NICE National Institute for Health and Care Excellence

NICE guidance

VibraTip for testing vibration perception to detect diabetic peripheral neuropathy

HealthTech guidance

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www.nice.org.uk/guidance/htg362

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces MTG22.

1 Recommendations

1.1 VibraTip shows potential to improve the detection of diabetic peripheral neuropathy and to provide cost savings to the NHS. VibraTip appears to be easy to use, portable and reliable in its functionality, but the current evidence does not support the case for its routine adoption in the NHS. Therefore, research is recommended to address uncertainties in the potential benefits to patients and the NHS of using VibraTip. Research is needed into the diagnostic accuracy of VibraTip compared with the 10 g monofilament and calibrated tuning fork in the diagnosis of peripheral neuropathy in people with diabetes. This research should also address the assessment of vibration perception compared with touch sensation in this clinical context. NICE will update this guidance when substantive new evidence becomes available.

2 The technology

Description of the technology

2.1 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 to test a person's vibration perception during routine checks for diabetic peripheral neuropathy in people with type 1 or type 2 diabetes.

2.2 The VibraTip probe is applied to the patient's foot twice: once while not 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 presence of diabetic peripheral neuropathy and the clinician may investigate further. VibraTip is intended as an alternative to, or replacement for, the devices that are currently used in NHS clinical practice for testing foot sensory function, such as the 10 g monofilament (light touch sensation) and the calibrated tuning fork or biothesiometer (vibration perception). 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 its battery life compared with the 10 g monofilament, which needs resting after every 10 full patient foot examinations.

2.3 VibraTip received a CE mark in March 2010 and is indicated to test for vibration perception in the foot during routine checks for diabetic peripheral neuropathy.

2.4 The cost of VibraTip stated in the sponsor's submission is £9.95 (excluding VAT) per device.

2.5 The sponsor's claimed patient and healthcare system benefits for VibraTip are:

- The ease and speed of the test, together with the device's reliability, means earlier diagnosis of neuropathy, leading to improved foot care, helping to prevent ulcers and amputations.

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

Current management

2.6 NICE guidelines on diabetic foot problems, type 1 diabetes in adults and type 1 and type 2 in diabetes in children and young people, recommend a structured programme of regular (annual) foot surveillance, risk assessment and education by trained personnel to raise awareness of the condition. The annual foot examination should include a visual check, palpation of pulses and assessment of foot sensory nerve function. The sensory nerve function component may include assessment of touch using a 10 g monofilament, or a test of vibration perception using either a biothesiometer or calibrated tuning fork. In clinical practice, biothesiometers are reported to have been replaced by neurothesiometers which work in the same way, but have a self-contained battery, allowing for greater portability. The 10 g monofilament should not be used to test more than 10 people per session and should be rested for 24 hours thereafter. Both NICE guidelines are currently being updated, with anticipated publication in 2015.

2.7 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 (nurses trained in dressing diabetic foot wounds and diabetologists with expertise in lower limb complications). The assessment will typically result in more frequent foot checks (every 3 to 6 months), with a vascular assessment and an assessment of footwear. For people at particularly high risk of ulcer formation, foot examinations may take place every 1 to 3 months, and include an intensive foot care education programme and the use of specialist footwear insoles and skin and nail care.

Self-monitoring and self-inspection is both taught and encouraged.

2.8 There is currently no agreed standard on the number or location of the sites on each foot which should be examined when testing for touch sensation or vibration perception.

3 Clinical evidence

Summary of clinical evidence

3.1 More detailed information on the clinical outcomes and evidence considered by the Committee is in the assessment report overview.

3.2 The clinical outcomes for VibraTip presented in the decision problem were:

- 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.

3.3 The sponsor's submission identified 9 studies: 4 journal papers, 2 conference abstracts, 2 unpublished studies and a technical study. The sponsor excluded the technical study and therefore presented 8 studies that were relevant to the scope. A literature search by the External Assessment Centre identified 2 additional studies (Bracewell et al. 2011, Baker 2012), as well as the 9 published studies presented by the sponsor. The External Assessment Centre considered that 6 of the 11 studies presented unique patient data relevant to the scope: 4 papers (Levy 2010, Bowling et al. 2012, Bracewell et al. 2012, Nizar et al. 2014) and 2 abstracts (Urbancic-Rovan et al. 2012, Garbas et al. 2013). The External Assessment Centre excluded the other 5 studies from further consideration: Bracewell et al. (2011) was a conference abstract which overlapped with the

Bracewell et al. (2012) study; Baker (2012) was a commentary on Bowling et al. (2012) and Bracewell et al. (2012); and Horsfield and Levy (2013) and Horsfield and Levy (unpublished) were technical papers with no information of direct relevance to the scope. However, they contain potentially useful information on the device's battery life and likely useable lifetime in clinical practice which the External Assessment Centre summarised in an appendix to the assessment report. Finally, a study by Levy and Greenwood was excluded because the intervention was outside the scope (VibraTip was used by patients in their own homes). All 6 relevant studies were diagnostic accuracy studies.

3.4 Bowling et al. (2012) was a cross-sectional diagnostic accuracy study that compared 2 index tests (VibraTip and the Ipswich touch test) with each of 2 reference standards: a neurothesiometer (vibration perception threshold ≥25 V) or the Neuropathy Disability Score, which is a composite outcome derived from pain sensation, vibration sensation, temperature sensation and ankle reflex. People (n=83) attending diabetes outpatient clinics in hospital and community settings in the UK were assessed using all 4 methods. The results showed that VibraTip had good agreement with the vibration perception threshold in the neurothesiometer (Cohen's kappa=0.973, p<0.001) and with the Neuropathy Disability Score (Cohen's kappa=0.921, p<0.001). The External Assessment Centre calculated that relative to the neurothesiometer, VibraTip's sensitivity was 1.00 (95% confidence interval [CI] 0.93 to 1.00) and its specificity was 0.97 (95% CI 0.82 to 1.00).

3.5 Bracewell et al. (2012) was a cross-sectional diagnostic accuracy study that compared 4 index tests (VibraTip, NeuroTip [a neurological examination pin which can exert a calibrated force], 10 g monofilament and 128 Hz tuning fork) with a neurothesiometer as a reference standard. It also attempted to establish the number of insensate sites that optimised accuracy for each test. The study population was 141 people with diabetes type 1 or 2 in secondary care in the UK, with a reported prevalence of diabetic peripheral neuropathy of 41%. The first part of the study tested intra-rater reliability of VibraTip in a population of 18 people with diabetes and at high risk of diabetic peripheral neuropathy (note: inter-rater reliability was the outcome specified in the scope). Results from successive readings, taken 2 to 3 weeks apart, demonstrated good intra-rater reliability (Cronbach's alpha = 0.88, no CI given). The main part of the study tested the comparative diagnostic accuracy of the 4 index tests compared with

the neurothesiometer. Of the 141 people recruited from a secondary care setting, 89% reported having no history of foot ulcers. The authors performed a receiver-operator characteristic analysis to find the optimum number of insensate sites which gave the best diagnostic accuracy for each test, and found that 2 or more out of 10 were optimal for VibraTip, 10 g monofilament and NeuroTip, while 1 or more was optimal for the tuning fork. From the results provided, the External Assessment Centre calculated VibraTip's sensitivity as 0.79 (95% CI 0.69 to 0.90) and its specificity as 0.82 (95% CI 0.74 to 0.90). Results for the 10 g monofilament were sensitivity 0.84 (0.75 to 0.94) and specificity 0.83 (0.75 to 0.91), and for the 128 Hz tuning fork were sensitivity 0.69 (0.57 to 0.81) and specificity 0.90 (0.84 to 0.97).

3.6 Levy (2010) was a cross-sectional study that compared 3 diagnostic devices in 100 people with diabetes having their annual review in a hospital or podiatry clinic in the UK. The aim of the study was to measure the level of agreement between VibraTip, a 10 g monofilament and a 128 Hz tuning fork. Agreement data between the tests were reported and the External Assessment Centre analysed the results, which showed no statistically significant difference between the tests.

3.7 Nizar et al. (2014) compared 2 index tests (VibraTip and a tuning fork) with a neurothesiometer as the reference standard. The study reported tests on 100 people with type 1 or 2 diabetes attending specialist clinics. Although the authors described the study as a 'cross-sectional diagnostic' design, it was based on a case-control design in which the researchers had prior knowledge of the patients' diabetic peripheral neuropathy status, and recruited them accordingly to make the prevalence of diabetic peripheral neuropathy exactly 50%. Results from the study show that the sensitivity of VibraTip was 0.92 (95% CI 0.81 to 0.98) and its specificity was 0.94 (95% CI 0.83 to 0.99). The authors concluded that VibraTip is comparable to the neurothesiometer and superior to the tuning fork in the detection of peripheral neuropathy, and that it could therefore be a useful screening tool in clinical practice.

3.8 Urbancic-Rovan et al. (2012) was a small pilot study reported as a conference abstract, which compared 5 index tests (VibraTip, 128 Hz tuning fork, 10 g monofilament, Tip Therm [which detects impaired skin temperature sensation] and Neuropad [described as a simple and cheap diagnostic tool for the evaluation of sweat gland function]) in 42 people attending diabetes outpatient clinics in

Slovenia. The results suggested that the 10 g monofilament had a much poorer sensitivity (positive in only 14.3% tests) compared with the other tests, including VibraTip (positive in 47.6% of tests).

3.9 Garbas et al. (2013) was a follow-up to the pilot study by Urbancic-Rovan et al. (2012) and is reported in a conference poster with few details. Based in a university medical centre in Slovenia, this large study (n=496) compared 2 index tests (VibraTip and 128 Hz tuning fork). The results indicate that there was no statistically significant inter-foot variability for either of the index tests and that the tuning fork was shown to be statistically significantly more sensitive than VibraTip in detecting impairment of vibration sensation.

3.10 The sponsor found no adverse event reports relating to VibraTip. No alerts have been issued and no information found in a search of the Medicines and Healthcare Products Regulatory Agency website.

3.11 The External Assessment Centre used the QUADAS-2 tool (revised Quality Assessment of Diagnostic Accuracy Studies) to critique the 6 diagnostic accuracy studies and noted a number of limitations:

- The risk of bias in all studies was high (poor description of the test procedures, lack of evidence of test application randomisation, lack of evidence that the testers were blinded to the patients' reference test results, biases in study populations).
- Three of the studies (Levy 2010, Urbancic-Rovan et al. 2012 and Garbas et al. 2013) lacked a reference test to diagnose diabetic peripheral neuropathy, making calculation of diagnostic accuracy parameters impossible.
- The population in 1 study (Bowling et al. 2012) had diabetic peripheral neuropathy of varying severity already diagnosed, and its target condition was 'at risk' feet.
- The study by Nizar et al. (2014) used a different reference standard to that of most other diabetic peripheral neuropathy studies (a neurothesiometer set at a threshold of 20 V rather than the widely applied 25 V). The same study reported diagnostic accuracy results for the tuning fork (frequency of the fork was not stated) which were not consistent with other published studies.

3.12 The External Assessment Centre considered that the Bracewell et al. (2012) study was the highest quality study and most closely matched the decision problem. It noted the results showed that there were no statistically significant differences in diagnostic accuracy between VibraTip and the 10 g monofilament or the 128 Hz tuning fork in the detection of peripheral neuropathy. The External Assessment Centre considered the optimisation of the thresholds for each device a limitation of this study, because it is not clear how generalisable these thresholds are to clinical practice. It also highlighted that it is unclear whether the study was sufficiently statistically powered to reliably conclude non-inferiority.

Committee considerations

3.13 The Committee noted the clinical evidence base for VibraTip was 6 diagnostic accuracy studies. It agreed with the External Assessment Centre's opinion that the studies were of relatively low methodological quality and had a high risk of bias, but it recognised that the general quality of evidence in this clinical area is low. The Committee agreed with the External Assessment Centre that Bracewell et al. (2102) was the study with most relevance to the scope. It also agreed that, although it would appear that VibraTip has a diagnostic accuracy comparable with that of the 10 g monofilament and the tuning fork, there remained some uncertainties. The Committee judged that these uncertainties were important, because even small differences in diagnostic accuracy might have serious consequences concerning post-diagnosis outcomes for these patients. The Committee concluded that further evidence based on a high-quality diagnostic accuracy study was needed to assess the clinical effectiveness of this technology.

3.14 The Committee discussed the comparators specified in the scope and received expert advice that the appropriate comparators for VibraTip are the 10 g monofilament and the calibrated tuning fork. Expert advice indicated the 10 g monofilament was routinely used in primary care, but practice varied in secondary care and could in some cases involve dual modalities measuring both touch and vibration sensation in testing for diabetic peripheral neuropathy. Clinical experts also agreed there was no accepted standard on the number or location of the sites to be tested on the foot. The Committee also heard expert advice that the neurothesiometer is the reference standard and that the

appropriate threshold voltage varied with the patient's age. The Committee concluded that the variability in the use of the devices in the diagnosis of diabetic peripheral neuropathy was an additional challenge to the collection of high-quality diagnostic accuracy information.

3.15 The Committee questioned the equivalence of touch sensation and vibration perception in the diagnosis of diabetic peripheral neuropathy. It was aware the foot sensory nerve function assessment, which is part of the annual foot examination described in NICE's guideline on diabetic foot problems, recommends either a touch sensation or vibration perception assessment. The clinical experts explained that testing vibration perception and touch sensation could be used separately or together to explore different conditions relevant to diabetic peripheral neuropathy and the diabetic foot at risk of ulceration, and that touch and vibration involved different nerve pathways. The Committee considered that research investigating the different diagnostic testing methodologies (VibraTip, the 10 g monofilament and the calibrated tuning fork) using nerve conduction measurements was feasible and had the potential to define the relative importance of impaired touch sensation and/or vibration perception in the progression of neuropathy.

3.16 The Committee considered the lack of evidence for clinical outcomes and patient benefits associated with the use of VibraTip. It noted that serious adverse consequences of diabetic peripheral neuropathy, such as ulcer formation and limb amputation, take several years to manifest and studies to directly measure these outcomes would be difficult to conduct.

4 NHS considerations

System impact

4.1 A claimed benefit of VibraTip is the reduced variability in results of diabetic peripheral neuropathy testing compared with the 10 g monofilament and the 128 Hz tuning fork. The Bracewell et al. (2012) study reported intra-rater reliability results for use of VibraTip in a small high risk patient population (n=18). An expert adviser reported that he is involved in a study of the accuracy of the use of VibraTip amongst different healthcare professionals in primary and secondary care.

4.2 The sponsor has claimed that little user training is needed with VibraTip. During the selection and routing of VibraTip, the Committee obtained expert advice that agreed that only minimal training would be needed, but there was no published evidence to support this.

4.3 The External Assessment Centre highlighted that the battery life of VibraTip has implications for the cost modelling. The Horsfield and Levy (2013) study was a technical assessment of 3 different activation patterns of VibraTip and the influence of these on battery life and the consistency of the stimulus. Results from a pattern designed to mimic use in clinical practice, showed that the amplitude reduced to 64% of its initial value after 3,500 activations, but the frequency only reduced to 94%. The authors concluded that each VibraTip could test at least 100 patients. The External Assessment Centre considered that there is some uncertainty about the estimate of 100 patients because the duration of each activation in the study was 0.5 seconds instead of the 1 second duration recommended in the VibraTip Instruction for Use. The External Assessment Centre concluded that poor repeatability of the stimulus due to reductions in the amplitude over time is an important limitation to the clinical repeatability of the test, and the effect of these reductions in amplitude on diagnostic accuracy are unknown.

Committee considerations

4.4 The Committee noted that detection, diagnosis and management of diabetic peripheral neuropathy is a very important clinical area which has the potential to affect millions of people in the UK, and that small improvements in the timing and rate of diabetic peripheral neuropathy detection have the potential to impact substantially on clinical costs.

4.5 The Committee considered that important aspects of the system benefits concerned the useable lifetime of both VibraTip and the 10 g monofilament, as well as the 'real world' availability of tuning forks in clinical settings, and the variability of tuning fork usage in clinical practice. Expert opinion and existing evidence provided limited information on these issues. The Committee noted there remained uncertainty and considered it important that these aspects be included in further research so that the clinical and economic implications could be assessed.

4.6 The Committee considered that credible evidence was presented by expert advisers that VibraTip was both easier to learn to use and to use, but there was limited clinical evidence to support these statements. The Committee discussed the time taken to do a test with VibraTip compared with the tuning fork and decided it was unclear that there would be significant time savings when using VibraTip.

4.7 The Committee considered that the technical evidence supporting the improved consistency of VibraTip compared with the calibrated tuning fork in the diagnosis of diabetic peripheral neuropathy was plausible, but that it was of low quality. It understood that there were uncertainties about the possibility of false negative results towards the end of the battery life of the device. The Committee decided that a high-quality diagnostic accuracy study could resolve these issues.

5 Cost considerations

Cost evidence

5.1 No relevant economic studies on VibraTip device were identified by the sponsor or the External Assessment Centre. The sponsor submitted a de novo cost analysis using a decision tree model representing the flow of the entire UK diabetic population through the patient pathway for diabetic foot inspections over a 3-year time horizon. Full details of all cost evidence considered by the Committee are available in the assessment report overview.

5.2 The decision tree model submitted had 2 arms: a current practice and an intervention arm, in which a proportion of patients were tested with VibraTip and current practice was used for the remainder. The current practice arm used either the 10 g monofilament or the tuning fork. In the base case it was assumed that 40% of the patients in the intervention arm were tested with VibraTip. Over the 3-year time horizon, patients in the pathway had a risk of ulceration, repeat ulceration and amputation. The parameters and transition probabilities which impacted on the patient pathway included the probability of developing diabetic peripheral neuropathy, risk of foot ulceration and risk of amputation. These values did not influence the base case results because the costs and transition probabilities were identical for both arms. The difference in cost between the arms depended on differences in the cost between the devices per patient examination.

5.3 The sponsor estimated the per-examination cost for each device based on the initial cost of the device, its estimated useful life and clinic throughput. The device costs in the sponsor's model were £9.95 for VibraTip, £15.20 for the 10 g monofilament and £28.80 for the tuning fork (all excluding VAT). The estimated per-examination cost was £0.01 for the 10 g monofilament, £0.008 for the tuning fork and £0.002 for VibraTip. The value of VibraTip was based on a useable lifetime of 5,000 activations. The External Assessment Centre did not agree with the sponsor's estimations of the pre-examination costs and recalculated these values.

5.4 For the base case in the sponsor's model, with a 40% adoption of VibraTip in the intervention arm, the cumulative costs for monitoring 2.9 million patients over 3 years were £1,467.86 million for VibraTip, £1,467.91 million for the 10 g monofilament and £1,467.90 million for the 128 Hz tuning fork. Therefore, the base case results with diabetes suggested a saving over 3 years of £50,000 for VibraTip compared with the 10 g monofilament and £40,000 for VibraTip compared with the tuning fork. This is equivalent to a saving of 1.7 pence per patient over 3 years compared with 10 g monofilament; and a saving of 1.4 pence per patient over 3 years compared with the tuning fork.

5.5 The sponsor presented a sensitivity analysis in which the adoption rate of VibraTip in the intervention arm was varied. The results showed that the savings were proportionate to the adoption rate. The sponsor also conducted a 2-way sensitivity analysis based on an assumption that VibraTip use was associated with a 1% relative risk reduction in ulcer formation compared with comparator devices; this was combined with a range of VibraTip adoption values. The results from this analysis showed a large increase in savings which reflected the high cost of treating ulcers and resultant amputation rates in the model. The External Assessment Centre noted that the assumption of a 1% reduction in ulcer rates was not based on the clinical evidence presented.

External Assessment Centre revisions to the economic model

5.6 The External Assessment Centre considered that a weakness of the decision tree model chosen is that the number of states increases geometrically for each time step and that a longer time period would have been more appropriate, as diabetic peripheral neuropathy often occurs years or decades after diabetes is diagnosed. The External Assessment Centre also highlighted that there is no link between the clinical evidence, which describes differences in diagnostic accuracy between VibraTip and its comparators, and the assumptions used in the economic model. Thus, the model assumed the devices were clinically equivalent and any differences in costs were caused by differences in the technology costs per patient examination rather than any difference in diagnostic performance.

5.7 The External Assessment Centre highlighted that some of the assumptions and parameter values used in the model could not be located in the references cited

and the rationale for using some parameters was unclear.

5.8 The External Assessment Centre considered that the unit costs presented by the sponsor were largely accurate, but that the sponsor's estimation of the per-examination costs was incorrect. The External Assessment Centre recalculated the per-examination costs for VibraTip based on the battery life evidence in Horsfield and Levy (2013) and obtained a range of values from £0.02 to £0.0995 depending on the number of sites (between 1 [1 foot] and 10 [5 per foot]) used per examination. For the Bailey's 10 g monofilament (a brand widely used in the NHS), the External Assessment Centre recalculated the per-examination costs as £0.076 based on 10 sites per examination, from monofilament useable lifetime data in a published technical study (Lavery et al. 2012). The External Assessment Centre was unable to calculate a per-examination cost for the tuning fork because of its unlimited useful life but considered that it would be very low.

5.9 The External Assessment Centre also highlighted a potentially important issue with both VibraTip and the 10 g monofilament, in that the operator may be unaware the devices are losing functionality (through battery discharge and reduced plasticity respectively). In both cases, clinical use beyond the devices' effective useful life would result in a reduced sensory force being applied to the patient and could result in increased false positives and associated increased costs.

5.10 In summary, the External Assessment Centre considered that the results of the de novo economic model did not provide comprehensive information with respect to the decision problem. If a cost minimisation analysis were adopted, including the per-examination device costs only, VibraTip might be more expensive than either comparator under heavy usage, with a plausible per-examination cost of between £0.0398 (for 4 sites per examination) and £0.0995 (for 10 sites per examination). This compares with a per-examination cost of £0.076 for the 10 g monofilament assuming 10 sites per examination. The External Assessment Centre concluded that the economic case for the adoption of VibraTip had not been demonstrated robustly.

Committee considerations

5.11 The Committee agreed with the External Assessment Centre's opinion that the economic model submitted did not fully address the costs and resources associated with the adoption of VibraTip. It recognised that the model did not capture any aspects of potential savings for changes resulting from differences in diagnostic accuracy between current practice and VibraTip. The Committee agreed with the External Assessment Centre that the introduction of any improvement in the diagnostic accuracy between the tests used to detect diabetic peripheral neuropathy would potentially have a substantial impact on overall clinical costs to the NHS. It noted that the small cost differences demonstrated in the current model were dependent only on the relative cost of the devices and the duration of their reusable lives.

5.12 The Committee concluded that further modelling would be needed of the economic case for adopting VibraTip, when this guidance is reviewed in the light of further research. This will need to include comparisons against the 10 g monofilament and the calibrated tuning fork. It will also need to include the impact of changes in diagnostic accuracy on long-term clinical outcomes, such as ulcer formation and amputation, which would manifest over at least a 5- to 10-year period.

6 Conclusions

6.1 The Committee concluded that VibraTip is a promising technology with the potential to have a positive impact on the diagnosis of diabetic peripheral neuropathy. However, the Committee considered that more evidence was needed on VibraTip's diagnostic performance compared with the 10 g monofilament and calibrated tuning fork. The Committee recommended that a high-quality diagnostic accuracy study comparing VibraTip with the 10 g monofilament and the calibrated tuning fork is needed to establish the comparative clinical benefits of the technologies, and also address the speed and ease of use of the devices. The data from this research, together with updated economic modelling, will enable the review of the current recommendations.

7 Committee members and NICE lead team

Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Bruce Campbell (Chair)
Consultant Vascular Surgeon, Royal Devon and Exeter Hospital

Dr Peter Groves (Vice Chair)
Consultant Cardiologist, Cardiff and Vale UHB

Ms Susan Bennett
Lay member

Dr Keith Blanshard
Consultant Interventional Radiologist, Leicester General Hospital

Professor Nigel Brunskill
Professor of Renal Medicine, University of Leicester

Mr Matthew Campbell-Hill
Lay member

Mr Andrew Chukwuemeka
Consultant Cardiothoracic Surgeon, Imperial College Healthcare NHS Trust

Professor Daniel Clark
Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

Professor Tony Freemont
Professor of Osteoarticular Pathology, University of Manchester

Professor Shaheen Hamdy
Professor of Neurogastroenterology, University of Manchester

Dr Jerry Hutchinson
Independent Medical Technology Advisor, Independent

Dr Cynthia Iglesias
Health Economist, University of York

Professor Mohammad Ilyas
Professor of Pathology, University of Nottingham

Dr Greg Irving
General Practitioner and Clinical Lecturer, University of Cambridge

Dr Eva Kaltenthaler
Reader in Health Technology Assessment, ScHARR, University of Sheffield

Dr Paul Knox
Reader in Vision Science, University of Liverpool

Dr Rory O'Connor
Senior Lecturer and Honorary Consultant Physician in Rehabilitation Medicine, University of Leeds

Mrs Karen Partington
Chief Executive, Lancashire Teaching Hospitals NHS Foundation Trust

Mr Brian Selman

Managing Director, Selman and Company Limited

Professor Wendy Tindale
Scientific Director, Sheffield Teaching Hospitals NHS Foundation Trust

Dr Allan Wailoo
Reader in Health Economics, ScHARR, University of Sheffield

Mr John Wilkinson
Director of Devices, MHRA

Dr Janelle Yorke
Senior Lecturer in Nursing, University of Manchester

Dr Amber Young
Consultant Paediatric Anaesthetist, Bristol Royal Hospital for Children

NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a technical expert, a patient expert, a non-expert member of the Medical Technologies Advisory Committee and a representative of the External Assessment Centre.

Paul Dimmock
Technical Analyst

Bernice Dillon
Technical Adviser

Edward Jude, George Dunn, Umesh Dashora
Lead Expert Advisers

Dan Clark
Non-Expert MTAC Member

Iain Willits and Helen Cole
External Assessment Centre Representatives

8 Sources of evidence considered by the Committee

The External Assessment Centre report for this assessment was prepared by Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH) and York Health Economics Consortium (YHEC) External Assessment Centre (External Assessment Centre):

- Willits I, Cole H, Sims A, et al., VibraTip for testing vibration perception in the detection of diabetic peripheral neuropathy, April 2014.

Submissions from the following sponsor:

- McCallan Medical

The following individuals gave their expert personal view on VibraTip by providing their expert comments on the draft scope and assessment report:

- Dr Edward Jude, ratified by Society for Endocrinology – clinical expert
- George Dunn, ratified by The Society of Chiropodists and Podiatrists – clinical expert
- Dr Umesh Dashora, ratified by Association of British Clinical Diabetologists – clinical expert

The following individuals gave their expert personal view on VibraTip in writing by completing an expert adviser questionnaire provided to the Committee:

- Ms Theresa Smyth, ratified by Royal College of Nursing – clinical expert
- Dr Aleksandar Radunovic, ratified by Association of British Neurologists – clinical expert
- Dr Yusuf A Rajabally, ratified by British Peripheral Nerve Society – clinical expert
- Dr Adrian Wills, ratified by British Peripheral Nerve Society – clinical expert
- Dr Paul Chadwick, ratified by The Society of Chiropodists and Podiatrists – clinical expert

- Mr Allister Campbell, ratified by The Society of Chiropodists and Podiatrists – clinical expert
- Dr John Winer, ratified by Association of British Neurologists
- Mr Neil R Baker, ratified by Diabetes UK – clinical expert
- Dr Frances Game, ratified by Association of British Clinical Diabetologists – clinical expert
- Professor Kamlesh Khunti, ratified by Royal College of General Practitioners – clinical expert

Update information

March 2015: Sections 1.1, 5.12 and 6.1 were updated.

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