NICE National Institute for Health and Care Excellence

NICE guidance

Pulmonary artery pressure technologies for remote monitoring of chronic heart failure

HealthTech guidance

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Your responsibility

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

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

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

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

Contents

1 Recommendations

Can be used

1.1 CardioMEMS HF System can be used as an option for remote monitoring of New York Heart Association (NYHA) class 3 chronic heart failure in adults at risk of hospitalisation who are:

- able to use the technology (with the help of a carer if necessary) and
- willing to adjust medication as directed.

More research is needed

1.2 More research is needed on the Cordella Pulmonary Artery Sensor System and the Cordella Heart Failure System for remote monitoring of NYHA class 3 chronic heart failure in adults before it can be funded by the NHS.

What this means in practice

Can be used

There is enough evidence to show that CardioMEMS HF System provides benefits and value for money, so it should be used routinely across the NHS, and paid for using core NHS funding.

More research is needed

There is not enough evidence to support funding Cordella Pulmonary Artery Sensor System and the Cordella Heart Failure System in the NHS.

Access to Cordella Pulmonary Artery Sensor System and the Cordella Heart Failure System should be through company, research or non-core NHS funding, and clinical or financial risks should be managed appropriately.

What research is needed

More research is needed on:

- the clinical effectiveness of the technology, including the impact on heart failure hospitalisations
- the short-term impact of the technology on quality of life
- defining which groups of people the technology is most suitable for.

Why the committee made these recommendations

Evidence from 3 randomised controlled trials shows that, when compared with usual care, CardioMEMS HF System (from here, CardioMEMS) can reduce heart failure hospitalisations in people with NYHA class 3 chronic heart failure who are at risk of hospitalisation. Evidence from non-comparative studies suggests that the Cordella Pulmonary Artery Sensor System and the Cordella Heart Failure System (from here, Cordella) may reduce heart failure hospitalisations, but this is unconfirmed. It is uncertain whether using either technology affects how long people live, or their quality of life. There are no trials directly comparing CardioMEMS with Cordella. An indirect comparison suggests no difference in heart failure hospitalisations between the 2 technologies. But this is uncertain because of the data used in the comparison.

Ongoing monitoring could be reassuring for people with chronic heart failure and help to quickly identify any need for medication changes. The technologies could reduce resource use in the NHS by reducing the number of heart failure hospitalisations. Use of the

technology can be aided by carers as needed. People using the technology need to be willing to adjust medication as directed in order to benefit and reduce the risk of hospitalisation.

Evidence from economic modelling shows that CardioMEMS is likely to be cost effective. The cost effectiveness of Cordella cannot be established because its cost is unknown. Also, because there is limited evidence on its clinical effectiveness, Cordella can only be used in research.

2 Information about the technologies

2.1 Pulmonary artery pressure (PAP) monitoring systems use implantable sensors to collect data on PAP to remotely monitor chronic heart failure. The aim of PAP technologies is to detect increases in PAP at an early stage. PAP increases mean that fluid is beginning to accumulate because of worsening heart failure. So, early detection increases the possibility of optimising medication, and avoiding decompensation of heart failure and hospitalisation.

2.2 A PAP sensor is implanted into a pulmonary artery using a right heart catheterisation procedure. NICE's HealthTech guidance on percutaneous implantation of PAP sensors for monitoring treatment of chronic heart failure recommends that the evidence on safety and efficacy is adequate to support this procedure.

2.3 People take daily PAP measurements at home. Data, including on pressure trends and waveforms, is collected and transmitted to an external monitor in the home. The monitor securely forwards this information to a remote database that can be accessed by the person's healthcare team. The aim of PAP technologies is to supplement usual monitoring for chronic heart failure. The decision to use the technology should be discussed with the person, who should be able and willing to use the technology, and to adjust their medication dose as requested by their care team. The technologies can replace some aspects of usual care for monitoring but not all, for example, regular check-ups will still be needed. The technologies do not make or confirm diagnosis of heart failure.

2.4 Two technologies were identified as relevant for inclusion in this evaluation:

- CardioMEMS HF System (from here, CardioMEMS)
- Cordella Pulmonary Artery Sensor System and Cordella Heart Failure System (from here, Cordella).

Table 1 Summary of pulmonary artery pressure monitoring technologies included in this evaluation

Technology	CardioMEMS HF System (from here, CardioMEMS; Abbott Medical)	Cordella Pulmonary Artery Sensor System and Cordella Heart Failure System (from here, Cordella; Endotronix/ Edwards Life Sciences)
Intended use	CardioMEMS is indicated for wirelessly measuring and monitoring PAP and heart rate for people with chronic heart failure. To have this technology in the UK, people need to have: • NYHA class 3 symptoms, and • a hospitalisation for heart failure within the last 12 months, regardless of ejection fraction status.	Cordella is intended to measure, record and transmit PAP data for people with NYHA class 3 heart failure who: • are at home on diuretics and guideline-directed medical therapy, and • have been stable for 30 days.
Contraindications	CardioMEMS is contraindicated for people who are unable to take dual antiplatelet therapy or anticoagulants following implantation.	Cordella is contraindicated for people who are unable to take dual antiplatelet therapy or anticoagulants following implantation.
CE mark status	Class 3 CE mark	Class 3 CE mark

Description	A small pressure sensor is permanently implanted in the distal pulmonary artery during a minimally invasive right heart catheterisation procedure. The sensor is secured with nitinol wire loops. It measures PAP changes, which reflect fluid retention in the lungs because of worsening chronic heart failure. At home, people use a portable electronics unit and a pillow with an embedded antenna. By lying down on the pillow and activating the technology, they take daily pressure readings by pressing a button. The data is sent wirelessly to a secure database for healthcare professionals to review. They can see trends and adjust medication and other treatments as needed, often before symptoms appear. This can potentially reduce the risk of decompensation of heart failure and hospitalisation.	A sensor is implanted in the pulmonary artery, and readings can be taken at home by holding a wireless handheld reader against the right pectoral region for 20 seconds. In addition to PAP data, this technology measures vital signs including blood pressure, heart rate, weight, and oxygen saturation. Collected data is sent to the myCordella Hub, which: • guides people on how to use the technology • asks health-related questions, and • transmits information to the myCordella Patient Management Portal for healthcare professionals to access. This technology aims to assist healthcare professionals in assessing and managing heart failure, potentially reducing hospitalisations.
NHS use	In the NHS in England, CardioMEMS has mostly been used in a trial setting and is not routinely used.	Cordella is not currently used in the NHS.

Price	£9,500	Not provided

Abbreviations: NYHA, New York Heart Association; PAP, pulmonary artery pressure.

3 Committee discussion

The diagnostics advisory committee considered evidence on pulmonary artery pressure (PAP) technologies for remote monitoring of chronic heart failure from several sources. This included evidence submitted by Abbott and Endotronix/Edwards Life Sciences, a review of clinical and cost evidence by the external assessment group (EAG), and responses from stakeholders. Full details are available in the project documents for this guidance.

The condition

3.1 Heart failure is caused by any structural or functional cardiac condition that impairs the heart's ability to function efficiently and pump blood around the body. The most common symptoms of heart failure are breathlessness, fatigue and oedema. Heart failure may be classified by ejection fraction:

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

Heart failure may also be classified by symptom severity and limitation of physical activity using the New York Heart Association (NYHA) classification system. This ranges from class 1 (no limitations) to class 4 (inability to carry out physical activity without discomfort and symptoms, which may be present at rest).

Current practice

3.2 NICE's guideline on diagnosing and managing chronic heart failure in adults recommends that monitoring of chronic heart failure should include:

- a clinical assessment of functional capacity, fluid status, cardiac rhythm, cognitive status and nutritional status
- a review of medication
- an assessment of renal function.

The European Society for Cardiology guideline on diagnosing and treating acute and chronic heart failure adds that heart failure management may involve in-person services or home-based telemonitoring. While care is usually followed up in heart failure clinics, people whose condition is suitable may be followed up by a range of healthcare professionals. This can include community heart failure nurses, GPs with a special interest in heart failure and specialist pharmacists. 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 depends on the clinical status and stability of the person's condition.

Unmet need

3.3 Heart failure accounts for 2% of all NHS inpatient bed days (a total of 1 million inpatient bed days each year) and 5% of all emergency medical admissions to hospital. The clinical experts said that heart failure is the most common reason that people over 60 years are admitted to hospital. Heart failure is very costly to the NHS and the majority of the costs are related to hospital admissions. Hospitalisations for heart failure can have an impact on the quality of life of people admitted with it. PAP monitoring technologies offer remote monitoring of chronic heart failure, with the aim of reducing hospitalisations for heart failure. The technologies would be used as an add-on to usual clinical management of NYHA class 3 heart failure. The committee concluded that the technologies would need to be integrated into specialist multidisciplinary heart failure services, with alerts and trend data monitored and managed by specialist healthcare professionals.

Clinical effectiveness

Clinical evidence

3.4 The committee discussed the evidence base for this evaluation, which consisted of:

- 3 randomised controlled trials (RCTs) comparing CardioMEMS with usual care (CHAMPION, GUIDE-HF and MONITOR-HF)
- 3 single-arm prospective studies for CardioMEMS, included for device-related outcomes only (COAST, MEMS-UK and CardioMEMS-PAS)
- 2 studies on patient experience of CardioMEMS (Assaad et al. 2018 and Haynes et al. 2020)
- 3 prospective single-arm studies for Cordella (SIRONA, SIRONA 2 and PROACTIVE-HF).

  PROACTIVE-HF was originally designed as an RCT and changed to a single-arm study part way through. This change was prompted by emerging evidence supporting PAP-guided management of NYHA class 3 heart failure, increased access to reimbursed PAP technology in the US and disruptions from the COVID-19 pandemic. Some data from the randomised phase of PROACTIVE-HF was included in the evaluation. Two studies included patient-survey results that contributed data on patient experience and satisfaction (PROACTIVE-HF and SIRONA 2).

Study size, quality and populations

3.5 The sample sizes of the studies included for the main review of clinical effectiveness outcomes ranged from 15 people (in SIRONA) to 1,000 people (in GUIDE-HF). The mean or median age of people in the studies ranged from 61 to 71 years across the studies. This is younger than the average age of people with first heart failure diagnosis in the UK, which is 77 years. There was a high proportion of men in the studies (for example, over 70% of people in CHAMPION were men). People included in the studies had NYHA class 3 heart failure and had

previously been hospitalised because of heart failure. One of the clinical experts explained that there is no reason to believe that the technology would be less beneficial for women, trans and non-binary people.

The committee concluded that the study populations were less diverse than the real-world population of people with heart failure in terms of gender, age and ethnicity.

Medication

3.6 One clinical expert explained that pharmacological management of chronic heart failure has changed since some of the studies were done, particularly for HFpEF. Previously, treatment for HFpEF relied on diuretics alone, but current practice includes mineralocorticoid receptor antagonists and sodium-glucose cotransporter 2 inhibitors in addition to diuretics. Most of the studies were done recently and reflect contemporary treatment of chronic heart failure. CHAMPION began enrolment in 2007 and reflected HFpEF treatment at the time. The committee concluded that this did not affect the interpretation of the results for this evaluation. This was because most people with HFpEF in the overall analysis of all the studies would have had treatment in line with contemporary treatment.

Heart failure hospitalisations

CardioMEMS

3.7 Evidence from 3 RCTs (CHAMPION, GUIDE-HF and MONITOR-HF) comparing the effect of CardioMEMS on heart failure hospitalisations with usual care was included in a meta-analysis. The results of the meta-analysis showed that CardioMEMS was associated with a reduction in heart failure hospitalisations compared with usual care, with high certainty in the evidence (summary hazard ratio [HR] 0.66, 95% confidence interval [CI] 0.57 to 0.76). The committee noted that in the largest trial, GUIDE-HF, people with NYHA class 2 to 4 heart failure were included.

The primary analysis was restricted to the NYHA class 3 population. Data for the

full trial population suggested an overall reduction in heart failure hospitalisation (HR 0.83, 95% CI 0.68 to 1.01). There was stronger evidence for a reduction in heart failure hospitalisations in the period before the COVID-19 pandemic (HR 0.72, 95% CI 0.57 to 0.92). But there was no statistically significant difference between the intervention and control group during the COVID-19 pandemic. The committee concluded that there was some evidence to support a reduction in heart failure hospitalisations with CardioMEMS.

Cordella

3.8 Data supplied by the manufacturer of Cordella for the randomised phase of PROACTIVE-HF suggested a reduction in heart failure hospitalisations with Cordella. But the committee thought that this was uncertain because of the small number of people in the randomised phase and some concerns about the risk of bias. The results of 2 of the non-comparative studies that evaluated Cordella suggested a reduction in heart failure hospitalisations. The committee concluded that the evidence was too uncertain to conclusively support that it reduced heart failure hospitalisations.

CardioMEMS compared with Cordella

3.9 An indirect comparison of CardioMEMS and Cordella was done using the evidence from the 3 RCTs of CardioMEMS and evidence from the RCT phase of PROACTIVE-HF. The results suggested no difference in heart failure hospitalisations between the 2 technologies. The committee noted that the comparator in PROACTIVE-HF differed from the comparator in the CardioMEMS trials, so this result was highly uncertain. The committee discussed that there was not enough evidence to show whether the 2 technologies could be considered to be equivalent. One clinical expert advised that this was unknown because the data for Cordella was limited and that there was also only limited real-world experience with the technology

All-cause mortality

3.10 All-cause mortality was evaluated as a secondary endpoint in the 3 RCTs on CardioMEMS, as well as in the comparative and single-arm phases of PROACTIVE-HF and SIRONA 2 on Cordella. The RCT results suggested a small decrease in all-cause mortality with CardioMEMS. For Cordella, data provided by its manufacturer for the comparative phase of PROACTIVE-HF suggested a small decrease in all-cause mortality. Confidence intervals were wide and consistent with both an increased and decreased risk of all-cause mortality for CardioMEMS (HR 0.91, 95% CI 0.70 to 1.17) and for Cordella (HR 0.51, 95% CI 0.20 to 1.32). Indirect comparison of Cordella with CardioMEMS suggested no evidence of a difference in all-cause mortality between the 2 technologies. But the estimate was very imprecise. The committee concluded that it was uncertain whether either technology reduced all-cause mortality from the evidence available.

Quality of life

3.11 All the studies provided data on health-related quality of life (HRQoL). This was measured using the EQ-5D-5L visual analogue scale, the Kansas City Cardiomyopathy Questionnaire (KCCQ) or the Minnesota Living with Heart Failure questionnaire. The impact of PAP monitoring technologies on HRQoL was mixed. For CardioMEMS, the studies had results in the opposite direction, so the findings were inconsistent. MONITOR-HF reported an increase in EQ-5D-5L score and GUIDE-HF reported a decrease. The summary estimate from the meta-analysis was a mean non-statistically significant increase in EQ-5D score of 1.75 (95% CI -6.03 to 9.53; a higher score is better). So, the summary estimate was of limited value. The overall result of the meta-analysis for the KCCQ was a mean non-statistically significant increase in KCCQ of 3.63 (95% CI -2.24 to 9.47; a higher score is better). For Cordella, data on HRQoL was limited and lacked direct comparisons, making it difficult to draw conclusions. The committee thought that the evidence for HRQoL and mortality was inconclusive for both technologies. It concluded that it was uncertain whether either technology improved HRQoL.

Safety

3.12 Data from the quantitative studies included in this evaluation showed that:

- Implantation failure was rare. Implantation of the technology failed in 1.7% of people (95% CI 0.8 to 2.9) with CardioMEMS and in 4.9% people (95% CI 3.1 to 7.0) with Cordella.
- Device- or system-, or procedure-related complications were rare. The summary proportion of these complications across trials was 0.7% (95% CI 0.3 to 1.3%) with CardioMEMS and 0.1% (95% CI 0.0 to 0.09%) with Cordella.
- Data from all quantitative studies except GUIDE-HF showed that the proportion of people with a sensor implanted in whom the sensor subsequently failed was low (0% to 1.2% overall). The summary estimate was 0.1% (95% CI 0.0 to 0.6) for CardioMEMS and 0% (95% CI 0.0 to 0.1) for Cordella. GUIDE-HF did not report sensor failure.

  The clinical experts explained that failure after implantation was rare and that, when implantation failure happens, it does not lead to products being discarded. The committee concluded that the technologies are safe to use and have an acceptable failure rate.

Patient selection

3.13 The evidence suggests that people with NYHA class 3 chronic heart failure who are at risk of hospitalisation, are most likely to benefit from using the technology. To benefit from using a PAP technology, people need to be comfortable with:

- having the procedure to implant the sensor
- taking routine measurements at home
- acting on any changes to their medication that are needed because of PAP changes.

  Qualitative data included in this evaluation suggested that people were positive about using the technologies and that the technologies improved

their understanding of their condition. The clinical experts said that people generally feel comfortable living with an implanted sensor and some people may feel reassured by knowing that their heart failure is being continuously monitored. But other people could feel uncomfortable with having a sensor implanted, living with it and find the monitoring requirements to be a burden. The person's ability to adhere to using the technology and medication changes, and their comfort with living with the implanted sensor, would need to be considered as part of shared decision-making.

Other options for remote monitoring of chronic heart failure are available, including algorithm-based remote monitoring systems, which use data from cardiac implantable devices, and virtual wards. Patient selection would also need to consider which methods of remote monitoring are available and would be most suitable for the person with heart failure. The committee concluded that patient selection would need to be carefully considered.

Cost effectiveness

Model design

3.14 The EAG developed a Markov model to estimate the cost effectiveness of remote PAP monitoring technologies compared with current monitoring practice (standard care). People with NYHA class 3 heart failure entered the model in a stable state, reflecting the health state for people whose condition has stabilised following an index admission. The model consisted of 8 mutually exclusive and exhaustive states:

- stable heart failure 1
- first recurrent heart failure hospitalisation
- stable heart failure 2
- second recurrent heart failure hospitalisation
- stable heart failure 3

- subsequent recurrent heart failure hospitalisation
- stable heart failure 4, and
- death.

The model used a cycle length of 1 month and a lifetime time horizon.

The key clinical input in the model was heart failure hospitalisation rates. In the model, the risk of having a subsequent heart failure hospitalisation increased with the number of previous heart failure hospitalisations. The effect of PAP monitoring was to reduce the rate of heart failure hospitalisations, and this effect was assumed to continue regardless of how many previous heart failure hospitalisations a patient had had. The risk of death increased with each stable state, and the utility associated with each stable state declined as heart failure hospitalisations increase. The committee agreed that the design of the model was appropriate.

Impact of heart failure hospitalisations

3.15 The committee discussed the key drivers of the model. One-way sensitivity analysis showed that the effectiveness of CardioMEMS at reducing heart failure hospitalisations had the largest impact on the incremental cost-effectiveness ratio (ICER). At the lower bound of the CardioMEMS hazard ratio, the ICER was reduced by over £17,000 per quality-adjusted life year (QALY). At the upper bound, the ICER was increased by over £40,000. All other variables included in the deterministic sensitivity analysis had a less than £10,000 impact on the ICER. The implant failure rate had the next biggest impact on the ICER, followed by the costs for third or subsequent recurrent heart failure hospitalisations. The committee concluded that heart failure hospitalisations were a key driver of the model.

Heart failure hospitalisation rates

3.16 Heart failure hospitalisation rates were calculated using data from 2 studies done

in the UK. The Lahoz et al. (2020) study reported data from 8,603 people with heart failure who had already had an index heart failure hospitalisation from the UK Clinical Practice Research Datalink. Lahoz et al. reported the median number of days to the next heart failure hospitalisation. From this, the EAG calculated the hazard ratio for a recurrent event compared with having no recurrent heart failure hospitalisations after the index heart failure hospitalisation. The EAG used data from COAST to estimate the recurrent heart failure hospitalisation rate in the first stable heart failure state in the Markov model. It did this using data from Lahoz et al. to adjust for the fact that the COAST data included people with multiple previous heart failure hospitalisations. Data in Lahoz et al. was not reported according to NYHA class. People with NYHA class 3 heart failure were more likely to be admitted to hospital than people with NYHA class 1 or 2. Lahoz et al. data was used to adjust the COAST data to account for the number of previous heart failure hospitalisations. So, the committee concluded that it was possible that heart failure hospitalisation rate may have been underestimated or overestimated. But it also noted that this was uncertain based on the data available.

Utilities

3.17 In the EAG's original base case, the utility value for the initial stable heart failure state was based on a published meta-analysis of utilities for people with heart failure (Santos et al. 2024). Reductions in utility were made for the second, third and fourth stable heart failure states using data from Gohler et al. (2009). As people progressed through the subsequent stable heart failure states, their utility declined. The clinical experts agreed that utility declines with each hospital admission. Utility data from the EAG's meta-analysis of trials of the technologies included in this evaluation were not used in the base case. This was because of a high degree of uncertainty in the results.

Alternative scenarios for capturing utilities in the model were considered, in which utility outcome data from the trials was directly applied in the model. In scenario 6a, data was applied from CHAMPION. The EAG had some concerns about using CHAMPION data because of how old it was and because the trial was done in the US. In scenario 6b, data was applied from MONITOR-HF. MONITOR-HF was done in the Netherlands, so was preferred by the EAG

because the data was from a European population. But the EAG had concerns about using data from MONITOR-HF because it took place during the COVID-19 pandemic lockdown. This could have affected the generalisability of the results to usual UK practice. In scenario 6c, utilities were used from MONITOR-HF for the first 12 months, and health-state-based utilities were used for extrapolation beyond 12 months. This scenario analysis resulted in an ICER of £36,000 per QALY gained for CardioMEMS. The committee concluded that scenario 6c was the most plausible of the analyses considered and agreed that scenario 6c should be adopted as the base case.

Healthcare professional costs

3.18 The clinical experts explained that the frequency of monitoring is likely to reduce after the initial implant. So, the frequency of 3 times per week used in the original model over the lifetime was likely an overestimate. The technologies can be set with parameters specific to the people using them. Also, they can alert people using them and their healthcare professionals when measurements fall outside of range. The model was based on a band 5 nurse monitoring PAP data. But a band 5 nurse would not be able to prescribe medications if the data shows that a change in medication is needed to avoid decompensation of heart failure. A doctor or nurse prescriber would need to prescribe the medication. The base case included 5 minutes per month of a medical consultant. This may have been insufficient if a doctor or nurse prescriber is needed to oversee medication changes and prescribe medication. So, the committee thought that the band 5 nurse costs in the model were likely to have been an underestimate.

The committee agreed that the appropriate monitoring schedule for people with stable heart failure would be to calibrate the technology after sensor implantation, then monitor weekly for the weeks 1, 2 and 3, then monitor every 3 months. The monitoring schedule would be repeated from the start if heart failure worsens.

Primary care resource use was not included in the model because there was no data on it. The clinical experts advised that, in the real world, people using the technology would remain under secondary care. The committee agreed that the omission of primary care resource use was not a limitation.

The cost effectiveness of CardioMEMS

3.19 The results of the original economic model suggested that the ICER for CardioMEMS in the probabilistic base-case analysis was £41,878 per QALY gained (deterministic analysis ICER was £41,569 per QALY gained). This is above the range that NICE considers an acceptable use of NHS resource. In the original analysis, all iterations of the probabilistic sensitivity analysis resulted in more health at a higher cost for CardioMEMS.

Following the first committee meeting, the EAG provided an updated base case with the following amendments reflecting the committee's preferred assumptions:

- Utilities data from MONITOR-HF were used for the first 12 months, and health-state-based utilities for extrapolation beyond 12 months, as described in section 3.16.
- The cost of the healthcare professional responsible for monitoring was changed from a band 5 nurse or cardiac physiologist to a band 7 nurse who could prescribe, as described in section 3.17.
- Data on medication changes from the GUIDE-HF and MONITOR-HF studies were used to determine when treatment escalation occurs, leading to more frequent monitoring.

  The updated model base-case ICER was £31,264 per QALY gained. The EAG included a scenario (scenario 4) that used the monitoring schedule described in section 3.17. The deterministic results of this scenario analysis suggested that the ICER for CardioMEMS was £14,037 per QALY gained. This is below the range that NICE considers an acceptable use of NHS resource.

Uncertainty in the model

Definition of worsening heart failure

3.20 The committee discussed the definition of worsening heart failure used to determine when more frequent monitoring is needed. The updated base case uses data on medication changes from GUIDE-HF and MONITOR-HF to estimate

the proportion of people whose heart failure has worsened and consequently need more frequent monitoring. The committee recognised that using data on medication changes was likely to be an overestimate of the proportion of people needing more frequent monitoring. This is because not all changes to medication would be made due to treatment escalation. The committee considered whether hospitalisation for heart failure should be used instead to determine the proportion of people who need more frequent monitoring. The committee considered that this would underestimate the proportion. This is because some people with worsening heart failure have treatment outside of hospital, for example in virtual wards, hospital at home or by outreach services. The committee concluded that medication changes was an appropriate method of capturing worsening heart failure in the model. But, it recognised that this is likely to overestimate the proportion of people who need more frequent monitoring in a 1-month cycle.

Frequency of monitoring

3.21 The committee discussed the frequency of monitoring needed for people with unstable heart failure. It heard from a clinical expert that more frequent monitoring is needed when heart failure is unstable (2 or 3 times per week). More frequent monitoring is usually only needed for around 2 weeks for most people with unstable heart failure. The model does not capture more frequent monitoring for people with unstable heart failure. The committee agreed that it would be difficult to quantify the monitoring of unstable heart failure and recognised this is an area of uncertainty in the model.

The committee discussed uncertainties in relation to frequency of monitoring. The estimate for reduction of hospitalisations for heart failure used in the model was based on data from clinical studies. The monitoring frequencies in the studies are more closely aligned with the original base case than the updated base case (that is, the monitoring in the trials is more frequent than in the updated base case). The committee discussed whether less frequent monitoring could impact the effectiveness of the technology at reducing hospitalisations for heart failure. There was no evidence showing the effect of different monitoring frequencies on hospitalisation for heart failure. A clinical expert explained that based on real-world experience, reduced monitoring frequency does not

negatively impact heart failure hospitalisations when people using the technology are well-educated about using it and take daily measurements. The clinical expert advised that consideration of trends over time and the use of alerts are key to effective monitoring, as opposed to frequent checking of daily measurements.

Place of PAP technologies in the care pathway

3.22 The committee discussed whether remote PAP monitoring replaces any aspects of routine care for monitoring. A clinical expert said that in practice some but not all routine outpatient appointments are replaced, and it is difficult to quantify. The impact of the technology on routine monitoring is not included in the model. The committee concluded that the impact on routine monitoring is uncertain, but that any reduction in routine appointments would improve the cost effectiveness of the technology.

Model results

3.23 The committee discussed the range of ICERs presented from the EAG's updated model and the uncertainties within the model. It agreed that scenario 4 of the EAG's updated model represents the monitoring frequency most likely to be implemented in the NHS. But it noted that the frequency of monitoring was subject to uncertainty and that the model results are sensitive to changes in this parameter. So it concluded that the most plausible ICER is likely to be higher than £14,037 per QALY gained. But, it is still likely to be within the range that NICE considers a cost-effective use of NHS resources. The committee also recognised the potential of the technology to help reduce inequalities for some groups, which was a potential uncaptured benefit within the analyses. So the committee concluded that CardioMEMS can be used as an option for remote monitoring of NYHA class 3 heart failure in adults.

The cost effectiveness of Cordella

3.24 The ICER for Cordella could not be estimated because its cost was unknown and clinical effectiveness evidence is inconclusive. In the model, the cost of Cordella

was assumed to be the same as the cost of CardioMEMS. This assumption was made to enable Cordella to be included in the model and was for illustrative purposes only. The committee concluded that it was not possible to estimate the cost effectiveness of Cordella.

Health Technology Wales model

3.25 The committee was aware that a model was developed for the Health Technology Wales appraisal of percutaneous implantation of PAP sensors for monitoring treatment of chronic heart failure. The committee discussed the key differences between the models and agreed that it preferred the model developed by the EAG. In the EAG's model, the disutility associated with hospitalisation for heart failure stopped after 1 month, but the disutility lasted for 1 year in the Health Technology Wales model. The committee agreed that 1 month was a more plausible timeframe for disutility because of hospitalisation and immediate recovery. In the EAG's model, the utility associated with each stable heart failure state decreased with each subsequent stable state. The committee agreed that this was clinically appropriate. Also, in the Health Technology Wales model, monitoring costs were based on a band 5 nurse monitoring PAP data. The committee recalled its earlier conclusion that a healthcare professional who can prescribe would need to do the monitoring.

Equality considerations

3.26 The technologies need people to take PAP measurements at home. People with cognitive impairment, problems with manual dexterity or learning disabilities, and people who do not have the necessary digital skills may need additional support to use the technology at home. Support may be provided by healthcare professionals, carers or, if available, digital enablers. The technologies are preprogrammed with a number of languages. If the required language is not preprogrammed, it would need to be added to the technology. Hospital attendance can be a burden, especially for people living in rural or coastal areas, which could involve a long journey on public transport or an expensive taxi. Remote monitoring could help reduce this burden by reducing unplanned and urgent hospital visits and some aspects of routine monitoring. It could also help to

improve access to specialist services for people living in geographically remote areas who live too far from hospital to be able to attend outpatient appointments.

The technologies could also help improve access to specialist heart failure services for people with HFpEF. The committee heard from a clinical expert that some heart failure specialist services are not available to people with HFpEF. This means that people with HFpEF might not have access to the same regular appointments for review of symptoms and titration of diuretics as people with HFmrEF and HFrEF. The committee recognised the potential for the technology to improve access to specialist care for people with HFpEF and people living in geographically remote areas.

Technical performance of the technologies is expected to be the same in all ethnic groups. But healthcare professionals should be aware of, and account for, other factors that could affect adherence to using the technologies and medication changes in ethnic minority groups. For example, cultural preferences, beliefs about medical treatment and degree of trust in medical professionals could affect adherence.

4 Committee members and NICE project team

This topic was considered by specialist committee members appointed for this topic and NICE's diagnostics advisory committee, which is a standing advisory committee of NICE.

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

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

Chairs

Brian Shine
Chair, diagnostics advisory committee

Neil Hawkins
Vice chair, diagnostics advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Nancy Pursey
Technical lead

Kimberley Carter
Technical adviser

Bruce Smith
Project manager

Rebecca Albrow
Associate director

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