Diabetic Footcare

Consultation on draft guideline - Stakeholder comments table
07/01/15 to 04/03/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	**Comments** Please insert each new comment in a new row	**Developer's response** Please respond to each comment
All Party Parliamentary Group on Vascular Disease	NICE	10	1.4.1	We support the recognition that referral for people with an active diabetic foot problem to the foot protection service or MDT within 24 hours. All commissioners should have a sub-24 hour policy to refer patients with suspected CLI to a MDT. Time is of the essence with this condition, and increased delay in treatment increases the risk of amputation.	Thank you for your response. Critical limb ischaemia is an important consideration however it falls outside the scope of this guideline. The management of critical limb ischaemia is covered by the recommendations from NICE CG147 on the diagnosis and management of lower limb peripheral arterial disease. We recognise the importance of good management of peripheral arterial disease and its relevance to this guideline. Therefore we have added in extra emphasis on the importance of good management of this condition in the introduction section with cross references to NICE CG147 there and within the recommendations.
Podiatry North West Clinical Effectiveness Group for Tissue Viability, Diabetes and Peripher	Full	10 & general	14 & general	Term 'diabetic foot ulcer' is first used here and referred to repeatedly throughout the document and makes recommendations specifically about a diabetic foot ulcer. It is important that the guideline define what is meant by the term diabetic foot ulcer in the same way as pressure ulcer NICE guidance defines a pressure ulcer.	Thank you for your response. In agreement with the guideline development group the following definition has been written and is added to the introduction section: "A foot ulcer can be defined as a localised injury to the skin and/or underlying tissue, below the ankle, in a person with diabetes." A glossary definition has also been added in the full version.

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al Arterial Disease					
Staffordshire & Stoke on Trent Partnership NHS Trust	NICE	10	14	Moderate risk – no list of risk factors	Thank you for your response. In the recommendation (1.3.4 NICE version) on the assessment of the feet of someone with diabetes, we have added clarification that the bullet pointed list refers to risk factors which are also referenced in the risk stratification recommendation (recommendation 1.3.6 NICE version).
British Infection Association	NICE	10	2	High risk- also to include previous osteomyelitis	Thank you for your response. If a patient gets osteomyelitis as a result of a diabetic foot problem they will have experienced a foot ulcer first (and people who have had previous ulcer are included in the high risk group).
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	10	General Section **"Assess the person's risk of**	The document copies other guidance in including under this heading people with an "active foot problem". An active foot problem cannot be a category of risk for developing one. The associated text is concerned not with prevention but with management. It really needs a new subheading. The same issue applies to the bullet point immediately below – the second from the bottom of the page. It is illogical to include a statement such as "Refer people with an active diabetic foot problem" under a	Thank you for your response. The guideline development group has clarified this recommendation by adding "Assess the person's current risk of an amputation or of developing a diabetic foot problem using the following risk stratification." By including the list of active foot problems in the risk stratification recommendation (1.3.6 NICE version) we are showing that active foot problems can be considered risk factors for amputation. As such they can be included with the list of other risk factors. Thank you for your point about

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			developing a foot problem"	heading which reads "Assessing the risk of developing a diabetic foot problem".	the incorrect heading on the bullet point below. This error has been corrected.
Staffordshire & Stoke on Trent Partnership NHS Trust	NICE	11	12	Diabetic foot infection – advocates moist wound dressings however felt that this should state 'follow local protocols'	Thank you for your response. The guideline development group agrees that the recommendation for moist wound dressing would not apply in all situations. The recommendation has been changed to say "wound dressing" for clinicians to be able to choose wound dressings as appropriate (or according to local existing protocols).
Staffordshire & Stoke on Trent Partnership NHS Trust	NICE	11	23	'definitive treatment' what does this mean?	Thank you for your response. Definitive treatment refers to the recommendations under the heading "treatment" in the "Charcot arthropathy" section. This is perhaps more obvious in the full recommendations section of the guideline where the recommendations follow on from each other (as opposed to the key priorities for implementation section). For clarity we have reworded the recommendation to state "Offer non weight bearing treatment until definitive treatment can be started by the

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					multidisciplinary foot care service." Definitive treatment is that which is offered by the multidisciplinary foot care service.
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	11	General Section **Diabetic foot infection**	What follows the title appears to be a list of recommendations to treat diabetic foot ulcers and not diabetic foot infection In particular. The first bullet on standard care reads "Offer 1 or more" of the following aspects of standard (ie good) wound care. This could be taken to mean that one is all that is needed when the intention is to use all that are required. See also section 1.5.4. Is the intention to recommend "moist" wound dressings or wound dressing which maintain a moist wound healing environment as these are not the same thing.	Thank you for your response. The error in the title of the key priorities for implementation section has been corrected. After discussion, the guideline development group (GDG) felt that the term '1 or more' is appropriate. The understanding is that clinicians will use all of the methods of standard care appropriate and this is not limited to one particular treatment. The GDG agrees that the recommendation for moist wound dressing would not apply in all situations. The recommendation has been changed to say "wound dressing" for clinicians to be able to choose wound dressings as appropriate (or according to local existing protocols).
Staffordshire University	Full	118	General	We need to highlight that effective biomechanically based clinical assessments needs to be developed.	Thank you for your response. We have emphasised the importance of a biomechanical assessment but only in the patient groups considered to be of moderate and high risk of developing

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					diabetic foot problems. This was the group for which evidence of benefit was found. The need for biomechanical assessment is included in the recommendation for the required skillset available for the foot protection team and also in the recommendation of the assessment that all patients with moderate and high risk should receive. The intricacy of what makes a true biomechanical assessment and what does not was beyond the scope of this guideline.
All Party Parliamentary Group on Vascular Disease	NICE	12	1.1.2 and 1.1.4.	We support the recognition of the need for a named consultant upon referral, and upon transfer to a multidisciplinary foot care team. This should be extended to ensure that there is a named contact person in all hospitals/within community teams 24 hours a day who is a member of the MDT in case of emergencies.	Thank you for your response. In response to comments regarding the management of diabetic foot emergencies, the guideline development group (GDG) have recrafted a recommendation to ensure that those with a life or limb threatening emergency receive the appropriate care. The recommendation now states: 1.1.1 If a person has a limb-threatening or life-threatening diabetic foot problem, refer them immediately to the multidisciplinary foot care

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					service or acute services (according to local protocols and pathways; also see recommendation 1.2.1), so they can be assessed and an individualised treatment plan put in place. Examples of limb-threatening and life-threatening diabetic foot problems include the following: • Ulceration with fever or any signs of sepsis. • Ulceration with limb ischaemia (see the NICE guideline on lower limb peripheral arterial disease). • Clinical concern that there is a

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					deep-seated soft tissue or bone infection (with or without ulceration). • Gangrene (with or without ulceration). The GDG recognised the need to protect these emergency cases by ensuring that they receive immediate care but also wanted to ensure that the recommendations should not be made too difficult to implement. The GDG considered that in some services it may not be possible to have a contact member of the multidisciplinary foot care service (MDFS) available 24 hours, 7 days a week. As a result these persons may be initially seen by acute services or the MDFS depending on local protocols and whether the person presents out of hours or not. Please note that we have also written the following recommendation ensuring that these patients should receive a 24 hour referral to the MDFS if admitted through acute services with a diabetic foot problem as a dominant clinical factor for inpatient care:

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					1.1.3 Refer the person to the multidisciplinary foot care service within 24 hours of the initial examination of the person's feet. Transfer the responsibility of care to a consultant member of the multidisciplinary foot care service if a diabetic foot problem is the dominant clinical factor for inpatient care.
Bard Limited	NICE	12	14	All commissioners and providers should have a clear pathway for patients suspected of increased risk of Peripheral Arterial Disease and the diabetic foot is pathway must be made standard practice, and the route that patients are referred to a hospital with Critical Limb Ischaemia should be rapid, clear, and properly understood by all healthcare workers from primary care up to specialist care should be channelled down to GPs practices, and up to provider hospitals. They should also have a policy for referral to a Multi-Disciplinary Team with clear links to secondary care. Many CCGs reported having no policy on either.	Thank you for your response. Critical limb ischaemia is an important consideration however it falls outside the scope of this guideline. The management of critical limb ischaemia is covered by the recommendations from NICE CG147 on the diagnosis and management of lower limb peripheral arterial disease. We recognise the importance of good management of peripheral arterial disease and its relevance to this guideline. Therefore we have added in extra emphasis on the importance of good management of this condition in the introduction section with cross references to NICE CG147 there and within the recommendations.
Staffordshire & Stoke on	NICE	12	15 (1.1.	Wording is 'vague'	Thank you for your response. This recommendation was carried over from the previous guideline, NICE CG119. The

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Trent Partnership NHS Trust			2)		wording must remain non-specific as this recommendation affects an inpatient presenting for any reason. The aim is to prevent a patient from receiving delayed care while they await the multidisciplinary foot care service. Naming a consultant as responsible will ensure prompt treatment by that person until, if appropriate, the multidisciplinary foot care service should be required to take over care.
Foot in Diabetes UK & College of Podiatry	NICE	12	19	The term MDT was used in CG119 however for consistency in the new guideline **MD Service** should be used	Thank you for your response. It has been noted that the term "team" remains in many parts of the guideline and these have been changed to 'service.'
Foot in Diabetes UK & College of Podiatry	NICE	12	5	Would it be easier to state that it relates to everyone with diabetes? Rather than describe each age group?	Thank you for your suggestion. The preface mentioned is necessary in order to ensure that people do not assume some recommendations apply to children and others do not. If we replace with "all people with diabetes," the emphasis on applicability to all ages may be lost.
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	12	General and 1.1.3 **"mu**	The document has introduced the welcome term, "multidisciplinary foot care service" – to complement the already used "foot protection service". The word "service" more accurately represents the facility that is intended. On this page, however, there are two places where the old term, "team" is	Thank you for your response. We agree that we should be more consistent with the terminology here. Changes have been made to the NICE guideline and full guideline and the term "team" replaced with "service."

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			ltidisciplinary footcare team"	used – presumably by mistake.	
University of Nottingham	Full	129	3 Table 39	Wholly agree and support the GDGs view that the outcomes of paramount importance in managing people with foot ulcers are promoting healing and reducing re-ulceration risk.	Thank you for your response.
Diabetes UK	NICE	13	1.2	This may not be the correct heading as this should include people's own homes where required and in residential care – these are not "healthcare settings" as such. The list that follows might specify residential and domiciliary settings (as on page 55 in full guideline)	Thank you for your suggestion. The scope does actually define settings as "all settings where NHS healthcare is commissioned or delivered," The word "healthcare" has been removed to make "Care across all settings" a less specific title above this section.
Cardiff and Vale UHB	NICE	13	1.2.1	Agree with recommendations but perhaps clarity on definition of community. Need to ensure all outreach settings have access to same level of care e.g. prisons. (partly covered by 1.2.4)	Thank you for your suggestion. The guideline development group discussed the addition of the word "prisons." In order to avoid listing a number of institutions by name it was felt that the recommendation could be reworded to state: "Healthcare professionals may

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					need to discuss, agree and make special arrangements for disabled people and people who are housebound or living in care settings, to ensure equality of access to foot care assessments and treatments." Thereby covering all settings in which care may be received, including prisons.
Cardiff and Vale UHB	NICE	13	1.2.3	A comprehensive MDFT, have the group considered the dietician for nutritional input, essential for wound healing and the role a physiotherapist might play in rehabilitation previously immobilised patients, specifically Charcot patients and those at risk to falls.	Thank you for your suggestion. The addition of rehabilitation services and a dietitian was discussed by the guideline development group who agreed that a further recommendation could be drafted to state that: "The multidisciplinary foot care service should also have access to rehabilitation, plastic surgery, health psychology and nutritional services."
Staffordshire & Stoke on Trent Partnership NHS Trust	NICE	13	17 (1.2.2)	No mention of district nurses and practice nurses being part of the foot protection team	Thank you for your suggestion. The addition of district nurses and practice nurses was discussed by the guideline development group who decided that the previous reference to "tissue viability" had been too specific and the wording was changed to: 1.2.2 The foot protection service should be led by a podiatrist with specialist training in diabetic foot problems, and should have access to healthcare professionals with skills in the following

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					areas: • Diabetology. • Biomechanics and orthoses. • Wound care. "Wound care" should now encompass the skill set of tissue viability and the required nursing care.
Staffordshire & Stoke on Trent Partnership NHS Trust	NICE	13	23 (1.2.3)	Psychologist should be included in this list	Thank you for your suggestion. The addition of psychologists was discussed by the guideline development group who agreed that a further recommendation would be drafted to state that: "The multidisciplinary foot care service should also have access to rehabilitation, plastic surgery, health psychology and nutritional services."
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	13	General Section ***"Care across all healthcare***	As other sections of the guidance (eg 1.4.1) include the recommendation that some problems should be referred for expert assessment to the foot protection service and some to multidisciplinary foot care service, the first bullet should be qualified in some way, such as by including the word 'selected': "…managing selected diabetic foot problems…". This would reflect the need for the protocols spelled out in the third bullet of this section. The second bullet introduces a new concept of problems "that cannot be managed by	Thank you for your response. The guideline development group (GDG) recognised the variability in level of care possible in foot protection services across the country. The GDG wanted to enable these services to treat the diabetic foot problems (for example healing foot ulcer <2cm in diameter) that they can while recognising that some diabetic foot protection services may not be able to treat any active diabetic foot problems. In these cases the multidisciplinary foot care service would still take over care under

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			settings" **1.2.1**	the foot protection service". There are a number of reasons why a particular person might be best managed by one or other service and the inclusion of this phrase is restrictive and would be better omitted. The actual criteria will be specified in the local protocols mentioned in the third bullet.	the recommendation that the multidisciplinary foot care service "manages the diabetic foot problems that cannot be managed by the foot protection service." The phrase "diabetic foot problems in the community" helps describe the types of problems that could potentially be managed by the foot protection service, including patients discharged from secondary care under multidisciplinary foot care services. The types of diabetic foot problem that must be referred to the multidisciplinary foot care service or acute services are outlined in further recommendations. The use of the term "selected" was discussed by the GDG who felt that it was not helpful and may raise more questions. The GDG agree that it will fall to the local protocols to define who can and cannot be treated by their foot protection services. Recommendations 1.4.1 and 1.4.2 refer back to the idea that the protocols and pathways will decide who can be managed by either service. Since the GDG have not stipulated who cannot be managed by the foot protection service (beyond acute Charcot foot and the emergency problems listed in 1.4.1)

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					the group did not agree that they were being overly restrictive here.
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	13	General Section ***"Care across all healthcare settings"*** **1.2.2**	The requirement that the FPS 'should' be led by a podiatrist is unnecessarily prescriptive. It will certainly apply in the majority of cases but not perhaps in all – especially if the relationship between community podiatry and other members of the footcare service becomes stretched by AQP. It would be better if 1.2.2 was made equivalent to 1.2.3 by stating that the service should be led simply by "a named and appropriately skilled healthcare professional".	Thank you for your response. The guideline development group chose podiatry to lead the foot protection service and this was decided on consensus based on the fact that a specialist podiatrist would be the healthcare professional best placed to triage across all services applicable to diabetic foot patients. We risk making the composition of a foot protection service unclear by suggesting a named and appropriately skilled healthcare professional should lead. Undoubtedly the service should have a lead to co-ordinate care and the GDG felt strongly that podiatry were the only specialty that would adequately be able to provide this role. This may not be the case for the multidisciplinary foot care service where the lead may be a diabetologist or a vascular surgeon. In order to encourage consistency of care it seems appropriate to continue to recommend a podiatrist lead although we recognise that there may be some challenges for implementation to meet the increased need for such podiatrists.

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University of Nottingham	Full	130	3 -12	Disagree that the way to achieve improved healing and reduction in reulceration is through information alone. Once again, the evidence regarding the effects of psychological and behavioural factors (e.g., low mood, coping, illness beliefs, adherence) on ulcer healing and reulceration and ulceration rates should encourage the GDG to make specific research recommendations regarding the development and evaluation of psychobehavioural interventions which focus on these modifiable factors (eg patient beliefs) and not information. Furthermore, it is suggested that research in this area should not focus only on interventions that can deliver behaviour change but which seek to achieve long-term maintenance of such change.	Thank you for your suggestion. The guideline development group discussed the suggestion for further research in this area and agreed that it could be beneficial. As such the research recommendation for education has been amended to include the development and use of psycho-behavioural interventions. After voting on their highest priorities for research the guideline development group also decided that this research recommendation should appear both in the full guidance and in the NICE version.
Staffordshire & Stoke on Trent Partnership NHS Trust	NICE	14	17 (1.3.2)	Young people with diabetes local training need identified	Thank you for your response.
EAST MIDLANDS DIABETI	NICE	14	General Sect	"The paediatric care team or the transitional care team should carry out an annual assessment of their feet and provide education about foot care". There is no	Thank you for your suggestion. There was very little evidence identified at all for this age group and as a result recommendations were made on

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C FOOT GROUP			ion ***Assessing the risk of developing a diabetic foot Problem 1.3.2***	evidence that education is effective in reducing the risk of the development of foot disease, particularly in this age group. The latter statement should be removed.	consensus with the guideline development group (GDG). The GDG considered that, based on their collective experience, there was value in educating young people about the benefits of proper foot care as a part of the education about good diabetes management. This would ease transition into adult care where they would need to be aware of the importance of good foot care.
Cardiff and Vale UHB	NICE	15	1.3.4	Had the group considered a foot examination could include joint mobility and muscle strength? This gives us the ability to assess their risks not just to ulceration but falls.	Thank you for your response. Risk of falls is not within the scope for this guideline and we had to restrict assessment guidance to those aspects particularly applicable to diabetic foot problems. Assessment for risk of falling is covered in NICE guideline CG161 Falls: assessment and prevention of falls in older people.
Podiatry North	NICE	15	1.3.5	'Interpret ankle brachial pressure index results carefully because calcified arteries	Thank you for your response. The use of ankle brachial pressure index for the

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West Clinical Effectiveness Group for Tissue Viability, Diabetes and Peripheral Arterial Disease				may falsely elevate results' As NICE PAD CG 147 is advocating the use of ABPIs asking for careful interpretation may lead to the discouragement of or discontinuation of this assessment modality. Would it not be better to advocate that ABPIs should not be used in isolation and need interpreting in context of clinical picture and symptoms	diagnosis and management of peripheral arterial disease is covered in NICE clinical guideline CG147 and we must defer to this guideline with regards to this test. Recommendation 1.3.5 was drafted to highlight that calcification of the arteries may falsely elevate results in diabetic patients. This was included because the issue is specific to the diabetic population and not mentioned by CG147. The ankle brachial pressure index must continue to be used as recommended for peripheral arterial disease in CG147. To make this clearer we have added a cross reference to CG147 within the recommendation: 1.3.5 Use ankle brachial pressure index in line with the NICE guideline on lower limb peripheral arterial disease. Interpret results carefully because calcified arteries may falsely elevate results. Otherwise, the guideline development group did not feel that the need to interpret results carefully (i.e. in view of the clinical picture) would discourage its use.
The Vascular	NICE	15	1.3.5	Ankle Brachial Pressure Index (ABPI). For the vascular aspect of in hospital diabetic	Thank you for your response. The use of ankle brachial pressure index for the

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Society				foot problems this is the area that causes confusion. The falsely elevated ABPI is often used as a general warning, but no specific advice is given. Some detail in the guideline about what teams should do in relation to the ABPI is required.	diagnosis and management of peripheral arterial disease is covered in NICE clinical guideline CG147 and we must defer to this guideline with regards to this test. Recommendation 1.3.5 was drafted to highlight that calcification of the arteries may falsely elevate results in diabetic patients. This was included because the issue is specific to the diabetic population and not mentioned by CG147. The ankle brachial pressure index must continue to be used as recommended for peripheral arterial disease in CG147. To make this clearer we have also added a cross reference to CG147 within the recommendation: 1.3.5 Use ankle brachial pressure index in line with the NICE guideline on lower limb peripheral arterial disease. Interpret results carefully because calcified arteries may falsely elevate results. Otherwise, the guideline development group did not feel that the need to interpret results carefully (i.e. in view of the clinical picture) would discourage its use. Other aspects relating to the diagnosis

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					and management of peripheral arterial disease fall outside the scope for this guideline.
British Infection Association	NICE	15	1.3.6	High risk- also to include previous oste0myelitis	Thank you for your suggestion. As the definition stands, people with previous foot ulcers are included in the high risk group along with those who have had a previous amputation. It seems unlikely that a person would get osteomyelitis secondary to diabetic foot without first developing a foot ulcer.
Cardiff and Vale UHB	NICE	15	1.3.6	Good to see Renal added as high risk and disabled adults in the moderate risk. To avoid confusion with the putting feet first pathway should the painful peripheral neuropathy still be in the active.	Thank you for your response. The guideline development group reviewed the evidence for the most effective risk stratification tools and recommended SIGN and therefore chose to stick closely to the approved criteria in this guidance with the exception of including renal disease as these patients need special consideration. With regards to the management of painful peripheral neuropathy we defer to NICE guideline CG173 **"**The pharmacological management of neuropathic pain in adults in non-specialist settings," referenced in the "other related NICE guidance" section.
Bard Limited	NICE	15	12	Ensuring patients receive an ABPI test as part of the early diagnostic and on-going care program in a hospital outpatient setting	Thank you for your suggestion. The use of ankle brachial pressure index for the diagnosis and management of peripheral

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				is key to reducing complications from peripheral arterial disease, reducing the number of lower limb amputations and highlighting overall cardiovascular wellbeing. We feel that if the ABPI test was included routinely it would make a difference to patient experience and outcomes. The ABPI test could also be included in regular diabetes foot checks, or when monitoring those individuals known to be at risk from peripheral arterial disease. By doing this it would provide a wider level of visibility which then would depend on expert interpretation.	arterial disease is covered in NICE clinical guideline CG147 and we must defer to this guideline with regards to this test. Recommendation 1.3.5 was drafted to highlight that calcification of the arteries may falsely elevate results in diabetic patients. This was included because the issue is specific to the diabetic population and not mentioned by CG147. To make this clearer we have also added a cross reference to CG147 within the recommendation. Other aspects relating to the diagnosis and management of peripheral arterial disease fall outside the scope for this guideline.
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	15	General **1.3.6**	See Comment 3, above. An active foot problem is not a risk factor for developing one. (comment ID51)	Thank you for your response. The guideline development group discussed the fact that active diseases were listed under this heading. It was decided to amend the wording in the heading to clarify that this was a list of risk factors not only for active disease but for amputation also.
Cardiff and Vale UHB	NICE	16	1.3.10	Although the group felt this wouldn't be too hard for the services to meet, does throw up challenges by the fact it requires sufficient enough information when received to make an initial assessment to whether moderate or high.	Thank you for your response. The guideline development group felt that it should be within the capability of the services involved to perform sufficient enough an examination to assess the risk in recommendation 1.3.6. This

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					examination (recommendation 1.3.4.) should be all that is required to appropriately categorise a person's risk.
Autonomed Limited	NICE	16	1.3.9	1.3.9 Amend from "□□*Assess the biomechanical status of the feet, including the need to provide specialist footwear and orthotics"* to: □□*Assess the biomechanical status of the feet, including the need to provide specialist footwear.* □□*Prescribe orthotics clinically proven to increase tissue perfusion and reduce peak pressures.*	Thank you for your response. The guideline development group reviewed evidence from trials including the use of bespoke and off the shelf footwear and have chosen to recommend it where appropriate in the management of those at moderate and high risk of developing a foot problem. The GDG did not feel able to go further than this as the evidence does not point to recommending a particular brand of orthoses. Furthermore the GDG had to be selective with the clinical outcomes of interest. Paramount to knowing if a prophylactic therapy would be clinically effective was to know if the intervention prevents the occurrence of ulcers or amputation. Outcomes such as peak pressure and increase to tissue perfusion were beyond the protocol of that particular review.
Cardiff and Vale UHB	NICE	16	1.3.9	Would not stipulate 'provide skin and nail care' would prefer to see given educational advice and individual treatment plan put into	The guideline development group looked at the evidence on podiatry and chiropody care which was of poor quality

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				place based on need.	and inconclusive. This was considered to be a reflection on the scarcity of evidence and not evidence of lack of effect. By consensus the GDG decided that the provision of nail and skin care is already part of the standard care provided by podiatrists and was received as standard care in many of the other studies that were examined. The evidence for educational programmes was not found to be effective when compared to a good standard level of education in clinical practice. The educational advice needs for these patients are laid out under the heading "Patient information and support for people at risk of developing a diabetic foot problem."
Sheffield Teaching Hospitals	NICE	16	19	It is not reasonable to expect the foot protection team (Podiatry) to routinely liaise with the GP re diabetes management and risk of CVS events. The only circumstance in which this would be appropriate would be the new detection of peripheral vascular disease in patients not already on an antiplatelet	Thank you for your response. The guideline development group (GDG) noted that they had recommended that the foot protection service should have access to healthcare professionals with skills in diabetology. The GDG considers that it is reasonable that the foot protection service takes a holistic view of the patient care including cardiovascular risk, management of diabetes and communicating with the patient's GP.
Autonomed	NICE	17	1.3.12	1.3.12 Amend from *"Information should include the following"* to	Thank you for your response.

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Limited				*"Information/action should include the following"* Amend from "□□*Footwear advice."* to: □□*Footwear advice and the prescription of orthotics clinically proven to increase tissue perfusion and reduce peak pressures.*	The guideline development group reviewed evidence from trials including the use of bespoke and off the shelf footwear and have chosen to recommend it where appropriate in the management of those at moderate and high risk of developing a foot problem. The GDG did not feel able to go further than this as the evidence does not point to recommending a particular brand of orthoses. Furthermore the GDG had to be selective with the outcomes of interest. Paramount to knowing if a prophylactic therapy would be clinically effective was to know if the intervention prevents the occurrence of ulcers or amputation. Outcomes such as peak pressure and increase to tissue perfusion were beyond the protocol of that particular review.
Diabetes UK	NICE	17	1.4.1 and 1.4.2	We are concerned that there is no guidance on timescales for actually assessing and treating an acute foot problem – the 2011 guidance on referring within 24 hours for triage is the only guidance here and has not been updated. We would like to see it made clear that people should be assessed and treated within 2 working days if they have active foot disease which is an acute	Thank you for your response. The guideline development group discussed the need to define when a patient with active foot disease and active foot disease which is an emergency should be triaged and treated by. The following two recommendations were drafted: 1.4.1 If a person has a limb-threatening

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				emergency – this is specified in some local protocols, but should be recognised as a clear recommendation here, in order to remedy the wide variation in outcomes for people with diabetes.	or life-threatening diabetic foot problem, refer them immediately to the multidisciplinary foot care service or acute services (according to local protocols and pathways; also see recommendation 1.2.1), so they can be assessed and an individualised treatment plan put in place. Examples of limb-threatening and life-threatening diabetic foot problems include the following: • Ulceration with fever or any signs of sepsis. • Ulceration with limb ischaemia (see the NICE guideline on lower limb peripheral arterial disease). • Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). • Gangrene (with or without ulceration). 1.4.2 For all other active diabetic foot problems, refer the person within 1 working day to the multidisciplinary foot care service or foot protection service (according to local protocols and pathways; also see recommendation 1.2.1) for triage within 1 further working day.

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Medtronic Limited	NICE	17	1.4.2	This guideline should highlight the fact that amputation must be seen as a failure to treat effectively rather than a routine treatment option. We suggest that the guideline specifically directs the MDT towards their end goal of minimising the risk of amputation. Whilst each local team may have a different strategy, there should be one unified goal across the healthcare system. We request that the following bullet in bold below (or similar wording) is added to 1.4.2 in order to address this point: • **"A key outcome of early referral is to reduce the outcome of amputation.** • If any of the following active diabetic foot problems are present, refer the person to the multidisciplinary foot care service within 24 hours so they can be assessed and an individualised treatment plan put in place according to local protocols"	Thank you for your response. Throughout the full guideline in the "linking evidence to recommendation" tables we make clear that the primary outcome is to prevent foot ulcers and, should this fail, the next best outcome is the promotion of ulceration healing. The GDG agrees that amputation is an avoidable complication. When making recommendations there must be a defined action and "A key outcome of early referral is to reduce the outcome of amputation," does not recommend a specific course of action. We hope that our recommendations overall reflect the same purpose, to primarily prevent both ulceration and amputation in patients with diabetes.
Staffordshire & Stoke on Trent	NICE	17	12 (1.3.12)	Patient information 'should be verbal and written' to be included	Thank you for your response. This suggestion has been added to both recommendations on giving information.

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Partnership NHS Trust					
Diabetes UK	NICE	17	General	This would appear to be a list of the information that everyone with diabetes should receive at an annual foot review – rather than just those "at risk" as the heading implies? We would like to see three headings and lists: - - information and support that everyone with diabetes should receive at annual foot review (survey evidence to Diabetes UK suggests that people do not always get any advice about footcare and prevention at annual foot review) It is most important that everyone is told what their level of risk is and what that means - information and support that those at risk should receive at annual foot review (if relevant) and from foot protection service - Information and support for those with an active foot problem	Thank you for your response. The heading has been reworded to state "patient information about the risk of developing a diabetic foot problem". The information recommendations include the need to inform the person of their own individual risk of developing a foot problem and the need for this information to be given at diagnosis of diabetes. The information requirements apply to whoever performs the review and this may be the foot protection service or the general practitioner but the information needs remain the same. Elsewhere in the guidance we have defined the information needs of those who have developed a diabetic foot problem.
Autonomed Limited	NICE	18	1.4.3	1.4.3 Amend from *"Information should include the following"* to *"Information/action should include the following"*	Thank you for your response. The guideline development group reviewed evidence from trials including

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				Amend from "□□*Footwear advice.*" to: □□*Footwear advice and the prescription of orthotics clinically proven to increase tissue perfusion and reduce peak pressures.*	the use of bespoke and off the shelf footwear and have chosen to recommend it where appropriate in the management of those at moderate and high risk of developing a foot problem. The GDG did not feel able to go further than this as the evidence does not point to recommending a particular brand of orthoses. Furthermore the group had to be selective with the outcomes of interest. Paramount to knowing if a prophylactic therapy would be clinically effective was to know if the intervention prevents the occurrence of ulcers or amputation. Outcomes such as peak pressure and increase to tissue perfusion were beyond the protocol of that particular review.
Sheffield Teaching Hospitals	NICE	18	15	Suggest 'consider' including pictures of diabetic foot problems rather than 'should'	Thank you for your response. The stipulation to show pictures for diabetic foot problems was based on evidence reviewed under the section on management strategies for those with diabetic foot problems. This was found to be part of an effective educational programme and after discussion the guideline development group did not feel that the recommendation should be downgraded to a weaker wording. This

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					was because it should not be too difficult to get a hold of pictures (online for example) and some patients respond better to visual information.
Staffordshire & Stoke on Trent Partnership NHS Trust	NICE	18	15 (1.4.3)	Pictures of diabetic foot problems – this has been shown to be ineffective in prevention of problems	Thank you for your response. The stipulation to show pictures for diabetic foot problems was based on evidence reviewed under section on management strategies for those with diabetic foot problems (section 4.9 full guideline). This was found to be part of an effective educational programme and after discussion the guideline development group did not feel that the recommendation should be removed. This was because it should not be very difficult to get a hold of pictures (online for example) and some patients respond better to visual information as presented in the evidence reviewed. Please note it is recommended for those who have developed a diabetic foot problem in order to prevent further diabetic foot problems.
Foot in Diabetes UK & College of Podiatry	Full	18	18,19	specify residential and domiciliary settings (as on page 55)	Thank you for your suggestion. The scope does actually define settings as "all settings where NHS healthcare is commissioned or delivered," The word "healthcare" has been removed to make "Care across all settings." We have also

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					recommended that: 1.2.5 Healthcare professionals may need to discuss, agree and make special arrangements for disabled people and people who are housebound or living in care settings, to ensure equality of access to foot care assessments and treatments.
Podiatry North West Clinical Effectiveness Group for Tissue Viability, Diabetes and Peripheral Arterial Disease	Full	18	32	'use a 10g monofilament to assess sensation' Previous guidelines have advocated specific makes of monofilament as these were the ones the evidence based was produced from.	Thank you for your response. The majority of the studies specified a 10g monofilament or Semmes-Weinstein 5.07 monofilament which is also a 10g monofilament.
Podiatry North West Clinical Effective	Full	18	32	10g monofilament use only for neuropathy assessment is only 91% specific in diagnosing neuropathy, therefore 9% of patients may be given false-positive results for neuropathy assessment (Pham et al,	Thank you for your response. The paper by Pham et al (2000) was also included in the current version of this guideline and the evidence discussed. The paper by Pham et al was one of 10 studies

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ness Group for Tissue Viability, Diabetes and Peripheral Arterial Disease				2000, used in previous NICE guidance). Although a useful tool in diagnosing should it not be advocated that symptomatic neuropathy should be fully investigated even if 10g monofilament test positive?	examined looking at the use of a 10g monofilament. The recommendation made was discussed by the guideline development group and it was agreed that, based on the review that we performed, it was not possible to rule out other ways of testing for neuropathy. As a result the recommendation (1.3.4) concerning the use of monofilament has been weakened to ensure that a full examination is performed but that a monofilament examination should form a part of this examination: • When examining a person's feet, remove their shoes, socks, bandages and dressings, and examine both feet for evidence of the following: □ Neuropathy (use a 10 g monofilament as part of a foot sensory examination). […]
Diabetes UK	Full	18	9	Whilst it is recommended that hospitals have a care pathway for people with diabetic foot problems and that adults with diabetes should have their risk assessed of developing a diabetic foot problem on any admission to hospital (line 28), there is no recommendation made about the action to be taken for people assessed to have medium / increased risk. We would urge the	Thank you for your suggestion. Recommendation 1.3.3 states that for adults with diabetes, assess their risk of developing a diabetic foot problem at the following times: when diabetes is diagnosed, at least annually thereafter, if problems arise, and on any admission to hospital.

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				inclusion of a recommendation to ensure foot protection for inpatients assessed at increased risk of foot problems. The National Diabetes Inpatient Audit (NADIA) in 2013 revealed that 1.4% of inpatients with diabetes developed a new foot lesion whilst in hospital. The Scottish Inpatient Diabetic Foot Audit in November 2013 revealed that: 2.4% of inpatients with diabetes developed a new foot lesion whilst in hospital, 60% who were discovered to be at risk of developing a foot ulcer did not have any pressure relief in place. In response to this the Scottish Diabetes Foot Action Group (SDFAG) has developed and launched a Check, Protect and Refer (CPR) for diabetic feet campaign to raise awareness of this problem and introduce appropriate pressure relief to prevent avoidable foot ulcers.	The point raised here was discussed with the guideline development group who felt that it identified a gap and the following recommendation was drafted in response: 1.3.12 People in hospital who are at moderate or high risk of developing a diabetic foot problem should be given a pressure redistribution device to offload heel pressure. On discharge they should be referred or notified to the foot protection service.
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	19	**1.5.2**	'Area' needs to be included in the list of features covered by the SINBAD classification.	Thank you for your response and for pointing out this error. It has now been corrected in the NICE and Full versions of the guidance.
Cardiff and Vale	NICE	19	1.5.4	Would suggest treatment should consist of as a bare minimum an assessment for	Thank you for your response. The recommendation covers pressure relief

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UHB				treatment of vascular, infection and pressure relief (VIP) and offer other treatments to aid the healing to include debridement and wound management dressings	through offloading, debridement and wound dressings. The management of infection is covered elsewhere in the recommendations and the control of ischaemia is covered by the NICE guideline CG147.
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	19	**1.5.5**	The word 'ischaemic' should be removed. It should be assumed that the professionals involved in deciding to use a non-removable cast are aware of the risks. The risks are only relative in any case and the inclusion of a blanket prohibition – especially one dependent on a term like 'ischaemic' which is difficult to define or measure in clinical practice – is unwise in guidance such as this.	The guideline development group felt it was inappropriate to generalise the use of total contact casting to the broad diabetic foot ulcer population, but recognised the findings of the evidence review provided an appropriate guide. They therefore agreed that the recommendation for using total contact non-removable casting should be guided by the population identified within the evidence review namely non-infected, non-ischaemic plantar diabetic foot ulcers. Other forms of offloading are still available for use. We defer to the NICE guideline CG147 on the definition of an ischaemic limb.
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	19	**1.5.7**	The word "team" is used instead of "service". In addition, the criteria listed for choosing the debridement technique in clinical practice include other criteria. These include tenderness and, depending on the definition used, peripheral arterial disease (or ischaemia).	Thank you for your response**.** We agree that a term should be used consistently and "multidisciplinary foot care service" will be used throughout. Your suggestion for criteria in choosing the debridement technique would fall under the relevant training and skills/expertise of the healthcare professional managing the

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					persons care and did not come out of the evidence reviewed.
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	19	**1.5.9**	The only available evidence for the use of negative pressure wound therapy is for post-operative wounds. The use of the word 'offer' is not justified by the evidence. The relevant (industry-funded and selectively published) reports of NPWT deliberately obscure (a) the inclusion of post-operative wounds and (b) the definition used for healing. This can be missed by systematic reviews conducted by people who do not work in the field. The intervention is not recommended by systematic reviews conducted by experts (eg Game et al, Diabetologia 2012, Dumville et al Cochrane collaboration 2013). There may be an evidence-based case for considering NPWT after *surgical* debridement but not after non-surgical debridement.	Thank you for your response. The guideline development group discussed the issues raised around negative pressure therapy and reviewed evidence presented for negative pressure therapy from both Blume et al and Armstrong et al. In agreement that negative pressure wound therapy is not used in general practice except after surgical debridement, the wording of the recommendation has been changed in line with this to state: 1.5.9 Consider negative pressure wound therapy after surgical debridement, on the advice of the multidisciplinary foot care service.
Bard Limited	NICE	19	12	Referral for revascularisation either by endovascular or open vascular intervention should be included and an option under control of ischaemia with the intent to address healing ulcers	Thank you for your response. Aspects relating to the management of peripheral arterial disease are covered by the NICE clinical guideline CG147 on the management of lower limb peripheral arterial disease.
Northern Diabetes Footcare Network	Full	19	14 -27	If page 19 summary section 14 – 27 is adopted this will require a Tier 3 Foot Protection Service / Wound Care Service in place.	Thank you for your response. Rather than dictating the need for all diabetic foot protection services to manage active diabetic foot problems in the community,

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				Triage of active foot disease for direction to Foot Protection and MDT services will work provided that local pathways are concordant with the North England Diabetes Footcare Network Active Foot Disease Pathway in that referrals are made to the Foot Protection Tier 3 (Hospital setting) service or Multi-Disciplinary Team tier 3 services. Both these tier 3 foot services have staff experienced / specialised to assess / identify which type of active foot disease is most suitable for which service By creating active foot disease caveats as to what is suitable for a MDT Service further strengthens the requirement of Vascular Services in the MDT & / or development of pathways - timelines for advanced vascular assessment (angiography). Foot Protection Tier 3 together with MDT will usually have relevant ancillary services e.g Radiology / Microbiology / Orthotist / Offloading etc. Neuropathic ulceration without deep tissue infection would come under remit of the foot protection team – more appropriate for tier 3 rather than tier 2 (community) due to services they can offer.	the guideline development group recognised the variability in level of care possible in foot protection services across the country. As a result the group wanted to enable foot protection services to treat the diabetic foot problems (for example healing foot ulcer <2cm in diameter) that they can but must also recognise that some diabetic foot protection services may not be able to treat any active diabetic foot problems. In either case the multidisciplinary foot care service should take over care where the foot protection service is not able to manage. It is up to local protocols to define this relationship as stated in recommendation 1.2.1, 1.4.1 and 1.4.2. Recommendations have been reworded for clarity and now refer back to recommendation 1.2.1. Following discussion of the recommendations for 24 hour referral the guideline development group redrafted recommendations using the term "working day" in preference to 24 hours: 1.4.1 If a limb or life threatening diabetic foot problem refer the person to the multidisciplinary foot care service or acute services immediately (according to

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				Statement is not concordant with the nationally adopted April 2012 Putting Feet First Pathway where all active foot disease is referred to the MDT – Putting Feet First Pathway will require amendment. However if the new guideline is classing foot protection service as community (Tier 2 on the region pathway) I feel this may: • Require up skilling of staff to enable triage i.e. assessment / identification of MDT suitable patients. • Concern that some community services are in a less able position to offer 24 hour access. • Community services are usually not able to offer a range of off-loading, control of foot infection – moist wound dressings if appropriate.	local protocols and pathways; also see recommendation 1.2.1) so they can be assessed and an individualised treatment plan put in place. Examples include: • Ulceration with fever or any signs of sepsis • Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). • Ulceration with limb ischaemia (also see NICE guideline on lower limb peripheral arterial disease). • Gangrene (with or without ulceration). 1.4.2 For all other active diabetic foot problems refer (according to local protocols and pathways; also see recommendation 1.2.1) to the multidisciplinary foot care service or foot protection service urgently (within 1 working day) for appropriate triage (within 1 further working day).
Northern Diabetes Footcare Network	Full	19	3	Feel this should not be a blanket statement: this is dependent on whether the patient has social / health care support in place e.g. carer / relative to inspect feet daily as with all patients with visual acuity / mobility problems / disabilities.	Thank you for your response. The guideline development group discussed and agreed that this was too broad a statement to include in the moderate risk category. Instead the guideline development group has recommended to

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					"Consider more frequent assessments for people who are unable to perform or receive foot inspection."
Podiatry North West Clinical Effectiveness Group for Tissue Viability, Diabetes and Peripheral Arterial Disease	Full	19 & general	3 & general	Does there need to be 2 separate risk factors of moderate risk and high risk? How about instead amalgamate the two to 'at risk'. Management of these 2 risk factors comes under the same bracket of foot protection team and referral onward dependant of clinical issues such as symptomatic neuropathy or peripheral arterial disease (both of which may just be moderate risk). Other recommendations where the 2 risk factors have individual outcome could then be changed e.g. 2 – 4 weeks or 6 – 8 weeks could be changed to within 4 weeks.	Thank you for your response. The benefit of splitting these patients into groups, aside from giving the clinician some idea of when risk has worsened, will also hopefully help to make the guidance easier to implement. Reducing the time to "within 4 weeks" for how soon newly referred patients must be seen, will put a greater strain on the foot protection service that will need to see all moderate risk persons quicker. This may make the targets unmanageable. For this reason, the GDG decided to maintain the existing wording.
British Foot and Ankle Surgery Society	Full	2.3.16	21	24 hours is hard to achieve especially re. Weekend admissions	Thank you for your response. The guideline states that persons should be referred within 24 hours of examination. The guideline development group felt this to be an achievable target. These recommendations were brought over from the previous guideline CG119.
EAST MIDLANDS DIABETI	NICE	20	**1.5.11**	This item should be deleted. There is no evidence to justify the use of dermal or skin substitutes as an adjunct to standard care, and none to justify the use fo the word,	Thank you for your response. The evidence reviewed did show significant improvement over the control group. The guideline development group noted the

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C FOOT GROUP				'consider'. As in point 11, this point may be missed in systematic reviews conducted by non experts in the field. The original key papers certainly demonstrated significant differences from controls but they did not highlight the fact that the performance in the control groups was unusually poor. Skin substitutes have been used widely in the USA but are now used increasingly less frequently – partly because of this and partly because they are not cost-effective (even in a remuneration based health service).	performance of control groups not only in these studies but also in many other papers that were presented. The expense of these treatments was also noted by the guideline development group who attempted to make the recommendation as conservative as possible. I.e. "consider" not "offer" and that the treatment should be given only as an adjunct to standard care, only when healing has not progressed and only on the advice of the multidisciplinary foot care service. The GDG felt that the conservative recommendation made was a good balance of the clinical evidence and experience of using skin or dermal substitutes in the NHS.
British Infection Association	NICE	20	1.6.1	Re: 1.6.1 We propose a change to section 1.6.1 to state: *If a diabetic foot infection is suspected and a wound is present, send a deep tissue sample (either soft tissue or bone sample from the base) after the wound has been cleaned and debrided for microbiological examination. If osteomyelitis is suspected, send a surgical bone biopsy.* *A superficial swab may contain surface*	Thank you for your response and for the meta analysis evidence provided. Systematic reviews were not included in this evidence review if out of date or not using the same parameters as those stipulated in the protocol (such as outcomes of interest). Observational research was gathered however only in the population of interest (i.e. Children, young people and adults with type 1 or type 2 diabetes). Nevertheless, the broader issue of superficial swab sampling was discussed with the

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				contaminants and may not represent the true cause of the deeper infection. We feel that a superficial swab may not provide useful information in the choice of antibiotic therapy for diabetic foot infections. Surface swabs may grow surface organisms and is unable to discriminate between organisms causing colonisation and infection. We looked at Clinical Guidelines from other associations worldwide that are published with regards to diabetic foot care. The International Best Practice Guidelines: Wound Management in Diabetic Foot Ulcers (2013) states that "All open wounds will be colonised with organisms, making the positive culture difficult to interpret" and "Superficial swabbing has been shown to be inaccurate as swab cultures are likely to grow surface contaminants and often miss the true pathogen(s) causing the infection." Canadian Diabetes Association Clinical Practice Guidelines on Foot Care (2013) states that "Specimens for culture from the surface of wounds, as opposed to deeper tissues obtained by debridement, are	guideline development group who amended the recommendation to state: 1.6.1 If a diabetic foot infection is suspected and a wound is present, send a soft tissue or bone sample from the base of the debrided wound for microbiological examination. If this cannot be obtained, take a deep swab because it may provide useful information on the choice of antibiotic therapy. The reference to superficial swab has been removed but the GDG consider that for smaller infected ulcers a deep swab would be the next best option. Thank you.

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				unreliable in determining the bacterial pathogens involved." Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections (2012) states "We suggest avoiding swab specimens, especially of inadequately debrided wounds, as they provide less accurate results". They do **not** advise to "obtain a specimen for culture without first cleansing or debriding the wound" and they do **not** advise to "obtain a specimen for culture by swabbing the wound or wound drainage." IDSA recommends "sending a specimen for culture that is from deep tissue, obtained by biopsy or curettage and after the wound has been cleansed and debrided." A meta-analysis in 2010 (Chakraborti C, et al) looking at the correlation between superficial wound cultures and deep tissue cultures in lower extremity infections , about half of whom are diabetic, found that the overall sensitivity was 49% (95% confidence interval [CI], 37-61%), specificity was 62% (95% CI, 51-74%), positive likelihood ratio [LR] 1.1 (95% CI, 0.71-1.5),	

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				and negative LR 0.67 (95% CI, 0.52-0.82). These demonstrate poor diagnostic utility for the use of diagnostic superficial wound swabs. Therefore, we feel that although a superficial swab specimen is convenient to obtain, it may provide inaccurate results, especially if the wound has not been cleaned and debrided. References International Best Practice Guidelines: Wound Management in Diabetic Foot Ulcers. Wounds International, 2013. Available from: www.woundsinternational.com Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections. Clin Infect Dis 2012; 54 (12): 132-173 Canadian Diabetes Association Clinical Practice Guidelines. Can J Diabetes 2013; 37 Suppl 1: S145-9 Chakraborti C., Le C. and Yanofsky, A. (2010), Sensitivity of superficial cultures in	

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				lower extremity wounds. J. Hosp. Med., 5: 415–420. doi: 10.1002/jhm.688	
Cardiff and Vale UHB	NICE	20	1.6.1	Would recommend deep swab rather than superficial if available	Thank you for your response. This issue was discussed by the guideline development group and the recommendation changed to: 1.6.1 If a diabetic foot infection is suspected and a wound is present, send a soft tissue or bone sample from the base of the debrided wound for microbiological examination. If this cannot be obtained, take a deep swab because it may provide useful information on the choice of antibiotic therapy. The reference to superficial swab has been removed in preference to a deep swab.
Sheffield Teaching Hospitals	NICE	20	24	It is not achievable in practice to always obtain soft tissue samples. Suggest tissue sample preferred option, deep swab next best option	Thank you for your response. This issue was discussed by the guideline development group and the recommendation changed to: 1.6.1 If a diabetic foot infection is suspected and a wound is present, send a soft tissue or bone sample from the base of the debrided wound for microbiological examination. If this cannot

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					be obtained, take a deep swab because it may provide useful information on the choice of antibiotic therapy. The reference to superficial swab has been removed in preference to a deep swab.
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	21	**1.6.12**	Antibiotics active against only Gram positive *cocci* (the word 'cocci' would be more precise here than 'bacteria') should usually be used in those who have not already had a course of them. Those who have been exposed to prior antibiotics are more likely to be infected with other organisms and may need an antibiotic with a broader spectrum of activity.	Thank you for your response. The guideline development group (GDG) felt the term "organism" sufficient for the purposes of the recommendation. The GDG reviewed the evidence on treatment of soft tissue infections and did not find any evidence to suggest against the use of antibiotics active against gram positive organisms in a patient who may have received such antibiotics in the past.
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	21	**1.6.4**	The inclusion of reference to a 'normal' probe to bone test implies that an abnormal probe to bone test is diagnostic. This conflicts with the published evidence from UK (Shone et al) and USA (Lavery et al) which shows that in out-patient practice, a positive probe to bone test has a specificity of only approximately 50%. This contrasts with data from in-patients in whom the pre-test probability is much higher. It would be better to remove reference to the probe to bone test from this section.	Thank you for your response. The evidence from both Shone and Lavery was included and presented to the guideline development group (GDG). The recommendation was intended to express the GDG's lack of confidence in the use of x-ray, inflammatory markers or probe to bone for diagnosis without considering the clinical picture or other investigations. In terms of which diagnostic tool should be used initially to determine the extent of infection, x-ray has been recommended in recommendation 1.6.2 with MRI to be

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					used for further investigation if required in recommendation 1.6.5.
Cardiff and Vale UHB	NICE	21	1.6.5	Would suggest adding: if not confirmed by initial and 'sequential' x-rays consider MRI to confirm diagnosis.	Thank you for your response. The guideline development group considered that this approach may not be appropriate. Radiography of the foot can be an insensitive test for detecting osteomyelitis (though still useful and readily available) and referral for MRI was considered the next best diagnostic tool (also taking into account the clinical picture). The feet of diabetic patients can deteriorate quickly in just a few weeks through delays in diagnosis and treatment, and the group felt it may not be wise to wait 2 weeks to repeat a test with low sensitivity.
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	21	**1.6.8**	The reference to sampling should be more specific, with deep spft tissue sampling required for soft tissue infection and consideration of bone niops of osteomyelitis is suspected.	Thank you for your response. This issue was discussed by the guideline development group and the recommendation changed to: 1.6.1 If a diabetic foot infection is suspected and a wound is present, send a soft tissue or bone sample from the base of the debrided wound for microbiological examination. If this cannot be obtained, take a deep swab because it may provide useful information on the choice of antibiotic therapy.

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					The reference to superficial swab has been removed in preference to a deep swab. It is noted that the clinician may not yet know how deep the infection is and therefore these recommended sampling techniques are the best options in any situation where infection is suspected. In smaller ulcers where debridement has not been necessary a deep swab is the next best option.
Kings College Hospital	Full	21	16 -19	Recommendation 3 - We believe that the guideline needs to be clear to ensure that patients have their feet checked at the point of admission or within 24 hrs of admission. As currently written, we believe it may allow for delay in examination of feet and then a further 24 hrs to refer onwards. Furthermore, We believe one of the recommendations in this section should include: 'Consider' screening all patients with diabetes being admitted for active diabetic foot problems and 'consider' risk screening and monitoring all people with diabetes admitted to hospital for potential foot problems during the hospitalization period.	Thank you for your response. Recommendation 1.3.3 states that "for adults with diabetes, assess their risk of developing a diabetic foot problem at the following times: when diabetes is diagnosed, at least annually thereafter, if problems arise, and on any admission to hospital." This should ensure that patients have their feet checked at the point of admission. The assessment will result in subsequent risk stratification and appropriate management as laid out in these guidelines. We hope that this achieves the desired effect.
Kings	Full	21	35	We believe that commissioners and local	Thank you for your response. The

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College Hospital				MDT foot service may need to identify their protocols for those with complex active foot disease (such as complex Charcot with midfoot and hindfoot deformity) and consider early referral to a centre of excellence if local services are unable to provide input with the intent of deformity stabilisation, deformity reconstruction or limb salvage.	guideline development group did not find any evidence on the referral of complex Charcot disease to centres of excellence and this seems to be a decision that would be left up to the triage of local multidisciplinary foot care services and commissioners. The group considered that the guidelines give sufficient breadth for decisions like these to be made depending on the capabilities of local services.
Diabetes UK	Full NICE	21 13	40 1.2.2	Should say biomechanics **/ orthotics** as in multidisciplinary foot care services below	Thank you for your response. The addition of a specialist in biomechanics and orthoses was agreed to clarify the original intention of the guideline development group.
Kings College Hospital	Full	21	40	Biomechanics and Orthotics (latter is important as poor footwear may lead to re-ulceration). As it stands, the delivery of acceptable orthotic service is patchy across the country.	Thank you for your response. The addition of a specialist in biomechanics and orthoses was agreed to clarify the original intention of the guideline development group.
British Orthopaedic Association	Full	21	42	The multidisciplinary foot care service should be led by a consultant physician/ Diabetologist. The fundamental requirement for healing is well controlled diabetes.	Thank you for your response. The guideline development group wanted to avoid assigning a lead to the multidisciplinary foot care service as this is likely to vary depending upon the centre. For instance some vascular centres may have a vascular surgeon as the lead. The group did not review any

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					evidence on who would be best placed to lead such a service and therefore recognise the autonomy of specialist services to place their own lead. That said the recommendation is made for an inpatient to have a "named consultant" in charge of care and timely treatment.
British Orthopaedic Association	Full	21	42	The multidisciplinary foot care service should be led by a consultant physician/ Diabetologist. The fundamental requirement for healing is well controlled diabetes.	Thank you for your response. The guideline development group wanted to avoid assigning a lead to the multidisciplinary foot care service as this is likely to vary depending upon the centre. For instance some vascular centres may have a vascular surgeon as the lead. The group did not review any evidence on who would be best placed to lead such a service and therefore recognise the autonomy of specialist services to place their own lead. That said the recommendation is made for an inpatient to have a "named consultant" in charge of care and timely treatment. We agree with your statement that the fundamental requirement for healing is well controlled diabetes.
Diabetes UK	Full	21	42 - 43	The Multidisciplinary Foot Care Service – we support the move to call this a service, but feel there should be some reference to the need for the various HCPs listed to be working together as a team.	Thank you for your response. The guideline development group (GDG) recognise that the multidisciplinary foot care service may take different forms depending upon the trust that it is within.

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					This service should have access to the specialist skills listed in recommendation 1.2.3. The service naturally will act as a team with quick referral pathways and communication between specialties depending upon the needs of the individual. We recognise that it may not always be appropriate to have all specialties present for all patients. For this reason the term "service" was felt to be preferable to "team." In relation to your comment the GDG has noted within the recommendations that the multidisciplinary foot care service may also be known as an interdisciplinary foot care service.
British Orthopaedic Association	Full	219	2	Advising neuropaths with insensate feet to non-weight-bear is difficult and may lead to injury. They often have other limitations to their mobility, such as a high BMI and other musculoskeletal pathologies. The patients will also need to be fitted with crutches. Thus it would be sensible to advise rest, minimisation of weightbearing and the to arrange early fitting of an off weightbearing device.	Thank you for your response. Evidence was considered in favour of early non-removable offloading. The guideline development group discussed the importance of offloading the suspected Charcot foot, even when diagnosis has not yet been confirmed. This was based on multiple studies that showed worse outcomes for those participants who had not received early offloading after onset of symptoms. The non-weight bearing of these patients is also a temporary measure until the diagnosis can be confirmed and an offloading device fitted

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					(hence referral within 1 working day).
British Orthopaedic Association	Full	219	2	Advising neuropaths with insensate feet to non-weightbear is difficult and may lead to injury. They often have other limitations to their mobility, such as a high BMI and other musculoskeletal pathologies. The patients will also need to be fitted with crutches. Thus it would be sensible to advise rest, minimisation of weightbearing and the to arrange early fitting of an off weightbearing device.	Thank you for your response. Evidence was considered in favour of early non-removable offloading. The guideline development group discussed the importance of offloading the suspected Charcot foot, even when diagnosis has not yet been confirmed. This was based on multiple studies that showed worse outcomes for those participants who had not received early offloading after onset of symptoms. The non-weight bearing of these patients is also a temporary measure until the diagnosis can be confirmed and an offloading device fitted (hence referral within 1 working day).
British Infection Association	NICE	22	1.6.15	"Usually 6 weeks" should be "usually at least 6 weeks"	Thank you for your response. The term "usually 6 weeks" was used since some patients may not require this if treated with alternative treatment methods such as early surgical intervention.
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	22	**1.6.15**	Delete the word "all". Some people with osteomyelitis are best treated by early elective surgery. Those who have had surgery may not need antiobiotics for 6 weeks. There is actually no reference at all to the use of early surgery in the management of bone infection and this clearly needs to be added. Consider including a bullet point listing of the factors	Thank you for your response. The word "all" has been removed. No evidence was found for the use of early surgery in osteomyelitis and diabetic foot and therefore the guideline development group were not able to make clear recommendations for its use. Recognising that surgery is used in clinical practice, however, the group used

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				that might make an expert team/service consider early elective surgery for bone infection.	the term (usually 6 weeks) in preference to (usually at least 6 weeks) for the length of antibiotic therapy required in patients with osteomyelitis.
Podiatry North West Clinical Effectiveness Group for Tissue Viability, Diabetes and Peripheral Arterial Disease	Full	23	1	As above (ID 136)	Thank you for your response.
Diabetes UK	Full	23	27/28	Add prophylactic insoles	Thank you for your response. The guideline development group considered the evidence on the use of insoles, footwear and orthoses and combinations of the above (usually used with specialist foot wear) and noted that there are good insoles and poor insoles. The term insole itself is actually rather poorly defined and may refer to off-the-shelf style insoles while the sum of the evidence seemed to

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					show benefit from bespoke (customised) orthoses and footwear. This would presumably include customised insoles but it was felt it would be potentially misleading to mention "insoles" since the GDG do not recommend insoles in all cases nor all types of insole. If patients are to be given customised insoles it would need to be for the moderate to high risk group after receiving biomechanical assessment and with the need for specialist footwear/orthoses identified.
Northern Diabetes Footcare Network	Full	23	40	This differs from the Putting Feet First Pathway (recommends 1 to 3 months) - if section 40 adopted Putting Feet First Pathway will require amendment. This increased frequency of High Risk Reassessment will put increased pressure on the Foot Protection Service. Organisations who refuse to put NICE clinical guidelines in place because they disagree with them, could leave themselves open to challenge. (Refer to May 2014 Thanet CCG Court Case regarding NICE Fertility Guidelines).	Thank you for your response. We have passed your comments to the NICE implementation support team to inform the support activities for this guideline.
EAST MIDLANDS DIABETI	NICE	23	General Miss	There needs to be a section on aftercare: expert management after the resolution of the active problem. This aftercare is obviously geared partly to reducing	Thank you for your response. To a large extent we wish to empower the multidisciplinary foot care service and their respective foot protection services to

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C FOOT GROUP			ion before **2 Research recommendations**	recurrence, partly to establishing a system of follow-up that will ensure early re-referral in the event of any recurrence and partly to reducing the risk of early cardiovascular death. It should be part of the local protocols for defining the responsibilities of different care groups.	have strong links with robust protocols and clear pathways laid out between services to ensure good transfer of patients from one service to another (such as in the case of aftercare). Please note that the addition of the rehabilitation care is now listed in the set of skills available to a multidisciplinary foot care service. In relation to a clear system of follow up, please also see that a patient who has suffered from a previous foot ulcer or amputation will fall into the high risk category for care which will ensure frequent follow ups of 1-2 months or more frequent if deemed necessary. This should ensure early re-referral in the event of any recurrence. The guideline development group has also placed an emphasis on cardiovascular risk with the following recommendation: 1.4.4 If people present with a diabetic foot problem, take into account that they may have an undiagnosed, increased risk of cardiovascular disease that may need further investigation and treatment.
Foot in Diabetes UK & College	NICE	23	Line 18 Line	"Disabled adults who cannot see their feet are at moderate risk" would this be better worded 'Those people with diabetes who are registered blind should be considered to	Thank you for your response. The guideline development group (GDG) discussed this and agreed that this was too broad a statement to include in the

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of Podiatry			23	be moderate risk". Disabled adults open up to all disabilities with poor sight? However highlighting this one example neglects the risk of very old people with diabetes or those who have had diabetes for a long time	moderate risk category. Instead the GDG has recommended to "Consider more frequent assessments for people who are unable to perform or receive foot inspection."
Diabetes UK	NICE	23 - 25	General	It is disappointing that there are not recommendations to encourage more research focused on prevention and care outside of hospital. For instance, generalised prevention mechanisms such as issue of insoles to low and increased risk, improved skin care/tissue viability to reduce callus. Also research into the most effective education models for people with diabetes.	Thank you for your response. In the full guideline there are research recommendations both for education and preventative mechanisms such as insoles. The NICE version of the guideline now includes the research recommendations considered highest priority by the guideline development group. These 5 research recommendations cover the areas of monitoring frequencies for those at risk, criteria for referral to the foot protection service, preventative strategies for Charcot foot and educational models which are all related to prevention.
Kings College Hospital	Full	24	16 -18	Recommendation 54 suggests referral to either foot protection service or local MDT team for **active** diabetic foot. This may create confusion in general practice, delay in referral and potentially cause worsening of the patient's condition. Whilst having robust local protocols may overcome this potential problem, we believe the correct process would be an urgent referral to the	Thank you for your response. This was the reason that the guideline development group (GDG) were keen to stipulate the need for robust local protocols and pathways. It is up to the local protocols to define who can and cannot be treated by their foot protection services and the group wanted to allow for autonomy of different services

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				local MDT, who after the initial assessment and triage, should request the foot protection service to take over if appropriate. Recommendation 55 could therefore be integrated with 54.	depending on their capabilities. The GDG recognised the variety in level of care possible in foot protection services across the country. As a result the group wanted to enable these services to treat the diabetic foot problems (for example healing foot ulcer <2cm in diameter) that they are able to treat while recognising that some diabetic foot protection services may not be able to treat any active diabetic foot problems. In these cases the multidisciplinary foot care service would still take over care under the recommendation that the multidisciplinary foot care service manages the diabetic foot problems that cannot be managed by the foot protection service. Furthermore the GDG developed the following guidance to ensure urgent referral of all cases and immediate referral of emergency cases: 1.4.1 If a limb or life threatening diabetic foot problem refer the person to the multidisciplinary foot care service or acute services immediately (according to local protocols and pathways; also see recommendation 1.2.1) so they can be

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					assessed and an individualised treatment plan put in place. Examples include: • Ulceration with fever or any signs of sepsis • Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). • Ulceration with limb ischaemia (also see NICE guideline on lower limb peripheral arterial disease). • Gangrene (with or without ulceration). 1.4.2 For all other active diabetic foot problems refer (according to local protocols or pathways; also see recommendation 1.2.1) to the multidisciplinary foot care service or foot protection service urgently (within 1 working day) for appropriate triage (within 1 further working day).
Podiatry North West Clinical Effectiveness Group for	Full	24	16 – 18	There is a clear statement that referral to assessment for moderate and high risk foot for new referral (6 – 8 weeks and 2 – 4 weeks respectively). Also once these patients are registered to the foot protection team there is clear statement for follow-up times, however, this guideline does not do the same for the 'active foot ulcer' category	Thank you for your response. The guideline development group discussed the issues that you have raised and redrafted two recommendations to state how soon both urgent and emergency diabetic foot problems should be referred and triaged:

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Tissue Viability, Diabetes and Peripheral Arterial Disease				and only asks for **referral within 24 hours** with local protocols underpinning. Should the guideline not advise as it has done with the foot protection team for moderate and high risk and give clear referral to treatment times not just rely on local protocols. I.e. one working day to MDfT – as the active ulcer group is the group that will most likely lead to amputation, CVI, MI and death.	1.4.1 If a limb or life threatening diabetic foot problem refer the person to the multidisciplinary foot care service or acute services immediately (according to local protocols and pathways; also see recommendation 1.2.1) so they can be assessed and an individualised treatment plan put in place. Examples include: • Ulceration with fever or any signs of sepsis • Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). • Ulceration with limb ischaemia (also see NICE guideline on lower limb peripheral arterial disease). • Gangrene (with or without ulceration). 1.4.2 For all other active diabetic foot problems refer (according to local protocols and pathways; also see recommendation 1.2.1) to the multidisciplinary foot care service or foot protection service urgently (within 1 working day) for appropriate triage (within 1 further working day). The time to treatment by the respective

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					teams will depend on the triage of the relevant services beyond which the GDG were not able to stipulate as a certain amount of autonomy must remain with the services depending on their respective capabilities and the protocols and pathways laid out regionally.
British Orthopaedic Association	Full	24	22	It is important to identify the rare patient who presents with sepsis and a collection of pus under pressure which requires **urgent** decompression by the on call orthopaedic or vascular surgical teams. A thorough debridement can be undertaken later on a semi-planned basis by a specialist surgical member of the multidisciplinary team.	Thank you for your response. The guideline development group discussed active diabetic foot problems in need of emergency attention and redrafted the following recommendation in the understanding that a multidisciplinary foot care service may not be able to provide 24/7 hour care: 1.4.1 If a limb or life threatening diabetic foot problem refer the person to the multidisciplinary foot care service or acute services immediately (according to local protocols and pathways; see recommendation 1.2.1) so they can be assessed and an individualised treatment plan put in place. Examples include: • Ulceration with fever or any signs of sepsis • Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). • Ulceration with limb ischaemia

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					(also see NICE guideline on lower limb peripheral arterial disease). • Gangrene (with or without ulceration).
British Orthopaedic Association	Full	24	22	It is important to identify the rare patient who presents with sepsis and a collection of pus under pressure which requires **urgent** decompression by the on call orthopaedic or vascular surgical teams. A thorough debridement can be undertaken later on a semi-planned basis by a specialist surgical member of the multidisciplinary team.	Thank you for your response. The guideline development group discussed active diabetic foot problems in need of emergency attention and redrafted the following recommendation in the understanding that a multidisciplinary foot care service may not be able to provide 24/7 hour care: 1.4.1 If a limb or life threatening diabetic foot problem refer the person to the multidisciplinary foot care service or acute services immediately (according to local protocols and pathways; also see recommendation 1.2.1) so they can be assessed and an individualised treatment plan put in place. Examples include: • Ulceration with fever or any signs of sepsis • Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). • Ulceration with limb ischaemia (also see NICE guideline on lower limb peripheral arterial disease). • Gangrene (with or without

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					ulceration).
Kings College Hospital	Full	24	27	Gangrene may need emergency referral to the oncall vascular surgical team.	Thank you for your response. The guideline development group discussed active diabetic foot problems in need of emergency attention and redrafted the following recommendation in the understanding that a multidisciplinary foot care service may not be able to provide 24/7 hour care: 1.4.1 If a limb or life threatening diabetic foot problem refer the person to the multidisciplinary foot care service or acute services immediately (according to local protocols and pathways; also see recommendation 1.2.1) so they can be assessed and an individualised treatment plan put in place. Examples include: • Ulceration with fever or any signs of sepsis • Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). • Ulceration with limb ischaemia (also see NICE guideline on lower limb peripheral arterial disease). • Gangrene (with or without ulceration).

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Kings College Hospital	Full	24	42	We especially applaud the fact that due emphasis is being placed in the guidelines on Cardiovascular risk assessment. While published data may not reflect clear clinical benefit in terms of all-cause mortality, we believe that our complex foot patients will greatly benefit from the emphasis and could be audited robustly in time for the next round of guideline development.	Thank you for your response.
Diabetes UK	Full	24	9	And advice about insoles	Thank you for your response. The guideline development group considered the evidence on the use of insoles, footwear and orthoses and combinations of the above (usually used with specialist foot wear) and noted that there are good insoles and poor insoles. The term insole itself is actually rather poorly defined and may refer to off-the-shelf style insoles. The sum of evidence seemed to show benefit from bespoke (customised) orthoses and footwear. This could include customised insoles but it was felt it would be potentially misleading to mention "insoles" since the GDG did not recommend insoles in all cases nor all types of insole. If patients are to be given customised insoles it would need to be for the moderate to high risk group after receiving biomechanical assessment and

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					the need for specialist footwear/orthotics identified.
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	24	General Section **2.3 Diabetic ulcer dressings**	The reference to honey helps to promote a product for which there is actually no scientific evidence of either efficacy or effectiveness in this field. Studies on applications and dressings are needed but honey does not deserve emphasis.	Thank you for your response. The guideline development group expressed interest in honey particularly since there is a growing evidence base in this area for wound care, just not for diabetic foot ulcer care. We agree this does not deserve a mention above other dressing types and have removed the reference.
Cheshire Diabetes Network	Full	25	12	While applauding the selection of treatment modalities, we find that one single option from the list to be short in regards to best quality treatment and a combination of the above modalities to be in order. therefore can you strengthen the language used in the recommendation to ensure that while good wound care is paramount, offloading must be used in conjunction with this.	Thank you for your response. After discussion, the guideline development group feels that the term '1 or more' is appropriate. The understanding is that clinicians will use all of the methods of standard care appropriate and this is not limited to one particular treatment.
Diabetes UK	Full NICE	25 19	17 1.5.	The word "moist" should be removed here – we suggest it could just say "wound dressings as appropriate"	The guideline development group agrees that the recommendation for moist wound dressing would not apply in all situations. The recommendation has been changed

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			4		to state "wound dressing" for clinicians to be able to choose wound dressings as appropriate (or depending on local existing protocols).
Diabetes UK	Full	25	17	Add - prescribe a device to keep their dressing dry while bathing or showering	The guideline development group decided that the recommendation for moist wound dressing would not apply in all situations and subsequently the wording of this recommendation has changed. The recommendation now states "wound dressing" for clinicians to be able to choose wound dressings as appropriate (or depending on local existing protocols). This may include the need for prescribing certain devices to keep dressings dry however the group did not feel that this needed stipulation within the guidance.
Foot in Diabetes UK & College of Podiatry	Full	25	17	"Specification of **moist** wound dressing not always appropriate	The guideline development group agrees that the recommendation for moist wound dressing would not apply in all situations. The recommendation has been changed to state "wound dressing," for clinicians to be able to choose wound dressings as appropriate (or depending on local existing protocols).
Diabetes UK	Full	25	29 and	The use of the word "consider" here implies that there are data supporting NPWT and skin substitutes. In the evidence part of the document and indeed in the call for further	Thank you for your response. There was some in-house cost effectiveness modelling performed for this review question. In discussing the analysis of

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			34	research it is clear that there is not. There is **some** but not a lot of good evidence for NPWT in post-surgical wounds but none for chronic wounds even post "debridement". Cochrane has come to a view that the evidence to support the use of NPWT is poor and there is certainly no cost effectiveness data in the UK. If this recommendation to consider NPWT remains it should be restricted to post-operative wounds.	negative pressure wound therapy performed for CG119 Diabetic foot problems: Inpatient management of diabetic foot problems (2011), the guideline development group noted that costs of the intervention have reduced considerably from those assumed in the 2011 analysis. Because the analysis is an undiscounted decision tree with a 1-year time-horizon, it was possible to isolate the contribution to net costs made by the intervention itself and, therefore, the ICER could be easily recalculated with lower costs. Rearranging these calculations, it could be seen that negative pressure wound therapy would provide QALY gains at an ICER of less than £20,000 per QALY so long as the complete course cost less than £1100, and it would be dominant (improving health and resulting in a reduction in net costs) if it cost less than £710. The guideline development group (GDG) was confident that, in their experience, current costs of negative pressure wound therapy are substantially lower than these figures. Therefore, although the GDG was aware of the significant limitations of the 2011 model, it was happy to see this analysis as an indication that negative pressure

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					wound therapy is likely to provide good value for money in the current NHS. Please also note that in light of the poor evidence the guideline development group has tried to make the recommendation as cautious as possible. Negative pressure wound therapy is not to be offered except on the advice of the multidisciplinary foot care service. After discussion the guideline development group agreed that the recommendation should also stipulate "after surgical debridement," as this reflects how the treatment is used in clinical practice and in the paper reviewed by Armstrong et al.
Cheshire Diabetes Network	Full	25	8	Whilst accepting the evidence regarding the Wagner classification, it seems odd to rule this classification system as totally out of hand versus the Diabetic foot. In extremis the use of a familiar grading system is more acceptable than none, and as many Tissue Viability Nursing services do not use specific Diabetic foot grading versus their own standards, this seems ill judged. Also, as part of Any Qualified Provider Contracting, Wagner Scale has been used as the scale of choice when referring back to Diabetic Foot services in the case of finding a wound and thus this recommendation does place one Body	Thank you for your response. A negative recommendation was made against the use of WAGNER as it was felt to be unsophisticated and not as clinically useful for grading the severity of ulcer in the UK population. This was largely due to the poor gradation of disease severity in the WAGNER tool compared to other available grading tools. The WAGNER classification system was also felt to provide less clinically useful information such as the ischaemic status of the patient's leg/foot. The guideline development group felt strongly that they wanted to recommend a grading system

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				versus another. May we therefore ask you to reconsider. It is noticeable that EPUAP scaling hasn't been considered yet is increasingly being used as part of Diabetic foot wound assessment especially in the field of Grade 3 and above being used to trigger Root Cause Analysis and this investigate the cause of wounds. By the way, EPUAP seems based upon Wagner.	that takes into account the important features in grading the severity of a diabetic foot wound.
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	25	General Section **2.5** ***Monitoring frequency for people at risk***	While it would be nice to know, it would be almost impossible to design the appropriate study – except in those at highest risk (those with a previous episode) because the incidence of new episodes for those at low or moderate risk is so low that the sample size for any study would be prohibitive if an RCT was planned. Funding and effort might be better spent on studies of, for example, the duration of antibiotic therapy for both soft tissue and bone infection, and assessing the value of bone biopsy in cases of suspected (for the purposes of diagnosis) and diagnosed (to determine antibiotic choice) osteomyelitis.	Thank you for your response. It is agreed that restricting to a randomised controlled design may be too limiting and the option for cohort design has been added. This research question was drafted as a response to the lack of evidence of any sort found in the review on monitoring frequencies for those at risk of developing a diabetic foot problem. Since we were able to identify this area in which research was lacking we were able to draft a research recommendation. We did not perform a review looking at specific durations of treatment for soft tissue and osteomyelitis infections and therefore did not highlight a paucity of research in this area.
British Orthopaedic	Full	26	14	Foot and ankle radiographs should be taken with the patient standing, if possible	Thank you for your response. The guideline development group agree that this is especially important in the case of

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Association					Charcot foot and have amended the recommendation accordingly. Please see below: 1.7.4 If acute Charcot arthropathy is suspected, request a weightbearing X-ray of the affected foot and ankle. Consider an MRI if the X-ray is normal but clinical suspicion still remains.
British Orthopaedic Association	Full	26	14	Foot and ankle radiographs should be taken with the patient standing, if possible	Thank you for your response. The guideline development group agree that this is especially important in the case of Charcot foot and have amended the recommendation accordingly. Please see below: 1.7.4 If acute Charcot arthropathy is suspected, request a weightbearing X-ray of the affected foot and ankle. Consider an MRI if the X-ray is normal but clinical suspicion still remains.
British Nuclear Medicine Society	Full	26	20 -21	We believe if the diagnosis of Osteomyelitis is suspected and not confirmed on X Rays, NICE should recommend MRI as the next evalaution. This is important especially in suspected Midfoot and hindfoot lesions and will help agree definite management plans with the patient. Plain Xrays are known to be a late indicator of osteomyelitis.	Thank you for your response. The information from Larcos et al was considered as part of the evidence found under the evidence review for this question. The trial by Palestra et al would not have been included under the evidence review since non-diabetic forms of Charcot were included in their population. The trial from Hopfner et al

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				The current draft does not advise Nuclear Medicine imaging. There is a role for such functional and particularly hybrid imaging especially in equivocal cases following converrional work up hard to diagnose cases. BNMS suggest the committee might include : 'consider' nuclear white cell scanning/ FDG PET CT for evaluation of osteomyelitis, if clinical uncertainty remains or equivocal MRI findings . Ref Larcos G, Brown ML, Sutton RT. Diagnosis of osteomyelitis of the foot in diabetic patients: value of 111In-leukocyte scintigraphy. AJR Am J Roentgenol 1991; 157:527–531 Palestro CJ, Mehta HH, Patel M, et al. Marrow versus infection in the Charcot joint: indium-111 leukocyte and technetium-99m sulfur colloid scintigraphy. J Nucl Med 1998;39:346–350 Keidar Z, Militianu D, Melamed E, Bar-Shalom R, Israel O. The diabetic foot: initial experience with 18F-FDG PET/CT. J Nucl Med 2005;46:444–449. Hopfner S,	was not English language but a similar study was found and included under the same author for this review. The study by Keidar et al is not blinded and does not state if the diagnosis was made on any one test alone and therefore cannot report sensitivities and specificities. The PET results seem to show the sensitivity to non-specific infection rather than osteomyelitis or soft tissue infection. This study was not included in the review for the previous guideline although it does show the localising ability of hybrid scans (which were used to add extra information to the diagnosis of infection). Recommendation 1.6.5 states "If osteomyelitis is suspected but is not confirmed by initial X ray, consider MRI to confirm the diagnosis." We consider this a recommendation of MRI as the next best evaluation following x-ray in the suspicion of osteomyelitis**.** The guideline development group (GDG) did not think it necessary to strengthen this to an "offer" since it may not apply in all situations where a clinician may decide that an MRI is not necessary. The GDG, in view of the evidence, were not inclined to change their stance and

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				Krolak C, Kessler S, Tiling R. Metabolism. 1999 Jul;48(7):922-7. The value of combined radionuclide and magnetic resonance imaging in the diagnosis and conservative management of minimal or localized osteomyelitis of the foot in diabetic patients. Vesco L1, Boulahdour H, Hamissa S, Kretz S, Montazel JL, Perlemuter L, Meignan M, Rahmouni A. Preoperative imaging of Charcot neuroarthropathy. Does the additional application of 18F-FDG-PET make sense? Nuklearmedizin 2005;45:15-20	draft a further recommendation on the use of nuclear bone medicine imaging since the evidence base was not strong enough to suggest its necessity.
Kings College Hospital	Full	26	20 -21	We believe if the diagnosis of Osteomyelitis is suspected and not confirmed on X Rays, NICE should recommend to 'offer' MRI rather than 'consider'. This is important especially in suspected Midfoot and hindfoot lesions and will help agree definite management plans with the patient . The current draft does not suggest Nuclear Medicine imaging. There is a role for such imaging especially in hard to diagnose cases. Perhaps the committee could revaluate the evidence to 'consider' white cell scanning/ FDG PET for evaluation of	Thank you for your response. Recommendation 1.6.5 states "If osteomyelitis is suspected but is not confirmed by initial X ray, consider MRI to confirm the diagnosis." We consider this a recommendation of MRI as the next best evaluation following x-ray in the suspicion of osteomyelitis**.** The guideline development group (GDG) did not think it necessary to strengthen this to an "offer" since it may not apply in all situations where a clinician may decide that an MRI is not necessary.

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				ostemyelitis, again usually after MRI	The GDG, in view of the evidence, were not inclined to change their stance and draft a further recommendation on the use of nuclear bone medicine imaging since the evidence base was not strong enough to suggest its necessity.
The United Kingdom Clinical Pharmacy Association	Full	26	31 -33	Choose the antibiotic therapy based on the severity of the foot infection, the care setting, and the person's preferences, clinical situation and medical history and, if more than one regimen is appropriate, select the one with the lowest acquisition cost. (This implies single therapy antibiotic use and excludes dual, triple or quadruple antibiotics regimens. Is this correct? Note; this recommendation is repeated on page 159 line 10	Thank you for your response. The term "regimen" was used as a non-specific term to allow for the fact that more than one antibiotic may be used; a person may have combination regimen of multiple therapies. To make this clearer the word regimen has been repeated so that the recommendation now states: 1.6.9 Choose the antibiotic therapy based on the severity of the foot infection, the care setting, and the person's preferences, clinical situation and medical history and, if more than one regimen is appropriate, select the regimen with the lowest acquisition cost. This rewording will also apply to the repetition of the recommendation further on in the document.
Kings College Hospital	Full	26	37 -38	We agree with the suggestion but we believe the authors intended this statement for empirical therapy but we believe antibiotic therapy should ideally be tailored	Thank you for your response following discussion by the guideline development group the recommendations were altered to make clear that we were talking about

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				within 48 hours in keeping with microbiological results. We believe, in chronic stable ulcers that have reulcerated a polymicrobial microbial aetiology is likely.	empirical therapy by adding the word "initially." 1.6.12 For mild foot infections, initially offer oral antibiotics with activity against gram-positive organisms. And 1.6.14 For moderate and severe foot infections, initially offer antibiotics with activity against gram-positive and gram-negative organisms, including anaerobic bacteria, as follows: The guideline development group did not feel that 48 hours needed to be stipulated since consideration of the clinical response needs to be taken into account also, as in the following recommendation: 1.6.10 Use the clinical response to antibiotics and the results of the microbiological examination to decide the targeted antibiotic regimen.
The United Kingdom Clinical Pharmac	Full	26	39	Do not use prolonged antibiotic therapy for mild soft tissue infections. What is meant by prolonged therapy? >2 weeks ? note this is repeated on p160 line 6.	Thank you for your response. Following discussion the guideline development group reviewed the recommendation and provided clarification as below:

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y Association				It should be noted that prolonged therapy is recommended be offered for more severe cases- the recommendation on line 5 on page 27 states (usually 6 weeks). Thus clarification should be stated for mild infections	1.6.13 Do not use prolonged antibiotic therapy (more than 14 days) for treatment of mild soft tissue infections. This rewording will also apply to the repetition of the recommendation further on in the document.
Northern Diabetes Footcare Network	Full	26	9 -11	Feel it would be beneficial to remove the word superficial ie change sentence from 'If this cannot be obtained, take a superficial swab because it may provide useful information on the choice' to 'If this cannot be obtained, take a swab from the debrided wound base because it may provide useful information on the choice.'	Thank you for your response. This issue was discussed with the guideline development group and the recommendation changed to: 1.6.1 If a diabetic foot infection is suspected and a wound is present, send a soft tissue or bone sample from the base of the debrided wound for microbiological examination. If this cannot be obtained, take a deep swab because it may provide useful information on the choice of antibiotic therapy. The reference to superficial swab has been removed in preference to a deep swab.
British Nuclear Medicine Society	Full	27	19 -20	We believe if the diagnosis of Charcot is suspected and not confirmed on X Rays, NICE should recommend further imaging evaluation. Please also 'consider' Nuclear Medicine	Thank you for your response and referenced papers, however the evidence review only included full papers and not abstracts (please see the protocol found in appendix C). The guideline development group discussed all other

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				Bone Scan (with SPECT CT if available) in cases of clinically suspected acute Charcot's with negative Xray findings Reference: K. Boddu, S. Hussain, G. Vivian, N Mulholland M. Edmonds, V. Kavarthapu Evaluation of acute Charcot foot using SPECT/CT imaging.Bone Joint J 2014 96-B:(SUPP 17) 27. 11/2014; Chantelau and Grützner Swiss Med Wkly. 2014;144:w13948 doi:10.4414/smw.2014.13948 J Nucl Med. 2011; 52 (Supplement 1):455 **The role of SPECT/CT in imaging the Charcot foot** **Anthony D'Sa[1], Mazin Al-Janabi[1], Nina Petrova[1] and Michael Edmonds**	evidence brought to light by the review and did not feel that they were able to confidently make a recommendation on the use of nuclear medicine bone scans. We have, however, recommended that: 1.7.4 If acute Charcot arthropathy is suspected, request a weightbearing X ray of the affected foot and ankle. Consider an MRI if the X ray is normal but clinical suspicion still remains. MRI is recommended as the next best imaging evaluation after a negative or equivocal radiograph.
Kings College Hospital	Full	27	19 -20	We believe if the diagnosis of Charcot is suspected and not confirmed on X Rays, NICE should recommend to 'offer' MRI rather than 'consider' – this is especially important in Active Stage 0 Charcot which is not apparent on X Ray imaging. Please also 'consider' Nuclear Medicine Bone Scan (with SPECT) . Reference: Chantelau and Grützner Swiss Med Wkly.	Thank you for your response and the referenced review paper. The guideline development group (GDG) discussed all evidence brought to light by the NICE review question and did not feel that they were able to confidently make a recommendation on the use of nuclear medicine bone scans. In recognition of the stage 0 Charcot foot the GDG has stipulated the situations in

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				2014;144:w13948 doi:10.4414/smw.2014.13948	which the condition should be suspected, ensured urgent referral and off-loading until diagnosis can be confirmed and recommended MRI as the next best diagnostic test should radiographs be negative or equivocal. The GDG felt that this constituted a recommendation of MRI as a second line investigation and that the language did not need to be stronger since an MRI may not always be necessary in every case. 1.7.2 Suspect acute Charcot arthropathy if there is redness, warmth, swelling or deformity (in particular, when the skin is intact), especially in the presence of peripheral neuropathy or renal failure. Think about acute Charcot arthropathy even when deformity is not present or pain is not reported. 1.7.3 Refer the person urgently (within 1 working day) to the multidisciplinary foot care service to confirm the diagnosis, and offer non weight bearing treatment until definitive treatment can be started. 1.7.4 If acute Charcot arthropathy is suspected, request a weightbearing X ray of the affected foot and ankle. Consider

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					an MRI if the X ray is normal but clinical suspicion still remains.
British Orthopaedic Association	Full	27 219 255	23 2 3	Why is a non-removable device specified? A removable device, if worn is equally effective. There appears to be no good quality evidence to justify the services, use of removable or non-removable off-loading devices. Many clinics do not have ready availability of casting and many patients prefer removable devices. Thus I do not support the recommendation for non-removable devices, this seems to be unsubstantiated and will lead to a delay in the treatment of patients where casting facilities are not readily available	Thank you for your response. The guideline development group (GDG) looked at a meta-analysis of the evidence comparing total contact casting versus removable cast walker. The total contact casting showed a significant improvement for the key outcomes of wound healing. Moreover there was a significant benefit in terms of complete wound healing in all trials comparing irremovable offloading strategies to removable strategies. This may well be because removable devices have to be worn to be effective and this may be a compliance issue. In terms of irremovable casting the GDG has chosen only to recommend this specific type of irremovable casting in the population in which it has been proven to show benefit i.e. plantar neuropathic, non-ischaemic, uninfected forefoot and midfoot ulcers and is therefore wrote a conservative recommendation which seems in line with the evidence found. The GDG felt that it should be within the capabilities of most services to have access to casting but have added more detail to the recommendation to ensure that no patient

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					experiences treatment delay. Please see below: 1.5.5 Offer non-removable casting to off-load plantar neuropathic, non-ischaemic, uninfected forefoot and midfoot ulcers. Offer an alternative offloading device until casting can be provided.
British Orthopaedic Association	Full	27 219 255	23 2 3	Why is a non-removable device specified? A removable device, if worn is equally effective. There appears to be no good quality evidence to justify the services, use of removable or non-removable off-loading devices. Many clinics do not have ready availability of casting and many patients prefer removable devices. Thus I do not support the recommendation for non-removable devices, this seems to be unsubstantiated and will lead to a delay in the treatment of patients where casting facilities are not readily available	Thank you for your response. The guideline development group (GDG) looked at a meta-analysis of the evidence comparing total contact casting versus removable cast walker. The total contact casting showed a significant improvement for the key outcomes of wound healing. Moreover there was a significant benefit in terms of complete wound healing in all trials comparing irremovable offloading strategies to removable strategies. This may well be because removable devices have to be worn to be effective and this may be a compliance issue. In terms of irremovable casting the GDG has chosen only to recommend this specific type of irremovable casting in the population in which it has been proven to show benefit i.e. plantar neuropathic, non-ischaemic, uninfected forefoot and midfoot ulcers and is therefore a conservative

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					recommendation which seems in line with the evidence found. The GDG felt that it should be within the capabilities of most services to have access to casting but have added more detail to the recommendation to ensure that no patient experiences treatment delay. Please see below: 1.5.5 Offer non-removable casting to off-load plantar neuropathic, non-ischaemic, uninfected forefoot and midfoot ulcers. Offer an alternative offloading device until casting can be provided.
Kings College Hospital	Full	27	36	We believe one should: 'Consider' referral of patient with Charcot disease and recurrent ulceration or those with complex deformity not allowing weight bearing without an offloading device to al centre of excellence for consideration of reconstructive surgery if there is no such local expertise.	Thank you for your response. The guideline development group did not review any evidence on the referral of complex Charcot disease to centres of excellence and this seems to be a decision that would be left up to the triage of local multidisciplinary foot care services and commissioners. We hope that the guidelines give sufficient breadth for decisions like these to be made depending on the capabilities of local services.
Staffordshire & Stoke on	NICE	3	9	No mention of small vessel disease	Thank you for your suggestion. We hope that we have covered the key issues relating the aetiology of diabetic foot

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Trent Partnership NHS Trust					within the introduction although we recognise that these may not be the only aetiological processes that exist.
Royal College of Paediatrics and Child Health	Full	3.1	22	This document has made clear recommendation son the frequency of screening for foot problems in Children < 12 years, and young people aged 12-17 years. These recommendations are based on absolutely NO evidence as is freely admitted in this document.	Thank you for your response. These recommendations were based upon consensus agreement as there was no evidence found for this age group. The guideline development group felt transitional services will prepare young people for movement into adult care by assessing the feet (which will happen at least annually as an adult). Educating young people about the risk of developing foot problems in later life was also decided by the committee to be very important. In terms of increased workload for the transitional and paediatric care teams we recognise the fact that children above the age of 12 receive annual assessment and that adding an examination of the feet was not felt to be an excessive divergent from current practice. The wording of the recommendation for children aged 12-17 years has been changed to make clear that assessment of feet is to be performed as part of the annual assessment (and not a separate assessment).

Diabetic Footcare

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Royal College of Paediatrics and Child Health	Full	3.2	22	This gives recommendations on how to examine feet, and both children and young people are included in this recommendation. Once again, there is NO evidence supplied to support this recommendation.	Thank you for your response. These recommendations were based upon consensus agreement as there was no evidence found for this age group. The guideline development group felt transitional services will prepare young people for movement into adult care by assessing feet (which will happen at least annually as an adult). Educating young people about the risk of developing foot problems in later life was also decided by the committee to be very important. In terms of increased work load for the transitional and paediatric care teams we recognised the fact that children above the age of 12 receive annual assessment and that adding an examination of the feet was not felt to be an excessive divergent from current practice. The wording of the recommendation for children aged 12-17 years has been changed to make clear that assessment of feet is to be performed as part of the annual assessment (and not a separate assessment).
University of Nottingham	Full	30	10 -18	Successive systematic reviews have drawn the same conclusion as the GDG namely that the evidence regarding the effectiveness of educational interventions is limited and inconclusive. This is not	Thank you for your comment. The guideline development group discussed your suggestion for further research in this area and agreed that it could be beneficial. The research recommendation

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				surprising as we know from many other areas of health research that while education may be necessary it is never sufficient in achieving behaviour change. What is surprising is that GDG conclusion that what is required is yet another trial of an educational intervention. In view of the mounting evidence that psychological and behavioural factors (e.g., low mood, coping, illness beliefs, adherence) influence ulcer outcomes; it would be timely for the GDG to suggest the development and evaluation of psychobehavioural interventions which focus on modifiable factors (such as patient beliefs) other than education. Furthermore, it is suggested that research in this area should not focus only on interventions that can deliver behaviour change but which seek to achieve long-term maintenance of such change.	for education has been amended to include the development and use of psycho-behavioural interventions.
Royal College of Paediatrics and Child Health	Full	4.5.6	69	According to our commenter, as a paediatrician involved in the care of CYP with diabetes, the impression of the Guideline is that there is minimal guidance for the prevention & management of diabetic foot problems in the young. The age of onset of T1D is decreasing and many adolescents have a disease burden of more than 10 years. The majority of children	Thank you for your response. In terms of prevention, the guideline development group has encouraged a greater education and preparation for children and young people to consider issues of the feet going into adult care. The annual assessment of feet will identify other common conditions such as verrucae and tinea. However, no evidence was found for the treatment of these conditions

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				with diabetes have feet with normal neurology & blood supply. Advice regarding the management of common conditions such as verrucae and tinea can be very variable especially when there are warnings against the use of proprietary medication in individuals with diabetes. In their clinical experience, the most difficult foot problem encountered in adolescents is painful peripheral neuropathy. The management of neuropathy is cross-referenced in the current diabetic foot guideline but this focuses predominantly on trigeminal neuralgia. We therefore think it may be helpful to make more reference to painful neuropathy in the text.	which fall outside the scope for this guideline. The treatment of peripheral neuropathy also falls outside the scope of this guideline. The referenced neuropathic pain guideline does cover the treatment of all neuropathic pain.
British Association of Prosthetists and Orthotists	Full	45 -46	9 ,19 and general	The GDG's decision to focus on skills rather than specific professions is understandable. However BAPO feel that the decision to refer generally to orthotist skills (e.g. 'biomechanics') or the professional field (e.g. 'orthotics') may prove unhelpful to facilitating good commissioning of orthotic services. Understanding, recognition and	Thank you for your response. After discussion and in response to this and other comments the list of skills required for a foot protection service was clarified by adding the words (and orthoses). The guideline development group has chosen to maintain their initial decision to define the skillset required as opposed to

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				funding of orthotic services nationally is varied and sometimes very poor. Similar to 'the GDG's experience [that] the podiatrist would be best placed to lead [diabetic foot services]', it is the position of BAPO that any complex orthotic treatment should only be provided by orthotists as they are the most highly trained and best placed to do so. Note that the orthotist is one of the few professions who are involved pre, peri and post acute episode and one of the main professions (along with podiatrists) involved with prevention. As a specialised and comparatively small profession, there would be some benefit to this NICE guideline making a clearer statement regarding orthotists in order to signpost commissioners and referrers to these services.	naming any particular job title as this makes the guideline less prescriptive, more future proof, and easier to implement: 1.2.2 The foot protection service should be led by a podiatrist with specialist training in diabetic foot problems, and should have access to healthcare professionals with skills in the following areas: • Diabetology. • Biomechanics and orthoses. • Wound care. We hope that this clarification will help a person receive appropriate biomechanical and orthotic assessment where required and that this will help signpost to orthotist services where appropriate. No evidence was reviewed to support making a stronger or more specific recommendation than this.
British Association of Prosthetists and Orthotists	Full	46	11 -22	Could there be an argument for inclusion of a Prosthetist at an earlier stage in the process when a major amputation is being considered? There are also areas where Prosthetists may manage partial foot amputations in this population and may be considered part of the multidisciplinary foot	Thank you for your response. The suggestion of the addition of a prosthetist was discussed with the guideline development group who drafted a new recommendation: 1.2.4 The multidisciplinary foot care

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				care service. If the current NICE approach of listing skills rather than professions were to be followed, 'prosthetics' could potentially be added to the skills list.	service should also have access to rehabilitation, plastic surgery, health psychology and nutritional services. We would expect that a prosthetist would be included under the rehabilitation services where appropriate.
University of Nottingham	Full	46	11 -22	Again, in view of the clear evidence that patients with diabetic foot ulcers often report low mood, difficulties in adherence and other behavioural issues; it would be important to consider extending the scope of multidisciplinary foot care services to include other specialities with relevant expertise (i.e., health psychologists) and/or to advocate that existing health care professionals are trained in appropriate methods/techniques to enable them to support patients.	Thank you for your response. The suggestion of the addition of a health psychologist was discussed by the guideline development group who drafted a new recommendation: 1.2.4 The multidisciplinary foot care service should also have access to rehabilitation, plastic surgery, health psychology and nutritional services.
McCallan Group, The	Appendix A	5		We seek confirmation that the Guidance Development Group member declaring an interest in appendix A (p.5) as follows: *"Receives reimbursement from Owen Mumford who manufacture the neuropen as monofilament and neurotip device, which was designed by Gerry Rayman approximately a decade ago"* was not involved, directly or indirectly, in the Q4.4 evidence search strategy, evidence review, discussions or recommendation to restrict	Thank you for your response. We can confirm that the guideline development group (GDG) member Gerry Rayman was absent from the GDG meeting at which the referenced recommendation was drafted and the evidence review was presented. Had the GDG member been able to attend the meeting, he would have been excluded from this section of the meeting due to his conflict of interest. Please also note the subsequent

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				neuropathy testing to the use of a 10g monofilament only. This confirmation is sought as a decision was taken and also listed in Appendix A to 'Declare and participate' for a similar declared interest "*Developed the Ipswich Touch Test for detecting sensory loss in the feet".*	changes in wording to this recommendation: 1.3.6 When examining a person's feet, remove their shoes, socks, bandages and dressings, and examine both feet for evidence of the following risk factors: • Neuropathy (use a 10 g monofilament as part of a foot sensory examination). • Limb ischaemia (also see the NICE guideline on lower limb peripheral arterial disease). • Ulceration. • Callus. • Infection and/or inflammation. • Deformity. • Gangrene. • Charcot arthropathy.
McCallan Group, The	Appendix C	5	General	Tools listed for examining feet exclude VibraTip yet NICE medical technology guidance has been developed for this tool and recognises the potential for this device in calling for further research whilst not wanting to preclude its use in NHS.	Thank you for your response. The recommendation's wording was discussed by the guideline development group. It was agreed that based on the review that we looked at it was not possible to rule out other ways of testing for neuropathy. As a result the recommendation concerning the use of monofilament has been weakened to ensure that a full examination is performed but that a monofilament

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					examination should form a part of this examination: • When examining a person's feet, remove their shoes, socks, bandages and dressings, and examine both feet for evidence of the following: □ Neuropathy (use a 10 g monofilament as part of a foot sensory examination). […]
Staffordshire University	Full	56	General	I still think biomechanics has a role to play and this should be reflected in the document.	Thank you for your response. Biomechanics has been listed as one of the specialist skills required of the foot protection team for moderate to high risk persons in order to assess for need of orthoses and as such its role has been reflected in the guidance.
McCallan Group, The	Full	59	Sect 4.4.2.2 general	The evidence search strategy relating to tests for examining the feet of people with diabetes concerns us. Papers were only included if they evaluated examination tools' ability to predict foot ulcers/amputations etc. It is well understood that neuropathy per se is a major risk factor for foot problems: and in attempting to improve outcomes, it is what happens after neuropathy detection (i.e. self-care, modifying patient behaviours, escalated education and more frequent check-ups etc.) that is more important than the tool used to confirm the neuropathy in	Thank you for your response. The protocol for this review question (see appendix C) does exclude case control studies. For a prognostic review case-control studies provide weaker levels of evidence and the sensitivity and specificity of a tool to detect neuropathy were not the outcomes of interest for this review. Rather the usefulness of an assessment tool for risk stratification to guide management was considered. As a result cohort studies were the highest quality evidence available. A large

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				the first place. Search criteria for evidence on screening tools selection excludes case-control studies. Knowing that evidence in this area is of general low quality – why exclude case-control studies, many of which are relatively well designed and aimed at confirming sensitivity & specificity of tools available to detect neuropathy? Appendix E (section 1.2) lists a large number of identified studies, titles of which appear wholly appropriate for validation of assessment tests, yet are excluded from this review.	proportion of prognostic evidence supported the use of monofilament testing as a prognostic tool. We did not review tools for the diagnosis of neuropathy but accept that neuropathy is an important risk factor for diabetic foot problems. The wording of the recommendation was discussed by the guideline development group. It was agreed that based on prognostic evidence it was not possible to rule out other ways of testing for neuropathy. As a result the recommendation concerning the use of monofilament has been weakened to ensure that a full examination is performed but that a monofilament examination should form a part of this examination: • When examining a person's feet, remove their shoes, socks, bandages and dressings, and examine both feet for evidence of the following: □ Neuropathy (use a 10 g monofilament as part of a foot sensory examination). […]
EAST MIDLAN	NICE	6	General	The wording is confusing. The heading talks of 'should' and 'should not' but the text does	Thank you for your suggestion. These headings are in place to explain the use

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DS DIABETIC FOOT GROUP			Section ***"Interventions that should (or should not) be used"***	not mention them and refers to other qualifying terms. The same applies to the following paragraph on the word 'could'.	of the terms "offer" and "consider" and to help readers understand the strength of recommendation implied by use of these words.
British Foot and Ankle Surgery Society	Full	6.1	26	This section is incomplete. No mention is made (throughout the document) of the life and limb threatening emergency that a foot abscess presents. A high index of suspicion (boggy swelling = abscess till proven otherwise) and a low threshold for urgent incision and drainage is important. Patients must not be just put on antibiotics while awaiting an MRI scan. Recognising these severe infections is imperative. Historically it has often fallen to vascular surgery, but new centralisation of services for vascular means that this role may fall to the on-call	Thank you for your response. The guideline development group discussed active diabetic foot problems in need of emergency attention and redrafted the following recommendation in the understanding that a multidisciplinary foot care service may not be able to provide 24/7 hour care: 1.4.1 If a limb or life threatening diabetic foot problem refer the person to the multidisciplinary foot care service or acute services immediately (according to

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				T&O consultant. He/she should drain the abscess and seek advice from the Foot and Ankle surgeon from the Diabetic Foot team regarding further debridement and definitive care. T&O consultants and registrars are not used to having to perform this critical role in the care of diabetic feet, and local education is important.	local protocols and pathways; also see recommendation 1.2.1) so they can be assessed and an individualised treatment plan put in place. Examples include: • Ulceration with fever or any signs of sepsis • Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). • Ulceration with limb ischaemia (also see NICE guideline on lower limb peripheral arterial disease). • Gangrene (with or without ulceration Thank you for your response regarding the implementation challenges faced by the centralisation of vascular services. We have passed it to the NICE implementation team to inform their support activities for this guideline.
McCallan Group, The	Full	63 -65	Table 17	See Other Considerations: Based on only the tightly-filtered and low quality evidence available **in this review**, the GDG effectively recommends discontinuation of all other methods of confirming loss of protective sensation in the foot other than touch testing with a 10g monofilament. This conflicts with previous NICE guidance (which includes vibration), international	Thank you for your response. The recommendation's wording was discussed by the guideline development group (GDG). It was agreed that based on prognostic evidence it was not possible to rule out other ways of testing for neuropathy. As a result the recommendation concerning the use of monofilament has been weakened to

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				guidelines and a number of risk scoring systems which include alternative modalities for testing loss of protective sensation. Is there any evidence to support NOT using vibration as a modality? Furthermore, concerns relating to monofilament performance and durability have not been communicated whatsoever (or reviewed?) in this guidance and should impact upon the GDG's assumptions of widespread general acceptability in general practice and relative cheap cost. The following articles relate: • Ann Fam Med. 2009 Nov-Dec;7(6):555-8. Accuracy of monofilament testing to diagnose peripheral neuropathy: a systematic review. Dros J, Wewerinke A, Bindels PJ, van Weert HC. • Diabetes Research and Clinical Practice 97 (2012) 399–404. Accuracy and durability of Semmes–Weinstein monofilaments: What is the useful service life? Lawrence A.	ensure that a full examination is performed but that a monofilament examination should form a part of this examination: • When examining a person's feet, remove their shoes, socks, bandages and dressings, and examine both feet for evidence of the following: □ Neuropathy (use a 10 g monofilament as part of a foot sensory examination). […] In terms of performance and durability the GDG advocates the need to use 10g monofilaments as recommended by the manufacturer, i.e. replacing a monofilament once it has reached the limit of its durability, but did not feel the need to stipulate this in the recommendation. The monofilament's performance is reflected in the evidence base reviewed where it was shown to be a useful assessment test for the categorising of diabetic patients as higher risk for developing diabetic foot problems. The GDG did not find evidence on the use of vibration sense alone as a predictor for diabetic foot problems.

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				Lavery, David E. Lavery, David C. Lavery, Javier LaFontaine, Manish Bharara, Bijan Najafi • Diabetes Care. 2000 Jul;23(7):984-8. Differences in the performance of commercially available 10-g monofilaments. Booth J, Young MJ. • Diabetes Res Clin Pract. 2010 Oct;90(1):1-7. doi: 10.1016/j.diabres.2010.06.021. Epub 2010 Jul 22. The clinical use of the 10g monofilament and its limitations: a review. Tan LS.	However the GDG did review evidence on various neuropathy scores which would have included some element of vibration sensory testing. Thank you for the research provided. Systematic reviews were not included under this review if out of date or not using the same parameters as those stipulated in the protocol (such as outcomes of interest; see appendix C). observational research was gathered however only in the population of interest (i.e. Children, young people and adults with type 1 or type 2 diabetes)
McCallan Group, The	Full	65	4	In the interests of patient safety and recognising the limitations associated with all tools available to detect neuropathy, we suggest that more than one modality to test foot sensation should be recommended.	Thank you for your response. The recommendation's wording was discussed by the guideline development group. It was agreed that based on the evidence that we looked at it was not possible to rule out other ways of testing for neuropathy. As a result the recommendation concerning the use of monofilament has been weakened to ensure that a full examination is performed but that a monofilament examination should form a part of this examination:

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					• When examining a person's feet, remove their shoes, socks, bandages and dressings, and examine both feet for evidence of the following: □ Neuropathy (use a 10 g monofilament as part of a foot sensory examination). […]
Cardiff and Vale UHB	Full	66	11	Would the group consider future research looking at frequency of assessments for the low risk patients and look at other screening models within diabetic care i.e. Retinopathy screening.	Thank you for your suggestion. We have two research recommendations that fell out of the reviews in other sections of the guidance. One on the optimum monitoring frequency for those at risk of developing a diabetic foot problem and one on the optimum monitoring frequency for those who have developed a diabetic foot problem. The assessment and management of retinopathy is outside of the scope for this guideline but is covered by the guideline for type 2 diabetes due to be published at the same time.
British Foot and Ankle Surgery Society	Full	8.7.12	27	Charcot is frequently overlooked, with ?DVT or cellulitis diagnosed instead. A diabetic patient with a red hot swollen leg should always have X-rays of the foot and ankle. Admitting medical teams and radiologists / sonographersperforming duplex scans should all be made aware of this "rule".	Thank you for your response. This seems in line with recommendation 1.7.2: "Charcot should be suspected if there is redness, warmth, swelling or deformity (in particular, when the skin is intact), especially in the presence of peripheral neuropathy or renal failure. Think about acute Charcot arthropathy even when

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					deformity is not present or pain is not reported." We have also stated: "if acute Charcot arthropathy is suspected, X ray the affected foot."
Diabetes UK	NICE	9	13	Guidance for commissioners should include the provision of good quality annual foot reviews by competent health care professionals	Thank you for your suggestion. It is the intention of this guidance to set out what skills are necessary to perform a competent assessment of a patient. These are laid out in the section headed "Assessing the risk of developing a diabetic foot problem." This review may not always be performed by a general practitioner but by defining what is required for assessment it is possible for consideration to be given to service configurations which have staff with the competencies to perform annual foot reviews.
Foot in Diabetes UK & College of Podiatry	NICE	9	13	Care setting guidance for commissioners should include **primary care role** and potentially community podiatry services to ensure **screening/assessment and education** are identified if there is any serious attempt at prevention. FPS referrals are for the symptomatic	Within this guidance we do wish to recognise the role of primary care but also recognise the fact that it might not always be the general practitioner who performs a patient's review (at least annual in most cases). Whoever performs this review has the responsibility of examining the person's feet and assessing the risk. Foot protection service referrals are appropriate in the

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					case of moderate and high risk as we have laid out in recommendation 1.3.8. From this referral onwards the patient should receive the prevention interventions laid out in recommendation 1.3.10. The education and information needs for all diabetic patients are laid out in recommendation 1.3.13.
Foot in Diabetes UK & College of Podiatry	NICE	9	2	The "**10 highest recommendations from the CDG"** were chosen however ten are not clearly identifiable	Thank you for your comment. Following the guideline development group's choice of top 10 recommendations, one of the recommendations was split into two recommendations after editing. We have now reduced the number of recommendations down to 10.
University of Nottingham	Full	92	14 -16 20-12; 37-39; 44-45	The evidence regarding the effectiveness of education in affecting ulceration rate and amputation is all of low quality, although it appears to suggest potential benefit. The GDG are again currently recommending further trials of education and an evaluation of its effects on these outcomes. However, as noted above, this is ill advised given what we know about the limits of education in promoting behaviour change. Once again it is suggested that the mounting evidence regarding the effects of psychological and behavioural factors (e.g., low mood, coping, illness beliefs, adherence) on ulcer outcomes should	Thank you for your suggestion. The guideline development group discussed your proposal for further research in this area and agreed that it could be beneficial. As such the research recommendation for education has been amended to include the development and use of psycho-behavioural interventions.

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				encourage the GDG to suggest the development and evaluation of psychobehavioural interventions which focus on these modifiable factors (eg patient beliefs) and not education. Furthermore, it is suggested that research in this area should not focus only on interventions that can deliver behaviour change but which seek to achieve long-term maintenance of such change.	
University of Nottingham	Full	93	3 -5, 7-8	The evidence regarding the effectiveness of education in affecting infection and hospitalisation is also of low quality, although it appears to suggest potential benefit. The GDG are again currently recommending further trials of education and an evaluation of its effects on these outcomes. However, as noted above, this is ill advised given what we know about the limits of education in promoting behaviour change. Once again it is suggested that the mounting evidence regarding the effects of psychological and behavioural factors (e.g., low mood, coping, illness beliefs, adherence) on ulcer outcomes should encourage the GDG to suggest the development and evaluation of psychobehavioural interventions which focus on these modifiable factors (eg	Thank you for your comment. The guideline development group discussed your proposal for further research in this area and agreed that it could be beneficial. As such the research recommendation for education has been amended to include the development and use of psycho-behavioural interventions.

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				patient beliefs) and not education. Furthermore, it is suggested that research in this area should not focus only on interventions that can deliver behaviour change but which seek to achieve long-term maintenance of such change.	
British Association of Prosthetists and Orthotists	Full	97	1 -2	BAPO welcome the recommendation that those at risk of ulceration should receive biomechanical assessment, and consideration of the need for orthoses and footwear. As specialists in biomechanics and orthotics, BAPO hold the view that orthotists are best placed to perform this role.	Thank you for your response, your opinion has been taken into account. The guideline development group has chosen to maintain their initial decision to define the skillset required as opposed to naming any particular job title as this makes the guideline less prescriptive, more future proof and easier to implement.
Staffordshire University	Full	97	General	Effectiveness of Footwear – our papers attached.	Thank you for sending this recent systematic review which has helped to highlight one paper that was missed both by this and the previous guideline. While added to the meta-analysis performed it has not changed the conclusions of this meta-analysis and recommendations regarding effectiveness of footwear and orthoses remain the same.
Royal College of Paediatrics and Child	Full	General		As no evidence is provided to support the recommendations made, this must be clearly stated. As a consultant paediatrician for 17 years, looking after a population of up to 250 children and young people with diabetes, I have never come across diabetic	Thank you for your response. These recommendations were based upon consensus agreement as there was no evidence found for this age group. This has been stipulated in the linking evidence to recommendation section of

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Health				foot disease. If it does exist in this patient group it must be extremely rare. However, these recommendations do lead to extra unnecessary workload for the children's diabetes team, and impact both on the Best Practice Tariff and Peer review. I believe that young people moving into the adult service need to be educated about the importance of foot care, but that this should not apply to children or teenagers, who should be encouraged to live a normal life. This life will include running around with no shoes on, wearing trainers and 6" high heels. I believe that these recommendations, apart from basic education about foot care, should not apply to children and young people < 18 years old.	the corresponding chapter. The guideline development group felt transitional services will prepare young people for movement into adult care by assessing the feet (which will happen at least annually as an adult). Educating young people about the risk of developing foot problems in later life was felt to be very important. In terms of increased workload for the transitional and paediatric care teams we recognised the fact that children above the age of 12 receive annual assessment and that adding an examination of the feet was not felt to be an excessive divergent from current practice. The recommendation has been reworded to make clearer that foot inspection should take place as part of the annual assessment and not a separate review.
All Party Parliamentary Group on Vascular Disease	NICE	General	General	More should be done to support early diagnosis and intervention. It should be made clear within the guidelines that amputation should be considered a failure, and a functioning foot with minimal surgery should be the success. Ensuring patients receive an ABPI test as part of the early diagnostic and on-going care program in a hospital outpatient setting	Thank you for your response. Throughout the full guideline in the linking evidence to recommendation tables we make clear that the primary outcome is foot ulcer prevention and should this fail the next best thing is the promotion of ulceration healing. The guideline development group (GDG) agrees that amputation is an avoidable complication. The laying out of targets for the frequency of review of

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				is key to reducing complications from peripheral arterial disease, reducing the number of lower limb amputations and highlighting overall cardiovascular wellbeing. The ABPI test should also be included in regular diabetes foot checks, or when monitoring those individuals known to be at risk from peripheral arterial disease. By doing this it would provide a wider level of visibility which then would depend on expert interpretation. Including an ABPI test as a routine test would make a difference to patient experience and outcomes.	patients and the recommendations around the foot protection service for the care of moderate and high risk patients are all geared to this effect, prevention is greater than cure. In terms of the ankle brachial pressure index this guideline must defer to the NICE CG147 on management of lower limb peripheral arterial disease. We have included the caveat on being aware of the calcification of arteries because this is an issue that affects the diabetic population and is not mentioned in CG147. To make clear our intentions regarding the ankle brachial pressure index we have added a cross reference to CG147 within recommendation 1.3.5.
All Party Parliamentary Group on Vascular Disease	NICE	General	General	The guidelines reference the need for clear pathways which deliver the best outcomes for patients. All commissioners and providers should have a clear pathway for patients suspected of increased risk of PAD and the diabetic foot. The Pennine Acute Hospitals Integrated PAD Care Pathway is an outstanding example of an effective service for baseline peripheral arterial assessment. The model	Thank you for your response. We agree that the pathways and protocols referenced should include clear instruction for peripheral arterial disease and we hope that our recommendations will encourage this. In other respects the guideline must defer to NICE CG147 on the management of peripheral arterial disease. The management of peripheral arterial disease is outside the scope for this particular guideline.

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				can be found in the Appendix provided with this submission, named 'Appendix 1'. Commissioners and providers should also have a policy for referral to a Multi-Disciplinary Team with clear links to secondary care. Too many CCGs do not have a policy on either.	The guideline development group agrees that commissioners and providers should have clear policies for referral to the multidisciplinary foot care service and have written the following recommendation (please see third bullet point): 1.2.1 Commissioners and service providers should ensure that the following are in place: • A foot protection service (for preventing diabetic foot problems, and for treating and managing diabetic foot problems in the community). • A multidisciplinary foot care service (for managing diabetic foot problems in hospital and in the community that cannot be managed by the foot protection service). This may also be known as an interdisciplinary foot care service. • Robust protocols and clear local pathways for the continued and integrated care of people across all settings, including emergency care and general practice. The protocols should set out the relationship between the foot protection service and the

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					multidisciplinary foot care service. • Regular reviews of treatment and patient outcomes, in line with the National Diabetes Foot Care Audit.
All Party Parliamentary Group on Vascular Disease	NICE	General	General	The guidelines should place a stronger emphasis on the annual checks that every diabetic should have, which includes a foot check. This annual check-up provides the forum for the healthcare professional to reinforce important messages to the patient, in particular the importance of early intervention to prevent amputation. Evidence from a recent Diabetes UK audit suggested that there is very low completion of this annual check. The guidelines should reiterate the importance of this annual check-up and should recommend the use of an effective Multi-Disciplinary Team as the means of ensuring this early-intervention happens.	Thank you for your response. We hope to reinforce the annual checks that all patients with diabetes should receive and these are laid out under the heading "frequency of assessments." The components of this assessment are laid out under the heading "assessing the risk of developing a diabetic foot problem." These are strong recommendations and we hope that they will have the effect of ensuring that these annual (or more frequent) checks are received. The recommendations spanning the foot protection service and links to the multidisciplinary foot care service are all geared towards catching diabetic foot disease risk as early as possible and having services in place to manage both increased risk and to catch and treat any diabetic foot disease early.
All Party Parliamentary Group on	Implementation	General	General	Recommendation 1.1.1: As stated above, the Pennine Acute Hospitals Integrated PAD Care Pathway is an outstanding example of an effective service for baseline peripheral arterial assessment. The model	Thank you for your response. We agree that the pathways and protocols referenced should include clear instruction for peripheral arterial disease and we hope that our recommendations

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Vascular Disease				can be found in the Appendix provided with this submission, named 'Appendix 1'.	will encourage this. In other respects, the guideline must defer to NICE CG147 on the management of peripheral arterial disease. The management of peripheral arterial disease is outside the scope for this particular guideline.
All Party Parliamentary Group on Vascular Disease	Implementation	General	General	Recommendation 1.2.1: With conditions such as diabetic foot and PAD early identification and intervention are crucial to preventing escalation of the condition and ultimately amputation. In many cases, particularly with elderly patients who live in more remote rural areas, patients are often reluctant to engage with their clinicians because they don't want to 'bother' their doctors especially when they are not experiencing any pain in a 'black toe'. One of the most important and effective ways of combating this is through effective educational programmes for all people suffering or at risk of PAD or Diabetic Foot. There are educational programmes in place but the questions are; how effective are these, who is responsible for ensuring their effectiveness, what are the incentives or sanctions if the programmes are happening or not happening and where is the budget for this? These questions must be answered in order to ensure that the most	Thank you for your response. It is an important point about the elderly persons. The guideline development group (GDG) have tried to account for this potentially underserved group by recommending that: Healthcare professionals may need to discuss, agree and make special arrangements for disabled people and people who are housebound or living in care settings, to ensure equality of access to foot care assessments and treatments. The benefit of an educational programme over and above a good standard of care (with education) was not shown by the evidence to provide additional benefit for those at risk of developing diabetic foot disease. Please see section 4.6 of the full guideline. However it was found to be more effective for those who had developed active disease as shown in section 4.9 of the full guideline and this is reflected in the recommendations drafted

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				effective educational programmes are in place at the local, regional and national levels. This education work must extend to training of care workers to identify early signs of diabetic foot or PAD. This is very much in line with the concept of "every contact counts" and will be increasingly important with the increased integration of health and social care services. This education of care workers has the potential to significantly contribute towards the prevention agenda and should be included in training programmes.	for the information needs of those who had developed a diabetic foot problem. Further research may be needed to define the circumstances where educational or behavioural interventions may prove effective in those at risk of developing diabetic foot problems. The training of healthcare professionals fell outside of the scope of this guideline and the group were not able to draft recommendations on this subject.
Autonomed	Implementation	General	General	Recommendation number 1-4: No challenge exists to put these into practice as all mechanisms allowing the adoption of the recommendations are already in place. The recommendations simply augment with a further degree of detail, action and guidance the existing guidelines which these will replace.	Thank you for your response. We have passed it to the NICE implementation team to inform the support activities for this guideline.
Autonomed Limited	NICE	General	General	The document title includes the term "prevention" but guidance or reference to recent advances in NHS approved preventative measures is missing. NHS Drug Tariff listing / prescription approval has recently been granted for a	Thank you for your response. The guideline development group (GDG) reviewed evidence from trials including the use of bespoke and off the shelf footwear and have chosen to recommend it where appropriate in the management

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				range of clinically proven orthotics to be used prophylactically, specifically targeting the prevention of diabetic foot ulcers. Clinically proven to reduce the risk and incidence of ulceration, controlled clinical trials (published) conducted within the NHS proved that by way of substantial peak pressure offload and increase to tissue perfusion, the two main contributory factors leading to diabetic foot ulceration are addressed. This subsequently gained NHS approval to be prescribed as a preventative measure for those deemed "at risk" Guidance should therefore indicate and sanction prescribing of any such appropriate evidence based, prophylactic treatments where formal scrutiny by the NHS has included verification of product efficacy and Health Economics benefits in order to gain acceptance for prescription issue Corresponding minor changes are suggested below.	of those at moderate and high risk of developing a foot problem. The evidence does not point to recommending a particular brand of orthoses. Furthermore the GDG had to be selective with the outcomes of interest. Paramount to knowing if a prophylactic therapy would be clinically effective was to know if the intervention prevents the occurrence of ulcers or amputation. Outcomes such as peak pressure and increase to tissue perfusion were beyond the protocol of that particular review.
British Association of	Full	General	General	'Orthotics' is used as a noun is several places where the term 'orthoses' should be used instead. This is confusing and	Thank you for your comment, your suggestion has been incorporated.

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Prosthetists and Orthotists				inaccurate. Note that in popular use 'orthotics' may refer to foot orthoses, however people with diabetes may require foot orthoses, orthotic/therapeutic footwear, or ankle-foot orthoses. This terminology is defined in international standard terminology ISO 8549-1:1989. For reference: Orthotic – used as an adjunctive/descriptive term – i.e. an orthotic department or an orthotic prescription Orthotics – used to describe the profession – i.e. the field of orthotics Orthosis – singular term for medical devices – i.e. a foot orthosis Orthoses – plural term – i.e. a pair of orthoses Orthotist – the clinician	
British Foot and Ankle Surgery Society	Full	General	General	Achieving some of the recommendations will challenge the vast majority of hospitals. Centralisation of vascular services is underway, and units bereft of vascular support will require a different team composition to those hospital s with vascular surgery. In the former it is the Foot and Ankle Orthopaedic surgeon who will shoulder the main surgical burden. "Within	Thank you for your response regarding the centralisation of the vascular services and the need for examples of working arrangements. We have passed it to the NICE implementation team to inform the support activities for this guideline. The recommendations have been redrafted to state timing (in working days) for referral and triage in urgent cases, and

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				24 hours" is then not achievable, even with large T&O depts that have more than one such surgeon and "24 hour working / seven day care" will not improve this. Local protocols that do the best they can will be needed. A close liaison with the central vascular hub is also critical. This guidance should offer some examples of Local Guidelines complete with details of the local manpower and team arrangements, so that other units can choose a system that is working elsewhere with similar resources and manpower.	immediate treatment for emergency diabetic foot problems: 1.4.1 If a limb or life threatening diabetic foot problem refer the person to the multidisciplinary foot care service or acute services immediately (according to local protocols and pathways; also see recommendation 1.2.1) so they can be assessed and an individualised treatment plan put in place. Examples include: • Ulceration with fever or any signs of sepsis • Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). • Ulceration with limb ischaemia (also see NICE guideline on lower limb peripheral arterial disease). • Gangrene (with or without ulceration). 1.4.2 For all other active diabetic foot problems refer (according to local protocols and pathways; also see recommendation 1.2.1) to the multidisciplinary foot care service or foot protection service urgently (within 1 working day) for appropriate triage (within

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					1 further working day).
British Foot and Ankle Surgery Society	Full	General	General	There is simply not enough emphasis on how best to care for the "Foot Attack" where urgent incision and drainage may be life saving. It is very important that the idea of a severe infection being treated by antibiotics alone is dismissed. "Never let the sun go down on pus" remains an important surgical aphorism.	Thank you for your response. The guideline development group discussed active diabetic foot problems in need of emergency attention and redrafted the following recommendation in the understanding that a multidisciplinary foot care service may not be able to provide 24/7 hour care: 1.4.1 If a person has a limb-threatening or life-threatening diabetic foot problem, refer them immediately to the multidisciplinary foot care service or acute services (according to local protocols and pathways; also see recommendation 1.2.1), so they can be assessed and an individualised treatment plan put in place. Examples of limb-threatening and life-threatening diabetic foot problems include the following: • Ulceration with fever or any signs of sepsis. • Ulceration with limb ischaemia (see the NICE guideline on lower limb peripheral arterial disease). • Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). • Gangrene (with or without

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					ulceration). The group felt that these recommendations should ensure that all life and limb threatening emergencies receive the immediate attention that they require according to local protocols.
British Infection Association	NICE	General	General	We agree with the use of mild, moderate and severe categorisation of DFI. However, you need to look deep into the guts of the document to see that this refers to IDSA or PEDIS systems. Perhaps this could be more prominent in the summary section?	Thank you for your response. Please see the footnote which is on the same page of the recommendations that mentions the treatment of mild, moderate and severe diabetic foot infection showing that these classifications come from IDSA and PEDIS. This footnote appears in both the NICE and full versions.
British Infection Association	NICE	General	General	Imaging advice recommends MRI if radiology is inconclusive. In practice it is often useful (and quicker) to repeat the plain X-RAY after 2 weeks and look for evidence of progression. It is not clear to me whether the evidence behind this alternative (pragmatic) strategy has been reviewed?	Thank you for your response. The guideline development group considered the evidence for radiology for the diagnosis of osteomyelitis. They concluded that radiography of the foot may be an insensitive test for detecting osteomyelitis (although the test is quick, inexpensive and readily available and may still be diagnostic) but that MRI should form the next best option due to the superior diagnostic accuracy shown in the evidence reviewed. Since the feet of diabetic patients can deteriorate quickly it was felt that it may be unwise to recommend waiting 2 weeks to repeat a

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					test with low sensitivity.
British Orthopaedic Association	Implementation	General	General	Recommendation number 6: Establishing a multidisciplinary foot care service will alter. At the current time it is important to note the centralisation of vascular services. This will alter the dynamic of diabetic foot care in the non-vascular centres. It will be important to engage diabetologists to lead the foot care service in the non-arterial centres. They will need surgical support in the non-arterial centres, this could be provided by a foot and ankle trained orthopaedic surgeon. Most orthopaedic department now include this subspeciality. The alternative is that there will be an increased need to transfer patients to the vascular centre for assessment. The establishment of networks will be central to maintaining the quality of care for the multidisciplinary foot care service.	Thank you for your response. We have passed it to the NICE implementation team to inform the support activities for this guideline.
British Orthopaedic Association	Implementation	General	General	Recommendation number 6: Multidisciplinary foot care services will alter, as at the current time vascular services are being centralised. This will alter the dynamic of diabetic foot care in the non-vascular centres. It will be important to engage diabetologists to lead the foot care service in the non-arterial centres.	Thank you for your response. We have passed it to the NICE implementation team to inform the support activities for this guideline.

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				They will need surgical support in the non-arterial centres, this could be provided by a foot and ankle trained orthopaedic surgeon. Most orthopaedic department now include this subspeciality. The alternative is that there will be an increased need to transfer patients to the vascular centre for assessment. The establishment of networks will be central to maintaining the quality of care for the multidisciplinary foot care service.	
British Orthopaedic Association	Full	General	General	We fully support the development of a multidisciplinary team is vital for managing patients with diabetic foot problems. We agree that this team should include both a vascular surgeon to deal with issues of ischaemia and an orthopaedic surgeon to deal with osteomyelitis, deformity and Charcot neuroarthropathy. There should be ready access to a plastic surgical service.	Thank you for your response. The suggestion of the addition of a plastic surgeon was discussed with the guideline development group who drafted a new recommendation: 1.2.4 The multidisciplinary foot care service should also have access to rehabilitation, plastic surgery, health psychology and nutritional services.
British Orthopaedic Association	Full	General	General	We fully support the development of a multidisciplinary team is vital for managing patients with diabetic foot problems. We agree that this team should include both a vascular surgeon to deal with issues of ischaemia and an orthopaedic surgeon to deal with osteomyelitis, deformity and Charcot neuroarthropathy. There should be	Thank you for your response. The suggestion of the addition of a plastic surgeon was discussed with the guideline development group who drafted a new recommendation: 1.2.4 The multidisciplinary foot care service should also have access to

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				ready access to a plastic surgical service.	rehabilitation, plastic surgery, health psychology and nutritional services.
British Society for Antimicrobial Chemotherapy	NICE	General	General	BSAC has no further comments to make to this update / consultation	Thank you for your response.
Cardiff and Vale UHB	Full	General	General	A very comprehensive review of the evidence available, leading to good recommendations to develop and enhance service delivery. The below points have been raised to enhance the document and be used for future reviews.	Thank you for your response.
Cheshire Diabetes Network	Implementation	General	General	Recommendation 3.1: the risk stratification has introduced some changes in particular changing Neuropathy and callus from moderate to high risk. The associated change from review recommendation from 3 monthly to 2 monthly may well push some services beyond their currently cut down on capabilities. It also takes many patients beyond the criteria for current AQP tendering which makes us wonder if this statement is based on clinical evidence alone.	Thank you for your response. We have passed it to the NICE implementation team to inform the support activities for this guideline.
Cheshire Diabetes	Implementatio	General	General	The new guideline does set interesting questions for those without foot services as	Thank you for your response. We have passed it to the NICE implementation

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Network	n			outlined. As 20% of Hospitals in the UK currently do not have Diabetic Foot services (National In patient Diabetes Audit 2013) and feel the ongoing squeeze on finances plus tighter restrictions on commissioning may bring an interesting scenario in Board rooms around the country. Therefore feel there is a struggle with the guideline overall though look forward to the challenge of getting this implemented.	team to inform the support activities for this guideline.
Cheshire Diabetes Network	Full	General	General	We found that whilst the document has considered many aspects of Diabetic foot health, regarding development and the Categorisation and overall implementation, the of a Practice Nurse who are most like;y to be categorising patient initially, could have adde to the Guideline development panel and to the overall Richness of this guidance.	Thank you for your feedback. When the guideline was initiated, it was a challenge recruiting a nurse with experience across community and secondary care who was available to participate on the guideline committee. However, please be assured that the nurse who sat on the group is a diabetes specialist who works across secondary and community care.
Cheshire Diabetes Network	Full	General	general	On review we mainly support the Guideline and hope this gives sufficient teeth to those who have struggled to get Diabetic Feet taken seriously in their area. One area we feel needs clarification is in referral to either Foot protection or MDT and the time scales involved. Is the referral to be completed within 24hours or is contact to be made by the respective teams to be made in the	Thank you for your response. The guideline development group discussed the need to define when a patient with active foot disease and active foot disease which is an emergency should be triaged and treated by. The following two recommendations were redrafted: 1.4.1 If a person has a limb-threatening

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				same timescale? it isn't entirely clear throughout the document and clarity is paramount.	or life-threatening diabetic foot problem, refer them immediately to the multidisciplinary foot care service or acute services (according to local protocols and pathways; also see recommendation 1.2.1), so they can be assessed and an individualised treatment plan put in place. Examples of limb-threatening and life-threatening diabetic foot problems include the following: • Ulceration with fever or any signs of sepsis. • Ulceration with limb ischaemia (see the NICE guideline on lower limb peripheral arterial disease). • Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). • Gangrene (with or without ulceration). 1.4.2 For all other active diabetic foot problems, refer the person within 1 working day to the multidisciplinary foot care service or foot protection service (according to local protocols and pathways; also see recommendation 1.2.1) for triage within 1 further working day.

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					The hope is that these changes will ensure greater clarity in the areas that you have identified.
Department of Health	NICE	General	General	Thank you for the opportunity to comment on the draft for the above clinical guideline. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation	Thank you for your response.
Diabetes UK	NICE	General	General	Recognising that 80% of amputations are preventable there should be greater emphasis on preventative models of care	Thank you for your response. The guideline development group (GDG) throughout the guideline considered the prevention of ulceration the most critical outcome. The manner in which the GDG hopes to encourage prevention is via the recommendations on foot protection services. The aim is that all moderate and high risk diabetic patients should receive this service and the increased frequency of assessments laid out in recommendation 1.3.11. All patients who are under these services should receive a biomechanical assessment and this includes the requirement to provide specialist foot wear and orthoses to those who need it. Footwear advice is listed in the section on information and support for those at risk. Please also see the two sections on the education and information

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					needs for those at risk of developing a diabetic foot problem and those who have developed diabetic foot problems. Protection of moderate/high risk patients in secondary care settings has also been considered in the following recommendation: 1.3.12 People in hospital who are at moderate or high risk of developing a diabetic foot problem should be given a pressure redistribution device to offload heel pressure. On discharge they should be referred or notified to the foot protection service. Additionally there are two research recommendations to encourage further research in the area of footwear, insoles and orthoses and also educational models and psycho-behavioural interventions for those at risk of developing diabetic foot problems.
Diabetes UK	Full	General	General	Prevention – whilst the guidance is titled the "prevention and management" of foot problems, there is very little about prevention of foot ulcers in the guidance.	Thank you for your response. The guideline development group (GDG) considers the prevention of ulceration our most critical outcome. The manner in

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				Neither is this flagged up as a priority area recommended for research. In the view of Diabetes UK this should be a priority. Ulcers precede about 80% of all amputations in people with diabetes, have a considerable impact on quality of life and are costly to the NHS. Guidance should be provided about foot protection including provision of orthoses, adapted footwear and education to people at risk of diabetes foot problems.	which the GDG hopes to encourage prevention is via the recommendations on foot protection services. The aim is that all moderate and high risk diabetic patients should receive this service and the increased frequency of assessments laid out in recommendation 1.3.11. All patients who are under these services should receive a biomechanical assessment and this includes the requirement to provide specialist foot wear and orthoses to those who need it. Footwear advice is also listed in the section on information and support for those at risk. The education needs are addressed in the section headed "Information and support for people at risk of developing a diabetic foot problem" The most effective educational models were also reviewed under section 4.6 of the guideline. The evidence was not strong for the efficacy of any particular educational programme. The GDG did however consider that education is clearly a good thing and that the evidence did not rule out the benefit of a good standard of education in clinical practice.

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					Thank you for your suggestion to make prevention higher priority for research recommendations. There are 2 relevant research recommendations, one requesting more research in the area of effective models of education or behavioural support, the other requesting more research in the area of effective methods of footwear intervention and orthotics. The GDG have made the research recommendation for education especially high priority and it will feature in the NICE version of the guideline.
EAST MIDLANDS DIABETIC FOOT GROUP	NICE	General	General	Overall, the document encapsulates current thought and is a welcome advance	Thank you for your response.
Foot in Diabetes UK & College of Podiatry	NICE	General	General	There are omissions of in the summary guidance, e.g. page 22 – the need to make provision for house bound and people in residential care. A check that all the main points have been flagged in the summary document	Thank you for your response. The recommendation you are referring to (recommendation 11) appears in the NICE version under section 1.2.5. We cannot see any omissions in the NICE version.
Foot in Diabetes UK &	NICE	General	General	the term 'limb ischaemia' be changed for the term 'peripheral arterial disease and critical limb ischaemia' throughout the	Thank you for your response. Assessment for limb ischaemia and peripheral arterial disease are included in

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College of Podiatry				document. The rationale is that when assessing for lower limb vascular disease in all people with diabetes – from early to late stage disease: 1. The clinician needs to focus on identifying early PAD, to reduce the risk of heart attack / stroke and related early death (via aggressive c.v. risk management) 2. The clinician needs to identify critical / severe limb ischaemia, to reduce the risk of amputation (via rapid referral to diabetes and vascular MDfT)	the following recommendation: 1.3.6 When examining a person's feet, remove their shoes, socks, bandages and dressings, and examine both feet for evidence of the following risk factors: • Neuropathy (use a 10 g monofilament as part of a foot sensory examination). • Limb ischaemia (also see the NICE guideline on lower limb peripheral arterial disease). • Ulceration. • Callus. • Infection and/or inflammation. • Deformity. • Gangrene. • Charcot arthropathy. We have referred to the NICE guideline CG147 on the diagnosis and management of peripheral limb ischaemia which lays out the assessment required to look for signs of peripheral limb ischaemia and critical limb ischaemia. Please also note the recommendation that was drafted to ensure that clinicians take into account the cardiovascular risk

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					of the diabetic foot patient: 1.4.4 If people present with a diabetic foot problem, take into account that they may have an undiagnosed, increased risk of cardiovascular disease that may need further investigation and treatment.
Foot in Diabetes UK & College of Podiatry	NICE	General	General	Recognising that 80% of amputations are preventable there should be greater emphasis on preventative models of care, even recognising that evidence may not be as strong as pharmacological evidence.	Thank you for your response. The guideline development group (GDG) considered the prevention of ulceration our most critical outcome. The GDG emphasises prevention through the recommendations on foot protection services. The aim is that all moderate and high risk diabetic patients should receive this service and the increased frequency of assessments for this patient group laid out in recommendation 1.3.11. All patients who are under these services should receive a biomechanical assessment and this includes the requirement to provide specialist foot wear and orthoses to those who need it. Footwear advice is listed in the section on information and support for those at risk. Please also see the two sections on the education and information needs for those at risk of developing a diabetic foot problem and those who have developed diabetic foot problems.

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					Protection of moderate/high risk patients in secondary care settings has also been made clearer with the following recommendation: 1.3.12 People in hospital who are at moderate or high risk of developing a diabetic foot problem should be given a pressure redistribution device to offload heel pressure. On discharge they should be referred or notified to the foot protection service. Additionally there will be two research recommendations to encourage further research in the area of footwear, insoles and orthoses and also educational models and psycho-behavioural interventions for those at risk of developing diabetic foot problems.
Foot in Diabetes UK & College of Podiatry	Full	General	General	no guidance on timescales for actually assessing and treating an acute foot problem is given previously 2011 cg119 referring within 24 hours for triage is the only guidance here and has not been updated. We would like to see it made clear that people should be assessed and treated within 1 working day if they have	Thank you for your response. The guideline development group discussed the need to define when a patient with active foot disease and active foot disease which is an emergency should be triaged and treated by. The following two recommendations were drafted:

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				active foot disease / acute emergency	1.4.1 If a person has a limb-threatening or life-threatening diabetic foot problem, refer them immediately to the multidisciplinary foot care service or acute services (according to local protocols and pathways; also see recommendation 1.2.1), so they can be assessed and an individualised treatment plan put in place. Examples of limb-threatening and life-threatening diabetic foot problems include the following: • Ulceration with fever or any signs of sepsis. • Ulceration with limb ischaemia (see the NICE guideline on lower limb peripheral arterial disease). • Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). • Gangrene (with or without ulceration). 1.4.2 For all other active diabetic foot problems, refer the person within 1 working day to the multidisciplinary foot care service or foot protection service (according to local protocols and pathways; also see recommendation 1.2.1) for triage within 1 further working day.

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Foot in Diabetes UK & College of Podiatry	Full	General	General	Prevention – whilst the guidance is titled the "prevention and management" of foot problems, there is very little about prevention of foot ulcers in the guidance. Neither is this flagged up as a priority area recommended for research. Guidance should be provided about foot protection including provision of othoses, adapted footwear and education to people at risk of diabetes foot problems.	Thank you for your response. The guideline development group (GDG) considered the prevention of ulceration the most critical outcome. The manner in which the GDG hopes to encourage prevention is via the recommendations on foot protection services. The aim is that all moderate and high risk diabetic patients should receive this service. All patients who are under these services should receive a biomechanical assessment and this includes the requirement to provide specialist foot wear and orthoses to those who need it. Footwear advice is also listed in the section on information and support for those at risk. The education needs are addressed in the section headed "Information and support for people at risk of developing a diabetic foot problem." The most effective educational models were also reviewed under section 4.6 of the guideline. The evidence was not strong for the efficacy of any particular educational programme. The GDG did, however, consider that education is beneficial and that the evidence did not rule out the benefit of a

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					good standard of education in clinical practice. Thank you for your suggestion to make prevention higher priority for research recommendations. There are 2 relevant research recommendations, one requesting more research in the area of effective models of education or behavioural support and the other requesting more research in the area of effective methods of footwear intervention and orthotics. The GDG have made the research recommendation for education especially high priority and it will feature in the NICE version of the guideline.
Medtronic Limited	NICE	General	General	Medtronic commends NICE on this guideline which will lead to better patient outcomes in this very important therapy area.	Thank you for your response.
Medtronic Limited	NICE	General	General	Medtronic supports the involvement of an Interventional Radiologist within the MDT to facilitate urgent referral for revascularisation and ultimately reducing the risk of costly and debilitating amputations.	Thank you for your response. Interventional radiology remains recommended as part of the multidisciplinary foot care service in recommendation 1.2.3.
Medtronic Limited	NICE	General	General	Medtronic supports the key priority that patients who present with active diabetic foot problems are referred to the multidisciplinary foot care service within 24	Thank you for your response. The guideline development group recommended a multidisciplinary foot care service (MDFS) within which rapid

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				hours. We would further encourage NICE to emphasise within its guidelines that: ➢ If the cause of diabetic foot ulceration is vascular, the rapid referral to an interventional radiologist **within this 24 hour period** is key to improving blood flow and saving the lower limb.	referrals can be made to the appropriate specialties depending on the requirements of the individual patient. The aim is that these decisions can be made within the MDFS and with respect to their specialist knowledge.
Medtronic Limited	NICE	General	General	Many critical limb ischemia patients with diabetes are referred too late to vascular specialists when little can be done to prevent lower limb amputation. It is important therefore to ensure primary care services are aware of the importance for early referral and the cost-effective interventions available, for example balloon angioplasty. We respectfully recommend the guideline should be more affirmative in encouraging commissioners of services and referrers to have a defined policy for referral of high risk patients to secondary care, early enough for these interventions to be possible.	Thank you for your response. We agree that the pathways and protocols referenced should include clear instruction for peripheral arterial disease and we hope that our recommendations will encourage this. The guideline must defer to CG147 on the management of peripheral arterial disease. The management of peripheral arterial disease is outside the scope of this guideline.
NHS England	NICE	General	General	The evidence base for prevention, diagnosis and management of diabetic foot disease, as highlighted in the full guidance document, is relatively sparse. The current	Thank you for your response. The guideline development group (GDG) agrees that the guideline does highlight the scarcity of evidence in several areas.

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				consultation guidance, while a very thorough piece of work, reflects that paucity of evidence. Given the morbidity associated with diabetic foot disease, the associated higher mortality risk, and the significant cost to the NHS, one wonders whether the clear paucity of evidence highlighted by this piece of work should be communicated formally to the NIHR to encourage more research within the field. There needs to be a greater overall emphasis on the need for cardiovascular disease risk factor attention - with approximately 50% mortality within 5 years of presentation with foot ulceration. Another general point is that the term "within 24 hours" is used repeatedly throughout the document. This assumes access 7 days a week to either foot protection team, or MDT or both. This is not the case in most areas of the country currently. While this will be provided by the vascular surgery component of the MDT on weekends at arterial centres, at non-arterial centres weekend availability of the MDT will rely on consultant diabetologists when they happen to be on call for general medicine, which will be only a minority of weekends.	We communicate this by producing research recommendation which will encourage funding in the highlighted areas. The 5 areas deemed most important in the NICE document will subsequently receive most attention from the National Institute for Health Research (NIHR). The group also agreed with your suggestion to have the Chair make a formal communication to the NIHR. This will be done for the research recommendation on intensive monitoring for those at risk of developing a diabetic foot problem (rated most highly by the committee in order of importance). In terms of the second point regarding cardiovascular risk, we agree that this is an important area which was why the GDG considered it important to highlight the need for the foot protection service to consider their patients diabetes management and cardiovascular risk in the recommendation below: 1.4.4 If people present with a diabetic foot problem, take into account that they may have an undiagnosed, increased risk of cardiovascular disease that may need further investigation and treatment.

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				The impact on workforce and resource allocation of the recommendation "within 24 hours", rather than "within 1 working day", is therefore highly significant, although clearly in the best interest of patients with diabetic foot disease. I am not aware of many, if any, services across the country where podiatrists are available on Saturdays and Sundays. Furthermore, consultant diabetologists are one of the major groups of physicians contributing to the general medical on-call rota in every hospital, and it may prove logistically very difficult for them to staff both general medical on call and new specialty on-call rotas.	The GDG has also suggested adding in a section in the introduction to the guideline that reflects the high mortality rate associated with cardiovascular disease in this patient group and the importance of good cardiovascular risk management. The GDG discussed the need to define when a patient with active foot disease and active foot disease which is an emergency should be triaged and treated by and the difficulties mentioned in your comment concerning 24 hour referral. In response, the group defined the diabetic foot problems that must receive immediate attention and the foot problems that could be safely seen within 72 hours (i.e. over a weekend). The following two recommendations were redrafted using the term "working day" instead of "24 hours" for clarity: 1.4.1 If a person has a limb-threatening or life-threatening diabetic foot problem, refer them immediately to the multidisciplinary foot care service or acute services (according to local protocols and pathways; also see recommendation 1.2.1), so they can be

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					assessed and an individualised treatment plan put in place. Examples of limb-threatening and life-threatening diabetic foot problems include the following: • Ulceration with fever or any signs of sepsis. • Ulceration with limb ischaemia (see the NICE guideline on lower limb peripheral arterial disease). • Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). • Gangrene (with or without ulceration). 1.4.2 For all other active diabetic foot problems, refer the person within 1 working day to the multidisciplinary foot care service or foot protection service (according to local protocols and pathways; also see recommendation 1.2.1) for triage within 1 further working day. Additionally the recommendation for 24 hour referral for those in inpatient settings remains in the understanding that appropriate triage will happen in these cases within 1 further working day also:

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					1.1.3 Refer the person to the multidisciplinary foot care team service within 24 hours of the initial examination of the person's feet. Transfer the responsibility of care to a consultant member of the multidisciplinary foot care team service if a diabetic foot problem is the dominant clinical factor for inpatient care. [2011] We recognise that your comment does suggest some challenges for implementation and we have passed your comments to the NICE implementation team to inform the support activities for this guideline.
NHS England	NICE	General	General	It is stated under key priorities for implementation that the GDG members chose their 10 highest ranking recommendations for implementation and a weighted average of their responses was calculated. However, at no point are those 10 recommendations listed.	Thank you for pointing this out. Following the guideline development group's choice of top 10 recommendations, one of the recommendations was split into two after editing which means there are 11 recommendations listed. We have removed the confusing statement and reduced the number of recommendations down to 10.
NHS England	NICE	General	General	1.3.4 - What is the performance of the 10g monofilament in assessing peripheral	Thank you for your response. The recommendation's wording was

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				neuropathy? In particular, the false negative rate, which is significant, needs to be appreciated by the clinicians performing the assessment.	discussed by the guideline development group (GDG) and it was agreed that, based on the prognostic evidence looked at, it was not possible to rule out other ways of testing for neuropathy. As a result the recommendation concerning the use of monofilament has been weakened to ensure that a full examination is performed but that a monofilament examination should form a part of this examination as there was evidence that monofilament was a useful test for assessing the risk of developing diabetic foot problems: • When examining a person's feet, remove their shoes, socks, bandages and dressings, and examine both feet for evidence of the following: Neuropathy (use a 10 g monofilament as part of a foot sensory examination). […] Therefore the current recommendation as it stands does not recommend the use of the monofilament alone but as part of the examination for neuropathy.
NHS England	NICE	General	General	1.3.11 - the suggested frequencies of assessment according to risk stratification.	Thank you for your response. The evidence base for both review questions

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				Has there been any form of assessment of consultations required per 1000 people with diabetes in order to inform the suggested frequencies? More specifically, is there the available work force to deliver on these suggestions for national standards of care?	on monitoring frequencies for those at risk of diabetic foot problems was unfortunately very poor and extremely scarce. The guideline development group produced the review frequencies based on their collective experience in clinical practice. The idea is that producing realistic targets will result in improved care and support for these persons over and above having none at all. We agree that these targets will have to be achievable. We recognise that your comment does suggest some challenges for implementation and we have passed your comments to the NICE implementation team to inform the support activities for this guideline.
NHS England	NICE	General	General	1.5.4 - Moist wound dressings if appropriate - why not just "the most appropriate wound dressing"?	The guideline development group agrees that the recommendation for moist wound dressing would not apply in all situations. The recommendation has been changed to state "wound dressing" for clinicians to be able to choose wound dressings as appropriate (or depending on local existing protocols)
NHS England	NICE	General	General	1.5.5 - Offer non-removable casting to off-load plantar neuropathic, non-ischaemic,	Thank you for your response. The guideline development group (GDG)

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				uninfected forefoot and midfoot ulcers - "consider" would be a more appropriate term, given the acknowledged extent of the evidence.	looked at a meta-analysis of the evidence comparing total contact casting versus removable cast walker. The total contact casting showed a significant improvement for the key outcome of wound healing. Moreover, there was a significant benefit in terms of complete wound healing in all trials comparing irremovable offloading strategies to removable strategies. This may well be because removable devices have to be worn to be effective and this may be a compliance issue. In terms of irremovable casting the GDG has chosen only to recommend this specific type of irremovable casting in the population in which it has been proven to show benefit i.e. plantar neuropathic, non-ischaemic, uninfected forefoot and midfoot ulcers and is therefore a conservative recommendation which seems in line with the evidence found.
NHS England	NICE	General	General	1.6.15 "Offer prolonged antibiotic treatment (usually 6 weeks) to all people with diabetes and osteomyelitis, according to local protocols." I can find no evidence presented in the Full Guidance to justify the 6 weeks suggestion.	The guideline development group (GDG) reviewed the evidence for antibiotics in people with diabetic foot infections and osteomyelitis. The group noted that people with osteomyelitis will require antibiotic therapy for a longer duration and therefore thought it was necessary to provide a specific recommendation to reflect this. The 6 week mark was taken

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					from the length of treatment usually seen in clinical practice for these patients and was reflective of the knowledge and consensus of the GDG. It was recognised that actually some patients may not need as long as 6 weeks if treated early, for example, by surgical intervention. A separate review was not undertaken for the length of treatment required for someone with osteomyelitis and the GDG made a consensus recommendation.
NHS England	NICE	General	General	1.7 - pain is a common feature of Charcot, and this should be stated.	The recommendation states "Suspect acute Charcot arthropathy if there is redness, warmth, swelling or deformity (in particular, when the skin is intact), especially in the presence of peripheral neuropathy or renal failure. Think about acute Charcot arthropathy even when deformity is not present or pain is not reported." The guideline development group felt that after reviewing the evidence it was important to stress that even in the absence of pain Charcot foot should be thought about. Especially since the common cause is diabetic neuropathy. A very low quality case control study of 59 participants with diabetes found significantly lower measures of superficial pain sensation, vibrational (tuning fork) sensation, deep

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					tendon reflex, and fine touch (Semmes-Weinstein monofilament) sensation in those with Charcot foot. They decided that, after reviewing the evidence, the most important symptoms to look out for in acute Charcot foot were the ones listed above i.e. a red, warm, swollen or deformed foot.
Podiatry North West Clinical Effectiveness Group for Tissue Viability, Diabetes and Peripheral Arterial Disease	Implementation	General	General	Recommendation number 9: Seeing High Risk within 2 – 4 weeks and Moderate Risk within 6 – 8 weeks. Podiatry service provision is tight and seeing patients within a set timeframe may be difficult for services to overcome especially with other service pressures such as AQP timeframes. However it is a good move by the GDG to have target times especially when you consider cancer referral to treatment times have meant a reduction in cancer related deaths, hopefully arterial disease in diabetes can have a similar reduction by making this recommendation. Ensuring appropriate staffing levels for foot protection services will help to overcome this, when staffing numbers are down tends to be when the patient treatment/ assessment times are delayed.	Thank you for your response. We have passed it to the NICE implementation team to inform the support activities for this guideline.
Royal College of	NICE	General	General	There are some contents in the full guideline which are missing from the summary document.	Thank you for your suggestion. The scope defines settings as "all settings where NHS healthcare is commissioned

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Nursing				There is referral to NHS settings which does not reflect that many people live at home, in care homes etc and are treated there.	or delivered, (including a person's home)." We have removed the word "healthcare" to make "Care across all settings" in the heading above recommendation 1.2.5. "People living in care settings" is now added to the list of people that may be in need of special arrangements in recommendation 1.2.5.
Royal College of Nursing	Full	General	General	We are concerned that there appears to be no guidance on timescales for actually assessing and treating an acute foot problem – other than the 2011 one which suggests referring within 24 hours for triage. The current view is that people with active foot disease should be assessed and treated within 2 working days as this is an acute emergency.	Thank you for your response. The guideline development group discussed the need to define when a patient with active foot disease and active foot disease which is an emergency should be triaged and treated by. The following two recommendations were drafted: 1.4.1 If a person has a limb-threatening or life-threatening diabetic foot problem, refer them immediately to the multidisciplinary foot care service or acute services (according to local protocols and pathways; also see recommendation 1.2.1), so they can be assessed and an individualised treatment plan put in place. Examples of limb-threatening and life-threatening diabetic foot problems include the following: • Ulceration with fever or any signs of sepsis. • Ulceration with limb ischaemia

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					(see the NICE guideline on lower limb peripheral arterial disease). • Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). • Gangrene (with or without ulceration). 1.4.2 For all other active diabetic foot problems, refer the person within 1 working day to the multidisciplinary foot care service or foot protection service (according to local protocols and pathways; also see recommendation 1.2.1) for triage within 1 further working day.
Royal College of Nursing	Full	General	General	There is very little about prevention of foot problems in this guidance despite the title. There is also no mention of footwear and orthotics. This is important to ensure effective foot care advice.	Thank you for your response. The guideline development group (GDG) considered the prevention of ulceration the most critical outcome. The manner in which the GDG hopes to encourage prevention is via the recommendations on foot protection services. The aim is that all moderate and high risk diabetic patients should receive this service and the increased frequency of assessments laid out in this guidance. As stated in the recommendations, all patients who are

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					under these services should receive a biomechanical assessment and this includes the requirement to provide specialist foot wear and orthoses to those who need it. Footwear advice is listed in the section on information and support for those at risk.
Royal College of Radiologists	Full	General	General	Radiography of the foot is an insensitive test for detecting osteomyelitis, fractures, neuro-arthropathy, or soft tissue infection in the feet of diabetic patients. There should be a low threshold for considering referral for MRI scanning in diabetic patients with foot problems. Whether referring a patient for radiographs or MRI, detail needs to be given about location of symptoms- ankle/heel/midfoot/metatarsals/MTPjoints etc. Failure to give such localising detail may result in whole-foot imaging which is less sensitive and less specific. Imaging, whether by xrays or MRI is most accurate when localised. If referring a diabetic patient for MRI of their foot, simultaneous fast track referral should be made to an Orthopaedic Surgeon with particular interest in the foot. Fast track multi-disciplinary pathways and team working for diabetic patients with foot	Thank you for your response. The idea of the multidisciplinary foot care service is to allow fast track between specialties and as outlined in the recommendation this would include the services of orthopaedics, diabetology, podiatry and radiology as and when required. Thank you for the information regarding MRI scanning. The guideline development group (GDG) did not consider that it is appropriate to stipulate that MRI should be offered in every circumstance following a negative radiograph. They felt that they had sufficiently endorsed MRI as the next best option for diagnosis of either osteomyelitis or acute Charcot foot should clinical suspicion remain. We also appreciate the information provided on the advice to make such scans as localising as possible but the

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				problems are essential . These should involve Orthopaedics/Diabetology/Podiatry/ Radiology Nuclear Medicine Bone scans should only be requested by an Orthopaedic Surgeon in the context of multi-disciplinary liaison. Comprehensive clinical details and pre test probability is required to optimise accuracy of Nuclear Medicine Bone scan interpretation. The feet of diabetic patients can deteriorate catastrophically in just a few weeks through delays in diagnosis...and through delay in treatment.	group had not reviewed evidence to suggest the need to stipulate this within the recommendations. The GDG discussed the review on investigations for infected diabetic foot and acute Charcot foot and did not feel that they were able to confidently make a recommendation on the use of nuclear medicine bone scans based on the evidence presented.
Staffordshire University	Full	General	General	In general the guidelines have improved and it is more informative. However, I am still concerned that not enough consideration has been given to biomechanics/ tissue mechanics issues. I am sure you would agree that biomechanics/ gait assessment is relevant to section 4.4 – 4.7. But there is very little mention of this. In the current NHS podiatry/ orthotic practice very little focus is given to clinical biomechanics in true sense, which involves all aspects of musclo skeletal and soft tissue mechanics. I think we will miss an opportunity if we don't reflect on this within this document.	Thank you for your response. We have emphasised the importance of a biomechanical assessment but only in the patient group considered to be of moderate and high risk of developing diabetic foot problems. It is included in the recommendation for the required skillset available to the foot protection team and also in the recommendation of the assessment that all patients with moderate and high risk should receive. In response to the point about biomechanics, the intricacy of what makes a true biomechanical assessment and what does not was beyond the scope

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					of this guideline.
Foot in Diabetes UK & College of Podiatry	NICE	P23	General	The research subjects are disappointing with little attention to any care outside of hospital. Primary Care education and screening. Generalised prevention mechanisms such as issue of insoles to low and increased risk, improved skin care/tissue viability to reduce callus, other forms of neuropathy assessment – NICE have already recommended further research into VibraTip so why not include here? Research into teaching and competencies of HCP's within the foot pathway and most effective education models for people with diabetes. In short more research focused on prevention not intervention. MDT and diabetic foot service used interchangeably and does not recognise that some teams are led by vascular surgeons, so the point as to when to refer to specialists, e.g. Vascular surgeons or interventional radiology becomes void.	Thank you for your response. The guideline development group (GDG) has endeavoured to consider the care of patients outside of the hospital, most notably by considering the risk categories of persons with diabetes who would need care under a foot protection service. The annual assessment for the majority of patients is the screening method by which higher risk persons are identified. In terms of education needs these are addressed in the section headed "Information and support for people at risk of developing a diabetic foot problem." These recommendations make clear where and when patients would receive education. In terms of the issue of insoles, the GDG does not endorse the use of insoles in low risk patients. Skin and nail care are included in the list of responsibilities under the foot protection service for those at moderate and high risk and access to tissue viability is made a requirement by recommending the need for specialists with expertise in wound care in recommendation 1.2.2. Thank you for your suggestion regarding other forms of neuropathy assessment.

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					The review on assessment tools for the stratification of risk did not highlight a paucity of evidence in this area and therefore a research recommendation was not drafted for the use of VibraTip. The recommendation on assessing for neuropathy was however weakened to ensure that monofilament was used as part of a full foot sensory examination, without ruling out other forms of testing for neuropathy. The competency and training of health care professionals was not highlighted as a priority for research recommendations. However, there is a research recommendation on effective educational models included in the full version of the guideline along with another on the use of footwear, insoles and orthoses for prevention. The GDG decided the research recommendation on educational models should also take priority by appearing in the NICE version of the guideline (with four other priority recommendations). Multidisciplinary foot care service and foot protection service is not used interchangeably. One is a service in the

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					community and the other is based in hospital settings. They are two different services offering different levels of foot care. Some multidisciplinary foot care services may well be led by a vascular surgeon and this is the reason that we have not specified a lead for this service. It is important that the two services are recognisably different in the guideline.