NICE National Institute for Health and Care Excellence

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

Diagnostics Assessment Report (DAR) - Comments

Stakeholder	Comment no.	Page no.	Section no.	Comment	EAG Response
National Wound Care Strategy Programme (NWCSP)	1	iv	Background	"*Leg ulcers are long-lasting wounds, usually treated by compression therapy. Compression therapy is not suitable for people with PAD, as it can affect the arterial blood supply.* " Only leg ulcers due to venous disease without significant arterial disease should be treated with compression. Suggest rewording as follows: "*Leg ulcers are long-lasting wounds, usually due to venous insufficiency, PAD or a mixture of both. Compression therapy is the most appropriate therapy for ulcers due to venous insufficiency but is not suitable for people with PAD, as it can restrict the arterial blood supply"*	We agree that the suggestion improves clarity but do not consider this a factual inaccuracy.
National Wound Care Strategy Programme (NWCSP)	2	iv	Background	"*However, this method can be uncomfortable for people with leg ulcers and automated devices have been proposed as a more acceptable alternative*" The more usual argument in favour of automated devices is that they are quicker to use in practice (as in the plain language summary) – so might be worth mentioning in the abstract? Suggest rewording as follows: *"However, it is proposed that automated devices may be quicker and more comfortable for people with leg ulcers and so provide a more acceptable alternative"* The BP cuff still inflates regardless of the method used, so not sure the pain rationale is the best example, at least not on it's own.	We agree that the suggestion improves clarity but does not consider this a factual inaccuracy.
National Wound Care Strategy Programme (NWCSP)	3	xiv	Scientific background Summary	"*Leg ulcers are wounds on the lower leg (below the knee) or foot that takes time to heal*" This phrasing isn't quite correct. Foot ulcers are wounds on the foot (occurring below the ankle/malleolus). Both wounds occur on the	Text has been amended as suggested.

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				"lower limb", but they are different and managed differently in practice. See National Wound Care Strategy Programme Lower Limb Recommendations for Clinical Care https://www.ahsnnetwork.com/wp-content/uploads/2020/11/Lower-Limb-Recommendations-20Nov20.pdf Suggest rewording as follows: *"Leg ulcers are defined as wounds that occur below the knee and either on or above the ankle (malleolus).* If, however, this study is also intended to cover foot ulcers, suggest rewording as follows: *"Leg ulcers are defined as wounds that occur below the knee and either on or above the ankle (malleolus). Foot ulcers are wounds on the foot (occurring below the ankle/malleolus).*	
National Wound Care Strategy Programme (NWCSP)	4	xv	Methods Clinical effectiveness	"*This included delayed venous ulcer healing due to false positive test results (indicating PAD, when ulcer was venous)*" An ABPI cannot diagnose venous insufficiency, only the level of arterial blood supply. Suggest rewording as follows: "*This included delayed venous ulcer healing due to false positive test results (indicating significant PAD, when there was no significant PAD)*"	We appreciate the clarification in wording. However, the text is correct in the context of how the leg ulcer pathway was modelled, where the causes of a leg ulcer were modelled to be either arterial, venous, or mixed aetiology. We do not consider this to be a factual inaccuracy.
National Wound Care Strategy Programme (NWCSP)	5	xvi	Methods Clinical effectiveness	"*The decision to structure the mixed Markov model similarly to the arterial only model was based on discussion with clinical experts who explained that, in clinical practice, the arterial component of disease is likely to take priority in the patient's care pathway."* This would benefit from a more detailed explanation. Suggest rewording as follows: *The decision to structure the mixed Markov model similarly to the arterial only model was based on discussion with clinical experts*	We accept that the revised wording may improve clarity, but the description as provided accurately reflects how and why we have modelled the disease pathway in the way we have. We do not consider this to be a factual inaccuracy.

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				who explained that, in clinical practice, managing arterial insufficiency was likely to take precedence over managing venous insufficiency, due to the greater clinical risks of unmanaged arterial disease.	
National Wound Care Strategy Programme (NWCSP)	6	xvi	Methods Clinical effectiveness	"*Costs of treating arterial disease, including endovascular and bypass procedures as well as follow up nursing care*" Endovenous procedures treat veins, not arteries, so it is not appropriate to group them together under costs of treating arterial disease. It is not clear whether the costs that were explored were only relevant to venous interventions or for both venous and arterial interventions.	Please note that our text refers to "endovascular" procedures, not "endovenous" procedures. By "endovascular" we refer to angioplasty and stenting, which are treatment options for the treatment of PAD and as such are included in our economic model. We confirm that these costs were not applied to the venous ulcer arm of the economic model. We do not consider this to be a factual inaccuracy.
National Wound Care Strategy Programme (NWCSP)	7	xix	Discussion	"*It is unclear whether automated tests could achieve tangible benefits in terms of a reduced time to referral for compression therapy in patients with venous disease*" Current recommendations advise that in the absence of "red flag" symptoms, mild graduated compression can be applied for people with leg wounds, without a doppler assessment (by people with the right capability/skill). The current recommendations are that people receive strong compression therapy following a comprehensive assessment, which includes vascular assessment and ABPI. The current phrasing implies there needs to be a 'referral' and ABPI before any compression can be applied. Suggest rewording as follows: *It is unclear whether automated tests could achieve tangible benefits in terms of a reduced time to compression therapy in patients with venous disease*"	We agree that the suggested wording is clearer, and it also more accurately reflects the economic modelling. We have amended the text on page xix as suggested.
National Wound Care Strategy Programme (NWCSP)	8	2	Chapter 2	See comment 3	Text has been amended as described

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National Wound Care Strategy Programme (NWCSP)	9	2	Chapter 2	*However, using compression to treat ulcers may cause damage by impairing the arterial supply to the ulcerated leg* This is only true if compression is applied to limbs with significant arterial disease Suggest rewording as follows: *However, using compression to treat leg ulcers where there is significant PAD may cause damage by impairing the arterial supply to the ulcerated leg*	We agree that the suggestion improves clarity but do not consider this a factual inaccuracy.
National Wound Care Strategy Programme (NWCSP)	10	4	2.4	*Measurement of the ankle brachial pressure index (ABPI) is widely used in clinical practice, to help identify people with PAD who should not receive compression therapy.* This implies that the assessment is only about the ABPI result. Suggest rewording as follows: *Measurement of the ankle brachial pressure index (ABPI) is widely used in clinical practice, as part of holistic assessment to diagnose the underlying cause of ulceration, to identify those with PAD who should not receive compression therapy.*	We agree that the suggestion improves clarity but do not consider this a factual inaccuracy.
National Wound Care Strategy Programme (NWCSP)	11	11	Care Pathways	"*Strong multi-component compression bandaging should be offered to people with chronic ankle/leg oedema not reduced by elevation, abnormal limb shape, copious exudate or very fragile skin*". The evidence as to what type of compression therapy is most effective is currently unclear and different types of patients may benefit from different types of compression systems. This sentence is not essential to this section so suggest it is deleted.	We agree that the suggestion improves clarity but do not consider this a factual inaccuracy.
National Wound Care Strategy Programme (NWCSP)	12	11	Care pathways	*People with leg ulcers with signs of arterial disease should be referred for vascular surgical/endovenous interventions and advice on compression and NICE clinical guideline CG147 on diagnosis and management of peripheral arterial disease should be followed.23 Whilst awaiting vascular expertise, mild graduated compression is* *appropriate in oedematous legs with no signs of arterial insufficiency*	We agree that the suggestion improves clarity but do not consider this a factual inaccuracy.

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				This advice is currently being updated in the NWCSP Lower Limb Recommendations as it is confusing. Suggest rewording as follows: *People with leg ulcers with suspected arterial disease should be referred for vascular surgical review. While awaiting vascular expertise, mild graduated compression is appropriate in oedematous legs with no clinical signs of arterial insufficiency.*	
National Wound Care Strategy Programme (NWCSP)	13	11	Care pathways	*Those with ABPI of 0.5-0.8 should receive reduced compression of 15-25mmHG* It is not clear where this recommendation comes from? Suggest rewording as follows and adding a reference: *Those with suspected arterial disease but with no clinical sign of arterial insufficiency should receive mild graduated compression.*	This statement is correctly referenced (reference 30, The Lymphoedema Framework)
National Wound Care Strategy Programme (NWCSP)	14	12	Care pathways	*Documentation by way of wound photography at least every 4 weeks is recommended* Wound photography is part of it, but the wound will also need to be measured and reassessed. Suggest rewording as follows: *Documentation of wound healing, that includes measurement and digital imaging at least every 4 weeks, is recommended*	This statement is correctly referenced (reference 30, The Lymphoedema Framework)
National Wound Care Strategy Programme (NWCSP)	15	13	Prevention of recurrence	*The SIGN Guideline 120 for management of chronic venous leg ulcers indicated that compression of at least 40mmHg should be applied. The guideline was withdrawn in August 2020 and is currently being refreshed."* SIGN actually recommended "Patients should be offered the strongest compression that maintains patient concordance." not 40mm hg.	Thank you for pointing this out. The text has been amended accordingly.
National Wound Care Strategy	16	98	Table 17	*Reduced time to applying compression to a venous ulcer due to automated tests*	We agree that in the economic model, using 'strong compression' instead of 'compression' would improve

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Programme (NWCSP)				Suggest rewording as follows*:* *Reduced time to applying strong compression to a venous ulcer due to automated tests*	clarity; however, we do not consider this to be a factual inaccuracy.
National Wound Care Strategy Programme (NWCSP)	17	119	venous	*Patients with a healed venous ulcer are assumed to require monitoring and preventative treatment for the first 2 years post-healing and none thereafter. We accept that this may be conservative, however under limited resources within the NHS it is not reasonable that healed patients would be monitored indefinitely.* We would challenge this assumption. Leg ulceration is a symptom of a chronic long-term condition that unless the underlying condition can be corrected, requires life-long management (as for asthma, diabetes and other long term conditions). What might limit the length of time is that many with leg ulcers are elderly and so the length of follow up will be limited by life span.	We thank NWCSP for raising this point. The objective of our economic modelling is to focus on the costs and benefits of treating and managing leg ulcers. This assumption is applied to the proportion of the cohort who have a healed venous ulcer, and who have **not** subsequently had a venous ulcer recurrence for a period of two years. These people can still incur healthcare costs if their ulcer returns. We appreciate that there is likely to be heterogeneity in clinical practice and that people may be monitored for recurrent venous leg ulcers through routine follow-ups of their long-term condition. We have, therefore, considered the impact on cost-effectiveness of assuming a six-monthly follow-up appointment for the remainder of a patient's life. This assumption increases the total costs for all test strategy arms but does not change incremental costs or impact on the cost-effectiveness results. Our view is that the description provided in the DAR accurately reflects the economic modelling assumptions and is not a factual inaccuracy.
National Wound Care Strategy Programme (NWCSP)	18	130	Overview of key assumptions	*It is assumed that primary amputation is rare, and that limb salvage is attempted using bypass and / or revascularization wherever possible, though it is more likely to be required for an inappropriately compressed arterial ulcer* Agree that primary amputation is rare. Amputation for an inappropriately compressed arterial ulcer is thought to be very, very rare.	We are grateful for this clarification and confirm that the noted assumptions are consistent with the economic modelling parameters.

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Ultrasound Technologies Ltd	19			The study has highlighted that none of the automated devices can actually give a true ABPI or even a true positive blood pressure. For many of the client/patient groups in the study the automatic device due to their on going arterial or venous disease clearly cannot be used effectively without giving additional problems . None of the devices studied in the report could automatically identify waveform morphology and label the displayed waveform correctly as tri phasic , bi phasic or monophonic and therefore would need an experienced practitioner to label manually. All automated devices gave false information of time requirements to test. As many of the automated devices in this study use simultaneously inflation cuffs, this could be a danger to patients with poor cerebral autoregulation or cardiac anomalies that old lead to undue peripheral pressure that may result in cardiac anomalies as many patients with PAD have been found to have some level of central vascular disease. The Bluedop Vascular Expert is not a fully automated device and would need an experienced practitioner to understand the results. The study has highlighted that none of the automated devices can actually measure venous flow, venous reflux or tissue perfusion	We thank the stakeholder for these comments.
Axelife	20	5	2,4 Table 1	Missing pOpmetre a medical device IIa certificated for measuring arterial stiffness, central blood pressure and IPS – PAS detection. The device is connected to the patient through photodiode sensors (photoplethysmographic) in order measure the difference in transit times between the toe and the finger. The sensors deliver the proper signals to the system. It transmits the image of these formatted signals, along with any other useful data, through a USB port in a PC, enabling the information to be displayed and processed.	The pOpmetre device was not included in the NICE scope for this assessment and, therefore, has not been included in this DAR.

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				The operation is simple while making it possible to obtain a reproducible measurement in less than 2 minutes. An analysis report is provided once obtaining the signal. 2 clinical studies habe been published to validate pOpmetre on PAD Amrani, S., Eveilleau, K., Fassbender, V., Obeid, H., Abi-Nasr, I., Giordana, P., ... & Leftheriotis, G. (2022). Assessment of the systolic rise time by photoplethysmography in peripheral arterial diseases: a comparative study with ultrasound Doppler. *European Heart Journal Open*, *2*(3), oeac032. https://pubmed.ncbi.nlm.nih.gov/35919340/ Obeid, H., Eveilleau, K., Hallab, M., Abi-Nasr, I., & Leftheriotis, G. (2022). Assessment of the PPG up-stroke time to predict peripheral lower limb arterial occlusive disease (PAOD): Application to the pOpmetre®. *Archives of Cardiovascular Diseases Supplements*, *14*(1), 101. https://www.sciencedirect.com/science/article/pii/S1878648021005917 **Public price for pOpmetre is 6500 euros meaning about 5660 pounds** This makes popmeter the best alternative to Doppler to detect people suspected of PAD in clinical routine and to avoid the patient being detected too late for his pathology. The device also allows by measuring arterial stiffness and central aortic pressure to improve the prevention and classification of cardiovascular diseases It is used in 350 establishments in France, both in hospitals and in the city. It is non-invasive, non-operator dependent, quick and easy to use.	

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				It can therefore be used in clinical practice in different centers and serve to detect and classify patients at risk of PAD and cardiovascular events. The output data are: - pulse wave velocity, -IPS - central aortic pressure	
MESI	21		General comment	The review focuses on data from studies available online, which is great and necessary, but we feel it does not focus on the holistic approach when it comes to leg ulcer healing, where ABPI measurement is just one of the first steps.	Please note that the scope of this assessment is to assess the diagnostic accuracy of automated test devices, and as such a direct assessment of the holistic clinical approach, which may vary in clinical practice, is beyond the scope of this assessment. However, we would like to clarify that many of the economic model scenarios consider the impact that a holistic patient assessment may have on the consequences of inaccurate test results. For example, in our moderate base case economic modelling scenario we assume that, for people with purely arterial disease, a false negative test result would be identified through a holistic patient assessment. The impact of a holistic patient assessment on the care pathways and on cost-effectiveness are varied extensively in scenario analyses.
MESI	22		General comment	In the research, there is no evidence on reports by or conversations with existing users of the technology on their experience, for which the references were provided in the initial stages of the assessment.	Please note that the main objectives of this assessment were i) to assess current published evidence on the diagnostic performance and clinical utility of automated devices for measuring ABPI in people with leg ulcers; ii) to develop an economic model to assess the cost-effectiveness of the automated devices under investigation. We consulted the NICE clinical experts to gather information on the use of these devices in clinical practice.
MESI	23		General comment	Automated devices have certain drawbacks, and I am sure all manufacturers and other stakeholders are aware of that, but the main goal should always be that every patient that requires a measurement of ABI can receive it.	We thank the company for their comments. The cost-effectiveness analysis explores scenario analyses where automated devices providing an accurate test result could potentially reduce venous ulcer healing time where manual doppler testing is not available. An additional addendum to

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					the DAR explores a range of scenarios around healing time reductions that might be realisable and includes threshold analyses for each of the test devices. We would, however, caution that these time gains are highly uncertain, and it is unclear in what settings/scenarios there would be no access to manual doppler testing in the community. Our understanding is that it would be rare for patients to require referral to secondary care purely for manual doppler testing.
MESI	24	7	Patient resting and position for the test	MESI mTABLET ABI does not require resting before the measurement – the measurement in the three extremities is conduced simultaneously, the same as with MESI ABPI MD. In addition to the 3-cuff simultaneous measurement, the device first measures the pressures in both arms to determine the higher of the two, which makes it adhere to the guidelines 100%.	Please note that the MESI mTABLET ABI manual section 5.3 states "*it is recommended that the patient lies still for at least 5 minutes before starting the measurement process*" [Adding The Patient; Performing Abi Measurement - MESI mTABLET ABI Instructions For Use Manual [Page 25] | ManualsLib]
MESI	25		9, 98	On P9, it is written (direct citation): *"People are required to lie down and remain still before and during the test. The procedure may take between 30 min to 1 hour to be completed according to the expertise of the operator and may involve two operators."*, while P98 mentions that automated measurements *"would not consistently shorten appointments"*. If the automated ABPI measurements do not require resting periods because the measurement is conducted simultaneously, this shortens the evaluation tremendously.	The economic model base case assumes that automated tests do reduce healthcare professional times and are therefore less costly to deliver, compared to manual (See table 20 of the DAR). The base case uses times obtained from the literature, with a scenario (number 3, Table 21) providing test costs using company-provided test times. The comment on page 98 is raised to describe the potential for uncertainty regarding whether these reductions in test completion times would translate to reductions in overall appointment times. The reason we raise this uncertainty is that because, during the rest period for manual testing, the healthcare professional may be conducting other tasks involved in the assessment of the patient's symptoms (e.g. consultation). These tasks may also need to be undertaken for patients receiving automated tests, in which case the modelled reduction in test timing may not always translate to the same magnitude of reduction in appointment time. This is not a factual inaccuracy, and an erratum is not provided.

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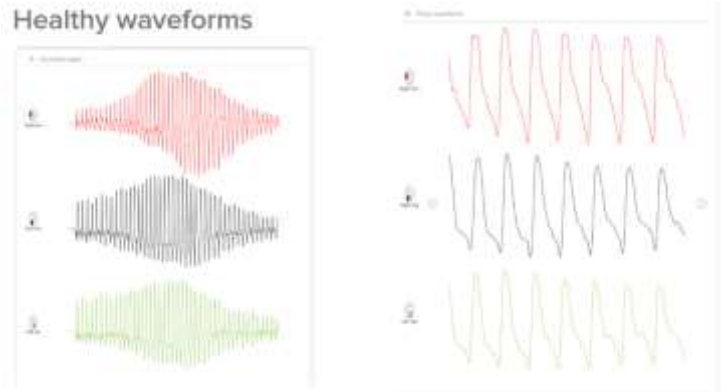
MESI	26		54	P54: The report states that there is a (direct citation) *"systematic tendency for the automated device to overestimate ABPI values with larger differences observed in the lower range of ABPI values"*. In such cases, MESI ABPI MD and MESI mTABLET ABI have a significant advantage: the presence of an entire pulse waveform and oscillation graph for the entirety of the deflation portion. From the oscillation graph, the clinician can determine whether the arteries were elastic (i.e., responded to being briefly compressed) or not. The pulse waveforms provide an assessment of the presence or absence of clearly pronounced pulses with clear dicrotic notch:  *Figure 1: Healthy waveforms obtained with MESI mTABLET ABI measurement*	Please note that we have not identified any published study assessing the performance of MESI mTABLET ABI. The included studies assessing the performance of MESI ABPI MD as well as other relevant devices reported a tendency for the automated device to overestimate ABPI values.

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				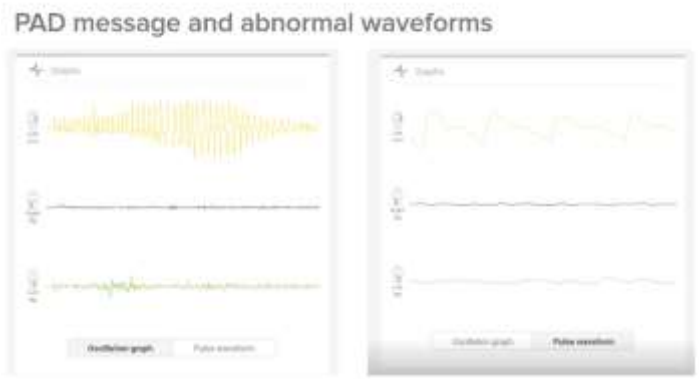 *Figure 2: Healthy waveforms obtained with MESI mTABLET ABI measurement* Analysing the pulse waveforms and oscillation graphs helps with the aforementioned holistic assessment. Additionally, MESI mTABLET has the possibility to add an automated Toe-Brachial Index measurement which also takes about a minute. This covers patients with falsely elevated ABI due to medial arterial calcification (diabetic patients, CKD patients), who are even more likely to be affected by lower limb ulcers.	
MESI	27	56	Time of ABPI measurement using the automated device and the reference device	Manual doppler assessment time has not included the rest time – this is the crucial difference between the manual and the automated devices. The estimated time for the manual ABPI was 12.1 minutes, which does not include the necessary resting period.	Please note that resting time, measurement time and total testing time were not reported consistently across studies. It was also unclear whether the resting time was used as 'consultation time' in some cases. For the economic model, our base case analysis assumes a total test time of 26.92 minutes for manual doppler.
MESI	28	57		Referring to the statement "Zebari et al. reported 28 error codes produced by the MESI ABPI MD device in 306 legs, with 6/28 error codes being considered technical failures": the PAD message the device produces is not and should not be considered an error	Please note that we reported the exact information extracted from the published study by Zebari et al. [i.e. 28 error codes produced by the MESI ABPI MD device in 306 legs, with 6/28 error codes being considered technical

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				message, but an indicator of absence of adequate pulses/insufficient number of obtained oscillations.	failures] (see Appendix 5 of the EAG report). Moreover, even if the error codes are considered indicators of the absence of adequate pulses/insufficient number of oscillations instead of technical failures the consequences of these inadequate readings are the same (e.g., the need to repeat the test).
MESI	29	67		I kindly ask you to spell MESI with capital letters throughout the document, thank you!	We acknowledge the company's request and clarify that in all cases we intend to use "MESI", not "Mesi". The EAG does not consider this to be a factual inaccuracy, just a typographical error. The EAG considers it to be clear from the text which test we refer to throughout.
MESI	30	90		The document exposes the problem of longer waiting lines or, more specifically, inconsistencies in waiting times, inconsistent care. Potentially long period that elapses from the occurrence of wounds to healing is not specifically mentioned. However: currently, as the document is designed, it seems to be just focusing on the ABPI value as the sole determinant in successful compression therapy. The reality is different: the clinician must (or should) perform a holistic assessment as soon as possible, as the ulcers are far more likely to heal if assessed early-on. This is what all automated devices are working towards: simplifying the procedure, allowing for the measurement to be performed in a shorter period of time and on ALL patients requiring it. If we are only looking at the ABI value, without additional determinants (visual assessment and bilateral comparison of skin, state of the toenails, determination of risk factors, conversation with the patient), we are taking the clinical decision making completely away from the clinician. I am re-submitting two posters with the emphasis on the time-saving and inclusivity aspect fully highlighted:	We would like to clarify that the base case economic model analysis already incorporates time savings associated with conducting automated tests compared to manual doppler testing (see responses to comments 25 and 27 above. We have provided several additional scenarios as an addendum to the DAR exploring a range of possible (but uncertain) time savings with regard to venous ulcer healing that might be achievable in scenarios or settings where access to manual doppler testing is not available. We would refer the stakeholder to the additional addendum documentation provided for the DAR committee meeting addressing this point. The text within the DAR is factually accurate and an erratum is not required to address this point.

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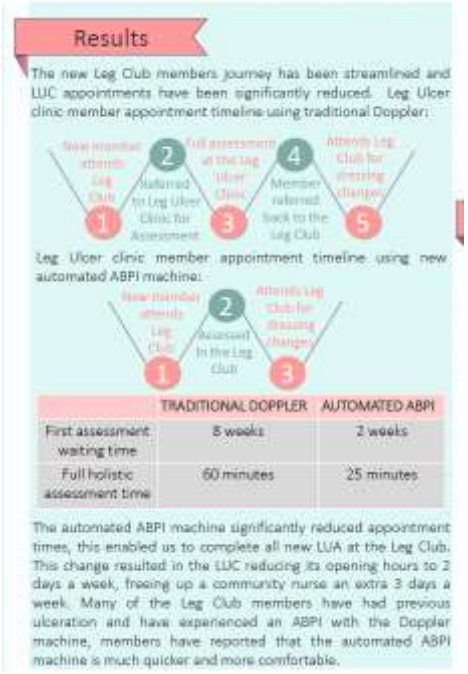
MESI	30 (comment continued)			 *Figure 3: New technology improves assessment in a busy Leg Club ® environment*	We have considered the information in terms of participants, intervention, comparator and outcomes (PICO) reported in the two posters submitted by MESI. Poster by **Kelly Buxey** [single author; unclear why the poster was created and where it was presented] • **Participants**: members of the Clacton-on-Sea Leg Club. No sample size or any information on the characteristic of the participants. The reasons for membership of the club are unclear. • **Intervention:** MESI ABPI MD. • **Comparator:** Manual Doppler. • **Outcomes:** First assessment waiting time, full holistic assessment time. • No details of what is included in these outcomes (e.g. resting time, consultation time, setting up software, measurement time) and on how many patients the outcomes were assessed. • No information on the expertise of the community nurses who carried out the assessment • No information on how many times the device produced inaccurate or unreadable results. Poster by a **Gill Dixon** [single author; unclear why the poster was created and where it was presented] • **Participants:** Unclear [community nursing setting]. No sample size or any information on the characteristic of the participants. The reason why patients were referred to the community nurse is not reported. • **Intervention:** MESI ABPI MD. • **Comparator:** Manual Doppler. • **Outcomes:** Difference in nursing time to take ABPI using automated device compared to manual Doppler; time from date of referral to ABPI measurement being taken.

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				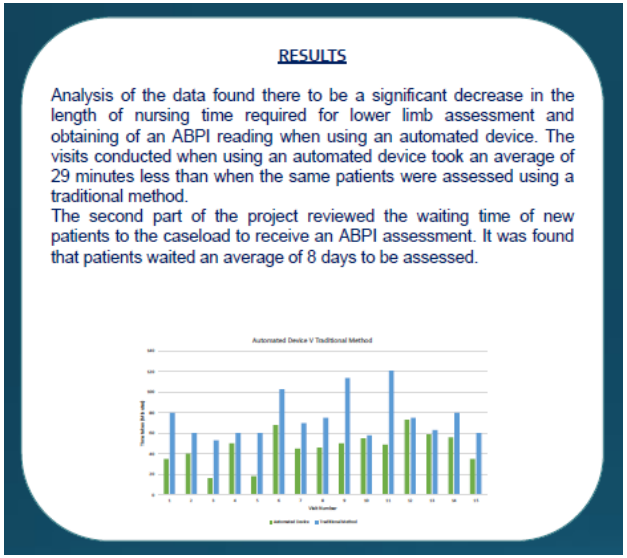 *Figure 4: Using Automated Innovation to Improve Practice in a Community Nursing Team*	• Unclear exactly what is included in the visit to take ABPI. • Unclear whether the visit also includes consultation time [and whether this was considered part of the resting time] for both devices. • No information on the expertise of the community nurses who carried out the assessment • No information on how many times the device produced inaccurate or unreadable results. • No further information on how the waiting time to receive a full leg assessment was assessed.
MESI	31	112	Price model	As MESI mTABLET ABI requires the same time for preparation ("rest") as MESI ABPI MD, the price model should be amended – from 5.00 to 2.00	The company provided information on MESI ABPI MD suggested that there was zero preparation or rest time required prior to conducting the MESI ABPI MD test. We considered this to be unreasonable and included a nominal 2-minute preparation time. Please also note that the MESI mTABLET ABI manual section 5.3 states "*it is recommended that the patient lies still for at least 5 minutes before starting the measurement process*". It is worth pointing out that a 3-minute difference in test times does not materially impact on the cost-effectiveness conclusions. The EAG does not consider this to be a factual inaccuracy.

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Comments on the economic model

Stakeholder	Issue	Description of problem	Description of proposed amendment	EAG Response
MESI	1	Page 112 describes Manual doppler costing £19.74. However, page 110 suggests “Some studies and “how to” guides suggest that two nurses may be required to complete the manual Doppler test, and the impact of this on costs is considered in scenario analyses.” because of proven inter-operator difference	The two-nurse bias should be noted in some way.	Please note that we explore the additional costs of requiring a second operator to conduct manual testing in scenario analyses only, and therefore there is no bias from two-nurse operators in the base case economic model. The EAG’s understanding is that in current UK practice it is unusual for two healthcare professionals to be required to conduct manual doppler testing. The EAG does not consider this to be a factual inaccuracy.