CareLink network service for remote monitoring of people with cardiac devices

Medtech innovation briefing

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Summary

The CareLink network service is a remote monitoring system for people with a Medtronic implantable cardiac device. The service uses the MyCareLink monitor or MyCareLink Smart (for smartphones or tablets) to collect data remotely from the device. These data are transferred to the patient's clinician through the CareLink network with the aim of reducing the need for face-to-face follow-up visits. Evidence from prospective studies of mixed quality suggests that the CareLink network service decreases the time from the detection of a clinical event to a clinical decision, and decreases the number of emergency visits and healthcare use in people with heart failure when compared with standard face-to-face follow-up. The CareLink network service showed a lower number of false negatives when compared with other home monitoring devices and had 100% event notification. The list price of the CareLink network service including all components and software is £970 (excluding VAT) per patient.

NICE has also published a medtech innovation briefing on the LATITUDE NXT remote

monitoring system for people with a compatible Boston Scientific implantable cardiac device.

Product summary and likely place in therapy

- The CareLink network service allows a person's implanted Medtronic cardiac device to be remotely monitored by a health professional. Data collected from the device is transferred securely to their clinician for review. CareAlert notifications are also generated and sent to the clinician if a clinical event or a problem with the device or device leads is detected.

- The CareLink network service is an alternative to face-to-face follow-up, with the aim of reducing the number of hospital visits and earlier detection of adverse events.

Effectiveness and safety

- The evidence in this briefing is based on 7 prospective studies (total patients n=3,776; CareLink patients n=2,015). Six of the 7 studies were randomised.

- One randomised study showed no significant difference in a composite outcome of hospitalisation and emergency room visits, in unscheduled electrophysiology clinic visits, or quality of life compared with face-to-face follow-up.

- One randomised study reported a shorter delay from device-detected events to clinical decisions, and a reduction in hospital visits for people using CareLink compared with those having face-to-face follow-up.

- One randomised study reported earlier detection of potentially important actionable events when using CareLink compared with trans-telephonic monitoring.

- One randomised study showed that Carelink reduced time to clinical decisions in response to clinical events (predominantly atrial arrhythmias) compared with face-to-face follow-up.

- One randomised study reported fewer emergency visits and healthcare resource use by patients with heart failure using CareLink compared with those having face-to-face follow-up.

- One randomised study reported no significant difference in heart failure-related hospitalisations, implantable cardioverter defibrillator shocks, or mortality in people

using CareLink compared with those having face-to-face follow-up.

- One non-randomised study reported fewer false-negative detected events for CareLink than with other remote monitoring devices, 100% event notification and a 21% false-positive rate.

Technical and patient factors

- The Carelink system uses either the MyCareLink monitor or the MyCarelink Smart to collect data from Medtronic implantable cardiac devices.

- For people with implanted Medtronic devices with wireless functionality, data are transferred automatically for their clinician to access on the CareLink network service.

- People who have implanted Medtronic cardiac devices without wireless functionality need to hold a reader over their implantable device to send information manually. This process typically takes less than 3 minutes but may take up to 12 minutes. Data are sent to their clinician immediately after retrieval.

- Data from the MyCareLink system are transferred securely through the Vodafone worldwide data network or roaming partners. Data from MyCareLink Smart are sent using the connectivity of the person's smartphone or tablet (iOS or Android) to the CareLink Network service. Clinicians access the data through a secure website.

Cost and resource use

The list price for the CareLink network service is £970 (excluding VAT), which includes administration for hospital CareLink network service set-up, 6 monthly CareLink hospital website upgrades, patient and clinician training and technical support, software updates, shipment, hardware, and hosting and secure server space.

Introduction

More than 2 million people experience arrhythmia each year in the UK. Atrial fibrillation, supraventricular tachycardia, bradycardia, heart block and ventricular fibrillation are the main types of arrhythmia (NHS Choices 2015). Ventricular arrhythmias caused about 75–80% of the 70,000 sudden cardiac deaths in England and Wales in 2010 (NICE technology appraisal on implantable cardioverter defibrillators and cardiac

resynchronisation therapy). In addition, around 900,000 people in the UK have heart failure, commonly caused by coronary artery disease and previous heart attack (NICE guideline on chronic heart failure in adults). Both arrhythmia and heart failure can significantly affect a person's quality of life as well as putting them at risk of sudden cardiac death or stroke.

The first-line treatment for arrhythmia and heart failure focuses on pharmacological therapy but when this is no longer effective or can no longer be used, one of the following implantable cardiac devices may be used:

- Pacemaker: monitors the heart's rhythm and sends small electrical pulses to restore normal rhythm if needed.

- Implantable cardioverter defibrillator: like a pacemaker, but can send larger electrical shocks for more serious heart rhythm problems that pacemakers cannot correct.

- Cardiac resynchronisation therapy with pacing device: improves the heart's pumping efficiency.

- Cardiac resynchronisation therapy with a defibrillator device: combines cardiac resynchronisation with pacing and implantable cardioverter defibrillator.

- Implantable loop recorder: records the heart's rhythm to provide information to help guide clinical decision-making.

People with implantable electronic cardiovascular devices need regular monitoring of their condition and the device. This is to ensure that the device is working correctly with the correct settings and to check battery life when applicable. Monitoring is usually done in face-to-face follow-up visits in a hospital outpatient setting at intervals scheduled by the person's clinician. Remote monitoring technology offers an alternative, enabling clinicians to monitor a person's device without them having to go to hospital, which could reduce outpatient visits, and may help with faster identification of abnormalities, if they arise.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

Medtronic was awarded an active implantable medical device CE mark for the CareLink network service in 2012. The CE mark covers various models of the CareLink monitor, and includes the MyCareLink patient monitoring system, MyCareLink Smart patient reader and device data management application software.

Description

The CareLink network service allows Medtronic implantable cardiac devices to be remotely monitored through a network that is accessible to a clinician at all times. Data is collected from a person's implanted cardiac device and stored on the Medtronic CareLink Clinician website. This website provides secure internet access to data received from implantable pacemakers, implantable cardioverter defibrillators, cardiac resynchronisation therapy with pacing devices, cardiac resynchronisation therapy with defibrillator devices, and implantable loop recorders. Clinicians can also receive CareAlert notifications, which are generated in response to clinical events, to quickly identify potential device problems before they become more serious. The CareLink network service may reduce the need for the person to attend face-to-face follow-up appointments with their clinician.

The service can be used with the MyCareLink or MyCareLink Smart patient monitors:

- The MyCareLink patient monitor can be used with implanted devices with or without wireless functionality. It collects data from the implanted device and transfers it to the CareLink network. The monitor is made up of the following components:

  — monitor base with monitor screen, cursor and accept buttons

  — removable reader.

- The MyCareLink Smart patient monitor is used with devices without wireless functionality. It uses a person's smartphone or tablet to collect and transmit device data. A hand-held smart reader is used to collect data from the implanted device. The smart reader communicates with the person's smartphone or tablet, via bluetooth and through a software application (available for iOS and Android), to transfer the data to the CareLink network.

Data collection using the CareLink network service depends on the type of Medtronic device that has been implanted. Some devices can transfer data wirelessly to the secure website at intervals scheduled by the person's clinician, and need little user interaction with the monitor. Wireless transmission from the device usually happens at night, which is why the monitor should be placed 0 to 3 metres from the person's bed. People can also start data transfer when they have symptomatic episodes.

For implantable cardiac devices without wireless transmission functionality, a reader is used. The person holds the reader over their implanted device, either against clothing or bare skin. The process typically takes less than 3 minutes but can take up to 12 minutes. The monitor, smartphone or tablet screen shows a green progress bar to indicate that the data is being read. Once all the device data has been read, the monitor, smartphone or tablet emits 2 short tones with an on-screen prompt to signal that data collection is complete.

The collected data is immediately sent to the CareLink network over Vodafone's worldwide data network (MyCareLink monitor) or via the person's smartphone or tablet mobile operator or wifi connectivity (MyCareLink Smart monitor). A green progress bar will indicate that the data is being transmitted followed by a green 'tick' if the transmission is successful.

Setting and intended use

The MyCareLink monitor or MyCarelink Smart collect and send data from a person's implanted Medtronic cardiac device to the CareLink network for clinicians to access. The CareLink network service is usually used in the person's home for remote management and monitoring of their implanted Medtronic cardiac device. The MyCareLink monitor needs to be plugged into an electricity supply to send and receive data and it can be used in another location if needed (such as, a hotel room when on holiday). The MyCareLink monitor also transfers CareAlert notifications to the person's clinician to give an early warning of a clinical event.

Current NHS options

Current NHS options for post-implantation follow-up of implantable cardiac devices include face-to-face outpatient device evaluations, remote management and remote monitoring.

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to the CareLink network service:

- Latitude (Boston Scientific). NICE has also published a medtech innovation briefing on the Latitude NXT system for remote monitoring of implanted cardiac devices.

- Merlin@home (St Jude Medical).

- BIOTRONIK Home Monitoring (Biotronik).

The CareLink network service is currently used by 163 NHS hospitals across the UK and Northern Ireland.

Costs and use of the technology

The price of the CareLink network service is subject to the EU Tender process through the Official Journal of the European Union. There is also a National Framework Agreement through the NHS Supply Chain (SC) as well as other collaborative tenders via procurement hubs. If a trust uses the NHS SC Agreement, they place an order for CareLink with the NHS SC and Medtronic ships the CareLink network service directly to the trust. For other collaborative tenders, the collaborative sets up the contract and pricing, but the trust places the order directly with Medtronic, and CareLink is shipped directly to the trust. In addition, some trusts have individual tendering processes. These decisions are made at a trust level in line with their local and regional policy for procurement in general.

The list price, excluding VAT, for the CareLink network service is £970 per patient. This includes:

- administration for hospital CareLink network service set-up

- access to secure server space for data hosting of any recent active patient data using CareLink

- unlimited healthcare professional users per hospital

- access to Vodafone worldwide data network and their roaming partners

- scheduled transmissions

- alert transmissions

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- patient-initiated transmissions

- MyCareLink hardware (MyCareLink monitor or MyCareLink Smart monitor smartphone or tablet solution for Android and iOS)

- hardware shipment and distribution

- direct technical service telephone support for patients and healthcare professionals

- 6-monthly CareLink hospital website upgrades

- 3-monthly CareLink monitor software upgrades

- training of healthcare professionals and patient groups

- online access for healthcare professionals to the Medtronic Academy for training on website updates

- access to the MyCareLink Connect patient website for personalised follow-up information, education and shared care with family and carers.

Likely place in therapy

People usually attend an outpatient department 4 to 6 weeks after a cardiac device has been implanted, so that the device can be checked. If this post-implantation follow-up shows that it is working correctly, the person will need to attend routine appointments with a cardiologist or cardiac physiologist. These visits are scheduled at 3- to 12-month intervals.

The CareLink network service is used to remotely manage and monitor a person's implanted Medtronic cardiac device. It is used to reduce routine out-patient appointments with a cardiologist or cardiac physiologist, because data are collected from the person's device at home and sent to their clinician. The person's clinician can then review the data using a secure website. If the data suggest a problem or if a CareAlert notification is sent to the person's clinician, an out-patient appointment can be scheduled if needed.

Specialist commentator comments

Implanted cardiac devices have an inbuilt alarm system that is triggered when a fault develops. One specialist commentator explained that patients can often miss the alarm

because they mistakenly identify the sound as a digital watch or a clock alarm. This commentator explained that the CareLink network service is useful because it also sends an alert email to the patient's clinician if there is a device fault. Two other specialist commentators also noted that the CareLink network service is useful for monitoring implantable cardioverter defibrillator battery life and problems with leads as they develop; one of the commentators also stated that CareLink can be used in planning implantable cardiac device replacements.

Three specialist commentators noted that CareLink network service can be used with implantable loop recorders to monitor symptomatic and non-symptomatic arrhythmias, blackouts, or intermittent palpitations. Two of these specialist commentators highlighted that patients do not need to attend a face-to-face appointment to download and clear the data, which is a more convenient way of capturing events on their loop recorders.

Two specialist commentators commented on using the CareLink system as an alternative to routine face-to-face appointments. One of these specialist commentators noted that the CareLink network service allows people using an implanted cardiac device, who are expected to have little or no change in their health condition, to have routine follow-up checks in their own home. In the specialist commentator's NHS trust, many patients live in rural areas with poor transport links and so benefit from remote monitoring. In this trust, devices are routinely checked twice a year with one check being remote and one a face-to-face assessment. The other specialist commentator noted that remote monitoring can safely reduce the number of routine clinic visits because the objective of these visits is to monitor device function. One of the specialist commentators noted that remote checks using the CareLink network service are technical follow-ups and may not include clinical questioning or drug reviews, and no physical assessment can be carried out.

One specialist commentator noted that the CareLink network service offers reassurance to patients with implantable cardioverter defibrillators.

One specialist commentator noted that the alert system is well-used in their hospital trust. They added that the alert system helps to identify ventricular arrhythmia and atrial arrhythmias, particularly atrial fibrillation, atrial flutter and atrial tachycardia.

One specialist commentator noted that the CareLink network service is useful in some patients for pre-empting implantable cardioverter defibrillator shocks, by allowing the need for early intervention with changes to medication or VT ablation. They added that the service can then be used to monitor the efficacy of treatment after discharge by

monitoring arrhythmia frequency and duration.

Two specialist commentators highlighted that the CareLink network service offers another level of reassurance to patients with implantable cardioverter defibrillators because the CareLink network service monitors devices outside of scheduled face-to-face follow-up visits.

One specialist commentator stated that remote monitoring does allow earlier identification of atrial arrhythmias and this may translate into earlier intervention. The commentator argued that this benefit is largely in patients not already on anticoagulation therapy or those with no history of atrial fibrillation.

One specialist commentator stated that the tariffs for remote follow-ups and face-to-face follow-ups are similar for hospital reimbursement.

Equality considerations

NICE is committed to promoting equality, and eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women

- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Implantable cardiac devices may be used in people of any age, but are more commonly used in those over 60 years. Age is a protected characteristic under the Equality Act 2010.

Patient and carer perspective

The Arrhythmia Alliance, a not-for-profit coalition of charities, patient groups, patients, carers, medical groups and allied professionals, was asked to comment on the CareLink network service. The organisation surveyed and carried out one-to-one interviews with

over 100 CareLink network service users and their carers. All users and their carers gave positive feedback.

Some CareLink network service users felt that it provides them with reassurance and allows them to live a normal life, because they know that their cardiac nurse will contact them if CareLink detects that something is wrong. They added that if they are worried, they can contact their cardiac nurse who can review the downloaded data to find out if there are any problems.

The Arrythmia Alliance believes that arrhythmia services have improved in and out of hospital since the introduction of the CareLink network service and that the data collected by it over time could be used to further improve outcomes for people with cardiac arrhythmias. The Arrythmia Alliance also states that the CareLink network service enables patients to be at the centre of their healthcare and self-manage their condition.

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website revealed no manufacturer Field Safety Notices or Medical Device Alerts for this device.

A search of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE) between January 2006 and January 2016 found 461 medical device reports relating to 'Medtronic CareLink', most of which appear to be related to a similarly named device that is not part of the CareLink network service. No patients were harmed by the device problems.

It should be noted that the MAUDE database is a passive surveillance system and potentially includes incomplete, inaccurate, untimely, unverified or biased data. The incidence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use (FDA, 2015).

Clinical evidence

Table 1 Summary of primary results from selected studies

Study	Study details	Results	Summary of findings
Al-Khatib et al. (2010) Prospective, randomised study Single centre (USA)	Remote monitoring (CareLink; n=76) at 3-month intervals for 12 months with a telephone call at 6 months and a face-to-face follow-up visit at 12 months. Control (n=75) patients attended face-to-face follow-ups at 3-month intervals for 12 months, unless there was a device-related issue. Median age (years): 63 CareLink; 63 control.	Rate of composite hospitalisations, emergency room visits and unscheduled visits to the EP clinic: CareLink 32%; control 34% (p=0.77). Number of hospitalisations: CareLink 23%; control 24% (p=0.88). Number of emergency room visits for cardiac cause: CareLink 7%; control 5% (p=0.74). Number of unscheduled visits to the EP clinic : CareLink 7%; control 7% (p=0.98).	There was no significant difference in the composite of cardiovascular hospitalisations, emergency room visits for a cardiac cause, and unscheduled visits to the EP clinic for device-related issues at 1 year. QoL and patient satisfaction were significantly better in the control arm than in the remote arm at 6 months but not at 12 months.

Study	Study details	Results	Summary of findings
Boriani et al. (2013). Prospective, RCT Multicentre, 32 centres from 6 countries (France, Hungary, Israel, Italy, Spain and Switzerland)	Remote monitoring (CareLink; n=76) at 4 and 12 months with activation of automatic alerts. Face-to-face follow-ups were scheduled at baseline and at 8 months. Control (n=72) patients attended face-to-face follow-ups at baseline and every 4 months for 12 months. Audible alerts for device integrity issues and VF detection were enabled for both groups. Mean age (years): 68 (CareLink); 67 (control).	Median delay between alert triggering to event review (days; 25th to 75th percentile): CareLink 3 (1 to 10); control 37 (14 to 71; p<0.001)	The median delay from device-detected events to clinical decisions was considerably and significantly shorter in the CareLink group compared with the control group. In-hospital visits were significantly reduced in the CareLink group. The annual rate of all-cause hospitalisations per patient did not differ between the 2 groups.

Study	Study details	Results	Summary of findings
Crossley et al. (2009) Prospective, randomised, parallel, unblinded, open-label clinical trial Multicentre, 50 centres (USA)	Remote monitoring (CareLink; n=602) at 3, 6 and 9 months and 1 face-to-face follow-up visit at 12 months. Control (n=295) patients had transtelephonic monitoring at 2, 4, 8 and 10 months and 1 face-to-face follow-up visit at 12 months. Patients with dual-chamber pacemakers had a face-to-face follow-up visit at 6 months. Mean age (years): 68 (CareLink); 69 (control).	Median time to first CAE (months): CareLink 4.9; control 6.3 ($p<0.0001$).	Remote pacemaker interrogation follow-up using the CareLink network service detected CAEs that were potentially important more quickly and more frequently than transtelephonic rhythm strip recordings.

Study	Study details	Results	Summary of findings
Crossley et al. (2011) Prospective and randomised Multicentre, 136 centres (USA)	Remote monitoring (CareLink; n=1014) at 3, 6, 9 and 12 months with face-to-face follow-ups at 1 and 15 months post-implantation. Control (n=983) patients had face-to-face follow-ups at 3, 6, 9 and 12 months. All audible patient alerts were disabled, except for those associated with lead and device integrity. Mean age (years): 65.2 (CareLink); 64.9 (control).	Median time from an event to clinical decision (days): CareLink 4.6; control 22 (p<0.001).	Wireless remote monitoring with automatic clinician alerts compared with standard face-to-face follow-up significantly reduced the time to a clinical decision in response to clinical events. Wireless monitoring was associated with a significant reduction in mean length of CV-related hospital stay.

Study	Study details	Results	Summary of findings
de Ruvo et al. (2015) Prospective, non-randomised study Single centre (Italy)	Remote monitoring with 4 different devices (n=211) with office face-to-face follow-ups at 1 and 12 months after implantation: CareLink (n=65); BIOTRONIK Home Monitoring (BHM; n=61); Boston Latitude (LAT; 49); St. Jude Merlin (SJM; 36). Mean age (years): 70 (CareLink); 70 (BHM); 66 (LAT); 67 (SJM).	Event notification through remote monitoring: CareLink 46/46; BHM 62/69; LAT 33/34; SJM 38/40. False positive remote monitoring detected events: CareLink 11; BHM 1; LAT 4; SJM 0. False negative remote monitoring-detected events: CareLink 0; BHM 7; LAT 1; SJM 2 ($p \leq 0.008$ after Bonferroni correction). Actionable events detected by remote monitoring: CareLink 12/14; BHM 31/34; LAT 20/24; SJM 6/8.	Although all remote monitoring systems effectively detected major events, daily transmission (using BHM) was independently associated with an increased probability of event detection compared with periodic transmission systems. The CareLink network service had fewer false negatives when compared with other home monitoring devices and had 100% event notification.

Study	Study details	Results	Summary of findings
Landolina et al. (2012) Prospective, randomised, open, study Multicentre, 6 centres (Italy)	Remote monitoring (CareLink; n=99) with audible alerts disabled, at 4 and 12 months with face-to-face follow-ups at 8 and 16 months. Control (n=101) patients had standard management consisting of scheduled visits at 4, 8, 12 and 16 months and patient response to audible alerts. Mean age (years): 66 (CareLink), 69 (control).	All emergency department and urgent face-to-face follow-ups: CareLink 75 (0.59 events per year); control 117 (0.93 events per year; IRR 0.65 95% CI 0.49 to 0.88; p=0.005).	Remote monitoring reduced emergency department or urgent face-to-face follow-up and, in general, total healthcare use by patients with HF with modern ICD/CRT-Ds. Compared with standard follow-up through face-to-face follow-up and audible ICD alerts, remote monitoring resulted in increased efficiency for healthcare providers and improved quality of care for patients.

Study	Study details	Results	Summary of findings
Luthje et al. (2015) Prospective, pilot randomised study Single centre (Germany)	Remote monitoring (CareLink; n=87) with OptiVol audible alerts turned off. Control (n=89) patients had face-to-face follow-up every 3 months with OptiVol audible alerts turned off. Mean age (years): CareLink 66; control 65.9.	Patients hospitalised for worsened HF during follow-up: CareLink 20; control 22. Mean number of emergency department visits: CareLink 0.10±0.25; control 0.10±0.23. Mean number of urgent care visits: CareLink 0.30±0.50; control 0.10±0.30 (p=0.0332) Total number of patients having ICD shocks: CareLink 15%; control 11%.	CareLink with fluid monitoring had no significant effect on HF-related hospitalisations, ICD shocks or mortality.

Abbreviations: CAE, clinically actionable event; CV, cardiovascular; CI, confidence interval; EP, electrophysiology; HF, heart failure; ICD, implantable cardioverter defibrillator; CRT-D, cardiac resynchronisation therapy with a defibrillator; IRR, incident rate ratio; RCT, randomised controlled trial; QoL, quality of life; VF, ventricular fibrillation.

Recent and ongoing studies

REM-HF is a multicentre randomised controlled trial (RCT) comparing routine downloads with weekly downloads from 3 remote monitoring systems: CareLink (Medtronic),

Merlin@home (St Jude's Medical) and Latitude (Boston Scientific). The study protocol has been published (Morgan et al. 2014) and recruitment has been completed; results are expected in the near future.

Costs and resource consequences

A cost-utility analysis based on the EVOLVO study (Landolina et al. 2012) has been carried out (Zanaboni et al. 2013). The EVOLVO study was a multicentre RCT in Italy, which compared a remote monitoring arm (CareLink network service) with a standard arm (face-to-face follow-up). The mean annual costs were €1,962.78 (£1,485.82) for patients on the home-monitoring arm and €2,130.01 (£1,612.42) for those on the standard arm. Although the home-monitoring arm showed a slight cost-saving, this was not significant (p=0.8). The authors did report a significant difference in the annual cost to the patients and family. The mean annual costs to patients were €291.36 (£220.56) for the home-monitoring arm and €381.34 (£288.67) for the standard arm (p=0.01). A cost-utility analysis on 180 of the patients showed a significant 0.065 quality-adjusted life-year increase (p=0.03) and a non-significant cost-saving of €888.10 (£672.29) per patient (p=0.33) in the home-monitoring arm over 16 months. Although this study was carried out in Italy, the results may be applicable to UK. Euro values have been estimated in pounds using an exchange rate of 1 EUR=0.757 GBP.

The following 2014/15 National Tariff Payment System costs for NHS (2013) cardiology outpatient attendances have been listed for information:

- first attendance, single professional: £164

- first attendance, multi-professional: £189

- follow-up attendance, single professional: £92

- follow-up attendance, multi-professional: £131.

Current reimbursement across the NHS for remote follow-up varies according to local arrangements.

Strengths and limitations of the evidence

The 7 included studies varied in quality but generally were of a reasonable standard. All included studies were prospective; 6 were randomised and compared CareLink monitoring

with a control. In general, patients in the control groups did not have remote monitoring and instead attended face-to-face follow-up. One study (de Ruvo et al. 2015) compared CareLink with other home monitoring devices. Four studies (Al-Khatib et al. 2010; Boriani et al. 2013; de Ruvo et al. 2015; Luthje et al. 2015) had low patient numbers. The remaining studies included a reasonable number of patients. Patient follow-ups were relatively short and in most studies were around 12 months. Two studies (Crossley et al. 2011; Luthje et al. 2015) had follow-ups at 15 months and 1 study (Landolina et al. 2012) had a 16-month follow-up. Although these 3 studies had longer follow-up periods, the follow-ups were short compared with functioning times for implantable cardioverter defibrillators or cardiac resynchronisation therapy devices, which can be between 6 to 10 years (NHS Choices).

Three studies (Al-Khatib et al. 2010; de Ruvo et al. 2015; Luthje et al. 2015) were carried out in a single centre, which could decrease selection bias because all patients were randomised to groups unlike some multicentre studies. For example, the study by Boriani et al. (2013) included patients from 32 centres across 6 countries. The large number of study sites coupled with the relatively low patient numbers could lead to participant selection bias, because low numbers of patients were recruited from each study site. However the results from multicentre studies (Boriani et al. 2013; Crossley et al. 2009; Crossley et al. 2011; Landolina et al. 2012) may be more generalisable to clinical practice than those from single-centre studies because data were collected at multiple sites and settings.

None of the included studies were carried out in the UK. Three studies (Al-Khatib et al. 2010; Crossley et al. 2009; Crossley et al. 2011) were done in the USA, so the results may not apply to UK practice. The remaining studies were carried out in Europe, except for Boriani et al. (2013) which included 1 centre in Israel. The results of these European-based studies may be more applicable to the UK.

Funding for 4 studies came from Medtronic (Boriani et al. 2013; Crossley et al. 2009; Crossley et al. 2011; Luthje et al. 2015). One or more authors in 2 studies (Al-Khatib et al. 2010; Luthje et al. 2015) were also previously funded by Medtronic and 1 or more authors in 3 studies (Boriani et al. 2013; Crossley et al. 2009; Landolina et al. 2012) were employed by Medtronic. The study by de Ruvo et al. (2015) had no funding from or affiliations with manufacturers.

Two papers (Crossley et al. 2009; Crossley et al. 2011) did not collect data on key outcomes, such as stroke or heart failure. Data on mortality were presented by Crossley et al. (2011). The paper by Crossley et al. (2011) did not include patients with atrial fibrillation

or patients having warfarin (anticoagulation therapy). The results observed in this study may not be seen in the 'real-world' where atrial fibrillation and anticoagulation therapy are both widespread.

The study by Landolina et al. (2012) did not describe what interventions, if any, were made by the clinicians to reduce emergency visits and did not show reduced hospitalisations as a result of using the device. Also, the reduction of emergency department or urgent office visits was balanced by increased additional visits as a result of alerts.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

- Atrial fibrillation: management (2014) NICE guideline CG180. Date for review: September 2016

- Transient loss of consciousness ('blackouts') in over 16s (2014) NICE guideline CG109. Date for review: October 2019

- Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block (2014) NICE technology appraisal guidance 324. Date for review: November 2017

- Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (2014) NICE technology appraisal guidance 314. Date for review: May 2017

- Chronic heart failure in adults: management (2010) NICE guideline CG108. Date for review: March 2018

- Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block (2005) NICE technology appraisal guidance 88. Date for review: to be confirmed; partially updated in NICE technology appraisal guidance 324

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Appendix

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Data tables

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Table 2 Overview of the Al-Khatib et al. (2010) study

Study component	Description
Objectives/ hypotheses	To determine if remote monitoring (using CareLink) of ICDs with or without CRT compared with quarterly in-clinic device interrogations improves patient outcomes and satisfaction with their ICD care.
Study design	Prospective, single-centre, randomised study.
Setting	Device clinics at a single US medical centre. Patients were enrolled between December 2006 and November 2007.

Study component	Description
Intervention and comparator	Patients were randomly assigned in equal proportions to have either quarterly in-clinic ICD interrogations, classified as standard of care, or remote monitoring of ICDs using the CareLink transmission monitor. Data on QoL (measured with the EQ-5D), patient satisfaction with ICD care, cardiac problems, ICD-related issues, and medications was collected at baseline, 6 months (by telephone for the intervention group) and 12 months after enrolment. **Intervention** Patients were advised to keep a log of dates and reasons for hospital admissions, and emergency room and EP clinic visits. They were asked to use the remote monitoring system every 3 months, and they were seen in the device clinic at 12 months and at any time for device-related issues. Device programming was at the discretion of the treating physician. None of the heart failure capabilities of the devices (for example, impedance, heart rate variability) were used in managing patients' conditions. **Control** Patients randomised to the control arm were seen in the ICD clinic every 3 months and at any time that their ICD physician decided to see them for a device-related issue.
Inclusion/ exclusion criteria	**Inclusion** Patients were eligible if they were 18 years and over, had an ICD with or without CRT for an approved indication, were planning to have their device followed-up at the medical centre, had a landline telephone, and were able to provide informed consent. **Exclusion** None stated.
Primary outcomes	Primary end point was a composite of cardiovascular hospitalisation, emergency room visits for a cardiac cause, and unscheduled visits to the EP clinic for device-related issues at 1 year. Secondary end points included use of evidence-based medications, health-related QoL, cost, cost-effectiveness, and patient satisfaction with ICD care.

Study component	Description
Statistical methods	Wilcoxon rank sum test to compare continuous variables and Chi-square test to compare categorical variables. Cumulative event rates were calculated using Kaplan–Meier and outcomes in the 2 arms of the study were compared using the log-rank test and intention-to-treat principle.
Patients included	n=151 (76 CareLink; 75 control) 73% male (CareLink); 72% male (control) Median age (years): 63 (CareLink); 63 (control) One patient was lost to follow-up and 4 withdrew (1 for lack of transport to clinic, 1 for a language barrier, and 2 moved to a nursing home), 7 patients died. 69 patients completed monitoring in the remote arm, and 70 in the standard care arm.
Results	There was no significant difference in the composite of cardiovascular hospitalisation, emergency room visits for a cardiac cause, and unscheduled visits to the EP clinic for device-related issues at 1 year (32% in the remote arm compared with 34% in the control arm; p=0.8), mortality, or cost between the 2 arms. QoL and patient satisfaction were significantly better in the control arm than in the remote arm at 6 months: 83 compared with 75 (p=0.002) and 88 compared with 75 (p=0.03) respectively, but not at 12 months.
Conclusions	There were no significant differences in cardiac-related resource utilisation at 1 year. But, given the small number of patients in this study, the real clinical and health economics impact of remote monitoring needs to be verified by a large, multicentre, randomised controlled trial.
Abbreviations: CRT, cardiac resynchronisation therapy; EP, electrophysiology; ICD, implantable cardioverter defibrillator; QoL, quality of life.	

Table 3 Summary of results from the Al-Khatib et al. (2010) study

	CareLink remote monitoring (n=76)	Face-to-face follow-up (n=75)	Analysis
Primary outcomes			

	CareLink remote monitoring (n=76)	Face-to-face follow-up (n=75)	Analysis
Rate of composite hospitalisations, cardiac-related emergency room visits and device-related unscheduled visits to the EP clinic	32%	34%	p=0.77
Number of hospitalisations	23%	24%	p=0.88 Most (66%) were for decompensated heart failure; 4 were for ICD shocks; 3 for right ventricular lead fracture; and 1 for generator replacement.
Number of cardiac-related emergency room visits	7%	5%	p=0.74
Number of device-related unscheduled visits to the EP clinic for issues	7%	7%	p=0.98
Selected secondary outcomes			
Rate of atrial fibrillation and flutter detected by the ICD during follow-up	45%	26%	p=0.01 No significant differences in these events at baseline.

	CareLink remote monitoring (n=76)	Face-to-face follow-up (n=75)	Analysis
Health-related quality of life (using EuroQoL thermometer)	75 (at 6 months) 80 (at 12 months)	83 (at 6 months) 80 (at 12 months)	p=0.002 p=0.47 None of the baseline QoL measures were significantly different between the 2 arms. There were no significant differences in the EuroQoL score at 6 or 12 months.
Patient satisfaction with ICD care	75 (at 6 months) 88 (at 12 months)	88 (at 6 months) 88 (at 12 months)	p=0.03 p=0.09 Patient satisfaction with their ICD care at baseline was similar between the 2 arms.
Cost-minimisation analysis	Patients' devices were interrogated remotely 3 times, each costing $102.79 (total $308.37) and once in clinic costing $66.36 or $89.92 (if the need for ICD programming is included). Total costs $374.73–$398.29.	Patients had 4 clinic visits each costing $66.36 or $89.92 (if the need for ICD programming is included). Total costs $265.44–$359.68.	The remote monitoring strategy was more expensive than current standard care (difference $38.61–$109.29). Given the age of this population (mean 63 years), the analysis did not include costs for lost time from work for patients' visits to the clinic. Travel-related expenses could further decrease the difference between the 2 arms.
Deaths	4 (5%)	3 (4%)	p=0.99 Cause of death was non-cardiac in 5 patients and unknown in 2. There were no device infections.

	CareLink remote monitoring (n=76)	Face-to-face follow-up (n=75)	Analysis
Abbreviations: EP, electrophysiology clinic; ICD, implantable cardioverter defibrillator; QoL, quality of life.			

Table 4 Overview of the Boriani et al. (2013) study

Study component	Description
Objectives/ hypotheses	To evaluate if remote monitoring can reduce time from device-detected events to clinical decisions.
Study design	Multicentre, randomised controlled trial.
Setting	32 centres from 6 countries (France, Hungary, Israel, Italy, Spain and Switzerland). Patients enrolled between May 2009 and April 2010 with a median follow-up of 12 months.
Intervention and comparator	Intervention: RM strategy using CareLink network service. Patients had face-to-face follow-ups at baseline and at 8 months, with remote follow-ups at 4 and 12 months, and activation of automatic alerts. Control: Standard management by scheduled face-to-face follow-ups at baseline and at every 4 months. Audible alerts for device integrity issues or for inactivated VF detection or therapy were activated in both groups.

Study component	Description
Inclusion/ exclusion criteria	**Inclusion** Patients in sinus rhythm with first implantation of CRT-D for systolic heart failure. Left ventricular systolic dysfunction (LVEF ≤35%), NYHA functional class III–IV. **Exclusion** Exclusion criteria were reported in Burri et al. (2010) as part of a trial design paper. Patients were excluded if they were not able to fully understand the instructions on remote monitoring using CareLink, had permanent AT/AF, had a CRT/CRT-D device implanted before, had medical conditions that would limit study participation, were <18 years, were enrolled in or intended to participate in another clinical trial that may have an impact on the study end points, met any exclusion criteria required by local law, were unable or refused to sign a patient informed consent form, had a life expectancy of <1 year in the opinion of the physician, and if they were pregnant or breastfeeding.
Primary outcomes	The delay between event onset to clinical action relating to that event. Secondary outcomes included: time from a clinical decision for any relevant event to the resolution of that event, QoL, in-hospital visits, automatic alert transmission and annual rate of all-cause hospitalisations.
Statistical methods	Continuous Gaussian variables were compared by the Student's t test for independent samples, whereas skewed distributions were compared using the Mann–Whitney nonparametric test. Differences in proportions were compared by applying Chi-square analysis. Rates of events were computed per 100 person years, as number of occurred events out of patient exposure time and reported separately for each arm. The exposure time was computed from the date of randomisation to the date of the last available information for each patient, either dropped out or died. Rates were compared using the Comparison Incidence Rates (Large Sample) Test. An alpha-level of 0.5 was used.
Patients included	n=148 (76 RM and 72 control). Average age 68 years (RM), 67 years (control). 75% male (RM), 72.4% male (control).

Study component	Description
Results	The median delay from device-detected events to clinical decisions was considerably shorter in the RM group compared with the control group: 2 (25th–75th percentile, 1–4) days compared with 29 (25th–75th percentile, 3–51) days respectively, p=0.004. In-hospital visits were reduced in the remote group (2.0 visits/patient/year compared with 3.2 visits/patient/year in the control group, 37.5% relative reduction, p<0.001). Automatic alerts were successfully transmitted in 93% of events happening outside the hospital in the RM group. The annual rate of all-cause hospitalisations per patient did not differ between the two groups (p=0.65).
Conclusions	RM in CRT-D patients with advanced heart failure allows physicians to promptly react to clinically relevant automatic alerts and significantly reduces the burden of in-hospital visits.
Abbreviations: AF, atrial fibrillation; CRT-D, cardiac resynchronisation therapy defibrillators; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; QoL, quality of life; RM, remote monitoring; VF, ventricular fibrillation.	

Table 5 Summary of results from the Boriani et al. (2013) study

	CareLink remote monitoring (76)	Face to face (n=72)	Analysis
Primary outcome			
Delay between event onset to clinical action	Alerts (n): 166 Median delay (25th–75th percentile) between alert triggering to event review (days): 3 (1–10)	Events matching alert criteria (n): 114 Median delay (25th–75th percentile) between alert triggering to event review (days): 37 (14–71)	p<0.001
Selected secondary outcomes			

	CareLink remote monitoring (76)	Face to face (n=72)	Analysis
Time from actionable device-detected event to clinical decisions	Device detected events: 37 Median time from event onset to related clinical decisions (days): 2 Device-detected events: 19 Median time from event onset to related clinical decisions (days): 29		p=0.004
In-hospital visits (scheduled, unscheduled and emergency visits)	144 (2 visits/year)	225 (3.2 visits/year)	p<0.001
Hospital admissions	19	22	p=0.65
QoL	Baseline score (25th–75th percentile): 41 (16 to 62) Change in score from baseline to 8-month follow-up (25th to 75th percentile): –17 (–32 to –2)	Baseline score (25th–75th percentile): 40 (18 to 53) Change in score from baseline to 8-month follow-up (25th–75th percentile): –10 (–23 to 0)	p=0.38 p=0.45
Change in clinical status from enrolment to 12-month follow-up	54% improved, 35%unchanged and 11% worsened	48% improved, 38% unchanged and 14% worsened	p=0.69
Deaths	n=5	n=2	
Successful alert transmission	144/155 (93%) of events (excluding alert transmissions that failed due to hospital admission)	NA	

	CareLink remote monitoring (76)	Face to face (n=72)	Analysis
Device-detected events	Patients who had at least 1 event satisfying the criteria for triggering a device alert: 57 (75%) Observed rate of OptiVol (events/year): 1.6 Rate of AT/AF burden and fast ventricular rate during AF episodes (events/year): 0.7	Patients who had at least 1 event satisfying the criteria for triggering a device alert: 48 (67%) Observed rate of OptiVol events/year: 1.5 Rate of AT/AF burden and fast ventricular rate during AF episodes (events/year): 0.2	p=0.28 p=0.59 p<0.001
Abbreviations: AF, atrial fibrillation; AT, atrial tachyarrhythmia; NA, not applicable; QoL, quality of life.			

Table 6 Overview of the Crossley et al. (2009) study

Study component	Description
Objectives/ hypotheses	To evaluate remote pacemaker interrogation for the earlier diagnosis of clinically actionable events compared with traditional transtelephonic monitoring and routine in-person evaluation.
Study design	Prospective, randomised, parallel, unblinded, multicentre, open-label clinical trial.
Setting	Study enrolment was from May 2004 to March 2007, in 50 US centres.

Study component	Description
Intervention and comparator	Patients were randomized in a 2:1 manner to the RM arm or the control arm using permuted block randomisation. **Intervention** Patient data in the RM arm were sent using the CareLink network service at 3, 6, and 9 months. **Comparator** The control arm patients did a TTM transmission at 2, 4, 8, and 10 months. At 6 months, patients with dual-chamber pacemakers were seen in person, and a TTM transmission was done by patients with single-chamber pacemakers. All patients: Pacemaker programming was at the discretion of the responsible physician except for 3 parameters. The study ended with a face-to-face follow-up visit at 12 months. Unscheduled transmissions and in-person evaluations were included in the analysis.
Inclusion/ exclusion criteria	**Inclusion criteria** Patients had to have a pacemaker compatible with the Medtronic CareLink remote monitoring service and were enrolled after the implantable pulse generator system was deemed stable. Patients with both single- and dual-chamber pacemakers were enrolled, at least 30 days after system modification, including new device implant, device upgrade, or lead changes. Patient had to have access to an analogue phone line, and be able to operate the TTM monitor and the CareLink Monitor. **Exclusion criteria** Exclusion criteria were reported in Chen et al. (2008) as part of a trial design paper. Patients were excluded if they were enrolled in another pacemaker clinical study that might confound the results of this trial, and if they were being considered for an ICD.
Primary outcomes	Time-to-first diagnosis of a CAE (patients without a CAE were censored at the exit date due to death, lost to follow-up, or study closure). CAEs were defined as events that needed a clinical decision for possible change of medication or further medical assessment.

Study component	Description
Statistical methods	The Peto and Peto modification of the Gehan–Wilcoxon test was done. An intent-to-treat analysis was performed. Only events diagnosed by the clinician counted toward the primary objective. A p value <0.05 indicated that the freedom from first diagnosis of CAE was significantly different when patients were followed with remote interrogation (RM) compared with those being followed with TTM and having scheduled face-to-face follow-up (control).
Patients included	n=897 (RM 602; control 295) 52% male (RM); 48% control Mean age (years): RM 68; control 69 382 patients with at least 1 CAE (RM 271;111 control) included in primary analysis.
Results	The mean time to first diagnosis of CAEs was earlier in the RM arm (5.7 months) than in the control arm (7.7 months). Three (2%) of the 190 events in the control arm and 446 (66%) of 676 events in the RM arm were identified remotely.
Conclusions	Remote pacemaker interrogation follow-up using the Medtronic CareLink network service detects CAE events that are potentially important more quickly and more frequently than transtelephonic rhythm strip recordings.
Abbreviations: CAE, clinically actionable events; ICD, implantable cardioverter defibrillator; RM, remote monitoring; TTM, transtelephonic monitoring.	

Table 7 Summary of results from the Crossley et al. (2009) study

	CareLink) remote monitoring (n=602)	Transtelephonic monitoring (n=295)	Analysis
Efficacy	271 (45%) patients had ≥1 CAE	111 (38%) patients had ≥1 CAE	
Primary outcome			

	CareLink) remote monitoring (n=602)	Transtelephonic monitoring (n=295)	Analysis
Time to first CAE	Mean 5.7 months Median 4.9 months 446 (66%) of 676 CAEs were detected during remote 'follow-up'.	Mean 7.7 months Median 6.3 months 3 (2%) of 190 CAEs were detected during a TTM transmission, all others were found during face-to-face follow-up evaluations.	Average follow-up of 375±140 days. Significant difference in median time to first CAE between groups; p<0.0001.
Selected secondary outcomes			
Number of CAEs reported per patient	1.123	0.644	The most frequent CAE reported was non-sustained VT, followed by AT/AF episodes lasting 48 hours or more.
Safety	Not reported		
Serious adverse events	Not reported		
Abbreviations: AT/AF, atrial tachycardia/atrial fibrillation; CAE, clinically actionable events; TTM, transtelephonic monitoring; VT, ventricular tachycardia.			

Table 8 Overview of the Crossley et al. (2011) study

Study component	Description
Objectives/ hypotheses	To determine if wireless remote monitoring with automatic clinician alerts (CareLink) reduces the time from a clinical event to a clinical decision in response to arrhythmias, cardiovascular disease progression, and device issues compared with patients having standard face-to-face follow-up care. A secondary objective was to compare the rates of cardiovascular health care use in patients in the remote arm with those in the face-to-face follow-up arm.

Study component	Description
Study design	Multicentre, prospective, randomised evaluation.
Setting	Patients were enrolled from November 2006 to May 2008. The last follow-up visit was in August 2009. The study was done in 136 US centres.
Intervention and comparator	**CareLink programming** To limit the number of device transmissions sent in the remote arm, a conservative approach was used to select alert thresholds. Only values needing clinician attention and possible intervention were specified. Exactly 1 automatic clinician alert could be sent for any 1 clinical event between face-to-face follow-up device interrogations. Clinicians had access to the entire set of device-collected diagnostics for all study patients. **Intervention** Patients in the remote arm had a home monitor, and their face-to-face follow-ups at 3, 6, 9, and 12 months were replaced with remote visits, including a remote device transmission. All automatic clinician alerts were enabled for patients in the remote arm. Audible patient alerts were disabled except for those related to lead and device integrity. These patients also had face-to-face follow-ups at 1 and 15 months. **Control** Patients in the control had face-to-face follow-ups at 3, 6, 9 and 12 months. Only audible patient alerts associated with lead and device integrity were enabled.

Study component	Description
Inclusion/ exclusion criteria	Adult patients with an implanted Medtronic wireless ICD or CRT-D system using the CareLink Network. After successful insertion of an ICD or CRT-D, patients were randomly assigned in a 1:1 manner, stratified by device type, to wireless remote monitoring or face-to-face follow-up care. **Inclusion criteria** Being able and willing to replace regularly scheduled face-to-face follow-ups with remote follow-ups; and being able to attend all required follow-up visits. **Exclusion criteria** Patients were excluded for: permanent AF (constant AF for which there were no plans to try to restore sinus rhythm); chronic warfarin therapy; having had a previous ICD, CRT device, or pacemaker; under 18 years; and having a life expectancy <15 months.
Primary outcomes	The primary outcome, time to clinical decision, was defined as the time from device detection of a clinical event to a decision being made in response to the event, as reported by the clinician or as shown by device data obtained at interrogation. The key secondary objective was to compare cardiovascular HCU rates.
Statistical methods	A Wilcoxon rank-sum test was used to compare the median time from event onset to clinical decision between treatment arms. To allow for multiple HCU events per patient, an Andersen–Gill proportional hazards regression model was used to compare the hazard rates for each type of HCU event (hospitalisation, ED, unscheduled office or urgent visit) between arms.
Patients included	n=1997 (1014 remote; 983 face-to-face) 70.5% male (remote); 71.7% male (face-to-face) Mean age (years): 65.2 (remote); 64.9 (face-to-face). 1980 patients were included in analysis (1,005 remote; 975 face-to-face).

Study component	Description
Results	The median time from clinical event to clinical decision per patient was reduced from 22 days in the face-to-face arm to 4.6 days in the remote arm (p<0.001). The HCU data showed a decrease in mean length of stay per CV hospitalisation visit from 4.0 days in the face-to-face arm to 3.3 days in the remote arm (p=0.002).
Conclusions	Wireless remote monitoring with automatic clinician alerts compared with standard face-to-face follow-up significantly reduced the time to a clinical decision in response to clinical events and was associated with a significant reduction in mean length of CV-related hospital stay.
Abbreviations: AF, atrial fibrillation; CRT, cardiac resynchronisation therapy; CRT-D, cardiac resynchronisation therapy with defibrillation; CV, cardiovascular; ED, emergency department; HCU, health care utilisation; ICD, implantable cardioverter-defibrillators; LOS, length of stay; NA, not applicable.	

Table 9 Summary of results from the Crossley et al. (2011) study

	CareLink remote monitoring (n=1014)	Face-to-face standard care (n=983)	Analysis
Efficacy	172 (17%) patients had ≥1 CE	145 (15%) patients had ≥1 CE	
Primary outcome			
Median time from an event to clinical decision	4.6 days	22 days	Reduction of 17.4 days (79%) A sensitivity analysis including multiple events of the same type between an event onset and a device interrogation/visit also showed a significant reduction from the time an event occurs to a clinical decision (p<0.001).
Selected secondary outcomes			

	CareLink remote monitoring (n=1014)	Face-to-face standard care (n=983)	Analysis
Automatic clinician alert transmissions	329 of 575 clinical events were triggered by an automatic clinician alert.	NA	246 clinical events did not trigger an automatic clinician alert because the alert was programmed off (7%) or the alert was not reset after being previously triggered (93%). Automatic clinician alerts were triggered but not successfully transmitted for 149 (45%) clinical events, mainly because the home monitor was not set up to send out transmissions. Clinicians classified automatic clinician alerts (140 events) as: 'meaningful' (62%); 'timed appropriately' (84%); 'it could have waited longer' (12%); 'didn't want to know at all' (2%).
Mean LOS during CV hospitalisation	3.3 days	4 days	The mean LOS during a CV hospitalisation was significantly reduced (18%, p=0.002) in the remote arm.
Annualised rate of CV HCU visits per patient	Hospitalisation: 0.50 ED: 0.24 Unscheduled clinic visit: 2.24	Hospitalisation: 0.47 ED: 0.21 Unscheduled clinic visit: 1.95	Hospitalisation: p=0.524 ED: p=0.325 Unscheduled clinic visit: p=0.099
Mean LOS per hospitalisation for patients with a clinical event during follow-up	3.2 days	4.3 days	p=0.007

	CareLink remote monitoring (n=1014)	Face-to-face standard care (n=983)	Analysis
Mean LOS per hospitalisation for patients without a clinical event during follow-up	3.3 days	3.9 days	Not significantly different
Mortality			Not significantly different for patients with an ICD (p=0.31) or patients with a CRT-D (p= 0.46).
Abbreviations: AF, atrial fibrillation; CE, clinical event; CI, confidence interval; CRT-D, cardiac resynchronisation therapy with defibrillation; CV, cardiovascular; ED, emergency department; HCU, health care utilisation; ICD, implantable cardioverter-defibrillators; LOS, length of stay.			

Table 10 Overview of the de Ruvo et al. (2015) study

Study component	Description
Objectives/ hypotheses	To estimate and compare the event-free rate at 1 year in 4 remote monitoring (RM) systems, and investigate the effect of periodicity of RM transmissions on early detection of clinical- and device-related events.
Study design	Prospective, single centre, non-randomised study.
Setting	A single Italian medical institution. Patients were enrolled between January 2009 and January 2011.

Study component	Description
Intervention and comparator	Intervention/comparator 21 patients with an ICD were monitored with 4 different HM devices: CareLink, BHM, LAT and SJM. Remote follow-ups were configured quarterly, except for the BHM (daily transmissions). All 4 RM technologies available on the market were used, assigned to patients before implant, and activated at discharge. In-hospital follow-ups were done for all technologies 1 and 12 months after implantation.
Inclusion/ exclusion criteria	**Inclusion** Patients with a standard indication for ICDs with or without CRT. Written informed consent was obtained from participating patients. **Exclusion** None stated.
Primary outcomes	The primary end point was time to investigator's first evaluation of a true-positive clinical- or device-related event during the first year after implant, whichever was first seen during a remote follow-up (whether or not it was triggered by an automatic alert) or during an in-person visit. An episode was classified as false positive if it did not trigger medical intervention other than device reprogramming. The number of RM transmissions, alerts, and the mean intervals between consecutive RM transmissions were also registered and compared.
Statistical methods	Sample distributions of continuous variables were tested for normality with the Shapiro–Wilk test. Categorical variables were reported as percentages. Comparisons among RM groups were done with the Kruskal–Wallis rank test for continuous variables using Bonferroni's correction for pair-wise multiple comparisons. Chi-square test was used for comparison of baseline categorical variables. Event-free rates were estimated with the product-limit method and Kaplan–Meier plots generated. Comparisons among groups were done with the log-rank test. Areas under Kaplan–Meier curves were calculated with the restricted mean method. Uni- and multivariate Cox proportional hazard models were used to investigate the association between event-free rate and frequency of RM transmissions.

Study component	Description
Patients included	n=211 patients with an ICD (65 CareLink; 61 BHM; 49 LAT; 36 SJM) 72% male (CareLink); 70% male (BHM); 70% male (LAT); 83% male (SJM). Mean age (years): 70 (CareLink); 70 (BHM); 66 (LAT); 67 (SJM).
Results	Event-free rates were 49% with BHM, 57% with LAT, 57% with CareLink, and 58% with SJM (log-rank, p=0.23). BHM generated 304 (IQR, 184–342) transmissions/patient /year, LAT 9 (8–11), CareLink 7 (5–10), and SJM 8 (7–14; p<0.000001). Eighty actionable events occurred at 1-year follow-up, 69 (86%) with RM systems; BHM was associated with a higher cumulative rate of actionable events. Daily transmissions were independently associated with an increased probability of event detection compared with periodic transmission systems. The chance of event detection was reduced by 20% (p=0.036) for a 1 month increase of the between-transmission interval (27% for actionable events, p=0.004).
Conclusions	Although all RM systems effectively detected major events, daily transmission was associated with a higher probability of early event detection.
Abbreviations: BHM, BIOTRONIK Home Monitoring; CareLink, Medtronic CareLink; CRT, cardiac resynchronisation therapy; ICD, implantable cardioverter defibrillator; IQR, interquartile range; LAT, Boston Latitude; RM, remote monitoring; SJM, St. Jude Merlin.	

Table 11 Summary of results from the de Ruvo et al. (2015) study

	CareLink (n=65)	BIOTRONIK Home Monitoring (n=61)	Boston Latitude	St. Jude Merlin	Analysis
Primary outcome					

	CareLink (n=65)	BIOTRONIK Home Monitoring (n=61)	Boston Latitude	St. Jude Merlin	Analysis
Event notification through RM	46/46	62/69	33/34	38/40	First event notification to physicians was provided by RM in 179 events (94%) either with automatic alerts or scheduled remote reports with abnormal data.
Selected secondary outcomes					
False-positive RM detected events	11	1	4	0	16 remotely detected false positive events (8%).
False-negative RM detected events	0	7 (4 deaths, 2 worsening HF, 1 undetected AF episode associated with atrial under-sensing)	1 (left ventricular lead dislodged)	2 (1 death, 1 atrial sensing issue)	10 events were not detected remotely. p>0.06 p≤0.008 after Bonferroni's correction
Actionable events detected by RM	12/14	31/34	20/24	6/8	80 events (42%) were actionable, 69 (86%) of which were detected remotely.
Cumulative rates of actionable events	22%	37%	45%	16%	p=0.005 log-rank test A statistically significant difference between BHM and CareLink was detected (p=0.007).

	CareLink (n=65)	BIOTRONIK Home Monitoring (n=61)	Boston Latitude	St. Jude Merlin	Analysis
Median maximum interval between transmissions (IQR) in days	93 (82–126)	9 (3–25)	70 (63–96)	86 (58–93)	The maximum expected duration of unmonitored periods was significantly shorter in the BHM system (p<0.0001).
Abbreviations: AF, atrial fibrillation; BHM, BIOTRONIK Home Monitoring; HF, heart failure; IQR, interquartile range; LAT, Boston Latitude; RM, remote monitoring; SJM, St. Jude Merlin.					

Table 12 Overview of the Landolina et al. (2012) study

Study component	Description
Objectives/ hypotheses	The EVOLVO study aimed to test the hypothesis that remote management, using CareLink, can reduce emergency healthcare use (emergency department or urgent face-to-face assessments) in patients with HF who have implanted wireless-transmission-enabled ICD/CRT-D with specific diagnostic features for HF, thereby increasing efficiency compared with standard management consisting of scheduled face-to-face follow-up and patient response to audible ICD alerts.
Study design	Prospective, randomised, open, multicentre study
Setting	Six centres in Italy. Patients enrolled from May 2008 to July 2009 and followed up for a 16-month period.
Intervention and comparator	**Intervention** RM strategy using CareLink network service with audible alerts disabled, at 4 and 12 months with face-to-face follow-ups at 8 and 16 months. **Comparator** Standard management consisting of scheduled visits at 4, 8, 12 and 16 months and patient response to audible alerts.

Study component	Description
Inclusion/ exclusion criteria	**Inclusion criteria** Left ventricular systolic dysfunction or LVEF≤35% documented at the moment of implantation; implantation with a wireless-transmission–enabled Medtronic ICD or CRT-D endowed with thoracic impedance measurement capabilities (OptiVol algorithm); ability and willingness to have remote follow-up instead of scheduled routine face-to-face follow-up visits; and ability to attend all required follow-up examinations at the study centre. **Exclusion criteria** Reported in Marzegalli et al. (2009) as part of a trial design paper. Patients were excluded if they were under 18 years, were unwilling or unable to give informed consent, had a life expectancy of <12 months, or were participating in another clinical study that may have an impact on the end points of the present study.

Study component	Description
Primary outcomes	**Primary Outcomes** All visits (ED and urgent face-to-face follow-ups) with an interval of <24 hours between the decision to see the patient and the visit. The events anticipated to prompt these visits were ICD alerts for system integrity, atrial and ventricular arrhythmias, decrease in intrathoracic impedance signifying possible fluid accumulation, and patient symptoms. To determine whether remote monitoring was associated with a different rate of ED and urgent face-to-face follow-up for HF, arrhythmias, or ICD-related events from patients in the standard arm. **Secondary Outcomes** Visits representing the primary end point were further subdivided: visits related to episodes of worsening of HF, and visits for arrhythmias or ICD-related episodes. The rate of total healthcare use (any face-to-face follow-up visit, emergency department visit, and hospitalisation needing at least 1 overnight stay) for HF, arrhythmias, or ICD events was also compared between groups. Visits were scrutinized and classified as necessary or unnecessary for the clinical management of the condition. The study also tested whether remote monitoring reduced the time from any alert condition to the ICD data review, modified the patient's clinical status as measured by the Clinical Composite Score, or modified the patient's QoL as measured by the Minnesota Living With Heart Failure Questionnaire.
Statistical methods	An intention-to-treat analysis was done for all objectives. Primary and secondary hypotheses were tested using the combined Mantel–Haenszel estimate stratified by centre and other potential confounders. Normality of distribution was tested with the nonparametric Kolmogorov-Smirnov test. Differences between mean data were compared using a t test for Gaussian variables and an F test to check the hypothesis of equality of variance. The Mann–Whitney nonparametric test was used to compare non-Gaussian variables. Differences in proportions were compared by application of Chi-square analysis or the Fisher exact test as appropriate.

Study component	Description
Patients included	n=200 patients (99 RM; 101 standard care) 81.8% male (RM); 75.2% male (standard care) Mean age (years): 66 (RM), 69 (standard care)
Results	Over 16 months, the primary end point was 35% less frequent in the remote arm (75 compared with 117; incidence density, 0.59 compared with 0.93 events per year; p=0.005). A 21% difference was seen in the rates of total healthcare visits for HF, arrhythmias, or ICD-related events (4.40 compared with 5.74 events per year; p<0.001). The time from an ICD alert condition to review of the data was reduced from 24.8 days in the standard arm to 1.4 days in the remote arm (p<0.001). The patients' clinical status was similar in the 2 groups, whereas a more favourable change in QOL was seen from baseline to 16 months in the remote arm (p=0.026).
Conclusions	The results showed that RM can reduce ED or urgent face-to-face follow-up and, in general, total healthcare use in patients with HF with modern ICD/CRT-D. Compared with standard follow-up through face-to-face follow-up and audible ICD alerts, RM resulted in increased efficiency for healthcare providers and improved quality of care for patients.
Abbreviations: CRT-D, cardiac resynchronisation therapy with defibrillator; CI, confidence interval; ED, emergency department; HF, heart failure; ICD, implantable cardioverter defibrillators; IRR, incident rate ratio; LVEF, left ventricular ejection fraction; QoL, quality of life; RM, remote monitoring.	

Table 13 Summary of results from the Landolina et al. (2012) study

	CareLink remote monitoring (n=99)	Face-to–face monitoring (n=101)	Analysis
Primary outcome			

	CareLink remote monitoring (n=99)	Face-to–face monitoring (n=101)	Analysis
All emergency department and urgent face-to-face follow-ups	75 visits 0.59 events per year	117 visits 0.93 events per year	IRR 0.65; 95% CI, 0.49–0.88 (p=0.005) IRR adjusted for centre, use of CRT, and ischaemic origin.
Selected secondary outcomes			
ED and urgent face-to-face follow-ups for worsening of HF	48 visits 0.38 events per year	92 visits 0.73 events per year	IRR=0.52; 95% CI, 0.37– 0.75 (p<0.001)
ED and urgent face-to-face follow-ups for arrhythmias or ICD-related episodes	27 visits 0.21 events per year	25 visits 0.20 events per year	IRR=1.14; 95% CI, 0.65–1.99 (p=0.649)
Healthcare use for HF, arrhythmias or device-related events	4.4 events per year	5.74 events per year	IRR=0.79; 95% CI, 0.71– 0.89 (p<0.001)
Hospitalisations needing at least 1 overnight stay	0.45 events per year	0.39 events per year	p=0.464
Wireless remote notifications (CareLink) and audible alerts (control)	2.5 events per year	2.4 events per year	IRR=1.04; 95% CI, 0.89 –1.23 (p=0.602)
Rate of appropriate additional visits due to alerts	86% (72/84)	53% (42/79)	p<0.001
Median time from alert to ICD data review	1.4 days (25th–75th percentile 0.8–7.3)	24.8 days (25th–75th percentile 9.5–48.8).	p<0.001

	CareLink remote monitoring (n=99)	Face-to–face monitoring (n=101)	Analysis
Change in QoL at 16 months	–2 (25th–75th percentile –17 to 8)	+2 (25th–75th percentile –7 to 10)	p=0.026
Change in clinical status from the time of enrolment to the 16-month follow-up visit	17% improved, 49% were unchanged, and 34% worsened.	20% improved, 36% were unchanged, 44% worsened.	No statistical difference
Abbreviations: CI, confidence interval; CRT cardiac resynchronisation therapy; CI, confidence interval; ED, emergency department; HF, heart failure; IRR, incident rate ratio; QoL, quality of life.			

Table 14 Overview of the Luthje et al. (2015) study

Study component	Description
Objectives/ hypotheses	To estimate the influence of remote monitoring with fluid monitoring using OptiVol alerts on the time-to-first heart failure related hospitalisations, ventricular tachyarrhythmia occurrence, and mortality when compared with standard clinical care.
Study design	A prospective, single-centre, randomised study
Setting	A single centre in Germany. Patients enrolled between December 2007 and April 2011, and followed up for 15 months.

Study component	Description
Intervention and comparator	**Intervention** Patients in the RM arm were connected to the Medtronic CareLink network. **Comparator** In the control group, standard face-to-face follow-ups were done every 3 months. Patients having CRT-D or ICD implants or replacements were randomised to RM including OptiVol ON (remote arm) compared with RM OFF (standard arm) and followed for 15 months. In both groups, the audible OptiVol alert was disabled.
Inclusion/ exclusion criteria	**Inclusion criteria** Patients >18 years needing an ICD or CRT-D according to current guidelines, or patients with a previously implanted device without FM feature and a replacement indication for battery depletion were included in the study after written informed consent. HF or a history of hospitalisation for decompensated HF was not a prerequisite for inclusion. **Exclusion criteria** Permanent atrial fibrillation, a life expectancy $\leq$15 months, pregnancy, and participation in another study.
Primary outcomes	The primary outcome was the time taken to first hospitalisation due to worsened heart failure and was stated in Zabel et al. (2013) as part of a study design paper.
Statistical methods	Differences in baseline characteristics were evaluated using student's t-test, a Chi-square test, or a Fisher's exact test, as appropriate. For time-to-first HF-related hospitalisation, time-to-first ICD shock, and time to death a Cox proportional hazard analysis, and Kaplan–Meier survival analysis with log-rank test were done.
Patients included	n=176 (87 CareLink; 89 control) 80.5 % male (CareLink); 74.2% (control) Mean age (years): 66 (CareLink); 65.9 (control).

Study component	Description
Results	Cox proportional hazard analysis on the time-to-first HF-related hospitalisation showed a hazard ratio of 1.23 (0.62–2.44; p=0.551) favouring the control group. In the remote group, 13 patients (15%) had ICD shocks compared with 10 patients (11%) in the control group (p=0.512). Average time-to-first ICD shock was 212±173 in the remote arm and 212+143 days in the control arm (p=0.994). The Kaplan–Meier estimate of mortality after 1 year was 8.6% (8 deaths) in the remote group compared with 4.6% in the control group (6 deaths; p=0.502).
Conclusions	RM in combination with FM had no significant effect on HF-related hospitalisations, ICD shocks or mortality.
Abbreviations: ICD, implantable cardioverter defibrillator; CRT-D, cardiac resynchronisation therapy and defibrillator; FM, fluid monitoring; HF, heart failure; RM, remote monitoring.	

Table 15 Summary of results from the Luthje et al. (2015) study

	CareLink remote monitoring (n=87)	Standard care group (n=89)	Analysis
OptiVol alerts	174 (78%) alerts (94 in patients with a CRT and 80 in patients with an ICD) in 68 patients (35 with a CRT and 33 with an ICD).		93 alerts were classified as true positive based on clinical assessment.
Patients hospitalised for worsened HF during follow-up	20	22	One patient in the RM group was hospitalised before an OptiVol Alert was sent.
Mean number of emergency department visits	0.10±0.25	0.10±0.23	No significant difference

	CareLink remote monitoring (n=87)	Standard care group (n=89)	Analysis
Mean number of urgent care visits	0.30±0.50	0.10±0.30	p=0.0332
Total number of patients having ICD shocks	13 (15%)	10 (11%)	
Number of patients having inappropriate ICD shocks	2 (2%)	2 (2%)	
Average time-to-first ICD shock	212±173 days	212±143 days	p=0.994 No significant difference (Kaplan–Meier analysis)
Number of deaths	8 (1 sudden cardiac; 3 non-sudden cardiac; 1 non-cardiac death. 3 deaths could not reliably be classified)	6 (1 sudden cardiac; 3 non-sudden cardiac; 2 non-cardiac deaths)	The Kaplan–Meier estimate of all-cause mortality after 1 year was 8.6% in the RM group compared with 4.6% in the control group. No significant difference was seen for time to death between the 2 groups.
Abbreviations: ICD, implantable cardioverter defibrillator; CRT-D, cardiac resynchronisation therapy and defibrillator; HF, heart failure.			

Search strategy and evidence selection

Search strategy

The following search strategy was used to search Ovid MEDLINE (R) 1946 to November Week 3 2015:

1 "Remote Monitoring Reduces Healthcare Use and Improves Quality of Care in Heart Failure Patients With Implantable Defibrillators".m_titl. (1)

2 "The Value of Wireless Remote Monitoring With Automatic Clinician Alerts".m_titl. (1)

3 Clinical Benefits of Remote Versus Transtelephonic Monitoring of Implanted Pacemakers.m_titl. (1)

4 "The MOnitoring Resynchronization dEvices and CARdiac patiEnts (MORE-CARE) randomized controlled trial: phase 1 results on dynamics of early intervention with remote monitoring.".m_titl. (1)

5 1 or 2 or 3 or 4 (4)

6 Telemedicine/ (13186)

7 Telemetry/ (8564)

8 Monitoring, Physiologic/ (47801)

9 Remote Consultation/ (3890)

10 6 or 7 or 8 or 9 (70728)

11 defibrillators, implantable/ or exp pacemaker, artificial/ (34302)

12 exp Cardiac Pacing, Artificial/ (21446)

13 11 or 12 (50131)

14 Coronary Artery Disease/ (43268)

15 Heart Failure/ (92598)

16 Cardiovascular Diseases/ (112154)

17 Arrhythmias, Cardiac/ (54372)

18 14 or 15 or 16 or 17 (293959)

19 10 and 13 and 18 (445)

20 Remote monitoring.ti,ab. (774)

21 (Telemedicine or telemetry).ti,ab. (10785)

22 20 or 21 (11465)

23 (cardiac resynchronization adj4 (device* or defibrillator*)).ab,ti. (785)

24 (implantable adj4 defibrillator*).ti,ab. (8920)

25 (pacemaker* or implantable loop recorder*).ti,ab. (29430)

26 23 or 24 or 25 (37455)

27 carelink.ti,ab. (49)

28 ((Heart or cardiac) adj failure).ab,ti. (119197)

29 (arrhythmia* or cardiovascular disease*).ab,ti. (166404)

30 28 or 29 (272228)

31 22 and 26 and 30 (144)

32 27 and 30 (9)

33 19 or 31 or 32 (553)

34 randomized controlled trial.pt. (417624)

35 controlled clinical trial.pt. (92270)

36 randomized.ab. (309508)

37 placebo.ab. (159698)

38 drug therapy.fs. (1862631)

39 randomly.ab. (219030)

40 trial.ab. (322047)

41 groups.ab. (1378466)

42 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 (3517639)

43 exp animals/ not humans.sh. (4156219)

44 42 not 43 (2999126)

45 33 and 44 (106)

46 limit 45 to english language (89)

The strategy was adapted for the following databases: Medline in Process, Embase, Cochrane Library (CENTRAL, CDSR, DARE, HTA, NHS EED), EconLit, Pubmed ('epub ahead of press').

The searches returned 656 references, which were reduced to 280 references after automatic and manual removal of duplications.

ClinicalTrials.gov and the International Clinical Trials Registry Platform (ICTRP) were searched to identify ongoing or in-development trials.

Evidence selection

Retrieved results were sifted using the selection criteria below:

- Population: People needing a cardiac device, for example, an implantable cardioverter defibrillator (ICD), a cardio resynchronisation therapy device (CRT), a cardio resynchronisation therapy with defibrillator device (CRT-D), pacemakers, and implantable loop recorders.

- Setting: In the person's home.

- Intervention: Medtronic CareLink Network.

- Comparators: Other similar home monitoring devices (for example, Biotronik, Boston Scientific Latitude, St Jude Medical Merlin), transtelephonic monitoring, and face-to-face visits.

- Outcomes:

  - time from device-detected events to clinical decisions

  - number of events reported

  - quality of life

  - in-hospital visits (scheduled and unscheduled)

  - hospital admissions

  - death

  - disease progression or clinical events

  - improved long-term clinical outcomes

  - length of stay

  - device malfunction

  - user difficulties with system.

Following the first sift, 75 references were obtained in full text because it was unclear from the title and abstract whether CareLink had been used. After reading the 75 full text references, 16 studies and 1 economic paper that matched our defined scope were identified.

The studies included in this briefing were prioritised if they were randomised controlled trials. One comparative paper was also included, because it compared outcomes from similar technologies, and 1 economic paper was also included.

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and are not formal NICE guidance.

Development of this briefing

This briefing was developed for NICE by Cedar. The interim process & methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

Project team

Cedar

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Specialist commentators

The following specialist commentators provided comments on a draft of this briefing:

- Dr Sern Lim, Consultant cardiologist, Queen Elizabeth Hospital, Birmingham

- Dr Stephen Murray, Consultant cardiologist, Newcastle Upon Tyne NHS Foundation Trust

- Mr Andrew Penney, Cardiac Device Service Manager/ Lead Cardiac Physiologist, Cardiff and Vale University Health Board

- Miss Sarah James, Cardiac physiologist, Cardiff and Vale University Health Board

Declarations of interest

Dr Stephen Murray has received consultancy fees and educational grants from Medtronic, St Jude Medical, Biosense Webster and Boston Scientific. Dr Murray has also received educational grants from Pfizer and Astra Zeneca.

Dr Sern Lim received an honorarium from St Jude Medical for teaching courses in 2015.