Diabetes suite – Diabetic foot disease

Consultation on draft guideline - Stakeholder comments table
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British Orthopaedic Association	Guideline	General	General	The overall consensus is that the current guidance reflects good practice in terms of risk stratification for diabetic foot problems and we would agree with the updated recommendations for the annual foot check. So, overall we are in agreement with the proposed guideline	Thank you for your comment.
Cumbria, Northumberland Tyne and Wear NHS trust	Statement 3			Intermittent scanned glucose monitoring would we ideal for this group of patient's. However we have a patient on the autism ward who cannot tolerate these devices as they require a sensor on the skin that is in place 24/7.	Thank you for your comment. The committee considered this issue and agreed that continuous glucose monitoring was beyond the scope of this guideline update. We will pass your comment to the NICE Quality Standards team who will consider this in any future update of the Quality Standard.
Cumbria, Northumberland Tyne and Wear NHS trust	Statement 4			the BNF states that SGLT-2 Inhibitors cannot be used in patients with an eGFR of less than 60-also there is a risk of norm glycaemic ketoacidosis which would be difficult to detect in a learning disability patient group	Thank you for your comment. The committee considered this issue and agreed that SGLT-2 inhibitors was beyond the scope of this guideline update. We will pass your comment to the NICE Quality Standards team who will consider this in any future update of the Quality Standard.
Cumbria, Northumberland Tyne and Wear NHS trust	Statement 6			assessment for diabetic foot problems-this would be brilliant but the availability of podiatry is very poor in our area and we find it very difficult to source a professional who can even cut the toenails of our diabetic patients	Thank you for your comment. We will pass your comment to the NICE Quality Standards team who will consider this in any future update of the Quality Standard.
Diabetes UK	EIA	3.2	General	When discussing groups who need additional consideration to encourage foot screening, we think people with type 2 diabetes who have put the condition into remission should be included,	Thank you for your comment. The committee agreed that these people should be added to the EIA so this document has been amended. During their discussion on this, they also agreed that people with

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				especially those with a history of micro and macrovascular complications. We are concerned that this growing population may be at risk of being overlooked for annual screening. Whilst there is no clear data on their experience of foot care currently, we feel it is important for the committee to be aware of and consider this.	type 1 diabetes in remission (such as those with a pancreas transplant) should also be included.
Diabetes UK	Guideline	General	General	We agree with the decision to retain the existing recommendations for healthcare professionals to check the feet of people with diabetes at least annually and make a research recommendation for further evidence on the safety and effectiveness of a biennial screening for those at low risk of problems. The research and evidence on moving to a biennial screening for those at low risk of foot problems is encouraging but we are also aware of wide variation in the quality of foot checks in different parts of the country. We would therefore need to ensure consistency in the quality of foot checks and application of foot risk stratification before we could confidently support a move to a lower frequency of checks. We also agree with the committee's view on the importance of the annual check as an opportunity to encourage good foot care generally, and of the practicalities of doing foot check at the same time as	Thank you for your comment.

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				the annual review all people with diabetes should receive. This can be easily added to annual review paperwork - if not already included - and help people with diabetes minimise the burden of attending multiple appointments.	
Diabetes UK	Guideline	General	General	Question 1: Rec. 1.3.7 – However, we would highlight the challenges to implementing this guideline in practice given the low rate of annual checks recorded in the latest National Diabetes Audit figures. This reported that just 27% of people in England with type 1 diabetes received all their recommended checks in 2020-21, compared with 42% in 2019-2020, and 37% of people with type 2 diabetes receiving all their recommended checks in 2020-21, compared with 58% in 2019-2020. In order to provide the education, support and care required by this guideline it is essential that services are supported to recover and improve the rates of people with diabetes receiving their annual checks.	Thank you for your comment. There was agreement amongst the committee that rates of annual foot screening in general practice are usually very good, notwithstanding the reduced face-to-face contact during Covid restrictions. While the number of patients receiving *all* their recommended checks may be low, the committee noted that rates for foot surveillance in particular were good, with National Diabetes Audit figures showing 72.5% of people with type 1 diabetes and 83.9% of people with type 2 diabetes received their foot check in 2019-2020. They acknowledged that rates were understandably lower for 2020-2021 (51.0% for people with type 1 diabetes and 59.4% for people with type 2 diabetes) They noted that annual foot examination and risk classification is a QOF indicator and agreed that services should be supported to deliver this.
Diabetes UK	Guideline	General	General	This guideline uses the term diabetic foot and we would recommend following the NHS 'Language Matters' guidance which favours the use of language which is person-centred, more inclusive and values based.	Thank you for your comment. The committee discussed this issue and agreed that it is simply a medical term used to name a medical problem. They also noted that 'diabetic foot' is listed in the ICD 11 as an accepted medical term. They reflected on terminology used in other guidelines, including diabetic retinopathy, diabetic neuropathy, diabetic

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				This has been shown to help lower anxiety, build confidence, educate and help to improve self-care. Therefore "diabetic foot" should become "foot problem associated with/related to diabetes" or "foot in diabetes". Reference: https://www.england.nhs.uk/wp-content/uploads/2018/06/language-matters.pdf	ketoacidosis, and considered the potential complexity of rewording almost every recommendation in the guideline. The committee therefore agreed to provide a definition of diabetic foot problems in the 'Terms used in this guideline' section and acknowledged some of these issues relating to language within that definition.
Diabetes UK	Guideline	General	General	We would suggest that 'Act Now' resources developed by iDEAL Diabetes could be a helpful additional aid to reference in this guideline. This simple tool can be used by all healthcare professionals when stratifying the risk of foot problems to encourage prompt referral to specialist services. Reference: https://idealdiabetes.com/act-now-education-resources/	Thank you. We are aware of this resource, but it is not a risk stratification tool and we are unable to link to resources that have not been subject to review by the committee.
Diabetes UK	Guideline	006	001	Rec 1.3.6 – We would suggest adding heel pressure sores to the section on high-risk foot problems as in practice they may not always be classified as a foot ulcer related to diabetes.	Thank you for your comment. It was not possible to add heel pressure sores to the section on high-risk foot problems as this recommendation is based on the SIGN system and new items cannot be added without evidence to support this. However, the committee added reference to heel pressure sores in the definition of diabetic foot problems provided in the 'terms used in this guideline' section.
Diabetic foot Network Wales	Guideline	004	001	Recommendation is fully supported through People having the right to be involved in discussions and	Thank you for your comment. The committee discussed your comment and agreed that people

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				make informed decisions about their care and further discuss your care and shared decision making with clinicians around your care. But there's an unequal balance of power unless there's an understanding of the person activation to be able to participate as equal partners through co-production and this needs to be reflected within such recommendations.	have the right to be involved in discussions and to make informed choices about their care. The link to NICE's information on making decisions about their care makes reference to the NICE shared decision making guideline which gives recommendations about how to put this into practice. It advises how to engage people using healthcare services in making joint decisions and how to provide information resources before, during, and after appointments.
Diabetic foot Network Wales	Guideline	007	001	Education needs to be tailor made to the person at the right time otherwise it becomes other whelming	Thank you for your comment. There are several references to education elsewhere in the guideline that were not part of this short update, so those recommendations remain in place. This includes recommendation 1.3.13 which emphasises the importance of giving information and clear explanations in both oral and written format; and recommendation 1.4.3: "provide information and clear explanations as part of the individualised treatment plan for people with a diabetic foot problem."
Diabetic foot Network Wales	Guideline	007	004	What is the evidence for this? We understood that many of those who are identified as low risk remain low risk. Should the guidance include what advice needs to be given such as good HbA1c control, daily	Thank you for your comment. It is correct that many of those identified as low risk remain low risk, but the evidence also indicated that some people do transition from low to moderate risk over time (e.g., data from Crawford 2020 showed 2.56% moved

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				monitoring of feet, seek prompt access to HCP when a problem is identified	from low to moderate risk and 1.99% moved from low to high risk over the 8 year follow-up period). The committee agreed that it was important to ensure people understood that their risk may change, even though the likelihood of that was quite small. The section on 'patient information about the risk of developing a diabetic foot problem' that the link in this bullet point refers to recommends providing information about basic foot care advice and the importance of foot care, foot emergencies and who to contact, footwear advice, the person's current individual risk of developing a foot problem, and information about diabetes and the importance of blood glucose control. Recommendation 1.4.3 of this guideline also emphasises the importance of giving information about diabetic foot problems, foot care, foot emergencies, wound care, diabetes, and blood glucose control.
Diabetic foot Network Wales	Guideline	007	028	Frequency should be based on need and understanding patient's activation and ability to support self-care and access at times of crisis. This is resource expensive using capacity that could be used to support access at times of crisis	Thank you for your comment. No additional economic burden is anticipated as the guideline recommendations are aligned with those already in place for the frequency of foot review. The committee agreed to stick with annual monitoring because this is a key interaction point to promote education on foot care among people with diabetes. Reducing the frequency tends to incorrectly signal that foot care isn't a priority and would lead to more

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					people developing severe foot conditions that require more expensive treatments at a later point.
Diabetic foot Network Wales	Guideline	008	001	Frequency should be based on need and understanding patient's activation and ability to support self care and access at times of crisis. This is resource expensive using capacity that could be used to support access at times of crisis	Thank you for your comment. No additional economic burden is anticipated as the guideline recommendations are aligned with those already in place for the frequency of foot review. The committee agreed to stick with annual monitoring because this is a key interaction point to promote education on foot care among people with diabetes. Reducing the frequency tends to incorrectly signal that foot care isn't a priority and would lead to more people developing severe foot conditions that require more expensive treatments at a later point.
Diabetic foot Network Wales	Guideline	008	005	Consider more frequent reassessments for people who are at moderate or high risk, does this contradict earlier reassessments in the guideline? However this should all be based on individual needs not purely perceived risk based on clinical observations as it assumes people with diabetes cant reduce their risks.	Thank you for your comment. The committee discussed your comment and did not consider this to contradict earlier recommendations on assessment or reassessment. They maintained that the recommended review frequency should be evidence-based, and this is captured in the recommendations.
Diabetic foot Network Wales	Guideline	009	020	The guidelines although discusses patient involvement is very clinically led and could be seen as paternalistic, leading to resource intensive prevention and management recommendations. The person with diabetes is the most critical intervention to support self-care and supports their co-produced decision making. The guidelines should be recommending further research into how use of	Thank you for your comment. When discussing whether the frequency of monitoring should be reduced for people with low risk, the committee highlighted the importance of annual monitoring appointments to promote education on foot care among people with diabetes, which could also help to support self-care and shared decision making.

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				Activation and behaviour science can support improved outcomes.	At the beginning of the recommendations, there is a link to NICE's information on making decisions about their care which makes reference to the NICE shared decision making guideline which gives recommendations about how to put this into practice. This guideline was supported by evidence reviews which examined patient activation and behaviour science (for example behaviour change models and frameworks).
English Diabetes Footcare Network – (EDFN)	Guideline	General	General	The language used within the guidelines requires review for inclusion of people living with a diagnosis of diabetes – The current language can be construed as potentially discriminatory. The Language Matters guidance (https://www.england.nhs.uk/wp-content/uploads/2018/06/language-matters.pdf) advocates the use of appropriate language; verbal, written and non-verbal (body language) which is more inclusive and values based, which has the potential to reduce anxiety, build confidence, educate and improve self-care. The term 'diabetic foot' is problematic and should be 'a foot/lower limb problem associated with diabetes' or 'the foot in diabetes', or 'diabetes foot'. From a Language Matters perspective, it is not the foot that is diabetic so we should be advocating the use of person-first language (e.g. foot in diabetes rather than diabetic foot)	Thank you for your comment. The committee] discussed this issue and agreed that it is simply a medical term used to name a medical problem. They also noted that 'diabetic foot' is listed in the ICD 11 as an accepted medical term. They reflected on terminology used in other guidelines, including diabetic retinopathy, diabetic neuropathy, diabetic ketoacidosis, and considered the potential complexity of rewording almost every recommendation in the guideline. The committee therefore agreed to provide a definition of diabetic foot problems in the 'Terms used in this guideline' section and acknowledged some of these issues relating to language within that definition.

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English Diabetes Footcare Network – (EDFN)	Guideline	General	General	There is repeated use of the term 'Diabetic Foot Problem' without an actual definition provided. A definition of the term is recommended in order to provide clarity.	Thank you for your suggestion. The committee agreed that it would be useful to include a definition of Diabetic Foot Problem. This has been added to the section 'Terms used in this guideline.'
English Diabetes Footcare Network – (EDFN)	Guideline	General	General	These guidelines differ from the latest Traffic Lights system and the literature which have recently been developed in Scotland and endorsed by the Scottish Government (SDFAG) and the Podiatry Managers Group for Scotland. Changes in diabetes foot screening, timelines and the pathways were reviewed and considered when reviewing this guideline. Have these new guidelines been used and compared against when developing this updated NICE guidance?	Thank you for your comment. The committee were aware of the Traffic Lights system and associated literature, but the publications did not meet the inclusion criteria for the evidence review and the Traffic Lights System visual materials were considered to be tools to support implementation of the SIGN system.
English Diabetes Footcare Network – (EDFN)	Guideline	General	General	There is a concern of services being vulnerable to litigation claims owing to the screening guidance having very tight timeline periods.	Thank you for your comment. This is an implementation issue. Your comments will be considered by NICE where relevant support activity is being planned.
English Diabetes Footcare Network – (EDFN)	Guideline	General	General	There is a great concern that the model of care being advised not being cost effective in practice	Thank you for your comment. No additional economic burden is anticipated from this guideline update because the recommendations are aligned with current practice. The committee agreed to stick with annual monitoring because this is a key interaction point to promote education on foot care among people with diabetes. Reducing the frequency could incorrectly signal that foot care isn't a priority and would lead to more people developing

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					severe foot conditions that require more expensive treatments at a later point.
English Diabetes Footcare Network – (EDFN)	Guideline	General	General	The MDT needs to be clearly defined and delineated. This differs from the NHS-England definition.	Thank you for your comment. The committee considered this issue and agreed that MDTs were beyond the scope of this guideline update.
English Diabetes Footcare Network – (EDFN)	Guideline	General	General	The people/professionals comprising the Foot Protection Service (FPS) needs to be clearly delineated (e.g. General Practitioners, Practice Nurses, District Nurses, Carers, Community Podiatrists, etc…) From reading this document, it appears as though the FPS is regarded just as community podiatry	Thank you for your comment. This short update focuses on risk assessment tools and frequency of foot review only, but elsewhere in the guideline there are recommendations that cover the professionals involved in the care of people with diabetic foot problems: 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. **[2015]** 1.2.3 The multidisciplinary foot care service should be led by a named healthcare professional, and consist of specialists with skills in the following areas: • Diabetology. • Podiatry. • Diabetes specialist nursing. • Vascular surgery. • Microbiology. • Orthopaedic surgery.

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					• Biomechanics and orthoses. • Interventional radiology. • Casting. • Wound care. **[2015]**
English Diabetes Footcare Network – (EDFN)	Guideline	General	General	The general screening guidelines are not realistic in practice – There need to be robust mechanisms in place to ensure nurses, GPs and other healthcare professionals are adequately set up to provide comprehensive screening at the required frequency and demand, referring onward in an appropriate and timely manner. There also needs to be adequate resources throughout the FPS. Some FPS may not be able to accommodate a moderate risk patient who does not have any specific concerns in the timeframes given, with concerns raised for primary care services having the resources to see patients every 3-6 months. There also needs to be assurance that the person completing the annual foot check within an annual diabetes review this is certified to conduct a comprehensive diabetes foot screening	Thank you for your comment. The committee reflected on this issue but agreed that these were commissioning and resource-based issues that were outside the scope of this guideline update. However, your comments relating to guideline implementation will be considered by NICE where relevant support activity is being planned.
English Diabetes Footcare Network – (EDFN)	Guideline	General	General	In terms of people having an annual foot check as part of their annual diabetes review, is there the assurance that the person completing this is certified to conduct a comprehensive diabetes foot screening?	Thank you for your comment. The committee agreed that one of the advantages of the SIGN system is that is can be completed by those without specialist knowledge of diabetic foot care. They agreed that it was beyond the scope of this update to be specific about who should do those foot checks or what

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					training they should receive – this is an implementation issue.
English Diabetes Footcare Network – (EDFN)	Guideline	General	General	For the neuropathy screening section, should other tests be included (such as the Ipswich Touch Toes Test, and the neurothesiometer?	Thank you for your comment. The method for assessing neuropathy is out of scope for this short update – the scope focuses on risk stratification tools and did not look at the evidence to determine the most effective way for assessing neuropathy. However, we will pass your comment on to the NICE surveillance team which monitors guidelines to ensure they are up to date.
English Diabetes Footcare Network – (EDFN)	Guideline	005 - 006	General	The term 'non-critical limb ischaemia' is new terminology being introduced which hasn't been defined and adds a further layer of complication within a subject which is already difficult. This terminology is not used in NICE CG147 or within the Society of Vascular Surgeons. A replacement for another term would be recommended, such as peripheral arterial disease (PAD), or talk about the severity of PAD and signpost to resources in order to provide clarification on the subject matter.	Thank you for your comment. The committee agreed to make this change, so the guideline has been edited in line with this suggestion.
English Diabetes Footcare Network – (EDFN)	Guideline	005	008	Neuropathy (use a properly calibrated 10g monofilament as part of a foot sensory examination). Can we standardise the number of points to check with the calibrated 10g monofilament? i.e., 3, 5 or 10? The International Working Group guidelines (IWGDF) is 3, FRAME is 5.	Thank you for your comment. The method for assessing neuropathy is out of scope for this short update – the scope focuses on risk stratification tools and did not look at the evidence to determine the most effective way for assessing neuropathy. However, we will pass your comment on to the NICE

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					surveillance team which monitors guidelines to ensure they are up to date.
English Diabetes Footcare Network – (EDFN)	Guideline	005	010	NICE guideline on peripheral arterial disease is missing information on when to refer to vascular services, and also does not advise in management of lower limb wounds with PAD	Thank you for your comment. The committee considered these issues and agreed these were beyond the scope of this guideline update. However, we will pass your comment on to the NICE surveillance team which monitors guidelines to ensure they are up to date.
English Diabetes Footcare Network – (EDFN)	Guideline	005	030	Terminology of non-critical limb ischaemia needs to be updated to non-chronic limb threatening ischaemia in line with the global vascular definitions throughout document	Thank you for your comment. The committee agreed to make this change, so the guideline has been edited in line with this suggestion.
English Diabetes Footcare Network – (EDFN)	Guideline	006	011	Should read: infection, and spreading infection	Thank you for your comment. The committee considered your comment and they decided to amend this to 'infection' only as they agreed that this captured all possible types of infection – mild, moderate, spreading, systemic.
English Diabetes Footcare Network – (EDFN)	Guideline	006	012	The guideline seems to be using the terminology of Critical Limb Ischaemia but not defining nor including chronic limb threatening ischaemia (CLTI). There is an opportunity to align language and messages with existing national (CG147) and international guidelines (Society of Vascular Surgeons) - "CLTI is a clinical syndrome defined by the presence of peripheral artery disease (PAD) in combination with rest pain, gangrene, or a lower limb ulceration >2 weeks duration." vs. CLI a threshold value of ischaemia rather than a	Thank you for your comment. The committee agreed to make this change, so the guideline has been edited in line with this suggestion.

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				continuum of severity, which will support the future research version/question of when to refer to multi-disciplinary foot service.	
English Diabetes Footcare Network – (EDFN)	Guideline	006	015	Use of the word red. There is a need to consider diversity in skin tones as typically on dark skin, "red" may not be evident. Should read as 'change in colour'? This would also make it in line with other national initiatives and directives (e.g., the ACTNOW campaign)	Thank you for your comment. This has been amended to 'change in colour.'
English Diabetes Footcare Network – (EDFN)	Guideline	007	004	Advise that they may progress to moderate or high risk and therefore may need to be reviewed more frequently	Thank you for your comment. The committee considered this suggestion but agreed that it was not a necessary addition because they wanted the recommendation to focus on the person's current review frequency (annual) rather than speculating on what review frequency they may or may not need in the future.
English Diabetes Footcare Network – (EDFN)	Guideline	008	007	There is a gap within the guidance on assessment times. Referral or triage within a service does not mean assessment and this is a big gap that needs to be addressed to ensure that there is standardisation, which will improve quality	Thank you for your comment. There are existing recommendations on assessment times that were not part of this short update (see recommendation 1.3.3), and there are also existing recommendations on reassessment times that were retained in this update (see recommendation 1.3.11). While referral or triage within a service may not mean assessment, recommendations 1.3.8, 1.3.9 and 1.3.10 all highlight that people referred to the foot protection service should be assessed, how soon those assessments should occur, and what those assessments should involve.

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English Diabetes Footcare Network – (EDFN)	Guideline	009	009	The actual function of the MDT needs to be clearly defined and not just delineate the individual healthcare professionals within it.	Thank you for your comment. Research recommendation 3 (Referral criteria for the foot protection service and the MDT foot care service) was not part of the scope of this short update, which focused on risk stratification tools and foot review frequency. We are not able to amend areas of the guideline that are out of scope and shown as greyed out text in the consultation documents.
English Diabetes Footcare Network – (EDFN)	Guideline	009	018	The evidence for dressing selection is poor, therefore there should not be any recommendations made until there is more robust evidence	Thank you for your comment. This section of the guideline relates to research recommendations so this has been identified as an area where more evidence is needed, and recommendations cannot yet be made. These research recommendations are also outside the scope of this short update and shown as greyed out text in the consultation documents.
English Diabetes Footcare Network – (EDFN)	Guideline	009	022	Patients should be referred as stated, however the expected timeline to assessment should be specified.	Thank you for your comment. Timelines between referral to the foot protection service and assessment were not part of this short update, which focused on risk assessment tools and frequency of foot review. However, existing recommendations that were outside the scope of this update remain in place, and recommendation 1.3.9 specifies that the foot protection service should assess newly referred people as follows: • Within 2 to 4 weeks for people who are at high risk of developing a diabetic foot problem

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					• Within 6 to 8 weeks for people who are at moderate risk of developing a diabetic foot problem
English Diabetes Footcare Network – (EDFN)	Guideline	011	017	This statement should be inclusive and use the term "multiprofessional"	Thank you for your comment. The committee discussed this suggestion and agreed to amend the sentence to say "it is a short and simple assessment with 3 items, so could be completed by primary care professionals without specialist knowledge of diabetic foot care."
Foot in Diabetes UK (FDUK)	Guideline	General	General	There is repeated use of the term 'Diabetic Foot Problem', it would seem prudent to give a definition of the term to provide clarity on the guideline by the user.	Thank you for your suggestion. The committee agreed that it would be useful to include a definition of Diabetic Foot Problem. This has been added to the section 'Terms used in this guideline.'
Foot in Diabetes UK (FDUK)	Guideline	General	General	The members of the Foot Protection Service need to be clearly delineated (includes GPs, PNs, DNs, patient carers, etc…). Reading this document, the FPS is regarded just as community podiatry.	Thank you for your comment. This short update focuses on risk assessment tools and frequency of foot review only, but elsewhere in the guideline there are recommendations that cover the professionals involved in the care of people with diabetic foot problems: 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. **[2015]** 1.2.3 The multidisciplinary foot care service should be led by a named healthcare professional, and

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					consist of specialists with skills in the following areas: • Diabetology. • Podiatry. • Diabetes specialist nursing. • Vascular surgery. • Microbiology. • Orthopaedic surgery. • Biomechanics and orthoses. • Interventional radiology. • Casting. • Wound care. **[2015]**
Foot in Diabetes UK (FDUK)	Guideline	General	General	FDUK believe that the general guidance for screening is unrealistic in practice where PCN's and GP federations are not set up to provide the screening adequately, and frequently then send large lists of patients requiring "urgent" assessments with untenable timeframes to under resourced Podiatry Teams. For example - Many podiatry services are not able to see moderate risk patients with no specific concerns, and the primary care teams do not have the resources to see patients every 3-6 months.	Thank you for your comment. The committee reflected on this issue but agreed that these were commissioning and resource-based issues that were outside the scope of this guideline update. However, your comments relating to guideline implementation will be considered by NICE where relevant support activity is being planned.
Foot in Diabetes UK (FDUK)	Guideline	General	General	FDUK raises concerns that the model of care is not cost effective in practice,	Thank you for your comment. No additional economic burden is anticipated from this guideline update because the recommendations are aligned with current practice. The committee agreed to stick with annual monitoring because this is a key

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					interaction point to promote education on foot care among people with diabetes.
Foot in Diabetes UK (FDUK)	Guideline	General	General	Guidance for screening with tight time periods is leaving services open to litigation claims	Thank you for your comment. This is an implementation issue and will be considered by NICE where relevant support activity is being planned.
Foot in Diabetes UK (FDUK)	Guideline	General	General	The MDT needs to be clearly defined and delineated. This differs from NHS-E.	Thank you for your comment. The committee considered this issue and agreed that MDTs were beyond the scope of this guideline update.
Foot in Diabetes UK (FDUK)	Guideline	General	General	Have the latest Traffic Lights system and the literature endorsed by the Scottish Government, the SDFAG and the Podiatry Managers Group for Scotland for the changes to Foot Screening in Scotland been reviewed and considered when reviewing this guideline?	Thank you for your comment. The committee were aware of the Traffic Lights system and associated literature, but the publications did not meet the inclusion criteria for the evidence review and the Traffic Lights System visual materials were considered to be tools to support implementation of the SIGN system.
Foot in Diabetes UK (FDUK)	Guideline	General	General	Neuropathy screening; should this not also include neurothesiometer, and the Ipswich test?	Thank you for your comment. The method for assessing neuropathy is out of scope for this short update – the scope focuses on risk stratification tools and did not look at the evidence to determine the most effective way for assessing neuropathy. However, we will pass your comment on to the NICE surveillance team which monitors guidelines to ensure they are up to date.
Foot in Diabetes UK (FDUK)	Guideline	General	General	In terms of people having an annual foot check as part of their annual diabetes review, is there the assurance that the person completing this is certified to conduct a comprehensive diabetes foot screening?	Thank you for your comment. The committee agreed that one of the advantages of the SIGN system is that is can be completed by those without specialist knowledge of diabetic foot care. They agreed that it was beyond the scope of this update to be specific

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					about who should do those foot checks or what training they should receive – this is an implementation issue.
Foot in Diabetes UK (FDUK)	Guideline	General	General	Language is not inclusive for those with diabetes, i.e. can be construed as discriminatory- "diabetic foot" The Language Matters guidance (https://www.england.nhs.uk/wp-content/uploads/2018/06/language-matters.pdf) favours use of language; verbal, written and non-verbal (body language) which is more inclusive and values based, can lower anxiety, build confidence, educate and help to improve self-care. Therefore 'diabetic foot' becomes foot problem associated with diabetes or foot in diabetes. From a Language Matters point of view they would say that it is not the foot that is diabetic so we should be using more person-first language (e.g. foot in diabetes rather than diabetic foot)	Thank you for your comment. The committee discussed this issue and agreed that it is simply a medical term used to name a medical problem. They also noted that 'diabetic foot' is listed in the ICD 11 as an accepted medical term. They reflected on terminology used in other guidelines, including diabetic retinopathy, diabetic neuropathy, diabetic ketoacidosis, and considered the potential complexity of rewording almost every recommendation in the guideline. The committee therefore agreed to provide a definition of diabetic foot problems in the 'Terms used in this guideline' section and acknowledged some of these issues relating to language within that definition.
Foot in Diabetes UK (FDUK)	Guideline	005 - 006	-	The term 'non-critical limb ischaemia' is a new terminology being introduced: • 1. without a definition, and • 2. further complicates an already relatively difficult subject. This is a terminology that is not used in either the Vascular Society Guidelines nor NICE CG147.	Thank you for your comment. The committee agreed to make this change, so the guideline has been edited in line with this suggestion.

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				FDUK would advocate its replacement for another term, such as peripheral arterial disease, or talk about severity of PAD but a link to source material would be needed for clarification.	
Foot in Diabetes UK (FDUK)	Guideline	005	008	Neuropathy (use a properly calibrated 10g monofilament as part of a foot sensory examination). Can we standardise the number of points to check with the calibrated 10g monofilament? i.e., 3, 5 or 10? The International Working Group guidelines (IWGDF) is 3, FRAME is 5.	Thank you for your comment. The method for assessing neuropathy is out of scope for this short update – the scope focuses on risk stratification tools and did not look at the evidence to determine the most effective way for assessing neuropathy. However, we will pass your comment on to the NICE surveillance team which monitors guidelines to ensure they are up to date.
Foot in Diabetes UK (FDUK)	Guideline	005	010	NICE guideline on peripheral arterial disease, has a missing gap on when to refer to Vascular services, and also a gap in management of lower limb wounds with PAD	Thank you for your comment. The committee considered these issues and agreed these were beyond the scope of this guideline update. However, we will pass your comment on to the NICE surveillance team which monitors guidelines to ensure they are up to date.
Foot in Diabetes UK (FDUK)	Guideline	005	030	Terminology of non-critical limb ischaemia needs to be updated to non-chronic limb threatening ischaemia in line with the global vascular definitions throughout document	Thank you for your comment. The committee agreed to make this change, so the guideline has been edited in line with this suggestion.
Foot in Diabetes UK (FDUK)	Guideline	006	011	Should read: infection, and spreading infection	Thank you for your comment. The committee considered your comment and they decided to amend this to 'infection' only as they agreed that this captured all possible types of infection – mild, moderate, spreading, systemic.

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Foot in Diabetes UK (FDUK)	Guideline	006	012	The guideline seems to be using the terminology of Critical Limb Ischaemia but not defining or including Chronic Limb Threatening Ischaemia (CLTI). This would be an opportunity to align its language and message with existing national (CG147) and international guidelines (Vascular Society) - "CLTI is a clinical syndrome defined by the presence of peripheral artery disease (PAD) in combination with rest pain, gangrene, or a lower limb ulceration >2 weeks duration." vs. CLI a threshold value of ischaemia rather than a continuum of severity, which will support the future research version/question of when to refer to MDFS	Thank you for your comment. The committee agreed to make this change, so the guideline has been edited in line with this suggestion.
Foot in Diabetes UK (FDUK)	Guideline	006	015	Use of the word red. There is a need to consider diversity in skin tones as typically on dark skin, "red" may not be evident. Should read as 'change in colour' ?	Thank you for your comment. This has been amended to 'change in colour.'
Foot in Diabetes UK (FDUK)	Guideline	007	004	Advise that they may progress to moderate or high risk, need to add on and therefore may need more regular review	Thank you for your comment. The committee considered this suggestion but agreed that it was not a necessary addition because they wanted the recommendation to focus on the person's current review frequency (annual) rather than speculating on what review frequency they may or may not need in the future.
Foot in Diabetes UK (FDUK)	Guideline	008	007	There is a gap within the guidance on assessment times. Referral or triage within a service does not mean assessment and this is a big gap that needs to be addressed to ensure that there is standardisation, which will improve quality	Thank you for your comment. There are existing recommendations on assessment times that were not part of this short update (see recommendation 1.3.3), and there are also existing recommendations on reassessment times that were retained in this

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					update (see recommendation 1.3.11). While referral or triage within a service may not mean assessment, recommendations 1.3.8, 1.3.9 and 1.3.10 all highlight that people referred to the foot protection service should be assessed, how soon those assessments should occur, and what those assessments should involve.
Foot in Diabetes UK (FDUK)	Guideline	009	009	The function of the MDT should be defined and not focus on stating the individuals within it.	Thank you for your comment. Research recommendation 3 (Referral criteria for the foot protection service and the MDT foot care service) was not part of the scope of this short update, which focused on risk stratification tools and foot review frequency. We are not able to amend areas of the guideline that are out of scope and shown as greyed out text in the consultation documents.
Foot in Diabetes UK (FDUK)	Guideline	009	018	The evidence for dressing selection is poor and therefore there should not be any recommendations made until there is more robust evidence.	Thank you for your comment. This section of the guideline relates to research recommendations so this has been identified as an area where more evidence is needed, and recommendations cannot yet be made. These research recommendations are also outside the scope of this short update and shown as greyed out text in the consultation documents.
Foot in Diabetes UK (FDUK)	Guideline	009	022	Patients should be referred as stated, however the expected timeline to assessment should be specified.	Thank you for your comment. Timelines between referral to the foot protection service and assessment were not part of this short update, which focused on risk assessment tools and frequency of foot review. However, existing recommendations that were outside the scope of this update remain in

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					place, and recommendation 1.3.9 specifies that the foot protection service should assess newly referred people as follows: • Within 2 to 4 weeks for people who are at high risk of developing a diabetic foot problem • Within 6 to 8 weeks for people who are at moderate risk of developing a diabetic foot problem
Foot in Diabetes UK (FDUK)	Guideline	011	017	This statement should be inclusive and use the term "multiprofessional".	Thank you for your comment. The committee discussed this suggestion and agreed to amend the sentence to say "it is a short and simple assessment with 3 items, so could be completed by primary care professionals without specialist knowledge of diabetic foot care."
Frimley Health NHS Foundation Trust	Guideline	General	General	Dear Chair and Guideline Committee Members, Thank you for the draft guideline for Diabetic foot problems: prevention and management. I wish to highlight the following points for feedback. - There should be a section on the emergency management of the Diabetic Foot Attack. This should include recognizing the limb and potentially life-threatening diagnosis, the recommended rapid referral pathways to appropriately trained teams from the community to secondary care, urgent prioritisation in theatres, debridement of sepsis and	Thank you for your comment. The scope of this short update was on risk stratification tools so emergency management of diabetic foot was out of scope. However, existing recommendations remain in place. Recommendation 1.4.1 states that: "If a person has a limb-threatening or life-threatening diabetic foot problem, refer them immediately to acute services and inform the multidisciplinary foot care service…, so they can be assessed, and an individualised treatment plan put in place."

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				devitalised tissues taking precedence before attempts at revascularisation. - ABPI assessment is still being recommended with caution by the draft guidelines. The committee should go one step further and recommend the assessment of toe pressures or Transcutaneous Oximetry TCpO2 readings in secondary care if PAD is suspected to enable WiFI classification of all at risk diabetic foot ulcers to bring the UK in line with the IWGDF guidelines and good international practice. Tissue perfusion is more useful in these patients. Thank you for your hard work.	The committee considered the assessment of toe pressures or Transcutaneous Oximetry TCpO2 readings in secondary care and agreed these were beyond the scope of this guideline update.
Leeds Community Healthcare NHS Trust	Guideline	011	001 - 031	I agree with keeping the decision to retain the existing recommendations. I agree with points raised.	Thank you for your comment.
Leeds Community Healthcare NHS Trust	Guideline	013	005 - 008	I agree with keeping the decision to retain the existing recommendations. I agree with points raised.	Thank you for your comment.
Manchester Metropolitan University	Evidence review B	General	General	Clinical trial evidence on the prevention of diabetic foot ulcers in high-risk patients using digital and emerging technologies is missing from the evidence review as part of this draft guideline. We strongly recommend inclusion: Abbott CA, Chatwin KE, Foden P, Hasan AN, Sange C, Rajbhandari SM, Reddy PN, Vileikyte L, Bowling FL, Boulton AJM & Reeves ND (2019). Innovative	Thank you for these references. The two suggested trials do not meet the review inclusion criteria – they present evidence for an insole system to monitor and provide feedback on high plantar pressure and examine the effect of this technology in preventing ulcer recurrence; digital interventions to prevent ulcer recurrence are excluded. The trials do not present a risk stratification system for assessing the

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				intelligent insole system reduces diabetic foot ulcer recurrence at plantar sites: a prospective, randomised, proof-of-concept study. Lancet Digital Health. 1(6):e308–18. Chatwin KE, Abbott CA, Rajbhandari SM, Reddy PN, Bowling FL, Boulton AJM & Reeves ND (2021). An intelligent insole system with personalised digital feedback reduces foot pressures during daily life: An 18-month randomised controlled trial. Diabetes Research and Clinical Practice.181, 109091.	risk of developing a DFU and therefore cannot be included in the review.
Manchester Metropolitan University	Evidence review B	General	General	Evidence showing that time spent being sedentary is a strong predictor of diabetic foot ulceration is missing from the evidence review as part of this guideline: Orlando G, Reeves ND, Boulton AJM, Ireland A, Federici G, Federici A, Hakhi J, Pugliese G & Balducci S (2021). Sedentary behaviour is an independent predictor of diabetic foot ulcer development: An 8-year prospective study. Diabetes Research and Clinical Practice. 177, 108877.	Thank you for this reference. Studies that only examined risk factors or predictors of diabetic foot ulceration, without incorporating those risk factors into a risk assessment / stratification tool, were excluded from the review. The committee discussed the impact of sedentary behaviour on diabetic foot problems, but as none of the included risk stratification models incorporated sedentary behaviour in their assessment, they were unable to include this in the recommended risk assessment system.
Manchester Metropolitan University	Evidence Review B	General	General	A recent paper has presented a robust diabetic foot ulcer risk stratification model/foot screening tool, very easy to perform by a wide range of health care professionals, and therefore likely to improve screening accuracy. The paper identified a critical, highly sensitive, barefoot peak plantar pressure	Thank you for this reference. The suggested paper presents data to show a barefoot peak plantar pressure threshold value of >4.1kg for identifying sites of *previous* DFU, but it does not present evidence of its ability to *predict* future foot ulceration. Furthermore, the paper does not report on the

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				threshold value of >4.1kg to identify sites of previous diabetic foot ulcer and, therefore, re-ulceration risk. We strongly recommend inclusion of this risk stratification paper in the evidence review as part of this guideline: Abbott CA, Chatwin KE, Rajbhandari SM, John KM, Pabbineedi S, Bowling FL, Boulton AJM, Reeves ND (2022) Site-Specific, Critical Threshold Barefoot Peak Plantar Pressure Associated with Diabetic Foot Ulcer History: A Novel Approach to Determine DFU Risk in the Clinical Setting. Medicina, 58, 166. Jan 2022 https://doi.org/10.3390/medicina58020166	validation of a model or assessment tool that can stratify patients into various risk groups and therefore does not meet the inclusion criteria for the review.
Manchester Metropolitan University	Guideline	General	General	In the key recommendations for research, we would suggest that there is an important emerging area for research that is completely missing as a section on its own – the impact of sedentary time on diabetic foot ulcer risk. There is emerging evidence now to show that time spent being sedentary is a strong predictor of diabetic foot ulceration. Specifically, an 8-year prospective study has shown that sedentary time was the strongest predictor of people with diabetic peripheral neuropathy who will go on to develop a diabetic foot ulcer: Orlando G, Reeves ND, Boulton AJM, Ireland A, Federici G, Federici A, Hakhi J, Pugliese G & Balducci S (2021). Sedentary behaviour is an independent predictor of diabetic foot ulcer	Thank you for this reference. Studies that only examined risk factors or predictors of diabetic foot ulceration, without incorporating those risk factors into a risk assessment / stratification tool, were excluded from the review. The committee discussed the impact of sedentary behaviour on diabetic foot problems, but as none of the included risk stratification models incorporated sedentary behaviour in their assessment, they were unable to include this in the recommended risk assessment system. The committee were unable to make a research recommendation on the impact of sedentary

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				development: An 8-year prospective study. Diabetes Research and Clinical Practice. 177, 108877. This fits with the 'physical stress theory' of foot tissues becoming deconditioned through lack of foot loading and therefore breaking down more easily when 'spikes' in foot loading activity occur. We strongly recommend considering adding this area as an emerging area of research under the section 'Key recommendations for research".	behaviour on diabetic foot ulcer risk because they did not look at sedentary behaviour in the evidence review, so it was not possible to establish whether there is a known evidence gap which needs addressing with a research recommendation, or if the evidence exists but wasn't included in the review.
Manchester Metropolitan University	Guideline	General	General	We welcome these guidelines, however, considering the focus on *prevention* of diabetic foot ulceration, there should be mention of the potential efficacy of pressure feedback technology. This technique has shown proof-of-concept efficacy as part of clinical trials and should at least be acknowledged as an emerging area where further evidence is needed to strengthen the case. The primary clinical trial evidence is: Abbott CA, Chatwin KE, Foden P, Hasan AN, Sange C, Rajbhandari SM, Reddy PN, Vileikyte L, Bowling FL, Boulton AJM & Reeves ND (2019). Innovative intelligent insole system reduces diabetic foot ulcer recurrence at plantar sites: a prospective, randomised, proof-of-concept study. Lancet Digital Health. 1(6):e308–18. Other clinical trial evidence in support of this is: Chatwin KE, Abbott CA, Rajbhandari SM, Reddy PN, Bowling FL, Boulton AJM & Reeves ND (2021).	Thank you for your comment. The focus of this short update is on risk assessment tools for stratifying risk groups rather than prevention interventions per se. However, the committee made a research recommendation about digital and emerging technologies.

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				An intelligent insole system with personalised digital feedback reduces foot pressures during daily life: An 18-month randomised controlled trial. Diabetes Research and Clinical Practice.181, 109091. We therefore strongly recommend reflecting this evidence through inclusion of plantar pressure feedback as a prevention consideration within the guideline.	
Manchester Metropolitan University	Guideline	009	001 - 006	We agree with this statement, but it is not complete. The question is asked: "*What is the effectiveness, cost-effectiveness and acceptability of digital and emerging technologies for assessing the risk of developing a diabetic foot problem*". In addition to assessing the *risk*, this question should be asking about the potential for "*prevention*" through these digital and emerging technologies.	Thank you for your comment. This suggestion has been added to the research recommendation.
Manchester Metropolitan University	Guideline	009	006	We welcome the mention of plantar pressure in the guidelines, but we recommend this statement should refer to "*devices that can measure and provide feedback on plantar pressure*" (see subsequent points 4-6 for justification).	Thank you for your comment. This suggestion has been added.
National Wound Care Strategy Programme (NHS England)	Guideline	005	030	Rec 1.3.6. Non-critical limb ischaemia is now referred to as 'non-chronic limb threatening ischaemia' (in line with the global vascular definitions throughout document) Suggest rewording in line with this.	Thank you for your comment. The committee agreed to make this change, so the guideline has been edited in line with this suggestion.
National Wound Care Strategy	Guideline	006	011	Rec 1.3.6. Spreading infection (should we be considering mild moderate infection as well?)	Thank you for your comment. The committee considered your comment and they decided to

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Programme (NHS England)					amend this to 'infection' only as they agreed that this captured all possible types of infection – mild, moderate, spreading, systemic.
National Wound Care Strategy Programme (NHS England)	Guideline	006	015	Rec 1.3.6 'Red' does not adequately consider diversity in skin tones (On dark skin, 'red' may not be evident).	Thank you for your comment. This has been amended to 'change in colour.'
National Wound Care Strategy Programme (NHS England)	Guideline	007	004	Rec. 1.3.7. Add to the advice that "they could progress to moderate or high risk", to say "so they may need more frequent review"	Thank you for your comment. The committee considered this suggestion but agreed that it was not a necessary addition because they wanted the recommendation to focus on the person's current review frequency (annual) rather than speculating on what review frequency they may or may not need in the future.
National Wound Care Strategy Programme (NHS England)	Guideline	011	017	Why the committee made the recommendations The current wording could be construed as patronising to certain professional groups. Suggest rewording to: "it is a short and simple assessment with only 3 items, so could be completed by those without specialist knowledge of diabetic foot care.	Thank you for your comment. The committee discussed this suggestion and agreed to amend the sentence to say "it is a short and simple assessment with 3 items, so could be completed by primary care professionals without specialist knowledge of diabetic foot care."
National Wound Care Strategy Programme (NHS England)	Guideline	011	026 - 027	By definition, a tool with an additional item will take longer to complete than a shorter tool but agree the difference is likely to be minimal. Suggest rewording as follows: "The committee think that compared to PODUS, the additional time required to complete SIGN will be minimal.	Thank you for your comment. The guideline has been edited in line with this suggestion.

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NHS England	Guideline	General	General	The guideline mentions an active diabetic foot problem but does not go on to recommend time frames or guidelines for how to manage such a problem. It is focussed on prevention which whilst important, does not help manage an acute issue.	Thank you for your comment. The focus of this short update is on risk assessment tools and frequency of foot review. The rest of the guideline remains unchanged and includes existing recommendations on how to manage an active diabetic foot problem (1.4.1 and 1.4.2 on referral for people with active diabetic foot problems; then all of sections 1.5, 1.6 and 1.7 include recommendations on the treatment and management of diabetic foot problems).
NHS England	Guideline	General	General	It would be good for the document to comment on the different wound grading systems and the evidence behind them (and hence which – if any specific one – people should use). Toe pressures and the WIFI (Wound, Ischaemia, Foot Infection) wound grading system are being talked about currently, and its association with clinical outcomes, and it doesn't appear to be included in here.	Thank you for your comment. Wound grading systems were out of scope for this short update, which focused on risk stratification tools that can help clinicians determine a patient's risk of developing a foot ulcer, rather than classifying ulcer severity. In the existing guideline that was not part of this update, recommendation 1.5.2 states "Use a standardised system to document the severity of the foot ulcer, such as the SINBAD (Site, Ischaemia, Neuropathy, Bacterial Infection, Area and Depth) or the University of Texas classification system."
Royal College of Paediatrics and Child Heath	General	General	General	If we take into consideration the negative impact of diabetic foot problems on the manpower, in addition to the cost of treatment and other medical services, the application of this guideline will have a positive economic feasibility.	Thank you for your support. We agree that taking into account the negative impact of diabetic foot problems on manpower would improve the economic feasibility of the recommendations, although we only consider costs that fall on health care and public sectors in the NICE reference case. There is potential that the recommendations would improve productivity and reduce comorbidities, and

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					therefore lead to economic savings at a societal level.
Royal College of Paediatrics and Child Heath	General	General	General	The challenges facing the implementation of this guideline may be: • Shortage in specialised, trained medical staff experienced in management. This issue also in facilities for diagnosis and therapy The other challenge is related to the patient and the community about education and awareness. This issue is regarding morbidity and mortality for that educational activities in this direction are mandatory to promote awareness about the diabetic foot problems. Emphasising on poor outcome if delayed in diagnosis and treatment.	Thank you for your response. Your comments will be considered by NICE where relevant support activity is being planned.
Royal College of Paediatrics and Child Heath	General	General	General	The commenter was happy with this guideline.	Thank you for your comment.
Royal College of Paediatrics and Child Heath	Guideline	004	008	Experts should specify what level of assessment is needed in the paediatric setting. Visual inspection likely to be sufficient in paediatric age range.	Thank you for your comment. The search terms included children and young people but no evidence on risk assessments in the paediatric setting was found so the committee were unable to make any specific recommendations about this population. The existing guideline that was not part of this short update contains the following recommendations for the paediatric age range:

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					1.3.1 For children with diabetes who are under 12 years, give them, and their family members or carers (as appropriate), basic foot care advice. 1.3.2 For young people with diabetes who are 12 to 17 years, the paediatric care team or the transitional care team should assess the young person's feet as part of their annual assessment and provide information about foot care. If a diabetic foot problem is found or suspected, the paediatric care team or the transitional care team should refer the young person to an appropriate specialist.
Royal College of Paediatrics and Child Heath	Guideline	005	005	For children, unlikely to find any neuropathy, therefore is monofilament/brachial index assessment needed? Monofilament/brachial index etc is not standard practice in paediatric settings and if recommended would need a significant uplift in training paediatrics and incur extra cost. We would suggest or ask for a discussion by experts – should the focus in children be on inspection and education/prevention? If experts agree, please amend in guideline both in terms of assessment (and risk stratification) and education.	Thank you for your comment. The committee considered the issues you have raised but noted that no evidence was identified on the use of risk stratification tools for children and young people, so they were unable to make any specific recommendations about this population. They considered making a research recommendation on risk assessments in a paediatric population, but on balance agreed that since diabetic foot problems in children are quite rare, the research may be difficult, and this area of research is less of a priority than other aspects of care for people with diabetic foot problems. The committee noted that there are existing recommendations for the paediatric age range that were not part of this short update:

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					1.3.1 For children with diabetes who are under 12 years, give them, and their family members or carers (as appropriate), basic foot care advice. 1.3.2 For young people with diabetes who are 12 to 17 years, the paediatric care team or the transitional care team should assess the young person's feet as part of their annual assessment, and provide information about foot care. If a diabetic foot problem is found or suspected, the paediatric care team or the transitional care team should refer the young person to an appropriate specialist.
Royal College of Paediatrics and Child Heath	Guideline	005	022	The absence of symptoms in a person with diabetes does not exclude foot disease; it may be asymptomatic neuropathy, peripheral artery disease, pre-ulcerative signs or even an ulcer.	Thank you for your comment. Recommendation 1.3.4 captures several risk factors or symptoms that are indicative of foot disease and should therefore be examined when conducting a diabetic foot assessment. Whilst it is acknowledged that an absence of symptoms does not exclude foot disease, it is nevertheless important to outline key indicators that should be considered when conducting a foot assessment.
Royal College of Paediatrics and Child Heath	Guideline	008	-	Recommendations for research. We would suggest adding assessment and education in paediatric settings. Please note, the evidence review does not appear to include any paediatric or children and young people references.	Thank you for your comment. The search for evidence included children and young people but no relevant studies for this population were identified. The committee considered making a research recommendation on risk stratification in a paediatric population but agreed that this was not a priority area for research due to foot ulcers in children being very rare.

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STADA UK (Thornton and Ross)	Evidence Review A	General	General	We believe as per the peer reviewed evidence paper as referenced below, people with diabetes and either peripheral neuropathy or peripheral arterial disease should have daily application of a urea-based emollient, initiated as early as possible. https://diabetesonthenet.com/diabetic-foot-journal/optimal-emollient-treatment-and-prevention-diabetic-foot-complications/	Thank you for providing this reference. The suggested trial does not meet the review inclusion criteria – it presents a summary report of a project that aimed to develop consensus statements from a multidisciplinary group of experts to provide clarity on the use of urea-based emollients in diabetes foot care. The paper does not present as risk stratification system for assessing the risk of developing a DFU. Use of urea-based emollients is outside the scope of this update.
STADA UK (Thornton and Ross)	Evidence Review A	General	General	We believe as per the peer reviewed evidence paper as referenced below, the concentration of urea-based emollient for treatment of hyperkeratosis on a persons foot who has diabetes is 10-25% strength depending on clinical presentation. https://diabetesonthenet.com/diabetic-foot-journal/optimal-emollient-treatment-and-prevention-diabetic-foot-complications/	Thank you for providing this reference. The suggested trial does not meet the review inclusion criteria – it presents a summary report of a project that aimed to develop consensus statements from a multidisciplinary group of experts to provide clarity on the use of urea-based emollients in diabetes foot care. The paper does not present as risk stratification system for assessing the risk of developing a DFU. Use of urea-based emollients is outside the scope of this update.
STADA UK (Thornton and Ross)	Evidence Review A	General	General	We believe as per the peer reviewed evidence paper as referenced below, all emollient formularies within the UK should have the option for a urea-based emollient with at 10%-25% strength. https://diabetesonthenet.com/diabetic-foot-journal/optimal-emollient-treatment-and-prevention-diabetic-foot-complications/	Thank you for providing this reference. The suggested trial does not meet the review inclusion criteria – it presents a summary report of a project that aimed to develop consensus statements from a multidisciplinary group of experts to provide clarity on the use of urea-based emollients in diabetes foot care. The paper does not present as risk stratification system for assessing the risk of

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					developing a DFU. Use of urea-based emollients is outside the scope of this update.
STADA UK (Thornton and Ross)	Evidence Review B	General	General	Our unpublished real world evidence study in Northwest London 2021 indicated there was a 35% lower risk of developing a foot ulcer for patients using urea-based emollients compared to non-urea-based emollients. There was an 80% higher risk of callus reoccurring in patients not using emollients compared to patients using urea-based emollients.	Thank you for this information. The focus of the review was on risk assessment tools or methods that can be used to stratify patients into various risk groups, rather than on interventions to reduce the risk of developing diabetic foot problems such as callous or ulcer.
The University of St Andrews	Evidence Review	007	008 – 010	1.1.2 - The evidence review excludes a systematic review (Crawford 2015) which contains analyses of age, sex, ethnicity, duration of diabetes, and presence of renal disease based on individual patient data collected from more than 16,000 people with diabetes who took part in 10 cohort studies worldwide. The reason given for excluding the Crawford 2015 review is because "it is not presented as a risk stratification tool". In fact, it reports the development and validation of the prognostic model that underlies the PODUS CPR and as such we believe it should be included in this NICE 2022 Evidence Review and considered as part of the PODUS CPR. With the exception of ethnicity, the statement on pg 8; "However these subgroups could not be analysed due to insufficient data" is only true if the Crawford 2015 review is excluded. (SEE CHAPTERS 4 AND 5, DEVELOPMENT OF THE MODEL AND VALIDATION OF THE MODEL)	Thank you for your comment. The Crawford 2015 paper was excluded because it presents a meta-analysis of risk factors for diabetic foot and a prediction model for foot ulceration, but it does not extend beyond that to clearly present the model as a risk stratification tool for use in clinical practice. It identifies the 3 main risk factors for ulceration but does not suggest how to use these risk factors to stratify people into separate risk groups, or how to assign scores to each factor to generate an overall risk score. There is insufficient detail on how a clinician would use these risk factors in daily practice during foot assessments. The paper also does not report outcome data that match those in the protocol (e.g., c-statistics) so no data could be extracted from this paper. For these reasons, the committee agreed this paper should be excluded. The committee considered the 3496 patients that could not be categorised by the SIGN system and

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				The primary PODUS model contained age, duration of diabetes, inability to feel a 10g monofilament, absent pedal pulses, sex and previous history of foot ulceration and this was validated externally and independently in a separate dataset (Boyko 2006). The results for three of the risk factors; age, duration of diabetes and sex were inconsistent and were therefore not retained (Crawford 2015, pg 62 and 63). The Crawford 2015 review also presents several models of different risk factors including the presence of renal disease. It also examined the performance of the recommended screening tools from SIGN, NICE and IWGDF in the PODUS dataset. When the SIGN stratification tool was applied to 11,568 patients' data in the PODUS IPD dataset 3496 patients were not categorised into any of the active/high, moderate or low definitions of risk, and use of this classification would mean that 14% of foot ulcers would be missed. (See Crawford 2015, CHAPTER 14, PAGE 77) This evidence is highly pertinent to the review since; "The aim of this review is to assess which risk stratification models/tools perform better in indicating risk of diabetic foot problems in people with type 1 or type 2 diabetes" (Evidence Review pg 6).	examined the evidence for this. They agreed that patients with deformity/callus but detectable pulses and sensitivity to monofilaments would be considered moderate risk due to the presence of foot deformity and no other risk factors. For patients with loss of sensation and signs of PVD but no deformity, they would be high risk due to absent pulses and unable to feel monofilament (2 risk factors present). For patients with deformity but no loss of sensation and no sign of PVD, they would be moderate risk because there is foot deformity present but no other risk factors. For patients with callus only, they would be low risk (SIGN definition and recommendation 1.3.6: no risk factors present except callus alone). The committee therefore disagreed that use of the SIGN system would result in patients that could not be categorised, and ulcers being missed.

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				In summary, the evidence from Crawford 2015 has not been considered by NICE before and should be included in the 2022 Evidence Review.	
The University of St Andrews	Evidence Review	011	010 - 011	1.1.6 Summary of Prognostic evidence The PODUS Clinical Prediction Rule is incompletely reported in the table on pg 11; the PODUS CPR generates risk score which informs a patient-specific probability of foot ulceration within 2 years (see table 3, Chappell 2021. doi:10.1136/ bmjdrc-2021-002150). **PODUS CPR is the only risk stratification tool that gives a person-specific risk of foot ulceration (probability) in a given time period and the Evidence Review should include the probabilities as published.**	Thank you for your comment. The table on page 11 presents the PODUS CPR items and their corresponding scores and is meant for descriptive purposes only; this section is designed to present a short description of all the included risk stratification systems. The patient-specific probabilities are reported further down in table 1.1.6.2.4 on page 17 of the evidence review; reference to this table has been added to the final sentence of this paragraph
The University of St Andrews	Evidence Review	011	019	Committees' discussion There are factual inaccuracies in the evidence review relating to the risk stratification tool published by Leese (2006): **"This stratification system was developed from a systematic review conducted by a multidisciplinary group…"** The SIGN stratification tool is not based on a systematic review. The authors of Leese (2006) cite 4 separate cohort studies as being the source of the risk factors but do not provide details about how these studies were identified, selected or used to inform the development of the stratification tool. (Rith-Najarin (1992), Peters (2001), Abbott (2002),	Thank you for your comment. This sentence had been amended to "The SIGN stratification tool was based on consensus of a multidisciplinary group of practitioners," and the committee were made aware of this correction. NICE evidence reviews do not include letters to the editor; the search was limited to prospective and retrospective cohort studies only. The committee acknowledged that the ethnic and social mix of the sample used to validate the SIGN tool may not be applicable to the broader UK patient

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				Murray (1996)). The SIGN stratification tool was based on consensus of a multidisciplinary group of practitioners. The Evidence Review does not include a letter to the editor of Diabetes Care (29:11 November 2006) from Professor Edward Boyko who highlighted the inclusion of only 3526/8923 (40%) of the sampled population in the analysis by Leese et al (2006) and questioned the validity of the findings and the degree of confidence with which the results could be recommended to the wider population. Following this criticism, a revised analysis of mostly the original data was published in 2011. (Leese 2011 DOI: 10.1111/j.1464-5491.2011.03297.x). The sample size of the study by Leese 2011 is n=3719 and patients were recruited from Tayside in Scotland. **In the light of this clarification, the committee may wish to re consider whether the ethnic and social mix of the sample in the SIGN stratification tool is applicable to the broader UK patient population.**	population, but they noted that this same sample (the Leese 2011 dataset) was also used to validate the PODUS CPR.
The University of St Andrews	Evidence Review	016	-	1.1.6.2.2 C statistics In the table of C statistics, it is stated that PODUS CPR was validated in a study by Monteiro-Soares in 2017 but it was the PODUS prognostic model reported in Crawford 2015 that Monteiro-Soares assessed. The PODUS CPR was only published in	Thank you for your comment. You are correct that the Monteiro-Soares 2017 paper validated the PODUS prognostic model reported in Crawford 2015. On this basis, the results for the PODUS reported in Monterio-Soares 2017 have been removed from the evidence review as they are

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				late 2020 in the Crawford et,al 2020 HTA report and in BMJ Open in 2021 (Chappell 2021) In the same table it is stated that the PODUS CPR had a population of 3770 but this is incorrect, the sample size was 8404. (See Chappell 2021)	based on the PODUS prognostic model rather than the 2020 PODUS CPR. The population of 3770 is a combination of Crawford 2020 (n=3324) and Monterio-Soares 2017 (n=446) as this was a meta-analysed result. However, the Monterio-Soares 2017 data has been removed from this table. It was assumed that the population used for the c-statistics analysis was from the external validation cohort (n=3324) but we now understand from your comments in this table that those analyses were performed on the development cohort. This was not clear in the Crawford 2020 or Chappell 2021 papers, particularly in Chappell 2021 where the section on area under the ROC curve for the CPR is contained under the subheading 'Validation of the CPR in the validation dataset'. The numbers in the table have been amended accordingly.
The University of St Andrews	Evidence Review	029	010	Committee discussion There are factual inaccuracies relating to the PODUS CPR in the committee's discussion and interpretation of the evidence that are a concern. The statement **"Crawford 2020 HTA was a well conducted study using a large UK-based sample and was assessed as being at low risk of bias, although the committee noted that the cohort was patients from Fife and they questioned whether the ethnic and social mix of this sample was applicable to the broader UK patient**	Thank you for your comment and the clarification provided over the development and validation populations. The reference to patients from Fife relates to the sample used to assess the frequency of foot review and ulceration rates in the follow up period, not the PODUS CPR validation work, so this has now been moved to the correct section of the committee discussion. The committee have been made aware of this amendment.

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				population." To clarify, the PODUS CPR is based on individual patient data from 4 studies which were used to develop the CPR. They were also reported in detail in the IPD meta-analysis (Crawford 2015). These 4 cohort studies (n=8255) were conducted in Europe and the USA. The largest dataset being that of Abbott (2002) (n=6603) which was conducted in Manchester. The second UK-based cohort (Crawford 2011) was conducted in Tayside in Scotland which included 1193 people. (Chappell 2021). The CPR includes data from n=8404 and was externally validated using the Leese dataset (n= 3412).	
The University of St Andrews	Evidence Review	030	010	In assessing the accuracy of a prognostic model, calibration (the agreement between predicted and observed outcome risks) and discrimination – Concordance (C) statistic (how well the tool distinguishes between those who do and do not develop the outcome of interest) are the statistical measures of choice rather than sensitivity or specificity. (Riley 2019 Prognostic Research in Health Care). The C statistic is the same as the area under the ROC curve, so it uses information from specificity and from all possible thresholds that are used to decide ulcer-prediction versus no ulcer-prediction. It is not possible to calibrate a stratification tool where the output is low/moderate or high, a	Thank you for your comment. We agree it is important to assess calibration and discrimination for prediction models, which is why these measures were prioritised in the review protocol and these data were reported when they were available. However, the committee agreed that data on sensitivity and specificity were also useful for decision making because they give a measure of performance at specific threshold values and provide information on the trade-off between false positives and false negatives that would be expected if these threshold values were adopted in practice. During their decision making the committee considered all the available evidence, including c-statistics and sensitivity and specificity data, alongside issues relating to implementation,

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				numerical estimate of risk is required. Calibration compares probabilities and "high risk" is a descriptor, not a probability. These considerations are exceptionally important since "The aim of this review is to assess which risk stratification models/tools perform better in indicating risk of diabetic foot problems in people with type 1 or type 2 diabetes"	justification for widespread change, and broader system factors. They agreed that overall the evidence did not show a strong enough benefit of using the PODUS system to justify the degree of change required to implement a new assessment tool.
The University of St Andrews	Evidence Review	030	030	On the basis of the wider generalisability of PODUS CPR due to its larger development population, it's C statistic and its ability to generate a person-specific probability of foot ulceration within a 2 year period we respectfully disagree with the statement that there is "**an absence of evidence strongly favouring one system".**	Thank you for your comment. The committee considered and discussed all these factors when examining the evidence and forming their recommendations. They maintain their position that there is insufficient justification to change from the existing SIGN system to PODUS.
The University of St Andrews	Evidence Review	030	035	We are respectful of the combined clinical expertise and experience of the members of the committee but our analyses of data from more than 10,000 people with diabetes do not strongly support the statement that renal disease is a known risk factor for foot ulceration. The HTA report by Crawford 2015 presents multivariable analyses for kidney problems in appendix 11 pg 100 and 101. In people who had never ulcerated before kidney function was not predictive of foot ulceration and only the Leese 2011 study found it to be predictive in a meta-analysis of data from 5 studies in people who had ulcerated before (re ulceration).	Thank you for your comment. The committee discussed the issue of renal disease at length. They considered the data you present showing that kidney function was not predictive of foot ulceration but agreed that the definition of kidney problems used in these analyses was broader and potentially included patients with less advanced kidney disease than the patients as defined in the recommendation. They discussed their clinical experiences of foot ulceration in people on dialysis and there was strong consensus that patients on renal replacement therapy are at high risk of developing a foot ulcer. The committee also noted that the renal impairment

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					assessment is not expected to add any significant time or complexity to the foot risk assessment.
The University of St Andrews	Evidence Review	031	013	We are unaware of evidence that the SIGN system is "well established" in clinical practice in any of the 4 nations of the UK except Scotland.	Thank you for your comment. This was the consensus view of committee members working in clinical practice across the UK. It should also be noted that the SIGN system was recommended in the previous update of this guideline in 2015 so it is expected that it would have been adopted in many practice settings.
The University of St Andrews	Evidence Review	068	-	Evidence Table D1 - The tabulated data for Crawford 2020 on pg 68 is factually inaccurate. This Evidence Review table reports a study with n=3412; **"The study was a validation dataset from an electronic register, which had taken data from General Practice records and Information Services Division NHS Scotland (information taken from Chappell 2021)".** In fact, this seems to be the Leese dataset which was used in the external validation of the PODUS CPR as described by Chappell (2021). The table also omits the person-specific probabilities of foot ulceration in a 2-year period as reported in Chappell 2021.	Thank you for your comment. Evidence Table D1 now contains information on both the development and validation cohorts. The person-specific probabilities do not need to be reported in the evidence tables – these tables are for descriptive characteristics of the study, not study findings. These probabilities are reported in table 1.1.6.2.4 of the evidence review.
The University of St Andrews	Evidence Review	068	-	Evidence Tables D1 - We note the omission of a PROBAST Risk of Bias assessment for Leese 2006 or Leese 2011. As the "**The aim of this review is to assess which risk stratification models/tools perform better in indicating risk of diabetic foot problems in people with type 1 or type 2**	Thank you for your comment. Leese 2006 and Leese 2011 were not papers that were included in the review as stand-alone inclusions, they were papers reported in the HTA (Crawford 2020). They do not need separate data extraction tables or risk of bias assessments.

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				diabetes" we believe a RoB assessment of the totality of evidence is merited.	

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*