NICE National Institute for Health and Care Excellence

DIAGNOSTICS ASSESSMENT PROGRAMME

Implantable cardiac monitors to detect atrial fibrillation after cryptogenic stroke

NICE Decision Support Unit report – Comments

Diagnostics Advisory Committee date: 27 November 2019

Comment number	Name and organisation	Section number	Comment	NICE Response/DSU considerations
1	NHS professional		I welcome the revised ICER and NNT based upon the adjusted code which are very much more realistic. Nevertheless, I note that the revised code utilises inputs from PRIMARY prevention studies and not secondary prevention studies. I would be keen to draw the attention of the team to the fact that second strokes are associated with more disability, higher mortality and a lower quality of life and therefore with higher costs both physical, financial and social. It is therefore inappropriate to use primary prevention data (Sterne and Welton) as inputs into the model. I would advice running the model again with only secondary prevention costs and outcomes.	DSU response: Our brief from NICE was to "quality assure the model and confirm that there are no errors in the coding of the EAG's updated model which could significantly impact the analyses and results." Sourcing new model parameters and re-running the modelling would require significantly extra work.
2	British Cardiovascular Society [Endorsed by the Royal College of Physicians]		Thanks for sending us the modelling analysis and reports for this. A few of us have tried our best to look them over, but honestly, we at the BCS are not really able to comment critically on the health economic assumptions and detail of the models used and so, have no objections to the conclusions drawn by the NICE DSU. From a clinical perspective, our view is that we feel there aren't yet any clear trial data to conclusively show that bursts of AF detected in asymptomatic patients are something that we can effectively treat with anticoagulation and thus reduce serious clinical events like strokes. There seem to be, as yet, too many unknown variables, such as – how long a burst of AF is significant? How many such episodes are needed to significantly increase thromboembolic risks? Does anticoagulation for such	

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			patients have a favourable long term risk/benefit in terms of stroke reduction? What sort of strokes are prevented by such a treatment? Large disabling or life-threatening strokes, or much less severe events? Or even asymptomatic events only detectable on brain imaging. As such, we are unsure how easy it will be to get a meaningful health economic model for these devices.	
3	Royal College of Physicians		The RCP is grateful for the opportunity to response to the above consultation. We would like to endorse the BCS response.	
4	Atrial Fibrillation Association		The Arrhythmia Alliance highly recommends ICM for the detection of AF and AF cryptogenic strokes	
5	Medtronic	General	Medtronic would like to thank NICE for the opportunity to comment on the DSU report. We appreciate the validation of the R-code by the DSU and understand that not all new analysis could be completed in the short time frame. To aid transparency for the committee and other stakeholders, we recommend adding documentation about the changes made to the EAG model before it was sent on to the DSU. It is evident from reading the R code that the new model has been corrected for the error in the treatment switching rules of the DOAC model which we pointed out in our response to the Draft Guidance. The error meant that the number of strokes avoided with Reveal LINQ were underestimated and the technology did not appear to be cost-effective as a result. Without mentioning the error, it is puzzling that the DSU reports their model results to be consistent with the EAG model while the stated results are substantially different to the original EAG model: The ICER in the DSU model for Reveal LINQ vs standard of care is £10,342 compared to £24,875 in the original EAG model.	DSU response: The comparisons in our report were between our final model and the model and associated ICERs we received, in which the corrections noted had already been made. It was assumed that the committee would already have been aware of these.

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6	Medtronic	General	Acknowledging that only the R code was validated during the additional analysis of the DSU, we would like to reiterate that there remain some limitations surrounding several assumptions in the EAG model which should be considered by the committee. These were documented in our response to the Draft Guidance, for example the fact that the EAG cost-effectiveness analysis is based on a pre-existing model principally designed for primary prevention of stroke in a different patient population.	
7	Biotronik	General	For this DSU report, we have no comments to submit.	