NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

DIAGNOSTICS ASSESSMENT PROGRAMME

Equality impact assessment – Guidance development

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

1. Have the potential equality issues identified during the scoping process been addressed by the Committee, and, if so, how?

Potential equality issues were discussed both in the scoping workshop 8 March 2022 and in the assessment subgroup meeting 23 March 2022.

The following were identified as potential equality issues relating to peripheral arterial disease and leg ulcers:

- The risk of peripheral arterial disease is greater in men, older people, people living in deprived areas and people from South Asian family background. People with diabetes also have an increased risk of peripheral arterial disease.

- Leg ulcers are common in people with sickle cell disease. Sickle cell disease is particularly common in people with African or Caribbean family background.

The following were identified as potential equality issues relating to the testing:

- Swelling of the leg, obesity or complex ulceration may make it difficult or painful to wear blood pressure cuffs. Some automated tests provide cuffless ankle pressure measurements and so might make the test more comfortable for these people. A patient expert noted that the automated devices may make measurement more comfortable for patients (see section 3.1 of the diagnostics consultation document). Clinical experts also highlighted that problems such as swelling may also impact on the diagnostic accuracy of automated devices. There was very limited evidence in people with leg ulcers and therefore the committee recommended that further studies assessing diagnostic accuracy of the devices in

people with leg ulcers should be undertaken (see section 3.4 and 4.1 of the diagnostics consultation document).

- People with leg ulcers who have back pain or other conditions in which laying on the back is painful, may find it difficult to lie flat for the length of time it may take to rest before and during a manual doppler test. If automated tests can make doing the test more comfortable or quicker, they may have particular benefits for this group. A patient expert highlighted that automated tests may be quicker and therefore more comfortable for people with leg ulcers (see section 3.1 of the diagnostics consultation document). The committee discussed the evidence on the time to undertake automated and manual ABPI assessment. They noted that although automated devices appear to reduce the time to undertake ABPI assessment, the amount of time saved and the impact of this on people with leg ulcers is uncertain (see section 3.8 of the diagnostics consultation document).

- The tests may not be suitable or work accurately for people who have had lymph nodes removed or damaged (and are at risk of lymphoedema), limb amputation or other conditions where blood pressure cannot be measured on both arms or legs.

- Similar to the manual doppler test used in current practice, the ABPI measured by the automated devices in the following people may look normal when in fact they have peripheral arterial disease: people with diabetes, rheumatoid arthritis, systemic vasculitis, atherosclerotic disease, advanced chronic renal failure or other conditions in which arterial calcification is common. Peripheral arterial disease could be detected in these groups using further information produced by doppler probes (doppler waveform). If automated devices do not use doppler technology, or produce an equivalent output to supplement ABPI, then performance in people with these conditions may be worse than use of a doppler probe (manual or automated). During the committee meeting, experts highlighted the importance of information provided by the doppler waveform to validate ABPI results for people with conditions such as diabetes (see section 3.5 of the diagnostics consultation document). It was noted that evidence around this population was limited and that diagnostic accuracy of the automated devices in people with diabetes was uncertain (see section 3.4 of the diagnostics consultation document). The committee recommended that the use of waveform or other similar outputs from the automated devices and the impact of this on clinical decision

making be considered when undertaking further research (see section 4.1 of the diagnostics consultation document).

2. Have any other potential equality issues been raised in the diagnostics assessment report, and, if so, how has the Committee addressed these?

No other potential equality issues were raised in the diagnostics assessment report.

3. Have any other potential equality issues been identified by the Committee, and, if so, how has the Committee addressed these?

A patient expert explained during the committee meeting that people with leg ulcers often have reduced mobility and therefore may find it difficult to travel to appointments. They highlighted that automated devices could be of benefit if they allowed for more assessments to be undertaken in the community (see section 3.1 of the diagnostics consultation document). The committee recommended that more consideration be given to where the devices may be used in practice when undertaking further research (see section 4.1 of the diagnostics consultation document).

4. Do the preliminary recommendations make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

No.

5. Is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?

No.

6. Are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 4 or 5, or otherwise fulfil NICE's obligations to promote equality?

Not applicable.

7. Have the Committee's considerations of equality issues been described in the diagnostics consultation document, and, if so, where?

The committee's considerations of the equality issues have been described in questions 1 and 3 of this document. The committee's research

recommendations are described in sections 1 and 4 of the diagnostics consultation document.

Approved by Associate Director (name): Rebecca Albrow

Date: 30/11/2022

Diagnostics guidance document

1. Have any additional potential equality issues been raised during the consultation, and, if so, how has the Committee addressed these?

No additional equality issues were raised during the consultation.

2. If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

The recommendation that the automated devices only be used in the context of research did not change after consultation. An additional recommendation (section 1.2 of the diagnostics guidance document) was made that the automated devices can continue to be used if they have already been purchased and are in use in the NHS. This was in response to comments that suggested they are being used in some areas and have helped to reduce assessment time. This may help to prevent introducing barriers to access where the automated devices have already been implemented. As noted in section 1 of this document there are people such as those who have had lymph nodes removed or damaged, limb amputation or other conditions where blood pressure cannot be measured on both arms or legs where the devices may not be suitable or work accurately. As noted in section 1.2 of the diagnostics guidance document, the committee highlighted that the devices can only continue to be used if people using them are aware of their limitations.

3. If the recommendations have changed after consultation, is there potential for the preliminary recommendations to have an adverse

impact on people with disabilities because of something that is a consequence of the disability?

The recommendation that the automated devices only be used in the context of research did not change after consultation. An additional recommendation was made that the automated devices can continue to be used if they have already been purchased and are in use in the NHS (section 1.2 of the diagnostics guidance document). This may help to prevent introducing barriers to access where the automated devices have already been implemented. As noted in section 1 of this document there are people such as those who have had lymph nodes removed or damaged, limb amputation or other conditions where blood pressure cannot be measured on both arms or legs where the devices may not be suitable or work accurately. As noted in section 1.2 of the diagnostics guidance document, the committee highlighted that the devices can only continue to be used if people using them are aware of their limitations.

4. If the recommendations have changed after consultation, are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?

No additional barriers or difficulties with access were identified in relation to the addition of recommendation 1.2.

5. Have the Committee's considerations of equality issues been described in the diagnostics guidance document, and, if so, where?

Difficulties in accessing ABPI assessment for those with mobility issues are discussed in section 3.1 of the DGD.

Issues around the diagnostic accuracy of the automated devices for people with conditions such as diabetes are discussed in section 3.4 and 3.5 of the DGD. They highlighted that it was important that outputs such as doppler waveform be used to validate ABPI results. The committee recommended that the use of waveform or other similar outputs from the automated devices and the impact of this on clinical decision making be considered when undertaking further research (see section 4.1 of the DGD).

Approved by Associate Director (name): Rebecca Albrow

Date: 06/03/2023