ESC HEART FAILURE
ESC Heart Failure 2020; **7**: 108–117
Published online 3 December 2019 in Wiley Online Library (wileyonlinelibrary.com) **DOI:** 10.1002/ehf2.12529

ORIGINAL RESEARCH ARTICLE

Triage-HF Plus: a novel device-based remote monitoring pathway to identify worsening heart failure

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Abstract

Aims Remote monitoring of patients with physiological data derived from cardiac implanted electronic devices (CIEDs) offers potential to reconfigure clinical services. The 'Heart Failure Risk Score' (HFRS) uses input from integrated device physiological monitoring to risk-stratify patients as low-risk, medium-risk, or high-risk of a heart failure event in the next 30 days. This study aimed to evaluate a novel clinical pathway utilizing a combination of CIED risk-stratification and telephone triage to identify patients with worsening heart failure (WHF).

Methods and results A prospective, single-centre, real-world evaluation of the 'Triage-HF Plus' clinical pathway (HFRS in combination with telephone triage) over a 27 month period. One hundred and fifty-seven high-risk HFRS transmissions were referred for telephone triage assessment. Interventions were at the discretion of the clinical assessor acting in accordance with clinical guidelines. An additional 3month consecutive sample of low and medium HFRS transmissions (control group) were also contacted for telephone triage assessment (n = 98). Successful telephone contact was made in 127 (81%) of referred high-risk HFRS cases: 71 (55.9%) were confirmed to have WHF requiring intervention; 19 (14.9%) had an alternative acute medical problem; one patient had been recently discharged from hospital with WHF; and 36 (28.0%) had no apparent cause for the high score. In the control group, only one patient had symptoms of WHF. The sensitivity and specificity of CIED-based remote monitoring to identify WHF 98.6% (92.5–100.0%) and 63.4% (55.2–71.0%), respectively.

Conclusions The Triage-HF Plus clinical pathway is a potentially useful remote monitoring tool for patients with heart failure and *in situ* CIEDs.

Keywords Health care innovation; Patient centred care; Disease management; Health care delivery systems; Telemedicine; Integrated diagnostics

Received: 10 March 2019; Revised: 8 August 2019; Accepted: 6 September 2019
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Introduction

Unplanned hospitalizations due to worsening heart failure (WHF) are common and expensive.[1] Although the majority of patients with WHF experience symptomatic deterioration in the days or weeks preceding a hospitalization, many do not seek medical attention until they present to the emergency department.

Temporal changes in physiological parameters may precede signs and symptoms of WHF.[2] Contemporary cardiac implantable electronic devices (CIEDs), including pacemakers for bradycardia, implantable cardioverter-defibrillators (ICD), and cardiac resynchronization therapy (CRT) devices have the ability to continuously monitor trends in physiological parameters such as thoracic impedance, Optivol™ fluid index (which tracks changes in thoracic impedance over time), arrhythmia burden, percentage of pacing, diurnal heart rate variability, and patient activity. There has therefore been significant interest in the potential use of real-time data from CIEDs for the remote monitoring (RM) and management of

HF.[3–6] In Medtronic systems, these physiological data are stored within the device until downloaded to the CareLink network at the time of a scheduled download, manually by the patient, or if an abnormal CareAlert is triggered.

The use of physiological parameters from CIEDs to facilitate RM is hotly debated.[7] Although many platforms have shown predictive accuracy,[8–10] interventional studies have demonstrated variable success.[3,6,11] This may in part be due to variability in the clinical pathways utilized to implement predictive algorithms. The failure of the Remote Management of Heart Failure Using Implantable Electronic Devices study (REM-HF) (a multicentre randomized control trial of active device-based RM versus usual care) to impact on outcomes has cast doubt onto the utility of CIED RM platforms to aid in the monitoring of HF stability.[3] The Heart Failure Risk Score (HFRS) is an algorithm that integrates physiological data from CIEDs to classify a patient's risk of HF hospitalization in the next 30 days as high, medium, or low.[9] In the initial validation study (a post-hoc analysis), the rate of HF hospitalization was 6.8% in the 'high-risk' HFRS group compared with only 0.6% in the low-risk HFRS group; a 10-fold increased risk. Further post-hoc analyses of HFRS performance have yielded comparable observations.[5,12,13] Prospective evaluation of the HFRS has been limited to a single study of 100 patients and 24 high HFRS transmissions.[14] Early results from this pilot are promising, however are yet to be replicated in larger studies. Large-scale real-world data are lacking.

At our institute, Medtronic CareLink transmissions from the ambulatory CIED population are routinely reviewed as part of the standard clinical practice. Similarly, we have incorporated CareLink transmissions based on HFRS into our clinical practice; high-risk alerts prompt a telephone consultation with the patient, based upon which appropriate clinical action is instigated—this has become known as the 'Triage-HF Plus pathway'. In this study, we prospectively evaluated the real-world accuracy of HFRS to identify patients with WHF and evaluated a novel clinical pathway (Triage-HF Plus) combining HFRS risk-stratification with telephone triage to facilitate their remote detection and active management.

Objectives

Our aims were (i) to evaluate the accuracy of the HFRS to identify patients with WHF and (ii) to evaluate the Triage-HF Plus clinical pathway.

Methods

Study design

Observational (evaluation of usual clinical care) cohort study undertaken according to STARD statement for reporting of diagnostic accuracy studies.[15]

Setting

The Manchester Heart Centre (MHC) is a tertiary referral centre for CIED implantation and follow-up that serves a local population of 213 000 patients and the wider conurbation of Greater Manchester.

Participants

Inclusion criteria

Adult patients with HFRS-enabled Medtronic CIEDs under follow-up at our hospital between 21 June 2016 and 21 September 2018 were included. Types of CIEDs included were CRT [CRT-D (with defibrillator) and CRT-P (with pacemaker)], ICDs, and permanent pacemakers.

Exclusion criteria

Patients aged <18 years were excluded. Patients with a high-risk HFRS who we were unable to contact by telephone on three separate occasions were not included (having excluded hospital admission as the reason for non-contact).

Ethics

The Institutional Research Board reviewed the proposal to respond to Medtronic CareLink HFRS-based alerts and approved the use of the One Clinical Service database as a data collection tool to support the service evaluation. On the basis that we routinely respond to CareLink alerts in our existing practice, the Ttriage-HF service evaluation would represent an extension of this existing clinical service. Specific consent for patient data to be used in this study was not therefore required. All patients provided written informed consent ahead of enrolment onto the CareLink network.

Protocol

All CareLink transmissions from patients with a HFRS-enabled device were routinely reviewed by a cardiac physiologist. The majority of patients were monitored via a 3monthly automated or manual remote download regimen with an additional annual face-to-face outpatient clinic review as per the HRS/EHRA recommendations.[16] In addition, patients have the option to perform manual downloads at any time that was encouraged in the setting of altered clinical status or new symptoms. If a patient's device had the 'CareAlert' function activated, a transmission would also be pulled immediately in response to detection of new atrial fibrillation, ventricular arrhythmia, or (if activated) high OptiVol™. At the time of each transmission, a HFRS was produced based on the highest daily score in the preceding 30 days. Following a review by a cardiac physiologist, all high-risk HFRS

transmissions were forwarded to a member of the Triage-HF Plus team (consultant cardiologist, general medicine specialist, or HF specialist nurse) to initiate a telephone consultation with the patient (*Figure 1*). High-risk HFRS transmissions referred within 30 days of a previous high score were not accepted by the Triage-HF team.

Telephone calls included standardized screening questions for clinical indicators of WHF (see *Table 1*). Telephone assessors also recorded their personal clinical impression of the patient's HF status on the basis of the responses; furthermore, they were prompted to record any possible alternative explanations for the high HFRS such as an acute medical problem or recent hospitalization. If patients had already been seen by another health care professional in relation to this episode and diagnosed either with WHF or an alternative medical problem, this information was documented.

Interventions following assessment were at the discretion of the health professional and recorded electronically. However, in cases deemed to have positive signs or symptoms of WHF, suggested actions were in line with routine clinical practice and included advising patients to (i) self-adjust their medication, (ii) present to their primary care physician who had been instructed of any proposed medication changes, or (iii) attend the outpatient HF clinic for a face-to-face

Figure 1 Triage-HF Plus Protocol. HFRS, Medtronic Heart Failure Risk Score.

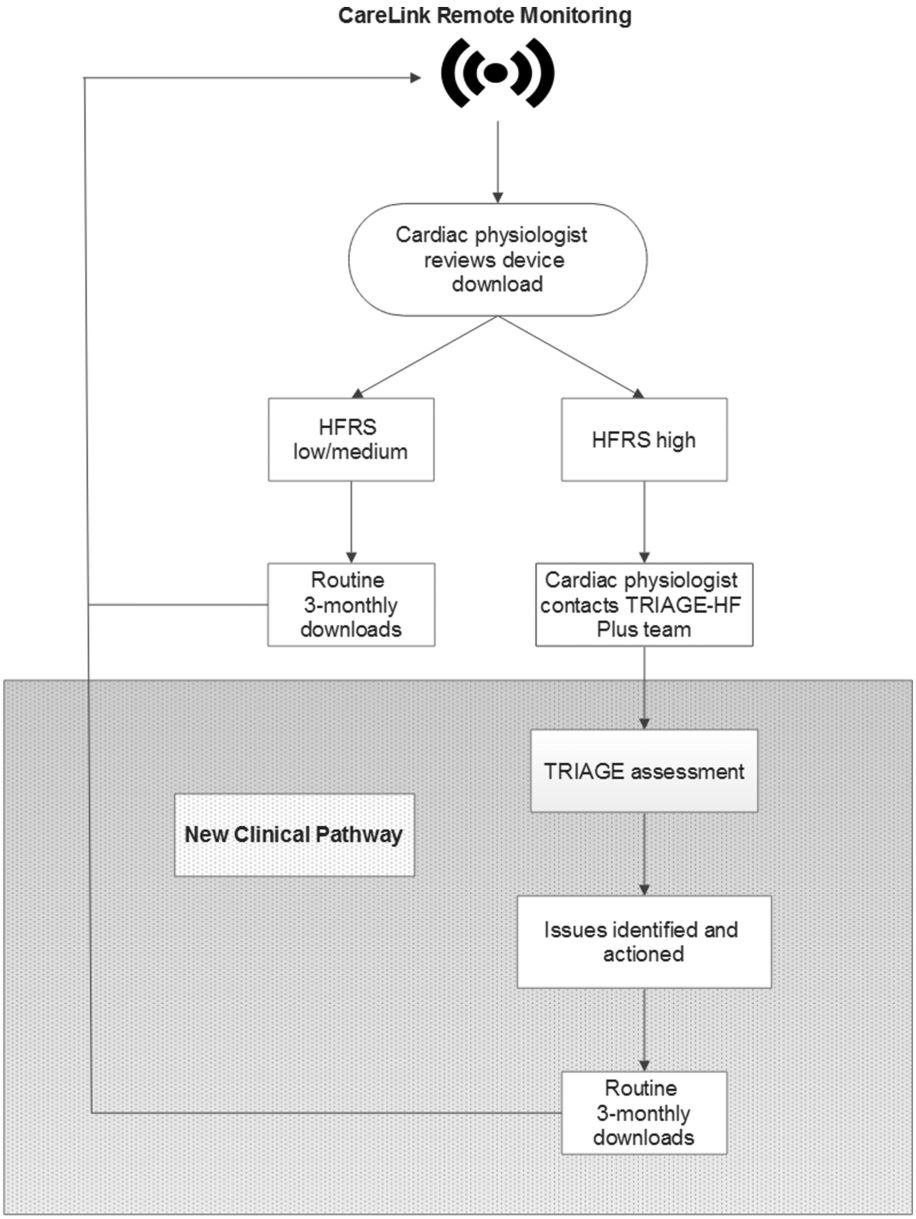


Table 1 Triage screening questions

Screening questions for indicators of worsening heart failure
1.Have you experienced any new or worsening breathlessness?
2.Have you experienced any new or worsening leg swelling?
3.Have you gained any weight?
4.Have you experienced any new or worsening fatigue?
Screening question to explore alternative or concomitant acute medical problem
5.Have you been experiencing any recent ill health or visited a doctor or nurse about anything else?

review. Cases where the diagnosis was not entirely clear were also brought to the HF clinic for a face-to-face review and further investigations where necessary. WHF was excluded in those patients who did not report a history consistent with WHF status compared with baseline. No changes were made to frequency of CIED remote transmissions as standard.

All transmissions meeting criteria for inclusion referred to the Triage-HF Plus team over the study period were added to the database. Demographic details were recorded for each unique patient at the time of the first recorded HFRS transmission during the study period. For any subsequent additional high HFRS transmission, only details of the transmission were recorded. Data regarding the overall number of transmissions received by the MHC were obtained from the online Medtronic platform (CareLink).

Comparative sample for low-risk and medium-risk Heart Failure Risk Score

Between 1 July and 1 September 2018, a 3 month sample of low-risk and medium-risk HFRS transmissions was contacted by telephone following their routine scheduled CareLink download episode. These patients were asked the same Triage-HF screening questions as those in the high-risk group, and their responses were recorded.

Definitions

'Triage positive' was considered to be the identification of WHF or any acute medical problem identified at the time of phone call. A WHF episode was diagnosed if, either at the time of telephone triage or subsequent face-to-face review, patients had any of the following: increasing shortness of breath or fatigue, worsening peripheral oedema, or weight gain suggestive fluid overload and not attributable to an alternative cause (*Table 1*). Alternative medical problems identified were defined as episodes of acute illness or an acute medical problem, such as a lower respiratory tract infection, which was judged to be the predominant issue. Patients could be deemed to have both an HF episode and a concurrent acute medical problem. For the purpose of diagnostic measures, the presence of WHF (alone or alongside an acute medical problem) was taken to be the reference standard.

Outcomes

The diagnostic accuracy of the HFRS to identify WHF was assessed by comparing high HFRS with correlating clinical diagnosis made by the assessing health care professional.

Statistical analysis

Data were managed and analysed on SPSS (version 23, 2015) and Microsoft Excel (Professional Plus 2016) software. Statistical significance was considered if $P < 0.05$. For a comparative analysis, Fisher's exact test was used for categorical data, and unpaired *t*-test for continuous data unless otherwise stated. Diagnostic measures of positive predictive values, sensitivity, and specificity were calculated by comparing the HFRS transmission risk level as high or low/medium against the reference standard, clinical diagnosis of WHF (alone or alongside an acute medical problem).

Results

High-risk Heart Failure Risk Score transmissions

Interrogation of the CareLink platform found that a total of 2329 CareLink transmissions with HFRS data were received by MHC during the evaluation period. Of these, 388 (16.7%) reported high-risk HFRS, 1182 (50.8%) reported medium-risk HFRS, and 759 (32.6%) reported low-risk HFRS. The Triage-HF Plus team were referred 157 (40.0%) of the high-risk HFRS transmissions. The 231 high-risk HFRS transmissions not referred were either repeated transmissions within the 30 day window or due to human error (referrals had to be made manually after review by a cardiac physiologist). Repeated downloads were very common as (i) patients could perform manual downloads at any time; (ii) patients were sometimes asked to repeat downloads manually; and (iii) additional downloads were sometimes performed when attending for an outpatient clinic review.

The most common abnormal HFRS parameters amongst all referred transmissions were low physical activity (89.7%), low thoracic impedance (i.e. high OptiVol™, 72.3%), and abnormal night ventricular rate (63.6%). Ninety-four (59.9%) transmissions were scheduled, 41 (26.1%) were unscheduled (assumed patient-triggered), 21 (13.4%) were automated CareAlerts, and one (0.6%) was transmitted whilst an inpatient.

Table 2 Patient demographics: high HFRS versus low/medium HFRS

Demographics	High HFRS patient cohort (n = 118) n (%)	Low/medium HFRS patient cohort (n = 113) n (%)	P value
Age (mean, SD)	71.5 ± 12.8	67.5 ± 14.9	0.027*
Sex (n, % male)	80, 67.8%	47, 41.6%	<0.001*
Type of device			
CRT-D	59 (50.0%)	34, 30.1%	0.003*
CRT-P	45 (38.1%)	49 (43.4%)	0.425
ICD	10 (8.5%)	15 (13.3%)	0.292
PPM	6 (5.0%)	15 (13.3%)	0.040*
Heart failure with reduced ejection fraction	91[a] (82.9%)	78[a] (69.6%)	0.178
Atrial fibrillation (including paroxysmal)	52 (44.1%)	44 (39.3%)	0.505
Ischaemic heart disease	76 (64.4%)	54[b] (48.6%)	0.017*
Chronic kidney disease stage 3 or greater	36 (30.5%)	33 (29.2%)	0.886
Diabetes	23 (19.5%)	22[c] (20.0%)	1
Chronic obstructive pulmonary disease	15[a] (12.8%)	19[c] (17.2%)	0.360
Prior AV node ablation	23 (19.5%)	11[a] (9.8%)	0.043*
Adult congenital heart disease	6 (5.1%)	17[a] (15.2%)	0.015*

AV, atrioventricular; CRT-D, cardiac resynchronizsation therapy device with defibrillator; CRT-P, cardiac resynchronization therapy device with pacemaker; PPM, pacemaker; SD, standard deviation.
[a]Data unavailable for one patient.
[b]Data unavailable for two patients.
[c]Data unavailable for three patients.
*denotes statistically significant at $p<0.05$.

Study population

Of the 157 transmissions received by the Triage-HF Plus team over the study period, there were 118 individual patients. Eighty-six patients had only one high-risk HFRS over the 27-month period, 27 had two, and five had three or more. In the low/medium HFRS comparative sample, there were 113 transmissions (113 individual patients), of which contact was made in 98 cases. Demographic details for the studied population, both those in the high HFRS group and those in the low/medium HFRS, are shown in *Table 2*. Of note, in the high HFRS cohort, patients were significantly older with a greater proportion of men, CRT-Ds, ischaemic heart disease, and prior AV-node ablation.

Telephone assessment

Contact was made following 127/157 (80.9%) high-risk HFRS transmissions. At telephone triage, 90 (70.9%) of contactable patients were 'Triage positive' with 71 being diagnosed with WHF (alone or alongside an acute medical problem) and required medical intervention. Nineteen had an alternative acute medical problem without WHF (of which 11 had a medical intervention). Thirty-six had no apparent cause for the high-risk HFRS, but the contact prompted opportunistic interventions in eight (*Figure 1*). In 30/157 (19.1%) transmissions, the patient was not contactable.

The 'Triage' questions suggested as part of the study protocol had 98.6% concordance with the practitioner's judgment on whether the patient had WHF. All patients with WHF at telephone screening received an intervention. *Figure 2* summarizes the clinical outcomes of the Triage positive and negative patients. *Figure 3* outlines the specific interventions.

Accuracy of low-risk and medium-risk Heart Failure Risk Score to exclude worsening heart failure (alone or alongside an acute medical problem)

Telephone contact was made for 98 patients within 30 days of their CareLink download. Of these, one patient reported WHF symptoms. No other acute medical issues were identified.

High-risk Heart Failure Risk Score to identify worsening heart failure (alone or alongside an acute medical problem)

Based upon the 71 Triage positive patients who had either isolated WHF (n=64), or WHF with a concurrent medical problem (n=7), the sensitivity and specificity of a high-risk HFRS to identify WHF were 98.6% (92.5–100.0%) and 63.4% (55.2–71.0%), respectively. Overall accuracy was 74.7% (68.5–80.2%). *Table 3* summarizes diagnostic outcomes following assessment by the Triage-HF Plus team.

High-risk Heart Failure Risk Score to identify alternative medical problems

In 19 cases, an alternative medical problem was identified without WHF. Broadening the scope of the HFRS to include all 'Triage positive' cases, that is, patients identified as having isolated WHF, WHF with concurrent medical problem, or alternative medical problem without WHF (n = 90). The sensitivity and specificity were 98.9% (94.0–100.0%) and 72.4% (64.0–79.8%), respectively. Overall accuracy was 83.1% (77.6–87.8%).

Figure 2 Outcomes from Triage assessment. HFRS, Medtronic Heart Failure Risk Score.

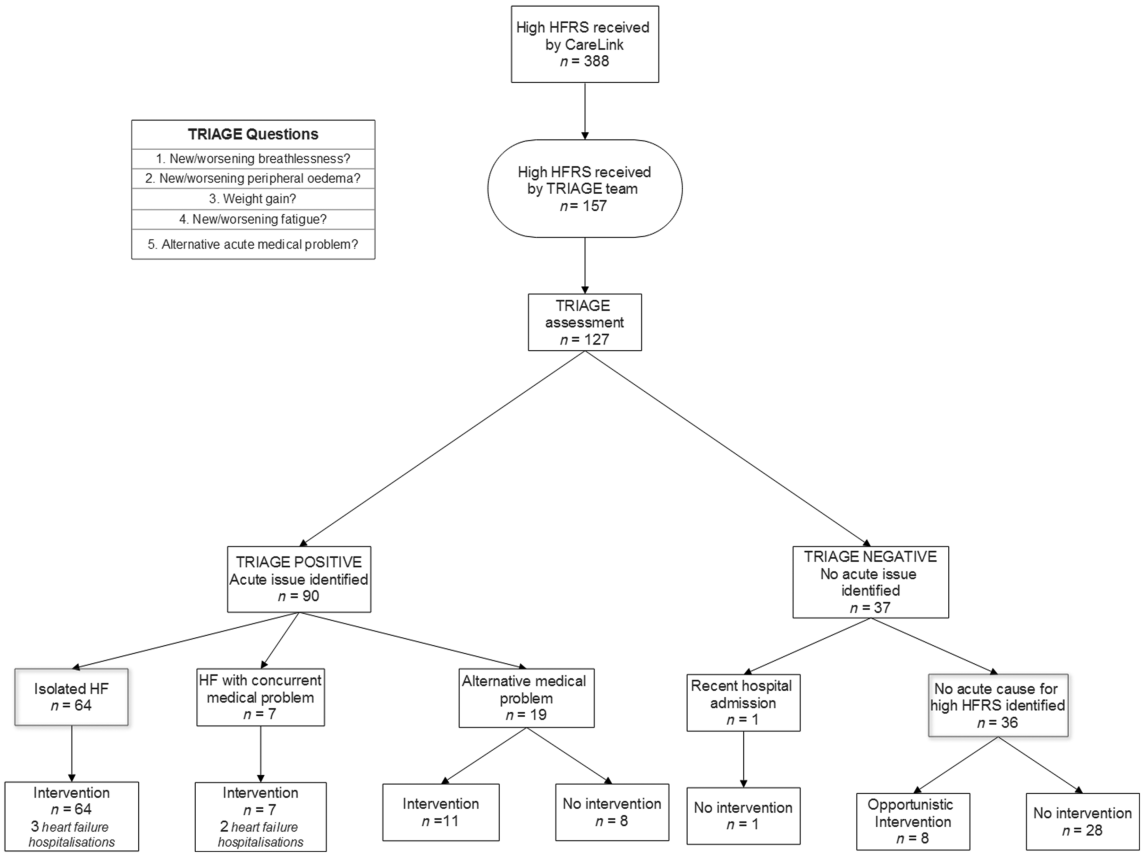
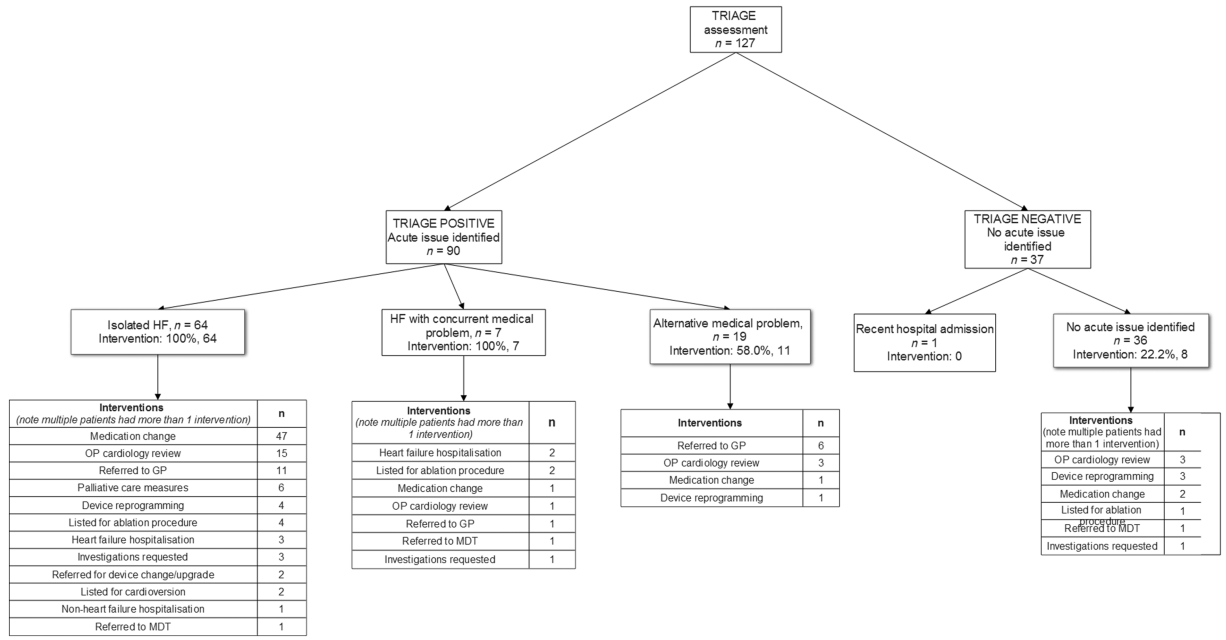


Figure 3 Interventions based on Triage outcome. HF, heart failure; GP, general practitioner; MDT, multidisciplinary team; OP, outpatient.



Interventions (note multiple patients had more than 1 intervention)	n
Medication change	47
OP cardiology review	15
Referred to GP	11
Palliative care measures	6
Device reprogramming	4
Listed for ablation procedure	4
Heart failure hospitalisation	3
Investigations requested	3
Referred for device change/upgrade	2
Listed for cardioversion	2
Non-heart failure hospitalisation	1
Referred to MDT	1

Interventions (note multiple patients had more than 1 intervention)	n
Heart failure hospitalisation	2
Listed for ablation procedure	2
Medication change	1
OP cardiology review	1
Referred to GP	1
Referred to MDT	1
Investigations requested	1

Interventions	n
Referred to GP	6
OP cardiology review	3
Medication change	1
Device reprogramming	1

Interventions (note multiple patients had more than 1 intervention)	n
OP cardiology review	3
Device reprogramming	3
Medication change	2
Listed for ablation procedure	1
Referred to MDT	1
Investigations requested	1

Table 3 Diagnostic outcomes following assessment by Triage-HF Plus team

	Clinical features of WHF and/or concomitant medical problem	No features of WHF	Total
High HFRS	71 (55.9%)	56 (44.1%)	127
Low/medium HFRS	1 (1.0%)	97 (99.0%)	98

HFRS, Medtronic Heart Failure Risk Score; WHF, worsening heart failure

Please see Supporting Information, *Table S1* for a breakdown of specific HFRS parameters, which contributed to a high HFRS for patients with WHF (alone or alongside an acute medical problem), alternative medical problem, and no acute issue identified.

Types of transmission

Forty (52.6%) scheduled transmissions were associated with WHF, compared with 20 (60.6%) patients triggered transmissions and 10 (52.6%) CareAlerts. This was not statistically significant on comparative analysis (χ^2, $P = 0.73$).

Discussion

In this study, we performed the largest real-world prospective evaluation of the HFRS algorithm to assess its accuracy in identifying WHF (alone or alongside an acute medical problem). We also evaluated the utility of the HFRS in combination with a simple telephone triage to provide a pragmatic clinical pathway for RM of the ambulatory HF population patients, allowing appropriate intervention for those deemed to be at elevated risk of HF hospitalization. The main findings of this study were the following: (i) the HFRS has high sensitivity and average specificity for detecting WHF (alone or alongside an acute medical problem), (ii) the Triage-HF Plus provides a novel, effective clinical pathway for the management of the ambulatory HF population, and (iii) we inadvertently identified the broader utility of the HFRS to identify other acute medical problems in this high health care utilization cohort.

The HFRS was designed to predict 30 day HF hospitalization. In this analysis, we tested the HFRS to identify WHF at the time of transmission within a pragmatic, real-world clinical pathway. The HFRS algorithm detects physiological parameters out-with or deviated beyond certain pre-defined thresholds; it is therefore plausible that these physiological changes may precede the development of clinically detectible signs or symptoms. The HFRS is derived from a combination of multiple parameters, with each in isolation being of limited significance. Clinically insignificant high HFRS may be triggered by transient, inconsequential shifts in parameters, particularly in patients with low-level physical activity. This is a limitation of the HFRS but perhaps highlights the potential for RM to be utilized for opportunistic intervention rather than solely acting as an event risk prediction tool.

Our results are of particular interest, as prior studies of RM and management of HF using CIED-derived data have failed to demonstrate improved patients outcomes[3,17] The REM-HF study was the largest randomized controlled study to evaluate active RM of device-based parameters in patients with ICD and CRT devices. REM-HF concluded that intensive management based on weekly device downloads did not alter the frequency of death or unplanned cardiovascular hospitalizations.[3] Triage-HF Plus differs from the REM-HF in three key ways: (i) Triage-HF Plus only actions high HFRS transmissions (REM-HF did not stratify the population according to HFRS and therefore would have considered all low-risk, medium-risk, and high-risk HFRS cases); (ii) Triage-HF Plus in its current format is an example of a high-tech and low-labour pathway, in that the upstream identification of high-risk cases by the HFRS algorithm using key physiological parameters is highly automated with relatively low labour required downstream to rule in or rule out an acute issue using a short telephone call (by comparison, in the active monitoring arm of REM-HF, routine downloads were reviewed by clinical teams on a weekly basis); and (iii) transmission frequencies remained unchanged (REM-HF performed weekly downloads). This significantly reduces the burden of implementation and allows prioritization of the least stable patients. In keeping with previous post-hoc analyses,[9,12,13] we identified a very low incidence of acute problems in the low–medium HFRS cohort, implying that proactively contacting these patients is not clinically useful due to a low event rate.

In the current study, the sensitivity of HFRS to identify WHF was high, but the specificity and positive predictive value were average—63.4% and 55.9%, respectively. Although the latter is suboptimal for a stand-alone *diagnostic* test, the use of HFRS in our pathway to streamline selected patients into a simple telephone assessment is low burden, low risk, and debatably a simple extension of optimal long-term condition monitoring. In this role, as an initial *screening* metric, it may be considered reasonable to accept the lower specificity and positive predictive value of HFRS, with error margins favouring false-positives rather than false-negatives, the intention being that the subsequent telephone triage assessment then refines the accuracy of the combined Triage-HF Plus pathway.

In the current study, comparison of the high HFRS and low/medium HFRS cohorts revealed significant differences in terms of patient demographics. This was anticipated as patients with more risk factors for unstable or progressive HF would be expected to be more likely to have abnormal physiological parameters. One interesting result was that the high HFRS had a significantly lower proportion of adult congenital heart disease patients. Whilst the relative significance of this is unclear, it is notable that this population is often a younger

heterogenous group, with less standardized indications for device therapy.

The story of RM using devices has progressed from single-physiological parameter data to sophisticated combined algorithms.[10,18,19] Partners HF used multiple physiological parameters as part of a combined device-based diagnostic algorithm to identify patients at increased risk of heart events in the next 30 days.[10] However, despite promising results from subsequent retrospective analyses, the failure to demonstrate impact on hard outcomes as presented in REM-HF and MORE-CARE was disappointing and threatened to close the door on this avenue of care. The Triage-HF Plus model permits a more focused strategy for RM of HF using integrated diagnostics, with a focus on the HFRS as an initial discriminatory tool. Moreover, one of the criticisms of previous studies of RM in HF has been that they have largely utilized active (practitioner-driven) monitoring strategies, with vast amounts of data reviewed by the clinical team with a seemingly low return. This draws attention to the fact that too much focus on the regular review of, often normal, unprocessed device-derived health related data has the potential to divert resources from direct patient facing care to administrative tasks. This highlights the point that whilst effort is important, knowing where to put the effort could ultimately make all the difference. Triage-HF Plus highlights the potential to utilize a passive monitoring strategy to manage these patients, with the need for telephone contact only in those patients who are likely to be affected by WHF or other medical issue.

Study limitations

This was an unblinded real-world evaluation of the HFRS. Assessors had freedom to intervene as felt clinically appropriate; therefore, decision making will have differed between individuals. This approach was chosen as this mirrors contemporary clinical practice. Whilst we acknowledge this as a limitation, as a single-centre evaluation with fairly homogenous guideline-directed practice amongst our clinical teams, we expect the impact of this limitation to be small.

Previous research has suggested that frequent transmissions to monitor device parameters are not clinically useful.[3,17] This study takes a more pragmatic approach, maintaining a normal 3-monthly transmission regime and accepting that some WHF events may be missed if this occurs out with the transmission window and the patient does not develop symptoms and proactively perform a manual download. As a consequence, on 71 occasions during this study, the HFRS was not high on the day of transmission, that is, the risk had 'peaked' prior to the time of review (55% were Triage negative). In 31 cases, it had been over 14 days since a high HFRS (48% Triage positive). Conversely, of those transmissions where the HFRS was high on the day of transmission, only 28% had been high for a week or less. Whilst this limits the scientific rigour with which this study can correlate the temporal relationship between HFRS and clinical features of WHF, it reflects the circumstances in which the HFRS would feasibly be used as part of a clinical pathway. Moving forward, learning from experience from this evaluation, limiting future evaluations to current generation CIEDs capable of transmitting real-time automated HFRS alerts to CareLink, would circumvent the problems posed by reliance on scheduled or manual downloads. A recent CareLink update means that the HFRS is now displayed on the CareLink transmission list, removing the need for cardiac physiologists to undertake a physical review of the download before referring on and allowing the Triage-HF team to directly identify all high HFRS cases.

The Triage-HF clinical team were not blinded to the risk score, and this had the potential to introduce a degree of cognitive bias when undertaking the telephone consultation with the patient, for both high and lower-risk cases. Our analysis relies on the assumption that WHF can, to a degree, be accurately determined over the phone by an experienced health care professional.

The Triage-HF clinical team were unable to contact 19% of patients following a high HFRS transmission—a relatively high proportion. Not everyone was contactable on the telephone numbers they had provided. Additionally, as MHC is a tertiary centre, sometimes contact details were unfortunately not up to date. A comparative analysis between patients whom were and were not contacted found they were similar in terms of demographics (see Supporting Information for more detail).

This study has not collected outcome data beyond the time of assessment; therefore, it remains unknown if the Triage-HF Plus pathway impacted on outcomes such as unplanned hospitalization and death. Similarly, we cannot compare outcomes for patients with high HFRS transmissions whom were contacted versus those whom were uncontactable. As a specialist centre, the MHC is not the local hospital for many patients under cardiac device follow-up. We do not have access to the hospitalization data for other hospital sites; therefore, it would be misleading to present data for MHC only—likely significantly underestimating hospitalization rates. This missing data could bias the accuracy of our results in terms of identifying WHF. In order for the HFRS to be formally validated as a screening tool, it requires internal and external validation in a blinded fashion across multiple sites. This study presents a real-world evaluation of a pragmatic clinical pathway based on the HFRS.

Future work

In this study, we have demonstrated the utility of the HFRS to serve as a first-line screening tool in individuals with HF and a CIED to identify patients who would benefit from a telephone assessment of HF stability and general health. Future work involves prospective collection of patient consent and ethical

approval to collect hospitalization/death data. We plan to expand the Triage-HF Plus protocol to other sites, with a view to undertaking a multicentre evaluation to establish the wider transferability of the clinical pathway.

Combining physiological device data with additional non-device parameters is an additional area of research with great potential to improve sophistication and accuracy. Multiple studies have demonstrated the utility of 'big data' from electronic health record data[20–22] and non-invasive telemonitoring[23,24] to aid risk stratification and predict 30 day HF hospitalization. Developing personalized algorithms that include temporally collected data from various sources is an exciting future prospect.

Conclusions

The Triage-HF Plus clinical pathway—combining the Medtronic HFRS and a simple telephone review—offers a feasible and clinically useful monitoring tool for HF patients with CIEDs.

Acknowledgement

We would like to acknowledge the contribution of Stuart Allen, Principle Cardiac Physiologist at Manchester University NHS Foundation Trust, for his advice pertaining to the study design and support with data collection.

Conflict of interest

F.Z.A. has previously received a research grant funded by Medtronic. F.Z.A. has received honoraria from Medtronic, Vifor, Astrazeneca, and Servier. J.K.T.'s post is currently funded by a fellowship grant supported by Medtronic. C.C. has received honoraria and speaking fees from Abbott and Medtronic. A.Z. has received honoraria from Medtronic, Abbott, and Boston Scientific. A.S. has received honoraria from Medtronic. A.G. receives a speaking fee from Medtronic for educational and training duties. The remaining authors have nothing to disclose.

Funding

No specific funding was granted to this study.

Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1. Comparison of contacted patients versus non-contacted patients following high HFRS transmission

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