National Institute for Health and Care Excellence

External Assessment Centre correspondence

Vibratip for testing vibration perception in the detection of diabetic neuropathy

The purpose of this table is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the sponsors' original submission. This is normally where the External Assessment Centre:

a) become aware of additional relevant evidence not submitted by the sponsor
b) need to check "real world" assumptions with NICE's expert advisers, or
c) need to ask the sponsor for additional information or data not included in the original submission, or
d) need to correspond with an organisation or individual outside of NICE

These events are recorded in the table to ensure that all information relevant to the assessment of the topic is made available to MTAC. The table is presented to MTAC in the Assessment Report Overview, and is made available at public consultation.

Table 1 Correspondence with sponsor
Table 2 Collated responses from expert advisers to EAC question

Table 1

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	Eleven initial clarification questions to McCallan Medical Ltd. Vibratip Sponsor, Danny O'Connell. Submitted by EAC for discussion at sponsor introductory teleconference 07/03/2014, hosted by NICE: 1) The CE certificate copy submitted with clinical evidence expired 10/09/2013. We have seen online that this has been renewed, but could we have a copy of the current, valid certificate for our records please?	**Verbal responses from Danny O'Connell to these eleven initial clarification questions. Summarised in this log by the EAC:** Pdf copy received 06/03/2014. CE mark expiry date 10/09/2018.	Filed for the record.
	2) We note from the Sponsor's submission that 4000 units of VibraTip have been sold. Could we confirm this figure is up to date and if the sponsor knows how many units were sold to English practices, and what the breakdown of primary and secondary care is?	UK sales channels include relatively few direct sales from McCallan website; the company also distributes through NHS Supply Chain and others. Therefore sponsor only able to comment on direct sales (130 to date). Just as a guess, breakdown of sales is approximately: Hospitals 10%; Podiatrists 50%; Primary care 40%.	Noted with thanks.
	3) The instructions for use (IFU) card (submitted as part of clinical evidence) imply only one test ('on' and 'off') on a patient's foot. Does the sponsor give any guidance to users about how many times the device should be applied to each foot (i.e. across how many separate sites on the foot) to complete a single foot examination? How does this compare with other	There are discrepancies in the literature about how many sites are tested and how many insensate sites determine the diagnosis of DPN. The NICE CG 10 guidelines do not specify how to conduct the foot examination in this level of detail. McCallan have listened to experts and are suggesting that whatever is currently being done in clinical practice for vibration perception	Noted with thanks.

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	technologies (e.g. 10g monofilament)?	testing can be done with VibraTip instead (like for like).	
	4) We note in the technical paper submitted (Horsfield and Levy 2013) that the amplitude of the Vibratip activations falls off over time as the battery power declines. How do you guide the user to know when the device is no longer fit for purpose and should be replaced (*i.e.* is there a threshold below which the amplitude of vibrations is no longer adequate for a reliable diagnostic test)?	No specific threshold given. From experience/current practice, a single Vibratip may last around a year. Clinicians should be able tell from the press of the button if the battery is running down as they will be able to feel the vibration in their fingers when they press the button – it will feel quite lack-lustre.	Noted with thanks.
	5) The two technical papers (Horsfield and Levy 2013 and same authors, unpublished, reporting results from manikin toe) indicate that the Vibratip frequency is ~210Hz (full battery power). Other sources state 'a little above 128Hz'. What is the full operating frequency of Vibratip?	Response received in email from D O'Connell 14/03/2014: Please see attached the specification sheets for the motors used inside a Vibratip. This forms part of the VibraTip Technical File - please can you consider confidential. See p.5, section 5 - the rated speed will determine the frequency of the vibration generated by the device and this is 12,000 rpm or 200Hz.	Noted with thanks and Vibratip Technical File retained within EAC as requested in confidence. Confirmation of 200Hz rated frequency of this device is supported by the technical papers submitted by the sponsor in Clinical Evidence submission (Horsfield and Levy 2013 and Horsfield and Levy 2014).
	6) Is the manikin toe (Horsfield and Levy, unpublished) intended for commercial production as a training tool, or was it developed solely for the technical testing	It would be possible to produce it for those who would like it for training purposes, but it is not intentionally produced for this. The prototype is	Noted with thanks.

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	paper?	being exhibited at podiatry/foot care meetings to get feedback on whether it would be useful as a training tool	
	7) In the final Scope, in the Claimed benefits section (1.3) it is stated that VibraTip could lead to 'earlier diagnosis of neuropathy'. Could the sponsor elaborate by which mechanism earlier diagnosis of neuropathy might be achieved, and are there any references to support this?	This is mainly down to the ease of use, therefore it is used more frequently and widespread – ultimately more cases of DPN are detected.	Noted with thanks. The final scope from NICE for this assessment has excluded any opportunistic testing for DPN outside of the recommended annual diabetic foot screen, or more frequent testing for those at increased or high risk, referred to a foot protection team.
	8) In section 3.9 of the evidence submission, page 16 of 87, the sponsor refers to tuning forks still being required for 'specialised neurological testing'. Can we confirm if tuning forks are still required for use by the specialist footcare team in more frequent testing of DPN patients for risk of ulceration? If not this, can the sponsor elucidate which clinical applications they mean by 'specialised neurological testing'?	Tuning forks also used for ENT and for audiometry purposes. They will still be used for these applications.	Noted with thanks.
	9) Two of the diagnostic studies provided in the sponsor's submission are in the form of a conference abstract (Urbanic-Rovan et al. 2012) and poster (Garbas et al	Contact details provided.	The EAC contacted Assoc.prof.Vilma Urbančič on 11/03/2014, to request

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	2013), with both authors belonging to the same Slovenian group. We would like to contact this group for more information on these studies if possible. Is the sponsor in communication with this group and do they have any contact details (e.g. e-mail addresses)?		confirmation of research methodology. That Correspondence is detailed later in this Log.
	10) The clinical evidence submission states that Conference Proceedings were searched by the sponsor in production of the Vibratip evidence base presented. Can the sponsor specify which Conferences were searched?	(i) Diabetes UK (ii) Annual College of Podiatry and Chiropody meeting (iii) Diabetic Foot Study Group (DFSG) Proceedings (iv) Malvern Diabetic Foot Conference. Additionally, in email from D O'Connell 14/03/2014: I have thought of some further places we check out for publications relating to 'Diabetic Neuropathy' or 'VibraTip' American Diabetes Association Conferences: http://ada.apprisor.org/epsSearch.cfm?compid=1 http://www.abstractsonline.com/plan/start.aspx?mkey=%7B89918D6D-3018-4EA9-9D4F-711F98A7AE5D%7D The International Diabetes Federation	To inform EAC grey literature search. No additional evidence to that submitted by sponsor was identified in the grey literature search by the EAC

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		Conferences: http://conference2.idf.org/MEL2013/World%20Diabetes%20Congress%202013/data/HtmlApp/main.html#open-sessions I occasionally interrogate US PubMed: http://www.ncbi.nlm.nih.gov/pubmed Every week I get an alert from biomedsearch, having registered my request for any known publications including keywords 'diabetic neuropathy': http://www.biomedsearch.com	
	11) Please could the sponsor inform us which software package is being used in preparation of the economic evidence submission?	Microsoft Excel.	Noted with thanks.
	An additional outcome of the sponsor meeting was that Danny O'Connell provided an updated copy of the Nizal et al. paper from original clinical evidence submission and confirmed publication anticipated in the March Issue of Br Journal for Diabetes and Vascular Disease. **On 21/03/2014, D O'Connell provided in email:** Please find attached final copy of Nizar paper, now published.		Final published version of Nizal et.al (March 2014) used in place of the copy submitted in original evidence submission: Br J Diabetes Vasc Dis 2014;14:26-29
	On 11/03/2014, a list of nine questions was sent by the EAC to 13 Expert Advisors named by NICE for this	**By 31/03/2014, 8 responses had been received and collated by the EAC into a**	To inform EAC report on the Clinical and Economic

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	project.	**single documented response: see separate document "NY EAC Questions to Vibratip Clinical Experts"**	Evidence Submission
	Also on 11/03/2014, an email was sent to Assoc.prof.Vilma Urbančič, posing three questions in relation to the two studies she had conducted and which were included as conference abstracts in clinical evidence submission by the sponsor. • In these studies, was a reference standard (gold standard) used to diagnose the patient's status for diabetic peripheral neuropathy? • If so, what was the underlying prevalence of diabetic neuropathy in these patients? • Are there any immediate plans to publish either of these studies in a peer-reviewed journal (in particular I'm thinking of the large n=496 study).	**Response received in email on 14/03/2014** We compared the findings obtained by Vibratip with the testing by 128-Hz tuning fork. Neither nerve conduction studies nor the vibration perception threshold by biothesiometer were performed. As you can see from the abstract, approx 36% of the study population could not feel the vibration.	Noted with thanks. Absence of gold standard comparator in these studies confirmed.
	Four questions were sent by the EAC to McCallan Medical Ltd. Vibratip Sponsor, Danny O'Connell on 15/04/2014. Email content is reproduced below: The NICE External Assessment Centre has been working on the Vibratip economic evidence submission for the past couple of weeks and we have a few queries on apparent conflicts between inputs to the model as described or referenced in 'Section C' of the submission document, versus those actually used in the executable model (Excel	**Danny O'Connell replied on 16/04/2014:** Thanks for your email yesterday. David **[Huckle – the economist consultant used by sponsor]** has looked into the questions you raised and provided the comments below to support the assumptions made. 1) These figures were derived to establish a rational model and provide an ulcer incidence	Noted with thanks.

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	spreadsheet). The EAC has found several of the input parameters do not seem to match the 'assumptions' table in the report. Can the sponsor please elaborate on how the following values were derived? 1) **Input variable used in model:** Proportion of Diabetics that Develop Foot/Leg Ulcers. **Value stated in assumptions:** 6% (5.8% cumulative 3 year incidence from Ramsey et al.) **Value(s) used in model:** 2% for routine risk, 5% for high risk. Unclear how these figures were derived.	comparable to that observed in the absence of definitive figures for incidence from high risk and supposedly controlled diabetics. A reasonable assumption was that incidence for High Risk patients would be more than double that of the controlled patients. If the new Ulcer Incidence lines are followed the 3-year incidence in the model is 5.5% of the starting patient numbers.	
	2) **Input variable used in model:** Ulcer recurrence after treatment **Value stated in assumptions:** 10% **Value(s) used in model:** Can be 5% (first recurrence) or 36% (second recurrence). In intervention arm, can also be 30% (manual over-ride).	2) The 5% (and 2%) figures are not recurrence but first incidence figures. The 36% is not recurrence but continued treatment (in other words 64% of those with an ulcer are treated, back under control but high risk.) The 30% figures is on the Year 1 High Risk line and allows for the final level of Amputations carried out. It was a stated assumption that the Amputees would come from this group, although acknowledged as not necessarily being the case in order to have a manageable model when the	Noted with thanks.

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		devices are being compared against each other.	
	3) **Input variable used in model:** Proportion of High Risk Diabetics resulting in Amputation **Value stated in assumptions:** 2% **Value(s) used in model:** Current practice: 36% [cell R99] Intervention: 5.99% [cells R36 and R66]	3) The "High Risk" group is made up of the Year 1 High Risks [cell G8], Year 1 "Controlled" that develop Ulcers [cell K123] and "Controlled" in Year 2 [cell O111] that develop an Ulcer. As noted above the Amputees actually come from all these groups and the figure ultimately used there [cell T99] gives an overall incidence of 3%. This is a close approximation to the assumptions and keeps the model structure again as a constant comparison for the different devices.	Noted with thanks.
	4) **Input variable used in model:** 'No event cells' **Value stated in assumptions:** Not discussed **Value(s) used in model:** 100% chance of remaining high risk [cells R75, R91, and R105; and cells R12 and R42]	4) These No Event cells were to balance in the Decision Tree model with the patients continuing at either Controlled or High Risk level. In the next snapshot period they would be in these groups at Year 1 together with new patients. High Risk at 210,738 [vs. Year 1 at 214,600] and Controlled at 2,672,085 [vs. Year 1 at 2,685,400].	Noted with thanks.

Table 2

NY EAC Questions to Vibratip Clinical Experts 11032014 Responses & ~~Nil Response~~

Name of Expert Advisers	Job Title	Professional Organisation/ Specialist Society	Nominated by	Ratified
Dr. Yusuf A. Rajabally	Consultant Neurologist, Honorary Senior Clinical Lecturer	British Peripheral Nerve Society	Specialist Society	-
Dr Adrian Wills	Consultant Neurologist	British Peripheral Nerve Society	Specialist Society	-
Mr George Dunn	Specialist Podiatrist	Society of Chiropodists and Podiatrists	Specialist Society	-
Dr Paul Chadwick	Principal Podiatrist	Society of Chiropodists and Podiatrists	Specialist Society	-
Mr Allister Campbell	Deputy Podiatry Services Manager	Society of Chiropodists and Podiatrists	Specialist Society	-
Dr Umesh Dashora	Consultant Endocinology and Diabetes	Association of British Clinical Diabetologists	Specialist Society	-
Dr John Winer	Consultant Neurologist	Association of British Neurologists	Specialist Society	-
Dr Frances Game	Consultant Diabetologist	Association of British Clinical Diabetologists	Specialist Society	-

Question 1: In vibration perception testing for diabetic peripheral neuropathy (DPN), is there a recommended testing protocol for the foot examination, such as:

a. Is there standard practice regarding number of sites / locations per foot which should be tested?

b. How many of those sites tested would be insensate for the foot examination to be reported as a positive result for DPN?

c. Are both feet tested and what happens if feet give conflicting results?

d. In light touch pressure testing for DPN (i.e. use of 10g monofilament), is the recommended testing protocol the same as for vibration perception testing? If not, how does the testing protocol using a 10g monofilament differ?

e. Are there any definitive reference sources we could use and cite regarding the optimal technique recommended for detection of diabetic peripheral neuropathy (e.g. reviews or text books)?

Expert Adviser	Q1 Response
Dr Yusuf A Rajabally **Consultant Neurologist, Honorary Senior Clinical Lecturer**	**a. Yes** **b. Depends on age: 1 or 2** **c. One side usually tested** **d. Single site** **e. There are numerous textbooks on peripheral neuropathy which refer to examination technique: eg Peripheral Neuropathy Dyck and Thomas**
Dr Adrian Wills **Consultant Neurologist**	**Blank**

Mr George Dunn **Specialist Podiatrist**	**a. recommendations can vary between which method is used, though a mixture of nerve assessment methods are usually recommended, i.e. 10g Monofilaments, Vibration testing, Hot and Cold and Neurotip/sharp blunt differentiation. In the case of 10 g monofilament, this can vary from 1 site per foot, as recommended by the Warwick Course (Diabetes MSc) to 10 sites per foot as recommended by University of Texas. In GB the main consensus appears to be 5 sites per foot and an overall score out of 10. For vibration sensation main consensus appears to be 2 sites per foot mainly 1st metatarso-phalangeal joint and medial malleolus of both feet.** **b. in 10g monofilament testing, 2 sites per foot or a score of 7/10 or less. for Vibration perception then 1 site per foot for a positive diagnosis for DPN.** **c. both feet are tested and whichever is the worst then will lead diagnosis, though if there are wildly varying results then may well trigger further tests to investigate why a large variance exists.** **d. 10g monofilament testing varies as more sites are used usually versus bony points for Vibration testing. as detailed above, in many testing recommendations, testing points for 10g monofilaments vary from 1 site per foot to 10 sites per foot. Used where I work presently, we use 5 sites per foot and add into a out of 10 score.** **e. Many including text book, Foot in Diabetes, Boulton and numerous research papers inc North West Diabetes Foot Study.**
Dr Paul Chadwick **Principal Podiatrist**	**a there is no standard test but most areas would use the IWGDF(2012) which states the dorsal of the proximal phalanx of the hallux** **B if we are just assessing vibration perception then as it is distal neuropathy absent in the one site should be enough for a screening process if you are looking at extent of pdn then you would include 3 other sites e.g 1st mpjt/ankle/tibial tuberosity** **C the patient is neuropathic by default** **D different in monofilament at least 3 sites are used with 3 tests at each site –see IWGDF 2012 for exact parameters** **E As above use either IWGDF or American diabetes association 4 sites—anymore (e.g as used in Scotland) are unnecessary**

Mr Allister Campbell **Deputy Podiatry Services Manager**	**a. Standard practice indicates that 5 sites per foot are tested, these are plantar aspects of both 1st Hallux; 1st, 3rd and 5th MPJ's; Plantar aspect of both heels** **b. A score <8 = sensory deficiency** **c. It is common that the results can differ between the 2 feet as DPN can often only present in 1 foot** **d. Same testing protocol is used when testing for vibration perception** **e. The Foot Risk Awareness and Management Education (FRAME) project as commissioned by the Scottish Government** **NICE - Review of Clinical Guideline (CG10): Type 2 diabetes: prevention and management of foot problems** **Tuning Fork Excels in Diabetic Neuropathy Dx; By: MIRIAM E. TUCKER; 09/15/09**
Dr Umesh Dashora **Consultant Endocinology and Diabetes**	**a. Yes (guidelines suggest either monofilament or vibration testing)** **b. >=2** **c. Abnormal.** **d. Similar** **e. Reviews comparing Monofilament/ 128hz turning fork/VPT** **Uptodate** **mple Screening Tests for Peripheral Neuropathy in the Diabetes ...** **care.diabetesjournals.org/content/24/2/250.long** **DF]** **diabetic neuropathy: diagnostic methods - Advanced Studies in ...** **www.jhasim.com/files/articlefiles/pdf/XASIM_Issue_4_8Ap650_661.pdf**
Dr John Winer **Consultant Neurologist**	**You need a diabetic physician to answer this. I don not personal use any specified protocol to diagnose a peripheral neuropathy clinically.**

Dr Frances Game **Consultant Diabetologist**	**a,b: Surprisingly there is no standardisation of the sites to be tested on the foot in England, although it is generally accepted that 5 sites on each foot should be tested and that if sensation is abnormal at 2 or more sites then the foot is at risk. The Scottish screening system uses 5 sites the 1st, 3rd and 5th metatarsal heads and the pulp of the 1st and 3rd toes, whereas Boulton et al recommend only 4 (1st, 3rd, 5th Metatarsal heads and pulp hallux), Diabetes Care 2004, vol 27 (6: 1459-) The best prospective data however from the North West Diabetes study (Abbott C et al, 2002 Diabetic Medicine, 19, 377–384) used only 3 sites; 1st and 5th metatarsal heads and the heel.** **c. Both feet are tested and the feet are treated individually.** **d. If vibration sensation with a 128Hz tuning fork or a neurosthesiometer is used, it is tested at the apex of the hallux only** **e. See references above. Please note that there is a subtle but important difference in making a diagnosis of peripheral sensory neuropathy, and diagnosing a foot that is at risk of ulceration which needs referral to a foot protection team. Hence why the paper by Abbott is so important as it defines the foot at risk**

Question 2: ***The Vibratip device, which is the subject of this NICE assessment, makes various claims, including being a more consistent and easier- to-use test than the tuning fork for vibration perception testing. Information from the manufacturer states:***

VibraTip™ provides a single, reference amplitude of vibration. Standard tuning forks (such as 128Hz), provide a standard frequency of vibration, but variable amplitude.

a. Is it more clinically important / relevant to have a consistent frequency or consistent amplitude for vibration perception testing in DPN?

b. Is there any clinical difference in testing for DPN with a vibration at 128Hz (tuning fork) or a vibration at a frequency of ~200Hz, or 50Hz (Neurothesiometer)?

Expert Adviser	Q2 Response

Expert Adviser	Q2 Response
Dr Yusuf A Rajabally **Consultant Neurologist, Honorary Senior Clinical Lecturer**	**a. This is an advantage to have consistent amplitude although frequency is also important as can be noticed when using a 128 Hz device versus a 256 Hz fork** **b. Yes**
Dr Adrian Wills **Consultant Neurologist**	**Blank**
Mr George Dunn **Specialist Podiatrist**	**a. I feel the consistency of amplitude is important as it removes the variance in starting testing, whether it is pinching the tunes of the Tuning fork, or striking against a solid object. In my experience this varies greatly from practitioner to practitioner. To my mind, constant frequency is important. I t is worth bearing in mind, that as time passed with the vibratip, the battery power reduces thus can affect the amplitude.** **b. if amplitude remains the same, the variable frequency of the neurothesiometer does allow for variance in nerve testing, but may activate other nerve endings rather than those purely associated with Vibration sensation.**
Dr Paul Chadwick **Principal Podiatrist**	**a not sure about this** **B all the evidence around the use of tuning for is based on the 128 hz tuning fork so there would be significant differences in using different frequenzy. The Neurothesiometer is based on amps and lack of feeling above 25 would indicate loss**
Mr Allister Campbell **Deputy Podiatry Services Manager**	**a. It is clinically important to have a consistent frequency/Amplitude for vibration testing in DPN** **b. The main factor when using a tuning fork is how proficient and the technique the clinician uses whereas the neurothesiometer is more user friendly and can give a more detailed and range of results?**
Dr Umesh Dashora **Consultant Endocinology and Diabetes**	**a. Not hugely relevant but one can see an advantage in consistent amplitude** **128 Hz is the recommended test**

Expert Adviser	Q2 Response
Dr John Winer **Consultant Neurologist**	**Consistent amplitude probably is more reproducible.** **b) I suspect not.**
Dr Frances Game **Consultant Diabetologist**	**a. As above it is important to distinguish between the diagnosis of peripheral sensory neuropathy and the diagnosis of an at risk foot. As currently the testing of an at risk foot is based on the 10g monofilament then the performance of the vibratip should be compared against that, preferably in prospective trials to establish whether it is really superior in picking out an at risk foot.** **b. The tuning fork test is very difficult for patients (and staff) to do correctly as they can often hear the tuning fork being struck. Although the manufacturers claim a more consistent frequency. When we tested them in our medical physics lab the frequency (although consistent) was not 128Hz**

Question 3: Other information from the manufacturer states (unreferenced):

"Loss of vibration perception is believed to precede loss of fine touch"

Do you agree with this statement and can you offer any additional detail / references please?

Expert Adviser	Q3 Response
Dr Yusuf A Rajabally **Consultant Neurologist, Honorary Senior Clinical Lecturer**	**Yes, this is believed although it is also clear that pain and temperature may also be lost concurrently.** **Llewelyn et al. Diabetic Neuropathies. In Peripheral Neuropathy 85;pp1951-1955 Dyck and Thomas Editors, Elsevier, Philadelphia 2005.**
Dr Adrian Wills **Consultant Neurologist**	**Depends on type of PN**
Mr George Dunn **Specialist Podiatrist**	**In my experience, many differing nerve modalities can be effected first and as such can vary from patient to patient. Therefore I do not agree with the above statement. However, Vibration perception testing is important.**
Dr Paul Chadwick **Principal Podiatrist**	**not sure about the evidence for this, it is suspected that early autonomic changes occur before loss of larger fibres. what we are trying to find out during a screen is " is does this person have neuropathy at whatever stage and is thus at increased risk of ulceration and can we do anything about preventing the ulcer forming.**
Mr Allister Campbell **Deputy Podiatry Services Manager**	**I do agree with this statement but I have no references to support this other than 30 years of clinical practice**

Dr Umesh Dashora **Consultant Endocinology and Diabetes**	**yes but many clinicians would argue that the difference is not clinically hugely relevant and testing for touch is more convenient.** **The Ipswich Touch Test - Diabetes Care** **care.diabetesjournals.org/content/34/7/1517.full** **Extract from uptodate: while describing neuropathy** **abnormalities of vibratory testing and proprioception that are often out of proportion to loss of pin prick or temperature sensation. Reflexes are reduced diffusely and are often absent.**
Dr John Winer **Consultant Neurologist**	**This does appear to be true clinically from experience but I cannot reference this.**
Dr Frances Game **Consultant Diabetologist**	**I do but as above it is not the early diagnosis of peripheral neuropathy that is important but the identification of the foot that is at risk of ulceration**

Question 4: What are the short and long term implications of false positive and false negative test results?

Expert Advisers	Comment
Dr Yusuf A Rajabally **Consultant Neurologist, Honorary Senior Clinical Lecturer**	**False positives will result in inappropriate diagnosis in patients without neuropathy and eventual unnecessary treatment.** **False negatives would appear less likely of consequence as would probably be picked up subsequently and as patients with symptoms would probably in any case be monitored and treated irrespective of the test result.**
Dr Adrian Wills **Consultant Neurologist**	**False positive-over investigation, anxiety, false negative delayed diagnosis**
Mr George Dunn **Specialist Podiatrist**	**False positive: would result in extra education for patients and also may result in more treatment being given than initially thought necessary. Therefore consequences to the patient are minimal, though this will add extra costs and further appointment blockade to the practitioner.** **False negative carry greater risk to the patient and as such are not acceptable to the post Francis NHS (not that they were acceptable before). in a case where a patient is falsely assessed then there are risks regarding lack of treatment intervention, lack of sensation and therefore likelihood of ulceration and possible limb loss in the worst case scenario.**
Dr Paul Chadwick **Principal Podiatrist**	**false positive –patient having unnecessary preventative foot care programme (4 appointments a year for life?)patient being distressed** **False negative short- person not referred to preventative foot care programme and subsequently ulcerating with all the resources required to manage that plus the human cost and increased risk of amputation**
Mr Allister Campbell **Deputy Podiatry Services Manager**	**Main implications are for the patient as ultimately they are getting the wrong information which could adversely affect the patient/professional relationship?**

Dr Umesh Dashora **Consultant Endocinology and Diabetes**	**False neg→ potential foot ulcers and increase in amputation risk if not diagnosed and foot care given.** **False Pos→ concern about implication of neuropathy.**
Dr John Winer **Consultant Neurologist**	**Again a diabetic physician would be better to answer this. The detection of neuropathy usually influences therapy and prognosis in both diabetic and other polyneuropathies.**
Dr Frances Game **Consultant Diabetologist**	**False positives overload the foot protection team with patients who do not need their care** **False negatives put the patient at risk of ulceration** **However this is not the only test in the annual foot screen**

Question 5: ***Are biothesiometers commonly used in primary care during annual foot checks, or would this be considered a specialist test, after referral to foot care team in secondary care?***

Expert Advisers	**Comment**
Dr Yusuf A Rajabally **Consultant Neurologist, Honorary Senior Clinical Lecturer**	**Primary care. Diabetes Clinics.**
Dr Adrian Wills **Consultant Neurologist**	**I am not a Primary Care Physician**
Mr George Dunn **Specialist Podiatrist**	**biothesiometers would be considered a specialist test and would therefore be sent on for specialist examination. However, in foot examination, mainly the multiple test modalities used are good at foot risk assessment.**
Dr Paul Chadwick **Principal Podiatrist**	**secondary care for research purposes only as they are expensive, and not easily transported**

Mr Allister Campbell **Deputy Podiatry Services Manager**	**Biothesiometers / Neurothesiometers are commonly used to carryout annual foot checks. However they are very expensive and are not very portable. Therefore they tend to be held in specific locations and are used to review suspect annual screening results carried out in locations, where one was not available?**
Dr Umesh Dashora **Consultant Endocinology and Diabetes**	**Not used in primary care. But used in secondary widely.**
Dr John Winer **Consultant Neurologist**	**I think the vibratip was intended for screening and could therefore be used in either primary or secondary care.**
Dr Frances Game **Consultant Diabetologist**	**Neurosthesiometers (no longer biosthsiometers) are a research tool only. I have never seen them used in routine clinical practice.**

Question 6: In the NICE clinical guideline on diabetic foot problems (CG10), it is recommended that neuropathy is tested for in primary care using a 10g monofilament OR testing for vibration sensation (e.g. using a tuning fork).In your experience, are these recommendations usually followed in practice, and does one method (10g monofilament or tuning fork) predominate in England?

Expert Advisers	Comment
Dr Yusuf A Rajabally **Consultant Neurologist, Honorary Senior Clinical Lecturer**	**I cannot answer this question.**
Dr Adrian Wills **Consultant Neurologist**	**See response to 5**
Mr George Dunn **Specialist Podiatrist**	**I would suggest that these are not necessarily followed in my experience and as such may not be reliable. However, in many cases and in areas where I have worked, both tests are used in practice particularly where Podiatry has had input in design of the foot risk pathway.** **In England I feel the 10g monofilament would be the test in predominant usage**
Dr Paul Chadwick **Principal Podiatrist**	**mixture most use 10g monofilament as standard then +/- tuning fork**
Mr Allister Campbell **Deputy Podiatry Services Manager**	**In Northern Ireland the monofilament is widely used for testing neuropathy and vibration is tested using a neurothesiometer or a tuning fork if a neurothesiometer was not available?**
Dr Umesh Dashora **Consultant Endocinology and Diabetes**	**Yes. Mostly only monofilament test used in primary care.**
Dr John Winer **Consultant Neurologist**	**I suspect the use of a filament is variable but I have had patients referred with filament results so some GP's do use this. It is rare for referrals to secondary care to document vibration threshold.**

Dr Frances Game **Consultant Diabetologist**	**The monofilament test prevails**

Question 7: Following detection of feet that are at increased or high risk of ulceration, NICE recommend referral to a foot protection team where more frequent assessment of feet is carried out (every 1-6 months depending on risk). In patients who have previously been diagnosed with DPN, is there any purpose in further testing for sensory loss during these follow up assessments, for instance because neuropathy reversible?

Expert Advisers	Comment
Dr Yusuf A Rajabally **Consultant Neurologist, Honorary Senior Clinical Lecturer**	**No.**
Dr Adrian Wills **Consultant Neurologist**	**??**
Mr George Dunn **Specialist Podiatrist**	**Neuropathy may be reversible when in the acute phase of neurological loss,however, s this is in the very initial stages of neuropathy, and can be mistaken for onset Painful neuropathy or hypersensitivity, this may be missed and the patient may proceed onto chronic long term neuropathy. It is always sensible to retest for neuropathy, particularly when a patient is progressing towards high risk feet from low to moderate risk. However, once a patient has ulcerated, they are always at highest risk of developing further wounds and as such testing in this situation may not be applicable.**
Dr Paul Chadwick **Principal Podiatrist**	**no only to discover the extent of DPN i.e how far up the leg**
Mr Allister Campbell **Deputy Podiatry Services Manager**	**With treatment, neuropathy can be seen to improve, especially if identified early. How frequently this should be reviewed can vary from patient to patient but should be done at a minimum of once every 6 months while they are still identified at increased or high risk of ulceration.**
Dr Umesh Dashora **Consultant Endocinology and Diabetes**	**Yes. It can be reversible sometimes. Deterioration would also guide intensity and nature of follow up.**

Dr John Winer **Consultant Neurologist**	**Neuropathy only rarely improves but lack of deterioration is evidence of success in therapy.**
Dr Frances Game **Consultant Diabetologist**	**There is probably little point in retesting as unless the diagnosis of DPN was wrong (and there was a cause other than diabetes)as the damage is considered irreversible.**

Question 8: How frequently are you advised to replace a tuning fork or how long do they last in your experience? Would this be a personal tool carried on person, or taken off shelf and shared in the clinic?

Expert Advisers	Comment
Dr Yusuf A Rajabally **Consultant Neurologist, Honorary Senior Clinical Lecturer**	**Once every several years….if ever!** **Rydel-Seiffer tuning forks are in my experience very long-lasting and perfectly functional.** **Tuning forks are shared more often, although are sometimes also carried on person.**
Dr Adrian Wills **Consultant Neurologist**	**They last until they are lost or stolen**
Mr George Dunn **Specialist Podiatrist**	**Most Tuning forks are shared in a clinical setting though dependent upon damage from usage their lifespan is much longer than that of a Monofilament, I am not aware of testing for removal and replacement of tuning forks, but may suggest yearly as an idea.**
Dr Paul Chadwick **Principal Podiatrist**	**they are fairly robust and not sure there is any guidance on replacing them they are usually carried as a personal tool for peripatetic podiatrists or per clinic for stationary**
Mr Allister Campbell **Deputy Podiatry Services Manager**	**Currently we only replace our tuning forks if they become damaged we have never received any manufacturer guidelines stating they should be replaced within any given period of time?**
Dr Umesh Dashora **Consultant Endocinology and Diabetes**	**Mostly never. Usually shared and kept in clinic shelf.**
Dr John Winer **Consultant Neurologist**	**I have my own but they are routinely provided in secondary care. I think they virtually last for ever unless you lose them.**
Dr Frances Game **Consultant Diabetologist**	**Tuning forks rarely need replacing**

Question 9: How frequently are you advised to replace a monofilament or how long do they last in your experience? Would this be a personal tool carried on person, or taken off shelf and shared in the clinic?

Expert Advisers	Comment
Dr Yusuf A Rajabally **Consultant Neurologist, Honorary Senior Clinical Lecturer**	**I am unable to answer this.**
Dr Adrian Wills **Consultant Neurologist**	**GP would need to answer this question**
Mr George Dunn **Specialist Podiatrist**	**It has been suggested that monofilaments need to be rested for 24hrs after 100 actuations, i.e. 10 patients and then replaced regularly particularly if the monofilaments are bent or are developing a memory (hard to assess). As these are taken off shelf and are multi use there usage is open to challenge as not having been replaced frequently enough to ensure correct calibration.**
Dr Paul Chadwick **Principal Podiatrist**	**there is a paper written by Young in the diabetic foot journal (the power of10?) this gives accurate advice on use and when to discard ie. Usually a personal tool**
Mr Allister Campbell **Deputy Podiatry Services Manager**	**Monofilaments are replaced after every 100 patients but are also rested for a minimum of 1 day after every 10 patients**
Dr Umesh Dashora **Consultant Endocinology and Diabetes**	**Advice to use not more than 10 patients/clinic. And should left on shelf to recover for 24 hrs.** **Usually shared in clinic and kept on shelf only.**
Dr John Winer **Consultant Neurologist**	**I have a filament but I never use it!**

Dr Frances Game **Consultant Diabetologist**	**They usually live in the clinic environment and are shared. They are only carried in pockets as they are small and tend to disappear.** **The filaments should be rested every 100 applications (10patients 10 sites per patient = 1 day) for 24 hours and depending on the type of monofilament may need replacing every few weeks (see Booth and Young, D Care 2000 Diabetes Care 23:984–988)**