NICE National Institute for Health and Care Excellence

Lead-I electrocardiogram (ECG) devices for detecting atrial fibrillation using single-time point testing in primary care

Diagnostics Assessment Report (DAR) - Comments

Stakeholder	Comment no.	Page no.	Section no.	Comment	EAG Response
MyDiagnostick	1.	100	Table 27	The Life of MyDiagnostick is at least 5 years. We have an install base of more then 3000 devices, since late 2012, and a failure rate of less then 1% . Please recalculate the annual cost.	Life span of MyDiagnostick has been updated to 5 years in the base case and results amended accordingly in the erratum.
MyDiagnostick	2.	100	Table 27	Kardia Mobile requires a smart phone. Thus the Unit Cost figure seems inappropriate low.	A scenario (Scenario F) to investigate the impact of including the cost of a supplementary smartphone/tablet for the Kardia Mobile device has been included in the addendum.
Zenicor Medical Systems AB	3.	100	Table 27	Cost per unit of Zenicor ECG not correct. Device AND licence cost **£1,980 for three years**. For ten years (life cycle of the device) the total cost is £6,600 which gives an **annual cost of £660**	Annual cost of the Zenicor-ECG device and licence has been updated to £613.27 in the base case and results amended accordingly in the erratum.
Zenicor Medical Systems AB	4.	100	Table 27	It seems a bit odd that cost for smartphone, or similar, that is needed for usage of the KardiaMobile is not included in the cost calculations as the device cannot be used without pairing.	Please see response to comment 2.
Lay stakeholder	5.	32	Table 2	There is only one reference to 'training' in the document (Table 2) and only one relevant reference to 'instruction'. Whilst there are a couple of references to declared 'ease of use' few if any manufacturers would endorse use	The impact of extra time associated with using the lead-I devices – whether training to use the devices or time taken to administer the test – has been tested in a sensitivity analysis and is included in the

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				without at least reading the instructions and trial use? The apparent omission of any reference to the time/costs to get a clinician proficient in the use of the I-lead device(s) seems a little naïve when it comes to selling the benefits to GPs etc?	model. The results are not explicitly presented in the report, as many other parameters have substantially more influence on the ICER per QALY gained. Results of the deterministic sensitivity analysis indicate that the ICER per QALY gained for each lead-I device increases by around £2,000 when an extra 7 minutes is added to each test performed.
Lay stakeholder	6.	100		Cost per lead-I ECG test. Where are comments on costs for cleaning of device for infection control? 12 lead- ECG are for patient contact at least, disposable one shot items whereas most if not all I-lead devices are same surface area used by each patient? So do these costs include any cleaning between patient use?	The manufacturers indicate that lead-I devices should be cleaned with alcohol hand gel (Kardia Mobile), antiseptic wipes (ImPulse), alcohol wipes (RhythmPad GP), a damp cloth (MyDiagnostick) or isopropanol solution (Zenicor-ECG). According to NHS Supply Chain,[1] catalogue prices for disposable wipes are around £0.02 per wipe and are likely to be similar per use for other cleaning supplies. These costs may be lower once contract discounts are taken into account. The EAG notes that including costs for cleaning lead-I devices would lead to a very small increase in the pairwise ICERs per QALY gained for each device compared with the standard pathway and there would be no change to the incremental costs when the lead-I devices are compared to one other.

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Lay stakeholder	7.	106	Table 36	Summary of base case assumptions. Would perhaps be correct/useful to state that the reference to 'Proportion of patients with paroxysmal AF not in AF at time of Holter monitor' should state duration of Holter i.e '7 day'?	The EAG acknowledges the comment and will revise the table in any future version of the report.
Lay stakeholder	8.	106	Table 36	Summary of base case assumptions. Extra time taken to administer lead-I ECG test shown as zero. Yet, page 100 states that there will be 5 extra minutes (when compared to MPP). As a lay person I find it hard to believe that many GPs will not see the time taken to set up, explain, *clean*, support and interpret the results, as being anything other than an increase compared to MPP. This apparent contradiction should perhaps be explained?	The text on page 100 has been amended in the erratum to indicate that no extra time has been included for using the lead-I devices. Please see response to comment 5 for the results of a sensitivity analysis around this assumption.
Lay stakeholder		107	4.3	Base Case Results At least to a Lay person's reading, this whole section is at best confusing or at worst incorrectly referencing. The opening para references the lead-I ECG in the context of a GP visit, presumably in primary care. However, each scenario whether primary or secondary located, commence their titles referencing the 12-lead ECG, followed by a subsequent (another?) 12-lead ECG. I expected them to be all read 'lead-I ECG in xx	The EAG acknowledges the comment and will revise the text in any future version of the report.

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				care, x days to 12-lead ECG'. Now either I have missed the meaning of Base case and perhaps a better explanation of why its 12-lead to 12–lead scenarios should be provided, or the whole section wants reviewing for incorrect referencing to 12-lead when it should on occasions be lead-I?	
Lay stakeholder	9.	several	several	Tables should have Headers repeating at top of pages where they break over pages to aid readability.	The EAG notes the comment and will revise formatting in any future version of the report.
Lay stakeholder	10.	108		Error code for Table 40 broken link	The EAG notes the comment and will revise formatting in any future version of the report.
NHS professional	11.	21	1:1:1	The meaning of non –valvular and Valvular AF causes confusion amongst wider audience. I suggest a clear definition of valvular AF be included to ensure it is clear this only applies to those with Mitral stenosis or mechanical valves in situ.	The EAG notes the comment and will clarify the definition of valvular AF in any future version of the report.
NHS professional	12.	93		Given NOACs more commonly referred to as DOACs….should there be some consistency here? Although appreciate NOAC is illustrated clearly in the index.	The EAG acknowledges the comment. No amendments made.
NHS professional	13.			Excellent illustration of all lead I devices and good presentation of current evidence and costings.	The EAG acknowledges the comment. No amendments made.

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1. NHS Supply Chain. NHS Supply Chain. 2018; Available from: https://www.supplychain.nhs.uk/. Accessed 2018 14/11/2018.