NICE National Institute for Health and Care Excellence

NICE HEALTH TECH PROGRAMME

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

Second Consultation Document – Comments

Comment number	Name and organisation	Section number	Comment	NICE response
1	Web Comment NHS England	All	NHS England echo the comments, concerns and proposal raised by the British Society for Heart Failure, namely: '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 therefore 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. This is data that is generated passively and continuously, without any additional human resource or patient footprint, which can help improve how we manage these patients.	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. Following consultation, the second sentence of section 1.1 has been updated to say 'They should be used as part of a specialist multidisciplinary heart failure service with alerts reviewed and acted on by specialist healthcare professionals'. Section 3.30 of the guidance has also been updated to include this change.

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			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 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 wholesale limit access of patients to the aforementioned technologies, even though they will continue to have these devices implanted and the information would be available - but 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.' My only comment would be that it is not just simply receiving the data which is important, but the review and intervention that follows. Is there any opportunity to suggest the expansion of the comment: "They	

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			should be used with specialist review of alerts" to something like "Data should be reviewed and acted on by health professionals associated with (or with access to) a specialist multidisciplinary HF service"? I feel this could be leveraged in clinical practice to align those reviewing the transmissions with the HF team.	
2	Web Comment Manchester University NHS Foundation Trust	1	"We welcome NICE position to use clinical HF alerts in people with heart failure, however context in which the alerts are framed is critically important. We have observed that a pathway in which to frame the response to the alerts is critically important, to ensure a consistent approach. We have created a pathway that is used across 8 hospitals in Greater Manchester (TriageHF Plus). Using this we have seen a significant impact on non-elective hospitalisation rates. Given its proven effectiveness, Could I suggest that NICE consider adopting TriageHF Plus as pathway with proven impact on outcomes standardised framework for implementing remote monitoring alerts in heart failure care. This would help ensure consistent, evidence-based responses and maximise the benefits of this technology across healthcare systems.	Thank you for your comment, which the committee has considered. Section 1.1 has been updated to include reference to the clinical pathways these algorithms are part of.

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			Otherwise releasing technology to new sites, with no context of how to use it could lead to confusion, variation in delivery and outcomes. https://onlinelibrary.wiley.com/doi/10.1002/ehf2.14821"	
3	Web Comment Manchester University NHS Foundation Trust		I agree with the committee recommendations. There is good evidence demonstrating benefit to patients by employing algorithm-based remote monitoring clinical pathways for the detection of heart failure decompensation. Risk is minimal, and the potential to improve pathways further makes me incredibly optimistic that future iterations with only improve effectiveness, efficiency, reliability and deliverability.	Thank you for your comment, which the committee has considered.
4	Web Comment Manchester University NHS Foundation Trust		Consider adding "as part of a clinical pathway" as the algorithm itself is only part of the clinical pathway delivering benefit to patients.	Thank you for your comment, which the committee has considered. Section 1.1 has been updated to include reference to the clinical pathways these algorithms are part of.
5	Web comment		Medtronic thanks the committee for their careful consideration of the evidence, we broadly agree with the draft recommendations and have no further comment.	Thank you for your comment.
6	Web comment		We welcome NICE’s amended draft guidance which now recommends HeartLogic as an option for people with heart failure and are pleased the committee	Thank you for your comment.

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			acknowledges the body of evidence supporting the diagnostic accuracy of HeartLogic.	
7	Boston Scientific		Please can you confirm, for the recommendation for further research on the listed outcomes, whether the committee's intention is to recommend comparative real-world data collection rather than "registry data" generically as is currently suggested (the latter being typically all-comer, non-comparative real-world data collection).	Thank you for your comment, which the committee has considered. The recommendation in section 1.1 to "use as an option" is not conditional on future collection of registry data. The committee discussed that to confirm the extent of the benefit seen in the studies, companies should work with the NHS to collect registry data for HeartLogic and TriageHF (see section 3.26). However, collection of comparative real-world data would also be welcomed if collection of this is planned in the future.
8	Web comment		We look forward to working with the NHS once the guidance has been published to further define the outcomes and logistics for the research recommended by NICE as part of their recommendations.	Thank you for your comment.

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	Web Comment Abbott Medical UK Ltd	All	Abbott requests that Corvue, and any mention of it is removed from this Draft guidance document. The reasons for this request are as follows: 1. Whilst “Triage HF” and “HeartLogic” are Holistic solutions drawing from multiple sensors and diagnostic data sets such as Heart rate, Heart sounds, activity, Respiration etc - Corvue is not, and instead is a standalone Algorithm using only Intrathoracic impedance, in the same way Medtronic’s Optivol system does: WEBLINK: Optivol . However, Abbott note Optivol is not mentioned anywhere in this guidance – QUESTION: Can NICE clarify why Optivol has not been reviewed as part of this guidance in the same way Corvue has please? 2. To compare stand-alone options such as Corvue, with Holistic solutions such as “Triage HF”/”HeartLogic” which use multiple sets of diagnostic data (of which Optivol is just one), is akin to comparing apples with oranges and is not a fair comparison, especially when we see “Optivol” has been excluded from this review. 3. As a result, and in order that this guidance properly assesses comparable offerings from suppliers in a fair and transparent way, we are happy for the rest of the document to be	Thank you for your comment, which the committee has considered. Technologies were considered suitable for inclusion in the assessment and subsequent economic analysis if they fit the scope of the assessment. In this case, algorithm-based remote monitoring systems were included if they are capable of identifying new onset acute heart failure or worsening signs of heart failure captured by CIED, and claim to ensure earlier access to interventions to help prevent symptoms occurring or worsening, improving health outcomes and reducing hospitalisations. Please note, OptiVol has been mentioned in section 2.11 of the guidance as one of the parameters that is monitored by the TriageHF Plus algorithm. OptiVol is not claimed to be a standalone measure to predict worsening heart failure or hospitalisation. For this reason, the clinical effectiveness of the TriageHF Plus algorithm has been assessed by considering evidence available on the algorithm as a whole, rather than independently assessing each parameter that is monitored by the algorithm. Therefore, OptiVol has indirectly been included in the assessment of TriageHF Plus. This is in the same way intrathoracic impedance has been considered in the assessment of CorVue.

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			published as is, but request that Corvue is excluded from this guidance in totality - in the same way “Optivol” (a comparable offering to Corvue) from Medtronic clearly has been.	

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10	Web Comment BIOTRONIK SE & Co KG	3	Comment 1.3, page 3 BIOTRONIK requests that the committee adds a specific sentence to confirm that the guidance excludes an assessment of the value of standard BIOTRONIK Home Monitoring, use of which is endorsed for patients with ICDs in all key HF management guidelines. The reasons are as follows: 1. BIOTRONIK's Home Monitoring is industry-leading technology and is the only remote monitoring solution that allows for automatic daily transmission of data without impacting device longevity. There already exists a wide body of evidence (and far more than for other remote monitoring solutions) to support the clinical and economic benefits of BIOTRONIK Home Monitoring for patients with CIEDs, healthcare providers, and the health care system, including evidence from multiple randomised controlled trials (e.g. Hindricks et al. 2014; Hindricks et al. 2017). HeartInsight is an additional and optional feature of BIOTRONIK's Home Monitoring Service Center (HMSC). HeartInsight is essentially an enhanced form of BIOTRONIK Home Monitoring for CIED patients with heart failure, that not only detects changes in the individual sensed	Thank you for your comment. Section 1.2 does not mention the BIOTRONIK Home Monitoring system. We have updated section 2.7 to make it clearer that HeartInsight algorithm is an optional feature that works with the BIOTRONIK Home Monitoring system.

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			parameters but allows for changes in these parameters to be collated into a single predictive score. The aim is to create a more holistic picture of the physiological changes occurring in the patient and in turn help to identify patients at higher risk of worsening heart failure events.	
11	Web Comment BIOTRONIK SE & Co KG	7-8	Comment 2.7-2.9, pp 7-8. BIOTRONIK requests that the committee revises the description of the HeartInsight algorithm as follows: HeartInsight is a predictive algorithm designed to monitor for early signs of worsening heart failure in people with compatible CIEDs. The HeartInsight algorithm combines (functional transformations of) the following seven parameters and an optional additional baseline clinical risk stratification into a single composite score (calculated daily): atrial burden, heart rate variability, general activity, thoracic impedance, heart rate, heart rate at rest and premature ventricular contractions. The HeartInsight system is configured to send an alert to an assigned healthcare professional when the index exceeds a prespecified (customisable) threshold over three successive transmissions (typically three consecutive days).	Thank you for your comment. The description of HeartInsight has been updated in sections 2.7-2.9 of the guidance to reflect your comment.

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			After exceeding the prespecified threshold, the composite index, referred to as the HF Score, indicates a higher risk of worsening heart failure. Upon receipt of an alert, an assigned healthcare professional needs to log on to the Home Monitoring Service Center (HMSC) website to review and assess the alert. Secondary notification of alerts may be sent via email or text message to additional assigned healthcare professionals. The HMSC system includes the CardioMessenger device, which transmits data automatically and daily from the implanted cardiac device to the BIOTRONIK Home Monitoring Service Center via a cellular network. Access to HeartInsight has a once-off cost of £450 per person. Standard Home Monitoring is a separate cost.	

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12	Boston Scientific		We would like to highlight a contradiction in the statements made in sections 3.18 and 3.21. Section 3.21 states that "conservative assumptions were made that there is no difference in heart-failure-related mortality rates between heart failure algorithms and their comparators." However, the original probabilistic sensitivity results discussed at the start of section 3.18 include the use of hazard ratios both above and below 1, which implies a difference in mortality which is not transparent and which conflicts with the statements made in section 3.21. We believe this is misleading and would recommend that section 3.18 is revised to contain only the final paragraph relating to the revised probabilistic sensitivity analysis that was carried out where the modelling did indeed assume no difference in mortality as is stated in section 3.21.	Thank you for your comment. Section 3.21 refers to the EAG's deterministic base-case model, rather than the probabilistic sensitivity analysis. As can be seen in Table 42 of the External Assessment Report ("base case parameters and assumptions"), a hazard ratio of 1 was assumed for mortality, indicating that no difference in mortality was assumed in the EAG's base case deterministic model. The probabilistic model results are presented in section 3.18. The first is for the original probabilistic sensitivity analysis in which the EAG assumed a probability distribution around mortality (hazard ration of 1). The second is an additional probabilistic sensitivity analysis in which no probability distribution was assumed around mortality. This was done because harms (such as death) when using heart failure algorithms are expected to be low. The wording in section 3.18 of the guidance has been updated to make the distinction between the different model scenarios clearer.
13	Web comment		Please remove the "or landline connection" from the end of the second sentence as you have stated in the opening sentence of this section	Thank you for your comment. Section 3.28 of the guidance has been updated to reflect this.

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			that technologies with a landline connection are excluded from the statements made.	

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