NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

VibraTip for testing vibration perception in the detection of diabetic peripheral neuropathy

1 Technology

1.1 Description of the technology

VibraTip (McCallan Medical) is a device resembling a small keyring fob that provides a near-silent vibration of consistent amplitude at a frequency similar to that of a calibrated tuning fork. It is intended for use when testing a person's vibration perception during routine checks for diabetic peripheral neuropathy (DPN) in people who have type 1 or type 2 diabetes.

The VibraTip probe is applied to the patient's foot twice: once while non-vibrating and once while vibrating; the patient is asked to indicate when they feel the vibration. If the vibration is not detected this may suggest the development of DPN and further investigation can be initiated. The VibraTip is intended as an alternative or replacement to the devices that are currently used in NHS clinical practice for testing foot sensory function such as the 10g monofilament (light touch/pressure sensation) and the calibrated tuning fork or biothesiometer (vibratory sensation). The device is designed to provide a consistent application compared with the variable vibration and cold touch of the tuning fork and to offer continuous operation over the battery life compared with the 10g monofilament which needs resting after every 10 full patient foot examinations.

1.2 Regulatory status

The VibraTip received a CE mark in March 2010 and is indicated to test for vibration perception in the foot during routine checks for DPN.

1.3 Claimed benefits

The benefits to patients claimed by the sponsor are:

- The ease and speed of the test together with the device's reliability mean earlier diagnosis of neuropathy leading to improved footcare and the prevention of ulcers and amputations.

The benefits to the healthcare system claimed by the sponsor are:

- Less user variability making the Vibratip test for DPN more consistent compared to a tuning fork test.
- The ease and speed of testing means little user training is required.
- Smaller size makes it more portable and accessible than comparators.
- Easily cleaned and tolerant to regular, routine cleaning facilitating compliance with infection control guidelines.

1.4 Relevant diseases and conditions

VibraTip is intended for use in testing vibration perception during routine checks for diabetic peripheral neuropathy in people who have type 1 or type 2 diabetes.

Diabetes affects an estimated 3.75 million people in the UK; of which it is thought that 850,000 are unaware that they have the condition. Around 60% of people with diabetes are susceptible to DPN and diabetes is the most common cause of peripheral neuropathy in the UK. The current prevalence rate of 7.4% for diabetes (diagnosed and undiagnosed) is likely to rise to 8.5% in 2020 and to 9.5% by 2030, driven by demographic changes and increasing obesity.

DPN is thought to result from high blood sugar levels causing nerve damage. Symptoms depend on the specific system affected, but include numbness, tingling and pain in the feet and hands, muscle weakness and foot ulcers.

Early diagnosis lowers the chance of developing serious complications, with studies showing a reduction or delay in nerve damage by meticulous blood sugar control.

1.5 Current management

NICE clinical guidelines 10 (currently being updated) and 15 (currently being updated) (for Type 2 and Type 1 diabetes, respectively) recommend a structured programme of regular (annual) foot surveillance, risk assessment and education by trained personnel, to raise awareness in patients. The annual foot examination includes a visual check, palpation of pulses and assessment of foot sensory nerve function. The sensory nerve function component of the annual foot check may include assessment of touch/pressure using a 10g monofilament or a test of vibration perception using either a biothesiometer or calibrated tuning fork. The 10g monofilament should not be used to test more than 10 patients in one session and should be rested for 24 hours thereafter.

Classification of risk (low, increased, high, ulcer present) in the annual check is on the basis of sensation, pulses, deformity, skin changes or previous ulcers. This may result in referral to a specialist foot protection team comprising podiatrists, orthotists and foot-care specialists. The assessment will typically result in increased foot checks every 3-6 months with a vascular assessment and an assessment of footwear. For patients at particularly high risk of ulcer formation, a foot examination may be undertaken every 1-3 months, incorporating an intensive foot-care education programme and the use of specialist footwear insoles and skin and nail care. Self-monitoring and self-inspection by patients is taught and encouraged.

2 Reasons for developing guidance on VibraTip for testing vibration perception in the detection of DPN

The Committee considered that VibraTip may offer benefits to patients and to the healthcare system, in respect of ease of use, consistency of stimulus and durability.

The Committee considered VibraTip may be helpful in detecting diabetic peripheral neuropathy in more patients.

3 Statement of the decision problem

	Draft scope issued by NICE	
Population	People (adults and children) with type 1 or 2 diabetes undergoing routine foot-care checks by health care workers in primary and secondary care settings	
Intervention	VibraTip	
Comparator(s)	The comparators are • a 10 g monofilament • a calibrated tuning fork • biothesiometer	
Outcomes	The outcome measures to consider include: • Sensitivity and specificity in assessment of vibration perception and/or light touch • Sensitivity and specificity in assessment of grade of neuropathy • Inter-rater agreement of assessment of grade of neuropathy • Accuracy of risk assessment in ulcer formation • Ulcer formation and amputation • Time taken for sensory testing • Quality of life • Device-related adverse events	
Cost analysis	The cost analysis will include both the 10 g monofilament and calibrated tuning fork as comparators. The use in both primary and secondary care settings should be considered Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	People with diabetes having routing annual checks in a primary care setting; people with diabetes having more frequent checks in a secondary care setting	
Special considerations, specifically related to equality issues	Diabetic neuropathy is more common with increasing age and males may develop DPN earlier than females, but neuropathic pain causes more morbidity in females than in males. More secondary complications from diabetic neuropathy have been shown to occur in people of Hispanic or African American family origin. People with diabetes are considered as disabled under the Equality Act 2010.	
	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No

	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No

4 Related NICE guidance

Published

- Foot care service for people with diabetes. NICE Commissioning Guide (2012). Available from http://www.nice.org.uk/usingguidance/commissioningguides/footcare/footcareservicediabetes.jsp Date for review: to be confirmed.
- Type 1 diabetes: Diagnosis and management of type 1 diabetes in children, young people and adults: NICE clinical guideline CG15 (2004, updated 2011). Available from: http://www.nice.org.uk/CG15 Date for review: 2015.
- Type 2 diabetes foot problems: Prevention and management of foot problems: NICE clinical guideline CG10 (2004). Available from: http://www.nice.org.uk/CG10 Date for review: 2011 – update currently underway.
- Diabetic foot problems: Inpatient management of diabetic foot problems: NICE clinical guideline CG119 (2011). Available from: http://www.nice.org.uk/guidance/CG119 Date for review: 2014.
- Diabetes in adults: Quality standard QS6 (2011). Available from: http://www.nice.org.uk/guidance/QS6. Date for review: 2011
- The percentage of patients with diabetes with a record of a foot examination and risk classification: 1) low risk (normal sensation, palpable pulses), 2) increased risk (neuropathy or absent pulses), 3) high risk (neuropathy or absent pulses plus deformity or skin changes or previous ulcer) or 4) ulcerated foot within the preceding 15 months: NICE QOF indicator NM13 (2010). Available from: http://www.nice.org.uk/aboutnice/qof/indicators_detail.jsp?summary=13080 Date for review: to be confirmed.

Under development

NICE is developing four pieces of guidance relating to diabetes over 2013-2015. Each piece of guidance will focus on a different element of the care pathway:

- Diabetes in Children (Type 1 and 2)
- Diabetes in Pregnancy
- Type 1 diabetes in adults
- Type 2 diabetes in adults

- Diabetic foot problems. Anticipated publication date – 2015. Final scope was published July 2013: guideline is an update of CG10 and a partial update of CG15. It will not cover the treatment of diabetic neuropathy.

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Royal College of GPs
- Royal College of Physicians
- National Diabetes Nurse Consultant Group
- Primary Care Diabetes Society
- Royal College of Nursing
- British Diabetic Association
- Association of British Clinical Diabetologists (ABCD)
- British Society for Clinical Neurophysiology
- The Neurological Alliance
- British Peripheral Nerve Society
- Association of British Neurologists (ABN)

5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Association of British Clinical Diabetologists (ABCD)
- Association of British Neurologists (ABN)
- British Peripheral Nerve Society
- British Society for Clinical Neurophysiology
- Diabetes UK
- National Diabetes Nurse Consultant
- Primary Care Diabetes Society
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Physicians
- Society for Endocrinology
- Society of Chiropodists & Podiatrists (Feet for Life)
- The Neurological Alliance

5.2 Patient organisations

At the selection stage, NICE's Patient and Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Afiya Trust
- Black and Ethnic Minority Diabetes Association (BEMDA)
- Black Health Agency (BHA)
- Diabetes Research & Wellness Foundation
- Diabetes UK
- Disabled Living Foundation (DLF)
- Equalities National Council
- Ethnic Health Foundation (EHF)

- Foot in Diabetes UK (FDUK)
- InDependent Diabetes Trust
- INsulin PUmp Therapy (INPUT)
- Juvenile Diabetes Research Foundation (JDRF)
- Muslim Health Network
- Network of Sikh Organisations UK
- South Asian Health Foundation (SAHF)
- Surya Foundation
- The Relatives and Residents Association (R&RA)
- UK Health Forum (formerly National Heart Forum)
- Weight Concern