HIGHLY CONFIDENTIAL

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Advisory Committee – Wednesday 19 June 2024

Algorithm-based remote monitoring of heart failure risk data in people with cardiac implantable electronic devices - 2nd meeting

The following documents are made available to the Committee:

1. **EAR addendum's -** prepared by external assessment group, Newcastle Technology Assessment Review Group, Newcastle University - Addtional analysis Singh et al study, additional PSA Analysis and additional Risk of Bias assessment.

2. **Responses to Consultation comments on the draft guidance** prepared by National Institute for Health and Care Excellence.

HIGHLY CONFIDENTIAL

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Advisory Committee – Wednesday 19 June 2024

Algorithm-based remote monitoring of heart failure risk data in people with cardiac implantable electronic devices - 2nd meeting

The following documents are made available to the Committee:

1. **EAR addendum's -** prepared by external assessment group, Newcastle Technology Assessment Review Group, Newcastle University - Addtional analysis Singh et al study, additional PSA Analysis and additional Risk of Bias assessment.

2. **Responses to Consultation comments on the draft guidance** prepared by National Institute for Health and Care Excellence.

Additional Analysis to Assessment Group's Report

Algorithm-based remote monitoring of heart failure risk data in people with cardiac implantable electronic devices

Produced by Newcastle Technology Assessment Review Group, Newcastle University

Authors
Ryan PW Kenny, Research Associate
Nawaraj Bhattarai, Senior Research Associate
Nicole O'Connor, Research Assistant
Sonia Garcia Gonzalez, Research Associate
Hannah O'Keefe, Research Associate
Sedighe Hosseini-Jebeli, Research Associate
Nick Meader, Principal Research Associate
Stephen Rice, Senior Lecturer

Correspondence to
Stephen Rice,
Population Health Sciences Institute,
Newcastle University, Newcastle upon Tyne, NE1 7RU,
Email: stephen.rice@newcastle.ac.uk

Date completed 12/06/2024

Source of funding:
This report was commissioned by the NIHR Evidence Synthesis Programme as project number *NIHR135894*.

Declared competing interests of the authors
None.

1. Summary results for Singh et al (2024) study

Singh et al (2024) was published after the date range of the systematic review and, at the request of NICE, the following is the summary of the data extracted from the Singh et al (2024) including the Author conclusions.

Singh et al 2024

N = 1458, ICD = 490, CRT-D = 968.

Mean Age (SD) = 74 (8) years

White = 86%

Male = 71%

Outcome	Data
Sensitivity for detecting usable HF events (pre-defined >40%) HF event = acute inpatient event with primary HF diagnosis, or a primary HF outpatient with IV diuretic therapy.	302 usable HG events (<11 unusable events) Sensitivity = 74.5% (95% CI: 69.2%-79.3%)
False positive alert rate per patient year (pre-defined <2.0)	1.48 per patient year (negative binomial estimate, 1.50, 95% CI: 1.42-1.59)
Mean (SD) alert duration	For the 2515 HeartLogic alerts at nominal setting (1.6 alerts per patient year) with an average alert duration of 42 (34) days.
Mean (SD) average alert lead time	For the 302 usable events, 49 (40) days.

Author conclusions:

HeartLogic performance using real-world cohort demonstrated a notable level of agreement with the results from the original study (Multisense trial) and with reports from clinical practice. Consistent early detection of worsening HF status with HeartLogic can enable a remote monitoring proactive intervention and personalised treatment optimisation. Whether this can prevent the progression of HF and decrease risk of hospitalisation remains to be evaluated.

2. No uncertainty in mortality and RMS device price

The following table and the figures report the cost-effectiveness results where no uncertainty was considered in mortality and RMS device price.

The list price (one-off £3650 per patient and no additional consumable or maintenance costs) for the HeartLogic algorithm was used. The EAR includes a confidential price for the HeartLogic algorithm.

Table 1: Probabilistic cost-effectiveness results when no uncertainty considered in mortality or RMS device price

Items	HeartLogic		TriageHF	
	I	*C*	*I*	*C*
Total				
Costs (£)	9343	17767	11682	20846
QALYs	5.84	5.83	5.84	5.82
Cumulative hospitalisations per person	1.20	4.28	2.65	6.36
Cumulative days in hospital	8.39	68.65	42.13	101.46
Cumulative Follow-up_1*	22.20	22.18	22.34	22.18
Cumulative Follow-up_2**	7.70	3.40	4.71	3.39
Proportion died after 40 years	0.97	0.97	0.97	0.97
Incremental (intervention versus comparator)				
Costs (£)	-8549		-9164	
QALYs	0.011		0.013	
Cumulative hospitalisations per person	-3.09		-3.71	
Cumulative days in hospital	-60		-59	
*Cumulative Follow-up_1**	0.02		0.16	
*Cumulative Follow-up_2***	4.30		1.32	
Proportion died after 40 years	0		0	
ICER	Dominant		Dominant	

I: Intervention; C: Comparator;

* Follow-up_1: Scheduled visits; **Follow-up_2: Unscheduled visits;

The cost-effectiveness acceptability curves (CEACs) (Figure 2 and Figure 4) show that both the HeartLogic and TriageHF RMS have a 100% probability of being cost-effective at willingness to pay (WTP) values of both £20,000 and £30,000.

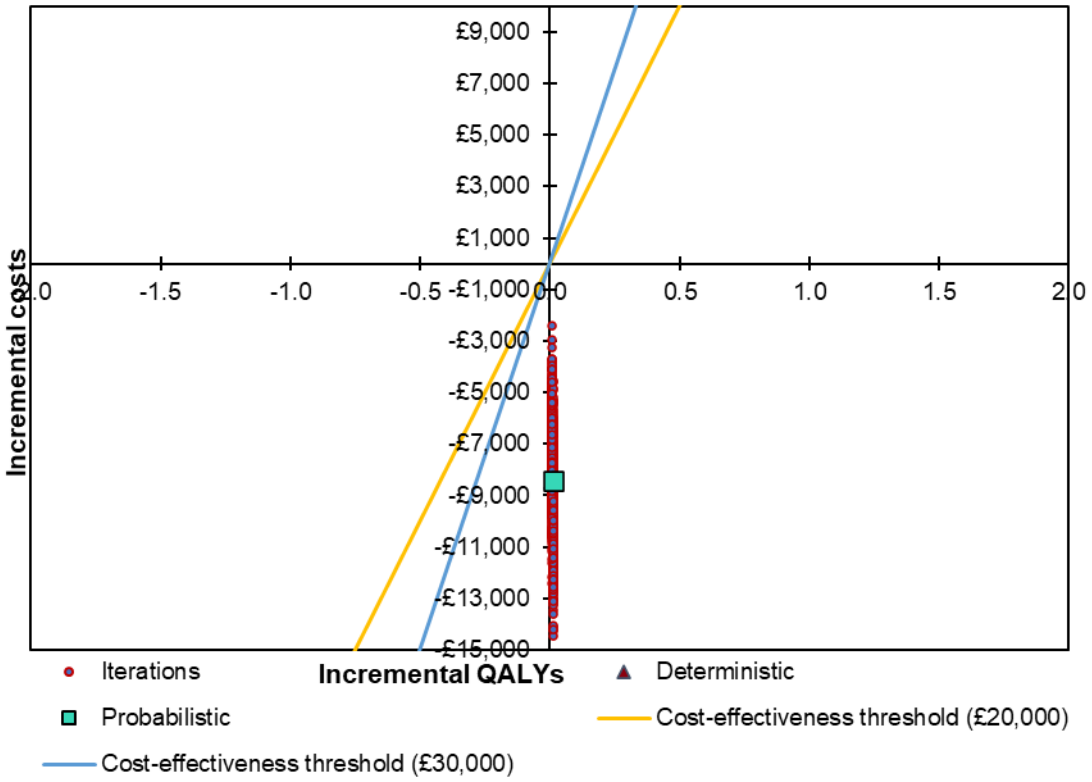

Figure 1: Cost-effectiveness plot with no uncertainty considered in mortality or RMS device costs (HeartLogic)

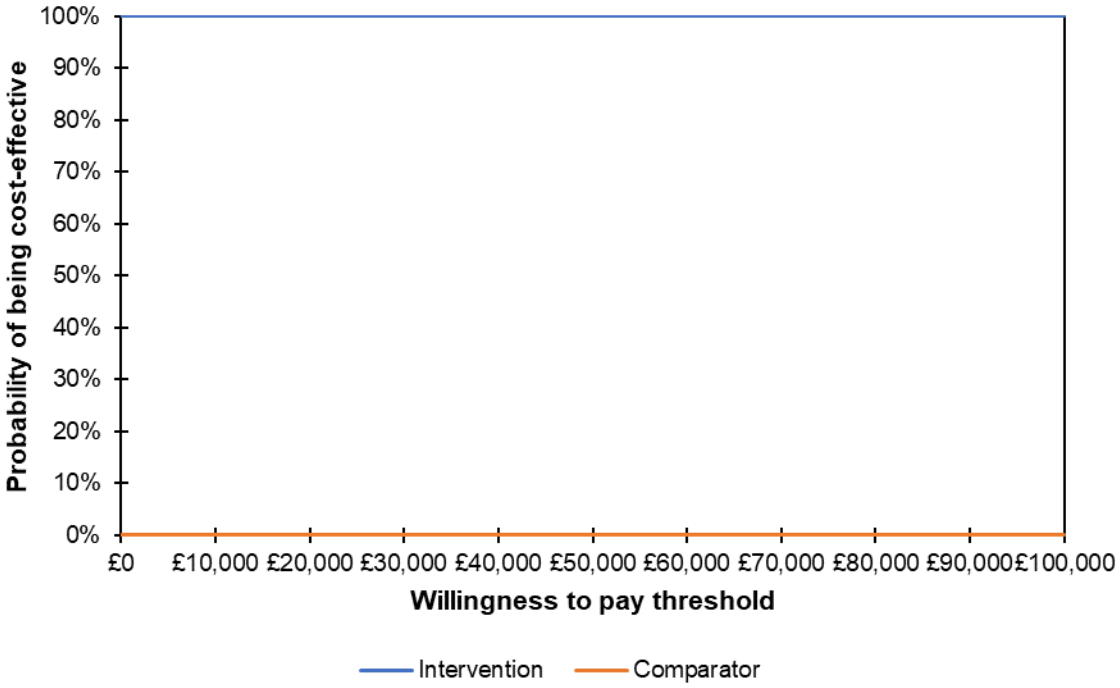

Figure 2: Cost-effectiveness acceptability curve with no uncertainty considered in mortality or RMS device costs (HeartLogic)

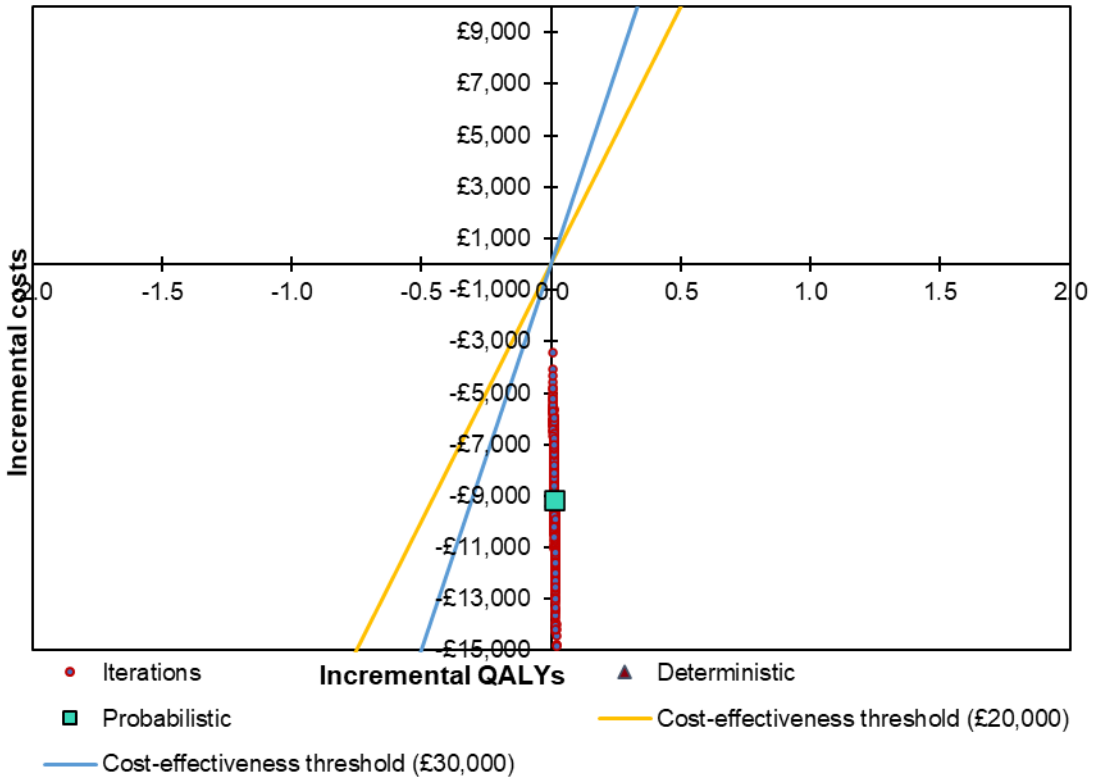

Figure 3: Cost-effectiveness plot with no uncertainty considered in mortality or RMS device costs (TriageHF)

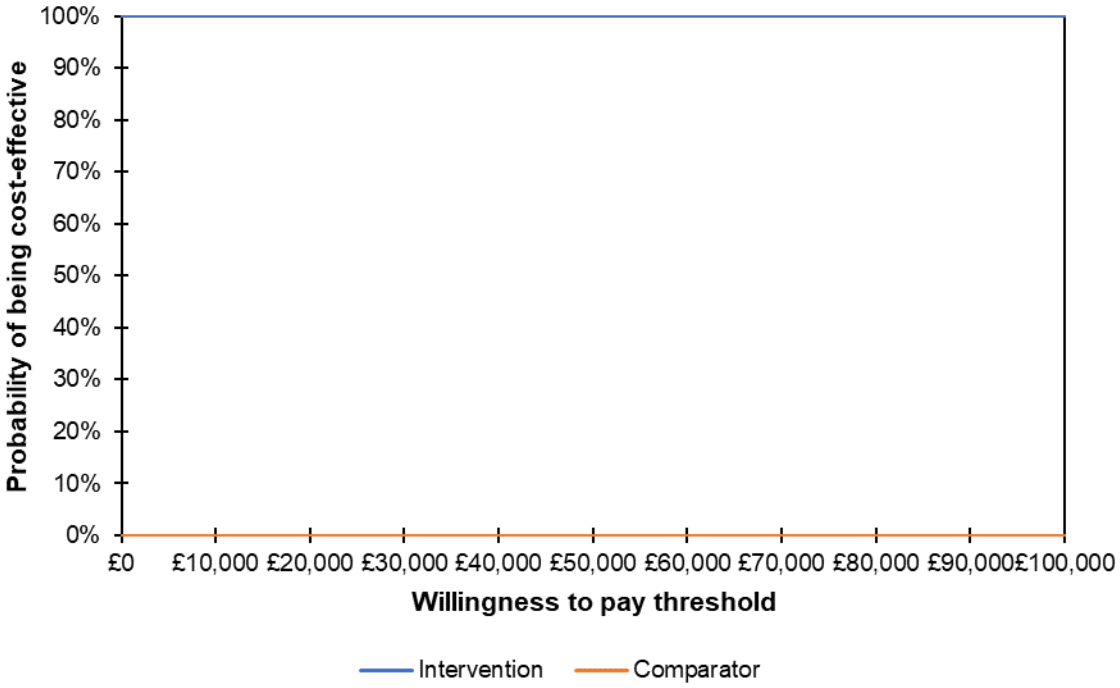

Figure 4: Cost-effectiveness acceptability curve with no uncertainty considered in mortality or RMS device costs (TriageHF)

3. EAG Response to TriageHF Plus – additional bias mitigation analysis

The following section relates to additional information and comments provided by the stakeholders post submission of the EAG report.

The EAG thanks [redacted] and [redacted] for their additional analyses. There were two main risks of bias highlighted in our earlier assessment of the study:

- A lack of clarity on whether the IPTW analyses had sufficiently adjusted for potential confounding between Triage-HF Plus and Usual Care.
- Risk of selection bias, due to the exclusion of 80 patients in the Triage-HF Plus group with "insufficient follow-up time" compared with no exclusions due to this criterion in controls.

Risk of confounding

We thank you for clarifying that Table 1 in Ahmed et al. (2024) refers to baseline characteristics after IPTW. Table 1 includes 16 statistical significance tests, by chance we expect approximately one of these tests to be statistically significant (assuming a threshold of $p<0.05$). Data from Table 1 shows there were 11/16 statistically significant differences in baseline characteristics. This is, in our view, strong evidence to question whether these groups are comparable.

We partly agree and partly disagree with the interpretation of the additional bias mitigation analysis:

[redacted]

However, we do not think it appropriate to assume these baseline differences will cancel one another out nor do we consider there to be good evidence for this strong assumption. This assumption of baseline differences (both known and unknown) cancelling each other out only applies to relatively large randomised controlled trials. There is no such guarantee in observational studies, where the aim is to minimize baseline differences for known and measurable confounders. A further uncertainty is in the potential for baseline differences related to additional unknown or unmeasured confounders in all observational studies.

The large number of baseline differences makes it difficult to predict how these factors will interact with one another, and how these interactions in turn will impact on the outcome (hospitalisation). Therefore, the direction and magnitude of bias is very difficult to predict. Given these many uncertainties, it is very difficult to know what the true effect of Triage-HF Plus is likely to be in this study. Therefore, we considered there was a critical risk of confounding.

Risk of selection bias
A further limitation of this study is the risk of selection bias.

1. As we previously reported, Table 1 of Ahmed et al (2024) indicates there were substantial differences in follow up time (mean difference of 129 days – follow up time was longer for the Usual Care group) between groups. [redacted] It is in the EAG's view that these substantial differences over a 2-year period, when aiming to compare the intervention with a time-matched control group, is an important limitation.

2. The methods section (p3) reports that eligible patients were included in the statistical analyses based on two factors:
   - enrolled prior to the end of the time horizon and
   - minimum of 90 days of transmission data was available

Figure 2 suggests a further exclusion criterion was added (insufficient follow up time) – we were unable to discern from the paper how this differs from the minimum of 90 days transmission data.

3. Substantial differences between groups excluded for insufficient follow up time (exclusion of 80 patients in Triage-HF Plus group and 0 patients in the control group) may reflect systematic differences between groups.

Conclusion
Taken together, these risks of confounding and selection bias provide strong justification for judging this study to be at critical risk of bias.

Reference
Ahmed F. Z., Sammut-Powell C., Martin G. P., Callan P., Cunnington C., Kahn M., Kale M., Weldon T., Harwood R., Fullwood C., Gerritse B., Lanctin D., Soken N., Campbell N. G., and Taylor J. K. Association of a device-based remote management heart failure pathway with outcomes: TriageHF Plus real-world evaluation. ESC Heart Failure 2024, doi: https://doi.org/10.1002/ehf2.14821.

Additional Analysis to Assessment Group's Report

Algorithm-based remote monitoring of heart failure risk data in people with cardiac implantable electronic devices

Produced by Newcastle Technology Assessment Review Group, Newcastle University

Authors
Ryan PW Kenny, Research Associate
Nawaraj Bhattarai, Senior Research Associate
Nicole O'Connor, Research Assistant
Sonia Garcia Gonzalez, Research Associate
Hannah O'Keefe, Research Associate
Sedighe Hosseini-Jebeli, Research Associate
Nick Meader, Principal Research Associate
Stephen Rice, Senior Lecturer

Correspondence to
Stephen Rice,
Population Health Sciences Institute,
Newcastle University, Newcastle upon Tyne, NE1 7RU,
Email: stephen.rice@newcastle.ac.uk

Date completed 12/06/2024

Source of funding:
This report was commissioned by the NIHR Evidence Synthesis Programme as project number *NIHR135894*.

Declared competing interests of the authors
None.

1. Summary results for Singh et al (2024) study

Singh et al (2024) was published after the date range of the systematic review and, at the request of NICE, the following is the summary of the data extracted from the Singh et al (2024) including the Author conclusions.

Singh et al 2024

N = 1458, ICD = 490, CRT-D = 968.

Mean Age (SD) = 74 (8) years

White = 86%

Male = 71%

Outcome	Data
Sensitivity for detecting usable HF events (pre-defined >40%) HF event = acute inpatient event with primary HF diagnosis, or a primary HF outpatient with IV diuretic therapy.	302 usable HG events (<11 unusable events) Sensitivity = 74.5% (95% CI: 69.2%-79.3%)
False positive alert rate per patient year (pre-defined <2.0)	1.48 per patient year (negative binomial estimate, 1.50, 95% CI: 1.42-1.59)
Mean (SD) alert duration	For the 2515 HeartLogic alerts at nominal setting (1.6 alerts per patient year) with an average alert duration of 42 (34) days.
Mean (SD) average alert lead time	For the 302 usable events, 49 (40) days.

Author conclusions:

HeartLogic performance using real-world cohort demonstrated a notable level of agreement with the results from the original study (Multisense trial) and with reports from clinical practice. Consistent early detection of worsening HF status with HeartLogic can enable a remote monitoring proactive intervention and personalised treatment optimisation. Whether this can prevent the progression of HF and decrease risk of hospitalisation remains to be evaluated.

2. No uncertainty in mortality and RMS device price

The following table and the figures report the cost-effectiveness results where no uncertainty was considered in mortality and RMS device price.

The list price (one-off £3650 per patient and no additional consumable or maintenance costs) for the HeartLogic algorithm was used. The EAR includes a confidential price for the HeartLogic algorithm.

Table 1: Probabilistic cost-effectiveness results when no uncertainty considered in mortality or RMS device price

Items	HeartLogic		TriageHF	
	I	*C*	*I*	*C*
Total				
Costs (£)	9343	17767	11682	20846
QALYs	5.84	5.83	5.84	5.82
Cumulative hospitalisations per person	1.20	4.28	2.65	6.36
Cumulative days in hospital	8.39	68.65	42.13	101.46
Cumulative Follow-up_1*	22.20	22.18	22.34	22.18
Cumulative Follow-up_2**	7.70	3.40	4.71	3.39
Proportion died after 40 years	0.97	0.97	0.97	0.97
Incremental (intervention versus comparator)				
Costs (£)	-8549		-9164	
QALYs	0.011		0.013	
Cumulative hospitalisations per person	-3.09		-3.71	
Cumulative days in hospital	-60		-59	
*Cumulative Follow-up_1**	0.02		0.16	
*Cumulative Follow-up_2***	4.30		1.32	
Proportion died after 40 years	0		0	
ICER	Dominant		Dominant	

I: Intervention; C: Comparator;

* Follow-up_1: Scheduled visits; **Follow-up_2: Unscheduled visits;

The cost-effectiveness acceptability curves (CEACs) (Figure 2 and Figure 4) show that both the HeartLogic and TriageHF RMS have a 100% probability of being cost-effective at willingness to pay (WTP) values of both £20,000 and £30,000.

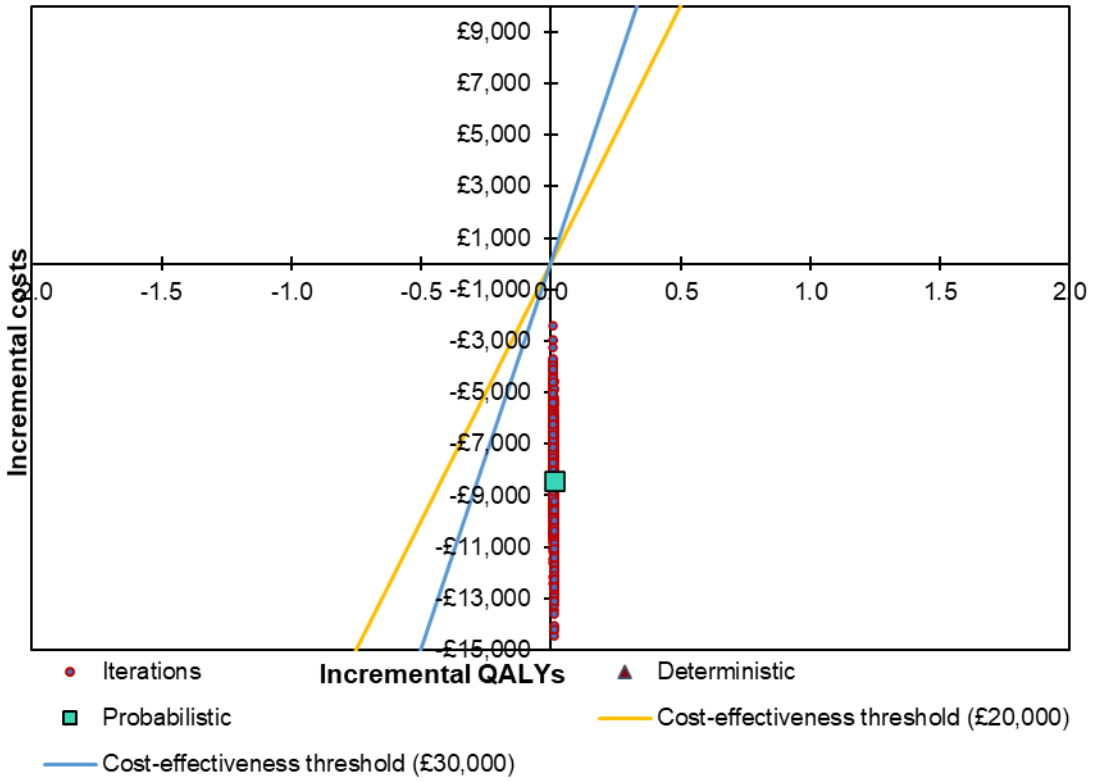

Figure 1: Cost-effectiveness plot with no uncertainty considered in mortality or RMS device costs (HeartLogic)

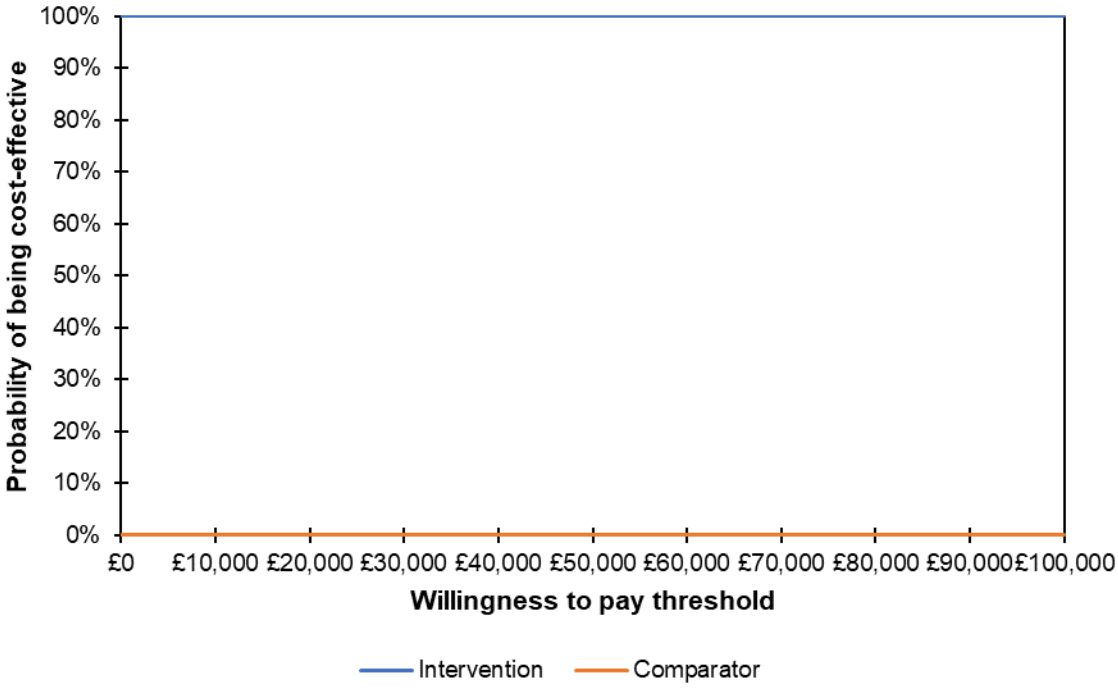

Figure 2: Cost-effectiveness acceptability curve with no uncertainty considered in mortality or RMS device costs (HeartLogic)

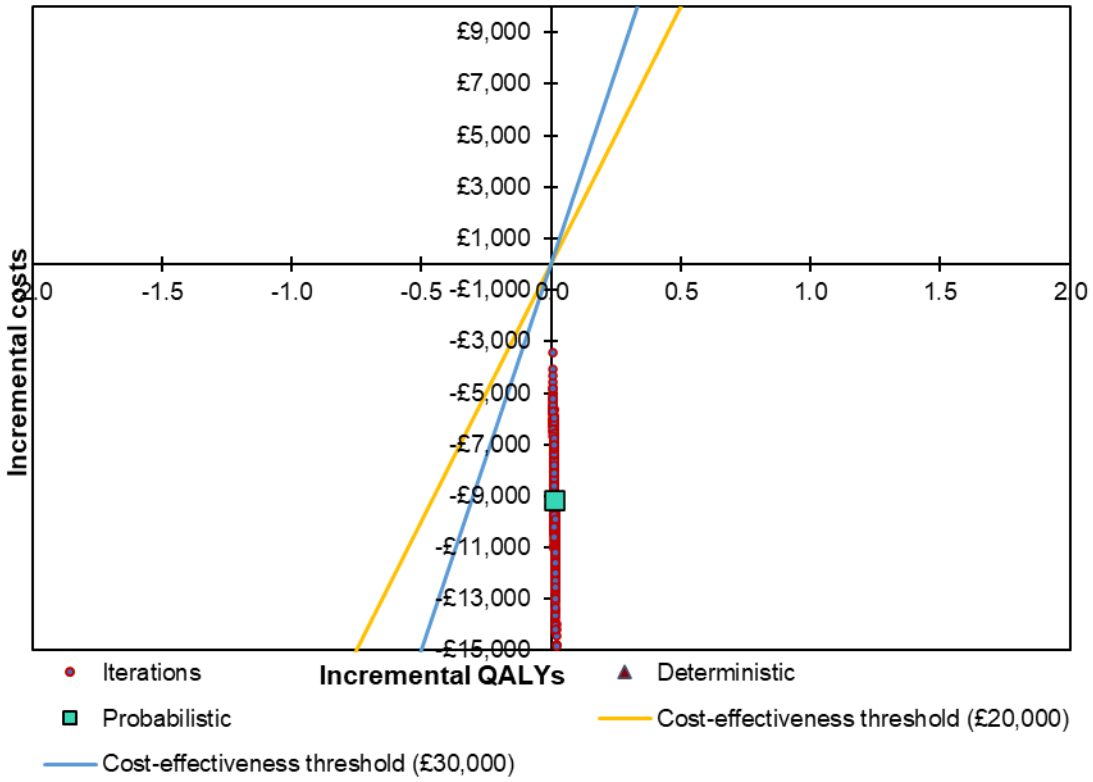

Figure 3: Cost-effectiveness plot with no uncertainty considered in mortality or RMS device costs (TriageHF)

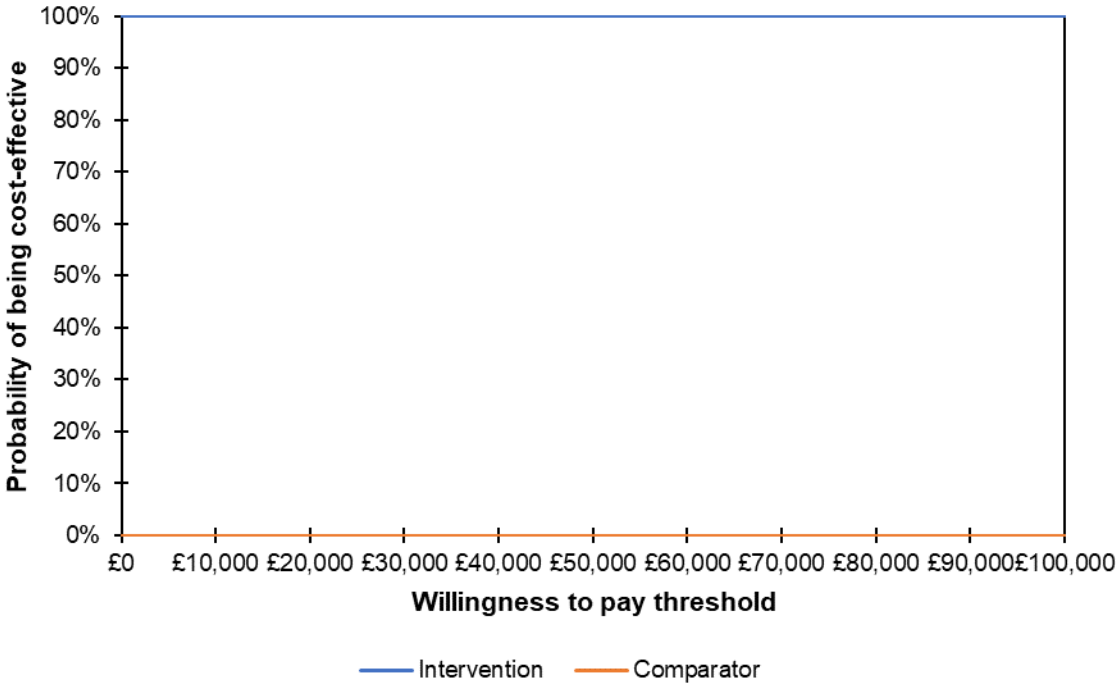

Figure 4: Cost-effectiveness acceptability curve with no uncertainty considered in mortality or RMS device costs (TriageHF)

3. EAG Response to TriageHF Plus – additional bias mitigation analysis

The following section relates to additional information and comments provided by the stakeholders post submission of the EAG report.

The EAG thanks [redacted] and [redacted] for their additional analyses. There were two main risks of bias highlighted in our earlier assessment of the study:

- A lack of clarity on whether the IPTW analyses had sufficiently adjusted for potential confounding between Triage-HF Plus and Usual Care.
- Risk of selection bias, due to the exclusion of 80 patients in the Triage-HF Plus group with "insufficient follow-up time" compared with no exclusions due to this criterion in controls.

Risk of confounding

We thank you for clarifying that Table 1 in Ahmed et al. (2024) refers to baseline characteristics after IPTW. Table 1 includes 16 statistical significance tests, by chance we expect approximately one of these tests to be statistically significant (assuming a threshold of $p<0.05$). Data from Table 1 shows there were 11/16 statistically significant differences in baseline characteristics. This is, in our view, strong evidence to question whether these groups are comparable.

We partly agree and partly disagree with the interpretation of the additional bias mitigation analysis:

[redacted]

[redacted]

However, we do not think it appropriate to assume these baseline differences will cancel one another out nor do we consider there to be good evidence for this strong assumption. This assumption of baseline differences (both known and unknown) cancelling each other out only applies to relatively large randomised controlled trials. There is no such guarantee in observational studies, where the aim is to minimize baseline differences for known and measurable confounders. A further uncertainty is in the potential for baseline differences related to additional unknown or unmeasured confounders in all observational studies.

The large number of baseline differences makes it difficult to predict how these factors will interact with one another, and how these interactions in turn will impact on the outcome (hospitalisation). Therefore, the direction and magnitude of bias is very difficult to predict. Given these many uncertainties, it is very difficult to know what the true effect of Triage-HF Plus is likely to be in this study. Therefore, we considered there was a critical risk of confounding.

Risk of selection bias

A further limitation of this study is the risk of selection bias.

1. As we previously reported, Table 1 of Ahmed et al (2024) indicates there were substantial differences in follow up time (mean difference of 129 days – follow up time was longer for the Usual Care group) between groups. [redacted] It is in the EAG's view that these substantial differences over a 2-year period, when aiming to compare the intervention with a time-matched control group, is an important limitation.

2. The methods section (p3) reports that eligible patients were included in the statistical analyses based on two factors:
   - enrolled prior to the end of the time horizon and
   - minimum of 90 days of transmission data was available

Figure 2 suggests a further exclusion criterion was added (insufficient follow up time) – we were unable to discern from the paper how this differs from the minimum of 90 days transmission data.

3. Substantial differences between groups excluded for insufficient follow up time (exclusion of 80 patients in Triage-HF Plus group and 0 patients in the control group) may reflect systematic differences between groups.

Conclusion

Taken together, these risks of confounding and selection bias provide strong justification for judging this study to be at critical risk of bias.

Reference

Ahmed F. Z., Sammut-Powell C., Martin G. P., Callan P., Cunnington C., Kahn M., Kale M., Weldon T., Harwood R., Fullwood C., Gerritse B., Lanctin D., Soken N., Campbell N. G., and Taylor J. K. Association of a device-based remote management heart failure pathway with outcomes: TriageHF Plus real-world evaluation. ESC Heart Failure 2024, doi: https://doi.org/10.1002/ehf2.14821.

NICE HEALTH TECH PROGRAMME

Heart failure algorithms for remote monitoring in people with cardiac implantable electronic devices

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 19 June 2024

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
1	Boston Scientific	All	Given the appreciable body of consistent evidence, positive UK clinical experience over the past 7 years and high probability of cost effectiveness (81%), we strongly disagree with the draft recommendation for HeartLogic to be used in research only. We feel a more proportionate recommendation for HeartLogic would be "recommended with evidence generation" which we understand has previously been used in the diagnostics programme (including for DG51 and DG57) and we would request that the recommendation be changed to this. We are concerned that a "can only be used in research" recommendation will have a pronounced negative impact on heart failure patients in the UK who could benefit from this technology whilst RCT data continues to be generated (https://clinicaltrials.gov/study/NCT06099158). All published evidence on HeartLogic to date is consistent in indicating this technology has clinical utility in the management of these patients and we are unclear why the overarching consistency in the evidence base has been disregarded. We note that the draft recommendations appear to conflict with national NHS priorities and policies, including those seeking improvement in "prevention… and better management of long-term conditions" (2024/25 priorities and operational planning guidance), "providing better connected, more personalised care in people's homes" (NHS @home), "boost[ing] out-of-hospital care" and "reduc[ing] pressure on emergency hospital services" and providing patients "with more personalised care when they need it" (NHS Long Term	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF [may be used] as options for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have heart failure. They should be used with specialist review of alerts. Companies should work with the NHS to collect registry data for HeartLogic and TriageHF on: hospitalisation rates, heart-failure-related mortality rates, rates of emergency department or primary care visits and patient-reported outcomes. See sections 1.1 and 1.2.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			Plan). Heart failure algorithms are designed to support these objectives.	
2	Boston Scientific	1.4, Why the committee made these recommend ations	We dispute NICE's statement that "more research is needed on "prognostic accuracy" for HeartLogic and feel this is not a reasonable interpretation of the evidence due to the volume and consistency therein. We request that this is removed from the recommendations. The committee cites "a lot of variation in the accuracy results" for HeartLogic and TriageHF as part of their rationale for this recommendation. This is factually inaccurate and wholly inconsistent to the findings reported elsewhere in the draft guidance document which state "data for HeartLogic show adequate to high sensitivity". This also conflicts with the EAR conclusions which state "HeartLogic had the highest and most consistent accuracy measures".	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF [may be used] as options for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have heart failure. They should be used with specialist review of alerts. Companies should work with the NHS to collect registry data for HeartLogic and TriageHF on: hospitalisation rates, heart-failure-related mortality rates, rates of emergency department or primary care visits and patient-reported outcomes. See sections 1.1 and 1.2.
3	Boston Scientific	1.4, Why the	We dispute NICE's statement that "more research is needed on "prognostic accuracy" for Heart Logic and feel this is not a	Thank you for your comment, which the

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
		committee made these recommend ations	reasonable interpretation of the evidence due to the volume and consistency therein. We request that this is removed from the recommendations.	committee has considered. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that HeartLogic can predict heart failure events (see section 3.6).
4	Medtronic	All	TriageHF Plus is an automated remote management heart failure care pathway that combines TriageHF alerts (high risk status transmissions) with structured phone-call based assessment. The NICE Diagnostic Assessment Committee have proposed draft guidance limiting the use of TriageHF Plus to “only in research.” We believe this draft recommendation is potentially perverse due to the following serious concerns: The draft decision does not take an appropriate proportional approach in considering the TriageHF Plus evidence base relative to its low cost (£100 per patient per year) and minimal associated clinical risks. Due to the low cost of TriageHF Plus technology and the high cost of hospitalisations in the UK, only a small reduction in hospitalisations is needed for TriageHF Plus to be cost saving – a finding validated in the EAG cost effectiveness model. As explained in later commentary, the Ahmed 2024 study provides the confidence needed that TriageHF Plus, as	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF [may be used] as options for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have heart failure. They should be used with specialist review of alerts. Companies should work with the NHS to collect registry data for HeartLogic and TriageHF on: hospitalisation rates, heart-failure-related mortality rates, rates of emergency

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			implemented in the UK, avoids sufficient hospitalisations to be cost saving. The key comparative effectiveness study for TriageHF Plus was rated as critical risk of bias – as will be shown in comments 2 and 3 – based on unsubstantiated rationale. This study was accepted for publication prior to the first Committee meeting, however, and it is now published in ESC Heart Failure. We also wish to note that peer review c/o ESC Heart Failure journal did not cite any risk of bias for the published Ahmed 2024 study. Therefore, we would like to suggest the DAC consider risk of bias to be 'moderate' rather than 'critical' (i.e. there were deviations from usual practice, but their impact on the outcome is expected to be slight). We believe the EAG's risk of bias assessment was excessively critical for both the comparative and algorithm validation evidence – see comments 2 and 3 below with supplementary evidence provided as academic in confidence. This proposed decision is at odds with several NHS England policies which aim to improve access to care through the digitalisation of care pathways and adoption of HF remote monitoring, including the NHS Long term Plan, NHS @home - Managing Heart Failure @home (MHF @home) and NHSE Guidance note: virtual ward care. TriageHF Plus is widely used and embedded in the system as part of HF remote monitoring pathway, the 'research only' decision would disadvantage people who live in remote communities, come from deprived socio-economic regions or those who are less mobile, potentially creating inequalities in	department or primary care visits and patient-reported outcomes. See sections 1.1 and 1.2.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			the delivery of HF care. The draft text and decision undervalues the current role of remote monitoring in patients with CIEDs for which heart failure (HF) monitoring is a component, the broad adoption (77 operational sites) of CIED-based HF monitoring in the UK, the extent to which current medical guidelines support CIED- based remote monitoring including HF monitoring, and the direct connection between individual HF metrics (for instance, intrathoracic impedance or arrhythmia burden) and TriageHF algorithm. The “only in research” decision is inconsistent with other recent technology evaluations with similar or less evidence. For example, a technology for remote monitoring of Parkinson’s disease [DG51, Jan 2024] was conditionally recommended if further evidence is generated. Please see comments 2-12 for further substantiation of our concerns.	
5	Medtronic	References	Ahmed F. Z., Sammut-Powell C., Martin G. P., Callan P., Cunnington C., Kahn M., Kale M., Weldon T., Harwood R., Fullwood C., Gerritse B., Lanctin D., Soken N., Campbell N. G., and Taylor J. K. (2024) Association of a device-based remote management heart failure pathway with outcomes: TriageHF Plus real-world evaluation, ESC Heart Failure, doi: https://doi.org/10.1002/ehf2.14821. https://onlinelibrary.wiley.com/doi/full/10.1002/ehf2.14821 Sammut-Powell C, Taylor JK, Motwani M, Leonard CM,	Thank you for providing these references.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			Martin GP, Ahmed FZ. Remotely Monitored Cardiac Implantable Electronic Device Data Predict All-Cause and Cardiovascular Unplanned Hospitalization. J Am Heart Assoc. 2022 Aug 16;11(16):e024526. doi: 10.1161/JAHA.121.024526. Epub 2022 Aug 9. PMID: 35943063; PMCID: PMC9496305. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9496305/ Magnocavallo M, Vetta G, Bernardini A, Piro A, Mei MC, Di Iorio M, Mariani MV, Della Rocca DG, Severino P, Quaglione R, Giunta G, Chimenti C, Miraldi F, Vizza CD, Fedele F, Lavalle C. Impact of COVID-19 Pandemic on Cardiac Electronic Device Management and Role of Remote Monitoring. Card Electrophysiol Clin. 2022 Mar;14(1):125-131. doi: 10.1016/j.ccep.2021.10.010. Epub 2021 Oct 30. PMID: 35221081; PMCID: PMC8556573. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8556573/pdf/main.pdf Cowie MR, Sarkar S, Koehler J, Whellan DJ, Crossley GH, Tang WH, Abraham WT, Sharma V, Santini M. Development and validation of an integrated diagnostic algorithm derived from parameters monitored in implantable devices for identifying patients at risk for heart failure hospitalization in an ambulatory setting. Eur Heart J. 2013 Aug;34(31):2472-80. doi: 10.1093/eurheartj/eht083. Epub 2013 Mar 19. PMID: 23513212; PMCID: PMC3743068. https://pubmed.ncbi.nlm.nih.gov/23513212/ Kennedy EE, Bowles KH, Aryal S. Systematic review of prediction models for postacute care destination decision-	

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			making. J Am Med Inform Assoc. 2021 Dec 28;29(1):176-186. doi: 10.1093/jamia/ocab197. PMID: 34757383; PMCID: PMC8714284. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8714284/ Venema E, Wessler BS, Paulus JK, Salah R, Raman G, Leung LY, Koethe BC, Nelson J, Park JG, van Klaveren D, Steyerberg EW, Kent DM. Large-scale validation of the prediction model risk of bias assessment Tool (PROBAST) using a short form: high risk of bias models show poorer discrimination. J Clin Epidemiol. 2021 Oct;138:32-39. doi: 10.1016/j.jclinepi.2021.06.017. Epub 2021 Jun 24. PMID: 34175377. https://pubmed.ncbi.nlm.nih.gov/34175377/ Kaiser I, Pfahlberg AB, Mathes S, Uter W, Diehl K, Steeb T, Heppt MV, Gefeller O. Inter-Rater Agreement in Assessing Risk of bias in Melanoma Prediction Studies Using the Prediction Model Risk of bias Assessment Tool (PROBAST): Results from a Controlled Experiment on the Effect of Specific Rater Training. J Clin Med. 2023 Mar 2;12(5):1976. doi: 10.3390/jcm12051976. PMID: 36902763; PMCID: PMC10003882. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10003882/ Sterne J A, HernÃ¡n M A, Reeves B C, SavoviÄ‡ J, Berkman N D, Viswanathan M et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions BMJ 2016; 355 :i4919 doi:10.1136/bmj.i4919 https://www.bmj.com/content/bmj/355/bmj.i4919.full.pdf	

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
6	Web comment	Research only guidance	In line with BHRS guidance, which recommend programming of clinical alerts and action on data which indicates heart failure decompensation in patients with CIEDs on remote monitoring, we currently monitor > 1000 patients across Greater Manchester using HF clinical alerts. This is limited to algorithms that have a low burden of alerting (2 alerts per 100 patients monitored per week). If guidance for research only is issued, what will happen to patients these 1000 patients who are currently being monitored in a research study, but will transition to usual care in the next 12 months? How would a decision for research only guidance impact the BHRS guidance?	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.
7	Web Comment		There is abundant evidence that implantable cardiac devices used in patients with heart failure, reduce morbidity and mortality by improving heart function and treating lethal ventricular arrhythmia. As such, they are recommended by NICE in eligible patients and already widely used on the NHS. Remote monitoring algorithms which are already incorporated within these devices as standard, have the ability to contribute to monitoring of patients for worsening symptoms and unplanned hospitalisations. This is demonstrated in the available evidence reviewed for this guidance, for both HeartLogic and TriageHF algorithms. These data are generated passively and continuously, without any additional human resource or patient footprint, and can help improve how we manage vulnerable people with heart failure.	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			Furthermore, the economic analysis in this guidance, while limited largely to observational data, demonstrated that only a small reduction in hospitalisations is required to demonstrate cost-effectiveness. This should not be trivialized as the financial burden of (and increased morbidity and mortality following) unplanned hospitalizations for heart failure remain considerable. The British Society for Heart Failure are of the opinion that a 'can only be used in research' recommendation, would unfairly limit the access of these technologies for our patients, even though they will continue to have these devices implanted. Potentially valuable information would be ignored - and with this recommendation, may be required to be disabled. We propose a 'can be used in NHS with evidence generation' which would allow patients ongoing use of these technologies, while requiring concurrent real-world data collection to support their use. This would also provide immediate comparison to ongoing large-scale trials such as PREEMPT-HF and would be in line with the NHS long term plan of incorporating digital tools and technologies in the way we manage our patients.	
8	Web Comment	hf-algorithms--draft-guidance-no-acicdocx	To whom it may concern, This is a letter regarding the consultation for the 'Heart failure algorithms for remote monitoring in people with cardiac implantable electronic devices' guidance.	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			The recommendation that these technologies should be used 'only in research' is incredibly disappointing, and I do not believe that the extent that they are already used and are ingrained within NHS practice has been appropriately captured. I would be interested to know whether scoping exercises have been performed to gather data on the number of Trusts already using these technologies. These technologies have helped to integrate the heart failure team and the cardiac physiology teams and has helped with mutually beneficial learning and a multidisciplinary approach to patient care. There has been a move towards remote care in the NHS, particularly with virtual wards and digital remote monitoring. Remote monitoring using CIEDs feeds into this well, and suggesting that this is rolled back does not appear to be in keeping with NHSE directives for virtual wards and Heart Failure @Home, in addition to the NHS 10 year plan and in fact seems to work directly against their success.	TriageHF may be used as options, as explained above in the response to comment number 1.
9	Web Comment	Can only be used in research 1	ABHI is disappointed in the recommendations of "can only be used in research" and "should not be used" for heart failure algorithms and is concerned that this will have a detrimental impact on patients who could benefit from these technologies.	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
				Because of the uncertainties in the evidence, HeartInsight was not recommended for routine use in the NHS. But, it may be better at predicting worsening heart failure and reducing hospitalisations than CIEDs without algorithms, so more research is recommended. See sections 1.3-1.6. Clinical trial evidence suggests that CorVue fails to detect some signs of worsening heart failure and has a high rate of false-positive alerts (alerts that are not followed by a heart failure event). So CorVue is not recommended for use in the NHS. See section 1.7. See section 1 for further rationale.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
10	Web Comment	Can only be used in research 1.3	These algorithms are already widely used in the NHS Trusts and the draft recommendations would represent a backwards step in current NHS practice and potentially a negative impact on staffing for those already utilising this technology if they need to revert to in-person monitoring for future patients.	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1. Because of the uncertainties in the evidence, HeartInsight was not recommended for routine use in the NHS. But, it may be better at detecting worsening heart failure and reducing hospitalisations than CIEDs without algorithms, so more research is recommended. See sections 1.3-1.6. Clinical trial evidence suggests that CorVue fails to detect some signs of worsening heart failure and has a high rate of false-positive alerts (alerts that are not followed by a heart

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
				failure event). So CorVue is not recommended for use in the NHS. See section 1.7. See section 1 for further rationale.
11	Web Comment		Technology already standard of care. The British Heart Rhythm Society recommend using alert based remote monitoring for patients with Heart Failure. There is already Real World Evidence which we are encouraged to acknowledge and consider, it has been tried and tested within the NHS setting and shown positive results. Well liked by patients. Relieves burden on outpatient clinics and hospital beds, provides a focus on patients who need more immediate attention. Recommending only for use in research is a backward step and not supporting NHS directives on adoption of technology to drive efficiencies and savings. It is low burden, low cost, low risk and should be widely available to patients.	The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.
12	Web Comment	1	Important to continue to collect data. Already good experience within the NHS and integrated into standard clinical care.	Thank you for your comment which the committee has considered.
13	Web Comment	Can only be used in research 1.1	More research welcomed	Thank you for your comment which the committee has considered.
14	Web Comment	Clinical need and	Important to use new technology especially low cost / low burden / low risk to manage fast growing Heart Failure population	Thank you for your comment which the committee has considered.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
		practice 2		
15	Web Comment		2. Mention of more research needed on hard endpoints such as admissions, rates of false positives, A & E visits, patient reported outcomes and prognostic accuracy are often difficult to achieve with heart failure studies. Real life use of the algorithms provides lots of useful information about how these technologies can be useful in clinical practice alongside traditional management and clinical assessment; often these are overlooked when the focus is on pure research findings.	Thank you for your comment, which the committee has considered.
16	Web Comment		Conclusion There is ongoing research for remote monitoring; however remote monitoring should become standard part of all heart failure protocols. The use of remote monitoring is extremely beneficial to our heart failure teams and is integral to the clinical pathway for patients. If remote monitoring was removed from our current clinical pathway, it would have a profound effect on our ability to manage patients in a clear, timely way to avoid unnecessary deterioration of patients. Current care delivery is in a proactive way, not reactive way as we used to work in the past. It is not used in isolation; but alongside clinical review by experienced nurses, which should be highlighted as part of this review. There are many centres across the UK who are utilising these algorithms in practice to manage their patients. NICE found economic modelling for TRIAGEHF and Heartlogic to be a cost-effective use of funding. The	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			conclusion of the draft report does not reflect the significant work, and positive utilisation in many centres of remote monitoring. If remote monitoring was withdrawn, it would pose a significant problem in terms of our care pathways and ultimately disruption to patients and HF pathways currently in place in the Region. While collecting real world data in the ongoing trials I would urge you to allow centres to continue using this technology, so as not to disrupt established, evidence based clinical pathways in which ensure excellent standards of patient care.	
17	Web Comment		Losing TRIAGEHF and HeartLogic would significantly impact our ability to manage heart failure (HF) patients effectively, given that these tools are integral to our standard of care and clinical pathways within our network. Without the real-time monitoring and risk alerts provided by TRIAGEHF and HeartLogic, early signs of HF deterioration might go unnoticed. This delay in detection can lead to more frequent and severe HF exacerbations, as interventions would only occur after noticeable symptoms develop or during scheduled clinic visits. Consequently, the proactive approach facilitated by these tools would be lost, leading to an increase in emergency admissions due to the inability to pre-emptively address rising risks, thereby escalating healthcare utilisation and associated costs. Moreover, timely interventions based on high-risk alerts have been shown to improve patient outcomes, including reducing mortality rates. Without these tools, the mortality rate among HF patients could increase, as critical opportunities to	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			intervene early and effectively would be missed. This would also negatively affect the overall efficiency of HF management. TRIAGEHF and HeartLogic streamline the management process by providing clear, actionable data to healthcare teams. Their absence would necessitate a return to more labour-intensive, less efficient methods of monitoring and managing HF, increasing the workload on healthcare providers and potentially leading to less optimal care.	
18	Web Comment		The disruption to established clinical pathways within our network would also be significant. Our current protocols are built around the integration of these tools, and removing them would require a substantial restructuring of care pathways, potentially leading to inconsistencies in care delivery and lapses in patient management during the transition period. Furthermore, TRIAGEHF and HeartLogic provide valuable feedback to healthcare teams, allowing for continuous improvement in patient management strategies. Without this feedback, our ability to quickly adapt and refine care plans based on real-time data would be severely limited, potentially stagnating advancements in HF care within our network. Finally, the reduction in unplanned hospitalisations and severe HF episodes due to these tools ultimately lowers healthcare costs. Their absence would likely lead to increased costs due to more frequent hospital admissions and the need for more intensive treatments once patients' conditions have deteriorated. In summary, the loss of TRIAGEHF and HeartLogic would	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			compromise our ability to manage HF patients effectively, leading to poorer health outcomes, higher healthcare utilisation, and significant disruption to our established clinical pathways. This would represent a considerable setback for our network, undermining the progress NICE has found the economic modelling for TRIAGEHF and HeartLogic to be a cost-effective use of NHS funding. This conclusion underscores the significant value these tools provide in managing heart failure (HF) patients. By enabling real-time monitoring and generating risk alerts, TRIAGEHF and HeartLogic facilitate early intervention, reducing the incidence of severe HF exacerbations and unplanned hospitalisations. This proactive approach not only improves patient outcomes and quality of life but also translates into substantial cost savings for the NHS by decreasing the need for emergency admissions and intensive treatments.	
19	Web Comment		Given this evidence of cost-effectiveness, I strongly oppose NICE's draft guidance suggesting these tools be used 'for research use only'. Such a recommendation would effectively withdraw TRIAGEHF and HeartLogic from being part of our standard of care, disrupting established clinical pathways and undermining the progress we have made in HF management. The withdrawal of these tools would mean reverting to less efficient and more reactive methods of patient monitoring, likely leading to higher healthcare utilisation and costs, as well as poorer health outcomes for our patients. The decision to limit TRIAGEHF and HeartLogic to research settings does not align with the demonstrated benefits they	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			offer in routine clinical practice. Instead, I advocate for the guidance to be revised to at least 'can be used in NHS with evidence generation'. This approach would allow continued use of these valuable tools while further accumulating real-world evidence to support their efficacy and cost-effectiveness. It is essential to maintain the integration of TRIAGEHF and HeartLogic within our HF management protocols to ensure that patients continue to receive the high standard of care they deserve. In conclusion, the economic modelling clearly supports the cost-effectiveness of TRIAGEHF and HeartLogic. Limiting their use to research settings would be a significant setback for HF care. I feel strongly that these tools should remain available within the NHS, under a framework that allows for ongoing evidence generation, to sustain and build upon the improvements in patient outcomes and cost savings they have already demonstrated.	
20	Web Comment [comment submitted twice by 2 separate people]		Of course, we need to be sure that these tools are cost effective and safe, we believe this technology has been tried and tested in our NHS system and is now successfully integrated into care pathways, the proposed recommendation would be a backward step and have severe detrimental impact on many patients and health care providers across the country. Each hospitalisation has negative impact on patient mortality and quality of life, removing remote monitoring for Heart Failure may impact significantly on timely care and ultimately outcomes for patients. We strongly urge NICE to reconsider	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1. Because of the uncertainties in the

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			the proposal to make this for use in research only and advise instead for routine clinical use. A patient who is remote-monitored is a less-costly and yet better cared for patient. A patient not understanding or recognising symptoms and delay to receiving advice and potential treatment is at high risk of further complications or in some cases death. As an organisation representing patients and their caregivers, having collated feedback and experiences from these patients, we strongly recommend the approval of remote monitoring of Heart Failure patients. Their health and safety should be paramount and remote monitoring provides this safety-net. Without it NICE could be putting lives at risk.	evidence, HeartInsight cannot be recommended for routine use in the NHS. But, it may be better at detecting worsening heart failure and reducing hospitalisations than CIEDs without algorithms, so more research is recommended. See section 1.3-1.6. Clinical trial evidence suggests that CorVue fails to detect some signs of worsening heart failure and has a high rate of false-positive alerts (alerts that are not followed by a heart failure event). So CorVue is not recommended for use in the NHS. See section 1.
21	Pumping Marvellous Foundation	1.1	I am trying to be constructive surrounding my comments, but this is a ridiculous decision to recommend the use for "Research Only" and not to be used routinely in the NHS – This is a disconnect with what the system is trying to achieve which is attempting to keep people out of hospitals, enabling early detection of signs and symptoms synonymous with	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			unplanned admissions. From a clinical standpoint surely, this is a useful tool to reduce the severity of decompensation and get a decompensating patient to their healthcare team as efficiently and cost saving as possible This is especially difficult to hear when remote monitoring through CIED's have been endorsed by international clinical practice guidelines and NICE have deemed the functionality as cost saving.	options, as explained above in the response to comment number 1. Because of the uncertainties in the evidence, HeartInsight cannot be recommended for routine use in the NHS. But, it may be better at detecting worsening heart failure and reducing hospitalisations than CIEDs without algorithms, so more research is recommended. Clinical trial evidence suggests that CorVue fails to detect some signs of worsening heart failure and has a high rate of false-positive alerts (alerts that are not followed by a heart failure event). So CorVue is not recommended for use in the NHS. See section 1.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
22	Pumping Marvellous Foundation	1.2	This type of technology should be funded through CORE NHS funding	Thank you for your comment which the committee has considered.
23	Pumping Marvellous Foundation		NICE - HealthTech Programme (Diagnostics) Re: Heart failure algorithms for remote monitoring in people with cardiac implantable electronic devices To Whom It May Concern, As the Founder and CEO of the Pumping Marvellous Foundation and a person with a diagnosis of heart failure, I am writing to express my deep concern regarding the potential removal of remote monitoring of heart failure alerts as a component of healthcare management. Remote monitoring has and will continue to radically change the way people with heart failure engage with healthcare providers who manage their conditions. For many patients, particularly those with chronic illnesses such as heart failure, remote monitoring can provide a lifeline, offering real-time insights into their health status and enabling timely interventions that have undoubtedly already improved care and impacted the lives of people with heart failure. The decision does not complement current thinking of keeping people out of hospital. It also does not promote that the NHS is open to evidence-based ways of improving patient treatments and care, patient safety, and access. It is a retrograde step.	Thank you for your comments, which the committee has considered.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			The proposal to remove remote monitoring as an option threatens to undermine our progress in managing patients' health effectively, utilising developing digital technologies. By taking away this vital tool, patients risk facing delays in receiving necessary care, experiencing undetected exacerbations of heart failure, and even facing avoidable hospitalisations. This is a risk we cannot afford to take. As the leading patient-led organisation focused on heart failure, we fully understand the importance of ensuring that healthcare interventions are evidence-based and cost-effective; we greatly support NICE. However, we urge NICE to consider the wealth of evidence demonstrating the benefits of remote monitoring in improving patient outcomes, reducing healthcare costs, and improving patient-reported metrics. Furthermore, we believe that patient perspectives must be central to any decision-making process regarding healthcare interventions. Individuals relying on remote monitoring to manage their conditions are not just statistics or data points. The people we represent are living, breathing individuals who can attest to the first-hand value and effectiveness of remote monitoring. In light of the potential impact on patient care and outcomes, we respectfully urge NICE to reconsider the proposal to remove remote monitoring as a clinical option. Instead, we encourage NICE to prioritise patient-centred approaches that uphold the right to access innovative and effective healthcare solutions and make decisions that prioritise patients' best interests.	

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			Thank you for considering our concerns. Yours sincerely [redacted] CEO and signed on behalf of the Clinical Advisory Committee of the Pumping Marvellous Foundation.	

THEME: Inconsistencies in recommendations

Comment number	Name and organisation	Section number	Comment	NICE responses
24	Medtronic	3.17	The committee considered the sample sizes to be small relative to the number of people living with, or at risk of, heart failure. There appears to be inconsistencies in what is considered an appropriate sample size relative to eligible population. In Diagnostics guidance [DG14] - Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system), published 24 September 2014 estimated that 1.4% of the population in the UK required anticoagulant therapy and that atrial fibrillation was the most common heart arrhythmia and affects around 800,000 people in the UK, or 1.3% of the population. Evidence included in the diagnostics assessment report, the mean sample size of 337 participants for RCTs included in the clinical effectiveness review (range 16 to 2922) The committee summary presented on 16th April 2024 estimated 920,000 people in the UK were living with HF in 2018 with an estimated 200,000 new diagnoses each year. Whilst these technologies may not be comparable, the relative AF populations are. However, the committee did not consider the sample sizes to be small relative to the number of people living with the condition.	Thank you for your comments, which the committee has considered. The guidance has been updated to reflect this.
25	Medtronic	All	As it stands, there is now disparity between EVA recommendations and DAP recommendations, whereby innovative technologies with a sparser evidence base are receiving positive recommendations for use in the NHS, with the condition for further evidence generation in the EVA programme (e.g. HTA17: Digital health technologies to help manage symptoms of psychosis and prevent relapse in adults and young people (March 2024), compared with new innovative technologies being routed to DAP where a higher evidentiary level is required for the same or lower level of recommendation. This disparity is concerning and needs to be addressed.	Thank you for your comments, which the committee has considered. The studies for HeartLogic and TriageHF were assessed as being at high risk of bias (producing uncertain

THEME: Inconsistencies in recommendations

Comment number	Name and organisation	Section number	Comment	NICE responses
			Further, within the DAP, recent decisions appear inconsistent. For example, a technology for remote monitoring of Parkinson's disease [DG51, Jan 2024] was conditionally recommended if further evidence is generated. This conditional recommendation comes despite concerns that the majority of the recommended technologies had little or no clinical evidence, according to the Diagnostic Assessment Report: "Although there is some promising evidence for STAT-ON and Kinesia 360, the EAG considers that the evidence is currently not sufficient to be confident that these technologies will produce clinical benefits for patients. The EAG considers that there is too little evidence for KinesiaU or PDMonitor to draw any conclusions as to their clinical value." Given that a key strength of the evidence submitted for TriageHF Plus is the extent of RWE studies in NHS settings, a similar conditional recommendation for TriageHF Plus would have been expected. This inconsistency in DAP recommendations is confusing and detrimental to the uptake of innovative low-cost technologies that are being currently used to avert unplanned hospital admissions.	results because of the study's design). The committee recognised the value of these studies in decision making despite concerns about their risk of bias. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
26	Boston Scientific	All	We are disappointed the NICE committee were not given the opportunity to consider relevant unpublished evidence from major NHS Trusts that was submitted earlier in the guidance development process and request that this be made available to them. Unpublished evidence provided through responses to a structured survey on clinical experience using HeartLogic in the NHS was submitted during the EAR consultation in February 2024. The External Assessment Group reported that it "would not meet our inclusion criteria" (response to comment 27, External Assessment Report (EAR) and economic model – Collated Comments) and we do not believe it was further disseminated to the committee as a result. Per sections 3.1.4 and 3.3.1 of the NICE health technology evaluations manual, evaluations "should consider a range of other relevant issues. For example… the experience of the healthcare system" and "NICE considers all types of evidence in its evaluations" so we are unclear why this evidence was not given due consideration in the first committee meeting. We have included below a summary of the survey and findings in appendix 2, and hope that the committee will be given an opportunity to review these as they form an important part of the clinical experience of HeartLogic in NHS settings. They also include unpublished yet relevant real world data from two Trusts using HeartLogic, which align with the broader UK experience and published clinical data overall.	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.
27	Web Comment		The HF clinic in Cork University Hospital Ireland commenced use of the Triage HF early warning system in January 2024. An efficient and effective remote check allows the team to identify patients at risk of congestion with a HIGH score and follow up either virtually or in person if deemed necessary. The workload is equivalent to approximately 2 extra reviews (usually by phone) in total per week with an outcome in preventing	Thank you for your comment, which the committee has considered. The committee considered clinician

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			worsening symptoms and possible hospitalisation. It is extremely beneficial to our cohort of patients who reside up to 2 hours travel from the hospital.	experience in their discussions at the second committee meeting on 19 June.
28	Web Comment	hf-algorithms--draft-guidance-no-acicdocx	In my own experience, these technologies have prevented a number of admissions for a variety of reasons; for example a patient with compliance issues who stops his heart failure therapies on a semi-regular basis is picked up before he becomes grossly overloaded when his Optivol rises, preventing at least three admissions a year in his case. Another patient has frequent exacerbations of COPD as well as decompensations of heart failure. He lived very remotely from the Trust which covered a wide, rural population. The scoring here helped significantly in the clinical assessment, and helped to determine the appropriate course of action. Additionally, this was a patient who did not call us himself when his symptoms were worsening. Again, I am confident that without the use of this technology he would have had multiple admissions.	Thank you for your comment, which the committee has considered. The committee considered patient and clinician experience in their discussions at the second committee meeting on 19 June.
29	Web Comment		In my experience as a cardiac physiologist triage HF is a very useful tool for predicting worsening heart failure. We always ring patients that trigger a High triage HF alert. In my experience it usually always predicts worsening heart failure or a cardiac event when I have rung the patients. If we did not have these device alerts we would not be notified early about the possibility of worsening heart failure and more patients will end up in A&E.	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.
30	Web Comment		I am a Consultant Cardiologist and HF Lead in a rural DGH. My community heart failure nursing team routinely uses alert-based HF remote monitoring as an adjunct to patient care. It allows us to identify patients at risk of	Thank you for your comment, which the committee has

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			decompensation early and thus action the alerts to modify and personalise the treatment plan. We have found this improves patient care, patient satisfaction and reduces unscheduled hospital admissions, particularly given the longer distances some of patients would have to travel to attend for a clinical review. Therefore an 'only for research' recommendation may result in remote monitoring no longer being available for this pt cohort in the future. I would envisage this would increase the need for in-person visits, clinic appointments and hospitalisations; and be a step backwards for patient care, especially as there is widespread usage of remote monitoring for ICD/CRT patients already in place. The HF diagnostics are a low cost additional tool that can be used in patient assessments and thus should not be restricted to Research only. This is not the only means we use to monitor pts but it is supplementary to the care we deliver, particularly as the national focus is shifting towards care delivered at home and virtual ward set ups. HF remote monitoring diagnostics can play a key role in this.	considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.
31	Web Comment		This would have a significant impact on our Standard of care as a clinic and our patients. TriageHF has proven with real world data, and through our practice of reducing unplanning HF admissions, intervening to treat the patient - meaning they dont decompensate and have better outcomes themselves, and save the hospital time, money and bed space.	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.
32	Web Comment		I am a consultant cardiologist subspecialising in Heart Failure and Devices. I use TRIAGE-HF and HeartLogic routinely for patient management and have found these to	Thank you for your comment, which the committee has considered. The committee

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			1. predict decomensation of heart failure in my patients, giving me the ability to guide them to the best pathway for their care (e.g., clinic review, HF nurse review, IV ambulatory unit) and thus to prevent hospital admissions 2. Allows me the opportunity to identify patients who are not optimised on modern heart failure management such as SGLT2 and ARNI 3. They are an adjunct to my clinical assessments of the patients when it is not overtly clear whether these patients are in decompensated heart failure (e.g., like body composition assessment for haemodalysis patients) 4.They also allow us to support our community HF nurses more comprehensively, and gives them confidence (as well as the patients) to perform remote visits as opposed to having obligatory face to face visits. 5. I would advocate the recommendation be changed to 'can be used in NHS with evidence generation', whic I feel is more proportionate. 6. I am concerned that by implementing a research only recommendation this could lead to limitation of patient access to this valuable technology. Thank you.	considered clinician experience in their discussions at the second committee meeting on 19 June.
33	Web Comment		To whom it may concern, This is a letter in response to the guidance that "Heart failure algorithms for remote monitoring in people with CIED" should be for 'only in research'. As a centre, we adapted to a rapidly changing area, that in a post-COVID era where home monitoring has become an integral part of our working lives. This in turn has lead to a far greater change in practice where we	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the

			don't physically see patients as often as we used to, relying on the home monitor to transmit the information from the device to us in clinic. This is where the benefits of the risk stratification tools – such as TriageHF/Heartlogic/HeartInsight come into play. We must bear in mind that as a Cardiac Physiologist, my area of expertise is not that of a Heart Failure consultant or a highly specialised nurse – but with the use of these tools, I can help provide a guide of a specific cohort of patients that I think would benefit from an interaction with the HF team. As a centre, we have over a 1500 devices (CRTDs/ICDs/CRTPs/some dual chamber PPMs) that can utilise these tools on their various platforms. It has become ingrained within our work flow (such as calling patients to further risk stratify when a TriageHF or Heartlogic, to determine if they are known to a HF team or if we can refer them on if we think that they would benefit from an interaction from a HF specialist). I have worked at Imperial for nearly 15 years, and in all my time, I could not think of a better example where we have clear integration with the local HF (and surrounding HF teams) because of the use these HF algorithms. I can attest to frequent success stories of ourselves and the HF team working in parallel to ensure a patient does not suffer from a HF admission and can be dealt with in the community. I think it is important to remember the NHS 10 year plan (https://www.longtermplan.nhs.uk/online-version/chapter-3-further-progress-on-care-quality-and-outcomes/better-care-for-major-health-conditions/cardiovascular-disease/): 3.70. People with heart failure and heart valve disease will be better supported by multi-disciplinary teams as part of primary care networks. 80% of heart failure is currently diagnosed in hospital, despite 40% of patients having symptoms that should have triggered an earlier assessment [118]. When admitted to hospital, we will improve rapid access to heart failure nurses so that more patients with heart failure, who are not on a cardiology ward, will receive specialist care and advice [119]. Better, personalised planning for patients will reduce nights spent in hospital and	second committee meeting on 19 June.

			reduce drug spend. Greater access to echocardiography in primary care will improve the investigation of those with breathlessness, and the early detection of heart failure and valve disease. If we are using the 10-year plan as a framework to work in, the diagnostic tools Triage HF/Heartlogic work synergistically. If the plan were to increase HF diagnosis outside of an In-Hospital setting – surely utilising risk stratification tools would be paramount to that. I have multiple examples of HF nurses contacting me in relation to medication changes in patients and whether they have had the desired effect, (the ultimate goal with this would be for the HF nurses to also have access to all this data, further decreasing the need of a conduit such as a Cardiac physiologist). This in turn has also lead to a change in practice for us whereby we are screening patients significantly earlier in thinking about upgrading devices. That in itself is a monumental culture shift – where in a pre-COVID era, I doubt that that would have come into our thought processes and we'd have likely waited for a consultant to make that decision (this in turn may have lead to the patient having multiple procedures when this could have been made at time of box change). It is also important to note, that virtual wards are becoming significantly more prevalent (we currently have a virtual HF ward here at Imperial) – and the use of this type of technology would be in-line with the current standard of care as per NHSE directives. I feel that if we were to revert to a system where the use of these technologies were limited/non-existent, that would definitely impede our ability to diagnose patients early enough to have potential benefits. I can think of a specific example of a patient that had severe heart failure, who had done a transmission for frequent Non-sustained Ventricular Tachycardia. On reviewing the transmission (using the cardiac compass as a guide), it was abundantly apparent he was in the midst of a HF event (and the NSVT was a consequence of being in HF). Looking back, I believe he would have triggered a TriageHF high score likely a month before I saw the transmission for him – but because the risk stratification	

			was not available at that time we were likely too late. This is example of the patients we are far more likely to catch and earlier by utilising these tools. I understand that there were some concerns raised by the committee with regards to safety. When a TriageHF/Heartlogic High alert is initiated, the responsibility (in terms of our work-flow) is for the Cardiac Physiologist to contact the patient and assess both the diagnostic data from device coupled with the symptomatic data provided from the patient. We found that by asking about their symptoms, it gave us far greater scope into whether we needed to act on the patient sooner rather than later. It must also be stressed that we also guide the patient, that they may not be symptomatic currently – these symptoms may develop and to please contact us back if they do. If they are symptomatic, our role is to facilitate contact with the HF team – whether that is directly with their own HF team or via the GP to refer to the local centre. There is some discordance at this point as HF care is primarily within the community and we rarely get to see the results (other than a change in status for the better on HF diagnostics). These tools are best utilised as the early warning indicator that they were intended for, hence in terms of safety – it triggers the normal treatment pathway for these patients, just sooner. The burden of this technology is relatively small – recent studies put this at ~10%. Thus, it means we can focus on the patients the require an intervention most. From the most recent publications, within that 10% that trigger a high warning – they only use a fraction of the allotted budget (in the region of ~50-60%). Anecdotally, the use of this technology hasn't created any extra burden in our clinical setting. Home monitoring connectivity has always been an issue (this is independent to the use of HF diagnostics). Here at Imperial, we have just employed a part time administrator whose primary focus will be to ensure that as many patients are connected to their home monitors as possible. A	

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			side effect of the use of HF diagnostic tools is that the HF nurses are far more invested in the home monitors being connected – I have done several talks with the local team to help them understand the benefits of being connected into home monitoring due to the ability to see TriageHF/Heartlogic scores more readily. Finally, we are moving into an era where App-based technology is becoming more readily available and used as a conduit for home monitoring. I think this is an area that we can wholly expand upon, as the potential in this area to utilise 2-way communication for example: to get patients symptomatic information without having to call them and have the ability to make a clinical decision based off this will likely hasten and improve the quality of treatment for a patient. Given that the current guidance from the BHRS is that: a) alert based remote follow up should be considered as the standard of care and b) action on data which points to heart failure decompensation is recommended – surely that falls within the lines utilising the HF diagnostic tools more readily. As stated earlier, Cardiac Physiologists are not specialists in this area – so having the freedom of use with this diagnostic tool will make my job in determining which cohort of patients to focus on and highlight to the HF team will be made significantly easier with tools such as TriageHF and Heartlogic. My suspicion with this technology, is that at some point (depending on the manufacturer such as Heartlogic is only on the ICD platform and Triage is on all ICDs/CRTP/Advisa model pacemakers) that these diagnostic tools will be prevalent on almost all devices. It is important to bear in mind, that the 30,000 CIED devices this could be applicable (as per the report) for will most definitely be a gross under-estimation.	

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
34	Web Comment	Clinical need and practice 2.3	Excellent patient compliance. Provides confidence to reduce number of in person patient visits and manage patients remotely.	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.
35	Web Comment		Feedback from Staff and Patients [redacted] HF Team Lead Preston 'As a heart failure team we use remote monitoring on a daily basis as a tool which is part of the holistic clinical heart failure assessment. Data / specifically alerts can be reviewed by the Heart Failure Team whilst the patient is face to face in clinic, which adds to the whole assessment of heart failure patients. It is not used in isolation. Patient assessment is always undertaken. Patients have voiced that they feel safe as they are being monitored and know we will contact them if there are any alerts. We will contact the patient if there is a high risk alert, assess symptoms and bring them back to clinic earlier if needed. There can be alerts where the patient feels well. In these cases, we use a watch and wait policy. The patient is reassured, and we continue to monitor them remotely. [redacted] ANP HF Team Blackpool Working within a multidisciplinary team across both community and	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			hospital settings, we can deliver a holistic service for patients on our caseload. We can also continue management and oversight of those who are then subsequently discharged from our caseload if required. The remote monitoring aspect of care means that we can offer further insight into our patient's HF management. The remote monitoring aspect means that patient engagement is improved, as they can escalate any symptom concerns if necessary. A heart failure assessment takes place via telephone initially, and then may generate further review with treatment change if necessary. Safe prescribing takes place in partnership with patient, GP (and consultant if necessary).	
36	Web Comment		The organisation that I work for and our regional network have been using Heartlogic since 2021. It is now embedded into our standard of care. At our Organisation we have approx 476 Heartlogic enabled CRT-Ds and 408 ICDs that are monitored and acted on on a weekly basis and have for almost 3 years. The alerts are shared across the Network with the responsible community HF team acting on and reviewing the Heartlogic alert. It is embedded into our clinical pathway. In July 2021 at our centre, HeartLogic was initiated in 212 patients with CRT-D devices. Throughout the subsequent 12 months, 34 hospitalisations occurred, primarily due to heart failure (HF), with a median hospital stay of 5 days. The total outpatient visits numbered 37, with 22 visits attributable to HF decompensation. During this period, HeartLogic alerts were triggered 197 times, on average 0.95 alerts per patient-year, primarily signalling impending HF exacerbations. These alerts demonstrated a sensitivity of 100%, with all HF hospitalisations detected during alert states. Therapeutic actions were taken in response to 82 alerts, including medication adjustments, with 37% of alerts necessitating hospitalisation or outpatient visits for clinical management. Overall, HeartLogic significantly contributed to the early detection and management of HF events, potentially reducing	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			unplanned hospital visits and improving patient outcomes. Before the availability of HeartLogic technology, the management pathway for patients with heart failure typically relied on periodic clinic visits and subjective assessments of symptoms. Patients would generally undergo scheduled follow-ups, during which clinicians would assess their clinical status, review symptoms, and adjust treatment plans accordingly. However, this approach often lacked continuous monitoring between appointments, which could result in delayed detection of deteriorating heart failure status and subsequent exacerbations. As a result, patients might experience more frequent hospitalisations or AED attendance due to unanticipated worsening of their condition. Patients are reviewed in person by Heart failure specialist nurses usually between 2-4 weekly. When a patient calls reporting an exacerbation of heart failure, initially I would assess the severity of the symptoms reported by the patient, including shortness of breath, fatigue, swelling, and changes in weight. Based on the assessment, I would likely instruct the patient to adjust their medication regimen as previously prescribed, such as increasing diuretics to alleviate fluid retention. I would then arrange a face-to-face review. If the symptoms persist or worsen, I would consider a hospital admission which may involve intravenous diuretics. I would advise the patient if they were not responding to diuretic increase to attend AED. Regular follow-up appointments would be scheduled to monitor the patient's progress and adjust treatment as necessary to optimise their heart failure management. With the introduction of HeartLogic, the management pathway for these patients has undergone a significant transformation. HeartLogic provides continuous remote monitoring of key physiological parameters associated with heart failure exacerbations. This allows for	

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			early detection of subtle changes indicative of worsening heart failure, even before symptoms become apparent to the patient. As a result, healthcare providers can intervene promptly with targeted therapies or adjustments to medication regimens, potentially preventing or mitigating the severity of heart failure exacerbations. Additionally, the use of HeartLogic reduces the reliance on subjective symptom reporting by patients, providing objective data to guide clinical decision-making. This objective data, combined with regular alerts and remote monitoring, enables a more proactive and personalised approach to managing heart failure. Consequently, patients may experience fewer unplanned hospital visits, reduced lengths of stay, and improved overall outcomes compared to the traditional management pathway. The management pathway for patients with heart failure has shifted from reactive and episodic care to proactive and continuous monitoring with the integration of HeartLogic technology. The implementation of HeartLogic technology brings a multitude of benefits to both patients and healthcare providers involved in heart failure care. For patients, HeartLogic offers proactive monitoring, enabling early detection of impending heart failure exacerbations, which can lead to timely interventions and reduced hospitalisations. HeartLogic streamlines patient management through continuous remote monitoring, facilitating more personalised care and enabling timely adjustments to treatment strategies based on real-time data. Additionally, it optimises clinic workflow by reducing the need for frequent in-person visits, allowing clinicians to focus their attention on patients who require more intensive care, ultimately leading to improved outcomes and resource utilisation in heart failure management.	
37	Web Comment		From a workflow and organisational perspective, HeartLogic streamlines patient management by enabling more efficient allocation of resources and optimising clinic workflow. The technology facilitates more personalised	Thank you for your comment which the committee has

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			and proactive care, allowing our healthcare team to intervene promptly and adjust treatment plans based on real-time data, ultimately leading to improved patient outcomes and enhanced overall efficiency within our organisation.	considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.
38	Web Comment		Our organisation and our network have been using TriageHF since 2018. It is embedded into our standard of care and we currently have over 2200 CRTD TriageHF monitored patients in our region. We completed a study of TriageHF. The study aimed to evaluate the effectiveness of using Cardiac Implantable Electronic Device (CIED)-generated Heart Failure Risk Score (HFRS) alerts within an integrated, multi-disciplinary approach to heart failure (HF) management. Conducted as a prospective, single-centre outcome study, it spanned from November 2018 to November 2020 and included patients with HFRS-enabled Medtronic CIEDs that generated "high risk" alerts. When these alerts were triggered, they were shared with local HF teams to prompt patient contact and appropriate interventions. Outcome data on healthcare utilisation (HCU) and mortality were collected, and HF teams provided feedback through a validated questionnaire. Results The study involved 188 patients with a mean age of 70 years, of whom 49% had a Charlson Comorbidity Score greater than 6. Over the study period, 367 high-risk alerts were noted, averaging 1.95 alerts per patient, with 23% of patients experiencing more than three alerts during follow-up. Of the patients, 39% (75 patients) were hospitalised within 4-6 weeks of an alert, with 28% (53 patients) experiencing unplanned admissions, and 13% (24 patients) specifically for decompensated HF. Additionally, 18% (33	Thank you for your comment which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			patients) died during the study period. The data indicated that having three or more alerts significantly increased the risk of HF hospitalisation, with a hazard ratio of 2.5 (confidence interval 1.1-5.6, p = 0.03). Conclusions The findings highlight that patients generating high-risk HFRS alerts typically have significant comorbidities and require extensive healthcare resources. An integrated, multi-disciplinary approach enables timely risk stratification and intervention, demonstrating that managing these patients effectively requires a holistic approach beyond just addressing heart failure. The integrated HF pathway received positive feedback from HF teams, underscoring its value in the comprehensive management of this complex patient cohort.	
39	Web Comment		[redacted] Cardiac Device / Heart Failure Specialist Nurse Blackpool Teaching Hospitals NHS Foundation Trust Blackpool Teaching Hospitals has been involved with remote monitoring of Heart Failure patients since 2011. Initially with The REM HF study then going on to look at TRIAGE HF from 2015 and then subsequently Heart Logic. We have no experience with HeartInsight or Corvue to date. We have also previously worked with Manchester Royal Infirmary looking at Triage HF in 2020 where high-risk scores had predictive accuracy for signs, symptoms and behaviours associated with heart failure decompensation.	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			Ahmed FZ, Taylor J, Green C, et al. Triage-HF Plus: a novel device-based remote monitoring pathway to identify worsening heart failure. ESC HeartFail. 2020;7:107-116. Our remote monitoring pathway at Blackpool involves our pacing team and all hospitals/ community Heart Failure teams within our Region having access to these remote systems as part of standard care for all patients with a ICD/CRTP/CRTD. Teams included in the remote monitoring include not only Blackpool Hospital and Community Teams but Preston, Chorley, South Lakes, Lancaster and East Lancashire in secondary clinics to allow satellite services to manage their own patients and see remote download information to assist management of their own caseload. Current caseload Boston Heart Logic 519 patients Medtronic Triage 570 Over the last 10 years we have worked with the device companies to look at ways to integrate these algorithms into practice in a way that helps to highlight patients who are deteriorating in a timely manner. It has also allowed us to manage the growing number of heart failure patients in a way that negates unnecessary routine follow up but is more proactive at looking for patients who need intervention. This has been vital for the wider heart failure teams to manage the volume of work in the system to streamline care to where it is needed in real time. Continuous monitoring via the device has given most patients reassurance	

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			that they are having some monitoring, and things will be highlighted if any problems arise. Historically before remote monitoring it was more ad hoc that we would be able to manage patients' exacerbations depending on whether they were due any appointments for review. Often, we would only be alerted to a decompensation when a patient arrived in A&E or medical wards having been symptomatic for some time. Both Triage and Heart Logic allow us to monitor key physiological parameters associated with Heart failure exacerbations. Often these may be subtle; but a clinical review either by telephone or face to face allows us adjust therapy as needed to avoid admission or deterioration and reduce reliance on patients reporting problems. Having been involved with the remote monitoring since the beginning, I have substantial experience of how this has had a positive impact and benefit on both patients and the hospital. We have not done any formal research on the remote monitoring, but constantly review our processes and how we utilise them in everyday practice; to optimise benefit in a changing healthcare environment, while keeping an eye on any developments via the ongoing research. All our teams value the addition resource remote technology gives us both pacing and heart failure teams. This was paramount during covid where we could not see patients face to face initially and patients were shielding. As we had these remote technologies in place it allowed us to continue to manage a bigger volume of patients at a very difficult time. Patients felt reassured to have the monitoring in place, and we were able to manage patients who were decompensating; utilising the information from remote monitoring. Blackpool HF team were selected as one of the early adopter sites for MHF@home project - NHS England » Managing heart failure @home the	

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			NHSE encouragement of remote monitoring. Having referenced our experience of remote monitoring via device and raising concern that patients without device deserved an alternative remote monitoring approach to their condition, given its value. We highlighted value to those from more deprived areas, without strong patient activation capability. We see the benefit of device-based HF diagnostics of greatest value to these populations as do NHSE.	

Appendix 2

Clinical Experience with HeartLogic in the NHS: Clinical Survey

Objective: To develop and administer a survey to capture real-world clinical experience of using HeartLogic to monitor heart failure for cardiac implantable device patients in the NHS.

Methods: A structured survey was developed to capture real-world experience of using HeartLogic in the NHS across six question domains (HeartLogic performance, integration of HeartLogic into patient care, patient outcomes with use of HeartLogic, generalisability of published clinical and economic data to the NHS, your experience of HeartLogic and patient experience of HeartLogic). Relevant clinicians in seven NHS Trusts , responsible for managing heart failure device care pathways, were approached via email in February 2024 to complete the survey, selected based on their high volume of HeartLogic usage.

Results: Five clinicians from five NHS Trusts responded to the survey request on behalf of their Trusts, with respondents comprising either heart failure nurses or heart failure cardiologists (see table 1). The responses provided comprehensive qualitative descriptions of how HeartLogic is utilised within their care pathways to facilitate additional monitoring for heart failure patients and the benefits and challenges they face with running such a service. Comments from these qualitative responses were grouped according to key themes and reported in table 2 below.

For questions where quantitative analysis was possible, surveys reported 80% of respondents (4 of 5) believed HeartLogic had resulted in changes to patients' quality of life and 80% (4 of 5) believed the use of HeartLogic had improved patient outcomes at their centres. 60% believed the use of HeartLogic had resulted in fewer unplanned hospital visits with the remaining 40% responding "Don't know" to this question.

Furthermore, two Trusts submitted detailed data on their usage of HeartLogic as follows:

Liverpool Heart and Chest Hospital: 1 year follow-up of 212 patients with CRT-D devices from July 2021

- 34 hospitalisations occurred, primarily due to heart failure (HF), with a median hospital stay of 5 days.
- The total outpatient visits numbered 37, with 22 visits attributable to HF decompensation.
- HeartLogic alerts were triggered 197 times, on average 0.95 alerts per patient-year, primarily signalling impending HF exacerbations. These alerts demonstrated a sensitivity of 100%, with all HF hospitalisations detected during alert states.

THEME: Clinician experience

- Therapeutic actions were taken in response to 82 alerts, including medication adjustments, with 37% of alerts necessitating hospitalisation or outpatient visits for clinical management.
- Overall, HeartLogic significantly contributed to the early detection and management of HF events, potentially reducing unplanned hospital visits and improving patient outcomes.

New Cross Hospital

- 143 patients between 2019 and 2021, the follow-up period was a median of 459 days (range 215-994).
- The median age of the cohort was 73 years and 74.1% were males. Roughly two thirds of the patients had ischaemic cause of LV dysfunction.
- 1.17 alerts per patient per year. One alert was seen in 40.6% of patients and 2 alerts in 25.9% of patients. Less than 10 of the 143 patients had more than 4 alerts. We were also assured that 58.0% did not have any activations, suggesting stable heart failure.
- The number of alerts that we get from HeartLogic certainly do not overwhelm our service

Table 1

NHS Trust	Region	Heartlogic integrated into HF device care pathway	Responded (Y/N)	Responders	Date of response
Blackpool Teaching Hospitals NHS Foundation Trust	North West	Yes since 2017	Yes	Cardiac device nurse	26 February 2024
Liverpool Heart & Chest Hospital NHS Foundation Trust	North West	Yes since 2021	Yes	Heart failure/complex device lead clinical nurse specialist	26 February 2024
Manchester Royal Infirmary, Manchester University NHS Foundation Trust	North West	Yes since 2019	Yes	Redacted	27 February 2024
The Royal Wolverhampton NHS Trust	Midlands	Yes since 2019	Yes	Consultant Cardiologist/ Electrophysiologist Lead for Electrophysiology and Devices	28 February 2024
Redacted	Midlands	Yes since 2023	Yes	Redacted	23 February 2024
Redacted	London	Yes since 2022	No	n/a	n/a
Redacted	South East	Yes since 2020	No	n/a	n/a

Table 2

Main themes	Selected expert input (please see attached questionnaires for all inputs)

HL can prevent hospital admissions	• "it feels like we do manage to intervene earlier and **prevent some hospitalisations**." [Cardiac Device Nurse, Blackpool Teaching Hospitals] • "Before HeartLogic was available, patients would either just be managed by their GP's or the Heart Failure Nurses (not all patients) and so in a sense they were 'forgotten'. The activation of the HeartLogic software means that the cardiology department is being proactive in managing their heart failure/LV systolic dysfunction, thus **preventing hospital admissions**" [Consultant Cardiologist, New Cross Hospital] • "**likely reduction in HF admissions** due to the ability to "catch" patients earlier in the HF cascade before they are symptomatic enough to become hospitalised" [Healthcare Professional, Manchester Royal Infirmary]
HL improved patient experience and quality of life	• "Most patients report they **feel safe** knowing someone is keeping an eye on them. They can forget about their condition day to day and get on with living while we make sure things are stable." [Cardiac Device Nurse, Blackpool Teaching Hospitals] • "Patients using HeartLogic have provided positive feedback on its impact on their heart failure management. Many have expressed a **sense of reassurance and empowerment** knowing that their condition is continuously monitored remotely, allowing for early detection of potential exacerbations. This proactive approach has instilled a greater sense of confidence in managing their HF. Patient's appreciate the convenience of fewer clinic visits and the ability to maintain a more active role in their care while still receiving timely interventions when needed. Overall, feedback from patients indicates that HeartLogic has **significantly improved their overall quality of life by providing peace of mind, enhancing convenience, and empowering them** to better manage their heart failure condition." [Heart Failure and Complex Device Lead Clinical Nurse Specialist, Liverpool Heart and Chest Hospital] • "The objective data provided by HeartLogic enables more personalised and targeted therapies, optimising symptom management and enhancing overall well-being. Overall, the implementation of HeartLogic has undoubtedly contributed to a **tangible improvement in the quality of life** for patients living with heart failure." [Heart Failure and Complex Device Lead Clinical Nurse Specialist, Liverpool Heart and Chest Hospital] • "In addition to the above (being able to prevent decompensation and to improve prognostic medication) patients seem to find it **psychologically beneficial** to know someone is monitoring their condition. It allows us to explore the reasons for decompensation, some of which are lifestyle related, e.g. drinking lots of fluid or eating salty foods, and reiterate self care strategies." [Heart Failure and Complex Device Lead Clinical Nurse Specialist, Liverpool Heart and Chest Hospital] • "I was surprised by how positive they were about the system. They are very welcoming of phone calls even when ultimately they are deemed well and no action is taken. They seem **reassured** that they are still being monitored." [Heart Failure Nurse, NHS Trust in England] • "When performing telephone triage of HeartLogic compatible patients, we receive regular feedback that they are **appreciative** of the additional follow up and that we are keeping an eye on them alongside their routine HF clinic visits." [Healthcare Professional, Manchester Royal Infirmary] • "Additionally, the decreased necessity for frequent clinic visits translates to a more convenient and **less burdensome healthcare experience for patients**, while simultaneously allowing healthcare providers to **allocate**

	their resources more efficiently towards those requiring heightened attention and care." [Heart Failure and Complex Device Lead Clinical Nurse Specialist, Liverpool Heart and Chest Hospital]
HL allows for optimisation of patient management, thereby preventing HF events and reducing resource use	• "With the introduction of HeartLogic, the management pathway for these patients has undergone a significant transformation. …. As a result [of early detection], healthcare providers **can intervene promptly** with targeted therapies or adjustments to medication regimens, **potentially preventing or mitigating the severity of heart failure exacerbations**." [Heart Failure and Complex Device Lead Clinical Nurse Specialist, Liverpool Heart and Chest Hospital] • With HeartLogic: "It's now a **proactive pathway** and will catch many patients who have been discharged from the community heart failure nurses and would otherwise have to try to obtain a GP appointment or present to secondary care via emergency pathways. Additionally this process allows us to pick up patients who may have been on optimal therapy when last seen by hospital or community specialist teams but could now be considered to be on sub-optimal therapy by current standards. **We can therefore improve their medication** in line with contemporary practice." [Heart Failure Nurse, NHS Trust in England] • "I have already made interventions to **avert worsening heart failure symptoms** and improved GDMT in patients who were no longer under ongoing specialist review." [Heart Failure Nurse, NHS Trust in England] • "By providing clinicians with real-time insights, HeartLogic facilitates the **optimisation of oral medications**, ensuring that treatment plans are tailored precisely to individual patient needs, thus maximising efficacy." [Heart Failure and Complex Device Lead Clinical Nurse Specialist, Liverpool Heart and Chest Hospital] • "Additionally, the use of HeartLogic reduces the reliance on subjective symptom reporting by patients, providing objective data to guide clinical decision-making. This objective data, combined with regular alerts and remote monitoring, enables a **more proactive and personalised approach** to managing heart failure. Consequently, patients may experience **fewer unplanned hospital visits, reduced lengths of stay, and improved overall outcomes** compared to the traditional management pathway." • "Utilisation of the HeartLogic algorithm witihin our physiologist-led service including review of HF diagnostic information and clinical assessment can shorten the time from patient presentation to HF review and therefore **streamline the existing standard of care**" [Healthcare Professional, Manchester Royal Infirmary] • "I find HeartLogic technology to be immensely beneficial in the management of heart failure patients. …. The convenience of remote monitoring and the potential for improved patient outcomes make a compelling case for HeartLogic to become the standard of care in heart failure management. Its integration into my routine clinical practice has **optimised resource utilisation, improved patient outcomes**, and ultimately enhances the overall quality of care for heart failure patients. I firmly believe that HeartLogic should be embraced as a standard component of heart failure management protocols." [Heart Failure and Complex Device Lead Clinical Nurse Specialist, Liverpool Heart and Chest Hospital]
Additional benefits:	• "it's allowed us to improve medical therapy for both short and long term clinical stability. Much **better collaboration** between HF team and physiologists and awareness of what each discipline can do to help patient outcomes." [Heart Failure Nurse, NHS Trust in England]

THEME: Clinician experience

○ Improved collaboration between medical teams ○ Reducing delay ○ Better management of patients in remote setting	• "Prior to HeartLogic, pacing team had to highlight any issues to heart failure team but now we have Heart Logic these alerts come direct to the HF teams to deal with **reducing delay**." [Cardiac Device Nurse, Blackpool Teaching Hospitals] • "The management pathway for patients with heart failure has shifted from reactive and episodic care to proactive and continuous monitoring with the integration of HeartLogic technology." [Heart failure/ complex device lead clinical nurse specialist, Liverpool Heart and Chest Hospital] • "Allows teams to see all patients device parameters to **better manage patients in the clinic and remote settings**." [Cardiac Device Nurse, Blackpool Teaching Hospitals]

Conclusions and implications: In the absence of local published data, these responses provide valuable additional insight into the clinical and patient experience of using HeartLogic in NHS practice. Current experience in the UK supports the findings of the studies in Heartlogic reducing hospital admissions, reducing resource use, reducing the potential for HF events, thereby reducing the uncertainty around these findings. Additionally, patients in the UK reported improved QoL with the use of HL to their clinicians.

THEME: Clinical benefits

Comment number	Name and organisation	Section number	Comment	NICE responses
40	Web comment	Has all the relevant evidence been taken into account?	2. Published data on TriageHF was not assessed during the consultation meeting. Evaluation of a Device-Based Remote Management Heart Failure Care Pathway on Hospitalization and Patient Outcomes: TriageHF Plus Real-World Clinical Evaluation. ESC Heart Failure. 2024. https://doi.org/10.1002/ehf2.14821 In the context of clinical care pathways, recently published data reports how alerts assessed as high risk drove interventions including diuretic titration and optimisation of GDMT. Both interventions have proven utility both have proven utility in managing episodes of HF decompensation or progression, in potentially modifying outcomes in favour of reducing hospitalisations and improving patient care. The purpose of the alerts is to identify patients who may be unstable or sub-optimally managed and steer more patients towards NICE chronic heart failure guideline directed care. In the study, compared to those who received usual care alone, those who received usual care + TriageHF Plus (alert-based monitoring within a remote monitoring pathway) had a 58% reduction in all-cause hospitalisations. In view of this data, first presented at ESC in 2022, the British Heart Foundation's 2022 press release on TriageHF Plus described it as a "game-changer for heart failure," with the potential to radically transform the monitoring and management of patients with heart failure between clinic visits.	Thank you for your comment, which the committee has considered. This study was published in May 2024, with the initial committee meeting taking place April 2024. Therefore an unpublished manuscript of this study was considered during the EAG's review. The committee concluded

Comment number	Name and organisation	Section number	Comment	NICE responses
				that while there are concerns regarding the quality of the comparative evidence from Ahmed et al., it is likely that TriageHF can reduce heart failure events compared with no algorithm use. See section 3.14.
41	Web comment	Are the summaries of clinical and cost-effectiveness reasonabl	It was apparent in the discussion and from the draft guidance that the primary function of device alerts was not clearly understood. I have therefore summarised below. Clarifying the purpose of using alert-based monitoring as an extension to usual HF care In people with cardiac devices, alert-based monitoring functions as a pre-hospital clinical early warning system. It's primary purpose is to identify patients whose health data indicates a change, typically a	Thank you for your comment, which the committee has

THEME: Clinical benefits

Comment number	Name and organisation	Section number	Comment	NICE responses
		e interpretations of the evidence	deterioration, to their clinical team. Alert based monitoring allows patients to be brought to the attention of healthcare professional without them having to ask for help, which is a key advantage for those who may struggle to advocate for themselves. This allows care to be delivered at times when it is needed, when the patient may be unwell and in need of medical attention, between scheduled clinic visits. The main purpose of device alerts is to flag patients whose health data has signalled a change to clinical teams. The initial response involves structured phone call assessment from a heart failure nurse to screen the patient for symptoms of worsening heart failure. Utilising HF alerts as a pre-hospital clinical early warning system, prompting clinical assessment via phone calls in the first instance, as part of a heart failure pathway, has demonstrated clinical impact. Aggregated data from 4 published studies (see table) identified an explanatory acute issue in approximately 7 in 10 cases assessed as high risk (column B). A passive RM tool that identifies 7 in 10 patients with an acute issue to medical teams has not been reported previously.	considered. The clinical experts helped to clarify the purpose of alert-based remote monitoring throughout the committee's discussions.
42	Web comment	Research only guidance	Impact of widening health inequalities, impacting patient outcomes. As an example of patients who have benefitted from HF alerts being programmed I have obtained consent from 2 patients to share the following data. The first is of a patient for whom we received a HF alert for in 2023, between scheduled appointments. Although the patient reported no significant change in their clinical condition initially, the data download revealed a notable decline in activity over the last few months and new onset atrial fibrillation. This prompted prescription of anticoagulants and in-person clinical assessment, revealing a significant rise in NT pro BNP and prompting dedicated assessment of cardiac status, confirming low cardiac output. This individual, initially identified through alerts from their device, subsequently underwent a heart transplant. In the second example, we received a TriageHF alert from a patient with HF and a CRT-D device, scheduled for a clinic visit in four months. The clinical data accompanying the alert signalled a change in	Thank you for your comment which the committee has considered. The committee considered patient benefits in its discussion

<table>
<tr><th>Comment number</th><th>Name and organisation</th><th>Section number</th><th>Comment</th><th>NICE responses</th></tr>
<tr><td></td><td></td><td></td><td>clinical status characterised by an increasing burden of atrial fibrillation, congestion, and a significant decline in physical activity. At phone call assessment, the patient reported becoming more sedentary with increasing fatigue. The patient was brought to clinic where NT pro BNP was now significantly increased, and right heart catheter confirmed low cardiac output. This patient from a diverse background, who did not make contact with our service prior to the alert, has gone on to receive a heart transplant.</td><td>at the second committee meeting on 19 June.</td></tr>
<tr><td>43</td><td>Web comment</td><td>More research is needed on: Rates of emergency department or primary care visits</td><td>We have previously published rates of emergency department visits.

Sammut-Powell et al. Journal of the American Heart Association. 2022;11:e024526

In the supplementary data of this publication, Accident and Emergency department attendance data, were combined with admitted patient care episodes as a composite outcome, providing a sensitivity analysis for the study (Tables S2 through S9 and Figures S2 and S3).

Analysis repeated using A&E attendance and APC hospitalisations as a joint outcome (Tables S2: S9)

Table S2: Non-elective hospitalisation episodes by maximum risk recorded within the previous 30 days, 6- and 12- months (APC and A&E as a joint outcome).
<table>
<tr><td></td><td colspan="4">Max risk recorded in previous 30 days</td><td colspan="4">Max risk recorded in previous 6 months</td><td colspan="4">Max risk recorded in previous 12 months</td><td></td></tr>
<tr><td></td><td>Low</td><td>Med</td><td>High</td><td>No txs received</td><td>Low</td><td>Med</td><td>High</td><td>No txs received</td><td>Low</td><td>Med</td><td>High</td><td>No txs received</td><td>Total</td></tr>
<tr><td>All-cause, n (%)</td><td>150 (24.9 %)</td><td>261 (43.3 %)</td><td>184 (30.5 %)</td><td>8 (1.3%)</td><td>17 (2.8 %)</td><td>277 (45.9 %)</td><td>307 (50.9 %)</td><td>2 (0.3%)</td><td>2 (0.3 %)</td><td>234 (38.8 %)</td><td>367 (60.9 %)</td><td>0 (0.0%)</td><td>603</td></tr>
<tr><td>CV, n (%)</td><td>31 (16.9 %)</td><td>81 (44.3 %)</td><td>67 (36.6 %)</td><td>4 (2.2%)</td><td>4 (2.2 %)</td><td>70 (38.3 %)</td><td>108 (59.0 %)</td><td>1 (0.5%)</td><td>1 (0.5 %)</td><td>61 (33.3 %)</td><td>121 (66.1 %)</td><td>0 (0.0%)</td><td>183</td></tr>
</table></td><td>Thank you for your comment which the committee has considered. TriageHF appeared dominant in the model results without any benefit assumed in the number of A&E visits. Any additional benefits would only strengthen this case for cost-effectiveness.

The EAG noted that</td></tr>
</table>

Comment number	Name and organisation	Section number	Comment	NICE responses
				this data was missed during the extraction phase of the review and was therefore not included. The data shows similar trends to the other included studies assessing the TriageHF algorithm. For example, the rates of hospitalisations and associated hazard ratio there were more people hospitalised in the medium and high

HF, n (%)	5 (10.6%)	12 (25.5%)	**28 (59.6%)**	2 (4.3%)	0 (0.0%)	12 (25.5%)	**34 (72.3%)**	1 (2.1%)	0 (0.0%)	12 (25.5%)	**35 (74.5%)**	0 (0.0%)	47

CV=Cardiovascular, HF=Heart Failure, txs=transmissions

Table S3: Maximum Triage-HFRS within 30-day diagnostic evaluation and associated non-elective hospitalisations (APC and A&E episodes).

30-day Diagnostic Evaluation Period Max Triage-HFRS	Total diagnostic evaluation periods	30-day Outcomes		
		All-cause hospitalisation (APC or A&E)	Cardiovascular hospitalisation (APC or A&E)	HF hospitalisation (APC only)
Low	2288 (33.6%)	98 (4.3%)	24 (1.0%)	6 (0.3%)
Medium	3535 (51.8%)	175 (5.0%)	48 (1.4%)	7 (0.2%)
High	996 (14.6%)	111 (11.2%)	42 (4.2%)	23 (2.3%)
Total	6819 (100%)	384 (5.6%)	114 (1.7%)	36 (0.5%)

APC = admitted patient care episode, HFRS = heart failure risk score, A&E = accident and emergency

Table S4: Demographics of patients with at least one 30-day hospitalisation outcome in prospective analysis (APC and A&E episodes).

	30-day Outcomes			All patients
	All-cause hospitalisation	Cardiovascular hospitalisation	HF hospitalisation	
Patients, n (%)	206	81	28	429
Age, mean (sd)	67.3 (16.5)	69.4 (16.7)	76.8 (9.8)	66.0 (15.5)
Male, n (%)	135 (65.5%)	60 (74.1%)	18 (64.3%)	271 (63.2%)
Device Type, n (%)				
CRT-D	82 (39.8%)	33 (40.7%)	12 (42.9%)	162 (37.8%)
CRT-P	84 (40.8%)	32 (39.5%)	13 (46.4%)	168 (39.02%)
ICD	19 (9.2%)	<5 (<5.0%)	<5 (<17.9%)	36 (8.4%)
PPM	21 (10.2%)	>11 (>13.6%)	<5 (<17.9%)	63 (14.7%)
NYHA				

Comment number	Name and organisation	Section number	Comment	NICE responses

No heart failure	25 (12.1%)	10 (12.3%)	<5 (<17.9%)	62 (14.5%)	
1	19 (9.2%)	8 (9.9%)	<5 (<17.9%)	53 (12.4%)	
2	72 (35.0%)	24 (29.6%)	5 (17.9%)	150 (35.0%)	
3+	79 (38.3%)	36 (44.4%)	21 (75.0%)	142 (33.1%)	
CKD stage 3 or higher	73 (35.4%)	36 (44.4%)	18 (64.3%)	132 (30.8%)	

HF = heart failure, CRT-D = cardiac resynchronisation therapy device with defibrillator, CRT-P = cardiac resynchronisation therapy device with pacemaker, ICD = implanted cardiac defibrillator, PPM = pacemaker, NYHA = New York Heart Association Functional Classification, CKD = chronic kidney disease

Table S5: Coefficients of frailty model using A&E and APC episodes as a combined outcome.

	All-cause hospitalisation within 30 days			Cardiovascular hospitalisation within 30 days		
Variable	Hazard Ratio	95% CI	p-value	Hazard Ratio	95% CI	p-value
Medium (vs Low)	0.986	0.748 – 1.301	0.92	1.150	0.676 – 1.959	0.61
High (vs Low)	**2.049**	1.474 - 2.846	**<0.001**	**3.320**	1.845 – 5.974	**<0.001**
No HF	1.148	0.623 - 2.113	0.66	1.012	0.343 - 2.983	0.98
Age	1.001	0.990 – 1.013	0.663	1.014	0.994 – 1.023	0.19
CRTP vs CRTD	0.699	0.487 – 1.002	0.05	0.662*	0.754 – 2.166	0.26
PPM vs CRTD	**0.478**	0.254 - 0.898	**0.02**	0.841*	0.262 - 2.698	0.77
ICD vs CRTD	0.562	0.280 - 1.124	0.10	0.169*	0.019-1.468	0.11
CKD stage 3 or higher	1.326	0.931 – 1.890	0.12	1.559*	1.054 – 2.306	0.06

risk groups than low risk. For medium vs low there was no statistically significant association (HR = 1.15, 95% CI: 0.68 to 2). For high vs low there was a statistically significant association (HR = 3.32, 95% CI: 1.85 to 5.97). The direction of these results is comparable to those reported in the other studies, with a higher risk status being associated

<table>
<tr><th>Comment number</th><th>Name and organisation</th><th>Section number</th><th>Comment</th><th>NICE responses</th></tr>
<tr><td></td><td></td><td></td><td>
HF = heart failure, CRT-D = cardiac resynchronisation therapy device with defibrillator, CRT-P = cardiac resynchronisation therapy device with pacemaker, ICD = implanted cardiac defibrillator, PPM = pacemaker, CKD = chronic kidney disease

Table S6: Coefficients for time-varying covariate frailty model for cardiovascular hospitalisation within 30-days (APC and A&E as a joint outcome.
<table>
<tr><td></td><td colspan="3">Cardiovascular hospitalisation within 30 days</td></tr>
<tr><td>Variable</td><td>Hazard Ratio</td><td>95% CI</td><td>p-value</td></tr>
<tr><td>Medium (vs Low)</td><td>1.150</td><td>0.676 – 1.959</td><td>0.61</td></tr>
<tr><td>High (vs Low)</td><td>3.320</td><td>1.845 – 5.974</td><td><0.001</td></tr>
<tr><td>No HF</td><td>1.012</td><td>0.343 - 2.983</td><td>0.98</td></tr>
<tr><td>Age</td><td>1.014</td><td>0.994 – 1.023</td><td>0.19</td></tr>
<tr><td>CRTP vs CRTD (0-15 days)</td><td>0.662</td><td>0.754 – 2.166</td><td>0.26</td></tr>
<tr><td>PPM vs CRTD (0-15 days)</td><td>0.841</td><td>0.262 - 2.698</td><td>0.77</td></tr>
<tr><td>ICD vs CRTD (0-15 days)</td><td>0.169</td><td>0.019-1.468</td><td>0.11</td></tr>
<tr><td>CKD stage 3 or higher (0-15 days)</td><td>1.559</td><td>1.054 – 2.306</td><td>0.06</td></tr>
<tr><td>CRTP vs CRTD (16-30 days)</td><td>0.598</td><td>0.261 - 1.369</td><td>0.22</td></tr>
<tr><td>PPM vs CRTD (16-30 days)</td><td>0.456</td><td>0.130 - 1.602</td><td>0.22</td></tr>
<tr><td>ICD vs CRTD (16-30 days)</td><td>2.277</td><td>0.220 - 23.527</td><td>0.49</td></tr>
<tr><td>CKD stage 3 or higher (16-30 days)</td><td>0.564</td><td>0.261 - 1.217</td><td>0.14</td></tr>
</table>
HF = heart failure, CRT-D = cardiac resynchronisation therapy device with defibrillator, CRT-P = cardiac resynchronisation therapy device with pacemaker, ICD = implanted cardiac defibrillator, PPM = pacemaker , CKD = chronic kidney disease

Table S7: Costs for hospitalisations in the retrospective analysis
<table>
<tr><td></td><td colspan="4">Max risk in previous 30 days</td></tr>
<tr><td></td><td>Low</td><td>Medium</td><td>High</td><td>No transmission</td></tr>
</table>
</td><td>with increased risk of hospitalisation. The EAG therefore do not believe missing this data has led to us not providing an accurate depiction of how TriageHF risk status is associated with risk of hospitalisation in a number of studies. With the main difference from the reported literature being the non-significant</td></tr>
</table>

Comment number	Name and organisation	Section number	Comment	NICE responses

	N	Cost	Missing	N	Cost	Missing	N	Cost	Missing	N	Cost	Missing
A&E episodes												
All-cause	78	£9,107	0	115	£14,057	1	52	£6,583	0	2	£221	0
Cardiovascular	11	£1,491	0	26	£3,671	0	17	£2,470	0	1	£130	0
Total costs (APC and A&E episodes combined)												
All-cause	151	£181,986	1	261	£389,896	4	184	£437,367	4	10	£10,312	2
Cardiovascular	31	£58,403	0	81	£139,897	0	67	£156,622	0	4	£6,250	0
HF	5	£14,676	0	12	£40,230	0	28	£94,135	0	2	£5,774	0

APC = admitted patient care episode, HFRS = heart failure risk score, A&E = accident and emergency, HF = heart failure

Supplementary Table S8: Costs for A&E and APC events within the prospective analysis.

30-day Diagnostic Evaluation Period Max Triage-HFRS	Total diagnostic evaluation periods	All-cause hospitalisation				Cardiovascular hospitalisation			HF hospitalisation		
		N	Total Cost	Missing	Average Cost	N	Total Cost	Average Cost	N	Total Cost	Average Cost
Low	2282 (33.6%)	98 (4.3%)	£95,133	2	£990.97	24 (1.1%)	£35,173	£1,465.55	6 (0.3%)	£18,561	£3,093.50
Medium	3530 (51.8%)	176 (5.0%)	£231,701	1	£1,324.01	48 (1.4%)	£84,819	£1,767.07	7 (0.2%)	£19,142	£2,734.58

association of a medium risk, which was generally reported as being statistically significant compared to low risk in the other studies assessing hospitalisation when using the TriageHF algorithm (number of studies = 5).

THEME: Clinical benefits

<table>
<tr><th>Comment number</th><th>Name and organisation</th><th>Section number</th><th>Comment</th><th>NICE responses</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>High</td><td>993 (14.6%)</td><td>111 (11.2 %)</td><td>£257,354</td><td>2</td><td>£2,361.05</td><td>42 (4.2 %)</td><td>£103,832</td><td>£2,472.20</td><td>23 (2.3 %)</td><td>£80,438</td><td>£3,497.31</td></tr>
<tr><td>Total</td><td>6805 (100%)</td><td>384 (5.6%)</td><td>£584,188</td><td>5</td><td>£1,541.40</td><td>114 (1.7 %)</td><td>£223,824</td><td>£1,963.37</td><td>36 (0.5 %)</td><td>£118,141</td><td>£3,281.70</td></tr>
</table>
HF = heart failure, HFRS = heart failure risk score. No missing data for cardiovascular and HF hospitalisation costs
</td><td></td></tr>
<tr><td>44</td><td>Web comment</td><td>Patient reported outcomes</td><td>These have been published.

A pre-specified secondary outcome included in the TriageHF Plus study included a patient reported outcome measure; assessment of change in status between initial phone call and 30-day follow-up (as measured by patient global impression of change (PGI-C).

Association of a Device-Based Remote Management Heart Failure Care Pathway with Hospitalisation and Patient Outcomes: TriageHF Plus Real-World Clinical Evaluation.

Patient and physician global assessments

Of the sixty-six 30-day follow-up calls where an action had been taken at initial assessment, 39 (59%) patients reported an improvement in symptoms (PGI-C), and 41 (62.1%) of HF specialists undertaking the assessment reported a subjective improvement in patient’s clinical state (PGA).</td><td>Thank you for your comment which the committee has considered.</td></tr>
<tr><td>45</td><td>Web Comment</td><td>Can only be used in research 1</td><td>Already tested within the NHS - demonstrating value in clinical practice and well received by patients.</td><td>Thank you for your comment which the committee has considered.</td></tr>
</table>

THEME: Clinical benefits

Comment number	Name and organisation	Section number	Comment	NICE responses
46	Web Comment		4.NICE guidance also recommends that Heart failure patients are reviewed every 6 months and remote monitoring helps some of this review process as patients are being continuously monitored not just every 6 or 12 months.	Thank you for your comment which the committee has considered.
47	Web Comment		The integration of HeartLogic technology heralds a transformative shift in heart failure care, yielding a spectrum of tangible benefits for patients. With its proactive monitoring capabilities, HeartLogic significantly diminishes the incidence of heart failure events by enabling early detection of impending exacerbations. This not only reduces morbidity but also enhances symptom control, affording patients a better quality of life. Heartlogic contributes to the deceleration of heart failure progression, a pivotal aspect in managing chronic conditions. By providing clinicians with real-time insights, HeartLogic facilitates the optimisation of oral medications, ensuring that treatment plans are tailored precisely to individual patient needs, thus maximising efficacy. Additionally, the decreased necessity for frequent clinic visits translates to a more convenient and less burdensome healthcare experience for patients, while simultaneously allowing healthcare providers to allocate their resources more efficiently towards those requiring heightened attention and care. In my opinion, the integration of HeartLogic technology has led to significant improvements in patients' quality of life. By providing continuous remote monitoring and early detection of impending heart failure exacerbations, HeartLogic has developed a proactive HF management approach allowing for timely interventions and adjustments to treatment plans, potentially reducing the frequency and severity of heart failure symptoms. Consequently, patients may experience fewer hospitalisations, AED attendances, and unplanned clinic appointments, leading to a reduced burden on their daily lives and a greater sense of stability and confidence in managing their condition. The objective data provided by HeartLogic enables more personalised and targeted therapies, optimising symptom management and enhancing overall well-being. Overall, the implementation of HeartLogic has undoubtedly contributed to a tangible improvement in the quality of life for patients living with heart failure. HeartLogic has introduced numerous benefits to both our patients and our hospital. For patients, the proactive monitoring offered by HeartLogic enables early detection of impending heart failure exacerbations, leading to timely interventions and reduced	Thank you for your comment which the committee has considered. The committee considered patient benefits in its discussion at the second committee meeting on 19 June.

THEME: Clinical benefits

Comment number	Name and organisation	Section number	Comment	NICE responses
			hospitalisations. This not only enhances patient outcomes but also fosters a sense of empowerment and confidence in managing their condition. Additionally, by providing continuous remote monitoring, HeartLogic reduces the need for frequent clinic visits, resulting in greater convenience and improved access to care for patients.	
48	Web Comment		I find HeartLogic technology to be immensely beneficial in the management of heart failure patients. Its continuous remote monitoring capabilities provide early detection of impending exacerbations, enabling timely interventions and reducing the burden of hospitalisations and adverse events. The proactive approach offered by HeartLogic empowers patients to take an active role in their care and fosters a sense of confidence and security in managing their condition. The convenience of remote monitoring and the potential for improved patient outcomes make a compelling case for HeartLogic to become the standard of care in heart failure management. Its integration into my routine clinical practice has optimised resource utilisation, improved patient outcomes, and ultimately enhances the overall quality of care for heart failure patients. I firmly believe that HeartLogic should be embraced as a standard component of heart failure management protocols.	Thank you for your comment which the committee has considered. The committee considered patient benefits in its discussion at the second committee meeting on 19 June.
49	Web Comment		Before the availability of the TRIAGEHF management pathway, heart failure (HF) patients with implanted Cardiac Implantable Electronic Devices (CIEDs) were monitored based on periodic clinical visits and subjective symptom reporting, often leading to delayed intervention and higher risk of adverse events. The management was reactive, relying heavily on patient-reported symptoms or routine check-ups, which might miss early signs of deterioration. With the introduction of the TRIAGEHF pathway, the management shifted to a proactive approach. The pathway uses CIED-generated Heart Failure Risk Score (HFRS) alerts to identify patients at high risk of HF decompensation in real-time. These alerts prompt immediate communication with local HF teams, facilitating timely patient contact and intervention. This allows for	Thank you for your comment which the committee has considered. The

THEME: Clinical benefits

Comment number	Name and organisation	Section number	Comment	NICE responses
			early detection and treatment of HF exacerbations, significantly reducing unplanned hospitalisations and potentially improving patient outcomes by addressing issues before they escalate. The integrated approach also promotes holistic care, addressing the multiple comorbidities often present in these patients.	committee considered patient benefits in its discussion at the second committee meeting on 19 June.
50	Web Comment		Additionally, proactive management through these tools helps maintain better overall health and quality of life for HF patients by preventing severe episodes and hospitalisations. Without them, patients are likely to experience more frequent and severe health issues, adversely affecting their day-to-day lives and overall wellbeing.	Thank you for your comment which the committee has considered. The committee considered patient benefits in its discussion at the second committee meeting on 19 June.

THEME: Clinical benefits

Comment number	Name and organisation	Section number	Comment	NICE responses
51	Web Comment [comment submitted twice by 2 separate people]		Remote monitoring algorithms provide a safety net and often identify patients well in advance of worsening symptoms, allowing earlier intervention and often averting the need for long and expensive hospital stays. It drives efficiencies for healthcare providers allowing them to focus on those patients most in need, reducing the need to see many patients face to face. Thereby reducing hospital visits and wait for appointments. The issue can be addressed remotely, quickly and efficiently, saving costs to NHS and time, anxiety and cost to the person and their caregivers. It also reduces their exposure to potential infection when visiting a hospital.	Thank you for your comment which the committee has considered. The committee considered patient benefits in its discussion at the second committee meeting on 19 June.

THEME: Patient experience

Comment number	Name and organisation	Section number	Comment	NICE responses
52	Web comment	False positives creating anxiety	This concern has not been substantiated in any of the clinical studies. As part of usual care, patients are often phoned routinely after device alerts of any kind. There is no adverse reporting to indicate that patients are being harmed by alert based monitoring or signals of increased anxiety reports as an adverse outcome int he TriageHF Plus pathway. In Greater Manchester we have enrolled almost 1,000 patients from across 8 hospitals into a heart failure care pathway that utilises heart failure alerts. As this was a clinical study, the HRA and REC required that we include safety reporting to capture instances of device failure or harm detected during the study. Since 2019, there have been no recorded adverse safety data, and only 3 individuals have withdrawn from the study. The alerts prompt structured phone call based assessments, which have previously been shown to be associated with improved patients outcomes and endorsed by the 2021 European Society of Cardiology (ESC) clinical practice guidelines for heart failure. This is based on a 2015 Cochrane meta-analysis reported structured telephone support and telemonitoring in HF to be associated with lower all-cause mortality and fewer HF hospitalisations. Healthcare practitioners are skilled in assessing patients for indicators worsening heart failure. A 10-minute phone call, utilised for the initial clinical assessment after a high alert, has not resulted in any instances of harm or reported anxiety. In fact, guideline-directed medical interventions, known to improve outcomes and prolong life, have been optimised, as evidenced by the findings of the TriageHF Plus study. Patients have declined exit from the study on moving out of area.	Thank you for your comment which the committee has considered. The committee considered patient benefits in its discussion at the second committee meeting on 19 June.
53	Web Comment		I'm a heart failure nurse who's been using Heart Logic and Triage HF for around five months. So still early days and in the realm of anecdote/experience but some impressions so far:	Thank you for your comment which the committee has

THEME: Patient experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			I've not come across any anxiety from patients following a call prompted by an alert. On the contrary people seem very reassured, even if nothing significant is found on clinical review, that they're being monitored. Patients in my locality, if optimised and stable, are discharged from specialist services. Particularly in the current climate with scarce GP appointments they do not have ready access to a review if they feel they are decompensating other than an emergency pathway. I've made medication changes in this group which appear to have halted worsening heart failure. It presents an opportunity to explore reasons for decompensation, e.g. lifestyle choices and medication compliance - self management advice is reiterated. My sense at this point is that as well as possibly preventing an admission it has resulted in quicker resolution of symptoms. I'm also picking up people within this group that may have been considered to be on optimal therapy at the point at which they were discharged but by current standards is lacking. I'm able to get these people onto contemporary GDMT.	considered. The committee considered patient benefits and clinician experience in its discussion at the second committee meeting on 19 June.
54	Web Comment		Comments about recommendations 1. There is possible anxiety the algorithms may increase patient contact due to false positives. However, in my experience and overall feedback from patients has been very positive as they feel reassured, well managed, and have a contact point ongoing. Anecdotally we have reduced the need for admission or decompensation with the use of this technology. Patients tell us that they feel more in control and safe, they like that they do not have to attend as many appointments, especially if they are well in themselves.	Thank you for your comment which the committee has considered. The committee considered patient experience and the benefits to patients in its discussion on 19 June.

THEME: Patient experience

Comment number	Name and organisation	Section number	Comment	NICE responses
55	Web Comment		Patient: GM Patient who has avoided several admissions being managed utilising remote technology. 'Knowing that I am being monitored all the time gives me great reassurance and often I get a call before I realise what the problem is. It gives me confidence and has stopped me having an admission many times. The nurses and pacemaker team who manage it are great' Patient: PJ Overall very supportive of its use in clinical practice. His opinion was he would prefer the clinician he is seeing has access to all available diagnostic/clinical tools to enable the right decisions about his condition. He went on to say he feels anxious when he has not been to clinic for a while, as he is very reassured with its use. '	Thank you for your comment which the committee has considered. The committee considered patient experience and the benefits to patients in its discussion on 19 June.
56	Web Comment		Patients using HeartLogic have provided positive feedback on its impact on their heart failure management. Many have expressed a sense of reassurance and empowerment knowing that their condition is continuously monitored remotely, allowing for early detection of potential exacerbations. This proactive approach has instilled a greater sense of confidence in managing their HF. Patient's appreciate the convenience of fewer clinic visits and the ability to maintain a more active role in their care while still receiving timely interventions when needed. Overall, feedback from patients indicates that HeartLogic has significantly improved their overall quality of life by providing peace of mind, enhancing convenience, and empowering them to better manage their heart failure condition.	Thank you for your comment which the committee has considered. The committee considered patient experience and the benefits to patients in its discussion on 19 June.

THEME: Patient experience

Comment number	Name and organisation	Section number	Comment	NICE responses
57	Web Comment [comment submitted twice by 2 separate people]		To whom it may concern, As Founder and Trustee of Arrhythmia Alliance, a collaboration of patients, caregivers, healthcare professionals, policy makers and all those affected by or involved in the care of people living with arrhythmias, I am writing to share feedback and concerns regarding the recent draft consultation document indicating that the remote monitoring of Heart Failure alerts may become unavailable except for use in research. We represent a large body of patients many of whom have a cardiac device to manage and monitor their condition. Over the last few years, especially during the pandemic, this technology has provided a lifeline and positively impacted many lives. Patients feel empowered and reassured that their health status is being monitored and able to 'get on with their lives'. We have one fantastic example of a patient who during the pandemic was too afraid to seek medical help despite feeling incredibly unwell. Thankfully the local nurse picked up his Heart Failure alert, contacted the patient by phone and from their discussion was able to understand how to manage his condition. Seamlessly, his local pharmacist delivered a new prescription, protecting an extremely vulnerable patient and responding quickly before things became much worse.	Thank you for your comment which the committee has considered. The committee considered patient experience and the benefits to patients in its discussion on 19 June.
58	Pumping Marvellous Foundation	1.1	I have run a poll in our patient community asking "If you had a cardiac pacemaker device like a CRT or ICD and it had a way of telling your heart failure team if your condition was getting worse, where they could react to this, would you want it activated and working?" We have run the poll for 18hrs – All 118 patients who responded said that they would want the intervention activated. You will see a further image that represents even more patients & 7 days later with 159 responses.	Thank you for your comment which the committee has considered.
59	Pumping Marvellous Foundation	3.1	I agree with the patient expert's opinions apart from I feel that false-positive alerts have been taken out of context and used as a lever to push for more research. In my humble opinion I do not believe that this in it's entirety would cause anxiety	Thank you for your comment which the

THEME: Patient experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			and stress. If you compare normal monitoring of ICD's and CRT devices where there is an alert created and it turns into a false-positive the vast majority of patients would prefer this, knowing that the reporting system works than nothing happening. I agree that if the frequency was significant then this may lead to anxiety and distress. If this was the case the functionality could be switched off at the request of the patient. A parallel discussion would be around medication side effects. Many patients are acutely aware of the side-effects, if any of medications. If these are experienced by the patient then a joint decision between the patient and their healthcare team is taken leading to an appropriate action, remove, remove and replace or manage. Worsening patient anxiety would be the worsening of their symptoms and not knowing what was causing it and when to interact with their healthcare team about it.	committee has considered. The committee considered patient experience and the benefits to patients in its discussion on 19 June.

THEME: Equality considerations

Comment number	Name and organisation	Section number	Comment	NICE responses
60	Boston Scientific	3.24-3.28	We disagree with a number of assertions included in the equalities section of the draft guidance and ask that the committee discuss these again. We believe that the ability to remotely monitor heart failure presents an opportunity to reduce inequities, particularly in underserved and remote communities or those with disabilities who may otherwise find it difficult to attend in-person appointments. We disagree with comments in section 3.28. The ability for quantitative data to be made available to clinicians, reporting the status of a patient, offers greater accessibility to those patients who may not feel comfortable initiating contact directly in the first instance. The quantitative patient-specific data provided by HeartLogic can allow for timely triaging of patients and of resources to obtain any needed interpreters for initial telephone calls or outpatient clinic appts as required.	Thank you for your comment which the committee has considered. The committee considered these ways in which HF algorithms could address health inequalities in their discussion on 19 June. An additional paragraph has been added to the guidance to reflect the potential for algorithm-based remote monitoring to reduce inequalities. See section 3.26.
61	Medtronic	All	Equality issues This current recommendation could lead to a variation in the access to care for HF patients due to geographical, socio-economic, and condition-based disparities. Evidence shows that people who live in areas of socioeconomic deprivation have higher rates of emergency admissions. Medtronic are concerned that a draft guidance recommendation of 'can only be used in research' would adversely affect patients from communities that are historically underserved including patients who are less mobile, elderly or those who live in remote areas and may inadvertently create an inequality in the delivery of care.	Thank you for your comment which the committee has considered. The committee considered these ways in which HF algorithms could address health inequalities in their discussion on 19 June. An additional paragraph has been added to the guidance to reflect the potential for algorithm-based remote monitoring to reduce

THEME: Equality considerations

Comment number	Name and organisation	Section number	Comment	NICE responses
			There is disparity in access to specialist nursing care in different parts of the country. Patients with HF with a preserved ejection fraction (HFpEF) in the main do not have the same access to specialist care and cardiac rehabilitation as those with a reduced ejection fraction (HFrEF). HF remote monitoring supports initiatives such as NHS@home to reduce inequalities across pathways and systems, aligning with the Core20Plus5 approach. We ask that the DAC strongly reconsider the draft guidance recommendations that TriageHF Plus 'Can only be used in research' as it potentially compounds the risk of limiting access for those who live in socioeconomic deprived communities, remote areas or those who are less mobile.	inequalities. See section 3.26.
62	Web comment	Equality issues	Remote monitoring systems are ideally positioned to reduce inequalities in access to healthcare. Device alerts, framed within a pathway like TriageHF Plus, create a system that screens the ambulatory device population and proactively identifies those individuals whose health-related data is the most abnormal (often the sickest people) and offers them help, without them needing to ask. A simple phone call assessment is used to confirm the circumstances of the alert. The system circumvents communication barriers and avoids the need for patients to have a deep understanding of accessing healthcare, relying instead on significant shifts in health data to provide assistance at times when the patient may be unwell, between scheduled appointments. Remotely monitored health data from cardiac devices provides heart failure specialists an insight into daily data spanning the last 14 months, which allows clinically important trends to be detected.	Thank you for your comment which the committee has considered. The committee considered these ways in which HF algorithms could address health inequalities in their discussion on 19 June. An additional paragraph has been added to the guidance to reflect the potential for algorithm-based remote monitoring to reduce inequalities. See section 3.26.

THEME: Equality considerations

Comment number	Name and organisation	Section number	Comment	NICE responses
			The point is that patients can deteriorate between scheduled clinic visits and NHS waiting times increased leading to long delays between clinical assessments. A proactive monitoring system that utilises device-HF alerts has provided a safety net for many clinical teams in the UK and functions as a HF monitoring tool. Given the various reasons discussed, proposing that device-HF alerts should continue as a primary area of research could potentially introduce new disparities in care for individuals with heart failure. Moreover, as the first international remote monitoring consensus (2023) provided a class 1 recommendation for configuring clinical alerts and a 2A indication for device-HF alerts to monitor incident HF and/or progression in individuals with devices, a recommendation to remain limited to research would create differing standards of remote monitoring between the UK and the rest of the world and set back progress.	
63	Web comment	Research only guidance and Equality issues	As a clinician, the conflicting UK clinical guidance (NICE vs BHRS and rest of the world) and recommendation for research only presents an ethical dilemma. We know that individuals from low-income, ethnic minorities, and women are less likely to take part in research, due to barriers such as non-inclusive research practices and communication. As a consequence, individuals from backgrounds under-represented in research are less likely to benefit from access to tools designed to improve access to clinical specialists and patient care if they remain for research only. Until such time that there is parity of representation in clinical studies these groups will have reduced access to validated tools like TriageHF.	Thank you for your comment which the committee has considered.

THEME: Equality considerations

Comment number	Name and organisation	Section number	Comment	NICE responses
			How will you ensure these groups are not disadvantaged in reversing a UK position to research only for TriageHF and HeartLogic, currently supported by BHRS?	
64	Web comment	On the call	Diversity among the expert panel Although not in the document, during the call I was reassured to hear of NICE's commitment to diverse representation in its panels, as evidenced by the presentations. However, all clinical experts on the panel were white male. Including clinical experts in device-HF remote monitoring from diverse backgrounds could have enriched the discussion with a range of experiences and perspectives, enhancing scientific discussions grounded in a robust understanding of the evidence.	Thank you for your comment which the committee has considered. NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. NICE makes every attempt to include a wide range of specialist committee members, but full committee attendance cannot be guaranteed for each topic due to individual members' availability.
65	Web Comment [comment submitted twice by 2 separate people]		The technology addresses health inequalities, many patients particularly those from ethnic minority groups and more deprived backgrounds do not seek medical assistance until they are blue lighted to A&E, remote monitoring can make all the difference, detecting a heart failure event early, before it becomes a crisis.	Thank you for your comment, which the committee has considered. An additional paragraph has been added to the guidance to reflect the potential for algorithm-based remote monitoring to reduce inequalities. See section 3.26.

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
66	Boston Scientific	1.4, Why the committee made these recommendations	We are disappointed that the totality of the evidence base on prognostic accuracy has not been taken into account collectively. HeartLogic has been externally validated repeatedly across different patient groups and geographies, in over 3,000 patients in total, with consistency in sensitivity outcomes reported. This should alleviate concerns over bias from any individual study.We would again like to highlight a key study that we do not believe has been made available to the committee but that we shared with NICE in our EAR consultation response in February 2024. Singh et al. (2024) presents the results of the US FDA-mandated post-approval study that evaluated the performance of HeartLogic in 1,458 patients and found an observed sensitivity of 74.5%. This is of significance given the study design was discussed and agreed upon with the FDA and thus the regulatory agency deemed the study sufficiently powered and appropriately designed to confirm the prognostic performance of HeartLogic. Further information on this study can be found in appendix 1 below. Appendix 1 Whilst we understand the Committee cannot review all evidence published after the assessment is underway, we would like to highlight Singh et al 2024. Below we include a summary of key points from this study. • US FDA-mandated prospective post-approval study evaluating Heartlogic performance in 1,458 patients, with 302 usable HF events	Thank you for your comment, which the committee has considered. The committee acknowledged that the risk of bias assessment of a study does not indicate that bias has been detected in the study. The committee concluded that while there are some concerns about the risk of bias of the prognostic accuracy studies, it is likely that HeartLogic can accurately predict heart failure events. At the second meeting, the committee considered Singh et al. in their overall judgement of the prognostic accuracy for HeartLogic. See section 3.6.

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
			• Real world evidence from ICD and CRT-D patients linked with Centers for Medicaid and Medicare Services (CMS) claims database • Pre-defined primary endpoints o Sensitivity >40% o False positive rate <2.0 per patient-year • Results o Sensitivity 74.5% o False positive rate 1.48 alerts per patient-year • Results exceeded FDA agreed endpoints This study had a large sample size, powering and robust design and performance assessment agreed upon with the FDA. This post-approval analysis confirms Heartlogic can accurately predict HF events with a low false positive rate (as demonstrated in the original validation study MultiSENSE) and aligns with UK clinical data and experience (see Appendix 2). We also note a further factual inaccuracy relating to statements around prognostic accuracy of HeartLogic, which we detail below in our comment 7.	
67	Medtronic	3.6	The committee notes that "For TriageHF, sensitivity (range = 37.4% to 87.9%) and specificity (range = 44.4% to 90.2%) showed considerable variability." The committee proceeds to note that "some of this variability was due to differences in the timeframes of the reporting and different outcome measures" and then ultimately concludes that "More research is needed on prognostic accuracy." TriageHF was developed with 3 risk levels (low, medium,	Thank you for your comment which the committee has considered. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that TriageHF can predict heart failure events.

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
			and high) to allow clinicians to choose whether to err on the side of sensitivity or specificity in managing heart failure patients. For instance, in Cowie 20134, including both medium and high heart failure status produces a sensitivity of 82.8%, although with lower specificity (45.8%). Focusing only on high alerts reduces the sensitivity to 46% while maximising specificity (90.2%). The TriageHF-directly care pathway popularised in the UK – TriageHF Plus – achieves an optimal balance of sensitivity and specificity by protocolising a device transmission 30 days after a patient transitions to medium risk status when it is triggered by elevated transthoracic impedance. The example of TriageHF Plus illustrates a key challenge with the committee's characterisation of TriageHF accuracy. With a robust set of 10 studies published on the prognostic value of TriageHF across several different groups of researchers and varying patient populations, some of which examined only "high" status while others examined "high + medium" status, a range of results is inevitable. Note that performing more research on prognostic accuracy – as the committee has recommended – can only degrade the committee's assessment of TriageHF accuracy evidence if their approach is to combine all studies into one range, and conclude that based on the range, there is uncertainty on the prognostic value of TriageHF. It is crucial for the committee to meaningfully examine the differences between the studies, their implications for the results observed, as well as to understand how the technology is being leveraged in clinical practice in the UK to develop an informed opinion on the accuracy/utility of TriageHF.	See section 3.7. This section has been updated to focus on the study endpoint of worsening heart failure in patients with a "high risk status".

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
68	Web comment	More research is needed on: prognostic accuracy	Prognostic data on TriageHF has been extensively published. The following summarises how High risk status confers adverse prognostic outlook for people with CIEDs and heart failure. Published data 1. Post-hoc analyses of randomised controlled trial data has consistently demonstrated that individuals identified High risk status confers between a 6-10.7 fold increased risk of HF hospitalisation in the next 30-days Cowie, M.R., S. Sarkar, J. Koehler, D.J. Whellan, et al., Development and validation of an integrated diagnostic algorithm derived from parameters monitored in implantable devices for identifying patients at risk for heart failure hospitalization in an ambulatory setting. European Heart Journal, 2013. 34(31): p. 2472-2480. Burri, H., A. Da Costa, A. Quesada, R.P. Ricci, et al., Risk stratification of cardiovascular and heart failure hospitalizations using integrated device diagnostics in patients with a cardiac resynchronization therapy defibrillator. EP Europace, 2018. 20(5): p. e69-e77. Gula, L.J., G.A. Wells, R. Yee, J. Koehler, et al., A novel algorithm to assess risk of heart failure exacerbation using ICD diagnostics: validation from RAFT. Heart Rhythm, 2014. 11(9): p. 1626-1631.	Thank you for your comment which the committee has considered. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that TriageHF can predict heart failure events. See section 3.7.

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
			Although non-RCT data, we have published data from a real-world UK cohort demonstrating that high risk status confers increased risk of death. During follow-up, 285 patients (65%) had a high-risk episode and 60 patients (14%) died (50 in high-risk group; 10 in never high-risk group). Significantly more cardiovascular deaths were observed in the high-risk group, with mortality rates across groups of high vs. never-high 10.3% vs. <4.0%; P = 0.03. Experiencing any high-risk episode was associated with a substantially increased risk of death [odds ratio (OR): 3.07, 95% confidence interval (CI): 1.57-6.58, P = 0.002]. Each high-risk episode ≥14 consecutive days was associated with increased odds of death (OR: 1.26, 95% CI: 1.06-1.48; P = 0.006). Ahmed, FZ et al. (2022). Remote monitoring data from cardiac implantable electronic devices predicts all-cause mortality, EP Europace, Volume 24, Issue 2, February 2022, Pages 245-255, https://doi.org/10.1093/europace/euab160	
69	Web comment	More research is needed on: Rates of false positives and unexplained alert rates	3. Sensitivity, Specificity, False Positives and Unexplained Alerts Sensitivity, specificity, and unexplained alert rate (referred to as UAR in the Multisense and TriageHF studies) are crucial metrics for assessing algorithm performance. However, it is	Thank you for your comment which the committee has considered. The committee noted that “false positive” alerts could still provide useful information in

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
			essential to consider the context and endpoints against which these metrics are assessed. Broadly speaking, sensitivity has been defined as the number of cases assessed as high risk who have the condition. Older studies of TriageHF used the clinical endpoint of 30-day HF hospitalisation as the endpoint ("condition") against which sensitivity and specificity was calculated. Hospitalisations due to heart attacks, arrhythmias, worsening HF symptoms managed with urgent outpatient appointments and escalating diuretic doses, were not counted. Therefore, if the objective is solely to determine whether a high-risk status identifies individuals hospitalised within 30 days, the definition of what constitutes a positive case becomes crucial. Cases of worsening heart failure (without hospitalisation), urgent outpatient visits, increased oral diuretics and even IV diuretics administered at home, do not contribute to this endpoint, leading to a lower sensitivity. A more comprehensive definition for assessing sensitivity would include all cases experiencing a clinical event, whether related to heart failure or not, by 30 days. Non-HF acute medical issues like exacerbations of COPD or a chest infection, which can lead to a change in clinical parameter like heart rate, fluid levels in the chest and reduced activity can trigger an alert. They are also universally recognised as clinically significant. For this reason, recent real world clinical studies have examined a broader range of endpoints (including HF and non-HF events, from patient-reported symptoms to hospitalisations), resulting in an increase in sensitivity.	reviewing heart failure patients. See section 3.8.

THEME: Prognostic accuracy

<table>
<tr><th>Comment number</th><th>Name and organisation</th><th>Section number</th><th>Comment</th><th>NICE responses</th></tr>
<tr><td></td><td></td><td></td><td>
It may be prudent to also consider other metrics. Real world clinical studies have examined a broader range of definitions for worsening heart failure and also assessed non-HF clinical issues. In the table below, approximately 7 in 10 cases assessed as high risk are identified as having a clinically relevant event by their clinical team. 3 of these studies are from the UK.
<table>
<tr><th>Study</th><th>Clinical events in high risk %</th><th>Sensitivity %</th><th>Specificity %</th></tr>
<tr><td>Ahmed, 2020</td><td>71%</td><td>98.6%</td><td>63.4%</td></tr>
<tr><td>Bachtiger, 2021(abstract)</td><td>59.8%</td><td>87.9%</td><td>59.4%</td></tr>
<tr><td>Garner, 2022</td><td>65%</td><td>-</td><td>-</td></tr>
<tr><td>Virani, 2018</td><td>83%</td><td>-</td><td>-</td></tr>
</table>
During the consultation meeting, concerns were voiced about false positives and the impact.

4. False positives vs. unexplained alerts

As mentioned earlier, not all false positives are truly false- they may represent non-HF, or non-cardiovascular events that have not been considered a true positive as they are not a heart failure event. When we set the window too narrow we miss other clinically important problems. Exacerbation of COPD, new onset uncontrolled atrial fibrillation and patient reported worsening breathlessness are all clinically significant issues that may be mis-classified as a false
</td><td></td></tr>
</table>

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
			positive, if a positive event is defined by HF events. Therefore, meticulous review of study methodology is essential. Considering these factors, recent studies on device alerts have shifted from reporting false positives to describing "unexplained alerts," quantified as the "unexplained alert rate," to facilitate comparison across studies. An alert is considered "false" only if it is "unexplained," meaning it is not associated with a clinical explanation (no change in symptoms and no identified acute clinical issues). In studies where reported, the UAR remains consistent across TriageHF studies, but most notably reported as 0.5 alerts per patient-year in the largest study involving over 20,000 patients in the US Optum healthcare database led by Zile. In other studies, even if the UAR is not explicitly reported, it can be calculated if the total number of alerts and the number of events detected are known.	
70	Web Comment	Prognostic accuracy 3.6	This statement seems contradictory to the evidence summarised in the committee papers. As summarised in Table 5, 8 papers reporting prognostic accuracy of HFRS, 4 of which were prospective design. On page 14, referring to 5 studies, the committee acknowledges that; “Across the endpoints, the results consistently show that there is an increased risk for HF, cardiovascular, and non-HF cardiovascular related hospitalisation when in a high-risk or medium-risk status, compared with low-risk status”	Thank you for your comment which the committee has considered. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that TriageHF can predict heart failure events. See section 3.7.

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
71	Web Comment	More research 1.4	False positives are often an indicator of another clinical event which may need some intervention - providing important physiological data for consideration in patient management strategies	Thank you for your comment, which the committee has considered. The committee noted that “false positive” alerts could still provide useful information in reviewing heart failure patients. See section 3.8.
72	Web Comment		3.False positive alerts are mentioned with regards to chest infection raising impedance, but this is still useful in reviewing a heart failure patient. This acute illness may also affect their heart failure (and increase the risk of decompensation) and with combined clinical assessment will structure a pathway for the patient. To most heart failure teams this is not seen as a false positive, but another flag to review the patient for a good reason. Reduced activity is also often a good indicator alongside other symptoms. These alerts are managed by experienced heart failure nurses who may know the patients well and be experts in clinical assessment.	Thank you for your comment, which the committee has considered. The committee noted that “false positive” alerts could still provide useful information in reviewing heart failure patients. See section 3.8.

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
73	Boston Scientific	1.4, Why the committee made these recommendations	The presentation of the risk of bias assessment is misleading. This has not been sufficiently defined anywhere in the draft guidance nor the EAR beyond a reference to it affecting “uncertainty about the evidence”. For clarity, we note that any rating of high/critical means that the chance of bias existing is high but does not mean that there is a high degree of bias, or even that any bias has been detected. This point has been clearly stated in EAR’s from other NICE diagnostic reviews. Furthermore, we note that, as the EAG acknowledged in their response to comment 22 of the EAR comments, “quality appraisal of studies is subjective” and given the ambiguity in their reporting, we remain unable to understand what specific concerns the EAG had in many of their risk of bias assessments. Please can the committee or EAG clarify what “robust analysis” would constitute for future studies where further evidence generation is recommended.	Thank you for your comment which the committee has considered. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that HeartLogic can predict heart failure events. See section 3.6. The EAG suggest that a “robust analysis” should include all relevant confounding variables/covariates to reduce potential bias in the study results.
74	Medtronic	3.12	In relation to the risk of bias in the Ahmed 2024 publication, the committee notes that “[The Ahmed et al, 2024] study was assessed as having critical risk of bias because of missing information, including whether propensity score matching was successful.” Firstly, Ahmed 2024 study is published in ESC Heart Failure and can be accessed at the following link: https://onlinelibrary.wiley.com/doi/full/10.1002/ehf2.148211	Thank you for your comment, which the committee has considered. The committee concluded that while there are concerns regarding the quality of the comparative evidence from Ahmed et al., it is likely that TriageHF can reduce heart failure events compared with no algorithm use. See section 3.14.

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
75	Web comment		Secondly, the information suggested by the EAG to be missing was not requested during peer review. However, we have submitted an “academic in confidence” supplement containing the following: A figure showing standardised mean differences (SMDs) – before and after propensity score adjustment – for the robust set of variables that were used in generating the propensity score: Age Sex CIED type (CRT-D, CRT-P, ICD) Atrial Fibrillation/flutter Ischaemic heart disease Adult congenital heart disease Prior cardiac ablation Diabetes Chronic kidney disease Left ventricular ejection fraction (LVEF) New York Heart Association class (NYHA) Number of hospitalisations in 6 months prior to the start of the study This figure shows that 1) prior to propensity score adjustment, baseline differences between the TriageHF and standard of care groups were small with only “Device Type” and “Age” exceeding a 20% difference and 2) after propensity score adjustment, these small differences between baseline variables were further reduced but not eliminated, with the difference for every variable being less	Thank you for this additional information. The EAG noted that the study by Ahmed 2024 was judged to be at critical risk of bias due to the risk of confounding and selection bias and it does not consider the additional analysis strong enough to support an amendment to the final risk of bias judgement. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that TriageHF can predict heart failure events. See section 3.7.

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
			than 20%. An analysis was included showing that the variables with the largest residual differences – device type and age – could not have accounted for the lower rate of hospitalisations in the TriageHF group. With respect to device type, this was conceptually due to a combination of ICD being more common in the TriageHF group, but CRT-P being more common in the standard of care group. Both CRT-P and ICD patients had a lower rate of hospitalisation compared to CRT-D, so mathematically these offset such that device type had nearly no net impact on hospitalisation rate. With respect to age, the TriageHF group was 2.6 years older than the standard of care group, and increasing age was associated with a higher hospitalisation rate. Thus, any residual confounding would bias toward a higher hospitalisation rate in the TriageHF group, rather than lower. The conclusion of the “academic in confidence” supplement is that it is very unlikely the 58% lower hospitalisation rate in the TriageHF group is due to residual confounding in observed baseline characteristics. While residual confounding could be present due to unobserved and time-varying factors, we believe this is mitigated by 1) the robust set of variables available leveraged in propensity score adjustment and 2) a COVID-19 sensitivity analysis performed – a key time varying factor in our study – that found TriageHF to still be	

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
			associated with lower hospitalisations, albeit with a smaller effect size (31% vs. 58%). Thus, as in any observational study, there is risk of residual bias in the Ahmed 2024 study. However, the study methods do not warrant that this risk is "critical" and is likely closer to "moderate."	
76	Medtronic	3.12	The committee proceeds to note that in Ahmed 2024 "the majority of hospitalisations being unrelated to heart failure or cardiovascular disease." The committee appears to suggest that the observed effect size is implausible, since this would require preventing hospitalisations "unrelated" to heart failure or cardiovascular and is thus evidence for the presence of bias. Indeed, the Ahmed 2024 study found 9% and 33% of hospitalisations to be coded as primary cause heart failure and cardiovascular, respectively. However, the conclusion drawn – that this is evidence of bias – is invalid for several reasons: It is invalid to assume that the remaining hospitalisations are unrelated to heart failure or cardiovascular disease. Heart failure is a multimorbid disease, and patients are often hospitalised with numerous contributing factors. The Ahmed 2024 study leveraged NHS administrative claims data to identify hospitalisations, and up to 20 ICD-10 codes are reported on claims for each admission. It is impossible to conclusively determine which of the listed ICD-10 codes represent acute diagnoses or chronic comorbidities. Thus, Ahmed 2024 study only used the	Thank you for this additional information. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that TriageHF can predict heart failure events. See section 3.7. The wording in section 3.14 of the guidance has been amended to remove "the majority of hospitalisations being unrelated to heart failure or cardiovascular disease".

Comment number	Name and organisation	Section number	Comment	NICE responses
			primary ICD-10 coding position in characterising that 9% and 33% represented heart failure and CV hospitalisations, respectively. However, this almost certainly represents a low estimate, and it is invalid to assume that the other 67% of hospitalisations are unrelated to heart failure or cardiovascular disease. It is invalid to assume that TriageHF-based management cannot reduce non-cardiovascular admissions. While the TriageHF algorithm was originally designed to predict pending heart failure exacerbations, Sammut-Powell 2022 demonstrated that TriageHF is also predictive of all-cause hospitalisations2. This is intuitive, given that some of the TriageHF input sensors are not specific to cardiovascular etiologies. For instance, an acute decrease in patient activity could be caused by a heart failure exacerbation, a COPD exacerbation, or sepsis. Moreover, the Ahmed 2024 study reported a broad range of pathways interventions that were not exclusive to the management of heart failure or cardiovascular disease, including referral to other specialists, referral to primary care team, lifestyle counseling, and further diagnostic testing. Therefore, it is plausible that TriageHF- directed action could prevent non-cardiovascular hospitalisations. Whilst the reduction in hospitalisations observed with TriageHF was very large, this is not necessarily evidence of bias and may have been due to COVID-19 increasing the true effect size of TriageHF-directed care. The intervention in Ahmed 2024 included, not only the TriageHF algorithm, but also a standardised pathway for	

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
			managing device data, a schedule for data review, as well as protocolised patient contact protocols and follow-up in the case of a high-status alert. Given that CIED follow-up was significantly impacted during the COVID-19 pandemic with patients unable to attend in-clinic visits3, the well-established TriageHF-based protocol for remote patient follow-up, which was not disrupted, may have accounted for a larger-than-anticipated effect size. Indeed, Bachtiger 2021 presented the utility of a TriageHF-directed protocol during the pandemic, concluding "The Triage-HF Plus pathway served as a useful remote monitoring tool for identifying patients with WHF whose care had been otherwise disrupted by the Covid-19 pandemic, allowing timely intervention and cementing the longer-term role for such models of care delivery. Crucially, in this multimorbid, high-cost population, relevant non-HF issues were also identified." This is further substantiated in Figure 4 of the Ahmed 2024 manuscript, in which a large increase in the hospitalisation rate was observed in the standard of care group between April 2020 – September 2020, while the rate of hospitalisation in the TriageHF group remained relatively consistent. In a pre-COVID-19 sensitivity analysis, an adjusted 31% lower rate of hospitalisations was observed in the TriageHF group, which may have been closer to the expected effect size in the absence of a COVID-19 pandemic.	
77	Medtronic	3.6	The committee notes that "All studies reporting prognostic accuracy data have a high risk of bias, for reasons including missing information and a lack of controlling for	Thank you for your comment which the committee has considered. The committee

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
			confounding factors…" This conclusion may be misleading for 2 reasons: The risk of bias assessment for the prognostic accuracy studies was performed using the PROBAST, which was developed to assess the risk of bias and applicability of prediction modeling studies. PROBAST asks 20 questions across 4 domains to determine the risk of bias and applicability of the study. Crucially, the overall bias and applicability risks are considered high if any individual question is rated as high, and there are no intermediate risk levels, just "high," "low," and "unclear." Multiple studies have shown how this very conservative assessment tool results in nearly every study being rated as "high" without any delineation with respect to relative importance of different questions, or the number of questions labelled as high5,6. For instance, a review of 102 studies in the Tufts registry found 98 to be at high risk of bias. Ultimately, forcing raters to choose between "high" or "low" results in low inter-rater reliability7. Therefore, we would encourage the committee to not dismiss the substantial evidence base on the accuracy of TriageHF, consisting of 10 published studies and over 40,000 patients, based on a high risk of bias assessment from PROBAST. The committee cites a lack of controlling for confounding factors as a reason for high bias in the prognostic accuracy studies. However, controlling for confounding	concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that TriageHF can predict heart failure events. The wording of section 3.7 has been updated to reflect the EAG's key concerns with the risk of bias of the prognostic accuracy studies using the PROBAST tool.

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
			factors is not a question or domain in the PROBAST tool. It is a question in the ROBINS-I assessment. However, the ROBINS-I assessment is designed specifically for observational studies comparing outcomes between 2 groups8and is thus not applicable to the prognostic accuracy studies. Ultimately, controlling for confounding is not an expected or intuitive steps in algorithm development studies, which are single arm and descriptive by nature.	
78	Web Comment	Prognostic accuracy 3.6	I note Sammut-Powell 2022 was considered at high risk of bias due to insufficient reporting of model performance. This was a paper of which, as second author, I know the data well. I am not aware anyone has contacted the authorship team for additional data requests. This prospective analysis of 435 patients considered various confounding factors in the analysis including age, heart failure diagnosis, device type and presence of kidney disease (additional information provided in supplementary material). It would be incredibly useful for us to know what missing data was considered critical to improve our manuscript reporting in the future.	Thank you for your comment which the committee has considered. The EAG noted that the final protocol for DAP72 stated attempts would be made to contact the authors if time allowed. The systematic review included 81 reports of 42 studies, many of which do not follow standard reporting guidelines; therefore, given the timescales, it was not feasible for the review team to contact individual authors for further information.
79	Web Comment	TriageHF 3.12	To highlight to the committee, the paper Ahmed et al., is now published (DOI: 10.1002/ehf2.14821). Again I was an author on this paper, therefore known the data well. To address the points made regarding critical	Thank you for your comment, which the committee has considered. The committee concluded that while there are concerns regarding the quality

			risk of bias because of: 1. Missing data on success of propensity score matching This was not requested or highlighted on peer-review, and unfortunately due to the University of Manchester cyber-incident, access to our analysis code is suspended. In response to this draft consultation, given the gravity this "missing data" may have on the outcome of this review, we have completed an additional bias mitigation analysis at Manchester University NHS Foundation Trust. I have emailed a copy of the report to diagnostics@nice.org.uk, but to summarise – the propensity score matching was "successful", reducing the small differences in characteristics between the cohorts to negligible levels. 2. Majority of hospitalisations being unrelated to heart failure or cardiovascular disease. All-cause hospitalisation was selected as our primary outcome measure for several reasons. Firstly, on a principled stance, patients with heart failure are often older with multimorbidity. Hospitalisation due to infections, medication side effects or general deterioration can all impact on heart failure stability (and vice-versa), and differentiating the "primary" episode diagnosis is often subjective and clinically unimportant. Ignoring hospitalisation episodes with a non-heart failure primary costing code would risk excluding prolonged or complex hospitalisation events where heart failure was indeed an active issue but not the most costly one - which tend to occur in patients whom probably have most to gain from remote monitoring due to frequent healthcare utilisation.	of the comparative evidence from Ahmed et al., it is likely that TriageHF can reduce heart failure events compared with no algorithm use. See section 3.14. The EAG considered the additional analysis and noted that the study by Ahmed 2024 was judged to be at critical risk of bias due to the risk of confounding and selection bias and it does not consider the additional analysis strong enough to support an amendment to the final risk of bias judgement.

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
			Secondly, from a practical perspective, coding systems for admitted patient care episodes (NHS England) are difficult to interpret. For this study, SUSHRG costing codes were selected, however up to 20 ICD-10 codes are reported per admission. There is no universally accepted method to differentiate which of these codes represent acute diagnoses versus coding of pre-existing comorbidities, thus inclusion would risk over-representation of heart failure decompensation episodes. I hope this explanation sets out the rationale for the approach taken.	
80	Web Comment		"First, we agree with the committee that more robust evidence, preferably a double-blinded randomized-controlled clinical trial on the clinical usefulness of HeartLogic® is absolutely needed. This was the main reason for us to publish real-world evidence data in smaller patient cohorts. Second, we would like to submit a response to the bias assessment that the committee has made on two of our publications. We hope that the committee appreciates this feedback. The committee states that Treskes et al. is at serious risk of bias due to a lack of adjustment for confounding factors. • This study compared hospitalization rates before and after activation of HeartLogic, thus eliminating any sources of confounding that might come from comparing two cohorts of patients in a non-randomized setting. In a	Thank you for your comment, which the committee has considered. The committee concluded that while there are concerns regarding the quality of the comparative evidence for HeartLogic, it is likely that HeartLogic can reduce heart failure events compared with no algorithm use. See section 3.13.

			pre/post analysis, patients serve as their own controls, so differences in baseline characteristics that might influence the outcome would not be a concern. • We do acknowledge that therapy from a cardiac resynchronization device can result in clinical improvement on its own, which is why we performed a subgroup analysis separating out the de novo CRT patients from those who had an ICD or >1 year with CRT. Both subgroups demonstrated significant reductions in hospitalizations between the pre-activation and post-activation period, indicating that this result was not due to the benefits of CRT alone. • We also acknowledge that the COVID-19 pandemic had significant impacts on clinical care, but most of the patients had completed follow-up prior to the start of the pandemic, so this should not have biased the results in a meaningful way. The committee also states that Feijen et al. is at serious risk of bias due to its retrospective nature together with the lack of blinding of the outcome assessor. • While we acknowledge are limitations inherent to a retrospective study design, we would like to emphasize that the intervention and comparator cohorts were clearly defined based on whether HeartLogic was enabled, so there should be no risk of differential misclassification of the interventions. • Outcome data was collected directly from electronic medical records and endpoints were clearly defined based	

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
			on definitions defined by the Standardized Data Collection for Cardiovascular Trials Initiative and the US Food and Drug Administration, which would limit any bias in the assessment of outcomes. Yours sincerely [redacted]	

THEME: Cost effectiveness

Comment number	Name and organisation	Section number	Comment	NICE responses
81	Boston Scientific	3.16	We are disappointed that HeartLogic was not recommended given the strength of results from the economic evaluation which already take into account some of the uncertainty reported in the risk of bias assessments. Even with important potential benefits of HeartLogic not captured by the model (e.g., mortality benefit, utility beyond hospitalisation decrement), and therefore with a very conservative model (as noted by the Committee in section 3.19), with the corrected probabilistic sensitivity analysis (see comment 1 in section B below), HeartLogic has 100% probability of being cost saving, and 100% probability of being cost-effective with all commonly used thresholds. Even with the probabilistic sensitivity analysis using the incorrect assumption, the probability of the current clinical practice of not using HeartLogic is 19% at a threshold of £20,000/QALY and still only 27% at a threshold of £30,000/QALY. While as with all healthcare interventions, especially non-pharmaceutical treatments, there are uncertainties in the data and patient numbers, the probabilistic sensitivity analysis captures this parameter uncertainty already and incorporates it in the probability of HeartLogic being cost-effective.	Thank you for your comment which the committee has considered. The committee concluded that HeartLogic and TriageHF are likely to be cost-effective uses of NHS resources. See section 3.20.

THEME: Cost effectiveness

Comment number	Name and organisation	Section number	Comment	NICE responses
82	Medtronic	3.16	"The committee noted that uncertainty around intervention costs and mortality were included in the probabilistic sensitivity analysis, and it would like to see an analysis done where these inputs are fixed." Medtronic have submitted a summary of evidence from additional probabilistic sensitivity analysis based on committee recommendations. These PSA results present a scenario with the high-risk flag resource use and the mortality excluded from the PSA, in accordance with EAG comments. The cost-effectiveness results were consistent with the original PSA. TriageHF Plus remained dominant compared to SoC, with a slight increase in the average ICER per QALY gained, -£610,120 in the original PSA to -£609,650 in the updated PSA. However, the percentage increase in the ICER was only 0.08%, which suggests that neither the uncertainty in the log-normal survival curve nor the cost of flagging as high risk of a HF event were not key drivers of cost-effectiveness. Indeed, in the deterministic results, the cost of flagging as high risk of a HF event per patient was only £152. Furthermore, the impact of decreasing the time horizon was evaluated in the scenario analysis. A ten-year reduction in	Thank you for your comment which the committee has considered. The results of Medtronic's additional probabilistic sensitivity analysis support those of the EAG's analysis. The committee concluded that HeartLogic and TriageHF are likely to be cost-effective uses of NHS resources. See section 3.20.

THEME: Cost effectiveness

Comment number	Name and organisation	Section number	Comment	NICE responses
			mortality caused a small 0.6% increase in the ICER, the smallest increase observed of all parameters explored in the scenario analysis. Results from the original analysis concluded that the key drivers of cost-effectiveness were parameters that affected the rate of hospitalisations and the high cost associated with each hospitalisation.	
83	Web Comment	hf-algorithms--draft-guidance-no-acicdocx	Whilst more data is needed regarding cost-effectiveness, my understanding from the consultation document is that there are indeed signals that they are cost effective. Recent publications have shown that the patients who alert as high on Triage HF are the most costly patients, using 50-65% of the heart failure budget- by acting early and preventing admissions, it seems unlikely that these technologies would be cost-prohibitive.	Thank you for your comment, which the committee has considered.

THEME: RWE framework

Comment number	Name and organisation	Section number	Comment	NICE responses
84	Medtronic	3.12	Despite the real-world evidence provided for Triage-HF Plus, aligning with the NICE RWE framework, in collaboration with NHS England and local AHSN (HIN), Medtronic are concerned that these data have not been given due consideration by the Committee. While the limitations of non-randomised evidence were discussed at the first DAC meeting, there was no discussion on what the appropriate level of evidence would be for TriageHF Plus given 1) the low cost per patient at £100 per patient per year and 2) there being – to our knowledge – no published safety concerns associated with using multiparametric algorithms for CIED-based HF management. Considering the low-cost and low clinical risk associated with TriageHF Plus -based management, it seems that this technology would be a strong candidate for potential NHS adoption as evaluated in this setting. Further, within the DAP, recent decisions appear inconsistent. For example, a technology for remote monitoring of Parkinson's disease [DG51, Jan 2024] was conditionally recommended if further evidence is generated. This conditional recommendation comes despite concerns that the majority of the recommended technologies had little or no clinical evidence, according to the Diagnostic Assessment Report: "Although there is some promising evidence for STAT-ON and Kinesia 360, the EAG considers that the evidence is currently not sufficient to be confident that these technologies will produce clinical benefits for	Thank you for your comment which the committee has considered. The committee considered the real-world evidence that is published for Triage HF. At the second meeting, the committee concluded that while there are concerns regarding the quality of the comparative evidence from Ahmed et al., it is likely that TriageHF can reduce heart failure events compared with no algorithm use. See section 3.14. The committee recommended that TriageHF may be used as an option for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have heart failure. This is explained above in the response to comment number 1, and sections 1.1 and 1.2 of the guidance.

THEME: RWE framework

Comment number	Name and organisation	Section number	Comment	NICE responses
			patients. The EAG considers that there is too little evidence for KinesiaU or PDMonitor to draw any conclusions as to their clinical value." Given that a key strength of the evidence submitted for TriageHF Plus is the extent of RWE studies in NHS settings, a similar conditional recommendation for TriageHF Plus would have been expected. This inconsistency in DAP recommendations is confusing and detrimental to the uptake of innovative low-cost technologies that are being currently used to avert unplanned hospital admissions. The DAC should reconsider TriageHF Plus for proportionate approval as it has NHS RWE published evidence https://onlinelibrary.wiley.com/doi/10.1002/ehf2.148211	
85	Web Comment	Reduced need for in-person appointments 3.24	ABHI notes that no RCT evidence was found for inclusion in the assessment. However, it is unclear how guidance from the NICE RWE framework has been applied in this assessment.	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
86	Medtronic	All	The 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic This consensus recommends remote monitoring as part of the standard of care (1A recommendation) and that alert parameters are customised to clinical indications (1B). It also states that it is reasonable to remotely monitor HF diagnostics to detect incident HF and/or progression (2A) The 2015 version of the HRS consensus, also endorsed by EHRA, had already highlighted that “Combined heart failure device diagnostics have been demonstrated to improve the identification of patients at a higher risk of subsequent heart failure hospitalisations.” British Heart Rhythm Society (BHRS) clinical standards and guidelines for the follow up of cardiac implantable electronic devices (CIEDs) for cardiac rhythm management - June 20223 mention that “All appropriate patients should have remote monitoring” “Appropriate alerts should be programmed on in patients with wireless-enables devices”	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			"Action on data which points to heart failure decompensation is recommended" "There should be a clear local protocol or pathway for patients with CIEDs whom show signs of worsening HF" "The use of multiple physiological parameters detected by CIEDs is emerging as novel way of predicting HF episodes before they occur." and "Cardiac clinical scientists/cardiac physiologists should thoroughly review HF diagnostic data". HF algorithms are an integral component of CIED RM which is standard of care considering "Several large, randomised studies as well as large registries and observational studies consistently demonstrated major organisational benefits, such as follow-up optimisation, and clinical benefits, with improved patient management and clinical outcome associated with RM" Limiting the use of HF algorithms to 'research only' is a risk to broader RM adoption while this practice should be standard of care. As a consequence, this could be a risk for	

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			the organisation of the healthcare system in England considering current staff shortage and therefore the difficulty to ensure the regular and appropriate in-office follow-up of CIED HF patients. Ultimately this could have an impact on patient outcomes in case risks of HF decompensation are not timely uncovered. Also, multiparametric data evaluation through human review is not working (REM HF study). HF algorithms can help to support an effective management process as a tool to streamline FU organisation for CIED patients with HF like it has been shown in TriageHF Plus evidence.	
87	Medtronic	All	This draft guidance recommendation does not reflect policies issued by NHS England which encourage the remote monitoring for HF population. Through the NHS long term plan, the NHS England has set out its plans to accelerate the redesign of patient care to future-proof the NHS including practical priorities that will drive NHS digital transformation such as: Creating straightforward digital access to NHS services and help patients and their carers manage their health.	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			Ensuring that clinicians can access and interact with patient records and care plans wherever they are. Using decision support to help clinicians in applying best practice, eliminate unwarranted variation across the whole pathway of care, and support patients in managing their health and condition. Using predictive techniques to support local health systems to plan care for populations. Using intuitive tools to capture data as a by-product of care in ways that empower clinicians and reduce the administrative burden. Remote monitoring for device-enable HF population aligns with the NHS Long-Term Plan such as; Managing Heart Failure @home and Virtual ward including Hospital at Home, which deliver on key aims and commitments to: Deliver earlier detection and diagnosis of HF and HVD. Improve rapid access to heart failure nurses on admission to hospital so that more patients with heart failure, who are not on a	

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			cardiology ward, will receive specialist care and advice. Better, personalised planning for patients will reduce the number of nights spent in hospital and reduce drug spend. Enable people with HF to be better supported by multi-disciplinary teams as part of PCNs. Improve access to and uptake of cardiac rehabilitation, which can save lives, improve quality of life and reduce hospital readmissions - the LTP sets a target of 33% of eligible people with HF being offered cardiac rehabilitation (CR) by 2028. Roll out personalised care to 2.5 million people by March 2024. We ask that the DAC committee strongly reconsider the draft guidance recommendations that TriageHF Plus 'Can only be used in research', as its at odds with NHS England's programme re: Managing Heart Failure @home, Virtual wards and it's linked objectives.	
88	Web comment	Has all the relevant evidence been taken into account?	Not all of the evidence has been taken into account. Regarding the decision to position remote monitoring alerts for HF as research only,	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			not all of the data has been taken into consideration. 1. Current international consensus document on programming clinical alerts in people with Heart Failure (HF) and a cardiac device and also the British Heart Rhythm Society Guidance. In May 2023 the first international RM consensus document was released jointly by 4 societies (Heart Rhythm Society, European Heart Rhythm Association, Latin American Heart Rhythm Society, Asia Pacific Heart Rhythm Society) to standardise recommendations for remote monitoring (RM) of pacemakers and defibrillators across the 4 continents of North and South America, Europe and Asia. The HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic recently recommended that in patients with CIEDs on RM, it is recommended that alert parameters be customised according to the individuals clinical indications [Class 1A recommendation], with a recommendation supporting the use of remotely monitored HF diagnostics to detect incident HF and/ or disease progression [Class 2A recommendation]. This is the same class of	

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			recommendation issued to monitor for ATP therapies of prolonged burdens of atrial fibrillation, which is routinely programmed in the UK. UK guidelines for remote monitoring recommend that all CIED patients whose devices have the capability should receive remote monitoring, and this extends to include programming of clinical alerts and action on data which indicates heart failure decompensation. In view of these considerations, a recommendation to remain limited to research would create differing standards of remote monitoring between the UK and the rest of the world and set back progress.	
89	Web comment	Are the recommendations sound, and a suitable basis for guidance to the NHS?	No. There is a disconnect between how remotely monitored clinical alerts are recommended for research only by NICE and how they are already supported for use in clinical practice in the UK (according to BHRS guidelines) and the rest of the world. Refer to comment 88.	Thank you for your comment, which the committee has considered.
90	Web comment	More research is needed on: Heart Failure mortality rates	There is already published data that telemonitoring and structured telephone support, supported by the 2021 ESC Heart Failure guidelines, improve patient outcomes.	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			A 2015 Cochrane meta-analysis reported structured telephone support and telemonitoring in HF to be associated with lower all-cause mortality and fewer HF hospitalisations. TriageHF Plus was designed to embed both telemonitoring and structured telephone support.	
91	Web Comment	hf-algorithms--draft-guidance-no-acicdocx	As specified in the consultation document, false positives are generally mitigated in practice as clinical reasoning is applied to every alert, and the algorithms are used to assist the assessment of the patient rather than to replace it, providing prompts to be used alongside standard of care. With this in mind, having this technology available but restricting its use seems to have a much higher potential for causing harm than having this technology utilised by cardiac physiologists and heart failure specialist teams. It seems clear that not acting on these alerts where they occur due to this NICE appraisal would lead to more deaths than if the technologies were freely used- I cannot think of way in which any other conclusion could be reached. I worry that this consultation document works directly against British Heart Rhythm Society guidelines, which clearly state that alert-based remote follow up should be considered as standard of care for CIED patients, and that action should be taken on	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF [may be used] as options for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have heart failure. They should be used as explained above in the response to comment number 1.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			data which points to heart failure decompensation. I worry therefore that the conclusion reached here essentially promotes substandard and therefore negligent practice in the NHS. These are early warning indicators- there are no clearly defined safety issues included in the consultation document.	
92	Web Comment	1	The draft recommendations appear at odds with national NHS priorities, policies and guidance (which these technologies could support), including: improving “prevention… and better management of long-term conditions” (2024/25 priorities and operational planning guidance) “improve access to virtual wards… supported by remote monitoring technology” (2024/25 priorities and operational planning guidance) “providing better connected, more personalised care in people’s homes” (NHS @home) “boost out-of-hospital care” (NHS Long Term Plan) “reduce pressure on emergency hospital	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			services (NHS Long Term Plan) providing patients “with more personalised care when they need it” (NHS Long Term Plan) “Cardiac clinical scientists/cardiac physiologists should thoroughly review HF diagnostic data” (BHRS clinical standards & guidelines for the follow up of CIEDs for cardiac rhythm management) “it is reasonable to remotely monitor HF diagnostics to detect incident HF and/or progression (2A)” (2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic)	
93	Web Comment	1	already standard of care in line with BHRS guidelines. Remote monitoring is well established and provides additional data when considering patient management strategies.	Thank you for your comment, which the committee has considered.
94	Web Comment	Can only be used in research 1	Technology already standard of care. The British Heart Rhythm Society recommend using alert based remote monitoring for patients with Heart Failure. There is already strong Real World Evidence which we are encouraged to acknowledge and consider, it has been tried and tested within the NHS setting.	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
95	Web Comment	Can only be used in research 1	already standard of care in line with BHRS guidelines. Remote monitoring is well established and provides additional data when considering patient management strategies, very useful.	Thank you for your comment, which the committee has considered.
96	Web Comment	Should not be used 1.5	In line with BHRS guidelines is helpful in clinical decision making	Thank you for your comment, which the committee has considered.
97	Web Comment		5.Existing BHRS recommendation also highlights the need for digital technology to monitor patients; and all appropriate patients should have remote monitoring, considered standard care if patients consent to it. Consent for remote monitoring should be standard, so patients know they are being continuously monitored. Alerts should be actioned in an appropriate timeframe, especially Heart Failure data.	Thank you for your comment, which the committee has considered.
98	Web Comment [comment submitted twice by 2 separate people]		The British Heart Rhythm Society clearly recommends: • All appropriate patients should have remote monitoring • Alert-based remote follow up should be considered as standard care for CIED patients • Action on data which points to heart failure decompensation is recommended The technology also very much aligns with NHS long term plans to manage patients	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			closer to home, the Heart Failure @ Home program and also the recent addition of virtual wards.	

THEME: Connectivity issues

Comment number	Name and organisation	Section number	Comment	NICE responses
99	Web comment	Failed transmissions	We have previously published data to indicate that missed transmissions are few (1.9%) Publications summarising missed transmission data Remote monitoring predicts All cause hospitalisation paper (Ahmed 2022) Limitations section: A small proportion of the transmission data was missing (1.9%), with most patients having no missing transmission data (n=396 [92.3%]). Of those who did have missing transmission data, the average number of days that a patient was missing transmission data was 10.1 days. **Debski et al** Missing data were in part related issues with the medium optivol. Hence the transmissions transitions from medium + Optivol -> high without clinical teams realising. The study did not report disconnected monitors so unclear what role this played in delayed transmissions **New generation devices** Today, real world clinical practice almost	Thank you for your comment which the committee has considered. The committee concluded that they have no concerns regarding transmission failure, as systems are in place to manage and resolve this. See section 3.15.

THEME: Connectivity issues

Comment number	Name and organisation	Section number	Comment	NICE responses
			exclusively includes new generation devices capable of performing automated transmissions. Legacy devices have been phased out. Few patients remain with older devices. **Remote monitoring predicts all cause mortality (2022)** "Periods without transmitted data are encountered in clinical practice, as was observed in 36 patients within the current evaluation (episodes: 45; median length: 65 days)" This evaluation included patients with non-automated (legacy) devices- subsequent real world studies have focussed on those with automated devices. It is important to note that the 45 episodes reported with missing data are relatively small compared to the >11,000 risk status episodes recorded. Lastly, it is relevant that the mortality was the focus of this study and included people who died in hospital. In the manuscript we clarified that patients who either died in the hospital, were discharged to a care home, or were palliated, would not have	

THEME: Connectivity issues

Comment number	Name and organisation	Section number	Comment	NICE responses
			their monitor paired upon discharge, leading to expected periods of missing data. **Disconnected monitors** We have documented small numbers of disconnected monitors, addressed by contacting and educating the patient. There have been no instances of device failure, no safety reporting submitted in the course of a 5 year UK clinical study and no evidence of harm.	

THEME: CorVue recommendation

Comment number	Name and organisation	Section number	Comment	NICE responses
100	Web Comment Abbott Medical	Should not be used 1.5	Abbott feel this wording is overly aggressive and does not reflect that Corvue can offer value to the NHS when used alongside other complimentary heart failure monitoring devices. Original Wording: CorVue should not be used for algorithm-based remote monitoring in people with CIEDs who have or are at risk of developing heart failure. Suggested new wording: There is insufficient evidence to support the efficacy of CorVue being used in isolation for algorithm-based remote monitoring in people with CIEDs who have or are at risk of developing heart failure, however - Corvue should still be considered by clinicians as a complementary therapy to be used alongside other approaches to a heart failure patients pathway of care.	Thank you for your comment which the committee has considered. The EAG noted that prognostic accuracy studies for CorVue showed a low to adequate sensitivity to predict heart failure events. Clinical experts noted that heart failure algorithms should have a high sensitivity. See section 3.4. Therefore, the committee concluded that CorVue should not be used.
101	Web Comment Abbott Medical	Should not be used 1.5	Abbott feels the language “So CorVue is not recommended for use in the NHS” is overly aggressive, is potentially anti-competitive, and could be misinterpreted by non-clinical / procurement staff in Trusts. This could potentially result in events such as deliberate exclusion of devices containing Corvue from procurement exercises where the specification of requirement is different to the one NICE have assessed in this case. NICE’s language used in section 3.9 talks about “uncertainty” around Corvue which is inconsistent with NICE’s categoric language used in this section 1.5. The wording used in section 1.5 by NICE clearly states some signs of worsening heart failure are predicted by Corvue and the use of Intrathoracic Impedance on which Corvue is based, is supported by	Thank you for your comment which the committee has considered. The EAG noted that prognostic accuracy studies for CorVue showed a low to adequate sensitivity to predict heart failure events. Clinical experts noted that heart failure algorithms should have a high sensitivity. See section 3.4. Therefore, the

THEME: CorVue recommendation

Comment number	Name and organisation	Section number	Comment	NICE responses
			published data here: https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.104.492207 As a result, we feel Corvue can offer value when used to complement other approaches to identifying and treating patients with heart failure. Original wording: Clinical trial evidence suggests that CorVue fails to predict some signs of worsening heart failure and has a high rate of false-positive alerts (alerts that are not followed by a heart failure event). So CorVue is not recommended for use in the NHS. Suggested new wording: Clinical trial evidence suggests that CorVue fails to predict some signs of worsening heart failure and has a high rate of false-positive alerts (alerts that are not followed by a heart failure event). As a result, the committee has uncertainty around the efficacy of CorVue's use as a sole solution for identifying Heart failure, but it should be considered to complement other approaches to a heart failure patients' pathway of care.	committee concluded that CorVue should not be used.
102	Web Comment	Should not be used 1.5	These algorithms are already widely used in the NHS Trusts and the draft recommendations would represent a backwards step in current NHS practice and potentially a negative impact on staffing for those already utilising this technology if they need to revert to in-person monitoring for future patients.	Thank you for your comment, which the committee has considered.

THEME: Editorial comments or inaccuracies

Comment number	Name and organisation	Section number	Comment	NICE responses
103	Boston Scientific	All	We note the following errors, factual inaccuracies and inconsistencies in the draft guidance and committee papers that we request are corrected. The draft recommendation is inconsistent with conclusions drawn within the evidence base and EAR pertaining to prognostic accuracy and false positives – see previous comments 2 and 3 above. The list of specialist committee members include Dr Alison Seed but lacks a reference to the fact she was not present for the first committee meeting on 16 April 2024. NICE confirmed verbally during a call on 9 May 2024 that no follow up input from her was or will be sought post the meeting and its conclusions. The implied endorsement by Dr Seed in the draft recommendations has mislead at least one HCP who stated to us that inclusion of her name within the document, and knowing she, and her centre, are the most experienced clinical users of these technologies within England, inferred she was involved in these discussions and therefore had input into the current draft guidance. The lowest reported sensitivity for HeartLogic of 66% (Santobuono et al.) relates to detection of cardiovascular hospitalisations (which includes but is more broad than heart failure hospitalisations). This is in contrast to other sensitivity rates referenced, which report sensitivity for detecting heart failure events or heart failure hospitalisations specifically. HeartLogic was developed and validated to detect worsening heart failure events. Those studies that evaluated ability to detect worsening HF specifically all demonstrated sensitivity >=70%.	Thank you for your comment, which the committee has considered. Dr Alison Seed was present for the second committee meeting on 19 June 2024, and contributed to the discussion leading to the committee's recommendations. The guidance has been edited to focus on the prognostic accuracy study endpoint of worsening heart failure. See section 3.6 of the guidance. The EAG agreed there were a reasonable number of participants with an event in the MultiSENSE study.

THEME: Editorial comments or inaccuracies

Comment number	Name and organisation	Section number	Comment	NICE responses
			The draft recommendations state “All studies reporting prognostic accuracy data for HeartLogic were assessed as having a high risk of bias because of… small number of people in the studies.” This is factually inaccurate: HeartLogic’s original validation study MultiSENSE included 900 patients (500 in the development set and 400 in the test set). The EAG response to our previous comment on this point acknowledged that this study “had a reasonable number of participants with the outcome.” Please correct this statement. The committee papers continue to erroneously state that Vigdor 2020 reported “26 of 38 alerts” as falsely positive. We are disappointed in this remaining factual inaccuracy despite our raising it to the EAGs attention previously and can only assume they were not able to correctly understand the publication. Indeed, as the External Assessment Group themselves quote in their response to comment 26 of the External Assessment Report comments, the study reported 26 of 38 patients experiencing a false positive alert. Characterising the false alert rate as 26/38 is incorrect and misleading, because the denominator should be higher than 38 alerts as patients can experience more than 1 alert. We reiterate that 26/38 reflects that 38 patients had at least one alert, and 26 patients had at least one false positive: the misrepresentation of this rate of patients experiencing a false positive should not be compared to data from other studies which report a rate of alerts found to be false positives. The committee papers incorrectly states “There was a numerical trend towards reductions in HF events when using HeartLogic compared with no algorithm use, but these were not always statistically significant.” Of the three studies that assessed the	The wording in the guidance has been updated to reflect the fact that not all prognostic accuracy studies had small numbers of people. See section 3.6. The EAG apologise for the misinterpretation of the Vigdor 2020 study, which is a conference abstract, as when reading the abstract it appears that 26 of 38 alerts are false positives. However, the clarification here helps to show that there were 38 patients, with multiple alerts and 26 of them had a false positive alert, however, this could have not been their only alert.

THEME: Editorial comments or inaccuracies

Comment number	Name and organisation	Section number	Comment	NICE responses
			impact of HeartLogic-guided patient management on HF hospitalisations, only one of these studies (Feijen et al.) assessed the impact of heart failure events and this study showed a significant reduction in HF events.	
104	Web Comment Abbott Medical	Can only be used in research 1.1	Abbott's view is that Inclusion of wording around “insufficient evidence” should be added to the beginning of this paragraph to reinforce the reason NICE are recommended further research: Original Wording: “More research is needed on 3 technologies for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have or are at risk of developing heart failure, before they can be routinely used in the NHS.” Suggested new wording: Evidence on efficacy is inadequate in quantity and quality for HeartInsight, HeartLogic and TriageHF. Accordingly, more research is needed on these 3 technologies for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have or are at risk of developing heart failure, before they can be routinely used in the NHS.	Thank you for your comment which the committee has considered. NICE works with editors to ensure the clarity of the guidance document.
105	Web Comment Abbott Medical	Prognostic accuracy 3.3	Abbott request a slight softening of the language used around Corvue failing to predict heart failure events, as in section 1.5 NICE states that Corvue does capture some signs of worsening heart failure. In section 3.9 NICE also uses language around uncertainty which we feel is better suited. There is inconsistency between the body of this document and summary statements made by NICE, which our below new	Thank you for your comment, which the committee has considered. The committee decided to not change the wording in the guidance for

THEME: Editorial comments or inaccuracies

Comment number	Name and organisation	Section number	Comment	NICE responses
			wording seeks to address. Original wording: The committee concluded that CorVue cannot accurately predict heart failure events. Suggested new wording: The committee concluded that there is uncertainty around CorVue's ability to accurately predict heart failure events.	CorVue. This is because across the study endpoints, the EAG noted that CorVue showed a low to adequate sensitivity to predict heart failure events, and the clinical experts noted that heart failure algorithms should have a high sensitivity. See section 3.4.

NICE HEALTH TECH PROGRAMME

Heart failure algorithms for remote monitoring in people with cardiac implantable electronic devices

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 19 June 2024

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
1	Boston Scientific	All	Given the appreciable body of consistent evidence, positive UK clinical experience over the past 7 years and high probability of cost effectiveness (81%), we strongly disagree with the draft recommendation for HeartLogic to be used in research only. We feel a more proportionate recommendation for HeartLogic would be "recommended with evidence generation" which we understand has previously been used in the diagnostics programme (including for DG51 and DG57) and we would request that the recommendation be changed to this. We are concerned that a "can only be used in research" recommendation will have a pronounced negative impact on heart failure patients in the UK who could benefit from this technology whilst RCT data continues to be generated (https://clinicaltrials.gov/study/NCT06099158). All published evidence on HeartLogic to date is consistent in indicating this technology has clinical utility in the management of these patients and we are unclear why the overarching consistency in the evidence base has been disregarded. We note that the draft recommendations appear to conflict with national NHS priorities and policies, including those seeking improvement in "prevention… and better management of long-term conditions" (2024/25 priorities and operational planning guidance), "providing better connected, more personalised care in people's homes" (NHS @home), "boost[ing] out-of-hospital care" and "reduc[ing] pressure on emergency hospital services" and providing patients "with more personalised care when they need it" (NHS Long Term	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF [may be used] as options for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have heart failure. They should be used with specialist review of alerts. Companies should work with the NHS to collect registry data for HeartLogic and TriageHF on: hospitalisation rates, heart-failure-related mortality rates, rates of emergency department or primary care visits and patient-reported outcomes. See sections 1.1 and 1.2.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			Plan). Heart failure algorithms are designed to support these objectives.	
2	Boston Scientific	1.4, Why the committee made these recommend ations	We dispute NICE's statement that "more research is needed on "prognostic accuracy" for HeartLogic and feel this is not a reasonable interpretation of the evidence due to the volume and consistency therein. We request that this is removed from the recommendations. The committee cites "a lot of variation in the accuracy results" for HeartLogic and TriageHF as part of their rationale for this recommendation. This is factually inaccurate and wholly inconsistent to the findings reported elsewhere in the draft guidance document which state "data for HeartLogic show adequate to high sensitivity". This also conflicts with the EAR conclusions which state "HeartLogic had the highest and most consistent accuracy measures".	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF [may be used] as options for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have heart failure. They should be used with specialist review of alerts. Companies should work with the NHS to collect registry data for HeartLogic and TriageHF on: hospitalisation rates, heart-failure-related mortality rates, rates of emergency department or primary care visits and patient-reported outcomes. See sections 1.1 and 1.2.
3	Boston Scientific	1.4, Why the	We dispute NICE's statement that "more research is needed on "prognostic accuracy" for Heart Logic and feel this is not a	Thank you for your comment, which the

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
		committee made these recommendations	reasonable interpretation of the evidence due to the volume and consistency therein. We request that this is removed from the recommendations.	committee has considered. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that HeartLogic can predict heart failure events (see section 3.6).
4	Medtronic	All	TriageHF Plus is an automated remote management heart failure care pathway that combines TriageHF alerts (high risk status transmissions) with structured phone-call based assessment. The NICE Diagnostic Assessment Committee have proposed draft guidance limiting the use of TriageHF Plus to "only in research." We believe this draft recommendation is potentially perverse due to the following serious concerns: The draft decision does not take an appropriate proportional approach in considering the TriageHF Plus evidence base relative to its low cost (£100 per patient per year) and minimal associated clinical risks. Due to the low cost of TriageHF Plus technology and the high cost of hospitalisations in the UK, only a small reduction in hospitalisations is needed for TriageHF Plus to be cost saving – a finding validated in the EAG cost effectiveness model. As explained in later commentary, the Ahmed 2024 study provides the confidence needed that TriageHF Plus, as	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF [may be used] as options for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have heart failure. They should be used with specialist review of alerts. Companies should work with the NHS to collect registry data for HeartLogic and TriageHF on: hospitalisation rates, heart-failure-related mortality rates, rates of emergency

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			implemented in the UK, avoids sufficient hospitalisations to be cost saving. The key comparative effectiveness study for TriageHF Plus was rated as critical risk of bias – as will be shown in comments 2 and 3 – based on unsubstantiated rationale. This study was accepted for publication prior to the first Committee meeting, however, and it is now published in ESC Heart Failure. We also wish to note that peer review c/o ESC Heart Failure journal did not cite any risk of bias for the published Ahmed 2024 study. Therefore, we would like to suggest the DAC consider risk of bias to be 'moderate' rather than 'critical' (i.e. there were deviations from usual practice, but their impact on the outcome is expected to be slight). We believe the EAG's risk of bias assessment was excessively critical for both the comparative and algorithm validation evidence – see comments 2 and 3 below with supplementary evidence provided as academic in confidence. This proposed decision is at odds with several NHS England policies which aim to improve access to care through the digitalisation of care pathways and adoption of HF remote monitoring, including the NHS Long term Plan, NHS @home - Managing Heart Failure @home (MHF @home) and NHSE Guidance note: virtual ward care. TriageHF Plus is widely used and embedded in the system as part of HF remote monitoring pathway, the 'research only' decision would disadvantage people who live in remote communities, come from deprived socio-economic regions or those who are less mobile, potentially creating inequalities in	department or primary care visits and patient-reported outcomes. See sections 1.1 and 1.2.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			the delivery of HF care. The draft text and decision undervalues the current role of remote monitoring in patients with CIEDs for which heart failure (HF) monitoring is a component, the broad adoption (77 operational sites) of CIED-based HF monitoring in the UK, the extent to which current medical guidelines support CIED- based remote monitoring including HF monitoring, and the direct connection between individual HF metrics (for instance, intrathoracic impedance or arrhythmia burden) and TriageHF algorithm. The “only in research” decision is inconsistent with other recent technology evaluations with similar or less evidence. For example, a technology for remote monitoring of Parkinson’s disease [DG51, Jan 2024] was conditionally recommended if further evidence is generated. Please see comments 2-12 for further substantiation of our concerns.	
5	Medtronic	References	Ahmed F. Z., Sammut-Powell C., Martin G. P., Callan P., Cunnington C., Kahn M., Kale M., Weldon T., Harwood R., Fullwood C., Gerritse B., Lanctin D., Soken N., Campbell N. G., and Taylor J. K. (2024) Association of a device-based remote management heart failure pathway with outcomes: TriageHF Plus real-world evaluation, ESC Heart Failure, doi: https://doi.org/10.1002/ehf2.14821. https://onlinelibrary.wiley.com/doi/full/10.1002/ehf2.14821 Sammut-Powell C, Taylor JK, Motwani M, Leonard CM,	Thank you for providing these references.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			Martin GP, Ahmed FZ. Remotely Monitored Cardiac Implantable Electronic Device Data Predict All-Cause and Cardiovascular Unplanned Hospitalization. J Am Heart Assoc. 2022 Aug 16;11(16):e024526. doi: 10.1161/JAHA.121.024526. Epub 2022 Aug 9. PMID: 35943063; PMCID: PMC9496305. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9496305/ Magnocavallo M, Vetta G, Bernardini A, Piro A, Mei MC, Di Iorio M, Mariani MV, Della Rocca DG, Severino P, Quaglione R, Giunta G, Chimenti C, Miraldi F, Vizza CD, Fedele F, Lavalle C. Impact of COVID-19 Pandemic on Cardiac Electronic Device Management and Role of Remote Monitoring. Card Electrophysiol Clin. 2022 Mar;14(1):125-131. doi: 10.1016/j.ccep.2021.10.010. Epub 2021 Oct 30. PMID: 35221081; PMCID: PMC8556573. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8556573/pdf/main.pdf Cowie MR, Sarkar S, Koehler J, Whellan DJ, Crossley GH, Tang WH, Abraham WT, Sharma V, Santini M. Development and validation of an integrated diagnostic algorithm derived from parameters monitored in implantable devices for identifying patients at risk for heart failure hospitalization in an ambulatory setting. Eur Heart J. 2013 Aug;34(31):2472-80. doi: 10.1093/eurheartj/eht083. Epub 2013 Mar 19. PMID: 23513212; PMCID: PMC3743068. https://pubmed.ncbi.nlm.nih.gov/23513212/ Kennedy EE, Bowles KH, Aryal S. Systematic review of prediction models for postacute care destination decision-	

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			making. J Am Med Inform Assoc. 2021 Dec 28;29(1):176-186. doi: 10.1093/jamia/ocab197. PMID: 34757383; PMCID: PMC8714284. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8714284/ Venema E, Wessler BS, Paulus JK, Salah R, Raman G, Leung LY, Koethe BC, Nelson J, Park JG, van Klaveren D, Steyerberg EW, Kent DM. Large-scale validation of the prediction model risk of bias assessment Tool (PROBAST) using a short form: high risk of bias models show poorer discrimination. J Clin Epidemiol. 2021 Oct;138:32-39. doi: 10.1016/j.jclinepi.2021.06.017. Epub 2021 Jun 24. PMID: 34175377. https://pubmed.ncbi.nlm.nih.gov/34175377/ Kaiser I, Pfahlberg AB, Mathes S, Uter W, Diehl K, Steeb T, Heppt MV, Gefeller O. Inter-Rater Agreement in Assessing Risk of bias in Melanoma Prediction Studies Using the Prediction Model Risk of bias Assessment Tool (PROBAST): Results from a Controlled Experiment on the Effect of Specific Rater Training. J Clin Med. 2023 Mar 2;12(5):1976. doi: 10.3390/jcm12051976. PMID: 36902763; PMCID: PMC10003882. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10003882/ Sterne J A, HernÃ¡n M A, Reeves B C, SavoviÄ‡ J, Berkman N D, Viswanathan M et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions BMJ 2016; 355 :i4919 doi:10.1136/bmj.i4919 https://www.bmj.com/content/bmj/355/bmj.i4919.full.pdf	

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
6	Web comment	Research only guidance	In line with BHRS guidance, which recommend programming of clinical alerts and action on data which indicates heart failure decompensation in patients with CIEDs on remote monitoring, we currently monitor > 1000 patients across Greater Manchester using HF clinical alerts. This is limited to algorithms that have a low burden of alerting (2 alerts per 100 patients monitored per week). If guidance for research only is issued, what will happen to patients these 1000 patients who are currently being monitored in a research study, but will transition to usual care in the next 12 months? How would a decision for research only guidance impact the BHRS guidance?	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.
7	Web Comment		There is abundant evidence that implantable cardiac devices used in patients with heart failure, reduce morbidity and mortality by improving heart function and treating lethal ventricular arrhythmia. As such, they are recommended by NICE in eligible patients and already widely used on the NHS. Remote monitoring algorithms which are already incorporated within these devices as standard, have the ability to contribute to monitoring of patients for worsening symptoms and unplanned hospitalisations. This is demonstrated in the available evidence reviewed for this guidance, for both HeartLogic and TriageHF algorithms. These data are generated passively and continuously, without any additional human resource or patient footprint, and can help improve how we manage vulnerable people with heart failure.	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			Furthermore, the economic analysis in this guidance, while limited largely to observational data, demonstrated that only a small reduction in hospitalisations is required to demonstrate cost-effectiveness. This should not be trivialized as the financial burden of (and increased morbidity and mortality following) unplanned hospitalizations for heart failure remain considerable. The British Society for Heart Failure are of the opinion that a 'can only be used in research' recommendation, would unfairly limit the access of these technologies for our patients, even though they will continue to have these devices implanted. Potentially valuable information would be ignored - and with this recommendation, may be required to be disabled. We propose a 'can be used in NHS with evidence generation' which would allow patients ongoing use of these technologies, while requiring concurrent real-world data collection to support their use. This would also provide immediate comparison to ongoing large-scale trials such as PREEMPT-HF and would be in line with the NHS long term plan of incorporating digital tools and technologies in the way we manage our patients.	
8	Web Comment	hf-algorithms--draft-guidance-no-acicdocx	To whom it may concern, This is a letter regarding the consultation for the 'Heart failure algorithms for remote monitoring in people with cardiac implantable electronic devices' guidance.	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			The recommendation that these technologies should be used 'only in research' is incredibly disappointing, and I do not believe that the extent that they are already used and are ingrained within NHS practice has been appropriately captured. I would be interested to know whether scoping exercises have been performed to gather data on the number of Trusts already using these technologies. These technologies have helped to integrate the heart failure team and the cardiac physiology teams and has helped with mutually beneficial learning and a multidisciplinary approach to patient care. There has been a move towards remote care in the NHS, particularly with virtual wards and digital remote monitoring. Remote monitoring using CIEDs feeds into this well, and suggesting that this is rolled back does not appear to be in keeping with NHSE directives for virtual wards and Heart Failure @Home, in addition to the NHS 10 year plan and in fact seems to work directly against their success.	TriageHF may be used as options, as explained above in the response to comment number 1.
9	Web Comment	Can only be used in research 1	ABHI is disappointed in the recommendations of "can only be used in research" and "should not be used" for heart failure algorithms and is concerned that this will have a detrimental impact on patients who could benefit from these technologies.	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
				Because of the uncertainties in the evidence, HeartInsight was not recommended for routine use in the NHS. But, it may be better at predicting worsening heart failure and reducing hospitalisations than CIEDs without algorithms, so more research is recommended. See sections 1.3-1.6. Clinical trial evidence suggests that CorVue fails to detect some signs of worsening heart failure and has a high rate of false-positive alerts (alerts that are not followed by a heart failure event). So CorVue is not recommended for use in the NHS. See section 1.7. See section 1 for further rationale.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
10	Web Comment	Can only be used in research 1.3	These algorithms are already widely used in the NHS Trusts and the draft recommendations would represent a backwards step in current NHS practice and potentially a negative impact on staffing for those already utilising this technology if they need to revert to in-person monitoring for future patients.	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1. Because of the uncertainties in the evidence, HeartInsight was not recommended for routine use in the NHS. But, it may be better at detecting worsening heart failure and reducing hospitalisations than CIEDs without algorithms, so more research is recommended. See sections 1.3-1.6. Clinical trial evidence suggests that CorVue fails to detect some signs of worsening heart failure and has a high rate of false-positive alerts (alerts that are not followed by a heart

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
				failure event). So CorVue is not recommended for use in the NHS. See section 1.7. See section 1 for further rationale.
11	Web Comment		Technology already standard of care. The British Heart Rhythm Society recommend using alert based remote monitoring for patients with Heart Failure. There is already Real World Evidence which we are encouraged to acknowledge and consider, it has been tried and tested within the NHS setting and shown positive results. Well liked by patients. Relieves burden on outpatient clinics and hospital beds, provides a focus on patients who need more immediate attention. Recommending only for use in research is a backward step and not supporting NHS directives on adoption of technology to drive efficiencies and savings. It is low burden, low cost, low risk and should be widely available to patients.	The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.
12	Web Comment	1	Important to continue to collect data. Already good experience within the NHS and integrated into standard clinical care.	Thank you for your comment which the committee has considered.
13	Web Comment	Can only be used in research 1.1	More research welcomed	Thank you for your comment which the committee has considered.
14	Web Comment	Clinical need and	Important to use new technology especially low cost / low burden / low risk to manage fast growing Heart Failure population	Thank you for your comment which the committee has considered.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
		practice 2		
15	Web Comment		2. Mention of more research needed on hard endpoints such as admissions, rates of false positives, A & E visits, patient reported outcomes and prognostic accuracy are often difficult to achieve with heart failure studies. Real life use of the algorithms provides lots of useful information about how these technologies can be useful in clinical practice alongside traditional management and clinical assessment; often these are overlooked when the focus is on pure research findings.	Thank you for your comment, which the committee has considered.
16	Web Comment		Conclusion There is ongoing research for remote monitoring; however remote monitoring should become standard part of all heart failure protocols. The use of remote monitoring is extremely beneficial to our heart failure teams and is integral to the clinical pathway for patients. If remote monitoring was removed from our current clinical pathway, it would have a profound effect on our ability to manage patients in a clear, timely way to avoid unnecessary deterioration of patients. Current care delivery is in a proactive way, not reactive way as we used to work in the past. It is not used in isolation; but alongside clinical review by experienced nurses, which should be highlighted as part of this review. There are many centres across the UK who are utilising these algorithms in practice to manage their patients. NICE found economic modelling for TRIAGEHF and Heartlogic to be a cost-effective use of funding. The	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			conclusion of the draft report does not reflect the significant work, and positive utilisation in many centres of remote monitoring. If remote monitoring was withdrawn, it would pose a significant problem in terms of our care pathways and ultimately disruption to patients and HF pathways currently in place in the Region. While collecting real world data in the ongoing trials I would urge you to allow centres to continue using this technology, so as not to disrupt established, evidence based clinical pathways in which ensure excellent standards of patient care.	
17	Web Comment		Losing TRIAGEHF and HeartLogic would significantly impact our ability to manage heart failure (HF) patients effectively, given that these tools are integral to our standard of care and clinical pathways within our network. Without the real-time monitoring and risk alerts provided by TRIAGEHF and HeartLogic, early signs of HF deterioration might go unnoticed. This delay in detection can lead to more frequent and severe HF exacerbations, as interventions would only occur after noticeable symptoms develop or during scheduled clinic visits. Consequently, the proactive approach facilitated by these tools would be lost, leading to an increase in emergency admissions due to the inability to pre-emptively address rising risks, thereby escalating healthcare utilisation and associated costs. Moreover, timely interventions based on high-risk alerts have been shown to improve patient outcomes, including reducing mortality rates. Without these tools, the mortality rate among HF patients could increase, as critical opportunities to	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			intervene early and effectively would be missed. This would also negatively affect the overall efficiency of HF management. TRIAGEHF and HeartLogic streamline the management process by providing clear, actionable data to healthcare teams. Their absence would necessitate a return to more labour-intensive, less efficient methods of monitoring and managing HF, increasing the workload on healthcare providers and potentially leading to less optimal care.	
18	Web Comment		The disruption to established clinical pathways within our network would also be significant. Our current protocols are built around the integration of these tools, and removing them would require a substantial restructuring of care pathways, potentially leading to inconsistencies in care delivery and lapses in patient management during the transition period. Furthermore, TRIAGEHF and HeartLogic provide valuable feedback to healthcare teams, allowing for continuous improvement in patient management strategies. Without this feedback, our ability to quickly adapt and refine care plans based on real-time data would be severely limited, potentially stagnating advancements in HF care within our network. Finally, the reduction in unplanned hospitalisations and severe HF episodes due to these tools ultimately lowers healthcare costs. Their absence would likely lead to increased costs due to more frequent hospital admissions and the need for more intensive treatments once patients' conditions have deteriorated. In summary, the loss of TRIAGEHF and HeartLogic would	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			compromise our ability to manage HF patients effectively, leading to poorer health outcomes, higher healthcare utilisation, and significant disruption to our established clinical pathways. This would represent a considerable setback for our network, undermining the progress NICE has found the economic modelling for TRIAGEHF and HeartLogic to be a cost-effective use of NHS funding. This conclusion underscores the significant value these tools provide in managing heart failure (HF) patients. By enabling real-time monitoring and generating risk alerts, TRIAGEHF and HeartLogic facilitate early intervention, reducing the incidence of severe HF exacerbations and unplanned hospitalisations. This proactive approach not only improves patient outcomes and quality of life but also translates into substantial cost savings for the NHS by decreasing the need for emergency admissions and intensive treatments.	
19	Web Comment		Given this evidence of cost-effectiveness, I strongly oppose NICE's draft guidance suggesting these tools be used 'for research use only'. Such a recommendation would effectively withdraw TRIAGEHF and HeartLogic from being part of our standard of care, disrupting established clinical pathways and undermining the progress we have made in HF management. The withdrawal of these tools would mean reverting to less efficient and more reactive methods of patient monitoring, likely leading to higher healthcare utilisation and costs, as well as poorer health outcomes for our patients. The decision to limit TRIAGEHF and HeartLogic to research settings does not align with the demonstrated benefits they	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			offer in routine clinical practice. Instead, I advocate for the guidance to be revised to at least 'can be used in NHS with evidence generation'. This approach would allow continued use of these valuable tools while further accumulating real-world evidence to support their efficacy and cost-effectiveness. It is essential to maintain the integration of TRIAGEHF and HeartLogic within our HF management protocols to ensure that patients continue to receive the high standard of care they deserve. In conclusion, the economic modelling clearly supports the cost-effectiveness of TRIAGEHF and HeartLogic. Limiting their use to research settings would be a significant setback for HF care. I feel strongly that these tools should remain available within the NHS, under a framework that allows for ongoing evidence generation, to sustain and build upon the improvements in patient outcomes and cost savings they have already demonstrated.	
20	Web Comment [comment submitted twice by 2 separate people]		Of course, we need to be sure that these tools are cost effective and safe, we believe this technology has been tried and tested in our NHS system and is now successfully integrated into care pathways, the proposed recommendation would be a backward step and have severe detrimental impact on many patients and health care providers across the country. Each hospitalisation has negative impact on patient mortality and quality of life, removing remote monitoring for Heart Failure may impact significantly on timely care and ultimately outcomes for patients. We strongly urge NICE to reconsider	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1. Because of the uncertainties in the

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			the proposal to make this for use in research only and advise instead for routine clinical use. A patient who is remote-monitored is a less-costly and yet better cared for patient. A patient not understanding or recognising symptoms and delay to receiving advice and potential treatment is at high risk of further complications or in some cases death. As an organisation representing patients and their caregivers, having collated feedback and experiences from these patients, we strongly recommend the approval of remote monitoring of Heart Failure patients. Their health and safety should be paramount and remote monitoring provides this safety-net. Without it NICE could be putting lives at risk.	evidence, HeartInsight cannot be recommended for routine use in the NHS. But, it may be better at detecting worsening heart failure and reducing hospitalisations than CIEDs without algorithms, so more research is recommended. See section 1.3-1.6. Clinical trial evidence suggests that CorVue fails to detect some signs of worsening heart failure and has a high rate of false-positive alerts (alerts that are not followed by a heart failure event). So CorVue is not recommended for use in the NHS. See section 1.
21	Pumping Marvellous Foundation	1.1	I am trying to be constructive surrounding my comments, but this is a ridiculous decision to recommend the use for "Research Only" and not to be used routinely in the NHS – This is a disconnect with what the system is trying to achieve which is attempting to keep people out of hospitals, enabling early detection of signs and symptoms synonymous with	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF may be used as

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			unplanned admissions. From a clinical standpoint surely, this is a useful tool to reduce the severity of decompensation and get a decompensating patient to their healthcare team as efficiently and cost saving as possible This is especially difficult to hear when remote monitoring through CIED's have been endorsed by international clinical practice guidelines and NICE have deemed the functionality as cost saving.	options, as explained above in the response to comment number 1. Because of the uncertainties in the evidence, HeartInsight cannot be recommended for routine use in the NHS. But, it may be better at detecting worsening heart failure and reducing hospitalisations than CIEDs without algorithms, so more research is recommended. Clinical trial evidence suggests that CorVue fails to detect some signs of worsening heart failure and has a high rate of false-positive alerts (alerts that are not followed by a heart failure event). So CorVue is not recommended for use in the NHS. See section 1.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
22	Pumping Marvellous Foundation	1.2	This type of technology should be funded through CORE NHS funding	Thank you for your comment which the committee has considered.
23	Pumping Marvellous Foundation		NICE - HealthTech Programme (Diagnostics) Re: Heart failure algorithms for remote monitoring in people with cardiac implantable electronic devices To Whom It May Concern, As the Founder and CEO of the Pumping Marvellous Foundation and a person with a diagnosis of heart failure, I am writing to express my deep concern regarding the potential removal of remote monitoring of heart failure alerts as a component of healthcare management. Remote monitoring has and will continue to radically change the way people with heart failure engage with healthcare providers who manage their conditions. For many patients, particularly those with chronic illnesses such as heart failure, remote monitoring can provide a lifeline, offering real-time insights into their health status and enabling timely interventions that have undoubtedly already improved care and impacted the lives of people with heart failure. The decision does not complement current thinking of keeping people out of hospital. It also does not promote that the NHS is open to evidence-based ways of improving patient treatments and care, patient safety, and access. It is a retrograde step.	Thank you for your comments, which the committee has considered.

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			The proposal to remove remote monitoring as an option threatens to undermine our progress in managing patients' health effectively, utilising developing digital technologies. By taking away this vital tool, patients risk facing delays in receiving necessary care, experiencing undetected exacerbations of heart failure, and even facing avoidable hospitalisations. This is a risk we cannot afford to take. As the leading patient-led organisation focused on heart failure, we fully understand the importance of ensuring that healthcare interventions are evidence-based and cost-effective; we greatly support NICE. However, we urge NICE to consider the wealth of evidence demonstrating the benefits of remote monitoring in improving patient outcomes, reducing healthcare costs, and improving patient-reported metrics. Furthermore, we believe that patient perspectives must be central to any decision-making process regarding healthcare interventions. Individuals relying on remote monitoring to manage their conditions are not just statistics or data points. The people we represent are living, breathing individuals who can attest to the first-hand value and effectiveness of remote monitoring. In light of the potential impact on patient care and outcomes, we respectfully urge NICE to reconsider the proposal to remove remote monitoring as a clinical option. Instead, we encourage NICE to prioritise patient-centred approaches that uphold the right to access innovative and effective healthcare solutions and make decisions that prioritise patients' best interests.	

THEME: Comments on the recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
			Thank you for considering our concerns. Yours sincerely [redacted] CEO and signed on behalf of the Clinical Advisory Committee of the Pumping Marvellous Foundation.	

THEME: Inconsistencies in recommendations

Comment number	Name and organisation	Section number	Comment	NICE responses
24	Medtronic	3.17	The committee considered the sample sizes to be small relative to the number of people living with, or at risk of, heart failure. There appears to be inconsistencies in what is considered an appropriate sample size relative to eligible population. In Diagnostics guidance [DG14] - Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system), published 24 September 2014 estimated that 1.4% of the population in the UK required anticoagulant therapy and that atrial fibrillation was the most common heart arrhythmia and affects around 800,000 people in the UK, or 1.3% of the population. Evidence included in the diagnostics assessment report, the mean sample size of 337 participants for RCTs included in the clinical effectiveness review (range 16 to 2922) The committee summary presented on 16th April 2024 estimated 920,000 people in the UK were living with HF in 2018 with an estimated 200,000 new diagnoses each year. Whilst these technologies may not be comparable, the relative AF populations are. However, the committee did not consider the sample sizes to be small relative to the number of people living with the condition.	Thank you for your comments, which the committee has considered. The guidance has been updated to reflect this.
25	Medtronic	All	As it stands, there is now disparity between EVA recommendations and DAP recommendations, whereby innovative technologies with a sparser evidence base are receiving positive recommendations for use in the NHS, with the condition for further evidence generation in the EVA programme (e.g. HTA17: Digital health technologies to help manage symptoms of psychosis and prevent relapse in adults and young people (March 2024), compared with new innovative technologies being routed to DAP where a higher evidentiary level is required for the same or lower level of recommendation. This disparity is concerning and needs to be addressed.	Thank you for your comments, which the committee has considered. The studies for HeartLogic and TriageHF were assessed as being at high risk of bias (producing uncertain

THEME: Inconsistencies in recommendations

Comment number	Name and organisation	Section number	Comment	NICE responses
			Further, within the DAP, recent decisions appear inconsistent. For example, a technology for remote monitoring of Parkinson's disease [DG51, Jan 2024] was conditionally recommended if further evidence is generated. This conditional recommendation comes despite concerns that the majority of the recommended technologies had little or no clinical evidence, according to the Diagnostic Assessment Report: "Although there is some promising evidence for STAT-ON and Kinesia 360, the EAG considers that the evidence is currently not sufficient to be confident that these technologies will produce clinical benefits for patients. The EAG considers that there is too little evidence for KinesiaU or PDMonitor to draw any conclusions as to their clinical value." Given that a key strength of the evidence submitted for TriageHF Plus is the extent of RWE studies in NHS settings, a similar conditional recommendation for TriageHF Plus would have been expected. This inconsistency in DAP recommendations is confusing and detrimental to the uptake of innovative low-cost technologies that are being currently used to avert unplanned hospital admissions.	results because of the study's design). The committee recognised the value of these studies in decision making despite concerns about their risk of bias. The committee concluded that HeartLogic and TriageHF may be used as options, as explained above in the response to comment number 1.

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
26	Boston Scientific	All	We are disappointed the NICE committee were not given the opportunity to consider relevant unpublished evidence from major NHS Trusts that was submitted earlier in the guidance development process and request that this be made available to them. Unpublished evidence provided through responses to a structured survey on clinical experience using HeartLogic in the NHS was submitted during the EAR consultation in February 2024. The External Assessment Group reported that it "would not meet our inclusion criteria" (response to comment 27, External Assessment Report (EAR) and economic model – Collated Comments) and we do not believe it was further disseminated to the committee as a result. Per sections 3.1.4 and 3.3.1 of the NICE health technology evaluations manual, evaluations "should consider a range of other relevant issues. For example… the experience of the healthcare system" and "NICE considers all types of evidence in its evaluations" so we are unclear why this evidence was not given due consideration in the first committee meeting. We have included below a summary of the survey and findings in appendix 2, and hope that the committee will be given an opportunity to review these as they form an important part of the clinical experience of HeartLogic in NHS settings. They also include unpublished yet relevant real world data from two Trusts using HeartLogic, which align with the broader UK experience and published clinical data overall.	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.
27	Web Comment		The HF clinic in Cork University Hospital Ireland commenced use of the Triage HF early warning system in January 2024. An efficient and effective remote check allows the team to identify patients at risk of congestion with a HIGH score and follow up either virtually or in person if deemed necessary. The workload is equivalent to approximately 2 extra reviews (usually by phone) in total per week with an outcome in preventing	Thank you for your comment, which the committee has considered. The committee considered clinician

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			worsening symptoms and possible hospitalisation. It is extremely beneficial to our cohort of patients who reside up to 2 hours travel from the hospital.	experience in their discussions at the second committee meeting on 19 June.
28	Web Comment	hf-algorithms--draft-guidance-no-acicdocx	In my own experience, these technologies have prevented a number of admissions for a variety of reasons; for example a patient with compliance issues who stops his heart failure therapies on a semi-regular basis is picked up before he becomes grossly overloaded when his Optivol rises, preventing at least three admissions a year in his case. Another patient has frequent exacerbations of COPD as well as decompensations of heart failure. He lived very remotely from the Trust which covered a wide, rural population. The scoring here helped significantly in the clinical assessment, and helped to determine the appropriate course of action. Additionally, this was a patient who did not call us himself when his symptoms were worsening. Again, I am confident that without the use of this technology he would have had multiple admissions.	Thank you for your comment, which the committee has considered. The committee considered patient and clinician experience in their discussions at the second committee meeting on 19 June.
29	Web Comment		In my experience as a cardiac physiologist triage HF is a very useful tool for predicting worsening heart failure. We always ring patients that trigger a High triage HF alert. In my experience it usually always predicts worsening heart failure or a cardiac event when I have rung the patients. If we did not have these device alerts we would not be notified early about the possibility of worsening heart failure and more patients will end up in A&E.	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.
30	Web Comment		I am a Consultant Cardiologist and HF Lead in a rural DGH. My community heart failure nursing team routinely uses alert-based HF remote monitoring as an adjunct to patient care. It allows us to identify patients at risk of	Thank you for your comment, which the committee has

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			decompensation early and thus action the alerts to modify and personalise the treatment plan. We have found this improves patient care, patient satisfaction and reduces unscheduled hospital admissions, particularly given the longer distances some of patients would have to travel to attend for a clinical review. Therefore an 'only for research' recommendation may result in remote monitoring no longer being available for this pt cohort in the future. I would envisage this would increase the need for in-person visits, clinic appointments and hospitalisations; and be a step backwards for patient care, especially as there is widespread usage of remote monitoring for ICD/CRT patients already in place. The HF diagnostics are a low cost additional tool that can be used in patient assessments and thus should not be restricted to Research only. This is not the only means we use to monitor pts but it is supplementary to the care we deliver, particularly as the national focus is shifting towards care delivered at home and virtual ward set ups. HF remote monitoring diagnostics can play a key role in this.	considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.
31	Web Comment		This would have a significant impact on our Standard of care as a clinic and our patients. TriageHF has proven with real world data, and through our practice of reducing unplanning HF admissions, intervening to treat the patient - meaning they dont decompensate and have better outcomes themselves, and save the hospital time, money and bed space.	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.
32	Web Comment		I am a consultant cardiologist subspecialising in Heart Failure and Devices. I use TRIAGE-HF and HeartLogic routinely for patient management and have found these to	Thank you for your comment, which the committee has considered. The committee

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			1. predict decomensation of heart failure in my patients, giving me the ability to guide them to the best pathway for their care (e.g., clinic review, HF nurse review, IV ambulatory unit) and thus to prevent hospital admissions 2. Allows me the opportunity to identify patients who are not optimised on modern heart failure management such as SGLT2 and ARNI 3. They are an adjunct to my clinical assessments of the patients when it is not overtly clear whether these patients are in decompensated heart failure (e.g., like body composition assessment for haemodalysis patients) 4.They also allow us to support our community HF nurses more comprehensively, and gives them confidence (as well as the patients) to perform remote visits as opposed to having obligatory face to face visits. 5. I would advocate the recommendation be changed to 'can be used in NHS with evidence generation', whic I feel is more proportionate. 6. I am concerned that by implementing a research only recommendation this could lead to limitation of patient access to this valuable technology. Thank you.	considered clinician experience in their discussions at the second committee meeting on 19 June.
33	Web Comment		To whom it may concern, This is a letter in response to the guidance that "Heart failure algorithms for remote monitoring in people with CIED" should be for 'only in research'. As a centre, we adapted to a rapidly changing area, that in a post-COVID era where home monitoring has become an integral part of our working lives. This in turn has lead to a far greater change in practice where we	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the

THEME: Clinician experience

			don't physically see patients as often as we used to, relying on the home monitor to transmit the information from the device to us in clinic. This is where the benefits of the risk stratification tools – such as TriageHF/Heartlogic/HeartInsight come into play. We must bear in mind that as a Cardiac Physiologist, my area of expertise is not that of a Heart Failure consultant or a highly specialised nurse – but with the use of these tools, I can help provide a guide of a specific cohort of patients that I think would benefit from an interaction with the HF team. As a centre, we have over a 1500 devices (CRTDs/ICDs/CRTPs/some dual chamber PPMs) that can utilise these tools on their various platforms. It has become ingrained within our work flow (such as calling patients to further risk stratify when a TriageHF or Heartlogic, to determine if they are known to a HF team or if we can refer them on if we think that they would benefit from an interaction from a HF specialist). I have worked at Imperial for nearly 15 years, and in all my time, I could not think of a better example where we have clear integration with the local HF (and surrounding HF teams) because of the use these HF algorithms. I can attest to frequent success stories of ourselves and the HF team working in parallel to ensure a patient does not suffer from a HF admission and can be dealt with in the community. I think it is important to remember the NHS 10 year plan (https://www.longtermplan.nhs.uk/online-version/chapter-3-further-progress-on-care-quality-and-outcomes/better-care-for-major-health-conditions/cardiovascular-disease/): 3.70. People with heart failure and heart valve disease will be better supported by multi-disciplinary teams as part of primary care networks. 80% of heart failure is currently diagnosed in hospital, despite 40% of patients having symptoms that should have triggered an earlier assessment [118]. When admitted to hospital, we will improve rapid access to heart failure nurses so that more patients with heart failure, who are not on a cardiology ward, will receive specialist care and advice [119]. Better, personalised planning for patients will reduce nights spent in hospital and	second committee meeting on 19 June.

			reduce drug spend. Greater access to echocardiography in primary care will improve the investigation of those with breathlessness, and the early detection of heart failure and valve disease. If we are using the 10-year plan as a framework to work in, the diagnostic tools Triage HF/Heartlogic work synergistically. If the plan were to increase HF diagnosis outside of an In-Hospital setting – surely utilising risk stratification tools would be paramount to that. I have multiple examples of HF nurses contacting me in relation to medication changes in patients and whether they have had the desired effect, (the ultimate goal with this would be for the HF nurses to also have access to all this data, further decreasing the need of a conduit such as a Cardiac physiologist). This in turn has also lead to a change in practice for us whereby we are screening patients significantly earlier in thinking about upgrading devices. That in itself is a monumental culture shift – where in a pre-COVID era, I doubt that that would have come into our thought processes and we'd have likely waited for a consultant to make that decision (this in turn may have lead to the patient having multiple procedures when this could have been made at time of box change). It is also important to note, that virtual wards are becoming significantly more prevalent (we currently have a virtual HF ward here at Imperial) – and the use of this type of technology would be in-line with the current standard of care as per NHSE directives. I feel that if we were to revert to a system where the use of these technologies were limited/non-existent, that would definitely impede our ability to diagnose patients early enough to have potential benefits. I can think of a specific example of a patient that had severe heart failure, who had done a transmission for frequent Non-sustained Ventricular Tachycardia. On reviewing the transmission (using the cardiac compass as a guide), it was abundantly apparent he was in the midst of a HF event (and the NSVT was a consequence of being in HF). Looking back, I believe he would have triggered a TriageHF high score likely a month before I saw the transmission for him – but because the risk stratification	

			was not available at that time we were likely too late. This is example of the patients we are far more likely to catch and earlier by utilising these tools. I understand that there were some concerns raised by the committee with regards to safety. When a TriageHF/Heartlogic High alert is initiated, the responsibility (in terms of our work-flow) is for the Cardiac Physiologist to contact the patient and assess both the diagnostic data from device coupled with the symptomatic data provided from the patient. We found that by asking about their symptoms, it gave us far greater scope into whether we needed to act on the patient sooner rather than later. It must also be stressed that we also guide the patient, that they may not be symptomatic currently – these symptoms may develop and to please contact us back if they do. If they are symptomatic, our role is to facilitate contact with the HF team – whether that is directly with their own HF team or via the GP to refer to the local centre. There is some discordance at this point as HF care is primarily within the community and we rarely get to see the results (other than a change in status for the better on HF diagnostics). These tools are best utilised as the early warning indicator that they were intended for, hence in terms of safety – it triggers the normal treatment pathway for these patients, just sooner. The burden of this technology is relatively small – recent studies put this at ~10%. Thus, it means we can focus on the patients the require an intervention most. From the most recent publications, within that 10% that trigger a high warning – they only use a fraction of the allotted budget (in the region of ~50-60%). Anecdotally, the use of this technology hasn't created any extra burden in our clinical setting. Home monitoring connectivity has always been an issue (this is independent to the use of HF diagnostics). Here at Imperial, we have just employed a part time administrator whose primary focus will be to ensure that as many patients are connected to their home monitors as possible. A	

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			side effect of the use of HF diagnostic tools is that the HF nurses are far more invested in the home monitors being connected – I have done several talks with the local team to help them understand the benefits of being connected into home monitoring due to the ability to see TriageHF/Heartlogic scores more readily. Finally, we are moving into an era where App-based technology is becoming more readily available and used as a conduit for home monitoring. I think this is an area that we can wholly expand upon, as the potential in this area to utilise 2-way communication for example: to get patients symptomatic information without having to call them and have the ability to make a clinical decision based off this will likely hasten and improve the quality of treatment for a patient. Given that the current guidance from the BHRS is that: a) alert based remote follow up should be considered as the standard of care and b) action on data which points to heart failure decompensation is recommended – surely that falls within the lines utilising the HF diagnostic tools more readily. As stated earlier, Cardiac Physiologists are not specialists in this area – so having the freedom of use with this diagnostic tool will make my job in determining which cohort of patients to focus on and highlight to the HF team will be made significantly easier with tools such as TriageHF and Heartlogic. My suspicion with this technology, is that at some point (depending on the manufacturer such as Heartlogic is only on the ICD platform and Triage is on all ICDs/CRTP/Advisa model pacemakers) that these diagnostic tools will be prevalent on almost all devices. It is important to bear in mind, that the 30,000 CIED devices this could be applicable (as per the report) for will most definitely be a gross under-estimation.	

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
34	Web Comment	Clinical need and practice 2.3	Excellent patient compliance. Provides confidence to reduce number of in person patient visits and manage patients remotely.	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.
35	Web Comment		Feedback from Staff and Patients [redacted] HF Team Lead Preston 'As a heart failure team we use remote monitoring on a daily basis as a tool which is part of the holistic clinical heart failure assessment. Data / specifically alerts can be reviewed by the Heart Failure Team whilst the patient is face to face in clinic, which adds to the whole assessment of heart failure patients. It is not used in isolation. Patient assessment is always undertaken. Patients have voiced that they feel safe as they are being monitored and know we will contact them if there are any alerts. We will contact the patient if there is a high risk alert, assess symptoms and bring them back to clinic earlier if needed. There can be alerts where the patient feels well. In these cases, we use a watch and wait policy. The patient is reassured, and we continue to monitor them remotely. [redacted] ANP HF Team Blackpool Working within a multidisciplinary team across both community and	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.

Comment number	Name and organisation	Section number	Comment	NICE responses
			hospital settings, we can deliver a holistic service for patients on our caseload. We can also continue management and oversight of those who are then subsequently discharged from our caseload if required. The remote monitoring aspect of care means that we can offer further insight into our patient's HF management. The remote monitoring aspect means that patient engagement is improved, as they can escalate any symptom concerns if necessary. A heart failure assessment takes place via telephone initially, and then may generate further review with treatment change if necessary. Safe prescribing takes place in partnership with patient, GP (and consultant if necessary).	
36	Web Comment		The organisation that I work for and our regional network have been using Heartlogic since 2021. It is now embedded into our standard of care. At our Organisation we have approx 476 Heartlogic enabled CRT-Ds and 408 ICDs that are monitored and acted on on a weekly basis and have for almost 3 years. The alerts are shared across the Network with the responsible community HF team acting on and reviewing the Heartlogic alert. It is embedded into our clinical pathway. In July 2021 at our centre, HeartLogic was initiated in 212 patients with CRT-D devices. Throughout the subsequent 12 months, 34 hospitalisations occurred, primarily due to heart failure (HF), with a median hospital stay of 5 days. The total outpatient visits numbered 37, with 22 visits attributable to HF decompensation. During this period, HeartLogic alerts were triggered 197 times, on average 0.95 alerts per patient-year, primarily signalling impending HF exacerbations. These alerts demonstrated a sensitivity of 100%, with all HF hospitalisations detected during alert states. Therapeutic actions were taken in response to 82 alerts, including medication adjustments, with 37% of alerts necessitating hospitalisation or outpatient visits for clinical management. Overall, HeartLogic significantly contributed to the early detection and management of HF events, potentially reducing	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			unplanned hospital visits and improving patient outcomes. Before the availability of HeartLogic technology, the management pathway for patients with heart failure typically relied on periodic clinic visits and subjective assessments of symptoms. Patients would generally undergo scheduled follow-ups, during which clinicians would assess their clinical status, review symptoms, and adjust treatment plans accordingly. However, this approach often lacked continuous monitoring between appointments, which could result in delayed detection of deteriorating heart failure status and subsequent exacerbations. As a result, patients might experience more frequent hospitalisations or AED attendance due to unanticipated worsening of their condition. Patients are reviewed in person by Heart failure specialist nurses usually between 2-4 weekly. When a patient calls reporting an exacerbation of heart failure, initially I would assess the severity of the symptoms reported by the patient, including shortness of breath, fatigue, swelling, and changes in weight. Based on the assessment, I would likely instruct the patient to adjust their medication regimen as previously prescribed, such as increasing diuretics to alleviate fluid retention. I would then arrange a face-to-face review. If the symptoms persist or worsen, I would consider a hospital admission which may involve intravenous diuretics. I would advise the patient if they were not responding to diuretic increase to attend AED. Regular follow-up appointments would be scheduled to monitor the patient's progress and adjust treatment as necessary to optimise their heart failure management. With the introduction of HeartLogic, the management pathway for these patients has undergone a significant transformation. HeartLogic provides continuous remote monitoring of key physiological parameters associated with heart failure exacerbations. This allows for	

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			early detection of subtle changes indicative of worsening heart failure, even before symptoms become apparent to the patient. As a result, healthcare providers can intervene promptly with targeted therapies or adjustments to medication regimens, potentially preventing or mitigating the severity of heart failure exacerbations. Additionally, the use of HeartLogic reduces the reliance on subjective symptom reporting by patients, providing objective data to guide clinical decision-making. This objective data, combined with regular alerts and remote monitoring, enables a more proactive and personalised approach to managing heart failure. Consequently, patients may experience fewer unplanned hospital visits, reduced lengths of stay, and improved overall outcomes compared to the traditional management pathway. The management pathway for patients with heart failure has shifted from reactive and episodic care to proactive and continuous monitoring with the integration of HeartLogic technology. The implementation of HeartLogic technology brings a multitude of benefits to both patients and healthcare providers involved in heart failure care. For patients, HeartLogic offers proactive monitoring, enabling early detection of impending heart failure exacerbations, which can lead to timely interventions and reduced hospitalisations. HeartLogic streamlines patient management through continuous remote monitoring, facilitating more personalised care and enabling timely adjustments to treatment strategies based on real-time data. Additionally, it optimises clinic workflow by reducing the need for frequent in-person visits, allowing clinicians to focus their attention on patients who require more intensive care, ultimately leading to improved outcomes and resource utilisation in heart failure management.	
37	Web Comment		From a workflow and organisational perspective, HeartLogic streamlines patient management by enabling more efficient allocation of resources and optimising clinic workflow. The technology facilitates more personalised	Thank you for your comment which the committee has

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			and proactive care, allowing our healthcare team to intervene promptly and adjust treatment plans based on real-time data, ultimately leading to improved patient outcomes and enhanced overall efficiency within our organisation.	considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.
38	Web Comment		Our organisation and our network have been using TriageHF since 2018. It is embedded into our standard of care and we currently have over 2200 CRTD TriageHF monitored patients in our region. We completed a study of TriageHF. The study aimed to evaluate the effectiveness of using Cardiac Implantable Electronic Device (CIED)-generated Heart Failure Risk Score (HFRS) alerts within an integrated, multi-disciplinary approach to heart failure (HF) management. Conducted as a prospective, single-centre outcome study, it spanned from November 2018 to November 2020 and included patients with HFRS-enabled Medtronic CIEDs that generated "high risk" alerts. When these alerts were triggered, they were shared with local HF teams to prompt patient contact and appropriate interventions. Outcome data on healthcare utilisation (HCU) and mortality were collected, and HF teams provided feedback through a validated questionnaire. Results The study involved 188 patients with a mean age of 70 years, of whom 49% had a Charlson Comorbidity Score greater than 6. Over the study period, 367 high-risk alerts were noted, averaging 1.95 alerts per patient, with 23% of patients experiencing more than three alerts during follow-up. Of the patients, 39% (75 patients) were hospitalised within 4-6 weeks of an alert, with 28% (53 patients) experiencing unplanned admissions, and 13% (24 patients) specifically for decompensated HF. Additionally, 18% (33	Thank you for your comment which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			patients) died during the study period. The data indicated that having three or more alerts significantly increased the risk of HF hospitalisation, with a hazard ratio of 2.5 (confidence interval 1.1-5.6, p = 0.03). Conclusions The findings highlight that patients generating high-risk HFRS alerts typically have significant comorbidities and require extensive healthcare resources. An integrated, multi-disciplinary approach enables timely risk stratification and intervention, demonstrating that managing these patients effectively requires a holistic approach beyond just addressing heart failure. The integrated HF pathway received positive feedback from HF teams, underscoring its value in the comprehensive management of this complex patient cohort.	
39	Web Comment		[redacted] Cardiac Device / Heart Failure Specialist Nurse Blackpool Teaching Hospitals NHS Foundation Trust Blackpool Teaching Hospitals has been involved with remote monitoring of Heart Failure patients since 2011. Initially with The REM HF study then going on to look at TRIAGE HF from 2015 and then subsequently Heart Logic. We have no experience with HeartInsight or Corvue to date. We have also previously worked with Manchester Royal Infirmary looking at Triage HF in 2020 where high-risk scores had predictive accuracy for signs, symptoms and behaviours associated with heart failure decompensation.	Thank you for your comment, which the committee has considered. The committee considered clinician experience in their discussions at the second committee meeting on 19 June.

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			Ahmed FZ, Taylor J, Green C, et al. Triage-HF Plus: a novel device-based remote monitoring pathway to identify worsening heart failure. ESC HeartFail. 2020;7:107-116. Our remote monitoring pathway at Blackpool involves our pacing team and all hospitals/ community Heart Failure teams within our Region having access to these remote systems as part of standard care for all patients with a ICD/CRTP/CRTD. Teams included in the remote monitoring include not only Blackpool Hospital and Community Teams but Preston, Chorley, South Lakes, Lancaster and East Lancashire in secondary clinics to allow satellite services to manage their own patients and see remote download information to assist management of their own caseload. Current caseload Boston Heart Logic 519 patients Medtronic Triage 570 Over the last 10 years we have worked with the device companies to look at ways to integrate these algorithms into practice in a way that helps to highlight patients who are deteriorating in a timely manner. It has also allowed us to manage the growing number of heart failure patients in a way that negates unnecessary routine follow up but is more proactive at looking for patients who need intervention. This has been vital for the wider heart failure teams to manage the volume of work in the system to streamline care to where it is needed in real time. Continuous monitoring via the device has given most patients reassurance	

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			that they are having some monitoring, and things will be highlighted if any problems arise. Historically before remote monitoring it was more ad hoc that we would be able to manage patients' exacerbations depending on whether they were due any appointments for review. Often, we would only be alerted to a decompensation when a patient arrived in A&E or medical wards having been symptomatic for some time. Both Triage and Heart Logic allow us to monitor key physiological parameters associated with Heart failure exacerbations. Often these may be subtle; but a clinical review either by telephone or face to face allows us adjust therapy as needed to avoid admission or deterioration and reduce reliance on patients reporting problems. Having been involved with the remote monitoring since the beginning, I have substantial experience of how this has had a positive impact and benefit on both patients and the hospital. We have not done any formal research on the remote monitoring, but constantly review our processes and how we utilise them in everyday practice; to optimise benefit in a changing healthcare environment, while keeping an eye on any developments via the ongoing research. All our teams value the addition resource remote technology gives us both pacing and heart failure teams. This was paramount during covid where we could not see patients face to face initially and patients were shielding. As we had these remote technologies in place it allowed us to continue to manage a bigger volume of patients at a very difficult time. Patients felt reassured to have the monitoring in place, and we were able to manage patients who were decompensating; utilising the information from remote monitoring. Blackpool HF team were selected as one of the early adopter sites for MHF@home project - NHS England » Managing heart failure @home the	

THEME: Clinician experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			NHSE encouragement of remote monitoring. Having referenced our experience of remote monitoring via device and raising concern that patients without device deserved an alternative remote monitoring approach to their condition, given its value. We highlighted value to those from more deprived areas, without strong patient activation capability. We see the benefit of device-based HF diagnostics of greatest value to these populations as do NHSE.	

Appendix 2

Clinical Experience with HeartLogic in the NHS: Clinical Survey

Objective: To develop and administer a survey to capture real-world clinical experience of using HeartLogic to monitor heart failure for cardiac implantable device patients in the NHS.

Methods: A structured survey was developed to capture real-world experience of using HeartLogic in the NHS across six question domains (HeartLogic performance, integration of HeartLogic into patient care, patient outcomes with use of HeartLogic, generalisability of published clinical and economic data to the NHS, your experience of HeartLogic and patient experience of HeartLogic). Relevant clinicians in seven NHS Trusts , responsible for managing heart failure device care pathways, were approached via email in February 2024 to complete the survey, selected based on their high volume of HeartLogic usage.

Results: Five clinicians from five NHS Trusts responded to the survey request on behalf of their Trusts, with respondents comprising either heart failure nurses or heart failure cardiologists (see table 1). The responses provided comprehensive qualitative descriptions of how HeartLogic is utilised within their care pathways to facilitate additional monitoring for heart failure patients and the benefits and challenges they face with running such a service. Comments from these qualitative responses were grouped according to key themes and reported in table 2 below.

For questions where quantitative analysis was possible, surveys reported 80% of respondents (4 of 5) believed HeartLogic had resulted in changes to patients' quality of life and 80% (4 of 5) believed the use of HeartLogic had improved patient outcomes at their centres. 60% believed the use of HeartLogic had resulted in fewer unplanned hospital visits with the remaining 40% responding "Don't know" to this question.

Furthermore, two Trusts submitted detailed data on their usage of HeartLogic as follows:

Liverpool Heart and Chest Hospital: 1 year follow-up of 212 patients with CRT-D devices from July 2021

- 34 hospitalisations occurred, primarily due to heart failure (HF), with a median hospital stay of 5 days.
- The total outpatient visits numbered 37, with 22 visits attributable to HF decompensation.
- HeartLogic alerts were triggered 197 times, on average 0.95 alerts per patient-year, primarily signalling impending HF exacerbations. These alerts demonstrated a sensitivity of 100%, with all HF hospitalisations detected during alert states.

THEME: Clinician experience

- Therapeutic actions were taken in response to 82 alerts, including medication adjustments, with 37% of alerts necessitating hospitalisation or outpatient visits for clinical management.
- Overall, HeartLogic significantly contributed to the early detection and management of HF events, potentially reducing unplanned hospital visits and improving patient outcomes.

New Cross Hospital

- 143 patients between 2019 and 2021, the follow-up period was a median of 459 days (range 215-994).
- The median age of the cohort was 73 years and 74.1% were males. Roughly two thirds of the patients had ischaemic cause of LV dysfunction.
- 1.17 alerts per patient per year. One alert was seen in 40.6% of patients and 2 alerts in 25.9% of patients. Less than 10 of the 143 patients had more than 4 alerts. We were also assured that 58.0% did not have any activations, suggesting stable heart failure.
- The number of alerts that we get from HeartLogic certainly do not overwhelm our service

Table 1

NHS Trust	Region	Heartlogic integrated into HF device care pathway	Responded (Y/N)	Responders	Date of response
Blackpool Teaching Hospitals NHS Foundation Trust	North West	Yes since 2017	Yes	Cardiac device nurse	26 February 2024
Liverpool Heart & Chest Hospital NHS Foundation Trust	North West	Yes since 2021	Yes	Heart failure/complex device lead clinical nurse specialist	26 February 2024
Manchester Royal Infirmary, Manchester University NHS Foundation Trust	North West	Yes since 2019	Yes	Redacted	27 February 2024
The Royal Wolverhampton NHS Trust	Midlands	Yes since 2019	Yes	Consultant Cardiologist/ Electrophysiologist Lead for Electrophysiology and Devices	28 February 2024
Redacted	Midlands	Yes since 2023	Yes	Redacted	23 February 2024
Redacted	London	Yes since 2022	No	n/a	n/a
Redacted	South East	Yes since 2020	No	n/a	n/a

Table 2

Main themes	Selected expert input (please see attached questionnaires for all inputs)

HL can prevent hospital admissions	• "it feels like we do manage to intervene earlier and **prevent some hospitalisations**." [Cardiac Device Nurse, Blackpool Teaching Hospitals] • "Before HeartLogic was available, patients would either just be managed by their GP's or the Heart Failure Nurses (not all patients) and so in a sense they were 'forgotten'. The activation of the HeartLogic software means that the cardiology department is being proactive in managing their heart failure/LV systolic dysfunction, thus **preventing hospital admissions**" [Consultant Cardiologist, New Cross Hospital] • "**likely reduction in HF admissions** due to the ability to "catch" patients earlier in the HF cascade before they are symptomatic enough to become hospitalised" [Healthcare Professional, Manchester Royal Infirmary]
HL improved patient experience and quality of life	• "Most patients report they **feel safe** knowing someone is keeping an eye on them. They can forget about their condition day to day and get on with living while we make sure things are stable." [Cardiac Device Nurse, Blackpool Teaching Hospitals] • "Patients using HeartLogic have provided positive feedback on its impact on their heart failure management. Many have expressed a **sense of reassurance and empowerment** knowing that their condition is continuously monitored remotely, allowing for early detection of potential exacerbations. This proactive approach has instilled a greater sense of confidence in managing their HF. Patient's appreciate the convenience of fewer clinic visits and the ability to maintain a more active role in their care while still receiving timely interventions when needed. Overall, feedback from patients indicates that HeartLogic has **significantly improved their overall quality of life by providing peace of mind, enhancing convenience, and empowering them** to better manage their heart failure condition." [Heart Failure and Complex Device Lead Clinical Nurse Specialist, Liverpool Heart and Chest Hospital] • "The objective data provided by HeartLogic enables more personalised and targeted therapies, optimising symptom management and enhancing overall well-being. Overall, the implementation of HeartLogic has undoubtedly contributed to a **tangible improvement in the quality of life** for patients living with heart failure." [Heart Failure and Complex Device Lead Clinical Nurse Specialist, Liverpool Heart and Chest Hospital] • "In addition to the above (being able to prevent decompensation and to improve prognostic medication) patients seem to find it **psychologically beneficial** to know someone is monitoring their condition. It allows us to explore the reasons for decompensation, some of which are lifestyle related, e.g. drinking lots of fluid or eating salty foods, and reiterate self care strategies." [Heart Failure and Complex Device Lead Clinical Nurse Specialist, Liverpool Heart and Chest Hospital] • "I was surprised by how positive they were about the system. They are very welcoming of phone calls even when ultimately they are deemed well and no action is taken. They seem **reassured** that they are still being monitored." [Heart Failure Nurse, NHS Trust in England] • "When performing telephone triage of HeartLogic compatible patients, we receive regular feedback that they are **appreciative** of the additional follow up and that we are keeping an eye on them alongside their routine HF clinic visits." [Healthcare Professional, Manchester Royal Infirmary] • "Additionally, the decreased necessity for frequent clinic visits translates to a more convenient and **less burdensome healthcare experience for patients**, while simultaneously allowing healthcare providers to **allocate**

	their resources more efficiently towards those requiring heightened attention and care." [Heart Failure and Complex Device Lead Clinical Nurse Specialist, Liverpool Heart and Chest Hospital]
HL allows for optimisation of patient management, thereby preventing HF events and reducing resource use	• "With the introduction of HeartLogic, the management pathway for these patients has undergone a significant transformation. …. As a result [of early detection], healthcare providers **can intervene promptly** with targeted therapies or adjustments to medication regimens, **potentially preventing or mitigating the severity of heart failure exacerbations**." [Heart Failure and Complex Device Lead Clinical Nurse Specialist, Liverpool Heart and Chest Hospital] • With HeartLogic: "It's now a **proactive pathway** and will catch many patients who have been discharged from the community heart failure nurses and would otherwise have to try to obtain a GP appointment or present to secondary care via emergency pathways. Additionally this process allows us to pick up patients who may have been on optimal therapy when last seen by hospital or community specialist teams but could now be considered to be on sub-optimal therapy by current standards. **We can therefore improve their medication** in line with contemporary practice." [Heart Failure Nurse, NHS Trust in England] • "I have already made interventions to **avert worsening heart failure symptoms** and improved GDMT in patients who were no longer under ongoing specialist review." [Heart Failure Nurse, NHS Trust in England] • "By providing clinicians with real-time insights, HeartLogic facilitates the **optimisation of oral medications**, ensuring that treatment plans are tailored precisely to individual patient needs, thus maximising efficacy." [Heart Failure and Complex Device Lead Clinical Nurse Specialist, Liverpool Heart and Chest Hospital] • "Additionally, the use of HeartLogic reduces the reliance on subjective symptom reporting by patients, providing objective data to guide clinical decision-making. This objective data, combined with regular alerts and remote monitoring, enables a **more proactive and personalised approach** to managing heart failure. Consequently, patients may experience **fewer unplanned hospital visits, reduced lengths of stay, and improved overall outcomes** compared to the traditional management pathway." • "Utilisation of the HeartLogic algorithm witihin our physiologist-led service including review of HF diagnostic information and clinical assessment can shorten the time from patient presentation to HF review and therefore **streamline the existing standard of care**" [Healthcare Professional, Manchester Royal Infirmary] • "I find HeartLogic technology to be immensely beneficial in the management of heart failure patients. …. The convenience of remote monitoring and the potential for improved patient outcomes make a compelling case for HeartLogic to become the standard of care in heart failure management. Its integration into my routine clinical practice has **optimised resource utilisation, improved patient outcomes**, and ultimately enhances the overall quality of care for heart failure patients. I firmly believe that HeartLogic should be embraced as a standard component of heart failure management protocols." [Heart Failure and Complex Device Lead Clinical Nurse Specialist, Liverpool Heart and Chest Hospital]
Additional benefits:	• "it's allowed us to improve medical therapy for both short and long term clinical stability. Much **better collaboration** between HF team and physiologists and awareness of what each discipline can do to help patient outcomes." [Heart Failure Nurse, NHS Trust in England]

THEME: Clinician experience

○ Improved collaboration between medical teams ○ Reducing delay ○ Better management of patients in remote setting	• "Prior to HeartLogic, pacing team had to highlight any issues to heart failure team but now we have Heart Logic these alerts come direct to the HF teams to deal with **reducing delay**." [Cardiac Device Nurse, Blackpool Teaching Hospitals] • "The management pathway for patients with heart failure has shifted from reactive and episodic care to proactive and continuous monitoring with the integration of HeartLogic technology." [Heart failure/ complex device lead clinical nurse specialist, Liverpool Heart and Chest Hospital] • "Allows teams to see all patients device parameters to **better manage patients in the clinic and remote settings**." [Cardiac Device Nurse, Blackpool Teaching Hospitals]

Conclusions and implications: In the absence of local published data, these responses provide valuable additional insight into the clinical and patient experience of using HeartLogic in NHS practice. Current experience in the UK supports the findings of the studies in Heartlogic reducing hospital admissions, reducing resource use, reducing the potential for HF events, thereby reducing the uncertainty around these findings. Additionally, patients in the UK reported improved QoL with the use of HL to their clinicians.

THEME: Clinical benefits

Comment number	Name and organisation	Section number	Comment	NICE responses
40	Web comment	Has all the relevant evidence been taken into account?	2. Published data on TriageHF was not assessed during the consultation meeting. Evaluation of a Device-Based Remote Management Heart Failure Care Pathway on Hospitalization and Patient Outcomes: TriageHF Plus Real-World Clinical Evaluation. ESC Heart Failure. 2024. https://doi.org/10.1002/ehf2.14821 In the context of clinical care pathways, recently published data reports how alerts assessed as high risk drove interventions including diuretic titration and optimisation of GDMT. Both interventions have proven utility both have proven utility in managing episodes of HF decompensation or progression, in potentially modifying outcomes in favour of reducing hospitalisations and improving patient care. The purpose of the alerts is to identify patients who may be unstable or sub-optimally managed and steer more patients towards NICE chronic heart failure guideline directed care. In the study, compared to those who received usual care alone, those who received usual care + TriageHF Plus (alert-based monitoring within a remote monitoring pathway) had a 58% reduction in all-cause hospitalisations. In view of this data, first presented at ESC in 2022, the British Heart Foundation's 2022 press release on TriageHF Plus described it as a "game-changer for heart failure," with the potential to radically transform the monitoring and management of patients with heart failure between clinic visits.	Thank you for your comment, which the committee has considered. This study was published in May 2024, with the initial committee meeting taking place April 2024. Therefore an unpublished manuscript of this study was considered during the EAG's review. The committee concluded

Comment number	Name and organisation	Section number	Comment	NICE responses
				that while there are concerns regarding the quality of the comparative evidence from Ahmed et al., it is likely that TriageHF can reduce heart failure events compared with no algorithm use. See section 3.14.
41	Web comment	Are the summaries of clinical and cost-effectiveness reasonabl	It was apparent in the discussion and from the draft guidance that the primary function of device alerts was not clearly understood. I have therefore summarised below. Clarifying the purpose of using alert-based monitoring as an extension to usual HF care In people with cardiac devices, alert-based monitoring functions as a pre-hospital clinical early warning system. It's primary purpose is to identify patients whose health data indicates a change, typically a	Thank you for your comment, which the committee has

Comment number	Name and organisation	Section number	Comment	NICE responses
		e interpretations of the evidence	deterioration, to their clinical team. Alert based monitoring allows patients to be brought to the attention of healthcare professional without them having to ask for help, which is a key advantage for those who may struggle to advocate for themselves. This allows care to be delivered at times when it is needed, when the patient may be unwell and in need of medical attention, between scheduled clinic visits. The main purpose of device alerts is to flag patients whose health data has signalled a change to clinical teams. The initial response involves structured phone call assessment from a heart failure nurse to screen the patient for symptoms of worsening heart failure. Utilising HF alerts as a pre-hospital clinical early warning system, prompting clinical assessment via phone calls in the first instance, as part of a heart failure pathway, has demonstrated clinical impact. Aggregated data from 4 published studies (see table) identified an explanatory acute issue in approximately 7 in 10 cases assessed as high risk (column B). A passive RM tool that identifies 7 in 10 patients with an acute issue to medical teams has not been reported previously.	considered. The clinical experts helped to clarify the purpose of alert-based remote monitoring throughout the committee's discussions.
42	Web comment	Research only guidance	Impact of widening health inequalities, impacting patient outcomes. As an example of patients who have benefitted from HF alerts being programmed I have obtained consent from 2 patients to share the following data. The first is of a patient for whom we received a HF alert for in 2023, between scheduled appointments. Although the patient reported no significant change in their clinical condition initially, the data download revealed a notable decline in activity over the last few months and new onset atrial fibrillation. This prompted prescription of anticoagulants and in-person clinical assessment, revealing a significant rise in NT pro BNP and prompting dedicated assessment of cardiac status, confirming low cardiac output. This individual, initially identified through alerts from their device, subsequently underwent a heart transplant. In the second example, we received a TriageHF alert from a patient with HF and a CRT-D device, scheduled for a clinic visit in four months. The clinical data accompanying the alert signalled a change in	Thank you for your comment which the committee has considered. The committee considered patient benefits in its discussion

<table>
<tr><th>Comment number</th><th>Name and organisation</th><th>Section number</th><th>Comment</th><th>NICE responses</th></tr>
<tr><td></td><td></td><td></td><td>clinical status characterised by an increasing burden of atrial fibrillation, congestion, and a significant decline in physical activity. At phone call assessment, the patient reported becoming more sedentary with increasing fatigue. The patient was brought to clinic where NT pro BNP was now significantly increased, and right heart catheter confirmed low cardiac output. This patient from a diverse background, who did not make contact with our service prior to the alert, has gone on to receive a heart transplant.</td><td>at the second committee meeting on 19 June.</td></tr>
<tr><td>43</td><td>Web comment</td><td>More research is needed on: Rates of emergency department or primary care visits</td><td>We have previously published rates of emergency department visits.

Sammut-Powell et al. Journal of the American Heart Association. 2022;11:e024526

In the supplementary data of this publication, Accident and Emergency department attendance data, were combined with admitted patient care episodes as a composite outcome, providing a sensitivity analysis for the study (Tables S2 through S9 and Figures S2 and S3).

Analysis repeated using A&E attendance and APC hospitalisations as a joint outcome (Tables S2: S9)

Table S2: Non-elective hospitalisation episodes by maximum risk recorded within the previous 30 days, 6- and 12- months (APC and A&E as a joint outcome).
<table>
<tr><td></td><td colspan="4">Max risk recorded in previous 30 days</td><td colspan="4">Max risk recorded in previous 6 months</td><td colspan="4">Max risk recorded in previous 12 months</td><td></td></tr>
<tr><td></td><td>Low</td><td>Med</td><td>High</td><td>No txs received</td><td>Low</td><td>Med</td><td>High</td><td>No txs received</td><td>Low</td><td>Med</td><td>High</td><td>No txs received</td><td>Total</td></tr>
<tr><td>All-cause, n (%)</td><td>150 (24.9 %)</td><td>261 (43.3 %)</td><td>184 (30.5 %)</td><td>8 (1.3%)</td><td>17 (2.8 %)</td><td>277 (45.9 %)</td><td>307 (50.9 %)</td><td>2 (0.3%)</td><td>2 (0.3 %)</td><td>234 (38.8 %)</td><td>367 (60.9 %)</td><td>0 (0.0%)</td><td>603</td></tr>
<tr><td>CV, n (%)</td><td>31 (16.9 %)</td><td>81 (44.3 %)</td><td>67 (36.6 %)</td><td>4 (2.2%)</td><td>4 (2.2 %)</td><td>70 (38.3 %)</td><td>108 (59.0 %)</td><td>1 (0.5%)</td><td>1 (0.5 %)</td><td>61 (33.3 %)</td><td>121 (66.1 %)</td><td>0 (0.0%)</td><td>183</td></tr>
</table></td><td>Thank you for your comment which the committee has considered. TriageHF appeared dominant in the model results without any benefit assumed in the number of A&E visits. Any additional benefits would only strengthen this case for cost-effectiveness.

The EAG noted that</td></tr>
</table>

Comment number	Name and organisation	Section number	Comment	NICE responses

HF, n (%)	5 (10.6 %)	12 (25.5 %)	**28 (59.6 %)**	2 (4.3%)	0 (0.0 %)	12 (25.5 %)	**34 (72.3 %)**	1 (2.1%)	0 (0.0 %)	12 (25.5 %)	**35 (74.5 %)**	0 (0.0%)	47

CV=Cardiovascular, HF=Heart Failure, txs=transmissions

Table S3: Maximum Triage-HFRS within 30-day diagnostic evaluation and associated non-elective hospitalisations (APC and A&E episodes).

30-day Diagnostic Evaluation Period Max Triage-HFRS	Total diagnostic evaluation periods	30-day Outcomes		
		All-cause hospitalisation (APC or A&E)	Cardiovascular hospitalisation (APC or A&E)	HF hospitalisation (APC only)
Low	2288 (33.6%)	98 (4.3%)	24 (1.0%)	6 (0.3%)
Medium	3535 (51.8%)	175 (5.0%)	48 (1.4%)	7 (0.2%)
High	996 (14.6%)	111 (11.2%)	42 (4.2%)	23 (2.3%)
Total	6819 (100%)	384 (5.6%)	114 (1.7%)	36 (0.5%)

APC = admitted patient care episode, HFRS = heart failure risk score, A&E = accident and emergency

Table S4: Demographics of patients with at least one 30-day hospitalisation outcome in prospective analysis (APC and A&E episodes).

	30-day Outcomes			All patients
	All-cause hospitalisation	Cardiovascular hospitalisation	HF hospitalisation	
Patients, n (%)	206	81	28	429
Age, mean (sd)	67.3 (16.5)	69.4 (16.7)	76.8 (9.8)	66.0 (15.5)
Male, n (%)	135 (65.5%)	60 (74.1%)	18 (64.3%)	271 (63.2%)
Device Type, n (%)				
CRT-D	82 (39.8%)	33 (40.7%)	12 (42.9%)	162 (37.8%)
CRT-P	84 (40.8%)	32 (39.5%)	13 (46.4%)	168 (39.02%)
ICD	19 (9.2%)	<5 (<5.0%)	<5 (<17.9%)	36 (8.4%)
PPM	21 (10.2%)	>11 (>13.6%)	<5 (<17.9%)	63 (14.7%)
NYHA				

this data was missed during the extraction phase of the review and was therefore not included. The data shows similar trends to the other included studies assessing the TriageHF algorithm. For example, the rates of hospitalisations and associated hazard ratio there were more people hospitalised in the medium and high

Comment number	Name and organisation	Section number	Comment	NICE responses

No heart failure	25 (12.1%)	10 (12.3%)	<5 (<17.9%)	62 (14.5%)
1	19 (9.2%)	8 (9.9%)	<5 (<17.9%)	53 (12.4%)
2	72 (35.0%)	24 (29.6%)	5 (17.9%)	150 (35.0%)
3+	79 (38.3%)	36 (44.4%)	21 (75.0%)	142 (33.1%)
CKD stage 3 or higher	73 (35.4%)	36 (44.4%)	18 (64.3%)	132 (30.8%)

HF = heart failure, CRT-D = cardiac resynchronisation therapy device with defibrillator, CRT-P = cardiac resynchronisation therapy device with pacemaker, ICD = implanted cardiac defibrillator, PPM = pacemaker, NYHA = New York Heart Association Functional Classification, CKD = chronic kidney disease

Table S5: Coefficients of frailty model using A&E and APC episodes as a combined outcome.

	All-cause hospitalisation within 30 days			Cardiovascular hospitalisation within 30 days		
Variable	Hazard Ratio	95% CI	p-value	Hazard Ratio	95% CI	p-value
Medium (vs Low)	0.986	0.748 – 1.301	0.92	1.150	0.676 – 1.959	0.61
High (vs Low)	**2.049**	1.474 - 2.846	**<0.001**	**3.320**	1.845 – 5.974	**<0.001**
No HF	1.148	0.623 - 2.113	0.66	1.012	0.343 - 2.983	0.98
Age	1.001	0.990 – 1.013	0.663	1.014	0.994 – 1.023	0.19
CRTP vs CRTD	0.699	0.487 – 1.002	0.05	0.662*	0.754 – 2.166	0.26
PPM vs CRTD	**0.478**	0.254 - 0.898	**0.02**	0.841*	0.262 - 2.698	0.77
ICD vs CRTD	0.562	0.280 - 1.124	0.10	0.169*	0.019-1.468	0.11
CKD stage 3 or higher	1.326	0.931 – 1.890	0.12	1.559*	1.054 – 2.306	0.06

risk groups than low risk. For medium vs low there was no statistically significant association (HR = 1.15, 95% CI: 0.68 to 2). For high vs low there was a statistically significant association (HR = 3.32, 95% CI: 1.85 to 5.97). The direction of these results is comparable to those reported in the other studies, with a higher risk status being associated

<table>
<tr><th>Comment number</th><th>Name and organisation</th><th>Section number</th><th>Comment</th><th>NICE responses</th></tr>
<tr><td></td><td></td><td></td><td>
HF = heart failure, CRT-D = cardiac resynchronisation therapy device with defibrillator, CRT-P = cardiac resynchronisation therapy device with pacemaker, ICD = implanted cardiac defibrillator, PPM = pacemaker, CKD = chronic kidney disease

Table S6: Coefficients for time-varying covariate frailty model for cardiovascular hospitalisation within 30-days (APC and A&E as a joint outcome.
<table>
<tr><td></td><td colspan="3">Cardiovascular hospitalisation within 30 days</td></tr>
<tr><td>Variable</td><td>Hazard Ratio</td><td>95% CI</td><td>p-value</td></tr>
<tr><td>Medium (vs Low)</td><td>1.150</td><td>0.676 – 1.959</td><td>0.61</td></tr>
<tr><td>High (vs Low)</td><td>3.320</td><td>1.845 – 5.974</td><td><0.001</td></tr>
<tr><td>No HF</td><td>1.012</td><td>0.343 - 2.983</td><td>0.98</td></tr>
<tr><td>Age</td><td>1.014</td><td>0.994 – 1.023</td><td>0.19</td></tr>
<tr><td>CRTP vs CRTD (0-15 days)</td><td>0.662</td><td>0.754 – 2.166</td><td>0.26</td></tr>
<tr><td>PPM vs CRTD (0-15 days)</td><td>0.841</td><td>0.262 - 2.698</td><td>0.77</td></tr>
<tr><td>ICD vs CRTD (0-15 days)</td><td>0.169</td><td>0.019-1.468</td><td>0.11</td></tr>
<tr><td>CKD stage 3 or higher (0-15 days)</td><td>1.559</td><td>1.054 – 2.306</td><td>0.06</td></tr>
<tr><td>CRTP vs CRTD (16-30 days)</td><td>0.598</td><td>0.261 - 1.369</td><td>0.22</td></tr>
<tr><td>PPM vs CRTD (16-30 days)</td><td>0.456</td><td>0.130 - 1.602</td><td>0.22</td></tr>
<tr><td>ICD vs CRTD (16-30 days)</td><td>2.277</td><td>0.220 - 23.527</td><td>0.49</td></tr>
<tr><td>CKD stage 3 or higher (16-30 days)</td><td>0.564</td><td>0.261 - 1.217</td><td>0.14</td></tr>
</table>
HF = heart failure, CRT-D = cardiac resynchronisation therapy device with defibrillator, CRT-P = cardiac resynchronisation therapy device with pacemaker, ICD = implanted cardiac defibrillator, PPM = pacemaker , CKD = chronic kidney disease

Table S7: Costs for hospitalisations in the retrospective analysis
<table>
<tr><td></td><td colspan="4">Max risk in previous 30 days</td></tr>
<tr><td></td><td>Low</td><td>Medium</td><td>High</td><td>No transmission</td></tr>
</table>
</td><td>with increased risk of hospitalisation. The EAG therefore do not believe missing this data has led to us not providing an accurate depiction of how TriageHF risk status is associated with risk of hospitalisation in a number of studies. With the main difference from the reported literature being the non-significant</td></tr>
</table>

Comment number	Name and organisation	Section number	Comment	NICE responses

	N	Cost	Missing	N	Cost	Missing	N	Cost	Missing	N	Cost	Missing
A&E episodes												
All-cause	78	£9,107	0	115	£14,057	1	52	£6,583	0	2	£221	0
Cardiovascular	11	£1,491	0	26	£3,671	0	17	£2,470	0	1	£130	0
Total costs (APC and A&E episodes combined)												
All-cause	151	£181,986	1	261	£389,896	4	184	£437,367	4	10	£10,312	2
Cardiovascular	31	£58,403	0	81	£139,897	0	67	£156,622	0	4	£6,250	0
HF	5	£14,676	0	12	£40,230	0	28	£94,135	0	2	£5,774	0

APC = admitted patient care episode, HFRS = heart failure risk score, A&E = accident and emergency, HF = heart failure

Supplementary Table S8: Costs for A&E and APC events within the prospective analysis.

30-day Diagnostic Evaluation Period Max Triage-HFRS	Total diagnostic evaluation periods	All-cause hospitalisation				Cardiovascular hospitalisation			HF hospitalisation		
		N	Total Cost	Missing	Average Cost	N	Total Cost	Average Cost	N	Total Cost	Average Cost
Low	2282 (33.6%)	98 (4.3%)	£95,133	2	£990.97	24 (1.1%)	£35,173	£1,465.55	6 (0.3%)	£18,561	£3,093.50
Medium	3530 (51.8%)	176 (5.0%)	£231,701	1	£1,324.01	48 (1.4%)	£84,819	£1,767.07	7 (0.2%)	£19,142	£2,734.58

association of a medium risk, which was generally reported as being statistically significant compared to low risk in the other studies assessing hospitalisation when using the TriageHF algorithm (number of studies = 5).

THEME: Clinical benefits

<table>
<tr><th>Comment number</th><th>Name and organisation</th><th>Section number</th><th>Comment</th><th>NICE responses</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>High</td><td>993 (14.6%)</td><td>111 (11.2 %)</td><td>£257,354</td><td>2</td><td>£2,361.05</td><td>42 (4.2 %)</td><td>£103,832</td><td>£2,472.20</td><td>23 (2.3 %)</td><td>£80,438</td><td>£3,497.31</td></tr>
<tr><td>Total</td><td>6805 (100%)</td><td>384 (5.6%)</td><td>£584,188</td><td>5</td><td>£1,541.40</td><td>114 (1.7 %)</td><td>£223,824</td><td>£1,963.37</td><td>36 (0.5 %)</td><td>£118,141</td><td>£3,281.70</td></tr>
</table>
HF = heart failure, HFRS = heart failure risk score. No missing data for cardiovascular and HF hospitalisation costs
</td><td></td></tr>
<tr><td>44</td><td>Web comment</td><td>Patient reported outcomes</td><td>These have been published.

A pre-specified secondary outcome included in the TriageHF Plus study included a patient reported outcome measure; assessment of change in status between initial phone call and 30-day follow-up (as measured by patient global impression of change (PGI-C).

Association of a Device-Based Remote Management Heart Failure Care Pathway with Hospitalisation and Patient Outcomes: TriageHF Plus Real-World Clinical Evaluation.

Patient and physician global assessments

Of the sixty-six 30-day follow-up calls where an action had been taken at initial assessment, 39 (59%) patients reported an improvement in symptoms (PGI-C), and 41 (62.1%) of HF specialists undertaking the assessment reported a subjective improvement in patient’s clinical state (PGA).</td><td>Thank you for your comment which the committee has considered.</td></tr>
<tr><td>45</td><td>Web Comment</td><td>Can only be used in research 1</td><td>Already tested within the NHS - demonstrating value in clinical practice and well received by patients.</td><td>Thank you for your comment which the committee has considered.</td></tr>
</table>

THEME: Clinical benefits

Comment number	Name and organisation	Section number	Comment	NICE responses
46	Web Comment		4.NICE guidance also recommends that Heart failure patients are reviewed every 6 months and remote monitoring helps some of this review process as patients are being continuously monitored not just every 6 or 12 months.	Thank you for your comment which the committee has considered.
47	Web Comment		The integration of HeartLogic technology heralds a transformative shift in heart failure care, yielding a spectrum of tangible benefits for patients. With its proactive monitoring capabilities, HeartLogic significantly diminishes the incidence of heart failure events by enabling early detection of impending exacerbations. This not only reduces morbidity but also enhances symptom control, affording patients a better quality of life. Heartlogic contributes to the deceleration of heart failure progression, a pivotal aspect in managing chronic conditions. By providing clinicians with real-time insights, HeartLogic facilitates the optimisation of oral medications, ensuring that treatment plans are tailored precisely to individual patient needs, thus maximising efficacy. Additionally, the decreased necessity for frequent clinic visits translates to a more convenient and less burdensome healthcare experience for patients, while simultaneously allowing healthcare providers to allocate their resources more efficiently towards those requiring heightened attention and care. In my opinion, the integration of HeartLogic technology has led to significant improvements in patients' quality of life. By providing continuous remote monitoring and early detection of impending heart failure exacerbations, HeartLogic has developed a proactive HF management approach allowing for timely interventions and adjustments to treatment plans, potentially reducing the frequency and severity of heart failure symptoms. Consequently, patients may experience fewer hospitalisations, AED attendances, and unplanned clinic appointments, leading to a reduced burden on their daily lives and a greater sense of stability and confidence in managing their condition. The objective data provided by HeartLogic enables more personalised and targeted therapies, optimising symptom management and enhancing overall well-being. Overall, the implementation of HeartLogic has undoubtedly contributed to a tangible improvement in the quality of life for patients living with heart failure. HeartLogic has introduced numerous benefits to both our patients and our hospital. For patients, the proactive monitoring offered by HeartLogic enables early detection of impending heart failure exacerbations, leading to timely interventions and reduced	Thank you for your comment which the committee has considered. The committee considered patient benefits in its discussion at the second committee meeting on 19 June.

THEME: Clinical benefits

Comment number	Name and organisation	Section number	Comment	NICE responses
			hospitalisations. This not only enhances patient outcomes but also fosters a sense of empowerment and confidence in managing their condition. Additionally, by providing continuous remote monitoring, HeartLogic reduces the need for frequent clinic visits, resulting in greater convenience and improved access to care for patients.	
48	Web Comment		I find HeartLogic technology to be immensely beneficial in the management of heart failure patients. Its continuous remote monitoring capabilities provide early detection of impending exacerbations, enabling timely interventions and reducing the burden of hospitalisations and adverse events. The proactive approach offered by HeartLogic empowers patients to take an active role in their care and fosters a sense of confidence and security in managing their condition. The convenience of remote monitoring and the potential for improved patient outcomes make a compelling case for HeartLogic to become the standard of care in heart failure management. Its integration into my routine clinical practice has optimised resource utilisation, improved patient outcomes, and ultimately enhances the overall quality of care for heart failure patients. I firmly believe that HeartLogic should be embraced as a standard component of heart failure management protocols.	Thank you for your comment which the committee has considered. The committee considered patient benefits in its discussion at the second committee meeting on 19 June.
49	Web Comment		Before the availability of the TRIAGEHF management pathway, heart failure (HF) patients with implanted Cardiac Implantable Electronic Devices (CIEDs) were monitored based on periodic clinical visits and subjective symptom reporting, often leading to delayed intervention and higher risk of adverse events. The management was reactive, relying heavily on patient-reported symptoms or routine check-ups, which might miss early signs of deterioration. With the introduction of the TRIAGEHF pathway, the management shifted to a proactive approach. The pathway uses CIED-generated Heart Failure Risk Score (HFRS) alerts to identify patients at high risk of HF decompensation in real-time. These alerts prompt immediate communication with local HF teams, facilitating timely patient contact and intervention. This allows for	Thank you for your comment which the committee has considered. The

THEME: Clinical benefits

Comment number	Name and organisation	Section number	Comment	NICE responses
			early detection and treatment of HF exacerbations, significantly reducing unplanned hospitalisations and potentially improving patient outcomes by addressing issues before they escalate. The integrated approach also promotes holistic care, addressing the multiple comorbidities often present in these patients.	committee considered patient benefits in its discussion at the second committee meeting on 19 June.
50	Web Comment		Additionally, proactive management through these tools helps maintain better overall health and quality of life for HF patients by preventing severe episodes and hospitalisations. Without them, patients are likely to experience more frequent and severe health issues, adversely affecting their day-to-day lives and overall wellbeing.	Thank you for your comment which the committee has considered. The committee considered patient benefits in its discussion at the second committee meeting on 19 June.

THEME: Clinical benefits

Comment number	Name and organisation	Section number	Comment	NICE responses
51	Web Comment [comment submitted twice by 2 separate people]		Remote monitoring algorithms provide a safety net and often identify patients well in advance of worsening symptoms, allowing earlier intervention and often averting the need for long and expensive hospital stays. It drives efficiencies for healthcare providers allowing them to focus on those patients most in need, reducing the need to see many patients face to face. Thereby reducing hospital visits and wait for appointments. The issue can be addressed remotely, quickly and efficiently, saving costs to NHS and time, anxiety and cost to the person and their caregivers. It also reduces their exposure to potential infection when visiting a hospital.	Thank you for your comment which the committee has considered. The committee considered patient benefits in its discussion at the second committee meeting on 19 June.

THEME: Patient experience

Comment number	Name and organisation	Section number	Comment	NICE responses
52	Web comment	False positives creating anxiety	This concern has not been substantiated in any of the clinical studies. As part of usual care, patients are often phoned routinely after device alerts of any kind. There is no adverse reporting to indicate that patients are being harmed by alert based monitoring or signals of increased anxiety reports as an adverse outcome int he TriageHF Plus pathway. In Greater Manchester we have enrolled almost 1,000 patients from across 8 hospitals into a heart failure care pathway that utilises heart failure alerts. As this was a clinical study, the HRA and REC required that we include safety reporting to capture instances of device failure or harm detected during the study. Since 2019, there have been no recorded adverse safety data, and only 3 individuals have withdrawn from the study. The alerts prompt structured phone call based assessments, which have previously been shown to be associated with improved patients outcomes and endorsed by the 2021 European Society of Cardiology (ESC) clinical practice guidelines for heart failure. This is based on a 2015 Cochrane meta-analysis reported structured telephone support and telemonitoring in HF to be associated with lower all-cause mortality and fewer HF hospitalisations. Healthcare practitioners are skilled in assessing patients for indicators worsening heart failure. A 10-minute phone call, utilised for the initial clinical assessment after a high alert, has not resulted in any instances of harm or reported anxiety. In fact, guideline-directed medical interventions, known to improve outcomes and prolong life, have been optimised, as evidenced by the findings of the TriageHF Plus study. Patients have declined exit from the study on moving out of area.	Thank you for your comment which the committee has considered. The committee considered patient benefits in its discussion at the second committee meeting on 19 June.
53	Web Comment		I'm a heart failure nurse who's been using Heart Logic and Triage HF for around five months. So still early days and in the realm of anecdote/experience but some impressions so far:	Thank you for your comment which the committee has

THEME: Patient experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			I've not come across any anxiety from patients following a call prompted by an alert. On the contrary people seem very reassured, even if nothing significant is found on clinical review, that they're being monitored. Patients in my locality, if optimised and stable, are discharged from specialist services. Particularly in the current climate with scarce GP appointments they do not have ready access to a review if they feel they are decompensating other than an emergency pathway. I've made medication changes in this group which appear to have halted worsening heart failure. It presents an opportunity to explore reasons for decompensation, e.g. lifestyle choices and medication compliance - self management advice is reiterated. My sense at this point is that as well as possibly preventing an admission it has resulted in quicker resolution of symptoms. I'm also picking up people within this group that may have been considered to be on optimal therapy at the point at which they were discharged but by current standards is lacking. I'm able to get these people onto contemporary GDMT.	considered. The committee considered patient benefits and clinician experience in its discussion at the second committee meeting on 19 June.
54	Web Comment		Comments about recommendations 1. There is possible anxiety the algorithms may increase patient contact due to false positives. However, in my experience and overall feedback from patients has been very positive as they feel reassured, well managed, and have a contact point ongoing. Anecdotally we have reduced the need for admission or decompensation with the use of this technology. Patients tell us that they feel more in control and safe, they like that they do not have to attend as many appointments, especially if they are well in themselves.	Thank you for your comment which the committee has considered. The committee considered patient experience and the benefits to patients in its discussion on 19 June.

THEME: Patient experience

Comment number	Name and organisation	Section number	Comment	NICE responses
55	Web Comment		Patient: GM Patient who has avoided several admissions being managed utilising remote technology. 'Knowing that I am being monitored all the time gives me great reassurance and often I get a call before I realise what the problem is. It gives me confidence and has stopped me having an admission many times. The nurses and pacemaker team who manage it are great' Patient: PJ Overall very supportive of its use in clinical practice. His opinion was he would prefer the clinician he is seeing has access to all available diagnostic/clinical tools to enable the right decisions about his condition. He went on to say he feels anxious when he has not been to clinic for a while, as he is very reassured with its use. '	Thank you for your comment which the committee has considered. The committee considered patient experience and the benefits to patients in its discussion on 19 June.
56	Web Comment		Patients using HeartLogic have provided positive feedback on its impact on their heart failure management. Many have expressed a sense of reassurance and empowerment knowing that their condition is continuously monitored remotely, allowing for early detection of potential exacerbations. This proactive approach has instilled a greater sense of confidence in managing their HF. Patient's appreciate the convenience of fewer clinic visits and the ability to maintain a more active role in their care while still receiving timely interventions when needed. Overall, feedback from patients indicates that HeartLogic has significantly improved their overall quality of life by providing peace of mind, enhancing convenience, and empowering them to better manage their heart failure condition.	Thank you for your comment which the committee has considered. The committee considered patient experience and the benefits to patients in its discussion on 19 June.

THEME: Patient experience

Comment number	Name and organisation	Section number	Comment	NICE responses
57	Web Comment [comment submitted twice by 2 separate people]		To whom it may concern, As Founder and Trustee of Arrhythmia Alliance, a collaboration of patients, caregivers, healthcare professionals, policy makers and all those affected by or involved in the care of people living with arrhythmias, I am writing to share feedback and concerns regarding the recent draft consultation document indicating that the remote monitoring of Heart Failure alerts may become unavailable except for use in research. We represent a large body of patients many of whom have a cardiac device to manage and monitor their condition. Over the last few years, especially during the pandemic, this technology has provided a lifeline and positively impacted many lives. Patients feel empowered and reassured that their health status is being monitored and able to 'get on with their lives'. We have one fantastic example of a patient who during the pandemic was too afraid to seek medical help despite feeling incredibly unwell. Thankfully the local nurse picked up his Heart Failure alert, contacted the patient by phone and from their discussion was able to understand how to manage his condition. Seamlessly, his local pharmacist delivered a new prescription, protecting an extremely vulnerable patient and responding quickly before things became much worse.	Thank you for your comment which the committee has considered. The committee considered patient experience and the benefits to patients in its discussion on 19 June.
58	Pumping Marvellous Foundation	1.1	I have run a poll in our patient community asking "If you had a cardiac pacemaker device like a CRT or ICD and it had a way of telling your heart failure team if your condition was getting worse, where they could react to this, would you want it activated and working?" We have run the poll for 18hrs – All 118 patients who responded said that they would want the intervention activated. You will see a further image that represents even more patients & 7 days later with 159 responses.	Thank you for your comment which the committee has considered.
59	Pumping Marvellous Foundation	3.1	I agree with the patient expert's opinions apart from I feel that false-positive alerts have been taken out of context and used as a lever to push for more research. In my humble opinion I do not believe that this in it's entirety would cause anxiety	Thank you for your comment which the

THEME: Patient experience

Comment number	Name and organisation	Section number	Comment	NICE responses
			and stress. If you compare normal monitoring of ICD's and CRT devices where there is an alert created and it turns into a false-positive the vast majority of patients would prefer this, knowing that the reporting system works than nothing happening. I agree that if the frequency was significant then this may lead to anxiety and distress. If this was the case the functionality could be switched off at the request of the patient. A parallel discussion would be around medication side effects. Many patients are acutely aware of the side-effects, if any of medications. If these are experienced by the patient then a joint decision between the patient and their healthcare team is taken leading to an appropriate action, remove, remove and replace or manage. Worsening patient anxiety would be the worsening of their symptoms and not knowing what was causing it and when to interact with their healthcare team about it.	committee has considered. The committee considered patient experience and the benefits to patients in its discussion on 19 June.

THEME: Equality considerations

Comment number	Name and organisation	Section number	Comment	NICE responses
60	Boston Scientific	3.24-3.28	We disagree with a number of assertions included in the equalities section of the draft guidance and ask that the committee discuss these again. We believe that the ability to remotely monitor heart failure presents an opportunity to reduce inequities, particularly in underserved and remote communities or those with disabilities who may otherwise find it difficult to attend in-person appointments. We disagree with comments in section 3.28. The ability for quantitative data to be made available to clinicians, reporting the status of a patient, offers greater accessibility to those patients who may not feel comfortable initiating contact directly in the first instance. The quantitative patient-specific data provided by HeartLogic can allow for timely triaging of patients and of resources to obtain any needed interpreters for initial telephone calls or outpatient clinic appts as required.	Thank you for your comment which the committee has considered. The committee considered these ways in which HF algorithms could address health inequalities in their discussion on 19 June. An additional paragraph has been added to the guidance to reflect the potential for algorithm-based remote monitoring to reduce inequalities. See section 3.26.
61	Medtronic	All	Equality issues This current recommendation could lead to a variation in the access to care for HF patients due to geographical, socio-economic, and condition-based disparities. Evidence shows that people who live in areas of socioeconomic deprivation have higher rates of emergency admissions. Medtronic are concerned that a draft guidance recommendation of 'can only be used in research' would adversely affect patients from communities that are historically underserved including patients who are less mobile, elderly or those who live in remote areas and may inadvertently create an inequality in the delivery of care.	Thank you for your comment which the committee has considered. The committee considered these ways in which HF algorithms could address health inequalities in their discussion on 19 June. An additional paragraph has been added to the guidance to reflect the potential for algorithm-based remote monitoring to reduce

THEME: Equality considerations

Comment number	Name and organisation	Section number	Comment	NICE responses
			There is disparity in access to specialist nursing care in different parts of the country. Patients with HF with a preserved ejection fraction (HFpEF) in the main do not have the same access to specialist care and cardiac rehabilitation as those with a reduced ejection fraction (HFrEF). HF remote monitoring supports initiatives such as NHS@home to reduce inequalities across pathways and systems, aligning with the Core20Plus5 approach. We ask that the DAC strongly reconsider the draft guidance recommendations that TriageHF Plus 'Can only be used in research' as it potentially compounds the risk of limiting access for those who live in socioeconomic deprived communities, remote areas or those who are less mobile.	inequalities. See section 3.26.
62	Web comment	Equality issues	Remote monitoring systems are ideally positioned to reduce inequalities in access to healthcare. Device alerts, framed within a pathway like TriageHF Plus, create a system that screens the ambulatory device population and proactively identifies those individuals whose health-related data is the most abnormal (often the sickest people) and offers them help, without them needing to ask. A simple phone call assessment is used to confirm the circumstances of the alert. The system circumvents communication barriers and avoids the need for patients to have a deep understanding of accessing healthcare, relying instead on significant shifts in health data to provide assistance at times when the patient may be unwell, between scheduled appointments. Remotely monitored health data from cardiac devices provides heart failure specialists an insight into daily data spanning the last 14 months, which allows clinically important trends to be detected.	Thank you for your comment which the committee has considered. The committee considered these ways in which HF algorithms could address health inequalities in their discussion on 19 June. An additional paragraph has been added to the guidance to reflect the potential for algorithm-based remote monitoring to reduce inequalities. See section 3.26.

THEME: Equality considerations

Comment number	Name and organisation	Section number	Comment	NICE responses
			The point is that patients can deteriorate between scheduled clinic visits and NHS waiting times increased leading to long delays between clinical assessments. A proactive monitoring system that utilises device-HF alerts has provided a safety net for many clinical teams in the UK and functions as a HF monitoring tool. Given the various reasons discussed, proposing that device-HF alerts should continue as a primary area of research could potentially introduce new disparities in care for individuals with heart failure. Moreover, as the first international remote monitoring consensus (2023) provided a class 1 recommendation for configuring clinical alerts and a 2A indication for device-HF alerts to monitor incident HF and/or progression in individuals with devices, a recommendation to remain limited to research would create differing standards of remote monitoring between the UK and the rest of the world and set back progress.	
63	Web comment	Research only guidance and Equality issues	As a clinician, the conflicting UK clinical guidance (NICE vs BHRS and rest of the world) and recommendation for research only presents an ethical dilemma. We know that individuals from low-income, ethnic minorities, and women are less likely to take part in research, due to barriers such as non-inclusive research practices and communication. As a consequence, individuals from backgrounds under-represented in research are less likely to benefit from access to tools designed to improve access to clinical specialists and patient care if they remain for research only. Until such time that there is parity of representation in clinical studies these groups will have reduced access to validated tools like TriageHF.	Thank you for your comment which the committee has considered.

THEME: Equality considerations

Comment number	Name and organisation	Section number	Comment	NICE responses
			How will you ensure these groups are not disadvantaged in reversing a UK position to research only for TriageHF and HeartLogic, currently supported by BHRS?	
64	Web comment	On the call	Diversity among the expert panel Although not in the document, during the call I was reassured to hear of NICE's commitment to diverse representation in its panels, as evidenced by the presentations. However, all clinical experts on the panel were white male. Including clinical experts in device-HF remote monitoring from diverse backgrounds could have enriched the discussion with a range of experiences and perspectives, enhancing scientific discussions grounded in a robust understanding of the evidence.	Thank you for your comment which the committee has considered. NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. NICE makes every attempt to include a wide range of specialist committee members, but full committee attendance cannot be guaranteed for each topic due to individual members' availability.
65	Web Comment [comment submitted twice by 2 separate people]		The technology addresses health inequalities, many patients particularly those from ethnic minority groups and more deprived backgrounds do not seek medical assistance until they are blue lighted to A&E, remote monitoring can make all the difference, detecting a heart failure event early, before it becomes a crisis.	Thank you for your comment, which the committee has considered. An additional paragraph has been added to the guidance to reflect the potential for algorithm-based remote monitoring to reduce inequalities. See section 3.26.

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
66	Boston Scientific	1.4, Why the committee made these recommendations	We are disappointed that the totality of the evidence base on prognostic accuracy has not been taken into account collectively. HeartLogic has been externally validated repeatedly across different patient groups and geographies, in over 3,000 patients in total, with consistency in sensitivity outcomes reported. This should alleviate concerns over bias from any individual study.We would again like to highlight a key study that we do not believe has been made available to the committee but that we shared with NICE in our EAR consultation response in February 2024. Singh et al. (2024) presents the results of the US FDA-mandated post-approval study that evaluated the performance of HeartLogic in 1,458 patients and found an observed sensitivity of 74.5%. This is of significance given the study design was discussed and agreed upon with the FDA and thus the regulatory agency deemed the study sufficiently powered and appropriately designed to confirm the prognostic performance of HeartLogic. Further information on this study can be found in appendix 1 below. Appendix 1 Whilst we understand the Committee cannot review all evidence published after the assessment is underway, we would like to highlight Singh et al 2024. Below we include a summary of key points from this study. • US FDA-mandated prospective post-approval study evaluating Heartlogic performance in 1,458 patients, with 302 usable HF events	Thank you for your comment, which the committee has considered. The committee acknowledged that the risk of bias assessment of a study does not indicate that bias has been detected in the study. The committee concluded that while there are some concerns about the risk of bias of the prognostic accuracy studies, it is likely that HeartLogic can accurately predict heart failure events. At the second meeting, the committee considered Singh et al. in their overall judgement of the prognostic accuracy for HeartLogic. See section 3.6.

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
			• Real world evidence from ICD and CRT-D patients linked with Centers for Medicaid and Medicare Services (CMS) claims database • Pre-defined primary endpoints o Sensitivity >40% o False positive rate <2.0 per patient-year • Results o Sensitivity 74.5% o False positive rate 1.48 alerts per patient-year • Results exceeded FDA agreed endpoints This study had a large sample size, powering and robust design and performance assessment agreed upon with the FDA. This post-approval analysis confirms Heartlogic can accurately predict HF events with a low false positive rate (as demonstrated in the original validation study MultiSENSE) and aligns with UK clinical data and experience (see Appendix 2). We also note a further factual inaccuracy relating to statements around prognostic accuracy of HeartLogic, which we detail below in our comment 7.	
67	Medtronic	3.6	The committee notes that "For TriageHF, sensitivity (range = 37.4% to 87.9%) and specificity (range = 44.4% to 90.2%) showed considerable variability." The committee proceeds to note that "some of this variability was due to differences in the timeframes of the reporting and different outcome measures" and then ultimately concludes that "More research is needed on prognostic accuracy." TriageHF was developed with 3 risk levels (low, medium,	Thank you for your comment which the committee has considered. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that TriageHF can predict heart failure events.

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
			and high) to allow clinicians to choose whether to err on the side of sensitivity or specificity in managing heart failure patients. For instance, in Cowie 20134, including both medium and high heart failure status produces a sensitivity of 82.8%, although with lower specificity (45.8%). Focusing only on high alerts reduces the sensitivity to 46% while maximising specificity (90.2%). The TriageHF-directly care pathway popularised in the UK – TriageHF Plus – achieves an optimal balance of sensitivity and specificity by protocolising a device transmission 30 days after a patient transitions to medium risk status when it is triggered by elevated transthoracic impedance. The example of TriageHF Plus illustrates a key challenge with the committee's characterisation of TriageHF accuracy. With a robust set of 10 studies published on the prognostic value of TriageHF across several different groups of researchers and varying patient populations, some of which examined only "high" status while others examined "high + medium" status, a range of results is inevitable. Note that performing more research on prognostic accuracy – as the committee has recommended – can only degrade the committee's assessment of TriageHF accuracy evidence if their approach is to combine all studies into one range, and conclude that based on the range, there is uncertainty on the prognostic value of TriageHF. It is crucial for the committee to meaningfully examine the differences between the studies, their implications for the results observed, as well as to understand how the technology is being leveraged in clinical practice in the UK to develop an informed opinion on the accuracy/utility of TriageHF.	See section 3.7. This section has been updated to focus on the study endpoint of worsening heart failure in patients with a "high risk status".

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
68	Web comment	More research is needed on: prognostic accuracy	Prognostic data on TriageHF has been extensively published. The following summarises how High risk status confers adverse prognostic outlook for people with CIEDs and heart failure. Published data 1. Post-hoc analyses of randomised controlled trial data has consistently demonstrated that individuals identified High risk status confers between a 6-10.7 fold increased risk of HF hospitalisation in the next 30-days Cowie, M.R., S. Sarkar, J. Koehler, D.J. Whellan, et al., Development and validation of an integrated diagnostic algorithm derived from parameters monitored in implantable devices for identifying patients at risk for heart failure hospitalization in an ambulatory setting. European Heart Journal, 2013. 34(31): p. 2472-2480. Burri, H., A. Da Costa, A. Quesada, R.P. Ricci, et al., Risk stratification of cardiovascular and heart failure hospitalizations using integrated device diagnostics in patients with a cardiac resynchronization therapy defibrillator. EP Europace, 2018. 20(5): p. e69-e77. Gula, L.J., G.A. Wells, R. Yee, J. Koehler, et al., A novel algorithm to assess risk of heart failure exacerbation using ICD diagnostics: validation from RAFT. Heart Rhythm, 2014. 11(9): p. 1626-1631.	Thank you for your comment which the committee has considered. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that TriageHF can predict heart failure events. See section 3.7.

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
			Although non-RCT data, we have published data from a real-world UK cohort demonstrating that high risk status confers increased risk of death. During follow-up, 285 patients (65%) had a high-risk episode and 60 patients (14%) died (50 in high-risk group; 10 in never high-risk group). Significantly more cardiovascular deaths were observed in the high-risk group, with mortality rates across groups of high vs. never-high 10.3% vs. <4.0%; P = 0.03. Experiencing any high-risk episode was associated with a substantially increased risk of death [odds ratio (OR): 3.07, 95% confidence interval (CI): 1.57-6.58, P = 0.002]. Each high-risk episode ≥14 consecutive days was associated with increased odds of death (OR: 1.26, 95% CI: 1.06-1.48; P = 0.006). Ahmed, FZ et al. (2022). Remote monitoring data from cardiac implantable electronic devices predicts all-cause mortality, EP Europace, Volume 24, Issue 2, February 2022, Pages 245-255, https://doi.org/10.1093/europace/euab160	
69	Web comment	More research is needed on: Rates of false positives and unexplained alert rates	3. Sensitivity, Specificity, False Positives and Unexplained Alerts Sensitivity, specificity, and unexplained alert rate (referred to as UAR in the Multisense and TriageHF studies) are crucial metrics for assessing algorithm performance. However, it is	Thank you for your comment which the committee has considered. The committee noted that “false positive” alerts could still provide useful information in

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
			essential to consider the context and endpoints against which these metrics are assessed. Broadly speaking, sensitivity has been defined as the number of cases assessed as high risk who have the condition. Older studies of TriageHF used the clinical endpoint of 30-day HF hospitalisation as the endpoint ("condition") against which sensitivity and specificity was calculated. Hospitalisations due to heart attacks, arrhythmias, worsening HF symptoms managed with urgent outpatient appointments and escalating diuretic doses, were not counted. Therefore, if the objective is solely to determine whether a high-risk status identifies individuals hospitalised within 30 days, the definition of what constitutes a positive case becomes crucial. Cases of worsening heart failure (without hospitalisation), urgent outpatient visits, increased oral diuretics and even IV diuretics administered at home, do not contribute to this endpoint, leading to a lower sensitivity. A more comprehensive definition for assessing sensitivity would include all cases experiencing a clinical event, whether related to heart failure or not, by 30 days. Non-HF acute medical issues like exacerbations of COPD or a chest infection, which can lead to a change in clinical parameter like heart rate, fluid levels in the chest and reduced activity can trigger an alert. They are also universally recognised as clinically significant. For this reason, recent real world clinical studies have examined a broader range of endpoints (including HF and non-HF events, from patient-reported symptoms to hospitalisations), resulting in an increase in sensitivity.	reviewing heart failure patients. See section 3.8.

THEME: Prognostic accuracy

<table>
<tr><th>Comment number</th><th>Name and organisation</th><th>Section number</th><th>Comment</th><th>NICE responses</th></tr>
<tr><td></td><td></td><td></td><td>
It may be prudent to also consider other metrics. Real world clinical studies have examined a broader range of definitions for worsening heart failure and also assessed non-HF clinical issues. In the table below, approximately 7 in 10 cases assessed as high risk are identified as having a clinically relevant event by their clinical team. 3 of these studies are from the UK.
<table>
<tr><th>Study</th><th>Clinical events in high risk %</th><th>Sensitivity %</th><th>Specificity %</th></tr>
<tr><td>Ahmed, 2020</td><td>71%</td><td>98.6%</td><td>63.4%</td></tr>
<tr><td>Bachtiger, 2021(abstract)</td><td>59.8%</td><td>87.9%</td><td>59.4%</td></tr>
<tr><td>Garner, 2022</td><td>65%</td><td>-</td><td>-</td></tr>
<tr><td>Virani, 2018</td><td>83%</td><td>-</td><td>-</td></tr>
</table>
During the consultation meeting, concerns were voiced about false positives and the impact.

4. False positives vs. unexplained alerts

As mentioned earlier, not all false positives are truly false- they may represent non-HF, or non-cardiovascular events that have not been considered a true positive as they are not a heart failure event. When we set the window too narrow we miss other clinically important problems. Exacerbation of COPD, new onset uncontrolled atrial fibrillation and patient reported worsening breathlessness are all clinically significant issues that may be mis-classified as a false
</td><td></td></tr>
</table>

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
			positive, if a positive event is defined by HF events. Therefore, meticulous review of study methodology is essential. Considering these factors, recent studies on device alerts have shifted from reporting false positives to describing "unexplained alerts," quantified as the "unexplained alert rate," to facilitate comparison across studies. An alert is considered "false" only if it is "unexplained," meaning it is not associated with a clinical explanation (no change in symptoms and no identified acute clinical issues). In studies where reported, the UAR remains consistent across TriageHF studies, but most notably reported as 0.5 alerts per patient-year in the largest study involving over 20,000 patients in the US Optum healthcare database led by Zile. In other studies, even if the UAR is not explicitly reported, it can be calculated if the total number of alerts and the number of events detected are known.	
70	Web Comment	Prognostic accuracy 3.6	This statement seems contradictory to the evidence summarised in the committee papers. As summarised in Table 5, 8 papers reporting prognostic accuracy of HFRS, 4 of which were prospective design. On page 14, referring to 5 studies, the committee acknowledges that; “Across the endpoints, the results consistently show that there is an increased risk for HF, cardiovascular, and non-HF cardiovascular related hospitalisation when in a high-risk or medium-risk status, compared with low-risk status”	Thank you for your comment which the committee has considered. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that TriageHF can predict heart failure events. See section 3.7.

THEME: Prognostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE responses
71	Web Comment	More research 1.4	False positives are often an indicator of another clinical event which may need some intervention - providing important physiological data for consideration in patient management strategies	Thank you for your comment, which the committee has considered. The committee noted that “false positive” alerts could still provide useful information in reviewing heart failure patients. See section 3.8.
72	Web Comment		3.False positive alerts are mentioned with regards to chest infection raising impedance, but this is still useful in reviewing a heart failure patient. This acute illness may also affect their heart failure (and increase the risk of decompensation) and with combined clinical assessment will structure a pathway for the patient. To most heart failure teams this is not seen as a false positive, but another flag to review the patient for a good reason. Reduced activity is also often a good indicator alongside other symptoms. These alerts are managed by experienced heart failure nurses who may know the patients well and be experts in clinical assessment.	Thank you for your comment, which the committee has considered. The committee noted that “false positive” alerts could still provide useful information in reviewing heart failure patients. See section 3.8.

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
73	Boston Scientific	1.4, Why the committee made these recommendations	The presentation of the risk of bias assessment is misleading. This has not been sufficiently defined anywhere in the draft guidance nor the EAR beyond a reference to it affecting “uncertainty about the evidence”. For clarity, we note that any rating of high/critical means that the chance of bias existing is high but does not mean that there is a high degree of bias, or even that any bias has been detected. This point has been clearly stated in EAR’s from other NICE diagnostic reviews. Furthermore, we note that, as the EAG acknowledged in their response to comment 22 of the EAR comments, “quality appraisal of studies is subjective” and given the ambiguity in their reporting, we remain unable to understand what specific concerns the EAG had in many of their risk of bias assessments. Please can the committee or EAG clarify what “robust analysis” would constitute for future studies where further evidence generation is recommended.	Thank you for your comment which the committee has considered. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that HeartLogic can predict heart failure events. See section 3.6. The EAG suggest that a “robust analysis” should include all relevant confounding variables/covariates to reduce potential bias in the study results.
74	Medtronic	3.12	In relation to the risk of bias in the Ahmed 2024 publication, the committee notes that “[The Ahmed et al, 2024] study was assessed as having critical risk of bias because of missing information, including whether propensity score matching was successful.” Firstly, Ahmed 2024 study is published in ESC Heart Failure and can be accessed at the following link: https://onlinelibrary.wiley.com/doi/full/10.1002/ehf2.148211	Thank you for your comment, which the committee has considered. The committee concluded that while there are concerns regarding the quality of the comparative evidence from Ahmed et al., it is likely that TriageHF can reduce heart failure events compared with no algorithm use. See section 3.14.

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
75	Web comment		Secondly, the information suggested by the EAG to be missing was not requested during peer review. However, we have submitted an “academic in confidence” supplement containing the following: A figure showing standardised mean differences (SMDs) – before and after propensity score adjustment – for the robust set of variables that were used in generating the propensity score: Age Sex CIED type (CRT-D, CRT-P, ICD) Atrial Fibrillation/flutter Ischaemic heart disease Adult congenital heart disease Prior cardiac ablation Diabetes Chronic kidney disease Left ventricular ejection fraction (LVEF) New York Heart Association class (NYHA) Number of hospitalisations in 6 months prior to the start of the study This figure shows that 1) prior to propensity score adjustment, baseline differences between the TriageHF and standard of care groups were small with only “Device Type” and “Age” exceeding a 20% difference and 2) after propensity score adjustment, these small differences between baseline variables were further reduced but not eliminated, with the difference for every variable being less	Thank you for this additional information. The EAG noted that the study by Ahmed 2024 was judged to be at critical risk of bias due to the risk of confounding and selection bias and it does not consider the additional analysis strong enough to support an amendment to the final risk of bias judgement. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that TriageHF can predict heart failure events. See section 3.7.

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
			than 20%. An analysis was included showing that the variables with the largest residual differences – device type and age – could not have accounted for the lower rate of hospitalisations in the TriageHF group. With respect to device type, this was conceptually due to a combination of ICD being more common in the TriageHF group, but CRT-P being more common in the standard of care group. Both CRT-P and ICD patients had a lower rate of hospitalisation compared to CRT-D, so mathematically these offset such that device type had nearly no net impact on hospitalisation rate. With respect to age, the TriageHF group was 2.6 years older than the standard of care group, and increasing age was associated with a higher hospitalisation rate. Thus, any residual confounding would bias toward a higher hospitalisation rate in the TriageHF group, rather than lower. The conclusion of the “academic in confidence” supplement is that it is very unlikely the 58% lower hospitalisation rate in the TriageHF group is due to residual confounding in observed baseline characteristics. While residual confounding could be present due to unobserved and time-varying factors, we believe this is mitigated by 1) the robust set of variables available leveraged in propensity score adjustment and 2) a COVID-19 sensitivity analysis performed – a key time varying factor in our study – that found TriageHF to still be	

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
			associated with lower hospitalisations, albeit with a smaller effect size (31% vs. 58%). Thus, as in any observational study, there is risk of residual bias in the Ahmed 2024 study. However, the study methods do not warrant that this risk is "critical" and is likely closer to "moderate."	
76	Medtronic	3.12	The committee proceeds to note that in Ahmed 2024 "the majority of hospitalisations being unrelated to heart failure or cardiovascular disease." The committee appears to suggest that the observed effect size is implausible, since this would require preventing hospitalisations "unrelated" to heart failure or cardiovascular and is thus evidence for the presence of bias. Indeed, the Ahmed 2024 study found 9% and 33% of hospitalisations to be coded as primary cause heart failure and cardiovascular, respectively. However, the conclusion drawn – that this is evidence of bias – is invalid for several reasons: It is invalid to assume that the remaining hospitalisations are unrelated to heart failure or cardiovascular disease. Heart failure is a multimorbid disease, and patients are often hospitalised with numerous contributing factors. The Ahmed 2024 study leveraged NHS administrative claims data to identify hospitalisations, and up to 20 ICD-10 codes are reported on claims for each admission. It is impossible to conclusively determine which of the listed ICD-10 codes represent acute diagnoses or chronic comorbidities. Thus, Ahmed 2024 study only used the	Thank you for this additional information. The committee concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that TriageHF can predict heart failure events. See section 3.7. The wording in section 3.14 of the guidance has been amended to remove "the majority of hospitalisations being unrelated to heart failure or cardiovascular disease".

Comment number	Name and organisation	Section number	Comment	NICE responses
			primary ICD-10 coding position in characterising that 9% and 33% represented heart failure and CV hospitalisations, respectively. However, this almost certainly represents a low estimate, and it is invalid to assume that the other 67% of hospitalisations are unrelated to heart failure or cardiovascular disease. It is invalid to assume that TriageHF-based management cannot reduce non-cardiovascular admissions. While the TriageHF algorithm was originally designed to predict pending heart failure exacerbations, Sammut-Powell 2022 demonstrated that TriageHF is also predictive of all-cause hospitalisations2. This is intuitive, given that some of the TriageHF input sensors are not specific to cardiovascular etiologies. For instance, an acute decrease in patient activity could be caused by a heart failure exacerbation, a COPD exacerbation, or sepsis. Moreover, the Ahmed 2024 study reported a broad range of pathways interventions that were not exclusive to the management of heart failure or cardiovascular disease, including referral to other specialists, referral to primary care team, lifestyle counseling, and further diagnostic testing. Therefore, it is plausible that TriageHF- directed action could prevent non-cardiovascular hospitalisations. Whilst the reduction in hospitalisations observed with TriageHF was very large, this is not necessarily evidence of bias and may have been due to COVID-19 increasing the true effect size of TriageHF-directed care. The intervention in Ahmed 2024 included, not only the TriageHF algorithm, but also a standardised pathway for	

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
			managing device data, a schedule for data review, as well as protocolised patient contact protocols and follow-up in the case of a high-status alert. Given that CIED follow-up was significantly impacted during the COVID-19 pandemic with patients unable to attend in-clinic visits3, the well-established TriageHF-based protocol for remote patient follow-up, which was not disrupted, may have accounted for a larger-than-anticipated effect size. Indeed, Bachtiger 2021 presented the utility of a TriageHF-directed protocol during the pandemic, concluding "The Triage-HF Plus pathway served as a useful remote monitoring tool for identifying patients with WHF whose care had been otherwise disrupted by the Covid-19 pandemic, allowing timely intervention and cementing the longer-term role for such models of care delivery. Crucially, in this multimorbid, high-cost population, relevant non-HF issues were also identified." This is further substantiated in Figure 4 of the Ahmed 2024 manuscript, in which a large increase in the hospitalisation rate was observed in the standard of care group between April 2020 – September 2020, while the rate of hospitalisation in the TriageHF group remained relatively consistent. In a pre-COVID-19 sensitivity analysis, an adjusted 31% lower rate of hospitalisations was observed in the TriageHF group, which may have been closer to the expected effect size in the absence of a COVID-19 pandemic.	
77	Medtronic	3.6	The committee notes that "All studies reporting prognostic accuracy data have a high risk of bias, for reasons including missing information and a lack of controlling for	Thank you for your comment which the committee has considered. The committee

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
			confounding factors…" This conclusion may be misleading for 2 reasons: The risk of bias assessment for the prognostic accuracy studies was performed using the PROBAST, which was developed to assess the risk of bias and applicability of prediction modeling studies. PROBAST asks 20 questions across 4 domains to determine the risk of bias and applicability of the study. Crucially, the overall bias and applicability risks are considered high if any individual question is rated as high, and there are no intermediate risk levels, just "high," "low," and "unclear." Multiple studies have shown how this very conservative assessment tool results in nearly every study being rated as "high" without any delineation with respect to relative importance of different questions, or the number of questions labelled as high5,6. For instance, a review of 102 studies in the Tufts registry found 98 to be at high risk of bias. Ultimately, forcing raters to choose between "high" or "low" results in low inter-rater reliability7. Therefore, we would encourage the committee to not dismiss the substantial evidence base on the accuracy of TriageHF, consisting of 10 published studies and over 40,000 patients, based on a high risk of bias assessment from PROBAST. The committee cites a lack of controlling for confounding factors as a reason for high bias in the prognostic accuracy studies. However, controlling for confounding	concluded that while there are some concerns regarding the quality of the prognostic accuracy data, it is likely that TriageHF can predict heart failure events. The wording of section 3.7 has been updated to reflect the EAG's key concerns with the risk of bias of the prognostic accuracy studies using the PROBAST tool.

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
			factors is not a question or domain in the PROBAST tool. It is a question in the ROBINS-I assessment. However, the ROBINS-I assessment is designed specifically for observational studies comparing outcomes between 2 groups8and is thus not applicable to the prognostic accuracy studies. Ultimately, controlling for confounding is not an expected or intuitive steps in algorithm development studies, which are single arm and descriptive by nature.	
78	Web Comment	Prognostic accuracy 3.6	I note Sammut-Powell 2022 was considered at high risk of bias due to insufficient reporting of model performance. This was a paper of which, as second author, I know the data well. I am not aware anyone has contacted the authorship team for additional data requests. This prospective analysis of 435 patients considered various confounding factors in the analysis including age, heart failure diagnosis, device type and presence of kidney disease (additional information provided in supplementary material). It would be incredibly useful for us to know what missing data was considered critical to improve our manuscript reporting in the future.	Thank you for your comment which the committee has considered. The EAG noted that the final protocol for DAP72 stated attempts would be made to contact the authors if time allowed. The systematic review included 81 reports of 42 studies, many of which do not follow standard reporting guidelines; therefore, given the timescales, it was not feasible for the review team to contact individual authors for further information.
79	Web Comment	TriageHF 3.12	To highlight to the committee, the paper Ahmed et al., is now published (DOI: 10.1002/ehf2.14821). Again I was an author on this paper, therefore known the data well. To address the points made regarding critical	Thank you for your comment, which the committee has considered. The committee concluded that while there are concerns regarding the quality

			risk of bias because of: 1. Missing data on success of propensity score matching This was not requested or highlighted on peer-review, and unfortunately due to the University of Manchester cyber-incident, access to our analysis code is suspended. In response to this draft consultation, given the gravity this "missing data" may have on the outcome of this review, we have completed an additional bias mitigation analysis at Manchester University NHS Foundation Trust. I have emailed a copy of the report to diagnostics@nice.org.uk, but to summarise – the propensity score matching was "successful", reducing the small differences in characteristics between the cohorts to negligible levels. 2. Majority of hospitalisations being unrelated to heart failure or cardiovascular disease. All-cause hospitalisation was selected as our primary outcome measure for several reasons. Firstly, on a principled stance, patients with heart failure are often older with multimorbidity. Hospitalisation due to infections, medication side effects or general deterioration can all impact on heart failure stability (and vice-versa), and differentiating the "primary" episode diagnosis is often subjective and clinically unimportant. Ignoring hospitalisation episodes with a non-heart failure primary costing code would risk excluding prolonged or complex hospitalisation events where heart failure was indeed an active issue but not the most costly one - which tend to occur in patients whom probably have most to gain from remote monitoring due to frequent healthcare utilisation.	of the comparative evidence from Ahmed et al., it is likely that TriageHF can reduce heart failure events compared with no algorithm use. See section 3.14. The EAG considered the additional analysis and noted that the study by Ahmed 2024 was judged to be at critical risk of bias due to the risk of confounding and selection bias and it does not consider the additional analysis strong enough to support an amendment to the final risk of bias judgement.

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
			Secondly, from a practical perspective, coding systems for admitted patient care episodes (NHS England) are difficult to interpret. For this study, SUSHRG costing codes were selected, however up to 20 ICD-10 codes are reported per admission. There is no universally accepted method to differentiate which of these codes represent acute diagnoses versus coding of pre-existing comorbidities, thus inclusion would risk over-representation of heart failure decompensation episodes. I hope this explanation sets out the rationale for the approach taken.	
80	Web Comment		"First, we agree with the committee that more robust evidence, preferably a double-blinded randomized-controlled clinical trial on the clinical usefulness of HeartLogic® is absolutely needed. This was the main reason for us to publish real-world evidence data in smaller patient cohorts. Second, we would like to submit a response to the bias assessment that the committee has made on two of our publications. We hope that the committee appreciates this feedback. The committee states that Treskes et al. is at serious risk of bias due to a lack of adjustment for confounding factors. • This study compared hospitalization rates before and after activation of HeartLogic, thus eliminating any sources of confounding that might come from comparing two cohorts of patients in a non-randomized setting. In a	Thank you for your comment, which the committee has considered. The committee concluded that while there are concerns regarding the quality of the comparative evidence for HeartLogic, it is likely that HeartLogic can reduce heart failure events compared with no algorithm use. See section 3.13.

			pre/post analysis, patients serve as their own controls, so differences in baseline characteristics that might influence the outcome would not be a concern. • We do acknowledge that therapy from a cardiac resynchronization device can result in clinical improvement on its own, which is why we performed a subgroup analysis separating out the de novo CRT patients from those who had an ICD or >1 year with CRT. Both subgroups demonstrated significant reductions in hospitalizations between the pre-activation and post-activation period, indicating that this result was not due to the benefits of CRT alone. • We also acknowledge that the COVID-19 pandemic had significant impacts on clinical care, but most of the patients had completed follow-up prior to the start of the pandemic, so this should not have biased the results in a meaningful way. The committee also states that Feijen et al. is at serious risk of bias due to its retrospective nature together with the lack of blinding of the outcome assessor. • While we acknowledge are limitations inherent to a retrospective study design, we would like to emphasize that the intervention and comparator cohorts were clearly defined based on whether HeartLogic was enabled, so there should be no risk of differential misclassification of the interventions. • Outcome data was collected directly from electronic medical records and endpoints were clearly defined based	

THEME: Risk of bias

Comment number	Name and organisation	Section number	Comment	NICE responses
			on definitions defined by the Standardized Data Collection for Cardiovascular Trials Initiative and the US Food and Drug Administration, which would limit any bias in the assessment of outcomes. Yours sincerely [redacted]	

THEME: Cost effectiveness

Comment number	Name and organisation	Section number	Comment	NICE responses
81	Boston Scientific	3.16	We are disappointed that HeartLogic was not recommended given the strength of results from the economic evaluation which already take into account some of the uncertainty reported in the risk of bias assessments. Even with important potential benefits of HeartLogic not captured by the model (e.g., mortality benefit, utility beyond hospitalisation decrement), and therefore with a very conservative model (as noted by the Committee in section 3.19), with the corrected probabilistic sensitivity analysis (see comment 1 in section B below), HeartLogic has 100% probability of being cost saving, and 100% probability of being cost-effective with all commonly used thresholds. Even with the probabilistic sensitivity analysis using the incorrect assumption, the probability of the current clinical practice of not using HeartLogic is 19% at a threshold of £20,000/QALY and still only 27% at a threshold of £30,000/QALY. While as with all healthcare interventions, especially non-pharmaceutical treatments, there are uncertainties in the data and patient numbers, the probabilistic sensitivity analysis captures this parameter uncertainty already and incorporates it in the probability of HeartLogic being cost-effective.	Thank you for your comment which the committee has considered. The committee concluded that HeartLogic and TriageHF are likely to be cost-effective uses of NHS resources. See section 3.20.

THEME: Cost effectiveness

Comment number	Name and organisation	Section number	Comment	NICE responses
82	Medtronic	3.16	"The committee noted that uncertainty around intervention costs and mortality were included in the probabilistic sensitivity analysis, and it would like to see an analysis done where these inputs are fixed." Medtronic have submitted a summary of evidence from additional probabilistic sensitivity analysis based on committee recommendations. These PSA results present a scenario with the high-risk flag resource use and the mortality excluded from the PSA, in accordance with EAG comments. The cost-effectiveness results were consistent with the original PSA. TriageHF Plus remained dominant compared to SoC, with a slight increase in the average ICER per QALY gained, -£610,120 in the original PSA to -£609,650 in the updated PSA. However, the percentage increase in the ICER was only 0.08%, which suggests that neither the uncertainty in the log-normal survival curve nor the cost of flagging as high risk of a HF event were not key drivers of cost-effectiveness. Indeed, in the deterministic results, the cost of flagging as high risk of a HF event per patient was only £152. Furthermore, the impact of decreasing the time horizon was evaluated in the scenario analysis. A ten-year reduction in	Thank you for your comment which the committee has considered. The results of Medtronic's additional probabilistic sensitivity analysis support those of the EAG's analysis. The committee concluded that HeartLogic and TriageHF are likely to be cost-effective uses of NHS resources. See section 3.20.

THEME: Cost effectiveness

Comment number	Name and organisation	Section number	Comment	NICE responses
			mortality caused a small 0.6% increase in the ICER, the smallest increase observed of all parameters explored in the scenario analysis. Results from the original analysis concluded that the key drivers of cost-effectiveness were parameters that affected the rate of hospitalisations and the high cost associated with each hospitalisation.	
83	Web Comment	hf-algorithms--draft-guidance-no-acicdocx	Whilst more data is needed regarding cost-effectiveness, my understanding from the consultation document is that there are indeed signals that they are cost effective. Recent publications have shown that the patients who alert as high on Triage HF are the most costly patients, using 50-65% of the heart failure budget- by acting early and preventing admissions, it seems unlikely that these technologies would be cost-prohibitive.	Thank you for your comment, which the committee has considered.

THEME: RWE framework

Comment number	Name and organisation	Section number	Comment	NICE responses
84	Medtronic	3.12	Despite the real-world evidence provided for Triage-HF Plus, aligning with the NICE RWE framework, in collaboration with NHS England and local AHSN (HIN), Medtronic are concerned that these data have not been given due consideration by the Committee. While the limitations of non-randomised evidence were discussed at the first DAC meeting, there was no discussion on what the appropriate level of evidence would be for TriageHF Plus given 1) the low cost per patient at £100 per patient per year and 2) there being – to our knowledge – no published safety concerns associated with using multiparametric algorithms for CIED-based HF management. Considering the low-cost and low clinical risk associated with TriageHF Plus -based management, it seems that this technology would be a strong candidate for potential NHS adoption as evaluated in this setting. Further, within the DAP, recent decisions appear inconsistent. For example, a technology for remote monitoring of Parkinson's disease [DG51, Jan 2024] was conditionally recommended if further evidence is generated. This conditional recommendation comes despite concerns that the majority of the recommended technologies had little or no clinical evidence, according to the Diagnostic Assessment Report: "Although there is some promising evidence for STAT-ON and Kinesia 360, the EAG considers that the evidence is currently not sufficient to be confident that these technologies will produce clinical benefits for	Thank you for your comment which the committee has considered. The committee considered the real-world evidence that is published for Triage HF. At the second meeting, the committee concluded that while there are concerns regarding the quality of the comparative evidence from Ahmed et al., it is likely that TriageHF can reduce heart failure events compared with no algorithm use. See section 3.14. The committee recommended that TriageHF may be used as an option for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have heart failure. This is explained above in the response to comment number 1, and sections 1.1 and 1.2 of the guidance.

THEME: RWE framework

Comment number	Name and organisation	Section number	Comment	NICE responses
			patients. The EAG considers that there is too little evidence for KinesiaU or PDMonitor to draw any conclusions as to their clinical value." Given that a key strength of the evidence submitted for TriageHF Plus is the extent of RWE studies in NHS settings, a similar conditional recommendation for TriageHF Plus would have been expected. This inconsistency in DAP recommendations is confusing and detrimental to the uptake of innovative low-cost technologies that are being currently used to avert unplanned hospital admissions. The DAC should reconsider TriageHF Plus for proportionate approval as it has NHS RWE published evidence https://onlinelibrary.wiley.com/doi/10.1002/ehf2.148211	
85	Web Comment	Reduced need for in-person appointments 3.24	ABHI notes that no RCT evidence was found for inclusion in the assessment. However, it is unclear how guidance from the NICE RWE framework has been applied in this assessment.	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
86	Medtronic	All	The 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic This consensus recommends remote monitoring as part of the standard of care (1A recommendation) and that alert parameters are customised to clinical indications (1B). It also states that it is reasonable to remotely monitor HF diagnostics to detect incident HF and/or progression (2A) The 2015 version of the HRS consensus, also endorsed by EHRA, had already highlighted that “Combined heart failure device diagnostics have been demonstrated to improve the identification of patients at a higher risk of subsequent heart failure hospitalisations.” British Heart Rhythm Society (BHRS) clinical standards and guidelines for the follow up of cardiac implantable electronic devices (CIEDs) for cardiac rhythm management - June 20223 mention that “All appropriate patients should have remote monitoring” “Appropriate alerts should be programmed on in patients with wireless-enables devices”	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			"Action on data which points to heart failure decompensation is recommended" "There should be a clear local protocol or pathway for patients with CIEDs whom show signs of worsening HF" "The use of multiple physiological parameters detected by CIEDs is emerging as novel way of predicting HF episodes before they occur." and "Cardiac clinical scientists/cardiac physiologists should thoroughly review HF diagnostic data". HF algorithms are an integral component of CIED RM which is standard of care considering "Several large, randomised studies as well as large registries and observational studies consistently demonstrated major organisational benefits, such as follow-up optimisation, and clinical benefits, with improved patient management and clinical outcome associated with RM" Limiting the use of HF algorithms to 'research only' is a risk to broader RM adoption while this practice should be standard of care. As a consequence, this could be a risk for	

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			the organisation of the healthcare system in England considering current staff shortage and therefore the difficulty to ensure the regular and appropriate in-office follow-up of CIED HF patients. Ultimately this could have an impact on patient outcomes in case risks of HF decompensation are not timely uncovered. Also, multiparametric data evaluation through human review is not working (REM HF study). HF algorithms can help to support an effective management process as a tool to streamline FU organisation for CIED patients with HF like it has been shown in TriageHF Plus evidence.	
87	Medtronic	All	This draft guidance recommendation does not reflect policies issued by NHS England which encourage the remote monitoring for HF population. Through the NHS long term plan, the NHS England has set out its plans to accelerate the redesign of patient care to future-proof the NHS including practical priorities that will drive NHS digital transformation such as: Creating straightforward digital access to NHS services and help patients and their carers manage their health.	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			Ensuring that clinicians can access and interact with patient records and care plans wherever they are. Using decision support to help clinicians in applying best practice, eliminate unwarranted variation across the whole pathway of care, and support patients in managing their health and condition. Using predictive techniques to support local health systems to plan care for populations. Using intuitive tools to capture data as a by-product of care in ways that empower clinicians and reduce the administrative burden. Remote monitoring for device-enable HF population aligns with the NHS Long-Term Plan such as; Managing Heart Failure @home and Virtual ward including Hospital at Home, which deliver on key aims and commitments to: Deliver earlier detection and diagnosis of HF and HVD. Improve rapid access to heart failure nurses on admission to hospital so that more patients with heart failure, who are not on a	

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			cardiology ward, will receive specialist care and advice. Better, personalised planning for patients will reduce the number of nights spent in hospital and reduce drug spend. Enable people with HF to be better supported by multi-disciplinary teams as part of PCNs. Improve access to and uptake of cardiac rehabilitation, which can save lives, improve quality of life and reduce hospital readmissions - the LTP sets a target of 33% of eligible people with HF being offered cardiac rehabilitation (CR) by 2028. Roll out personalised care to 2.5 million people by March 2024. We ask that the DAC committee strongly reconsider the draft guidance recommendations that TriageHF Plus 'Can only be used in research', as its at odds with NHS England's programme re: Managing Heart Failure @home, Virtual wards and it's linked objectives.	
88	Web comment	Has all the relevant evidence been taken into account?	Not all of the evidence has been taken into account. Regarding the decision to position remote monitoring alerts for HF as research only,	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			not all of the data has been taken into consideration. 1. Current international consensus document on programming clinical alerts in people with Heart Failure (HF) and a cardiac device and also the British Heart Rhythm Society Guidance. In May 2023 the first international RM consensus document was released jointly by 4 societies (Heart Rhythm Society, European Heart Rhythm Association, Latin American Heart Rhythm Society, Asia Pacific Heart Rhythm Society) to standardise recommendations for remote monitoring (RM) of pacemakers and defibrillators across the 4 continents of North and South America, Europe and Asia. The HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic recently recommended that in patients with CIEDs on RM, it is recommended that alert parameters be customised according to the individuals clinical indications [Class 1A recommendation], with a recommendation supporting the use of remotely monitored HF diagnostics to detect incident HF and/ or disease progression [Class 2A recommendation]. This is the same class of	

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			recommendation issued to monitor for ATP therapies of prolonged burdens of atrial fibrillation, which is routinely programmed in the UK. UK guidelines for remote monitoring recommend that all CIED patients whose devices have the capability should receive remote monitoring, and this extends to include programming of clinical alerts and action on data which indicates heart failure decompensation. In view of these considerations, a recommendation to remain limited to research would create differing standards of remote monitoring between the UK and the rest of the world and set back progress.	
89	Web comment	Are the recommendations sound, and a suitable basis for guidance to the NHS?	No. There is a disconnect between how remotely monitored clinical alerts are recommended for research only by NICE and how they are already supported for use in clinical practice in the UK (according to BHRS guidelines) and the rest of the world. Refer to comment 88.	Thank you for your comment, which the committee has considered.
90	Web comment	More research is needed on: Heart Failure mortality rates	There is already published data that telemonitoring and structured telephone support, supported by the 2021 ESC Heart Failure guidelines, improve patient outcomes.	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			A 2015 Cochrane meta-analysis reported structured telephone support and telemonitoring in HF to be associated with lower all-cause mortality and fewer HF hospitalisations. TriageHF Plus was designed to embed both telemonitoring and structured telephone support.	
91	Web Comment	hf-algorithms--draft-guidance-no-acicdocx	As specified in the consultation document, false positives are generally mitigated in practice as clinical reasoning is applied to every alert, and the algorithms are used to assist the assessment of the patient rather than to replace it, providing prompts to be used alongside standard of care. With this in mind, having this technology available but restricting its use seems to have a much higher potential for causing harm than having this technology utilised by cardiac physiologists and heart failure specialist teams. It seems clear that not acting on these alerts where they occur due to this NICE appraisal would lead to more deaths than if the technologies were freely used- I cannot think of way in which any other conclusion could be reached. I worry that this consultation document works directly against British Heart Rhythm Society guidelines, which clearly state that alert-based remote follow up should be considered as standard of care for CIED patients, and that action should be taken on	Thank you for your comment, which the committee has considered. The committee concluded that HeartLogic and TriageHF [may be used] as options for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have heart failure. They should be used as explained above in the response to comment number 1.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			data which points to heart failure decompensation. I worry therefore that the conclusion reached here essentially promotes substandard and therefore negligent practice in the NHS. These are early warning indicators- there are no clearly defined safety issues included in the consultation document.	
92	Web Comment	1	The draft recommendations appear at odds with national NHS priorities, policies and guidance (which these technologies could support), including: improving “prevention… and better management of long-term conditions” (2024/25 priorities and operational planning guidance) “improve access to virtual wards… supported by remote monitoring technology” (2024/25 priorities and operational planning guidance) “providing better connected, more personalised care in people’s homes” (NHS @home) “boost out-of-hospital care” (NHS Long Term Plan) “reduce pressure on emergency hospital	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			services (NHS Long Term Plan) providing patients “with more personalised care when they need it” (NHS Long Term Plan) “Cardiac clinical scientists/cardiac physiologists should thoroughly review HF diagnostic data” (BHRS clinical standards & guidelines for the follow up of CIEDs for cardiac rhythm management) “it is reasonable to remotely monitor HF diagnostics to detect incident HF and/or progression (2A)” (2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic)	
93	Web Comment	1	already standard of care in line with BHRS guidelines. Remote monitoring is well established and provides additional data when considering patient management strategies.	Thank you for your comment, which the committee has considered.
94	Web Comment	Can only be used in research 1	Technology already standard of care. The British Heart Rhythm Society recommend using alert based remote monitoring for patients with Heart Failure. There is already strong Real World Evidence which we are encouraged to acknowledge and consider, it has been tried and tested within the NHS setting.	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
95	Web Comment	Can only be used in research 1	already standard of care in line with BHRS guidelines. Remote monitoring is well established and provides additional data when considering patient management strategies, very useful.	Thank you for your comment, which the committee has considered.
96	Web Comment	Should not be used 1.5	In line with BHRS guidelines is helpful in clinical decision making	Thank you for your comment, which the committee has considered.
97	Web Comment		5.Existing BHRS recommendation also highlights the need for digital technology to monitor patients; and all appropriate patients should have remote monitoring, considered standard care if patients consent to it. Consent for remote monitoring should be standard, so patients know they are being continuously monitored. Alerts should be actioned in an appropriate timeframe, especially Heart Failure data.	Thank you for your comment, which the committee has considered.
98	Web Comment [comment submitted twice by 2 separate people]		The British Heart Rhythm Society clearly recommends: • All appropriate patients should have remote monitoring • Alert-based remote follow up should be considered as standard care for CIED patients • Action on data which points to heart failure decompensation is recommended The technology also very much aligns with NHS long term plans to manage patients	Thank you for your comment, which the committee has considered.

THEME: Consistency with other guidelines or NHS policy

Comment number	Name and organisation	Section number	Comment	NICE responses
			closer to home, the Heart Failure @ Home program and also the recent addition of virtual wards.	

THEME: Connectivity issues

Comment number	Name and organisation	Section number	Comment	NICE responses
99	Web comment	Failed transmissions	We have previously published data to indicate that missed transmissions are few (1.9%) Publications summarising missed transmission data Remote monitoring predicts All cause hospitalisation paper (Ahmed 2022) Limitations section: A small proportion of the transmission data was missing (1.9%), with most patients having no missing transmission data (n=396 [92.3%]). Of those who did have missing transmission data, the average number of days that a patient was missing transmission data was 10.1 days. **Debski et al** Missing data were in part related issues with the medium optivol. Hence the transmissions transitions from medium + Optivol -> high without clinical teams realising. The study did not report disconnected monitors so unclear what role this played in delayed transmissions **New generation devices** Today, real world clinical practice almost	Thank you for your comment which the committee has considered. The committee concluded that they have no concerns regarding transmission failure, as systems are in place to manage and resolve this. See section 3.15.

THEME: Connectivity issues

Comment number	Name and organisation	Section number	Comment	NICE responses
			exclusively includes new generation devices capable of performing automated transmissions. Legacy devices have been phased out. Few patients remain with older devices. **Remote monitoring predicts all cause mortality (2022)** "Periods without transmitted data are encountered in clinical practice, as was observed in 36 patients within the current evaluation (episodes: 45; median length: 65 days)" This evaluation included patients with non-automated (legacy) devices- subsequent real world studies have focussed on those with automated devices. It is important to note that the 45 episodes reported with missing data are relatively small compared to the >11,000 risk status episodes recorded. Lastly, it is relevant that the mortality was the focus of this study and included people who died in hospital. In the manuscript we clarified that patients who either died in the hospital, were discharged to a care home, or were palliated, would not have	

THEME: Connectivity issues

Comment number	Name and organisation	Section number	Comment	NICE responses
			their monitor paired upon discharge, leading to expected periods of missing data. **Disconnected monitors** We have documented small numbers of disconnected monitors, addressed by contacting and educating the patient. There have been no instances of device failure, no safety reporting submitted in the course of a 5 year UK clinical study and no evidence of harm.	

THEME: CorVue recommendation

Comment number	Name and organisation	Section number	Comment	NICE responses
100	Web Comment Abbott Medical	Should not be used 1.5	Abbott feel this wording is overly aggressive and does not reflect that Corvue can offer value to the NHS when used alongside other complimentary heart failure monitoring devices. Original Wording: CorVue should not be used for algorithm-based remote monitoring in people with CIEDs who have or are at risk of developing heart failure. Suggested new wording: There is insufficient evidence to support the efficacy of CorVue being used in isolation for algorithm-based remote monitoring in people with CIEDs who have or are at risk of developing heart failure, however - Corvue should still be considered by clinicians as a complementary therapy to be used alongside other approaches to a heart failure patients pathway of care.	Thank you for your comment which the committee has considered. The EAG noted that prognostic accuracy studies for CorVue showed a low to adequate sensitivity to predict heart failure events. Clinical experts noted that heart failure algorithms should have a high sensitivity. See section 3.4. Therefore, the committee concluded that CorVue should not be used.
101	Web Comment Abbott Medical	Should not be used 1.5	Abbott feels the language “So CorVue is not recommended for use in the NHS” is overly aggressive, is potentially anti-competitive, and could be misinterpreted by non-clinical / procurement staff in Trusts. This could potentially result in events such as deliberate exclusion of devices containing Corvue from procurement exercises where the specification of requirement is different to the one NICE have assessed in this case. NICE’s language used in section 3.9 talks about “uncertainty” around Corvue which is inconsistent with NICE’s categoric language used in this section 1.5. The wording used in section 1.5 by NICE clearly states some signs of worsening heart failure are predicted by Corvue and the use of Intrathoracic Impedance on which Corvue is based, is supported by	Thank you for your comment which the committee has considered. The EAG noted that prognostic accuracy studies for CorVue showed a low to adequate sensitivity to predict heart failure events. Clinical experts noted that heart failure algorithms should have a high sensitivity. See section 3.4. Therefore, the

THEME: CorVue recommendation

Comment number	Name and organisation	Section number	Comment	NICE responses
			published data here: https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.104.492207 As a result, we feel Corvue can offer value when used to complement other approaches to identifying and treating patients with heart failure. Original wording: Clinical trial evidence suggests that CorVue fails to predict some signs of worsening heart failure and has a high rate of false-positive alerts (alerts that are not followed by a heart failure event). So CorVue is not recommended for use in the NHS. Suggested new wording: Clinical trial evidence suggests that CorVue fails to predict some signs of worsening heart failure and has a high rate of false-positive alerts (alerts that are not followed by a heart failure event). As a result, the committee has uncertainty around the efficacy of CorVue's use as a sole solution for identifying Heart failure, but it should be considered to complement other approaches to a heart failure patients' pathway of care.	committee concluded that CorVue should not be used.
102	Web Comment	Should not be used 1.5	These algorithms are already widely used in the NHS Trusts and the draft recommendations would represent a backwards step in current NHS practice and potentially a negative impact on staffing for those already utilising this technology if they need to revert to in-person monitoring for future patients.	Thank you for your comment, which the committee has considered.

THEME: Editorial comments or inaccuracies

Comment number	Name and organisation	Section number	Comment	NICE responses
103	Boston Scientific	All	We note the following errors, factual inaccuracies and inconsistencies in the draft guidance and committee papers that we request are corrected. The draft recommendation is inconsistent with conclusions drawn within the evidence base and EAR pertaining to prognostic accuracy and false positives – see previous comments 2 and 3 above. The list of specialist committee members include Dr Alison Seed but lacks a reference to the fact she was not present for the first committee meeting on 16 April 2024. NICE confirmed verbally during a call on 9 May 2024 that no follow up input from her was or will be sought post the meeting and its conclusions. The implied endorsement by Dr Seed in the draft recommendations has mislead at least one HCP who stated to us that inclusion of her name within the document, and knowing she, and her centre, are the most experienced clinical users of these technologies within England, inferred she was involved in these discussions and therefore had input into the current draft guidance. The lowest reported sensitivity for HeartLogic of 66% (Santobuono et al.) relates to detection of cardiovascular hospitalisations (which includes but is more broad than heart failure hospitalisations). This is in contrast to other sensitivity rates referenced, which report sensitivity for detecting heart failure events or heart failure hospitalisations specifically. HeartLogic was developed and validated to detect worsening heart failure events. Those studies that evaluated ability to detect worsening HF specifically all demonstrated sensitivity >=70%.	Thank you for your comment, which the committee has considered. Dr Alison Seed was present for the second committee meeting on 19 June 2024, and contributed to the discussion leading to the committee's recommendations. The guidance has been edited to focus on the prognostic accuracy study endpoint of worsening heart failure. See section 3.6 of the guidance. The EAG agreed there were a reasonable number of participants with an event in the MultiSENSE study.

THEME: Editorial comments or inaccuracies

Comment number	Name and organisation	Section number	Comment	NICE responses
			The draft recommendations state "All studies reporting prognostic accuracy data for HeartLogic were assessed as having a high risk of bias because of… small number of people in the studies." This is factually inaccurate: HeartLogic's original validation study MultiSENSE included 900 patients (500 in the development set and 400 in the test set). The EAG response to our previous comment on this point acknowledged that this study "had a reasonable number of participants with the outcome." Please correct this statement. The committee papers continue to erroneously state that Vigdor 2020 reported "26 of 38 alerts" as falsely positive. We are disappointed in this remaining factual inaccuracy despite our raising it to the EAGs attention previously and can only assume they were not able to correctly understand the publication. Indeed, as the External Assessment Group themselves quote in their response to comment 26 of the External Assessment Report comments, the study reported 26 of 38 patients experiencing a false positive alert. Characterising the false alert rate as 26/38 is incorrect and misleading, because the denominator should be higher than 38 alerts as patients can experience more than 1 alert. We reiterate that 26/38 reflects that 38 patients had at least one alert, and 26 patients had at least one false positive: the misrepresentation of this rate of patients experiencing a false positive should not be compared to data from other studies which report a rate of alerts found to be false positives. The committee papers incorrectly states "There was a numerical trend towards reductions in HF events when using HeartLogic compared with no algorithm use, but these were not always statistically significant." Of the three studies that assessed the	The wording in the guidance has been updated to reflect the fact that not all prognostic accuracy studies had small numbers of people. See section 3.6. The EAG apologise for the misinterpretation of the Vigdor 2020 study, which is a conference abstract, as when reading the abstract it appears that 26 of 38 alerts are false positives. However, the clarification here helps to show that there were 38 patients, with multiple alerts and 26 of them had a false positive alert, however, this could have not been their only alert.

THEME: Editorial comments or inaccuracies

Comment number	Name and organisation	Section number	Comment	NICE responses
			impact of HeartLogic-guided patient management on HF hospitalisations, only one of these studies (Feijen et al.) assessed the impact of heart failure events and this study showed a significant reduction in HF events.	
104	Web Comment Abbott Medical	Can only be used in research 1.1	Abbott's view is that Inclusion of wording around “insufficient evidence” should be added to the beginning of this paragraph to reinforce the reason NICE are recommended further research: Original Wording: “More research is needed on 3 technologies for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have or are at risk of developing heart failure, before they can be routinely used in the NHS.” Suggested new wording: Evidence on efficacy is inadequate in quantity and quality for HeartInsight, HeartLogic and TriageHF. Accordingly, more research is needed on these 3 technologies for algorithm-based remote monitoring in people with cardiac implantable electronic devices (CIEDs) who have or are at risk of developing heart failure, before they can be routinely used in the NHS.	Thank you for your comment which the committee has considered. NICE works with editors to ensure the clarity of the guidance document.
105	Web Comment Abbott Medical	Prognostic accuracy 3.3	Abbott request a slight softening of the language used around Corvue failing to predict heart failure events, as in section 1.5 NICE states that Corvue does capture some signs of worsening heart failure. In section 3.9 NICE also uses language around uncertainty which we feel is better suited. There is inconsistency between the body of this document and summary statements made by NICE, which our below new	Thank you for your comment, which the committee has considered. The committee decided to not change the wording in the guidance for

THEME: Editorial comments or inaccuracies

Comment number	Name and organisation	Section number	Comment	NICE responses
			wording seeks to address. Original wording: The committee concluded that CorVue cannot accurately predict heart failure events. Suggested new wording: The committee concluded that there is uncertainty around CorVue's ability to accurately predict heart failure events.	CorVue. This is because across the study endpoints, the EAG noted that CorVue showed a low to adequate sensitivity to predict heart failure events, and the clinical experts noted that heart failure algorithms should have a high sensitivity. See section 3.4.