Technoleg Iechyd Cymru
Health Technology Wales

# Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

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| **Topic:** | Heart failure risk status tool and telephone triage for remote monitoring of worsening heart failure |
| **Topic exploration report number:** | TER278 |

## Introduction and aims

Health Technology Wales researchers searched for evidence on heart failure risk status (HFRS) and Triage-HF.

Heart failure is a condition associated with significant morbidity and mortality. Heart failure is associated with increased healthcare utilisation as well as negatively impacting quality of life. Heart failure is a common cause of hospitalisation, NICE (2014) reported over 67,000 admissions in England and Wales, it was the leading cause of hospital admission for those aged over 65.

Temporal changes in physiological parameters may precede symptoms of worsening heart failure. Cardiac implantable devices can continuously monitor trends in physiological parameters, allowing remote monitoring and management. Predictive algorithms could integrate physiological data from the implantable devices and classify patients' risk for heart failure and hospitalisation. Predictive algorithms could identify worsening heart failure and offer an opportunity for timely intervention and active management (Ahmed et al. 2020b).

## Summary of evidence

### Primary studies

The study by Virani et al. (2018) was conducted in 100 patients and it showed that high HFRS has good predictive accuracy for patient-reported signs, symptoms and behaviours associated with worsening of heart failure. The authors concluded that HFRS may be a useful tool for ambulatory heart failure monitoring to improve both patient-centred and health system level outcomes.

The study by Burri et al. (2018) used a post hoc analysis of data from 722 patients looking to validate the HFRS for stratifying patient risk. The study assessed the association of HFRS with heart failure symptoms and investigated the utility for triage using automatic alerts. The results

indicated that a high HFRS was associated with a significantly increased risk of admission over the next 30 days. The authors concluded that HFRS may be useful for deploying automatic remote monitoring alerts.

The real-world evaluation of a clinical pathway by Ahmed et al. (2020b), called Triage-HF Plus, involving HFRS plus telephone triage investigated 157 high-risk HFRS transmissions refered for telephone triage. From the successful telephonic contacts made for 127 patients, 71 patients had confirmed worsening of heart failure and 19 had an alternative acute medical problem. The authors consluded that Triage-HF Plus is a potentially useful remote monitoring tool for patients with heart failure and cardiac implanted electronic devices.

### Ongoing clinical trials

Two relevant clinical trials were identified with completion dates estimated in December 2021 and January 2027. Both trials appear to follow an observation cohort design.

## Areas of uncertainty

Although a limited amount of evidence highlights some benefits associated with the use of the technology, multiple areas of uncertainty remain to be clarified. These include:

- Has the HFRS algorithm been validated as a clinical tool?
- Does the technology have the right regulatory approval for use?
- Could the algorithm and associated clinical pathway be used only with a single manufacturer of cardiac implantable devices?
- Does the algorithm constitute a technology used for diagnostics? If so, does it require diagnostic accuracy studies in order to prove its effectiveness?
- What constitutes standard of care for the management of patients with cardiac implantable devices/heart failure?

## Conclusions

The identified evidence shows that a potential improvement in the management of patients with heart failure may be achieved as a result of the intervention. However, the evidence base on both the algorithm and the new clinical pathway is limite. The addition of clinical studies that follow a randomised controlled design would be beneficial for understanding the impact of this intervention.

## Brief literature search results

| Resource | Results |
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| HTA organisations | |
| Healthcare Improvement Scotland | We did not identify any relevant guidance from this source. |
| Health Technology Assessment Group | We did not identify any relevant evidence from this source. |
| Health Information and Quality Authority | We did not identify any relevant guidance from this source. |
| EUnetHTA | We did not identify any relevant guidance from this source. |
| International HTA Database | We did not identify any relevant guidance from this source. |
| UK guidelines and guidance | |
| SIGN | We did not identify any relevant guidance from this source. |
| NICE | We did not identify any relevant guidance from this source. |
| Secondary literature and economic evaluations | |
| https://www.epistemonikos.org/en/ | We did not identify any relevant evidence from this source. |
| https://www.tripdatabase.com/ | We did not identify any relevant evidence from this source. |
| Cochrane library | We did not identify any relevant evidence from this source. |
| Medline (via Ovid or Pubmed) | We did not identify any relevant evidence from this source. |
| Primary studies | |
| https://www.epistemonikos.org/en/ | We did not identify any relevant evidence from this source. |
| https://www.tripdatabase.com/ | Virani SA, Sharma V, McCann M, et al. (2018). Prospective evaluation of integrated device diagnostics for heart failure management: results of the TRIAGE-HF study. ESC Heart Failure. 5(5): 809-17. doi: 10.1002/ehf2.12309 |
| Cochrane library | We did not identify any relevant evidence from this source. |
| Medline | Burri H, Da Costa A, Quesada A, et al. (2018). Risk stratification of cardiovascular and heart failure hospitalizations using integrated device diagnostics in patients with a cardiac resynchronization therapy defibrillator. Ep Europace. 20(5): e69-e77. |
| Ongoing primary or secondary research | |
| PROSPERO database | We did not identify any relevant evidence from this source. |
| Clinicaltrials.gov | NCT04489225 - Personalized Therapy Study - HFRS (TriageHF) Post Approval Study. Observational, cohort, prospective. Estimate study completion date: January 2027.<br>NCT04177199 - What is the Workload Burden Associated With Using the Triage HF+ Care Pathway? (TRIAGE-HF). Observational, cohort, prospective. Estimated study completion date: December 2021. |
| Other | |
| Evidence used for background section | NICE. (2014). Acute heart failure: diagnosis and management [CG187]. National Institute for Health and Care Excellence. Available at: https://www.nice.org.uk/guidance/cg187 [Accessed 06.05.2021]. |

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| Evidence provided by topic proposer | Ahmed FZ, Crosbie C, Kahn M, et al. (2020a). Protecting the most vulnerable during COVID-19 and beyond: a case report on the remote management of heart failure patients with cardiac implantable electronic devices. European Heart Journal: Case Reports.<br>Ahmed FZ, Taylor JK, Green C, et al. (2020b). Triage-HF Plus: a novel device-based remote monitoring pathway to identify worsening heart failure. ESC Heart Failure. 7(1): 108-17. doi: https://doi.org/10.1002/ehf2.12529<br>Virani SA, Sharma V, McCann M, et al. (2018). Prospective evaluation of integrated device diagnostics for heart failure management: results of the TRIAGE-HF study. ESC Heart Failure. 5(5): 809-17. doi: 10.1002/ehf2.12309 |

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| **Date of search:** | *May 2021* |
| **Concepts used:** | Triage-HF, Triage Heart Failure, heart failure risk status, HFRS |