or well-being)).ti,ab.
6. sickness impact profile.ti,ab.
7. disability adjusted life.ti,ab.
8. (qal* or qtime* or qwb* or daly*).ti,ab.
9. (euroqol* or eq5d* or eq 5d*).ti,ab.
10. (qol* or hql* or hqol* or h qol* or hrqol* or hr qol*).ti,ab.
11. (health utility* or utility score* or disutilit*).ti,ab.
12. (hui or hui1 or hui2 or hui3).ti,ab.
13. health* year* equivalent*.ti,ab.
14. (hye or hyes).ti,ab.
15. rosser.ti,ab.
16. (willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab.
17. (sf36 or sf 36 or short form 36 or shortform 36 or shortform36).ti,ab.
18. (sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab.
19. (sf12 or sf 12 or short form 12 or shortform 12 or shortform12).ti,ab.
20. (sf8 or sf 8 or short form 8 or shortform 8 or shortform8).ti,ab.
21. (sf6 or sf 6 or short form 6 or shortform 6 or shortform6).ti,ab.
22. or/1-21

Databases searched in addition to the clinical effectiveness and economic review sources were searched as detailed below.

CEA Registry

Via: <https://cevr.tuftsmedicalcenter.org/databases/cea-registry>

Date range searched: Inception to August 2023

Date of search: 7 August 2023

Records retrieved: 6

“remote monitoring”

“heart monitoring”

“cardiac monitoring”

RePEc

Via: <https://ideas.repec.org/>

Date range searched: Inception to August 2023

Date of search: 7 August 2023

Records retrieved: 2

“remote monitoring”

“heart monitoring”

“cardiac monitoring”

ScHARRHUD

Via: <https://scharrhud.org/>

Date range searched: Inception to August 2023

Date of search: 7 August 2023

Records retrieved: 4

Title OR abstract:

Heart failure AND remote monitoring

Cardiac AND remote monitoring

Appendix 4 List of excluded records

Wrong intervention (n = 323)

Wrong outcome (n = 50)

Wrong publication type (n = 45)

Wrong study design (n = 9)

Wrong population (n = 5)

TABLE 41 Excluded records and reasons for exclusion

Reason for exclusion	Reference
Wrong intervention (n = 323)	1. Zile MR, Costanzo MRR, Butler J, Ippolito EM, Zhang Y, Stapleton RB, <i>et al.</i> Safety and effectiveness of an individualized risk stratification based medication intervention strategy: the intervene HF Study. <i>Journal of Cardiac Failure</i> 2019;25:S101. https://doi.org/10.1016/j.cardfail.2019.07.289 2. Zanotto G, Visentin E, rini D, Bassi M, Cassinadri E, Rocchetto E, <i>et al.</i> Implementation of a fully remote monitoring model for pacemakers: 3 years assessment of the in-hospital visits. <i>European Heart Journal</i> 2016;37:1044. https://doi.org/10.1093/eurheartj/ehw434 3. Zambon E, Miani D, Narciso M, Comisso J, Indrigo S, Facchin D, <i>et al.</i> Remote monitoring of ICD patients by carelink system. <i>Giornale Italiano di Cardiologia</i> 2011;12:157S-8S. https://doi.org/10.1714/641.7477 4. Zakeri R, Morgan JM, Phillips P, Kitt S, Ng GA, McComb JM, <i>et al.</i> Impact of remote monitoring on clinical outcomes for patients with heart failure and atrial fibrillation: results from the REM-HF trial. <i>European Journal of Heart Failure</i> 2020;22:543–53. https://doi.org/10.1002/ehf.1709 5. Zabel M, Willich SN, Geller JC, Brachmann J, Kuhlkamp V, Dissmann R, <i>et al.</i> A randomized comparison of economic and clinical effects of automatic remote monitoring versus control in patients with ICDS: The monitor-ICD study. <i>Heart Rhythm</i> 2017;14:S58. 6. Zabel M, Willich SN, Geller JC, Brachmann J, Kuehlkamp V, Dissmann R, <i>et al.</i> The MONITOR-ICD study: A randomized comparison of economic and clinical effects of automatic remote monitoring versus control in patients with ICDs. <i>European Heart Journal</i> 2017;38:868. https://doi.org/10.1093/eurheartj/ehx502.P4254 7. Xhaet O, Deceuninck O, Sprimont P, Dormal F, Ballant E, Go-vaerts G, <i>et al.</i> Prospective evaluation of the impact of remote monitoring to follow patient with implantable device in the routine practice of an electrophysiological centre. <i>Acta Cardiologica</i> 2014;68:98–9. https://doi.org/10.2143/AC.69.1.3011350 8. Wintrich J, Pavlicek V, Brachmann J, Bosch R, Butter C, Oswald H, <i>et al.</i> Remote monitoring with appropriate reaction to alerts was associated with improved outcomes in chronic heart failure: results from the OptiLink HF Study. <i>Circulation Arrhythmia and Electrophysiology</i> 2021;14:e008693. https://doi.org/10.1161/CIRCEP.120.008693 9. Wilkoff BL, Richards M, Sharma AD, Wold N, Jones PW, Perschbacher D, <i>et al.</i> Heart rate score and heart rate variability predict mortality in CRT-D patients. <i>Heart Rhythm</i> 2015;12:S62. 10. Wetzel UR, Geller JC, Kautzner J, Moertel H, Schumacher B, Taborsky M, <i>et al.</i> Remote follow-up for icd-therapy in patients meeting madit ii criteria – The reform trial. <i>Heart Rhythm</i> 2009;6:S259. 11. Watanabe E, Yamazaki F, Goto T, Asai T, Yamamoto T, Hirooka K, <i>et al.</i> Remote management of pacemaker patients with biennial in-clinic evaluation: continuous home monitoring in the Japanese at-home study: a randomized clinical trial. <i>Circulation Arrhythmia and Electrophysiology</i> 2020;13:e007734. https://doi.org/10.1161/CIRCEP.119.007734 12. Wang R, Huang H, Liu Y, Kong B. Clinical application of remote monitoring in post-pacemaker implantation follow-up. <i>Biomedical Research (India)</i> 2017;28:5733–8. 13. Vogtmann T, Marek A, Stiller S, Kuhlkamp V, Loscher S, Schaarschmidt J, <i>et al.</i> Centralized daily wireless remote home monitoring in a prospective, multicenter study: Effort and effect on the clinical management of patients with devices. <i>Journal of Interventional Cardiac Electrophysiology</i> 2010;27:247. https://doi.org/10.1007/s10840-010-9483-7 14. Versteeg H, Timmermans I, Widdershoven J, Kimman G-J, Prevot S, Rauwolf T, <i>et al.</i> Effect of remote monitoring on patient-reported outcomes in European heart failure patients with an implantable cardioverter-defibrillator: primary results of the REMOTE-CIED randomized trial. <i>Europace: European Pacing, Arrhythmias, and Cardiac Electrophysiology: Journal of the Working Groups on Cardiac Pacing, Arrhythmias, and Cardiac Cellular Electrophysiology of the European Society of Cardiology</i> 2019;21:1360–8. https://doi.org/10.1093/europace/euz140 15. Versteeg H, Pedersen SS, Mastenbroek MH, Redekop WK, Schwab JO, Mabo P, <i>et al.</i> Patient perspective on remote monitoring of cardiovascular implantable electronic devices: rationale and design of the REMOTE-CIED study. <i>Netherlands Heart Journal: Monthly Journal of the Netherlands Society of Cardiology and the Netherlands Heart Foundation</i> 2014;22:423–8. https://doi.org/10.1007/s12471-014-0587-z 16. Varma N, Schweikert R, Michalski J. Role of automatic continuous monitoring immediately following ICD implant-the trust trial. <i>Heart Rhythm</i> 2015;12:S63.

continued

TABLE 41 Excluded records and reasons for exclusion (continued)

Reason for exclusion	Reference
	17. Varma N, Pavri B, Stambler B, Michalski J. Are problems occurring in ICD patients missed during remote management? Conventional follow up compared to automatic remote monitoring in the TRUST trial. <i>European Heart Journal</i> 2011;32:312. https://doi.org/10.1093/eurheartj/ehr322
	18. Varma N, Pavri B, Michalski J, Stambler B. Do heart failure patients with ICDs managed remotely suffer increased adverse event rates? Automatic remote monitoring compared to conventional follow up in the TRUST trial. <i>Europace</i> 2011;13. https://doi.org/10.1093/europace/eur225
	19. Varma N, Michalski J, Stambler B, Pavri BB. Superiority of automatic remote monitoring compared with in-person evaluation for scheduled ICD follow-up in the TRUST trial – testing execution of the recommendations. <i>European Heart Journal</i> 2014;35:1345–52. https://doi.org/10.1093/eurheartj/ehu066
	20. Varma N, Michalski J, Pavri B. Superiority of remote monitoring compared to in-person follow up for maintaining scheduled ICD follow up- results from the trust trial. <i>Heart rhythm</i> 2013;10:S158.
	21. Varma N, Michalski J, Epstein AE, Schweikert R. Automatic remote monitoring of implantable cardioverter-defibrillator lead and generator performance the lumos-T safely reduces routine office device follow-up (TRUST) Trial. <i>Circulation: Arrhythmia and Electrophysiology</i> 2010;3:428–36. https://doi.org/10.1161/CIRCEP.110.951962
	22. Varma N, Michalski J. Alert notifications during automatic wireless remote monitoring of implantable cardioverter-defibrillators: Load, characteristics, and clinical utility. <i>Heart Rhythm</i> 2023;20:473–4. https://doi.org/10.1016/j.hrthm.2022.11.019
	23. Varma N, Michalski J. Prolonged remote monitoring without in-person evaluation in advanced heart failure patients: Is there a risk? <i>Journal of Cardiac Failure</i> 2014;20:S67. https://doi.org/10.1016/j.cardfail.2014.06.191
	24. Varma N, Michalski J. Do failed remote evaluations result from transmission failure or (mis-)handling by receiving facilities? Home Monitoring in the TRUST trial. <i>Europace</i> 2013;15:ii54. https://doi.org/10.1093/europace/eut200
	25. Varma N, Michalski J. What is the value of in-person evaluations prompted by alert notifications during ICD remote monitoring? the Trust trial. <i>European Heart Journal</i> 2012;33:992. https://doi.org/10.1093/eurheartj/ehs284
	26. Varma N, Michalski J. Event notifications by remote monitoring systems performing automatic daily checks: Load, characteristics and clinical utility. the trust multicenter icd trial. <i>Heart Rhythm</i> 2011;8:S157. https://doi.org/10.1016/j.hrthm.2011.03.025
	27. Varma N, Love CJ, Schweikert R, Moll P, Michalski J, Epstein AE. Automatic remote monitoring utilizing daily transmissions: transmission reliability and implantable cardioverter defibrillator battery longevity in the TRUST trial. <i>Europace: European Pacing, Arrhythmias, and Cardiac Electrophysiology: Journal of the Working Groups on Cardiac Pacing, Arrhythmias, and Cardiac Cellular Electrophysiology of the European Society of Cardiology</i> 2018;20:622–8. https://doi.org/10.1093/europace/eux059
	28. Varma N, Love CJ, Michalski J, Epstein AE. Alert-Based ICD Follow-Up: A Model of Digitally Driven Remote Patient Monitoring. <i>JACC Clinical Electrophysiology</i> 2021; https://doi.org/10.1016/j.jacep.2021.01.008 .
	29. Varma N, Epstein A, Irnpen A, Gibson L, Love C. Event notifications by remote monitoring systems performing automatic daily checks: Load, characteristics and clinical utility. <i>European Heart Journal</i> 2009;30:307–8. https://doi.org/10.1093/eurheartj/ehp414
	30. Van Heel L, Seiler A, Seger JJ, Lippman N, Jeffery C, Doshi A, et al. Improving remote monitoring of pacemakers: First report of a smartphone/tablet-based remote monitoring system. <i>Circulation</i> 2016;134.
	31. Vaccari D, Zanolto G, Calo L, Quagliione R, Favale S, Mantovani G, et al. Homeguide registry: Background, objectives, study design and enrolled population. <i>Journal of Cardiovascular Electrophysiology</i> 2011;22:S78. https://doi.org/10.1111/j.1540-8167.2011.02154.x
	32. Vaccari D, Vittadello S, Zamprogno R, Masaro G, Stefanini G, Alitto F, et al. Organization and management of PM/ICD patients follow-up: The continuous management of the acute events is feasible and at low consumption of human resources. <i>Journal of Cardiovascular Electrophysiology</i> 2009;20:S54. https://doi.org/10.1111/j.1540-8167.2009.01586.x
	33. Utrecht UMC, Corporation BS, University T, Center EM. Patient Perspective on Remote Monitoring of Cardiovascular Implantable Electronic Devices. In: https://clinicaltrials.gov/show/NCT01691586 ; 2013.
	34. University RSM. Remote Monitoring System for Patients, Who Had Myocardial Infarction. In: https://clinicaltrials.gov/show/NCT04424368 ; 2018.
	35. University Hospital L, France B. Efficacy, Safety and Cost of Remote Monitoring of Patients With Cardiac Resynchronization Therapy. In: https://clinicaltrials.gov/show/NCT03012490 ; 2017.
	36. Trust VVH, Vestfold THo, Oslo Uo, Hospital OU, Stavanger Uo. Remote Monitoring After Heart Failure. In: https://clinicaltrials.gov/show/NCT05447598 ; 2023.
	37. Trust MUNHSF, Medtronic, Trust PAHNHS. What is the Workload Burden Associated With Using the Triage HF + Care Pathway? In: https://clinicaltrials.gov/show/NCT04177199 ; 2019.
	38. Trembath R, Azucena C, Stain N, Cowie MR. Remote device monitoring for crt-d leads to substantial reduction in the need for 'routine' pacing clinic. <i>European Journal of Heart Failure, Supplement</i> 2009;8:ii52. https://doi.org/10.1093/eurjhf/hfp063
	39. Trembath L, Azucena C, Stain N, Cowie MR. Remote device monitoring for CRT-D leads to substantial reduction in the need for 'routine' visits to a pacing clinic. <i>European Heart Journal</i> 2009;30:417. https://doi.org/10.1093/eurheartj/ehp414
	40. Townsend S, Denman R. 770 MyCarelink Heart Smartphone Application: An Early Single Centre Experience. <i>Heart Lung and Circulation</i> 2020;29:S383. https://doi.org/10.1016/j.hlc.2020.09.777
	41. Timmermans I, Meine M, Szendey I, Aring J, Romero Roldan J, van Erven L, et al. Remote monitoring of implantable cardioverter defibrillators: Patient experiences and preferences for follow-up. <i>Pacing and Clinical Electrophysiology: PACE</i> 2019;42:120–9. https://doi.org/10.1111/pace.13574
	42. Tijskens M, Huybrechts W, Heibuchel H. Visitless initiation of remote monitoring of cardiac implantable electronic devices during the COVID-19 pandemic. <i>Acta Cardiologica</i> 2020;75:587–8. https://doi.org/10.1080/00015385.2020.1814524

TABLE 41 Excluded records and reasons for exclusion (continued)

Reason for exclusion	Reference
	43. Thudt K, Wollmann CH, Rhabek S, Vock P, Mayr H. Management of patients with implantable cardioverter defibrillators and atrial fibrillation by using medtronic carelink network – Remote monitoring system. <i>European Heart Journal</i> 2009;30:412. https://doi.org/10.1093/eurheartj/ehp414
	44. Thudt K, Raatikainen MJP, Perego GB, Marquie C, Busca R, Lercher P. Remote monitoring of ICD/CRT-D Patients in 4 European countries – A study of the patient impact. <i>Journal of Cardiovascular Electrophysiology</i> 2009;20:S63–S4. https://doi.org/10.1111/j.1540-8167.2009.01586.x
	45. Thambidorai S, Jones P, Wold N, Cha YM, Varma N. Right ventricular pacing and the change in atrial arrhythmia burden after cardiac resynchronization therapy: Altitude remote monitoring study. <i>Heart Rhythm</i> 2012;9:S228. https://doi.org/10.1016/j.hrthm.2012.03.032
	46. Thakur RK, Faulknier B, Snell JD, Dalai N, Richards M. Remote monitoring is associated with reduction in mortality in pacemaker patients. <i>Heart Rhythm</i> 2013;10:S294.
	47. Tang WHW, Warman EN, Johnson JW, Small RS, Heywood JT. Threshold crossing of device-based intrathoracic impedance trends identifies relatively increased mortality risk. <i>European Heart Journal</i> 2012;33:2189–96. https://doi.org/10.1093/eurheartj/ehs121
	48. Tang WHW, Warman EN, Johnson J, Small RS, Heywood JT. Incremental prognostic value for number or duration of threshold crossing of impedance trends in heart failure. <i>Heart Rhythm</i> 2011;8:S156–S7. https://doi.org/10.1016/j.hrthm.2011.03.025
	49. Tang WHW, Small RS, Heywood JT, Andriulli J. Device-based remote monitoring as contemporary heart failure disease management: Baseline characteristics of patients enrolled in the OptiVol Care Pathway study. <i>Journal of Cardiac Failure</i> 2010;16:S69. https://doi.org/10.1016/j.cardfail.2010.06.241
	50. Tajstra M, Sokal A, Gadula-Gacek E, Kurek A, Wozniak A, Niedziela J, et al. Remote supervision to decrease hospitalization rate (RESULT) study in patients with implanted cardioverter-defibrillator. <i>Europace</i> 2020;22:769–76. https://doi.org/10.1093/europace/eaab072
	51. Tajstra M, Dyrbus M, Grabowski M, Rokicki JK, Nowak M, Gasior M. The use of remote monitoring of patients with cardiac implantable electronic devices in Poland. <i>Kardiologia polska</i> 2022;80:479–81. https://doi.org/10.33963/KP.a2022.0050
	52. Sullivan RM, Seth M, Berg K, Stolen KQ, Jones PW, Russo AM, et al. Does change in device detected frequency of non-sustained or diverted episodes serve as a marker for inappropriate shock therapy? Analyses from the INTRINSIC RV and ALTITUDE-REDUCES Trials. <i>Europace</i> 2014;16:668–73. https://doi.org/10.1093/europace/eut426
	53. Soth-Hansen M, Witt CT, Rasmussen M, Kristensen J, Gerdes C, Nielsen JC. Time until diagnosis of clinical events with different remote monitoring systems in implantable cardioverter-defibrillator patients. <i>Heart Rhythm</i> 2018;15:1648–54. https://doi.org/10.1016/j.hrthm.2018.05.025
	54. Sood N, Charaf E, Powell B, Cao M, Carter N, Jones P, et al. Real world efficacy and comparison of right ventricular vs. biventricular anti-tachycardia pacing in cardiac resynchronization therapy- defibrillator (CRT-D): Results from the altitude study. <i>Heart Rhythm</i> 2013;10:S111–S2.
	55. Small RS, Samara MA, Sarkar S, Kofflin P, Norman H. Remote heart failure management utilizing a risk stratification algorithm incorporating device and external diagnostics. <i>Journal of Cardiac Failure</i> 2017;23:S57.
	56. Silvetti MS, Saputo FA, Palmieri R, Placidi S, Santucci L, Di Mambro C, et al. Results of remote follow-up and monitoring in young patients with cardiac implantable electronic devices. <i>Cardiology in the young</i> 2016;26:53–60. https://doi.org/10.1017/S1047951114002613
	57. Sharma V, Whellan D, Koehler J, Warman E, Abraham W. Device diagnostics can stratify patients at varying risk of heart failure hospitalization. <i>Journal of the American College of Cardiology</i> 2013;61:E673. https://doi.org/10.1016/S0735-1097%2813%2960673-7
	58. Sharma V, Borlaug BA, Abeyratne A, Cho Y, Chung ES. Rate responsive pacing is associated with lower mortality in dual-chamber pacemaker patients. <i>Circulation</i> 2017;136.
	59. Shanmugam N, Boerdlein A, Proff J, Ong P, Valencia O, Maier SK, et al. Detection of atrial high-rate events by continuous home monitoring: clinical significance in the heart failure-cardiac resynchronization therapy population. <i>EP: Europace</i> 2012;14:230–7. https://doi.org/10.1093/europace/eur293
	60. Seiler A, Biundo E, Di Bacco M, Rosemas S, Nicolle E, Lanctin D, et al. Clinic time required for remote and in-person management of patients with cardiac devices: time and motion workflow evaluation. <i>JMIR Cardio</i> 2021;5:e27720. https://doi.org/10.2196/27720
	61. Se B, Kg C, Alegre I, Porto aSCdMd. Full Early Atrial Diagnostics in Single Chamber ICD Patients Using the DX Lead and Home Monitoring in Brazil. In: https://clinicaltrials.gov/show/NCT04869527 ; 2021.
	62. Se B, Kg C. Assessment of Intracardiac Electrograms Transmitted by Home Monitoring for the Remote Follow-up of Pacemaker (PREMS). In: https://clinicaltrials.gov/show/NCT02174484 ; 2014.
	63. Se B, Kg C. Ability of Home Monitoring® to Detect and Manage the Inappropriate Diagnoses in Implantable Cardioverter Defibrillators. In: https://clinicaltrials.gov/show/NCT01594112 ; 2012.
	64. Se B, Kg C. Follow-up of Patients With Implantable Cardioverter Defibrillators by Home Monitoring (ANVITE). In: https://clinicaltrials.gov/show/NCT00858559 ; 2009.

continued

TABLE 41 Excluded records and reasons for exclusion (continued)

Reason for exclusion	Reference
	65. Schwab JO, Stoepel C, Balke A, Lauter J. Properties of VF therapies in ICD patients transmitted by a new remote monitoring system-first results of the german carelink analytics device database. <i>Heart Rhythm</i> 2012; 9 :S226. https://doi.org/10.1016/j.hrthm.2012.03.032
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continued

TABLE 41 Excluded records and reasons for exclusion (continued)

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TABLE 41 Excluded records and reasons for exclusion (continued)

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TABLE 41 Excluded records and reasons for exclusion (continued)

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TABLE 41 Excluded records and reasons for exclusion (continued)

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continued

TABLE 41 Excluded records and reasons for exclusion (continued)

Reason for exclusion	Reference
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Wrong publication type (n = 45)	1. In-time enrollment completed: BIOTRONIK home monitoring® clinical study to assess improvement in heart failure management. <i>EP Lab Digest</i> 2011;11:2p-p. 2. BIOTRONIK Launches CardioMessenger smart portable device for pacemaker and ICD patients. <i>EP Lab Digest</i> 2016;16:44-. 3. Boston Scientific announces positive late-breaking clinical trial data for the HeartLogic™ heart failure diagnostic. <i>EP Lab Digest</i> 2017;17:34–6. 4. Ahmed R, Thakur P, Biviano AB, Clerkin K, Garan H, Wan EY. Heart failure measurements using heartlogic directly correlates with increased burden of atrial fibrillation. <i>Circulation</i> 2021;144. https://doi.org/10.1161/circ.144.suppl-1.6902 5. Al-Razo O, Gonzalez E, Alej, re M, Represa T, Silvestre J, et al. The role of Pacemaker remote follow-up in early detection and management of lead complications and patient medical care. <i>European Journal of Preventive Cardiology</i> 2015;22:S99. https://doi.org/10.1177/2047487315586743 6. Al-Razzo O, Gonzalez Villegas E, Alej, re M, Represa T, Sartor L, et al. Pacemaker remote follow-up: 5 years experience of 1540 cases. <i>European Heart Journal</i> 2013;34:490. 7. Alotaibi S, Hern, ez-Montfort J, Ali OE, El-Chilali K, Perez BA. Remote monitoring of implantable cardiac devices in heart failure patients: a systematic review and meta-analysis of randomized controlled trials. <i>Heart Failure Reviews</i> 2020;25:469–79. https://doi.org/10.1007/s10741-020-09923-1 8. Brasca FM, Peregó GB. Remote monitoring of implantable electronic devices to predict heart failure decompensation. <i>Expert Review of Medical Devices</i> 2021;18:9–12. https://doi.org/10.1080/17434440.2021.2018298 9. Brown J, Bilchick K, Alonso A, Warman E. Optivol impedance threshold crossing predicts patients with higher mortality or hospitalization risk among medicare recipients. <i>Journal of Cardiac Failure</i> 2015;21:S122. 10. Curnis A, Cerini M, Lipari A, Pagnoni C, Ashofair N, Mutti MG, et al. Impact of remote monitoring to response of therapy with biventricular device: A single center experience. <i>Journal of Cardiovascular Electrophysiology</i> 2011;22:S160–S1. https://doi.org/10.1111/j.1540-8167.2011.02154.x 11. Defaye P, Cassagneau R, Pellet N, eneynde C, Martin A, Moisei R, et al. Remote monitoring follow-up of 533 ICD/CRT-D recipients: A very low rate of inappropriate shocks. <i>Archives of Cardiovascular Diseases Supplements</i> 2013;5:59.

TABLE 41 Excluded records and reasons for exclusion (continued)

Reason for exclusion	Reference
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	13. Defaye P, Pellet N, eneynde C, Moisei R, Martin A, Jacon P. Remote monitoring follow-up of 632 ICD/CRT-D recipients: A very low rate of inappropriate shocks. <i>Europace</i> 2013;15:ii192. https://doi.org/10.1093/europace/eut184
	14. Dewl, TA, Carter N, Jones P, Saxon L, Lovelock J, et al. Influence of ventricular arrhythmia rate and device programming on anti-tachycardia pacing efficacy: Results from the altitude study. <i>Heart Rhythm</i> 2014;11:S64. https://doi.org/10.1016/j.hrthm.2014.03.026
	15. Ewald GA, Gilliam FR, Sweeney RJ. Automated HF decompensation detection: Results from the decompensation detection study (DECODE). <i>Journal of Cardiac Failure</i> 2009;15:S122. https://doi.org/10.1016/j.cardfail.2009.06.065
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	17. Ewald GA, Roosevelt Gilliam F, Sweeney RJ. Changes in remote-monitored external sensors prior to HF decompensation. <i>Heart Rhythm</i> 2009;6:S382–S3.
	18. Feijen M, Egorova AD, Beeres SLMA, Treskes RW. Early Detection of fluid retention in patients with advanced heart failure: a review of a novel multisensory algorithm, HeartLogic™. <i>Sensors (Basel, Switzerland)</i> 2021;21. https://doi.org/10.3390/s21041361
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	22. Gilliam FR, Day JD, Hayes DL, Boehmer JP, Heidenreich PA, Jones PW, et al. Comparison of tachycardia detection programming and shock incidence in the altitude study. <i>Heart Rhythm</i> 2010;7:S178. https://doi.org/10.1016/j.hrthm.2010.03.030
	23. Gilliam FR, Day JD, Hayes DL, Boehmer JP, Heidenreich PA, Jones PW, et al. Tachycardia detection programming and shock incidence in the ALTITUDE study. <i>Europace</i> 2010;12:i57.
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	29. Isath A, Vaidya V, Yogeswaran V, Deshmukh A, Asirvatham S, Hayes D, et al. Follow up of patients with ventricular high rate events detected on remote monitoring of pacemakers. <i>Journal of the American College of Cardiology</i> 2018;71. https://doi.org/10.1016/S0735-1097%2818%2930854-4
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	33. Morichelli L, Porfili A, Quarta L, Sassi A, Cadeddu N, Magris B, et al. The remote control of implantable devices: Organizational impact and resource consumption in a cardiology outpatient clinic. <i>Giornale Italiano di Cardiologia</i> 2011;12:e11. https://doi.org/10.1714/986.10737
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continued

TABLE 41 Excluded records and reasons for exclusion (continued)

Reason for exclusion	Reference
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Wrong study design (n = 9)	1. Capucci A, Ammirati F, Favale S, Pecora D, Petracci B, Calo L, <i>et al.</i> Preliminary experience with the multisensor HeartLogic algorithm for heart failure monitoring: A case series report. <i>Europace</i> 2019;21:ii517. 2. Capucci A, ro, Santini L, Favale S, Pecora D, Petracci B, <i>et al.</i> Preliminary experience with the multisensor HeartLogic algorithm for heart failure monitoring: a retrospective case series report. <i>ESC Heart Failure</i> 2019;6:308–18. https://doi.org/10.1002/ehf2.12394 3. Chilcote JL, Summers RP, Vaz DG, Barber R, Wariar R, Guichard JL. Concurrent Assessment of the CardioMEMS HF System and HeartLogic HF Diagnostic: a retrospective case series. <i>Journal of Cardiac Failure</i> 2022;28:44–55. https://doi.org/10.1016/j.cardfail.2021.07.010 4. Gatto M, Dominici T, Rinaldi M, Rinaldi D, Percoco F, Tung M, <i>et al.</i> TWIDDLER SYNDROME AND HEART FAILURE: INTEGRATION OF REMOTE MONITORING AND CARDIOLOGY TELECONSULTATION FOR OPTIMAL MANAGEMENT. <i>European Heart Journal. Supplement</i> 2022;24:C12. https://doi.org/10.1093/eurheartj/suac011.023 5. Mariani MV, Lavalle C, Forleo GB, Della Rocca DG, Martino A, Panuccio M, <i>et al.</i> HeartLogic TM: real-world data-efficiency, resource consumption, and workflow optimization. <i>European Heart Journal Supplements: Journal of the European Society of Cardiology</i> 2023;25:C331–C6. https://doi.org/10.1093/eurheartjsupp/suad058 6. McGee MJ, Ray M, Brienesse SC, Sritharan S, Boyle AJ, Jackson N, <i>et al.</i> Remote monitoring in patients with heart failure with cardiac implantable electronic devices: a systematic review and meta-analysis. <i>Open Heart</i> 2022;9. https://doi.org/10.1136/openhrt-2022-002096 7. Michael McGee MRAS. Benefits of remote monitoring in patients with cardiac implantable electronic devices who have heart failure: systematic review. 8. Pitman B, Stokes M, Walton C, Wong C, Lau D, ers P. The sound of heart failure; heartlogic heart failure index alerts for a patient with left ventricular pacing turned off. <i>Journal of Arrhythmia</i> 2019;35:597. https://doi.org/10.1002/joa3.12277 9. Santini L, Mahfouz K, Schirripa V, Danisi N, Leone M, Mangone G, <i>et al.</i> Preliminary experience with a novel Multisensor algorithm for heart failure monitoring: The HeartLogic index. <i>Clinical Case Reports</i> 2018;6:1317–20. https://doi.org/10.1002/ccr3.1573
Wrong population (n = 5)	1. Yoruk A, Aktas MK, Huang DT, Gosev I, Black C, Kutuyifa V, <i>et al.</i> assessment of arrhythmia burden through the use of an implantable cardiac monitor in patients with a continuous flow left ventricular assist device. <i>Journal of Heart and Lung Transplantation</i> 2020;39:S190. https://doi.org/10.1016/j.healun.2020.01.782 2. El Oualid Amara M, Montagnier C, Cheggour S, Boursier M, Gully C, Barnay C, <i>et al.</i> Early detection and treatment of supraventricular arrhythmia with remote monitoring can prevent its progression in pacemaker patients: The randomized, multicenter SETAM trial. <i>Journal of the American College of Cardiology</i> 2015;65:A388. 3. Nagel B, Janousek J, Koestenberger M, Maier R, Sauseng W, Strenger V, <i>et al.</i> Remote monitoring leads to early recognition and treatment of critical arrhythmias in adults after atrial switch operation for transposition of the great arteries. <i>Circulation Journal</i> 2014;78:450–6. https://doi.org/10.1253/circj.CJ-13-0670 4. Maluski A, Sacher F, Bordachar P, Deplagne A, Haissaguerre M, Clementy J. Implantable cardioverter defibrillator in Brugada syndrome: Interest of remote ICD monitoring. <i>Mediterranean Journal of Pacing and Electrophysiology</i> 2007;9:75–81. 5. Heuvel LMvd, Sarina T, Sweeting J, Yeates L, Bates K, Spinks C, <i>et al.</i> A prospective longitudinal study of health-related quality of life and psychological wellbeing after an implantable cardioverter defibrillator in patients with genetic heart diseases. <i>medRxiv</i> 2021;. https://doi.org/10.1101/2021.04.26.21256086

Appendix 5 Ongoing studies

TABLE 42 Ongoing studies

Study details	Study design	Population	Intervention	Primary outcome	Estimated completion date
NCT03579641, (2018) ¹¹⁸ USA, Australia, Canada, Hong Kong, Europe and the UK	Prospective cohort	Heart failure	HeartLogic	Association of HeartLogic sensors with 30-day HF re-admission	Results submitted December 2023 (not yet published)
NCT04619888, (2020) ¹¹⁹ France	Prospective cohort	Heart failure	HeartLogic	Annual rate of unplanned hospitalisations for heart failure	July 2023
NCT04489225, (2020) ¹²⁰ USA, Europe, Switzerland and the UK.	Prospective cohort	Heart failure	TriageHF	PPV of HFRS High Risk Status associated with worsening heart failure	January 2027
NCT05761249, (2023) ¹²¹	Prospective cohort	Heart failure	HeartInsight	Rate of worsening heart failure hospitalisation after HeartInsight activation	September 2027
Garcia, (2022) ¹²² France	Cohort	Heart failure	HeartLogic	Unscheduled hospitalisation for HF	Unknown

Appendix 6 Characteristics of included studies for the clinical effectiveness

TABLE 43 Characteristics of included studies and baseline demographics for CorVue

Study details: Author (year) Country Study population	Publication type	Study design	Age (years) Mean (SD) unless otherwise specified	NYHA class n (%) unless otherwise specified	Sex (male) n (%) unless otherwise specified	Device type n (%) unless otherwise stated	Treatments at baseline n (%) unless otherwise stated	Comorbidities n (%) unless otherwise stated
Benezet -Mazuecos (2016) Unclear HF	Abstr.	Cohort	71 (11)	NR	56 (80)	ICD: 35 CRT-D: 35	NR	NR
Binkley (2012) USA Risk of acute HF	FT	Retrospective cohort (Development and validation)	66 (12) range: 42–85	III: 72 (96) IV: 3 (4)	52 (69)	CRT-D: 75	ACEI/ARB: 65 (87) Beta-blocker: 69 (92) Diuretics: 68 (91) Antiarrhythmics, class I or class III: 11 (15) Cardiac glycosides: 27 (36) Nitrates: 22 (29)	Prior MI: 33 (44) Prior unstable angina: 10 (13) Prior CABG: 23 (31) Prior coronary revascularisation, PTCA/stents: 25 (33) Ischemic cardiomyopathies: 42 (56) Nonischemic cardiomyopathies: 33 (44)
Forleo (2013) (Forleo, 2011) Italy HF	FT Abstr.	Prospective cohort	69 (9.9)	Mean (SD) 2.5 (0.7)	64 (80%)	NR	Beta-blocker at discharge: 78 ACE and/or ARB at dis- charge: 73	Hypertension: 65 History of AF: 22 Diabetes: 30 CAD: 45
Palfy (2015) Unclear Unclear	Abstr.	Cohort	70 (1)	I: 38 (59%) II: 20 (31%) III: 7 (11%)	78%	ICD: 36 CRT-D: 29	NR	NR
Palfy 2018 (Martinez Milla 2017) Unclear Unclear	FT Abstr.	Prospective cohort	67 (1)	I: 27 (51.9%) II: 18 (34.0%) III: 8 (15.1%)	42 (79.2%)	CRT-D: 26 ICD: 27	Beta-blockers: 53 (100) ACEI/ARB: 47 (88.7) MRA: 33 (62.3) Digoxin: 6 (11.3) Diuretics: 39 (79.6)	NR
Santini (2012) Unclear HF	Abstr.	Cohort	66 (10.3)	NR	35 (92%)	NR	NR	NR
Shapiro (2017) USA HF	FT	Retrospective cohort (Medical Chart Review) of CorVue device compared to standard protocol	Range 65 - 88	III: 120 (100)	89 (74.2%)	ICD: 60 No implantable device: 60	Beta-blockers: NR ACE I: NR ARBs: NR Diuretics: NR Digoxin: NR Nitrates and hydralazine in combination: NR Aldosterone antagonists: NR Anticoagulants or alternate anticoagulation medications: NR	NR

continued

TABLE 43 Characteristics of included studies and baseline demographics for CorVue (continued)

Study details:								
Author (year)								
Country								
Study population	Publication type	Study design	Age (years) Mean (SD) unless otherwise specified	NYHA class n (%) unless otherwise specified	Sex (male) n (%) unless otherwise specified	Device type n (%) unless otherwise stated	Treatments at baseline n (%) unless otherwise stated	Comorbidities n (%) unless otherwise stated
Wakabayashi (2021) Japan HF	FT	Retrospective cohort	Mean (range) 79 (71–84)	NR	33 (67.3)	PPM: 23 (46.9) ICD: 20 (40.8) CRT-D: 6 (12.2)	Antiplatelet agents: 18 (36.7) Anticoagulant agents: 17 (34.7) β-Blockers: 20 (40.8) ACEIs or ARBs: 21 (42.9) CCB: 13 (26.5) Diuretics: 22 (44.9) Statins: 9 (18.4)	BMI (kg/m ²) mean (range): 23.1 (20.8–25.0) Hypertension: 21 (42.9%) Diabetes mellitus: 17 (34.7%) Dyslipidemia: 28 (57.1%) Previous HF: 10 (20.4%) Valvular heart disease: 8 (16.3%) CAD: 8 (16.3%)

Abstr., abstract; ACE I, angiotensin-converting enzyme inhibitor; A2RB, angiotensin 2 receptor blockers; BMI, body mass index; CRT-D, cardiac resynchronisation therapy with defibrillator; FT, full text; ICD, implantable cardioverter defibrillator; HF, heart failure; MRA, mineralocorticoid receptor antagonist; NR, not reported; NYHA, New York Heart Association; PPM, permanent pacemaker.

TABLE 44 Characteristics of included studies and baseline demographics for HeartInsight

Study details:			Age (years) Mean (SD) unless otherwise specified	NYHA class n (%) unless otherwise specified	Sex (male) n (%) unless otherwise specified	Device type n (%) unless otherwise stated	Treatments at baseline n (%) unless otherwise stated	Comorbidities n (%) unless otherwise stated
Author (year)	Publication type	Study design						
D'Onofrio (2022)	FT	Prospective	Median (IQR)	All	All	All	All	All
(D'Onofrio 2019)	Abstr.	cohort	All = 69.1	II: 446 (48.8)	744 (81.0)	CRT-D: 403 (43.9)	Diuretics: 797 (86.8)	History of
(Padeletti, 2015)	Protocol		(60.7-75.9)	III: 467 (51.2)	Derivation 366	Derivation	Beta-blockers: 793 (86.4)	hypertension: 604
(NCT01836510)	ClinicalTrial		Development = 69	Derivation	(80.1)	CRT-D: 202 (44.2)	ACE: 523 (57.0)	Diabetes: 323
Italy and Spain			(60.7-757)	II: 225 (49.4)	Validation 378	Validation	Aldosterone antagonists: 240	Chronic kidney
HF			Validation = 69	III: 230 (50.6)	(82.0)	CRT-D: 201 (43.6)	(26.1)	disease: 194
			(60.8-76.1)	Validation			ARB: 196 (21.3)	AF history: 129
				II: 221 (48.2)			CCB: 75 (8.2)	Stroke/TIA: 69
				III: 237 (51.8)			Statins: 553 (60.2)	Valvular surgery:
							Antiplatelets: 596 (64.9)	68
							Anticoagulants: 228 (24.8)	Derivation
							Amiodarone: 169 (18.4)	History of
							Derivation	hypertension: 295
							Diuretics: 400 (87.5)	(64.6)
							Beta-blockers: 395 (86.4)	Diabetes: 153
							ACE: 259 (56.7)	(33.6)
							Aldosterone antagonists: 133	Chronic kidney
							(29.1)	disease: 107
							ARB: 100 (21.9)	(23.4)
							CCB: 36 (7.9)	AF history: 68 (15)
							Statins: 286 (62.6)	Stroke/TIA: 33
							Antiplatelets: 298 (65.2)	(7.2)
							Anticoagulants: 109 (23.9)	Valvular surgery:
							Amiodarone: 81 (17.7)	37 (8.1)
							Validation	Validation
							Diuretics: 397 (86.1)	History of
							Beta-blockers: 398 (86.3)	hypertension: 309
							ACE: 264 (57.3)	(67)
							Aldosterone antagonists: 107	Diabetes: 170
							(23.2)	(37.2)
							ARB: 96 (20.8)	Chronic kidney
							CCB: 39 (8.5)	disease: 87 (18.9)
							Statins: 267 (57.9)	AF history: 61
							Antiplatelets = 298 (64.6)	(13.3)
							Anticoagulants = 119 (25.8)	Stroke/TIA: 36
							Amiodarone = 88 (19.1)	(7.8)
								Valvular surgery:
								31 (6.7)

Abstr, abstract; ACE, angiotensin-converting enzyme; A2RB, angiotensin 2 receptor blocker; CRT-D, cardiac resynchronisation therapy with defibrillator; HF, heart failure; FT, full text; ICD, implantable cardioverter defibrillator; NYHA, New York Heart Association; TIA, transient ischaemic attack.

TABLE 45 Characteristics of included studies and baseline demographics for HeartLogic

Study details: Author (year) Country Study population	Publication type	Study design	Age (yrs.) Mean (SD) unless otherwise specified	NYHA n (%) unless otherwise specified	Sex (male) n (%) unless otherwise specified	Device type n (%) unless otherwise stated	Treatments at baseline n (%) unless otherwise stated	Comorbidities n (%) unless otherwise stated
Boehmer (2017) (Boehmer, 2017) USA, Czech Republic, Hong Kong, Hungary, Israel, Italy, Malaysia, Netherlands, Slovakia, Thailand, United Kingdom HF	FT Abstr. Trial entry	Prospective cohort	Development 66 (10.9) Validation 67 (10.3)	Development I: 5% II: 64% III: 27% IV: 0% Validation I: 4% II: 64% III: 25% IV: 1%	Development 387 (73) Validation 314 (71)	NR	Development Anticoagulants: 462 (88) Beta-blockers: 490 (94) Diuretics: 399 (76) ACE, ARBs: 436 (83) Aldosterone: 196 (37) Vasoactive drugs: 123 (23) Cardiac glycosides: 139 (27) Antiarrhythmic meds: 113 (22) CCB: 42 (8) Validation Anticoagulants: 356 (82) Beta-blockers: 405 (93) Diuretics: 340 (78) ACE, ARBs: 354 (81) Aldosterone: 193 (44) Vasoactive drugs: 102 (23) Cardiac glycosides: 107 (25) Antiarrhythmic meds: 97 (22) CCB: 31 (7)	Development History of cardiac ischemia: 277 (52) History of dilated cardiomyopathy: 301 (57) History of valvular disease: 162 (31) History of valve surgery: 50 (9) Previous MI: 211 (40) Previous CABG: 156 (29) AF: 136 (26) Renal disease: 143 (27) Validation History of cardiac ischemia: 217 (49) History of dilated cardiomyopathy: 271 (61) History of valvular disease: 130 (29) History of valve surgery: 40 (9) Previous MI: 171 (39) Previous CABG: 128 (29) AF: 118 (27) Renal disease: 101 (23)
Calo (2021) (Calo, 2020) (Calo, 2021) Italy HF	FT Abstr. Abstr.	Prospective cohort	69 (11)	I: 25 II: 197 III: 135 IV: 9	286 (78)	CRT: 281 (77)	Beta-blocker: 333 ACEi, ARB, ARNI: 288 Aldosterone antagonist: 110 Diuretic: 326 Antiarrhythmic: 106 Ivabradine: 37	AF history: 144 AF on implantation: 77 Valvular disease: 77 CAD: 165 Diabetes: 112 COPD: 73 Chronic kidney disease: 121 Hypertension: 240
Chang (2020) USA HF	Abstr.	Retrospective cohort with external control	NR	NR	NR	CRT-D: 40	NR	NR

Study details: Author (year) Country Study population	Publication type	Study design	Age (yrs.) Mean (SD) unless otherwise specified	NYHA n (%) unless otherwise specified	Sex (male) n (%) unless otherwise specified	Device type n (%) unless otherwise stated	Treatments at baseline n (%) unless otherwise stated	Comorbidities n (%) unless otherwise stated
De Juan Baguda (2022) (De Juan Baguda 2021) (De Juan Baguda 2021) Spain HF	FT Abstr. Abstr.	Prospective cohort (phase 3) and Retrospective cohort (phase 1 and 2)	68 (10)	I: 47 (16) II: 166 (58) III: 75 (26)	222 (77)	CRT-D: 234 (81) ICD: 241 (84)	Beta-blockers: 274 (95) ACEI, ARB, or valsartan/sacubitril: 265 (92) valsartan/sacubitril: 145 (50) MRAs: 215 (75) Diuretics: 207 (72) Amiodarone: 64 (22) Ivabradine: 35 (12)	History of AF = 112 (39) AF at implantation = 66 (23) Hypertension = 214 (74) Diabetes = 116 (40) Dyslipidemia = 169 (59) Smoking = 175 (64) (incl. 144 ex-smokers) COPD = 48 (17) Chronic kidney disease = 77 (27) On haemodialysis = 5 (2) Previous stroke = 31 (11) Sleep apnea-hypopnea syndrome = 33 (11)
De Ruvo (2019) (De Ruvo, 2019) (D'Onofrio, 2019) Italy HF	Abstr. Abstr. Abstr.	Prospective cohort	71 (10)	NR	74 (73)	NR	NR	NR
Ebrille (2021) Italy HF	Abstr.	Prospective cohort	73 (7)	NR	39 (72)	CRT: 54	NR	NR
Feijen (2023) (Feijen, 2022) Europe HF	FT Abstr.	Retrospective cohort (propensity matched)	Median (IQR) before matching non-HL = 67 (59.3-74) HL = 68 (58.3-75) after matching non-HL = 68 (60.5-75) HL = 68 (58.5-75.5)	Before matching non-HeartLogic III and IV: 67 (30.2) HeartLogic III and IV: 47 (30.5) After matching non-HeartLogic III and IV: 39 (30.7) HeartLogic III and IV: 38 (29.9)	Before matching non-HeartLogic 173 (77.9) HeartLogic 123 (79.9) After matching non-HeartLogic 101 (79.5) HeartLogic 102 (80.3)	No CRT function before matching (only ICD) non-HL = 124 (55.9) HL = 52 (33.8) after matching non-HL = 52 (40.9) HL = 52 (40.9)	NR	before matching non-HL Ischemic etiology = 117 (52.7) Diabetes = 63 (28.4) HL Ischemic etiology = 71 (46.1) Diabetes = 25 (16.2) after matching non-HL Ischemic etiology = 62 (48.8) Diabetes = 28 (22) HL Ischemic etiology = 58 (45.7) Diabetes = 25 (19.7)

continued

TABLE 45 Characteristics of included studies and baseline demographics for HeartLogic (continued)

Study details: Author (year) Country Study population	Publication type	Study design	Age (yrs.) Mean (SD) unless otherwise specified	NYHA n (%) unless otherwise specified	Sex (male) n (%) unless otherwise specified	Device type n (%) unless otherwise stated	Treatments at baseline n (%) unless otherwise stated	Comorbidities n (%) unless otherwise stated
Gardner (2018) Czech Republic, Germany, Hong Kong, Hungary, Israel, Italy, Mala ysia, Netherlands, Slovakia, Thailand, United Kingdom, United States HF	FT	Prospective cohort (secondary analysis)	67 (10.5)	I: 43 (5) II: 605 (67) III: 241 (27) IV: 4 (< 1) Not available: 7 (1)	654 (73)	CRT-D: 900	ACE/ARB: 748 (83) Beta-blocker: 839 (93) MRAs: 360 (40) Diuretics: 694 (77) Vasodilators: 210 (23) Cardiac glycosides: 231 (26) Antiarrhythmic medications: 193 (21)	History of cardiac ischemia = 457 (51) Diabetes = 380 (42) History of renal disease = 226 (25) History of AF or atrial flutter = 306 (34)
Guerra (2022) (Guerra, 2022) (Guerra, 2022) Italy HF	FT Abstr. Abstr.	Prospective cohort	69 (11)	I: 13 (6) II: 101 (44) III: 108 (47) IV: 7 (3)	171 (75)	CRT: 197 (86%)	Beta-blocker: 204 (89) ACE, ARB, ARNI: 198 (86) Diuretics: 207 (90) Antiarrhythmic: 191 (28) Ivabradine: 26 (11)	CAD: 108 (47) AF history: 91 (40) Diabetes: 75 (33) COPD: 47 (20) Chronic kidney disease: 85 (37) Hypertension: 153 (67)
Henry (2022) Belgium HF	Abstr.	Retrospective cohort	NR	NR	NR	ICD: NR CRT-D: NR	NR	NR
Lerman (2023) USA HF (LVAD pts.)	FT	Retrospective cohort	Median (IQR) 69 (66-72)	NR	10 (71)	NR	MRA: 7 (50) Loop diuretics: 13 (92.9) Beta-blockers: 13 (92.9) ACEi/ARB: 11 (78.6) Calc channel blockers: 3 (21.4) Hydralazine: 7 (50) Nitrates: 1 (7.1)	Chronic pulmonary disease: 7 (50) Atrial fibrillation/flutter: 10 (71.4) Hypertension: 12 (85.7) Coronary disease: 14 (100) Diabetes = 7 (50) BMI > 30 = 8 (57.1) MI = 4 (28.6) CKD grade 3 or higher = 10 (71.4)
Pecora (2020) Italy HF	Abstr.	Prospective cohort	71 (10)	NR	76 (73)	NR	NR	NR
Perez Serrano (2019) Spain Unclear	Abstr.	Prospective cohort	66	NR	15 (83)	ICD: NR CRT-D: NR	NR	NR

Study details: Author (year) Country Study population	Publication type	Study design	Age (yrs.) Mean (SD) unless otherwise specified	NYHA n (%) unless otherwise specified	Sex (male) n (%) unless otherwise specified	Device type n (%) unless otherwise stated	Treatments at baseline n (%) unless otherwise stated	Comorbidities n (%) unless otherwise stated
Santini (2020) (Santini, 2020) Italy HF	FT Abstr.	Prospective cohort	71 (10)	I: 2 (2) II: 46 (44) III: 53 (51) IV: 3 (3)	76 (73)	CRT: 96 (92)	Beta-blocker: 97 (93) ACE: 54 (52) Diuretics: 97 (93) Antiarrhythmic: 27 (26) Ivabradine: 12 (11)	AF history: 44 (42) AF on implantation: 23 (22) Valvular disease: 24 (23) Diabetes: 32 (31) COPD: 21 (19) Chronic kidney disease: 38 (36) Hypertension: 79 (76)
Santobuono (2023) (D'Onofrio 2023) (Santobuono, 2022) Italy HF	FT FT Abstr.	Prospective cohort	69 (10)	I: 36 (6) II: 351 (62) III: 171 (30) IV: 10 (2)	453 (80)	ICD: 158 CRT-D: 410	Beta-blocker: 520 (92) ACE-I, ARB or ARNI: 536 (94) Diuretics: 506 (89) Antiarrhythmic: 116 (20)	Diabetes: 167 (29) COPD: 89 (16) Chronic kidney disease: 153 (27) Hypertension: 334 (59)
Treskes (2021) Belgium, the Netherlands and Switzerland HF	FT	Retrospective pre-post study design	67 (10.3)	I: 15 (20) II: 35 (47) III: 24 (32)	62 (84)	CRT-D: 64 ICD: 10	Pre activation Beta-blocker: 56 (82) ACE-I/ARB/ARNI: 56 (82) MRA: 36 (53) Diuretics: 47 (69) Ivabradine: 3 (4) Post activation Beta-blocker: 61 (89) ACE-I/ARB/ARNI: 56 (82) MRA: 45 (66) Diuretics: 48 (70) Ivabradine: 3 (4)	Diabetes: 15 (20)
Vigdor (2020) USA HF	Abstr.	Prospective cohort	NR	NR	NR	NR	NR	NR
Wariar (2023) (Wariar, 2022) USA HF	Abstr. Abstr.	Retrospective cohort	Predominantly 65 years and older	NR	Predominately male	CRT-D: 1078 (69) ICD: 31%	NR	Hypertension: 87.4% Hyperlipidemia: 80.3% Diabetes: 51.3% Ischemic heart disease: 87.7% Congestive heart failure: 84.7% Atrial fibrillation: 40.1% COPD: 30.6% Chronic kidney disease: 54.2%

continued

TABLE 45 Characteristics of included studies and baseline demographics for HeartLogic (*continued*)

Study details: Author (year) Country Study population	Publication type	Study design	Age (yrs.) Mean (SD) unless otherwise specified	NYHA n (%) unless otherwise specified	Sex (male) n (%) unless otherwise specified	Device type n (%) unless otherwise stated	Treatments at baseline n (%) unless otherwise stated	Comorbidities n (%) unless otherwise stated
Hernandez (2022) (Hernandes, 2021) (NCT03237858) USA HF	FT Abstr. Trial entry	Prospective cohort	67 (12)	NR	129 (68)	CRT-D: 132 (69) ICD: 59 (31)	Loop diuretic: 158 (83) Thiazide diuretic: 17 (9) ACEI or ARB: 103 (54) ARNI: 51 (27) MRA: 82 (43) Beta-blocker: 184 (96) Vasodilators: 35 (18)	Ischemic heart disease: 90 (47) Dilated cardiomyopathy: 75 (39) Idiopathic cardiomyopathy: 20 (11) Valvular disease: 48 (25) MI: 73 (38) CABG: 49 (26) Chronic obstructive lung disease: 28 (15) Pulmonary hypertension: 14 (7) Peripheral vascular disease: 25 (14) Cerebrovascular disease: 32 (17) Renal dysfunction: 50 (26) Hypertension: 144 (76) Diabetes: 69 (36) Hyperlipidemia: 134 (70) Sleep apnea: 45 (25) Depression: 34 (18) Hepatic disease: 11 (6) Anaemia: 27 (14)
Abstr, abstract; ACE, angiotensin-converting enzyme; AF, atrial fibrillation; A2RB, angiotensin 2 receptor blockers; ARNI, angiotensin receptor/neprilysin inhibitor; BMI, body mass index; CABG, coronary artery bypass graft; CRT-D, cardiac resynchronisation therapy with defibrillator; COPD, chronic obstructive pulmonary disease; FT, full text; HF, heart failure; ICD, implantable cardioverter defibrillator; MRA, mineralocorticoid receptor antagonist; NYHA, New York Heart Association; TIA, transient ischaemic attack.								

TABLE 46 Characteristics of included studies and baseline demographics for TriageHF

Study details: Author (year) Country Study population	Publication type	Study design	Age (yrs) Mean (SD) unless otherwise specified	NYHA class n (%) unless otherwise specified	Sex (male) n (%) unless otherwise specified	Device type n (%) unless otherwise stated	Treatments at baseline n (%) unless otherwise stated	Comorbidities n (%) unless otherwise stated
Ahmed (2022) (Ahmed, 2023 unpublished) (Ahmed, 2021) (Ahmed, 2021) UK HF and no HF	Abstr. FT Abstr. Abstr.	Prospective cohort (data set Sept 2019–June 2021)	66 (15.5)	No HF: 62 (14.1) I: 56 (12.8) II: 151 (34.4) III: 147 (33.5) Not available: 23 (5.2)	278 (63.3)	CRT-D: 167 CRT-P: 172 ICD: 36 PPM: 64	Beta-blockers: 320 (79.6) Ace-I/ARB/ARNI: 274 (68.5) MRA: 149 (37.3) Diuretic: 206 (51.5)	Ischaemic heart disease: 238 (55.5) Adult congenital heart disease: 39 (9.0) Prior ablation: 71 (16.4) Prior MI: 141 (34.1) COPD: 55 (13.0) Diabetes: 28 (19.2) Chronic kidney disease stage (CKD) > 3: 135 (31.0)
Bachtiger (2021) UK Unclear	Abstr.	Prospective cohort	NR	NR	NR	NR	NR	NR
Burri (2018) Unclear Unclear	FT	Cohort (Secondary analysis using data from the MORE- CARE randomised trial)	66 (10)	I: 52 (7.3%) II: 226 (31.8%) III: 413 (58.2%) IV: 19 (2.7%) Not reported: 12 (1.7%)	549 (76.3%)	CRT-D: 722	Diuretic: 648 (91.3) Beta-blocker: 640 (90.1) ACE-inhibitor or ARBII: 579 (81.5) Antiarrhythmic: 183 (25.8) Antiplatelet: 439 (61.8) Oral anticoagulants: 160 (22.5)	Ischemic heart disease: 316 (44.1) History of AF: 125 (17.5) History of sustained VT/VF: 81 (11.3) Previous valve surgery: 62 (8.7) Diabetes: 246 (35.0) Hypertension: 327 (46.0) Previous TIA or stroke: 52 (7.3) COPD: 104 (4.6)
Cardoso (2020) Portugal Unclear	Abstr.	Prospective cohort	68 (9.8)	II, III and IV: NR 46%	NR	CRT: NR	NR	NR

continued

TABLE 46 Characteristics of included studies and baseline demographics for TriageHF (continued)

Study details: Author (year) Country Study population	Publication type	Study design	Age (yrs) Mean (SD) unless otherwise specified	NYHA class n (%) unless otherwise specified	Sex (male) n (%) unless otherwise specified	Device type n (%) unless otherwise stated	Treatments at baseline n (%) unless otherwise stated	Comorbidities n (%) unless otherwise stated
Cowie (2013) Unclear Unclear	FT	Develop- ment study – observa- tional and randomised Validation study – observa- tional and randomised	Development 68 (11) Validation 67 (11)	Develop- ment set I: 2 II: 19 III: 76 IV: 3 Validation set I: 4 II: 22 III: 70 IV: 4	Development set 69 Validation set 74	Development set ICD: 0 CRT-D: 100 Validation set ICD:4 CRT-D: 96	Development set ACE/ARB: 70% Beta-blockers: 87% Diuretics: 77% Digoxin: 29% Aldosterone antagonist: 26% AAD: 18% Antiplatelet or anticoagu- lant: 86% Warfarin: 33% Validation set ACE/ARB: 84% Beta-blockers: 88% Diuretics: 87% Digoxin: 33% Aldosterone antagonist: 22% AAD: 22% Antiplatelet or anticoagu- lant: 61% Warfarin: 25%	Development set Ischaemic: 63% MI: 43% Hypertension: 70% Diabetes: 37% History of AF: 21% LVEF 35%: 96% Validation set Ischaemic: 61% MI: 48% Hypertension: 62% Diabetes: 38% History of AF: 32% LVEF 35%: 92%
Debski (2021) UK HF	Abstr.	Prospective cohort	74 (10)	NR	82%	CRT-D:132	NR	NR
Garner (2022) UK Unclear	FT	Prospective cohort	70 (11.5)	NR	147 (78)	CRTD: 176 (94) CRTP: 9 (5) ICD: 3 (1)	ACE/ARB: 126 (67) ARNI: 34 (18) Beta-blocker: 175 (93) MRA: 116 (62) Diuretic: 135 (72)	Diabetes: 71 (38) BMI Mean (SD): 29.6 (6.2) Clinical frailty score Mean (S.D): 4.1 (1.5) Charleson comorbidity score Mean (S.D): 5.5 (2.3)
Gula (2014) 34 International centres (RAFT trial) HF	FT	Validation study using data from RCT	66 (9)	II: 1062 (87) III: 162 (13)	1013 (83)	CRT-D: 741 ICD: 483	ACE I: 967 (79) ARB: 269 (22) Beta-Blockers: 1100 (90) Diuretics: 1005 (82) Statins: 847 (69) Nitrates: 329 (27) Digoxin: 393 (32) Ca Channel Blocker: 137 (11) AAD: 175 (14) Anticoag/platelet: 1093 (89)	Ischemic: 798 (65%) Renal Dysfunction: 213 (17%) Pulmonary: 308 (25%) Hypertension: 530 (43%) Diabetes: 408 (33%) Chronic AF: 133 (11%) VT/VF: 226 (18%) Mean LVEF (SD): 23% ($\pm$ 5)
Koehler (2019) Unclear HF	Abstr.	Cohort	NR	NR	NR	CRT-D: NR ICD: NR	NR	NR

Study details: Author (year) Country Study population	Publication type	Study design	Age (yrs) Mean (SD) unless otherwise specified	NYHA class n (%) unless otherwise specified	Sex (male) n (%) unless otherwise specified	Device type n (%) unless otherwise stated	Treatments at baseline n (%) unless otherwise stated	Comorbidities n (%) unless otherwise stated
Okumura (2020) Japan Unclear	FT	Prospective cohort	68 (11.9)	I: 20 (6) II: 162 (52) III: 128 (41) IV: 4 (1)	220 (69.8)	CRT-D: 315	Beta-blocker: 264 (83.8) ACE-I: 136 (43.2) ARB: 88 (27.9) Diuretic: 249 (79.0) Nitrate: 16 (5.1) Statin: 116 (36.8) MRA: 177 (56.2)	Ischemic cardiomyopathy: 74 (23.5) Non-ischemic cardiomyopathy: 184 (58.4) AF: 126 (40) Paroxysmal AF: 63 (20) Persistent AF: 15 (4.8) Long-standing persistent AF: 48 (15.2) Hypertension: 100 (31.7) Chronic kidney disease: 99 (31.4) Diabetes: 93 (29.5) Type I: 3 (1.0) Type II: 90 (28.6) Sleep apnea: 30 (9.5) Bronchial asthma: 14 (4.4) COPD: 6 (1.9)
Sammut-Powell (2022) (Ahmed, 2022) (Ahmed, 2020) (Ahmed, 2020) (Ahmed, 2018) (Ahmed, 2018) UK HF	FT FT FT Abstr. Abstr. Abstr.	Prospective cohort	66 (15.5)	No HF: 62 (14.3) I: 55 (12.6) II: 151 (34.7) III and IV: 145 (33.3)	276 (63.4)	CRT-D: 166 (38.2) CRT-P: 170 (39.0) ICD: 36 (8.3) PPM: 63 (14.5)	Beta-blockers: 319 (79.8) ACE-I/ARB/ARNI: 273 (68.6) MRA: 149 (37.5) Diuretic: 206 (51.8)	Diabetes: 103 (23.7) COPD: 54 (12.4) Chronic kidney disease stage ≥ 3: 134 (30.8) At least one comorbidity: 388 (89.2)
Virani (2018) (Virani 2016 - outcome changes to clinical mgmt) (Virani, 2016) (Zieroth 2016) Canada Unclear	FT Abstr. Abstr. Abstr.	Prospective cohort	67 (11.0)	I: 16 (16) II: 50 (50) III: 32 (32) IV: 0 (0) Not available: 2 (2)	78 (78%)	CRT-D: 69 (69) ICD-DR: 20 (20) ICD-VR: 11 (11)	Beta-blockers: 95 (95) ACE inhibitors: 56 (56) A2RB: 28 (28) MRA: 49 (49) Diuretic: 81 (81) Nitrate: 17 (17)	History of ventricular arrhythmia: 30 (30%) Type II diabetes: 41 (41%) COPD: 17 (17%) Sleep apnoea: 16 (16%) Hypertension: 64 (64%)
Zile (2020) (Zile, 2020) (Zile, 2020) USA HF and risk of acute HF	FT Abstr. Abstr.	Retrospec- tive cohort	66 (12)	NR	16,371 (71)	ICD: 11,878 (52) CRT-D: 11,023 (48)	ACE-I/ARB: 16,118 (70) Beta-blockers: 11,998 (52) Diuretics: 15,085 (66) Spironolactone: 6558 (29) Sacubitril/ valsartan: 194 (1) Vasodilator/nitrate: 12,767 (56) AAD: 16,919 (74) Anticoagulation: 9524 (42)	Hypertension: 15,450 (67) HF: 14,276 (62) Diabetes: 7623 (33) CAD: 14,574 (64) MI: 7365 (32) Vascular disease: 2643 (12) AF: 8222 (36) Renal dysfunction: 5211 (23) Stroke/TIA: 4289 (19)

continued

TABLE 46 Characteristics of included studies and baseline demographics for TriageHF (*continued*)

Study details: Author (year) Country Study population	Publication type	Study design	Age (yrs) Mean (SD) unless otherwise specified	NYHA class n (%) unless otherwise specified	Sex (male) n (%) unless otherwise specified	Device type n (%) unless otherwise stated	Treatments at baseline n (%) unless otherwise stated	Comorbidities n (%) unless otherwise stated
Zile 2021 USA With and without HF	FT	Prospective cohort	73 (9) range 46–92	Class II: 27 (41) Class III: 39 (59)	Male 46 (70)	CRT-D: 66	ACE-I/ARB/ARNI: 48 (73) Beta-blockers: 57 (86) Diuretics: 55 (83) MRAs: 19 (29) Vasodilators: 17 (26) Digitalis compounds: 16 (24) AAD: 15 (23) CCB: 3 (4) HCN channel blockers: 2 (3)	Ischemic cardiomyopathy: 38 (58) Non-ischemic cardiomyopathy: 21 (32) Hypertrophic cardiomyopathy: 1 (1) Hypertension: 42 (64) MI: 27 (41) Peripheral vascular disease: 18 (27) AF: 40 (61) Atrial flutter: 7 (11) COPD: 13 (20) Diabetes mellitus: 28 (42) Chronic renal dysfunction: 16 (24) Stroke: 8 (12)

AAD, antiarrhythmic drug; Abstr, abstract; ACE, angiotensin-converting enzyme; AF, atrial fibrillation; A2RB, angiotensin 2 receptor blockers; ARNI, angiotensin receptor/neprilysin inhibitor; BMI, body mass index; CABG, coronary artery bypass graft; CAD, coronary artery disease; CCB, calcium channel blocker; COPD, chronic obstructive pulmonary disease; CRT-D, cardiac resynchronisation therapy with defibrillator; CRT-P, cardiac resynchronisation therapy with pacemaker; FT, full text; HF, heart failure; ICD, implantable cardioverter defibrillator; ICD-DR, implantable cardioverter defibrillator dual chamber; ICD-VR, implantable cardioverter defibrillator single chamber; MI, myocardial infarction; MRA, mineralocorticoid receptor antagonist; NYHA, New York Heart Association; PPM, permanent pacemaker; TIA, transient ischaemic attack; VT/VF, ventricular tachycardia/ventricular fibrillation.

Appendix 7 Studies reporting development and validation cohorts in the same study, full results including development cohort

TABLE 47 Prognostic accuracy results for both development and validation studies

Author (year)	Study design (n)	Intervention	Study end point	AUC (95% CI)	Sensitivity (95% CI; %)	Specificity (95% CI; %)	PPV (95% CI; %)	NPV (95% CI; %)
D'Onofrio (2022) ⁴⁵	Prospective cohort (overall n = 918, development n = 457, validation n = 378)	HeartInsight	Primary: First post implant worsening HF hospitalisation Secondary: any HF hospitalisation, outpatient IVI or death	Primary end point Development = 0.89 (0.83 to 0.95) Validation = NR Secondary end point Development = NR Validation = NR	Development 3.5 to 4.5 = 81.5 (61.9 to 93.7) to 63.0 (42.4 to 80.6) Validation; primary end point 3.5 = 72.4 (52.8 to 87.3) 4.0 = 65.5 (45.7 to 82.1) 4.5 = 65.5 (45.7 to 82.1) Validation; secondary end point 3.5 = 64.5 (51.3 to 76.2) 4.0 = 59.7 (46.4 to 71.9) 4.5 = 54.8 (41.7 to 67.5)	Development 3.5 to 4.5 = 82.6 (78.2 to 86.5) to 90.7 (89.0 to 94.9) Validation; primary end point 3.5 = 75.8 (75.6 to 75.9) 4.0 = 82.4 (82.3 to 82.5) 4.5 = 86.7 (86.6 to 86.8) Validation; secondary end point 3.5 = 75.3 (75.2 to 75.4) 4.0 = 82.0 (81.9 to 82.2) 4.5 = 86.5 (86.4 to 86.6)	Development NR Validation; primary end point NR Validation; secondary end point 3.5 to 4.5 = 5.3 to 7.7	Development NR Validation; primary end point NR Validation; secondary end point 3.5 to 4.5 = 96.6 to 96.7
Boehmer (2017) ⁵⁶	Prospective cohort (overall n = 900, development n = 500, validation n = 400)	HeartLogic	HF events of hospitalisations and clinic visits with change to treatment with primary cause of HF worsening	Development = NR Validation = NR	Development = 82.0 Validation = 70.0 (55.4 to 82.1)	Development = NR Validation = 85.7	Development = NR Validation = 11.3	Development = NR Validation = 99.98

AUC, area under the curve; HF, heart failure; IVI, intravenous intervention.

Appendix 8 Economics tables and figures

TABLE 48 Mortality rates and assumptions in the economic model

RMS in general	Mortality	Source	HR compared to the intervention
Base case			
Implantable cardio-verter defibrillator (ICD) implantation	36% at 5 years	Bottle <i>et al.</i> 2021	1 (assumed, as there was no evidence on mortality for the intervention)

The HF population utilities in subgroups of NYHA class ([Table 49](#)) were obtained from Griffiths *et al.*¹¹³ The EAG made the assumption that the mean utility for the undiagnosed subgroup was the same as for the NYHA class 1 subgroup. The UK general population utility 0.84^{114,115} was subtracted from the HF population utilities in subgroups of NYHA class ([Table 49](#)) to derive the utility decrement for HF population in each NYHA class ([Table 50](#)). The percentage of patients in each NYHA class was obtained from the Medtronic submission,¹⁰⁰ and this was used to calculate the weighted average utility decrement for a patient with HF ([Table 50](#)). In addition, a separate utility decrement for a hospitalisation event was calculated. Utility decrements for hospitalisation by NYHA class were also obtained from Griffiths *et al.*¹¹³ These were multiplied by the same patient distribution across NYHA class percentages from the Medtronic submission¹⁰⁰ to derive the weighted average utility decrement for hospitalisation ([Table 51](#)). HF utility decrements were applied to HF population alive at each model cycle; however, the hospitalisation decrement was only applied to the proportion hospitalised in each cycle.

TABLE 49 Heart failure utilities

HF subgroups	Mean utility	Population (%)	Source
Undiagnosed	0.82	8.7%	Mean utility ¹¹³ Population (%) ¹⁰⁰
NYHA class I	0.82	20.8%	
NYHA class II	0.74	43.3%	
NYHA class III	0.64	26.6%	
NYHA class IV	0.46	0.5%	

TABLE 50 Population utility used to derive HF utility decrement

HF subgroups	Population utility	Source	Utility decrement derived ^a
Undiagnosed	0.84	^{114,115}	-0.02
NYHA class I			-0.02
NYHA class II			-0.11
NYHA class III			-0.20
NYHA class IV			-0.39
Weighted average HF utility decrement derived using population distribution in Table 49			-0.107

a 0.84 subtracted from mean utility in [Table 49](#). Estimates rounded to two decimal places.

TABLE 51 Hospitalisation utility decrement

HF subgroups	Mean utility decrement (derived)	Source
Undiagnosed	-0.040	113
NYHA class I	-0.040	
NYHA class II	-0.070	
NYHA class III	-0.100	
NYHA class IV	-0.290	
Weighted average hospitalisation utility decrement derived using population distribution in Table 49	-0.070 ^a	

^a Calculated using the weights reported in [Table 49](#).

TABLE 52 Remote monitoring system costs

Remote monitoring system	Cost (exc. VAT)	Unit	Modelled cost
CorVue and Merlin.net PCN	Free of charge with the device; no additional consumables and maintenance costs	One-off	£0
HeartInsight and BIOTRONIK Home Monitoring	£450/patient; no additional charge on maintenance/consumables	One-off	£450/patient
HeartLogic and LATITUDE NXT Heart Failure Management System	(confidential information has been removed)/patient; (confidential information has been removed); no additional consumable or maintenance costs	One-off	Confidential information has been removed
TriageHF and CareLink remote monitoring (TriageHF Plus)	£100/patient/year No additional charges	Yearly	£8.33 per month per patient

TABLE 53 Time for staff training and responding an alert

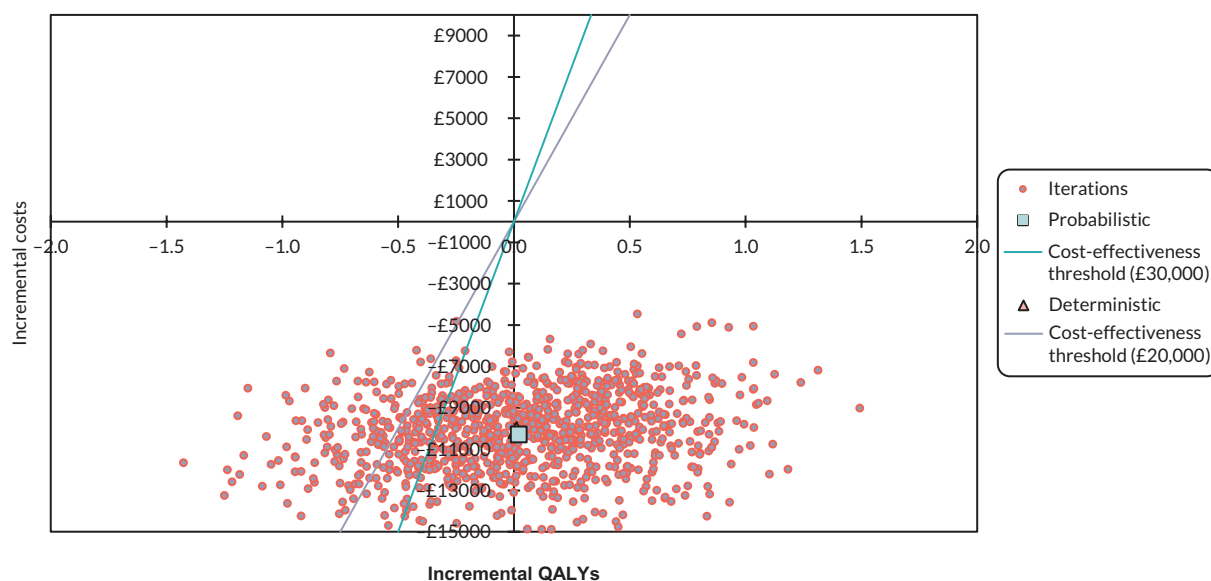
Remote monitoring system	Staff time	
	Training time	Time to respond to 1 alert
CorVue and Merlin.net PCN	30 minutes	5 minutes to read an alert and evaluate the diagnostic trend data
HeartInsight and BIOTRONIK Home Monitoring	1 hour	20 minutes per case, 40 minutes for complex cases. Average 30 minutes used.
HeartLogic and LATITUDE NXT Heart Failure Management System	1 hour (assumed)	5 minutes to review alerts, plus 10–20 minutes to action an alert. Average 20 minutes (15 minutes to action alert plus 5 minutes to review alerts) used.
TriageHF and CareLink remote monitoring (TriageHF Plus)	1 hour (assumed)	30 minute per week

TABLE 54 Costs of staff training and actioning an alert

Remote monitoring system	Number of RMS alerts per patient per year	Cost		Unit cost of staff time (source: PSSRU) ¹¹⁶
		Staff training time ^a	Staff time per alert ^b	
CorVue and Merlin.net PCN	0.31 (assumed equal to unscheduled visits) ⁹⁷	£26.50	£0.11	£53 per hour (cost of hospital-based Band 6 Physiologist-used in the base-case analyses) £59 per hour (cost of hospital-based specialist nurse – used in the scenario analyses)
HeartInsight and BIOTRONIK Home Monitoring	0.31 (assumed equal to unscheduled visits) ⁹⁷	£53	£0.69	
HeartLogic and LATITUDE NXT Heart Failure Management System	0.71 ⁷²	£53	£1.31	
TriageHF and CareLink remote monitoring (TriageHF Plus)	Confidential information has been removed	£53	Confidential information has been removed	

a One-off costs, derived as a product of staff training time for each device in [Table 39](#) and unit cost of £53 per hour of staff time.

b Monthly costs, derived as a product of average number of alerts per month, average time spent per alert and unit cost of £53 per hour of staff time.

**FIGURE 8** Cost-effectiveness plot – HeartLogic.

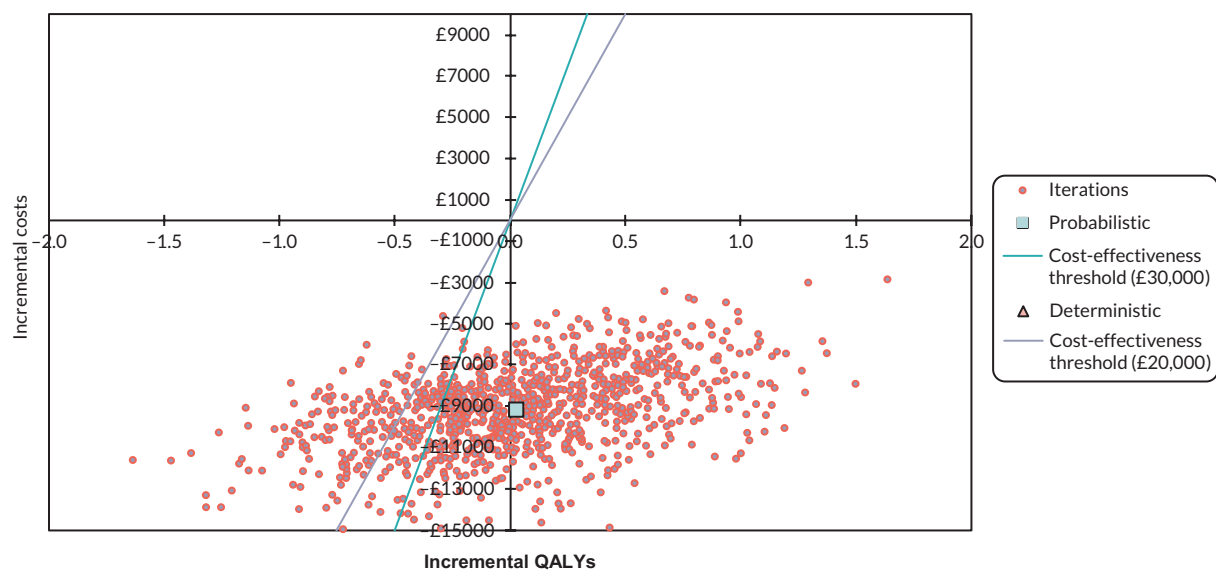


FIGURE 9 Cost-effectiveness plot – TriageHF.

EME
HSDR
HTA
PGfAR
PHR

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