NICE National Institute for Health and Care Excellence

DIAGNOSTICS ASSESSMENT PROGRAMME

Automated ankle brachial pressure index measurement devices for assessing peripheral arterial disease in people with leg ulcers

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 16 February 2023

THEME: Automated devices may reduce some barriers to testing

Comment number	Name and organisation	Section number	Comment	NICE response
1	Web comment - Livewell	Committee-discussion Leg ulcers can be painful and ABPI assessment can be uncomfortable 3.1	Anecdotally, we are aware of many instances where patients will have refused ABPI assessments for months or years due to fear over pain and discomfort. Being able to offer an alternative assessment gives patients choice and has allowed them to access treatments which may not have been available, such as full compression, earlier. Manual ABPI assessments are frequently painful and invasive for patients, who will most likely have ulceration on the site of assessment. By using automated ABPI assessment there is a cohort patient who will be able to be assessed and implement treatment early on who otherwise would have to await further assessment or specialist review by Vascular etc. prior to commencing treatment. It would be interesting to hear the opinions of patients with regards to risk versus opportunity to start in therapy earlier. In community settings, access to transport and distance from acute hospitals is often a barrier for patients attending secondary services, such as vascular, meaning without an	Thank you for your comment which the committee considered. The potential benefits of using automated devices, including pain reduction during ABPI assessment and improved access to assessment/treatment are described in section 3.1 and 3.2 of the DGD. However, it was noted that there was limited evidence around the time taken for an ABPI assessment using automated vs manual doppler, and the impact on patient discomfort (section 3.8 DGD). As described in section 3.3 of the DGD, there was also uncertainty about where the devices would fit best in the care pathway. Section 3.5 of the DGD describes the committee's concern with implementing the automated devices in settings where there is less expertise in assessing people for peripheral arterial disease (PAD).

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			alternative assessment they may be unable to access appropriate treatment.	

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THEME: How automated devices can be used in the care pathway

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2	Web comment - Livewell	Committee-discussion How the automated devices fit into the care pathway is unclear 3.3	Our current Lower limb training provision focusses on holistic leg assessment. The automated ABPI assessment is then an additional tool which helps clinicians with decision making.	Thank you for your comment which the committee has considered. The committee concerns about the diagnostic accuracy of the automated devices and use by staff with less expertise in assessing people for PAD are discussed in section 3.5 of the DGD.
5	Web comment - Livewell	committee-discussion The impact of automated devices on the time taken for ABPI assessment is uncertain 3.8. Selected text	ABPI assessments used as a tool to help support clinical decision making. Therefore, automated ABPIs should either confirm or challenge clinical decision making as part of a full holistic assessment which will ultimately inform the clinical decision. They can work as a screening tool within our community services, to eliminate PAD as part of an assessment by highly trained clinicians for patients who are asymptomatic with no arterial signs or symptoms. If our clinicians have concerns regarding arterial signs and symptoms, they would generally use a manual ABPI to gather more information due to the known risk of failure using automated machines in this cohort of patients.	Thank you for your comments which the committee has considered. The committee had concerns about the diagnostic accuracy of the automated devices and the risk of missing people with PAD are discussed in section 3.5 of the DGD. A clinical expert advised that if technical failure occurred this increased assessment time in their experience (see section 3.8 of the DGD).

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		"They also noted that technical failure of the automated devices could mean manual Doppler would then need to be done, increasing the length of the overall assessment."	Furthermore, failure of the automated machine may waste 15 minutes, but could also save the additional 45 minutes required to undertake a manual ABPI on all patients.	
8	Huntleigh Healthcare	1.1	We feel that the wording of the recommendation 1.1 that the device should only be used for research purposes is too strong a comment and not fully justified. Automated devices such as the Dopplex Ability when used in accordance with the instructions for use, we feel, can be used safely and very effectively exclude arterial disease. We acknowledge that false negatives are possible in certain patient groups but would point to research that	Thank you for your comment which the committee has considered. The reasons for the recommendations are described in section 1 of the DGD. Committee members had concerns about the sensitivity of the automated devices and risk of missing arterial disease are

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			notes sensitivity of up to 98% when the numeric ABPI value is taken alongside either Pulse Volume Recording, which a device such as the Dopplex Ability generates. We feel therefore that such device can and should be used clinically in order to provide an improved standard of care over current practice where it is acknowledged in research such as that by Guest et al that ABPIs are only carried out in 16% of cases where it is indicated.	described in section 3.5 of the DGD. No studies were found which reported diagnostic accuracy data in people with leg ulcers. The committee concluded that the diagnostic accuracy data could not be generalised to a leg ulcer population and therefore there is considerable uncertainty about the diagnostic accuracy of the automated devices in this population (see section 3.4 of the DGD). The committee discussed the risks of services that are already using the devices continuing to use them. They concluded that they could continue to be used where already in use provided users are aware of the limitations and risks of missing PAD and that data is collected to show the impact of using the automated devices (see section 3.10 of the DGD). The recommendations in section 1.2 of the DGD have been updated to reflect this.

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2	Livewell	3.3	Another consideration is the training requirement for manual ABPI assessments. The manual ABPI is seen as a more specialist skill. It would be challenging to undertake this additional training for all community staff currently undertaking automated ABPI assessments, as well as keep on top of competence. A manual ABPI is only as reliable and effective as the practitioner undertaking the assessment and therefore could be as much at risk of inaccuracies as the automated ABPI. This also limits the skill mix of staff who complete these assessments as the more specialist manual ABPI is currently completed by senior registered staff.	Thank you for your comment which the committee has considered. Section 1 of the DGD has been updated to clarify that where automated devices have already been implemented, they can continue to be used but centres must contribute to data collection. They should also be aware of the limitations of the evidence and ensure there is sufficient expertise to minimise any risks. Committee's concerns about the diagnostic accuracy of the devices and use of the devices by staff with less expertise in assessing PAD are discussed in section 3.5 of the DGD.
6	Web comment - Livewell	committee-discussion Automated devices are unlikely to be	By assessing patients more quickly and providing therapeutic compression earlier in patients with venous disease, there is existing evidence that patients will heal more quickly. Using automated ABPI assessment takes approximately half the time it does for a manual assessment in our	Thank you for your comment which the committee has considered. The EAG did not identify any published evidence demonstrating this magnitude of time savings with automated devices (see section 3.8 of the DGD). Various scenarios

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		cost effective unless they reduce time to treatment 3.9	experience. Our community services are allocated time for automated ABPI (30mins) or manual ABPI (60mins). This means that twice as many automated ABPI assessments can be performed in the same time period. Patients receive their full assessment more quickly, thereby could start strong compression earlier, leading to increased healing and increased ulcer-free days. Furthermore, there is a training cost associated with developing the skills required to undertake a manual ABPI assessment, as well as the skill mixed required to undertake the reassessment. We regularly train Band 4 practitioners to undertake routine re-assessments using an automated ABPI, but these B4s do not have the required skills to undertake a manual ABPI assessment.	were explored in the EAGs economic model to explore this uncertainty. No evidence was identified showing the impact of the automated devices on time to treatment or on health outcomes. The committee therefore concluded that the impact of the automated devices on these outcomes was uncertain (see sections 3.6 to 3.8). The recommendations in section 1.2 of the DGD have been updated following discussions during the committee meeting about continued use of the devices where they have already been implemented. The committee recommends that centres can continue to use the automated devices but that data must be collected by centres already using the devices to support a future assessment. It would be helpful if centres could collect data on how using the automated devices impact on the time

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				of the assessment, time to treatment and clinical outcomes.
3	Web comment - Livewell	committee-discussion The impact of automated devices on the time taken for ABPI assessment is uncertain 3.8	As per the NWCSP implementation site activities, the recommended allocated time for a "first assessment" to be performed is a 90 minute appointment or visit, within 2 weeks of presentation. This would be extremely challenging to undertake a full holistic assessment of bilateral leg ulceration including a manual ABPI, which would take up the majority of the 90minutes. We believe that the majority of Leg ulcer services will be working with 90 minute first assessment slots, meaning that a change to manual ABPIs would have a significant and detrimental effect on these services nationally, increasing wait times and making the 2 week assessment time frame extremely challenging to achieve. Furthermore, it could mean that other factors, such as psychosocial and environmental factors, are not explored due to clinicians running out of time, thereby having a negative effect on holistic care planning.	Thank you for your comment which the committee has considered. As described in section 3.2 of the DGD, clinical experts said that waiting lists for ABPI assessment vary across the country. The EAG did not identify any evidence demonstrating that automated devices substantially affected the time of the ABPI assessment (see section 3.8 of the DGD). No evidence was identified that explored the impact of automated devices on health outcomes (see section 3.6 of the DGD). Section 1 of the DGD has been updated to clarify that where automated devices have already been implemented they can continue to be used but centres must contribute to data collection. They should also be aware of the limitations of the

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				evidence and ensure there is sufficient expertise to minimise any risks.
4	Web comment - Livewell	committee-discussion The impact of automated devices on the time taken for ABPI assessment is uncertain 3.8 Selected text "a few minutes faster than manual assessment"	Our community clinics would usually allocate 30minutes to undertake an Automated ABPI assessment, compared to 60 mins to undertake this manually, effectively doubling the time required.	Thank you for your comment which the committee has considered. The EAG did not identify any published evidence demonstrating this magnitude of time savings with automated devices (see section 3.8 of the DGD). Various scenarios were explored in the EAGs economic model to explore this uncertainty. The economic model incorporated reduced rest time, testing time and interpretation time for automated devices compared with manual. The recommendation in section 1.2 has been updated to clarify that where the devices are already in use they can continue to be used but that centres should collect data to demonstrate the impact of using the automated devices.

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				Recommendations on further research can be found in section 1.3 of the DGD.
7	Web comment - Livewell	committee-discussion Automated devices are unlikely to be cost effective unless they reduce time to treatment 3.9	As per NWCSP recommendations, assessments should be undertaken within 2 weeks of presentation. Automated ABPI allows for a shorter appointment or visit time and therefore services are more likely to achieve 2 week assessment timeframe, thereby meaning patients access treatment earlier	Thank you for your comment which the committee has considered. The EAG did not identify any evidence assessing the impact of automated ABPI assessment on time to treatment or health outcomes (see sections 3.6 and 3.7 of the DGD). Evidence on the time of assessment with automated vs manual ABPI was limited and therefore the committee concluded the amount of time saved and the impact of this is uncertain (see section 3.8 of the DGD).
9	Huntleigh Healthcare	1.2	We question the finding that Automated devices do not save time. Given that automated devices do not require resting time we do not understand how they do not save time. We understand that it may be necessary, in certain patient groups to carry out a subsequent doppler assessment but given the automated system can be used during the “resting” time prior to doppler this would not effectively increase the overall time taken to carry out the	Thank you for your comment which the committee has considered. The committee concluded that the evidence suggests that automated devices do reduce the time taken for ABPI assessment but that the amount of time saved and impact of this are uncertain

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			assessment. Additionally such device allow a greater number of staff to be utilised and a greater number of assessments to be carried out. Therefore reducing overall the time to screening and the screening time.	because of limited evidence. A clinical expert advised during the committee that in their experience a technical failure of an automated device did increase the length of the assessment (see section 3.8 of the DGD). Committees concerns about staff with less expertise in assessing PAD using the automated devices are detailed in section 3.5 of the DGD. No evidence was identified showing the impact of the automated devices on time to treatment or health outcomes (see section 3.6 and 3.7).
10	Huntleigh Healthcare	3.8	Following on from the comment above - Even in the event of a technical failure of an automated machine. The overall length of the assessment would not be increased as the patient would have been effectively resting during the failed automated device assessment and therefore no additional time would be taken, over a doppler assessment alone. This would also be true for where additional	Thank you for your comment which the committee has considered. As described in section 3.8 of the DGD limited evidence was identified on the impact of the automated devices on the time of the assessment. As noted, a

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			screening is indicated by either an elevated (>1.3) ABPI or abnormal PVR waveforms.	clinical expert with experience of using an automated device found that technical failure did result in a longer assessment time in their experience. The modelling conducted by the EAG assumed people did not require further referral following technical failure of the device and costs associated with technical failure were minimal in the economic model.

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11	Huntleigh Healthcare	Table 1	Where is this cost per unit figure derived from as the Dopplex Ability List price in the UK is only £2,749	Thank you for your comment which the committee has considered. The EAG confirms that the list price of £2,749 was applied in the economic model. Additional costs of software, additional cuffs and other fixed costs were added based on details provided by the companies or available from other product documentation. The DGD has now been updated in section 2.7 to include this information.
12	Microlife Health Management Ltd	Summary of the characteristics of the devices considered for this appraisal	This puts the whole costing of the WBP devices at a severe disadvantage and therefore needs addressing and recalculating. The time along with the other devices is disproportionate. We have stated the time for the whole procedure including placing the cuffs. Based on our competitors comments our device takes the same amount of time I, E 1 Minute to perform an ABPI Measurement	Thank you for your comment which the committee has considered. Test times for the base case cost-effectiveness analysis were obtained from the systematic literature review where information on timing was available. Due to the limited data available the EAG conducted additional scenario analyses where the test times provided by the companies were used

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				(see scenario 3, table 21 in the diagnostic assessment report). The choice of values (literature review or company provided) does not influence the conclusions of the cost-effectiveness analysis.
13	Microlife Health Management Ltd	Patient Resting time	According to all guidelines and clinical studies at least 5 minutes resting time is needed as you cannot do anything about gravity.	Thank you for your comment which the committee has considered. Details of rest times included in the cost calculations are provided in table 20 in the diagnostics assessment report. Rest times were obtained from the literature review and additional scenario analyses were conducted using information provided by the companies. The choice of values (literature review or company provided) does not influence the conclusions of the cost-effectiveness analysis.
14	Microlife Health Management Ltd	Time of ABPI	It's reported that the WBP device took 14.4mins compared to the MESI 10.7mins and the doppler 12.1mins because the added time was due to the WBP device identifying the arm with the highest reading – this is as you are all aware	Thank you for your comment which the committee has considered. Times relating to the length of assessment with automated and manual

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			according to the guidelines. The MESI device just guesses the arm with the highest reading which is against all clinical procedures and therefore to obtain a comparison of both the MESI device and manual doppler at least 5 minutes must be added to both these procedures. Under these circumstances the MESSI would take 15.7min and the Manual Doppler 17.1min.	devices were obtained from the literature review and additional scenario analyses were conducted using information provided by the companies. The choice of values (literature review or company provided) does not influence the conclusions of the cost-effectiveness analysis.
15a	Microlife Health Management Ltd	Test cost calculations	WBP ABI price includes everything to perform tests on 90% of the population. 2 x M Cuffs (22-32cm), 2 x L Cuffs (32-42) & M Ankle Cuff. **£1,695** WBP Vascular price includes everything to perform tests on 90% of the population. 2 x M Cuffs (22-32cm), 2 x L Cuffs (32-42) & M Ankle Cuff. **£1,995**	Thank you for your comment which the committee has considered. The EAG confirms that these prices have been used in the economic model.
15b	Microlife Health Management Ltd	Additional Cuffs	£250 is quoted to complete a cuff set – this is somewhat miss leading as these are additional and includes Cuffs for extra patient groups which other devices are not capable of measuring. 3 years and upwards 2 x S Cuffs (14-22) £80 Obese Cuffs 2 x L-XL Cuffs (32-52cm) £100 L Ankle Cuff £70	Thank you for your comment which the committee has considered. The EAG confirms that the costs of additional cuffs have been included for all devices where applicable and these prices have been used in the economic model.
16	Microlife Health Management Ltd	Software	Our device is supplied with free software https://www.microlife.uk.com/support/watchbp-office	Thank you for your comment which the committee has considered. The EAG confirms that no cost of software was applied for this device in the economic model.

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17	Microlife Health Management Ltd	Other fixed costs	Not sure where this £200 comes from and should be removed	Thank you for your comment which the committee has considered. The EAG clarified that this relates to the cost of a roll stand which was provided by the company. Removing this cost would reduce the cost per test by £0.01 and therefore has no impact on the conclusions of the cost-effectiveness analysis.
18	Microlife Health Management Ltd	Total fixed cost	This should be WBP ABI £1,695 (with 5 cuffs to perform 90% of all procedures) £1,945 (including additional cuffs for remaining 10% of patients) WBP Vascular £1,995 & £2,245 respectively	Thank you for your comment which the committee has considered. The EAG confirms that these prices have been used in the economic model.
19	Microlife Health Management Ltd	Number of Cuffs	10 cuffs in Total 2 x S Cuff (14-22cm) 2 x M Cuff (22-32cm) 2 x L Cuff (32-42cm) 2 x L-XL Cuff (32-52cm) 1 x Ankle ***1 x L Ankle***	Thank you for your comment which the committee has considered.
20	Microlife Health Management Ltd	Replacement Cuff Cost	Average price for all cuffs and sizes £55 standard sizes £40	Thank you for your comment which the committee has considered. The EAG confirms that the costs of additional cuffs are calculated as (2x£40)

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				+(2x£50) + (1x£70) based on company provided information. When allocated on a cost per test basis, the impact on overall test cost is minimal. This therefore has no impact on the conclusions of the cost-effectiveness analysis.
21	Microlife Health Management Ltd	Device cost per test	This needs to be re-calculated based on above assumptions	Thank you for your comment which the committee has considered. The EAG confirms that the cost calculations are consistent with the information provided by the company here and during the assessment.
22	Microlife Health Management Ltd	Re-test cost per test	These need to be recalculated based on all comments – especially based on comment 1 page 6 where the time has been vastly disproportional	Thank you for your comment which the committee has considered. The EAG confirms that the cost calculations are consistent with the information provided by the company here and during the assessment.
23	Microlife Health Management Ltd	Total cost per test	These need to be recalculated based on all comments - especially based on comment 1 page 6 where the time has been vastly disproportional all further tables 21, 22, 25 & 26 to be re-evaluated and addressed.	Thank you for your comment which the committee has considered. The EAG confirms that the cost calculations are consistent with the information provided

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				by the company here and during the assessment.