NICE National Institute for Health and Care Excellence

NICE advice

TriageHF Plus for remotely monitoring people with cardiac implantable electronic devices at risk of heart failure or worsening heart failure

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is TriageHF Plus. It is a care pathway that includes a heart failure risk score (HFRS), an online data management platform and telephone assessment. It is used to remotely monitor people at risk of heart failure or worsening heart failure. It must be used alongside Medtronic cardiac implantable electronic devices (CIEDs) and the NICE medtech innovation briefing on CareLink network service for remote monitoring of people with cardiac devices.
- The **innovative aspects** are that, unlike other HFRSs, the TriageHF score is automated and updated every 30 days.

- The intended **place in therapy** would be alongside standard care for people at risk of heart failure or worsening heart failure.
- The **main points from the evidence** summarised in this briefing are from 7 studies (prospective cohort studies that include 3 full text articles and 4 conference abstracts) including a total of 2,110 adults with Medtronic CIEDs. They suggest that TriageHF Plus may be an effective care pathway for remotely monitoring people at risk of heart failure or worsening heart failure.
- **Key uncertainties** around the evidence or technology are that all of the evidence comes from observational studies mostly done by the same research group. The lack of a concurrent control arm in any study makes it difficult to understand the impact of TriageHF Plus on patient or healthcare system outcomes. Some evidence is published in poster abstract form so detail is limited.
- **Experts advised** that larger scale, controlled studies comparing TriageHF Plus with standard care are needed to demonstrate the claimed benefits. Multidisciplinary team involvement, training and service alignment between heart failure and cardiac physiology services is necessary for successful implementation. Additional workload burden from a large number of high-risk alerts, as well as costs, could be a barrier for its adoption.
- A **safety issue** identified by experts is the possibility of false-positive alerts, which could lead to unnecessary clinical contact and potential increased anxiety.
- The average **cost** of TriageHF Plus is approximately £43 per person per year (based on an estimated average number of eligible people per centre).

The technology

TriageHF Plus (Medtronic) is a care pathway that uses a heart failure risk score, an online data management platform and telephone assessment to remotely monitor people at risk of heart failure or worsening heart failure. It can only be used for people who have a Medtronic cardiac implantable electronic device (CIED) and needs the CareLink network service (see NICE's medtech innovation briefing on CareLink network service for remote monitoring of people with cardiac devices).

TriageHF Plus uses health-related data collected from a person's Medtronic CIED. Data is transferred from the Medtronic CIED using the advice in NICE's medtech innovation

briefing on CareLink network service. TriageHF Plus uses this data to categorise the person's risk (low, medium or high) of hospitalisation from heart failure events. The risk status reported for the next 30 days is based on the maximum daily risk status from the previous 30 days. The company claims that people with a high-risk score are 10 times more likely to be hospitalised within the next 30 days than those with a low-risk score. People who have high risk of heart failure events are contacted for a telephone appointment with a heart failure nurse.

TriageHF Plus creates a risk status by assessing the following parameters: atrial tachycardia (AT) or atrial fibrillation (AF) burden, ventricular rate during AT or AF, OptiVol fluid index (which tracks changes in thoracic impedance over time), patient activity, night ventricular rate, heart rate variability, percent of ventricular pacing, treated ventricular tachycardia or ventricular fibrillation, and defibrillator shocks.

Innovations

Unlike other risk scores, the TriageHF score is automated and updated every 30 days. Remote monitoring data is collected from Medtronic CIEDs, and people with a high-risk score are contacted by telephone. The company claims that the combination of a CIED, risk score and telephone assessment could better detect people at risk of heart failure, heart failure decompensation or fatal mortality events.

Current care pathway

NICE's technology appraisal guidance on implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure recommends using implantable cardioverter-defibrillators (ICDs), cardiac resynchronisation therapy (CRT) with defibrillator, or CRT with pacing as treatment options for specific groups that overlap with the intended population for TriageHF Plus. TriageHF Plus can only be used with Medtronic devices. One expert said that eligibility for the technology will vary between centres, because use of Medtronic CIEDs varies.

NICE's guideline on chronic heart failure in adults: diagnosis and management recommends that all people with chronic heart failure should have monitoring. Monitoring should include a clinical assessment of functional capacity, fluid status, cardiac rhythm (minimum of examining the pulse), cognitive status, nutritional status, a medication review and an assessment of renal function. The monitoring frequency should depend on the

stability of the condition but is needed at least 6-monthly for stable proven heart failure.

The British Heart Rhythm Society's clinical standards and guidelines for the follow up of cardiac implantable electronic devices (CIEDs) for cardiac rhythm management states that managing heart failure is a multidisciplinary process. It recommends that monitoring includes a regular technical review of device function, monitoring of symptoms, and management of new and changing conditions. For suspected worsening heart failure, centres should have a clear local protocol for people with CIEDs. Device follow up can be done face to face or remotely.

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

The following publications have been identified as relevant to this care pathway:

- NICE guideline on acute heart failure: diagnosis and management
- NICE guideline on chronic heart failure in adults: diagnosis and management
- NICE medtech innovation briefing on CareLink network service for remote monitoring of people with cardiac devices
- NICE technology appraisal guidance on implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure
- British Heart Rhythm Society's clinical standards and guidelines for the follow up of cardiac implantable electronic devices (CIEDs) for cardiac rhythm management.

Population, setting and intended user

TriageHF Plus is intended to be used with standard care to remotely monitor people at risk of heart failure or worsening heart failure. The technology can only be used in people with OptiVol-enabled Medtronic CIEDs but the software can be added to devices retrospectively.

TriageHF Plus can be used in primary, secondary or tertiary care depending on local heart failure management protocols and pathways. The technology can be used by different

healthcare professionals including cardiologists, cardiac physiologists, clinical pharmacists, GPs, and heart failure nurses in a hospital or community setting. The company provides face-to-face training and access to online and paper educational resources. The company also provides ongoing support from a team of heart failure specialists.

Costs

Technology costs

TriageHF Plus costs approximately £43 (excluding VAT) per person per year (based on an estimated average number of eligible people per centre). The company has an annual license fee of £17,113 per hospital site. This includes data management and software upgrades within the year of purchase. The company also has annual fees for IT maintenance, support, and data analytics of £6,994, and an initial IT governance and activation fee of £1,651.

Resource consequences

The company states that 6 NHS Trusts are currently following the TriageHF Plus care pathway.

TriageHF Plus is used with standard care and so it initially costs more than standard care alone. The company claims that the technology could lead to cost savings by reducing healthcare professional's time per assessment, optimising heart failure medication use, reducing the number of outpatient visits, reducing unplanned hospital admissions and preventing full heart failure decompensation that needs managing in hospital.

The company states that adoption of TriageHF Plus could need re-allocation of resources. If a person with disease classified as high risk cannot be contacted by telephone, the company recommends notifying their GP to make them aware. The company states that the CareLink remote monitoring platform and the TriageHF Plus data management platform are needed for people with TriageHF Plus enabled CIEDs.

Regulatory information

TriageHF Plus is a CE marked class IIb medical device regulated under the active implantable medical device (AIMD) directive.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Heart failure is most common in older people, so older people are more likely to use this technology. Age is a protected characteristic under the Equality Act 2010. TriageHF Plus can only be used with Medtronic cardiac resynchronisation therapy and implantable cardioverter-defibrillator devices with OptiVol capability.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement for medtech innovation briefings. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Seven studies are summarised in this briefing including 2,110 people. The studies are prospective cohort studies and come from 3 full text articles and 4 conference abstracts. There are also development and validation studies for the TriageHF risk score (a component of the TriageHF Plus care pathway) that are not summarised in detail in this briefing (Burri et al. 2018, Cowie et al. 2013, Gula et al. 2014, Koehler et al. 2019 and Whellan et al. 2010).

There are further abstracts evaluating the TriageHF Plus care pathway that are not summarised in this briefing because they are based on analyses of studies already captured below, or are lacking in detail (Ahmed et al. 2020a, Ahmed et al. 2018, Virani et

al. 2016a, Virani et al. 2016b, Virani et al. 2016c and Zieroth et al. 2016).

The clinical evidence and its strengths and limitations are summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The evidence base for the technology is of low to moderate methodological quality. Six of the 7 included studies were done in the UK and so are generalisable to the NHS. The evidence mainly comes from observational studies done by the same research group, so the samples may have some overlap between publications. Some evidence is published in poster abstract form so detail is limited.

The evidence suggests that a high heart failure risk score combined with a telephone assessment may be a useful screening pathway for people at risk of heart failure or with worsening heart failure. However, none of the included studies were randomised and only 1 study made a comparison of TriageHF Plus with standard care (via an unselected historical control group). All 7 studies contained a telephone assessment, but some did not need this and screening questions were not standardised. Three of the studies had authors who had received funding from the company or were company employees. The evidence base would benefit from randomised controlled trials comparing the technology with standard care, focused on cardiovascular and all-cause unplanned hospitalisations, death and other long-term health outcomes.

Ahmed et al. (2021)a

Study size, design and location

Prospective multi-centre cohort study of 415 people with Medtronic cardiac implantable electronic device (CIED) in the UK.

Intervention and comparator

TriageHF Plus compared with a historical control group receiving standard care.

Key outcomes

In the TriageHF Plus cohort there were 135 unplanned all-cause hospitalisations, compared with 358 in the standard care cohort. Rates per person per year for all-cause admissions (0.41 versus 0.57, p=0.001), cardiovascular admissions (0.14 versus 0.29, p=0.037) and heart failure admissions (0.02 versus 0.07, p=0.003) were all significantly lower in the TriageHF Plus cohort.

Strengths and limitations

This study is reported in poster abstract form only, so detail is limited. The control group was based on retrospective data, so treatment allocation was not randomised and there is potential for selection bias.

Ahmed et al. (2019)

Study size, design and location

Prospective single-centre real-world evaluation of 231 people in the TriageHF Plus care pathway in the UK.

Intervention and comparator

TriageHF Plus high heart failure risk score (HFRS) with telephone assessment compared with low or medium HFRS with telephone assessment.

Key outcomes

Over 27 months, 118 people had a high HFRS. There were 113 people with a low or medium HFRS. Telephone contact was made in 127 out of 157 (80.9%) high HFRS cases. At telephone consultation, 90 out of 127 contacts (70.9%) had worsening heart failure or another acute medical problem. Out of 127 contacts, 36 had no apparent cause for high HFRS, but the telephone contact prompted interventions in 8 cases. In the low or medium HFRS comparator group, 98 out of 113 people (86.7%) could be contacted. Of these, 1 person reported worsening heart failure symptoms. No other acute medical issues were identified. The telephone questions specified in the study protocol had 98.6% concordance with the healthcare professional's judgement on whether a person had worsening heart failure. In the 71 people who had either isolated worsening heart failure

(n=64), or worsening heart failure with a concurrent medical problem (n=7), the sensitivity of a high HFRS to identify worsening heart failure was 98.6% (92.5 to 100.0%) and specificity was 63.4% (55.2 to 71.0%). Overall accuracy was 74.7% (68.5 to 80.2%).

Strengths and limitations

This is a real-world evaluation of the TriageHF Plus care pathway. The study did not collect outcome data beyond the time of assessment and cannot be used to understand the impact of TriageHF Plus on outcomes such as unplanned hospitalisation and death. It also cannot compare outcomes for people with high HFRS alerts who were contacted versus those who were uncontactable.

Garner et al. (2022)

Study size, design and location

Prospective single centre cohort study of 188 people with Medtronic CIED in the UK.

Intervention and comparator

TriageHF Plus, no comparator.

Key outcomes

Over 24 months, 367 high HFRS alerts were received for 188 people. The mean number of alerts per person was 1.95, and 44 (23%) people had more than 3 high alerts. Contact was made for 303 (87%) alerts. No intervention was needed for 128 (35%) alerts (68 were asymptomatic, 49 were improving clinically and 11 had previously been actioned). There were 53 (28%) unplanned hospital admissions within 6 weeks of the high alert, and 24 of these were for heart failure decompensation. A total of 33 (18%) people died during follow up. The authors concluded that people with high-risk alerts are comorbid and have significant healthcare resource use. The study described the effect on workload, noting that there was only a small number of high-risk alerts when these were shared between different teams. Some users felt that they became unfamiliar with the care pathway, which led to reduced staff engagement.

Strengths and limitations

This study was done in the UK and is generalisable to the NHS. It gives an insight into the implementation of TriageHF Plus within the NHS after 2 years, including the impact on workload. The main limitation is the non-comparative design. Without a control, the impact on outcomes cannot be attributed to TriageHF Plus. One author has received fees from Medtronic for educational activities, grants and consultancy work. Two authors have received honoraria from Medtronic for training and educational activity.

Virani et al. (2018)

Study size, design and location

Prospective multi-centre evaluation of 100 people with systolic heart failure implanted with a Medtronic CIED in Canada.

Intervention and comparator

TriageHF Plus HFRS, no comparator.

Key outcomes

After 8 months, 87 people were included in the study, 5 people withdrew because of system modifications, 3 people died and 5 people withdrew for other reasons or were lost to follow up. During the study, 24 high HFRS alerts were received, resulting in telephone contact in 16 people. Symptoms and behaviours associated with worsening heart failure were seen in 83% of telephone interviews. Excluding non-compliance, symptoms and behaviours of worsening heart failure were identified in 63% of telephone interviews. During the study, 31 medium risk alerts (8.4%) resulted in a telephone assessment based on healthcare professional's discretion. Excluding non-compliance, 25 interviews showed 1 symptom or behaviour of worsening heart failure. At the beginning and end of the study, HFRS-estimated risk burden correlated well with healthcare professional's clinical assessment of heart failure risk in the next 90 days ($p<0.05$ for baseline and exit visit). Interventions occurred in 13 (54%) people with high-risk scores and 24 (6.4% of all and 77% of contacted) people with medium risk scores. A total of 28 hospitalisations happened during the study, 13 of which were thought to be heart-failure related.

Strengths and limitations

This study suggests that a high HFRS correlates with signs, symptoms and behaviours associated with worsening heart failure. The study did not need a standardised telephone assessment in response to a high-risk score, or a minimum alert frequency, so clinical status may have differed between alerts and it does not adhere to TriageHF Plus requirements. Two authors received research grants from Medtronic and 3 authors are employees of Medtronic.

Ahmed et al. (2021)b

Study size, design and location

Prospective real-world evaluation of 415 people with Medtronic CIED in the UK.

Intervention and comparator

TriageHF Plus, no comparator.

Key outcomes

Over 15 months, 159 TriageHF Plus assessments were triggered for 102 people. Successful contact was made in 148 (93%) alerts (median time to contact 3 days, median call length 10 minutes). During the study, 70 out of 148 (47%) alerts identified an acute medical issue, including worsening HF for 47 (32%) alerts and non-HF issues for 33 (22%) alerts. Interventions were done in 44 cases (63% of acute issues). For those without an acute medical issue (n=78), 13 (17%) reported recent hospitalisation or intervention. Out of 148 contacts, 110 (77%) had a 30 day follow-up telephone assessment (median call length 9 minutes). There were 24 out of 30 (80%) cases with an acute medical issue and an intervention with reported improvements at 30 days. In 5 cases the person was hospitalised within 30 days of initial assessment. Average weekly workload to manage the whole population (n=415) was 96.4 minutes.

Strengths and limitations

This study is reported in poster abstract form only, so detail is limited. Without a control, the impact on outcomes cannot be attributed to TriageHF Plus.

Bachtiger et al. (2021)

Study size, design and location

Prospective real-world evaluation of 435 people with Medtronic CIEDs in the UK.

Intervention and comparator

TriageHF Plus, no comparator.

Key outcomes

During the study, 87 high HFRS alerts were received and followed up for a telephone assessment. Out of 82 people, 72 (82.8%) with a high-risk score were successfully contacted. Clinical diagnoses for people with high-risk scores included isolated heart failure (18.3%), heart failure concurrent to medical problem (5.7%), alternative medical problem (10.3%) and recent hospital admission (8.0%). Telephone assessment confirmed there was no acute cause for the high-risk scores in 40.2% of people. The sensitivity for detection of worsening heart failure was 87.9% (0.77 to 0.99) and specificity was 59.4% (0.50 to 0.69).

Strengths and limitations

This study is reported in poster abstract form only, so detail is limited. Without a control, the impact on outcomes cannot be attributed to TriageHF Plus.

Ahmed et al. (2020)c

Study size, design and location

Prospective evaluation of 326 people with Medtronic CIEDs in the UK.

Intervention and comparator

TriageHF Plus, no comparator.

Key outcomes

Telephone contact was made with 245 people with a high HFRS. At telephone assessment, 194 (79.1%) people reported an acute medical issue, 137 (70.6%) reported symptoms consistent with worsening heart failure needing intervention, and 57 (29.4%) had an alternative acute medical problem. 51 (26.2%) people had no apparent reason for the high-risk score. The sensitivity of CIED-based remote monitoring to identify any heart failure and non-heart failure events needing intervention was 99.5% (97.2 to 99.9%) and specificity was 65.5% (57.3 to 73.2%). Positive predictive value was 79.2%. The negative predictive value of a non-high-risk score to rule out an acute event was 98.9%. Overall accuracy of the pathway to identify an acute issue (heart failure or non-heart failure related) was 84.8%.

Strengths and limitations

This study is reported in poster abstract form only, so detail is limited. Without a control, the impact on outcomes cannot be attributed to TriageHF Plus.

Sustainability

The company claims that TriageHF Plus has an environmental, health, safety and energy (EHSE) evaluation integrated into its product design, manufacturing, distribution procurement, business processes and services. It claims that this will reduce EHSE risks, improve EHSE performance of operations, improve product and packaging across their lifecycle, and promote pollution prevention and the efficient use of energy.

Recent and ongoing studies

What is the workload burden associated with using the TriageHF Plus care pathway? A Prospective TriageHF Plus evaluation. ClinicalTrials.gov identifier: NCT04177199. Status: recruiting. Indication: heart failure. Device: TriageHF Plus. Estimated study completion date: October 1, 2023. Country: United Kingdom.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not

represent NICE's view.

All 4 experts were familiar with the technology and 3 had used the technology before.

Level of innovation

All experts agreed that TriageHF Plus is an innovative care pathway for managing risk of heart failure or worsening heart failure in people with cardiac implantable electronic devices (CIEDs). Two experts said that it is different to current standard care because patient symptoms can be monitored remotely. Another expert said that it varied from current standard care because a patient can be assessed for risk of heart failure or worsening heart failure automatically and more efficiently, which could lead to more people being assessed. Two experts felt that the technology could replace current standard care for people with compatible devices. Two experts said that the technology would be used in addition to standard care, with 1 stating that it needs clinician interpretation, assessment and action. All 4 experts said that other competing technologies are available that offer remote monitoring capabilities depending on the type or brand of device. One expert said that these competing technologies have less structured alerts and less validation than TriageHF Plus. Another expert said that TriageHF Plus was unique as it can measure OptiVol fluid index tracking thoracic impedance and it does not rely on the patient entering data to prompt or influence the timing of data collection.

Potential patient impact

All experts agreed that TriageHF Plus may lead to earlier identification of people at risk of heart failure decompensation, which could result in earlier intervention and fewer hospitalisations. Two experts said that it could lead to improved patient outcomes and health status. One expert said that people will benefit from reduced face-to-face reviews. The experts agreed that TriageHF Plus could be beneficial for people with Medtronic CIEDs who are at risk of heart failure. One expert specifically noted that it would be beneficial for people with a diagnosis of heart failure and reduced ejection fraction. One expert stated that the number of people eligible for TriageHF Plus will vary between centres depending on the usage of Medtronic CIEDs.

Potential system impact

All the experts agreed that TriageHF Plus could change the current care pathway and reduce the burden of monitoring and follow up for heart failure. Three experts felt that the technology could reduce hospitalisations, and 2 experts said it could also reduce the number of hospital visits and healthcare professional resources. All experts agreed that there would be an initial upfront cost for the technology, but that this could lead to cost savings over time by reducing hospitalisations.

All experts agreed that system benefits could be seen if a robust pathway is in place for the technology. Three experts said that multidisciplinary team involvement between heart failure and cardiac physiology services is necessary for successful implementation. One expert said that appropriate IT infrastructure and phone services should be in place for clinicians. One expert also said that a robust community heart failure service is likely to be needed, to ensure that risks identified as part of the TriageHF Plus care pathway result in action to improve patient care. One expert stated that the high number of alerts generated by the technology could lead to a high volume of additional work which would need additional staffing arrangements. They also said that chronic understaffing of heart failure services and recent increases in the number of heart failure patients may make implementation of TriageHF Plus difficult. Another expert agreed that the additional workload burden, as well as costs, could be a barrier for adoption. However, Garner et al. (2022) describes a small effect on workload, but with the challenge that some users became unfamiliar and less engaged with the pathway due to receiving few high alerts.

General comments

All 4 experts said that specific training for staff in cardiac physiology and heart failure services would be needed to use the technology. All the experts agreed that there are no potential harms from the technology if it is implemented effectively. Three experts said that the technology could produce false-positive alerts, and 2 experts stated that this could lead to unnecessary contact from the heart failure nurse, which could lead to increased patient anxiety. One expert noted that in Ahmed et al. (2019), no concerning patient features were identified in 29% of high-risk alerts, which represents a relatively high rate of false-positive alerts. One expert also said that there was a potential risk of unactioned heart failure events if there was long-term sickness in the clinical team, or if they were unable to contact patients.

One expert felt that the evidence base for TriageHF is currently limited, and another stated

the need for a randomised controlled trial comparing standard care with TriageHF Plus. The experts felt that future studies would benefit from including the following outcomes: heart failure hospitalisation, heart failure symptoms, response to alerts within 1 week, changes in medications or treatments arising from alert responses, healthcare resource use, quality of life and patient satisfaction. One expert also noted a need to establish the health economic case for using the technology in practice.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Matthew Kahn, consultant cardiologist, Liverpool Heart and Chest Hospital. Part of an ongoing study looking at the use of TriageHF Plus. Has been on the advisory board for TriageHF Plus and has received speaker fees from Medtronic.
- Dr Archana Rao, consultant cardiologist, Liverpool Heart and Chest Hospital. Has received honoraria for educational activity with Medtronic.
- Dr James Gamble, consultant cardiologist, Oxford University Hospitals NHS Foundation Trust. Has been paid by Medtronic to give an educational talk about cardiac resynchronisation therapy (not TriageHF Plus). Received sponsorship from Medtronic to attend educational events.
- Toni Weldon, lead heart failure specialist nurse, Northern Care Alliance. Received compensation for participating in TriageHF Plus steering committee meeting.

Development of this briefing

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

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